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The Editorial Board kindly informs that since 2014 *Nowiny Lekarskie* has been renamed to *Journal of Medical Science*.

The renaming was caused by using English as the language of publications and by a wide range of other organisational changes. They were necessary to follow dynamic transformations on the publishing market. The Editors also wanted to improve the factual and publishing standard of the journal. We wish to assure our readers that we will continue the good tradition of *Nowiny Lekarskie*.

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ORIGINAL PAPER

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Definitions of health and disease among physicians and Społem PSS employees

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ABSTRACT

Aim. Definitions of health and disease play an important role in the organization and functioning of a health care system. The meanings attached to both phenomena also shape individual's health behaviours and may be more important for their understanding that one's social status. Thus, the aim of the study was to determine how the educational status and kind of work influence the concepts of health and disease. It also aimed to determine what criteria do physicians and Społem PSS employees use while talking about health and disease and whether lay concepts of health differ from their professional counterparts.

Material and Methods. The research was carried out between May and August 2013 among one hundred physicians and one hundred Społem PSS employees. Thus, the results refer to people who are professionally active. Respondents were questioned via a structured questionnaire which contained questions on their self-definitions of health and disease and the criteria of their evaluation.

Results. The research has revealed important differences in definitions of health and disease between physicians and clerks from Społem PSS. While physicians used a medical criterion to define health more often, Społem PSS employees defined it according to mixed and subjective criteria. As for disease, while respondents from both groups defined it mainly in medical criteria, all Społem PSS employees described it in pathological terms; physicians, however, defined it mainly as an abstract lack of well-being. On the other hand, many respondents understood both phenomena as multidimensional which proves that both terms contain many contradicting meanings and are difficult to articulate. Also among physicians, high tendency to overmedicalization of many phenomena was observed.

Conclusions. It has been proven that educational status and kind of work influence the way people understand health and disease. Thus, this research may be useful for health education and in planning health promotion and preventive actions.

Keywords: disease, definitions of health and disease, health, physicians, sociology of health and illness, Społem PSS employees.

Introduction

While the discussion on the nature of heath and disease seems to be purely academic, and some even claim that both terms are useless for both medical theory and practice [1, 2], the concepts of health and disease are crucial for the organization and functioning of medicine [3]. It stems from the fact that the models of heath and disease held by physicians influence the choice of study object, scientific theory and methodology used for its explanation, argumentation and formation of hypothesis and interpretation of the results' [4, 5]. They also determine who can obtain medical care and influence the type of care that is provided to patients. The accepted, even if only *implicite*, definitions of health and illness may be the reason why medical professionals do not take under consideration some factors in the etiology of disease and alternative

therapeutic measures [6]. The models of health and disease held by physicians may also determine whether the impact is being put on therapy or prevention and health promotion.

At the same time, when health awareness, personal health beliefs and lifestyle are regarded as the most important factors that shape health behaviours, modern health promotion attaches a special meaning not only to professional, scientific models of health and disease but also to their popular interpretations [7–11]. Thus, knowing the subjective meanings lay people attach to health and disease allows for understanding and explanation of one's health and medical behaviours. Moreover, they can be even more important than one's social status [12]. Lay definitions of health and disease present in public awareness decide whether and individual will be defined by others as sick and whether they define themselves as such and will look for a confirmation of such self-diagnosis in the doctor's office. What is more, while they may be a reason why patients ignore the first symptoms of disease, at the time they may also provoke too many claims from patients and lead to overmedicalization.

On the other hand, different definitions of health and disease held by physicians may be the reason why some doctors ignore some states claimed by their patients [13, 14], as it was in the case of the so called contested illness, such as fibromygalia, chronic fatigue syndrome, myofascial pain syndrome, multiple chemical sensitivity syndrome or posttraumatic stress disorder [15–17]. While such illnesses cause patients' suffering and discomfort, they are often not recognized by medicine and sometimes neglected. For that reason, the discrepancy between lay and medical concepts and definitions of health and disease is one of the main sources of patients' dissatisfaction with medical care and may become the reason why they look for alternative, nonmedical healing methods [18, 19]. It should be no surprise since health and disease criteria held in popular awareness often diverge from the medical criteria. For example, a research conducted by Boczkowski and Włodarczyk [10] showed that 80% adults have different ideas on what their good health means than their physicians.

A classical comparative study by Herzlich on middle class people in Paris and rural regions of Normandy demonstrated three main popular concepts of health: health as 'being', 'having' and 'doing'. The first category, referred to as 'health in a vacuum' implied the absence of disease, while 'having' health meant that it was regarded as a positive resource, capital and reserve, i.e. a type of biological capacity that enables an individual to cope with illness and which increases or decreases over time. Finally, health was also defined as a kind of physical fitness, equilibrium or function defined by each individual as normal health and which is rarely achieved (health as 'doing') [20]. In another study on elderly people in Aberdeen, Scotland, Williams identified three concepts of health: health as the absence of disease, health as a dimension of strength, weakness and exhaustion and health as functional fitness [21]. A study by D'Houtarda i Fielda [22] showed that manual workers expressed negative and instrumental definitions of health more often than non-manual workers who have positive and personalised concepts of health. Also, studies by Blaxter [23, 24] and Puchalski [7, 25] demonstrated that low educated employees and working class people have a more negative attitude toward their health and are more likely to hold functional conceptualisations of health.

On the other hand, studies conducted among healthcare providers show that most physicians are inclined to think about health and disease according to the medical model and stress mainly laboratory values and examinations within a normal range and technological solutions, and are not concerned with psychic, emotional, spiritual, social and environmental factors [6, 26]. Conversely, many lay people and nonmedical healers prefer wellbeing, holistic or adaptational models of health which operate with a different set of values, include other than physical dimensions of health and are more open toward alternative therapies (19). A study by Julliard, Klimenko and Jacob conducted among 73 healthcare practitioners proved that depending on whether they belonged to mainstream healthcare (MH), complementary and alternative healthcare (CAH) or integrative healthcare (IH), they presented different definitions of heath and disease. MH practitioners defined health mainly as 'good functioning ', which included such conceptualizations as: 'being able to contribute and be productive', 'being able to pursue personal goals', an ability of 'the body to do the things that one wants it to do' and an 'ability to handle daily activities'. At the same time, they recognized physical health as its most important dimension and psychic, emotional and social spheres were defined as abstract and difficult to evaluate. In that group, health was also defined as wellbeing and freedom from physical and mental disease and/or absence of pain and lack of disability and normal measurable physical parameters. On the other hand, representatives of CAH pointed to health as 'well-being', 'resilience' and 'adaptability to the environment' more often. They also defined health as 'aware-

ness and appropriate action' and 'balance'. At the same CAH practitioners stressed nonphysical dimensions of health: spiritual, psychic, emotional, environmental and social and pointed to their mutual connections. the last group of practitioners – IH, like the respondents from the first group, also stressed the functional dimension of health and described it as 'having all body systems functioning at their optimal level' which enables 'life and happiness'. On the other hand, in contrast to MH practitioners, they tended to stress that health is a well-being of the body, the mind and the spirit. Less frequently, they also defined it in negative terms as 'absence of disease', and, like CAH practitioners, they were more inclined to point to the adaptational model of health and perceived it as a 'ability to adapt to the environment' and 'balance'. Like the respondents from CAH group, IH practitioners also stressed the interrelated nature of the components of health and defined it as 'wholeness and integrity'. Most importantly, all IH practitioners included spirituality as an important component of health [6].

Another study by Klimenko, Julliard, Lu and Song [26] showed that health providers define health mainly through its reference to 'physiologically normal organ functioning' (84%), 'absence of pain' (59%), 'each patient's unique understanding of well-being' (59%) and 'lack of disease' (50%). Nevertheless, when representatives of mainstream medicine (MM), complementary and alternative medicine (CAM) and integrative medicine (IM) were asked to choose only one answer, those from the first group (MM) pointed to 'Age-appropriate functioning to pursue goals and enjoy life' (90% and 74% CAM), and the second group to a 'balance between the aspects of life, of the body/mind/spirit, or of the inner and outer worlds' (87% CAM and 73% MM). Similar differences were present in their definitions of disease. While MM practitioners understood it mainly in pathological terms as an 'abnormal organ function' (91% and 79% CAM practitioners) and 'abnormal laboratory values' (68% and 49% CAM) complementary and alternative medicine providers defined disease as an 'imbalance of body or mind functions or aspects of life' (92% and 70% MM), an 'inability to adapt to the environment' (70% and 45% MM) and 'lack of spiritual connection' (54% and 22% MM).

Thus, the aim of the present study was to determine how the educational status and kind of work influence concepts of health and disease. It also aimed to determine what criteria physicians and Społem PSS employees use while talking about health and disease and whether lay concepts of health and disease differ from their professional counterparts.

Materials and Methods

The study was carried out between May and August 2015 among one hundred physicians working on their speciality and one hundred Społem PSS employees. Thus, the results refer to people who are professionally active. Respondents were questioned via a structured questionnaire which contained open-ended questions on their self-definitions of health and disease and the criteria of their evaluation.

The group of physicians consisted of 47 females and 53 males. 57% were married and 20% single. The majority were aged 26–35 (60%) and 36–45 (22%). Most of the physicians lived in big agglomerations with a population of over 500 thousand (80%). All of them graduated from a medical university and were professionally active. Most of them declared an income of over 2500 PLN (620 euros) per month. In contrast, the sample of Społem PSS were in their majority female (93%), out of which 64% were married and 20% single. 10% were divorced. Most of them were aged over 45 (51%) or between 36–45 years of age (32%) and lived either in big agglomerations with a population of over 500 thousand (68%) or in smaller towns with 100–500 thousand inhabitants (14%). Most had completed their education at the level of vocational school (60%) or high school (38%). Only two persons were university graduates. Over half of Społem PSS employees reported an income of up to 1500 PLN (370 euros) per month (54%) while only 7% earned more than 2500 PLN (620 euros).

The StatSoft's Statistica 10. PL form was used for a statistical analysis. For the evaluation of variables, correlation Chi^2 test was used and for intergroup comparisons examined for ordinal variables, U Mann-Whitney and Kruskal-Wallis tests were used. The distribution of the variable 'number of diseases indicated' was analysed with Shapiro-Wilk test. As it was not significantly different from a normal intergroup comparison, other parametric methods were used: the t test for independent variables and one-way analysis of variance. A statistical significance was assumed to be $\alpha = 0.05$. The results $p < 0.05$ were recognized as statistically significant.

Results

The different understanding of health and disease among the physicians and Społem PSS employees examined was revealed in just the first two open questions where the respondents were asked to define both phenomena ($p < 0.05$) (**Table 1** and **2**), and were more significant in the case of health. Among the physicians

Table 1. Definitions of health in the opinions of physicians and Społem PSS employees

		Profession		Total
		Physicians	Społem PSS employees	
Definitions of health	medical criteria	61.0%	22.0%	41.5%
	mixed criteria	19.0%	30.0%	24.5%
	subjective criteria	10.0%	23.0%	16.5%
	functional criteria	2.0%	5.0%	3.5%
	negative criteria	2.0%	6.0%	4.0%
	adaptational criteria	2.0%	1.0%	1.5%
	axiological criteria	4.0%	12.0%	8.0%
	vitalistic criteria	0%	1.0%	0.5%
Total		100.0%	100.0%	100.0%

Table 2. Definitions of disease in the opinions of physicians and Społem PSS employees

		Profession		Total
		Physicians	Społem PSS employees	
Definitions of disease	medical criteria	49.0%	33.0%	41.0%
	negative criteria	18.0%	13.%	15.5%
	mixed criteria	14.0%	28.0%	21.0%
	adaptational criteria	7.0%	0%	3.5%
	subjective criteria	5.0%	12.0%	8.5%
	functional criteria	4.0%	10.0%	7.0%
	others	3.0%	4.0%	3.5%
Total		100.0%	100.0%	100.0%

it was mainly defined through medical criteria (61%), out of which over one half (54%) referred to the so called holistic definition of health by the World Health Organization which defines it as 'a state of complete physical, mental and social well-being'. On the other hand, such criteria also included such answers as: 'viability of organism' (4%), 'proper functioning of organism' (2%) and 'lack of genetic defects and necessity of medical treatment' (1%). Almost 1/5 of the physicians examined (19%) defined health as a multidimensional phenomenon and used mixed criteria to describe it. In such cases the most common was the combination of medical and functional criteria (4%): Health is physical and mental well-being that enables performance of social roles (P46); subjective and functional criteria (3%): Health means feeling good, psychic and physical comfort that allows free (without limitations) performance of everyday activities (P12); subjective and negative criteria: (3%): It [health] is good mood, physical and psychic comfort and lack of diseases (P4) and medical and subjective criteria (3%): A state when a person feels fine, and basic laboratory test do not show abnormalities (L60). Moreover, some physicians mixed medical and negative criteria (2%), medical and adaptational criteria (1%), adaptational and functional criteria (1%), negative, subjective and functional criteria (1%) or even negative, subjective, functional and medical criteria all at once (1%). The third most common definition of health among physicians was the one based on the subjective criterion which referred to feeling good and lack of feeling of discomfort (10%). Typical were such formulations as: A state of a very good mood without feeling of physical and psychic discomfort (P79) and Lack of ailments and good well-being (P94). Moreover, although less frequently, some physicians defined health according to the axiological criterion (4%) as a basic value that determines the sense of existence (P47) or plenitude/feeling of happiness (P59), the functional criterion (2%), where it meant [a]bility to perform ascribed social roles (P23) or An ability to act without any limitations (P83), the negative criterion (2%) as simply 'lack of disease' and the adaptational criterion when it was defined as 'homeostasis' or 'internal balance' (2%).

In contrast, Społem PSS employees defined health mainly through mixed criteria (30%), although most frequently they combined subjective and functional criteria (6%) and medical and subjective criteria (5%). Thus, it was understood as ' [p]hysical and psychic well-being and an ability to proper functioning and fulfilling professional duties (S50) or Health is fitness of the body and feeling good (S55). In this group, the respondents defined health in subjective terms twice as often as physicians did (23% to 10%). Commonly, they

referred to it simply as: A state of good physical and mental well-being (S4). A similar number of Społem PSS employees defined health in medical categories (22%). Nevertheless, in contrast to physicians, they did not speak about it in terms of WHO's well-being (only 6% in comparison to 54% of physicians) but 'proper functioning of the body' (12%), as: Good body condition (S96) or A state of body in which it does not show any signs or ailments which would be abnormal or atypical (S91). Moreover, 12% of Społem PSS employees defined health according to the axiological criterion as 'the most important value' (S2), 'a treasure' (S34), 'happiness' (S39), 'the highest good' (S44) and 'superior good' (S79) or even 'a gift from God' (S62): Health is the most important thing in the life of every person. No one and nothing can replace it, as it is the ESSENCE of our lives [the emphasis is original]. Quite surprisingly, only 6% of the employees examined described health as 'lack of disease', and still fewer (5%) according to the functional criterion, when they emphasized one's ability to work.

Also, disease was defined by physicians mostly in medical terms (49%), and especially as a 'lack of well-being' (33%). Surprisingly, much fewer respondents from that group described it according to a pathological criterion (13%). In such a case it was defined as: Disturbance of functioning of the body (P31), A set of symptoms that point to the abnormality in one of the bodily organs (P60), A state of disturbance of the structure/function of organs/systems (P85) or A dysfunction of an organ that results in clinical symptoms (P86). Moreover, it was also referred to as 'a deviation from medical norms' (2%), 'low quality of life' (1%) and 'described nosologic unit' (1%). The second most frequent concept of disease among physicians was its negative definition: disease as lack of health (18%). The third concept was defined by mixed criteria (14%), and especially a combination of medical and functional criteria (7%): A disturbance of functioning of the body that impairs functioning in everyday life (P69), Loss of physical and mental well-being, which impairs realization of one's role in society (P46); subjective and functional criteria (2%): It is a factor that potentially limits one's ability to act at the state of well-being (P83) and medical and subjective criteria (2%): A state of disturbance of feeling good which requires medical control/observation/treatment (P11), A dysfunction of a bodily organ or a group of organs that causes a feeling of discomfort (P28). 7% of the physicians examined described disease according to the adaptational criterion as: A disturbance in the state of psychosocial harmony (P88). Only 5% of respondents defined it in subjective categories, as a State that causes physical and mental discomfort (P40) or An unpleasant or painful feeling of one's own body (P82). Even fewer physicians (4%) understood it as a capacity to function normally: A state that makes one unable to be fully active in many dimensions of life (P21) or Any kind of limitation which prevents one from leading a normal life (P45).

As for Społem PSS employees, their perception of disease was mostly built around medical criteria (33%). In contrast to physicians, for all of them it meant some pathological state within the body. Typically, they referred to it as: [a]n impairment of the body by viruses and microbes (S1), A state in which there can be observed an undesirable reaction of bodily organs to external or internal factors (S33) or [d]eterioration of laboratory values diagnosed by a physician (S38). Much more often than physicians, Społem PSS employees defined disease using mixed criteria (S28% vs 14% physicians). In such a case, more frequently they combined medical and subjective criteria (10%) and defined it as: An ailment, when a person is in pain, some genetic disease (S51), Disease is a state when we are feeling bad. It is an ailment that results from pathological changes in the body and the disturbances of proper function of organs (S58). On the other hand, medical and functional and subjective and functional combinations used by physicians were less frequent among Społem PSS employees (4%): Disease is a dysfunction of the body that impairs normal functioning (S72) or Disease is a state in which a person feels bad and is unable to work at home and in the office (S66). Moreover, in this group the respondents also used combinations of other criteria, including: subjective and negative (3%), subjective and vitalistic (2%), vitalistic and functional (2%), negative and vitalistic (1%), subjective, negative and functional (1%) and functional, subjective and medical (1%). Surprisingly, this group defined disease in negative criteria less frequently than physicians (13% vs 18%). On the other hand, they used the subjective criterion more often than physicians (12% vs 5% of physicians). In such instances, while referring to a 'feeling of discomfort' and 'pain and/or suffering', they described it as a state in which [a] person feels bad (S69) or [w]e experience physical or psychic pain (S29). Quite unexpectedly, Społem PSS employees rarely defined health as a functional limitation (10%), especially in work: Disease is a temporary inability to work (S45).

The differences in the perception of health and disease between both groups was further confirmed by questions regarding the criteria of health and disease.

Figure 1 shows that for a vast majority of physicians (72%), health is a state of physical, mental and social well-being, whereas only 15% of Społem PSS employees found the WHO'S definition of health as appropriate. In contrast, in the latter group, the respondents chose the medical criterion much more often and defined health as a normal functioning of the body (33% vs 12% of physicians). Surprisingly, only 19% of Społem PSS employees described health using the negative criterion and defined it as absence of disease. Moreover, they also identified health as a unique resource and a capital (14%). Such results confirm our conclusion that educational status and kind of occupation determine the definitions of health (contingency coefficient C = 0.534, Cramér's V = 0.632, $p < 0.05$).

There was also a difference, although not so significant, in the way both groups described the essence of disease (contingency coefficient C = 0.349, Cramér's V = 0.372, $p < 0.05$) (**Figure 2**). Significantly many more physicians (73%) than Społem PSS employees (54%) perceived disease in medical categories either as a state of disability and discomfort or pathology and/or dysfunction of the body. On the other hand, Społem PSS employees frequently chose the negative criterion and defined it as absence of health (43% vs 23% of physicians).

The kind of work also determined the criteria that shape perception of health among physicians and Społem PSS employees. As shown in **Figure 3**, the differences between both groups are statistically significant (contingency coefficient C = 0.428, Cramér's V = 0.474, $p < 0.05$). While nearly one half of the physicians questioned (49%) indicated 'well-being' as the most important criterion of health, Społem PSS employees chose 'normal test results' (32%). It was surprising as it was presumed that it is physicians who are more likely to choose the objective, medical criterion that is strictly linked to medical knowledge, while employees often prefer the subjective criterion.

The Authors also asked about the criteria that determine perception of one's health (**Figure 4**). In both groups, they were similar ($p > 0.05$) as both physicians and Społem PSS employees emphasized the subjective and the vitalistic criteria. What can be observed is that there is a similarity between the personal and the general criteria of health among physicians. On the other hand, only 7% of Społem PSS employees identified normal test results as an important health indicator. The majority replied that they define themselves as healthy when they are feeling well and have energy to do things (89%).

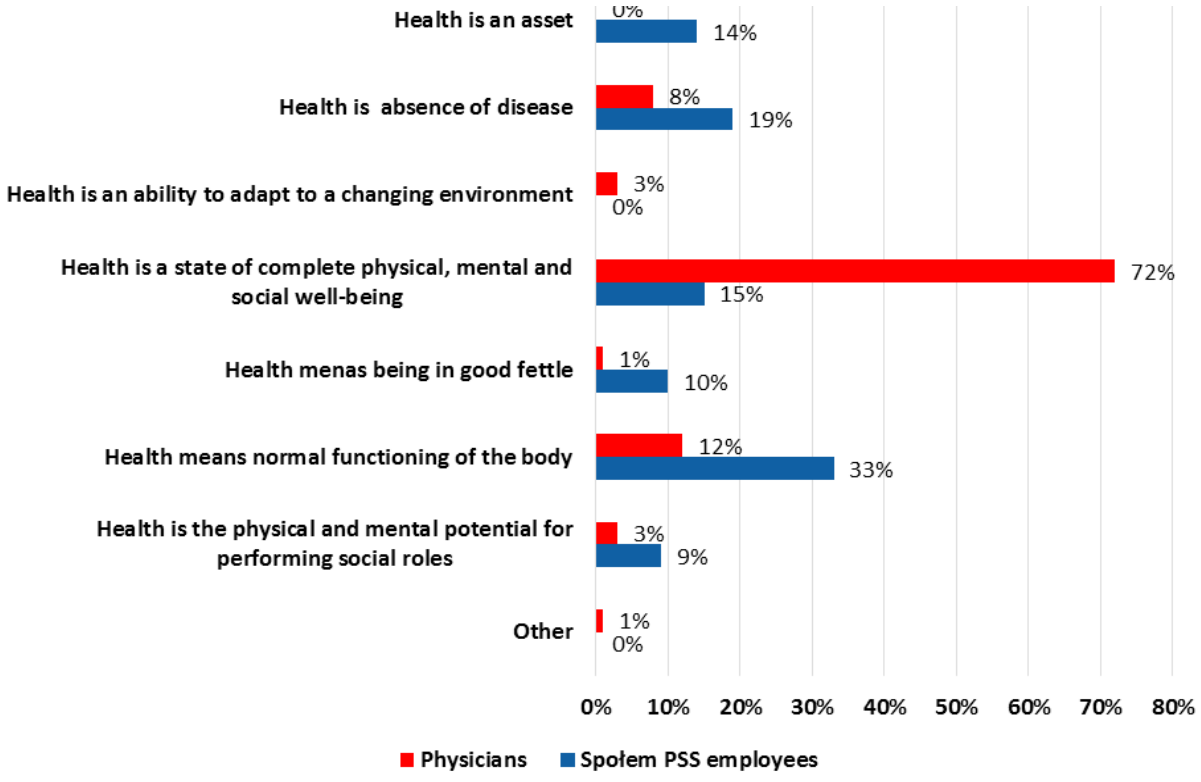

Figure. 1. Statements on the essence of health in the opinions of physicians and Społem PSS employees

The respondents were also asked to enumerate the determinants of health from the most important (1) to the least important (5). As shown in **Table 3**, the differences between the groups are statistically significant. Both groups emphasized lifestyle and genetic factors as the most important determinants of health. The biggest difference can be observed in their opinions on the role of the healthcare system. While for Społem PSS employees it was the third most important health determinant, for physicians this factor is one of the least importance.

The respondents did not differ in their opinions on the importance of the dimensions of health (**Table 4**). Both groups declared physical and mental health as its most important dimensions and neglected the importance of environmental health.

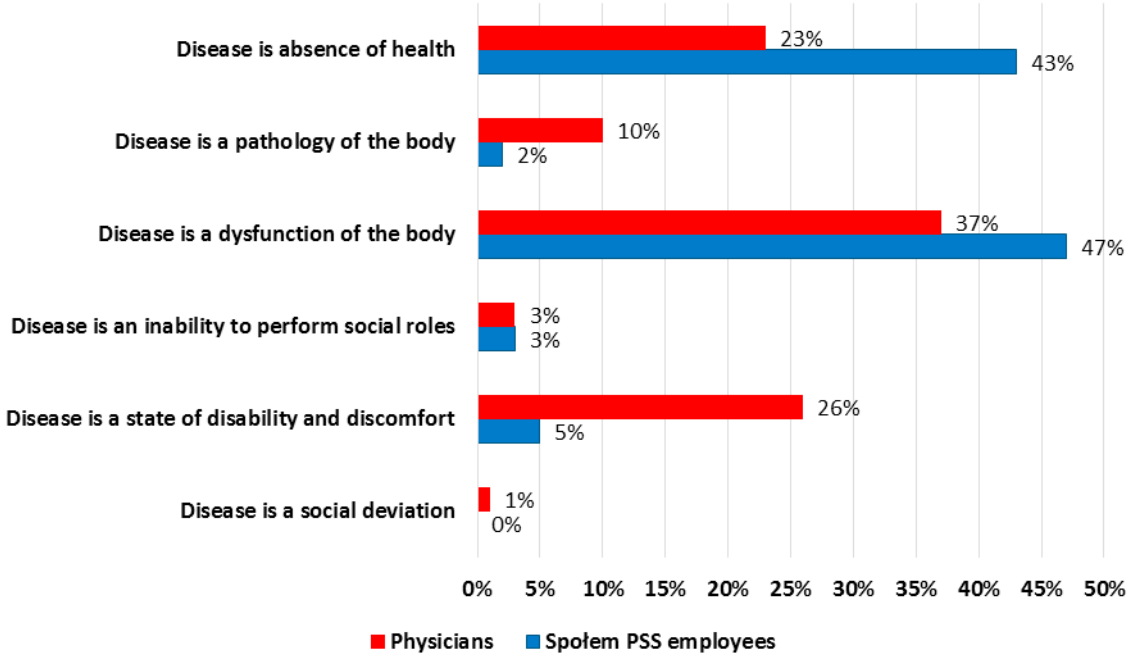

Figure 2. Statements on the essence of disease in the opinions of physicians and Społem PSS employees

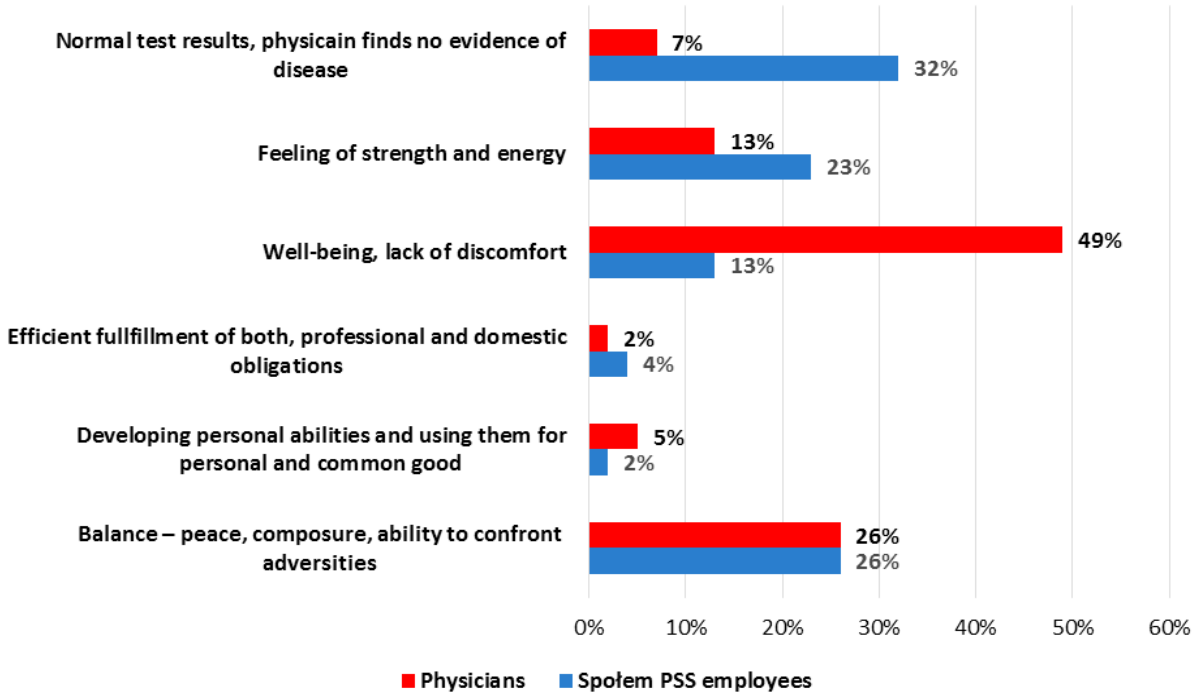

Figure 3. Criteria that shape perception of health among physicians and Społem PSS employee

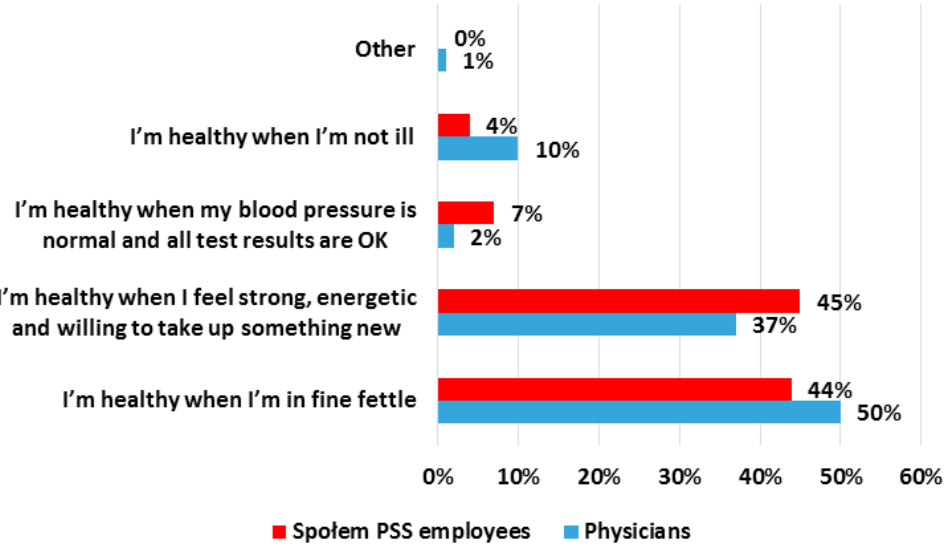

Figure 4. Criteria that determine perception of one's health among physicians and Społem PSS employees

Table 3. Determinants of health in the opinions of physicians and Społem PSS employees

Factors	Average		Standard deviation		p
	Physicians	Społem PSS employees	Physicians	Społem PSS employees	
Genetic factors	2.49	1.96	1.45	1.21	0.0146
Physical environment	3.02	3.8	1.04	0.92	0.0000
Social environment	3.58	4.3	1.21	0.92	0.0000
Lifestyle	1.65	1.94	0.81	0.97	0.0437
Healthcare	4.22	2.98	0.94	1.20	0.0000

Table 4. Opinions of physicians and Społem PSS employees on the importance of the dimensions of health

Dimensions of health	Average		Standard deviation		P
	Physicians	Społem PSS employees	Physicians	Społem PSS employees	
Physical health	2.15	1.55	1.72	1.08	0.0536
Social health	5.10	5.40	1.47	1.39	0.1582
Mental health	2.15	1.93	1.33	0.88	0.5413
Emotional health	3.38	3.69	1.14	1.11	0.0616
Intellectual health	4.34	4.76	1.24	1.34	0.0455
Environmental health	5.97	5.82	1.20	1.10	0.1522
Spiritual health	4.88	4.82	2.00	1.79	0.6208

The respondents were also asked to declare which of the conditions shown to them they consider as a disease/illness that deserves medical treatment (**Table 5**). Out of 55 positions listed, in 33 cases significant differences between both groups were observed. The biggest differences were noted in the cases of: suicide, cellulitis, small penis syndrome, premenstrual syndrome, sudden infant death syndrome and the conditions resulting in learning problems, which physicians defined as deserving medical treatment far more often than Społem PSS employees. In general, physicians chose, on average, 31.31 conditions, whereas Społem PSS employees only 24.4 (**Table 6**). This confirms the hypothesis that among physicians there exists a tendency to overmedicalize many dimensions of life. It is also worth mentioning that there was a group of physicians that might be called 'virtuosos of medicalization' (6%), who marked almost every condition as needing medical treatment. There were even two physicians who marked all of them. On the other hand, some Społem PSS employees denied medical status of such medical conditions as depression, AIDS or cancer.

Table 5. Opinions of physicians and Społem PSS employees on medical status of some chosen phenomena

Which of the following conditions do you consider as a disease/illness that deserves medical treatment?	Physicians		Społem PSS employees		p
	n	%	N	%	
labour	3	3.0%	2	2.0%	p = 0.65061
ageing	3	3.0%	3	3.0%	p = 1.0000
menopause	23	23.0%	27	27.0%	p = 0.51363
andropause	18	18.0%	16	16.0%	p = 0.70655
hair loss	23	23.0%	16	16.0%	p = 0.21155
osteoporosis	85	85.0%	74	74.0%	p = 0.05402
dying	6	6.0%	5	5.0%	p = 0.75644
kleptomania	59	59.0%	41	41.0%	p = 0.01091
rape	45	45.0%	25	25.0%	p = 0.00303
murder	30	30.0%	20	20.0%	p = 0.10247
aggression and violence	51	51.0%	50	50.0%	p = 0.88753
homosexuality	15	15.0%	27	27.0%	p = 0.03723
masturbation	6	6.0%	12	12.0%	p = 0.13821
pedophilia	70	70.0%	59	59.0%	p = 0.10406
sexoholism	60	60.0%	45	45.0%	p = 0.03367
asexuality	38	38.0%	28	28.0%	p = 0.13263
schizophrenia	96	96.0%	80	80.0%	p = 0.00050
depression	98	98.0%	92	92.0%	p = 0.05158
alcoholism	95	95.0%	83	83.0%	p = 0.00669
drug addiction	95	95.0%	83	83.0%	p = 0.00669
anorexia nervosa	94	94.0%	82	82.0%	p = 0.00902
bulimia nervosa	94	94.0%	80	80.0%	p = 0.00324
obesity	89	89.0%	66	66.0%	p = 0.00010
hyperactivity	58	58.0%	58	58.0%	p = 1.0000
impotence	79	79.0%	52	52.0%	p = 0.00006
suicide	55	55.0%	20	20.0%	p = 0.00000
sickle cell anaemia	76	76.0%	55	55.0%	p = 0.00179
down syndrome	57	57.0%	65	65.0%	p = 0.24614
dwarfism	59	59.0%	44	44.0%	p = 0.03381
deafness	89	89.0%	70	70.0%	p = 0.00087
blindness	81	81.0%	70	70.0%	p = 0.07053
hypertension	96	96.0%	89	89.0%	p = 0.06021
allergy	94	94.0%	85	85.0%	p = 0.03790
workaholism	53	53.0%	24	24.0%	p = 0.00003
increased sweating	72	72.0%	44	44.0%	p = 0.00006
turning grey	4	4.0%	4	4.0%	p = 1.0000
hangover	24	24.0%	5	5.0%	p = 0.00014
cellulitis	38	38.0%	7	7.0%	p = 0.00000
small penis syndrome	27	27.0%	5	5.0%	p = 0.00002
jet leg	15	15.0%	2	2.0%	p = 0.00098
freckles	3	3.0%	0	0.0%	p = 0.08095
high cholesterol	86	86.0%	88	88.0%	p = 0.67411
autism	79	79.0%	65	65.0%	p = 0.02747
premenstrual syndrome	46	46.0%	9	9.0%	p = 0.00000
Internet addiction disorder	66	66.0%	39	39.0%	p = 0.00013
shoplifting	59	59.0%	38	38.0%	p = 0.00297
AIDS	96	96.0%	87	87.0%	p = 0.02249
cancer	98	98.0%	97	97.0%	p = 0.65061
sudden infant death syndrome	50	50.0%	27	27.0%	p = 0.00083
hypochondriasis	52	52.0%	35	35.0%	p = 0.01532
infertility	93	93.0%	79	79.0%	p = 0.00433
dyslexia	58	58.0%	46	46.0%	p = 0.08943
dysgraphia	57	57.0%	40	40.0%	p = 0.01616
dysorthogtaphia	58	58.0%	40	40.0%	p = 0.01089
dyscalculia	57	57.0%	35	35.0%	p = 0.00180
Total	100	100.0%	100	100.0%	

Table 6. Average number of phenomena defined as disease/illness that deserve medical treatment

Average		T	p	Standard deviation	
Physicians	Społem PSS employees			Physicians	Społem PSS employees
31.31	24.4	5.12	0.0000	8.86	10.17

Discussion and Conclusions

This research has helped to answer the question: How do physicians and Społem PSS employees define health and disease and what criteria do they use to assess their health status? The results show that there are significant differences between both groups, which confirms the findings from other studies [6–12, 20–26]. And while in some cases the differences were not big, they were statistically significant and clearly oriented, which confirms the fact that education and kind of work influence the concepts of health and disease held by respondents. While physicians generally defined health using medical criteria (61%), Społem PSS employees used mixed criteria (30% vs 19% of physicians). Moreover, they described it in subjective categories as a feeling of discomfort more often (23% vs. 10% of physicians). Although in both groups medical definitions of health were the most frequent, Społem PSS employees defined it as normal functioning of the body far more often (33%), and physicians saw it rather as a state of physical, mental and social well-being (72%). On the other hand, while physicians from our study defined health according to the holistic model, they used biomedical criteria to describe it. Surprisingly, most physicians (49%) chose good mood as its most important criterion, while for Społem PSS employees normal test results (32%) were the most important. Quite unexpectedly, physical workers preferred medical and pathological criteria over functional, subjective and negative ones.

In both groups, disease was mainly defined according to medical criteria: 49% of physicians and 33% of Społem PSS employees. However, while for the former it meant 'absence of well-being', for the latter it was a pathology of the body (33%).

It is significant that for many respondents (19% of physicians and 30% of Społem PSS employees in the case of health and, respectively, 14% and 28% in the case of disease) understood both phenomena as multidimensional, consisting of many different states and described them using mixed criteria. What is also important is that the medical model of health and disease does not contradict their popular models and acceptance for the holistic, functional or subjective model can go along with biomedical criteria. Thus, the results of our study confirm the assumption that the concepts of health and disease of most of the respondents, both medical professionals and laymen, in their majority are composed of many, sometimes contradictory, health belief models. Although many respondents used categories typical of the biomedical model, and defined health as 'normal functioning of the body' and disease as 'a pathology of the body', some elements of the other models, i. e. negative, holistic, functional, subjective, environmental or axiological, were also present. Such nonmedical understanding was exemplified by concepts like: 'well-being', 'normal functioning', 'the highest good' or 'a resource', 'balance', 'homeostasis' or 'adaptation to the environment'. Thus, apart from some differences, it can be observed that popular definitions of health and disease held by Społem PSS employees consist of elements of both scientific (biomedical) model and holistic one. On the other hand, many physicians defined both phenomena in accordance with the popular model held by lay people. Therefore, it can be concluded that for the respondents the terms of health and disease are complex and difficult to verbalize.

The research, however, did not confirm the presumed differences in the perceived determinants and dimensions of health. Both groups identified lifestyle and genetic factors as the most important determinants of human health. Nevertheless, while Społem PSS employees also emphasized the role of the healthcare system, physicians did not see its importance for preserving health. On the other hand, the respondents from both groups defined physical and mental health as its most important dimensions.

What turned out to be statistically significant was the tendency of physicians to overmedicalize social life as they tended to perceive more conditions than Społem PSS employees as a disease/illness that requires treatment.

All in all, by showing professional and lay conceptualizations of health and disease, this research may be useful for health education purposes and in planning of health promotion and health prevention programs [25]. On the other hand, the common usage of medical criteria of health and disease by Społem PSS employees seems to show a growing health awareness in this study group. However, the negative and fatalistic concepts of health held by many of them can hinder the implementation of health programs basing on personal responsibility for one's health.

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ORIGINAL PAPER

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Teachers' evaluation of the project "Little Physician" by the Polish Academy of Kids run at the Poznan University of Medical Sciences

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ABSTRACT

Introduction. The project "Little Physician" has been run for over four years as a joint project of the Poznań University of Medical Sciences and the Polish Academy of Kids. It is an innovative undertaking in the international educational market, where young 'scientists' aged from 6 to 12 contribute to the classes and pursue their research interest in the broadly understood field of natural science.
Aim. The aim of this research was to probe the opinions of the teachers participating in the "Little Physician" initiative.
Material and Methods. The research was conducted on the population of 32 teachers. The applied technique was an interview based on an original questionnaire consisted of respondent`s particulars and 7 questions evaluating the usefulness, quality and thematic range of the classes, as well as the lecturers' competencies and organisation of the classes.
Results. The usefulness of the project was positively evaluated by all the interviewees (81% rated it as "very good", 19% thought it was "good"). As many as 75% of the respondents decided that the thematic range of the lectures was "very good". An even higher percentage assessed very positively the competencies of the adults giving lectures, the coordinators of the classes, the lecture halls and the manner in which classes were conducted.
Conclusions. The project is very highly evaluated by the teachers supervising the participating children. The high assessment stems from the high competencies of the coordinators and lecturers participating in the classes, an accurate choice of issue or subjects discussed.

Keywords: schoolkids, teaching, medicine, innovation.

Introduction

The project "Little Physician" has been run for over four years as a joint project of the Poznań University of Medical Sciences and the Polish Academy of Kids. The idea of opening up the universities to children regardless of their social status or school achievements came from the Polish Academy of Kids Association working closely with over 20 higher education institutions and scientific centres in Poland and abroad [1, 2].

"Little Physician" is an innovative undertaking in the international educational market – the first university run by kids, where young 'scientists' aged from 6 to 12 contribute to the classes and pursue their research interest in the broadly understood field of natural science. The classes carried out by the representatives of various medical fields are not only supposed to get young students acquainted with human physiology, diseases and medicines, but also provide an opportu-

Table 1. Grades assigned by the teachers to each question in the questionnaire

Question:	Grade				
	Very poor/low 1 point	Poor/low 2 points	Average 3 points	Good 4 points	Very good 5 points
Usefulness of the project	0	0	0	6	26
Quality of the classes	0	0	1	7	24
Thematic range of the lectures	0	0	0	8	24
Competencies of the adult lecturers	0	0	0	5	27
Environment of the classes	0	0	0	2	30
Organisation of the classes	0	0	0	7	25
Competencies of the project coordinators	0	0	0	3	29

nity for practical learning of first aid, as well as developing proper emergency behaviours. Encounters with science help shaping health-promoting attitudes, correct eating habits and personal care in children.

School is one of the oldest social institutions, designed to prepare the young generation for adult life. Thanks to their knowledge, experience and professional skills, teachers play a crucial role in the process of schooling and education [3–5].

Early education is particularly important for shaping attitudes and, as a consequence, the entire personality of pupils. It is the younger children, grade 1–3, who are exceptionally vulnerable to external influence and who show great eagerness and curiosity to learn about the world around them. Therefore, as far as this age group is concerned, the organising skills of the leading teacher have a considerable impact on the children's future development and professional career [6].

Aim

The aim of this research was to probe the opinions of the teachers participating in the "Little Physician" initiative. The usefulness of the project, the quality, organisation and environment in which the classes took place, as well as their thematic range and teaching staff's competencies were the main points of interest.

Materials and methods

The questionnaire was carried out in April 2016 among 32 teachers (30 women and 2 men) age 22–55 who in the academic year 2015/2016 participated in the "Little Physician" project as group supervisors. The respondents represented 16 school groups: 13 from Poznań and 3 from Wielkopolka region (voivodeship) — Mieścisko, Krotoszyn, Granowo, comprising 400 children. The teachers were of various level of professional advancement, namely 8 apprentices, 22 appointed teachers and 2 certified teachers.

The questionnaire consisted of respondent`s particulars and 7 questions evaluating the usefulness, quality and thematic range of the classes, as well as the lecturers' competencies and organisation of the classes. The responses were categorised within the scale from 1 to 5 where 1 stood for "very poor/low" and 5 for "very good". The respondents were also asked about their willingness to participate in similar projects in the future. The possible answers included "yes", "no" and "I am not sure".

Results

Table 1. presents the responses given by the teachers. The usefulness of the project was positively evaluated by all the interviewees, of whom 81% rated it as "very good" while only 19% thought it was "good". Only one teacher perceived the quality of the classes as "average". As many as 75% of the respondents decided that the thematic range of the lectures was "very good". An even higher percentage assessed very positively the competencies of the adults giving lectures (84%), the coordinators of the classes (91%), the environment in which the classes took place (94%) and the manner in which they were conducted (78%). **Table 2**. presents the average score for each tested category.

Table 2. Average score for each tested category of the questionnaire

Question	Average score
Usefulness of the project	4.8
Quality of the classes	4.7
Thematic range of the lectures	4.75
Competencies of the adult lecturers	4.8
Environment of the classes	4.9
Organisation of the classes	4.8
Competencies of the project coordinators	4.9

Discussion

Traditional school education does not teach children scientific approach to problems and theories. It is contemporarily believed that learning is a natural process, similar to growth and development [7]. The idea of the "Little Physician" matches perfectly the new theories regarding learning processes. Many authors underline that it is enthusiasm and joy of discovering that is the key to learning [8]. According to the most recent research, enthusiasm allows the brain to develop, while its lack leads to re-playing the previously stored information only and not to any development [9]. Therefore, the main idea behind the project the "Little Physician" is promotion of the autonomy and creativity of the youngest pupils. It is aimed at stimulating the cognitive activity, popularising knowledge and sustaining the children's primary curiosity about the world around them. It draws from the observation of children who, provided with the right tools and research spaces, can actually contribute to the world of science [10]. Participation in the extracurricular classes allows children not only to get acquainted with the latest scientific achievements but also to develop their own scientific passions which can be shared with their peers. In this way, science becomes a fascinating adventure and a very personal experience [11, 12].

It has been known for a long time that the initial few years at school determine the child's attitude towards further education, provide the basic knowledge of the world and shape the character. The teacher becomes a particularly important person in the child's life, supporting his/her creative activities and influencing his/her future level of motivation and interest in learning [12].

According to teachers, encounters with science organised out of school become an additional challenge for them involving time management, keeping discipline and ensuring funding [13].

However, despite these difficulties, since the very beginning in 2012 the "Little Physician" has been very popular among primary school teachers of Wielkpolska. Undoubtedly, free enrolment for pupils and their supervisors is a great advantage.

The "Little Physician" project is carried out within the structure the University of Medical Sciences in Poznań and by its employees, but it engages the audience in the process of active education, who are given the possibility to present their own knowledge by giving their own lectures. The classes have been organised regularly for the last five years. Each academic year the participants meet 9 times – monthly from October to June for a two-hour class. During this time young students listen to lectures given by the academic staff of the university and their own peers. Children prepare independent presentations following their passion for certain topics, and subsequently deliver them as lectures in front of the entire audience. In this way, the reasons underlying the project are being confirmed and once again show that an immediate contact with science through experiment and university lab shapes a very different attitude towards learning, encourages studying, exploration and discovering new information. Moreover, compared to their peers, children participating in the meetings feel happier and are prouder of their work [14, 15].

In primary teaching, increasing attention is paid to health education. Its goal is not only to change behaviour (e.g. caring about one's health), but also to develop children's skills and abilities to consciously act for the benefit of their own health and of the environment they live in [16, 17].

Teachers of grades 1–3 particularly have a great opportunity to develop health attitudes in pupils, given the possibility of implementing the educational content not only in rational physical education, but also through shaping hygienic habits, or paying attention to diet. All those topics are subject of the project [18].

A highly positive evaluation of the "Little Physician" that has been carried out for the last four years within the structures of our university, results in its increasing popularity among primary schools. Moreover, this form of education provides new didactic experience to university teachers since children are a very different audience from their regular students. However, those who one decided to take up the challenge and lecture to a group of 400 children, as well as answer all of their very inquisitive questions in an accessible way, are very happy to continue and participate in the following editions. It is another great advantage of this educational program that the knowledge acquired by the young students is transferred to others, as the participants of the project become leaders, organise lectures and presentations in their own schools, or take active part as lecturers in International Children Conferences, in this way promoting both the project and the university.

Conclusions

The project "Little Physician" is very highly evaluated by the teachers supervising the participating children. The high assessment stems from the high competen-

cies of the coordinators and lecturers participating in the classes, an accurate choice of issue or subjects discussed as well as the environment (quality of lecture halls) in which the classes take place. Participation in the project encourages cognitive curiosity in children and inspires further scientific activities in school.

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The nutritional status and nutrition habits in a group of patients with end stage renal failure treated with hemodialysis

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ABSTRACT

Aim. The aim of the study was to assess the nutritional status and nutrition habits in a group of patients with end stage renal failure treated with hemodialysis.

Material and Methods. The study group consisted of 50 patients treated with hemodialysis, including 16 women and 34 men. The average age of researched patients was 67.02 ± 10.71 years. We used an authorial questionnaire in the research, which contained questions about feeding behavior and nutritional status. In addition, patients underwent anthropometric measurements.

Results. The research revealed that the nutritional status of patients with chronic kidney disease treated with hemodialysis was poor. The supply of energy, carbohydrates, protein and dietary fiber in the studied group were 1583.41 ± 379.55 kcal, 222.68 ± 55.08 g, 63.75 ± 15.25 g and 55.75 ± 18.55 g respectively, which were all below the standard daily requirement. The deficiencies of magnesium, iron and vitamins were also observed. More than half of respondents (52%) ate only 3 meals a day.

Conclusions. The results of research show that both – nutritional state and eating habits of patients were abnormal and deviated from the dietary recommendations for this group of patients. Changes of the nutrition will positively influence the nutritional state of patients, as well as improve their quality and length of life.

Keywords: nutrition; hemodialysis; malnutirion.

Introduction

Chronic kidney disease (CKD) recently has been included into a group of civilization diseases. CKD is a special entity in this group of diseases, because it can be both a cause and a result of cardiac syndrome X. The increase in the frequency of occurrence of CKD contributes to the need for dialysis treatment on a greater scale, complicated with malnutrition. Research by Aparicio et al [1] on a large group (n = 7000) of patients with CKD showed, that the lower albumin level (<35 g/l), prealbumin (<300 mg/l) and nPNA (normalized protein nitrogen appearance) (<1 g/kg body mass/24h) applies to respectively 20%, 36% and 35% of them. As Carrero et al. states [2] poor nutritional state is diagnosed in 35–60% of dialyzed patients and is linked to two types of disturbances. One of them is protein energy malnutrition (PEM), which is a factor that increases mortality both in conservative treatment as well as during the dialysis treatment. Already in the early phases of CKD a reduction in the non-fat body mass can be observed. Lower concentration of protein in the blood serum and decreased cellular immunity are also characteristic. Deficiencies of mineral elements i.e. zinc, iron, selenium and vitamins: B6, C, D, folic acid and carotenoids. The main cause of PEM during a chronic kidney disease are: increased loss of nutritional elements, metabolic acidosis, decreased intake of food caused by appetite loss as well as hormonal and metabolic disturbances. Sec-

ond type of malnutrition is malnutrition induced by the pro-inflammatory cytokines secreted as a result of CKD concomitant illnesses [3]. This type is called malnutrition inflammation complex syndrome (MICS) and often coexists with atherosclerosis as malnutrition inflammation atherosclerosis (MIA) syndrome [4]. The activation of the inflammatory process results in an increased cytokine synthesis and intensification of secretion of pro-inflammatory cytokines i.e. TNF-α, IL-1 and IL-6. This cases an increase in the basal energy expenditure with simultaneous decrease in appetite, hypercatabolism of proteins and suppression of transferrin and albumin synthesis in the liver. In this type of malnutrition more frequent dialysis or change in the way of nutrition in not effective. The comorbid diseases need to be treated, especially inflammatory states [5, 6].

Because of the fact that poor nutritional state is an element impinging on the course of treatment as well as on the quality and length of life of dialyzed patients we need to put special attention on the necessity for its assessment. Taking on an appropriate nutritional therapy, based on both the education as to the adequate energy supply, macro and microelemnts (**Table 1** and **2**) as well as supervision as to the application of dietary recommendations in daily meal planning, is also crucial. Only due to such an approach an effective countermeasure against malnutrition and development of comorbid metabolic disturbances, among others, disturbances in lipid metabolism (i.e. hypergliceridemia, lowering the level of high-density cholesterol (HDL) and an increase in the low-density cholesterol concentration (LDL)) as well as deregulation in the carbohydrate metabolism expressed as insulin resistance, is possible.

Aim

The aim of the study was the nutritional state assessment of patients with chronic kidney disease treated with hemodialysis. The assessment was done through the analysis of anthropometric measurements (body mass, BMI) and chosen biochemical parameters. Furthermore, the dependencies between the anthropometric measurements and chosen biochemical parameters as well as the consumption of nutritional components were analyzed. On the basis of qualitative and quantitative analysis of conducted 24-hour interviews the way of nutrition was evaluated with particular con-

Table 1. Recommendations for energy, macro- and microelements dietary supplementation for the patient treated with dialysis [7–9]

	KDOQI (Kidney Disease Outcomes Quality Initiative)	ESPEN 2009 (The European Society for Clinical Nutrition and Metabolism)	NKF (National Kidney Foundation)
Energy	35 kcal/kg body mass/24h		35 kcal/kg body mass/24h in patients up to 60 years old 30–35 kcal/kg body mass/24h in patients > 60 years old
Protein	1.0–1.2 g/kg body mass/24h	1.2–1.4 g/kg body mass/24h (> 50% HBV) In patients treated with chronic peritonial dialysis 1.2–1.5 g/kg body mass/24h (> 50% HBV)	1.2 g/kg body mass/24h (> 50% HBV) In patients treated with chronic peritonial dialysis 1.2–1.3 g/kg body mass/24h (> 50% HBV)
Carbohydrates	50–60%	–	
Fiber	20–30 g/24h		
Fats	25–30% < 7% saturated fatty acids, approximately 10% polyunsaturated fatty acids, 20% monounsaturated fatty acids.		
Fluids	1–1.5 l/24h may be increased by the 24h urine volume	1l + urine volume	–
Sodium	1800–2500 mg/24h	1800–2500 mg/24h	–
Potassium	1500–2000 mg/24h	2000–2500 mg/dl	
Phosphorus	800–1000 mg/24h	800–1000 mg/24h	
Folic acid	1 mg/24h		
Vitamin B1	10–20 mg/24h		
Vitaminy C	30–60 mg/24h		

Table 2. Recommended supplementation doses of vitamins and minerals according to the European Best Practice Guidelines (EBPG) [10, 11]

Vitamin / mineral element	Dosage
B1 (thiamine)	1.1–1.2 mg
B2 (riboflavin)	1.1–1.3 mg
B5 (pantothenic acid)	5 mg
B6 (pyridoksine)	10 mg
B12 (cobalamin)	2.4 µg
C (ascorbic acid)	75–90 mg
PP (niacin)	14–16 mg
H (biotin)	30 µg
Folic acid	1 mg
A (retinol)	supplementation is not required
D	0.25–1 µg
E (L-tocopherol)	400–800 jm
K	supplementation is not required
Phosphorus	800–1000 mg/24h
Calcium	2000 mg
Sodium	2000–2300 mg/24h
Potassium	50–70 mmol (1950–2730 mg/24h)
Iron	8 mg for men, 23 mg for women
Magnesium	200–300 mg
Zinc	10–15 mg for men, 8–12 mg for women (supplementation is not required)
Selenium	55 µg (supplementation is not required)

sideration of caloric values of consumed meals and contribution of macroelements in coverage of the daily energy demand.

Materials and Methods

The study was conducted on the group of 50 people with the diagnosis of end stage renal insufficiency treated with hemodialysis. Among the patients were 16 women and 34 men. The data was collected during the period between February and March 2014 in the Hemodialysis Laboratory of the Nephrology, Transplantology and Internal Diseases Department of Heliodor Swiecicki Clinical Hospital at Poznan University of Medical Science and the Dialysis Station – Dialysis Center Fresenius Station no.71 in Poznan. After informing the respondents about the aim, voluntary aspect and anonymity of the conducted research and after obtaining a written consent to perform them, the way of nutrition was assessed and anthropometric and biochemical measurements were performed.

In order to assess the way of nutrition an original questionnaire survey, containing both open and closed ended questions. The survey questions concerned socio-statistical data and nutritional habits. On the basis of 24-hour interview from 3 randomly chosen days (2 week days and 1 day free from work) daily demand coverage for energy, makro- and microelements were assessed. The results obtained were than analyzed with the use of a Dietician 2012 computer program and compared with the nutritional norms for particular population groups (Human Nutrients and Nutritional Norms of the Food and Nutrition Institute updated in 2012) as well as recommendations of ESPEN (The European Society for Clinical Nutrition and Metabolism).

Body mass measurements were performed with the use of standard medical scale with the accuracy to 0.5 kg, and the height measurement with the use of a measuring rod with the accuracy to 0.5 cm. Based on the acquired anthropometric characteristics the body mass index (BMI) was calculated, by dividing the body mass value in kilograms by the square value of the height measurement in meters. Furthermore in patients the arm circumference was measured (on the arm of the non-dominant hand in the middle of the length between the acromion and the olecranon process) with the use of a measuring tape with the accuracy to 0.5 cm.

The daily energy requirement (DER) of patients was calculated by multiplying the value of basal metabolic rate (BMR) set by the Harrison-Benedict equation, by the appropriate active metabolic rate (AMR) for each evaluated patient.

Statistical analysis of results

The data analysis was performed with the use of a descriptive statistical method of a computer program Statistica10. In order to assess the nutritional status and nutrition habits in a group of patients the Shapiro-Wilk test of normality was used in the first step. For the statistical description of variables, functions such as: arithmetic mean and standard deviation (square root of variance, in other words the square root from the second central moment), were used. The differences between variables were assessed with the appraisal of statistical significance (p). In all tests a p value ≤ 0.05 was considered to be statistically significant. Statistical hypothesis were verified on the level of significance: very high significance ($p \leq 0.001$), high significance ($p \leq 0.01$) and significance of result ($p \leq 0.05$).

Results

Average age of the researched population was 67.02 ± 10.71 years. Studies showed statistically significant positive correlation between the duration of the disease and the length of dialysis treatment (p = 0.010, r = 0.359). The characteristics of researched population are shown in **Table 3**.

Table 3. Characteristics of researched population

Characteristic	Number (n)	Percent (%)
Place of residence:		
Rural area	3	6
City < 100000 inhabitants	14	28
City > 100000 inhabitants	33	66
Education:		
Vocational edication	24	48
Secondary education	16	32
Primary education	6	12
Higher education	4	8
Financial situation:		
Good	21	54
Average	27	42
Bad	2	4
Duration of disease	9.66 ± 10.86 years	
Length of dialysis treatment	2.53 ± 2.10 years	
Concomitant diseases	41	82
Including:		
Diabetes	16	32
Hypertension	17	34
Thyroid diseases	3	6
Cardiovascular diseases	12	24
Other	27	54

Assesment of nutritional state

Based on the conducted anthropometric studies it was assessed that the average body mass in the studied population was 76.45 ± 15.42 kg, height 1.70 ± 0.08 m and the value of BMI 26.51 ± 4.97 kg/m^2, where its lower level was noted in women. A statistically significant, positive correlation was shown between the patients financial status and BMI value (p = 0.028, r = 0.31035). Average level of albumin in the patient group with CKD was at the lower level of the norm (36.64 ± 4.02 g/l) and significantly correlated with the blood serum iron concentration (p = 0.011, r = 0.358) (**Table 4**).

Assessment of consumption

Conducted analysis of nutrition manner based on the 24-hour interview, showed that the average supply of energy oscillated on the level of 1583.41 ± 379.55 kcal and was too low in relation to the population demand, which was on average 2401.59 ± 499.89 kcal. Significant deficit was observed in the demand coverage for carbohydrates (222.68 ± 55.08 g), protein (63.75 ± 15.25 g) and fat (55.75 ± 18.55 g), although the percent dispersion of daily energy requirement for the particular macroelements was appropriate. Insufficient 24-hour consumption of calcium (387.45 ± 206.64 mg), magnesium (218.54 ± 66.84 mg), iron (8.13 ± 2.31 mg) and vitamin D (1.90 ± 2,67 µg) were also noted (**Table 5**). Despite considerable vitamin and mineral deficiencies in the diet of patients studied, only 12% of them admitted that they are taking the supplementation that was recommended by the doctor – mostly calcium formulations.

A statistically significant correlation was found in the study between the energy consumption and the value of daily energy requirement in patients (respectively p = 0.035, r = 0.300). Furthermore, a negative dependency was observed between consumed energy and the frequency of snacking (p = 0.015, r = -0.344).

Table 4. Measurements and anthropometric indices of nutritional state

	Mean	SD	Minimum	Maximum
Height [cm]	1.70	0.08	1.50	1.90
Body mass [kg]	76.45	15.42	45.00	114.00
BMI [kg/m^2]	26.51	4.97	17.58	39.45
Arm cercumference [cm]	29.54	3.54	19.00	38.00
Albumins [g/l]	36.64	4.02	27.00	45.00
Iron [mg/dl]	64.46	21.60	16.00	117.00

Table 5. Daily food rations consumption levels

	Mean	SD	Minimum	Maximum
Energy	1583.41	379.55	695.91	2360.03
Energy from fat [%]	31.02	5.74	18.32	46.43
Energy from protein [%]	16.37	2.92	12.25	24.56
Energy from carbohydrates [%]	52.62	5.92	37.98	66.88
Total protein [g]	63.75	15.25	23.09	97.89
Total fat [g]	55.75	18.55	15.16	92.35
Total carbohydrates [g]	222.68	55.08	113.53	335.30
Dietary fiber [g]	18.13	5.48	8.93	34.54
Sodium [mg]	1872.22	581.99	850.91	3085.14
Potassium [mg]	2408.82	638.82	1331.86	3915.20
Calcium [mg]	387.45	206.64	130.70	1301.83
Phosphorus [mg]	969.13	240.98	341.62	1735.72
Magnezium [mg]	218.54	66.84	109.49	468.37
Iron [mg]	8.13	2.31	4.04	14.28
Vitamin D [µg]	1.90	2.67	0.17	19.41

Nutritional manner assessment

Most surveyed people (52%) admitted, that they consume three meals during the day. A total of 19 patients (38%) admitted to the planning of 4–5 meals in their daily menu. Only 5 patients (10%) disclosed that they most often consume 1–2 meals per day, however none of the people asked answered that they eat more than 5 meals per day. More than 3/4 (76%) of the respondents ate their meals always or very often at the same times, wherein 24 people (48%) declared, that they keep at least a 3 hour break between the last meal of the day and sleep time. Somewhat shorter – 2 hour break was kept by 20 people (40%) and 6 patients revealed that they usually eat 30–60 minutes before going to sleep. Among the surveyed 26 people (52%) declared irregularity in the times of meal consumption. There exists a negative correlation, between the regularity of meal consumption and the frequency of snacking ($p = 0.033$, $r=-0.301$). Patients, who declared that they eat their meals always at the same time admitted, that they do not have the habit of snacking between their meals. Among the foods preferred as snacks, most (30%) of people chose fruits, 12% sweets, 8% a piece chose nuts and sandwiches. Individual people admitted, that when snacking they choose vegetables or milk products.

Among the surveyed only 19 people (32%) chose whole grain wheat products. Mixed grain baked goods were eaten by 15 people (30%) and 16 patients (32%) were in favor of white bread. Besides bread, the most often chosen flower products by patients were traditional wheat pasta (26%) and white rice (16%).

Amidst patients with CKD treated with dialysis 19 people (38%) answered, that they consume meat 3–4 times per week, 13 (26%) of the respondents consumes meat products daily and 12 (24%) eat meat once a week. Among the studied the preferred kind of meat was poultry – 17 people (34%) chose it. Fourteen investigated (28%) consume both poultry and pork meat in similar proportions.

Over half of the patients – 28 (56%) people eat fish once a week, 11 people (22%) sporadically, 5 (10%) few times a month, 4 people (8%) do not eat fish at all, and only 2 people (4%) eat fish 3–4 times per week.

With regard to eating dairy products, close to half of the respondents (48% of people) declare, that they eat milk products daily, 20 people (40%) 3–4 times per week, 3 patients (6%) eat dairy once a week, 2 (4%) sporadically and 1 person (2%) does not eat dairy products at all.

Satisfactory results were obtained on the field of consumption of fruits and vegetables. Considerable share of evaluated (close to 70%) ate fruits daily (35 people) and vegetables (34 people). Five people (10%) ate fruits sporadically, 4 people (8%) once a week and 3 of the surveyed (6%) ate fruits 3–4 times per week. Only 2 patients did not eat fruits at all. In turn, 10 people (20%) declared consumption of vegetables 3–4 times per week and 3 patients each (6%) admitted to eating vegetables once a week or sporadically. A total of 21 patients (42%) consumed fruits and vegetables in the raw form, the same amount of people prefered fruits and vegetables both in raw and

cooked forms. Only 8 of the evaluated (16%) chooses only cooked fruits and vegetables.

When asked about the amount of fluids consumed, almost half of the people (48%) answered, that they normally ingest 1.5–2 liters of fluids per day. Most patients, exactly 24% of them, drink mineral water, coffee and tea. The least amount of people, only 2% consume solely coffee or only fruit juices and tea.

On the question concerning appetite 44 people (88%) answered, that in the period of last three months their appetite has not changed. Three people (6%) noticed slight, and one person considerable appetite loss. Only one from the surveyed patients observed in themselves increased appetite.

Most often used type of fat for the purpose of spreading it on bread was butter (60% of evaluated), whereas during cooking and hot meal preparation patients usually chose vegetable oils (76%). Among the techniques of food preparation, the surveyed preferred mostly boiling in water and baking. Only 12% of the studied admitted, that they eat solely fried meals. When selecting appropriate spices no significant differences among the respondents were seen – similar percent of the researched used all – salt, pepper, herbs as well as ready-made mixtures of spices.

Most of the studied, 18 people (36%) consumed sweets sporadically, 14 (28%) of them every day, 8 (16%) 3–4 times per week, 6 (12%) of the questioned never ate sweets, 3 (6%) ate sweets once a week and only one person (2%) few times a week.

Full abstinence from alcohol was declared by a total of 76% of the evaluated. Twelve percent of the respondents admitted that they drink alcohol less frequently then once a month, 8% reaches for it 2–3 times a month, whereas 2 patients disclosed that they consume alcohol more frequently than once a week. Most often chosen by the surveyed alcoholic beverage was beer and wine. Considerable fraction of the researched (84%) does not smoke cigarettes.

The results of the question concerning physical activity shows promise. Close to 40% of the respondents disclose that they undertake physical activity daily, 20% works out 3–4 times a week, 10% 5–6 times a week and 4% 1–2 times a week or sporadically. Only 22% of the studied do not undertake any physical activity (**Figure 1**).

Discussion

People treated with dialysis are vulnerable for the development of malnutrition, what in consequence significantly lowers patient's quality of life, and increases the occurrence risk for cardiovascular incidents. Thorough analysis of the nutrition manner and the state of nutrition is an effective tool allowing for the early detection of poor nutrition state as well as dietary mistakes made by patients, leading to an effective countermeasure against their negative results.

As the study showed, in 62% of patients the BMI was > 25 kg/m^2. Numerous epidemiological data concerning the general population show the existence of positive dependency between obesity and mortality [12, 13]. However in patients with CKD treated with hemodialysis, the occurrence of a so called "reversed epidemiology" phenomenon is being described. This phenomenon states, that higher BMI assures longer survival and improves patients prognosis [14]. In studies on large (over 5 thousand people) populations of patients treated with hemodialysis Chazot et al. showed that, in people with overweight or obesity, the risk of death is lower as compared with people having normal or lower body mass [15]. Similarly, Fleischmann et al. observed, that increase in BMI of one unit above 24.99 kg/m^2 decreases the risk of death of patients with CKD even by 30% [16].

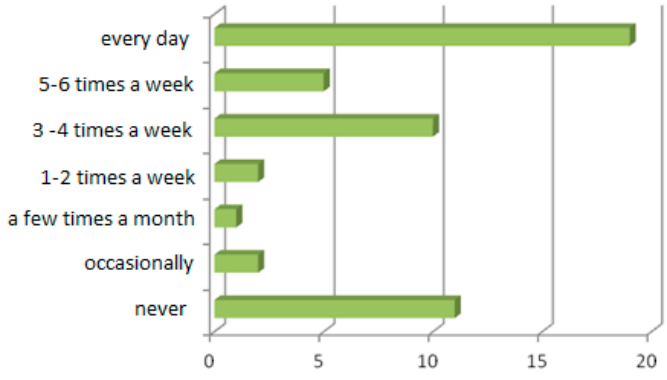

Figure 1. Frequency of physical activity undertaking

Well balanced diet of patients with CKD complements pharmacological treatment in a significant way, slows down the disease progress and enhances nutrition state [17, 18]. As the conducted study showed, the average energetic value of the respondents diet was 1554.49 ± 435.04 kcal/day and was significantly lowered in comparison to the patients demand, which according to the norm reaches 2401.59 ± 499.89 kcal/day. Similar results were obtained by Rocco et al., who showed that, the average energy supply of patients with chronic renal failure was at a level of 1566 ± 636 kcal/day [19]. In the study by Lou et al. the coverage of the energy demand was slightly higher and totaled 2018.5 ± 104.0 kcal/day which still comprises unsatisfactory value in relation to the ESPEN recommendations [20]. Furthermore, the analysis of 24-hour interviews showed deficient supply of protein in the diet of patients with chronic renal insufficiency treated with dialysis. The same results were obtained by Alshatwi et al [21] disclosing, that in almost 82% of patients the protein consumption was lower than 1.2 g/kg BM and on average totaled 0.8 ± 0.4 g/kg BM. Morais et al. studies [18] also showed inadequate protein consumption in the diet of dialyzed patients – the average protein supply in the population mentioned was 74.3 ± 16.6 g/d. Despite the promising share of fruits and vegetables in the respondent diet, inadequate consumption of dietary fiber was observed. Similar results were also obtained in different studies [17, 22–24].

Data analysis showed that substantial deficiencies of calcium and iron occur in the diet of studied patients. These are caused by inadequate contribution of the products which are its good sources in the coverage of daily food rations. Similar results were acquired by Gajewska et al [25] and Lou et al [20]. Therefore, in dialysis treated patients with CKD supplementation with calcium formulations, active form of vitamin D and iron is advised [26].

In the case of sodium, potassium and phosphorus, adequate coverage of the demand in the diet was observed, although other researchers suggested the occurrence of deregulation (both too low and too high level) in regard to the supply of the mentioned microelements [17, 20, 22, 23, 27].

Conclusions

1. Patients with chronic kidney disease treated with dialysis comprise a heterogenic group with regard to nutritional state and the manner of nutrition.
2. Patient's diet is characterized by too low energy supply as well as inadequate consumption of macroelements – in particular carbohydrates and protein.
3. Deficiencies of mineral components and vitamins occur in studied patients' diet.
4. Anthropometric indicators of patients with chronic renal disease treated with dialysis point to disturbances in nutrition state.
5. Well balanced diet of patients with CKD compliments pharmacological treatment in a significant way, impedes the disease progress and improves the nutritional state. Therefore it is important to draw special attention of the medical community on the need to change patients manner of nutrition with particular consideration of nutritional education and the supervision of adherence to the dietary recommendations.

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Conflict of interest statement
The authors declare no conflict of interest.

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Assessment of quality of life in outpatients with osteoarthritis

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ABSTRACT

Introduction. Osteoarthritis is a chronic and one of the most often appearing causes of the afflictions on the part of the motor organ. A chronic condition has a negative impact on all areas of human functioning. Its occurrence, but mainly the severity of its symptoms results in significant reduction in quality of life, which is why it is important to assess the effects of the treatment process and rehabilitation.

Aim. Assessment of quality of life of patients with osteoarthritis as regards variables such as age, gender, duration of the disease.

Material and Methods. The study includes a group of 40 patients diagnosed with osteoarthritis treated in the Health Centre of General Physicians in Mieścisko, Poland in the period from October 2014 to January 2015. The tool which was used to investigate the quality of life of people with osteoarthritis was the Polish version of the scale Arthritis Impact Measurement Scales 2 (AIMS-2).

Results. The lowest level of the quality of life was indicated by the subjects in the areas of: arthritis pain (6.54 ± 1.96), walking and bending (6.51 ± 2.81) and mobility (7.21 ± 2.06). The highest level of quality of life occurred in the areas of: support from family and friends (1.56 ± 2.16), household tasks (2.47 ± 3.16), self-care (2.50 ± 2.92), arm function (2.58 ± 2.72), hand and finger function (2.71 ± 3.03), work (2.67 ± 2.38) and mood (3.14 ± 1.56). The youngest participants obtained a result of higher level of the quality of life, which was subject to deteriorate with age.

Conclusions. Patients with osteoarthritis require a permanent, comprehensive, multifaceted and multidirectional proceedings in order to improve comfort and quality of life.

Keywords: quality of life, osteoarthritis, outpatient treatment, Arthritis Impact Measurement Scales-2.

Introduction

Osteoarthritis is a chronic and one of the most often appearing causes of the afflictions on the part of the motor organ [1, 2]. For the first time this disease was considered as a separate disease entity in 1907. For many years osteoarthritis was regarded as a result of the natural ageing process. Currently it is known that numerous genetic, biochemical, mechanical and of inflammatory nature factors correspond to the formation of degenerative changes and their advancement [3].

In particular, this medical condition is regarding elderly people. It is manifested in between 40 and 60 years old and its frequency is increasing with age. More severe forms of the disease occur in women [3]. According to E.J. Kucharz [2], this disease mostly affects knee joints, hip joints and hands. It is estimated that 67% of women and 55% of men over age 55 have been diagnosed with osteoarthritis. For people over 80 years old this percentage increases significantly. These data show that osteoarthritis is the overriding problem in the ageing societies of Europe.

A chronic condition has a negative impact on all areas of human functioning. Its occurrence, but main-

ly the severity of its symptoms results in significant reduction in quality of life, which is why it is important to assess the effects of the treatment process and rehabilitation. This should aim for the improvement of well-being and functioning of a patient within the framework of the basic activities of daily life, with a particular effect on "life competencies" and quality of life [4].

Aim

The aim of the study was to assess the quality of life of patients with osteoarthritis on the basis of the Polish version of the scale Arthritis Impact Measurement Scales-2 (AIMS-2).

In the study the following research questions were asked:

1. What is the quality of life of patients with osteoarthritis in respective areas of AIMS-2 scale?
2. Does the quality of life in respective areas of AIMS-2 scale depend on the gender of respondents?
3. Does the quality of life in respective areas of AIMS-2 scale depend on the age of the respondents?
4. Does the quality of life in respective areas of AIMS-2 scale depend on the duration of the disease?

Material and Methods

The study was conducted among the patients of Health Centre of General Physicians in Mieścisko, Poland in the period from October 2014 to January 2015. The study includes a group of 40 patients diagnosed with osteoarthritis treated in this clinic. A diagnosis of osteoarthritis has been established on the basis of the radiological criteria of the disease. Most of the patients were also under the medical supervision of a rheumatologist. The nature of the research was voluntary. Participants were also informed that the survey is anonymous and free of charge.

The tool which was used to investigate the quality of life of people with osteoarthritis was the Polish version of the scale Arthritis Impact Measurement Scales 2 (AIMS-2). It was developed by the Center for Rheumatic Diseases in Boston. The scale consists of two parts. The first part consists of 57 questions that help examine the quality of life in 12 the following areas: mobility, walking and bending, hand and finger function, arm function, arthritis pain, the ability to self-care, household task, work, social activity, support from family and friends, the level of emotional tension and mood. The areas can be divided into the physical, social interaction, symptom, role and affect subscales [5–7].

The range of scores is from 0 (good functioning and good quality of life) to 10 (poor functioning and poor quality of life). Each of the above-mentioned scales takes into account four or five positions with five alternative answers: from "always" to "never" and from "every day" to "not at all" [6]. In the second part questions for determining the level of contentment and life satisfaction of patients and their individual assessment of the impact of the disease on the functioning in separate areas are included. The latter part refers to questions indicating the areas of quality of life, in which patients wish to see improvement.

The last part of the questionnaire presents questions relating to the perception of the respondents of the current and future state of health as well as socio-demographic data. The obtained results can be classified into the assessment model of three or five components [6].

Characteristics of the participants

The study was conducted among 40 patients (13 men and 27 women) suffering from osteoarthritis. Most respondents were aged over 70 years old (35%). The average age of study participants was 63.38 ± 16.36 years old. Most respondents were 68 years old. The oldest participant was 91 years old, while the youngest was 24 years old. The largest group of respondents were married (62.5%). Much less participants were widowed (25%) and the least numerous group consisted of unmarried participants (12.5%). Most respondents completed secondary school (47.5%). Every fourth person had vocational education (25%). The smallest group consisted of participants with primary (15%) and higher education (12.5%). The family income was often located in the range of 1501–3000 PLN (37.5%). The average income was 2587.68 ± 2357.47 PLN. The highest income reached 12500 PLN, while the lowest 600 PLN. Most frequently respondents were suffering from the disease more than ten years (37.50%). Slightly fewer people were suffering for less than five years (35%) and the least suffered from six to ten years (27.50%). The average duration of the disease was 11.85 ± 9.72 years. The longest duration of the disease was forty years and the shortest was two years.

The detailed characteristics of the study group in terms of socio-demographic variables is shown in **Table 1**.

Table 1. Demographic and clinical characteristics in outpatients with osteoarthritis

Variables	Characteristics of variables	N	%
Age in years	Age ≤ 55	13	32.50
	Age 56–70	13	32.50
	Age > 70	14	35.00
	Mean	63.38	
	SD	16.36	
	Mode	68	
	Median	68	
	Max	91	
	Min	24	
Gender	Male	13	32.50
	Female	27	67.50
Marital status	Married	25	62.50
	Widowed	10	25.00
	Never married	5	12.50
Educational level	Primary	6	15.00
	Technical	10	25.00
	Secondary	19	47.50
	University education	5	12.50
Approximate family income	≤ 1500 PLN	14	35.00
	1501–3000 PLN	15	37.50
	> 3000 PLN	11	27.50
	Mean	2587.68	
	SD	± 2357.47	
	Mode	4000	
	Median	1850	
	Max	12500	
	Min	600	
Duration of the disease in years	≤ 5 years	14	35.00
	6–10 years	11	27.50
	> 10 years	15	37.50
	Mean	11.85	
	SD	± 9.72	
	Mode	20	
	Median	9	
	Max	40	
	Min	2	

Statistical analysis

In order to prepare the test results, descriptive and elementary methods of statistical inference were used. Statistical analysis compared the results according to gender, age and duration of the disease. To test the hypotheses, chi-square test was used. The level of significance was accepted as $p < 0.05$. In addition, the Spearman correlation was also used.

Results

Analyzing the results obtained by patients suffering from osteoarthritis in 12 areas in the first part of the AIMS-2 questionnaire, it can be stated that the highest level of quality of life occurred in the areas of: support from family and friends (1.56 ± 2.16), household tasks (2.47 ± 3.16), self-care (2.50 ± 2.92), arm function (2.58 ± 2.72), hand and finger function (2.71 ± 3.03), work (2.67 ± 2.38) and mood (3.14 ± 1.56).

The lowest level of quality of life were observed around: arthritis pain (6.54 ± 1.96), walking and bending (6.51 ± 2.81) and mobility (7.21 ± 2.06). In addition, overall results of each of the subscales were compared and it is noticed that the highest level of quality of life occurred in the subscale of roles (2.67 ± 2.38), indicating slightly more than average degree of quality of life, and by far the lowest in the symptom subscale (6.54 ± 1, 96), which indicates a low level of quality of life (**Table 2**, **Figures 1**, **2**, **3**).

Table 2. AIMS-2 scale in outpatients with osteoarthritis

AIMS-2 scale	No. of patients	Mean	SD	Mode	Median	Max	Min
Mobility	40	7.21	± 2.06	5	7	10	5
Walking and bending	40	6.51	± 2.81	10	7	10	1
Hand and finger function	40	2.71	± 3.03	0	2	10	0
Arm function	40	2.58	± 2.72	0	2	10	0
Self-care	40	2.50	± 2.92	0	2	10	0
Household task	40	2.47	± 3.16	0	1	10	0
Social activity	40	4.34	± 2.15	5	5	10	0
Support from family	40	1.56	± 2.16	0	0	10	0
Arthritis pain	40	6.54	± 1.96	9	7	10	2
Work	15*	2.67	± 2.38	3	2	8	0
Level of tension	40	5.15	± 1.47	5	6	8	3
Mood	40	3.14	± 1.56	2	3	7	1

Scores range from 0–10; 0 – high assessment, 10 – poor assessment
* A number of the employed patients

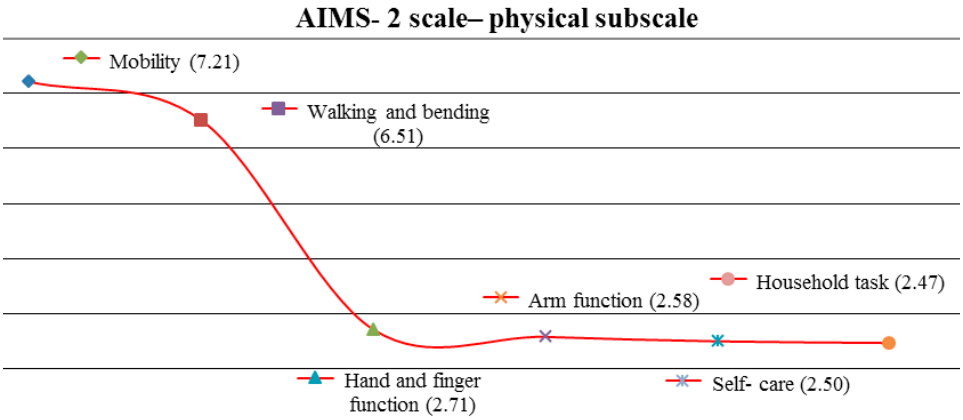

Figure 1. The average values of the particular areas of the AIMS-2 scale. Scores range from 0–10; 0 – high assessment, 10 – poor assessment

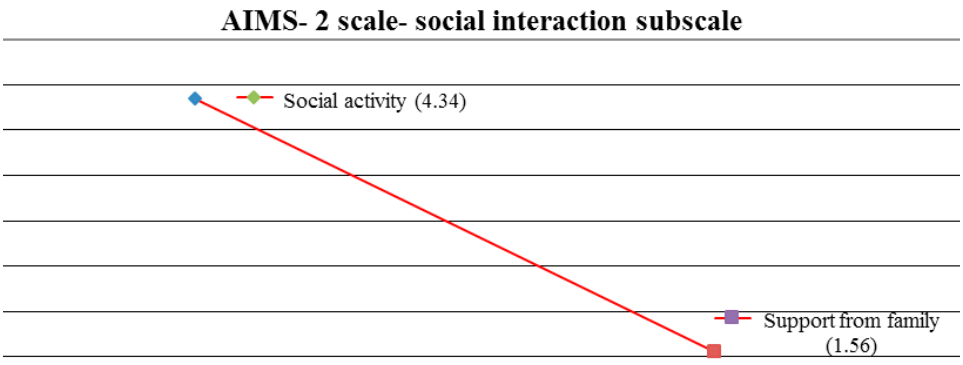

Figure 2. The average values of the particular areas of the AIMS-2 scale. Scores range from 0–10; 0 – high assessment, 10 – poor assessment

The second part of the AIMS-2 questionnaire was also analyzed. The questionnaire contained questions relating to the level of life satisfaction of patients, the impact of the disease on their functioning and the areas of quality of life requiring changes according to the views of the patients. Due to the results one can observe that the patients experienced an average quality of life in terms of satisfaction with their health condition in 12 areas of health (4.64 ± 2.22) and the impact of the disease on each of them (4.54 ± 1.87).

Analyzing the subsequent results obtained by patients it was noticed that the respondents rated

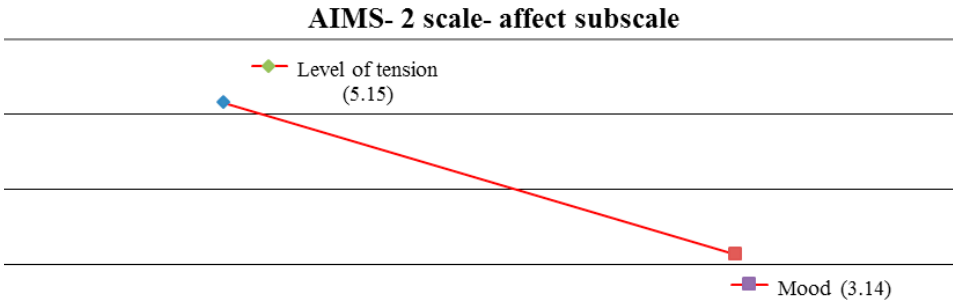

Figure 3. The average values of the particular areas of the AIMS-2 scale. Scores range from 0–10; 0 – high assessment, 10 – poor assessment

Table 3. Subjective assessment of health in outpatients with osteoarthritis

AIMS -2 scale	Mean (± SD)	Mode	Median	Max	Min
Satisfaction with each health area	4.64 (± 2.22)	3	4	9	2
Arthritis impact on each area of health	4.54 (± 1.87)	5	5	8	1
Assessment of the current state of health	7.41 (± 2.32)	7	7	10	3
Contentment of the current state of health	5.38 (± 2.57)	5	5	10	3
Arthritis impact	5.69 (± 2.40)	5	5	10	0

Scores range from 0–10; 0 – high assessment, 10 – poor assessment

Table 4. Areas for improvement

Refers to the last month	N	%
Mobility level	7	17.50
Walking and bending	24	60.00
Hand and finger function	6	15.00
Arm function	3	7.50
Self-care	5	12.50
Household tasks	11	27.50
Social activity	5	12.50
Support from family	4	10.00
Arthritis pain	25	62.50
Work	8	20.00
Level of tension	4	10.00
Mood	15	37.50
None of the domains requires improving	1	2.50

their health at a low level (7.41 ± 2.32) and they were pleased with the current state of health at a moderate level (5.38 ± 2.57). It was also observed that the influence of the disease on their lives (5.69 ± 2.40) indicates a moderate state of health, compared with other people (**Table 3**).

From **Table 4** one can indicate that 62% of patients would expect improvement in arthritis pain, and 60% in terms of walking and bending, and subsequently mood 37.50%. Quite often, as an area in need of improvement, respondents indicated work associated with household tasks (27.50%) and work understood as a professional activity (20%), as well as the level of mobility (17.50%). Least likely as areas for improvement respondents indicated self-care and social activity (12,50%) and support from family (10%), as well as the arm function (7.50%). Only one person (2.50%) did not identify any area that requires improvement.

The research shows that the results obtained from the individual subscales by a group of men and women showed a statistically significant difference in social interaction subscale, where p = 0.038 (**Table 5**, **Figure 4**). In addition, based on the analysis, it was found that the highest level of quality of life in the physical subscale was represented by the youngest respondents, being the age of 55 inclusive (2.76 ± 1.51). Next in line were people aged 56–70 years (3.64 ± 1.69). The lowest level of quality of life in the physical subscale

Table 5. AIMS-2 scale in outpatients with osteoarthritis and gender

AIMS-2 scale	Women		Men		p
	N	Mean (SD)	N	Mean (SD)	
Physical	27	4.09 (± 2.33)	13	3.80 (± 2.51)	F = 0.136; p = 0.714
Social interaction	27	2.53 (± 1.66)	13	3.82 (± 2.01)	F = 4.642; p = 0.038
Symptom	27	6.76 (± 1.80)	13	6.08 (± 2.26)	F = 1.063; p = 0.309
Role	11	3.18 (± 2.55)	4	1.25 (± 1.02)	F = 2.083; p = 0.173
Affect	27	4.06 (± 1.45)	13	4.33 (± 1.29)	F = 0.329; p = 0.570

Scores range 0–10; 0 – high quality of life, 10 – poor quality of life

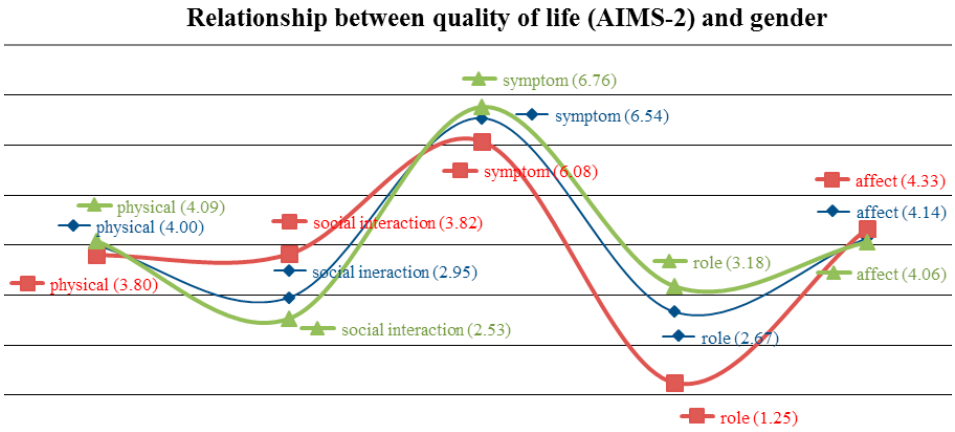

Figure 4. Men (line with squares), women (line with triangles), mean score (line with dots). Scores range from 0–10; 0 – high assessment, 10 – poor assessment

Table 6. AIMS-2 scale in outpatients with osteoarthritis and age

AIMS -2 scale	age ≤ 55		age 56–70		age > 70		p
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	
Physical	13	2.76 (± 1.51)	13	3.64 (± 1.69)	14	5.48 (± 2.81)	F = 5.908; p = 0.006
Social interaction	13	2.83 (± 1.49)	13	2.19 (± 1.25)	14	3.77 (± 2.36)	F = 2.715; p = 0.079
Symptom	13	5.73 (± 1.90)	13	6.58 (± 1.46)	14	7.25 (± 2.25)	F = 2.142; p = 0.132
Role	9	2.5 (± 2.34)	6	2.92 (± 2.64)	0		F = 0.103; p = 0.753
Affect	13	4.08 (± 1.32)	13	3.77 (± 1.59)	14	4.55 (± 1.24)	F = 1.101; p = 0.343

Scores range 0–10; 0 – high quality of life, 10 – poor quality of life

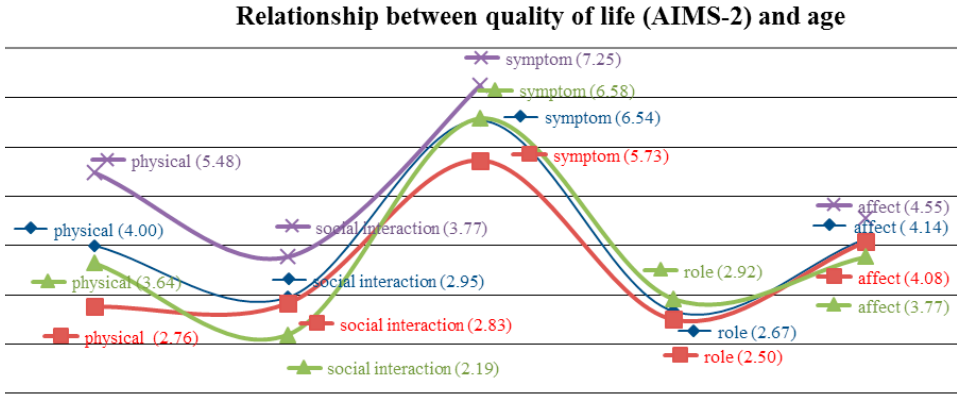

Figure 5. Age ≤ 55 (line with squares), age 56–70 (line with triangles), age > 70 (line with x-mark), mean score (line with dots). Scores range from 0–10; 0 – high assessment, 10 – poor assessment

Table 7. AIMS-2 scale in outpatients with osteoarthritis and duration of the disease

AIMS-2 scale	≤ 5 years		6–10 years		> 10 years		p
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	
Physical	14	2.93 (± 1.70)	11	4.55 (± 2.76)	15	4.58 (± 2.38)	F = 2.334; p = 0.111
Social interaction	14	3.00 (± 2.08)	11	2.32 (± 1.69)	15	3.36 (± 1.75)	F = 0.993; p = 0.380
Symptom	14	6.07 (± 1.71)	11	6.73 (± 1.89)	15	6.83 (± 2.27)	F = 0.604; p = 0.552
Role	6	2.81 (± 2.87)	7	2.86 (± 2.42)	2	1.56 (± 0.44)	F = 0.221; p = 0.805
Affect	14	3.88 (± 1.42)	11	4.18 (± 1.68)	15	4.37 (± 1.18)	F = 0.446; p = 0.644

Score range 0–10; 0 – high quality of life, 10 – poor quality of life

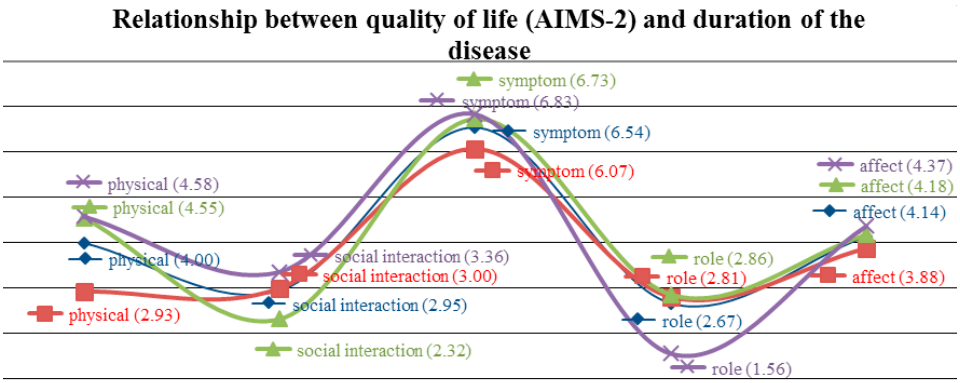

Figure 6. ≤ 5 years (line with squares), 6–10 years (line with triangles), > 10 years (line with x-mark), mean score (line with dots)

Table 8. Spearman correlations between AIMS-2 scale and age and duration of the disease

AIMS-2 scale	Age	Duration of the disease
Physical	0.56	0.25
Social interaction	0.27	0.12
Symptom	0.44	0.17
Role	0.09	-0.04
Affect	0.20	0.08

was represented by the oldest respondents at the age of more than 70 years of age (5.48 ± 2.81).

These relationships are statistically significant (p = 0.005) (**Table 6**, **Figure 5**). In all analyzed subscales a weak positive correlation between age and the audited subscale was demonstrated (**Table 8**). This means that the elderly represent a lower standard of living in all investigated subscales.

The relationship between subscales and duration of the disease was analyzed as well (**Table 7**, **Figure 6**). In none of these subscales a significant statistical dependence was indicated, however, a weak positive correlation between the duration of illness and subscales of AIMS-2 sheet was demonstrated. For physical, social interaction, symptom and affect subscales the correlations were positive. In the case of role subscale there was a negative correlation, which means that the shorter the duration of the disease, the better the quality of life resulting from social roles (**Table 8**).

Discussion

In recent years, the quality of life has become an important aspect in daily medical practice and nursing, as well as the issue, which is still a matter of interest in many research environments [7]. The patients, through the assessment of their own health are included in the overall therapeutic process [8]. Using the Polish version of the scale AIMS-2, a group of 40 patients diagnosed with osteoarthritis were tested, in which 67.50% were women and the remaining 32.50% were men. The study shows that osteoarthritis is more common

among women, therefore in research conducted by other researchers women represent more than half of the patients [9, 6, 10].

The analysis showed that subjects operate very well in the area concerning running a household tasks. The slightly worse result concerned the self-care and hand and finger function. The lowest result was obtained by the respondents in the field of walking and bending and mobility. Salaffi et al. reached similar conclusions [11].

In addition, the following study and the studies of the above authors (Salaffi et al.) confirmed that the lowest quality of life occurs in the areas of arthritis pain and walking and bending. According to the research conducted by Grygielska J. [12], for more than 70% of respondents it is fairly difficult to do activities related to engagement of hand joints and joints of the lower limbs "too many stairs, too heavy door." Similar results were obtained in study by Sierakowska et al. [8]. The aim of the study was to identify health problems in patients with osteoarthritis. The results indicated worse functioning of the patients in the physical subscale and they were related to mobility, ability to work, arthritis pain and household tasks. Rosemann et al. [10] also indicated that patients suffering from osteoarthritis demonstrated lower physical abilities of the lower part of the body. Additionally, the authors identified female sex as a group having a higher level of disability in the lower part of the body.

The study shows that in the subsacle of social interaction, the best results occurred in the area of help from the closest people: friends and family. In contrast, poorer quality of life of respondents was demonstrated in the area of social activity.

Similar conclusions were reached by Sierakowska et al. [8]. The authors divided the patients evaluating the sense of social isolation into three groups: patients suffering social isolation all the time (group I), in the states of deterioration of general health (group II) and patients not experiencing social isolation at all (group III). The analysis showed that the progressive and chronic nature of the disease had a negative impact on the sense of social isolation and limited the performance of social roles. These problems intensified with age.

Patients comprising the first group numbered 34 people and they were over the age of 77 years old. After comparing these groups, a conclusion was made that it was the subjects of group I who assessed their functioning in four domains of HRQOL very poorly. Bączyk G. et al. [6] reached similar conclusions. They conducted a study in a group of Polish patients with rheumatoid arthritis. The population of 390 patients with rheumatoid arthritis showed the best results in the area of "support from friends and family," and the worst of the area "arthritis pain".

The following study also obtained the results presenting low quality of life in the analyzed symptom subscale. After reviewing the literature, it was observed that according to Sierakowska M. et al. [8], patients indicate arthritis pain as the dominant symptom of osteoarthritis (64 of 100 respondents).

After analyzing the data obtained in the subscale of roles, according to authors' own measurements, it is clear that more than half of the respondents were not able to work during the last month (57.5% of all respondents). In statistical terms the average score in this area of functioning is 2.67, which indicates little more than the average level of quality of life. Other authors, that is: Bączyk G. et al. [13] in their research comparing the functioning and quality of life of patients with osteoarthritis and rheumatoid arthritis based on a questionnaire AIMS-2 showed that the average value in the work area stands at 4.2, and therefore the 97 respondents with osteoarthritis rated the quality of life in this area much worse.

In the case of the affect subscale, results of the study showed that the higher level of the quality of life was observed in the mood area, while the lower quality of life was noticed in the level of tension area. The average result in statistical analysis in this subscale was 4.14. This reflects the average level of quality of life in this subscale. Very similar mean score (4.42) in this area was reached by the respondents participating in the research conducted by Bączyk G. et al. [13]. Similar conclusions were reached in the measurements of Sierakowska M. et al. [8]. They found that among 100 patients participating in the study, 64 respondents, mostly women, felt a state of depressed mood all the time. Patients in this group evaluated their quality of life related to the functioning in all domains much lower (physical, psychological, environmental, social).

After analyzing the following research, the relationship between the subscale of social interaction and gender was found. Women in the gender subscale have a higher level of quality of life compared to the quality of life in men. This is confirmed by research conducted by Majda et al. [14], which show that women indicated a higher level of quality of life, both before and after hip replacement surgery. Thus it was demonstrated that gender is a variable that determines the quality of life of the participating patients. A review of available literature provides information on the deterioration of the quality of life with age. One example is a study

conducted by Chacon JG et al. [15]. The results of his research showed a significant correlation between the result of the final scale of AIMS and the age group of patients suffering from osteoarthritis. This is also confirmed by the results of the following study showing that the youngest patients participating in the study have the highest level of quality of life, which is considerably reduced with age. This dependency is demonstrated in the physical subscale. The correlation between the subscale of social interactions and age was proven as well. Namely, people aged 56–70 years have the highest level of quality of life. A lower level is indicated by the subjects aged up to 50 years. The lowest rate of the quality of life was indicated by people over the age of 70 years.

Evaluation of the quality of life of patients with osteoarthritis is essential, because it is of great clinical importance. It concerns not only the sphere of therapy and rehabilitation, but also social, emotional and professional. Therefore patients with the described disease entity require a permanent, comprehensive, multifaceted and multidirectional proceedings in order to improve comfort and quality of life [16].

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Conflict of interest statement
The authors declare no conflict of interest.

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Quality of life patients after surgical treatment of laryngeal cancer

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ABSTRACT

Introduction. The assessment of the quality of life in cancer patients requires a multidisciplinary approach and an evaluation of emotional, social and physical conditions. Objectives. The aim of the study was to analyze the quality of life patients after surgical treatment of laryngeal cancer but before the next stage of therapy, i.e. radiotherapy.
Material and Methods. The study group comprised 60 patients aged 44–82 years, with laryngeal cancer treated at the Radiotherapy Wards of Wielkopolskie Centrum Onkologii, Poznań, Poland. The Polish versions of the QLQ C-30 and the cancer-specific EORTC QLQ H&N35 questionnaires were used.
Results. Mean score for the general health status (QLQ C-30) was 56.81. Mean values for the physical, role, cognitive, social and emotional functioning were 81.11, 80.83, 75.28, 70.00 and 54.72, respectively. The following constituted the main problems for laryngectomees: difficulty gaining weight (75.00), necessity to take nutritional supplements (58.33), sense of smell and taste problems (57.78), weight loss (56.67), articulation problems (56.67). A statistically significant difference ($p = 0.002$) was observed with regard to emotional functioning, with mean values of 28.83 and 60.51 for women and men, respectively. Also, a statistically significant difference ($p = 0.01$) was observed with regard to social functioning, with mean values of 45.53 and 75.51 for women and men, respectively. Conclusions. There exists a definite need to investigate the quality of life by means of patient self-evaluation of the symptoms in order to monitor patient status and establish an individual therapeutic, care and psychological approach.

Keywords: quality of life, laryngeal cancer, QLQ C-30, EORTC QLQ H&N35.

Introduction

Epidemiologic data demonstrates a steady increase in the incidence of laryngeal cancers, with higher morbidity among men as compared to women. Laryngeal cancer is most often detected in regular smokers and consumers of alcohol, especially distilled beverages. It is the fourth most common malignancy in men, after lung, stomach and prostate cancers, but twenty-seventh in women. Laryngeal cancer remains the most frequent neoplasm among the head and neck carcinomas, which constitute 5% of all registered malignancies in Poland, with 7.2% among the male and 1.8% among the female population [1, 2]. According to epidemiologic data, the incidence rates among men have stabilized in recent years but increased among women [3, 4, 6].

The symptoms largely depend on the location of the primary site [3]. Laryngeal cancer is associated with mutilating surgical procedures as partial or complete removal of the larynx is performed. It is the consequence of either delayed presentation to a family doctor or referral to a specialist and ignorance of symptoms by family doctors and the patients themselves. The treatment is often initiated in advanced stages of the disease, what has significant negative effect on the outcome and quality of life. The treatment

process of laryngeal cancer is associated with problems and inconveniences resulting from the diagnostic and therapeutic management [4]. The evaluation of the quality of life in cancer patients requires a multidisciplinary approach and evaluation of emotional, social and physical conditions. Specificity of laryngeal cancer treatment ought to take into account disfiguration (tracheostomy tube), eating disorders, problems with communication, and social conditions. Numerous years of research on quality of life help generate the form of questionnaires that nowadays are commonly used in the evaluation of quality of life in cancer patients [5].

Aim

The aim of the study was to analyze the quality of life patients after surgical treatment of laryngeal cancer but before the next stage of therapy, i.e. radiotherapy.

Patient population

The study was conducted in 60 patients with laryngeal cancer between August 2011 and October 2013 at the Radiotherapy Wards of Wielkopolskie Centrum Onkologii, Poznań, Poland. The inclusion criterion was laryngeal cancer and laryngectomy.

The examination was performed in all patients after surgical treatment but before the next stage of therapy, i.e. radiotherapy.

Histopathology confirmed squamous carcinoma in all laryngectomees. All participants were informed about the objective of the study and assured of their anonymity. Informed consent was obtained from all subjects, followed by instruction on how to complete the questionnaire.

The study was approved by the Ethical Review Committee at the Poznan University of Medical Sciences.

Methods

The Polish version of the QLQ C-30 (version 3.0) was used to investigate quality of life. The questionnaire is applicable in all oncologic patients, regardless of cancer type, and assess the impact of the complaints on the quality of life and effect of the disease on various types of functioning [7]. Also, QLQ C-30 evaluates the general health status of patients, their physical, role, emotional, cognitive, and social functioning. The scores range from 0 to 100 points, with high scores signifying either better life quality (with regard to general health status, physical, role, emotional, cognitive, and social functioning) or more severe symptom-related complaints (with regard to the impact of the symptoms on the quality of life).

Additionally, Polish version of the EORTC QLQ H&N35 questionnaire, investigating the incidence of cancer-specific symptoms in patients treated for head and neck cancer, was used. The tool evaluates various aspects of life on seven different functioning scales. One answer is to be selected on a 4-point scale ('not at all', 'a little', 'significantly', 'greatly').

The answer choices (points) were converted into numbers using a typical database. The scores ranged from 0 to 100 points, with high scores signifying more severe symptom-related complaints (with regard to the impact of the symptoms on the quality of life).

An approval for using the two questionnaires was obtained from the European Organization for Research and Treatment of Cancer (EORTC), Quality of Life Unit, Brussels.

Statistical analysis

Values calculated for the selected measuring instruments were used to assess the quality of life of the laryngectomees and the following measures of descriptive statistics were used: mean, median, standard deviation, incidence, and percent values of fractions. Laven and Kolmogorov-Smirnov tests evaluated the normality of dependent variables. Mann-Whitney test was applied to compare two independent groups. Spearman's correlation was used to investigate correlations between mean values for the QLQ C-30 quality of life scale and H&N35 symptom intensity scale. The p-value of <0.05 was considered statistically significant.

Results

The study group (11 women and 49 men, aged 44–82) included laryngectomees with different levels of education (8 – primary, 27 - VET, 17 – secondary, and 8 – tertiary) and types of professions (in the subgroup of men: driver – 9, farmer – 5, bricklayer – 4, teacher – 3, accountant – 3, carpenter – 3, ironworker – 3, house painter – 2, security officer – 2, baker – 2, as well as gardener, building technician, electrical engineer, woodworker, fine artist, electroplater, steelworker, tire technician, car mechanic, welder, mechanic technician, and women: teacher – 2, shop assistant

– 2, hairdresser – 1, accountant – 1, seamstress – 1, IT specialist – 1, no profession – 3). The respondents declared contact with various hazardous substances in the course of their professional career (paints and varnish – 3, construction chemicals and fertilizers – 2, fumes – 2, galvanized steel – 2, wood dust – 2, flour dust – 3, noise – 1) or prolonged work in hazardous locations (contaminated area near alumina plant - 2, printing house – 1, iron foundry – 1, tire production – 1, magnetic field – 1). Over half of the respondents failed to answer that question.

Twenty-seven people admitted to smoking (50–75 cigarettes/day for 25–35 years – 5 patients, 30–40/day for 25–30 years – 9, 20–35/day for 25–35 years – 17, 6–15/day for 20–30 – 6). Also, the patients reported time elapsed from first symptom to seeking medical help (> 6 months – 17, > 1 year – 11, > 3 months – 8, > 7 months – 6, > 4 months – 2, >5 months – 2, >8 months – 2, > 2 years – 2, whereas 5 subjects sought medical advice after: 1 month, 9 and 10 months, 1.5 and 3 years). Thirteen patients were diagnosed with stage T3 and 47 with T4.

Evaluation of the quality of life

Mean value (QLQ-C30 scale) for the general health status in laryngectomees was 56.81. Mean values for physical functioning, role, cognitive, social, and emotional functioning were 81.11, 80.83, 75.28, 70.00 and 54.72, respectively.

The analysis of mean values for complaints, from the most to the least intensified, revealed the following: constipation (47.22), financial difficulties (43.89), insomnia (39.44), fatigue (32.22), loss of appetite (28.33), dyspnoea (21.11), pain (20.56), nausea and vomiting (8.06), and diarrhea (1.67). The results are presented in **Table 1**.

Table 2 presents scores on QLQ-H&N35 symptom intensity. Analysis of mean values revealed that the greatest problem for laryngectomees were: difficulty gaining weight (75.0), necessity to use nutritional supplements (58.33), sense of smell and taste problems (57.78), weight loss (56.67), articulation problems (56.67), problems with social contacts (54.78), loss of libido (46.11), increased stickiness of the saliva (46.11), general feeling of being ill (46.11), necessity to use painkillers (38.33), tooth loss (35.56), mouth dryness (32.78), swallowing difficulty (29.31), limited mouth opening (28.33), problems with social eating (28.06), pain (26.53) (**Table 2**).

Table 3 presents differences in scores on QLQ-C30 with regard to gender and age. The respondents were subdivided into women and men, and into two age-groups: < 60 and ≥ 60. Statistically significant differences were observed in emotional functioning ($p = 0.002$), with mean values of 28.83 and 60.51 for women and men, respectively. Also, a statistically significant difference was noted in social functioning ($p = 0.01$), with mean values of 45.53 and 75.51 for women and men, respectively.

Table 1. Quality of life (QLQ-C30) scores (N = 60)

Aspects	Mean (± SD)	Median	Min.	Max.
Global health status*	56.81 ± 19.92	58.33	16.67	100.00
Functioning scales*				
Physical functioning	81.11 ± 13.23	86.67	46.67	100.00
Role functioning	80.83 ± 23.54	83.33	33.33	100.00
Emotional functioning	54.72 ± 28.84	62.50	0.00	100.00
Cognitive functioning	75.28 ± 20.70	83.33	33.33	100.00
Social functioning	70.00 ± 29.72	66.67	0.00	100.00
Symptom scales**				
Fatigue	32.22 ± 20.63	33.33	0.00	88.89
Nausea/vomiting	8.06 ± 14.87	10.00	0.00	66.67
Pain	20.56 ± 21.56	16.67	0.00	83.33
Dyspnoea	21.11 ± 21.23	33.33	0.00	100.00
Insomnia	39.44 ± 33.33	33.33	0.00	100.00
Appetite loss	28.33 ± 31.79	16.67	0.00	100.00
Constipation	47.22 ± 41.30	33.33	0.00	100.00
Diarrhea	1.67 ± 7.33	5.00	0.00	33.33
Financial difficulties	43.89 ± 32.76	33.33	0.00	100.00

* Higher scores on the global health status and functioning scale represent a better quality of life.
** Higher scores on the symptom scale represent more severe symptom-related complaints.

Table 2. Scores on QLQ-H&N35 (N = 60)

Symptoms**	Mean (± SD)	Median	Min.	Max.
Pain	26.53 ± 25.56	20.83	0.00	75.00
Swallowing difficulty	29.31 ± 22.94	25.00	0.00	66.67
Sense of smell&taste problems	57.78 ± 30.45	50.00	0.00	100.00
Articulation problems	56.67 ± 23.21	66.67	0.00	100.00
Problems with social eating	28.06 ± 0.07	25.00	0.00	100.00
Problems with social contacts	54.78 ± 33.12	60.00	0.00	100.00
Loss of libido	46.11 ± 38.25	33.33	0.00	100.00
Tooth loss	35.56 ± 39.71	33.33	0.00	100.00
Limited mouth opening	28.33 ± 38.73	28.00	0.00	100.00
Dry mouth	32.78 ± 34.44	33.33	0.00	100.00
Sticky saliva	46.11 ± 35.30	33.33	0.00	100.00
Coughing	32.22 ± 28.10	33.33	0.00	66.67
Felt ill	46.11 ± 32.53	50.00	0.00	100.00
Painkillers	38.33 ± 49.03	43.00	0.00	100.00
Nutritional supplements	58.33 ± 49.72	100.00	0.00	100.00
Weight loss	56.67 ± 49.97	100.00	0.00	100.00
Weight gain	75.00 ± 43.67	100.00	0.00	100.00

** Higher scores on the symptom scale represent more severe symptom-related complaints

Table 3. Effect of age and gender on quality of life (N = 60)

Aspects of quality of life QLQ-C30	Mean (± SD)	*P* value
General health status		
Age < 60 (n = 34)	58.32 ± 20.12	0.260
Age ≥ 60 (n = 26)	54.80 ± 19.91	
Women (n = 11)	65.22 ± 13.32	0.076
Men (n = 49)	54.91 ± 20.80	
Physical functioning		
Age < 60	82.0 ± 12.34	0.665
Age ≥ 60	80.0 ± 14,55	
Women	83.64 ± 11.73	0.468
Men	80.52 ± 13.67	
Role functioning		
Age < 60	83.32 ± 22.12	0.429
Age ≥ 60	77.64 ± 25.43	
Women	77.34 ± 15.45	0.163
Men	81.66 ± 25.17	
Emotional functioning		
Age < 60	57.15 ± 29.36	0.596
Age ≥ 60	51.64 ± 28.53	
Women	28.83 ± 19.83	0.002
Men	60.51 ± 27.42	
Cognitive functioning		
Age < 60	75.55 ± 21.0	0.994
Age ≥ 60	75.01 ± 20.74	
Women	71.24 ± 25.90	0.717
Men	76.24 ± 19.51	
Social functioning		
Age < 60	67.21 ± 32.22	0.561
Age ≥ 60	73.74 ± 26.34	
Women	45.53 ± 32.63	0.01
Men	75.51 ± 26.43	

The analysis of mean values for quality of life (QLQ C-30) and symptom intensity (H&N35) revealed a correlation between social functioning and the following symptoms: discomfort (-0.427), fatigue (-0.225), nausea and vomiting (-0.588), pain (-0.604), loss of appetite (-0.455), and constipation (-0.399). A correlation was found between general health status and swallowing difficulty (-0.333), and between emotional functioning and the following symptoms: sense of smell and taste problems (-0.495), nausea and vomiting (-0.290), insomnia (-0.295), and constipation (-0.289). Also, a relation was detected between articulation problem and the following kinds of functioning: role (-0.394), emotional (-0.498), cognitive (-0.256), pain (-0.350), dyspnoea (-0.393), insomnia (-0.287), and diarrhea (-0.293). Problems with social eating correlated with the following types of functioning: physical (-0.547), role (-0.288), emotional (-0.317), cognitive (-0.358), and with fatigue (-0.559), nausea and vomiting (-0.318), pain (-0.357), dyspnoea (-0.290), loss of appetite (-0.436), and constipation (-0.340) (**Table 3**).

Discussion

Cancer is the leading cause of death among all psychosomatic disorders and has a significant impact on psychophysical status of patients. The diagnosis is a challenge and leaves cancer patients with numer-

ous problems. Malignancy, especially in its advanced stages, is always connected with physical and emotional suffering, what greatly lowers self-esteem of the affected individuals.

Apart from genetic factors, alcohol and tobacco use are the two main risk factors for laryngeal cancer. It is predominantly diagnosed in patients smoking tobacco (cigarettes, pipe), chewing tobacco, and consuming excessive amounts of alcohol. Both these factors, tobacco and alcohol, statistically significantly increase the risk for laryngeal cancer. In case of tobacco, time of exposure as well as intensity (smoking 20 cigarettes/day equals 13-fold higher risk) are vital. Unfortunately, not only active but also passive smoker are at risk, with the latter at a 5.5-fold higher risk for disease [1, 2]. Almost half of the participants in our study reported smoking and did not stop despite the illness and treatment. Active smokers (i.e. during therapy) declared they had been smoking 20–25 cigarettes per day for approximately 25–35 years, what indicates that long-term tobacco use is a high-risk factor for malignancy. Rzewnicki et al., investigated 92 people and reported that both, regular smokers and consumers of excessive amounts of alcohol (often combined), constituted the vast majority (95%) of the study population. Thus, they confirmed the risk for cancer in tobacco and alcohol users [3], not to mention that active and passive smoking in general is a high risk for disease factor [1, 2]. Zatoński W. et al., confirmed that theory and proved that daily exposure to tobacco smoke, active or passive, is a powerful risk factor for the development of laryngeal cancer. They found daily exposure to tobacco smoke to be almost identical in the group of young adults (< 45 years of age) and older patients [1, 3]. De Bruin-Visser C. et al., compared regular ex-smokers and active smokers [4] and found positive effects on the general health status in the majority of former smokers. Interestingly, positive effects were visible also in cases when the number of smoked cigarettes was only limited. Therefore, there is a clear need for head-and-neck cancer patients to stop smoking. Our analysis of the impact of sociodemographic factors on quality of life revealed deteriorated quality of life in terms of physical functioning in older patients, what confirms negative consequences of cancer, especially in the situation of threat to life. Despite considerable diversity of the obtained results, no statistical significance with regard to sociodemographic factors (age, gender, education, marital status, place of inhabitance) was found. Younger adults (< 60) evaluate their quality of life, physical, role, emotional and higher, and cognitive functioning higher, whereas older patients (≥ 60) cope with social functioning better, what was demonstrated by Derks W. et al., and Bernardi D. et al. [5, 6]. In the available literature on the quality of life, especially reports by Bjordal K. et al., de Graeff A. et al., and Williamson J.D., sociodemographic situation takes an important place in the evaluation of health status in cancer patients, even despite diversified results [7–11]. The effect of age, gender, or education may impact health behavior of cancer patients [11]. Lifestyle is commonly believed to play a decisive role in cancer risk.

Both questionnaires, EORTC QLQC30 and QLQ-H&N35, are important sources of information about physical and psychosocial aspects of quality of life in cancer patients and are often used by numerous authors, especially Bjordal K, Kassa S. and others [7–9]. These tools assess the general quality of life, as well as the impact of cancer and therapy on the affected individuals. They also allow for a better grasp of possible physical, emotional, social and functional consequences of different treatment methods, and better choice of management. The analysis of the EORTC C-30 questionnaire revealed that younger patients cope better with physical, role, emotional and cognitive functioning and evaluate their quality of life higher as compared to older subjects, who cope better with social functioning but scored lower on physical functioning and symptoms of fatigue. No statistically significant differences between women and men, despite age group, were detected. Derks W. et al., studied 78 older adults (> 70 years of age) and demonstrated significantly deteriorated physical functioning as compared to younger patients, who in turn reported pain as the most persistent adverse symptom. Other dominant symptoms in the older population were fatigue, swallowing difficulty, and dry mouth, what might be connected with the process of ageing [5]. According to de Graeff A. et al., sociodemographic factors and their analysis are prognostic factors in cancer patients [11]. Evaluation of health-related risk factors, lifestyle (smoking and alcohol use), and marital status helps establish the right management of the disease. The available literature offers proof that swallowing difficulty is the most common complaint in older patients operated on due to laryngeal cancer. It is noted significantly more frequently in that age group because impaired swallowing is an inevitable consequence of ageing [12–14]. Specificity of head-and-neck cancer ought to take into consideration eating disorders, disfiguration, disrupted communication with the environ-

ment, including closest family and friends, as well as acceptance of social conditions. Also, it is important to take into consideration problems with social functioning due to tracheostomy tube, which many patients find extremely hard to accept. A suitable tool, such as EORTC H&N35, which evaluates swallowing, speech, sense of smell and taste, pain intensity, the condition of the oral cavity and teeth, sexual performance, body weight, use of nutritional supplements offers a possibility to analyze these symptoms as predictors of the health status of the patient.

In our study, the most bothersome symptoms for the majority of patients were pain, insomnia, the necessity to use painkillers, dyspnoea, and swallowing difficulty, followed by tooth loss, problems with communication, social eating, mouth dryness, sticky saliva, limited mouth opening, and coughing fits. The analysis of the EORTC H&N35 scores revealed that most of the investigated patients reported partial loss of taste and smell. There was also a necessity to use nutritional supplements to prevent weight loss.

Żmijewska-Tomczak M et al., assessed the changes in QoL before and at the end of the course of Radiotherapy (RT) in 205 patients with head and neck cancer using the Polish version of the questionnaires EORTC QLQ-C30 and QLQ-H&N35. Their study shows the greatest negative impact of RT was observed in terms of damage to the sense of taste and smell, weight loss, dry mouth, thick saliva retention, pain, loss of appetite, nausea and vomiting as well as fatigue. [15]

Cancer is usually associated with weight loss, especially in case of head-and-neck carcinomas [16, 17]. Malnutrition significantly impacts the strength of the skeletal muscles and decreases energy reservoir in cancer patients, adversely influencing their immunity and making them more prone to infections [14]. Also, malnutrition is often accompanied by depression which is a common occurrence in cancer. Hammerlid E. et al., demonstrated that only one-third of cancer patients with diagnosed malnutrition survived 2 years, whereas the score was two-fold higher in the group of well-nourished subjects [16].

Difficulty communicating turned out to be the main complaint in patients after laryngeal surgeries, with physical dexterity playing a less important role. Difficulty adjusting to social environment and social avoidance in the family were also reported [17–19], as well as the necessity to use nutritional supplements to avoid weight loss in most cases.

The majority of study participants admitted to problems with social contacts, articulation, and speech which made caused communication difficulty or even breakdown. Swallowing difficulty, problems with social eating, and the general feeling of being ill, are a common occurrence among cancer patients [16, 21, 22], distinctly demonstrating the challenges of the life after laryngectomy and with tracheostomy tube.

The overall quality of life among the investigated subjects indicated general physical and psychological discomfort, especially in women, in terms of emotional and social functioning.

Most respondents reported deteriorating contacts with the environment. Patient reservation before the surgery according to Fang F. et al. [20], confirmed that fact. All of the above mentioned complaints are highly bothersome and demand adjustment to the new reality, and post-laryngectomy life is extremely challenging for the affected individuals. Pre-surgery symptoms often intensify post-surgery, particularly weight loss, appetite loss, dry mouth, and tooth loss, making everyday life very difficult. Weight loss, and the consequent malnutrition, both decrease immunity and lead to infections [17, 19].

Head and neck cancer patients are at particularly high risk for lasting consequences for health and psyche due to the fact that laryngectomy results in complete loss of normal voice. It is especially arduous for laryngectomees and may even be the basis for declaring disability, especially changes in the body image which require acceptance and signal a new life situation, what was confirmed by the study of Ackerstaff AH. et al. [21], and a study by Dropkin MJ. [22] and others [23, 24].

Conclusions

The need to investigate quality of life by means of patient self-evaluation of the symptoms in order to monitor patient status and establish an individual therapeutic, care and psychological approach, is unquestionable.

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Conflict of interest statement
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Determining the title to appear before court in cases of indemnity for damages caused to patients

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ABSTRACT

The issue of the title to appear before court mentioned in the title, is poorly known both to patients and to medical staff, in particular to doctors. However, in practice this is very important because of the growing number of cases of this type pending before the regional medical adjudication committees, as well as common courts. For that reason, it is worth discussing legal regulations in this field. This is also the purpose of the author of this publication.

Keywords: damages caused to patients, courts, legal regulations.

The issue of the title to appear before court mentioned in the title, is poorly known both to patients and to medical staff, in particular to doctors. However, in practice this is very important because of the growing number of cases of this type pending before the regional medical adjudication committees, as well as common courts. For that reason, it is worth discussing legal regulations in this field. This is also the purpose of the author of this publication.

The issue of the title to appear before court is related to the issue of compensation for patients for the damage caused during the provision of medical services. Nowadays, it is one of the most important issues of medical law. In the civil law doctrine, the title to appear before court is defined as the right to seek legal protection in the lawsuit[1]. This means that both a person performing the medical profession and patient may be the plaintiff or the defendant. The problem of legitimacy is present in every procedure but it plays a particularly important role in the civil process. In this process that institution has been founded and developed.

The concept of the title to appear before court is related to another civil concept, i.e. the ability to undertake legal action in civil proceedings (capacity to sue or to be sued). It has a character of absolute prerequisite. This means that if a patient or a doctor haven't this capacity or they have been deprived of it, they can't take part in the action for damages. This term refers to an ability to undertake legal actions related to prosecution a claim in a court. The Code of Civil Procedure grants capacity to sue or to be sued to the following persons[2]:

1. physical person who has a capacity to enter into legal actions (patients, medical staff)[3],
2. legal person and organizational units, so-called imperfect artificial person (health care entity).

Referring the issue of the title to appear before court to cases related to defective granted health ben-

[1] Cf. W. Dolecki, Postępowanie cywilne, Warszawa 2005, p. 43; A. Klein, Elementy zobowiązaniowego stosunku prawnego, Wrocław 2005, p. 125 et seq.

[2] Article 65 § 1 of the Code of Civil Procedure.

[3] Adults who are not legally incapacitated have full capacity for legal acts (article 11 of the Civil Code).

efits, it should be pointed out that this issue is of prime importance in the action for damages. These are cases brought by patients to common courts not only in connection with medical errors but also with other circumstances related to the functioning of health care entities. These errors, as well as the circumstances indicated, can lead to certain health damage. The substance of the trial is to present the states of two parties and its aim is to resolve the dispute. On the one hand, it's the state of person performing the medical profession (for example a doctor), on the other – a patient who has been harmed due to mismanaged medical services. In this situation an important issue but not always easy to resolve is the question of defining both parties of the dispute, and in particular determining who the defendant is. The plaintiff is a patient or his heirs under specified conditions.

The correct determination of the defendant requires careful examination of many circumstances. Especially the legal basis for the implementation of a particular medical service. The legal basis may be very different, but usually it is based on a specific contract. The contract may be a civil contract so defined by the regulations of the Civil Code (contract, mandate contract) or an employment regulated by labor law. The category to which the contract is assigned, influences the granting of legitimacy to participate in the process of person performing the medical profession who has provided a particular medical service. It is worth emphasizing that the title to appear before court doesn't constitute a general attribute of this person. It is not a permanent feature. Therefore, it must be assessed in each process because it constitutes a special right or obligation to appear before a court as a party in a particular case. In view of the above, the fact of being the perpetrator of the harm suffered by the patient doesn't prejudge the need to act as the defendant. There must be other factors that determine the participation or not, in the process, in particular, the appropriate employment relationship of a person practicing a medical profession, especially a doctor. This relationship determines the existence of passive capacity to be a party in a lawsuit. It is a type of legal obligation and concerns the defendant, justifying his presence in a process in this capacity. Determining who has this capacity is crucial for the patient. It influences the possibility of using his right of action. It means the same as the right to sue and conduct a particular process. If this can't be determined, the patient is at risk of dismissing the claim. Therefore, the court must assess whether the potential parties so the plaintiff and the defendant have the appropriate legitimacy or not, at the time of adjudication on the substance of the dispute at the latest. It would seem that establishing a capacity to sue is only a simple formality. However, it isn't always a simply formality. The case is complicated, e.g. in case of patient's death. According to article 445 § 3 of the Civil Code a claim for compensation passes to the heirs only when it was considered in writing, or the action is brought during the life of the injured person. However, it should be noted this concerns a non-material damage, so harm. The Polish legal system provides the possibility of indemnification for harm only exceptionally. Therefore, it is difficult to obtain indemnification in this kind of process. It is difficult to imagine a situation in which a patient predicting his death as a result of mismanaged medical services, brings an action. Moreover, it would be premature because it would be before the actual occurrence of harm. He hasn't got a substantive capacity. It means that he has a subjective right or legal interest that can be protected by the court. This interest can be proved only after suffering harm, and not in relation to the probability of its experience. It means in each case a future and uncertain event. This can't be the basis for the formulation of a court action[4].

However, it is important to distinguish situations when the plaintiff claims compensation for material damage, so for real harm to health. In such cases the rules of granting a right to sue to persons other than the injured person indicate article 446 of the Civil Code. It is worth pointing out its contents in entirety. Thus, according to § 1 of this provision if, as a result of bodily injury or health disorder the patient dies, the person obliged to repair the damage, should pay medical and funeral costs to the person who incurs these costs. Moreover, the person for whom the deceased had a statutory maintenance obligation may request from the person obliged to compensate (e.g. a doctor) a pension calculated according to the victim's needs and to the earning and financial possibilities the deceased person throughout the probable duration of the maintenance obligation. The same pension can be demanded by other close relatives to whom the deceased person voluntarily and permanently provided means of subsistence if it follows from the circumstances that the principles of community life so require.

A very important regulation is § 3 of this provision. This regulation recognizes a right to sue in cases of compensation to the closest members of the deceased's family if, as a result of his death, their liv-

[4] Cf. W. Siedlecki, Z. Świeboda, *Postępowanie cywilne, Zarys wykładu*, 2 edition, Warszawa 2000, p. 87.

ing standard has deteriorated significantly. The claim for compensation goes to them regardless of whether the claim is brought during his life or not. However, the patient's heirs can be only compensated when the patient could receive a compensation if he lived at the time of the judgment. In addition, the compensation may only be to the extent that it corresponds to the damage that occurred up to the day of his death[5]. Therefore, the circle of persons who can have a right to sue is severely restricted in this case. Similarly, the court may also grant a right to sue to seek a monetary recompense for the harm suffered (§ 4).

In addition, it must also be pointed out that the absence of a right to sue or capacity to be sued leads in principle to the dismissal of claim. However, there is a possibility of avoiding such far-reaching consequences. If it turns out that the patient filed the suit against the person who shouldn't be the defendant in the case, the court at his request or the defendant's request (doctor, other medical practitioner) will call the right person to take part in case. This situation will took place, among others, after examination by the court the employment relationship which connects the person who provides medical services as a result of which a patient suffers damage (including harm) with a health care entity.

Discussing the importance of the issue of the title to appear before court for today's healthcare market, it is important to note that in practice patients bring a suit against medical staff. It is relatively rare that the defendants are medical entities. This is probably due to a lack of knowledge of legal regulations concerning claims related to defective performance of health care services and – in a way right directly combining the damage – with the person who led to this.

Anyway, the possibility to assign a capacity to be sued depends on the nature of the employment relationship in the medical entity which isn't known by patients generally. Therefore patients and medical staff should be informed about the nature of the employment relationship. This would make it easier to identify the process parties correctly. Such information could be available for example in the form of brochures available to interested people. Both patients and people practicing a medical profession have the right to use, in the possible action for damages, formal objections, in particular a lack of capacity to be sued. It is worth raising always this kind of objection, regardless of whether liability rules for damage arising out of the provision of health services is only in the field of civil law, or some aspects are regulated by labor law.

Discussing the problem of determining the capacity to be sued, so a capacity to appear before the court as a defendant, it is worth noting that at present doctors are employed in public hospitals on the basis of contracts and contracts of employment. The first is a type of civil law agreement, the second is a kind of privileged agreements visible among others in the elements of immunity in the field of civil liability. On the other hand, the standard of employment in non-public hospitals, or clinics and private clinics is employment on the basis of civil law, i.e. contracts, contract of mandate or contracts for the provision of medical services. However, the last type of employment contracts doesn't provide protection against civil liability. This is the exclusion of immunity in this regard. In other words, these agreements don't deprive a capacity to be sued but they exclude the vast majority of circumstances that allow to rely on its absence in the action for damages. It follows the conclusion that the importance of the type of employment of medical staff is clearly increasing nowadays due to the liability for damages[6]. Therefore, it is worthwhile to discuss different types of medical staff's employment and consequences of civil liability for damage caused to patients due to mismanaged health care services.

The first type is employment contract-based job that is essential but it is gradually limited nowadays. It arises as a result of the conclusion of a contract of employment which the principles and essence are determined by the norms of the Labor Code. A worker within the meaning of the Labor Code is only a person employed on the basis of an employment contract, employment relationship based on appointment, nomination, agreement for co-operative employment (article 2 of the Labor Code).

A feature that distinguishes the contract of employment from the so-called civil contracts (contract, contract involving performance), is a specific subject of this contract. In fact, it is work performed personally, under the conditions of subordination, in a place designated by an employer, as well as at his risk[7]. During the

[5] Resolution of 7 judges of the Supreme Court of October 26, 1970, III PZP 22/70, OSN CP 1971, no. 7–8, pos. 120.

[6] Widely about this i.a. P. Stępniak, Prawne aspekty odpowiedzialności cywilnej zakładu opieki zdrowotnej oraz jego personelu (in:) Sprawne zarządzanie zakładem opieki zdrowotnej, M. Głowacka , J, Galicki (ed.), Poznań 2010.

[7] Cf. Judgment of the Supreme Court of 18 June 1998, I PKN 191/98, OSP 1999, no. 10, pos. 184; also: Kodeks pracy. Komentarz (ed.) B. Wagner, Gdańsk 2004, p. 35.

analysis the characteristics of the contract of employment of medical personnel, it is worthwhile to note that its nature and legal status determine the relationship of authority. The organization of medical entities is based on that relationship. The relationship of authority between a person practicing a medical profession (e.g. a doctor or a nurse) is regulated by two legal regulations, located in different areas of law, but complementary to each other. The first one is article 430 of the Civil Code, second article 120 §1 of the Labor Code. Article 430 of the Civil Code states the following:

who, on his own account, entrusts the performance of action to a person who, while performing the action, is subjected to his management and is obliged to follow his instructions, is liable for damage caused by a fault of the person during the performing of the entrusted action.

This regulation governs the rules of liability of a superior for a subordinate (e.g. a medical entity that entrusts the operation). Therefore, follows from the wording of mentioned regulation, a material premise of liability for damage is the relation of authority and subordination between them. Therefore, a supervisor is a medical entity. The medical entity, on its own account, entrusts the performance of an action to doctors and nurses, person who, while performing the action is subject to his management. They are also obliged to follow a superior's instructions. They perform the tasks entrusted to them to the account and risk of the medical entity which employs them.

The rule above is confirmed by article 120 § 1 of the Labor Code. It states that in the event of causing harm to a third party by the employee during the performance of his duties, only the employer is obligated to compensate damage. This means that the medical staff haven't got a capacity to be sued in cases of compensation for damages caused to patients during the provision of medical services. Consequently, this capacity is granted to the employer who is the supervisor.

However, in the doctrine of medical law the question of the autonomy of doctors during provision of medical services raises doubts[8]. They are professionals prepared to perform medical tasks in the course of specialized studies as well as obtaining specific specialization. They have a wide range of autonomy in making medical decisions[9]. Nevertheless, it must be assumed that it only covers strictly medical activities related to the application of medical art. This isn't applied to activities that accompany them, such as technical and organizational issues (e.g. choice of operating block, type of medical equipment used, scheduling and operating rules, team selection, selection and protection of tool, etc.). In this regard, decisions are taken by the authority of the medical entity, i.e. their superior.

An important consequence of the above-mentioned characteristics of employment of doctors, nurses, midwives, and other medical professions is the specific regulation of the civil liability of medical personnel for the damage caused to patients in connection with the provision of health services. They are defined by article 114–122 of the Labor Code.

Generally it can be estimated that an employee of a medical entity who, due to failure to perform or improper performance of work obligations, has caused harm his employer due to his fault, shall be liable for financial responsibility according to the principles which are clearly mitigated as compared with the general civil law system. One element of this mitigation is the transfer of capacity to be sued to the employer. According to the content of article 114, and article 120 § 1 of the Labor Code in particular, he is entitled to employment immunity. This immunity excludes the capacity to be sued[10]. This means that a doctor, nurse or paramedic can't be a party to the lawsuit. When they are sued, it is enough to declare that they have been performed a defective medical service as a staff member of a hospital, a clinic, a laboratory, etc. to evade participation in the case. As a consequence, the court calls the medical entity who employs them. However, it should be noted that the employment of staff in such way is associated with a certain economic risk which can be minimized by promoting alternative employment relationship.

However, the principles of civil liability relieve doctors, nurses, midwives, etc. from the obligation to diligent and careful provision of health services is very beneficial. On the contrary, they must be performed in accordance with the best medical knowledge, with the due care required in certain medical circumstances. Violation of these rules allows to talk about the unlawfulness of the employee's action and his guilt. This is the basis of his civil liability, at the same time the con-

[8] Śliwka M. Zakres odpowiedzialności podmiotu leczniczego wobec pacjentów. In: Pasowicz M. (ed.). Zarządzanie podmiotami leczniczymi. Kraków 2012; p. 221.

[9] Bieńka G. (ed.). Komentarz do kodeksu cywilnego. Warszawa 2005; p. 365.

[10] Dzienis P. Odpowiedzialność cywilna za szkody wyrządzone przy udzielaniu świadczeń zdrowotnych. In: Górski A, Dzienis P Bieńka G (eds.). Regulacje prawne w ochronie zdrowia. Białystok 2006; p. 173.

ditions sine qua non of this liability. However, a medical entity must investigate whether the following conditions exist at the same time to apply to a subordinate or to a court for compensation:

1. a person who provided health care services acted unlawfully, i.e. the person has failed to perform or improperly performed employee duties, which consisted of conscientious medical help[11];
2. there is a causal link between the harm done to the patient and this unlawful act. It is therefore concluded that it is important that an employer, i.e. a medical entity, checks the doctor's qualifications and draws up a detailed description of employee responsibilities. This will prevent it from finding out whether a doctor violated unlawfully his obligations. This description becomes particularly important if the injury was caused to the patient not by mistake but because of the circumstances caused by doctor's or nurse's fault (for example, they were late for surgery, the doctor didn't monitor long enough and intensive patient health after medical treatment, etc.);
3. the doctor's action, a nurse's or other medical practitioners' action was culpable. This issue should be developed more.

Discussing the concept of guilt in general, it should be stated that it is a deviation from the required diligence in certain circumstances during the performance of professional activities. The diligence is required in all professional activities performed by medical staff regardless of its category. It follows that the guilt of a doctor, a nurse or a midwife, etc., is stated when comparing their medical performance with the accepted model, there are deviations from it. In other words, a good doctor, a nurse, is someone who, in identical conditions, would avoid harming the patient. Their guilt can appear in three forms:

1. negligence. This refers to the lack of due diligence and caution during the performance of professional activities, in particular the deviation from accepted procedures, premature cessation of treatment,
2. awkwardness and inattention,
3. forgetfulness or omission, e.g. omission of necessary diagnostic tests, lack of precaution in predicting the effects of surgery, failure to inform the patient of necessary rehabilitation, necessity of continuation of treatment, control tests, etc.[12]

[11] Conscientious and careful execution of employee obligations is imposed by article 100 of the Labor Code.

[12] Serwach M. Przesłanki odpowiedzialności cywilnej lekarza za szkodę wyrządzoną pacjentowi w orzecznictwie sądów polskich. Prawo i Medycyna. 2006;4.

It is worth noting that the specific form and degree of the fault are irrelevant for the purpose of establishing liability for damages. According to the general jurisdiction of the common courts and the doctrine of civil law, a doctor is responsible for every form of civil guilty and regardless of its degree[13]. It should be assumed that the above applies also to a nurse and midwife as a higher qualified, specialized staff.

Discussing the importance of guilt for liability for injury to patients, it should pay attention to the difference between doctor's or nurse's guilt and a mistake in medicinal art[14]. An example of such a mistake is the medication error. This type of error itself doesn't determine whether the action is culpable. In the jurisprudence the concept of error is defined narrowly for a long time. It only refers to a doctor's act or omission in the field of medical diagnosis and therapy, which is contrary to the principles of medical knowledge, but within the scope available to the doctor[15]. It is worth emphasizing this last part, because according to it, medication error constitutes an objective element of guilt[16]. In other words, this is due to a doctor's activity who violates the principles of medical knowledge. However, it can be – and it is usually – completely independent of a particular person. More precisely, it is independent of his individual characteristics, inclinations and skills, as well as the circumstances in which he undertook activities in the field of diagnosis and therapy. In a such situation, it can't cause his civil liability. For the incurrence of liability for damage, it is necessary a subjective fault simultaneously. This is the case when a doctor doesn't give due diligence in providing health care services. The error arises when a doctor is aware of the duty to act diligently but doesn't perform it. Even worse, when such consciousness doesn't exist, though he should have it. Thus, for example, civil liability doesn't arise in the case of a misdiagnosis in a healthy person, justified by the symptoms present. There is no damage if as a result of this misdiagnosis, the treatment was taken and in the event of a real illness would be appropriate, and this treatment didn't bring negative consequences for the person besides transient ailments. We can't ask for a doctor to be infallible, as well as stop him or

[13] Chodzi tu także o winę najlżejszą. Cf.: Nesterowicz M, op. cit., p. 277; Zajdel J. Prawo medyczne dla kardiologów. Łódź 2009; p. 149.

[14] Cf. Judgement of the Supreme Court, April 1, 1955, case number: IV CR39/54, public. W OSN 1957/1, pos. 7.

[15] Kokot R, Banasiewicz M. Z problematyki karnej za błąd w sztuce lekarskiej. Nowa kodyfikacja prawa karnego, vol. XXIV. Wrocław 2009; p.71.

[16] Marek Z. Błąd medyczny. Kraków 1999; p. 110.

her from making decisions about treatment in doubtful situations. It would be difficult to prove that he violates patients' interests[17].

In addition to all that was said above about the benefits of employment contract-based job what is evident in the employee's benefit principles of determining his civil liability, it is worthwhile to give some remarks about the solidarity. This is the situation when more than one person have a capacity to sue or to be sued. In our field of interest, it involves the patient and the medical staff and the medical entity which employs them on the employee's rights. However, the subject of a patient's claim is only one benefit, i.e. the payment of compensation. Its fulfillment expires the entire joint and several liability. It is easy to notice that on the basis of such construction the patient could sue both the doctor and the hospital. He could also choose to sue some entity in particular or both simultaneously.

In terms of joint and several liability, provisions of the labor law radically adjust the scope of such liability in favor of the doctor. They exclude his joint and several liability with the employing entity. He benefits from the loss of his capacity to be sued in the action for damages[18]. This means that in every case when a doctor is employed on the basis of an employment contract, only the medical entity is responsible for any errors and omissions made by him, in particular for errors in medicinal art. This applies to any entity, whether public or non-public (e.g. hospital, medical co-operative, and even private clinics).

In summary, the civil liability of medical personnel for defective treatment, negligence, etc., employed on the basis of a contract of employment, has been greatly reduced by the provisions of labor law. This is manifested in the transfer of his legitimacy to appear before the court as defendant to the medical entity, e.g. hospital. The hospital has only the right of recourse against the staff. However, it may only use it when the damage done to the patient has been compensate. This means that it must first occur in the process itself, based on the capacity to be sued.

The regulations on civil liability for damage caused to patients while providing medical services on the basis of employment based on civil law contracts, are much less favorable. A mandate contract is an example of civil law contract currently used in the medical services market. Its essence is defined in article 734 § 1 and 735 § 1 of the Civil Code. So, in accordance with article 734 § 1 and article 735 § 1 of the Civil Code, under the mandate contract, the mandatory commits to perform a specific legal act for the mandator. If neither the contract nor the circumstances indicate that the mandatory has committed to perform the mandate contract without remuneration, remuneration is due for performing the mandate. It follows from the above provisions that the contract of mandate is distinct from the contract of employment. The point is, in particular, that the mandatory (doctor, nurse, etc.) does not work – does not provide medical services under the direction of the mandator (medical entity) but entirely on his own account. In addition, they are not obliged to perform it at the place indicated by this entity. However, the result of the exclusion from the relationship of supremacy is that the mandatory retains a capacity to be sued, both group and individual. As a consequence, they can be sued alone or together with the medical entity (the principle of solidarity) in the process of compensation for damages caused to the patient.

This situation is much less favorable for medical staff, especially doctors, nurses and midwives. The injured patient can only sue the doctors, e.g. in the situation when the medical entity employing them becomes e.g. insolvent. In a such case, a doctor will be obliged to pay the full amount even if the compensation was awarded from the hospital and the doctor jointly and severally.

A similar situation exists in the case of employment based on the contract. In both cases, the doctor has a capacity to be sued (beside the medicinal entity who employed him). Doctors' civil liability on the basis of such legitimacy is unlimited in principle. This means that in the event of injury they are personally responsible, i.e., the entire property. It is therefore worth insuring yourself against the risk of such liability. Insurance excludes the capacity to be sued.

By concluding a short overview of the issue of determining the title to appear before court in action for damages because of the harm caused to patients during and in connection with provision of health services, it is worthwhile to formulate the general conclusions, summarizing the most important theses.

The modern labor market and medical services is very flexible. This is reflected in the legal regulations governing the risk of harm to patients using these services. Their development and simultaneous differentiation of the level of protection from civil liability is the

[17] A similar position was taken by the Supreme Court in its judgment of 8 December 1970 in case II CR 543/70; public. OSN 1971, pos. 136.

[18] Cf. art. 120 § 1 of the Labor Code: in case of causing damage to a third party by an employee while performing employment duties, only the employer is obliged to repair it.

consequence of the rules of market economy. This has its advantages and disadvantages indicated above.

So, the legal solutions discussed above allow to conclude different employment contracts depending on the needs of employers, doctors, nurses, midwives, etc. Each of them must however evaluate and decide what he wants to achieve through a specific agreement. Different employment contracts give not only different benefits, such as remuneration, but involve different risks..

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Do children with supraventricular tachycardia treated with ablation therapy have similar quality of life as healthy children?

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ABSTRACT

Introduction. There are a few available studies evaluating quality of life (QoL) in pediatric patients with supraventricular tachycardia (SVT) treated with ablation but they are based on small groups of patients. The aim of the paper was to compare the QoL in children with SVT treated with successful ablation with the group of healthy children.

Materials and Methods. The study included 122 SVT children who underwent a successful ablation therapy and 83 healthy children. The Qol was assessed, using the WHOQOL-BREF and the Pediatric Arrhythmia Related Score (PARS) - a specific questionnaire developed by the authors, related to patients' own feelings and observations concerning arrhythmia.

Results. On the basis of WHOQOL-BREF no significant differences were found in all the measured domains. On the basis of PARS in SVT-group the patients still reported significantly increased symptoms within physical domain in comparison with the healthy group (1.8 ± 0.5 vs 1.6 ± 0.3; $p = 0.0195$) as well as increased negative feelings within psychological domain (2.3 ± 0.7 vs 2.1 ± 0.6; $p = 0.0172$).

Conclusions. On the basis of the general questionnaire all scores in SVT group are comparable with healthy children. When analyzing PARS questionnaire six months after the ablation procedure the physical and psychological functioning of SVT children was still worse than in the group of healthy children. On the basis of the performed analysis we believe that PARS questionnaire is a more useful and sensitive tool than WHOQOL-BREF when evaluating ablation influence on patients' QoL.

Keywords: arrhythmia, pediatric, quality of life.

Introduction

Supraventricular tachycardia (SVT), which is the most common symptomatic arrhythmia in children, may result in a multitude of negative feelings and consequently impede the comfort of life [1–3]. The most common mechanisms of SVT in children are the following: atrioventricular reentrant tachycardia (AVRT), atrioventricular nodal reentrant tachycardia (AVNRT) or atrial ectopic tachycardia (AET) [1, 2] . Palpitation, syncope, chest pain, dyspnea, dizziness, lower exercise tolerance are the most typical symptoms in children with SVT [1]. Psychological dysfunction such as anxiety or depressive symptoms are also common in patients with arrhythmia [4, 5]. The symptoms of SVT and the related limitations, such as

missing school, admissions to the emergency room, regular check-ups, avoidance of physical exercises, necessary medications and their possible side effects may all affect the quality of life (QoL) and psychosocial functioning of SVT patients [3].

There are a lot of studies which show that arrhythmia significantly affects the QoL both in the adults and children with arrhythmia [3, 6–11]. Currently, radiofrequency ablation (RFA) or cryoablation is a standard care, recommended as the method of choice in patients with SVT [12–14]. The previous studies indicate that ablation is a safe and effective method to manage children with SVT. However, the majority of these studies focus on the effectiveness of ablation solely as the method to eliminate arrhythmia substrate. Regression of arrhythmia and thus the objective improvement of the health condition as a result of the provided treatment do not always imply the improvement of the QoL and a subjective perception of the health and therefore the evaluation of the applied treatment on the QoL appears to be important. There are a lot of studies that prove positive influence of ablation therapy on QoL of adult patients [15–17]. The available analyses of pediatric patients with arrhythmia confirm the positive effects of ablation on the QoL but they are scarce [3, 18, 19]. The number of studies comparing QoL of pediatric patients treated successfully with ablation with normal population is not sufficient [3, 19]. The Constitution of the World Health Organization (WHO) defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [20]. The aim of the paper was to compare the QoL in children with SVT treated with successful ablation with the group of healthy children. Are SVT children who underwent a successful ablation treatment healthy, according to WHO definition?

Materials and Methods

Patients

In this study we enrolled a group of SVT children aged 7–18 with a diagnosed SVT treated with ablation therapy at the Department of Pediatric Cardiology, Poznan University of Medical Sciences, Poland in 2010–2014. Patients with organic heart disease or other chronic condition that could impede the QoL were excluded from the study. Also, we enrolled a group of healthy children, aged 7–18, selected by pediatricians during the routine check-ups in 2014–2015. On entering the study all patients underwent a detailed interview and a physical examination. SVT children completed the WHOQOL-BREF questionnaire and the PARS questionnaire six months after the ablation treatment. The healthy children completed the WHOQOL-BREF questionnaire and the abbreviated PARS questionnaire during pediatrician check-ups. All patients and their parents provided a written consent to participate in the study.

The parameters of QoL were assessed in SVT children who underwent a successful ablation treatment and the collected results were compared with the group of healthy children.

The study protocol was approved by the Bioethics Committee of the University of Medical Sciences, Poznan, Poland.

WHOQOL-BREF

The WHOQOL-BREF instrument comprises 26 items which measure the following broad domains: physical health, psychological, social relationships, and environment [21]. The WHOQOL-BREF is a shorter version of the original instrument that may be more convenient to use in large research studies or clinical trials [21]. Each domain is assessed on a 0–100 point scale; the higher the score obtained in one domain the higher QoL. There are also two questions of WHOQOL-BREF questionnaire which are analyzed separately: question No. 1, concerning individual general perception of QoL and question No. 2, concerning individual general perception of one's own health. Considering the patients' age the question regarding sexual activity, social domain part, was removed from the questionnaire.

Pediatric Arrhythmia Related Score (PARS)

The questionnaire regarding patients' own feelings and observations connected with arrhythmia (Pediatric Arrhythmia Related Score- PARS), which was developed by pediatric cardiologists in collaboration with a clinical psychologist and adjusted to the group of arrhythmia children was the second instrument used in the study. This questionnaire was already used in our study evaluating QoL in children with SVT [10].

Questions in this questionnaire are grouped into 3 domains: physical, regarding the symptoms perceived as specific or likely to accompany SVT; medical satisfaction, concerning cooperation with medical care

professionals; and psychological domain- referring to emotional condition of the studied individuals. Each domain is assessed on a 1–5 point scale and numeric results of individual areas are 'negatively directed', i.e. the lower numeric value the higher the QoL. Specific details regarding PARS questionnaire are available in our previous study [10]. Only the questions regarding physical and psychological aspects were used in the current study, assuming that the questions referring to medical satisfaction are inappropriate to be analyzed in the group of healthy children.

Statistical analysis

Statistical calculations were performed using the statistica data analysis software system (STATISTICA 10). Data were considered significant at $p < 0.05$. Both groups were statistically compared with regard to age, gender, a place of living, and education. Due to the fact that there was no correlation with normal distribution, the comparison of patients' age was performed using the nonparametric Mann-Whitney U test. The same test was used to compare education. Gender and a place of living were compared using the $\chi 2$ with Yates correction test. The age was determined by a mean value, standard deviation, a median and IQR. The Gender, a place of living and education were presented as proper numbers in categories and relevant percentage values. In the study we compared the scores obtained in 4 domains of WHOQOL-BREF questionnaire and 2 domains of PARS questionnaire of SVT children and healthy children. Moreover, two questions from WHOQOL-BREF and all questions from PARS were analyzed separately. The nonparametric Mann-Whitney U test was used to perform comparisons of the above QoL parameters between the both groups of patients.

Results

The study included 122 SVT children who underwent a successful ablation treatment. On the basis of the electrophysiological study the following forms of SVT were diagnosed: AVRT– 59.8%, AVNRT- 35.3%, AET- 4.9%. All the children in SVT group presented clinical symptoms before ablation. The mean ± SD age of the first SVT episode was 10.1 ± 4.6 years (median/IQR: 11.5/8.0). In the SVT group antiarrhythmic drugs were taken by 89 (72.9%) of the patients, while the remaining children were not treated pharmacologically.

Patient demographics are shown in **Table 1**.

WHOQOL-BREF

SVT group demonstrated no differences in comparison with healthy children in all the analyzed domains of WHOQOL-BREF questionnaire (the mean ± SD value on a 0–100 scale was: physical 79.4 ± 14.8 vs 82.0 ± 12.1; psychological 77.8 ± 16.0 vs 81.6 ± 13.9; social relationships 80.7 ± 17.3 vs 80.5 ± 16.6; environment 77.4 ± 14.0 vs 79.2 ± 15.6 **(Figure 1).**

On the basis of the analyzed responses on a five-point Likert scale, the general satisfaction with the QoL and general satisfaction with the health condition was also comparable in both groups of patients. Only one child (1.2%) of the healthy group was dissatisfied with their QoL (mean 4.3; median 4.0; IQR 1.0), whereas none of the children in SVT group were dis-

Table 1. Patient demographics

	SVT children group	Healthy children group	*p* value
Patient No.	122	83	
Age [mean ± SD (median/IQR)]	13.9 ± 2.8 (14.5/4.0)	12.9 ± 3.5 (13.0/6.0)	0.1107
Gender [n (%)]			
Boys	55 (45.1)	38 (45.8)	0.9731
Girls	67 (54.9)	45 (54.2)	
Place of living [n (%)]			
village	40 (32.8)	23 (27.7)	0.4522
town	82 (67.2)	60 (72.3)	
Education [n (%)]			
1. Primary School	35 (28.7)	35 (42.2)	0.2366
2. Secondary School	47 (38.5)	22 (26.5)	
3. Basic Vocational School	1 (0.8)	1 (1.2)	
4. Technical College	10 (8.2)	6 (7.2)	
5. High School	29 (23.8)	19 (22.9)	

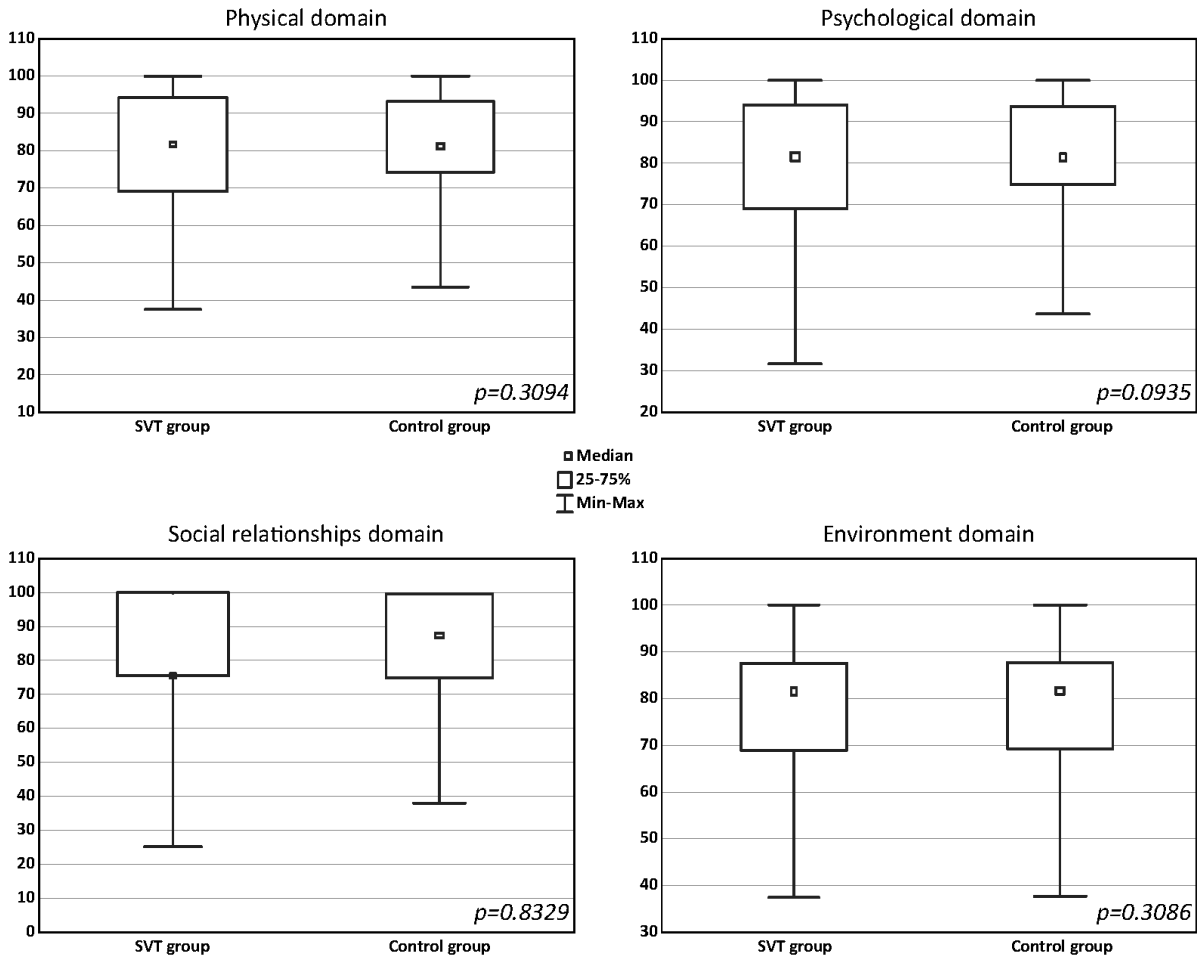

Figure 1. WHOQOL-BREF scores. Comparison of SVT children after ablation and healthy children. Values are presented as median; 25–75 percentile and minimum-maximum

satisfied (mean 4.3; median 4.0; IQR 1.0); similarly, only one child (0.82%) in arrhythmia children group was dissatisfied with their general health condition (mean 4.2; median 4.0; IQR 1.0) whereas nobody in the group of healthy children expressed their dissatisfaction (mean 4.2; median 4.0; IQR 1.0) **(Figure 2).**

PARS (authors' own questionnaire)

The PARS questionnaire still showed significant differences between the study groups in the both compared domains (the mean ± SD value on a 1–5 was: physical 1.8 ± 0.5 vs 1.6 ± 0.3; psychological 2.3 ± 0.7 vs 2.1 ± 0.6) **(Figure 3).**

Physical domain showed significantly higher intensity of negative feelings in SVT group after ablation in 6 out of 13 questions related to the discussed domain **(Table 2)**. Psychological domain showed differences in only 1 out of 7 related questions. SVT patients after ablation were still more nervous when compared with the healthy children **(Table 2)**.

Discussion

In the present study we found that the QoL of SVT patients is similar to control group when analyzing the general questionnaire, but the QoL of SVT patients is still lower in the specific questionnaire in comparison with the healthy children. Healthy children reported similar general satisfaction with the QoL and general satisfaction with the health condition as SVT children.

As mentioned above, there are few available studies evaluating and comparing with a normative population the QoL of pediatric patients with SVT who underwent ablation. Additionally, these studies are based on a significantly lower number of patients in comparison with our study group. Strieper et al. evaluated the QoL in 27 children with SVT [3]. This study demonstrated that six months following a successful ablation the total mean scores were comparable with healthy children [3]. Abo-Haded examined a group of 38 pediatric patients with SVT who underwent

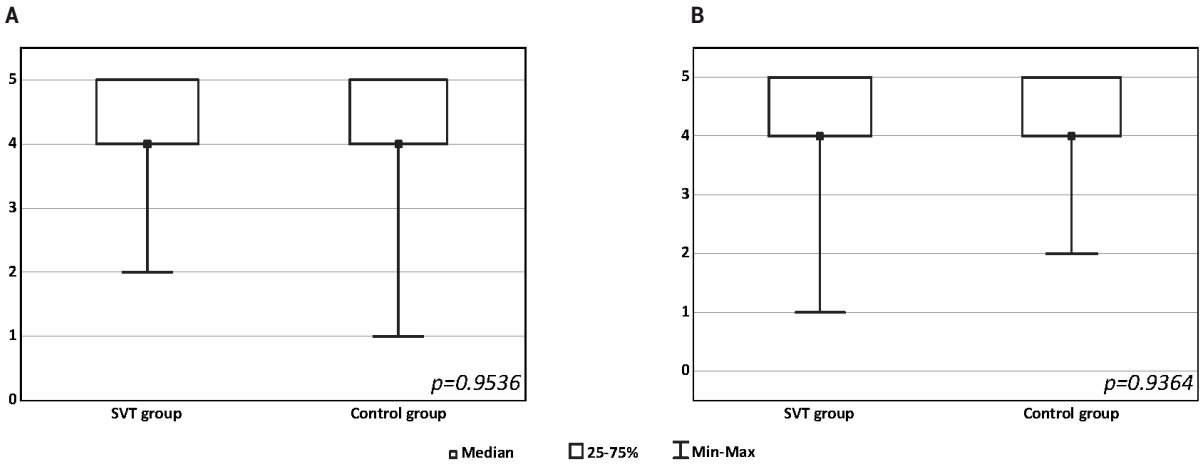

Figure 2. General satisfaction with the quality of life (A) and with the health condition (B). Comparison of SVT children after ablation and healthy children. Values are presented as median; 25–75 percentile and minimum-maximum

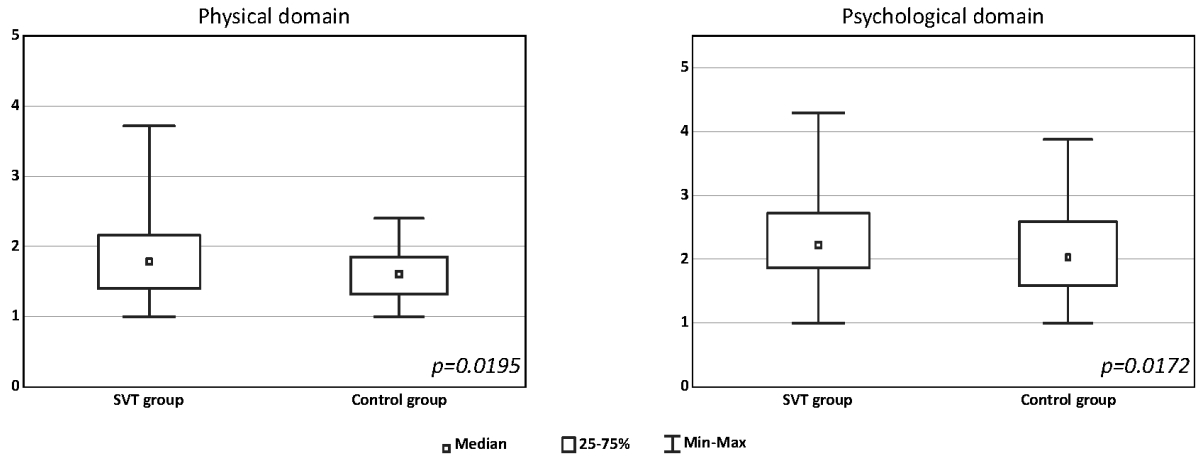

Figure 3. PARS scores. Comparison of SVT children after ablation and healthy children.Values are presented as median; 25–75 percentile and minimum-maximum

a successful ablation; his study showed that the data after ablation are similar to the general pediatric population scores [19]. The authors of these studies used PedsQL Cardiac Module, which was validated by Uzark et al. for pediatric patients with heart conditions; however, it is not available in a Polish language version [22, 23]. In our study we used the PARS questionnaire which evaluates patient's individual feelings and observations and it is adjusted to the arrhythmia group. PARS has been already used in a previously published study assessing QoL in pediatric population with SVT [10]. In this study [10] we compared 180 SVT children with the control group of 83 healthy children and we proved a significant impairment of QoL in SVT children in comparison with the healthy group. In the current study we also used a group of healthy patients as a benchmark to analyze the scores obtained in SVT group after ablation treatment. To our knowledge it is currently the most numerous pediatric SVT group treated with ablation, described in the available literature, comparing QoL with healthy children.

In the current study, on the basis of WHO-QOL-BREF questionnaire there were no differences found between study groups, unlike in PARS instrument which showed differences in the both analyzed domains. In the previous study [10] physical domain of PARS showed significantly increased symptoms in SVT group in 11 out of 13 questions, whereas in the current study there were still significantly increased negative feelings in 6 questions. In the previous study psychological domain of PARS showed differences in 3 out of 7 related questions: SVT patients were more likely to cry, experience sadness and nervousness when compared with the healthy children [10], whereas the current study showed only one difference, i.e. SVT patients after successful

Table 2. PARS questions and scores. Comparison of SVT children after ablation and healthy children; data presented as mean and median

Questions (the answers are provided using 1–5 point scale where '1' means 'absolutely not' and '5' means 'absolutely yes')	SVT children group		healthy children group		P value
	Mean	Median	Mean	Median	
Physical domain					
1. Do you have dyspnea?	1.6	1.0	1.3	1.0	.0012
2. Do you have palpitations?	1.8	1.5	1.3	1.0	<.0001
3. Do you have pain behind your breastbone?	1.7	1.0	1.3	1.0	.0003
4. Do you ever faint?	1.2	1.0	1.2	1.0	.9637
5. Do you seem to pass urine more frequently than usual?	1.5	1.0	1.4	1.0	.3418
6. Do you ever have a blurred vision? (e.g. scotoma)	1.8	1.5	1.8	2.0	.7433
7. Do you think you are more pale than your friends or do you happen to become pale suddenly?	1.7	1.0	1.5	1.0	.0803
8. Do you experience situations in which you sweat more than your friends?	1.9	1.0	1.5	1.0	.0235
9. Do you ever feel nauseous?	1.7	1.0	1.7	1.0	.9439
10. Do you have headaches?	2.4	2.0	2.6	3.0	.1635
11. Do you have stomach aches?	1.9	2.0	2.4	3.0	.0011
12. Do you sometimes feel suddenly cold without a reason?	1.8	1.5	1.5	1.0	.0429
13. Do you think you are weaker than your peers?	2.5	2.5	1.6	1.0	< .0001
Psychological domain					
1. Do you often cry?	2.1	2.0	1.9	2.0	.4398
2. Is it easy to make you cry?	2.5	2.0	2.2	2.0	.1409
3. Do you think you are more nervous than your peers?	2.6	2.0	2.0	2.0	.0018
4. Do you think you are sadder than your peers?	1.9	2.0	1.6	1.0	.0648
5. Do you think you are happier than your peers?	2.7	3.0	2.7	3.0	.9456
6. Do you think you are more lonely than your peers?	1.7	1.0	1.6	1.0	.3487
7. Can you count on your friends?	4.0	4.0	4.3	5.0	.0651

ablation still felt more nervous than the healthy peers. In the previous study we assumed that "General questionnaires provide more time-stable results and may not identify small but significant changes in the QoL" [10]. On the basis of the performed analysis we believe that PARS questionnaire is a more useful and sensitive tool than WHOQOL-BREF when evaluating ablation influence on patients' QoL.

Nowadays QoL evaluation is a very important element to determine the clinical benefit of the performed treatment. There are many studies assessing the QoL of patients with various cardiac arrhythmias confirming the significant improvement in investigated fields after ablation [3, 6–11]. However, cardiology patients who are seriously concerned about their heart condition may still report worse QoL than healthy population despite successful therapy, which was proved in the current study.

Study limitations

Only the children under 7 years of age were included in the study and therefore the study does not cover the whole range of the patients' age who undergo ablation treatment. It was assumed, that children below 7 years of age might have problems with understanding all the questions contained in questionnaires and thus, they could have difficulties providing autonomous (or with a little help from adults) answers to all the questions.

Perspectives

- Further studies concerning QoL in children with arrhythmia, also after ablation treatment with a longer follow-up period.
- Further improvement of QoL evaluation tools in arrhythmia children.
- Determination of the factors affecting QoL deterioration in SVT children as well as optimization of arrhythmia treatment in children, considering the effects of these factors on QoL.
- Expansion of examinations to include parent proxy-report instrument in relation to their child's disease. It may be essential in cases when, due to the young age, cognitive impairment or severity of illness, children are unable to complete QoL instrument. Apart from this, parent proxy-report reflects parents' impression of their child QoL that may affect the healthcare.

Conclusions

Six months after the ablation procedure the general satisfaction with health condition and general satisfaction with the QoL of SVT children is comparable to the healthy children. On the basis of the general questionnaire all scores are comparable with the healthy children.

When analyzing PARS questionnaire six months after the ablation procedure the physical and psychological functioning of SVT children is still worse in comparison with the healthy children.

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Conflict of interest statement
The authors declare no conflict of interest.

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ORIGINAL PAPER

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Evaluation of the effect of selected social and demographic criteria on the frequency of the consumption of lunch and products purchased at school by pupils

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ABSTRACT

Introduction. The research shows that eating disorders currently occur in 22% of girls and 28% of boys. Such high overweight and obesity rates are often caused by unbalanced diet, low nutritional awareness of students and parents and, in consequence, bad nutritional habits developed at home. Nutritional awareness of mothers can affect the dietary behaviour and choices of children and, in consequence, their proper nutritional status.
Aim. The aim of the research was to evaluate the frequency of the consumption of breakfast and lunch prepared at home and the frequency of purchases in school shops and vending machines in relation to the child's sex and the mother's educational level.
Material and Methods. The research material consisted of a survey questionnaire from 76 children aged 9 years, containing questions related to the frequency of consuming breakfast and lunch prepared at home, the frequency of purchasing food products in school shops/vending machines in the past three months and the types of those products.
Results. On the basis of conducted research, it was found that the sex of a child did not have any effect on the number of meals consumed ($p = 0.14$), the frequency of consuming breakfast at home ($p = 0.44$), the frequency of consuming lunch (brought from home) at school ($p = 0.46$), or the frequency of purchasing products in school shops/vending machines ($p = 0.50$). It was found that mothers' educational level had an effect on dietary habits of children ($p < 0.001$). Children of mothers with vocational education significantly more often did not consume breakfast at home. Mother's education also showed a statistically significant effect on the frequency of consuming lunch at school ($p = 0.02$) and the frequency of purchasing food products in school shops ($p < 0.001$).
Conclusions. The frequency of consuming breakfast and lunch and the frequency of buying food products in school shops/vending machines was significantly statistically dependent on the mother's level of education.

Keywords: students, frequency, breakfast consumption, purchase of products at school, sex, mother's educational level, nutritional status.

Introduction

For many years there has been an increase in the number of overweight and obese children in Poland. The research shows that those disorders occur in 22% of girls and 28% of boys [9]. Such high overweight and obesity rates are often caused by an unbalanced diet rich in highly processed products, with a significant share of fat and/or sugar, i.e. "fast-food" products,

sweets, sweetened beverages, low in fruit, vegetables and dairy products [9]. What is also alarming is an excessively high calorific value of meals consumed and their improper distribution during a day which, combined with low physical activity, is the main cause of improper nutrition status of children in Poland [23, 17].

Breakfast is the first meal after the night break and its consumption is particularly important for children of school age. The research conducted in Poland indicates that some school-age children do not have breakfast and are not properly prepared for an increased mental effort in school, which can affect their school results [1, 6, 18]. On the other hand, a growing trend for energy value consumed at school has been observed, particularly with no control of the range of products sold at school, which was, first of all, the fault of school shops/vending machines providing pupils with easy access to products high in fat and monosaccharides[20,25]. This can also result from low nutritional awareness of pupils and parents and, in consequence, poor nutritional habits developed, among others, at home[10], including skipping breakfast at home and not bringing lunch from home to school [19, 30]. Since it is mothers who are most often responsible for preparing meals for their children, the nutritional awareness of mothers can translate into dietary behaviours and choices of children, and, in consequence, to their proper nutritional status.

Aim

The aim of the research was to evaluate the frequency of consumption of breakfast and lunch prepared at home, and the frequency of purchases in school shops and vending machines in relation to the child's sex and the mother's level of education, as well as to analyse the effect of the above-mentioned factors and eating habits on the nutritional status of pupils from two primary schools in Koszalin.

Material and Methods

The study was carried out in spring 2015 among 76 pupils aged 9 years. The survey questionnaire contained questions related to the frequency of consuming breakfast and lunch prepared at home, the frequency of purchasing food products in school shops/vending machines in the past three months and the types of those products. School shops in two primary schools in Koszalin offered a similar range of food products. Food products purchased by students were considered as consumed. Additionally, the children's body weights and heights were measured and body mass index (BMI) value were calculated (necessary to calculate the Cole index), which permitted the degree of obesity or underweight in children to be evaluated according to the McLaren and Red classification scheme [13].

The statistical analysis was accomplished with Statistica 12 software. An evaluation of the effect of the child's sex and the mother's level of education on the examined dietary behaviours and evaluation of the nutritional status of the surveyed children was prepared with the use ofthechi-square test and by calculating Spearman's correlation index to determine the relations within the dietary behaviours of the children. The significance level of $\alpha = 0.05$ was assumed for all calculations.

Results and discussion

Boys made up 53% of the examined group and girls accounted for 47%. The sex of a child did not have any effect on the number of meals consumed ($p = 0.14$), the frequency of eating breakfast at home ($p = 0.44$), the frequency of consuming lunch at school (brought from home) ($p = 0.46$), or the frequency of purchasing food products in school shops/vending machines ($p = 0.50$) (**Table 1**). However, it should be emphasized that 17% girls and 20% boys had a lower number of meals per day than the recommended 4–5 [27, 29], which could result in lower school results and a higher level of fatigue among children during mental work and physical activity [1, 6]. What is also alarming is the fact that only 3/4 of children, on average, had breakfast every day (14% more boys than girls) and the same percentage took their lunch every day to school (18% more girls than boys). As many as 38% of children bought food products in school shops/vending machines during the day, several times a day or every day (14% more girls than boys).

The mothers' educational level had an effect on the dietary habits of children ($p < 0.001$). Children of mothers with vocational education significantly more frequently did not have their breakfast at home, while as many as 86% children in this group did not have breakfast at all or had it twice a week. In the group of mothers with secondary and higher education, no cases of skipping breakfast or having it less frequently than several times a week were recorded. Mothers' education also had a statistically significant effect on the frequency of lunch consumption at school ($p = 0.02$). Only 29% children of mothers with vocational education were aware of the importance of proper nutrition

Table 1. Eating habits of studied group of children according to gender and mother's education

The tested factor		Total n = 76	Gender		p*	Mother's education			p*
			Girls n = 36 (47%)	Boys n = 40 (53%)		Vocational n = 14 (18%)	secondary n = 24 (32%)	higher n = 38 (50%)	
Number of meals eaten during the day	1–2	2 (3%)	0 (0%)	2 (5%)	0,14	2 (14%)	0 (0%)	0 (0%)	0,91
	3	12 (16%)	6 (17%)	6 (15%)		2 (14%)	4 (17%)	6 (16 %)	
	4	40(53%)	24 (66%)	16 (40%)		6 (43%)	14 (58%)	20 (52%)	
	≥ 5	22 (28%)	6 (17%)	16 (40%)		4 (29%)	6 (25%)	12 (32%)	
Frequency of consumption of breakfast at home	I do not consume	10 (13%)	6 (17%)	4 (10 %)	0,44	10 (72%)	0 (0%)	0 (0%)	< 0,001
	2 times / week.	2 (3%)	0 (0%)	2 (5%)		2 (14%)	0 (0%)	0 (0%)	
	every other day	8 (10%)	6 (17%)	2 (5%)		0 (0%)	4 (17%)	4 (12%)	
	daily	56 (74%)	24 (66%)	32 (80%)		2 (14%)	20 (93%)	34 (88%)	
Frequency of consumption of second breakfast brought from home	I do not consume	6 (8%)	0 (0%)	6 (15%)	0,46	2 (14%)	2 (9%)	2 (6%)	0,02
	2 times / week.	10 (13%)	4 (11%)	6 (15%)		6 (43%)	4 (17%)	0 (0%)	
	every other day	4 (5%)	2 (6%)	2 (5%)		2 (14%)	0 (0%)	2 (6%)	
	daily	56 (74%)	30 (83%)	26 (65%)		4 (29%)	18 (74%)	34 (88%)	
Frequency of purchase products in school shop/machine	I'm not buying	8 (10%)	4 (11%)	4 (10%)	0,50	0 (0%)	8 (33%)	0 (0%)	<0,001
	several times /month	26 (34%)	10 (28%)	16 (40%)		0 (0%)	8 (33%)	18 (47%)	
	1 time / week.	14 (18%)	6 (17%)	8 (20%)		0 (0%)	2 (9%)	12 (32%)	
	several Times/week.	20 (28%)	14 (39%)	6 (15%)		6 (43%)	6 (25%)	8 (21%)	
	daily	8 (10%)	2 (5%)	6 (15%)		8 (57%)	0 (0%)	0 (0 %)	

* Chi2 test; p-values> 0.05 indicate no statistically significant differences

in providing their children with lunch for school. For mothers with secondary or higher education, those values were significantly higher and amounted to 74% and 88%, respectively. It should be presumed that the fact of not having breakfast at home or lunch at school by a higher percentage of children of mothers with vocational education was the reason why all children in this group purchased products in the school shop at least a few times a week, which was recorded for only 21–25% of the examined children in the group of mothers with secondary or higher education ($p < 0.001$). The educational level of mothers did not have a significant effect on the number of meals consumed ($p = 0.91$), although it was only in the group of mothers with vocational education that children had less than 3 meals a day (14%), which should be described as improper.

Similar results concerning breakfast consumption frequency were obtained by Sadowska [16], who reported that in the group of children aged 7–9 years, breakfast was consumed every day or often by 74% girls and 72% boys, and lunch was always consumed by 67% of girls and 83% of boys. In a study by Czeczelewski [2], carried out among children at the average age of 11, about 88% children had breakfast, and in a study by Wawrzyniak et al. [22], the consumption of breakfast every day was found for 60% children aged 11–13, while 33% of the examined children had breakfast only sometimes and 7% of children never had breakfast. The research carried out by the WHO in 2013/2014 demonstrated that breakfast was consumed every day by 70% of girls and 71% of boys aged 11 [8].

The education of the mother, as a person in the family with a major impact on the child's nutrition, was reflected in the dietary habits of a child in relation to having breakfast and lunch, or purchasing food products in school shops, as it has been demonstrated in own research and research by other authors. This was also confirmed by analyses carried out among junior secondary school students in Bytom [26], in which it was proven that children of mothers with higher education had breakfast more often and ate fewer sweets than children of mothers with vocational education. A similar trend was also demonstrated in research carried out in Brazil regarding the relationship between the mother's education and her care about the quality of child nutrition [5]. Dutch children whose mothers had higher education also consumed more fruit and vegetables than children of mothers with vocational education [24]. In turn, in the research carried out among American children from rural areas, a relationship was demonstrated between the proper dietary habits of boys whose mothers had higher education level [14].

In own research, as regards products purchased most often in school shops, children most often declared buying sweets (65% boys and 33% girls), juices (55% boys and 50% girls), lollipops (50% boys, 44% girls), mineral water (40% boys and 50% girls), crisps (45% boys and 28% girls) and jellies (40% boys and 39% girls). When buying products in school shops, children were driven primarily by the taste (sweet, salty) and external appearance (colour), without paying attention to nutritional value [20]. Shop assistants from primary

schools in Wrocław confirmed that children most often bought sweets (bars, jellies, lollipops) and products high in fat (crisps) [25]. It is a highly important issue since own research demonstrated an inverse relation between consuming breakfast and lunch prepared at home and the frequency of purchasing products in school shops/vending machines ($p < 0.001$) (**Table 2**).

Family environment exerts a significant effect on the dietary habits of children. Many behaviours observed at home become the children's own habits [28, 7]. The nutritional value of meals consumed by children depends on the nutritional knowledge of the children and their parents [21]. American research carried out among 12-year-old children showed that parents often did not know what their children bought or ate at school [14]. Very often, adults do not realize that the money given to the child for buying lunch was used to buy products high in fat and sugar, purchased in a shop at or near the school. It should also be emphasized that children making purchases on their own feel more adult and independent and are, therefore, particularly exposed to making dietary mistakes [21]. The

Table 2. The relationship between eating habits of studied

Tested parameter	Frequency of consumption of breakfast at home	Frequency of consumption of secondo breakfast brought from home	Frequency of purchase products in school shop/machine
Number of meals eaten during the day	0,01* p = 0,97	0,01 p = 0,99	-0,10 p = 0,53
Frequency of consumption of breakfast at home		0,48 p = 0,002	-0,64 p < 0,001
Frequency of consumption of second breakfast brought from home			-0,58 p < 0,001

* Spearman correlation coefficients; $p \leq 0.05$ values indicate statistically significant differences

Table 3. The nutritional status of the studied group of children on the basis of the Cole's index depending on gender and mother's education

Nutritional status	Total n = 76	Gender		p*	Mother's education			p*
		Girls n = 36 (47%)	Boys n = 40 (53%)		vocational n = 14 (18%)	secondary n = 24 (32%)	higher n = 38 (50%)	
Malnutrition/Destruction	8 (11%)	2 (6%)	6 (15%)	0,40	0 (0%)	4 (17%)	4 (12%)	0,49
Normal values	28 (37%)	14 (39%)	14 (35%)		4 (29%)	10 (42%)	14 (36%)	
Overweight	18 (24%)	12 (33%)	6 (15%)		6 (42%)	2 (9%)	10 (26%)	
Obesity	22 (28%)	8 (22%)	14 (35%)		4 (29%)	8 (32%)	10 (26%)	

* Chi2 test; p-values> 0.05 indicate no statistically significant differences

Table 4. The impact of eating habits in the studied group of children on the nutritional status

The tested factor		Total n = 76	Nutritional status				p*
			Malnutrition/ Destruction n = 8 (11%)	Normal values n = 28 (37%)	Overweight n = 18 (24%)	Obesity n = 22 (28%)	
Number of meals eaten during the day	1–2	2 (3%)	0 (0%)	0 (0%)	0 (0%)	2 (9%)	0,98
	3	12 (16%)	0 (0%)	4 (14%)	4 (22%)	4 (18%)	
	4	40 (53%)	6 (75%)	14 (50%)	10 (56%)	10 (45%)	
	≥ 5	22 (28%)	2 (25%)	10 (36%)	4 (22%)	6 (28%)	
Frequency of consumption of breakfast at home	I do not consume	10 (13%)	0 (0%)	4 (14%)	4 (22%)	2 (9%)	0,85
	2 times/week	2 (3%)	0 (0%)	0 (0%)	0 (0%)	2 (9%)	
	every other day	8 (10%)	0 (0%)	4 (14%)	2 (11%)	2 (9%)	
	daily	56 (74%)	8 (100%)	20 (72%)	12 (67%)	16 (73%)	
Frequency of consumption of second breakfast brought from home	I do not consume	6 (8%)	0 (0%)	2 (7%)	0 (0%)	6 (28%)	0,31
	2 times/week	10 (13%)	0 (0%)	6 (21%)	0 (0%)	2 (9%)	
	every other day	4 (5%)	0 (0%)	0 (0%)	2 (11%)	2 (9%)	
	daily	56 (74%)	8 (100%)	20 (72%)	16 (89%)	12 (54%)	
Frequency of purchase products in school shop/machine	I'm not buying	8 (10%)	2 (25%)	2 (7%)	0 (0%)	4 (18%)	0,13
	several times/month	26 (34%)	6 (75%)	14 (50%)	2 (11%)	4 (18%)	
	1 time/week	14 (18%)	0 (0%)	2 (7%)	6 (33%)	6 (28%)	
	several times/eek	20 (28%)	0 (0%)	6 (21%)	10 (56%)	4 (18%)	
	daily	8 (10%)	0 (0%)	4 (15%)	0 (0%)	4 (18%)	

* Chi2 test; p-values> 0.05 indicate no statistically significant differences

research conducted in 2007 in Warsaw among pupils of the fourth grade of primary school and their parents revealed differences in the evaluation of lunch consumption by children (28% children declared having lunch while 69% of parents declared that their children had lunch). This discrepancy also concerned the consumption of sweets (79% children declared consumption of sweets, while 60% of parents declared that their children consumed sweets) [4].

The nutritional status of children was not related to the sex of the subjects or to the level of education of mothers ($p > 0.05$) (**Table 3**), although a higher percentage of girls than boys were overweight (by 18%), while a reverse trend was observed in the case of obesity, where 13% more boys than girls were characterized by this nutritional status. Only 37% of the subjects were characterized by proper body mass, with significant obesity (28%) and overweight (24%) among children. The current results demonstrated that the examined group of 9-year-old pupils from Koszalin follows the growing trend in the number of children with eating disorders [8]. Jończyk et al. [11], examining a group of 11-year-old children from Piekary Śląskie observed overweight in 15% and obesity in 20% of children. In turn, Kolarczyk et al. [12] on the basis of the research concerning children from Kraków, found a shift in the BMI values in children aged 9–10 towards higher values. It should also be emphasized that, despite a lack of statistically significant differences, up to 71% of children in the group of mothers with vocational education in this study had excessive body weight, and this was a much higher index than in the group of mothers with secondary (41%) or higher education (52%).

No effect of the investigated dietary habits on the nutritional status of children was found for the examined group of children ($p > 0.05$) (**Table 4**), although in the group with obesity, the largest percentage of children had 3 or less meals (27%), which is incorrect in regard to healthy nutrition and could lead to obesity [17, 3]. Additionally, none of the children demonstrating malnutrition status made purchases in school shops/vending machines more often than several times a month.

Findings and conclusions

1. The frequency of consuming breakfast and lunch and the frequency of buying food products in school shops/vending machines was significantly statistically dependent on the mother's level of education. Children who consumed breakfast and lunch prepared at home rarely purchased products in school shops/vending machines.
2. No statistical relationships were found between the educational level of the mother, sex, dietary habits of children or their nutritional status.
3. It seems appropriate to increase the nutritional awareness of parents and children.

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Conflict of interest statement
The authors declare no conflict of interest.

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Is compliance with lifestyle modifications dependent on sociodemographic factors and awareness of HF symptoms? Impact of lifestyle changes on HF patients' wellbeing

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ABSTRACT

Aim. The aim of this study was to obtain information, whether patients with heart failure (HF) follow medical indications and if there are any sociodemographic differences between compliant and noncompliant patients and how lifestyle changes contribute to the patients' wellbeing.
Material and Methods. A survey was carried out in 198 patients hospitalized in I Clinic of Cardiology in Poznan. Patients were divided into groups: P1 – no lifestyle changes, P2 – 1 of 4 verified lifestyle modifications, P3 – 2 or 3 verified lifestyle modifications, P4 – all 4 verified lifestyle modifications.
Results. People over the age of 65 mostly constitute groups of low compliance (p = 0.055). Men are more eager to change their lifestyle (91.4% in P3 and 85.7% in P4). Women belong mainly to groups with low compliance (p = 0.0001). Respondents who reported condition improvement were less likely to describe decreased sexual activity (59.6% vs 38.2%, p = 0.078), which acted as an important determinant of family relations. However, our analysis demonstrated a non-significant impact of adherence to indicated lifestyle modifications on patients' wellbeing
Conclusions. Compliant patients are statistically younger and more often male. Level of education is the least important determinant of compliance. There is no significant impact of adherence to indicated lifestyle modifications on patient's wellbeing. Compliant patients are less likely to reduce their sexual activity, which showed to be an important family relationship factor.

Keywords: heart failure, compliance, lifestyle, sexual activity, wellbeing.

Introduction

Over 23 million people worldwide suffer from heart failure (HF) [1]. The European Society of Cardiology defines heart failure as a "clinical syndrome in which patients have typical symptoms and signs resulting from an abnormality of cardiac structure and function" [2]. It's a final stage of most forms of cardiovascular disease, not a disease per se [3].

Heart failure belongs to the category of cardiovascular chronic diseases which are characterized by long duration and slow progression and leads to premature death [4]. All kinds of people are affected by chronic diseases, but the prevalence tends to increase with age [5].

Heart failure can usually be controlled, but not cured. Daily symptoms and complications can shorten patient's life expectancy and worsen the quality of

life [6]. Despite more effective therapeutic interventions and surgical management of HF, prevalence is rising, with an estimated 2% prevalence in people over 45 years old in developed countries. The lifetime risk in the general population is 1 in 5, and according to the prognosis – the incidence in the next two decades will increase by 25 percent [1, 7]. Particularly important risk factors for HF, such as obesity, metabolic syndrome and DM can often be caused by unhealthy lifestyle [8–10].

Treatment of HF patients has proven to be challenging and requiring a multidimensional approach. Self – assessment of the disease depends on many aspects. Compliance to medication is important but is still only one of factors influencing the patient's condition [11]. Significant part of the HF treatment, as many other chronic conditions, is based on patient's self-management [12].

According to the research the biggest struggle is not a lifelong therapeutic treatment, but lifestyle modification [13] – increased exercise, lowering of body mass index, reduced-sodium diet, moderation of alcohol consumption or quitting smoking requires much effort and determination [14, 15]. These behavioral modifications, together with filling prescriptions and taking medication properly are the examples of therapeutic behaviors. Following these recommendations is referred to as compliance [16].

Materials and Methods

A cross – sectional study in patients with Heart Failure was conducted. There was a total of 198 patients – 49 females, 152 males, aged from 20 to 92 years, with a diagnosis of heart failure of any etiology. Patients were to be excluded due to intellectual disability, which could affect the awareness of participation and lack of agreement for participation in the study. Surveys had been taken between October 2014 and December 2015 in I Clinic of Cardiology, Poznan University of Medical Science (PUMS).

Collected demographic data included age, sex and education level. At baseline, patients had New York Heart Association functional class assessed. Patients were asked to complete questionnaires designed specifically for this project. Impact of behavioral modifications on HF patients' quality of life and satisfaction of the treatment were evaluated. All interviews were conducted verbally in Polish by the authors of this study. Patients agreeing to participate provided informed consent.

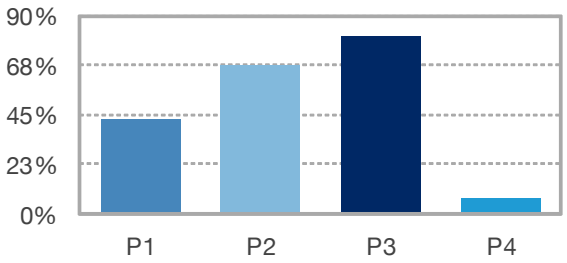

Figure 1. Number of patients in groups P1–P4

Patients were divided into 4 groups: P1 – medication adherent, no lifestyle changes, P2 – medication adherent and any 1 of verified lifestyle modifications, P3 – medication adherent, 2 or 3 of verified lifestyle modifications, P4 – medication adherent and all 4 verified lifestyle modifications. Patients' distribution is shown in **Figure 1**.

After dividing patients into 4 groups, it was analyzed whether age, NYHA class, gender, duration of HF or education levels influenced the patient's self-care behavior.

Moreover, reliance between awareness of symptoms and level of adherence within each group was investigated. For the purpose of this study, patients recognizing more than 4 symptoms as alarming (out of 8 assessed: shortness of breath at rest, edema, awakening shortness of breath, syncope, chest pain persisting even after administration of nitroglycerin, increased palpitations, inability to sleep in a supine position, rapid pulse rate) were found to be aware of their condition.

Verified lifestyle modifications

Amongst regimens influencing the incidence of chronic diseases regular physical activity, well-balanced diet, moderation of alcohol consumption and weight reduction were chosen [17, 18]. Regular physical activity improves the quality of life. Exercise training such as cycling or walking is indicated for HF patients. It is available and easily accessible [19, 20]. The European Society of Cardiology heart failure recommends regular physical activity for stable NYHA class I–III [21–23]. According to Heart Failure Society of America (HFSA) 2010 guidelines, HF patients should exercise in moderate intensity for 30 minutes each day, five days per week. Participants of this study were asked the question 'Do you exercise in compliance with your doctor's recommendations?' There was no investigation of intensity or type of exercise, determining the efficacy of the training [24]. Compliance to

dietary recommendations in HF is one of the most frequent self-care behaviors recommended to patients with heart failure. It is advised by many HF guidelines [23, 25] Striking a balance in sodium intake is essential – too much sodium may lead to fluid retention and hypertension [26], while too aggressive sodium restriction is found to worsen the neurohormonal profile of HF patients [27]. Obesity is an independent risk factor for the development of HF [28, 29]. Intentional weight loss in obese patients can reduce many components of obesity-related heart disease such as blood volume reduction and cardiac output reduction. It leads to regression of structural changes – left ventricular diastolic and systolic dysfunction improvement [6, 30]. The obesity paradox in HF patients cannot be forgotten – weight loss ≥ 5% was associated with high long-term mortality [31]. Most epidemiologic data indicates possible benefits of moderate drinking on the risk and mortality of HF [32]. However, it should be considered that heavy alcohol consumption is a relevant problem in Poland [33]. The risk of HF in patients, who haven't had myocardial infarction, is 1.7-fold higher among heavy drinkers than in abstainers. Moreover, among patients with alcoholic cardiomyopathy and alcoholism without abstinence it is a strong predictor of cardiac death [34].

Statistical analysis

All data analyses were performed using Kruskall-Wallis ANOVA and chi-squared test in Statistica Version 12. $P < 0.05$ was regarded as statistically significant.

Aim

The aim of this study was to obtain information, on whether there are sociodemographic differences between patients who are compliant and noncompliant in following medical indications. The purpose was to assess how abiding by doctors' indications contributes to the HF patients' wellbeing.

Results

Sample characteristics

A total of 198 patients with a confirmed diagnosis of chronic heart failure accepted the invitation to participate in the study. One patient did not give the answer regarding age, 7 patients were not evaluated in terms of New York Heart Association Functional Classification, 1 patient didn't report the level of his education and in case of two patients the year of diagnosis is unknown. Despite missing data these patients weren't excluded. There was no influence on the investigated factors. 43 (21.7%) of 198 patients were taking medication only, without adjusting to any investigated lifestyle-change indication (well-balanced diet, sport activity, body weight loss, alcohol consumption reduction). 43 Patients belong to P1 group, 66 – P2, 80 – P3 and 7 to P4. More than a half of the participants (55.6%) were classified as P1 and P2, claiming to be non-adherent to behavior modifications indicated by a physician, or to be adherent to one lifestyle-change. It means that more than a half of patients were non-compliant. Sociodemographic characteristics of patients are presented in **Table 1**.

Table 1. Characteristic of patients with CHF at baseline (N = 198)

Characteristics N (%)	Generally	P1	P2	P3	P4
Gender (p = 0.0001)					
Male	150 (76%)	25 (58%)	45 (67%)	74 (91%)	6 (86%)
Female	48 (24%)	18 (42%)	22 (33%)	7 (9%)	1 (14%)
Age of patient (years) (p = 0.054)					
Average (standard deviaton)	58.0 (± 14.4)	59.3 (± 15)	60.4 (± 16.3)	55.3 (± 12.4)	59.0 (± 5.7)
Educational level (p = 0.85)					
Primary education	35 (18%)	6 (14%)	15 (22%)	13 (16%)	1 (14%)
Secondary education	130 (66%)	28 (65%)	41 (61%)	56 (70%)	5 (71%)
Tertiary education	32 (16%)	9 (21%)	11 (16%)	11 (14%)	1 (14%)
NYHA classification (p = 0.29)					
I	10 (5%)	2 (5%)	2 (3%)	6 (8%)	1 (14%)
II	56 (29%)	10 (24%)	17 (26%)	26 (33%)	3 (43%)
III	74 (38%)	17 (40%)	28 (43%)	28 (35%)	1 (14%)
IV	51 (26%)	13 (31%)	18 (28%)	19 (24%)	2 (29%)
Duration of HF (years) (p = 0.023)					
Average (standard deviation)	11.7 (± 11.4)	16.2 (± 14.8)	10.9 (± 10.7)	9.5 (± 9.0)	16.3 (± 11.7)

The mean age of patients in the sample was 58 years. Over the half of the patients (70%) were not older than 65 years (**Figure 2**). The majority were men (75.53%). Most (81.5%) had at least secondary education. NYHA Classification distributions among the patients were as follows: Class I, 10 patients (5.15%); Class II, 56 patients (28.9%); Class III, 74 patients (38.1%); Class IV, 51 patients (26.29%). More than the half of the patients (59.3%) have suffered from HF not longer than 10 years (**Figure 3** and **4**).

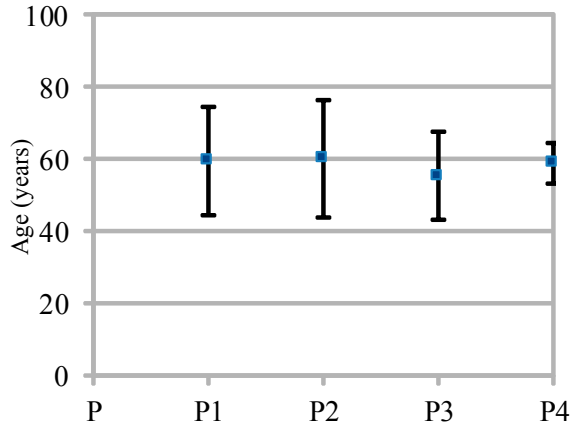

Figure 2. Mean age of patients in groups P1–P4

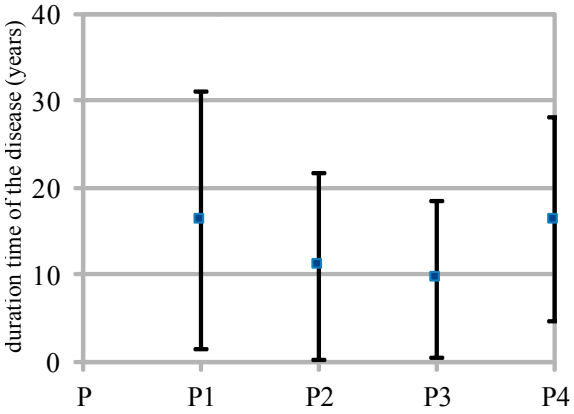

Figure 3. Mean durations time of HF in groups P1–P4

Characteristic of groups

P1 43 (21.7%) of 198 patients were taking medication only, without adjusting to any investigated lifestyle-change indication. Among them 31 participants (72%) observed the improvement of the quality of life. 1 person (2.3%) could not evaluate the impact of the treatment and 11 patients (25.6%) didn't see the improvement of the health condition. Adherence to prescribed medications to prevent and control symptoms is essential in the heart failure management [35]. According to the study from 2013, belief in the efficacy of the pharmacology and satisfaction of the treatment are positively correlated with the adherence to medication [36].

P2 Of the total sample, 67 (33.8%) patients were classified to group P2, as medication adherent and compliant with any 1 of 4 verified lifestyle modifications. Among them 51 (77.3%) observed reduction of heart failure symptoms. 3 of them (4.5%) couldn't assess the impact of the treatment, and 12 (18.2%) didn't see the enhancement.

Lifestyle modifications require more time and effort than adherence to medication [37]. An interesting study by Nieuwenhuis M et al. concluded that patients were less compliant with exercise regimen than to diet. It might be due to physical symptoms and a lack of energy [38]. In this study diet modification was the most common change in patients' behavior. 61 out of 198 patients declared to be adherent to balanced diet, while only 41 decided to exercise regularly.

P3 Group P3 is the most numerous group in the study. 81 (40.9%) out of 198 patients declared to be adherent to medication and to 2 or 3 lifestyle modifications. 64 (80%) of them were satisfied of the treatment, 6 (7.5%) didn't know, and 10 (12.3%) could not see the improvement of their health condition after indication of the treatment. Tremendous effects

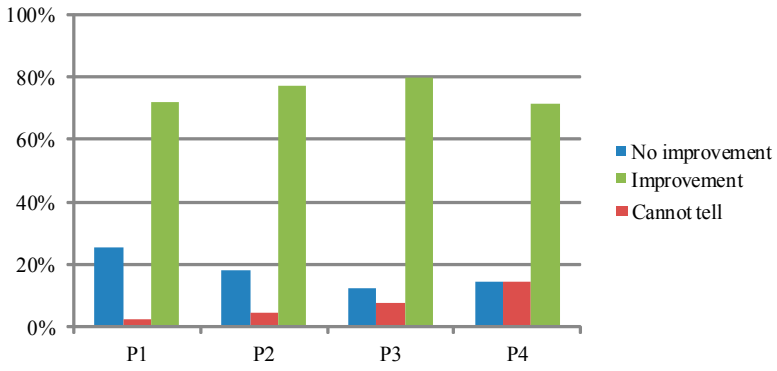

Figure 4. Condition perception by HF patients after treatment introduction (p = 0.48)

were noticed when diet modification and regular physical activity were followed [39].

P4 7 patients (3.5%) were the most disciplined and compliant with all four non-pharmacological recommendations. Compliance with lifestyle modifications ass usually associated with condition improvement [40]. It reflects in this study – 5 (72.1%) P4 patients reported condition improvement. 1 person (14.3%) could not assess, and 1 (14.3%) observed worsening of the health condition.

Age

The mean age is the lowest in P3 (55 years) and the highest in P2 (60 years). Groups P1 and P4 show similar mean age (59 years). Significant differences were observed in the age structure of P groups. People over the age of 65 constitute 34% in P1 and 44% in P2, groups of lower compliance. In the groups of high compliance people over the age of 65 constitute a small group of patients, respectively 17% in P3 and 14% in the P4.

Education

All the P groups are characterized by similar educational pattern. Results are shown in **Table 1**. The highest percentage of patients with a higher education was observed in the group of worst compliance (21%), while in groups with better compliance (P3 and P4) the percentage of those patients was approximately 14%.

NYHA

P1 – a group of the worst compliance – constitutes the majority of patients with advanced heart failure – NYHA III and IV. The percentage of these patients becomes gradually smaller in groups of better compliance: P2 – 71% and P3 – 59%. In P4 patients constitute already a minority with 43%.

Duration of HF

Patients in P1 suffer from HF an average of 16.2 years. The mean time of duration of HF was the shortest in P3 – 9.5 years, not much longer in P2 – 11 years, and 16.3 years in P4. There is a statistically significant P (0.0234). 71% of the most compliant patients (P4) suffer from HF longer than 10 years. The percentage of patients suffering for over 10 years is also very high in the group with the worst compliance – 55%. The majority of P2 (61%) and P3 (69%) patients suffer from HF not longer than 10 years.

Awareness of symptoms

HF patients should contact a healthcare provider in case of worsening symptoms. Patients were asked which symptoms they find alarming and requiring a medical intervention. Considering 3 or more out of 8 symptoms as alarming was recognized as the equivalent of awareness of the disease profile. A relationship between awareness of the symptoms and compliance was noticed. Patients, who would contact a physician when worsening of the symptoms, occur more compliant with the recommendations. Adherent to medication only patients (P1) did not consider worsening of the symptoms as requiring a contact with healthcare provider. In P4 patients were much more aware of the worsening the symptoms. Over 80% of patients would contact a doctor when they occur. 59% of pstients in P2 and 67% in P3 indicated a gradual, growing trend (**Table 2**).

Satisfaction of the treatment

Of the total of 196 patients who answered this question, 151 (77%) observed condition improvement, 11 (5.6%) couldn't evaluate the impact of the therapy, and 34 (17.3%) reported, that there was no condition improvement despite the treatment.

Poor compliance was observed in P4. This group is the smallest in members (7 out of 196 follow all of the physician's indications). 72% of P1 patients declared to benefit from the treatment, nevertheless every fourth patient in this group reports no significant change in the intensity of symptoms. In P2 77% of patients declared a noticeable improvement, while among P3 it is up to 80%. Patients in P3 see no effects of the treatment twice rarely than patients in P3. The values in P4 do not appear quite as spectacular as compared to the previous groups. Only 71% of patients declared benefit from the treatment. These values should be read in the context of the low frequencies of the P4 group- the total of only 7 patients. 14% of patients who did not report symptoms were represented in fact only by one patient.

Table 2. Awareness of symptoms in groups P1–P4 (p = 0,16)

	P1	P2	P3	P4
Low awareness of symptoms	21(49%)	27 (40.3%)	26 (32%)	1 (14.3%)
High awareness of symptoms	22 (51%)	40 (59.7%)	55 (68%)	6 (85.7%)

Gender

The majority of patients were men (75.8%), women constitute less than 1/4 of the patients. Women belong mainly to groups with low compliance (42% in P1 and 33% in P2). Men are more eager to change their lifestyle. 91.4% in P3 and 85.7% in P4 are men.

Sexual activity

Respondents who reported condition improvement were less likely to describe decreased sexual activity (59.6% vs 38.2%) (p = 0.078), which acted in our study as an important determinant of the family relations.

Discussion

While being discharged from the PUMS Hospital, every patient is given recommendations. They can be divided into 4 categories: pharmacological indications, lifestyle modifications impacting the quality of life and outcome prognosis, action plans and follow-up schedule. This study focuses on adherence to medication and lifestyle changes. These aspects were considered as easy to assess by the patient and not requiring a follow-up survey. Only 78.1% of patients introduced changes in their lifestyle. Taking medication is a passive act, while lifestyle modifications require self-discipline. There is no effect seen at the beginning, but persistence yields results. It greatly affects therapeutic efficacy. According to this study, patients more compliant and eager to modify their lifestyle were more satisfied with the treatment and had a better state of being, however there is no statistically significant P (p = 0.48). Jing Jin et al. conducted a study reviewing factors affecting therapeutic compliance. Correlation between adherence to medication and age was one of the conclusions – younger patients (middle aged patients and under 40 years old) take medication less regularly than older patients [41]. In our study all patients declared in compliance with medication, but the motives can be related to non-pharmacological compliance as well. Younger patients are often not adherent due to work and other commitments, which don't leave much time for the regimens. Younger patients have much better survival than older patients. Less comorbidities, such as diabetes, edema or atrial fibrillation, improve their overall health condition. Despite that, non-compliance to the indications worsens the symptoms more severely than in older patients [42].Moreover, older age by itself is not a reason of worse adherence to medication. Amongst patients with HF only, age is not the determinant of lack of compliance with medical recommendations [43]. Remarkably there was found no correlation between the level of education and compliance. Patients with secondary education were the majority in each group P1–P4, with the percentage accounting for 61–72%. It could have been expected that better educated patients should have more knowledge about the disease, should be more aware of the symptoms and be more compliant. There are several studies proving this theory [44–46]. Some studies, including this one, found no association between level of education and compliance [47]. In other, patients with lower educational level are more compliant [48], perhaps due to more trust in doctor's recommendation [41]. There was a low relationship found between NYHA functional class and compliance. The results are shown in **Table 1**. It's noticeable that patients from P1 and P2 groups were classified in majority as NYHA III (P1 – 41%, P2 – 44%). Patients with lower NYHA grade and better health condition – relieved of mild symptoms – abide by more indications [49]. Patients from P3 had NYHA II and NYHA III profile in similar percentage (NYHA II – 33%, NYHA III – 36%). In the most compliant group, P4, the great majority of patients – 43% – had NYHA II profile. Several studies have shown a correlation between gender and lifestyle modification [50]. It was shown, that there are gender differences in patterns of healthy behaviors. Men tend to be more compliant with diet and physical activity recommendations, perhaps due to fewer family duties than women [51, 52]. Our study confirms this theory. Men belong to groups with better compliance (P3, P4), introducing more lifestyle-changes to their lives than women.

Limitations

Participation in this study was voluntary, not all of the qualified patients agreed to sign a consent form. The survey was subjective, based on self – reporting and recalls bias. It is believed that what patients marked in the survey is true, but possibility of overestimating their compliance cannot be excluded. The study refers to patients from one hospital and one ward only.

Conclusion

Groups of different compliance levels turned out to be characterized with different social patterns regarding age, gender and duration of HF. Patients in groups of better compliance tend to be statistically younger and with rather mild HF. Men are more eager to modify their lifestyle and introduce more behavioral changes than

woman. Differences in education level were the least significant. Our analysis demonstrated a non-significant statistically (p = 0.482) impact of compliance to indicated lifestyle modifications on–improvement of patients' wellbeing. Patients in the high compliance groups (P3–P4) were less likely to reduce their sexual activity, which occurred to be an important family relationship factor.

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Conflict of interest statement
The authors declare no conflict of interest.

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There are no sources of funding to declare.

Ethical approval
All procedures in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent
Informed consent was obtained from all individual participants before conducting the survey.

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BRIEF REPORTS

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Pharmacist's age affect information provided for pharmacy clients about generic substitution

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ABSTRACT

Introduction. According to WHO, increase in usage of generic drugs may be one of the ways to reduce costs of healthcare systems around the world. However, according to scientific data, physicians and pharmacists doubt in their effectiveness – the reason for that is not well known. Due to this fact an evidence of factors affecting their opinion is being searched for.
Aim. The aim of this study was to assess whether correlation exist between the age of pharmacist and the way information about generic drugs is provided.
Material and Methods. This was a questionnaire-based study. Especially prepared questionnaire was made available to pharmacists of Lodzkie province. Survey was conducted in Lodz (81.8%) and other towns of lodzkie province.
Results. One hundred and forty eight pharmacists working in Lodzkie province have answered the questionnaire (84.5% women and 13.5% men, aged 23–59, working mainly in private pharmacies – 89.1%). Most of pharmacists (47; 31.8%) younger than 35 years provided information about generic drugs, after being asked about it. Most of pharmacists older than 35 years had given information before patients asked them about it. Correlation analysis revealed that strong statistically significant correlation between pharmacist's age and the moment when he provides an information about generic drugs exist ($P < 0.05$).
Conclusions. Age of pharmacists affect their commitment to provide information about generic drugs for pharmacy clients.

Keywords: generic drugs, generics, questionnaire study, pharmacists' opinions.

Introduction

Generic medicines are cheaper equivalents of brand name drugs. Instead of long lasting clinical trials, their introduction to the market is preceded by bioequivalent studies. Although there is no convincing evidence supporting the fact that generic drugs are inferior to brand name drugs [1], a number of healthcare professionals including pharmacists question equality between them [2]. In literature some problems were highlighted regarding medications of narrow therapeutic index [3, 4]: antiepileptics [5], levothyroxine [6] and warfarin [7]. In contrast other study confirmed that there was no difference between generic and brand-name medications used in cardiology [8]. The study analyzed 9 main groups of drugs: beta-blockers, diuretics, calcium channel blockers, antiplatelet agents, statins, angiotensin-converting enzyme inhibitors and alpha-blockers [8]. Because of contradicting views on generic drugs, an urgent necessity arises to determine the reasons of doubt in cheaper equivalents. If we look at the decision process and who is deciding about the finally bought medication, we may indicate three persons. Pharmacist, together with physician and patient, are the ones who decide which drug – brand name or generic – will be used by patient. When dispensing a medication pharmacists decide which drug to sell to

the client, thus their opinion on generics and decision which they make highly matters. Knowing the drivers of this decision would enable promotion of generic drugs and more cost-effective therapy to the patient. Moreover it would help in building decision models for these professionals. In order to do that factors affecting pharmacists decisions should be identified. One of them may be pharmacist's age.

Aim

The aim of this study was to answer the question whether pharmacist age (and indirectly pharmacist experience) affect the moment in which he informs patient about generic drug and thus does it affect indirectly the choice of generic or brand name drug.

Material and methods

Especially prepared questionnaire was distributed in a paper copies among pharmacists working in lodzkie province pharmacies. Surveys were personally given to pharmacists from randomly chosen pharmacies in Lodz (81,8%) and other lodzkie province cities (18,2%). The questions presented in the pharmacy were: "If patient wants to buy brand name drug, do you inform him/her about the choice of buying cheaper equivalents of these drugs?" with possible answers: 'yes, I inform before patients ask about them', 'yes, I inform when patient asks', 'I do not inform'. These questions were a part of bigger survey including a total number of 38 enquiries. Additionaly demographic data was collected: age, gender and other. Questionnaire filling was voluntary and anonymous. The results underwent statistical analysis.

Results

One hundred and forty eight pharmacists answered the questions including 125 females (84,5%) and 20 males (13,5%), 3 persons did not determine their gender. Participants' age was 23–59 years (average 35,8; median 35), most of them worked in private pharmacies (132; 89,1%), the rest – in public pharmacies (12 people; 10,9%). Pharmacists worked in their occupation for 1 to 35 years, average 11 years. Results are presented in **Table 1**.

In the group of participants aged more than 35 years most of pharmacists (44 persons; 64%) inform about the choice of drug exchange before patient asks about it. In contrary most of pharmacists younger than or equal 35 years inform patients after they ask about this possibility (47 participants; 60%).

Correlation analysis confirmed statistical relevance between information given by pharmacists about the choice of exchange of brand name drug to generic drug and pharmacist age ($p < 0.005$). Pharmacists older than 35 years are more eager to inform patients about the possible exchange of brand name drug to generic drug, before patients ask about it themselves.

Discussion

According to World Health Organisation increase of generic drugs usage may be one of the ways to reduce healthcare costs around the world [2]. Although Polish generic drugs market is one of the biggest in European Union, there is still place for their promotion [9]. It is so, because many physicians and pharmacists present negative opinions about generic drugs [10], although the evidence for it is missing [11]. Questions asked in our study were a part of larger questionnaire designed to check the opinions of pharmacists on generic medications. The aim of described in this paper part of our study was to indirectly find out whether the older is the pharmacist, the more his opinion changes towards generic drugs utilization. Opinions of pharmacists regarding generic drugs were presented in previously published papers [12,13]. It was presented that most of pharmacists knew their duty to inform patients about possible exchange of prescribed drugs – this process of change is called 'generic substitution' [14]. Thus, according to this study the older pharmacist is, the

Table 1. Influence of pharmacist age on the moment of giving information to patient about the choice of changing the drug from brand name to generic

The information given by pharmacist about the choice of changing the drug	Age				Total	
	Less or equal 35		More than 35			
	Number of participants	Fraction	Number of participants	Fraction	Number of participants	Fraction
Informs before patient asks	32	0,40	44	0,64	76	0,51
Informs after patient asked	47	0,60	25	0,36	72	0,49
Total	79	1,00	69	1,00	148	1,00
Statistical analysis	Test Chi^2_{Person} = 8,00 **p < 0.005**; Test Chi^2_{NW} = 8,06 **p < 0.005**					

more eager to use this process in his daily routine. Polish pharmacist is obliged to propose drug exchange to cheaper (generic) drug to every patient according to Polish regulations [15]. However this refers only to reimbursed medications [15].

Results of our study are consistent with recent study by Drozdowska A. and Hermanowski T [16]. In that study on representative sample of Polish pharmacies authors found that less experienced pharmacists were less likely to inform consumers about the availability of cheaper generic substitutes. Our study also confirms that pharmacist experience plays a role in the way patients are informed by pharmacists. However our study was focused on situation when pharmacist gives the information to the patient (before or after patient asks about it) and not on general frequency of asking the patient. Our results show that the interaction with patient also matters in conveying the information about generic drugs and confirms that less experienced pharmacists may present less information about generics to the patient.

There are many survey-based studies in literature devoted to generic drugs and their perception by pharmacists. Quintal et al. [17] were studying opinions of patients and pharmacists. Four hundered patients and 95 pharmacists took part in survey conducted in Coimbra in Portugal. Portugese pharmacists very often (91.6%) advised their patients generic medicines. Most of them (83.2%) claimed that knowledge of patients about generic medications is not sufficient. In recent US study of 553 licensed pharmacists authors found that pharmacists for their self-treatment prefer generic OTC medications to brand OTC medications (62 to 5% respectively) and they do it regardless of health symptoms [18]. In an Iranian study of 1205 pharmacists, 73.6% of them claimed that they substitute generic medicine once it is available [19], thus the preference of generic medications was also confirmed. Majority (92.9%) of eighty four Nigerian pharmacists were supporting generic substitution and most of them (68.2%) preferred generic medicines to brand ones [20]. Chong et al. presented perceptions of future generic substitution policy of Malaysian pharmacists [21]. Majority of respondents (93.6%) agreed that this should be a right of pharmacists. Nonetheless these studies did not find a correlation similar to our study to support the thesis that pharmacists age affect the information given to the patient about generic drugs, as they were not aimed at such association.

Our study presents that correlation between pharmacists' age and the moment when they inform patients about possibility of changing the drug are probable. The older pharmacist is, the more likely that he will inform his client before being asked for such information. The reason for that remains unknown. It is possible that the older is pharmacist, the more knowledge has about regulations including obligation to inform patients about drug change [15]. Perhaps the will to inform patients by more experienced pharmacists is driven by their own knowledge about possibility of such exchange or perhaps they want patients to be more satisfied with their visit in pharmacy. These are hypotheses which need further research. As far as we are concerned the correlation described in this study was found for the first time, and at the moment there is no similar data in available literature. This is than a start for extended studies on influence of age and pharmacist experience on their decisions made in pharmacy.

A limitation of this study is not representative study population. Although only 148 pharmacists from lodzkie province filled in the questionnaire, statistical correlation was strong. The probability value (p-value) below 0.005 suggests that association between pharmacists age and information given to the patient is very strong and should be confirmed also in bigger representative populations.

Our findings suggest that there is a strong correlation between the age of pharmacist (and due to that his experience) and the way to provide information for the patient about generic medications. There are two conclusions that can be drawn from these results. First one: the information given by young pharmacists about generic medications may be less effective than older ones. Second: in order to improve information given to patients in pharmacies about generic medicines, pharmacists 35 years old or younger should be reminded about this possibility in the first place. Although they probably now about generic substitution for some reason do not inform patients. By improving this procedure, an increase in generic medications utilization may be expected.

Perspectives

Results of this study suggest that the younger is the pharmacist, the lower probability that patients will be informed about their choice of switching to cheaper equivalent of brand name drug before patient asks about it. Because generic drugs are cheaper equivalents of brand-name drugs patients should have the option to exchange prescribed brand name drugs. It

will not be possible if they are not informed about such possibility, thus a campaign to inform younger pharmacists about their obligation to advise patients should be implemented. Prospective studies on younger pharmacists should be conducted in order to find what action improves message conveyed by pharmacists..

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REVIEW PAPER

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The legal basis for the functioning of teaching hospitals in Poland: selected issues

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ABSTRACT

The teaching hospitals occupy a unique position in the health care system. The specific nature of teaching hospitals calls for a different legal regime from that governing other hospitals. Their activity includes not only the provision of health care, but also teaching, under- and postgraduate training, and conducting research and clinical trials. Teaching hospitals operate as autonomous public health care units endowed with legal personality, founded by institutions of higher education. This fact is not reflected in the provisions of generally applicable law, which lack regulations relating to the particular nature of the activity carried out by this type of health care entity.

Keywords: teaching hospitals, health care system, institution of higher education, right to health.

Preliminary remarks

Teaching hospitals occupy a unique position in the health care system. Due to their activity, which includes not only the provision of health care, but also teaching, under- and postgraduate training, and conducting research and clinical trials, they play a special role vis-a-vis general hospitals. This role, however, is not reflected in legal reality. Enacting a new piece of legislation on teaching hospitals with the exclusive aim of addressing the functioning of these facilities in the health care system has been at the centre of debate for many years. The question of teaching hospitals' functioning concerns, in particular, the funding of their additional tasks, which are distinct from the tasks performed by other health care entities. Teaching hospitals—just like other health care entities—participate in tenders organised by the National Health Fund on the same terms as other facilities, despite providing highly specialised services, in addition to carrying out the aforementioned research and clinical trials, and training medical staff.

Teaching hospitals operate as autonomous public health care units (*samodzielne publiczne zakłady opieki zdrowotnej*) endowed with legal personality, founded by institutions of higher education. Sometimes the autonomy these entities enjoy is merely illusory, because it is limited by the decisions made by the founder, i.e. an institution of higher education, which in reality determines the teaching hospital's structure. A very important aspect of the hospitals' operation is the existence of academic teachers within the structure of teaching hospitals, whose primary place of employment are institutions of higher education rather than teaching hospitals themselves. The purpose of this article is to present the legal basis for the functioning of teaching hospitals in the organisational structure of the health care system.

It should be emphasised that due to their multifunctionality, teaching hospitals fulfil a very important role in the health care system: they jointly perform the abovementioned therapeutic, research, and academic tasks. In addition, these hospitals train students and offer adequate scientific and diagnostic support. Furthermore, teaching hospitals are required to organise medical internships and expert consultations. They are

often the hospitals of last resort, treating complicated cases whose treatment frequently generates higher costs. For teaching and research purposes, these hospitals often use enhanced diagnosis for their patients. They are a key component in any health care system, because they affect the quality of education new graduates receive and, indirectly, shape the whole system of health care [1].

Currently, there are forty-two teaching hospitals functioning in Poland. These entities, alongside municipal-, district-, and province-level hospitals, medical institutes, hospitals established by the Minister of Health, the Minister of the Interior and Administration, or the Minister of National Defence, non-public local self-government owned hospitals, and other non-public hospitals, make up the health care system, which provides health care services in the hospital sector. Hospitals—as basic elements in the health care system—render a triad of services: provision of health care, supply of so-called benefits in kind (*świadczenia rzeczowe*), and supply of so-called hotel services (*świadczenia hotelarskie*) [2].

The legal basis for the functioning of teaching hospitals

The adoption of the Act of 15 April 2011 on *Therapeutic Activity* [3] brought about a significant shift in the functioning of health care entities. First of all, the statute replaced the Act of 20 August 1991 on *Heath Care Units*, which had been in operation for nearly 20 years, introducing a number of changes to the process of organising and financing health care services in Poland. One of the main goals of the new piece of legislation was to "organise and unify the forms of providing health care services." The drafters intended the new law to ensure the consistency and comprehensiveness of the health care system. In addition, the lawmakers abandoned the concept of a health care unit, which was previously considered the dominant form of carrying out the provision of health care services.

Currently, Article 1(1) of the Therapeutic Activity Act (TAA) sets forth the principles for conducting therapeutic activity. Therapeutic activity is defined as providing health care services. It may also include:

1. promoting health, or
2. performing educational and research tasks in connection with providing health care services and promoting health, including but not limited to implementing new technologies and methods of treatment.

Pursuant to Article 54(1) of the TAA, teaching hospitals acting as autonomous public health care units (APHCU) manage the property they hold. That said, the fixed assets of an APHCU may be disposed of, leased, rented out, let for holding in usufruct, and lent for use only in accordance with the conditions laid down by the APHCU's founding body (Art. 54(2) of the TAA). These conditions include, in particular, the requirement to obtain consent from the founder for disposing of, leasing, renting out, letting for holding in usufruct, and lending for use of fixed assets. First and foremost, it should be noted that teaching hospitals view the funds allocated for their operation, including, especially, for the execution of highly specialised procedures, as inadequate to actual needs. Furthermore, teaching hospitals witness a constant rise in prices for materials, attributed primarily to providing cost-intensive services (i.a.: drug therapy programmes, chemotherapy, organ transplantation, and selected invasive procedures, in which the biggest expenses are implants), which are rarely rendered by other hospitals, e.g. district-owned hospitals [4].

Institution of higher education for medical studies as a founder of a teaching hospital

It bears pointing out that teaching hospitals operate under two legal instruments of equal status, namely the Therapeutic Activity Act and the Law on Higher Education [5]. This duality causes many practical problems regarding, *inter alia*, the position and tasks of the founders, the particular nature of issues concerning the founders' property, with which teaching hospitals typically operate, as well as the matter of co-financing training activities through the teaching hospitals' funds.

It is important to mention that 1948 is considered the year institutions of higher education for medical studies established teaching hospitals. Pursuant to Article 3 of the Act on *Social Health Care Units and Planned Economy in Health Service* [6], the state set up and maintained specialised treatment units that serviced the area of at least one province, including, *inter alia*, teaching hospitals. Under Article 5 of the same statute, teaching hospitals were defined as hospitals whose wards, either all or most, were used for the purposes of training and research by higher education institutions. In addition, the law provided that in cities with state-run teaching hospitals, the Minister of Health and the Minister of Education had the authority to incorporate into

these hospitals, as wards, autonomous medical teaching and research facilities. At present, Poland lacks regulations comprehensively covering the functioning of teaching hospitals in the health care system. Although the need to adopt a separate statute on teaching hospitals has long been recognised, legislative work on the bill has not yet been completed.

In accordance with the provisions of Article 13(3) of the Law on Higher Education (LHE), an institution of higher education for medical studies or a basic organisational unit of an institution of higher education operating in the field of medical sciences may be involved, as part of its tasks, in providing medical care in the scope and forms set forth in the legislation on therapeutic activity. Pursuant to Article 18 of the LHE, a public institution of higher education is established, liquidated, and merged with another public institution of higher education by means of statutory law. Moreover, Article 106 of the LHE provides that the undertaking by institutions of higher education of teaching, academic, research, experimentation, artistic, sporting, rehabilitation, and diagnostic activity does not constitute economic activity for the purposes of the provisions of the Act of 2 July 2004 on the Freedom of Economic Activity [7]. Legal literature on the subject emphasises the need for implementing so-called control tools that allow for separating teaching hospitals' activity of rendering health care services from teaching and scientific research, which could boost the efficiency of teaching hospitals' financial management [8].

In compliance with Article 6(6) of the TAA, institutions of higher education may run health care entities in the form of capital companies: a limited liability company or a joint-stock company. Furthermore, Article 6(7) of the TAA stipulates that in a capital company conducting therapeutic activity related to the performance of teaching and research tasks in connection with the provision of health care services and the promotion of health, the face value of shares or stocks held jointly by institutions of higher education for medical studies may not exceed fifty-one percent of the company's share capital. Aside from the institutions of higher education for medical studies, shares or stocks in these companies may be held only by the State Treasury, local self-government units, and State Treasury companies of particular importance to the state economy. What is more, institutions of higher education may also continue carrying out therapeutic activity as autonomous public health care units founded by the institutions of higher education for medical studies or establish new autonomous public health care units by way of merging at least two already existing autonomous public health care units in the manner provided for in Article 66(1)(2) of the TAA. Pursuant to Article 201(1) of the TTA, they may not, however, establish new autonomous public health care units, with the exception of APHCUs formed upon a merger. In conclusion, operating a health care entity as a joint-stock company is the only legally permitted form of engaging in the provision of health care services available to institutions of higher education. The institutions themselves may not carry out therapeutic activity.

As a founding body of a teaching hospital, an institution of higher education may decide to liquidate it in accordance with the rules laid down in Article 60 of the TAA. The liquidation takes place by means of an ordinance, an instruction, or a resolution of the competent founding body. It also requires passing a resolution by the founder's faculty senate.

Teaching hospital personnel

Institutions of higher education for medical studies are public institutions of higher education supervised by the Minister of Health (Article 2(1)(27) of the LHE). Article 13 of the LHE enumerates the principal objectives of an institution of higher education, which include:

1. providing education that enables the students to acquire and advance their knowledge, as well as gain skills necessary in professional life;
2. fostering through education a spirit of responsibility for the Polish State, the consolidation of democratic principles and a respect for human rights;
3. conducting research and development activities, providing research services and transferring technology into the economy;
4. training and development of academic faculty;
5. popularising and disseminating advances in science, national culture, and technology, including by collecting and making available library and information resources;
6. providing postgraduate programmes, courses, and training in order to develop essential new skills to satisfy the labour market's demands through a system of life-long learning;
7. creating conditions for the physical development of students;
8. actively supporting local and regional communities;
9. creating conditions for disabled persons to fully participate in:
   - the processes of learning,
   - the research.

Article 87 of the LHE stipulates that hospitals serve as teaching and research facilities for institutions of higher education for medical studies (or other institutions of higher education providing teaching and conducting research in the field of medical sciences). The functioning of hospitals is governed by the regulation of the Therapeutic Activity Act. Pursuant to Article 92(1) of the TAA, academic teachers and individuals enrolled as doctoral students at institutions of higher education for medical studies are employed at the health care entities established or run by the institutions of higher education for medical studies, i.e. by teaching hospitals, and at the organisational units made available to the institution of higher education in compliance with Article 89(2) or (3) of the TAA. The wording of this provision precludes academic teachers in institutions of higher education for medical studies from pursuing self-employment, which would allow them to enter into civil-law contracts acting as entrepreneurs, i.e. operate under contracts concluded in the course of their individual medical practice (individual specialist medical practice) [9]. Employment referred to in Article 92 of the TAA stands for salaried employment, not self-employment [10].

The obligation of academic teachers employed in institutions of higher education for medical studies or other institutions of higher education operating in the field of medical sciences are set forth in Article 112 of the LHE. Academic teachers are engaged in the provision of health care by performing teaching and research tasks in connection with medical services delivered in organisational units dedicated to carrying out teaching and research activity, which were made available for such institutions of higher education in accordance with the provisions of the TAA. Furthermore, the law stipulates that health care services are delivered by academic teachers under separate contracts concluded with entities conducting therapeutic activity and providing the organisational units. In practice, what transpires from the application of this provision is that academic teachers remain in two employment relationships and perform work for two separate employers: an institution of higher education and a teaching hospital. Zdzisław Kubot argues that hiring an academic teacher employed by an institution of higher education for medical studies in a teaching hospital constitutes additional and secondary employment in relation to employment at the institution of higher education for medical studies, meeting the criteria for so-called elite employment. The elite of academic teachers of medicine perform specialised work for the benefit and under the direction of both employing entities, while the nature of their employment involves performing work in the conditions set down by those in management positions at the institutions of higher education for medical studies and at the teaching hospitals [11]. In its judgement of 14 May 2012 [12], the Supreme Court confirmed that with regard to training future physicians, the practice of the profession of an academic teacher combines both theoretical and practical aspects; hence, teachers have to both run theoretical courses and carry out practical research, and teaching has to include presenting the practical side of the theoretical issues taught.

In compliance with Article 107 of the LHE, employees of an institution of higher education include both academic and non-academic staff. The same legal instrument lists academic staff as:

- research and teaching staff,
- teaching staff,
- research staff,
- qualified librarians, and qualified archive and information system staff.

In accordance with Article 118 of the LHE, the employment relationship of academic staff is established on the basis of an appointment or an employment contract. Only academic staff who hold the academic title of *profesor* (professor) may be employed by appointment. Employment by appointment is on a full-time basis. Other staff members are employed pursuant to the provisions of the Labour Code.

Section II chapter IV of the TAA is devoted to issues of therapeutic activity of special character, namely involving the performance of educational and research tasks connected with providing health care services and promoting health. Article 89 of the TAA provides that teaching hospitals are obligated to:

1) carry out therapeutic activity consisting in the provision of health care services and the performance of educational and research tasks in connection with providing health care services and promoting health, including but not limited to implementing new technologies and methods of treatment;
2) perform tasks consisting in providing undergraduate and postgraduate training in medical professions in connection with providing healthcare services and promoting health;
3. make organisational units dedicated to providing undergraduate and postgraduate training in medical professions available to institutions of higher education for medical studies.

The effect of the aforementioned regulations is that a health care entity that has been established or is operated by an institution of higher education for medical studies is required to make available organisational units dedicated to providing under- and postgraduate education in medical professions to the institution of higher education for medical studies. Such an entity (a teaching hospital) is tasked with participating in the preparation of students for practicing the medical profession, as well as with educating them. For the purposes of identification, its name should contain the word *uniwersytecki* (teaching) [2].

Article 89 (4)(1) of the TAA stipulates that the provision of organisational units is subject to civil-law contracts concluded between institutions of higher education for medical studies and entities carrying out therapeutic activity. The law sets forth the essential elements of such contracts, providing in 89(5) of the TAA that, at minimum, they should include:

1. duration of the contract and terms for early termination;
2. funds due to the provider on account of executing the contract, manner of transferring the funds, and rules governing settlement;
3. list of movable and immovable property made available for purposes of executing the contract, manner of property provision, and terms and conditions for property use;
4. indication of number and professional qualifications of academic teachers designated to perform tasks referred to in section 1 at the provider;
5. circumstances constituting grounds for change in contractual terms;
6. rules on civil law liability for damage caused by students, participants in doctoral studies, or academic teachers and rules of procedure on breaches of terms laid down by the provider;
7. rules for carrying out supervision by the institution of higher education for medical studies over performance of teaching and research tasks in the organisational unit provided;
8. rules for resolving disputes arising out of executing the contract.

It should be noted that according to the provisions of Article 89(6)(1) of the TAA, the designations: *klinika*, *kliniczny*, and *uniwersytecki* may be used solely by the providers and organisational units made avilable under contracts for providing organisational units to institutions of higher education for medical studies. From a practical point of view, these contracts to a great extent determine the mutual functioning of the two entities: teaching hospitals and institutions of higher education for medical studies.

Conclusion

To sum up the foregoing reflections, teaching hospitals play a crucial role in the health care system. The specific nature of teaching hospitals calls for a different legal regime from that governing other hospitals. Unfortunately, this fact is not reflected in the provisions of generally applicable law, which lack regulations relating to the particular nature of the activity carried out by this type of health care entity. Specifically, it is worth noting that the National Health Fund has failed to take into account teaching hospitals' special role as hospitals of the highest referral level. One possible solution is to introduce—via an amendment to the Act on Health Care Services Financed from Public Funds—a network of hospitals comprised of hospitals that meet statutorily defined criteria. Teaching hospitals would be included in the network as part of national hospitals—functioning as highly specialised hospitals assigned with treating patients suffering from rare diseases and with complicated health conditions. The special role teaching hospitals occupy in the health care system has long been emphasised; thus, it is necessary to regulate their position through a detailed specification of the tasks performed by institutions of higher education for medical studies supervising research and teaching activity. Attention should also be directed to the profound significance these entities have in the process of educating and training physicians, dentists, and other medical personnel. Leaving the supervision of the operations of teaching hospitals in the hands of institutions of higher education for medical studies guarantees better fulfilment of teaching tasks.

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REVIEW PAPER

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Revitalization of facial skin based on preparations of patient own blood

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ABSTRACT

Aging is a natural, unavoidable physiological process of every human being. Aesthetic medicine, a rapidly growing on field of medicine, slows down this process. Autonomic mezotherapy is a specific type of needle mezotherapy using autologous platelets suspended in a small amount of plasma. Possibilities of use of blood preparations were discussed using 9 items of national literature and 5 foreign reports. The role of the plaques is not only a hemostatic function but also a function of cellular repair by the content of biologically active substances. The biostimulating effect consists in the activation of different cell types by growth factors. The technological change of the gel formulation creates new possibilities for the extension of aesthetic medicine.

Keywords: plate rich plasma, PRP, GPS, PROF, CGF Harmony, facial revitalization.

Introduction

One of the stages of the life is aging of the whole organism. Aging is a natural, unavoidable physiological process of every human being. It would be most beneficial if aging was the slowest possible process, in the best possible health and without any ailments. Aesthetic medicine, a rapidly growing field of medicine, supports this process by slowing it down. The philosophy of Aesthetic medicine is firstly the prevention and treatment of coexisting diseases, and in the rest is the correction, that is, the correction of minor beauty defects, but it disseminates. Also a healthy lifestyle and health prevention in people undergoing specific treatments. Aesthetic medicine offers in a minimally invasive way and accessible to everyone, effectively getting rid of various minor defects, which improves the quality of life. It should be emphasized that the most often corrected skin is the face. In addition, ensuring the well-being through the use of specific aesthetic medicine treatments can meet the need for self-care [1]. The aim of the work is to show the possibility of improving the condition of the facial skin based on the preparations of their own blood. Material and method

Material consisted of 9 articles from the Polish literature and PubMed 2 literature reviews and 3 articles on clinical case studies and their assessment in the aspect of therapeutic use, improvement of facial skin condition, blood plasma obtained from aesthetic medicine patients.

Results

Analysis of 9 items of Polish literature has shown that platelet-rich plasma (PRP) is one of the safer, less invasive facial and neck conditioning treatments.

Plate-rich plasma therapy is very widely used in medicine. Platelet rich plasma contains 1 mm³ of autologous patient platelets, 1 million platelets and proteins: fibrin, fibronectin and vitronectin. After activation, thrombocytes release numerous platelet-derived growth factors (PDGFaa, PDGFbb and PDGFab),

transforming growth factor beta (TGFb1 and TGFb2), epidermal growth factor (EGF), vascular endothelial growth factor (VEGF), and fibroblast growth factor [2].

In aesthetic medicine, PRP treatments are used for revitalization treatment of various types of baldness and prevention of hair loss, treatment of venous ulcers and the removal of many other minor imperfections, affecting healing of wounds by increasing the number of cells and angiogenesis. PRP has proven properties of beneficial biostimulation of skin cells, including fibroblasts, to produce new elliptical collagen fibers and to create a network of new blood vessels (angiogenesis). It affects the healing by increasing the number of cells (mitogenesis), and thus supports regenerative processes. Platelet-rich treatments are used as monotherapy or in combination with other treatments, such as laser therapy, for example, in the removal of scars, stretch marks [3].

Plasma preparation involves taking the right amount of blood from the patient into an anticoagulant syringe, for example: sodium citrate. Then the blood is centrifuged using a special centrifuge, and to boost the degranulation of the growth factor activator – calcium chloride – $CaCl_2$ or thrombin. This preparation is administered by intradermal injection or by mesotherapy using a roll. PRP is also used regeneratively after the treatment of aesthetic medicine in the form of a mask [2]. The effect of using a series of treatments using platelet rich plasma is to improve flexibility, texture, skin tension, smooth wrinkles, and rejuvenate skin tone. Improving the condition of the skin using mesotherapy with autologous plasma is one of the basic suggestions for face aesthetic medicine. This treatment can also be used to improve the eye area, increasing the firmness of the eyelid and removing the dark circles under the eyes after a single application – **Figure 1**.

Surowiak et al. [6] found that PRP treatments are a reliable method of skin revitalization. Augustyniak and co-authors [4] suggest that the use of PRP plasma after the first treatment improves skin firmness and coloration, stimulates collagen synthesis and fibroblast divisions. This noticeable improvement in the skin, which becomes tense, should continue as it gives better results according to Szpringer's [5] thesis that the stimulation of dermal fibroblast proliferation by PRP is dose-dependent. In addition, the author describes the use of rich platelets next generation GPS in skin regeneration. Surowiak [6] emphasizes that the use of platelet-rich plasma is a well-documented method. The author compared the expression of procollagen type 1 and intensified proliferation in fibroblasts incubated with PRP using the MyCells-PRP kit. Studies were conducted in cell culture conditions where stimulation of fibroblast divisions was stimulated and collagen synthesis stimulated.

Many authors believe that platelet-rich plasma belongs to modern regenerative procedures that rejuvenate the skin. This so-called. Anti-aging therapy serves to rebuild the tissues by utilizing the body's own capabilities. High-protein plasma is defined as a growth factor concentrate because it contains high levels of growth cytokines that stimulate certain stages of tissue regeneration [7]. PRP also has plasma proteins in addition to platelets. Platelet degranulation starts at the injection site, releases growth factors and causes cell proliferation, capillary formation and the formation of new collagen fibers that gradually improve the firmness, color, and elasticity of the skin. Plate-rich preparation also has the ability to maintain an adequate level of hydration in the skin [8]. PRP as aesthetic medicine is injected in points, exactly in the skin of the neck, neckline or face, and even hands, but rich plasma has a much broader application in various

Figure 1. Documentation of the patient's face prior to PRP, during exercise, one month after a single treatment in the lower eyelids. Documentation from own collections of Facial Aesthetics Laboratory Chair of Orthopedics and Orthodontics of Poznan University of Medical Sciences

fields of medicine especially in orthopedics such as in damaged Achilles tendon, During the treatment of diabetic foot ulcer, after facial surgeries such as face-lifting, as well as transplants of adipose tissue, exzema, hyperpigmentation, skin atrophy, hair loss and consequent baldness. [7, 8]. The authors emphasize that platelet-rich plasma is a tissue of its own and thus exhibits high levels of safety and reduces the risk of side effects. PRP should be taken and injected under sterile conditions. Due to the fact that the preparation is autologous, there is no allergic and immune reaction. All treatment with PRP is painless and patients can immediately return to their daily activities after the injection. The treatment of rich plasma can be combined not only with laser therapy, but also with carboxytherapy or lipolifting, and even mesotherapy with rich plaque on the scalp.

Autonomic mesotherapy is a specific type of needle mesotherapy using autologous platelets suspended in a small amount of plasma. Tile role is not only a hemostatic function, as Szpringer and Szpringer [8] state, but thanks to the content of biologically active substances, cell repair function. The biostimulation effect of PRP is the activation of different cell types by GFs growth factors. Activation, or granulation degeneration with growth factors, also occurs automatically by tissue contact (possible without activator). Due to the high content of growth factors and stem cells, the plasma revitalizes and regenerates the skin, stimulates fibroblasts to produce new collagen, comes to the so-called autologous cell renewal (regeneration of skin cells, through the action of own growth factors and stem cells), thus firming the skin and smoothing wrinkles. Growth factors included in PRP are shown in **Table 1**.

The authors further state that there are many plasma systems available on the market. They differ in the way of recovery of platelets and growth factors from blood, the presence of leukocyte fractions and the medical apparatus included in the kit. PRP is applied to the skin of the face area and especially to the eye by mesotherapy. Several series are recommended at intervals of 1 month followed by maintenance 1 time for 3 months. Post-operative complications include swelling, hematoma, and redness that resolve spontaneously within a few days. Contraindications for the treatment are: blood disorders, HIV, AIDS, cancer, pregnancy, lactation, autoimmune diseases and local inflammatory processes and skin infections. A slightly different preparation is platelet rich fibrin (platelet rich fibrin) is also obtained from the patient's blood, through a longer spinning treatment. Contains blood platelets, growth factors, mesenchymal stem cells, all components that promote healing and neovascularization. The advantage of PRF is the absence of infectious complications due to the presence of immune enhancing factors. Indications and contraindications are similar to those of PRP [10]. The range of possibilities to use your own blood in regeneration is steadily increasing, which confirms that it is still one of the most effective facial revitalizing remedies available.

The analysis of two English-language literature reviews [12, 13] did not provide a clear answer for the clinical use of PRP. In both articles, the authors underline the need for further studies on the efficacy of plate-rich plasma with the additional suggestion that it is preferable to give plasma to other medicaments in one patient and the patient's face should be divided into right and left sides as comparative to obtain a more objective outcome after the procedure without Share of individual variability.

Just as the Aesthetic medicine is growing rapidly in the world, its branches are growing rapidly. This dynamic development is also related to platelet-rich plasma therapy, as evidenced by three articles informing about the new formula of this preparation. New in PRP treatments is low-platelet protein agglutination and agitation with growth factors and CD34 + CGF – Concentrated Growth Factor – isolated from the patient's blood stem cells and concentrated CGF growth factors are injected into the skin with mesotherapy. CGF growth factors are proteins that regulate complex healing processes and increase tissue regeneration without side effects. The treatment pro-

Table 1. Growth factors included in PRP [11]

Name of growth factor	Effect of stimulation
EGF epidermal growth factor	Stimulates the proliferation and differentiation of epidermal cells, stimulates angiogenesis
FGF fibroblast growth factor	Stimulates endothelial cell proliferation, fibroblasts, stimulates angiogenesis, stimulates collagen and HA synthesis
IGF insulin growth factor	Stimulates the proliferation and differentiation of fibroblasts
PDGF plateled derivet growth factor	Stimulates cell mitosis, epitelialization, angiogenesis, ECM synthesis (extracellular matrix)
TGF-β1 transforming growth factor	Stimulates DNA synthesis, collagen and proliferation of various cell types
VEGF vascular endothelial growth factor	Stimulates angiogenesis

vides a natural, safe, firm and more radically healthy complexion, accelerating the regenerative processes [16]. CGF is a perfect supplement to other Aesthetic medicine treatments such as laser treatments, chemical peels, carboxytherapy, fillings. Additionally, CGF improves fat and hair survival [14].

The treatment involves the administration of own CD34 + stem cells and Activated Plasma Albumin Gel delivered from blood proteins under the skin. Thanks to this technology, the physician performing the procedure can adjust the density of the gel to the needs of the patient. Growth factors are released longer in a controlled manner, which results in stronger stimulation and regenerative effects. CGF Harmony is perfect for revitalizing your face, neck, back and hands. To perform the CGF Harmony and the entire kit consist of the Medifuge 200 (Centrifuge). Medifage is additionally equipped with UVC decontamination mode. The second device is the Activated Plasma Albumin Gel (APAG), a low-plate plasma heating device for obtaining a biologically compatible polymeric material used as a filler in Aesthetic Medicine [15]. Research results on CGF and CD34 + have been developed, published and published in many fields of medicine such as Biology, Biochemistry, Orthopedics, Maxillofacial Surgery, Dentistry, General Surgery, Gynecology, Sports Medicine and Aesthetic Medicine.

Summary

PRP can be applied to the skin of the whole body being a biocompatible product with no risk of allergy or intolerance, which is not irrelevant in facial skin treatments. Plasma (PRP and PRF) are alternative treatments for patients who may not be able to apply other aesthetic facial treatments such as hyaluronic acid to achieve satisfactory results after the first administration and are safe for prolonged use. Research on the effectiveness of facial rejuvenation therapy after administration of the patient's own blood specimen should be continued on the basis of a unified protocol.

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Conflict of interest statement
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REVIEW PAPER

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Single nucleotide polymorphisms in desaturases genes – effect on docosahexaenoic acid levels in maternal and fetal tissues and early development of the child

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ABSTRACT

Polyunsaturated fatty acids (PUFAs) beneficially affect an optimal fetal growth and development right after birth. This effect is particularly significant for the growth and maturation of brain. Therefore, an appropriate maternal regimens for PUFAs supplementation, during pregnancy and lactation, may influence birth outcome and infant health. Recently, it has been shown that genetic profile is an another factor determining long-chain polyunsaturated fatty acids (LC-PUFA) composition in human tissues. Single Nucleotide Polymorphisms (SNPs) in the fatty desaturase 1 and 2 (FADS1 and FADS2) modify endogenous synthesis of PUFAs indicating that PUFAs blood concentration may depend on genetic background. What is more, a number of studies indicate that maternal FADS gene variants by their influence on LC-PUFAs synthesis are associated with child's health right after birth as well as within first years of life. Determining individual dietary recommendations for clinical practice can be beneficial for both mother and the child.

Keywords: pregnancy, supplementation, infant, FADS1, FADS2.

Introduction

Polyunsaturated fatty acids (PUFAs) play an important role including maintaining the fluidity of cell membranes and acting as precursors of eicosanoids, for example prostaglandins or thromboxanes, which are involved in inflammatory process. In addition, it has been shown that omega-3 fatty acids, among other properties like cholesterol-lowering and protective against the development of diabetes, cardiovascular pathologies, exhibits the essential role in proper development of the brain [1]. In neonates, particularly DHA is essential for the proper development of retina and nervous system, which is reflected by the accumulation of DHA in a fetus in the brain and the retina, especially during the 3 trimester of pregnancy and up to 2 years of age [2].

There are two main groups of PUFAs: omega-6 fatty acids, including linoleic acid (LA) (C18: 2, n-6), γ-linolenic acid (GLA) (C18: 3, n-6), arachidonic acid (ARA) (C20: 4, n-6). And omega-3 fatty acids, among which we distinguish α-linolenic acid (ALA) (C18: 3, n-3), eicosapentaenoic acid (EPA) (C20: 5, n-3), docosahexaenoic acid (DHA) (C22: 6, n-3). Linoleic acid and α-linolenic acid are essential unsaturated fatty acids because the human body does not have the proper enzymes to synthesize them. On the other hand, if these two acids are delivered in the right amount, it is possible to convert them into other PUFAs (**Figure 1**). From α-linolenic acid, eicosapentaenoic acid and

docosahexaenoic acid are produced, whereas arachidonic acid and γ-linolenic acid are produced from linoleic acid.

Human ability to synthesize the LC-PUFAs depends on FADS1 and FADS2 genes, deposited on chromosome 11 (11q12-Q13.1) respectively encoding the Δ^5-desaturase (D5D) and the Δ^6-desaturase (D6D) [3]. Although both genes are expressed in most tissues, the highest level thereof is observed in the liver [4].

Both omega-3 fatty acids and omega-6 are metabolized by the same pathway of desaturation and elongation, resulting in competition between the two families, particularly at the Δ^6-desaturase, which converts linoleic and linolenic acid respectively to 18: 4n-3 and 18: 3n-6 [3]. Interestingly, women have a greater ability than men to synthesize DHA from their precursors, which can be explained by the effect of estrogen on increasing the activity of Δ^6-desaturase [5]. The purpose of this article is to review the study of single nucleotide polymorphisms in desaturase genes, their effects on DHA levels in blood and other tissues of pregnant women, in relation to the development and health of the newborn and child.

Single nucleotide polymorphisms in the FADS gene cluster

In 2006 a first genetic study demonstrating the relationship between plasma phospholipid composition and single nucleotide polymorphism in FADS genes has emerged. It appeared, that the minor allele carriers have a reduced ability to convert omega-3 and omega-6 fatty acids into their long chain products [6]. Studies of mothers and neonates under physiological conditions without supplementation of DHA showed a strong inverse relationship between the minor alleles for two desaturase SNPs and concentration of DHA and eicosapentaenoic acid (EPA) [2, 7]. Variants rs1535 and rs174575 FADS2 impact on a lower concentration of polyunsaturated fatty acids of both the maternal blood and umbilical cord blood [7]. It has also been found that SNPs in the FADS gene have a stronger effect on omega-6 fatty acids, resulting in an increase in linoleic acid levels and decrease in arachidonic acid in minor allele carriers. FADS gene polymorphism can explain 29% of the variance of arachidonic acid [2].

Table 1. SNPs in desaturases genes (following [4])

	Position	Alleles (1/2)
FADS1		
rs174546	3'UTR	C/T
FADS2		
rs968567	5'UTR	C/T
rs174570	Intron 1	C/T
rs174572	Intron 1	C/T
rs2072114	Intron 1	C/T
rs2072114	Intron 1	A/G
rs174587	Intron 4	C/T
rs174589	Intron 5	C/G
rs174602	Intron 5	T/C
rs498793	Intron 6	T/C
rs526126	Intron 6	C/G
rs174611	Intron 7	T/C
rs174616	Intron 7	G/A

FADS1 and FADS2 genes, encoding the Δ^5-desaturase (D5D) and the Δ^6-desaturase (D6D), which play a major role in the desaturation and the elongation pathway n-6 and n-3 LC-PUFA, have been mapped in 2000 on chromosome 11q12- 13.1. These two genes are located close together and with gene third desaturase FADS3 form together FADS gene cluster [8]. Over the past few years, scientists increasingly began to pay attention to the relationship between the occurrence of different allelic variants of these genes, the degree of activity of this particular desaturases and the same content in the tissues of the substrates and products of their activities [4, 8]. At least a dozen polymorphisms have been identified that may have a different effect. They can be located both in the noncoding regions, ie. 5 'UTR, 3' UTR, introns or gene promoter and in coding regions [4]. **Table 1** shows 13 discovered and investigated alleles.

All of them except rs498793 and rs526126 are significantly associated with higher levels of linoleic acid C18: 2, n-6 and five of them (rs174546, rs968567, rs174572, rs174589, and rs174611) are associated with a higher C20:3, n-6 acid level. Minor alleles of all SNPs except one – rs498793 cause reduction of the level of arachidonic acid. Also, three SNPs (rs174546, rs174572, rs174589) are associated with significantly lower levels of eicosapentaenoic acid (C20: 5 n-3). All haplotypes containing rs174546 minor allele showed a lower activity of Δ^5-desaturase, and rs968567 minor allele was associated with a higher activity of the Δ^6-desaturase [4]. However, another study showed that the polymorphisms may also favorably influence the activity of the desaturases and thereby increase the level of LC-PUFAs. Alleles rs3834458 and rs1535 are responsible for higher levels of DHA and EPA. This is due to increased activity of the enzyme in the last stage of the synthesis of long chain fatty acid products [3].

In order to show the importance of the effect of single nucleotide polymorphism of the amount of DHA there was also conducted a study comparing the con-

Table 2. Fatty acids content in mother's milk depending on SNPs in desaturases genes (following [9])

Fatty acid	g/ 100 g fatty AIDS		
rs174575	**C/C, n = 25**	**C/G, n = 23**	**G/G, n = 6**
16:1, n-7	2.18 ± 0.54	2.54 ± 0.56	2.58 ± 0.72
18:1, n-9	34.00 ± 4.21	35.07 ± 3.19	35.56 ± 1.77
18:2, n-6	13.7 ± 2.89	13.0 ± 2.60	14.8 ± 2.60
18:3, n-6	0.10 ± 0.05	0.11 ± 0.04	0.10 ± 0.06
20:4, n-6	0.43 ± 0.09	0.42 ± 0.08	0.33 ± 0.04
20:5, n-3	0.10 ± 0.08	0.07 ± 0.03	0.04 ± 0.02
22:6, n-3	0.32 ± 0.25	0.24 ± 0.11	0.16 ± 0.07
rs174553	**A/A , n = 13**	**A/G, n = 24**	**G/G, n = 17**
16:1, n-7	2.16 ± 0.55	2.36 ± 0.54	2.56 ± 0.65
18:1, n-9	33.5 ± 4.21	34.3 ± 3.81	36.0 ± 2.29
18:2, n-6	13.0 ± 2.78	13.5 ± 3.22	14.0 ± 1.96
18:3, n-6	0.11 ± 0.05	0.11 ± 0.04	0.09 ± 0.05
20:4, n-6	0.46 ± 0.08	0.44 ± 0.08	0.36 ± 0.07
20:5, n-3	0.10 ± 0.05	0.09 ± 0.07	0.05 ± 0.02
22:6, n-3	0.26 ± 0.14	0.31 ± 0.25	0.21 ± 0.09

centration of fatty acids and their long-chain products, including DHA in the mother's milk and their genotype. In women with rs174553, rs174583, rs99780, rs174575 minor alleles level of DHA as well as EPA or ARA was reduced compared with women without polymorphism [9], as seen in **Table 2**.

The effects of single nucleotide polymorphism in the FADS gene cluster are very important examples of interactions between genotypes, nutrition and their effects on the phenotype. Research indicates that FADS genotype is associated with the occurrence of various diseases, especially in children, which may be due to different amounts of polyunsaturated fatty acids, transported from the mother, whether it be through the placenta during pregnancy or after birth with milk [9].

DHA intake during pregnancy and lactation – SNPs effect on DHA levels

The dietary sources of omega-3 fatty acids in the diet include fish, walnuts, linseed oil, rapeseed, almonds and algae, while the main source of omega-6 are vegetable oils, such as soybean, sunflower, grape seed, corn, peanut, sesame oil [10]. Omega-3 and omega-6 fatty acids source may also be eggs, but their ratio and concentration depend on the way the hens are fed [11]. As already mentioned, consumed omega-3 and omega-6 acids such as linoleic acid and α-linolenic acid must first be converted to their long chain products in the pathway shown in **Figure 1**. It is therefore preferable to consume direct sources of docosahexaenoic acid such as fish- mackerel, cod, salmon, herring, sole, but also algae and oil from them [10, 12].

During pregnancy and lactation, EPA, DHA, ARA and their precursors are transported from mother to child, respectively, by placenta or with mother's milk, to provide an optimal growth, the development of the nervous and immune system or visual acuity [9]. Numerous studies indicate that during pregnancy and lactation, DHA intake should be at least 200 mg per day. This demand can be covered by the consumption of 1–2 servings of fish per week or by taking supplements containing DHA in the case of low consumption of dietary sources of fatty acid [5, 13]. Recently, the role of endogenous synthesis of long chain products of omega-3 and omega-6 acids by the enzymes called desaturases has also been noted.

In a study of pregnant women who consume fish, it was demonstrated that the level of DHA (approx. 7% erythrocyte FA) and AA was significantly lower in the third trimester of pregnancy until the birth of a child. Furthermore, this correlated with an increase in the concentration of these acids in the umbilical cord, which indicates increased transport to the fetus. On the other hand, mothers who did not eat fish or very small amounts, have DHA level in erythrocytes signifi-

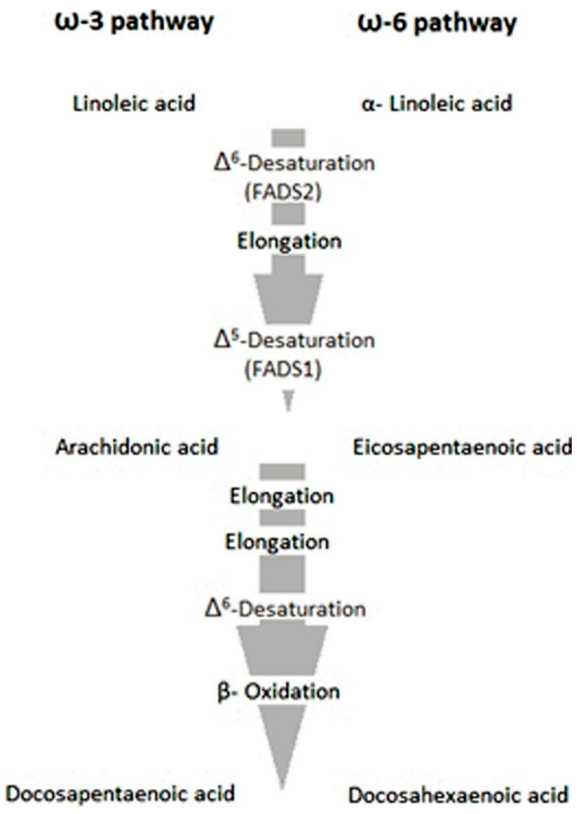

Figure 1. Omega-3 and omega-6 desaturation/elongation pathway (following [6])

cantly lower (about 2% FA) and did not change during pregnancy. However, to provide the necessary DHA for the baby, a compensatory increase conversion of ALA to DHA [15]. It was also pointed out that low fish consumption during pregnancy has been associated with delayed cognitive development of the child unlike the development of children whose mothers ate large amounts of fish, ran efficiently and effectively [5, 16]. Hibbeln et. al. have asked nearly 12,000 pregnant women to complete a survey on the amount of seafood consumed. Then, among children aged 6 months and 8 years, factors such as intelligence, communication skills and motor skills were compared. Results showed that the lower consumption of fish during pregnancy, the worse results obtained by the child [16].

Moreover it has been shown that a high consumption of fish and thus higher DHA supply may decline the genetic effect of SNPs on endogenous synthesis of this fatty acid. It was confirmed by a study on a group of pregnant women, living in Seychelles and consuming large amounts of fish. Yeates et.al. studied the effect of the FADS genotype on DHA and other blood fatty acids. This study showed that the rs3834458 genotype was associated with a 20% lower blood arachidonic acid level and a 42% higher LA: AA ratio, but no change in EPA or DHA levels was observed, which may be due to high intake of these fatty acids [17].

Some studies analyzed the relationship between consumption of fish rich in DHA by the mother and birth weight of the child. Most of them showed a positive correlation, which means a positive effect of LC-PUFA on the duration of pregnancy and fetal weight gain. Consumption of the DHA in excess of 200 mg per day, compared to consuming barely 34 mg results in an increase in birth weights, on average about 28g. In addition, also maternal genotype and SNPs occurring in desaturase genes are related to birth weight. Mothers who are homozygous for the minor allele (eg. FADS1 rs174556) gave birth lighter children, and the child's weight was not associated with a child's genotype [18]. Also mothers which are homozygous for rs174602 in FADS2 gene have children with lower weight, which is associated with lower levels of DHA because of the lower activity of Δ^5-desaturase, controlling important step in the conversion of n-3 EPA to DHA [19]. In one study also noted the interaction between the consumption of AA and DHA and genotype – maternal intake of DHA increased the weight of the infant, whereas consumption of AA decreased the weight, but only in women who are homozygous for the minor allele [18].

Consumption of a large amount of DHA, or taking supplements can result in prevention of preterm birth, allowing a longer intrauterine fetal growth and higher birth weight [18]. This was also noted in a study where women were supplemented with 800 or 600 mg DHA/day or placebo [20]. The pre-term pregnancy rate in women taking DHA was 1.3% compared to 2.22% in the placebo group. Thus, consumption of foods rich in DHA or supplementation of this fatty acid can reduce significantly the risk of too low birthweight and preterm birth [18–20].

The level of LC-PUFA in the human milk vary according to the SNPs in the desaturase genes. Homozygous for the minor allele rs174553, rs174583 or rs99780 have much lower levels in milk ARA, EPA, DHA and higher 20:2 n-6 due to the lower activity of the Δ^5-desaturase and Δ^6-desaturase which are present also in the mammary gland. This is very disadvantageous for the newborn baby for which the DHA contained in breast milk is essential for the normal development of the nervous system. Studies have shown better development of the nervous system and the vision in infants fed with milk containing > 0.32g compared to those fed 0.2 g DHA / 100 g fatty acids [9]. Another study analyzed the relationship between genetic variants of FADS1 and FADS2 and the content of LC-PUFA in the mother's colostrum. Most of these polymorphisms have adverse effects and cause lower blood levels of DHA, EPA, AA. The variants of rs174537, rs174570, rs2072114, rs174602, rs526126, rs174626, rs174464 and rs174468, which are associated with significantly lower AA content, have been detected here. Minor alleles rs174602 and rs174464 are clearly associated with a lower content of DHA in the blood, while the other showed the same direction at a concentration of DHA, as in the case of AA [14].

DHA supplementation and SNPs in FADS gene cluster – pregnancy outcomes and newborn health

As mentioned before, studies has showed that high consumption or supplementation of pregnant women with DHA can result in better pregnancy effects and can impact child development. Maintaining the adequate balance of DHA in the mother's and the child's tissues can be done by proper nutrition or supplementation of this fatty acid [12]. Unfortunately it is demonstrated that among Polish women aged 19–30 years, the average DHA intake was 110 mg, and among women aged 31–50 years – 120 mg, which does not cover

the minimum dose of 200 mg per day recommended by the Institute of Nutrition and Food [21], what may cause concern for the proper development of newborn babies. It was confirmed that supplementation of 200 mg DHA for 4 months after birth by mother results in up to 75% higher concentration in milk [22]. Especially in relation to the decreasing consumption of fish, eg. in the Nordic countries [5], it should be taken care of appropriate supplementation of this compound to provide the opportunity for your child to a suitable, undisturbed development and avoid the risk of various disorders in the future.

The rapid development of the brain (brain growth spurt) takes place predominantly in the 3rd trimester of pregnancy and during first year of age [13, 14], when the LC-PUFA are delivered from mother, first are transported through the placenta, then from breast milk. The greater part of the dry weight of the brain are lipids, of which 35% are long chain products of fatty acids [14]. LC-PUFA during fetal and early postnatal life are involved in the formation of the structure of cell membranes of neurons, myelination and in production of neurotransmitters such as dopamine or serotonin [13, 14]. In addition, DHA may affect the regulation of gene expression in the brain and participate in the processes of learning and memory, as it take part in the development of pre- and postsynaptic proteins involved in the transmission [13].

Therefore it was not surprising that children of pregnant women whose diet is deficient in LC-PUFA, consume little fish or are not supplemented with DHA showed delayed development, characterized by a lower level of IQ and poorer communication skills [13]. Colombo et.al. demonstrated that infants at the age of 4,6, 9 and 12 months whose mothers was supplemented with DHA in an amount of 600 mg per day, could be more focused and better maintain attention compared to children of placebo-treated women. Moreover, the same study showed a positive correlation between supplementation and weight of the child (average difference approximately 360g) and head circumference (difference of approx. 1.5cm) [23]. This confirms the positive correlation between DHA supplementation and neonatal development what many studies confirmed.

Numerous studies have examined the effects of DHA supplementation, FADS genotypes, and the impact on health and development of newborns and children in later years. Supplementation of EPA / DHA during both pregnancy and lactation has also been correlated positively with the contents of DHA in the maternal RBC phospholipids [5]. In a study conducted in the United States, women who were homozygous for the minor allele of rs174533 FADS1 had lower levels of AA and DHA in the blood, whereas it increased significantly after supplementation with 600 mg of DHA during the last two trimesters of pregnancy [19]. This has been confirmed by research showing that the effect of FADS genotype also becomes less important in the case of fish oil supplementation, among those who had low levels of DHA in the blood at the beginning [17]. In another study 96 women received placebo (soybean and corn oil), while 195 women received 600 mg DHA from algae, 3 capsules per day for the last 2 trimesters. The study showed that among women with rs174533 minor allele placebo-treated women had lower DHA levels than women with a major allele. However, in the DHA supplemented group the level of this fatty acid was not depended on the genotype, and were higher in both groups with minor and major allele, compared to placebo. In the same study the level of DHA and other fatty acids in the plasma of infants was measured. DHA content in the group of children whose mothers were supplemented was significantly higher in comparison to the control group. The concentration of DHA in the first group was 4.81 ± 1.12% of the total fatty acid content, while in the control group 3.57 ± 1.08% [24].

This was shown in the study of premature infants who was born less than 33 weeks of pregnancy in order to assess the impact of breastfeeding mothers DHA supplementation on visual development [25]. Some women received six capsules containing 500 mg of DHA per day, while women from the control sample received soybean oil capsules, not containing DHA. They tested then visual evoked potential (VEP) acuity in infants ages 2 and 4 months. They were significantly higher in children 4-month fed by mothers supplemented with DHA, whereas no difference was noted in the age of two months, which may be associated with different sensitivity to methods of measurement in these two age ranges. Interestingly, the changes were much more clearly marked in male infants [25].

The importance of a balance between DHA and AA is also emphasized. It is very important for the development of the nervous system and the immune system [17]. Detected unfavorable relationship between the ratio of n-6 / n-3 on both psychomotor development and communication skills at 20 months of age [17] indicates that the balance between AA and DHA is required to ensure optimal development of a child. Moreover, it has also been proven that supplementation DHA lowers the level of arachidonic acid in women with rs174533 and rs174575 minor alleles respective-

ly in FADS1 and FADS2 genes, whereas this does not occur in pregnant women with major variants of these alleles, which changes the ratio of DHA to ARA, but the physiological effects of these changes are not yet known [24].

Also significant is the effect of DHA supplementation during pregnancy and breastfeeding on the development of the infant's immune system. In order to demonstrate the relationship, examined more than a hundred families were examined. At least one person from each family suffers from allergy [26]. Pregnant women received a supplement containing either EPA and DHA or placebo. The children were subjected to allergic tests at the ages of 3, 6, 12 and 24 months. The proportions of children's blood fatty acids, chemokine and antibodies against diphtheria and tetanus were also analyzed. It has been shown that children of DHA-supplemented women had lower concentrations of IL-13 and CCL17, which are associated with the proliferation of Th2 cells, which favors the development of allergies [26]. The Th2 / Th1 lymphocyte ratio was also lowered. In addition, in children whose mothers did not have allergies and were supplemented with DHA, a stronger response to tetanus and diphtheria vaccine was demonstrated, and higher levels of antibody in the blood against these pathogens, showing that supplementation can enhance the child's immunity from birth and prevent to some degree development of allergy [26].

Another aspect is the duration of pregnancy. Women who are homozygous with the minor allele have a tendency to significantly shorter pregnancy period. Supplementation and diet rich in DHA increase this time. Neither the mother nor the child's genotype did not modify the association between maternal PUFA intake and the duration of pregnancy [18]. However, an inverse relationship was observed between the level of arachidonic acid and the length of pregnancy, which is associated with the production of larger quantities of arachidonic acid products, e.g. prostaglandin E_2 and prostaglandin $F_{2,}$ which support uterine contractions [18], while n-3 PUFAs may delay the delivery by inhibiting the production of these compounds. Also in the case of low consumption of fish and seafood or absence of supplementation of DHA levels of these two fatty acids decline in the mother's body, because of their transportation and use by the fetus [5]. This involves a greater risk of postpartum depression in the mother, which also has a negative impact on the mother-child relationship [5]. It is therefore important to maintain the adequate amount of DHA in the circulation of pregnant women by appropriate diet and possible supplementation, especially in case of presence adverse desaturase variants, which reduce the amount of DHA during pregnancy.

DHA supplementation and effect of SNPs on disease occurrence in children

Supplementation of LC-PUFA and their precursors, during pregnancy and lactation, and polymorphisms in D6D and D5D genes may also have a long-term effects on health and child development [6]. First aspect is the issue of the impact of LC-PUFA on the development of allergies in children. Differentiation of unsaturated fatty acids in the blood of children remains strongly dependent on the genotype of FADS [27]. Barman et.al. studied the relation between the occurrence of SNPs in FADS1 and FADS2 genes, as well as in elongase gene (ELOVL), with the occurrence of allergies in children. Blood samples were taken at birth and then at 13 years old. Children, which showed the presence of rs102275 and rs174448 minor alleles, had lower levels of arachidonic acid, and increased levels of 20:3 n-6 acid, what reduce significantly the risk of atopic eczema, but not inhaled allergens. ELOVL polymorphism did not influence the occurrence of allergies [28].This study indicates the significant role of LC-PUFA in the development of eczema, and showed that reduced activity of desaturases reduces this risk. In the study of children from Germany, the relationship between FADS variants and atopic eczema was also confirmed.

However, in another study, this relationship was not explicitly confirmed. In one of the tested groups in which were children from the Netherlands, no relationship was obtained between the occurrence of variation PUFA and eczema in children, what does not allowed to confirm the role of fatty acids as precursors of pro-inflammatory molecules taking part in the development of allergies [27]. However, among children from Germany, the relationship between FADS variants and atopic eczema was confirmed. These discrepancies indicate the need for further studies in the field that will demonstrate the link between FADS1 and FADS2 genotypes, PUFA differentiation and allergy in children.

Another important issue is the effect of mother's DHA supplementation on the intelligence level of the child. A study of 2839 pairs of mother-child (8 years), indicated that lower level of arachidonic acid and docosahexaenoic acid is associated with lower IQ of the child. Lower DHA levels correlated with IQ decreased

by 1.5 score. At the same time, with decreased DHA concentrations, the concentration of 22: 5n-6 and 22: 4n-6 acids increased, replacing DHA during its deficiency. However, this substitution impairs the growth of axons and formation of synapses [29]. The lower level of arachidonic acid and the lower IQ at its deficiency may be associated with changes in the production of eicosanoids, which leads to a reduced electrical activity in the brain and the immune response. Also another study showed the relationship between supplementation and the level of IQ of the child (4 years). It was performed among randomly selected women who were supplemented from 18 weeks of gestation to 3 months after delivery of 10ml of cod liver oil or received placebo- corn oil. Children of mothers who had been taking DHA showed about 4 points higher IQ level [30].

According to the results obtained, SNPs in the mother's desaturase genes exert a strong influence on fetal and infant fatty acid levels, and the DHA concentration in their tissues correlates with the amount of parental intake of the mother. However, according to one study, this effect disappears with age [7]. These contradictions indicate the need for further research in this field.

Summary

The existence of SNPs in FADS and their effect on the fatty acid composition in tissues has already been well established. It is certain that the presence of multiple variants of the alleles of desaturase genes modifies their activity and disturbs the balance of PUFAs and their long chain products in the body [7, 8, 14]. Ongoing researches try to discover new polymorphisms and FADS gene variants.

It is now known that DHA and other long-chain PUFAs – EPA and AA, play a very important role in the development of the fetus and newborn. Especially DHA is responsible for the proper functioning of such important organ as brain [2]. Therefore, it is important to supply the appropriate amount of this fatty acid initially through the placenta with the mother's blood and then with the breast milk. In addition, the increasing importance when it comes to providing DHA to the fetus and the baby during breast-feeding and for widely understood and proper development of the baby's health, gaining the genetic background associated with the presence of different variants of desaturase genes. SNPs according to the locations in gene can variously modify the activity of these enzymes by changing the level of DHA or other LC-PUFA in the tissues of the mother and the child. The presence of polymorphisms has a significant impact on the process of endogenous synthesis DHA from precursors supplied with the diet. Attention is paid now to the relationship between the intake and supplementation of DHA and genetic background [24]. These are undoubtedly very important issues that will make a chance to ensure an optimal child development from the first days of intrauterine life.

However, there are also many questions about the relationship between the SNPs, the content of LC-PUFA and the occurrence of many diseases, such as allergies, diabetes, cardiovascular disease in different age groups. Studies on the impact of polymorphism often provide contradictory information, which is often also associated with the selection of the study group, their origin, age, environment, and also studied variants of the FADS gene alleles.

Furthermore, an interesting issue, although certainly far distant for the present, is if it would be possible to determine the genotype of FADS in women, so as to detect whether they are in a group having a minor alleles, which impair the pathway of endogenous production of DHA. It would allow to apply a correspondingly larger supplementation, to compensate for the lack of the endogenous synthesis and provide the appropriate development of the baby from the first weeks of intrauterine life. It is also interesting to note that supplementation with larger amounts of DHA can neutralize the negative effects of SNPs. Women who supplemented 600 mg of DHA and were the minor allele carriers had significantly higher levels of DHA in plasma compared to those taking placebo [24]. Therefore, supplementation of larger amounts than the recommended 200 mg can cause positive effects. Women at risk of premature labor should consume as much as 1000 milligrams a day, which can prevent them from miscarriage [31].

All this issues require numerous studies that will draw conclusions and discover facts that allow us to complete the knowledge about the importance and the role of fatty acids and their long chain products in human body and the effects of their disturbed equilibrium. They can also present wider range of very important place of genetics and genetic background in the regulation of many physiological processes..

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REVIEW PAPER

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Risks of nutritional supplements consumption by pregnant women

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ABSTRACT

During pregnancy the demand for nutrients, energy, vitamins and minerals increases. The diet used during pregnancy and before conception should provide the best conditions for the development of young, but often it is insufficient to cover the demands for both a pregnant woman and the fetus. Therefore pregnant woman, in the case of nutritional deficiencies and inability to cover them as the part of the daily diet, is often obliged to supplement the nutrition that she and the baby need. Moreover, the deficit of the nutritional elements during this period may increase the risk of various types of disorders complicating the pregnancy and affecting the development and the health of the baby. The working scheme of medicines may be changed due to nutritional supplements through the increase of their excretion, decrease in their absorption and/or disruption of metabolism. Many adverse events can occur due to the simultaneous application of both nutrition supplements and medicinal products. Therefore, the decision of including a supplementary diet should be made very carefully and individually for every patient. The use of nutrition supplements for expectant mothers should always be consulted with a physician or a pharmacist.

Keywords: pregnant woman, nutritional supplements, interactions with drugs, vitamins, minerals, adverse events.

Introduction

The literature defines nutritional supplements as products being the source of concentrated nutrients and other components having a physiological effect on human body [1]. Their use may mitigate the risk of occurrence of certain diseases [2]. However, it should be stressed, that according to the Polish Law, nutritional supplements are not medicinal products but are treated as nutritional products [3, 4]. Currently, both in Polish and English literature, there is a lack of unambiguous guidelines on diet supplementation during the period of preconception, pregnancy, post-partum and lactation.

Nutritional supplements

Balanced vitamin and nutrient intake should be accompanied by a proper diet and/or use of multivitamin preparations. Following recommendations of the EU, each active component of a nutritional supplement should produce its expected effect, and the size of dose should exceed the minimum dose proven to be preventive and therapeutic. Additionally, the amount of vitamins and minerals constituting the nutritional supplement composition should be adjusted to the appropriate diet to minimize the risk of exceeding a safe dose [5]. Moreover, specialists emphasize that nutritional supplementation, in particular, during pregnancy, post-partum period, and lactation period should be controlled by a physician [6].

It should be emphasized that the lack of detailed regulations on the components contained in nutritional supplements other than vitamins or minerals causes both Polish and European market of the nutritional-supplements to be characterized by a very wide vari-

ety of its products. Based on the information included in the European Commission report [7], there are over 400 substances that can be used for the production of nutritional supplements. While, over a half of all nutritional supplements available on the EU nutritional markets are vitamins and minerals, both in the form of separate substances and vitamin complexes. The remaining nutritional supplements available on the EU market are classified into six categories [7]:

1. amino acids, e.g., L-arginine,
2. enzymes, e.g., lactase, papain,
3. prebiotics and probiotics, e.g., inulin, Lactobacillus acidophilus, Bifidobacterium species, yeasts,
4. essential fatty acids, e.g., gamma-linolenic acid, fish oil (DHA/EPA), linseed oil (Linum usitatissimum), borago seed oil (Borago officinalis),
5. plant compounds, e.g.,aloe (Aloe vera), ginkgo (Ginkgo biloba), ginseng (Panax ginseng), garlic (Allium sativum), green tea extract (Camellia sinensis), Garcinia cambogia extract, guarana extract (Paullinia cupana),
6. other substances, such as lycopene, lutein, Q10 coenzyme, taurine, carnitine, inositol, chitosan, spirulina, soybean isoflavones.

Food supplements present on EU markets contain mostly plant raw materials traditionally originated from Europe. Pharmacopoeial raw materials are also contained in composition of nutritional supplements. However, the latter should be used in considerably lower doses than those specified for them as medicinal doses. Following manufacturer declarations of nutritional supplement, currently available preparations exhibit a wide range of effects on the whole organism and its individual systems and/or organs [8, 9]. The nutritional supplements available on the nutritional market have the capability to support the immune system; support the musculoskeletal system; delay the aging process; enhance skin, hair, and nails` appearance; support functioning of the organs of hearing and vision; support the process of weight loss; support the functioning of the cardiovascular system; support the functioning of the digestive system; support the functioning of the organisms during the period of greater physical effort [9].

Risks of nutritional supplement use

As mentioned earlier, nutritional supplements may exhibit nutritional and/or other physiological effect. Contrary to medicinal products, nutritional supplements do not exhibit metabolic effect. However, difficulties in the classification of individual substances are observed, primarily due to the similar appearance of product packaging, wide distribution of nutritional supplement advertisements, and the fact that a potential consumer often has difficulties in distinguishing nutritional supplements from medicinal products (particularly those occurring in the form of tablets or capsules). Also the differences in nutritional supplement classification in individual EU member states and non-Community countries, as Norway or Switzerland, play significant role in this context. The lack of harmonization of the European Union law and law of the European countries that do not belong to the EU in reference to nutritional supplements creates a situation that in certain countries these products are admitted to the market circulation as nutritional supplements, while in others are admitted as medicinal products, thus being subjected to completely different regulations [9].

Following the regulations of the Act on the nutritional and nutrition safety of August 25, 2006 (Journal of Laws of 2006, No. 171, Item 1225 with subsequent amendments), labeling, presentation, and advertisement of nutritional supplements cannot contain information stating or suggesting to the potential buyer that a balanced and varied diet cannot provide enough nutrients for the normal functioning of the system. In addition, the cited Act indicated that labeling, presentations, and advertisements of nutritional supplement, similar to other nutritional products, cannot mislead the consumer and shall neither attribute a nutritional product, including nutritional supplement, the property of preventing or treating diseases, nor refer to such properties. The assumption referring to the avoidance of misleading consumers primarily refers to the characteristics of the nutritional product (nutritional supplement), including its name, type, properties, composition, shelf life, source, place of origin, and/or manufacture/production methods. All products covered by the Act on the nutritional and nutrition safety [12] should not mislead consumers by suggesting that a nutritional product, including nutritional supplements, exhibits effects or properties, which in reality it does not possess.

Oftentimes, the cause for irregular nutritional supplement or dermocosmetics usage was the incidence of different side effects resulting from their use by a pregnant woman. Nutritional supplements introduced to the market circulation may pose a risk for the health and even life of their consumers. These preparations often contribute to better implementation of

dietary recommendations. However, the use of nutritional supplements should relate to the existing risk of vitamin or mineral overdosing, which in turn may cause disclosure of negative side effects of their overdosing. Ensuring the safety of nutritional supplement use is a responsibility of their manufacturers. Nutritional supplement manufacturers are obliged to provide labels with information on the possible contraindications of their usage, possible interactions with other nutritional supplements or medicines for both sold on the basis of medical prescription and over-the-counter medicines, possible interactions with other nutritional components, and the possible need to consult the usage of specific nutritional supplements with a physician or dietician before its application [11].

Following the current state of knowledge, improper use of nutritional supplements, unjustified supplementation, consumption of higher nutritional supplement doses than those suggested by the manufacturer, lack of reliable information on labels of nutritional supplements, and concomitant application of a larger amount of supplements may be linked to the risk of adverse effects. The literature mentions the most common types of this kind of action: incidence of discolors and skin changes, color change of stool and/or urine, increased risk of lung cancer in smokers using higher than recommended beta-carotene supplementation, or intensification of antithrombotic effect with the concomitant use of vitamin E supplements and antithrombotic medicines [13].

In many cases, the vitamin and mineral supplementation may contribute to better or proper implementation of dietary recommendations. However, nutrition experts are warning that although nutritional supplements are treated in the Community law as nutritional products for particular nutritional uses, their usage can be linked to the incidence of certain side effects. There are reports indicating that the use of high dosages of certain nutritional supplements may be harmful to health. Therefore, an individual diet supplementation without the confirmation of the real health requirements of a person using nutritional supplements may pose a risk of exceeding the upper safe levels of their consumption [14].

Nutritional supplements may alter the effect of medicines used by the patient. The most common changes involve a decrease of the absorption of active substances contained in medicines. This assumption primarily refers to antibiotics, anti-tremor medicines, preparations used in the therapy of cardiovascular diseases, and numerous other medications. The concomitant use of nutritional supplements and medicines may also contribute to the increase of drug excretion from the organism. In the case of both decreased absorption and increased excretion of medicines, a decrease of the amount of medications in the organism occurs, thus decreasing their therapeutic effect. In such a situation, the therapy proposed by the physician may not give the projected effects, bring effects at a later-than-assumed date, or cause postponed effects. A very important adverse effect resulting from the interaction between the co-application of medications and nutritional supplements is also the disturbance or change to the metabolism of the taken preparations [15].

Very common interactions between co-applied medications and nutritional supplements are interactions between plant and medicinal preparations. The existence of these interactions is primarily caused by the presence of active compounds such as flavonoids, furanocoumarins, alkaloids, terpenes, glycosides, anthocyanins, catechins, saponins, and anthraquinones. The mentioned compounds may interact with a certain medicinal substance, competing for the receptor-binding site. Such phenomena occur in the case of certain weight-loss-aiding products. Their effect is focused on the increase of intestinal peristalsis. This in turn may lead to a decrease of absorption of numerous medicines. Similar effect is exhibited by preparations containing mucus, in particular linseed, marshmallow, and narrow leaf plantain, reducing the availability of the used drug in the intestinal mucosa, thus weakening the intestinal absorption of these medicines. Interactions between medicines and nutritional supplement that contain plant components may also lead to the situation, where the plant components contained in nutritional supplements influence the metabolism of therapeutic substances. Such influence may cause a decrease or increase of the medicine's concentration in the blood of the patient, thus changing the efficiency of the conducted pharmacotherapy [10].

Another very common interaction type is interaction of medications used with nutritional supplements containing high amounts of vitamins. This results primarily from the widespread perception of nutritional supplements as being safe, accompanied by the lack of knowledge on the negative influence of too high vitamin supply or interaction between vitamins and certain medication groups [15]. Folic acid, constituting one of the most commonly used nutritional supplements intake by women planning to get pregnant and pregnant women, decreases phenytoin concentration

in the blood. This may contribute to the decreased efficacy of the medication, while phenytoin exhibits the capability of decreasing folic acid level in the blood serum. Thus, folate level examination every six months is recommended for the patients treated with phenytoin, and, if necessary, administering folic acid at higher doses is suggested [10, 16].

A variety of interactions with co-applied medications may also occur for numerous minerals. Mixing of nutritional supplements containing mineral preparations with antibiotics may contribute to the decrease of absorption of these medicines, and thus decrease their action and disclose possible complications resulting from uncured infection. Therefore, it is recommended to consult a physician or pharmacist about the possibility of using a certain nutritional supplement with medication [15].

One of preparation groups used by, i.e., pregnant women is nutritional supplement containing magnesium. It should be emphasized that the use of magnesium with other medications may have an adverse effect on their absorption or metabolism. The concomitant use of magnesium supplements and medications used in arterial hypertension treatment contributes to a decrease of the effect of medication via decrease of its bioavailability. Moreover, researchers demonstrated that the use of Mg considerably decreases Fe absorption, which may eventually lead to the development of anemia. In addition, Mg belongs to the group of substances decreasing absorption of antibacterial medications, decreasing the effect of antithrombotic, antifungal, antipsychotic, anti-anxiety medications, and cardiac glycosides that increase the strength of the contraction of heart muscle and decrease the contraction rate [17].

The concomitant intake of supplements containing Mg and medications dilating the bronchi or medications used in the Parkinson's disease leads to the increased effect of these medications, which may cause the occurrence of adverse symptoms in the patient, including nausea, vomiting, headaches, skeletal muscle tremors, insomnia, irritation, reduced blood pressure, and cardiac disorders [17].

Many women planning to get pregnant and who are pregnant use calcium supplements in order to supply the increased demand for this mineral. Calcium used without the consultation with a physician or pharmacist can decrease the effect of Ca channel blockers, particularly in the case of patients with angina or patients with cardiac arrhythmia. In addition, Ca, similar to the majority of minerals, decreases absorption of the majority of antibiotic groups used in the respiratory infections and urinary infections. As demonstrated by specialists, the decrease of antibiotic concentration in the blood of patient also using calcium supplements may reach up to 50%. Such a decrease of antibiotic concentration may eventually cause the therapy to become ineffective. Calcium ions may also cause the increase of toxicity of cardiac glycosides, which are used in the therapy of cardiac arrhythmia [18].

In addition, due to the elevated risk of anemia, numerous women planning to get pregnant and who are pregnant use nutritional supplements containing Fe. However, it should be emphasized that the concomitant use of Fe preparations and certain medications may entail adverse health consequences. Iron decreases the effect of antibacterial medications. It has a negative effect on the absorption of drugs to treatment for the Parkinson's disease by significantly decreasing the absorption of these preparations. It also decreases the absorption of the preparations used in the treatment for arterial hypertension. It should be remembered that bisphosphonates, i.e., preparations used in therapy of bone diseases, exhibit the capability of binding Ca and Fe while this ability contributes to the decrease of medication absorption in the blood [19].

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Conflict of interest statement
The authors declare no conflict of interest.

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