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Adverse Reactions and Complication in Voluntary Blood Donors

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ABSTRACT

Background: Blood transfusion is a process by which blood replacement is performed in the treatment of various diseases with disorders of the number or function of blood cells or after bleeding. Blood helps save human lives and treat various diseases. Blood and blood products for the treatment of patients are prepared from the blood of voluntary donors. **Objective:** The aim of this study was to examine the frequency of adverse reactions in voluntary blood donors at the Polyclinic for Transfusion at the University Clinical Center Tuzla in the period January 1-December 31, 2021. and, also, to determining the frequency, is to determine the severity of adverse reactions and the causes that led to them (gender, age, place of donation, whether they are more common during the first or repeated blood donation) as well as the consequences they leave behind. **Methods:** Our research includes voluntary blood donors who, in the period from January 1, 2021 until December 31, 2021, donated blood at the Polyclinic for Transfusion at the University Clinical Center Tuzla (UCC Tuzla). All donors have been selected according to earlier set criteria, according to the recommendations of the World Health Organization and the Council of Europe, involving age (≥18 years), weight (≥55kg), hemoglobin level (≥125g/dl for women, ≥135g/dl for men), hematocrit level (≥38% for women, ≥41g/dl for men), pulse (50-100 /min) and blood pressure (120/80-160/100mmHg). Each donor voluntarily filled out a uniformed questionnaire that involved data about personal and family history, as well as prior blood donations. **Results:** In the Polyclinic for Transfusion UCC Tuzla, a study was conducted about adverse reactions among voluntary blood donors. During 2021 there were 14191 blood donors. From that number of donors, there were 75,4% (107000) fitting donors, while those who have been returned because they haven't satisfied donating criteria were 24,6% (3487). From the number of those who have donated blood (10700), negative reactions appeared in 1,8% (195) blood donors. When it comes to gender, adverse reactions were recorded in 75,9% (148) male donors and 24,1% (47) female donors concerning the total number of donors with adverse reactions. Our research showed that the prevalence of adverse reactions in voluntary blood donors is relatively low (1.8%). The adverse reactions are the result of vasovagal reactions, and most often occur in younger people (18 to 30 years old) in 55.9% of donors. **Conclusion:** Considering the low percentage of adverse reactions in relation to the total number of blood donors, and that they are mostly mild in intensity, it can be concluded that donating blood is safe process, and doesn't leave lasting consequences for the blood donor's health, and every donor returns to daily activities very quickly.

Keywords: voluntary blood donors, adverse reactions, complications.

1. BACKGROUND

Blood transfusion is a process by which blood replacement is performed in the treatment of various diseases with disorders of the number or function of blood cells or after bleeding. Blood helps save human lives and treat various diseases. Blood and blood products for the treatment of patients are prepared from the blood of voluntary donors. Blood donors can be every healthy person who can donate 350ml-450ml of blood without any negative outcome, without receiving any financial compensation (1, 2). New voluntary

blood donor is the donor who has never donated blood before. Regular voluntary donor is a voluntary non-remunerated blood donor who donates blood on a regular basis without a long break each year. Family or replacement blood donor is a donor who gives blood when it is required by a member of the patient's family or community (3). Before donating blood, a medical examination of the donor is performed which determines the state of health of the donors who came to donate blood. After the examination, the doctor decides whether the donor can donate blood. The doctor adheres to the adopted Criteria for the selection of donors and the Criteria for permanent and temporary postponement of blood donation (10). However, some donors may experience adverse reaction before, during and after donating blood. The etiology of these reactions is different. In general, it is considered that fear is the main cause of these reactions and the biggest percentage appears with first-time blood donors and it decreases with every following blood donation. How different etiological factors affect the appearance of these reactions in donors can be seen by the fact that the donor collapses before or shows any unwanted reaction after donating blood, if blood is drawn without solid prior psychological preparation, in conditions of crowding and improvisation (4). Donation blood from healthy donors ensures the availability of blood components for transfusion, which is a fundamental principle of modern health care (5, 6). Adverse reaction before, during and 6 to 8 hours after blood donation are most often the result of sudden hemodynamic changes caused by the acute loss of certain amount of blood (350-500ml) to which the donor's cardiovascular system cannot quickly adapt. The frequency of complication during blood donation is 3-5% (1). According to the International Society of Blood Transfusion (ISBT) and the Working Group for the European/International Hemovigilance Network (EHN/IHN) which provided a standing for monitoring complications related to blood donation (EHN/IHN and ISBT version 2007, 2008, 2014) given explanation of the categorization of adverse reactions. They are divided into local and general, and generally are further classified into mild, moderate and severe (7, 8). General reactions are usually due to vasovagal response (VVR) or hyperventilation. VVR represents the reaction of the neurovegetative system to stress, which, in addition to emotional excitement, can also be caused by acute blood loss. Central thalamic pathways in the central nervous system are stimulated by emotions and hyperventilation. In the first phase there is an increase in stroke volume and peripheral vascular resistance, and thus an increase in arterial blood pressure, and in the second phase, a decrease in peripheral vascular sympathetic activity vasodilatation, hypotension and a decrease in blood flow to the brain. The activity of ventricular baroreceptors decrease with age, so younger people are predisposed, and older people are less susceptible to VVR (7,9). Mild side effects (weakness, lassitude, sweating, rapid breathing, dizziness, nausea, increased nervousness, excitement) were observed in about 50%, medium (dizzines followed by short-term loss of consciousness, vomiting) in about 40-45%, and severe reactions requiring third-party assistance-intervention to prevent permanent impairment of body function (convulsions, incontinence, tonic-clonic spasms, urination and defecation, prolonged loss of consciousness, temporary cessation of breathing with cyanosis) in 1 to 3% of blood donors (1, 4, 8, 10). All potential blood donors fill out and sign the Blood Donor Questionnaire (personal anamnestic data on health status, habits and travel) for each blood donation which is standardized and created based on the recommendations of the Council of Europe (7, 11). There is a positive correlation between the occurrence of acute and late complication during blood donation and age, gender, weight and psychological factors (fear, nervousness, complications during previous blood donations) (1).

2. OBJECTIVE

Voluntary blood donation is the collection of blood and its components necessary for treatment and application in the most urgent situations. Therefore, with this paper, we wanted to examine the frequency of adverse reactions in voluntary blood donors at the Polyclinic for Transfusion at the University Clinical Center Tuzla in the period 01.01.-31.12.2021. The objectives of paper, in addition to determining the frequency, is to determine the severity of adverse reactions and the causes that led to them (gender, age, place of donation, whether they are more common during the first or repeated blood donation) as well as the consequences they leave behind.

3. MATERIAL AND METHODS

Our research includes voluntary blood donors who, in the period from January 1, 2021 until December 31, 2021, donated blood at the Polyclinic for Transfusion at the University Clinical Center Tuzla (UCC Tuzla). All donors have been selected according to earlier set criteria, according to the recommendations of the World Health Organization and the Council of Europe (12, 13), involving age (≥18 years), weight (≥55kg), hemoglobin level (≥125g/dl for women, ≥135g/dl for men), hematocrit level (≥38% for women, ≥41g/dl for men), pulse (50-100 / min) and blood pressure (120/80-160/100mmHg). Each donor voluntarily filled out a uniformed questionnaire that involved data about personal and family history, as well as prior blood donations. All donors have been informed to restrain from cigarettes 2 hours before and after donating blood and that they are obligated to have breakfast and input a lot of fluid before donating and that they should stay for observation 10-15 minutes after donating. For the purpose of writing this paper we used the retrospective data from the information system of Polyclinic for Blood Transfusion UCC Tuzla in the specified period. We used the information about the total number of donors, and the number of donors who have had some negative reactions before, during, and after donating blood. We have taken into consideration information related to sex, age, whether they are multiple or first-time donors, the type of donation (family/replacement or self-initiative/regular voluntary blood donors), and place of donating (whether it is inside the facility or

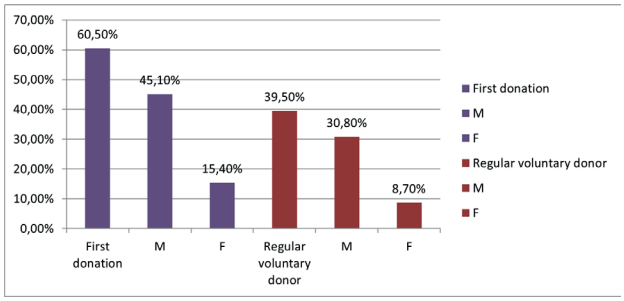

Figure 1. Adverse reaction in relation to the number of blood donations and gender (Regular voluntary donor-who donate blood several times a year, M-male, F-female blood donors)

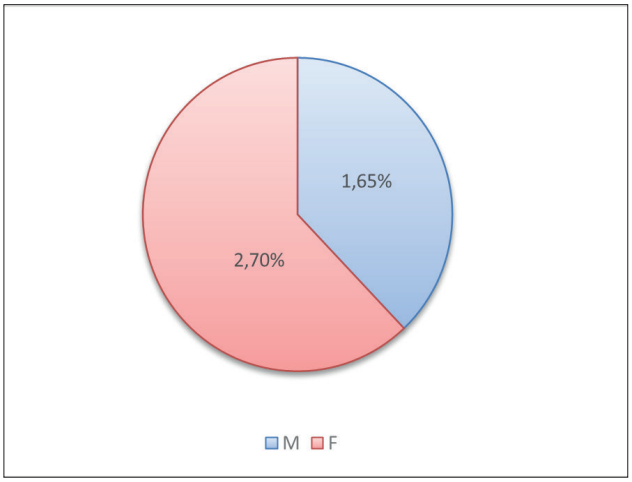

Figure 2. Adverse reaction in relation to gender (M-male, F-female)

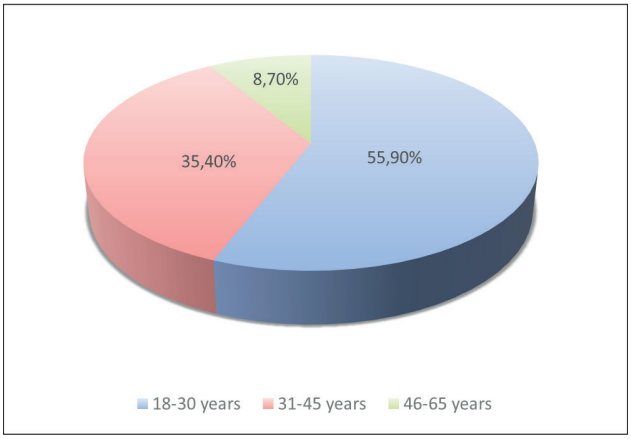

Figure 3. Adverse reaction according to age

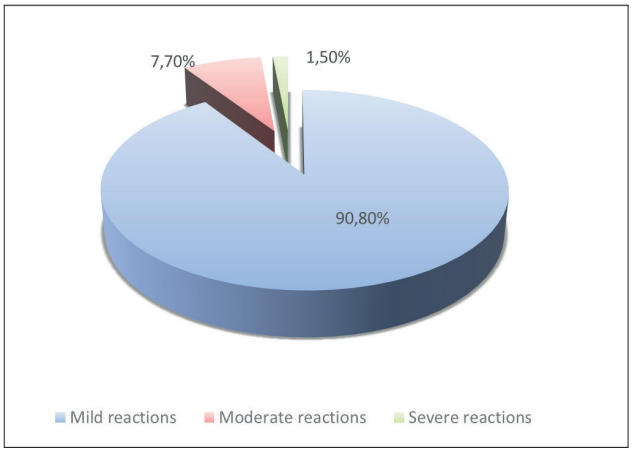

Figure 4. Adverse reaction according to the severity of the occurrence

actions organized outside the facility of the Polyclinic). We have also used available anamnestic information about the possible cause of adverse reactions. Data were collected using Microsoft Excel tables. For the statistical analysis, we used standard statistic parameters (average value, standard methods (%), Hi square test, Med Calc's statistical calculator and SPSS Statistics free calculator), and $p<0,05$ is considered significant. For the collection and publication of data we have received the consent of the Ethics Committee of the UCC Tuzla.

4. RESULTS

In the Polyclinic for Transfusion UCC Tuzla, a study was conducted about adverse reactions among voluntary blood donors. During 2021 there were 14191 blood donors. From that number of donors, there were 75,4% (107000) fitting donors, while those who have been returned because they haven't satisfied donating criteria were 24,6% (3487). From the number of those who have donated blood (10700), negative reactions appeared in 1,8% (195) blood donors. Figure 1 shows adverse reactions in relation to the number of blood donations and gender. When it comes to gender, adverse reactions were recorded in 75,9% (148) male donors and 24,1% (47) female donors concerning the total number of donors with adverse reactions.

In relation to the total number of donors, there were 83,9% (8977) male donors, and 16,1 (1723) female blood donors. Figure 2 shows adverse reaction in relation to gender, from the total number of male and female blood donors.

In relation to gender, adverse reaction occur more often in female than in male blood donors by 1.1%.

Figure 3 shows the number of adverse reactions according to age, blood donors are divided into three groups. The P value is statistically significant with $p<0,05$ which indicates that there is a significant difference in the donor's age in the occurrence of unwanted effects, and they occur more often in younger blood donors in group from 18 to 30 years old ($p=0.0008$).

Concerning the place of donating blood adverse reactions inside the Polyclinic for Transfusion were recorded in 1.46% (156) blood donors, which is 1,1% more than organized actions outside the facility, where was 0.36% (39) reactions. The data show that there is a statistically significant difference in relation to the place of blood donation, adverse reactions occur more often when donating blood in the facility compared to organized actions outside the institution ($p=0.0003$).

Figure 4 shows the adverse reactions in relation to the severity of the reactions.

Table 1 shows the types of the most common adverse reactions, labeled as mild, moderate and severe adverse reactions. There is a statistical significant difference in the occurrence between mild and moderate and severe complications, mild reactions occur more often ($p=0.002$).

According to the type of donation, the most common

Type of adverse reactions	Number	Percentage (%)
Mild adverse reactions		
Dizzines	62	31.8
Nausea	57	29.2
Pallor	31	15.9
Feeling of warmth and discomfort, malaise	22	11.3
Moderate and severe adverse reactions		
Short-term loss of consciousness	15	7.7
Sweating with loss of consciousness	3	1.5
Tonic-clonic convulsions	3	1.5
Vomiting	1	0.5
Headache after donation	1	0.5

Table 1. The type of adverse reactions

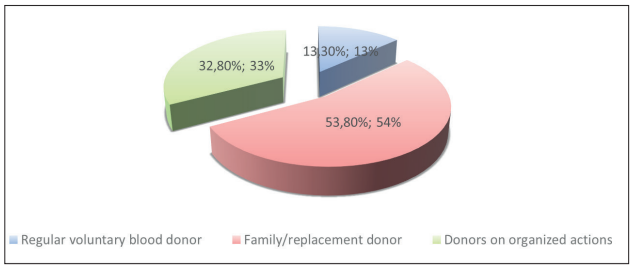

Figure 5. Adverse reactions according to the type of blood donor: Regular voluntary blood donor (donor who donated blood on their own initiative), family/replacement donor (who donate blood for a specific patient, relative or friend), donors on organized actions (blood donors who donate blood at organized donation drives outside the Polyclinic for Transfusiology in other companies, local communities..)

adverse reactions were registered with family/replacement donors (these are donors who came to donate blood for a specific patient).

Figure 5 shows the number of adverse reactions according to the type of blood donors. There is a statistically significant difference between blood donors. Adverse reactions occur more often in donors who came to donate blood for a specific patient (p=0.001).

Adverse reactions occur more often in donors who came to donate blood for the first time (60,5%) compared to multiple blood donors (39,5%) by 21 %. Adverse reactions occurred during puncture in 55,4% (108) of blood donors, and after a puncture in 44,6% (87) of the total number of adverse reactions.

5. DISCUSSION

The Polyclinic for Transfusion Medicine has the responsibility to ensure blood supplies for the needs of patients, and ensure maximum blood donors' safety. An Italian study 2007, revealed the prevalence of 1,2% of adverse reactions (14). A large study from Japan from 2013, of 98.389 blood donors reported a positive adverse reaction rate of 2,8% (15). The results from Pakistan match a 2012 study in India, which demonstrated adverse events in 2,5% of healthy blood donors (16). A relatively high prevalence of 4,9% was demonstrated in a study in Bangladesh, which was performed in a randomized selection of whole blood donors (17). In our research, adverse reactions were registered in 1,82% of blood donors to the total number of blood donors. A study from Pakistan in 2016. Showed a higher number of adverse reactions in donors younger than 30 years (349 subjects out of 537 reported reactions) (5). Our results show that adverse reactions occur more often in donors between the ages of 18 and 30, 55,9% of blood donors. A study conducted in India, in 2016, reported that adverse reactions occur 4 times more often in female blood donors, with general symptoms (women: 6.5%, men: 1.74%) (18), our results showed more frequent occurrence of adverse reactions in female blood donors compared to the total number of women who donated blood (women: 2.7%, men: 1.65%). In India in 2020, out of 116 reported adverse reactions, 70.7% were in female and 29.3% in men, in donors who donate blood first time adverse reactions occurred in 81.1% and 18.9% in regular voluntary blood donors (19). In our study, of the 195 reported reactions, 75.9% occurred in male blood donors and 24.1% in female, than in 60.5% in donor who donated blood first time and 39.5% in regular voluntary blood donors. In a descriptive study in a Nigerian hospital in 2017, mild reactions occurred in 78.26% and severe reactions in 27.4% (20). In study in India, 2020., 76% donors had mild, 18% moderate and 6% severe reactions (21). Of the total number of adverse reactions, 90,8% of donors had a mild form, 7,7% were moderately severe and 1,54% were severe. Compared to a study conducted in Brazil where almost 95% of donors had mild reactions, 4.6% moderate and 0.9% severe adverse reactions (22). In the Center for Transfusion medicine Split, the most common reactions were mild intensity (23). Like other authors, severe reactions were 6% in India in 2020. (21), 0.9% severe reaction in Brazil, in 2012. (22), we had a low incidence of serious side effects (1.5%) and didn't report severe events such as myocardial infarction or thrombophlebitis, which are really rare unwanted complications of blood donation. The frequency of donor adverse reactions could have a negative impact on donor return rates. Donors will refrain from re-donating, which reduces the blood supply in donor centers (24). About 9% of donors who had an adverse reaction during the first donation did not return to donate blood (25).

6. CONCLUSION

Our research showed that the prevalence of adverse reactions in voluntary blood donors is relatively low (1.8%). The adverse reactions are the result of vasovagal reactions, and most often occur in younger people (18 to 30 years old) in 55.9% of donors. Considering the low percentage of adverse reactions in relation to the total number of blood donors, and that they are mostly mild in intensity, it can be concluded that donating blood is safe process, and doesn't leave lasting consequences for the blood donor's health, and every donor returns to daily activities very quickly.

Limitation of the study

The research was conducted only in one transfusion center in Bosnia and Herzegovina, which could be considered as study limitation, as well as the lack of data on

adverse reactions of donors from other centers in BiH and the region. In the future, all transfusion centers in BiH and region should conducted a multicenter study about adverse reactions in blood donors on a larger number of subjects, with the aim of proving that it is a safe process, without harmful consequences and that it does occur in very low percentage. In this way, we would additionally motivate the younger population to donate blood, because this is the only way we can ensure sufficient supplies of blood for the patient's treatment.

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REFERENCES

1. Grgičević D., Transfuzijska medicina, Medicinska naklada Zagreb, 1995: 98-102.
2. Balint B., Transfuziologija, Zavod za udžbenike i nastavna sredstva, Beograd, 2004: 223-240.
3. State blood Transfusion Council, Uttar Pradesh, Definition related to blood donors/donations. Available online at: http://sbtcup.org/Defination.aspx (accessed on 21 January 2023).
4. Bošković S. Transfuziologija, Svjetlost Sarajevo, 1981: 36-40.
5. Sultan S, Amjad Baig M. et all, Adverse Reactions in Allogeneic Blood Donors: A Tertiary Care Experience from a Developing Country. Oman Med J. 2016; 31(2): 124-128. doi: 10.5001/omj.2016.24.
6. Eder AF, Dy BA, Kennedy JM, Notari EP, Strupp A, Wissel ME, et al. The American Red Cross donor hemovigilance program: Complications of blood donation reported in 2006. Transfusion. 2008; 48(9): 1809-1819. doi: 10.1111/j.1537-2995.2008.01811.x.
7. Kovač M, Balint B, Bogdanović G., Bazična i klinička transfuziologija, Medicinski fakultet Univerziteta u Beogradu, Akademska misao Beograd, 2020: 65-68.
8. Working group on Complication related to Blood donation, International Society of Blood Transfusion Working Party on Haemovigilance and European Hemovigilance Network (2008), Standard for Surveillance of Complications Related to Blood Donation. Retrieved March18 2010. Available: http://www.isbt-web.org/documentation/default.asp (accessed on: 18 January 2023).
9. Popovski MA, Vasovagal donor reactions: An important issue with implication for the blood supply. Transfusion. 2002; 42(12): 1534-1536. doi: 10.1046/j.1537-2995.2002.00297.x.
10. European Committee on Blood Transfusion. Guide to the preparation, use and quality assurance of blood components.19th ed.Strasbourg, France:European Directorate for the Quality of Medicines and Health Care, 2016. Availabe on: https://www.edqm.eu/en/blood-guide (accessed on: 18 January 2023).
11. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. Official Journal of the European Union, L33,8/02/2003.
12. Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components. EUROPA; 2004. Available: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:091:0025:0039:EN:PDF (accessed on 20 January 2023).
13. Blood donor selection Guidelines on Assessing Donor Suitability for Blood Donation, 2012. Available at: https://apps.who.int/iris/bitstream/handle/10665/76724/9789241548519_eng.pdf (accessed on 20 January 2023).
14. Crocco A. And D□Elia D., Adverse reactions during voluntary donation of blood and/or blood components. A statistical-epidemiological study. Blood Transfus. 2007; 5(3): 143–152. doi: 10.2450/2007.0005-07
15. Inaba S, Takanashi M, Matsuzaki K, Ono Y, Nakajima K, Shibata R, et al. Analysis of a questionnaire on adverse reactions to blood donation in Japan. Transfus Apher Sci. 2013; 48(1): 21-34. doi: 10.1016/j.transci.2012.07.012.
16. Agnihotri N, Marwaha N, Sharma RR. Analysis of adverse events and predisposing factors in voluntary and replacement whole blood donors: A study from north India. Asian J Transfus Sci. 2012; 6(2): 155-160. doi: 10.4103/0973-6247.98922.
17. Mahbub-ul-Alam M, Hyder MS, Khan MB, Islam MA. Adverse donor reaction during and immediately after Venesection. TAJ: Journal of Teachers Association 2007; 20(1): 39-47, doi: https://doi.org/10.3329/taj.v20i1.3088.
18. Kumar Agarwal R, Periyavan S. Complications related to blood donation: A multicenter study of the prevalence and influencing factors in voluntary blood donation camps in Karnataka, India. Asian J Transfus Sci. 2016; 10(1): 53-58. doi: 10.4103/0973-6247.165840.
19. Sandhya M, Purushottam R, Sowmya TS, Adverse Reactions in Whole Blood Donors: An Experience in a Tertiary Health Care Centre. Saudi Journal of Pathology and Microbiology. 2020. doi: 10.36348/sjpm.2020.v05i12.007.
20. Aneke John C, Ezeh Theodora U, Nwosu Gloria A, Anumba Chika E, Adverse reactions to blood donation: A descriptive study of 3520 blood donors in a Nigerian tertiary hospital. Med J DY Patil Univ. 2017; 10: 36-40. doi: 10.4103/0975-2870.197894.
21. Navkudkar A, Desai P, Rajadhakshaya S. Post-donation telephonic interview: A tool for active follow-up of voluntary whole blood donors for analysis of frequency and predisposing factors of adverse reactions. Indian J Med Sci. 2021; 73(3): 317-22. doi:10.25259/IJMS_499_2020.
22. Goncalez TT, Sabino CC. et all, Vasovagal reactions in whole blood donors at three REDS-II blood centers in Brazil, Transfusion 2012; 52(5): 1070-1078. doi:10.1111/j.1537-2995.2011.03432.x.
23. Lušić M. Reakcije i komplikacije kod dobrovoljnih darivatelja krvi u Centru za transfuzijsku medicinu KBC Split od 2013. do 2015., Master's thesis / Diplomski rad 2016. Available online at: https://urn.nsk.hr/urn:nbn:hr:176:772385 (accessed on: 26 December 2022).
24. Dogra A, Sidhu M, Dogra M, Raina TR. Study of adverse whole blood donor reactions in normal healthy blood donors: Experience of tertiary health care centre in Jammu region. Indian J Hematol Blood Transfus. 2015; 31(1): 142-145. doi: 10.1007/s12288-014-0396-y
25. Van Dongen A, Abraham C, Ruiter RA, Veldhuizen IJ. The influence of adverse reactions, subjective distress, and anxiety on retention of first time blood donors. Transfusion. 2013; 53(2): 337 343. doi: 10.1111/j.1537-2995.2012.03810.x.