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Original Article

Utility of Vessel-Sealing Systems in Thyroid Surgery

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The LigaSure™ vessel-sealing system (VSS) represents a new approach to intraoperative ligation. This clinical study retrospectively examined the utility of the VSS in thyroid surgery. In this study, we analyzed 56 consecutive patients who underwent thyroid surgery. Characteristics such as operative duration, the volume of intraoperative hemorrhage, and postoperative course were analyzed and compared between thyroid surgery using the VSS or conventional handtie methods.
The present results indicate no significant differences in operative duration, volume of intraoperative hemorrhage, postoperative course, or duration of postoperative drainage between surgeries using the VSS or conventional methods. However, the postoperative hospital stay was found to be significantly shorter ($p<0.05$) with the VSS. No serious postoperative complications were encountered, and no significant differences were observed in the frequency of postoperative complications between methods. The VSS may simplify procedures for thyroid surgery, and hemostasis is effective for both thyroid vessels and thyroid parenchyma. However, further evaluation is warranted to adequately determine the relative merits of the VSS compared to conventional handtie methods.

Key words: LigaSure™, vessel-sealing system (VSS), thyroid surgery, video assisted neck surgery (VANS), bipolar electrothermal coagulation system

Over the past few years, various hemostasis devices have been developed and applied to the field of laparoscopic surgery. Among these devices, bipolar electrothermal coagulation performed using the LigaSure™ vessel-sealing system (VSS; Valleylab, CO, USA) has been widely adopted in abdominal and pelvic surgery[1–4]. The system includes a feedback-controlled electrothermal mechanism designed to seal vessels through the application of energy and physical pressure.

Hemorrhage represents one of the most common complications in thyroid surgery. The main sources of bleeding are injured thyroid vessels and thyroid parenchymal bleeding, and hemorrhage can be intra- or postoperative. Ligations, sutures, and clips have all been used for hemorrhage control[5], but these efforts can endanger adjacent structures such as the recurrent and superior laryngeal nerves. Such risks emphasize the importance of efficient and safe methods for controlling hemorrhage in thyroid surgery.

The present retrospective study compared clinical outcomes between thyroid surgeries performed using this new electrothermal VSS and conventional handtie methods.

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Materials and Methods

Patients. Subjects included 56 consecutive

patients who underwent thyroid surgery between January 2003 and March 2004 in the Department of Cancer and Thoracic Surgery at Okayama University Graduate School of Medicine and Dentistry, Japan. Of these 56, 4 patients (7.1%) who underwent mediastinal lymph node dissection due to extensive mediastinal lymph node metastasis or lymph node recurrence (conventional procedure, n=3; VSS, n=1) were excluded from the study. The remaining 52 patients were evaluated. From January 2003 to August 2003, thyroid surgery was performed using conventional procedures (n=30; conventional group), with thyroid vessels ligated using silk threads and surgical stumps of resected thyroid parenchyma sutured. From September 2003 to March 2004, thyroid surgeries were performed using electrothermal coagulation with a LigaSure Precise™ (Valleylab) VSS (n=22; VSS group). The operative procedure using the VSS was as follows: 1) anterior neck muscles were retracted by blunt dissection; 2) thyroid vessels (artery and vein) were sealed using VSS and resected by scissors; 3) thyroid parenchyma was grasped by VSS and sealed, and the center of the sealed area was then sharply resected by scissors; and 4) the thyroid stump was not sutured. The conventional group comprised 22 females and 8 males, with a mean age of 50.3 years (range, 19–73 years). The VSS group comprised 22 females, with a mean age of 56.8 years (range, 19–77 years). Overall resectability was 100% for the 52 patients. No patients died during the initial hospitalization, and all patients were discharged ≤ 15 days postoperatively.

Methods. Demographic and clinical information was obtained from patient records for age, gender, underlying pathology, surgical procedure, operative duration, total volume of intraoperative hemorrhage, duration and total volume of postoperative drain discharge, surgical complications, and postoperative hospital stay. Data were compared between treatment groups.

Sealing level power achieved using the VSS was level 3, and all operations were performed by the same surgeon using the same procedures.

Postoperative drainage was ended when the volume of discharge reached < 20 ml/day. Postoperative complications were evaluated up until the time of discharge. This course of postoperative management was decided upon based on the clinical pathway. The postoperative hospital stay was also determined according to the decision tree for the clinical pathway. Detailed criteria for discharge were as follows: at least 2 days after the removal of drainage, there was no gauze soiling from the removal site of the drain, sufficient oral intake, no signs of infection, no fluid collection or hematoma formation in the surgical site, and no complications causing a disturbance of everyday life.

Pathological diagnosis and classification of primary cancers were performed by a minimum of 2 pathologists in accordance with the TNM classification of the UICC and the General Rules for Thyroid Cancer Study in Surgery and Pathology in Japan.

Data analysis. Statistical analyses of clinicopathological factors were performed using the Mann-Whitney U-test for operative duration, total volume of intraoperative hemorrhage, duration of postoperative drainage, total volume of postoperative drain discharge, surgical complications, and postoperative hospital stay. The χ^2 test was used for comparisons of age, gender, underlying pathology, and surgical procedure. Values of $p<0.05$ were considered statistically significant. All data were analyzed with StatView for Windows (SAS Institute Inc., Cary, NC, USA).

Results

Clinicopathological data. Patient characteristics are listed in Table 1. No significant differences in patient age were identified between groups, although the proportion of females was higher in the VSS group than in the conventional group ($p<0.05$).

Surgical procedures in the conventional group included: total thyroidectomy, n=1 (3.3%); subtotal thyroidectomy, n=3 (10%); hemithyroidectomy, n=20 (67.7%); video-assisted neck surgery (VANS), n=5 (16.7%); and extirpation, n=1 (3.3%). Of these, 10 patients (33.3%) underwent modified neck dissection. Surgical procedures for the VSS group comprised: total thyroidectomy, n=6 (27.2%); subtotal thyroidectomy, n=1 (4.5%); hemithyroidectomy, n=7 (31.8%); and VANS, n=8 (36.3%). In the VSS group, 2 patients (9.1%) were converted from VANS to open hemithyroidectomy following procedural difficulties. Modified neck dissection was performed for

Table 1 Patient characteristics and surgical procedures

Patients Characteristics	Total	Conventional	VSS	*p*-value
Age	52.8	50.3	56.9	0.396
Gender (F/M)	44/8	22/8	22/0	0.015
Operative Procedure	**Total**	**Conventional**	**VSS**	***p*-value**
Total thyroidectomy	7	1	6	0.0332*
Subtotal thyroidectomy	4	3	1	0.6288
Hemi thyroidectomy	27	20	7	0.0275*
VANS	13	5	8	0.1948
VANS for cancer	4	0	4	0.0270*
Extirpation	1	1	0	1.000
Total	52	30	22	

* : $p < 0.05$

4 patients (18.1%) in the VSS group. Hemithyroidectomy was significantly more common in the conventional group (p=0.0275), while total thyroidectomy was significantly more common in the VSS group (p=0.0332).

No significant differences were identified between the groups with regard to underlying pathology (Table 2). In the conventional group, underlying pathologies comprised: thyroid cancer, n=11 (36.7%); adenoma, n=14 (46.7%); hyperthyroidism, n=4 (13.3%); and other, n=1 (3.3%). In the VSS group, underlying pathologies comprised: thyroid cancer, 9 (40.9%); adenoma, n=11 (50.0%); hyperthyroidism, n=1 (4.5%); and other, n=1 (4.5%).

Table 2 Histopathological diagnosis of disease

	Total	Conventional	VSS	*p*-value
Thyroid cancer	20	11	9	0.9822
Stage				
stage Ⅰ, Ⅱ	10	8	2	0.0697
stage Ⅳ	3	0	3	0.0866
Adenoma	25	14	11	0.8121
Hyperthyroidism	5	4	1	0.3813
Other	2	1	1	1.000
Total	52	30	22	

Among patients who underwent surgery for cancer, 8 patients (72.7%) displayed stage I or II disease in the conventional group, compared to 2 patients (22.2%) in the VSS group. No significant difference in the distribution of cancer stages was observed between groups, although early-stage disease tended to occur more frequently in the conventional group (p=0.0697).

Patient outcomes. Clinical parameters for procedures are listed in Table 3. The mean operative duration was 100.5 min in the conventional group and 135.2 min in the VSS group. Intraoperative blood loss was 93.2 ml in the conventional group and 89.0 ml in the VSS group. The duration and total volume of postoperative drain discharge were 2.88 days and 132.8 ml in the conventional group and 2.67 days and 121.9 ml in the VSS group. Postoperative surgical complications were experienced by 2 patients (6.7%; temporal recurrent nerve palsy, n=1; chylous discharge, n=1) in the conventional group and 2 (9.1%; temporal recurrent nerve palsy, n=1; chylous discharge, n=1) in the VSS group. The postoperative hospital stay was 7.25 days (range, 3–13 days) in the conventional group and 6.0 days (range, 4–15 days) in the VSS group. No significant

Table 3 Clinical parameters and results of both methods

Clinical parameters	Conventional Mean, (95%CI)	VSS Mean, (95%CI)	*p*-value
Operation time (min)	100.6 (80.56–120.55)	135.3 (108.09–162.45)	0.3382
Intraoperative blood loss (g)	92.0 (45.52–132.58)	93.2 (51.03–135.41)	0.6474
Duration of postoperative drainage (day)	2.9 (2.22– 3.58)	2.7 (2.02– 3.28)	0.5509
Total amount of drainage (ml)	132.8 (83.40–190.50)	121.9 (87.61–156.27)	0.6604
Postoperative hospital stay (day)	7.3 (4.48– 7.52)	6.0 (6.25– 8.25)	0.0298*
Complication rate (%)	10.0	9.1	0.6391

95%CI: 95% confidence interval * : $p < 0.05$

Table 4 Clinical parameters and results of both methods excluded VANS cases

Clinical parameters	Conventional Mean, (95%CI)	VSS Mean, (95%CI)	*p*-value
Operation time (min)	102.3 (82.15–128.64)	83.8 (64.18–113.45)	0.270
Intraoperative blood loss (g)	76.8 (33.39–120.25)	61.8 (16.77–106.85)	0.962
Duration of postoperative drainage (day)	2.8 (1.45– 3.11)	2.6 (2.09– 3.14)	0.923
Total amount of drainage (ml)	139.7 (75.08–204.32)	113.5 (69.19–157.71)	0.560
Postoperative hospital stay (day)	7.4 (6.15– 8.55)	5.8 (4.27– 7.11)	0.037*
Complication rate (%)	8.0	14.3	0.608

95%CI: 95% confidence interval * : $p < 0.05$

Table 5 Comparison of operation time and postoperative hospital stay between both methods excluded VANS and total thyroidectomy cases

Clinical parameters	Conventional Mean, (95%CI)	VSS Mean, (95%CI)	*p*-value
Operation time (min)	88.3 (72.24–104.92)	65.6 (50.24–81.0)	0.096
Postoperative hospital stay (day)	7.1 (5.94– 8.16)	5.0 (3.33–6.67)	0.013*

95%CI: 95% confidence interval * : $p < 0.05$

differences were recognized between groups with regard to operative duration, total volume of intraoperative hemorrhage, duration of postoperative drainage, total volume of postoperative drain discharge, or number of complications. However, the postoperative hospital stay was significantly shorter (p=0.0298) in the VSS group. Moreover, as for the postoperative hospital stay, significant difference was recognized in patients who did not undergo VANS and/or the total thyroidectomy group (Table 4, 5)

Discussion

In all surgical procedures, bleeding represents one of the most common and serious complications. Hemostasis is clearly of utmost importance in thyroid surgery to control and divide the numerous vessels before excision of the gland. Conventional thyroid surgery involves handtied ligatures to control bleeding from vessels and parenchyma before division, and various hemostastic methods have been utilized. Current methods include the use of ligation, sutures, clips, staples, and coagulation (unipolar, bipolar and ultrasonic[6, 7]. Among these methods, bipolar electrothermal coagulation using the LigaSure™ bipolar VSS has found numerous applications in various types of abdominal and pelvic surgery[1–4]. The system includes a feedback-controlled electrothermal mechanism designed to seal vessels through the application of energy and physical pressure. While the vessel walls are held in tight apposition under pressure, electrothermal energy melts collagen and elastin fibers present in the walls. The feedback mechanism automatically stops energy delivery when tissue sealing is complete. The entire process takes 2–5 s, depending on the vessel size and type of included tissue. The sealed zone is then divided using scissors. Sealing with this technique is effective in vessels ≤ 7 mm in diameter[8].

The effectiveness of this VSS has been reported in various surgical fields[9–11]. One of the major reasons for this effectiveness is the reduction in the duration of surgery, due to the simplification of procedures and hemostasis. For example, Hasegawa *et al.* [12] have reported that laparoscopic colectomy could be shortened to approximately 40 min compared with conventional clip ligature procedures. The utility of the system is particularly evident in laparoscopic surgery, where more traditional methods of hemostasis can prove to be difficult to perform and unsafe.

The LigaSure VSS has also recently been applied to use in parenchymal organs. Horgan *et al.* [2] have demonstrated the usefulness of the system for parenchymal division during hepatectomy. Teramoto *et al.* [13] have revealed that the LigaSure VSS is useful for division during pancreatectomy. They analyzed the burst resistance pressure and clinicopatho-

logical features of surgical stumps of the cystic, biliary and, pancreatic ducts after resection using the VSS. The mean burst pressure of the cystic duct after fusion using the VSS was 180 mmHg, with a perfectly sealed cut surface and no apparent leakage of bile or pancreatic juice. Teramoto *et al.* [13]. have thus concluded that the device is useful and safe for hepato-biliary-pancreatic surgery.

Few reports, on the other hand, have described use of the VSS in thyroid surgery. Ashkenazi *et al.* [14] have reported sutureless thyroidectomy using an electrothermal VSS, and stated that the main advantages of the VSS method are reduced operative duration and the reduction of risks associated with using sutures and clips. Sandonato *et al.* [15] have analyzed their experiences with 67 total thyroidectomies performed using the VSS, noting that complications such as transient recurrent palsy and hypoparathyroidism were significantly less frequent than they had reported in an analysis of 579 total thyroidectomy cases[16]. In the present study, no significant differences were observed between the conventional handtie procedure and VSS methods with regard to operative duration, total volume of intraoperative hemorrhage, duration of postoperative drainage, total volume of postoperative drain discharge, or number of complications. However, we must take into account the discordance of patient background between the 2 groups; for example, the number of patients who underwent VANS tended to be higher in the VSS group than in the conventional group. On the other hand, the results of additional analysis with patients, excluding those who underwent VANS, suggested that postoperative hospital stay was not associated with the VANS patient population. The present study was unable to demonstrate the superiority of VSS for shortening operative duration; however, the VSS group did display at least equal outcomes for the duration and volume of postoperative discharge, and these results might be partially attributable to the reduction in the postoperative hospital stay. We could not clarify other possible factors associated with the post operative hospital stay. However, we can at least say that the procedure with VSS with no knot-tying would not have a negative impact on the early course of postoperative patients.

Finally, we must consider the cost of this device. Previous reports have demonstrated that in those undergoing VSS, there is an additional cost of 600 Euro per patients for the disposable tip of the instrument used. Therefore, further consideration must be given to the routine use of the device

In conclusion, our results demonstrate that thyroid surgery with VSS is comparable to conventional handtie procedures with regard to safety and efficacy. This device could simplify thyroid surgery procedures, although cautious consideration is needed before routine use of this device can be advocated.

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