

PERIOPERATIVE PATIENT MANAGEMENT

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Epidemiology of adverse outcomes in high surgical risk patients in elective abdominal surgery: results of a prospective observational multicenter study STOPRISK

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ПЕРИОПЕРАЦИОННОЕ ВЕДЕНИЕ ПАЦИЕНТОВ

Эпидемиология неблагоприятных исходов у пациентов высокого операционного риска в плановой абдоминальной хирургии: результаты проспективного наблюдательного многоцентрового исследования STOPRISK

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Abstract

INTRODUCTION: The epidemiology of adverse outcomes after abdominal surgery remains one of the key problems of modern surgery and anesthesiology-resuscitation because of an aging population and an increasing prevalence of comorbidity. **OBJECTIVE:** To describe the epidemiology of postoperative complications in high risk patients undergoing elective abdominal surgery and to compare their outcomes with the overall STOPRISK cohort. **MATERIALS AND METHODS:** A prospective, multicenter observational cohort study was conducted in 38 Russian centers and included 11 478 adults undergoing elective surgery on abdominal and pelvic organs; among them, 1367 patients (11.9 %) met guideline based criteria for high surgical risk. Postoperative complications within 30 days were recorded according to EPCO definitions and graded using the Clavien—Dindo classification, with detailed assessment of frequency, structure, severity and timing. **RESULTS:** In the high risk subgroup, at least one complication occurred in 14.2 % of patients and mortality was 1.8 %, approximately threefold higher than in the overall cohort (4.5 and 0.62 %, respectively). The most frequent complications were postoperative ileus (4.8 %), postoperative bleeding (2.6 %), wound infection and pneumonia (2.4 % each),

Реферат

АКТУАЛЬНОСТЬ: Эпидемиология неблагоприятных исходов после абдоминальных операций остается одной из ключевых проблем современной хирургии и анестезиологии-реаниматологии на фоне старения популяции и нарастающей распространенности коморбидности. **ЦЕЛЬ ИССЛЕДОВАНИЯ:** Определить частоту, структуру, тяжесть, сроки развития послеоперационных осложнений и сравнить полученные данные у пациентов высокого операционного риска с таковыми в общей популяции пациентов после плановых абдоминальных операций на основе анализа базы STOPRISK и зарубежных регистров. **МАТЕРИАЛЫ И МЕТОДЫ:** Проведено проспективное наблюдательное многоцентровое когортное исследование в 38 центрах России, включившее 11 478 пациентов, перенесших плановые операции на органах брюшной полости и малого таза; из них 1367 (11,9 %) отнесены к высокому операционному риску по критериям европейских рекомендаций. Оценивали структуру, частоту, тяжесть по классификации хирургических осложнений Clavien—Dindo и сроки развития осложнений в течение 30 сут после операции с использованием стандартов EPCO. **РЕЗУЛЬТАТЫ:** У пациентов высокого риска осложнения развились у 14,2 %,

anastomotic leakage (2.1 %), acute kidney injury and postoperative delirium (1.9 % each). Overall, 68.5 % of events were severe complications (Clavien—Dindo \geq III), usually requiring intensive care and/or invasive interventions. Two thirds of all complications occurred within the first 5 postoperative days, which also concentrated most severe and fatal events, including circulatory arrest, severe respiratory and renal failure. **CONCLUSIONS:** High risk surgical patients, while representing a small proportion of the elective abdominal population, account for a disproportionately large share of severe complications and deaths. These findings support the implementation of targeted protocols for intensive monitoring, early diagnosis and prevention during the early postoperative window, as well as refinement of national perioperative risk stratification tools and resource planning.

KEYWORDS: high risk surgical patients, elective abdominal surgery, postoperative complications, Clavien—Dindo classification, perioperative risk, national registry, intensive care

REGISTRATION: The study is registered in the clinicaltrials.gov database, NCT03945968

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и летальность составила 1,8 %, что примерно в три раза выше, чем в общей когорте (4,5 и 0,62 % соответственно). Наиболее частыми осложнениями были парез кишечника (4,8 %), послеоперационное кровотечение (2,6 %), раневая инфекция и пневмония (по 2,4 %), несостоятельность анастомоза (2,1 %), острое повреждение почек и послеоперационный делирий (по 1,9 %). Среди всех зарегистрированных событий 68,5 % осложнений относились к тяжелым (Clavien—Dindo \geq III) и чаще требовали лечения в отделении реанимации и интенсивной терапии. Две трети осложнений возникли в первые 5 сут после операции, причем именно в эти сроки концентрировались тяжелые и фатальные события. **ВЫВОДЫ:** Пациенты высокого операционного риска формируют непропорционально большую долю тяжелых осложнений и летальных исходов. Полученные данные обосновывают необходимость таргетированных протоколов интенсивного мониторинга и профилактики в первые 5 сут, а также калибровки национальных инструментов стратификации риска и планирования ресурсов.

КЛЮЧЕВЫЕ СЛОВА: пациенты высокого операционного риска, плановая абдоминальная хирургия, послеоперационные осложнения, классификация хирургических осложнений Clavien—Dindo, периоперационный риск, национальный регистр, интенсивная терапия

РЕГИСТРАЦИЯ: Исследование зарегистрировано в базе clinicaltrials.gov, NCT03945968

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Introduction

Epidemiology of adverse outcomes after abdominal surgery remains one of the key problems of modern surgery, anesthesiology and intensive care against the background of population aging and increasing prevalence of comorbidity [1–6]. At the same time, patients with high operational risk, being a minority among operated patients, form a disproportionately large share of postoperative complications and deaths, which is shown both in international registers and in national studies [2, 6–8].

According to multicenter observational studies, the prevalence of comorbidities and severe perioperative organ lesions is directly related to an increase in the incidence of complications, the need for intensive care resources, and an increase in mortality [3, 4, 6, 7, 9]. In large cohorts of surgical patients, it has been shown that perioperative organ injuries are associated with a significant increase in adverse outcomes, and in elderly patients and patients with high comorbidity, their contribution to mortality is particularly significant [3, 4]. At the same time, despite the development of ERAS-protocols and the improvement of perioperative management, the risk of severe complications after abdominal interventions, including infections, bleeding, cardiovascular and respiratory complications, remains clinically significant [1, 3, 6, 7].

Previously, the national prospective multicenter STOPRISK study showed a high incidence of comorbidity and associated postoperative complications in elective abdominal surgery, and described the epidemiology of adverse outcomes in the general cohort of patients [6, 7, 9]. However, the group of patients with high operational risk was not identified and analyzed in detail in these publications. It is not known exactly how complications are distributed in this group of patients by type, severity, and time intervals after surgery, although patients with high operational risk make the main contribution to resource-intensive adverse outcomes [6, 7, 9]. At the same time, the modern system of risk stratification and planning of postoperative follow-up requires not only an assessment of the 30-day total complication rate, but also an understanding of the time windows of maximum risk for various types of complications [8, 10, 11].

Of particular importance is the assessment of the severity of complications according to the Clavien–Dindo scale, which makes it possible to standardize the registration of events and compare data from various studies and registers [12]. The use of this classification in different countries has shown its reproducibility and clinical significance, and the association of the Clavien–Dindo severity distribution with outcomes after abdominal surgery has opened up opportunities for targeted prevention and rehabilitation strategies [13–15].

Analysis of the periods of occurrence of complications (from day 1–3-to-day 16–30) in high-risk patients made it possible to identify critical intervals for intensive monitor-

ing, improved routing, and personalized use of intensive care resources [6, 7, 10].

Against this background, an analysis of data on the epidemiology of adverse outcomes specifically in the group of high-risk patients with an assessment of the frequency, structure, severity and timing of complications can become the basis for improving national recommendations on preoperative risk stratification, planning postoperative follow-up and resource provision in elective abdominal surgery, as well as for comparison with data from international registries and initiatives for quality control of surgical care.

This analysis was pre-planned in the STOPRISK registry protocol as a study of a subgroup of high-risk patients with a focus on the structure, severity, and time profile of postoperative complications [9]. Such approach made it possible to compare the epidemiology of adverse outcomes in this group with the general population of the register and international data, and to reduce the risk of post-factum interpretations [16].

Objective

To determine the frequency, structure, severity, and timing of postoperative complications and compare the data obtained in patients with high surgical risk with those in the general population of patients after elective abdominal surgery based on the analysis of the STOPRISK database and foreign registers.

Materials and methods

A prospective observational multicenter cohort study was conducted based on the national STOPRISK registry, which included a pre-planned analysis of a subgroup of high-risk patients after elective abdominal surgery in accordance with the STROBE guidelines for reporting observational studies [16]. From July 1, 2019 to April 30, 2024, 38 centers representing 8 federal districts included 12,000 patients operated on the abdominal and pelvic organs. All centers were approved by local ethics committees prior to the study. Patients signed a voluntary informed consent to participate in the study [9]. The study protocol included collecting information about all patients who met the inclusion criteria for the selected day.

Gender and age characteristics, comorbidity, and features of anesthesia and surgery were recorded in all patients after assessment of compliance with the inclusion criteria. In the postoperative period, 30-day deaths and complications were recorded based on EPCO criteria EPCO [17].

After excluding 522 (4.4 %) cases due to missing or incomplete data, 11,478 operated patients were included in the subsequent analysis. Depending on the degree of surgical risk (Table 1), they were divided into patients with low risk — 3630 individuals (31.6 %), medium risk — 6481 indi-

viduals (56.5 %), and high risk — 1367 individuals (11.9 %). Of these, 7164 women (62.4 %) and 4314 men (37.6 %) were registered.

At the first stage of the study, the frequency and structure of complications in patients with high surgical risk were determined, at the second stage, the severity of complications was analyzed according to the Clavien-Dindo classification of surgical complications, and at the third stage, the period of development of complications was analyzed based on days 1 to 3, 4 to 5, 6 to 8, 9 to 15, 16 to 30 and after 30 days [10].

Registration of the study

The study is registered in the international database <https://clinicaltrials.gov> under the auspices of the All-Russian Public Organization “Federation of Anesthesiologists and Resuscitators” (chief researcher — I.B. Zabolotskikh), study number NCT03945968. All the main researchers of the centers signed the document “Confirmation of verification of the data entered in the registration forms”.

Statistical analysis

Statistical analysis was performed using the Excel application and included selecting a pivot table in the layout, analyzing data in several tables in the pivot table report in Excel, and creating links between them in the Power Pivot table [9]. Quantitative data were presented as the mean and standard deviation, or the median and interquartile range (Q1–Q3), depending on the nature of the distribution (normality was assessed using the Shapiro-Wilk test). Categorical indicators were presented as absolute values and fractions (%). Pearson’s chi-square test or Fisher’s exact test were used to compare shares, and Student’s *t* — test or Mann-Whitney test were used to compare quantitative vari-

ables, depending on the distribution. All tests were two-sided; differences were considered statistically significant at $p < 0.05$.

Results

Of the 1,367 patients with high surgical risk, 194 (14.2 %) developed postoperative complications, 24 (1.8 %) had a fatal outcome, while isolated (1 complication) complications prevailed (108 patients, 55.7 %). Concomitant complications (2 or more) were observed in 86 patients (44.3 %). The most frequent complications in patients with high surgical risk were intestinal paresis (4.8 %), wound infection, postoperative bleeding, pneumonia (2.4–2.6 %), anastomosis failure (2.1 %), acute kidney injury, postoperative delirium (1.9 %), cardiac arrest with a fatal outcome (1.8 %), acute respiratory failure (ARF) and sepsis (1.5 %), arrhythmias, ARDS, and re-intubation (1.3–1.5 %). Other complications were observed with a frequency of 0.4 % or lower. Thus, surgical, infectious, and respiratory complications were most common in high-risk patients (Table 2).

Figure 1 shows the structure of complications. A total of 378 complications were registered. The most frequent complications included intestinal paresis — 65 (17.2 %), postoperative bleeding — 35 (9.3 %), wound infection — 33 (8.7 %), pneumonia — 33 (8.7 %), anastomotic leakage — 29 (7.7 %), acute kidney injury and postoperative delirium — 26 (6.9 %), cardiac arrest with a fatal outcome — 24 (6.3 %), sepsis, acute respiratory failure — 20 (5.3 %), less often arrhythmias — 4.8 %, acute respiratory distress syndrome — 4.0 %, re-intubation — 3.4 %, acute myocardial infarction — 1.6 %, wound dehiscence — 1.3 %. Pulmonary embolism, cardiogenic pulmonary edema, and non-fatal cardiac arrest were each observed in 0.8 % of cases, and CVA was rarely observed in 0.3 % of cases.

Table 1. Stratification of surgical risk [11]

Low risk (< 1 %)	Medium risk (1–5 %)	High risk (> 5 %)
Surgical interventions:	Intraperitoneal:	Thoracic interventions on the aorta and large vessels
■ On the body surface	■ Splenectomy, hernia repair with plastic surgery, cholecystectomy	Open revascularization of the lower limb or amputation or thromboembolism
■ On the mammary gland	■ On the carotid arteries with clinical symptoms (carotid endarterectomy or stenting)	Operations on the pancreatoduodenal zone
■ Dental	■ Angioplasty of peripheral arteries	Liver resection, biliary tract surgery
■ On the thyroid gland	■ Endovascular correction of aneurysms	Esophagoectomy
■ Ophthalmological	■ Head and neck surgery	Operations for intestinal perforation
■ Reconstructive	■ Neurological or major orthopedic (hip and spine) operations	Adrenal resection
■ On the carotid arteries without clinical symptoms (carotid endarterectomy or stenting)	■ Large urological and gynecological	Cystectomy
■ Small gynecological	■ Kidney transplantation	Pneumonectomy
■ Small orthopedic (meniscectomy)	■ Small intrathoracic	Lung or liver transplantation
■ Minor urological procedures (transurethral resection of the prostate gland)		

Table 2. Total number and incidence of complications

Adverse outcomes	Total number	Percentage of total
Cardiac		
Arrhythmias	18	1.3
Non fatal cardiac arrest	3	0.2
Cardiac arrest with subsequent fatal outcome	24	1.8
Cardiogenic pulmonary edema	3	0.2
Acute myocardial infarction	6	0.4
Pulmonary embolism	3	0.2
Acute cerebrovascular accident	1	0.1
Respiratory		
Acute respiratory distress syndrome	15	1.1
Pneumonia	33	2.4
Acute respiratory failure	20	1.5
Tracheal re-intubation	13	1.0
Infectious		
Wound infection	33	2.4
Sepsis	20	1.5
Cerebral		
Postoperative delirium	26	1.9
Renal		
Acute kidney injury	26	1.9
Surgical		
Anastomotic leakage	29	2.1
Intestinal paresis	65	4.8
Postoperative bleeding	35	2.6
Wound dehiscence	5	0.4

Figure 2 shows the severity of complications. Grade I complications were observed in 4 cases (1.1 %). Grade II complications were seen in 115 cases (30.4 %), grade IIIa — in 66 cases (17.5 %), grade IIIb — in 34 cases (9.0 %), grade IVa — in 98 cases (25.9 %), grade IVb — in 37 cases (9.8 %), grade V — in 24 cases (6.3 %). The severity of complications was mainly grade II for intestinal paresis, grade II and III for wound infection, wound dehiscence and arrhythmias, and grade IV for delirium, sepsis, tracheal re-intubation, and acute kidney injury. Thus, 68.5 % of the complications were severe (grade III and higher), which usually required treatment of these patients in the intensive care unit.

Most of the complications (as shown in Figure 3) were detected on days 1 to 3 (128 complications — 33.9 %) and days 4 to 5 (109 complications — 28.8 %). Fifty-four complications (14.3 %) were detected on days 6 to 8, 57 complications (15.1 %) — on days 9 to 15, 26 complications (6.9 %) — on days 16 to 30. Four complications developed in the period over 30 days (1.1 %).

Table 3 shows that heterogeneity is noted in the timing of the development of various complications. Thus, among cardiac complications, arrhythmias were observed mainly on days 1–3 and 4–5; non-fatal cardiac arrest was noted on days 1–3 and 9–15, the overwhelming majority of cases of cardiogenic pulmonary edema were observed on days 4–5 of the postoperative period. Among respiratory complications (acute respiratory distress syndrome, pneumonia, ARD), the greatest number of complications was detected on day 8. Infectious complications (wound infection, sepsis) mainly developed on days 1–3, 4–5, 9–15. Cerebral complications (delirium) and renal complications (acute kidney injury) developed on days 1–3. Surgical complications (anastomotic leakage, postoperative bleeding and wound dehiscence) were seen at all stages of follow-up, but mainly on days 1–3, 4–5, wound dehiscence in 20 % of cases was also recorded on days 9–15.

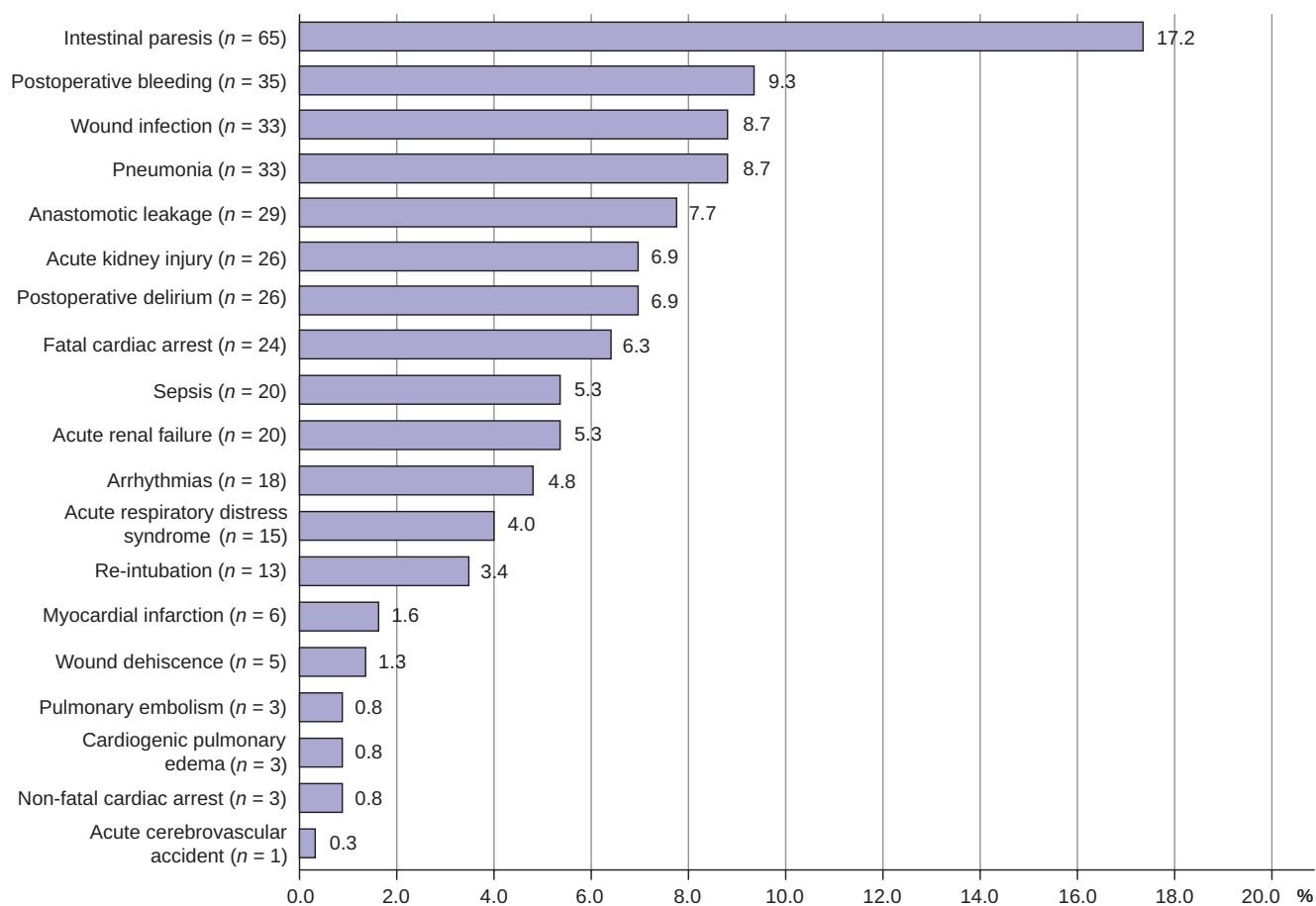


Fig. 1. Structure of complications (n = 378)

Epidemiological "gradient" between high surgical risk patients and the general population of the STOPRISK database

In this study, we performed a detailed analysis of the frequency, structure, severity, and timing of postoperative complications in high-risk patients compared with the general population of patients undergoing elective abdominal surgery in the STOPRISK registry (Table 4). Despite the fact that patients with high surgical risk accounted for only 11.9 % of the sample (1,367 out of 11,478), they made a disproportionate contribution to adverse outcomes, determining more than 80 % of all complications and deaths. This is crucial for the interpretation of aggregated indicators for the entire cohort, since the "average" values for the general population largely reflected the epidemiological profile of high-risk patients.

Comparison of complication rates and mortality between groups shows a pronounced risk gradient. In the general population, complications developed in 4.5 % of patients, while in the high-risk subgroup they occurred in 14.2 % ($p < 0.0001$), while the 30-day mortality rate increased from 0.62 % to 1.8 % ($p < 0.0001$). While maintaining a similar hierarchy of leading complications (postoperative intestinal paresis, bleeding, pneumonia, anastomosis

failure, acute renal failure, sepsis, and circulatory arrest), an approximately three-fold increase in the absolute and relative frequency in the high-risk subgroup was observed for most nosologies. Thus, the incidence of postoperative intestinal paresis increased from 1.4 % to 4.8 % ($p < 0.0001$), bleeding—from 0.8 % to 2.6 % ($p < 0.0001$), pneumonia — from 0.79 % to 2.4 % ($p < 0.0001$), anastomosis failure — from 0.58 % to 2.1 % ($p < 0.0001$), which emphasizes the quantitative rather than qualitative difference in the epidemiological profile of the high postoperative risk subgroup from the general cohort.

Of particular importance is the assessment of the severity of complications. In the general population, complications of grade \geq III on the Clavien–Dindo scale accounted for 62 % of all episodes, while in the high — risk subgroup it was already 68.5 % ($p \approx 0.025$), while, first of all, the proportion of complications requiring intensive care and invasive interventions (IIIb–IVa) increased. Although a global comparison of the total distribution on the Clavien-Dindo classification of surgical complications grades between groups (I–V) revealed only a tendency to differences ($p = 0.07$), statistically significant differences were noted for individual categories: Thus, the proportion of grade I complications was lower in the high-risk subgroup (1.1 % vs 2.9 %; $p = 0.049$), and the proportion of IVa complications was

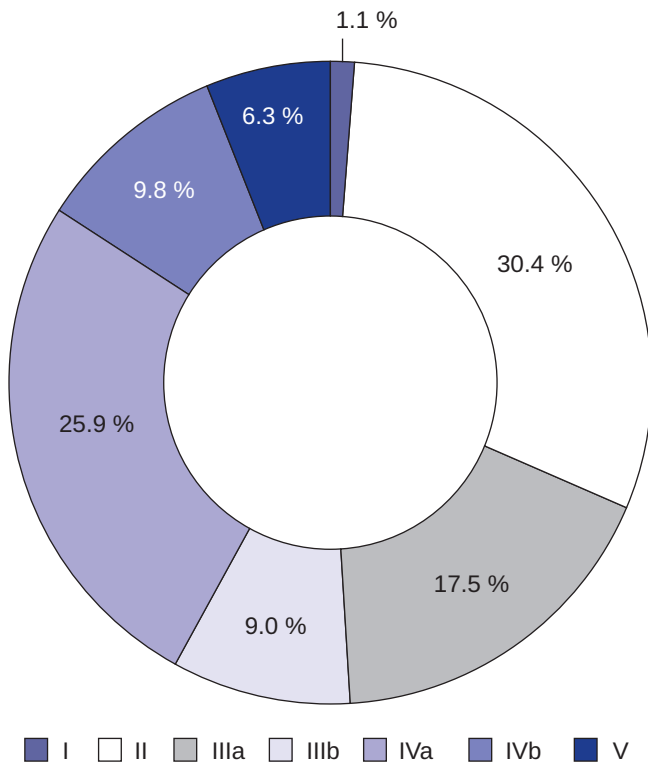


Fig. 2. Severity of complications according to the Clavien-Dindo classification of surgical complications ($n = 378$)

higher (25.9 % vs 20.0 %; $p = 0.019$). Taken together, this indicated that high-risk patients were not only more likely to develop complications, but also developed more severe forms of complications.

Analysis of individual nosologies showed the proportion of severe complications in the high-risk subgroup. The incidence of sepsis increased from 0.35 % to 1.5 % ($p < 0.0001$), acute kidney injury — from 0.52 % to 1.9 % ($p < 0.0001$), and circulatory failure with a fatal outcome — from 0.41 % to 1.8 % ($p < 0.0001$). Given that these complications are associated with high mortality and long-term intensive care, the epidemiological “shift” of their frequency towards the high-risk subgroup explains a significant part of the overall mortality of the register. It is significant that even with a relatively small proportion of such patients in the sample, they determine the main indicators of surgical care effectiveness at the level of the healthcare system.

The temporal complication profile also confirmed the critical role of the high-risk subgroup. In the general population, the maximum number of complications was recorded in the first 5 days (36.6 % on day 1–3 and 30.5 % on day 4–5), followed by a decrease in the frequency of events. In the high-risk subgroup, two-thirds of complications also occurred in the first 5 days, while in the early intervals (days 1–3 and 4–5), a large proportion of severe and fatal events were detected, including circulatory arrest, severe respiratory and renal failure. These data highlight the existence of a narrow “therapeutic window” of the early postoperative

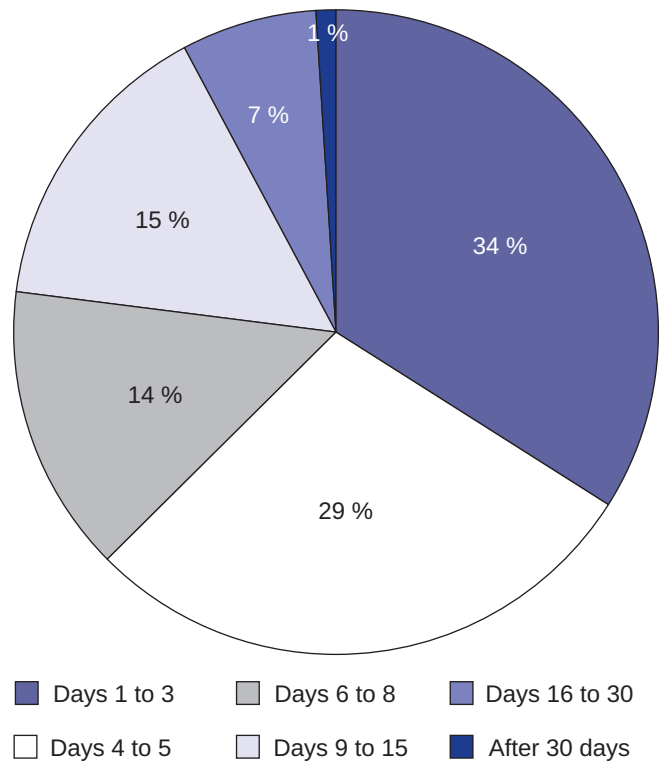


Fig. 3. Timing and incidence of complications (%)

period, during which targeted monitoring and prevention measures in high-risk patients potentially have the maximum effect.

From an epidemiological point of view, the identification of a high-risk subgroup within the general STOPRISK cohort allowed us to reinterpret the previously published results of the register and avoid “blurring” the risk in the analysis of a mixed population. A significant concentration of complications and deaths in a relatively small group of patients showed discrepancies between the aggregated indicators of different registries (for example, NSQIP, LASOS, ASOS), where the proportion of high-risk patients could differ significantly. From a practical point of view, this means that even a moderate improvement in the perioperative management and organization of care in the subgroup of high operational risk can lead to a disproportionately large reduction in the overall postoperative morbidity and mortality in the national health system.

Discussion

The epidemiology of complications identified in high-risk surgical patients in the STOPRISK study is generally comparable with the results of large international programs and randomized trials in elective abdominal surgery (Table 5). In our cohort, the incidence of any 30-day postoperative complications was 14.2 % (194 out of 1367 patients; 95 % CI approximately 12.3–16.1 %), while the

Table 3. Periods and frequency of complications in patients with high risk of complication development

Adverse outcomes	Number of complications											
	Days 1 to 3		Days 4 to 5		Days 6 to 8		Days 9 to 15		Days 16–30		After 30 days	
	Abs.	%	Abs.	%	Abs.	%	Abs.	%	Abs.	%	Abs.	%
Cardiac												
Arrhythmias	13	72.2	4	22.2	0	0.0	1	5.6	0	0	0	0
Non-fatal cardiac arrest	1	33.3	1	33.3	0	0.0	1	33.3	0	0	0	0
Cardiac arrest with fatal outcome	7	29.2	1	4.2	4	16.7	4	16.7	5	20.8	3	12.5
Cardiogenic pulmonary edema	0	0.0	2	66.7	0	0.0	1	33.3	0	0	0	0
Acute myocardial infarction	1	16.7	2	33.3	1	16.7	2	33.3	0	0	0	0
Pulmonary embolism	1	33.3	0	0.0	0	0.0	1	33.3	1	33.3	0	0
Acute violation of cerebral circulation	1	100.0	0	0.0	0	0.0	0	0.0	0	0	0	0
Respiratory												
Acute respiratory distress syndrome	5	33.3	3	20.0	3	20.0	4	26.7	0	0	0	0
Pneumonia	7	21.2	4	12.1	10	30.3	8	24.2	4	12.1	0	0
Acute respiratory failure	11	55.0	1	5.0	1	5.0	4	20.0	3	15.0	0	0
Re-intubation	1	7.7	0	0.0	4	30.8	5	38.5	3	23.1	0	0
Infectious												
Wound infection	7	21.2	7	21.2	5	15.2	9	27.3	5	15.2	0	0
Sepsis	4	20.0	3	15.0	5	25.0	6	30.0	2	10	0	0
Cerebral												
Postoperative delirium	23	88.5	2	7.7	0	0.0	1	3.8	0	0	0	0
Renal												
Acute kidney injury	19	73.1	4	15.4	2	7.7	0	0.0	0	0	1	3.8
Surgical												
Anastomotic leakage	12	41.4	9	31.0	6	20.7	2	6.9	0	0	0	0
Intestinal paresis	0	0.0	56	86.2	7	10.8	1	1.5	1	1.5	0	0
Postoperative bleeding	14	40.0	7	20.0	6	17.1	6	17.1	2	5.7	0	0
Wound dehiscence	0	0.0	4	80.0	0	0.0	1	20.0	0	0	0	0

proportion mortality was 1.8 % (24 out of 1367; 95% CI approximately 1.1–2.6 %), which fits into the range of indicators, described for elective extensive abdominal surgeries in high-risk patients in foreign registries and cohort studies. It is important that 68.5 % of the reported complications were severe (Clavien–Dindo III–V), that is, they required invasive interventions and/or treatment in the intensive care unit, which emphasizes the concentration of adverse outcomes in the high-risk subgroup [18, 19].

Comparison with the ACS-NSQIP program data shows that the total complication rate in our high-risk patients (14.2 %) is similar to the typical values for elective extensive abdominal surgeries in international regis-

tries, where the proportion of patients with at least one complication is usually in the range of 10–20 %, and the mortality rate is in the range of 1–3 %. At the same time, the proportion of severe complications in STOPRISK (more than two-thirds of all events) was in the upper part of the range described in the literature for serious complications comparable in severity to the Clavien–Dindo III–IV categories in quality registers. This distribution confirmed that the identification of a high-risk subgroup based on operational risk and comorbidity allowed us to “focus” most of the severe postoperative pathology on a relatively small part of the general surgical population [18, 19].

Table 4. The most clinically significant complications and severity on the Clavien-Dindo classification of surgical complications in the general population and in patients with high surgical risk (STOPRISK)

Indicator / complication	Total STOPRISK population (n = 11,478)	High operational risk (n = 1,367)	p (chi-square / Fisher)
Patients with ≥ 1 complication, n (%)	521 (4.5 %)	194 (14.2 %)	p < 0.0001
Mortality, n (%)	71 (0.62 %)	24 (1.8 %)	p < 0.0001
Postoperative intestinal paresis, n (% of the total cohort)	161 (1.4 %)	65 (4.8 %)	p < 0.0001
Postoperative bleeding, n (%)	92 (0.8 %)	35 (2.6 %)	p < 0.0001
Pneumonia, n (%)	91 (0.79 %)	33 (2.4 %)	p < 0.0001
Anastomosis failure, n (%)	66 (0.58 %)	29 (2.1 %)	p < 0.0001
Acute renal failure, n (%)	60 (0.52 %)	26 (1.9 %)	p < 0.0001
Sepsis, n (%)	40 (0.35 %)	20 (1.5 %)	p < 0.0001
Fatal circulatory arrest, n (%)	47 (0.41 %)	24 (1.8 %)	p < 0.0001
Clavien-Dindo I, n (% of all complications)	27 (2.9 %)	4 (1.1 %)	p = 0.049
Clavien-Dindo II, n (%)	330 (35.1 %)	115 (30.4 %)	p = 0.10
Clavien-Dindo IIIa, n (%)	159 (16.9 %)	66 (17.5 %)	p = 0.82
Clavien-Dindo IIIb, n (%)	80 (8.5 %)	34 (9.0 %)	p = 0.78
Clavien-Dindo IVa, n (%)	188 (20.0 %)	98 (25.9 %)	p = 0.019
Clavien-Dindo IVb, n (%)	108 (11.5 %)	37 (9.8 %)	p = 0.37
Clavien-Dindo V, n (%)	47 (5.0 %)	24 (6.3 %)	p = 0.33
Clavien-Dindo complications ≥ III (IIIa-V), n (% of all complications)	582/939 (62 %)	259/378 (68.5 %)	p = 0.025

The results of STOPRISK are also consistent with data from randomized trials in high-risk patients who underwent extensive abdominal surgery. In the FLASH study, which included patients with an increased risk of postoperative acute kidney injury, the composite endpoint of “death or serious complication” on day 14 was observed in 32–36 % of patients, with a 28-day mortality rate of about 2–4 %, which reflects a more severe outcome profile, but an order of magnitude comparable in mortality in the high-risk subgroup. In the INPRESS study, in patients at high risk of organ dysfunction, the primary outcome rate (SIRS with organ dysfunction by day 7) reached 38–52 %, and the mortality rate by day 30 was about 5–6 %, with most complications also classified as serious organ damage. Against this background, the indicators in our sample appear moderate in terms of the frequency of any complications and mortality, but show a high proportion of severe events, which is probably due to the peculiarities of high-risk criteria and the structure of interventions in the STOPRISK study [20, 21].

Finally, data from large observational cohort studies in ASA III–IV patients who underwent extensive abdominal surgery also confirmed the comparability of the results. In a number of similar studies, the incidence of any complications reached 25–40 %, with the proportion of severe complications (Clavien-Dindo III–V or equivalent) about 10–20 % and 30-/90-day mortality rate at the level of 1–3 %.

Against this background, the complication rate in the STOPRISK cohort is slightly lower, while the concentration of severe outcomes among reported complications is higher than usually described in international series, which may reflect both active prevention and early detection of mild events, and the selectivity of the selected high-risk subgroup. Taken together, a comparison with international registries and RCTs confirms that the epidemiological profile of complications in high-risk patients in the Russian cohort is generally consistent with global data for elective abdominal surgery, while emphasizing the critical burden of severe complications in this subgroup [18, 22–24].

The obtained complication rate (14.2 %) is comparable to the range of 15–20 % given in modern studies for elective abdominal surgery in comorbid patients, but it is noticeably lower than the indicators recorded in mixed cohorts (emergency + elective surgery), where the complication rate can reach 30–38 % [13].

The most frequent complication in our sample was intestinal paresis (17.2 %), which is fully consistent with the global epidemiological data for 2020–2025, which estimated the frequency of postoperative intestinal paresis in the range of 10–25 % after major abdominal operations. Current meta-analyses have shown that despite the introduction of ERAS protocols, intestinal paresis remains the leading cause of prolonged hospitalization and patient dis-

Table 5. Comparison of complication epidemiology in high surgical risk patients undergoing elective abdominal surgery

Study	Population and high-risk criteria	Rate		
		Of any complications	Severe complications, Clavien-Dindo III–V	Deaths
Present study	1367 patients with high surgical risk, ASA II–III	14.2 %	68.5 %	1.8 %
[19, 20]	ASA II–IV	15–20 %	6–12 %	1–3 %
[21]	775 patients with a high risk of acute kidney injury	32–36 %	32–36 %	2.3–4.1 %
[22]	Patients over 50 years of age with high comorbidity	38.1–51.7 %	46.3–63.4 %	5–6 %
[24]	Elderly patients ASA III–IV	25–40 %	10–20 %	1–3 %

Note: For international studies, typical ranges are provided based on published data for high-risk patients undergoing elective extensive abdominal surgery; emergency interventions are not included in these estimates.

comfort. Our observation about the predominance of intestinal paresis over surgical infections (wound infection – 8.7 %) correlates with the trend to reduce the frequency of infection due to modern prevention measures, while functional disorders of the gastrointestinal tract remain a difficult component of the surgical stress response [1]. A critical finding is a high proportion of severe complications (62 % on the Clavien-Dindo scale \geq III) and their development in the early stages (2/3 of cases in the first 5 days). This contradicts a number of opinions about the “delayed” nature of complications in somatically severe patients and emphasizes the need for intensive monitoring in the early postoperative period. The current literature also notes that early diagnosis of complications is a key factor in reducing mortality, which in our study was 1.8 % [5]. Our data are limited to a sample of planned patients, which does not allow us to extrapolate conclusions to emergency surgery, where the complication profile shifts towards sepsis and multiple organ failure. Nevertheless, the revealed profile (dominance of paresis and severe complications in the first 5 days) justifies the need for personalized protocols of perioperative management for a subgroup of high-risk patients. In terms of the number of complications, the STOPRISK study in high-risk patients showed results comparable to the NSQIP database, which included patients after extensive abdominal operations in elective surgery (14.2 % in STOPRISK versus 12.5 % in NSQIP) [8]. According to the Clavien-Dindo classification, the majority (30.4 %) of the complications identified in the STOPRISK study are classified as grade II, i.e. they can be stopped with the help of pharmacological agents. Complications requiring surgical correction under local anesthesia (grade IIIa) were detected in 17.5 % of patients, and organ failure (grade IV a) was detected in 25.9 %, which is generally consistent with the data of the world literature [15]. There are indications that the number of complications and their severity are not significantly related to the type of surgery [15]. Compared to the analysis of the general STOPRISK population [6], an increase in the number of IVa and V grade complications was observed.

Strengths and limitations

Key strengths of our study include a prospective multicenter design with a planned analysis of a subgroup of high-risk patients, national coverage (38 centers from 8 federal districts), and registration under the pre-published STOPRISK registry protocol. Standardized registration of outcomes in accordance with EPCO criteria and the Clavien-Dindo classification of surgical complications, as well as a detailed description of the time profile and structure of complications, ensure high clinical validity and reproducibility of the results obtained.

The study has a number of limitations. First, the analysis is limited to elective abdominal surgery, which does not allow us to directly extrapolate the identified patterns to emergency interventions and other types of operations. Second, despite the relatively small proportion of patients with incomplete data (4.4 %), their exclusion may lead to a bias in risk assessment; however, a comparison of the main demographic and clinical characteristics between the groups with complete and incomplete data did not reveal significant differences. Third, it is impossible to completely exclude the influence of uncontrolled confounding factors (including inter-center differences in the structure of operations and perioperative management). These features should be taken into account when interpreting the results and planning further studies aimed at clarifying causal relationships and evaluating the effects of specific interventions in high-risk patients.

Conclusion

Patients with high surgical risk, making up only about 12 % of the total planned abdominal surgical population, form a disproportionately high percent of severe complications (68.5 %) and deaths, and the overwhelming majority of events occur in the early stages (the first 5 days after surgery). In patients with high surgical risk, isolated (1 complication) complications prevailed in the structure of com-

plications (55.7 % among the population of patients with complications), while combined complications (2 or more) were observed in 44.3 %. Intestinal paresis was the most common complication in the general population. Wound infection, postoperative bleeding, and pneumonia were the next most important complications, while the least common were stroke and non-fatal cardiac arrest. Severe (grade

III and higher) complications accounted for 68.5 %, which usually required treatment in the intensive care unit.

These data justify the need for specialized, targeted protocols for intensive monitoring, early diagnosis and prevention in this particular subset of patients, and can also be used to calibrate and improve national tools for perioperative risk stratification and resource planning.

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