International Journal of Surgery 46 (2017) 61–70

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.journal-surgery.net

Liposomal bupivacaine versus interscalene nerve block for pain control after total shoulder arthroplasty: A systematic review and meta-analysis

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HIGHLIGHTS

- To compare the efficiency of liposomal bupivacaine infiltration and interscalene nerve block for pain control after TAS.
- Only RCTs were selected.
- Compared with INB, liposomal bupivacaine had comparative effectiveness on reducing both pain scores.

ARTICLE INFO

Article history:
Received 18 May 2017
Received in revised form
15 July 2017
Accepted 20 August 2017
Available online 24 August 2017

Keywords:
Liposomal bupivacaine
Interscalene nerve block
Pain control
Total shoulder arthroplasty
Meta-analysis

ABSTRACT

Objective: To illustrate the efficacy liposomal bupivacaine versus interscalene nerve block for pain management after total shoulder arthroplasty.
Methods: A systematic search was performed in Medline, PubMed, Embase, ScienceDirect and the Cochrane Library. Data on patients prepared for total shoulder arthroplasty in studies that compared liposomal bupivacaine versus interscalene nerve block were retrieved. The endpoints were the visual analogue scale (VAS) and opioid consumption. Fixed/random effect model was used according to the heterogeneity tested by I^2 statistic. Software of Stata 11.0 was used for pooling the final outcomes.
Results: Four randomized controlled trials (RCTs) including 510 patients met the inclusion criteria. The present meta-analysis indicated that there were no significant differences between groups in terms of VAS score at 12 h, 24 h, and 48 h ($p > 0.05$). No significant differences were found regarding to opioid consumption at postoperative 12 h, 24 h and 48 h ($p > 0.05$).
Conclusion: Compared with interscalene nerve block, liposomal bupivacaine had comparative effectiveness on reducing both pain scores and opioid consumption. Higher quality RCTs are required for further research.

1. Introduction

Total shoulder arthroplasty (TSA) has well-documented efficacy in alleviating pain and improving function in patients with degenerative arthritis in the glenohumeral joint [1]. With the aging population, the annual number of TSA is rising. Previous studies show that more than fifty-three thousand TSAs operations were performed in 2011 in the United States [2]. However, TSA was usually associated with moderate to severe postoperative pain. Recent articles have indicated that it was critically important for adequate pain management, which could contribute to a decreased risk of postoperative complications. A multimodal analgesia regime including local infiltration analgesia, peripheral nerve block, and patient-controlled analgesia has been recommended as an effective analgesic technique to manage pain in patients undergoing TSA [3–5].

Peripheral nerve blocks have become an increasingly popular method of providing regional anesthesia after TSA. It has shown excellent efficacy in reducing pain, opioid requirements and the length of hospital stay for patients undergoing TSA [6]. Interscalene nerve block was proposed as a gold standard for analgesia and was widely applied for pain control in TSA. However, much literature has shown that it was associated with potential neurologic complications and a high failure rate, which reported at 10%–20% [7].

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http://dx.doi.org/10.1016/j.ijsu.2017.08.569
1743-9191/

Table 1
EMBASE search strategy.

#1.	'pain control*':ti,ab
#2.	'pain management'/exp
#3.	'pain relief'/exp
#4.	'morphine*':ti,ab
#5.	'opioid '/exp
#6.	#1 and #4
#7.	#2 and #4
#8.	#3 and #4
#9.	#1 and #5
#10.	#2 and #5
#11.	#3 and #5
#12.	'interscalene nerve block*':ti,ab
#13.	'indwelling interscalene catheter '/exp
#14.	'liposomal bupivacaine*':ti,ab
#15.	#12 and #14
#16.	#13 and #14
#17.	shoulder*:ti,ab
#18.	arthroplasty/exp
#19.	replacement/exp
#20.	#17 or#18 or #19

Local infiltration analgesia is also suggested for postoperative pain control at the surgical site and to avoid the need for additional anesthetic procedures. Although previous articles have reported the obvious benefit in TSA, traditional local anesthetics were criticized for a short half time, which may influence the effect of analgesia [8,9]. Liposomal bupivacaine is a long-acting anesthetic whose acting process is when bupivacaine is encapsulated into multivesicular liposomes, making it a slow and controlled release from the liposomes [10]. Several studies have reported that in the setting of joint arthroplasty, liposomal bupivacaine has shown equal efficacy to adductor canal or femoral nerve blocks [11,12].

The comparison of liposomal bupivacaine infiltration and interscalene nerve block for pain management in TSA was seldom reported. And the published studies were criticized for small sample sizes and short-term follow-up. Thus, there is a lack of reliable scientific evidence. We conducted a meta-analysis from randomized controlled trials (RCTs) to illustrate the efficacy of liposomal bupivacaine versus interscalene nerve block for pain management after TSA.

2. Methods

2.1. Search strategy

We searched the electronic databases including Embase (1980–2017.05), PubMed (1966–2017.05), ScienceDirect (1985–2017.05), Web of Science (1950–2017.05) and Cochrane Library for potential relevant studies. A complete search strategy for Embase was provided in Table 1. The references of the included

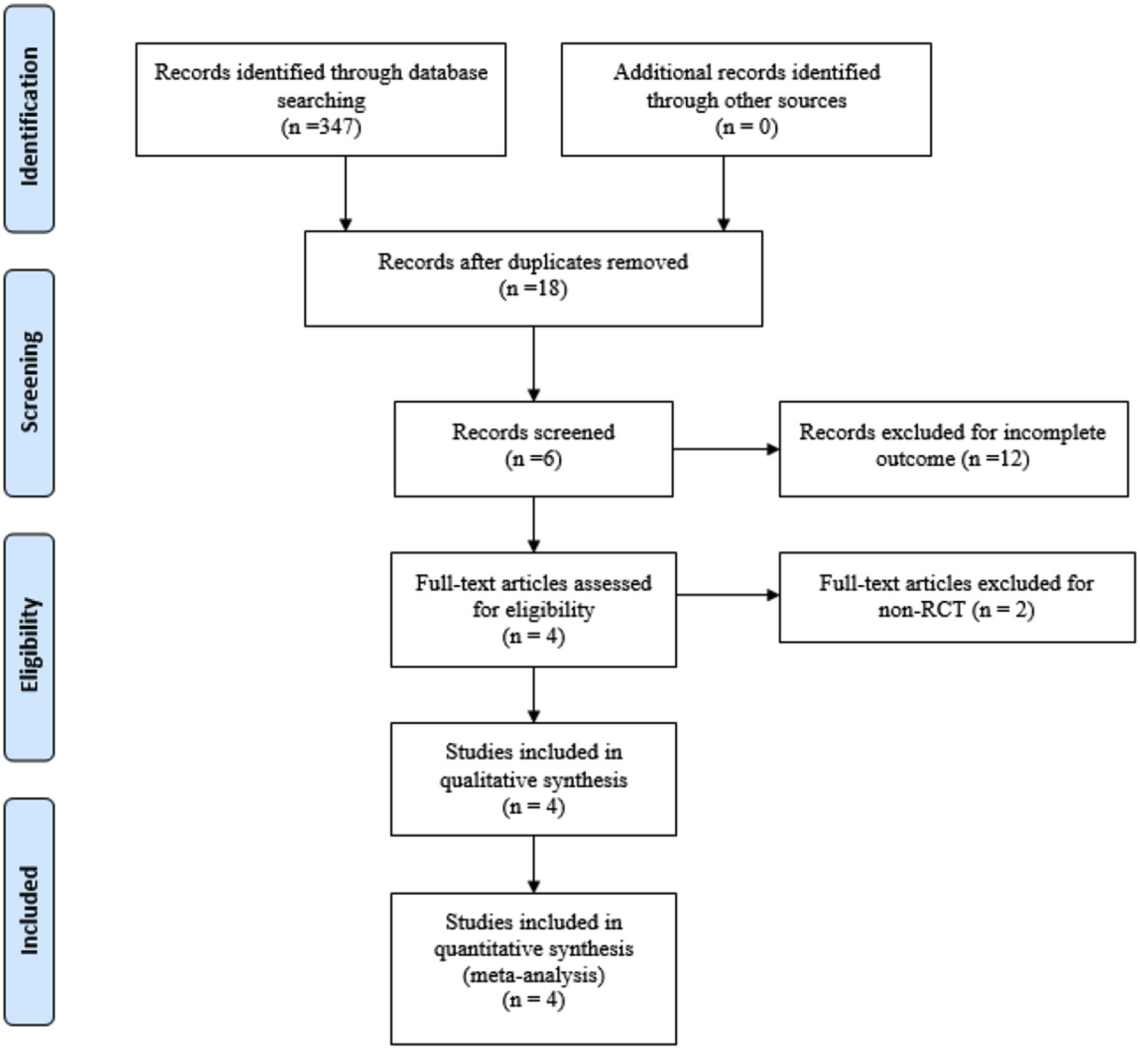


Fig. 1. Search results and the selection procedure.

literature were also checked for potentially relevant studies. We placed no restrictions on the publication language. The key words used in search methods including: “analgesia” OR “pain management” OR “pain control” OR “liposomal bupivacaine” OR “interscalene nerve block” AND “total shoulder replacement or arthroplasty”. A third reviewer acted as a judge if there was any disagreement. The retrieval process is presented in Fig. 1.

2.2. Inclusion and exclusion criteria

Patients: adult human subjects (age>18 years) prepared for total shoulder arthroplasty; Intervention: use liposomal bupivacaine for pain management as an intervention group; Comparison: administration interscalene nerve block as a comparison group; Outcomes: visual analogue scale (VAS) at 12 h, 24 h and 48 h, total opioid consumption at 12 h, 24 h and 48 h; Study design: RCTs. Studies would be excluded from present meta-analysis for incomplete data, case reports, conference abstract or review articles.

2.3. Selection criteria

Two reviewers independently scanned the abstracts of the potential articles identified by the above searches. Subsequently, the full text of the studies that met the inclusion criteria was screened, and a final decision was made. A senior author had the final decision in any case of disagreement regarding which studies to include.

2.4. Date extraction

Two authors independently extracted the relevant data using a predefined data extraction form created as a Microsoft Excel. We also noted the details of trial method, participant characteristics, intervention, and outcomes in the characteristics of included studies table. We resolved disagreements by consensus or by involving a third person. One review author transferred data into the Review Manager. Details of incomplete data of included studies are obtained by consulting the corresponding author. For included studies, we extracted the following data. First author names, published year, sample size, study design, comparable baseline, analgesic methods, and duration of follow-up. For continuous outcomes (e.g. VAS scale and opioid consumption): We extracted the mean and standard deviation (SD) of the outcome. For dichotomous outcomes (e.g. adverse events): We extracted the number of participants in each treatment arm who experienced the outcome of interest and the number of participants assessed at the endpoint in order to estimate a risk difference. We did not impute missing outcome data and attempted to contact trial authors to obtain missing data if necessary.

2.5. Quality assessment

According to Cochrane Handbook for Systematic Reviews of Interventions 5.0, the risk of bias of the included studies was assessed by two authors independently. Disagreements were resolved by discussion. A third author was the adjudicator when no consensus was achieved. We applied the “assessing the risk of bias”

Table 2
Trials characteristics.

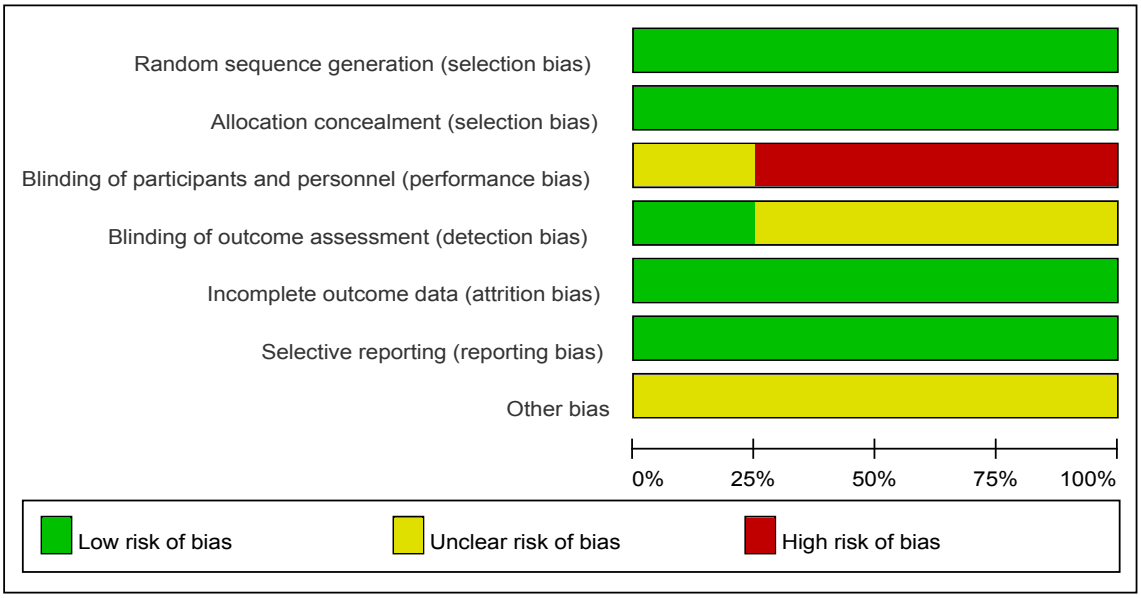
Studies	Reference type	Location	Cases	Mean age	Female patient	Drug dose of LB	Technique of LB	Drug dose of INB	Technique of INB	Concomitant Pain	Follow up
			(LB/INB)	(LB/INB)	(LB/INB)						
William 2016	RCT	USA	58/156	68/66	36/83	20 mL (266 mg) of liposomal bupivacaine	0.5-mL aliquots via multiple needle	20 mL 0.5% bupivacaine with 1:200,000 epinephrine	indwelling INB by an 18-gauge needle to inject around the brachial plexus nerve trunks with the guidance of ultrasound	oral morphine equivalent	3 months
Namdari 2017	RCT	USA	78/78	68.4/70.9	38/47	20 mL (266 mg) of liposomal bupivacaine	A 22-gauge needle was utilized and multiple aliquots of 0.5 mL were injected	30 mL of 0.5% ropivacaine	A single injection was performed with the guidance of ultrasound	PCA with opioids	2 months
Okoroha 2017	RCT	USA	26/31	69.4/67.1	14/15	20 mL (266 mg) of liposomal bupivacaine	1-inch, 18-gauge needle was used to administer the injection	40 mL of 0.5% ropivacaine	A single injection into the nerve sheath of the brachial plexus with the guidance of ultrasound	PCA with opioids	4 months
Abildgaard 2017	RCT	USA	37/46	67.8/70.1	16/32	20 mL (266 mg) of liposomal bupivacaine	syringe	0.5% ropivacaine 8 mL/h	An indwelling catheter was placed at the time of INB with the guidance of ultrasound	oral morphine equivalent	3 months

LB: Liposomal Bupivacaine, INB: interscalene nerve block, PCA: patient-control-analgesia.

Table 3
Methodological quality of the randomized controlled trials.

Study	Random Sequence Generation	Allocation Concealment	Blinding of participates and personal	Blinding of outcome assessment	Incomplete Outcome Data	Selective Reporting	Other bias
Abildgaard,2017	low risk	low risk	high risk	unclear risk	low risk	low risk unclear	
Namdari,2017	low risk	low risk	high risk	unclear risk	low risk	low risk unclear	
Okoroha,2017	low risk	low risk	high risk	low risk	low risk	low risk unclear	
William,2016	low risk	low risk	unclear risk	unclear risk	low risk	low risk unclear	

Table 4
Risk of bias.



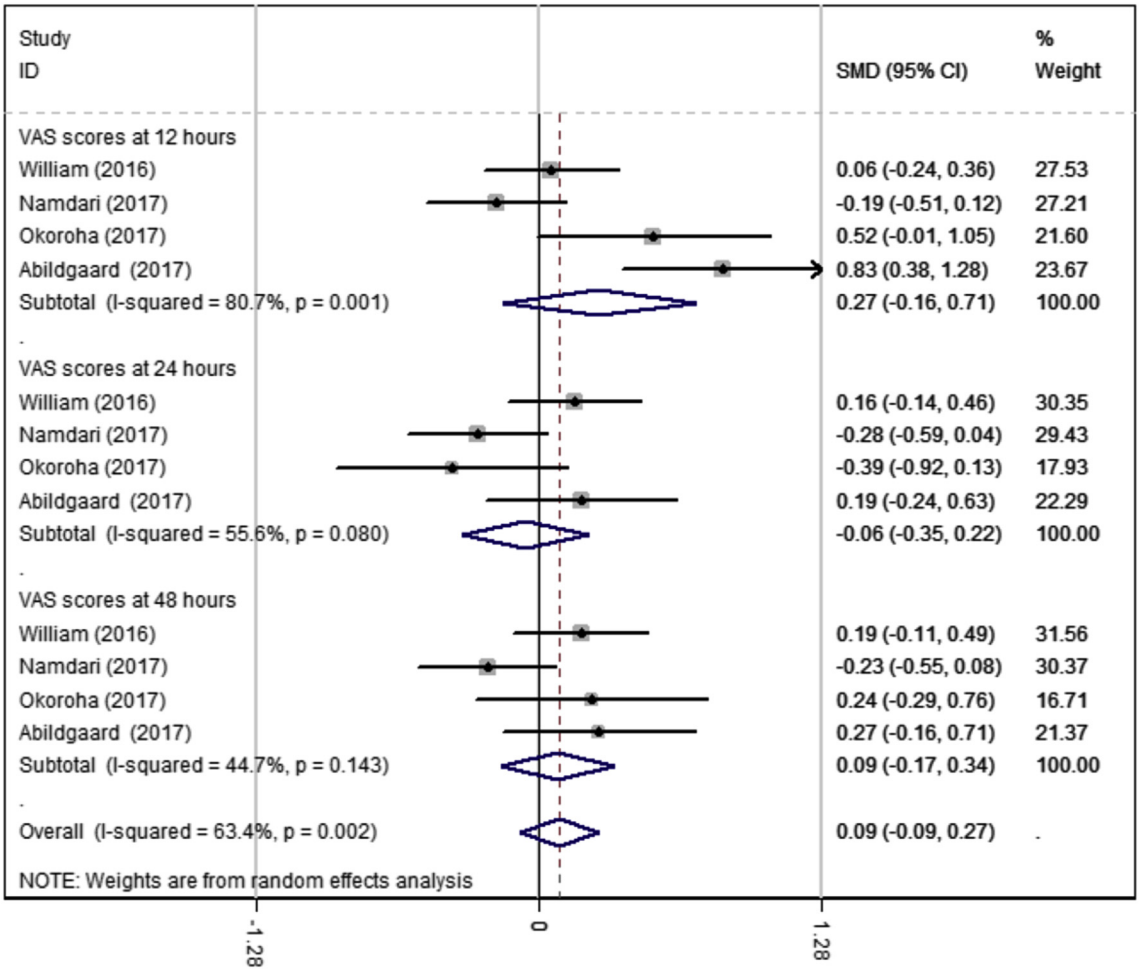


Fig. 2. Forest plot diagram showing VAS scores following TSA.

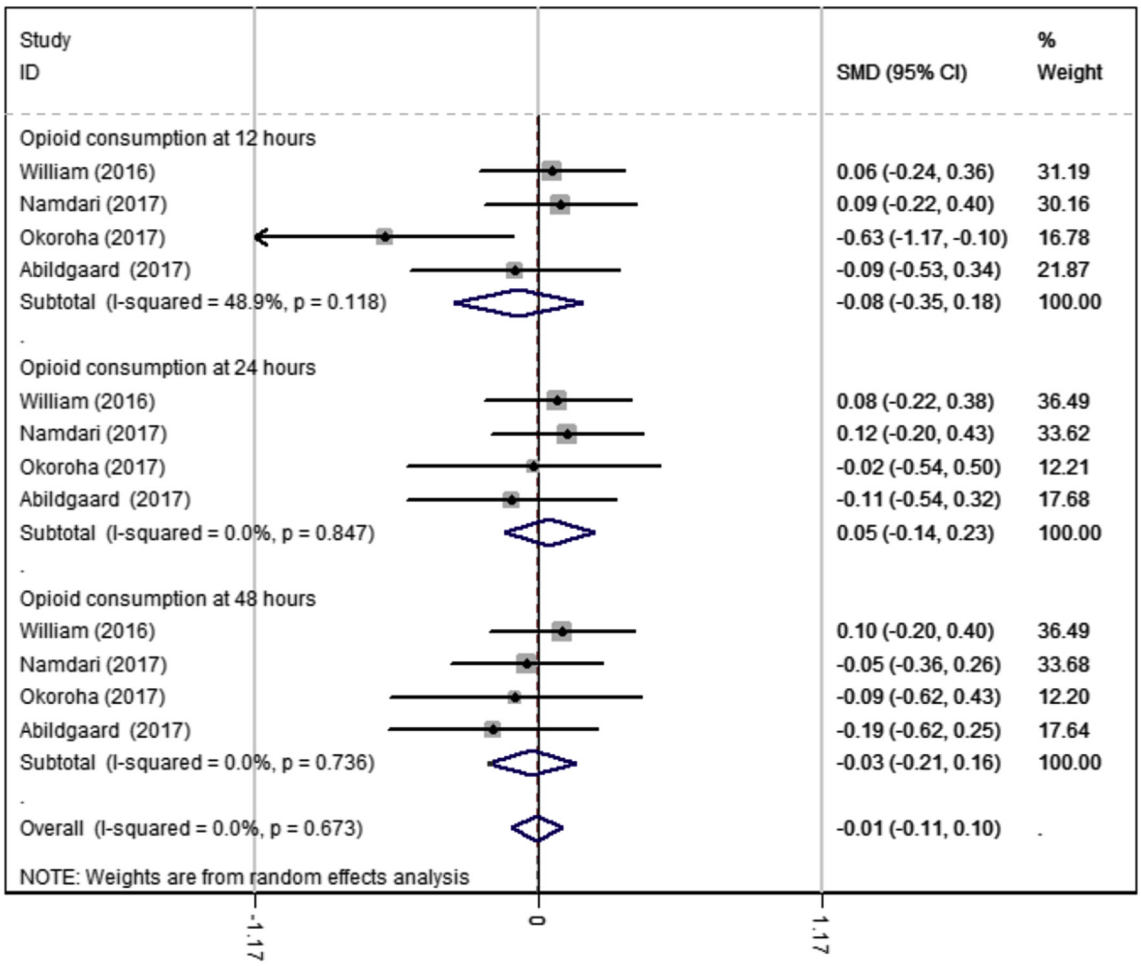


Fig. 3. Forest plot diagram showing opioid consumption following TSA.

table, which include the following key domains: adequate sequence generation, allocation of concealment, blinding, incomplete outcome data, free of selective reporting and free of other bias. Each item was recorded by "Yes", "No", or "Unclear". Each risk of bias item was presented as a percentage across all included studies. The percentage indicated the proportion of different levels of risk of bias for each item. Power analysis for each outcome was also calculated by Power and Precision software.

The qualities of evidence of main outcomes in present meta-analysis were evaluated using the Recommendations Assessment, Development and Evaluation (GRADE) system [13] including the following items: risk of bias, inconsistency, indirectness, imprecision and publication bias. Two authors independently score all the items of the GRADE systems which may influence quality of evidence. Items that may raise the quality of evidence was recorded by 0, +1 and + 2. Items that may lower the quality of evidence was recorded by 0, -1 and -2. A senior reviewer is consult in case of disagreement. Finally, GRADE systems will overall evaluate the results. The recommendation level of evidence is classified into the following categories: (1) high, which means that further research is unlikely to change confidence in the effect estimate; (2) moderate, which means that further research is likely to significantly change confidence in the effect estimate and may change the estimate; (3) low, which means that further research is likely to significantly change confidence in the effect estimate and to change the estimate; and (4) very low, which means that any effect estimate is uncertain.

2.6. Data analysis and statistical methods

All calculations were carried out with Stata 11.0 (The Cochrane Collaboration, Oxford, United Kingdom). We planned to pool the results using the random-effects model, which would better incorporate the clinical heterogeneity typical among small studies. We hypothesized that the different articles were estimating randomly different yet related intervention effects. By choosing the more conservative random-effects model, confidence intervals for the average intervention effect would be wider. The results of dichotomous outcomes (postoperative adverse effects, including the risk of nausea and vomiting) were expressed as risk difference (RD) with 95% confidence intervals (CIs). For continuous various outcomes (VAS scores, opioid consumption, length of stay), mean difference (MD) or standard mean difference (SMD) with a 95% confidence intervals (CIs) was applied for assessment.

3. Results

3.1. Search result

A total of 347 studies were identified through the initial search.

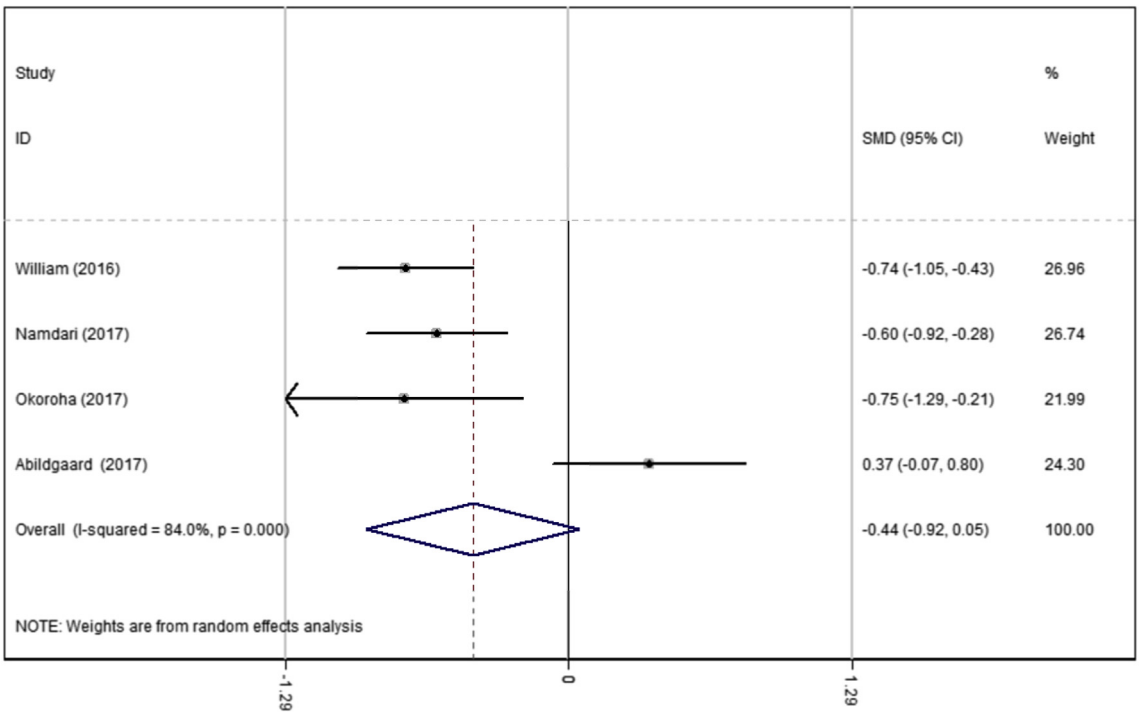


Fig. 4. Forest plot diagram showing length of stay following TSA.

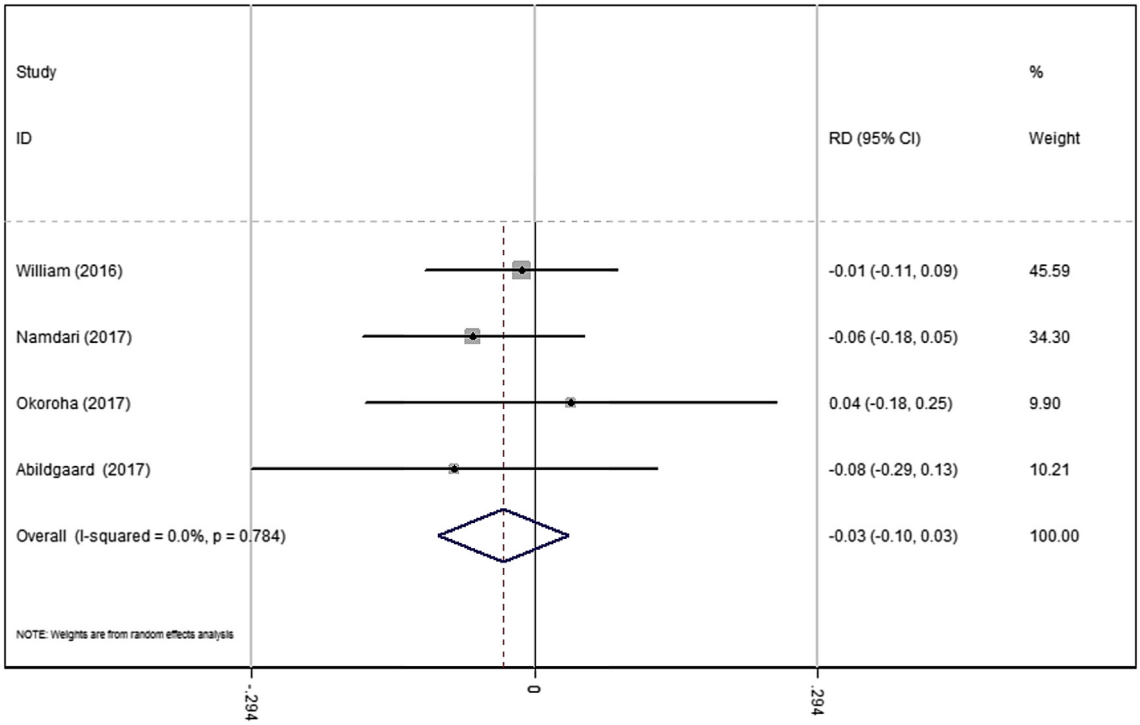


Fig. 5. Forest plot diagram showing incidence of nausea following TSA.

By scanning the abstracts, 343 reports that did not meet inclusion criteria were excluded from the current meta-analysis. Finally, four RCTs [14–17] published between 2016 and 2017 were included in the present meta-analysis. Overall, the four studies included 199 patients in the liposomal bupivacaine groups and 311 patients in the interscalene nerve block groups.

3.2. Study characteristics

Demographic characteristics of the included studies are summarized in Table 2. The sample size ranged from 57 to 214. Experimental groups applied local infiltration of liposomal bupivacaine. A 22-gauge needle was utilized and multiple aliquots of 0.5 mL

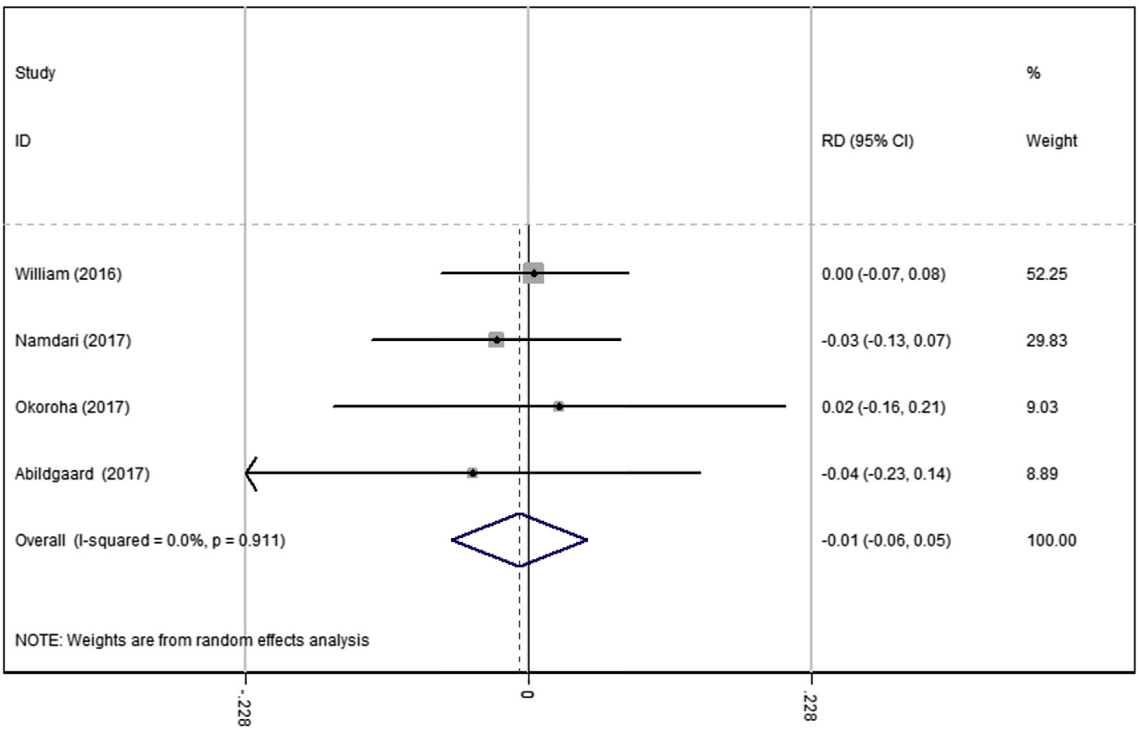


Fig. 6. Forest plot diagram showing incidence of vomiting following TSA.

were injected into the anteriorcapsule, subscapularis, deltoid, pectoralis major, and subcutaneous fat layer along the extent of both sides of the deltopectoral incision. Control groups received interscalene nerve block under ultrasound guidance. Two studies [14,17] reported that an indwelling catheter was placed at the time of the interscalene block and left in place postoperatively throughout admission. Others applied single injection under ultrasound guidance. The duration of the follow-up ranged from two to four months.

3.3. Risk of bias

The Cochrane Handbook for Systematic Review of Interventions was consulted to assess risk of bias of the RCTs (Table 3). All RCTs provide clear inclusion and exclusion criteria and described their randomization methodology, and all articles described the use of computer-generated randomization. All RCTs reported allocation concealment by closed envelope or other techniques. None RCTs provided double blinding. Only one [16] of them had attempted to blind assessors. All of them suggest the outcomes for at least 95% of the patients. Each risk of bias item is presented as the percentage across all included studies, which indicates the proportion of different levels of risk of bias for each item (Table 4).

3.4. Outcomes for meta-analysis

3.4.1. VAS scores

Four studies [14–17] showed the VAS scores following TSA. A random-effects model was used. No significant difference was identified regarding the VAS scores at 12 h (SMD = 0.273, 95% CI: −0.164 to 0.710, P = 0.221, power = 89.2%), 24 h (SMD = −0.061, 95% CI: −0.346 to 0.225, P = 0.678, power = 90.9%) or 48 h (SMD = 0.086, 95% CI: −0.168 to 0.341, P = 0.507, power = 93.1%; Fig. 2) between groups.

3.4.2. Opioid consumption

Opioid consumption at 12–24 h after TSA was reported in four articles [14–17]. A random-effects model was used. The present meta-analysis indicated that there was no significant difference between groups in terms of opioid consumption at 12 h (SMD = −0.082, 95% CI: −0.348 to 0.184, P = 0.545, power = 83.7%), 24 h (SMD = 0.046, 95% CI: −0.136 to 0.228, P = 0.618, power = 81.2%) or 48 h (SMD = −0.025, 95% CI: −0.207 to 0.157, P = 0.785, power = 85.0%; Fig. 3).

3.4.3. Length of hospital stay (LOS)

Four articles [14–17] provided the outcome of LOS. A random-effects model was used. There was no significant difference between the two groups (SMD = −0.437, 95% CI: −0.920 to 0.046, P = 0.076; Fig. 4).

3.4.4. Nausea

Four studies reported the postoperative complications of nausea. A random-effects model was used. No significant difference in the incidence of nausea was found between the two groups (RD = −0.033, 95% CI: −0.100 to 0.034, P = 0.333; Fig. 5).

3.4.5. Vomiting

Four articles reported the postoperative complications of vomiting following TSA. A random-effects model was used. There was no significant difference in terms of the incidence of vomiting between the groups (RD = −0.007, 95% CI: −0.062 to 0.048, P = 0.807; Fig. 6).

3.4.6. Evidence level and publication bias

The overall evidence quality for each outcome was moderate to low (Table 5) which means that further research is likely to significantly change confidence in the effect estimate and to change the estimate. As only four RCTs were included, publication bias was assessed by the most important outcome for VAS scores at 12 h.

Table 5
The GRADE evidence quality for main outcome.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Liposomal bupivacaine groups	Interscalene nerve block groups	Relative (95% CI)	Absolute		
VAS scores at 12 h (follow-up 2 to 4 months; Better indicated by lower values)												
4	randomised trials	no serious limitations	serious	no serious indirectness	no serious imprecision	none	199	311	–	SMD = 0.273, 95% CI: −0.164 to 0.710	⊕⊕⊕O MODERATE	CRITICAL
VAS scores at 24 h (follow-up 2 to 4 months; Better indicated by lower values)												
4	randomised trials	no serious limitations	serious	no serious indirectness	no serious imprecision	none	199	311	–	SMD = −0.061, 95% CI: −0.346 to 0.225	⊕⊕⊕O MODERATE	CRITICAL
VAS scores at 48 h (follow-up 2 to 4 months; Better indicated by lower values)												
4	randomised trials	no serious limitations	serious	no serious indirectness	no serious imprecision	none	199	311	–	SMD = 0.086, 95% CI: −0.168 to 0.341	⊕⊕⊕O MODERATE	CRITICAL
Opioid consumption at 12 h (follow-up 2 to 4 months; Better indicated by lower values)												
4	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	no serious imprecision	none	199	311	–	SMD = −0.082, 95% CI: −0.348 to 0.184	⊕⊕⊕⊕ HIGH	CRITICAL
Opioid consumption at 24 h (follow-up 2 to 4 months; Better indicated by lower values)												
4	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	no serious imprecision	none	199	311	–	SMD = 0.046, 95% CI: −0.136 to 0.228	⊕⊕⊕⊕ HIGH	CRITICAL
Opioid consumption at 48 h (follow-up 2 to 4 months; Better indicated by lower values)												
4	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	no serious imprecision	none	199	311	–	SMD = −0.025, 95% CI: −0.207 to 0.157	⊕⊕⊕⊕ HIGH	CRITICAL

Presented in Fig. 7, funnel plots were symmetrical and low risk of publication bias was found, however, publication bias could not be excluded as the reliability of this kind of assessment was weak especially when a low number of studies were included.

4. Discussion

As far as we know, this is the first meta-analysis to compare local infiltration of liposomal bupivacaine and interscalene nerve block for pain control after TSA. The present meta-analysis indicated that local liposomal bupivacaine infiltration showed comparative effectiveness compared to an interscalene nerve block in reducing pain scores and opioid consumption. In addition, no increased risk of the incidence of postoperative complications was identified.

The annual number of TSA is rising with the growing elderly population. TSA is an effective surgical procedure that improves function and relieves pain. However, postoperative pain associated with TAS was an important issue that should be addressed. Adequate pain control contributes to early functional recovery and minimizes postoperative complications and medical costs.

Regional anesthesia in the form of interscalene nerve block has been recognized to be an effective mode for pain management after TAS. Local infiltration anesthesia is commonly used and has demonstrated satisfactory and favorable results in joint surgery. However, the use of older local anesthetics showed a limited duration of analgesia. Liposomal bupivacaine acts as a long-acting, local anesthetic [18]. The U.S. Food and Drug Administration have approved it for administration into the surgical site, with proven safety in both animal and human studies. This suspension is created using a lipid-based delivery system that encapsulates the drug in multivesicular liposomal particles that then release the drug over a 72 h time period. Theoretically, liposomal bupivacaine is superior compared with traditional local anesthetics in pain control [19,20]. In addition, local infiltration of anesthetics is a simple technique that can be done without an anesthetist. Ma et al. [21] showed that compared with the traditional bupivacaine, liposomal bupivacaine shows better pain control and reduces the length of hospital stay after total hip arthroplasty. Ma et al. [22] found that liposomal bupivacaine provides similar pain relief to femoral nerve block following total knee arthroplasty. In addition, liposomal bupivacaine could significantly reduce the consumption of morphine equivalents compared without an increased risk of adverse events.

A commonly used perioperative pain control modality during TSA is an interscalene nerve block. It is associated with less postoperative pain, less narcotic use, shorter length of hospital stay as well as an increase in early joint range of motion. The interscalene brachia plexus nerve block is considered the “gold standard” for shoulder analgesia. Various articles have demonstrated that interscalene nerve block was effective in reducing pain and opioid consumption for patients undergoing TSA [23]. Angerame et al. [24] reported that an interscalene nerve block was effective in controlling pain and limiting opioid consumption while avoiding the risk of potentially severe complications and high cost. Abdallah et al. [3] showed that an interscalene nerve block is associated with increased patient satisfaction and shoulder range of motion, most likely resulting from the potent analgesia these nerve blocks provide.

Although effective at decreasing opioid requirements, peripheral nerve blocks expose the patient to an additional procedure with associated complications. Neurologic complications, including persistent neurologic pain, dysesthesia down the arm, postoperative paralysis, perineural entrapment of the catheter, vocal cord paralysis, and hemidiaphragmatic paralysis from phrenic nerve palsy, have also been described [25,26]. Therefore, the optimal analgesia regime remains controversial. The present meta-

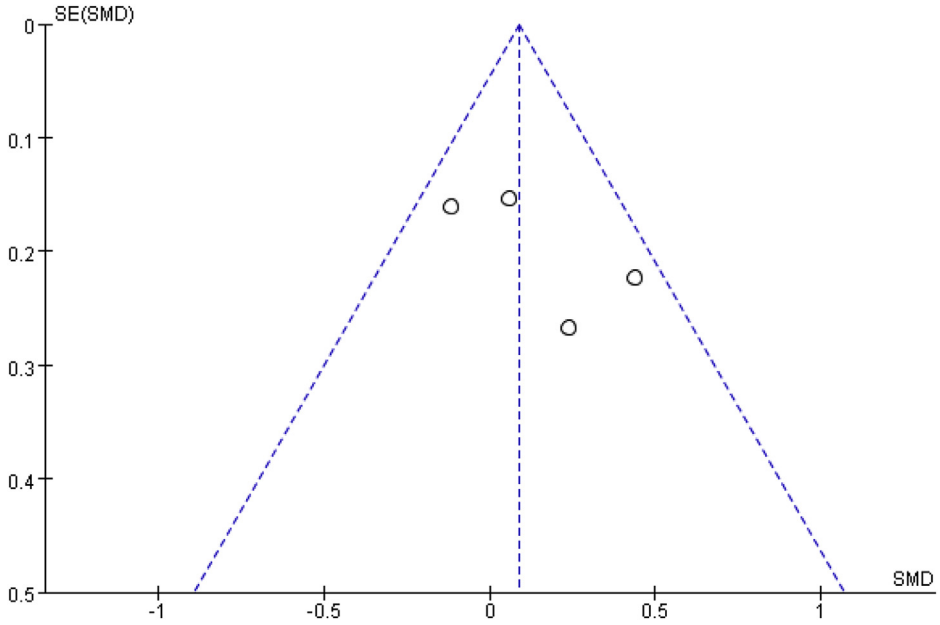


Fig. 7. Funnel plot of VAS scores at 12 h following TSA.

analysis demonstrated that there was no significant difference regarding VAS scores between groups. However, the statistical power may be lower because of the small sample size.

Additional opioids were used as an adjunct to concomitant pain control. Patients preferred the personal control aspect of patient-control-analgesia (PCA) and the rapid onset. In our study, opioid consumption was considered an objective means to measure pain. Opioid-related adverse effects including nausea, vomiting, respiratory depression, and pruritus were well known and drew our attention [27,28]. Besides the side effects, drug dependence is also an important issue related to opioid administration that should be considered. It was crucial to minimize the opioid consumption for patients and improve their recovery and satisfaction. The present meta-analysis indicated that there was no significant difference between liposomal bupivacaine infiltration groups and interscalene nerve block groups regarding the opioid consumption.

Analgesia efficacy is not the only concern when evaluating the analgesic effect. Nausea and vomiting are well-known side effects that are related to systemic use of morphine. Adequate analgesia protocol could decrease opioid consumption and subsequently decrease the risk of postoperative complications. The present meta-analysis showed that there was no significant difference between groups for the incidence of nausea and vomiting. Other complications such as thrombotic events, pneumonia, and cardiac events were reported in the individual article. No significant difference was found. Considering that only four RCTs were included in our study, large sample sizes from high quality RCTs are, therefore, needed.

Some limitations in the present meta-analysis exist that should be noted. (1) Only four RCTs were included in the present meta-analysis, and the sample size was relatively small, so the outcome should be treated cautiously; (2) Functional outcome is an important parameter, due to the insufficiency of relevant data, we cannot perform a meta-analysis; (3) Due to the limited number of included studies, subgroup analyses were not performed for VAS scores; therefore, we could not determine the sources of heterogeneity; (4) Type and dose of analgesic drug which has been used for intercostal nerve block were various, which may generate heterogeneity; (5) Short-term follow-up may lead to the underestimation of complications; (6) Publication bias is an inherent weakness that exists in all meta-analyses.

Despite the limitations above, this study is the first meta-analysis from RCTs to illustrate the efficacy of liposomal bupivacaine versus interscalene nerve block for pain management after total shoulder arthroplasty. High-quality RCTs with a large sample size are required to investigate the adequate analgesia protocol and potential adverse effects in future studies.

5. Conclusion

Compared with interscalene nerve block, liposomal bupivacaine had comparative effectiveness on reducing both pain scores and opioid consumption. Higher quality RCTs are required for further research.

Ethical approval

All analyses were based on previous published studies, thus no ethical approval and patient consent are required.

Funding

None.

Author contribution

Kun Wang: data collections, revised the manuscript and writing. Hong-xia Zhang: study design.

Conflict of interest

The authors declare that they have no competing interests.

Research registration unique identifying number (UIN)

reviewregistry212.

Trial registry number – ISRCTN

None.

Guarantor

Hong-xia Zhang.

Acknowledgments

None.

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