STAGING IN THE TREATMENT OF CHRONIC CALCULOUS CHOLECYSTITIS, COMPLICATED BY CHOLEDOCHOLITHIASIS

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ABSTRACT

BACKGROUND: Chronic calculous cholecystitis is the most widespread disease in scheduled surgery departments, which in 10–15% of observations is complicated by choledocholithiasis. As of today, the commonly acknowledged staged treatment tactics includes first an endoscopic lithoextraction, later followed by the laparoscopic cholecystectomy, with the durations of performing the latter not being defined. AIM: To define the optimal timings of performing the laparoscopic cholecystectomy after an endoscopic lithoextraction in cases of chronic calculous cholecystitis, complicated by choledocholithiasis. **METHODS:** The research included patients with chronic calculous cholecystitis, complicated by choledocholithiasis, which during the period of 2016-2023 years have received surgical aid at the Federal State Budgetary Institution "Federal Scientific and Clinical Center" of the Federal Medical-Biological Agency of Russia (n=87). Simultaneous endoscopic lithoextraction and laparoscopic cholecystectomy were carried out in 20 patients; 19 patients were operated within a single hospitalization with undergoing endoscopic lithoextraction and in 3 days — laparoscopic cholecystectomy (early cholecystectomy); in 48 patients laparoscopic cholecystectomy was delayed by 1-2 months after the endoscopic lithoextraction (interval cholecystectomy). RESULTS: When comparing the treatment results in three groups of patients, no statistically significant differences were observed, however, in the group of interval cholecystectomy, a tendency was shown for increasing the surgery duration, the conversion rate and the number of complications. CONCLUSION: In patients, not having signs of severe course of the disease, it is possible to perform simultaneous endoscopic lithoextraction and laparoscopic cholecystectomy. In the absence of complications, the applicable options include early (within 3 days) conducting the laparoscopic cholecystectomy, which does not worsen the results, however, it alleviates the necessity of repeated hospitalization and, probably, slightly decreases the risk of complications.

Keywords: cholecystectomy; choledocholithiasis; gall stone disease; chronic cholecystitis; endoscopic retrograde cholangiopancreatography.

For citation:

Smirnov AV, Stankevich VR, Sazonov DV, Akhmedianov AR, Keshvedinova AA, Solovyev NA, Ivanov YuV, Khabazov RI. Staging in the treatment of chronic calculous cholecystitis, complicated by choledocholithiasis. *Journal of Clinical Practice*. 2024;15(4):38–45. doi: https://doi.org/10.17816/clinpract642585

Submitted 05.12.2024

Revised 17.12.2024

Published online 17.12.2024

BACKGROUND

Cholecystectomy caused by the presence of chronic cholecystitis is the most widespread scheduled surgery in Russia. According to data from the information-analytical bulletin "Surgical Aid in the Russian Federation", the number of cholecystectomies in 2023 was 152 220 [1]. The occurrence rate of choledocholithiasis caused by the gall stone disease, according to different estimations, varies from 5 to 30% (with a mean of 10–15%) among the total number of gall stone disease patients [2]. In the existing clinical recommendations, after endoscopic lithoextraction in cases of chronic calculous cholecystitis, complicated by choledocholithiasis, a necessity is postulated of performing laparoscopic cholecystectomy [3], however, the optimal timings of its execution are determined only in local guidelines [4]. The accumulated data indicate that, when choosing the follow-up tactics, the prognosis in the patients significantly worsens: an increase is reported in the rates of recurrences (2-fold) and in the total mortality [5].

There are three principally different tactical approaches — simultaneous surgery, early cholecystectomy, which, in turn, is divided into cholecystectomy conducted in 3, 7 and 14 days, and the interval cholecystectomy (within the periods from 14 days to several months). The option that is widely acknowledged is the interval cholecystectomy. In this case, there are no unfavorable risk factors of developing complications, such as the mechanical jaundice and local



ЭТАПНОСТЬ В ЛЕЧЕНИИ ХРОНИЧЕСКОГО КАЛЬКУЛЁЗНОГО ХОЛЕЦИСТИТА, ОСЛОЖНЁННОГО ХОЛЕДОХОЛИТИАЗОМ

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АННОТАЦИЯ

Обоснование. Хронический калькулёзный холецистит — наиболее распространённое заболевание в плановой хирургии, которое в 10–15% наблюдений осложняется холедохолитиазом. На сегодняшний день общепризнана поэтапная тактика лечения, когда первоначально производится эндоскопическая литоэкстракция, а затем лапароскопическая холецистэктомия, при этом сроки выполнения последней не определены. Цель исследования — определить оптимальные сроки выполнения лапароскопической холецистэктомии после эндоскопической литоэкстракции при хроническом калькулёзном холецистите, осложнённом холедохолитиазом. Методы. В исследование включены больные хроническим калькулёзным холециститом, осложнённым холедохолитиазом, которым в 2016–2023 годах оказывали хирургическую помощь в ФГБУ ФНКЦ ФМБА России (n=87). Симультанная эндоскопическая литоэкстракция и лапароскопическая холецистэктомия проведены 20 пациентам; 19 больным в рамках одной госпитализации выполнены эндоскопическая литоэкстракция и в течение 3 дней лапароскопическая холецистэктомия (ранняя холецистэктомия); 48 пациентам лапароскопическая холецистэктомия была отсрочена на 1-2 месяца после эндоскопической литоэкстракции (интервальная холецистэктомия). Результаты. При сравнении результатов лечения трёх групп пациентов статистически значимых отличий не получено, однако в группе интервальной холецистэктомии отмечена тенденция к увеличению длительности операции, частоты конверсий и числа осложнений. Заключение. У пациентов, не имеющих признаков тяжёлого течения заболевания. возможно выполнение симультанной эндоскопической литоэкстракции и лапароскопической холецистэктомии. При отсутствии осложнений целесообразно раннее (в течение 3 дней) выполнение лапароскопической холецистэктомии, которая не приводит к ухудшению результатов, однако избавляет от необходимости повторной госпитализации и, вероятно, несколько снижает риск осложнений.

Ключевые слова: холецистэктомия; холедохолитиаз; желчнокаменная болезнь; хронический холецистит; эндоскопическая ретроградная холангиопанкреатография.

Для цитирования:

Смирнов А.В., Станкевич В.Р., Сазонов Д.В., Ахмедьянов А.Р., Кешвединова А.А., Соловьев Н.А., Иванов Ю.В., Хабазов Р.И. Этапность в лечении хронического калькулёзного холецистита, осложнённого холедохолитиазом. *Клиническая практика.* 2024;15(4):38–45. doi: https://doi.org/10.17816/clinpract642585

Поступила 05.12.2024 Принята 17.12.2024 Опубликована online 17.12.2024

inflammatory reaction resulting due to the concrement passage and endoscopic manipulations. However, in a number of research works, it was demonstrated that interval cholecystectomy is associated with the risk of iatrogenic injury of the common bile duct and of the duodenum, with larger conversion rates and higher rates of purulent-septic complications, there is also a risk of developing repeated unfavorable biliary events (repeated choledocholithiasis, acute cholecystitis, cholangitis, acute biliary pancreatitis), which even more aggravate the patient status and lead to long-term therapy. Simultaneous endoscopic retrograde cholangiopancreatography (ERCP) and cholecystectomy (hybrid surgery) allow for avoiding

repeated general anesthesia and provide a possibility of shortening the treatment duration, however, they require coordination of the surgical and endoscopic teams along with the corresponding equipment required in the surgery room, which is not available in all the medical organizations. Besides, in case of developing complications, their correction can be difficult.

Due to the abovementioned, it is necessary to analyze the experience of treating the patients with chronic calculous cholecystitis combined with choledocholithiasis with further drafting specific recommendations.

Research aim — to define the optimal timings for conducting the laparoscopic cholecystectomy after

an endoscopic retrograde cholangiopancreatography with lithoextraction in cases of calculous cholecystitis combined with choledocholithiasis.

METHODS

Research design

A retrospective comparative research was carried out, which has analyzed the treatment results in three groups of patients with gall stone disease, chronic calculous cholecystitis and choledocholithiasis, which were treated using the staged treatment tactics. The groups were assigned according to the intervals of performing cholecystectomies after the endoscopic intervention: group 1 — interval cholecystectomy after \geq 1 month; group 2 — early cholecystectomy within the nearest 3 days; group 3 — simultaneous cholecystectomy.

In order to provide better relevance of the research conclusions, the following conformity criteria were applied.

Conformity criteria

Inclusion criteria: clinical-instrumental signs of chronic calculous cholecystitis combined with choledocholithiasis; patients aged 18 years and older; absence of previous surgeries involving the organs of the hepatopancreatobiliary zone, as well as absence of developmental defects in the bile ducts; completed cases of using staged treatment tactics (conducted and successful endoscopic removal of concrements from the bile ducts, and cholecystectomy).

Non-inclusion criteria: class B and C mechanical jaundice (according to the classification by E.I. Galperin); signs of acute cholecystitis and/or cholangitis; signs of acute biliary pancreatitis; presence of oncological diseases during the treatment process; acute myocardial infarction, acute impairment of cerebral circulation, thromboembolic complications of cardiovascular diseases within the last 2 months: terminal stages of kidney damage; decompensated status of the organs or systems; coagulation disorders. The non-inclusion of patients with class B or C mechanical jaundice means that, with the initial presence of complications of the disease, significantly aggravating it, namely the renal failure, the encephalopathy (hepatic failure), gastro-intestinal hemorrhages and sepsis, the patients were not included into the research.

Exclusion criteria. A total of 2 patients were excluded from the research, in which, after the ERCP, endoscopic papillosphincterotomy and lithoextraction, there was insufficient data to rule out the retroduodenal

perforation due to significant quantities of free gas in the abdominal cavity, which required open-access surgical intervention at the extent of laparotomy, cholecystectomy and duodenal mobilization (The Kocher manoeuvre). Perforation was not confirmed in both cases, the patients underwent external cholangiostomy via the cystic duct, followed by draining of the abdominal cavity and of retroperitoneal space.

Research facilities

The research work was carried out within the premises of the Federal State Budgetary Institution "Federal Scientific and Clinical Centre for Specialized Types of Medical Care and Medical Technologies of the Federal Medical-Biological Agency" (FSBI Federal Scientific and Clinical Center of the Federal Medical-Biological Agency of Russia).

Research Duration

The research work was arranged within a time period from January 2016 until December, 2023 (8 years).

Medical Procedure Description

Simultaneous intervention was carried out in the following order. Initially, laparoscopic access was used to resect the gall bladder (after the ERCP, the small intestine gets expanded with gas, which complicates the course of laparoscopic cholecystectomy), then followed the carbon dioxide desufflation from the abdominal cavity, but without extracting the troacars. The next step was the endoscopic intervention, which included the ERCP, the endoscopic papillosphincterotomy and lithoextraction. According to indications, lithotripsy was also conducted (mechanical or laser-assisted) with the endoprosthetic treatment of the bile ducts. Upon the completion of the endoscopic intervention, pneumoperitoneum was applied once again with the control assessment of the surgical intervention zone. The draining was done at the discretion of the operating surgeon.

Laparoscopic cholecystectomy was conducted at the conventional manner using four ports in accordance with principles of the critical view of safety (CVS). The bladder was extracted after being put into the container via the troacar access at the umbilical area or through the epigastric troacar.

The endoscopic intervention was carried out by a single endoscopist in the settings of the general anesthesia. The detailed description of the ERCP is provided in earlier publications [6]. In all the patients,



prophylaxis of acute post-manipulation pancreatitis was arranged by means of rectal administration of 100 mg Diclofenac directly before intervention (2 h) and intravenous drip infusion of Octreotide at a dosage of 600 μ g/day.

After the ERCP, all the patients were prescribed (for 24h) control testing for blood pancreatic amylase level along with the ultrasound examinations of the abdominal cavity. Hyperamylasemia with the value exceeding 3x the upper margin of the reference ranges and the presence of infiltration in the area of the hepatoduodenal ligament was considered a contraindication to the early conduct of laparoscopic cholecystectomy.

Research findings

The assessment included direct cholecystectomy results, such as surgery time, intraoperative complications, the number and the type of postoperative complications (classification by Clavien-Dindo, 2004), the duration of stay at the In-Patient Department. The surgery duration in the simultaneous surgery group was evaluated with subtracting the endoscopic intervention time. The postoperative bed days were counted only after cholecystectomy. The remote results were followed up within not less than 1 year after surgery.

The criteria for "complex" choledocholithiasis used were the commonly acknowledged ones and they were previously described by the number of authors [7].

Ethical review

The research work was carried out in accordance with the ethical standards of the Helsinki Declaration of the World Medical Association "Ethical Principles for Medical Research Involving Human Participants" amended in 2013. All the research participants were informed about the duration and the type of research. All the patients have signed an informed voluntary consent for treatment and undergoing surgeries, as well as for using the anonymized data on their health status for scientific purposes. The research was approved by the local Ethics Committee of the Federal State Budgetary Institution "Federal Scientific and Clinical Center" of the Federal Medical-Biological Agency of Russia (protocol No. 5, dated 15.05.2024.).

Statistical analysis

The minimal required sample size included 19 participants in each group in order to have the possibility to reject the null hypothesis with 80% power at the level of α =0.05. The calculations of the sample

size were done using the PS Power and Sample Size Calculations software (version 3.0.11 for MS Windows). The qualitative data were provided as absolute values and percentages, while the quantitative ones — as the mean values with standard deviations. In order to test the differences for significance, we have used the following tests: qualitative variables were analyzed using the chi-square test (χ 2), the quantitative ones — using the Mann–Whitney test. The software used was IBM SPSS 27. The *p* value was set at the level of <0.05 for significant results.

RESULTS

Research sample (participants)

Within the time period of 2016-2023, at the Federal State Budgetary Institution "Federal Scientific and Clinical Center" of the Federal Medical-Biological Agency of Russia, a total of 1429 cholecystectomies and 278 endoscopic interventions in the biliary tracts were carried out for the reason of gall stone disease and its complications. The research included 87 patients with a combination of chronic calculous cholecystitis and choledocholithiasis (6% of the total number of cholecystectomies), which had a successful endoscopic removal of concrements from the bile ducts and laparoscopic cholecystectomy: 20 patients had simultaneous laparoscopic cholecystectomy and ERCP, 19 had received laparoscopic cholecystectomy in 3 days after ERCP within a B single hospitalization, 48 — ERCP and laparoscopic cholecystectomy, delayed by 1-6 months. The groups of patients were comparable in terms of demographic characteristics. The characteristics of the patients and the treatment results are provided in table 1.

Primary findings

In the group interval laparoscopic of cholecystectomy, there were significantly more reports of having a "complex" choledocholithiasis (18.75%) and mechanical jaundice (39.6%), however, statistical significance for these differences was not achieved (p > 0.05). The duration of surgery was the highest in the group of interval laparoscopic cholecystectomy, however, the statistical significance was not shown (p > 0.05). Hyperamylasemia during the first 24 hours after ERCP was reported in 10 (11.5%) cases out of 87, in 8/48 (16.6%) for the group of interval tactics and in 2/20 (10%) in the group of simultaneous intervention. In the group of early laparoscopic cholecystectomy, there were no reports of hyperamylasemia, for its presence served as a contraindication to performing

Table 1

Parameter	Laparoscopic cholecystectomy		
	simultaneous <i>n</i> =20	early <i>n</i> =19	interval <i>n</i> =48
Age, years	55.4±7.2	61.6±11.2	64.5±13.7
Males, n (%)	9 (45)	8 (42.1)	21 (43.75)
Females, n (%)	11 (55)	11 (57.9)	27 (56.25)
"Complex" choledocholithiasis, n (%)	2 (10)	0	9 (18.75)
Mechanical jaundice, n (%)	5 (25)	3 (15.8)	19 (39.6)
Surgery time	52.5±23.7	60.4±24.8	72.3±30
Conversion, <i>n</i> (%)	0	0	3 (6.25)
Postoperative bed days	3.5±0.6	3.8±0.7	4.1±2.45
Complications, n (%)	0	0	2 (4.2)

Characteristics of the patients and treatment results

Note. Upon the statistical analysis of data, none of parameter has shown significance of the differences (p <0.05).

laparoscopic cholecystectomy. In 4/87 (4.6%) patients hyperamylasemia was combined with signs of acute pancreatitis. None of the patients has required repeated invasive interventions or treatment at the Intensive Care Unit. There were no cases of intraoperative hemorrhages (intra-abdominal ones and the ones from the zone of the major duodenal papilla). During the laparoscopic cholecystectomy, none of the reports had iatrogenic damage of the bile ducts. No conversions were reported in the group of simultaneous and early intervention, while the group of interval laparoscopic cholecystectomy had 3/48 (6.25%) of conversions (p > 0.05).

After laparoscopic cholecystectomy, the groups of simultaneous and early surgery had no reported cases of complications. In the group of interval laparoscopic cholecystectomy, there was one case of laparotomy wound suppuration (in a patient with conversion) and a single case of suture sinus in the area of the epigastric troacar access, developing in one month after surgery.

The duration of hospitalization after laparoscopic cholecystectomy was the most long-term in the group of interval approach, however, no statistical significance was demonstrated for these differences (p > 0.05). In the group of interval laparoscopic cholecystectomy, repeated hospitalizations before undergoing surgery due to the recurrence of choledocholithiasis or developing acute cholecystitis were reported in 3 (6.25%) cases. There were no fatal outcomes.

DISCUSSION

The optimal surgical tactics for the complicated course of the gall stone disease, when the patient has both the chronic calculous cholecystitis and the choledocholithiasis, is still a matter of discussion. Currently, the commonly acknowledged tactics is the staged one, when the patient initially undergoes an endoscopic intervention, aimed at the sanitation of the bile ducts from the concrements, followed by cholecystectomy. A recent meta-analysis including 13 research works (n=2598), published during the period from 2002 until 2019, has shown that cholecystectomy is statistically significantly resulting in a decrease in the risk of biliary events and mortality (odds ratio, OR, 0.38; p=0.03) [8]. And, if the necessity of cholecystectomy was justified, the optimal timings of its conduct with regard to the endoscopic intervention in the biliary ducts with the presence of choledocholithiasis are not defined. The simultaneous approach, when the laparoscopic cholecystectomy and the endoscopic intervention are performed simultaneously, has shown its benefits as a significant decrease of therapy durations [9]. Besides, during the simultaneous surgery, the "rendezvous" method can be used - which is the antegrade transvesical cannulation of the bile duct, during which, the surgeon uses the vesical duct to introduce the endoscopic guide wire, which, in turn, can be extracted using the duodenoscope [10]. This method allows for successfully performing endoscopic papillosphincterotomy and endoscopic lithoextraction in case of difficult cannulation of the major duodenal papilla. However, simultaneous surgery is only possible in the settings of good coordination between the surgical and endoscopic services of the clinical institution, while the equipment level of the operating room should allow implementing a hybrid approach expressed as using the X-ray apparatus (the C-arch). Taking into consideration the highlighted organization difficulties, it is not applicable to recommend the routine implementation of simultaneous interventions.

The passage of the concrements along the common bile duct and performing endoscopic manipulations in the bile ducts with the administration of the contrasting agent inevitably results in the development of local inflammatory reaction, the swelling of the hepatoduodenal ligament, which makes difficult performing cholecystectomies. Besides, in part of the patients, mechanical jaundice develops, which can also negatively affect the number of cholecystectomy complications. Within this context, in the routine clinical practice, the interval approach has become widespread, when cholecystectomy is delayed by 2 weeks up to several months to allow for a regress of inflammatory-infiltrative changes in hepatopancreatobiliary area. However, the inflammatory reaction can progress into tissue scarring, when the manipulations in the Calot's triangle become more complex than at the acute phase of the inflammation. In the research by E. Bergeron et al. [11], it was shown that, when sparing the gall bladder after the endoscopic treatment of choledocholithiasis, repeated biliary events (acute cholecystitis, choledocholithiasis, cholangitis, cholangiogenic liver abscesses, pancreatitis) develop in 28.5% of the cases within a median time of 34 days with a rate of 2.5% already in 1 week. As opposed to this, after cholecystectomy, biliary events were reported only in 1.9% of the patients. Patients with repeated biliary events had significantly longer hospitalization time, more long-term post-operative hospital stay and higher rates of open-access surgeries.

A.M. Beliaev et al. [12] inform that the delay of laparoscopic cholecystectomy after endoscopic lithoextraction (double-stage approach with an interval of 16 weeks) is associated with a 10-fold higher risk of serious iatrogenic damage to the biliary ducts and 3-fold higher risk of converting the laparoscopic surgery to the open-access one. With this, 23% of the patients were repeatedly hospitalized with the diagnosis of acute calculous cholecystitis or acute pancreatitis after ERCP and sphincterotomy, which indicates the necessity of performing preventive laparoscopic cholecystectomy as earlier as possible. R. Senocak et al. [13], when comparing the patients undergoing staged interventions, came to the following conclusion: laparoscopic cholecystectomy needs to be performed 2 weeks after the ERCP, upon exceeding this time, the risk of conversion significantly increases. C. Friis et al. [14] have published a systematic review of observational and randomized trials, which allowed the authors to state that the safest option is the laparoscopic cholecystectomy within the first 24 hours after ERCP (4.2% of conversions). With the delay by 24-72 hours, the

risks of conversion increase up to 7.6%, with the delay time exceeding 2 weeks — up to 14%. The systematic review and meta-analysis by N. Poprom et al. [15], including 4 randomized and 4 retrospective trials with total number of patients being 1327, has shown that, in patients undergoing cholecystectomy after ERCP at the same day or within 72 hours, the risk of complications (with insignificant but notable absolute decrease of the duration of stay at the In-Patient Department and of the surgery time) was decreased by 37–73%.

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In 2022, a research was published that was headed by the Head Surgeon of the Moscow Healthcare Department, an academician of the RAS, A.V. Shabunin [4]. Within the premises of the Surgical Clinical Unit of the Botkin Hospital, an analysis was done for the treatment results of 229 patients. It was found that laparoscopic cholecystectomy, conducted simultaneously and early after the ERCP along with lithoextraction, is characterized by significantly lesser surgery duration, as well as by significantly lesser number of postoperative complications. The authors make a conclusion that, for patients with complicated gall stone disease, the most preferable is the simultaneous or earlier conduct of laparoscopic cholecystectomy after ERCP.

Our results correlated with the results from other authors: we have similar data on surgery duration, hospitalization duration and the number of conversions. The small number of complications in our research can be explained by the fact that all the surgical interventions were carried out by highly qualified surgeons.

Research limitations

As a result of analyzing the publications on the given topics, an overwhelming impression has developed that the important unfavorable events in all the trials occurred rarely, while the confidence intervals were located over a wide range. The same has also happened upon analyzing our own experience. None of the patients had iatrogenic damage of the common bile duct or duodenum, no lethal cases were registered. The obtained differences on the conversion rate and surgery duration, despite being worse in the group of interval cholecystectomy, were not supported by statistical significance due to the small sample size. It is worth noting that, after applying the non-inclusion criteria for ensuring the relevance of the results, the number of patients in our clinics was small — 87 for 8 years (or 9–11 patients per a year). However, a recent systematic review has presented only 1327 patients enlisted into the trials during the time period from 2005 until 2020 [15]. This circumstance

makes out experience significant. Arranging further multicenter research works with a unified methodology should allow for obtaining more specific answers to the question about the optimal tactics for treating this category of patients.

CONCLUSION

Modern technologies allow for providing medical aid to the patients with chronic calculous cholecystitis and choledocholithiasis at high levels of efficiency and safety. In patients not having signs of the severe course of the disease, it is possible to perform simultaneous ERCP, endoscopic papillosphincterotomy and lithoextraction along with laparoscopic cholecystectomy. In the absence of ERCP complications, the practicable option is the early (within 3 days) performing laparoscopic cholecystectomy, which does not worsen the results, however, it relieves from the necessity of repeated hospitalization and, probably, slightly decreases the risk of complications.

ADDITIONAL INFORMATION

Funding source. The research and publication of the article are financed by the state assignment of the Federal Medical and Biological Agency of Russia (code: "Cholelithiasis").

Competing interests. The authors declare that they have no competing interests.

Authors' contribution. D.V. Sazonov, A.V. Smirnov, Yu.V. Ivanov. V.R. Stankevich. N.A. Solovvev. A.R. Akhmedianov, A.A. Keshvedinova - performing surgical operations on patients; A.V. Smirnov - general concept, search and analytical work, processing and discussion of the study results, writing the text of the article; A.R. Akhmedianov, A.A. Keshvedinova — search and analytical work, discussion of the study results, writing the text of the article; N.A. Solovyev, Yu.V. Ivanov, R.I. Khabazov - general concept, management of patient treatment and discussion of the study results, editing the text. The authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work.

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