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HEAD AND NECK

Efficacy and safety of LigaSure™ small jaw instrument in thyroidectomy: a 1-year prospective observational study

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Abstract

Purpose To compare the efficacy and safety profiles of LigaSure™ small jaw instrument (LSJI) versus conventional technique in patients undergoing open thyroidectomy.

Methods This single-center, prospective, observational study conducted in Zhejiang Provincial Cancer Hospital enrolled patients who underwent thyroidectomy between September 2013 and September 2014. The primary study outcomes included determination of blood loss, operative duration, length of hospital stay, and drainage volume. The secondary outcomes included evaluation of recurrent laryngeal nerve palsy, postoperative bleeding, and hypoparathyroidism.

Results A total of 842 patients undergoing thyroidectomy either with conventional method ($n=440$) or with LSJI ($n=402$) were enrolled. A significantly reduced operative time and intraoperative blood loss were noted in the LSJI group ($p<.001$) compared with the conventional group. Further, the LSJI group also demonstrated a significantly lower postoperative drainage ($p<.05$) compared with the conventional group. Length of hospital stay and incidence of postoperative complications were similar in both the LSJI and conventional groups.

Conclusion LigaSure hemostasis in thyroidectomy appears to result in significantly reduced operative time, intraoperative blood loss, and postoperative drainage compared with the conventional method in Chinese patients.

Keywords Blood loss · LigaSure™ small jaw instrument · Hemithyroidectomy · Postoperative complications · Thyroidectomy

Introduction

Thyroid gland disorder is the second most prevalent endocrinal disorder, and thus thyroidectomy is one of the most common surgeries performed in general surgery [1, 2]. Thyroidectomy may be associated with postoperative complications, such as recurrent laryngeal nerve injury (RLN), hematoma, and hypocalcemia [2, 3]. Due to the complexity of the blood supply system in thyroid gland, thyroidectomy requires precise devascularization of the thyroid gland and prompt and effective hemostasis [3, 4]. Though effective for hemostasis, the conventional methods of vessel ligation are limited by the tedious procedure, long operative time, and complications such as thermal injury, recurrent nerve injury, and hypothyroidism [5, 6]. Therefore, an increasing number of surgeons have started using vessel sealing devices, which allow effective ligation and hemostasis in shorter operative time, minimal postoperative complications and cost-effectiveness [7, 8].

LigaSure is an electronic vessel sealing (EVS) that liquifies and reforms collagen and elastin for achieving hemostasis, via application of electrical energy and pressure [6]. LigaSure™ small jaw instrument (LSJI; Medtronic, Boulder, CO, USA) is a bipolar electrosurgical device with a capacity of sealing vessels up to 7 mm in diameter and a reduced thermal spread due to a lower temperature profile [3]. The device has demonstrated propitious outcomes in terms of reducing blood loss, operative duration, and length of hospital stay compared with conventional sutures [9, 10]. With its ability to achieve a vessel coagulation of ≤ 7 mm with a minimal thermal spread of ≤ 2 mm to the adjacent tissues, LSJI has become the most favored device for vessel sealing in abdominal, urological, and thyroid surgeries [11–15].

Evidence from published literature has shown encouraging results of LSJI usage in thyroid surgeries [3, 5, 11].

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However, most of the studies included a small sample size and reports on LSJI in thyroid surgeries with large patient populations are limited. In China, the number of patients undergoing thyroidectomy for thyroid diseases is increasing continuously [16, 17]. Since, the main objective of the surgeons during thyroidectomy is to achieve effective hemostasis along with shorter operative time and faster postoperative recovery [7]; in this study, we aimed to compare the efficacy and safety of LSJI versus conventional methods in a large Chinese cohort undergoing thyroidectomy.

Materials and methods

Study design

This single-center, prospective, observational study was conducted in Zhejiang Provincial Cancer Hospital in China between September 2013 and September 2014. The study protocol was approved by the local institutional review board and health authorities of Zhejiang Provincial Cancer Hospital. The study was conducted in accordance with the principles of Good Clinical Practices and Declaration of Helsinki (1964 and its revisions). Patients who provided written informed consent, were enrolled in the study.

Patient population

Based on the thyroidectomy technique used, patients were categorized into two cohorts: hemithyroidectomy group and unilateral thyroid cancer radical surgery group (hemithyroidectomy combined with central lymph node dissection). Patients in each cohort were subcategorized into LSJI (Fig. 1) and conventional groups, based on the vessel ligation method. Thyroidectomy was performed by two surgeons with similar skill levels and with > 20 years' experience in thyroidectomy.

Patients were included in the study if they required primary thyroid gland surgery, did not have serious internal diseases and a history of neck trauma and neck deformity. Patients were excluded if they had any lateral neck lymph node metastasis, severe extra-glandular invasion, hoarseness of voice, and other serious diseases including metabolic disorder of calcium. In addition, patients undergoing a repeat thyroidectomy, cervical lymphadenectomy or parathyroidectomy, or with a history of previous thyroidectomy were also excluded.

Surgical technique

All patients received a collar incision with a size of 4–6 cm on the anterior neck. The thyroid gland was exposed after cutting apart the hypodermis and platysma using an electronic knife, followed by separation of the anterior cervical muscle. In the conventional hemostasis technique, the thyroid gland was removed using an electronic knife to suture the blood vessels, scavenge the central lymph node, ligate the lymphatic vessels, and remove the isthmus. The procedure using LSJI included a blunt dissection of tissues along with the sealing of blood vessels. The LSJI hemostasis technique required no sutures after isthmus and lymphatic vessels resection. Every effort was made to identify and protect the RLNs and parathyroid glands. A closed suction drain was placed in the thyroid region and was removed after 3–4 days or when the 24-h fluid amount was < 10 mL.

Study outcomes

Patient demographics and thyroid pathological data were collected. The primary outcome measures were amount

Fig. 1 LigaSure™ small jaw instrument; medtronic, ForceTriad™ energy platform. (1) ForceTriad™ energy platform. (2) LigaSure™ small jaw instrument

of blood loss, operative duration, length of hospital stay, and drainage volume. Operative duration was calculated from the start of the skin incision till the time of wound closure. Surgical gauze was used to measure intraoperative blood loss. The gauze was weighed before and after the surgery. The difference in weight reflected the amount of intraoperative blood loss. Postoperative blood loss (mL) was assessed from the total amount of blood (mL) in the redivac drain.

In addition, postoperative complications including RLN palsy, postoperative bleeding, and hypoparathyroidism were monitored. Hypoparathyroidism was defined as a requirement of calcium or vitamin D supplementation after surgery. Patients were examined for RLN palsy by direct or indirect laryngoscopy on postoperative day 1 and by an otolaryngologist in case of voice-related complaints. Hypoparathyroidism and RLN palsy were considered temporary if recovery was evident in < 3 months after the surgery and permanent if recovery was not apparent 3 months after the surgery.

Statistical analysis

Statistical analysis was performed using GraphPad Prism version 6.0 (GraphPad Software, San Diego, CA). Descriptive statistics was used to summarize the baseline characteristics in terms of numbers, mean, standard deviation (SD) or median (range), wherever applicable. All primary variables were also presented in terms of mean ± SD. Comparisons of continuous variables were performed by the unpaired Student *t* test. A *p* value of < .05 was considered statistically significant.

Results

Baseline characteristics

A total of 842 consecutive patients were enrolled, including 410 for hemithyroidectomy and 432 for unilateral thyroid cancer radical surgery. The patient clinical characteristics and flow chart are detailed in Table 1 and Fig. 2, respectively. Clinical characteristics of patients in both the LSJI (mean age 40.03 ± 12.91 years, 56.02% males) and conventional cohorts (mean age 40.06 ± 13.85 years, 60.16% males) were similar (Table 1).

Primary outcome measures

The mean operative time of the LSJI group was significantly shorter than that of the conventional group for both hemithyroidectomy (50.08 ± 6.65 versus 58.51 ± 10.14 min $p < .001$) and unilateral thyroid cancer radical surgery (57.84 ± 6.61 versus 60.59 ± 6.95 min $p < .001$; Fig. 3a). The overall operative duration was 54.03 ± 7.68 min (range 39–80 min) in the LSJI subgroup and 59.58 ± 8.69 min (range 40–90 min) in the conventional group, and the difference was statistically significant ($p < .001$; Fig. 3a). The LSJI group showed approximately 10% shorter operative duration compared with the conventional group.

Compared with conventional methods, use of LSJI caused significantly lesser blood loss in patients undergoing hemithyroidectomy (15.36 ± 4.47 versus 21.19 ± 7.24 mL, $p < .001$) and unilateral thyroid surgery (16.29 ± 5.68 versus 17.26 ± 4.31 mL, $p = .004$). This was also reflected in the overall group, where the mean blood loss was significantly less in the LSJI group than in the conventional group

Table 1 Patient baseline characteristics

	Hemi-thyroidectomy		Thyroid cancer radical resection		Sum	
	LSJI	Conventional	LSJI	Conventional	LSJI	Conventional
Gender, M/F	69/147	70/124	89/135	81/127	158/282	151/251
Age, years (mean ± SD)	39.81 ± 12.96	40.48 ± 13.49	40.24 ± 12.91	39.66 ± 14.16	40.03 ± 12.91	40.06 ± 13.85
Indication for operation, *n*						
Multinodular goiter	205	175	0	0	205	175
Lymphocytic thyroiditis	11	19	0	0	11	19
Thyroid carcinoma	0	0	224	208	224	208
Pathology diagnosis, *n*						
Multinodular goiter	185	172	0	0	185	172
Lymphocytic thyroiditis	31	22	0	0	31	22
Papillary carcinoma	0	0	220	207	220	207
Medullary carcinoma	0	0	1	0	1	0
Follicular carcinoma	0	0	3	1	3	1

F female, *LSJI* LigaSure™ small jaw instrument, *M* male, *SD* standard deviation

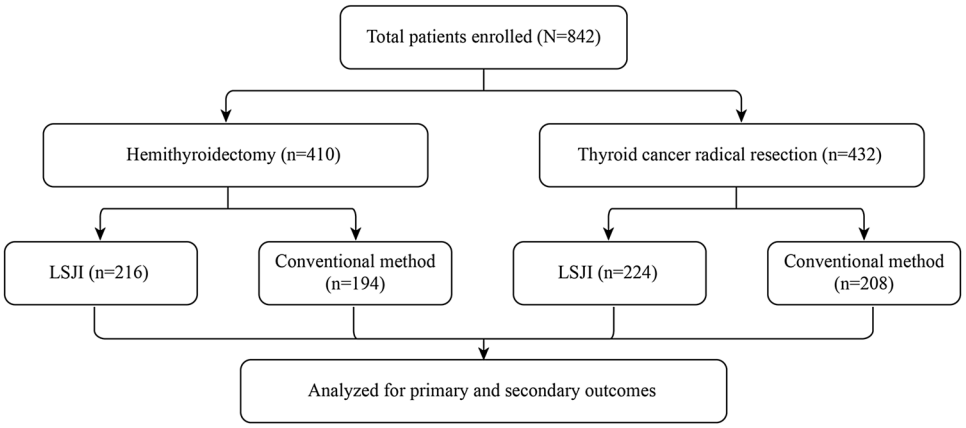

Fig. 2 Patient flow chart

for both hemithyroidectomy and unilateral thyroid cancer radical surgery (overall 15.83 ± 5.14 versus 19.16 ± 6.22 mL, $p < .001$; Fig. 3b). Approximately, 16% lesser blood loss was demonstrated in the LSJI group compared with the conventional methods. Regardless of the type of thyroidectomy, postoperative drainage volume was significantly lower ($p < .001$) in the LSJI group than in the conventional group, especially on postoperative day 1 (23.83 ± 4.60 mL in LSJI versus 25.51 ± 4.87 mL in conventional group, $p < .001$) and day 2 (15.70 ± 3.60 mL in LSJI versus 17.20 ± 3.82 mL in conventional group, $p = .002$; Fig. 3c). A similar trend of significantly lower drainage volume was overserved with use of LSJI compared with conventional methods in hemithyroidectomy ($p < .001$) and unilateral thyroid surgery ($p < .001$); except for the non-significant difference in drainage volume on day 3 after hemithyroidectomy ($p = .138$ Fig. 3c). The duration of hospital stay was similar in LSJI and conventional groups (3.57 ± 0.82 and 3.60 ± 0.80 days, respectively).

Complication rate

The most common postoperative complications associated with thyroidectomy were RLN and postoperative bleedings (Table 2). As we did not consider hypoparathyroidism if recovery occurred within 3 months, no incidence of permanent hypoparathyroidism was observed in both cohorts. None of the patients required reoperation for postoperative hemorrhage.

Discussion

LigaSure EVS is a novel hemostatic method that produces a consistent sealing of vessels with minimal thermal spread and tissue charring. Our study demonstrated a significantly shorter mean operative duration with LSJI compared with the conventional methods regardless of the type of thyroidectomy. The LSJI-associated shorter operative duration may result from the unique beneficial characteristics of LSJI, such as effective ligation of blood vessels, muscles, and thyroid tissues without requiring other surgical instruments and minimizing unnecessary movements during the operation. Previous studies have also reported that operative time can be reduced by 6.4–32.4 min by LigaSure compared with the conventional method for thyroidectomy [11, 12, 18, 19]. The meta-analysis by Yao et al. has shown a significantly reduced operative duration by LigaSure for thyroidectomy compared with the conventional method (weighted mean difference = − 11.97 min, 95% confidence interval −16.42 to − 7.53 min, $p < .001$) [20]. Studies by Bircan et al. [3], Molnar et al. [5], Kirdak et al. [21], and Schiphorst et al. [22] reported a similar operative time as reported in the current study. For example, the study by Schiphorst et al. has demonstrated that the operative time of thyroid surgery is 10 min shorter when using LSJI than using the conventional method (56 versus 66 min, respectively, $p = .001$) [22].

We also found that the overall blood loss was significantly lesser with LSJI than with the conventional method, which may be associated with unique cutting function of LSJI. Similar results have been reported by Cipolla et al. [23] Gentile et al. [24] and Kuboki et al. [25]. Although Hirunwiwatkul et al. reported a significantly reduced intraoperative hemorrhage with LigaSure during thyroidectomy than with the conventional method, postoperative blood loss was not significantly different [11]. Furthermore, Yao et al. found no significant differences in the amount of intraoperative blood loss, length of hospital stay, and postoperative complication rates after thyroidectomy with LSJI and conventional methods [20]. In our study, length of hospital stay was similar in the LSJI and conventional groups.

No previous study has reported the comparison of post thyroidectomy drainage with LSJI versus conventional method. To the best of our knowledge, the current study was the first to examine postoperative drainage following the use of LSJI in thyroidectomy. For breast cancer surgery, Antonio

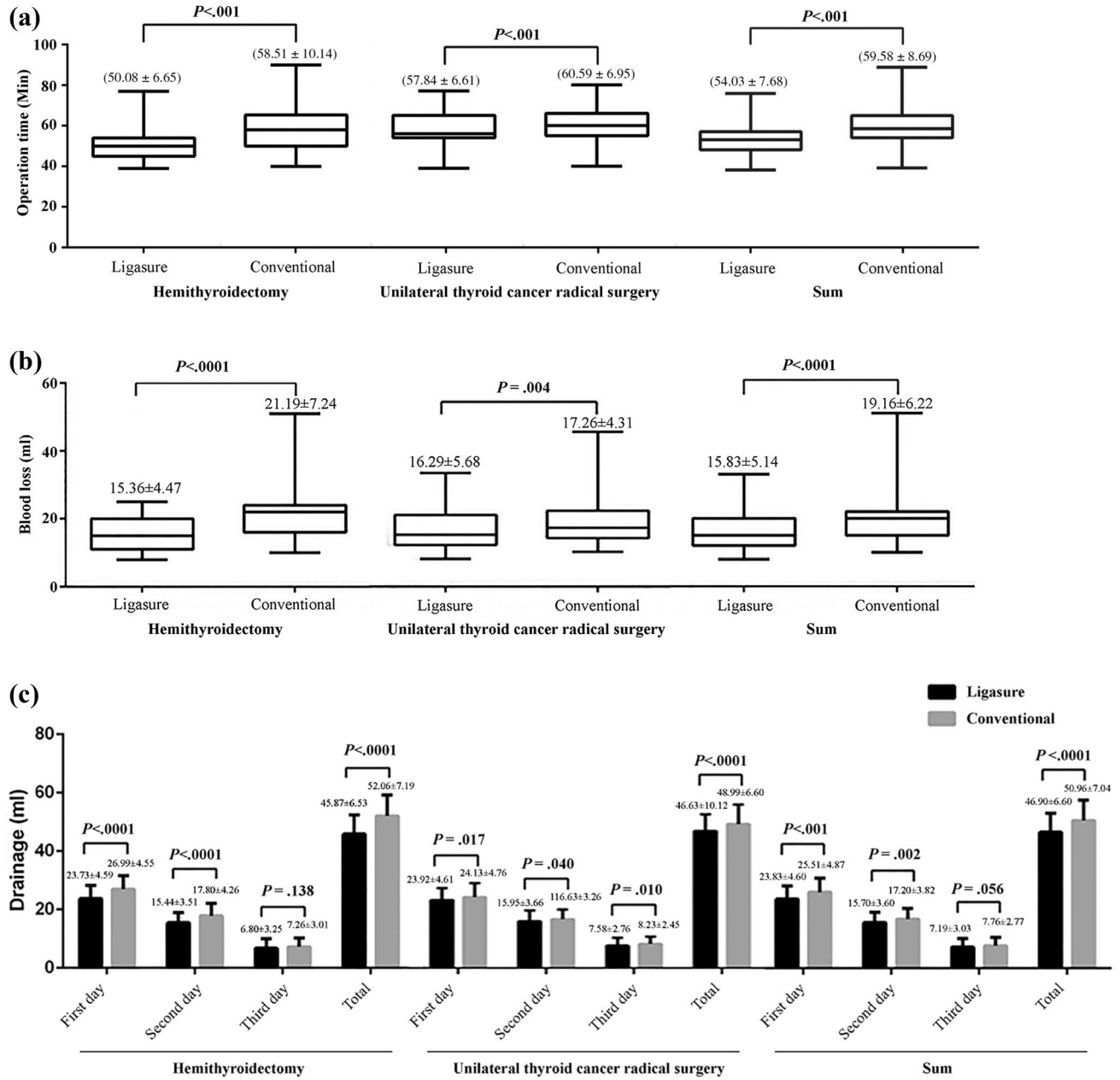

Fig. 3 **a** Mean operative time in patients treated with LigaSure and conventional methods in the hemithyroidectomy and thyroid cancer radical resection cohorts. **b** Mean blood loss in patients treated with LigaSure and conventional methods in hemithyroidectomy and thyroid cancer radical resection cohorts. **c** Postoperative drainage in patients treated with LigaSure and conventional methods in the hemithyroidectomy and thyroid cancer radical resection cohorts

et al. had reported insignificant differences in total drainage volume after axillary dissection between the LSJI and conventional methods [26]. However, in our study, the postoperative drainage in LSJI cohort was significantly reduced compared with the conventional group on postoperative days 1 and 2. This may be due to the better sealing achieved with LSJI on lymphatic vessels and capillaries.

The incidence of postoperative complications was low in the current study and similar in the LSJI and conventional cohorts. We did not observe permanent hypoparathyroidism in our patient cohort, which may be due to the reduced blood loss by LSJI. Intraoperative blood loss reduction could facilitate easier identification of parathyroid glands during thyroidectomy. Previous prospective and retrospective clinical studies have reported no significant difference in complication rates between LigaSure and conventional methods; however, LSJI was associated with higher operative cost [23, 24, 27].

Table 2 Postoperative complications

	Hemithyroidectomy		Thyroid cancer radical resection	
	LSJI	Conventional	LSJI	Conventional
RLN palsy	0	0	1	2
Temporary	0	0	1	1
Permanent	0	0	0	1
Postoperative bleeding	1	0	1	1
Hypoparathyroidism	0	0	0	0

LSJI LigaSure™ small jaw instrument, *RLN* recurrent laryngeal nerve

Thyroidectomy performed using LSJI may be more expensive than the conventional technique and add to the cost burden. However, with the advantages such as shorter operative time, larger surgery volume, easier anesthesia care, and lower staff costs, LSJI may actually improve the cost effectiveness [14, 20, 22].

Our study did not evaluate the operative cost, which might be a limitation of the study. Therefore, further studies are warranted to investigate the cost effectiveness of LSJI versus conventional methods in patients undergoing thyroidectomy.

Conclusion

In conclusion, use of LSJI in thyroidectomy appeared to reduce operative time, blood loss, and drainage volume compared with the conventional method, suggesting LSJI to be a better hemostatic technique.

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Author contributions X-CM, CC, and K-JW contributed in conceptualizing the study design, data collection, analysis, and interpretation. All authors were involved in interpretation of results, manuscript writing, and approval of the final draft.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval This study was approved by the institutional review board of the Zhejiang Cancer Hospital.

Informed consent The study was conducted in accordance with the principles of Goof Clinical Practices and Declaration of Helsinki (1964 and its revisions). Patients who provided written informed consent, were enrolled in the study.

Data sharing statement No additional data available.

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