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Risk factors for complications and mortality after esophagectomy with immediate esophagoplasty within the rational accelerated perioperative rehabilitation (RAPOR) program: a retrospective observational study

Факторы риска осложнений и летальности после эзофагэктомии с одномоментной пластикой пищевода в рамках программы рациональной ускоренной периоперационной реабилитации (РУПОР): ретроспективное наблюдательное исследование

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Abstract

INTRODUCTION: Esophagectomy with immediate esophagoplasty is a high-risk procedure, with the worldwide incidence of postoperative complications reaching up to 65 % and mortality up to 7.8 %, even in high-volume centers. This underscores the need to identify additional predictors of postoperative complications and mortality. **OBJECTIVE:** Improving outcomes of esophagectomy performed within the Rational Accelerated Perioperative Rehabilitation (RAPOR) program by identifying and minimizing risk factors for complications and mortality. **MATERIALS AND METHODS:** Between 2012 and 2024, 500 elective esophagectomy with immediate esophagoplasty were performed at the Vishnevsky National Medical Research Center of Surgery. Perioperative management followed the RAPOR program, which includes an interdisciplinary and individualized team approach. Statistical analysis included logistic regression and odds ratio (OR) calculation. **RESULTS:** Postoperative complications were observed in 29.2 % of patients, pneumonia — in 10 %, anastomotic leakage and graft necrosis — in 6.6 %. Post-esophagectomy mortality was 1.4 %. Risk factors for complications were: age (OR 1.03), comorbidity index (OR 1.17), ASA score (OR 1.46), duration of surgery (OR 1.04), pre-existing pulmonary disease (OR 1.84), history of cardiac arrhythmia (OR 2.16), history of neurological disease (OR 3.03), C-reactive protein level on 1 day (OR 1.01), and lactate level on ICU admission (OR 1.27). Risk factors for postoperative pneumonia were: age

Реферат

АКТУАЛЬНОСТЬ: Эзофагэктомия с одномоментной пластикой пищевода — вмешательство высокого риска. Частота осложнений достигает 65 %, а летальность — 7,8 % даже в крупных специализированных центрах. Необходим поиск дополнительных факторов прогнозирования осложнений и летального исхода. **ЦЕЛЬ ИССЛЕДОВАНИЯ:** Улучшение результатов эзофагэктомии, выполненной в рамках программы рационально ускоренной периоперационной реабилитации (РУПОР) путем определения и минимизации факторов риска (ФР) осложнений и летальности. **МАТЕРИАЛЫ И МЕТОДЫ:** В ФГБУ «НМИЦ хирургии им. А.В. Вишневского» МЗ РФ в 2012–2024 гг. выполнили ретроспективное исследование 500 плановых эзофагэктомий с одномоментной эзофагопластикой. Периоперационное обеспечение проводили по программе РУПОР, основанной на междисциплинарном индивидуальном командном подходе. Статистический анализ включал логистическую регрессию, расчет отношений шансов (ОШ). **РЕЗУЛЬТАТЫ:** ФР осложнений: возраст (ОШ 1,03), индекс коморбидности (ОШ 1,17), оценка по шкале American Society of Anesthesiologists (ASA) (ОШ 1,46), длительность операции (ОШ 1,04), заболевания легких (ОШ 1,84), нарушение ритма сердца в анамнезе (ОШ 2,16), неврологические заболевания (ОШ 3,03); уровень С-реактивного белка на первые сутки (ОШ 1,01) и лактата при поступлении в реанимацию (ОШ 1,27). ФР послеоперационной

(OR 1.03), pre-existing pulmonary disease (OR 2.61) and history of cardiac arrhythmia (OR 2.58), NRS-2002 score (OR 1.52), ASA score (OR 1.78), duration of surgery (OR 1.05), and high intraoperative infusion volume (OR 1.2). Risk factors for anastomotic leakage and graft necrosis included age (OR 1.03). Risk factors for mortality were: high comorbidity index (OR 1.44) and NRS-2002 score (OR 3.15), history of cardiac arrhythmia (OR 6.02), prolonged mechanical ventilation (OR 19.4), and high intraoperative infusion volume (OR 1.7). **CONCLUSIONS:** Age, comorbidity index, ASA score, duration of surgery, lung diseases, neurological diseases, and cardiac arrhythmias in the medical history are risk factors for postoperative complications. High comorbidity index, NRS-2002 score, cardiac arrhythmias in the medical history, prolonged mechanical ventilation, and large intraoperative fluid infusion volume remain risk factors for mortality.

KEYWORDS: esophagectomy, esophagoplasty, enhanced recovery after surgery, esophageal neoplasms, esophageal achalasia, esophageal stenosis

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пневмонии: возраст (ОШ 1,03), заболевания легких (ОШ 2,61) и нарушения ритма сердца в анамнезе (ОШ 2,58), оценка по Nutrition Risk Screening-2002 (NRS-2002) (ОШ 1,52) и по шкале ASA (ОШ 1,78), длительность операции (ОШ 1,05) и большой интраоперационный объем инфузионной терапии (ОШ 1,2). ФР несостоятельности анастомоза и некроза трансплантата: возраст (ОШ 1,03). ФР летального исхода: высокий индекс коморбидности (ОШ 1,44) и балл по NRS-2002 (ОШ 3,15), нарушение ритма сердца в анамнезе (ОШ 6,02), продленная искусственная вентиляция легких (ОШ 19,4), большой интраоперационный объем инфузии (ОШ 1,7). **ВЫВОДЫ:** Возраст, индекс коморбидности, оценка по ASA, длительность операции, заболевания легких, неврологические заболевания и нарушения ритма сердца в анамнезе являются ФР послеоперационных осложнений. Высокий индекс коморбидности, балл по NRS-2002, нарушения ритма сердца в анамнезе, продленная искусственная вентиляция легких и большой интраоперационный объем инфузии остаются ФР летального исхода.

КЛЮЧЕВЫЕ СЛОВА: эзофагэктомия, эзофагопластика, ускоренная реабилитация после операции, периоперационное обеспечение, рак пищевода, ахалазия, стриктура пищевода

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Introduction

High-risk surgeries involve procedures with more than 5 % risk of cardiovascular death, myocardial infarction or stroke within 30 days after procedure [1, 2]. However, perioperative risk is a broader concept. Different scales and indices are still used to assess patient's comorbidities and physical status such as the Charlson Comorbidity Index [3, 4] and the American Society of Anesthesiologists (ASA) physical status classification system [5, 6]. These tools are

not used for direct prediction of perioperative complications but can help in patient-related risk stratification. For greater objectivity, the American College of Surgeons suggests using its modern, multifactorial surgical risk calculator [7]. Furthermore, assessment of the risk of complications and mortality is possible using a calculator based on the Pythia database from the Duke University Health System [8] and the American MySurgeryRisk model [9].

Esophagectomy with immediate esophagoplasty is a high-risk procedure. Even in high-volume centers rate of complication after esophagectomy reaches up to 65 %, and mortality up to 7.8 % [10]. Modern approaches to perioperative risk assessment in routine practice focus on determining the risk of mortality or specific complications [11]. Risk factors for complications are identified based on single-center studies and meta-analyses, multicenter randomized trials, and systematic reviews. Most studies indicate that male sex, smoking, pulmonary disease, diabetes mellitus, chronic kidney disease, coronary artery disease, hypertension, and peripheral arterial disease are the risk factors for complications [12–14].

At the A.V. Vishnevsky National Medical Research Center of Surgery (NMRCS), a program of Rationally Accelerated Perioperative Rehabilitation (RAPOR) was developed. It is based on the recommendations of the Enhanced Recovery After Surgery (ERAS) society. As a result, the outcomes of esophagectomy at the NMRCS are significantly better then worldwide — the complication rate is 29.2 %, and mortality is 1.4 % [15]. However, it remains unclear which risk factors influence complications and mortality within the framework of the RAPOR program.

Objective

To improve the outcomes of esophagectomy with immediate esophagoplasty performed within the RAPOR program by identifying and minimizing risk factors of complications and mortality.

Materials and methods

A retrospective cohort study was conducted at the NMRCS. Between November 2012 and April 2024 500 elective esophagectomies with immediate esophagoplasty for benign and malignant esophageal diseases were made. The study included all patients who underwent primary esophagectomy with immediate esophagoplasty within the RAPOR program, performed by a single operating surgeon. Exclusion criteria were emergency intervention and a change of the operating surgeon. Patient observation was conducted throughout the perioperative period.

Within the RAPOR program, during the outpatient period, patients were evaluated by an intradisciplinary team (surgeon, intensive care specialist) who formulated a plan of diagnostic procedures and preoperative preparation. All patients were assessed using the Charlson Comorbidity Index, nutritional status according to the Nutrition Risk Score 2002 (NRS-2002), physical status according to the ASA classification, and cardiovascular risk according to the Lee Index. Particular attention was paid to the preoperative correction of malnutrition.

All patients underwent preoperative echocardiography, ultrasound examination of the brachiocephalic arteries, and veins of the lower extremities. For patients with coronary artery disease, diabetes mellitus, generalized atherosclerosis, or low tolerance to physical activity, additional myocardial scintigraphy or stress echocardiography was prescribed. Invasive diagnostics and correction of concomitant cardiovascular pathology were performed when necessary.

Prophylaxis for thromboembolic complications was initiated 12 hours before the intervention. The intradisciplinary team includes a consistent team of anesthesiologists responsible for the intraoperative phase (3 physicians over the retrospective period). During the intervention, normovolemia and normothermia were maintained, and multimodal analgesia, antibiotic prophylaxis, and prevention of postoperative nausea and vomiting (dexamethasone 4–8 mg before anesthesia induction, ondansetron 4–8 mg before extubation) were administered. Esophagectomy was performed via an open transthoracic or transhiatal approach. In the postoperative period, prophylaxis for thromboembolic complications, multimodal analgesia, and infusion therapy were continued. On postoperative day (POD) 1, patients were transferred to the specialized surgical department. The median length of stay in the intensive care unit was 0.67 days. On the surgical department, patients had their pleural drain and urinary catheter removed and were mobilized. Treatment in both the specialized department and the ICU was managed by the surgeon and intensive care specialist, with consultation of other specialists as needed. The intensive care specialist is a staff member of the surgical department.

The RAPOR program is dynamic and has evolved over time: since 2016, cervical drainage was abandoned; since 2017, nasogastric decompression was abandoned; and in 2017, early oral feeding was implemented. The majority of patients followed a traditional postoperative nutritional support regimen with total parenteral nutrition until POD 5 and initiation of pureed food from POD 7. However, 19.2 % of patients were allowed oral water intake from POD 1, sipping from POD 2, and pureed food from POD 4. Clinical and laboratory monitoring was conducted throughout the perioperative period. Complications were classified according to the unified registry of the Esophagectomy Complications Consensus Group [16]. The median duration of the postoperative hospital stay was 9 days. More details about the RAPOR program, its outcomes, and their comparison with global data can be found in another publication [15].

This study evaluated the impact of the following factors on outcomes: sex, age, body mass index, initial diagnosis,

smoking, NRS-2002 score, ASA class, Charlson comorbidity index, Lee Index, prehabilitation, anamnesis data (previous esophageal or gastric surgery, history of myocardial infarction, stroke, chronic kidney disease, neurological diseases, arrhythmias, peripheral arterial disease, diabetes mellitus, thyroid disorders, pulmonary disease (chronic obstructive pulmonary disease (COPD), bronchial asthma, pneumofibrosis, bronchiectasis)), duration of esophagectomy, surgical approach, prolonged mechanical ventilation, total intraoperative fluid volume (including replacement of losses), laboratory parameters on the day before esophagectomy and on POD 1 in the ICU (leukocytes, lymphocytes, C-reactive protein, total protein, albumin, hemoglobin, lactate), and early oral feeding (Table 1).

Table 1. Summary table of descriptive statistics for analyzed parameters (n = 500)

Parameter	Value
Gender	
Male	299 (59.8 %)
Female	201 (40.2 %)
Age, years	
Mean (SD)	56.3 (13.7)
Median [Min, Max]	59.0 [18.0; 89.0]
Body mass index, kg/m^2	
Mean (SD)	24.0 (5.09)
Median [Min, Max]	23.5 [14.4; 40.0]
Diagnosis	
Achalasia	114 (22.8 %)
Esophageal stricture	128 (25.6 %)
Cancer	230 (46.0 %)
Fistula	6 (1.2 %)
Other	22 (4.4 %)
NRS-2002	
Mean (SD)	2.73 (0.849)
Median [Min, Max]	3.00 [1.00; 5.00]
Comorbidity index	
Mean (SD)	3.44 (2.49)
Median [Min, Max]	3.00 [0; 10.0]
Anamnesis data	
Pulmonary disease	62 (12.4 %)
Neurological disease	18 (3.6 %)
Diabetes mellitus	42 (8.4 %)
Peripheral arterial disease	29 (5.8 %)
Arrhythmia	52 (10.4 %)
Chronic kidney disease	9 (1.8 %)
Myocardial infarction	39 (7.8 %)
Stroke	19 (3.8 %)
Thyroid disorders	30 (6.0 %)
Previous esophageal or gastric surgery	232 (46.4 %)
Smoking	134 (26.8 %)
Surgical approach	
Transthoracic	223 (44.6 %)
Transhiatal	277 (55.4 %)
Duration of operation, min	
Mean (SD)	404 (105)
Median [Min, Max]	390 [230; 780]
Total intraoperative infusion therapy volume minus loss compensation, ml/kg/h	
Mean (SD)	4.42 (1.68)
Median [Min, Max]	4.29 [–0.751; 14.0]
Immediate extubation	441 (88.2 %)
Early oral feeding	96 (19.2 %)
Prehabilitation	144 (28.8 %)
Leucocytes preoperative, ×10^9/L	
Mean (SD)	6.93 (3.66)
Median [Min, Max]	6.20 [2.72; 45.0]
Missing	134 (26.8 %)
Lymphocytes preoperative, ×10^9/L	
Mean (SD)	1.77 (0.560)
Median [Min, Max]	1.76 [0.560; 3.10]
Missing	406 (81.2 %)
C-reactive protein preoperative, g/L	
Mean (SD)	11.3 (27.3)
Median [Min, Max]	2.30 [0.200; 235]
Missing	310 (62.0 %)
C-reactive protein on POD 1, g/L	
Mean (SD)	106 (47.7)
Median [Min, Max]	101 [1.55; 281]
Missing	315 (63.0 %)
Total protein preoperative, g/L	
Mean (SD)	70.3 (7.01)
Median [Min, Max]	71.0 [38.0; 90.8]
Missing	37 (7.4 %)
Total protein on POD 1, g/L	
Mean (SD)	52.7 (5.85)
Median [Min, Max]	53.0 [37.0; 73.0]

Continuation of the tabl. 1

End of the tabl. 1

Parameter	Value
Missing	169 (33.8 %)
Albumin preoperative, g/L	
Mean (SD)	40.3 (5.15)
Median [Min, Max]	40.5 [26.0; 68.4]
Missing	143 (28.6 %)
Albumin on POD 1, g/L	
Mean (SD)	29.9 (4.11)
Median [Min, Max]	30.0 [18.0; 55.0]
Missing	195 (39.0 %)
Hemoglobin preoperative, g/L	
Mean (SD)	108 (16.1)
Median [Min, Max]	109 [73.0; 152]
Lactate in ICU, mmol/L	
Mean (SD)	2.63 (1.35)
Median [Min, Max]	2.30 [0.600; 9.70]

Note: ICU — intensive care unit; POD — postoperative day; SD — standard deviation.

Statistical analysis

Statistical analysis of the data was performed using R software, version 4.3.1., 2023. Descriptive statistics are presented as absolute and relative frequencies for categorical variables, and as mean (standard deviation (SD)) and median [minimum, maximum] for quantitative variables. The significance of differences in descriptive statistics was not tested. Logistic regression was used to analyze the association of factors with complications. P-values and 95 % confidence intervals calculated using the Wald method are provided for regression coefficients. Robust standard errors (HC4 sandwich type) were used. Association analysis was performed both without covariate adjustment (unadjusted odds ratios (OR)) and with adjustment for sex and age (adjusted OR). Tests were conducted at a significance level of 0.05. No data imputation for missing values was performed. Available case analysis was used. The study was exploratory that's why no adjustments for multiple comparisons were made.

Results

Risk factors for postoperative complications

Postoperative complications occurred in 29.2 % of patients. In the descriptive analysis comparing the group of patients with complications (n = 146) and those without (n = 354), it was found that among patients with complications:

- There were more men (66.4 *vs* 57.1 %);
- The mean age was approximately 4 years higher (55 *vs* 59.4 years);
- There were more oncology patients (56.2 *vs* 41.8 %);
- The mean comorbidity index was approximately 1 point higher (4.22 *vs* 3.12);
- Patients with pulmonary disease (18.5 *vs* 9.9 %) and arrhythmias in anamnesis (17.8 *vs* 7.3 %) were more frequent;
- There were nearly twice as many patients who underwent transthoracic esophagectomy (61.6 *vs* 37.6 %);
- The duration of surgery was approximately 50 minutes longer (437 *vs* 391 min).

Regression analysis revealed a statistically significant association with postoperative complications, both with and without adjustment for sex and age, for the following factors: age, comorbidity index, pulmonary disease, arrhythmias in anamnesis, duration of surgery, transthoracic approach, C-reactive protein level on POD 1, and lactate level upon ICU admission (Table 2).

Table 2. Risk factors for complications after esophagectomy with immediate esophagoplasty performed within the framework of RAPOR program (n = 500)

Risk factor	OR	*p*	95 % CI	
			L	U
Gender (reference: male)				
Female	0.67	0.053	0.45	1.01
	0.64	*0.036*	*0.43*	*0.97*
Age				
	1.03	0.003	1.01	1.04
	1.03	*0.002*	*1.01*	*1.04*
Diagnosis (reference: achalasia)				
Esophageal stricture	1.39	0.290	0.75	2.58
	1.34	*0.361*	*0.71*	*2.52*
Fistula	4.18	0.233	0.40	43.90
	3.52	*0.330*	*0.28*	*44.17*
Cancer	2.32	0.002	1.35	3.97
	1.70	*0.081*	*0.94*	*3.10*
Other	1.95	0.229	0.66	5.80
	1.89	*0.256*	*0.63*	*5.66*
Comorbidity index				
	1.20	0.000	1.11	1.29
	1.17	*0.009*	*1.04*	*1.32*
ASA				
	1.68	0.000	1.26	2.24
	1.46	*0.021*	*1.06*	*2.02*

End of the tabl. 2

Risk factor	OR	*p*	95 % CI	
			L	U
C-reactive protein on POD 1				
	1.01	0.042	1.00	1.01
	1.01	*0.037*	*1.00*	*1.02*
Lactate in ICU				
	1.26	0.001	1.10	1.45
	1.27	*0.002*	*1.09*	*1.48*
Pulmonary disease (reference: no)				
Yes	2.08	0.010	1.19	3.64
	1.84	*0.033*	*1.05*	*3.24*
Neurological disease (reference: no)				
Yes	2.53	0.085	0.88	7.26
	3.03	*0.040*	*1.05*	*8.71*
Arrhythmia (reference: no)				
Yes	2.75	0.001	1.50	5.02
	2.16	*0.018*	*1.14*	*4.07*
Approach (reference: transthoracic)				
Transhiatal	0.37	0.000	0.25	0.56
	0.42	*0.000*	*0.28*	*0.64*
Duration of operation, 10 min				
	1.04	0.000	1.02	1.06
	1.04	*0.000*	*1.02*	*1.06*
Early oral feeding (reference: no)				
Yes	0.35	0.001	0.19	0.65
	0.40	*0.004*	*0.21*	*0.74*

Note: ASA — American Society of Anesthesiologists Physical Status Classification System; CI — confidence interval; ICU — intensive care unit; L — lower limit; OR — odds ratio; POD — postoperative day; U — upper limit.
Here and further in Tables 2–5, uncorrected OR values are indicated in regular font, while corrected OR values are in italics.

With each additional year of life, the odds of complications increase by 1–4 %. Each point on the comorbidity index is associated with ~20 % increase in the odds of complications. An increase of C-reactive protein on POD 1 by 1 g/L is associated with a 1 % increase in the odds of complications, while an increase of lactate in ICU by 1 mmol/L is associated with ~26 % increase in the odds of complications. Pulmonary disease and arrythmias in anamnesis double the risk of complications. Every ten minutes of surgery are associated with a 2–6 % increase in the odds of complications.

A transhiatal esophagectomy is associated with ~60 % reduction in the risk of complications. Early initiation of oral feeding also reduces the odds of complications by ~60 %. However, the early feeding group initially included younger patients with a lower comorbidity index. The lower complication rate in this group is likely associated with this fact.

For some factors, we observed conflicting results. Male sex in the unadjusted analysis showed an association with complications bordering on statistical significance. After adjusting for age, the odds of complications in women were lower by 36 % compared to men.

In the unadjusted analysis, a neurological disease did not have a significant impact on postoperative complications. However, after adjustment for sex and age, they became a risk factor, increasing the risk of complications threefold.

Furthermore, in the unadjusted analysis, oncology patients had twice the odds of complications compared to patients with achalasia. However, after adjusting for sex and age, the statistical significance of the primary diagnosis disappeared.

Preoperative albumin level appeared as a protective factor in the unadjusted analysis. Each 1 g/L reduced the odds of complications by 1–12 %. However, after adjustment for sex and age, statistical significance was lost. It can both to reduce the risk of complications by 11 % or to increase it by 1 %.

Risk factors for postoperative pneumonia

Postoperative pneumonia was the most frequent complication after esophagectomy within the RAPOR program. It was diagnosed in 10 % of patients. The results of the descriptive analysis assessing risk factors for pneumonia showed similar findings to those for overall complications. In the group of patients with postoperative pneumonia (n = 50):

- There were more men (68 *vs* 58.9 %);
- The mean age was approximately 5 years higher (55.8 *vs* 60.5 years);
- There were more oncology patients (56 *vs* 44.9 %);
- The mean comorbidity index was approximately 1 point higher (4.36 *vs* 3.34);
- Patients with pulmonary disease (26 *vs* 10.9 %) and arrhythmias (24 *vs* 8.9 %) in anamnesis were more frequent;
- Transthoracic esophagectomy was performed more often (70 *vs* 41.8 %);
- The duration of surgery was approximately 60 minutes longer (459 *vs* 398 min);
- Prehabilitation was conducted more frequently (40 *vs* 27.6 %).

Regression analysis revealed a statistically significant association pneumonia with age, pulmonary disease and arrhythmias in anamnesis, malnutrition and duration of surgery (Table 3).

Table 3. Risk factors for pneumonia after esophagectomy with immediate esophagoplasty performed within the framework of RAPOR program (n = 500)

Risk factor	OR	p	95 % CI	
			L	U
Age				
	1.03	0.042	1.00	1.06
	1.03	*0.039*	*1.00*	*1.06*
NRS-2002				
	1.52	0.019	1.07	2.15
	1.52	*0.022*	*1.06*	*2.19*
Smoking (reference: no)				
Yes	1.07	0.841	0.56	2.06
	1.01	*0.985*	*0.48*	*2.13*
Comorbidity index				
	1.18	0.008	1.04	1.32
	1.11	*0.169*	*0.96*	*1.29*
ASA				
	2.01	0.003	1.27	3.19
	1.78	*0.029*	*1.06*	*3.00*
Albumin preoperative				
	0.88	0.002	0.81	0.95
	0.90	*0.010*	*0.82*	*0.97*
Pulmonary disease (reference: no)				
Yes	2.95	0.003	1.44	6.04
	2.61	*0.007*	*1.30*	*5.27*
Arrhythmia (reference: no)				
Yes	3.32	0.002	1.57	7.02
	2.58	*0.018*	*1.18*	*5.63*
Approach (reference: transthoracic)				
Transhiatal	0.31	0.000	0.16	0.58
	0.35	*0.002*	*0.18*	*0.69*
Duration of operation, 10 min				
	1.05	0.000	1.02	1.08
	1.05	*0.001*	*1.02*	*1.08*
Total intraoperative infusion therapy volume minus loss compensation				
	1.17	0.071	0.99	1.39
	1.20	*0.041*	*1.01*	*1.43*

Note: ASA — American Society of Anesthesiologists Physical Status Classification System; CI — confidence interval; L — lower limit; OR — odds ratio; NRS-2002 — Nutrition Risk Screening 2002; POD — postoperative day; U — upper limit.

Each year of life increases the odds of pneumonia by ~3 %. Each point on the NRS-2002 scale is associated with ~50 % increase in the risk of pneumonia, and each ASA point with an ~80 % increase. Every ten minutes of operation increase the risk of pneumonia by 2–8 %. Pulmonary disease almost triples the odds of pneumonia, while arrhythmias in anamnesis increases them by approximately 2.5–3.3 times. However, the adjusted OR for arrhythmias is lower (2.58) than the unadjusted OR (3.36). This indicates that cardiac arrhythmias themselves are associated with older age and/or male sex.

We identified not only risk factors for pneumonia but also protective factors. Performing a transhiatal esophagectomy reduces the odds of pneumonia by ~70 %. A high preoperative albumin level also contributes to a reduced risk of pneumonia. Each 1 g/L is associated with ~10 % reduction in risk. Furthermore, early oral feeding was associated with an ~75 % reduction in the odds of pneumonia.

In the unadjusted analysis, total intraoperative fluid volume minus the replacement of losses, did not significantly impact postoperative pneumonia. However, after adjustment for sex and age, it emerged as a risk factor. Each additional mL/kg/h was associated with ~20 % increase in the risk of pneumonia.

Conflicting results were received when assessing the comorbidity index. In the unadjusted analysis, each point on the index increased the odds of pneumonia by 4–32 %. However, in the adjusted analysis, statistical significance was lost. Such differences may indicate that the index itself is associated with sex and age.

For the remaining factors studied, the associations did not reach statistical significance. However, wide confidence intervals do not allow us to rule out potentially clinically significant associations when assessing these factors in a larger sample.

Risk factors for anastomotic leak and conduit necrosis

The statistical power of the study decreases with a low incidence of complications. Anastomotic leak and conduit necrosis observed in 6.6 % of patients. Descriptive analysis revealed that among patients who occurred these complications:

- The mean age was approximately 4 years higher (60.5 *vs* 56 years);
- There were more oncology patients (60.6 *vs* 40.5 %);
- The mean comorbidity index was approximately 1 point higher (4.33 *vs* 3.38);
- Transthoracic esophagectomy was performed more often (60.6 *vs* 43.5 %);
- A history of other esophageal or gastric surgeries was less frequent (27.3 *vs* 47.8 %).

Based on regression analysis, only one reliable risk factor for anastomotic leak and conduit necrosis was identified — age (Table 4). Each year of life increases the risk of anastomotic leak/conduit necrosis by 3 %.

Table 4. Risk factors for anastomotic leakage, apical and subtotal conduit necrosis after esophagectomy with immediate esophagoplasty performed within the framework of RAPOR program (n = 500)

Risk factor	OR	p	95 % CI	
			L	U
Age				
	1.03	0.040	1.00	1.05
	1.03	*0.037*	*1.00*	*1.06*
Diagnosis (reference: achalasia)				
Fistula	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*
Comorbidity index				
	1.16	0.023	1.02	1.32
	1.08	*0.466*	*0.88*	*1.32*
Peripheral arterial disease (reference: no)				
Yes	3.28	0.035	1.09	9.88
	2.19	*0.186*	*0.69*	*6.96*
Chronic kidney disease (reference: no)				
Yes	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*
Previous esophageal or gastric surgery (reference: no)				
Yes	0.41	0.027	0.19	0.90
	0.49	*0.069*	*0.23*	*1.06*

Note: CI — confidence interval; L — lower limit; OR — odds ratio; U — upper limit.

The impact of the comorbidity index and a peripheral arterial disease on complications is conflicting. In the unadjusted analysis, each unit of the comorbidity index was associated with a 16 % increase in the odds of these complications. Peripheral arterial disease was associated with a 2-fold increase in the risk of complications. However, after adjustment for sex and age, statistical significance was lost. With age, the comorbidity index and the likelihood of generalized atherosclerosis increase in patients.

A similar situation was observed when assessing the impact of a history of gastric or esophageal surgery on complications. In the unadjusted analysis, this factor reduced the odds of anastomotic leak and conduit necrosis by 10–81 %. After adjustment for sex and age, the significance of this parameter disappeared.

Furthermore, in patients with a diagnosis of esophageal fistula and those with chronic kidney disease, anastomotic leak or conduit necrosis did not develop. Based on the model, these might appear to be absolute protective factors. However, this is likely due to the extreme rarity of these factors among the patients. Thus, these findings are statistical artifacts and have no practical value.

Risk factors for mortality

Mortality within the RAPOR program was 1.4 % (7 patients). The rarity of this event significantly limits the possibilities for statistical analysis and substantially reduces the precision of the estimates.

Based on descriptive analysis, it was determined that in the mortality group:

- The mean age was approximately 5 years higher (61.6 *vs* 56.2 years);
- The mean body mass index was approximately 5 units lower (19.5 *vs* 24.1 kg/m^2);
- The mean NRS-2002 score was 1 point higher (3.71 *vs* 2.71);
- The mean comorbidity index was approximately 3 points higher (5.43 *vs* 3.41);
- The mean total intraoperative fluid volume minus replacement of losses was 2 mL/kg/h higher (6.34 *vs* 4.39 mL/kg/h);
- Prolonged mechanical ventilation was required more frequently (71.4 % *vs* 11 %);
- Myocardial infarction in anamnesis was approximately 4 times more often (28.6 % *vs* 7.5 %), and a peripheral arterial disease was approximately 5 times more often (28.6 % *vs* 5.5 %);
- The frequency of cardiac arrhythmias in anamnesis was approximately 4 times higher (42.9 % *vs* 9.9 %);
- The frequency of thyroid disorders in anamnesis was approximately 4 times higher (14.3 % *vs* 5.9 %);
- Transthoracic esophagectomy was performed more often (70 % *vs* 41.8 %);
- The duration of surgery was approximately 60 minutes longer (459 *vs* 398 min);
- Prehabilitation was conducted more frequently (57.1 % *vs* 28.4 %).

Regression analysis revealed that risk factors for mortality included malnutrition, cardiac arrhythmias in anamnesis, prolonged mechanical ventilation, and total protein level on POD 1 (Table 5).

A low total protein level on POD 1 was statistically significantly associated with an increased risk of mortality. Each additional 1 g/L of total protein on POD 1 reduced the odds of mortality by ~12 %.

Malnutrition was a significant risk factor for mortality. Each additional point on the NRS-2002 scale increased the odds of mortality approximately threefold. However, the confidence interval for this measurement was very wide. One point on the NRS-2002 could increase mortality by as little as 23 % or as much as 711 %. At the same time, each additional kg/m^2 of body mass index reduced the odds of mortality by ~25 %.

Arrhythmias in anamnesis were associated with a 6-fold increase in the odds of mortality, and prolonged mechani-

Table 5. Risk factors for mortality after esophagectomy with immediate esophagoplasty performed within the framework of RAPOR program (n = 500)

Risk factor	OR	p	95 % CI	
			L	U
Body mass index				
	0.77	0.000	0.69	0.87
	0.74	*0.000*	*0.64*	*0.85*
Diagnosis (reference: achalasia)				
Esophageal stricture	1.79	0.636	0.16	20.22
	1.66	*0.690*	*0.14*	*19.72*
Fistula	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*
Cancer	2.00	0.539	0.22	18.23
	1.22	*0.879*	*0.10*	*14.89*
Other	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*
NRS-2002				
	3.11	0.010	1.31	7.39
	3.15	*0.017*	*1.23*	*8.11*
Comorbidity index				
	1.37	0.220	0.83	2.28
	1.44	*0.016*	*1.07*	*1.94*
ASA				
	4.45	0.028	1.18	16.81
	4.14	*0.081*	*0.84*	*20.38*
Total protein on POD 1				
	0.88	0.004	0.80	0.96
	0.86	*0.011*	*0.76*	*0.97*
Albumin preoperative				
	0.83	0.054	0.69	1.00
	0.84	*0.117*	*0.68*	*1.04*
Neurological disease (reference: no)				
Yes	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*
Diabetes mellitus (reference: no)				
Yes	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*
Peripheral arterial disease (reference: no)				
Yes	6.87	0.033	1.16	40.57
	5.18	*0.104*	*0.71*	*37.70*
Arrhythmia (reference: no)				
Yes	6.77	0.016	1.42	32.25
	6.02	*0.020*	*1.33*	*27.28*
Total intraoperative infusion therapy volume minus loss compensation				
	1.57	0.063	0.98	2.51
	1.70	*0.002*	*1.21*	*2.40*
Extubation (reference: immediate extubation)				
Prolonged mechanical ventilation	20.32	0.000	3.78	109.32
	19.39	*0.001*	*3.31*	*113.56*
Early oral feeding (reference: no)				
Yes	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*
Stroke in anamnesis (reference: no)				
Yes	0.00	0.000	0.00	0.00
	0.00	*0.000*	*0.00*	*0.00*

End of the tabl. 5

Note: U — upper limit; CI — confidence interval; L — lower limit, OR — odds ratio; POD — postoperative day; ASA — American Society of Anesthesiologists Physical Status Classification System; NRS-2002 — Nutrition Risk Screening 2002.

cal ventilation — with an 18-fold increase. However, these measurements also had very wide confidence intervals. Such variability in the estimates in these and previous cases is due to the rarity of mortality in our study. Furthermore, prolonged mechanical ventilation was more likely a result of the patient's serious or critical condition leading to mortality, rather than its cause.

The comorbidity index and total intraoperative fluid volume showed no statistical significance in the unadjusted analysis, but after adjustment for sex and age, they emerged as risk factors for mortality. Each unit of the comorbidity index increased the odds of mortality by 44 %, and each mL/kg/h of total intraoperative fluid volume — by 70 %.

The ASA class and peripheral arterial disease before adjustment increased the odds of an adverse outcome by 4.5 and 6 times, respectively. However, after adjustment, the statistical significance of these parameters disappeared, as they are themselves associated with age.

For several factors (pulmonary and neurological disease, diabetes mellitus, stroke in anamnesis, fistulas and other primary diagnoses, early oral feeding), the regression yielded results with apparent statistical significance. However, this is a consequence of the small number of patients with the factor and the small number of patients with mortality.

For the remaining factors, associations did not reach statistical significance. However, wide confidence intervals do not allow us to rule out the potential presence of clinically significant associations.

Discussion

Identifying risk factors for complications allows to improve patients' treatment outcomes through their preoperative correction. A large number of studies are aimed at identifying risk factors. Their results serve as a benchmark for other hospitals and are taken into account while developing perioperative care programs and protocols.

A series of studies have identified that risk factors for complications in esophagectomy with immediate esophagoplasty are age, emergency surgery, race, diabetes mellitus, history of hypertension, history of COPD, smoking, ASA class > III, male sex and coronary artery disease [12, 13]. Risk factors for mortality include age, race, history of COPD, ASA class > III, coronary artery disease, wound infection, body mass index < 18.5 kg/m^2, myocardial infarction, connective tissue disease, peripheral arterial disease, history of severe liver dysfunction, neoadjuvant treatment and low-volume hospital [12, 13, 17]. Risk factors for anastomotic leak include chronic kidney disease, peripheral arterial disease, diabetes mellitus, history of COPD, hypertension, coronary artery disease, ASA class ≥ III, and male sex [13]. Risk factors for postoperative pneumonia are smoking, age over 60 years, and a history of lung disease and diabetes mellitus [14, 18–20]. In recent years, many studies have emerged on the impact of preoperative physical status and sarcopenia on postoperative complications [21–23].

In a multicenter study by Mitzman B. et al. (2018), it was found that both underweight and overweight were associated with an increased incidence of pulmonary and infectious complications. A body mass index > 25 kg/m^2 was associated with an increased incidence of cardiovascular and thromboembolic complications. Body mass index had no impact on gastrointestinal or urological complications [24].

The RAPOR program, developed at the NMRCS, is based on an individualized, team-based, interdisciplinary approach for each patient. It is based on elements of the ERAS. However, in practice, the ERAS protocol represents a standard, formal approach to the patient, feasible only during uncomplicated perioperative period. At the NMRCS, the strict protocol and patient standardization were replaced with a flexible, personalized perioperative care program. In this program, all applicable ERAS elements for a given specific situation are utilized at each moment. For elderly or comorbid patients, these are supplemented with specialized therapeutic techniques based on existing risk factors for postoperative complications and mortality, or on complications that have already developed. Importantly, the omission of one or more standard elements does not negate adherence to the program.

The transition from a multidisciplinary to an interdisciplinary approach fostered closer collaboration among specialists. Members of the interdisciplinary team (surgeons, anesthesiologists, intensive care specialists and nurses) work together within the same department and are involved in the patient's care throughout the entire perioperative period.

Thanks to the implementation of the RAPOR program at the NMRCS, the safe treatment of elderly and comorbid patients became possible. Among the 500 patients, 34 % had a Charlson Comorbidity Index greater than 5, 49 % had an ASA physical status of III, 8.6 % had ASA IV, and 12.8 % of patients were over 70 years old. Notably, the postoperative complication rate was 29.2 %, and postoperative mortality was 1.4 %. To assess the effectiveness of the program, we previously compared the results from the NMRCS with data from large multicenter studies and a single-center study conducted within ERAS protocols. In all these studies, complications were assessed using a unified registry. Thanks to the RAPOR program, the complication rate at the NMRC Surgery (29.2 *vs* 54 %, 59 %, and 65 %) is significantly lower than global rates, while mortality remains comparable (1.4 *vs* 0.9 %, 2.4 %, and 1.7 %) [15].

Within the framework of the RAPOR program, several standard risk factors, such as a history of myocardial infarction, peripheral arterial disease, diabetes mellitus, chronic kidney disease, and smoking, did not influence the development of postoperative complications. Furthermore, we have previously demonstrated that preoperative sarcopenia isn't a risk factor under the RAPOR program [25]. The preoperative assessment of the cardiovascular system, aimed at identifying and correcting hemodynamically significant stenoses of the coronary and carotid arteries, perioperative patient monitoring with control of hemodynamic parameters and glycemia by members of the interdisciplinary team, and early patient mobilization all contributed to the safety of the intra- and postoperative periods and helped eliminate the influence of some risk factors on the outcome.

As in other studies, the risk of complications at the NMRCS increases in elderly patients with a pulmonary disease (COPD, bronchial asthma) in anamnesis, despite all preventive measures undertaken. All patients use an incentive spirometer both before and after surgery. Additionally, patients receive nebulizer therapy with mucolytics and antiseptics for the first 5 postoperative days. The development of additional measures is likely necessary to reduce the significance of these factors. Interestingly, patient smoking did not affect treatment outcomes.

The statistical analysis revealed an association between a history of neurological diseases and the rate of postoperative complications. This was a statistical finding, as we did not observe a direct connection between these data and the outcome in the course of clinical work. A history of cardiac arrhythmias is a risk factor for postoperative complica-

tions. However, an association between a history of myocardial infarction and complications or mortality was not confirmed. Despite the RAPOR program's specific focus on the preoperative correction of malnutrition, it remains a risk factor for postoperative pneumonia and mortality. This may be related to the patient's baseline asthenization and weakness of the respiratory muscles.

Furthermore, age, ASA class, Charlson Comorbidity Index, and duration of surgery demonstrated prognostic significance. It is logical that comorbid patients undergoing technically more complex and, consequently, longer operations have a higher probability of postoperative complications and mortality. Notably, the transhiatal approach requires less time and contributes to improved treatment outcomes. On one hand, the number of comorbidities increase with age; on the other hand, the body's reserves diminish and asthenization develops. We have demonstrated an association between pulmonary, neurological diseases, and arrhythmias and the development of complications. Other diseases, in isolation, did not influence the outcomes of esophagectomy. However, the combined effect of these factors, expressed through the comorbidity index and ASA class, proved to be statistically significant.

In this study, goal-directed fluid therapy was administered intraoperatively. Nevertheless, a large total intraoperative fluid volume contributed to an increased risk of pulmonary complications and mortality. This was likely influenced by intraoperative capillary leak or blood loss, which required an increased volume of infusion.

Laboratory parameters were assessed to identify possible predictors of complications before their actual development. High lactate levels upon ICU admission and high C-reactive protein levels on POD 1 were associated with postoperative complications overall. Conversely, in patients with high preoperative albumin levels and high total protein levels on POD 1, the probability of postoperative complications and mortality, respectively, was reduced. This indicates that a normal body mass index, the absence of malnutrition, and a relatively small volume of intra- and postoperative blood loss contribute to improved patient outcomes.

Conclusion

Within the framework of the RAPOR program, age, comorbidity index, ASA class, duration of surgery, and pulmonary and neurological diseases, cardiac arrhythmias in anamnesis are risk factors for postoperative complications. A high comorbidity index, high NRS-2002 score, arrhythmias in anamnesis, prolonged mechanical ventilation, and a large intraoperative fluid volume remain risk factors for mortality. Standard risk factors (history of myocardial infarction, diabetes mellitus, peripheral arterial disease, chronic kidney disease, smoking) do not influence the development of postoperative complications or mortality. Further research is needed to identify additional measures to reduce the impact of a pulmonary disease, cardiac arrhythmias and neurological diseases on patient treatment outcomes.

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