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Prognostic model of the probability of successful extubation in the operating room after simultaneous kidney and pancreas transplantation

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Abstract

Introduction. *Early extubation at the end of surgery has a beneficial effect on the postoperative recovery of patients. Prolonged and highly traumatic surgery in recipients with severe initial pathology and* *compromised homeostasis doesn't allow for safe procedure of early extubation in simultaneous kidney and pancreas transplantation (SKPT). This article aims at assessing the impact of recipient-related factors and intraoperative clinical factors on the possibility of successful extubation in the operating room after SKPT.*

Objective. *To develop and substantiate a prognostic model for determining the probability of successful extubation in the operating room after SKPT depending on the impact of recipient-dependent factors and intraoperative clinical factors.*

Material and methods. *A prospective single-center non-randomized study was conducted, enrolling 85 recipients who underwent SKPT in the N.V. Sklifosovsky Research Institute for Emergency Medicine in the period from 01.01.2008 to 31.11.2024. Among the recipients included in the study, there were 52 men (61%) and 33 women (39%); their median age was 35(31;39) full years. All patients were allocated in two groups. Group I included the patients who were successfully extubated at the end of surgery; group II included the patients non-extubated at the end of surgery who were transferred to the intensive care unit for prolonged mechanical ventilation. Using the binary logistic regression method, a prognostic model was developed for the probability of successful extubation of patients in the operating room after SKPT taking into account the presence of recipient-dependent factors and intraoperative clinical with their step-by-step exclusion according to Wald statistics.*

Results. *The prognostic model of the possibility of successful extubation in the operating room was found statistically significant ($p<0.001$), with a sensitivity and specificity of 76.7% and 73.8%, respectively. Among recipient-dependent factors, an adjusted statistical significance was shown by body mass index ($p=0.003$) and the history of renal replacement therapy duration ($p=0.037$). Among intraoperative clinical* *factors, an adjusted statistical significance was shown by the epidural component of anesthesia ($p<0.001$), mean blood pressure ≥90 mmHg on reperfusion ($p=0.048$), the surgery duration factor ($p=0.029$), a total amount of fentanyl ($p<0.001$), and a total amount of cisatracurium ($p=0.044$).*

Conclusion. *The prognostic model makes it possible to determine the tactics of intraoperative management of patients and optimize the strategy of anesthesiological support in order to ensure possible successful extubation of patients after the SKPT surgery.*

Keywords: simultaneous kidney and pancreas transplantation, prognostic model, early extubation in the operating room, recipient-dependent factors, intraoperative clinical factors

Conflict of interests	Authors declare no conflict of interest
Financing	The study was performed without external funding

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BMI, body mass index

CI, confidence interval

CKD 5, chronic kidney disease, stage 5

DM 1, diabetes mellitus type 1

MAP, mean arterial pressure

MLV, mechanical lung ventilation

RRT, renal replacement therapy

SKPT, simultaneous kidney and pancreas transplantation

Introduction

Currently, diabetes mellitus (DM) and its complications represent a global problem in the healthcare system worldwide. The data of the International Diabetes Federation is disappointing, according to which there are currently more than 537 million patients with DM worldwide, and it is predicted that by 2045 every eighth inhabitant of the planet will suffer from this disease [1].

Simultaneous kidney and pancreas transplantation (SKPT) is considered by a number of authors to be the operation of choice and the “gold standard” for the definitive treatment of type 1 diabetes (DM 1) and the diabetic nephropathy resulting in stage 5 chronic kidney disease (CKD 5) [2]. This operation leads to a steady improvement in the quality of life of patients by achieving euglycemia, slowing down or stopping secondary diabetic complications [3–5].

Numerous studies have demonstrated the beneficial effects of early post-surgery extubation on postoperative recovery of patients [6, 7]. According to a number of authors, this helps to reduce the incidence of adverse outcomes associated with prolonged mechanical lung ventilation, reduce the number of bed days spent in intensive care units, and reduce costs associated with the patient hospital length of stay [7, 8]. Predictors such as a younger age, male gender, body mass index (BMI) within normal limits, and a higher left ventricular ejection fraction may contribute to early extubation of patients after surgery [9]. The method of anesthesia also significantly affects the time of extubation. In addition, studies have shown that the use of drugs such as propofol and alfentanil increases the rates of extubation at the end of surgery [10]. A careful examination of patients, timely detection and compensation of concomitant pathology, the use of epidural analgesia as part of multicomponent general anesthesia are important for the successful implementation of early extubation protocols for SKPT [11, 12]. However, long and highly traumatic surgery in recipients with severe initial pathology and strained homeostasis mechanisms does not always allow for the safe implementation of the early extubation procedure that may be associated with high risks of developing postoperative complications and adverse outcomes [12, 13].

Among the factors influencing outcomes in SKPT, a separate group of recipient-dependent factors is distinguished [14, 15]. These include age, gender, BMI, type and duration of diabetes mellitus, type and duration of renal replacement therapy (RRT), and the presence of comorbid pathology [16–18]. The impact of this group of factors on the possibility of successful extubation in the operating room after SKPT has not been determined.

The objective was to develop and validate a prognostic model to determine the probability of successful extubation in the operating room after simultaneous kidney and pancreas transplantation taking into account the impact of recipient-dependent and intraoperative clinical factors.

Material and methods

A prospective study with retrospective control of 85 patients who underwent SKPT at the N.V. Sklifosovsky Research Institute for Emergency Medicine from 01.01.2008 to 31.12.2024 was conducted.

The inclusion criteria for the study were:

– Patients suffering from type 1 diabetes, in combination with CKD 5 as a result of diabetic nephropathy, who have undergone SKPT;

– Patients must be 18 years of age or older;

– Patient’s consent to participate in the study.

The criteria for exclusion from the study were:

- Isolated kidney transplantation;

– Pancreas transplantation after previous kidney transplantation;

- Patient's refusal to participate in the study.

The characteristics of the recipients are presented in Table 1.

Table 1. General characteristics of the recipients

Parameter	Numerical value
Gender: male/female n (%)/n (%)	52 (61%)/ 33 (39%)
Age, full years, Me (Q_1;Q_3)	35 (31;39)
BMI, kg/m^2, Me(Q_1;Q_3)	20.82 (19.54;22.58)
History of DM1 duration at the time of surgery, full years, Me (Q_1;Q_3)	25 (20;29)
History of RRT duration, years, Me (Q_1;Q_3)	2.5 (1;4)

Criteria for successful extubation in the operating room

Successful extubation was defined as a tracheal extubation at the end of surgery in the operating room with no need for re-intubation within 48 hours, and a routine extubation was defined as a tracheal extubation in the Intensive Care Unit. The decision to extubate patients in the operating room was based on standardized and generally accepted criteria: spontaneous unassisted breathing with adequate oxygenation (SpO_2>95%, with $FiO_2 \leq 0.5$); stable hemodynamics with minimal doses of vasopressor support; a complete clinical cessation of muscle relaxation determined by raising the head for 5 seconds and squeezing the examiner's hand; ability to follow simple verbal commands; appropriate metabolic status and normothermia. All patients were transferred to the Intensive Care Unit after surgery.

Distribution of patients into study groups

Patients who were successfully extubated at the end of surgery were allocated to group I, patients who were not extubated at the end of surgery and transferred to the Intensive Care Unit while on prolonged mechanical ventilation were assigned to group II.

Clinical and demographic characteristics of patients in both groups are presented in Table 2.

Table 2. Clinical and demographic characteristics of patients in groups

Parameter	Group I (n=43)	Group II (n=42)	p
Age, full years Me (Q_1;Q_3)	34 (31;38.5)	35 (31;39)	0.663*
Gender, male/female n (%)/n (%)	18 (41.9%)/25 (58.1%)	15 (35.7%)/27 (64.3%)	0.338**
BMI, kg/m^2 Me (Q_1;Q_3)	21.15 (19.6;22.63)	20.73 (19.4;22.19)	0.437*
History of type 1 diabetes duration, full years Me (Q_1;Q_3)	24 (20;28)	25 (20;29)	0.609*
History of RRT duration, full years Me (Q_1;Q_3)	2(1;4)	3 (1;5)	0.075*
Associated cardiac pathology:			
Hypertension, n (%)	15 (34.9%)	13 (31%)	0.149**
Ischemic heart disease, n (%)	14 (32.6%)	11 (26.2%)	0.415**

* Mann–Whitney U-test
** Pearson's X-square test

Methodology for developing a predictive model

Using the binary logistic regression method, a prognostic model of the probability of successful extubation of patients in the operating room after SKPT was developed with regard to the impact of recipient-dependent factors and intraoperative clinical factors with their step-by-step exclusion according to Wald statistics. The resulting model is described by the equation (1):

$$P = 1 / (1 + e^{-z}) * 100\%$$

$$z = a_1x_1 + a_2x_2 + \ldots + a_nx_n + a_0 \quad (1),$$

where P is the probability of hospital mortality in %; z is the exponent in the logistic function; $x_1 \ldots x_n$ are independent factors; $a_a \ldots a_n$ are regression coefficients; a_0 is a constant; e is the Euler number, a mathematical constant (≈ 2.718). The threshold value of the logistic function P was determined using the ROC curve analysis method.

The recipient-dependent factors included in the model were the following: the recipient age at the time of surgery, gender, BMI, history of type 1 diabetes duration, RRT type, RRT duration, the presence of concomitant cardiac pathology. Of the concomitant cardiac pathology, 2 nosological units were included in the model: hypertension and ischemic heart disease. The intraoperative clinical factors included: mean arterial pressure (MAP) no lower than 90 mm Hg at the time of reperfusion, the use of combined general anesthesia with an epidural component of analgesia as an anesthesia method, glycemia level in recipients in the range of 5–10 mmol/L at the end surgery, the surgery duration, the blood loss volume, the infusion-transfusion therapy volume, doses of vasopressor support, diuresis volume, total doses of fentanyl and cisatracurium.

Peculiarities of anesthesia

In patients with an epidural component of analgesia, 0.75% ropivacaine solution was used as the epidural anesthetic. Epidural space was catheterized at the Th8–Th9 level in patients in the lateral decubitus position in the operating room before induction anesthesia. Ropivacaine was administered through a drug dosing devise at a rate from 3 to 10 ml/h (0.16 to 0.54 mg/kg/h). The selected dosage of ropivacaine was selected to create a sympathetic and analgesic segmental blockade at the level of the iliac vessels, as well as the segments of the duodenum or jejunum used to form anastomoses with the duodenum of the pancreatoduodenal complex. The total dose of ropivacaine did not exceed the maximum permissible one.

Statistical data processing

Quantitative parameters were assessed for compliance with normal distribution using the Shapiro–Wilk test (for a sample size of less than 50). Quantitative parameters with normal distribution were described using arithmetic means and standard deviations (M±SD). In the absence of normal distribution, quantitative data were described using the median and the lower and upper quartiles (Me (Q_1;Q_3)). Categorical data were described using absolute values and percentages (n (%)). The comparison of two groups by a quantitative parameter with normal distribution, provided that variances were equal, was performed using Student's t-test. The comparison of two groups by a quantitative parameter with a non-normal distribution was performed using the Mann–Whitney U-test. The comparison of percentages in the analysis of four-field contingency tables was performed using Fisher's exact test (for expected event values less than 10) and Pearson's Chi-square test (for expected event values greater than 10). Results of multifactorial effect on the likelihood of successful extubation in the operating room are presented as a table with adjusted odds ratios, i.e., provided that there is no change in other factors included in the model, with a 95% confidence interval (CI) and the corresponding p, the differences were considered statistically significant at $p<0.05$.

Results

All patients extubated in the operating room were safely transferred to the intensive care unit after surgery and were not intubated within the next 48 hours.

We developed a prognostic model to determine the probability of successful extubation of patients in the operating room in relationship to the presence of recipient-dependent factors and intraoperative factors. In total, 20 potential prognostic parameters were studied. The final prognostic model was obtained at the 13th step and included 7 prognostic parameters. The observed relationship is described by equation (1):

$$P = 1/ (1+ e^{-z}) * 100\%,$$

$$\text{where } z = 1.33 + 1.68*Xepid + 0.46*Xrmap + 0.11*Xbmi - 0.22* Xrrt - 0.11* Xsurg - 1.11*Xfent - 0.639*Xcisat \quad (1)$$

where P is the probability of successful extubation in the operating room (%); Xepid is the epidural component of anesthesia (0 for absence, 1 for presence); Xrmap is the mean arterial pressure on reperfusion at least 90 mm Hg (0 for absence, 1 for presence); Xbmi is the body mass index (kg/m^2); Xrrt is the history of renal replacement therapy duration (full years); Xsurg is the surgery duration (hours), Xfent is the amount of fentanyl administered during surgery (mg), Xcisat is the amount of cisatracurium administered during surgery (mg).

The resulting regression model is statistically significant ($p<0.001$). Based on the value of the pseudo-R squared Nigelkirk coefficient of determination, 36.3% of the variance in the probability of successful extubation of patients in the operating room is attributed to the factors included in the model.

Based on the values of the regression coefficients, the factor of the epidural component of analgesia, MAP on reperfusion, BMI had a direct relationship with the probability of successful extubation in the operating room. Factors such as the history of RRT duration, the surgery duration, the total dose of fentanyl and the total dose of cisatracurium were inversely related to the probability of successful extubation in the operating room. The characteristics of each factor are presented in Table 3.

Table 3. Characteristics of the relationship between the predictors of the model (1) and the probability of successful extubation of patients in the operating room

Predictors	Unadjusted values		Adjusted values	
	COR [95% CI]	p	AOR [95% CI]	p
Epidural component	3.63 [0.98–5.67]	0.047*	5.36 [1.14–25.2]	<0.001*
MAP $\geq$ 90 mm Hg	1.63 [0.63–4.53]	0.294	3.59 [1.43–16.83]	0.048*
BMI	1.09 [0.93–3.26]	0.181	3.34 [1.51–6.38]	0.003*
History of RRT duration	0.83 [0.73–0.91]	0.045*	0.81 [0.66–0.98]	0.037*
Surgery duration	0.99 [0.91–1.01]	0.138	0.84 [0.69–0.95]	0.029*
Amount of fentanyl	0.74 [0.14–0.38]	0.002*	0.33 [0.23–0.74]	<0.001*
Amount of cisatracurium	0.97 [0.95–1.45]	0.178	0.53 [0.16–0.72]	0.044*

* the predictor influence is statistically significant (p<0.05)

Based on the presented Table 3, it follows that in the presence of the epidural component of anesthesia, the chances of successful extubation in the operating room increased by 5.36 times; the probability of successful extubation increased by 3.59 times if the mean arterial pressure of at least 90 mm Hg was recorded during reperfusion; with an increase in BMI by 1 kg/m^2, the chances of successful extubation increased by 3.34 times; with an increase in the duration of RRT by 1 year, the chances of successful extubation in the operating room decreased by 1.23 times. With an increase in surgery duration by every hour, the chances of extubation in the operating room decreased by 1.2 times. An increase in the amount of fentanyl by 1 mg was accompanied by a decrease in the chances of successful extubation in the operating room by 3.03 times; with an increase in the amount of cisatracurium by every 1 mg by the end of the operation, the chances of successful extubation decreased by 1.89 times.

Figure 1 compares the adjusted odds ratio values with 95% CI for the studied factors included in model (1).

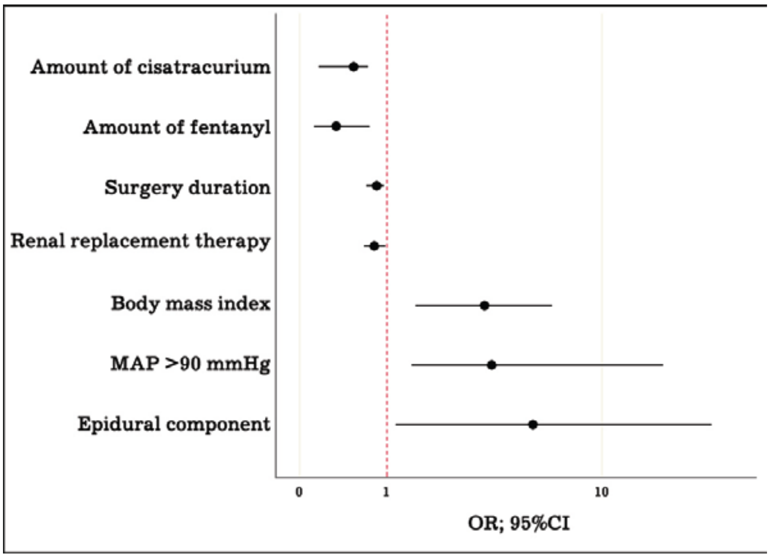

Fig. 1. Odds ratio estimates with 95% CI for the studied predictors of the probability of successful extubation in the operating room

The threshold value of the P logistic function was determined using the ROC curve analysis method. The resulting curve is shown in Fig. 2.

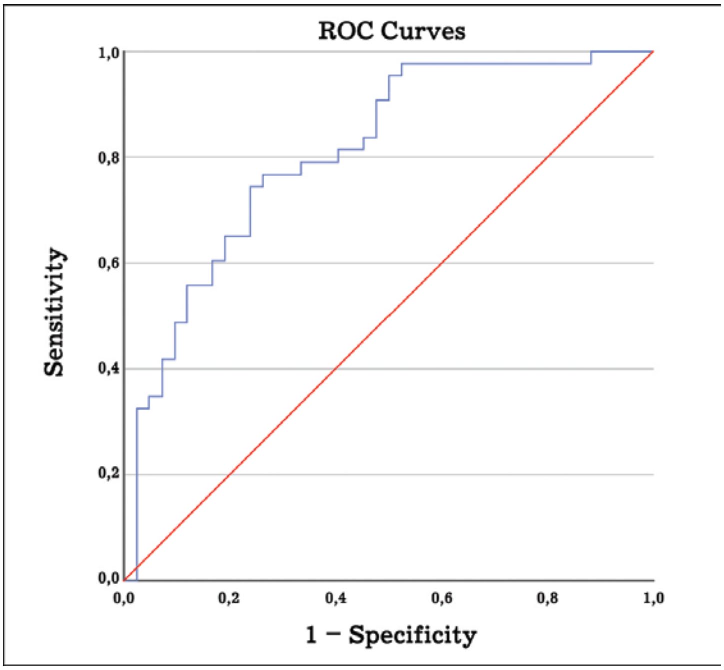

Fig. 2. ROC-curve characterizing the relationship between the probability of successful extubation in the operating room and prognostic function values (1)

The area under the ROC curve was 0.81±0.47 (95% CI [0.72–0.91]). The value of the logistic function (1) at the cut-off point was 47.2%. At P greater than or equal to 47.2%, a high probability of successful extubation in the operating room was determined, and at P less than 47.2%, a low probability of successful extubation in the operating room was determined. The sensitivity and specificity of the model (1) at this cut-off value were 76.7% and 73.8%, respectively.

Discussion

It is generally accepted that recipient-dependent factors affect early and long-term outcomes in SKPT [19, 20]. Recipient age, gender, BMI, history of type 1 diabetes duration, the history of RRT type and duration, as well as the presence of concomitant pathology can reduce the overall graft and recipient survival rates, but their impact on the possibility of early extubation has not been sufficiently studied [21–23]. According to numerous sources, diabetes mellitus is the main factor associated with the risk of developing cardiovascular diseases in this group of patients [24, 25]. The impact of cardiovascular diseases is increasingly significant due to the expanded criteria for the candidates for SKPT, and, accordingly, with the increase in the number of older recipients with a higher risk of having this pathology [26–28]. According to a number of authors, up to 60% of unfavorable outcomes and perioperative complications after SKPT are associated with the presence of such cardiac diseases as coronary heart disease, chronic heart failure, and hypertension disease [29, 30]. Among the intraoperative factors influencing the possibility of early extubation, S. Skurzak et al. in their study, indicated the significance of surgery duration, the volume of infusion-transfusion therapy, the level of lactate and the doses of administered vasopressors

[31]. In the study of M. S. Chae et al., among the intraoperative factors included in the model of early extubation in patients after liver transplantation, the hemodynamic intraoperative parameters were considered, including at the time of graft reperfusion [32]. Values of intraoperative hemodynamic parameters, especially at the time of graft reperfusion, and their impact on outcomes in SKPT were also assessed in our studies [33]. However, their significance on the possibility of early extubation in the operating room has not been studied. Nguyen et al. in their study showed the significance of young age, male gender, higher BMI, and higher left ventricular ejection fraction as factors associated with early extubation of patients after major surgeries [9].

Our model included both recipient-dependent factors and intraoperative clinical factors. Among recipient-dependent factors, the history of RRT duration was inversely related to the possibility of successful extubation in the operating room, which is generally consistent with its impact on the outcomes in SKPT. Webb et al. showed in their study that the history of dialysis for up to 4 years did not affect the overall survival and graft survival, a longer period of dialysis (more than 4 years) was associated with a slightly lower survival of patients [34]. As for BMI, this factor had a direct relationship to the likelihood of successful extubation in the operating room, despite conflicting data in the literature [35, 36]. Patients who were operated on in our center had a BMI that did not exceed normal values, and often being at the lower limit of the norm 20.82 (19.54;22.58) kg/m^2. Accordingly, our model does not clearly demonstrate a negative relationship between excess body weight and the likelihood of successful extubation; on the contrary, a direct relationship is shown, i.e. patients with a normal BMI had a higher probability of successful extubation compared to patients whose BMI tended to low values.

Among the intraoperative clinical factors, the factor of epidural anesthesia as part of multicomponent anesthesia and the factor of MAP equal or higher 90 mm Hg during reperfusion showed a direct relationship with successful extubation of patients in the operating room. The use of the epidural component of anesthesia allowed the use of smaller doses of narcotic analgesics, muscle relaxants and inhalation anesthetics to achieve a sufficient antinociceptive and anesthetic effect, which had a favorable effect on the function of the nephrograft, and also allowed for early extubation of the patient at the end of surgery [11, 37, 38]. On the other hand, an increase in the number of anesthetic drugs showed a negative association with the possibility of successful extubation, which was related to slower elimination and the accumulation of the corresponding metabolites in the body. Maintaining an optimal level of intraoperative arterial pressure, especially at the time of reperfusion, is important for the successful functioning of kidney and pancreas grafts in the early postoperative period [33, 39]. This factor ensures the stability of homeostasis parameters, which undoubtedly contributes to the possibility of successful extubation in the operating room, which was shown in our model. The surgery duration factor showed an inverse relationship with the possibility of successful extubation in the operating room, which is consistent with literature data [40].

Thus, the predictive model we have developed for the probability of successful extubation of patients in the operating room considering the presence of recipient-dependent factors and intraoperative clinical factors allows us to determine the tactics of intraoperative patient treatment and optimize the strategy of anesthetic management for the purpose of possible successful extubation of patients after SKPT.

We should note that our study had limitations related to the study design, namely its single-center, retrospective nature, the absence of a control group. In addition, monitoring of neuromuscular block during anesthesia in patients was beyond the scope of our study, which, if had been studied, would have warranted a more objective assessment of residual relaxation at the end of surgery.

Conclusions

1.The developed predictive model for the possibility of successful extubation in the operating room is statistically significant ($p<0.001$), with a sensitivity and specificity of 76.7% and 73.8%, respectively.

2.Among recipient-dependent factors, adjusted statistical significance was demonstrated by body mass index ($p=0.003$) and the history of renal replacement therapy duration ($p=0.037$). With an increase in body mass index by 1 kg/m^2, the chances of successful extubation increased by 3.34 times, while with an increase in the history of renal replacement therapy duration by 1 year, they decreased by 1.23 times.

3.Among the intraoperative clinical factors, the adjusted statistical significance was shown by the presence of an epidural component of analgesia as part of general multicomponent anesthesia ($p<0.001$), mean arterial pressure equal or higher 90 mm Hg at reperfusion ($p=0.048$), the surgery duration factor ($p=0.029$), as well as the total amount of fentanyl ($p<0.001$) and cisatracurium ($p=0.044$). With the presence of an epidural component, the chances of successful extubation in the operating room increased by 5.36 times, and increased by 3.59 time if the mean arterial pressure at reperfusion was equal or higher 90 mm Hg. With the surgery duration increase for every hour, the chances of successful extubation in the operating room decreased by 1.2 times. An increase in the amount of fentanyl by 1 mg was accompanied by a 3.03-fold decrease in the chances of successful extubation in the operating room, meanwhile with an increase in the amount of cisatracurium by every 1 mg, those chances decreased by 1.89 times.

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