Journal of Health Study and Medicine

2020, No. 1

Redaktor naczelny / Editor in chief
dr n. med. Joanna Sułkowska

Skład / Adjustment, Typesetting
Witold Kowalczyk

ISSN 2451-1471

ul. Kilińskiego 109
90-011 Łódź
tel./fax: (042) 676 25 29 wew. 339
e-mail: wydawnictwo@spoleczna.pl

Wersja elektroniczna publikacji jest wersją podstawową, dostępną na stronie:
jhsm.san.edu.pl
E-version is the original version of the article, available:
jhsm.san.edu.pl

Artykuły recenzowane / All the articles published are subject to reviews.

Journal of Health Study and Medicine
2020, No. 1
pp. 5-21
DOI 10.36145/JHSM2020.01

Dietary Vitamin D Intake Does Not Significantly Affect Plasma 25(OH)D Concentration in Patients with Ischaemic Heart Disease

Małgorzata Godala[1]
https://orcid.org/0000-0003-3579-8537

Ewelina Gaszyńska[1]
https://orcid.org/0000-0001-7568-3502

Izabela Materek-Kuśmierkiewicz[2]
https://orcid.org/0000-0001-5912-4516

Dariusz Moczulski[2]
https://orcid.org/0000-0002-0926-9909

Jan Kowalski[3]
https://orcid.org/0000-0003-0621-1768

[1] Department of Nutrition and Epidemiology, Medical University of Lodz, Poland
[2] Department of Internal Medicine and Nephrodiabetology, Medical University of Lodz, Poland
[3] Department of Internal Medicine and Cardiac Rehabilitation, Medical University of Lodz, Poland

Address for correspondence

Małgorzata Godala
Department of Nutrition and Epidemiology
Medical University of Lodz
7/9 Żeligowskiego Str., 90-752 Lodz, Poland
e-mail: malgorzata.godala@umed.lodz.pl

Abstract

Background: *Cardiovascular diseases are one of the main public health issues in developed and developing countries. Many recent studies indicate pleiotropic diverse functions of vitamin D.*

Aim: *The objective of this study was to evaluate 25(OH)D concentration in plasma of patients suffering from different types of ischaemic heart disease (STEMI, NSTEMI, stable angina pectoris), prevalence of its deficiencies in these patients and relations between 25(OH)D plasma level and traditional biomarkers for cardiovascular diseases.*

Results: *In the conducted study a mean 25(OH)D concentration was 13.7±3.8 and was below the recommended normal limit. The lowest mean concentration, 7.5±3.2 ng/ml, was observed in patients with NSTEMI, in those with STEMI – 13.4±2.1 ng/ml, and in patients with SAP – 19.6±4.2 ng/ml. No correlation was found between plasma vitamin D concentration and its dietary intake in all groups of patients. 25(OH)D concentration negatively correlated with age (r=-0.27), BMI (r=-0.31) and waist circumference (r=-0.29) in the studied group. Patients with normoglycaemia had a significantly higher 25(OH)D concentration than those with glucose intolerance and type 2 diabetes (p=0.02), in patients with type 2 diabetes and glucose intolerance 25(OH)D concentration correlated negatively with serum glucose level (r=-0.29) and TG concentration (r=-0.31), and positively with HDL level (r=0.27).*

Conclusion: *A non-supplemented well-balanced diet does not significantly affect plasma 25(OH)D concentration. Occurrence of vitamin D deficiencies in patients with ischemic heart disease should be regarded as an independent factor increasing the risk of cardiovascular diseases.*

Introduction

Cardiovascular diseases are one of the main public health issues in developed and developing countries. Many recent studies indicate pleiotropic and diverse functions of vitamin D and its deficiency correlates positively with a higher risk of cardiovascular diseases, arterial hypertension, dyslipidaemia, obesity or metabolic syndrome. Moreover, it has been proved that vitamin D deficiency affects progress of the atherosclerotic process [1,2].

Ischaemic heart disease includes all conditions involving ischaemia of the cardiac muscle related to lesions in coronary arteries. We may distinguish stable coronary syndromes, e.g. stable angina pectoris (SAP) and acute coronary syndromes (ACS) – with or without ST segment elevation (STEMI or NSTEMI). The most common cause of ischemic heart disease is coronary atherosclerosis and the cause of ACS – a sudden blockage of the coronary artery by a thrombus which forms on damaged atherosclerotic plaque.

Vitamin D regulates many mechanisms that have impact on the cardiovascular system, and its active form is 1.25 dihydroxy vitamin D with a peculiar intracellular receptor VDR. Most (90%) of the recommended daily intake is obtained from synthesis in the skin, the remaining part should be supplemented by proper diet. The amount of vitamin D production in the skin depends on the season of the year, degree of cloudiness and air pollution, geographic latitude or skin pigmentation [1,3].

Vitamin D regulates homeostasis of calcium and phosphates, increases calcium absorption from the intestines and takes part (together with parathormone) in calcium resorption in the kidneys. It is also associated with arterial blood pressure regulation, and its level correlates inversely with plasma renin activity. Moreover, vitamin D deficiencies increase the risk of diabetes development since it may affect intracellular calcium concentration in pancreatic cells, which stimulates insulin production. It is also believed to have an impact on lipids metabolism, as its deficiency increases the systemic insulin resistance deteriorating the lipid profile, as well as the process of atherosclerotic plague formation. Therefore, there

are reasonable grounds for evaluating its level in patients with coronary disease [4,5,6].

The objective of this study was to evaluate 25(OH)D concentration in plasma of patients suffering from different types of ischaemic heart disease (STEMI, NSTEMI, stable angina pectoris), prevalence of its deficiencies in these patients and relations between 25(OH)D plasma level and traditional biomarkers for cardiovascular diseases.

Material and methods

Study population

The study included 192 patients, 112 males and 80 females, aged 41-65 (mean 54.4±4.3 years).

Biochemical analyses

Fasting blood glucose was determined with a reaction between glucose and ATP catalysed by hexokinase; TG concentration was enzymatically measured with coupled reactions in which TG was hydrolysed to produce glycerol; TC was measured with reactions using cholesteryl ester hydrolase, cholesterol oxidase, and peroxidase; HDL was measured using a heparin-manganese precipitation method; LDL was assessed using Friedewald rule.

The concentration of 25-hydroxy vitamin D (25-OH-D) was evaluated with the application of the LIAISON® test using chemiluminescent immunoassay (CLIA) technology. The plasma level of 25(OH)D ≥30 ng/ml was considered normal, between 20 ng/ml and 30 ng/ml – suboptimal (hypovitaminosis) and ≤20 ng/ml – insufficient (deficiency) [7].

Anthropometry analyses

Body mass index (BMI) was calculated as weight (kilograms) divided by height in meters squared. Waist circumference was measured at the midpoint between the bottom of the rib cage and above the top of the iliac crest during minimal respiration.

Nutritional evaluation

The food intake was assessed using a twenty-four-hour dietary recalls (24HR), in accordance with the guidelines of the National Food and Nutrition Institute in Warsaw [8,9]. A total of 576 24HR (three 24HR for each patient) were obtained from subjects by the interviewer and means of consumption were calculated for each nutrient. The "Album of photographs of food products and dishes" of the National Food and Nutrition Institute of Warsaw was used to determine normal size of the consumed portions [9]. The vitamin D intake was determined with "Charts of nutritive values of products and foods" and "Standards of Human Nutrition" using Diet 5.0 software (license No: 52/PD/2013), accorded to the National Food and Nutrition Institute of Warsaw. The degree of insufficient intake of vitamin D was estimated according to the adequate intake standards (AI=15μg per day) [8,10].

Statistical analyses

Statistical analysis was performed using Statistica 7.1 PL and Office 2010 software. The normal distribution was determined using the Shapiro--Wilk test. Continuous variables are presented as the mean value ± standard deviation (SD). The comparison between averages of two independent groups was made using Student's t test and Mann-Whitney U test for continuous variables, chi-square and Fisher's exact tests were applied for dichotomic ones. Correlations were assessed by Spearman's and Pearson's coefficient. One-way analysis of variance (ANOVA) with the post--hoc Bonferroni test for multiple comparisons was used to determine if differences exist between means of patients belonging to different groups, $p<0.05$ was considered to be significant.

The study was approved by the Bioethics Committee of the Medical University in Lodz (No. RNN/556/10/KB). A written consent was obtained from all research participants.

Results

Baseline groups characteristics

Characteristics of the studied groups are shown in Table 1. The three subgroups did not differ with regard to age, gender and smoking habits. Exactly 25% of the studied group were diagnosed with diabetes mellitus, 17.71% – impaired glucose tolerance and 88.54% – hypertension. The three subgroups differ according to anthropometric and lipid profile parameters except for TC. The highest TG and LDL concentration was found in NSTEMI patients whereas the highest HDL – in SAP patients. Patients with NSTEMI were characterised by the highest BMI and waist circumference.

Table 1. Characteristics of the study group

	NSTEMI (n=56)	STEMI (n=62)	SAP (n=74)	p-value
	Mean ±SD / %(n)	Mean ±SD / %(n)	Mean ±SD / %(n)	
Age [years]	53.2±4,2	57.4±5.3	52.7±3,7	sn
Sex [% females]	42.9 (24)	41.9 (26)	40.5 (30)	sn
Current smokers [%]	39.3 (22)	29.0 (18)	32.4 (24)	sn
T2D [%]	28.6 (16)	22.6 (14)	24.3 (18)	<0.001[c]
IGT [%]	17.9 (10)	16.1 (10)	18.9 (14)	sn
HT [%]	96.4 (54)	80.6 (50)	89.2 (66)	sn
BMI [kg/m^2]	32.5±2.6	27.4±6.9	29.7±3.4	<0.0001[a]
Waist [cm]	104.54±8.9	96.66±12.3	101.8±8.2	<0.0001[a]
Glc [mmol/l]	5.7±0.9	5.7±1.2	5.8±0.35	<0.0001[b]
TG [mmol/l]	1.9±1.9	1.7±0.7	1.6±0.2	<0.0001[b]
TC [mmol/l]	4.5±1.8	4.5±0.9	4,6±1.2	sn
HDL [mmol/l]	1.2±0.1	1.3±0.2	1.4±0.4	<0.0001[a]
LDL [mmol/l]	2.9±0.8	2.7±0.7	2.7±0.2	<0.0001[a]
25(OH)D [ng/ml]	7.5±3.2	13.4±2.1	19.6±4.2	<0.00001[a]

a – Student's t test, b – Mann-Whitney U test, c – $\chi 2$ test, sn – statistically non important

Nutritional characteristics

The studied groups were well nourished according to the total energy intake, total protein, carbohydrates and fats intake, as well as dietary fibre (Table 2). The groups did not differ according to the absolute values of the energy obtained from macronutrients intake, also several similarities were found between the groups regarding minerals intake (sodium, potassium, phosphorus, magnesium, iron, copper, zinc, iodine) and vitamins (B vitamins, vitamin A, vitamin D).

The percentage of the group with deficient of the vitamin D consumption of the AI standard was 81.25% (n=156). A detailed analysis of the kind of products commonly chosen by the study group indicated dairy products, meat and fish.

Table 2. Dietary intake in the study group

	NSTEMI (n=56)	STEMI (n=62)	SAP (n=74)	p-value
	Mean ±SD	Mean ±SD	Mean ±SD	
Total energy [kcal/d]	1957±405	1896 ±348	2005±316	sn
Proteins [g/d]	107±29	96 ±28	99±27	sn
Fats [g/d]	84 ±33	76 ±31	82±28	sn
Carbohydrates [g/d]	278±38	277±41	269±32	sn
Cholesterol [mg/d]	321 ±85	272 ±95	289 ±43	sn
SFA [g/d]	35±12	31±16	32±12	sn
MUFA [g/d]	30±24	31±17	33±21	sn
PUFA [g/d]	12±8	11±6	10±11	sn
Fiber [g/d]	24 ±8	23 ±7	25±5	sn
Vtamin D [µg]	4.9±1.2	5.3±1.7	4.7±1.6	sn

sn – statistically non important

25(OH)D concentration and its correlations

In the conducted study a mean 25(OH)D concentration was 13.7±3.8 and was below the recommended normal limit. The lowest mean concentration, 7.5±3.2 ng/ml, was observed in patients with NSTEMI, in those with

STEMI – 13.4±2.1 ng/ml, and in patients with SAP – 19.6±4.2 ng/ml. There was a statistically significant difference between the values. No correlation was found between plasma vitamin D concentration and its dietary intake in all groups of patients.

Plasma 25(OH)D concentration below 20 ng/ml was observed in 53.12% (n=102) of the subjects, significantly more frequently in NSTEMI patients than in the other groups, whereas hypovitaminosis (25(OH)D concentration of 20-30 ng/ml) – in 46.88% (n=90), most often in patients with stable coronary diseases. In none of the subjects the recommended 25(OH)D concentration, over 30 ng/ml, was observed. Moreover, among those with 25(OH)D deficiency as many as 43.14% (n=44) had 25(OH)D concentration below 10 ng/ml (Table 3).

Table 3. Prevalence of 25(OH)D deficiencies and hypovitaminosis in various types of ischaemic heart disease

Plasma 25(OH)D concentration (ng/ml)	NSTEMI (n=28)	STEMI (n=31)	SAP (n=37)	p
	% (n)	% (n)	% (n)	
0-19 (deficiency)	78.57 (22)	54.84 (17)	32.4 (12)	χ^2=108.16, p<0.00001
20-30 (hypovitaminosis)	21.43 (6)	45.16 (14)	67.6 (25)	

Seasonality of changes in plasma 25(OH)D levels was observed. Patients admitted in the first quarter of the year (January-March) had the lowest mean 25(OH)D concentration, whereas the highest one in the fourth quarter (October-December) (7.24±2.1 ng/ml vs. 15.78±2.9 ng/ml, p=0.008). In the second quarter the mean 25(OH)D concentration was 11.37±3.1 ng/ml, and in the third quarter – 13.56±2.4.2ng/ml (p=0.005).

25(OH)D concentration negatively correlated with age (r=-0.27), BMI (r=-0.31) and waist circumference (r=-0.29) in studied group. Patients with normoglycaemia had a significantly higher 25(OH)D concentration than those with glucose intolerance and type 2 diabetes (p=0.02 (Table 4)). Moreover, in patients with type 2 diabetes and glucose intolerance 25(OH)D concentration correlated negatively with serum glu-

cose level (r=-0.29) and TG concentration (r=-0.31), and positively with HDL level (r=0.27). Such relations were not observed in the group of patients with normoglycaemia.

Table 4. Mean 25(OH)D concentration with respect to sex and carbohydrate metabolism disorders

Females (n=40)	Males (n=56)	All (n=96)	p
10.7±2.6	13.5±4.2	12.9±3.1	0.12
NG (n=55)	IGT (n=17)	T2D (24)	p
19.2±4.7	11.3±4.2	8.6±1,7	0.02

Discussion

Epidemiologic studies show that cardiovascular system diseases are the main cause of deaths in industrialised countries, and in developing countries rate of deaths due to these diseases will increase [11]. Recent data indicates that acute cardiovascular syndromes NSTEMI occur more often than STEMI [12], and mortality in both groups is similar [13,14,15]. The inflammatory process is a factor that initiates atherosclerotic plague rupture and development of acute coronary syndrome. Other factors include vitamin D deficiency and hyperglycaemia which is a strong predictive factor of death in NSTEMI patients, and persistent increased fasting blood glucose level indicate poor prognosis [16,17].

In the conducted study it was proved that patients with ischemic heart disease have lower than recommended plasma 25(OH)D level, and in none of the patients the optimal level was observed. Whereas, a significantly lower 25(OH)D concentration was recorded in the group of patients with acute coronary syndrome NSTEMI. Seasonal variations in 25(OH)D concentration were found and the lowest values were recorded in the first quarter of the year. There was also a relation shown between disturbed carbohydrate metabolism and lipid profile and low 25(OH)D concentration. Moreover, the risk of 25(OH)D deficiencies in the studied

types of ischemic heart disease was estimated, and the highest predictive values were observed in the group of NSTEMI patients.

In many studies it has been proven that vitamin D deficiencies are a common phenomenon occurring in many populations, particularly among obese people with metabolic disturbances and circulatory system diseases [18,19,20], despite the general awareness of recommended vitamin D supplementation, particularly in autumn and winter seasons [21,22]. It has not been clearly defined yet what 25(OH)D concentration may be considered optimal. In European populations the established recommended range is 30-50 ng/ml [22]. According to Polish and European recommendations 25(OH)D level of 20-30 ng/ml is considered as hypovitaminosis (suboptimal concentration), whereas below 20 ng/ml is defined as vitamin D deficiency in the body [22,23]. Global recommendations are less restrictive – vitamin D concentration below 10 ng/ml is regarded as deficiency [6]. In the conducted study we observed too low 25(OH)D concentration in all the patients with ischemic heart disease, and in over 50% of the subjects the concentration was below 20 ng/ml. These results correspond to those obtained by other researchers [4,23]. It must be emphasised that very low 25(OH)D concentration occurred significantly more often in the group of NSTEMI patients than among those with STEMI and stable angina pectoris. The results were not confirmed in De Metrio study in which no differences in 25(OH)D concentration were identified between STEMI and NSTEMI patients [24].

Despite very low 25(OH)D concentrations in the patients, seasonal variations were found with the highest level being recorded in the first quarter of the year (January-March). Variations in 25(OH)D concentration depending on seasons of the year were confirmed by many studies [2,25,26]. It is particularly evident in Northern countries where sunshine exposure, especially in autumn and winter, is insufficient for vitamin D synthesis in the skin. It may be particularly important for people with a high risk of cardiovascular diseases, mainly the elderly, in whom a decreased vitamin D synthesis in the skin may be expected.

In literature, many epidemiologic studies, both Polish and European, indicate very common occurrence of 25(OH)D deficiencies [27,28,29], particularly in patients with cardiovascular diseases [3,5,23,30]. Among factors increasing the risk of vitamin D deficiencies there are being a representative of dark-skinned ethnic groups, a distance of one's place of living from the equator, obesity or being female [3,4,31]. However, in the conducted study this data was not confirmed. Females had lower 25(OH)D concentrations than males but those differences were not statistically significant. Due to the fact that the group was not very diversified in respect of nutrition level (all the patients were overweight or obese), it was not possible to estimate the impact of this factor vitamin D nutrition.

On the other hand, a negative correlation was shown between 25(OH)D and TG concentrations and a positive correlation with HDL level. Moreover, a significant relation was found to exist between diabetes occurrence and glucose intolerance and 25(OH)D concentration, which corresponds to the results obtained by other researchers [4,32]. The patients suffering from diabetes and glucose intolerance had lower 25(OH)D concentrations than those with normal glucose level. Diabetes and glucose intolerance are common in patients with ischemic heart disease, nevertheless, it has not been established yet whether vitamin D deficiency affects carbohydrate metabolism and whether vitamin D supplementation may improve it. Regardless of vitamin D mechanism of action analysed in the light of carbohydrate metabolism balance, it appears necessary to monitor vitamin D nutrition in these patients.

Vitamin D plays an important role in cardiovascular diseases prophylaxis, among others by regulating arterial blood pressure, insulin sensitivity or condition of blood vessels. Many studies confirmed a strong relation between vitamin D deficiencies and a high risk of cardiovascular diseases resulting both from modification of known risk factors as well as a direct impact on the vascular endothelium. Although there is still a need to conduct further studies on the relation of vitamin D with incidence and mortality due to cardiovascular diseases and many other

conditions, vitamin D deficiencies should be regarded as a significant threat to public health.

Conclusion

A non-supplemented well-balanced diet does not significantly affect plasma 25(OH)D concentration. Occurrence of vitamin D deficiencies in patients with ischemic heart disease should be regarded as an independent factor increasing the risk of cardiovascular diseases.

References

1. Ford ES, Ajani UA, McGuire LC, Liu S. Concentrations of serum vitamin D and the metabolic syndrome among U.S. adults. Diabetes Care 2005; 28(5): 1228-1230. https://doi.org/10.2337/diacare.28.5.1228.

2. Muscogiuri G, Sorice GP, Ajjan R, Mezza T, Pilz S, Prioletta A et al. Can vitamin D deficiency cause diabetes and cardiovascular diseases? Present evidence and future perspectives. Nutr Metab Cardiovasc Dis 2012; 22(2): 81-87.

3. Lips P. Vitamin D status and nutrition in Europe and Asia. J Steroid Biochem Mol Biol 2007; 103(3-5): 620-625.

4. Tokarz A, Kuśnierz-Cabała B, Kuźniewski M, Gacoń J, Mazur-Laskowska M, Stępień EŁ. Seasonal effect of vitamin D deficiency in patients with acute myocardial infarction. Kardiol Pol 2016; 74(8): 786-792. https://doi.org/10.5603/KP.a2016.0002.

5. Skaaby T, Husemoen LL, Pisinger C, Jørgensen T, Thuesen BH, Fenger M et al. Vitamin D status and changes in cardiovascular risk factors: a prospective study of a general population. Cardiology 2012; 123(1): 62-70. https://doi.org/10.1159/000341277.

6. Huotari A, Herzig KH. Vitamin D and living in northern latitudes: an endemic risk area for vitamin D deficiency. Int J Circumpolar Health 2008; 67(2-3): 164-178.

7. Płudowski P, Karczmarewicz E, Bayer M, Carter G, Chlebna-Sokół D, Czech-Kowalska J et al. Practical guidelines for the supplementation of vitamin D and the treatment of deficits in Central Europe – recommended vitamin D intakes in the general population and groups at risk of vitamin D deficiency. Pol J Endocrinol 2013; 64(4): 319-327.

8. Jarosz M. Standards of Human Nutrition. Warsaw: National Food and Nutrition Institute; 2012.

9. Szponar L, Wolnicka K, Rychlik E. Album of photographs of food products and dishes. Warsaw: National Food and Nutrition Institute; 2000.

10. Kunachowicz H, Nadolna I, Przygoda B, Iwanow K. Charts of nutritive values of products and foods. Third edition expanded and updated. Warsaw: PZWL; 2005.

11. Murray CJ, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. Lancet 1997; 349: 1498-1504.

12. Yeh RW, Sidney S, Chandra M, Sorel M, Selby JV, Go AS. Population trends in the incidence and outcomes of acute myocardial infarction. N Engl J Med 2010; 362(23): 2155-2165. https://doi.org/10.1056/NEJMoa0908610.

13. Mandelzweig L, Battler A, Boyko V, Bueno H, Danchin N, Filippatoset G et al. The second Euro Heart Survey on acute coronary syndromes: characteristics, treatment and outcome of patients with ACS in Europe and Mediterranean Basin in 2004. Eur Heart J 2006; 27(19): 2285-2293.

14. Savonitto S, Ardissino D, Granger CB et al. Prognostic value of the admission electrocardiogram in acute coronary syndromes. JAMA 1999; 281(8): 707-713. https://doi.org/10.1001/jama.281.8.707.

15. Lindahl B, Toss H, Siegbahn A, Venge P, Wallentin L. Markers of myocardial damage and inflammation in relation to long-term mortality in unstable coronary artery disease. FRISC study group. Fragmin during instability in coronary artery disease. N Engl J Med 2000; 343(16): 1139-1147.

16. Aronson D, Hammerman H, Suleiman M, Markiewicz W. Usefulness of changes in fasting glucose during hospitalization to predict long-term mortality in patients with acute myocardial infarction. Am J Cardiol 2009; 104(8): 1013-1017. https://doi.org/10.1016/j.amjcard.2009.05.053.

17. Suleiman M, Hammerman H, Boulos M, Kapeliovich MR, Suleiman A et al. Fasting glucose in an important independent risk factor for 30-daymortality in patients with acute myocardial infarction: a prospective study. Circulation 2005; 111(6): 754-760.

18. Muldowney S, Lucey AJ, Paschos G, Martínez JA, Bandarra N, Thorsdottir I et al. Relationship between vitamin D status and cardio-metabolic risk factors in young European adults. Ann Nutr Metab 2011; 58(2): 85-93. https://doi.org/10.1159/000324600.

19. Tamer G, Mesci B, Tamer I, Kilic D, Arik S. Is vitamin D deficiency an independent risk factor for obesity and abdominal obesity in women? Endokrynol Pol 2012; 63(3): 196-201.

20. Vacek JL, Vanga SR, Good M, Lai SM, Lakkireddy D, Howard PA. Vitamin D deficiency and supplementation and relation to cardiovascular health. Am J Cardiology 2012; 109(3): 359-363. https://doi.org/10.1016/j.amjcard.2011.09.020.

21. Ribeiro Mandarino N, das Chagas Monteiro F, Leal Salgado JV, Lages JS, Filho NS. Is vitamin D deficiency a new risk factor for cardiovascular disease? Open Cardiovasc Med J 2015; 9: 40-49. https://doi.org/10.2174/1874192401509010040.

22. Płudowski P, Grant WB, Bhattoa HP, Bayer M, Povoroznyuk V, Rudenka M et al. Vitamin D status in Central Europe. Int J Endocrinol 2014; 589587. https://doi.org/10.1155/2014/589587.

23. Goleniewska B, Kacprzak M, Zielińska M. Vitamin D level and extent of coronary stenotic lesions in patients with first acute myocardial infarction. Cardiol J 2014; 21(1): 18-23. https://doi.org/10.5603/CJ.a2013.0048.

24. De Metrio M, Milazzo V, Rubino M, Cabiati A, Moltrasio M, Marana I et al. Vitamin D plasma levels and in-hospital and 1-year outcomes in acute coronary syndromes. Medicine 2015; 94(19): e857. https://doi.org/10.1097/MD.0000000000000857.

25. Lee JH, O'Keefe JH, Bell D, Hensrud DD, Holick MF. Vitamin D deficiency an important, common, and easily treatable cardiovascular risk factor? J Am Coll Cardiol 2008; 52(54): 1949-1956. https://doi.org/10.1016/j.jacc.2008.08.050.

26. Lee JH, Gadi R, Spertus JA, Tang F, O'Keefe JH. Prevalence of vitamin D deficiency in patients with acute myocardial infarction. Am J Cardiol 2011; 107(11): 1636-1638. https://doi.org/10.1016/j.amjcard.2011.01.048.

27. Forrest KYZ, Stuhldreher WL. Prevalence and correlates of vitamin D deficiency in US adults. Nutr Res 2010; 31(1): 48-54. https://doi.org/10.1016/j.nutres.2010.12.001.

28. Lu L, Yu Z, Pan A, Hu FB, Franco OH, Li H et al. Plasma 25-hydroxyvitamin D concentration and metabolic syndrome among middle-aged and elderly Chinese individuals. Diabetes Care 2009; 32(7): 1278-1283. https://doi.org/10.2337/dc09-0209.

29. Hyppönen E, Power C. Hypovitaminosis D in British adults at age 45 y: nationwide cohort study of dietary and lifestyle predictors. Am J Clin Nutr 2007; 85(3): 860-868.

30. Pera Ł, Sygitowicz G, Białek S, Łukaszkiewicz J, Sitkiewicz D. Vitamin D and statins: action in preventing cardiovascular events. Kardiol Pol 2012; 70(12): 1296-1298.

31. Schierbeck LL, Rejnmark L, Tofteng CL, Stilgren L, Eiken P, Mosekildeet L et al. Vitamin D deficiency in postmenopausal, healthy women predicts increased cardiovascular events: a 16-year follow-up study. Eur J Endocrinol 2012; 167: 553-560.

32. Verdoia M, Schaffer A, Barbieri L, Di Giovine G, Mariono P, Suryapranata M et al. Impact of gender difference on vitamin D status and its relationship with the extent of coronary artery disease. Nutr Metab Cardiovasc Dis 2015; 5(25): 464-470. https://doi.org/10.1016/j.numecd.2015.01.009.

Journal of Health Study and Medicine
2020, No. 1
pp. 23-44
DOI 10.36145/JHSM2020.02

The Impact of Oscillatory Vibrations on Lymphoedema of the Lower Limbs

Anna Pęczkowska[1]

[1] Institute of Health Sciences, University of Social Sciences, Lodz, Poland

Address for correspondence

Anna Pęczkowska
Opolczyna 21D/30
92-417 Lodz, Poland
e-mail: a.peczkowska@wp.pl

Abstract

Introduction: *According to WHO studies, over 300 million people worldwide suffer from oedema [1]. It is estimated that in Poland the number of patients with lymphoedema is about 300,000 [2]. In the majority of the cases the lymphoedema turns into chronic incurable disease which requires constant control and treatment. In the case of lower limbs, the oedema is often associated with other chronic diseases, e.g. diabetes, severe obesity or chronic venous insufficiency. In such cases, it is very important for the patient to understand the cause of the oedema, the irreversibility of the changes, and the fact that the therapy will be necessary for the rest of their life. Unfortunately, the lack of proper and comprehensive treatment results not only from insufficient awareness and patient's knowledge, but also from the limited possibilities of public health care.*

Objectives: *The aim of the study was to determine the impact of oscillatory-cycloid vibrations (OCV) on the 1st and 2nd degree oedema of the lower limbs.*

Material and methods: *The study involved 47 patients who developed first- and second-degree oedema. Patients underwent 10 oscillatory-cycloid vibrations treatments for 5 consecutive days. Their G1 and G2 circumferences were measured before and after therapy and filled in a questionnaire.*

Results: *Measurements of lower limb circumferences at the ankle and calf have decreased: average circumference of the left ankle from 27.04 cm to 25.3 cm and average circumference of the right ankle from 26.81 cm to 25.36 cm, while the average circumference of the left calf from 41.36 cm to 39.15 cm and average right calf circumference from 40.89 cm to 39.11. 78.7% of patients experienced a reduction in oedema, 42.6% noticed smaller cramps in their limbs, and 38.3% of patients declared feeling lighter in their legs.*

Conclusions: *1. Oscillating-cycloid vibration treatment can be an effective method of reducing the first- and second-degree oedema. 2. Vibration therapy*

can be used as a method supporting the treatment of oedema in patients with peripheral circulatory insufficiency or can be used as secondary prevention to maintain the effects after the phase of maximum oedema reduction. 3. The subjective feelings of patients confirm the effectiveness of the performed procedures.

Key words: *lymphoedema, venous insufficiency of the lower limbs, oscillatory--cycloid vibrations.*

Introduction

Although there is no definite definition of lymphoedema that would be consistent with international consensus, based on existing literature, oedema can be defined as pathological, excessive fluid accumulation in lymphatic vessels and in the extracellular space [1,2]. The problem with congestive lymphatic insufficiency and hence lymphoedema is rarely the result of congenital vascular malformations that usually manifest themselves from early childhood [3].

Most often, oedema occurs due to [4,5]:

1. neoplastic diseases involving lymph nodes and radiation therapy,
2. chronic venous insufficiency (30% of cases of oedema are due to deep vein thrombosis),
3. surgical procedures and injuries,
4. viral, bacterial and parasitic infections.

Chronic venous disease is one of the most common vascular diseases. Among the European population, 40-60% of women and 15-30% of men suffer from this disease, while in the Polish population 47% of women and 37% of men showed signs of venous disease. Incidence increases significantly with age [6,7].

The main cause of venous insufficiency is the reduction of venous wall tone and impairment of venous valve function in both deep and superficial vessels.

It causes:

1. development of venous hypertension, which is responsible for the development of pathological changes in the veins and tissues around the vessel,
2. slower venous outflow from the lower limbs,
3. the formation of reflux in the superficial and deep veins, which is further intensified by standing position, warmth, obesity and pregnancy,
4. development of varicose veins and venous ulceration.

Congestive processes in microcirculation and venous hypertension lead to adhesion, migration and activation of leukocytes, which, as a result, damages microcirculation, resulting in excessive capillary permeability. This, in turn, causes swelling of the limbs and impaired tissue nutrition (trophic changes appear in the form of discolouration, inflammation of the subcutaneous tissue and ulceration) [7]. All this consequently leads to functional failure of lymphatic vessels and affects the degeneration of the walls of lymphatic vessels and the overgrowth of their light with protein-cellular material [8].

It is estimated that venous insufficiency is the cause of lymphoedema in about 300 million people worldwide [9].

To diagnose the cause of oedema, a thorough interview, clinical examination along with limb volume measurement and in some cases imaging tests (lymphoscintigraphy, Doppler ultrasound of the venous system) are important [10]. To correctly determine the degree of lymphoedema of the lower limbs, Brunner's classification can be used [11,12]:

1. 1st degree – a slight swelling that covers the foot and lower leg, most often visible at the end of the day and disappearing automatically after the elevation of the limb;
2. 2nd degree – swelling occurs throughout the day and disappears after a night. Stemmer's symptom appears, i.e. thickening of the subcutaneous tissue and skin, which prevents the pinching of the skin fold above the second toe;
3. 3rd degree – permanent oedema, but without deformity of the limb;
4. 4th degree – permanent oedema causing deformities of the limb, skin lesions may appear in the form of: eczema, erysipelas, lymphatic fistulas;
5. 5th degree – called "elephantiasis", is characterised by large swelling, which significantly distorts the lower limb. It is accompanied by thickening of the skin, muscle changes and impaired limb function.

Current medical knowledge and scientific research confirm that the key role in the treatment of lymphoedema is physiotherapy, which should start with the patient's education. Unfortunately, most patients or people at risk of lymphoedema do not have sufficient awareness and knowledge about the disease itself and the risks of not receiving treatment. For this reason, particular attention should be paid to introducing patients with oedema to lymphatic educational and preventive measures to the rehabilitation program. Early treatment prevents the appearance of complications and allows complete reduction of oedema.

One of the basic forms of prevention in cardiovascular failure should be physical activity. Analysing statistical data, it can be said that physical activity after the age of 40 is inversely proportional to the frequency of incidence. Cardiovascular insufficiency increases with age, while physical activity decreases at higher age ranges [13]. Reduced physical activity in the elderly may be due to many factors, including co-morbidities characterised by high intensity of pain, which can effectively discourage motor activities. Lack of movement, in turn, intensifies the congestive processes of the lymph and venous systems.

Given the effect of vibration on the circulatory and lymphatic systems in the form of:

- elimination of congestive symptoms,
- reduction of oedema,
- better venous outflow,
- lower blood resistance in the arteries, which facilitates the work of the heart,
- widening of blood vessels and an increase in the speed of blood circulation,
- increased oxygen and nutrient supply to organs,

it can be assumed that oscillatory-cycloid vibrations (OCV) may complement the daily motor activity of patients and may support preventive actions in the field of reducing lymphoedema in people with congestive heart insufficiency.

The aim of this study was to determine whether and to what extent oscillatory-cycloid vibrations (OCV) will affect the reduction of lower limb circumferences in patients with oedema and whether it can be a method used to support primary and secondary oedema prevention in chronic peripheral circulatory insufficiency in the lower limbs.

Material and methods

47 people took part in the study, the vast majority of whom were women (89.4%).

Among the surveyed population, the decisive number of respondents was in the age range of 61-80 years (80.9%). Other age groups were respectively: 18-40 years – 2.1%, 41-60 years – 12.8% and over 80 years – 4.3%.

Prior to the study patients were interviewed to be included or excluded. During the interview, patients were asked about cardiovascular diseases and co-morbidities, as well as co-morbidities, as noted in the survey.

Based on the interview, the study group excluded:

1. patients during treatment and after a history of cancer,
2. people whose oedema was the result of surgery or mechanical injury and the tissues did not fully heal,
3. people who are diagnosed with the acute phase inflammation.

The study included people who had a history of oedema and ailments related to lower limb circulatory system insufficiency. The most common problems that patients declared were: oedema (100%), varicose veins (74.5%), telangiectasias (74.5%), hypertension (55.3%) and cramps (55.3%). Oedema reported by patients was classified as first and second-degree oedema.

Co-morbidities that may affect cardiovascular insufficiency of the lower limbs were diagnosed in the following percentage of respondents: obesity – 25.5%; diabetes – 23.4%.

Patients participating in the study had measurements of lower limb circumferences at levels:

1. G1 – 1st shin, circumference of the lower leg in the thickest place (the results are described as calf measurement)
2. G2 – 2nd shin, measurement just above the ankle (measurement of the ankle joint, but for simplicity the results are described as ankle measurement).

Measurements were made on the first day before starting the therapy and on the last day of therapy after the end of the treatment.

Each patient underwent 10 oscillatory-cycloid vibration treatments on a Vitberg + medical apparatus with an attached specialised module for lower limb massage, which was carried out over the next 5 days. Each treatment lasted 29 minutes and 10 seconds and 2 treatments were performed without a break between them on one day. The operation characteristics of the apparatus in terms of frequency, amplitude and acceleration are presented in Table 1.

The vibration treatment was performed with A program, the characteristics of which are presented in Figure 1 in A1 in accordance with the instructions for use (Figure 2).

Table 1. Parameters of the oscillating-cycloid vibrations

Massage Intensity	Acceleration		Amplitude		Frequency	
	Min [m/s2]	Max [m/s2]	Min [mm]	Max [mm]	Min [Hz]	Max [Hz]
1	0.01	6.9	0.01	0.21	10.1	42.5
2	0.1	10.5	0.01	0.21	10.3	43.6
3	0.1	11.5	0.01	0.21	11.6	47.5
4	0.1	13.5	0.01	0.19	19.3	52.2

Source: Rehabilitacyjny Aparat Masujący Vitberg+. Instrukcja użytkowania. Nowy Sącz: Vitberg; 2016.

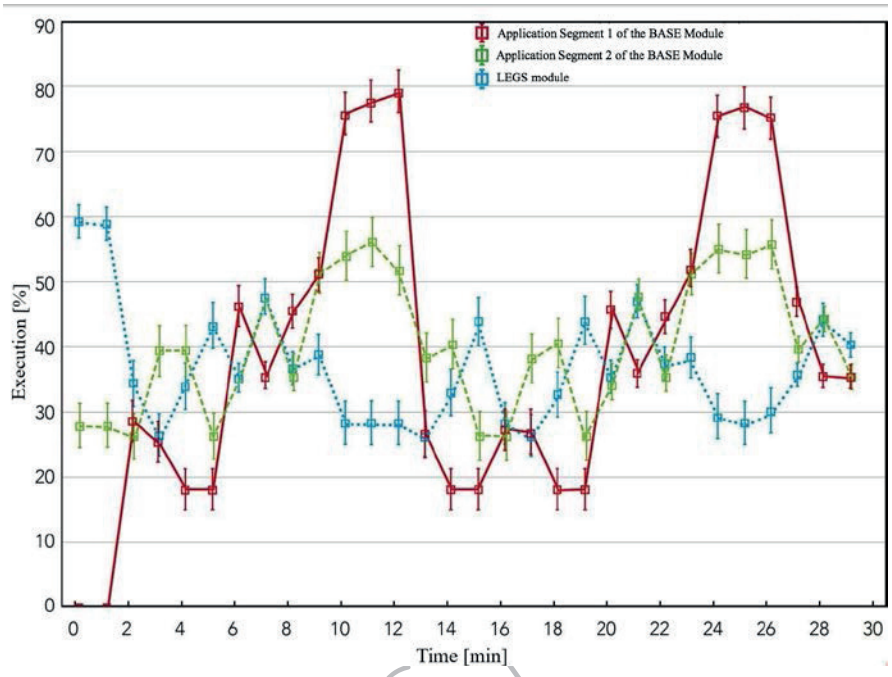

Figure 1. Characteristics of the program A (LEGS) in the Vitberg + apparatus in position A1 [14]

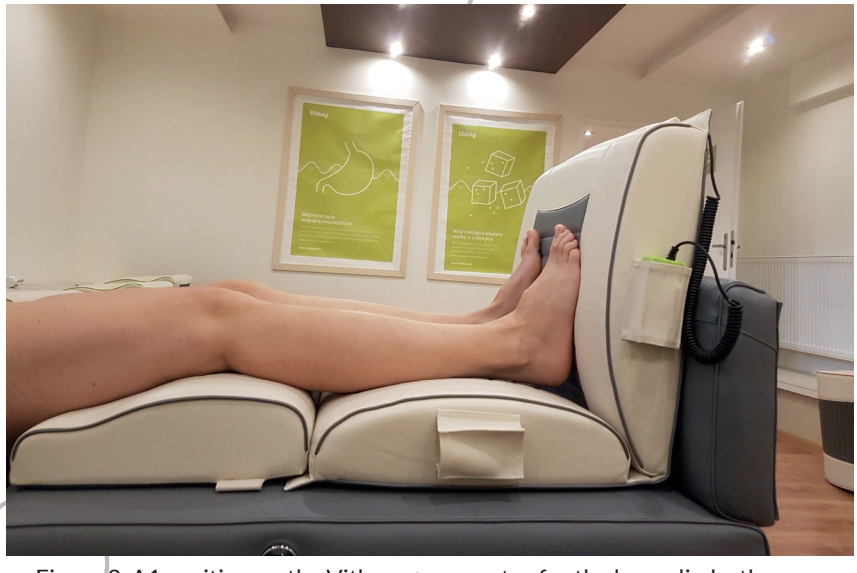

Figure 2. A1 position on the Vitberg + apparatus for the lower limbs therapy

Source: own.

Results

After analysis of the measurement of lower limb circumferences before and after the vibration treatment, it was found that the circumferences are reduced in all four measurements: G1 and G2 left limb and G1 and G2 right limb. The results are presented for each measurement in Tables 2 and 3 separately.

Table 2. Measures of median tendency and dispersion along with the values of t-Student test for dependent samples: circumference of the left calf and ankle – before and after the treatments (N=47)

	Left calf – before treatment	Left calf – after treatment	Left ankle – before treatment	Left ankle – after treatment
Average	41.36	39.15	27.04	25.30
Median	41.00	39.00	27.00	25.00
Standard deviation	3.46	3.09	3.03	2.50
Minimum	36.00	35.00	21.00	21.00
Maximum	52.00	49.00	35.00	30.00
Slant	.798	.833	.271	-.085
Kurtosis	.663	.726	-.273	-.956
t-Student test	t=9.906; p<0.001		t=10.392; p<0.001	

Table 3. Measures of median tendency and dispersion along with the values of t-Student test for dependent samples: circumference of the right calf and ankle – before and after the treatments (N=47)

	Right calf – before treatment	Right calf – after treatment	Right ankle – before treatment	Right ankle – after treatment
Average	40.89	39.11	26.81	25.36
Median	41.00	39.00	27.00	26.00
Standard deviation	3.39	3.18	2.72	2.44
Minimum	35.00	34.00	22.00	21.00
Maximum	52.00	50.00	34.00	30.00
Slant	.669	.807	.305	-.189
Kurtosis	1.081	1.522	-.357	-1.033
t-Student test	t=8.577; p<0.001		t=7.539; p<0.001	

Analysis of the G1 measurement of the left lower limb (Figure 3):

1. Before the treatments, the average circumference of the patients' left calf was 41.36 cm with a standard deviation of 3.46 cm, with the lowest recorded measurement being 36 cm and the highest 52 cm. The median value is 41 cm. The distribution of measurements obtained was rightwards skewed and had a greater concentration around the middle value than the normal distribution.
2. After the procedures, the average circumference of the left calf of the subjects was 39.15 cm, the standard deviation was 3.09 cm. The minimum value of the circumference was 35 cm, while the maximum was 49 cm, and the median obtained was 39 cm. The distribution of recorded measurements was rightward skewed and had a greater concentration around the central value than the normal distribution.

Analysis of the G2 measurement of the left lower limb (Figure 4):

1. Before the treatments, the average circumference of the patients' ankle was 27.04 cm with a standard deviation of 3.03 cm, with the lowest recorded measurement being 21 cm and the highest 35 cm.

The middle value is 27 cm. The distribution of measurements obtained was rightward skewed and had a lower concentration around the median value than the normal distribution.

2. The average circumference of the left ankle of the subjects after treatment was 25.3 cm, the standard deviation is 2.5 cm, with a minimum value of 21 cm and a maximum of 30 cm. The median was 25.5 cm. The distribution of measurements obtained was leftward skewed and had a lower concentration around the median value than the normal distribution.

Analysis of the G1 measurement of the right lower limb (Figure 5):

1. Before the treatments, the average circumference of the patients' right calf was 40.89 cm with a standard deviation of 3.39 cm, and the median value was 41 cm. The lowest recorded measurement is 35 cm, while the highest was 52 cm. The distribution of measurements obtained was rightward skewed and had a greater concentration around the median value than the normal distribution.
2. The average circumference of the right ankle of the subjects after treatment was 39.11 cm, the standard deviation is 3.18 cm, with a minimum value of 34 cm and a maximum of 50 cm. The median was 39 cm. The distribution of measurements obtained was rightward skewed and had a higher concentration around the median value than the normal distribution.

Analysis of the G2 measurement of the right lower limb (Figure 6):

1. Before the treatments, the average circumference of the patients' right ankle was 26.81 cm with a standard deviation of 2.72 cm, with the lowest recorded measurement being 22 cm and the highest 34 cm. The median value was 27 cm. The distribution of measurements obtained was rightward skewed and had a lower concentration around the median value than the normal distribution.
2. The average circumference of the right ankle of the subjects after treatment was 25.36 cm, the standard deviation is 2.44 cm, with a minimum value of 21 cm and a maximum of 26 cm. The minimum value is 21 cm, while the maximum is 30 cm. The distri-

bution of measurements obtained was leftward skewed and had a lower concentration around the middle value than the normal distribution.

Analysis by t-Student test for dependent samples showed a significant difference in the case of G1 and G2 measurements for the left and right lower limbs made before and after the treatments.

Based on all 4 measurements, it was noticed that the performed treatments were highly effective in reducing lower limb oedema.

The subjective feelings of patients were also analysed, and it was noticed that the majority of respondents after the treatments noticed a reduction of oedema (78.7%). A relatively high percentage of respondents also felt smaller cramps (42.6%) and had a feeling of lighter lower limbs (38.3%). In turn, 36.2% of respondents noticed warmer feet. The respondents noticed better feeling in the limbs (17%) the least frequently.

To illustrate the results, a photo of the left limb of one of the patients was taken before and after the procedures, as illustrated in Figure 7.

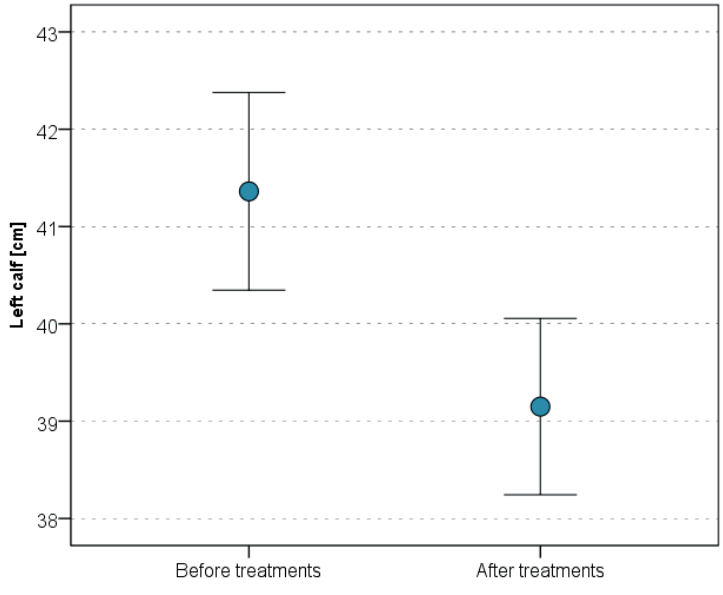

Figure 3. Average with 95% confidence interval: left calf circumference – before and after treatments (N=47)

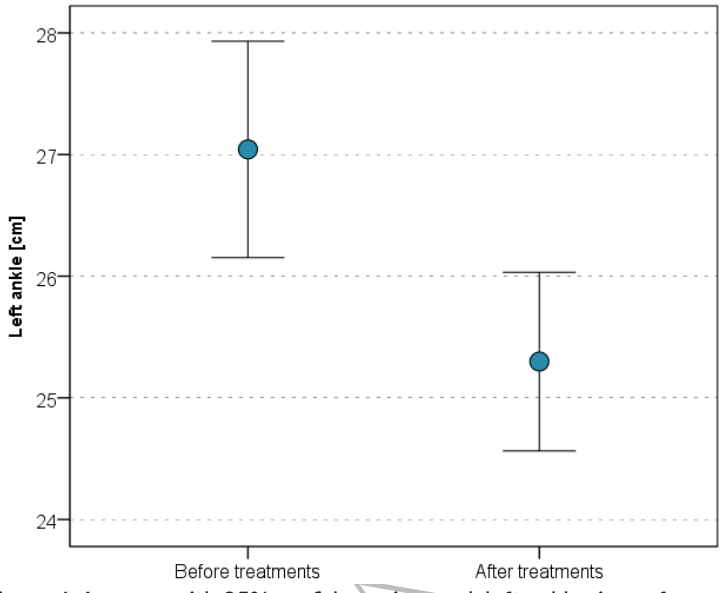

Figure 4. Average with 95% confidence interval: left ankle circumference – before and after treatments (N=47)

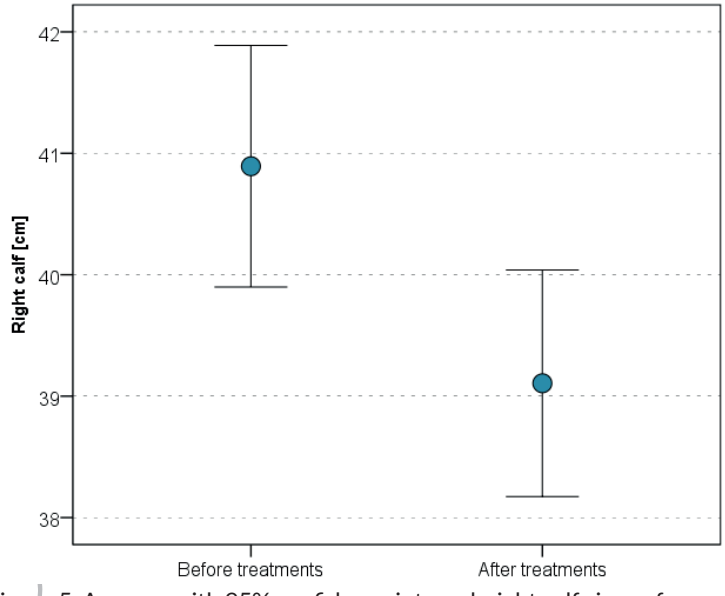

Figure 5. Average with 95% confidence interval: right calf circumference – before and after treatments (N=47)

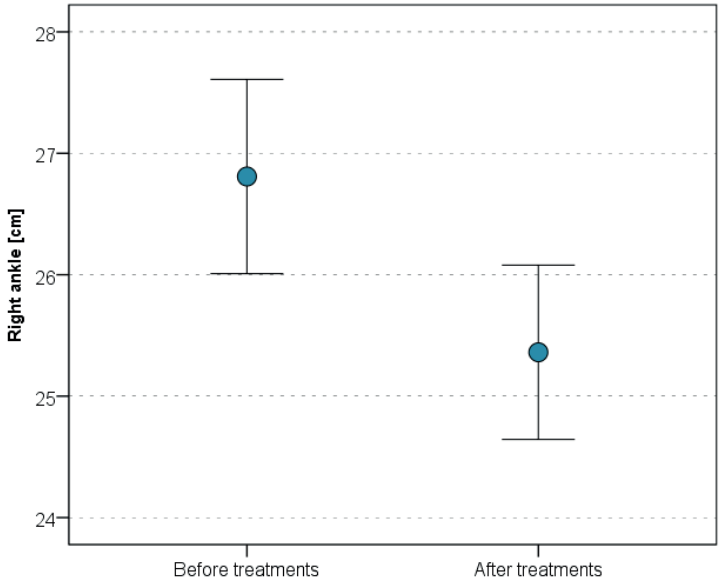

Figure 6. Average with 95% confidence interval: right ankle circumference – before and after treatments (N=47)

Figure 7. Photo of the patient's left lower limb: a – before the vibration treatment, b – after the 10 vibration treatments

Source: own.

Discussion

In the literature there are numerous studies on the effects of vibrations on the cardiovascular system in both healthy people and the elderly who have been diagnosed with cardiovascular insufficiency. The effect of vibrations on the cardiovascular system may have an indirect effect on the lymphatic system, as improving blood flow in the arteries and veins may reduce peripheral circulatory insufficiency and congestive processes, which in turn may reduce the risk of oedema.

Kerschan-Schindl et al. examined 20 healthy adults to assess changes in blood volume in muscles after applying vibrations to the entire muscle. After applying the vibrations, the following effects were achieved: an increase in blood circulation in the calf and thigh muscles, an increase in the average blood flow velocity in the popliteal artery from 6.5 to 13.0 cm/s and its lower resistance index [14].

In turn, Pośpiech et al. in the work "The impact of low-frequency vibrations on selected physiological parameters of athletes" after applying the vibration noticed: a decrease in the value of systolic pressure, a decrease in pulse rate, an increase in body temperature, a decrease in body weight and a decrease in body fat. In their conclusions, the authors pointed out that vibrations increase blood flow due to a decrease in peripheral vascular resistance resulting from greater blood flow through the working muscles that are actively involved in vibration absorption [15].

Similar research was carried out by Z. Damijan who published the results in 2009 in the work entitled: "Trening wibracyjny w rehabilitacji kardiologicznej (Vibration training in cardiac rehabilitation)". During the study, Damijan noticed: in 96% of respondents a decrease in systolic pressure, a decrease in heart rate in 92% of subjects, a lower percentage of body fat in 76% of patients and a lower body weight for all subjects, and a decrease in total cholesterol in 76% of the sample. In addition, he found an increase in temperature in 88% of subjects and an increase in HDL cholesterol in 76% of people participating in the study. The summary states the usefulness of vibration training in cardiac rehabilitation due

to positive effects in the field of hypertension, obesity, atherosclerosis and physical fitness [16].

Among many research works there is also a direct reference to the applied vibration for oedema.

Narin et al. in their work used a device that was designed to produce vibrations similar to the physiological vibrations of the human body, its tissues and organs. These vibrations were called Matrix Rhythm Therapy (MRT). They were used in the case report of a 36-year-old woman with lymphoedema. In the summary, the researchers point out that self-treatment did not effectively reduce oedema, but it can have a positive effect on oedema if it is used for a long time and repeatedly. Researchers also point out that MRT can be combined with compression therapy, which can make a positive contribution to the use of Comprehensive Oedema Therapy [17].

The literature also meets research on the comparison of effects when using manual lymphatic drainage and manual drainage combined with deep oscillations. In 2008, Jahr et al. examined 21 women with secondary lymphoedema of the upper limbs and chest after surgery. They divided them into 2 groups: the first study group (n=11) had 12 manual lymph drainage procedures supplemented with deep oscillations, while the second control group (n=10) had manual drainage alone. Summing up their research, the researchers wrote that the additional deep oscillations complementing manual lymphatic drainage can significantly reduce pain and oedema compared to lymphatic drainage alone [18].

In 2016, Teo et al. also compared the effects of MLD (manual lymphatic drainage) with MLD in combination with deep oscillations, using the HIVAMAT 200 device. The average lower limb volume reduction when using MLD in combination with oscillations was 902 ml, while the average leg volume reduction only for MLD was 707 ml. The study used high resolution ultrasonography to analyse oedema. Researchers concluded that the limbs treated with MLD and deep oscillations showed a much greater reduction in oedema than limbs treated with MLD alone [19].

In the literature, there are also studies on the reduction of oedema after the use of vibrations in other disease entities than circulatory insufficiency in the lower limbs. In "Rheumatology" in 2014 the study of Skopowska et al. was published, who examined 44 people suffering from gonarthrosis. Patients were subjected to vibroacoustic therapy for 15 minutes on a Vitafon-T device, which has a wave frequency from 30 Hz to 18000 Hz and an amplitude of vibrations from 0.0001 to 0.05 mm. They noticed that vibroacoustic therapy had positive analgesic and anti-oedema therapeutic effects, which also improved the functional efficiency of patients [20].

In turn, Vladeva et al. (2018) examined 50 patients with knee joint replacement. For the study, they used Deep Oscillations, which are deep therapeutic oscillations that use tissue vibrations with a minimal external mechanical effect and combined them with kinesiotherapy. During the study, deep oscillations were shown to be effective in reducing inflammation, oedema and pain, and increasing the range of motion in early rehabilitation after knee replacement. The combination of oscillations and appropriate exercises gives better results in terms of the rate of functional regeneration [21].

Other studies that addressed the effect of vibration on the lymphatic system are studies by Stewart et al. who examined 18 women aged 46-63. They used a vibrating platform which they placed on the tilting table footrest using measurements at 0, 15, and 45 Hz. During the study, a change in microvascular filtration under the influence of vibration and an increase in lymphatic flow was observed [22].

The conclusions of the above studies suggest the need for further research and observation of the impact of vibration on the cardiovascular system, including the lymphatic system. The need for research on larger samples and for a long time was also highlighted.

Conclusions

1. The values of the t-Student test for dependent samples to test the effectiveness of the applied procedures testify to the occurrence of a significant difference in measurements of lower limb circumferences made before and after the procedures, which indicates the high effectiveness of the performed procedures in reducing the 1st degree oedema.
2. The subjective feelings of patients confirm the effectiveness of the performed procedures in reducing swelling of the lower limbs.
3. Based on the results obtained, it can be concluded that vibration therapy can be used as a method supporting the treatment of first- and second-degree oedema in patients with peripheral circulatory insufficiency. It can also be used as secondary prevention to maintain effects after the phase of maximum oedema reduction.
4. To confirm the results, further tests should be carried out on a larger sample with 2 groups: test and control with a single blind. It is also worth considering research for a group of patients with 3rd degree lymphoedema.

References

1. Domaszewska-Szostek A. Mechanizm proliferacji i różnicowania keratynocytów w zastoju limfatycznym kończyn dolnych – wpływ cytokin i czynników wzrostu płynu tkankowego/limfy. Warszawa; 2011 [Internet]. Available from: http://rcin.org.pl/Content/16086/WA697_33077_ZS327_Mech-poli-i-roz-Doma_I.pdf.

2. Płoszaj O, Malińska M, Hagner-Derengowska M, Kałużny K. Manual lymphatic drainage with comprehensive anti-diabetic therapy (MLD/CDT) as a method of treatment of lymphoedema – literature review. Journal of Education, Health and Sport 2017; 7(8): 878-893.

3. Grądalski T, Ochałek K. W stronę systemu opieki medycznej w zastoinowej niewydolności chłonnej – głos w dyskusji. Acta Angiol 2013; 19(1): 46-49.

4. Fiodorenko-Dumas Ż, Paprocka-Borowicz M, Dumas I, Kołcz-Trzęsicka A. Jakość życia i stan pacjentów z obrzękiem kończyn dolnych. Medycyna Ogólna i Nauki o Zdrowiu 2012; 18(3): 247-251.

5. Podgórska K, Drożdż K, Bieniek A, Szuba A. Liposuction in the treatment of idiopathic lower extremity lymphoedema. Acta Angiol 2011; 17(4): 271-276.

6. Zubilewicz R, Jaroszyński A. Przewlekła choroba żylna. Forum Medycyny Rodzinnej 2015; 9(5): 400-404.

7. Neubauer-Geryk J, Bieniaszewski L. Przewlekła choroba żylna – patofizjologia, obraz kliniczny i leczenie. Choroby Serca i Naczyń 2009; 6(3): 135-141.

8. Ochałek K, Grądalski T. Postępowanie w profilaktyce i leczeniu zachowawczym obrzęku chłonnego. Medycyna Paliatywna w Praktyce 2017; 11(1): 24-30.

9. Szuba A. Choroby naczyń chłonnych. In: Szczeklik A, ed. Choroby wewnętrzne. Vol 1. Medycyna Praktyczna. Kraków; 2005, pp. 437-440.

10. Kozikowska J, Łuczak J. Obrzęk limfatyczny – patomechanizm, podział, zasady leczenia. Przewodnik Lekarza; 2001 [Internet]. Available from: http://forum-onkologiczne.com.pl/pliki/Obrzek_limfatyczny.pdf.

11. Zborowski A. Masaż klasyczny. Kraków: Wyd. Kasper; 2012.

12. Magiera L. Masaż w kosmetyce i odnowie biologicznej. Kraków: BIO-STYL; 2012.

13. Piekarzewska M, Wieczorkowski R, Zajenkowska-Kozłowska A. Stan zdrowia ludności Polski w 2014 r. Warszawa: Główny Urząd Statystyczny; 2016.

14. Rehabilitacyjny Aparat Masujący Vitberg+. Instrukcja użytkowania. Nowy Sącz: Vitberg; 2016.

15. Kerschan-Schindl K, Grampp S, Henk C, Resch H, Preisinger E, Imhof H. Whole-body vibration exercise leads to alterations in muscle blood volume. Clinical Physiology and Functional Imaging 2001; 21(3): 377-382.

16. Pośpiech S, Czapkowicz-Pośpiech R, Barucha P, Błaszczyk J. Wpływ drgań wibracyjnych o nieskiej częstotliwości na wybrane parametry fizjologiczne sportowców. Aktualne Problemy Biomechaniki 2016; 10.

17. Damijan Z. Trening wibracyjny w rehabilitacji kardiologicznej. Acta Bio-Optica et Informatica Medica 2009; 4(15).

18. Narin AN, Alpozgen AZ, Kulli HD. Effects of matrix rhythm therapy on primary lymphedema: a case report. Journal of Physical Therapy Science 2016; 28(8): 2418-2421.

19. Jahr S, Schoppe B, Reisshauer A. Effect of Treatment with Low-Intensity and Extremely Low-Frequency Electrostatic Fields (Deep Oscillation®) on Breast Tissue and Pain in Patients with Secondary Breast Lymphoedema. Journal of Rehabilitation Medicine 2008; 40(8): 645-650.

20. Teo I, Coulborn A, Munnoch DA. Use of the HIVAMAT® 200 with manual lymphatic drainage in the management of lower-limb lymphoedema and lipoedema. Journal of Lymphoedema 2016; 11(1): 49-53.

21. Skopowska A, Biernacki M, Dekowska M, Ożóg P, Grochowska A. Wpływ terapii wibroakustycznej na stan funkcjonalny osób z gonartrozą. Doniesienie wstępne. Reumatologia 2014; 52(5): 292-298.

22. Vladeva E, Mihaylova M, Bacheva D, Todorov I. Our experience with using Deep Oscillation in early rehabilitation of patients with arthoplasty of the knee joint. Varna Medical Forum 2018; 7(1): 66-70.

23. Stewart JM, Karman C, Montgomery LD, McLeod KJ. Plantar vibration improves leg fluid flow in perimenopausal women. Am J Physiol Regul Integr Comp Physiol 2005; 288(3): R623-9.

Journal of Health Study and Medicine
2020, No. 1
pp. 45-70
DOI 10.36145/JHSM2020.03

Exposure to Environmental Tobacco Smoke and Tobacco-free Homes among Pregnant Women

Michał Szulc[1]
https://orcid.org/0000-0002-0942-3822

Piotr Wojtysiak[1]
https://orcid.org/0000-0002-7462-2246

Jolanta Kałużna[1]

Dorota Kaleta[1]
https://orcid.org/0000-0001-8453-8235

[1] Department of Hygiene and Health Promotion, Medical University of Lodz, Poland

Address for correspondence

Dorota Kaleta
Department of Hygiene and Health Promotion
Medical University of Lodz
7/9 Żeligowskiego Str., 90-752 Lodz, Poland
e-mail: dorota.kaleta@umed.lodz.pl

Abstract

Introduction: *According to the British Medical Association, there is no safe level of exposure to secondhand smoke. Passive smoking can cause difficulties in getting pregnant, low birth weight, and premature births. Children exposed to environmental tobacco smoke have an increased risk of asthma, lower respiratory tract infections, bronchitis, middle ear disease, bacterial meningitis and sudden infant death syndrome, as well as overall reduced respiratory function.*

Aim: *The aim of the study was to assess exposure to passive smoking and to analyze socioeconomic correlations associated with passive exposure to tobacco smoke among pregnant women.*

Material and metods: *A cross-sectional study was conducted among pregnant women receiving antenatal care at the Poviat Health Care Complex in Piotrków Trybunalski in 2018. The research tool was a questionnaire. The study design received a positive opinion of the Bioethics Committee at the Medical University of Lodz RNN/ 386/17/EC of December 19, 2017 and the consent of the head of this unit.*

Results: *Over 30% of the respondents were exposed to passive smoking. The most common exposure was at home (23.5%), at work (22.5%) and in the car (18.8%). Former and current smokers were more likely to be exposed to secondhand smoke (OR=2.09, 95% CI: 1.00-4.38 p<0.05 and OR=19.48 95% CI: 6.53-58, 20 p<0.001). Women whose partner smoked were at more than six times greater risk of exposure to tobacco smoke (OR=6.44 95% CI: 2.57-16.16, p<0.01). Women with very low monthly income were at almost twice the risk of passive smoking (OR=1.66, 95% CI: 1.08-2.81 p<0.05) compared to high-income respondents. Smokers more often lived in homes where complete smoking bans were not introduced (OR=1.71, 95% CI: 1.32-2.21; p<0.001).*

Conclusions: *There is a need for interventions to encourage smoking bans in pregnant homes, together with arrangements enabling policy makers to develop measures to effectively implement interventions to introduce tobacco-free home policies.*

Key words: *passive smoking, pregnancy, socioeconomic status, smoke-free homes.*

Introduction

Passive smoking, also known as exposure to environmental tobacco smoke, is the inhalation of smoke generated by other people during cigarette smoking. The American Environmental Protection Agency (EPA) classifies environmental tobacco smoke as a class A carcinogen (known to man) along with asbestos, arsenic, benzene and radon gas [1]. According to the British Medical Association, there is no safe level of exposure to secondhand smoke [2]. Non-smoking women who are exposed to secondhand smoke during pregnancy are more likely to give birth to children with lower weights [3]. Infants born by non-smoking women whose partners smoke weigh less than babies born by non-smoking couples [4]. Exposure to passive smoking is also significantly associated with preterm labor [5]. Other studies suggest that non-smoking women at risk of secondhand smoke are at greater risk of difficulties in becoming pregnant, premature or stillbirth, miscarriage and childbirth with birth defects [6,7]. In addition, some evidence suggests that female fertility may be impaired during utero if the woman's mother was exposed to secondhand smoke during pregnancy [8]. It was found that exposure to secondhand smoke may also be harmful in terms of successful pregnancy outcomes in women undergoing in vitro fertilization (IVF) or other assisted reproductive technology (ART) [9]. Lack of attention, ability to concentrate and attention deficit hyperactivity disorder have also been associated with exposure to passive smoking at home, in addition to smoking by the mother during pregnancy [10]. Exposure to secondhand smoke at home is strongly associated with middle ear disease in children [11]. Some studies suggest that prenatal and postnatal exposure to tobacco smoke induces leukemia, especially acute lymphoblastic leukemia. In 2010, The Royal College of Physicians published a groundbreaking report entitled "Secondhand smoke and children". The report recognizes the importance of smoking ban legislation in reducing exposure to passive smoking in the workplace but notes that the main source of exposure for non-smokers is home, and children are particularly at risk [12]. The authors conclude

that, secondhand smoke at home poses a serious health risk to millions of UK children living with smokers' and that, secondhand smoke is a significant cause of infant morbidity and mortality'. The report confirms that a child exposed to SHS is at an increased risk of developing asthma, lower respiratory tract infections, bronchitis, ear diseases, bacterial meningitis and sudden infant death syndrome, as well as overall reduced respiratory function [13].

Material and methods

Study was conducted among pregnant women receiving antenatal care at the Poviat Health Care Complex in Piotrków Trybunalski in 2018. The respondents were recruited at the outpatient clinic of the Poviat Health Care Team in Piotrków Trybunalski. The study design received a positive opinion of the Bioethics Committee at the Medical University of Lodz RNN/386/17/EC of December 19, 2017 and the consent of the head of this unit. All women agreed to participate in the study. For women under 18 years of age after obtaining the written consent of a parent or legal guardian were included in the study. The study was conducted from January 2018 to December 2018. The research tool was a questionnaire. The questions in the questionnaire cover the following issues: sociodemographic data, smoking and use of e-cigarettes by both pregnant woman and her partner, smoking intentions, exposure to secondhand smoke.

Results

The study involved 600 pregnant out of 1,326 patients receiving antenatal care at the Poviat Health Care Center in Piotrków Trybunalski in 2018 – the response rate is 45.2%. The detailed characteristics of the subjects are given in Table 1.

Over 30% of respondents were exposed to second hand smoke, 65.5% were not exposed. In the group exposed to passive smoking, 14.3% were non-smokers, 4.2% declared to quit smoking and 16% continued smo-

king during pregnancy (Table 2). Home (23.5%), car (18.8%), work (22.5%) were mentioned as the most common place of exposure, 28% of respondents indicated another place (Table 3). The average number of hours of exposure to tobacco smoke was 5.1±3.4/day, which gives 35.5±23.9 hours per week. Complete regulations regarding smoking ban were adopted only in 26.3% (n=158) of the study participants. The respondents were also asked how often tobacco is smoked in their homes, regardless of the smoking ban: at least once a week, at least once a month, less often than once a month, 10.0%, 21.3%, 32.5 %, 14.7%, 21.5% of respondents respectively (Table 4).

Passive exposure to tobacco smoke was significantly associated with factors such as respondent smoking status, education, employment, living with a smoking partner, and monthly income per family member. Former and current smokers were significantly more likely to be exposed to secondhand smoke OR=2.09, 95% CI: 1.00-4.38 p<0.05 and OR = 19.48 95% CI: 6.53-58, 20 p<0.001. The probability of passive exposure to tobacco smoke in pregnant women with basic education was three times higher (OR=2.91, 95% CI: 1.17-7.21, p<0.05) compared to people with higher education. Women who are not working because of taking care for a child or other family member have a higher risk of passive smoking compared to those who are active (OR=1.12, 95% CI: 1.11-2.84 p<0.01). Compared with women living with a non-smoking partner, those whose partner smoked were at more than a six-fold greater risk of passive exposure to tobacco smoke (OR=6.44 95% CI: 2.57-16.16, p<0.01). In addition, women declaring a very low monthly income below PLN 700 were at almost twice the risk of passive smoking (OR=1.66, 95% CI: 1.08-2.81 p<0.05) compared to respondents whose income exceeded 2000 PLN per month (Table 5).

In comparison with non-smokers, smokers more often lived in homes where complete smoking bans were not introduced (OR=1.71, 95% CI: 1.32-2.21; p<0.001). Odds ratios (OR) and 95% confidence intervals (CI) for not introducing a total smoking ban at home have shown that respondents who were unaware of the risks of exposure to ETS had a much gre-

ater chance of not entering a smoking ban at home compared to people who are aware of such threats (OR=1.28, 95% CI: 1.00-1.65, p<0.05). Other variables in the analysis were not significantly associated with the lack of introduction of smoke-free home rules (Table 6).

Discussion

In the study of Adamek et al. 32% of pregnant women were exposed to secondhand smoke [14]. In his subsequent works, Adamek also shows that exposure to passive smoking occurs in 30% of pregnant women, especially in their place of residence [15]. Similarly, in Jędrzejczyk's study, 32% of non-smoking pregnant women were exposed to secondhand smoke [16]. Bilar et al. noted that just over a half of pregnant women were not exposed to tobacco smoke. On the other hand, non-smoking but passively exposed women constituted about 19% of the respondents [17]. A study by Do et al. showed that 23% of pregnant women were exposed to tobacco smoke [18]. In a study by Balwicki et al. from 2007, it was observed that about 45% of pregnant women were exposed to secondhand smoke. In this group, 31.4% were non-smokers, 14.9% declared smoking cessation during pregnancy, and 30.7% respectively continued smoking during pregnancy. Pregnant women indicated home as the main place of exposure – home, then public places and the workplace in third place [19]. In 2017, 12% of Poles admitted that in their homes there was permission to smoke tobacco without any restrictions. About 7% of respondents declared that cigarettes were smoked in their homes in locked rooms designated for this purpose. In about 20% of the respondents' homes, tobacco was smoked, but only outside, e.g. on a terrace or balcony. About 87% of smokers said they smoke at home. In addition, around 36% of them said they smoke without any restrictions, i.e. all over the house. In 76% of homes of non-smoking respondents, smoking was strictly forbidden. In addition, 13% of Poles indicated exposure to passive smoking in their place of residence. The smoking percentage of women exposed to tobacco smoke at home was 22%, and men 27%. While

11% non-smoking women and 8% non-smoking men were exposed to secondhand smoke. The results from all previous editions of the study carried out by Kantar Public show that the percentage of people exposed to secondhand smoke in their workplace in the last few years has been systematically decreasing from 14% in 2009 to about 8% in 2013-2017. Admittedly in 2015 there was an increase in the frequency of exposure to passive smoking in the workplace, but in 2017 its level returned to the level of 2013 – 8%. The percentage of households in which a total smoking ban was introduced was relatively low and only 26.3% of pregnant respondents residing in the Piotrków poviat declared introducing a smoking ban at home. Earlier data based on the GATS survey conducted in 2009-2010 say a percentage of 37.1%. As with ETS exposure, there is no previous comparative data covering rural population or current surveys available for the entire population that would illustrate the total percentage of households with total smoking ban. Passive exposure of pregnant women to tobacco smoke was significantly associated with factors such as the status of smoking respondents, education, employment, living with a smoking partner, monthly income per family member. The following features were associated with the lack of a complete ban on smoking in the place of residence: smoking status, education, concern about the harmfulness of smoking to the fetus, trimester of pregnancy. Analyzes based on the results of previous studies also showed significant relationships regarding smoking at home, i.e. smoking and lack of awareness about the risks associated with ETS exposure. Stronger relationships, e.g. permitting smoking in the homes of smokers (compared to non-smokers) seem obvious and confirmed by other research in this field [20,21]. In the study by Milcarz et al. overall 19.4% of respondents were exposed to ETS at home, including 17.1% men and 20.4% women. In the non-smoking group 15.5% of respondents (6.6% men and 18.3% women) were exposed to ETS at their place of residence ($p<0.0001$). In the smokers group 25.0% of respondents (25.1% men and 25.5% women) were exposed to ETS in the last month ($p>0.05$). However, total smoking bans were adopted by 22.1% of study participants. In the non-smoking group 25.5% of respon-

dents implemented a total ban on smoking in their place of residence. Among smokers 16.5% of respondents (17.3% men and 15.9% women) implemented a complete smoking ban at home [22]. In Poland, Kaleta et al. showed that at the smokers' home the risk of not introducing a total smoking ban was twice as high compared to non-smokers [20]. Similarly, Heck et al. showed that the introduction of a complete smoking ban at home is correlated with the household's smoking status and the demographic characteristics of respondents [23]. In the study of Kaleta et al., the lack of knowledge about negative health effects related to passive smoking was an important factor reducing the frequency of introduction of smoking bans at respondents' homes. Respondents who were not aware of the harmful effects of passive smoking were at about twice the risk of not introducing the smoking bans at home, compared with respondents perceiving exposure to passive smoking as harmful [20].

References

1. US EPA. Respiratory health effects of passive smoking. United States Environmental Protection Agency. Washington DC, EPA/600/6-90/006F; 1992.

2. Promoting a tobacco-free society. A summary paper from the BMA board of science; London: British Medical Association; 2015.

3. Urbaniak T, Klejewski A, Sobczyk K. Influence of smoking on pregnancy course and fetal development. Przegląd Lekarski 2015; 72(3): 144-147.

4. Khader YS, Al-Akour N, Alzubi IM, Lataifeh I. The association between second hand smoke and low birth weight and preterm delivery. Matern Child Health J 2011; 15(4): 453-459. https://doi.org/10.1007/s10995-010-0599-2.

5. Mojibyan M, Karimi M, Bidaki R, Rafiee P, Zare A. Exposure to second--hand smoke during pregnancy and preterm delivery. J High Risk Behav Addict 2013; 1(4): 149-153. https://doi.org/10.5812/ijhrba.7630.

6. Hoyt AT, Canfield MA, Romitti PA et al. Association between maternal periconceptional exposure to secondhand tobacco smoke and major birth defects. Am J Obtest Gynecol 2016; 215(5): 613.e1-613.e11. https://doi.org/10.1016/j.ajog.2016.07.022.

7. Nieuwenhuijsen MJ, Dadvand P, Grellier J, Martinez D, Vrijheid M. Environmental risk factors of pregnancy outcomes: a summary of recent metaanalyses of epidemiological studies. Environ Health 2013; 12: 6. https://doi.org/10.1186/1476-069X-12-6.

8. Ye X, Skjaerven R, Basso O et al. In utero exposure to tobacco smoke and subsequent reduced fertility in females. Hum Reprod 2010; 25(11): 2901-6. https://doi.org/1010.1093/humrep/deq235.

9. Penzias AS. Recurrent IVF failure: other factors. Fertil Steril 2012; 97(5): 1033-8. https://doi.org/10.1016/j.fertnstert.2012.03.017.

10. Tiesler CM, Sausenthaler S, Chen ChM et al. Passive smoking and behavioural problems in children: results from the LISA plus prospective birth cohort study. Environ Res 2011; 111(8): 1173-9.

11. Zhou S. Rosenthal DG, Sherman S, Zeikoff J, Gordon T, Weitzman M. Physical, behavioral, and cognitive effects of prenatal tobacco and postnatal secondhand smoke exposure. Curr Probl Pediatr Adolesc Health Care 2014; 44(8): 219-241. https://doi.org/10.1016/j.cppeds.2014.03.007.

12. Milne E, Greenop KR, Scott RJ et al. Parental prenatal smoking and risk of childhood acute lymphoblastic leukemia. Am J Epidemiol 2012; 175(1): 43-53. https://doi.org/10.1093/aje/kwr275.

13. Passive smoking and children. A report of the Tobacco Advisory Group of the Royal College of Physicians. London, RCP; 2010, p. ix.

14. Adamek R, Klejewski A, Urbaniak T et al. Socio-economic determinants of smoking during pregnancy and birth weight of newborns. Przegl Lek 2007; 64(10): 622-625.

15. Adamek R, Anholcer A, Florek E. Zdrowotne konsekwencje czynnej i biernej ekspozycji kobiet ciężarnych na dym tytoniowy – przegląd badań. Ginekol Prakt 2001; 9(3): 30, 32-33.

16. Jędrzejczyk T, Zarzeczna-Baran M, Balwicki Ł. Palenie wśród kobiet ciężarnych w Gdańsku – społeczne uwarunkowania zjawiska. Probl Hig Epidemiol 2006; 87: 264.

17. Bilar M, Baraniak A, Celewicz Z. Nikotynizm wśród kobiet ciężarnych w populacji szczecińskiej. Zdr Publ 1999; 99(9): 307-311.

18. Do EK, Green TL, Prom-Wormley EC, Fuemmeler BF. Social determinants of smoke exposure during pregnancy: Findings from waves 1 & 2 of the Population Assessment of Tobacco and Health (PATH) Study. Prev Med Rep 2018; 12: 312-320. https://doi.org/10.1016/j.pmedr.2018.10.020.

19. Balwicki Ł, Zarzeczna-Baran M, Wierucki Ł et al. Smoking among pregnant women in small towns in Poland. Int J Public Health 2016; 61: 111-118. https://doi.org/10.1007/s00038-015-0735-2.

20. Kaleta D, Fronczak A, Usidame B, Dziankowska-Zaborszczyk E, Makowiec-Dąbrowska T, Wojtysiak P. Implementation of smoke-free homes in Poland. Int J Occup Med Environ Health 2016; 29: 137-148.

21. Nahhas GJ, Braak D, Cummings KM et al. Rules about smoking and vaping in the home: findings from the 2016 International Tobacco Control Four Country Smoking and Vaping Survey. Addiction 2019. https://doi.org/10.1111/add.14579.

22. Milcarz K, Bąk-Romaniszyn L, Kaleta D. Environmental Tobacco Smoke Exposure and Smoke-Free Rules in Homes among Socially-Disadvantaged Populations in Poland. Int J Environ Res Public Health 2017; 14(4): pii: E447. https://doi.org/10.3390/ijerph14040447.

23. Heck JE, Stücker I, Allwright S et al. Home and workplace smoking bans in Italy, Ireland, Sweden, France and the Czech Republic. Eur Respir J 2010; 35: 969-979. https://doi.org/10.1183/09031936.00066809.

Table 1. Characteristics of the study population (n=600)

Characteristic		N	%
Age in years			
	min-max average median	19-41 26 5.6	
	<19	10	1.7
	20-24	120	20.0
	25-29	243	40.5
	30-34	159	26.5
	35-39	65	10.8
	40-44	3	0.5
	45+	0	0.0
Week of pregnancy at the time of the study		$\bar{x}$ 31.5; median 35.0 SD 9.5	
Trimester of pregnancy			
	I trimester	32	2.0
	II trimester	128	15.9
	III trimester	440	82.1
Education			
	basic	129	21.5
	professional	153	25.5
	average	231	38.5
	higher	87	14.5
Currently pregnancy			
	1	270	45.0
	2	210	35.0
	3	85	14.2
	4	20	3.3
	5	10	1.7
	6	5	0.8
Delivery			
	one delivery	270	45.0
	many deliveries	330	55.0

Number of deliveries			
	0	270	45.0
	1	245	40.8
	2	60	10.0
	3	15	2.5
	4	5	0.8
	5	5	0.8
Employment			
	employed	465	77.5
	unemployed	35	5.8
	other	90	15.0
	no answer	10	1.7
Type of work			
	physical work (predominance of physical effort)	180	38.7
	intellectual work (predominance of mental effort)	285	61.3
Marital status			
	married	474	79.0
	single	117	19.5
	widow/divorced	9	1.5
Living with a partner			
	Yes	562	93.7
	No	38	6.3
Subjective income assessment "makes ends meet"			
	with great difficulty	0	0.0
	with difficulty	25	4.2
	with some difficulty	248	41.3
	fairly easy	206	34.3
	easily	88	14.7
	very easy	33	5.5
Monthly income			

	up to 500 PLN	20	3.3
	over 500 to 700 PLN	49	8.2
	over 700 to 1000 PLN	213	35.5
	over 1000 to 1500 PLN	188	31.3
	over 1500 to 2000 PLN	86	14.3
	over 2000 to 2500 PLN	17	2.8
	over 2500 PLN	27	4.5
Subjective assessment of health condition			
	very good	245	40.8
	good	275	45.8
	neither good nor bad	70	11.7
	bad	5	0.8
	very bad	5	0.8
Family help and support			
	at all	30	5.0
	sometimes	110	18.3
	often	85	14.2
	always	375	62.5

Table 2. Exposure to environmental tobacco smoke among pregnant women (N=600)

Exposure to environmental tobacco smoke	N	%
not exposed to secondhand smoke	393	65.5
exposed to secondhand smoke		
- non-smoking during pregnancy	86	14.3
- quit smoking during pregnancy	25	4.2
- continues smoking during pregnancy	96	16.0
Sum	600	100%

Table 3. Passive exposure to tobacco smoke of pregnant women (N=600)

Answer	N	%
Where are you most often exposed to tobacco smoke:		
at work	135	22.5
at home	141	23.5
in the car I travel	113	18.8
other place	168	28.0
No data	43	7.2
Does your husband/partner smoke cigarettes?		
Yes	253	42.2
No	347	57.8
Did your parents smoke cigarettes?		
none of them	124	20.7
only father	195	32.5
only mother	57	9.5
both	224	37,3
Do your friends smoke cigarettes?		
none of them	103	17.2
some of them	422	70.3
most or all of them	75	12.5

Table 4. Implementation of smoking bans at respondent homes (N=600)

Answer	N	%
Which of the following best describes your smoking policy at home?		
smoking is allowed	122	20.3
smoking is prohibited, although there are exceptions to this rule	157	26.2
smoking is completely prohibited	158	26.3
no rules	163	27.2
lack of total protection against tobacco smoke	442	73.7
How often are cigarettes smoked inside your home (regardless of applicable rules)?		
every day	60	10.0
at least once a week	128	21.3
at least once a month	195	32.5
less than once a month	88	14.7
never	129	21.5

Table 5. Odds Ratios (OR) and 95% Confidence Intervals (CI) for passive exposure to tobacco smoke in the studied group (n=600) depending on selected features

Characteristic	Sum (n)	Women exposed to secondhand smoke N=207 (34,5%)		Univariate logistic regression		Multivariate logistic regression [a]	
		n	%	OR	95% CI	OR	95% CI
Age (years)							
19-24	130 (21.7)	59	45.4	1.43	0.78-2.61		
25-29	243 (40.5)	73	30.0	0.74	0.42-1.30		
30-34	159 (26.5)	50	31.5	0.79	0.43-1.43		
35-44	68 (11.3)	25	36.8	1.00	reference		
Smoking status							
never smoking	316 (52.7)	62	19.6	1.00	reference	1.00	reference
smoking in the past	165 (27.5)	49	29.7	1.73*	1.11-2.67	2.09*	1.00-4.38
smoking currently	119 (19.8)	96	80.7	17.10***	10.02-29.17	19.48***	6.53-58.20

Education							
basic	129 (21.5)	55	42.6	3.88***	1.98-7.58	2.91*	1.17-7.21
professional	153 (25.5)	55	35.6	2.93***	1.51-5.67	2.30	0.82-6.47
secondary	231 (38.5)	83	35.9	2.92***	1.55-5.51	1.11	0.46-2.67
higher	87 (14.5)	14	16.1	1.00	reference	1.00	reference
Employment							
employed	465 (78.8)	146	31.4	1.00	reference	1.00	reference
unemployed (seeking and not working)	35 (5.9)	16	45.7	1.84	0.92-3.69	1.04	0.63-1.93
other (does not work because of taking care of a child or other family member)	90 (15.2)	41	45.6	1.82**	1.15-2.90	1.12**	1.11-2.84
Marital status							
married	474 (79.0)	153	32.3	1.00	reference	1.00	reference
single, widow, divorced	126 (21.0)	54	42.8	1.57*	1.05-2.35	1.20	0.62-2.32
Partner smokes							
Yes	253 (42.2)	147	58.1	6.63***	4.56-9.64	6.44**	2.57-16.16
No	347 (57.8)	60	17.3	1.00	reference	1.00	reference

Other people (parents, friends) smoke							
Yes	563 (93.8)	198	35.2	1.69	0.78-3.65		
No	37 (6.2)	9	24.3	1.00	reference		
Household income assessment							
very high	33 (5.5)	12	36.4	1.00	reference		
high	88 (14.7)	31	35.2	0.95	0.41-2.23		
average	206 (34.3)	65	31.5	0.81	0.37-1.76		
low	248 (41.3)	85	34.3	0.91	0.42-1.97		
very low	25 (4.2)	14	56.0	2.23	0.76-6.50		
Income							
very low <700 PLN	69 (11.5)	37	53.6	3.47**	1.51-7.97	1.66*	1.08-2.81
low, above 700 to 1000 PLN	213 (35.5)	71	33.3	1.50	0.71-3.15	1.28	0.74-2.08
average, above 1000 to 1500 PLN	188 (31.3)	55	29.3	1.24	0.58-2.63	1.13	0.69-3.14
high, above 1500 to 2000 PLN	86 (14.3)	33	38.4	1.88	0.83-4.20	1.29	0.39-4.23
very high >2000 PLN	44 (7.3)	11	25.0	1.00	reference	1.00	reference

Subjective health assessment							
very good	245 (40.8)	89	36.3	1.00	reference		
good	275 (45.8)	90	32.7	0.85	0.59-1.23		
neither good nor bad	70 (11.7)	24	34.3	0.91	0.52-1.60		
bad or very bad	10 (1.7)	4	40.0	1.17	0.32-4.27		
Concern about the harmful effects of smoking							
Yes	355 (59.2)	104	29.3	1.00	reference	1.00	reference
No	245 (40.8)	103	42.0	1.75***	1.24-2.46	1.66	0.98-2.81
Concern about the harmful effects of smoking on the fetus							
Yes	293 (48.8)	81	27.6	1.00	reference	1.00	reference
No	307 (51.2)	126	41.0	1.82***	1.29-2.57	1.73	0.97-3.12
Trimester							
I trimester	32 (2.0)	13	40.6	1.48	0.71-3.09	1.10	0.35-3.43
II trimester	128 (15.9)	55	43.0	1.63*	1.09-2.44	1.10	0.60-2.01
III trimester	440 (82.1)	139	31.6	1.00	reference	1.00	reference

Having children							
Yes	270 (45.0)	79	29.3	1.00	reference	1.00	reference
No	330 (55.0)	128	38.3	1.53*	1.09-2.16	1.34	0.75-2.38
The use of e-cigarettes							
in the past	137 (22.8)	58	42.3	1.66**	1.12-2.46	1.04	0.56-1.92
currently	23 (3.8)	14	60.9	3.51**	1.48-8.33	3.52	0.92-13.41
never	440 (73.3)	135	30.7	1.00	reference	1.00	reference

[a] The model includes all statistically significant variables in univariate logistic regression *** p≤0.001 ** p≤0.01 * p ≤0.05.

Table 6. Odds ratios and confidence intervals for not introducing a total smoking ban in pregnant women' places of residence depending on selected features

Characteristic	Sum (n)	No smoking ban N=442 (73,7%)		Univariate logistic regression		Multivariate logistic regression a	
		n	%	OR	95% CI	OR	95% CI
Age (years)							
19-24	130(21.7)	102	78.5	1.86	0.97-3.58		
25-29	243(40.5)	188	77.4	1.75	0.97-3.14		
30-34	159(26.5)	107	67.3	1.05	0.58-1.92		
35-44	68 (11.3)	45	66.2	1.00	reference		
Smoking status							
never smoking	316 (52.7)	223	70.6	1.00	reference	1.00	reference
smoking in the past	165 (27.5)	121	73.3	1.15	0.75-1.75	1.04	0.42-1.63
smoking currently	119 (19.8)	98	82.4	1.95**	1.14-3.31	1.16*	1.02-1.96
Partner smokes							
Yes	253 (42.2)	195	77.1	1.36	1.94-1.98		
No	347 (57.8)	247	71.2	1.00	reference		

Other people (parents, friends) smoke							
Yes	563 (93.8)	420	74.6	2.00**	1.01-3.97		
No	37 (6.2)	22	59.5	1.00	reference	1.00	reference
Education							
basic	129 (21.5)	82	63.6	2.05**	1.18-3.57	1.78*	1.00-3.21
professional	153 (25.5)	125	81.7	5.25***	2.91-9.46	4.65***	2.40-8.93
secondary	231 (38.5)	195	84.4	6.36***	3.66-11.07	6.01***	3.26-11.07
higher	87 (14.5)	40	46.0	1.00	reference	1.00	reference
Employment							
employed	465 (78.8)	336	72.4	1.00	reference		
unemployed (seeking and not working)	35 (5.9)	28	80.0	1.54	0.65-3.61		
other (does not work because of caring for a child or other family member)	90 (15.2)	69	76.7	1.26	0.74-2.14		
Marital status							
married	474 (79.0)	356	75.1	1.14	0.91-2.16		
single, widow, divorced	126 (21.0)	86	68.3	1.00	reference		

Household income assessment							
very high	33 (5.5)	23	69.7	1.00	reference		
high	88 (14.7)	50	56.8	0.57	0.24-1.35		
average	206 (34.3)	153	74.3	1.26	0.56-2.81		
low	248 (41.3)	196	79.0	1.64	0.73-3.66		
very low	25 (4.2)	20	80.0	1.74	0.51-5.96		
Income							
very low <700 PLN	69 (11.5)	53	76.8	2.29**	1.01-5.22	1.08	0.43-2.73
low, above 700 to 1000 PLN	213 (35.5)	170	79.8	2.74**	1.37-5.45	1.27	0.58-2.26
average, above 1000 to 1500 PLN	188 (31.3)	134	71.3	1.72	0.87-3.39	1.21	0.66-2.83
high, above 1500 to 2000 PLN	86 (14.3)	59	68.6	1.51	0.71-3.22	1.14	0.51-2.56
very high>2000 PLN	44 (7.3)	26	59.1	1.00	reference	1.00	reference
Subjective health assessment							
Very good	245 (40.8)	175	71.4	1.00	reference		
Good	275 (45.8)	207	75.3	1.22	0.82-1.80		
Neither good nor bad	70 (11.7)	52	74.3	1.16	0.63-2.12		
Bad or very bad	10 (1.7)	8	80.0	1.60	0.33-7.75		

Concern about the harmful effects of smoking							
Yes	355 (59.2)	271	76.3	1.40	0.97-2.02		
No	245 (40.8)	171	69.8	1.00	reference		
Concern about the harmful effects of smoking on the fetus							
Yes	293 (48.8)	202	68.9	1.00	reference	1.00	reference
No	307 (51.2)	240	78.2	1.61**	1.12-2.33	1.69**	1.12-2.55
Trimester							
I trimester	32 (2.0)	24	75.0	1.27	0.56-2.91	1.54	0.61-3.89
II trimester	128 (15.9)	109	85.2	2.43***	1.43-4.13	2.30**	1.30-4.02
III trimester	440 (82.1)	309	70.2	1.00	reference	1.00	reference
Having children							
Yes	270 (45.0)	195	72.2	1.00	reference		
No	330 (55.0)	247	74.8	1.15	0.79-1.65		
The use of e-cigarettes							
in the past	137 (22.8)	106	77.4	1.31	0.83-2.06		
currently	23 (3.8)	18	78.3	1.38	0.50-3.81		
never	440 (73.3)	318	72.3	1.00	reference		

Journal of Health Study and Medicine
2020, No. 1
pp. 71-91
DOI 10.36145/JHSM2020.04

The Impact of Sound on a Fixed Spectrum and Intensity on Selected Parameters of Stability

Marzena Mańdziuk[1]
https://orcid.org/0000-0001-6204-2335

Blanka Martowska[1]
https://orcid.org/0000-0002-7326-2488

Marlena Krawczyk-Suszek[1]
https://orcid.org/0000-0003-4100-588X

Katarzyna Kubicka[2]

Piotr Szpunar[3]

Krzysztof Kołodziej[3]

Jerzy Bednarski[4]
https://orcid.org/0000-0002-0186-3268

[1] Department of Physiotherapy, Faculty of Medicine, University of Information Technology and Management in Rzeszow, Poland

[2] Medical Center MEDYK in Rzeszow, Outpatient Rehabilitation Specialist, Rzeszow, Poland

[3] University of Rzeszow, Institute of Physiotherapy, Rzeszow, Poland

[4] Department of Human Anatomy, Chair of Human Anatomy, Medical University of Lublin, Poland

Address for correspondence

Marzena Mańdziuk
University of Information Technology and Management in Rzeszow
Department of Physiotherapy
Kielnarowa 386a, 36-020 Tyczyn, Rzeszow, Poland
e-mail: mmandziuk@wsiz.rzeszow.pl

Abstract

Introduction: *Maintaining body balance requires integration of vestibular, proprioceptive and visual information. The effectiveness of postural control system has great importance in humans life – it is an essential condition of security of moving and doing life important activities. Stability disturbances could be a result of individual activity, as well as it could be an effect of interaction with the environment.*

The aim of this study was to assess an influence of auditory stimuli on selected parameters of body stability, which was measured among young, healthy and physically active subjects.

Methods: The research was carried out on a group of 60 people; aged 19-25 (21±1,67).

The force platform, Cosmogamma, was used to examine static maintenance of postural stability in variety of auditory conditions (relative silence; with music through headphones; immediately after music exposure).

The analysis of results showed a statistically significant influence of music (with established spectrum) on the following stability parameters: Mean Loading Point (plane X and Y), Average Speed, Lateral Speed and Subtended Area. However, the difference between postural stability of female and male had insignificant influence only (without dependence on auditory conditions).

Key words: *balance, postural stability, posturography, acoustic stimulus, acoustic sensitivity.*

Introduction

The balance control system can be regarded as a control system with three entry points, including: vestibular system, visual system and deep sensory receptors. The obtained information is provided and processed by the central nervous system and then passed to the effector organs – muscles of a trunk and extremities as well as eyeballs, resulting in the posture coordination reactions [1,2,3].

The research showed that for healthy persons, the postural stability in space, in the conditions of even, hard ground, 70% depends on the proprioreceptors located in muscles, tendons, joints and skin. Other systems provide subsequently: 20% (vestibular system) and 10% (visual system) of the information. However, when the ground is changed for uneven, less stable, the key role in the stability control is played by the deep sensory receptors and the visual system over the vestibular system [4,5]. If the information from the proprioreceptors and the visual system is incorrect or it is significantly reduced (e.g. in the situation of standing or walking in the dark, especially on soft and irregular surface), the vestibular system will play the key role in the balance control process [5,6].

In the static posturography, most often the basis to assess balance involves the analysis of small, involuntary movements of the centre of gravity of a body while standing still. These movements i.e. sway of the body, usually cause the view of the centre of gravity oscillate within a radius of a few millimetres to several centimetres. They are usually associated with the change of the position of the centre of gravity (COG), the view of which, in upright posture, is in a small specific area of a supporting surface. This area is approximately 5 cm forward in relation to the lateral malleolus of the ankle joint. Due to the significant cost, time-consuming and low availability of the measurement of oscillation of the centre of gravity of a body, it seems to be beneficial to replace it with a measurement of displacement of the centre of foot pressure (COP). In the case of free standing, the passes of both signals are very close (their compliance is up to 97%), and the sways amplitude is burdened with a negligible error

[2,7,8,9,10,11]. A posturographic platform is a device commonly used in the research of body posture, in static conditions, i.e. a small plate equipped with a set of three or four sensors, recording pressure forces and moments of these forces, exerted by feet to the ground. The supports equipped with these sensors record a displacement of the centre of gravity of a body of a researched person in the platform plane. The value of displacements is automatically subjected to computer analysis, and currently displayed on a monitor. Based on the data obtained, the computer calculates the location of the centre of foot pressure (in static conditions also with the view of the centre of gravity of the body), and its sways are presented in a graphic form, as statokinesiogram. The registration of the centre of feet pressure, executed in time, allows to follow and measure the momentum of sways of the whole body (stabilogram). In order to avoid errors in the interpretation of the data, the computer analysis is applied, taking into account the patient's weight and height. The application of such a processing system allows to calculate a series of parameters: speed of sways of the body, mean sways value, maximum sways amplitude, expanded surface field and Romberg indicators (analysed in the case of two consecutive tests: with open and closed eyes) [12,1,13,14,15].

It was not easy to define standards for posturographic variables. A serious obstacle constitutes a lack of population without postural defects and dysfunctions, because these disorders influence the result of the posturographic research. On the one hand, narrowing of the researched group to persons without any loss prevents from the specification of "standards", and on the other hand, its extension influences the substantial enlargement of the range of variation of the measured parameters.

The purpose of this work is to specify the influence of the acoustic stimuli on selected parameters of stability of standing posture of young, healthy and physically fit persons. The following was assessed: average load point, maximum sway, mean sway, average speed, lateral speed, antero-posterior speed, subtended area, speed area, time within circle R13 and R25 mm.

Materials and methods

The researched group consisted of 60 people: 19 men (31.7%) and 41 women (68.3%) aged 19-25 (average 21±1.67). All people expressed their written consent to the research. The research of balance for the assessment of static posture of a patient was executed on Cosmogamma balance platform (Figure 1). The system consists of a stability-metric platform and a computer connected to it, with a suitable computer program. In addition to the listed equipment, the research stand has a CD player and widely available inner ear canal type earphones (Philips SHE9503). A song, unknown to the researched persons, was used as the auditory stimulus. Spanish lyrics prevented from focusing on the words and singing. A spectral characteristic of the song as a potential source of balance interference was developed at the Institute of Physics, University of Rzeszow (Figure 1).

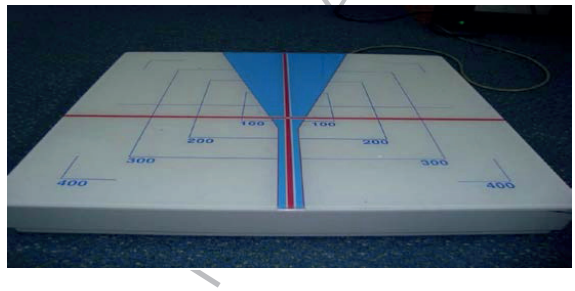

Figure 1. Cosmogamma platform ready for operation

Cosmogamma platform is a system that monitors changes in the position of the centre of foot pressure (CFP) by providing a variety of assessment parameters, such as: graphical representation of the oscillation of the CFP (static-dynamic diaphragm), graphical representation of the oscillation in the antero-posterior direction (static diagram), load distribution and frequency spectrogram based on Fourier analysis (FFT). This device is characterised by high repeatability of executed measurements and is considered a good method for the balance assessment [16]. The stability-metric research was executed in accordance with the recom-

mended methodology. During the first test, the conditions of relative silence were assured. The researched persons stood on the platform barefoot, in upright position, with their hands along a torso and a head towards. Just a few metres away, vertical straps were attached on a wall (Figure 2, Figure 3).

Figure 2. A – Correct positioning of feet, the view from the top. B – Correct positioning of feet, the view from the side

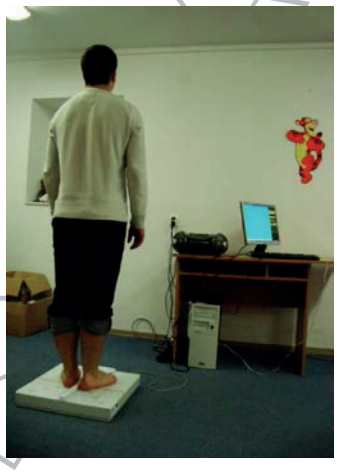

Figure 3. The research stand during the measurement

The computer screen was reversed to prevent from possible visual control of the oscillation of the COP (feedback) during the test. Particular attention was paid to the correct positioning of the patient's feet, the recommended distance of 2 cm between heels was kept, feet were positioned at an angle of 30°, lateral ankles were positioned on the horizontal

red line (Figure 2A, B). The justification of such rigorous compliance with the methodology of positioning is to provide conditions for the accuracy of the measurements, because only if they are met, the centre of gravity of the posture lies in the sagittal axis of the platform. In order to facilitate correct positioning, the form of feet positioning was used. The research stand is shown in Figure 3.

The research procedure included three subsequent tests, which were executed while standing on both feet, with open eyes, in the sagittal plane of the platform. The test period was subsequently: 1 min. (conditions of relative silence), 2 min. (music administered directly into the ear canal by earphones), 1 min. (the earphones in ears, no music). All three tests were executed directly after each other, and the researched persons were each time informed about the beginning and end of the test. In order to assure the repeatability of the method, the scale of the panel sensitivity of all researched persons was the same, i.e. 200 mm. Similarly, the volume of the heard song during the tests with music was the same for all researched persons. Before the measurements were executed, all the participants had been informed about the progress and the appropriateness of the experiment being executed, and the use of its results. In addition, the harmlessness of the executed research was assured.

Research results

The obtained results of the survey and the stability were entered to MS Excel, in which the initial analysis was executed. In order to carry out a thorough analysis, Excel file was imported to Statistica 6.0 PL. In the work, the commonly used methods of descriptive statistics were employed, which allowed to specify the compatibility of the results with the normal distribution. Arithmetic mean, median and standard deviations were calculated. Minimum and maximum values of individual parameters were specified, as well. Mutual relations between the tests were researched using non-parametric tests.

In the researched population, parameter changes were assessed in terms of postural stability during three subsequent tests – in conditions of relative silence, during the operation of the acoustic stimulus, and immediately after stopping. The basis of the assessment involved the parameters generated by the centre of feet pressure on the platform. An original survey was the source of the information on the researched group. The largest portion of the respondents started listening by earphones approximately 2-3 years ago (Figure 4).

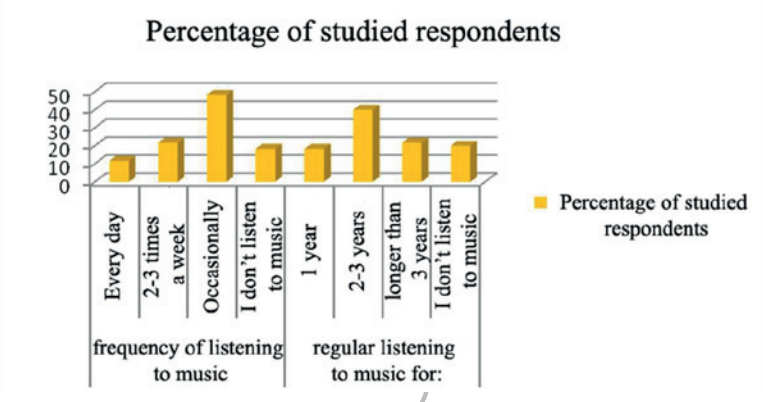

Figure 4. The frequency of listening to music by the respondents

Analysed parameters of posturogram

The non-parametric Wilcoxon matched pairs test was executed in order to specify the relationships between the various parameters.

Null hypothesis – H0: the results of the analysed parameters do not differ. Alternative hypothesis – Ha: the results of analysed parameters are different.

In the research, statistically significant variables were with the significance level of $p=0.05$, $p<0.05$ (Figure 5).

The difference in the mean load point in the lateral plane of the platform between measurement II (with music) and measurement I (condi-

tions of relative peace) is statistically significant (Figure 5). The significance level is equal to 0.04. The mean value of the load point in the lateral plane is higher in the conditions of relative silence (2.62). The sways range of the mean load point in the lateral plane of the platform for the tested group is from 5 mm to 10 mm for measurement I and -5 mm to 5 mm for measurement II (Figure 6).

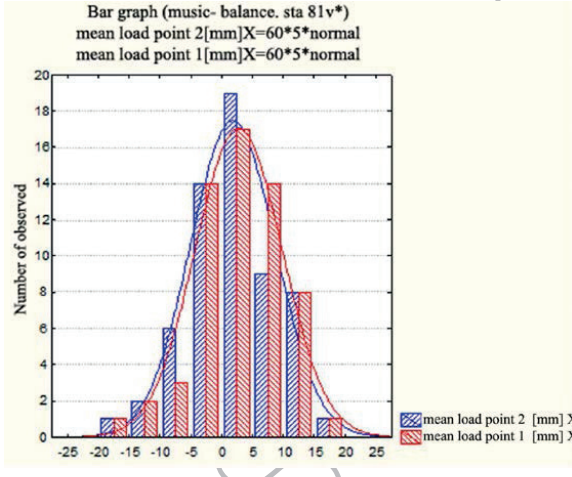

Figure 5. The difference in the mean load point in the lateral plane of the platform between measurement II (with music), and measurement I (conditions of relative silence)

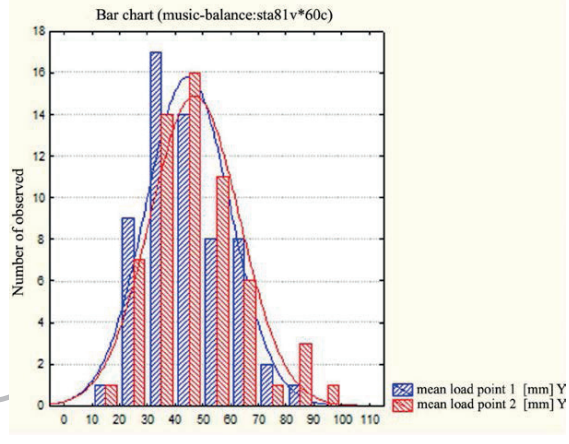

Figure 6. The difference in the mean load point in the anterior-posterior plane, between measurement II (with music), and measurement of I (conditions of relative silence)

The difference in the mean load point in the anterior-posterior plane between measurement II and I is statistically significant (Figure 6). Statistical significance is 0.003. The average value of the analysed parameter is higher in measurement 2 (with music). The sway range of the mean load point in the anterior-posterior plane for the researched group is in the range of 30-50 mm for measurement I and 30-60 mm for measurement II.

The mean value of the average speed of the centre of feet pressure on the ground is slightly higher in measurement I (Figure 7). The range of values for the analysed parameter is from 6 mm to 12 mm for both tests.

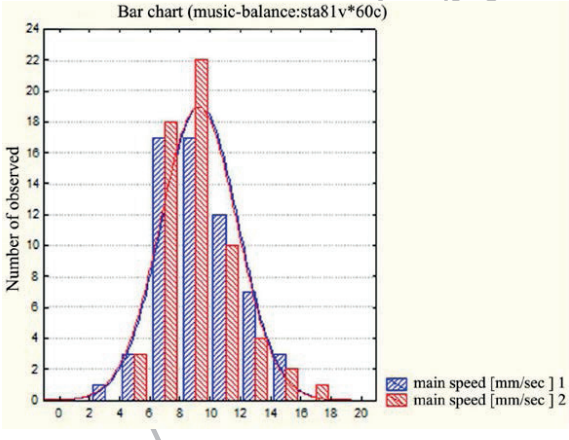

Figure 7. The difference in the average speed between tests I and II

The significance of the difference of the average speed between measurements I and III was measured (Figure 8). It is statistically significant. The significance level is equal to 0.0009. The mean value of the average speed is higher in the group of the researched persons in the conditions of relative silence compared to the group of persons with earphones in their ears, without music played. The range of the analysed parameter for test I is from 6 mm to 12 mm, while in test III: from 6 mm to 10 mm.

The significance of the difference of the average speed between measurements II and III was measured (Figure 9). It is statistically significant for the level of significance equal to 0.03. The mean value of the lateral

speed is higher in the group of the researched persons listening to music compared to the group of persons with earphones in their ears, without music played. The range of the analysed parameter for tests II and III is from 2 mm to 5 mm.

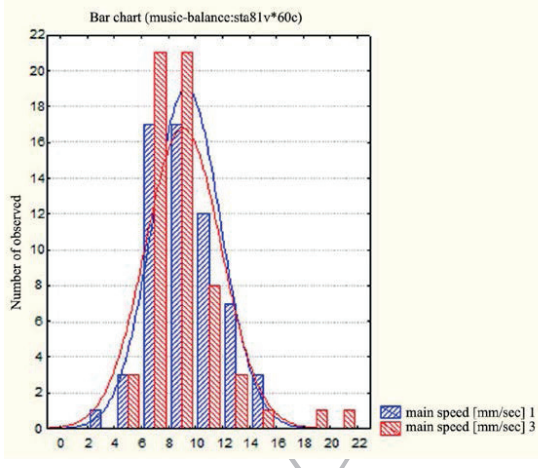

Figure 8. The difference in the average speed between tests I and III

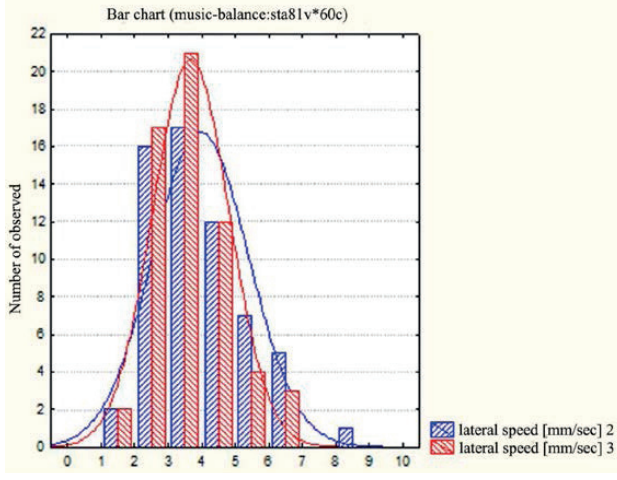

Figure 9. The difference in the lateral speed between measurement I and III

In addition, the difference in the lateral speed in two measurements: in the conditions of relative silence (measurement I) and in the conditions of silence, with earphones in their ears (measurement III) was measured

and illustrated in Figure 10. The mean value of the analysed parameter is higher for the group of persons in the conditions of relative silence. The range of the analysed parameter for measurement I is from 3 mm to 5 mm, while for measurement III: from 2 mm to 5 mm (Figure 10).

As shown in fig. 11, the measurement value of the subtended area is more than twice higher in the conditions of music (8.39) compared to the measurement in the conditions of relative silence (4). This difference is statistically significant for $p=0.000<\alpha$ (Figure 11).

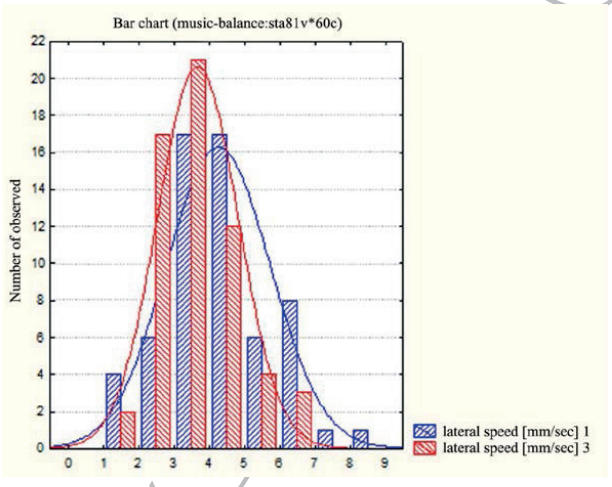

Figure 10. The difference in the lateral speed between measurement I and III

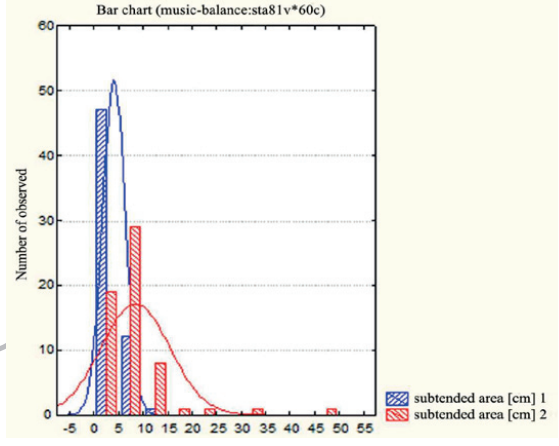

Figure 11. The difference of the subtended area between measurements I and II

In addition, the difference of the subtended area between measurement II and III was measured (fig. 11). In the test with music the mean value of this parameter is 8.39, while in test III: 3.75 (Figure 12).

The significance of any of the researched parameters is not lower than 0.05, that is, none of the parameters depends on gender.

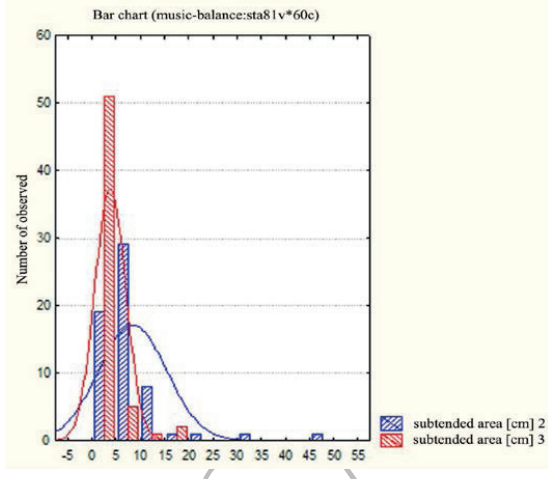

Figure 12. The difference of the subtended area between measurements II and III

Discussion

The smooth operation of the balance control system of a body is important in human life. It allows to safely and securely move and execute important activities. In case of any disturbances of ability to maintain a stable position, the risk of falling and injury increases. For this reason, it is justified to search for factors (extracorpereal and autosomal) influencing on increased and decreased stability. The efficiency of the balance system depends on the cooperation between labyrinth, cerebellum, eye, proprioreceptors located in muscles and joints, and feet touch receptors [2,17]. The constant interaction of various environmental factors, on which a human is exposed, tends to conduct research on their influence on the process of balance control. This work is an attempt of such searches. The most important aspect of the research was to specify the effect of aco-

ustic stimuli on postural stability. The executed research indicates the appearance of the interaction between the acoustic stimuli, and the process of maintaining body stability. The influence of the acoustic stimuli on postural stability is related to the proximity of receptors, i.e. auditory and vestibular in inner ear. Their stimulation can be proved by results of the research the documented by Russolo, in which he observed decreased postural stability under the influence of the acoustic stimuli of high intensity (118.5 dB) and the particular characteristics of frequency (500 Hz) [18]. Similar results for the acoustic stimuli above 100 dB were documented in other works [19,20]. An interesting fact seems to be a positive influence of the acoustic stimuli on the quality control of postural stability. Polechoński stresses its increase under the influence of certain sounds. Based on the executed experiments, he proved that white noise (of continuous, sustainable characteristics of spectrum power) and supporters' applause of a certain intensity (60, 80, 100 dB), shortens the area of the resulting pressure point on the ground. In another research, the author used music as an acoustic stimulus. In this case, he recorded the improved stability in the conditions of exposure to music, as well. Despite the fact that the first and the second research were executed in static conditions, the author suggests that the successfully obtained results can be transferred to the conditions of dynamic stability. The research on motility issues support the thesis [19,20]. Bearing in mind the significant influence of the intensity of the acoustic stimulus on body stability, it seems necessary to specify it exactly. In executed own research, all persons were stimulated with the same music, with the same spectrum. The measurement of the mean intensity and the spectrum frequency is beyond the scope of this work. As it is known, three systems are directly involved in control of posture maintaining: the vestibular system, visual system and deep sensory receptors [2,3]. In addition to these systems, some researchers also emphasise an important role of hearing information coming from the surrounding (audio-feedback) to the process of maintaining stability. The research executed with patients with hearing loss within the vestibular system can prove the aforementioned statement. In order to assess the degree

of relationship between hearing stimuli, and the stability of a body, other control systems (soft ground, limited visual control) were excluded. The only information about the posture sway involved auditory signals, the occurrence of which were the reason for improved postural stability [21]. The experiments executed in recent years suggest another possible interaction between auditory and postural stability – no recorded auditory influence [22]. In the case of own research, one can also observe this trend for selected parameters (no statistically significant difference). A probable cause of such a result can be the fact that the whole researched group consisted of young, healthy persons with high compensation abilities (no balance disorders). The influence of habituation phenomenon seems to be crucial; most researched persons had used earphones for listening to music for a long time, which probably largely excluded balance disorders. Tanaca stresses differences in maintaining balance in the elderly and the young, as a result of operation of the auditory signals. He researched two groups, a group consisted of young people (21.9 years old) and consisted of the elderly (68.9 years old). In the older group, under the influence of "moving" auditory stimuli, he recorded higher sways in the lateral plane than in the representatives of the young. In the light of these results, the author suggested that balance of the elderly largely depends on the auditory information, and therefore it is disrupted under the influence of such signals more easily [23]. An important aspect of the research was to specify the influence of gender on balance parameters. Different acoustic conditions of the tests allowed both to assess the comparative stability of women and men in the conditions of relative silence, and to compare the sensitivity of their posture to acoustic stimuli. Significant differences between postural stability for men and women did not appear, however, in the case of any of the analysed parameters, regardless of the acoustic conditions. Polechoński obtained completely different test results. In the executed experiments with closed and open eyes, in the conditions of relative silence, better stability was a feature typical of women, which was explained with their favourable body proportions [19,20]. However, some authors, pointing to anatomically smaller supporting area of women

than men, do not notice the gender dimorphism in body balance [24,25]. To some extent, this was specified in further research executed by Polechoński with the acoustical stimulation. Based on the obtained results, one could not clearly state whether the sensitivity of the balance control system of body posture is dependent on gender (the results of most tests were similar). Significant differences appeared, however, in the measurements without visual control, suggesting higher sensitivity of the balance control system of women during exposure to acoustic stimuli [19,20]. The issue of the influence of the acoustic stimuli on postural stability is still not known. The executed research can be regarded as an introduction to further analyses, specifying their directions.

In the future, the researched group should certainly be extended in order to be considered as a representative of the population. The execution of the research not only in different acoustic conditions, but with limited access to information from other sources of postural control (variable conditions of visual control, a ground with different textures and hardness) seems to be beneficial. It is also interesting to research the relationship of the stability parameters and the auditory frequency. Executing a comparative analysis of the posturographic research results, one should remember that are often executed in different conditions, they involve a different procedure and the researched persons are of different age.

Conclusions

The research results allow to form the following conclusions:

1. Postural stability both in the conditions of relative silence, and the acoustic stimuli is not dependent on gender.
2. Music with a fixed spectrum has statistically significant influence on balance of the following parameters:
   - Mean load point X and Y
   - Average speed
   - Lateral speed
   - Subtended area, increasing their range.

3. The use of earphones without music (III test) significantly increased the parameters of the average and lateral speed compared with test I, where for a period of 1 minute, the time of absolute silence dominated.

References

1. Błaszczyk JW, Czerwosz L. Stabilność posturalna w procesie starzenia, przed fizjoterapią i po fizjoterapii. Gerontologia Polska 2005; 13: 25-36.

2. Błaszczyk JW. Biomechanika kliniczna. Warszawa: PZWL; 2004: 192-131.

3. Held-Ziółkowska M. Równowaga statyczna i dynamiczna ciała. Magazyn Otolaryngologiczny 2006; 5(2, 18): 39-57.

4. Peterka RJ. Sensorimotor integration in human postural control. J. Neurophsysiol 2002; 88(3): 1097-1118.

5. Zając M, Orendorz-Frączkowska K, Kubacka M, Żak T, Noczyńska A. Narząd przedsionkowy i kontrola posturalna w przebiegu autoimmunizacyjnych chorób tarczycy u dzieci. Otorynolaryngologia 2015; 14(4): 222-227.

6. Baloh RW, Honorubia V. Clinical neurophyhsiology of the vestibular system. Philadelphia: FA Davis Company; 1990.

7. Flis K, Pepłowski P, Kalejta M, Kowalczyk A, Błaszczyk J. Posturografia statyczna i parametry oceny stabilności posturalnej. In: Gajda J, ed. Modelowanie i pomiary w medycynie. Materiały III Sympozjum. Krynica; 2001.

8. Gurfinkel EV. Physical foundations of the stabilography. Agressologie 1973; 14: 9-14.

9. Kuczyński M. Control of upright stance: from assessment methods to mechanisms. Human Movement 2000; 2(2): 34-43.

10. Kubiczkowa J, Szkup K. Statokinezjometria, technika i zastosowanie. Otolaryng Pol 1974; 38: 279-286.

11. Kruczkowski D. Zdolność równowagi ciała – rzetelność pomiaru i oceny przy wykorzystaniu platformy tensometrycznej. Rocznik Naukowy AWF w Gdańsku 2000; 9.

12. Nashner LM. Computerized dynamic posturography. In: Jacobson GP, Newman CW, Kartush JM, eds. Handbook of balance function testing. St. Louis: Mosby Year Book; 1993, pp. 280-305.

13. Kubiczkowa J, Kubiczek-Jagielska M. Posturografia w ocenie sprawności układu równowagi. In: Janczewski G, ed. Biblioteczka Prospera Meniere'a 3. Warszawa: Solvay Pharma; 1999.

14. Kapilevich LV, Koshel'skaya EV, Krivoshyokov SG. Physiological Basis of the Improvement of Movement Accuracy on the Basis of Stabilographic Training with Biological Feedback. Human Physiology 2015; 41(4): 404-411.

15. Kruchinin PA. Mechanical models of sabilometry. Russian Journal of Biomechanics 2014; 18(2): 158-166.

16. Ocetkiewicz T, Skalska A, Grodzicki T. Badanie równowagi przy użyciu platformy balansowej – ocena powtarzalności metody. Gerontolgia Polska 2006; 14(1): 144-148.

17. Kubiczkowa J. Testy statyczne i kinetyczne. In: Janczewski G, Latkowski B, eds. Otoneurologia. Warszawa: BEL CORP Scientific Publication; 1998, pp. 263-274.

18. Russolo M. Sound-evoked postural responses in normal subjects. Acta Otolaryngol 2002; 122: 21-27.

19. Polechoński J, Błaszczyk JW. The Effect of Acoustic Noise on Postural Sway in Male and Female Subjects. Journal of Human Kinetics 2006; 15: 37-52.

20. Polechoński J. Bodźce akustyczne a stabilność postawy ciała. Katowice: AWF; 2007.

21. Dozza M, Horak FB, Chiari L. Auditory biofeedback substitutes for loss of sensory information in maintaining stance. Exp Brain Res 2007: 178(1): 3-48.

22. Palm HG, Strobel J, Achatz G, Luebken F, Friemert B. The role and interaction of visual and auditory afferents in postural stability. Gait & Posture 2009; 30(3): 328-333.

23. Tanaka T, Kojima S, Takeda H, Ino S, Ifukube T. The influence of moving auditory stimuli on standing balance in healthy young adults and the elderly. Ergonomics 2001; 44(15): 1403-12.

24. Raczek J, Mynarski W, Ljach W. Teoretyczno-empiryczne podstawy kształtowania i diagnoazowania koordynacyjnychz dolności motorycznych. Katowice: AWF; 1998.

25. Kejonen P, Kauranen K, Ahasan R, Vanharanta H. Motion analysism measurements of body movements during standing: association with age and sex. International Journal of Rehabilitation Research 2002; 25(4): 297-304.

Journal of Health Study and Medicine
2020, No. 1
pp. 93-115
DOI 10.36145/JHSM2020.05

Assessment of Factors Conditioning Stress and Burnout in a Group of Nurses Employed at the University Clinical Hospital of the Medical University of Lodz

Agnieszka Jóźwik[1]

Beata Karpińska-Marszałek[1]

[1] Department of Social Medicine, the Chair of Social and Preventive Medicine of the Medical University of Lodz, Poland

Address for correspondence

Agnieszka Jóźwik
Department of Social Medicine, the Chair of Social and Preventive Medicine
of the Medical University of Lodz
7/9 Żeligowskiego Str., 90-136 Lodz, Poland
e-mail: agnieszka.jozwik@wss.zgierz.pl

Abstract

Introduction: *The World Health Organization declared stress a disease of the 21st century. Its health consequences can be painful and long lasting. Stress is one of the common threats in the modern work environment. Nurse care in medical units is one of the most difficult organisational forms. The work of a nurse is associated with constant exposure to stress factors that may cause burnout.*

Material and methods: *The study was conducted among 120 nurses employed at the University Clinical Hospital of the Military Medical Academy – Central Veterans Hospital in Q3 2017.*

Objective: *The aim of the article was an attempt to diagnose stress factors and determine their degree of impact, while assessing the risk of burnout among nursing staff.*

Results: *The major stress factors are discussed in this paper. Aspects affecting the emergence of the concept of occupational burnout among nursing staff were characterised. This study has proven that stress is an inherent process in the work of a nurse. Based on the respondents' answers, the inadequate remuneration, high responsibility, lack of equipment, lack of promotion opportunities should be considered the most important stress factors. Interpersonal relationships with the patient and their family can affect the feeling of stress.*

Conclusions: *The vital element is that the choice of this profession was motivated by the will to help others and the recognition of this profession as prestigious. A positive message is that despite the difficulties of the profession, most of the respondents go to work with satisfaction or sense of duty.*

Key words: *stress, burnout, nurse, stress, stress factors.*

The concept of stress

The concept of stress was introduced to the dictionary by Hans Hugo Selye, who devoted 50 years of research to studying this phenomenon. For this reason, he was nicknamed Dr. Stress. Selye was the first to hypothesise that a number of somatic diseases is the result of man's inability to cope with stress. He called this phenomenon the so-called "general adaptation syndrome deficiency" and described it in his first book on stress in 1956 entitled "The Stress of Life".

Stress is a concept that most people perceive negatively, and the very feeling of stress is perceived by them as a weakness, hindering effective action.

The World Health Organization has defined stress as "the disease of the century, because the cause of the colourful and dangerous picture of adaptation disorders can be physical, as well as chemical, toxic, infectious, psychological and sociopathic factors" [1].

"Stress" in encyclopaedic terms is "a state of load on the psychological regulation system, arising in a situation of danger, obstruction or impossibility of achieving goals, tasks, values important for the individual" [2].

There are several definitions of stress that should be presented in three categories:

- Stress – stimulus – severe, bothersome and distracting from activity: this type describes various, troublesome situations that cause stress, e.g. noise in the workplace, illness, death.
- Stress as a reaction to an onerous stimulus from the outside: determination of reactions that appear both physically and mentally in a person in response to unpleasant situations, e.g. worse performance of a task.
- Stress as an effective adaptive relationship occurring among the adaptation capabilities of an individual and stress factors. Taking preventive behaviour is an experiment to restore balance [3].

A certain level of motivating stress is necessary for the productive functioning of a person. Too low level can cause a decrease in motivation, pas-

sivity and boredom. Too high can contribute to excessive experience through tension, difficulty concentrating, incapacity or slowing of reflexes.

Work-related stress is the most important health and safety challenge. It is present in our lives and despite many fears of its effects, we often cannot prevent it. It is a motivating factor in all disciplines of life. Every fourth employee is an addressee of stress, and research shows that stress is experienced on 50-60% of all critical working days. This can mean a tremendous cost in both the constellation of health disorders and the mediocre economic balance. Stress in the workplace does not distinguish between functions or positions. It can affect anybody. It occurs in both public and private sectors, in a small and large enterprise. It carries a huge burden on the health and safety of individuals, but also affects the activity of national organisations and economies. "Stress triggers a certain alarm situation, thanks to which the body prepares for increased defensive activity. The nervous system is stimulated, hormones conducive to sharpening of the senses are released, the pulse accelerates, breathing becomes more intense, muscles tighten. Despite some individual differences, our physiological responses are similar. Short-term stress is not very burdensome for our bodies, long-term experience of stress can be extremely harmful to our health and senses" [4].

Stress caused by work, says M. Gólcz, has a huge impact on the organisation of the entire workplace. Employees and managers experiencing excessive stress are most often on the verge of physical and mental exhaustion. It should be borne in mind that people working under severe and chronic stress are more likely to get sick. It also affects their performance and making more mistakes, and thus, reduces the efficiency of their work. They are usually more assertive in carrying out tasks, they use sick leave or holiday more often. There is probability of circumventing legal provisions and basic safety principles. It happens extremely often that this is a cause of accidents at work. Lack of commitment and loss of willingness to work is another dominant aspect of employees exposed to excessive stress. In extreme situations, they often give notice and leave work [5].

The concept of occupational burnout, its causes and symptoms

The problem of occupational stress is strongly associated to occupational burnout. The metaphorical term "burn out" clearly indicates the composition of one's exhaustion due to stressful job predilections. What should be taken into account when wanting to recognise a burnout syndrome? Emotional exhaustion, i.e. excessive fatigue, lack of dynamics and expression is routinely given.

In this case, it can be described as a much more significant amount of work that a person must do to achieve guaranteed results. Workers exposed to burnout syndrome often see excessive indifference towards them in relation to other people. Confidences are deprived of their current character and become outdated. This condition is also associated with the minimisation of satisfaction with one's own professional activities – a decrease in the sense of one's own skills and work dynamics comes into play [6]. Occupational burnout, occupational burnout syndrome, and burnout syndrome – a condition when work is no longer satisfying, an employee ceases to evolve professionally, they feel uncomfortable due to overwork and are dissatisfied with their duties, which they enjoyed the day before.

This is a result of stress associated with the overwork condition, most often determined in professions requiring many contacts with people, i.e. among psychologists, educators, doctors, nurses teachers and paramedics and others. People who experience burnout syndrome are those who were workaholics before.

According to Christina Maslach, there are three components of occupational burnout. They are referred to as:

1. Emotional exhaustion – a feeling of inertia and a large outflow of strength caused by excessive psychological and emotional requirements that were set for the employee (or they set such unrealistic requirements to their own abilities);
2. Depersonalisation – defines a feeling of far-reaching barbarism, impersonality, cynical looking at other people, a decrease in sensitivity towards others;

3. Lowering the perception of one's own achievements – the feeling of wasting time and effort on one's work result [7].

The nature of the work of nursing staff

Working as a nurse is extremely difficult and multi-tasking. First of all, it is focused on meeting the needs of the patient, but they also largely work with medical documentation. Performing nursing and treatment work, operating medical equipment and devices as well as cooperation with the staff and the patient's family often requires predispositions and skills [8].

The profession of a nurse should be exercised by a person with specific professional qualifications, the right to practice a profession, as well as having the skills to cooperate in an interdisciplinary team [9].

The manner in which a nurse and midwife perform work is regulated by the Act of 15 July 2011 on the professions of nurse and midwife.

The provisions of the Act define the profession of midwife and nurse as a free and independent profession, consisting in providing health services, in particular:

1. recognising the patient's health conditions and needs;
2. recognising patient care problems;
3. planning and providing patient care;
4. independent provision, within a specified scope, of preventive, diagnostic, therapeutic and rehabilitation services as well as medical rescue operations;
5. the implementation of medical orders in the process of diagnosis, treatment and rehabilitation;
6. deciding on the type and scope of care and nursing benefits;
7. health education and health promotion [10].

Nurse care in medical units is one of the most difficult organisational forms. Its aim is to provide the patient with round-the-clock care in a continuous, uninterrupted work system, i.e. both on working days and on Sundays and holidays. The work system in hospitals is usually of one shift – 7 hours 35 minutes or two 12-hour shifts [11,12].

In their work nurses encounter stress from various sources on a daily basis. First of all connected with the patient, their medical problems, often with a threat to life and health, and the necessity of making sudden decisions. The patient's family, therapeutic team, mutual interactions, work environment and conditions as well as high responsibility are also a source of stress [13].

Material and methods

As part of the work, the thesis was put forward that the work of a nurse due to its specificity is associated with increased stress than other professions.

The purpose of the article was to attempt to diagnose stress factors and determine the degree of impact of these factors, while assessing the risk of burnout among nurses employed at the University Clinical Hospital of the Medical University of Lodz, Military Medical Academy – Central Veterans Hospital.

The following research questions were asked in the paper:

1. Is burnout related to the nurse's seniority?
2. Is burnout syndrome related to the nurse's age?
3. What are the most stressful factors?
4. Does the nurse's profession affect their personal life?
5. Do professional relationships influence the feeling of burnout?

Methodology

The study was conducted among 120 nurses employed at the University Clinical Hospital of the Military Medical Academy – Central Veterans Hospital in Q3 2017.

After obtaining informed consent, staff were asked to fill out the questionnaire voluntarily and independently.

The tool used for the study was the author's questionnaire, containing closed questions and using a four-level and five-grade assessment scale.

The form in MS Excel was used for statistical processing. Table 1 shows the age of the studied group and the gender of respondents.

Table 1. Research group characteristics

Category	(%)
AGE	
20-30	27%
31-40	28%
41-50	39%
51-60	4%
over 61	2%
GENDER	
Female	93%
Male	7%
EDUCATION	
vocational	1%
secondary	7%
bachelor's degree	24%
master's degree	68%

Among 120 respondents, the largest group were middle aged (41-50) women (93%). Only 1% of respondents had vocational education. 92% of respondents had bachelor's and master's degrees.

Most nurses pointed to the average material situation. 30% considered their financial situation as good. In a group of 9% of respondents, extreme feelings of their situation were noticed. And so 2% described it as very good, while 7% described it as bad or very bad. This is illustrated in Figure 1.

The largest seniority group (30%) are nurses with 16 to 20 years of experience. 25% of respondents reported seniority from 11 to 15 years. The seniority of 23% of nurses ranged from one to 5 years, and from 6 to 10 years – 16% of respondents. 5% have worked in the profession for over 20 years, and only 1% for less than 1 year. The seniority is shown in Figure 2.

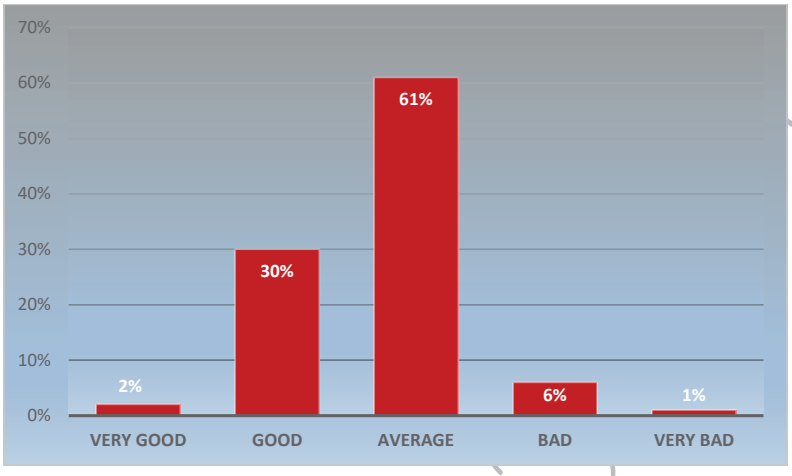

Figure 1. Material status

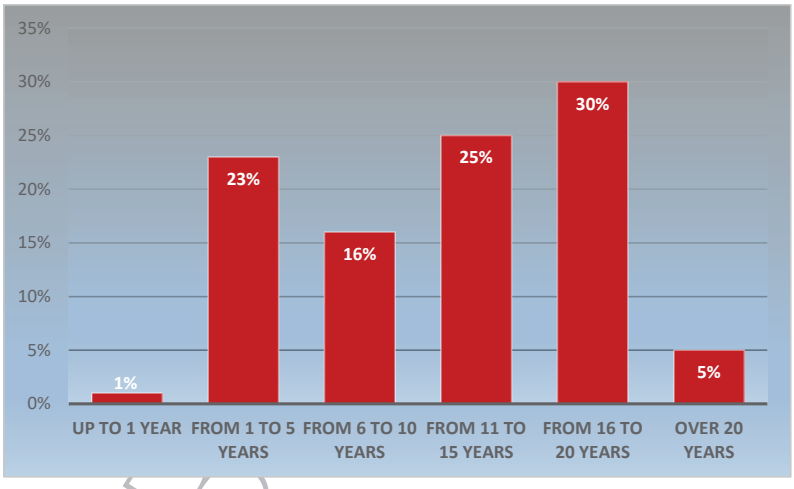

Figure 2. Seniority

Almost 90% of respondents felt stress at work very often and often. 12% admitted to feeling stress rarely. None of the respondents indicated the answer „Never", which may suggest that they all feel stress as an inseparable element of work. Feeling stress at work is shown in Figure 3.

For most respondents, stress is an unnecessary element of work (56%), while almost a third of respondents consider it necessary, but to a limited extent. Only one percent of respondents considered stress as

a motivator for work and identified its existence as significant. 10% of respondents had no opinion on this matter. The answers to the questions are shown in Figure 4.

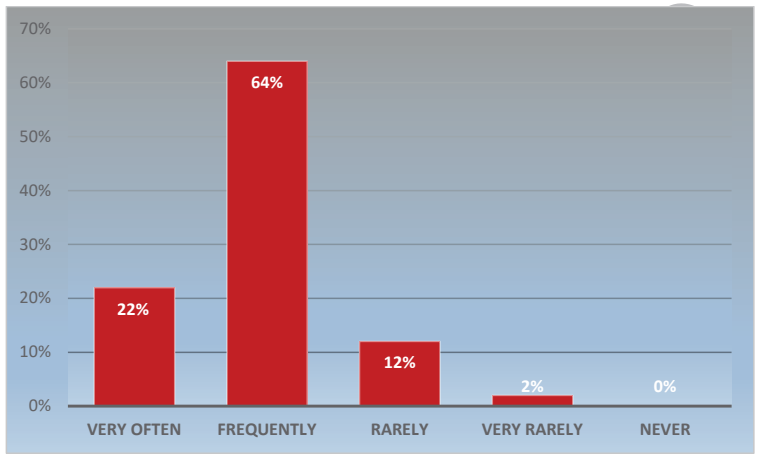

Figure 3. Feeling stress at work

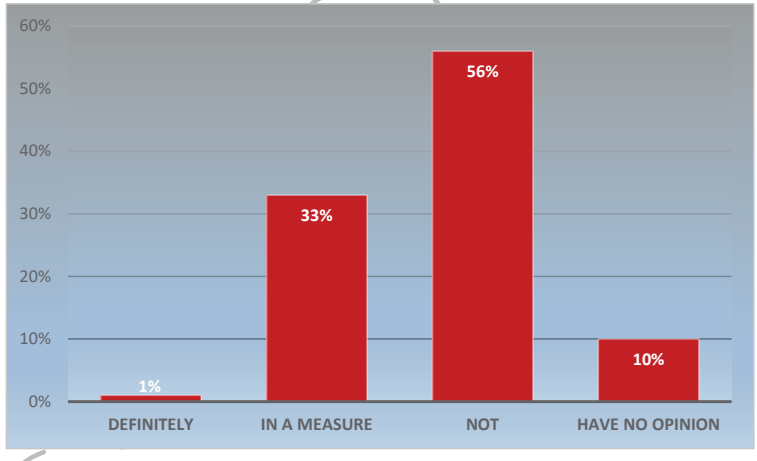

Figure 4. Stress at work

The most stressful factors for the largest group of respondents were:

1. Too low remuneration (65% of respondents gave this answer 5 points),
2. Lack of resources, equipment and materials needed for work (82% of respondents gave this answer 4 points),
3. Too high responsibility (57% of respondents gave this answer 4 points),
4. Time pressure (60% of respondents gave this answer 4 points)
5. No prospects for professional development and promotion (75% of respondents gave this answer 4 points).
6. Strained relations with patients and their families (level 4 for 68%), strained relations with other staff (level 4 for 52%).

Respondents were the least stressed by: constant contact with harmful substances (86% of respondents gave 1 point to this answer), contact with death (44% gave 2 points), shift work (64% gave 2 points), poor work organisation (1 points for 54% of respondents), employment uncertainty (1 point for 87% of respondents). In addition, the respondents did not stress the necessity of making quick decisions (2 points for 71% of people) and monotony (1 point for 90% of people). Physical and mental overload with work was considered to be a factor causing average stress (50%, 3 points). Rivalry among employees is less than 40 percent (3 points for 39% of respondents). Factors causing stress at work are specified in Table 2.

Negative emotions (anxiety and fear) related to the attitude to going to work are observed only in 6% of the staff. A positive symptom is that a 43% group goes to work with satisfaction, while 29% comes to work with a sense of duty. Lack of attitude is manifested by the group of indifferent, constituting 22%. None of the respondents indicated other than the given attitudes in coming to work. Figure 5 illustrates the attitude towards going to work of the respondents.

Table 2. Factors causing stress at work

	Very low	Low	Average	High	Very high
Contact with death	5%	44%	23%	22%	6%
Too high responsibility	4%	7%	7%	57%	25%
Pressure of time	1%	2%	32%	60%	5%
Constant contact with harmful substances	86%	12%	1%	1%	0%
Lack of prospects for professional development and promotion	2%	9%	13%	75%	1%
Physical and mental overload with work	0%	1%	50%	33%	16%
Shift work	0%	64%	25%	7%	4%
Strained relations with patients and their parents	0%	0%	2%	68%	30%
Strained relations with other staff	2%	3%	33%	52%	5%
Rivalry among employees	7%	20%	39%	23%	11%
Poor work organisation	54%	12%	26%	8%	0%
Employment uncertainty	87%	2%	11%	0%	0%
Too low remuneration	0%	0%	3%	32%	65%
Lack of resources, equipment and materials needed for work	0%	0%	1%	82%	17%
Necessity of prompt decision making	0%	71%	0%	15%	14%
Monotony	90%	2%	2%	6%	0%

Figure 5. Attitude to going to work

A disturbing fact is that as many as 57% of respondents show dissatisfaction with the conditions in the workplace. Housing conditions, outdated equipment, often the lack of disposable equipment and difficult interpersonal contacts have an impact on the assessment. Every fourth respondent described the conditions as good. This is illustrated in Figure 6.

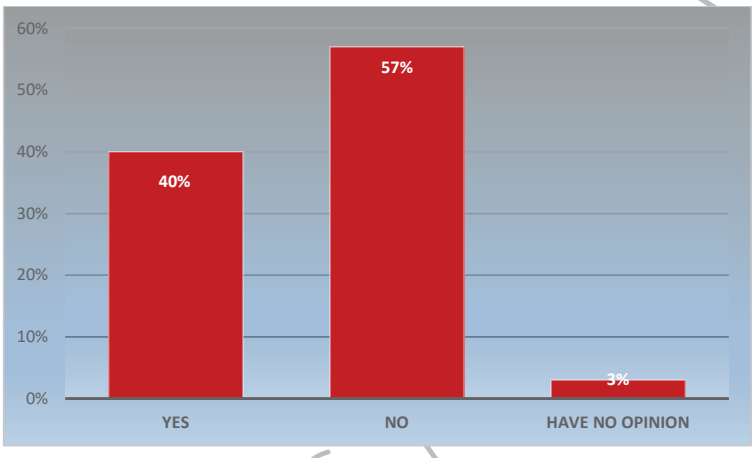

Figure 6. Conditions at work

The declared level of satisfaction with the work performed was usually average or quite high and was awarded 3 or 4 points (42% and 39%). Full satisfaction was recorded only in the case of 6% of respondents, while its complete lack in 2%. Lack of job satisfaction may be related to the lack of satisfaction with the remuneration for the work performed. As much as 88% of respondents admitted the lack of satisfaction with the received remuneration (42% declared dissatisfaction and 46% declared minimal satisfaction). The remaining 12% awarded 3 or 4 points (9% and 3%, respectively). Nobody showed one hundred percent satisfaction with their salary.

Over 86% of respondents did not see any opportunities for promotion (Figure 7).

The desire to help was in 76% of cases an argument for choosing this difficult profession. When choosing, 87% of nurses were aware of being needed. Despite the difficulties of the profession, over 60% of respon-

dents recognised the profession as prestigious. Family relations were not without significance, because about 20% of the respondents chose this profession because of the work of a loved one (Figure 8).

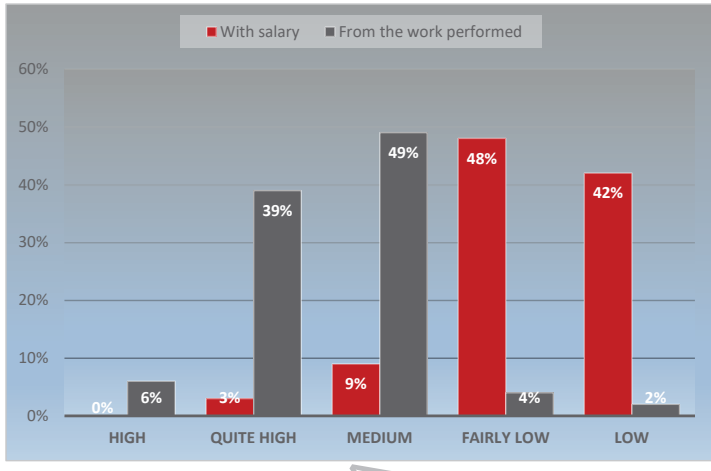

Figure 7. Satisfaction level

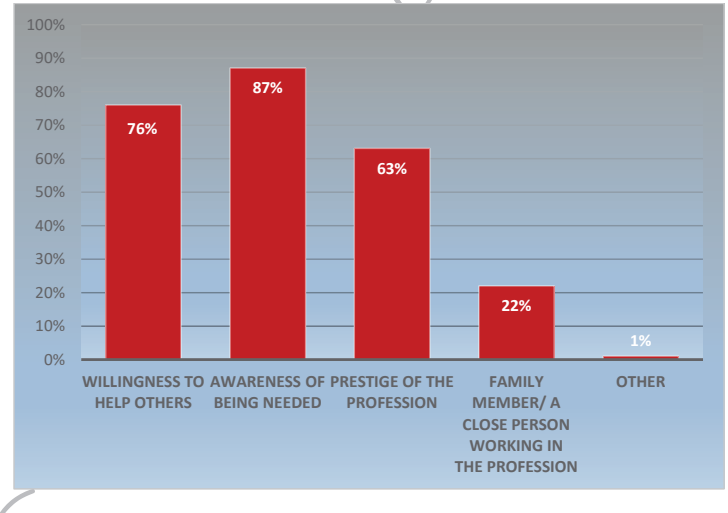

Figure 8. Reasons for choice

Over 50% of respondents said that communication between colleagues was successful. Unfortunately, almost 60% indicated that they are burdened too much. Less than 50% of nurses rated positively the relationship between subordinates and superiors. The most difficult aspect

turned out to be remuneration for work, because 89% considered it inadequate (Table 3).

Table 3. Relations at work

	YES	NO
Is communication between colleagues successful?	52%	
At work, can you count on mutual support?	57%	
Are employees burdened with excess duties?	59%	
Are employee-subordinate relations successful?	46%	
Is the remuneration adequate to the work performed?		89%
Is the responsibility for the tasks performed too high?	38%	

The respondents pointed to the lack of power and energy to work (18%), loss of motivation (11%) as well as fatigue and emotional exhaustion. These symptoms were indicated as occurring frequently. The occurrence of these symptoms has sometimes been determined by more staff (45%, 39% 19%, respectively). 43% of respondents indicated that stress at work affects their personal lives, but more than 50% can distinguish between private and professional life. The manner of answering is given in Table 4.

Figure 9 illustrates the impact of long-term stress on the occurrence of the somatic symptoms set out in the previous question.

81% of respondents believe that long-term perception of work-related stress can affect the occurrence of the symptoms described in the previous question.

An extremely important fact is the possible help in case of failures illustrated by Figure 10. In the event of failures, most respondents can count on the help of a loved one. Only 1% can count on the help of a specialist, and 7% from a superior.

Table 4. Symptoms of burnout

	Never	Rarely	Sometimes	Frequently
Irritation with minor setbacks at work	2%	40%	53%	5%
Lack of faith in one's own abilities	1%	51%	41%	7%
Lack of empathy and indifference in relations with patients	42%	34%	23%	1%
Irritability and lack of patience with patients	2%	49%	42%	7%
Avoiding personal contacts with patients	21%	69%	9%	1%
Inability to concentrate	11%	74%	12%	3%
Mistakes and errors in the performance of tasks at work	1%	84%	13%	2%
Lack of power and energy for work	5%	32%	45%	18%
Loss of motivation	3%	39%	47%	11%
Discouragement to work	27%	41%	28%	4%
Feeling that I'm not good enough	8%	74%	9%	9%
Emotional fatigue and exhaustion	5%	63%	19%	13%
Colds, headaches, infections	1%	47%	50%	2%
Weight loss or overweight	78%	15%	5%	2%
Problems with sleeping	38%	43%	16%	3%
Problems with alcohol and tobacco abuse	94%	4%	2%	0%
Resignation and lack of prospects	20%	65%	6%	9%
Irritability, anxiety, depressive states	10%	63%	21%	6%
Anger and aggression	71%	24%	3%	2%

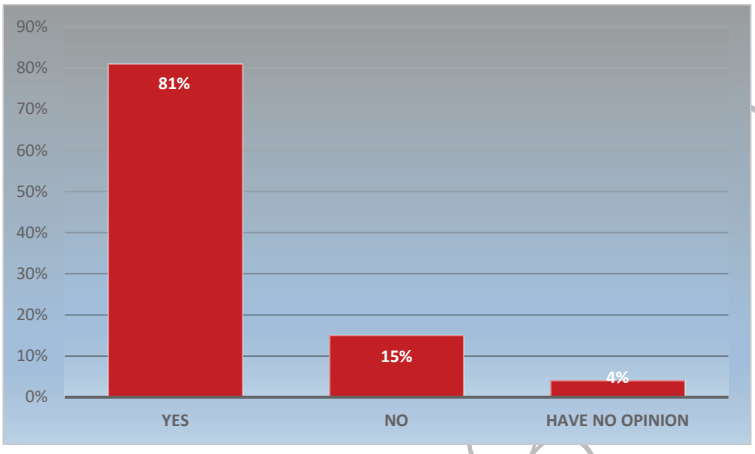

Figure 9. Feeling stress

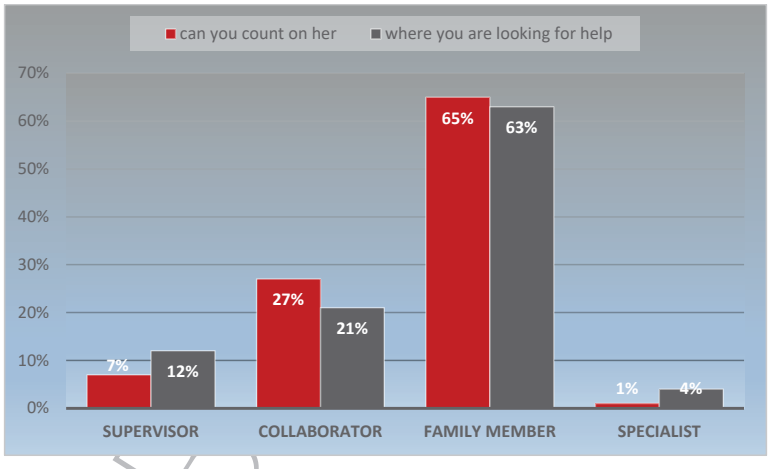

Figure 10. Persons offering assistance to respondents in case of failures

Discussion

The article is based on an attempt to diagnose stress factors that affect burnout in a group of nurses employed at the University Clinical Hospital of the Medical University of Lodz. The group subjected to the test is homogeneous due to their occupation, but it differs in gender, seniority and age.

The largest group in terms of age are employees between 41 and 50 years of age (39%). The least numerous are people over 51 years of age. 27% of respondents are 20-30 years old. The vast majority of the staff have higher education (68% higher master's, 24% bachelor's). Only 7% are people with secondary education and 1% – vocational.

Most of the respondents have worked for over 11 years (11-15-25%, 16-20-30%), which is more than half of the respondents. Only 5% indicated seniority over 20 years, while extremely short (one year) 1%.

As Mastalerz has stated, work can be a source of satisfaction, but at the same time it can be associated with too high emotional burden, which in fact can lead to burnout.

This study shows that 86% of respondents experience stress at work often or very often. Only 1% described the very rare occurrence of stress at work. None of the respondents gave an answer that confirms that stress never occurred.

The results of Modzelewska and Kulik show that as many as 73.3% of nurses in Lublin hospitals felt stress related to their work [13,14,15].

Importantly, 56% of our respondents, although experiencing stress, do not think it is needed. The results of already published studies show that stress is not affected by the ward in which nurses work [16].

However, important factors determining the level of stress were established. And so, as much as 65% described the lack of adequate remuneration as significant (weight 5). There were as many as 88% people who did not feel satisfied with their remuneration, 42% of which declared low satisfaction, and 46% minimum. Basińska's research has shown that low remuneration is a stress factor for staff and can lead to frustration and dissatisfaction [17].

In the 21st century, the selection of equipment and resources by the workplace seems simple. However, 82% of respondents admitted that the lack of the above also causes dissatisfaction, and sometimes can cause stress. Other factors listed by the respondents were too high responsibility (57% weight 4), interpersonal relations with the patient and their family (68% – 4) and contact with death (44% – 4).

The latter is inseparable in the work of a nurse.

What may seem irrational is that 71% of respondents do not see making quick decisions as a stress factor.

Professional promotion turned out to be an important factor for the respondents, but it was poorly assessed by 86% of respondents, which may suggest the lack of possibility and transparency of a possible promotion. Nursing staff has developed a separation of the professional and personal sphere. 58% of respondents claim that they can separate these spheres.

Conclusions

1. This study has proven that stress is an inherent process in the work of a nurse. 86% of respondents said they felt stress.
2. Based on the respondents' answers, the inadequate remuneration, high responsibility, lack of work equipment, lack of promotion opportunities should be considered the most important stress factors.
3. Interpersonal relationships with the patient and their family can affect the feeling of stress.
4. The choice of this profession was motivated by the will to help others and the recognition of this profession as prestigious.
5. The promotion system is not transparent (86% of respondents assess poorly their chances of promotion).
6. Despite the difficulties of the profession, most of the respondents go to work with satisfaction or sense of duty.
7. 43% of staff felt the negative impact of stress on private life.

Occupational burnout refers to the state of exhaustion of the body. The article discusses the definition and conceptualization of the concept. Although both occupational burnout and engagement are associated with important work-related outcomes, burnout appears to be more strongly associated with health outcomes, while engagement with work is more closely associated with motivational outcomes [18].

Burnout is considered a socio-cultural concept or set of symptoms. They were considered a professional syndrome associated with unemployment and employment. From the beginning of 2022, it will be possible to get sick leave for this condition. According to the International Statistical Classification of Diseases (ICD-11) maintained by the World Health Organization, burnout can be diagnosed [19]. We know, after all, that this phenomenon is multidimensional, because it changes the employee's behaviour, affects their attitude and interrelationships with people, and affects their health.

References

1. Grochmal S. Zaufaj sobie. Warszawa: Państwowy Zakład Wydawnictw Lekarskich; 1987, p. 56.

2. Grygorczuk A. Pojęcie stresu w medycynie i psychologii. Psychiatria 2008; 5(3): 111-115.

3. Heszen-Niejodek I. Polska adaptacja kwestionariusza S. Folkman i R.S. Lazarusa do badania sposobów radzenia sobie ze stresem (WCQ). Katowice: Uniwersytet Śląski; 1989.

4. A. Łuczak, D. Żołnierczyk-Zreda. Praca a stres. Bezpieczeństwo Pracy 2002; 10: 2-5.

5. Gólcz M. Stres w pracy. Poradnik dla pracodawcy. PIP. Warszawa: Główny Inspektorat Pracy; 2016, pp. 8-9.

6. Tucholski S. Christiny Maslach. Koncepcja wypalenia zawodowego: etapy rozwoju. Przegląd Psychologiczny 2001; 44(3): 301-317; Jaworowska A. LBQ Kwestionariusz Wypalenia Zawodowego Massimo Santinello. Podręcznik. Polska Normalizacja. Warszawa: Pracownia Testów Psychologicznych Polskiego Towarzystwa Psychologicznego; 2014.

7. Christiny Maslach koncepcja wypalenia zawodowego: etapy rozwoju. Przegląd Psychologiczny 2001; 44(3): 301-317 [Internet]. Available from: https://www.kul.pl/files/714/media/3.44.2001.art.2.pdf [cited 27.12.2017].

8. Ogińska-Bulik N, Kaflik-Pieróg M. Stres zawodowy w służbach ratowniczych. Łódź: Wyd. Wyższej Szkoły Humanistyczno-Ekonomicznej; 2006, pp. 42-43.

9. Ogińska-Bulik N. Stres zawodowy w zawodach usług społecznych. Źródła-konsekwencje-zapobieganie. Warszawa: Wyd. Difin; 2006, p. 31; Zakres kompetencji pielęgniarki specjalisty. Zalecenia Międzynarodowej Rady Pielęgniarek. Polskie Towarzystwo Pielęgniarskie 2009/Rewizja 2014 [Internet]. Available from: http://www.ptp.na1.pl/pliki/pdf/ICN_Zarys_Komp_Piel_Spec_2010.pdf [cited 24.10.2019].

10. Oniszczenko W. Stres to brzmi groźnie. Warszawa: WSiP; 1993, p. 11; Przedmiot i Prawo wykonywania zawodu pielęgniarki w świetle nowej ustawy o zawodach pielęgniarek i położnych [Internet]. Available from: https://www.prawo.pl/zdrowie/przedmiot-i-prawo-wykonywania-zawodu-pielegniarki-w-swietle-nowej-ustawy-o-zawodach-pielegniarki-i-poloznej,262076.html [cited 23.06.2016].

11. Papadatou, D, Anagnostopoulos F, Monos D. Factors contributing to the developrnent of burnout in oncology nursing. British Journal of Medical Psychology 1994; 67(2): 187-199.

12. Pietraszek A, Charzyńska-Gula M, Łuczyk M et al. Analiza przyczyn stresu zawodowego w opinii pielęgniarek. Journal of Education, Health and Sport 2016; 6(9): 643-652.

13. Skorupska-Król A, Szabla A, Bodys-Cupak I. Opinie pielęgniarek na temat czynników stresogennych związanych z ich środowiskiem pracy. Pielęgniarstwo XXI wieku 2014; 1(46): 23-26.

14. Sowińska K, Kresowicz K, Gaworska-Krzemińska A, Świetlik D. Wypalenie zawodowe i satysfakcja zawodowa w opinii pielęgniarek. Probl Pielęg 2012; 20(3): 361-368; Kupcewicz E, Szczypiński W, Kędzia A. Satysfakcja z życia w kontekście życia zawodowego pielęgniarek. Piel Zdr Publ 2018; 8(1): 27-32.

15. Steciwko A, Mastalerz-Migas A, eds. Stres oraz wypalenie zawodowe. Jak rozpoznać, zapobiegać, leczyć. Wrocław: Elsevier Urban & Partner; 2012, pp. 47-48.

16. Sutton C. Psychologia dla pracowników socjalnych. Gdańsk: Wyd. GWP.

17. Szewczuk W, ed. Słownik Psychologiczny. Warszawa: Wyd. Wiedza Powszechna; 1985, p. 297.

18. Tucholska S. Wypalenie zawodowe nauczycieli. Psychologiczna analiza zjawiska i jego psychologicznych uwarunkowań. Lublin: Wyd. KUL; 2009, pp. 45-57.

19. Markowska Klaudia [Internet]. Available from https://businessinsider.com.pl/rozwoj-osobisty/zdrowie/wypalenie-zawodowe-to-choroba-zwolnienie-lekarskie/j32l6e8 [cited 13.10.2019].

Journal of Health Study and Medicine
2020, No. 1
pp. 117-129
DOI 10.36145/JHSM2020.06

The Clinical Trials Analysis of Active Ingredient in Mutations of BRCA1 and BRCA2 Genes in Patients with Breast Cancer

Mikołaj Bartoszkiewicz[1]
https://orcid.org/0000-0002-8728-5998

[1] Department of Biology of Lipid Disorders, Poznan University of Medical Sciences, Poland

Address for correspondence

Mikołaj Bartoszkiewicz
Department of Biology of Lipid Disorders
Poznan University of Medical Sciences
Rokietnicka 7 Str., 60-806 Poznan, Poland
e-mail: m.bartoszkiewicz@ump.edu.pl

Abstract

Background: *Breast cancer is the most commonly diagnosed cancer in women all around the world. In 2018 alone, this type of cancer has been diagnosed in 2 million cases. Women who are transmitters of the BRCA mutation are more likely to get breast and ovarian cancer at their young age than women who do not possess this kind of genetic mutation.*

Objectives: *This project aims to analyze clinical studies in the mutation of genes BRCA1 and BRCA2 in breast cancer. Specifying the active substances allows the approximation of which substances are being examined at the moment as innovations.*

Material and methods: *The web database www.clinicaltrials.gov was used for the analysis of clinical studies related to BRCA1 and BRCA2 mutations. The analysis covered research conducted in the European Union and the United States.*

Results: *The most clinical trials of BRCA1 and BRCA2 gene mutations in breast cancer are conducted in the USA – 9 studies, which indicates a 56.2% share in the entire market of research in medicinal products in this indication. Of the EU countries, the majority of research is conducted in Spain – 6 (37.5%). Most of the clinical studies are conducted in an active substance Talazoparib – 6 types of research.*

Conclusion: *Clinical studies in breast cancer in the BRCA1 and BRCA2 gene mutations give hope to many patients waiting for innovative treatments. The United States is conducting more clinical trials in this disease than the European Union.*

Key words: *clinical trials, cancer, BRCA1 gene, BRCA2 gene, mutation.*

Introduction

Breast cancer is the most commonly diagnosed cancer in women all around the world. In 2018 alone, this type of cancer has been diagnosed in 2 million cases. It is estimated that around 5-10% of breast cancer has a genetic origin [1]. One of the genetic factors, which may cause breast and ovarian cancer is the mutation of genes BRCA1 and BRCA2. BRCA1 and BRCA2 are tumor suppressor genes. Their main role is to fix damaged fragments of the DNA, playing an important role in providing stability to the varying genetic material of the cell. When any of these genes are mutated or are not modified in a way that protein end product is not created or does not function correctly, the damaged DNA cannot be fixed. As a result, these types of cells are at risk of genetic changes, which may lead to malignant transformations. Patrimonial BRCA1 and BRCA2 mutations increase the risk of breast and ovarian cancer in women, in addition to increasing the possibility of developing other cancers. Women who are transmitters of the BRCA mutation are more likely to get breast and ovarian cancer at their young age than women who do not possess this kind of genetic mutation. This mutation may be inherited from mother or father, every child of a parent who has the variation of this gene has a 50% chance to inherit this mutation [2]. Women inheriting the BRCA1 or BRCA2 mutation have an approximately 50% to 80% chance of developing breast cancer in their lifetime, as well as a 40% chance of developing ovarian cancer [3]. The average age of getting breast cancer in BRCA1 mutation is forty years old. This mutation very often redounds to medullary carcinoma of the breast in cases of low expression of the estrogen receptor. The oncology clinical studies are a huge chance to access innovative medications for patients; therefore, the development of research of the product is significantly essential. The enormous number of clinical studies conducted on breast cancer allows the oncologist to fit adequate treatments and to present access to innovative therapies. The analysis of studies in breast cancer of BRCA1 and BRCA2 genes allows approximating the amount of research, their stages, and the best treatments accessible on the market.

Material and methods

The web database www.clinicaltrials.gov was used for the clinical study analysis, which relates to mutation BRCA1 and BRCA2. It is a database of international clinical studies that are either private or founded by public resources. The information is provided by the US National Library of Medicine, in which the analysis of the amount of research associated with mutation BRCA1 and BRCA2, stages of research, and tested treatment schemes was made. The data covers the period from the 1st of January to the 25th of January 2020. The analysis covered the research conducted in the European Union and the United States.

Aim

This project aims to analyze clinical studies in the mutation of genes BRCA1 and BRCA2 in breast cancer. Specifying the active substances allows the approximation of which substances are being examined at the moment as innovations. The analysis will also determine the country where the most significant amount of clinical studies in BRCA1 and BRCA2 mutation was conducted, divided into the phases of the research.

Results

During the analysis period, there are 16 clinical studies associated with mutation of BRCA1 and BRCA2 gene in breast cancer, where 9 of them are in the US, and seven are in the EU. There are six clinical trials in the recruitment stage, and ten are in the active stage. Figure 1 shows the number of clinical trials divided into phases.

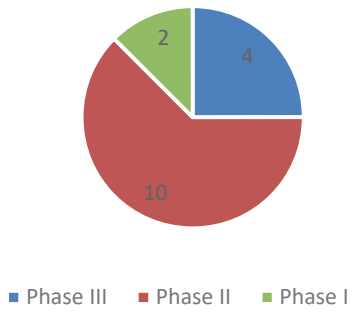

Figure 1. Division by the phase of gene mutation studies BRCA1 and BRCA2 in breast cancer

Analyzing the following diagram (figure 1) we can notice that most of those studies with BRCA1 and BRCA2 gene mutation in breast cancer are conducted in the second phase – 10 studies, then the third phase – 4 trials, and in the third place is phase number one – 2 studies.

Table 1 presents all the countries included in the analysis. The most clinical trials of BRCA1 and BRCA2 gene mutations in breast cancer are conducted in the USA – 9 studies, which indicates a 56.2% share in the entire market of research in medicinal products in this indication. Of the EU countries, the majority of research is conducted in Spain – 6 (37.5%), followed by France, Poland, and the UK – 5 (31.2%), the third places are Hungary and Italy – 4 (25%). Furthermore, EU countries do not exceed 19% market share in the clinical trials of BRCA1 and BRCA2 gene mutation in breast cancer in the EU and the US. Nine of the EU countries do not conduct any medical research in this diagnosis.

Table 2 presents clinical experiments by NCT numbers (clinical trials number from the clinicaltrials.gov database): the active substance being tested and the countries that participate in the project. When analyzing the active substance, which during the analysis period was most often studied in clinical trial projects in the EU and the US, Talazoparib comes first – 6 studies (37.5%). Olaparib is second – 3 studies (19%), Niraparib, and Veliparib are in the third place – 2 (12.5%). The fourth place take

active substances: ABT-888, Temozolomide, Denosumab, and Pembrolizumab after 1 study (6.2%).

Table 1. The countries participating in the analysis

Country	Number of clinical trials
US	9
Spain	6
France	5
Poland	5
UK	5
Hungary	4
Italy	4
Belgium	3
Germany	3
Sweden	3
Czechia	2
Netherlands	2
Romania	2
Bulgaria	1
Denmark	1
Greece	1
Finland	1
Ireland	1
Portugal	1
Austria	0
Cyprus	0
Estonia	0
Latvia	0
Lithunia	0
Luxembourg	0
Malta	0
Slovakia	0
Slovenia	0

Table 2. The clinical experiments by NCT numbers, divided in to:
active substance, phase, country and status

NCT number	Active substance	Phase	Country	Status
NCT 0200622	Olaparib	3	Bulgaria, Czechia, France, Germany, Hungary, Italy, Spain, Sweden, Poland, Romania, UK, US	Active
NCT 01945775	Talazoparib	3	Belgium, France, Germany, Ireland, Italy, Spain, Poland, UK, US	Active
NCT 01905592	Niraparib	3	Belgium, France, Greece, Hungary, Italy, Netherlands, Spain, Portugal, Poland, UK, US	Active
NCT 01506609	Veliparib	2	Belgium, Czechia, Denmark, Finland, France, Hungary, Netherlands, Spain, Sweden, Poland, Romania, US	Active
NCT 03286842	Olaparib	3	Hungary, Itlay, France, Germany, Spain, Poland, UK, US	Active
NCT 01078622	Olaparib	2	Spain, US	Active
NCT 02034916	Talazoparib	2	UK	Active
NCT 01009788	ABT-888, Temozolomide	2	US	Active
NCT 02282345	Talazoparib	2	US	Active
NCT 02286687	Talazoparib	2	US	Recruitment
NCT 03382574	Denosumab	1	US	Recruitment
NCT 03428802	Pembrolizumab	2	US	Recruitment
NCT 03329937	Niraparib	1	US	Recruitment
NCT 01149083	Veliparib	2	US	Active
NCT 02401347	Talazoparib	2	US	Recruitment
NCT 03499353	Talazoparib	2	US	Recruitment

Discussion

During the analyzed period, seven active substances were tested in the BRCA1 and BRCA2 gene mutations in breast cancer. Most of the clinical studies are conducted in an active substance Talazoparib – 6 types of research, which from the 16th of October 2018 is officially approved by the FDA as medicine in advanced treatment of breast cancer in BRCA positive patients [4]. The second place is Olaparib – 3 trials, which is registered in Europe and the United States in the treatment of ovarian cancer in further line therapy [5]. The use of this medicine may not reach the full potential; therefore, there are conducted other clinical studies in differential diagnosis and treatment lines, which gives hopes to ill patients. Another active substance is Veliparib – 4 types of research, which from 2014 is in the third stage of ovarian cancer recognition, triple-negative breast cancer, and non-small-cell lung carcinoma [6]. Niraparib also 2 trials; it was approved for treating ovarian cancer on 27th of March 2017 in the US and in Europe on 16th of November 2017 [7,8]. Another active substance, which is tested in the event of BRCA mutation, is the Tremelimumab – 1 trial, which was unsuccessfully tested in the recognition of malignant melanoma, mesothelioma, and non-small-cell lung cancer [9]. Temozolomide – 1 trial is registered as a medicine for patients with newly diagnosed glioblastoma multiforme in a combination of x-ray therapy, and next with monotherapy [10]. The last two active substances that have proven effects are Pembrolizumab and Denosumab. Pembrolizumab is a humanized antibody used in cancer immunotherapy. Pembrolizumab is approved by the FDA for several different cancers [11]. Denosumab is a human monoclonal antibody for the treatment of osteoporosis, treatment-induced bone loss, metastases to bone, and giant cell tumor of bone [12,13]. In the United States, more research is being carried out in this diagnosis than in the European Union. The United States also dominate in terms of clinical trials during recruitment. About 58% of clinical trials in breast cancer worldwide are conducted in the United States. The clinical trials market in the United States has more significant development potential than the

European Union market. One EU concept for improving the situation of clinical trials is a Regulation (EU) No 536/2014 of the European Parliament and of the Council of the 16th of April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. The primary purpose of the Regulation is to streamline and shorten the procedure for obtaining permits for clinical trials of medicinal products. It provides for the submission of one central application (via the Internet portal), which will allow sponsors to avoid the preparation of various documentation and international application forms for global clinical trials. Due to delays in creating the portal, the application of this Regulation has been postponed several times. According to unofficial information, it is planned until the end of the first quarter of 2020 [14]. Oncologist engagement in clinical trials has an effect on patient recruitment, which in turn can affect trial success. Encouraging primary care physicians to a patient participant in clinical trials should be the next step in improving the EU clinical trial market. A survey conducted in Canada on 127 physicians by Bylund L. et al, shows that primary care physicians may be an important group to target in trying to improve cancer clinical trial participation among minority patients. Future work should explore methods of an educational intervention for such interested providers [15]. A survey conducted on 221 oncologists by Somkin CP. et al shows that to increase trial participation, there is a critical need for infrastructure to support trials, especially additional support staff and research nurses. In addition, there is a need for better intra-organizational communication and consideration of the impact of trial design on internal health plan resources. This research supports the need to continue a national dialogue about the broadly defined benefits and costs of clinical trials to patients, physicians, and health plans [16].

Conclusion

Clinical studies in breast cancer in the BRCA1 and BRCA2 gene mutations give hope to many patients waiting for innovative treatments. The

United States is conducting more clinical trials in this disease than the European Union. The most commonly studied drug substance is Talazoparib. Most studies are conducted in phase III. Of the European Union countries, Spain is the country where the largest number of studies on medicinal products in the BRCA1 and BRCA2 gene mutations are carried out in breast cancer.

References

1. Bray F, Ferlay J, Soerjomataram I, Siegel R, Torre A, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA: A Cancer Journal for Clinicians 2018; 68(6): 394-424. https://doi.org/10.3322/caac.21492.

2. Weitzel JN, Lagos VI, Cullinane CA, Gambol PJ, Culver JO, Blazer KR et al. Limited family atructure and BRCA gene mutation status in single cases of breast cancer. Journal of the American Medical Association 2007; 297(23): 2587-2595. https://doi.org/10.1001/jama.297.23.2587.

3. Couch FJ, DeShano ML, Blackwood MA, Calzone K, Stopfer J, Campea L et al. BRCA1 mutations in women attending clinics that evaluate the risk of breast cancer. NEJM 1997; 336(20): 1409-1415. https://doi.org/10.1056/NEJM199705153362002.

4. Food and Drug Administration [Internet]. Available from: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-talazoparib--gbrcam-her2-negative-locally-advanced-or-metastatic-breast-cancer [cited 20.01.2020].

5. Ledermann J, Harter P, Gourley C, Friedlander M, Vergote I, Rustin G et al. Olaparib maintenance therapy in platinum-sensitive relapsed ovarian cancer. NEJM 2012; 366(15): 1382-1392. https://doi.org/10.1056/NEJMoa1105535.

6. Rugo HS, Olopade OI, DeMichele A, Yau C, van 't Veer LJ, Buxton MB et al. Adaptive randomization of veliparib-carboplatin treatment in breast cancer. NEJM 2016; 375(1): 23-34. https://doi.org/10.1056/NEJMoa1513749.

7. The European Society for Medical Oncology (ESMO) [Internet]. Available from: https://www.esmo.org/oncology-news/Niraparib-Receives-FDA-Fast-Track-Designation-for-the-Treatment-of-Recurrent-Platinum-Sensitive-Ovarian-Fallopian-Tube-or-Primary-Peritoneal-Cancer [cited 20.01.2020].

8. Food and Drug Administration [Internet]. Available from: https://www.fda.gov/drugs/resources-information-approved-drugs/niraparib-zejula [cited 20.01.2020].

9. Ribas A, Hauschild A, Kefford R, Punt CJ, Haanen JB, Marmol M et al. Phase III, open-label, randomized, comparative study of tremelimumab (CP-675,206) and chemotherapy (temozolomide [TMZ] or dacarbazine [DTIC]) in patients with advanced melanoma. Journal of Clinical Oncology 2016; 26(15): LBA9011.

10. European Medicines Agency [Internet]. Available from: https://www.ema.europa.eu/en/documents/product-information/temozolomide-sun-epar-product-information_pl.pdf [cited 21.01.2020].

11. Syn NL, Teng MWL, Mok TSK, Soo RA. De-novo and acquired resistance to immune checkpoint targeting. The Lancet Oncology 2017; 18(12): e731-e741. https://doi.org/10.1016/s1470-2045(17)30607-1.

12. McClung MR, Lewiecki EM, Cohen SB, Bolognese MA, Woodson GC, Moffett AH et al. (February 2006). Denosumab in postmenopausal women with low bone mineral density. The New England Journal of Medicine 2006; 354(8): 821-831. https://doi.org/10.1056/NEJMoa044459.

13. European Medicines Agency [Internet]. Available from: https://www.ema.europa.eu/en/documents/overview/prolia-epar-summary-public_en.pdf [cited 21.01.2020].

14. Official Journal of the European Union. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [cited 21.01.2020].

15. Bylund CL, Weiss ES, Michaels M et al. Primary care physicians' attitudes and beliefs about cancer clinical trials. Clin Trials 2017; 14(5): 518-525. https://doi.org/10.1177/1740774517717722.

16. Somkin CP, Altschuler A, Ackerson L, Geiger AM, Greene SM, Mouchawar J et al. Organizational barriers to physician participation in cancer clinical trials. Am J Manag Care 2005; 11(7): 413-421.

Journal of Health Study and Medicine
2020, No. 1
pp. 131-150
DOI 10.36145/JHSM2020.07

Investigating Health Behaviors as a Basis for Developing Health Education Programs for Children and Adolescents from Rural Areas

Katarzyna Sygit[1]
https://orcid.org/0000-0001-7173-2266

Marian Sygit[1]
https://orcid.org/0000-0002-7902-7761

Jan Krakowiak[2]
https://orcid.org/0000-0002-3435-9658

[1] State Vocational Academy in Kalisz, Poland
[2] Medical University of Lodz, Poland

Address for correspondence

Katarzyna Sygit
State Vocational Academy in Kalisz
4 Nowy Świat Str., 62-800 Kalisz, Poland
e-mail: ksygit@poczta.onet.pl

Abstract

Unfavorable living conditions, particularly in rural areas, and the relatively low level of health culture (manifested by incorrect nutrition, insufficient physical activity, alcohol abuse, and smoking) do not promote health of the population.
The aim of this study was an assessment of research on health behaviors, based on literature, which could serve as a basis for developing health education programs for children and adolescents from rural areas.
Specialist literature indicates that health education is neglected, non-uniform, and conditioned by various factors: both environmental and individual. Therefore, identifying threats, pointing to their conditions, and diagnosing situations, especially among school adolescents, is particularly needed and welcomed.
The issue of researching health behaviors of young people, especially from rural areas, as well as the development of a compatible research tool, is of utmost importance. The lack of such a tool results in problems when one needs to compare research results obtained by various authors. The theoretical knowledge and implementation of some health programs often does not bring any practical results.
What is needed are specific actions aimed at promoting health at school and at home, as well as the ability to use existing knowledge to analyze and search for factors conditioning health behavior of adolescents.

Key words: *health programs, rural areas, health situation, health behaviors, health education.*

Introduction

Health behaviors of young people, particularly from rural areas, have become the subject of interest of numerous researchers in recent years [1,2,3,4,5].

This issue is very current and important in terms of searching for the causes of unsatisfactory health condition of children and adolescents [6,7,8].

In Poland and Europe, health behaviors are a particularly burning issue, therefore finding a solution or making decisions in this regard seems to be very urgent. Currently, many adverse health behaviors are observed in school groups from urban and rural areas; at the same time, it is increasingly difficult to observe health-promoting health behaviors [12,9,10,11].

Health and education of children and adolescents translate into a healthy and prosperous future. Health behaviors of pupils, as suggested by numerous studies, are in the process of shaping [12,13,14,15]. They are flawed with many irregularities; in order to eliminate or reduce their impact, it is necessary for the pupils to be able to actively implement rules of conduct which will give them a sense of value, responsibility for their own health and for others'. For this to happen, a young person should know that for maintaining and improving health, enhancing knowledge and following the rules of healthy lifestyle are needed; this is not easy because the majority of our society is accustomed to an unhealthy lifestyle and ignoring doctors' warnings, which causes e.g. deterioration of children and adolescents' health [16,17,18,19].

The aim of the study

The aim of this study was an assessment of research on health behaviors, based on literature, which could serve as a basis for developing health education programs for children and adolescents from rural areas.

Review methods

The paper includes studies in Polish and English, published in 2000-2017, which were selected on the basis of a review of the following databases: Web of Science, ResearchGate, Google Scholar. The databases were searched using the following keywords and their combinations: health behaviors, health education, health programs, rural environment, health promotion and literature analysis of the discussed issue.

Review results

Health situation of children from rural areas

Children and adolescents constitute over 30% of the total Polish population. An analysis of the age structure of children and adolescents by residence indicates that the size of the youngest age groups in rural areas is increasing, with the size of these groups in cities is getting smaller (Table 1).

Unfavorable living conditions, particularly in rural areas, and the relatively low level of health culture (manifested by incorrect nutrition, insufficient physical activity, alcohol abuse, smoking) do not promote health of the population. Country's health situation, including situation of children and adolescents, is assessed as highly unsatisfactory [8,19].

In the child population, this is reflected by the still too high infant mortality, a high rate of various types of birth defects, while in older children and adolescents in high morbidity (Table 2), high disability rate and mortality rate [8].

Table 1. The size of children and adolescents' age groups, by place of residence (in thousands and %)

Age group	Total		Urban		Rural	
	in thousands	in %	in thousands	in %	in thousands	in %
0-4	2387.2	100.0	1331.4	55.8	1055.8	44.2
5-9	2936.6	100.0	1672.6	57.0	1264.0	43.0
10-14	3337.3	100.0	2017.9	60.5	1319.4	39.5
15-19	3253.9	100.0	2054.8	56.2	1199.0	36.8

Source: State of health of the Polish population in 2016, Central Statistical Office (GUS) in Poland 2016 [8].

Table 2. Data on the state of health of children and adolescents from the West Pomeranian voivodship

Total number of children and adolescents	2016/17 school year	1	2	3	4	5	6	7	8	9	10	11	12
348275	West Pomeranian voivodship	14161	28847	5008	40557	10745	4548	3407	2123	82726	77375	7848	272
	% of all children	40.7	8.3	1.4	11.6	3.1	1.3	1.0	0.6	23.8	22.2	2.3	0.1

Source: State of health of the Polish population in 2016. Central Statistical Office (GUS) [8].

Legend:

1 – children with deviations of total health; 2 – disorders in somatic development; 3 – disorders in mental development; 4 – vision defects and diseases; 5 – chronic ear diseases; 6 – chronic respiratory diseases; 7 – cardiovascular disease; 8 – chronic urinary tract diseases; 9 – permanent damage to the musculoskeletal system; 10 – including disorders of body statics; 11 – other diseases requiring active care; 12 – including diabetes.

Trends in morbidity and mortality in the population of Polish children and adolescents are quite constant.

The compiled structure of hospitalizations by age and main causes of morbidity indicate that respiratory diseases are the cause of 23.4% of all hospitalizations, while:

- injuries and disorders – 16.2%
- digestive system diseases – 14.7%
- infectious diseases – 7.6%
- urinary tract diseases – 7.0%
- diseases of the nervous system – 6.9% [8,20].

The six main reasons for hospitalization amount to 75% of cases of hospitalization for patients aged 1-19. With age, there is a decrease in the frequency of hospitalizations due to:

- respiratory diseases (from 37.2% in the 1-4 age group to 8.5% in the 15-19 age group),
- congenital malformations (from 6.1% to 1.7%), while the incidence of hospitalizations due to injuries increases (from 12.3% to 22.4%).

An important reason for hospitalization of girls aged 15-19 in Poland and worldwide are obstetric causes: complications of pregnancy, childbirth, and puerperium [6,8,21].

Comparison of hospitalization rates in terms of patients' place of residence indicates that main causes of morbidity (except for complications of pregnancy and childbirth) have a significantly higher hospitalization rate in cities than in the rural areas [8].

The mortality rate of children and adolescents, despite its decline, is still higher in Poland than in other European countries (especially in the boys' population). In 2016, 4,127 deaths were registered in the group of children and adolescents, which gives a rate of 36.3%/100,000 of population, which is lower by 1.1% than in 2010. 2,267 deaths of children and adolescents took place in urban areas and 1,960 deaths in the rural environment (respectively 32.4 and 42/100,000 of population). As many as 65% of deaths in this age group were boys' deaths.

The most common causes of death for children and adolescents were: accidents, poisoning and injuries (51.9% of all deaths), cancer (14.4%), nervous system diseases (8.6%), birth defects (7.5%) and cardiovascular diseases [6,19].

A disturbing upward trend is the suicide deaths of children and adolescents.

According to the data of the Central Statistical Office (GUS), 85% of parents assess the state of health of their children aged 0-14 as 'very good' or 'good'. The study also shows that a quarter of children suffer from at least one chronic disease. The highest percentage of chronically ill patients is in the 10-14 age group, while the lowest in the 0-4 age group [19].

According to parents, children most often suffer from chronic allergic diseases (9.9%), posture defects (7%), lung diseases, including bronchitis, asthma (4.7%), neuroses (2.4%) (mainly children aged 10-14) [22].

Boys are more prone to sickness than girls. As many as 11.2% of children have hearing, vision and speaking problems – definitely more in the urban areas (13%) than in the countryside (8.8%).

The research indicates that urban adolescents more often show weight deficiencies than their peers from rural areas (13% versus 7%) [21,23,24]. The state of health of urban children and youth seems worse than that of children and youth from the countryside, regardless of the financial status of the family.

Health behaviors of children from rural areas

The deteriorating health situation of the society, as well as numerous health threats and health problems of the population, force us to look for ways to improve the situation. Health should be taken care of at every stage of life: both in childhood and later on. One should think about their own health, how to maintain it and improve as early as in the school period. During the development of correct habits and attitudes, there must be space for healthy lifestyle, protecting one's own health, and health education [4,25,26,27].

Specialist literature indicates that this sphere of life and health education is somewhat neglected, undoubtedly highly diversified, and conditioned by various factors: both environmental and individual [19,28,29].

Therefore, identifying threats, discovering their conditions, and diagnosing situations, especially amongst school adolescents, is particularly needed and welcomed. The creation of health promotion and prevention programs for the school-aged group must be based on a fully reliable diagnosis of the social situation – documented and monitored.

Information from school environments as well as daily press reports indicate a need for specific actions in the field of school health education, led by a qualified staff of educators. These are the expectations and needs of young people and those who are not indifferent to their health [19,30].

According to B. Woynarowska, health behaviors should be defined as behaviors or actions (or lack thereof) which directly or indirectly affect human health and well-being [19].

The following health behaviors may be distinguished: health-promoting (pro-health, positive), such as physical activity, proper nutrition, maintaining cleanliness of the body and the environment, maintaining safety or maintaining a proper relationship between people; and behaviors that threaten health (anti-health, negative), such as smoking, alcohol abuse, use of other psychoactive substances, risky sexual behavior [19,31,32,33].

Health behaviors of young people, particularly in recent years, have become the subject of interest of numerous researchers [1,5,9,10,20,34].

This issue is very current and important in terms of searching for the causes of unsatisfactory health condition of children and adolescents.

Studies on health behaviors of school children were initiated in Europe in 1982 in three countries: Finland, Norway, and England. The research program was approved by the World Health Organization (WHO) as a comparative research program in Europe, repeated every 4 years. The first series of studies was carried out in 1983-1984 in 4 countries, the second in 1985-1986 in 11 countries, the third in 1989-1990 in 14 coun-

tries and the fourth in 1993-1994 in 22 countries and Canada. Poland was admitted as a full member of the international group in 1989 and participated in the third and fourth series of studies [23].

In Poland, health behaviors are a particularly burning issue, therefore finding a solution or making decisions in this regard seems to be very urgent. This may be demonstrated by data on the morbidity rates, and consequently disability and death rates, because 75% of all deaths are caused by cardiovascular diseases, cancer and injuries [8,19]. The report of the National Health Program stated that if the linear increase in mortality is maintained, the death rate per 100,000 people in 2020 will reach 800 [19].

Increased expenditure on health care cannot mitigate this problem. It is important to take advantage of the fact that corrective medicine has only a minor impact on health. Hence, primary prevention offers promising benefits, implemented through appropriate modification of human behavior, improving awareness and health culture of the society [11,19].

Currently in Poland many adverse health behaviors are observed in school-age groups from urban and rural areas, while it is increasingly difficult to observe health-promoting health behaviors. Health and education of children and adolescents translate into a healthy and prosperous future. In Poland, the number of children and adolescents reaches 12.2 million, which equals 32% of the total population of the country; their psycho-physical condition is not the best: the average 15-year-old will probably live 6-7 years shorter than their peer in developed countries. Polish youth assess their own health increasingly worse: as many as 13% of pupils aged 11-15 believe that they are 'not very healthy', while e.g. in Hungary, it is only 1% [19,11,22].

Individual and population health depends on 4 groups of factors: lifestyle and health behaviors are the most important (they condition 50-60% of health potential), then physico-social environment (20-25%), genetic factors (approx. 20%), and healthcare (10%) [6,7,11,19]. Health education – especially introduced in rural schools – may help solve the problem [19,35,36].

Schools offer a great opportunity to impart knowledge about health and to develop skills and values important for a healthy future. Education prepares children for independence and the role of a healthy and productive individual. Therefore, health education should play the most important role not only in the aspect of health, but also education itself [19].

Meeting the most important health-oriented needs will ensure the health of the whole society. This goal is justified by the deteriorating health condition of Poles [21].

According to numerous studies, health behaviors of pupils are not ultimately shaped. They are flawed with many irregularities; in order to eliminate or reduce their impact, it is necessary for the pupils to be able to actively implement rules of conduct which will give them a sense of value, responsibility for their own others' health. For this to happen, a young person should know that for maintaining and enhancing health, knowledge and following the rules of healthy lifestyle are needed; this is not easy because the majority of our society is accustomed to an unhealthy lifestyle and ignoring doctors' warnings – which causes deterioration of children and adolescents' health [12,32,33,37].

The issue of researching health behaviors of young people, also from rural areas, as well as the development of a compatible research tool, is of utmost importance. The lack of such a tool results in problems when one needs to compare research results obtained by various authors.

The theoretical knowledge and implementation of some health programs often does not bring any practical results.

What is needed are specific actions aimed at promoting health at school and at home, as well as the ability to use existing knowledge to analyze and search for factors conditioning health behavior of adolescents. Skillful combination of thinking, actions and knowledge of factors that condition health behaviors will help counteract one-sided learning tendencies, and will focus more on skills and versatility in harmonious development of adolescents. It is a necessity because today's schools do not fully prepare their pupils for life [12,20,38,39].

To achieve this goal, child's upbringing should start from an early age, and be based on a proper health education program to shape health behaviors. "Education is the foundation of freedom" (J. Tischner) because only a free man can work creatively and solve current challenges – including those related to their own health. Health education clearly supports this process and plays a part in who the child becomes, how independent they will be in their actions, in experiencing the truth, and in choosing the way to preserve – or even improve – their own health and improve the health situation of rural adolescents [29,30,39].

Conclusions

1. The practical significance of the study and analysis of health behaviors – to provide health education in rural areas

In order to form a strategy in the field of health education addressed to schoolchildren and adolescents in rural areas, it is important to know the perception of health in this environment. Research on pupils' health awareness can be divided into groups: e.g. a health self-assessment, confrontation with classic definitions that take into account age, gender, etc. [39].

Providing children with health knowledge, developing their skills, beliefs and attitudes, we may facilitate a healthy lifestyle, and improve their health and quality of life. Health education at school is believed to be the most profitable, long-term investment in the society's health.

When developing educational programs, it is assumed that health education consists of acquiring knowledge, shaping skills, beliefs and attitudes necessary to preserve and improve one's own health and health of other people.

Therefore, the goal of school health education must be to help pupils:

- make responsible decisions that enable them to develop harmoniously and in health,
- develop a healthy lifestyle,

- identify their own health problems and take measures to solve them [28,29].

The concept of comprehensive health education at school (recommended by WHO) assumes:

- taking into account the holistic approach to health (in all of its aspects) and factors that condition health which are related to people, the environment and living conditions,
- using all circumstances for the purpose of health education,
- striving to unify health information that pupils receive from various sources – family, school, peers, mass media, advertising,
- encouraging pupils to a healthy lifestyle and creating conditions and opportunities that promote pro-health behaviors at school [19,23].

2. The role of a parent in health education

Parents are an important element in the health education of children and adolescents – in accordance with the WHO motto: 'Health begins at home'. Parents are the first health educators of their children and play this role even during the child's school education [1,19,29].

The effectiveness of this parental education depends on parents' education, social status, understanding of health issues, attitude towards health issues, economic status, worldview, etc. Hence, the ultimate effectiveness of health education depends on the extent to which the school initiates and develops cooperation with parents, which should include:

1. Determining the most important topics with parents and joint analysis of the possibility of their implementation, as well as educating parents,
2. Giving parents the opportunity to report back about what the child has learnt from the lesson, and what the effects of school education are.
3. Encouraging parents who have appropriate knowledge and skills to volunteer to conduct certain classes at school.
4. Organizing health-related events at school together [4,29,30,35].

Recent years served for the development of educational programs offered to schools on various health topics.

It is important for each school to develop its own child health protection program. Due to the procedure for developing specific educational programs, health education should help them (but also other members of the school community, i.e. teachers and parents of pupils):

- acquire and verify knowledge about how to stay healthy,
- shape and modify the so-called 'life skills' (in the context of health regeneration),
- shape or change beliefs,
- shape or verify attitudes necessary to keep, improve and restore one's own health and health of other people [19,35,40].

In young person's life there are situations directly related to keeping health (e.g. vaccinations or a decision to visit a doctor) and ones related indirectly (which are much more common), such as various elements of a lifestyle: rest, nutrition, physical activity.

These situations are accompanied by specific behaviors which directly or indirectly affect health. Health education program for pupils should therefore address these situations and behaviors.

The education system offers a great opportunity to affect the health of children and adolescents. Naturally, it should not be forgotten that the process of socialization is dominated by the family, therefore patterns observed at home may either strengthen or be in conflict with the patterns of a healthy lifestyle.

References

1. Brooks FM, Magnusson J, Spencer N, Morgan A. Adolescent multiple risk behaviour: an asset approach to the role of family, school and community. Journal of Public Health 2012; 34: 48-56.

2. Hanson MD, Chen E. Socioeconomic Status and Health Behaviors in Adolescence: A Review of the Literature. Journal of Behavioral Medicine 2017; 30: 263-285. https://doi.org/10.1007/s10865-007-9098-3.

3. Janssen E, van Osch L, de Vries H, Lechner L. Examining direct and indirect pathways to health behaviour: the influence of cognitive and affective probability beliefs. Health Psychol 2013; 28: 546-560. https://doi.org/10.1080/08870446.2012.751108.

4. Ponczek D, Olszowy I. Styl życia młodzieży i jego wpływ na zdrowie [Youth lifestyle and its impact on health]. Probl Hig Epidemiol 2012; 93: 260-268.27 (in Polish).

5. Arora T, Hosseini-Araghi M, Bishop J. The complexity of obesity in U.K. adolescents: relationships with quantity and type of technology, sleep duration and quality, academic performance and aspiration. Pediatr Obes 2013; 8: 358-366. https://doi.org/10.1111/j.2047-6310.2012.00119.x.

6. Woynarowska B, Oblacińska A. Stan zdrowia dzieci i młodzieży w Polsce. Najważniejsze problemy zdrowotne [Health status of children and adolescents in Poland. The most important health problems]. Studia BAS 2014; 2: 41-64 (in Polish).

7. Gessert C, Waring S, Bailey-Davis L, Conway P, Roberts M, VanWormer J. Rural definition of health: a systematic literature review. BMC Public Health 2015; 15: 378-384. https://doi.org/10.1186/s12889-015-1658-9.

8. Stan zdrowia ludności Polski w 2016 r. [The health status of the Polish population in 2016]. Warszawa: Główny Urząd Statystyczny; 2017 (in Polish).

9. Delisle T, Werch C, Wong A. Relationship Between Frequency and Intensity of Physical Activity and Health Behaviours of Adolescents. J Sch Health 2010; 80: 134-140. https://doi.org/10.1111/j.1746--1561.2009.00477.x.

10. Lipowski M. Level of optimism and health behavior in athletes. Med Sci Monit 2012; 18: 39-43. https://doi.org/10.12659/msm.882200.

11. Mazur J. Zdrowie i zachowania zdrowotne młodzieży szkolnej w Polsce na tle wybranych uwarunkowań socjodemograficznych [Health and health behaviors of schoolchildren in Poland in the context of selected sociodemographic conditions]. Wyniki Badań HBSC 2015 (in Polish).

12. Currie C, Roberts C, Morgan A, Smith R, Settertobulte W, Samdal O et al. Young people's health in context. Health Behaviour in School--aged Children (HBSC) study: in-ternational report from the 2001/2002 survey. Health Policy for Children and Adolescents 2014; 4: 1319.

13. Resnick MD, Catalano RF, Sawyer SM, Viner R, Patton GC. Seizing the opportunities of adole-scent health. Lancet 2012; 379: 1564-1567.

14. Jackson CA, Henderson M, Frank JW, Haw SJ. An overview of prevention of multiple risk beha-viour in adolescence and young adulthood. Journal of Public Health 2012; 34: 31-40. https://doi.org/10.1093/pubmed/fdr113.

15. Domaradzki J. O definicjach zdrowia i choroby [About definitions of health and disease]. Folia Medica Lodziensia 2013; 40: 5-29 (in Polish).

16. Raudsepp L, Viira R. Sociocultural Correlates of Physical Activity in Adolescents. Pediatric Exercise Science 2000; 12: 51-60. https://doi.org/10.1123/pes.12.1.51.

17. Lazzeri G, Azzolini E, Pammolli A, Simi R, Meoni V, Giacchi MV. Factors associated with unheal-thy behaviours and health outcomes: a cross-sectional study among tuscan adolescents (Italy). International Journal for Equity in Health 2014; 13: 83. https://doi.org/10.1186/s12939-014-0083-5.

18. Haug E, Samdal O, Morgan A, Ravens-Sieberer U, Currie C. Overweight in school-aged children in 35 countries: associations witheating habits, physical activity, socioeconomic status and perce-ived health. WHO Europe 2016; 14: 14-21.

19. Woynarowska B. Edukacja zdrowotna [Health education]. Warszawa: Wydawnictwo Naukowe PWN; 2017 (in Polish).

20. Currie C, Zanotti C, Morgan A, Currie D, Looze M, Roberts C et al. Social determinants of health and well-being among young people. Key findings from the Health Behaviour in School-aged Children (HBSC) study: international report from the 2009/2010 survey.

21. Wojtyniak B, Goryński P, Moskalewicz B. Sytuacja zdrowotna ludności Polski i jej uwarunkowania [The health situation of the Polish population and its determinants]. Warszawa: Narodowy Instytut Zdrowia Publicznego – Państwowy Zakład Higieny; 2012 (in Polish).

22. Raport z badań. Polacy o swoim zdrowiu oraz prozdrowotnych zachowaniach i aktywnościach [Research report. Poles about their health and pro-health behaviors and activities]. Warszawa: CBOS; 2012 (in Polish).

23. World Health Organization, European strategy for child and adolescent health and development, WHO Regional Office for Europe. Copenhagen; 2015 (EURO/05/5048378). Wyniki badań HBSC 2015.

24. Mazur J, Mierzejewska E. Współczesne podejście do oceny stanu zdrowia dzieci i młodzieży na poziomie populacji [A contemporary approach to assessing the health status of children and adolescents at the population level]. Medycyna Wieku Rozwojowego 2014; 8: 16-23 (in Polish).

25. Farmer S, Hanratty B. The relationship between subjective wellbeing, low income and substance use among schoolchildren in the north west of England: a cross-sectional study. Journal of Public Health 2012; 34: 512-522. https://doi.org/10.1093/pubmed/fds022.

26. Sawyer SM, Afifi RA, Bearinger LH, Blakemore SJ, Dick B, Ezeh AC, Patton GC. Adolescence: a foundation for future health. Lancet 2012; 379: 1630-1640. https://doi.org/10.1016/S0140-6736(12)60072-5.

27. Ferreira I, van der Horst K, Wendel-Vos W, Kremers S, van Lenthe FJ, Brug J. Environmental correlates of physical activity in youth – a review and update. The International Association for the Study of Obesity 2016; 13: 129-154. https://doi.org/10.1111/j.1467-789X.2006.00264.x.

28. Posłuszna M. Edukacja zdrowotna we współczesnej szkole – program prozdrowotny [Health education in contemporary school – health program]. Problemy Pielęgniarstwa 2010; 18: 13-19 (in Polish).

29. Charońska E, Janus B. Modele edukacji zdrowotnej [Models of health education]. Zeszyty Naukowe Kraków 2004; 74: 54-62 (in Polish).

30. Antoszczuk G. Promocja zdrowia w przedszkolnej edukacji zdrowotnej [Health promotion in pre-school health education]. Wychowanie Fizyczne i Zdrowotne 2005; 2: 29-34 (in Polish).

31. Sygit M. Zdrowie Publiczne [Public Health]. Warszawa: Wolters Kluwer Polska; 2017.

32. Viner RM, Ozer EM, Denny S, Marmot M, Resnick M, Fatusi A et al. Adolescence and the social determinants of health. Lancet 2012; 379: 1641-1652. https://doi.org/10.1016/S0140-6736(12)60149-4.

33. Heszen I, Sęk H. Behawioralne uwarunkowania zdrowia i choroby [Behavioral determinants of health and disease]. In: Heszen I, Sęk H, eds. Psychologia zdrowia [Health psychology]. Warszawa: PWN; 2012, pp. 90-104 (in Polish).

34. Gordon-Larsen P, McMurray RG, Popkin BM. Determinants of Adolescent Physical Activity and Inactivity Patterns. Pediatrics 2000; 105: 83.

35. Charzyńska-Gula M, Jaworska M, Bogusz R, Bartoszek A. Rodzina i szkoła jako źródła informacji zdrowotnej – opinie uczniów [Family and school as sources of health information – students' opinions]. Medycyna Ogólna i Nauki o Zdrowiu 2013; 19: 3-10 (in Polish).

36. Olejniczak D. Praktyczne wykorzystanie health literacy – alfabetyzmu zdrowotnego, jako narzędzia osiągania celów zdrowotnych [Practical use of health-literacy as a tool for achieving health golas]. Journal of Education, Health and Sport 2016; 6: 34-45 (in Polish).

37. Cazuza de Farias Júnior J, Mendonça G, Florindo AA, Gomes de Barros MV. Reliability and validity of a physical activity social support assessment scale in adolescents – ASAFA. Scale, Revista Brasileira de Epidemiologia 2014; 17: 355-370.

38. Suls J, Krantz DS, Williams GC. Three strategies for bridging different levels of analysis and embracing the biopsychosocial model. Health Psychol 2013; 32: 597-601. https://doi.org/doi: 10.1037/a0031197.

39. Borzucka-Sitkiewicz K, Kowalczewska-Grabowska K. The New Perspectives of Health Promoting Schools Development – Current Situation in Europe and Poland. The New Educational Review 2010; 21: 45-52.

40. Wojciechowska K. Nauczyciel przewodnikiem w procesie promowania zdrowia w szkole [A teacher's guide in the process of promoting school health]. Roczniki Pedagogiczne 2014; 6: 2014 (in Polish).

Journal of Health Study and Medicine
2020, No. 1
pp. 151-166
DOI 10.36145/JHSM2020.08

Oral Health Status in Adults with Cystic Fibrosis – Dental and Microbiological Assessment

Sylwia Jarzynka[1]
https://orcid.org/0000-0002-9269-3494

Gabriela Olędzka[1]
https://orcid.org/0000-0001-7090-6156

Anna Minkiewicz[1]
https://orcid.org/0000-0002-1249-7670

Bartłomiej Iwańczyk[2]
https://orcid.org/0000-0002-9684-0308

Joanna Chudekbrak[3]

Paulina Gulatowska[3]

Wojciech Skorupa[4]

Jacek Nowak[5]
https://orcid.org/0000-0002-4117-2920

Ewa Augustynowicz-Kopeć[6]
https://orcid.org/0000-0001-6162-8748

[1] Department of Medical Biology, Medical University of Warsaw, Poland
[2] The Chair and Department of Oral Surgery, Medical University of Lublin, Poland
[3] Student Research Club, Medical University of Warsaw, Poland
[4] First Clinic of Lung Diseases, Institute of Tuberculosis and Lung Diseases, Warsaw, Poland
[5] Department of Oral Surgery, Medical University of Warsaw, Poland
[6] Department of Microbiology, Institute of Tuberculosis and Lung Diseases, Warsaw, Poland

Address for correspondence

Bartłomiej Iwańczyk
The Chair and Department of Oral Surgery
Medical University of Lublin
7 Karmelicka Str., 20-081 Lublin, Poland
e-mail: dent.iwanczyk@gmail.com

Abstract

Oral health status during cystic fibrosis may have an influence on respiratory system infections in the group of cystic fibrosis (CF) patients. This important clinical problem was taken in research in the Department of Medical Biology, Medical University of Warsaw, in cooperation with Institute of Tuberculosis and Lung Diseases in Warsaw. In this project an oral health status in the group of adult CF patients was examined. The aim of the current study was to report a case of 33-year old woman, treated in the Institute of Tuberculosis and Lung Diseases. The woman was qualified to the dental and microbiological examinations because of the particularly intensified lesions in her oral cavity. Research included a dental history, evaluation of the dentition and a microbiological analysis. The dental study involved an oral hygiene and a previous treatment. During examination of an oral cavity, attention was paid to: enamel and mucosa defects, dental and periodontal condition, decay intensity, dental plaque index and bleeding index. Saliva properties were analysed, using Saliva Check Buffer test. CRT Bacteria test was used to evaluate presence of cariogenic bacteria. What is more, the Cone Beam Computed Tomography was performed. Basing on the research, it was demonstrated that CF may influence reduced saliva secretion and microbiological changes, resulting in a development of intensified dental caries. Reported case may contribute to formulate a dental care program in CF patients.

Key words: *oral health status, cystic fibrosis.*

Introduction

Cystic fibrosis (CF) is a congenital, incurable, multi-system genetic disease. In the Caucasian population, cystic fibrosis is the most common autosomal recessive inherited disease [1,2]. The highest incidence of cystic fibrosis is observed in northern European countries – 1:2500/3500 births in which every 25th person is a carrier of the cystic fibrosis gene [3].

In Poland, the CF group is estimated at around 2,000 patients [4,5]. In contrast, the Polish Cystic Fibrosis Registry only covers 1,600 patients. The survival of patients with CF in Poland is much shorter (median death 22 years) than in other countries. In Western Europe, the median death increases >40 years [3,6]. 1/3 of Polish patients with CF are adults [4]. With the progress of medicine, this group is constantly growing.

Cystic fibrosis is caused by mutations in the CFTR (cystic fibrosis transmembrane conductance regulator) gene located on the long arm of chromosome 7. The mutations lead to disorders in transport of chloride ions and increase in absorption of sodium ions and water in the membranes of epithelial glands of exocrine glands. As a result, the secretion thickens and increases, which causes disorders of the functioning of many organs. Thick secretions and mucous plugs are mainly found in the lungs, pancreas, liver and gastrointestinal tract [4].

Dysfunctions occurring in both respiratory and digestive systems may predispose cystic fibrosis patients to the development of oral diseases, in particular caries and periodontal disease. Dental problems and antibiotic therapy undertaken in the course of cystic fibrosis may affect the incidence of respiratory infections in this group of patients [1,3]. Invasive respiratory tract infections are the main cause of hospitalisation and premature deaths of CF patients [5,6]. In cystic fibrosis, good oral health can have a significant impact on a patient's overall well-being.

Aim of the research

Dental and microbiological assessment of oral health in adults with cystic fibrosis.

Material and methods

Research was carried out at the Department of Medical Biology in cooperation with the Department of Dental Surgery of the Medical University of Warsaw. The study involved 10 adults with cystic fibrosis (7 women and 3 men, average age 30.1±6.52), treated at the Institute of Tuberculosis and Lung Diseases in Warsaw. Patients with particularly severe lesions in the mouth were qualified for the study.

The project involved subject tests, including general and dental history. The subject tests were dental procedures in the oral cavity and microbiological development of clinical samples taken from patients.

Dental examinations and lesions were evaluated in the structure of enamel, changes on the mucosa, the state of teeth and periodontium, the presence of caries. The DMFT (Decayed, Missing, and Filled Permanent Teeth) index was determined. The API oral hygiene index (*Approximal Plaque Index*) indicating the level of dental plaque and the BoP (bleeding on probing) index were determined. The biochemical properties of saliva samples were determined using the Saliva Check Buffer (*Vivadent*) test.

Microbiological tests included the assessment of the presence of cariogenic bacteria *Lactobacillus* spp. and *Streptococcus mutans* in the mouth with the use of the CRT Bacteria test (*Vivadent*). In addition, studies were performed on the occurrence of *Staphylococcus aureus* strains in samples of patients' saliva as a potential respiratory pathogen.

Results

General history

Subjective studies found that patients were chronically taking a number of primary therapy medications. Mucus-reducing preparations such as Pulmozyme® were mainly used in nebulisation. Patients were taking bronchodilators, including Sabumalin®. In patients with diagnosed asthma, Salmex® was additionally used in therapy. Patients were supplemented with enzyme preparations (Kreon 25,000®, Proursan®).

In hormonal disorders i.e. diabetes or hypothyroidism or hyperthyroidism, insulin and/or thyroid hormones have been used. Patients were subjected to constant antimicrobial therapy. Bactericidal antibiotics were used, mainly against Gram-negative bacteria, including Colistin® from the polymyxin group. Subjective tests showed a reduced value of forced expiratory volume in one second (FEV1), on average 57.4% of the value due. Continuous inhalations with 3% sodium chloride were conducted as a support.

Dental history

Information was obtained on regular attendance for follow-up and therapeutic visits to the dentist. The patients performed hygienic activities properly. Most patients brushed their teeth twice a day, using a manual and electric brush alternately, using toothpaste with a high abrasion rate. Five patients (50%) reported subjective discomfort in the mouth. The main causes of discomfort reported by patients were the occurrence of dry mouth, gum and tooth pain, and a feeling of too little saliva. In one case, the patient experienced increased salivation (Table 1).

Table 1. Characteristics of the studied group of patients with cystic fibrosis

Patient No.	Age	Enamel lesions	Other changes	Subjective discomfort
1	57	-	-	dryness sore gums toothache
2	33	hypoplasia hypomineralisa-tion	-	dryness little saliva
3	27	hipoplazja	-	-
4	31	-	bruxism abraded chewing surfaces	-
5	22	hypoplasia hypomineralisa-tion	-	-
6	22	hypoplasia	-	dryness
7	27	-	-	-
8	21	discoloration	-	dryness
9	32	-	gingivitis	large amount of saliva
10	29	hypoplasia	-	-

Dental examination

In the intraoral examination, in 6 patients (60%) changes in the structure of hypoplasia, hypomineralisation and discoloration of enamel were found. No changes in the enamel structure were observed in 4 patients (40%). Additional changes were found in 2 patients, including abraded chewing surfaces (bruxism) and gingivitis (Table 1). The oral mucosa of patients was faded.

The dentition of the patients was assessed. One patient (32 teeth) presented the full dentition. Other patients had shortages, respectively: 31 teeth – 2 patients, 30 – 3, 29 – 1, 25 – 1, 24 – 1 and 21 teeth – 1 patient (Table 2).

In half of the patients (5 patients) ≥50% of dentition was affected with caries, including two people where caries was observed in all

teeth (100%). The above data allowed calculating the caries severity index (DMFT) in the range of 3-27. In one case a very low DMFT index of 3 was observed. The patient had twenty-nine teeth in his mouth, he lost three teeth due to complications of caries. In the remaining four patients, the DMFT index ranged from 9-15. Of 24-31 teeth present in the oral cavity, 37.5%-48.4% of them had cavities, teeth were affected by caries or filled teeth during treatment because of this (Table 2).

Table 2. Dental indicators of oral health of patients with cystic fibrosis

Index name	Index values obtained in patients with cystic fibrosis	Interpretation
DMFT	3-27: 27 – 1 patient (10%) 25 – 1 patient (10%) 21 – 1 patient (10%) 17 – 1 patient (10%) 15 – 2 patients (20%) 12 – 2 patients (20%) 9 – 1 patient (10%) 3 – 1 patients (10%)	significant number of teeth with carious changes
API norm: <39% sufficient condition <25% – optimal hygiene	16-61%: <25% – 1 patient (10%) <39% – 2 patients (20%) >45% – 7 patient (70%)	sufficient or poor oral hygiene, to be improved
BoP norm: <10%	3-68,9%: >10% – 9 patients (90%) within norm – 1 patient (10%)	moderate and high extent of gingivitis
pH norm: 6,8-7,8	5,8-7,8: <6,8 – 5 patients (50%) within norm – 5 patients (50%)	too low, enamel demineralisation possible
Buffer capacity norm: 10-12	2-12: <10 – 7 patients (70%) within norm – 3 patients (30%)	reduced acid neutralisation capacity

The API oral hygiene index revealed the presence of dental plaque in the range of 16% to 61% of interdental spaces examined. An optimal API rate of <25% was obtained for only one patient. A fairly good oral hygiene index <39% was obtained for two patients. Seven patients showed a sufficient and poor level of hygiene (API> 45%), with a recommendation for improved hygiene (Table 2).

According to the BoP index, between 90% and 68.9% of bleeding sites were observed in 90% of patients due to gum probing. Only one patient's BoP result was within the norms and was 3% (Table 2).

Saliva buffer capacity and pH were also assessed in dental tests using the Saliva Check Buffer test. Normal buffer capacity was obtained in three patients. Seven patients had low results, which meant a reduced ability to neutralize acids. 50% of patients had normal pH values in the range of 6.8-7.8. In the second half of the group of patients low pH values compared to normal values (5.8-6.6) were obtained, which reduced the possibility of enamel demineralisation (Table 2).

Microbiological tests of the oral cavity

The conducted microbiological tests with the use of CRT Bacteria tests allowed to determine the level of cariogenic bacteria in samples of stimulated saliva taken from patients. In five patients (50%), very numerous (≥105cfu/ml) granulosa of *Streptococcus mutans* type, acid-forming streptococci involved in the development of caries were grown. The amount of *S. mutans* in saliva from 104 to 105cfu/ml, promotes the deposition of these microorganisms in the plaque and initiates caries. Other patients (50%) were in a group of low risk of developing caries: <105 cfu/ml or no growth in *S. mutans* (Table 3).

the next isolates from patients were *Lactobacillus* bacteria. 4 patients (40%) who were cultured with ≥105 cfu bacteria per ml of saliva were classified as high risk of caries. This type of bacteria is acidophilic and acid-forming, constituting the second important group of pathogens involved in the development of caries. Low levels of these cariogenic bacteria were found in six patients (60%) (Table 3).

Table 3. The level of cariogenic bacteria in the saliva of patients with cystic fibrosis

Caries-causing bacteria	Number of colonies (CFU/ml)	Number of patients	Interpretation of bacterial levels
Streptococcus mutans	≥105	5(50%)	high
	<105	1(10%)	low
	brak wyhodowania	4(40%)	-
Lactobacillus spp.	≥105	4(40%)	high
	<105	6(60%)	low

During microbiological tests, saliva samples were cultured for *Staphylococcus aureus* strains. This species is the most common etiological factor in respiratory tract infections in patients with cystic fibrosis. Very numerous and numerous colonies of *S. aureus* (≥105-104 cfu/ml) were cultured from three patients (30%). Single S. aureus colonies were isolated from four patients (40%). The growth of these bacteria was not determined in three patients (30%) (Table 4).

Table 4. Appearance of Staphylococcus aureus in saliva samples of patients with cystic fibrosis

Cultured Staphylococcus aureus	Number of patients
≥105 – 104 cfu/ml	4 (40%)
Single colonies (102 cfu/ml)	3 (30%)
Lack of growth	3 (30%)

Discussion

The oral health status of cystic fibrosis is a significant clinical problem. Dental disorders, including caries and periodontitis, may deregulate the microbiome of the mouth. Oral conditions, bacterial imbalance and cystic fibrosis persistent antibiotic therapy predispose to the development of invasive, fatal infections in the respiratory and digestive systems. The topic of infection in children with cystic fibrosis is constantly raised in the literature. In contrast, research on the adult patient population, both glo-

bally and in Poland, is much less common. The available literature lacks a comprehensive assessment of the oral condition of a group of adults with CF. In addition, available data often leads to contradictory conclusions [13]. Therefore, the research presented in this paper is a very important report, especially in the aspect of prophylaxis of invasive respiratory tract infections.

Many authors dealing with the subject of cystic fibrosis point to a constantly growing population of patients with cystic fibrosis. According to the results of the Burgel et al study, by 2025 the number of patients may increase by up to 50%. According to estimates, up to 75% will be adults. The research concerned a large group of patients treated in 34 European countries. According to researchers' estimates, in Poland in 2025, nearly 78% of patients will be adults [15]. That is why research conducted in this group of patients is so important. New diagnostic and therapeutic problems are emerging that still pose a challenge to medicine. New CFTR protein mutations are diagnosed, in which the combination of clinical symptoms, including dental ones, is constantly changing.

The results of many Polish and world studies indicate poor oral condition and great importance of dental treatment in the group of patients with cystic fibrosis, both children and adults. Some researchers indicate that CF patients are at risk of developing periodontal and oral mucosa diseases due to frequent upper respiratory tract infections and oral respiration [15]. Similar conclusions are presented by Ferrazzano et al. who estimated a larger number of tartar in CF patients, usually on the surface of the lower front teeth [11].

In the literature, you can also find studies showing good oral health in this group of patients [14]. According to Peker et al., continuous intake of antibiotics may reduce the number of bacteria in the oral cavity, in particular cariogenic ones, i.e. *Streptococcus mutans*. These studies have shown that chronic antibiotic therapy can be an inhibitor of bacterial biofilm development in the oral cavity and thus reduce tooth decay [14].

The presented clinical case of an adult patient with cystic fibrosis confirms the relationship between the state of oral health and the develop-

ment of infection and the general well-being of patients. The patient had dental disorders, high caries, dental plaque and bleeding gums as well as a high percentage of caries. At the same time, the patient was diagnosed with chronic infections of bacterial and fungal aetiology requiring antimicrobial therapy.

Analysing the given clinical case and available literature data, it seems reasonable to undertake further dental and microbiological tests in people with cystic fibrosis. In addition, it seems necessary to compare the results of tests performed in both groups of patients, children and adults. The basis of preventive and therapeutic measures is the development of a long-term dental management plan for CF patients, which can translate into reduction in the percentage of invasive respiratory infections, more effective primary and antimicrobial therapy, higher percentage of successful, uncomplicated infections, lung transplantation and longer patient survival.

Results

Enamel lesions, hypoplasia, discoloration and hypomineralisation were observed in patients. Four patients had particularly advanced lesions. The average bleeding index was 33.28%, which proved a moderate extent of inflammation. Nearly half of the respondents (45.38%) showed a high plaque index. Significant advancement of caries was observed in the majority of patients. The DMFT index was on average 16.2, which accounted for more than half of the teeth affected by carious lesions. Studies have shown a reduced saliva buffer capacity, on average at 6.8 and normal saliva pH values (6.8). A high percentage of caries-forming bacteria of the *Lactobacillus* and *Streptococcus mutans* types. In terms of the number of cariogenic bacteria in saliva, patients were classified in classes 2 and 3 – with a high level of cariogenic bacteria (>105 CFU/ml of saliva). At the same time, patients were diagnosed with chronic infections of bacterial and fungal aetiology requiring antimicrobial therapy.

Summary

The oral health condition is worse or without significant differences compared to the oral cavity of healthy patients, there is a need to continue research with the extension of the research group.

The results of the research are an introduction to the development of a scientific program on the principles of dental management in patients with cystic fibrosis.

The basis of preventive and therapeutic measures is the development of a long-term dental management plan for CF patients, which can translate into a reduction in the percentage of invasive respiratory infections, more effective primary and antimicrobial therapy, a higher percentage of successful, uncomplicated infections, lung transplantation and longer patient survival.

The condition of oral health may affect the survival rate and improve the quality of life of patients with cystic fibrosis. The results of global and Polish scientific research indicate a significant relationship between the state of oral health and oral microbiome in the pathogenesis of invasive respiratory infections of bacterial and fungal aetiology [7-10].

In the light of the above-mentioned studies, the most common oral health disorders in CF patients are: developmental defects, enamel defects and discolouration, reduced salivation, high levels of caries and an increase in oral colonisation with *Streptococcus mutans* streptococci and other cariogenic bacteria [1,11-13]. It seems that the development of these diseases is influenced by CFTR protein dysfunction, regulating the level of mineralisation and enamel pH, as well as the use of long-term antibiotic therapy, mainly from the tetracycline and carbapenem groups [6,9,13-16]. Other oral disorders in this group of patients are periodontal and mucosal diseases, mainly inflammation and an increased amount of tartar, usually found on the surface of the lower front teeth [16-19].

References

1. Chi DL. Dental caries prevalence in children and adolescents with cystic fibrosis: a qualitative systematic review and recommendations for future research. Int J Paediatr Dent 2013; 23(5): 376-86.

2. Pogorzelski A. Data not published. Rabka-Zdrój: Instytut Gruźlicy i Chorób Płuc; 2012.

3. Harrington N, Barry PJ, Barry SM. Dental treatment for people with cystic fibrosis. Eur Arch Paediatr Dent 2016; 17: 95-203.

4. Walkowiak J, Pogorzelski A, Sands D, Skorupa W, Milanowski A, Nowakowska A. Zasady rozpoznawania i leczenia mukowiscydozy. Standardy Medyczne Pediatria 2009; 6: 352-378.

5. Mazurek H. Mukowiscydoza – problemy diagnostyczno-terapeutyczne. Terapia 2012; 11-12: 50-53.

6. Gray RD, Downey D, Taggart CC. Biomarkers tomonitor exacerbations in cystic fibrosis. Expert Rev Respir Med 2017; 4: 255-257.

7. Stężowska-Kubiak S. Charakterystyka epidemiologiczno-kliniczna polskiej populacji chorych na mukowiscydozę [Doctoral dissertation]. Poznań: Uniwersytet Medyczny; 2011, p. 99.

8. Reeves P, Molloy K, Pohl K, McElvaney NG. Hypertonic saline in treatment of pulmonary disease in cystic fibrosis. Sci World J 2012; 465230.

9. Valenza G, Tappe D, Turnwald D et al. Prevalence and antimicrobial susceptibility of microorganisms isolated from sputa of patients with cystic fibrosis. J Cyst Fibros 2008; 7: 123-127.

10. Garczewska B, Jarzynka S, Kuś J, Skorupa W, Augustynowicz-Kopeć E. Fungal infection of cystic fibrosis patients – single center experience. Pneumonol Alergol Pol 2016, 84: 151-159.

11. Ferrazzano GF, Orlando S, Sangianantoni G, Cantile T, Ingenito A. Dental and periodontal health status in children affected by cystic fibrosis in a southern Italian region. Eur J Paediat Dent 2009; 10(2): 65-68.

12. Mahboubi MA, Carmody LA, Foster BK, Kalikin LM, VanDevanter DR, LiPuma JJ. Culture-based and culture-independent bacteriologic analysis of cystic fibrosis respiratory specimens. J Clin Microbiol 2016; 54(3): 613-619.

13. Caldas RR, Le Gall F, Revert K et al. Pseudomonas aeruginosa and periodontal pathogens in the oral cavity and lungs of cystic fibrosis patients: a case-control study. J Clin Microbiol 2015; 53(6): 1898-1907.

14. Peker S, Mete S, Gokdemir Y, Karadag B, Kargul B. Related factors of dental caries and molar incisor hypomineralisation in a group of children with cystic fibrosis. Eur Arch Paediat Dent 2014; 15: 275-280.

15. Burgel PR, Bellis G, Olesen HV et al. Future trends in cystic fibrosis demography in 34 European countries, Task Force on The Provision of Care for Adults with Cystic Fibrosis in Europe. Eur Respir J 2015; 46: 133-141.

16. Górska R, Konopka T. Periodontologia współczesna. Warszawa: Med Tour Press International; 2013, pp. 71-75.

17. Dupont L. Lung transplantation in cystic fibrosis patients with difficult to treat lung infections. Curr Opin Pulm Med 2017; 23(6): 574-579.

18. Sarvas EW, Huebner CE, Scott JM, Aps JK, Chi DL. Dental utilization for Medicaid-enrolled children with cystic fibrosis. Spec Care Dent 2016; 36(6): 315-320.

19. Olejniczak M, Emerich-Poplatek K, Wierchoła B, Adamowicz-Klepalska B. Stan przyzębia i periodontologiczne potrzeby lecznicze u chorych na mukowiscydozę. Dent Med Probl 2004; 41(3): 461-467.