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Criteria for Diagnosis and Evaluation of Frailty Syndrome

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Abstract: Frailty syndrome is defined as a progressive state of reducing the body's physiological reserves with age and is characterized by an in-

creased susceptibility to sudden, disproportionate deterioration in functioning, after which it is impossible to return to previous fitness and independence. The typical clinical symptoms of this syndrome include generalized weakness, decreased strength and muscle mass, deterioration of exertion tolerance, slowing of movement, loss of balance, deterioration of cognitive functions, weight loss or malnutrition. Frailty syndrome worsens the prognosis for seniors, increases the risk of reduced physical and/or mental performance, dependence on others, may cause hospitalization, lead to postoperative complications, social withdrawal, and ultimately premature death. Among the most important interventions in the prevention and treatment of frailty syndrome is regular and thoughtfully planned physical activity. The incidence of frailty syndrome increases with age – it affects from 2%–5% of respondents aged 18–34, and in people over 65, it ranges from 4%–59%. Based on research conducted in Poland, it is estimated that frailty syndrome affects 6.7% of the elderly, including 30% of people aged 75–80 and 50% of people over 80 years of age. Most often, frailty is diagnosed based on an interview and physical examination. An important issue in its identification is the lack of unambiguous diagnostic criteria for evaluating the syndrome. The most common tool for evaluating the frailty syndrome in the context of physical limitations are the criteria developed by Linda Fried, introduced and described based on the analysis of the Cardiovascular Health Study clinical trials.

Key words: frailty syndrome, frailty syndrome risk factors, frailty syndrome evaluation

Preface

As the elderly population continues to grow within the society, the likelihood of frailty syndrome, which may be characterized by an increased susceptibility to the acceleration of the ageing process, increases significantly. The typical clinical symptoms of this syndrome include generalized weakness, decreased strength and muscle mass, deterioration of exertion tolerance, slowing of movement, loss of balance, deterioration of cognitive functions, weight loss or malnutrition.

Frailty syndrome is defined as a progressive state of reducing the body's physiological reserves with age and is characterized by an increased susceptibility to sudden, disproportionate deterioration in functioning, after which it is impossible to return to previous fitness and independence. The incidence of the frailty syndrome increases with age – it affects from 2%–5% of respondents aged 18–34, and in people over 65, it ranges from 4%–59%.

Factors resulting from the progression of the ageing process and those related to the occurrence of chronic diseases and psychosocial factors contribute to the manifestation of the symptoms of this syndrome. So far, no universal scale has been established that would serve as the only one for diagnosing this syndrome. Most often, frailty is diagnosed based on an interview and physical examination.

Introduction

A common phenomenon currently observed in Poland and globally is an increase in the elderly population. This trend directly influences the profile of patients undergoing rehabilitation. Increasingly, physiotherapy is used for the elderly, who have chronic diseases and difficulties in performing basic everyday activities [1].

According to the definition, ageing is a progressive reduction in the body's physiological reserves, limiting its functional capacity as a result of the accumulation of senile changes that impair the function of organs and systems [1].

Although the progression of ageing is inevitable, the pace of ageing varies, including physical, mental, and/or social functioning changes. The United Nations assume 65 years of age as the beginning of old age, and the World Health Organization (WHO) assumes 60 years of age [2].

As the elderly population continues to grow in society, the likelihood of frailty syndrome, which may be characterized by an increased susceptibility to the acceleration of the ageing process, increases significantly. The typical clinical symptoms of this syndrome include: generalized weakness, decreased strength and muscle mass, deterioration of ex-

ertion tolerance, slowing of movement, loss of balance, deterioration of cognitive functions, weight loss or malnutrition [3, 4].

Frailty syndrome worsens the prognosis for seniors, increases the risk of reduced physical and/or mental performance, dependence on others, may cause hospitalization, lead to postoperative complications, social withdrawal and ultimately premature death [5].

Early detection of frailty or symptoms that predispose the occurrence of the syndrome is important to prevent the progression of the changes. Among the most important interventions in the prevention and treatment of frailty syndrome is regular and properly planned physical activity [6].

Physical exercises have a beneficial effect on the functioning of the elderly. They can help to improve balance and coordination, increase walking speed, muscle strength and range of motion, thus reducing the risk of a fall. Moreover, they positively affect the mental state – they prevent the occurrence of depression and promote cognitive health [7].

This article aims to present up-to-date information on the criteria for diagnosis and evaluation of frailty syndrome based on available literature.

Definition of Frailty syndrome

Frailty syndrome**,** otherwise qualified as a syndrome of weakness, fatigue or fragility, is defined as a progressive state of reducing the body's physiological reserves with age and is characterized by an increased susceptibility to sudden, disproportionate deterioration in functioning, after which it is impossible to return to the previous fitness and independence [8].

In a situation where an unfavourable stress factor occurs (illness, trauma, physiological, psychosocial, environmental factor), the functional state of a person with frailty syndrome decreases rapidly due to the limited ability to maintain homeostasis. This means that the available reserves of the body are insufficient to counteract and deal with the situation. A person who does not show signs of frailty will respond to the same stress factor with a short-term impairment of functioning followed by a complete recovery. Frailty includes changes in physical, mental or social functioning and is often referred to as a transitional state –

between a period of full fitness or disability. In order to describe frailty syndrome, two concepts have been developed that are commonly cited in the literature. Two models have been determined: a phenotypic model – of physical frailty and a model of deficits accumulation – frailty in a multidimensional context [9].

According to the authors of the first concept, frailty syndrome is diagnosed when at least three out of five of the following physical deficits occur:

- unintentional weight loss,
- subjective feeling of fatigue,
- slower walking speed,
- weakening of handshake strength
- limited physical activity [10].

In a situation where one or two of the symptoms presented above are present, people belonging to the pre-frail group may be identified, who are at an increased risk of frailty [10].

The second concept of defining frailty syndrome is multidimensional and considers the relationships between the physical, mental, and social spheres. This model consists of summing up the deficits that reduce physiological reserves and predispose to the development of frailty, i.e., symptoms, diseases, impairment of physical and cognitive abilities, psychosocial factors, and abnormalities in additional tests (laboratory and imaging). The frailty index is the ratio of the deficits identified compared to all factors considered for evaluation. In this context, frailty is a condition associated with deficits at at least one level of the person's functioning [11].

The researchers who study the frailty syndrome point out that it is often difficult to recognize its symptoms. This may apply to both family members who care for the elderly person and medical personnel. Some dependencies and similarities between related concepts may make it difficult to diagnose frailty and are sometimes even incorrectly equated with it. The overlapping issues are:

1. Progression of the ageing process – a stage of natural changes resulting from the decrease in the body's physiological reserves. Research confirms that the incidence of frailty increases with age, but it

does not affect all elderly people. Many seniors reach very advanced age without showing symptoms of frailty, and it has also been proven that frailty may affect people under 65 [10].

2. Multimorbidity – is defined as the simultaneous presence of two or more chronic diseases. The presence of one or more morbidities increases the risk of frailty but is not synonymous with it. Diseases most often result from damage to physiological systems, while frailty syndrome was defined as the state of weakening of these systems [3].

3. Disability, which is evaluated in terms of limitation in performing daily life activities, but is characterized by a stable functional state, as opposed to frailty, where often a small factor can result in a breakdown of homeostasis [10, 12].

Risk factors

Despite difficulties in establishing an unambiguous definition of frailty syndrome, it is widely believed that it is multidimensional. Factors resulting from the progressive ageing process and those related to the occurrence of chronic diseases and psychosocial factors contribute to the occurrence of the symptoms of this syndrome – the interaction between them often leads to the development of frailty. The table shows the most frequently mentioned indicators [4, 10, 13–17]:

Table 1. Risk factors for frailty syndrome. Compiled based on [4, 10, 13–18]

1. Factors related to physiological changes, pathophysiological: • advanced age • increase in inflammatory markers • disorders of the immune and endocrine systems • malnutrition • loss of skeletal muscle mass
2. Chronic diseases: • cardiovascular diseases • chronic obstructive pulmonary disease • chronic kidney disease • type 2 diabetes • stroke • arthritis • obesity • iron deficiency anaemia
3. Psychological factors: • cognitive impairment • depression and the use of antidepressants
4. Socio-demographic factors: • female sex • low level of education • marital status • poverty • loneliness
5. Others: • low, limited physical fitness, • gait abnormalities and loss of balance • vision impairment • use of sedatives • multi-drug therapy

Source: own study.

Pathophysiology

The main process important in the pathophysiology of the frailty syndrome is an increase in pro-inflammatory cytokines, such as: interleukins (IL-6, IL-1, IL-2), C-reactive proteins and an increase of the level of leukocytes, especially monocytes and neutrophils, to the upper limits of the normal range. Consequently, a chronic inflammatory process affects the functioning of the following systems:

- endocrine system,
- musculoskeletal system,
- cardiovascular system,
- hematopoietic system [19].

Disorders of the endocrine system include: decreased levels of sex hormones and growth hormone and disorders of corticosteroid secretion. The above changes and activity of inflammatory factors intensify catabolism and lead to loss of muscle mass and strength, decreased activity and motor performance, and further to osteopenia, osteoporosis, weight loss and a gradual deterioration of cognitive functions [4].

Additionally, the frailty syndrome is also associated with a reduction in the level of insulin-like growth factor (IGF-1) and the concentration of haemoglobin, albumin, and the deficiency of nutrients and vitamins. Disorders in the coagulation and fibrinolysis systems include: increased concentration of fibrinogen, coagulation factor VII and D-dimers and constitute other activators of inflammatory processes [8].

Epidemiology

The incidence of frailty syndrome increases with age – it affects from 2%–5% of respondents aged 18–34 [20], and in people over 65, it ranges from 4%–59% [21]. The result is influenced by the type of criteria used to evaluate frailty. When the study group covers people over 50, the percentage is lower when the diagnosis considers only physical factors and higher when the scale includes the multidimensional aspect [20]. Sex also has a significant impact on the evaluation – frailty is more common

in women. Predisposition to develop frailty, i.e. pre-frail status, is demonstrated by 35–50% of people over 65 [22].

Based on studies conducted in Poland, it is estimated that the frailty syndrome affects 6.7% of the elderly, including 30% of people aged 75–80 and 50% over 80 years of age [4].

Evaluation of the frailty syndrome – scales used to evaluate the functional state of the patient

In the available literature, there are many tools used to diagnose frailty syndrome. So far, no universal scale has been established that would serve as the only one for diagnosing this syndrome. Most often, frailty is diagnosed based on an interview and physical examination. The choice of the appropriate method depends largely on who the research will concern and under what circumstances it is to be conducted. It is necessary to consider the following factors:

- place of examination – hospital, clinic, or long-term care facility,
- person carrying out the examination (doctor, nurse, physiotherapist, guardian),
- condition and age of the patient
- existing limitations and diseases of the examined person [23].

Some scales consider only factors related to physical health in the diagnosis of frailty syndrome (one-dimensional scales) and tools that also include the psychological and social aspect (multidimensional scales). Depending on the evaluation method, there are subjective, objective and hybrid scales [24, 25].

Examples, including the type of scale, are presented in Tables 2 and 3.

Table 2. Classification of failty syndrome evaluation scales depending on the evaluation methods [25]

Objective scales	Subjective scales	Hybrid scales (subjective and objective)
Physical Frailty Score	Tilburg Frailty Indicator	Frailty Index
Modified Physical Performance Test	Clinical Frailty Scale CSHA	FRAIL scale
	Groningen Frailty Indicator	Edmonton Frail Scale
	Vulnerable Elderly Survey –13	Fried's Frailty Phenotype
		Study of Osteoporotic Fractures index

Source: own study.

Table 3. Classification of frailty syndrome evaluation scales depending on the evaluation methods [24–26]

One-dimensional scales	Multidimensional scales
Fried's Frailty Phenotype	Tilburg Frailty Indicator
SPPB (Short Physical Performance Battery)	Edmonton Frail Scale

Source: own study.

The most common tool for evaluating frailty syndrome in the context of physical limitations is the scale developed by Linda Fried, introduced and described based on an analysis of the Cardiovascular Health Study of more than 5,000 people 65 years of age and older. According to this concept, frailty syndrome is diagnosed when at least three out of the following five deficits occurs [10]:

- unintentional weight loss (>5 kg in 12 months).
- weakness – evaluated based on handshake strength measured with a dynamometer, considering age and body mass index (BMI);
- exhaustion – determined using the depression scale (CES-D, Center for Epidemiologic Studies Depression Scale);

- gait speed reduction – measured by the speed of walking (15 feet – approx. 4.6 m), considering sex and height of the examined person;
- decreased physical activity – based on the shortened version of the Minnesota Leisure Time Activity Questionnaire.

The presence of one or two of the symptoms listed above indicates an increased risk of frailty. These people qualify for the so-called pre-frail group [10].

An alternative tool that considers the physical limitations of patients is the SHARE-FI questionnaire. The scale was developed based on the analysis of a study performed in European countries, conducted on a population of several thousand people over 50 years of age [27].

The advantage of this tool is its affordability and the possibility of quick application in screening tests conducted during primary health care [27, 28].

The SHARE-FI questionnaire considers the following criteria:

- weight loss verified by determining the occurrence of loss of appetite issues;
- feeling of exhaustion, which is defined by a positive answer to the question "did you have too little energy to do what you wanted to do in the last month?";
- walking difficulties identified by questions about issues with a walking distance of 100 m or climbing stairs;
- low physical activity described by the frequency of activities requiring low to moderate energy levels, e.g., gardening, walking;
- weakness determined by measuring the handshake strength [29].

The scale is available through online calculators, constructed separately for both sexes. Based on the answers provided and the measurements taken, patients are classified into one of three groups: without frailty symptoms, susceptible to the development of the syndrome, and with frailty.

Many authors emphasize the need to evaluate frailty not only in terms of physical limitations but also in taking into account changes in the mental and social sphere because they significantly contribute to the occurrence of frailty syndrome symptoms [30–32].

An example of a multidimensional scale constructed in this way is the Tilburg Frailty Indicator [33]. The advantage of this tool is the possibility of carrying out the examination (up to 15 minutes) in everyday clinical practice, and it does not require the physical presence of the examined person. The scale was adapted to Polish conditions by Uchmanowicz and others [34].

The questionnaire consists of two parts. The first one concerns the socio-demographic characteristics of the respondent (sex, age, marital status, country of origin, level of education and monthly income). The second part contains 15 questions covering the three components of frailty. Among them, eight concern physical health, unintentional weight loss, difficulty in walking, imbalance, hearing impairment, visual impairment, lack of strength in the hands, and physical fatigue. The next four questions are related to evaluating cognitive abilities, depression, anxiety, and coping symptoms, and the remaining questions are related to social relations and social support. Overall, the score may range from 0 to 15 points. Frailty is diagnosed at a value equal to or greater than 5 [35].

Another tool used to evaluate frailty syndrome in multidimensional terms is the Frailty Index, otherwise defined as the deficit accumulation index. The test consists of summing up health deficits, i.e., symptoms, diseases, impairments in physical and cognitive abilities, psychosocial factors, and abnormalities in additional tests (laboratory and imaging). The indicator is presented as the ratio of the identified deficits to all factors that have been considered. The greater the number of deficits in a person, the greater the respondent's probability of presenting the frailty syndrome [36]. Research confirms that the Frailty Index is strongly linked to the risk of death, institutionalization and deterioration of health when at least 30 variables were included [37, 38].

Conclusions

Research on the frailty syndrome has been going on since the 90s, yet there is still no clear definition and criteria for diagnosing the syndrome. In order to describe frailty, two concepts have been developed that are cited in the literature. Two models have been determined: a phenotypic

model – of physical frailty and a model of deficits accumulation – frailty in a multidimensional context [9].

The common feature of both models and characteristic of this syndrome is a reduction of the body's physiological reserves. Regardless of the definition used, the authors of the publication agree unanimously that the aetiology of frailty is multidimensional [31, 32].

The factors that have a significant impact on the occurrence of the syndrome include: advanced age, the presence of chronic diseases, psychological and socio-demographic factors. In many publications, authors emphasize that increased inflammation parameters and changes and disorders in the musculoskeletal, endocrine and hematopoietic systems contribute to the occurrence of the frailty syndrome [4, 19].

Due to the serious consequences and poorer prognosis in frail patients, it is important to identify as early as possible those who are at risk of developing the syndrome or are already presenting disturbing symptoms of frailty. An important issue in its identification is the lack of unambiguous diagnostic criteria for evaluating the frailty syndrome [39].

The selection of the appropriate scale for testing depends on the characteristics of the research group. The variety of tools causes difficulties in conducting clinical trials and comparing the obtained results in one group of patients [40].

Since thoughtfully planned physical activity plays a significant role in preventing and treating people with frailty syndrome, knowledge about this issue may be important for a physiotherapist dealing with such patients.

References

1. **Wieczorowska-Tobis K, Kostka T, Borowicz AM** (eds.). Fizjoterapia w geriatrii. Warszawa: PZWL; 2011.

2. **Kijak RJ,** Szarota Z. Starość Między diagnozą a działaniem. Publikacja współfinansowana ze środków Unii Europejskiej w ramach Europejskiego Funduszu Społecznego. Warszawa; 2013 [Internet]. Available from: www.crzl.gov.pl.

3. **Gabryś T, Bajorek A, Malinowska-Lipień I.** Zespół słabości – zasadniczy problem zdrowotny osób starszych, cz. I. Gerontologia Polska 2015; 1: 29–33.

4. **Sobczyńska M, Główczyńska R, Opolski G.** Zwiększanie przez zespół kruchości częstości występowania powikłań u pacjentów poddawanych zabiegom kardiologii inwazyjnej i operacjom kardiochirurgicznym. Folia Cardiol 2017 Dec 29; 12(6): 557–564.

5. **Łęgosz P, Krzowski B, Płatek AE, Ryś A, Semczuk-Kaczmarek K, Szymański FM, Małdyk P.** Zespół kruchości w gabinecie lekarza praktyka – o czym należy pamiętać? Varia Medica 2018; 2(3): 222–228 [Internet]. Available from: www.journals.viamedica.pl/varia_medica.

6. **Ignasiak Z, Sebastjan A, Kaczorowska A, Skrzek A.** Estimation of the risk of the frailty syndrome in the independent – living population of older people. Aging Clin Exp Res 2020; 32(11): 2233–2240. https://doi.org/10.1007/s40520-019-01439-5.

7. **Aguirre LE, Villareal DT.** Physical Exercise as Therapy for Frailty. Nestle Nutr Inst Workshop Ser 2015; 83: 83–92 [Internet]. Available from: https://pubmed.ncbi.nlm.nih.gov/26524568/.

8. **Korzonek M, Fenger W, Czarnota-Chlewicka J, Bikowska M.** Zespół słabości – geriatryczny problem XXI w. Frailty syndrom – a geriatric problem of 21st century. Hygeia Public Health 2018; 53(1): 31–38 [Internet]. Available from: www.h-ph.pl.

9. **Rockwood K, Howlett SE.** Fifteen years of progress in understanding frailty and health in aging. BMC Medicine 2018; 16 [Internet]. Available from: https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-018-1223-3.

10. **Fried LP, Tangen CM, Walston J, Newman AB, Hirsch C, Gottdiener J** et al. Frailty in Older Adults: Evidence for a Phenotype. J Gerontol A Biol Sci Med Sci 2001 Mar 1; 56(3): M146–157.

11. **Zão A, Magalhães S, Santos M.** Frailty in cardiovascular disease: Screening tools. Rev Port Cardiol (Engl Ed) 2019 Feb; 38(2): 143–158 [Internet]. Available from: https://pubmed.ncbi.nlm.nih.gov/30879899/.

12. **Fried LP, Cohen AA, Xue Q-L, Walston J, Bandeen-Roche K, Varadhan R.** The physical frailty syndrome as a transition from homeostatic symphony to cacophony. Nat Aging 2021 Jan 14; 1(1): 36–46 [Internet]. Available from: https://www.nature.com/articles/s43587-020-00017-z.

13. **Fried LP, Espinoza SE.** Risk Factors for Frailty in the Older Adult. Clinical Geriatrics 2007; 15(6): 37–44 [Internet]. Available from: https://www.researchgate.net/publication/252764592.

14. **Cheong CY, Nyunt MSZ, Gao Q, Gwee X, Choo RWM, Yap KB** et al. Risk Factors of Progression to Frailty: Findings from the Singapore Longitudinal Ageing Study. J Nutr Heal Aging 2020 Jan 1; 24(1): 98–106 [Internet]. Available from: https://pubmed.ncbi.nlm.nih.gov/31886815/.

15. **Clegg A, Young J, Iliffe S, Rikkert MO, Rockwood K.** Frailty in elderly people. The Lancet 2013 Mar 2; 381(9868): 752–622.

16. **Barbosa da Silva A, Queiroz de Souza I, da Silva IK, Borges Lopes Tavares da Silva M, Oliveira dos Santos AC.** Factors Associated with Frailty Syndrome in Older Adults. J Nutr Heal Aging 2020 Feb 1; 24(2): 218–222.

17. **Hoogendijk EO, Afilalo J, Ensrud KE, Kowal P, Onder G, Fried LP.** Frailty: implications for clinical practice and public health. The Lancet 2019 Oct 12; 394(10206): 1365–1375.

18. **Satake S, Arai H.** Chapter 1 Frailty: Definition, diagnosis, epidemiology. Geriatr Gerontol Int 2020 Feb 12; 20(S1): 7–13 [Internet]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/ggi.13830.

19. **Sokołowski R, Sokołowska N, Czajkowska A, Węgrzyn E, Zukow W** et al. Patogeneza zespołu kruchości (Patogenesis of Frailty Syndrome). Journal of Health Sciences 4(9): 197–204 [Internet]. Available from: https://www.researchgate.net/publication/265964572_Patogeneza_zespolu_kruchosci_Patogenesis_of_Frailty_Syndrome.

20. **Kehler DS, Ferguson T, Stammers AN, Bohm C, Arora RC, Duhamel TA** et al. Prevalence of frailty in Canadians 18–79 years old in the Canadian Health Measures Survey. BMC Geriatr 2017 Dec 21; 17(1): 28 [Internet]. Available from: http://bmcgeriatr.biomedcentral.com/articles/10.1186/s12877-017-0423-6.

21. **Rohrmann S.** Epidemiology of Frailty in Older People. Adv Exp Med Biol 2020; 1216: 21–27 [Internet]. Available from: https://pubmed.ncbi.nlm.nih.gov/31894543/.

22. **Sacha J, Sacha M, Soboń J, Borysiuk Z, Feusette P.** Is it Time to Begin a Public Campaign Concerning Frailty and Pre-frailty? A Review Article. Front Physiol 2017 Jul 11; 8: 484 [Internet]. Available from: https://pubmed.ncbi.nlm.nih.gov/28744225/.

23. **Uchmanowicz I, Nessler J, Gobbens R, Gackowski A, Kurpas D, Straburzynska-Migaj E** et al. Coexisting Frailty With Heart Failure. Front Physiol 2019 Jul 3; 10: 791 [Internet]. Available from: https://www.frontiersin.org/articles/10.3389/fphys.2019.00791/full.

24. **Sacha M, Sacha J.** Zespół kruchości – podejście jedno-i wielowymiarowe. Frailty syndrome – uni- and multidimensional approach. Geriatria 2017; 11: 290–293.

25. **Seiffert P, Maślanka-Seiffert B, Derejczyk J, Marcisz C.** Frailty – narzędzia diagnostyczne stosowane w praktyce klinicznej. Frailty – diagnostic tools in clinical practice. Geriatria 2018; 12: 142–149.

26. **Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG** et al. A Short Physical Performance Battery Assessing Lower Extremity Function: Association with Self-Reported Disability and Prediction of Mortality and Nursing Home Admission. J Gerontol 1994 Mar 1; 49(2): M85–94 [Internet]. Available from: https://academic.oup.com/geronj/article/49/2/M85/595537.

27. **Romero-Ortuno R, Walsh CD, Lawlor BA, Kenny RA.** A Frailty Instrument for Primary Care: Findings from the Survey of Health, Ageing and Retirement in Europe (SHARE). BMC Geriatr 2010 Dec 24; 10(1): 57 [Internet]. Available from: http://bmcgeriatr.biomedcentral.com/articles/10.1186/1471-2318-10-57.

28. **Romero-Ortuno R, O'Shea D, Kenny RA.** The SHARE frailty instrument for primary care predicts incident disability in a European population – based sample. Qual Prim Care 2011; 19(5): 301–309.

29. **Muszalik M, Borowiak E, Kotarba A, Puto G, Doroszkiewicz H, Kędziora-Kornatowska K.** Adaptation and reliability testing of the share-fi instrument for the assessment of risk of frailty syndrome among older polish patients. Fam Med Prim Care Rev 2018; 20(1): 36–40. https://doi.org/10.5114/fmpcr.2018.73702.

30. **Morley JE, Vellas B, Abellan van Kan G, Anker SD, Bauer JM, Bernabei R** et al. Frailty consensus: A call to action. J Am Med Dir Assoc 2013 Jun 1; 14(6): 392–397.

31. **Wleklik M, Uchmanowicz I, Jankowska EA, Vitale C, Lisiak M, Drozd M** et al. Multidimensional Approach to Frailty. Front Psychol 2020 Mar 25; 11: 564 [Internet]. Available from: https://www.frontiersin.org/article/10.3389/fpsyg.2020.00564/full.

32. **Kojima G, Liljas AEM, Iliffe S.** Frailty syndrome: Implications and challenges for health care policy. Risk Management and Healthcare Policy 2019 Feb 14; 12: 23–30.

33. **Gobbens RJJ, Boersma P, Uchmanowicz I, Santiago LM.** The tilburg frailty indicator (TFI): New evidence for its validity. Clin Interv Aging 2020; 15: 265–274.

34. **Uchmanowicz I, Jankowska-Polańska B, Uchmanowicz B, Kowalczuk K, Gobbens RJJ.** Validity and Reliability of the Polish Version of the Tilburg Frailty Indicator (TFI). J Frailty Aging 2016; 5(1): 27–32.

35. **Wleklik M, Uchmanowicz I.** Wskaźnik słabowitości Tilburga – proste narzędzie badawcze do identyfikacji pacjentów z zespołem kruchości. Współczesne Pielęgniarstwo i Ochrona Zdrowia 2015; 4(4): 82–84.

36. **Mitnitski A, Rockwood K.** Aging as a process of deficit accumulation: Its utility and origin. Interdiscip Top Gerontol 2015; 40: 85–98 [Internet]. Available from: https://pubmed.ncbi.nlm.nih.gov/25341515/.

37. **Walston JD, Bandeen-Roche K.** Frailty: A tale of two concepts. BMC Medicine 2015; 13: 185.

38. **Pérez-Zepeda MU, Cesari M, Carrillo-Vega MF, Salinas-Escudero G, Tella-Vega P, García-Peña C.** A frailty index from next-of-kin data: A cross-sectional analysis from the Mexican health and aging study. Biomed Res Int 2017; 6069374.

39. **Uchmanowicz I, Lisiak M, Jankowska-Polańska B.** Narzędzia badawcze stosowane w ocenie zespołu kruchości. Gerontol Pol 2014; 22(1): 1–8.

40. **Piejko L, Nawrat-Szoltysik A.** Zespół kruchości – wyzwanie w starzejącym się społeczeństwie. Hygeia Public Health 2016; 51(4): 329–334.

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Sex-determining Region Y-related (SRY) High-mobility Group Box 4 (SOX4) Immunoexpression in Colorectal Cancer as an Unappreciated Parameter for More Individual Approach in Cancer Disease – A Preliminary Study

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Abstract

Background: Colorectal cancer is one of the most important problems that medicine has to face nowadays. Despite the development of new diagnostic tools and therapeutic strategies in oncology, it still takes the leading position regarding cancer related deaths, which proves the presence of undiscovered part of its biology. Therefore, is justified to search for new biomarkers to determine better colorectal cancer biology. Sex-determining region Y-related (SRY) high-mobility group box 4 (SOX4) is currently highly investigated protein which expression was identified in many pathological processes, including malignancies with the highest mortality rates and which seems to be a promising marker related to cancer progression.
Objectives: The aim of the study was to evaluate SOX4 expression level in colorectal cancer cells and search for its potential relation to the estab-

lished prognostic parameters for more individual approach in cancer disease.

Material and methods: Immunohistochemical evaluation of the SOX4 protein expression in colorectal cancer cells supported by statistical analysis of the relation to tumour stage, grade, and presence of lymph node metastases, as well as chosen histoclinical features.

Results: Obtain results showed for the first time complex expression of SOX4 in colorectal cancer. There were revealed differences of SOX4 immunoexpression regarding tumour grade, lymph node status, and tumour ulceration, as well as potential relation between SOX4 expression and patients' age and sex and grade 1 histological malignancy of the tumour.

Conclusions: Obtained results support the role of the SOX4 in colorectal cancer biology and for the first time indicate the relation with the established prognostic factors: tumour grade and lymph node status. The findings revealed in presented studies alight SOX4 expression as a promising parameter for colorectal cancer more individual approach with prospective clinical impact.

Key words: colorectal neoplasms; biomarkers; prognosis; transcription factors

Introduction

Colorectal cancer (CRC) is one of the most commonly diagnosed malignancy worldwide and also one of the leading causes of cancer related deaths [1]. There are the established histoclinical prognostic parameters for CRC patients as clinical advancement of cancer disease (stage), level of histological malignancy (grade) and lymph node status as well as the other biomarkers with proved utility, first of all carcinoembryonic antigen (CEA) which is related to a like hood of the recurrences of colorectal carcinoma. Another widely used parameter is CA 19-9, which elevated postoperative levels indicate poorer prognosis [2]. Based on the developing knowledge of CRC biology a lot of new treatment methods were discovered and successfully applied in the past few years 5-year survival rate varies from 90% in stage I to around 10% in stage IV and recently reached the plateau [3–5]. Progressive, however still unsatisfactory, res-

ults make a growing need for further studies to reveal new biomarkers for more individual approach in CDC disease.

There are evaluated numerous potential biomarkers, nowadays, mostly nucleic acids (RNA/DNA/messenger RNA/microRNAs), cytokines, antibodies, and various proteins [6].

In the recent years the role of proteins expression in colorectal carcinoma gains in value but the results are not unambiguous. Among these, especially interested seems to be Sex-determining region Y-related (SRY) high-mobility group box 4 (SOX4) protein due to its part in cancer proliferation and growth, already proved in the other cancer including entities with the highest mortality [7–10].

SOX4 is a transcription factor protein encoded by the SOX4 gene, which belongs to SOXC subgroup of the SOX family [11]. It plays an important role in the embryonal development, influence the apoptosis, resulting in the cell death but also can be present in the tumorigenesis [12]. The expression of SOX4 was observed in over 20 types of malignancies, including breast cancer, bladder cancer and prostate cancer [7–10]. Although a lot of researches were performed the exact role of SOX4 in complicated biology of cancer cells is still unknown. The scientific attempts to determine SOX4 influence are highly limited, however they suggest the role of this protein in the proliferation of the cancer cells [13].

The study presents the first complex evaluation of SOX4 expression in relation to the established prognostic parameters (stage, grade, lymph node status) and chosen histoclinical features (patients' age and gender, tumour ulceration) to determine needed future study directions and potential value of SOX4 evaluation for more individual CDC approach.

Material and methods

There were chosen 20 representative colorectal adenocarcinoma cases for the study from the archives of the Department of Pathomorphology, Chair of Oncology Medical University of Lodz, Poland for the presented preliminary studies, according to the agreement of Bioethics Committee of the Medical University of Lodz RNN/351/19/KE. Paraffin embedded

CRC tissues were used for further evaluation – paraffin sections with a thickness of 3–4 micrometres were used to prepare routine slides stained with hematoxylin and eosin (H + E) for routine histological examination as well as and for immunohistochemical tests in the PowerVision detection system by ImmunoLogic according to the immunoperoxidase method, using the primary rabbit polyclonal antibodies directed against SOX4 by Thermo Fisher Scientific.

For immunohistochemical study, paraffin sections, after being placed on adhesive slides and dried in an incubator at 56°C for 1 hour, were subjected to dewaxing in a series consisting of xylenes and alcohols of decreasing concentrations (96%, 80%, 70%, 60%). Endogenous peroxidase activity was then inhibited with a 3% solution of perhydrol in methanol for 5 minutes. In order to restore tissue antigenicity and open the path for antibodies, the following procedure was used: Sections were heated in a Target Retrieval Solution at pH 9.0 DAKO, in a water bath at 95°C for 45 min. After cooling, the sections were washed twice in 0.05 M TRIS buffer (TBS) at pH 7.6 for 5 min. Then they were subjected to an overnight incubation in a refrigerator at 4°C in a humid chamber with appropriately diluted antibodies anti-SOX4 1:20. After incubation, the sections were washed twice in TBS buffer and the ImmunoLogic PowerVision two-step visualization system was used to visualize the antigen-antibody reaction. The first step of the reaction consisted of a 30-minute incubation in the above-mentioned conditions with a polymer labelled with peroxidase and associated with secondary goat antibodies directed against the polyclonal rabbit antibodies used. The last stage of detection was an enzymatic reaction in which a coloured product arised when the substrate for peroxidase – 3,3`-diaminobenzidine tetrachloride (DAB) was used (incubation time with DAB solution – 2 min.). Then, the nuclei were stained with Meyer's hematoxylin (2 min.) and the sections were dehydrated in a series of alcohols of increasing concentrations (70%, 80%, 96%) and passed through a series of acetones and xylenes. Thus prepared, they were embedded in the anhydrous Histokit medium. The negative control of the method were sections in which the primary antibodies were replaced with TBS buffer using the immunohistochemical procedure described hereinafter. Sections showing a previously known

strong positive response to the test antigen were used as positive controls. The microscopic slides were assessed with the use of a light microscope. Histological examination according to the currently used protocols was performed and SOX4 expression was estimated (defined as brown coloration of cancer cell nuclei) and presented as an index for each CRC case. Histoclinical analysis was done regarding patients' related features (age, gender), tumour related features (grade, ulceration), and cancer disease related features (stage, lymph node status, distant metastases, recurrences). The collected immunohistoclinical data were analysed in the R environment (R 4.0.2) with rstatix and ggpubr packages. The normality of distribution was analysed with the Shapiro-Wilk test followed by Levene's test to analyse the homogeneity of variance. The hypotheses were tested by applying a non-parametric signed rank Wilcox test or in the case of normally distributed data the t-test. Comparisons between three groups were performed with a non-parametric Kruskal-Wallis test. Correlations were evaluated with the Spearman coefficient. All of the results were statistically significant if $p<0.05$.

Summary of the study group and details of histoclinical features chosen for the study are presented in Table 1.

Table 1. Characteristic of histoclinical features chosen for the study

Chosen parameter		Characteristic
Patients' related features	Age	Min. 54; Max. 95; Average: 71.95 (years)
	Gender	Male: 14; Female: 5
Tumour related features	Grade	Grade 1: 7 Grade 2: 7 Grade 3: 6
	Ulceration	Present: 7 Absent: 11
Cancer disease related features (stage, lymph node status, distant metastases = 1, recurrences = 0)	Stage	Stage 1: 5 Stage 2: 2 Stage 3: 6 Stage 4: 1
	Metastases in the lymph nodes	Present: 7 Absent: 7

Source: own study.

Results

SOX4 immunoexpression was found in all the examined CRC cases and appeared various with differences in gender, age, stage, grade study subgroups as well as between the tumours with and without ulceration, and with and without metastases in the lymph nodes.

The SOX4 indices appeared as follow:

Among males, the median SOX4 expression was 57.5% (mean=54.5±14.2), whereas among females it was higher and reached 64% (mean=56.7±12.7).

Median index for grade 1 (g1), grade 2 (g2), and grade 3 (g3) tumours was 58% (mean=52.4±17.3), 66% (mean=61.9±6.96), and 58% (mean=52.8±15.5), accordingly (Figure 1).

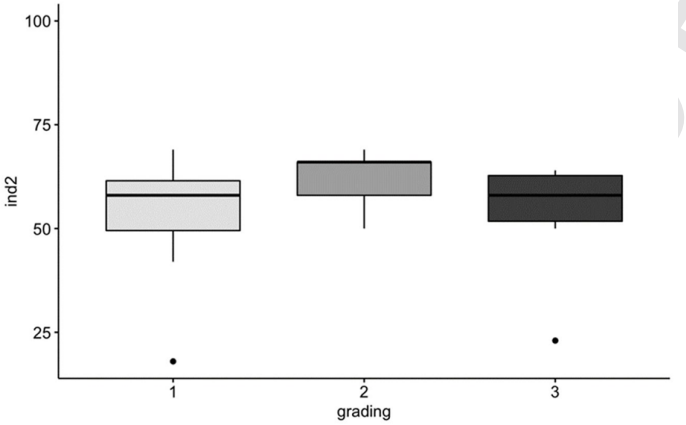

Figure 1. The box-plot presented the values of SOX4 immunoexpression indices (ind2) in tumours with different histological level of malignancy, grade 1, 2, and 3, appropriately (grading)

The median index in the stage 1 group was 57% (mean 53.6±7.64), although in the stage 3 group median index was higher (median=61.5, mean=55.2±17.1) (limited data for the other stages) (Figure 2).

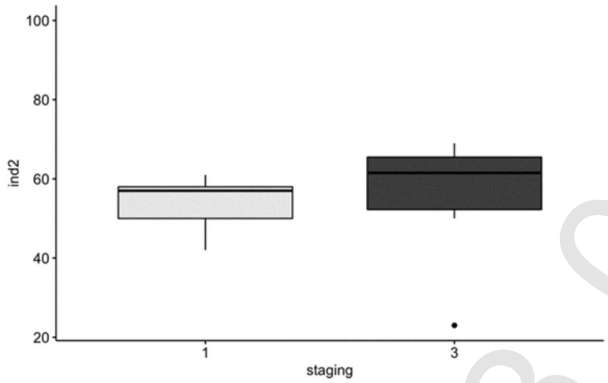

Figure 2. The value difference of SOX4 expression between stages 1 and 3

SOX4 immunoexpression index in CRC cases without lymph node metastases reached 57% (mean=50±15.9), while among patients with present lymph node metastasis achieved 61.5% (mean=60.8±6.91) (Figure 3, Figure 4 and Figure 5).

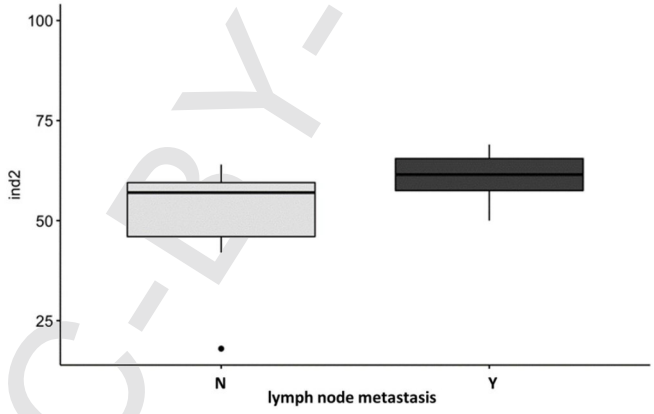

Figure 3. The box-plot presented the values of SOX4 immunoexpression indices (ind2) in tumours with different lymph node status (without metastases – N, and with lymph node metastases – T)

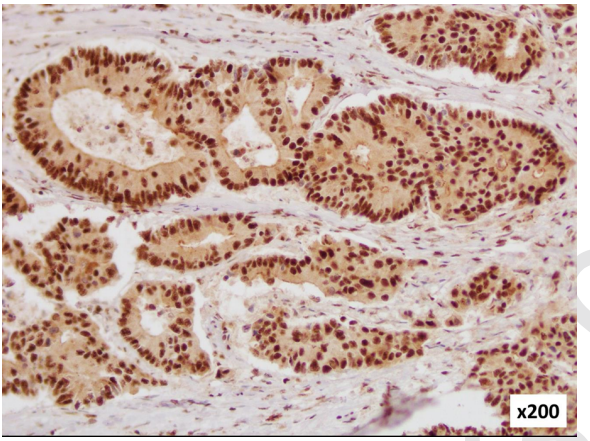

Figure 4. SOX4 immunoexpression in colorectal cancer cells (lymph nodes metastases present), orig. magn. 200x

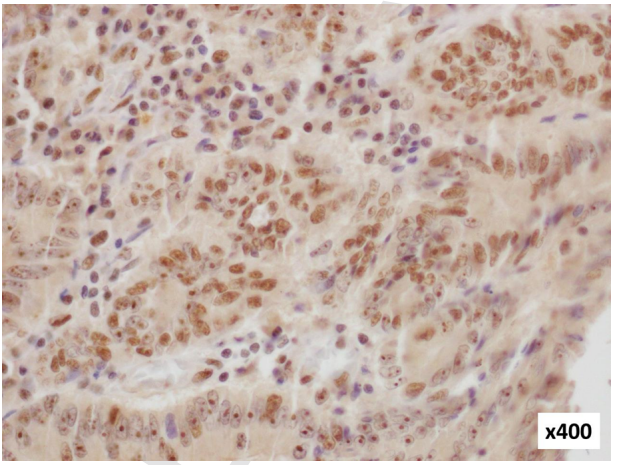

Figure 5. SOX4 immunoexpression in colorectal cancer cells (lymph nodes metastases absent), orig. magn. 400x

SOX4 immunoexpression index in CRC cases without ulceration reached 57% (mean=55.9±8.51), while in cases with ulceration the median index raised to 61% (mean=53.6±20.1) (Figure 6).

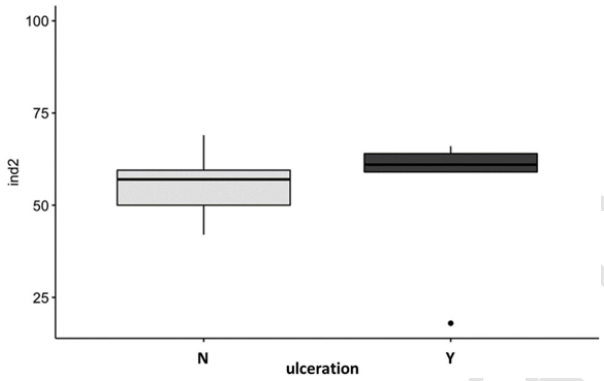

Figure 6. The box-plot presented the values of SOX4 immunoexpression indices (ind2) in tumours without ulceration – N, and with ulceration – T)

Additionally, there was observed a moderate association of the examined SOX4 index and age among females (rho=0.67), and similar correlations between the SOX4 index and patients' age among grade 1 (rho=0.57) and grade 3 tumours (rho=0.41) (Figure 7, 8, 9).

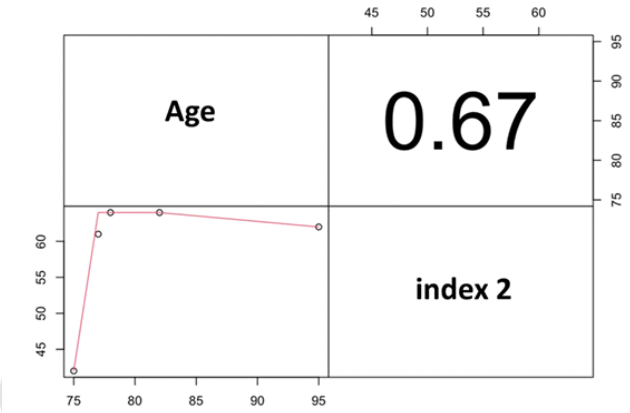

Figure 7. Correlation between SOX4 immunoexpression (index 2) and patients age among females – rho Spearman

Figure 8. Correlation between SOX4 immunoexpression (index 2) and age among grade 1 tumours – rho Spearman

Figure 9. Correlation between SOX4 immunoexpression (index 2) and age among grade 1 tumours – rho Spearman

The observed differences in SOX4 immunoexpresion in gender, age, stage, grade study subgroups and between the tumours with and without ulceration, and with and without metastases in the lymph nodes, have not

appeared to be statistically significant, the most probably they have not achieved the minimum threshold of statistical significance due to the limited studied subgroups, where only huge differences within homogeneous groups may be proven, however they illustrated the complex immunophenotypes of CRC tumours and indicate the direction of future evaluations in more numerous groups.

Discussion

Colorectal adenocarcinoma is associated with high mortality and morbidity worldwide, e.g.: according to the American Cancer Society, about 135,430 people were diagnosed with colon cancer in one year (2014) and that same year, about 50,260 people died from the disease, what perfectly illustrated why CRC is found to be one of the leading medical problems nowadays, regarding the relation between incidence and mortality rates. On the other hand, prognosis for CRC patients has improved in the last several years, and according to the Colorectal Cancer Coalition, the mortality rate for people with colon cancer has decreased by roughly 30 percent from 1991 through 2009.

Despite remarkable progress in currently used treatment modes is still far from expected results and completely personalized strategies. Many factors affect the prognosis in individual cases, these widely established according to the National Cancer Institute, include: stage of cancer disease, tumour grade, lymph node involvement, and the others less understood and able to be analysed and compared as general health status or colon blockage.

Although CRC is highly investigated malignancy, complete understanding of its biology and the same possibilities of prognostication are limited. The molecular features that could potentially become the prognostic and predictive factors are believed to be one of the most important discoveries of the modern medicine. No wonder they appear in many fields of biological sciences and are considered almost equally important as histological or clinical image of the disease. The perfect example of such a molecule being a transcription factor is Sex-determining region Y-related (SRY) high-mobility group box 4 (SOX4). The literature shows

that SOX4 is overexpressed in variety of tumours and suggested that it plays a crucial role in their development and progression [14]. It that has been proved to be associated with tumour progression and poor clinical outcome in several cancers [15]. Numerous malignancies were examined in the context of SOX4 overexpression, in prostate cancer SOX4 expression has been shown to correspond to high Gleason score and the presence of distant metastasis, which is strongly bounded with a poor prognosis in this neoplasm [16]. Its important role was also confirmed in research on the patients with hepatocellular carcinoma and proliferating effect was also evidenced in breast adenocarcinoma [10, 17]. Mostly there was observed and analysed the difference of SOX4 expression between normal and cancerous cells without histoclinical context based on comparison with the normal tissue, to show upregulation of the examined process in cancer [18, 19]. In presented studies there was performed the complex analysis which included the assessment of SOX4 expression in the cancer cells. In presented studies the first attempt was made to establish the diversity in expression of SOX4 in colorectal carcinoma, and search for CRC immunoprofile relation to complex spectrum of parameters including both, well excepted prognostic markers, as well as chosen histoclinical features to assess potential prognostic impact of SOX4 immunoexpression evaluation.

SOX4 expression was identified in numerous types of malignancies [14]. In presented studies it was observed in 100% of CRC cases, what stays in compliance with the literature, however immunoprofiles of CRC cases differed in relation to the examined features.

Stage of cancer disease is the most universal prognostic parameter in oncology age According to the National Cancer Institute (US), patients with stage 1 CRC have about 93% of survival rate while stage II is between 72% and 85%, and stage III is still as high as 83%. The prognosis of stage IV is the poorest and only 8% five years' survival rate is observed.

Regarding the stage, the examined SOX4 immunoexpression in CRC cases appeared to change in subsequent stages of cancer disease which stays in compliance with the other authors findings in literature –in sev-

eral other cancers SOX4 expression has been proved to be associated with tumour progression and poor clinical outcome [15].

The relationship between expression of SOX4 and the level of histological malignancy (grade) was studied on the examples of not only epithelial neoplasms but also mesenchymal origin malignancies such as osteosarcoma and revealed the connection between SOX4 expression and tumour grade, what made the survival of cancer patients poorer in comparison to population with normal levels of SOX4 protein expression [20].

In the literature it was also suggested that overexpression of nuclear SOX4 can appear prognostic marker for colon cancer and can be used as a predictive marker in this group of patients, either [19]. The results of presented studies stay in compliance with a utility of SOX4 expression as a prognostic parameter in CRC group of malignancies. According to the authors' knowledge there were no studies which covered the complex evaluation of SOX4 expression with other relevant histoclinical factors, including widely accepted prognostic markers. Although our studies did not show statistical significance in this matter (the most probably they have not achieved the minimum threshold of statistical significance due to the limited study subgroups), there were observed differences within CRC subgroups which seems to be promising and indicate the direction of future studies in more numerous groups with potential prognostic impact.

Another crucial factor which influences the survival rate of CRC patients is the presence of metastases in the lymph nodes. Although the topics of lymph node staging are still under discussion (e.g.: the definition and controversies in tumour deposits, isolated cancer cells and micrometastasis, lymph node ratio as a prognostic stratification factor) the histological evaluation of lymph nodes status remains crucial for postoperative treatment and prognosis prediction [21].

In presented studies the difference in SOX4 expression between the CRS tumours with positive lymph nodes status and without metastases to the lymph nodes were observed. It also stays in compliance with literature. After the analysis of still limited studies on the relation between cancer disease advancement and SOX4 expression we found the data which support the relation of SOX4 expression to the presence of metastases in both: regional lymph nodes and distant organs. It is believed

that the association of SOX4 expression and metastatic processes is related to migration and invasion of the cell line, what was proved on the example of the development and metastasizing in renal cell carcinoma [22]. SOX4 was evidenced to have an impact on growth and formation of metastases in lymph nodes in breast cancer, either [23]. The connection between lymph node metastasis and the advancement of the tumour and its correlation with upregulation of SOX4 was also described in gastric cancer [24]. Surprise, regarding the fact that colorectal carcinoma is one of leading causes of death due to cancer diseases worldwide no studies of correlation of SOX4 expression and presence of lymph node metastasis in this malignancy were found. Since the lymph node metastasis have their role in prognosis in colorectal cancer the relation of their appearance with the expression of SOX4, which role was already proved in other malignancies should undergo research with a broader scope. We hope that further studies in this area could give an answer to many questions about the course of the neoplastic process and potentially make the prediction if metastasis occur in specific patient possible, including CRC patients with potential benefits of more personalized treatment strategies based on SOX4 evaluation as suggested in presented studies.

The presence of ulceration – the next examined feature is believed to be typical for malignant growths and proved to be a significant prognostic factor in some of them with influence even on survival rate [25]. In colorectal cancer, besides the well-known prognostic factors, the presence of ulceration seems to also play a role in the course of the disease and influences the prognosis for CRC patients [26, 27]. Not many data are possible to find in literature which present the prognostic significance of the fact of colon ulceration and majority of them reflects inflammatory processes, mostly inflammatory bowel disease (ulcerative colitis and Crohn disease). However, in CRC it was observed that the appearance of the ulceration in majority of cases accompanied advanced stages of cancer disease. In presented studies the difference in SOX4 immunoexpression was observed between tumours with and without ulceration. Although without confirmation of statistical significance, the idea of investigation of the relationship between SOX4 expression and ulceration should not be forgotten in the future researches, similarly to the last sur-

prising findings: a moderate association of SOX4 index and age among females, and correlations between the SOX4 index and patients' age among grade 1 and grade 3 tumours which hard to be explained in this preliminary step of investigation may appear important for CRC biology and patients' fate in future.

Concluding remarks

For the first time the complex SOX4 immunoprofile of colorectal cancer was showed as well as its differences in relation to complex spectrum of histoclinical features including the established prognostic parameters. The study alights previously unknown part of CRC biology and brings promising findings which potentially may contribute to better understanding of this disease and improvement of treatment strategies due to their personalization. Regarding the fact that colorectal cancer as one of the most important challenge of today's medicine, each new direction of studies which potentially may benefit with reduction of CRC patients' mortality by influence of disease progression processes should be considered.

References

1. **Araghi M, Soerjomataram I, Jenkins M, Brierley J** et al. Global trends in colorectal cancer mortality: projections to the year 2035. Int J Cancer 2019; 144(12): 2992–3000.

2. **Shin JK, Kim HC, Lee WY, Yun SH** et al. High preoperative serum CA 19-9 levels can predict poor oncologic outcomes in colorectal cancer patients on propensity score analysis. Ann Surg Treat Res 2019; 96(3): 107–115.

3. **Labianca R, Beretta GD, Kildani B,Milesi L** et al. Colon cancer. Crit Rev Oncol Hematol 2010; 74(2): 106–133.

4. **Brenner H, Kloor M, Pox CP.** Colorectal cancer. The Lancet 2014; 383(9927): 1490–1502.

5. **Lopez G, Boggio F, Ferrero S, Fusco N, Del Gobbo A.** Molecular and Immunohistochemical Markers with Prognostic and Predictive Significance in Liver Metastases from Colorectal Carcinoma. IJMS 2018; 19(10): 3014.

6. **Nikolaou S, Qiu S, Fiorentino F, Rasheed S, Tekkis P, Kontovounisios C.** Systematic review of blood diagnostic markers in colorectal cancer. Tech Coloproctol 2018; 22(7): 481–498.

7. **Dong H, Hu J, Wang L, Qi M** et al. SOX4 is activated by C-MYC in prostate cancer. Med Oncol 2019; 36(11): 92.

8. **Moran JD, Kim HH, Li Z, Moreno CS.** SOX4 regulates invasion of bladder cancer cells via repression of WNT5a. Int J Oncol 2019;55(2): 359–370.

9. **Moreno CS.** SOX4: The unappreciated oncogene.Seminars in Cancer Biology 2019; 67: 57–64.

10. **Zhang J, Chai S, Ruan X.** SOX4 Serves an Oncogenic Role in the Tumourigenesis of Human Breast Adenocarcinoma by Promoting Cell Proliferation, Migration and Inhibiting Apoptosis. Recent Pat Anticancer Drug Discov 2020; 15(1): 49–58.

11. **Hanieh H, Ahmed EA, Vishnubalaji R, Alajez NM.** SOX4: Epigenetic regulation and role in tumorigenesis. Semin Cancer Biol 2020; 67: 91–104.

12. SOX4 SRY-box transcription factor 4 [Homo sapiens (human)] – Gene –NCBIn.d. [Internet]. Available from: https://www.ncbi.nlm.nih.gov/gene?Db=gene&Cmd=ShowDetailView&TermToSearch=6659 [citedJuly 6 2021].

13. **Wang B, Li Y, Tan F, Xiao Z.** Increased expression of SOX4 is associated with colorectal cancer progression. Tumour Biol 2016; 37(7): 9131–9137.

14. **Vervoort SJ, van Boxtel R, Coffer PJ.** The role of SRY – related HMG box transcription factor 4 (SOX4) in tumorigenesis and metastasis: friend or foe? Oncogene 2013; 32(29): 3397–3409.

15. **Liu Y, Zeng S, Jiang X, Lai D, Su Z.** SOX4 inducestumourinvasion by targeting EMT-related pathway in prostate cancer. Tumour Biol 2017; 39(5): 1010428317694539.

16. **Wang L, Zhang J, Yang X, Chang YWY** et al. SOX4 is associated with poor prognosis in prostate cancer and promotes epithelial-mesenchymal transition in vitro. Prostate Cancer Prostatic Dis 2013; 16(4): 301–307.

17. **Tsai CN, Yu SC, Lee CW** et al. SOX4 activates CXCL12 in hepatocellular carcinoma cells to modulate endothelial cell migration and angiogenesis in vivo. Oncogene 2020; 39(24): 4695–4710.

18. **Lin C-M, Fang C-L, Hseu Y-C, Chen C-L** et al. Clinical and Prognostic Implications of Transcription Factor SOX4 in Patients with Colon Cancer. PLoS One 2013; 8: e67128.

19. **MouT-Y, Zhang R-R, Wang Y-N.** MiRNA –212 acts as atumour–suppressor in colorectal carcinoma through targeting SOX4. Eur Rev Med Pharmacol Sci 2019; 23(24): 10751–10760.

20. **Bao Z-Q, Zhang C-C, Xiao Y-Z, Zhou J-S, Tao Y-S, Chai D-M.** Over-expression of Sox4 and β-catenin is associated with a less favorable prognosis of osteosarcoma. J Huazhong Univ Sci Technolog Med Sci 2016; 36(2): 193–199.

21. **Jin M, Frankel WL.** Lymph Node Metastasis in Colorectal Cancer. Surgical Oncology Clinics of North America 2018; 27(2): 401–412.

22. **Ruan H, Yang H, Wei H, Xiao W** et al. Overexpression of SOX4 promotes cell migration and invasion of renal cell carcinoma by inducing epithelial-mesenchymal transition. Int J Oncol 2017; 51(1): 336–346.

23. **Zhang J, Xiao C, Feng Z, Gong Y** et al. SOX4 promotes the growth and metastasis of breast cancer. Cancer Cell Int 2020; 20: 468.

24. **Yuan X, Wang S, Liu M, Lu Z** et al. Histological and Pathological Assessment of miR-204 and SOX4 Levels in Gastric Cancer Patients. Biomed Res Int 2017; 6894675.

25. **Callender GG, McMasters KM.** What does ulceration of a melanoma mean for prognosis? Adv Surg 2011; 45: 225–236.

26. **Micu BV, Vesa ŞC, Pop TR, Micu CM.** Evaluation of prognostic factors for 5 year – survival after surgery for colorectal cancer. Ann Ital Chir 2020; 91: 41–48.

27. **Poornakala S, Prema NS.** A study of morphological prognostic factors in colorectal cancer and survival analysis. Indian J Pathol Microbiol 2019; 62(1): 36–42.

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Motivations for Volunteering among Future Healthcare Professionals during the COVID-19 Epidemic: A Case Study from Poland

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Abstract

Background: Ever since the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) stuck health care systems in many countries have been seriously burdened. Simultaneously, thousands of medical students across Europe have volunteered to support the fight against the COVID-19 pandemic.
Objectives: The paper aims to analyse the motivations for the volunteering among future healthcare professionals in times of a coronavirus outbreak.
Material and methods: The study was conducted among 311 students of Poznan University of Medical Sciences, Poland, who answered questions regarding the reasons they became involved in voluntary service during the pandemic. Answers were used to categorize respondents' motivations for their voluntary service in different functions.
Results: While four functions served by volunteering during the coronavirus pandemic have been identified: values, enhancement, career and social, students were mainly motivated by altruistic reasons: the ideal of doing good, helping others and giving something back to the community. Moreover, many believed that as future health professionals it was their duty to engage, whatever the risk. Gender and religiosity were the key factors conditioning students' motivations.
Conclusions: While volunteering has served many purposes during the coronavirus pandemic, value-based motivations were the primary force behind students' engagement. At the same time, students' religiosity seems the key factor that determined their motivations.

Key words: COVID-19 pandemic; future healthcare professionals; motivations, voluntary service, Poland

Backround

The first case of SARS-CoV-2 infection confirmed by a laboratory test in Poland was announced officially on 4 March 2020, while the first person

infected with the coronavirus disease 2019 (COVID-19) died on 12 March. Consequently, between 10 and 20 of March lockdown-type control measures were imposed by the Polish government which included the closing of schools and universities, cancelling all mass events and forbidding non-essential travels. Non-family gatherings were also limited to two persons and religious gatherings to six. Moreover, starting from 15 of March Poland temporarily closed its borders to non-citizens, international flights and rail services were suspended and all Polish citizens returning from abroad had to undergo a two weeks long voluntary quarantine. Finally, in accord with the ordinance of the Minister of Health a state of epidemic was announced on 20 of March, which resulted in other restrictions including: the temporary restoration of border controls, closing of shopping centres, restaurants and bars, and banning of public gatherings of more than 50 people. Despite all these measures, up till 1 of July 2021 there has been confirmed 2,880,596 cases of infections and 75,135 of patients died [1]. At the same time, in comparison to other European countries, including Italy, Spain or the United Kingdom, the incidence of COVID-19 in Poland during that time was still relatively low at 3.3 total cases per 1 million population [2].

Simultaneously, thousands of medical students in Poland have volunteered their services to support the fight against the coronavirus pandemic. Starting from 12 of March 2020, Poznan University of Medical Sciences (PUMS) started encouraging its students to volunteer, and a day later its rector and the governor of Wielkopolska province signed an agreement which made it possible for volunteers to work in local hospitals and sanitary-epidemiological stations. Immediately, students from the faculties of Medicine, Pharmacy and Health Sciences reported their willingness to help in fighting the COVID-19 pandemic. Consequently, more than five hundred students volunteered in hospitals, emergency units, hospital pharmacies, sanitary-epidemiological stations and the university's diagnostic laboratory where they care for patients, conduct epidemiological interviews over the phone, take a medical history from those infected, help in administrative and office work, give telephone advices in call centres, translate English texts about COVID-19, sew pro-

tective masks or help in distribution of medical equipment to healthcare units.

Their service is of special importance because in many countries health care systems have been seriously burdened by the SARS-CoV-2. Moreover, healthcare professionals are at the highest risk of being infected and according to the Chief Sanitary Inspectorate 95,057 healthcare professionals in Poland were infected, including: 22,493 physicians, 57,060 nurses, 5,488 midwives, 3,317 paramedics, 2,536 pharmacists, 2,254 dentists, 1,879 laboratory diagnosticians and 30 feldshers. Moreover, 222 medics have died: 106 physicians, 78 nurses, 14 dentists, 7 paramedics, 6 midwifes, 5 pharmacists, 4 feldshers and 2 laboratory diagnosticians [3].

Nevertheless, students' volunteering is not limited to helping in hospitals and medical institutions as they have also organized so called 'Koronalia', which provides help for medics and their families' everyday activities. Moreover, they engage in informative actions in social media and sanitary-epidemiological stations, translate English texts about COVID-19 and make supplies of personal protective equipment.

At the same time, many research endeavours show that modernisation of societies and the individualization of the young generation provokes a shift from traditional, community volunteering to its more individualistic forms, i.e. voluntary activities driven by collective or altruistic motives are being replaced by individualised and goal-oriented volunteering [4–9]. Thus, while there is plenty of research on the motivations and experiences of college and university student volunteers [10–15], this paper aims to analyse the motivations for the volunteering of Polish medical students' during the COVID-19 pandemic.

Material and Methods

Study design

The study was conducted between 5 and 30 of May 2020 among students of Poznan University of Medical Sciences, Poland. The survey was conducted with a standard questionnaire that was constructed from themes

based on a review of the literature and the study's aim. Initially, an application was submitted to the University Student Council Board (USCB) to obtain permission to complete the study. The process of elaborating the questionnaire followed the guidelines of the European Statistical System [16]. First, during an online focus-group meeting five students and one sociologist elaborated a list of important issues on students volunteering, which resulted in developing a questionnaire which was assessed by six external reviewers (four members of the USCB, one physician and one sociologist). Second, the questionnaire was pre-tested via an online questionnaire with another five students. Based on the pilot study, three question were reformulated. The final version of the questionnaire was again evaluated by another three external reviewers. After receiving final approval from USCB, an online survey was distributed to all those students who have volunteered. Additionally, ethics approval and research governance approval were obtained from the PUMS Bioethics Committee (KB – 831/20).

Questionnaire

The questionnaire included three sections. The first asked questions regarding students' reactions to pandemic crisis and anxieties related to voluntary service. The second section included questions regarding the main reasons students volunteered. Participants were also asked to indicate their agreement with the answers on a scale of 1–5, and mean values have been computed for these variables based on all responses, which were used to categorize respondents' motivations for volunteering into different functions. Thus, four main functions of volunteering were identified: values (when volunteering appeals to altruism and public service), enhancement (which relates to psychological development and personal growth), career (when volunteering serves as a mean for developing personal career) and social (which relates to one's desire to establish relationships with others) [10]. The last section of the questionnaire gathered demographic information regarding gender, faculty, year of study, religiosity and earlier experience with the voluntary service.

Statistics

The data collected in the questionnaires were verified and checked for completeness, quality and consistency and exported into the statistical package JASP (Version 0.12.2). The results are presented as descriptive statistics. Welch's unequal variances *t*-test was used to compare differences between sub-groups (faculty, study year, gender and religiosity). A 5% level of significance was used for all the hypothesis tests. Effect size is given by Cohen's d. A reliability analysis was conducted, and the internal consistency of the questionnaire (Cronbach's α=0.807, McDonald's ω=0.817) was found to be sufficient for the purposes of the study.

Results

An e-mail invitation was sent to all 492 students engaged in voluntary service till 5 of May; and 63.2% (311 students) agreed to participate in the study (Table 1). Students who refused to participate in the study did so because they were unwilling to discuss their attitudes towards volunteering, lacked the time or the interest to take part in the study or had resigned due to personal reasons. 216 respondents were females (69.5%), while 95 were males (30.5%), all of Polish origin. Students who were in the last two of the three years of their studies volunteered more often than those who studied in the first, second or third year (201, 64.6% vs 100, 35.4% respectively). The vast majority of respondents studied medicine 70.4% (n=219). Among other volunteers, nursing and pharmacy students predominated (6.1%, n=19). Of those reporting a religious affiliation, 195 (62.7%) were members of the Roman Catholic Church, while 76 (24.5%) declared themselves as atheists and 34 (10.9%) as agnostics. 1/3rd of those who declared themselves as believers defined themselves as 'practicing believers' (n=103, 33.1 %), while 106 as "non-believers who do not practice" (34.1%). Simultaneously, although for 101 students, religion was somehow important (32.5%), for 210 it was of little significance (34.4 %) or irrelevant (33.1%). Of 223 (71.7%) students who declared that they had been volunteering before the epidem-

ics, 75 (24.1%) did so more than five times, 83 (26.7%) 3–5 times and 20 (6.4) only once.

Table 1. Socio-demographic characteristics of students

Characteristics	N (%)
Gender	
Female	216 (69.5)
Male	95 (30.5)
Year of study	
1	30 (9.7)
2	43 (13.8)
3	37 (11.9)
4	84 (27)
5	62 (19.9)
6	55 (17.7)
Faculty	
Medicine	219 (70.4)
Dentistry	11 (3.5)
Nursing	19 (6.1)
Midwifery	7 (2.3)
Medical analytics	13 (4.2)
Pharmacy	19 (6.1)
Physiotherapy	7 (2.3)
Public health	6 (1.9)
Other	10 (3.2)
Confession	
Roman Catholic	195 (62.7)
Other Christian	4 (1.3)
Agnostic	34 (10.9)
Atheist	76 (24.5)
Other	2 (0.6)
Religious practices	
Believing/practicing	103 (33.1)

Believing /not practicing	97 (31.2)
Nonbeliever/practicing	5 (1.6)
Nonbeliever/not practicing	106 (34.1)
What role does religion play in your life?	
Significant, it influences my life decisions and choices	36 (11.6)
Rather big, I try to follow religious principle in my life	65 (20.9)
Little, I separate religion from public issues	107 (34.4)
None, it is irrelevant to me	103 (33.1)
Have you ever been engaged in voluntary service before?	
Yes	223 (71.7)
No	88 (28.3)
How many times have you volunteered before?	
1	20 (6.4)
2	45 (14.5)
3–5	83 (26.7)
6–10	22 (7.1)
>10	53 (17)

Source: own elaboration.

Although after hearing the news about the coronavirus outbreak most students' reacted with fear over their loved ones (62.7%) and their own future (27.7%) or with anger (36.3%), the majority of respondents felt a strong willingness to act (65.3%). Table 2 shows that the main reason why students decided to volunteer during the coronavirus pandemic was their belief that the role of a medic is to engage and help those in need whatever the risk (24.4%). Next was their desire to help others (22.2%), followed by the willingness to be a part of something important (14.5%), the desire of gaining skills useful in their future profession (10.9%) and the belief that volunteering was better than sitting at home and studying or being bored (9.6%).

Table 2. Main motives of students' involvement in voluntary service during the coronavirus pandemic

What was the main reason to engage in voluntary service during the coronavirus pandemic	**N (%)**
To put my voluntary participation into my future application documents	5 (1.6)
To gain experience needed in my future profession	34 (10.9)
To establish new connections that will be useful in the future	1 (0.3)
I believe it is important to help others	69 (22.2)
I believe that the role of medics is to engage and help whatever the risk is	76 (24.4)
It gives me the opportunity to pay something back for all I have received myself	5 (1.6)
I wanted to be a part of something important	45 (14.5)
To experience the adventure	8 (2.6)
It gives me the opportunity to realise my passion	10 (3.2)
It is better than sitting at home and studying or to be bored	30 (9.6)
To meet new people, make new connections and friends	1 (0.3)
I was advised by my teacher/parent that I may benefit from it	2 (0.6)
I was encouraged by a friend who also volunteered	2 (0.6)
Other	23 (7.4)

Source: own elaboration.

Table 3 presents different functions of volunteering during the pandemic among students. The values function ranked the highest, with a mean of 3.88. Next was the enhancement function (M=3.19), followed by the career (M=2.97) and the social function (M=2.7). The most highly ranked altruistic/value-driven motivations were the desire to help others (M=4.41) and to give something back to the community (M=4.16), followed by the desire of being a part of something important (M=3.71) and

sonal motivations, the wish to realize one's passion (M=3.56) and the desire of having a sense of duty and pride dominated (M=3.51). On the other hand, students who were more driven by career related motivations wanted to gain new knowledge and skills that they could use in their future profession (M=3.69) and hoped to gain professional experience (M=2.57). Some also hoped for establishing new contacts that might benefit their future career (M=3.69). Less than half of the students were motivated by the desire to put volunteering on their résumé (M=2.08). The response "To help others" in our study group ranked the highest among our respondents and differed in a statistically significant way from each of the other responses (p=0.000). The least ranked motivations referred to the social dimension of volunteering: while many students wished to work with other people (M=3.41), or hoped to make new friends and establish new connections (M=2.77), few students were motivated to volunteer to gain recognition from their professors or friends (M=1.92).

Table 3. Students' motivations

	1	2	3	4	5	Mean
To enhance my professional résumé (Career)	139	67	57	37	11	2.08
To get new knowledge and skills that might be useful in my future profession (Career)	24	31	68	81	107	3.69
To gain professional experience (Career)	31	35	60	103	82	3.55
To make new contacts that might help me in the future (Career)	76	80	79	53	23	2.57
To help others (Value)	3	10	28	84	186	4.41
To give something from myself to the community (Value)	8	18	41	93	151	4.16
To realize the duty of public service inherent to the medical profession (Value)	46	38	57	69	101	3.45
To help succeed in the fight against the pandemic (Value)	24	29	59	107	92	3.69
To participate in something important (Value)	25	31	59	90	106	3.71
To have a sense of duty and pride (Enhancement)	29	47	52	101	82	3.51
To realize my passion (Enhancement)	27	33	73	95	83	3.56
To experience the adventure and to tell my kids in the future that I was a part of it (Enhancement)	78	61	64	70	38	2.77
To fill free time (Enhancement)	78	45	63	74	51	2.92
To make new friends and establish new connections (Social)	76	80	79	53	23	2.77
To work with other people (Social)	30	49	68	93	71	3.41
To gain the recognition of my professors, family and friends (Social)	146	82	48	32	3	1.92

Source: own elaboration.

The comparison of the results of the students' responses, when divided into groups according to the faculty or year of study, was inconclusive. Significantly statistical differences were revealed when we divided volunteers by gender and according to the importance of religion

in their life. In Table 4 differences in motivation are presented for the subgroups created according to the above criteria. In the group of students in whose life religion plays a significant role we had 26 females and 10 males, so there was no gender disproportion in this subgroup in comparison with the whole study group (p=0.7). The motivation differences between gender groups were found in 4 cases, and between the groups identified on the basis of the attitude to religion – in 5 cases.

Table 4. Motivation differences in sub-groups

Question	Female vs. male (216 vs. 95)				Students in whose life religion plays significant role vs. others (275 vs. 36)			
	t	df	P	Cohen's d	t	df	p	Cohen's d
To enhance my professional résumé	0.481	182.486	0.631	0.059	1.888	46.472	0.065	0.324
To get new knowledge and skills	1.136	165.266	0.258	0.142	-0.259	42.675	0.797	-0.048
To gain professional experience	0.672	179.136	0.502	0.083	-0.184	44.574	0.855	-0.033
To make new friends and establish new connections	-0.309	172.353	0.757	-0.038	0.367	42.441	0.716	0.068
To work with other people	1.372	167.920	0.172	0.171	-0.550	42.035	0.585	-0.103
To help others	3.190	141.469	**0.002**	0.414	-7.119	125.116	**<0.001**	-0.806
To give something from myself to the community	2.060	155.378	**0.041**	0.262	-4.597	68.686	**<0.001**	-0.631
To realize the duty of public service inherent to the medical profession	1.430	167.185	0.155	0.179	-3.158	47.822	**0.003**	-0.530
To participate in something important	1.091	165.943	0.277	0.137	-1.791	43.195	0.080	-0.327
To do something important and have a sense of duty and pride	0.715	158.719	0.476	0.090	-1.836	44.192	0.073	-0.328
To help succeed in the fight against the pandemic	1.511	165.019	0.133	0.190	-1.409	43.112	0.166	-0.258
To realize my passion: helping others	1.991	173.143	**0.048**	0.247	-4.048	49.521	**<0.001**	-0.663
To experience the adventure and to tell my kids in the future that I was a part of it	-0.930	166.255	0.353	-0.116	-0.262	42.503	0.795	-0.048
To make new contacts that might help me in the future	-0.063	180.053	0.950	-0.008	-0.052	42.691	0.959	-0.010
To fill free time	-2.055	181.349	**0.041**	-0.252	3.861	45.998	**<0.001**	0.668
To gain the recognition of my professors, family and friends	-0.288	156.360	0.774	-0.037	0.328	42.945	0.745	0.060

Source: Statistically significant results are written in bold characters.

Discussion

This study shows that similar to other countries, future healthcare professionals in Poland expressed a strong interest in active participation during the current health care emergency [17–24]. This is of special importance because especially during the COVID-19 crisis many countries are challenged not only by the virus itself but also by the staff shortages which makes the managing of patients even more difficult. This in turn, creates the risk that the entire healthcare system might collapse. The study also shows that while volunteerism constitutes the chief example of civic consciousness and responsibility it has much in common with social activism which if primarily focused on acting together for a common and specific purpose [25].

At the same time, while many research endeavours suggest that the frequency of traditional, value-based volunteering is decreasing and especially young peoples' volunteering is more oriented toward personal growth and their career [4–9] this study reveals that more students agreed with the motivational statements associated with altruism and public service, while the career and social dimension of volunteering recorded much lower means. Although all the students were aware of the potential benefits of volunteering in terms of acquiring new skills or experiences that might benefit their future professional career, either through establishing new connections or enhancing their professional résumé, career motivations were not the main reason for becoming involved. On the contrary, most students were driven by the ideal of doing good, helping others and giving something back to the community. This is in line with other studies that emphasized the importance of these values over other motivations. For example, Gage and Thapa [15] found that students' volunteerism is mostly motivated by their desire to help others and expand their character.

What is important is that among altruistic reasons the prime motivator was students' belief that volunteering during the COVID-19 outbreak was a unique vocation, i.e. they believed that as future health professionals it was their duty to engage and help whatever the risk. Thus, in con-

trast to Cloke et al. [26] who showed that people volunteer because 'they want to' rather than out of a sense of civic responsibility, this study shows that in the time of an epidemic students were also motivated by the ethical imperative to serve society, healthcare professionals and those who are disadvantaged. This should not come as a surprise because when asked why they chose medicine many students respond that they are driven by the desire to help people [14, 17–24, 27].

Nevertheless, in accord with Fényes and Pusztai [9], many volunteers from our study reported being driven by more individualistic and career motives, i.e. they hoped that volunteering will help them to grow personally, gain new knowledge and skills or develop their personal career. At the same time, although students were motivated to some degree by a general awareness of the need to enhance their CV, the desire to pass their summer internships or to gain recognition from others, including their professors, rarely was any of these motives in the first place, though they were acknowledged by many, though not all, students. Thus, although Handy et al. [8] rightly suggest that many students focus on the so called résumé building in volunteering, this study confirms Holdsworth's [12] observation that the learning opportunities of volunteering are not necessarily directly related to future employment opportunities or to current studies, but may be more to do with young people's negotiation of their transition to adulthood. Thus, while students recognised that volunteering is something to put on their résumé, for the majority it was in the nature of an additional benefit rather than a prior motivation. Nevertheless, students were aware that by helping others they were also helping themselves. Finally, this study did not reveal a group of students motivated by social reasons, i.e. the desire to make new friends and work with other people. At the same time, it should be stressed that students' volunteering motivations were often a mixture of altruistic and egoistical drivers [4, 5, 7, 8, 12].

Finally, this study shows that gender and religiosity were the key factors that determined students' motivations to volunteer. In general, females and students who defined themselves as practicing believers for whom religion was important, favoured value-expressive motivations, primarily the feeling of moral duty and the desire of helping others, more

often, while males and nonbelievers frequently favoured instrumental attitudes [7–9, 14, 2]. Moreover, it seems that the influence of religiosity on volunteers' motivations was stronger than the one of demographic characteristics.

Strengths and limitations

Although to the best of our knowledge this is the first study on the future healthcare professionals' students' motivations to volunteer during the COVID-19 pandemic, it also has a few limitations. First, although the questionnaire was sent to all students who engaged in the voluntary project such non-random sampling prevented an analysis of the socio-demographic and socio-cultural background of the issues discussed in the research. Second, although the response rate was high, the study included students from only one medical university in the country. Third, this study represents solely the opinions of students who agreed to participate in the study. Consequently, the results cannot be generalized on the entire population of future health professionals. Finally, to understand better volunteers' motivations more in-depth studies would be required. However, some advantages of this study should also be acknowledged. Most importantly, as this is the first study on students' motivations to volunteer during a coronavirus pandemic in Poland, it may stimulate further research on the topic.

Conclusions

While many research endeavours show that, increasingly, young people volunteer mostly for individualistic reasons, this study suggests that during the coronavirus epidemic students' reported being mainly driven by altruistic and community orientated reasons. Nevertheless, although most of the students who declared that after hearing about the epidemic they felt a strong willingness to act, it seems that even in a time of health crisis in reality volunteering serves many purposes. Indeed, while value-based motivations were the primary force behind students' volunteering

followed by personal enhancement motivations, many respondents wanted to learn new skills and gain professional experience or establish new contacts. Nevertheless, for most of the students volunteering was not a part of a strategic goal to enhance their CVs. What is also important is that students' religiosity seems the key factor that determined their motivations.

Authors' contributions

JD designed the study and collected the data. DW performed the statistical analyses. JD and DW conducted the literature search, had full access to all of the study data, discussed the results of the questionnaire and interpreted the data. Both authors wrote the manuscript and approved its final version.

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Conflict of Interest

The authors declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical approval

This study was performed in line with the principles of the Declaration of Helsinki. The questionnaire and methodology for this study were approved by the vice-rector for didactics of the PUMS, Poland and the USCB. Ethics approval and research governance approval were obtained from the PUMS Bioethics Committee (KB – 831/20).

Informed consent

Informed consent was obtained from all individual participants included in the study.

References

1. Portal gov.pl. Koronawirus: informacje i zalecenia [Internet]. Available from: https://www.gov.pl/web/koronawirus [cited 1.07.2021].

2. Poland Coronavirus: Worldometer [Internet]. Worldometers.info. Available from: https://www.worldometers.info/coronavirus/country/poland/ [cited 1.07.2021].

3. **Mroczek A.** Dane resortu zdrowia o zakażeniach i kwarantannie wśród medyków [Internet]. Available from: https://cowzdrowiu.pl/aktualnosci/post/dane-resortu-zdrowia-o-zakazeniach-i-kwarantannie-wsrod-medykow [cited 13.04.2021].

4. **Hustinx L.** Individualism and new styles of youth volunteering: An empirical exploration. Voluntary Action 2001; 3(2): 47–55.

5. **Brooks K.** Talking about volunteering: A discourse analysis approach to volunteer motivations. Voluntary Action 2002; 4(3): 13–50.

6. **Hustinx L, Lammertyn F.** Collective and reflexive styles of volunteering: A sociological modernization perspective. Society 2003; 14(2): 167–187.

7. **Rehberg W.** Altruistic individualists: Motivations for international volunteering among young adults in Switzerland. Voluntas 2005; 16(2): 109–122.

8. **Handy F, Cnaan RA, Hustinx L, Kang C, Brudney JL, Haski-Leventhal D, Holmes K, Meijs LCPM, Pessi AB, Ranade B, Yamauchi N, Zrinscak S.** A cross-cultural examination of student volunteering: Is it all about résumé building? Nonprof Volunt Sec Q 2009; 39(3): 498–523.

9. **Fényes H, Pusztai G.** Volunteering among higher education students. Focusing on the micro-level effects on volunteering. J Soc Res Policy 2012; 3(1): 73–95.

10. **Clary EG, Snyder M, Ridge RD, Copeland J, Stukas AA, Haugen J, Miene P.** Understanding and assessing the motivations of volunteers: A functional approach. J Pers Soc Psychol 1998; 74(6), 1516–1530.

11. **Clary EG, Snyder M.** The motivations to volunteer: Theoretical and practical considerations. Curr Dir Psychol Sci 2002; 8(5): 156–159.

12. **Holdsworth C.** Why volunteer? Understanding motivations for student volunteering. Brit J Educ Stud 2010; 58(4): 421–437.

13. **Cnaan RA, Smith KA, Holmes K, Haski-Leventhal D, Handy F, Brudney JL.** Motivations and benefits of student volunteering: comparing regular, occasional, and non-volunteers in five countries. Can J Nonprof Soc Econ Res 2010; 1(1): 65–81.

14. **Fletcher TD, Major DA.** Medical students' motivations to volunteer: An examination of the nature of gender differences. Sex Roles 2004; 51(1/2): 109–114.

15. **Gage RL, Thapa B.** Volunteer motivations and constraints among college students: Analysis of the volunteer function inventory and leisure constraints models. Nonprof Volunt Sec Q 2011; 41(3): 405–430.

16**. Eurostat. Brancato G, Macchia S, Murgia M, Signore M, Simeoni G, Blanke K, Körner T, Nimmergut A, Lima P, Paulino R, Hoffmeyer-Zlotnik JHP**. The handbook of recommended practices for questionnaire development and testing in the European statistical system, 2004 [Internet]. Available from: https://unstats.un.org/unsd/EconStatKB/KnowledgebaseArticle10364.aspx [cited 13.06.2021].

17. **Rupley D, Grilo SA, Kondragunta S, Amiel J, Matseoane-Peterssen D, Catallozzi M, Westhoff CL.** Mobilization of health professions students during the COVID-19 pandemic. Semin Perinatol 2020; 44(7): 151276. https://doi: 10.1016/j.semperi.2020.151276.

18. **Rasmussen S, Sperling P, Poulsen MS, Emmersen J, Andersen S.** Medical students for health-care staff shortages during the COVID-19 pandemic. Lancet 2020; 395(10234): 79–80.

19. **Gallagher T, Schleyer A.** "We signed up for this!" – student and trainee responses to the COVID-19 pandemic. New Eng J Med 2020; 382:e96. https://doi: 10.1056/NEJMp2005234.

20. **Miller DG, Pierson L, Doernberg S.** The role of medical students during the COVID-19 pandemic. Ann Intern Med 2020; M20–1281. https://doi: 10.7326/M20-1281.

21 **Drexler R, Hambrecht JM, Oldhafer KJ.** Involvement of medical students during the coronavirus disease 2019 pandemic: A cross-sectional survey study. Cureus 2020; 12(8): e10147. https://doi.org/10.7759/cureus.10147.

22. **Thomson E, Lovegrove S.** 'Let us help' – Why senior medical students are the next step in battling the COVID-19 Pandemic. Int J Clin Pract 2020; 74(8): e13516. https://doi: 10.1111/ijcp.13516.

23. **Soled D, Goel S, Barry D**, Erfani P, Joseph N, Kochis M, Uppal N, Velasquez D, Vora K, Scott KW. Medical student mobilization during a crisis: Lessons from a COVID-19 Medical Student Response Team. Acad Med 2020; 95(9): 1384–1387.

24. **Stokes DC.** Senior medical students in the COVID-19 response: An opportunity to be proactive. Acad Emerg Med 2020; 27(4): 343–345.

25. **Ayala L.** Trained for democracy: The differing effects of voluntary and involuntary organizations on political participation. Polit Res Quart 2000; 53(1): 99–115.

26. **Cloke P, Johnsen S, May J.** Ethical citizenship? Volunteers and the ethics of providing services for homeless people. Geoforum 2007; 38(6): 1089–110.

27. **Schroeder T, Dhatt R, Hudson J, Nyhof-Young J.** Investigating barriers to volunteerism in a medical school volunteer patient program: A program development project. Univ Tor Med J 2017; 94(2): 42–46.

28. **Cnaan RA, Amrofell LM**. Mapping volunteer activity. Nonprof Volunt Sec Q 1994; 23(4): 335–351.

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Selected Unfair Business Practices in the Time of COVID-19 Pandemic

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Abstract

Objectives: One of the main objectives of the paper is to present and describe some unfair and unethical business practices in the health sector during the ongoing pandemic.
Research design & methods: The Authors conducted a comparative research study using public reports, administrative proceedings and national legislations.
Findings: The study revealed that the described malpractices and misconducts occurred on examined markets intensified during the pandemic. Some of them happened for the first time on this occasion.
Implications/Recommendations: The public governances and other competent organs should continue their supervisory activities and public information and education campaigns in order to highlight the frauds and unethical conducts that occur and will occur on the market.
Contribution/Value added: The Authors decided to conduct their research on this specific topic not only because it constitutes a particularly relevant issue in this critical time, but also because there is a lack of such comprehensive and comparative presentation of the unethical and deceitful practices that took place in the public health sector due to the spread of COVID-19.

Article classification: research article

Key words: unethical conducts, health sector, consumer protection, COVID-19, unfair business practices
JEL classification: I18; K19

Introduction

As the new virus spread across the world, many traders found a new way to gain some extra profits through unethical, aggressive and illegal practices.

In other words, one could say that the rapid spread of the SARS-CoV-2 virus is accompanied by the rapid spread of numerous, ever-rising scams and abusive practices aimed at deceiving a vast range of worried and anxious people. The pressure selling techniques of various products and services can not only be overwhelming and confusing, but they can, and very often they do in fact, be dangerous and harmful to many consumers. Many traders by generating false pressure and disorientation tend to deprive consumers of the sufficient time to make a sound and informed purchasing decision.

In this particular period of persistent uncertainty, it is very easy to fall into the trap and to be fooled by unethical practices and false, unrealistic, 'healthcare' promises made by dishonest professionals.

Due to the spread of COVID-19 around the world, many of us are concerned about our and our families' health and life. In this arduous moment we are particularly susceptible to be fooled by manipulating advertising claims regarding dreamlike treatments, medications, medical and non-medical devices that would be able to 'help', 'provide relief', 'prevent', 'protect against', 'diagnose', 'cure', 'combat' the SARS-CoV-2 virus (COVID-19) or its side effects.

Rogue vendors promise or even guarantee the extraordinary, magical effects of their offered products or services. To do so, they make use of various deceptive, misleading or even aggressive sales strategies, such as 'right here and right now', 'the unique opportunity', 'special discount', and so on. They exploit the customer's altered judgment skills caused by fear and anxiety about the ever-increasing number of infected people and the risk of death.

The misleading advertisements may use false certificates, licenses or endorsements (through a logo or name) from medical professionals, experts, celebrities, national or international institutions or government agencies, academic reviews, scientific results or articles.

Some groups of people are more vulnerable than others because of their age, illiteracy, health problems, naivety, lower resistance to pressure, and so forth. Nevertheless, anyone could be a victim. Therefore, the issue is greatly relevant and even very dangerous in certain cases.

These practices may take place on the Internet (so-called online scams) or in the storefronts and may concern different kinds of products or services. For these reasons, special attention should be paid to all information, claims and products' features provided by traders, as they may not only be 'innocent', ineffective or unnecessary, but also fake or even dangerous to our life or health.

We must be aware that currently there is "no scientific proof that any food or food supplements can cure or prevent COVID-19 infections" [1].

As it will be illustrated, there are a wide range of fraudulent behaviours that have occurred and still occur in almost every single country. However, the present paper focuses on only a few selected countries, in particular Poland and Italy.

The 'Covid-19 unfair practices'

This section briefly describes some kinds of deceitful practices of dishonest professionals that occurred during the last year of the pandemic. It aims also at presenting some selected important measures taken by the national competent authorities in order to combat these dishonest and abusive conducts and behaviours.

The particular attention is paid to the Italian Antitrust Authority (*Autorità Garante della Concorrenza del Mercato*, AGCM) and the Polish Competition Authority (*Urząd Ochrony Konkurencji i Konsumentów*) that supervise and enforce national laws and other sectoral regulations regarding unfair commercial practices and misleading advertising.

As it has been reported by the Advertising Standard Authority of New Zealand, advertising claims regarding COVID-19 can be actual or implied.

Actual claims, such as "this product helps treat the symptom of COVID-19 infection" are generally obvious to customers.

The implied assertations are less obvious. Implied claims can be present in advertisings through the use of words, phrases, sound and imagery (or a combination of these) such that a consumer who views or hears the advertisement draws the conclusion that the claim is related to

COVID-19. For example, "this product will help protect you from the currently circulating viruses and other bugs" [2].

• The 'Wish' platform

The investigation [3] lunched on 31 March 2020 by the Italian Authority, AGCM, was referred to the sale of the products for "the prevention of contagious from" [4] the COVID-19. The products in questions were the FFP2 masks, mask and gloves explicitly promoted as 'anti-coronavirus', a special *test* kits [5] to self-diagnose the presence of the virus. However, after the intervention of AGCM, the professionals responsible for the platform have adopted new policies, which satisfied the Authority.

• Tiger Shop

On 8 April 2019 the AGCM opened an investigation [6] against Tiger Group S.r.l., a company present on the Italian market. In this case, the Authority adopted a special *interim* measure, ordering the suspension, of the advertising and sale of the FFP2 category protective masks on the online shop 'tigershop.it'. The advertised products were considerably different from those that consumers received. The products did not possess all the advertised properties; there was no proof of the vaunted certification. They were offered at high prices and with claims, such as "the last pieces available", moreover the actual delivery time was significantly longer than the one promised by the trader on his website (24/48h). For these reasons, the practices in question were likely to mislead a large number of consumers, and therefore, in the light of the gravity of the infraction and the urgency, the adoption of the urgent measure (the suspension) was considered essential.

• Oxystore.it [7]

The practices in question consisted of the advertising of products for oxygen therapy that claimed unproven antiviral and anti-COVID-19 capabilities. The website contained suggestive claims about the ability to combat COVID-19 by promoting oxygen therapy as one of the most effective solutions for treating symptoms associated with the

Coronavirus. The trader attempted to sell 'prevention kits' [8] designed by 'Oxystore' for 995 euros and to exploit consumers' fear through exaggerating descriptions about the sanitary situation. The AGCM found the advertisements and claims to be misleading and false. They were highly susceptible to induce consumers into believing that the Oxygen Therapy, through the oxygen concentrator, would be able to prevent the Coronavirus[4]. In addition, the professional did not include any information about the possible risk or collateral effects of using of the product. In consideration of the gravity of the infraction, the Authority ordered the immediate elimination of any reference to the preventive and therapeutic efficacy of the advertised products against COVID-19.

- *Kaletra* drug

This is a case of the promotion and marketing of an antiviral drug [9] for the treatment of HIV infections (sold exclusively on medical prescription). Kaletra "was advertised as a product with proven effectiveness against coronavirus and offered at a price of about 384 euro for the small pack or 659 euro for the large pack" [10]. The Italian Authority ordered the immediate suspension of the promotional practices because of the illegal, misleading and aggressive conducts of two online pharmacies.

- *Amantadyna* drug

A similar case has also occurred in Poland, where some public individuals, such as Vice Minister of Justice [11] have informed about positive effects of the drug called Amantadyna (Amantadine). This drug is generally used to treat the *Influenza A* virus and Parkinson's disease. However, the alleged good effects of Amantadyna for the treatment of the Coronavirus were first affirmed by a doctor from Przemyśl – Włodzimierz Bodnar.

The issue is particularly serious and potentially dangerous because there is no scientific evidence of Amantadine's ability to cure the Coronavirus. It becomes even more relevant when the affirmations come from a specialist. This case not only triggered a public discussion among

4. Similar situation occurred in the case of marketing and selling of the drug called 'Kaletra'.

experts, but it has also involved the Office of Professional Liability in Kraków which is an organ of the Supreme Medical Chamber (*Naczelna Izba Lekarska*). Moreover, a resident of Przemyśl submitted a notification to the Public Prosecutor's Office in Przemyśl accusing, *inter alia*, doctor Bodnar, the National Health Fund (*Narodowy Fundusz Zdrowia*), the Sanitary Inspector of Przemyśl, the Supreme Medical Chamber and others of conscious endangering the lives and health of citizens due to their inertia regarding the potentially dangerous statements about Amantadine provided by doctor Bodnar[5].

- 'Covid fees'

It is worthy stressed, that not only unfair conducts of dishonest professionals may be detrimental to consumers, but there are also many other circumstances related to trustworthy subjects and professionals, such as pharmacies that rapidly increase the prices of some specific products (i.e. protective masks and other devices, medications, vitamins, food supplements, sanitizer products) or doctors, dentists, etc., by increasing the prices for their services, so-called additional service fees, or 'Covid fees'[6].

- Exploitative wholesale pricing for hospitals

In February, two wholesalers terminated the contracts with hospitals for the supply of personal protective equipment to subsequently obtain higher prices for the same products.

Thus, these were not just the sudden price increases for specific products sold to hospitals, but a deliberate practice of withdrawing from contracts in order to fix prices. The increased prices appeared without any objective justification. For this reason, the intervention of the Polish Competition Authority was justified.

As the President of UOKiK stated, these practices are "not only shameful, but also contrary to the law" [12]. Moreover, the questioned action may violate not only the consumer and competition laws, but also

5. For more detailed information *see* https://korsosanockie.pl/wiadomosci/doktor-wlodzimierz-bodnar-oskarzany-przez-mieszkanca-przemysla-jest-zawiadomienie-do-prokuratury/nfYSKX7SHT14MPzkUwqQ.

6. As an example, *see* https://www.uokik.gov.pl/news.php?news_id=16459&news_page=8.

the polish "Penal Code provisions by causing a state of widespread danger to life or health" [12].

- Vaccine Lottery in Germany [13]

The case regards vaccination in at a nursing home Frankfurt, where a 'lottery' was organised among the patients in order to identify who and when should receive a coronavirus vaccine. The case was reported on Twitter by Lutz Stroppe, former Secretary of State of the German Health Ministry.

As we could note, there are several kinds of unlawful, unfair and dishonest practices that have occurred, are occurring and may still occur in the next days and months.

They mislead, confuse and scam many consumers, abuse their trust and exploit the (medical) illiteracy of many of them. Sometimes they are exaggerated, emphasising false qualities, rising and/or promising unrealistic expectations and effects. They play on the consumer's fear in these particularly unpredictable times.

The measure to be taken shall be decisive but also carefully balanced because; as it has been noted by OECD "bringing excessive pricing cases in a crisis also comes with risks. Interventions aimed against price increase can lead to diversion of products to the places where prices are not regulated, and hence allowed to increase" (OECD, 2020, p. 4).

'Anti-Covid' movements

Another highly dangerous, ever-growing problem is the proliferation of various groups that attempt to negate the existence of COVID-19 or the use of protections, such as 'no masks', 'no vax', and so on.

These movements generate much fake news. Thus, readers are provided with harmful conspiracy theories [14]. They falsely claim that wearing protective masks can be harmful to our health, or encourage people to ignore social distancing, and so on.

They believe that situations and events that are difficult to understand are secretly planned and manipulated by some powerful forces. Conspirators offer explanations, ignore scientific evidence, provide evidence that fits and supports their theories. "They falsely suggest that nothing hap-

pens by accident and that there are no coincidences" [14]. Due to the fast-moving information environment, fake news and conspiracy theories are spread very quickly through many different communication channels, such as social networks, blogs, radio, TV, forums, and can come from various sources, such as friends, family members, colleagues, some specialists and professionals (i.e., actors, politicians or even doctors with different opinions). These practices can have serious consequences in the society, especially when they come from potentially trustworthy people.

As it has been stated by the Director-General of UNESCO: "Conspiracy theories can cause real harm to people, to their health, and also to their physical safety. They amplify and legitimize misconceptions about the pandemic and reinforce stereotypes which can fuel violence and violent extremist ideologies" [15].

One of the most recent dangerous cases occurred in the USA [16], where a pharmacist, employee of a hospital in Wisconsin, have manipulated and damaged over 500 doses of coronavirus vaccines at the hospital (by leaving them outside the refrigerator for many hours). He believed the vaccines could be harmful to humans and capable of altering their DNA, leading to "the end of the world". He was arrested and accused of endangering safety and damages to property.

Consequently, as we can see, the spread of fake news may produce many different effects, from sudden price increases for products and services, misleading marketing and the sale of 'magical' products, to the proliferation of false and conspiracy theories that can greatly endanger the public health sector.

In many countries there are guidelines and advice[7], warnings, and even Browser extension[8] regarding false news, statements, unverified claims, and misleading contents. However, there is evidence that the spread of misinformation is also so by computer-controlled robots (so called Bots) [17, 18]. In this matter, BigTech companies and other website providers

7. *See* https://ec.europa.eu/info/sites/info/files/live_work_travel_in_the_eu/unesco-conspiracy-english-1.jpg; Polish project called 'FakeHunter' [https://fakehunter.pap.pl]; Italian project called 'Cartesio' [https://cartesio.news].

8. As an example, *see* NewsGuard [https://www.newsguardtech.com/].

must take immediate and appropriate actions in order to remove the false information and, if possible, ban the fake content suppliers.

Conclusions

Thus, as we could note, there are many practices which are able to induce consumers (already significantly conditioned by the current emergency), to purchase products on the basis of the belief generated by misleading or false advertisements. It must be emphasised that therapeutic and health advertising is very important as consumers often rely on such products, devices and services for their health and well-being[9].

Practices that exploit the anxiety and fear of the consumers to induce them to purchase the advertised products must be promptly banned and punished.

Consumers have to keep in mind that, in accordance with the legal provisions, such as Unfair Commercial Practice Directive[10] and national legislations, no claims are allowed which imply that a product has characteristics or functions that it does not have.

Moreover, making false affirmations that a product is unique or that a quantity is limited, such as 'last pieces', 'only available today'[11] and so on, in order to push customers into buying it quickly is another unethical plot.

In such situations, consumers should report misleading, deceptive or false claims and advertisings directly to the online platform or to the consumer protection authorities. There is also a specific tool called 'Safety Gate'[12] provided by the European Commission that can help identify dangerous non-food products found in European Union countries. It also

9. In accordance with the Principle 1 of the Therapeutic and Health Advertising Code of New Zealand.

10. As an example, 'Falsely claiming that a product is able to cure illnesses, dysfunctions or malformations' No. 17 of Annex I (so-called 'blacklist') of the Unfair Commercial Practices Directive.

11. No. 7 of Annex I (so-called 'blacklist') of the Unfair Commercial Practices Directive prohibits in all circumstances to state that a product is only available for a very limited time when it is not true.

12. https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications&lng=en.

provides information on the risks and the measures taken by national competent authorities in order to prevent or restrict the marketing and sale of dangerous goods.

Moreover, consumers should be cautious about believing every information, statement and theory present on the Internet, including those shared by family or friends. We should verify the real source and the reliability of claims before sharing them with others to prevent the spread of fake news. Special attention should also be paid to dangerous public affirmations made by specialists who induce consumers to cure the Coronavirus by their own by assuming medications developed and prescribed for a different infection or virus.

Thus, as it has been reported, there are many actions taken at European and national levels aimed at stopping scams and tackling unfair commercial practices. Nonetheless, consumers should try to self-assess the risks and protect themselves by being more cautious and paying more attention to advertising, various claims, terms and conditions of contracts and highly exaggerated statements.

References

1. European Commisuin. European Commission – European Commission. Scams related to COVID-19 [Internet]. Available from: https://ec.europa.eu/info/live-work-travel-eu/consumer-rights-and-complaints/enforcement-consumer-protection/scams-related-covid-19_en [cited 15.05.2021].

2. Advertising Standards Authority. ASA – Advertising Standards Authority. AdHelp information service COVID-19 and advertising therapeutic and health products or services [Internet]. Available from: http://www.asa.co.nz/wp-content/uploads/2020/04/ASA-AdHelp-COVID-19-LAST-UPDATED-April-23-2020.pdf [cited 13.04.2021].

3. Autorità garante della concorrenza e del mercato. AGCM – Autorita' Garante della Concorrenza e del Mercato [Internet]. Available from: https://www.agcm.it/dotcmsdoc/allegati-news/PS11734%20non%20adozione%20misure%20cautelari.pdf [cited 16.04.2021].

4. Autorità garante della concorrenza e del mercato. PS11727 – ICA: coronavirus, the shutdown was ordered of the website http://testcoronavirus.shop/it that markets a test for COVID-19 self-diagnosis, 24.03.2020 [Internet]. Available from: https://en.agcm.it/en/media/press-releases/2020/4/PS11734 [cited 16.05.2021].

5. Autorità garante della concorrenza e del mercato. Stampa PS11734 – Antitrust: proceedings initiated against the www.wish.com platform, 3.04.2020 [Internet]. Available from: https://en.agcm.it/en/media/press-releases/2020/4/PS11734 [cited 14.11.2021].

6. Regolamento sulle procedure istruttorie in materia di pubblicità ingannevole e comparativa, pratiche commerciali scorrette, violazione dei diritti dei consumatori nei contratti, violazione del divieto di discriminazioni e clausole vessatorie, Uchwała nr 25411, 15.04.2015 (Włochy) [Internet]. Available from: https://www.agcm.it/dotcmsdoc/allegati-news/PS11736%20misure%20cautelari.pdf [cited 20.04.2021].

7. AGCM – Autorita' Garante della Concorrenza e del Mercato Stampa PS11732 – ICA: "Regolamento sulle procedure istruttorie in materia di pubblicità ingannevole e comparativa, pratiche commerciali scorrette, violazione dei diritti dei consumatori nei contratti, violazione del divieto di discriminazioni e clausole vessatorie", 15.04.2015 (Włochy) [Internet]. Available from: https://www.agcm.it/dotcmsdoc/allegati-news/PS11732%20chiusura%20cautelare.pdf [cited 20.04.2021].

8. AGCM – Autorita' Garante della Concorrenza e del Mercato. Stampa PS11752 – ICA: antitrust acts to prevent online unfair practices: proceedings against vova.com, for the sale of Covid-19 prevention and diagnostic products, 29.04.2020 [Internet]. Available from: https://en.agcm.it/en/media/press-releases/2020/5/PS11752 [cited 15.05.2021].

9. AGCM – Autorita' Garante della Concorrenza e del Mercato. PS11722 – ICA: coronavirus emergency, the authority orders the removal of any reference to preventive effectiveness against COVID-19 with respect to the products advertised and marketed on the https://carlitashop.com website and the associated ins-

tagram page, 22.03.2020 [Internet]. Available from: https://en.agcm.it/en/media/press-releases/2020/3/PS11722 [cited 17.05.2021].

10. AGCM – Autorita' Garante della Concorrenza e del Mercato. PS11733-PS11735 – ICA: coronavirus emergency, the Authority orders the shutdown of the https://farmaciamaschile.it and http://farmacia-generica.it websites, 30.03.2020 [Internet]. Available from: https://en.agcm.it/en/media/press-releases/2020/4/PS11733-PS11735 [cited 17.05.2021].

11. **Czermiński J.** Rzeczpospolita [Internet]. Wiceminister: Amantadyna działa skutecznie na COVID, 12.01.2021. Available from: https://www.rp.pl/Koronawirus-SARS-CoV-2/210119831-Wiceminister-Amantadyna-dziala-skutecznie-na-COVID.html [cited 18.04.2021].

12. Office of Competition and Consumer Protection. UOKiK – Strona główna [Internet]. UOKiK – About us – About us – News – UOKiK's proceedings on wholesalers' unfair conduct towards hospitals, 04.03.2020. Available from: https://www.uokik.gov.pl/news.php?news_id=16277&news_page=11 [cited 18.05.2021].

13. **Web R.** Il Messaggero. Germania choc, lotterie nelle case di riposo per stabilire chi deve essere vaccinato, 02.01.2021. Available from: https://www.ilmessaggero.it/mondo/lotteria_vaccino_germania_anziani_rsa_cosa_sta_succedendo_davvero-5677172.html [cited 16.05.2021].

14. European Commission – European Commission. Identifying conspiracy theories [Internet]. Available from: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/fighting-disinformation/identifying-conspiracy-theories_en [cited 15.05.2021].

15. UNESCO. #ThinkBeforeSharing – Stop the spread of conspiracy theories [Internet]. Available from: https://en.unesco.org/themes/gced/thinkbeforesharing [cited 15.04.2021].

16. CNN. Wisconsin police arrest former hospital worker whose alleged actions led hospital to throw out more than 500 vaccine doses, 01.01.2021 [Internet]. Available from: https://edition.cnn.com/2020/12/31/us/wisconsin-coronavirus-vaccine-vials/index.html [cited 16.04.2021].

17. NPR Cookie Consent and Choices [Internet]. Researchers: nearly half of accounts tweeting about coronavirus are likely bots, 20.05.2020 [Internet]. Available from: http://www.npr.org/sections/coronavirus-live-updates/2020/05/20/859814085/researchers-nearly-half-of-accounts-tweeting-about-coronavirus-are-likely-bots?t=1590061905702&t=1611222577632 [cited 19.04.2021].

18. European Commission. Safety Gate for dangerous non-food products [Internet]. Available from: https://ec.europa.eu/safety-gate-alerts/screen/webReport [cited 21.05. 2021].

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The Use of Latex Powdered Gloves in Health Care and Skin Problems on the Hands: A Pilot Study in Croatian Hospitals

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Abstract

Background: The prevalence of latex allergy in the population of health-care workers is higher than in the general population. In the last decade, the use of powder gloves has been reduced or banned due to the risk of

developing adverse effects and diseases to individuals exposed to them. Latex gloves are used on a daily basis in Croatian hospitals. Powdered latex gloves are still in everyday use in Croatia.

Objectives: The aim of this cross-sectional study was to do screening among healthcare professionals for hand diseases after wearing gloves, and to test a positive correlation between symptoms on the hands and work in the hospital.

Subjects and methods: The data were collected by the self-assessment questionnaire The Latex Allergy Screening Questionnaire. The participants were healthcare workers who regularly use latex gloves in hospitals.

Results: The study included 455 healthcare workers: 361 nurses, 71 physicians, and 23 other healthcare workers. The most often symptoms of dermatitis occur in workers who use gloves for more than three hours a day, with the highest frequency in the group wearing gloves between 3 and 5 hours a day. Contact dermatitis develops more significantly in the participants who wear gloves more than 5 hours a day (P=0.001). Of all participants, after latex glove use, 45.05% had various symptoms on the skin of the hand related to gloves use and 18% reported contact urticaria after contact with latex gloves. Most of them (89.8%) who suffered from various symptoms related to gloves, did not have any symptoms when they were on holiday or sick leave.

Conclusion: Nearly half of the participants have some problems with the skin after wearing latex gloves. Most participants have had those symptoms withdrawn when they took a sick leave or a vacation. The ban on powdered gloves should be considered as a preventive measure.

Key words: rubber gloves; health care workers; occupational health, hospital

Introduction

Latex (lat. Latex) as a natural and high quality product has a wide use in the clinical and dental practice, rubber industry, footwear industry, chil-

dren's toys, in the manufacturing of various rubber products such as dental prostheses, braces and condoms. In medicine, it is mostly used for making gloves and various types of catheters [1, 2]. Ninety-nine percent of natural rubber comes from a single source: a white milky fluid from the plant Hevea Brasiliensis. There are many proteins in the cells of the natural milky liquid of latex which are known to be strong allergens [3–6], especially if the trees are treated with stimulant and unnaturally forced to grow. Latex exposure at a workplace is one of the major risk factors for developing latex allergy [2, 5, 7, 8, 9]. The frequent use of latex gloves, especially powdered gloves, classifies healthcare professionals into the risk group for the development of professional allergies [10, 11, 12]. The risk is related not only to health care providers, but also to patients who may experience severe hypersensitivity reactions [13].

The frequency of latex allergy is higher in people with atopic diathesis, eczema or allergies to fruits and vegetables [14–16]. In the mid-1990s, the prevalence of allergy to Heva proteins in the general population was estimated to 3 to 9.5 percent [5–7]. Wu and authors conclude that high prevalence of latex allergy remains among healthcare workers, susceptible patients, and general population worldwide (9.7%, 7.2%, and 4.3%, respectively) [17]. Allergic reactions are most often manifested as skin allergies of varying degrees [18, 19]. The most severe reactions among patients occur during invasive surgical procedures, because they enable a rapid absorption of allergens [20].

In 2016, the American Food and Drug Administration (FDA) banned the use of powdered medical gloves because of a high risk of developing adverse effects and diseases to individuals exposed to them [27]. The risk relates to health care providers but also to the patients who may experience severe respiratory tract infections and hypersensitivity reactions. Powder particles can stimulate the immune response of the patient's body during surgery, leading to granuloma formation around the powder particle or the formation of adhesion, which can lead to surgical complications [19]. However, in many products in the world there are only limited number of latex derived products that have been approved and regulated by government agencies, such as FDA, whereas the majority of finished products do not label whether they contain latex. Latex gloves are

used on a daily basis in Croatian hospitals. Powdered latex gloves are still in common use in Croatia. The aim of the study was to research the prevalence of the hand dermatitis of healthcare workers in hospitals, and to test the positive correlation between dermatitis and work in hospital, as well as positive correlation between symptoms of allergic reactions to the commercial products in everyday life.

Methods

The standardized Allergy Screening Questionnaire, created by the American Latex Allergy Association – ALAA translated to Croatian, was used in the study [21]. The self-reported questionnaire is used for screening for latex allergy and the participants reported all the skin problems related to the use of latex gloves.

The final survey questionnaire collected additional following data: job position, occupation, length of service, gender, age group and the hours of wearing gloves daily. Prior to completing the questionnaire, the participants signed the informed consent form. The filled questionnaires were collected in special boxes.

Healthcare workers in two Croatian hospitals were invited to fill in the questionnaire, and they received written information about the research and the approval of the hospital management and Ethics Committee. The participation in the study was anonymous and voluntary. They were included in the study regardless of earlier subjective latex related disorders. Healthcare workers who were not wearing gloves as personal protective equipment were excluded from the study. The participants in this study were healthcare workers from different clinical departments who wear medical gloves at work every day. Out of 467 participants, 12 respondents did not answer the question about how often do they wear gloves daily and were therefore excluded from the statistical data processing related to the characteristics of the participants.

Research was carried out at the University Hospital Centre Zagreb and Clinical Hospital Dubrava in Zagreb (between March and May in 2018) This study was approved by the Ethics Committee of the University of Zagreb School of Medicine, by the Ethics Committee of Univer-

sity Hospital Centre Zagreb, the Ethics Committee of Clinical Hospital Dubrava, and the management of both hospitals. The hospitals confirmed that powdered latex gloves are regularly ordered by the hospitals in Croatia.

Statistical analysis

Descriptive statistics were made for all the examined variables, and the differences in the distribution of the individual categorical values were analysed by the $\chi 2$ test. All the differences with P values less than 0.05 were considered significant. In this study, the connection of contact dermatitis symptoms that occur after wearing latex gloves at a workplace with cessation of wearing gloves during a sick leave or a vacation was analysed, as well as risk factors outside the workplace that cause similar symptoms and exposure to latex in the first year of life. The software used in this analysis is IBM SPSS Statistics software version 25.0 licensed for the Faculty of Medicine, University of Zagreb.

Results

Demographic data and the data on daily glove wear are shown in Table 1. Most of the healthcare workers who participated in the study and regularly wear gloves, were nurses and medical technicians. Nurses (336/361; 93%) more often wear gloves every day (P=0.001) than doctors do (52/71; 73%). Healthcare workers who wear gloves every day, usually wear them 3 to 5 hours a day (141/410; 34.4%). The most important results were found in: the daily gloves use in hours, the withdrawal of symptoms during the sick leave or vacation, the use of latex free gloves, suspected latex allergy, and the allergic reaction after contact with a rubber product outside of work.

The most often symptoms of dermatitis occur in workers who use gloves for more than three hours a day, with the highest frequency in the group wearing gloves between 3 and 5 hours a day. Contact dermatitis develop more significantly in the participants who wear gloves more

than 5 hours a day (P=0.001). Almost half of the participants who use latex gloves responded positively to the issue of rash, itching, flaky or cracked skin, or contact dermatitis.

When asked if the symptoms of contact dermatitis withdraw after a sick leave or a vacation, about three quarter of the participants (184/205; 89.8%) answered positively. From the total of participants (N=205) who had symptoms of contact dermatitis after wearing latex gloves, 179 participants suggested they sometimes uses latex-free gloves as well. Furthermore, 149 (83.2%) of these 179 participants, stated that they had no symptoms of dermatitis related to the latex free gloves.

Anamnestic data on exposure to latex are shown in Table 2. Participants who have dermatitis at work have more often medical history of invasive procedure in the first year of life (14/205; 6,8%) than participants without dermatitis (6/239; 0,03%) (P=0.02).

Correlation between self-reported hand dermatitis at work and symptoms of allergic reactions to the latex in everyday life are shown in the Table 3. Of the total sample, 18% (82/455) indicated that they had hives, itching, redness within 30 minutes and /or vesicular disease during the day, after wearing gloves or in the presence of people wearing gloves. Healthcare workers with symptoms of contact dermatitis have significantly higher incidence of hives than people without contact dermatitis. People with symptoms of contact dermatitis are more likely to develop an allergic reaction when they are in contact with other latex-containing products such as wearing rubber clothing or elastic straps (P=0.00), blowing balloons (P=0.03), using condoms, diaphragms and other sexual aids (P=0.00) (Table 3).

Discussion

The symptoms of contact dermatitis associated with wearing latex gloves appeared in nearly half the participants (45.05%). This reaction is usually limited to the parts of the skin in contact with rubber products. Since health professionals often work in a wet environment and are exposed to many irritants, apart from allergic contact dermatitis, they can also develop irritant dermatitis so it cannot be concluded which type it is. In

some subsequent studies, allergy tests have shown that prevalence of allergic contact dermatitis is significantly lower than the overall prevalence obtained by the questionnaire [20]. This research confirmed that most of the participants that develop symptoms of contact dermatitis have professional ethology dermatitis, because 89.8% of participants responded that the symptoms completely withdraw during the vacation or a sick leave. In this research, the participants with the symptoms of contact dermatitis are more likely to have an allergic reaction outside of their workplace, such as medical examinations involving contact with mucous membranes, blowing balloons, using condoms and wearing rubber clothing or footwear (P=0,00). Contact dermatitis symptoms associated with wearing latex gloves occur more often in the participants who have undergone a surgery or other invasive procedures in their first year of life (P=0,02).

This research has confirmed that the participants with symptoms of contact dermatitis have much more frequent allergic reactions after a medical examination during which there is a contact of latex with a mucous membrane (dental, gynaecological, digital rectal exam) compared to the participants without contact dermatitis. The symptoms of an allergic reaction after a medical examination or other invasive procedure occurred at 8.3% of participants, which is significantly higher than with those who did not have the symptoms of contact dermatitis (P=0.00). This confirmed that sensitization on latex proteins in a workplace, puts workers at risk of developing allergic reactions of varying intensity during personal medical examinations. It is important to note that wearing latex gloves during an episode of irritant dermatitis enhances the absorption of latex allergen and increases the risk of developing an allergic reaction to latex [21]. Also, contact dermatitis may be the first sign of an allergy development to latex and repeated exposure to latex can lead to more serious allergic reactions [22, 23]. The literature describes an anaphylactic reaction during a gynaecological examination in a nurse suffering from latex induced contact dermatitis on her hands, to which she has been exposed continually despite the symptoms. Latex allergy in this patient was subsequently confirmed by a prick test [13].

In this study, most of the symptoms occur in workers who use gloves for more than three hours a day. Since the frequency of symptoms is

greatest in those who wear gloves for hours, there is a possibility that they have developed irritant dermatitis caused by working in a wet environment or it may be the result of re-exposure to a weak irritant such as the powder in the gloves. The research carried out at the University Hospital in Bari confirmed that the most of reported cases of dermatitis are related to irritant contact dermatitis (85.1%) most commonly caused by exposure to chemicals found in latex gloves (bacterial endotoxins, ethylene oxide, powder) and wet work [24]. Wearing gloves continuously for more than two hours (in continuity) is considered working in a wet environment [25].

There is a significantly larger number of participants who had undergone a surgery or other invasive procedures in the first year of their life, had symptoms of contact dermatitis (14/205; 6.8%) in comparison to those who had not undergone that kind of surgery (P=0.02). This research confirmed that the people who had undergone surgery or other invasive procedures in the first year of their lives, had more frequent symptoms of contact dermatitis or serious adverse events than those who had not been subjected to surgery in their infancy [26]. The literature describes a case of a four-year-old boy who developed an anaphylactic reaction five minutes after the beginning of a congenital strabismus operation. Subsequent testing confirmed the allergy to latex protein. Given that the boy had not previously been subjected to surgery, it was presumed that he had been exposed to latex through his mother who regularly used latex gloves during her work as a cosmetician in her home [20].

In this study, 18% of participants had the symptoms of urticaria associated with wearing latex gloves. What cannot be claimed with certainty is that this is an allergic reaction caused by specific latex proteins, since no specific IgE antibodies were measured in these participants. Half of the participants who had hives suffer from hay-fever, which goes in favour of atopic tendency. Other study of Work Ability Index in Croatian hospitals showed that a part of healthcare workers reported skin problems at work. Allergic dermatitis confirmed by medical doctor was present in 15% (109/721) nurses and in 15% (46/300) physicians [28].

The limitation of this study is that the questionnaire is used only for the screening on the latex allergy. It cannot be concluded that it is certainly the latex allergy, because there is no allergy test, such as prick test,

IgE antibodies or provocation test have been used. According to the literature, the most reliable indicator of latex allergy is a detailed anamnesis along with associating exposure and symptoms.

The results show that it is advisable to initiate an education on the use of latex gloves in the field of health protection at work, and to influence policy makers to ban the use of latex glove powders, which many other countries have already done [27]. After the implementation of the policy restricting the use of powdered gloves, some authors conclude that the medical community needs more understanding and education about latex gloves, latex sensitization, and available alternatives.

Conclusion

This research confirmed that healthcare workers reported dermatological symptoms related to their working conditions and personal protective equipment. In this research, it can be concluded that the skin symptoms appear dominantly on the skin of the hand and after wearing latex gloves. Nearly half of the participants in the healthcare population have changed in the skin of their hands after wearing latex gloves. Most participants with symptoms of contact dermatitis have had those symptoms withdrawn when they took a sick leave or a vacation, which goes in favour of the professional ethology of the disease. Some of them have latex-related symptoms after using the rubber products in everyday life. A further research concerning latex gloves, powdered latex gloves and other latex products in a hospital setting is important. Education about latex, the awareness about everyday products containing latex is very important, as well as avoiding powdered latex gloves since they may be an occupational hazard. The ban on powdered gloves should be considered as a preventive measure.

References

1. **Jacob JL, d'Auzac J, Prevôt JC.** The composition of natural latex from Hevea brasiliensis. Clin Rev Allergy 1993; 11(3): 325. https://doi: 10.1007/BF02914415.

2. **Alenius H, Kurup V, Kelly K, Palosuo T, Turjanmaa K, Fink J.** Latex allergy: frequent occurrence of IgE antibodies to a cluster of 11 latex proteins in patients with spina bifida and histories of anaphylaxis. J Lab Clin Med 1994; 123(5): 712–720.

3. **Breiteneder H, Scheiner O.** Molecular and immunological characteristics of latex allergens. Int Arch Allergy Immunol 1998; 116: 83–92. https://doi: 10.1159/000023930.

4. **Sussman GL, Beezhold DH, Liss G.** Latex allergy: historical perspective. Methods 2002; 27(1): 3–9. https://doi: 10.1016/S1046-2023(02)00045-2.

5. **Sussman GL, Tarlo S, Dolovich J.** The spectrum of IgE-mediated responses to latex. JAMA 1991; 265(21): 2844–2847.

6. **Ownby DR, Ownby HE, McCullough J, Shafer AW.** The prevalence of anti-latex IgE antibodies in 1000 volunteer blood donors. J Allergy Clin Immunol 1996; 97(6): 1188–1192. https://doi: 10.1016/s0091-6749(96)70183-5.

7. **Lebenbom-Mansour MH, Oesterle JR, Ownby DR, Jenett MK, Post SK, Zaglaniczy K.** The incidence of latex sensitivity in ambulatory surgical patients: a correlation of historical factors with positive serum immunoglobin E levels. Anesth Analg 1997; 85(1): 44–49. https://doi: 10.1097/00000539-199707000-00008.

8. **Bittner C, Velasco Garrido M, Krach LH, Harth V.** Content of Asthmagen natural rubber latex allergens in commercial disposable gloves. In: Cohen IR, Lajtha A, Lambris JD et al, eds. Advances in Experimental Medicine and Biology. Boston: Springer; 2016.

9. **Kujundžić Brkulj M, and Macan J.** Skin Protection at Work in Croatian Hairdressers Results of the Evahair Questionnaire Developed Within the EU Project 'Safehair'. Arh Hig Rada Toksikol 2013; 64(2): 295–303. https://doi:10.2478/10004-1254-64-2013-2333.

10. **Charous BL, Hamilton RG, Yunginger JW.** Occupational latex exposure: characteristics of contact and systemic reactions in 47 workers. J Allergy Clin Immunol 1994; 94(1): 12–18. https://doi.org/10.1016/0091-6749(94)90065-5.

11. **Baur X, Jäger D.** Airborne antigens from latex gloves. Lancet 1990; 335(8694): 912. https://doi.org/10.1016/0140-6736(90)90508-3.

12. **Turjanmaa K.** Incidence of immediate allergy to latex gloves in hospital personnel. Contact Dermatitis 1987; 17(5): 270–275. https://doi.org/10.1111/j.1600-0536.1987.tb01476.x.

13. **Zahariev Vukšinić K, Knežević B, Bogadi-Šare A, Bubaš M, Krišto D, Pejnović N.** Anaphylactic Reaction to Latex in a Health Care Worker: Case Report. Acta Dermatovenerolica Croatica 2012; 20(3): 197–214 [Internet]. Available from: https://hrcak.srce.hr/89124.

14. **Hamann CP, Kick SA.** Allergies associated with medical gloves. Manufacturing issues. Dermatol Clin 1994; 12(3): 547–559. https://doi.org/10.1016/S0733-8635(18)30159-1.

15. **Truscott W, Roley L**. Glove-associated reactions: addressing an increasing concern. Dermatol Nurs 1995; 7(5): 283–290.

16. **Phaswana SM, Naidoo S.** The prevalence of latex sensitisation and allergy and associated risk factors among healthcare workers using hypoallergenic latex gloves at King Edward VIII Hospital, KwaZulu-Natal South Africa: a cross-sectional study. BMJ Open 2013; 3(12): e002900. https://doi.org/10.1136/bmjopen-2013-002900.

17. **Wu M, McIntosh J, Liu J**. Current prevalence rate of latex allergy: Why it remains a problem? J Occup Health 2016; 58(2): 138–144.

18. **Hamilton RG.** Latex allergy: Epidemiology, clinical manifestations, and diagnosis. UpToDate, displayed 29 Nov 2017 [Internet]. Available from: www.uptodate.com.

19. National Institutes of Occupational Safety and Health (NIOSH). NIOSH Allert. Preventing Allergic reactions to natural rubber latex in the workplace. Publication No. 97–135, June 1997 [Internet]. Available from: https://www.cdc.gov/niosh/docs/97-135/pdfs/97-135.pdf.

20. **Malsy M, Leberle R, Ehehalt K, Sinner B, Hobbhahn J.** Anaphylactic reaction 5 minutes after the start of surgery: a case report. BMC Res Notes 2015; 8: 117. https://doi.org/10.1186/s13104-015-1060-9.

21. The American Latext Allergy Association (ALAA). Latex Allergy Screening Questionnaire, 2014, Displayed 29 Nov 2017 [Internet]. Available from: https://allergyasthmanetwork.org/wp-content/uploads/2020/05/latex-allergy-screening-questionnaire.pdf.

22. **Verna N, Di Giampaolo L, Renzetti A, Balatsinou L, Di Stefano F, Di Gioacchino G, Di Rocco P, Schiavone C, Boscolo P, Di Gioacchino M.** Prevalence and Risk Factors for Latex-Related Diseases Among Healthcare Workers in an Italian General Hospital. Ann Clin Lab Sci Spring 2003; 33(2): 184–191.

23. **Toraason M, Sussman G, Biagini R, Meade J, Beezhold D, Germolec D.** Latex allergy in the workplace. Toxicol Sci 2000; 58(1): 5–14. https://doi.org/10.1093/toxsci/58.1.5.

24. **Nettis, EG, Assennato A, Ferrannini A, Tursi A.** Type I allergy to natural rubber latex and tipe IV allergy to rubber chemicals in health care workers with glove-related skin symptoms. Clinical & Experimental Allergy 2002; 32(3): 441–447. https://doi.org/10.1046/j.1365-2222.2002.01308.x.

25. **Behroozy AG, Keegel T.** Wet-work Exposure: A Main Risk Factor for Occupational Hand Dermatitis. Safety and Health at Work 2014; 5(4): 175–180. https://dx.doi.org/10.1016%2Fj.shaw.2014.08.001.

26. **Lee W, Lee JH, Park DJ, Kim HH.** A case of anaphylactic shock attributed to latex allergy during gastric cancer surgery. Journal of the Korean Surgical Society 2011 Dec; 81(Suppl 1): S30–S33. https://dx.doi.org/10.4174%2Fjkss.2011.81.Suppl1.S30.

27. The American Food and Drug Administration (FDA). Medical Device Bans, 2020 [Internet]. Available from: https://www.fda.gov/MedicalDevices/Safety/MedicalDeviceBans/default.htm.

28. **Knezevic H.** 374 Prevalence of allergy related skin and respiratory diseases among healthcare workers in Croatia. Occupational and Environmental Medicine 2018; 75: A53.

29. **Nguyen K, Kohli A.** Latex Allergy. Treasure Island (FL): StatPearls Publishing; 2021.

Table 1. Demographic characteristic of healthcare workers (N=455)

Latex exposure		N	%
Do you wear latex gloves regularly or are you in other way exposed to latex?	yes	410	90,1%
	no	45	9,9%
Do you have a medical history of operations or other invasive procedure?	yes	43	9,5%
	no	411	90,5%
Do you have a history of operation or other invasive procedure in the first year of your life?	yes	20	4,4%
	no	435	95,6%

Table 2. Self-reported exposure to latex by the participants (N=455)

	Symptoms of allergy		**Hand dermatitis N (205)**	**Without dermatitis N (250)**	**No answer**	**P**
At work	Hives, red itchy swollen hands within 30 minutes within a day after wearing latex gloves	N %	74/205 36%	8/218 3.54%	32 0.07 %	0.001
In everyday life	Itching, swelling or other allergy symptoms following medical exams as a patient	N %	17/205 8,3%	2/228 0,01%	22 0,05%	0.001
	Swelling or difficulty breathing after blowing up a balloon	N %	4/205 2%	0/228 0%	22 0,05%	0.03
	Itching or swelling after use of condoms, diaphragms or latex sexual aids	N %	19/204 9,3%	1/227 0,004%	24 0,05%	0.001
	Itching or discomfort after use of rubber or elastic bands or clothing	N %	50/203 24,4%	9/227 0,04%	25 0,05%	0.001

Table 3. Correlation between self-reported hand dermatitis at work and symptoms of allergic symptoms to the latex in everyday life.

Item		N	%
Profession	Nurse	361	79,3 %
	Physician	71	15,6 %
	Other hospital staff	23	5,1 %
Gender	Male	77	16,9 %
	Female	378	83,1 %
Age	<30	129	28,4 %
	30–45	176	38,7 %
	45–60	136	29,9 %
	>60	14	3,1 %
Length of service in healthcare	≤10 years	183	40,2 %
	11–20 years	97	21,3 %
	21–30 years	95	20,9 %
	≥31 years	80	17,6 %
Daily glove use	<1h	79	17,4 %
	1–3h	115	25,3 %
	3–5h	147	32,3 %
	>5h	114	25,1 %

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Assessment of the Effectiveness of Classic Massage with the Use of Trigger Points Therapy Elements in Patients Suffering from Pain in the Lumbosacral Spine

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Abstract

Introduction: Nowadays, back pain is a very common problem, especially in the area of lower back. Classic massage is one of the methods of reducing back pain and is included in the therapeutic procedure.
Purpose: The purpose of the study was to compare the effectiveness of classic massage and massage with the trigger points therapy elements in patients with painful ailments by cutting the lumbosacral spine.
Material and method of the study: The study involved 84 patients with pain in the lumbosacral spine. The subjects were divided into two groups. Group I included 42 people (50.0%) who received classic massage, and group II included another 42 people (50.0%) who received classic massage with the trigger points therapy elements. A proprietary questionnaire was used for the analysis, which allowed for the assessment of the effectiveness of the applied treatment, supplemented with the VAS scale and the Thomayer test.
Results: The results of the study show a statistically significant difference between the intensity of perceived pain measured before and after the procedures in both group I ($p<0.001$) and group II ($p<0.001$). The average improvement achieved by the patients from group I was 2.88 points, and by the patients from group II to 4.48 points. On the other hand, the average improvement in the Thomayer test obtained by the patients from group I was 2.12 cm, and by the patients from group II was 3.68 cm. The difference in the treatment effect in the two groups was statistically significant ($p<0.001$).
Conclusions: Classic massage with the trigger points therapy elements has a better effect on improving spine mobility in the patients with pain in the lumbosacral spine and reduces pain to a greater extent compared to classic massage.

Key words: rehabilitation, massage, trigger points therapy

Introduction

Nowadays, diseases and ailments of the musculoskeletal system of the spine are diagnosed more and more often in the society. This is one of the key social, economic and medical problems [1], and is associated with a change in the human lifestyle, minimised physical effort, which results in muscle weakness, obesity, the formation of an incorrect body posture or inappropriate stress on the spine during work. Pain syndromes of the lumbosacral spine often begins chronic, progressive ailments causing disability, inability to work actively and limitations of activity in everyday life [2].

Pain in the lumbosacral spine is associated with discopathy or the presence of a root conflict the most often. In addition, other possible sources of pathology should not be ignored, e.g., in hip joints, sacroiliac joints, inter-process joints, as well as rheumatic, oncological and myofascial grounds [3]. As a result of high mobility in the lumbar spine and the loads it is exposed to, pain symptoms occur at the level of 65% [4]. According to studies conducted in Poland, 72% of people under 40 years of age experience lower back pain, and as far as people over 40 years of age are concerned, it concerns 30% of women and 66% of men [5].

The first information about massage appeared approximately 3000 BC. However, when it comes to applying it in medicine, the first study on its effects and physiology was carried out by the doctor and surgeon, Ambrose Pare, in the 16th century. Classic massage consists in mechanical deformation of tissues and thus causing an indirect and direct influence on individual systems in the human body. It can be defined as a set of different grips that are performed in the correct order, and their effect is to induce a tissue reaction [6, 7].

Classic message causes beneficial effects when treating back pain by reducing muscle tension, reducing pain sensitivity or increasing local blood supply. Therapeutic massage significantly affects the emotional state, reduces tension and stress, which is helpful in the treatment of back pain. Patients assess the procedure as pleasant and relaxing, which positively influences the healing process and constitutes a safe and effective therapy [8].

Aim

The purpose of the study was to compare the effectiveness of classic massage and massage using the trigger points therapy elements in the treatment of pain in the lumbosacral spine.

Material and method of the study

Characteristics of the examined group

The study was carried out in a group of 61 women (72.6%) and 23 men (27.4%). Women were the majority in each group. The groups did not differ significantly in terms of gender structure (p=0.807) (Table 1).

The study involved 84 patients with pain in the lumbosacral spine. The subjects were divided into two groups created according to the type of surgery that was used to reduce their pain. The criterion for inclusion of the patient in group I was the carried-out classic massage treatment (the group consisted of 42 people; 50.0% of the total), the inclusion criterion in group II was the classical massage treatment with the trigger points therapy elements (42 people; 50.0% of the total) (Table 2.).

Study tool

A proprietary questionnaire was used for the analysis, which allowed for the assessment of the effectiveness of the applied treatment, supplemented with the VAS scale and the Thomayer test. The VAS scale is a visual-analogue scale for assessing the level of perceived pain. The patients ticked the intensity of pain twice: before and after rehabilitation, in points from 0 to 10. However, the Thomayer test was used to assess the extent of forward flexion of the spine [9].

Data analysis

Statistical analysis of the collected material was carried out in the Statistica 13.1 package. Only non-parametric tests were used to analyse the

variables. The choice of this type of tests was conditioned by the failure to meet the basic assumptions of the parametric tests, i.e., the compliance of the distributions of the studied variables with the normal distribution, which was verified with the Shapiro-Wilk test. The Mann-Whitney U test was used to assess the differences in the two compared groups. The Wilcoxon's pairwise test was used to assess the within-group variability in the two populations. The Cramer's V (2x3, 4x5, etc. tables) and Phi (2x2 tables) tests were used to assess the relationship between the selected variables for questions on nominal scales. They are measures of symmetry based on the chi-square test that provide information on the strength of the relationship between the variables in the crosstabs. All measures of compound strength are normalised to take values between (0–1), so, respectively from 0–0.29 – weak dependence, 0.30–0.49 – moderate dependence, 0.5–1 – strong correlation [10]. Descriptive statistics were calculated for numerical variables, i.e., mean, median, minimum, maximum, the first and the third quartiles and standard deviation. The level of statistical significance was $p<0.05$.

Results

The mean age of all patients was 51.7±13.98 years. The mean age of the patients in group I was 52.95±15.02 years, while the mean age of the patients in group II was 50.45±12.92 years. The age of the patients from the two groups did not differ significantly (p=0.239). The group was homogeneous in terms of age (Table 3).

The mean duration of pain was 88.11 months, mean 102.62 months for the subjects from group I and 73.6 months for subjects from group II. This difference was statistically insignificant (p=0.205). The chronic nature of the perceived back pain was confirmed over time (Table 3).

The degree to which pain made it difficult for the patients to perform in everyday life was rated on a scale from 0 to 10 points, where more points meant greater difficulties caused by pain. The level of the impact of pain on the performance of everyday activities was estimated at 4.73 points in the total number of the patients ±1.72 points. In group I, the

average score was 4.81 points, and in group II, 4.64 points. This difference was statistically insignificant (p=0.333) (Table 3).

The effectiveness of the classic massage treatment was rated on a scale from 0 to 10 points, where the higher number of points meant greater effectiveness. The effectiveness of the applied treatment was determined in group I at the average level of 6.05 points, ±2.34 points, while in group II at the average level of 6.1 points ±2.36 points. This difference was statistically insignificant (p=0.606) (Table 3).

The presence of a statistically significant difference between the range of spine mobility in the measurement before and after the procedures was confirmed both in group I (p<0.001) and in group II (p<0.001). As far as the patients of group I are concerned, the average result of the Thomayer test was 10.93 cm measured before the treatment, and 8.81 cm after the treatment. As far as the patients of group II are concerned, the average result of the Thomayer test was 8.67 cm measured before the treatment, and 4.99 cm after the treatment. The average improvement achieved by the patients from group I was 2.12 cm, and by the patients from group II to 3.68 cm. The difference in terms of the effect applied in the two treatment groups was statistically significant (p<0.001). Similarly, the range of spine mobility found in the two groups in the measurement after the treatment was significant (p=0.013). However, no statistically significant differences in terms of the range of spine mobility were confirmed in the two groups measured before the therapy (p=0.216) (Table 4).

There was a statistically significant difference between the magnitude of the perceived pain intensity measured before and after the procedures, both in group I (p<0.001) and in group II (p<0.001). As far as the patients from group I, the average pain intensity before the treatment was estimated at 5.93 points, and after the treatment at 3.05 points. As far as the patients from group II, the average pain intensity before the treatment was estimated at 6.36 points, and after the treatment at 1.88 points. The average improvement achieved by the patients from group I was 2.88 points, and by the patients from group II to 4.48 points. The difference in terms of the effect applied in the two treatment groups was statistically significant (p<0.001). Similarly, the level of pain intensity experienced by the patients from the two groups when measured after the treatment

($p<0.001$) was significant. There were no statistically significant differences in pain intensity in the two groups measured before the therapy ($p=0.145$) (Table 4).

In the whole series of treatments, all patients assessed the first one as the most painful. Most respondents believed that the first treatments were very painful, and the subsequent ones were more and more pleasant (40 people – 47.6%). It was shown that the patients from group I felt well during the whole series of treatments without increasing pain statistically more often than the patients from group II. In addition, the patients from group II declared that the first treatments were very painful, the next ones are more and more pleasant, and the improvement was felt after the first treatments statistically more often than the patients from group I. This relationship was statistically significant ($p<0.001$) with a moderate strength of the relationship (Cramer $V=0.46$) (Table 5).

The massage treatments were pleasant for the majority of the patients; only some grips were felt more by them (43 people – 51.2%). The patients from group II indicated the feeling of pain during the procedure more often than the patients from group I, while the patients from group I more often indicated that the procedure was painless. This difference was statistically significant ($p<0.001$), and the described relationship was strong (Cramer $V=0.56$) (Table 6).

Discussion

Modern lifestyle affects the intensification of degenerative processes within the musculoskeletal system. Increased tension of the paraspinal muscles always occurs during spinal overload disease, and long-term contracted muscles cause back pain. Increased muscle tension affects the blood supply to the muscle, causing the accumulation of metabolic products in it. In classic massage, the mechanical stimulus directed at the patient's tissues causes numerous changes as well as local and general reactions. The local action consists in the local expansion of blood and lymph vessels as a result of the techniques used. The consequence of these actions involves the improved disturbed tissue metabolism. Central action affects the body through the nervous system. Irritation of extero-

and prioprioceptors (skin, skeletal muscles) causes increased impulsation of the cerebral cortex, stimulating nerve conduction and influencing the normalisation of the functioning of internal organs. Depending on the massage techniques used, it can have a stimulating or toning effect on the nervous system [11]. During the massage, it is possible not only to easily feel the trigger points, but also to effectively prevent their formation, reduce the intensity of pain through their earlier detection and treatment [12].

In the light of the conducted study, the feeling of back pain after the therapeutic massage decreased significantly [13]. In addition, the habitual attitude adopted during the pain was abolished [14]. It was noticed that massage has a statistically significant ($p<0.05$) effect on reducing back pain in the lumbosacral region [15], on improving the quality of life [16] and increasing the level of physical activity [8]. In connection with the patient education about the correct posture and proper movement habits, it can contribute to the prevention of future pain incidents [17].

The available literature confirms the effectiveness of the use of therapeutic massage in various forms in order to reduce pain in patients with back pain. In the studied group of the patients treated with therapeutic massage, a reduction in the level of pain assessed on the VAS scale was achieved [18].

The studies of Qiao J. et al. revealed statistically significant differences between the range of spine mobility in the measurements performed before and after the therapy ($p<0.001$) [19]. Classic massage positively impacted on the improvement of spine mobility in all three planes [20]. Both confirmed a statistically significant difference between the intensity of perceived pain measured before and after the procedures [21].

The studies carried out among 3,096 patients over 18 years of age revealed the fact that there is no certainty that massage is an effective method of treating pain in the lower spine. In acute, subacute and chronic conditions, improvement of pain results with massage was shown only in a short period of observation. Functional improvement was observed in subacute and chronic participants, but only in short period of observation [22].

Classic massage in combination with elements of trigger points therapy is a valuable and effective technique aimed at alleviating back pain.

After a series of classical massage treatments with the trigger points elements, a statistically significant ($p<0.05$) reduction of pain in the lumbosacral spine was achieved. In addition, the patients achieved the improvement in everyday activities. A decrease in palpation tenderness of soft tissues was observed, but no improvement in the range of mobility of the spine and chest was noted [23]. According to the studies carried out by Kocak A.O. et al., the use of the trigger points therapy elements reduces pain, where the mean VAS score decreased by 0.41±1.30 [24]. The use of the trigger points is an effective therapy, but long-term treatment is required in chronic cases [25].

The rehabilitation program for each patient should always be adapted and implemented individually. During therapy, some physiotherapeutic methods are combined to achieve better therapeutic effects.

Conclusions

1. Classic massage with the trigger points therapy elements significantly improves the mobility of the spine in the patients with pain in the lumbosacral spine compared to classic massage.
2. Classic massage reduces pain after the treatment to a lesser extent compared to classic massage with the trigger points elements.
3. There is a greater subjective feeling of pain in a massage treatment with the trigger points therapy elements in the first treatments compared to classic massage.

References

1. **Maciuk M, Krajewska-Kulak E, Klimaszewska K.** Self-assessment of low back pain incidence in professionally active nurses. Probl Hig Epidemiol 2012; 93(4): 728–738.

2. **Depa A, Drużbicki M.** Assessment of frequency of lumbalgia occurrence with relation to the character of performed work. Przegląd Medyczny Uniwersytetu Rzeszowskiego 2008; 1: 34–41.

3. **Krawczyk-Wasielewska A.** Skuteczność wybranych algorytmów postępowania fizjoterapeutycznego w leczeniu objawowym przewlekłych zespołów bólowych dolnego odcinka kręgosłupa z promieniowaniem do kończyny dolnej. Rozprawa doktorska. Poznań: Uniwersytet Medyczny im. Karola Marcinkowskiego; 2013.

4. **Morton M.** Back pain syndromes. Przew Lek 2008; 5: 45–47.

5. **Kołodziej K, Kwolek A, Rusek W, Przysada G, Szpunar P.** Correlation between lower extremities symmetrical index and intensification of lower back pain in patients after hospital rehabilitation. Przegląd Medyczny Uniwersytetu Rzeszowskiego 2005; 3: 234–236.

6. **Zborowski A.** Classic massage. Kraków: AZ; 2005.

7. **Podgórski T.** Massage in rehabilitation and sport. Warszawa: AWF; 1996.

8. **Orlikowska A, Kawa M, Jurkiewicz J, Podgórska M.** Ocena skuteczności masażu klasycznego w obniżeniu dolegliwości bólowych występujących w obrębie kręgosłupa. In: Podgórska M, ed. Choroby XXI wieku – wyzwania w pracy fizjoterapeuty. Gdańsk: Wydawnictwo Wyższej Szkoły Zarządzania; 2017.

9. **Bolach B, Szafraniec R, Bolach E.** Evaluation of effectiveness of a 10-day ambulatory physiotherapy program in the process of rehabilitation of people with discopathy ofthe lumbosacral spine. In: Olszówka M, Niścior M, eds. Innowacje w fizjoterapii, t. 2. Lublin: TYGIEL; 2015.

10. **Nawojczyk M.** Przewodnik po statystyce dla socjologów. Kraków: SPSS Polska; 2002.

11. **Ćwirlej A, Ćwirlej A, Gregorowicz-Cieślik H.** Classical and aromatherapeutical massage in spine pains. Przegląd Medyczny Uniwersytetu Rzeszowskiego 2005; 4: 366–371.

12 **Chaitow L, Fritz S.** Masaż leczniczy. Badanie i leczenie mięśniowo-powięziowych punktów spustowych. Wrocław: Elsevier Urban & Partner; 2010.

13. **Daneau C, Cantin V, Descarreaux M.** Effect of Massage on Clinical and Physiological Variables During Muscle Fatigue Task in Participants With Chronic Low Back Pain: A Crossover Study. Journal of Manipulative and Physiological Therapeutics 2019; 42(1): 55–65.

14. **Wilk I.** The effectiveness of therapeutic massage in lumbar and cervical spine pain syndrome – case study. Puls Uczelni 2015; 9(2): 24–27.

15. **Kałużna A, Kałużny K, Kochański B, Kluska K, Płoszaj O, Zukow W, Hagner W.** Evaluation of the results of treatment of chronic back pain in the lumbosacral segment by use of the classical massage. J Educ Health Sport 2015; 5(9): 577–586.

16. **Boguszewski D, Krupiński M, Białoszewski D.** Assessment of the Effect of Swedish Massage and Acupressure in Rehabilitation of Patients with Low Back Pain. Preliminary Report. Ortopedia Traumatologia Rehabilitacja 2017; 19(6): 513–521.

17. **Wilk I.** The effectiveness of therapeutic massage in lumbar spine pain syndrome. Puls Uczelni 2014; 8(2): 28–32.

18. **Krawczyk-Suszek M, Szlichta-Kołeczek K, Bednarski J.** Efficacy of rehabilitation in patients with segmental discopathy lumbar-sacral spine. World Scientific News 2018; 111: 40–50.

19. **Qiao J, Zhang S-L, Zhang J, Feng D.** A study on the paraspinal muscle surface electromyography in acute nonspecific lower back pain. Medicine (Baltimore) 2019; 98(34): e16904.

20. **Ćwirlej A, Ćwirlej A, Maciejczak A.** Effects of therapeutic massage in spine pains. Przegląd Medyczny Uniwersytetu Rzeszowskiego 2007; 3: 253–257.

21. **Joseph LH, Hancharoenkul B, Sitilertpisan P, Pirunsan U, Paungmali A.** Effects of Massage as a Combination Therapy with Lumbopelvic Stability Exercises as Compared to Standard Massage Therapy in Low Back Pain: a Randomized Cross-Over Study. International Journal of Therapeutic Massage & Bodywork 2018; 11(4): 16–22.

22. **Furlan AD, Giraldo M, Baskwill A, Irvin E, Imamura M.** Massage for low-back pain. Cochrane Database of Systematic Reviews 2015; 9: 1–115.

23. **Chochołowska M, Marcinkowski JT, Rąglewska P, Babiak J.** Swedish massage therapy and vibration massage of trigger points in elderly patients with low back pain and depression. Probl Hig Epidemiol 2011; 92(3): 428–435.

24. **Kocak AO, Ahiskalioglu A, Sengun E, Gur STA, Akbas I.** Comparison of intravenous NSAIDs and trigger point injection for low back pain in ED: A prospective randomized study. The American Journal of Emergency Medicine 2019; 37(10): 1927–1931.

25. **Kameda M, Tanimae H.** Effectiveness of active soft tissue release and trigger point block for the diagnosis and treatment of low back and leg pain of predominantly gluteus medius origin: a report of 115 cases. Journal of Physical Therapy Science 2019; 31(2): 141–148.

Table 1. Division of the patients by gender

Gender	Group I		Group II		Total	
	n	%	n	%	n	%
Female	31	73,8%	30	71,4%	61	72,6%
Male	11	26,2%	12	28,6%	23	27,4%
Total	42	100,0%	42	100,0%	84	100,0%
p	$\chi^2(1)=0,06$ p=0,807					

n – number of observations; % – percent

Table 2. Type of carried out treatment

Type of carried out treatment	n	%
Classic massage	42	50.0%
Classic massage with the trigger points therapy elements	42	50.0%
Total	84	100.0%

n – number of observations; % – percent

Table 3. Analysis of the mean values of parameters in the compared groups

Variable	Group I		Group II		p
	$\overline{x}$	SD	$\overline{x}$	SD	
Age	52.95	15.02	50.45	12.92	0.239
Duration of pain (in months)	102.62	124.90	73.60	118.93	0.205
Degree to which pain makes it difficult for the patients to perform in everyday life (scale of 0-10 points)	4.81	1.86	4.64	1.57	0.333
Assessment of the effectiveness of classic massage	6.05	2.34	6.10	2.36	0.606

$\overline{x}$ – arithmetic average; SD – standard deviation; p – level of significance of differences

Table 4. Assessment of the average parameters of the Thomayer test and the VAS scale in individual groups of the patients and in subsequent measurements

Variable	Group I		Group II		p
	$\overline{x}$	SD	$\overline{x}$	SD	
Thomayer test (before therapy)	10.93	8.32	8.67	6.75	0.216
Thomayer test (after therapy)	8.81	7.28	4.99	5.29	**0.013**
Difference	-2.12	3.40	-3.68	2.56	**<0.001**
VAS scale (before therapy)	5.93	1.47	6.36	1.08	0.145
VAS scale (after therapy)	3.05	1.40	1.88	1.17	**<0.001**
Difference	-2.88	1.71	-4.48	1.21	**<0.001**

$\overline{x}$ – arithmetic average; SD – standard deviation; p – level of significance of differences

Table 5. Feelings accompanying the treatments

Feelings accompanying the treatments	Group I		Group II		Total	
	n	%	n	%	n	%
The first treatments were very painful, the next ones were more and more pleasant	16	38.1%	24	57.1%	40	47.6%
Well-being during the entire series of treatments, no intensification of pain	20	47.6%	3	7.1%	23	27.4%
Malaise during the entire series of treatments	0	0.0%	0	0.0%	0	0.0%
Improvement was felt after the first treatments	6	14.3%	15	35.7%	21	25.0%
Total	42	100.0%	42	100.0%	84	100.0%
p	**$\chi^2(2)=18.02$ p<0.001 V Cramer=0.46**					

n – number of observations; % – percent; χ^2 – Pearson Chi^2 test result; p – level of significance of differences

Table 6. Assessment of the pain intensity of the procedure

Assessment of the pain intensity of the procedure	**Group I**		**Group II**		**Total**	
	n	%	n	%	n	%
Painful	5	11.9%	25	59.5%	30	35.7%
Painless	10	23.8%	0	0.0%	10	11.9%
Very painful, hard to stand	1	2.4%	0	0.0%	1	1.2%
Pleasant, only some of the grips are felt more	26	61.9%	17	40.5%	43	51.2%
Total	42	100.0%	42	100.0%	84	100.0%
p	**$\chi^2(3)=26.21$ p<0.001 V Cramer=0.56**					

n – number of observations; % – percent; χ^2 – Pearson Chi^2 test result; p – level of significance of difference