Comparative study between Harmonic FOCUSTM to clamp and tie technique for total thyroidectomy

Adil K. Saloom* **CABS, MRCS**
Mohammed Q. AbdulJabbar** **CABS DGS**

Abstract:

Background: Thyroid surgery has undergone many changes during the past 2 decades, including the introduction of new surgical techniques such as endoscopic or video-assisted approaches, anesthesia care, intraoperative nerve monitoring and new hemostatic tools

Objectives: to assess the efficacy and safety of Harmonic Focus shears in total thyroidectomy compared with conventional surgical technique.

Patients and methods: prospective study conducted from October 2011 till January 2016, two handers and nine patients with benign and malignant thyroid diseases, scheduled for total thyroidectomy in a governor and private hospitals were enrolled randomly into 2 groups, group A consists of 105 patient who undergone a total thyroidectomy using a harmonic FOCUSTM , and group B consists of 104 patients who underwent total thyroidectomy with conventional surgical technique.

Results: Eleven patients had papillary thyroid carcinoma: 6 (5.7%) of them in group A and 5(4.8%) in group B. Eighty seven (82.9%) patients in group A had non toxic MNG, and 12(11.4%) patients had toxic MNG, 90 (86.5%) patients in group B had non toxic MNG while the other 9 (8.7%) had toxic MNG. Mean operative time was significantly lower in group A compared to Group B (100+/- 34 vs. 119+/- 30mins, respectively). In group A mean calcium level at first post-operative day was 8.36 +/- 0.54 mg/dl. In group B mean value was 8.12+/- 0.56 mg/dl. This difference was not statistically significant. There were no significant difference between the two groups concerning transient hypocalcemia requiring calcium and Vitamin D therapy: 11(10.5%) patients in group A versus 12(11.5%) in group B. No permanent hypocalcemia was found in both groups. Two patients had transient vocal cord palsy in group A(1.9%) versus 3 patients in group B (2.8%)

Conclusions: The HF is a reliable, comfortable and safe instrument alternative to knot tying technique, very suitable hand-piece for total thyroidectomy. It creates a clean, bloodless surgical field, and there is an advantage for the surgeon to use a single tool for both dissection and hemostasis. Moreover, the HF is a time-saving option, allowing for a significant reduction of operative time, without affecting parathyroid function, need for medical therapy, and hemostasis in the early post-operative period.

Keywords: Harmonic Focus, Total thyroidectomy, hypocalcemia, operative time, recurrent laryngeal nerve injury.

Fac Med Baghdad 2016; Vol.58, No.3
Received: Aug,2016
Accepted: Aug.2016

Introduction:

Thyroid surgery has undergone many changes during the past 2 decades, including the introduction of new surgical techniques such as endoscopic or video-assisted approaches(1), anesthesia care, intraoperative nerve monitoring and new hemostatic tools (2). Despite these changes, surgical principles established by the pioneers have always been strictly adhered to in terms of good exposure of the thyroid gland, clear identification of the nerves and parathyroid glands, and perfect hemostasis(3). The combination of all these changes, making thyroid surgery less invasive today than ever before, yields better cosmetic results, reduced surgical time, greater postoperative comfort, lower mortality rates, and shorter hospital stay(4).

Hemostasis in thyroid surgery may be achieved mechanically by tying a knot or applying clips or using energy from a traditional monopolar or bipolar cautery system, electro-thermal bipolar sealing system (LigaSure),or ultrasonic device (Harmonic, Ethicon Endo-Surgery). The high-frequency energy transmitted by the active blade of ultrasonically activated devices allows vessels and tissues to be coagulated and cut. (5,6)

The Harmonic Focus curved shears, ergonomically fashioned for open thyroidectomy and enabling dissection, coagulation, and cutting, offer several advantages over previous devices used in thyroid surgery (Harmonic HS002, Harmonic HC145, and Harmonic CS-14C) in terms of size and weight of the hand-piece, hand-activated trigger system, and versatility(7,8,9). Although this instrument, designed for delicate dissection, shows markedly improved ergonomics, there are no available data based on prospective randomized studies showing the efficacy, safety, or advantages of its use compared with

**Baghdad Teaching Hospital.*
mohammedmk5@gmail.com

traditional dissection in total thyroidectomy(10,11).

The aim of the current study is to assess the efficacy and safety of Harmonic Focus shears in total thyroidectomy compared with traditional methods using a clamp-and-tie technique.

Patients and methods:

This is a prospective study conducted from October 2011 till January 2016, 209 patients with benign and malignant thyroid diseases, scheduled for total thyroidectomy in Baghdad teaching hospital, Al-Hayat private hospital and Al-Mukhtar private hospital ,were enrolled randomly into 2 groups, group A consists of 105 patient who undergone a total thyroidectomy using a harmonic FOCUSTM , and group B consists of 104 patients who underwent total thyroidectomy with conventional surgical technique.

All patients were informed about the surgical procedure and possible complications, giving their written consent preoperatively.

Exclusion criteria included the need for central and/or lateral compartment lymphadenectomy, concomitant parathyroid disorder and patients with recurrent goiter.

Preoperative work up: All patient were sent for thyroid function test(TSH, T3 and T4), measurement of serum calcium, CXR ,neck ultrasound, and indirect laryngoscopy to assess the vocal cords mobility.

Surgical technique: All patient were operated by the same surgeon, with total extra capsular thyroidectomy. In group B, the superior thyroid arteries and veins, middle thyroid veins and inferior thyroid veins, together with other vascularized structures were divided after being tied with conventional absorbable sutures(VicrylTM 0 or 3/0). In group A division of vessels and structures was obtained using only the Harmonic FOCUSTM (Ethicon EndoSurgery, USA). The instrument vibrates at the frequency of 55 kHz when dividing the tissue, and the power setting can be adjusted to different levels in order to control the speed of cutting and coagulation. In the present study, power level 3 was used when dividing larger vessels like the superior arteries and veins and inferior veins, whereas level 5 was used with smaller vessels like capsule veins. The superior artery and vein was divided close to the gland to avoid damage to superior laryngeal nerve.

Further surgical steps were similar for both groups. Monopolar and bipolar electrocautery were used as accessory instruments. Recurrent laryngeal nerves and parathyroid glands were always identified. A redivac drain was placed after surgical procedure in both groups and removed on the first post operative day.

The Primary end points were: operative time from skin incision to skin closure, calcium levels and early post operative complications (bleeding, hypocalcemia and recurrent laryngeal nerve injury).

Serum calcium level was measured at first post operative day in all patients. Indications for postoperative medical therapy with oral calcium and Vitamin D analogues were serum calcium level of < 8.0 mg/dl and/or clinical signs or symptoms of hypocalcemia. Follow-up was performed one week,4 weeks and again 6 months after the operation. At follow-up, serum thyroid hormone concentrations and serum levels of total calcium were measured, and complications were recorded.

Statistical analysis was performed using Student's t test for continuous variables and Fisher exact test for categorical variables. The results were expressed as mean ± SD if not stated otherwise. All tests were double-sided and the level of statistical significance was set at a p value of less than 0.05.

Results:

Eleven patients had papillary thyroid carcinoma: 6 (5.7%) of them in group A and 5(4.8%) of them in group B. eighty seven (82.9%) patients in group A had non toxic MNG, and 12(11.4%) patients had toxic MNG, 90 (86.5%) patients in group B had non toxic MNG while the other 9 (8.7%) had toxic MNG (Table 1).

Table 1 patient demographic and preoperative diagnosis

	GROUP A(N= 105)	GROUP B(N=104)
AGE (MEAN±SD)	49 ± 12	48 ± 14
GENDER, N (%)		
MALE	12 (11.4%)	14 (13.5%)
FEMALE	93 (88.6%)	90 (86.5%)
THYROID MALIGNANCY, N(%)	6 (5.7%)	5 (4.8%)
NON TOXIC MNG, N(%)	87 (82.9%)	90 (86.5%)
TOXIC MNG, N(%)	12 (11.4%)	9 (8.7%)

Mean operative time was significantly lower in group A compared to Group B (100 ± 34 vs. 119 ± 30mins, respectively, P.value 0.01).

In group A mean calcium level at first post-operative day was 8.36 ± 0.54 mg/dl. In group B mean value was 8.12 ± 0.56 mg/dl. This difference was not statistically significant.

There were no significant difference between the two groups concerning transient hypocalcemia requiring calcium and Vitamin D therapy: 11(10.5%) patients in group A versus 12(11.5%) in group B, P. Value (>0.05). No permanent hypocalcemia was found in both groups (table 2).

There were no intraoperative complications for both groups.

One post operative bleeding requiring reoperation was observed in group B due to slipped ligature. Two patients (1.9%) developed slight transient unilateral nerve palsy documented by indirect laryngoscopy in group A, and 3 patients(2.8%) developed slight transient recurrent laryngeal nerve injury in group B, no patients developed permanent recurrent nerve injury (table 2)

Mean post operative hospital stay was similar in both study groups (24h±12 h in group A vs. 24h±12h in group B, p. Value >0.05).

Table2 comparison of the operative and post operative results

	Group A	Group B	p.Value
Operative Time (min) mean ± SD	100± 34	119±30	0.01
Calcium, day 1 p.o (mg/dl) mean ±SD	8.36±0.54	8.12± 0.56	Ns
Post op medical therapy for transient hypocalcemia, n(%)	11(10.5%)	12 (11.5%)	Ns
Permanent hypocalcemia	0	0	Ns
Post op bleeding (re-operation), n(%)	0	1 (0.96%)	Ns
Permanent recurrent laryngeal nerve injury , n	0	0	-
Transient recurrent nerve palsy	2(1.9%)	3 (2.8%)	Ns
Hospital stay, hours (mean±SD)	24±12	24±12	Ns

Discussion:

During the last decades many devices have been introduced into clinical practice aiming to facilitate surgical procedures, and ultrasonically activated shears are an example. These instruments employ mechanical energy for simultaneous coagulation and tissue cutting. The active blade vibrates at 55.5 kHz, dividing tissue by breaking down hydrogen bonds and denaturing proteins at temperatures ranging from to 50 to 100ºC, causing less injury to the surrounding tissue than either electrosurgical devices (12). Today the Harmonic Scalpel (HS) is widely used in several fields of surgery (13,14), in laparoscopic and open technique; it has proven to be a safe and useful device in neck surgery, but some surgeon consider this tool to be cumbersome for fine dissection(6, 15). The Harmonic Focus is a new device characterized by lesser weight and smaller size compared to previous shears; the thin and curved tip, associated to the ergonomic shape and consequent handiness, guarantees precise and safe dissection, very useful for thyroid surgery(15). In our study, the use of the Harmonic focus was associated with a statistically significant reduction in operative time, with a mean advantage of 20 min for each surgical procedure, and this result was found in many studies done by Siperstein et al(16), Parker et al(17) and Zanghi et al (18). These findings are clinically relevant because they can lead to a shorter anesthesia time and, as a result, to a lower burden for patients and faster postsurgical recovery. Additionally, the shorter operating time could determine the possibility of performing more procedures in the same session with a reduction of the waiting list for patients. Homeostasis with harmonic focus is quick and effective and we did not observe any post operative hemorrhage in harmonic focus group, in clamp and tie group there was only one case with bleeding that required reoperation but this result was statistically not significant, other studies by Materazzi et al(19) and Gentileschi (20)reveled the same result. Regarding recurrent laryngeal nerves, we found two transient unilateral hypomotility of vocal cord in harmonic focus group, whereas we had 3 cases of transient unilateral hypomotility of vocal cord in knot tying group. No permanent injury was identified in To minimize this risk, we use to irrigate the surgical field with physiologic saline solution during coagulation near the nervous structures, reducing in this way the local temperature and consequently potential thermal damage, and this result is the same studies done by Materazzi et al (19) and Mourad et al (21) The rate of transient hypocalcemia has been reported as 5%–15% and permanent hypocalcemia rates have been reported as 5% in total thyroidectomies (22), in our study there was no permanent hypocalcemia in both groups, Mourad et al(21) also had zero permanent hypocalcemia in harmonic focus and knot tying groups. Transient hypocalcemia in this study was 10.5% in group A vs 11.5% in group B and the difference was statistically not significant between the 2 studied groups many studied done by Gentileschi et al(20) and Hahn et al(23), agreed with these results. The relationship between the type of hemostasis applied during thyroid surgery and of hospital stay remains unclear: we found a mean length of 24h in both groups. Conversely, a recent study showing a shorter hospital stay in patients undergoing an Ultracision procedure (24).

Conclusions:

According to our results, the HF is a reliable, comfortable and safe instrument alternative to knot tying technique, very suitable hand-piece for total thyroidectomy. It creates a clean, bloodless surgical field, and there is an advantage for the surgeon to use a single tool for both dissection and hemostasis.

Moreover, the HF is a time-saving option, allowing for a significant reduction of operative time, without affecting parathyroid function, need for medical therapy, recurrent nerve injury and hemostasis in the early post-operative period.

References:

1- Miccoli P, Bellantone R, Mourad M, et al. Minimally invasive video-assisted thyroidectomy: multiinstitutional experience. World J Surg, 2002;26:972–5.

2- Snyder S, Roberson C, Cummings C, et al, local anesthesia with monitoring anesthesia care vs General anesthesia in thyroidectomy: a randomized study. Arch Surg,2006;141:167-173.

3- Voutilainen P, and Haglund C, ultrasonically activated shears in thyroidectomy: a randomized trial, Ann Surg 2000;231:322-328.

4- Ortega J, Sala C, Flor B, et al, Efficacy and cost effectiveness of the ultracision harmonic scalpel in thyroid surgery: an analysis of 200 cases in a randomized trial, J Laparoendosc Adv Surg Tech, 2004;14:9-12.

5- Cordon C, Fajardo R, Ramirez J, et al, A randomized prospective parallel group study comparing the harmonic scalpel to electrocautery in thyroidectomy, Surgery, 2005;137:337-341.

6- Miccoli P, Berti P, Dionigi G, et al, Randomized controlled trial of harmonic scalpel use during thyroidectomy, Arch Otolaryngol Head Neck Surg, 2006;132:1069-1073.

7- Kilic M, Keskek M, Ertan T, et al, A prospective randomized trial comparing the harmonic scalpel with conventional knot tying in thyroidectom, Adv Ther,2007;24:632-638.

8- Lombardi C, Raffaelli M, Cicchetti A, et al, The use of harmonic scalpel versus knot tying for conventional open thyroidectomy: results of a prospective randomized study, Langenbecks Arch Surg, 2008;393:627-631.

9- Yildirim O, Umit T, Ebru M, et al, ultrasonic harmonic scalpel in total thyroidectomies, Adv Ther, 2008;25:260-265.

10- P, Loven L, Westerdahl J, et al, Use of the harmonic scalpel versus conventional hemostatic techniques in patients with Grave disease undergoing total thyroidectomy: a prospective randomized controlled trial, Langenbecks Arch Surg,2008;393:675-680.

11- Sartori P, De Fina S, Colombo G, et al, ligasure versus ultracision in thyroid surgery: a prospective randomized study, Langenbecks Arch Surg,2008;393:655-658.

12- McCarus S, physiologic mechanism of the ultrasonically activated scalpel, J Am Assoc Gynecol Laparosc, 1996; 3:601-608.

13- Gertsch P, Pelloni A, Guerra A, et al, Initial experience with the harmonic scalpel in liver surgery. Hepatogastroenterology,2000; 47:763–766.

14- Ohtsuka T, Wolf RK, Wurnig P et al, Thoracoscopic limited pericardial resection with an ultrasonic scalpel, Ann Thorac Surg,1998; 65:855–856

15- Karvounaris DC, Antonopolous V, Psarras K, et al , Efficacy and safety of ultrasonically activated shears in thyroid surgery, Head Neck, 2006; 28:1028–1031.

16- Siperstein A, Berber E, and Morkoyun E, The use of the harmonic scalpel vs conventional knot tying for vessel ligation in thyroid surgery, Arch Surg, 2002;137:137-142.

17- Parker D, Krupa K, Esler R, et al, Use of the harmonic scalpel in thyroidectomy, ANZ J Surg, 2009;79:476-480.

18- Zanghi A, Cavallaro A, Di Vita M, et al, The safety of harmonic® FOCUS in open thyroidectomy: A prospective, randomized study comparing the harmonic® FOCUS and traditional suture ligation (knot and tie) technique, International Journal of Surgery, 2014, article in press.

19- Materazzi G, Caravaglios G, Matteucci V, et al, The impact of the harmonic FOCUS™ on complications in thyroid surgery: a prospective multicenter study, Updated Surg, 2013, 1-5.

20- Gentileschi P, D'Ugo S, Iaculli E, et al, Harmonic Focus™ versus "knot tying" during total thyroidectomy: a randomized trial, Updates Surg, 2011;63:277-281.

21- Mourad M, Rulli F, Robert A, et al, Randomized clinical trial on Harmonic focus shears versus clamp-and-tie technique for total thyroidectomy, The American Journal of Surgery, 2011;202:168-174.

22- Yildirim O, Umit T, Ebru M, et al, ultrasonic Harmonic scalpel in total thyroidectomy, Adv Ther, 2008;25(3):260-265.

23- Hahn C, Trolle W, and Sørensen C, Harmonic focus in thyroidectomy for substernal goiter, Auris Nasus Larynx, 2015;42:311-317.

24- Papavramidis T, Sapalidis K, Michaloulos N, et al, UltraCision harmonic scalpel versus clamp-and-tie total thyroidectomy: a clinical trial, Head. Neck, 2010;32: 723-727.