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Local anesthetic infusion pump for pain management following open inguinal hernia repair: A meta-analysis

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ABSTRACT

Objectives: Open inguinal hernia repair is one of the most painful procedures in day surgery. A continuous ambulatory analgesic is thought to reduce postoperative pain when it is applied to the surgical site. The aim of this study is to evaluate the efficacy of local anesthetic infusion pump following open inguinal hernia repair for the reduction of postoperative pain.

Methods: We conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) that have investigated the outcomes of using an infusion pump for delivering a local anesthetic contrasted to a control group for open inguinal hernia repair. Pain was assessed from Day 1 to Day 5 following the surgery. The secondary outcomes included analgesia use and postoperative complications.

Results: We reviewed 5 trials that totaled 288 patients. The analgesic effects of bupivacaine (4 trials) and ropivacaine (one trial) were compared with a placebo group. The pooled mean difference in the score measuring the degree of pain diminished significantly at Day 1 to Day 4 in the experimental group. Two studies have reported that the number of analgesics required also decreased in the experimental group. No bupivacaine-related complication was reported.

Conclusion: Our results revealed that applying a local anesthetic infusion pump following inguinal hernia repairs was more efficacious for reducing postoperative pain than a placebo. However, the findings were based on a small body of evidence in which methodological quality was not high. The potential benefits of applying a local anesthetic infusion pump to hernia repair must still be adequately investigated using further RCTs.

1. Introduction

Acute postoperative groin pain is a frequent complication that occurs after an open inguinal hernia. After a day-case inguinal hernia repair, 10% of patients experience severe postoperative pain requiring a general practitioner to administer intramuscular opiates [1]. In addition, the pain following an inguinal hernia repair is more intense when patients mobilize or cough postoperatively; consequently, patients tend to prefer the comfort of their hospital bed, thus increasing the hospital stay [2,3].

Multiple modalities have been used to treat groin pain complications; these methods include administering oral opiates and intramuscular or intravenous analgesia agents, and implementing pre-emptive and postoperative blockades by using locoregional anesthesia, ilioinguinal nerve blockades, ilioinguinal neurectomies, and caudal blockades [4–6]. Systemic analgesics such as opioids might cause nausea, vomiting, itching, respiratory problems, sedation, and increase the duration of postoperative ileus, [7,8] whereas non-steroidal anti-inflammatory drugs might cause gastrointestinal upset. These side effects can be reduced by lowering the amount of opioid drugs that are administered.

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Reducing postoperative pain and the daily administration of narcotics to patients following inguinal repairs is, therefore, critical to achieving more rapid recovery and shorter hospitalization.

An alternative approach to pain relief is to continuously infiltrate a wound via an indwelling irrigation apparatus by using a local anesthetic solution. Because this method uses a fine catheter inserted into the wound before surgical closure, it can reduce postoperative opiate requirements [9]. Several randomized controlled trials (RCTs) have investigated the efficacy of applying a local anesthetic infusion pump in patients undergoing open inguinal hernia repair; however, the results have been inconclusive [10,11]. Therefore, we conducted a systematic review and meta-analysis of the evidence that is available to date on the outcomes of the use of an infusion pump for delivering local anesthetics to open inguinal hernia repair.

2. Materials and methods

2.1. Inclusion criteria

Our analysis included only previous RCTs that evaluated the outcome of applying a local anesthetic infusion pump in open inguinal hernia repair. The studies were required to clearly define the criteria used to include and exclude the patients for the study, to report the anesthetic and the surgical hernia repair techniques, and to define and evaluate the postoperative pain and the use of the appropriate study controls. Previous RCTs were excluded from our meta-analysis based on the following criteria: (1) they included patients who underwent other surgical procedures concomitantly, such as laparoscopic hernioplasty; (2) they included appropriate data that could not be extracted or calculated from the published results; or (3) they duplicated the reporting of patient cohorts.

2.2. Search strategy and study selection

Studies were identified using computerized searches of the PubMed, EMBASE, SCOPUS, and Cochrane central registers of controlled trial databases, as well as the ClinicalTrials.gov registry (http://clinicaltrials.gov/). The following terms were used for MeSH and free-text searching: *inguinal hernia*, *hernia repair*, *hernioplasty*, *herniorrhaphy*, *local anesthesia*, *local anesthetic*, *continuous infusion*, *pump*, and *pain control*. The "related articles" function in PubMed was used to broaden each search; we reviewed all the abstracts, the study reports, and the related citations that were retrieved. No language restrictions were applied. The last search was performed in November 2013. We also identified additional studies by reviewing the reference sections of the relevant publications and by consulting with experts in the field of abdominal surgery.

2.3. Data extraction

Baseline and outcome data were independently extracted by 2 reviewers. The study design, the participant characteristics, the inclusion and exclusion criteria, the matching criteria, the anesthetic techniques used, the complications, and the operative and postoperative parameters were extracted. The inconsistencies between the findings of the 2 reviewers were resolved by a third reviewer.

2.4. Methodological quality appraisal

We assessed the methodological quality of each study based on the adequacy of the randomization, the allocation concealment, the blinding of the patients and the outcome assessors, the reporting of the study withdrawals, the performance of an intention-to-treat analysis, and other possible biases.

2.5. Outcomes and statistical analysis

The primary outcome was the severity of postoperative pain from Day 1 to Day 5. The secondary outcomes included complications and analgesia consumption.

All the data were entered and analyzed using Review Manager, version 5 (Cochrane Collaboration, Oxford, England). A meta-analysis was performed following the PRISMA guidelines [12]. When necessary, standard deviations were estimated using the confidence interval limits, the standard error, or the range values provided in previous studies. The effect sizes of the dichotomous outcomes were reported as risks ratios (RR), and the mean difference was reported for continuous outcomes. The precision of the effect sizes was based on a 95% confidence interval (CI). A pooled estimate of the RR and the mean difference was computed using the DerSimonian and Laird random-effect model [13]. This model appropriately estimates the average treatment effect when trials are statistically heterogeneous, and it usually yields relatively wide CIs, thereby producing more conservative statistical claims.

To evaluate the statistical heterogeneity and the inconsistency of the treatment effects across the studies, Cochrane's Q test and I^2 statistics were respectively used. The statistical significance was set at 0.10 for Cochrane's Q test. The proportion of the total outcome variability that was attributable to the variability across the studies was quantified as I^2.

3. Results

3.1. Characteristics of the trials

The flowchart in Fig. 1 shows the process that was used to screen and select the RCTs. Our initial search yielded 451 citations. Based on the mentioned screening criteria, 277 titles and abstracts were excluded. We reviewed the full text of the remaining 174 reports; 168 studies were excluded for the following reasons: one trial was

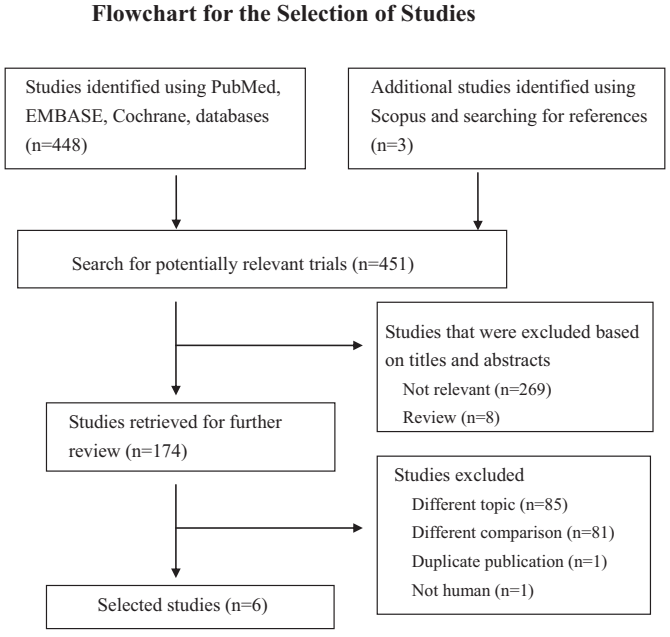

Fig. 1. Flowchart describing the selection of the randomized controlled trials for our meta-analysis.

Table 1
Characteristics of the selected randomized controlled trials.

Study [year]	Institutions/ surgeons	Anesthesia/surgical technique/ catheter position	Patient no. (no. of male)	Age, years	Intervention
Lau [2003]	Not reported	General anesthesia/ Linchenstein/under aponeurosis	I: 20 (18)	I: 49 (43–62)[a]	I: 0.5% bupivacaine 100 mL in pump continuously running 2 mL/h
			N: 24 (23)	N: 60 (51–66)	N: No pump
LeBlanc [2005]	Not reported	General anesthesia/ Prolene Hernia System/subcutaneously	I: 29 (29)	Not reported	I: 0.5% bupivacaine 100 mL in pump continuously running 2 mL/h for 48 h
			C: 23 (21)		C: Saline instead of bupivacaine
Oakley [1998]	Not reported	General anesthesia/Linchenstein/ under aponeurosis	I: 25 (23)	I: 53 (17–83)[b]	I: 0.5% bupivacaine 100 mL in pump continuously running 2 mL/h for 50 h
			C: 24 (22)	C: 58 (21–78)	C: Saline instead of bupivacaine
			N: 23 (23)	N: 56 (23–81)	N: No pump
Sanchez [2004]	1 hospital/ 1 surgeon	General anesthesia/polypropylene mesh and plug/under aponeurosis	I: 23 (22)	I: 39 ± 15	I: 0.25% bupivacaine 100 mL in pump continuously running 2 mL/h for 48 h
			C: 22 (21)	C: 41 ± 13	C: Saline instead of bupivacaine
Schurr [2004]	1 hospital/ 2 surgeons	General anesthesia/polypropylene mesh (89%), nonmesh repairs (11%)/under aponeurosis	I: 35	48 ± 16	I: 0.5% bupivacaine 120 mL in pump continuously running 2 mL/h for 60 h
			C: 37		C: Saline instead of bupivacaine
Stewart [2004]	1 hospital	General anesthesia/Linchenstein (98%), McVay repair (2%)/subcutaneously	I: 23 (23)	I: 51	I: 7.5 mg/mL ropivacaine 100 mL in pump continuously running 4 mL/h
			C: 24 (21)	C: 49	C: Saline instead of bupivacaine

C: control group; I: intervention group; N: no pump group.
[a] Values are presented as mean ± standard deviation except: median (range).
[b] Values are presented as mean ± standard deviation except: mean (range).

not human study; 81 studies have evaluated local anesthesia with other drugs that were administered using different methods; one study was a duplicate publication of a single trial that reported the long-term outcomes of using an infusion pump [14]; and 85 studies have addressed other aspects of inguinal hernia treatments. The 6 remaining RCTs were selected for our study [10,11,15–18]; the characteristics of each are listed in Table 1.

These 6 trials were published between 1998 and 2005, and the sample sizes ranged from 44 to 72 patients. All enrolled patients were recruited to undergo an elective unilateral open inguinal hernia repair. The patients with recurrent hernia were excluded in 3 trials [10,15,17]. Two trials recruited patients undergoing a day-case hernia repair, [11,18] and 2 of the eligible trials clearly reported that hernia repairs were performed by a specific number of surgeons in a single unit [15,16]. In all the selected trials, surgery was executed under general anesthesia. Most patients received a Lichtenstein repair, although LeBlanc et al. conducted an inguinal hernia repair in the manner of the Prolene Hernia System, [10] and Sanchez et al. [15] used a polypropylene mesh and a plug to repair the hernia defects that had been previously described by Robbins and Rutkow [19]. The infusion catheter was positioned in the subcutaneous layer in 2 trials, [10,17] and 4 studies had reported that the catheter was placed under the external oblique aponeurosis [10,15,16,18].

The continuous application of an infusion pump varied considerably across the trials. In 5 selected trials, 100–120 mL of bupivacaine was delivered by continuously using the pump at 2 mL/h for 48–60 h [10,11,15,16,18]. The dosages of bupivacaine and the placebo were adjusted according to the various protocols. One study compared the analgesic effect of ropivacaine with saline [17]. The baseline characteristics were balanced between the 2 treatment groups in the 6 RCTs.

Our assessment of the methodological quality of the 6 selected RCTs is summarized in Table 2. Three studies have used acceptable randomization methods, [10,15,18] and 2 studies have clearly described the allocation concealment method [15,17]. All studies have reported the blinding of the patients and the outcome assessors, except for Lau et al. [18]. All studies have performed an intention-to-treat analysis, except for Schurr et al. [16]. The number of patients lost to follow-up was acceptable (<20%) in all studies. Furthermore, 4 of 79 patients were dropped from the study because of the infusion pumps' failure, and they inadvertently pulled out [16]. Other biases that were found in the studies included non-uniform surgical procedures between the 2 treatment groups, [16] the involvement in the study of an undefined number of surgeons, [11,18] and the support of 2 studies by a grant from the manufacturer of the infusion pump that the studies used [10,17].

3.2. Pain scores

Pain was assessed postoperatively by 4 studies using a 10-point visual analog scale (0 = no pain, 10 = worst possible pain) from Day 1 to Day 5 [11,15,16,18]. LeBlanc et al. evaluated the pain severity scores on a 5-point scale (1 = no pain, 5 = worst pain), [10] whereas Stewart et al. collected postoperative pain data every 4 h for 1 day at rest, sitting out of bed, and walking [17]. To compare the outcome measures, we converted all studies to a 10-point scale. The data from 2 RCTs were not used in our pain score analysis because they did not report the standard deviation of the mean score, which was needed for pooling the data [10,17]. The pooled mean difference in the score measuring the degree of pain postoperatively was −1.79 (95% CI: from −2.51 to −1.08) on Day 1, −1.18 (95% CI: from −2.17 to −0.18) on Day 2, −1.41 (95% CI: from −2.28 to −0.55) on Day 3, and -1.21 (95% CI: from −2.08 to −0. 33) on Day 4. This demonstrates that the use of a local anesthetic infusion pump was favored to reduce the severity of postoperative pain. However, the groups showed no significant difference between in their postoperative pain scores, with a weighted mean difference of −1.07 (95% CI: from −2.57 to 0.44) on Day 5 (Fig. 2). The value of I^2 was 0% from Day 1 to Day 4 postoperatively, indicating no heterogeneity across the studies.

One study, the data of which were not pooled in our meta-analysis, revealed that the postoperative pain score was significantly lower in the ropivacaine group compared with the saline group on Day 1 when sitting and walking [17]. However, the pain scores between the 2 groups were not significant in LeBlanc study [10].

3.3. Analgesia consumption

We were unable to pool the data regarding analgesia consumption because the clinical parameters among the selected trials

Table 2
Methodological quality assessment of selected trials.

Study [year]	Country	Allocation generation	Allocation concealment	Double blinding	Data analysis	Loss to follow-up	Other bias
Lau [2003]	Hong Kong	Random number	Unclear	No	ITT	None	Undefined number of surgeons involved
LeBlanc [2005]	United States	Computer generated	Unclear	Yes	ITT	None	Supported by a grant from the manufacturer
Oakley [1998]	United Kingdom	Unclear	Unclear	Yes	ITT	None	Undefined number of surgeons involved
Sanchez [2004]	United States	Random number table	Adequate	Yes	ITT	None	Undefined risk
Schurr [2004]	United States	Unclear	Unclear	Yes	PP	8.8%	Surgical procedures was not uniform
Stewart [2004]	Australia	Unclear	Adequate	Yes	ITT	None	Supported by a grant from the manufacturer

ITT, Intention-to-treat; PP, Per-protocol.

were not uniformly reported. However, no significant difference was reported in the requirements for postoperative analgesia between the study groups in 3 of the selected trials [11,15,16]. Lau et al. indicated that none of the pump group patients requested analgesics, but 6 patients of the control group required analgesic supplement ($P = 0.025$) before being discharged [18]. LeBlanc et al. reported that the daily and total narcotic usages for all 5 days in the study were significantly less ($P < 0.05$) in the local anesthesia infusion pump group, [10] and Stewart et al. reported that the mean dose of morphine required was significantly lower in the ropivacaine group than in the control group ($P < 0.05$) [17].

3.4. Complications

No experimental drugs-related complications, such as seroma, tinnitus, oral numbness, or circumoral pallor, were reported in 5 included trials [10,11,15,17,18]. A similar incidence of metallic taste and ringing in the ears during the postoperative Day 1 and Day 2 was reported between groups [16]. No difference in the incidence of wound infection (4% in both groups) in one trial was found [11].

4. Discussion

Acute postoperative pain is common following an open inguinal hernia repair. The use of a local anesthetic infusion pump during an open inguinal hernia repair might reduce the postoperative pain. Overall, our meta-analysis indicated that the continuous instillation of bupivacaine or ropivacine in the surgical wound during an open inguinal repair resulted in greater pain reduction compared with controls. In addition, 3 of our included studies have indicated that the amount of narcotic requirement was significantly lower in the experimental group than in control group [10,17,18]. Moreover, no experimental drug-related complications were reported. Therefore, attempting to reduce the postoperative pain after a hernia repair by using a continuous infusion of local anesthetic seems reasonable.

The instillation of local anesthetics for reducing postoperative pain after a surgical procedure remains controversial. One RCT with 73 patients evaluated the effects of continuously infusing local anesthetic after the laparoscopic ventral hernia repair. The results indicated that using an elastomeric pain pump device neither measurably reduced the postoperative pain scores, the use of narcotics, the time taken for bowel function, nor the length of the hospital stay after a laparoscopic ventral hernia repair [20]. A recent meta-analysis indicated that an extraperitoneal infusion of bupivacaine following a laparoscopic total extraperitoneal inguinal hernioplasty did not display any benefit over a placebo regarding pain reduction and the requirements for postoperative analgesia [21]. However, one trial, which evaluated the use of infiltrating a wound by employing a local anesthetic in repeated dosages given to the patient by using a catheter, showed a decrease in postoperative pain after an open inguinal hernia repair [22]. Our results supported the analgesic effects of using an infusion pump for delivering a local anesthetic to repair an open inguinal hernia. Because an open inguinal repair is associated with increased postoperative pain, a longer hospital stay, and a slower recovery compared with a laparoscopic inguinal hernioplasty, [23] a local anesthetic instillation might more effectively on an open inguinal hernia than a laparoscopic procedure.

The optimal dose for delivering a local anesthetic for an open inguinal hernia repair is inconclusive. In the studies that were included in this analysis, both the 0.25% dose [15] and 0.5% dose [11,16,18] of bupivacaine can effectively reduce postoperative pain. A more elevated concentration of bupivacaine might more effectively enhance its analgesic effect. However, one potential disadvantage of local anesthesia instillation is the formation of a seroma. Nevertheless, our selected RCTs did not report any bupivacaine-related complications, such as seroma, tinnitus, or circumoral pallor. In particular, no wound infection was reported in 5 of our selected RCTs, [10,15–18] which would be of particular concern because of the use of a synthetic mesh.

One RCT included in our study evaluated the outcome of a local infusion with ropivacaine [17]. Ropivacaine has an inferior motor blockade, cardiotoxicity, and central nervous system toxicity compared to bupivacaine, allowing more elevated doses to be used safely [24]. However, one RCT, which evaluated the outcomes of the self-administration of ropivacaine and bupivacaine by applying a catheter to the surgical wound after an inguinal hernia repair, showed no statistically significant differences between the groups regarding the efficacy and safety of this approach [22].

The development of portable elastomeric infusion pumps can make the infusion of postoperative local anesthetic more easily available. Numerous clinical applications have recently been described, such as thoracic and gynecological surgeries [25,26]. Open hernia repairs have been rated among the top 3 most painful procedures in day surgery [7]. Our study demonstrated lower pain scores and a reduced requirement for rescue analgesia in the experimental groups compared with the placebo groups. Therefore, despite the increased cost of using an infusion pump, a substantial economic benefit still results from employing this technique in a day-surgery protocol.

The studies included in our analysis displayed considerable heterogeneity, which was attributable to various clinical factors. First, the surgical techniques used were not identical across all studies. LeBlanc et al. used the Prolene Hernia System, [10] Sanchez et al. used a polypropylene mesh and a plug [15] for hernioplasty, and most of the patients received a Lichtenstein repair [11,17,18]. Moreover, one trial did not standardize the hernioplasty method [16]. An infusion catheter was positioned in the subcutaneous layer in 2 trials, [10,17] and placed under the external oblique aponeurosis in other trials [11,15,16,18]. The timing and dosage of a continuous local anesthesia instillation were also different across the studies. Differences in the characteristics of the patients and the practice of the surgeons might also have contributed to heterogeneity in the data.

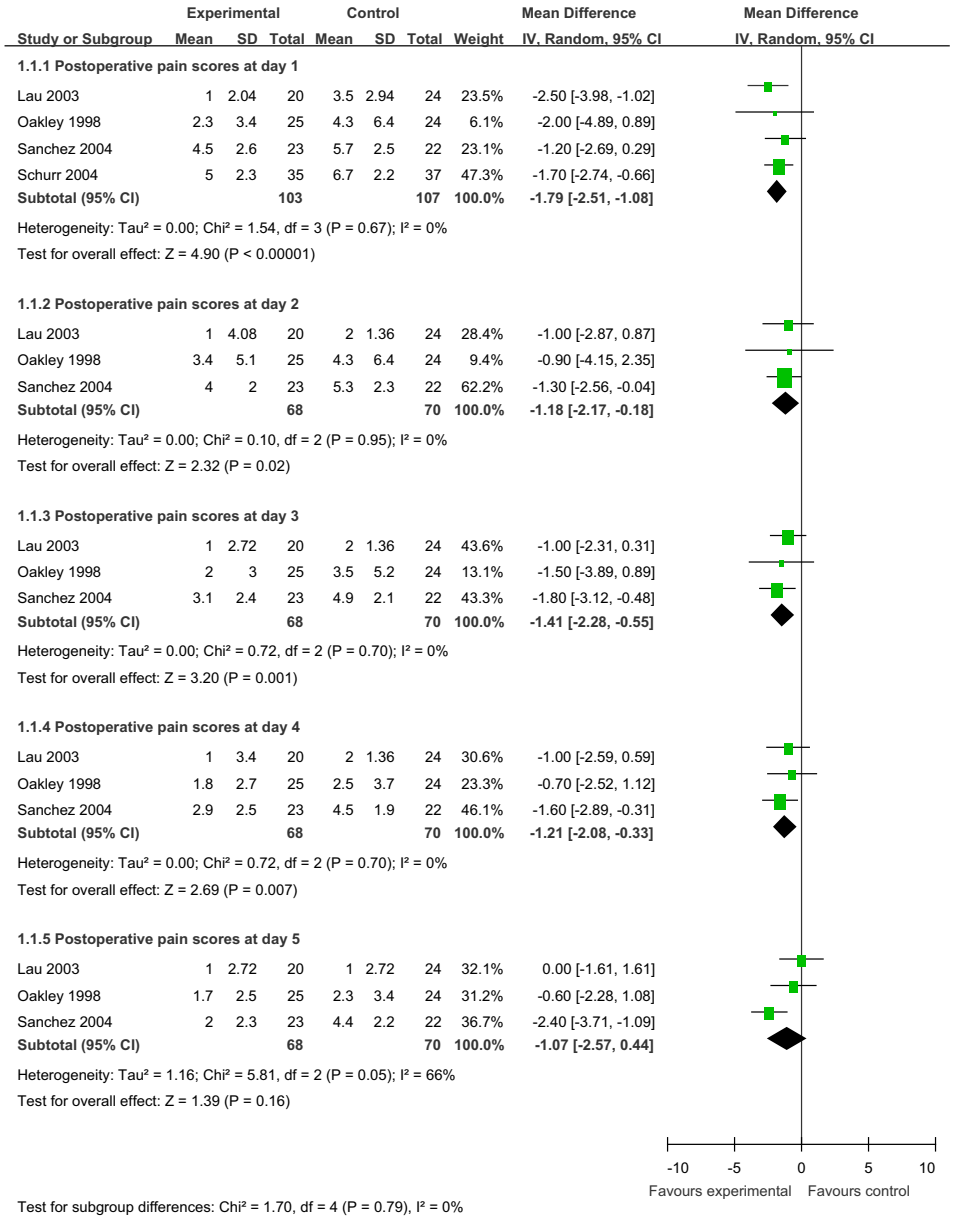

Fig. 2. Forest plot of the comparison of the local anesthetic infusion pump versus the control. The outcome was the incidence of postoperative pain at days 1–5.

Our study has limitations. First, the studies that it included used small samples, ranging from 20 to 29 patients per group, which might detract from the statistical power of the results. Second, several studies did not report the details of the generation and concealment of the allocation, and displayed other bias risks, such as the undetermined number of surgeons involved in the study. Finally, several of our primary and secondary outcomes were variably reported, thus potentially limiting the inferences based on our analysis.

In conclusion, the results of our meta-analysis revealed that applying a local anesthetic infusion pump following an inguinal hernia repair reduced postoperative pain compared to the placebo treatments during postoperative Day 1 to Day 4. However, the findings were based on a small body of evidence in which the methodological quality was not high. Based on the evidence that was reviewed, further research involving large RCTs might be warranted.

Ethical approval

None to declare.

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Author contribution

Chien-Chih Wu – Study design, data collections, data analysis, writing.

Ka-Wai Tam – Study design, data collections, data analysis, writing.

Chyi-Huey Bai – Data analysis.

Ming-Te Huang – Review of article.

Chih-Hsiung Wu – Review of article.

Conflicts of interest

The authors Chien-Chih Wu, Chyi-Huey Bai, Ming-Te Huang, Chih-Hsiung Wu, and Ka-Wai Tam have no conflicts of interest.

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