Pope John Paul II State School of Higher Education in Biała Podlaska

Health Problems of Civilization

Volume 12 / Issue 4 / Year 2018

Scientific journal of Pope John Paul II State School of Higher Education
in Biała Podlaska, published since 2007.

Biała Podlaska 2018

Health Problems of Civilization
(Formerly *Human and Health*) ISSN 2353-6942, eISSN 2354-0265

Publisher
Pope John Paul II State School
of Higher Education in Biała Podlaska,
Sidorska 95/97, 21-500 Biała Podlaska
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Cover design, DTP and print
Advertising Agency TOP

Translation/proof-reading
Izabela Dąbrowska, MD ONLINE

Journal indexed in:
Emerging Sources Citation Index (Web of Science, Clarivate Analytics), Index Copernicus, ICV 2017: 100, International Committee of Medical Journal Editors (ICMJE), Polish Ministry of Science and Higher Education: 9 points, AGRO, ProQuest, Polish Medical Bibliography, Polish Medical Library (GBL), WorldCat, ROAD Directory of Open Access Scholarly Resources, DOAJ, Bielefeld Academic Search Engine, Harvard Libraries University of California Libraries

Ministerstwo Nauki i Szkolnictwa Wyższego

Zwiększenie udziału zagranicznych recenzentów w czasopiśmie „Health Problems of Civilization" – zadanie finansowane w ramach umowy Nr 583/P-DUN/2017 ze środków Ministra Nauki i Szkolnictwa Wyższego przeznaczonych na działalność upowszechniającą naukę

Digitalizacja czasopisma „Health Problems of Civilization" – zadanie finansowane w ramach umowy Nr 583/P-DUN/2017 ze środków Ministra Nauki i Szkolnictwa Wyższego przeznaczonych na działalność upowszechniającą naukę

Poprawa jakości języka anglojęzycznych artykułów publikowanych w czasopiśmie „Health Problems of Civilization" w celu podniesienia renomy czasopisma – zadanie finansowane w ramach umowy 819/P-DUN/2018 ze środków Ministra Nauki i Szkolnictwa Wyższego przeznaczonych na działalność upowszechniającą naukę

Ministry of Science and Higher Education
Republic of Poland

Increase in the participation of foreign reviewers in "Health Problems of Civilization" – task financed under the agreement No. 583/P-DUN/2017 by the Minister of Science and Higher Education allocated to the activities of disseminating science

Digitalization of "Health Problems of Civilization" – task financed under the agreement No. 583/P-DUN/2017 by the Minister of Science and Higher Education allocated to the activities of disseminating science

Improving the quality of articles written in English and published in "Health Problems of Civilization" to enhance its reputation – task financed under the agreement No. 819/P-DUN/2018 by the Minister of Science and Higher Education allocated to the activities of disseminating science

The online version is the original version of this journal.
Full electronic version available online at: www.termedia.pl/hpc.

Printed in 100 copies

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ORYGINALNY ARTYKUŁ NAUKOWY

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ISSN 2353-6942

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D. Data interpretation
interpretacja danych
E. Preparation of manuscript
przygotowanie artykułu
F. Literature analysis/search
wyszukiwanie i analiza literatury
G. Funds collection
zebranie funduszy

Summary

Background. Within the last few decades, the prevalence of obesity has increased rapidly throughout the world. Epidemiological studies indicate a relationship of several types of cancer with obesity. The study aimed was to analyse the relation between body mass index (BMI) and the risk of developing gastric cancer.
Material and methods. A multicenter case-control study was conducted between 2010 and 2015 in Poland. The study included 152 patients with gastric cancer and 152 patients with normal results of esophagogastroduodenoscopy performed in the same period and matched for age, education and sex. BMI was calculated by using patients' height and weight. An analysis of environmental factors associated with the risk of gastric cancer was performed.
Results. The group with the diagnosis of gastric cancer was characterised by significantly higher regular consumption of alcohol and was found to include a higher percentage of smokers compared to the control group. In a subgroup analysis, it was found that there was a significantly higher body mass index among both men and women diagnosed with gastric cancer. A relation between gastric cancer and both overweight (BMI 25.0-29.9 kg / m^2) and obesity (BMI≥30 kg / m^2) was established. In a multivariate analysis, this was an independent risk factor for gastric cancer.
Conclusions. We suggest that BMI should be considered as an independent risk factor for developing gastric adenocarcinoma, which should lead to further research leading to the development of recommendations for the prevention of gastric cancer for people with high BMI.

Keywords: gastric cancer, body mass index, public health, overweight

Streszczenie

Wprowadzenie. W ciągu ostatnich kilku dekad występowanie nadwagi i otyłości wzrasta gwałtownie. Badania epidemiologiczne wskazują na związek kilku typów nowotworów złośliwych z nadwagą i otyłością. Celem naszej pracy była analiza relacji pomiędzy wskaźnikiem masy ciała (BMI) a ryzykiem zachorowania na gruczołowego raka żołądka.
Materiał i metody. Wieloośrodkowe badanie kliniczno-kontrolne zostało przeprowadzone w latach 2010 do 2015 w województwie pomorskim w Polsce. Do badania włączono 152 pacjentów z rakiem żołądka i 152 pacjentów z prawidłowymi wynikami ezofagoduodendoskopii wykonywanymi w tym samym okresie. Przypadki zostały dopasowane pod względem wieku, wykształcenia i płci. BMI obliczano na podstawie wzrostu i wagi pacjenta. Dodatkowo przeprowadzono analizę czynników środowiskowych mogących mieć związek z ryzykiem zachorowania na gruczołowego raka żołądka.
Wyniki. W grupie z rozpoznaniem raka żołądka stwierdzano wyraźnie wyższą częstość regularnego spożywania alkoholu i wyższy odsetek osób palących w porównaniu do grupy kontrolnej. W analizie podgrup stwierdzono znacznie podwyższony wskaźnik masy ciała zarówno wśród mężczyzn jak i kobiet, u których zdiagnozowano raka żołądka w stosunku do grupy kontrolnej. Relacja pomiędzy występowaniem raka żołądka i nadwagi (BMI 25.0-29.9 kg / m^2) lub otyłości (BMI≥30 kg / m^2) była istotna statystycznie. W analizie wieloczynnikowej podwyższony BMI był niezależnym czynnikiem ryzyka rozwoju gruczołowego raka żołądka.
Wnioski. Sugerujemy, że BMI należy traktować jako niezależny czynnik ryzyka rozwoju gruczolakoraka żołądka, co powinno prowadzić do dalszych badań prowadzących do opracowania zaleceń dotyczących zapobieganiu i wczesnemu wykrywaniu raka żołądka u osób z wysokim BMI.

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References: 36
Submitted: 2017 Jan 25
Accepted: 2017 Feb 28

Słowa kluczowe: rak żołądka, wskaźnik masy ciała, zdrowie publiczne, nadwaga

Adamowicz K. Association between Body Mass Index and gastric cancer in Pomeranian men and women. Health Prob Civil. 2018; 12(4): 231-237. https://doi.org/10.5114/hpc.2018.76517

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Introdution

Over the past decades, there has been observed a continuous increase in the incidence of adenocarcinoma of the distal oesophagus, gastroesophageal junction and of the stomach (later in this paper, to simplify it, we will use the name: gastric adenocarcinoma) [1]. Despite the decreasing incidence of gastric cancer in recent decades all over the world, it remains the fourth most common cancer and the third leading cause of cancer-related deaths in men and the fifth leading cause of cancer-related deaths in women [2]. There is evidence that specific environmental factors increase the risk of gastric cancer, e.g. smoking, excessive alcohol intake, low intake of fruit and vegetables and high intake of smoked food [3-5]. Moreover, a relationship between the risk of gastric cancer and chronic Helicobacter pylori infection has been found [6]. Most of these data come from Asian countries. This is, however, consistent with the data presented in the report of the World Cancer Research Fund and the American Institute for Cancer Research (WCRF / AICR) in 2007, where the major causes of cancers are environmental factors and factors related to lifestyle, such as diet, insufficient physical activity, excessive alcohol consumption and smoking [7].

The prevalence of overweight and obesity has been increasing worldwide in recent decades. It is well known that obesity leads to many adverse health effects, including increased risk of cancer. Many studies support the hypothesis that elevated BMI is associated with an increased risk of certain cancers, e.g. there is a well-demonstrated association between obesity and an increased risk of developing colorectal cancer, pancreatic cancer, and kidney cancer [8-13]. On the other hand, there are reports in the literature of a reduced risk of developing lung cancer with increasing BMI [14-15]. In addition, no correlation has been established between BMI and the risk of prostate cancer [16-17], or rectal cancer [18-19]. Given the various effects BMI has on the incidence of various cancers, the question of obesity's influence on the long-term incidence of cancers is still open to debate.

In the case of gastric cancer, several studies have shown a correlation between body mass index (BMI) and an increased risk of gastric cancer, which was confirmed in the meta-analysis [20]. In some studies, however, this correlation remained inconclusive, dependent on sex, the type of obesity, or Helicobacter pylori infection [21-24]. The purpose of the study presented here was to investigate the relationship between BMI and the risk of gastric cancer in the Polish society (taking into consideration the family history and the infection of Helicobacter pylori in gastric cancer, against eating habits, alcohol consumption and smoking).

Material and methods

The study included a total of three hundred and four people who had esophagogastroduodenoscopy in the F. Ceynowa Specialist Hospital in Wejherowo and in the Regional Oncology Centre in Gdansk, Poland, from May 2010 to December 2015. During this period a total of 153 cases of gastric adenocarcinoma were diagnosed by histopathology. One person was excluded from the study due to incomplete survey data. The control group was selected and matched from healthy patients who had esophagogastroduodenoscopy at the same time. Each case was matched individually with a control according to certain characteristics such as age, education, and gender. All study participants had their case history taken by a gastroenterologist, a surgeon, or a clinical oncologist, including their medical history, family history of cancers, obstetric/gynecological history in women and the factors related to lifestyle, including smoking and alcohol consumption. In each patient, a test for the presence of Helicobacter pylori infection was performed. Anthropometric information (height and weight) were measured by a qualified treatment nurse. Body weight and height were measured according to standard protocols with an accuracy corresponding to 0.1 kg and 1.0 cm. The study was based on a retrospective analysis of documents and the clinical treatment history of patients. Before the analysis, a database was prepared, consisting of the following columns: age, sex, education, smoking, alcohol consumption, significant burdens and chronic diseases, family history of diseases, gynecological history, Helicobacter pylori infection, height, weight, BMI, the final diagnosis. A current smoker was defined as a person who had smoked an average of at least one cigarette per day during the preceding 12 months. A former smoker was defined as someone who did not meet this definition but had smoked before. People who had never smoked were considered non-smokers. Drinking alcohol was defined as consuming at least three alcoholic drinks of any kind per week. These data were obtained basing on patients' own reporting in a standard patient questionnaire. A positive family history of gastric cancer was defined as an occurrence of this disease in first and /or second-degree relatives. The presence of chronic diseases was defined as answering "yes" to the question: "Have you ever been diagnosed with the following chronic diseases?". All patients were weighed and measured by a treatment nurse. BMI was defined as the ratio of the body weight (expressed in kg) divided by the square of the body height (in meters) (weight [kg] / height [m2]). BMI ranges were adopted in accordance with the definitions from WHO criteria. BMI values were divided into four groups:

underweight (BMI of less than 18.5 kg / m2), normal BMI (from 18.5 to 24.99 kg / m2), overweight (from 25 to 29.99 kg / m2) and obesity (≥ 30.0 kg / m2) (Table 1).

Table 1. BMI by WHO

body mass index	classification
0–18.49	underweight
18.5–24.9	normal
25–29.9	overweight
30–34.9	obese
35–40 and above	morbidly obese

The project was approved by the Bioethics Commission at the Regional Medical Council in Gdansk and by the directors of both hospitals. The condition of consent was the preparation of a database with complete anonymity of the study group.

Statistical methods

To calculate the BMI, measurements of height and weight carried at the day of esophagogastroduodenoscopy (the body weight in kilograms divided by the square of the body height in meters) were used. Differences in epidemiological factors between the groups of patients with gastric adenocarcinoma and the control group were tested using the Student's t-test for continuous variables and the Chi-square test for categorical variables. All tests were two-tailed and a p-value less than 0.05 was considered statistically significant. For statistical calculations, programs: Microsoft Excel version 2003 and PQStat version 1.4. were used.

To examine the relationship between BMI and the risk of gastric cancer, non-parametric logistic regression was used. For this purpose, following variables were used: age (continuous), smoking, alcohol consumption, family history of gastric cancer, chronic diseases (separately for patients with diabetes, chronic gastritis, and stomach ulcers), and Helicobacter pylori infection. In addition, for women, menopause was included in the logistic regression analysis.

Results

During the study (on average 66 months for both centres) 153 cases of gastric adenocarcinoma were found. Selected epidemiological data and the characteristics of the respondents are summarised in Table 2.

Table 2. Selected characteristics of 152 gastric cancer cases and 152 controls

variable	men					women				
	case (n = 109)		control (n = 109)		p	case (n = 43)		control (n = 43)		p
	n	%	n	%		n	%	n	%	
age (years, mean ± SD)	63.6 ± 9.3		63.3 ± 9.8		0.47	64.3 ± 8.7		64.0 ± 9.3		0.71
smoking	83	76.1	64	58.7	<0.01	25	58.1	11	25.5	<0.01
drinking alcohol	68	62.3	42	38.5	<0.01	12	27.9	7	16.2	<0.01
family history of gastric cancer	29	26.6	6	5.5	<0.01	9	20.9	1	2.3	<0.01
medical history										
diabetes mellitus	12	11.0	13	11.9	0.16	6	13.9	5	11.6	0.35
chronic gastritis	23	21.1	15	13.7	<0.01	7	16.2	8	18.6	0.41
helicobacter pylori infection	72	66.1	70	54.2	0.18	36	83.7	35	81.4	0.49
menopause						41	95.3	39	90.7	0.37
BMI Information (mean ± SD)										
BMI	27.3 ± 1.18		24.8 ± 1.22		<0.01	29,4 ± 1.73		26.3 ± 1.1		<0.01
height (cm)	173.5 ± 9.8		173.2 ± 9.4		0.24	165.8 ± 7.9		165.5 ± 8.4		0.29
weight (kg)	83.1 ± 11.4		75.5 ± 10.8		<0.01	81.2 ± 10.8		72.6 ± 7.7		<0.01

p value calculated by Chi-square test for categorical variables and t test for continuous variables

The mean age of the patients was 63.6 for men and 64.3 for women. The group of patients with gastric cancer was more likely to have a positive family history of gastric cancer than the control group (26.6% vs 5.5% for men and 20.9% vs. 2.3% for women respectively). In addition, the group with cancer included more smokers, both among men (76.1% vs 58.7%) and among women (58.1% vs 25.5%). Alcohol consumption was also more frequent in patients with gastric cancer, both in men (62.3% vs. 38.5%) and women (27.9% vs 16.2%). Moreover, in the case of men, there was a difference established in the incidence of chronic gastritis and peptic ulcers (21.1% vs 13.7%). In women, there was no difference of this kind (16.2% vs 18.6%). There was no statistically significant difference between groups, when it comes to the percentage of post-menopausal women (95.3% vs 90.7%). No effect of Helicobacter pylori infection on the increased risk of gastric adenocarcinoma was found.

Body weight was significantly higher in patients diagnosed with gastric cancer compared to the control group, both among men (88.1 ± 11.4 kg and 80.5 ± 10.8 kg respectively) and women (86.2 ± 10, 8 compared to 77.6 ± 7.7 kg).

The relation between BMI and the risk of gastric cancer is shown graphically in Fig. 1.

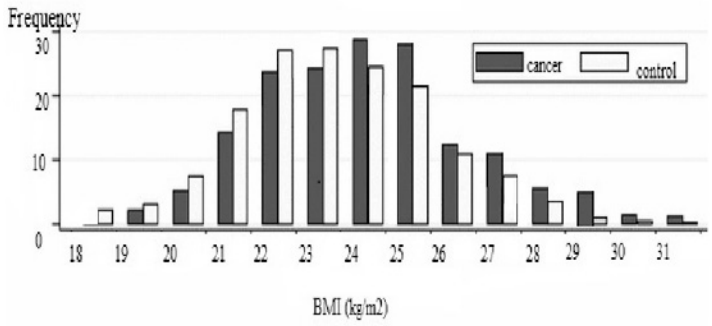

Figure 1. The association between BMI and gastric cancer risk

Taking BMI of 21.75 kg / m2 as an optimum, the risk of gastric cancer increases in men with BMI higher than or equal to 25.0 kg / m2, whereas in women, the risk increases in patients with BMI of 25.3 kg / m2 or more. The odds ratio is estimated at more than two in men with BMI over 28.7 kg / m2 and in women with BMI over 28.5 kg / m2.

Discussion

Over the past several decades we have seen a significant increase in the incidence of adenocarcinoma of the gastroesophageal junction in the populations of Western countries, in contrast to a decrease in the incidence of cancer of the distal stomach [25]. In the literature, there is a hypothesis that this trend is a result of an increasing rate of Helicobacter pylori eradication. This hypothesis may indicate that adenocarcinomas are not associated with Helicobacter pylori infection but with other environmental factors, such as diet, smoking, alcohol consumption and obesity. In our study, we analysed the relationship between BMI, smoking, alcohol consumption, and increased risk of gastric cancer, assuming that BMI is associated with an increased risk of gastric cancer. Our results indicate that the BMI is a substantial risk factor for developing gastric cancer. After excluding the impact of other known epidemiological risk factors for developing gastric cancer, high BMI has remained significantly related to the risk of gastric cancer (both in men and women).

There are at least a few mechanisms that may explain the relation between overweight and obesity and an increased risk of developing this type of cancer. First, the accumulation of body fat increases the concentration of endogenous hormones, such as insulin and the insulin-like growth factor-1, as well as steroids. The result of these hormones' influence is an increase in cell proliferation and the weakening of apoptosis, which, consequently, spurs the growth of malignant cells. Also, insulin resistance and chronic hyperinsulinemia, produced by the metabolic adaptation to increased levels of free fatty acids circulation from adipose tissue can be conducive to developing cancer [26]. Secondly, overweight and obesity can promote the formation of Barrett's oesophagus, which is a precancerous condition [27]. One possible mechanism is an increase of intra-abdominal pressure on the lower oesophageal sphincter [26, 28]. Thirdly, the level of estrogen, which is closely associated with obesity, may be associated with an increased risk of certain cancers [29]. Fourth, obesity increases the release of inflammatory mediators that can promote tumour growth [30]. It is also suggested that obese people have prolonged passage through the oesophagus, resulting in a longer contact time between the oesophageal mucosa and food (containing potentially carcinogenic ingredients) [31].

However, even these suggested mechanisms explaining the link between obesity and the development of cancer are not sufficient. Reflecting on other causes, one must mention population ageing. People live longer, and the incidence of cancer has been significantly associated with ageing [32]. In the present study, the risk of gastric cancer was related to age and was significantly higher in patients older than 60, in comparison with those under the age of 60.

Another well-known risk factor for cancer is tobacco smoke, containing many chemical carcinogens, which can operate through direct contact with gastric mucosa or indirectly by the flow of blood. The cause-effect relationship between smoking and gastric cancer has been the subject of controversy in the past 20 years. A meta-analysis published in 1997 showed, however, that such a relation exists [33]. Our study also shows an increased risk of gastric cancer among current smokers. This correlation has been observed in both men and women.

The risk of gastric cancer is increased in patients with a positive family history of this cancer [34]. The risk of gastric cancer increases from 1.5 to 3.5 times in the case of family history of the disease. Of course, this may be since relatives tend to be exposed to the same environmental risk factors, but the influence of genetic factors cannot be excluded. Our study confirms that the presence of gastric cancer in first- and second-degree relatives increases the risk of developing this type of cancer. In addition, the risk was independent of smoking tobacco, BMI, education, sex, and age in the multivariate analysis.

This study has, however, several potential limitations, which should be considered in the analysis. Firstly, our study has a potential bias. Patients were recruited from hospitals performing treatments for gastric cancer. Secondly, the control group was not completely healthy. These were patients who volunteered to perform esophagogastroduodenoscopy, due to gastroenterological symptoms. To overcome this problem, we have compared the cases of disease with a control group, which had the same demographic profile and comorbidities. In fact, there is no significant difference between the groups regarding education, age, and sex. These variables were equalised in the selection of the control group.

Recently, a meta-analysis based on prospective studies has demonstrated that BMI is a risk factor for developing gastric cancer [35]. However, half of the studies which were included were based on self-reports of anthropometric data, which could lead to an overestimation of the relative risk [36]. The advantage of our study is that the data on weight and height were collected by a qualified nurse. As for the history of smoking and alcohol consumption, the situation was different, and the amount of alcohol consumed was very imprecise. Besides, our study did not include other factors, such as diet, physical activity or the amount of non-steroidal anti-inflammatory drugs taken.

Conclusions

Although the study involved a small population, it revealed a positive relation between BMI and gastric cancer. In summary, this study provides additional information to previous studies on the effect of BMI on the risk of gastric cancer. The results of our study may shed light on public health, stressing the importance of weight control in the prevention of gastric cancer. We suggest that BMI should be considered as an independent risk factor for developing gastric adenocarcinoma, which should lead to further research leading to the development of recommendations for the prevention of gastric cancer for people with high BMI.

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ORIGINAL PAPER
ORYGINALNY ARTYKUŁ NAUKOWY

Health Prob Civil. 2018, Volume 12, Issue 4
ISSN 2353-6942

EDUCATION ON HEALTHY EATING IMPROVED NUTRITION-RELATED PRACTICES IN POLISH PRESCHOOLS

EDUKACJA NA TEMAT PRAWIDŁOWEGO ŻYWIENIA POPRAWIŁA PRAKTYKI ZWIĄZANE Z REALIZACJĄ ŻYWIENIA W PRZEDSZKOLACH W POLSCE

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Authors' contribution
Wkład autorów:
A. Study design/planning
zaplanowanie badań
B. Data collection/entry
zebranie danych
C. Data analysis/statistics
dane – analiza i statystyki
D. Data interpretation
interpretacja danych
E. Preparation of manuscript
przygotowanie artykułu
F. Literature analysis/search
wyszukiwanie i analiza literatury
G. Funds collection
zebranie funduszy

Summary

Background. Improving the nutritional knowledge of the preschool staff responsible for nutrition can translate into better quality menus served to children. The purpose of the present study was to evaluate the effects of a nutrition education program in participating preschools. As criteria for evaluation of the program, changes in selected nutritional practices reported by the institutions' staff as well as their opinion on the program were analyzed.

Material and methods. The research consisted primarily of a survey, performed in 2015 and repeated in 2016 in randomly selected preschools participating in the program "Eating healthy, growing healthy" in Poland. In 2015, 66 institutions were included in the survey, and in 2016, 138 preschools were included. In both, the CATI method was used for data collection, and data were collected by specially trained interviewers. Respondents were asked about selected nutrition-related practices in the institution (e.g. usage of salt/sugar, water availability, meal presentation). They also evaluated the suitability of the program for diet planning in the preschool setting.

Results. Preschool managers evaluated the project very highly in terms of value and usefulness of the content in their daily practice. The program has brought results in changing nutrition practices: salt and sugar in the children's meals were reduced, water availability was increased, and menus were adapted to current nutritional recommendations. The high evaluation of the program increased the reported interest in participating in similar programs in the future, however, it did not translate into a greater willingness to include paid "healthy eating" workshops in the institutions.

Conclusions. Nutrition education improved the quality of nutrition in preschools, but in order to reach a wide range of institutions, it is necessary to focus on the implementation of free-of-charge educational programs.

Keywords: education, nutrition, children, preschools

Streszczenie

Wprowadzenie. Wiedza żywieniowa personelu odpowiedzialnego za żywienie dzieci w placówkach może przekładać się na lepszą jakość oferowanych w przedszkolach jadłospisów. Celem pracy była ocena efektów programu edukacyjnego w zakresie żywienia w uczestniczących przedszkolach. Jako kryteria oceny uwzględniono zmiany w wybranych praktykach żywieniowych deklarowane przez personel instytucji, a także ich opinię na temat programu.

Materiał i metody. Badanie przeprowadzono w 2015 r. i powtórzono w 2016 r. w losowo wybranych przedszkolach uczestniczących w programie edukacyjnym „Zdrowo jemy, zdrowo rośniemy" w Polsce. W 2015 r. w badaniu wzięło udział 66 instytucji, a w 2016 r. 138 przedszkoli. Dane zostały zebrane przez specjalnie przeszkolonych ankieterów metodą CATI. Respondentów zapytano o wybrane praktyki związane z żywieniem w instytucjach (np. stosowanie soli/cukru, dostępność wody, prezentację posiłków). Respondenci ocenili także przydatność programu w planowaniu diety w placówkach przedszkolnych.

Wyniki. Pracownicy przedszkoli bardzo wysoko oceniali projekt pod względem merytorycznym oraz przydatności informacji w codziennej praktyce. Program przyczynił się do poprawy praktyk żywieniowych: redukcji soli i cukru w posiłkach dla dzieci, większej dostępności wody i dostosowaniu jadłospisów do aktualnych zaleceń żywieniowych. Wysoka ocena programu zwiększyła deklarowane zainteresowanie uczestnictwem w podobnych programach w przyszłości. Nie przełożyło się to jednak na większą gotowość do uczestniczenia w płatnej edukacji na temat zdrowego żywienia.

Wnioski. Edukacja żywieniowa poprawiła jakość żywienia w przedszkolach. Jednak, aby dotrzeć do szerokiej rzeszy placówek wychowania przedszkolnego, konieczne jest wprowadzenie bezpłatnych programów edukacyjnych.

Słowa kluczowe: edukacja, żywienie, dzieci, przedszkola

Tables: 0
Figures: 6
References: 30
Submitted: 2017 Dec 18
Accepted: 2018 May 10

Myszkowska-Ryciak J, Harton A. Education on healthy eating improved nutrition-related practices in Polish preschools. Health Prob Civil. 2018; 12(4): 238-246. https://doi.org/10.5114/hpc.2018.79986

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Introduction

In the widespread epidemic of overweight and obesity, appropriate nutrition during the stage of growth and development is particularly important. Excess body mass in childhood translates into an increased risk of obesity in adulthood [1, 2]. In addition, eating habits are developed in childhood, and this translates into nutritional choices in adulthood. At the age of 3-5 years, the child's diet is still largely dependent on the parents, but the child's external environment is becoming more and more influential [3]. This is particularly pronounced in children attending preschool. In this institution, the child spends up to 10 hours a day and consumes at least 3 meals, which include up to 75% of the daily energy and nutrient intake [4]. This makes preschool an ideal setting for the promotion of healthy eating [5].

In Poland in 2015-2016 over 1.1 million children aged 3-5 years attended more than 21 000 preschool day care centers (DCCs) [6]. Adequate nutrition in these institutions is therefore crucial for the proper nutritional status of the pediatric population aged 3-5 years old in Poland. In this aspect, nutrition education is essential to increase knowledge and awareness of the correct composition of children meals, especially in terms of the adequate amount of vegetables, fruits, milk and milk products, and reduction of sugar and salt intake [4, 7, 8, 9]. Such educational actions should be first directed to parents/caregivers, as they decide on the child's diet. But this education also needs to include others, especially those who have an impact on diet planning, i.e. staff of childcare facilities [7, 8]. To be effective, educational activities should be always conducted by specially trained experts, have a broad range, and have consistent goals and scope.

An example of a nationwide nutritional education project implemented in kindergartens is the program "Mom, Dad, I prefer water!" which was initiated by Żywiec Zdrój S.A. in 2009 [10]. Its aim is to highlight the role of water in the daily diet, to draw attention to the issue of environmental protection, and to support in the development of healthy eating habits in children. Despite the long implementation period and nationwide coverage, there are no scientific publications assessing its effectiveness. Another example of an educational program directed both to preschool children and their parents is "Correct child nutrition and adult person health" conducted in 6 preschools in Cracow in 2006 [11]. In this program children participated in workshops on the acceptance of fresh fruits and vegetables, and parents were educated on the correlations between childhood nutrition and the development of select lifestyle diseases. However, this program also lacks information on its effectiveness, i.e. its impact on the consumption of fruits and vegetables by children or their presence in preschool menus.

"Eating healthy, growing healthy" (EHGH) is a unique, comprehensive educational program initiated by the Nutricia Foundation, whose main purpose was to promote the principles of proper nutrition in nurseries and preschools and to develop proper nutritional habits among children [12]. DCC staff, parents and caregivers of children received nutrition education from specially trained educators - nutritionists and specialists in the field of dietetics, human nutrition and health promotion. The educational activities included lectures, consultations and nutrition workshops, which were free-of-charge for participating institutions. In total, 2638 institutions (including nurseries, preschools, and other types of DCCs for children aged 0.5–6 years old throughout Poland) participated in the program, of which 1347 were directly involved. 13,214 employees of these institutions were educated directly. To maintain a high level of quality in the program, nutrition education was provided by specially trained professionals. Within the program, 170 graduates of dietetics or human nutrition completed a 24-hour nutrition training, preparing them for the role of nutrition educators. Afterwards, educators passed through a 6-month internship in DCCs, involving a series of workshops for staff (free of charge) on topics related to healthy diet and planning and preparing meals for children. The overview of the project EHGH is presented in Figure 1 and described in a previous paper [13].

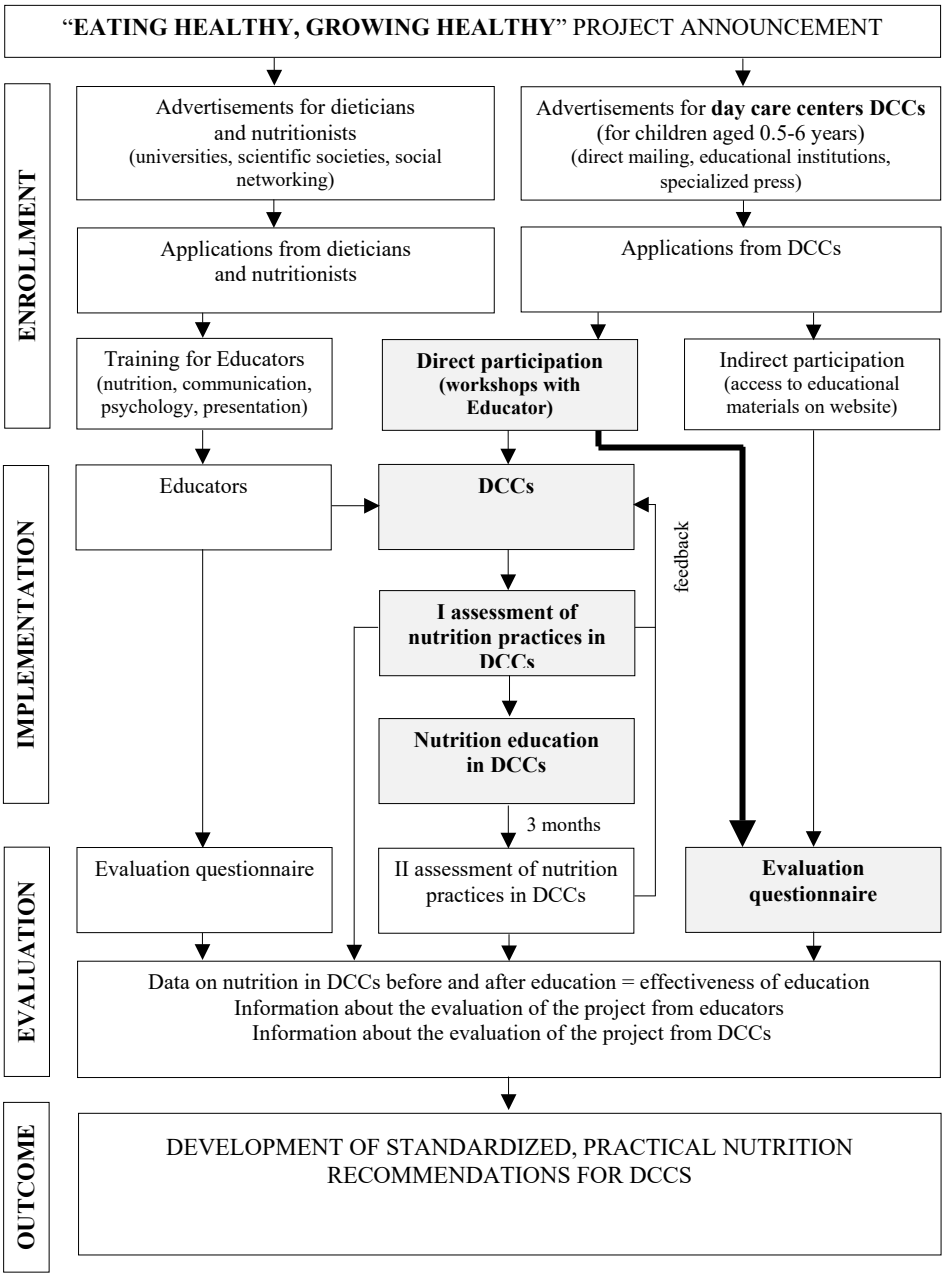

Figure 1. The overview of the program "Eating healthy, growing healthy". The program stages discussed in this article are highlighted in gray

The purpose of the present study was to evaluate the effects of a nutrition education program in participating preschools. The criteria for evaluation were changes in selected nutritional practices according to the institutions' staff, as well as their opinion on the program.

Material and methods

The first survey was conducted in May and June 2015 and the second in November 2016. They included randomly selected preschools in Poland which took part in the program "Eating healthy, growing healthy". The aim of the program was to improve the nutrition of children in day care centers through nutritional education of the staff conducted by specially trained educators. Evaluation of the effectiveness of education was an important part of the project. The chosen criteria for evaluation were changes in selected nutritional practices as reported by the institutions' staff and the staff's opinion of the program. To accomplish this evaluation, 66 preschools were randomly selected from the total group of preschools which finished the education program for the survey in

2015, and 138 preschools were randomly selected due to the larger number of participating institutions in 2016. The CATI (Computer-Assisted Telephone Interviewing) method was used. Phone interviews were conducted with DCC managers and data was collected by specially-trained interviewers. The main goal of the research was to determine the effects of the above-described educational program on selected aspects of nutrition in participating institutions. Additionally, the survey was intended to obtain information on the usefulness of the knowledge provided within the program, and the willingness to participate in similar programs in the future. Respondents were asked about selected nutrition-related practices in institutions that have gone through the training program (e.g. usage of salt/sugar, water availability, meal presentation), as well as their opinion of the suitability of the program in diet planning.

This article focuses on the evaluation of the program by the managers of preschools (directors or manciple officers), including the evaluation of nutrition education and the reported changes in selected nutrition-related practices.

Results

Preschool staff highly appreciated the value of the training provided within the program. In 2016, 80% of respondents appraised the merits of the program as very good, compared to 61% in 2015. Within these two surveys only two respondents expressed a negative opinion about the content of the program (in 2016). This assessment was reflected in the reported high frequency of use of acquired knowledge in everyday practice in DCC. It is worth emphasizing that the following year of the program had an increased number of surveyed staff that described the use of the acquired information in daily practice as "very good." Within two years of the program's beginning, only 6 of 204 respondents found the acquired knowledge was not practical enough to affect the nutrition of children in their institution (Fig. 2).

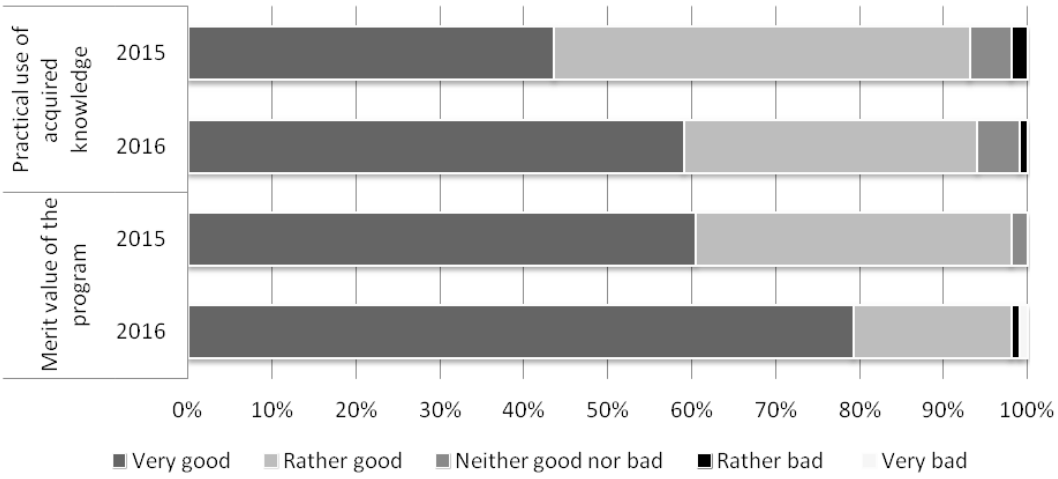

Figure 2. The evaluation of the value of the program and the practical application of acquired knowledge in every day practice by preschool staff

Within the program, free workshops with a variety of nutritional topics addressing important and critical aspects of children's nutrition were offered to the institutions. Each facility participating in the program could select the most desired topics based on its needs and knowledge of its staff. The topics of workshops chosen by the institutions are shown in Figure 3.

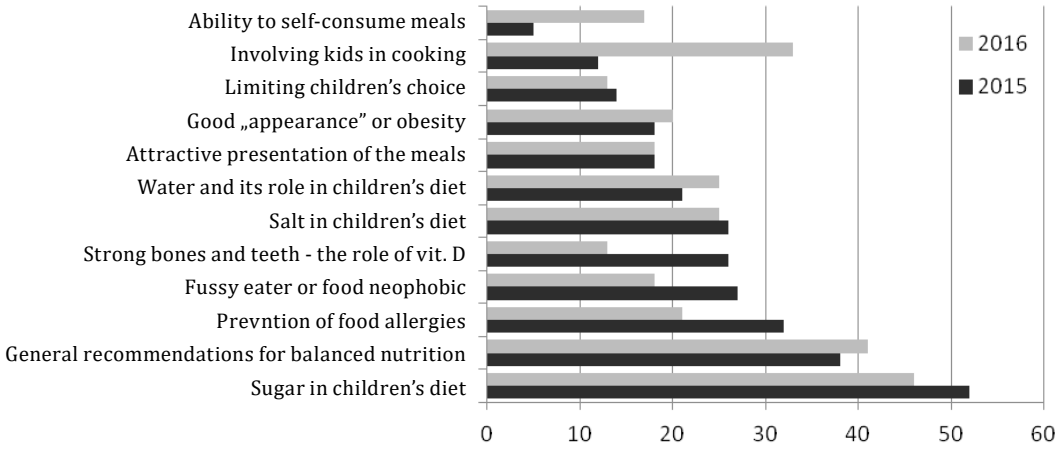

Figure 3. Interest in particular topics of the workshops reported by the respondents (%)

The workshops about sugar in children's diet were the most often chosen by preschools, both in 2015 and 2016. The second most frequent choice was the workshop on general recommendations for a balanced diet. In 2015 the third choice was the topic of prevention of food allergies, whereas in 2016 it was methods of involving children in preparing meals. Interestingly, in 2016 there was an almost three-fold increased interest in the workshop supporting the ability of children to consume meals by themselves.

Participation in the program was expected to contribute to changes in the nutrition of children in institutions. Changes in selected nutrition-related practices in kindergartens reported by respondents are presented in Figure 4.

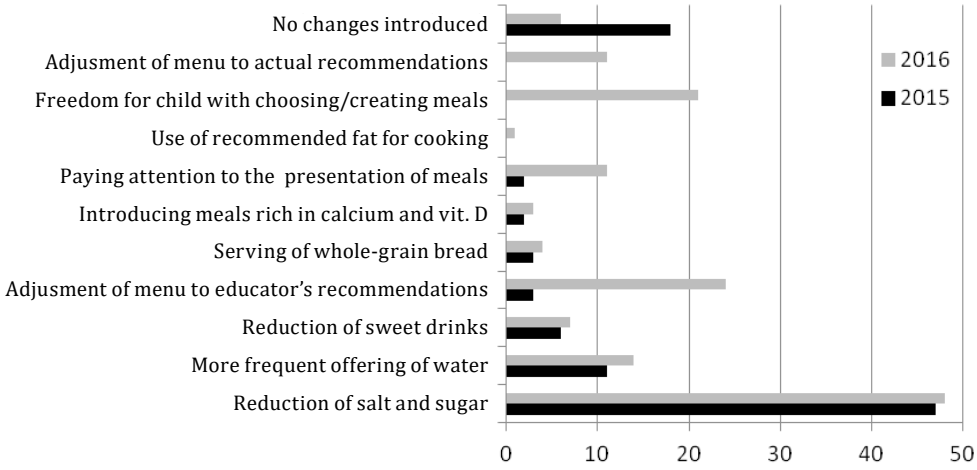

Figure 4. Changes in nutrition-related practices caused by education as reported by preschool staff (%)

Most respondents reported a decrease in sugar and salt in children's food and increased availability of water. In 2016 every fourth respondent reported adjustments in the menu suggested by the educator, and more than 20% allowed greater freedom for children in choosing/creating their meals. It is worth pointing out that the number of respondents who reported no change decreased by 3 times in 2016 compared to 2015.

The survey was lengthened in 2016 and respondents were asked to identify the most attractive part of the program. Nearly half of the respondents most appreciated support in creating correct eating habits in children, and 28% appreciated the various forms of cooperation. A similar number of respondents considered as most important the no-cost training and transferred nutritional knowledge (Fig. 5).

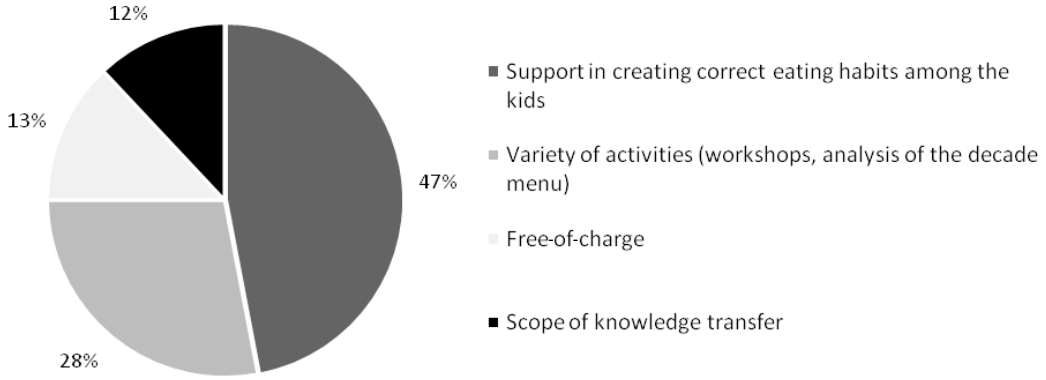

Figure 5. The most important elements of the program in the respondents' opinion (%)

Declared interest in attending similar programs and willingness to include paid nutrition workshops in the educational offerings of the institution are presented in Figure 6.

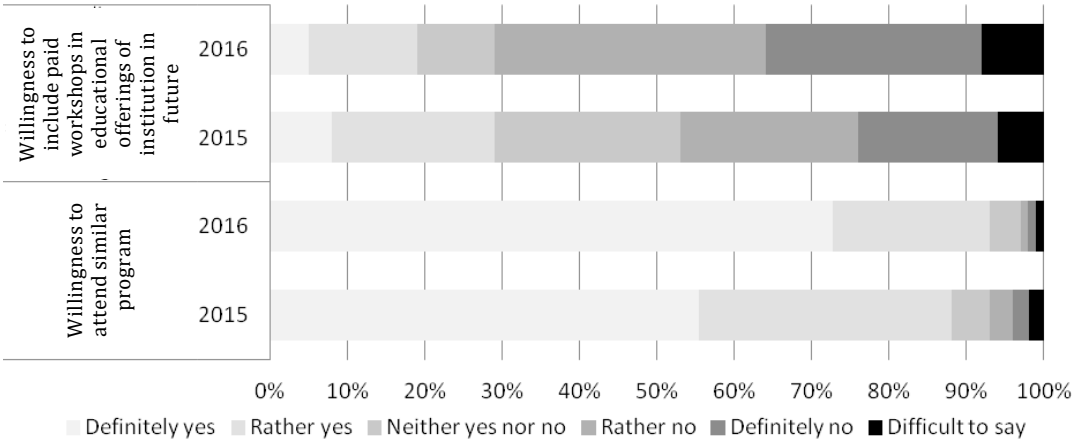

Figure 6. Declared interest in attending in similar programs and willingness to include paid nutrition education in the educational offerings of the institution

In 2015, over half of the respondents expressed their strong willingness to participate in a similar program in the future. In 2016, the number of such responses increased to almost three quarters. At the same time, the number of negative responses decreased to less than half of the first year. Despite the generally declared willingness to participate in similar programs, a small number of respondents were inclined to include paid "healthy eating" workshops in the preschool education program. In 2015 41% of respondents reported no such desire, and in 2016 this number increased to 63%. Among the reasons for this were listed: lack of funds for such activities (78%), no need for such activities (7%), and others (15%).

In 2016, respondents were also asked to identify groups to whom similar programs should be directed in the future. According to the respondents, such programs in future should focus on parents (64%) followed by children (30%). The respondents listed staff from institutions in third place (22%).

Discussion

Preschoolers are more likely than teenagers to be influenced by parents and caregivers in an eating environment [14]. Among the social factors within the childcare environment, caregivers' feeding practices were strongly connected with children's dietary intake [15]. Therefore, pre-school educators can significantly shape children's eating habits, and should be a primary focus for obesity prevention programs in this age group. The American Academy of Nutrition and Dietetics recommends that preschool caregivers be a role model for children and encourage healthy eating, support children's hunger and satiety cues, serve family style meals, and not force children to eat [7]. However, for such activities, nutritional knowledge and awareness of nutritional risk factors for diet-related diseases are essential. This is especially important in the absence of precise legal regulations

covering the principles of nutrition in institutions. In Poland, by the 1st September 2015 there was no mandatory law regulating nutrition in kindergartens. Since then, the Minister of Health introduced a regulation, which defined exactly what foods products could be used for children's nutrition, reduced sugar and salt, and defined the number of portions of vegetables, fruits, dairy products and fish in DCCs menus [16]. Unfortunately, due to the lack of relevant information and an education campaign, the regulation met with great social criticism and was repealed after a year. The current regulations are very general and allow great flexibility in planning child feeding [17]. Therefore, nutrition education for kindergarten staff in Poland is crucial, and should be conducted systematically and on a large scale.

The worldwide problem of excessive body weight also affects Poland, including young children [18]. In preventing obesity, it is very important to limit the sugar content as well as to serve drinking water instead of sweetened drinks [19, 20, 21]. Workshops on these topics were offered within our educational program and were very often chosen by the institution. This may indicate that despite the high availability of professional literature on the topic [21], institutions need specialist support. Frequent reports of sugar restriction, and the introduction of water by respondents can be considered a result of the workshops and demonstrate the success of the program.

In preventing obesity, the key is energy balance, which is associated with self-regulation of food consumption. American Academy of Nutrition and Dietetics recommends that childcare providers help children to understand their feelings of hunger and satiety. Preschool educators can support children in recognizing their feelings of hunger and satiety by using verbal comments during the meal (e.g., "Are you full?") to draw children's attention to their internal signals of hunger and satiety [22]. Developing training for preschool caregivers that focuses on using verbal comments during meal times to get children to understand their hunger and satiety is a viable and inexpensive approach that may help children self-regulate their dietary intake [23]. A similar effect has been observed with food and beverages served in family style, where children can decide on their own portion size and serve themselves [7]. It is worth emphasizing that interest in these topics increased in 2016, and more respondents reported changes in this direction, as well as involving children in meal preparation.

The next important topic that was presented as an educational offering of the program was calcium and vitamin D deficiencies. Irregularities in this area are very often observed in different age groups, including pre-school children [24, 25]. This situation may result from irregularities at the planning stage of preschool menus [26], which might be improved by education [27, 28].

It is worth emphasizing that both the thematic scope and the practical application of the information obtained were very well appreciated by the respondents. These results tended to increase in 2016. Many institutions have reported that they completed changes suggested by the educator, and have particularly appreciated help in shaping correct eating habits in children. Such a high rating by the respondents could have resulted from very good educational preparation of the educators. It is worth mentioning that the training included not only nutritional information, but also methods of effective communication with different recipients.

This study has some limitations. Data collection was limited to a technically possible test sample. The data collected during interviews with staff were self-reported (not observational), which might have led to response bias. It will be possible to make a conclusion about the effectiveness of the program after its completion. The qualitative and quantitative evaluation of the institutions' menus before and after nutrition workshops has been planned for objective evaluation of program results. At present, based on the data presented in this paper and preliminary observations [27, 28] we can assume that nutrition education has a positive impact on improving the quality of feeding in preschools. The other authors also point to the need for nutrition education addressed to the personnel of childcare institutions [24, 25, 29, 30].

Conclusions

The program "Eating healthy, growing healthy" has been evaluated positively by respondents. Compared to data from 2015, the program evaluation in 2016 was even better in many aspects. And most importantly, results showed that the educational form of the project has brought real results in changing nutrition-related practices in DCCs, particularly in areas such as: limiting salt and sugar in meals prepared for children, offering water more frequently, and adapting the menu to the actual nutritional recommendations. The respondents of the surveyed preschools also declared that greater attention is paid to the presentation of meals prepared for children as well as to children's freedom of food selection and portion size. The institutions were aware of the need for similar programs directed not only to staff members but primarily to parents, and later children.

The good appraisal of the program and the practical results of the education increased interest in similar programs in the future. However, this increase in interest did not translate into a greater willingness to include

paid healthy eating workshops in the educational offerings of the institutions. The idea of including such activities has only been moderately accepted, not because of the content's merit, but because of the lack of funds for such a project. In planning similar programs, it is worth considering the possibility of obtaining external funds. It seems that only through free educational programs can a wide range of institutions be reached. It is worth stressing that proper nutrition of children must be treated as an investment in their healthy development, and there is an urgent need for a systematic solution to improve nutrition in preschools.

Acknowledgments

This research was financed by Danone Ecosysteme research and education grant within the program "Eating healthy, growing healthy". The authors of this publication want to express their gratitude to the Nutricia Foundation and partners of "Eating healthy, growing healthy" program: The Comenius Foundation for Child Development, The Institute of Mother and Child, The Academic Business Incubators and Educators involved in the project.

Conflicts of Interest: The authors declare no conflict of interest. The founding sponsors had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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REVIEW PAPER
ARTYKUŁ PRZEGLĄDOWY

Health Prob Civil. 2018, Volume 12, Issue 4
ISSN 2353-6942

DIRECT FACTOR XA INHIBITOR IN THE PREVENTION OF THROMBOEMBOLISM

BEZPOŚREDNIE WPROWADZENIE INHIBITORU CZYNNIKA XA W ZAPOBIEGANIU ŻYLNEJ CHOROBY ZAKRZEPOWO-ZATOROWEJ

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D. Data interpretation
interpretacja danych
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Summary

Venous thromboembolism is the third most common cause of vascular death after myocardial infarction and stroke, and is associated with considerable morbidity and premature mortality. The incidence of the most serious consequence of venous thromboembolism, fatal pulmonary embolism, ranges from 0.01% to 5% among hospitalised medical patients with multiple risk factors, and is currently considered the commonest avoidable cause of hospital death. Rivaroxaban is a small-molecule factor Xa inhibitor that belongs to a new class of direct oral anticoagulant agents that directly inhibit single enzymes in the coagulation pathway. Rivaroxaban has many advantages over vitamin K antagonists and unfractionated heparin and may become an alternative to traditional anticoagulant agents in patients at risk for thromboembolism. Moreover, antidotes exist and are in the progress of development, both specific and non-specific, for the treatment of overdose or side effects, including bleeding.

Keywords: venous thromboembolism, anticoagulants, rivaroxaban

Streszczenie

Żylna choroba zakrzepowo-zatorowa jest trzecią najczęstszą przyczyną śmierci naczyniowej tuż po zawale mięśnia sercowego i udarze mózgu, związana jest także z dużą zachorowalnością i przedwczesną umieralnością. Najpoważniejsze konsekwencje żylnej choroby zakrzepowo-zatorowej oraz śmiertelnej zatorowości płucnej występują w przedziale od 0,01% do 5% wśród hospitalizowanych pacjentów medycznych, u których stwierdzono wiele czynników ryzyka i są obecnie uważane za najczęstszą możliwą do uniknięcia przyczynę śmierci szpitalnej. Rivaroxaban jest drobnocząsteczkowym inhibitorem czynnika Xa, który należy do nowych bezpośrednich doustnych środków przeciwzakrzepowych, które bezpośrednio hamują pojedyncze enzymy w szlaku krzepnięcia. Rivaroksaban charakteryzuje się wieloma zaletami w porównaniu z antagonistami witaminy K i niefrakcjonowaną heparyną i może stać się alternatywą dla tradycyjnych leków przeciwzakrzepowych u pacjentów zagrożonych chorobą zakrzepowo-zatorową. Ponadto istnieją antidota (niektóre są w procesie rozwoju), zarówno swoiste, jak i nieswoiste, stosowane w celu leczenia przedawkowania lub działań niepożądanych, w tym krwawienia.

Tables: 2
Figures: 1
References: 32
Submitted: 2018 Apr 25
Accepted: 2018 Jun 26

Słowa kluczowe: żylna choroba zakrzepowo-zatorowa, leki przeciwzakrzepowe, rywaroksaban

Meretskyi V, Meretska I, Pertsovych V. Direct factor Xa inhibibitor in the prevention of thromboembolism. Health Prob Civil. 2018; 12(4): 247-254. https://doi.org/10.5114/hpc.2018.79987

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Introduction

Venous thromboembolism (VTE), including pulmonary embolism (PE) and deep vein thrombosis (DVT), is considered to be the third most likely cause of vascular death after stroke and myocardial infarction. According to various sources, it is associated with considerable morbidity and premature mortality [1, 2]. Interestingly, VTE is 100 times more frequent among hospitalised patients compared to the general population, and an objectively diagnosed DVT can be detected in up to 80% of high-risk surgical and medical patients who are not on thromboprophylaxis. The incidence of the most dangerous consequence of VTE, which is fatal PE, ranges from 0.01% (low-risk surgical patients) up to 5% (hospitalised medical patients with multiple risk factors). Pulmonary embolism is currently considered by the general public as the most common but avoidable cause of death in a hospital. In addition, VTE is often associated with long-term clinically significant complications, including post-thrombotic syndrome, chronic pulmonary hypertension, among others [3, 4, 5, 6].

The mainstay of VTE treatment is anticoagulation [1]. Many traditional anticoagulant agents including vitamin K antagonists, low molecular weight heparins, unfractionated heparin (UFH), and fondaparinux are widely available and used for the prevention and treatment of thromboembolic diseases. However, these agents have several limitations, including the requirement for regular coagulation monitoring (VKAs and UFH) and the need for parenteral administration (fondaparinux, UFH, low molecular weight heparin) and multiple interactions with other drugs and with food. To overcome some of these challenges, researchers developed a new class of anticoagulant drugs with comparable efficacy to existing agents, but with improved ease of use (for example: oral administration and no need for laboratory monitoring) [3]. In addition, the new direct oral anticoagulant agents (DOACs) as a class are associated with significantly less intracranial haemorrhage than warfarin, thus mitigating the most feared complication of anticoagulation treatment. These data support the need to develop target-specific oral anticoagulants which can directly inhibit coagulation pathway through single enzymes, such as Factor Xa or thrombin [7, 8, 9].

Rivaroxaban is approved for the treatment of deep venous thrombosis, pulmonary embolism. In addition, it is approved for the prevention of recurrent DVT/PE, stroke, systemic embolism in patients with non-valvular atrial fibrillation (AF), who have one or more risk factors, in combination with antiplatelet agents, for the prevention of atherothrombotic events following acute coronary syndrome (ACS) in patients with elevated levels of cardiac biomarkers. Each of these therapeutic indications has a specific regimen with different dosing, administration frequencies, and treatment durations [7, 10, 11, 12, 13].

Pharmacological Properties

Rivaroxaban (scientific name 5-chloro-N-[[(5S)-2-oxo-3-[4-(3-oxomorpholin-4-yl)phenyl]-1,3-oxazolidin-5-yl]methyl]thiophene-2-carboxamide) is considered a small-molecule factor Xa inhibitor due to its molecular weight, 436 g/mol. Rivaroxaban is slightly soluble in several organic solvents and is practically insoluble in polar solvents, such as water.

In Vitro Studies

Factor Xa Inhibition

Rivaroxaban works through the inhibition of factor Xa in a concentration-dependent manner. It is a competitive inhibitor for the amidolytic activity associated with factor Xa (Fig. 1). It has a rapid onset of action and is reversible. Factor Xa is essential for blood coagulation and is activated by both the extrinsic and intrinsic coagulation pathways. Factor Xa transforms prothrombin into thrombin through the prothrombinase complex, resulting in fibrin clot formation and activation of the platelets by thrombin [14, 15].

Rivaroxaban is selective for human factor Xa, for which it possesses >10 000-fold greater selectivity compared to other biologically similar serine proteases. Factor Xa inhibition is species-dependent, and this has been demonstrated for a number of factor Xa inhibitors. Rivaroxaban has a similar affinity to purified human and rabbit factor Xa, but a lower affinity to rat factor Xa.

Inhibition of Thrombin Formation

In vitro studies using platelet-poor or platelet-rich plasma demonstrated that rivaroxaban prolonged the initiation phase of generation of thrombin and reduced the thrombin burst during the propagation phase.

Rivaroxaban inhibited thrombin generation in human plasma obtained from healthy volunteers through the inhibition of factor Xa (intrinsic and extrinsic coagulation pathways).

Plasma Clotting Times

Rivaroxaban has satisfactory anticoagulant effects in human plasma. The drug prolonged prothrombin time (PT), activated partial thromboplastin time in a concentration-dependent manner. The sensitivity for PT was greater. Meanwhile, prolongation of clotting time differed depending on the PT or activated partial thromboplastin time reagent used. This is because rivaroxaban reactivity in the clotting assays was influenced by the composition of reagents. This variation cannot be reduced through the conversion of PT values calculated in seconds to internationally recognized, normalized ratio values. Therefore, in our opinion, PT and activated partial thromboplastin times are not very useful for the measurement of the pharmacodynamic effects of rivaroxaban.

Thrombin–Thrombomodulin-Activated Protein C System

The coagulation pathway has negative and positive feedback reactions in order to regulate haemostasis, and anticoagulants at therapeutic doses, in ideal conditions, should not influence negative feedback mechanisms, which are important in downregulating coagulation. One of the negative feedback mechanisms is the thrombin–thrombomodulin-activated protein C system, which usually limits further generation of thrombin by inhibiting both factor Va and factor VIIIa. "In vitro" investigations of human plasma from healthy people or protein C-deficient plasma, factor Xa inhibitors, such as rivaroxaban, suppressed thrombin generation, depending on concentration, after stimulation by tissue factor and in the presence or absence of the thrombomodulin. This means that rivaroxaban does not significantly influence thrombin–thrombomodulin-activated protein C system.

Platelet Aggregation

Rivaroxaban does not influence collagen induced platelet aggregation, or that induced by adenosine diphosphate, the selective agonist of prostaglandin H2/thromboxane A2 receptor U46619, or platelet aggregation induced by thrombin. However, rivaroxaban effectively inhibits tissue factor-induced platelet aggregation through the inhibition of thrombin generation in the case of defibrinated plasma. In addition to the anticoagulant effects of factor Xa inhibitor, this effect on aggregation of platelets may be particularly useful for the prevention or treatment of arterial thrombosis [14].

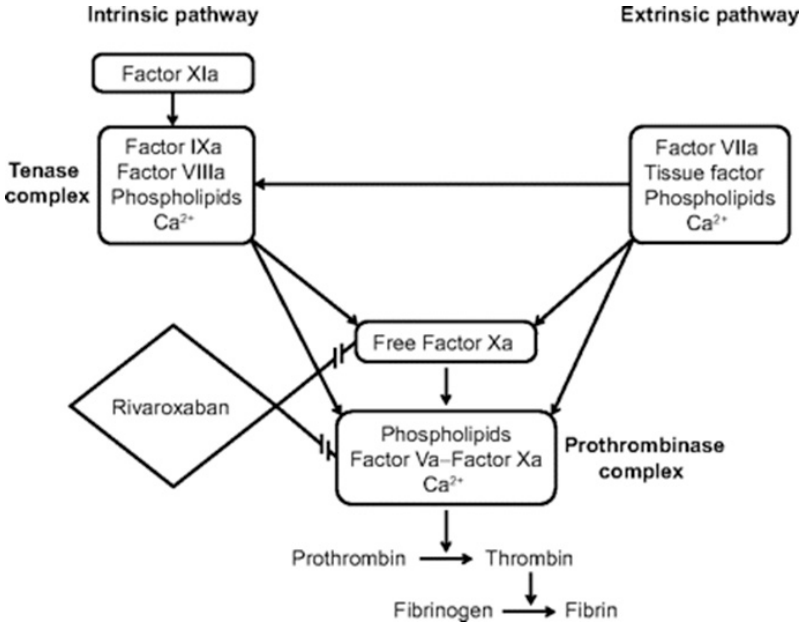

Figure 1. Factor Xa role in the coagulation cascade. Tissue factor/factor VIIa activates factor X and factor IX. Factor IXa activates factor X. Factor Xa binds factor Va, but on membrane surfaces. The prothrombinase and tenase both trigger the amplified thrombin formation. Rivaroxaban inhibits factor Xa, either free or within the prothrombinase [14]

In Vivo Studies and Dosing

Rivaroxaban reduced thrombus formation in venous thrombosis models (including fibrin-rich and platelet-poor), where a combination of injection of tissue factor and stasis was used to induce formation of thrombus.

The substance showed sufficient dose-dependent activity against thrombus in arterial (fibrin-poor and platelet-rich) thrombosis models, including arteriovenous shunt model using rats and rabbits, as well as ferric chloride model (rats and mice). These results were consistent with the role of this coagulation system in thrombus formation in arteria.

The rivaroxaban anti-haemostatic effect was studied in well-characterized bleeding models in rats (tail transection bleeding time model), as well as rabbits (ear-bleeding time model). Bleeding times were not affected at antithrombotic doses below ED50, which are required for antithrombotic efficacy in the bleeding time models. Moreover, while using higher doses (rat tail-bleeding time model), the bleeding times were prolonged in a dose-dependent manner. Therefore, considering antithrombotic results, these data show that rivaroxaban may have a favourable efficacy-to-bleeding ratio [14].

Rivaroxaban has oral bioavailability of 80–100% at the 10 mg dose, irrespective of food intake. Under well fed conditions, 10 mg, 15 mg and 20 mg tablets of rivaroxaban showed dose-proportional bioavailability. In a fasted state, rivaroxaban pharmacokinetics are fairly linear (up to 15 mg once daily). In addition, oral bioavailability is reduced to 66% after a 20 mg tablet. Bioavailability decreases at higher doses due to poor solubility. Ingested food does not affect the area under concentration–time curve, nor the maximum plasma concentration (Cmax) of a 10 mg dose. Rivaroxaban administered as an oral dose is absorbed rapidly, with Cmax occurring 2–4 hours after the tablet intake [4]. Plasma protein binding values vary between biological species (rats - 98.7%; rabbits - 76.6%; and humans - 92% to 95%). Serum albumin is the main circulating binding component [15, 16].

Removal of rivaroxaban from plasma occurs with a terminal half-life of 5 to 9 hours for young individuals and 11 to13 hours for elderly patients. Rivaroxaban is metabolized by several completely independent metabolic pathways, which involve different classes of enzymes. The substance has a dual mode of elimination. Approximately two-thirds of the dose undergoes metabolic degradation by CYP450-dependent (CYP3A4, 212) or CYP-independent mechanisms, half of which is eliminated renally, with the other half using the hepatobiliary route. The final one-third of the dose goes through direct renal excretion with no changes in chemical structure of the active substance, mainly via active renal secretion. The drug has no major actively circulating blood metabolites [7, 14, 17, 18].

Age, gender, body weight have not been shown to exert clinically significant effects on the pharmacokinetic or pharmacodynamic profiles of rivaroxaban [14, 18]. The International Society on Thrombosis and Haemostasis suggests that direct oral anticoagulants should not be used in patients weighing one hundred kilograms or more, as there are very limited clinical data available for the patients with these weights. The available pharmacokinetic/pharmacodynamic data suggested that decreased drug exposures, shorter half-lives and reduced peak concentrations occurred with increasing weight, which in turn raised concerns about possibility of under-dosing [19]. In patients who have had mild (creatinine clearance 50 to 79 mL/min), moderate (creatinine clearance 30 to 49 mL/min), or severe (creatinine clearance more than 30 mL/min) impairment of renal function, the area under the plasma concentration curve was 44%, 52%, and 64% higher, respectively, comparing to control subjects. In those cases, maximum plasma concentration was relatively unaffected. Among patients who suffered mild (Child–Pugh A) hepatic functional impairment, researchers found no clinically relevant differences regarding pharmacokinetics and pharmacodynamics of rivaroxaban. To summarize, these findings suggest that the drug can be used for individuals with varying physical characteristics (such as age, body weight, gender, mild to moderate impairment of renal function, and mild hepatic functional impairment) at the same fixed dose, without requirements for dose adjustment or required routine coagulation monitoring [14].

Rivaroxaban levels may be affected by inhibitors and inducers of the P-glycoprotein transport protein and CYP3A4 enzyme. Rivaroxaban is a substrate of CYP3A4/ 5, CYP2J2, and the P-glycoprotein and ATP-binding cassette G2 (ABCG2) transporters. Concomitant use should be avoided and alternative anticoagulants considered for strong double-action CYP3A4 and P-glycoprotein inducers (rifampin, carbamazepine, phenytoin, St. John's wort), which in turn can decrease rivaroxaban levels. Due to the potential for an increase in rivaroxaban effect, concomitant use should also be avoided and alternate anticoagulants considered when strong dual CYP3A4 and P-glycoprotein inhibitors (ketoconazole, itraconazole, HIV protease inhibitors, conivaptan) are used. For concomitant use of weak or moderate dual CYP3A4 and P-glycoprotein inhibitors (amiodarone, verapamil, diltiazem, erythromycin, chloramphenicol, cimetidine) in the presence of CrCl 15 to 80 mL/minute, alternative anticoagulant use should be considered [17, 20]. Histamine H2-receptor antagonists, such as ranitidine (a CYP3A4 inhibitor), as well as the antacid aluminum–magnesium hydroxide, have no significant effect on the

pharmacokinetics and pharmacodynamics of the rivaroxaban [14].

Rivaroxaban showed favourable safety and tolerance levels in healthy individuals [14]. However, it is advisable to avoid rivaroxaban in patients with a high risk of gastrointestinal tract bleeding, as some evidence exists about higher GI bleeding rates compared to warfarin.

Rivaroxaban should not be used in pregnancy and in females who are breast feeding. Moreover, women of child-bearing age should be advised appropriately [19].

Prior to beginning of treatment, a full blood count, baseline coagulation screen, urea and electrolytes (including renal function), and liver function tests should be performed. Table 1 gives guidance for the recommended doses of rivaroxaban [19].

Table 1. Dosing advices for rivaroxaban [19]

	Rivaroxaban
Standard Dose	Days 1-21: 15mg bd orally (with food) Day 22 and forward: 20mg od orally (with food)
Renal impairment	Warfarin preferred if CrCl less than 30ml/min Do not use the drug if CrCl less than 15ml/min
	Day 22 onwards (if CrCl 30-49ml/min): consider reducing to 15mg od if the patient's risk of bleeding outweighs the risk of recurrence
Hepatic impairment and dysfunction	Rivaroxaban is contraindicated for the patients with hepatic disease associated with coagulopathy, clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C
Switching from dalteparin	Rivaroxaban should be used instead of the next scheduled dalteparin administration
Switching to dalteparin	Give the first dose of dalteparin at the time when the next rivaroxaban dose is due
Switching from warfarin	Stop warfarin; start rivaroxaban once INR is 2.5 or less (do not forget about higher initial dosing if within three weeks after an acute event)
Switching to warfarin	Co-administer rivaroxaban and warfarin together until INR is 2 or higher

Patients who have proximal DVT or PE must be treated for three months or longer. In cases of the first proximal DVT or a PE associated with transient risk factors, the use of rivaroxaban will usually stop after three months. Long term treatment would be considered in case of recurrent thrombosis, or for the patients with on-going risk factor, or those having unprovoked proximal DVT or PE. It might be feasible to decide on finite (such as three months duration) or indefinite anticoagulation after treatment has started, though many patients (for example, those with a first unprovoked proximal DVT or PE) would to be reviewed after three months in order to decide whether to stop anticoagulation treatment or maybe continue it indefinitely [19].

Patients must be informed about the risk of missing a rivaroxaban dose due to its rapid onset and offset of anticoagulant activity. Therefore, even one day without rivaroxaban will cause the patient to become un-anticoagulated [21].

Rivaroxaban is used to prevent venous thromboembolism among adult patients undergoing elective hip or knee replacement surgery, treatment of DVT and PE, and to prevent recurrent DVT and PE among adult patients. Rivaroxaban showed superiority compared to standard therapy with enoxaparin in cases of orthopaedic surgery without significant increase in the major bleeding rate [14].

The duration of the therapy and dose should be determined on case by case basis after careful assessment of the treatment benefits comparing to the risks for bleeding (Table 2).

Table 2. The duration of therapy with rivaroxaban and dose selection

	Time Period	**Dosing schedule**	**Total daily dose**
Treatment and prevention of recurrent DVT and PE	Day 1 to day 21	15 mg twice daily	30 mg total
	Day 22 and forward	20 mg once daily	20 mg total
Prevention of recurrent DVT and PE	Following completion of 6 months therapy for DVT or PE	10 mg once daily or 20 mg once daily	10 mg total or 20 mg total

Rivaroxaban plus aspirin improves survival and reduces stroke and heart attack in patients with stable coronary or peripheral artery disease, according to late-breaking results from the COMPASS trial. Rivaroxaban, at both a treatment dose (20 mg) and a thrombo-prophylactic dose (10 mg), was more effective than aspirin in the prevention of recurrent venous thromboembolism among patients who were in equipoise for continued anticoagulation [1].

Since rivaroxaban is administered in fixed doses, routine measurement of the drug levels in plasma or its pharmacodynamic effects are not required or recommended. However, there are certain clinical scenarios in which coagulation testing and measurement of drug levels are necessary, such as episodes of bleeding, peri-operative management, suspected over dosage either from drug interactions or intentional overdose, renal impairment or as a measure of suspected non-compliance [8]. The choice of the laboratory test for rivaroxaban levels will depend on the clinical situation. For example, if qualitative determination of the presence of rivaroxaban in the blood is needed, the PT test is appropriate, given that a rivaroxaban-sensitive reagent is used. On the other hand, if quantitative measurement of plasma rivaroxaban is needed, an anti-Factor XNA chromogenic assay together with rivaroxaban standard solutions and controls with results expressed as rivaroxaban concentration (μg/l) can give precise and accurate results. No matter which test is being used, interpretation of results must take into account the timing of blood sampling (considering pharmacokinetics of rivaroxaban), as well as differences in the functionality of the assays [7, 8, 20].

Rivaroxaban antidotes against overdose or bleeding

Research conducted by Eikelboom J.W. et al. reported a favourable benefit-risk profile for the use of DOACs. However, they are still associated, as are any anticoagulants, with a significant risk of bleeding [22].

According to [23], one of the major drawbacks of direct oral anticoagulants compared to warfarin was absence of specific antidotes which can reverse the anticoagulant effect in case of emergencies, such as overdose due to the medical negligence or excessive bleeding. The same authors suggested that several non-specific substances can be administered in situations of DOACs overdoses, including frozen plasma, Prothrombin Complex Concentrate (PCC), or activated Prothrombin Complex Concentrate (PCC), recombinant activated factor VII, as well as haemodialysis and activated charcoal, but the bleeding cessation success was not quite rapid or obvious. It was suggested by J.W. Eikelboom et al. [22] that fresh frozen plasma cannot be used to negate the bleeding effect as large volumes are needed. Prothrombin complex concentrates (PCCs) are purified and viral inactivated concentrates of vitamin K-dependent coagulation factors, which are obtained from pooled normal plasma [24]. Even PCC, which has 25 times more blood clotting factors than frozen plasma, is associated with low, but not negligible, risk of thromboembolic adverse events. 3-factor and 4-factor PCCs are available on the market [24]. Some researchers noted a favourable outcome after 4-factor PCC administration in six of eighteen patients with intracranial haemorrhage who were treated with rivaroxaban or apixaban [25]. Activated PCC (aPCC), or factor VIII inhibitor bypassing agent (FEIBA, Baxter, Deerfield, IL, USA), was developed as one of the pro-haemostatic agents for the management of haemophiliacs. aPCC is a surface-activated PCC which contains small amounts of FIXa, FXa, as well as thrombin, and larger quantities of FVIIa. According to Vanden Daelen et al., aPCC corrected all thrombin generation factors *in vitro* in plasma obtained from healthy volunteers who were administered rivaroxaban, and reduced blood loss in animals after administration of rivaroxaban [26]. Recombinant activated factor VII (rFVIIa; NovoSeven, Novo Nordisk, Bagsvaerd, Denmark) is a recombinant protein developed originally to treat and prevent bleeding in patients with haemophilia with inhibitors to factor VIII or IX [27]. However, considering the significant thrombin generating burst induced by rFVIIa and the pre-existing thrombogenic diathesis, rFVIIa may only be considered as a last-resort option in case of life- or organ-threatening bleeding, especially regarding patients with acute ischaemia.

Several therapies which are aimed at reduction of drug exposure include rivaroxaban absorption reduction from gastrointestinal tract and rivaroxaban removal from the blood, using activated charcoal and haemodialysis, respectively. Activated charcoal is a physically and chemically processed form of carbon that can bind oral drugs, thus reducing their absorption from the intestines. Although activated charcoal proved to be useful in reducing absorption of dabigatran and apixaban [28, 29], we did not find any information regarding rivaroxaban. However, the use of activated charcoal to reduce absorption still might be considered in case of a recent overdose with rivaroxaban, using a standard dosing of 30–50 g for adults per intake [30]. Haemodialysis cannot remove rivaroxaban efficiently, as it is highly protein bound [31].

In our opinion, the best option for treating excessive bleeding caused by rivaroxaban administration in the future may be the use of targeted reversal agents.

Recently, a specific reversal agent against factor Xa inhibitors was developed, known as Andexanet alfa

(PRT064445, AndexXa®, Portola Pharmaceuticals, South San Francisco, CA, USA) [22]. Andexanet alfa is a modified human recombinant factor Xa which is catalytically inactive, though retains high-affinity binding to direct factor Xa inhibitors or heparin-antithrombin III complexes. Andexanet alfa induced complete reversal of either apixaban or rivaroxaban anticoagulant activity rapidly (approximately two minutes after administration), without any adverse effects in two recent completed parallel phase III trials – ANNEXA-A and ANNEXA-R. The phase four clinical trial (ANNEXA-4) is under way.

One more antidote was proposed, namely, aripazine (PER-977), which is thought to be an effective antidote against not only rivaroxaban, but also dabigatran, apixaban, subcutaneous fondaparinux and LMWH. It is also known as ciraparantag (Perosphere Pharmaceuticals, Danbury, CT, USA), and is a small, water-soluble, synthetic cationic molecule which reverses unfractionated heparin, low-molecular-weight heparin and fondaparinux using non-covalent hydrogen binding and charge–charge interactions. It is capable of DOACs inactivation through non-covalent hydrogen binding [32]. Ciraparantag (aripazine) was shown to reverse the anticoagulant effect of all DOACs in thrombo-elastographic studies and animal models.

Conclusions

1. The selective factor Xa inhibitor rivaroxaban belongs to a new class of anticoagulant drugs, which are designed to overcome the deficiencies of current deep vein thrombosis and pulmonary embolism therapies.
2. Rivaroxaban has many advantages over VKAs and UFH, including a rapid onset and cessation of anticoagulant effect, fixed dosing, fewer drug and dietary interactions and no monitoring requirement.
3. The pharmacodynamics and stable pharmacokinetic profiles, which were found to be predictable, together with the wide therapeutic window, enhance the likelihood that oral factor Xa inhibitors, including rivaroxaban, might become alternatives to vitamin K antagonists, unfractionated heparin, and low molecular weight heparins for the patients with a risk of thromboembolism.
4. Effective antidotes exist and are in the progress of development for the treatment of rivaroxaban overdose or side effects, such as bleeding.

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ORIGINAL PAPER
ORYGINALNY ARTYKUŁ NAUKOWY

Health Prob Civil. 2018, Volume 12, Issue 4
ISSN 2353-6942

PREVALENCE OF INSOMNIA AND DEPRESSION IN PATIENTS WITH AGE-RELATED MACULAR DEGENERATION

BEZSENNOŚĆ I ZACHOWANIA DEPRESYJNE U PACJENTÓW ZE ZWYRODNIENIEM PLAMKI ŻÓŁTEJ ZWIĄZANYM Z WIEKIEM

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Authors' contribution
Wkład autorów:
A. Study design/planning
zaplanowanie badań
B. Data collection/entry
zebranie danych
C. Data analysis/statistics
dane – analiza i statystyki
D. Data interpretation
interpretacja danych
E. Preparation of manuscript
przygotowanie artykułu
F. Literature analysis/search
wyszukiwanie i analiza literatury
G. Funds collection
zebranie funduszy

Summary

Background. Age Related Macular Degeneration (AMD) affecting the organ of vision, impairs central vision. The study objective was (1) to define the prevalence of sleep disorders and depressive symptoms in patients with AMD, (2) to assess the relationship of depressive symptoms and insomnia with chosen demographic data, (3) to assess a potential correlation of the exacerbating vision quality with depressive symptoms and sleep disorders. **Material and methods.** The study involved 105 patients, women and men aged 45-88. Patients were asked to complete an original questionnaire subjected to validation, the Beck Depression Inventory and the Athens's Insomnia Scale. **Results.** The results were analysed statistically, showing that 71% of the respondents had insomnia and 70% suffered from depression. The patients' age, time from the diagnosis, marital and occupational status were not found to be related to depression or sleep disorders. Type of education, financial status and family support were significantly correlated with the prevalence of depression and sleep disorders. No correlation was observed between the exacerbation of vision disorders and enhanced depressive symptoms and insomnia. However, such correlation was noted with subjective stress reactions. **Conclusions.** Since patients with AMD are at a greater risk of sleep disorders and depression they should remain under professional care of a multidisciplinary team, including an ophthalmologist, a family doctor, a psychiatrist and a psychologist.

Keywords: age related macular degeneration, AMD, insomnia, depression

Streszczenie

Wprowadzenie. Zwyrodnienie plamki żółtej związane z wiekiem (AMD, Age Related Macular Degeneration) jest schorzeniem narządu wzroku, które istotnie upośledza widzenie centralne. Celem badania było: (1) określenie częstości występowania zaburzeń snu oraz objawów depresyjnych u pacjentów z AMD, (2) zbadanie zależności pomiędzy objawami depresyjnymi i bezsennością a wybranymi danymi demograficznymi, (3) oszacowanie korelacji pomiędzy pogarszaniem się jakości widzenia a objawami depresyjnymi i zaburzeniami snu. **Materiał i metody.** W badaniu wzięło udział 105 pacjentów, kobiet i mężczyzn w wieku od 45 do 88 lat. Pacjenci poproszeni zostali o wypełnienie autorskiej zwalidowanej ankiety , skali depresji Becka oraz Ateńskiej Skali Bezsenności. **Wyniki.** Stwierdzono, że na bezsenność cierpi 71% respondentów, natomiast objawy depresji występują u 70% badanych. Wiek badanych, czas od postawienia diagnozy, stan cywilny oraz status zawodowy nie były związane z zaburzeniami depresyjnymi oraz snu. Rodzaj wykształcania, sytuacja materialna oraz wsparcie ze strony najbliższych (rodziny) były istotnie skorelowane z częstością występowania zaburzeń depresyjnych oraz snu. Nie stwierdzono korelacji pomiędzy narastaniem zaburzeń jakości widzenia a nasileniem objawów depresyjnych i bezsennością, natomiast taką zależność zaobserwowano w odniesieniu do subiektywnej reakcji stresowej. **Wnioski.** Chorzy na AMD są grupą pacjentów podwyższonego ryzyka wystąpienia zaburzeń snu oraz rozwoju depresji i w związku z tym powinni zostać objęci opieką wielodyscyplinarnego zespołu, w którym oprócz lekarza okulisty powinien znaleźć się lekarz rodzinny, psychiatra oraz psycholog.

Słowa kluczowe: zwyrodnienie plamki żółtej związane z wiekiem, AMD, bezsenność, depresja

Tables: 4
Figures: 2
References: 30
Submitted: 2017 March 03
Accepted: 2017 Apr 04

Nowak E, Kulik A, Wróbel J, Nowak G, Nowak D, Roczniak W, et al. Prevalence of insomnia and depression in patients with age-related macular degeneration. Health Prob Civil. 2018; 12(4): 255-264. https://doi.org/10.5114/hpc.2018.76518

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Introduction

The process of ageing is associated with a number of various organic changes occurring in all cells, tissues, organs and systems of the body, including the organ of vision and the central nervous system (CNS). The involution processes of the CNS may lead to specific disorders, commonly treated as a natural and predictable aspect of ageing. This refers to circadian rhythm disturbances, i.e. sleep/wakefulness and mood disorders that manifest themselves primarily in the form of depression [1].

Epidemiological data indicate that at least 3% of the population suffer from depression. This ratio seems to be higher in European countries (4%). The estimates taking into account the so-called masked depression reach 10% and only 20% of patients benefit from specialised medical care. Clinicians believe that depression is much more frequent in the elderly. However, only a few studies have confirmed the existence of such relationship [2].

Also daily clinical practice shows that patients with depression (major depression according to DSM) represent up to 50% of elderly patients treated in psychiatric wards; 40% of patients in daily psychiatric wards and equally significant percentage of patients in residents' homes (30-40%) or those treated by family doctors (15-30%) [3]. These data appear to be inconsistent with the results of a population study, suggesting that the prevalence of major depression in the elderly does not differ significantly from that observed among younger people (4.6 – 9.3%) [4].

One of the elements that negatively affect mental health is vision deterioration and the resulting decrease in the quality of life. According to the WHO reports, vision impairment concerns about 20% of the elderly on a global scale [5] and, importantly, it is steadily increasing. Most of the previous studies addressing the problem of depressive disorders and their association with age-related vision disorders have focused mainly on diseases that can be successfully treated (e.g. glaucoma, cataracts). No attempt, however, has been made to diagnose eye diseases which caused vision impairment [6, 7].

Loss of central vision considerably interferes with daily functioning, e.g. reading, recognising faces, performing activities that require good near vision, which significantly affects the quality of life, independence, self-sufficiency and widely understood mood [8]. In contrast, glaucoma is often characterised by an insidious onset of retinal fibre nerve damage responsible for peripheral vision, so that its impact on daily activities may be visible only in very advanced stages of the disease. Furthermore, in contrast to cataract and glaucoma, current treatment options for AMD are limited, and the methods leading to slowing down the disease progression are unsatisfactory [9].

AMD is a disease associated with enhanced ageing of the macular region, which is characterised by (1) geographic atrophy of pigment epithelium (2), retinal pigment epithelium detachment (3), subretinal or choroidal neovascularisation under pigment epithelium (4), and effusions and hemorrhages with fibrous and glial scar formation [10]. AMD is the leading cause of irreversible vision loss (blindness) in people over the age of 50 in developed countries. Numerous statistical data show that the disease affects approximately 10% of the population aged 65-74 years, and 30% - over 75 years of age [11].

The pathogenesis of AMD is complex and not fully elucidated. The processes involved in AMD include (1) lipofuscinogenesis (in pigment epithelial cells) and (2) drusogenesis (formation of drusen between the layer of the retinal pigment epithelium and Bruch's membrane). Two primary forms of AMD are distinguished, i.e. atrophic (dry) and exudative (wet). Each of the two is originally a disorder of retinal blood supply. The dry form of AMD is much more common (about 85%), and so far no effective treatment has been found for this group of patients [10, 12].

Despite intensive research into the pathogenesis, course and treatment of AMD there is still a lot of confusion and controversy. Thus, patients diagnosed with AMD have no choice but to accept the quality of life associated with the disease accompanied by progressive blindness. Up to date, most studies on AMD have focused on the effectiveness of treatment and other factors influencing the progression of vision loss and deterioration of visual acuity. Some studies, however, have pointed to the need for thorough evaluation of the quality of life of patients with AMD since visual acuity alone may not provide an adequate basis for the assessment.

Since AMD can manifest itself by the impairment of central vision, deterioration of contrast sensitivity, the presence of metamorphopsia, micropsia, macropsia and others, it can significantly impair the quality of life (difficulty reading documents, the use of watch, recognizing people's faces, etc.) and at the same time be a dominant stressogenic factor for people affected by AMD. However, few studies concerning these issues provide ambiguous data.

Therefore, the aim of the current research was to: (1) assess the severity of insomnia and depressive symptoms in patients with previously diagnosed and clinically confirmed macular degeneration associated with age, (2) estimate possible correlation of vision deterioration with depressive symptoms and sleep disorders, (3) examine the relationship between depressive symptoms and insomnia, and selected demographic data.

Material and methods

The study involved 105 patients with AMD, both sexes, aged from 45 to 88 years, who reported at the Ophthalmic Outpatient Clinic for a routine check-up. They had been previously diagnosed with age-related macular degeneration, which was clinically confirmed. After ophthalmic examination, patients were asked to complete a validated questionnaire prepared by the researchers, the Beck Depression Inventory (Beck) and the Athens Insomnia Scale (ATE).

The survey contained a number of basic questions concerning gender, age, place of residence, etc., and referring to the disease course, medical treatment, subjective evaluation of vision (distorted vision, a spot in front of the eye) and subjective assessment of the severity of stress response due to impaired vision.

The ATE is the scale in which the examined person chooses answers to 8 questions assessing the following components: falling asleep, waking up during the night, waking up in the morning, total sleep time, sleep quality, mood next day, mental and physical efficiency the next day and sleepiness during the day. Each response is assigned a point value from 0 (no difficulty) to 3 (severe difficulty). The total score ranges from 0 to 24 points. The higher the result, the more inferior the quality of sleep. The assessment relates to the quality of sleep during the past week [13].

The BECK scale is one of the most commonly used methods to measure the severity of depression. It consists of 21 points evaluating the intensity of symptoms ranging from 0 to 3. Interpretation of the results is based on the following score: 0 to 9 points: no symptoms of depression; 10 to 19: light depression; 20 to 25: mild depression; above 25 points: severe depression [14].

Qualifying patients to the survey was based on the following inclusion criteria: (a) clinically recognised AMD, (b) age from 45 to 90 years, and (c) patient's consent to take part in the study. The exclusion criteria were: (a) other ophthalmic diseases that accompany AMD impairing visual acuity (e.g. glaucoma, diabetic retinopathy), (b) a very advanced form of AMD where visual acuity prevents accurate completion of the survey, and (c) patient's refusal to take part in the study.

Since 12 questionnaires were filled incorrectly (out of 117), only 105 questionnaires were included in further analysis. Selected parameters from the patient's documentation, such as the maximum obtained distance and near visual acuity, and type of AMD treatment were also evaluated.

The assessment of near vision according to Snellen charts (SN) adopted the following distribution: D 0.50 - 0.75 - very good; D 1.00 - 1.25 - good; D 1.50 - 2.00 - average; D 2.25 - 3.00 - poor; D (fails to read optotypes) - very poor (for the purpose of statistical analysis the number 4.00 was assumed). To assess distance vision according to Snellen charts (V) the following distribution was adopted: 0.8-1.0 D - very good; D 0.5-0.7 - good; 0.2-0.4 D - average; D 0.02-0.1-poor; hand movement in front of the eye - very poor.

The study was approved by the Bioethics Committee of the SUM, 21 June 2011. No: CDF / 0022 / KB1 / 74 / I / 11.

Statistical analysis was performed using STATISTICA 8.0 PL and MS Excel 2007. Values calculated for quantitative variables were expressed as the arithmetic mean, standard deviation (SD) or percentage, and for qualitative variables in percentages. The statistical analysis was performed with nonparametric Mann-U-Whitney and Kruskal-Wallis tests. The Spearman test was used to evaluate correlations. P value <0.05 was estimated as statistically significant.

Results

The mean age of the surveyed patients was 69.9 years (median 72 years) and the average time from the diagnosis was 3.9 years (median 3 years). There were 10% of patients over 80 years of age, 47% between 71 - 80 years of age, 27% aged 61-70 years, 15% aged 60-50 years and 2% below the age of 50. Women accounted for 66% of the respondents, 34% were men. In the study group, 65% of the respondents were married and 35% - single. Higher education was declared by 13% of the respondents, secondary by 54% and primary by 32%. As many as 88% of the respondents were professionally inactive, the remaining 10% performed physical work and 2% mental work. In 43% of the respondents financial status was good, in 52% - average and in 5% - bad. Family support was described as good by 38% of the respondents, average by 54%, and none by 8% (Table 1).

Table 1. Selected sociodemographic data

Data	Values (%)
Age	
<50	2
50-60	15
61-70	27
71-80	47
>80	10
Gender	
Men	34
Women	66
Marital status	
Married	65
Single	35
Education	
Primary	32
Secondary	54
Higher	13
Occupational status	
Mental work	2
Physical work	10
Non-working	88
Financial status	
Good	43
Average	52
Bad	5
Family support	
Good	38
Average	54
Lacking	8

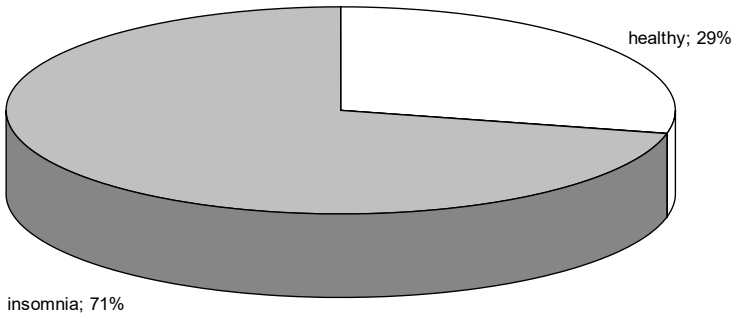
The largest group of respondents were those diagnosed within 3 years before the survey (58%), 22% 4-6 years, 11% 7-9 years, the remaining patients over 10 years. Visual disturbances known as "image distortion" or "spot" in the central vision were declared by 68% of the respondents. In the subjective assessment of the severity of "stress response" in patients with blurred vision associated with AMD and thus difficulties in everyday functioning (e.g. difficulty in reading documents, using the watch, recognition of signs, faces, etc.) as many as 74% of patients experienced stress-related vision problems (38% answered "definitely yes", 36% "rather yes", 21% "rather not" and 5% "not"). Thirty-two per cent of the respondents were treated with monoclonal antibodies and 68% with vitamin preparations. Laser therapy was not used at all. Changes in dietary habits after the diagnosis of AMD were declared only by 34% of the patients, 18% admitted cigarette smoking at present and 30% smoking in the past (Table 2).

Table 2. Selected ophthalmic parameters and other disease-related data

Data	Values (%)
Time from the diagnosis (years)	
<3	58
4-6	22
7-9	11
>9	9
Visual disturbances *distorted image or spot*	
Present	68
Absent	32

Subjective assessment of stress response severity	
Definitely YES	38
Rather YES	36
Rather NOT	21
Definitely NOT	5
Type of treatment	
Monoclonal antibodies	32
Vitamin preparations	68
Laser therapy	0
Changes in dietary habits	
Yes	34
No	66
Smoking	
Still smoke	18
Past habit	30

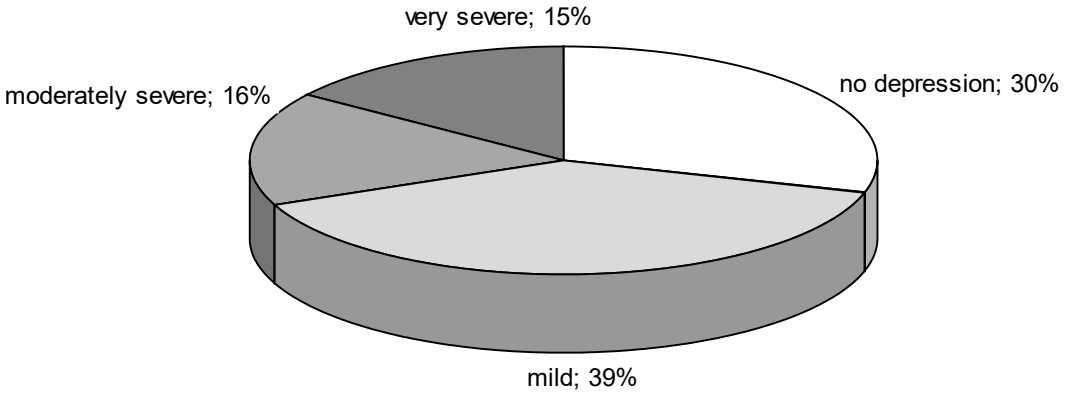
Insomnia was diagnosed in 71% of the respondents (6 or more points in the Athens Insomnia Scale) (Fig. 1).



The Athens's Insominia Scale

Figure 1. The prevalence of insomnia in patients with AMD

Depressive disorders were found in 70% of the respondents, including mild depression symptoms in 39%, moderately severe in 16% and very severe in 15%. No symptoms of depression were found in 30% of the respondents (Fig. 2).



The Beck Depression Inventory

Figure 2. The prevalence of depression in patients with AMD

Comorbid diseases, such as hypertension, ischemic myocardial disease, arrhythmias were diagnosed in 72%, 29% and 12% of the study subjects, respectively. Among other frequently mentioned diseases was diabetes (14%). None of the respondents mentioned taking antidepressants or antipsychotic drugs (data not shown in a tabular form).

Among the surveyed patients, 73% showed a very good and 27% a good visual acuity for near vision (in the eye with better vision). In the eye with worse vision, 35% of the patients showed a very good visual acuity for near vision, 23% good, 11% average, 14% poor and 16% very poor. A very good visual acuity for distant vision was found in 56%, good in 31%, average in 11% and poor in 1% (in the eye with better vision). In the eye with worse vision, 22% of the patients had a very good visual acuity for distant vision, 23% good, 22% average, 25% poor and 9% very poor (Table 3).

Table 3. Vision quality in patients with AMD

Vision quality	Values (%)
Near vision	
”Better” eye	
Very good	73
Good	27
Average	0
Poor	0
Very poor	0
”Worse” eye	
Very good	35
Good	23
Average	11
Poor	14
Very poor	16
Distance vision	
”Better” eye	
Very good	56
Good	31
Average	11
Poor	1
Very poor	0
”Worse” eye	
Very good	22
Good	23
Average	22
Poor	25
Very poor	9

In the study population of AMD patients, women were significantly more likely to suffer from insomnia than men (72% and 28%, respectively), and were also significantly more likely to have depressive symptoms. There was no correlation between the type of education and the results of ATE, while less educated patients were significantly more likely to show depressive symptoms. Moreover, patients with worse financial status and with no family support significantly more frequently suffered from insomnia and depression.

Furthermore, a moderately strong correlation was revealed between ATE results and Beck Depression Inventory data (Spearman R = 0.6317, p <0.05). It was shown that the severity of “stress response” increased with a deterioration of near and distance vision, both for the eye with better and worse vision. It was also found that the presence of visual disturbances in the form of a distorted image or spot deteriorated the quality of near and distance vision (for the eye with better and worse vision) (Table 4).

Table 4. Statistical analysis of chosen parameters

Analysed parameters	N valid	ATE (p value)	BECK (p value)
Gender	105	**<0.05**	**<0.05**
Age	105	0.090	0.078
Education	105	0.075	**< 0.05**
Occupational status	105	0.639	0.606
Marital status	105	0.477	0.719
Financial status	105	**< 0.05**	**< 0.05**

Family support	105	**< 0.05**	**< 0.05**
Time from AMD diagnosis (years)	105	0.565	0.3847
Assessment of stress response	105	0.996	0.515
Near vision – better eye	105	0.625	0.505
Near vision – worse eye	105	0.057	0.090
Distance vision – better eye	105	0.231	0.715
Distance vision – worse eye	105	0.934	0.394
ATE	105	-	**<0.05**
Analysed parameters	**N valid**	**Assessment of stress response**	**Distorted vision or spot**
Near vision – better eye	105	**< 0.05**	**< 0.05**
Near vision – worse eye	105	**< 0.05**	**< 0.05**
Distance vision – better eye	105	**< 0.05**	**< 0.05**
Distance vision – worse eye	105	**< 0.05**	**< 0.05**

Discussion

Among many factors that can negatively affect person's mental health, vision deterioration and in consequence decreased life quality are mentioned. AMD is an eye disorder caused by retinal damage in the macula which significantly impairs central vision and has a poor prognosis. Relatively early patients complain of difficulty reading documents, seeing the time on the watch, recognising faces and signs, etc. All this interferes with daily functioning, hinders independence and self-sufficiency, and is also a strong stressogenic factor for the people affected.

There are no literature data on sleep disorders in patients with AMD. However, insomnia can be found in as many as 50% [15] to 83% [16] of respondents with severe deterioration of vision (10% of vision in one eye) or entirely blind. In our study, 71% of AMD patients had insomnia.

It should be remembered that sleep disorders are very specific of depression and by some authors considered a very strong biomarker of the disease. Complaints of sleeplessness are common in people over the age of 65, who report this problem as a major one to their family doctors [17]. It is easier for patients to inform about sleep disorders and insomnia than dejection, sadness or depression. They treat insomnia as a somatic disease, like abdominal or chest pain. It is easier to describe it in a parametric way in contrast to depression Although depression usually starts with insomnia, patients may complain of sleeplessness directly before the onset of lower mood or at different times [18]. The results of the current study confirmed a correlation between sleep disorders and depressive symptoms in patients with AMD.

Using the Beck's Depression Scale, we found symptoms of mild depression in 39%, moderate to severe in 16%, and very severe in 15% of the respondents. In total, 70% of the study population with AMD showed symptoms typical of depression, which seems to be very disturbing. Our study results appear to be twice as high as the reported world data. Brody et al. [19] using the Geriatric Depression Scale found that 32.5% of AMD patients (mean age 80 years) met the criteria for depression and the proportion was twice as much as for the age-matched population without ophthalmic diseases.

Also, Rovner et al. [20] presented similar data (33%), and Qian et al. [21] found depression in 39.3% of patients with inflammatory diseases of the eye. These results seem alarming, especially if we consider that they are similar or even higher than those reported in coronary artery disease (18%), cerebral infarction (26%) and cancer (15-29%).

It is worth noting that the prevalence of depression in the elderly population with no health complaints and somatic or mental diseases ranges from 8% to 16% [22, 23]. The discrepancy in the results between the current study and the investigations cited above can be explained by differences in research methodology, i.e. using different scales to estimate the symptoms of depression and adopting the cut-off point of 9 for healthy people in the Beck's scale, and not 13 as reported elsewhere [21]. The discrepancies may also be explained by socio-economic variables, hindered access to health care and differences in the involvement of state institutions in helping AMD patients in Poland and the world. This hypothesis has been supported by the results of studies conducted on the Polish population. Weterle and Sołtysiak [24] analysing the prevalence and estimating the number of undiagnosed cases of depressive disorders in patients over 65 who were hospitalised in the geriatric ward, found depressive symptoms in 41.7% of patients.

In the current study, the majority of patients with depressive symptoms were women - 80.9% (52% of all women surveyed), as compared to 22.6% of male respondents. On the other hand, Kowalska et al. [25] who

assessed patients (mean age 77.7 years) rehabilitated in the Care and Nursing Home found 71.6% of patients with cognitive impairment, 16.5% with mild cognitive impairment without features of dementia and only 11.8% with good results. In contrast, depressive symptoms on admission to the ward were noted in 65.2% of patients (evaluation using the geriatric depression scale) and depressed mood was observed in nearly 70% of patients hospitalised due to orthopedic injuries and stroke. Thus, the results better reflect the diversity of the Polish population of patients and are consistent with our findings. It should be noted, however, that the figures quoted above relate to hospitalised patients. Research conducted among outpatients has revealed a much lower figure (about 41%) [25], whereas data for the general population are even lower, indicating that approximately 15-20% of people over the age of 65 show depressive symptoms [3].

As previously stated, in the currently analysed group of patients with AMD 70% showed symptoms typical of depression, but at the same time, no correlation was noted of vision deterioration with depression severity and sleep disorders. Also, Chojnacka [26] found that patients with cataract (approximately 90% of the study patients) or other ophthalmic diseases (the remaining 10% - glaucoma or AMD) showed no relationship between the decrease in visual acuity and the presence and severity of depressive symptoms. Moreover, she failed to find a correlation between depressive symptoms and additional somatic diseases (and their number), but showed a relationship between the quality of life and depressive symptoms (the worse the quality of life of patients the more significant the severity of depression). The above may be difficult to explain, since permanent deterioration of visual acuity usually leads to significantly reduced independence, difficulties in performing daily activities, and problems with human relations due to fear of falling down or not recognising friends' faces.

In the current study, no relationship was also found between the age of patients, their occupational status, marital status, time from AMD diagnosis and the presence of depressive symptoms and insomnia. Lack of such correlations between demographic data and such parameters as anxiety, depression, etc., in people with impaired vision, has also been confirmed by other researchers [27].

At the same time, we found that depressive disorders and insomnia are more common in women than in men, which is consistent with the works of other authors. The rate of at least one depression episode in women is 7-21% as compared to men (2.6-13%).

It is worth noting that these gender differences are fairly cohesive all over the world. The pathomechanism of mental disorders in women is a combination of a number of factors, including genetic, hormonal (hormones involved in the regulation of the menstrual cycle) and psychosocial associated with functioning in the family and at work. Some of them do not refer to men, which may partially explain the differences observed. The results of the current study also indicate that education, economic status and family support among AMD patients correlates with the severity and prevalence of depressive disorders and insomnia.

Less educated patients, with reduced financial status, deprived of family support often exhibit depression symptoms and sleep problems. The interpretation of these results should take into consideration that the average age of the study population was 70 years and thus, all the study participants were elderly. There are many indications that the risk of depression and insomnia in this population is significantly associated with the specificity of this life period. Depressive disorders in the elderly can be subject to many psychological, social and biological (organic) factors. In the elderly years, the major role is attributed to the latter, but equally important are the psychological and social aspects, and their mutual relations are usually difficult to identify, as they can coexist and overlap.

Social factors may include difficult financial conditions, loneliness and in consequence social isolation, as well as negative social attitudes towards the ageing process. Among the most important psychological factors, there are the so-called "losses", e.g. the loss of beloved and friends, the socio-occupational status, health, private property and the associated feeling of inaction and helplessness. Importantly, the awareness that these losses are usually irreversible further intensifies the severity of this phenomenon [24]. Other researchers have also confirmed that worse financial situation, lack of family support and poor education are factors that favour the occurrence of depression and insomnia [28].

As mentioned earlier, substantial vision deterioration in patients with AMD can be the cause of disability. Williams et al. [27] conducted a survey assessing the quality of life in 86 AMD patients with a very poor visual acuity. He showed that the quality of life of AMD patients was significantly worse, not only compared to the general population, but also to patients with other serious diseases, such as chronic obstructive pulmonary disease or AIDS. He also showed that compared to the overall population (subjects without visual impairment), patients with AMD were 8 times more likely to experience problems with doing the shopping, 13 times more prone to problems with managing their finances, 4 times more often having problems with preparing food, 9 times more likely to have problems with minor housework, 12 times more prone to problems associated with using the phone. These difficulties were not without an effect on mental wellbeing, as the cited authors who

used the Profile of Mood States (POMS) correlated the emotional state of the study patients with other scales evaluating other parameters (quality of life, self-assessment of health status, physical activity, etc.).

The cited authors have revealed that AMD patients experience anxiety, tension, anger and annoyance that increase with vision deterioration. The emotional state of this group of patients is similar to that observed among patients with malignant melanoma, AIDS and those waiting for bone marrow transplantation. Their results partly confirm the observations made in the current study. The subjective assessment of the severity of "stress response" to blurred vision associated with AMD and thus difficulties in everyday functioning (e.g. reading documents, using a watch, recognising people's faces, etc.) showed that 74% of the patients experience stress related to vision problems (38% of respondents answered "definitely yes", 36% "rather yes", 21% "rather not" and 5% "definitely not").

Moreover, a relationship was found between the presence of a "distorted image or spot" and the quality of near and distance vision and between the quality of near and distance vision and the intensity of stress response, i.e. the subjective feeling of discomfort and stress increased with vision deterioration in patients with AMD.

It is also worth mentioning that most of the patients surveyed (66%) declared no change in their dietary habits despite being diagnosed with AMD. It has been known that at least some of the factors predisposing to the development of this disease are defined as modifiable (dietary habits, smoking, diabetes, cardiovascular disease), i.e. the ones the patient can change. This can be considered a failure not only on the part of the patients, but also health care workers, as according to Lawrenson and Evans [29] in the UK this type of information is provided only by 67.9% of the medical staff to patients diagnosed with AMD and by 53.6% to patients at risk of developing the disease. In my research, 61% of the respondents started taking vitamins and nutritional supplements after diagnosis. Similar data have been reported in other countries [30].

Conclusions

In conclusion, it should be noted that the vast majority of studies evaluating the effect of macular degeneration and its treatment on the prevalence of depressive disorders, anxiety, insomnia and life quality, have focused mainly on the loss of vision and deterioration of visual acuity. The results of this study indicate, however, that visual acuity alone does not provide an adequate basis for the assessment of these parameters. AMD may affect the eyes in many ways and may not only cause deterioration of visual acuity but also impair central vision, metamorphopsia, micropsia and macropsia. It can deteriorate contrast sensitivity and extend glare recovery time, which can significantly impair the quality of life, be a powerful stressogenic factor and in consequence lead to depression.

The results of my research show that patients with AMD are at risk of developing depression and therefore should be cared for by a multidisciplinary team, including an ophthalmologist, a family doctor, a psychiatrist and a psychologist.

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REVIEW PAPER
ARTYKUŁ PRZEGLĄDOWY

Health Prob Civil. 2018, Volume 12, Issue 4
ISSN 2353-6942

PART II. PHYSICAL ACTIVITY OF SOCIAL AND PROFESSIONAL GROUPS
DZIAŁ II. AKTYWNOŚĆ FIZYCZNA GRUP SPOŁECZNYCH I ZAWODOWYCH

PHYSICAL ACTIVITY IN PROMOTING HEALTH OF THE ELDERLY

AKTYWNOŚĆ RUCHOWA W PROMOCJI ZDROWIA OSÓB STARSZYCH

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Authors' contribution
Wkład autorów:
A. Study design/planning
zaplanowanie badań
B. Data collection/entry
zebranie danych
C. Data analysis/statistics
dane – analiza i statystyki
D. Data interpretation
interpretacja danych
E. Preparation of manuscript
przygotowanie artykułu
F. Literature analysis/search
wyszukiwanie i analiza literatury
G. Funds collection
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Summary

Ageing, as a physiological process in human ontogenesis, is inevitable. However, it can assume a mild form. What can slow down involutionary processes within the limits of optimal human abilities and biological needs is physical activity. In addition, physical activity seems to be of great importance in the treatment and rehabilitation of various injuries and old-age diseases.

The primary objective of the paper is to show the health benefits of physical activity in involutionary processes; that is ageing of individual physiological systems and human motor skills. The work bases on available and current literature on the subject which forwards research in this field and draws on the sources relating to this particular issue. Many extensive studies indicate that physical activity is an essential element of health promotion and gerontological prophylaxis. General improvement of health due to physical activity refers to the improvement of cardiovascular and respiratory functions, prevention of degenerative changes in the spine, prevention of civilisation diseases, mental relaxation, pleasure, satisfaction, socialisation, escape from loneliness, counteracting boredom, everyday monotony, as well as spending much time in a valuable way. Properly selected and health stimulation training can enhance the general physical fitness, through better motor functions.

Along with an overall increase in life expectancy, there appears a greater need to develop research on the role of physical activity in the elderly. Physical activity in old age is a precious element of a healthy lifestyle, prevention and therapy in many diseases. It reinforces independence till old age, which is vital in coping with stress.

Keywords: physical activity, health promotion, elderly

Streszczenie

Starzenie się jest fizjologicznym procesem w ontogenezie człowieka. Proces ten jest nieunikniony, jednak można mu nadać łagodny charakter. Szczególnie ważne miejsce w spowalnianiu procesów inwolucyjnych zajmuje aktywność ruchowa mieszcząca się w granicach optymalnych możliwości człowieka i jego biologicznych potrzeb. Poza tym aktywność fizyczna posiada ogromne znaczenie w procesie leczenia i rehabilitacji różnych urazów i chorób wieku starczego.

Głównym celem pracy jest ukazanie walorów zdrowotnych aktywności ruchowej na tle procesów inwolucyjnych, tj. starzenia się poszczególnych układów fizjologicznych i zdolności motorycznych człowieka. Praca oparta jest na dostępnej i aktualnej literaturze przedmiotu, ukazującej badania z tego zakresu. Dokonano wyboru badań opierając się na źródłach podporządkowanych tematowi pracy. Wiele obszernych badań wskazuje na to, iż aktywność ruchowa stanowi ważny element promocji zdrowia i profilaktyki gerontologicznej. Ogólna poprawa stanu zdrowia za sprawą aktywności fizycznej dotyczy usprawnienia funkcji układu krążenia i oddychania, zapobiegania zmianom zwyrodnieniowym kręgosłupa, profilaktyki powstawania chorób cywilizacyjnych, odprężenia psychicznego, przyjemności, zadowolenia, socjalizacji, ucieczki przed samotnością, przeciwdziałania nudzie, monotonii dnia codziennego, wypełniania dużych ilości czasu w sposób wartościowy. Odpowiednio dobrany i stymulowany trening zdrowotny sprzyja poprawie ogólnej sprawności fizycznej, poprzez wyższą jakość wszystkich cech motorycznych.

Wraz z tendencją do przedłużania się długości życia zwiększają się potrzeby rozwoju badań naukowych nad rolą aktywności fizycznej osób w starszym wieku. Aktywność fizyczna w starszym wieku jest wyjątkowo cennym elementem zdrowego stylu życia, profilaktyki i terapii wielu chorób, przedłuża niezależność do późnej starości i jest ważnym czynnikiem radzenia sobie ze stresem.

Słowa kluczowe: aktywność ruchowa, promocja zdrowia, osoby starsze

Tables: 0
Figures: 0
References: 30
Submitted: 2018 Feb 01
Accepted: 2018 Jun 07

Parnicka U. Physical activity in promoting health of the elderly. Health Prob Civil. 2018; 12(4): 265-271. https://doi.org/10.5114/hpc.2018.77840

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Introduction

The ageing of the population in developed and developing countries for over a dozen years has become an increasingly acute social problem. Therefore, issues related to ageing and old age have recently become particularly important. This problem is vital for many scientists in various fields, including physical education [1]. Research into older people not only helps to better understand the process itself but also contributes to the improvement of their quality of life. Currently, this social group is becoming more and more important given that, in the coming years, the elderly will grow in numbers [2].

Health promotion is usually defined as a process that allows for increased control over one's health, improve it and take responsibility for own health and life. With regard to the promotion of health in the elderly, the WHO has, inter alia, the following aims: prolonging the period of one's activity and independence, preventing and relieving psychophysical disorders, providing care that enables individual autonomy, giving up various forms of institutional care for the family, reducing stress in terminal diseases; delaying the necessity of turning to various types of medical and care services.

The implementation of the above is possible through actions aimed at ensuring equity in healthcare and reducing differences in the health-level of various social groups, adding a component of life satisfaction - providing opportunities to develop and use physical and mental potential of people related to knowledge, skills and motivation in order to create own health, enhancing one's health - reducing the incidence of diseases and disability, raising the level of psychosomatic fitness, improving well-being, strengthening and developing health potential, extending life expectancy by eliminating premature deaths [3].

Physical activity and physiological involutionary changes

The ageing process stands for involutionary changes taking place in the human body with progressing age. Ageing is often accompanied by degenerative changes, which include, among others, reduction of muscle strength and tension, weakening of the bones, weaker breathing, reduced mobility of the chest, weakening of aerobic and anaerobic capacity, prolonged reaction time and many other health problems [4]. Specialists believe that these involutionary changes can be slowed down by regular physical exercise and rational nutrition [5].

While implementing pro-health activities, physical activity simultaneously impacts all components of this process, including preservation and enhancement of health, self-recognition, development of positive personality traits, shaping physical fitness and efficiency, as well as mental rest, relaxation, seeking and establishing social contacts. Furthermore, any discussion on physical activity in the context of health promotion in the elderly involves the basic physiological phenomena that occur in the human body in the ageing process:

- Multidirectional biochemical changes visible in the body's ageing process such as the changing oxygen and protein metabolism [6];
- Changes in the composition of the body - reduction in muscle mass and body water, as well as changes in fat content and bone mass [7];
- Reduced capacity of the lungs, their maximum lung ventilation and maximum oxygen uptake. The chest expansion reduces, the capillary vessels disappear in the inter-bubble septum, which affects the deterioration of gas diffusion and causes inadequate oxygenation of the blood [8];
- Age-related changes appear in the circulatory system as a result of calcium deposits and cholesterol deposits in the inner part of blood vessels, which leads to numerous diseases of the elderly age [9];
- Age-related changes in the nervous tissue are a consequence of the reduction and disappearance of nerve cells. The reduction of sensitivity of all senses is most visible. There appears the so-called mental numbness characterised by slower learning, remembering, thinking, problem-solving skills and coping with stress [10];
- Age-related changes in the digestive system are characterised by the disappearance of some enzymes responsible for food digestion and a reduction in the secretion of gastric juices. The oral mucosa becomes thinner, drier, losing its elasticity. The intestinal peristalsis is released, which has an adverse effect on the process of food absorption and excretion of unnecessary metabolic products, the consequence of which are constipation and indigestion [11];
- Ageing of the renal-urinary system is manifested by a reduction in renal mass, which results in a decrease in blood flow. The number of active renal glomeruli is decreasing. As a result, kidneys are very sensitive even to short-term ischemia. Bladder capacity is reduced, the urine volume is increased and the urethra becomes shorter. All this causes urination disorders [12];

- Ageing of the reproductive system has its consequences in the cessation of reproductive functions. Menopause is characterised by a loss of function of ovarian follicles to respond to gonadotropic hormones, which decreases estrogen concentration. This causes hormonal changes affecting the entire body. In men, there is a decrease in testosterone levels, the process of spermatogenesis is less efficient and live sperm / capable of fertilisation is weakened. The prostate gland undergoes degenerative changes. It tends to increase and cause cancer [13].

The goal of the exercise meant for the elderly is:

- maintaining the efficiency of all physiological systems (circulatory, respiratory, motor, digestive, nervous and other systems) as long as possible;
- maintaining physical fitness, allowing the person to perform basic, everyday life activities, such as dressing, cleaning, shopping, etc.;
- enabling mental relaxation, pleasure, satisfaction;
- socialisation - escaping from the loneliness of everyday life, willingness to be with people;
- managing the excess of free time in a valuable way;
- better functioning of sense organs, orientation in space, balance, coordination and imagination;
- managing emotional states;
- weight control, prevention of overweight and obesity;
- counteracting the development of atherosclerosis, diabetes, arterial hypertension, coronary artery disease and osteoporosis;
- increasing the activity of the immune system.

There is a social justification for increasing physical activity in older people, which is forwarded by the World Health Organization / WHO /. It recommends the following:

1. *Reducing the cost of social and health-care*. Lack of physical activity and sedentary lifestyle reduce one's independence and contribute to the occurrence of many chronic diseases. A physically active lifestyle can help delay the onset of physical weakness and illness, thus significantly reducing the cost of health and social care.
2. *Increasing the working capacity of elderly people*. A physically active lifestyle helps older people maintain functional independence and optimises the extent to which they are able to actively participate in society.
3. *Promoting a positive and active image in older people.* A society that promotes the physically active lifestyle in older people can better benefit from their wealth of possessed experience and knowledge.

Physical activity of the elderly - selected research

The area of research on ageing processes and the impact on these processes is a relatively young field. Gerontology, a science with a broad, multidisciplinary range, combines, among others, medicine, physiology, biology, psychology, pedagogy, economics and law. Out of it grew a field that is of great importance for shaping the future of old age, i.e. gerontological prophylaxis.

The prolongation of human life has caused that, both in the world and in Poland, issues related to the elderly have become the subject of numerous sciences drawing the attention of many researchers [14]. Many studies have been conducted into health and social aspects of ageing population in recent years [15]. Much research is directed at the prevention of premature functional failure, lowering the incidence and increasing the quality and length of human life. Further, much research is in particular focused on the impact of physical activity on the reduction of heart disease, obesity, hypertension, cancer, diabetes, osteoporosis, depression, falls and other injuries [16].

The motor skills of a human deteriorate very quickly over the years. Every decade in one's life significantly weakens all motor features, including muscle strength, motor coordination, etc. While observing over 6,000 people aged 55 to 75 years for a period of 7 years, W. Starosta [17] proved that, during this period of life, the motor coordination is significantly impaired, and after the age of 55, the sense balance systematically worsens the person's control over the maintenance of the position of the body. The above changes clearly indicate that the elderly become less and less physically fit, and consequently more susceptible to various diseases. Consequently, their dependence on others increases. Accordingly, gerontological prophylaxis is not only about reducing the risk of illnesses but also about improving the general physical condition of the older organism.

Numerous clinical and physiological studies have shown that physically active people slow down the natural process of physical fitness and efficiency loss, while in physically inactive persons it is much faster [18]. Research by E. Kozdroń [19] in a group of people over 65 participating in a 6-month recreational activity programme showed a significant improvement in the overall muscular strength, spinal flexibility and arm strength. In

turn, 5-year observations conducted by E. Cormeli et al. [20] in a large population of persons over 65 showed a significant impact of physical exercise on improving their physical performance, which is almost entirely dependent on the clinical condition of the circulatory system. Further, the literature on the subject described the beneficial effects of using strength exercises by older people. After a few weeks of such exercises, muscle strength increases, and so does their mass in the subsequent stages. An extensive review of forms of strength training used by various researchers and their influence on the muscular strength in the elderly can also be found in the studies by N. A. Ratamess et al. [21].

The most popular and health-oriented form of physical activity in older people is endurance training, whose effect has been confirmed by many studies in the field. Thanks to endurance exercises, the aerobic capacity increases and maintains until later in life at a similar level as in physically inactive persons, but younger by 30-40 years [22].

Epidemiological studies indicate that the lack of exercise, in addition to excessive carbohydrate intake, impairs its tolerance in the body, which in older age may lead to the occurrence of type II diabetes. This disorder consists in the reduced absorption of glucose by the tissues due to their reduced sensitivity to insulin/insulin resistance/, which leads to increased blood glucose/hyperglycemia/. Meanwhile, physical effort increases glucose uptake in working muscles, which leads to normalisation of blood levels [23].

Regular physical exercise is not only a potential factor in improving physical fitness, but also positively affecting the mental fitness of the elderly. P. Lampinen et al. [24] showed that mental fitness and well-being in the elderly are closely related to physical activity. The authors claim that regular physical exercise is a potential factor preventing ageing and favourably affecting the well-being of the elderly.

One can find numerous evidences confirming the salutary effect of physical activity on the health potential of the elderly in the literature on the subject [25]. In turn, A. Gębska-Kuczerawska [26] in her research on a group of people over 65 showed that the physically active enjoy a better psychophysical condition, are less burdened with cardiovascular diseases, and also use hospital care less frequently.

Numerous multicentre studies on the elderly population conducted in various cultural backgrounds, be it Greek, Brazilian or Italian, confirmed that an active, healthy lifestyle associated with physical exercise and proper nutrition are a prerequisite for good physical and mental health, being the most critical factor for successful ageing [27].

Forms of physical activity for elderly people

The most commonly used forms of physical recreation for the elderly having protective effects include walking and marches, rehabilitation gymnastics, games and motion games, Nordic walking, music classes, swimming and gymnastics in the water.

Walks, marches

The most accessible and popular forms of personal recreation are daily walks, which can be followed through the year irrespective of the season or weather. They mean not only being active, but also getting the best benefit from air and sun. As a common form of physical recreation, walking has many advantages:

- it can be done any time;
- it can be done everywhere (in the neighbourhood, a local park, around the city, etc.);
- it is an activity done in the open air;
- it is rarely harmful;
- it is not exhausting, requires less effort than most forms of physical activity;
- it does not require a costly outfit or cause additional costs;
- it is utilitarian and can become part of other activities.

A slightly more intense form of walking are marches, which are recommended by specialists as generally available, safe, moderate and healthy physical exercises. Treated as an affordable form of aerobic exercise, they improve the way the heart and cardiovascular system work [28].

Rehabilitation gymnastics

Gymnastics is the most common form in organised physical recreation programmes for the elderly. It also occupies a leading position in individual activity. Gymnastics can be considered as one of the most versatile and most accessible forms of movement. It can be followed in various conditions (sports hall, hall, open air, beach, etc.), using various accessories (tapes, weights, sticks, etc.) and attractive props (e.g. music). Its essence makes it

also an element of other forms of movement, for example, a part of warm-up or support exercises. It provides an opportunity to adapt each exercise to exercisers' abilities.

Rehabilitation gymnastics is a versatile and attractive form of activity that enables achieving the following effects:

- making joints flexible and strengthening the whole body movement apparatus;
- improving the respiratory function - reducing respiratory frequency in favour of deeper breathing;
- strengthening abdominal muscles and bringing beneficial effects to internal organs (e.g. stomach, intestines, liver);
- preventing constipation and haemorrhoids;
- improving motor coordination;
- improving the mobility of the chest wall;
- strengthening of the myocardium, extending small arteries and capillaries, improving blood supply conditions of individual tissues and organs;
- increasing and improving metabolism;
- improving psychophysical well-being, i.e. self-confidence, satisfaction with interpersonal contacts, decreasing emotional tension;
- making the individual more active and emotional [29].

Motion games and activities

Motion games and games should be regarded as an element that complements the process of improving the body's capabilities. Combining gymnastic activities with games and motion games brings excellent effects.

Games and motion games are a form of activities affecting the comprehensive human development and fulfil both the educational and recreational role. Their social character allows for forgetting about one's problems, ailments and loneliness. The fun movement conducted in a friendly atmosphere allows for eliminating stress and making friends.

Fun and games in a peer group, in addition to the pro-health values of physical activity, also satisfy other needs that are not met in the family, such as the need to talk, exchange experiences, integrate, provide a sense of belonging, acceptance, etc. Motion games and activities should be treated as an element complementing the process of improving older people's health and life. Due to their versatility, the ease of performance and the fun and entertainment element, they are ideal for use in various conditions (hall, outside, etc.) as a variety of all recreational activities. The unlimited movement opportunities, emotional commitment and contentment are elements that mobilise the strength to do better exercise.

Outdoor classes - Nordic walking

Outdoor forms of recreation, primarily due to their cognitive and economic health benefits, are very popular in older people.

They are one of the most pro-health forms of physical activity of this age group. Benefits of outdoor activities are unquestionable, and the possibility of using the natural environment (forest, water, terrain, climate, nature monuments) is the way by which health-related goals of physical activity can be most easily achieved. An essential element of the outdoor activity is also the hardening of the body, which is possible due to different atmospheric conditions, such as temperature, sun, humidity, wind or rain or snow.

Recently, one of the forms of physical activity followed in the outdoors is Nordic walking, popularly referred to as a walk with sticks. While walking with sticks, the load on the knees and spine is reduced, which is crucial especially in overweight people. In addition, the undoubted benefit of this form of physical recreation for the elderly is increasing the balance and stability of the body. The dosing of physical loads is individual for each person, and there are no contraindications to engaging in this physical activity.

While walking with sticks, we relieve joints and spine, improve physical condition and well-being. Nordic walking is an intense workout of legs, buttocks, hips, back, arms and shoulders. It ideally supports weight reduction. It also reduces the risk of osteoporosis, improves cardiovascular and respiratory fitness, prevents diabetes and lowers cholesterol. Further, it is an ideal remedy for depression, and it reduces the level of stress hormones and strengthens the immune system. Involving almost 90% of the whole body's muscles, Nordic walking consumes approx. 400 kcal/hour. compared to 280 kcal. during a normal walk. Energy consumption increases when using poles by 20% compared to an ordinary walk without sticks and the heart rate is 5-17 beats per minute higher.

Nordic walking is a great aerobic workout for the cardiovascular and respiratory systems. Pumping (i.e. opening the hand while pushing the stick back and closing it when returning) greatly improves blood circulation in the upper half of the body. Nordic walking also stands for relaxation and renewing the nervous system. Being in the open air in the natural environment and kind people is a remedy for nerves and a rest for the mind. Physical effort removes stress hormones from the body (cortisol and adrenaline) and increases the level of happiness hormones (endorphins). Training in forests by the sea or the mountains is an excellent solution to regain lost life energy and achieve better mental balance [30].

Other forms of activity for older people

Morning or evening gymnastics are other forms of physical activity suitable for the elderly. It is a highly individualised form of the movement whose intensity and range of exercises should depend on the specific abilities of the person.

During the morning gymnastics, one should involve bigger muscle groups, stimulate individual physiological systems and, consequently, allow the body to perform everyday activities.

The next form is dance and dance games - recently more and more popular in older recipients. It is not about a social dance, but a group dance, e.g. the so-called "five o'clock dances" in sanatorium and holiday centres, dance in a circle, dancing with chairs or dances from other parts of the world. All forms of dance are proper if they bring positive emotions both emotional, connected with establishing contacts with other people, and those resulting from physical effort. Dance is usually accompanied by music, which enhances mood and atmosphere and provides various emotional experiences.

Also, swimming is quite an attractive form of physical activity for the elderly. The water environment creates specific conditions that help relieve joints, increase their mobility and muscle strength and reduce pain in joints. An attractive form of activities in the water can be various types of exercises, in which non-swimmers can also participate. Recently, an example of such activities is quite popular aqua aerobics. Every move in the water causes resistance, which results in higher body efficiency than in a similar exercise in the gym. At the same time, muscles, thanks to the aquatic environment and body weight, have better conditions for loosening and being massaged by water. Water classes are especially recommended for people with degenerative diseases and back pain in rheumatic diseases and in obese people. Relaxation can be experienced even by those with severe movement limitations.

Many older people do Pilates exercises to improve the own body. It is a system of exercises of the whole body consisting in combining precisely performed exercises with breathing with calm (what is significant is the quality of movement, not the number of repetitions). Their essence is stretching, tightening and loosening muscles. This system is aimed at improving the flexibility, strength, balance and awareness of one's body. Many people willingly engage in working in the gardens and on plots. This type of utilitarian effort is quite versatile and has a positive effect on the whole body. Supplemented with gymnastic exercises, which are corrective and flexible, it plays a positive role model in the physical recreation of the elderly.

Finally, there are quite popular, traditional and individual forms of physical activity for grandparents/grandmothers – taking care of grandchildren. Being excluded from professional life, the elderly (often widowed) often regard this "grandfathering" as the only bright side of life, which allows for thinking about the future and strengthens the emotional bond with grandchildren. The joy of spending time with a grandchild manifests itself in the play, which often takes the form of a movement. In joint games with children, grandparents/grandmothers become partners involving both the mental and physical health.

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ORIGINAL PAPER
ORYGINALNY ARTYKUŁ NAUKOWY

Health Prob Civil. 2018, Volume 12, Issue 4
ISSN 2353-6942

FACTORS MOTIVATING PARTICIPATION IN PHYSICAL ACTIVITY IN STUDENTS OF WARSAW UNIVERISTY BY GENDER

CZYNNIKI MOTYWUJĄCE DO PODEJMOWANIA AKTYWNOŚCI FIZYCZNEJ PRZEZ STUDENTÓW UNIWERSYTETU WARSZAWSKIEGO WEDŁUG PŁCI

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Authors' contribution
Wkład autorów:
A. Study design/planning
zaplanowanie badań
B. Data collection/entry
zebranie danych
C. Data analysis/statistics
dane – analiza i statystyki
D. Data interpretation
interpretacja danych
E. Preparation of manuscript
przygotowanie artykułu
F. Literature analysis/search
wyszukiwanie i analiza literatury
G. Funds collection
zebranie funduszy

Summary

Background. Physical activity is the primary factor in maintaining health and fitness. The minimal amount of physical activity per week is about 150 minutes of moderate activity. There are also many different motivation factors for activity, depending on various characteristics, for example, gender. The following article aims to prove how far gender can differentiate the motivation factor determining the amount of students' physical activity.
Material and methods. The study was carried out in 2016 in a group of 694 students of Warsaw University. The tool used to conduct the research was a proprietary questionnaire.
Results. The study showed that there are distinct differences between women and men. Firstly, the study allows for stating that students demonstrate different attitudes towards recreational activity. The second important outcome shows that intrinsic motivation is stronger in female students, while extrinsic factors play an essential role in males.
Conclusions. The obtained results on physical activity of students of Warsaw University remain partially in line with those found in other universities. Fitness improvement, weight reduction and well-being are the main motivation factors affecting the amount of physical activity. Another factor pointed out by students, and strongly emphasised by women, is taking care of own figure and physical condition. The element of pleasure concomitant with physical activity also becomes one of the most significant motivating factors for students of Warsaw University. Furthermore, male students are more likely to be driven by competition and self-examination, while females are more into weight control.

Keywords: physical activity, gender, motivation

Streszczenie

Wprowadzenie. Aktywność fizyczna to jeden z czynników utrzymania zdrowia. Minimalny potrzebny poziom aktywności fizycznej to 150 minut umiarkowanej aktywności tygodniowo. Istnieje wiele czynników motywujących człowieka do podejmowania aktywności, a czynniki te zależą między innymi od płci. Niniejszy artykuł ma na celu ukazanie różnic w czynnikach motywujących do aktywności fizycznej wśród studentów i studentek Uniwersytetu Warszawskiego.
Materiał i metody. Badanie zostało przeprowadzone w 2016 roku wśród 694 studentów Uniwersytetu Warszawskiego. Wykorzystano autorski kwestionariusz ankiety.
Wyniki. Badanie pokazało, że istnieją pewne różnice pomiędzy aktywnością fizyczną kobiet i mężczyzn. Studenci posiadają różne nastawienie do podejmowania aktywności fizycznej. Motywacja wewnętrzna (wrodzona) do podejmowania aktywności jest wyraźnie silniejsza wśród kobiet, u mężczyzn dominuje motywacja zewnętrzna.
Wnioski. Wyniki przeprowadzonych badań potwierdzają wiele z wyników osiągniętych w badaniach innych autorów. Rozwijanie sprawności fizycznej, reedukacja masy ciała oraz poprawa samopoczucia to najczęściej wymieniane czynniki motywujące do podejmowania aktywności fizycznej. Inne czynniki motywujące to - wskazane częściej przez kobiety – potrzeba dbania o sylwetkę i kondycję fizyczną. Ważnym czynnikiem motywującym do podejmowania ruchu w czasie wolnym jest związana z aktywnością fizyczną przyjemność. Mężczyźni są częściej zmotywowani poprzez możliwość podejmowania rywalizacji i chęć sprawdzenia własnych możliwości, podczas gdy dla kobiet silniejszym motywatorem jest możliwość kontroli masy ciała.

Tables: 3
Figures: 0
References: 29
Submitted: 2018 Apr 24
Accepted: 2018 Jun 07

Słowa kluczowe: aktywność fizyczna, płeć, motywacja

Fuhrmann MM. Factors motivating participation in physical activity in students of Warsaw University by gender. Health Prob Civil. 2018; 12(4): 272-277. https://doi.org/10.5114/hpc.2018.78782

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Introduction

The primary purpose of physical activity is to improve physical and mental health [1], and the need for testing the activity is based on the willingness to improve physical activity plans [2, 3]. Others point to some impact of physical activity on individual disease entities, from the group of heart, cardiovasular, bone or chronic diseases, as well as an impact on weight loss, an increase of energy and well-being [4, 5, 6]. The baseline of activity needed to achieve the above-mentioned effects is 150 minutes of moderate-intensity exercise per week. Physical activity is most crucial for young people, because of future health and social advantages [7].

It is a common object of interest in many studies on physical activity both in Poland and abroad [8, 9, 10, 11, 12, 13]. The percentage of students participating in physical activity is very diverse, but still considered low. Another noticeable phenomenon is the decrease in physical activity after starting education [2, 14], as well as the age-conditioned decline in willingness to undertake physical activity [15, 16, 17, 18, 19]. The only exception shall be the case studies of Ashford, Biddle and Gouda [20], where mental health, socio-psychological or well-being motives were stronger in people over 45 years.

When it comes to physical activity management, it is essential to know the incentives to start that activity in the first place. Motivation means being "moved" to do something [21]. Kilpatrick, Hebert and Bartholomew highlight such characteristics as social belonging to the given group, appearance, competition, pleasure, health, agility, regeneration, recognition of the environment, strength and endurance, stress and weight management. According to Alvin Hung Chih Yu, motivational factors include health, appearance, social needs, self-education and pleasure. Teixeira, Carraca, Markland, Silva and Ryan [22] indicate that most young people have no motivation for physical activity or they have a low extrinsic motivation that does not lead to long-term activity.

One of the theories used to explain the motivation for taking physical activity is self-motivation theory (SDT) [23]. This theory forwards two different groups of incentives – intrinsic and extrinsic motivation. The first group includes satisfaction, joy, pleasure, personal achievements and excitement. The other group involves factors referred to as "instrumental reasons", which include, among others, a desire to avoid exclusion from the social group. The theory assumes that human beings demonstrate three basic psychological needs: a need for autonomy, competence and relatedness [14]. The extent of these needs is determined by the type of motivation. The types of motivation for meeting the abovementioned needs according to SDT are presented in Table 1.

Table 1. Motivation factors according to self-motivation theory (SDT)

Locus of inner control	**Locus of external control**			
True inner motivation	Weak external regulation	Strong external regulation	External regulation	Lack of motivation
"I exercise because it's fun"	"I exercise because I want to look good"	"I exercise because I don't want to feel guilt for leaving my team"	"I exercise because my parents want it"	"I think exercising is a waste of time"
Action to feel joy and comfort, incentives are not required	Action is run by internally defined values	Action is taken as an internal need, but the cause is an external effects	Action is ruled by system of penalty and incentive	Action is not happening because there is no need to

Source: Kaupuzs A. The relationship between physical activity and exercise motivation of the first year students from Rezekne Augtskola. Lase Journal of Sport Science. 2013; 4(1): 3-15.

On the other hand, Ingledew and Markland [24] consider personality traits as the source of motivation determining participation in PA. This results in particular motives leading to undertaking physical activity. The latter are then translated into activity-related behaviours. They also highlight the one's ability to influence behaviour directly through personality traits. The result of those elements is the actual participation in physical activity.

Material and methods

The presented results were collected in a survey conducted among 694 students of Warsaw University in 2016. The tool used to carry out the research was a proprietary questionnaire. Students represented different fields and stages of the study. The majority of the respondents (67.8%) were women. Nearly 65% of the students declared regular physical activity – 2-3 times a week (52.1%).

The study included 23 motivation factors for undertaking physical activity. They were divided into 7 groups of mental, aesthetic, health, personality, economic, social and spatial factors. Each factor was evaluated on a five-point scale: 'it definitely doesn't matter', 'it doesn't matter', 'it's hard to say', 'it matters', and 'it definitely matters'. In the compilation of motivation factors, two of the strongest responses were presented. For further analysis, two extreme (positive and negative) responses were cumulated, resulting in creating a three-step scale. Next, using the SPSS v. 24.0 package, a chi-square test was performed to examine the relationship between the respondents' gender (nominal variable) and the declared validity of the motivation factors (ordinal variable). The connection between the above variables was verified based on statistical significance and the cut-off level of 0.05.

Results

The most critical motivation factor for undertaking physical activity by students was the need to take care of themselves. This option was chosen by 90.5% of the female respondents. Health considerations came second (89.1%), and the desire to have a slim silhouette was a third option (84.9%). Other factors were chosen less frequently - the general need to be active, motivated slightly more than 70% of the women, and the pleasure from taking physical activity was an important factor for 66.7% of the students, just like hygienic considerations (66.5%). Among men, the most crucial incentive was pleasure, but it was chosen by less than 80% of the students. Health considerations came second (76.5%), followed by the need for self-care (73.9%). Similarly, as in the case of female students, the fourth most common answer was the need for activity (70.4%). The other two factors were the desire to have a slim silhouette (7.1%) and relaxation (65.4%).

The study allowed for determining the differences in motivation for physical activity depending on gender. The main difference between the two groups of students was the attachment of women to physicality and appearance and, in the case of men, to character and personality issues. The factors with the most significant indication differences were identified, and the differences were statistically significant (11 factors). In the case of two factors, the differences followed a statistical tendency. The factor with the most significant difference, i.e. „overweight" – was chosen by 57.2% of women and 27.5% of men. The second place in women was the desire to have a slim figure, where the difference in indications was 17.8 percentage points. Other factors that were more noticeable among women include the need for self-care, health considerations, the availability of fitness clubs, multi-pass and the availability of green areas. Men focused more on competition (24.9 percentage points difference), ambition, character formation, pleasure, desire to impress others and the opportunity to spend time with friends. On the level of statistical tendency, the differences concerned pleasure and the possibility to spend time with the ones that students actually care about.

Table 2. Factors that motivate students to undertake physical activity (in %)

Motivation factor	Women			Men			Chi square df = 2	Statistical significance
	Not important	Hard to say	Important	Not important	Hard to say	Important		
Health considerations	3.2	7.7	89.1	5.2	18.3	76.5	12.746	0.002
Hygiene considerations	8.8	24.6	66.5	13.1	28.8	58.2	3.501	0.174
Need for activity	12.0	16.9	71.1	11.8	17.8	70.4	0.052	0.975
Pleasure	10.2	23.2	66.7	7.2	15.0	77.8	5.949	0.051
Relaxation	16.5	24.9	58.6	11.8	22.9	65.4	2.416	0.299
Character shaping	30.9	26.3	42.8	24.2	19.6	56.2	7.197	**0.027**
Medical recommendation	78.9	10.6	10.6	78.4	9.8	11.8	0.189	0.910
Need for competition	76.8	12.7	10.6	43.4	21.1	35.5	53.373	**<0.0001**
Ambition	33.0	28.1	38.9	19.0	24.8	56.2	13.958	**0.001**
Desire to impress others	67.6	16.9	15.5	49.0	24.8	26.1	14.671	**0.001**
Need for self-care	3.2	6.3	90.5	8.5	17.6	73.9	21.357	**<0.0001**
Overweight	27.4	15.4	57.2	61.4	11.1	27.5	49.581	**0.0001**
Silhouette shaping	4.6	10.6	84.9	19.7	13.2	67.1	27.619	**0.0001**
Availability of fitness club network	55.4	21.1	23.5	68.4	19.7	11.8	9.807	**0.007**

Availability of green areas	38.0	27.5	34.5	50.0	19.7	30.3	6.290	**0.043**
Outoor gyms	69.1	19.3	11.6	71.2	17.0	11.8	0.353	0.838
Meeting with friends	56.5	20.0	23.5	50.3	15.7	34.0	5.721	0.057
Meeting new people	67.0	17.5	15.4	59.2	21.7	19.1	2.632	0.268
Fashion	78.5	13.7	7.7	81.7	11.8	6.5	0.620	0.733
Multi-pass	73.0	9.8	17.2	85.6	5.2	9.2	9.090	**0.011**
Physically active family	76.5	11.2	12.3	72.5	17.6	9.8	3.786	0.151
Physically active friends	51.9	24.9	23.2	51.6	25.5	22.9	0.018	0.991
Need for leisure time management	30.6	32.7	36.6	26.8	31.4	41.8	1.260	0.533

Source: Own work on the basis of own research

Table 3. Most significant indication differences in motivation factors for undertaking physical activity in students of Warsaw University

Women		Men	
Factor	**Indication difference**	**Factor**	**Indication difference**
Overweight	29.7	Need for competition	24.9
Slim silhouette	17.8	Ambition	17.3
Need for self-care	16.6	Character shaping	13.4
Health considerations	12.6	Pleasure	11.1
Availability of fitness clubs	11.7	Desire to impress others	10.6
Multi-pass	8.0	Meeting friends	10.5
Availability of green areas	4.2		

Source: Author's own research

Discussion

The study leads to the conclusion that motivating factors for women are more clearly related to physicality and appearance. Women pointed out overweight, the need for a slim figure or self-care more often than men. What is interesting is that female students are more likely encouraged to undertake physical activity due to the environment (fitness clubs or the availability of green areas) or their economic situation (having a multi-pass[1]). Male students tend to focus more on factors related to personality, character traits and perception by others. They point to the need for competition, ambition or ability to shape character through activity, and the desire to impress others. Only on the level of statistical tendency, they chose pleasure (statistical significance 0.051) or the possibility of meeting friends more often than female students (statistical significance 0.057).

The factors indicated by women such as health considerations and the need for self-care show that they are more likely to have intrinsic motivation. In the case of men, the external factors (perception by others, perception of themselves) were stronger. In addition, women were more likely to be motivated by circumstances not included in SDT.

The factors observed in male students are related to the development of assertiveness, their desire to achieve new goals and self-esteem [25]. Among women, health considerations are crucial as motivation factors for participation in physical activity. Health is a natural result of physical activity; that is why such motivation does not seem surprising. In all of these considerations, one thing is particularly interesting – it is the fact that women tend to be more aware of health aspect, whereas young people consider "health", as something they do not need to care about.

It is worth stressing that intrinsic motivation is stronger in female students, while the extrinsic factors play an essential role in male students. In addition, factors outside the SDT theory associated with recreational space and their economic condition seem more important to women.

Given the division of motivational factors into four groups proposed by Gavin, Keough, Abravanel, Moudrakovski, Mcbrearty [25], which outlined mental health, pleasure, and stress reduction factors, female

1 A special pass for the use of sports facilities (fitness clubs, etc.) most often at no extra charge throughout the country; it allows one to use various sports and leisure facilities with one contract and a pass, most often co-funded by the employer, so the cost of such pass is often much lower than the cost of a regular gym or pool pass.

students are more often characterised by factors from the second group, while male students are more often associated with factors related to pleasure and mental strength. The observed differences may suggest that female students show greater concern for health issues and they are aware of such aspects. Furthermore, as women in general, they often pay attention to their appearance and, by taking up physical activity, they want to be in good shape to be noticed by others, as well as enhance their external attractiveness. In turn, men show greater attachment to such masculine traits as the need to compete or face more significant challenges. One can even say that for female students physical activity is nothing more than just a means to an end, whereas for male students it is an end in and of itself because by the very fact of being active they are accepted by the environment.

Conclusions

The obtained results on physical activity in Warsaw University students remain partially in line with those found in other universities. And so, Łuczak and Kroma [26] point out fitness improvement, weight reduction and well-being as main motivation factors. In Dębska's [27] study, the primary drive for physical activity is taking care of own figure and physical condition, a factor also pointed out by students (strongly emphasised by women). Siwiński and Tauber [28] pointed to the element of pleasure derived from physical activity, which has also become one of the most important motivating factors for students of Warsaw University. Kilpatrick, Hebert, Bartholomew [2] reported that men are more likely motivated by competition and self-examination, while women are more into weight control. Likewise, Asford, Biddle and Goudas [20] found out that male students were more motivated by endurance issues than females, and their research conclusions indicated the differences in motivation by gender. Finally, Baj-Korpak, Korpak, Szepeluk and Sudol [29] state that health is the prime factor determining physical activity.

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Health Prob Civil. 2018, Volume 12, Issue 4
ISSN 2353-6942

PART III. OTHER
DZIAŁ III. INNE

PLATELETS AND THE CLINICAL COURSE OF CROHN'S DISEASE

PŁYTKI KRWI A PRZEBIEG KLINICZNY CHOROBY LEŚNIOWSKIEGO-CROHNA

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Authors' contribution
Wkład autorów:
A. Study design/planning
zaplanowanie badań
B. Data collection/entry
zebranie danych
C. Data analysis/statistics
dane – analiza i statystyki
D. Data interpretation
interpretacja danych
E. Preparation of manuscript
przygotowanie artykułu
F. Literature analysis/search
wyszukiwanie i analiza literatury
G. Funds collection
zebranie funduszy

Summary

Background. Crohn's disease (CD) is a chronic, autoimmune, inflammatory bowel disease (IBD) characterised by periods of exacerbations and remissions. Autoimmune disorders caused by undetermined factors lead to inflammation in the intestinal mucosa. Presently, there is a growing interest in the role of platelets in the assessment of inflammatory lesions in CD. Accordingly, the aim of this study was to answer the question of whether routinely measured platelet indices: concentration of platelets (PLT), the mean platelet volume (MPV), plateletcrit (PCT) could become biomarkers for monitoring the course of CD.
Material and methods. In the study programme, there were enrolled 100 patients with a diagnosed CD with a different clinical course, disease location and heterogeneous therapy. In all patients, there were collected blood and stool samples for the assessment of CRP, blood count and fecal calprotectin evaluation. The clinical state of each patient was classified using the Harvey-Bradshaw index.
Results. The study showed a positive, statistically significant correlation between fecal calprotectin, CRP, WBC, the Harvey-Bradshaw index and the number of platelets and PCT. Furthermore, the analysis showed a statistically significant negative correlation between MPV and the number of WBC, CRP and fecal calprotectin.
Conclusions. Our study showed that platelet indices are a valuable, non-invasive and widely accessible method to assess mucosal healing and the clinical status of the patient.

Keywords: Crohn disease, inflammatory bowel disease, platelets, mean platelet volume

Streszczenie

Wprowadzenie. Choroba Leśniowskiego-Crohna (CD) należy do przewlekłych nieswoistych chorób zapalnych jelit (IBD) o podłożu autoimmunologicznym, przebiegająca z okresami zaostrzeń i remisji. U jej podstaw leżą zaburzenia autoimmunologiczne wywołane przez nieokreślone czynniki, prowadzące do zmian zapalnych w błonie śluzowej jelita. Rośnie zainteresowanie płytkami krwi w aspekcie oceny stanu zaawansowania zmian zapalnych w CD. Celem pracy była odpowiedź na pytanie, czy rutynowo oznaczane w morfologii krwi parametry płytkowe: ilość płytek krwi (PLT), średnia objętość płytek krwi (MPV), płytkokryt (PCT) mogą być wskaźnikami służącymi do monitorowania przebiegu CD.
Materiał i metody. Do badań zakwalifikowano 100 pacjentów o zróżnicowanym przebiegu klinicznym, lokalizacji zmian i stosowanej terapii. U wszystkich chorych pobrano krew oraz próbki do stolca celem oznaczenia CRP, morfologii krwi oraz kalprotektyny w kale. Stan kliniczny każdego pacjenta oceniano wykorzystując wskaźnik Harvey- Bradshaw.
Wyniki. Wykazano istotnie statystyczną dodatnią korelacje pomiędzy kalprotektyną, CRP, WBC, wskaźnikiem Harvey-Bradshaw oraz ilością płytek krwi i płytkokrytem. Analiza wykazała także istotnie statystyczną ujemną korelację pomiędzy MPV i ilością WBC, CRP oraz kalprotektyną.
Wnioski. W naszym badaniu wykazano, że parametry płytkowe mogą stanowić użyteczną, nieinwazyjną i powszechnie dostępną metodę, służącą do oceny gojenia śluzówkowego i stanu klinicznego pacjenta z CD.

Tables: 6
Figures: 2
References: 25
Submitted: 2017 May 18
Accepted: 2017 Jul 12

Słowa kluczowe: choroba Leśniowskiego-Crohna, nieswoiste zapalenie jelit, płytki krwi, MPV

Padysz M, Stec-Michalska K, Banasik J, Gąsiorowska A. Platelets and the clinical course of Crohn's disease. Health Prob Civil. 2018; 12(4): 278-284. https://doi.org/10.5114/hpc.2018.78783

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Introduction

Crohn's disease (CD) is a chronic inflammatory autoimmune bowel disease (IBD), with periods of exacerbation and remission. The etiopathogenesis of the disease is complex and not fully understood. Its underlying autoimmune disorders are caused by undetermined factors leading to inflammatory processes in the intestinal mucosa. They are accompanied by abnormal blood clotting, there is a mutual interaction that triggers the mechanism of a vicious circle [1]. The key link between these processes are platelets (PLT) [2]. Hence, the question of whether the parameters of the platelets marked with standard blood count could be used as a non-invasive marker to monitor the severity of inflammation in CD. In the blood count, we can measure concentration of PLT (standard 150-400 thousand/µl), the mean platelet volume MPV (standard 7-12 fl, plateletcrit PCT-platelet volume ratio to the total (standard 0.14-0.36%), P-LCR- percentage of platelet large cell ratio over 20 fl (standard 0.2-5%), as well as the rate of variation in the volume of blood platelets, which reflects the anisocytosis PDW-platelet distribution width (reference values 6.1-11 fl PDW% 40-60%) [3].

The most commonly designated biomarkers of inflammation in CD are C- reactive protein CRP, the concentration of white blood cells (WBC) and, recently, calprotectin in feces, regarded as the most reliable marker to monitor mucosal healing [4]. Calprotectin is secreted into the extracellular space under the influence of pro-inflammatory cytokines released by neutrophils or monocytes. This protein has pro-apoptotic and bactericidal activity by the ability to bind calcium and zinc ions [5]. The value of <100 µg/g of feces is considered the norm. Its concentration in feces below 150 µg/g of stool is considered as the cut-off point of mucosal healing in IBD [6]. Calprotectin in feces is not degraded by the microflora, as it is stable and resistant to proteolysis for about seven days at room temperature and at 20 °C to approx. 3 months [7]. The aim of this study was to answer the question of whether routinely measured indices in the blood count of PLT, MPV, PCT could be used in everyday clinical practice to monitor the course of CD on the basis of an analysis of their correlation between CRP, WBC and calprotectin in feces in terms of clinical and endoscopic remission.

Material and methods

In the study programme there were enrolled 100 patients with CD, W:50/M:50 at the age of (33.5 ± 11) treated in the Department of Gastroenterology and Outpatient Clinic in Medical University of Lodz, with a different clinical course, localisation of lesions and heterogeneous therapy (Table 1).

Table 1. Characteristics of the study group patients with CD

Parameter	
Gender (Women:Men)	50:50
Age (years)	range 19-62 average 33.5±11
Localisation of intestinal lesions **L1- ileum** **L2- colon** **L3- ileum + colon** **L3+L4- L3 +upper gastrointestinal tract**	 n=20 W:11/M:9 n=25 W:12/M:13 n=51 W:25/M:26 n=4 W:2/M:2

The diagnosis of CD was determined basing on the criteria of European Crohn's and Colitis Organisation ECCO [8]. The criteria of exclusion included the lack of informed consent of the patient to participate in the study, age under 18 years and the presence of other chronic diseases. Initially, the clinical condition of each patient was evaluated using the most widely used Harvey-Bradshaw (H-B) index, the simplified scale of CDAI (Crohn's Disease Activity Index) [9]. H-B index takes into account 5 parameters of the day before the visit: general well-being, severity of abdominal pain, the number of liquid stools, abdominal mass, and associated complications. Remission is defined as <5 points, mild disease 5-7 pts, moderate disease 8-16 pts, severe disease >16 pts. This index correlates well with the results of the CDAI scale [10].

To determine the complete blood count and necessary biochemical parameters in serum, 2 mL of venous blood was collected from all patients to standard tubes containing EDTA. WBC, PLT, MPV, PCT, CRP were routinely marked (no later than 2 hours after collection). The concentration of calprotectin in feces was determined using quantitative immunochromatographic tests (QUANTUM BLUE), calibrated in the range of 100 to 1,800 µg/g (Table 2). The feces samples were stored at -20 °C.

Table 2. Mean values of platelet indices, CRP, WBC and calprotectin in the whole study group

	Platelet indices			CRP	WBC	Calprotectin
	PLT	MPV	PCT			
average± standard deviation	319.42 ±151.7	10.39 ±1.25	0.33±0.13	26.55±41.68	6.96±2.75	777.46±659.62

Abbreviations: PLT- platelets; MPV-mean platelet volume; PCT- plateletcrit; CRP- C reactive protein; WBC-white blood cells

Statistical analysis

The results were statistically analysed using Statistica software and Excel. The statistical analysis was performed using the Spearman's rank test and Mann-Whitney *U* test. In all analyses, the significance level was set at p = 0.05.

Ethics

The study was approved by the Bioethical Committee of the Medical University of Lodz.

Results

Eligible patients are characterised by age, gender and localisation of inflammatory lesions in the intestine and clinical status of CD advancement, calculating the ratio of H-B. The collected data are shown in Table 1 and Table 5.

Then, the mutual correlation between the platelet parameters: PLT, MPV, PCT and CRP, WBC, calprotectin was rated (Table 3).

Table 3. Correlation between the platelet parameters and inflammatory markers (CRP, WBC, calprotectin)

	PLT		MPV		PCT	
	R	p	R	p	R	p
Calprotectin	0.427180	0.000009	-0.365616	0.000269	0.383067	0.000127
CRP	0.486171	0.000000	-0.337453	0.000825	0.458504	0.000003
WBC	0.486070	0.000000	-0.206445	0.044727	0.499170	0.000000

Abbreviations: PLT- platelets; MPV-mean platelet volume; PCT- plateletcrit; CRP- C reactive protein; WBC-white blood cells

It indicated a statistically significant positive correlation between calprotectin, CRP and leukocytosis, and the concentration of PLT and PCT ($p < 0.05$).

With an increase of inflammatory parameters in patients with CD (CRP, leukocytosis, fecal calprotectin) a significant increase is visible in serum concentrations of the PLT and PCT indices.

The graphical relationship between the concentration of calprotectin in feces and the concentration of PLT is shown in Figure 1.

It was decided to present graphically only the correlation between fecal and platelet parameters because it is of the highest diagnostic value in the assessment of mucosal healing in CD.

There was a negative correlation between MPV and CRP, WBC and calprotectin (Table 3), which might indicate that, with the increase of inflammatory parameters, MPV is decreased ($p < 0.05$).

Another parameter subjected to analysis was the H-B index in correlation with platelet parameters and calprotectin. There was a significant statistical correlation between H-B index and the number of platelets ($p < 0.05$; $r = 0.37$) and PCT ($p < 0.05$; $r = 0.32$). In addition, there was a positive correlation between the H-B index and the concentration of calprotectin in feces ($p < 0.0001$, $r = 0.41$). In MPV, no significant relationship between the H-B index and calprotectin was observed, although there was noted an inversely proportional trend (Table 4).

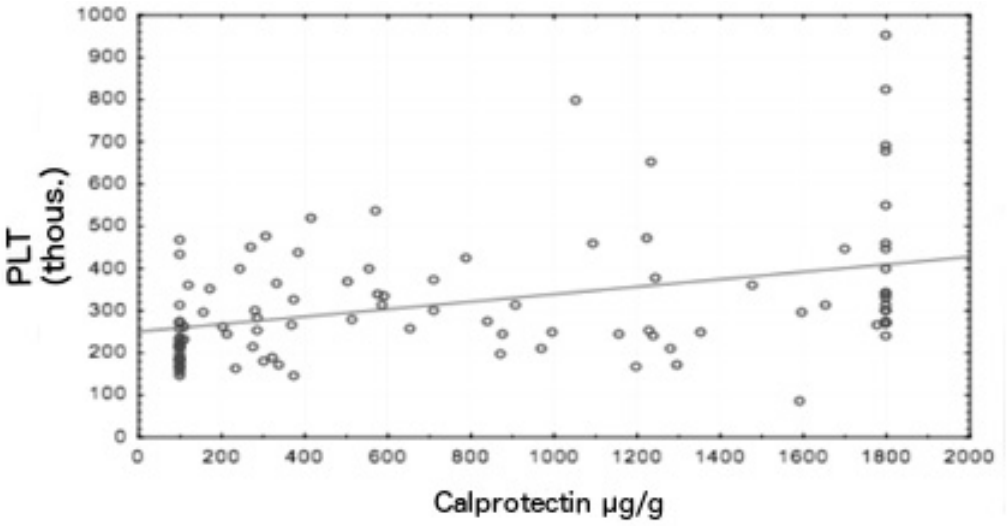

Figure 1. The correlation between the number of platelets (PLT) and the concentration of calprotectin in faeces of patients with CD

Table 4. Harvey-Bradshaw index correlation with platelet parameters and calprotectin

	Harvey-Bradshaw index	
	R	**P**
PLT	0.375609	0.000118
MPV	-1.152324	0.140580
PCT	0.319018	0.001627
Calprotectin	0.414463	0.000018

Abbreviations: PLT- platelets; MPV-mean platelet volume; PCT- plateletcrit

From a clinical point of view, there is an interesting relationship between platelet parameters and the clinical and mucosal severity of CD. Thus, there was analysed the relationship between the concentration of calprotectin in feces, platelet parameters in patients in clinical remission (H-B index <5 pts) and in the period of exacerbation (H-B index -5-16 pts). Among the enrolled patients there were selected: 31 persons during clinical remission and 69 during clinical exacerbation of the disease. In patients with clinical exacerbation of CD (H-B ratio greater than 5 pts), there are significantly higher values of calprotectin, PLT, PCT ($p < 0.05$), with no statistical significance in relation to the MPV (Table 5).

Table 5. Comparison of average values of calprotectin in feces and platelet parameters in patients in clinical remission (H-B index <5 points) and in the period of exacerbation (H-B index -5-16 points)

	H-B index <5 points. n = 31 average ± standard deviation	**H-B index 5-16 points n=69 average ± standard deviation**	**p**
Calprotectin	481.3 ±512.5	910.5 ±678.0	0.019
PLT	259.7 ±106.6	346.2 ±161.7	0.0008
MPV	10.5±1.1	10.4 ±1.3	0.4424
PCT	0.27±0.10	0.35 ±0.13	0.0064

Abbreviations: PLT- platelets; MPV-mean platelet volume; PCT- plateletcrit

Then, the obtained results were analysed for their suitability assessment of blood platelet parameters in the context of mucosal healing taking into account the concentration of calprotectin in feces. The examined patients were divided into two groups: 26 patients in remission (concentration of calprotectin in the feces ≤150 µg/g) and 74 patients with active inflammatory lesions in the intestinal wall (calprotectin in the feces >150 µg/g), irrespective of disease activity in the H-B scale. The obtained results are shown in Table 6.

Table 6. Comparison of average values of platelet parameters in patients in remission (concentration of calprotectin in the feces ≤ 150 μg/g) and in patients with active disease (calprotectin in the feces> 150 μg/g)

	The concentration of calprotectin		
	≤ 150 ug/g n=26 average ± standard deviation	**>150 ug/g n=74 average ± standard deviation**	**p**
PLT	237.0±80.1	348.4±160.5	0.0000
MPV	10.9±1.1	10.2±1.3	0.0051
PCT	0.26±0.09	0.35±0.13	0.0001

Abbreviations: PLT- platelets; MPV-mean platelet volume; PCT- plateletcrit

Average values of PLT and PCT are significantly statistically higher ($p < 0.05$) in patients with active mucosal lesions compared to those in remission (calprotectin <150 μg/g of fecal), while platelet volume is significantly decreased - MPV ($p < 0.05$).

This means that a comparative analysis of the concentration of PLT, MPV and PCT in patients with CD from routinely carried out complete blood cell count provide valuable information relating to inflammatory lesions in the intestinal wall.

Discussion

Intensive research on the participation of PLT in inflammatory processes and its impact on the immune system is being carried out [11]. PLT secrete proteins directly combating bacteria called PMP (platelet microbicidal proteins) and active forms of oxygen. Releasing chemokines affect the anti-inflammatory activity of leukocytes [12].

Besides, it is now known that the severity of inflammation in IBD is accompanied by an increase in the concentration of PLT and morphology disorders [2]. The earliest observations were made already in 1968, when the presence of thrombocytosis in the active phase of IBD was documented [13]. Subsequent reports confirmed a positive correlation between the clinical activity of the disease and the number of blood platelets [14]. Our study confirmed a positive correlation between the number of platelets in the serum and the severity of the clinical condition (index H-B) (Table 4) and the healing of the mucous membranes on the basis of the concentration of calprotectin in feces (Tables 3, 5). Some researchers propose using thrombocytosis in the differential diagnosis of IBD and infectious diarrhea [15].

The IBD platelets circulate in the state of excessive activity; they tend to aggregate due to coagulation factors. During in vitro studies in patients with IBD, there was noticed a trend for spontaneous activation of PLT in more than 30%, regardless of the severity of the disease [16]. It is believed that excessive activation of thrombocytes is a specific feature of IBD [17]. Selective P-glycoprotein (platelet-leukocyte aggregates) belonging to adhesion molecules is expressed on activated platelets and stimulates the formation of aggregates of platelets and leukocytes. It has been shown that it significantly increases the concentration of PLAs in patients with IBD. Accordingly, there is a beneficial effect of azathioprine's used in the treatment of IBD, as it lowers the PLAs inhibiting the phosphorylation of adenosine [18].

Most interest in the determined parameters of blood platelets was aroused by MPV [19, 20]. The released inflammatory mediators stimulate the bone marrow to produce more PLT at the expense of its maturation time, as there are released fewer platelets. At the same time, more and more active PLT are consumed in inflammation.

In our study, patients with CD revealed that the higher the concentration of calprotectin and CRP, the significantly lower MPV ($p < 0.05$) (Table 3, Figure 2).

We have obtained interesting data in the comparative analysis of MPV value in patients with the concentration of calprotectin in feces above and below 150 μg/g of the feces. The value of MPV in patients with severe mucosal lesions is lower than in those in the period of mucosa remission ($p < 0.05$) (Table 6). There are reports suggesting that the decline in the value of MPV in CD may be a useful marker for predicting the loss of response to infliximab therapy [21]. Hence, MPV monitoring could affect the treatment modification. The more so that the present study showed no significant correlation between MPV and the clinical activity of the disease by the Harvey Bradshaw index (Tables 4, 5).

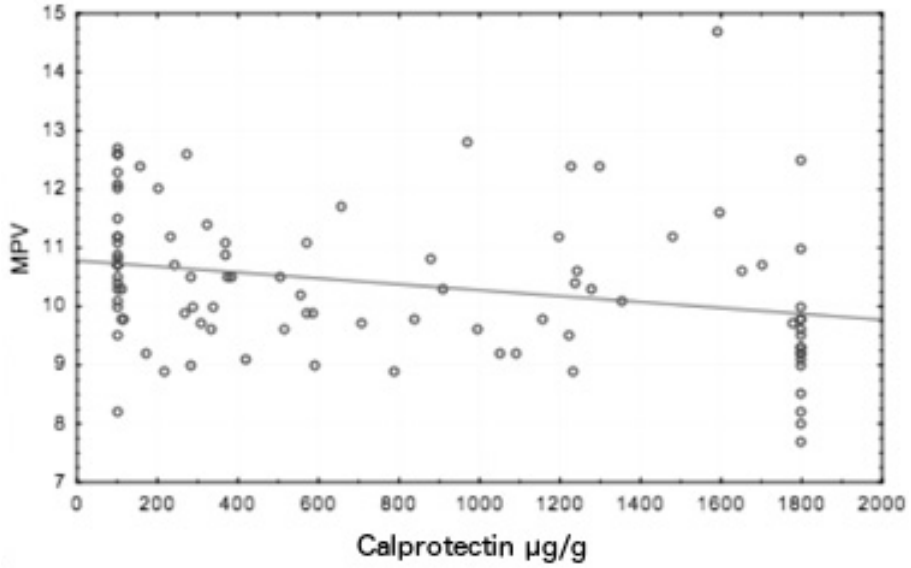

Figure 2. Graph showing the correlation between the values of MPV and the concentration of calprotectin in the faeces of patients with CD.

Some reports identified an increased expression in active platelets of CD40 ligand protein, which plays a key role in the release of pro-inflammatory cytokines [22]. The increased expression was found in biopsies taken at the inflamed mucosa of the ileum or colon of patients with CD and colitis ulcerosa [23, 24]. Therefore, it has been suggested that these patients are administered low molecular weight heparin during exacerbation requiring hospitalisation [25].

The increase in the total volume of the platelet in inflammation reflects PCT. In our study, we have shown a positive correlation between the growth parameters of inflammation (calprotectin, CRP, WBC) and PCT (Table 3). Moreover, we have observed a similar relationship with regard to the clinical condition of the patients.

Conclusions

The analysis of the platelet parameters contained in the blood counts routinely performed in patients with CD could become a valuable non-invasive, inexpensive and widely accessible method to assess mucosal healing and the clinical status of the patient.

The observed increase in PLT, PCT and MPV reduction can be helpful in decision-making used to expand laboratory diagnostics and imaging, and thus optimising the therapy. There is a further need for research into the role of platelets in the pathogenesis of CD conducted on a large population of patients.

Acknowledgements

This work was supported by a grant No. 502-03 / 5-006-02 / 502-54-074 from Medical University of Lodz.

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ORIGINAL PAPER
ORYGINALNY ARTYKUŁ NAUKOWY

Health Prob Civil. 2018, Volume 12, Issue 4
ISSN 2353-6942

INFLUENCE OF UV-C RADIATION ON THE MICROBIOLOGICAL PURITY IN SELECTED SPECIES OF HERBS

WPŁYW PROMIENIOWANIA UV-C NA CZYSTOŚĆ MIKROBIOLOGICZNĄ WYBRANYCH GATUNKÓW ZIÓŁ

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Authors' contribution
Wkład autorów:
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zaplanowanie badań
B. Data collection/entry
zebranie danych
C. Data analysis/statistics
dane – analiza i statystyki
D. Data interpretation
interpretacja danych
E. Preparation of manuscript
przygotowanie artykułu
F. Literature analysis/search
wyszukiwanie i analiza literatury
G. Funds collection
zebranie funduszy

Summary

Background. Herbs are used in both the food and pharmaceutical industry. The quality of products received from herbal raw materials depends primarily on the microbiological purity of herbs. The presence of germs in food products contributes to developing alimentary infections and to the contamination of food with mycotoxins. Decontamination with ultraviolet UV-C rays is a proven way to enhance the microbiological purity of food products as radiation directly affects the structure of the nucleic acid of living organisms and destroys them without selective biocidal activity. The aim of the study was to determine the microbiological purity of selected species of herbs and assess the possibility of using UV-C radiation to increase it.
Material and methods. The scope of work included the separation of three dimensional fractions of dried herbs such as thyme, medical cistus and stinging nettle, and then subjecting them to UV-C light and determining the total number of germs in the herbs with respect to the control sample, which consisted of untreated herbs.
Results. The tested herbs were characterised by diversified microbiological purity, depending on the species and a type of size fraction. Sterilisation of herbs with UV-C radiations allowed for increasing their microbiological purity as compared to the control sample, in the case of the fraction with the largest particle size by about 37% – thyme, 73% – cistus and 30% – nettle.
Conclusions. The use of UV-C radiation allowed for considerable reduction of the number of germs found in the examined herbs.

Keywords: UV-C sterilization, microbiological purity, thyme, medical cistus, stinging nettle

Streszczenie

Wprowadzenie. Zioła znajdują zastosowanie zarówno w przemyśle spożywczym jak i farmaceutycznym. Jakość produktów otrzymywanych z surowców zielarskich zależy przede wszystkim od czystości mikrobiologicznej ziół. Obecność drobnoustrojów w produktach żywnościowych przyczynia się do powstawania infekcji pokarmowych oraz skażenia mikotoksynami. Dekontaminacja przy pomocy promieni ultrafioletowych UV-C stanowi sprawdzony sposób zwiększenia czystości mikrobiologicznej produktów spożywczych, gdyż promieniowanie to bezpośrednio wpływa na strukturę kwasów nukleinowych organizmów żywych i niszczy je, przy czym nie wykazuje wybiórczej aktywności biobójczej. Celem pracy było określenie czystości mikrobiologicznej wybranych gatunków ziół i ocena możliwości wykorzystania promieniowania UV-C do jej zwiększenia.
Materiał i metody. Zakres pracy obejmował rozdzielenie na trzy frakcje wymiarowe suszonych ziół takich jak tymianek pospolity, czystek lekarski i pokrzywa zwyczajna, a następnie poddanie ich działaniu promieni UV-C i określenie ogólnej liczby drobnoustrojów w ziołach w odniesieniu do próby kontrolnej, którą stanowiły zioła nie poddane obróbce.
Wyniki. Badane zioła charakteryzowały się zróżnicowaną czystością mikrobiologiczną zależną od ich gatunku oraz rodzaju frakcji wymiarowej. Sterylizacja ziół promieniami UV-C umożliwiła zwiększenie ich czystości mikrobiologicznej w stosunku do próby kontrolnej, w przypadku frakcji o największym wymiarze cząstek odpowiednio o około 37%- tymianek pospolity, 73%- czystek lekarski i o 30%- pokrzywa zwyczajna.
Wnioski. Zastosowanie promieniowania UV-C pozwoliło w znaczący sposób zmniejszyć ilość drobnoustrojów obecnych w badanych ziołach.

Słowa kluczowe: sterylizacja UV-C, czystość mikrobiologiczna, tymianek pospolity, czystek lekarski, pokrzywa zwyczajna

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Figures: 1
References: 26
Submitted: 2016 Dec 28
Accepted: 2017 Jan 05

Kozak-Kalita MJ, Sobczak P, Zawiślak K, Mazur J, Panasiewicz M, Żukiewicz-Sobczak WA. Influence of UV-C radiation on the microbiological purity in selected species of herbs. Health Prob Civil. 2018; 12(4): 285-290. https://doi.org/10.5114/hpc.2018.77838

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Introduction

Herbal raw materials are widely used in the food, pharmaceutical and cosmetic industries. Herbs can be used in the form of dried, whole or ground/shredded plant parts, their blends, essential oils, herbal extracts, or microcapsules. Because of their characteristic aromatic and preservative properties, they are used as natural agents for extending the shelf life of food and as spices [1, 2]. Herbs and herbal preparations are used in therapies assisting conventional medicine and are also components of food products belonging to the group of functional foods. Health-improving properties of herbal raw materials stem from the presence of biologically active compounds, including glycosides, flavonoids, alkaloids and essential oils. Herbs can, however, be significantly contaminated by diverse microflora [3-5].

Dried herbs have a low water content, which hinders the growth of germs and occurrence of undesirable chemical reactions. However, despite the presence of antibiotic substances and moisture content, which is unfavourable for most germs, they can be colonised by generically and quantitatively diversified microflora. The microbiological quality of herbs mainly depends on the part of the plant which yields raw herbal material, because the level of microbiological contamination results from the varying degree of contact between parts of the plant and the external environment during cultivation (primary factors), as well as their susceptibility to reinfection during further processing, storage or transport (secondary factors) [6-10]. Contamination of herbs with microorganisms can cause changes in their sensory characteristics, chemical composition, and also pose a danger for the health of consumers, because of the possible occurrence of mycotoxins and pathogens. As demonstrated by literature data, the degree of herb infection can be very high and the overall quantity of microorganisms in certain types of herbal raw materials can reach 10^8CFU/g. The recommendations published in the Polish quality norms impose increasingly higher restrictions on the degree of microbiological contamination in herbs. These requirements include both the recommended and warning indicators pertaining to specific groups of microorganisms [8, 10-12].

Microbiological quality of herbal raw materials can be increased by providing adequate hygiene and sanitary conditions in the course of drying and grinding or shredding processes, as well as by storing them at the appropriate temperature. High microbiological contamination of herbal raw materials necessitates their decontamination. In addition to the well-known and long used methods such as e.g.: high temperature or chemical agents, a new and rapidly developing method of increasing product safety is provided by sterilization with UV-C radiation [13-15].

Sterilisation with ultraviolet UV radiation allows one to quickly and effectively neutralise microorganisms. UV radiation occurs naturally in nature as part of the solar light spectrum. The wavelength, intensity of its operation and distance from the source affects the properties of ultraviolet radiation. Sterilisation is conducted using high - energy UV-C rays and consist in treating microorganism cells with short 210-328 nm wavelength radiation which is lethal for microbes. UV-C radiation directly impacts the structure of nucleic acids in microorganisms and, as evidenced by tests, the most effective wavelength for inactivating microbes is the radiation band of 254 nm. UV-C rays tear apart the links of DNA and RNA chains, thus destroying bacteria, fungi, moulds and other microorganisms. Moreover, UV-C rays cause denaturation of proteins in living organisms and inhibit the formation of suboxides and free radicals, which are also toxic to the cell [16].

At the beginning, the UV-C technology was only used in medicine to disinfect surgical instruments, but now it is also increasingly often applied in the food industry. It is a good solution in the case of products which cannot be treated with high temperatures. UV-C radiation would also work in conditions where humidity is increased, which encourages the reproduction of microorganisms in the air, on the machinery and equipment, as well as on the processed raw materials. Sterilisation with UV radiation is completely safe for humans. Moreover, its use provides additional protection for workers against microorganisms without negative impact on the environment. UV-C also allows for the reduction of unpleasant odours and extends the shelf life of food products [17, 18].

Appropriate selection of the irradiation dose allows for rapid elimination of more than 99% of harmful microorganisms, preventing them from reproducing, while ensuring a high level of safety for people and extension of the produced food durability. What is important, UV-C radiation does not show selective biocidal activity [16].

The aim of the study was to determine the microbiological purity of selected species of herbs and assess the possibility of using UV-C radiation to increase its degree. The scope of studies included exposure of dried herbs to UV-C rays in the sterilisation chamber for granular or ground/shredded materials (patent No W.125446) and quantitative indication of their microbiological purity as compared to the control sample.

Material and methods

The research material comprised the following three types of dried herbs, sourced from herb processing plants located in Lublin Voivodeship, such as thyme *(Thymus vulgaris)*, Cistus (*Cistus ladaniferus*) and stinging nettle *(Urtica dioica L.)*. Using a laboratory AS 200 Retsch vibratory sieve shaker, raw materials were evaluated for granulometric size composition in accordance with the PN-R-64798:2009P norm, which enabled them to determine the average particle size and the degree of fragmentation. For this purpose, seven sieves with mesh size of 0.1 mm, 0.2 mm, 0.5 mm, 1 mm, 2 mm, 3.15 mm, 4 mm were applied. Then, the herbs were separated into three fractions with a particle size of <1 mm, 1-2 mm> 2 mm. The moisture content of particular herbs was estimated in accordance with the applicable standard (ISO 6496: 2002) [19] with the oven-drying method (t=105°C).

Dried herbs were sterilised with UV-C radiation in a sterilising chamber for granulated materials. The control sample comprised raw materials which had not undergone treatment. The device, in which herbs were sterilized has an air-tight housing with internal UV radiators, equipped with a power and control system with an irradiation time setting control, as well as a rack for the input material. In order to carry out sterilisation, a sample weighing 1 g was sourced and spread in a thin layer in the container for this material and then it was exposed to UV-C radiation for 60, 120 and 180 s. The container with the material was located at a distance of 20 mm from the UV lamp [20].

The quantitative determination of the microbiological purity of the dried herb was performed by using the plate method in accordance with the standard (BS EN ISO 4833:2004). The measurement was based on weighing a sample of 0.5 g and then transferring it to a 50 ml sterile Falcon tube and filling it up with distilled water. Then, the sample was inoculated onto a plate with a standardised medium - agar and incubated at 32° C for 48 hours. After this time had expired the total number of microorganisms was counted [21]. The research was conducted at the Research Centres (EAT, CBNI) at the Pope John Paul II State School of Higher Education in Biała Podlaska. Sterilization and determination of the microbiological purity for each of the examined herb fractions was performed in three repetitions. The number of microorganisms was expressed as the colony forming units in 1 g of product (CFU g^{-1}) and transposed into a logarithmic form (log CFU g^{-1}).

Results and discussion

The research was conducted in accordance with the developed methodology. Table 1 shows the results of measuring the fragmentation of the dried herbs and in Figure 1 their sieve analysis is shown, which helped in determining the average particle size of the tested raw materials.

Table 1. Level of dried herbs fragmentation

Raw material type	Level of fragmentation
Thymus vulgaris	1.045 ± 0.0133
Cistus	1.876 ± 0.0346
Urtica	0.8915 ± 0.0711

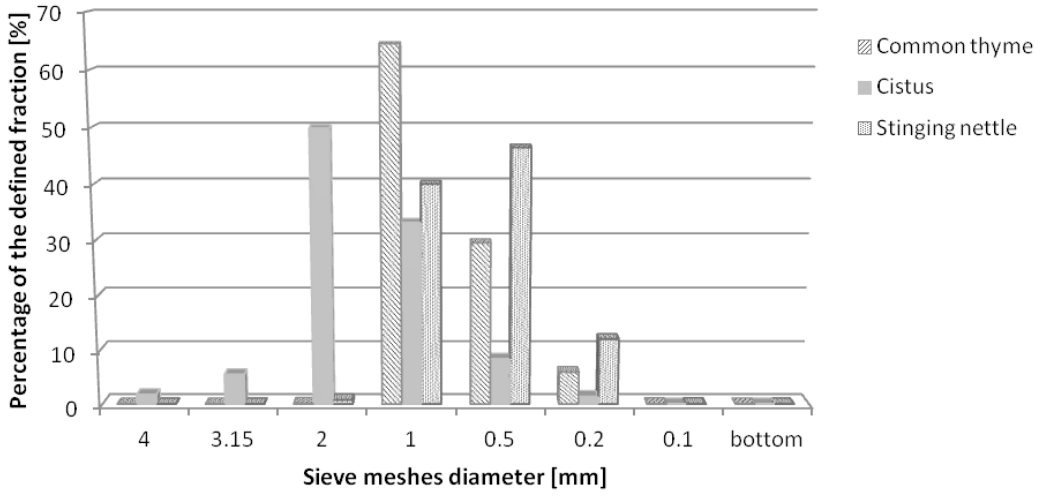

Figure 1. Sieve analysis of dried herbs – percentage participation of fraction on the sieves

Dried herbs were characterised by varying degrees of fragmentation. The stinging nettle was the most fragmented, and the cistus had the largest particle size. The sieve analysis showed the common thyme to have more than 64% share in the <1 mm fraction, the cistus almost 50% share in the <2 mm fraction and the stinging nettle more than 46% share in the <0.5 mm fraction. In the tested herbs, there did not occur fractions with a particle size below 0.2 mm.

The measurement results of the moisture content of dried herbs are presented in Table 2.

Table 2. Moisture content of dried herbs depending on the fraction size

Raw material type	Fraction size [mm]	Moisture content [%]
Thymus vulgaris	< 1	8.74 ± 0.62
	1 – 2	8.40 ± 0.52
	> 2	7.96 ± 1.31
Cistus	< 1	10.06 ± 0.27
	1 – 2	9.88 ± 0.17
	> 2	9.06 ± 1.43
Stinging nettle	< 1	9.44 ± 1.21
	1 – 2	9.13 ± 0.70
	> 2	9.93 ± 0.26

The tested herbal materials have similar moisture content of less than 14%, which prevents the growth of mould [9]. The lowest moisture content is characteristic of thyme, and the highest one of cistus. Herb fractions with a particle size > 2 mm have lower moisture content compared to the finer fractions.

Table 3 shows the results of microbiological purity of the dried herbs, depending on their particle size and the duration of sterilization.

Table 3. Microbiological purity of dried herbs depending on the size fraction and the sterilization time

Raw material type	Fraction size [mm]	Sterilisation time [s]	Total number of microorganisms [CFU · g^{-1}]
Thymus vulgaris	< 1	0	UNC
		60	490
		120	388
		180	220
	1-2	0	UNC
		60	240
		120	250
		180	200
	> 2	0	400
		60	350
		120	264
		180	250
Cistus	< 1	0	UNC
		60	150
		120	200
		180	150
	1-2	0	250
		60	214
		120	210
		180	180
	> 2	0	300
		60	265
		120	200
		180	80

Raw material type	Fraction size [mm]	Sterilisation time [s]	Total number of microorganisms [CFU · g^{-1}]
Urtica dioica	< 1	0	UNC + yeast
		60	Npl
		120	Npl
		180	400
	1-2	0	UNC + yeast
		60	380
		120	350
		180	350
	> 2	0	UNC
		60	400
		120	350
		180	350

UNC (the uncountable colonies) > 500 CFU

The tested herbs were characterized by varying degrees of contamination, depending on the plant species and degree of fragmentation. The greatest number of microorganisms was determined in the smallest fractions of herbs – above 500 CFU (> 2.70 log CFU g^{-1}).

The stinging nettle was characterized by a much higher degree of microbial contamination in comparison with other herb genera, which is associated with a different way of harvesting herbal raw materials in each case. In addition, research has shown the presence of yeast in stinging nettle fractions, with a particle size of <1 and 1-2 mm. The cistus and thyme were harvested on plantations, but the stinging nettle was obtained from natural stands, which could cause a reduction in the quality of the material obtained, because it was exposed to herbicides or cultivation treatments [22, 23].

The use of UV-C sterilisation allowed for reducing the number of microorganisms and removing the yeast present in herbs, when compared with the control sample. Extending the time of UV-C radiation operating on the studied herbs resulted in a significant reduction of the number of microorganisms present in all fractions of herbal raw materials. For example, in the case of the herbs with the greatest particle size, from 2.60 to 2.40 log CFU g^{-1} for thyme, from 2.48 to 1.90 log CFU g^{-1} for the cistus and above and 2.70 to 2.54 log CFU g^{-1} for stinging nettle.

The results of the analyses performed by Wójcik-Stopczyńska et al. (2009) on the evaluation of microbiological purity of dried herbs offered on the Polish market by different manufacturers were similar. Research has shown that the total number of microorganisms in raw herbal material ranged from 1.76 to 6.19 log CFU g^{-1} depending on the species of the raw material [24]. Similar results were obtained by Aguilera et al. (2005), who, while studying the dried herb, marked the total micro-organism content from<1.0 to 6.0 log CFU · g^{-1} [25]. However, the studies of other authors indicate that in dried spices and herbs, the total number of bacteria reaches a higher level (106-108 CFU · g^{-1}) [12, 26].

The comparison of the obtained results of research with the Polish standards (Farmakopea) and the guidelines of the International Commission on Microbiological Specifications for Foods (ICMSF) indicates that all the herbs investigated in this work are characterised by acceptable microbiological contamination (10^{7}CFU· g^{-1} or mL) [8, 26].

Conclusions

1. The smallest particle size was found in the stinging nettle, while the cistus had the largest particles.
2. The moisture content of the studied herbal raw materials is below 14%, which protects them from moulds.
3. Dried herbs showed diverse microbiological purity, where the cistus was the least contaminated one and the nettle had the finest particle size fraction, which may stem from a different way of harvesting these herbs.
4. Sterilisation by irradiation with UV-C for 3 minutes allows for a considerable reduction of the number of microorganisms present in herbs, in comparison with the control sample.
5. The use of a new device for UV-C sterilisation of granulated and finely fragmented materials can increase the microbiological purity of herbs, but one must perform further studies with extended duration of their sterilisation.

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- W oryginalnych artykułach naukowych i artykułach przeglądowych, 4400 słów, łącznie z tabelami i bibliografią – ok. 20 stron, napisanych komputerowo, z podwójnym odstępem, z czcionką 11 pkt i 30 pozycjami literatury,
- W studiach przypadków, 1000 słów, łącznie z tabelami i bibliografią – ok. 7 stron, napisanych komputerowo, z podwójnym odstępem, z czcionką 11 pkt i z 10 pozycjami literatury;
- W artykułach od redakcji, 1500 słów wyłączając spis literatury – ok. 10 stron, z podwójnym odstępem, z czcionką 11 punktów, 15 pozycjami literatury, bez streszczenia i słów kluczowych; tabele i ryciny mogą być dołączone, artykuł może zawierać podział na sekcje;
- W recenzjach książek – 750 słów, bez podziału na sekcje, bez słów kluczowych i streszczenia.

Artykuły przekraczające wymaganą długość lub liczbę pozycji literatury będą rozstrzygane w drodze indywidualnej decyzji Redaktora Naczelnego.

Oryginalne artykuły naukowe powinny zawierać następujące elementy:

- Tytuł (w j. polskim i j. angielskim)
- Słowa kluczowe (z Medical Subject Headings [MeSH], katalog Index Medicus; w j. polskim i j. angielskim)
- Streszczenie (150-250 słów, w j. polskim i j. angielskim, podzielone na części)
- Wprowadzenie
- Materiał i metody
- Wyniki
- Dyskusja
- Wnioski
- Ujawnienia i uznania
- Bibliografia

Studia przypadków powinny zawierać następujące elementy:

- Tytuł (w j. polskim i j. angielskim)

- Słowa kluczowe (z Medical Subject Headings [MeSH], katalog Index Medicus; w j. polskim i j. angielskim)
- Streszczenie (150-200 słów, w j. polskim i w j. angielskim, podzielone na części)
- Wstęp
- Opis przypadku
- Wnioski
- Bibliografia

Artykuły przeglądowe powinny zawierać następujące elementy:

- Tytuł (w j. polskim i j. angielskim)
- Słowa kluczowe (z Medical Subject Headings [MeSH], katalog Index Medicus; w j. polskim i j. angielskim)
- Streszczenie (150-250 słów, w j. polskim i j. angielskim)
- Wstęp
- Cel pracy
- Krótki opis stanu wiedzy
- Wnioski
- Bibliografia

Tabele

Tabele powinny być ponumerowane zgodnie z ich kolejnością w tekście. Tekst powinien zawierać odniesienia do tabel.

Każda tabela powinna być przesłana w osobnym pliku.

Ilustracje

Każdy rysunek powinien być wysłany w osobnym pliku, nie zawartym w tekście.

Obrazki najlepiej przesłać w formacie TIF lub EPS. Format JPG jest także dozwolony.

Wszystkie obrazki, zarówno fotografie, wykresy, jak i diagramy, powinny być ponumerowane kolejno, zgodnie z pojawieniem się w tekście.

Cytaty i bibliografia

Pozycje literatury powinny być cytowane w nawiasach kwadratowych w kolejności cytowania.

Bibliografia powinna być ułożona w kolejności cytowania w tekście. Jeżeli liczba autorów przekracza 6, po 6 nazwisku należy dopisać „et al.".

Cytowanie czasopisma:

Tomao P, Ciceroni L, D'Ovidio MC, De Rosa M, Vonesch N, Iavicoli S, et al. Prevalence and incidence of antibodies to Borrelia burgdorferi and to tick-borne encephalitis virus in agricultural and forestry workers from Tuscany, Italy. Eur J Clin Microbiol Infect Dis. 2005; 24(7): 457–463.

Czasopismo – suplement:

Zajkowska J. Lyme borreliosis – guidelines of treatment and expectations of patients. Przegl Epidemiol. 2008; 62(Suppl.1): 142–151 (po polsku).

Tom czasopisma z numerem części:

Abend SM, Kulish N. The psychoanalytic method from an epistemological viewpoint. Int J Psychoanal. 2002;83(Pt 2):491-5.

Cytat z czasopisma online:

Zhang M, Holman CD, Price SD, Sanfilippo FM, Preen DB, Bulsara MK. Comorbidity and repeat admission to hospital for adverse drug reactions in older adults: retrospective cohort study. BMJ. 2009 Jan 7;338:a2752. doi: 10.1136/bmj.a2752.

Publikacja elektroniczna przed drukowaną:

Yu WM, Hawley TS, Hawley RG, Qu CK. Immortalization of yolk sac-derived precursor cells. Blood. 2002 Nov 15;100(10):3828-31. Epub 2002 Jul 5.

Książka:

Biernat E. Aktywność fizyczna mieszkańców Warszawy. Na przykładzie wybranych grup zawodowych. Warszawa: Oficyna Wydawnicza SGH; 2011 (in Polish).

Rozdział z książki:

Piątkowska M. Uczestnictwo Polaków w aktywności fizycznej w porównaniu do innych krajów Unii Europejskiej. In: Buśko K, Charzewska J, Kaczanowski K., editors. Współczesne metody badań aktywności, sprawności i wydolności fizycznej człowieka. Warszawa: Akademia Wychowania Fizycznego w Warszawie; 2010. p. 38-57 (in Polish).

Zapowiedzi/w druku:

Tian D, Araki H, Stahl E, Bergelson J, Kreitman M. Signature of balancing selection in Arabidopsis. Proc Natl Acad Sci U S A. Forthcoming 2002.

Materiały opublikowane online nieposiadające numeru DOI:

Abood S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. Am J Nurs [Internet]. 2002 Jun [cited 2002 Aug 12]; 102(6): [about 1 p.]. Available from: http://www.nursingworld.org/AJN/2002/june/Wawatch.htmArticle

Proces recenzji

Zarejestrowane manuskrypty są przesyłane do 2-3 niezależnych ekspertów do oceny naukowej. Przesłane artykuły są akceptowane do publikacji po otrzymaniu pozytywnej opinii niezależnych recenzentów. „Health Problems of Civilization" prowadzi proces recenzji „double-blind", w którym autorzy nie znają tożsamości recenzentów, a recenzenci – tożsamości autorów. Proces oceny zajmuje zazwyczaj 2-4 miesiące.

Obowiązki i odpowiedzialność autorów

Autor jest zobowiązany do przygotowania i przesłania artykułu zgodnie z wymogami ustanowionymi przez redakcję czasopisma. Ponadto, autor powinien dołączyć oświadczenie, które zawiera: oświadczenie o oryginalności artykułu (artykuł niepublikowany dotąd nigdzie indziej), integralność praw autorskich innych osób, brak konfliktu interesów, jak również zgodę na publikację artykułu w czasopiśmie. Autorzy są obowiązani do ujawnienia wszelkich finansowych lub osobowych powiązań, które mogą spowodować stronniczość w odniesieniu do ich pracy.

Obowiązki i odpowiedzialność recenzentów

Artykuły są wybierane do publikacji w drodze systemu podwójnej ślepej selekcji i publikowane w trybie open access. Recenzenci obowiązani są do oceny artykułu poprzez panel redakcyjny, bazując na przygotowanych pytaniach. Recenzent ma również możliwość przesyłania oddzielnych komentarzy umieszczonych w tekście artykułu

Obowiązki i odpowiedzialność redaktorów

Redaktorzy decydują, które artykuły powinny być zaakceptowane do publikacji. Redaktorzy wypełniają swoje obowiązki w sposób wyważony, obiektywny i sprawiedliwy, unikając dyskryminacji ze względu na płeć, orientację, religijne bądź polityczne poglądy, pochodzenie etniczne lub geograficzne autorów.

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