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SYSTEMATIC REVIEW

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Evaluation of quality and quantity of randomized controlled trials in hepatobiliary surgery: A scoping/mapping review

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Abstract

Aim: To evaluate the quantity and quality of randomized controlled trials (RCTs) in hepatobiliary surgery and for identifying gaps in current evidences.

Methods: A systematic search was conducted in MEDLINE (via PubMed), Web of Science, and Cochrane Controlled Register of Trials (CENTRAL) for RCTs of hepatobiliary surgery published from inception until the end of 2023. The quality of each study was assessed using the Cochrane risk-of-bias (RoB) tool. The associations between risk of bias and the region and publication date were also assessed. Evidence mapping was performed to identify research gaps in the field.

Results: The study included 1187 records. The number and proportion of published randomized controlled trials (RCTs) in hepatobiliary surgery increased over time, from 13 RCTs (.0005% of publications) in 1970–1979 to 201 RCTs (.003% of publications) in 2020–2023. There was a significant increase in the number of studies with a low risk of bias in RoB domains ($p < .01$). The proportion of RCTs with low risk of bias improved significantly after the introduction of CONSORT guidelines ($p < .001$). The evidence mapping revealed a significant research focus on major and minor hepatectomy and cholecystectomy. However, gaps were identified in liver cyst surgery and hepatobiliary vascular surgery. Additionally, there are gaps in the field of perioperative management and nutrition intervention.

Conclusion: The quantity and quality of RCTs in hepatobiliary surgery have increased over time, but there is still room for improvement. We have identified gaps in current research that can be addressed in future studies.

KEYWORDS

evidence map, hepatobiliary surgery, quality assessment, randomized controlled trial, risk of bias

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1 | INTRODUCTION

Surgery is a therapeutic option for both benign and malignant lesions of the hepatobiliary tract, resulting in reduced morbidity and mortality rates and improved quality of life.[1–3] As the introduction of surgical resection as a treatment for hepatobiliary diseases, significant advancements have been made in surgical techniques, patient management and postoperative care, leading to better outcomes for patients.[4] Despite advancements, achieving consistently favourable outcomes in hepatobiliary surgery remains a challenge. To address this issue, it is crucial to assess the existing literature on hepatobiliary surgery and conduct an evidence-based analysis to identify areas for improvement and optimization in the different fields of the preoperative, intraoperative, and postoperative periods, as well as different types of surgical and non-surgical interventions.[5]

Randomized controlled trials (RCTs) provide the strongest level of evidence after meta-analyses of RCTs[6] and are standard for clinical research and evaluation of therapeutic efficacy in medicine.[6–8] Nonetheless, surgical RCTs are more difficult to conduct than non-surgical RCTs because of methodological and ethical constraints. This means that fewer RCTs have evaluated surgical interventions. In addition, the methodological and reporting quality of existing trials is poor, which means there is limited high-quality evidence on which to base surgical decisions.[9] A comprehensive summary of RCTs in the field of hepatobiliary surgery could facilitate the translation of research evidence into clinical practice, leading to improved patient outcomes, enhanced quality of care, and optimized resource utilization in healthcare systems.[10] However, such a review has not yet been published.[11]

Evidence-based practice in hepatobiliary surgery could be facilitated by evidence mapping. This provides a comprehensive and detailed summary of the literature and identifies current trends in the field, helping researchers to target research gaps. It also highlights trends and weaknesses such as poor methodological quality in the existing research that can be addressed in future studies. This information also guides stakeholders and financial funders when deciding which studies to support.[12]

The current study aimed to systematically explore the quantity and quality of published RCTs and to map the existing evidence on surgical management of hepatobiliary diseases. This may guide future research and investment in the field of hepatobiliary surgery.

2 | METHODS

This scoping/mapping review complies with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[13] statement and was conducted in line with the Cochrane Handbook for Systematic Reviews and Interventions.[14]

2.1 | Literature search

Relevant RCTs were identified via a systematic literature search of articles published in MEDLINE (via PubMed), Web of Science, and Cochrane Controlled Register of Trials (CENTRAL) databases until end of 2023, as previously reported.[15] There were no restrictions on date and language of publication. The search term strategy is provided in Data S1.

2.2 | Trial selection

Inclusion criteria were (1) RCTs investigating surgical and perioperative (nutrition, pharmacological, etc.) interventions in hepatobiliary surgery and (2) RCTs comparing non-surgical interventions (endoscopic and radiologic) with surgical ones. Studies evaluating only neoadjuvant or adjuvant therapy without assessing surgical interventions and studies involving pancreatic biliary tract interventions were excluded. We also excluded studies on liver transplantation.

Two reviewers (EA, AR) independently assessed the titles and abstracts of all retrieved articles and if at least one reviewer considered the article as eligible for further evaluation, it was included in the full-text screening. In case of conflict between reviewers, agreement was reached by consultation with a third reviewer (AM). In the event of multiple publication of one RCT, the main publication was included in analysis. Four researchers (EA, AM, AR, EK) extracted data from selected RCTs into a pre-structured Microsoft Excel data sheet (version 2019, Microsoft). Any conflict during data extraction was resolved by discussion with a top investigator. The following data were extracted: year, first author, journal, region (Africa, Asia, Australia and Oceania, Europe, North America, South America), sample size, follow-up duration, type of disease (bile duct obstruction due to tumour, biliary tract lesions, cirrhosis, portal hypertension, hepatobiliary stones, hepatobiliary trauma, infections, liver cystic diseases, liver metastases, primary

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benign liver tumours, primary malignant liver tumours), type of operation (biliary tract surgery, cholecystectomy, hepatobiliary vascular surgery, liver cyst operation, major liver resection, minor liver resection, multivisceral resection), type of intervention (pharmaceutical, medical device, nutrition, perioperative management, surgical strategy, perioperative non-surgical procedure), other factors (timing of the surgery and conservative management of the patients) and quality assessment (described later). The types of diseases, operations, and interventions were classified by the senior surgeon.

2.3 | Risk of bias assessment

We used the updated Cochrane risk-of-bias tool (RoB 2)[16] presented in the Cochrane Handbook for Systematic Reviews and Interventions[14] to assess the methodological quality of the trials. The assessment included random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other sources of bias (baseline participant characteristics, sample size, intention-to-treat analysis). Bias was categorized according to three levels: 'low risk of bias', 'some concerns' and 'high risk of bias'. If blinding was not stated, the risk of bias for these dimensions was judged as 'some concerns'. To assess the methodological quality of each study, two reviewers (EA, AR) evaluated each RCT using the RoB 2 tool.[16] In case of conflict between reviewers, agreement was reached by discussion with a third reviewer (AM).

2.4 | Evidence mapping

To construct an evidence, map and identify evidence gaps, RCTs were plotted by type of intervention against type of operation and type of disease as spheres. The colour of the spheres represents the regions in which the studies were conducted and the size of the spheres represents the number of trials.

2.5 | Statistical analysis

Categorical variables were described as frequencies and proportions and continuous variables as mean and median values. The RCTs were categorized into three groups (before 1996, between 1997 and 2010, and after 2010) according to when the first version of the CONSORT statement was published in 1996 and then updated in 2010. The RCTs were also divided into the six groups according to the decade in which they were published (1970–1979, 1980–1989, 1990–1999, 2000–2009, 2010–2019 and 2020–2023). Studies were further categorized according to the region of publication (Europe, Asia and North America). Categorical variables were compared between groups using the chi-squared test. Statistical analyses were performed using SPSS version 27 (IBM Corp., Armonk, NY, USA), Excel version 2019 (Microsoft, Redmond, Washington, USA), and JMP version 11 (SAS Institute, Cary, NC, USA). The probabilities of .05 or less were accepted as significant ($p < .05$).

3 | RESULTS

3.1 | Search results

The electronic search of MEDLINE, Web of Science, and CENTRAL databases retrieved 33,593 records. After removal of 12,175 duplicates, 21,418 records underwent primary screening of titles and abstracts, from which 2030 records were selected for full-text evaluation according to the inclusion and exclusion criteria. Of these, 1187 RCTs were considered eligible and included in the quality assessment (Figure 1).

3.2 | Study characteristics

According to the affiliation of the first author, most RCTs were conducted in Asia (549, 46.2%) and Europe (431, 36.3%), followed by North America (136, 11.5%), Africa (39, 3.3%), Australia and Oceania (19, 1.6%) and South America (13, 1%). Most RCTs (1118, 94.3%) were published in English, followed by Chinese (29, 2.4%), German (17, 1.4%), Italian (8, .7%), Spanish (4, .3%), French (4, .3%), Japanese (3, .2%), Russian (2, .2%), Polish (1, .1%) and Dutch (1, .1%).

The included RCTs were most frequently published in *Surgical Endoscopy* (78, 6.6%) followed by *Annals of Surgery* (73, 6.1%), *British Journal of Surgery* (69, 5.8%), *The American Journal of Surgery* (35, 2.9%), *Hepatogastroenterology* (34, 2.9%), *Surgery* (27, 2.3%), *World Journal of Surgery* (25, 2.1%), and *The Archives of Surgery* (*JAMA Surgery*) (22, 1.8%). In total, 164 (13.8%) articles were published in journals with an impact factor ≥ 10.

The RCTs included a total of 150,036 patients, with 11–1114 patients enrolled in each RCT (median, 90 patients). Regarding the sample size, 55.1% of RCTs had a sample size less than 100 patients, 30.2% between 100 and 200, and only 14.7S% included more than 200 patients.

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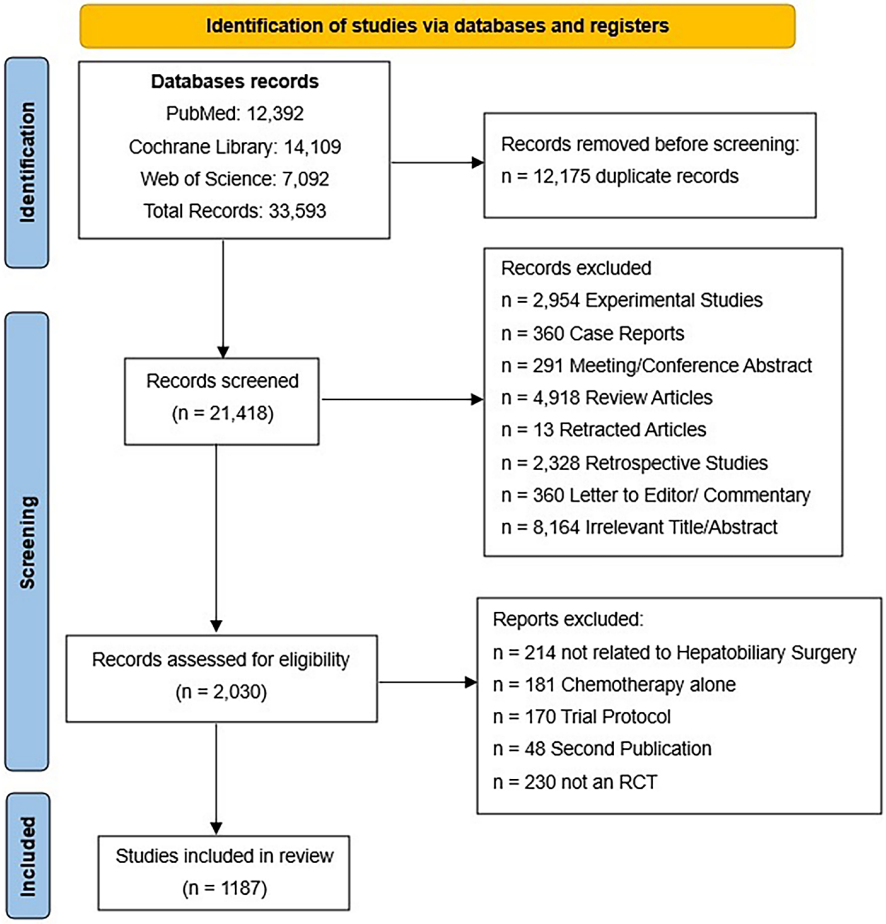

FIGURE 1 PRISMA flow chart.

The duration of follow-up was reported in 1105 (93.1%) articles and ranged from 1 day to 180 months (median follow-up of 1 month). Of these, 43.3% reported a follow-up of less than 1 month, 37.6% of 1 month to 1 year, and 19.1% of more than 1 year.

Most RCTs focused on one type of disease (905, 76.2%), followed by two types of disease (254, 21.4%), and three types of disease (28, 2.4%). Hepatobiliary lithiasis such as cholecystolithiasis and choledocholithiasis was the primary disease in 576 studies (48.5%) followed by primary malignant tumours of the liver such as hepatocellular carcinoma and cholangiocarcinoma (374, 31.5%), metastatic disease of the liver (148, 12.5%), cirrhosis portal hypertension (33, 2.8%), hepatobiliary infectious disease (11, .9%), biliary tract lesions (13, 1.1%), cystic liver disease (13, 1.1%), primary benign liver tumours (7, .6%), and trauma (2, .2%).

Only one field of intervention was reported in most studies (682, 57.5%), followed by two field of interventions (436, 36.7%), and three field of interventions (67, 5.6%). The most common field of intervention was surgical strategies (669, 56.3%), followed by pharmaceutical interventions (446, 37.6%), medical devices (225, 21.5%), perioperative management (166, 14%), perioperative non-surgical procedures (132, 11.1%), other interventions such as conservative management (57, 4.8%), and nutritional interventions (38, 3.2%). In regards to surgical operation, only one type of surgical operation was reported in most studies (676, 56.9%), followed by two types of operation (493, 41.5%), three types of operation (15, 1.3%) and four types of operation (3, .2%). Cholecystectomy was the most frequent operation (552, 46.5%), followed by major liver resection (510, 43%), minor liver resection (464, 39.1%), biliary tract surgeries (133, 11.2%), hepatobiliary vascular surgery (31, 2.6%), multivisceral resection (17, 1.4%), and liver cyst operations (15, 1.3%). Both major and minor liver resection were reported in 433 (36.5%) RCTs, determined by the Couinaud classification.[17]

3.3 | Quality assessment

Out of 1187 RCTs, 86 articles were not included in the quality assessment (69 were not in English and 17 did not have full texts), leaving 1101 RCTs in the risk of bias evaluation. Random sequence generation was sufficiently reported in 739 (62.3%) RCTs and concealment of allocation in 582 (49%) RCTs, so these studies were all considered as having a low risk of bias in these domains. However, these domains were not sufficiently reported in 13 (1%) trials, so these were judged as having

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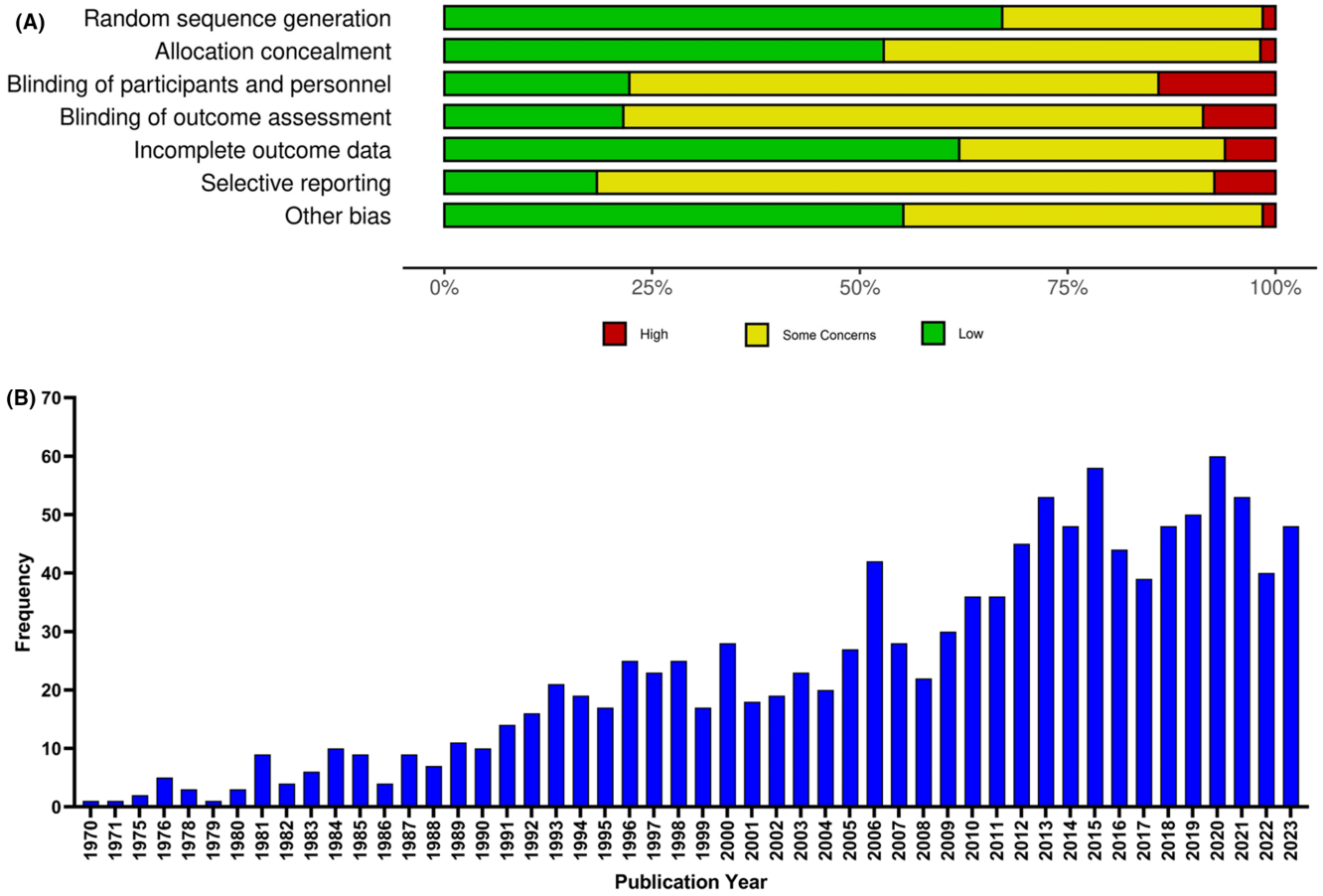

FIGURE 2 Risk of bias assessment in all included RCTs.

a high risk of bias (Figure 2). Most RCTs did not provide enough data concerning the blinding methods; 701 (59%) studies, and were judged as having some concerns of bias regarding blinding of the participants and personnel and 768 (64.7%) studies were judged as having some concerns of bias in blinding of outcome assessors. Participants and personnel were adequately blinded in 245 (20.6%) trials and the outcome assessor was adequately blinded in 237 (19.9%) studies. With regard to missing data, 682 (57.5%) studies were assessed as having a low risk of bias and 67 (5.6%) trials were judged as having a high risk of bias. Only 190 (16%) RCTs reported trial registration or study protocols, and were judged as having a low risk of bias in this domain. With regard to other sources of bias, 608 (51.2%) trials were judged as having a low risk of bias and 17 (1.4%) trials were judged as having a high risk of bias.

3.4 | Quality and quantity progress over time

The number of RCTs published in the field of hepatobiliary surgery has increased over the last 50 years. Only 13 RCTs were published in 1970–1979, followed by 72 in 1980–1989, 187 in 1990–1999, 257 in 2000–2009, 457 in 2010–2029 and 201 in 2020–2023. The CONSORT was first introduced in 1996 and the second version in 2010 and was endorsed by journals worldwide. With regard to this, 173 studies were published before 1996, 295 were published in 1997–2010, and 658 were published after 2010. The number of studies with a low risk of bias increased significantly after the CONSORT was introduced in 1996 in all domains ($p < .01$) except blinding of participants and personnel. Significantly more studies published after 2010 had a low risk of bias than those studies published before 2010 ($p < .01$) in all domains except incomplete outcome data, for which the frequency of studies with a low risk of bias decreased from 1997–2010 to after 2010 (67% to 60%) (Figure 3A). There were significantly more trials with a low risk of bias regarding random sequence generation, concealment of allocation, blinding of outcome assessment, selective reporting, and other bias after 2010 in comparison to other decades ($p < .001$). Fewer studies had a low risk of bias in the blinding domain than in the other domains, and no significant difference was seen between studies published before and after 2010 regarding blinding

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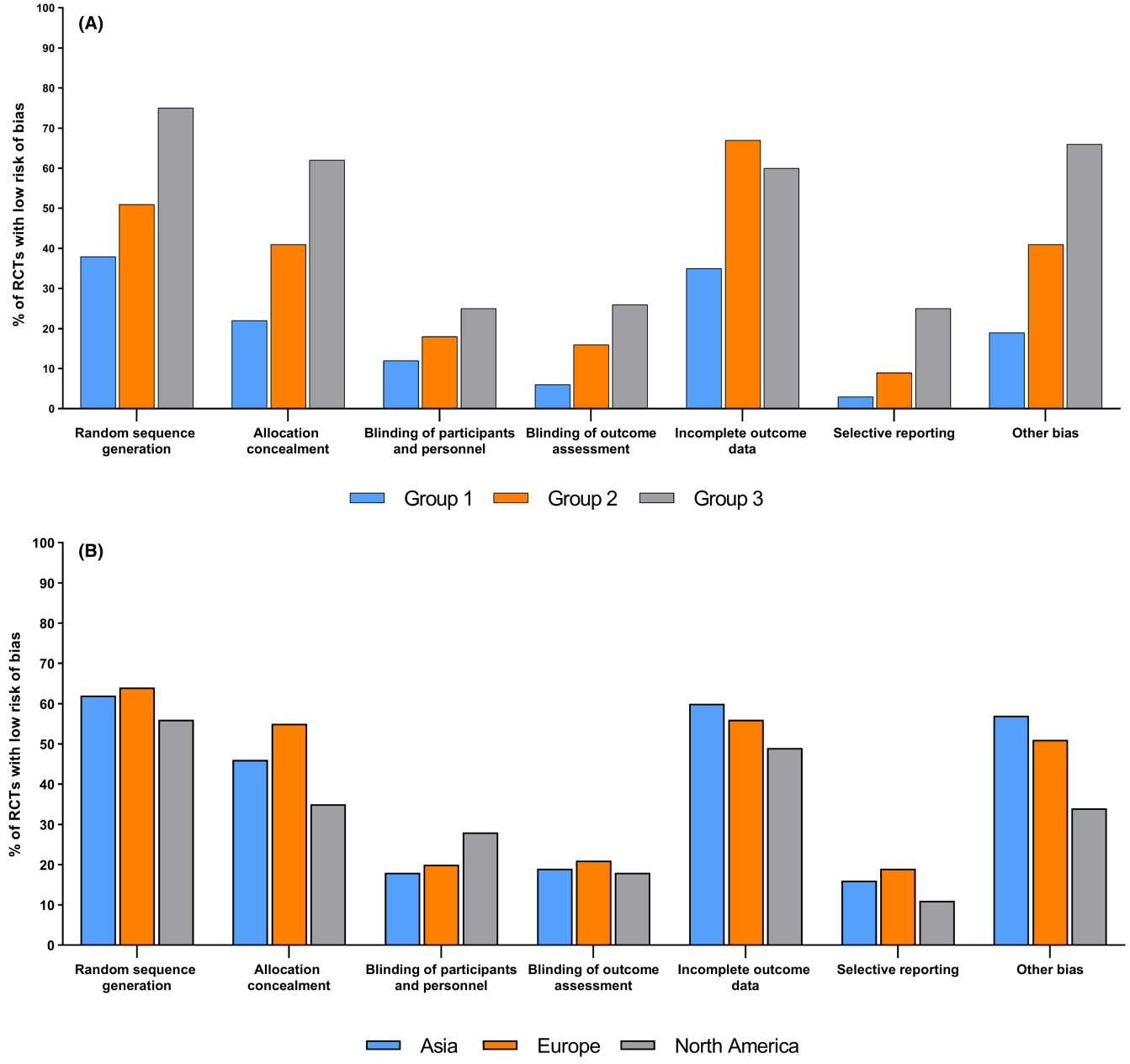

FIGURE 3 (A) Quality of RCTs conducted before 1996 (Group I), between 1997 and 2010 (Group II), and after 2010 (Group III), (B) Quality of RCTs conducted in three different regions (Europa, Asia, and North America).

of participants and personnel. Concerning incomplete outcome data, the number of RCTs with a low risk of bias increased through until 2010 and then decreased slightly.

We also analysed the effect of study region on the risk of bias. More studies from Europe had a low risk of bias in the allocation concealment domain than the studies from North America and Asia did ($p < .001$). However, more studies from North America had a low risk of bias in the blinding of participants and personnel domain than studies from Asia and Europe ($p < .01$). More studies from Asia had a low risk of bias in the domain of other biases than studies from the other regions did ($p < .01$) (Figure 3B). No significant differences were detected between groups in the remaining domains.

3.5 | Evidence mapping

To identify gaps in the current evidence in hepatobiliary surgery, two diagrams were developed from the extracted data. Type of disease and type of operation were plotted against the type of intervention (Figures 4 and 5). In these diagrams, larger spheres indicate that more trials were conducted whereas smaller spheres/spots or no spheres indicate evidence gaps. Numerous studies have been

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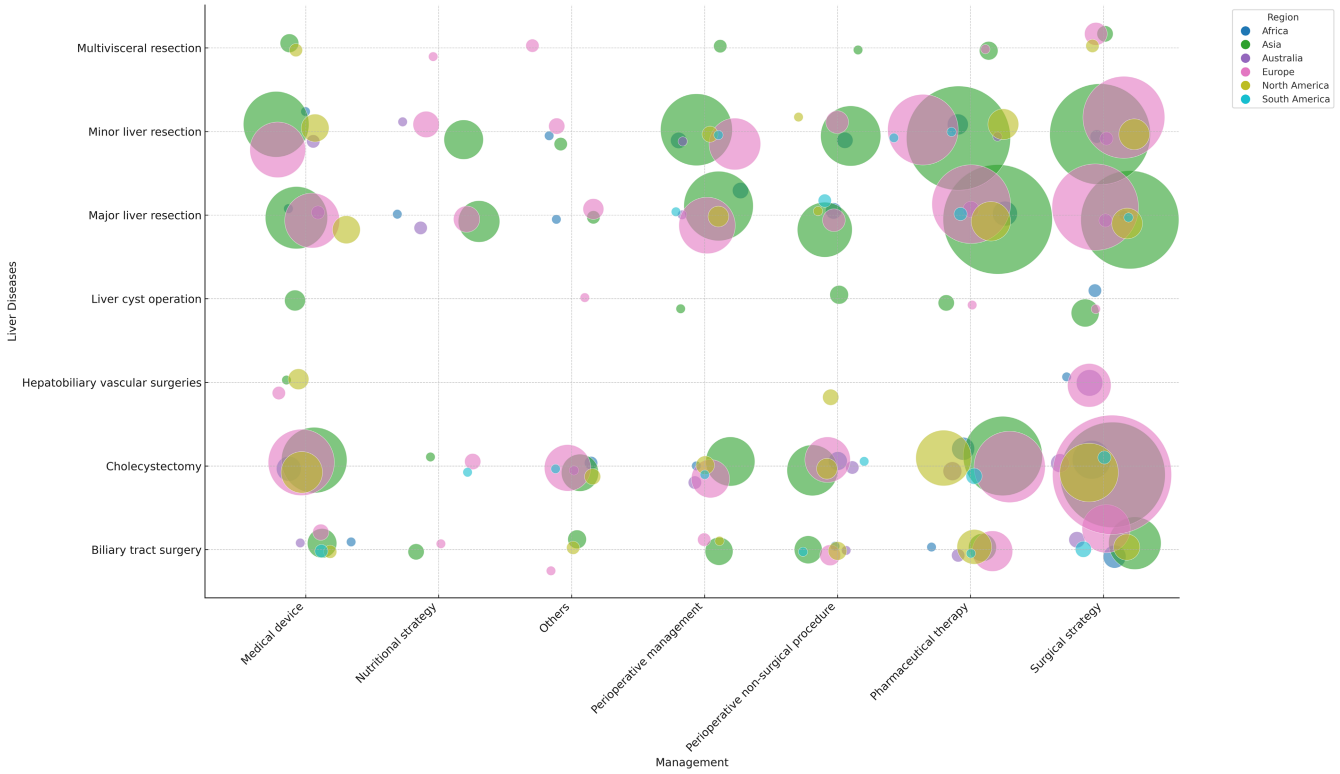

FIGURE 4 Evidence maps showing type of operation in relation to type of intervention by regional distribution.

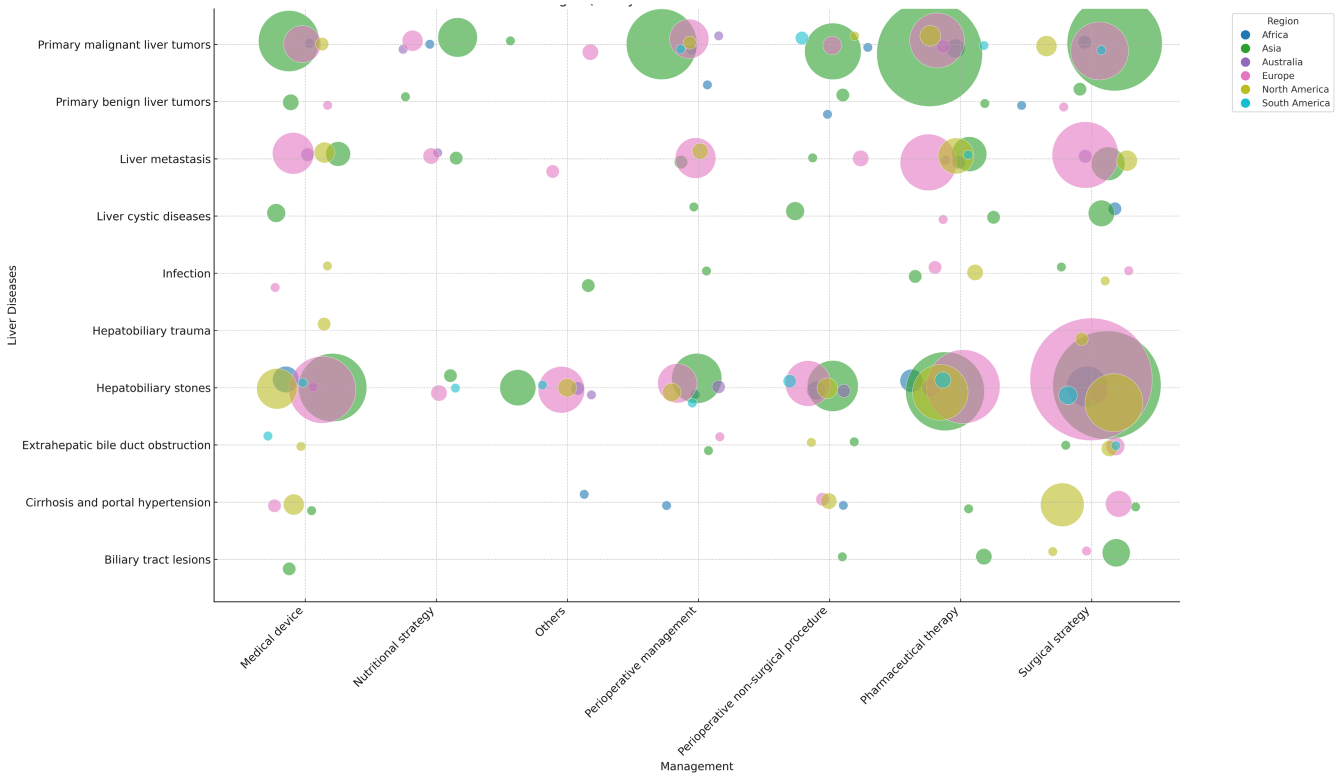

FIGURE 5 Evidence maps showing type of disease in relation to type of intervention by regional distribution.

conducted on major and minor liver resection as well as cholecystectomy. However, there is a lack of research, particularly in perioperative management and nutrition, on liver cyst operations and hepatobiliary vascular surgery in certain regions. This indicates a gap in evidence in these fields. Considering the type of disease, many studies

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reported on malignant liver disease and hepatobiliary stones, whereas considerable gaps were detected for cystic liver diseases, benign liver tumours, biliary tract lesions and hepatobiliary trauma, particularly with regard to surgical strategy, perioperative management, pharmaceuticals and nutrition.

4 | DISCUSSION

This study evaluated the number and quality of RCTs published in the field of hepatobiliary surgery. The number and quality of RCTs in the field of hepatobiliary surgery increased significantly between 1970 and 2023. Even so, there appears to be abundant room for improvement of methodological quality in this field. Evidence mapping revealed that considerable research has been performed on the perioperative, surgical, and pharmaceutical management of malignant liver diseases and biliary stones whereas considerable evidence gaps still exist for perioperative care in patients with biliary lesions, hepatobiliary infections, primary benign liver tumours, and cystic hepatic diseases.

According to our study, the proportion of randomized controlled trials (RCTs) on hepatobiliary surgery in medical literature has increased from .0005% (out of 2,458,623 publications) in the 1970s to .003% (out of 6,233,613 publications) in the 2020s. In fact, the number of RCTs in hepatobiliary surgery has increased six-fold over the last 50 years. The number of RCTs investigating cholecystectomy has increased over the years. However, the proportion of trials in this topic among all hepatobiliary surgery trials decreased from 77% in the 1970s to 35% in the 2020s. And the resulting insights from this growing research has helped to establish this technique as the standard treatment for cholelithiasis. Increased number of the patients, improvement of the diagnostic modalities, establishment of the unified surgical method as well as growth in other fields of the hepatobiliary can attribute to the increasing number of the RCTs in the field of the cholecystectomy, while decreasing its percentage among hepatobiliary surgery trials. Similarly, the number of studies investigating liver resection has also increased (from no studies in 1970 to 60% of studies in 2020s) and this had promoted the dramatic surgical advance in liver resection over the last 20 years, including improvements in diagnostic methods and devices, interdisciplinary perioperative management, postoperative care, and intraoperative techniques.[5]

Evidence maps detect gaps in current knowledge and identify important areas for future research in an easy to visualize format.[12] This helps researchers, stakeholders, investors, and funding institutions to allocate limited resources most effectively. In this study, evidence mapping revealed that considerable research has been done on the treatment of liver tumours with liver resection and the treatment of hepatobiliary stones with cholecystectomy. These diseases have a high prevalence and thereby a significant impact on the health system. Therefore, stakeholder interest in these fields is likely to remain strong and investment in RCTs to advance surgical devices, surgical techniques, pharmaceutical and perioperative care will also remain strong in the coming years.

Other hepatobiliary diseases, such as benign liver tumours, liver cysts, and infectious diseases were not as well researched, possibly because of their low incidence or because they can usually be managed with conservative and pharmaceutical therapies. Surgical intervention is only necessary if there are acute symptoms or a worsening condition. For example, most patients with liver hemangioma are managed conservatively with observation and a wait-and-see approach, except when the lesion gets bigger and may rupture, symptoms are affecting the patient's quality of life, or malignancies cannot be ruled out. In these situations, surgery is considered. Because surgical management is not a common approach for treating hemangioma, guidelines on the indications and surgical strategies of hemangioma are limited. Although multicentre studies are needed to increase our knowledge of these uncommon diseases, the overall impact they have on patients' quality of life should be considered, when funders and researchers are investing resources into such studies. Additionally, considering the importance of the methodological quality of the reports, comprehensive assessment of the quality of the studies is necessary.

Results of RCTs influence clinical decisions; therefore, the limitations and methodological quality of these studies need to be carefully assessed.[18] The CONSORT statement was introduced to improve the quality of RCTs and has been endorsed by many medical journals as the standard method of reporting RCTs.[19–21] We found that introduction of the first CONSORT statement in 1996 and the adaption of this original statement in 2010 significantly improved the quality of RCTs in the field of hepatobiliary surgery.[22] However, despite this increase in quality, we observed that the compliance of RCTs to the CONSORT statement remains suboptimal and that surgical interventions investigated in most trials lack adequate methodology.[23]

To ensure proper randomization, it is necessary to generate a randomized allocation sequence and adequately conceal this sequence during enrolment. In previous literature regarding proper randomization in surgical trials and pancreatic surgery trials, proper randomization was found in 47%[24] and 55%[25] of clinical trials respectively. We have observed that proper randomization was conducted in 62.2% of trials in the field of hepatobiliary surgery. Besides, concealment of the generated sequence is also

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important. Although it is easy to implement, only 49% of trials included in this study reported adequate concealment. This is in agreement with the results of other systematic reviews.[24–27]

The study revealed that blinding, especially of surgeons, personnel, participants, and outcome assessors, was not adequately reported in articles, even those published in high impact journals. This lack of blinding made it difficult to assess the study's quality. Of the studies analysed, almost 14% were assumed to be triple-blind, meaning blinding of patients, personnel, and outcome assessors, and were judged to have a low risk of bias. About 7% were double-blind, involving blinding of patients and personnel. The authors of some of these trials argue that blinding of the outcome assessor was not necessary to measure patient-reported outcomes such as pain and quality of life. Our findings are in agreement with those of other studies. A 2004 review on the quality of surgical RCTs reported proper blinding of participants in just 8.2% of trials and of outcome assessors in 17.1% of trials.[28] A recent review of RCTs on pancreatic surgery reported proper blinding of participants and personnel in 22.1% of studies.[25] Another review of RCTs on spinal cord injury showed proper blinding of participants in 28.3% of studies, of personnel in 15% of studies, and of outcome assessors in 37.1% of studies.[29]

We have observed improvement in all RoB-2 domain except to incomplete outcome data, which increased until 2010 and after that, it decreased slightly. This issue can be justified by factors such as changes in research practices such as evolving methodological standards, variability in data collection methods, or challenges in ensuring data completeness and accuracy.[30] Blinding of surgeons in surgical RCTs is difficult because of the nature of surgical intervention. Blinding of patients also can be complicated in some surgical trials, such as when open surgery is compared with minimally invasive or sham operations. Saying that a study is 'single' or 'double' blind without explaining what this means can lead to misjudgment of the study quality and should be avoided.[31,32] Although blinding of patients and surgeons is difficult, the blinding of outcome assessors is easier and can reduce the increased risk of bias caused by insufficient blinding of participants and personnel.[32–34] Unclear reporting of randomization, concealment, and blinding was observed in many publications[27,28,35–37] and some of these studies suggested that this was due to inadequate reporting rather than poor design and methodology.[38–40] While the quality of RCTs in hepatobiliary surgery improved, a strong focus for improving randomization and allocation, in addition to the blinding is recommended to decrease the overall risk of bias.

Registering a trial in a registry before the study begins increases integrity and transparency and reduces bias related to selective reporting of outcomes. These registries also identify any duplicate trials, helping researchers and funders to focus their attention and resources on the most useful line of study. Although the number of trial registrations have increased over the years, more than 70% of the RCTs included in this study did not report a trial registration or previously published protocols.

The study population in this study (median sample size of 90) was higher than those reported in reviews on spinal cord injury[29] (median sample size of 28) and pancreatic surgery[25] (median sample size of 70.5). The follow-up times reported in the RCTs in our review (between 1 day and 180 months) were also similar to those reported in a previous systematic review.[25,29,41]

Most RCTs in our study were conducted in Asia and Europe with only a few conducted in North America. This may reflect the higher incidence of hepatobiliary diseases in Asian populations[42] and the increase in funding and multinational research institutions in European countries. A recent review on the characteristics of surgical RCTs also reported more trials in Europe than in North America,[43] in agreement with our findings. Differences in study quality were observed between regions. Studies from North America had a lower risk of bias in blinding domains whereas studies from Europe had a lower risk of bias in allocation concealment domains. The journal impact factor also appears to affect study quality, with studies published in journals with an impact factor higher than 10 having significantly higher quality in random sequence generation, incomplete outcome data, selective reporting, and other biases than studies published in journals with an impact factor of less than 10. This suggests better methodological quality of publications in higher impact journals. Most high-impact RCTs were conducted in Europe (45.9%) in our study, which is supported by the results of other reviews that studies performed in Europe have a higher methodological quality.[24]

The current systematic review has shown that the number and quality of hepatobiliary surgery trials has increased over the last five decades. However, the quality of the studies is not optimal yet. There are considerable evidence gaps that need to be filled which include the perioperative management and nutritional intervention of the hepatobiliary surgery. Considering the type of hepatobiliary disease, there is also an obvious gap in cystic liver disease, benign liver tumours, biliary tract lesions, and hepatobiliary trauma. These evidence gaps should be considered and prioritized by researchers and funders conducting upcoming clinical trials. There are some important limitations to our study. First, we did not include trials on liver transplantation and donor hepatectomy because these should be discussed separately in another review. Second, we did not evaluate the

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correlation between study quality and study outcome because of the high number of included studies. To advance the quality and relevance of research in hepatobiliary surgery, it is essential to emphasize the need for specific recommendations for future research priorities. This includes addressing identified evidence gaps, such as perioperative care in various hepatobiliary conditions, and methodological deficiencies in RCTs, such as issues with randomization, blinding, and trial registration. Researchers and funders can contribute to achieving this goal. These recommendations can guide future research efforts and ensure that advancements in the field are evidence-based and methodologically sound, ultimately benefiting patient care and clinical practice.

5 | CONCLUSION

The evaluation of RCTs in hepatobiliary surgery has shown significant progress over the years, with increasing numbers and improved methodological quality. However, there are still notable gaps in evidence, particularly in areas such as perioperative management, benign liver tumours, and cystic hepatic diseases. To address these gaps, specific recommendations for future research priorities are necessary. This includes identifying underexplored clinical domains and enhancing methodological rigour in RCTs.

AUTHOR CONTRIBUTIONS

A. Majlesara and A. Mehrabi formulated and designed the study. A. Majlesara, E. Aminizadeh, A. Ramouz, E. Khajeh, M. Shahrbaf and F. Borges acquired and extracted the data, with G. Goncavles and M. Golriz providing supervision. E. Aminizadeh, A. Ramouz and M. Shahrbaf analysed data and A. Majlesara, E. Aminizadeh, A. Ramouz, F. Borges, G. Goncalves, C. Carvalho and A. Mehrabi interpreted the results. E. Aminizadeh, A. Ramouz and A. Majlesara drafted the initial manuscript. All authors reviewed and revised the manuscript for intellectual content, had full access to all the data in the study, and had final approval of the submitted manuscript for publication. All authors accept responsibility to submit for publication.

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All authors declare no conflict of interests.

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