ORIGINAL ARTICLE
(CC BY-SA)
UDC: 174::616.12-089]:614.253.83
DOI: https://doi.org/10.2298/VSP200115029K

Informed consent in cardiac surgery – current institutional practice and legislation

Pristanak informisanog pacijenta u kardiohirurgiji – aktuelna institucionalna praksa i zakonodavstvo

Milica Karadžić Kočica*†, Hristina Ugrinović*†, Miloš Grujić†‡, Dejan Lazović†, Filip Vučićević†, Goran Panić†, Mladen Kočica†

University Clinical Center of Serbia, *Center for Anaesthesiology, Reanimatology and Intensive Therapy, †Clinic for Cardiac Surgery, Belgrade, Serbia; ‡University of Belgrade, Faculty of Medicine, Belgrade, Serbia

Abstract

Background/Aim. Growing waiting lists for cardiac surgery have become a real problem in the Republic of Serbia, imposing serious difficulties in patient-surgeon communication. The aim of the study was to determine the current state of the institutional informed consent policy before elective cardiac surgical procedures in light of actual national legislation. **Methods.** An anonymous, voluntary survey was conducted among 200 consecutive patients at the Clinic for Cardiac Surgery, University Clinical Centre of Serbia, from September to December 2019, after signing an official institutional consent form. A targeted questionnaire was created to determine the quantity and quality of patients' information about general and the most important aspects of cardiac surgical care. **Results.** The mean age of respondents was 66.2 years, with male predominance (68.0%), homogenous ethnicity, and low-to-middle (84.0%) education levels. A significant percentage had no information on the type of surgery (16.0%), extracorporeal circulation (46.0%), anaesthesia (56.0%) and transfusion (51.5%). Of those having some information, 7.0–20.0% graded them sufficient. The worst situation was recorded concerning risks of disease and surgical treatment, where 88.0% of patients had no information and almost 90.0% had some information and graded them as non-sufficient. Surprisingly, 81.5% of patients signed the consent form without any prior discussion with the operating surgeon. For 56.0% of patients, the information in the actual consent form was clear and sufficient. While 85.5% of patients claimed the importance, the others (14.5%) were not interested to know the most relevant information about their disease and surgery. **Conclusion.** The results unambiguously indicate an unacceptably low level of our patients' information about the cardiac surgical procedure, extracorporeal circulation, anesthesia, transfusion, and estimated risk. The majority of them (85.5%) comprehends the importance and expects timely and adequate information. An extremely high percentage (81.5%) of patients had no chance to discuss the procedure with the operating surgeon. Both surgical indifference and insufficient knowledge of professional, ethical, and legal importance are the most important reasons for the actual informed consent policy in cardiac surgery.

Key words:
ethic, medical; informed consent; legislation; physician-patient relation; risk assessment; therapeutics; thoracic surgery; serbia.

Apstrakt

Uvod/Ciljevi. Sve duže liste čekanja za kardiohirurgiju u Republici Srbiji postale su problem i ozbiljno otežavaju komunikaciju između lekara i bolesnika. Cilj rada bio je da se u svetlu aktuelnog nacionalnog zakonodavstva utvrdi trenutno stanje institucionalne prakse pristanka informisanog pacijenta pre elektivnih kardiohirurških operacija. **Metode.** Istraživanje je sprovedeno na 200 uzastopnih bolesnika, koji su potpisali zvanični obrazac o pristanku inforimsanog pacijenta u Klinici za kardiohirurgiju Univerzitetskog Kliničkog centra Srbije, od septembra do decembra 2019. godine. Za tu potrebu, kreiran je ciljani upitnik za utvrđivanje kvaliteta i kvantiteta informacija o opštim i najvažnijim aspektima kardiohirurške nege. **Rezultati.** Srednja starost ispitanika bila je 66,2 godine, sa predominacijom bolesnika muškog pola (68,0%), homogenom etničkom pripadnošću i niskim ili srednjim (84,0%) nivoom obrazovanja. Značajan procenat bolesnika nije bio informisan o vrsti hirurgije (16,0%), vantelesnom krvotoku (46,0%), anesteziji (56,0%) i transfuziji (51,5%). Od onih bolesnika koji su bili delimično informisani, 7,0–20,0% je navedene informacije ocenilo dovoljnim. Najniža informisanost zabeležena je u pogledu informisanosti o rizicima od bolesti i hirurškog lečenja, gde

Correspondence to: Mladen J. Kočica, University Clinical Center of Serbia, Clinic for Cardiac Surgery, Dr. Kosta Todorović 8, 11 000, Belgrade, Serbia. E-mail: kocica@sbb.rs

88,0% bolesnika nije imalo nikakve informacije, dok je skoro 90,0% delimično informisanih ocenilo te informacije kao nedovoljne. Čak 81,5% bolesnika potpisalo je saglasnost za operaciju bez ikakve prethodne konsultacije sa svojim hirurgom. Za 56,0% bolesnika informacije u aktuelnom obrascu pristanka informisanog pacijenta okarakterisane su kao jasne i dovoljne. Dok je 85,5% bolesnika tvrdilo da je to važno, ostali bolesnici (14,5%) nisu uopšte bili zainteresovani za dobijanje najvažnih informacija o njihovoj bolesti i operaciji. **Zaključak.** Rezultati ispitivanja ukazuju na neprihvatljivo nizak nivo informisanosti naših bolesnika o kardiohirurškom zahvatu, vantelesnoj cirkulaciji, anesteziji, transfuziji i procenjenim rizicima. Većina ispitanih bolesnika (85,5%) shvatila je važnost obaveštenosti i očekuje pravovremene i adekvatne informacije. Izuzetno visok procenat bolesnika (81,5%) bili su oni koji nisu imali priliku da razgovaraju o proceduri sa odgovornim hirurgom. Nezainteresovanost hirurga i nedovoljno poznavanje profesionalnog, etičkog i pravnog značaja pristanka informisanog pacijenta najvažniji su razlozi za trenutno stanje institucionalne prakse u vezi sa ovim pitanjem u kardiohirurgiji.

Ključne reči:
etika, medicinska; pristanak informisanog pacijenta; zakonodavstvo; lekar-bolesnik odnos; rizik, procena; lečenje; hirurgija, torakalna; srbija.

Introduction

Patient-centered care is widely recognized as a core dimension of quality and one of the most pressing priorities in modern healthcare systems. Accordingly, during the last century, informed consent (IC) became a professional obligation, legal necessity, and ethical imperative [1–3]. Essentially, IC is not simply about getting a patient's signature on the consent form as a liability waiver but "…the process of providing patients with sufficient information that allows them to make a voluntary and informed decision whether to undergo or forego a procedure, provided that the information given is capable of being understood by the patient" [3]. Moreover, as a specific kind of "emotional inoculation" to the patients overwhelmed by anxiety, IC helps them develop a "psychological immunity" to the stressful effects of surgery, resulting in a better outcome [4].

Yet, in cardiac surgery and some other highly specialized areas of modern medicine, it is almost impossible to convey all the knowledge required for IC in the limited time available [5, 6].

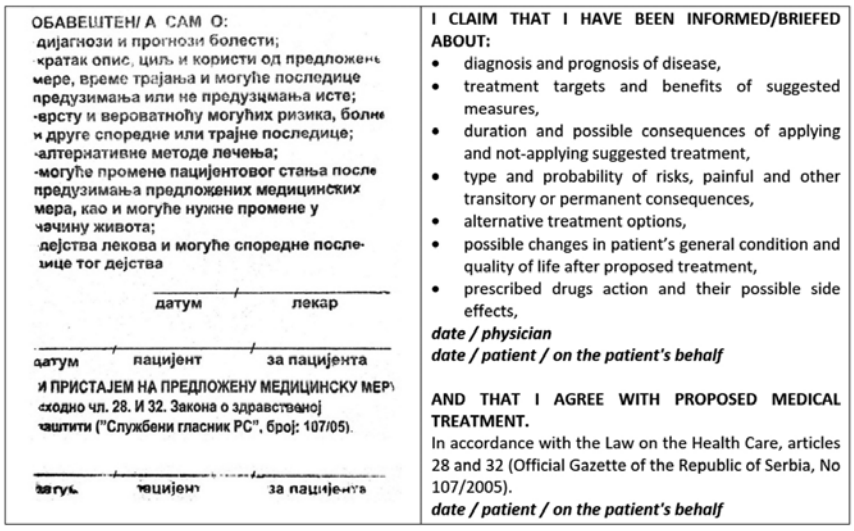
Growing waiting lists for cardiac surgery became a real and top priority problem in the Republic of Serbia (ROS), imposing serious difficulties in patient-surgeon communication. The aim of this study was to determine the current state of the IC concept before elective cardiac surgical procedures and analyze it considering actual legislation in the ROS.

Methods

The cross-sectional study, approved by the Institutional Review Board, used a targeted survey questionnaire (Supplement 1) and 200 consecutive patients admitted to the Clinic for Cardiac Surgery, Emergency Center of the University Clinical Center of Serbia, from September to December 2019, who voluntarily consented to complete it anonymously after having signed an actual consent form (Figure 1).

The first part of the questionnaire, containing 10 questions, was targeted to determine the quantity and quality of patients' information about general and the most important aspects of clinical cardiac surgical care (surgical procedure, extracorporeal circulation, anesthesia, transfusion, estimated risk). The second part of the questionnaire with three additional questions was aimed to depict a patient's opinion on the clarity and importance of information gained before surgery.

In addition, we created two completely new guides for patients bearing in mind what they should be aware of before signing the consent for cardiac surgery (Supplements 2 and 3).



ОБАВЕШТЕН/ А САМ О:
-дијагнози и прогнози болести;
-кратак опис, циљ и користи од предложен
мере, време трајања и могуће последице
предузимања или не предузимања исте;
-врсту и вероватноћу могућих ризика, болн
и друге споредне или трајне последице;
-алтернативне методе лечења;
-могуће промене пацијентовог стања после
предузимања предложених медицинских
мера, као и могуће нужне промене у
начину живота;
-дејства лекова и могуће споредне после-
дице тог дејства

датум лекар

датум пацијент за пацијента

И ПРИСТАЈЕМ НА ПРЕДЛОЖЕНУ МЕДИЦИНСКУ МЕР
сходно чл. 28. И 32. Закона о здравственој
заштити ("Службени гласник РС", број: 107/05).

датум пацијент за пацијента

I CLAIM THAT I HAVE BEEN INFORMED/BRIEFED ABOUT:

- diagnosis and prognosis of disease,
- treatment targets and benefits of suggested measures,
- duration and possible consequences of applying and not-applying suggested treatment,
- type and probability of risks, painful and other transitory or permanent consequences,
- alternative treatment options,
- possible changes in patient's general condition and quality of life after proposed treatment,
- prescribed drugs action and their possible side effects,

date / physician
date / patient / on the patient's behalf

AND THAT I AGREE WITH PROPOSED MEDICAL TREATMENT.
In accordance with the Law on the Health Care, articles 28 and 32 (Official Gazette of the Republic of Serbia, No 107/2005).
date / patient / on the patient's behalf

Fig. 1 – Left: Original consent form (stamp) currently in use in the Republic of Serbia in Serbian (Cyrillic) language; Right: The same consent form translated into the English language.

Results

The general characteristics of 200 surveyed patients are summarized in Table 1.

Table 1

Patients' general characteristics

Characteristics	Patients
Age (years)	66.2 (21–92)
Gender	
male	136 (68.0)
female	64 (32.0)
Ethnicity	
Serbian	190 (95.0)
other	10 (5.0)
Education	
low (primary, incomplete primary)	67 (33.5)
middle (secondary)	101 (50.5)
high (high, higher)	32 (16.0)
Indication for surgery	
coronary	88 (44.0)
valvular	52 (26.0)
combined	37 (18.5)
other	23 (11.5)

Results are shown as number (%) of patients except age which is shown as mean (range).

The mean age of 66.2 years and male predominance (68%) depicted the reality of the population in the ROS submitted to cardiac surgical procedures. Concerning ethnicity, the group was almost homogenous. The patients were of different educational levels, with the majority (84.0%) being with low (incomplete primary or primary) and middle (secondary) education. Indications for the cardiac surgical procedure were different, and this fact was a salutary fact for this survey.

Despite the already signed consent form (Figure 1), the results in the first part of the questionnaire (Table 2) generally indicated a low level of patient information about the upcoming cardiac surgery procedure on the type of cardiac surgery procedure they expect, extracorporeal circulation, anesthesia, and transfusion. Of those having information about the upcoming surgery, only 7.0–20.0% graded them as sufficient and satisfactory. Surprisingly, the worst situation was recorded in questions about risks of disease and upcoming surgical treatment, where 88.0% of patients had no information about it, and almost 90.0% of those with some information graded them insufficient.

The second part of the questionnaire (Table 3), where patients were asked to express their opinions on the clarity

Table 2

Quantity and quality of patient's information about general and the most important aspects of clinical cardiac surgical care

Questions	Answers, n (%)
1. Do you know which type of cardiac surgical procedure you will be submitted to (e.g., coronary, valvular, aortic, etc.)?	
yes	168 (84)
no	32 (16)
2. How do you grade your information about upcoming cardiac surgical operation?	
good (+)	33 (19.5)
average (±)	97 (58.0)
poor (−)	38 (22.5)
3. Do you know what extracorporeal circulation or heart-lung machine is?	
yes	108 (54)
no	92 (46)
4. How do you grade your information about extracorporeal circulation?	
good (+)	10 (9.5)
average (±)	36 (33.5)
poor (−)	62 (57.0)
5. Do you know which type of anaesthesia you will be submitted to (e.g., local, regional, general)?	
yes	88 (44)
no	112 (56)
6. How do you grade your information about cardiac surgical anaesthesia?	
good (+)	10 (11.0)
average (±)	30 (34.5)
poor (−)	48 (54.5)
7. Do you know that you will most likely receive blood, plasma, or derivatives during and/or after upcoming surgery?	
yes	97 (48.5)
no	103 (51.5)
8. How do you grade your information about perioperative transfusion?	
good (+)	7 (7.0)
average (±)	24 (25.0)
poor (−)	66 (68)
9. Do you know what the estimated individual risks of your disease(s) and upcoming surgical treatment are?	
yes	24 (12)
no	176 (88)
10. How do you grade your information about perioperative risks?	
good (+)	3 (12.0)
average (±)	11 (45.5)
poor (−)	10 (42.5)

Table 3

Patient's opinion on the clarity and importance of information gained before surgery

Questions	Answers, n (%)	
	yes	no
1. Did you talk with your operating surgeon about the upcoming operation?	37 (18.5)	163 (81.5)
2. Was the text of the consent form you have signed completely clear?	112 (56.0)	88 (44.0)
3. Do you consider that all relevant information related to your upcoming surgery should be explained to you?	171 (85.5)	29 (14.5)

and importance of information gained before surgery, revealed rather confusing and contradictory facts. It was surprising that 81.5% of patients signed the actual consent form (Figure 1) without any discussion about relevant issues with the operating surgeon. For slightly more than half of them (56.0%), the information offered in the consent form was clear and sufficient. Yet, 85.5% think that all relevant information about upcoming surgery should be explained to them. At the same time, 14.5% of patients are not interested at all to know even the most relevant information about their disease and surgery.

Discussion

Historically, during the last century, the importance of the IC concept was strengthened mainly in the courts. In January 1908, Mary Schloendorff was submitted to surgical intervention and suffered severe hand complications, even though she had adamantly declined it beforehand. After that, Schloendorff sued the hospital and won a 50,000 USD suit [7]. Justice Benjamin Cardozo famously wrote in the Court's opinion (Schloendorff vs. Society of New York Hospitals trial): "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." [3].

Paul G. Gebhard was an American attorney credited with creating the phrase "informed consent" in a 1957 medical malpractice case, in which a patient contended that a physician at a Stanford University hospital (i.e., Frank A. Gerbode 1907–1984, a famous surgeon and former president of American Association for Thoracic Surgery) had not fully disclosed the risks in a recommended treatment (i.e., translumbar aortography) [3].

Patients' rights are given great importance at the international, regional, and national levels through different agreements, declarations and charters, special laws or provisions of various laws that are fulfilled, protected, and respected by these rights [3, 8–10].

By adopting the Law on Patients' Rights (LPR) in 2013 and the Law on Health Care (LHC) in 2019, to harmonize national with European Union legislative, the Government of the ROS defined 19 distinctive rights, three of which (i.e., the right to information, the right to notice, and the right to consent) directly define IC, while several others indirectly support this issue [1, 2]. Quality of legislation is a formal and necessary framework, but the quality of the actual practice is more important, an essential component of any efficient healthcare system [11]. The same is true for patient rights and IC as a part of them.

Cardiovascular diseases remain the major burden for the healthcare system in the ROS [12]. In the absence of accurate data, it is a rough estimation that out of six million inhabitants, up to 10,000 patients annually need some kind of cardiac surgical intervention. The actual annual capacity of the five national cardiac surgical centers is 50–60% of that number [13]. Attempts to solve the problem of growing waiting lists by increasing the number of patients operated within existing capacities decreased "time per patient", negatively affecting the quality of care in many aspects.

Effective LPR does not oblige medical doctors (i.e., operating surgeons) to participate in the IC process but uses the term "authorized health care professional" instead [10]. Thus, in practice, a cardiac surgical patient may be informed by nurses or less experienced doctors (e.g., residents, fellows). Our study has shown that 81.5% of patients have not even seen their operating surgeon before the operation (Table 2). On the one hand, this fact is not strictly against LPR, but on the other hand, it definitively precludes the patient from being appropriately informed before signing the consent, as evident from Table 3. In a cross-sectional study at nine surgical hospitals, Agozzino et al. [14] showed much better results than ours, and still, they find their IC practice insufficient. Results of our survey also identify 85.5% of patients claiming their need to be properly informed (Table 2). This fact, along with the previous one, indicates that both legislation and practice should be more precise and efficient. The consent form (i.e., "stamp"), used in our institutional cardiac surgical practice (Figure 1), is a copy of the list of generic information the patient should have before surgery, taken from LPR [10]. Essentially, it is not IC but rather a liability waiver document. Moreover, LPR applied to cardiac surgical patients (i.e., expecting invasive medical treatment), in different articles [7, 10, 14, 15] insists that effective oral communication, even without the patient's explicit request, obligatory precede their voluntary consent and signature [2]. Law does not limit cardiac surgical centers to establish appropriate IC practice, so the actual practice is predominantly professional deficiency, depicting sluggishness and indifference among cardiac surgeons in ROS.

This kind of performing "the modern clinical ritual of trust" on a global level was nicely caricatured by Glyn Elwyn, who also raised the question of whether the nowadays patient consents were a "decision or assumption" [15]. Similarly, many others wondered if ICs for cardiac surgical

patients were "achievable" and "truly informed" [5, 16]. Although both the meaning and performance of IC are still debatable, illustrating rather social (i.e., population, legislative, health care systems) than medical and ethical differences, the efforts to adjust and improve IC practice are globally evident [8–10, 14, 17, 18]. In a comprehensive review by Hall et al. [9], finding no universally accepted standards, they nicely concluded that IC should be pragmatical: "…aimed to facilitate and document a good-faith effort to involve patients in medical decisions to whatever degree they are interested and able". Salzburg's statement on shared decision-making recognized that the IC concept has emerged from multiple disciplines and accordingly launched suggestions for its improvements on different "addresses" (i.e., clinicians, patients, researchers, editors, journalists, policymakers) [8].

It was not only the result of this study and available literature but rather our professional and ethical compulsion that motivated us to propose and initiate a completely new approach to the cardiac surgical IC practice. Educating the patient, like Brenner et al. [4] and many others [6, 19, 20] described, may help overcome different weak points of the IC process, allowing the patient and surgeon to develop an alliance rather than rivalry. Accordingly, we designed completely new consent forms (generic and disease-specific) covering all important issues that patients should be aware of before signing the consent for cardiac surgery (Supplements 2 and 3). These forms, written in non purely medical language empirically recognized to be understandable by our average patient (age and education level), are distributed during the patient's first visit when admission for the elective cardiac surgical procedure is scheduled. We had in mind that the majority (84%) of our examinees had an education level in accordance with the population of the ROS [21]. Thus, they have enough time to read and understand their content and (alone or with the help of family members and others) be well prepared to ask additional questions before they sign the consent form. Moreover, as a part of our initiative, we prepared the second edition of our patient-dedicated monograph, "Life after heart surgery: initial recovery", to create an integrated system of preoperative and postoperative notification for timely and more complete patient informing [22]. For any further enhancements (e.g., internet portal, audio-visual material, telemedical support, etc.), it is necessary to launch an initiative for the amendment of the LPR [10] specifying other alternative ways to inform patients. In more developed healthcare systems and cardiac surgical hospitals, a case manager is responsible for coordinating patient care throughout the cardiac surgical care continuum and ensuring the effective coordination and continuation of patient care from presurgery to postsurgery treatments [23]. Our healthcare system still does not recognize this professional profile, so we will have to propose it to our healthcare authorities. Meanwhile, we intend to start (weekly) with inpatient "guided virtual cardiac surgical tours", a form of interactive education where newly admitted patients would be able to see video material with all clinical wards and technologies explained by surgeons and nurses. With all these activities towards the improvement of our traditional IC policy, we hope to achieve a new level of confidence which would, in turn, result in better surgical outcomes.

Conclusion

The results of this study unambiguously indicate an unacceptably low level of our patients' information about the forthcoming cardiac surgical procedure, extracorporeal circulation, anesthesia, transfusion, and estimated risk, despite the already signed consent form. The majority of them (85.5%) comprehend the importance and expect timely and adequate information. It is not the patients' attitude or legislative restrictions to blame for such inadequate IC policy. An extremely high percentage (81.5%) of patients who had no chance to discuss the procedure with the operating surgeon indicates that both surgical indifference and insufficient knowledge of professional, ethical, and legal importance are the most important reasons for actual IC policy in cardiac surgery. The measures we took to change and improve established IC practice in national cardiac surgery should be validated with similar, more extended studies in the future.

Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest

None declared.

R E F E R E N C E S

1. Government of Republic of Serbia, Ministry of Health. The Law on the Health Care. Official Gazette of the Republic of Serbia, No 25/2019; 2019.
2. Government of Republic of Serbia, Ministry of Health. The Law on Patients' Rights. Official Gazette of the Republic of Serbia, No 45/2013; 2013.
3. *Forrester K, Griffiths D.* Consent. In: *Forrester K, Griffiths D*, editors. Essentials of Law for Medical Practitioners. Australia, Sydney: Elsevier Health Sciences; 2011. p. 143–77.
4. *Brenner LH, Brenner AT, Horowitz D.* Beyond informed consent: educating the patient. Clin Orthop Relat Res 2009; 467(2): 348–51.
5. *Mishra PK, Ozalp F, Gardner RS, Arangannal A, Murday A.* Informed consent in cardiac surgery: is it truly informed? J Cardiovasc Med (Hagerstown) 2006; 7(9): 675–81.
6. *Vohra HA, Ledsham J, Vohra H, Patel RL.* Issues concerning consent in patients undergoing cardiac surgery-the need for patient-directed improvements: a UK perspective. Cardiovasc Surg 2003; 11(1): 64–9.
7. Historical Newspaper Archives. Loses $50,000 Suit. Santa Cruz, California: Santa Cruz Sentinel 1911 [cited 2020 24 february]. Available from: https://www.newspapers.com/clip/3998404/mary_schloendorff_plaintiff_in/.

8. Salzburg Global Seminar. Salzburg statement on shared decision making. BMJ 2011; 342: d1745.
9. *Hall DE, Prochazka AV, Fink AS*. Informed consent for clinical treatment. CMAJ 2012; 184(5): 533–40.
10. *Kakar H, Gambhir RS, Singh S, Kaur A, Nanda T*. Informed consent: corner stone in ethical medical and dental practice. J Family Med Prim Care 2014; 3(1): 68–71.
11. *Dickov V*. Inadequacy the health system in serbia and corrupt institutions. Mater Sociomed 2012; 24(4): 262–7.
12. Institute of Public Health of Serbia. Health Statistical Yearbook of Republic Serbia 2018. Belgrade: Institute of Public Health of Serbia; 2018. p. 422–43.
13. *Kočica M*. The Helical Ventricular Myocardial Band of Torrent-Guasp as the Basis for the Surgical Treatment of Post-infarction Remodeled Left Ventricle [dissertation]. Belgrade: Faculty of Medicine, University of Belgrade; 2015. (Serbian)
14. *Agozzino E, Borrelli S, Cancellieri M, Carfora FM, Di Lorenzo T, Attena F*. Does written informed consent adequately inform surgical patients? A cross sectional study. BMC Med Ethics 2019; 20(1): 1.
15. *Elwyn G*. Patient consent-decision or assumption? BMJ 2008; 336(7656): 1259–60.
16. *Larobina ME, Merry CJ, Negri JC, Pick AW*. Is informed consent in cardiac surgery and percutaneous coronary intervention achievable? ANZ J Surg 2007; 77(7): 530–4.
17. *Kavarana MN, Sade RM*. Ethical issues in cardiac surgery. Future Cardiol 2012; 8(3): 451–65.
18. *Paterick TJ, Carson GV, Allen MC, Paterick TE*. Medical informed consent: general considerations for physicians. Mayo Clin Proc 2008; 83(3): 313–9.
19. *Mishra PK, Mathias H, Millar K, Nagrajan K, Murday A*. A randomized controlled trial to assess the effect of audiotaped consultations on the quality of informed consent in cardiac surgery. Arch Surg 2010; 145(4): 383–8.
20. *Villanueva C, Talwar A, Doyle M*. Improving informed consent in cardiac surgery by enhancing preoperative education. Patient Educ Couns 2018; 101(12): 2047–53.
21. Statistical Office of the Republic of Serbia. Population. Belgrade: Stat Yearb Serb 2017; 2017. p. 42.
22. *Panic G, Ristic M, Kocica M, Babic U, Simonovic P, Basri P*, et al. Life after heart surgery: initial recovery. Panic G, editor. In: NAZIV KNJIGE Belgrade: Interclima Graphics; 2010. p. 52.
23. *Miller M, Beauman G*. Preoperative Assessment. In: *Conte JV, Baumgartner WA, Todd Dorman MDF, Sharon G, Owens C,* editors. The Johns Hopkins Manual of Cardiac Surgical Care: Mobile Medicine Series. Australia, Sydbey: Elsevier Health Sciences; 2007. p. 3–17.

Received on January 15, 2021
Accepted on March 15, 2021
Online First March 2021

Supplement 1

SURVEY QUESTIONNAIRE

THE LEVEL OF YOUR INFORMATION ABOUT THE UPCOMING OPERATION

Please read the questions carefully and answer them. The way to fill out the survey is simple - circle the number in front of one of the answers provided. The purpose of this survey is to find out to what extent you are informed about your upcoming surgery. Analysis of the results of the survey will help us improve this segment of our activity.

The survey is anonymous and should not be signed.

1) Do you know what type of surgery/procedure will be performed on you?
1. Yes, I know
2. No, I don't know

2) To what extent are you informed about the upcoming surgery/procedure?
1. I am fully informed
2. I am partially informed
3. I am a little or not at all informed

3) To what extent are you informed about the possible following complications of the operation/procedure?

1. I am fully informed
2. I am partially informed
3. I am a little or not at all informed

4) Do you know that most open-heart surgeries are done using the technology of extracorporeal blood flow (during operation, your heart and lungs do not work)?
1. Yes, I know
2. No, I don't know

5) To what extent are you informed about the possible risks of using the technology of extracorporeal blood flow?
1. I am fully informed
2. I am partially informed
3. I am a little or not at all informed

6) Do you know which type of anaesthesia will be applied to you during surgery (general, regional, local, etc.)?
1. Yes, I know
2. No, I don't know

7) To what extent are you informed about the possible risks and complications of applying anesthesia?
1. I am fully informed
2. I am partially informed
3. I am a little or not at all informed

8) Do you know that you will most likely receive blood, plasma or its derivatives during and after surgery?
1. Yes, I know
2. No, I don't know

9) To what extent are you informed about possible accompanying phenomena and complications of the use of blood, plasma and its derivatives?
1. I am fully informed
2. I am partially informed
3. I am a little or not at all informed

10) Do you know how much your operational risk (Euro Score, STS) is in percentages?
1. Yes, I know
2. No, I don't know

11) Is the text of the consent form that you sign for the operation completely clear?
1. Yes, I know what I signed, and everything is clear to me
2. I am not sure, or I do not know

12) Do you consider that all the above important information related to the upcoming operation should be available to you?
1. Yes, I am interested in getting to know all the information before surgery
2. No, I am not interested

Thank you for your participation in this survey.

Supplement 2

01. GENERIC CONSENT FORM FOR CARDIAC SURGERY PROCEDURE

I confirm that I have read in written form and that the selected physician has explained the following issues to me:

1. My general health and proposed procedure, including additional procedures and proceedings. If intraoperative findings are not in line with preoperative diagnostics, I approve additional procedures. I understood the risks, including those specific to me.
2. That this procedure requires the use of anesthesia. I realize the risks of administering anesthesia, including those specific to me.
3. Possibilities of alternative procedures and the risks associated with them.
4. The prognosis of my disease and the risks if the proposed surgery is not done.
5. That there is no guarantee that my condition after the surgical procedure will be significantly better despite the professional efforts of the doctors and staff.
6. That the procedure may require the use of blood transfusions and/or blood products.
7. That a sample of my blood and/or tissues may be taken and used to make a definitive diagnosis and apply an adequate treatment, following the current state of health.
8. If suddenly a life-threatening situation arises during or after a procedure, proceedings and procedures may be applied in accordance with generally accepted principles to save my life.
9. That doctors who do not have the title of specialist can participate in my surgical treatment.

I was allowed to read and ask for more information on the following:

1. The procedure that will be performed.
2. Use and risks of extracorporeal blood flow.
3. Applying sedation and anesthesia.
4. Applying blood transfusions and blood products.
5. The overall individual risk of cardiac surgery treatment calculated and objectified using the Euro Score II and/or STS calculator.

I had the opportunity to ask my chosen physician questions about general health, the proposed procedure and the risks and the application of other therapeutic options. I was pleased with the answers to the questions asked.

I consent to the proposed cardiac surgery treatment on my own will and in a state of full and clear awareness, fully informed of the forthcoming cardiac surgery procedure and its risks, as well as possible complications.

I realized that it was my right to change my mind at any time before the procedure, even after signing this consent.

Belgrade, ……. …….

Date Medical record No

…… ……. …….

Doctor signature Patient signature Authorized person signature

Supplement 3

2. CORONARY ARTERY BYPASS SURGERY - INFORMATION FOR PATIENT

In most cases, these surgical procedures are performed using extracorporeal blood flow. Procedures include the use of general anesthesia and the frequent use of blood transfusions and/or blood products. These types of operations may include the use of veins from your hands and/or feet and/or arteries located inside the chest (internal thoracic artery), less often the radial arteries of the hands, and extremely rarely the gastroepiploic arteries (the artery that runs along with the gastric band), which includes the opening of the abdominal cavity. The purpose of surgery is to establish a bypass flow of blood (from the aorta or subclavian artery) to the coronary artery (cardiac artery) below the site of narrowing or obstruction. The newly established bloodstream will deliver an adequate amount of blood and oxygen to the compromised part of the heart muscle and allow it to be functional to the extent necessary.

After admission to the hospital and placement in the hospital room, preoperative protocol preparation procedures will be performed. The day before the surgery, your hygiene preparation (bathing, shaving) is performed. On the day of surgery, you will be taken to a cardiac surgery room and taken into general anesthesia (immediately before and during surgery, you are in a controlled sleep state, unconscious). The surgery opens the thorax, most commonly by a longitudinal surgical incision in the middle of the sternum, and surgery is performed on the heart itself. When you wake up after completion of the surgery, you will be in the Intensive Care Unit connected to an artificial respiration machine. After clinical examination and laboratory findings confirm that you are capable of breathing independently, separation from the apparatus and removal of the endotracheal tube (plastic tube) from your mouth will be performed. Postoperative stay in the Intensive Care Unit in the absence of complications usually lasts 24-48 hours. After removal of the chest drains (plastic tubes inserted through the skin into the chest during surgery) and proper preparation, you will be transferred to the semi-Intensive Care Unit or the General Care Unit, where further postoperative hospital care continues. It involves getting out of bed and moving, doing physical exercises, administering appropriate medication, taking blood samples for laboratory tests, postoperative ultrasound examination of the heart, etc. If necessary, transfusions of blood and/or blood products may be used for therapeutic purposes. Discharge from the Cardiac Surgery Clinic is usually planned for the seventh postoperative day. Depending on your general condition, you may be discharged for home treatment or referred for further treatment to a regional healthcare facility.

During surgery as well as postoperatively, unwanted complications can occur.

THE MOST COMMON COMPLICATIONS (in total, more than 5% of patients)

1. Bleeding from a surgical incision or the chest. This condition may require transfusion of blood, plasma, or derivatives thereof and, in the cranial line, reopening of the thorax.
2. Heart rhythm disorders, which are usually transient and usually require medical treatment.
3. Cognitive impairment, short-term memory loss, difficulty concentrating and reading, and blurred vision, which can take several weeks after surgery.
4. Chest pain and/or insensitivity of the chest wall (a consequence of surgical access and/or use of the internal thoracic artery for graft) may be transient, last for months, or occasionally occur.
5. Feeling of "shortness of breath" and easy fatigue for less effort, which may be transient or permanent, depending on the functional state of the heart after surgery.
6. Inadequate healing of a surgical incision wound. After 1-2 months, there may be thickening and scarring accompanied by pain.
7. Deep vein thrombosis is characterized by painful swelling of the leg, which in rare cases causes embolism of the lungs, which can be life-threatening.

RARE COMPLICATIONS (in total 1-5%)

1. Lung collapse as a result of compression by air and/or fluid, which may require placement of the chest drainage, to facilitate respiratory function. It is more common in smokers or if there is a previous lung disease (emphysema, chronic bronchitis).
2. Renal insufficiency (renal impairment). It is more common in patients with preoperatively impaired renal function. The occurrence of this complication may require hemodialysis.
3. Infection of the mediastinum (midgut), chest, surgical cuts on the arm or leg, rarely followed by septic conditions. This will require the administration of antibiotics and, possibly, additional surgery (debridement, stabilization of the sternum).
4. Perioperative myocardial infarction, in extent from mild to severe.
5. Acute thrombosis of the graft may require an additional procedure.
6. Pulmonary function impairment, which, in addition to medication administration, may require the use of artificial respiration and/or tracheostomy devices.
7. Disorders of cardiac conduction or rhythm. This complication may require the implantation of a permanent pacemaker.
8. Problems in the functioning of the abdominal organs. An acute bleeding ulcer of the stomach or duodenum occurs, which may require the use of blood transfusion and/or blood products, gastroscopic intervention, and surgical treatment.
9. Stroke whose effects can be long-lasting.

EXTREMELY RARE COMPLICATIONS

1. Decubitus formation as a consequence of postoperative severe general weakness or for other reasons when the mobilization of the patient from the bed is not possible. This complication requires frequent dressings and, if necessary, additional surgical procedures.
2. Intraoperative burn formation when using the necessary electrical devices (thermocouple). Despite the implementation of all available prevention measures, an accidental generation of anomalous circuits can occur. The burns are treated by dressing and possibly applying antibiotics and additional surgical procedures.
3. Transmission of blood transmissible diseases by transfusions of blood and/or blood products.

Information on your operational risk calculated by the Euro Score II and/or STS calculator and expressed as a percentage will be available to you on the day of admission to the Cardiac Surgery Clinic.
You will be informed about the risks of using extracorporeal blood flow technology, general anesthesia, and transfusions of blood and/or blood products.
The fatal outcome may be due to the procedure proposed and undertaken.
If the proposed surgical procedure is not accepted as a solution, the natural course of the disease, despite the use of medication, will lead to exacerbation of the problems and the eventual appearance of emergencies. Acute exacerbations of the disease (acute heart attack, acute impairment of global heart function, malignant heart rhythm disorders) can be life-threatening and can cause sudden cardiac death. Life expectancy will be shorter and quality of life in progressive deterioration.

Belgrade, ……. …….
Date Medical record No

…… ……. …….
Doctor signature Patient signature Authorized person signature