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Interventions: “[LC] versus [PTGBD+LC] for [clinical efficacy and safety] in [acute cholecystitis]: A protocol for a systematic review”

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ADMINISTRATIVE INFORMATION

Support - The Project of Changsha Science and Technology Bureau.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023110106

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 November 2023 and was last updated on 27 November 2023.

INTRODUCTION

Review question / Objective “The aim of this systematic review is to compare [LC] and [PTGBD+LC] in terms of efficacy and acceptability in the [the clinical efficacy and safety of acute cholecystitis] to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce [adverse reactionOutcome] in [acute cholecystitis], [LC] or [PTGBD+LC]?”.

Condition being studied (1) Research type: Clinical randomized controlled trials; (2) Research subject: Diagnosed as AC; (3) Intervention measures: The control group received LC treatment; The experimental group received PTGBD combined with LC treatment; (4) Outcome measures: Clinical efficacy indicators, including

surgical time, intraoperative blood loss, conversion rate to open surgery, postoperative hospital stay, and total hospital stay; Safety indicators, including the total incidence of postoperative complications, the incidence of postoperative bile leakage, bile duct injury, abdominal bleeding, and wound infection.

METHODS

Participant or population Diagnosed as AC; Intervention measures: The control group received LC treatment; The experimental group received PTGBD combined with LC treatment.

Intervention Laparoscopic cholecystectomy.

Comparator percutaneous transhepatic gallbladder drainage combined with laparoscopic cholecystectomy.

Study designs to be included Clinical randomized controlled trials.

Eligibility criteria Inclusion criteria: (1) Study type: Clinical randomized controlled trial; (2) Research subject: Diagnosed as AC; (3) Intervention measures: The control group received LC treatment; The experimental group received PTGBD combined with LC treatment; (4) Outcome measures: Clinical efficacy indicators, including surgical time, intraoperative blood loss, conversion rate to open surgery, postoperative hospital stay, and total hospital stay; Safety indicators, including the total incidence of postoperative complications, the incidence of postoperative bile leakage, bile duct injury, abdominal bleeding, and wound infection. Exclusion criteria: (1) Basic research, abstracts, conference papers, reviews, meta-analysis, systematic evaluation, case report literature; (2) Non Chinese and English literature; (3) Repetitive literature: articles with similar research directions published by the same author in the same study; (4) Literature with a research population of less than 20; (5) Literature that cannot obtain full text, statistical methods are inappropriate, data cannot be extracted, or data is incomplete.

Information sources Pubmed, Web of Science, Embase, Cochrane Library, CNKI, Wanfang, and other databases.

Main outcome(s) Surgical time, intraoperative bleeding volume, conversion rate to open surgery, postoperative hospital stay, total hospital stay; The overall incidence of postoperative complications, as well as the incidence of postoperative bile leakage, bile duct injury, abdominal bleeding, and wound infection.

Quality assessment / Risk of bias analysis Newcastle-Ottawa Scale.

Strategy of data synthesis For binary variables, OR and 95% CI are used as outcome measures, while for continuous numerical variables, mean difference (MD) and 95% CI are used as outcome measures; Calculate I^2 Value detection of heterogeneity between studies, when $P \geq 0.1$, $I^2 < 50\%$, use a fixed effects model; When $P < 0.1$, $I^2 \geq 50\%$, use a random effects model and analyze the reasons for heterogeneity; Use funnel plot to evaluate publication bias of included literature; $P < 0.05$ indicates a statistically significant difference.

Subgroup analysis None.

Sensitivity analysis None.

Country(ies) involved The countries involved in the article are all China.

Keywords Acute cholecystitis, percutaneous transhepatic gallbladder puncture drainage, laparoscopic cholecystectomy, meta-analysis, efficacy.

Contributions of each author

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