

Systematic Review

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Laparoscopic or open paediatric inguinal hernia repair – a systematic review

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ABSTRACT

Introduction: Inguinal hernia repair is the most common surgical procedure in paediatric patients. Despite limited evidence, an increasing number of surgeons suggest laparoscopic repair as an alternative to the gold standard of open repair. This review critically analysed post-operative clinical outcome on open versus laparoscopic inguinal hernia repair in paediatric patients. Before initiating the study, recurrence was defined as the primary outcome, and secondary outcomes were early post-operative pain, operation time and surgical site infections.

Methods: The PRISMA guidelines were followed. Using strict inclusion and exclusion criteria, the following databases were searched: MEDLINE, Cochrane Library, Web of Science and Embase (May 2019).

Retrospective and uncontrolled studies were excluded.

Results: Five studies were identified, four randomised controlled trials (n = 272) and one controlled prospective study (n = 85) which included a total of 357 patients. Generally, the studies included few patients, were highly heterogenic and were overall of moderate quality. With a follow-up time ranging from three months to 14 years, there was no difference in recurrence rate after unilateral open (0-2%) versus unilateral laparoscopic (0-4%) or bilateral open versus bilateral laparoscopic repair (n = 281; p > 0.05 in all studies). There were no other significant differences in any of the outcomes, including post-operative pain (p > 0.05).

Conclusions: There is no solid evidence that clinical outcome is improved after laparoscopic paediatric inguinal hernia repair compared with the gold standard.

KEY POINTS

- An increasing number of paediatric surgeons are advocating for primary laparoscopic inguinal hernia repair instead of the current open repair.
- Studies comparing primary laparoscopic hernia repair with open repair are heterogenous in methodology and there are very few high-quality studies.
- There is no significant difference in current literature between primary paediatric laparoscopic versus open repair in regard to recurrence, post-operative pain and operative time.

The prevalence of groin hernia repair peaks in childhood at 0-5 years (males 1.4%; females 0.4%) and in adults at 75-80 years (males 4.1%; females 0.36%) [1, 2]. The open repair is the gold standard as evidenced by nationwide data (n = 2,476) [3]. By performing an open repair, the integrity of the abdominal cavity is respected as opposed to a laparoscopic approach to repair [4]. However, since the introduction of laparoscopy in general surgery 30 years ago [5] in paediatric inguinal hernia repair [6, 7] and especially in the past decade, an increasing number of surgeons have argued for laparoscopic paediatric repair.

One previous systematic review and four meta-analyses have analysed the clinical results of open versus laparoscopic paediatric inguinal hernia repair [8-14]. Unfortunately, the methodology was weak in most reviews and did not follow the premises of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [15]. Despite analysing mostly small, highly heterogenic studies with poorly defined outcomes and even pooling of unilateral and bilateral repair, the authors of the reviews [8, 9] advocated for laparoscopic rather than open repair. A recent meta-analysis pooling data from a heterogenic pool of studies found that open and laparoscopic repair are equivalent in terms of recurrence rates, surgical time and length of hospitalisation. However, laparoscopic repair is associated with an increased risk of wound infection, but a decreased risk of ascending testis [10]. The most recent meta-analysis from 2019 (including ten controlled non-randomised and randomised trials) pragmatically concluded that evidence supports paediatric inguinal hernia repair according to the surgeon's preference, either open or laparoscopic [13]. With reviews and meta-analysis including studies with different inclusion and exclusion criteria pointing in different directions, a critical clarification of the evidence on paediatric inguinal hernia repair is important.

For the above-mentioned reasons, this systematic review aimed to conduct a critical review of the literature comparing clinical outcome after non-mesh open versus laparoscopic inguinal hernia repair in paediatric patients. Due to the heterogenic and often poor-quality literature, it was decided not to supplement the present review with a meta-analysis. The primary outcome was recurrence after a primary inguinal hernia repair. Early post-operative pain, operation time and surgical site infections (SSI) were registered as well. There was an insufficient number of studies describing outcomes after umbilical hernia repair, and paediatric umbilical hernia is not included in the study at hand.

Methods

A literature search was performed in MEDLINE, Embase, Web of Science and the Cochrane Library databases up to May 2019. This systematic review was conducted in accordance with the PRISMA statement and 2009 checklist [15]. Before the initiation of the study, the literature search strategy and outcome parameters were determined. Based on the PICOS approach, participants, interventions, comparisons, outcomes and study design keywords were selected. Here, we use MEDLINE as an example of the systematic searches. The MEDLINE search string was: (("Hernia, Abdominal"[Mesh]) OR ((abdominal hernia[Text Word] OR inguinal hernia[Text Word] AND ((child[Text Word] OR children[Text Word] OR infant[Text Word] OR infants[Text Word] OR adolescent[Text Word]))) Filters: Publication date from 1997/01/01 to 2019/05/01; Humans; English. Furthermore, a full review of abstracts from the reference lists of the included articles was scrutinised to identify relevant additional articles.

Only randomised controlled trials (RCT) and prospective controlled studies (restricted to full-text publications in English language) on primary inguinal hernia repair in patients < 17 years of age were included. Retrospective and uncontrolled studies were excluded from the analysis. Only studies with well-defined primary or secondary clinical outcomes (recurrence, post-operative pain, operation time and surgical infection) were included. Studies using paediatric/child mesh repair as routine or studies focusing on pathophysiological outcomes such as testicular blood perfusion were not included. Outcomes in sub-groups of patients such as obese patients were not addressed. Excluded from the literature analysis were studies reporting un-specified hernias other than inguinal hernias, operation on acute incarcerated hernia, pooling of data without separate surgical procedure analysis and repair techniques not reporting surgical technique, patients with congenital malformations, narrative reviews and publications before 1995 (to our knowledge, the first study on paediatric laparoscopic inguinal hernia repair was published in 1998 [6, 7]).

Two authors independently scrutinised all titles and abstracts. In case of discrepancies, a consensus was obtained by the two authors. Full-text manuscripts were selected independently and analysed by the same two authors. This review is registered in PROSPERO with the following identification number: CRD42018087956; it was registered before the initiation of the present study analysis. The following data were extracted: study design, number of patients, surgical technique, recurrence, operation time, follow-up, early post-operative pain and SSI.

Quality assessment was guided by criteria from the United States National Institutes of Health for RCT and prospective controlled studies. The assessment tool has been used extensively in the surgical literature including in hernia studies. Based on these criteria, studies were classified as being of high, moderate, or poor quality (A, B, or C, respectively). The maximum score was 20 and classification (good = 18-20; moderate = 15-17; ≤ 14 = poor) was arbitrary, as suggested by Slim et al [14]. Assessment was blinded between the two authors and conducted by the two authors of this study.

The reported p-values in the results section are derived from the original intergroup analysis of RCTs in the present systematic review.

Results

Overall, studies were dominated by highly heterogeneous methodology, follow-up length and outcome definitions. Five studies matched the inclusion criteria, four RCTs (n = 272) [2, 16-19] and one prospective controlled (n = 85); a total of 357 paediatric patients (**Figure 1**). The main results are presented in **Table 1**. Unilateral open versus unilateral laparoscopic paediatric hernia repair was compared in four studies (three RCTs and one controlled prospective study (n = 281)). Bilateral open versus bilateral laparoscopic paediatric hernia repair was compared in three RCTs including a total of 76 patients. Study quality was poor in one [19], moderate in three [2, 17, 18] and high in one study [16].

TABLE 1 / Data from all included studies directly comparing laparoscopic repair with open repair.

Reference	Study quality	Surgical technique	Study arms (patients, n)	Recurrence, %	Post-operative pain	Operative duration, min.	SSI	Age	FU, mo. s
<i>RCT</i>									
Gause et al, 2017 [16]	High	Not specified vs subcutaneous endoscopically assisted ligation of the internal ring	Open unilat (10) vs lap unilat (17) Open bilat (5) vs lap bilat (9)	0 vs 0 0 vs 11	→ →	53 vs. 27* 50 vs. 38	→ →	≤ 3 yrs	24
Chan et al, 2005 [2]	Moderate	Double ligation vs purse-string suture	Open unilat (40) vs lap unilat (40) Open bilat (2) vs lap bilat (1)	0 vs 0 0 vs 0	↑ →	18 vs. 23* 39 vs 34	→ →	> 3 mo.s	11-12
Koivusalo et al, 2009 [17]	Moderate	Not specified vs N-shaped suture	Open unilat (42) vs lap unilat (47)	2.4 vs 4.3	↓	38 vs. 63*	→	4-16 mo.s	24
Celebi et al, 2014 [18]	Moderate	Ligation of the sac vs purse-string suture	Open bilat (31) vs lap bilat (28)	0 vs 0	→	38 vs. 33	-	6-14 yrs	3-24
<i>Pros control</i>									
Saranga Bharathi et al, 2008 [19]	Poor	High ligation and opening of the distal sac vs purse-string suture	Open unilat (34) vs lap unilat (51)	0 vs 0	→	30 vs. 25	→	< 14 yrs	3.5

bilat = bilateral repair; FU = follow-up time; lap = laparoscopic; pros control = prospective controlled study; RCT = randomised controlled trial; SSI = surgical site infections; unilat = unilateral repair.

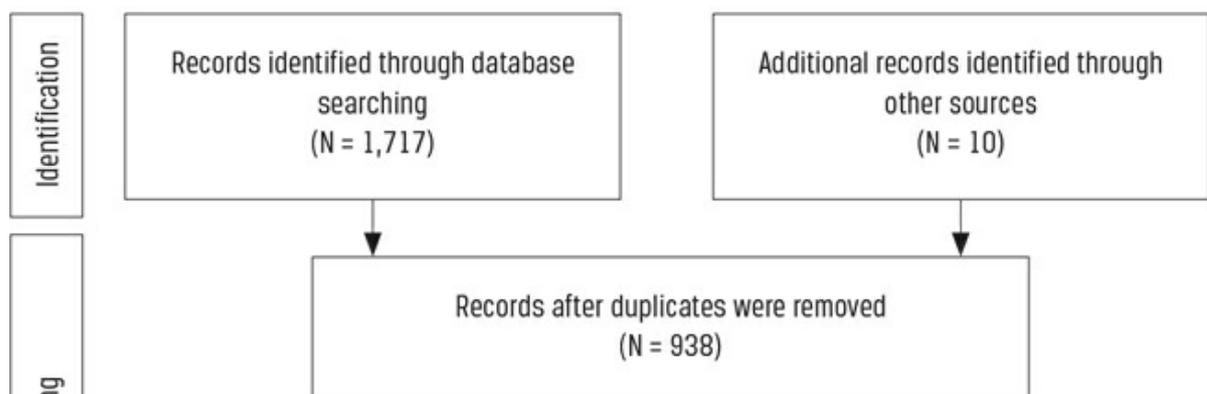
↑: statistically significant better outcome after lap repair.

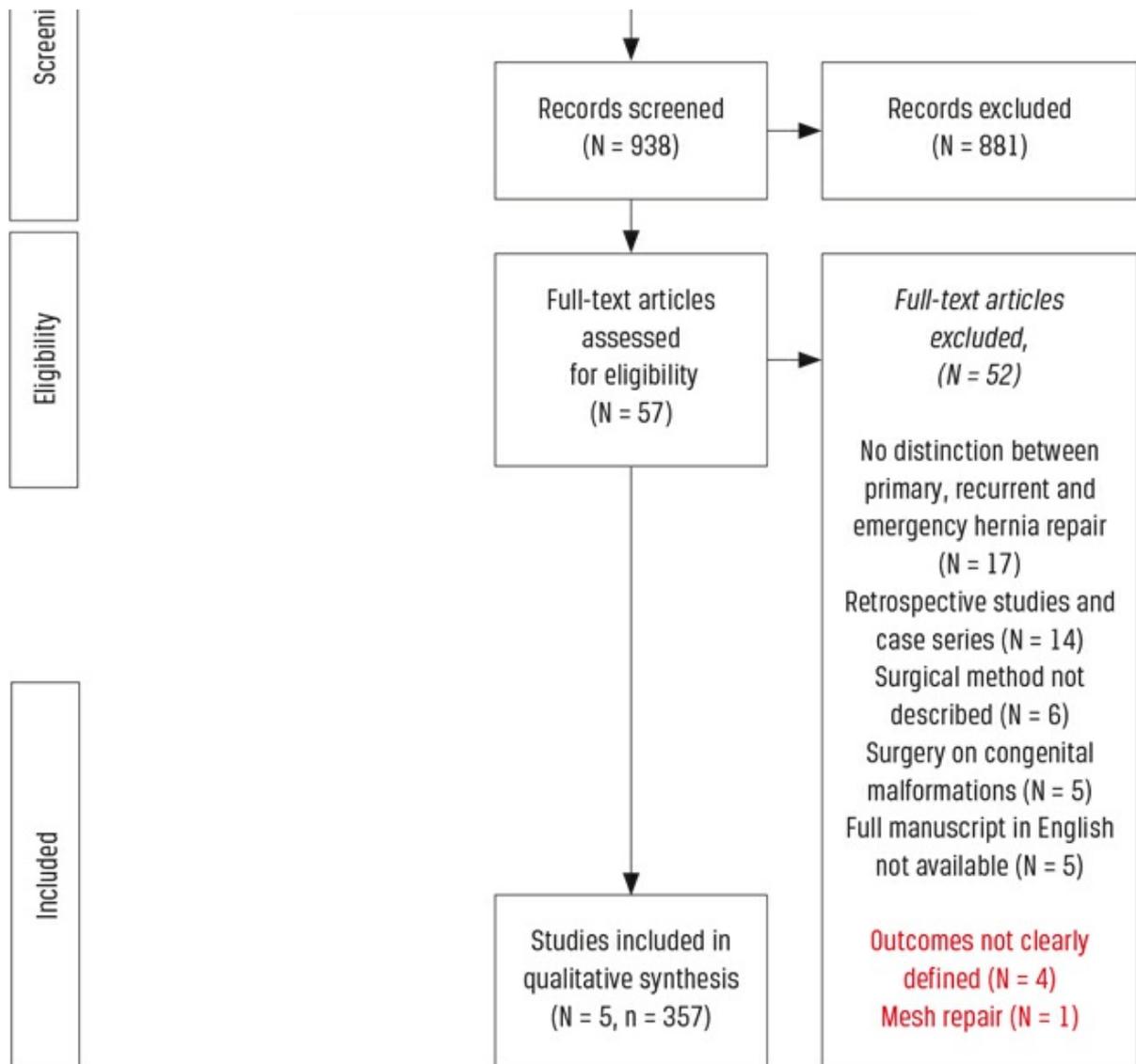
→: no statistically significant difference between lap repair and open repair.

↓: statistically significantly poorer result after lap repair than after open repair.

*) p < 0.05.

FIGURE 1 / PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) study flow diagram.





N = number of studies, n = number of paediatric patients.

Recurrence

Recurrence was reported in three RCTs after unilateral hernia repair [2, 16, 17] and in one prospective controlled study [19]. In none of the studies was recurrence assessment defined, and no information on recurrence was provided (questionnaire, physical, radiology, etc. assessment). The risk of recurrence in open unilateral repair was 0-2%. In unilateral laparoscopic repair, the risk of recurrence was 0-4%. There were three patients with recurrence after bilateral laparoscopic repair and one in the open bilateral repair groups.

In summary, there was no apparent difference in recurrence between open and laparoscopic paediatric inguinal hernia repair for either unilateral or bilateral repairs. Recurrence rates were similar in both open and laparoscopic repair. No p-values were reported in the included studies.

Post-operative pain

All five studies reported specifically on post-operative pain [2, 16-19]. A variety of pain scales – the Children’s and Infants Postoperative Pain Scale, Children’s Hospital of Eastern Ontario Pain Scale, and more generic scales like the Numeric Rating Scales – were used. One RCT found no significant differences in pain between unilateral open and unilateral laparoscopic repair [16] ($p = 0.55$), pain was measured every hour for six hours and then every six hours for twelve hours. One study found a significantly higher post-operative pain in unilateral open repair than in unilateral laparoscopic repair [2] ($p = 0.03$). Pain level was recorded every hour for the first six hours and then every six hours until discharge. Finally, one study reported less pain with unilateral open surgery than with unilateral laparoscopic repair [17] ($p < 0.05$) (pain was measured by a nurse when deemed necessary until discharge, and then by a phone call made by a nurse; hereafter parents scored pain on a structured scale until the third morning). No difference in pain was reported in the prospective controlled study by Saranga Bharathi et al [19] ($p > 0.05$). Three RCTs compared post-operative pain after bilateral open ($n = 38$) versus bilateral laparoscopic hernia repair ($n = 38$) [2, 16, 18]. There was no significant difference in post-operative pain between bilateral open versus bilateral laparoscopic repair, except in the study by Celebi et al ($n = 59$), where post-operative pain in the first hour after surgery was significantly lower in the laparoscopic group than in the open group ($p = 0.036$). However, pain was not significantly different at later measurements (pain was repeatedly recorded during the first 24 hours) [18].

In summary, there was no important difference between open and laparoscopic repair, for either unilateral or bilateral repair.

Operative time

Operative time was investigated in all five included studies [2, 16-19]. Two out of the three included RCT studies reported a shorter operative time for open unilateral inguinal hernia repair than for unilateral laparoscopic repair ($p < 0.001$) [2, 17]. The third RCT reported a longer operative time for unilateral open hernia repair than for unilateral laparoscopic repair ($p < 0.01$) [16]. However, the authors defined a unilateral open repair as an open hernia repair with a subsequent diagnostic laparoscopic visualisation of the contralateral groin area.

Three RCTs investigated bilateral open hernia versus bilateral laparoscopic hernia repair and found no significant differences in operative time ($p > 0.05$) [16] (Table 1) (none of these studies compared unilateral with bilateral hernia repair). In these studies, patients in both surgical groups were diagnosed preoperatively with bilateral hernias.

In summary, there was no important difference between open and laparoscopic repair

Surgical site infection

Four studies compared the incidence of post-operative infections between open and laparoscopic repair [2, 16, 17, 19]. None of the studies defined SSI. No difference in SSI was reported in

unilateral open versus unilateral laparoscopic repair based on three RCTs and one prospective controlled study [2, 16, 17, 19] ($p > 0.05$). The infection rate after both open and laparoscopic repair was $\leq 2\%$. No difference in post-operative infection was reported in bilateral open versus bilateral laparoscopic repair ($p > 0.05$) [2, 16]. The studies included in the present review did not allow for discrimination between SSI and surgical site occurrence (infection, seroma, wound dehiscence, or even the extremely rare formation of an enterocutaneous fistula).

In summary, there was no difference in SSI between open and laparoscopic paediatric inguinal hernia repair for either unilateral or a bilateral repair.

Discussion

Open repair for a unilateral paediatric inguinal hernia is considered the gold standard, respecting the integrity of the abdominal cavity. This study basically found no clinical advantages for laparoscopic repair. The surgical evidence is based on only a few RCTs and one prospective (controlled) study with an overall moderate study quality. Laparoscopy might, in theory, be more beneficial in the case of bilateral repair, but due to the low numbers of patients included in the comparison of bilateral laparoscopic versus open repair, the optimal treatment of bilateral inguinal hernias cannot be determined; also, the optimal treatment of a recurrent hernia cannot be concluded due to the lack of studies. Four of the included studies included primary inguinal hernias exclusively [2, 16-18], whereas one study did not provide any information [19].

Open repair of paediatric inguinal hernia is performed with a variety of modifications such as external ring incision, hernial sac twisting, and double and single ligation [20]. There is no international consensus on the optimal open technique for paediatric inguinal hernia repair, and the optimal technique is not supported by solid evidence [21-23]. The results from the present review elucidate the lack of solid evidence for an evidence-based beneficial outcome of laparoscopic hernia repair in children compared with open repair. Outcomes from retrospective studies including a large number of children demonstrate very low complication rates for open repair in the paediatric patient group (1.1-1.2%) [3, 24, 25]. Therefore, a shift in surgical management of paediatric hernia from open repair to laparoscopic repair would require solid evidence from large high-quality RCT studies and possibly large nationwide database studies including long follow-up on the risk of recurrence. Based on pooled data from small, heterogeneous, retrospective studies and the limited number of RCTs, two previous systematic reviews concluded that a laparoscopic approach is beneficial [8, 9]. The third and latest meta-analysis [10] reported insignificant findings between laparoscopic and open repair but advocated for laparoscopic repair if the necessary expertise was available. This conclusion may, however, run contrary to the doctrine that a gold standard treatment should not be replaced by a novel treatment unless benefits are supported by substantial evidence. As long as an intervention has not been scientifically or ethically proven to be superior to that the gold standard, the standard should not be discarded [8-13].

Some studies advocate for the benefits of laparoscopy owing to its ability to identify a

contralateral patent processus vaginalis. However, the need for systematic contralateral exploration is controversial [26]. The natural history of a patent processus vaginalis is closure within two months after birth in 40% and within two years in another 20% [27]. Among the remaining 40%, clinical hernias may develop in half. Thus, the finding of a patent processus vaginalis in the absence of a clinical hernia is not a clear indicator of a future hernia.

Furthermore, data from large prospective studies and a meta-analysis of children with unilateral inguinal hernia set the overall risk of metachronous hernia in the 5-12% range [28].

In the present systematic review, the insufficiency of data made it impossible to evaluate the potential benefit of a laparoscopic approach in specific subgroups, such as infants or patients with direct hernia/pantaloon hernia. It was also impossible to evaluate a potential advantage of any type of procedure with respect to infrequent complications such as iatrogenic cryptorchidism or testicular atrophy [9].

Unlike previous systematic reviews including meta-analyses [8-13], the present review was conducted in accordance with the recommended Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) for meta-analyses [13], and before its initiation, it was reported to PROSPERO, a register for systematic reviews. Due to a lack of data from the studies, a sub-analysis (age versus operation time) was not possible. The recent meta-analysis by Kantor et al included five RCTs and 16 non-RCTs [10]. However, in our study, we excluded the RCT by Shalaby et al as they included recurrent hernias and excluded unilateral hernias in non-obese children in their analysis [28]. Based on above-mentioned studies, Kantor et al [10] compared recurrence, operative time, length of hospitalisation, SSI, and risk of ascending testis, and reported that open and laparoscopic repair were equivalent; furthermore an increased risk of infection in laparoscopic repair and decreased risk of ascending testis was reported. Feng et al [8] conducted a meta-analysis based on five RCTs including the study by Shalaby et al [28]. After pooling all outcomes from the included RCTs, they concluded that laparoscopic herniotomy (LH) LH is favoured owing to a significantly reduced number of post-operative complications, although there were some inter-study discrepancies in defining outcomes, e.g. operative time and post-operative complications. Esposito et al conducted a systematic review with five RCTs and 48 non-RCTs; based on these data, they concluded that bilateral LH is faster than open herniotomy (OH) OH, but otherwise found no differences in outcomes such as recurrence [9]. A meta-analysis from 2011 including two RCTs and eight non-RCTs reported a longer operative time for LH and found no other significant differences between OH and LH [11]. Yang et al [12] included three RCTs and four non-RCTs in their meta-analysis; based on the included studies, they concluded that LH might lower the rate of metachronic contralateral hernia, but otherwise no differences were reported. A recent systematic review and meta-analysis by Olesen et al [13] included ten controlled trials. In contrast, the present systematic review included *only* five controlled trials (one non-randomised and four randomised trials) [28-32]. Thus, Olesen et al included studies with a mixture of hernia repairs (umbilical and inguinal, primary and recurrent inguinal hernia repair, including mesh repair) and studies focusing on perfusion of testicular arteries. The study by

Shalaby et al [28] included recurrent hernia repair, and they excluded non-obese children from their study. Hence, these studies were excluded from the present review analysis.

The present review has limitations. The most important is the limited number of included studies (and few patients) and the high level of heterogeneity and low or moderate study quality. Moreover, the results and conclusions may be criticised by the subjective nature of the conclusions that were not based on a meta-analysis. The use of post-operative pain as an endpoint may be questionable. Post-operative pain scores are the result of two factors; the pain itself and the amount of analgesia given. However, the literature included in the present review did not uniformly report dose and type of analgesia. In addition, the parameter of post-operative convalescence (which includes post-operative pain) is likely more relevant and this should include length of hospital stay and also time to full feeds (in infants) and time to normal activities (in older children).

To elucidate the efficacy of laparoscopic repair of paediatric inguinal hernia further, there is a need for RCTs supplemented by large prospective high-quality registries with clear definitions of outcomes adhering to reporting guidelines, agreement on surgical technique, and avoidance of the learning curve effect in both groups. Also, clearly differentiating between the type of patient (elective versus emergency, unilateral versus bilateral hernia; contralateral exploration versus no exploration, age (neonates or infants versus older children)) is very important in order to detect subgroups where the laparoscopic approach might be beneficial. Studies should also focus on the value of the procedure in the long term, and this should include evaluation of cosmesis, (direct and indirect) costs and later quality of life, such as fertility issues in adulthood due to iatrogenic cryptorchidism or trauma of the vas in bilaterally treated patients. Laparoscopic inguinal hernia repair in children might conceptually prove to be beneficial in case of a hernia recurrence after open inguinal hernia repair, as has been shown in adult inguinal hernia repair [33] because a virgin anatomical plane is used in those circumstances. This will probably only be elucidated by nationwide registry data since large high-quality studies may be difficult to conduct due to the rare occurrence of paediatric inguinal recurrent hernia [3].

Conclusions

At best, this review revealed an equivalence between open and laparoscopic paediatric inguinal hernia repair. Due to the doctrine that introduction of a novel treatment (laparoscopic repair) should prove to be better than a gold standard treatment (open repair) before routine use is adopted, this critical literature review does not support laparoscopic inguinal hernia repair in children as a replacement for the open approach as the gold standard.

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