

Is bipolar sealer superior than standard electrocautery for blood loss control after primary total knee arthroplasty

A meta-analysis

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Abstract

Background: Whether bipolar sealer (BS) is superior to standard electrocautery in patients with primary total knee arthroplasty (TKA) remains controversial. Thus, we conducted this meta-analysis involving comparative studies (S) to evaluate whether administration with BS (I) was associated with less blood loss (O) than standard electrocautery (C) after primary TKA (P).

Methods: PubMed (1950–January 2017), EMBASE (1974–January 2017), the Cochrane Library (January 2017 Issue 3), and the Google database (1950–January 2017) were systematically searched. Studies were included in accordance with Population, Intervention, Comparison, Outcomes, and Setting including criteria. Only the patients prepared for primary TKA and administrated with BS as the intervention group and standard electrocautery as control group were included in this meta-analysis. Outcomes include need for transfusion, total blood loss, blood loss in drainage, hemoglobin at discharge, hemoglobin drop, and length of hospital stay. Continuous outcomes and discontinuous outcomes were expressed as weighted mean difference (WMD) and risk ratio (RR) with corresponding confidence intervals (CIs), respectively. Stata 13.0 software was used for relevant data calculation.

Results: A total of 7 clinical trials with 718 patients (398 patients in BS group and 320 in standard electrocautery group) were finally included in this meta-analysis. The pooled results indicated that administration with BS was associated with little reduction of total blood loss (WMD = -123.80, 95%CI -236.56 to -11.04, $P = .031$). There was no significant difference between the need for transfusion, blood loss in drainage, hemoglobin at discharge, hemoglobin drop, and length of hospital stay ($P > .05$).

Conclusion: Based on the current meta-analysis, we found no evidence to support the routine use of bipolar sealer in the management of blood loss in primary TKA. Since the poor quality of the included studies, more randomized controlled trials are still needed to further identify the efficacy of BS after primary TKA.

Abbreviations: CENTRAL = Cochrane Controlled Trials Register, MD = mean difference, Mesh = medical subject heading, PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses, RCTs = randomized controlled trials, RR = risk ratio, TKA = total knee arthroplasty, TXA = tranexamic acid.

Keywords: bipolar sealer, blood loss, meta-analysis, total knee arthroplasty

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1. Introduction

Primary total knee arthroplasty (TKA) is associated with extensive blood loss and a need for intraoperative and postoperative blood transfusion.^[1,2] Blood transfusion is associated with ethical, technical, and financial shortcomings.^[3,4] Intraoperative blood loss accounts a large portion of total blood loss in primary TKA.^[5,6] Standard electrocautery has been used widespread to keep bleeding away from the operative field by blood vessel cauterization; however, administration with standard electrocautery has been accompanied by severe patient burns, operating room fires and even tissue necrosis.^[7–9] Bipolar sealers (BSs) combined bipolar radiofrequency energy with continuous saline flow to prevent charring or burning tissue or produce smoke^[2,10] and the temperature at tissue is 100°C or less. There have been several randomized controlled trials (RCTs) published; however, there is no consensus about the efficacy of BS in reducing blood loss and need for transfusion after primary TKA. Thus, we perform this meta-analysis to further identify the efficacy of BS after primary TKA. The purpose of this

meta-analysis was to assess whether bipolar sealer was superior than standard electrocautery in terms of the need for transfusion, total blood loss, blood loss in drainage, hemoglobin at discharge, hemoglobin drop, and length of hospital stay.

2. Materials and methods

The method of this study was designed and reported according to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)^[11] and the Cochrane Handbook for Systematic Reviews of Interventions. It was prospectively registered in the Researchregistry (reviewregistry674). Methods of this meta-analysis were based on Population, Intervention, Comparison, Outcomes, and Setting guidelines.

2.1. Search strategies

The electronic databases PubMed (1950–January 2017), EMBASE (1974–January 2017), the Cochrane Library (January 2017 Issue 3), and the Google database (1950–January 2017) were systematically searched by two reviewers (ZYS and ZHL). The detailed PubMed search strategy can be seen in Supplement S1, <http://links.lww.com/MD/D354>. In addition, the reference lists of all the full-text literatures and relevant meta-analysis were reviewed to identify any initially omitted studies. There was no restriction on the language of the publication. Meta-analysis was collected from published data and thus ethical review or approval was not necessary. The reliability of the study selection was determined by Cohen's kappa test, and the acceptable threshold value was set at 0.61.^[12]

2.2. Inclusion criteria and exclusion criteria

The following criteria were predefined for inclusion:

- (1) Participants (P): Patients undergoing primary TKA.
- (2) Interventions (I): The comparison group was an administration of BS.
- (3) Comparisons (C): The comparison group was with standard electrocautery.
- (4) Outcomes (O): Need for transfusion, total blood loss, blood loss in drainage, hemoglobin at discharge, hemoglobin drop, and length of hospital stay.
- (5) Study design (S): RCTs and non-RCTs were included.

Studies were excluded if they:

- (1) overlapping with other studies or overlapping with data from the same authors,
- (2) letter or meeting abstracts,
- (3) had no control group or intervention groups (bipolar sealer),
- (4) did not report results adequately.

2.3. Study quality

Two reviewers (ZYS and ZHL) independently assessed the quality of the eligible studies according to the *Cochrane Handbook for Systematic Reviews of Interventions*. Any discrepancies were solved by a discussion or consulted a senior reviewer (HQZ). Assessment criteria included the following 7 domains:

- i) random sequence generation,
- ii) allocation sequence concealment,
- iii) blinding of participants and personnel,
- iv) blinding of outcome assessment,

- v) incomplete outcome data,
- vi) selective outcome reporting, and
- vii) other biases.^[13]

All domains were evaluated as “low”, “high”, or “unclear”. Kappa values were used to measure the degree of agreement between the 2 reviewers and were rated as follows: fair, 0.40 to 0.59; good, 0.60 to 0.74; and excellent, 0.75 or more.^[12]

2.4. Data extraction

The following data were extracted and recorded in Microsoft Excel (Microsoft Corporation, Redmond, Washington):

- (1) Demographic data about the patients in the literature, first author's name, publication date, published country, the patient sample size of BS and standard electrocautery, and the ratio of male patients.
- (2) Surgery type, study type, prosthesis type, the thromboprophylaxis to prevent the occurrence of DVT; and follow-up.
- (3) Outcomes: need for transfusion, total blood loss, blood loss in drainage, hemoglobin at discharge, hemoglobin drop, and length of hospital stay.

2.5. Quality of evidence assessment

Two reviewers (ZYS and HQZ) independently evaluated the quality of evidence assessment in accordance with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.^[14] Risk of bias, inconsistency, indirectness, imprecision and publication bias were the assessment items.^[14,15] Each result was classified as high, moderate, low, or very low. GRADE Pro software (GRADEpro, version 3.6) was used to construct summary tables for the included studies.

2.6. Outcome measures and statistical analysis

The main outcomes were need for transfusion, total blood loss, blood loss in drainage, hemoglobin at discharge, hemoglobin drop, and length of hospital stay. Continuous outcomes (total blood loss, blood loss in drainage, hemoglobin at discharge, and hemoglobin drop) were expressed as the mean differences (MDs) and respective 95% confidence intervals (CIs). Dichotomous outcomes (need for transfusion) were expressed as relative risks (RRs) with 95% CIs. Statistical significance was set at $P < .05$ to summarize findings across the trials. Risk of bias assessment of each involved RCTs was conducted according to the *Cochrane Handbook for Systematic Reviews of Interventions*. Non-RCTs were assessed by Newcastle-Ottawa Scale (NOS).^[16] The meta-analysis was performed using Stata software, version 12.0 (Stata Corp., College Station, TX). Statistical heterogeneity was tested using the chi-squared test and I^2 statistic. Random model was used to perform the meta-analysis. If the heterogeneity is large, a sensitivity analysis and subgroup analysis were conducted to further seek out the source of heterogeneity. Publication bias was assessed by funnel plot and quantitatively assessed by Begg's test. Publications were considered to have no publication bias if the funnel plot was symmetrical and the P value was $> .05$.

3. Results

3.1. Search results

The literature search and selection process are illustrated in Figure 1. The initial search yielded 361 papers (PubMed=112,

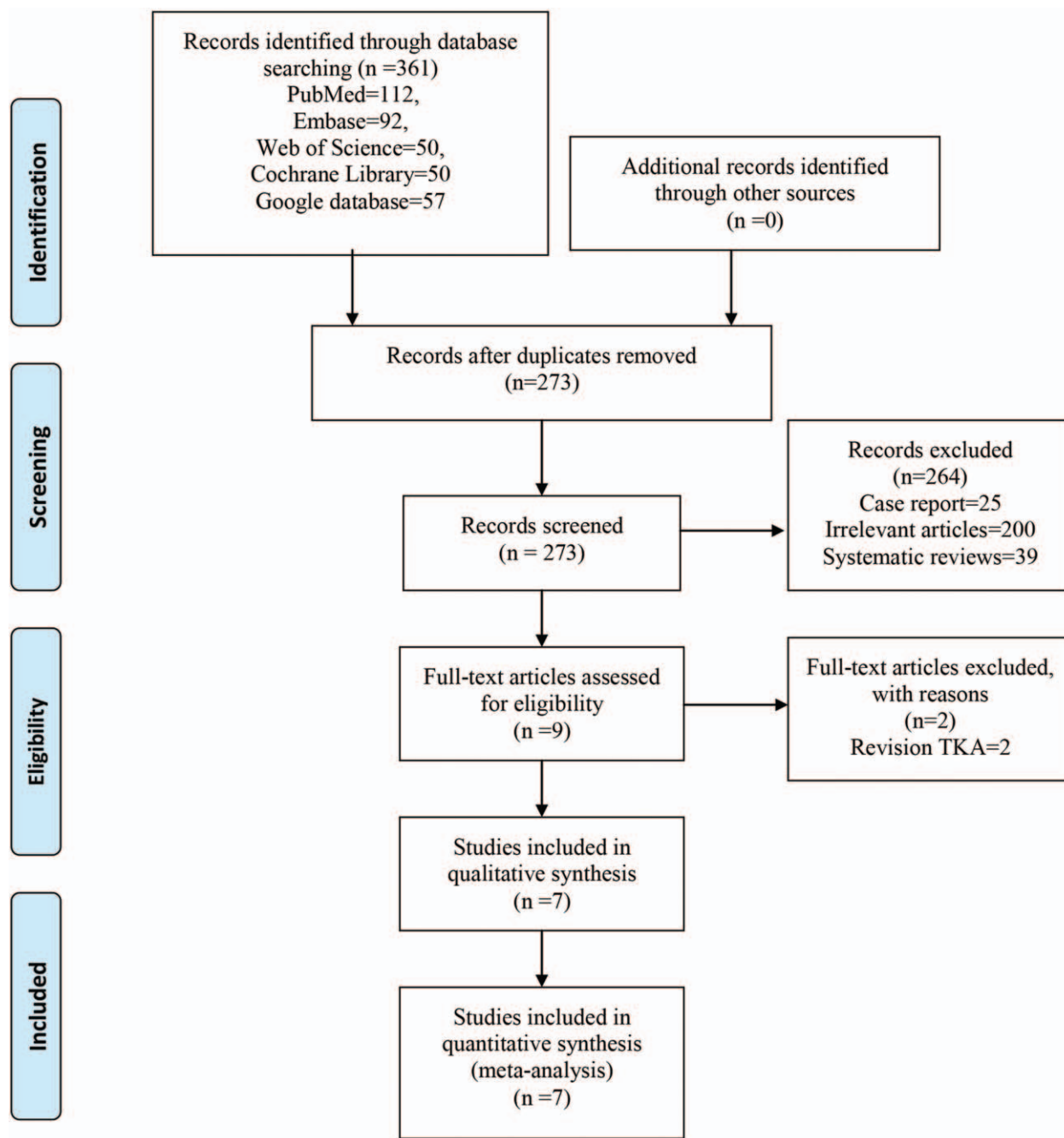


Figure 1. Flow diagram for study selection.

Embase=92, Web of Science=50, Cochrane Library=50, Google database=57); 273 papers were read after excluding the duplicates by Endnote Software (Version X7, Thompson Reuters, USA). Next, 264 papers were excluded based on the inclusion criteria. 2 papers were then excluded as the participants were revision TKAs.^[17,18] Of these, we included 7 clinical trials with 718 patients (398 patients in BS group and 320 in standard electrocautery group) in the meta-analysis.^[2,19-26] The sample size from each study ranged from 20 to 203 and the mean age ranged from 55.9 to 72.2. The general characteristic of the included studies is shown in Table 1 and Supplement S2, <http://links.lww.com/MD/D354>. There was no significant difference

between the preoperative hematology screening such as anemia and coagulopathy.

3.2. Quality assessment

The quality assessment of included RCTs is shown in Figures 2 and 3. Two studies reported the random sequence generation and allocation concealment,^[20,24] one study^[23] did not report the method of random sequence generation and allocation concealment and thus was classified as “unclear bias”. Surgeons performed TKAs and it was not blinded to the personnel.^[20,23,24] The quality of blinding to outcome assessment, incomplete

Table 1
The general characteristic of the included studies.

Author and yr	Country	Case (BP/C)	Mean age (BP/C)	Male patients (BP/C)	Intervention	Control	Study type	Prosthesis	TXA use	Outcomes	Prophylactic antithrombotic	Follow-up
Diedo 2013	USA	30/90	65.7/67.3	NS	Bipolar sealer	Standard electrocautery	RCS	NS	NS	1	NS	3 d
Marulanda 2009	USA	35/34	66/66	22/23	Bipolar sealer	Standard electrocautery	RCTs	NS	NS	1, 2, 3, 5, 6, 7	NS	3 mo
Pfeiffer 2005	Germany	20/20	72/NS	13/NS	Bipolar sealer	Standard electrocautery	PCS	Cemented	NS	2, 3, 4	LMWH	NS
Plymale 2012	USA	50/61	38/51	64.9/66.3	Bipolar sealer	Standard electrocautery	RCTs	Cemented	NS	1, 3, 4, 5	LMWH	2 d
Seviciu 2016	USA	31/32	64.8/62.9	14/14	Bipolar sealer	Standard electrocautery	RCTs	Cemented	NS	2, 5, 7	NS	3 d
Kamath 2014	USA	29/42	59.1/63.4	15/28	Bipolar sealer	Standard electrocautery	CCS	NS	NS	1, 2, 3, 4, 5, 6, 7	Aspirin or warfarin	NS
Rosenthal 2016	USA	203/41	65/61.5	NS	Bipolar sealer	Standard electrocautery	RCS	Cemented	NS	1, 2, 3, 4, 5, 7	Enoxaparin 30 mg	NS

BP/C=bipolar sealer/control, CCS=case controlled study, LMWH=low molecular weight heparin, NS=not stated, PCS=prospective controlled study, RCS=retrospective comparable study, RCTs= randomized controlled trials, TKA=total knee arthroplasty, TXA=tranexamic acid, 1=need for transfusion, 2=total blood loss, 3=blood loss in drainage, 4=hemoglobin at discharge, 5=hemoglobin drop, 6=transfusion unit per patient, 7=length of hospital stay.

outcome data, selective reporting, and other bias were all with low bias. The quality of non-RCTs is shown in Table 2. The total score of Diedo et al,^[19] Pfeiffer et al,^[22] Kamath et al,^[25] and Rosenthal et al^[26] was 18, 24, 17, and 23, respectively.

3.3. Quality of evidence assessment

A summary of the quality of the evidence based on the GRADE approach is shown in Supplement S3, <http://links.lww.com/MD/D354>. The GRADE level of evidence was moderate for need for transfusion, low for total blood loss and hemoglobin at discharge, very low for blood loss in drainage, hemoglobin drop and length of hospital stay.

4. Results of meta-analysis

4.1. Need for transfusion

A total of five trials tested the need for transfusion after TKA, and pooled meta-analysis indicated that there is no significant difference between the BS and standard electrocautery in terms

Table 2
The minors quality score of the non-RCTs; “0” represent high risk of bias; “1” represent unclear risk of bias; “2” represent low risk of bias.

Items	Diedo 2013	Pfeiffer 2005	Kamath 2014	Rosenthal 2016
A clearly stated aim	2	2	2	2
Inclusion of consecutive patients	1	2	2	2
Prospective collection of data	1	2	0	1
Endpoints appropriate to the aim of the stud	2	2	2	2
Unbiased assessment of the study endpoint	0	2	0	2
Follow-up period appropriate to the aim of the study	2	2	2	2
Loss to follow-up less than 5%	2	2	2	2
Prospective calculation of the study size	0	2	0	2
An adequate control group	2	2	2	2
Contemporary groups	2	2	1	2
Baseline equivalence of groups	2	2	2	2
Adequate statistical analyses	2	2	2	2
Total scores	18	24	17	23

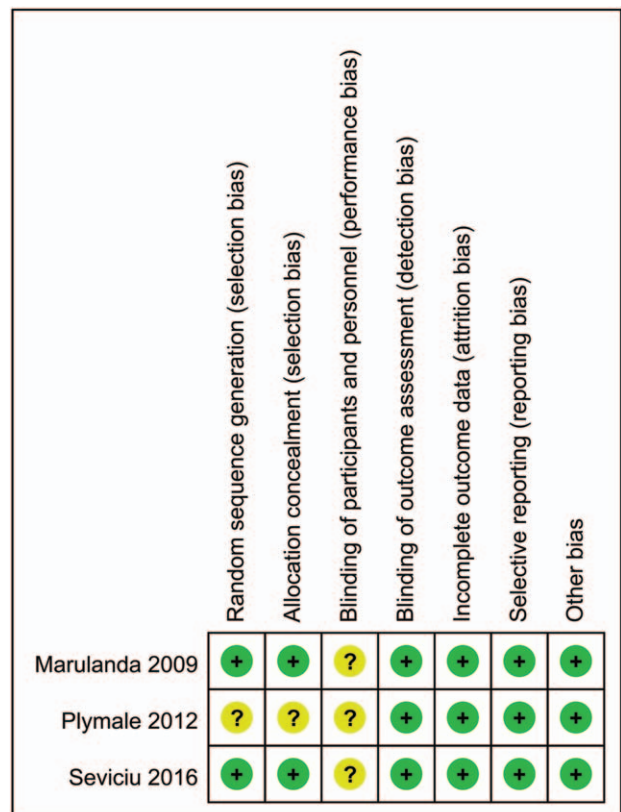


Figure 2. Risk of bias summary.

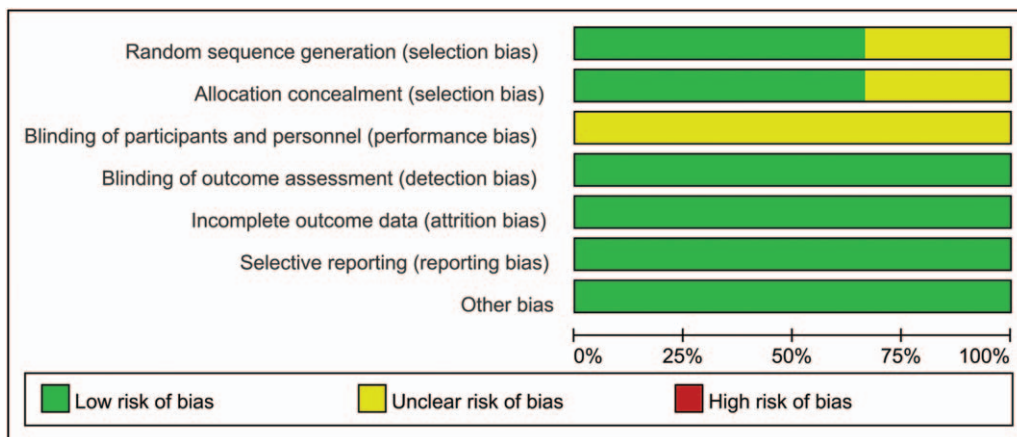


Figure 3. Risk of bias graph.

of the need for transfusion (RR=0.86, 95%CI 0.61–1.21, $P=.337$, Fig. 4) with low heterogeneity ($I^2=38.4%$, $P=.165$).

A funnel plot was drawn and shows that there is no bias between the included studies indicating a need for transfusion (Fig. 5A); moreover, the P value obtained from the Begg’s test is 0.806 and this also indicated that there is no bias (Fig. 5B).

4.2. Total blood loss

A total of five trials reported the total blood loss after TKA and pooled results indicating that the BS can decrease the total blood loss in a statistically significant manner with a mean of 123.80 ml (weighted mean difference (WMD)=−123.80, 95%CI −236.56 to −11.04, $P=.031$, Fig. 6) with high heterogeneity ($I^2=74.3%$, $P=.004$).

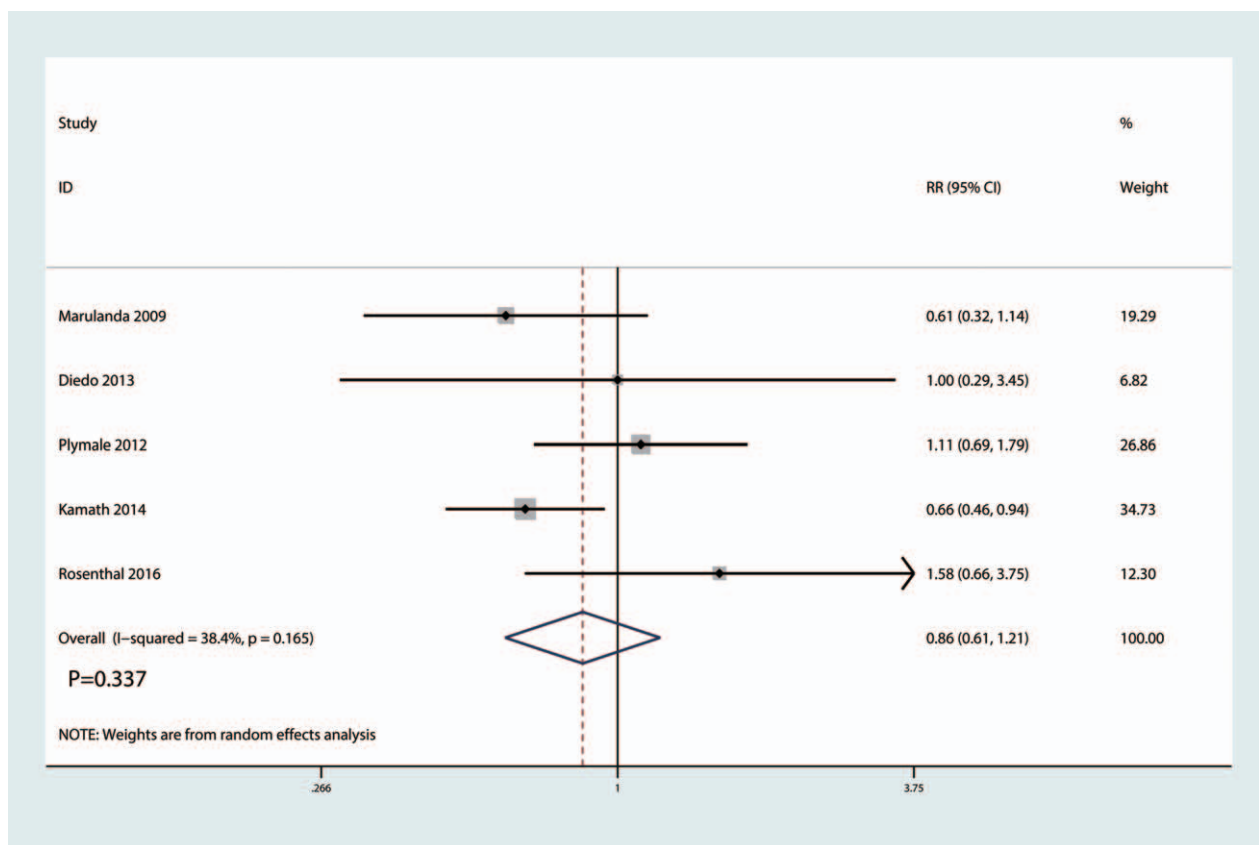


Figure 4. Forest plots comparing need for transfusion between BS and standard electrocautery from the included studies.

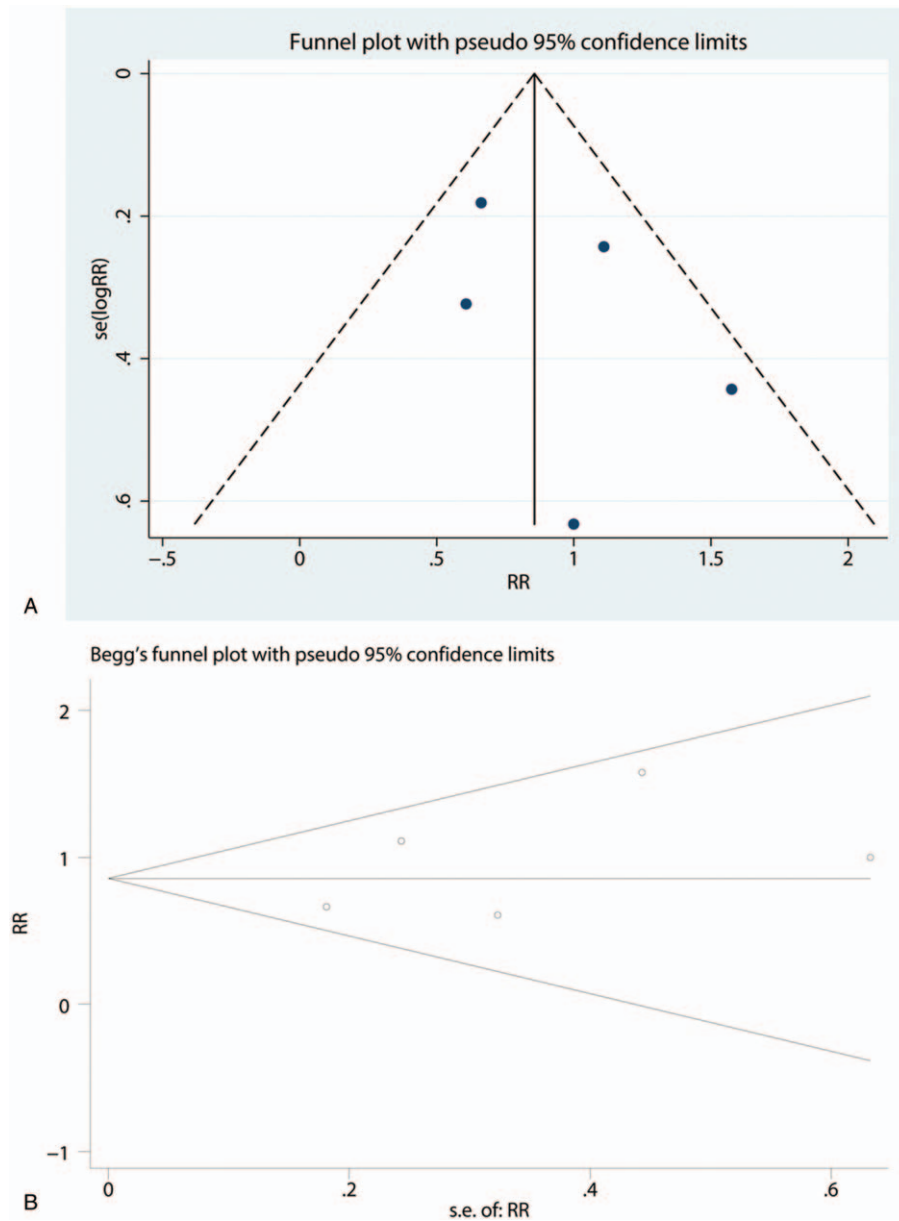


Figure 5. (A) Funnel plot for intraoperative blood loss and (B) Begg's test for the need for transfusion.

The results of sensitivity analysis show that no studies affected the heterogeneity of the total blood loss, and the detail of this information is shown in Figure 7.

4.3. Blood loss in drainage

Four trials were performed about the blood loss in drainage after primary TKA, and pooled meta-analysis indicated that there is no significant difference between the bipolar and standard electrocautery in terms of blood loss in drainage after primary TKA (WMD = -47.29, 95% CI -271.14 to 176.56, $P = .679$, Fig. 8) with high heterogeneity ($I^2 = 89.9\%$, $P = .000$).

4.4. Hemoglobin at discharge

Three studies were available for the data of hemoglobin at discharge. Results indicated that there was no significant

difference between the hemoglobin at discharge (WMD = 0.23, 95% CI -0.29 to 0.75, $P = .380$, Fig. 9) with high heterogeneity ($I^2 = 78.1\%$, $P = .003$).

4.5. Hemoglobin drop

A total of five trials with 394 patients reported the hemoglobin drop after primary TKA, and pooled meta-analysis indicated that there is no significant difference between the BS and standard electrocautery in terms of hemoglobin drop (WMD = 0.11, 95% CI -0.38 to 0.59, $P = .668$, Fig. 10) with high heterogeneity ($I^2 = 78.7\%$, $P = .001$).

4.6. Length of hospital stay

Three trials with 203 patients reported the length of the hospital stay after the use of the BS and standard electrocautery. Results

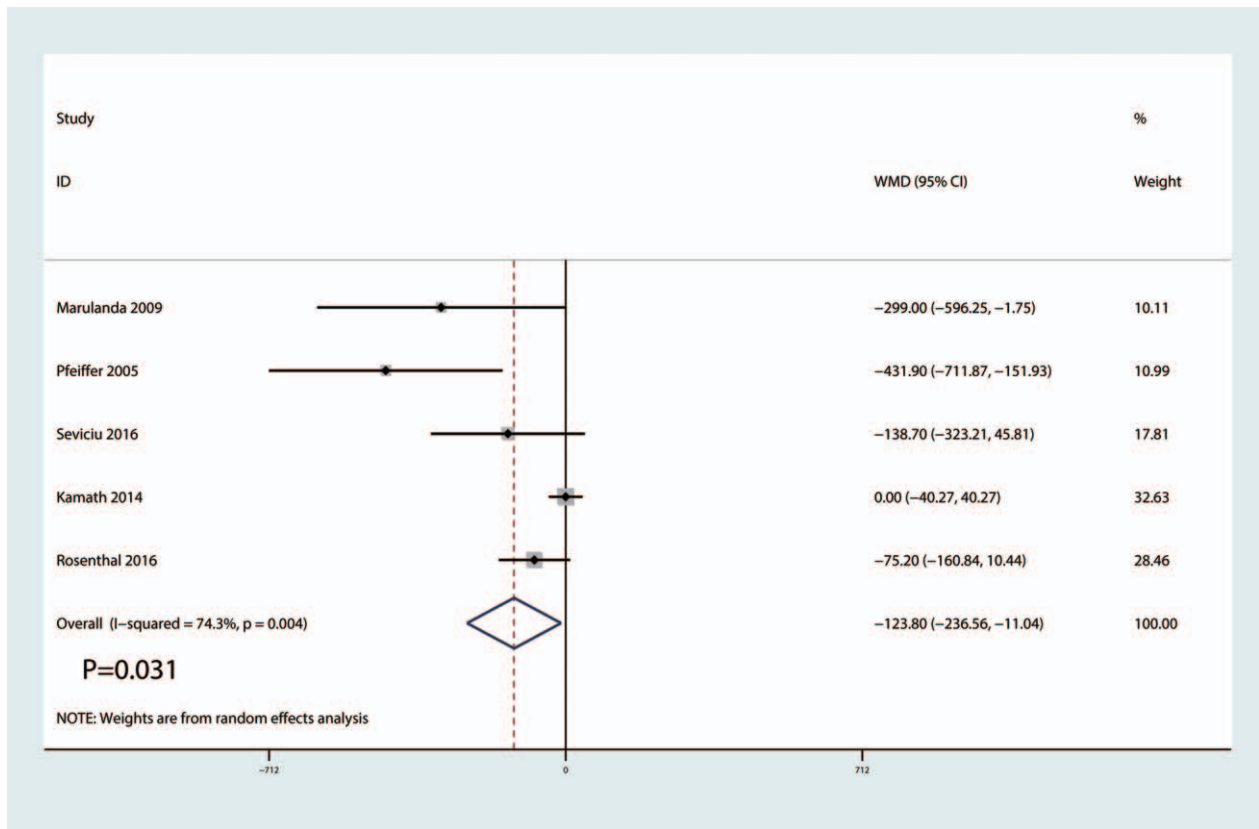


Figure 6. Forest plots comparing total blood loss between BS and standard electrocautery from the included studies.

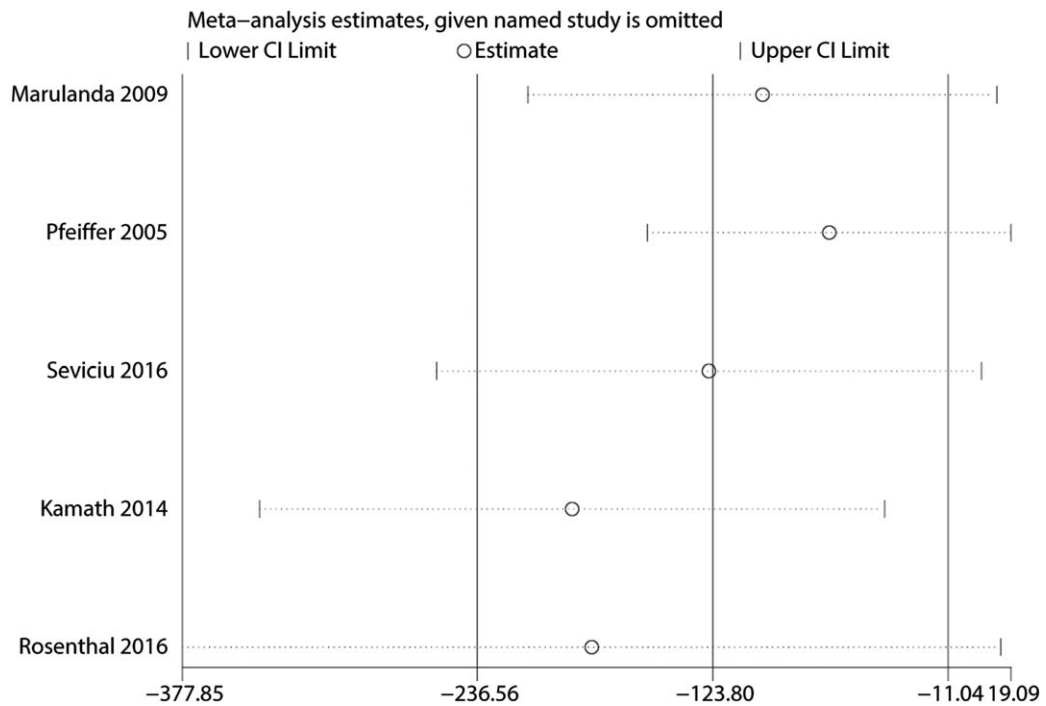


Figure 7. Sensitivity analysis of the total blood loss.

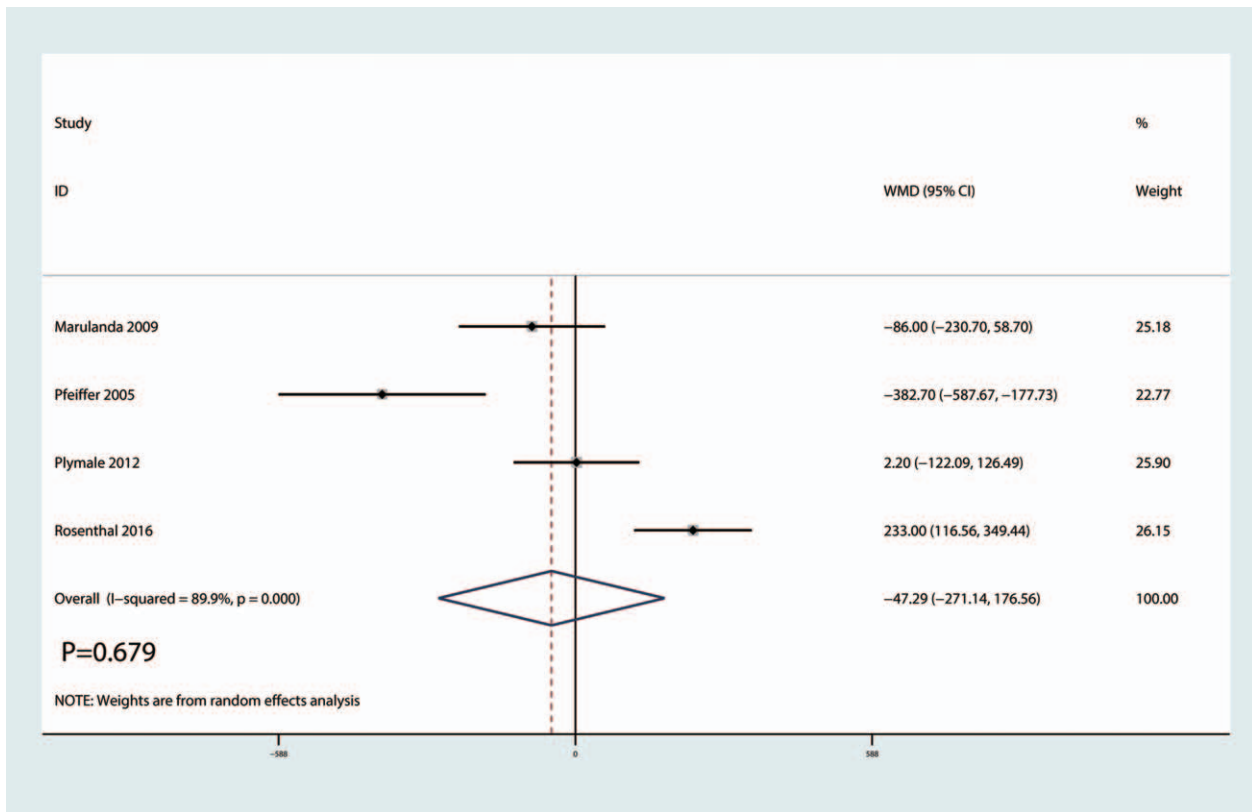


Figure 8. Forest plots comparing blood loss in drainage between BS and standard electrocautery from the included studies.

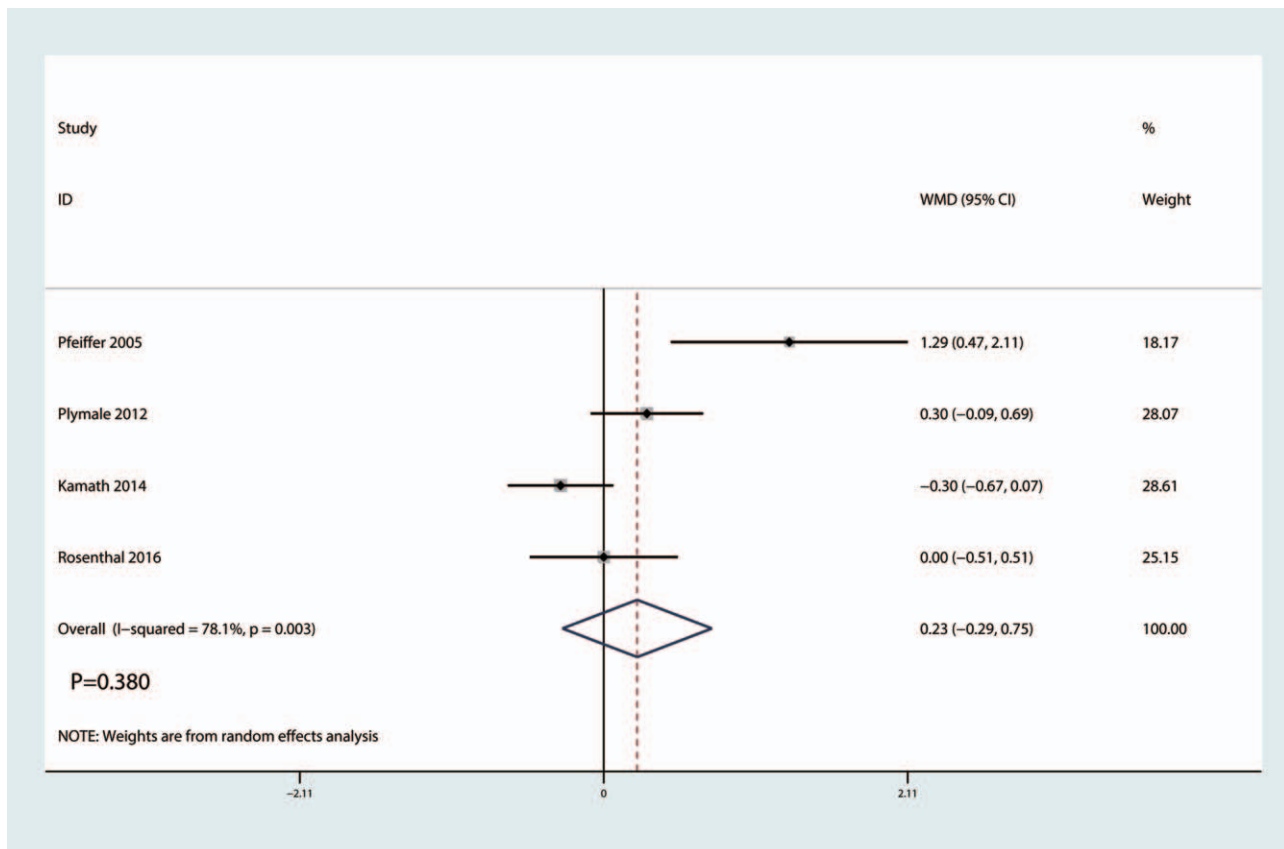


Figure 9. Forest plots comparing hemoglobin at discharge between BS and standard electrocautery from the included studies.

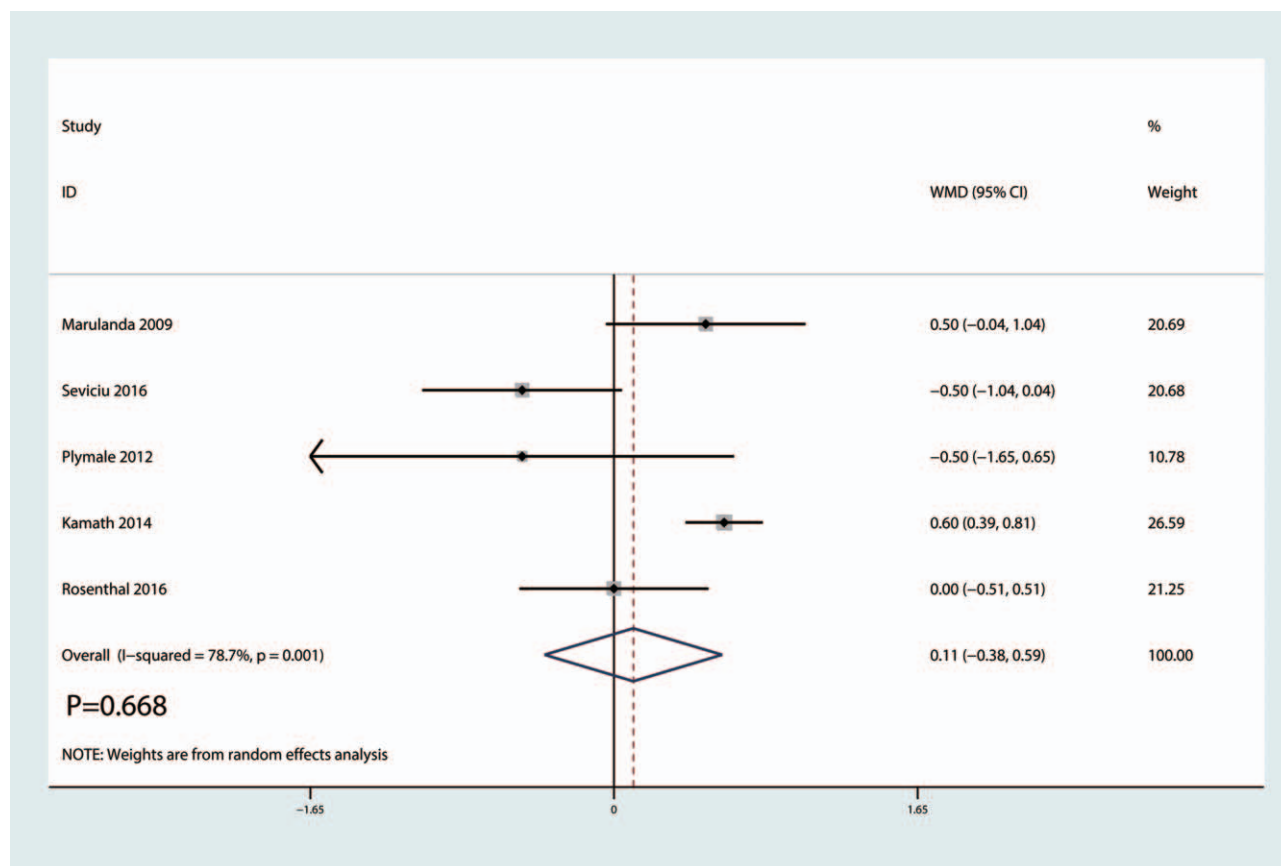


Figure 10. Forest plots comparing hemoglobin drop between BS and standard electrocautery from the included studies.

indicated that there was no significant difference between the length of hospital stay (WMD = -0.05, 95% CI -0.23 to 0.13, $P = .590$, Fig. 11) with no heterogeneity ($I^2 = 0.0\%$, $P = .779$).

4.7. Subgroup analysis

All the variables show a large heterogeneity between the included studies, and thus a subgroup analysis was conducted to further analyze the results. Since RCTs and non-RCTs were both included in this meta-analysis, subgroup analysis was based on the research type of the included studies. The final results are shown in Table 3.

5. Discussion

To our knowledge, no previous study has assessed the effectiveness and safety based on the BS and standard electrocautery following primary TKA. Final results indicated that BS can decrease the total blood loss by 123.80 ml in a statistically significant manner. However, no statistical significance was found between the hemoglobin drop, need for transfusion, and hospital stay. The GRADE level of evidence was moderate for need for transfusion, low for total blood loss and hemoglobin at discharge, very low for blood loss in drainage, hemoglobin drop and length of hospital stay.

Yang et al^[27] revealed that administration with BS was associated with a small, but not clinically important, reduction in intraoperative blood than standard electrocautery in primary

THA. The pooled results indicated that BS can decrease the total blood loss in a statistically significant manner with a mean of 123.80 ml. A total blood loss with 123.80 ml seems not clinically important. Min et al^[28] conducted an updated meta-analysis and revealed that BS was associated with a reduction of total blood loss by 226.57 ml in primary THA. Li et al^[29] revealed that BS was associated with a reduction of total blood loss by 165.23 ml. However, primary TKAs and revision TKAs were all included in that study. Because of the large heterogeneity, subgroup was then performed and results indicated that BS was associated with a reduction of total blood loss by 131.95 ml in the RCTs.

Perioperative blood loss during TKA is reported at about 800 ml to 1800 ml, and postoperative anemia has an adverse effect on morbidity and mortality of affected patients.^[30-35] There were no significant differences between hemoglobin at discharge, hemoglobin drop, need for transfusion, blood loss in drainage, and length of hospital stay ($P > .05$). The subgroup analyses results indicated that there was still heterogeneity between the studies in terms of hemoglobin drop and the need for transfusion. Fukui et al^[36] revealed that BS was effective in shortening the length of hospital stay in lumbar posterolateral fusion. Marulanda et al^[2,20] published two relevant studies about the hemostasis effects of BS in reducing intraoperative blood loss in primary TKA. Final results indicated that BS may be of limited benefit except in intraoperative blood loss.

Meanwhile, complications associated with BS have also emerged, including the concern of early postoperative periprosthetic femoral condyle fracture after extensive administration in

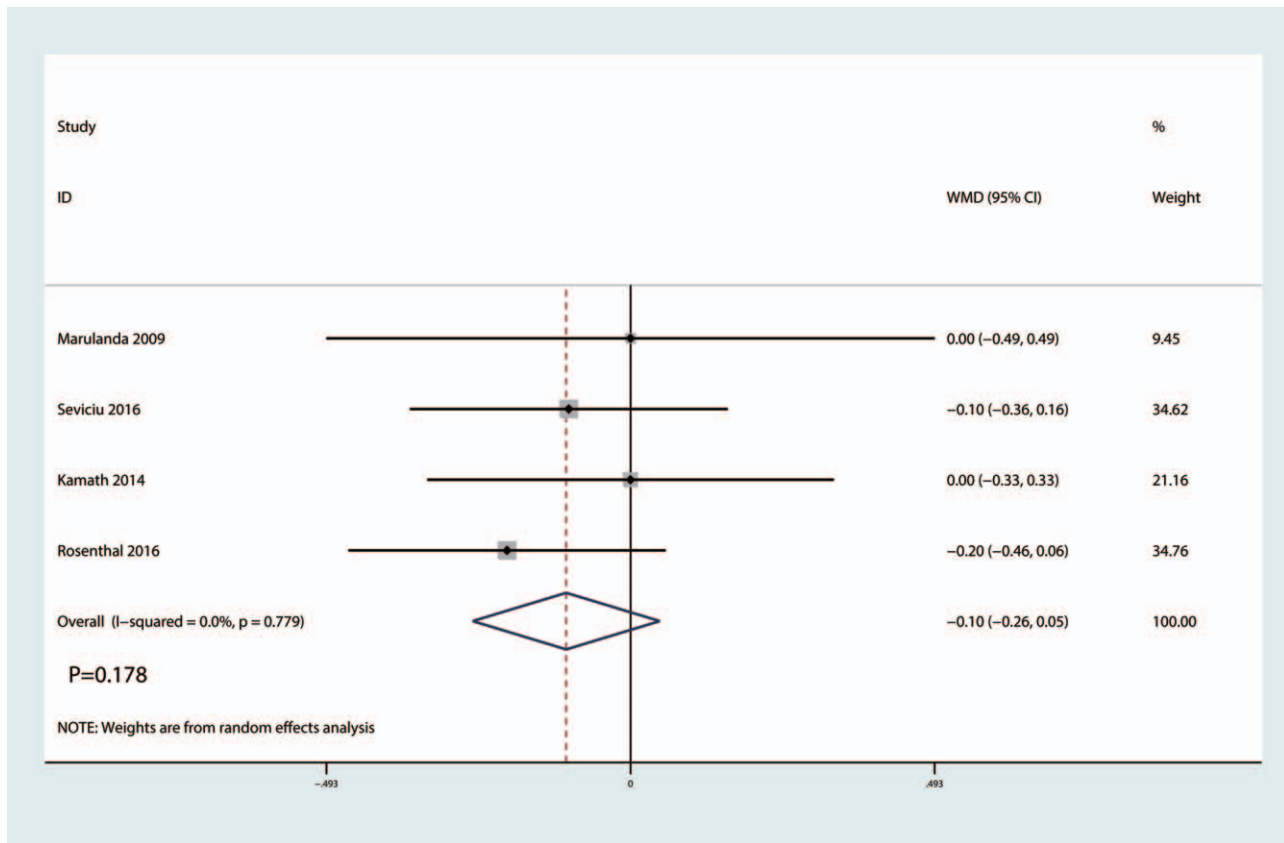


Figure 11. Forest plots comparing the length of hospital stay between BS and standard electrocautery from the included studies.

revision TKA.^[37] The occurrence of complications was attempted to be compiled to assess the safety of BS; however, there was insufficient data to support the safety of BS in primary TKA. One study revealed that BS can decrease the occurrence of infection in revision TKAs^[38] and this affects the need for more studies to further identify.

A major strength of current meta-analysis was the patients' selection and rigorous statistical calculation. PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL),

Web of Science and Google scholar were systematically retrieved and no language was restrained. Finally, a total of seven trials fulfilled the inclusive criteria and thus were included in this meta-analysis.

The overall methodological quality of the included 3 RCTs was relatively high. Only one study did not state the randomized sequential generation and did not reveal the allocation concealment and blinding. Another two trials give detailed information on the randomized sequential generation, allocation concealment,

Table 3
Subgroup analysis that compared bipolar sealer and standard electrocautery in studies that only included RCTs.

Variables	Studies (n)	Patients (n)	P-value	Incidence		Model
				95%CI	Heterogeneity P-value (I ²)	
Hemoglobin drop						
RCTs	3	244	.812	-0.414, 0.315	72.1	Random
Total blood loss						
RCTs	2	132	.036	-150.05, -26.52	0	Fixed
Blood loss in drainage						
RCTs	2	180	.464	-129.53, 59.04	0	Fixed
Length of hospital stay						
RCTs	2	132	.513	-0.287, 0.206	0	Random
Need for transfusion						
RCTs	2	180	.593	0.474, 1.531	55	Random
Hemoglobin at discharge						
RCTs	2	215	.255	-0.33, 0.61	61	Random

CI=confidence interval, RCTs=randomized controlled trials.

and blinding. Though 4 non-RCTs were included in our meta-analysis, the baseline of the included non-RCTs was relative with one accord and relatively high quality.

There were several limitations in this meta-analysis:

- (1) only 3 RCTs and 4 non-RCTs were included, the relative small number of the eligible studies will affect the final results;
- (2) the duration of follow-up in some studies was unclear, and long-term follow-up was needed for testing the function outcomes of hips;
- (3) the publication bias that existed in the meta-analysis influenced the results;
- (4) the concomitant use of TXA may have confounded the data in any of the studies as this likely has a significant effect on blood loss reduction during primary TKA;
- (5) the included studies did report on tourniquet time, and longer tourniquet time would expect a reduction in intraoperative blood loss for that series and possibly a reduced transfusion rate for primary TKA and may cause heterogeneity between the studies;
- (6) the heterogeneity among the studies will also affect the final conclusion, although we tried to use subgroup analysis to solve it.

6. Conclusion

BS has limited hemostasis effects after primary TKA. What's more, there was no significant difference between the two groups in terms of the length of hospital stay. Due to the included number and the quality of the studies, there is still a need for high-quality RCTs to further identify the effect of BS on the blood loss in TKA.

We did not recommend BS as a routine hemostasis method in primary TKA patients. Future studies should be focused on the knee functional outcomes and the potential complications during surgery.

Author contributions

Data curation: Xinxin Chen, Xiao Wang.

Visualization: Wenhui Yang.

Writing – original draft: Wenhui Yang.

Writing – review and editing: Xinxin Chen, Xiao Wang.

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