https://doi.org/10.22416/1382-4376-2023-33-5-28-40
UDC 616.366-002+616.366-003.7]:001.89.001.37

Analytical Approach to the Selection of Research Topics for Gallstone Disease and Acute Cholecystitis (an Overview of Cochrane Reviews)

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Aim: description of modern methods of statistical evaluation of the world evidence base to determine the direction of promising scientific research in diagnosis and treatment of cholelithiasis and cholecystitis.
Materials and methods. The umbrella review of systematic reviews and meta-analyses of the Cochrane Library has been conducted, identifying topics for which further evidence-based research is needed. The information obtained by the Cochrane expert panels through Trial Sequential Analysis (TSA), Diversity-Adjusted Required Information Size (DARIS) calculations, and Z-curve monitoring on benefit, harm, or futility boundary plots is systematized.
Results. There were established multidirectional trends and significantly different levels of achievement of evidence-based results. These should be taken into account when determining the prospect of further evidence-based studies.
In the context of bile duct injury between early and delayed laparoscopic cholecystectomy, number of complications between early and delayed laparoscopic cholecystectomy, small-incision cholecystectomy and laparoscopic cholecystectomy, single-port and standard four-ports cholecystectomy and low-pressure laparoscopy the required size of meta-analysis information is unlikely to be achieved — in current versions of Cochrane library DARIS is less than 1 % of required. The same applies to mortality, the probability of developing serious complications and the conversion rate of various minimally invasive procedures, as the required sample sizes (hundreds of thousands of observations) are difficult to achieve — currently range is from 0.03 to 21.9 %.
On the contrary, the achieved values from the estimated DARIS in establishing the differences in the duration between minimally invasive surgery options (21.2 to 76 %), in some issues of pain management in the immediate postoperative period (43.6 to 92.6 %) and additional intraoperative anesthesia (13.7 to 14.9 %) and Z-curve monitoring give hope for their achievement in the foreseeable future.
There is little prospect of continuing evidence-based studies to determine the need for intraperitoneal anesthetic instillation, differences in the duration of hospitalization after various minimally invasive surgeries, since new information is unlikely to change the conclusions of meta-analyses (the required information size has been achieved by 100 %).
Conclusion. It is necessary to take into account the results of a TSA analysis of Cochrane expert groups, when choosing research topics in patients with gallstone disease and acute cholecystitis.
Keywords: gallstone disease, acute cholecystitis, evidence-based medicine, Cochrane meta-analysis, sample size calculation
Conflict of interest: the authors declare that there is no conflict of interest.

For citation: Panin S.I., Nechay T.V., Sazhin A.V., Puzikova A.V. Analytical Approach to the Selection of Research Topics for Gallstone Disease and Acute Cholecystitis (an Overview of Cochrane reviews). Russian Journal of Gastroenterology, Hepatology, Coloproctology. 2023;33(5):28–40. https://doi. org/10.22416/1382-4376-2023-33-5-28-40

Аналитический подход к выбору тематики научных исследований при желчнокаменной болезни и холецистите (обзор обзоров)

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Цель: провести анализ систематических обзоров и метаанализов для определения направлений перспективных научных исследований диагностики и лечения желчнокаменной болезни и холецистита.

Материалы и методы. Проведен обзор систематических обзоров и метаанализов библиотеки Кокрейна в свете определения тематик, по которым проведение доказательных исследований имеет научно-практическую значимость. Систематизирована информация, полученная экспертными группами Кокрейна в ходе последовательного анализа (Trial Sequentional Analysis, TSA), вычисления требуемого размера информации с поправкой на разнообразие (Diversity-Adjusted Required Information Size, DARIS) и мониторинга хода Z-кривой на графиках границ пользы (benefit), вреда (harm) или тщетности (futility).
Результаты. Установлены разнонаправленные тенденции и существенно отличающийся уровень достижения доказательных результатов, которые необходимо учитывать при определении перспективности дальнейших доказательных исследований.
Необходимые размеры выборки в метаанализах по частоте травмы желчных протоков при сравнении ранней или отсроченной лапароскопической холецистэктомии, анализе количества осложнений после ранней и отсроченной лапароскопической холецистэктомии, мини-лапаротомной холецистэктомии и лапароскопической холецистэктомии, однопортовой и стандартной четырехпортовой лапароскопической холецистэктомии и изучении методик применения пониженного давления в брюшной полости являются труднодостижимыми — в актуальных версиях библиотеки Кокрейна DARIS составляет менее 1 % от должного. То же самое относится и к летальности, вероятности развития опасных для жизни осложнений и уровню конверсии различных мини-инвазивных вмешательств, поскольку требуемые размеры выборки (до сотен тысяч наблюдений) трудно достижимы и на данный момент варьируют от 0,03 до 21,9 %.
Напротив, достигнутые показатели от расчетных значений DARIS при установлении различий по длительности между вариантами мини-инвазивных операций (21,2–76 %), по некоторым вопросам обезболивания в ближайшем послеоперационном периоде (43,6–92,6 %) и дополнительной интраоперационной анестезии (13,7–14,9 %) и мониторинг соответствующих графиков последовательных TSA-анализов позволяют надеяться на их достижение в обозримом будущем.
Малоперспективно продолжение доказательных исследований с целью определения необходимости использования интраперитонеальной инстилляции обезболивающих средств, отличий по длительности стационарного лечения после различных мини-инвазивных операций, поскольку новые сведения вряд ли смогут изменить выводы метаанализов (требуемые размеры информации достигнуты на 100 %).
Заключение. При выборе тематик исследований у больных с желчнокаменной болезнью и холециститом необходимо учитывать результаты последовательного TSA-анализа экспертных групп Кокрейна.
Ключевые слова: желчнокаменная болезнь, острый холецистит, доказательная медицина, метаанализ Кокрейна, расчет выборки
Конфликт интересов: авторы заявляют об отсутствии конфликта интересов.

Для цитирования: Панин С.И., Нечай Т.В., Сажин А.В., Пузикова А.В. Аналитический подход к выбору тематики научных исследований при желчнокаменной болезни и холецистите (обзор обзоров). Российский журнал гастроэнтерологии, гепатологии, колопроктологии. 2023;33(5):28–40. https://doi org/10.22416/1382-4376-2023-33-5-28-40

Introduction

Scientific search in medicine involves the identification of new, previously unknown data and patterns. The subject component in relation to surgical specialties forms a request to improve the results of treatment of diseases and reduce the number of complications. The relevance of choosing the direction of scientific research in surgery directly correlates with the prevalence of nosological forms and inversely correlates with satisfaction with the quality of treatment at the present stage.

Surgical treatment of cholelithiasis and its complications is one of the most studied knowledge areas in medicine. This is partly due to the high incidence and frequency of surgical treatment, estimated in our country by hundreds of thousands of operations per year [1].

For these reasons, the choice of the subject of evidence-based research in cholelithiasis and cholecystitis is a relevant task. A preliminary assessment of the sources for the given keywords showed that about five hundred randomized clinical trials were conducted on the topic of cholelithiasis in the world practice, including works from the Russian Federation [2], the great majority of which were analyzed in the form of systematic reviews and meta-analyses.

When planning scientific works, it is necessary to proceed from their practical significance for healthcare and the theoretical advisability of conducting research in general. On the one hand, it is pointless to engage in further scientific research in relation to precisely established aspects, new data will not be able to change the conclusions of the previous ones. At the same time, in regard to those aspects in which it is extremely difficult to establish differences in evidence-based medicine, new work may be hopeless. Finally, with a formalized assessment, meta-analyses, like any other scientific work, can differ significantly in quality [3–5].

The published work is one of the tools for selecting and evaluating planned studies for the prospects of their implementation and the benefits for the existing scientific knowledge base on the example of

the available evidence base of cholelithiasis and cholecystitis.

Aim: to describe modern methods of statistical evaluation of the world evidence base to determine the direction of promising scientific research in diagnosis and treatment of cholelithiasis and cholecystitis.

Materials and methods

According to the typology of scientific publications, the umbrella review is a search and analytical scientific work aimed at studying medical problems with a large number of evidence-based studies and published systematic reviews and meta-analyses. In these situations, repeated analysis of primary works is not useful, and in order to obtain the entire picture of the studied phenomenon, as well as to develop recommendations for further research, this method was proposed [6, 7].

An electronic search for up-to-date versions of Cochrane's systematic reviews and meta-analyses was conducted on the Cochrane Library website (https://www.cochranelibrary.com) using the keywords "gallstone", "cholecystitis". During the manual search, meta-analyses presented in the group of reviews "Gastroenterology & Hepatology" in the subsection "Gallbladder & Bile Duct Disease" were additionally analyzed and selected.

When assessing the scientific and practical significance of the research results conducted by Cochrane's expert groups, we proceeded from the unified scales of the level of evidence and grades of recommendations approved by the Ministry of Health of the Russian Federation [8].

In terms of determining the topics on which it is necessary to continue evidence-based research, we systematized the information obtained by Cochrane expert groups through Trial Sequential Analysis (TSA) and Z-curve monitoring on benefit, harm or futility boundary plots [9]. The software of TSA analysis allows you to calculate the parameter designated in the Russian-language literature as the Diversity-Adjusted Required Information Size (DARIS) [10]. In essence, this is the threshold number of participants that must be included in the meta-analysis to determine the significant advantages of the studied interventions in one of the comparison groups without the risk of random error or establishing the fact that it is impossible to determine these differences.

To systematize information on certain aspects of the problem, the authors of this article have developed summary tables indicating information about the Cochrane expert groups that conducted

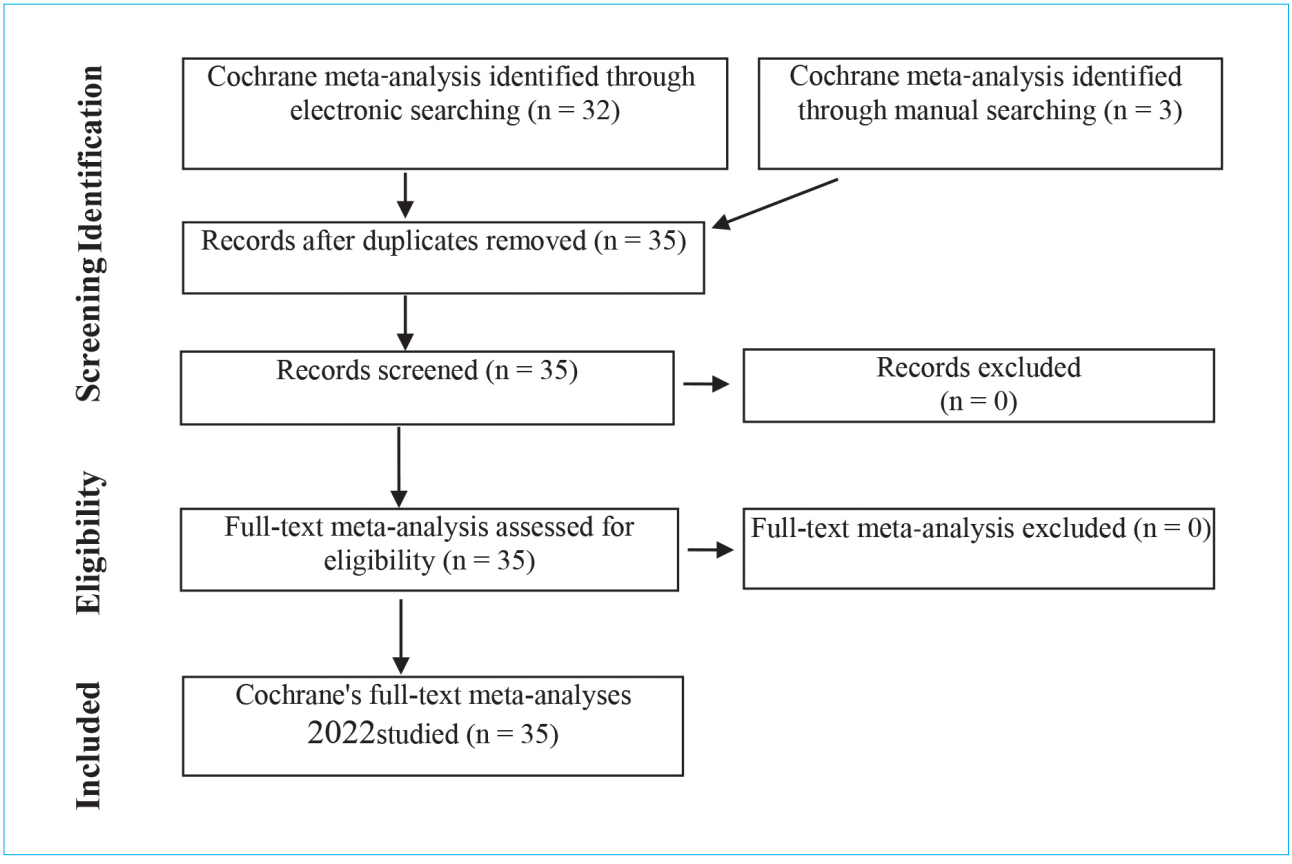

Figure. Stages of selection of Cochrane meta-analyses for umbrella review

Рисунок. Этапы отбора метаанализов Кокрейна для обзора обзоров

meta-analysis, the year of its publication and the subject of the meta-analysis. The tables also contain data on the calculated values of DARIS, the percentage (%) of achieving this parameter is indicated next to the threshold number of participants according to information from the current versions of meta-analyses presented on the Cochrane Library website.

Results

Thirty-five systematic reviews of the Cochrane Library focus on cholelithiasis and its surgical treatment [11–45] (Fig. 1).

The main information about the topics of these studies and the results obtained in meta-analyses were presented in our study in 2022 [46]. At the same time in 29 publications of the Cochrane Library the results of systematic reviews made it possible to conduct meta-analyses of randomized trials (RCTs), the conclusions and recommendations of which correspond to the level of evidence 1 and the grades of recommendations A.

Systematization of information from various Cochrane meta-analyses published after 2010 (from the moment when the results of TSA analysis of gallstone disease were published in Cochrane meta-analyses) allowed us to establish that primary studies on such topics as: methods of the cystic duct occlusion, 3D-visualization and robotic assistance in laparoscopic cholecystectomy (LCE), cholecystostomy in patients at risk group are not enough to calculate DARIS.

The diversity-adjusted required information size (DARIS) to establish differences in bile duct injury (Table 1) when comparing LCE and small-incision cholecystectomy requires about 20,000 participants (13 % achieved), when comparing between early and delayed LCE in acute cholecystitis — about 78,000 participants, while in meta-analysis less than 1 % DARIS.

The diversity-adjusted required information size to establish differences in the frequency of significant severe complications of surgical treatment of cholelithiasis is presented in nine studies and only in one meta-analysis (comparison of laparoscopic and small-incision cholecystectomy) it reaches 81 % of the required information size, determined taking with low-bias risk heterogeneity-adjusted information size (LBHIS) taken into account. In other studies, DARIS varies from 11,000 to 281,000, and in Cochrane reviews, only less than 1 % and up to 5 % of the DARIS was accrued (Table 2).

The proportion of participants in whom the laparoscopic cholecystectomy had to be converted to open cholecystectomy is considered in four meta-analyses and in one of them a fifth part of the required 2225 samples was achieved. According to the other meta-analysis [17, 21, 23], the diversity-adjusted required information size varies from 13,000 to 100,000, which is from less than 1 % and up to 2 % of the required sample size (Table 3).

Ten calculations of the required information size for assessment of mortality after cholecystectomy were presented in eight meta-analyses. The DARIS varies from 352,000 to 1,363,732 and, based on the proportion of participants, only 0.03–0.47 % of the diversity-adjusted required information size was reached (Table 4).

Differences in the duration of operations can be considered definite when comparing between a miniport laparoscopic cholecystectomy and standard port laparoscopic cholecystectomy, abdominal wall lift versus laparoscopic cholecystectomy and low pressure pneumoperitoneum. Further RCTs are needed to establish or refute differences in the duration of interventions for single-port laparoscopic cholecystectomy and four-ports laparoscopic cholecystectomy, as well as early and delayed operations for acute cholecystitis. In these meta-analyses the estimated proportion

Table 1. Required sample size for bile duct injury

Таблица 1. Необходимый размер выборки по травме желчных протоков

Cochrane Research Group (year) ***Исследовательская группа Кокрейна (год)***	**Subjects of systematic review and meta-analysis** ***Тематика систематического обзора и метаанализа***	**DARIS**	
		n	**%**
Keus F., et al. (2006, 2010*) [43, 47]	LCE / MCE *ЛХЭ / МХЭ*	19,964**	13
Gurusamy K.S., et al. (2013) [26]	Early LCE / Delayed LCE *Ранняя ЛХЭ / Отсроченная ЛХЭ*	77,854	0.56

Note: LCE — laparoscopic cholecystectomy; MCE — mini-access cholecystectomy; * — published after a Cochrane review [47]; ** — LBHIS (low-bias risk heterogeneity-adjusted information size).

Примечание: ЛХЭ — лапароскопическая холецистэктомия; МХЭ — холецистэктомия из мини-доступа; * — опубликовано после проведения Кокрейновского обзора [47]; ** — LBHIS (low-bias risk heterogeneity-adjusted information size, размер информации с поправкой на неоднородность с низким риском смещения).

Table 2. Required sample size by the number of complications

Таблица 2. Необходимый размер выборки по количеству осложнений

Cochrane Research Group (year) ***Исследовательская группа Кокрейна (год)***	**Subjects of systematic review and meta-analysis** ***Тематика систематического обзора и метаанализа***	**DARIS**	
		n	**%**
Keus F., et al. (2006, 2010*) [43, 47*]	LCE / MCE (calculation of LBHIS**) *ЛХЭ / МХЭ (расчет LBHIS**)*	3142**	81 %
Gurusamy K.S., et al. (2013) [26]	Early LCE / Delayed LCE *Ранняя ЛХЭ / Отсроченная ЛХЭ*	13,493	3.25
Gurusamy K.S., et al. (2013) [23]	Miniport LCE / Standard four-port LCE *Мини-портовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	52,796	0.87
Gurusamy K.S., et al. (2013) [21]	LCE with mini pneumoperitoneum / Normal intra-abdominal pressure during LCE *ЛХЭ с мини-пневмоперитонеумом / Обычное внутрибрюшное давление при ЛХЭ*	281,294	0.14
	LCE with lifting technologies / Standard four-port LCE *ЛХЭ с лифтинговыми технологиями / Стандартная четырехпортовая ЛХЭ*	58,231	0.59
	LCE with drainage / LCE without drainage *ЛХЭ с дренированием / ЛХЭ без дренирования*	175,965	0.63
Gurusamy K.S., et al. (2014) [17]	Single-port LCE / Standard four-port LCE *Однопортовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	234,831	0.27
Loizides S., et al. (2014) [16]	LCE with local anesthesia for wounds / LCE without local wound anesthesia *ЛХЭ с местным обезболиванием ран / ЛХЭ без местного обезболивания ран*	185.703	0.29
Gurusamy K.S., et al. (2014) [12]	Pain relief with NSAIDs (after LCE) / Control group without NSAIDs (after LCE) *Обезболивание НПВС (после ЛХЭ) / Группа контроля без НПВС (после ЛХЭ)*	11,338	4.79
Gurusamy K.S., et al. (2014) [13]	Instillation of anesthetic at the beginning of LCE / Instillation of anesthetic at the end of LCE *Инстилляция анестетика в начале ЛХЭ / Инстилляция анестетика в конце ЛХЭ*	34,685	0.32
Rutherford D., et al. (2021) [15]	LCE with intraperitoneal instillation of anesthetic / LCE without intraperitoneal instillation *ЛХЭ с интраперитонеальной инстилляцией анестетика / ЛХЭ без интраперитонеальной инстилляции*	50,949	1.9

Note: LCE — laparoscopic cholecystectomy; MCE — mini-access cholecystectomy; NSAIDs — non-steroidal anti-inflammatory drugs; * — published after a Cochrane review [47]; ** — LBHIS (low-bias risk heterogeneity-adjusted information size).

Примечание: ЛХЭ — лапароскопическая холецистэктомия; МХЭ — холецистэктомия из мини-доступа; НПВС — нестероидные противовоспалительные средства; * — опубликовано после проведения Кокрейновского обзора [47]; ** — LBHIS (low-bias risk heterogeneity-adjusted information size, размер информации с поправкой на неоднородность с низким риском смещения).

of the required information sample size ranges from 21 to 76 % (Table 5). At the same time, the Z-curve's monitoring shows that achieving 100 % DARIS will most likely not change the available meta-analysis result about the longer duration of single-port laparoscopic cholecystectomy and the four-ports LCE. But the final conclusions about the differences in duration between early and delayed LCE in acute cholecystitis and LCE with low pressure pneumoperitoneum and standard-pressure pneumoperitoneum LCE are not yet clear and additional RCTs are highly desirable.

Table 3. The required sample size to study the conversion rate

Таблица 3. Необходимый размер выборки для изучения частоты конверсии

Cochrane Research Group (year) ***Исследовательская группа Кокрейна (год)***	**Subjects of systematic review and meta-analysis** ***Тематика систематического обзора и метаанализа***	**DARIS**	
		n	**%**
Gurusamy K.S., et al. (2013) [26]	Early LCE / Delayed LCE *Ранняя ЛХЭ / Отсроченная ЛХЭ*	2225	21.9
Gurusamy K.S., et al. (2013) [23]	Miniport LCE / Standard four-port LCE *Мини-портовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	36,124	1.85
Gurusamy K.S., et al. (2013) [21]	LCE with minipneumoperitoneum / Standard four-port LCE *ЛХЭ с мини-пневмоперитонеумом / Стандартная четырехпортовая ЛХЭ*	100,279	0.55
	LCE with minipneumoperitoneum and lifting / Standard four-port LCE *ЛХЭ с мини-пневмоперитонеумом и лифтингом / Стандартная четырехпортовая ЛХЭ*	13,493	0.43
	LCE with lifting technologies / Standard four-port LCE *ЛХЭ с лифтинговыми технологиями / Стандартная четырехпортовая ЛХЭ*	22,911	2.01
Gurusamy K.S., et al. (2014) [17]	Single-port LCE / Standard four-port LCE *Однопортовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	40,918	1.42

Note: LCE — laparoscopic cholecystectomy.

Примечание: ЛХЭ — лапароскопическая холецистэктомия.

Table 4. Required sample size for assessing mortality after cholecystectomy

Таблица 4. Необходимый размер выборки по оценке летальности после холецистэктомии

Cochrane Research Group (year) ***Исследовательская группа Кокрейна (год)***	**Subjects of systematic review and meta-analysis** ***Тематика систематического обзора и метаанализа***	**DARIS**	
		n	**%**
Gurusamy K.S., et al. (2013) [23]	Miniport LCE / Standard four-port LCE *Мини-портовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	352,564	0.12
Gurusamy K.S., et al. (2013) [17]	Single-port LCE / Standard four-port LCE *Однопортовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	352,564	0.18
Vaughan J., et al. (2013) [24]	LCE with day stay / LCE with stay in the “day + night” mode *ЛХЭ с дневным пребыванием / ЛХЭ с пребыванием в режиме «день + ночь»*	352,564	0.14
Gurusamy K.S., et al. (2013) [21]	LCE with minipneumoperitoneum / Standard four-port LCE *ЛХЭ с мини-пневмоперитонеумом / Стандартная четырехпортовая ЛХЭ*	352,564	0.12
	LCE with minipneumoperitoneum and lifting / Standard four-port LCE *ЛХЭ с мини-пневмоперитонеумом и лифтингом / Стандартная четырехпортовая ЛХЭ*	352,564	0.12
	LCE with lifting technologies / Standard four-port LCE *ЛХЭ с лифтинговыми технологиями / Стандартная четырехпортовая ЛХЭ*	352,564	0.11

Table 4 continued. Required sample size for assessing mortality after cholecystectomy

Продолжение таблицы 4. Необходимый размер выборки по оценке летальности после холецистэктомии

Gurusamy K.S., et al. (2013) [20]	LCE with drainage / LCE without drainage *ЛХЭ с дренированием / ЛХЭ без дренирования*	352,564	0.47
Gurusamy K.S., et al. (2014) [13]	Instillation of anesthetic at the beginning of LCE / Instillation of anesthetic at the end of LCE *Инстилляция анестетика в начале ЛХЭ / Инстилляция анестетика в конце ЛХЭ*	352,564	0.03
Loizides S., et al. (2014) [16]	LCE with local anesthesia for wounds / LCE without local wound anesthesia *ЛХЭ с местным обезболиванием ран / ЛХЭ без местного обезболивания ран*	352,564	0.15
Rutherford D., et al. (2021) [15]	LCE with intraperitoneal instillation / LCE without intraperitoneal instillation *ЛХЭ с интраперитонеальной инстилляцией / ЛХЭ без интраперитонеальной инстилляции*	1,363 732	0.03

Note: LCE — laparoscopic cholecystectomy.

Примечание: ЛХЭ — лапароскопическая холецистэктомия.

Table 5. Required sample size by operation duration

Таблица 5. Необходимый размер выборки по длительности операций

Cochrane Research Group (year) ***Исследовательская группа Кокрейна (год)***	**Subjects of systematic review and meta-analysis** ***Тематика систематического обзора и метаанализа***	**DARIS**	
		n	**%**
Gurusamy K.S., et al. (2013) [23]	Miniport LCE / Standard four-port LCE *Мини-портовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	189	100
Gurusamy K.S., et al. (2013) [21]	LCE with minipneumoperitoneum / Standard four-port LCE *ЛХЭ с мини-пневмоперитонеумом / Стандартная четырехпортовая ЛХЭ*	37	100
	LCE with minipneumoperitoneum and lifting / Standard four-port LCE *ЛХЭ с мини-пневмоперитонеумом и лифтингом / Стандартная четырехпортовая ЛХЭ*	505	21.18
	LCE with lifting technologies / Standard four-port LCE *ЛХЭ с лифтинговыми технологиями / Стандартная четырехпортовая ЛХЭ*	304	100
Gurusamy K.S., et al. (2013) [26]	Early LCE / Delayed LCE *Ранняя ЛХЭ / Отсроченная ЛХЭ*	1107	44.1
Gurusamy K.S., et al. (2014) [17]	Single-port LCE / Standard four-port LCE *Однопортовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	1124	76

Note: LCE — laparoscopic cholecystectomy.

Примечание: ЛХЭ — лапароскопическая холецистэктомия.

In regard to the severity of pain syndrome in the first 4–8 hours after LCE and the need for intraperitoneal instillation and local anesthesia of wounds, the new published RCTs will unlikely to change the conclusions of meta-analyses (the required information size in the meta-analysis was achieved). But on the issues of time for applying these procedures, at the beginning or at the end of LCE, as well as on options for anesthesia after surgery, additional studies can be conducted, since in meta-analyses from 5 to 95 % of the DARIS was achieved in 1344 and 445 observations respectively (Table 6). At the same

Table 6. Required sample size by severity of pain syndrome (4–8 hours after surgery)

Таблица 6. Необходимый размер выборки по выраженности болевого синдрома (4–8 часов после операции)

Cochrane Research Group (year) *Исследовательская группа Кокрейна (год)*	Subjects of systematic review and meta-analysis *Тематика систематического обзора и метаанализа*	DARIS	
		n	%
Vaughan J., et al. (2013) [24]	LCE with day stay / LCE with stay in the "day + night" mode *ЛХЭ с дневным пребыванием / ЛХЭ с пребыванием в режиме «день + ночь»*	359	54.3
Gurusamy K.S., et al. (2014) [13]	Instillation of anesthetic at the beginning of LCE / Instillation of anesthetic at the end of LCE *Инстилляция анестетика в начале ЛХЭ / Инстилляция анестетика в конце ЛХЭ*	563	14.9
	Instillation of anesthetic (aerosol) / Instillation of anesthetic (solution) *Инстилляция анестетика (аэрозоль) / Инстилляция анестетика (раствор)*	17,109	0.58
Loizides S., et al. (2014) [16]	LCE with local anesthesia for wounds / LCE without local wound anesthesia *ЛХЭ с местным обезболиванием ран / ЛХЭ без местного обезболивания ран*	789	100
	Local anesthesia before incision (LCE) / At the end of the operation (LCE) *Местное обезболивание до разреза (ЛХЭ) / В конце операции (ЛХЭ)*	1344	5.65
Gurusamy K.S., et al. (2014) [12]	Pain relief with NSAIDs (after LCE) / Control group without NSAIDs (after LCE) *Обезболивание НПВС (после ЛХЭ) / Группа контроля без НПВС (после ЛХЭ)*	2050	48.7
	Pain relief with opioids (after LCE) / Control group without opioids (after LCE) *Обезболивание опиоидами (после ЛХЭ) / Группа контроля без опиоидов (после ЛХЭ)*	445	95.5
Rutherford D., et al. (2021) [15]	LCE with intraperitoneal instillation / LCE without intraperitoneal instillation *ЛХЭ с интраперитонеальной инстилляцией / ЛХЭ без интраперитонеальной инстилляции*	1095	100

Note: LCE — laparoscopic cholecystectomy; NSAIDs — non-steroidal anti-inflammatory drugs.

Примечание: ЛХЭ — лапароскопическая холецистэктомия; НПВС — нестероидные противовоспалительные средства.

time, the Z-curve shows a low probability of changing the conclusions of the current meta-analyses on the validity of the use of NSAIDs and opioid analgesics (comparisons were made with placebo) in the early postoperative period after LCE and the need for RCTs to establish the best time for wound anesthesia (at the beginning or at the end of LCE).

There were also differences in the severity of pain syndrome in the period of 9–24 hours after LCE. The advantages of local anesthesia of wounds and instillation of painkillers during LCE can be considered justified; DARIS was achieved by 100 %. However, the most appropriate time for these manipulations, the form of the anesthetic (aerosol or solution) and the features of anesthesia after LCE require clarification (Table 7). An additional trial sequential analysis allows us to justify the importance of RCTs aimed at determining the best time for additional intraoperative anesthesia of wounds during LCE and the absence of the need for subsequent comparative studies of NSAIDs and opioid analgesics with placebo drugs in these hours of the postoperative period.

Comparative evaluation of the duration of inpatient treatment can be considered justified, based on the results of four meta-analyses, when comparing the four-ports laparoscopic cholecystectomy with other minimally invasive variants of this operation. The evaluation of the differences between LCE with additional local anesthesia of wounds and without it

Table 7. Required sample size by severity of pain syndrome (9–24 hours after surgery)

Таблица 7. Необходимый размер выборки по выраженности болевого синдрома (9–24 часа после операции)

Cochrane Research Group (year) *Исследовательская группа Кокрейна (год)*	Subjects of systematic review and meta-analysis *Тематика систематического обзора и метаанализа*	DARIS	
		n	%
Gurusamy K.S., et al. (2014) [13]	Instillation of anesthetic at the beginning of LCE / Instillation of anesthetic at the end of LCE *Инстилляция анестетика в начале ЛХЭ / Инстилляция анестетика в конце ЛХЭ*	612	13.7
	Instillation of anesthetic (aerosol) / Instillation of anesthetic (solution) *Инстилляция анестетика (аэрозоль) / Инстилляция анестетика (раствор)*	9847	1.02
Loizides S., et al. (2014) [16]	LCE with local anesthesia for wounds / LCE without local wound anesthesia *ЛХЭ с местным обезболиванием ран / ЛХЭ без местного обезболивания ран*	168	100
Gurusamy K.S., et al. (2014) [12]	Pain relief with NSAIDs (after LCE) / Control group without NSAIDs (after LCE) Обезболивание НПВС (после ЛХЭ) / *Группа контроля без НПВС (после ЛХЭ)*	1525	46.3
	Pain relief with opioids (after LCE) / Control group without opioids (after LCE) Обезболивание опиоидами (после ЛХЭ) / *Группа контроля без опиоидов (после ЛХЭ)*	392	92.6
Rutherford D., et al. (2021) [15]	LCE with intraperitoneal instillation / LCE without intraperitoneal instillation *ЛХЭ с интраперитонеальной инстилляцией / ЛХЭ без интраперитонеальной инстилляции*	2920	100

Note: LCE — laparoscopic cholecystectomy.

Примечание: ЛХЭ — лапароскопическая холецистэктомия.

requires completion. The required sample size is 931 patients, 35 % of the DARIS has been reached in the meta-analysis (Table 8).

Discussion

Surgical treatment of symptomatic cholecystolithiasis according to international recommendations and guidelines currently has no alternative. Despite the progress in surgical and anesthesiological technologies, the development of the era of laparoscopic surgery of the gastrointestinal tract and its modifications (single-port surgery and transluminal interventions), surgeons reaching learning curve, the frequency of intra- and postoperative complications remain at the same level and have no tendency to decrease. According to one of the latest foreign studies obtained after studying the results of treatment of 1,102,071 patients, the average incidence of serious complications remains at about 7 % without a tendency to decrease over 9 years [49].

Further improvement of the results of treatment of a certain nosological form begins with an analysis of existing techniques in terms of their safety, efficacy, and effectiveness. However, outside rigorous methodology studies it is impossible to determine which part of unfavorable outcomes and unsatisfactory results is based not on the methodology itself or its aspect or on the human and technical error. Randomized studies minimize the risk of major systematic errors in each individual work, and the methodology of systematic review and meta-analysis allows us to summarize the world experience as a whole qualitatively and quantitatively. Thus, evidence-based medicine allows not only to draw reasonable conclusions based on the total results of already completed studies, but also on the basis of the currently available evidence base, to determine promising future research and “empty results” scientific search.

Since 2010, the studies of Cochrane expert groups on the topic of gallstone disease have presented the results of Trial Sequential Analysis (TSA), which allows to establish the required sample size or Diversity-Adjusted Required Information Size (DARIS), according to which it is possible to make

Table 8. Required sample size by duration of inpatient treatment
Таблица 8. Необходимый размер выборки по длительности стационарного лечения

Cochrane Research Group (year) *Исследовательская группа Кокрейна (год)*	Subjects of systematic review and meta-analysis *Тематика систематического обзора и метаанализа*	DARIS	
		n	%
Gurusamy K.S., et al. (2013) [23]	Miniport LCE / Standard four-port LCE *Мини-портовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	20	100
Gurusamy K.S., et al. (2013) [17]	Single-port LCE / Standard four-port LCE *Однопортовая ЛХЭ / Стандартная четырехпортовая ЛХЭ*	222	100
Gurusamy K.S., et al. (2013) [14]	LCE with minipneumoperitoneum / Standard four-port LCE *ЛХЭ с мини-пневмоперитонеумом / Стандартная четырехпортовая ЛХЭ*	183	100
Gurusamy K.S., et al. (2014)* [48]	LCE with intraperitoneal instillation / LCE without intraperitoneal instillation (DARIS calculation with a difference of 1 bed day) *ЛХЭ с интраперитонеальной инстилляцией / ЛХЭ без интраперитонеальной инстилляции (расчет DARIS с разницей 1 койко-день)*	107	100
Loizides S., et al. (2014) [16]	LCE with local anesthesia for wounds / LCE without local wound anesthesia *ЛХЭ с местным обезболиванием ран / ЛХЭ без местного обезболивания ран*	931	35.1
Rutherford D., et al. (2021)* [15]	LCE with intraperitoneal instillation / LCE without intraperitoneal instillation (DARIS calculation with a difference of 0.5 bed-day) *ЛХЭ с интраперитонеальной инстилляцией / ЛХЭ без интраперитонеальной инстилляции (расчет DARIS с разницей 0,5 койко-дня)*	775	100

Note: LCE — laparoscopic cholecystectomy; NSAIDs — non-steroidal anti-inflammatory drugs; * — current and previous versions of the Cochrane review meta-analysis with different DARIS calculation parameters [14, 48].
Примечание: ЛХЭ — лапароскопическая холецистэктомия; НПВС — нестероидные противовоспалительные средства; * — актуальная и предшествующая версии метаанализа Кокрейновского обзора с различными параметрами расчета DARIS [14, 48].

conclusions about differences without risk a random error. In the specialized literature on the importance of TSA for checking results J. Brok et al. (2009) noted that the conclusions of the final meta-analyses may be inconclusive and are at risk of random error due to repetitive testing of accumulating data [9]. TSA avoids type I and type II errors, even with a small number of primary studies selected for meta-analysis, by calculating the required number of participants and Z-curve monitoring on benefit, harm, or futility boundary plots.

Conclusion

Analytical work on the study of the Diversity-Adjusted Required Information Size (DARIS) presented in Cochrane meta-analyses in the study of gallstone disease and acute cholecystitis allows us to assume the high accuracy of the tool discussed in this article in planning potential studies and to state the existing multidirectional trends that need to be taken into account in the future.

In the context of bile duct injury between early and delayed LCE, the number of complications between early and delayed LCE, small-incision cholecystectomy and LCE, single-port and standard four-ports LCE and methods of low pressure laparoscopy the required size of the meta-analysis information is unlikely to be achieved — in the current versions of the Cochrane library DARIS is less than 1 %. The same applies to mortality, the probability of developing serious complications and the conversion rate of various minimally invasive procedures, as the required sample sizes (hundreds of thousands of observations) are difficult to achieve — current range from 0.03 to 21.9 %.

On the contrary, the achieved values from the estimated DARIS in establishing the differences in duration between the minimally invasive surgery options (21.2–76 %), in some issues of pain management in the immediate postoperative period

(43.6–92.6 %) and additional intraoperative anesthesia (13.7–14.9 %) and Z-curve give hope for their achievement in the foreseeable future.

There is little prospect of continuing evidence-based studies to determine the need for intraperitoneal anesthetic instillation, differences in the duration hospitalization after various minimally invasive surgeries, since new information is unlikely to change the conclusions of meta-analyses (the required information size has been achieved by 100 %).

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Submitted: 10.03.2023 Accepted: 30.06.2023 Published: 30.10.2023
Поступила: 10.03.2023 Принята: 30.06.2023 Опубликована: 30.10.2023

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