

Comparison of hematoma incidence between vessel-sealant devices and conventional hemostasis after thyroid operations

Ahmed A.M. Khyrallah, Gamal G. Shemy

Department of General Surgery, Faculty of Medicine, Al-Azhar University, Assiut, Egypt

Correspondence to Ahmed A.M. Khyrallah, MD, Department of General Surgery, Faculty of Medicine, Al-Azhar University, Assiut, Zipcode 71511, Egypt. Mob: 00201020463373; e-mail: akhyrallah@yahoo.com

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Background

Vessel-sealing devices (VSDs) were promoted for usage in thyroid surgeries, but, the connotation of their usage with postoperative hematoma of the neck, is an infrequent but possibly fatal complication, which has not been adequately investigated.

Aim and objectives

The aim of the study was comparing of complication incidence between VSDs and conventional hemostasis (CH) after thyroid operations.

Patients and methods

This was a retrospective cohort investigation, in which 849 patients matched inclusion criteria and were included in the study. Data on cases experiencing thyroid surgical operation from January 2017 to May 2021 were retrospectively taken out from medical documents of Al-Azhar Assiut Hospital.

Results

As regards outcomes, we demonstrated that 1.2% in the VS group and 4.3% in the CH group had postoperative hematoma, mean±SD of the surgical period was 123.6 ±66.54 and 109.7±68.21 min in VS and CH groups, respectively, while as regards hospitalization, we found that mean±SD of harmonic scalpel was 1.01±1.75 and 1.32±2.09 days in VS and CH groups, respectively, and there is a significant difference between the groups regarding hematoma, surgical period, and hospitalization.

Conclusion

The current work revealed that the usage of VSDs throughout thyroid surgical operation was accompanied by reduction in the development of a postoperative hematoma in comparison with the CH methods. Given the strength of these results, the easiness of inclusions of these devices into operation, and the influence a postoperative hematoma may have, surgeons and hospitals might take into consideration the inclusion of VSDs into their practices.

Keywords:

hematoma, hemostasis, postoperative, thyroid, vessel sealing

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Introduction

Thyroidectomy is one of the commonest-made surgical operations in the neck and it is the prime treating option in the mainstream of thyroidal disorders. The rate of complications from the entire thyroidectomy is small: now, the death rate for this operation is about 0%, and the total rate of complications is less than 3% [1].

Lately, the case number experiencing thyroid surgical operation has raised widely because of a rise in the diagnosing of thyroid-small tumors. While thyroidectomy is a comparatively secure operation, it can be accompanied by various clinical postoperative complications. Postoperative neck hematoma (PNH) is a rare but potentially deadly complication of thyroid operations. In severe patients, PNH causes airway compressing, leading to acute respirational distress or even mortality, and emergency-operative

intervention is frequently needed. It is mainly related to short-stay thyroidectomy on an outpatient [2].

Throughout operative history, several practical developments about hemostasis have appeared. Energy-built hemostatic tools are progressively being utilized and have shown to be possibly supportive in neck-surgical operations. Not all of these 'energy devices' depend on a similar shape of energy. LigaSure (LSJ Medtronic, Covidien Product, Minneapolis, Minnesota, USA) uses radiofrequency (transported bipolar energy to produce fusions of vessels) [3], harmonic scalpel (HS, Harmonic Focus; Ethicon, Johnson and Johnson, Cincinnati, Ohio,

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USA) as an alternative, converting the electric power into mechanical vibrations, giving ultrasonic (US) vibrations. Last, thunder beat by Olympus, is a hybrid device that mixes harmonic and RF energies, permitting a quicker time of use on the tissue [4].

Operative hemostasis is a vital constituent in avoiding postoperative hematoma formations. Conventional hemostasis (CH) and controlling of vascular pedicles comprise ligation of separate vessels with hand ties or metal clips and separation by a scalpel, scissors, or electrocautery. Suture ligation is timewasting and has a knot-slippage risk; metal clips are rapidly used but subject to dislodgment, and electrocautery has the risk of heat-made injuries to adjacent tissue [5,6].

Energy-based vessel-sealing devices (VSDs) were utilized as a substitute technique to perform hemostasis. The HS (Ethicon Inc.) utilizes high-frequency US energy to concurrently cut and coagulate vessels of the tissue. The Liga-Sure (Medtronic) utilizes exactly transported bipolar energy to produce fusions of vessels of diameter up to 0.7 cm [7].

The Focus HS utilizes US-blade vibrations at 55 Hz within 80 μ m. The subsequent mechanical power is transported to the proteins of tissues and denatures them by cutting the hydrogen bonds [6]. It was revealed that heat injuries made by the US are decreased when matched to electrocoagulation, which employs elevated temperature ringing between 150 and 400°C. The LigaSure Precise Vessel Sealing device is a bipolar coagulating tool that denatures the vascular barrier collagen and elastin. The two devices were revealed to consistently seal vessels of diameter up to 0.7 cm [8].

In the current work, we assessed the correlation of VSDs, involving HS and LigaSure, in comparison with CH technique in thyroid surgeries. We assumed that there was a nonsignificant change among the two methods for the primary outcomes of PNH and thereafter thyroidectomy.

Patients and methods

The data of cases experiencing thyroid-surgical operations from January 2017 to May 2021 were retrospectively collected from Al-Azhar Hospital, Assiut medical documentations. We accepted cases with associated tumors in the neck and head. We investigated the cases and the surgical data, together with the postoperative outcome. The ethical approval for the study from the hospital scientific committee was obtained (Alazher Universty Hospital). Informed signed consent was obtained from every patient.

Cases have not been included if they have lost data for clinically important neck hematoma or VSD usage. Accepted cases of thyroid surgery with lateral and central neck dissection simultaneously were involved, but did not include the case of thyroidectomy done as a minor operation as a stage of a main simultaneous neck and head procedure, like a laryngectomy or main free-flap-reconstructive surgical operation. Further exclusion criteria involve minimally invasive thyroid surgery and nonelective surgical operation.

Variables analyzed

The rest of the case parameters were collected: ages, sex, preceding neck irradiations, presentations at diagnosing (symptomatic or incidental), substernal goiters, hyperthyroidism, preceding thyroid operations, pathological results (malignant vs. benign), and pathologically lymphocytic thyroiditis.

The surgical features investigated were degree of the surgical operation (total vs. partial thyroidectomy), simultaneous lymph-node neck dissections, the usage of energy-built vessel sealing tools - HSs (Ethicon Inc., Bridgewater, New Jersey, US) or Liga-Sure (Medtronic, Dublin, Ireland) - versus the conservative techniques (electrocoagulation and 'clamp-and-tie'), the usage of the hemostatic agents' operative (Ethicon Inc.), and the settlement of an operative drain.

The period till the PNH development has been estimated by the period in hours from the termination of the thyroidectomy till the beginning of the reintervention surgery. Given the struggle in documentation when a wound hematoma is initially recognized, we suppose the period from the first procedure till the reoperation is a more dependable estimate. The cause of the blood loss, when recognized, was detected, in addition to the necessity for the tracheostomy to confirm airway patency.

Outcomes

The initial exposures of concern were the usage of VSD (HS, Liga-Sure, or other VSDs). The principal outcome, postoperative hematoma, has been managed as a dual variable, involving any postoperative hematoma noticed, needing treatment with open evacuations, bedside aspirations, or returning to the surgical room.

The second results were recurrent laryngeal nerve injuries, surgical period, and hospitalization period. Recurrent laryngeal nerve injuries or dysfunction was reported as if the case suffered signs of continual hoarseness, continual voice weakness, or continual vocal tone alteration. As some cases have soreness or hoarseness directly afterward

extubation, hoarseness only reported on the first postoperative day was not involved. No information on preoperative vocal cord motions or whether the nerve dysfunctions have been diagnosed via laryngoscopy was obtainable.

Statistical analysis

The collected data have been analyzed via IBM-SPSS-20 (IBM Co., Armonk, New York, USA). For the continuous variables, the data are presented as median and range values. Frequency distribution was utilized to define the categorical variables (numbers of cases and comparative percent). For statistical assessment of the changes among the groups, the nonparametric Mann–Whitney *U* testing has been utilized. The categorical parameters have been analyzed via the χ^2 testing for 2 2 tables, and the Fisher exact testing has been utilized when at minimum one predictable frequency less than 5. To find out the normality of the data, the Shapiro–Wilk testing has been employed. Odds ratios (ORs) and their respective 95% confidence interval (95% CI) have been assessed, depending on a logistic-regression model and the stepwise forward method, and the level of significance of 10% was assumed to choose the variables.

Results

In this retrospective study, 849 patients matched inclusion criteria and were included in the study, divided into two groups: group (1) 498 patients using VSD, group (2) 351 patients using CH in thyroid operations.

In group 1 (VSD), six patients and 15 patients in group 2 (CH) develop PNH and all patients need surgical intervention to manage the hematoma.

Table 1 shows that the two groups were comparable without statistical significance; however, BMI was high significantly in the VSD group in comparison with the CH group.

Died groups in regard to indications of thyroid operation, central neck dissection performed and multifocal or unifocal cancer (Table 2).

Table 3 shows that there is a significant change among the study groups, VSD group shows a decrease in hematomas, RNI, decrease in the surgical period, and hospitalization.

Discussion

Lately, the case number experiencing thyroid-surgical operations has improved widely because of a rise in the minor thyroid-tumor diagnosis. While thyroidectomy is a comparatively secure way, it can be accompanied by some postoperative clinical complications. PNH is a rare but possible deadly complication of thyroid-surgical operations [9].

Several risk factors for postthyroidectomy hemorrhage were recognized. Primary controlling of changeable risk factors can upgrade case outcomes. Opposing to

Table 1 Baseline characteristics

Baseline characteristics	VSD (N=498)	Conventional hemostasis (N=351)	<i>P</i>
Age (years)	51.76±5.62	52.28±4.74	0.158
Sex [<i>n</i> (%)]			
Male	122 (24.5)	96 (27.4)	0.349
Female	376 (75.5)	255 (72.6)	
BMI (kg/m ²)	29.17±3.28	28.34±3.51	0.001*
Comorbidities [<i>n</i> (%)]			
Smoking	179 (35.9)	121 (34.5)	0.659
Hyperlipidemia	75 (15.1)	63 (17.9)	0.262
DM	70 (14.1)	40 (11.4)	0.257
HTN	199 (40)	124 (35.3)	0.171
Dyspnea	37 (7.4)	22 (6.3)	0.512
History of severe COPD	15 (3)	11 (3.1)	0.919
History of bleeding disorder	7 (1.4)	5 (1.4)	0.982
ASA class [<i>n</i> (%)]			
I–II	314 (63.1)	242 (68.9)	0.075
≥III	184 (36.9)	109 (31.1)	
Long-term corticosteroid use [<i>n</i> (%)]	15 (3)	11 (3.1)	0.919
>10% weight loss in past 6 months [<i>n</i> (%)]	3 (0.6)	3 (0.9)	0.666
Disseminated cancer [<i>n</i> (%)]	4 (0.8)	4 (1.1)	0.617

ASA, American Society of Anesthesiology; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HTN, hypertension; VSD, vessel-sealing device.

Table 2 Clinical characteristics

	VSD (N=498) [n (%)]	Conventional hemostasis (N=351) [n (%)]	P
Thyroid operation indications			
Goiter multinodular	192 (38.4)	91 (25.9)	
Severe goiter, substernal	30 (6)	15 (4.3)	0.0002*
Grave's disease	34 (6.8)	17 (4.8)	
Malignant tumor	67 (13.5)	72 (20.5)	
Single nodule or neoplasm	165 (33.1)	149 (41.6)	
Other indication	11 (2.2)	11 (3.1)	
Preoperative needle biopsy results			
Follicular neoplasm	82 (16.5)	42 (12)	
Hurthle cell neoplasm	30 (6)	20 (5.7)	
Indeterminate results	74 (14.9)	47 (13.4)	0.161
Suspicious for papillary cancer	105 (21.1)	94 (26.8)	
Not done	139 (27.9)	89 (25.4)	
Other	68 (13.7)	59 (16.8)	
Total or subtotal thyroidectomy	320 (64.3)	207 (59)	0.118
Clinical thyroid toxicity	65 (13.1)	31 (8.8)	0.056
Prior neck operation	46 (9.2)	42 (12)	0.199
Central neck dissection performed	111 (22.3)	106 (30.2)	0.009*
T stage			
T0	3 (0.6)	1 (0.3)	
T1	98 (19.7)	83 (23.6)	0.157
T2	29 (5.8)	29 (8.3)	
T3	49 (9.8)	42 (12)	
T4	3 (0.6)	4 (1.1)	
Multifocal or unifocal cancer			
Unifocal	112 (22.5)	87 (24.8)	0.006*

VSD, vessel-sealing device. *There is a significant change among the studied groups in regard to indications of thyroid operation, central neck dissection performed and multifocal or unifocal cancer.

Table 3 Outcome

	VSD (N=498) [n (%)]	Conventional hemostasis (N=351) [n (%)]	P
Hematoma	6 (1.2)	15 (4.3)	0.005*
Recurrent laryngeal nerve (temporary-permanent)	31 (6.22)	28 (7.9)	0.006*
Surgical period (min) (mean±SD)	109.7 ±66.54	123.6±68.21	0.003*
Hospitalization (days) (mean±SD)	1.01 ±1.75	1.32±2.09	0.021*

VSD, vessel-sealing device. *There is a significant change among the study groups in regard to hematoma, surgical period and hospitalization.

the recurrent-rate laryngeal nerve paresis and hypoparathyroidism, neither the usage of the novel operative/technical novelties (energy-dependent tools, EBD), lesser-invasive resection (lobectomy), or strict standardization have decreased the occurrence of blood loss. Even the introductions of current homeostatic agents look not to decrease significantly the incidence of blood loss [10].

Numerous strategies intended to keep up careful hemostasis are by and by utilized: ligation and

stitching (strings, cuts, and staplers), coagulation (monopolar and bipolar electrocoagulation), US coagulations (Ultracision, Harmonic Scalpel), and electro-energy devices (Liga-Sure Vessel Sealing System; Valleylab, Boulder, Colorado, USA) [11].

LigaSure VSD is another hemostatic gadget. It is a bipolar electrosurgical gadget, fixing vessels of diameter up to 0.7 cm, by denaturation of elastin and collagen into vessel divider and the surrounding connecting tissues. The LigaSure had a reduced energy-spread mode [12].

The HS was presented to the surgeons about 20-years ago. Utilizing a mechanical vibration at 55.5-kHz frequency, this instrument can cut and coagulate tissues at the same time. The supposed benefits of utilizing this instrument over old-style electrocautery involve lesser cross-thermal tissue injuries, the absence of neuromuscular stimulations, and the escaping of electrical power transmissions to or through the case [13].

The aim of this study was comparing of complication incidence between VSDs and CH after thyroid surgeries.

This study was a retrospective cohort investigation, in which 849 patients matched inclusion criteria and included in the study. Information on cases experiencing thyroid-surgical operations from January 2017 to May 2021 was collected retrospectively from medical documentation.

In the present study, as regards baseline demographic characteristics, the mean age in VSD was 51.76 ± 5.62 years, and was 52.28 ± 4.74 years in CH, the mean of BMI in VSD was 29.17 ± 3.28 , and was 28.34 ± 3.51 in CH, the two groups were comparable without statistical significance; however, BMI was high significantly in the VSD group in comparison with CH group.

In comparison with the study of de Carvalho *et al.* [9], 5900 cases who experienced thyroid-surgical operations have been involved. The age median was 45.3 years (range: 7–96 years), and 4826 (82%) cases were females. The majority of cases – 4554 (77.3%) – were functioned owing to nonpalpable nodules parenthetically noticed throughout a radiologic process. Clinically, 148 (2.5%) cases had a substernal goiter. Only 180 (3.2%) cases were admitted to surgical operations because of hyperthyroidism. In total, 264 (4.9%) cases had formerly experienced thyroid operation. Past preceding neck (thyroid) irradiations were detected in 103 (1.7%) patients.

Mosalam *et al.* [14] reported that regarding demographic data, the age mean of the involved patients was 48.34 and 49.26 years for groups 1 and 2, respectively. Females were 70% (seven patients) and 80% (eight patients) of the studied groups correspondingly. Concerning comorbidities, two patients had a past history of diabetes mellitus in each group, but high blood pressure was detected in two (20%) patients and one (10%) patient in the studied groups, respectively.

Thyroidectomy is the commonest neck endocrine surgical operation, it is a highly précised surgery having many possible complications, involving wound infections, seroma or hematoma, hypocalcemia, laryngeal nerve injuries, lacerations of the esophagus or trachea, chyle fistula, dysphagia, etc. Postoperative hematoma, hypocalcemia, and recurrent laryngeal nerve palsy are the commonest operative complications of thyroid operation that can severely harm the quality of life and may even be deadly. Consequently, thyroid surgeons should do their best efforts to reduce the possible incidence of these operative complications [15].

In the current study, as regards thyroid-operation indications, we found that majority of the cases in both groups had goiter multinodular by 38.4 and 25.9% in VSD and CH respectively, followed by single nodule or neoplasm in VSD and CH by 33.1 and 41.6%, respectively, and there are significant changes among the studied groups concerning indications of thyroid operation, central neck dissection performed, and multifocal or unifocal cancer.

In agreement with our findings, the study of Ferri *et al.* [16] aimed to match surgical parameters, postoperative outcome, and operative complications of open entire thyroidectomy when utilizing the HS versus CH and reported that simple multinodular goiter was in 29 patients in HS and 31 cases in CH, toxic multinodular goiter was among 11 cases in HS and in 10 cases in the CH group, and Graves' disease was in four patients in the HS group and in five patients in the CH group, while differentiated carcinoma was present in six cases in the HS group and four patients in the CH group.

Furthermore, de Carvalho *et al.* [9] reported that the majority of cases (91%) experienced an entire thyroidectomy. Simultaneous lymph-node dissection was done in 717 (12.2%) patients: 547 (76.3%) cases have grade-VI neck clearances, and 170 (23.7%) experienced central and side neck dissections. Energy-dependent operative sealing instruments have been employed in 1505 (25.5%) cases: the HS in 1072 (18.2%), and LigaSure in 433 (7.3%) cases. In the other 4395 (74.5%) cases, the CH method (coagulations with electrocautery and ligation of vessels of the blood) has been employed. An adjunctive hemostatic agent (surgical) and surgical drains have been utilized in 1631 (27.6%) and 2327 (41.8%) cases in order.

Moreover, our results are supported by the study of Siu *et al.* [17], which reported that significant changes were found among the groups concerning indications of thyroid operation, central neck dissection performed, previous neck operation, intraoperative nerve monitoring, preoperative needle-biopsy result, and multifocal or unifocal cancer where *P* value less than 0.001.

In de Carvalho *et al.* [9] report, all cases have stayed at the hospital for a minimum 1 day, and they were followed up postoperatively for at least 7 days, they supposed that this interval of following up is enough to detect any late incidence of wound hematoma,

they detected 35 (62.5%) cases that have PNH throughout the same hospital stay in 6 h of the operation.

Godballe *et al.* [18] concluded that the median interval for the beginning of postoperative hemorrhage was 3 h (range, 0 and 105 h). In a multi-institutionally universal case-control research involving 20 cases, Campbell *et al.* [19] concluded that 47% of hematoma cases reoperated within 6 h, and 79%, in 24 h afterward thyroidectomy operation.

Siu *et al.* [17] reported that in the identical sample (3271 cases for every group), CH was associated with higher cases of developing a neck hematoma: 78 (2.39%) cases compared with 34 (1.04%) hematomas in the VSD group. No change was detected in the chances of recurrent laryngeal nerve injuries [occurrence-rate ratio (ORR), 0.90; 95% CI, 0.73–1.11]. No change was observed in the surgical period among VSD and CH (ORR, 0.99; 95% CI, 0.96–1.01), while the hospitalization period was significantly extended for the CH group in comparison with the VSD group (ORR, 1.29; 95% CI, 1.23–1.36). On the other hand, in the present study, as regards outcomes, we demonstrated that 1.2% in the VSD group and 4.3% in the CH group had postoperative hematoma and recurrent laryngeal nerve (temporary-permanent) 6.22 and 7.9% in the VSD and CH groups, respectively. Mean±SD of the surgical period was 109.7±66.54 and 123.6±68.21 min in the VSD and CH groups respectively, while as regards hospitalization, we found that mean±SD of HS was 1.01±1.75 and 1.32±2.09 days in VS and CH groups, respectively, and there is a significant difference between the groups regarding hematoma, surgical period, and hospitalization. Increased surgical period in the CH group not related to intraoperative bleeding. Also, intraoperative bleeding not necessarily associated with postoperative hematoma or increased hospitalization. Decrease of RNI in the VSD group related to decreased energy transmission through tissues. A meta-analysis of Ecker *et al.* [20], in the earlier decade, revealed that usage of VSDs is correlated with decreased operational room period by 22.3–23.1 mins and intraoperative bleeding by 13.9–20.0 ml. The decreased surgical period is advantageous for the cases and healthcare system, whereas the clinical significance of reduced intraoperative bleeding is not clear. Decreased intraoperative bleeding does not essentially translate to a decreased postoperative risk of hematoma, which remains one of the most worrying complications afterward thyroid-surgical operation.

In a study done by Mosalam *et al.* [14], they reported that no difference was detected regarding postoperative pain between the two study groups ($P=0.97$). One (10%) patient in group 1 suffered from hematoma and has been managed by operative explorations, while no cases developed that complication in the other group ($P=0.372$). The two groups have a similar range of hospitalization thereafter surgery (2 days).

In our study, the decrease in the time of hospitalization in group 1 (VSD) than group 2 was due to the decrease of complications in group 1.

Moreover, Ferri *et al.* [16] reported that the average surgical period was significantly short in the HS group (44.9±8.3 min) in comparison with the CH group (69.5±10.7 min). The entire drainage-fluid size was lower in HS in comparison with CH (37.4±2.4 vs. 56.1±4.2, respectively). The rate of complications was detected in the two groups. Two (4%) transient recurrent laryngeal nerve palsies have been detected in the CH group and no one (0%) in the HS group. No cases advanced everlasting palsy.

Observational reports are the topic to data bias from misclassification of parameters or outcomes. Upcoming investigations must involve an economic study to find out if costs saved from the reduction of complications and surgical period outweigh the supplementary instrumental costs of VSDs. As healthcare systems count value-based care initiatives, it is significant to nonstop evaluate the economics of novel technology and instruments.

Conclusion

The current work revealed that the usage of VSDs in thyroid-surgical operation was accompanied by reduced development of postoperative hematoma in comparison with the CH technique. Given the strength of the present results, the easiness of inclusion of these instruments into practices, and the impact a postoperative hematoma could have, surgeons and hospitals can consider the inclusion of VSDs into their practices.

From our study, the use of the VSDs during the entire thyroidectomy is a dependable and secure device that significantly decreases surgical period, intraoperative bleeding, and postoperative drainages. Its usage is more operative than conventional techniques. Furthermore, the rate of postoperative complications

(bleeding, recurrent laryngeal nerve palsy) and hospitalization is low.

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Conflicts of interest

There are no conflicts of interest.

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