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Review Article

Open versus laparoscopic pyloromyotomy for infantile hypertrophic pyloric stenosis: a systematic review and meta-analysis

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Abstract: Objectives: The aim of this meta-analysis is to compare the efficacy and safety of open versus laparoscopic pyloromyotomy for Infantile Hypertrophic Pyloric Stenosis. Methods: We performed a systematic literature search, using PubMed, The Cochrane Library, Embase, for randomized studies comparing open pyloromyotomy and laparoscopic pyloromyotomy for Infantile Hypertrophic Pyloric Stenosis. We conducted meta-analysis when possible and described other outcomes narratively. Results: Six randomized controlled clinical trials were included, with a total of 680 infants (343 in the laparoscopic group, 337 in the open group). The results of our meta-analysis showed no significant differences in overall complications between the groups (RR 1.05, P=0.84, 95% CI: 0.67 to 1.64); major complications (RR 2.01, P=0.10, 95% CI: 0.87 to 4.62); operating time (SMD: -1.21, P=0.44, 95% CI: -0.74 to 0.32). The laparoscopic group was associated with a higher incidence of incomplete pyloromyotomy (RR 6.57, P=0.03, 95% CI: 1.19 to 36.22). Patients who underwent laparoscopic pyloromyotomy had a shorter time to reach full feeding (SMD: -0.40, P=0.006, 95% CI: -0.69 to -0.11), shorter length of postoperative hospital stay (SMD: -0.18, P=0.04, 95% CI: -0.36 to -0.01). Results from two RCTs showed a better cosmetic outcome after laparoscopic pyloromyotomy compared to open procedure. Three other RCTs indicated a higher score of postoperative pain and more doses of analgesic drugs are needed after the open technique. Conclusion: Our meta-analysis demonstrates that both LP and OP are equally safe and effective techniques for the surgical management of IHPS, with LP being associated with a shorter time to reach full feeds; shorter length of postoperative hospital stay; better cosmetic outcome, and less postoperative pain.

Keywords: Pediatric surgery, infantile hypertrophic pyloric stenosis, laparoscopic surgery, meta-analysis, systematic review

Introduction

Infantile Hypertrophic Pyloric Stenosis (IHPS) is a common disease of young infants caused by hypertrophy of the pylorus, which can progress to complete obstruction of the gastric outlet, leading to projectile vomiting, and it requires surgery. IHPS occurs in approximately 2-5 per 1,000 live births, with a male-to-female ratio of 4:1 [1]. The standard surgical management of IHPS has been the longitudinal splitting of the seromuscular layer of the pylorus through a transverse right upper abdominal incision, first described by Ramstedt in 1912 [2]. Tan and Bianchi, then, changed the surgical approach using a circum-umbilical skinfold incision [3]. The development of the technology has allowed the introduction of laparoscopic pyloromyotomy (LP) by Alain in 1991 [4]. Since then, laparoscopic pyloromyotomy has gained wide popularity in the west for its assumed advantages, including shorter operating time, faster recovery, less postoperative pain, shorter length of postoperative hospital stay, and improved cosmetic outcome [5, 6]. Both open and laparoscopic procedures are widely utilized [7]. Results from several randomized controlled trials have been conflicting as to which surgical procedure is superior in terms of safety and efficacy [8-13]. Besides, it remains under debate whether laparoscopic pyloromyotomy may results in higher complications rate, like incomplete pyloromyotomy, mucosal perforations. Several systematic reviews and meta-analyses have been conducted but the results were inconsistent [14-18].

Therefore, we conducted this systematic review and meta-analysis to compare which surgical technique is superior in terms of major complications (incomplete pyloromyotomy and mucosal perforation), overall complications, incomplete pyloromyotomy, operating time, time to full feeding, length of postoperative hospital stay, postoperative pain, and cosmetic results.

Material and methods

Data sources

A systematic literature search was performed using PubMed database, Embase, Cochrane library database, on all randomized controlled studies from inception to 1 August 2021 comparing laparoscopic pyloromyotomy (LP) and open pyloromyotomy (OP) for IHPS. Keywords and medical subject heading (MeSH) terms used were "Pyloric Stenosis, Hypertrophic", "pyloromyotomy", "laparoscopic", "open". The search was limited to studies published in English. Two authors (HE Liang-Cai, LI Shi-Wei) independently performed an electronic database search to identify studies that met the eligibility criteria. The reference lists of potentially eligible studies were also checked for additional publications.

Selection criteria

Studies that met all the following criteria were included in the meta-analysis: (1) the trial was a randomized clinical trial; (2) the study was designed to compare surgical outcomes of infants with IHPS between laparoscopic pyloromyotomy and open procedures; and (3) Report on at least two of the outcome measures (incomplete pyloromyotomy, mucosal perforation, overall complications, operative time, time to full feeds, length of postoperative hospital stay, cosmetic results, postoperative pain).

Data collection and analysis

For all included studies, two authors (HE Liang-Cai, LI Shi-Wei) independently extracted the following data from each study: first author, year of publication, center type, the surgical technique of open group, number of subjects operated on with each technique, primary and secondary outcome measures. We estimated the sample mean and standard deviation (SD) using McGrath's method when the outcome of continuous variables was reported in sample median and one or both of (i) the minimum and maximum values and (ii) the first and third quartiles [19].

Review Manager (RevMan) [Computer program]. Version 5.4. (The Cochrane Collaboration, 2020) was used for data entry and statistical analysis. Heterogeneity among studies was assessed using I-square statistic to determine whether a fixed ($I^2<50\%$) or random ($I^2>50\%$) effect model should be used. Dichotomous outcomes were expressed in risk ratios (RR) with their 95% confidence interval (CI) values. Continuous variables were expressed in mean difference (MD) when measured similarly between studies, and in standard mean difference (SMD) when measured in different ways. Statistical significance was assessed using the Z test, and the pooled data were considered to be statistically significant at $P<0.05$.

Assessment of risk of bias in included studies

The quality of RCT studies was assessed independently by two reviewers using the Cochrane Collaboration's risk for bias assessment tool, which evaluated the selection bias (random-sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), and reporting bias (selective outcome reporting). Each criterion was assessed as low risk for bias, high risk for bias, or uncertain risk for bias. Disagreements were resolved by group discussion.

Results

The literature research yielded 107 potentially relevant studies. After a review of the abstracts and removal of duplicates, 27 studies were selected for further assessment. When inclusion criteria were applied, 6 randomized controlled trials with a total of 680 patients were finally eligible for this study, which was shown in **Figure 1**. Study details and the quality evaluation of all included RCTs are given in **Table 1** and **Figure 2**, respectively.

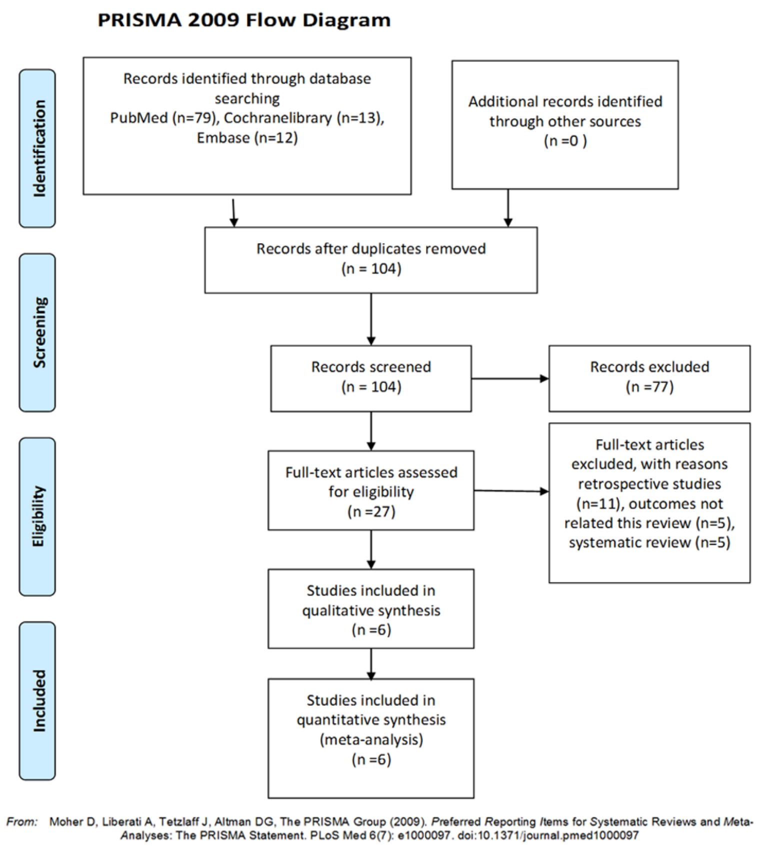

Figure 1. Flow diagram of the selection process of the studies included in the Meta-analysis.

Complications

All 6 studies described intraoperative and postoperative complications, which were hand-checked and classified into overall complications, major complications (mucosal perforation, incomplete pyloromyotomy), incomplete pyloromyotomy. There were 14 (4.1%) major complications in the laparoscopic group and 6 (1.8%) in the open group, and the difference was not significant between LP and OP (RR 2.01, P=0.10, 95% CI: 0.87 to 4.62, **Figure 3**) when a fixed-effects approach was used. 8 (2.3%) incomplete pyloromyotomy occurred in patients who underwent LP which required revision pyloromyotomy, compared to zero in the open group. The results reached a significant difference (RR=6.57, P=0.03, 95% CI: 1.19 to 36.22, **Figure 4**). There were no significant differences (RR 1.05, P=0.84, 95% CI: 0.67 to 1.64, **Figure 5**) in terms of overall complications between laparoscopic group 34 (9.9%) and open group 33 (9.7%).

Operating time

Three studies found that the LP group was associated with a statistically shorter operating time between the LP group and OP group, while two studies concluded there is no difference, and the study of Leclair et al found a shorter duration of surgery in OP group than LP group, which was statistically significant. We pooled the results and found no statistical difference in operating time (SMD: -1.21, P=0.44, 95% CI: -0.74 to 0.32, **Figure 6**) between the LP group and the OP group.

Time to full feeding

All studies reported the time after surgery to reach full feeding. Four studies were reported data in the form of mean time and standard deviation, one in median (IQR, range), which were transformed into mean time and standard deviation using McGrath's method. besides, the study of Siddiqui et al - only reported the mean time to full feeding without standard deviation or interquartile range, and we reached the author for the needed results but it was unavailable. Overall the data revealed no significant difference between the LP group and OP group. In summary, the standard mean difference in time to full feeding was -0.40 h in our study, in favor of the LP group, and this difference was statistically significant (SMD: -0.40, P=0.006, 95% CI: -0.69 to -0.11, **Figure 7**).

Length of postoperative hospital stay

All included studies reported on the length of postoperative hospital stay. We excluded the data from the study of Leclair et al, for discharged patients on the third postoperative day unless an event occurred. Again, we cannot include the data of Siddiqui for how the results were presented. we found a statistically shorter length of postoperative hospital stay (SMD:

Table 1. Baseline characteristics of included studies

Reference	Publication of Year	country	n (LP, OP)	Center type	Open group Surgical procedure
Greason et al	1997	USA	20 (10, 10)	Single	umbilical fold incision
Leclair et al	2007	France	102 (50, 52)	Single	circum-umbilical approach
St. Peter et al	2006	USA	200 (100, 100)	Single	according to surgeon's personal technique
Hall et al	2009	UK	180 (87, 93)	Multicenter	supra-umbilical incision
Siddiqui et al	2012	USA	98 (56, 42)	Single	right upper quadrant incision
Ismail et al	2020	Egypt	80 (40, 40)	single	upper right transverse incision

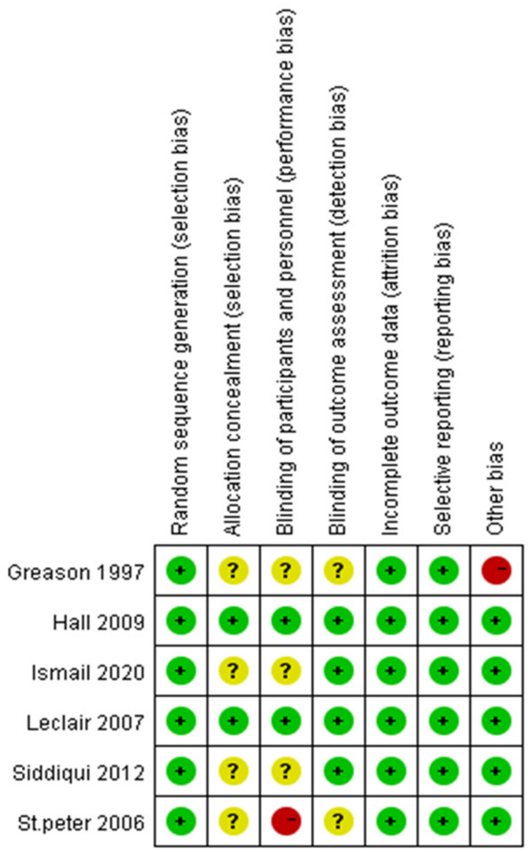

Figure 2. Quality assessment of risk bias in the studies included.

-0.18, P=0.04, 95% CI: -0.36 to -0.01, **Figure 8**) in the LP group compared to the OP group.

Cosmetic results

Two studies compared the cosmetic results between the LP group and the OP group, both in favor of the LP group. We could not do a meta-analysis of this outcome, because of how the outcome was measured. In the study of Siddiqui et al, a modified BIQ to measure parents' satisfaction with the child's body image was used, and parents described statistically significant better cosmetic results. In the study of Ismail et al, parents' satisfaction with their children's cosmetic outcome was assessed by reporting their impression (very good, good, or poor), and parents reported very good cosmetic results in 90% of cases in the LP group compared to 72.5% in the OP group.

Postoperative pain

Three studies reported on the outcome of postoperative pain. The number of doses of analgesic drugs was recorded for quantitative analysis. All three studies reported statistically fewer doses of analgesic drugs usage in the laparoscopic group compared to the open group.

Discussion

The studies included in our meta-analysis are of high quality. All of the included studies had baseline characteristics between two groups. In this study, we found the laparoscopic approach was found to be as safe as the open approach. There is no difference in major complications and overall complications, but a slightly higher rate of incomplete pyloromyotomy was found. This is in line with several other studies [20-22]. This may be explained by the lack of tactile sensation in laparoscopic procedures and the over cautiousness to avoid mucosal perforation. The impact of a learning curve on the results of LP cannot be ignored [23]. Van Der Bilt et al [21] showed that with the increase of laparoscopic skills, the rate of complete pyloromyotomy declined from 8.3% to 2.7%. In terms of time-related results, our review shows that there is no statistical difference in operating time, but laparoscopic approach is associated with faster recovery, shorter time to reach full feeding, and quicker discharge. Our study shows that laparoscopic

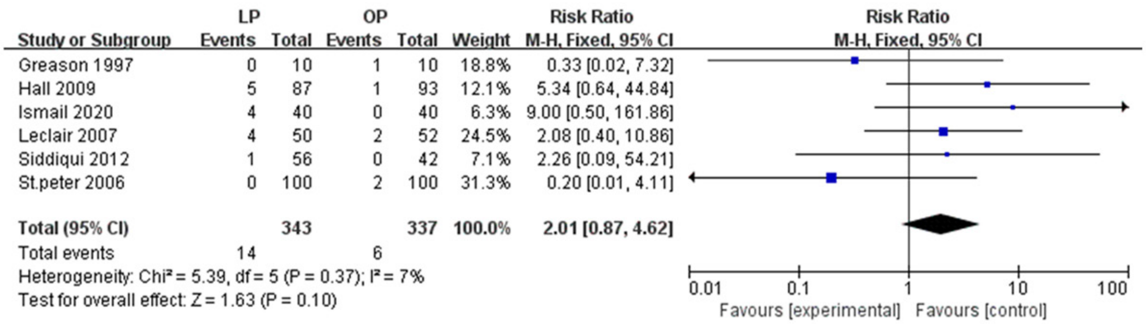

Figure 3. Forest plot of risk ratio with confidence intervals for major complications.

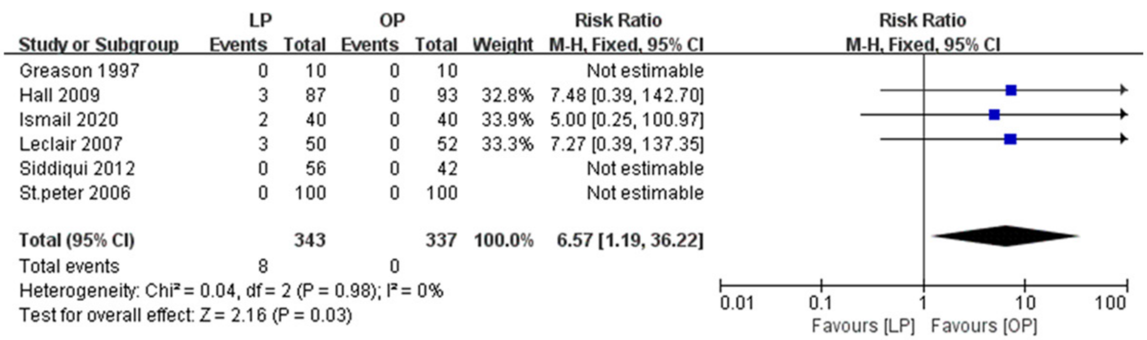

Figure 4. Forest plot of risk ratio for incomplete pyloromyotomy.

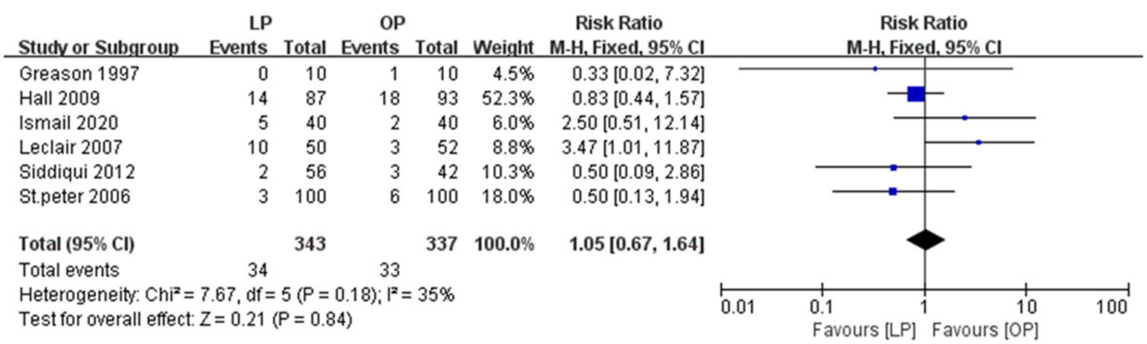

Figure 5. Forest ploy of risk ratio for overall complications.

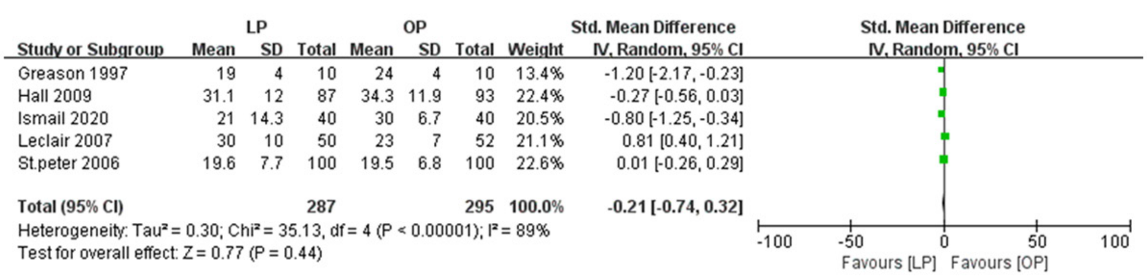

Figure 6. Forest plot for operating time.

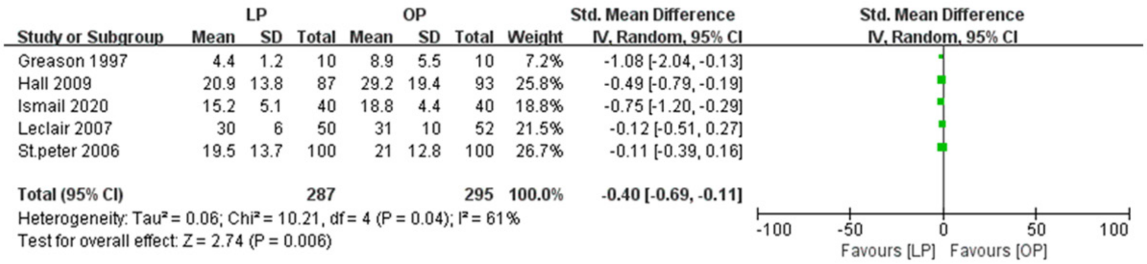

Figure 7. Forest plot for time to full feeds.

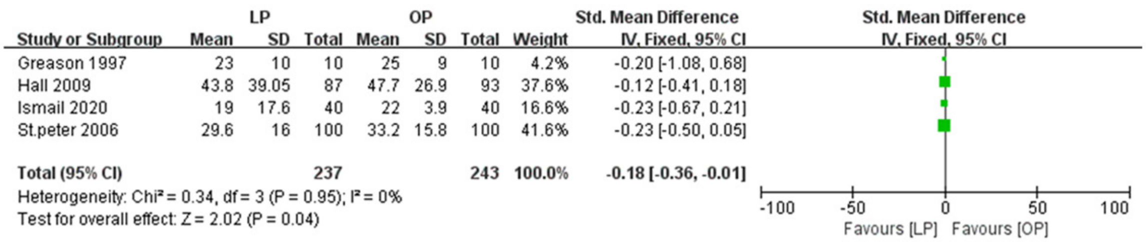

Figure 8. Forest plot for length of postoperative hospital stay.

approach may result in less postoperative pain and fewer doses of analgesics drugs compared with an open approach, as reported by Lemoine et al [24]. The laparoscopic approach also has a cosmetic benefit over open surgery as demonstrated in our review. This is also confirmed by the study of Harcourt et al [25] and St Peter et al [6]. However, this conclusion may be weakened by the fact that this result comes from two studies in which an open approach was performed by less right upper quadrant incision instead of a more aesthetic supraumbilical skinfold incision.

Our results were consistent with previous systematic reviews. The most recent by Sathya et al [17], published in 2017, included only five randomized studies comparing laparoscopic approach with an open approach.

However, our meta-analysis has several limitations. First, the number of included studies is small. The construction of funnel plots cannot be made to examine the publication bias because of the small number of included studies. Statistical heterogeneity of data also exists in the analysis of operating time and time to full feeding. This may be explained by the hospital types, surgeon's level of skill, and proficiency. The variation of postoperative feeding schedule between each study may impact the time to reach full feeds as well as the length of the postoperative length of hospital stay. The exact follow-up time was not always given in included studies [8]. The application of English-language only search may cause missing of some relevant data.

Conclusion

This systematic review suggests that both LP and OP are safe and LP is associated with a modestly higher incidence of major complications, especially incomplete pyloromyotomy, but faster recovery and better cosmetic results, and less postoperative pain. Therefore, we recommend the LP over OP in the treatment of IHPS.

Disclosure of conflict of interest

None.

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