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# original article

## Update on sutureless thyroidectomy

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#### SUMMARY: Update on sutureless thyroidectomy.

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Introduction. The Harmonic scalpel ("Focus" and the new version "Focus+") is one of the first devices for surgical simultaneous cutting and tissue coagulation which allows to obtain dissection and hemostasis by direct application of ultrasound and allows minimally invasive surgical procedures with minimal lateral thermal spread and, thus, minimal adjacent tissue destruction. The aim of the study is to complete the previous study that we made in 2014, based on the TT performed between January 2008 and December 2013, with new data about TT performed in our Surgical Division between January 2014 and December 2016 and compare the outcome using the Ultrasonic scalpel versus the device Ligasure in term of safety, operative time, overall drainage volume, complications, hospital stay.

Patients and methods. 250 patients were randomized into two groups: Group A where Ultracision were used and Group B where the Ligasure device was used.

Results. The results of the group A and of the Group B 2014-2016 have been compared with the results of the previous study and we found that they are similar, but asymptomatic hypocalcaemia increased in the patients of the new study.

Conclusions. We found that the use of Ultrasonic scalpel and Ligasure is effective both in the hemostasis of all vessels and in dissection of tissues and confirm the results of our first study without significant difference in the rate of post-operative morbidity with these two different energy based devices used.

KEY WORDS: Ultrasound - Radiofrequency - Thyroidectomy.

## Introduction

Total thyroidectomy (TT) is the gold standard for the surgical treatment of many thyroid disorders as goiter and cancer. Furthermore, there is an increase in nodular thyroid conditions prevalence with aging: almost 50% of patients > 65 years demonstrates nodules on ultrasound examination with a similar prevalence among autopsies performed in the general population (1, 2). Thyroid is a richly vascularized organ, so the hemostasis is a priority to avoid hard complications. An exhaustive hemostasis makes it possible to prevent: potential lesions of the parathyroid glands with consequential hypoparathyroidism, damage of the laryngeal

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nerves and dangerous post-operative bleeding. Hemostasis obtained with traditional methods, such as clamp and tie, use of clips or electrocautery, fibrin glue, is time consuming and carry the risk of knot slipping, dislodgment and thermal damage (3). Recently, innovative vessel sealing devices have been recommended in order to give a valuable contribution in terms of accuracy of hemostasis, reducing of operative time and postoperative pain, safety, knowing that the reduction of surgical times is a necessity in terms of cost effectiveness (4-7). The Harmonic scalpel ("Focus" and the new version "Focus+") is one of the first devices for surgical simultaneous cutting and tissue coagulation which allows to obtain dissection and hemostasis by direct application of ultrasound and allows minimally invasive surgical procedures with minimal lateral thermal spread and, thus, minimal adjacent tissue destruction (8). Another device used in the study was the Ligasure Small Jaw, an electrosurgical ra-

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diofrequency device with haemostatic mechanism causing a biologic seal which closes tightly the vessels (9-17). The aim of the study is to complete the previous study that we made in 2014, based on the TT performed between January 2008 and December 2013, with new data about TT performed in our Surgical Division between January 2014 and December2016(18). Primary endpoint of changes is to compare the data between the two studies and understand if it possible to confirm the results of our first study. This study is a prospective one as the previous and the data analyzed are: analysis of complications, surgical time, overall drainage volume and average time of hospitalization (19-27).

## Patients and methods

From January 2014 to December 2016 300 patients with thyroidal disease required surgical treatment and 250 of them were enrolled in our study. The 250 patients undergoing total thyroidectomy (TT) gave informed consent to the study.

Exclusion criteria of the patients enrolled in the study were: age over 70 years, need for central or lateral compartment lymphadenectomy, recurrent goiter, previous neck irradiation or radioiodine ablation.

Pre-operative data regarding age, gender, preoperative serum calcium and thyroid pathology were prospectively collected.

The post-operative evaluation included analysis both of complications (laryngeal nerve palsy, hypoparathyroidism, blood loss, hematoma, seroma, wound infection) and the features of the pre and postsurgery parameters (size of the thyroid specimen, postoperative serum calcium levels, overall drained, pain medications, histopathologic diagnosis, reoperations, length of hospital stay, final outcome).

The patients were divided into 2 groups (A and B) of 125 patients in randomized way and not considering the age.

Group A patients underwent TT with the ultrasonic scalpel (Harmonic Focus) while in group B patients underwent TT with Ligasure (Precise/Small Jaw).

Surgical technique requires MIT (Minimally Invasive Thyroidectomy) approach (3-5 cm incision) in presence of a nodule between 35 and 50 mm and/or thyroid total volume between 30 and 80 ml. In presence of thyroid volumes greater than 80 ml and/or a thyroid nodule larger than 50 mm, high risk carcinoma CT (Conventional Thyroidectomy) performed through incision greater than 5.5 cm was indicated.

The duration of surgery was estimated in minutes from skin incision to skin closure.

Ligatures on all vessels including the superior thyroid artery, were performed with these two devices.

A really important step of the study was controlling the hemostasis obtained with both devices. Always a drain was placed on the thyroid bed as part of the study protocol, in order to quantify blood loss during the first 24 hours.

Other important step of the study was the monitoring of Serum calcium levels on the 12, 24, 48 h postoperatively.

The patients were discharged between the 2nd and 4th post-operative day.

Statistical analysis were performed using dedicated statistical software (SPSS, version 17.0); unpaired T test and Fischer's exact test with a two sided P value <0.05 were used when appropriated.

## Results

We performed 250 TT, 125 by the means of Harmonic (Group A) and 125 by the means of Ligasure (Group B). The comparative preoperative data between the two groups are shown in Table 1.

There were no significant differences between the two groups regarding: serum calcium values pre-and post-surgery, re-operations, weight and diameter of the thyroid specimen, final histopathological diagnosis. The average hospital stay was similar in group A and group B (2,3 days) (Table 2).

Incidence of complications did not differ significantly in each groups:

In Group A one patient (0.8%) had a transient palsy of the recurrent laryngeal nerve that regressed after 8 weeks; transient hypocalcaemia has been observed in 14 (11.2%) patients, 9 of whom (64.2% of 14 patients) were asymptomatic and they regressed in 3–6 months after medical therapy with oral calcium and vitamin D (Table 3).

In group B, the patients with transient palsy of the recurrent laryngeal nerve were 2 (1.6%) with only one definitive palsy (0.8%). Incidence of transient hypocalcaemia was 22.4% (28 patients); 10 asymptomatic hypocalcaemia (8%) regressed with oral calcium supplements and vitamin D analogues supplements in the next 4 months. No patient developed definitive hypocalcaemia and no reinterventation was necessary

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	Total	Group A	Group B	
Number of patients	250	125	125	
Media age	48 (16-70)	45	47	
Male patients	80	35	45	
Female patients	170	90	80	
Benign disease	208 (83,2%)	100	108	
Malign disease	42 (16,8%)	25	17	

#### TABLE 1 - COMPARATIVE PREOPERATIVE DATA.

#### TABLE 2 - POSTOPERATIVE EVALUATION.

	Total	Group A	Group B	р
Number of patients	250	125	125	
Operative time (min.)	74 +/- 6	65 +/- 16	75 +/- 11	ns
Postoperative calcium level (mg/dl)	8,7	8,4	8,3	ns
Drained volume	50 +/- 25cc	50 +/- 20cc	55 +/- 25cc	ns
Hospital stay (days)	2,3	2,3	2,3	ns
Reoperation	0	0	0	ns

#### TABLE 3 - COMPLICATIONS.

	Group A (2008-2013)	Group A (2014-2016)
Transient palsy of recurrent laryngeal nerve	1%	0.8%
Transient hypocalcaemia	18%	11.2%
Asymptomatic hypocalcaemia	9%	7.2%
Permanent hypocalcaemia	0	0
Re-operation	0.8%	0

#### TABLE 4 - COMPLICATIONS.

	Group B (2008-2013)	Group B (2014-2016)
Transient palsy of recurrent laryngeal nerve	2%	1.6%
Permanent palsy of recurrent laryngeal nerve	0.5%	0.8%
Transient hypocalcaemia	20%	22.4%
Asymptomatic hypocalcaemia	5%	8%
Permanent hypocalcaemia	0.5%	0
Re-operation	0	0

(Table 4). The seromas and hematomas were solved by conservative treatment (antibiotic therapy and aspirative drainage).

Considering operative time the average value of

the group A was not significantly lower ( $65 \pm 16 \text{ min}$ ) than group B ( $75 \pm 11 \text{ min}$ ) (P 0.27). The amount of drainage was similar: group A 50 ± 20 cc, group B 55 ± 25 cc (P 0.32).

Finally the results of the group A and of the Group B 2014-2016 have been compared with the results of the previous study and we found that they are similar, but asymptomatic hypocalcaemia increased in the patients of the new study in the group B.

Histology revealed a benign disease in 208 cases (83.2%) (multinodular goiters, Hashimoto's thyroiditis, Basedow disease) and in 42 cases (16.8%) malignancy (papillary and follicular carcinoma).

So we can say that incidence rate of benign and malignancy diseases was similar to the previous study (83.5% B - 16.5% M).

## Discussion

The use of ultrasonic mechanical energy gave us the possibility to improve dissection and coagulation, bettering hemostasis and reducing operative times (4-9). The Harmonic scalpel is a device that use high frequency ultrasonic energy to gain a coagulative seal of vessels and tissues, cutting them at frequency of 55.5 kHz, reaching a temperatures under 100°C, so that thermal damage is reduced on near tissues. In thyroid surgery several studies have shown that the use of ultrasonic scalpel is safe and effective (13-17). The ultrasonic scalpel, in fact, compared to the traditional technique, provide benefits at several levels: for the patient, for the surgeon and for the healthcare facility when it is used. In particular, the literature confirms there is less blood loss (45%), less post-operative pain ( 40.5%), lower consumption of pain medication (38%), less drainage volume (50.5%), smaller and better esthetic scars, significant reduction in operative time (47% on average), rapid and effective hemostasis with minimal tissue damages, a significant reduction of time also in terms of use of the operating room (24 min), reducing use of economic resources by the medical institution (28-30).

The initial suggestion for using of ultrasonic scalpels was for vessels not exceeding 3 mm. The technological development with provided and ergonomic tools has led to the use on vessels up to 5 mm in diameter offering a precise and accurate surgical dissection, such as the thyroid surgery, with a great saving of surgical times.

Lateral thermal damage is limited up to 2 mm beyond the tissue grasped within the forceps of the device. This is an important property in thyroid surgery because it allows safe vascular ligation with minimal risk for damage to the recurrent laryngeal nerve, the external branch of the superior laryngeal nerve, and the parathyroid glands. Moreover there have been several studies that prove the safety and efficiency of the this device for the superior thyroid artery (4, 11, 23).

The main advantage of device Ligasure are related to high current with low voltage output and less thermal spread. The haemostatic mechanism works applying a calibrated amount of energy, causing a biologic seal which closes tightly the vessels up to 7 mm of diameter.

Glover (27) compared the Ligasure Precise and the Ligasure Small Jaw: there was not any significant difference on the incidence of complications (hematoma, temporary/permanent hypoparathyroidism or temporary/ permanent recurrent laryngeal nerve injury).

Pergel (26) studied the effect of Ligasure and clamp and tie technique on post-operative complications on the recurrent laryngeal and parathyroid glands.

Lang (29) in a systematic review of the literature (8 studies with 963 patients) observed reduction of volume of blood loss and operating time in the Harmonic Scalpel group compared to the Ligasure group. The clinical significance hot these findings remained questionable because the overall mean difference appeared small.

Chang (31) in 1935 consecutive patients underwent total thyroidectomy (1163 using a suture less technique with Ligasure or Ultracision) observed no difference in post-operative complications but mean operative time significantly lower in the suture less group.

Zarebczan (24) in 231 patients observed no difference in the rate of complications between Harmonic and Ligasure but reduction of operative time in the Harmonic Scalpel group.

Kwak (30) in 832 patients who required thyroidectomy for papillary thyroid cancer randomized in two groups treated with harmonic Scalpel or Ligasure Precise observed no statistically significant difference in the operative times, postoperative transient hypoparathyroidism and permanent recurrent laryngeal nerve injuries.

Dionigi (31) in a total of 182 consecutive patients scheduled for open thyroidectomy with Focus shear and Ligasure LF demonstrated only significantly lower early postoperative levels of PTH in the Focus group.

Bove (32) in a retrospective case-matched study about effectiveness and outcome in 240 total thyroidectomy of the Harmonic Focus and Ligasure Precise observed a significant reduction of the operative time with Harmonic Focus with no statistically differences in post-operative complications.

Hammad (33) in 301 patients underwent thyroid surgery observed lower incidence of post-operative transient hypocalcemia in the Ligasure group compared to the Harmonic Focus scalpel group.

Revelli (34) in a meta-analysis of 1458 patients observed lower rate of hypocalcemia in the Harmonic Focus group compared to the Harmonic scalpel.

Zhang (35) in a meta-analysis of 813 patients observed significant reduced operative time in the Ligasure group compared to the Harmonic Focus scalpel.

Luo (36) in a meta-analysis found that Harmonic Scalpel was associated with a significant 9,78 min. reduction in operation time than Ligasure.

Tolone (37) in 255 patients with 105 patients with age > 70 years observed no significant difference between the elderly and the young patients with similar results with Harmonic Focus scalpel and Ligasure.

Uludag (38) in 60 patients observed better voice quality in late post-operative period without statistical difference in the group with Ligasure compared to the Harmonic scalpel group.

## Conclusion

Considering the technical feature we found that the use of Ultrasonic scalpel and Ligasure is effective both in the hemostasis of all vessels and in dissection of tissues near the course of the laryngeal nerves, respecting the safety margins, and Berry's and Gruber's ligaments.

Moreover this devices have a lateral thermal spread of 2 mm, so that this is a remarkable advantage in comparison to high temperature achieved by mono- or bipolar scalpel near the noble structures such as recurrent laryngeal nerves and parathyroid glands.

A really important aspect is the correct use of the Ultrasonic Scalpel because the temperature may rise over 100°C in case of prolonged activation (> 10 seconds) or high frequency use (levels 4 and 5). However keeping the correct parameters and precautions, such as low power setting (level 3), short application time (< 10 seconds) and a suitable distance from structures to be preserved (between 3 e 5 mm), the device grants a safe and efficacy use.

The detected complications (transient recurrent laryngeal nerve palsy, transient hypoparathyroidism) were similar in both groups, according to the literature (8, 12, 15). Nowadays operative time is perhaps the most significant feature in all comparative studies, to highlight the real advantage of using systems of hemostasis and dissection alternative to traditional ones. Moreover, the reduction of operative times allows to decrease operating room occupancy costs. Probably the only disadvantage of this devices is the cost of the single-use, but other studies analyzing and comparing costs, confirm that the investment on the device can be easily amortized if surgical operative times is saved. In fact this aspect allows to increase the number of surgical procedures in the same surgical session and reduces the anesthesia costs, pain drugs and hospital stay, therefore decreasing the overall hospital costs.

In conclusion this study confirm the results of our first study without significant difference in the rate of post-operative morbidity with these two different energy based devices used.

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