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KNOWLEDGE, EXPERIENCE AND ATTITUTE OF PATIENTS REGARDING MATERIOVIGILANCE SYSTEM IN THE REPUBLIC OF NORTH MACEDONIA

ЗНАЕЊАТА, ИСКУСТВАТА И СТАВОВИТЕ НА ПАЦИЕНТИТЕ ЗА СИСТЕМОТ ЗА МАТЕРИОВИГИЛАНЦА ВО РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА

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Abstract

Introduction. Materiovigilance is a structured approach aimed at detecting, collecting, monitoring, evaluating, and ensuring the appropriateness of new safety data concerning medical devices and potential incidents of use. **This paper aims** to explore patients' knowledge, experiences, and attitudes regarding the established materiovigilance system in the Republic of North Macedonia, considering that patients may also report adverse reactions to medical devices. **Material and Method.** To achieve this aim, we conducted a cross-sectional study utilizing a survey questionnaire among 200 patients seeking dental services at the PHI University Dental Clinical Center Ss. Panteleimon in Skopje. The collected data underwent statistical analysis. **Results.** The majority of patients demonstrated limited awareness of medical devices, lacked knowledge about the national materiovigilance system, and were unfamiliar with its purpose. None of the patients reported experiencing adverse reactions to medical devices, nor had they observed such events in others. Most patients indicated they would inform their prescribing or dispensing healthcare provider if they encountered an adverse reaction. Furthermore, 94% of patients expressed the belief that they should not necessarily be aware of their ability to report adverse reactions to medical devices. **Conclusion.** Our study reveals that patients exhibited minimal understanding of the materiovigilance system and displayed a notably negative inclination toward reporting adverse events associated with medical device use. We assume that greater implementation of the materiovigilance system and cooperation between universities, healthcare professionals, patients, manufacturers, government and national agencies, media, civil society and international organizations working on medical device safety is needed.. **Key words:** materiovigilance, patients, medical devices.

Апстракт

Вовед. Материовигиланца претставува систем кој се применува за откривање, собирање, следење, процена и обезбедување на соодветност на новите податоци за безбедноста на медицинското средство поврзано со можните инциденти од употребата. Имајќи предвид дека и пациентите можат да пријавуваат несакани реакции (ефекти) од медицинските средства, целта на трудот е да ги прикаже знаењата, искуствата и ставовите на пациентите за воспоставениот систем за материовигиланца во Република Северна Македонија. **Материјал и метод.** За да одговориме на поставената цел, спроведовме студија на пресек, со користење на анкетен прашалник кај 200 пациенти кои дошле за добивање на стоматолошка услуга во ЈЗУ Универзитетски стоматолошки клинички центар ,,Св. Пантелејмон" во Скопје. Добиените податоци беа статистички обработени. **Резултати.** Мнозинството од пациентите не знаат што претставува медицинско средство, немаат познавања за воспоставениот национален систем на материовигиланца и не ја знаат целта на овој систем. Ниту еден пациент не смета дека му се случила несакана реакција (ефект) /настан предизвикана од употреба на медицинско средство, ниту пак виделе ваква појава кај некој друг. Мнозинството пациенти ќе го известат лекарот/фармацевтот кој им го препишал/издал медицинското средство во случај на забележана несакана реакција. 94% од пациентите сметаат дека не треба да знаат дека можат да ги пријават несаканите реакции (ефекти) /настани од медицинското средство. **Заклучок:** Пациентите во нашето истражување имаа минимални познавања за системот за материовигиланца и загрижува нивниот негативен став за пријавување на несаканите настани предизвикани од употреба на медицинско средство. Сметаме дека е потребна поголема имплементација на системот на материовигиланца и соработка помеѓу универзитетите, здравствените работници, пациентите, производителите, владата и националните агенции, медиумите, граѓанските здруженија и меѓународните организации кои работат во областа на безбедноста на медицинските средства. **Клучни зборови:** материовигиланца, пациенти, медицински средства.

Introduction

The realm of medical devices encompasses a diverse array of products, ranging from single-use disposables to long-term implantables, and from monitoring to diagnostic or therapeutic tools, with delivery mechanisms spanning electronic, mechanical, or chemical means. Moreover, these products involve both users and patients, often overlapping, and are utilized across various settings, from hospitals to home care[1]. Therefore, stakeholders such as practitioners, policymakers, regulators, and patients must continually assess aspects like safety, effectiveness, and quality assurance with each new product entering the market. Long-term pharmacovigilance efforts address these parameters. A parallel concept and approach, termed materiovigilance, has been adapted for medical devices[2].

The term materiovigilance was first introduced in Macedonian legislation through the enactment of the Law on Medicines and Medical Devices in 2007[3]. In the preceding law[4] incidents resulting from the use of medical devices were referenced. The current law defines materiovigilance as a system designed to detect, collect, monitor, evaluate, and ensure the appropriateness of new safety data concerning medical devices and potential incidents of use[3]. Alongside this law, the Agency for Medicines and Medical devices of Republic of North Macedonia (MALMED) was mandated to establish and maintain a materiovigilance system. The governing sublegislative document overseeing the materiovigilance system in the Republic of North Macedonia was adopted in 2016. With the recent Rulebook are regulated the methods of reporting side effects during the use of the medical device, the types of reactions they cause, the actions of health professionals and suppliers, as well as the way of organizing the system for monitoring side effects and reactions from medical device[5].

The objective of materiovigilance is to improve protection of health and safety of patients, users, and others by reducing the likelihood of reoccurrence of incidents related to medical devices elsewhere. This can be achieved by evaluating adverse event reports and dissemination of information that may reduce the likelihood of adverse events, prevent repetition of adverse events, or alleviate consequences of such repetition[6]. Accumulation of risk-benefit information about devices continues beyond the point of regulatory decision-making for market approval into the post-approval period. Various tools have been developed to specifically evaluate device performance in the post-approval setting[7]. Organizing a program and raising awareness about reporting of medical device side effects could help improve spontaneous reporting with patient and caregivers' safety[8].

The national regulatory agency, MALMED, facilitates the submission of adverse reactions to medical devices by: 1) manufacturers or holders of product registration, 2) users of medical devices (including health facilities, professionals, and patients), and 3) third parties (e.g., distributors or wholesalers)[9]. The listed entities are required to submit a report on an adverse reaction to the medical device, and based on the collected data on the adverse reactions of the medical device and identifying new knowledge related to its safety, MALMED can take measures to ensure the safety of the medical device.

Considering patients' ability to report adverse reactions and actively participate in the materiovigilance system through spontaneous reporting, our paper **aims** to assess patients' knowledge, experiences, and attitudes regarding the established materiovigilance system in the Republic of North Macedonia.

Material and method

To achieve our research aim, we conducted a cross-sectional study involving 200 patients seeking dental services at the PHI University Dental Clinical Center Ss. Panteleimon in Skopje. The study included patients aged 18-65 with at least a secondary education.

A survey questionnaire comprising 15 questions was utilized to assess patients' knowledge, experiences, and attitudes toward the materiovigilance system in our country. The collected data were statistically processed using SPSS Statistica v23 for Windows, with tests adequate to the sample characteristics. Results of the study are presented with total numbers and percentages. Chi-square test was used to find the association between two attributes at $p<0.05$ significance.

Results

Of the 200 patients included in our study, 44.5% were male and 55.5% were female. The average age of all respondents was 46.1±13.1 years. Regarding education level, 45.5% had secondary education, while 54.5% had higher education. The majority of surveyed patients, 88.5%, resided in urban areas, with only 11.5% in rural areas. In terms of ethnicity, Macedonians comprised 61.5%, Albanians 20.0%, Roma 8.5%, and others (including Turks, Serbs, Vlachs, and others) accounted for 10.0%.

Considering the purpose of our paper and the nature of the questions posed to patients, we organized the results into three parts. The first part, focusing on patients' knowledge of the materiovigilance system, is presented through two tables. The second part pertains to patients' experiences with the materiovigilance system, while the third part addresses their attitudes toward the system.

1. Patients' knowledge regarding materiovigilance system

Table 1. Summary of patient's knowledge regarding materiovigilance

Question	Affirmative answer		Negative answer		Answer not provided	
	number	%	number	%	number	%
Q1. Have you ever heard of the term materiovigilance?	6	3.0	158	79.0	36	18.0
Q2. Do you know that medical devices can cause side effects/events?	22	11.0	104	52.0	74	37.0
Q3. Has medical devices adverse event reporting system been established in the Republic of North Macedonia?	4	2.0	74	37.0	122	61.0

Table 2. Correct and incorrect answers of patient's regarding medical devices and materiovigilance

Question	Correct answer		Incorrect answer	
	number	%	number	%
Q4. Which of the following is a medical device?	34	17.0	166	83.0
Q5. Is the term medical device and medical instrument the same term?	4	2.0	196	98.0
Q6. If you consider that the system of materiovigilance is in place, which regulatory body is responsible for monitoring adverse reactions (effects) / events from a medical device?	2	1.0	198	99.0
Q7. Who do you think can report an adverse reaction (effect)/event from a medical device?	50	25.0	150	75
Q8. What is the purpose of reporting adverse reactions (effects)/events caused by the use of a medical device?	26	13.0	174	87.0

The percentage difference between confirmed and negative responses of patients, on questions shown in table no. 1, which refer to the knowledge of the materiovigilance system, is statistically significant for $p<0.05$ (Difference test, p=.0000).

In Table 2, on Question 4, 17.0% of the surveyed patients provided the accurate response acknowledging medical instruments, implantation tools, plasters, gauzes, medical technology devices, and their corresponding software as constituting medical devices. Conversely, merely 2.0% of respondents correctly identified "medical device" and "medical instrument" as synonymous terms, as indicated in Question 5. Notably, only 1.0% of participants were aware that the MALMED serves as the regulatory body responsible for monitoring adverse reactions/events stemming from medical devices, as highlighted in Question 6, indicating a concerning lack of awareness. Regarding Question 7, 25.0% of respondents correctly recognized that patients, beyond healthcare professionals, can report adverse reactions/events associated with medical device usage. However, only 13.0% of respondents correctly identified the purpose of reporting adverse reactions/events as enhancing patient safety, as presented in Question 8. There is a statistically significant percentage difference between respondents providing correct versus incorrect answers (Difference test, $p < 0.05$, $p = 0.0000$

2. Patients' experience regarding materiovigilance system

Table 3. Summary of patient's experience regarding an adverse reaction (effect) / event caused by the use of a medical device

Question	Affirmative answer		Negative answer		Answer not provided	
	number	%	number	%	number	%
Q9. Have you ever had an adverse reaction (effect)/event caused by the use of a medical device?	0	0	118	59.0	82	41.0
Q10. Have you ever seen an adverse reaction (effect)/event from a medication that happened to someone else?	0	0	80	40.0	120	60.0
Q11. Have you ever reported an adverse reaction (effect)/event caused by the use of a medical device?Q8. What is the purpose of reporting adverse reactions (effects)/events caused by the use of a medical device?	0	0	200	100.0	0	0

The percentage difference between those who gave an affirmative answer versus those who gave a negative answer of the questions presented in table 3 is statistically significant for $p<0.05$ (Difference test, p=.0000).

3. Summary of patient's attitudes regarding materiovigilance

Table 4. Summary of patient's attitudes regarding materiovigilance

Question	Affirmative answer		Negative answer		Answer not provided	
	number	%	number	%	number	%
Q12. Do you think it is necessary to report adverse reactions (effects)/events from the use of medical devices?	98	49.0	58	29.0	44	22.0
Q13. Do you think that establishing a system for reporting adverse reactions (effects)/events from medical devices is useful for the public?	82	41.0	80	40.0	38	19.0
Q14. Do you think that patients should know that they can report adverse reactions (effects)/events from the medical device?	4	2.0	188	94.0	8	4.0

Regarding Question 12, a statistically significant percentage difference was observed between respondents who affirmed versus those who negated, with a p-value less than 0.05 (Difference test, $p = 0.0207$), underscoring the importance of the findings. For the Question 13, the percentage difference between respondents exhibiting positive versus negative attitudes was statistically insignificant, with a p-value greater than 0.05, indicating no significant association (Difference test, $p > 0.05$). No significant associations were found between gender, age (above and below 40 years), level of education, place of residence, and ethnicity, and the responses to Question 13. Regarding Question 14, a statistically significant percentage difference was observed between respondents who

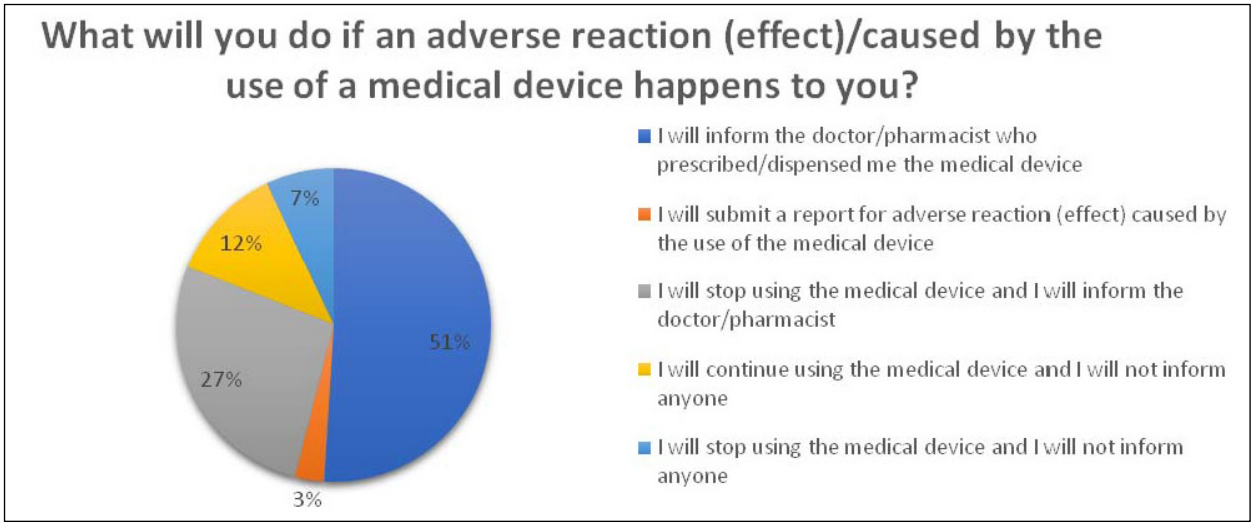

Chart 1. *Responses of patients in their behavior if an adverse reaction (effect) / event caused by the use of a medical device occurs*

answered affirmatively versus those who did not, with a p-value less than 0.05 (Difference test, p=0.0000), highlighting the significance of the response pattern.

The percentage difference between those who give an answer that they will inform the doctor/pharmacist who prescribed/issued the medical device versus those who give other answers is statistically significant for p<0.05 (Difference test, p=.0000).

Discussion

Adverse medical device events, particularly those among higher risk devices with serious negative implications for patient outcomes, have garnered widespread attention through media reports and even litigation, and calls to action for implementing measures that balance access to innovative medical devices with strategies that minimise associated risk and enhance patient safety[10]. The best evidence suggests that medical devices can also cause substantial harm. Errors that underlie device-related injuries are often categorised into three groups: manufacturer-related errors, user errors and use or design errors[11]. In the United State of America (USA), more than 1 million adverse medical device events occur annually, at a rate of 6.3 events per 1000 patient days[12]. Studies conducted by World Health Organization (WHO) suggest that adverse medical device events might be particularly problematic in developing countries, where medical equipment is often improperly maintained or replaced, placing patients at great risk[13,14]. One study from a transitional nation found that the rates of infection from medical devices alone were 34.2 per 1000 patient days in the hospital[14].

Within the available literature, only one study has examined patients' knowledge and attitudes regarding the materiovigilance system. The sole paper addressing this topic, authored by Aslani P. et al., explored the knowledge and attitudes of 29 patients/users in Sydney, Australia, concerning medical devices and the reporting of adverse events stemming from their usage. Consequently, our research aims to juxtapose the findings of our study with those obtained in this aforementioned investigation[15].

In our survey, we aimed to evaluate patients' knowledge regarding medical devices by prompting them to identify what constitutes a medical device. However, only 17.0% of respondents provided a correct answer, while 83.0% provided incorrect responses. The statistically significant percentage difference between those who provided correct versus incorrect answers underscores the need for improved awareness (Difference test, p = 0.0000). Similarly, when asked if the term "medical device" is synonymous with "medical instrument," only 2.0% of respondents answered correctly. Again, a statistically significant percentage difference was noted between correct and incorrect responses (Difference test, p = 0.0000). Contrary to our findings, the study conducted by Aslani P. et al.[15]. revealed that patients exhibited a robust understanding of medical devices. Through enumerating various types of medical devices, the authors concluded that respondents possessed familiarity with the term "medical device." Compared to our respondents, those in the aforementioned study demonstrated superior knowledge regarding medical devices.

When queried about their awareness of the potential for medical devices to cause unwanted reactions or

effects, only 11.0% of respondents acknowledged this possibility. In contrast, the study by Aslani P. et al.[15] revealed that all respondents were familiar with adverse events and their association with medical device usage.

In our study, respondents were asked if they had ever experienced or witnessed adverse reactions or events resulting from medical device use, to which none responded affirmatively. Conversely, in a study conducted in Australia, several patients reported experiencing adverse reactions caused by medical device usage[15]. This discrepancy suggests that our patients may have insufficient awareness of potential adverse events or may consider them to be normal occurrences. This perception could stem from inadequate health education. This perspective is corroborated by the findings of Tong V. et al.[16], which highlight how patients comprehend information about side effects. However, it's essential to note that the disparity between our results and those of the Sydney study could be attributed to differences in sample size and methodological approaches. Our study included 200 respondents and utilized a survey questionnaire, while Aslani P. et al.[15] employed focus groups and direct interaction with 29 respondents to ascertain their knowledge and attitudes regarding medical devices and adverse event reporting.

In our survey, questions were incorporated to gauge patients' knowledge about the materiovigilance system. Our findings indicate a lack of awareness among patients regarding the existence of the materiovigilance system in our country, the regulatory body responsible for monitoring adverse reactions/events from medical devices, and the purpose of reporting such events. Remarkably, 96.0% of respondents had not even heard of the term "materiovigilance." Similarly, insufficient knowledge about reporting adverse events was noted in the study conducted by Aslani P. et al.[15]. The majority of respondents in their study were unaware of the regulatory body responsible for monitoring adverse drug events and the purpose of reporting. We hypothesize that our respondents' lack of awareness may stem from their limited prior experience with adverse events resulting from medical device usage. Notably, none of our respondents reported experiencing adverse reactions/events caused by medical devices, thereby obviating the need for knowledge about reporting channels.

In contrast, respondents in the study by Aslani P. et al.[15] expressed support for reporting adverse reactions/events through national platforms, indicating a divergence in attitudes between our respondents and theirs.

When queried about their course of action in the event of experiencing an adverse reaction/event from the use of a medical device, our survey revealed various responses among respondents. Fifty-one percent indicated they would inform the doctor/pharmacist who prescribed/dispensed the medical device, while 3.0% stated they would file a report for adverse reaction to the medical device. Additionally, 27.0% expressed they would cease using the medical device and inform the doctor/pharmacist, whereas 12.0% would continue usage without informing anyone. Seven percent declared they would discontinue usage without informing anyone. In a study conducted in Australia[15], respondents exhibited a preference for reporting adverse events caused by medical device usage to their doctor. The authors attributed this preference to the nature of medical devices, including the potential for implantation, and the challenges in distinguishing whether adverse effects are related to usage or integral to treatment. However, depending on the severity of the side effect, a substantial number of respondents indicated they would report the event to the manufacturer. This inclination may facilitate the promotion of spontaneous reporting, as manufacturers are obligated to report adverse events to regulatory bodies. Patients have the option to report adverse events directly to regulatory bodies or through manufacturers, who can provide additional data on adverse effects of medical device usage. Pharmaceutical companies play a pivotal role in both medical device and drug vigilance systems[17].

Manufacturers, government agencies, medical practitioners, and patients/caregivers must cooperate closely for a materiovigilance program to be successful[18]. Social media, like LinkedIn, Facebook, Twitter, YouTube, help to provide users with rapid and up-to-date information on rational selection and undesired events and promote health- and science-related developments and issues[19]. This will ultimately make the users and practitioners aware of the latest regulatory actions or provisions related to the device[2].

Consumers in the USA are somewhat aware of reporting MDAEs like quality issues and administration errors experienced with devices and filling the Form FDA 3500B and reporting via MedWatch voluntary reporting system[20]. In Australia, the Therapeutic Goods Administration (TGA) has developed a website to empower the users' reporting practice[21]. Similarly, in New Zealand, the MedSafe system developed a form for the consumers to be filled in the Word document format and send via email on its website[22]. The reporting by the consumers helps practitioners, pharmacists, and policymakers to know the users' perspectives and concerns on devices in strengthening the reporting systems and ultimately in focusing on the quality products[2].

In order to maintain patient safety and the materiovigilance program, it is imperative that any adverse

events associated to devices are appropriately reported. A benefit-risk ratio will be established as a result of the ongoing collection of adverse reactions and the signal detection procedure, which will assist provide data about the dangers and advantages of the devices. Since materiovigilance is a continuous process, the information gathered over time will assist patients and healthcare providers in making more educated decisions[18].

Conclusions

The patients in our study had minimal knowledge of the materiovigilance system and their negative attitude towards reporting adverse events caused by the use of a medical device is worrying. We assume that greater implementation of the materiovigilance system and cooperation between universities, healthcare professionals, patients, manufacturers, government and national agencies, media, civil society and international organizations working on medical device safety is needed.

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