Published online: 20 July 2023

Original papers

DOI: 10.5604/01.3001.0053.8074

# AWARENESS AND PERCEPTION OF *IN VITRO* FERTILIZATION AS AN INFERTILITY TREATMENT METHOD AMONG POLISH WOMEN: A CROSS-SECTIONAL STUDY

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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:** Assisted reproductive technology (ART) as an infertility therapy remains controversial, although it has been available for more than four decades, with more than five million people estimated to have received the treatment worldwide. In Poland, the legitimacy and acceptability of *in vitro* fertilization (IVF) are still debated in the public and political realms, with NaProTechnology being the recommended publicly funded method of infertility treatment.

**Aim of the study:** This paper presents the current perceptions and opinions of Polish women of reproductive age on infertility treatment, with particular reference to IVF.

**Material and methods:** The study used an original questionnaire to survey 226 women aged 18-49 on their knowledge and attitudes toward IVF.

**Results:** A high level of knowledge concerning IVF as a method of infertility treatment was demonstrated by 19.9% of respondents. Most women interviewed (65%) had a positive attitude toward IVF, 4.6% would use IVF regardless of the cost, and 12.4% would never use IVF. Only 5.8% of respondents thought that access to infertility treatment is guaranteed in Poland.

**Conclusions:** This is the first study conducted in Poland in which participants professed that their Catholic faith did not influence their lack of acceptance of IVF. Most respondents held the opinion that access to infertility treatment is not guaranteed in Poland. Given the increasing scale of the infertility problem, detailed monitoring of attitudes and acceptance of IVF is needed to support those in Poland struggling with the condition.

KEYWORDS: in vitro fertilization, attitudes, infertility, Poland

#### BACKGROUND

Estimates indicate that between 48 and 186 million people are infertile globally [1-3]. Therefore, the World Health Organization (WHO) has recognized infertility as a disease of civilization and is devoting increasing attention to reproductive health and infertility treatments. The most reliable medical data from prospective randomized controlled trials (RCTs) demonstrate that assisted reproductive technologies (ART), including *in vitro* fertilization (IVF), prove most effective in infertility treatment [4]. ART



use has increased recently, primarily due to the postponement of parenthood, and there is no reason to believe this trend will change in highly developed countries. Recent estimates suggest that by 2100, 3% of the world's population will be born using ART [5]. Although ART has been available for over four decades, and more than 5 million babies have been born through its use worldwide, interventions such as IVF are still unavailable or difficult to access in many countries. The right to access safe and effective reproductive therapies is considered a vital element of reproductive healthcare.

The decision to use IVF may not only be based on clinical and economic considerations but also ethical principles, with religion still playing a critical role in IVF acceptance in many countries. Poland is a nonsecular country where personal, social, and political attitudes are shaped strongly by religion and moral code [6]. Despite the availability of IVF for more than three decades, its legitimacy and acceptance are still debated in the public and political realms [7, 8, 9]. Infertility treatment is guaranteed in Poland by the Act on Infertility Treatment of 25 June 2015 [10], but a new range of treatment methods introduced in 2019, funded by the Polish state budget, includes natural reproductive technology (NaProTechnology) instead of the previously reimbursed IVF procedure [11].

NaProTechnology is a form of natural family planning using health science to monitor and maintain female reproductive and gynecological health. The principle idea of NaProTechnology is based on the Creighton Model, which tracks fertility through observations of cervical mucus [12]. However, the treatment algorithm offered within NaProTechnology is not supported by RCT data. Therefore, healthcare professionals do not think that NaProTechnology can be recommended for infertility treatment [4]. The lack of guaranteed public funding for evidencebased IVF results in unequal access for citizens. Moreover, ARTs are completely unacceptable to the Roman Catholic Church for doctrinal reasons, so the ethical aspect of IVF treatment is a common dilemma for Catholics faced with the decision of choosing a treatment in line with European recommendations and global standards [12]. In Poland, 95% of the population identifies as Catholic, though IVF acceptance is increasing steadily (from 60% in 2008 to 79% in 2012) among infertile couples despite the ethical and religious dilemmas involved [8]. Nonetheless, the acceptance rate is still well below other Western European countries [14]. Thanks to preimplantation genetic testing, IVF offers the possibility of screening embryos for genetic defects, thus reducing the risk of genetic disorders, offering the chance of healthy offspring to those with monogenic diseases, and avoiding the risks associated with an invasive diagnosis.

Developing medicines is accompanied by discussions on the ethical, legal, and social issues of the innovations introduced, but therapeutic regimens formulated using scientific evidence and international recommendations should ensure acceptance and accessibility of medical technologies for all patients. However, the issue of IVF is particularly delicate, as it not only involves people struggling with infertility and wishing to have offspring but also a new life in the prenatal and preimplantation stages of development. It is not uncommon for false or scientifically unconfirmed information to be disseminated within the public debate on the techniques or medical procedures associated with IVF in the broadest sense, as well as the alleged developmental defects and morphological characteristics of children born by this method. The risks of possible health complications and monitoring of adverse effects of IVF are also rarely discussed.

### **AIM OF THE STUDY**

This paper presents the current perceptions and opinions of Polish women of reproductive age on infertility treatment, with a particular emphasis on IVF.

#### **MATERIAL AND METHODS**

## **Design and data collection**

Data were collected using a self-completed original questionnaire developed based on a literature review and focused discussions among the authors. An electronic version of the survey was posted on a social network (Facebook), in a public and private forum, and was available from December 2021 to March 2022. Facebook was chosen as a platform because it held almost 78 percent of the social media market share in Poland in 2021. The survey was conducted online to ensure anonymity and provide greater convenience to respondents, and also because the coronavirus disease-19 (COVID-19) pandemic limited inperson meetings. An anonymous questionnaire was initially piloted on 12 women to assess the adequacy of the study tool, the clarity of questions, the time required, and the availability of data sought. The results obtained were not taken into consideration for the current study. To ensure a confidence level of 95%, the minimal sample size was determined as 196 participants, assuming that 15% of the population of reproductive age in Poland declared a problem with fertility.

The following inclusion criteria were applied: Polish females aged 18 to 49 and consent to partici-

pate in the study. Incomplete survey responses or lack of response were the exclusion criteria. A total of 226 completed questionnaires were collected and analyzed. The questionnaires were anonymous and coded. The survey consisted of two parts (Supplementary Material), with the first part collecting social and demographic data, such as age, place of residence, religion, education, marital status, number of children, number of pregnancies, experiences with becoming pregnant, and infertility treatment. In the second part, subjects were asked about their knowledge of and attitudes toward IVF as an infertility treatment. The questionnaire also contained ten questions exploring participant awareness of various issues linked to infertility treatment. For each singlechoice question (questions: 11, 12, 14, 19, 20, 21, 23, 24, 25), the respondent could obtain 1 point for a correct answer, resulting in a total of 9 points. For the compound question (question 13), it was possible to obtain several points corresponding to the number of correct answers indicated, up to a maximum of 7 points. Thus, the highest score possible was 16. A score of 7 points or less was classified as a low level of knowledge, and a score of 12 or more points as a high level of knowledge.

# **Ethical considerations**

Ethical review and approval were not required for the study with human participants in accordance with institutional requirements and national laws. Subjects provided informed consent to participate and were informed of the purpose of the study before giving their responses.

# Data analysis

The study population was characterized using descriptive statistics. Categorical variables were expressed as numbers (n) and proportions (%), and quantitative variables as measures of central tendency - mean (M) and median (Me), standard deviation (SD), and minimum and maximum values. Depending on the type of dependent variable, groups were compared using a chi-squared test. The Shapiro-Wilk test assessed the distribution of the quantitative data. After determining the data distribution (inconsistent with a normal distribution), the Mann-Whitney U test (UMW, Z) compared two groups, and the Kruskal-Wallis test (KW, H) assessed three or more groups. Spearman's correlation (R) evaluated relationships. The statistical significance level was defined as p<0.05. All statistical calculations employed Statistica software version 13.1 (StatSoft Poland, Krakow, Poland).

## RESULTS

# **Participant characteristics**

A total of 226 women aged 18-49 participated in the study. The largest group was aged 18-26 (60.6%; n=137), had a university education (68.1%; n=154), lived in cities (63.3%; n=143), and were in a civil partnership (65.9%; n=149). A total of 175 (77.4%) respondents declared they were Catholic, 98 (43%) had a child or were pregnant at the time of the study, 100 (44.2%) had no children and were not pregnant but planned on having children in the future, and 12.4% (n=28) had no offspring, were not pregnant, and did not plan on having children in the future. Of those who had children or were pregnant, 91.8% (n=90) conceived naturally, and 8.2% (n=8) became pregnant through medical procedures. Meanwhile, 14.2% (n=32) of respondents experienced difficulties becoming pregnant, and 34.1% (n=77) did not face any problems. An infertility diagnosis was reported by 28 female respondents (12.4%) and 22 partners of respondents (9.7%). Table 1 presents detailed characteristics of the respondents.

Assessment of women's knowledge of *in vitro* fertilization as an infertility treatment method

A low level of knowledge on IVF as a method of infertility treatment (less than 50% of correct answers) was revealed for 35.8% (n=81) of respondents, a medium level of knowledge for 44.2% (n=100), and a high level (more than 75% of correct answers) for 19.9% (n=45). The lowest knowledge level score of 4 points was recorded for 12 respondents (9.7%), and two respondents (0.9%) attained the highest score of 15 points. The larger the place of residence of those surveyed, in terms of population, the significantly higher their knowledge (positive correlation coefficient Rho=0.21, p<0.002). Meanwhile, those living in rural areas appeared to have the poorest knowledge (Table 2), and respondents with a higher education level (Rho=0.33, p<0.0001), particularly in a medical or biological field, had a significantly higher level of IVF knowledge (mean correct answers of: 65.3% vs. 45.1%, p<0.0001). Women who had experienced difficulties becoming pregnant (60.1% vs. no difficulties: 49.3%; p<0.04) and those with positive attitudes toward the IVF procedure (57.1% vs. 53.7% and 45.1%; p<0.0001) also had significantly better knowledge of IVF as an infertility treatment method.

Respondents were most familiar with infertility treatments such as IVF (87.2%; n=197), diet and lifestyle changes (76.5%; n=173), ovulation stimulation (73.9%; n=167), intrauterine insemination (58.8%; n=133), spermatogenesis stimulation (40.7%; n=92), surgical treatment (36.7%; n=83), and NaProTechnology (27.4%; n=62). Among respondents who indi-

# Table 1. Characteristics of the study group

			Frequency		
Variable		N	%		
	18-26 years	137	60.6		
	27-34 years	45	19.9		
Age	35-40 years	22	9.7		
	41-49 years	22	9.7		
	countryside	83	36.7		
	town < 50,000	34	15.0		
Place of residence	town 50-150,000	38	16.8		
	town >150,000	71	31.4		
	Catholicism	175	77.4		
	Orthodox Christianity	1	0.4		
Religion	Jehovah's Witness	0	0.0		
	other	9	4.0		
	Non-believer	41	18.1		
	primary	1	0.4		
	vocational	7	3.1		
Education	secondary	64	28.3		
	tertiary	154	68.1		
	medical/biological	88	38.9		
Education profile	non-medical/non-biological	138	61.1		
	single	69	30.5		
	married	100	44.2		
Marital status	civil partnership	49	21.7		
	divorced	8	3.5		
	I have children / I am pregnant	98	43.4		
Children	I do not have children / I plan to have children	100	44.2		
	I do not have children and I do not want to / do not plan to have children	28	12.4		
Dragnancy as a regult of natural conception	yes	90	91.8		
Pregnancy as a result of natural conception	no	8	8.2		
	yes	32	14.2		
Difficulty getting pregnant	no	77	34.1		
	difficult to say	89	39.4		
	yes	28	12.4		
Infertility diagnosis started in the participant	no	198	87.6		
Infertility diagnosis started in the participant's	yes	22	9.7		
partner	no	204	90.3		
Total		226	100.0		

cated that there were effective infertility treatments (72.6%; n=164), those with a vocational education were statistically dominant (87.5% vs. secondary and higher education: 60.9% and 76.6%, p<0.03). The group of respondents with a vocational education was significantly more likely than those with a higher or secondary education to indicate the possibility of using egg banks for IVF procedures in Poland (62.5% vs. 43.5% and 26.6%, p<0.02). A small proportion of

respondents (5.8%; n=13) indicated that access to infertility treatment is guaranteed in Poland, while most (65.5%; n=148) stated that infertility treatment was only available privately, and 28.8% (n=65) felt that it was difficult to access.

The majority of women interviewed (65%; n=147) had a positive attitude toward the IVF procedure, 31% (n=70) were neutral, and 4% ( n=9) had a negative attitude. It should be emphasized that the opinions

	• • • •		(D)		Min	Min	Statistics	
Va	ariable	м	SD	Ме	Min	Max	Test/value	р
Total		52.6	19.6	56.3	12.5	93.8	_	_
	18-26 years	54.2	19.2	56.3	12.5	93.8		
	27-34 years	57.3	19.2	56.3	12.5	87.5		0.4.54
Age	35-40 years	50.2	20.6	53.1	18.8	87.5	R=-0.09	0.171
	41-49 years	44.0	19.3	46.9	12.5	87.5		
	village	49.3	19.3	50.0	12.5	87.5		
	town <50.000	51.0	19.2	56.3	18.8	81.3		0.000
Place of residence	town 50.000-150.000	52.1	20.2	53.1	18.8	87.5	R=0.21	0.002
	town >150.000	59.7	18.6	62.5	12.5	93.8		
	Catholic	53.8	20.0	56.3	12.5	93.8		
Denomination	other	45.0	18.4	40.6	18.8	75.0	H=1.97	0.357
	non-believer	54.4	18.2	56.3	12.5	93.8		
	vocational	46.5	11.6	50.0	25.0	62.5		
Education	secondary	43.4	17.5	43.8	12.5	81.3	R=0.33	0.000
	tertiary	57.7	19.1	62.5	12.5	93.8		
Medical/biological	yes	65.3	16.8	68.8	12.5	93.8		
education	no	45.1	17.0	43.8	12.5	87.5	Z=-7.63 0.	0.000
	single	52.8	20.6	56.3	12.5	93.8		
	married	53.7	19.1	56.3	12.5	87.5		0.124
Marital status	civil partnership	55.8	19.2	56.3	18.8	93.8	H=6.27	
	divorced	38.2	14.3	40.6	18.8	56.3		
	I have a child/I am pregnant	51.7	19.4	50.0	12.5	87.5		
Children	I do not want to have children/I do not plan to have children	54.3	21.1	56.3	12.5	93.8	H=1.36	0.509
	I do not have children and I do not want to/ I do not plan to have children	55.2	14.1	56.3	18.8	81.3		
Natural concep-	yes	50.6	19.3	50.0	12.5	87.5		
tion	no	61.4	19.9	62.5	18.8	87.5	Z=-1.74	0.076
	yes	60.1	18.3	62.5	18.8	87.5		
Difficulty getting	no	49.3	20.3	50.0	12.5	87.5	H=6.41	0.041
Program	hard to say	52.7	20.4	56.3	12.5	93.8	]	
	positive	57.1	18.1	56.3	18.8	93.8		
Attitude toward	negative	53.7	15.6	50.0	37.5	81.3	H=15.89	0.000
1.11	neutral	45.1	20.8	43.8	12.5	93.8	0.000	

Table 2. Knowledge about in vitro fertilization as	s a method of infertility treatment in t	he study group based on the	e percentage of answers
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\* M – mean value; SD – standard deviation; Me – median; Min-Max – minimum-maximum.

and knowledge regarding IVF were not influenced by the religious denomination of the respondent. Nearly half of the women surveyed (48.2%; n=109) held neutral attitudes towards sperm banks/egg banks, with positive attitudes held by 45.6% (n=103) and negative attitudes held by 6.2% (n=14). Almost half of the respondents would use an *in vitro* procedure regardless of the cost (49.6%; n=112), 27.9% (n=63) would only use the procedure if it was free or subsidized, 10.2% (n=23) would use it with ethical reservations, and 12.4% (n=28) would never use IVF.

Residents of large cities (more than 150,000 inhabitants) were significantly more likely to declare that they would not use an *in vitro* method of infertility treatment regardless of the possibility of funding. Irrespective of the cost, people with a vocational education were significantly more likely to undergo IVF procedures than those with a secondary or tertiary education. Less than half of the respondents (38.9%; n=88) believed that child adoption could be an alternative to infertility treatment, including IVF. On the contrary, 23.9% (n=54) of the respondents believed the opposite, with the remaining 37.2% (n=84) answering "difficult to say." Most women surveyed (68.6%; n=155) were not concerned that the IVF method might result in a higher risk of genetic defects/mutations in the child. Women who wanted to have children in the future (23%; n=23), as well as childless women without plans to have children in the future (17.9%; n=5), were significantly more likely than women who had children or were pregnant, to believe that children born through IVF may have a higher risk of genetic defects/mutations (Chi2=11.6, p=0.020).

# Discussion

Education, prevention, and treatment of diseases, including infertility, should always use current scientific knowledge and be based on the principles of evidence-based medicine (EBM). IVF is recognized as the most important and effective ART treatment for infertility and is often applied when there is no therapeutic alternative [4]. Despite the 40-year history of this method, awarded the Nobel Prize in 2010, it still arouses much controversy due to ethical and legal concerns, often shaped by religious and philosophical convictions. In many countries, these reservations are no longer related to whether IVF is ethically justified per se but to particular aspects of it, such as the upper age limit of the patient, the morality of embryo storage, IVF in single women and same-sex couples, preimplantation genetic testing, and gamete and embryo sharing [15-19].

Wdowiak et al. reported a lower quality of life for patients treated for infertility in Poland compared to other Western European countries [20], which may be linked to limitations in accessing infertility treatment, lack of reimbursement for ART treatments, or lack of widespread social acceptance of ART methods, including IVF. Considering the scale of the infertility problem, there is a need for detailed monitoring of attitudes and acceptance of IVF, and an explanation of such findings, to provide support to people struggling with infertility in Poland.

People's attitudes consist of behavioral, emotional, and cognitive components. Personal experience of conceptual problems results in greater acceptance and improved knowledge of the IVF method. Similar to our research, a study by Malin et al., conducted in Poland, found IVF knowledge was associated with positive attitudes towards IVF [9], though this was not confirmed by an Iranian study or research on more than 6,000 individuals across six European countries: France, Germany, Italy, Spain, Sweden, and the United Kingdom [21, 22]. Positive attitudes toward IVF, acceptance of gamete donation, and optimism regarding the efficacy of the method were independent of knowledge, age, gender, sexual orientation, or place of residence. Remarkably, previous studies showed that negative beliefs were strongly associated with increased fertility knowledge and mainly observed in women, subjects with higher education, childless people, those in work, and individuals living in more economically developed countries [23, 24].

Research confirms minor differences in responses depending on the country of residence and the diversity of cultural, social, and religious norms. Indeed, increased skepticism toward gamete donation was reported in Italy, a country commonly regarded as Catholic [25, 26]. In our study, 12.4% of respondents declared they would not use the IVF procedure under any circumstances, consistent with a 2012 report in which 14% of the public would not use IVF, even though they believe the method should be available to infertile couples. Respondents who rejected the use of IVF as an infertility treatment based their decision on moral values (79%) [14]. Such a correlation between opinion on IVF and religious worldview was described in earlier studies conducted in Poland [9, 27, 28], although our results are the first to show no association between the Catholic religion and nonacceptance of IVF, even though ART is not accepted by the Vatican [29]. Therefore, it is crucial to analyze the factors and experiences influencing the change of attitudes and acceptance and the reinforcement of positive attitudes towards IVF procedures in highly Catholic countries, including Poland.

In contrast to previously published results, inhabitants of large cities (more than 150,000 inhabitants) declared significantly more often that they would not use IVF regardless of the possibility of government subsidization. The present study took place after the lockdown experienced during the COVID-19 pandemic, after which a migration trend from large cities to smaller towns occurred in Poland, and this change may have influenced the results obtained. In the study group, women with a low-level education (vocational) were statistically more likely to indicate the possibility of using egg banks for the IVF procedure and declared that they would use IVF regardless of the cost. The attitude of this group may be due to identification-based trust in medical personnel and treatment methods, which is rooted in intention rather than knowledge (knowledge-based trust) [30].

A complex interaction exists between rapid scientific development and changing social values, with the widespread availability of IVF also limited by high costs in many countries. The majority of survey participants believed that IVF is an effective method of infertility treatment (72.6%), and as many as 87.6% of respondents would use it, of whom 49.6% would use it regardless of the cost, which shows that there is a high expectation of easy access to infertility treatment services in Poland. Other Polish studies confirmed this finding, emphasizing the need for reimbursement of infertility treatment [31]. Only a small number of respondents (5.8%) believed that access to fertility treatments is guaranteed in Poland, while 65% of subjects thought that such treatments are only provided by private healthcare.

Whether IVF should be publicly funded is the subject of much debate [32]. In many countries, including Poland, one of the 30 most developed economies in the world, more attention needs to be paid to infertility diagnosis and treatment for social reasons at the national level. According to the demographic forecast, the population of Poland will decrease in the next 35 years by up to 11.6% compared to the 2015 population [33]. Fertility rates could increase through improved family planning projects, health education, diagnosis, and the acceptance of effective fertility treatments. However, in a study published in 2019, respondents indicated that the availability of IVF might encourage people to delay conception and that there should therefore be an age limit on the availability of this procedure and a cap on public funding [22]. Female respondents indicated the need for such restrictions more often.

In Poland, the national health strategy constitutes an obstacle to the availability and acceptance of IVF as a fertility treatment method. Furthermore, the social stigmatization of children born using this procedure and their parents remains an issue. Therefore, monitoring social attitudes and acceptance of various ARTs and providing quality EBM-based reproductive health education, including sexual education for citizens and medical personnel, is crucial. The present work is a preliminary study of large-scale research on reproductive health education and current problems with decreased conception rates in Central European countries.

# **Study limitations**

The present study had certain limitations, and findings should be interpreted cautiously. Indeed, the cross-sectional design limits conclusions concerning the direction of changes over time. Additional studies with a larger sample size are required to further characterize the attitudes of Polish women toward IVF as an infertility treatment method. As such, the study should be treated as an initial exploration and used to advise future longitudinal studies. Additionally, the data were collected on one social network platform (Facebook) and only among females, which may limit the generalization of the results to the Polish population.

# **CONCLUSIONS**

Given the increasing scale of the infertility problem, detailed monitoring of attitudes and IVF acceptance is needed to support those struggling with the disease. The current study is the first conducted in Poland in which respondents held positive or neutral attitudes toward IVF and in which the participants' professed that the Catholic faith did not influence their lack of acceptance. Accounting for the sociodemographic diversity and different susceptibilities to particular anti-IVF arguments among Polish citizens is crucial for understanding the societal attitudes toward IVF as an infertility treatment method.

Supplementary Material: Questionnaire. An English version of the questionnaire used in the study.

# Appendix 1: Questionnaire. An English version of the questionnaire used in the study

1. Age

- a) 18-26 years
- b) 27-34 years
- c) 35-40 years
- d) 41-49 years
- 2. Place of residence
  - a) Village
  - b) Town with up to 50.000 inhabitants
  - c) Town with up to 150.000 inhabitants
  - d) Town with more than 150.000 inhabitants
- 3. Denomination
  - a) Catholicism
  - b) Orthodox Christianity
  - c) Jehovah's Witness

- d) Other
- e) Non-believer
- 4. Education
  - a) Primary
  - b) Secondary
  - c) Vocational
  - d) Tertiary medical/biological
  - e) Non-medical tertiary education
- 5. Marital status
  - a) Single
  - b) Married
  - c) Civil partnership
  - d) Divorced
  - e) Widowed

- 6. Do you have children? (After answering 'a' or 'b' please go to question 7; after answering 'c' please skip questions 7, 8, 9)
  - a) I have children / I am pregnant
  - b) No, but I want to/plan to have children
  - c) No, and I do not want/do not plan to have children
- 7. Is/was the pregnancy the result of natural conception?
  - a) Yes
  - b) No
- 8. Have you experienced difficulties getting pregnant?
  - a) Yes
  - b) No
- 9. Have you ever started an infertility diagnosis?
  - a) Yes
  - b) No
- 10. Has your partner ever started an infertility diagnosis?
  - a) Yes
  - b) No
- 11. In your opinion, what is the most common cause of problems in getting pregnant?
  - a) Male infertility
  - b) Female infertility
  - c) Couple infertility
  - d) Idiopathic infertility (no identifiable cause)
- 12. In your opinion, are there effective treatments for infertility?
  - a) Yes
  - b) No
  - c) I don't know
- 13. What methods of infertility treatment do you know? (several answers possible)
  - a) Stimulation of ovulation
  - b) Stimulation of spermatogenesis
  - c) Diet and lifestyle changes
  - d) Intrauterine insemination
  - (e) In vitro fertilization (IVF)
  - f) NaProTechnology
  - g) Surgical treatment
- 14. What do you think the in vitro procedure consists of?
  - a) In vitro fertilization is a medical procedure involving the fertilization of several egg cells by sperm outside the female reproductive system, under laboratory conditions, and immediate transfer to the uterus.

- b) In vitro fertilization is a medical procedure involving the fertilization of several egg cells by sperm outside the female reproductive system, under laboratory conditions, and transfer to the uterus after several days.
- c) In vitro fertilization is a medical procedure involving the intrauterine administration of male sperm.
- d) I do not know what this procedure consists of
- 15. What is your attitude toward in vitro fertilization?
  - a) Positive
  - b) Negative
  - c) Neutral
- 16. How do you know about the in vitro procedure? (several answers possible)
  - a) Internet forums
  - b) Websites of infertility clinics
  - c) Women's magazines/magazines
  - d) Specialized literature
  - e) Doctor
  - f) Midwife
  - g) Television
  - h) Friends
  - i) Other
- 17. Would you use IVF if necessary?
  - a) Yes, regardless of cost
  - b) Yes, if it was a free/subsidized procedure
  - c) Yes, but with ethical doubts
  - d) No
- 18. In your opinion, can adoption of a child be an alternative to infertility treatment, including IVF?
  - a) Yes
  - b) No
  - c) Difficult to say
- 19. Is it true that the IVF procedure in Poland can only be undertaken once?
  - a) Yes
  - b) No
  - c) I don't know
- 20. Is it possible to use sperm banks in Poland for the IVF procedure?
  - a) Yes
  - b) No
  - c) I don't know
- 21. Is it possible to use egg cell banks for the IVF procedure in Poland?
  - a) Yes
  - b) No
  - c) I don't know

- 22. What is your attitude toward sperm banks/egg cell banks?
  - a) Positive
  - b) Negative
  - c) Neutral
- 23. Do you think the IVF procedure is painful?
  - a) Yes
  - b) No
  - c) I don't know
- 24. Are you worried that children born as a result of IVF may have a higher risk of genetic defects/ mutations?
  - a) Yes
  - b) No
  - c) I don't know

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- 25. What do you think happens to embryos not used in the IVF procedure?
  - a) They are frozen
  - b) They are destroyed
  - c) Difficult to say
- 26. In your opinion, is access to infertility treatment guaranteed in Poland?
  - a) Yes, treatment is widely available
  - b) Yes, but these are mainly private healthcare facilities
  - c) No, treatment is difficult to access

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Word count: 3360 • Tabl	• Figures: 0	• References: 33
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## Sources of funding:

The research was funded by the authors.

## **Conflicts of interests:**

The authors report that there were no conflicts of interest.

#### Cite this article as:

Stankiewicz P, Nieradko-Iwanicka B, Witkowska-Zimny M. Awareness and perception of in vitro fertilization as an infertility treatment method among Polish women: a cross-sectional study. Med Sci Pulse 2023;17(3):1-10. DOI: 10.5604/01.3001.0053.8074.

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Reviews

DOI: 10.5604/01.3001.0053.8075

# OVERPROTECTIVE MOTHER OR MUNCHAUSEN SYNDROME BY PROXY? CHARACTERISTICS OF THE DISEASE BASED ON A LITERATURE REVIEW

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## ABSTRACT

**Background:** Munchausen syndrome by proxy (MSBP), first described by Meadow in 1977, is a mental disorder in which the caregiver or parent (usually the mother) causes the child to become ill to attract attention. The disease most often affects women, with sufferers usually appearing very caring and involved in the treatment. However, they harm the child, leading to physical and mental damage and sometimes death. The caregiver fabricates disease symptoms and will report false symptoms in the child or directly cause the disease. Moreover, they agree to diagnostic procedures and numerous medical interventions and deny the cause of the disease, and after separation from the caregiver, the child's condition improves.

**Aim of the study:** The purpose of this review is to present a characterization of MSBP, taking into account its diagnostic difficulties, treatment methods, and consequences for the child.

**Material and methods:** All relevant publications were retrieved from the PubMed and Google Scholar databases, with keywords including "Munchausen syndrome by proxy" (PubMed – 780 results; Google Scholar – 10500 results), "Munchausen syndrome by proxy diagnosis" (PubMed – 612 results; Google Scholar – 7940 results), and "Munchausen syndrome by proxy treatment" (PubMed – 301 results; Google Scholar – 8210 results), with 53 papers selected. Half of the studies had been published in the last five years.

**Results:** The main MSBP diagnostic difficulties include the low age of the victims and the frequent changes of treatment centers, which often worsen the child's condition. According to some scientists, MSBP psychotherapy treatment may produce the expected results for the patient and child. Children can die or develop future mental and physical problems as a result of their parent's disorder.

**Conclusions:** MSBP is a disease that is usually severe and difficult to diagnose and treat, and to which children fall victim. In order to diagnose MSBP, attending physician vigilance is essential.

**KEYWORDS:** Munchausen syndrome by proxy, medical child abuse, diagnosis



# BACKGROUND

Many caring mothers are often overly concerned with their children's safety, health, and happiness. However, worrying about the condition of their children sometimes causes anxiety - after all, every mother wants the best for her children. But where is the line drawn between a caring mother and a mother who can harm her child?

Munchausen syndrome by proxy (MSBP) is a mental disorder characterized by the caregiver or parent (most often the mother) causing a pathological state in a child, such as a mental or physical illness. The purpose of such behavior is to attract other people's attention or gain sympathy [1-3]. According to Flaherty and Macmillan, such activity focuses on the child and not the caregiver and is a form of child abuse [4]. MSBP is classified into sham disorders, in which the caregiver uses cunning to make the child a patient, often leading to health damage that may cause death [2].

The syndrome was named in honor of a German named Baron von Munchausen, who lived in the 18th century and became a symbol of "colorful blasphemy" due to giving false information about himself and exaggerating his achievements (there were even numerous fairy tales in his honor) [5]. MSBP was first described by Meadow in 1977 as a disease entity in which parents or caregivers, almost always the mother, lie about a child's illness and fabricate symptoms. However, Munchausen syndrome, from which MSBP originates, was already described in 1951 by Asher [6-9].

There are no accurate MSBP epidemiology data in the literature, which may be influenced by its diagnostic difficulty, with current evidence focused mainly on severe cases. Therefore, it is possible to underestimate the statistics of the disease [6,10,11]. In Poland, MSBP frequency is estimated at 3/100,000 children, with several cases reported annually (Berent et al., 2012) [12]. McClure et al. estimate the total incidence of MSBP victims under 16 at 0.5/100,000 and children under one at 2.8/100,000 [13-14]. According to Denny et al., MSBP has an incidence of 2/100,000 in New Zealand in children under 16, with a median age at diagnosis of 2.7 years. As such, the most common MSBP victims are preschool children [15]. Unal et al. reported a frequency of 0.4/100,000 in children under 16 and 2-2.8/100,000 in children under one [16]. Meanwhile, research by Bass et al. (2011) showed that children under five are the most common victims [17]. In a Turkish study by Ozdemir et al. (2015), victim age ranged from two months to 13 years, with a mean of nine months (diagnosis ranged from four months to 13 years, with an average of 46.5 months) [18]. According to Sheridan et al. (2003), the age of abused children ranges from a few weeks to adulthood (the mean age of victims was four years, while the average diagnosis was made at 21.8 months) [19].

Research indicates that MSBP perpetrators are usually women (92-100%), young people (25-31), and married people (42-79%) [16-24]. Despite much research on MSBP, its etiology remains controversial, with most of the available research focusing on the profile of the victims, not the perpetrators [16,24]. It appears that women are more likely to abuse their children through medical means, with the same research suggesting that working in the healthcare profession is more common among MSBP perpetrators. However, many perpetrators fabricated their professional history to gain the trust of medical personnel [25].

It seems correct to say that, in many cases of MSBP, the perpetrator will have mental disorders. Indeed, personality, mood, and somatic disorders are often present, with borderline personality disorder being the most frequently reported. Dube et al. also described a high rate of depression and substance abuse, while Weierich and Nock demonstrated a relationship between self-harm and MSBP [26-27]. However, the absence of any psychopathology was reported in 4.59% of cases (Sirka et al., 2018) [21]. Mental stress can also trigger an obstetric event that can disrupt the mother-child relationship. Therefore, it would be wise to monitor women for MSBP by interviewing them in maternity wards [16].

MSBP has four essential characteristics, including the deliberate fabrication of disease or somatic symptoms by the caregiver, in which they present the child as sick, handicapped, disabled, or injured. The child then undergoes many diagnostic procedures, and the perpetrator denies the cause of the child's illness. The child's symptoms disappear after separation from the perpetrator during their hospital stay, although cases have been reported where the child is abused during hospitalization (Vennemann, 2005), and the child's condition deteriorates after discharge. The caregiver's action may be one-off or recurrent, with the latter occurring much more often [6,19,20,27]. A caregiver may fabricate a history of false symptoms or directly cause disease in the child through drugs, toxins, infectious agents, choking, changing laboratory samples, and falsifying body temperature, which leads to medical interventions and sometimes serious invasive procedures and surgery. These actions result in the child suffering physical and mental harm [28-29].

#### **AIM OF THE STUDY**

The article aimed to review reports on MSBP diagnostic difficulties, treatment methods, and longterm consequences for the child. In addition, based on the results, we also consider whether perpetrators are guilty of committing a crime.

## **MATERIAL AND METHODS**

The inclusion criteria used in the review included publication date, compliance with the topic, and reliability.

# **Eligibility criteria**

We analyzed studies published between 1951 and 2022 to present the history of the disease from its first description (1951). However, to enhance the study's credibility, the scientific evidence regarding diagnosis and treatment described in the results, and the epidemiological and etiology data in the introduction, are mainly based on works from the last ten years (35 references).

Sample: mothers with suspected MSBP presenting to health centers with children.

Phenomena of interest: disorder diagnosis, available treatment methods and their effectiveness, and the consequences of the disease for the child.

Evaluation: Any patient reporting will be evaluated.

Design: All types of observational studies, including cohort, case-control, and individual case studies.

Research type: qualitative, quantitative, and mixed studies.

# Search strategy

The search was conducted using the PubMed and Google Scholar databases. The source texts were last reviewed on 25.10.2022. Keywords used included "Munchausen syndrome by proxy," "Munchausen syndrome by proxy diagnosis," and "Munchausen syndrome by proxy treatment."

# **Data collection process**

Each of the three authors reviewed selected scientific articles for inclusion in the review, with each working independently. Abstracts were initially read, followed by full articles of the selected studies. The extracted data included the following information: recorded cases of MSBP, diagnostic possibilities and methods, treatment effectiveness, and consequences for the child. The risk of bias for each study was independently assessed by the same authors. The collected data are presented in text form to allow for a thorough understanding of the topic under discussion.

All relevant publications were retrieved from the PubMed and Google Scholar databases using the keywords: "Munchausen syndrome by proxy" (PubMed – 780 results; Google Scholar – 10500 results), "Munchausen syndrome by proxy diagnosis" (PubMed-612 results; Google Scholar – 7940 results), and "Munchausen syndrome by proxy treatment" (PubMed – 301 results; Google Scholar – 8210 results), with 53 papers selected. More than half of them (35 results) were published in the last ten years.

# RESULTS

## **Study selection**

Of the articles found, 53 studies were ultimately qualified for review since some did not meet the inclusion criteria after reviewing the abstract, while some of those meeting the criteria were disqualified due to low credibility (insufficient evidence).

#### Discussion

MSBP mimics a variety of disease entities that range from mild to severe to possibly fatal. Ozdemir et al. (2015) showed a range of symptoms in MSBP victims, such as seizures, hypoglycemia, apnea, chronic abscesses, bleeding, hemiplegia, and sexual abuse [16]. Sirka et al. (2018) described a cutaneous form of MSBP in a 15-month-old child who was consulted from six months of age due to blisters and erosions on the skin (leaving leaf-shaped scars), which suggested burns (the smell of various oils and the flow of hot oil from the skin surface) [21].

Kuhne et al. (2019) described the case of a nineyear-old boy who was repeatedly hospitalized due to seizures with a disturbance of consciousness. The mother had a history of rash, photosensitivity, alopecia, arthralgia, hypertension, haematuria, seizures, and the presence of antinuclear antibodies (though laboratory tests in the hospital did not show any other antibodies or abnormalities). Previously, the child was in medical institutions with fever and hematuria, while on another occasion, he presented with fever, headache, vomiting, photophobia, phonophobia, and dizziness. Physical examination revealed agitation, confusion, atactic gait, slurred speech, horizontal nystagmus, painful facial expressions, tachycardia, and weight loss, but magnetic resonance imaging (MRI) and cerebral spinal fluid (CSF) samples indicated no abnormalities. MSBP mimicking systemic lupus erythematosus (SLE) was suspected, and phenytoin intoxication was confirmed (more than twice the normal concentration). The child was separated from the mother [30].

Sahin et al. (2020) presented a case report of a 15-month-old boy admitted to an infectious disease clinic with suspected acute gastroenteritis. The baby developed a high fever due to intravenous fluid administration, and his blood showed the development of many microorganisms, which suggested MSBP [31]. Nogueira-de-Almeida et al. (2018) presented a rare case of MSBP in a 4.5-year-old boy who was consulted for obesity in a nutrition clinic 100 km from his place of residence. The child was examined previously in several other centers for severe obesity (48 consultations, during which numerous complaints were reported). The boy's mother, who appeared to be caring, provided a nutritional questionnaire in which she indicated an extremely low caloric intake and vigorous physical activity, inconsistent with the clinical description, and a BMI (body mass index) of 29.3kg/m2. Laboratory test results were normal (as were hormonal, genetic, and neurological tests), and obesity treatment was unsuccessful. MSBP was diagnosed, though the mother refused psychiatric treatment and became aggressive [32].

Gupta et al. (2021) described the case of a 4-yearold girl brought to the emergency room by her mother with symptoms of polyuria, polydipsia, and weight loss. The mother reported high glucose and glycosylated hemoglobin (HbA1c) levels, which might suggest diabetes (there was a family history of diabetes, and the woman had gestational diabetes). Test results showed normal glucose and HbA1c levels, although home tests continued to indicate high glucose levels, and a "private" laboratory found that HbA1c levels were still elevated (both parameters were normal again in the clinic). During hospitalization, the child had normal parameters (extended diagnostics were carried out), and suspected MSBP was diagnosed [33].

According to Deaton et al. (2022), there were 181 exposures to superwarfarin in the USA in 2014, of which 142 were in children under the age of six, and 170 were found to be unaware. No major clinical episodes or deaths were reported [34].

The Diagnostic and Statistical Manual of Mental Disorders (DSM) describes that the perpetrator's goal is to maintain the diseased role by proxy. In cases of MSBP, a child is often affected. There must be no external motives for this disorder, such as financial benefits, avoiding legal problems, or free time from work. As such, MSBP is not included in the simulation [29,21,35]. According to Scheuerman et al., the stimulus for such behavior is satisfaction with the tests and treatment of the child (victim). The mother attempts to make the child dependent on her by becoming involved in their care and the treatment process [21,35]. Moreover, the mother is overly protective and uses the child to attract attention (at the child's expense) in order to satisfy her desires [36].

A diagnostic difficulty in MSBP is the low age of the victims, which makes determining the cause and nature of the injuries challenging. Indeed, the most common victims are newborns, infants, and young children, with a mean age of 39.8 months, according to Trendak et al. [36]. A doctor's vigilance and suspicion, and an interview with family members, are essential for an MSBP diagnosis. As such, pediatricians should be alert to discrepancies in the history of the child during physical examination, and attention is especially important when the child's condition improves while in the hospital and worsens after discharge [4,21]. The diagnostic and therapeutic problem also involves the patient's denial of the diagnosis, with mothers often raising reservations, becoming hostile, and changing to another facility, which leads to a vicious circle. In addition, the affected person agrees to have the child tested but ignores the pain and suffering associated with numerous medical interventions.

Frequent delays in MSBP diagnosis contribute to further deterioration of the child's condition [36-37]. Later in life, MSBP victims are often diagnosed with mental health disorders, including behavioral, attention, and sleep disorders, post-traumatic stress disorders (PTSD), and MSBP toward future children [36].

- 1. The perpetrator falsifies physical or psychological signs or symptoms or causes injury to another person (victim).
- The perpetrator presents the person (victim) as sick, injured, or disabled.
- 3. The behavior occurs in the absence of external incentives.
- 4. Other mental or psychosomatic disorders are excluded, and the behavior cannot be explained by another disorder

Figure 1. The diagnostic criteria for Munchausen syndrome by proxy according to the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5) [6, 38-39]

- 1. A history of repeated injuries (physical or mental), illnesses, and hospitalizations
- 2. Reports of physical and mental injuries that no one else can confirm
- 3. Symptoms disappear after the victim is isolated from the perpetrator
- 4. Symptoms worsen after discharge from the hospital
- 5. Inconsistent symptoms
- 6. Excessive involvement in medical matters
- 7. Increased relationships with patients and healthcare professionals
- 8. The perpetrator speaks for the child
- 9. Symptoms similar to other patients appear during hospitalization
- 10. Symptoms do not fit any disorder and do not match test results
- 11. Sustained response to treatment
- 12. Pathological lies (pseudologia fantastica)

Figure 2. Alarming symptoms [6,40].

The prognosis largely depends on the severity of the physical and psychological injuries sustained. Filho et al. claim that treating MSBP causes many difficulties for specialists. In their opinion, based on the reviews and empirical reports of clinicians, it can be concluded that no psychological therapy provides the intended effects for this disease [6]. However, Nicol and Eccles think there are cases in which therapy brings the intended effect, but only in specific circumstances, such as when the patient is well motivated to confront their difficulties, has at least an average level of intelligence, and has no significant family and social problems.

The most substantial problem for psychotherapists is the fact that they have to trust the patient's truthfulness [41]. Boyd et al. believe that the patient's greatest chance of recovery is to stay in a psychiatric hospital and receive supportive, analytical, or psychoanalysis psychotherapy. Unfortunately, there is no information on long-term prognosis since the patient may go to another hospital and start the process anew. Nonetheless, a study showed improvement after psychiatric therapy in one in four respondents [42]. In four cases reported by Lopez-Rico et al., psychotherapy brought about good results by helping to repair the toxic relationship between mother and child and reinstating the autonomy and individuality of the victim.

The best results are gained by therapy in which the child is treated without the mother present. As a result, the highest level of separation of the child from the mother is achieved, indicating that the caregiver and victim require psychological help. The first step to successful treatment involves establishing a good relationship between the mother and the therapist based on mutual trust. The task of the therapy is to develop the mother's self-esteem, empathy, and ability to cope with stressful situations. Additionally, fathers should receive treatment, as they are most often described as not being involved in family life. A perpetrator's psychotherapy is based on working through childhood traumatic experiences, the relationship with her mother, and building and repairing her own identity. Moreover, socio-behavioral therapy is useful as it helps improve social skills and introduces new ways of meeting emotional needs other than child abuse [43].

It is common for a patient to manipulate doctors and their children to meet their own psychological needs, so therapy should focus on searching for and working through past situations that may have led to such a state. Most often, this includes a history of trauma or illness during which the patient experienced concern from others [44]. Lin and Chan believe that MSBP may be associated with personality disorders, such as narcissistic personality disorder or borderline personality disorder. The authors argue that psychotherapy may be effective in such cases, but there is no evidence that biological or psychological therapy is effective. Long-term supportive psychotherapy and, after some time, confrontational psychotherapy can increase awareness of their diagnosis and improve compliance with therapeutic recommendations [45]. Unfortunately, only 12% of patients consent to treatment.

Diagnosis and treatment of MSBP are extremely difficult. However, diagnosis of the disorder remains crucial. The only question remaining is, who is guilty of committing a crime, and who is the victim? Sigal et al. [46] and Glaser [47] describe the phenomenon of a triple relationship between the perpetrator, the victim, and the medical staff. In order to increase credibility, the caregiver often falsifies test results and exaggerates or invents the child's ailments. Doctors are often unaware of the caregiver's intentions and consent to tests, treatments, or other aids, such as wheelchairs and financial support. The task of doctors is to not overlook the child's healable ailments and prevent unintentional harm from excessive examinations and unnecessary treatment. However, the actions of caregivers and doctors lead to the general deterioration of the child's physical and mental health, though it is unintentional in the case of doctors. In summary, the mother's actions consist of deception, obtaining material help, and perpetuating misconceptions about the child's health. In order to meet their needs, the caregiver requires doctors to confirm the poor condition of the child. In response, doctors and health care professionals may inadvertently cause harm to a child. All of these activities cause the victim anxiety about their health condition, the development of mental illnesses, false beliefs about their condition, and social isolation [46,47].

The frequency of death and serious medical events associated with MSBP is not exactly known. The mortality rate has been estimated at 9-31% but is most often in the range of 9-10% [48]. Unal et al. report that it occurs in 6-10% of MSBP cases [9], while Zarankiewicz et al. indicate mortality levels of up to 33% [49]. As many as 8.5% of the siblings of victims are also abused by their parents [41], and according to a meta-analysis of 451 cases of MSBP, 61% of 210 siblings showed signs of abuse, and 25% died [18,48]. In the case of MSBP described, asphyxiation by the mother caused the female victim's death [48]. The woman confessed to abusing her other two children by closing their mouths and nose, though the cause of death was unknown due to the failure to perform an autopsy. However, this case is considered serial MSBP. When an infant has an unexplained death, physicians should pay attention to the presence of the disease in the remaining children [48-50]. Tozzo et al. emphasized the role of clinicians in appropriate patient care and making the best medical decisions,

as well as dealing with the ethical aspects of these activities [51].

According to Glazier, MSBP victims suffer from multiple physical and psychological ailments, such as bedwetting, developmental delay, and irreversible brain damage with consequent learning disabilities, social phobias, hypochondria, difficulty concentrating, nightmares, being prone to theft, and even tetraplegia [52]. Developmental delay may occur in children aged five, and more than half also suffer from another chronic disease [53]. Zarankiewicz et al. share Glazier's views on the consequences of MSBP victims later in life. They also describe a greater risk of these children developing depression, anxiety, PTSD, and growth failure, than the rest of society.

There is a hypothesis suggesting that victims may experience MSBP in the future. Moreover, MSBP victims may be reluctant to seek medical attention, even if they have an acute illness. In addition, They may have difficulties with the proper perception of their own body, making it challenging for them to recognize disease symptoms [49]. Bertulli et al. believe that MSBP victims could experience physical and psychological injuries or even die as a result of unnecessary and potentially harmful tests and treatments [1].

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# Limitations

MSBP research is limited by the diagnostic difficulties hindering the accurate estimation of its incidence. In addition, the disorder is only suspected in many cases because the perpetrator often has excessive suspicion of healthcare providers and will regularly change treatment centers. Therefore, the credibility of studies decreases due to insufficient evidence of treatments. Perhaps increased suspicion and awareness of medical child abuse among healthcare professionals and improved recording could help to increase the base of verified cases and allow a robust assessment of therapy effectiveness.

## **CONCLUSIONS**

MSBP is a disease that is usually severe and difficult to diagnose and treat, and to which a child falls victim. Attention is drawn to the child's suffering, and they may develop mental and physical problems in the future or even die. Therefore, the vigilance of pediatricians and family history is necessary for a diagnosis and the commencement of therapy as soon as possible for the mother and the child.

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Word count: 3536	• Tables: 0	• Figures: 2	• References: 53

## Sources of funding:

The research was funded by the authors.

## **Conflicts of interests:**

The authors report that there were no conflicts of interest.

#### Cite this article as:

Rusinowska B, Satoral M, Tybulczuk B, Romanek Z, Sękowska M, Pyrka Z. Overprotective mother or Munchausen syndrome by proxy? Characteristics of the disease based on a literature review. Med Sci Pulse 2023;17(3):11-18. DOI: 10.5604/01.3001.0053.8075.

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Reviews

# EFFECTS OF METFORMIN ON VITAMIN B12 LEVELS, INCLUDING DOSE AND DURATION OF THERAPY: A NARRATIVE REVIEW

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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:** Metformin, a biguanide derivative medication, is administered worldwide as the first-line treatment for patients with type 2 diabetes mellitus. Despite its many advantages, it is not devoid of side effects. As many studies have evidenced thus far, metformin treatment may increase the risk of vitamin B12 deficiency, with the prevalence of this deficiency varying from 1.8% to 53.2%. We performed a review of studies to summarize their results and present dose and duration associations between metformin therapy and serum cobalamin levels.

**Aim of the study:** The purpose of this study was to evaluate the relationship between metformin and vitamin B12 deficiency from a historical perspective.

**Material and Methods:** Thirty articles focused on vitamin B12 deficiency during metformin therapy, collected from the PubMed database from 1971 to July 2021, were analyzed.

**Results:** Based on the literature reviewed, we observed a prevalence of vitamin B12 deficiency with metformin use ranging from 1.8% to 53.2%, with a median of 11.2%. In studies with follow-up longer than six months, the incidence of vitamin B12 deficiency during metformin treatment was approximately 6–10%. The vast majority of studies showed an inverse correlation between dose and length of metformin intake and serum vitamin B12 levels. The findings of three out of 16 analyzed studies proved dose-only associations, and the other three showed time-only effects. Two studies found no relationship with these variables.

**Conclusions:** Patients undergoing long-term metformin therapy, especially at high doses, should have their vitamin B12 levels measured regularly to protect them from complications resulting from cobalamin deficiency.

KEYWORDS: Vitamin B12, Vitamin B12 Deficiency, Diabetes Mellitus, Metformin

# BACKGROUND

Diabetes mellitus (DM) is a chronic disease that usually causes severe complications and enormous healthcare costs [1]. The prevalence of DM continues to increase in both developed and developing countries [2]. According to the International Diabetes Federation (IDF), in 2019, type 2 DM affected an estimated 463 million people, and it is projected to reach 700 million by 2045 [3].



Vitamin B12 (cobalamin) is a water-soluble vitamin that is extracted from animal-sourced foods. Cobalamin, in combination with intrinsic factor (IF), is absorbed in the terminal ileum [4,5]. The prevalence of vitamin B12 deficiency varies between 12% and 20%. Cobalamin deficiency increases with age [6]. Vitamin B12 deficiency has three primary etiologies: dietary insufficiency (usually a strict vegan diet for years or due to a lack of dietary intake in the elderly), autoimmune (anti-intrinsic factor antibodies in pernicious anemia), and malabsorption (due to inflammatory bowel diseases or bariatric surgery) [6,7]. Cobalamin deficiency mainly manifests as macrocytic anemia. Other complications of vitamin B12 deficiency may include peripheral neuropathy, glossitis, diarrhea, headaches, and neuropsychiatric disorders [7].

Metformin is an oral biguanide derivative administered as the first-line treatment for type 2 DM [8]. Its glucose-lowering effect is achieved due to the suppression of hepatic gluconeogenesis, which intensifies insulin-mediated glucose uptake and utilization in peripheral tissues [9,10]. It is also used to treat insulin-resistance conditions like polycystic ovary syndrome, human immunodeficiency virus (HIV)associated lipodystrophy, acanthosis nigricans, and, possibly, dementia-type neurodegenerative disorders [11]. Vancura et al. presented metformin as an anticancer agent owing to findings in several studies revealing decreased expression of cell proliferation marker (Ki-67) during treatment [9]. The mechanism of metformin includes inhibiting the electron transport chain and ATP synthesis, as well as regulating adenosine monophosphate (AMP)-activated protein kinase (AMPK) and the mechanistic targets of rapamycin complex 1 (mTORC1) [9]. AMPK activation influences pathways involved in glucose and lipid metabolism, mitochondrial biogenesis, autophagy, circadian rhythm, and cell growth [12]. McCraight et al. reported a reduction in ileal bile acid absorption, resulting in an increasing bile acid pool within the intestine, which may lead to lower cholesterol levels [13]. The osmotic effect due to an elevated luminal bile salt concentration can result in diarrhea associated with metformin intake [13]. The most common side effect of metformin is diarrhea. Liver damage or lactic acidosis have been reported with lower frequencies [12]. Several studies presented below provide evidence of metformin-induced lowering of cobalamin levels. This effect appears mostly in patients with long-term treatment and higher doses of metformin [4]. It also explains that modifications in bile acid metabolism, disturbances in IF secretion, and bacterial overgrowth in the small intestine could be the reasons for vitamin B12 deficiency [14]. Metformin may also influence calcium-dependent absorption of the vitamin B12–IF complex in the terminal ileum [4].

### **AIM OF THE STUDY**

The purpose of this study was to evaluate the relationship between metformin and vitamin B12 deficiency from a historical perspective.

# **Material and methods**

The PubMed database was searched for the period from 1971 to July 2021. The search was restricted to articles in the English language and studies performed on human subjects. The search used the terms (including synonyms): "metformin" and "vitamin B12 deficiency". In total, 170 articles were identified. The "free full text" filter was then applied, and 79 matching results were obtained. Thereafter, case reports, reviews, systematic reviews, and meta-analyses were excluded. Sixty articles were matched, of which we included those that contained information about a dose of metformin, a duration of metformin treatment, and a population of vitamin B12 deficiency. Ultimately, 30 articles were analyzed.

#### RESULTS

From the 30 publications that met our inclusion criteria, data such as the dose of metformin, duration of treatment, and percentage of patients with vitamin B12 deficiency were retrieved. The results are presented in Table 1 ordered by their year of publication.

#### **DISCUSSION**

The first reports of a relationship between vitamin B12 deficiency and metformin therapy appeared in 1971 when Tomkin et al. [15] published the results of their study in which vitamin B12 deficiency was found in 21 (30%) of 70 patients undergoing chronic metformin therapy. The researchers were unable to determine a potential cause for this phenomenon, but they did bring attention to its existence, which initiated a number of further studies. One of the first studies inspired by this discovery was a study by Berger et al. [16] on the malabsorption of cobalamin given 2 hours after metformin administration and at 7 and 14 days after metformin administration. Their study reported no statistically significant effect of metformin on vitamin B12 absorption, but its important limitation was the small number of subjects studied (12). However, it may have encouraged subsequent investigators to search for other possible pathways of metformin's effect on cobalamin. In the following years, studies

Author	Year	Population N	Dose of metformin (mg/d)	Duration of metformin treatment	Population with B12 deficiency N (%)
Tomkin	1971	71	1500-2000	4-7±0-4 years	4 (5.6%)
Stowers	1971	114	mean 3300	mean 4.4 years	20 (17.5%)
Bauman	2000	14	850–2550	4 months	2 (14.3%)
Wulffele	2003	171	mean 2163	16 weeks	3 (1.8%)
Ting	2006	465	2000±700	2–5 years (median 4)	155 (33.3%)
Sahin	2007	74	850–1700	6 weeks	0
Nervo	2010	144	median 2550	median 4 years	10 (6.9%)
de Jager	2010	192	mean 2050	4.3 years	19 (9.9%)
Kos	2012	297	mean 1500	4 years	_
Iftikhar	2013	114	two groups: mean 2100 (±497) and 1582 (±632)	mean 8.96±4.74 years	35 (30.7%)
Sato	2013	62	1100	2.9 years	8 (13%)
de Groot-Kamphuis	2013	164	2050	median 4.9 years	23 (14.1%)
Ко	2014	799	mean 1,194.1±453.0	mean 4.6±3.4 years	76 (9.5%)
Biemans	2014	550	1306±570	mean 64.1±43.2 months	126 (22.9%)
Akinlade	2015	81	two groups: ≤1000 and >1000	two groups: <10 years and >10 years	7 (8.6%)
Aroda	2016	753	1700	9.5±4.4 years	56 (7.4%)
Damião	2016	231	1500-2550	5–13 years	52 (22.5%)
Ahmed	2016	121	2400±700	9.6±6.8 years	34 (28.1%)
Lohmann	2017	237	850	0.5 year	15 (6.3%)
Kancheria	2017	1369	≥500	>0.5 year	104 (7.6%)
Rodríguez-Gutiérrez	2017	100	≥850	30.6 (SD±43.7) months	4 (4%)
Wong	2018	188	1110±483	5.4±3.5	100 (53.2%)
Metaxas	2018	29	1900±600	>0.5 year	11 (39.3%)
Alharbi	2018	319	three groups: <1000, 1000- 2000, and >2000	three groups: <1 year, 1–4 years, and >4 years	30 (9.4%)
Alvarez	2019	162	1536±614	108±90 months	12 (7.4%)
Kim	2019	1111	1339±479	10.1±7.0 years	247 (22.2%)
Alshammari	2019	16	828.13±150.52	10.27±7.99 years	2 (12.5%)
Serra	2020	123482	>500	47.0±34.0 months	3750 (3%)
Shivaprasad	2020	2061	1344.2±544.5	5.0±2.9 years	505 (24.5%)
Tesega	2021	80	1200±644.35	1–20 years (median 4)	4 (5%)

Table 1. Characteristics of all studies reviewed arranged chronologically

have been conducted in an attempt to gain a greater understanding of this phenomenon, as well as to determine whether it is dependent on various factors, such as the dose or duration of therapy. Some researchers have examined whether there are any factors that reduce the effect of metformin on vitamin B12 levels. The study by Wulfelle et al. [17] indicated that increased calcium intake may reverse this effect, and this was also mentioned by Bauman et al. [18]. Factors that may increase this risk were also studied by Ting et al. [19], who observed no increase in the risk of metformin-induced cobalamin deficiency with chronic use of H2 blockers or proton pump inhibitors. In our review, we found that the prevalence of vitamin B12 deficiency in metformin users ranged from 1.8% to 53.2%, with a median of 11.2%. Previous reports found frequencies of 6–30% [20,21]. The study by Wong et al. [22] evidenced the highest prevalence (53.2%) of vitamin B12 deficiency, but, as the researchers themselves pointed out, the mean age of the subjects was significantly higher (83.3 years) compared to other studies (range: 58.5–64 years). This was probably due to the study design: the subjects were elderly people residing in long-term care institutions. The elderly have an increased risk of developing B12 deficiency, with the prevalence ranging from 5% to 40%.

It is also worth noting that there have been isolated reports of the influence of gender on the incidence of vitamin B12 deficiency after metformin treatment. Most studies do not show a statistically significant difference regarding gender, but the study by Alvarez et al. [23] found a significant difference in cobalamin levels in male patients. Moreover, a study by Alharbi et al. [24] found that women had a higher risk of B12 deficiency. Other reports on the influence of ethnic background (e.g., the study by Ahmed et al. [25], which included 73.5% Afro-American patients) indicated that this ethnicity was a significant protective factor for vitamin B12 deficiency. In contrast, the report by Reinstatler et al. [26] concluded that there are no statistically significant differences between races.

In the majority of studies, one important inclusion criterion was a minimum duration of metformin use of 6 months [27,28]. As an exception, Damião et al. [20] adopted 3 years as a minimum duration. In their study, the long duration of prior metformin use was argued for the more frequent occurrence of vitamin B12 deficiency after 5–10 years in the course of metformin therapy. Presumably, this delay in the incidence of deficiency is related to the significant reserves of this vitamin in the liver [20,29].

Despite many studies that have shown a relationship between metformin and vitamin B12 deficiency, it is important to mention those that have not found such an effect. One such study is that of Elhadd et al. [30], who demonstrated no effect of metformin on cobalamin deficiency. Their study was conducted on 362 subjects, 235 of whom were taking metformin. It revealed that among the subjects taking metformin, the incidence of vitamin B12 deficiency was 8%, and among those not taking metformin, the incidence was 19%. Quite relevant information in this study may be the fact that the cut-off value for vitamin B12 deficiency was <133 pmol/L, which is one of the lowest cut-off values among studies on this topic. There are also studies that reveal an effect of dose but not duration of metformin therapy. According to Sugawara et al. [31], long-term metformin therapy had no effect on increasing the incidence of cobalamin deficiency. However, as the investigators themselves indicate, the Japanese population that was included in their study was found to be a low-risk population for vitamin B12 deficiency due to a diet based largely on fish and seafood.

In our review, we included a study by Sahin et al. [32] in which none of the subjects developed vitamin B12 deficiency after starting metformin therapy. In their study, vitamin B12 levels were measured before the administration of metformin and after 6 weeks of treatment. There was no statistically significant decrease in cobalamin levels. However, a decrease of 20.2 pg/mL was noted. We cannot rule out that, as mentioned above, because of short follow-up, the subjects did not develop deficiency due to hepatic stores of cobalamin. If the therapy had been continued for a longer period, a statistically significant decrease leading to vitamin B12 deficiency might have been shown.

In the study by Wulfelle et al. [17], the followup period was longer than in that of Sahin et al. [32] (i.e., 16 weeks). This study revealed a decrease in vitamin B12 levels in the metformin group after 16 weeks of treatment of approximately 14%. Compared with vitamin B12 levels in the control group (placebo-treated group), these changes were statistically significant. Approximately 2% of subjects in the metformin group had vitamin B12 deficiency after 16 weeks of treatment [18]. This percentage is the lowest among the studies that found vitamin B12 deficiency after metformin administration. However, we can infer more about its association with vitamin B12 after a longer follow-up period for metformintreated patients.

In an earlier study by Bauman et al. [18], the follow-up period was 4 months. Similarly, vitamin B12 levels were measured at 3 months after metformin administration in the study group. The average cobalamin levels in those patients dropped from approximately 400 pg/mL before metformin was administered to less than 280 pg/mL. By the third month of therapy, vitamin B12 levels were above 280 pg/mL. Due to the small number of subjects (14), the percentage of subjects with vitamin B12 deficiency was relatively high (14.3%) [17].

The Lohmann et al. [33] study was conducted on non-diabetic women diagnosed with breast cancer. Vitamin B12 levels were checked before metformin was administered and after 6 months of metformin therapy at 850 mg per day. As a result of the intervention, the median vitamin B12 level in the study group decreased from 390 pmol/L at baseline to 320 pmol/L after 6 months, which was statistically significant compared with the control group. Those with vitamin B12 deficiency after 6 months of the study represented 6.3% of metformin users.

In the study by de Jager et al. [34], after 52 months of treatment with metformin at an average dose of 2050 mg per day, a decrease in vitamin B12 levels of 89.8 pmol/L was observed. In the control group, on the other hand, the average vitamin B12 levels increased by 0.2 pmol/L. Compared to the control group, the average vitamin B12 levels decreased by 19% in the patients treated with metformin. After a 4-year follow-up period, cobalamin deficiency was noted in 19 patients, representing 9.9% of the study group.

The study by Aroda et al. [14] had the longest follow-up period and a sizable study population (1489 subjects at the end of the study, including 753 in the metformin-treated group), compared to the previous ones analyzed above. After an average of 5 years in the metformin group, 37 (4.3%) subjects had vitamin B12 deficiency, and after an average of 13 years, it was present in 56 (7.4%) of the subjects. In the placebo group, it was 20 (2.3%) and 40 (5.4%), respectively.

In summary, the effect of metformin on the occurrence of vitamin B12 deficiency is evident and increases with follow-up time. Starting from the study with the shortest follow-up of 6 weeks, in which cobalamin deficiency was not observed, a gradual increase in frequency was noted. This observation largely depended on the size of the study population. However, in studies with a follow-up period longer than 6 months, we observed that the incidence of vitamin B12 deficiency during metformin treatment was approximately 6–10%.

It is evident that the dose and duration of metformin treatment have been proven to be the most important factors responsible for decreases in serum vitamin B12 levels.

Bauman et al. [18] divided 21 patients into two groups: metformin (n = 14) and non-metformin (n = 7). The study lasted 4 months in total. The initial dose of 850 mg/day was changed after 2 weeks to 850 mg twice a day for 2 weeks, and then to 850 mg three times a day. The cut-off value for serum total cobalamin deficiency was defined as <200 pg/mL. Twelve out of 14 metformin users had decreased cobalamin levels after 3 and 4 months. Only two patients out of this group met the requirements of deficiency after 3 months and two patients after 4 months of receiving metformin. The deficient cobalamin level was observed both after 3 and 4 months. The study showed an inverse correlation between the duration of treatment and serum levels of vitamin B12.

Different findings were presented in a randomized, placebo-controlled study by Wulffele et al. [17]. The authors reported that 14% of patients under metformin treatment had decreased cobalamin values in the 16-week trial period. Eight patients at the beginning and eight at the end of the study had lower vitamin B12 levels compared to the reference values (180–700 pmol/L). It was concluded that metformin's actual dose did not influence the results. The short-term therapy trial is probably insufficient to prove the time-related effect of metformin on serum cobalamin values.

The study conducted by Ting et al. [19] involved 155 patients on metformin therapy and 310 control group participants. The results of a nested case–control study confirmed that metformin dose is the most important factor leading to vitamin B12 deficiency. During post hoc analysis, metformin takers were divided into three groups according to daily dose: ≤1000 mg, 1000–2000 mg, and ≥2000 mg. The study proved that each added 1000 mg per day increased the risk of cobalamin deficiency twice. Comparing the metformin group in terms of treatment duration, the possibility of vitamin B12 deficiency was higher in users ≥3 years than users <3 years.

Sahin et al. [32], in their 6-week trial, compared the influence of metformin and rosiglitazone on serum vitamin B12 levels. Patients prepared for the study for 4 weeks by following a diet and leading an active lifestyle. Then, the first group (n = 74) started metformin treatment with an increasing dose from 850 mg to 1700 mg daily, and the second group (n = 55) received rosiglitazone therapy of 4 mg per day for 6 weeks. The short-term treatment results did not show any important changes in vitamin B12 serum levels. Additionally, there were no prominent differences between the first and second groups. The authors did not exclude the fact that longer treatment could be associated with cobalamin deficiency and may start earlier than we predicted.

A cross-sectional study by Nervo et al. [35] involved 144 patients receiving metformin therapy. In 10 patients, vitamin B12 levels were lower than 125 pmol/L, and in 53 participants, the levels were 125–250 pmol/L. The results showed a negative correlation with the length of metformin treatment. The median duration of metformin intake was 4 years. The 25th and 75th percentiles were 2 and 8.1 years, respectively. The study did not confirm a correlation between metformin dose and vitamin B12 values.

The randomized, placebo-controlled, double-blind trial by de Jager et al. [34] included 131 metformin takers and 146 patients in the placebo group. At the end of the study, complete laboratory results were accessible for 127 and 129 patients in the metformin and placebo groups, respectively. The average daily dose of metformin was 2050 mg. The cut-off value for vitamin B12 deficiency was <150 pmol/L. The study demonstrated a 7.2% higher risk of vitamin B12 deficiency in the metformin group compared to the placebo group. The number of individuals who must be treated in order for one to become deficient (number needed to harm) was 13.8 per 4.3 years of the conducted study. The trial proved that the metformin-induced vitamin B12 decrease was positively correlated with time. Moreover, the decrease among some patients was significant and required vitamin B12 supplementation.

The retrospective review by Kos et al. [36], as well as previous studies, demonstrated that the vitamin B12-lowering effect caused by metformin increases over time. During 4 years of metformin treatment, serum cobalamin levels decreased each year. There was a notable difference between the placebo and metformin groups.

The case-control study by Iftikhar et al. [37] confirmed a negative correlation of dose and duration of metformin treatment with serum cobalamin levels. The cut-off point for vitamin B12 deficiency was <150 pg/mL. The trial involved 114 metformin users and 105 patients as a control group. Among the metformin users, 31 out of 114 developed vitamin B12 deficiency. This deficient group was characterized by a higher dose and longer duration of medication intake. The mean daily dose and metformin duration were 2042 mg and 28.2 months in the vitamin B12-deficient patients and 1607 mg and 18.8 months in the non-deficient patients.

Slightly different results are presented in the observational study by Sato et al. [38]. They reported no relationship between the length of metformin treatment and cobalamin levels. However, an inverse correlation between metformin dose and vitamin B12 levels was proven, as in prior findings. Cobalamin deficiency was defined as a vitamin B12 concentration lower than 150 pmol/L. This value was observed in 13% of metformin takers, with a mean daily dosage of approximately 1100 mg.

Similar results were found in the Groot et al. [39] cross-sectional study. It enrolled 164 metformintreated patients, of whom 14.1% had vitamin B12 deficiency. The cut-off point for deficiency was a serum vitamin B12 level lower than 150 pmol/L. The average duration was 4.9 years. The minimum, 25th percentile, 75th percentile, and maximum were 0.04, 1.7, 8.1, and 31.9 years, respectively. Treatment length did not significantly influence cobalamin levels in this study. The average dose was 2050 mg. Furthermore, the authors discovered that each additional 100 mg of metformin decreased cobalamin values by 3.77 pmol/L, simultaneously increasing the risk of deficiency by 8%.

The Ko et al. [40] study involved 799 metformintaking patients with a treatment history duration longer than 3 months. The cut-off point for vitamin B12 deficiency was 300 pg/mL or less. Cobalamin deficiency occurred in 76 participants. Analysis showed that the mean duration and dose in the deficient group were 6.9 years and 1488.8 mg, compared to 4.4 years and 1163.1 mg in the non-deficient group. Unlike prior studies, this trial is characterized by a precise division according to dose and length of metformin therapy. The authors categorized patients into three groups according to therapy duration: <4 years, 4–10 years, and  $\geq 10$  years. Among the deficient group, the highest percentage (56.6%) was found in the second time frame, while in the non-deficient group, 58.9% were classified in the first time frame. Furthermore, the majority of normal vitamin B12 level patients received daily doses ≤1000 mg compared to the deficient population who received 1000-2000 mg or ≥2000 mg of metformin. The risk of cobalamin deficiency calculated in their findings was four-fold higher in patients receiving treatment for at least 10 years and a dose of 2000 mg than those with a history of metformin shorter than 4 years and a dose of 1000 mg or less.

The results reported by Akinlade et al. [29] in their cross-sectional study are consistent with those of many previous studies in proving an association between dose and duration of metformin treatment with decreased serum cobalamin levels. The cut-off point for vitamin B12 deficiency was less than 200 pg/dL, while borderline deficiency was between 200 and 300 pg/dL. The study enrolled 81 metformintreated patients with a history of metformin therapy longer than 5 years. The participants were divided into groups according to daily dose and length of medication intake: 1000 mg or less (n = 56) or more than 1000 mg (n = 25) and less than 10 years (n = 50) or 10 or more years (n = 31), respectively. The analysis revealed lower cobalamin values in the population receiving higher doses for a longer period.

The Wong et al. [22] retrospective study focused on metformin therapy's correlation with cobalamin deficiency in elderly patients (i.e., 65 years and older). In total, 1996 patients were enrolled; among those, 188 were treated with metformin. The cut-off point for vitamin B12 deficiency was less than 150 pmol/L. Among the metformin-treated group, seven subjects were excluded from the analysis. In this group of 174 patients, cobalamin deficiency occurred in 54% of cases. These 174 patients were categorized into deficient and non-deficient groups. Among them, there was a division based on dose and duration: <1500 mg or  $\geq$ 1500 mg per day and  $\leq$ 2 years or >2 years. The risk of deficiency was more than doubled in the subgroup with longer duration and higher dose. However, this study was characterized by an older population and a lower mean dose than prior studies, which may have affected the results. Furthermore, the research population consisted of residents of long-term care institutions; therefore, considering older age, other comorbidities affecting the increased risk of vitamin B12 deficiency were possible.

Alharbi et al. [24] enrolled 319 metformin takers and 93 non-metformin takers. Deficiency was defined as less than 132.8 pmol/L and occurred in 9.4% and 2.2% in the metformin and non-metformin groups, respectively. For the purposes of analysis, patients from each group were further categorized in terms of duration (<1 year, 1–4 years, and >4 years) and metformin dose (<1000, 1000–2000, and >2000 mg). As with many previous studies, this research proved a negative correlation between dose and metformin duration, leading to serum vitamin B12 decreases below the normal range.

Another cross-sectional study by Kim et al. [21] enrolled 1111 patients with more than a 6-month history of metformin therapy. The cut-off point for vitamin B12 deficiency was less than 300 pg/mL.

The deficiency criterion was fulfilled by 22.2% of the patients. The mean duration was approximately 10.1 years, with a mean dose of approximately 1339 mg/day in the whole study population. No significant association was found between serum cobalamin levels and metformin duration. Patients with a metformin treatment duration shorter than 10 years accounted for 44.5% and 55.5%, those between 10 and 20 years accounted for 42.1% and 35%, and those with 20 or more years accounted for 13.4%and 9.5% in the deficient and non-deficient groups, respectively. Metformin dose was revealed to be a major factor associated with decreased serum vitamin B12 levels and demonstrated an inverse correlation effect. In groups divided by metformin dose (<1000, ≥1000 but <1500, ≥1500 but <2000, and ≥2000 mg) the percentages of the population affected were 8.5% and 23.4%, 15% and 24.9%, 46.2% and 39.5%, and 30.4% and 12.3% in the deficient and non-deficient groups, respectively.

Finally, a study enrolled 80 patients with a history of metformin intake of 5 months or longer. This cross-sectional study by Tesega et al. revealed vitamin B12 deficiency in 5% of subjects. The mean metformin treatment length was 4 years, and the mean dose per day was approximately 1200 mg. In terms of metformin duration, participants were divided into two groups: less than 4 years or 4 and more years. According to dose, there were three groups of patients: those receiving >1500 mg, those receiving 1000-1500 mg, or those receiving >1500 mg of metformin daily. All vitamin B12-deficient patients took >1500 mg of metformin for 4 or more years. By obtaining these results, the research corresponds to previous research, showing an inverse correlation between dose, duration, and serum cobalamin increase [4].

To summarize, the vast majority of studies revealed an inverse correlation between dose and

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length of metformin intake and vitamin B12 serum levels. Three out of 16 analyzed studies proved a dose-only association and the other three time-only effects. Two studies found no relationship with these variables. These results may be explained by short trial periods.

# Limitations of the study

This review has some limitations. First of all, we would like to emphasize that this is not a professional systematic review but only a subjective review of studies. Our exclusion of case reports, reviews, systematic reviews, and meta-analyses was intended to analyze the original studies themselves but may have limited the wider view of the results obtained. Additionally, only articles containing information about metformin dose, metformin treatment duration, and population of vitamin B12 deficiency were included in the study, which may have led to a limitation of our review. Many of the cited articles also have limitations, which we endeavored to discuss above; however, these limitations may have influenced our results.

# **CONCLUSIONS**

Like many researchers before us, we identified the importance of determining vitamin B12 levels in patients treated with metformin, especially at high doses administered for many years. It is extremely important to avoid the development of complications owing to vitamin B12 deficiency in patients with DM, because diabetic neuropathy can obscure the picture of neuropathy from vitamin B12 deficiency, which, up to a point, is reversible.

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Word count: 4637	• Tables: 1	• Figures: 0	• References: 40
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# Sources of funding:

The research was funded by the authors.

# **Conflicts of interests**:

The authors report that there were no conflicts of interest.

# Cite this article as:

Wójcik-Kula A, Tomys-Składowska J, Januszko-Giergielewicz B. Effects of metformin on vitamin B12 levels, including dose and duration of therapy: a narrative review. Med Sci Pulse 2023;17(3):19-27. DOI: 10.5604/01.3001.0053.8584.

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# ANALYSIS OF MENUS IN SELECTED DAYCARE CENTERS IN THE OPOLE PROVINCE: AN OBSERVATIONAL STUDY

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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 the first years of a child's life, eating habits and preferences are formed. The main influence on the nutrition of a child between 13 and 36 months of age is the people who take care of him. The nursery is also responsible for providing children with adequate food.

**Aim of the study:** This study aimed to analyze the menus of children aged 1 to 3 in selected daycare facilities in the Opolskie Voivodeship.

**Material and methods:** The analysis concerned 10-day menus obtained from 8 different regional institutions looking after children aged 1–3 years. The analysis was based on a comparison of menus with the current nutritional standards and evaluated in terms of quantity.

**Results:** The results showed an excess of protein (388%) and sodium (529%) intake and insufficient coverage of the requirements for vitamin D (6.5%), calcium (87%), and iron (83%).

**Conclusions:** The analysis of the menus showed a number of irregularities in the nutrition of children aged 1–3 staying in care and educational institutions. This analysis revealed the weak points of nursery diets.

KEYWORDS: diet, child nutrition, menu, nursery

## BACKGROUND

Nutritionists and people dealing with the issues of nutrition point to the increasingly clear trend of being overweight among adolescents. According to the results of research published in 2019 by the Central Statistical Office, 57% of adults in Poland were overweight or obese. At the end of 2019, almost 65% of all men had a relatively high body mass index (about 46% were overweight, and less than 20% were obese). Additionally, nearly 49% of adult women were classified with a body mass index at an overweight or obese level (more than 31% were overweight, and almost 18% were obese). In the two youngest age groups (aged 15–19 and 20–29), a relatively low percentage of overweight or obese people was recorded (16% of people aged 15–19 and 35% of people aged 20–29). In the next two age groups (aged 30–39 and 40–49), there was a systematic increase in the share of overweight or obese people (50% among people aged 30–39 and 60% among people aged 40–49). In the last three



age groups (aged 50–59, 60–69, and 70–79), the percentage of overweight or obese people was at a similar level – about 70%. In the last age group (80 years and older), 63% of people had this problem [1]. In the case of preschool children (up to 6 years of age), the obesity epidemic has become a fact. In the first decade of the 21st century, the percentage of obese girls and boys from this group in Poland was high and amounted to 8% [2]. Among the four main factors that determine human health, lifestyle has an impact on total mortality of up to 50%. The remaining factors are biological (20%), environmental (20%), and healthcare (only 10%) [3,4].

Obesity is a condition in which excess body weight occurs due to the excessive growth of adipose tissue, exceeding 20% of the weight for age, sex, and height [5]. However, the education of society in the field of proper nutrition seems to be crucial, as overweight and obesity can be easily observed among the youngest children, whose eating habits are derived from their closest patterns.

These are the very early years of a child's life when food habits and preferences are formed. The main influence on the diet of a child between the ages of 13 and 36 months is the people who look after them. The fast lifestyle and urgent need to quickly return to work right after giving birth causes more and more children to be sent to nurseries. The main task of such facilities, apart from child care, is to provide adequate nutrition. A very often observed phenomenon among carers is the lack of sufficient knowledge about the products that can be given to a child at certain stages of development [6]. Dietary errors in children aged 5 to 36 months can cause abnormal weight in 32% of children [7]. An adequate diet during the preschool years (usually 2-5 years) is crucial for a children's short- and long-term health. A proper balance of nutrients can improve the cognitive development of children [8]. What is more, it reduces the risk of overweight and obesity (in the short term) [9]. Eating habits developed in the nursery and preschool period affect the risk of better or worse health throughout life [10].

When feeding children, attention should be paid to the appropriate frequency and organization of meals and selection of products to ensure the child is adequately supplied with energy during the day. Young children should receive 4 to 5 meals a day [6], including three main meals and one or two extra meals. The diet of a small child should resemble the easily digestible diet of an adult. The desired food preparation technique is cooking. Vegetarian or other elimination diets that may cause deficiencies of essential nutrients are not recommended [11]. The effects of improper nutrition at a young age (1–3 years) affect the risk of cardiovascular diseases, hypertension, overweight, obesity, metabolic syndrome, diabetes, and glucose intolerance in adulthood [12]. One of the most commonly observed deficiencies in a children's diet is a negligible amount of vegetables. Products in this group are the basis for soups and salads. They are an important source of minerals, carbohydrates, and vitamins. In the children's diet, it is best to use fresh, seasonal vegetables. Fruits, including juices, are a source of energy in the form of simple and complex carbohydrates. Minerals present in fruits regulate many processes happening in the body. Vitamins, especially vitamin C and pro-vitamin A, have anti-inflammatory and antioxidant effects [6]. The source of power in fats can affect brain development. Fats contain vitamins A, D, and E. Because of the negative effect on a child's growth and development, limiting the amount of fats in their diet is highly dissuaded. Butter and vegetable oils (rapeseed and olive oil) are advised to be given [6, 11]. Harmful products for children or products whose amount should be reduced significantly are mushrooms, raw meat, sugar, salt, ready and highly processed food, and unhealthy, fizzy drinks [13]. Nurseries should provide 75% of the recommended daily food rations for children [14]. The menus should provide the amount of nutrients adequate for both age and physical activity. When arranging the menu, elements such as taste preferences and the ability to bite, chew, or use cutlery should be taken into account [15]. It is also very important to remember that a properly arranged menu covers energy needs and provides all the necessary nutrients [16, 17]. Children spend 7–8 hours a day in the nursery or kindergarten, so the meals served during this stay should be properly balanced to ensure their proper development [18].

## **AIM OF THE STUDY**

This study aimed to analyze the menus of children aged 1 to 3 in selected daycare facilities in the Opolskie Voivodeship. Their menus were compared with the current nutritional standards, which assume the coverage of demand at a level of 75%. The menus were analyzed quantitatively, checking whether the nutrition was adequate. The quantitative analysis concerned selected micronutrients included in the meals.

## **MATERIAL AND METHODS**

# **Study design**

For the quantitative analysis of studies, information about the level of coverage in children of energy, protein, fat, carbohydrates, iron, vitamin D, and sodium were obtained. Nutritional value tables to determine the content of the analyzed ingredients were used. A qualitative analysis (understood as an evaluation of compliance with basic recommendations for the supply of macro and micronutrients) was conducted within each food group, as well as a quantitative analysis limited to the analysis of the declared portion sizes served within a meal.

The research sample consisted of 8 collective catering facilities located in the Opole Voivodeship. The criteria for selecting the facilities included diversity in the area of meal preparation. The sample included facilities with their own kitchen facilities as well as those that relied on external companies for meal delivery. The analysis was conducted under real conditions without interfering with the planned ten-day meal schedules served to children in the nurseries. From the evaluators' perspective, parameters such as the size of the facility, the number of groups in the nurseries, and the ethnic diversity of the children were not significant in assessing the dietary plans. The study was conducted as an illustrative study to determine whether or not deviations from nutritional norms existed. The location was important, as it allowed for specific references to the particular area. This was particularly relevant in terms of identifying any observed deviations from nutritional norms for the entities responsible for monitoring the children's nutrition in the facilities. This practice did not involve identifying specific nurseries but rather signaling potential problems in general. During the study, the facilities were encoded and ensured anonymity, in which the facilities had access to the data. The facilities were randomly selected, and the ten-day meal schedules were obtained during a single period. This practice was important to enable data comparison between facilities. During the collection of data on the meal plans, interviews were conducted to determine, for example, whether meals were prepared on-site, whether the plans were developed in collaboration with a nutrition specialist, or whether computer applications supporting meal planning were used. After obtaining data on the menus, including ingredients, portion sizes, and frequency of serving, a qualitative analysis (understood as an evaluation of compliance with basic recommendations for the supply of macro and micronutrients) was conducted within each food group, as well as a quantitative analysis limited to the analysis of the declared portion sizes served within a meal. Measuring the portion sizes served to children seemed unnecessary due to differences in the manual abilities of the nursery's wards. Different levels of self-feeding skills excluded the accuracy of information on portion sizes as it did not guarantee that the provided portion size was consumed. In the next step, the nutritional and caloric values of the consumed meals were calculated, and the data were statistically processed to highlight differences in energy and nutrient intake between the analyzed groups. The obtained data were compared with applicable standards and nutritional recommendations, which enabled summarizing the study and formulating conclusions.

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### **Data source**

For the purposes of this study, 8 menus for 10 days (decade menus) were obtained from 8 different regional institutions looking after children aged 1–3 years. The menus were from the autumn period. These menus were the source of data for analysis. The research was carried out in facilities located in the Opolskie Voivodeship.

To determine the amount of each food group, the study used a standardized amount of grams from kindergartens. Quantitative analysis made it possible to determine which groups of products dominate or are missing in the children's diet, as well as to determine whether they deviate from the quantitative norms.

# **Statistical methods**

The research results were described quantitatively in Excel. The data obtained for the analysis were compared with the applicable standards and recommendations regarding nutrition and the requirements for individual ingredients in children aged 1 to 3 years.

# RESULTS

Table 1 shows the comparison of the feeding rations from the nurseries with the model. The data presented in the table respects the percentage of compliance and the average amount of food rations with the model nutrition ration served in nurseries. The highest breach was observed in the group of meat and cooked meats. Their supply was exceeded by 331%. In the case of mixed-type bread, the supply was exceeded twice if compared with the model ration. The average coverage of the demand for flour and pasta was only 34% of the recommended intake in nurseries. A similar situation was with vegetable oils (39%).

Table 1. The comparison of model food intake with the amount of specific foods, calculated on the basis of analyzed menus,	, and the percent-
age of implementation of the model ration [17]	

Products	Daily amount in the model ration [g]	75% of daily amount in model ration [g]	Amount in the nursery [g]	The percentage of compliance with the model ration food [%]
	Cereal	products and potatoes		
Mixed type bread	20	15	29	193
Flour and pasta	25	18.7	6.6	35
Groats, rice, breakfast cereals	30	22.5	21.7	96
Potatoes	80-100	67.5	55.4	82
	Fr	uit and vegetables		·
Vegetables	200	150	102	68
Fruit	250	187.5	101	54
	Mill	k and dairy products		
Milk	450	337.5	166.4	49
Dairy fermented drinks	100	75	39.6	53
Cottage cheese	12.5	9.4	9	96
Rennet cheese	2	1.5	1.8	120
	Meat, o	ooked meats, fish, eggs		
Meat, poultry, cooked meats	20	15	49.7	331
Fish	10	7.5	8.7	116
Eggs	30	23	18	78
		Fats		
Animal: butter and cream	6	4.5	6	133
Vegetable: oil	10	7.5	2.9	39
Sugar and sweets	20	15	16.1	107

Table 2. The average daily intake and the percentage of implementation of feeding recommendations in the nursery [11,13,16,20]

Component	Unit	Daily amount in the model ration	75% of daily amount in model ration	Amount in the nursery	The percentage of compliance with the model ration food [%]
Energy	kcal	1000	750	640.24	85
Protein	g	13	9.75	37.84	388
Fats	g	39	29.25	20.67	71
Carbohydrates	g	115	86.25	96.31	112
Calcium	mg	600	450	393.65	87
Iron	mg	5	3.75	3.11	83
Vitamin D	μg	15	11.25	0.73	6.5
Sodium	mg	750	562.50	2975.62	529

Children received nearly half the amount of fruits, milk, and milk-fermented drinks than they should. The best situation is in the supply of porridge rice and cereals, cottage cheese, sugars, and sweets. The difference in consumption of these products is on minimum value (less or close to 1 gram).

Figures 1–8 show a comparison of feeding rations (average from decade menus) in all tested nurseries with the required feeding quantities.

Two of the eight analyzed menus exceed the standards for energy supply in the nursery. In other diets, there are deficiencies from about 65 to 309 kcal, which indicate a significant energy deficiency. The average amount of energy supplied in the diets of nurseries participating in the study is 640.24 kcal which constitutes 85% of the recommended consumption in the nursery and 65% of the daily requirement (Table 2). The level of protein con-



Figure 1. The comparison of the energy content in the feeding rations in all tested nurseries with the recommended quantities



Figure 2. The comparison of the protein content in the feeding rations in all tested nurseries with the recommended quantities



Figure 3. The comparison of the fat content in the feeding rations in all tested nurseries with the recommended quantities



Figure 4. The comparison of the carbohydrate content in the feeding rations in all tested nurseries with the recommended quantities



Figure 5. The comparison of calcium content in the feeding rations in all tested nurseries with the recommended quantities



Figure 6. The comparison of iron content in the feeding rations in all tested nurseries with the recommended quantities



Figure 7. The comparison of vitamin D content in the feeding rations in all tested nurseries with the recommended quantities



Figure 8. The comparison of sodium content in the feeding rations in all tested nurseries with the recommended quantities

sumption significantly exceeds the recommended amount, both calculated for nursery nutrition and for the daily amount. According to Table 2, nutrition in the nursery covers 388% of protein requirements and 291% of the required protein per day. This result is especially magnified by one of the daycare facilities, where the daily protein intake amount was 81.7 grams. However, even after eliminating this nursery from the calculations, this number was still exceeded. The recommendations regarding the supply of carbohydrates were exceeded and were implemented in the nurseries' nutrition at the level of 112%, while in terms of the daily demand, they covered 84% of the norm (Table 1). In the case of two nurseries, the level of carbohydrates supplied was not achieved. Also, in the case of two nurseries, the amount of carbohydrates supplied exceeded the daily norms. The menus do not cover the daily requirement for calcium - the amount of this element is too small as the average supply is 393.65 mg which accounts for 87% of the recommended consumption in nurseries and 66% of the daily requirement (Table 2). Also, the supply of iron is not ensured, it amounts to an average of 83% of the recommended consumption in a nursery and 62% of the daily requirement (Table 2). Vitamin D deficiencies were very common and amounted to only 6.5% of the recommended consumption in a nursery and 4.9% in relation to daily needs (Table 2). In the case of sodium intake, a significant excess of the norm was noted (529%).

Results presented in Figure 1 show that the lowest energy level was obtained in facility no. 3 (only 441.1 kcal) and the highest (above the norm) in facility no. 5 (845.8 kcal). What's more, in facility no. 3, almost all the analyzed ingredients (except sodium) were deficient. An excessive supply of protein was observed for all institutions (Figure 2), but the highest values were obtained for facilities 7 and 8 (81.7 g and 63.3 g, respectively). In addition, the high protein values in facility 7 also contributed to the high sodium intake (39.3 mg, Figure 8). None of the institutions managed to achieve the norm of fats, but in institutions 2 and 3, it is most notable (15.9 g and 14.6 g, respectively, Figure 3). Only facility no. 2 had a carbohydrate content close to the norm (86.8 g, Figure 4). On the other hand, facility no. 3 obtained the lowest level of this ingredient (62.0 g, Figure 4). Six of the eight analyzed menus had calcium deficiencies, and the other two exceeded the norm (Figure 5). On the other hand, in the case of iron, half of the analyzed menus did not provide the norm of intake, and the other half was characterized by an excess of this component (Figure 6). Very low values were obtained for vitamin D (Figure 7). At the same time, the menus from facilities 3 and 4 had the lowest amount of this vitamin (only  $0.34 \ \mu g$  and 0.31µg, respectively). The maximum amount of vitamin D that the children were provided with the diets in the analyzed menus was 1.5  $\mu$ g and was found in the menu of facility no. 7. All the analyzed menus were characterized by a significant excess of sodium (more than five times the norm), and the highest values were obtained for facilities no. 3, 5, and 7 (39.1 mg, 39.3 mg, and 39.3 mg, respectively, Figure 8). The analysis of menus from individual facilities shows numerous errors. However, three of the selected facilities significantly exceeded standards in relation to the tested ingredients (8 parameters). On this basis, it is possible to indicate that facilities no. 3, 7, and 8 had the largest deviations from the norms recorded. At the same time, for facility no. 3, 5 of the 8 analyzed parameters record deviations (compared to other facilities) from the norms.

# Discussion

The issue of an inadequately balanced diet for children aged 1-3 years in nurseries was also observed by other authors. In correlation to the existing publications, it may be easily observed that despite the recommendations, prevention of vitamin D deficiencies is still at a low level [1]. The research conducted by Lukasik and others on the parents' awareness of a proper diet in cases of children aged 1-3 years pointed to the lack of vitamin D in the diet suggesting the need for supplementation under pediatrician control. The analysis of menus in selected nurseries in Łódź also showed a very low intake of this vitamin [19]. Their results also reflect too high protein consumption and insufficient iron supply, similar to our research. There was also a problem in nurseries in Łódź, because the children's diet had more calories than the recommended values. In nurseries in Białystok, there has been too high of an intake of foods rich in protein fulfilling approximately 250% of the implementation of the RDA standard [20]. In a study conducted on a group of 3-year-old children, the results showed the intake of protein and carbohydrates was exceeded by three times the safe consumption of sodium. In contrast, the average intake of calcium, iron, and phosphorus was below the recommended levels. The lowest intake was observed for vitamin D (90% of respondents) and B3 (60% of respondents) [1]. The authors of Weker et al. made similar observations, indicating insufficient consumption of energy and ingredients such as fat, calcium, iodine, vitamin D, and vitamin E and an excess of protein, sucrose, and sodium in the diet of children aged 13-36 months [6]. The problems with vitamin D supply in nurseries were also observed in a study led by Trafalska. The same study yielded an over-supply of protein and sucrose and an under-supply of vitamin E and iron [21]. In a study

conducted among children under 11 years of age, an increased risk of being overweight was observed in the group fed a high-protein diet [22]. The analysis of the results acquired in a number of studies leads to the conclusion that the common problem seems to be deficiencies, in the diet of children 1–3 years, of vitamin D, calcium, and iron with an excessive intake of proteins at the same time. The significant excess protein intake must be particularly emphasized. Despite its importance during the period of intense physical growth, it should not be consumed in such large quantities. What needs to be emphasized is that the other authors' findings resulted in the same conclusion. Excess protein consumption can overburden the liver and kidneys by increasing the amount of nitrogen compounds being excreted. Additionally, a long-lasting high-protein diet may later in life contribute to the formation of metabolic disorders, e.g., aberrant methylation processes and increased synthesis of homocysteine which are precursors for the development of atherosclerotic processes [23]. On the contrary, a deficiency of vitamin D and calcium may lead to disorders of skeletal development and later to demineralization and bone deformation. Insufficient iron consumption can result in a decrease in physical conditioning, the development of anemia, disorders of concentration and memory, and even the proper functioning of the heart [5]. Moreover, one of the factors in obesity among children is improper qualitative and/or quantitative nutrition, especially overfeeding children [24]. The obtained results indicate an improper diet in terms of quality.

In connection with the cyclical problem of improper diets in children at nurseries, an act on the care of children under the age of 3 was amended, imposing the obligations to provide children with proper nutrition on the organizers of mass catering (mainly intendants, directors, and dedicated persons). Following these changes, a guide entitled "Nutrition of children in nurseries. Practical implementation of current standards and recommendations" was published [7].

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However, it turns out that the determinants of food consumption by children are complex, and so far, not an effective approach has been found to ensure the appropriate quality of a children's diet [25,26].

# Limitations

The results presented in this article refer merely to menus. The actual child nutrition must be examined in relation to the weight of food that children consume. Knowing only how much meal the child received is not equal to the information of how much food was physically consumed. The research presented in this paper is preliminary tests. Currently, the research methodology for studying the actual consumption of food rations in nurseries and kindergartens has been developed.

# **CONCLUSIONS**

The analysis of the menus included a quantitative analysis of selected elements and micronutrients and showed a number of irregularities in the nutrition of children aged 1-3 staying in care and educational institutions. The analysis revealed the weak points of nursery diets. The main problem turned out to be the supply of too much protein (388% of the norm for the nursery) and sodium (529% of the norm for the nursery). On the other hand, too few minerals, electrolytes, and vitamins (lack of vegetables and fruits). The greatest deficiency in the diet was noted for vitamin D, the coverage of the norm was only 6.5%. The reasons for the excess of protein and sodium can be found in the excessive supply of meat, bread, and rennet cheese. On the other hand, a deficiency of minerals and vitamins (especially vitamin D) may result from an insufficient supply of vegetables and fruits, milk, and fermented milk products. It is also worth enriching the diet with vegetable oils, as our analysis showed their deficiency.

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Sources of funding:         The research was funded by the authors.         Conflicts of interests:         The authors report that there were no conflicts of interest.         Cite this article as:         Bitos Ł, Matuszek D, Polańsczyk E, Grzywacz Ż, Berest E.         Analysis of menus in selected daycare centers in the Opole province: an observational study.         Med Sci Pulse 2023;17(3):28-36. DOI: 10.5604/01.3001.0053.8590.         Corresponding author:         Ewa Polańczyk         Email: e.polanczyk@po.edu.pl         Opole University of Technology,         Faculty of Production Engineering and Logistics,         Opole, Poland         Other authors/contact:         Łukasz Bilos         Email: d.matuszek@po.edu.pl         Dominika Matuszek         Email: d.matuszek@po.edu.pl         Žaneta Grzywacz         Email: z.grzywacz@po.edu.pl         Žaneta Grzywacz         Email: z.grzywacz@po.edu.pl         Ekbieta Berest       Reviewed: 5 August 2023         Ekbieta Berest       Reviewed: 5 August 2023         Email:ela.nowak92@gmail.com       Accepte: 10 August 202	Word count: 3958	• Tables: 2	• Figures: 8	• References: 26
Conflicts of interests:         The authors report that there were no conflicts of interest.         Cite this article as:         Bitos Ł, Matuszek D, Polańsczyk E, Grzywacz Ż, Berest E.         Analysis of menus in selected daycare centers in the Opole province: an observational study.         Med Sci Pulse 2023;17(3):28-36. DOI: 10.5604/01.3001.0053.8590.         Corresponding author:         Ewa Polańczyk         Bemail: e.polanczyk@po.edu.pl         Opole University of Technology,         Faculty of Production Engineering and Logistics,         Opole, Poland         Other authors/contact:         Łukasz Bitos         Email: l.bitos@po.edu.pl         Dominika Matuszek         Email: d.matuszek@po.edu.pl         Zaneta Grzywacz         Email: z.grzywacz@po.edu.pl         Żaneta Brest         Elżbieta Berest         Endile.a.nowak92@gmail.com	<b>Sources of fundi</b> The research was f	<b>•g:</b> unded by the authors.		
Cite this article as:Bilos Ł, Matuszek D, Polańsczyk E, Grzywacz Ż, Berest E.Analysis of menus in selected daycare centers in the Opole province: an observational study.Med Sci Pulse 2023;17(3):28-36. DOI: 10.5604/01.3001.0053.8590.Corresponding author:Ewa PolańczykEmail: e.polanczyk@po.edu.plOpole University of Technology,Faculty of Production Engineering and Logistics,Opole, PolandOther authors/contact:Łukasz BilosEmail: l.bilos@po.edu.plOominika MatuszekEmail: d.matuszek@po.edu.plDominika MatuszekEmail: d.matuszek@po.edu.plŻaneta GrzywaczEizbieta BerestReceived: 17 April 2023Erailela.nowak92@gmail.com	<b>Conflicts of inter</b> The authors report	<b>rests:</b> that there were no conflicts of	of interest.	
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Original papers

# PLANNED PLACE OF BIRTH AND ITS RELATIONSHIP TO EMOTIONS AND FEAR IN POLISH WOMEN DURING THE COVID-19 PANDEMIC

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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 COVID-19 pandemic, which started in December 2019, significantly changed the lives of people worldwide. A group particularly affected by the SARS-CoV-2 virus were women who experienced pregnancy and childbirth during the pandemic, many of whom began to look for an alternative to the hospital as a safe place for delivery.

**Aim of the study:** To examine how the COVID-19 pandemic affected the choice of place of delivery and whether fear and emotions were determinants of this choice.

**Material and methods:** This study was conducted on a group of 123 postpartum women who completed an online survey during the COVID-19 pandemic in 2020–2021. The research tools used were a custom-designed questionnaire that recorded the place of birth and feelings related to the thought of giving birth, and the Generalized Anxiety Questionnaire (GAD-7).

**Results:** Among women who experienced a hospital birth during the pandemic, many of them would now choose to give birth at home, while women who gave birth at home tended not to want to change their decision. Overall, women who gave birth at home and women who gave birth in a hospital did not differ in their levels of perceived generalized anxiety (n=123, p=0.439). However, their feelings did differ when it came to a fear of giving birth without the support of a husband. Fear of childbirth without a husband's support was correlated with generalized anxiety only in women who gave birth at home (rho=0.674, p=0.016).

**Conclusions:** Generalized anxiety affected women who gave birth at home and in the hospital. This anxiety was associated with a fear of giving birth without the support of a husband/partner. Women who would not have decided to give birth at home before the pandemic tended to choose home as a place of delivery during the pandemic.

KEYWORDS: parturition, home childbirth, emotional regulation, COVID-19, GAD-7



#### BACKGROUND

The COVID-19 pandemic, which started in December 2019, significantly changed the lives of individuals worldwide. In Poland, the first cases of people infected with the virus were detected on March 4, 2020 [1]. Following this initial detection, several restrictions were introduced in the country to prevent the spread of the virus. Information chaos and images in the traditional and social media from other countries created an atmosphere of uncertainty and fear.

One group particularly affected by the SARS-CoV-2 virus was women who experienced pregnancy and childbirth during the pandemic. During pregnancy, women undergo many changes, including physical, hormonal, and psychological (e.g., fear of the future, fear of childbirth, and fear for the health of the child). This also happens in normal, non-pandemic conditions [2]. The pandemic, especially at the beginning when the world knew very little about the SARS-CoV-2 virus, was especially difficult for pregnant women. Studies have indicated that the level of anxiety in pregnant women was higher than in the general population before COVID-19 [3].

The changes that took place in the Polish health system that particularly affected pregnant women included a transition to a remote system of medical consultations, the inability to participate in a partner's ultrasound examination, the suspension of childbirth classes, and a restriction on family deliveries. Decisions on family deliveries were made by the hospital manager, taking into account an individual assessment of current hospital conditions [4].

Women began to look for a place to give birth that would meet their need for safety, taking into consideration giving birth with a partner, without a mask, and without fear of infecting themselves or the child with the SARS-CoV-2 virus. An alternative location that would meet the criteria for a safe childbirth outside of the hospital included their own homes. However, due to a lack of funding from the National Health Fund, a shortage of medical personnel ready to visit homes outside of large cities, and the detailed qualifications dictated by the Standards of Perinatal Care, the options for choosing the place of delivery were limited [5].

## **AIM OF THE STUDY**

This study surveyed Polish women to examine how the pandemic influenced the choice of place of delivery, and how fear and emotions were determinants of the place of birth.

#### **MATERIAL AND METHODS**

## **Study design**

This study was conducted using a survey among postpartum women during the COVID-19 pandemic. The study was carried out between the end of 2020 and early 2021. All respondents were informed about the aims and purpose of the study. This study was approved by the Bioethics Committee of Medical University of Warsaw (No. AKBE/40/2021). The survey was made available on the Internet on various forums and parenting groups. Participation in the study was voluntary. A total of 131 questionnaires were received, of which 8 were rejected due to incomplete answers.

## **Participants**

Analyses were conducted on a group of 123 women who completed the online survey. The inclusion criterion for the study was vaginal delivery in Poland during the first or second wave of the pandemic. The exclusion criteria were an incomplete online form, cesarean section delivery, preterm delivery, birth before the declaration of a pandemic in Poland, and delivery outside of the study period.

The required sample size was calculated based on the population of women of reproductive age in Poland (n=9,527,000) and the number of births in hospitals (n=355,336) and homes (n=1,265) in 2020 (GUS) [6]. Assuming a statistical significance level of 0.05 and a test power of 0.80, the required test group size was 12 individuals and the required control group size was 100. In the current study, the study group consists of 12 people, and the control group of 111.

## Data sources/measurement

The research tools used were a custom questionnaire that recorded the place of birth and feelings related to the thought of giving birth, and the Generalized Anxiety Questionnaire (GAD-7).

The Generalized Anxiety Questionnaire (GAD-7) in the Polish language version was used to assess the level of anxiety and to assess the risk of a generalized anxiety disorder (GAD). The questionnaire consists of 7 questions answered on a four-point Likert scale. The questions contained in the survey assess the feelings of nervousness, tension, fear, and the ability to relax and control emotions. Each question can be scored from 0 to 3 points. The number of points indicates the frequency of occurrence of a given phenomenon (i.e., 0 points indicates that the phenomenon does not oc-

cur, 1 point indicates that the phenomenon occurs for several days, 2 points indicate more than half of the days, and 3 points indicates every day in the last 14 days). The interpretation of the results depends on the number of points obtained and allows one to assess the degree of anxiety faced by an individual. A score of 5 indicates mild anxiety, 10 indicates moderate anxiety, and 15 indicates severe anxiety. Obtaining a score of 10 points or higher indicates a high probability of generalized anxiety disorder [7].

Questions for the custom questionnaire were created by obstetrics students at the Medical University of Warsaw. For this questionnaire, the women were asked if they would choose to give birth at home if they had given birth before the pandemic, and whether, after their own experience of childbirth (in the hospital or at home), they would choose home as a place of birth. Other questions examined women's feelings about fear of pain, complications, infection, lack of a husband's support, positive attitudes to childbirth, and joy about the upcoming childbirth using a 5-point Likert scale (from 1-strongly disagree to 5-strongly agree).

# **Statistical methods**

The normality distributions of the data were checked using the Shapiro–Wilk test. As the data were not normally distributed, the differences between the groups were tested using the Mann–Whitney U test. Correlations between the data were assessed using Spearman's rank correlations. Qualitative variables were compared using the chi-squared test with a continuity correction. The reliability (Cronbach's alpha) of the GAD-7 was 0.69. Statistical significance was assumed at p < 0.05. Statistical analyses were carried out using Statistica v 13.3.

# RESULTS

## Characteristics of the study group

Most of the respondents were under 27 years of age (n=33, 57%), had a higher education (n=72, 58.54%), and gave birth in a hospital (n=111, 90.24%). The full characteristics of the group are presented in Table 1

Demographics	Number	%	Average GAD-7 (± SD)	Median GAD-7 (min-max)						
Age										
18-26 years	33	56.91	5.85 (± 4.92)	5.0 (0-21)						
27–35 years	70	26.83	7.64 (± 4.95)	7.0 (0–18)						
Over 36 years	20	16.26	7.95 (± 4.95)	7.5 (0–21)						
Education										
Primary/professional	7	5.69	6.57 (± 3.78)	6.0 (1–13)						
Medium	44	35.77	7.25 (± 5.09)	7.0 (0–21)						
Higher	72	58.54	7.25 (± 5.05)	7.0 (0–21)						
	Dom	icile								
Village	26	21.14	6.73 (± 5.62)	5.50 (0–21)						
City up to 50,000 residents	21	17.07	6.14 (± 6.30)	5.00 (0-17)						
City of 50,000 to 150,000 residents	36	11.38	5.07 (± 5.09)	6.00 (0-12)						
City of 150,000 to 500,000 residents	14	29.27	7.25 (± 5.51)	7.00 (0–15)						
City over 500,000 residents	26	21.14	9.65 (± 5.55)	8.00 (0-21)						
	Income	e level								
No liquid income	5	4.07	8.80 (± 5.59)	11.00 (1–14)						
Below pln 2,500	9	7.32	7.78 (± 7.87)	4.00 (1-21)						
Pln 2,501–3,500	13	10.57	5.23 (± 5.37)	5.00 (0-18)						
Pln 3,501-4,500	41	33.33	7.41 (± 5.01)	7.00 (0–21)						
Over pln 4,501	55	44.72	7.29 (± 4.25)	7.00 (0–19)						
	High-risk p	pregnancy								
Yes	103	83.74	9.20 (± 5.45)	9.00 (0-21)						
No	20	16.26	6.83 (± 4.80)	7.00 (0-21)						
	Place of	f birth								
Hospital	111	90.24	7.37 (± 5.03)	7.00 (0-21)						
House	12	9.76	5.75 (± 4.27)	6.50 (0-12)						

Table 1. Group characteristics (n=123)

## Main results

Figure 1 shows the pattern of decisions made by the women. The survey showed that 9.76% (n=12) of the women gave birth at home, while 90.24%(n=111) of the women gave birth in a hospital. Only 8.1% (n=9) of women from the group giving birth in a hospital declared that before the pandemic, they would have decided to give birth at home, and 20.72% (n=23) did not know if they would. After experiencing childbirth in a hospital during the pandemic, 17 of these women (15.3%) would decide to give birth at home, and 20 women (18%) did not know whether they would decide to do this. All women who declared a desire to give birth at home before the pandemic (n=5, 41.67%) did not want to change this decision after experiencing a home birth.



Figure 1. Women's decisions about where to give birth

The average level of anxiety as measured by the GAD-7 questionnaire for the whole group was  $7.21\pm4.97$  and the median was 7.00 (0-21). The anxiety of women experiencing a high-risk pregnancy was not statistically different from women experiencing a normal pregnancy (n=123, p=0.064). The results regarding the levels of anxiety among the respondents separated by group are presented in Table 2.

To examine the relationships between the demographic data and anxiety, correlations between the demographic data and the level of anxiety were calculated using Spearman's rank correlations. These correlations separated by group are presented in Table 3.

Women who gave birth at home and women who gave birth in a hospital did not differ in the overall scores of perceived generalized anxiety (n=123,

Table 2. The levels of anxiety among the female respondents by group (n=123)

Level of anxiety	N (%)	Hospital birth (n=111)	Home birth (n=12)
None (0–4)	38 (30.89%)	33 (29.73%)	5 (41.67%)
Mild anxiety (5–9)	49 (39.84%)	45 (40.54%)	4 (33.33%)
Moderate anxi- ety (10–14)	27 (21.95%)	24 (21.62%)	3 (25.00%)
Severe anxiety (≥15)	9 (7.32%)	9 (7.32%)	0

p=0.439). The feelings of women who gave birth at home and those who gave birth in a hospital differed only in terms of the fear of giving birth without the support of the husband. Women who gave birth at

home compared to women who gave birth in a hospital were statistically significantly less afraid of childbirth without the support of their husbands than women who gave birth in a hospital (z=2.14, p=0.026). Fear of childbirth without the husband's support was correlated with generalized anxiety only in women who gave birth at home (rho=0.674, p=0.016).

Table 3. Correlations between the demographic data and the anxiety scores by group

	Hospital bi (n=111)	irth )	Home birth (n=12)		
Demo- graphics	Spearman Correlation Coefficient P (r)		Spearman Correlation Coefficient (r)	Р	
Age (n=123)	0.199	0.037*	0.072	0.823	
Education (n=123)	0.030	0.756	-0.099	0.760	
Place of residence (n=123)	0.266	0.005*	-0.030	0.927	
Net income (per family) (n=118)	0.096	0.328	-0.365	0.244	

\* p<0.05.

Correlations between the anxiety scores and women's feelings about childbirth separated by group are presented in Table 4. Table 4. Correlations between the anxiety scores and women's feelings about childbirth by group (n=123)

	Hospital (n=11	birth 1)	Home birth (n=12)		
Feelings	Spearman Correla- tion Coef- ficient (r)		Spearman Correla- tion Coef- ficient (r)	р	
Positive attitude towards childbirth resulting from good preparation	-0.181	0.058	-0.094	0.771	
Fear of labor pain	-0.026	0.786	0.417	0.177	
Fear of compli- cations during childbirth	-0.100	0.297	0.183	0.570	
Fear of giving birth without the support of her husband	0.057	0.551	0.674	0.016*	
Fear of SARS-CoV-2 infection in hospital	0.192	0.043*	0.407	0.189	
Positive feelings resulting from support from loved ones	-0.190	0.046*	0.052	0.874	
Joy at the thought of the upcoming birth	-0.221	0.020*	-0.195	0.544	

\* p < 0.05

Table 5. Differences between emotions in groups of women giving birth at home or in the hospital (n=123) \*\*

Emotions	Whole group N (%)	Hospital birth (n=111)	Home birth (n=12)	р
Fear	50 (40.65%)	47 (42.34%)	3 (25.00%)	0.245
Loneliness	41 (33.33%)	41 (36.94%)	0	0.010*
Sadness	43 (34.96%)	40 (36.04%)	3 (25.00%)	0.446
Pain	6 (4.88%)	6 (5.41%)	0	_
Lack of a sense of agency	34 (27.64%)	33 (29.73%)	1 (8.33%)	0.115
Fear of the future	72 (58.54%)	69 (62.16%)	3 (25.00%)	0.013*
A sense of limitation	83 (67.48%)	76 (68.47%)	7 (58.33%)	0.476
Јоу	7 (5.69%)	3 (2.70%)	4 (33.33%)	<0.001*
Luck	2 (1.63%)	2 (1.80%)	0	_
Composure	9 (7.32%)	8 (7.21%)	1 (8.33%)	0.887
Positive thinking	21 (17.07%)	15 (13.51%)	6 (50.00%)	0.001*
Faith it will get better	46 (37.40%)	38 (34.23%)	8 (66.67%)	0.027*
Ready for action	28 (22.76%)	22 (19.82%)	6 (50.00%)	0.018*

\* p < 0.05, \*\* possibility to select more than one option.

The main emotions that women experienced since the announcement of the pandemic were a sense of limitation (n=83, 67.48%), fear of the future (n=72, 58.54%), and fear (n=50, 40.65%). Differences between emotions across the groups of women giving birth at home or in the hospital are presented in Table 5.

# DISCUSSION

The current results show the general situation of home births in Poland, the decision-making process regarding the place of birth, and whether the pandemic situation and a women's own experience of childbirth changed their approach to home births. The study indicates that some women who would not have decided to give birth at home before the COVID-19 pandemic would now choose to give birth outside of the hospital.

# **Home births**

According to the data from the Central Statistical Office, home births represented 0.35% of all births in 2020. The low rate of home births may be due to several factors that limit the possibility of giving birth at home. For a home birth to be safe, a woman should undergo a detailed examination for out-of-hospital delivery in accordance with the Standards of Perinatal Care. A pregnancy that is complicated and requires special care disgualifies a woman from home birth. Another element that affects the choice of place of delivery is a lack of financing from the National Health Fund for home births. An analysis of commercial online data shows that the cost of home birth in Poland varies between PLN 2,000-4,000, depending on the location and the midwife's hourly rate. Lack of funding is a discriminatory factor for many families who cannot afford a commercial service. Another problem limiting the number of home births is a dearth of midwives ready to deliver at home. Currently, on the website of the Well Born Association, only 20 midwives are ready to support a woman during a home birth in Poland, of which 6 work in the Mazowieckie Voivodeship, mainly in Warsaw [8].

According to Baranowska et al. [9], the number of home births doubled in 2020, during the first and second waves of the pandemic. At this time, women were aware that the pandemic contributed to a tightening of safety rules at hospitals. While hospitals tried to eliminate the risk of contracting the SARS-CoV-2 virus, the quality of perinatal care, which was previously guaranteed by the Standards of Perinatal Care, decreased [10].

A similar situation also occurred in other countries. According to a study conducted in the USA, women who gave birth in their own homes or in a hospital birthing center were more satisfied with childbirth [11]. Researchers have also shown that in Russia, as many as 70% of women gave birth without the support of partners, and their rights to make informed decisions and deliver in accordance with a pre-prepared birth plan were respected only during home birth [12].

# The SARS-CoV-2 virus and childbirth

The COVID-19 pandemic has particularly affected pregnant women. The first and second waves of the pandemic, in particular, brought many changes that decreased the joy of experiencing pregnancy and childbirth. The logistics of perinatal care have also changed. According to a NIK (Najwyższa Izba Kontroli – Supreme Audit Office ) report, some obstetrics and gynecology wards were changed into infectious diseases wards, thus blocking the possibility of giving birth in a facility chosen by patients [13]. This mobilized women to reflect on the place of childbirth. The current study examined how the COVID-19 pandemic contributed to changes in the perception of the home as a potential place of birth in Polish women.

The results show that the pandemic increased the interest in home births. In the current sample, 12 women (9.75%) gave birth at home, and 111 (90.25%) women gave birth in hospital. As discussed above, the proportion of hospital births may result from many factors, including a lack of reimbursement from the National Health Fund, a lack of qualifications for home births, and low availability of midwives who perform home births. In addition, the inability to use pharmacological anesthesia could have a demotivating influence on the choice to have a home birth [14].

A different view on the high percentage of deliveries in hospitals is held by Preis et al. [15], according to whom the choice of the place of delivery results from the perception of the risk of infection with the SARS-CoV-2 virus, but also from psychological factors, such as preparation for childbirth or fear of childbirth. According to these researchers, regardless of the COV-ID-19 pandemic, home birth is chosen by women who believe that childbirth is a natural physiological process for which no special preparation is required and that the best place to give birth is at home.

Some studies have indicated that women were less afraid of childbirth during the COVID-19 pandemic as the transition to remote work, which resulted in more free time and a better work-life balance, allowed for greater preparation [16]. Other work has shown that some women who do not feel prepared for childbirth and are afraid of its course tend to choose the hospital as a birthplace. For this group of women, the fear of childbirth is greater than the SARS-CoV-2 virus, which is why they choose the hospital as a place for delivery [15].

The current study surveyed Polish women to verify how the pandemic influenced the choice of the place of delivery and whether the fear and emotions that accompanied women during the COVID-19 pandemic were determinants of the place of delivery. For the group of women that gave birth at a hospital during the pandemic, nearly one-sixth of them (n=17, 15.3%) would now decide to give birth at home, and nearly one-fifth (n=20, 18%) do not know if they would. The majority of women who decided to give birth at home (n=7, 58.33) declared that, before the pandemic, they wanted to give birth in a hospital but, due to the pandemic, they decided to give birth at home. Therefore, these results show an increase in the interest in home births during the COVID-19 pandemic.

The available literature also shows that a similar situation occurred in other European countries, as well as in the USA and Australia [17, 18, 19]. An increase in the number of out-of-hospital births was observed even in countries such as the Netherlands, where women, regardless of the pandemic, choose home births more often than in other countries [20]. The largest increases in interest in home births occurred during the first and second waves of the pandemic but, currently, the level of interest in home births remains higher than before the pandemic [16, 17, 21].

Many women give birth in the hospital because they are afraid of giving birth outside of the hospital. However, according to research on women who gave birth at home, the pandemic was just a justification and motivation to give birth at home. Home birth gave them the possibility of greater self-realization. These women had dreamed about it but, before the pandemic, they were too afraid to give birth outside the hospital. For some women, home birth became a viable alternative after negative experiences in the hospital, such as prolonged convalescence after childbirth, problems with breastfeeding, and postpartum depression [22].

# Anxiety and the choice of place of birth

The current results show that generalized anxiety during the COVID-19 pandemic in the women who gave birth at home and those who gave birth in a hospital did not differ from each other (n=123, p=0.439). However, for the current data, it is not possible to determine whether the anxiety experienced was due to the fear of childbirth as a medical procedure or fear of infection with the SARS-CoV-2 virus. According to the literature, a score of 10 or more on the GAD-7 is an indication for further detailed diagnostics. This means that 29% of the surveyed women who gave birth in a hospital and 25% of the women who gave birth at home had moderate generalized anxiety that required extended diagnostics (Table 2).

Previous studies have not directly assessed whether the presence of generalized anxiety contributes to the choice of the place of delivery. However, there are studies among pregnant women that confirm that the level of anxiety in this population before COVID-19 was higher than in the general population. It has also been compared to the level of fear experienced by medical personnel in hospitals admitting infected patients [23]. Other researchers have confirmed that the COVID-19 pandemic has had a moderate to severe impact on the mental health of pregnant women, leading to a 72% increase in anxiety symptoms [24].

Previous research has also pointed to the risk of COVID-19 infection [11,22,25,27], risk of transmission of the virus to the child [27], lack of information, loneliness, and obstetric interventions aimed at quick delivery as the main cause of fear of pregnancyrelated complications, such as induction of labor in the 39th week of pregnancy, perforation of the amniotic sac, or cesarean sections [11, 22]. Women are also afraid of poorer care [20] and separation from their children [11]. Factors specifically related to the newborn include fear of fetal death, neonatal complications, and disability[14].

Research conducted by Iranian scientists showed that, during the existing pandemic, pregnant women were most afraid of hospital visits, safety procedures, and their child's health. Their well-being was also lowered by information presented on social media and the fear of infection [26]. The above studies confirm the current results indicating that the SARS-CoV-2 virus contributed to increased anxiety in pregnant women.

We also examined correlations between the levels of generalized anxiety and women's feelings about childbirth. The results suggest that the feelings of women who gave birth at home and those who gave birth at a hospital differ only in terms of the fear of giving birth without the support of the husband. Fear of giving birth without the husband's support was correlated with generalized anxiety only in women who gave birth at home. In this group, women who had a higher level of generalized anxiety had a higher level of fear of giving birth without the support of their husbands. In addition, women who gave birth at home compared to women who gave birth in a hospital were statistically significantly less afraid of childbirth without the support of their husbands than women who gave birth in a hospital (z=2.14, p=0.026).

After examining the above results, it can be assumed that the increased interest in home births during the COVID-19 pandemic resulted from the possibility of giving birth with the support of the husband. While previous research has not directly examined fear resulting mainly from the absence of the husband, research conducted by Goyal et al. shows that unaccompanied childbirth and a lowered standard of care can harm women [28].

## Emotions and the choice of place of birth

Emotions are an inseparable part of life. There are likely differences in emotions between the women who gave birth at home during the pandemic and those who decided to give birth in a hospital. Undoubtedly, each of them made a decision that was aimed at making them feel comfortable and safe. They were guided by what was important to them.

While previous research does not show what emotions accompanied women during childbirth during the pandemic, the current results indicate that emotions differed between the groups of women giving birth at home and in the hospital. Table 5 shows the range of emotions that the studied women experienced. In the case of home births, the percentage of negative emotions was statistically significantly lower in terms of fear of the future (n=69, 62.16% vs. n=3, 25%, p=0.013) and loneliness (n=47, 42.34% vs. n=0, p=0.010). There were also statistically significant differences among positive feelings, including the belief that things would get better (n=38, 34.23% vs. n=8, 66.67%, p=0.027), positive thinking (n=15, 13.51% vs. n=6, 50%, p=0.001), and joy (n=3, 2.70% vs. n=4, 33.33%, p=0.001). Although women giving birth in a hospital were more likely to struggle with negative emotions during childbirth, they still did not want to give birth at home.

# Limitations of the study

This study was conducted on a group of women who gave birth during the first and second waves of the pandemic, but it was not specified whether they were women giving birth for the first time or if it was their second birth. In future research, it would be beneficial to check whether home birth is chosen by more women who have experienced childbirth or by women giving birth for the first time. It would also

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be useful to determine whether there are differences in the levels of anxiety experienced by women giving birth again compared to those who have never given birth before. The aspect of anesthesia during labor was also not included in our study. Thus, we do not know if some women decided not to give birth at home because of the lack of anesthesia. However, no statistically significant differences were found between the level of fear of labor pain in women in terms of the place of delivery. An additional limitation of the current study is the small group of women giving birth at home, which could have given an incomplete picture of their situation.

#### **CONCLUSIONS**

Home births in Poland are limited by a lack of subsidies, a lack of available midwives in various regions of the country, and restrictive qualifications. Despite these restrictions, the number of home births doubled in Poland during the COVID-19 pandemic. The current results indicate that generalized anxiety affects women who gave birth at home and in the hospital to the same extent. This anxiety correlates with the fear of giving birth without the support of a husband/partner in women who have decided to give birth at home, and this may be the reason for the increased interest in home births during the pandemic. Women who would not have decided to give birth at home before the pandemic would choose home as a place of birth during the pandemic due to the limited or even suspended family deliveries in hospitals. In addition, positive emotions more often accompanied women who gave birth at home.

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Word count: 4531	• Tables: 5	• Figures: 1	• References: 28
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# Sources of funding:

The research was funded by the authors.

## **Conflicts of interests**:

The authors report that there were no conflicts of interest.

# Cite this article as:

Damentko A, Damra O, Dąbrowska K, Kiersnowska I, Bączek G. Planned place of birth and its relationship to emotions and fear in Polish women during the COVID-19 pandemic. Med Sci Pulse 2023;17(3):37-46. DOI: 10.5604/01.3001.0053.8606.

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DOI: 10.5604/01.3001.0053.8637

# QUALITY OF LIFE AND SELF-EFFICACY AMONG PARENTS OF CHILDREN AFTER TRANSPLANTATION: A PILOT STUDY

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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:** Organ transplantation often proves to be the only way to save a young patient's life. However, it is associated with a long-term stay in the hospital and the need to change the lifestyle of not only the patients but also their entire family. This largely affects the child's family situation as well as the relationships between their relatives. Therefore, it is important to determine the factors that have the greatest impact on the quality of life (QoL) of the parents after transplantation and their self-efficacy assessment. This will facilitate providing parents in need with help and showing them support.

**Aim of the study:** This research aimed to assess the QoL and self-efficacy among parents of children after organ transplantation, as well as the correlation between QoL and self-efficacy.

**Material and methods:** The study was conducted using a shortened version of the Quality of Life Questionnaire (WHOQOL BREF), the Satisfaction with Life Scale (SWLS), and the General Self-Efficacy Scale (GSES), as well as a self-designed questionnaire. The research group consisted of 54 people, of which 49 questionnaires were subject to statistical analysis.

**Results:** The sten score for the level of satisfaction with life in the research group was 5.88. QoL in the physical and mental domains was on average (M=12.93 and M=13.04, respectively), and in the social and environmental domains (M=16.40 and M=15.09, respectively). The sten score for the level of self-efficacy assessed by the respondents was 7.09. A relationship between the level of perceived self-efficacy and QoL was observed.

**Conclusions:** This study indicates an average level of satisfaction with life, average to high results in terms of QoL, and a fairly high level of self-efficacy, which had an impact on the QoL of parents of children after transplantation.

**KEYWORDS:** organ transplantation, quality of life, self-efficacy, parents

## BACKGROUND

Organ transplants, which are often the only treatment for organ failure, have been considered almost routine for several years now. The survival statistics of patients after transplantation are currently very satisfactory, with the 5-year survival rate being 80% [1]. Transplantation is not, however, a definitive treatment, but an ongoing chronic disease process [2]. This is associated with the need to use daily immunosuppression [3,4], the fear of transplant rejection [5], and the possible occurrence of complications [6,7,8,9]. A long-term illness, a prolonged stay with the child in the hospital, and stress related to



the surgery can affect family relations, both between the patient and their parents, as well as among other family members. It is estimated that it may take up to 5 years for parents to adapt to the new situation that is their child's illness. The illness also affects the development of the child. Frequent and long-term stays in the hospital may lead to a deterioration in the child's school performance and intellectual level, reduced physical fitness, worse self-perception, uncertainty, and internal inhibitions [10]. The disease limits the child's mental and social activities.

Studies indicate a reduced quality of life for parents of children with chronic diseases [11,12,13]. It is assumed that quality of life is a multidimensional concept [14] concerning a number of important aspects of human life, including health [15]. It involves functioning in physical, mental, and social areas, which can be affected by the illness or the treatment, or both. Quality of life can be assessed either objectively or subjectively, and various factors should be taken into account in this assessment [14].

The concept of self-efficacy is defined as the level of self-esteem and respect for one's own competence in the face of life challenges [16]. It allows a person to accurately assess the situation in looking for the right ways to deal with possible life adversities [17]. People who show a higher sense of self-efficacy are more motivated to act, which translates into better results in their activities as well as self-development [16]. Such people may have relatively stable emotions despite the pressure [18]. People with low selfefficacy, in turn, more often feel helpless in difficult life situations [16]. In addition, self-efficacy allows a person to assess their own involvement and degree of perseverance in pursuing a goal [16], and to increase their concentration and self-control [19,20].

Therefore, it is important to determine the factors that have the greatest impact on the quality of life of the parents of children after transplantation and their self-efficacy assessment. These problems should not be ignored in the therapeutic process of a young patient. It will then be possible to provide parents in need with help and support.

### **AIM OF THE STUDY**

This research aimed to assess the quality of life and self-efficacy among parents of children after organ transplantation, as well as the correlation between the quality of life and self-efficacy.

## **MATERIAL AND METHODS**

# Study design and setting

This was a cross-sectional observational study, carried out at the Children's Memorial Health Institute, in the General Surgery and Organ Transplantation Clinic, at the Organ Transplantation Department, where kidney and liver transplants are performed in children.

## **Participants**

Fifty-four people were asked to participate in the study, of which 4 refused to participate after reading the questions, and one failed to complete the questionnaire in full. Ultimately, 49 parents of children after kidney and liver transplantation participated in the study. Due to the epidemic situation prevailing during the study and the related ban on visits, reaching a larger number of respondents proved difficult. Throughout the study period, only one guardian was allowed to stay with each child. In addition, carrying out this type of study directly at the Organ Transplantation Department is associated with a limited possibility of reaching respondents due to the number of transplants performed.

## **Data sources**

The consent of the Deputy Director for Nursing, the Head of the Clinic, and the Ward Nurse was obtained for the study. The research was conducted from October 2021 to April 2022. Before completing the questionnaire, the respondents were informed about the purpose of the study and asked for their consent to participate in it. They were further informed that the collected data is confidential and will be used for scientific purposes only. Participation in the study was voluntary, conscious, and anonymous. Each participant could withdraw from the study at any time without giving a reason.

#### Measurement

The survey questionnaire consisted of 4 parts:

The first part of the study was an original questionnaire containing questions about socio-demographic details such as age, gender, place of residence, level of education, marital status, professional and social status, partner support, and number of children. Questions regarding the communication of the respondents with the medical staff and the psychological help received were also included.

The second part was a shortened version of the World Health Organization Quality of Life (WHOQOL BREF) [21] in the Polish adaptation by Wołowicka & Jaracz [22]. The questionnaire was designed to assess the quality of life of both healthy and sick people. It consists of 26 questions concerning four domains of life such as physical (DOM<sub>1</sub>), mental (DOM<sub>2</sub>), social (DOM<sub>3</sub>), and environmental (DOM<sub>4</sub>). In addition, the WHOQOL-BREF contains two questions that are an-

alyzed separately. Question 1, is the individual's general perception of the quality of life, and question 2, is the individual's general perception of their own health. The scores ranged from 1 to 5 points. A maximum of 20 points could be obtained in each domain. The higher the score, the higher the quality of life. The areas assessed by respondents included everyday life activities, ability to work, self-esteem, spirituality, social support, financial resources, healthcare, transportation, etc.

The third part of the questionnaire was the Satisfaction With Life Scale (SWLS) by Diener et al. [23] in the Polish adaptation by Juczyński [24]. This is a short method that consists of 5 statements. Subjects are asked to respond to each of the given statements by selecting an answer from "strongly disagree" (1 point) to "strongly agree" (7 points). The total SWLS score ranges from 5 to 35 points, with higher scores reflecting greater satisfaction with life. Then, the scores were converted into a standardized sten scale. The interpretation of the results is as follows: 1-4 sten scores are low, 5–6 sten scores are average, and 7–10 sten scores are high [25]. The Cronbach's alpha SWLS reliability index was established in a study of 371 people and turned out to be satisfactory (0.81). For the original version, the reliability index (Cronbach's alpha) is 0.87.

The fourth part of the questionnaire concerns the sense of self-efficacy of the parents of children after transplantation. The Generalized Self-Efficacy Scale (GSES) by Schwarzer & Jerusalem [26] in the Polish adaptation by Juczyński [27] was used. It is a 10-question research tool that enables the measurement of the subjective feeling of self-efficacy when encountering various difficult situations. There were 4 answers to choose from for each question. They were scored as follows: 1 point - "Not at all true", 2 points - "Hardly true", 3 points - "Moderately true", and 4 points - "Exactly true". The numerical values were added together to give an overall score ranging from 10 to 40 points. After summing up all the points, a self-efficacy score was obtained. The higher the number of points the respondent receives, the higher the self-efficacy index. The raw scores are then converted into standardized sten norms. The interpretation of the results is as follows: 1-4 sten scores are low, 5-6 sten scores are average, and 7-10 sten scores are high. The coefficients of correlation of individual statements with the overall score were high and ranged from 0.47 to 0.63, while the average Cronbach's alpha coefficient was 0.85. The reliability of the scale assessed in a group of 85 people using the test-retest method (after 5 weeks) was 0.78 [16].

# **Ethics**

This study was approved by the Bioethics Committee at the Medical University of Warsaw, with the number AKBE /190/2021. Furthermore, the consent of the Deputy Director for Nursing, the Head of the Clinic, and the Ward Nurse were obtained. All eligible participants were informed about the objectives of the study. They were also assured of voluntary participation and confidentiality of the information.

# **Statistical methods**

The normality of the distributions was tested with the Kolmogorov-Smirnov test. The hypotheses were verified using the Mann-Whitney U test and Spearman's rho correlation coefficient. The results were considered statistically significant when the value of the calculated test probability met the condition of a p-value  $\leq$  0.05. Calculations were made using the Statistica 10.0 software by StatSoft Polska.

#### RESULTS

# Characteristics of the study group

Women constituted 81.63% of the research group and men constituted 18.6%. Most of the respondents (44.9%) were aged 30-39 and came from large cities with 31,000 to 300,000 inhabitants (38.8%). Secondary and higher education was completed by 46.9% of participants. Most (63.3%) were professionally active and 91.8% of the respondents were in a relationship. They typically had one or two children (44.9% and 42.9%, respectively). The vast majority of the respondents could count on their partner's support (91.8%), which is consistent with the number of people being in a relationship. They mainly assessed their communication with the medical staff as very good (42.6%), and 83.7% declared that they could count on the staff's support. Only 20.8% of the research subjects used the help of a psychologist (Table 1).

Participants	n	%				
Sex						
Female	40	81.63				
Male	9	18.6				
Age						
20-29 years old	7	14.2				
30-39 years old	22	44.9				
40-49 years old	19	38.9				
More than 50 years	1	2.0				
Place of residence						
Village	14	28.6				
City with up to 30,000 inhabitants	3	6.1				

Table 1. Socio-demographic characteristics of the research group

Participants	n	%					
City with 31,000 to 300,000 inhabitants	19	38.8					
City with more than 300,000 inhabitants	13	26.5					
Education							
Elementary	0	0.0					
Vocational	3	6.1					
Secondary	23	46.9					
Higher	23	46.9					
Professional statu	s						
Professional work	31	63.3					
Care/leave	18	36.7					
Marital status							
In a relationship	45	91.8					
Single	4	8.2					
Number of children							
One child	22	44.9					
Two children	22	42.9					
Three children	4	8.2					
Four/five children	1	2.0					
Partner support							
Yes	41	84.6					
No	8	15.4					
Communication with med	ical staff						
Excellent	4	8.5					
Very good	21	42.6					
Good	14	27.7					
Rather good	10	21.4					
Poor	0	0.0					
Medical staff suppo	rt						
Full support	41	83.7					
Partial support	8	16.3					
Using the help of a psych	ologist						
Yes	10	20.8					
No	39	79.2					

### **MAIN RESULTS**

The sten score for the level of satisfaction with life measured on the SWLS scale was 5.88, which indicates an average level of satisfaction with life. In the case of the measurement according to the WHOQL BREF, a different level of quality of life was observed, depending on the domain. In the physical and mental domains, the score describing the quality of life is slightly above the average maximum value (M=12.93, SD=1.65 and M=13.04, SD=1.52, respectively), whereas for the social and environmental domains, the scores were close to the maximum value (M=16.40, SD=2.26 and M=15.09, SD=2.11, respectively). According to the GSES scale, the participants obtained a sten score of 7.09, which indicates high values in terms of self-efficacy (Table 2).

A statistically significant difference was observed between the size of the place of residence (rho=-0.3, p=0.04) and education (rho=-0.33, p=0.021) versus the quality of life at the social level (DOM<sub>2</sub>), indicating a lower quality of life among people from larger cities and with higher education. The number of children turned out to be significantly related to the SWLS scale, respondents with more children had a higher satisfaction with life (rho=0.397, p=0.007). Higher results in terms of satisfaction with life (SWLS) and self-efficacy (GSES) were obtained among professionally active people (Z=111.5, p=0.047). A relationship was also observed between the support of medical staff and the quality of life in the mental domain - DOM<sub>2</sub> (Z=72.5, p=0.013, Table 3).

A statistically significant positive relationship was found between self-efficacy (GSES) versus satisfaction with life (SWLS) and three out of the four domains of quality of life (WHOQOL BREF). The higher the self-efficacy among the respondents, the higher

Table 2. Descriptive statistics according to the scales: SWLS; WHOQOL BREF (DOM, DOM, DOM, DOM,); GSES

Parameter	М	SD	Me	Мо	Min.	Max.				
SWLS										
SWLS	21.76	5.80	21.00	20.00	8.00	34.00				
SWLS <sub>sten</sub>	5.88	2.01	6.00	5.00	1.00	10.00				
	WHOQOL BREF									
DOM <sub>1</sub>	12.93	1.65	13.14	12.00	8.00	16.00				
DOM <sub>2</sub>	13.04	1.52	12.80	12.00	10.40	18.40				
DOM <sub>3</sub>	16.40	2.26	16.00	17.33	9.33	20.00				
DOM <sub>4</sub>	15.09	2.11	15.00	14.50	10.00	19.50				
GSES										
GSES	31.43	4.15	31.00	30.00	22.00	40.00				
GSES <sub>sten</sub>	7.09	1.57	7.00	7.00	4.00	10.00				

M - mean; SD - standard deviation; Me - Median; Mo - mode; Min. - minimum; Max. - maximum.

_			WHOQOL BREF				
Parameter		SWLS	DOM <sub>1</sub>	DOM <sub>2</sub>	DOM <sub>3</sub>	DOM <sub>4</sub>	GSES
Age	Spearman's rho	-0.131	0.126	-0.072	-0.146	0.029	0.112
	р	0.390	0.388	0.621	0.318	0.846	0.459
Place of residence	Spearman's rho	-0.161	0.073	-0.128	-0.303	-0.049	-0.055
	р	0.303	0.629	0.396	0.040	0.745	0.721
Education	Spearman's rho	-0.217	0.168	0.002	-0.330	-0.075	-0.086
	р	0.152	0.249	0.992	0.021	0.610	0.569
Number of children	Spearman's rho	0.397	0.117	-0.092	0.153	0.244	0.016
	р	0.007	0.423	0.530	0.294	0.091	0.917
Sex	Z	100.5	132.0	106.0	173.0	162.0	107.5
	р	0.308	0.211	0.050	0.854	0.641	0.051
Professional status	Z	111.5	156.5	188.0	158.0	158.0	111.5
	р	0.047	0.292	0.845	0.307	0.315	0.047
Partner support	Z	72.5	69.5	83.5	98.5	75.0	72.5
	р	0.818	0.239	0.492	0.886	0.330	0.820
Medical staff support	Z	123.0	92.5	72.5	116.5	128.5	93.5
	р	0.522	0.059	0.013	0.220	0.382	0.061
Using the help of a psychologist	Z	122.5	164.0	152.5	188.0	175.5	145.0
	р	0.182	0.327	0.223	0.698	0.491	0.627

Table 3. SWLS	, WHOQOL	BREF,	GSES	scores	vs socio–der	nographic	variables
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Spearman's rho – Spearman correlation; Z – Mann–Whitney U test; p – statistical significance.

the intensity of life satisfaction ( $\rho$ =0.48, p=0.001), quality of life at the somatic ( $\rho$ =0.53, p<0.001), so-

cial ( $\rho$ =0.48, p=0.001), and environmental ( $\rho$ =0.45, p=0.001) levels (Table 4).

Table 4. Correlation between self-efficacy versus satisfaction with life and quality of life

Parameter		CINIL C	WHOQOL BREF			
		SWL5	DOM <sub>1</sub>	DOM <sub>2</sub>	DOM <sub>3</sub>	DOM <sub>4</sub>
GSES	Spearman's rho	0.476	0.529	0.116	0.479	0.454
	р	0.001	<0.001	0.437	0.001	0.001

Spearman's rho – Spearman correlation; p – statistical significance.

# DISCUSSION

# **Key results**

In this study, the quality of life and self-efficacy among parents of children after organ transplantation, as well as the correlation between the quality of life and self-efficacy, were assessed. In the entire research group, the average sten score of satisfaction with life according to the SWLS questionnaire was 5.88. Slightly higher results were obtained according to individual domains of the WHOQOL BREF questionnaire, at the borderline between average and high results. With the GSES scale, the sten score was 7.09, indicating a fairly high sense of self-efficacy. In addition, a statistically significant positive correlation was found between the quality of life and self-efficacy.

# Generalizability

There are not many studies evaluating the quality of life of parents of children after transplantation in the literature. To the best of the authors' knowledge, this topic has not yet appeared in the Polish-language literature. The topics discussed so far concerned the quality of life of parents or carers of children with other diseases or the well-being of the patients themselves [28,29,30]. However, parents of transplanted children struggle with a number of issues related to both the disease and the care of the child and sometimes have to give up their professional work for this reason. Meanwhile, the well-being of parents can be a key factor in improving the well-being of the child [11].

The fact that the results obtained in our study in terms of the quality of life of parents of children after transplantation were rather satisfactory is not quite consistent with the results obtained by Kikuchi et al., who indicated low values of quality of life in parents and family functioning after organ transplantation in their children. The authors also emphasized the need to support parents and family both before and after transplantation, as well as in the long term [31]. In another study, conducted by Manificat et al., mothers had a reduced quality of life resulting from the child's illness and the need for psychological support [11]. Duvant et al., in turn, noted higher quality of life indicators among parents of children after transplantation compared to children suffering from other chronic diseases [2]. Denny et al. found that impaired family functioning is directly related to a decrease in the quality of life [32].

The discovery in our study was an above-average result in terms of self-efficacy demonstrated by the subjects. In our opinion, high self-efficacy enhances the perceived quality of life. Similar results were obtained by Adamus et al., who studied this indicator among mothers of children with cerebral palsy [33]. Studies by Sałacińska also indicated a higher sense of self-efficacy among parents of chronically ill children [34]. Dąbrowska claims that a high level of selfefficacy is related to the determination of mothers to pursue the goal of ensuring the best possible development of their children [35]. It is noteworthy that the extraordinary circumstances in which they find themselves strongly motivate them to seek appropriate treatment for their children. This psychological mechanism is also observed in other aspects of life, parents generally show great determination to ensure the safety and health of their families. This applies equally to the financial, legal, social, and health spheres.

Another important factor determining the quality of life of the respondents was the declared good communication with and support received from the medical staff. In the WHOQOL BREF scale, respondents achieved the highest scores in the social and environmental domains (M=16.40 and M=15.09, respectively). According to Grochans et al., one of the main factors affecting the quality of life is the effectiveness of the support that those in need receive [36]. Furthermore, a study by Rachel et al. demonstrated that the lack of institutional and social support reduces the quality of life of carers [37]. With our study, a surprising result was the low impact of psychological help on perceived quality of life and self-efficacy, although psychologists are usually part of the treatment team. This may be due to the fact that only a few of the research subjects reported a significantly low quality of life and required therapy.

In our study, professionally active respondents showed a higher level of quality of life compared to those who declared being full-time carers of their child or on leave. In addition, the people who cared for their child rather than being professionally active were women, i.e., they were more exposed to stress and inconveniences resulting from staying with their child in the hospital or from participating in medical procedures. These results were confirmed by the research conducted by Repka et al., which showed that fathers declared a lower level of fatigue in everyday life and a higher level of satisfaction with life [28]. The same research confirms that working caregivers report less fatigue than those caring for a sick child. This may be due to the fact that fathers spend more time away from home, while mothers devote their time to caring for a sick child. Furthermore, job satisfaction may be an additional factor in improving the quality of life [28]. An important factor influencing the declared quality of life was also the number of children. Our research has shown that parents with only one child report a lower quality of life measured by the SWLS form than parents with more than one child. This may be due to the fact that their thoughts and actions are not focused exclusively on the sick child, but also their other, healthy children. In addition, after reaching the appropriate age, siblings often take over some of the responsibilities related to caring for a sick family member, which relieves the parents mentally and physically.

# Limitations of the study

The results of our research should be considered from the point of view of certain limitations, mainly due to the small sample size of the study and the limitation of the study to one center, but also a small number of reports evaluating the aspects we studied, which made it difficult to compare the results with those obtained by other authors. Due to the epidemic situation during the study and the related ban on visits, reaching a larger number of respondents proved difficult. Throughout the study period, only one guardian was allowed to stay with each child. In addition, carrying out this type of study directly at the Organ Transplantation Department is associated with a limited possibility of reaching respondents due to the number of transplants performed. Despite its limitations, this study highlights the importance of support and self-efficacy in terms of quality of life. Thus, it may serve as an indication for medical staff in the area of determining solutions to support parents of children after transplantation.

# **CONCLUSIONS**

The study indicates an average level of satisfaction with life, average to high results in terms of quality of life, and a fairly high level of self-efficacy, which had

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an impact on the quality of life of parents of children after transplantation. Research should be continued and extended to other centers to provide further information.

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Word count: 3092	• Tables: 5	• Figures: 0	• References: 37	
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#### **Sources of funding:**

The research was funded by the authors.

#### **Conflicts of interests**:

The authors report that there were no conflicts of interest.

#### Cite this article as:

Dziedzic B, Karnas E, Kobos E, Czyżewski Ł. Quality of life and self-efficacy among parents of children after transplantation: a pilot study. Med Sci Pulse 2023;17(3):47-54. DOI: 10.5604/01.3001.0053.8637.

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DOI: 10.5604/01.3001.0053.8710

# SPIRAL DISSECTION OF THE LEFT CORONARY ARTERY AS A RARE AND SERIOUS COMPLICATION OF CORONARY ANGIOGRAPHY: A CASE REPORT

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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:** Iatrogenic spiral dissection of the coronary artery is a rare but serious complication of coronary angiography (CA). CA is a commonly used standard imaging method that is considered safe.

**Aim of the study:** To demonstrate a rare complication of CA that significantly changed the patients' outcome.

Material and methods: A retrospective review of the procedure and patient follow-up was undertaken.

**Case report:** A 56-year-old female with type two atrial septal defects complicated by heart failure (HF), complaining of gradual HF worsening and two episodes of syncope, was admitted for preoperative assessment. Before cardiac surgery, an elective CA revealed no coronary artery stenoses. However, the procedure was complicated by spiral dissection of the left main coronary artery continuing towards the left anterior descending artery. Immediate percutaneous coronary angioplasty was performed, with a good acute angiographic and clinical result. Subsequently, the patient developed a periprocedural inferolateral myocardial infarction and cardiac arrest due to pulseless electrical activity. Cardiopulmonary resuscitation was ineffective.

**Conclusions:** The take-home message of the case presented is that even a relatively safe procedure can be complicated and that less invasive imaging modalities should be considered before CA.

**KEYWORDS:** coronary angiography, coronary artery dissection, percutaneous coronary intervention, computed tomography angiography

## BACKGROUND

Coronary angiography (CA) is the coronary artery anatomy imaging gold standard. Potential CA complications include death, stroke, major bleeding at the access site, cardiac arrest, and allergic reactions, though it is considered safe and has a complication rate of less than 0.2% [1]. One of the rare CA complications is spiral coronary artery dissection (SD) resulting from catheter manipulation or contrast media injection, most frequently following 6 French (F) catheter application [2]. In-hospital mortality rates range from 6.5% to 8.5%, with type F dissection fatalities usually occurring in females [3,4]. Non-coaxial catheter positioning followed by the contrast media jet results in an



inadvertent mechanical separation of the vessel wall layers and consequently creates a false lumen in the artery wall that reduces the true lumen diameter, which significantly limits the coronary flow, and thus results in myocardial ischemia or infarction.

SD occurs at a frequency of 0.09% [5], while right coronary artery (RCA) dissection is observed more frequently at a rate of 0.14%, and left main coronary artery dissection is very rare (0.07%) irrespective of the vascular access site [6-8]. The prevailing hypothesis suggests that the principal cause is the angle between the proximal segment of the coronary artery and the aortic sinus wall. The aortic-coronary angle is almost straight in cases involving the left coronary artery (LCA) orifice. As such, coaxial catheter insertion is simple, and vessel wall injury is less likely. Histologically, a greater number of smooth muscle cells embedded within and expressing large amounts of type I collagen have been observed, making it more resistant to acting forces [9].

There is evidence of greater SD incidence in the absence of atherosclerotic plaques among young women. The primary cause is hormonal balance disorders that affect the arterial endothelium due to the expression of estrogen and progesterone receptors [10,11]. Connective tissue disorders may also predispose to dissections.

## **AIM OF THE STUDY**

The article presents coronary artery SD as a rare and serious complication of CA that can result in patient death. The case report also aimed to draw attention to the technical achievements that permit less invasive imaging of coronary artery stenoses.

#### **MATERIAL AND METHODS**

A retrospective review of patient management and observation was undertaken based on the analysis of medical records, interviews, physical examinations, and patient observations during her hospital stay.

## **CASE REPORT**

A 56-year-old non-smoker female with type two atrial septal defect complicated by heart failure (HF), complaining of gradual HF worsening and two episodes of syncope, was admitted for preoperative assessment. Her medical and family history was irrelevant. Blood cell counts, lipids, glucose, creatinine, electrolytes, thyroid stimulating hormone (TSH), and troponin were within normal limits. Transesophageal echocardiography (TEE) confirmed a hemodynamically significant interatrial left-to-right shunt through the two adjacent defects of  $12 \times 7$  mm (0.6 cm<sup>2</sup>) and  $12 \times 5$  mm (0.5 cm<sup>2</sup>). Simultaneously, a fragment of the septum was observed consisting of two tissue bundles with an 11 mm gap between them. The elective CA revealed no significant atherosclerotic plaques in the epicardial coronary arteries (Fig. 1). During the contrast media injections via the Judkins left 3.5 5 F catheter, an SD occurred in the LCA that originated from the left main trunk (LM) and continued towards the middle segment of the left anterior descending artery (LAD).

A successful percutaneous coronary intervention (PCI) followed by implantation of three drugeluting stents was performed (Fig. 2). Intravascular ultrasonography (IVUS) confirmed the dissection and guidewire placement in the vessel true lumen (Fig. 3) and demonstrated good acute clinical and angiographic results (Fig. 4). The patient developed a periprocedural myocardial infarction confirmed by t ST-segment elevation in I and augmented vector left (AVL) leads, ST-segment depression in II, III, and AV foot (AVF) leads, together with hypokinesis of the middle segments of the lateral and inferolateral walls, as well as the basal and middle segments of the anterior wall. Serum cardiac troponin increased to 1763 ng/L (reference range: 0 - 14.1 ng/dL). On the second day after the procedure, sudden cardiac arrest occurred through the pulseless electrical activity (PEA) mechanism. The cardiopulmonary resuscitation was ineffective, and the patient was pronounced dead.

## Discussion

We present a rare case of iatrogenic coronary artery dissection during an elective CA. Spiral coronary dissection is a serious complication that significantly affects the short and long-term prognosis following diagnostic procedures. Progress in the non-invasive assessment of coronary arteries has resulted in the development of high-resolution computed tomography scanners (angio-CT) with the ability to visualize the coronary arteries. The reduction in the number of invasive angiographies translates into benefits for the patients and a decrease in the rates of possible complications, which is particularly important before high-risk cardiac surgery. Recently, Lecomte et al. demonstrated that angio-CT seems to be a safe option in patients referred for transcatheter aortic valve replacement, resulting in a 47% reduction in the invasive angiography rate [12]. So far, there are no clear guidelines on imaging modality selection prior to elective cardiac surgery.

The choice of iatrogenic coronary artery dissection treatment method depends on the dissection extent



Figure 1. Antero-posterior cranial views of the right (Panel A) and left (Panel B) coronary arteries



Figure 2. The guidewire in the true lumen (Panel A) and stent positioning in the distal (Panel B), middle (Panel C), and proximal (Panel D) segment of the left coronary artery



Figure 3. Spiral dissection passing from the left main coronary artery towards the middle segment of the left anterior descending artery (antero-posterior caudal view, Panels A-C). Intravascular ultrasound image with the probe in the true lumen (Panel D)



Figure 4. The final angiographic result in the cranial (A) and caudal (B) views

and includes conservative treatment, stent implantation, or coronary artery bypass grafting (CABG) [3]. Applying the coronary artery dissection scale proposed by the National Heart, Lung, and Blood Institute may be helpful in the decision-making process. The classification includes dissection types from A to F, where stenting is successfully performed in the types D to F [5]. PCI was performed since the dissection described in this case report was qualified as type F.

In the present case, the 5 F catheter used was associated with the complication. The smaller the catheter diameter, the faster the administration of fluid, which can lead to vessel wall injury. However, radial access, especially in females, usually requires a 5 F diameter due to the smaller radial artery, which reduces the mechanical complication rate.

Intravascular imaging is crucial in the management of coronary dissections. IVUS [13] and optical coherence tomography (OCT) [14] allow for a thorough analysis of coronary anatomy, precise stent selection and implantation, and the assessment of the final PCI result. In addition, the guidewire position

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may be quickly verified and confirmed by intravascular imaging [15].

Relatively safe procedures cannot be considered free of complications, and even an immediate coronary flow restoration in a patient with acute myocardial infarction does not reduce the mortality rate to zero.

# **Study limitations**

The study was limited by including only one patient. In the future, it is worth expanding the research with additional case studies that will allow for the comparison of various non-invasive diagnostic and therapeutic possibilities.

## **CONCLUSIONS**

Iatrogenic SD is a rare but serious complication of invasive CA. Less invasive imaging modalities should be considered prior to cardiac surgery referral.

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Word count: 1210	• Tables: 0	• Figures: 4	• References: 15
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# Sources of funding:

The research was funded by the authors.

# **Conflicts of interests:**

The authors report that there were no conflicts of interest.

## Cite this article as:

Wesołowski M, Cudzik-Dziurzyńska J, Błaszczyk A, Sadowski M. Spiral dissection of the left coronary artery as a rare and serious complication of coronary angiography: a case report. Med Sci Pulse 2023;17(3):55-60. DOI: 10.5604/01.3001.0053.8710.

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Marcin Sadowski Email: msadowski@ujk.edu.pl Received: 3 August 2023 Reviewed: 26 August 2023 Accepted: 2 September 2023 Original papers

# RESILIENCE INDEX AND MENTAL STRESS OF NURSING STAFF WORKING IN INTENSIVE CARE UNITS DURING THE SARS-COV-2 PANDEMIC

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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:** Resilience, or mental toughness, is the ability to effectively cope in challenging circumstances. High resilience levels allow for faster adaptation in extreme situations.

**Aim of the study:** An assessment of resilience, mental stress, and self-reported work environment among nursing staff in intensive care units (ICUs) during the SARS-CoV-2 pandemic.

**Material and methods:** The study involved 102 nursing staff working in ICUs. Data collection used the Resilience Coping Scale (RCS-25), Meister's psychological strain scale, and an original work environment self-assessment scale.

**Results:** The overall mean score of the respondents on the resilience scale was 74.11 points out of a possible 100, while they scored an average of 24.36 points out of 50 on the mental stress scale. Staff working in hospitals converted into infectious disease sites (p=0.000) or in infectious hospitals with a third level of referral (p=0.012) assessed their working environment significantly better in the context of the coronavirus disease 19 (COVID-19) pandemic. Medical staff who worked longer at their current workplace, those with longer seniority in the profession, and those who were older scored higher in the resilience areas. The younger the respondent, the more mentally stressed they were in general (rho=-0.200), in non-specific areas (rho=-0.217), and in monotony (rho=-0.211). Those who did not feel well equipped with personal protective equipment showed lower resilience.

**Conclusions.** Respondents were characterized by average resilience and second-level mental stress, while those with higher resilience suffered lower mental stress. We recommend organizing training to strengthen mental toughness, the identification of resilience factors, and the assessment of mental stress in the work environment in the context of the ongoing pandemic. The data obtained could be used to adjust working conditions during the next pandemic.

KEYWORDS: nurse, intensive care unit, resilience, mental stress, mental strain, COVID-19

#### BACKGROUND

Resilience, or mental resilience, is the ability to effectively deal with challenging situations and is also defined as effectively withstanding adversity and responding to changing circumstances, including stress, conflict, or threat [1]. High resilience allows for faster adaptation in extreme situations. Mealer et al. define resilience as the ability of intensive care unit (ICU) nurses to cope with their work setting



and maintain healthy and stable mental well-being despite exposure to extreme stressors [2]. Labrague et al. found that individuals with higher resilience coped better with the new challenges associated with the outbreak of the coronavirus disease 19 (COVID-19) pandemic [3]. Since these personality traits can be worked on and reinforced, organizational and psychological support and learning strategies promoting resilience are critical. Persistence and determination, a sense of humor and openness to new experiences, coping-supporting personal competencies, and accepting negative emotions are resilience factors that determine life satisfaction. The prevalence of low immunity among healthcare professionals during the pandemic was estimated to be 23% (26% from January to March 2020), which was significantly lower compared to the general population [4,5]. Frontline COVID-19 healthcare workers had a higher prevalence of low immunity (93.6%) compared to other healthcare workers (6.2%) [4].

Mealer et al. showed that ICU nurses with high resilience scores were 18-50% less likely to develop post-traumatic stress disorder (PTSD) than those with low resilience scores [6]. A lower degree of psychological resilience demonstrated by nurses working in the ICU during the COVID-19 pandemic was associated with higher levels of depression and burnout [7]. Moreover, nurses with higher psychological resilience showed a lower turnover intention during the pandemic [8]. Data confirm a significant negative association between overall resilience and psychological distress among healthcare professionals during the COVID-19 pandemic [9]. Mental strain is closely related to working conditions, routine, effort, and psychological fatigue and is a subjective response of an employee to mental overload (rushing, problems, conflicts, and responsibility), monotony (wearisome work and a low level of satisfaction), and non-specific strain (work repletion, reduced productivity at work over time, nervousness, and fatigue) [10]. Excessive tasks and duties accompanied by time deficits lead to overload and chronic fatigue, which negatively affects efficiency and correctness when performing duties. Furthermore, work is associated with great responsibility, and long-term stress is mentally exhausting, which leads to medical errors [11].

A recent systematic review found that 54% of nurses experience a high mental workload, which is higher among ICU nurses than among those in other hospital wards. The analysis demonstrated that the mental workload of frontline nurses increased significantly during the COVID-19 pandemic [12]. Moreover, nurses caring for COVID-19 patients experienced a higher workload, lower quality of work life, significantly higher average working hours, and more overtime compared to nurses caring for patients in non-COVID-19 wards [13]. Overall mental workload scores indicate that ICU nurses have a heavy work-load [14].

Poor working conditions, responsibility for human life, stress, the mental strain associated with the death of patients, shift work, time pressures, and urgent decision-making, on which human life depends, are the sources of psychological strain among nurses. Excessive duties accelerate fatigue, physical exhaustion, and occupational burnout, leading to a deterioration in performance [15]. Intensification of negative factors such as stress, fatigue, and time pressure causes physical overload, which may lead to health deterioration or occupational disease. Shen et al. showed that the psychological stress among ICU nurses working during the COVID-19 pandemic was associated with the following problems: significant work overload and fatigue, anxiety about possible infection, unknown work environment and work processes, lack of experience in infectious diseases, depression related to treatment failures, and concerns about one's own family [16].

Chronic mental stress occurs when the work is highly burdensome, monotonous, and performed under challenging conditions, often leading to burnout. As such, understanding the risk factors and alleviating them to prevent the consequences of mental strain is worthwhile [17]. The study can help to understand the effective predictors of resilience and mental strain. An analysis of the working environment may point to the needs of employees that could improve working comfort, efficiency, and well-being.

#### **AIM OF THE STUDY**

To assess resilience, mental strain, and self-reported work environment among nursing staff in ICUs during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic.

## **MATERIAL AND METHODS**

#### **Study design**

Cross-sectional study.

#### **Participants**

A total of 102 nurses participated in the study. Current professional activity and ICU employment of more than three months were the inclusion criteria.

#### Setting

This online cross-sectional survey was conducted between March and May 2020 during the COVID-

19 pandemic in Poland. The survey provided information about the purpose of the study, as well as the voluntary participation and anonymity of the participants. Due to the challenging epidemiological situation caused by a considerable increase in coronavirus-infected patients in ICUs and the inability to distribute pen-and-pencil surveys (due to the lockdown), the questionnaire was made available on Facebook in two private groups for nurses working in anesthesia and ICUs, with a total of 9,027 members. As the questionnaire was completed and returned anonymously, it was impossible to link the responses to specific individuals or groups within which they were completed. The epidemiological situation and workload of ICU personnel during this period of the pandemic may have been a significant factor limiting interest in survey participation.

According to current legal acts, questionnaires and non-invasive research do not require the approval of the university bioethics committee.

# Measurement

The Polish version of the resilience assessment scale (SPP-25) developed by Ogińska-Bulik and Juczyński was used to measure mental resilience [18]. SPP-25 contains 25 statements on various personality traits that make up resilience, which also equates to mental toughness. The assessment is scored on a five-point Likert scale, with responses to the statements interpreted as 0 – definitely not, 1 – rather not, 2 – hard to say, 3 - rather yes, or 4 - definitely yes. The tool measures overall resilience level, considered a personality trait, and its five factors: 1) perseverance and determination, 2) openness to new experiences and sense of humor, 3) competencies and tolerance of negative emotions, 4) tolerance of failures and treating life as a challenge, and 5) optimism and the ability to mobilize in difficult situations. The overall SPP-25 result is the sum of five factors, including five items. The higher the score, the higher the level of resilience. The Cronbach's alpha for the questionnaire was  $\alpha$ =0.89.

The Polish version of Meister's questionnaire, developed by Dębska, was used to assess mental stress [10]. The questionnaire measures mental strain associated with work based on the subjective assessment by an employee. It consists of ten items divided into three subscales in the following categories: mental overload (rushing, high responsibility, problems, and conflicts), monotony overload (monotony, weariness with work, and low level of satisfaction), and nonspecific stress (nervousness, work overload, fatigue, and lower productivity at work). The degree of mental stress was assessed using the tool key. A scale consisting of ten questions corresponding to the following components of the statements was used to assess the level of mental stress. Each question is assigned to a specific element: overload, monotony, and non-specific factors.

The originally developed scale for work environment self-assessment in the context of the SRAS-CoV-2 pandemic consisted of seven questions assessed on a Likert-type scale with the following interpretation: 1 - definitely not, 2 - rather not, 3 - hard to say, 4 - rather yes, 5 - definitely yes. Higher values corresponded to a better work environment rating.

# **Statistical analysis**

The Mann-Whitney U rank test was used to verify significant differences between two independent groups, and the Kruskal Wallis (H) test was employed for comparisons between more than two groups. Spearman's rho correlation index was used to investigate correlations between the variables. Statistical inference was performed at a standard significance level of p < 0.05.

# RESULTS

# **Study group characteristics**

A total of 102 nurses, with women accounting for the majority of respondents (95.1%), participated in the study. The mean age of the respondents was 34±10.4 years, and the mean nursing seniority was 11±11.24 years, while the mean length of employment in the current workplace was 8±8.54 years. Most of the respondents were employed in tertiary hospitals (59.8%), in non-infectious wards (55.9%), and full-time (94.2%). On average, four to five nurses (30.4%) worked on wards during their last three shifts. The mean number of nurses working in a ward during the last three shifts was 8±6.59. A total of 35.3% and 32.4% of respondents had very frequent contact with patients suspected of being infected with SARS-CoV-2 or COVID-19 patients, respectively. Among those who had contact with patients suspected of being infected with coronavirus (n=84), the respondents declared providing care for an average of 4±3.74 patients during the last three shifts. As for respondents who had contact with COVID-19 patients (n=61), they declared an average of 5±5.2 patients with COVID-19 during their last three shifts.

## **Main results**

# Resilience

The mean overall score for the Resilience Scale was 74.11 out of 100. Among the five dimensions assessed, the lowest mean score of 13.43 was obtained

for optimism and the ability to mobilize in difficult situations (Table 1).

	Total					
Factors	М	SD	Min	Max		
Persistence and determina- tion in action	15.15	2.47	8	20		
Openness towards new experiences and a sense of humor	15.89	2.24	11	20		
Personal skills to cope and tolerance to negative emo- tions	14.60	2.52	7	20		
Tolerance to failure and view life as a challenge	15.04	2.12	8	20		
An optimistic attitude towards life and the ability to self-mobilization in difficult situations	13.43	2.89	6	20		
Resiliency Assessment Scale – total	74.11	9.94	50	97		

Table 1. Resiliency – descriptive statistics

Explanations: M – Mean difference; SD – Standard Deviation; Min – minimum; Max – maximum.

The analysis of resilience levels in the study group showed that nearly half of the respondents were characterized by average mental toughness (46.1%); low mental toughness was demonstrated in 21.6% of the respondents, while 32.4% demonstrated high mental toughness.

Perseverance and determination (rho=0.219), competence, and tolerance of negative emotions

(rho=0.237) increased with respondent age. There were no significant differences between the respondents based on their education, either for mental resilience in general or for its dimensions (p=0.539). Those with children aged up to 18 were more tolerant of failure and more likely to treat life as a challenge than those with no children in this age range (p=0.077). Perseverance and determination increased with increasing employment time at their current workplace (rho=0.251) and longer seniority in the profession (rho=0.245). Significant correlations were also found between competence and tolerance of negative emotions and overall seniority.

The comparison of resilience scores based on the type of hospital in which the respondents worked and the type of ward (infectious or non-infectious) showed no significant differences (p>0.05). Also, the number of nurses working in a ward was not significantly associated with mental strain. The frequency of contact with patients suspected of being infected with SARS-CoV-2 and those with COVID-19 did not differentiate the respondents in terms of resilience (p>0.05). No significant correlation was found between the number of patients suspected of being infected with SARS-CoV-2 or suffering from COVID-19 resilience level (p>0.05).

In general, higher resilience was shown by respondents who positively rated personal protective equipment (PPE) and those who could not unequivocally rate PPE than those who rated such protection negatively (p=0.068) (Table 2).

Respondents who could not unequivocally state whether the hospital they work in organized train-

Table 2. Resilience and feeling of being equipped with personal protective equipment at work

	The feeling of being equipped with PPE							
Factors	No (N=36)		Not sure (N=17)		Yes (N=49)		н	р
	м	SD	м	SD	м	SD		
Persistence and determination in action	14.31	2.72	15.24	2.44	15.73	2.14	7.471	0.024
Openness towards new experiences and a sense of humor	15.22	2.26	16.41	2.27	16.20	2.15	5.264	0.072
Personal skills to cope and tolerance to negative emotions	14.08	2.64	15.29	2.17	14.73	2.51	3.567	0.168
Tolerance to failure and view life as a challenge	14.75	1.96	15.24	2.46	15.18	2.12	1.470	0.480
An optimistic attitude towards life and the ability to self-mobilization in difficult situations	12.58	3.03	14.00	3.10	13.86	2.61	3.870	0.144
Resiliency Assessment Scale – total	70.94	10.05	76.18	10.94	75.71	9.09	5.365	0.068

Explanations: M – mean difference; SD – standard deviation; H – Kruskal-Wallis test; p – statistical significance.

ing courses on how to deal with a patient suspected of having SARS-CoV-2 infection showed significantly lower resilience in general (65.56) and for two out of five resilience factors compared to those who gave a positive or a negative answer to this question (Table 3).

	Organisation of training							
Factors	No (N=50)		Not sure (N=9)		Yes (N=43)		н	р
	м	SD	М	SD	М	SD		
Persistence and determination in action	15.04	2.24	13.78	2.99	15.56	2.56	3.988	0.136
Openness towards new experiences and a sense of humor	15.84	2.08	14.33	2.12	16.28	2.34	5.294	0.071
Personal skills to cope and tolerance to negative emotions	14.66	2.18	12.56	3.05	14.95	2.64	5.596	0.061
Tolerance to failure and view life as a challenge	15.10	2.02	13.44	1.81	15.30	2.18	6.664	0.036
An optimistic attitude towards life and the ability to self-mobilization in difficult situations	13.44	2.96	11.44	2.30	13.84	2.80	5.867	0.053
Resiliency Assessment Scale – total	74.08	9.25	65.56	8.95	75.93	10.17	7.411	0.025

Table 3. Resilience and assessment of the organization of training concerning the care of patients suspected of being infected with coronavirus

Explanations: M - mean difference; SD - standard deviation; H - Kruskal-Wallis test; p - statistical significance.

The overall level of resilience and its components did not differ significantly among the respondents depending on how they assessed the possibility of attending a hospital-arranged consultation with a psychologist if needed (p>0.05).

# Mental strain

In the study group, grade 1 mental strain was shown in 47.1%, grade 2 in 36.3%, and grade 3 in 16.7% of nurses. The respondents showed the most severe mental strain in dimensions such as time pressure (3.74) and high responsibility (3.73) (Figure 1).

Overall, the respondents had a mean score of 24.36 out of 50 on the mental strain scale (Table 4).

The analyses showed that the younger the respondents, the more mentally burdened they were in terms of work monotony (rho=-0.211), non-

Table 4. Descriptive statistics of answers to questions included in the Meister questionnaire

	Total						
Factors	М	SD	Min	Max			
Overload	9.75	2.60	4	15			
Monotony	4.93	1.52	3	9			
Nonspecific load	9.69	3.56	4	20			
Total	24.36	6.28	12	42			

Explanations: M  $\,-\,$  mean difference; SD  $\,-\,$  standard deviation; Min - minimum; Max - maximum.

specific (rho=-0.217), and general mental strain (rho=-0.200). No differences were found in the severity of mental strain based on education (p=0.757) or having children up to 18 years of age (p=0.127). Seniority in the current workplace, and in general, did not significantly differentiate the respondents (p>0.05). Those employed in hospitals with different



Figure 1. Components of Meister questionnaire statements – mean difference

reference levels did not differ in their severity of mental stress (p=0.386). Also, the type of ward did not significantly differentiate mental stress (p=0.938). Meanwhile, the severity of mental stress increased for the monotony factor with an increasing number of nurses in a given ward (p<0.05).

There were no significant differences in mental strain based on the frequency of contact with patients suspected of being infected with SARS-CoV-2 (p=0.196). Also, mental strain did not differ significantly (p=0.612) depending on the frequency of contact with COVID-19 patients. There were no significant correlations between mental strain and the number of patients suspected of being infected with SARS-CoV-2 or those with COVID-19 (p>0.05).

Mental strain did not differ among respondents based on their assessment of the sense of protection using PPE at work (p=0.238). Those who found it difficult to state whether their hospital organized training courses on how to deal with patients suspected of having SARS-CoV-2 infection showed higher overall mental strain (p=0.046). The respondents did not differ (p=0.989) in the severity of mental stress based on whether or not the hospital they worked in provided consultations with a psychologist.

# *Self-reported work environment in the context of the SARS-CoV-2 pandemic*

Among all of the questions included in this scale, the attitude to the fight against the coronavirus was rated the highest (M=3.72). A sense of good protection from using PPE at work ranked second (M=3.09). The organization of training courses by the hospital on how to deal with patients suspected of having SARS-CoV-2 infection came third (M=2.86). Meanwhile, the possibility of having a coronavirus test performed in the hospital was rated worst (M=2.69). The average score for self-reported work environment was 20.78 out of 35 (Table 5).

Table 5. Self-assessment of the working environment – descriptive statistics

Statements	М	SD	Min	Max
Do you have a positive attitude towards the fight against coronavirus?	3.72	0.98	1	5
Do you work beyond your capabilities?	2.83	1.19	1	5
Do you feel well equipped with personal protective equipment at work?	3.09	1.40	1	5
Has the hospital where you work provided training concerning the care of patients suspected of being infected with SARS-CoV-2?	2.86	1.55	1	5
If necessary, can you count on a talk with a psychologist initiated by the hospital?	2.85	1.44	1	5
Does the hospital give you the opportunity to test yourself for coronavirus?	2.69	1.42	1	5
When you are off duty, do you worry that you may already be infected? (and that you should not put your family at risk when coming back home)	2.75	1.35	1	5
Self-assessment of working environment	20.78	5.11	9	30

Explanations: M - mean difference; SD - standard deviation; Min - minimum; Max - maximum.

There were no significant correlations between the self-rating of the work environment and the age of the respondents. The respondents did not differ in their assessment of their work environment (p=0.410) based on their education level. Those who did not have children aged under 18 years assessed their work environment significantly higher than those with children under 18 years.

Nurses employed in tertiary hospitals gave significantly higher rates to their work environment in the context of the SARS-CoV-2 pandemic (p=0.012) than those working in first and second-referencelevel hospitals. Respondents working in hospitals transformed into infectious units or infectious disease hospitals rated their work environment significantly higher (p=0.000) than those employed in noninfectious hospitals. The self-assessment of the work environment did not significantly correlate with the number of nurses working in the ward. The respondents who had very frequent contact with COVID-19 patients rated their work environment significantly better than those who rarely had contact with such patients. The rating of the work environment increased with an increasing number of COVID-19 patients cared for during the last three shifts (rho=0.397).

# Mental strain and resilience, and self-rated work environment

Overall, negative correlations were found between the resilience score and mental stress (rho=-0.463). The higher the score on the resilience scale obtained by the respondents, the lower their mental strain (Table 6).

The data show that the greater the overload of respondents, the lower their level of competence

Resilience/Self-assessment	Mental stress					
of the working environment	Overload	Monotony	Nonspecific load	Total		
Persistence and determination in action	0.023	-0.393**	-0.348**	-0.270**		
Openness towards new experiences and a sense of humor	-0.180	-0.393**	-0.363**	-0.373**		
Personal skills to cope and tolerance to negative emotions	-0.230*	-0.321**	-0.434**	-0.410**		
Tolerance of failure and viewing life as a challenge	-0.195*	-0.471**	-0.471**	-0.457**		
An optimistic attitude towards life and the ability to self- mobilization in difficult situations	-0.309**	-0.345**	-0.409**	-0.439**		
Resiliency Assessment Scale -total	-0.216*	-0.439**	-0.481**	-0.463**		
Self-assessment of working environment – total	-0.160	-0.169	-0.353**	-0.303**		

Table 6. Correlations between the mental stress scale, the resilience scale, and the working environment self-assessment scale

\* p<0.05; \*\* p<0.01 correlations were statistically significant.

(rho=-0.230) and tolerance of negative emotions, tolerance to failure, and treating life as a challenge (rho=-0.195), as well as their ability to mobilize in challenging situations, and vice versa (rho=-0.309). A negative correlation was also found between the self-rating of the work environment and non-specific stress (rho=-0.353), as well as the overall result on the mental stress scale (rho=-0.303). All correlations were negative, except for statistically insignificant overload and persistence and determination (rho=0.023).

# DISCUSSION

Determining whether resilience can be responsible for coping with extreme stress such as the SARS-CoV-2 pandemic and the analysis of the indicators of mental stress and environmental self-rating during this pandemic seems critical for planning interventions to improve working conditions and reinforce mental resilience among nurses. The study was conducted from March to May 2020, in the initial period of the SARS-CoV-2 pandemic, when the number of new cases of coronavirus infection in Poland was low. As of March 31, 2020, 2311 cases of coronavirus infection and 33 deaths were recorded, and as of May 25, 2020, there were 21,631 infected persons and 1007 deaths [19]. No significant correlations were found between the number of patients suspected of being infected with coronavirus or suffering from COVID-19 who were cared for and the level of resilience in the study group. This could be due to the relatively low number of COVID-19 patients during the first wave of the pandemic in Poland.

In general, the respondents presented with average resilience (a score of 74.11), which is higher than the findings reported by other authors for groups of medical personnel during the coronavirus pandemic. Studies using CPP-25 found mean scores (range 0–100) ranging from 59 to 73 [20]. Lower resilience was characteristic of nurses working in hospitals in Iran (a score of 61.18) [21]. In Great Britain, 18.9% of nurses working with patients with respiratory diseases (including COVID-19) showed a low or very low level of resilience during the pandemic [22].

Resilience helps to effectively cope with COVID-19-related stress [23]. We showed that the dimensions of mental resilience, such as perseverance and determination, as well as competencies and tolerance of negative emotions, increased with increasing seniority and the age of respondents. Similar findings were reported by Afshari et al., who indicated age, professional experience, and education as predictors of nurse resilience [21]. Roberts et al. also observed a higher level of anxiety and lower resilience among less experiences during the COVID-19 pandemic [22]. Sull et al. also showed that resilience increased with age [24].

Our study confirms that the younger the respondents, the higher the mental strain in terms of work monotony, non-specific stress, and overall mental stress. Dębska et al. also demonstrated this by showing that longer seniority and seniority in a specific position reduced the level of monotony, though it contributed slightly to overload. Furthermore, the length of seniority in a given workplace increases overload, and it can be assumed that it is a substantial risk factor for occupational burnout [17].

We showed in our study that respondents with children younger than 18 were more tolerant of failure and more likely to treat life as a challenge than those who did not have children in this age range. Afshari et al. have shown an inverse correlation between having children and the overall resilience score among nurses [21]. This may be because living with family and concerns about bringing the virus home generated anxiety and stress during the COVID-19 pandemic [25].

The lack of adequate protection against the virus or incomplete PPE was the primary source of anxiety at work during the pandemic [26]. In this study, those who felt well protected by PPE showed significantly higher persistence and determination, greater openness to new experiences, a sense of humor, and overall greater resilience. Ahmad et al. assessed the impact of the availability of protection and training on the number of infections and the spread of the SARS-CoV-2 virus in Pakistan and showed that training in donning and doffing of PPE, social distancing, isolation, and quarantine effectively increased the protection of personnel [27]. Additionally, those trained in hand hygiene were less likely to contract the virus. The analysis of our findings showed that those uncertain whether the hospital they worked in organized training on the management of a patient suspected of being infected with SARS-CoV-2 showed significantly lower overall resilience. Huang et al. showed that the availability of appropriate protective measures was one of the independent factors influencing mental resistance [28].

Our study showed grade 2 mental stress in ICU nursing staff. Kaducakova and Lehotska, who assessed mental stress among nurses working in social welfare centers, also showed grade 2 mental stress and a tendency to overload [29]. This can affect the subjective condition and performance of nursing staff. The authors also found that the greatest mental stress was related to time pressure, high responsibility levels, fatigue, and chronic workload, which is so exhausting that it does not allow for work to be performed at a constant efficiency level. In this study, the mean level of mental strain in psychological overload in ICU nurses scored 9.75 out of 15.

The current study does not confirm that seniority in the profession in general or at the current workplace is significantly associated with mental stress. Dębska et al. showed that longer seniority is associated with higher levels of mental stress, overload, and monotony [17]. In a study by Labrague et al., over 90% of nurses from the Philippines reported that they were not sufficiently prepared to treat COVID-19 patients, and only 20.3% of the respondents expressed their willingness to care for infected patients [3]. In this study, 65.3% of nurses expressed a definitely positive or a rather positive attitude toward combating coronavirus.

Our study showed that those employees of tertiary hospitals rated the work environment in the context of the SARS-CoV-2 pandemic significantly higher than those working in first and second-reference-level hospitals. Employees of infectious disease hospitals or hospitals transformed into infectious disease units gave significantly higher ratings to their work environment than those working in non-infectious hospitals. This may have been because such workplaces received the highest financing and had better protective measures.

The surveyed nursing staff were characterized by higher resilience and lower mental stress. Huffman et al. pointed out that during the SARS-CoV-2 pandemic, medical personnel experienced higher levels of stress, which is coped with more effectively by those with higher mental toughness [30]. Higher resilience allows staff to deal more effectively with challenges, anxiety, fatigue, and sleep disturbances. Increased resilience can help nurses reduce emotional exhaustion and increase work engagement [31].

The conducted analyses may serve as a basis for planning further research in this area. However, the study had several limitations. It was conducted on a small group of respondents, which makes it impossible to generalize the results to the entire population of ICU nursing personnel. Another limitation was the collection of data for analysis using electronic questionnaires due to the pandemic, which could exclude older individuals from the study due to their lack of computer skills or difficulty accessing the questionnaires. In future research in this field, it would be interesting to assess resilience and mental stress over a longer time after the outbreak of the pandemic, with the participation of a representative group of nurses.

# **Study limitations**

This study had several limitations. We used an electronic questionnaire for data collection due to the SARS-CoV-2 coronavirus pandemic, which made it impossible to conduct the study in hospital departments. Due to the small number of respondents participating in the study, the results should not be generalized to the entire population of ICU nursing personnel. This was a cross-sectional study that may not reflect the resilience and mental stress of the population over time. However, these phenomena change over time and with the evolving environment. Therefore, there is a need to present the psychological aspects of the COVID-19 pandemic over a longer and more perspective period.

# **CONCLUSIONS**

The presented study allows for the following conclusions: the surveyed nursing staff were characterized by higher resilience and lower mental stress; nurses showing higher mental toughness have a sense of adequate protection with PPE; nurses assessing their work environment better in the context of the SARS-CoV-2 pandemic have higher resilience and lower mental stress.

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Word count: 4667	• Tables: 6	• Figures: 1	• References: 31
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## Sources of funding:

The research was funded by the authors.

# **Conflicts of interests:**

The authors report that there were no conflicts of interest.

#### Cite this article as:

Januszek D, Kobos E, Dziedzic B. Resilience index and mental stress of nursing staff working in intensive care units during the SARS-CoV-2 pandemic. Med Sci Pulse 2023;17(3):61-70. DOI: 10.5604/01.3001.0053.8890.

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# COMPARISON OF THE EFFECTIVENESS OF SELECTED PHYSIOTHERAPY METHODS FOR THE TREATMENT OF TENNIS ELBOW SYNDROME: A CASE REPORT

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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:** Tennis elbow is a common ailment with which patients present to the physiotherapy office. It is characterized by pain in the area of the attachment of the tendons of the extensor muscles of the wrist to the lateral epicondyle of the humerus and the proximal part of the extensor muscles of the wrist, reduced grip strength, and limited function of the upper limb. The condition can result from trauma, but in most cases, it is the result of overload, with factors such as degeneration and relative ischemia, repetitive grasping movements, scar tissue, and contracture playing a role. In these cases, diagnosis is based on history, functional tests, and palpation of structures within the lateral epicondyle of the humerus.

**Aim of the study:** To compare and evaluate the effectiveness of selected physiotherapy methods used in the treatment of tendinopathy of the lateral epicondyle region of the humerus.

**Case report:** Medical cases of four men aged 40–55 years complaining of pain in the lateral epicondyle region of the humerus are presented. Palpation examination, functional tests, and symptoms indicated that they had "tennis elbow syndrome". Treatment included low-energy laser ultrasound, low-frequency magnetic field, radial shock wave, nitrogen vapor cryotherapy, and deep transverse massage, according to Cyriax.

**Conclusions:** Among the selected physiotherapeutic methods, radial shock wave therapy and deep transverse massage, according to Cyriax, showed the greatest effectiveness.

KEYWORDS: pain, tendinopathy, physiotherapy, tennis elbow

#### BACKGROUND

Tennis elbow – enthesopathy of the proximal wrist extensor muscles – is the term used to describe the condition of a patient who presents with pain in the lateral epicondyle region of the humerus, decreased hand grip strength, and reduced function of the upper limb [1]. The condition affects people between the ages of 35 and 55 years. Clinical symptoms include pain in the lateral aspect of the

elbow that increases during resisted dorsiflexion. As it turns out, pain in this area is most often complained of not by tennis players but by office workers, information technology workers, seamstresses, manual laborers performing jobs involving lifting, and those who perform repetitive tasks with their hands in some discomfort. In general, people who perform physical work involving high mechanical loads on the upper limb and/or who maintain a nonphysiological position of the forearm and hand for



long periods of time are at risk for this condition [2].

As a result of repeated microtrauma in the area of the attachment on the lateral epicondyle, degenerative changes in collagen and disruption of blood supply to the tissues occur [3].

Tennis elbow can, of course, be the result of some extensive trauma to the elbow joint, but in most cases, it is the result of persistent overloading of the tissues, which can consequently lead to numerous microinjuries.

Therefore, tennis elbow should not be classified as tendinitis but rather as tendinosis. The beginning of this change in thinking came after the publication of histopathological results that did not confirm the presence of an inflammatory infiltrate. Instead, microtrauma lesions, granulation tissue, and degenerative changes with little or no inflammation were found. No prostaglandin E2 was detected in the short wrist radial extensor tendon compared to the healthy tendon. This indicates a lack of inflammatory changes in the tendons of patients with tennis elbow [1].

Factors that play an important role in the process of the "formation" of tennis elbow include:

- degeneration of the tissue and relative ischemia
- repetitive grasping movements
- scar tissue and contracture [4].

During the physical examination, it is important to obtain information about the mechanism of pain onset and the nature and duration of the discomfort. Characteristics of this condition include long-lasting pain that is worse during dorsiflexion of the wrist and physical activities that require performing this movement with resistance. Magnetic resonance imaging is rarely performed [5].

#### **AIM OF THE STUDY**

The purpose of this study was to compare the effectiveness of selected physical therapy methods



Figure 1. Cozen test

used to treat tendinopathy of the lateral epicondyle region of the humerus.

## **MATERIAL AND METHODS**

## Study design and setting

All information and data on the patients' health status were obtained during interviews and physical examinations. The patients were informed of the intention of the study and agreed to participate. The study was conducted in a private physiotherapy office, "Orthopedic Medicine, Ultrasound and Physiotherapy", in Kolobrzeg, Poland.

## **Participants**

The medical cases of four patients complaining of pain in the lateral epicondyle region of the humerus were used to compare the effectiveness of selected treatment methods. All patients were men aged 40–55 years. Common features were that all subjects had not previously complained of pain that would indicate symptoms of tendinopathy or enthesopathy of the lateral epicondyle region, their work was physical labor, and they came to the physiotherapy office within 10 days of the onset of obvious symptoms.

#### **Diagnostic methods/Data sources**

- 1. Interview
- 2. Palpation diagnosis
- 3. Functional tests:
  - Cozen test (Figure 1)
  - Maudsley test (Figure 2)
  - Mill's test (Figure 3a,b)
  - Chair lift test (Figure 4) [6].



Figure 2. Maudsley test

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Figure 3a. Mill's test



Figure 4. Chair lift test

# Methods of evaluating the results of therapy

1. Scoring system based on the criteria of Verhaar et al.:

Excellent:

 complete resolution of pain in the area of the lateral epicondyle of the humerus

- patient satisfied with the results of therapy

– no subjective loss of grip strength

– no pain during dorsiflexion of the wrist against resistance

Good:

- occasional pain in the area of the lateral epicondyle of the humerus after intensive exercise

- patient satisfied with the results of therapy

– no or little subjective loss of grip strength



Figure 3b: Mill's test

– no pain during dorsiflexion of the wrist against resistance

Satisfactory:

 discomfort in the area of the lateral epicondyle of the humerus after strenuous exercise, but at a more tolerable level than before treatment began

patient satisfied or moderately satisfied with treatment results

– mild or moderate pain induced during dorsiflexion of the wrist against resistance

– mild or moderate subjective loss of grip strength

Bad:

 no reduction in pain in the area of the lateral epicondyle of the humerus

 $\ -$  patient dissatisfied with the results of treatment

severe subjective loss of grip strength

 severe pain caused by dorsal flexion of the wrist against resistance [7].

2. Visual analog scale (VAS) for pain: from 0 (no pain at all) to 10 (maximum pain- imaginable).

## RESULTS

## Medical procedures performed on the patients

The treatment included low-energy laser (Astar-Abr, Polaris 2, PM-IR 808 nm/200mW), ultrasound (BTL-4710 Smart, HandsFree Sono 12 head), low-frequency magnetic field (BTL-4920 Smart, applica-tor-double disk), radial shock wave therapy (RSWT) (BTL-6000 SWT Topline Power), nitrogen vapor cry-otherapy (Kriomedpol, Kriopol R), and deep transverse massage (DTM) according to Cyriax.

## Patient 1:

The first patient was treated with popular physical therapy treatments, including low-energy laser, ultrasound, and low-frequency magnetic field. The therapy was preceded by the functional tests mentioned in this article. All tests were positive. The pain was in the area of the lateral epicondyle of the humerus and 2 cm below toward the front of the wrist. VAS scale: 4. Physical therapy was performed daily for two weeks, from Monday to Friday, for a total of 10 treatment days. The patient had three treatments per day, one after another. The duration of the treatments was as follows: low-frequency magnetic field (10 min) (dose of 35 Hz, 6 mT), ultrasound (5 min) (dose of 0.8 W/  $cm^2$ ), and low-energy laser (5 min) (dose of 8 J/ $cm^2$ ). Effects of therapy: pain during wrist extension resistance test decreased slightly (VAS: 2). Verhaar et al. scoring system: satisfactory.

## **Patient 2:**

The second patient received RSWT. The therapy was preceded by the functional tests mentioned in this article. All tests were positive except the Maudsley test. Pain persisted in the area of the tendon attachment of the short wrist extensor muscle and on the tendon itself. VAS scale: 5. Shockwave: five treatments every three days (dose of 2,000 strokes, 10 Hz, 1.8 to 2.6 bar), with doses increasing during each subsequent treatment. The therapy lasted 2.5 weeks. Treatment effects: pain disappeared completely. VAS: 0. Resistance tests resulted in no discomfort. Verhaar et al. scoring system: excellent.

### **Patient 3**:

The third patient underwent DTM, according to Cyriax. The therapy was preceded by the functional tests mentioned in this article. All tests were positive except the Maudsley test. The pain was localized mainly in the gastrocnemius portion of the short wrist extensor muscle. VAS scale: 4. DTM: 12 sessions for the first five days every day for 15 minutes, then every two days for 15 minutes each. Effects of therapy: pain during resisted movement subsided. VAS: 0. Slight tenderness of the muscle belly area remained. Pain absent at the course of the tendon itself and at the transition of the tendon to the muscle belly. Verhaar et al. scoring system: good.

## Patient 4:

A fourth patient was treated with cryotherapy using nitrogen vapor. The therapy was preceded by the functional tests mentioned in this article. All tests were positive. In this case, the pain was localized around the lateral epicondyle of the humerus and above it in the area of the tendon attachment of the extensor longus muscle of the wrist. At the same time, according to the patient, the pain periodically spread to the entire lateral side of the elbow. VAS scale: 4. Hence, the decision was made to use cryotherapy in his case in order to cover a larger treatment area simultaneously. Cryotherapy-like physical treatments: 10 treatments, three minutes each, performed daily. Treatment effect: Reduced pain sensation and greater comfort when performing wrist movements against resistance. VAS: 1. Verhaar et al. scoring system: satisfactory.

### **DISCUSSION**

### **Key results**

Tennis elbow is a relatively common condition. It affects people from various occupational groups. The most important factors are the differential diagnosis to pinpoint the exact location of the problem at a particular site of tissue near the lateral epicondyle of the humerus and then the appropriate choice of therapy for each case.

Patients	Type of therapy	VAS before therapy	VAS after therapy	Verhaar et al. score
Patient 1	Physical therapy	4	2	Satisfactory
Patient 2	RSWT	5	0	Excellent
Patient 3	Cyriax's DTM	4	0	Good
Patient 4	Cryotherapy	4	1	Satisfactory

Table 1. Results of tennis elbow treatment

The VAS scale refers to wrist movement against resistance.

The selection of treatment methods for specific types of damage must be individualized for each patient. As can be seen from case reports, the most effective treatment method for this condition among those selected and described in this article is RSWT. RSWT works at a relatively shallow level, and the problem is localized in this region. Next, equally high pain relief was achieved with DTM therapy. Next came cryotherapy treatment, followed by conventional physical therapy methods. These provided relatively little improvement, but it cannot be clearly stated that they are ineffective.

## Interpretation

According to authors of publications treating this problem, RSWT appears to be an effective and

promising method for treating lateral epicondylar enthesopathy of the humerus. Most original research of high methodological quality (equal to or higher than 7 on the PEDro scale) has confirmed the therapeutic effectiveness of RSWT procedures [9,10,11,12]. It is estimated that up to 87% of patients with tennis elbow are satisfied with RSWT [11].

Among the available treatments for tennis elbow, kinesitherapy and manual therapy can also be used, or therapy can be extended to include forms of massage and kinesiotaping.

According to the authors of publications on the use of manual therapy in diagnosis and treatment, it is important to correctly identify the damaged structure that may be causing the clinical symptoms. Functional tests, among others, play an important role in this process. Manual therapy, thanks to its numerous therapeutic techniques (DTM, Mill manipulation, etc.), allows for the precise treatment of damaged tissues. It is noteworthy that these techniques are safe and comfortable for the patient.

The patient's continuation of functional training at home can result in long-term results [13].

Transverse and functional massage, mobilization techniques for tennis elbow according to the Mulligan Concept, home exercises according to the Mulligan Concept, and kinesiotaping (muscle–fascia application) can also be used to manage pain from the lateral epicondyle area of the humerus. Therapy for tennis elbow, combining both manual techniques and various forms of massage or kinesiotaping, is an effective form of conservative treatment [8].

However, when there are no positive therapeutic effects despite the treatment used, surgery may be performed. Based on their study, Junk et al. claim that an indication for surgery is unsuccessful physical therapy treatment lasting a minimum of six months. The authors also note that the results of surgery depend on the duration of pain and are worse in patients with chronic tennis elbow syndrome (pain duration of more than six months) [14].

A separate issue is steroid blocks, whose effect on tennis elbow complaints is inconclusive. Stud-

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ies by Stahl and Kaufman have shown that steroid treatment produces only short-term improvements [15]. During surgical procedures that involve the removal of necrotic and inflamed tissue in the lateral epicondyle of the humerus, steroid deposits are often found at injection sites [16].

## Generalizability

Although the location of the problem causing the pain varied from patient to patient, the problem remained the same, and the treatment methods could be used interchangeably with greater or lesser effectiveness.

## **Study limitations**

A limitation of the study may be its small number of participants.

## Recommendations

The most important factors are the differential diagnosis to determine the problem and the time elapsed between the onset of obvious pain symptoms and the intervention of a physiotherapist.

## **CONCLUSIONS**

1. Tennis elbow is not an inflammatory condition. Therapies that contribute to reducing inflammation should be omitted in favor of therapies that accelerate tissue regeneration and produce long-term pain relief.

2. Among the physiotherapeutic methods used, radial shock wave therapy and deep transverse massage, according to Cyriax, showed the highest effectiveness.

3. The other methods did not show such high therapeutic efficacy, although it cannot be clearly stated that they are ineffective.

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Word count: 2165	• Tables: 1	• Figures: 4	• References: 16
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## **Sources of funding:**

The research was funded by the authors.

### **Conflicts of interests**:

The authors report that there were no conflicts of interest.

### Cite this article as:

Piątek PJ, Błaszczyk J. Comparison of the effectiveness of selected physiotherapy methods for the treatment of tennis elbow syndrome: a case report Med Sci Pulse 2023;17(3):71-76. DOI: 10.5604/01.3001.0053.8998.

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## BENZO(A)PYRENE – AN AIR POLLUTANT HARMFUL TO HEALTH IN EUROPEAN COUNTRIES

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## ABSTRACT

**Background:** Benzo(a)pyrenes are organic compounds from the polycyclic aromatic hydrocarbons group known for their carcinogenic properties. Benzo(a)pyrenes form from incomplete combustion of organic matter, such as biomass or fossil fuels.

**Aim of the study:** To investigate whether respiratory diseases and malignant neoplasm-related deaths correlate with air concentrations of benzo(a)pyrene in European countries.

**Material and methods:** Publicly available data regarding benzo(a)pyrene concentration were obtained from the EUROSTAT database and divided by territory based on the nomenclature for territorial units for statistics 2 (NUTS2). Diseases were defined using the International Classification of Diseases 10<sup>th</sup> revision (ICD-10).

**Results:** There was a positive correlation of medium effect (r=0.442; p<0.001) between the annual mean benzo(a)pyrene concentration and deaths due to malignant neoplasms, with the strongest correlation being malignant bladder neoplasms (r=0.502; p<0.001). There was also a positive correlation of a moderately weak effect (r=0.221; p=0.002) between the annual mean concentration of benzo(a)pyrene and deaths due to respiratory diseases, with the strongest correlation for pneumonia of various etiologies, which had a positive correlation of medium effect (r=0.496; p<0.001). Linear regression models showed that reducing the concentration of benzo(a)pyrene by 1 ng/m<sup>3</sup> will reduce the frequency of deaths due to malignant laryngeal neoplasms by 0.816 per 1000 residents, malignant bladder neoplasms by 1.41 per 1000 residents, and deaths due to pneumonia by 11.26 per 1000 residents.

**Conclusions:** We found that benzo(a)pyrene concentration had a moderate correlation with death due to respiratory diseases and malignant neoplasms. More in-depth studies regarding other factors, such as patient age, are needed.

**KEYWORDS:** benzopyrenes, air pollution, respiratory tract diseases, neoplasms

## BACKGROUND

Benzo(a)pyrenes (BaPs) are organic compounds belonging to the polycyclic aromatic group. From the wide variety of polycyclic aromatic hydrocarbons, BaPs are considered the most toxic and are also the best-studied representatives of this group [1]. There are two structural isomers differing in the location of the benzene ring attachment to pyrene, including BaP [2] and the less common benzo(e) pyrene (BeP) [3].

BaP is classified by the International Agency for Research on Cancer (IARC) as a Group 1 carcinogen, which means that there is sufficient evidence to con-



firm the carcinogenic properties of the compound. BeP is classified as Group 3 by the IARC, meaning it is not possible to assess its carcinogenic properties due to insufficient data.

BaPs form from incomplete combustion of organic matter at temperatures between 300 and 600 °C. Their primary source in the atmosphere is the burning of wood and other types of biomass on private properties, as well as emissions from motor vehicles, particularly those powered by diesel engines, but BaP is formed during the combustion of any organic matter or fossil fuel [4]. In humans, one of the most significant sources of BaP is cigarette smoke, especially in tobacco-induced lung cancer [5].

BaPs are proven to be a risk factor for developing lung cancer [6]. However, other malignant neoplasms such as throat, larynx, bladder, or skin cancer can develop due to BaP exposure [7].

### **AIM OF THE STUDY**

In this paper, we searched for a relationship between BaP concentration in the European Union nomenclature for territorial units for statistics 2 (EU NUTS2) sub-regions and death rates from the most common respiratory diseases and malignant neoplasms.

## **MATERIAL AND METHODS**

### Data

The study used data from public sources under the Creative Commons 4.0 license. Data on measurements of BaP concentrations in particles with a diameter of less than 10  $\mu$ m (PM10) came from the European Environment Agency (EEA) database. Data on deaths was obtained from the EUROSTAT database created by the European Commission. Standardized death rates per 1,000 inhabitants were used for the distinguished causes of death in the designated NUTS 2 areas. The most recent available dataset from 2020 was selected, which combined data on an annual basis.

Diagnoses of diseases for hospitalization rates were defined using the International Classification of Diseases 10<sup>th</sup> revision (ICD-10). The following diseases were distinguished: malignant neoplasms (C00-C97); malignant neoplasms of lip, oral cavity, and pharynx (C00-C14); malignant neoplasm of colon, rectum, and anus (C18-C21); malignant neoplasm of larynx (C32); malignant neoplasm of trachea, bronchus, and lung (C33-C34); malignant neoplasm of bladder (C67); diseases of the respiratory system (J00-J99); pneumonia (J12-J18); chronic lower respiratory diseases (J40-J47); and asthma (J45-J46).

The study used a territorial division based on NUTS and data provided by EUROSTAT. The data is presented at the NUTS 2 level.

#### **Statistical analysis**

Data from air quality stations was aggregated for the NUTS2 areas, calculating the annual average concentration of BaP for the sub-regions. For standardized death rates, the Shapiro-Wilk test assessed the normality of quantitative variables. Correlations were calculated using Pearson's r coefficient. The significance level was set at  $\alpha$ =0.05. The analysis employed TIBCO Statistica 13 (TIBCO, CA, USA), QGIS 3.32, and Microsoft Excel (Microsoft Corporation, WA, USA).

### RESULTS

In the periods analyzed, the mean annual concentration of BaP in the studied subregions was 0.604 ng/m<sup>3</sup>. The lowest mean concentrations of BaP were recorded in Jan Mayen and Svalbard in Norway (NOOB; 0.002 ng/m<sup>3</sup>) and Östra Mellansverige in Sweden (SE12; 0.013 ng/m<sup>3</sup>). In contrast, the highest were observed in sub-regions of Poland, including Małopolskie (PL21; 6.154 ng/m<sup>3</sup>), Śląskie (PL22; 6.037 ng/m<sup>3</sup>), and Świętokrzyskie (PL72; 4.317 ng/m<sup>3</sup>). The lowest mean BaP concentration was recorded in Sweden (SE; 0.030 ng/m3), while the highest was in Poland (PL; 3.170 ng/m<sup>3</sup>). The average annual concentrations of BaP in the analyzed NUTS2 sub-regions are presented in Figure 1.

## **Correlations**

There was a positive correlation, of medium effect (r=0.442; p<0.001), between the annual mean concentration of BaP and deaths due to malignant neoplasms. In the malignant neoplasms, the strongest correlation was shown for malignant neoplasms of the bladder, which had a positive correlation with a strong effect (r=0.502; p<0.001). The next neoplasm with the strongest relationship with the annual mean BaP concentration was malignant neoplasm of the larynx, which demonstrated a strong positive correlation (r=0.543; p<0.001). The remaining distinguished cancers correlated with the annual mean concentration of BaP with similar strength (r=0.324 - 0.390). In regions with a higher annual concentration of BaP, there was a higher frequency of deaths due to malignant neoplasms among the studied residents.



Figure 1. A map of benzo(a)pyrene (BaP) concentrations in nomenclature for territorial units for statistics 2 (NUTS2) sub-regions (2020)

There was a positive correlation of moderately weak effect (r=0.221; p=0.002) between the annual mean BaP concentration and deaths due to respiratory diseases. Among respiratory diseases, the strongest correlation was shown for pneumonia of various etiologies, which had a medium effect positive correlation (r=0.496; p<0.001). In regions with a higher annual concentration of BaP, there was a higher death rate due to respiratory diseases among the studied residents, but it was lower than the cases of malignant neoplasms. The exact results of Pearson's correlation analysis are presented in Table 1.

Table 1. Correlations between death rates and BaP concentration in selected NUTS2 subregions

Death rates	М	SD	r	р
Malignant neoplasms (C00-C97)	242.240	32.457	0.442	0.000
Malignant neoplasms of the lip, oral cavity, and pharynx (C00-C14)	6.037	2.368	0.390	0.000
Malignant neoplasm of the colon, rectum, and anus (C18-C21)	21.343	5.204	0.364	0.000
Malignant neoplasm of the larynx (C32)	2.175	1.409	0.502	0.000
Malignant neoplasm of the trachea, bronchus, and lung (C33-C34)	47.787	11.131	0.324	0.000
Malignant neoplasm of the bladder (C67)	7.738	2.383	0.543	0.000
Diseases of the respiratory system (J00-J99)	68.768	20.418	0.221	0.002
Pneumonia (J12-J18)	23.511	17.913	0.496	0.000
Chronic lower respiratory diseases (J40-J47)	28.553	11.924	-0.179	0.014
Asthma (J45-J46).	1.190	0.674	0.232	0.001

## Linear regression models

For the three distinguished diseases with the highest correlation coefficients, linear regression models of death frequency were created. The independent variable was the annual mean BaP concentration in the analyzed regions.

For malignant neoplasms of the larynx, the difference between the actual values and the values predicted by the model for the dependent variable was 1.2, representing 55.2% of the mean for the dependent variable. The coefficient of determination ( $R^2$ =0.274), the value of the F statistic (72.033), and the corresponding probability level (p<0.001) indicate the statistical significance of the model. These values can be interpreted to mean that reducing the annual average concentration of BaP by 1 ng/m<sup>3</sup> will reduce the frequency of deaths due to malignant neoplasms of the larynx by 0.816 per 1000 residents of the studied regions.

In the case of malignant neoplasms of the bladder, the difference between the actual values and the values predicted by the model for the dependent variable was 2.01, representing 25.9% of the mean for the dependent variable. The coefficient of determination ( $R^2$ =0.288), the value of the F statistic (76.978), and its corresponding probability level (p<0.001) indicate the statistical significance of the model. These values can be interpreted to mean that reducing the annual mean BaP concentration by 1 ng/m<sup>3</sup> will reduce the frequency of deaths due to malignant neoplasms of the bladder by 1.41 per 1000 residents of the studied regions.

For pneumonia of various etiologies, the mean difference between the actual values and values predicted by the model for the dependent variable was 14.726, representing 62.6% of the average for the dependent variable. The coefficient of determination ( $R^{2-}0.324$ ), the value of the F statistic (91.170), and its corresponding probability level (p<0.001) indicate the statistical significance of the model. These values can be interpreted to mean that reducing the annual mean BaP concentration by 1 ng/m<sup>3</sup> will reduce the frequency of deaths due to pneumonia by 11.26 per 1000 residents of the studied regions.

### DISCUSSION

The toxicity of BaPs and their impact on carcinogenesis is complex and is related to at least several different metabolic pathways of these compounds, whose products have carcinogenic properties. For this reason, BaPs are classified as procarcinogens [8]. The best-known mechanism is the diol-epoxide pathway, in which a sequence of metabolic transformations catalyzed by cytochrome P450 (*CYP1A1*), cytochrome P450 1B1 (CYP1B1), and epoxide hydrolase leads to the formation of diol-epoxides - compounds that react directly with the deoxyribonucleic acid (DNA) of cells. BaP diol-epoxides form stable covalent bonds, mainly with the purine bases - deoxyguanosine and deoxyadenosine. These modifications to DNA structure can lead to disruptions in transcription, replication, and DNA repair processes [9]. In the lung tissues of mice exposed to BaP-containing products, transformations and mutations have been found in oncogenes and suppressor genes typical of lung cancer, such as in Kirsten rat sarcoma virus (KRAS) and p53 genes [10]. The best-known and proven correlation with exposure to BaP is the risk of developing lung cancer. In the case of other cancers, such as throat, larynx, bladder, or skin cancer, data obtained in analyses indicate a lower degree of correlation compared to lung cancer. In a 2014 metaanalysis [7], including results from 13 cohort studies among workers in aluminum processing plants, steel mills, and asphalt production plants, a statistically significant correlation was found between exposure to polycyclic aromatic hydrocarbons and the development of lung cancer and a borderline significant correlation with bladder cancer.

In addition to its carcinogenic properties, it has been suggested that BaP can exacerbate skin and mucous membrane inflammation. Such properties have been confirmed in murine and human cell models of conditions such as psoriasis, palmoplantar pustulosis, acne [11-13], and neuro oxidative stress [14] due to increased synthesis and release of pro-inflammatory cytokines. BaP also affects mucous membranes by stimulating the expression of mucin 5AC (MUC5AC), which leads to increased mucus production that can intensify asthma symptoms [15].

In vitro studies on human bladder tissues [16] indicate a very high potential for BaP to induce changes in the DNA of bladder epithelial cells, which is likely to significantly impact carcinogenesis. However, the statistical analyses conducted so far [17] have not allowed for a clear confirmation of a significant causal relationship. Our results fit this trend and indicate the need for a large-scale cohort study that would unequivocally confirm or exclude such a relationship.

The result of increased mortality due to malignant neoplasms of the larynx obtained in our analysis has a proven molecular basis and pathomechanism. However, a meta-analysis of the available literature [7] shows conflicting results from similar studies, and there is no clear evidence of increased incidence and mortality due to laryngeal neoplasms associated with exposure to BaP. In a study by CE Mitchell [18], the distribution of BaP was evaluated in rats after inhalation using tritium-labeled BaP. By analyzing section preparations, a significant increase in radiation from the decay of tritium atoms was found in all respiratory system tissues, including the nasal cavity, trachea, larynx, lungs, and lymph nodes draining lymph from the trachea and bronchi, as well as the kidneys and liver [17]. In another study [16], the effect of BaP on cell cultures derived from the larynx and bronchi was analyzed *in vitro*. The formation of carcinogenic diol-epoxides covalently bound to DNA in response to BaP exposure was confirmed.

Our results show a correlation between exposure to BaP in the air and the risk of death due to pneumonia. In a study conducted by Clark et al., the inhibitory effect of BaP on the functioning of the immune system was demonstrated and explained. Exposure of macrophages to BaP led to a decrease in the potential for activation of the CD32 receptor (FcyRII) by immunoglobulin G (IgG) by approximately 30% and disrupted macrophage functions such as phagocytosis and the generation of an oxidative burst, thereby increasing the risk of infection [19]. A large-scale ten-year cohort study conducted between 1992 and 2002 involving 1263 pregnant women and their children assessed whether the distance between a pregnant woman's residence and a road with high traffic intensity was related to the risk of respiratory tract infection in newborns [20]. The study showed a relationship between distance from the road and estimated that the average risk of infection decreased by 8% for each additional 100 meters from the street. Since emissions from internal combustion engines are one of the primary sources of polycyclic aromatic hydrocarbons, our results correspond with other studies. However, the endpoint analyzed in our study

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was death due to pneumonia, not the incidence of respiratory tract infections associated with exposure to BaP. Therefore, further analyses are necessary to assess the direct correlation since no similar studies were found in the available literature.

The distribution of air quality stations and the associated accuracy of BaP concentration monitoring in different regions of the EU is variable, leading to an underestimation of the real impact on health and significantly complicating the interpretation of results. It is estimated that statistics assessing the increase in cancer incidence are underestimated by about 20%. Measurement probes are usually concentrated within cities and industrial centers and less frequently located in agricultural and forest areas. As a result, there is massive uncertainty about the concentrations of polycyclic aromatic hydrocarbons in the air in some regions of Europe, such as Romania, Portugal, Greece, Croatia, and Balkan countries, which makes interpreting the obtained data challenging [21].

## **CONCLUSIONS**

This study found that BaP concentrations had a moderate positive correlation with death due to respiratory diseases and malignant neoplasms. However, this analysis used the death of the affected person as its only endpoint. There is a need for further studies on this topic to determine the extent to which BaP affects malignant neoplasms and pulmonary diseases depending on the age of the patient, their prognosis, and other factors such as smoking.

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Word count: 2351	• Tables: 1	• Figures: 1	• References: 21
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## Sources of funding:

The research was funded by the authors.

### **Conflicts of interests**:

The authors report that there were no conflicts of interest.

#### Cite this article as:

Jasiura A, Gorzel M, Warchoł K, Lipczyńska W. Benzo(a)pyrene - an air pollutant harmful to health in European countries Med Sci Pulse 2023;17(3):77-82. DOI: 10.5604/01.3001.0053.9255

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