

A meta-analysis comparing the outcomes of LigaSure Small Jaw versus clamp-and-tie technique or Harmonic Focus Scalpel in thyroidectomy

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Abstract

Background: LigaSure (LS) Small Jaw is a surgical hemostasis equipment that is newly introduced in thyroid surgery. The objective of this study is to assess the short-term efficacy and safety outcomes of LS Small Jaw compared with clamp-and-tie technique or Harmonic Focus Scalpel in thyroidectomy.

Methods: A literature search was performed in the PubMed and Embase databases (until June 12, 2016) that reported the comparisons between LS Small Jaw and other techniques in thyroidectomy. Quality assessments were performed according to The Cochrane Collaboration's risk of bias tool and a modification of the Newcastle-Ottawa Scale in randomized controlled trials (RCTs) and non-RCTs, respectively. All statistical analyses were conducted using RevMan 5.3.

Results: Finally, 7 studies with 813 patients were included into the meta-analysis, and all included studies were comparable with moderate-to-high quality. There was significant reduced operative time in LS Small Jaw, compared with clamp-and-tie (mean difference [MD] = -17.49, 95% confidence interval [CI]: -22.20 to 12.77, $P < 0.00001$) or Harmonic Focus Scalpel (MD = -2.29, 95% CI: -3.19 to 1.39, $P < 0.00001$). Besides, other perioperative outcomes including intraoperative blood loss and postoperative blood loss favored LS Small Jaw compared with clamp-and-tie. In terms of complications, less-temporary hypocalcemia rate was observed in LS Small Jaw compared with clamp-and-tie (odds ratio [OR] = 0.49, 95% CI: 0.27-0.90, $P = 0.02$), although no significant difference was detected compared with Harmonic Focus Scalpel (OR = 0.47, 95% CI: 0.14-1.56, $P = 0.22$). Other complications such as length of hospital stay, permanent hypocalcemia, temporary or permanent recurrent laryngeal nerve palsy, and hematomas were not significant.

Conclusion: In conclusion, LS Small Jaw is more favorable than clamp-and-tie technique or Harmonic Focus Scalpel in thyroidectomy.

Abbreviations: CI = confidence interval, HR = hazard ratio, LS = LigaSure, MD = mean difference, NOS = Newcastle-Ottawa Scale, OR = odds ratio, RCT = randomized controlled trial, RLN = recurrent laryngeal nerve.

Keywords: clamp-and-tie, complications, Harmonic Focus Scalpel, LigaSure Small Jaw, meta-analysis

1. Introduction

Thyroidectomy is one of the most commonly performed procedures in head and neck surgery all over the world. Due

to rich arterial and venous sources in the thyroid gland and close to the main lateral cervical vessels (carotid artery and jugular vein), recurrent laryngeal nerve (RLN), prompt and effective hemostasis in thyroid surgery is crucial.^[1,2] Efficacy in hemostasis may make a difference in operative time, perioperative blood loss, and degrees of injury to laryngeal nerve, parathyroid.^[3-5]

Ligation of blood vessels is often time consuming, and the use of sutures and their application technique requires experience and a prolonged learning curve. In recent years, several new equipments have advanced the practice of thyroid surgery, such as Harmonic Focus Scalpel and vessel sealing system.^[6] Harmonic Focus Scalpel is a device that is widely used in many surgical practices. Small Jaw is a new generation of the LigaSure (LS) (LigaSure, Covidien, Minneapolis, Minnesota, USA) for use in thyroid surgery. This device is capable of dissection, ligation, and cutting in thyroid surgery, making hemostasis more effective and operating time shorter.^[7] In this study, LS Small Jaw was compared with Harmonic Focus Scalpel or clamp-and-tie in terms of operative time; intraoperative blood loss; postoperative blood loss; length of hospital stay; and complications including temporary/permanent hypocalcemia, temporary/permanent RLN palsy, seromas, hematomas, and infection.

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2. Methods

2.1. Study search

A systematic search was conducted in the PubMed, Embase database, and the Cochrane Central Register of Controlled Trials ClinicalTrials.gov (<http://www.clinicaltrials.gov>) with no limits (until June 2, 2016). Our search terms were LS Small Jaw, thyroidectomy/thyroid surgery, and surgical outcome. In addition, previously published studies on the topic of the interest were reviewed. We manually searched the references of all retrieved articles.

2.2. Study selection

The inclusion criteria were as follows: the studies that estimated the impact of surgical instruments on thyroidectomy, surgical procedure comparing LS Small Jaw and clamp-and-tie or Harmonic Focus Scalpel, the studies providing short or surgical outcomes, and available data for each surgical regimen. The exclusion criteria were as follows: the patients in studies underwent other treatment such as hepatectomy, just 1 surgical regimen (LS Small Jaw) was reported, other surgical technique such as LS precise was compared, and studies lacking available data.

Search results were imported into bibliographic citation management software (EndNote X7, Endnote, Thomson Scientific, Philadelphia, Pennsylvania, USA). The authors screened imported titles and abstracts to identify potential studies, and then, full texts were carefully read to match the inclusion and exclusion criteria. Disagreements were resolved through discussion or asking for advice from the corresponding author.

2.3. Data extraction and quality assessment

The first 2 authors independently extracted data from potential included studies. Baseline information included first author, published year, number of patients, intervention, study design, and country. The following outcome data were extracted: operative time; intraoperative blood loss; postoperative blood loss; length of hospital stay; and complications including temporary/permanent hypocalcemia, temporary/permanent RLN palsy, hematomas, and infection.

As for study qualitative assessment, we used The Cochrane Collaboration's risk of bias tool^[8] to evaluate the quality of randomized controlled trials (RCTs). Six domains including random sequence generation, allocation concealment, blinding of participants and researchers, blinding of outcome assessment, incomplete outcome data, and selective reporting were independently taken into evaluating risk of bias. For non-RCTs, a modification of the Newcastle-Ottawa Scale (NOS)^[9] with 3 domains of selection, comparability, and outcome was induced. Five main factors were investigated: operation indication, operation type (total thyroidectomy or hemithyroidectomy), age, sex, and body mass index. Out of a total of 6 stars, studies that valued more than 4 stars were recognized as being moderate-to-high quality.

2.4. Statistical analysis and outcome definition

We analyzed the data using (Review manager, Cochrane, London, United Kingdom) (Version 5.3). Odds ratios (ORs) or hazard ratios (HRs) along with 95% confidence intervals (CI) were used for analyzing dichotomous data and mean differences (MDs) along with 95% CI for continuous data. Heterogeneity test, in order to measure the variation among included studies,

was expressed with the I^2 index and P value. In addition, substantial significance was set when $P < 0.10$, thus a random effect model was used, and sensitivity analysis was performed by sequentially omitting each study to test the influence of individual study. When, $P \geq 0.10$, a fixed-effect model was induced. For outcomes, the value of $P < 0.05$ was considered to indicate statistical significance.

Intraoperative and postoperative blood losses were estimated. Postoperative complications were recorded till discharge from hospital. Permanent hypocalcemia or RLN palsy was followed till 6 to 12 months after surgery.

3. Results

3.1. Characteristics of studies

The flow diagram of the detailed selection process is summarized in Fig. 1. Briefly, a total of 16 abstracts were identified after removing out duplications in the primary electronic and manual searches. After screening the potential full texts of hit abstracts, 7 studies including a total of 813 patients who underwent thyroidectomy compared the surgical outcomes between LS Small Jaw and clamp-and-tie/Harmonic Focus Scalpel.^[10–16] Among them, 5 studies (386 patients) compared LS Small Jaw and clamp-and-tie,^[10,11,13,15,16] and the residual 2 studies (427 patients) compared LS Small Jaw and Harmonic Focus Scalpel for thyroidectomy.^[12,14] The baseline characteristics of all studies are listed in Table 1.

3.2. Quality judgments of studies

LS Small Jaw is an emerging instrument used in thyroidectomy. It is not hard to randomly allocate thyroidectomy into LS Small Jaw or other instruments. So the included 4 of total 7 researches were prospective randomized studies,^[10,11,13,14] and another 3 studies were 2 retrospective controlled studies^[15,16] and 1 prospective

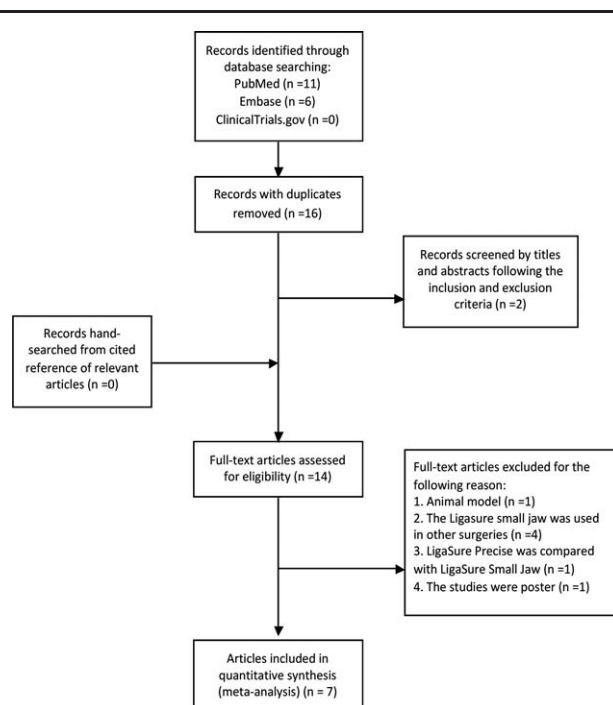


Figure 1. Flow diagram of meta-analysis study selection process.

Table 1

Basic characteristics of all pooled studies in the meta-analysis.

Reference	No. of patients		Intervention	Study design	Country
	LigaSure Small Jaw	Others			
Bircan et al ^[10]	32	22	LigaSure Small Jaw vs clamp-and-tie	Prospective randomized controlled	Turkey
Coiro et al ^[11]	95	95	LigaSure Small Jaw vs clamp-and-tie	Prospective randomized controlled	Italy
Hammad et al ^[12]	161	140	LigaSure Small Jaw vs Harmonic Focus Scalpel	Prospective controlled	USA
Hirunwiwatkul and Tungkavivachagul ^[13]	20	20	LigaSure Small Jaw vs clamp-and-tie	Prospective randomized controlled	Thailand
Hwang et al ^[14]	64	62	LigaSure Small Jaw vs Harmonic Focus Scalpel	Prospective randomized controlled	Korea
Kuboki et al ^[15]	39	43	LigaSure Small Jaw vs clamp-and-tie	Retrospective controlled	Japan
Molnar et al ^[16]	10	10	LigaSure Small Jaw vs clamp-and-tie	Retrospective controlled	Romania

Table 2

Quality assessment of studies in the meta-analysis.

Reference	Selection		Comparability		Outcome assessment		Random sequence generation	Allocation concealment	Blinding of participants and researchers	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Quality judgment
	1	2	3	4	5								
Bircan et al ^{[10],*}							+	?	+	?	+	+	++++
Coiro et al ^{[11],*}							+	?	?	?	+	+	+++
Hammad et al ^{[12],†}	★	★	★	★	★								★★★★★
Hirunwiwatkul and Tungkavivachagul ^{[13],*}							+	+	+	+	?	+	++++
Hwang et al ^{[14],*}							+	?	?	+	+	+	++++
Kuboki et al ^{[15],†}	★	★	★★	★	★								★★★★★
Molnar et al ^{[16],†}	★	★	★	★	-								★★★★

* + low risk of bias; ? unclear risk of bias.

† Selection: (1) Is the subject definition adequate or described? (if yes, 1 star); (2) Was the subject representative of the total population? (1 star, if truly or obviously; no stars if subjects were selected group or not described); Comparability: (3) Did the study have no differences between LigaSure Small Jaw and clamp-and-tie/Harmonic Focus Scalpel for thyroidectomy? Five main factors were considered: operation indication, operation type (total thyroidectomy or hemithyroidectomy), age, sex, and body mass index (if yes, 2 stars; 1 star if there were no other differences between the 2 groups even if 1 or more of these 5 characteristics was not reported; no star was assigned if the 2 groups differed); Outcome assessment: (4) Clearly defined outcome of interest (if yes, 1 star); (5) Adequacy of follow-up (1 star if less than 20% of thyroidectomy lost to follow-up, otherwise no stars).

nonrandomized study.^[12] As for qualitative assessment, Table 2 showed the evaluation of each study followed by The Cochrane Collaboration’s risk of bias tool and modified NOS. All included studies were comparable with moderate-to-high quality.

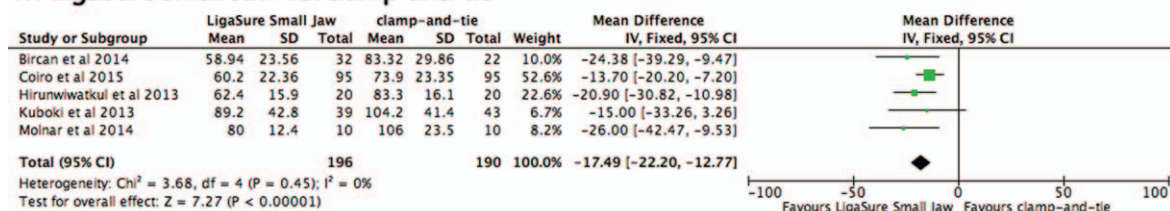
3.3. Outcomes

In terms of operative time, all 7 studies were pooled in the analysis. Among them, 5 of total 7 researches compare LS Small

Jaw with clamp-and-tie, and there is significant reduced operative time in LS Small Jaw group (MD = -17.49, 95% CI: -22.20 to 12.77, $P < 0.00001$).^[10,11,13,15,16] The other 2 studies reported the similar significant reduced operative time when LS Small Jaw is compared with Harmonic Focus Scalpel (MD = -2.29, 95% CI: -3.19 to 1.39, $P < 0.00001$) (Fig. 2).^[12,14] Moreover, funnel plot of operative time in all studies showed no obvious evidence of publication bias (Fig. 3). In addition, other perioperative outcomes including intraoperative blood loss and postoperative

1. operative time

1.1 LigaSure Small Jaw VS. clamp-and-tie



1.2 LigaSure Small Jaw VS. Harmonic Focus Scalpel

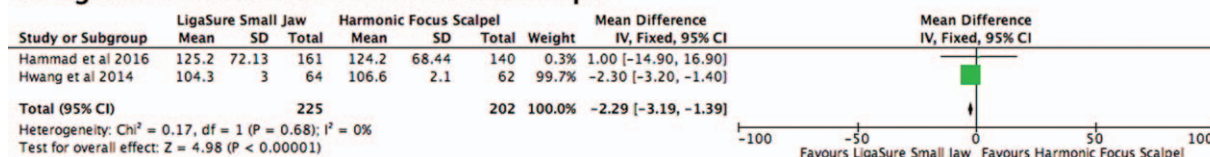


Figure 2. Forest plot of operative time in all included studies.

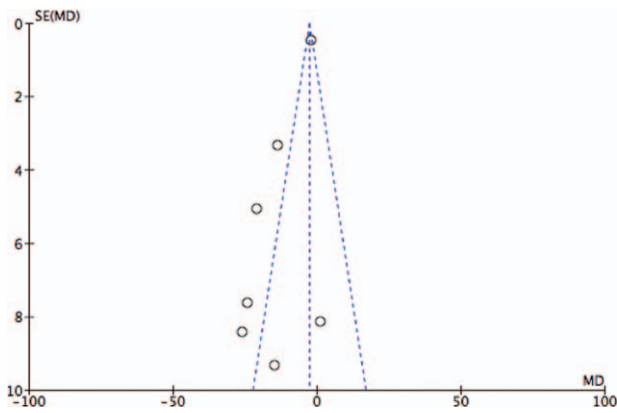


Figure 3. Funnel plot of operative time in all included studies.

blood loss, favoring LS Small Jaw, compared with clamp-and-tie are shown in Table 3.

With respect to complications, temporary/permanent hypocalcemia, temporary/permanent RLN palsy, hematomas, and infection were recorded into analysis. Temporary hypocalcemia was assessed in 2 of total 7 studies, showing no significant

difference between LS Small Jaw and Harmonic Focus Scalpel for thyroidectomy (OR=0.47, 95% CI: 0.14–1.56, $P=0.22$) (Fig. 4).^[12,14] However, less-temporary hypocalcemia rate in LS Small Jaw was highly significant than clamp-and-tie in 4 studies (OR=0.49, 95% CI: 0.27–0.90, $P=0.02$) (Fig. 4).^[10,11,15,16] In the quantitative analysis of temporary RLN palsy, 6 studies reported available data,^[10–12,14–16] and LS Small Jaw did not bring any significant benefits compared with whether clamp-and-tie (HR=0.97, 95% CI: 0.41–2.28, $P=0.94$) or Harmonic Focus Scalpel (HR=0.73, 95% CI: 0.33–1.64, $P=0.45$) (Fig. 5). Other complications such as length of hospital stay, permanent hypocalcemia, permanent RLN palsy, and hematomas are briefly detailed in Table 3. Specially, 1 secondary complication, infection was not demonstrated in 3 studies with no significance within groups.^[11,14,15]

3.4. Heterogeneity

High heterogeneity was only detected concerning intraoperative blood loss ($I^2=76\%$, $P=0.02$), and then, sensitivity analysis was conducted by omitting each single study. Study from Hammad et al^[12] contributed high weight in the outcome, and there was significant reduced intraoperative blood loss in LS Small Jaw group after omitting it ($P=0.04$).

Table 3

Pooled other outcomes of LigaSure Small Jaw versus clamp-and-tie in all studies.

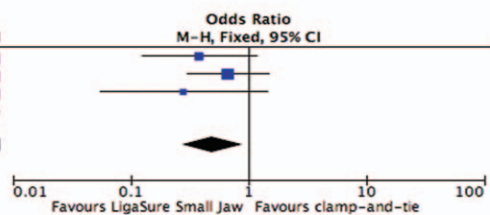
	Number of studies	Patients		Test of heterogeneity		MD/OR (95% CI)	P for effect size	Analysis model
		LigaSure Small Jaw	Clamp-and-tie/Harmonic Focus Scalpel	I^2 , %	P			
Intraoperative blood loss	2	115	115	76	0.04	-14.35 (-28.08, -0.62)	0.04	Random
Postoperative blood loss	2	115	115	8	0.30	-6.43 (-12.16, -0.71)	0.03	Fixed
Length of hospital stay	3	81	75	35	0.21	1.04 (-0.25, 2.33)	0.12	Fixed
Permanent hypocalcemia	4	176	170	0	0.57	1.76 (0.23, 13.39)	0.59	Fixed
Permanent RLN palsy	4	176	170	0	0.73	0.97 (0.41, 2.28)	0.94	Fixed
Hematomas	4	176	170	0	0.53	0.94 (0.21, 4.19)	0.94	Fixed

CI = confidence interval, MD = mean difference, OR = odds ratio, RLN = recurrent laryngeal nerve.

2. temporary hypocalcemia

2.1 LigaSure Small Jaw VS. clamp-and-tie

Study or Subgroup	LigaSure Small Jaw		clamp-and-tie		Weight	Odds Ratio	M-H, Fixed, 95% CI
	Events	Total	Events	Total			
Bircan et al 2014	10	32	12	22	31.6%	0.38 [0.12, 1.17]	
Colro et al 2015	12	95	17	95	48.0%	0.66 [0.30, 1.48]	
Kuboki et al 2013	2	39	7	43	20.4%	0.28 [0.05, 1.43]	
Molnar et al 2014	0	10	0	10		Not estimable	
Total (95% CI)		176		170	100.0%	0.49 [0.27, 0.90]	
Total events	24		36				
Heterogeneity: $\text{Chi}^2 = 1.21$, $\text{df} = 2$ ($P = 0.55$); $I^2 = 0\%$							
Test for overall effect: $Z = 2.30$ ($P = 0.02$)							



2.2 LigaSure Small Jaw VS. Harmonic Focus Scalpel

Study or Subgroup	LigaSure Small Jaw		Harmonic Focus Scalpel		Weight	Odds Ratio	M-H, Random, 95% CI
	Events	Total	Events	Total			
Hammad et al 2016	3	161	11	140	40.4%	0.22 [0.06, 0.82]	
Hwang et al 2014	22	64	25	62	59.6%	0.78 [0.38, 1.60]	
Total (95% CI)		225		202	100.0%	0.47 [0.14, 1.56]	
Total events	25		36				
Heterogeneity: $\text{Tau}^2 = 0.50$; $\text{Chi}^2 = 2.73$, $\text{df} = 1$ ($P = 0.10$); $I^2 = 63\%$							
Test for overall effect: $Z = 1.23$ ($P = 0.22$)							

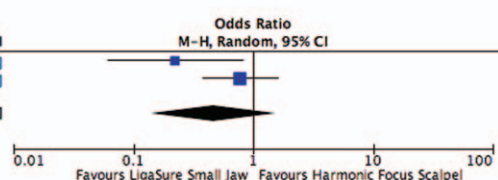
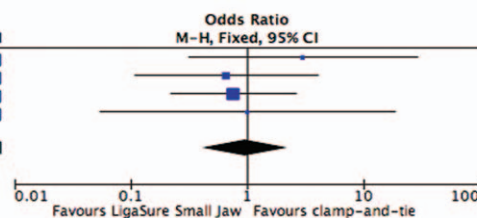


Figure 4. Forest plot of temporary hypocalcemia in all included studies.

3. temporary RLN palsy

3.1 LigaSure Small Jaw VS. clamp-and-tie

Study or Subgroup	LigaSure Small Jaw		clamp-and-tie		Weight	Odds Ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
Bircan et al 2014	4	32	1	22	9.7%	3.00 [0.31, 28.84]
Coiro et al 2015	2	95	3	95	27.5%	0.66 [0.11, 4.04]
Kuboki et al 2013	5	39	7	43	54.4%	0.76 [0.22, 2.61]
Molinar et al 2014	1	10	1	10	8.4%	1.00 [0.05, 18.57]
Total (95% CI)		176		170	100.0%	0.97 [0.41, 2.28]
Total events	12		12			
Heterogeneity: $\text{Chi}^2 = 1.28$, $\text{df} = 3$ ($P = 0.73$); $I^2 = 0\%$						
Test for overall effect: $Z = 0.07$ ($P = 0.94$)						



3.2 LigaSure Small Jaw VS. Harmonic Focus Scalpel

Study or Subgroup	LigaSure Small Jaw		Harmonic Focus Scalpel		Weight	Odds Ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
Hammad et al 2016	11	161	13	140	92.8%	0.72 [0.31, 1.65]
Hwang et al 2014	1	64	1	62	7.2%	0.97 [0.06, 15.83]
Total (95% CI)		225		202	100.0%	0.73 [0.33, 1.64]
Total events	12		14			
Heterogeneity: $\text{Chi}^2 = 0.04$, $\text{df} = 1$ ($P = 0.84$); $I^2 = 0\%$						
Test for overall effect: $Z = 0.75$ ($P = 0.45$)						

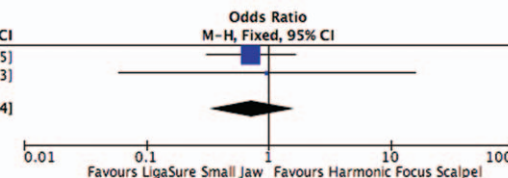


Figure 5. Forest plot of temporary recurrent laryngeal nerve palsy in all included studies.

4. Discussion

This meta-analysis is specifically designed to compare the short- and long-term outcomes between LS Small Jaw and other hemostasis techniques (clamp-and-tie and Harmonic Focus Scalpel) in thyroidectomy. Finally, after pooling enough eligible data from patients who underwent thyroidectomy, LS Small Jaw is proven favorable with regard to operative time and temporary hypocalcemia, as well as equal perioperative bleeding and RLN injury.

As a novel instrument for surgical hemostasis, LS Small Jaw was initially used during thyroidectomy in 2011, which mainly sealed vessels up to 7mm in diameter.^[10,17] Previous studies have shown controversial results in terms of operative time, perioperative bleeding, temporary hypocalcemia, and RLN injury. Therefore, our meta-analysis mainly focuses on the safety of this innovation instrument.

Our meta-analysis demonstrates favorable perioperative outcomes including shorter operative time and less perioperative blood loss in LS Small Jaw. Those benefits are in accordance to previous preliminary outcomes,^[11,13] likely supporting the popularization of LS Small Jaw in thyroidectomy. Moreover, LS Small Jaw connects with better control of hemostasis, which may bring about reduced operative bleeding, as well as reduced operative duration and shorter hospitalization.

As for complication, the data on permanent hypocalcemia and RLN palsy are not significant. However, temporary hypocalcemia, a crucial endpoint for assessing the safety of LS Small Jaw instrument, is significantly less compared with clamp-and-tie, although no significant difference is observed compared with Harmonic Focus Scalpel. Theoretically, since LS Small Jaw and Harmonic Focus Scalpel are both energy-based devices, they are predicted to have similar outcomes in terms of postoperative hypocalcemia. However, lack of sufficient data (only 2 studies) leads these results to be interpreted carefully.^[12,14] Concerning the safety of LS Small Jaw in thyroidectomy, the usage of LS Small Jaw in thyroidectomy not only reduces the incidence of short-term hypocalcemia, but also acquires comparable long-term hypocalcemia and RLN palsy.

In terms of sensitivity analysis, the primary pooled estimation of the outcomes is consistent with that of the sensitivity analysis when 1 study was extracted out, which may indicate that our pooled results had good quality.

Finally, there are some limitations in our research: first, although most included studies are prospective, RCTs and non-RCTs are pooled for some outcomes because of the lack of available data and studies. Second, relatively high heterogeneity among studies was estimated for intraoperative blood loss. Lastly, the fact that not all included studies were RCTs may decrease the power of our outcome. So, caution should be taken to explain the pooled results because of the limitations of our study.

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