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**LADIES AND GENTLEMEN, FACULTY, GRADUATES  
AND STUDENTS OF UNIVERSITIES, READERS  
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We are pleased to announce the publication of this year's second issue of *Medical Science Pulse*. We are sure our readers will appreciate the broad range of content in this issue.

We invite our readers to cooperate with the editorial team as section editors or reviewers, submit your manuscripts and publish your text in an accessible environment.

We invite students, graduates, scientists and employees of medical universities and schools as well as other scientific and research institutions: to build your academic achievements, increase potential citations of your research, participate in the important process of popularizing science, and to publish theses in the form of a scientific article.

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The constantly improving quality of research articles, increasing internationalisation and the dynamic growth of the journal allows it to meet the professional assessment criteria assessed by health scientists and medical experts. Last year *Medical Science Pulse* was positively evaluated by experts in a competition by the Minister of Science and Higher Education under the "Support for scientific journals" *de minimis* programme and awarded 20 points.

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articles in the journal; Improvement of substantive level of reviews; Dissemination of information about the journal" are financed by the Ministry of Science and Higher Education *de minimis* programme within the framework of "Support for scientific journals" project – contract number 147/WCN/2019/1.

The research-based part of the quarterly includes original papers on characteristics of the Evenk children's psychoemotional spherecase (Siberia), gender difference in circulatory adjustment to head up tilt test in healthstudies, comparison of risk factors for low birth weight among mothers, surgical outcomes of patients with peroneal nerve injury, protein intake among people undertaking muscle strength training, women's expectations and preferences for care of the newborn, exhaled nitric oxide in smokers and former smokers with chronic obstructive pulmonary disease, role of a midwife in cervical cancer prevention, negative and positive effects of trauma among patients. Case reports on: non-nutritional use of breast milk and the use of dry needling to treat painful shoulder syndrome and a review on personalised medicine – best practices exchange and personal health implementation in European regions.

We would like to inform you about the change of the publisher of the *Medical Science Pulse* quarterly in relation to the regulation issued by the Ministry of Science and Higher Education on merging the Opole Medical School with the University of Opole on 15 July 2020 (Journal of Laws of 25 May 2020, item 938).

At this point, the time in which our journal functioned and developed as Opole Medical School's scientific project is coming to an end. We would like to express our thanks to the authors, readers, members

of the Scientific Board, editors, reviewers and university authorities, especially the Rector – Dr hab. Tomasz Halski, for their active engagement in publishing all the issues of Medical Science Pulse, constant support and the joy of co-creation and development of this crucial form of scientific communication in the country and abroad.

We would like to ensure all interested parties that the journal functions and will continue uninterrupted and in a timely fashion. We invite all authors with new

findings, in line with the journal's scope, to submit their manuscripts via our website: <https://medicalsciencepulse.com/resources/html/cms/DEPOSITSMANUSCRIPT>

We look forward to new and further successes with the University of Opole!

As the summer holidays approach, we wish you all a pleasant time, safe and healthy, and a happy return to academic and professional duties in the new academic year 2020/2021.

# CHARACTERISTICS OF THE PSYCHOEMOTIONAL SPHERE AMONG EVENK CHILDREN

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A – study design, B – data collection, C – statistical analysis, D – interpretation of data, E – manuscript preparation, F – literature review, G – sourcing of funding

## ABSTRACT

**Background:** In Russia, there is an active ongoing process of national revival of the indigenous small-numbered peoples of the North Siberia, such as the Evenks. Revival of the younger generation, in particular, remains a priority. The state helps to solve the problems of education and adaptation of Evenk children to modern life. This is necessary because parents, hunters, and reindeer herders have a nomadic lifestyle. The educational feature of Evenk children is to study and live in a boarding school after elementary school graduation. Success of adaptation largely depends on the ability to account for the ethnopsychological specificity of Evenk children.

**Aim of the study:** To study characteristics of the psychoemotional sphere and identify ethnospecific indicators for the adaptation of Evenk children to a boarding school.

**Material and methods:** Pupils (N = 409) aged 10–16 from the village boarding school of Evenkia, Krasnoyarsk Territory, Russia were examined. Pupils consisted of 132 Evenk children and 277 Russian children. The emotional sphere was evaluated according to Eysenck Personality Inventory (EPI) and lateral phenotype was evaluated according to Bragina & Dobrokhotova.

**Results:** We found that Evenk children show a predominant pattern of left laterality ( $p = 0.024$ ). In addition, relative to Russian children, Evenk children are more likely to show the introverted personality type ( $p = 0.035$ ). Relative to Russian children, Evenk children are more restrained in their emotional manifestations, have greater difficulty in communicating with strangers, answer with monosyllables, and show a less vivid emotional reaction to praise. Further, relative to Russian children, Evenk children are more likely to show a high level of emotional stability (i.e., 9–10 points;  $p = 0.001$ ).

**Conclusions:** The present study examined the psychoemotional characteristics of Evenk children. We identified ethnospecific indicators, including an introversion personality type combined with emotional stability and left laterality. Identification of these characteristics allowed us to form a risk group of children in adaptation. Ethnospecific indicators of the psycho-emotional sphere should be considered for effective management of the adaptation of children in a boarding school.

**KEYWORDS:** introversion, psychological, extraversion, personality development, child

## BACKGROUND

In modern Russia, the ability to preserve and strengthen the health of the younger generation is closely related to the ability to adapt to real life conditions. These conditions can include nature-climatic, socio-hygienic, and stress-related factors [1]. These con-

ditions are particularly important to consider within regions that are characterized by unusually harsh environmental conditions. One example region is Evenkia, which is located in the North-East part of Russia, within the Siberia, Krasnoyarsk territory. A small number of indigenous people of the North – the ‘Evenks’ – live

in Evenkia, along with families of migrants from the central and southern regions of Russia [2]. Evenks are the most ancient people in Russia, and originally lived in the North-East part of Russia. The traditional economic activity of Evenks include hunting and reindeer breeding, which initially led to a nomadic lifestyle [3].

In the days of the Soviet Union, the way of life of the northern people began to change. Northern residents received the benefits of civilization, and the opportunity to study and choose a profession. These factors had a significant positive effect on northern residents. On the other hand, however, these changes deprived the Evenks of their usual way of life, including part of the traditional cultural values and knowledge of the nomadic way of life.

Currently, there is an ongoing national movement to revive the indigenous small-numbered peoples of northern Russia, including the Evenks. New forms of management are being created; for example, tribal communities are being created in locations of traditional ancestral habitat. With these new conditions, problems related to education and adaptation to modern life have become salient. The success of solving these problems will largely depend upon the use of physiologically adequate methods, including in school education [4]. These methods must consider the ethnopsychological specificity of the younger generation of Evenks. To this end, we propose methods for assessing the psychoemotional sphere by laterality and Eysenck Personality Inventory (EPI), which are widely used indicators of left-right laterality, personality type, and emotional stability or neuroticism. Laterality, lateralization, or left-right laterality is defined as a fundamental principle of nervous system [5]. Left-right laterality an important feature of not only human brain organization, but brain organization of all vertebrates [6]. Brain laterality is consistent with the well-known presence of asymmetry in the hands, legs, eyes, and ears [6,7]. Left-right laterality is currently being actively studied in the case of normal and pathological conditions [8–13].

Personality type refers to the psychological classification of different types of individuals. Personality types are sometimes distinguished from personality traits, with the latter embodying a smaller grouping of behavioral tendencies. Personality types are sometimes said to involve qualitative differences between people, whereas personality traits may be construed as quantitative differences.

The Swiss psychiatrist, Carl Jung's first achievement was to differentiate two classes of people, according to attitude types: (1) extraverted (i.e., outward-looking) and (2) introverted (i.e., inward-looking). Later, Jung differentiated four functions of the mind: (1) thinking, (2) feeling, (3) sensation, and (4) intuition. One or more of functions of the mind can predominate in a given individual. Results of this study were embodied in *Psychologische Typen* (1921; 1923). Jung's wide scholarship was well manifested in that publication, as well as, in *The Psychology of the Unconscious*.

According to theories of personality types, introverts and extraverts are two fundamentally different categories of people. According to theories of personality traits, in contrast, introversion and extraversion are on a continuum, with many individuals in the middle.

The wise personality is associated with integrative, noncognitive, and transpersonal personality types. The wise personality is often characterized by openness to experiences, agreeableness, conscientiousness, extraversion, emotional stability (i.e., low neuroticism), and a greater sense of psychological and subjective well-being [14].

The indicator of the emotional sphere is an introspective self-report questionnaire that differs among various psychological preferences for how people perceive the world and make decisions. Type Indicator is based on the conceptual theory proposed by Carl Jung [15].

In this study, we used the EPI to analyze indicators of children's' emotional sphere, introversion vs. extraversion, and neuroticism vs. emotional stability [16].

## AIM OF THE STUDY

The present study aimed to examine characteristics of the psychoemotional sphere and identify ethnospecific indicators for adaptation of Evenk children to a boarding school.

## MATERIAL AND METHODS

### Study design

The study sample consisted of 409 children, ages 10–16 years. This sample was 98% of all pupils from the boarding school of interest. Of the 409 children, 132 were Evenk children, who came from camps to the village boarding school in which they now live and study. The remaining 277 were Russian children who were living with their family in the village. The boarding school is now located in the Evenks village of Krasnoyarsk Territory, Russia.

Study inclusion criteria consisted of the following: permanent residence in Evenkia from the date of birth, and pupils from the Evenks village boarding school. The Evenk participants (i.e., the study sample;  $n = 132$ ) consisted of 59 (45%) boys and 73 (55%) girls. The Russian participants (i.e., the comparison group;  $n = 277$ ) consisted of 113 (41%) boys and 164 (59%) girls. The studies were conducted after informed consent was obtained. Eight students did not agree to participate in the survey and were thus excluded. Evenk participants ranged in age from 11–14 ( $M = 12$  yrs), and Russian participants ranged in age from 11–1 ( $M = 12$  yrs). There were no age differences in gender distribution.

### Data collection

The study was conducted at the beginning of the school year. This was a retrospective analysis conducted

in October–November 2019. Before starting the study, pupils were informed about the purpose and methodology, as well as, the opportunity for removal from the study at any time. Survey respondents were informed that survey response would be anonymous and participant was voluntary.

## Measures

### Eysenck's Personality Inventory (EPI) (Extroversion/Introversion)

The EPI was used to evaluate the emotional sphere [16]. The EPI was accessed via the Internet (<https://apsiholog.ru/psychological-tests/>). The EPI measures two pervasive, independent dimensions of personality: Extraversion-Introversion and Neuroticism-Stability. These two dimensions account for the majority of the variance in the personality domain. Each form contains 57 unique "Yes-No" items. A falsification scale was included to detect the presence of response distortion. Three scores are derived from the EPI. The first, sociability or 'lie score' (out of 9), measures how socially desirable the respondent is trying to be in responding. Those who score 5 or more on this scale are likely trying to respond in a desirable way and are not likely being honest in their responses. Second, the 'E score' (out of 24), measures how much of an extrovert is the respondent. Third, the 'N score' (out of 24), measures how neurotic the respondent is [16,17]. The EPI measures extraversion as a reasonable mix of impulsivity and sociability [17,18]. Cronbach's  $\alpha$  based on the results of the described project: 0.804.

### Laterality

Left-right laterality was measured using experiments proposed by Bragina and Dobrokhotova (1998) [19]. The degree of manual asymmetry was determined from all participants. Four trials were conducted on the hand, and three trials each were conducted on the feet, eyes, and ears. The asymmetry of the arms, feet, eyes, and ears was determined by the prevalence of left and right values in each case. Symmetry was defined when the sum of the left indicator was equal to the sum of the

right indicator. Mixed profiles were recorded at various combinations of left and right indicators.

### Bioethics committee approval

The study was approved by the Scientific Research Institute of the North Medical Problems, Siberian Branch of the Russian Academy of Sciences, Krasnoyarsk, Russia (03.12.2019, N3).

### Statistical methods

Statistical analyses were carried out using the STATISTICA software package ver. 6.0. Qualitative characteristic differences were assessed using the  $\chi^2$  test. For relatively small samples, a two-sided Fisher exact test was applied. The differences at  $p < 0.05$  were considered to be statistically significant [20].

## RESULTS

The distribution of laterality among children living in Evenkia is shown in Tab. 1.

The distribution of the laterality differs across groups (i.e., Evenk, Russian,  $p = 0.036$ ). The combined laterality has no statistical differences in the studied groups of children. Right laterality was shown to prevail among Russian children ( $p = 0.043$ ). A relatively small group of children were ambidextrous or showed left laterality. Importantly, left laterality was prevalent among Evenk children ( $p = 0.024$ ). Thus, left laterality characterizes the emotional sphere inherent by in Evenk children.

In the next stage, we analyzed the indicators of the children emotional sphere, according to the EPI "intro-extroversion" and "neuroticism-emotional stability" dimensions. The results of these analyses are shown in Tab. 2.

The distribution of the EPI (intro-extroversion) was shown to vary based on group (i.e., Russian, Evenk;  $p = 0.046$ ).

The extroverted personality type prevailed among Russian children ( $p = 0.036$ ). According to the EPI, the level of extroversion across both examined groups of children was in the range of moderate extroversion

Table 1. Distribution of laterality among children living in Evenkia.

| Laterality<br>(left or right laterality)                                       | Evenk children<br>n=132<br>[1] |                             | Russian children<br>n=277<br>[2] |                             | Statistical significance |                       |
|--|--------------------------------|-----------------------------|----------------------------------|-----------------------------|--------------------------|-----------------------|
|  | Abs.                           | %<br>95 Confidence interval | Abs.                             | %<br>95 Confidence interval | $\chi^2$                 | P                     |
| Right laterality   | 47                             | 35.6<br>27.94–44.09         | 128                              | 46.2<br>40.42–52.10         | 4.11                     | $p_{1-2} = 0.043$     |
| Combined laterality  | 56                             | 42.4<br>34.30–50.96         | 115                              | 41.5<br>35.86–47.40         | 0.3                      | $p_{1-2} = 0.862$     |
| Ambidextral  | 15                             | 11.4<br>7.00–17.92          | 21                               | 7.6<br>5.02–11.31           | 1.59                     | $p_{1-2} = 0.207$     |
| Left laterality  | 14                             | 10.6<br>6.45–17.03          | 13                               | 4.7%<br>2.78–7.86           | 5.07                     | $p_{1-2} = 0.024$     |
| Chi-squared test for contingency table (4 × 2) of Laterality by Children group |                                |                             |                                  |                             | 8.55                     | df = 3<br>$p = 0.036$ |

Table 2. Emotional sphere indicators of Evenk children according to the Eysenck Personality Inventory (EPI).

| Analyzed indicators   | Evenk children<br>n=132<br>[1] |                             | Russian children<br>n=277<br>[2] |                             | Statistical significance |                     |
|---|--------------------------------|-----------------------------|----------------------------------|-----------------------------|--------------------------|---------------------|
|   | Abs.                           | %<br>95 Confidence interval | Abs.                             | %<br>95 Confidence interval | $\chi^2$                 | P                   |
| Introversion  | 61                             | 46.2<br>37.92–54.71         | 98                               | 35.4<br>29.98–41.18         | 4.42                     | $p_{1-2}=0.035$     |
| Extroversion  | 71                             | 53.8<br>45.28–62.10         | 179                              | 64.6<br>58.81–70.01         | 4.40                     | $p_{1-2} = 0.036$   |
| Chi-squared test for contingency table (2 × 2) of EPI (intro-extroversion) by Children group              |                                |                             |                                  |                             | 3.97                     | df = 1<br>p = 0.046 |
| Neuroticism   | 28                             | 21.2<br>15.11–28.96         | 95                               | 34.3<br>28.95–40.07         | 12.40                    | $p_{1-2} < 0.001$   |
| Emotional Stability   | 104                            | 78.8<br>71.03–84.88         | 182                              | 65.7<br>59.92–71.05         | 11.59                    | $p_{1-2} = 0.001$   |
| Chi-squared test for contingency table (2 × 2) of EPI (neuroticism-emotional stability) by Children group |                                |                             |                                  |                             | 6.67                     | df = 1<br>p = 0.010 |

(i.e., 14–15 points). Moderate extroverts are characterized by personality characteristics including vitality, optimism, activity, contact, and individuality.

In contrast to Russian children, the introverted personality was prevalent among Evenk children ( $p = 0.035$ ) across both groups, children were in the range of moderate introversion (9–10 points).

The distribution of the EPI neuroticism-emotional stability dimension was shown to vary based on group (i.e., Russian, Evenk;  $p = 0.010$ ).

The index of emotional stability, determined using the EPI “neuroticism-emotional stability” continuum, was more prevalent than neuroticism among Evenk children ( $p = 0.001$ ). The majority of Evenk children (over 65%) showed levels of emotional stability in the range of average emotional stability (11–12 points) and approaching high emotional stability (9–10 points).

Neuroticism was more common than emotional stability among Russian children ( $p < 0.001$ ). The level of neuroticism was shown to reach a moderate degree (16–17 points) across both groups. Neuroticism in schoolchildren is manifested by a sense of uncertainty, fluctuation of mood, and a tendency to delay emotions.

## DISCUSSION

### Key results

The results reveal the formation of neurotic personality traits in this group of schoolchildren, which may complicate adaptation. The present study demonstrates the ethnopsychologic specificity of the younger generation of Evenk children. In particular, there was a predominance of left laterality among Evenk children in contrast to Russian children. The ratio of extroverts to introverts was 50:50. The introverted personality type was in the range of moderate introversion (9–10 points) and the index of emotional stability was in the range of average emotional stability (11–12 points), approaching the level of high emotional stability (9–10 points). According to Eysenck’s theory, introverts are individuals with naturally high levels of arousal. Given

the tendency to experience high arousal levels, introverts tend to seek activities and environments where they can escape from overstimulation. The naturally high arousal levels also make introverts more alert and primed to take in more information from the environment. Escaping somewhere to have time alone to recharge gives introverts the opportunity to process and reflect on what they have learned.

### Interpretation

The ethnopsychologic specificity of the younger generation of the Evenk indicate how children perceive the world and make decisions

### Emotional sphere indicators of Evenk children according to the Eysenck Personality Inventory

The study of personality type according to the EPI among Evenk children revealed a high frequency of the introverted personality type in combination with emotional stability.

Children with an introverted personality type are characterized by restraint, a tendency for self-analysis, and internal experiences [21]. As compared to non-indigenous children, indigenous children from Evenkia are (1) more restrained in their emotional manifestations, (2) find it difficult to communicate with unfamiliar adults, (3) answer questions monosyllabically, and (4) prefer to choose their words carefully rather than using time or energy on needless chit-chat. According to Dyakonova [22], because introverts tend to be inward turning, they also spend more time examining their own internal experiences. Introverts tend to enjoy simply thinking about and examining things in their own minds. Self-awareness and self-understanding is important to introverts, so they often devote a great deal of time to learning more about themselves. This might involve exploring hobbies they enjoy, thinking about their lives.

Evenk children like to watch their parents do their usual work, often repeatedly, until they feel that they can replicate the actions on their own. Thus, Evenk children learn from personal experiences and prefer to prac-

tice somewhere private where they can build their skills and abilities. Evenk children constantly need praise and support, but praise or comment has no intense emotional reaction. The identified features of emotional status and behavior in Evenk children are consistent with results reported in the literature [23–25].

### Distribution of laterality among Evenk children

Our research shows a distinctive feature of laterality distribution among Evenk indigenous children. In particular, a greater proportion of Evenk children show left laterality. This observation points to a right-brain-asymmetry among Evenk children, which may explain their emotional characteristics and behavior. According to various researchers, children with right hemisphere dominance are characterized by non-verbal intelligence, which is manifested by difficulties in learning, difficulties in grammar, and word selection in oral speech [26]. According to Sirotnyuk, right-brain-asymmetry of thinking of northern children is characterized by an orientation to high appreciation and praise, and a prestigious position in the collective [27].

At the same time, 50% of Evenk pupils with right laterality and left-brain-asymmetry may have a verbal nature of thinking. Evenk and Russian children who are characterized by right laterality may be the most adaptable to approved educational programs.

### Generalizability

The present study examined the characteristics of the psychoemotional sphere of Evenk children. We found ethnospecific indicators that can be used to help children adapt to a boarding school. Particular attention was drawn to Evenk children, who received ethnically specific indicators such as the personality type of introversion in combination with emotional stability and left laterality. Evenk children with this combination may be most likely to have difficulty adapting. According to Eysenck's theory, introverts are individuals with naturally high levels of arousal and emotional stability. This high arousal and emotional stability can easily

transition to a high degree of neuroticism. In that context, 50% of Evenk pupils may be in this at-risk group. At-risk Evenk pupils may require health-saving technology or a tutor for adaptation (for example, a senior student). It is necessary to transmit this information to the school leaders for effective management of the adaptation of children in a boarding school.

### Limitations of the study

The study was limited to a relatively small sample of Evenk children, ages 15–16 years. Given the relatively restricted sample size, we were underpowered to examine gender and age differences. Future studies should examine a larger sample size and include parents of the children. For example, Evenk children in this age often accompany their parents to the taiga for fishing. This is traditional life style of Evenk people.

### CONCLUSIONS

1. This study examined characteristics of the Evenk children's' psychoemotional sphere and revealed ethnospecific indicators. In particular, Evenk children were likely to demonstrate an introverted personality type combined with emotional stability and left laterality. Isolating these indicators should allow for the identification of an at-risk group of children in adaptation.
2. This study also examined ethnospecific indicators of the psychoemotional sphere of Evenk children. In contrast to Russian children, Evenk children showed an increase in left laterality and decrease in right laterality. Relative to Russian children, Evenk children demonstrated a relatively equal distribution of introversion vs. extraversion, but a predominance of emotional stability.
3. Ethnospecific indicators of the psychoemotional sphere should be considered for effective management of the adaptation of children in a boarding school.

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# GENDER DIFFERENCES IN CIRCULATORY ADJUSTMENT TO HEAD-UP TILT TEST IN HEALTH

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**A** – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

## ABSTRACT

**Background:** A tilt table test is a useful, non-invasive technique that has been used for the last few decades to detect autonomic failure. The response to tilting may vary physiologically between sexes.

**Aim of the study:** To assess the gender-specific changes in cardiovascular response to a tilt test in healthy subjects.

**Material and methods:** This experimental study was conducted on 90 healthy males and females aged 18–60 years, from 2019 to 2020. Forty-five male subjects and 45 female subjects were included. Using a motorized tilt table, a tilt table test was performed at 60 degrees for 10 minutes. An automatic sphygmomanometer was used to measure blood pressure (BP), and heart rate (HR) and a pulse oximeter was used for the measurement of peripheral capillary oxygen saturation (SpO<sub>2</sub>). An independent sample t test, a multiple regression analysis and a chi squared test were conducted for statistical analyses.

**Results:** A significantly greater drop in systolic blood pressure (SBP) was observed in females, compared to males after tilting. In 5.5% of the subjects, orthostatic intolerance occurred, but there were no significant age or gender-specific differences in subjects with orthostatic intolerance.

**Conclusions:** This study concluded that in response to tilting, cardiovascular response was less pronounced in females.

**KEYWORDS:** male, female, tilt test, SBP, DBP

## BACKGROUND

Recurrent episodes of unexplained syncope are a common and challenging problem in clinical practice [1]. Many patients in outpatient departments complain of “blackout” or “washout” episodes, which often perplexes physicians [2]. The evaluation and determination of the exact cause of syncope is particularly challenging due to its multifactorial triggers [3]. Physicians and cardiologists often find it difficult to manage patients with recurrent, unexplained syncope as no diagnosis can be made possible in about 50% of cases [4].

Syncope due to orthostatic intolerance, is the second most common symptom, which is the key manifestation of autonomic failure [5–6]. Orthostatic hypoten-

sion (OH) is defined as a drop in systolic blood pressure (SBP) of  $\geq 20$  mm Hg or a drop in diastolic blood pressure (DBP) of  $\geq 10$  mmHg, within 3 minutes of standing, or head-up tilt (HUT) test to at least 60 degrees on a tilt table [6–7]. The tilt test measures the response of changes in heart rate and blood pressure in response to gravity. Disease-related causes of syncope range from common benign problems to severe life-threatening disorders [4]. To detect autonomic failure, tilt table testing has become a widely-accepted tool in the clinical assessment of patients presenting with syncopal manifestations. A passive tilt test provokes orthostatic stress, resulting in blood redistribution towards the lower parts of the body and circulatory adjustment by cardiovascular reflexes [8]. During orthostatic stress,

the distribution of blood volume to maintain homeostasis is different between sexes [9].

Males and females differ in many aspects of physiology such as hormonal, haemodynamic, homeostatic balance, and many others. Very few studies have observed gender differences in orthostatic tolerance. One study observed a higher HR in females and higher DBP in males [10]. This finding contradicts another group of researchers, who did not find a gender difference in HR or mean arterial pressure (MAP) [11]. Due to these conflicting reports, our study was designed to investigate the gender effect on circulatory adjustment to postural challenge by tilt test.

### AIM OF THE STUDY

This study was aimed at measuring and comparing the changes in heart rate, systolic and diastolic pressure before and after tilt in both males and females.

### Hypothesis

We hypothesized that there would be gender-related differences in the circulatory adjustment to a postural challenge.

### MATERIAL AND METHODS

#### Study design and setting

This study was carried out to observe the gender effect on cardiovascular response to tilt test in apparently healthy subjects of both sexes from March 2019 to February 2020 at the Department of Physiology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbag, Dhaka. Heart rate and BP changes after tilting were compared in healthy male and female subjects.

#### Study participants

A total of 90 apparently healthy male and female subjects between the ages of 18 and 60 years were recruited among the relatives and attendants of patients, hospital staff and students, through personal contacts and advertisement.

Measurement of blood haemoglobin, thyroid-stimulating hormone, serum alanine transaminase, serum creatinine, fasting blood sugar levels and electrocardiogram (ECG) was done to exclude subjects with diabetes, thyroid disorder, anaemia, liver disease, renal and cardiovascular disease. None of the participants had a history of fainting or unconsciousness or showed an abnormality on the ECG.

#### Study size and sampling

In this study, purposive sampling was done to select the participants. Our sample size was based on the estimation of differences in mean DBP between two groups (effect size) which was previously published in a similar study [12].

### Ethical issues

The ethical and technical aspects of the study protocol involving human subjects was approved by the Institutional Review Board (IRB) of BSMMU.

### Data collection

After informed written consent was obtained from the participants, they were requested to visit the Department of Physiology, BSMMU on a specified date. Detailed personal, medical, dietary, drug history and menstrual history was taken. Thorough physical examination was performed and height and weight were taken to calculate body mass index (BMI). All information was documented in a prefixed datasheet.

The tilt table test was performed in an autonomic nerve function laboratory in a quiet room, where ambient temperature was maintained at 25°C. The subjects were instructed to fast for at least one hour, asked not to drink or smoke, and asked to urinate. After 10 minutes of supine rest, tilting was done at a 60 degree angle using a motorized tilt table (Hi-Lo Mode; 220 volts; Cat No: IEMR4093HL; International Electro Medical Co, India). Heart rate, systolic blood pressure and diastolic blood pressure were measured with a digital sphygmomanometer (Omron automatic blood pressure monitor: HEM-7120) and the mean arterial pressure (MAP) was calculated. Peripheral capillary oxygen saturation (SpO<sub>2</sub>) was also measured by a fingertip pulse oximeter (YK-88LED). All aforementioned variables were recorded before and after tilting at 60 degrees, every minute for 10 minutes. To maximize the orthostatic stress, subjects were asked to avoid the movement of lower limbs.

### Study outcomes

The primary outcome measures of this study included the maximum change in HR, SBP and DBP after tilting which is considered as the cardiovascular response to tilt test.

### Statistical analysis

Data was expressed as mean  $\pm$  standard deviation (SD) and percentage. Statistical analysis was performed using SPSS version 22. An independent samples t test was used to compare the confounding factors and study variables between males and females. Multiple regression analysis and chi squared tests were performed as applicable. A p value of <0.05 was considered to be statistically significant.

### RESULTS

#### Participants

A total of 100 subjects were examined for eligibility and 90 eligible subjects were enrolled. Data of all 90 subjects were included for analysis and there was no missing data.

## General characteristics

In this study, there were no significant differences in mean age, BMI and the number of male and female participants. Blood pressure however, was significantly lower in females (Tab. 1).

Table 1. Age, BMI and blood pressure of males and females (n=90).

| Variables                | Male (n=45)   | Female (n=45) | p value |
|--------------------------|---------------|---------------|---------|
| Age (years)              | 40.05 ± 11.46 | 38.44 ± 10.57 | 0.493   |
| BMI (kg/m <sup>2</sup> ) | 24.15 ± 3.15  | 24.65 ± 3.41  | 0.469   |
| SBP (mm Hg)              | 121.42 ± 9.8  | 109.73 ± 13.1 | 0.001   |
| DBP (mm Hg)              | 77.6 ± 7.8    | 70.55 ± 9.3   | 0.001   |

Data is expressed as mean ± SD. Statistical analyses were done by independent samples t test; n: number of subjects in each group.

## Tilting

A lower drop in SBP, which was statistically significant, was found in females after tilting (Tab. 2).

Table 2. Drop in SBP, rise in DBP, rise in MAP, rise in HR and Drop in SpO<sub>2</sub> response in males and females (N=90).

| Variables                    | Males (n=45) | Females (n=45) |
|------------------------------|--------------|----------------|
| Rise in HR (beats/min)       | 10.27 ± 6.44 | 10.51 ± 4.75   |
| Drop in SpO <sub>2</sub> (%) | 5.13 ± 4.36  | 5.05 ± 4.07    |
| Drop in SBP (mm Hg)          | 6.82 ± 4.15  | 9.42 ± 5.31*   |
| Rise in DBP (mm Hg)          | 8.38 ± 4.18  | 7.04 ± 4.66    |
| Rise in MAP (mm Hg)          | 5.81 ± 3.77  | 5.26 ± 3.35    |

Data is expressed as mean ± SD. Statistical analyses were done by independent samples t test; HR: heart rate; SpO<sub>2</sub>: peripheral capillary oxygen saturation; SBP: systolic blood pressure; DBP: diastolic blood pressure; MAP: mean arterial pressure; number of the subjects in each groups; N: total number of subjects; \* - p < 0.05.

A significant negative correlation of rise of HR (p < 0.05) was found with older age and female subjects (gender). A significant positive correlation in drop of SBP (p < 0.05) was noted with age, however a significant negative correlation was found with female subjects (gender). In addition, there was a significant inverse relationship in the rise of DBP (p < 0.05) and rise of MAP (p < 0.05), which was noted with age only (Tab. 3).

In this study, a total of five (5.5%) subjects were affected with orthostatic intolerance. (Fig. 1). There were no significant differences in age and gender distribution of subjects with a positive outcome.

## Discussion

In our study, the tilt response of all parameters was compared between females and males irrespective of age and BMI, to observe gender differences on the cardiovascular response to gravitational stress in apparently healthy subjects. A significantly greater drop in SBP was found in females compared to males. This finding is similar with that of Jarvis et al., who found a lower mean SBP and DBP in females but no difference in HR between females and males after tilt [10]. In contrast,

Table 3. Multiple regression analysis of rise in HR, drop in SBP, rise in DBP and rise in MAP (dependent variables) with age, BMI and gender (independent variables) (N= 90).

| Variables |             | Coefficients |        | 95% CI      |             | p value  |
|-----------|-------------|--------------|--------|-------------|-------------|----------|
|           |             | B            | β      | Lower limit | Upper limit |          |
| ΔHR       | Constant    | 27.844       |        | 18.022      | 37.666      | 0.000*** |
|           | Age (years) | -0.164       | -0.317 | -0.265      | -0.063      | 0.002**  |
|           | Gender      | -0.443       | -0.039 | -2.664      | 1.778       | 0.014**  |
| ΔSBP      | Constant    | 2.244        |        | -6.165      | 10.653      | 0.597    |
|           | Age (years) | 0.140        | 0.312  | 0.053       | 0.226       | 0.002**  |
|           | Gender      | -2.731       | -0.279 | -4.632      | -0.829      | 0.005**  |
| ΔDBP      | Constant    | 8.426        |        | 0.788       | 16.06       | 0.031    |
|           | Age (years) | -0.163       | -0.4   | -0.242      | -0.084      | 0.000*** |
|           | Gender      | 1.659        | 0.187  | -0.068      | 3.386       | 0.06     |
| ΔMAP      | Constant    | 4.251        |        | -2.207      | 10.71       | 0.194    |
|           | Age (years) | -0.082       | -0.254 | -0.149      | -0.016      | 0.016**  |
|           | Gender      | 0.757        | 0.107  | -0.703      | 2.218       | 0.222    |

Statistical analyses were done by multiple regression analysis; ΔHR: change in heart rate; ΔSBP: change in systolic blood pressure; ΔDBP: change in diastolic blood pressure; ΔMAP: change in mean arterial pressure; N: total number of subjects; \*\* - p < 0.01; \*\*\* - p < 0.001.

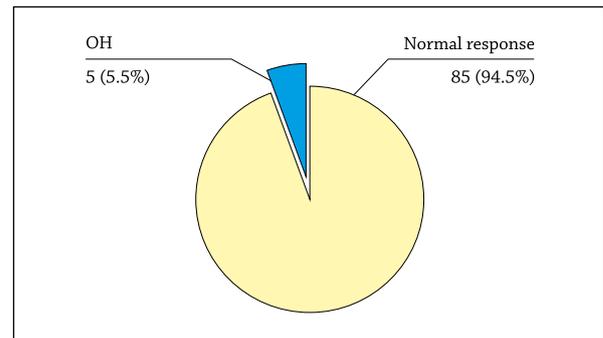


Figure 1. Frequency distribution (%) of all the study subjects with orthostatic hypotension (OH). Cut point of OH: drop in SBP ≥ 20 mm Hg and drop in DBP ≥ 10 mm Hg [7].

Schondorf and Low did not find any significant change in SBP between sexes following tilt test [11]. These authors suggested a gender-specific difference in BP regulation, and less orthostatic tolerance in females.

In the present study, no significant difference in post-tilt HR, SpO<sub>2</sub>, DBP and MAP was found between females and males after tilting.

In addition, the comparison of orthostatic tolerance between females and males demonstrated a lower cardiovascular adjustment in females as evidenced by greater drop in SBP in response to postural challenge, suggesting a gender-specific difference in cardiovascular response to orthostatic stress. This is further supported by a higher frequency of OH in females. All these observations therefore suggest that females are more susceptible to orthostatic intolerance than males.

For further detail of variation of orthostatic tolerance due to phasic variation of menstrual cycle, previous studies suggested greater changes during the luteal phase [13–14]. Some studies, however, did not

find any phasic difference in menstrual cycle in orthostatic tolerance [15].

In our study the phasic variation of the menstrual cycle on orthostatic stress on female was not explored.

In addition, the significant greater drop in SBP, observed in females than males strongly suggest less sympathetic response in females than males and the changes of baroreflex function maybe different between sexes [10–11].

This observed gender difference may be attributed to less splanchnic vasoconstriction and more blood pooling in the splanchnic region in females. This creates less venous return to the heart, less cardiac output and a greater drop in SBP in females [13].

The non-significant difference of DBP, MAP in the present study suggests that there was no difference in the compensatory increase of total peripheral resistance between females and males. A greater rise of DBP and MAP in males was associated with an increased peripheral resistance due to sympathetic over excitation [11].

Moreover, the non-significant difference of HR between females and males in this study suggests that there is no gender variation in parasympathetic response to postural change. Jarvis et al. also did not find HR differences between sexes [10]. Shoemaker et al. observed a significant increase in HR in females than that of males [16]. Conversely, HR was significantly higher in males than females which was witnessed by Schondorf and Low [11]. These investigators suggested that, the inhibitory baroreflex involved in the control of vasomotor and cardiomotor tone is less in females than males, which is responsible for less increment of HR in females [11]. Okada et al. also found lower baroreceptor sensitivity (BRS) in females than males [17].

In addition, difference of SpO<sub>2</sub> after tilt was not significant when compared between females and males in this study.

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# COMPARISON OF RISK FACTORS FOR LOW BIRTH WEIGHT AMONG MOTHERS WITH NORMAL AND LOW BIRTH WEIGHT BABIES

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**A** – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

## ABSTRACT

**Background:** Low birth weight is an alarming problem in developing countries and has severe future complications.

**Aim of the study:** Our study aimed to compare the risk factors among mothers with low and normal birth weight babies.

**Material and methods:** A cross-sectional study was carried out on 1000 mothers with normal and low birth weight babies (500 per group) over two years. Maternal parameters including age, hemoglobin levels, gravida, maternal weight gain, height, pregnancy-induced hypertension, etc., were collected along with anthropometric data of the child. We compared risk factors among the low and normal birth weight babies using the chi-square test, determining statistical significance at  $p < 0.05$ , and high statistical significance at  $p < 0.01$ .

**Results:** Highly statistically significant associations were observed between low birth weight and seven variables: maternal age ( $p = 0.0074$ ), maternal height ( $p < 0.0001$ ), weight ( $p < 0.0001$ ), weight gain ( $p < 0.0001$ ), hemoglobin ( $p < 0.0001$ ), severe anemia ( $p < 0.0001$ ), and pregnancy-induced hypertension ( $p < 0.0001$ ).

**Conclusions:** Our study observed significant modifiable risk factors like weight gain, weight, hemoglobin, and anemia among mothers with low birth weight babies. If we focus on raising awareness surrounding these risk factors, there may be an improvement in the birth weight of babies in this population.

**KEYWORDS:** infant, low birth weight, hemoglobin, risk factors, anemia, India

## BACKGROUND

Low birth weight (LBW) is the principal cause of fetal and postnatal deaths, and is one of the most pressing preventable public health problems prevalent in developing countries [1]. LBW babies are live babies who are weighing less than 2500 grams regardless of their gestational age and measured before the occurrence of remarkable postnatal weight loss [2,3]. According to the latest World Health Organization (WHO) data published in 2017, low birth weight deaths in India reached 3.75% of total mortality, and ranked 17th in the world [4]. In 2015, 20.5 million newborns, an estimated 14.6% of all babies born globally that year, suffered from low birth weight [5]. These babies were more likely to die

during their first month of life, and those who survive face lifelong consequences including a higher risk of stunted growth, low IQ, and adult-onset chronic conditions such as obesity and diabetes [5]. Death among low birth weight neonates is 20 times higher than normal birth weight infants [6,7]. In our region of study, the majority of patients are from rural areas, and are mostly unaware of the factors contributing to low birth weight. Therefore, we aimed to assess the risk factors causing low birth weight among low and normal birth weight babies. The result may assist in the planning of effective management strategies, and may contribute to reducing the prevalence of low birth weight to some extent.

## AIM OF THE STUDY

Our study aimed to compare the risk factors among mothers with low and normal birth weight babies.

## MATERIAL AND METHODS

### Study design

A comparative observational study was carried out among mothers with normal and low birth weight babies.

### Study duration and study site

The study duration was two years (October 2017 to October 2019), and was carried out in a maternity in-patient ward, Department of Obstetrics and Gynecology.

### Study participants

Mothers with normal and low birth weight babies were included. Mothers who got abortion, with insufficient data in the case sheet were excluded from the study. Written informed consent was obtained from all participants.

### Sampling technique and sample size

Simple random sampling technique was employed to select the subjects. The sample size for each group was 500 (n=1000).

### Data collection

Maternal parameters such as age, height, weight, weight gain, gravidity, level of hemoglobin, presence or absence of hypertension, gestational diabetes mellitus, history of abortions, history of multiple pregnancies, information about urinary tract infection during pregnancy etc., were collected from obstetrics records. We interacted with mothers (if they were willing to cooperate for data collection) or with care takers for any other significant data. The babies were categorized into very low birth weight (<1500 g), low birth weight (<2500 g) and normal birth weight (>2500 g).

### Data analysis

Frequency, mean, and standard deviation were calculated for quantitative data. Chi-square test was used to compare the association of risk factors for low birth weight among mothers with normal birth weight and mothers with low birth weight. Minitab (version 18.0) was used. A  $p < 0.05$  was considered statistically significant, and a  $p < 0.01$  was considered as highly statistically significant association.

## RESULTS

Tab. 1 represents the proportion of risk factors among mothers with low vs. normal birth weight. The mean age of mothers with low birth weight was  $18.76 \pm 0.84$  years. The proportion of mothers with

maternal age <20 years (53.4%), maternal height <145 cm (60.6%), weight <40 kg (12.8%), maternal weight gain <7 kg (23%), Hemoglobin <10 g/dL (94.4%), severe anemia <7 g/dl Hb (23.6%) and pregnancy-induced hypertension (16.6%) was higher than mothers with normal weight babies. Only 7.4% of mothers with low birth weight babies reported urinary tract infection.

Table 1. Distribution and comparison of risk factors among low and normal birth weight babies.

| Name of the risk factor | Very LBW  | LBW | Total | NBW         | p-value     |         |
|-------------------------|-----------|-----|-------|-------------|-------------|---------|
| Maternal Age            | <20 years | 59  | 208   | 267 (53.4%) | 226 (45.2%) | 0.0074  |
|                         | >20 years | 37  | 196   | 233 (46.6%) | 274 (54.8%) |         |
| Maternal Height         | <145 cm   | 66  | 237   | 303 (60.6%) | 90 (18%)    | <0.0001 |
|                         | >145 cm   | 30  | 167   | 197 (39.4%) | 410 (82%)   |         |
| Maternal Weight         | <40 kg    | 14  | 50    | 64 (12.8%)  | 5 (1%)      | <0.0001 |
|                         | >40 kg    | 82  | 354   | 436 (87.2%) | 495 (99%)   |         |
| Weight Gain             | <7 kg     | 59  | 60    | 119 (23%)   | 7 (1.4%)    | <0.0001 |
|                         | >7 kg     | 37  | 344   | 381 (76.2%) | 493 (98.6%) |         |
| Hemoglobin              | <10 g     | 87  | 385   | 472 (94.4%) | 89 (17.8%)  | <0.0001 |
|                         | >10 g     | 9   | 19    | 28 (5.6%)   | 411 (82.2%) |         |
| Severe Anemia           | <7 g      | 33  | 85    | 118 (23.6%) | 67 (13.4%)  | <0.0001 |
|                         | >7 g      | 54  | 300   | 382 (76.4%) | 433 (85.4%) |         |
| PIH                     | Present   | 34  | 49    | 83 (16.6%)  | 15 (3%)     | <0.0001 |
|                         | Absent    | 62  | 355   | 417 (83.4%) | 485 (97%)   |         |
| UTI                     |           | 10  | 27    | 37 (7.4%)   | -           | -       |

LBW = Low Birth Weight; NBW = Normal Birth Weight; PIH = Pregnancy Induced Hypertension; UTI = Urinary Tract Infection;  $p < 0.01$  is statistically highly significant.

## DISCUSSION

### Key results

We observed a highly statistically significant association ( $p < 0.01$ ) between low birth weight of babies and maternal factors including age, height, weight, weight gain, hemoglobin, severe anemia, and pregnancy induced hypertension.

### Interpretation

We observed that 53.4% of low birth weight babies are born to mothers aged less than 20 years; few studies reported similar findings [8,9]. Maternal age was highly statistically significantly associated with low birth weight ( $p=0.007$ ); Ahankari et al. [10] also reported a similar association ( $p=0.008$ ). However, Domple et al. [11] reported contrasting findings. The National Population Policy of India states that poor physical, mental, and emotional development of pregnant women less than 21 years old will result in low birth weight babies. In this regard, they suggested delayed marriages for girls younger than 21 years, and also to make contraception widely available to delay age at first pregnancy [12].

We observed a highly statistically significant association with low birth weight and maternal height

( $p < 0.0001$ ). Dimple et al. [11], Kader et al. [13] reported statistically significant associations of low birth weight babies with maternal height. Women with short stature (height  $< 145$  cm) are at risk of delivering low birth babies [13]. Maternal height could affect intrauterine growth, and any deficiency in stature could impose physical limitations on the fetus [14]. However, the cut-off point for the maternal height varies across populations and ethnicities, as identified by similar studies conducted in different regions and countries [15–17].

The mean weight of mothers with low birth weight was  $36.8 \pm 2.3$  kg. We observed a highly statistically significant association with maternal weight. Agarwal et al. [9], Chhabra [18] also reported a statistically significant association. A low pre-pregnancy is a marker for minimal tissue nutrient reserves [19], and changes in maternal blood flow prevent the fetus from receiving an adequate supply of nutrients [20]. Lower volume expansion in malnourished underweight women decreases micronutrient status and may reduce fetal growth [21].

We observed a highly statistically significant association with maternal weight gain ( $p < 0.0001$ ); some studies have reported similar results [11,16,22–24]. Intrauterine growth depends upon calorie intake and nutritional stores, mostly fat. Inadequate weight gain will affect this and contributes to low birth weight babies [25].

We observed a highly statistically significant association between low birth weight and hemoglobin ( $p < 0.0001$ ), as well as severe anemia ( $p < 0.001$ ); some studies reported statistically significant association between low birth weight and hemoglobin [2,11,22]. Anemia, especially if critical, could impair oxygen delivery to the fetus and thus interfere with healthy intrauterine growth or pregnancy duration [14]. Two major mechanisms by which anemia causes low birth weight are intrauterine growth restriction due to low oxygenation, and reduced size and surface of the placenta

[26,27]. The importance of iron, and thus hemoglobin, in the development of the fetus, is well established. Indian women are known to be iron deficient. Therefore, the Reproductive and Child Health Program included the provision of iron supplements to pregnant women [28].

We observed a statistically significant association between low birth weight and pregnancy-induced hypertension ( $p < 0.0001$ ). Dimple et al. [11], Bhaskar et al. [29] reported significant association, while Sengupta et al. [30] reported no association. Adequate blood flow to fetus depends on both systolic and diastolic blood pressure [14], and decreased blood perfusion leads to intrauterine growth retardation and low birth weight [31]. We observed 7.4% of urinary tract infection cases among mothers. Infection causes fever, and the resulting changes in the level of cytokines due to mobilization of the maternal immune system [32], unregulated apoptosis, and transcription of heat shock proteins, may divert resources away from normal protein synthesis and development [33].

### Limitations of the study

Data on urinary tract infection of mothers with normal birth weight babies cannot be obtained because of insufficient data.

### CONCLUSIONS

Maternal weight gain, weight, hemoglobin levels, and anemia were the observed risk factors observed among our study subjects. Awareness surrounding these modifiable risk factors may help improve the birth weight of babies.

### ETHICAL APPROVAL

The study was approved by the ethical committee (VIPT/IEC/49/2017).

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# THE SURGICAL OUTCOMES OF PATIENTS WITH PERONEAL NERVE INJURY: A CLINICAL STUDY

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## ABSTRACT

**Background:** Nervus peroneus communis (NPC) is the most frequently entrapped nerve in the lower extremity. Although first-line treatments for peroneal nerve injury include conservative methods, patients who do not show benefit are further treated with surgical decompression.

**Aim of the study:** The purpose of this study was to investigate the clinical and functional results of patients who were surgically treated for peroneal nerve injury.

**Material and methods:** This retrospective study reports on 20 consecutive patients who underwent surgery for peroneal nerve damage between March 2012 and December 2015. Visual Analogue Scale (VAS) pain scores and neurological examinations were evaluated preoperatively and at the last postoperative visit (mean follow-up period = 10.2 months). All parameters were analyzed using Mann-Whitney U tests and results were considered significant using a  $p < 0.05$  threshold.

**Results:** According to the British Medical Council Motor Strength Evaluation Scale, 80% ( $n = 16$ ) of patients showed an improvement and 20% showed no change ( $n = 4$ ). VAS pain scores significantly decreased ( $p < 0.05$ ) from the preoperative ( $M \pm SD = 5.9 \pm 0.4$ ) to the postoperative time point. ( $1.6 \pm 0.3$ ).

**Conclusions:** Our data suggest positive results for surgical removal of reversible causes among peroneal nerve damage cases who do not respond to conservative treatment.

**KEYWORDS:** nervus peroneus communis, entrapment, surgery

## BACKGROUND

Compression of the peripheral nerve between ligaments or within the fibrous bone canals is known as “entrapment neuropathy”. The nervus peroneus communis (NPC) is the most frequently entrapped nerve in the lower extremity [1]. The NPC originates from the sciatic nerve and passes distal to the popliteal fossa where it then separates into two main branches – the deep and superficial peroneal nerves. The NPC has an extremely superficial course below the fibula head where it is covered only by skin and subcutaneous tissue [2,3]. In addition, because the fibula head is hypermobile, the nerve is most often injured in this region [4].

Common causes of NPC injury include trauma, presence of a mass in the fibula head or in the proximal lower leg, conditions which cause increased pressure in the fibula head (e.g., related to the position or application of a plaster cast), intraneural tumors, and excessive weight loss [5–7].

The most frequently reported presenting symptom is difficulty in walking which develops in conjunction with weakness in the foot dorsoflexors. The Tinel test is also generally positive [3]. The most commonly used diagnostic method is nerve conduction study. Although first-line treatments for peroneal nerve injury include conservative methods, patients who do not show benefit are further treated with surgical decompression [8].

## AIM OF THE STUDY

The aim of this study was to evaluate the clinical and functional results of patients who were surgically treated for NPC injury.

## MATERIAL AND METHODS

### Settings

Ethics committee approval was obtained for the study from the KTO Karatay University Faculty of

Medicine (2018/006). Written informed consent was obtained from all patients for photographing and inclusion in the study.

### Participants

This retrospective study reports on 20 consecutive patients who underwent surgery for peroneal nerve damage between March 2012 and December 2015.

### Data sources/measurement

Nerve conduction study of the NPC was used to determine nerve damage and entrapment at the level of the fibula head. Nerve conduction results demonstrated conduction block and a slowing in the rate of transmission in the NPC at the level of the fibula head among all patients. Patients with partial motor loss were first treated with conservative methods whereas patients who presented following trauma or with a foot drop were immediately admitted for surgery. The lesion etiologies are shown in Tab. 1.

Neurological examinations were conducted according to the British Medical Council Motor Strength Evaluation Scale and Visual Analogue Scale (VAS) leg pain was administered to each patient preoperatively and at the last postoperative visit.

**Surgical Procedure:** All patients underwent general anesthesia. Surgery was performed in the supine position and the knee was flexed into the appropriate position. The skin incision was made on the midline of the thigh, starting a few centimeters proximal to the popliteal fold and continuing in the inferior direction. The incision was extended to as far as 6-8 cm below the fibula head from approximately 1 cm medial of the biceps femoris tendon by turning laterally to cross the fibula. The popliteal fascia was opened by deepening the incision. The peroneal nerve was revealed below the biceps tendon. The entry of the nerve below the posterior edge

Table 1. Diagnosis of patients with peroneal nerve injury.

| Diagnosis                                   | n | %  |
|---|---|----|
| Long time working in the squatting position | 7 | 35 |
| Following knee surgery                      | 5 | 25 |
| Falling down                                | 4 | 20 |
| Long plaster or orthosis                    | 2 | 10 |
| Ganglion cysts                              | 2 | 10 |



Figure 1. This photograph shows position of the knee, skin incision and decompressed nerve in one exemplar patient.

of the peroneus longus muscle was followed and the separation of the nerve into the superficial and deep branches was observed. Part of the deep surface of the extensor digitorum longus muscle was opened and the deep nerve branch was released (see Fig. 1).

If a mass or cyst was identified within the nerve, entry to the nerve was made by opening the perineurium. The cyst or mass was subsequently excised with aspiration and tissue forceps (Fig. 2).



Figure 2. Intraoperative photograph demonstrating an intraneuronal ganglion cyst in an exemplar patient.

## Statistical analysis

According to Kolmogorov Smirnov test, the data were not normally distributed. Thus, nonparametric tests were performed. Statistical analysis was performed using Mann-Whitney U tests with SPSS 20.0 for Windows. Results were considered significant at a  $p < 0.05$  threshold.

## RESULTS

Twelve of the 20 patients were males, eight were females and the  $M \pm SD$  age was  $47.8 \pm 4.3$  years. Operations were applied to the right side of the body in 65% of patients and to the left side in 35%. The average time for operation from the onset of the symptoms was  $2.8 \pm 0.9$  months and the mean follow-up period was 10.2 months.

According to the British Medical Council Motor Strength Evaluation Scale, 80% ( $n = 16$ ) of patients showed an improvement and 20% showed no change ( $n = 4$ ). VAS pain scores significantly decreased ( $p < 0.01$ ) from the preoperative ( $M \pm SD = 5.9 \pm 0.4$ ) to the post-operative time point ( $1.6 \pm 0.3$ ). No patients in the study showed major complications after surgery.

## DISCUSSION

NPC damage can be caused by knee surgery, trauma, ganglion cysts, bone tumors, nerve tumors, thyrotoxicosis, excessive weight loss, alcoholism, and vasculitis [8–13].

Clinical symptoms can vary from complete-incomplete nerve damage, include paraesthesia and pain down the outer aspect of the leg, cutaneous sensation, weakness of the foot or foot-drop. Steppage gait develops in patients to prevent stumbling due to loss of strength in the feet [8]. The Tinel test is generally positive around the fibula head [5,14].

The most useful tests include a study of nerve conduction and assessment of the lesion. Conduction block and a slowing in the rate of transmission for conduction is also frequently observed in the NPC at the level of the fibula head. Nerve conduction studies should also be performed during preoperative assessments of differential diagnosis of the foot-drop [15]. In our study, two patients had previously undergone lumbar disc herniation surgery which may have contributed to foot-drop.

The surgical strategy should be determined according to the underlying pathology and the aim should be

adequate decompression of the nerve. Ganglion cysts play a significant role in compression syndromes of the peroneal nerve at the fibula head. Synovial fluid leaking from the tibiofibular joint following trauma can lead to the formation of a ganglion cyst which can put pressure on the nerve. The formation of a ganglion cyst can also create pressure effects from outside the nerve, as well as, damage by entering the nerve from the perineurium [8,10,13]. Two patients in the present study presented with ganglion cysts that had entered the peroneal nerve. These two patients presented with painful foot-drop. In both cases, the cysts were drained by opening the nerve perineurium, and adequate decompression was provided (Fig. 2). Although pain levels were reduced, there was no recovery in motor functioning. Optimal recovery of peroneal nerve damage is obtained with a full knowledge of the etiology and severity of the lesion, the application of the necessary clinical and electrophysiological tests, and appropriate treatment methods and timing.

In our study, surgical decompression was applied to NPC entrapment syndrome patients. Significant improvement was observed in motor functions and VAS pain scores of the patients, and no major complications were noted.

## LIMITATIONS OF THE STUDY

This study was limited by the retrospective design. Nonetheless, the present findings may contribute to the treatment of NPC entrapment syndrome. Another limitation of the study is lack of diagnostics with high-resolution ultrasound, which is now regarded as a standard complementary procedure in nerve conduction studies. High-resolution ultrasound can also be used preoperatively to delineate the site and morphological basis of peroneal neuropathy (e.g., intraneural cyst or nerve tumor).

## Recommendations

Surgery should be kept in mind in case of reversible peroneal nerve paralysis according to etiology.

## CONCLUSIONS

In conclusion, NPC damage generally occurs in the fibula head because of the anatomical properties. In cases that do not respond to conservative treatment, when the reversible causes are surgically removed, the results are generally good.

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# PROTEIN INTAKE AMONG HEALTHY ADULTS UNDERTAKING REGULAR MUSCLE STRENGTH TRAINING

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## ABSTRACT

**Background:** Protein is a basic macronutrient supplied to the body via food intake and one of the key dietary elements of physically-active populations.

**Aim of the study:** The aim of the study was to analyze the protein intake of healthy adults undertaking regular muscle strength training.

**Material and methods:** This study was conducted on 168 healthy adults: 84 women (25.9±6.1 years) and 84 men (25.5±5.4 years) performing strength training on a regular basis (~4 times a week). Protein intake was determined using a structured questionnaire to quantify the amount, source, and frequency of protein consumed.

**Results:** The participants declared an average daily protein intake of 153.8±50.2 g, with women reporting lower intake (115.9±28.3 g) than men (184.8±42.2 g) ( $p < 0.001$ ). The main sources of protein were poultry meat, dairy products (e.g. milk, eggs), and protein supplements. 79% of participants declared using protein supplements, but no differences between women (79%) and men (80%) were found ( $p > 0.05$ ). The amount of protein supplied by supplementation was, on average, 37.3±21.5 g with a lesser amount reported by women (28.6±13.2 g) than men (45.5±24.5 g) ( $p < 0.001$ ). 62.9% of participants consumed supplements in the form of whey protein concentrate and 42.6% took protein supplements immediately after training.

**Conclusions:** The study participants consumed an excess amount of protein in comparison to the recommended daily intake. Protein supplementation accounted for a ¼ of daily protein intake, most often consumed immediately after training and generally in the form of whey protein concentrate. Nutritional education is necessary to align the eating habits and supplemental intake of physically active adults, relative to strength-training demands.

**KEYWORDS:** protein, nutrition, amateur athletes, muscle strength training

## BACKGROUND

Proteins consist of amino acids the building blocks for all body tissue. Protein is the macronutrient supplied to the body with food. It is also one of the key dietary elements of populations with a high level of physical activity (PA), especially among those engaged in regular strength training that activates the major muscle groups.

Muscle protein turnover in the human body is a constant process involving muscle protein synthesis (MPS) and muscle protein breakdown (MPB). Over time, the net balance between MPS and MPB will determine whether an individual experiences a decrease, maintenance

and increase in overall muscle mass. PA, especially resistance training, and nutritional intake (e.g. carbohydrate and protein availability), have a significant impact on this process [1,2]. Resistance training stimulates MPS, but also MPB. Depending on the method and quality of protein supplied, MPS may persist for up to 24 hours after training or longer in the case of large training volumes [3]. The time of protein intake, the number of meals containing protein during the day, the intervals between meals and between meals, and training are extremely important [4,5]. Studies show that protein consumed immediately after physical exercise has the greatest impact on muscle hypertrophy [6].

Current recommendations suggest higher protein demands for highly active populations to maximize metabolic adaptation to training [7,8]. The American Dietetic Association (ADA), Dietitians of Canada (DC) and American College of Sports Medicine (ACSM) issued a joint position in 2016, specifying the norms of protein intake for athletes at 1.2–2.0 g/kg of bodyweight (BW)/day [9]. A similar guideline was offered by the International Society of Sports Nutrition (ISSN), with a daily protein intake of 1.4–2.0 g/kg of BW/ per day for populations engaged in high levels of physical activity [10]. In 2017, Morton in his meta-analysis recommended protein intake for individuals involved in strength training at 1.62 g/kg per day [11]. In a recent meta-analysis, Iraki and colleagues stated that 1.6–2.2 g/kg of BW is a sufficient (daily) amount of protein and should be consumed across 3–6 meals during the day [12]. Larger amounts of protein may be necessary during periods of intensified training [12,13]; thus, the amount of protein consumed every day can differ according to exercising demands. To estimate the protein demands for a given person, it is necessary to consider the amount of time, intensity and frequency of training, training period, availability of energy and other nutrients occurring in the diet [9].

Demand for protein should be covered by a classic, well-balanced diet. The main sources of whole protein are dairy products, meat sources and legume seeds. There is evidence that proteins derived from dairy products, and consumed after resistance training sessions, can lead to increases in muscle strength and mass [6,14,15]. Milk, lean meat, and protein supplements (egg, soy, whey, and casein proteins) are thought to intensify MPS [16]. Studies also show that protein supplements taken by those populations involved in strength training is relatively high [10,17]. However, supplementation with protein preparations is generally recommended for populations with high physical demands, and who are not able to meet their protein needs by consuming conventional meals [9].

## AIM OF THE STUDY

The aim of this study was to analyze the protein intake of healthy adults, currently participating in regular strength training, with a specific focus on the amount of consumed protein, sources of protein, and frequency of consumption.

## MATERIAL AND METHODS

### Participants and study design

The study included 168 healthy adults, aged 18–47 years, who were recruited from sport clubs in Lodz across several strength sports: triathlon, bodybuilding training, weightlifting and crossfit. The criteria for inclusion was regular participation in one of above

muscular strength training. Each person voluntarily agreed to participate in this study.

This study was carried out in 2017 and 2018. A structured questionnaire was used to collect the data. The questionnaire contained sixteen closed and short-answer questions about: sex, age, body mass, height, training, basic nutritional habits, protein and protein supplements taken. Each person completed the questionnaire before training starts and the results were sent back to the lead researcher.

### Statistical methods

The data collected were analyzed in the Statistica 13.0 software package. The normality of data distribution was checked and verified using the Shapiro-Wilk test. All analyzed variables were normally distributed. Means and standard deviations for the study variables were calculated. Comparisons between women and men on each variable were carried out using an independent student T-test for quantitative variables. P-values of less than 0.05 were considered statistically significant.

## RESULTS

### Participants

The study cohort comprised of 84 women and 84 men with a mean age of 25.7±5.8 years. The BMI values were 24.1±3.8 kg/m<sup>2</sup> overall, but were higher among men than women. The reported number of training sessions per week was 4.0±1.2 and the duration of a single workout was 79.0±25.2 min. The length of individual training sessions were longer for men (by 13.5 min) than that reported by women (p<0.05). Data is presented in Tab. 1.

Table 1. Characteristic of study group.

| Tested parameter                      | Average values |              |            |
|---------------------------------------|----------------|--------------|------------|
|                                       | All (n=168)    | Women (n=84) | Men (n=84) |
| Age [years]                           | 25.7±5.8       | 25.9±6.1     | 25.5±5.4   |
| Body mass [kg]                        | 73.1±16.4      | 61.0±8.9     | 85.3±12.8  |
| Height [cm]                           | 173.4±9.2      | 166.5±5.8    | 180.3±6.3  |
| BMI [kg/m <sup>2</sup> ]              | 24.1±3.8       | 22.0±2.8     | 26.2±3.6   |
| Training sessions per week [number]   | 4.0±1.2        | 3.8±1.0      | 4.1±1.3    |
| Duration of a training session [mins] | 79.0±25.2      | 72.3±21.0*   | 85.8±27.0  |

Statistical significance women vs. men: \* p<0.05, \*\* p<0.01

### Main results

Overall, 60.12% of respondents declared eating 4 meals/day, including 70.24% of women and 50% of men, whereas only 1 woman (0.60% of all respondents) declared only 1 meal/day. 39.29% women and 27.38% men eat meals regularly, its mean every 3–4 hours (Tab. 2.)

Table 2. Number and regularity of meals during the day in study group.

| Tested parameter             |        | All (n=168) |       | Women (n=84) |         | Men (n=84) |        |
|------------------------------|--------|-------------|-------|--------------|---------|------------|--------|
|                              |        | n           | [%]   | n            | [%]     | n          | [%]    |
| Number of meals during a day | 2      | 1           | 0.60  | 1            | 1.19    | 0          | 0.00   |
|                              | 3      | 20          | 11.90 | 5            | 5.95    | 15         | 17.86* |
|                              | 4      | 101         | 60.12 | 59           | 70.24** | 42         | 50.00  |
|                              | ≥5     | 46          | 27.38 | 19           | 22.62   | 27         | 32.14  |
| Regularity of meals          | Yes    | 56          | 33.33 | 33           | 39.29   | 23         | 27.38  |
|                              | Partly | 56          | 33.33 | 26           | 30.95   | 30         | 35.71  |
|                              | No     | 56          | 33.33 | 25           | 29.76   | 31         | 36.90  |

Statistical significance women vs. men: \*  $p < 0.05$ , \*\*  $p < 0.01$

Respondents ( $n = 131$ ) consumed an average of  $153.8 \pm 50.2$  g of protein per day, but at a lower overall level among women ( $n = 59$ )  $115.9 \pm 28.3$  g than men ( $n = 72$ )  $184.8 \pm 42.2$  g ( $p < .001$ ). Poultry was consumed several times a week for many participants (43.45%)

and equally among women and men. Pork and beef, veal and lamb were consumed 1–3 times a month by 34.52% and 49.40% respectively. Fish and seafood, among 37.50%, were consumed 1–3 times a month. 25.60% declared that they do not consume milk, including 32.14% women and 19.05% men, while 22.02% consumed milk daily: 23.81% women and 20.24% men. Dairy products were consumed several times a week. Many participants – 36.31% – declared that they consumed legume seeds 1–3 times a month, while 21.43% did not consume legume seeds. 38.10% of participants ate eggs every day, including 41.67% women and 34.52% men. Data are showed in Tab. 3.

79% of participants reported taking protein supplements: 79% of women and 80% of men. The average amount of protein consumed during the day ( $n = 130$ ) from supplements was  $37.3 \pm 21.5$  g, which is  $\frac{1}{4}$  of the total amount of daily protein intake. Women ( $n = 63$ ) consumed  $28.6 \pm 13.2$  g of protein via supplementation, compared to  $45.5 \pm 24.5$  g for men ( $n = 67$ ) ( $p < .001$ ).

Table 3. Frequency of high protein products intake.

| Source of protein                 |       | Never |       | 1-3 for a month |       | 1 for a week |       | A few times for a week |       | Everyday |       | A few times for a day |       |
|-----------------------------------|-------|-------|-------|-----------------|-------|--------------|-------|------------------------|-------|----------|-------|-----------------------|-------|
|                                   |       | n     | %     | n               | %     | n            | %     | n                      | %     | n        | %     | n                     | %     |
| Poultry                           | All   | 3     | 1.79  | 10              | 5.95  | 13           | 7.74  | 73                     | 43.45 | 34       | 20.24 | 35                    | 20.83 |
|                                   | Women | 2     | 2.38  | 7               | 8.33  | 8            | 9.52  | 39                     | 46.43 | 14       | 16.67 | 14                    | 16.67 |
|                                   | Men   | 1     | 1.19  | 3               | 3.57  | 5            | 5.95  | 34                     | 40.48 | 20       | 23.81 | 21                    | 25.00 |
| Pork                              | All   | 19    | 11.31 | 58              | 34.52 | 38           | 22.62 | 45                     | 26.79 | 5        | 2.98  | 3                     | 1.79  |
|                                   | Women | 14    | 16.67 | 28              | 33.33 | 19           | 22.62 | 19                     | 22.62 | 2        | 2.38  | 2                     | 2.38  |
|                                   | Men   | 5     | 5.95  | 30              | 35.71 | 19           | 22.62 | 26                     | 30.95 | 3        | 3.57  | 1                     | 1.19  |
| Beef, veal, lamb                  | All   | 32    | 19.05 | 83              | 49.40 | 25           | 14.88 | 25                     | 14.88 | 1        | 0.60  | 2                     | 1.19  |
|                                   | Women | 18    | 21.43 | 39              | 46.43 | 13           | 15.48 | 13                     | 15.48 | 0        | 0.00  | 1                     | 1.19  |
|                                   | Men   | 14    | 16.67 | 44              | 52.38 | 12           | 14.29 | 12                     | 14.29 | 1        | 1.19  | 1                     | 1.19  |
| Fish and seafood                  | All   | 15    | 8.93  | 63              | 37.50 | 61           | 36.31 | 24                     | 14.29 | 5        | 2.98  | 0                     | 0.00  |
|                                   | Women | 3     | 3.57  | 29              | 34.52 | 32           | 38.10 | 16                     | 19.05 | 4        | 4.76  | 0                     | 0.00  |
|                                   | Men   | 12    | 14.29 | 34              | 40.48 | 29           | 34.52 | 8                      | 9.52  | 1        | 1.19  | 0                     | 0.00  |
| Milk                              | All   | 43    | 25.60 | 29              | 17.26 | 9            | 5.36  | 32                     | 19.05 | 37       | 22.02 | 18                    | 10.71 |
|                                   | Women | 27    | 32.14 | 12              | 14.29 | 1            | 1.19  | 15                     | 17.86 | 20       | 23.81 | 9                     | 10.71 |
|                                   | Men   | 16    | 19.05 | 17              | 20.24 | 8            | 9.52  | 17                     | 20.24 | 17       | 20.24 | 9                     | 10.71 |
| Natural yogurt, kefir, buttermilk | All   | 26    | 15.48 | 32              | 19.05 | 23           | 13.69 | 42                     | 25.00 | 34       | 20.24 | 11                    | 6.55  |
|                                   | Women | 11    | 13.10 | 13              | 15.48 | 12           | 14.29 | 20                     | 23.81 | 21       | 25.00 | 7                     | 8.33  |
|                                   | Men   | 15    | 17.86 | 19              | 22.62 | 11           | 13.10 | 22                     | 26.19 | 13       | 15.48 | 4                     | 4.76  |
| Cottage cheese                    | All   | 20    | 11.90 | 21              | 12.50 | 23           | 13.69 | 58                     | 34.52 | 32       | 19.05 | 14                    | 8.33  |
|                                   | Women | 10    | 11.90 | 10              | 11.90 | 15           | 17.86 | 28                     | 33.33 | 16       | 19.05 | 5                     | 5.95  |
|                                   | Men   | 10    | 11.90 | 11              | 13.10 | 8            | 9.52  | 30                     | 35.71 | 16       | 19.05 | 9                     | 10.71 |
| Pulses                            | All   | 36    | 21.43 | 61              | 36.31 | 39           | 23.21 | 26                     | 15.48 | 5        | 2.98  | 1                     | 0.60  |
|                                   | Women | 14    | 16.67 | 31              | 36.90 | 21           | 25.00 | 15                     | 17.86 | 2        | 2.38  | 1                     | 1.19  |
|                                   | Men   | 22    | 26.19 | 30              | 35.71 | 18           | 21.43 | 11                     | 13.10 | 3        | 3.57  | 0                     | 0.00  |
| Eggs                              | All   | 4     | 2.38  | 12              | 7.14  | 15           | 8.93  | 59                     | 35.12 | 64       | 38.10 | 14                    | 8.33  |
|                                   | Women | 3     | 3.57  | 4               | 4.76  | 6            | 7.14  | 31                     | 36.90 | 35       | 41.67 | 5                     | 5.95  |
|                                   | Men   | 1     | 1.19  | 8               | 9.52  | 9            | 10.71 | 28                     | 33.33 | 29       | 34.52 | 9                     | 10.71 |

A small number (20.47%) of participants used protein supplements to accelerate post-workout regeneration, including 22.12% women and 18.63% men. Some men (21.57%) used protein supplements to accelerate muscle growth. Over a third of adults (39.07%) reported taking nutrients for other reasons, including improving the palatability of dishes, a replacement for conventional protein sources or an easy way to meet protein demand.

The most frequently chosen form of protein supplement was whey protein concentrate (WPC) and whey protein isolate (WPI), constituting 62.96% and 29.63% of all respondents' responses. WPC was taken by 56.25% women and 69.51% men, while WPI was taken by 37.5% women and 21.95% men ( $p < 0.05$ ).

A large number (42.62%) of adults consumed a protein supplement after training: 42.53% women and 42.71% men, whilst 33.33% consumed protein supplements with meals: 40.23% women and 27.08% men. 40% of our cohort declared taking amino acid supplements. Most individuals were taking creatine (53.13%) and BCAAs (19.79%), whilst a small number (15.63%) used other amino acid supplements, including glutamine, EAA, leucine, arginine and citrulline. Data presented in Tab. 4.

## DISCUSSION

The study aim was to analyze self-reported protein intake among healthy adults who, on a regular basis, participated in strength training. The outcomes were quantified in terms of the amount, source, and frequency of protein intake.

The average BMI was  $24.1 \pm 3.8 \text{ kg/m}^2$ , which means that the study group was characterized by a normal body size. However, the BMI values of men were  $26.2 \pm 3.6 \text{ kg/m}^2$ , suggesting an overweight group, whilst the values for women at  $22.0 \pm 2.8 \text{ kg/m}^2$  are consistent with a normal body size. Of course, BMI is not an appropriate tool for assessing the body composition of active populations, because it does not take into account the amount of muscle and fat tissue, which can differ significantly between highly active and sedentary populations with a similar BMI.

The number of daily meals and time interval between meals are important principals of proper nutrition for the general population, including athletic groups. In the present study, 60.12% of all respondents declared eating 4 meals throughout the day. The amount of meals consumed per day, particularly among highly active groups, can differ [18–23]. In the present study, 33.33% of all respondents declared somewhat regular meals each day.

Table 4. Characteristics of protein supplements intake in study group.

| Tested parameter                       |                                 | All (n=132) |       | Women |        | Men |       |
|--|---------------------------------|-------------|-------|-------|--------|-----|-------|
|  |                                 | n           | [%]   | n     | [%]    | n   | [%]   |
| Purpose of protein supplements intake  | regeneration acceleration       | 44          | 20.47 | 25    | 22.12  | 19  | 18.63 |
|  | ↑ muscles mass                  | 38          | 17.67 | 16    | 14.16  | 22  | 21.57 |
|  | ↓ body mass                     | 23          | 10.70 | 14    | 12.39  | 9   | 8.82  |
|  | ↑ muscles strength              | 20          | 9.30  | 10    | 8.85   | 10  | 9.80  |
|  | ↑ physical capacity             | 6           | 2.79  | 4     | 3.54   | 2   | 1.96  |
|  | other                           | 84          | 39.07 | 44    | 38.94  | 40  | 39.22 |
| Type of protein supplements intake     | WPC – Whey Protein Concentrate  | 102         | 62.96 | 45    | 56.25  | 57  | 69.51 |
|  | WPI – Whey Protein Isolate      | 48          | 29.63 | 30    | 37.50* | 18  | 21.95 |
|  | WPH – Whey protein Hydrolysate  | 2           | 1.23  | 1     | 1.25   | 1   | 1.22  |
|  | casein                          | 6           | 3.70  | 1     | 1.25   | 5   | 6.10  |
|  | other                           | 4           | 2.47  | 3     | 3.75   | 1   | 1.22  |
| Duration of protein supplements intake | before training                 | 10          | 5.46  | 4     | 4.60   | 6   | 6.25  |
|  | after training                  | 78          | 42.62 | 37    | 42.53  | 41  | 42.71 |
|  | during training                 | 0           | 0.00  | 0     | 0.00   | 0   | 0.00  |
|  | between meals                   | 13          | 7.10  | 3     | 3.45   | 10  | 10.42 |
|  | with meals                      | 61          | 33.33 | 35    | 40.23  | 26  | 27.08 |
|  | before sleep                    | 21          | 11.48 | 8     | 9.20   | 13  | 13.54 |
| Tested parameter                       |                                 | All (n=67)  |       | Women |        | Men |       |
|  |                                 | n           | [%]   | n     | [%]    | n   | [%]   |
| Aminoacid supplements intake           | creatine                        | 51          | 53.13 | 11    | 42.31  | 40  | 57.14 |
|  | BCAA – branch chain amino acids | 19          | 19.79 | 10    | 38.46  | 9   | 12.86 |
|  | B-alanine                       | 11          | 11.46 | 3     | 11.54  | 8   | 11.43 |
|  | other                           | 15          | 15.63 | 2     | 7.69   | 13  | 18.57 |

Statistical significance women vs. men: \*  $p < 0.05$

Protein requirements should be determined individually for each person, depending on factors like training time, intensity and frequency, degree of advancement, energy availability and other nutrients in the diet. In this work, the amount of protein consumed was  $153.8 \pm 3.8$  g per day overall, but with lower protein consumption among women ( $115.9 \pm 28.3$  g) than that seen for men ( $184.8 \pm 42.2$  g). Women and men consumed 1.9 g/kg and 2.2 g/kg of protein (normalized for BW/day), respectively. Since the study involved active adults, but not highly active athletes, protein intake was deemed too high in relation to current recommendations [9–12]. Other data reflect these results, including Gondek et al. [24] who showed that men taking part in strength training consumed 187.52 g of protein per day. In a study by Chappell [25], the amount of protein ingested was  $254 \pm 92.7$  g/day among males and  $172 \pm 28.3$  g/day among females, with others reporting similar differences between men ( $276.7 \pm 82.1$  g/day) and women ( $209.4 \pm 38.4$  g/day) [26]. Pilis et al. [27] found that protein intake among powerlifters was 171.93 g/day, which coincides with the current results. In the study by Całyniuk et al. [28], protein intake among powerlifters and weightlifters was 197.48 g and 197.91g, being successively higher than our observations Gogojewicz et al. [29] assessed the amount of protein consumed by women participating in fitness classes, which was  $54.8 \pm 15$  g, being half the amount consumed by women in this work. Oliver et al. [30] conducted a study outside of the starting season, among other strength-training disciplines, and found that protein consumption was 1.18 g/kg of BW/day, which is insufficient based on current guidelines. Ismael [31] showed that protein intake amongst bodybuilders was  $163.4 \pm 70.4$  g/day.

The demand for protein should be covered by a conventional diet. It is extremely important to choose the appropriate food products and source of complete protein. Wholesome animal products will provide wholesome protein. In this research, those products containing protein most often were poultry, milk, natural yogurt, kefir, buttermilk, cottage cheese and eggs, while the consumption of fish and milk were less frequent. Both fish and milk should be included in the diet, as natural sources of wholesome protein, but also other vital nutrients that have a positive effect on exercise capacity and post-workout regeneration [32].

In studies conducted by other authors [21,23,25], meat appeared in the diet of populations almost every day, whilst our results showed that 43.45% respondents ate poultry several times a week and consumed pork (34.52%) and beef (49.40%) 1–3 times a month.

Contrary to the present study, where 37.50% consumed fish 1–3 times a month and 36.31% once a week, other studies noted that fish products were consumed daily or several times a week [21,23,25]. Current recommendations suggest at least 2 servings of fish a week [33]. Legume seeds are a particularly good substitute for animal products and good source of wholesome protein. Indeed, 36.31% of our respondents consumed

legume seeds 1–3 times a month. Other studies have reported similar intake levels [23,25].

Studies show that milk enhances protein synthesis and thus, should be adopted as part of a balanced diet amongst physically active people [16,34]. We found that 25.60% of adults tested herein did not drink milk at all, while 22.02% consumed milk every day. In other studies, milk and dairy products are consumed daily [23] or several times a week [21]. Eggs are also a good source of protein. Therefore, it should be present in the diet for highly active individuals [33]. Not surprisingly, 38.10% of our participants consumed eggs daily, while 35.12% ate eggs several times a week, similar to other research in this area [25,35].

Morton et al. [11] indicated that protein supplementation can replenish a conventional diet and thus, have a positive effect on the development of muscle strength and mass. In 2016, Thomas et al. [36] draw a different conclusion in their meta-analysis, whereby protein supplementation did not significantly augment the beneficial effects of resistance exercise training. In present study, 79% of all respondents declared taking protein supplements, 79% of all women and 80% of all men. The number of people using protein supplements is similar to other studies [37–38]. In the present study, the amount of protein taken via supplementation was  $37.3 \pm 21.5$  g overall, but less for women  $28.6 \pm 3.2$  g versus men  $45.5 \pm 24.5$  g. In other work, the amount of protein taken by supplementation was highly variable; 38 g [27], 74.38 g [29], 46.71 g [39] among men undertaking strength training. The values obtained coincide somewhat with the present results.

Respondents justified the use of protein-based supplements to ensure, amongst other factors, faster regeneration (20.47% of all respondents), increase muscle mass (17.67%) and muscle strength (9.30%).

Our results showed that the most frequently chosen protein supplement is whey protein hydrolysate (WPH) and whey protein isolate (WPI) 62.96% and 29.63% respectively. Among amino acid supplements, respondents most often declared creatine (53.13%) and brain chain amino acids (BCAAs) (19.79%) intake. Respondents declared that they took supplements after training (42.62%) and with meals (33.33%). In other studies, the most frequently chosen protein supplement was creatine, protein nutrients, BCAA and other amino acids [37,38,40].

Both the present work and previous studies have shown that the use of protein supplements is popular among populations who regularly engage in strength training. The most used supplements include protein supplements, creatine and BCAAs.

The study results are limited by subjective reporting of protein intake, which may underestimate or overestimate actual consumption of this, and other, dietary factors. In addition, we did not dissect the nature of protein needs across different types of athletes or between groups employing different strength training protocols.

## CONCLUSIONS

The balance between protein demand and supplementation is often mis-matched, as we saw in the current study. The main sources of protein are poultry, dairy products, and eggs. They also supply protein from protein supplements which constitute  $\frac{1}{4}$  of the amount

of total protein delivered daily. Whey protein concentrate, creatine and BCAA are the most common supplements. Nutrition-based educational programs are necessary to modify eating habits and better align supplement intake among healthy, physical active adults involved in strength training.

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# WOMEN'S EXPECTATIONS AND PREFERENCES FOR CARE OF THE NEWBORN IN THE IMMEDIATE POSTPARTUM PERIOD

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**A** – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

## ABSTRACT

**Background:** The Regulation of the Minister of Health issued on 16th August 2018 addressed the matter of the organizational standard of perinatal care which determines guidelines concerning care of the newborn baby, in which skin-to-skin contact and early breastfeeding are important.

**Aim of the study:** The aim of this study is to explore women's preferences concerning care of the newborn in the immediate postpartum period.

**Material and methods:** 130 patients attending the Pro-Familia specialist hospital in Rzeszow participated in this research. The cohort consisted of pregnant women who had attended the doctor supervising their pregnancy before delivery. The research was carried out from March to April 2013 and the data collected was statistically analyzed, assuming a significance level of  $p < 0.05$ .

**Results:** Pregnant women most often expressed a preference of an accompanying person to cut the newborn's umbilical cord (59.2%), with 23.1% preferring a member of the medical team to do so. The majority (89.2%) of pregnant women wanted their baby to be laid on their stomach immediately following delivery to ensure skin-to-skin contact. In terms of Apgar scoring, 69.2% of women expected information about the Apgar score of their newborn immediately after delivery. Most women (60%) wished their newborn to be given routine vaccinations for hepatitis B and tuberculosis (BCG). Patients most often declare that they want to breastfeed exclusively (77.7%), with 29.2% of women expressing a wish to obtain more information about breastfeeding and 31.5% wishing to consult with a lactation specialist.

**Conclusions:** Pregnant women expect skin-to-skin contact immediately after delivery, the umbilical cord to be cut by an accompanying person and would like to be told their newborn's Apgar score. The women studied prefer exclusively breastfeeding, and express a wish to obtain information regarding lactation, and expect to be able to consult with a lactation specialist.

**KEYWORDS:** perinatal care, expectations, midwife, standard

## BACKGROUND

A dozen or so years ago, a baby was most often born not on the mother's abdomen but on the delivery bed and was taken to the neonatal ward immediately after delivery. This was explained by the need for the postnatal mother and baby to rest following delivery, as well as the "warming up" and observation of the neo-

nate. The mother could see her newborn baby only after a few hours [1]. In recent times, a new concept of perinatal care has appeared, taking into consideration the preferences of the mother and her family, which has enabled changes in perinatal care and care of the newborn baby [2]. The Regulation of the Minister of Health issued on August 16th 2018 guaranteed these

changes in the organizational standard of perinatal care, which determines guidelines for care of the newborn baby, in which skin-to-skin contact and early start of the first breastfeeding is emphasized [3]. The introduction of this new standard of perinatal care serves to improve the quality of services in the field of perinatal care. Formalizing the standard of care into the form of a legal act is expected to affect women's decisions concerning medical care [4].

In perinatal care now, great emphasis is placed on early physical contact between a mother and the newborn baby. This is achieved by placing the newborn on the mother's abdomen immediately following delivery. In the two hours following delivery, breastfeeding is encouraged to begin whenever possible. The assessment of the newborn baby and the anthropometric measurements are only made two hours after birth. The body-to-body contact should be stopped only if the health of a mother or a baby is threatened [1,3]. Close contact between a mother and a baby, especially during initial period, has an extremely beneficial effect influencing the acceptance of the newborn baby by the mother, regulation of the newborn's physiology and the strengthening of mutual bonds. This close contact also has a hormonal benefit, in stimulating the release of oxytocin. Oxytocin acts to stimulate lactation, reduce the risk of postpartum hemorrhage, reduce maternal stress levels and helps to regulate the temperature of the newborn [1,2]. Research shows that women who hold a baby right after birth in their arms, show less fear, greater faith in their own strengths, and greater ability to independently care for her newborn baby on the third day after delivery, when compared with mothers who were separated from their newborn following delivery [5].

## AIM OF THE STUDY

The aim of the study is to explore women's preferences regarding care of the newborn baby following delivery.

## MATERIAL AND METHODS

### Study design

The study was conducted among pregnant women in March and April 2013. The consent of the local bioethics commission was obtained for conducting the research. All respondents were informed about the subject of the study, the aim and the possibility of resigning from the study. Also, they were assured of preserving their complete anonymity.

### Participants

The study cohort comprises 130 qualifying patients who returned completed questionnaires. The study included pregnant women who attended the antenatal clinic of the Pro-Familia Specialist Hospital in Rzeszow

before delivery and met the following inclusion criteria: study area (city), pregnant patients who expected a short delivery, had their own ideas for delivery and prepared for it. The exclusion criteria consisted of: study area (village), non-pregnant patients.

### Data sources/measurement

In this study the research tool used was a survey constructed on the basis of available literature on the subject. The survey was divided into three parts: formal and organizational, basic (questions of various nature) and the medical record. The survey used closed, semi-open and open-ended questions to acquire information on women's preferences for newborn care.

### Statistical analyses

To study the relationship between variables the V Cramer and Phi tests were used to analyze questions on nominal scales. The chi-square test was used to check the existence of correlations in the entire research population. For questions on ordinal scales, Kendall Tb and Kendall Tc tests were used [6]. Calculations were made with the use of SPSS Statistics 20, assuming a significance level of  $p < 0.05$ . Chi-square test of independence, t test for independent variables and one-way analysis of variance (ANOVA) and Tukey's post-hoc test were carried out [7].

## RESULTS

### Characteristics of the study group

The average age of women surveyed was 27.7 +/- 1. They were predominantly married women (76.2%), 37.0% resided in a big city and the cohort studied generally had achieved higher education. Most women surveyed (53.1%) were currently in their first pregnancy (Tab. 1).

Table 1. Characteristics of the research group.

|                       |                            |                              |                         |                    |             |
|-----------------------|----------------------------|------------------------------|-------------------------|--------------------|-------------|
| Maternal age          | ≤ 24                       | 25 - 35                      | > 35                    |                    |             |
|                       | (N= 37) 28.5%              | (N= 86) 66.2%                | (N= 7) 5.4%             |                    |             |
| Place of residence    | City < 50,000 residents    | City > 50,000 residents      | Countryside             |                    |             |
|                       | (N= 40) 30.8%              | (N= 49) 37.7%                | (N= 41) 31.5%           |                    |             |
| Education             | Basic vocational education | Secondary level of education | Undergraduate education | Tertiary education |             |
|                       | (N = 2) 1.5%               | (N= 29) 22.3%                | (N= 25) 19.2%           | (N= 74) 56.9%      |             |
| Marital status        | Married                    | Unmarried                    | Co-habiting             |                    |             |
|                       | (N= 99) 76.2%              | (N= 17) 13.1%                | (N= 14) 10.8%           |                    |             |
| Number of pregnancies | 0                          | 1                            | 2                       | 3                  | 4           |
|                       | (N= 69) 53.1%              | (N= 40) 30.8%                | (N= 14) 10.8%           | (N= 5) 3.8%        | (N= 2) 1.5% |

### Main results

Women generally prefer immediate skin-to-skin contact, with 89.2% (n=116) of women preferring the

newborn to be laid on her stomach after delivery to ensure this early physical contact. When asked about preferences regarding the cutting of the umbilical cord, women most often indicated a preference for the umbilical cord to be cut by an accompanying person (59.2%, n=77), while 23.1% (n=30) would like this performed by a member of medical staff, and 2.3% (n=3) would like to cut the umbilical cord themselves (Tab. 2). One sixth of women; (15.4%, n=20) would like to cut the umbilical cord only after its pulsation has ceased.

Table 2. Maternal preferences regarding the umbilical cord.

| Maternal preferences                                       | N  | Percentage |
|--|----|------------|
| To be cut only after pulsation ceased                      | 20 | 15.4       |
| For the umbilical cord to be cut by an accompanying person | 77 | 59.2       |
| For the umbilical cord to be cut by myself                 | 3  | 2.3        |
| For the umbilical cord to be cut by medical staff          | 30 | 23.1       |

In terms of the newborn's Apgar score; 69.2% of women expressed a preference to be told their baby's Apgar score. Most women (60%, n=78) would like their newborn to receive hepatitis B and BCG vaccinations, and 26.2% (n=34) expressed a preference to feed their baby prior to any vaccinations (Tab. 3).

Women most often wish to breastfeed exclusively (77.7%, n=101), 29.2% (n=38) would like to obtain more information about breastfeeding and 31.5% (n=41) expect a consultation with a lactation specialist. Only 4.6% of women (n=6) plan to exclusively bottle feed (Tab. 4).

There is statistical significance between maternal age and desire to be informed if bottle feeding is necessary (p=0.008). There is also statistical significance between parity and preference to obtain more information regarding breastfeeding, with primiparous women being more likely to wish information regarding breastfeeding than parous women. Taking into consideration their education, no statistically significant relationship is found (p>0.05) (Tab. 5).

Table 3. Maternal preferences of medical staff following delivery.

| Maternal preferences  | N   | Percent |
|---|-----|---------|
| To have the newborn placed on my stomach "skin to skin" contact   | 116 | 89.2%   |
| To be informed about the baby's gender and time of birth before cutting the umbilical cord                | 75  | 57.7%   |
| I would like my accompanying person to be present during measurements and the first examination of a baby | 66  | 50.8%   |
| I would like to be informed of my baby's Apgar score  | 90  | 69.2%   |
| I would like to feed my baby before any planned vaccinations (about 30 min.)                              | 34  | 26.2%   |
| While I recovery I would like to have my baby with me at all times  | 46  | 35.4%   |
| I would like my baby to be in an adaptable room for newborns  | 2   | 1.5%    |
| I would like my baby to be in a neonatal room only at night   | 7   | 5.4%    |
| I would like to be given medication to provoke contractions to facilitate delivery of the placenta        | 16  | 12.3%   |
| I would like to deliver the placenta without being given medication to provoke contractions               | 26  | 20.0%   |
| I would like to be informed about the baby's examinations and any preventive activities                   | 71  | 54.6%   |
| I do not want my baby to be provided with HBV and BCG vaccinations  | 1   | 0.8%    |
| I want my baby to be provided with HBV and BCG vaccinations   | 78  | 60.0%   |
| I want my baby to be washed during the first day following delivery                                       | 14  | 10.8%   |
| I want my baby to be examined before going home in an adaptable room                                      | 60  | 46.2%   |
| I do not want my baby to be examined before going home in an adaptable room                               | 1   | 0.8%    |
| I want any procedures with the baby to be done in my or my partner's presence                             | 60  | 46.2%   |

Table 4. Maternal preferences regarding feeding.

| Maternal preferences  | N   | Percentage |
|---|-----|------------|
| To breast-feed exclusively                                  | 101 | 77.7%      |
| I do not want my baby to be bottle fed in any way           | 18  | 13.8%      |
| Please inform me if bottle feeding is necessary             | 25  | 19.2%      |
| I do not want my baby to be given a dummy                   | 17  | 13.1%      |
| I would like to obtain more information about breastfeeding | 38  | 29.2%      |
| I would like to consult with a lactation specialist         | 41  | 31.5%      |
| I plan to bottle feed exclusively                           | 6   | 4.6%       |

Table 5. Correlations between age, parity, and preferences in terms of feeding a baby.

|   |     | Age    |      |         |      |      |      | Number of deliveries |      |    |      |    |      |    |       |
|---|-----|--------|------|---------|------|------|------|----------------------|------|----|------|----|------|----|-------|
|   |     | ≤ 24   |      | 25 - 35 |      | > 35 |      | 0                    |      | 1  |      | 2  |      | 3+ |       |
|   |     | N      | %    | N       | %    | N    | %    | N                    | %    | N  | %    | N  | %    | N  | %     |
| To breast-feed exclusively                    | yes | 25     | 67.6 | 70      | 81.4 | 6    | 85.7 | 56                   | 74.7 | 33 | 80.5 | 10 | 83.3 | 2  | 100.0 |
|   | p   | p>0.05 |      |         |      |      |      | p>0.05               |      |    |      |    |      |    |       |
| To not bottle feed                            | yes | 4      | 10.8 | 14      | 16.3 | 0    | 0.0  | 11                   | 14.7 | 5  | 12.2 | 2  | 16.7 | 0  | 0.0   |
|   | p   | p>0.05 |      |         |      |      |      | p>0.05               |      |    |      |    |      |    |       |
| To be informed if bottle feeding is necessary | yes | 13     | 35.1 | 10      | 11.6 | 2    | 28.6 | 17                   | 22.7 | 6  | 14.6 | 0  | 0.0  | 2  | 100.0 |
|   | p   | .008*  |      |         |      |      |      | .006*                |      |    |      |    |      |    |       |
| To not give a dummy                           | yes | 6      | 16.2 | 10      | 11.6 | 1    | 14.3 | 11                   | 14.7 | 3  | 7.3  | 2  | 16.7 | 1  | 50.0  |
|   | p   | p>0.05 |      |         |      |      |      | p>0.05               |      |    |      |    |      |    |       |
| To obtain more information concerning feeding | yes | 9      | 24.3 | 29      | 33.7 | 0    | 0.0  | 30                   | 40.0 | 6  | 14.6 | 2  | 16.7 | 0  | 0.0   |
|   | p   | p>0.05 |      |         |      |      |      | .017*                |      |    |      |    |      |    |       |
| To consult with a lactation specialist        | yes | 17     | 45.9 | 22      | 25.6 | 2    | 28.6 | 27                   | 36.0 | 12 | 29.3 | 2  | 16.7 | 0  | 0.0   |
|   | p   | p>0.05 |      |         |      |      |      | p>0.05               |      |    |      |    |      |    |       |
| To bottle feed exclusively                    | yes | 2      | 5.4  | 4       | 4.7  | 0    | 0.0  | 4                    | 5.3  | 2  | 4.9  | 0  | 0.0  | 0  | 0.0   |
|   | p   | p>0.05 |      |         |      |      |      | p>0.05               |      |    |      |    |      |    |       |

## DISCUSSION

The involvement of the woman in the decision-making process during the perinatal period influences positive experiences during pregnancy, delivery and puerperium, and invokes a sense of control of the perinatal experience and of the care of the newborn baby.

Skin-to-skin contact with the newborn is of utmost importance for a mother post-delivery. Research by Augustyniuk et al. showed that direct contact with the baby following delivery was expected by 82.75% of respondents [5], and according to Pawlicka et al. as much as 95% of respondents preferred it [8]. In a paper by Fuks, it was noted that the first contact of a mother with the newborn depends on method of delivery. After a caesarean section, 4.12% of the respondents had no possibility of direct contact with the newborn due to the newborn's condition; furthermore only 12.3% of the respondents were able to have direct cheek contact with the newborn following caesarean section and only 17.8% of postpartum women benefitted from a full 2-hour skin-to-skin contact after delivery. The results of this research are thought-provoking as 13.3% of women did not achieve 2 hours of skin-to-skin contact. It was noted that in 28.7% of cases the skin-to-skin contact lasted only for a few minutes after delivery before the baby was taken for examination [9]. According to Romańska et al. uninterrupted skin-to-skin contact for 2 hours after a delivery, together with initiation of breastfeeding was observed in 3/4 of women (76%). Women were significantly more likely to have 2 hours of skin-to-skin if they had a delivery plan (83 vs. 71%;  $p=0.44$ ) [10]. Bajek's research shows the positive impact of direct skin to skin contact of mothers and babies immediately after delivery when it comes to the development and health of newborns. Newborns experiencing skin-to-skin have fewer episodes of apnea and bradycardia after birth, and go on to have more favorable weight gain [11]. Direct skin-to-skin contact immediately after delivery has been established as a key moment for bonding between a mother and a baby [10,12,13].

Surveys of Pawluczuk et al. carried out in an obstetrics and gynecology ward in the "rooming in" system show that 81% of the respondents had decided to breastfeed [14]. Similar observations were made in our own research, where a large percentage of women surveyed wish to exclusively breastfeed. On the basis of their own research Pawlicka et al. states that 94% of women wanted the first feeding to take place immediately following delivery [8]. Małańczuk et al. found out that 37.1% of postpartum women following caesarean section (without indicating the type of anesthesia) had first contact with the newborn baby within 6 hours of surgery, however this means 62.9% of women had first contact with their baby more than 6 hours following delivery. The time of the first feeding also depends on the type of delivery. Newborns delivered via caesarean section were 5 times more likely to be fed later when compared to those delivered vaginally. Twice fewer new-

borns born by caesarean section were placed to breast within the recommended time up to 6 hours after surgery as compared with vaginally born babies. The reasons for the later placement of the newborn baby to breast in more than 60% of these postpartum women after caesarean section are a topic of deeper analysis. In this group, as many as 52.7% of women reported the time of first placement to breast from 18 hours to over 24 hours after caesarean section [15]. Makara-Studzińska et al. reports that it is important that the first feeding takes place within the first two hours following delivery. This author noted that difficulties in breastfeeding at the second to third day after caesarean section were less often experienced by women whose newborns were placed to the breast within 2 hours of delivery (39.1%), and difficulties were more often experienced by women whose babies were placed to the breast later than two hours following delivery. Of the women who enjoyed early breastfeeding after caesarean section, 69.6% reported no difficulties with breastfeeding [16].

Studies by Deluga et al. showed that 68.9% of respondents expect assistance from medical staff with placing the baby to the breast. However, it is worrying that medical staff are involved in lactation advice to varying degrees [17]. According to Makara-Studzińska, 38.4% of women had difficulties with breastfeeding and the majority of the respondents (90.2%) in this study received help from staff in improving breastfeeding technique [15,16,18].

Pawluczuk et al. noted that mothers from cities are more likely to decide to breastfeed their babies, and this relationship is observed among younger (up to 35 years of age) and older women. On the basis of this research, it may be concluded that women from cities are more mature and aware of the benefits of breastfeeding [14]. Our own research has shown that women between 25-35 years of age, as well as those who have delivered fewer babies more often expect information concerning breastfeeding. This situation is likely a result of less experience and knowledge of breastfeeding

In own study, 13.8% of the respondents did not want their babies to be bottle fed in any way. Surveys by Pawluczuk et al. show that 5% of the respondents wanted their babies to be bottle fed because they had no food of their own. Research show that a large percentage (47.7%) of babies were fed in obstetric-neonatal wards [14]. Gebuza et al. noted that 33 babies out of 100 participating in the research were fed with formula. The decision to feed the baby with formula in 26 cases was made by the mother, because of difficulties with feeding; in 5 cases by a midwife; and in 2 cases the decision was made by a doctor [19]. Bottle feeding negatively influences the course of breastfeeding because it reduces the production of breast milk, and bottle fed babies do not have the same desire to breastfeed. Feeding with formula may cause the mother to lose faith in the possibility of breastfeeding, so it is important formula is to be recommended only when necessary [20].

Over half of the respondents wanted to be informed about the newborn baby's examinations and any preventive activities. In research by Pankrac et al., the majority of women were constantly informed about the newborn's health condition (72.8%), with 2.2% being informed in a casual or incomprehensible manner, and 1.1% not informed at all [21].

In own research, almost a half of the respondents expect all procedures performed with the newborn baby to take place in their or their partner's presence. As many as 71.4% of the respondents in the research by Makara-Studzińska et al. wanted the care of the newborn to be done in their presence. Makara-Studzińska et al. noted an alarming fact that as many as 28.6% of respondents indicated that these treatments were not done at all in their presence or not all of them were done in their presence [16].

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## Limitations of the study

The present study was conducted over a short period of time and had a small sample size. In future studies, a larger population size would be beneficial. Another limitation of the study was using only one tool to measure women's preferences for newborn care after delivery.

## CONCLUSIONS

1. Pregnant women expect direct skin-to-skin contact immediately after delivery, to have the umbilical cord by an accompanying person and to receive information regarding their newborn's Apgar score.
2. Pregnant women prefer breastfeeding.

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# EXHALED NITRIC OXIDE IN SMOKERS AND FORMER SMOKERS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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**A** – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

## ABSTRACT

**Background:** Measurement of fractional exhaled nitric oxide (FeNO) is a useful technique for detection of eosinophilic airway inflammation and assessment of efficiency of corticosteroid treatment in patients with respiratory disease. Generally studies agree that measurement of FeNO is a useful non-invasive biomarker in patients with chronic obstructive pulmonary disease (COPD), however, there are reports that do not confirm such a relationship between FeNO and COPD.

**Aim of the study:** The main objective of this study was to investigate FeNO levels in Polish patients with COPD compared to healthy controls. As a secondary objective, we assessed the influence of smoking on FeNO levels in healthy patients, and patients with COPD.

**Material and methods:** FeNO concentration was measured using an electrochemical analyzer in healthy non-smokers (n=21), healthy smokers (n=25), and former smokers with COPD (n=30) and smokers with COPD (n=38). General characteristics, hematological variables and serum biochemical parameters were also obtained and analyzed using the Kruskal-Wallis test.

**Results:** FeNO measurement revealed significantly reduced NO levels in healthy smokers compared to healthy non-smokers, former smokers with COPD and smokers with COPD (median [range]: 14 [6–17] vs. 21 [15–29], 25 [15–53], and 19 [11–32] ppb, respectively,  $p < 0.001$ ). Moreover, we found increased FeNO levels in ex-smokers with COPD compared with smokers with COPD ( $p < 0.05$ ). No associations between FeNO and other analyzed parameters were found.

**Conclusions:** Levels of FeNO, measured by with an electrochemical analyzer, were elevated among patients with COPD compared to healthy non-smoking controls. Moreover, our study confirms that smoking results in a reduction in FeNO concentration in both healthy patients and patients with COPD.

**KEYWORDS:** nitric oxide, smoking, respiratory diseases, chronic obstructive pulmonary disease

## BACKGROUND

Chronic obstructive pulmonary disease (COPD) is a chronic lung disease that causes abnormalities of both airway and lung parenchyma leading to progressive limitation in lung airflow. COPD might be considered as a complex systemic disease which is not only restricted to the lungs, but also associated with impairment in multiple organs causing renal and hormonal abnormalities, malnutrition, muscle wasting, osteoporosis, and anemia [1]. Patients with COPD have systemic inflammation, which is related to severity of disease and due

to pathological cell damage, including epithelial cell injury, caused by oxidative and nitrosative stress (NS) induced by cigarette smoke [2].

According to recent reports by Quaderi and Hurst [3] and Polverino and Celli [4] more than 300 million people have COPD worldwide, and COPD will be the third leading cause of death by 2030, and particularly prevalent in low and middle income countries. Globally, COPD mainly affects smokers, with 80-90% of patients with COPD having a smoking history. Moreover, the disease is more common in men and in older people [5].

For many years, the measurement of the concentration of nitric oxide (NO) in exhaled air from the upper and lower airways has been used as a non-invasive test for determining the level of inflammation in children and adults with respiratory diseases including cystic fibrosis, asthma, and allergic rhinitis [6-8]. Measurement of NO is a low cost, quick and painless test commonly used in the diagnosis of respiratory disease and as an aid in determining management.

Nevertheless, despite many reports, the usefulness of NO measurements for assessment of inflammation in COPD patients and in healthy patients is contentious. Significantly increased expression of inducible NO synthase has been observed in central and small airways as well as in peripheral lung tissue of patients with COPD suggesting that NO is closely associated with the pathogenesis of COPD [9-11].

The main aim of this study was to compare levels of exhaled NO (fractional exhaled NO; FeNO) measured using an electrochemical analyzer in patients with COPD (smokers and non-smokers) with healthy smokers and non-smokers. Moreover, we analyzed the influence of smoking on FeNO levels in healthy volunteers and patients with COPD since there is still insufficient data on Polish patients.

## MATERIAL AND METHODS

The study was approved by the Bioethics Committee of the University of Rzeszow (22/02/2019). Participants were acquainted with the conditions of participation and provided signed informed consent to participate in the study.

### Study group

The study included 68 patients with stable chronic obstructive pulmonary disease (COPD), among whom 38 were smokers (average:  $20.4 \pm 5.1$  pack years of smoking) and 30 former smokers (non-smoking for a minimum of 15 years). Patients were diagnosed with COPD by a pulmonologist based on recommendations of the European Respiratory Society [12] at the Allergology Outpatient Department, Provincial Hospital No 2 in Rzeszow. Patients with COPD were being treated with  $\beta_2$  adrenoreceptor agonists (Salbutamol (Ventolin), 1 mg/mL (0.1%) nebulized solution, GlaxoSmithKline, UK) without any corticosteroid treatment.

The control group was made up of healthy people without a history of respiratory disease who were matched with the study group in terms of patient gender and age. Among the 46 healthy people, there were 21 non-smokers with no smoking history, and 25 smokers (average:  $18.6 \pm 4.3$  pack years of smoking) who declared that they smoke about 1 pack of cigarettes per day. Participants in the control group had not taken any medication for 1 month prior to participation in the study.

All patients with COPD and healthy controls had no confirmed atopic dermatitis which is a factor that can affect the measured concentration of nitric oxide.

Patient with COPD were excluded if they had serious respiratory infections, pulmonary arterial hypertension, other accompanying diseases, had received nasal or inhaled corticosteroid treatment, and or were not able to take the NO measurement or refused to participate in the study. Moreover, they were excluded if the forced expiratory volume in one second by spirometry was less than 60% or if they had been hospitalized within 30 days prior to NO measurement. The study was conducted between January and April 2019.

Patient characteristics are presented in Tab. 1.

### Nitric oxide measurement

FeNO concentration was measured using an Hyp'Air FeNO electrochemical analyzer (MediSoft, Belgium) with a measurement range of 0 to 600 ppb (parts per billion), which measured NO in expired air from the upper and lower respiratory tract. The analyzer was calibrated according to the manufacturer's instructions.

Nitric oxide was measured three times for each patient according to the recommendations of the American Thoracic Society [13]. The three measurements were averaged for each patient.

Nitric oxide measurement is measured via the exhalation of air through a disposable mouthpiece under a constant flow of 50 mL/sec for 6 seconds. Participants did not eat, drink, smoke, or exercise within the 3 hours prior to measurement. Nitric oxide was measured prior to spirometry testing.

### Other tests

The COPD diagnosis was confirmed with a spirometry test using a standard device (Lungtest 1000 MES SJ, Poland) as recommended [14]. Additionally, blood counts were performed using the ADVIA2120i automatic hematology analyzer (Siemens Healthineers, Germany).

C-reactive protein (CRP) concentration was determined using a VITROS 250 analyzer (Ortho Clinical Diagnostics, Johnson and Johnson, USA). Vitamin D was determined with Elecsys® Vitamin D total II (Roche Diagnostics, Mannheim, Germany).

Total immunoglobulin E (IgE) was determined using an enzyme immunoassay kit (VIDAS bioMérieux SA, France) according to the manufacturer's instructions.

### Statistical analysis

The results are presented as the median, 25th and 75th percentile, and range. The results were analyzed using the Kruskal-Wallis test (the obtained results do not have a normality of distribution). Spearman's rank correlation coefficient as well as multivariable regression analysis was employed to estimate the relationships between FeNO and patients' results, assuming linear dependence using STATISTICA (version 13.1, StatSoft Inc. 2016, Tulsa, OK, USA) and MedCalc® (version 19.0.4, MedCalc Software, Ostend, Belgium) software.

Table 1. General characteristics, hematologic variables, serum biochemical parameters and spirometry results of control and study group patients with COPD.<sup>a</sup>

| Parameter and reference range                | Control group, non-smokers (A)                            |             | Control group, smokers (B)                                |              | Patients with COPD, ex-smokers (C)                        |              | Patients with COPD, smokers                               |              |
|--|---|-------------|---|--------------|---|--------------|---|--------------|
|  | median (25 <sup>th</sup> and 75 <sup>th</sup> percentile) | range       | median (25 <sup>th</sup> and 75 <sup>th</sup> percentile) | range        | median (25 <sup>th</sup> and 75 <sup>th</sup> percentile) | range        | median (25 <sup>th</sup> and 75 <sup>th</sup> percentile) | range        |
| n  | 21  |             | 25  |              | 30  |              | 38  |              |
| Sex (F/M)                                    | 12/9  |             | 15/10   |              | 14/16   |              | 17/21   |              |
| Age (years)                                  | 55 (49; 67)   | 42 – 79     | 57 (51; 68)   | 44 – 78      | 58 (49; 64)   | 46 – 82      | 59 (53; 63)   | 40 – 81      |
| Weight (kg)                                  | 81 (77; 87)   | 65 – 108    | 80 (71; 89)   | 62 – 114     | 79 (74; 88)   | 55 – 120     | 79.3 (67; 85)   | 59 – 116     |
| Height (cm)                                  | 165 (160; 172)  | 156 – 184   | 166 (159; 172)  | 152 – 195    | 169 (162; 177)  | 152 – 185    | 168 (164; 175)  | 151 – 186    |
| BMI  | 20.4 (18.8; 21)   | 18.4 – 25.9 | 19.5 (17.5; 23)   | 17.8 – 28.9  | 19.7 (16.2; 22.5)   | 17.6 – 29.4  | 20.1 (17.3; 23.4)   | 17.4 – 29.1  |
| WBC (*10 <sup>3</sup> /μl) [4 – 11]          | 6.35 (5.4; 7.2)   | 4.08 – 11   | 6.5 (5.8; 8.1)  | 4.17 – 10.43 | 7.6 (6.9; 10.2) <sup>A p&lt;0.05</sup>                    | 4.91 – 12.98 | 8.35 (6.8; 9.7) <sup>A p&lt;0.01</sup>                    | 4.76 – 11.15 |
| % Neutrophils [50 – 70]                      | 66.4 (64; 70.4)   | 56.3 – 75.1 | 65.3 (60; 67)   | 53.7 – 73.2  | 66.8 (62.8; 71.4)   | 50.6 – 81.7  | 66.4 (61; 69)   | 40.1 – 75.4  |
| % Lymphocytes [25 – 40]                      | 28.4 (26.8; 30.9)   | 22.7 – 37.9 | 29.1 (27.6; 31.4)   | 20.9 – 37    | 25.4 (22.7; 28.4) <sup>B p&lt;0.05</sup>                  | 19.3 – 35.4  | 29.7 (26.4; 33) <sup>C p&lt;0.05</sup>                    | 20 – 39.8    |
| % Monocytes [0 – 10]                         | 6.3 (5.8; 6.9)  | 4.6 – 8     | 6.4 (5.9; 7.1)  | 4.7 – 8.2    | 6.7 (6; 7.6)  | 3.9 – 8.8    | 6.7 (6.1; 7.8)  | 4.2 – 11.4   |
| % Eosinophils [0 – 5]                        | 1.3 (0.9; 1.9)  | 0.3 – 3.9   | 1.1 (0.7; 1.3)  | 0.3 – 5.4    | 3 (1.8; 4.2)  | 0.2 – 5.1    | 3 (2.2; 4.1)  | 0.4 – 6.8    |
| % Basophils [0 – 1.5]                        | 0.5 (0.4; 0.6)  | 0.3 – 0.8   | 0.5 (0.3; 0.6)  | 0.2 – 0.8    | 0.6 (0.4; 0.7)  | 0.2 – 1.1    | 0.5 (0.4; 0.7)  | 0.2 – 1.1    |
| Eosinophils (*10 <sup>3</sup> /μl) [0 – 0.5] | 0.1 (0.08; 0.14)  | 0.02 – 0.43 | 0.08 (0.06; 0.13)   | 0.02 – 0.49  | 0.14 (0.07; 0.23)   | 0.02 – 0.48  | 0.14 (0.08; 0.21)   | 0.04 – 0.65  |
| CRP (mg/l) [0 – 5]                           | 1.5 (1; 3.1)  | 0.5 – 5.4   | 2.6 (1.5; 3.7)  | 0.3 – 6.2    | 3.7 (2.6; 5.1) <sup>A p&lt;0.01; B p&lt;0.05</sup>        | 1.5 – 12.2   | 4 (2.4; 6.8) <sup>A p&lt;0.001; B p&lt;0.05</sup>         | 0.7 – 11.2   |
| Vitamin D (ng/ml) [30 – 80]                  | 38.7 (28.7; 40.6)   | 20.7 – 48.5 | 30 (26.8; 37)   | 19.4 – 48.6  | 25 (16.7; 30.5) <sup>A p&lt;0.001; B p&lt;0.05</sup>      | 11.4 – 40.6  | 24.9 (19.6; 30.7) <sup>A p&lt;0.001</sup>                 | 11.3 – 46.5  |
| Total IgE (kU/l)                             | 13.7 (9.4; 37)  | 1.4 – 98.2  | 20.4 (12.6; 46.1)   | 5.5 – 134.02 | 100 (66.8; 120.4) <sup>A p&lt;0.001; B p&lt;0.001</sup>   | 15.6 – 267.1 | 99.9 (55.8; 164.7) <sup>A p&lt;0.001; B p&lt;0.001</sup>  | 11.4 – 450.6 |
| VC (%)                                       | 109 (103; 123)  | 91 – 139    | 102 (99; 111)   | 83 – 127     | 72.5 (65; 76) <sup>A p&lt;0.001; B p&lt;0.001</sup>       | 60 – 82      | 64.5 (61; 72) <sup>A p&lt;0.001; B p&lt;0.001</sup>       | 60 – 84      |
| FVC (%)                                      | 105 (99; 116)   | 89 – 131    | 105 (102; 113)  | 87 – 136     | 67.5 (65; 75) <sup>A p&lt;0.001; B p&lt;0.001</sup>       | 62 – 79      | 65 (61; 68) <sup>A p&lt;0.001; B p&lt;0.001</sup>         | 60 – 79      |
| FEV1 (%)                                     | 103 (98; 114)   | 78 – 121    | 100 (99; 112)   | 89 – 128     | 70.5 (64; 75) <sup>A p&lt;0.001; B p&lt;0.001</sup>       | 62 – 79      | 69 (62; 73) <sup>A p&lt;0.001; B p&lt;0.001</sup>         | 61 – 78      |
| FEV1/FVC (%)                                 | 99 (97; 103)  | 85 – 105    | 98 (95; 100)  | 84 – 115     | 68.5 (64; 75) <sup>A p&lt;0.001; B p&lt;0.001</sup>       | 61 – 80      | 65 (62; 68) <sup>A p&lt;0.001; B p&lt;0.001</sup>         | 60 – 78      |
| FeNO (ppb)                                   | 21 (19; 23)   | 15 – 29     | 14 (11; 15) <sup>A p&lt;0.001</sup>                       | 6 – 17       | 25 (21; 34) <sup>A p&lt;0.001</sup>                       | 15 – 53      | 19 (17; 23) <sup>A p&lt;0.001; C p&lt;0.05</sup>          | 11 – 32      |

<sup>a</sup>Data is presented as median (25<sup>th</sup> and 75<sup>th</sup> percentile) and range for each separate group. Difference in mean was analyzed using the Kruskal–Wallis test using Statistica software (version 13.1, StatSoft Inc. 2016, Tulsa, OK, USA, www.statsoft.com), statistical significance  $p<0.001$ ,  $p<0.01$  or  $p<0.05$  was indicated when comparing the study groups and control groups.

**RESULTS**

General characteristics, hematological variables, serum biochemical parameters and spirometry results of patients with COPD and healthy control groups are presented in Tab. 1. There was no difference in age, weight, height, and body mass index (BMI) between studied groups. Sex distribution among groups was similar. Patients with COPD, both ex-smokers and smokers, had significantly higher white blood cell levels in peripheral blood than the non-smoking control group ( $p < 0.05$  and  $p < 0.01$ ). There was no difference in the percentage of eosinophils, neutrophils, or basophils between groups. There was a decreased percentage of lymphocytes in former smoking patients with COPD compared with the non-smoking control group. The highest concentration of CRP was found in smokers with COPD (median: 4 mg/L). Decreased concentration of vitamin D was noted in ex-smokers with COPD (25 ng/mL vs. 38.7 ng/L,  $p < 0.001$  when compared to non-smoking controls) and smokers with COPD (24.9 ng/mL,  $p < 0.001$  when compared to non-smoking controls). Total IgE was significantly elevated in former smokers and smokers with COPD ( $p < 0.001$  when compared to both smoking and non-smoking control groups).

FeNO measurement revealed significantly reduced NO level in smoking controls compared to non-smoking controls, ex-smokers and smokers with COPD (median: 14 vs. 21, 25, and 19 ppb, respectively,  $p < 0.001$ ). Moreover, we found increased FeNO level in former smokers with COPD when compared with control ( $p < 0.05$ ). Differences between FeNO levels are shown in Fig. 1.

Associations between FeNO level and the patient's general characteristics, hematological variables, biochemical parameters and spirometry results

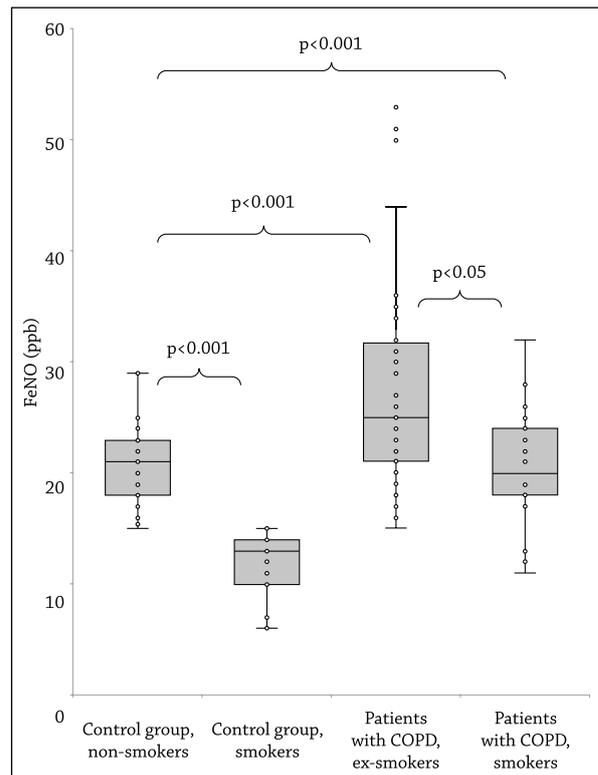


Figure 1. Levels of FeNO in healthy controls (non-smokers and smokers) and in patients with COPD (ex-smokers and smokers).

was estimated by using Spearman's correlation and multivariable regression analysis. Spearman's rank correlation coefficients and p values of each separate disease are shown in Tab. 2. Coefficients and p value from multivariable analysis model are shown in Tab. 3. We found no associations between FeNO and other parameters analyzed.

Table 2. Spearman's rank correlation coefficients and p values<sup>a</sup>.

| Parameter             | Control group, non-smokers |       | Control group, smokers |       | Patients with COPD, non-smokers |       | Patients with COPD, smokers |       |
|-----------------------|----------------------------|-------|------------------------|-------|---------------------------------|-------|-----------------------------|-------|
|                       | R                          | p     | R                      | p     | R                               | p     | R                           | p     |
| Age                   | 0.068                      | 0.770 | -0.151                 | 0.470 | -0.343                          | 0.063 | -0.068                      | 0.687 |
| Weight                | 0.068                      | 0.770 | -0.151                 | 0.470 | -0.343                          | 0.063 | -0.068                      | 0.687 |
| Height                | -0.052                     | 0.824 | -0.107                 | 0.612 | 0.083                           | 0.661 | 0.091                       | 0.585 |
| BMI                   | -0.015                     | 0.948 | -0.095                 | 0.653 | -0.371                          | 0.064 | -0.134                      | 0.422 |
| WBC                   | -0.255                     | 0.264 | -0.241                 | 0.247 | -0.190                          | 0.315 | 0.113                       | 0.501 |
| % Neutrophils         | -0.071                     | 0.761 | -0.222                 | 0.287 | -0.183                          | 0.332 | 0.142                       | 0.394 |
| % Lymphocytes         | -0.220                     | 0.338 | -0.337                 | 0.099 | 0.062                           | 0.746 | -0.006                      | 0.970 |
| % Monocytes           | 0.141                      | 0.543 | 0.360                  | 0.077 | -0.071                          | 0.709 | -0.157                      | 0.345 |
| % Eosinophils         | -0.016                     | 0.946 | 0.208                  | 0.319 | 0.001                           | 0.995 | -0.007                      | 0.967 |
| % Basophils           | -0.067                     | 0.772 | -0.653                 | 0.051 | 0.124                           | 0.514 | 0.016                       | 0.925 |
| Eosinophils           | 0.076                      | 0.745 | 0.242                  | 0.244 | 0.050                           | 0.793 | -0.216                      | 0.192 |
| CRP                   | -0.032                     | 0.890 | -0.058                 | 0.783 | 0.108                           | 0.571 | -0.116                      | 0.490 |
| Vitamin D             | -0.144                     | 0.534 | -0.375                 | 0.065 | -0.014                          | 0.939 | -0.233                      | 0.159 |
| Total IgE             | 0.003                      | 0.989 | 0.207                  | 0.320 | 0.162                           | 0.392 | -0.106                      | 0.526 |
| VC                    | 0.104                      | 0.653 | 0.014                  | 0.947 | -0.055                          | 0.773 | 0.123                       | 0.461 |
| FVC                   | -0.033                     | 0.887 | 0.209                  | 0.317 | 0.341                           | 0.065 | -0.106                      | 0.525 |
| FEV <sub>1</sub>      | -0.003                     | 0.990 | 0.147                  | 0.482 | 0.186                           | 0.326 | -0.154                      | 0.356 |
| FEV <sub>1</sub> /FVC | -0.236                     | 0.303 | -0.191                 | 0.360 | 0.124                           | 0.514 | -0.137                      | 0.409 |

<sup>a</sup>Spearman's rank correlation coefficients and p values were estimated using Statistica software (version 13.1, StatSoft Inc. 2016, Tulsa, OK, USA, www.statsoft.com).

Table 3. Regression coefficient and p values of the multivariable regression analysis<sup>a</sup>.

| Parameter             | Control group, non-smokers |       | Control group, smokers |       | Patients with COPD, non-smokers |       | Patients with COPD, smokers |       |
|-----------------------|----------------------------|-------|------------------------|-------|---------------------------------|-------|-----------------------------|-------|
|                       | b                          | p     | b                      | p     | b                               | p     | b                           | p     |
| Age                   | 0.088                      | 0.954 | 0.115                  | 0.845 | -0.162                          | 0.786 | -0.025                      | 0.962 |
| Weight                | 0.088                      | 0.954 | 0.115                  | 0.845 | -0.162                          | 0.786 | -0.025                      | 0.962 |
| Height                | -0.114                     | 0.915 | 0.029                  | 0.944 | 0.133                           | 0.737 | 0.127                       | 0.708 |
| BMI                   | 0.163                      | 0.901 | -0.198                 | 0.734 | 0.005                           | 0.993 | 0.037                       | 0.944 |
| WBC                   | -0.582                     | 0.521 | 0.132                  | 0.673 | -0.120                          | 0.660 | 0.221                       | 0.422 |
| % Neutrophils         | -0.196                     | 0.783 | -0.219                 | 0.493 | -0.071                          | 0.836 | 0.050                       | 0.855 |
| % Lymphocytes         | -0.058                     | 0.930 | -0.166                 | 0.576 | 0.095                           | 0.757 | 0.017                       | 0.946 |
| % Monocytes           | 0.255                      | 0.744 | 0.191                  | 0.511 | 0.043                           | 0.873 | 0.055                       | 0.816 |
| % Eosinophils         | 0.065                      | 0.953 | 0.322                  | 0.419 | 0.164                           | 0.602 | -0.006                      | 0.980 |
| % Basophils           | -0.246                     | 0.740 | -0.401                 | 0.237 | 0.098                           | 0.743 | -0.018                      | 0.945 |
| Eosinophils           | 0.164                      | 0.883 | 0.054                  | 0.889 | -0.164                          | 0.541 | -0.087                      | 0.793 |
| CRP                   | 0.129                      | 0.896 | -0.090                 | 0.774 | 0.302                           | 0.345 | -0.171                      | 0.493 |
| Vitamin D             | -0.232                     | 0.751 | -0.216                 | 0.457 | -0.136                          | 0.695 | -0.134                      | 0.565 |
| Total IgE             | -0.156                     | 0.841 | 0.139                  | 0.628 | -0.006                          | 0.983 | -0.110                      | 0.693 |
| VC                    | 0.681                      | 0.579 | 0.144                  | 0.724 | -0.085                          | 0.797 | -0.025                      | 0.924 |
| FVC                   | -0.445                     | 0.701 | 0.072                  | 0.877 | -0.264                          | 0.354 | 0.070                       | 0.762 |
| FEV <sub>1</sub>      | 0.100                      | 0.936 | 0.114                  | 0.786 | -0.037                          | 0.920 | 0.052                       | 0.855 |
| FEV <sub>1</sub> /FVC | -0.175                     | 0.846 | -0.265                 | 0.406 | 0.278                           | 0.434 | -0.271                      | 0.274 |

<sup>a</sup>Regression coefficients and p values were estimated using Statistica software (version 13.1, StatSoft Inc. 2016, Tulsa, OK, USA, www.statsoft.com).

## DISCUSSION

Measurement of FeNO is a useful technique for detection of eosinophilic airway inflammation and assessment of efficiency of corticosteroid treatment in patients with respiratory disease, particularly asthmatic patients. However, there are conflicting reports concerning the usefulness of FeNO measurements in COPD patients as a non-invasive biomarker used for disease control.

Our study supports earlier findings about the influence of smoking on the level of FeNO among healthy and COPD patients. Similar to our results, Habib et al. and Malinowski et al. showed that healthy current smokers have lower FeNO levels measured using a chemiluminescence analyzer than a non-smoking group (14.0 vs. 22.8 ppb and 16.62 vs. 24.35 ppb) [15,16]. Furthermore, our study revealed that smokers with COPD had lower FeNO levels measured by electrochemical analyzer as compared with ex-smokers with COPD (19 vs. 25 ppb). Decreased FeNO levels among smokers with COPD has also been confirmed by many other researchers who had measured FeNO with a chemiluminescence analyzer [17-20]. Lower levels of FeNO among smokers may be explained by the fact that smoke from cigarettes damages epithelial cells and downregulates expression of nitric oxide synthase. Free radicals generated from cigarette smoke may also react with NO leading to its inactivation [21].

Moreover, higher concentrations of FeNO as well as a wider range were found in patients with COPD com-

pared with healthy controls (25 ppb, range 15–53 ppb vs. 21 ppb, range 15–29 ppb), this is in agreement with a study by Beg (56.54 ± 28.01 vs. 22 ± 6.69 ppb) [22].

Assays of nitrite in healthy controls and COPD patients reveal that nitrite levels are increased in the serum of patients with COPD. Nitrite can be converted into NO which may lead to impaired vascular NO generation and endothelial dysfunction [23]. Increased production of NO could also be caused by overexpression of inducible NO synthase in airway epithelial and inflammatory cells in patients with COPD [9,24]. Moreover, due to the fact that NO is used to synthesize reactive nitrogen species, its increased concentration might cause an increased in nitrosative stress which contributes to the pathophysiology of the airway inflammatory and obstruction in COPD [2,24].

However, there are several reports indicating that FeNO level does not differ between healthy controls and patients with COPD. Ichinose and Shrestha showed that levels of FeNO in healthy controls and COPD patients in Nepal and Japan were similar and statistically non-significant (mean 14 vs. 10, and 9.1 vs 11.3 ppb, respectively) [24,25]. Moreover, no statistically significant association between FeNO, COPD, and COPD severity was found among patients in the United States [26].

On the other hand, report by Alcázar-Navarrete showed that FeNO level >20 ppb is associated with the higher risk of acute exacerbations in patients with COPD, which suggests that measurements of FeNO are justified and necessary [27]. Analysis of FeNO results by

using receiver operating characteristic curves showed an optimal cutoff value of >22.5 ppb and 25.5 ppb FeNO for distinguishing asthma-COPD overlap syndrome from COPD [28,29].

Measurement of FeNO and peripheral blood eosinophil counts might be useful for differentiation of patients with asthma and COPD [30]. FeNO measurement might be also helpful in assessment of efficiency of inhaled corticosteroids treatment among COPD patients as these drugs are known to cause a decrease in the FeNO level which may reflect improvement in lung condition [19].

CRP level was significantly higher in COPD patients compared to healthy controls as well as in smokers compared with non-smokers. Serum CRP has also been found to be significantly higher in severe COPD compared with a healthy group [31]. Hao et al. also observed increased CRP in serum of smoking patients with COPD compared to non-smoking patients with COPD ( $2.94 \pm 3.11$  vs.  $2.54 \pm 2.79$   $\mu\text{g/mL}$ ) [32]. A reduced level of vitamin D in patients with COPD was shown in many reports, and lower concentration of plasma vitamin D is associated with increased disease severity and higher risk of future exacerbations in patients with COPD [33].

Similarly, elevated IgE may be correlated with symptoms such as dyspnea, and impairment of lung function [34].

Among known factors that influence FeNO level are height, weight, age, sex, atopy, environmental exposures and eosinophil counts, however, many studies indicate that NO level is actually independent of these factors [35-38].

In our study, we did not find any associations between FeNO and other parameters in healthy subjects or patients with COPD. Likewise, no association between FeNO level and circulating eosinophils was observed by Alcázar-Navarrete [27]. There was no correlation between FeNO and blood eosinophilic percentage in 163 patients with COPD, however, FeNO levels were predictive of sputum eosinophilia [39]. Chou et al. established the cutoff of 23.5 ppb FeNO as predictor of sputum eosinophilia in COPD patients [40].

FeNO level in COPD subjects was found to be inversely related to the FEV<sub>1</sub>/FVC ratio in a report by Beg ( $r=-0.5855$ ,  $p=0.0278$ ) while no such correlation was found in a healthy group [22].

Similarly, FeNO was positively correlated with the percentage of eosinophils in induced sputum ( $p<0.01$ ) in Chinese COPD patients [29].

Hence, it should be emphasized that the results of nitric oxide measurements should be interpreted with caution.

In summary, FeNO measurement may be an easy, noninvasive, and cost-effective technique for the diagnosis and management of patients with COPD. Levels of FeNO, measured by using an electrochemical analyzer, were elevated among patients with COPD compared to healthy controls. Moreover, our study confirmed that smoking is associated with a reduced concentration of nitric oxide exhaled from the lower airways in both patients with and without COPD. However, it seems that further research is needed, especially regarding the effects of various factors on nitric oxide levels.

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# ROLE OF A MIDWIFE IN CERVICAL CANCER PREVENTION BASED ON A STUDY OF THE POPULATION OF WOMEN RESIDING IN THE BIALSKI POWIAT

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## ABSTRACT

**Background:** Cancer, next to cardiovascular disease, obesity, diabetes, accidents, and mental illness, is one of the most common diseases of the 21st century. In the female population, cervical cancer is most often diagnosed at late stages.

**Aim of the study:** The goal of the study is to determine the opinions of women who reside in Bialski powiat about midwife participation in cervical cancer screening and prevention.

**Material and methods:** The study group was recruited from randomly selected patients from two physiotherapy offices in the Bialski powiat, as well as students and employees of the State University Pope John Paul II in Biala Podlaska. The research tool consisted of the author's questionnaire concerning the role of midwives in cervical cancer prevention and consisted of 25 questions.

**Results:** Almost half of the respondents or 44.2% (76) believe that the role of a midwife in cervical cancer prevention is based on health education given to women about cervical cancer screening and prevention. 27.3% (47) believe that the role of a midwife in prevention is based on the availability of cytological pap smears. Most or 56% (14) respondents from the age group over 55 and 29.2% (7) surveyed in the 18–25 age group knew about the important role of midwives performing cytological pap smear as part of a prevention strategy against cervical cancer.

**Conclusions:** 1. The knowledge base of the women examined, regarding the role of a midwife in the prevention of cervical cancer, is lacking or insufficient. 2. The role of the midwife in the prevention of cervical cancer is unknown to young women in the 18–25 age group.

**KEYWORDS:** cervical cancer, midwife, cancer prevention

## BACKGROUND

Cancer, next to cardiovascular disease, obesity, diabetes, accidents, and mental illness, is one of the most common diseases of the 21st century [1].

In the female population, cervical cancer is often diagnosed at later stages. The high incidence and mortality among young women with cervical cancer have been a serious problem, not only in Poland, but also globally for many years. The incidence and mortality rates for cervical cancer in Poland are among the highest in the European Union [2].

The data from the National Cancer Registry show that in 2017, in the 20–44 age range, the incidence rate was 6%, while the mortality rate was 10% [2]. Chronic HPV (Human Papillomavirus) infection accounts for

90% of cases. Infections with the HPV virus in countries with a high incidence of cervical cancer are in the range of 10–20%, while in countries with a low incidence, the rate is 5–10% [3]. HPV infection is the most important risk factor for cervical cancer. The main oncogenic type of the virus is HPV 16 (detected in up to 53% of cases of cancer and cervical intra-epithelial neoplasia – CIN1–CIN3), [4]. The second oncogenic type is type 18 (detected in 15% of cases). Probable factors include early sexual intercourse, a large number of sexual partners, a large (> 5) number of deliveries, smoking, low socioeconomic status, cervical dysplasia, use of oral hormonal contraception, a diet low in vitamin C, some reproductive organ infections (chlamydia, gonorrhea, herpes virus, cytomegalovirus), family history

of cancer [5]. Early cervical cancer is asymptomatic, and that's why screening is so important as a prevention strategy [6].

Cancer prevention is the primary goal in the health-care system. The midwife's activities and role in the prevention of cancer, including cervical cancer, should help shape the right attitude of women towards preventive examinations.

### AIM OF THE STUDY

The goal is midwife participation in cervical cancer prevention based on a study of the population of women residing in the Bialski powiat.

### MATERIAL AND METHODS

#### Study population

The study group was recruited from randomly selected patients of two physiotherapy offices in the Bialski powiat, as well as students and employees of the State University Pope John Paul II in Biala Podlaska.

#### Data collection

The study included a group of 172 women, residing in the Bialski powiat. The research was conducted during the period from January to December 2017.

#### Questionnaires

The research tool was the author's questionnaire on the role of a midwife in cervical cancer prevention,

Table 1. Characteristics of the study group.

| Study group        |                                     | N=172 | %    |
|--------------------|-------------------------------------|-------|------|
| Age                | 18–25 years                         | 24    | 6.8  |
|                    | 26–35 years                         | 27    | 7.7  |
|                    | 36–45 years                         | 55    | 15.6 |
|                    | 46–55 years                         | 41    | 11.6 |
|                    | 55+ years                           | 25    | 14.5 |
| Education          | Primary                             | 19    | 11.0 |
|                    | Vocational                          | 27    | 15.7 |
|                    | Secondary                           | 56    | 32.6 |
|                    | Higher                              | 70    | 40.7 |
| Place of residence | Village                             | 84    | 48.8 |
|                    | City below 50,000 of population     | 54    | 31.4 |
|                    | City with over 50,000 of population | 34    | 19.8 |

consisting of 25 questions. Detailed results are presented in Tab. 1.

#### Statistical analysis

Obtained results were subjected to statistical analysis performed by the STATISTICA v 10. program using the Pearson Chi-square test. A significance level of  $p < 0.05$  was adopted.

### RESULTS

The results are shown in the tables. The results of the study presented in Tab. 2 indicate the number of participants in the midwives' health education program

Table 2. Midwife's participation in cervical cancer prevention in the assessment of examined women.

| Content of the question   | N=172   | %  |      |
|---|---|----|------|
| What do you think the role of a midwife in health education-related to cervical cancer is:    | Informational   | 61 | 35.5 |
|   | Related with a health hazard  | 77 | 44.8 |
|   | Raising awareness of the risk factors for cancer of the reproductive organs | 33 | 19.2 |
|   | I don't know midwife's role   | 1  | 0.6  |
| Midwife's role in cervical cancer prevention is:  | The possibility of taking a smear   | 47 | 27.3 |
|   | The smear is only taken by a doctor   | 15 | 8.7  |
|   | Health education in the field of cervical cancer                            | 76 | 44.2 |
|   | I do not know   | 34 | 19.8 |
| The midwife's participation in the prevention of cervical cancer is related to:               | Identifying factors that increase the risk of developing cervical cancer    | 32 | 18.6 |
|   | Taking a smear  | 22 | 12.8 |
|   | The midwife is not involved in the prevention of cervical cancer            | 84 | 48.8 |
|   | I don't know  | 34 | 19.8 |
| The midwife's role in preventing cervical cancer is:  | Encouraging women to eliminate risk factors from everyday life              | 62 | 36.3 |
|   | Shaping positive attitudes of women towards cytological tests               | 42 | 24.6 |
|   | Eliminating fear of undesirable health detection                            | 20 | 11.7 |
|   | I do not know   | 47 | 27.5 |
| How do you assess the role of a midwife in cervical cancer prevention?                        | Very well   | 45 | 26.2 |
|   | Well  | 68 | 39.5 |
|   | Sufficient  | 17 | 9.9  |
|   | Insufficient  | 9  | 5.2  |
|   | I will not give a grade   | 33 | 19.2 |
| If you perform a cytological examination in a gynecological office, on whose initiative?      | Own   | 91 | 52.9 |
|   | Doctor  | 54 | 31.4 |
|   | Midwife   | 12 | 7.0  |
|   | Friend  | 15 | 8.7  |
| Information on factors that increase the risk of developing cervical cancer is obtained from: | Midwife   | 25 | 14.6 |
|   | Doctor  | 54 | 31.6 |
|   | Internet  | 54 | 31.0 |
|   | Medical magazines   | 30 | 17.5 |
|   | Friend  | 8  | 4.7  |

related to cervical cancer. 44.8% (77) of respondents believe that the role of a midwife is associated with health risk, while 35.5% (61) of respondents believe that the midwife's role is informative, and 19.2% (34) of respondents indicate the role of the midwife is to make women aware of risk factors for reproductive cancer. Only 0.6% (1) of respondents do not know the role of a midwife. Almost half of the respondents or 44.2% (76) believe that the role of a midwife in cervical cancer prevention is based on health education in the field of cervical cancer, and 27.3% (47) believe that the role of a midwife in prevention is based on the availability of performing a cytological smear. Detailed results are presented in Tab. 2.

Tab. 3 presents an analysis of the midwife's participation in the prevention of cervical cancer, stratified by the age group of the examined women.

The results of the research in Tab. 3 show that the highest percentage of respondents or 63% (17) in the age group 26–35 determined that the midwife's participation in health education is associated with health risk.

Most or 56% (14) respondents from the age group over 55 and 29.2% (7) surveyed in the 18–25 age group knew about the possibility of a midwife performing a cytological smear as part of preventive measures. According to more than half of the respondents – 62.5% (15) from the 18–25 age group, believed that the midwife does not participate in the prevention of cervical cancer. A high percentage of respondents in particular age groups indicated that the midwife's role is to encourage women to eliminate risk factors from everyday life and to shape positive attitudes of women towards cytological tests. 44% (18) of respondents in the group over 55 years of age rated the role of a midwife very well, as

Table 3. Comparative analysis of midwife's participation in cervical cancer prevention by age.

| Content of the question   |   | 18–25 years<br>(n=24) | 26–35 years<br>(n=27) | 36–45 years<br>(n=55) | 46–55 years<br>(n=41) | above 56 years | $\chi^2$ | P       |
|---|---|-----------------------|-----------------------|-----------------------|-----------------------|----------------|----------|---------|
| What do you think the role of a midwife in health education related to cervical cancer is:    | Informational   | 41.7% (10)            | 25.9% (7)             | 45.5% (25)            | 34.2% (14)            | 20.0% (5)      | 22.28    | 0.0345* |
|   | Related with health hazard  | 37.5% (9)             | 63.0% (17)            | 45.5% (25)            | 41.5% (17)            | 36.0% (9)      |          |         |
|   | Raising awareness of the risk factors for cancer of the reproductive organs | 20.8% (5)             | 11.1% (3)             | 9.1% (5)              | 22.0% (9)             | 44.0% (11)     |          |         |
|   | I don't know midwife's role   | 0.0% (0)              | 0.0% (0)              | 0.0% (0)              | 2.4% (1)              | 0.0% (0)       |          |         |
| Midwife's role in cervical cancer prevention is:  | The possibility of taking a smear   | 29.2% (7)             | 18.5% (5)             | 14.6% (8)             | 31.7% (13)            | 56.0% (14)     | 20.66    | 0.0556  |
|   | The smear is only taken by a doctor   | 8.3% (2)              | 7.4% (2)              | 12.7% (15)            | 7.3% (3)              | 4.0% (1)       |          |         |
|   | Health education in the field of cervical cancer                            | 50.0% (12)            | 40.7% (11)            | 49.1% (27)            | 46.3% (9)             | 28.0% (7)      |          |         |
|   | I don't know  | 12.5% (3)             | 33.3% (9)             | 23.6% (13)            | 14.6% (6)             | 12.0% (3)      |          |         |
| The midwife's participation in the prevention of cervical cancer is related:                  | Identifying factors that increase the risk of developing cervical cancer    | 16.7% (4)             | 18.5% (5)             | 18.2% (10)            | 24.4% (10)            | 12.0% (3)      | 12.44    | 0.4111  |
|   | Taking a smear  | 12.5% (3)             | 18.5% (5)             | 18.2% (10)            | 7.3% (3)              | 4.0% (1)       |          |         |
|   | The midwife is not involved in the prevention of cervical cancer            | 62.5% (15)            | 3.0% (10)             | 49.1% (27)            | 46.3% (9)             | 52.0% (13)     |          |         |
|   | I don't know  | 8.3% (2)              | 25.9% (8)             | 14.6% (8)             | 22.0% (9)             | 32.0% (8)      |          |         |
| The midwife's role in preventing cervical cancer is:  | Encouraging women to eliminate risk factors from everyday life              | 43.5% (10)            | 33.3% (9)             | 41.8% (23)            | 34.2% (14)            | 24.0% (6)      | 12.70    | 0.3912  |
|   | Shaping positive attitudes of women towards cytological tests               | 13.0% (3)             | 18.5% (5)             | 27.3% (15)            | 34.2% (14)            | 20.0% (5)      |          |         |
|   | I don't know  | 21.7% (6)             | 11.1% (3)             | 9.1% (5)              | 9.8% (4)              | 12.0% (3)      |          |         |
|   | Eliminating fear of undesirable health detection                            | 21.7% (6)             | 37.0% (10)            | 21.8% (12)            | 22.0% (9)             | 44.0% (11)     |          |         |
| How do you assess the role of a midwife in cervical cancer prevention?                        | Very well   | 20.8% (5)             | 29.6% (8)             | 14.6% (8)             | 31.7% (13)            | 44.0% (11)     | 16.36    | 0.4279  |
|   | Well  | 50.0% (12)            | 40.7% (11)            | 41.8% (23)            | 31.7% (13)            | 36.0% (9)      |          |         |
|   | Sufficient  | 12.5% (3)             | 7.4% (2)              | 14.6% (8)             | 9.8% (4)              | 0.0% (0)       |          |         |
|   | Insufficient  | 0.0% (0)              | 7.4% (2)              | 7.3% (4)              | 7.3% (3)              | 0.0% (0)       |          |         |
|   | I will not give a grade   | 16.7% (4)             | 14.8% (4)             | 21.8% (12)            | 19.5% (8)             | 20.0% (5)      |          |         |
| Information on factors that increase the risk of developing cervical cancer is obtained from: | Midwife   | 8.3% (2)              | 3.7% (1)              | 21.8% (12)            | 15.0% (6)             | 16.0% (4)      | 15.52    | 0.4871  |
|   | Doctor  | 29.2% (7)             | 37.0% (10)            | 25.5% (14)            | 25.0% (10)            | 52.0% (13)     |          |         |
|   | Internet  | 37.5% (9)             | 37.0% (10)            | 32.7% (18)            | 30.0% (12)            | 20.0% (5)      |          |         |
|   | Medical magazines   | 20.8% (5)             | 14.8% (4)             | 18.2% (10)            | 22.5% (9)             | 8.0% (2)       |          |         |
|   | Friend  | 4.2% (1)              | 7.4% (2)              | 1.8% (1)              | 7.3% (3)              | 4.0% (1)       |          |         |

$\chi^2$  – Chi Pearson square test value; \* Significant differentiation at  $p < 0.05$ .

did 50% (12) of those surveyed in the group of 18–25 years old, and 14.6% (8) in the group of 36–45 years old, but the role of the midwife was insufficient in 7.4% (2) of respondents in the 26–35 age group. With regard to learning from a midwife, 21.8% (12) of the respondents in the age group, 36–45, obtained information on factors that increased the risk of developing cervical cancer.

## DISCUSSION

The vast majority of the profession of midwives in Poland is associated primarily with their role in the maternity ward. The scope of her duties is much broader, and she is a specialist in healthcare for women, including cancer prevention.

Prevention of diseases begins with understanding an existing health problem. The essence of prevention is also looking for risk factors. Prevention in cervical cancer involves periodic preventive cytological examinations. The best preventive examination for this type of cancer is cervical cytology. In addition, testing for the presence of human papillomavirus (HPV), and administering vaccinations are also preventative [7].

Thanks to the Cervical Cancer Prevention Program, the number of women who report for cytological tests shows an upward trend from 12.7% in 2006 to 42.11% in 2015 [2]. Over half of women in Poland do not have regular cytological tests despite the existence of preventive programs. In Poland, due to low reporting rates for preventive examinations, 5-year survival among patients with cervical cancer did not change during the first decade of the 21st century: 54.1% in 2000–2002 compared to 54.4% in 2003–2005 [2]. There is little research in the literature regarding midwives' role and participation in cervical cancer prevention.

Studies have shown that almost half of those surveyed – 48.8% (85) believe that midwives do not participate in the prevention of cervical cancer. Only 7% (12) of respondents underwent cytological tests, which are the basis for the prevention of cervical cancer, at the midwife's initiative. The results of the study by Jankowska et al. conducted in a group of 135 women

indicated that a cytological examination on the initiative of a midwife was only performed on a small percentage of women 3% (4), [8]. High participation in population screening is necessary for optimal prevention of cervical cancer. Research carried out by Miriam showed that only 16,437 women aged 33–60 (<4%) took part in the HPV testing program (conducted by midwives) from the group of 413,487 women [9].

Research by Kawalek et al. conducted on midwives, who practiced health education among women, showed that the priority in midwives' activities was to promote knowledge about breast cancer prevention and cervical cancer screening and prevention [10]. Focus studies conducted by Koç et al. conducted on 156 women indicate that the reason for ignoring cervical cancer screening was: inadequate knowledge of cytological tests, fear of cancer and death, and the fear of getting bad results [11]. Wiszniewska et al. pointed to the untapped potential of preventive measures and health promotion in Poland and the need to include professionals involved in the prevention of cancer among working women [12]. The cytological examination program in Poland was implemented in 2005. Many public health experts believe that educational activities play a key role in the prevention of cervical cancer. In Poland, no information or educational strategy has been developed to support preventive measures regarding the risk of HPV infection. These types of activities were of local nature and were implemented by non-governmental or private entities [13].

## Limitations of the study

There is little research in the literature regarding midwife's participation in cervical cancer prevention.

## CONCLUSIONS

1. The knowledge of the examined group of women regarding the role of a midwife in the prevention of cervical cancer is insufficient.
2. The role of a midwife in the prevention of cervical cancer is unknown to young women in the 18–25 age group.

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# POSITIVE AND NEGATIVE EFFECTS OF TRAUMA IN PATIENTS AFTER MYOCARDIAL INFARCTION: THE ROLE OF TYPE D PERSONALITY

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## ABSTRACT

**Background:** Experiencing a myocardial infarction threatens the health and life of the patient; therefore, it can be perceived as a traumatic event. Indeed, myocardial infarction may result in negative consequences, including symptoms of posttraumatic stress disorder (PTSD). However, it is also possible to experience positive effects from traumatic events, which is expressed as posttraumatic growth. Personality characteristics, including type D (i.e., distressed) personality, are among several factors that have been shown determine the occurrence of negative and positive consequences after exposure to trauma.

**Aim of the study:** The aim of the present study was to establish the role of distressed personality in the occurrence of negative and positive effects of trauma resulting from myocardial infarction.

**Material and methods:** The study included a total of 80 patients after myocardial infarction. Sixty-three patients aged 43–85 years (M=67, SD=10.76) were included in the final analysis. The majority of respondents were men (61.9%). Patients completed a survey with three standardized measurement tools: the PTSD Checklist for DSM-5 (PCL-5), the Posttraumatic Growth Inventory (PTGI), and the Type D Scale (DS-14).

**Results:** Negative affectivity was positively associated with PTSD symptoms, and this association was strongest for negative changes in cognition or mood. Social inhibition was not associated with PTSD symptoms, except for increased arousal and reactivity. Both dimensions of type D personality were positively related to one factor of posttraumatic growth: changes in the spiritual sphere.

**Conclusions:** Reducing the severity of negative affectivity may decrease PTSD symptoms and thus contribute to improved psychosocial functioning among patients who have experienced myocardial infarction.

**KEYWORDS:** trauma, posttraumatic stress, posttraumatic growth, type D personality, myocardial infarction

## BACKGROUND

Experiencing a myocardial infarction (MI) is considered to be a powerful stressor associated with a threat to human health and life. Therefore, a MI can be perceived as a traumatic event. Trauma can have many negative consequences, including symptoms of posttraumatic stress disorder (PTSD). According to the DSM-5 classification, PTSD includes symptoms that fall within the scope of four criteria: intrusion, avoidance, negative cognitive and/or emotional changes, and increased arousal and/or excessive reactivity [1].

The incidence of PTSD symptoms in patients with MI has been confirmed by previous studies [2–9]. The prevalence of full-blown PTSD one month after the incident has been shown to range from 4 to 24% [8],

although some authors indicate that PTSD may affect up to 30% of patients following MI [9].

The occurrence of PTSD among MI patients may lead to longer hospital stays, the development of other disorders (e.g., anxiety, depression), and to the deterioration of quality of life. PTSD may also increase the risk of a second heart attack and other cardiovascular problems. Consistent with this notion, cardiovascular patients with PTSD show a higher risk of mortality [10].

The experience of a traumatic event may also be associated with positive consequences, most often in the form of posttraumatic growth (PTG). PTG can include positive changes in self-perception, relationships with others, and life philosophy, such as appre-

ciation for life and spiritual changes [11–13]. Multiple studies have demonstrated the occurrence of positive posttraumatic changes among patients with MI [14–17]. The incidence of PTG in MI patients was also confirmed by several Polish studies [6,18,19].

Not all patients exhibit PTSD after traumatic events. Similarly, not all patients will experience PTG. The consequences of traumatic events are determined by a number of factors, including the personality traits of the individual, particularly type D personality.

Type D, also referred to as distressed personality, consists of two main dimensions: negative affectivity and social inhibition [20,21]. These dimensions are treated as relatively constant personality traits. Negative affectivity is expressed as the tendency to experience negative emotions, such as hostility, anger, fear, or irritation. Indicators of social inhibition can include limiting social contacts, distancing oneself from others, and refraining from showing emotions, particularly negative emotions. It should be noted that the limited expression of emotions is conscious in nature, which is mainly due to the fear of disapproval and rejection by others.

Available data indicate that type D individuals are more susceptible to mental disorders, including PTSD, depression, phobia, and panic attacks [22]. To our knowledge, there are no studies examining the role of type D personality in the occurrence of PTG among patients with MI. We predict that type D personality will inhibit the occurrence of positive posttraumatic changes among patients with MI. To our knowledge, the only study on type D personality and PTG in any population demonstrates no association between these variables [19].

## AIM OF THE STUDY

The aim of the current study was to determine the relationship between type D personality and negative and positive consequences of trauma associated with MI. PTSD symptoms were considered to be an indicator of negative consequences, whereas PTG was an indicator of positive consequences. We evaluated the following queries:

- What is the prevalence of PTSD symptoms and PTG among patients with MI?
- Are demographic (e.g., gender, age) or clinical variables (e.g., presence of chronic diseases, number of MIs, time since MI, time spent in rehabilitation, and number of experienced traumatic events) associated with PTSD and PTG among MI patients?
- Is there a connection between the dimensions of type D personality and PTSD symptoms and PTG among MI patients?
- Do dimensions of type D personality predict symptoms of PTSD or PTG among MI patients?

A research model presented by American researchers [11,12] highlights the importance of personality traits in the occurrence of both negative and positive conse-

quences of trauma. Based on this model, we predicted that both dimensions of type D personality (i.e., negative affectivity and social inhibition) would be positively associated with PTSD symptoms, and negatively associated with PTG.

## MATERIAL AND METHODS

### Study design, setting and duration

This survey study included a total 80 individuals who experienced MI during the year immediately prior to the study. The survey was anonymous and voluntary, and approved by the relevant bioethics committee. The study was conducted from December 2017 to June 2018 in rehabilitation wards in two hospitals located in the city of Lodz.

### Inclusion criteria

The final analysis included 63 out of the 80 patients who (1) successfully completed the questionnaires (n=78) and (2) confirmed that the experience of MI was traumatic for them (n=65). The study group consisted of patients ranging in age from 43 to 85 years (M=67, SD=10.76). The majority of the survey respondents were men (61.9%). As shown in Tab. 1, most of the subjects had undergone surgical operation, about one in four experienced several heart attacks, and the majority had additional chronic somatic diseases. The time that had elapsed since the most recent heart attack varied and ranged from 7 to 250 days. The duration of the

Table 1. Characteristics of the study group.

| Medical variables and experience of traumatic events |   | N  | Percent |
|--|---|----|---------|
| Surgical procedure:                                  | • yes   | 45 | 71.4    |
|  | • no  | 18 | 28.6    |
| Number of myocardial infarctions experienced:        | • one   | 46 | 73.0    |
|  | • two   | 10 | 15.9    |
|  | • three   | 5  | 7.9     |
|  | • four  | 2  | 3.2     |
| Presence of chronic somatic diseases:                | • no chronic diseases                                       | 15 | 23.8    |
|  | • related to the cardiovascular system                      | 17 | 27.0    |
|  | • not related to the cardiovascular system                  | 15 | 23.8    |
|  | • the co-occurrence of diseases linked to different systems | 16 | 25.4    |
| Experience of other traumatic events:                | • yes   | 54 | 75.7    |
|  | • no  | 9  | 14.3    |
| Number of experienced traumatic events:              | • one   | 23 | 36.5    |
|  | • two   | 14 | 22.2    |
|  | • three   | 8  | 12.7    |
|  | • four  | 4  | 6.3     |
|  | • five  | 3  | 4.8     |
|  | • six   | 1  | 1.6     |
|  | • seven   | 1  | 1.6     |

rehabilitation stay ranged from 1 to 245 days. The distribution of study characteristics is presented in Tab. 1.

Beyond MI, the most frequently experienced traumatic events included loss of a loved one (36.5%), chronic or acute illness (22.2%), and being a victim of crime (12.7%).

## Methodology

The survey used in this study included a variety of demographic and clinical questions such as gender, age, number of infarctions experienced, time elapsed since the last infarction, length of stay in rehabilitation, whether surgery was performed or not, presence of chronic diseases, whether the infarction was perceived as a traumatic event, and the type and number of experienced traumatic events. The survey also include three standardized questionnaires: the PTSD Checklist for DSM-5 (PCL-5), the Posttraumatic Growth Inventory (PTGI), and the type D measurement scale (DS-14).

The PCL-5 was originally developed by Weathers et al. [23] and adapted to the Polish conditions by Oginska-Bulik, Juczynski, Lis-Turlejska, and Merecz-Kot [24]. The PCL-5 consists of 20 statements relating to four symptom subscales: intrusion, avoidance, negative changes in the cognitive and/or emotional sphere, and increased arousal and reactivity.

The PTGI was originally developed by Tedeschi and Calhoun [11] and adapted to the Polish conditions by Oginska-Bulik and Juczynski [25]. The PTGI consists of 21 statements describing various positive changes that can occur following a traumatic event. The Polish version of the PTGI includes four factors: changes in (1) self-perception, (2) relationships with others, (3) appreciation of life, and (4) in the spiritual sphere.

The DS-14 type D measurement scale was originally developed by Denollet [20] was adapted to the Polish conditions by Oginska-Bulik, Juczynski, and Denollet [26]. The scale consists of 14 statements; 7 of the 14 statements are related to negative affectivity, and 7 are related to social inhibition. Participants rate each statement using a 5-point Likert scale ranging from 0 (false) to 4 (true). Statements contributing to each subscale are summed for a subscale total. A participant is classified as type D personality when subscale scores on both dimensions (negative affectivity, social inhibition) are greater than or equal to 10.

## Statistical analysis

Statistical analysis was performed using IBM SPSS software version 22.0.

## RESULTS

First, we computed mean values of the variables of interest, and tested for associations among these variables. Next, we tested whether D-personality dimensions can predict symptoms of PTSD and/or PTG.

The distribution of obtained data was normal or close to normal; therefore, parametric tests were used

in the analyses. The mean PTSD results obtained from the cardiac patients examined ( $M=15.92$ ;  $SD=11.38$ ) did not differ from the results obtained in Polish standardization studies [24]. Using the cut-off point set for PCL-5 (i.e., greater than or equal to 33), only 8% of survey respondents ( $n=5$  patients) in the present study were at a high probability for the occurrence of PTSD. The remaining 92% of patients ( $n=58$ ) showed a low probability of PTSD.

The mean PTG score ( $M=37.05$ ;  $SD=17.67$ ) for the examined patients corresponds to a sten score of 3, which indicates a relatively small magnitude of growth after trauma. A more detailed analysis, including standards developed for PTGI [25], indicated that 80.9% of patients ( $n=51$ ) showed low PTG levels, 14.3% ( $n=9$ ) showed medium PTG levels, and only 4.8% ( $n=3$ ) demonstrated high PTG levels. The average results for type D personality dimensions (negative affectivity:  $M=10.95$ ;  $SD=6.35$ ; social inhibition:  $M=7.30$ ;  $SD=5.10$ ) were similar to averages obtained in standardization studies [26]. In accordance with the adopted criteria, a type D personality is indicated by scores of at least 10 points in *both* dimensions. In the present study, 42.8% of patients ( $n=27$ ) met the criteria for type D personality.

There was no overall effect of gender on PTSD symptom scores (men:  $M=15.74$ ;  $SD=12.85$ ; women:  $M=16.21$ ;  $SD=8.71$ ;  $t=0.15$ ) or PTG (men:  $M=40.38$ ;  $SD=19.91$ ; women:  $M=31.63$ ;  $SD=11.72$ ;  $t=1.95$ ). Also, the intensity of negative (PTSD symptoms) and positive (PTG) consequences of trauma did not differ based on whether or not the patient underwent surgery (PTSD among patients who underwent surgery:  $M=16.22$ ,  $SD=11.45$ ; PTSD among patients who did not undergo surgery:  $M=15.17$ ,  $SD=11.48$ ;  $t=0.33$ ; PTG among patients who underwent surgery:  $M=38.67$ ,  $SD=17.91$ ; PTG among patients who did not undergo surgery:  $M=33.00$ ,  $SD=16.86$ ;  $t=1.15$ ).

The occurrence or absence of chronic somatic disease was not associated with the severity of PTSD symptoms ( $F=2.21$ ;  $p<0.09$ ) or PTG ( $F=2.23$ ;  $p<0.09$ ). Other variables included in the study (e.g., age, number of MIs, time elapsed since MI, rehabilitation time, and number of traumatic events) were not significantly associated with PTSD intensity ( $r=0.21$ ,  $0.20$ ,  $-0.05$ ,  $0.15$  and  $0.01$ , respectively) nor PTG ( $r=-0.17$ ,  $0.01$ ,  $0.04$ ,  $-0.04$  and  $0.03$ , respectively).

Next, we tested whether dimensions of type D personality were related to PTSD symptoms or PTG (Tab. 2).

As shown in Tab. 2, both dimensions of type D personality were positively associated with PTSD symptoms. The strength of the association between type D personality and PTSD symptoms was stronger for negative affectivity as compared to social inhibition. The factors most strongly associated with type D personality dimensions were negative changes in cognitive and emotional spheres. PTSD symptoms of increased arousal and reactivity were positively associated with both negative affectivity and social inhibition. Type D

Table 2. Correlation coefficients between type D dimensions and consequences of experienced trauma.

| PTSD and PTG                                     | Type D personality dimension |                   |
|--|------------------------------|-------------------|
|  | Negative affectivity         | Social inhibition |
| PTSD – total                                     | 0.61***                      | 0.26*             |
| • intrusion/re-experience                        | 0.49***                      | 0.18              |
| • avoidance                                      | 0.40**                       | 0.21              |
| • negative alterations in cognitions and/or mood | 0.58***                      | 0.17              |
| • increased arousal and reactivity               | 0.52***                      | 0.32**            |
| PTG – total                                      | 0.14                         | 0.00              |
| • changes in self-perceptions                    | 0.05                         | -0.01             |
| • changes in relations with others               | 0.22                         | 0.04              |
| • appreciation of life                           | 0.16                         | 0.03              |
| • spiritual changes                              | 0.32**                       | 0.29*             |

\*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$ .

personality dimensions were not significantly associated with total PTG. PTG changes in the spiritual sphere was the only factor that showed significant positive correlations with both negative affectivity and social inhibition dimensions.

Next, we performed a series of regression analyses (stepwise, progressive) to test whether type D personality dimensions predict symptoms of PTSD or PTG. The dependent variable in these models was total or subscale scores of either PTSD or PTG. The independent variable was either negative affectivity or social inhibition. Results indicated a significant role for negative affectivity in the development and/or maintenance of PTSD symptoms. Negative affectivity was shown to predict overall PTSD, explaining 36% of the variance in the dependent variable ( $Beta=0.61$ ,  $R^2=0.36$ ), as well as, symptoms falling within the scope of all 4 criteria (intrusion:  $Beta=0.48$ ,  $R^2=0.23$ ; avoidance:  $Beta=0.40$ ,  $R^2=0.15$ ; negative cognitive and emotional changes:  $Beta=0.64$ ,  $R^2=0.35$ ; increased arousal and reactivity:  $Beta=0.52$ ,  $R^2=0.26$ ). Type D personality dimensions did not significantly predict PTG.

## DISCUSSION

Overall, results of the present study suggest a low intensity of both negative and positive posttraumatic changes in a group of patients with MI. Only 8% of survey respondents exhibited a high probability of occurrence of PTSD and only 4.8% showed a high level of PTG resulting from the MI. These results are inconsistent with previous studies showing a higher prevalence of PTSD symptoms among MI patients [2–5]. Further, in previous Polish studies [6,27], the prevalence of at least moderate PTSD among cardiac patients was 30%. Differences between the current study and prior studies may be attributed to the use of different measurement tools. In particular, in the latter-mentioned Polish study, the Impact of Events Scale was used whereas the PCL-5 was used in the present study. In addition, a low

intensity of PTSD may result from the belief by some individuals that MI does not pose a significant threat to life, or a belief in the effectiveness of treatment. These possibilities are partially confirmed by the data collected for this study. In particular, we found that nearly 16% of the patients surveyed in this study did not consider MI to be a traumatic event. In addition, some patients may have perceived other experienced life events to be more severe than the heart attack. Further, participating in cardiac rehabilitation, which mitigated the negative effects of trauma, was also an important factor. These results lead to a question of whether, and to what extent, the experience of MI is actually a traumatic event. However, the answer to this question requires further research.

We also found a low intensity of PTG among patients with MI. This finding is also inconsistent with the results of other studies. A prior study of patients after MI and using the same tool found high PTG in 25% of patients [19]. Similarly, in studies involving cardiac patients with heart transplants, PTG intensity was high [27]. The low level of growth after trauma in MI patients in the present study may be due to the low intensity of PTSD. A prior experience of negative changes may be a necessary condition for the occurrence of positive changes. Thus, the stronger the negative changes, the greater the PTG. The observed results for PTG may have also been influenced by the study criteria applied, particularly the time elapsed since the MI, which ranged from 1 to 245 days. Positive changes associated with the re-evaluation of one's own life do not appear suddenly; rather, PTG is a gradual process that is associated with the passage of time.

In the present study, patients with MI also showed a relatively low intensity of negative affectivity and social inhibition. The percentage of MI patients with type D personality in the present study was lower than the percentage reported in a study of Dutch individuals [20] and in previous Polish studies [19,21]. This discrepancy may be related to the predominance of men in the present study group. Several previous studies have demonstrated that men score lower than women on type D dimensions, particularly for the negative affectivity subscale [20,21]. Participation in the cardiac rehabilitation program may have also contributed to the low scores on type D personality dimensions.

Results of the present study demonstrate a positive relationship between both dimensions of distressed personality and PTSD symptoms. Negative affectivity was found to play a significant role in the development and/or maintenance of PTSD symptoms. Indeed, negative affectivity was a significant predictor of overall PTSD symptoms, as well as, all PTSD subscales. The effects of negative affectivity on PTSD subscales were particularly salient for PTSD symptoms related to negative changes in cognitive and emotional spheres. This result is in line with our hypotheses. It is important to note that emotions experienced are significantly positively associated with the way that individuals per-

ceive reality. Accordingly, people with high levels of negative emotions may be more likely to perceive and interpret the world negatively, particularly in terms of risk. Interestingly, we found that distressed personality traits were not associated with the occurrence of PTG among MI patients. Rather, distressed personality traits were associated with changes in PTG that were specific to the spiritual sphere, which is in line with previous research findings [19].

### Limitations of the study

Limitations of the current study should be mentioned, including a relatively small group of patients with MI. Further, this study was cross-sectional in design, which precludes conclusions about cause and effect dependencies in an unambiguous way. Furthermore, the present study considered symptoms of PTSD rather than clinical diagnoses. Future studies should include a wider group of patients and evaluate the impact of other personality characteristics, as well as, coping strategies on the occurrence of negative and positive outcomes following traumatic events. Longitudinal studies would also be useful to test the dynamics of posttraumatic changes.

It is also worth noting several potential implications for clinical practice. Knowledge of the importance of

personality traits (e.g., type D) as a risk factor for the development of PTSD can enable early detection of at-risk individuals. Such knowledge may also increase the effectiveness of rehabilitation and reduce the risk of recurrent MI.

To improve patient functioning following a MI, it is also important to PTSD symptoms. Cognitive-behavioral therapy and/or a type D personality modification may be useful approaches for reducing the severity of PTSD symptoms. Programs implemented to modify type D personality traits are often based on stress reduction and/or attention training. These programs have produced positive expected results in the form of reduced negative affectivity and social inhibition [28].

### CONCLUSIONS

The results of the present study enrich the knowledge about the traumatic consequences of MI and, above all, indicate that the presence of personality type D (particularly negative emotional dimension) predicts the occurrence of PTSD following MI. Future studies are needed to clarify differences observed between the present results and prior studies, and to extend these results.

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# NON-NUTRITIONAL USE OF BREAST MILK FOR UMBILICAL CORD STUMP CARE: A CASE REPORT

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## ABSTRACT

**Background:** Human milk, in addition to nutrients, contains many biologically active substances including immunoglobulins, growth factors, cytokines, and a diverse population of somatic cells. Breast milk involves no risk of allergy, contains antibodies, and contains factors such as epidermal growth factor (EGF) and erythropoietin, which may promote the growth and repair of skin cells. The discovery of stem cells and the HAMLET complex in breast milk has led to increased interest in human milk as a natural medicine.

**Aim of the study:** The aim of the study was to identify the effect of topical application of breast milk on the separation time of the umbilical cord stump in newborns.

**Case report:** This paper presents the case of a patient who decided to treat her child's umbilical cord stump with colostrum/breast milk because her two older children had experienced long umbilical stump separation times. As a result of this treatment, separation of the stump occurred 90 hours after labor. There were no abnormalities in the construction of the navel, complications, or separation disorders of the umbilical cord stump.

**Conclusions:** This research demonstrates that colostrum/mother's milk was used as an easy, cheap, effective, and natural method of umbilical cord care.

**KEYWORDS:** breast milk, colostrum, umbilical cord care, separation time, milk therapy

## BACKGROUND

Human milk is considered to be the gold standard in infant nutrition, providing optimal nutrients for normal growth and development. However, since ancient times, breast milk was used as a combination of good nutrition and medication for diseased infants [1]. Human milk contains multiple bioactive and immunomodulatory compounds, as well as cellular components such as leukocytes, epithelial, progenitor, and stem cells, as well as commensal and beneficial bacteria [2]. The discovery of stem cells, the HAMLET (human alpha-lactalbumin made lethal to tumor cells) complex, and probiotic bacteria in human milk has resulted in renewed interest in human breast milk as a natural medicine. Recently, a few studies have been published on the non-nutritional, topical anti-inflammatory effects of human milk for severe eye dryness and eye lesions, sore nipples, and as an atopic eczema treatment [3]. A study by

Allam et al. showed that the mean umbilical cord separation time in a group that used breast milk as topical navel treatment was significantly shorter ( $p < 0.001$ ) than in a dry cord care group [4].

It is important to provide proper care for the portion of the cord that remains attached to a newborn's navel until it heals and separates from the umbilicus, which usually occurs within two weeks after birth. The remnant umbilical cord stump and the area surrounding the navel provides a route of access for bacteria to enter a newborn's body, which creates the risk for navel infection and sepsis. To avoid these undesirable effects, studies have long attempted to determine methods of umbilical stump care that are the most efficient. The World Health Organization (WHO) advocates the use of clean, dry umbilical cord care in high-resource settings but since 1998, the WHO has also pointed to research on the use of colostrum/breast milk in the care of the umbilical cord [5,6].

## AIM OF THE STUDY

This report presents the case of a patient who decided to treat the umbilical cord stump of her newborn using her breast milk, as her two older children had experienced long umbilical stump separation times.

## CASE PRESENTATION

The study was conducted with the approval of the Second Local Ethics Committee at the Medical University of Warsaw (KB/239/2016). Written information about the study was added to the patient's medical records. The patient retained the right to withdraw from the procedure for medically justified reasons. The patient participated in a detailed interview that was conducted to obtain information on her current state of health, any presence of chronic diseases, medication use, lifestyle, diet, pregnancy history, and number of childbirths. An umbilical stump care chart was prepared for treating the umbilical stump of her newborn with the patient's own colostrum/breast milk. The subject was a 29-year-old Polish woman in her fourth pregnancy and third childbirth. She suffered from insulin-dependent gestational diabetes mellitus (GDMG2) and was closely monitored by a diabetic clinic. Her glucose values throughout the pregnancy remained within normal ranges after long-acting overnight insulin doses. The pregnancy proceeded without complications. The interview indicated that her first child's umbilical cord stump had separated 25 days after parturition. For this child, octenisept liquid (octenidinum dihydrochloridum 0.1%, phenoxyetanolum 2%) had been used in umbilical care for the first 20 days. The child had jaundice and was treated with phototherapy. The newborn left the hospital on the tenth day after birth. With the second child, the umbilical cord separated on day 18 after birth. Octenisept liquid was also used for this child.

This study was conducted on a healthy female newborn with a birth weight of 3340 g, born through natural childbirth in week 39 of pregnancy. The infant scored 10 points on the Apgar scale at 1, 3, 5 and 10 minutes after birth. The umbilical cord was cut off and clamped with a sterile plastic clip at a distance of about 2.5 to 3 cm from the abdominal wall, after blood pulsation in the umbilical cord had stopped. The stump with the clip was not cleaned with disinfectant or a sterile swab. The infant was in skin-to-skin contact with the mother and was breastfed, on and off, for two-and-a-half hours. Colostrum was first applied to the umbilical cord in the third postpartum hour. The mother had a full body bath, including her breasts. Immediately before the milk was applied, she washed her hands to ensure they were clean and hygienic. The mother applied a few drops of colostrum directly from her breast to the umbilical stump: on its top at the intersection above the clip, along its entire length, width, and on the base at the abdominal wall, spreading the colostrum with her fingers. Three hours after birth, the umbilical stump was photographed (Fig. 1). Colostrum

was next applied eight hours after the first application, and was reapplied every eight hours over the next few days. Each time, the mother washed her hands, wiped mucus secretions from the umbilical stump using a sterile dry swab, and washed the stump using the expressed colostrum with sterile gauze. She then wiped the stump again with sterile gauze and applied a few drops of milk directly from her breast to the entire stump and its base, leaving it on for a few minutes to dry. The milk was spread gently with sterile gauze. During the entire procedure, the disposable diaper was tucked away so as to not cover the stump. The infant was not bathed in water before the stump separated and was instead cleaned using water-soaked cosmetic cotton swabs and sterile gauze.

During the first day after birth, a reduction in stump volume and a change in its color from white to milky-yellow were observed, and an odorless mucus secretion was seen at the base of the cord. On the second day, the umbilical cord's diameter had markedly reduced; there was also a noticeable change in the color and consistency of the Wharton's jelly and the cord blood vessels. Much less mucus was secreted compared to the previous day. There were no signs of inflammation.

Seventy hours after birth, the umbilical stump had turned completely black along its entire length. No mucus secretion around the navel was observed. The stump did not show signs of inflammation. C-reactive protein (CRP) levels were 11.01 mg/L (the reference range for an infant that is up to 1 month old is 0.00 – 6.00 mg/L) (Fig. 1).

We determined the nutrient content of the breast milk in terms of fat, crude protein, carbohydrates, and energy. The mother's milk sample was collected in sterile tubes on the third postpartum day, unpasteurized, pooled, and frozen at -20°C. The sample was analyzed in triplicate. The analysis was performed using a human milk analyzer (MIRIS AB), following the manufacturer's recommendations. This device is an analytical instrument used to determine the nutritional content of human milk through mid-infrared transmission spectroscopy. On the third day after delivery, the nutrient contents of the milk were: 1.5 g/dL protein (SD 0.08), 5.4 g/dL fat (SD 0.1), 6.8 g/dL carbohydrates, and 64 kcal/dL energy (SD 1.2).

The umbilical stump was separated 90 hours after birth (the fourth day). There were no abnormalities, complications, or disorders related to the separation. A few hours after separation, only slight bleeding from the navel could be observed, which persisted for seven days, though decreasing each day. The navel has a normal anatomical structure. During the entire care procedure, the umbilical stump was never soiled with urine or feces, and so there was no need to wash it with soap and water. The CRP value on the 5th day after birth was 4.39 mg/L.

The newborn had jaundice beginning on day 2 postpartum, with the highest concentration of total bilirubin (15.76 mg/dL) on day 3. Phototherapy was started on the fourth day after birth (after 78 hours). The mother



Figure 1. Photographs of the umbilical cord stump: A – 3 hours post birth; B – 20 hours post birth; C – 40 hours post birth; D – 70 hours post birth; E – 96 hours post birth.

and child were discharged from hospital on day 5 after delivery, at which point the total bilirubin concentration was 13.59 mg/dL.

## DISCUSSION

According to scientific literature, the time for umbilical cord separation ranges from 4 to 16 days depending on the intervention and study setting [7]. Before full separation, the umbilical cord stump can be considered a healing wound, and thus poses to be a possible route of infection. Hence, shortening the time to separation is important in preventing infections in the

neonatal period, and reduces the probability of omphalitis, systemic infection, and sepsis [3]. The nature of optimal umbilical cord care is controversial, but the method of care employed undoubtedly affects the time to cord separation.

In this study, topical application of breast milk as an umbilical cord stump care method led to a much shorter umbilical cord stump separation time compared to the separation times of the woman's previous children, whose stumps separated in weeks 3 and 4 after birth. In addition, the mother did not report any difficulties associated with the use of this cord care method. These conclusions agree with the results

of a study by Allam et al., who tested mothers' satisfaction in using human milk to care for umbilical stumps. The vast majority of women were very satisfied with the effects of the methods used and the ease of care [4]. This is a very important aspect, as newborn navel care can be a problem for many parents.

Umbilical cord separation is a complex process. The cord dries and becomes mummified, and histological study has shown that polymorphonuclear leukocytes infiltrate the area between the drying cord stump and vital tissues of the abdominal wall, forming a demarcation zone. Human milk contains many leukocytes, as well as immunological and anti-infective agents. Studies in the past decades have demonstrated that human milk is a potent immunocompetent agent containing a variety of rich components, each of which has a role in the immunologic protection of infants. Breast milk may enhance umbilical cord separation through the action of polymorphonuclear leukocytes, proteolytic enzymes, or other immunologic agents that act as natural antimicrobials. Abbaszadeh et al. compared the effects of topical human breast milk on umbilical cord separation time to the dry care recommended by the WHO, which involves application of chlorhexidine. The studies showed that the mean cord separation time in the human breast milk group was significantly shorter than the other groups [8]. Umbilical cord antiseptic practices remain somewhat controversial and variable, even in high-resource countries with relatively aseptic conditions at delivery.

Actions reducing exposure of the cord stump to symbiotic flora will increase separation time. It is suggested that intensified elimination of symbiotic bacteria through the use of antibacterial agents for the care of the umbilical cord results in a limited inflow of leukocytes to the separation area and impaired digestion of dead tissues. In our opinion, the specific composition of the fresh milk microbiota may also be important. Promoting colonization of the umbilical cord by nonpathogenic bacteria may prevent the development of neonatal omphalitis. Skin-to-skin contact with the mother, "room-in" systems, and the mother's milk can create an environment conducive to colonization by less pathogenic bacteria acquired from the mother's flora. This helps to reduce colonization and infection by potentially pathogenic organisms that are ubiquitous in the hospital environment.

How the stem and progenitor cells in breast milk affect navel nursing is unclear, but if stem cells are

used in regenerative medicine, they are unlikely to be irrelevant here. It is clear that factors other than the simple choice of cord care method might affect umbilical stump separation time. Clinical procedures for cord care are based on research from developed countries. Therefore, research findings from developed countries are difficult to apply in developing countries as they have significant differences in resource availability, social customs, environmental cleanliness, and bacteriological profile. In developing countries, there have been few randomized trials to investigate the impact of different cord care regimens, including use of mother's breast milk, on umbilical cord separation time. Our research is the first study from Poland, and from any developed country, to show that breast milk can be used for umbilical cord care. As a non-nutritional use of breast milk, this may be considered as an example of personalized medicine. Human milk is a natural agent that is biologically suitable for the body, has no side effects, is readily available, and can be used by people of all social and economic backgrounds; it can therefore be universally recommended as an effective agent for umbilical cord nursing. Further research, including studies in both developing and developed countries, is recommended to confirm our results on the positive effects of topical breast milk application in umbilical cord care. Treating the umbilical cord stump with human milk may also help convince mothers to continue to breastfeed with their own milk, as it is a substance that possesses extraordinary properties beyond nutrition. Gaining greater insight into human milk composition, including the multitude of immunologically active compounds that it contains, creates the prospect of using breast milk as a cheap and relatively easily available therapeutic agent for navel care. Further research is recommended to find and verify the benefits that we have reported in this study, as well as identify any potential risks associated with the use of breast milk for therapeutic purposes.

## CONCLUSIONS

The topical application of breast milk in umbilical cord care leads to a shorter cord separation time and can be used as cheap, effective, and natural method for umbilical cord care. The mother in this study was very satisfied with the effects of the methods used and the ease of care associated with the application of breast milk to the navel of her infant.

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# THE USE OF DRY NEEDLING TO TREAT PAINFUL SHOULDER SYNDROME: A CASE REPORT

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## ABSTRACT

**Background:** Painful shoulder syndrome is a common condition in society. Most patients experience pain and reduced mobility of the affected limb, which can have an impact on the quality of life. This report presents a case of a patient with pain and reduced range of motion in the left shoulder.

**Aim of the study:** The study aim was to evaluate the efficacy of dry needling in the treatment of painful shoulder syndrome, based on functional measures of pain, disability and range of motion.

**Case report:** A 42-year old patient reported pain in her left shoulder. A series of 6 dry needling sessions were performed, twice a week, for a period of 3 weeks. Prior to, and immediately after, the therapy a subjective pain assessment using the VAS pain rating scale and an assessment of the degree of disability using the Modified Laitinen Pain Questionnaire were performed. The range of motion within the shoulder girdle was also measured with a goniometer.

**Conclusions:** Following the dry needling therapy, a reduction in pain and improved shoulder girdle mobility was observed.

**KEYWORDS:** painful shoulder syndrome, dry needling, VAS scale, Laitinen Questionnaire, goniometer

## BACKGROUND

Painful shoulder syndrome, similar to lower back pain, is a musculoskeletal disorder that affects an increasing number of people. This syndrome is measured by both clinical signs and structural changes, as seen in medical imaging [1]. It can be caused by degenerative changes, and damage or injury to individual functional elements that are part of the shoulder girdle. Recurrent microtraumas in joints in this area offer another causative pathway [2].

The most common symptom of the painful shoulder syndrome is the presence of pain and a significant reduction in mobility, which impedes daily activities and thus the quality of life of the patient [3]. The therapeutic approach to alleviate this syndrome includes conservative treatments, such as pharmacotherapy, kinesiotherapy, physical therapy and massage [4]. An increasingly popular methods for pain management is dry needling, which can also improve joint range of motion and patterns of muscle activation [5].

Dry needling was first used by Karel Lewit, a physician from the former Czechoslovakia. This therapy usually involves a series of muscular punctures at different angles to induce a muscle contraction [6]. The purpose of dry needling therapy is to provoke a local twitch response, which in effect induces a relaxation of the entire treated muscle.

Research suggests that dry needling can effectively reduce pain, improve mobility and significantly enhance a patient's daily functioning. Dry needling has been shown to be an effective intervention in patients with chronic shoulder pain and a limited range of motion. Pain reduction is achieved, among other things, by stimulation of myofascial trigger points, which can be extremely sensitive to pressure [7].

## AIM OF THE STUDY

The purpose of this study was to assess the efficacy of dry needling in the treatment of painful shoulder

syndrome, as determined by functional measures of pain, disability and range of motion.

### CASE REPORT

The subject for this case report was a 42-year-old female (height 175 cm, weight 83 kg and BMI 27.1) who reported pain in her left shoulder during the interview. The pain was exacerbated when trying to perform flexion and abduction movements within the shoulder joint. It had started about three months earlier after a workout at the gym, without injury. The greatest ailments were noticeable on the anterior and lateral sides. The patient had not previously complained of pain in the left shoulder area. She defined the pain as a pulsing, burning and pulling sensation. She reported difficulty in performing basic tasks such as reaching up, lifting a limb to get her hair done, fastening her bra, putting on a T-shirt or sweater. During each of these activities, she reported some pain and a limited range of motion in the shoulder area. The patient is physically active, and regularly engages in cycling, roller skating and gym workouts.

Based on an ultrasound examination (Fig. 1) the patient's right shoulder area was diagnosed with minor damage to the tendon of the infraspinatus muscle and associated edema. No lesions in the tendon of the long head of biceps brachii muscle, and no abnormalities in the acromioclavicular joint, were evident. A blood test conducted during the time of pain did not indicate any inflammation.



Figure 1. Ultrasound result of the patient [personal records].

The patient's body posture was also examined. Slight asymmetry of the location of the shoulder girdle, as well as the position of the upper limb during adduction and internal rotation, was observed. The range of flexion, extension and abduction movements of the arm were assessed.

Prior to the study, the patient was informed of the purpose and principles of the dry needling treatment, at which time the benefits and possible side effects were presented. The patient gave written consent to participate in the study, which was approved by the Bioethical Commission of the state medi-

cal higher vocational school in Opole (no. KB/258/FI/2020).

### THERAPY

The patient was treated using dry needling twice a week for a period of 3 weeks – a total of 6 procedures were carried out. During each session, dry needling was performed on the trigger points of the infraspinatus and levator scapulae muscles, the descending part of the trapezius muscle, and the anterior and intermediate part of the deltoid muscle. The exact location and depth of penetration were controlled using real-time ultrasound (Fig. 2). Disposable sterile therapeutic needles (manufactured by SOMA, Poland), made of Japanese stainless steel, 0.3 mm thick and 30 and 50 mm long, were used for the treatment. Each session lasted about 40 minutes. The procedures were performed in a manner to ensure the patient's comfort, whilst following hygiene and safety regulations.



Figure 2. Ultrasound image of dry needling applied to the intermediate part of the deltoid muscle.

Therapy efficacy was determined by 3 functional outcomes. To describe the subjective measure of pain, the visual analog scale (VAS) was used in which the patient self-reported measures of symptoms on a simple 0-10 scale (0 – “no pain”, 10 – “the worst pain”).

To assess the degree of disability, the Modified Laitinen Pain Questionnaire was used, which contains questions about 4 criteria: pain intensity, frequency of pain, use of painkillers, and decrease in mobility. The patient described each criterion using a 5-step scale:

- 0 indicates no pain, no medication use, and full mobility,
- 1 indicates mild, intermittent pain, use of medication only in case of emergency and partial decrease in mobility,
- 2 indicates severe, frequent pain, frequent use of medicines in low doses, and reduced mobility preventing work,
- 3 indicates very frequent and severe pain, so the patient needs partial help,
- 4 means that the pain is constant and very severe, so the patient needs complete assistance.

The range of motion in the shoulder joint and within the shoulder girdle was measured using a goniometer. Each movement was made and scored three times, giving the average value. All tests were carried out before and after the treatment period by the same therapist.

## RESULTS

The patient reported a reduction in pain by 6 points according to the VAS scale. Before the therapy, the patient assessed pain at the level of 7 points, which may indicate severe pain, while after the therapy she assessed pain at the level of 1 point.

An improvement in the degree of disability according to the Modified Laitinen Pain Questionnaire was also observed (Tab. 1).

Table 1. Comparison of changes in pain as assessed with the Laitinen Questionnaire before and after the treatment.

| Laitinen scale criteria | The sum of points |                 |
|-------------------------|-------------------|-----------------|
|                         | Before treatment  | After treatment |
| Intensity of pain       | 2                 | 1               |
| Frequency of pain       | 2                 | 0.5             |
| Use of painkillers      | 2                 | 0               |
| Decrease in mobility    | 1                 | 0               |

The patient also experienced an increase in the range of flexion, extension and abduction movements around the shoulder girdle following the treatment period (Tab. 2).

Table 2. Measurements of selected ranges of motion within the patient's shoulder girdle before and after therapy.

| Range of motion  | Sagittal plane |           | Coronal plane |
|------------------|----------------|-----------|---------------|
|                  | Flexion        | Extension | Abduction     |
| Before treatment | 80°            | 30°       | 75°           |
| After treatment  | 165°           | 50°       | 155°          |

## DISCUSSION

Dry needling is being used increasingly to relieve pain associated with muscular disorders. In the described case study, dry needling therapy was shown to be effective in reducing pain and increasing range of motion of the shoulder girdle. This therapeutic method does, however, require knowledge and skills in the identification of tissues which exhibit increased tension and soreness. Proper anatomical knowledge, experience and an individual approach to each patient is essential.

According to Dommerholt [5], dry needling, in addition to reducing local pain, increases the range of motion and patterns of muscle activity, whilst inducing changes in the chemical environment of localized trigger points. Polish researchers [6] have described dry needling as an effective technique when analyzing various methods for the treatment of myofascial trig-

ger points. In their report, Arias-Buría et al. [8] evaluated the effects of using a one-off dry needling session on trigger points in postoperative shoulder pain. Their findings suggest that a single procedure can reduce pain and increase shoulder functioning in people with postoperative pain.

Evidence confirming the effectiveness of the dry needling method was presented by Li Tang et al. [9]. They performed a series of procedures on a patient suffering from spasticity within the shoulder joint. Their results suggest that dry needling in the myofascial trigger points can effectively increase arm range of motion. Other researchers [10], following a meta-analysis of relevant data, suggest that dry needling is effective in short-term pain management, increasing range of motion, and improving the quality of life.

As in our case report, Clewley et al. [11] presented results indicating the effectiveness of dry needling in both reducing pain and increasing joint (shoulder) range of motion. Additionally, Passigli et al. [12] reported a beneficial effect of dry needling therapy in a patient with painful shoulder syndrome, where they observed an immediate improvement in mobility and a significant reduction in pain. They also suggest conducting further research to determine long-term outcomes. In a randomized controlled clinical trial, Ziaefar et al. [13] evaluated the efficacy of dry needling in patients suffering from pain in the descending part of the trapezius muscle. Consequent to receiving positive results, they recommended this method for pain management.

The broad application of dry needling was further demonstrated by Calvo-Lobo et al. [14]. They evaluated the effectiveness of this therapy in treating nonspecific shoulder pain in an elderly population. The primary result was significant pain relief in these patients.

Collectively, these findings confirm the usefulness of dry needling therapies as a tool to alleviate painful shoulder syndrome and associated outcomes. The results of our study indicate that, a relatively short treatment schedule (6 sessions over 3 weeks), can promote improvements that approach normal healthy functioning. It is, therefore, appropriate to use dry needling as a non-pharmacological and increasingly accessible method. Further studies are warranted using a larger cohort, and for a longer observational period, so that potential long-term effects can be evaluated, e.g. one month after the end of the treatment.

## CONCLUSIONS

In this case study, the dry needling method was found to be effective in treating painful shoulder syndrome and related outcomes in our patient. The primary outcomes included a significant reduction in pain and an increase in the range of motion in the shoulder examined.

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# PERSONALISED MEDICINE – BEST PRACTICES EXCHANGE AND PERSONAL HEALTH IMPLEMENTATION IN EUROPEAN REGIONS – A QUALITATIVE STUDY CONCEPT UNDER THE REGIONS4PERMED (H2020) PROJECT

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## ABSTRACT

Personalised medicine (PM) is the adaptation of medical treatment to an individual patient. More importantly, PM offers the potential to detect disease earlier when it is easier to treat effectively. PM is beginning to overcome the limitations of traditional medicine. In PM there are many potential benefits and facilitators but also many barriers. The goals of the Regions4PerMed project are to set up the first interregional cooperation on PM, align strategies and financial instruments, and most importantly, identify primary barriers in personal medicine adoption in the health care system and systematic actions to remove as many of them as possible to create a future where PM is fully integrated into real life settings. Each key action activity will be followed by a focus group or semi-structured qualitative interview. The questions asked during the research will concern barriers and facilitators of PM implementation in the country of a subject and will concern: medical big data and electronic medical records; health technology in connected and integrated care; the health industry; facilitate the innovation flow in health care; socio-economic aspects. The qualitative study outcomes are supposed to bring more qualitative data to the discussion. They could be implemented to the daily practice of the health care system's stakeholders through the best practices transferred to all five key strategic areas of the Regions4PerMed project.

**KEYWORDS:** personalised medicine, personalised health, prevention, regional policies, interregional cooperation

## BACKGROUND

In the early 20th century the first connection between genetic inheritance and susceptibility to disease was seen [1]. In 2003, the first sequencing of the human genome was completed and cost over £2 billion for a single sequence with the work of tens of thousands of scientists in the UK, the US, and around the world [2]. Today, because of new sequencing technology, there has been a dramatic drop in the cost, which coupled with the availability of the high-speed computing needed for analysis, means it is possible to consider this technology as part of routine healthcare [3].

In the face of this potential huge leap forward, the fact that personalised health lacks the cooperation and

coordination needed to organise the still very fragmented field is a severe drawback to its development and to the placement of investments in an effective manner. For this reason, it is crucial to direct major efforts towards coordinating and aligning relevant stakeholders in personalised health action across Europe and beyond; create a participatory approach; build trust; enable a multi-stakeholder process; channel investments towards Personalised Health [4].

Personalised medicine (PM) is a move away from a “one size fits all” approach to the treatment and care of patients with a particular condition, to one which uses new approaches to better manage patients' health and target therapies to achieve the best outcomes in the management of a patient's disease or predisposition

to disease. It uses diagnostic tests, functional genomic technologies, molecular pathways, etc. [3].

PM addresses the challenges of common medicines not being effective in treating large numbers of patients. This adds to rising health care costs due to more prevalent chronic diseases and an aging population. However, PM is tailor-made prevention and treatment strategies for individuals or groups, so patients receive specific therapies that will work best for them and no money is wasted on trial and error treatments [5].

### CONCEPT OF THE PROJECT

The Interregional Coordination For A Fast And Deep Uptake Of Personalised Health (Regions4PerMed [6,7]) main goal is to increase the involvement of relevant stakeholders (regional authorities, researchers, policy makers, and cluster organisations) for the implementation of personalised health. Another predominant goal is to set up the first interregional cooperation on PM, align strategies and financial instruments, identify key investment areas, and release a European regional agenda in order to foster the delivery of PM services to patients and citizens. The project aims to: support the coordination of regional policies and innovation programmes in PM in order to accelerate the employment of PM for citizens and patients; strengthen cooperation between Horizon 2020 and ESIF on PM aspects; ensure complementarity between RIS3 diagnostics priority and RIS3 personalised medicine priority mappings; establish a permanent dialogue between European regions regarding a fast and full implementation of PM; strengthen industrial specialisation areas in Europe and allow PM to flourish as an emerging industry; enable interregional joint investment on PM including a stable link with the Vanguard Initiative and with the European Innovation Council; provide guidance to the EC for the next Multiannual Financial Framework (MFF) as well as Research Framework Programme; provide guidance to EC, Member States, and regional authorities on the next European Structural and Investment Funds (ESIF) Operational Programme.

The other specific objectives of the project are: organise technical dialogue among regions around five Key Strategic Areas (KA) and through five thematic workshops; provide a final action plan of strategic areas of investments; establish a HUB of European initiatives and partnerships on PM (PerMed HUB); contribute to the realisation of the IC PerMed action plan; provide guidelines in the form of a report to regional authorities on how PM can boost local economies and keep the EU competitive; provide guidelines on how to address PM within the Smart Specialisation Strategies (RIS3); build and maintain a database of PH research and innovation and monitor programmes and projects that can be easily replicated elsewhere.

At the core of the project are five regional authorities and organisations representing European regions strongly committed to PM and the Wrocław Medical

University as an academic partner of the consortium. These authorities act as the Executive Board for the interregional coordination and are mainly responsible for the implementation of the project activities concentrated around the five key strategic thematic areas [6].

### FIVE STRATEGIC AREAS OF THE PROJECT VS. BARRIERS AND FACILITATORS OF PM IMPLEMENTATION IN EUROPEAN REGIONS

#### Medical big data and electronic medical records

With the broad adoption of electronic medical record (EMR) systems, researchers can mine vast amounts of patient data, searching for the best predictors of health outcomes. Many of these predictors may lie in the genome, the encoded representation of each person's DNA. As gene sequencing continues to evolve from a complex, expensive research tool to a routine, affordable screening test, most of us are likely to have our DNA fully digitised, vastly expanding the already large store of electronic health data preserved in or linked to our EMRs [8].

Technological innovation has triggered an explosion in data production that will soon reach exabyte proportions. There is great potential for "big data" to improve health, but at the same time, "big data" also prompts new challenges [6]. The main barriers in this strategic area are that the technologies to store and analyse big data and the ability to model them are not fully developed yet. Creating a system that makes big data robust will be the biggest challenge.

To study PM we need to navigate and integrate clinical information (e.g. medical diagnosis, medical images, and patient histories) and biological data (e.g. genes, protein sequences, functions, and biological processes and pathways) that have diverse formats and are generated from different and heterogeneous sources. Data integration and making use of different data sources is at the core of PM. An important aspect to ensure data quality is data standardisation and terminologies with semantic mapping. A big challenge in ensuring data quality is understanding both syntactic and semantic differences in data sources and how they can be harmonised. It should summarise or abstract data in a meaningful way to translate data to information and knowledge. It still needs to be investigated to effectively translate large amounts of data to make use of it in decision-making. Health care data is continuously changing and evolving. These rapid changes in data pose a significant challenge in creating relevant domain models on-demand to be useful for searching, browsing, and analysis of real-time content. In turn, "this requires addressing the following issues: the ability to filter, prioritise, and rank the data (relevant to the domain or use case); the ability to process and ingest data quickly; and the ability

to cull, evolve, and hone in on relevant background knowledge” [9].

### **Health technology in connected and integrated care**

Both electronic health (eHealth) and mobile health (mHealth) are becoming prominent components of health care. eHealth and mHealth encompass a vast spectrum of health care services, ranging from electronic prescribing and medical records, to text message prompts to remind patients to take their medicines. eHealth and mHealth are thus becoming prominent components of health care [10].

A main goal of this phase is the employment of medical data registered systems. Additionally, this phase aims to increase big data capacity to solve problems, such as the poor quality of collected medical data. For example, weak, insufficient, incomplete, incorrect data, or data saved in various formats. The other goal considered in this phase is to increase knowledge and to strengthen the involvement of citizens and communities in the monitoring system; measurable/inadequate use of ICT is the result of inadequate access to medical data and lack of trust in its quality [6]. Many pilot projects are being done worldwide and areas of opportunity are being identified on a global impact. Despite the potential of mHealth applications, the majority of initiatives fail in the pilot stage, thus limiting long-term impact. Barriers to large-scale adoption such as standards, security, and interoperability are also being identified [11].

### **Health industry (drive health care innovations)**

The foundation for any personalised medical treatment is laid by a valid and precise diagnosis. For some diseases this can be a single biomarker, such as the identification of a genetic mutation, however for many diseases a more complex patient profile that moves far beyond “simple” genetics may be needed, including more phenotypical information.

In addition, precision diagnoses can be further optimised when coupled with new technologies, such as those which provide rapid and real-time results and those that can be used at the point of care. This key strategic area will be elaborated in the third workshop and will consider clinical studies, joint research, standardisation, Living Labs, training, technology transfer, and demonstration activities [6].

In this area several basic barriers can be mentioned. First, it can be difficult to get funding for innovative pharmaceutical ventures undertaken by start-up companies, as access to venture capital is severely limited across EU. Also, access to standardised data and bio-material of sufficient quality is not yet developed to its full potential (see above, KA1), increasing development cost for individual companies. In addition, IP

regulation is partially leading to an increasing use of trade secrets instead of patents blocking a free-flowing knowledge transfer. Another barrier is related to changes in EU regulations that alter the processes to be passed to obtain market access for novel diagnostics (Regulation 2017/745 and 2017/246) and pharmaceuticals (Regulation 536/2014), which have been updated by the EU, but which are not yet fully implemented, thus creating some degree of uncertainty for the industry. However, a major hurdle to the market entry of novel health approaches are the processes that need to be undergone for obtaining reimbursement within the national public health systems, as these are highly diverse and differ from country to country, making market introduction especially difficult for innovative start-up companies and putting large international incumbents at an advantage. For decades, big players of the pharmaceutical industry have relied on blockbuster approaches in product development. Increasing patients’ stratification by introducing additional diagnostics can potentially reduce their market base instead of increasing it, making it less attractive for such companies to engage in pursuing personalised approaches. In contrast, market introduction of products that do not rely on reimbursement but rather address health-oriented consumers directly, is more straightforward making it more attractive for industries to address this private market instead of public health markets. This may lead to the effect that novel preventive approaches become more accessible to privileged EU citizens. The widespread use of novel monitoring devices such as arm-wrists, smart-watches, etc. is a clear indication of this development, whereas the use of continuous monitoring are rather the exception than the rule in public health settings.

### **Facilitate the innovation flow in health care**

The health care ecosystem faces multiple, complex challenges: increase in chronic diseases, population aging, emergence of new issues (health promotion, aging disability, social isolation, etc.), increase in social and territorial health inequalities, failing to seek medical treatment, increase in the cost of certain treatments, expectations for personalised approaches to care, etc., as well as the obvious financial constraints on the health care ecosystem. We observe a large spectrum of innovative responses to these challenges: technological, product and service innovations, organisational and managerial innovations, innovations in business models, renewal of R&D processes, innovations in governance, management and evaluation, public regulation often inspired by New Public Management, and finally innovations that renew the range of stakeholders in these movements [12]. The basic barrier is a provider-centric model of health care and yet the personal medicine must play a decisive role in the long-term sustainability of health systems. The fourth workshop will

invite leading organisations and experts with successful programmes and experience in the adoption of PM technologies by health care organisations. It will be organised around five subcategories:

- a. Research and innovation infrastructures exploitation models to boost innovation.
- b. Innovative Procurement Tools (PCP & PPI).
- c. Screening and prevention programmes.
- d. Procurement based on clinical outcomes from PM technologies.
- e. Smart and future hospitals [4].

### Socio-economic aspects

In order to guarantee the social and economic sustainability of health care, personalised health needs to produce changes in: A) training/education – new managers and professional figures need to be trained; B) facilitate a vertical integration between basic, translational research, technological development, and innovation processes; C) empower patients and citizens; D) guarantee interdisciplinarity [4].

One of the most relevant issues policy makers around the world have to deal with is the decision over whether or not to fund new health technologies when their uptake promise improved patient outcomes at an additional cost for the health care system compared to standard care [13].

PM is expected to have an impact on health care budgets, however, there is a widespread scepticism about the financial impact of PM. According to the report 56% of managed care executives feel that PM will increase cost of prescription medicines [14]. This is one of the main barriers for the introduction of PM.

PM is becoming one of the most debated topics on public and private health agendas worldwide. It has supporters among the industry, patient organisations, health care professionals, academics, funders, and politicians. Devoting energies and resources to pursue (and hopefully realize) the promises of person-centred health care would seem to be a win-win strategy for a number of stakeholders [13]. The scientific, economic, and societal barriers for these objectives are considerable; overcoming the hurdles will require new ways for scientists to engage with each other, new relations between patients, and industries and finally, will require new strategic partnerships among all stakeholders in the PM field [15].

Some regional and national systems have already created innovation tools, like Innovative Procurement, and screening programmes to facilitate the adoption of these technologies in routine hospital practices. Other health care organisations are creating and refining systems to increase and accelerate the innovation flow around PM in their facilities. Hospitals are also favouring links with the industry through their research and innovation infrastructures. Important lessons learned from all these experiences should certainly contribute to accelerating the adoption of PM technologies across Europe. They should also contribute to the definition

of new policies and investment decisions at the European, national, and regional level. Considering the aims, scope, and national and international context of Regions4PerMed, one of the obstacles identified to the achievement of the project results is the Political Commitment. It should be worked on carefully by gathering, assessing, and providing response to the regional authorities in need of it. The use of appropriate dissemination and communication tools is essential to maintain a high level of interest and adequate level of response. Connected to the Political Commitment, another potential barrier may be conflicts between regional and national competencies. Especially in those countries where health care systems are managed at a territorial level, it should be very carefully assessed whether activities of Regions4PerMed Action are fully complementary and do not conflict with national competencies [4].

### SCIENTIFIC CONTRIBUTION

#### Qualitative study - semi-structured qualitative interviews

Qualitative research focuses on understanding a research query as either a humanistic or idealistic approach. Qualitative method is used to understand people's beliefs, experiences, attitudes, behaviour, and interactions, which generates non-numerical data. The integration of qualitative research into studies is a research strategy that is gaining increased attention across disciplines. Although once viewed as philosophically incongruent with experimental research, qualitative research is now recognised for its ability to add a new dimension to interventional studies that cannot be obtained through measurement of variables alone [16]. Qualitative research gives voice to the participants in the study. Semi-structured in-depth interviews are commonly used in qualitative research and are the most frequent qualitative data source in health services research. This method typically consists of a dialogue between researcher and participant, guided by a flexible interview protocol and supplemented by follow-up questions, probes, and comments. The method allows the researcher to collect open-ended data, to explore participant thoughts, feelings, and beliefs about a particular topic and to delve deeply into personal and sometimes sensitive issues. Even with few resources, researchers can use semi-structured interviews. In contrast to i.e. surveys, researchers can conduct a highly meaningful project with interviews with as few as 8–12 participants. Semi-structured interviews can be conducted in multiple ways (i.e., face to face, telephone, text/email, individual, group, brief, or in-depth) [17].

A focus group, also known as a focus group interview, is a moderated conversation of several people on a designated area of interest. This qualitative method is one of the necessary tools. Focus research is mainly

aimed at identifying research problems and deepening quantitative interviews previously conducted.

Wrocław Medical University, an academic partner of the consortium, would like to add a scientific aspect to the project. After each key action a focus group or semi-structured qualitative interview shall take place. The questions asked during the research will concern barriers and facilitators during PM implementation in the country of a subject. Questions will be asked to members of the project advisory board/representatives of the Interregional Committee from the region where the actions take place and chosen conference/workshop speakers. The question will concern every key action mentioned above: medical big data and electronic medical records; health technology in connected and integrated care; health industry; facilitation of the Innovation flow in health care; socio-economic aspects.

### EXPECTED OUTCOME OF THE PROJECT

In order to create an environment in which PM can thrive for the patients' best outcomes, there is an urgent need for systematic actions to remove as many barriers as possible [18]. The focus group analyses along with semi-structured interviews are supposed to bring more qualitative data to the discussion. The qualitative study outcomes could be implemented into daily practice of the health care system's stakeholders through the best practices transferred to all five key strategic areas.

For KA1 in terms of Medical Big Data and Electronic Medical Records we suppose that qualitative study out-

comes will help in creating a base to build an international cooperation for a continually learning health care infrastructure with real-time knowledge production.

For KA2 in the field of mHealth and eHealth it is desirable to create supra-regional cooperation and a network for building effective mHealth application solutions.

For KA3 in the health industry (drive health care innovations) it is expected, in connection with the participation in the project of the regional authorities, to generate ideas for more harmonised approaches for reimbursement decisions that would be sent, in the form of recommendations, to central authorities of European countries to support the market entry of PM solutions within the public health care systems.

KA4 in the area of facilitating the innovation flow in health care, it is expected to make health care authorities more aware of their innovation needs and more aware of how to acquire research and innovation products.

KA5 in terms of socio-economic aspects could benefit from the qualitative study by identifying the biggest mistakes in the creation of educational materials and approaches for the training of managers and other professionals in the field of PM.

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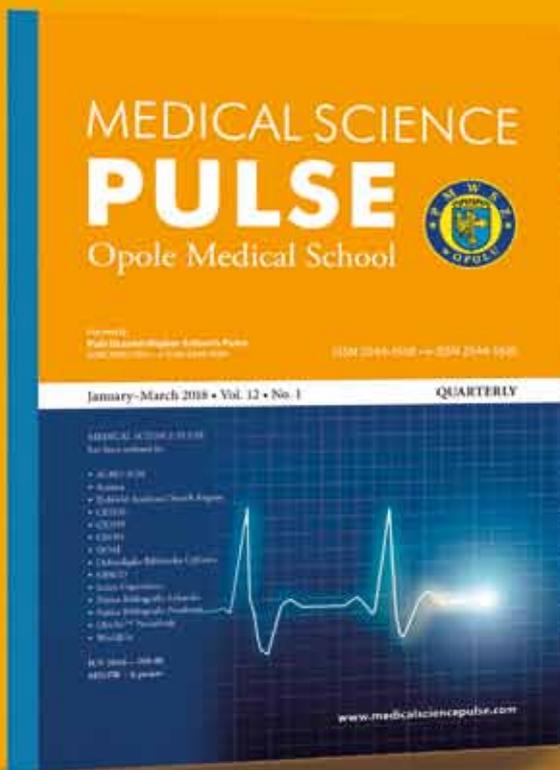
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