National multicenter prospective observational study "The role of concomitant diseases in poSTOPerative complications RISK stratification — STOPRISK": study protocol

Национальное многоцентровое проспективное обсервационное исследование «Роль сопутствующих заболеваний в стратификации риска послеоперационных осложнений» — STOPRISK: протокол исследования

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Abstract

INTRODUCTION: Advances in modern anesthesiology have significantly reduced the risk of anesthesia compared to the last century, however, the level of perioperative in-hospital mortality after elective major abdominal surgery is still high at the moment. Poor outcome prediction is the cornerstone of individualized perioperative management of high-risk patients aimed at preventing complications. Despite the fact that a large number of risk assessment tools have been developed over the past decades, the accuracy of the forecast is still far from required. According to the literature data, models based on the study of risk factors in the national population of patients, of which comorbidities make the greatest contribution, have the greatest accuracy. **MATERIALS AND METHODS: Design:** prospective observational study. **Setting:** National multicenter study of patients in surgical hospitals. **Patients:** Patients undergoing abdominal surgery. Interventions: Not provided. **RESULTS:** The developed design was registered in the ClinicalTrials.gov database, a study organized by the Federation of Anesthesiologists and Resuscitators of Russia in cooperation with the Kuban State Medical University has now begun, 38 centers are participating in it, two papers have been published based on the results of an interim analysis. **CONCLUSIONS:** The study is of great scientific and medical and social importance, as a result of the analysis of the data obtained, the role of concomitant diseases in the development of an adverse outcome will be studied and a national risk assessment model will be developed.

REGISTRATION: Clinicaltrials.gov identifier: NCT03945968. Registered May 10, 2019.

Реферат

АКТУАЛЬНОСТЬ: Успехи современной анестезиологии позволили значительно снизить риск осложнений анестезии по сравнению с прошлым веком, однако уровень периоперационной внутрибольничной летальности после плановых обширных абдоминальных операций на данный момент все еще остается высоким. Прогнозирование неблагоприятного исхода является краеугольным камнем индивидуализации периоперационного ведения пациентов высокого риска, направленного на предупреждение осложнений. Несмотря на то что за последние десятилетия разработано большое количество инструментов оценки риска, точность прогноза все еще далека от необходимой. Как показывают данные литературы, наибольшей точностью обладают модели, основанные на изучении факторов риска в национальной популяции пациентов, из которых наибольший вклад вносят сопутствующие заболевания. **МАТЕРИАЛЫ И МЕТОДЫ:** Проспективное наблюдательное исследование. **Условия:** Национальное многоцентровое исследование пациентов хирургических стационаров. **Пациенты:** Пациенты, подвергающиеся оперативным вмешательствам на органах брюшной полости. **Вмешательства:** Не предусмотрены. **РЕЗУЛЬТАТЫ:** Разработанный дизайн был зарегистрирован в базе данных ClinicalTrials.gov, в настоящее время исследование, организованное Федерацией анестезиологов и реаниматологов России совместно с Кубанским государственным медицинским университетом, началось, в нем участвует 38 центров, опубликовано две работы по результатам промежуточного анализа. **ВЫВОДЫ:** Исследование имеет важное научное и медико-социальное значение, в результате анализа полученных данных будут изучена роль сопутствующих заболеваний в развитии неблагоприятного исхода и разработана национальная модель оценки риска.

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Introduction

The successes of modern anesthesiology have significantly reduced the risk of anesthesia compared to the last century. However, the level of perioperative hospital mortality after elective surgery currently averages about 0.5 % [1]. It is estimated that more than 313 million adults worldwide undergo surgical interventions annually [2]. Thus, the number of deaths may result in several million deaths each year worldwide. Nevertheless, the study of the risk of death is associated with certain difficulties, since over the past half century this indicator has decreased a hundred times and studies involving an elusive number of subjects are required for the study.

Current research focuses on other outcome criteria — significant and minor postoperative complications. Thus, anesthetic risk is most often understood as the risk of postoperative complications. The rate of these complications varies in a wide range, ranging from 3 to 18 % [3-5]. The differences in the data are explained by the lack of clear definitions and differences in the design of studies, but the fact that the development of a postoperative complication increases the risk of death several times can be considered indisputable [1]. However, despite the importance of this issue, there is no clear idea in the modern literature about what is a high risk and which of the patients corresponds to this category.

Understanding whether a patient belongs to the high-risk category is an extremely important task — it allows you to obtain meaningful informed consent of the patient, as well as to understand whether strategies for preventing complications should be applied (goal-directed fluid therapy, protective mechanical ventilation, features of postoperative care, etc.).

Attempts of creating preoperative risk stratification tool have been made for many decades, some scales assess the initial physical status (ASA scale) [6, 7] and predict mortality, others assess the risk of specific complications (Revised cardiac index Lee, respiratory risk scale, etc.) [8, 9].

Scales that include intraoperative and postoperative indicators, such as a series of POSSUM scales are also being

developed [10]. The analysis shows that in routine clinical practice, these scales are not used very often, which is due to their limitations: subjectivity, technical complexity and often low specificity and sensitivity.

Concomitant diseases are the strongest predictors of postoperative adverse events and mortality. It has been demonstrated that the Charlson comorbidity index of 3 or more increases the risk of death by 16 times within a year after surgery [11]. In addition, in most clinical studies, the ASA classification of physical status as a kind of comprehensive assessment of patients' comorbidity has repeatedly proved to be one of the strongest independent predictors of postoperative morbidity and mortality, despite the fact that this assessment is based on subjective perception [12, 13].

The main concomitant diseases that are independent predictors of perioperative complications are diseases of the cardiovascular and respiratory systems [14]. Increasing age, anemia, obesity, diabetes mellitus — these conditions also increase the risk of an unfavorable outcome [15-18]. Diseases of the central nervous system and neuromuscular diseases significantly disrupt the function of respiratory system, can change the level of autonomous regulation of the cardiovascular system, lead to significant cognitive disorders and nutritional insufficiency, which also increases the risk of perioperative complications [19].

On the other hand, in large-scale observational studies of recent years performed in a number of foreign countries, concomitant diseases were not identified as independent predictors of the development of postoperative complications [5], and preoperative assessment systems based on concomitant diseases, such as POSPOM, demonstrate contradictory prognostic value in non-cardiac surgery — from underestimating the risk of death [20] to its overestimation [21].

Thus, data on the impact of concomitant diseases on perioperative risk are contradictory and may be influenced by differences in the frequency and structure of these diseases in heterogeneous populations, as well as in different treatment strategies for cardiovascular, respiratory and other diseases. Identification of these risk factors is necessary to understand the pathophysiology of complications and to identify potential ways to reduce the anesthetic risk, such as correction of concomitant disease. Conducting a national study on the identification of risk factors for an unfavorable outcome is the first integral step towards creating a set of measures to improve the quality of perioperative care and reduce mortality [22].

Perioperative risk, of course, depends not only on the presence of concomitant diseases and their combinations, but also on the severity of surgical trauma [1, 23], as well as on the level of exposure to drugs for anesthesia and anesthetic techniques [5], therefore, risk stratification without taking into account of these factors also does not seem appropriate.

Objective. The aim of this study is to increase the accuracy of stratification of patients with high surgical and anesthetic risk in abdominal surgery and to identify ways to prevent postoperative complications.

It is planned to conduct a national multicenter prospective observational study using a questionnaire (see appendix 1) and a computer database developed on its basis.

The study has passed the registration procedure in the database ClinicalTrials.gov (The protocol of the study is available on the website ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT03945968)

Dates of the study: 01.06.2019-31.05.2024.

Materials and methods

Inclusion criteria: patients over 18 years of age undergoing elective abdominal surgery, whose physical status corresponds to Class I–III according to ASA–PS classification.

Exclusion criteria: inability to assess the factors included in the questionnaire, acute massive blood loss, aspiration, bronchospasm, anaphylactic reactions, malignant hyperthermia, transurethral and transvaginal surgery, interventions on peripheral vessels and heart, thoracic operations, neck and head surgery, trauma surgery.

Estimated parameters

- Age, gender, body weight.
- Class of physical status according to ASA.
- Presence and type of concomitant disease.
- Treatment received by the patient.
- Type and severity of surgical intervention [24].
- Type of anesthesia.
- Integral scales: cognitive function according to the Montreal test [25], respiratory risk scales [9], Revised cardiac index Lee [8] and NSQIP tool (Gupta index) [26] severity of liver failure according to MELD [27] stage of CKD according to GFR and albuminuria [28], degree of COPD according to GOLD [29].
- Laboratory and instrumental markers.
- Postoperative outcomes: 30-day mortality and complications (according to ESA-ESICM definitions, 2015).
- Duration of stay in ICU and hospital, re-hospitalization.

Primary endpoints

1. To identify the structure and the rate of concomitant diseases in the preoperative period.
2. To determine the effect of concomitant diseases, type and severity of surgery on the postoperative complications risk and 30-day mortality.

3. To identify risk factors for postoperative complications and death.
4. To develop and validate a model of surgical and anesthetic risk in abdominal surgery.

Secondary endpoints

1. To analyze the frequency and causes of re-hospitalizations, the duration of stay of patients in the ICU and in the hospital.
2. To identify the frequency and structure of postoperative complications in abdominal surgery.
3. To evaluate and validate the known surgical and anesthetic risk stratification tools in non-cardiac sugery.
4. To stratify patients with high surgical and anesthetic risk.
5. To analyze the structure of anesthesia methods used in open and laparoscopic abdominal surgery.
6. To evaluate and validate respiratory risk assessment scales in the study population.
7. Compare the prognostic value of the revised cardiac index Lee and the NSQIP calculator in predicting of cardiovascular complications.
8. To study the contribution of CKD to the development of complications, to evaluate and validate the value of the RIFLE (Risk, Injury, Failure, Loss, and End-stage renal disease) and KDIGO (Kidney Disease: Improving Global Outcomes) scales in predicting of postoperative complications.
9. To clarify the frequency of use of renin-angiotensin-aldosterone system inhibitors and the effect of their withdrawal on the frequency of postoperative complications.
10. To analyze the frequency of occurrence of preoperative cognitive dysfunction in various age groups and identify risk factors for its development.
11. To evaluate the effectiveness of antibiotic prophylaxis in the prevention of infectious complications.
12. To evaluate the effectiveness of mechanical bowel preparation in the prevention of postoperative complications.
13. To study the role of the breath-holding test in prediction of postoperative complications and stratification of patients with high surgical and anesthetic risk.
14. To investigate the effect of perioperative fluid balance on the rate of postoperative complications.
15. To clarify the validity and frequency of the analyzed pharmacological agent's usage and its role in the development of postoperative complications

The sequence of the study

1. The data is recorded in an Excel electronic database in a single format for all centers.
2. All centers were approved by the local ethics committee prior to the start of the study.
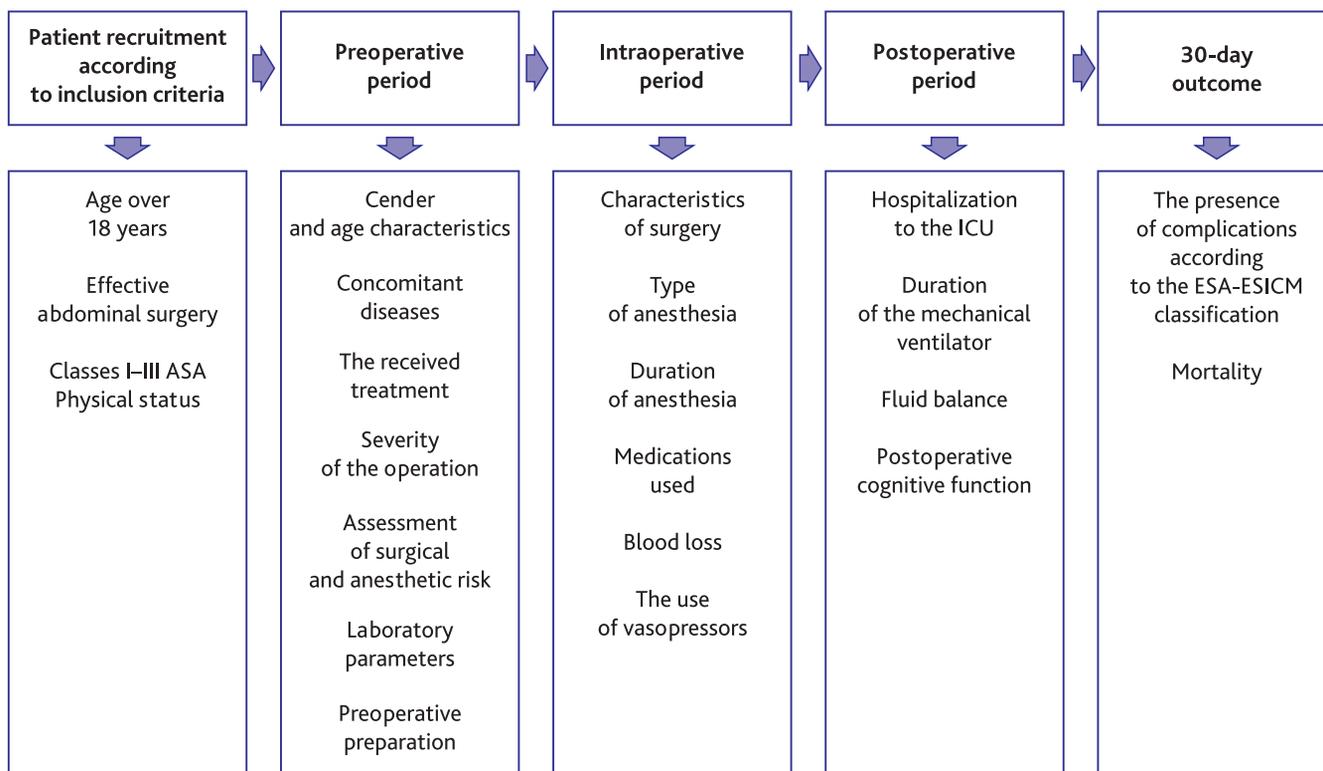

Patient recruitment according to inclusion criteria	Preoperative period	Intraoperative period	Postoperative period	30-day outcome
Age over 18 years

Effective abdominal surgery

Classes I–III ASA Physical status | Cender and age characteristics

Concomitant diseases

The received treatment

Severity of the operation

Assessment of surgical and anesthetic risk

Laboratory parameters

Preoperative preparation | Characteristics of surgery

Type of anesthesia

Duration of anesthesia

Medications used

Blood loss

The use of vasopressors | Hospitalization to the ICU

Duration of the mechanical ventilator

Fluid balance

Postoperative cognitive function | The presence of complications according to the ESA-ESICM classification

Mortality |

Fig. 1. Scheme of the study protocol

3. The study includes all patients operated on during one day and meeting the inclusion/exclusion criteria with registration in the questionnaire.
4. All patients must sign an informed consent to participate in the study.
5. Before surgery, data about the patient and all the studied factors specified in the study protocol are entered into the database.
6. All patients included in the study are monitored before discharge from the hospital with the registration of the data specified in the protocol.
7. The stages of protocol are shown in Fig. 1.
8. Every last day of the month, all completed cases are sent as a separate Excel file to the study coordinator.
9. The originals of the questionnaires are kept in the centers for the entire duration of the study and for 5 years after its completion

Statistical analysis

The sample size was calculated taking into account the fact that at least 10 cases of postoperative complications per factor included in the final regression model are required. Taking into account the wide range of the frequency of complications in previous studies (from 3 % to 20 %), we selected a lower bound for a more accurate assessment. To include 20 potential risk factors into the regression model, 200 cases of postoperative complications are required. The rate if complication is approximately 3 %, so we have to recruit at least 7000 participants. To take into account the risk of data loss, and to assess all potential risk factors, the size of the required sample was increased to 12,000 people, which will also allow us to assess the contribution of concomitant diseases to individual groups of complications. An additional 4000 will be recruited to validate the predictive model. The inclusion of the patient in the main and validated group will be carried out randomly.

The distribution of the studied parameters will be evaluated using the Kogmogorov—Smirnov test. Continuous data will be presented as median and interquartile range for normal distribution and as mean and standard deviation for nonparametric distribution. Categorical variables will be presented in the number of patients and the percentage.

For the initial assessment of the association of the factor with postoperative complications, a single-factor analysis will be performed using the χ^2 test and the Mann—Whitney test. All variables with a significant relationship identified in the univariate analysis ($p < 0.05$) will be included in the logistic regression if there is no colinearity between them (correlation coefficient less than 0.25). The logistic regression model will be carried out using the step-by-step inclusion method in which the presence of a complication will be a dependent variable. Potential predictors will be removed if this exception does not lead to a significant change in the likelihood ratio. The criterion for excluding the factor will be set at a significance level of 0.05. Adjusted odds ratios and 95 % confidence intervals will also be calculated.

The obtained predictive model will be evaluated in a validated group using ROC analysis and the Hosmer—Lemeshov test.

Patient recruitment and current results

The recruitment of patients to the study was started in July 2019, currently, at the end of June 2022, 6689 patients were included in the study (Fig. 2).

An interim analysis of the data showed that the probability of an unfavorable outcome can be assessed using factors such as the surgery severity level and the initial physical sta-
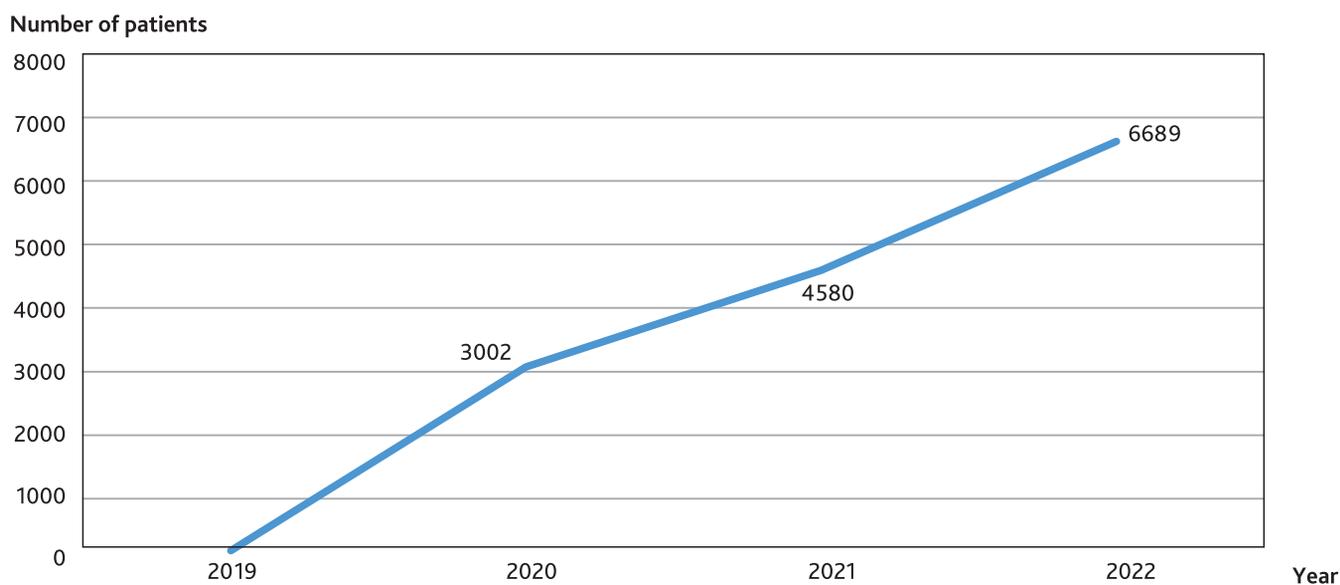
Number of patients

Fig. 2. Dynamics of enrollment of patients in the study

tus, but its prognostic value for determining the risk of mortality is clearly insufficient, and its ability in assessing the risk of postoperative complications are even less [30].

As the analysis of 2022 showed, modern prognostic tools (ASA [American Society of Anesthesiologists] scale, the SORT scale [Surgical Outcome Risk Tool], the SRS scale [Surgical Risk Scale], the POSPOM scale [Preoperative Score to Predict Postoperative Mortality], the NZRISK scale [New Zealand RISK] and the SMPM scale [Surgical Mortality Probability Model]) have good prognostic value in assessing the risk of 30-day mortality after elective abdominal surgery. The ASA scale as the only assessment tool cannot be used to predict mortality and postoperative complications after abdominal surgery, the best results were found for the NZRISK and POSPOM scales, however, they do not accurately identify high-risk patients. Preliminary results, as well as foreign experience, allow us to conclude that the development of a national risk assessment tool based on the study of the contribution of concomitant diseases, age and severity of surgical intervention is a promising, urgent and extremely important medical and social task [31].

Conclusion

For the first time in Russian Federation, a multicenter study is planned and is being conducted to assess the risk factors for an unfavorable outcome in abdominal surgery. This study will allow to determine the role of concomitant diseases in the development of postoperative complications and mortality, as well as to create a national model for assessing perioperative risk.

Author contribution. All authors according to the ICMJE criteria participated in the development of the concept of the article, obtaining and analyzing factual data, writing and editing the text of the article, checking and approving the text of the article.

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Appendix

PATIENT'S QUESTIONNAIRE

Center code _____

Patient code _____

Medical chart _____

Gender _____

Weight _____   Height _____

Diagnosis _____

_____

_____

I. Registrable factors

1. Age _____

2. Characteristics of surgery

   2.1. Surgery date _____

   2.2. Duration of surgery _____ minutes

   2.3. Type of surgery (select)

      ☐ Open upper abdominal surgery

      ☐ Open coloproctological surgery

      ☐ Open gynecological surgery

      ☐ Open urological surgery

      ☐ Open surgery on abdominal vessels

      ☐ Abdominal wall surgery

      ☐ Laparoscopic surgery

   2.4. Surgery risk (select)

      ☐ Low

      ☐ Medium

      ☐ High

3. Concomitant diseases

   3.1. Enter a history of the concomitant diseases

      ☐ Ischemic heart disease (functional class _____)

      ☐ Arterial hypertension (stage _____, degree _____, risk _____)

      ☐ Chronic cardiac failure (functional class _____)

      ☐ Arrhythmias

      (specify _____)

      ☐ Chronic obstructive pulmonary disease (_____ degree)

      ☐ Asthma (_____ degree)

      ☐ Smoking (for _____ years)

      ☐ Chronic renal disease (_____ stage)

      ☐ Suffered cerebrovascular accident (_____ years ago)

      ☐ Functionally independent patient

      ☐ Partially dependent patient

      ☐ Fully dependent patient

      ☐ There is hemiplegia

      ☐ Epilepsy

- [ ] Parkinson's disease
- [ ] Alzheimer's disease
- [ ] Neuromuscular diseases
- [ ] Diabetes mellitu (_____ type)
- [ ] Oncological diseases (select, if present)
- [ ] Widespread cancer (select, if present)
- [ ] Another disease _____

3.2. Current medications

- [ ] Beta-blockers
- [ ] APF (angiotensin-converting enzyme) inhibitors.
  (Drug stopped before surgery? (Yes/No) If yes — stop _____ hours in advance.)
- [ ] Angiotensin-2 receptor blockers.
  (rug stopped before surgery? (Yes/No) If yes, stop _____ hours in advance.)
- [ ] Aldosterone antagonists
- [ ] Statins
- [ ] Anticoagulants/antiplatelet agents
- [ ] Diuretics
- [ ] Bronchodilators
- [ ] Corticosteroids systemically
- [ ] Insulin
- [ ] Oral antidiabetic drugs
- [ ] Anticonvulsants
- [ ] Iron preparations
- [ ] Preoperative antibiotic prophylaxis (specify drug group and duration _____)
- [ ] Mechanical bowel preparation (check if performed)

3.3. Risk assessment methods

3.3.1. Integrative scales

- [ ] ASA physical status _____
- [ ] Revised Lee index _____ (points)
- [ ] NSQIP score, probability of a myocardial infarction or cardiac arrest _____ %
- [ ] Respiratory Complications Risk Scale _____ (points)
- [ ] MELD csore (in presense of hepatic failure) _____
- [ ] Shtange test _____ seconds
- [ ] Cognitive status _____ MoCA points

3.3.2. Laboratory markers

3.3.2.1. Hemoglobin _____ g/L

3.3.2.2. Hematocrit _____ %

3.3.2.3. The level of glycated hemoglobin (in the presence of diabetes mellitus) _____ g/L

3.3.2.4. Serum albumine _____ g/L

3.3.3. Instrumental Methods

3.3.3.1. Ejection fraction of the left ventricle _____ %

3.3.3.2. Forced vital capacity1 _____

3.3.3.3. Forced vital capacity _____

4. Intraoperative factors

4.1. Anesthesia type (select)

- [ ] Spinal
- [ ] Epidural
- [ ] Combined spinal-epidural

☐ Combined inhalational

☐ Total intravenous anesthesia

☐ General with epidural anesthesia

4.2. Intraoperative blood loss _____ mL

4.3. Infusion volume _____ mL

4.4. Need for vasopressors (Yes/No)

4.5. Need for hemotransfusion (Yes/No)

4.6. Type of anesthetic to maintain anesthesia _____

4.7. Muscle relaxation drug _____

4.8. Apply decurarization (Yes/No))

4.9. Use of neuromuscular blockade monitoring (Yes/No)

5. Postoperative factors

5.1. Transfer to intensive care unit (Yes/No)

5.2. Time to extubation after anesthetics are turned off (_____ minutes)

5.3. Postoperative cumulative balance by the end of the 1st day of the postoperative period (_____ mL)

5.4. Postoperative cumulative balance by the end of 3 days postoperative period (_____ mL)

5.5. Cognitive function on the 7th day after surgery (_____ points)

II. Registered outcomes

1. Outcome: died / was discharged from the hospital

2. Observed postoperative complications and days of development after surgery

☐ Acute kidney injury (_____ days)

☐ ARDS (_____ days)

☐ Anastomotic failure (_____ days)

☐ Arrhythmias (_____ days)

☐ Cardiac arrest (_____ days)

☐ Cardiogenic pulmonary edema (_____ days)

☐ Postoperative delirium (_____ days)

☐ Myocardial infarction (_____ days)

☐ Pneumonia (_____ days)

☐ Intestinal paresis (_____ days)

☐ Postoperative bleeding (_____ days)

☐ Pulmonary embolism (_____ days)

☐ Acute cerebrovascular accident (_____ days)

☐ Wound infection (_____ days)

3. Length of stay in the ICU _____ (days)

4. Length of stay in the hospital _____ (days)

5. 30 day outcome:

a) death (Yes/No)

b) readmission (Yes/No)

Date of inclusion in the study _____

Date of final completion of the questionnaire _____