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Comparison of liposomal bupivacaine infiltration versus interscalene nerve block for pain control in total shoulder arthroplasty

A meta-analysis of randomized control trails

Xiuling Cao, MB[a,*], Fang Pan, MD[b]

Abstract

Background: This meta-analysis aimed to compare the efficiency and safety of liposomal bupivacaine infiltration and interscalene nerve block for pain control after total shoulder arthroplasty.

Methods: A systematic search was performed in Medline (1966 to May 2017), PubMed (1966 to May 2017), Embase (1980 to May 2017), ScienceDirect (1985 to May 2017) and the Cochrane Library. Only randomized controlled trials (RCTs) were included. Reported surgical outcomes, including visual analogue scale (VAS) scores, opioid consumption, length of stay, and postoperative adverse effects including the risk of nausea and vomiting. Meta-analysis was performed using Stata 11.0 software.

Results: Four 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 hours (standard mean difference [SMD] = 0.272, 95% CI: −0.150 to 0.695, $P = .207$), 24 hours (SMD = −0.056, 95% CI: −0.458 to 0.346, $P = 0.785$), and 48 hours (SMD = 0.183, 95% CI: −0.148 to 0.513, $P = .278$). Liposomal bupivacaine infiltration groups required an equivalent amount of opioids at postoperative 12 hours (SMD = −0.039, 95% CI: −0.222 to 0.143, $P = .672$), 24 hours (SMD = 0.046, 95% CI: −0.136 to 0.228, $P = .618$) and 48 hours (SMD = −0.025, 95% CI: −0.207 to 0.157, $P = .785$).

Conclusion: Liposomal bupivacaine infiltration provides equivalent postoperative pain control compared with interscalene nerve block following total shoulder arthroplasty. Both of them can reduce the consumption of opioids without severe adverse effects. More high-quality RCTs with long follow-up period are necessary for proper comparisons of the efficacy and safety of liposomal bupivacaine infiltration with interscalene nerve block.

Abbreviations: LOS = length of stay, RCTs = randomized controlled trials, TSA = total shoulder arthroplasty, VAS = visual analogue scale.

Keywords: interscalene nerve block, liposomal bupivacaine, meta-analysis, pain control, total shoulder arthroplasty

1. Introduction

Total shoulder arthroplasty (TSA) has been shown well-recognized efficacy in improving functional outcome for patients with glenohumeral arthritis.[1] With the aging population, the number of TSAs is increasing. It has been estimated that >50,000 TSAs are performed in 2011 in the United States which predicts an increasing trend and requirement for the next few years.[2] However, a majority of patients would suffer moderate-to-severe postoperative pain. Effective pain control contributes to early ambulation and maintaining of motor function. In addition, the risk of thrombotic events and medical costs would be decreased under adequate analgesia. Multiple analgesic strategies have been applied, including intravenous opioids, local infiltration analgesia, and peripheral nerve block.[3–5]

Regional analgesia with peripheral nerve block has shown excellent efficacy in pain relief, reducing length of hospital stay, and improving satisfaction for patients undergoing TSA.[6] Interscalene nerve block, which was considered gold standard for shoulder analgesia was widely used for pain management in shoulder arthroplasty. However, it was criticized for potential neurologic complications and high failure rate reported as 3.3% to 14% by some experts.[7]

Local infiltration analgesia is also recommended for postoperative pain management for its convenience and safe. An analgesia cocktail consisting of a mixture of ropivacaine, ketorolac, and opioid was commonly used. Several studies have reported the various benefits of analgesia after surgical procedure, however, a short duration of action limit the clinical application.[8,9]

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XLC and FP conceived the design of the study. FP performed and collected the data and contributed to the design of the study. XLC finished the manuscript. Both the authors read and approved the final manuscript.

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[a] Department of Anesthesiology, Beijing Obstetrics and Gynecology Hospital, Capital Medical University, [b] Department of Anesthesiology and Pain Medicine, Peking University People's Hospital, Peking University, Beijing, China.

[*] Correspondence: Xiuling Cao, Department of Anesthesiology, Beijing Obstetrics and Gynecology Hospital, Capital Medical University, Beijing, 100026, China (e-mail: 3469660377@qq.com).

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Liposomal bupivacaine is a long-acting anesthetic, whose acting process is that bupivacaine is encapsulated into multivesicular liposomes, causing a slow and controlled release from the liposomes.[10] Previous studies have reported that liposomal bupivacaine was as effectives as femoral nerve block in joint arthroplasty surgery.[11,12]

The comparison of liposomal bupivacaine infiltration and interscalene nerve block for pain management in TSA is seldom reported. Thus, there is a lack of scientific evidence. Therefore, we performed a meta-analysis from randomized controlled trials (RCTs) to compare the efficiency and safety of liposomal bupivacaine infiltration and interscalene nerve block for pain control after TSA.t

2. Methods

This systematic review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The study was approved by the ethics committee of the Beijing Obstetrics and Gynecology Hospital.

2.1. Search strategy

Two researchers searched independently for the relevant studies, including Embase (1980 to May 2017), PubMed (1966 to May 2017), ScienceDirect (1985 to May 2017), Web of Science (1950 to May 2017), and Cochrane Library. Reference lists of all the potential included studies and relevant reviews were hand-searched for any additional trials. No restrictions were imposed on language. The Mesh terms and their combinations used in the search were as follows: "analgesia" OR "pain management" OR "pain control" OR "liposomal bupivacaine" OR "interscalene nerve block" AND "total shoulder arthroplasty or replacement." A third reviewer acted as a judge if there was any disagreement. The retrieval process is presented in Figure 1.

2.2. Inclusion and exclusion criteria

Studies were considered eligible if they met the following criteria: published clinical randomized control trails (RCTs); patients undergoing TSAs, experiment group received local liposomal bupivacaine infiltration for pain management and control group

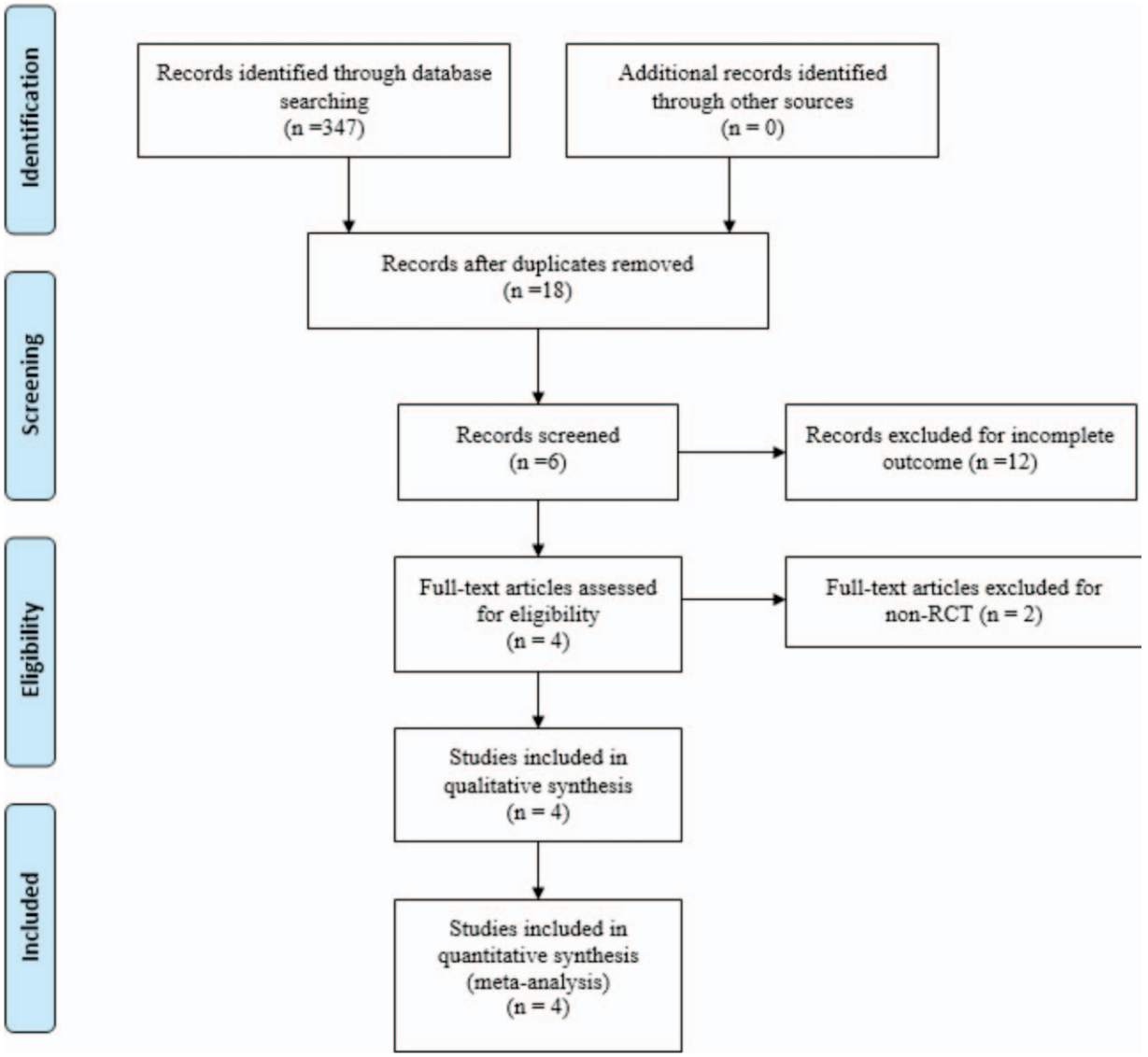


Figure 1. Search results and the selection procedure.

received interscalene nerve block; reported surgical outcomes, including visual analogue scale (VAS) scores, opioid consumption, length of stay (LOS), and postoperative adverse effects, including the risk of nausea and vomiting. Studies were excluded from present meta-analysis for incomplete data, case reports, conference abstract, or review articles.

2.3. Selection criteria

Two authors independently reviewed all the abstracts of the potential studies identified by the aforementioned searches. After an initial decision, full text of the studies that potentially met the inclusion criteria were reviewed and final decision was made. A senior reviewer was consulted in case of disagreement regarding which studies to include.

2.4. Date extraction

Two authors independently extracted the relevant data from the included articles. Details of incomplete data of included studies were obtained by consulting the corresponding author. Following data was extracted: first author names, published year, sample size, study design, comparable baseline, analgesic methods, and duration of follow-up. Other relevant data was also extracted from individual studies.

2.5. Quality assessment

Quality assessment of the included RCTs was assessed by 2 authors independently using the Cochrane Collaboration's tool. We conducted "risk of bias" table including the following key points: random sequence generation, allocation concealment, blinding, incomplete outcome data, and free of selective reporting and 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.

The qualities of evidence of main outcomes in present meta-analysis were evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system including the following items: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Two authors independently scored all the items of the GRADE systems which may influence quality of evidence. Items that may raise the quality of evidence were recorded by 0, +1, and +2. Items that may lower the quality of evidence were recorded by 0, −1, and −2. A senior reviewer was consulted in case of disagreement. Finally, GRADE systems overall evaluated the results. The recommendation level of evidence is classified into the following categories: high, which means that further research is unlikely to change confidence in the effect estimate; moderate, which means that further research is likely to significantly change confidence in the effect estimate and may change the estimate; low, which means that further research is likely to significantly change confidence in the effect estimate and to change the estimate; and 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). Statistical heterogeneity was assessed based on the value of P and I^2 using the standard χ^2 test. When $I^2 > 50\%$, $P < 0.1$ was considered to be significantly heterogeneous. The random-effect model was performed for meta-analysis; otherwise, the fixed-effect model was used. 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, and LOS), mean difference (MD) or standard mean difference (SMD) with a 95% confidence intervals (CIs) was applied for assessment.

3. Results

3.1. Search result

In the primary search, 347 articles were reviewed. Finally, 4 RCTs[13–16] met eligibility criteria of the present meta-analysis. Overall, the 4 studies included 199 patients in the liposomal bupivacaine group and 311 patients in the interscalene nerve block group.

3.2. Study characteristics

Demographic characteristics of the included studies are summarized in Table 1. The sample size of the included studies ranged from 57 to 214. All of them compared efficiency and safety between liposomal bupivacaine infiltration and interscalene nerve block for pain management in TSA. All experimental groups received 266 mg of liposomal bupivacaine infiltration and control groups received interscalene nerve block under ultrasound guidance, using ropivacaine or bupivacaine. All studies

Table 1

Trials' characteristics.

Studies	Reference type	Location	Cases (LB/INB)	Mean age (LB/INB)	Female patient (LB/INB)	Drug dose of LB	Drug dose of INB	Concomitant pain	Follow-up
William, 2016	RCT	USA	58/156	68/66	36/83	20 mL (266 mg) of liposomal bupivacaine	20 mL 0.5% bupivacaine with 1:200,000 epinephrine	Oral morphine equivalent	3 mo
Namdari, 2017	RCT	USA	78/78	68.4/70.9	38/47	20 mL (266 mg) of liposomal bupivacaine	30 mL of 0.5% ropivacaine	PCA with opioids	2 mo
Okoroha, 2017	RCT	USA	26/31	69.4/67.1	14/15	20 mL (266 mg) of liposomal bupivacaine	40 mL of 0.5% ropivacaine	PCA with opioids	4 mo
Abildgaard, 2017	RCT	USA	37/46	67.8/70.1	16/32	20 mL (266 mg) of liposomal bupivacaine	0.5% ropivacaine 8 mL/h	Oral morphine equivalent	3 mo

INB = interscalene nerve block, LB = liposomal bupivacaine, PCA = patient-control-analgesia, RCT = randomized controlled trials.

reported that surgical procedure was operated by same team. The follow-up period ranged from 2 to 4 months.

3.3. Risk of bias assessment

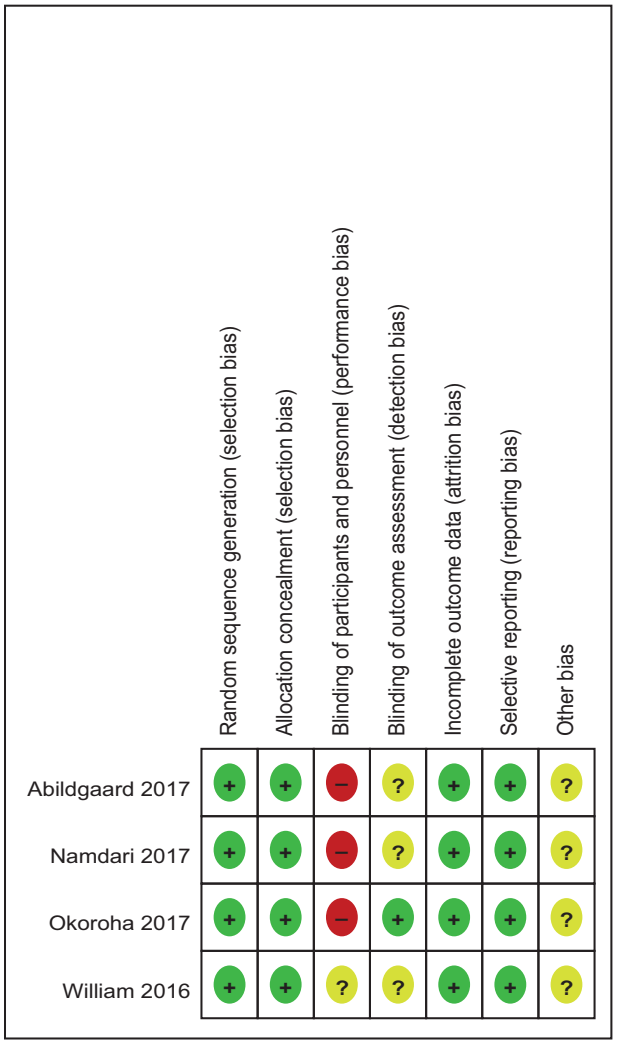
Quality assessment of the RCTs was based on the Cochrane Collaboration's tool (Table 2). All RCTs provide clear inclusion and exclusion criteria and suggest a methodology of randomization, all of which described that randomization algorithm was generated from computer. All RCTs stated allocate concealment was achieved by sealed envelope. None RCTs provided double blinding. Only one[15] 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 3). None of them performed intent-to-treatment analysis, thus a potential risk for type II statistical error would exist.

3.4. Outcomes for meta-analysis

3.4.1. AS scores at 12 hours. Four articles[13–16] reported the VAS scores at 12 hours following TSA. There was significant heterogeneity among the studies ($\chi^2=14.54$, df = 3, $I^2=79.4\%$, $P=.002$); therefore, a random-effects model was used. Pooled results demonstrated there was no significant difference regarding VAS scores at 12 hours between groups (SMD = 0.272, 95% CI: −0.150 to 0.695, $P=.207$; Fig. 2).

Table 2

Methodological quality of the RCTs.



RCT = randomized controlled trial.

3.4.2. VAS scores at 24 hours. Four studies[13–16] reported VAS scores at 24 hours following TSA. There was significant heterogeneity among the studies ($\chi^2=13.32$, df = 3, $I^2=77.5\%$, $P=.004$); therefore, a random-effects model was applied. No significant difference was identified regarding the VAS scores at 24 hours between groups (SMD = −0.056, 95% CI: −0.458 to 0.346, $P=.785$; Fig. 3).

3.4.3. VAS scores at 48 hours. Four reports[13–16] provided the outcomes of VAS scores at 48 hours following TSA. There was significant heterogeneity among these studies, therefore, a random-effects model was used ($\chi^2=9.00$, df = 3, $I^2=66.7\%$, $P=.278$). There was no significant difference between the 2 groups (SMD = 0.183, 95% CI: −0.148 to 0.513, $P=.278$; Fig. 4).

3.4.4. Opioid consumption at 12 hours. Opioid consumption at 12 hours after TSA was reported in 4 articles.[13–16] No significant heterogeneity among these studies was found ($\chi^2=5.88$, df = 3, $I^2=48.9\%$, $P=.118$), therefore, a fixed-effects model was used. Opioid consumption at 12 hours was similar in 2 groups (SMD = −0.039, 95% CI: −0.222 to 0.143, $P=.672$; Fig. 5).

3.4.5. Opioid consumption at 24 hours. Four studies[13–16] reported data regarding opioid consumption 24 hours after TSA. There was no significant heterogeneity among the pooled data ($\chi^2=0.81$, df = 3, $I^2=0\%$, $P=.847$), therefore a fixed-effects model was used. There was no significance between the 2 groups in opioid consumption at 24 hours after TSA (SMD = 0.046, 95% CI: −0.136 to 0.228, $P=.618$; Fig. 6).

3.4.6. Opioid consumption at 48 hours. Four articles[13–16] reported the outcome of opioid consumption at 48 hours after TSA. There was no significant heterogeneity among the pooled data ($\chi^2=1.21$, df = 3, $I^2=0\%$, $P=.736$), therefore a fixed-effects model was used. There was no significance between the 2 groups in opioid consumption at 48 hours after TSA (SMD = −0.025, 95% CI: −0.207 to 0.157, $P=.785$; Fig. 7).

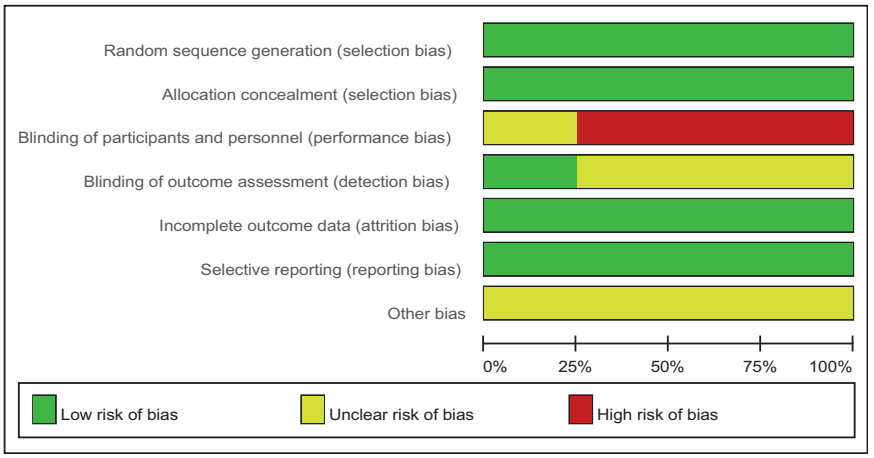
3.4.7. Length of hospital stay. Four studies[13–16] reported the length of hospital stay. Significant heterogeneity was identified in the pooled results; therefore, a random-effects model was used ($\chi^2=18.70$, df = 3, $I^2=84\%$, $P=.000$). There was no significant difference between the 2 groups (SMD = −0.437, 95% CI: −0.920 to 0.046, $P=.076$; Fig. 8).

3.4.8. Occurrence of nausea. The occurrence of nausea was provided in 4 studies.[13–16] No significant heterogeneity among these studies was found; therefore, a fixed-effects model was used ($\chi^2=1.07$, df = 3, $I^2=0\%$, $P=.784$). There was no significant difference between the 2 groups (RD = −0.037, 95% CI: −0.107 to 0.033, $P=.300$; Fig. 9).

3.4.9. Occurrence of vomiting. Four studies[13–16] reported the incidence of vomiting. We found no statistical heterogeneity and a fixed-effects model was applied ($\chi^2=0.54$, df = 3, $I^2=0\%$, $P=.911$). The meta-analysis showed no significant difference between groups (RD = −0.012, 95% CI: −0.070 to 0.047, $P=.695$; Fig. 10).

Table 3

Risk of bias.



3.4.10. Evidence level. All main outcomes in this meta-analysis were evaluated using the GRADE system (Table 4).

The overall evidence quality for each outcome was moderate to low which means that further research is likely to significantly change confidence in the effect estimate and to change the estimate. This finding may lower the confidence in any recommendations.

4. Discussion

To the best of our knowledge, this is the first meta-analysis from RCTs to compare the efficiency and safety of local liposomal bupivacaine infiltration and interscalene nerve block for pain control after TSA. The most important finding of the present meta-analysis was that local liposomal bupivacaine infiltration showed equivalent analgesic effect compared with interscalene nerve block. No significant difference regarding opioids consumption and postoperative complications were identified.

With the aging population, the occurrence of glenohumeral arthritis is increasing, and TSA is a popular treatment to improve motor function and relieve pain. However, TAS was usually associated with moderate-to-severe postoperative pain. Consensus has been reached that effective pain control following major orthopedic surgery is important for functional recovery. Regional anesthesia has been proven to be an effective method in setting of postoperative pain. Local infiltration anesthesia is widely used and shows excellent outcomes for pain relief after TSA; however,

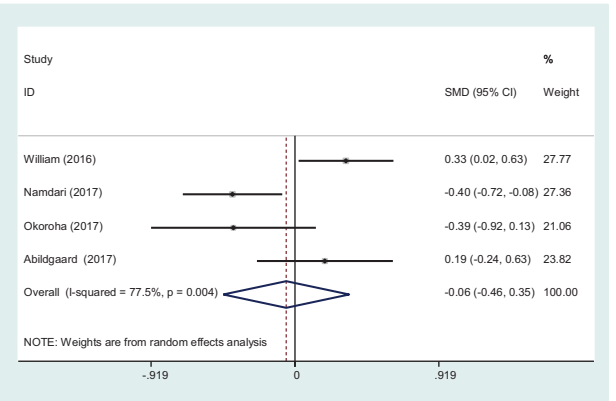


Figure 3. Forest plot diagram showing VAS scores at 24 h following TSA. TSA = total shoulder arthroplasty, VAS = visual analogue scale.

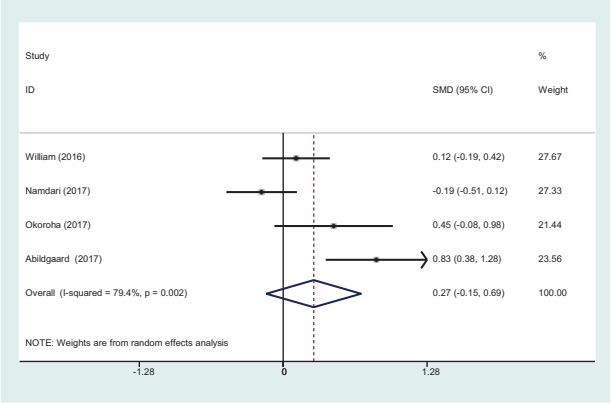


Figure 2. Forest plot diagram showing VAS scores at 12 h following TSA. TSA = total shoulder arthroplasty, VAS = visual analogue scale.

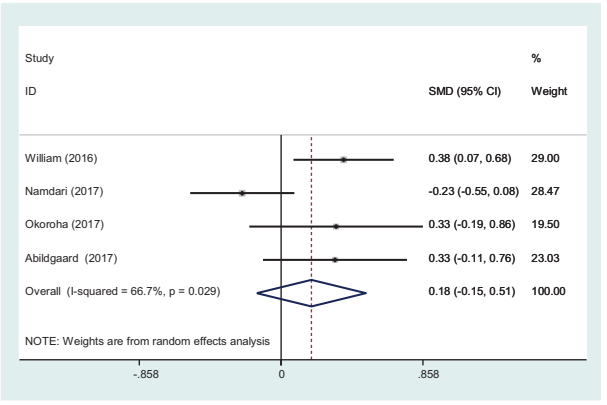


Figure 4. Forest plot diagram showing VAS scores at 48 h following TSA. TSA = total shoulder arthroplasty, VAS = visual analogue scale.

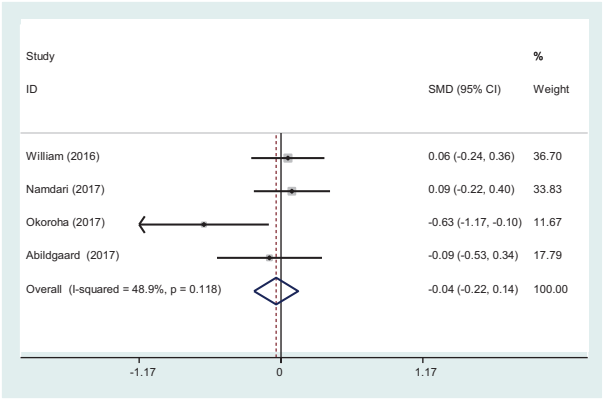


Figure 5. Forest plot diagram showing opioid consumption at 12 h following TSA. TSA = total shoulder arthroplasty.

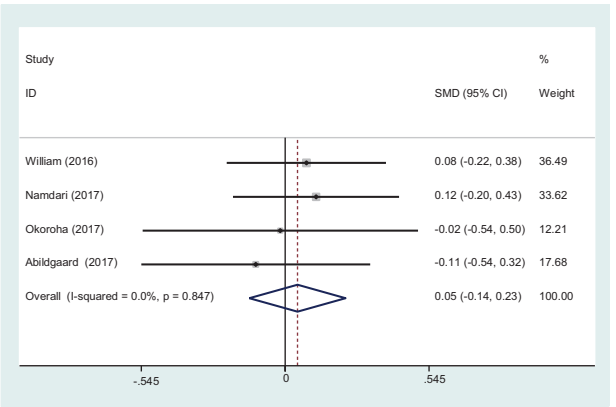


Figure 6. Forest plot diagram showing opioid consumption at 24 h following TSA. TSA = total shoulder arthroplasty.

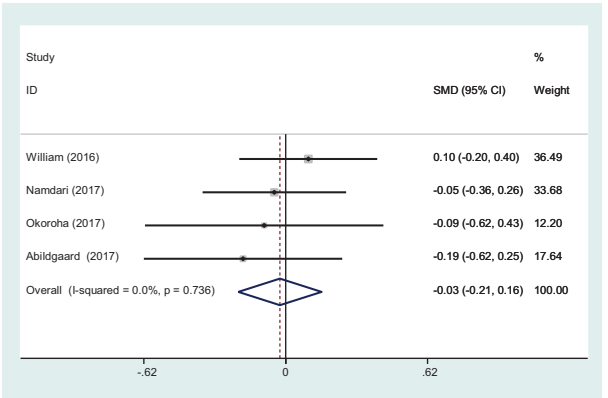


Figure 7. Forest plot diagram showing opioid consumption at 48 h following TSA. TSA = total shoulder arthroplasty.

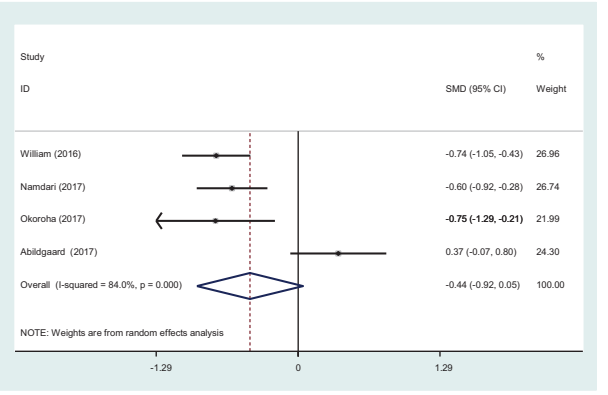


Figure 8. Forest plot diagram showing LOS following TSA. LOS = length of stay, TSA = total shoulder arthroplasty.

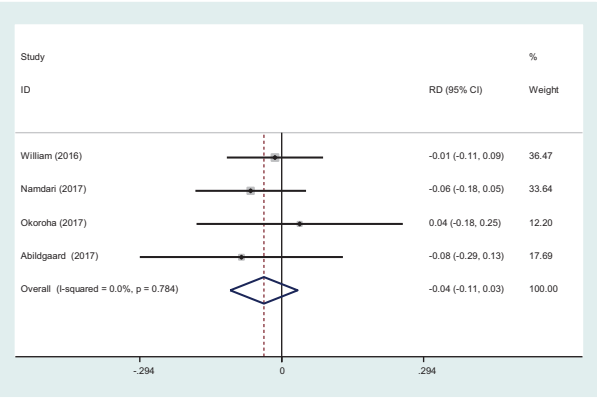


Figure 9. Forest plot diagram showing incidence of nausea following TSA. TSA = total shoulder arthroplasty.

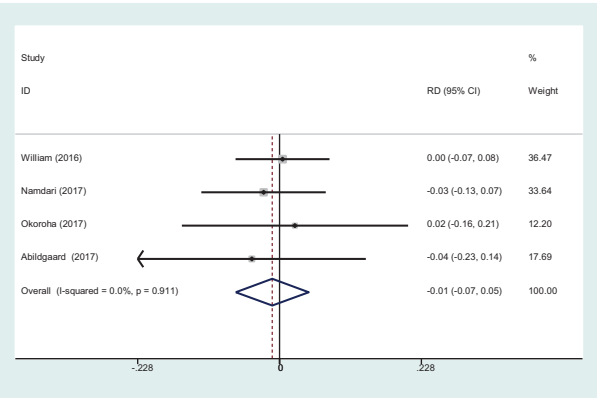


Figure 10. Forest plot diagram showing incidence of vomiting following TSA. TSA = total shoulder arthroplasty.

Table 4

The GRADE evidence quality for the main outcome.

Quality assessment							No. of patients		Effect			
No. of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Liposomal bupivacaine groups	Interscalene nerve block groups	Relative (95% CI)	Absolute	Quality	Importance
VAS scores at 12 h (follow-up 2–4 mo; better indicated by lower values)												
4	Randomized trials	No serious limitations	Serious	No serious indirectness	No serious imprecision	None	199	311	—	SMD 0.272 higher (0.150 lower to 0.695 higher)	⊕⊕⊕○ MODERATE	CRITICAL
VAS scores at 24 h (follow-up 2–4 mo; better indicated by lower values)												
4	Randomized trials	No serious limitations	Serious	No serious indirectness	No serious imprecision	None	199	311	—	SMD 0.056 lower (0.458 lower to 0.346 higher)	⊕⊕⊕○ MODERATE	CRITICAL
VAS scores at 48 h (follow-up 2–4 mo; better indicated by lower values)												
4	Randomized trials	No serious limitations	Serious	No serious indirectness	No serious imprecision	None	199	311	—	SMD 0.183 higher (0.148 lower to 0.513 higher)	⊕⊕⊕○ MODERATE	CRITICAL
Opioid consumption at 12 h (follow-up 2–4 mo; better indicated by lower values)												
4	Randomized trials	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	None	199	311	—	SMD 0.039 lower (0.222 lower to 0.143 higher)	⊕⊕⊕⊕ HIGH	CRITICAL
Opioid consumption at 24 hours (follow-up 2–4 mo; better indicated by lower values)												
4	Randomized trials	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	None	199	311	—	SMD 0.046 higher (0.136 lower to 0.228 higher)	⊕⊕⊕⊕ HIGH	CRITICAL
Opioid consumption at 48 hours (follow-up 2–4 mo; better indicated by lower values)												
4	Randomized trials	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	None	199	311	—	SMD 0.025 lower (0.207 lower to 0.157 higher)	⊕⊕⊕⊕ HIGH	CRITICAL

SMD = standard mean difference, VAS = visual analogue scale.

it has been criticized for short-term action. Liposomal bupivacaine is a long-acting, local anesthetic which is injected via single-dose infiltration to produce analgesic effect.[17] It has been approved by the Food and Drug Administration in 2011. In the acting process, bupivacaine is encapsulated into multivesicular liposomes, resulting in a slow and controlled release from the liposomes. Therefore, analgesic effect can sustain as long as 72 to 96 hours.[18,19] Furthermore, local administration of anesthetics is a simple technique that can be performed without anesthetist. Wang et al[20] showed that liposomal bupivacaine infiltration promotes superior pain relief and less postoperative complications compared with traditional bupivacaine after total joint arthroplasty. Liu et al[21] found that local liposomal bupivacaine injection provided a significant beneficial effect over femoral nerve block in improving the pain in major orthopedic surgery.

Interscalene nerve block is an efficient method of regional anesthesia for upper arm surgery, especially in the shoulder region and it was considered an alternative choice to provide analgesia after TAS. Several reports of interscalene nerve block have shown its effectiveness in postoperative pain management in TSA.[22] Stundner et al[23] demonstrated that interscalene nerve block was associated with an improved pain relief and reduced morphine consumption after TSA. Abdallah et al[24] showed that patients' rehabilitation and satisfaction have improved with the use of interscalene nerve block. Despite the well-established benefits of interscalene nerve block, the safety of interscalene nerve block has been assessed in a number of previous studies. Misamore et al[25] reported that 16% of the subjects were associated with immediate postoperative block side effect, which influenced early recovery and satisfaction. Thus, there was a controversy regarding the efficiency and safety of liposomal bupivacaine infiltration and interscalene nerve block for pain management in TSA. The present meta-analysis indicated that there was no significant difference regarding VAS scores within the first 48 hours between groups.

Opioids are usually used as adjunct to multimodal analgesia protocol. Also, the analgesic effect of the additional opioids provides a long postoperative period without pain. Opioid consumption is also considered as an objective method of measuring pain. However, drug-related side effects, such as nausea, vomiting, headache, and respiratory depression were frequently reported in previous articles.[26,27] Moreover, long-term opioid use may result in drug dependence which is an important issue that should be considered. Effective analgesia protocol is crucial to reduce the consumption of opioids. The present meta-analysis indicated that there was no significant difference between liposomal bupivacaine infiltration group and interscalene nerve block group regarding the opioid consumption.

Postoperative complications were major concerns following additional opioids. Nausea and vomiting are well-known side effects which 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. Considering that only 4 RCTs were included in our study, large sample sizes from high quality RCTs are, therefore, needed.

There are several potential limitations in the present meta-analysis. Only 4 articles with small sample size were included. Some important data were insufficient such as range of motion, making it difficult to analyze. Considering the small number of the included studies, subgroup analysis was not performed. Different dose of local anesthetics in each group may affect the results. Short duration of follow-up in the included studies may result in an underestimation of side effects.

Despite the aforementioned limitations, this study is the first meta-analysis from RCTs to compare the efficiency and safety of liposomal bupivacaine infiltration and interscalene nerve block for pain control after TSA. High-quality RCTs with large sample size are required to investigate the adequate analgesia protocol and potential adverse effects in future studies.

5. Conclusion

Liposomal bupivacaine infiltration provides equivalent postoperative pain control compared with interscalene nerve block following TSA. Both of them can reduce the consumption of opioids without severe adverse effects. More high-quality RCTs with long follow-up period are necessary for proper comparisons of the efficacy and safety of liposomal bupivacaine infiltration with interscalene nerve block.

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