ORIGINAL ARTICLE

Comparison of postoperative bleeding using harmonic scalpel and LigaSure in thyroid surgery: a 15-year single-centre retrospective study

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ABSTRACT

Aim Thyroidectomy is the most common operation in the field of endocrine surgery. The aim of this study was to compare the use of LigaSure vessel (LS) and harmonic scalpel (HS) in 1653 total thyroidectomies between January 2008 and March of 2023, with regards to analysis of surgical bleeding complications duration the hospital stay and operative surgical time.

Methods It is a retrospective analysis of a prospectively maintained database. Patients have been categorized into two groups: Group A included 718 patients from January 2008 to May 2013 when LS was used, and the Group B included 935 patients from June 2013 to March 2023 when HS was used.

Results From the total of 14 postoperative bleeding cases that occurred in patients of Group A, only in 4 of them it was necessary to have a reoperation. The other 10 cases involved minor haemorrhages, while from the total of 6 postoperative bleeding cases that happened to patients of Group B, there were 4 cases that needed a reoperation (p-value >0.05) and 2 patients with minor haemorrhages. The postoperative evaluation of minor bleedings revealed statistically significant differences between the two groups (p-value < 0.05). The average hospital stay was similar in the two groups.

Conclusion Both devices exhibit identical safety profiles in thyroidectomies specifically regarding major bleeding complications that require reoperation. Additionally, HS was found to be more effective at achieving haemostasis, especially in the subgroup of patients with thyroid carcinoma. The results of the present study may be useful for high-volume centres performing numerous thyroidectomies every day.

Key words: bleeding, complications, LigaSure, thyroidectomy, UltraCision

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INTRODUCTION

Thyroid gland diseases are the second in prevalence of endocrine disorders after diabetes mellitus, with nodular goitre being diagnosed with increasing frequency in geographical areas affected by iodine deficiency (1,2). The surgical therapeutic method of choice for the treatment of thyroid-related conditions is thyroidectomy, which has become the most frequently performed operation in the field of endocrine surgery (3,4). Advances pertaining to anaesthesia, antisepsis, as well as innovations regarding the surgical instruments and surgical techniques have increased the efficiency and safety of thyroidectomy as a treatment approach, while also minimizing morbidity and nearly eradicating the associated mortality (5,6).

Haemostasis, which can be achieved through various means intraoperatively, is of paramount importance to avert possible complications (7). Vessel cauterization using electrocautery or other thermal haemostatic devices, ligation methods such as clamping and tying or using clips and haemostatic agents such as fibrin glue, are the classic methods used to ensure that haemostasis is achieved (8,9). The most widely used haemostatic tools are the ultrasound-based Harmonic Focus scalpel (Ethicon, Cincinnati, OH, USA) and the LigaSure Precise Vessel Sealing System (Medtronic, Minneapolis, MN, USA) (10). The Focus Harmonic scalpel consists of a blade vibrating at the frequency of 55 Hz over the distance of 80μm. The mechanical energy that is produced by the ultrasonically vibrating blade is transferred to proteins of the apprehended tissue causing the formation of a coagulum created by their denaturation, which seals the vessels, leading to haemostasis (11). The LigaSure Precise Vessel Sealing System is a bipolar diathermy coagulation device that harnesses thermal energy in order to denature the collagen and elastin that make up the vascular wall (10). Traditional knot tying and the use of both surgical tools have been compared in multiple studies; however, a study juxtaposing the two devices has yet to be conducted (12,13). In 2013 the device of choice in our department changed, owing not to medical reasons but to a new deal that was made with another company by the Manager of the University Hospital of Patras that better fitted the hospital's budget.

The aim of this study was to compare the use of LigaSure vessel (LS) and harmonic scalpel (HS) in 1653 total thyroidectomy cases between January of 2008 and March of 2023, with the main points of consideration being complications associated with surgical bleeding, duration of patient hospitalization and operative time.

PATIENTS AND METHODS

Patients and study design

All patient details undergoing thyroid surgery in the Department of Surgery, General University Hospital of Patras between January of 2008 and March of 2023, were logged prospectively into the Department's database. The data were retrieved and analysed retrospectively. The patients were categorized into two groups: Group A included 718 patients from January 2008 to May 2013 when the ligature was used, and the Group B included 935 patients from June 2013 to March 2023 when the harmonic scalpel was used. The total number of postoperative bleeding cases, surgical time and the duration of hospital stay between the two groups were compared. Haemorrhages that required reoperation, as well as minor haemorrhages (subcutaneous), which did not undergo a reoperation, were included.

A total of 1653 patients who underwent thyroidectomy between January 2008 and March of 2023 were included in the study.

Patients with history of intake of anticoagulant agents, as well as patients with impairment of coagulation tests were excluded from the study. Also, all the patients who had undergone near total thyroidectomy or thyroid lobectomy were excluded from the final analysis.

Methods

Thyroidectomy. The patient was placed in the reverse Trendelenburg position on the operating table in order to ensure satisfactory venous drainage of the neck, and more specifically the internal jugular vein. Placing a pillow between the patient's scapulae extends the neck facilitating access to the thyroid gland. A transverse skin incision was then made, 3-4 cm above the fossa jugularis sternalis spanning the gap between the medial border of each of the sternocleidomastoid muscles. In cases of large lesions or should la-

teral lymph node dissection was indicated, the incision could be extended as necessary. The subcutaneous fat and the platysma were then divided and the upper and lower flaps, extending respectively to the thyroid notch and the suprasternal notch, were developed while taking care to remain superficial to the anterior jugular veins. The fascia of the strap muscles (the sternothyroid, the sternohyoid and the omohyoid) was then incised sagitally along the midline and the muscles themselves were laterally retracted, allowing for dislocation and medial displacement of the lobe. The middle thyroid vein should then be identified and ligated. The thyroid lobe was displaced inferiorly, and the superior thyroid vessels were ligated, ideally as proximately to the lobe as possible. The main concern during the ligation of the superior thyroid artery was the safeguarding of the external laryngeal nerve, as its damage leads to partial paralysis of the ipsilateral vocal cord. The parathyroid glands which lie adjacent to the thyroid should be preserved during the operation, ensuring that they rest in situ and that their arterial supply remains unperturbed. The superior parathyroid gland reposes posteriorly to the upper lobe of the thyroid gland, approximately 1 cm cephalad the junction point of the inferior thyroid artery and the recurrent laryngeal nerve. The inferior parathyroid glands lie most commonly on the anterior surface or the posterolateral border of the inferior pole of the thyroid gland, in the area between the isthmus and the caudal tip of the lobe. The recurrent laryngeal nerve (RLN) is the most important anatomical structure that should be considered during ligation of the inferior thyroid arteries as its anatomy varies widely. The left RLN is found posteriorly to the artery in 50-55% of the cases, anteriorly in 11-12% while the remaining 33% were located between the arterial branches that sprout from the central arterial trunk (3,5). The right RLN on the other hand, lies between the distal branches of the inferior thyroid artery in 50% of the patients, in 18-20% it is found dorsally to the artery and in one third of the cases it passes ventrally to the vessel (3,5).

Recurrent laryngeal nerve paralysis: anatomy and etiology. The vast anatomical variations of the course of the RLN have led to it being identified intra-operatively with the uses of intermittent intra-operative neuro-monitoring so as to ensure that it is not damaged (3,5). If a lobectomy is performed, the isthmus, which normally bridges the two lobes, is divided. In total thyroidectomies, no macroscopically visible thyroid tissue should be left *in situ*, with the isthmus and the pyramidal lobe (when present) being removed in addition to the left and right lobes. A drainage system, usually a Jackson-Pratt, is placed in the surgical site and the incision is sutured with 4.0 nylon stitches, which are removed on the first postoperative day (14).

Statistical analysis

Student's t-test for normally distributed variables, Mann – Whitney U test for skewed variables, and Fisher's exact tests were used to compare results between the groups. A $p<0.05$ was considered statistically significant.

RESULTS

A total of 718 thyroid operations were performed between January 2008 and May 2013. There were 214 males and 504 females with a mean age of 52 (range 14–85) years (Table 1). All patients underwent total thyroidectomy by using LigaSure small jaw open sealer, which was the device used in thyroid surgery in the Department of Surgery of University Hospital of Patras in that

Table 1. Patients' demographic data and indications for surgery

Variable	Multinodular goitre			Graves' disease			Thyroid carcinoma			Thyroid adenoma		
	Group A	Group B	p	Group A	Group	p	Group A	Group B	p	Group	Group B	p
No of patients	664	821	NS	8	14	NS	44	91	NS	2	9	NS
Males/Females (No)	300/364	271/550	NS	3/5	8/6	NS	20/24	50/41	NS	1/1	5/4	NS
Mean (range) age (Years)	48,7 (14-84)	51,1 (16-81)	NS	43,1 (19-78)	42,4 (15-82)	NS	52 (17-75)	52 (17-78)	NS	48.1 (14-84)	48.6 (14-84)	NS
Mean±SD operative time (min)	87.9±8	76.8±14.2	<0.05	98.4±15.4	89.1±12	<0.05	87.9±10	81.8±13	<0.05	76.8±14.2	75.8±14	NS
Mean±SD hospitalization (days)	2.1±3.2	2.3±3.6	NS	2.6±3.9	2.4±3.6	NS	2,5±3.1	2,6±3.5	NS	2.3±3	2.2±2.8	NS

Group A, Ligature Group; Group B, Ultracision Group; NS, not significant

period. After May 2013, a total of 935 thyroid operations were performed. There were 334 males and 701 females with a mean age of 54 (range 15–82) years. UltraCision CD 14C Harmonic Scalpel was the device used in thyroidectomies since May 2013.

Of these 718 patients, 664 (92.5%) from Group A had Multinodular Goitre, while Graves' disease was diagnosed in eight (1.11%) patients. Thyroid cancer was identified in 44 (6.13%) patients from Group A. From January 2008 to May 2013, when the LigaSure small jaw open sealer was used, there were four patients with Graves' disease with postoperative bleeding after thyroidectomy. Four out of eight (50%) patients with Graves' disease had postoperative bleeding after the surgery, while only two of 14 (14.3%) patients with Graves' disease had postoperative bleeding from June 2013 to March 2023, when UltraCision Harmonic was used (p=0.07). From the total of 14 postoperative bleedings that occurred to patients of Group A, where LigaSure was used, reoperation was necessary in only four. The other 10 cases involved minor haemorrhages. From the total of six postoperative bleeding cases that happened to patients of Group B, there were also four cases that needed a reoperation, but only two with minor haemorrhages. The total for postoperative bleeding cases and the minor postoperative bleeding cases in the subgroup of patients with thyroid carcinoma, was statistically different (p<0.05) (Table 2).

Regarding the operative time, there was significant difference (p< 0.05) between HS group and LS group; mean and SD were 91.9±7.4 minutes (min), and 79.8±14.1 min, respectively. The average hospital stay was similar in the two groups (3±3.2 and 3±3.6, respectively (p >0.05).

Table 2. Number of postoperative bleeding cases (minor and major bleeding which need reoperation) for each kind of thyroid disorder that underwent total thyroidectomy

Indication for surgery	Minor bleeding			Major bleeding reoperation		
	Group A	Group B	p	Group A	Group B	p
Multinodular goitre	3	0	NS	1	1	NS
Graves' disease	3	1	0.07	1	1	NS
Thyroid carcinoma	4	1	0.02	2	2	NS
Thyroid adenoma	0	0	NS	0	0	NS
Total	10	2	0.03	4	4	NS

Group A, Ligature Group; Group B, Ultracision Group;
NS, Not significant

DISCUSSION

Thyroid gland excision is an operation performed by general surgeons globally that constitutes the main treatment option for an array of thyroid diseases. Indications of thyroidectomy include: malignancy (suspected or definitive), massive goitre with compression effects on adjacent anatomical structures, thyroid nodules exhibiting decreased or no radioiodine uptake (cold nodules) during thyroid scans as well as a the patient's preference for an efficient and decisive treatment of their condition (15,16). The amount of thyroid tissue that should be excised depending on the diagnosis, continues to be a point of debate amongst researchers, with a consensus regarding the size of the thyroid gland that ought to be left in situ yet to be achieved (16).

Post thyroidectomy hematomas are a rare complication taking place in <1 to 2% of thyroidectomies, which nevertheless bear increased significance as they can possibly lead to airway obstruction (17,18). In our study, 12 cases of post-operative hematoma were observed out of the total of 718 thyroidectomies (0.95%), with the patient undergoing operative exploration of the surgical site in 0.63% cases due to persistent haemorrhage and airway obstruction. Both LigaSure and harmonic scalpel have demonstrated to be safe in thyroid operations. Articles that were published in 2003 and 2004, describing the experience of using the LigaSure and the harmonic scalpel, concluded that both devices exhibited acceptable safety profiles when used during thyroid surgery (19-21). Our study has showcased that both devices exhibit identical safety profiles in thyroidectomies specifically regarding major bleeding complications that require reoperation. Additionally, HS was found to be more effective at achieving haemostasis, especially in the subgroup of patients with thyroid carcinoma.

The deployment of devises such as HS and LS during surgery has been found to lessen operation duration (22). In our study, the use of UltraCision has been found to correlate with shorter surgical time in comparison to ligature. This observation can be attributed to a multitude of causes. Decreased time required to achieve adequate haemostasis is a potential reason, however, other points such as the experience and expertise of surgeons performing these operations should also be considered (23).

The major advantage of this study is its sample size of 1653 patients, making it the largest of its kind in current literature; however, the fact that is a retrospective study, drawing data from a single institution constitute its main weak point. The difference between these two devices significantly decreased operative time while using harmonic scalpel, as well as a decrease regarding minor bleedings cases in the comparison with the LigaSure device. However, since most studies have not detected any discrepancy between the achievement of haemostasis when using the Ligature or UltraCision devices in haemostasis, further analysis is warranted.

Study limitations were the experience of surgeons gained over the years in the University Hospital of Patras and the small number of postoperative bleeding cases.

In conclusion, the present study showed cased that both devices exhibit identical safety profiles in thyroidectomies specifically regarding major bleeding complications that require reoperation. Additionally, HS was found to be more effective at achieving haemostasis, especially in the subgroup of patients with thyroid carcinoma. The postoperative morbidity was not affected. The results of the present study may be useful for high-volume centres performing numerous thyroidectomies every day.

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TRANSPARENCY DECLARATION

Conflict of interests: None to declare.

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