

HARMONIC SCALPEL VERSUS CONVENTIONAL TECHNIQUE IN TOTAL THYROIDECTOMY (COMPARATIVE STUDY)

By

Sawsan S. Mohamed, Mohamed O. Alfy, and Mohamed Sh. Zarad

Department of General Surgery, Faculty of Medicine (Girls), Al-Azhar University

Corresponding author: Sawsan Soliman Mohamed, **Mobile:** 01001464690

E-mail: dr.sawsan_soliman@yahoo.com

ABSTRACT

Background: Thyroid gland is a highly vascular organ. So, doing thyroidectomy requires good hemostasis even for the small blood vessels either through conventional tie technique which is time-consuming or through the use of a harmonic scalpel.

Objective: To evaluate the real benefits of the Harmonic Scalpel in total thyroidectomies when compared with conventional ligation, in terms of operative time, postoperative drainage, and complications.

Patients and methods: This randomized, prospective observational study was carried out at Al-Zahraa University Hospital, Al-Azhar University, Cairo, Egypt. Written informed consents were obtained from Seventy-six patients with benign goiter disorders who were scheduled for elective total thyroidectomy during a period from August 2019 to October 2020. Thirty eight patients were submitted to conventional thyroidectomy (group A), and thirty eight underwent thyroidectomy using a harmonic scalpel (group B).

Results: There was no statistical difference between the two groups as regards demographic data, hospital stay, recurrent laryngeal nerve injury, and hypocalcemia, but there was a statistically significant difference as regards operative time (76.9 ± 15.1 min in group A versus 89.23 ± 17.68 in group B) and drainage volume (111.75 ± 56.57 mls in group A versus 89 ± 16.21 mls in group B).

Conclusion: Harmonic scalpel for total thyroidectomy is a better choice compared to the conventional tie technique as regards operative time and postoperative drainage volume.

Key Words: Total thyroidectomy; Harmonic scalpel; conventional tie technique; hemostasis.

INTRODUCTION

Thyroidectomy is a commonly performed operation in endocrine surgery. It is the most convenient therapeutic choice in the treatment of many thyroid disorders through surgical interference (*Al-Dhahiry and Hameed; 2015*).

Safe thyroid surgery requires meticulous hemostasis and careful control of bleeding. Whereas the thyroid has a rich blood supply, prompt hemostasis is

crucial to avoid intraoperative bleeding, obtain good visualization of the surgical field, and prevent damage to structures such as parathyroid glands or laryngeal nerves. The main sources of bleeding are injured thyroid vessels and thyroid parenchymal bleeding (*Revelli et al., 2016*).

The conventional technique requires massive clamp-and-tie maneuvers for the small thyroid vessels and if the use of the conventional technique is time-

consuming. On the other hand, using instruments as mono or bipolar diathermy can be unsafe because of the risk of damaging the surrounding structures caused by the adjacent thermal spread. Focus harmonic scalpel is a good solution because it is a device specifically designed for having an accurate dissection and efficient hemostasis in all the procedures realized in a narrow operating field as in thyroid surgery (*Minni et al., 2016*).

Harmonic scalpel allows simultaneous cutting and coagulation of vessels by using mechanical ultrasound energy at a frequency of 55.5 kHz (*Cannizzaro et al., 2014*).

It has been shown that thermal injury induced by ultrasound is reduced when compared to electrocoagulation, which uses higher temperatures (150– 4008C) (*Migliore et al., 2013*).

Using harmonic focus, blood vessels with a diameter until 5 mm did not need additional protection by ligation, and this implicates a significant decrease of total operative time as shown in our study and even a significant reduction of the use of material (sutures, clips) (*Minni et al., 2016*).

This prospective randomized study aimed to evaluate the real benefits of the Harmonic Scalpel in total thyroidectomies when compared with conventional ligation, in terms of operative time, postoperative drainage, length of stay, and complications.

PATIENTS AND METHODS

This randomized, prospective observational study was carried at Al-Zahraa University Hospital, Faculty of

Medicine for girls, Al-Azhar University, Cairo, Egypt. Written informed consents were obtained from Seventy-six patients with benign goiter disorders who were scheduled for elective total thyroidectomy after obtaining approval from the hospital ethical committee during a period from August 2019 to October 2020.

All selected patients presented with goiters which were diagnosed by clinical examination, ultrasound scan, and confirmed by histopathological examination of the biopsy taken.

All patients presented with simple nodular goiter and solitary thyroid nodule. Exclusion criteria were: Patients who refused to participate in the study, presence of preoperative vocal cord dysfunction, giant goiter, Grave's disease, retrosternal goiter, toxic goiter, and patients unfit for general anesthesia.

All patients were subjected to detailed personal data, general and local examination, Laboratory investigations (preoperative preparation and thyroid hormone levels), Radiology by ultrasound (US).

Patients were randomized into two groups according to the hemostatic technique:

Group (A): Conventional thyroidectomy group (CT), where dissection and hemostasis were performed using conventional materials (Vicryl 3-0/2-0, stitches, and monopolar or bipolar electrocautery).

Group (B): Harmonic scalpel group (HS), in which the Harmonic Focus was used. The application of ultrasound to tissues was performed during the entire procedure

to obtain three purposes synergistically: coagulation, cutting, and cavitation.

All surgical procedures were performed under general anesthesia with endotracheal intubation. All operations were performed using a standardized capsular dissection technique through a collar incision. The lobe of the thyroid gland was progressively dissected away from strap muscles; its vascular pedicles were ligated with Vicryl 2/0 suture or coagulated and divided with HS. The thyroid lobe was progressively dissected off the trachea after the recurrent laryngeal nerves and parathyroid glands were identified and dissected off the thyroid capsule. After securing hemostasis, a suction drain was routinely put in the thyroid bed as a part of the study protocol to measure the amount of blood loss during the first 48 hours.

The parameters considered in this study were operative time (time from skin incision to the end of wound closure), amount of drainage, time of positioning of drainage balloons (the drains were removed if drainage volume was less than 10 ml in 24 hours).

Statistical analysis:

Data were collected, revised, coded, and entered into the Statistical Package for the Social Sciences (IBM SPSS) version 23 (IBM Corp., Armonk, New York, USA). The quantitative data were presented as mean, standard deviations, and ranges and were compared by independent t-test or Mann–Whitney U test. Qualitative data were presented as numbers and percentages and were compared by the Chi-square test (χ^2) or Fisher's Exact test. P-value was considered significant at $p < 0.05$.

RESULTS

Seventy-six patients were included in this study, 38 patients underwent total thyroidectomy using conventional tie technique (group A) and 38 patients underwent total thyroidectomy using harmonic scalpel (group B). There was no significant difference was observed in mean age, gender, Co-morbidities, mean hospital stay, hypocalcemia, and wound seroma of either group.

Regarding the operative time of surgery was significantly shorter in the harmonic group (HS) than in the conventional technique group (CT):

76.9±15.1 min vs 89.23±17.68 respectively.

Regarding drainage volume, there was a statistically significant difference between the two groups.

No significant difference for temporary RLN palsy rate was found between groups. We experienced no case of permanent RLN paralysis.

All patients who were complicated postoperatively by hypoparathyroidism recovered within 2 months, while no patient was complicated by permanent hypoparathyroidism (**Table 1**).

Table (1): Comparison between the two groups (Mean ± SD)

Parameters	Groups	Group A (CT)	Group B (HS)	P-value
		No. = 38	No. = 38	
Age (years)				0.814
Mean±SD		39±11.3	39.6±10.8	
Range		21–57	25–55	
Sex				0.497
Male		6 (15.7%)	4 (10.5%)	
Female		32 (84.3%)	34 (89.5%)	
Co-morbidities				0.723
HTN		5 (13.1%)	4 (10.5%)	
Diabetes		3 (7.8%)	2 (5.26%)	
Operative time (min)				0.002
Range		60-140	48-120	
Mean±SD		89.23±17.68	76.9±15.1	
Drainage volume (mls)		111.75±56.57	89 ± 16.21	0.020
Hospital stay (days)		2.7 ± 0.6	2.6 ± 1	0.599
Recurrent laryngeal nerve injury				1.000
Transient		2 (5.2%)	2 (5.2%)	
Permanent		0 (0.0%)	0 (0.0%)	
Hypocalcemia				0.455
Transient		5 (13.1%)	3 (7.9%)	
Permanent		0 (0.0%)	0 (0.0%)	
Wound seroma		1 (2.6%)	0 (0.0%)	0.314
Reoperation		0 (0.0%)	0 (0.0%)	NA

DISCUSSION

This study compared between harmonic scalpel and conventional tie technique in total thyroidectomy in which there was no significant difference was observed in mean age, gender, co-morbidities, mean hospital stay, hypocalcemia, and wound seroma of either group, but there was a statistically significant difference between the two groups, as regarding operative time.

Using Harmonic focus ultrasonic scalpel, there was a significantly decreased amount of drainage after surgery, and this was confirmed by numerous randomized trials that reported an important intra-operative blood loss reduction in addition to a post-operative drainage decrease (*Duan et al., 2013*).

It is of fundamental importance to properly use this device in the vicinity of extremely delicate structures such as the RLN. Though *Carlander et al. (2012)* showed that a Harmonic scalpel (HS) causes less trauma to adjacent nerve fibers than bipolar electro-surgery, also HS may cause nerve injury at close distances (*Revelli et al., 2016*).

HS seals vessels up to 5 mm in diameter offering a precise and accurate surgical dissection as in the thyroid surgery with a great saving of operative times. Its lateral thermal damage is limited up to 2 mm beyond the tissue grasped within the forceps of the device (*Cannizzaro et al., 2016*).

The use of advanced vessel sealing devices has been recommended in several studies regarding thyroid surgery, reporting the efficacy of hemostasis, reduction of operative time, postoperative pain, transient hypocalcemia, use of hemostatic agents, and cost (*Bove et al., 2012* and *Materazzi et al., 2013*).

Luo et al. (2017) performed a meta-analysis that compared harmonic scalpel and LigaSure hemostatic devices with the conventional clamp-and-tie technique of hemostasis in goiter- or cancer-related thyroid surgery. They found some differences in clinical outcomes between the three hemostatic modalities. Compared with the conventional hemostasis, there was a significant reduction in operation time with both the harmonic scalpel and LigaSure.

Contin et al. (2013) and *Garas et al. (2013)* performed a pair-wise meta-analysis and a network meta-analysis to compare the efficacy of ultrasonic harmonic scalpel, LigaSure, and the conventional hemostatic procedures in thyroid surgery. Both studies found that harmonic scalpel and LigaSure were associated with shorter operation time for thyroidectomy than the conventional hemostasis, and that harmonic scalpel was associated with the shortest operative time.

The reduction in operative times, as is true with any surgical procedure, typically will reduce the risk of surgical-site infection and may lead to faster patient recovery time (*Elfenbein et al., 2014*).

Sutureless thyroidectomy not only reduces the operative time, but also reduces the iatrogenic complications like

neurovascular injuries around the thyroid gland (*Cannizzaro et al., 2016*).

Chang et al. (2011) observed no statistical difference in postoperative complications, but the mean of operative time was significantly lower in the sutureless groups.

Lang et al. (2013) in a systematic review of the literature observed a reduction of volume of blood loss and operating time in the HS group compared to the LigaSure group.

Focus Harmonic Scalpel has certain advantages over conventional Haemostasis in protecting parathyroid glands, reducing the incidence of transient hypoparathyroidism and hypocalcemia in thyroid surgery, especially for patients with thyroid cancer (*Xu et al., 2019*).

Ruggiero et al. (2018) found that the use of an ultrasonic scalpel is effective both in the hemostasis of all vessels and in the dissection of tissues near the course of the laryngeal nerves, respecting the safety margins, and Berry's and Gruber's ligaments. Moreover, this device has 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.

CONCLUSION

The use of a Harmonic scalpel during thyroidectomy reduced the operative time and postoperative blood loss.

Conflict of Interest: No conflict of interest was declared by the authors.

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المبضع التوافقي مقابل التقنية التقليدية في إستئصال الغدة الدرقية الكلي (دراسة مقارنة)

سوسن سليمان محمد سليمان، محمد عمر محمد الالفى، محمد شحاته زرد

قسم الجراحة العامة، كلية طب بنات الأزهر

E-mail: dr.sawsan_soliman@yahoo.com

خلفية البحث: تعتبر الغدة الدرقية عضوًا وعائياً للغاية، لذا فإن استئصال الغدة الدرقية يتطلب إرقاء جيداً حتى للأوعية الدموية الصغيرة إما من خلال تقنية الربط التقليدية التي تستغرق وقتاً طويلاً أو من خلال استخدام مشرط متناسق.

الهدف من البحث: تقييم الفوائد الحقيقية للمشرط التوافقي في استئصال الغدة الدرقية الكلي عند مقارنتها بالربط التقليدي من حيث وقت العملية، والصرف بعد الجراحة، والمضاعفات.

المرضى وطرق البحث: أجريت هذه الدراسة الاستطلاعية العشوائية في مستشفى الزهراء الجامعي، جامعة الأزهر، القاهرة، مصر. وقد تم الحصول على موافقات مستنيرة مكتوبة من ستة وسبعين مريضاً يعانون من اضطرابات تضخم الغدة الدرقية الحميدة والذين كان من المقرر إجراء استئصال كامل للغدة الدرقية الاختياري خلال الفترة من أغسطس 2019 إلى أكتوبر 2020. خضع 38 مريضاً لاستئصال الغدة الدرقية التقليدي (المجموعة أ) وخضع 38 مريضاً لاستئصال الغدة الدرقية باستخدام مشرط متناسق.

نتائج البحث: لم يكن هناك فرقاً إحصائياً بين المجموعتين فيما يتعلق بالبيانات الديموغرافية، والإقامة في المستشفى، وإصابة العصب الحنجري المتكرر، ونقص كالسيوم الدم، ولكن كان هناك فرق ذا دلالة

إحصائية فيما يتعلق بوقت العملية (15.1 ± 76.9) دقيقة في المجموعة أ مقابل (17.68 ± 89.23 في المجموعة ب) وحجم الصرف (111.75 ± 56.57 مل في المجموعة أ مقابل 16.21 ± 89 مل في المجموعة ب).

الاستنتاج: الموضع التوافقي لاستئصال الغدة الدرقية الكلي هو الخيار الأفضل مقارنة بتقنية الربط التقليدية فيما يتعلق بوقت العملية وحجم التصريف بعد الجراحة.

الكلمات الدالة: استئصال الغدة الدرقية الكلي، الموضع التوافقي، التقنية التقليدية، التخثر.