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Early nasogastric and nasojejunal feeding in patients with predictors of severe acute pancreatitis: a randomized controlled trial

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Abstract

OBJECTIVE: Studying the influence of early nasogastric (NG) and nasojejunal (NJ) probe feeding in patients with predictors of severe acute pancreatitis on the disease course and outcome of the disease. **MATERIALS AND METHODS:** An open randomized controlled study was performed in Neftyanik Occupational Healthcare Facility ICU. 64 patients with predictors of severe acute pancreatitis (APACHE II > 8, CRP > 150 mg/l, SOFA > 2) randomized by the envelope method for early (the first 24 hours) nasogastic or nasojejunal feeding. The standard polymer feeding formula enriched with dietary fibers was administered during the first 5 (five) days taking into account its tolerability. Raw data were statistically processed using SPSS-26 software. **RESULTS:** Comparison of the NG (n = 33) *vs*. NJ (n = 31) groups produced the following results: the duration (days) of treatment in the hospital was 21 (12; 42) *vs*. 24 (11; 35), p = 0.715; in ICU — 4 (2; 20) *vs*. 4 (3; 13), p = 0.803; mechanical ventilation (MV) — 1 (1; 3) *vs*. 1 (1; 1), p = 0.124; mortality — OR 0.830 (95 % CI 0.201–3.422), p = 0.796; severity (moderately severe or severe) — OR 1.29 (95 % CI 0.483–3.448), p = 0.611; number of patients subjected to surgery during the first period of the disease — OR 0.774 (95 % CI 0.243–2.467), p = 0.665; and second period of the disease — OR 1.682 (95 % CI 0.623–4.546), p = 0.305. **CONCLUSIONS:** No difference has been found between the groups of patients with severe disease predictors, who received early nasogastric or nasojejunal tube feeding using a standard polymer formula with dietary fibers during early acute pancreatitis, as regards duration of treatment in the hospital, in ICU, numbers of mechanically ventilated patients,

Раннее назогастральное и назоеюнальное питание у пациентов с предикторами тяжелого течения острого панкреатита: рандомизированное контролируемое исследование

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Реферат

ЦЕЛЬ ИССЛЕДОВАНИЯ: Оценить влияние раннего назогастрального (НГ) и назоеюнального (НЕ) зондового питания у пациентов с предикторами тяжелого острого панкреатита на течение и исход заболевания. **МАТЕРИАЛЫ И МЕТОДЫ:** Проведено открытое рандомизированное контролируемое исследование в отделении реанимации и интенсивной терапии (ОРИТ) АО МСЧ «Нефтяник» г. Тюмени. Участников исследования (n = 64) с предикторами тяжелого течения острого панкреатита (APACHE II > 8, СРБ > 150 мг/л, SOFA > 2) рандоминизировали слепым методом для раннего (первые 24 ч) НГ- и НЕ-питания. Питательная смесь (стандартная полимерная, обогащенная пищевыми волокнами) вводилась в первые 5 сут с учетом ее переносимости. Статистическая обработка материала выполнена пакетом программ SPSS-26. **РЕЗУЛЬТАТЫ:** При сравнении групп с НГ-питанием (n = 33) и НЕ-питанием (n = 31) не обнаружено статистически значимой разницы: по продолжительности лечения в стационаре — 21 (12; 42) и 24 (11; 35) сут, p = 0,715; в ОРИТ — 4 (2; 20) и 4 (3; 13) сут, p = 0,803; искусственной вентиляции легких (ИВЛ) — 1 (1; 3) и 1 (1; 1) сут, p = 0,124; летальности — отношение шансов (ОШ) 0,830 (95 %-й доверительный интервал [95 % ДИ] 0,201–3,422), p = 0,796; форме заболевания (среднетяжелая или тяжелая) — ОШ 1,29 (95 % ДИ 0,483–3,448), p = 0,611; количеству прооперированных пациентов в первый период заболевания — ОШ 0,774 (95 % ДИ 0,243–2,467), p = 0,665, во второй период заболевания — ОШ 1,682 (95 % ДИ 0,623–4,546), p = 0,305. **ВЫВОДЫ:** Между группами, получавшими ран-

patients operated during the first and second disease periods, disease severity or mortality.

KEYWORDS: acute pancreatitis, ICU, tube feeding, polymer, dietary fibers

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раннее энтеральное питание в назогастральный или назоеюнальный зонд, в начальный период острого панкреатита с предикторами тяжелого течения, у которых использовалась стандартная полимерная смесь с пищевыми волокнами, не обнаружены отличия по продолжительности лечения в стационаре, в ОРИТ, длительности нахождения на ИВЛ, количеству прооперированных в первый и во второй периоды заболевания, форме заболевания и показателям летальности.

КЛЮЧЕВЫЕ СЛОВА: острый панкреатит, отделение интенсивной терапии, питание в зонд, полимерные пищевые волокна

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Introduction

Acute pancreatitis (AP) is an inflammatory disease of the pancreas caused by a number of different etiological factors, the most common of them being alcohol abuse and gallbladder stones [1, 2]. The current classification adopted in 2012 in Atlanta defines three forms of the disease: mild, moderate, and severe [3]. In addition to these forms, Dellinger E.P. et al. (2012) distinguish critical AP characterized by persistent organ failure and infected (peri-)pancreatic necrosis [4]. About 15–25 % of AP patients suffer from a moderate or severe disease with 8–20 % mortality rate [1, 5, 6]. The high catabolic activity with the negative nitrogen balance during severe AP [7, 8] is associated with a local and systemic inflammation; hence, a timely and adequate nutritive support in this group of patients is essential. Not so long ago, during the disease onset period, parenteral administration of nutrients was a routine practice of treatment for AP patients, but systematic reviews and meta-analyses of randomized studies have shown that administration of liquid nutrients directly into the stomach or small bowel is associated with a lower level of mortality, infections, multiple organ failures, and surgeries [9–11]. At present, enteral feeding is preferable to provide feeding during a severe AP. However, the advantages of enteral (EF) compared to parenteral feeding become most obvious when EF is commenced early — within 48 hours [12, 13]. In case of a severe pancreatitis, EF can be performed via either a nasojejunal (NJ) or nasogastric (NG) tube because the advantage of one over the other has not been proven [5]. During the first few days it can be very difficult to determine the form that AP will take in spite of existing predictors of prognosis [14, 15]. Considering the above, it would be relevant to assess the influence of early NG and NJ feeding at the onset of AP with predictors of severity on the disease progression.

Objective

The purpose of the study is to assess the influence of early nasogastric and nasojejunal tube feeding in patients with predictors of a severe acute pancreatitis on the course and outcome of the disease.

Materials and methods

An open randomized controlled study was performed in the Intensive Care Unit (ICU) of Medical and Sanitary Unit "Neftyanik", Tyumen. The study was approved by the local Biomedical Ethical Committee. The criteria for inclusion into the study were: the diagnosis of acute pancreatitis, the first period of the disease [3], and the presence of at least one predictor of severe course — C-reactive protein > 150 mg/L, a score of more than 8 according to the Acute Physiology And Chronic Health Evaluation (APACHE) II scale, a score of more than 2 according to the Sepsis-Related Organ Failure (SOFA) scale [16]. The exclusion criteria were: an age older than 80 years, terminal chronic disease, shock, lactate > 4 mmol/L, acute renal failure. The withdrawal criteria were: changed diagnosis, development of a shock, acute renal failure, increased lactate > 4 mmol/L. AP was diagnosed based on the distinct clinical pattern supported by laboratory and instrumental methods of diagnosis [3]. In addition, the BISAP (Bedside Index of Severity in Acute Pancreatitis) score was calculated [17]. Randomization into the NG- or NJ-tube feeding group was carried out by the sealed code envelope method (35/35). In the course of the study, 4 patients were withdrawn due to shock development (2 subjects in each group), 1 patient — because a different diagnosis was made (tumor of the head of pancreas with destruction), 1 patient — because of the acute kidney injury development. Feeding was commenced within the first 12–24 hours from admission to ICU, using a standard isocaloric formula enriched with dietary fibers (BBraun Nutricomp Standard Fiber, Germany). In the NJ-tube feeding group, the tube was complemented with a NG tube. The formula was administered continuously by drop infusion. Stomach decompression was performed every 6 hours in the NG-tube feeding group while in the NJ-tube feeding group it was continuous. The initial speed of EF was 15 mL/h (kcal/h), thereafter, it was increased by 15–30 mL/h every subsequent day. The prescribed volume of EF was 250 mL/day (kcal/day) for the first day to be increased by 250–300 ml/day (kcal/day) every subsequent day subject to tolerance. If nausea, vomiting, increased pain syndrome, the discharge via the nasogastric tube > 500 mL/h occurred, the speed was halved or the feeding was discontinued unless the aforementioned symptoms disappeared. Later, after the feeding intolerance symptoms were reversed, the speed was gradually increased to the previous speed. No additional parenteral feeding was used during the 5 days of the study. Later on, the form of the disease was recorded according to the existent classification [3]. The minimal size of the sample was calculated by formula:

$$n = \frac{Z^2(pq)}{e},$$

where n is the sample size (n = 64); Z (1.96) is the normalized deviate at 95 % confidence probability; p is the incidence of pancreatic necrosis (20 %) [6]; q = (100 – p); e is the allowable error of sample, which is 9.8 % that corresponds to ordinary reliability [18].

Raw data were statistically processed using SPSS-26 software package (IBM, USA). After verification of the normality of distribution by the Shapiro-Wilk test, the result is presented as a mean with root-mean-square deviation M ± σ or a median with quartiles Me (Q25; Q75). For comparison between the groups, parametric and nonparametric criteria were used; the odds ratio was found by logistic. The null hypothesis was discarded at $p < 0.05$.

Results

Table 1 presents characteristics of the patients included into the study. The NG- and NJ- feeding groups were comparable between themselves.

Table 2 shows that the early EF delivery path rendered no influence on the condition severity progression during the first 48 hours.

During the course of the study (5 days), practically equal amounts of protein and energy were administered to the patients, taking into consideration feeding tolerance (Table 3).

Table 4 gives the data about surgeries performed on the patients during their treatment in the hospital and their number. There was no statistically significant difference between the NG- and NJ-tube feeding groups in the indices being compared.

Table 5 shows the treatment results, according to which the EF technique during the first 5 days for AP with predictors of a severe course rendered no influence on the treatment results; however, the number of surgeries in patients who underwent surgery in the NJ group was statistically significantly fewer.

To find out the influence of NG- and NJ-tube feeding on the disease course and outcome, one-way logistic regression was carried out. According to the findings, the EF delivery technique during the first 5 days did not affect development of the disease form (moderate or severe) — OR 1.29 (95 % CI 0.483–3.448), p = 0.611; mortality— OR 0.830 (95 % CI 0.201–3.422), p = 0.796; number of patients operated on during the 1st period of the disease — OR 0.774 (95 % CI 0.243–2.467), p = 0.665; during the 2nd period of the disease — OR 1.682 (95 % CI 0.623–4.546), p = 0.305.

Table 1. Characteristics of patients

Index	Feeding		p	Disease Course		p	Disease Outcome		p
	NG (*n* = 33)	NJ (*n* = 31)		moderate (*n* = 31)	severe (*n* = 33)		survived (*n* = 55)	Died (*n* = 9)	
Sex, m/f	20/13	19/12	1.0**	16/15	23/10	0.138**	34/21	5/4	0728#
BMI, kg/m²	27.8 (23.8; 34.3)	29.0 ± 6.4	0.941*	26 (23.1; 31.1)	30.2 ± 6.0	0.031*	27.5 (24; 32)	31.7 ± 5.0	0.084*
Age, years	43 ± 11	46 (34; 58)	0.323*	42 ± 13	41 (32; 50)	0.246*	41 (33; 52)	57 (50; 65)	0.007*
IHD, %	5 (15.2)	7 (22.6)	0.531#	3 (9.7)	9 (27.3)	0.109#	7 (12.7)	5 (55.6)	0.009#
HD, %	11 (33.3)	14 (45.2)	0.939**	10 (32.3)**	15 (45.5)	0.315	19 (34.5)	6 (66.7)	0.137**
II DM, %	2 (6.1)	1 (3.2)	0.667#	1 (3.2)	4 (12.1)	0.356#	2 (3.6)	3 (33.3)	0.017#
BA/ COPD, %	1 (3.0)	1 (3.2)	1.0#	1 (3.2)	1 (3.0)	1.0#	2 (3.6)	9 (100)	1#
CHF, %	1 (3.0)	2 (6.5)	0.607#	2 (6.5)	1 (3.0)	0.607#	2 (3.6)	1 (11.1)	0.37#

Table 2. Severity of the condition and predictors of severe course of acute pancreatitis on the day of admission and after 48 hours

Index	Feeding		p
	NG (*n* = 33)	NJ (*n* = 31)	
APACHE-II 24, score	5.0 (3; 7)	6 (3.5; 10)	0.365*
APACHE-II 48, score	7.6 ± 5.2	7.3 ± 4.5	0.953**
SOFA 24, score	2.0 (1.0; 2.0)	2.0 (1.0; 3.0)	0.335*
SOFA 48, score	2.0 (1.0; 4.0)	1.0 (0; 2.5)	0.146*
Urea 24, mmol/L	4.2 (2.7; 5.6)	5.9 ± 2.7	0.234*
Urea 48, mmol/L	4.6 (2.8; 6.4)	5.9 (3.7; 8.2)	0.141*
BISAP 24, score	1.0 (1.0; 1.0)	1.0 (1.0; 2.0)	0.122*
BISAP 48, score	1.0 (0; 2.0)	1.0 (0; 2.0)	0.701*
SIRS 24, score	2.0 (2.0; 2.0)	2.0 (2.0; 2.0)	0.677*
SIRS 48, score	1.0 (1.0; 3.0)	1.0 (1.0; 2.0)	0.468*
CRP 24, mg/L	81.5 ± 58.2	89.7 ± 57.9	0.568*
CRP 48, mg/L	182 (148; 199)	184 ± 57,7	0,799*

*Mann-Whitney *U*-test. **T-test.
24 — during the first 24 hours; 48 — after 48 hours; APACHE — Acute Physiology And Chronic Health Evaluation; BISAP — Bedside Index of Severity in Acute Pancreatitis; CRP — C-reactive protein; NG — feeding through the nasogastric tube; NJ — feeding through the nasojejunal tube; SIRS — systemic inflammation response syndrome; SOFA — Sepsis-related Organ Failure.

Table 3. Protein and energy were delivered in the first 5 days of the disease

Index	Protein, g/kg/day		p	Energy, kcal/kg/day		p
	NG (*n* = 33)	NJ (*n* = 31)		NG (*n* = 33)	NJ (*n* = 31)	
Day 1	0.12 (0.11; 0.14)	0.12 (0.11; 0.14)	0.919*	2.93 (2.61; 3.29)	2.89 (2.58; 3.43)	0.957*
Day 2	0.24 (0.19; 0.27)	0.24 (0.21; 0.30)	0.356*	5.93 (4.63; 6.85)	6.1 (5.21; 7.35)	0.409*
Day 3	0.40 ± 0.14	0.40 ± 0.14	0.906**	10.22 ± 3.48	10.11 ± 3.58	0.929**
Day 4	0.56 ± 0.18	0.52 ± 0.16	0.781**	14.0 ± 4.54	13.07 ± 4.16	0.773**
Day 5	0.60 ± 0.20	0.54 ± 0.19	0.693**	15.01 ± 5.09	13.71 ± 4.76	0.710**
Total for 5 days	1.95 ± 0.59	1.89 (1.33; 2.21)	0.519*	48.75 ± 14.65	47.14 (33.17; 55.26)	0.515*

*Mann-Whitney *U*-test. **T-test.
NG — nasogastric feeding; NJ — nasojejunal feeding.

Table 4. Surgery performed in patients with predictors of severe acute pancreatitis

Index, *n* (%)	Feeding		*p*
	NG (*n* = 33)	NJ (*n* = 31)	
Severe course	16 (48.5)	17 (54.8)	0.611*
Moderate course	17 (51.5)	14 (45.2)	
Number of patients subjected to surgery during the 1st period of the disease	26 (78.8)	23 (74.2)	0.771*
1 surgery each	21 (63.6)	21 (67.7)	—
2 surgeries each	3 (9.1)	2 (6.5)	—
3 surgeries each	2 (6.1)	—	—
Laparoscopic abdominal drainage	20 (60.6)	20 (64.5)	0.747*
Laparotomy and abdominal drainage	8 (24.2)	3 (9.7)	0.186**
Intra-abdominal hemostasis	1 (3)	1 (3.2)	0.964**
Omentobursostomy	2 (6.1)	—	0.493**
Retroperitoneal drainage	1 (3)	—	1.0**
Cholecystectomy	—	1 (3.2)	0.484**
Gallbladder puncture drainage	1 (3)	—	1.0**
Thoracostomy	3 (9.1)	—	0.239**
Number of patients subjected to surgery during the 2nd period of the disease	18 (54.5)	17 (54.8)	0.258*
Omental sac lavage and/or sequestrotomy	14 (42.2)	14 (45.2)	0.617*
Lancing of omental sac abscess	2 (6.1)	—	0.493**
Lumbotomy and retroperitoneal drainage	2 (6.1)	3 (9.7)	0.787**
Omental sac cyst drainage	2 (6.1)	3 (9.7)	0.787**
Puncture drainage of an omental sac cyst	—	2 (6.5)	0.231**
Enterostoma with application of Y-shaped anastomosis	1 (3)	1 (3.2)	1.0**
Thoracostomy	1 (3)	—	1.0**

* Pearson's χ^2. ** Fisher's test.
NG — nasogastric tube feeding; NJ — nasojejunal tube feeding.

Table 5. Treatment results for patients with predictors of severe acute pancreatitis

Index	Feeding		*p**
	NG (*n* = 33)	NJ (*n* = 31)	
BD total, days	21 (12; 42)	24 (11; 35)	0.715
BD on mechanical ventilation, days	1 (1; 3)	1 (1; 1)	0.124
BD in ICU, days	4 (2; 20)	4 (3; 13)	0.803
Number of surgeries in patients operated on during the 1st period of the disease	1.0 (1.0; 1.0)	1.0 (0.5; 1.0)	0.362
Number of surgeries in patients operated on during the 2nd period of the disease	5.3 ± 2.9	3.8 ± 3.6	< 0.001
Mortality, %	5 (15.2)	4 (12.9)	1.0

*Mann-Whitney *U* test.
BD — bed-day; NG — nasogastric tube feeding; NJ — nasojejunal tube feeding.

Discussion

Acute pancreatitis is a disease with a prolonged unpredictable course, absence of any preventive and specific therapy that can radically arrest disease progression. Severe AP is characterized by a high speed of catabolism due to release of multiple inflammatory mediators and subsequent development of the systemic inflammation response syn-

drome [19–21]. In our work, groups of patients with NG- or NJ-tube feeding were comparable in age, body mass index (BMI), sex, comorbid conditions (see Table 1). In the group of severe AP patients, BMI was statistically significantly greater than in moderate AP patients (see Table 1), which is in agreement with the known studies according to which BMI > 25 kg/m^2 increases the risk of severe AP and BMI > 30 kg/m^2 — mortality [22]. Age is a death risk factor in severe AP patients [23, 24]. In our study, the deceased patients were statistically significantly older (see Table 1). The comorbidity of patients in the groups under study was comparable. Expectedly, among the deceased patients, type II diabetes mellitus [25, 26] and ischemic heart disease (IHD) statistically occurred more frequently, because it known that even without concomitant IHD, in 40 % of patients with severe AP and hypotonia, electrocardiogram records changes typical for myocardial hypoxia with increased specific cardiac markers associated with disease severity and mortality [27].

Stratification of the risk of severe AP forms is important because, as a rule, a mild form of the disease does not lead to the lethal outcome and does not require high material inputs for its treatment in contrast to severe forms that develop in 12–20 % of cases and are associated with high mortality (15–30 %) and considerable material inputs into treatment [28]. Many studies have demonstrated that an accurate prognosis of the AP form requires a 48-hour interval of time, which was proven at the symposium in Atlanta where the importance of accurate rather than premature prognosis of AP was underlined [3, 29, 30]. Today, there is no reference predictor capable of forecasting the AP form during the first 48 hours of hospitalization [31]. In our work, the dynamics of SIRS, BISAP and blood urea during the first 48 hours was assessed retrospectively [32]. One can see from the findings presented in Table 2, that there was no statistically significant difference between the NG- and NJ-tube feeding groups in the indices being compared.

Not so long ago, dietary restriction was considered an obligatory component of AP treatment to limit stimulation of gallbladder exocrine secretion, but the new recently obtained data about gut microbiome and importance of maintaining the intestinal mucosal barrier by means of EF have shifted the paradigm in favor of early EF [19, 33]. Compared to initial total parenteral nutrition, early EF reduced mortality, incidence of infections, multiple organ failure, and necessity of surgery, which is supported by several large-scale meta-analyses. Analysis of subgroups of patients only with severe or predictably severe AP has shown that mortality was lower by more than 80 % in the EF group [10, 34–36]. The advantage of EF is its ability to support the intestinal barrier integrity diminishing bacteria and bacterial endotoxin entering the systemic blood flow [6]. EF stimulates intestinal motility and increases its blood flow [37]. The meta-analysis by Song et al. (2018) included 10 randomized controlled studies involving 1051 patients with a severe or predictably severe AP. In that paper, a comparison of the influence of early EF commenced within the first 48 hours of admission versus late enteral/parenteral feeding was undertaken. The researchers discovered that early EF decreases mortality, development of multiple organ failure, necessity of surgical intervention, the number of local and systemic infections [38]. Traditionally, the preferred method of EF was NJ-tube feeding because it was believed that such technique of delivering nutrients does not stimulate the secretory function of the gland. However, from 2005 onwards, several randomized controlled studies have demonstrated that NG-tube feeding is well tolerated by patients and, compared to NJ-tube feeding, does not entail increase of mortality. The key advantage of NG-tube feeding was that a nasogastric tube can be inserted by nursing staff without physician's participation in contrast to a nasojejunal tube, which is inserted either by a physician or by an endoscopic team using special equipment. The latest meta-analysis comparing the NG- *vs*. NJ-tube feeding in severe AP patients concluded that an advantage of neither method of the enteral tube feeding was proven [5]. The authors paid special attention to the fact that not all of the patients included into the analyzed studies [39–42] met the criteria of severe AP according to the new classification adopted in Atlanta (2012) [3], while one of the papers gave authors' definition of the AP severity [43]. Commencement of EF in those papers varied within the interval of 24 to 72 hours of paid development or hospital admission. In all papers, a semi-elemental EF was used. In contrast to the existing investigations, in our study we used a standard polymer formula with addition of dietary fibers, which does not disagree with the current recommendations of the European Society for Clinical Nutrition and Metabolism (2020) [44] or the Cochrane review (2015) that included 15 studies (1,376 participants) and did not find evidence in favor of any particular enteral formula during AP [45]. The retrospective study carried out in 2018 in Japan also showed absence of any clinical benefit between usage of an elemental formula versus a semi-elemental or polymer formula in AP patients [46]. Chen T. et al. [47] evaluated the role of soluble dietary fibers as an intestinal motility modulator during severe AP. Patients who received polydextrose with soluble dietary fivers required less time to achieve the target energy level (7 *vs*. 5 days; $p < 0.001$) and showed lower feeding intolerance indices (25 *vs*. 59 %, $p < 0.05$) compared to the group of patients who received feeding without dietary fibers.

There was no statistically significant difference in the duration of in-hospital treatment, time in ICU, the mechanical ventilation time, or mortality between the groups of NG- and NJ-tube feeding. An additional analysis of our findings has shown that the EF method does not affect the criteria of AP severity prognosis assessed according to APACHE II, SOFA, BISAP, and concentration of urea and C-reactive protein [48]. Taking into account the available data and our findings, the key factor of successful early EF during AP with predictors of a severe course is a personalized approach to each patient with regard to his/her energy requirement of rest [49], presence of factors affecting EF tolerance [50], introduction of methods capable of forecasting successful application of different EF techniques [51, 52].

Conclusion

No difference was found between the groups, which received early enteral feeding using a standard polymer formula with dietary fibers via a nasogastric or nasojejunal tube during the onset period of acute pancreatitis with predictors of a severe disease, in the duration of in-hospital treatment, time in ICU, time on mechanical ventilation, number of surgeries performed during the 1st or 2nd periods of the disease, the form of the disease, or mortality indices.

Limitations of the study

Patients with a pancreatogenic shock and oligoanuria were not included into or were withdrawn from the study during the study period.

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

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