Systematic Review and Meta-Analysis

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Laparoscopic versus open herniorrhaphy for children with inguinal hernia

A meta-analysis of randomized controlled trials

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Abstract

Purpose: The aim of this study was to compare the effectiveness between laparoscopic herniorrhaphy (LH) and open herniorrhaphy (OH) in children with inguinal hernia.

Methods: PubMed, EmBase, and the Cochrane library were searched to select trials from their inception till April 2019. The summary of relative risks (RRs) and weighted mean differences (WMDs) with corresponding 95% confidence intervals (CIs) were employed to evaluate the treatment effectiveness between LH and OH.

Results: Six randomized controlled trials (RCTs) including a total of 594 children were selected. No significant differences were observed between LH and OH regarding the risk of postoperative complications. However, LH significantly reduced the risk of major postoperative complications when compared with OH. Moreover, LH showed association with a shorter operative time in bilateral inguinal hernia when compared with OH, whereas no significant difference between groups for unilateral inguinal hernia. Finally, children who received LH showed association with longer time to discharge than those who received OH, whereas no significant difference was observed between the groups for time to resume full activity.

Conclusions: These findings suggested that children who received LH had protection against major postoperative complications than those who received OH. Moreover, children who received LH had shorter operative time, and longer time to discharge.

Abbreviations: CI = confidence interval, LH = laparoscopic herniorrhaphy, OH = open herniorrhaphy, RCTs = randomized controlled trials, RRs = relative risks, WMDs = weighted mean differences.

Keywords: infants, inguinal hernia, laparoscopic herniorrhaphy, meta-analysis, open herniorrhaphy, pediatric population

1. Introduction

Pediatric inguinal hernia is caused by failure of the processus vaginalis to close and obliterate spontaneously, allowing for herniation as the abdominal contents protrude beyond the peritoneal cavity.[1] Inguinal hernia accounted for 13.7%, 8.2%, 7.7%, and 6.3% in children <1.500 g, 1.500 to 1.999 g, 2.000 to 2.499 g, and ≥2.500 g birth weight.[2] According to a previous study, the incidence of inguinal hernias was 1.2 per 1000 person-years.[3] Open herniorrhaphy (OH) is a traditional method and is the first-choice of treatment for children with inguinal hernia, and is associated with lower rates of recurrence and morbidity.[4] Currently, OH has been shifted to laparoscopic herniorrhaphy (LH), as most of the surgeons have become facile using this approach in pediatric surgery.[5]

LH is the time honored treatment due to its minimally invasive surgery, which allows the contralateral evaluation of patent processus vaginalis.[6,7] However, the treatment effectiveness between LH and OH in children with inguinal hernia remained controversial. Nowadays, no specific indicator is employed to recommend the use of LH or OH based on age, size, and body weight.[8,9] However, the use of LH in small babies has posed a challenge to pediatric surgeons, limiting its use in neonates or infants by inexperienced surgeons.[10,11] Although several previous meta-analyses have been conducted on this topic, the reported results were not comprehensive, and inconsistencies existed in the results.[12,13] Due to advancements in technology

Editor: Johannes Mayr.

The authors report no conflicts of interest.

Data availability statement: The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

Ethics approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Supplemental Digital Content is available for this article.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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How to cite this article: Liu G, Zhang W, Zhou J, Sun B, Jiang B, Wang H. Laparoscopic versus open herniorrhaphy for children with inguinal hernia: A meta-analysis of randomized controlled trials. Medicine 2020;99:33(e21557).

Received: 1 April 2020 / Received in final form: 5 June 2020 / Accepted: 3 July 2020

http://dx.doi.org/10.1097/MD.0000000000021557

and experience in LH, the treatment effectiveness between LH and OH should be updated in children with inguinal hernia. Therefore, this current meta-analysis was conducted to compare the effectiveness of LH and OH in children with inguinal hernia based on randomized controlled trials (RCTs).

2. Methods

2.1. Data sources, search strategy, and selection criteria

This study was performed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Statement,[14] and the details are presented in Checklist S1. The studies that are designed as RCTs and those that compared the treatment effectiveness between LH and OH were considered eligible. There are no restrictions regarding publication language and status. A comprehensive electronic search was carried out from PubMed, EmBase, and the Cochrane library to identify potential studies using the keywords ("laparoscopy" OR "laparoscopic") AND "open" AND "herniorrhaphy" AND "inguinalhernia" AND "randomized controlled trials" till April 2019. Moreover, the manual searching of the reference lists of retrieved trials was conducted to identify for any new eligible trial.

The literature search and study selection were performed by 2 authors independently, and any conflicts between them were settled by an additional author by reviewing the search strategy and inclusion criteria. The study was eligible if the following criteria were met: patients (children diagnosed with inguinal hernia irrespective of the side); intervention (LH); control (OH); outcomes (the study should at least report 1 of the following: postoperative complications, major postoperative complications, hypertrophic scar, skin sensitivity, transient hydrocele, contralateral hernia, latrogenic ascent of the testis, peritoneal bleed, postoperative vomiting, scrotal edema, stitch granuloma, testicular atrophy, pain, recurrence, operative time, time to discharge, and time to resume full activity); and study design (the study should have RCT design). If sample population was published in multiple articles, the most recent article was selected for this meta-analysis. Studies designed as letters, reviews, case reports, case series, case–controls, and cohorts were excluded.

2.2. Data collection and quality assessment

Two independent authors carried out data collection and quality assessment processes, and inconsistent results were resolved by group discussion, and an additional author made the final decision by referring to the original article. The following data were collected: first authors' surname, publication year, country, sample size, mean age, number and percent of boys, side, approaches, trocars, follow-up duration, and reported outcomes. The quality of included trials were assessed by Jadad scale based on randomization (1 or 0), concealment of the treatment allocation (1 or 0), blinding (1 or 0), completeness of follow-up (1 or 0), and the use of intention-to-treat analysis (1 or 0), with 0 (poor) to 5 (best) scores based on the quality.[15]

2.3. Statistical analysis

The results of overall and specific postoperative complications were assigned as categorical data and the relative risk (RR) with its 95% confidence interval (CI) was calculated by the occurrence of events and sample size in LH and OR group in individual trials. Moreover, the results of operative time, time to discharge, and time to resume full activity were analyzed as continuous data and the weighted mean difference (WMD) and its 95% CI were calculated by using means, standard deviation, and sample size in LH and OR groups in individual trials. The summary results were calculated using the random-effects model.[16,17] Heterogeneity across the included trials for each outcome was assessed by I^2 and Q statistic, and $I^2 > 50.0\%$ or $P < .10$ indicates significant heterogeneity.[18,19] Sensitivity analyses for postoperative complications and operative time were conducted to assess the influence of each trial.[20] Subgroup analysis for postoperative complications was conducted based on country, mean age, percentage of boys, side, approach, and study quality, and P values between subgroups were calculated using the interaction test. Publication biases for postoperative complications and operative time were conducted using funnel plots, Egger,[21] and Begg[22] tests. The inspection level of pooled results was 2-sided and $P < .05$ was regarded as statistically significant. All statistical analyses were conducted using STATA software (version 10.0 StateCorp, TX).

3. Results

3.1. Literature search

The initial search from PubMed, EmBase, and the Cochrane library identified a total of 149 records. Of these, 127 articles were excluded after screening reviewing the titles and abstracts. The remaining 22 studies were retrieved for further evaluation, and 16 studies were excluded due to the following reasons: study designed as observational (n = 7), compared with other treatment strategies (n = 5), and no sufficient data (n = 4). Finally, 6 RCTs published between 2005 and 2017 were selected for this meta-analysis.[23–28] No additional trial was identified through manual searching of the reference lists of retrieved studies. The results of trials selection process are shown in Figure 1.

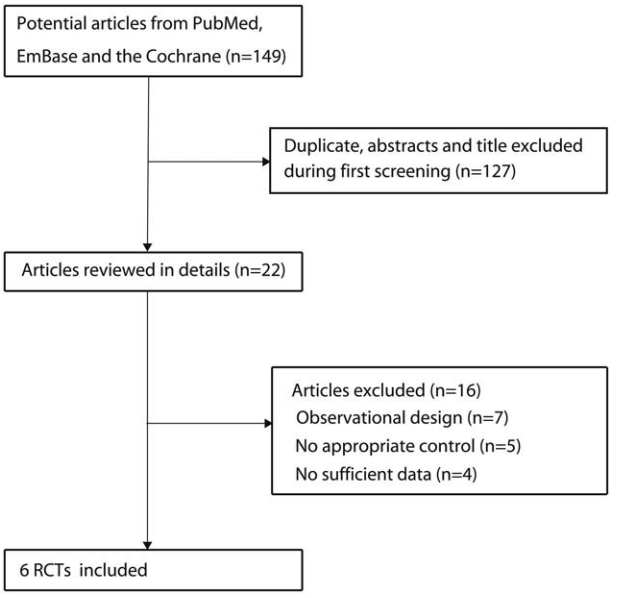

Figure 1. Flow diagram of literature search and trials selection process. RCT = randomized controlled trial.

Table 1

Summary of baseline characteristics of included studies.

Study	Publication year	Country	Sample size	Mean age, y	Boys (%)	Side (L/R/B)	Approaches	Trocars	Follow-up duration	Jadad scales
Chan et al[23]	2005	China	83	50.9 mo	67 (80.7%)	34/46/3	Intraperitoneal	Two 3 mm; one 5 mm	12.0 mo	4
Bharathi et al[24]	2008	India	69	52.5 mo	62 (89.9%)	25/44/0	Extraperitoneal	Three 5 mm	3.5 mo	2
Koivusalo et al[25]	2009	Finland	89	72.0 months	66 (74.2%)	35/54/0	Intraperitoneal	Three 5 mm	6.0 and 24.0 mo	4
Shalaby et al[26]	2012	Egypt	250	61.6 mo	130 (52.0%)	NA	Extraperitoneal	One 5 mm	24.0 mo	3
Celebi e al[27]	2014	Turkey	62	96.3 mo	62 (100.0%)	0/0/62	Intraperitoneal	Two 3 mm; one 5 mm	3.0 and 24.0 mo	4
Gause et al[28]	2017	USA	41	9.3 mo	31 (75.6%)	NA	Intraperitoneal	NA	24.0 mo	3

3.2. Study characteristics

The study characteristics of these 6 selected trials are summarized in Table 1. The 6 RCTs included 594 children (418 boys and 176 girls) with inguinal hernia in this study. The sample size of the included trials ranged from 41 to 250, and the mean age of enrolled patients ranged from 9.3 to 96.3 months. One trial was conducted in the United States, 1 trial in Finland, 1 trial in Turkey, 1 trial in Egypt, 1 trial in India, and the remaining 1 trial in China. Four trials used intraperitoneal approach, and the remaining 2 trials employed extraperitoneal approach. The follow-up duration ranged from 3.0 to 24.0 months. Study quality was assessed by Jadad scale, where 3 trials have scored 4, 2 trials scored 3, and the remaining 1 trial scored 2.

4. Meta-analysis

Data regarding the effect of LH versus OH on the risk of postoperative complications were available in 6 trials. Overall, the LH showed no significant effect on the risk of postoperative complications when compared with OH (RR: 0.63; 95% CI: 0.29–1.34; $P=.230$; Fig. 2), and observed an unimportant heterogeneity among the included trials. Sensitivity analysis indicated LH might protect against the risk of postoperative complications when the trial conducted by Celebi et al[27] was excluded, as this trial specifically included patients with greater age (Supplementary Figure 1, http://links.lww.com/MD/E687). Subgroup analysis indicated side ($P=.066$) and approach ($P=.091$) might affect the effectiveness between LH and OH on the risk of postoperative complications. Moreover, subgroup analysis indicated that LH was associated with reduced risk of postoperative complications in patients who are not assigned to unilateral or bilateral inguinal hernia (Table 2). No other significant differences between LH and OH on the risk of postoperative complications were detected based on the predefined factors.

The summary results of major postoperative complications and specific adverse events are shown in Figures 3 and 4. Overall, the children who received LH had a reduced risk of major postoperative complications than those who received OH (RR: 0.31; 95% CI: 0.10–0.91; $P=.034$, without evidence of heterogeneity), whereas no significant differences between groups regarding the risk of hypertrophic scar (RR: 0.26; 95% CI: 0.04–1.59; $P=.144$, without evidence of heterogeneity), skin sensitivity (RR: 1.00; 95% CI: 0.04–24.57; $P=.998$; with significant heterogeneity), transient hydrocele (RR: 1.30; 95% CI: 0.45–3.70; $P=.629$, without evidence of heterogeneity), contralateral hernia (RR: 0.44; 95% CI: 0.03–6.68; $P=.557$, with significant heterogeneity), iatrogenic ascent of the testis (RR: 0.12; 95% CI: 0.01–2.15; $P=.149$), peritoneal bleeding (RR: 4.86; 95% CI: 0.24–97.69; $P=.302$), postoperative vomiting (RR: 0.35; 95% CI: 0.04–3.27; $P=.356$, without evidence of heterogeneity), scrotal edema (RR: 0.19; 95% CI: 0.01–3.91; $P=.285$), stitch

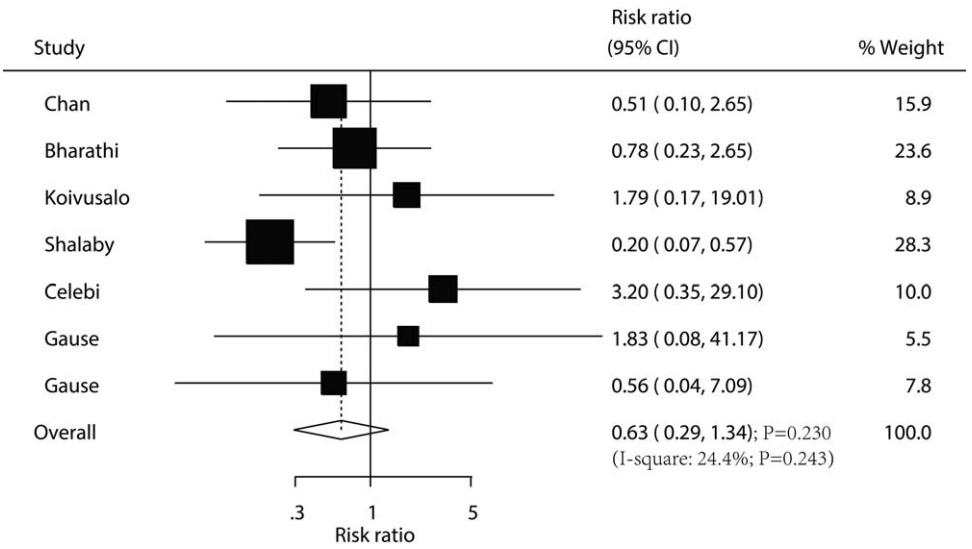

Figure 2. Laparoscopic herniorrhaphy versus open herniorrhaphy on the risk of postoperative complications. CI = confidence interval.

Table 2

Subgroup analysis of postoperative complications.

Factor	Subgroups	No. of cohorts	RR and 95% CI	*P*	Heterogeneity (%)/*P*	Interaction *P*
Country	Developed	3	1.19 (0.26–5.41)	0.822	0.0 (0.764)	0.267
	Developing	4	0.56 (0.20–1.58)	0.273	51.3 (0.104)	
Mean age, mo	≥60.0	3	0.84 (0.12–5.82)	0.860	69.8 (0.036)	0.392
	<60.0	4	0.71 (0.29–1.71)	0.444	0.0 (0.904)	
Percentage of boys (%)	≥80.0	3	0.87 (0.35–2.13)	0.755	0.0 (0.411)	0.158
	<80.0	4	0.48 (0.15–1.58)	0.228	27.8 (0.245)	
Side	Unilateral	3	1.00 (0.36–2.79)	0.999	0.0 (0.762)	0.066
	Bilateral	2	1.50 (0.27–8.33)	0.643	5.2 (0.305)	
	Both	2	0.26 (0.11–0.63)	0.003	0.0 (0.341)	
Approach	Intraperitoneal	5	1.07 (0.40–2.88)	0.897	0.0 (0.684)	0.091
	Extraperitoneal	2	0.38 (0.10–1.46)	0.158	64.3 (0.094)	
Jadad scales	4	3	1.13 (0.36–3.58)	0.831	0.0 (0.388)	0.142
	3 or 2	4	0.44 (0.18–1.09)	0.076	22.6 (0.275)	

CI = confidence interval, RR = relative risk.

granuloma (RR: 0.34; 95% CI: 0.01–8.14; $P=.507$), testicular atrophy (RR: 0.15; 95% CI: 0.01–2.88; $P=.209$), pain (RR: 7.45; 95% CI: 0.40–138.49; $P=.178$), and recurrence (RR: 0.74; 95% CI: 0.14–3.84; $P=.721$, with unimportant heterogeneity) were observed.

Data regarding the effect of LH versus OH on operative time in unilateral and bilateral inguinal hernia were available in 5 and 4 trials, respectively (Fig. 5). Overall, no significant difference between LH and OH on the duration of operative time (WMD: −2.91; 95% CI: −8.85 to 3.03; $P=.337$), and substantial heterogeneity among the included trials was observed. Sensitivity analysis indicated that LH might be associated with shorter operative time when compared with OH (Supplementary Figure 2, http://links.lww.com/MD/E688). Moreover, LH showed association with shorter operative time in children with bilateral inguinal hernia (WMD: −8.13; 95% CI: −12.08 to −4.19; $P<.001$), whereas no significant difference was observed in children with unilateral inguinal hernia (WMD: −0.30; 95% CI: −10.54 to 9.94; $P=.954$).

Data regarding the effect of LH versus OH on time to discharge and time to resume full activity were available in 3 and 4 trials, respectively. Children who received LH took longer time to discharge than those who received OH (WMD: 1.06; 95% CI: 0.29–1.84; $P=.007$; without evidence of heterogeneity; Fig. 6), whereas LH versus OH showed no significant effects on time to resume full activity (WMD: −2.14; 95% CI: −21.09 to 16.81; $P=.825$; with significant heterogeneity; Fig. 7).

4.1. Publication bias

Review of the funntabel plots did not rule out any potential publication biases (Supplementary Figures 3, http://links.lww.com/MD/E689 and 4, http://links.lww.com/MD/E690). The results of Egger and Begg tests indicated no significant

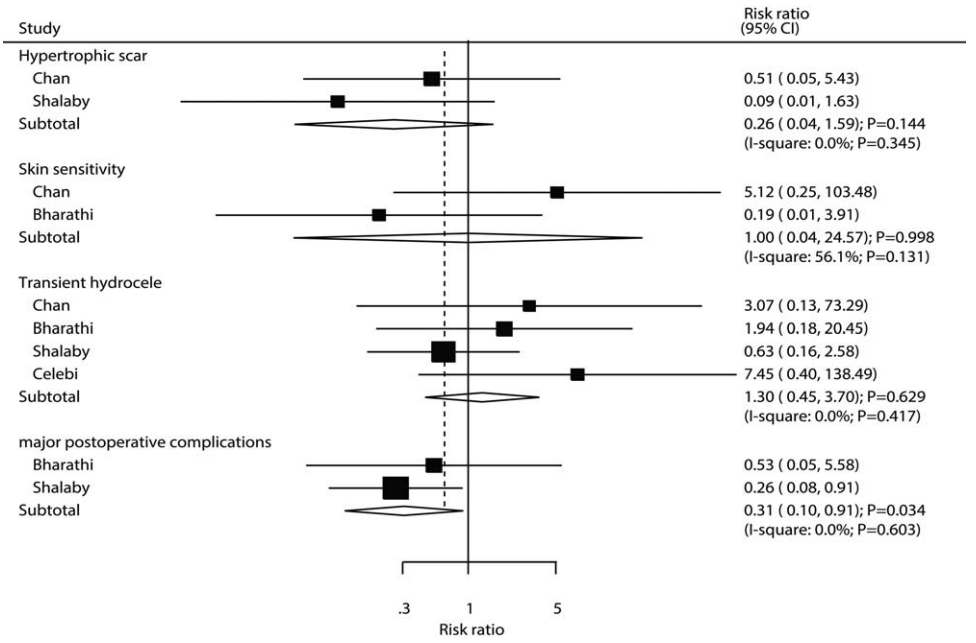

Figure 3. Summary results for the risk of major postoperative complications, transient hydrocele, hypertrophic scar, and skin sensitivity. CI = confidence interval.

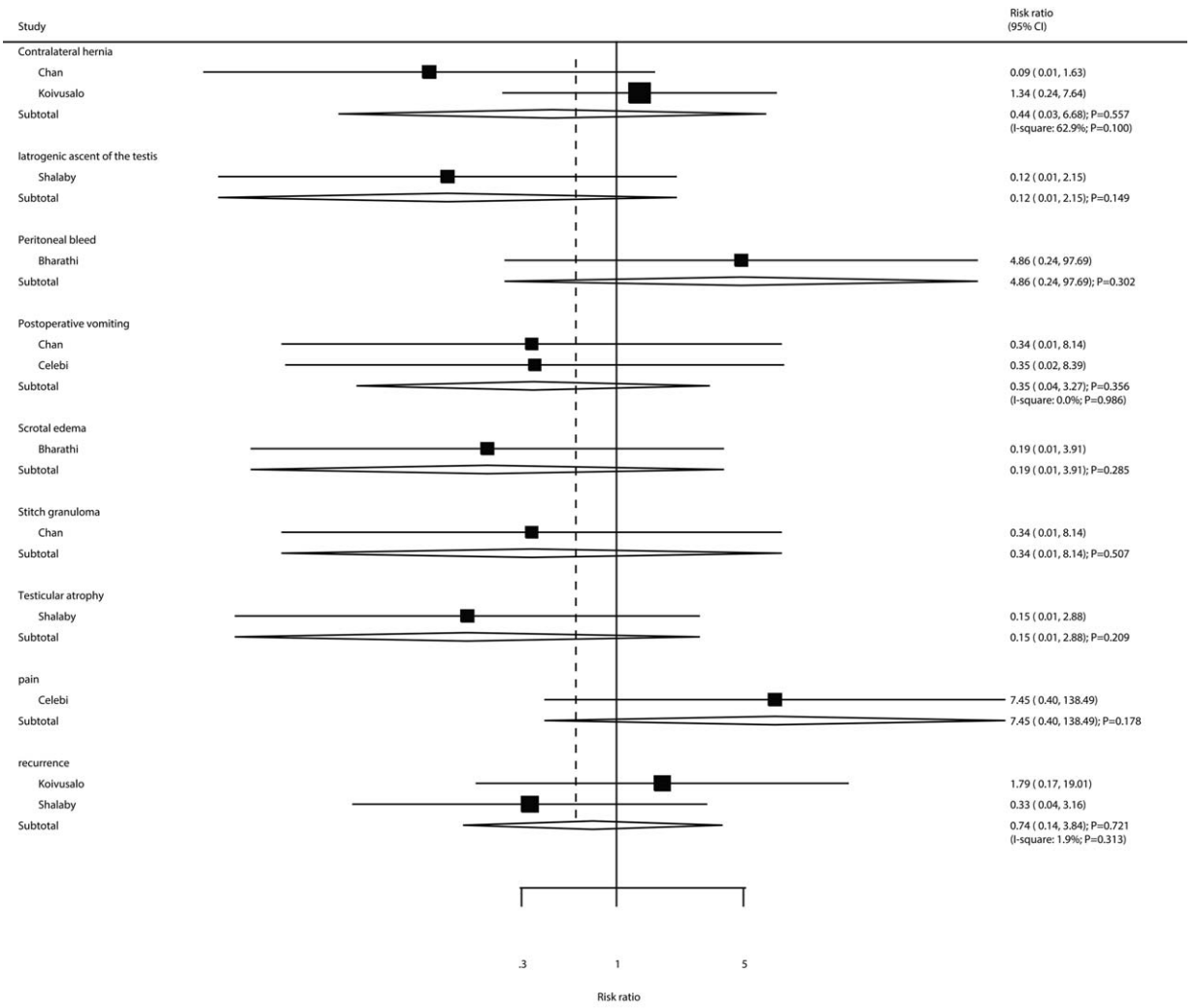

Figure 4. Summary results of the risk of other specific adverse events. CI = confidence interval.

publication biases for postoperative complications (*P* value for Egger: .065; *P* value for Begg: .368) and operative time (*P* value for Egger: .669; *P* value for Begg: .754).

5. Discussion

The present study selected 6 RCTs including 594 inguinal hernia children with wide range of patients' characteristics. The results of this study indicated that LH showed association with reduced risk of major postoperative complications and increased time to discharge when compared with OH. Moreover, bilateral inguinal hernia children who received LH had significantly reduced operative time when compared with OH, whereas no other significant difference was observed between LH and OH.

A meta-analysis conducted by Yang et al based on 3 RCTs and 4 observational studies showed that LH was associated with shorter operative time for bilateral hernias and lower risk of metachronic contralateral hernia when compared with OH. However, no significant differences between groups regarding patients' age, sex, affected side, operative time for unilateral hernias, hospital stay, time to resume full activity, recurrence, and complications were observed.[12] However, this study contained both RCT and observational studies, which might induce uncontrolled biases and overestimation of the pooled results. Another meta-analysis conducted by Feng et al based on 5 RCTs found that LH with extraperitoneal approach showed association with shorter operative time for unilateral and bilateral hernias.[13] Moreover, they pointed out that LH could protect against postoperative complications, especially the major postoperative complications in male children. Furthermore, no significant differences between groups regarding the risk of recurrence were observed. However, the analysis just on the basis of 5 RCTs and the pooled conclusions were variable. Moreover, stratified analyses were conducted based on the side and approaches, whereas the potential role of other characteristics was not well illustrated. The present study not only updated the results reported from previous meta-analysis,[13] the results of specific postoperative events were also reported.

No significant difference between LH and OH regarding the risk of postoperative complications was observed, whereas LH was associated with low risk of major postoperative complications. Most of the included studies reported no significant

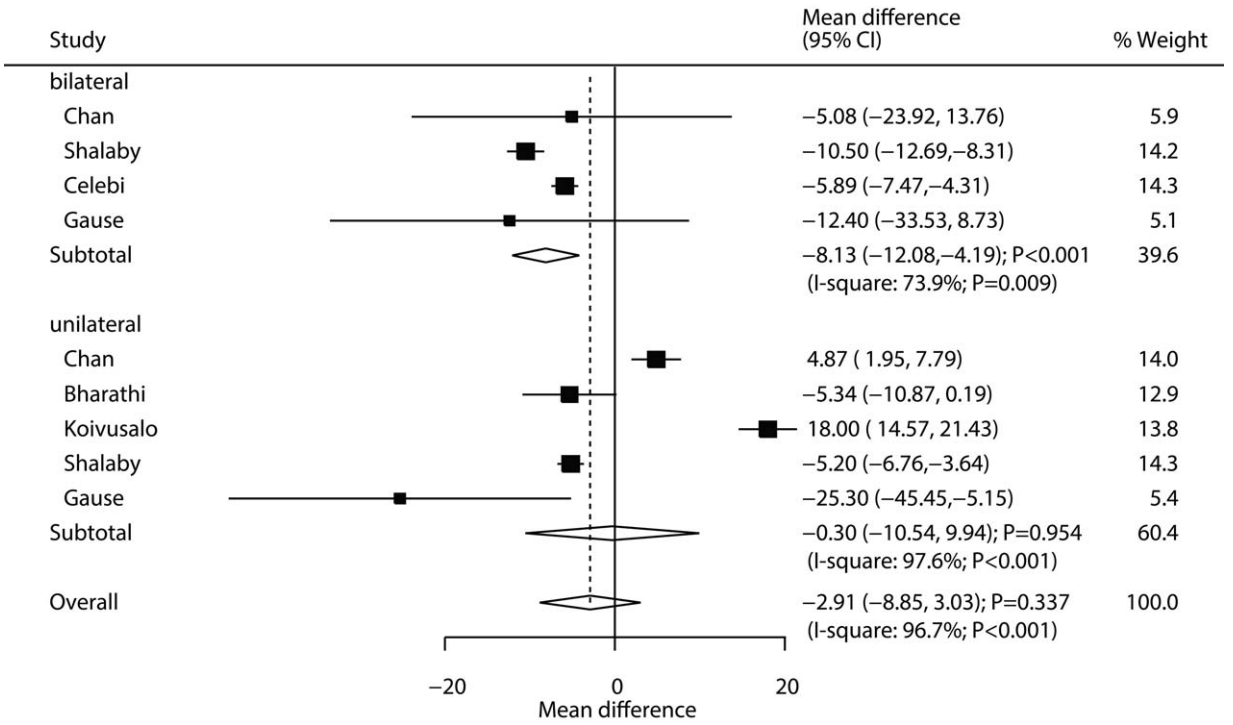

Figure 5. Laparoscopic herniorrhaphy versus open herniorrhaphy on operative time. CI = confidence interval.

differences between LH and OH regarding the risk of postoperative complications, whereas the study conducted by Shalaby et al reported patients undergoing LH had reduced operative time, lower risk of recurrence, no testicular atrophy, no iatrogenic ascent of the testis, and excellent cosmetic results.[26] The reason for this potentially reduced risk of postoperative complications or major postoperative complications in LH could be due to that the pediatric patients who received LH had protection against the risk of adverse events related to anesthesia, including death, cardiac events, permanent neurologic injury, and respiratory events such as desaturation, apnea, or laryngospasm.[29] Moreover, subgroup analysis indicated that the risk of postoperative complications in LH group was significantly reduced when the pooled studies did not include the side of inguinal hernia. Therefore, the treatment effects between LH and OH on the risk of postoperative complications according to side

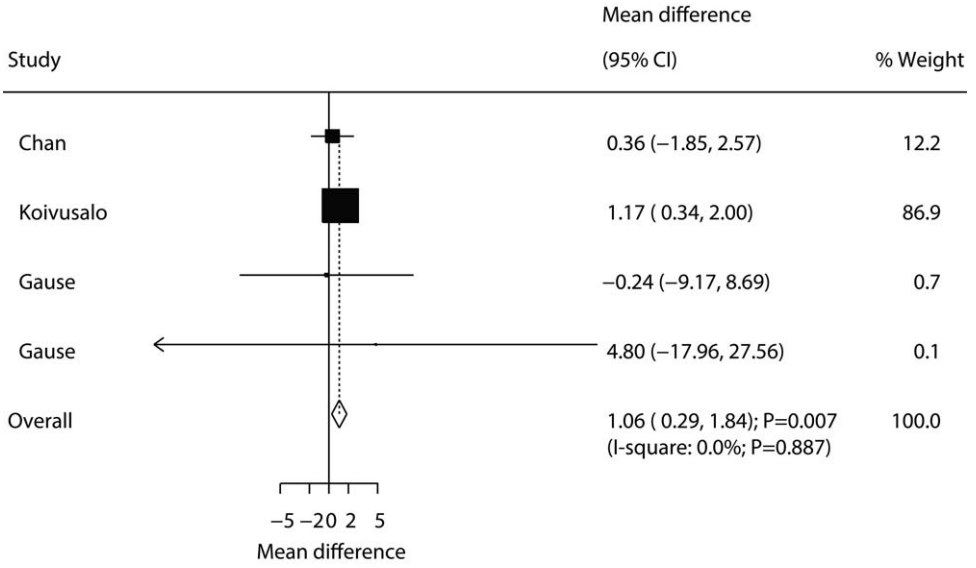

Figure 6. Laparoscopic herniorrhaphy versus open herniorrhaphy on time to discharge. CI = confidence interval.

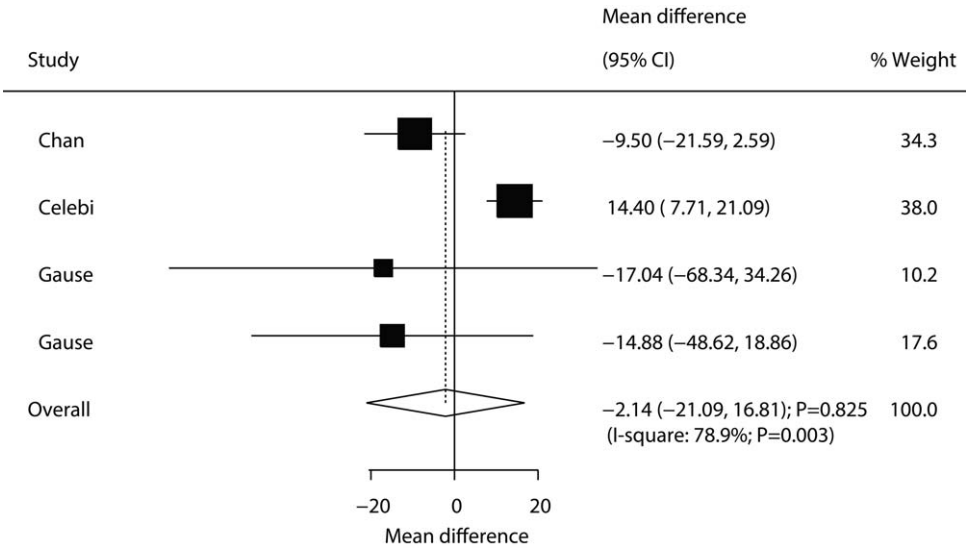

Figure 7. Laparoscopic herniorrhaphy versus open herniorrhaphy on time to resume full activity.

requires further studies for verification. Finally, no significant differences between groups regarding the risk of specific adverse events were observed. The reason for this could be due to that the trials that reported the risk of specific adverse events and event rates were lower than expected, producing wider 95% CIs, that is, with no statistically significant differences.

The summary results indicated that LH was associated with shorter operative time when compared with OH in children with bilateral inguinal hernia, whereas the time to discharge in LH group was significantly longer than those in OH group. The potential reason for this shorter operative time in LH group could be due to that the pediatric patients in LH group required less time under anesthesia for surgery than those in open technique. The longer time to discharge in LH group was mainly observed in the study conducted by Koivusalo et al,[25] which indicated that LH was associated with increased operation time and postoperative pain when compared with OH. The reason for this could be that the operative time in this study involved the closure of port incisions including fascia, injection of local anesthetic and wound dressings, and LH was conducted by 2 senior pediatric surgeons with considerable experience.[30]

However, there are several limitations in this study that needs to be addressed. First, the severity of inguinal hernia and background therapies intraoperatively were not available in most of the trials, which might affect the prognosis of inguinal hernia. Secondly, the summary results of numerous specific adverse events were reported in fewer trials, which might vary and require further trials for verification. Thirdly, publication bias was inevitable as the present study was based on published RCTs. Finally, the analysis of this study was based on pooled data, restricting us from conducting a more detailed stratified analysis.

In conclusion, the results of this study indicated that LH had a beneficial effect on the risk of postoperative complications, especially on major postoperative complications. Moreover, LH was associated with shorter operative time in bilateral inguinal hernia and longer time to discharge. Further large-scale RCTs should be conducted to compare the treatment effectiveness of LH with OH in children with inguinal hernia based on the side of the disease and approach used for LH.

Author contributions

Concept and design: Hao Wang, Guoqing Liu, Wenxian Zhang.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Guoqing Liu, Wenxian Zhang, Jianfeng Zhou.
Critical revision of the manuscript for important intellectual content: Bin Sun, Bin Jiang, Hao Wang.
Statistical analysis: Guoqing Liu, Wenxian Zhang.

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