

Research Article

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Comparative Effectiveness of Early and Delayed Surgical Interventions in Patients with Acute Adhesive Intestinal Obstruction: A Multicenter Controlled Randomized Trial Prospective Study

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ABSTRACT Acute adhesive intestinal obstruction (AAIO) is one of the most common pathological conditions, making a significant contribution to the spectrum of urgent surgical diseases. Treatment of such patients consists of conservative therapy and surgical treatment, the indications for which vary within the domestic and foreign recommendations. Existing works in the format of observational cohort studies devoted to the comparative efficacy and safety of various terms of non-surgical treatment of AAIO indicate in favor of long terms of conservative therapy, contributing to an increase in its efficacy without a negative impact on the outcomes of operated patients. However, these studies contain a number of features that limit their external validity, due to which conducting a study in a randomized format seemed justified.

AIM OF THE STUDY Evaluation of the efficacy and safety of extending the duration of non-surgical treatment of patients with AAIO.

RESEARCH MATERIALS For the study, 216 patients with AAIO were selected, who, in accordance with the chosen randomization method, were distributed into the main (117 patients) and comparison groups (99 patients). During the implementation of the algorithm of actions, it was possible to achieve non-surgical resolution of AAIO phenomena in 86 patients (73.5%) of the main group, which, although statistically insignificant, exceeded the similar indicator of the comparison group, where successful conservative measures were carried out in 61 patients (61.6%) ($\chi^2=3.48$, $p=0.06$). Such results were probably achieved due to the longer duration of inpatient conservative treatment, which in the main group was 47.1 ± 32.4 versus 16.8 ± 14.2 hours in the comparison group ($p<0.001$). Comparison of the frequency of resection interventions, postoperative complications and average bed-day did not demonstrate statistically significant differences in all compared parameters.

CONCLUSION The extension of the duration of conservative therapy from 16.8 ± 14.2 to 47.1 ± 32.4 hours demonstrated a positive trend of increasing the frequency of non-surgical resolution of acute adhesive intestinal obstruction without a negative impact on the immediate outcomes of operated patients.

Keywords: adhesive disease, acute adhesive intestinal obstruction, peritoneal adhesions, non-surgical treatment of acute intestinal obstruction, adhesiolysis

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AAIO — acute adhesive intestinal obstruction

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INTRODUCTION

Acute adhesive intestinal obstruction (AAIO) is one of the most common pathological conditions, making a significant contribution to the spectrum of urgent surgical diseases. Treatment of such patients consists of conservative therapy and surgical treatment, the indications for which vary within the domestic and foreign recommendations. In particular, foreign practice provides for long-term trial conservative therapy - up to 72-96 hours [1-3], while in Russian practice, significantly shorter periods are considered as a pathogenetic component of decompensated AAO, requiring urgent surgical intervention. Existing studies in the format of observational cohort studies devoted to the comparative effectiveness and safety of various periods of non-surgical treatment of AAO indicate in favor of long periods of conservative therapy, which contribute to an increase in its effectiveness without a negative impact on the outcomes of operated patients.

A search for studies of higher methodological quality revealed only one systematic review comparing the results of using different durations of conservative therapy, however, this study analyzes studies that include patients with signs of strangulation intestinal obstruction, peritonitis, and tumor-related obstruction [4], which limits the application of the obtained results in the practice of treating AKI.

Given the lack of a convincing evidence base and to justify the feasibility of conducting a randomized study, a systematic review was conducted to identify the safest durations of conservative therapy in patients with AKI [5]. The results obtained in the course of this review suggested that the calculation of the maximum permissible duration of conservative therapy should still be based on the

duration of the AKI episode, and the total duration of ileus can be safely extended to 89 hours regardless of the method of conservative therapy practiced, be it standard treatment or the introduction of undiluted Gastrografin (a water-soluble contrast agent) to determine the passage through the gastrointestinal tract. Such tactics, on the one hand, would not contradict the standards of long-term non-surgical treatment accepted abroad, and on the other hand, it would expand the concept of decompensated intestinal obstruction to the periods determined in the course of the above systematic review. Using this information, an algorithm for treating patients with AAIO was developed and implemented within the framework of a randomized study.

The aim of this work was to evaluate the effectiveness and safety of extending the duration of non-surgical treatment of patients with OSA.

RESEARCH DESIGN AND METHODS

To achieve this goal, a randomized controlled parallel study was conducted at 5 hospitals in St. Petersburg: FSBEI HE "North-Western State Medical University named after I.I. Mechnikov" of the Ministry of Health of the Russian Federation, St. Petersburg Research Institute of Emergency Medicine named after I.I. Dzhanelidze, St. Petersburg State Budgetary Healthcare Institution "City Hospital of the Holy Martyr Elizabeth", St. Petersburg State Budgetary Healthcare Institution "City Mariinsky Hospital" and St. Petersburg State Budgetary Healthcare Institution "City Hospital No. 26". Among 4 of the specified medical institutions, patient recruitment was carried out from 01.01.2023 to 31.12.2023, in another hospital (City Mariinsky Hospital), research work was carried out in the time period from 01.03.2023 to 31.12.2023. The study included adult patients who were diagnosed with AKI

at the initial examination stage according to the criteria set out in the national clinical guidelines of the Russian Society of Surgeons "Acute non-tumor intestinal obstruction in adults" for 2021. The following signs were defined as exclusion criteria:

- pediatric patients, pregnant women;
- patients with acute intestinal obstruction (AIO) of non-adhesive etiology, diagnosed at any stage of the initial examination, observation in a hospital setting, or surgical treatment;
- with signs of peritonitis or strangulation intestinal obstruction identified at the stage of the initial examination;
- with early AAIO, the criterion for which was the presence of anamnestic surgical intervention - within 6 weeks prior to admission.

The method of distributing patients into groups was the quasi-randomization method based on the calendar method: after checking for compliance with the inclusion criteria, patients born in an even year were distributed into the main group, and those born in an odd year were distributed into the comparison group. Given the specific nature of the medical field under study, the blinding procedure for study participants at all levels, as well as concealment of distribution, was naturally not carried out. Patients were divided into 2 groups - comparison and main.

Treatment in the comparison group was carried out in accordance with the generally accepted practice described in the recommendations of the Russian Society of Surgeons for the treatment of non-neoplastic AIO, and the degree of compensation of intestinal obstruction phenomena was determined. In the presence of signs of decompensated AIO, patients underwent urgent surgical intervention after short-term preoperative preparation. In other situations, treatment was started with conservative measures, including gastric probing, infusion therapy, and enterography. The latter was performed by introducing a contrast agent into a gastric tube with subsequent overview images of the abdominal cavity 6, 12, 18, and 24 hours after the contrast administration. Persistence of AIO signs for 12–24 hours of trial conservative therapy served as the basis for urgent surgical intervention; the flow of contrast into the colon was regarded as a success of conservative therapy.

In the main group, all patients underwent conservative therapy, the volume of which corresponded to that in the comparison group. As for the duration of non-surgical treatment, it was determined based on the duration of the disease, in accordance with the following formula:

$$\text{Duration of conservative therapy} = 72 \text{ hours} - \text{duration of the disease}$$

The duration of the disease was calculated in accordance with the anamnestic indications of the onset of pain. After the specified period, the effectiveness of non-surgical treatment was assessed, including a control image of the abdominal organs - the absence of contrast in the colon served as an indication for urgent surgical intervention. In addition, the appearance of positive peritoneal signs at any stage of treatment, as well as deterioration of the condition, potentially indicating the development of intestinal ischemia, were also considered as an indication for stopping conservative therapy in favor of emergency surgery. The criteria for deterioration of the condition included increased abdominal pain, an increase in the level of leukocytosis, and uncorrectable hyperkalemia. The sequence of actions from the moment of diagnosis to the registration of treatment outcomes is schematically shown in Fig. 1.

The main treatment outcomes assessed were the frequency of non-operative resolution of the ASCN phenomena, which was observed upon the entry of the contrast agent into the colon. In order to determine the safety of the algorithm proposed in the main group, a comparative assessment of the severity of postoperative complications according to the *Clavien–Dindo classification* [6] and the frequency of resection interventions was also carried out. A comparative analysis of the obtained results was carried out based on the characteristics of the analyzed parameters: qualitative and non-parametric data were analyzed using variance analysis (χ^2 criterion), and Student's *t*-test was used to compare quantitative parametric data. Statistical calculations were performed using *IBM SPSS Statistics ver. 26.0* software.

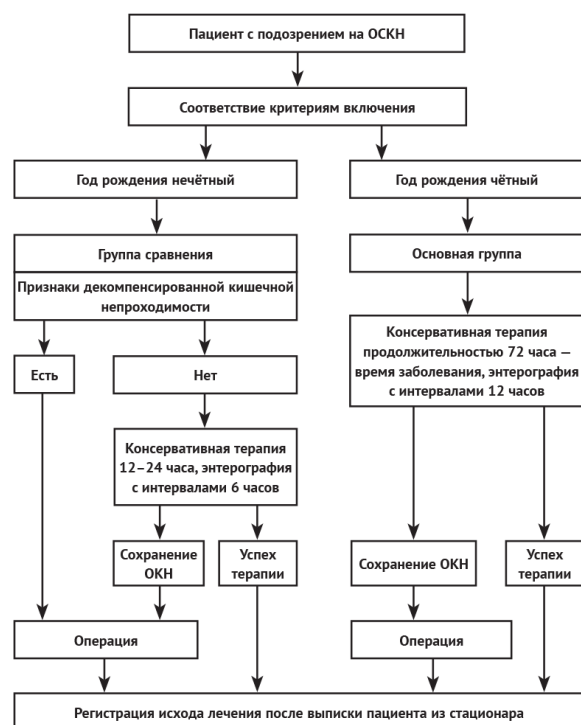


Fig. 1. Scheme of patient inclusion in the study, distribution into groups and description of interventions

Notes: ОКН - acute intestinal obstruction; ОСКН - acute adhesive intestinal obstruction

The study design, inclusion criteria, description of interventions, and estimated sample size were previously published and registered in the International Clinical Trials Registry of the US National Institutes of Health (www.clinicaltrials.gov) under number NCT05841069. The study was approved by the local ethics committee of the I.I. Mechnikov North-Western State Medical University of the Ministry of Health of the Russian Federation, meeting minutes No. 11 dated 07.12.2022.

RESEARCH MATERIAL

Initially, during the study, 388 patients were distributed into study groups, however, a more detailed retrospective analysis required excluding a significant number of patients due to the discrepancy between their characteristics and the diagnostic criteria for AAIO. In particular, in some cases, the diagnosis of AAIB was established only on the basis of the presence of pain syndrome of unclear etiology and the fact of anamnestic surgical intervention, while no laboratory or instrumental signs of intestinal

obstruction were recorded, including during radiographic examination. Guided by stricter diagnostic criteria, 216 patients with AAIO were selected for the study, who, in accordance with the selected randomization method, were distributed into the main (117 patients) and comparison groups (99 patients). Speaking about general somatic characteristics, women equally predominated in both groups: 81 (69.2%) in the main group versus 66 patients (66.7%) in the comparison group (Pearson $\chi^2 = 0.162, p = 0.68$). The average age of patients was 62.9 ± 18.8 and 64.6 ± 18.7 years in the main and comparison groups, respectively ($p = 0.513$), varying widely from 19 to 94 years.

In 201 examined patients (93.1%), anamnestic indications of previous surgical interventions on the abdominal organs were revealed, the average number of which was 1.45 ± 0.91 and 1.26 ± 0.79 in the main and comparison groups, respectively ($p = 0.106$). In the overwhelming majority of cases (75 patients (64.1%) in the main group and 63 patients (63.6%) in the comparison group), a single intervention on the abdominal organs took place. It should be noted that 15 patients (6.9%) denied the fact of previous abdominal surgical interventions, and no scars on the anterior abdominal wall were found in them during objective examination. However, there are a number of works indicating [7–10] adhesive disease as the leading cause of intestinal obstruction in patients with an intact abdomen, so these patients were also included in the study.

Taking into account the average age of the examined patients, the majority of cases were found to have a multimorbid background, the severity of which was assessed according to the CIRS-G (Cumulative Illness Rating Scale for Geriatrics, [11]) scale. Taking into account that all the examined patients initially had bowel disease, assessed at 3 or 4 points depending on the success of conservative measures, as well as a number of comorbid conditions associated with age-related atherosclerosis, the average scale score in the studied groups of patients was 14.3 ± 5.3 . Information on the assessment of multimorbidity within the compared groups is shown in Fig. 2. In order to objectify further comparison of treatment results, the CIRS-G values were separately calculated in patients operated on for AAIO. and in patients in whom conservative therapy was ultimately successful.

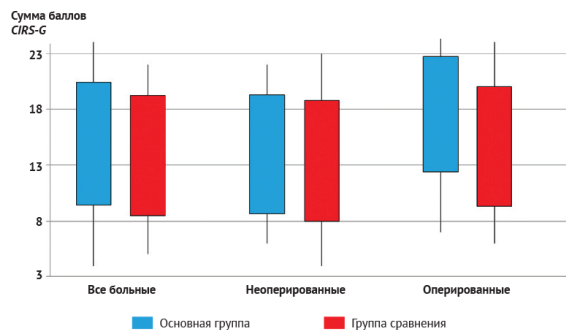


Fig. 2. Severity of morbidity in accordance with the CIRS-G scale values in operated and non-operated patients of the compared groups

Based on the presented information, no significant differences were found when comparing the morbid background: the *CIRS-G* scores were 14.9 ± 5.5 and 13.9 ± 5.4 points ($p = 0.16$) in the main and comparison groups, respectively. On the contrary, the analysis of this indicator in the subgroups of patients who underwent urgent surgery for acute coronary heart failure demonstrated differences in favor of the comparison group patients, where the total score was statistically lower than the same parameter in the main group: 14.6 ± 5.3 versus 17.6 ± 5.1 points ($p = 0.03$). Thus, the analysis of the studied patient groups did not reveal any significant differences in most general somatic characteristics.

As for the duration of an attack of intestinal obstruction as a key factor in determining the duration of conservative measures in the main group, some difficulties arose in determining this parameter. In particular, many patients found it difficult to indicate the time of onset of pain due to the presence of memory disorders or a progradient onset of the disease. In view of this, in non-obvious situations, the duration of the attack before admission to the hospital was established on the basis of other signs of intestinal obstruction - vomiting and bloating. Based on such settings, the average duration of the disease at the time of hospitalization was 23.1 ± 19.4 and 24.0 ± 22.7 hours in the main and comparison groups, respectively ($p = 0.79$), varying widely from 1 hour to 5 days. Speaking about the distribution of this parameter by subgroups of patients operated and treated conservatively, it was uneven in different groups. In particular, in the main group, the average prehospital duration of an attack of intestinal obstruction was the same among patients with

successful non-surgical treatment and those operated on urgently, amounting to 22.4 ± 14.2 and 24.7 ± 19.3 hours, respectively ($p = 0.71$). On the contrary, in the comparison group, the prehospital duration of ileus was statistically significantly higher among patients who managed to avoid surgery — 28.5 ± 22.1 versus 16.8 ± 8.7 hours in the subgroup operated on urgently ($p = 0.02$). This circumstance indirectly confirms the fact that the total duration of an attack of intestinal obstruction is one of the leading predictors of the success of non-surgical treatment.

However, the duration of the episode is by no means the only parameter of the severity of intestinal obstruction. Due to the lack of a single tool for assessing the severity of the pathomorphosis of the disease under study, a number of clinical and laboratory-instrumental signs were additionally subjected to comparative assessment. The results of the comparison are summarized in Table 1.

Based on the presented data, no significant differences in clinical symptoms were revealed: the distribution of patients with different types of pain syndrome or dyspeptic symptoms was approximately the same in both compared groups (the significance level was higher than 0.05 in all cases). The presence and severity of dehydration phenomena as one of the leading syndromes of AKI was assessed based on clinical signs, hematocrit levels and laboratory manifestations of prerenal renal failure, including diselectrolyte disorders. It was the presence of the latter factor that served as the basis for stating the fact of clinically significant dehydration, the frequency of which was analyzed in the compared groups, and no statistically significant differences were revealed based on the comparison results ($\chi^2 = 0.39$, $p = 0.53$). As for the most accessible marker of the inflammatory process in clinical practice - the level of leukocytes - its values in the compared groups of patients also did not demonstrate clinically significant differences, with the exception of a somewhat uneven distribution in favor of the subgroups of operated patients, where leukocytosis was higher on average.

Instrumental diagnostics of AAIO. was limited to performing X-ray and ultrasound examinations. It was decided to refrain from including computed tomography in the routine complex of examinations during the planning of the design of the work in order to avoid reducing the external validity of the study.

Based on the data presented in Table 1, ultrasound symptoms, which consisted of dilated intestinal loops, pendulum-like peristalsis, and free fluid in the abdominal cavity, were equally expressed in both compared groups ($p > 0.05$ for each symptom separately and for their combinations). Similarly, radiographic data confirming the fact of intestinal obstruction, as well as their absence, were recorded with approximately the same frequency ($\chi^2 = 2.35$, $p = 0.31$).

Of course, most of the analyzed criteria of OCI correlate to a small extent with the severity of intestinal obstruction. However, even their comparative analysis did not reveal any significant differences, which, together with a similar comorbid background, allows us to assume the absence of statistically significant differences in the initial parameters of the examined patients, reducing the potential difference in the results obtained only to differences in treatment tactics.

Table 1

Symptoms of acute intestinal obstruction in compared groups of patients

Indicator		Patients examined		χ^2	r
		Main group ($n = 117$)	Comparison group ($n = 99$)		
Abdominal pain, n (%)	None	32 (27.4)	28 (28.3)	1.62	0.45
	Spastic	63 (53.8)	46 (46.5)		
	Constant	22 (18.8)	25 (25.3)		
Abdominal distension, n (%)	No	31 (26.5)	17 (17.2)	2.70	0.10
	Eat	86 (73.5)	82 (82.8)		
Vomiting, n (%)	No	31 (26.5)	33 (33.3)	1.21	0.55
	Gastric contents	58 (49.6)	44 (44.4)		
	Intestinal contents	28 (23.9)	22 (22.2)		
Laboratory signs of dehydration, n (%)	All patients	69 (58.5)	62 (62.6)	0.39	0.53
	Unoperated	46 (53.5)	39 (63.9)	1.96	0.16
	Operated	23 (74.2)	23 (60.5)	1.43	0.23
Average leukocyte count, $\times 10^9/l$	All patients	11.4 \pm 4.3	10.5 \pm 4.7	n/a	0.12
	Unoperated	10.7 \pm 4.1	9.2 \pm 3.9	n/a	0.03
	Operated	13.1 \pm 4.5	12.3 \pm 5.3	n/a	0.49
Ultrasound signs of acute intestinal obstruction, n (%)	Loop expansion	53 (44.9)	38 (38.8)	0.82	0.36
	Pendulum-like peristalsis	42 (35.6)	30 (30.6)	0.59	0.44
	Free liquid	33 (28.0)	28 (28.6)	0.01	0.92
Radiological signs of acute intestinal obstruction, n (%)	No	15 (12.9)	20 (20.2)	2.35	0.31
	Single levels	60 (51.7)	50 (50.5)		
	Multiple levels	42 (35.3)	29 (29.3)		

RESULTS OBTAINED

In the course of implementing the described algorithm of actions, it was possible to achieve non-surgical resolution of the phenomena of AAIO. in 86 patients (73.5%) of the main group, which exceeded the similar indicator of the comparison group, where successful conservative measures were carried out in 61 patients (61.6%). However, it should be noted that the identified differences were on the border of statistical significance (Pearson's $\chi^2 = 3.48$, $p = 0.06$). Such results were probably achieved due to the longer

duration of inpatient conservative treatment, which in the main group was 47.1 ± 32.4 versus 16.8 ± 14.2 hours in the comparison group ($p < 0.001$). The maximum recorded duration of inpatient observation was 112 hours in one of the patients of the main group, who refused surgical intervention for a long time, which was ultimately avoided. Before proceeding to consider the outcomes of such treatment, it seems appropriate to conduct a comparative analysis of the characteristics of the surgical interventions performed, the results of which are presented in Table 2.

Table 2

Characteristics of the surgical interventions performed in the compared groups of patients

Indicator		Examined operated patients		χ^2	r
		Main group ($n = 31$)	Comparison group ($n = 38$)		
Operational access, n (%)	Laparoscopic	2 (6.5)	3 (7.9)	1.28	0.53
	Laparoscopic with conversion	4 (12.9)	9 (23.7)		
	Laparotomy	25 (80.6)	26 (68.4)		
Nature of effusion in the abdominal cavity, n (%)	No	11 (35.5)	7 (18.4)	2.62	0.27
	Serous	19 (61.3)	29 (76.3)		
	Serous-fibrinous	1 (3.2)	2 (5.3)		
Small bowel diameter above obstruction, n (%)	No more than 3 cm	6 (19.4)	12 (31.6)	3.56	0.31
	3-5 cm	17 (54.8)	21 (55.2)		
	5-7 cm	7 (22.6)	3 (7.9)		
	More than 7 cm	1 (3.2)	2 (2.9)		
Character of spontaneous peristalsis, n (%)	Saved	11 (35.5)	14 (36.8)	0.12	0.94
	Weakened	15 (48.4)	19 (50.0)		
	Absent	5 (16.1)	5 (13.2)		
Strangulations detected intraoperatively, n (%)		4 (12.9)	5 (13.2)	0.001	0.96
Intestinal resections due to necrosis, n (%)		2 (6.5)	2 (5.3)	0.04	0.83
Peritonitis detected intraoperatively, n (%)		1 (3.2)	2 (5.3)	0.17	0.68
Nasogastrintestinal intubation, n (%)		9 (29.0)	8 (21.1)	0.56	0.44
Duration of surgical intervention, min		124.8±38.1	95.6±54.2	not applicable	0.01

Based on the presented data, attempts at laparoscopic adhesiolysis were successful in 2 patients of the main group and 3 patients of the comparison group. In another 4 (12.9%) and 9 (23.7%) patients, respectively, conversion of access was performed due to the impossibility of unambiguously identifying and eliminating the cause of intestinal obstruction; in all other patients, surgical treatment began with a midline laparotomy. The absence of differences in surgical approaches ($\chi^2 = 1.28$, $p = 0.53$) indicates that the extension of the terms of conservative therapy within the specified limits did not lead to a limitation of the possibilities of endovideosurgical access in the treatment of patients with ASO.

As for intraoperative findings, no significant differences in the nature of the effusion in the abdominal cavity, as well as the degree of intestinal expansion within the compared groups were found. In most cases, transparent serous effusion without signs of infection was detected intraoperatively - in 19 (61.3%) and 29 (76.3%) patients of the main and comparison groups, respectively ($\chi^2 = 2.62$, $p = 0.27$). Turbid discharge with a fibrinous component, indicating the development of complicated surgical infection, was detected intraoperatively in 1 patient of the main and 2 patients of the comparison group, while in none of the above observations were data on intestinal necrosis, the appearance of acute ulcers or other sources of secondary peritonitis revealed. Most likely, the development of the infectious process in these patients was due to the translocation of pathogenic microflora through the intestinal wall without violating its anatomical integrity. In none of the cases indicated did the degree of pathomorphological changes in the abdominal cavity require sanitizing relaparotomies, and a single intervention was sufficient to eliminate the infectious process in the abdominal cavity.

The practice of increasing the duration of conservative measures in the main group inevitably led to an increase in the total duration of ileus preceding surgery. The specified period ultimately amounted to 71.3 ± 34.5 and 36.8 ± 36.2 hours in the main and comparison groups, respectively ($p < 0.001$). Taking into account such significant differences, the number of patients in the main group with a small intestine diameter exceeding 5 cm at the time of surgery was slightly higher than in the comparison group: 7 (22.6%) versus 3 (7.9%) patients, respectively. However, these differences

did not reach a statistically significant level due to the predominance of patients with a moderate degree of small intestine dilation in the comparison group ($\chi^2 = 3.56$, $p = 0.31$). The extension of the duration of conservative therapy also did not significantly affect the degree of peristalsis disorder in the intestine located above the obstruction sites (Table 2).

Thus, due to the absence of a convincing difference in the degree of small intestine dilation and inhibition of peristaltic activity, the frequency of nasogastrintestinal intubation as the most radical variant of intestinal decompression was also comparable in the main and comparison groups, amounting to 29.0% and 21.1%, respectively ($\chi^2 = 0.56$, $p = 0.44$). In the overwhelming majority of cases, it was possible to limit ourselves to intubation of the initial sections of the small intestine with a gastric tube.

Taking into account the reasonable difficulties in diagnostics of conditions accompanied by intestinal ischemia, cases of late detection of strangulation variants of ICS also occurred. Thus, among patients of the main group, internal strangulation of the intestine was detected intraoperatively in 4 cases (12.9%), of which the need for resection due to necrotic changes arose in 2 patients (6.5%). Similar indicators in the comparison group were 5 (13.2%) and 2 patients (5.3%), respectively, and did not demonstrate statistically significant differences from the main group ($p > 0.05$). None of the mentioned patients with strangulation IS showed signs of complicated surgical infection or violation of the anatomical integrity of the intestine. As for the average duration of surgical intervention, in the main group it was statistically significantly higher than among patients of the comparison group: 124.8 ± 38.1 and 95.6 ± 54.2 minutes ($p = 0.01$), respectively. Considering that the frequency of nasointestinal intubations and intestinal resections in the main group did not exceed similar indicators in the comparison group, the difference in the duration of the surgical procedure was largely due to the severity of the adhesive process, which weakly correlated with the severity of the symptoms of adhesive disease.

To summarize the above, the extension of the duration of conservative therapy did not lead to a limitation of the possibilities of endovideosurgical access in the treatment of AAIO, an increase in the incidence of complicated surgical infection, the need

for total intestinal intubation and resection interventions.

Data on the frequency and severity of postoperative complications are shown in Fig. 3. In most cases — 21 patients (67.7%) in the main group and 25 patients (65.8%) in the comparison group — the postoperative period was uneventful, and no deviations from the norm were recorded. Another 3 (9.7%) and 4 patients (10.5%) in the main and comparison groups, respectively, had complications of the 1st degree according to *Clavien-Dindo*, consisting mainly of suppuration of postoperative wounds, which in none of the observations required any invasive treatment and were eliminated within a few days. As for more serious postoperative deviations, they were reduced to bronchopulmonary complications and were detected in 2 patients in the main group and 3 patients in the comparison group. The need for repeated surgical interventions arose in 1 patient of the main group against the background of early postoperative SCI and in 1 patient of the comparison group, where relaparotomy was performed on a planned basis to assess the viability of intestinal loops after resection intervention. Without taking into account adverse outcomes, the analysis of the frequency and severity of postoperative complications did not demonstrate significant differences within the compared groups of patients ($\chi^2 = 3.93$, $p = 0.56$).

Fatal outcomes were recorded in 5 (4.3%) and 4 patients (4.0%) of the main and comparison groups, respectively (Pearson $\chi^2 = 6.5$, $p = 0.09$). It should be

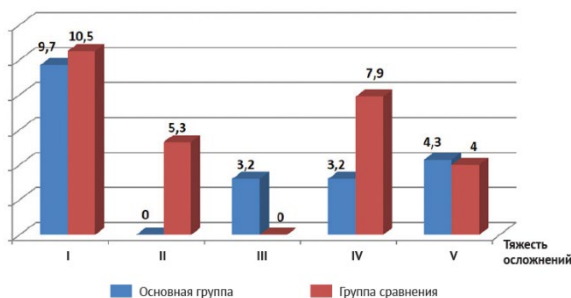


Fig. 3. Frequency and severity structure of postoperative complications according to the Clavien–Dindo classification

noted that no correlation was observed between the duration of inpatient treatment and the probability of an unfavorable outcome: the average duration of conservative measures among deceased patients in the main group was 47.6 ± 16.5 hours, which did not exceed the same parameter among surviving patients - 47.0 ± 34.9 hours ($p = 0.97$). Moreover, in the comparison group, the duration of non-surgical treatment among patients with unfavorable outcomes was slightly lower than in the cohort of surviving patients (8.6 ± 3.0 versus 21.35 ± 19.2 hours), although these differences did not reach a statistically significant level ($p = 0.38$). In most cases, the unfavorable outcome occurred against the background of acutely developing cardiovascular failure, which subsequently appeared as the cause of death. An intra-abdominal complication that caused the development of sepsis, which contributed to the occurrence of an unfavorable outcome, was recorded in one operated patient of the control group: *post mortem*, necrosis of a section of the intestine of ischemic genesis of non-strangulation genesis was detected. Thus, no significant differences in the frequency and structure of causes of death in the compared groups were also revealed.

Average inpatient bed days are shown in Fig. 4.

Based on the presented data, the extension of the terms of conservative therapy did not significantly affect the average bed-day of the studied medical histories of patients: 6.3 ± 5.5 in the main group versus 6.6 ± 5.8 days in the comparison group ($p = 0.66$). Similarly, the duration of treatment of operated patients also did not change significantly, varying within 12.1 ± 6.8 days in the main group and 11.8 ± 6.2 days in the comparison group. The exception, naturally, were patients in whom conservative measures were successful and surgical intervention was avoided: in the main group, the average bed-day slightly exceeded that in the comparison group, amounting to 4.2 ± 3.1 versus 3.4 ± 1.8 . However, the level of significance of this trend was on the border of statistical significance ($p = 0.07$), so these differences can be neglected.

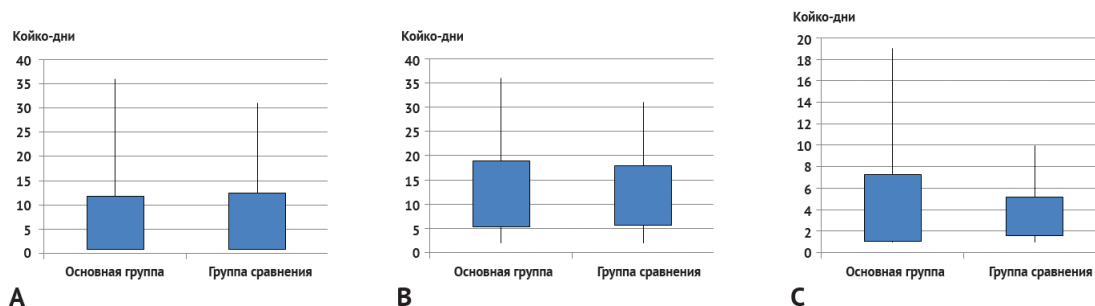


Fig. 4. Average hospital stays in the compared groups among all patients (A), operated for acute adhesive intestinal obstruction (B) and treated conservatively (C)

CONCLUSION

During the randomization procedure, the patients examined, selected according to the inclusion criteria, were divided into approximately equal groups with a total of 216 people. This sample size exceeded that planned at the stage of study design, therefore the required study power (adopted as 80% at a significance level of 0.05 and an assumed difference in the frequency of non-surgical resolution of acute adhesive intestinal obstruction of 20%) was provided by sufficient clinical material. Analysis of age, gender distribution, as well as the degree of burden of multimorbidity (objectified according to the *CIRS-G scale*) did not reveal statistically significant differences within the compared groups, due to which the influence of general somatic parameters on the outcomes was not taken into account further. As for the comparative assessment of the severity of an attack of acute intestinal obstruction, it was carried out by an isolated comparison of the frequency and severity of clinical, laboratory and instrumental symptoms, as well as the total duration of ileus. Certainly, most of these parameters only indirectly reflect the depth of pathomorphological changes in the abdominal cavity and associated syndrome complexes. However, the absence of statistically and clinically significant differences in these features allowed us to assume the similarity of the study groups in terms of the severity of mechanical intestinal obstruction, and, ultimately, to associate the difference in treatment outcomes only with changes in the duration of non-surgical measures.

The introduction into practice of the terms of conservative therapy, set in arithmetic dependence on the total duration of ileus, on the one hand, allowed to preserve the concept of decompensated intestinal obstruction, which is practically not

mentioned in foreign studies, and on the other hand, made it possible to extend the total duration of non-surgical measures in the main group by 30.3 ± 12.9 hours. Such changes contributed to an increase in the frequency of successful conservative measures, although statistically insignificant, from 61.6 to 73.5% ($p = 0.07$). An increase in the duration of preoperative observation of patients with acute adhesive intestinal obstruction did not lead to an aggravation of pathomorphological changes in the abdominal cavity, which was proven by comparing the frequency of ischemic lesions, the degree of dilation and impaired peristaltic activity of the intestine. Moreover, an increase in the number of untimely diagnosed strangulation forms of intestinal obstruction and complicated surgical infection was also not noted.

As for the immediate treatment outcomes, reflecting the potential safety of the algorithm practiced in the main group, no negative consequences were recorded either. This concerns both the frequency and structure of the causes of adverse outcomes, and other non-fatal complications. Also, despite the fact that no targeted assessment of the economic effect was made, it can be assumed that there was no negative impact in this direction, given the absence of statistically significant differences in the average bed-days of the studied patient groups.

CONCLUSIONS

To summarize the study, the extension of the non-surgical treatment period for patients with acute adhesive intestinal obstruction by 30.3 ± 12.9 hours led to the following results:

1. Non-operative resolution of acute adhesive intestinal obstruction was recorded in 86 (73.5%) and 61 patients (61.6%) of the main and comparison groups, respectively ($p = 0.06$).

2. No negative impact on immediate postoperative outcomes, the frequency and structure of complications, and the average hospital stay was recorded. Fatal outcomes were recorded in 5 (4.3%) and 4 patients (4.0%) in the main and comparison groups, respectively ($p = 0.09$);

3. The average duration of conservative measures among deceased patients in the main group was 47.6 ± 16.5 hours, which did not exceed the same parameter among surviving patients - 47.0 ± 34.9 hours ($p = 0.97$).

It is obviously premature to compare the obtained results with foreign practice, since the average duration of attempts at non-operative resolution in the main group (47.1 ± 32.4 hours) was still almost a day less than the WSES 72 hours. In any case, during the randomized study, the *non nocere principle* was fully observed, and a positive trend was revealed, justifying the prospects for further expansion of the terms of conservative treatment of patients with acute adhesive intestinal obstruction of non-strangulation genesis.

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