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ORIGINAL ARTICLE

THE USE OF FOCUS ULTRACISION SCALPEL VERSUS KNOT TYING FOR OPEN THYROIDECTOMY: A PROSPECTIVE RANDOMIZED STUDY

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Abstract

Aim: This study aimed at comparing the safety of the focus harmonic scalpel (HS) during conventional "open" thyroidectomy (CT) versus knot tying technique (KT).

Methods: Forty-six patients scheduled for conventional total thyroidectomy (TT) were included in the study and randomly assigned to TT with the use of HS (HS group 23 patients) or with knot tying technique (KT group 23 patients).

Results: Mean operative time was significantly shorter in the HS group ($P < 0.001$). There were reduction in the post-operative complications. The number of patients in whom a drain was used was lower in HS than CT groups (10 vs 23, $P < 0.001$= S). The total drainage fluid volume was lower in HS than in CT (40.4 ±35.4 vs 46.1 ± 40.1ml respectively, P= NS).

Conclusions: HS is a safe alternative to KT, allowing for a significant reduction of operative time without increasing complications rate.

Keywords: Harmonic scalpel, Thyroid, safe surgery.

INTRODUCTION

During the last decade, alternative techniques for improving safety, effectiveness and even invasiveness of thyroidectomy have been proposed, including video-assisted and endoscopic surgery, nerve monitoring and less invasive forms of anaesthesia.(1) Total thyroidectomy is defined as total bilateral extracapsular lobectomy.(2)

Bleeding remains one of the major postoperative complications of thyroid surgery, with the potential to cause life-threatening airway obstruction. During thyroidectomy, bleeding can obscure the operative field, making safe dissection of the recurrent laryngeal nerve (RLN) and parathyroid glands difficult. Effective vessel haemostasis can be achieved by using the traditional clamp-and-tie (C&T) technique. Newer techniques of vessel haemostasis hope to be more rapid while achieving the same effectiveness. Several studies have reported the successful use of bipolar vessel sealing systems(3) or the harmonic scalpel(4) in shortening the length of thyroid surgery and reducing blood loss, while retaining a good safety profile. However, these techniques do incur the cost of generators and hand pieces, which may be difficult to justify in some departments.(5)

It has been claimed that the use of the harmonic scalpel decreases operative time, complications and bleeding in abdominal surgery,(6) thoracic surgery,(7) parotid surgery(8) and thyroid surgery.(9)

By using electro-surgery, heat is transferred to the tissue with coagulation. The harmonic scalpel has a different effect on the tissue due to the mechanism of energy

generation.[10] Furthermore, HS produces aerosol exposure when cutting and coagulating the tissue, which does not harvest any viable cells.[11]

Its recent wide use has favoured research on designing reliable ultrasonically activated shears to be used in neck surgery.[12]

Its role in minimally invasive thyroid surgery is well defined.[13] HS has been proposed also for conventional thyroidectomy (CT).[14] But there is still some criticism about its routine use in CT, mainly related to the cost of the instrumentation.[15]

In this prospective randomised study, we evaluated the safety, cost- effectiveness and the impact on the surgical outcome of the utilisation of the HS during CT.

PATIENTS AND METHODS

In Mansoura Univeristy Principal Hospital, From January 1st 2009 through December 31 th 2009, 46 adult patients, with benign or malignant thyroid disease and scheduled for total thyroidectomy (TT) at the Surgical Department, were randomized into two groups according to the hemostatic technique: conventional technique of tying and knots (CT group 23 patients) or Focus Harmonic Scalpel (HS group 23 patients) (Ultracision®, Ethicon Endosurgery, Cincinnati, OH, USA) A single set of focus harmonic scalpel was enough to operate for at least 10 cases as recommended by the manufacturer and it was sterilized by antiseptic solution although, in the current study, we used only 3 sets.

The exclusion criteria were age <18 years, previous neck surgery or irradiation, need for neck lymph node block dissection and concomitant parathyroid disorders.

All the 46 eligible patients were randomized into two groups by means of closed envelopes opened by a nurse not included in this study. Institutional Review Board approval was ob-tained before study initiation.

Preoperative informed consent from all patients was obtained. There were five males and 41 females, mean age (56 ± 14 years). Twenty eight patients were affected by simple multinodular goiter, four by differentiated thyroid cancer, ten by Toxic goiter and four by thyroiditis. All the patients underwent preoperative indirect laryngoscopy in the ENT unit in Mansoura Univeristy hospital to assess vocal cord motility.

All the surgical procedures were performed by an experienced surgeon or by a resident operating under supervision.

Total thyroidectomy was performed through a standard 6-cm cervicotomy incision. In patients with differentiated thyroid cancer, no lymph node dissection was performed. In the conventional technique group (CT), all ligatures were performed by tying and knots with absorbable ligatures (poly-glactin 910, 2/0 and 3/0 as required; Vicryl™, Ethicon). In the Harmonic Scalpel group (HS), the open shear scissor grip CS-14C (Harmonic®, Ethicon Endo-Surgery) was always used and the resulting thyroidectomy was sutureless (Figs. 1-6).

Recurrent laryngeal nerves (RLN) and parathyroids were always identified anatomically. A closed suction drain was always used after thyroidectomy in the thyroid bed and removed after 24 hours in the CT group[16] but drain was used in the HS group in only ten cases, as there was a mixture of blunt and HS dissection with bloody fieled (due to inadequate dissection).

Intraoperative blood losses were estimated by weighing surgical sponges before and after surgery and by the blood volume in the suction device without use of any intraoperative invasive monitoring. Follow-up evaluation was obtained by outpatient consultation 1 and 3 months later. Patients with voice abnormalities underwent postoperative laryngoscopy. although, the anaesthetist check the vocal cords immediately post operative. The following data were recorded: age, gender, pathology, hemostatic technique, complications, intra-operative blood losses, operating time, and length of hospital stay.

The data were analyzed using SPSS 14.0 for Windows (SPSS Inc., Chicago, IL, USA). Continuous data were compared by one-way analysis of variance and categorical data were analyzed by chi-square and Fischer's exact test. The results were expressed as mean ± SD and $p < 0.05$ was accepted to be statistically significant.

RESULTS

All patient character and postoperative diagnosis are summarized in Table 1. No significant difference was found between the two groups concerning final histology, mean thyroid weight and mean hospital stay Tables 1,2.

The mean operative time was significantly shorter in the HS group (45.3 ± 16.3 minute) compared with the CT group (65. 5 ± 15.3 minute; $P < 0.001$; Table 2) as no time consumed for knot tying or for changing the instrument needed for dissection.

The number of patients in whom a drain was used was lower in HS than CT groups (10 vs 23, $P < 0.001$= S) which may be due to good haemostasis achieved by harmonic scalpel. The total drainage fluid volume was lower in HS than in CT (40.4 ±35.4 vs 46.1 ± 40.1 respectively, P= NS) because the harmonic scalpel is less injurious for tissues Complications rate was observed in both groups Table 2. One (4.3%) transient nerve palsies were observed in CT group and no one (0%) in the HS group which could be explained by the fact that the thermal effect is more consized for a limited surface area about 0.5 mm as with no permanent palsy (P= NS). Transient hypocalcemia was observed in 2 (8.6%) patients in the CT group. No patient developed permanent hypoparathyroidism (P= NS).

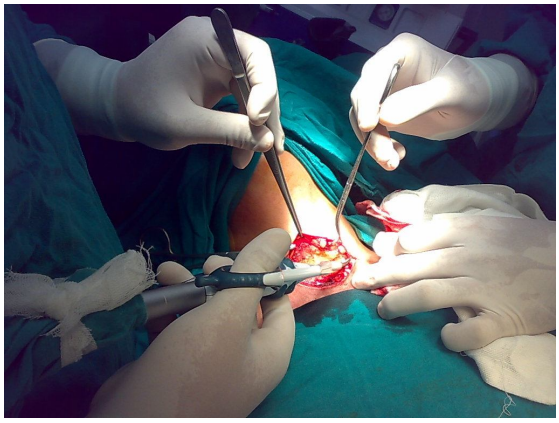

Fig 1. Skin incision using focus harmonic scalpel.

Fig 4. Skin closure without drain.

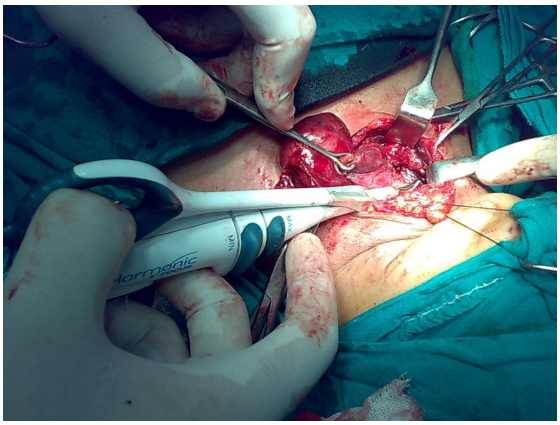

Fig 2. Dissection of superior thyroid pedicle by focus harmonic scalpel.

Fig 5. Focus harmonic shear.

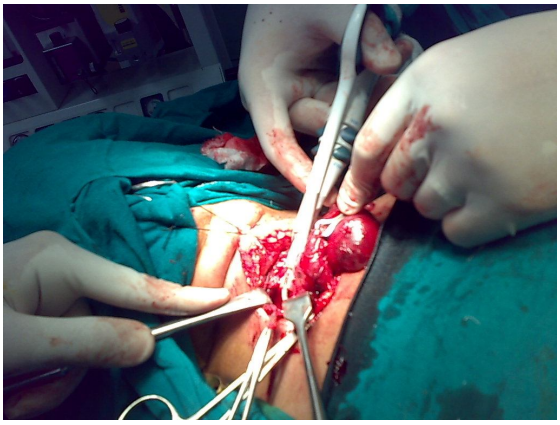

Fig 3. Sealing of inferior thyroid artery by focus harmonic scalpel.

Fig 6. Postoperative thyroid specimen.

Table 1. Demographic characteristics, preoperative diagnosis and postoperative pathologic findings in HS and KT groups.

	HS group (23 patients)	KT group (23 patients)	P value
Age (mean ± SD) years (range)	49.5 ± 14.2 (20–72)	52.5 ± 23.4 (25–74)	NS
Sex (male / female)	3 / 20	2 / 21	NS
Post-operative final diagnosis			
Simple MNG	11	17	NS
Toxic MNG	6	4	
differentiated carcinoma	2	2	
Thyroiditis	1	3	
Thyroid weight (mean ± SD) grams	44.4 ± 33.2 (9–150)	53.7 ± 54.3 (7–326)	NS

MNG=multinodular goiter.

Table 2. Operative and postoperative data.

	HS group (23 patients)	KT group (23 patients)	P value
Operative time (mean ± SD) minutes	45.3 ± 16.3	65.5 ± 15.3	<0.001
Drains (yes / no.)	10 / 23	23 / 23	<0.001
Drainage fluid volume (mean ± SD) ml	40.4 ± 35.4	46.1 ± 40.1	NS
Complications			
Bleeding (re-operation)	0	1	NS
Recurrent nerve palsy			
Transient	0	1	NS
Permanent	0	0	NS
Transient hypocalcemia	0	2	NS
Definitive hypoparathyroidism	0	0	NS

SD standard deviation, NS not significant.

DISCUSSION

The thyroid is a highly vascularised organ, and therefore it is important to achieve good haemostasis during thyroid surgery. Using ligatures are probably the most common way to accomplish a good haemostasis. The use of mono- or bipolar diathermy is also common, but they are regularly not efficient enough for larger vessels like the superior thyroid arteries. Influenced by its favourable use in other surgical fields, the harmonic scalpel has, since the1990s, become more frequently used also in thyroid surgery.[17]

The harmonic scalpel was chosen because of its favorable use in cardiac, general, laparoscopic, and gynecologic surgery. The harmonic scalpel system consists of a generator, foot pedal, cord, hand piece, and disposable blade. The generator produces a natural harmonic frequency of 55,000 Hz. The acoustic wave is then transmitted down the shaft of the scalpel to the active blade, causing it to vibrate at the very same frequency. When the active blade contacts tissues, the transmitted acoustic wave causes cavitational fragmentation and cavitational cutting rather than electrical or thermal coagulation. The harmonic scalpel has been shown to effectively seal and cut a vessel up to 3 mm in diameter. Less heat is generated than with conventional mono-polar or bi-polar diathermy because it does not operate through electrical energy. consequently far less thermal energy is transmitted to the surrounding structures and the chance of thermal injury is reduced.[18]

Considering that the thyroid gland has a rich blood supply, thorough hemostasis is fundamental in thyroid surgery. Suture ligation of individual vessels has been the standard technique in most centers. Although this is a very efficient technique for vessel bleeding control, it is time consuming. Many surgeons have been adopting electro-coagulation. Despite the potential risk of damaging surrounding tissue, its impact on surgical speed has been its main appeal. The role of HS in minimally

invasive thyroid surgery is well defined and emphasized since its use allows an excellent haemostasis in small operative space, reducing the operative time with comparable morbidity rates.[12]

Conversely, its role in CT is still debated. Indeed, one should obviously demonstrate that it allows at least the same results of the conventional technique of tying and knot in terms of complication rate and surgical outcome without increasing the overall costs of the procedure .So far, several published, comparative and observational, studies have variably reported some significant advantages in terms of operative time,[19] complications rate and reductions in incision size.[20]

Our results showed that thyroidectomy using focus scalpel is at least as safe as knot tying technique for achieving haemostasis during conventional TT, with less morbidity rate than KT group.

In other words, the results of this study definitively demonstrated that thyroidectomy with the use of the HS is as safe as with that using the knot tying technique.

In this study, there were two complications related to skin injuries in the KT group which occurred accidentely Neither resulted in permanent scarring. There were no skin injuries in HS group. There were no incidences of permanent recurrent laryngeal nerve injury or permanent hypocalcemia. There was a single case in the KT group presented with post-operative hematoma, which was re-operated although, there was a drain as it was included in the CT group and the cause of hematoma was a subcutaneous artery

Alternatively, the conventional knot tying technique in a resectional surgical procedure as thyroidectomy requires a large number of surgical ties and therefore is time-consuming. Reduction of the time spent with the conventional ligature can significantly reduce the operative time in this procedure. The results of the present study confirm that the use of focus HS during CT allows for a significant reduction in operative time, which, in our experience, was about 30% when compared with the conventional knot tying technique. Obviously, since time spent in the operating room is expensive,[21] this would counterbalance the cost of the HS hand piece and eventually result in a overall cost reduction.

In Conclusion HS is a safe, efficacious and cost-effective alternative to knot tying technique for CT, allowing for a significant reduction of operative time (about 30%) with reduction in the complications rate and overall costs of the procedure. The significant shorter operative time could ultimately determine the possibility to perform more procedure in the same operative session with a potential better reduction of the overall costs.

REFERENCES

1. Duh QY. What's new in general surgery: endocrine surgery. J Am Coll Surg. 2005;201:746–53.

2. Bellantone R, Lombardi CP, Bossola M, Boscherini M, De Crea C, Alesina PF et al. Total thyroidectomy for management of benign thyroid disease: a review of 526 cases. World J Surg. 2002:26:1468–71.

3. Manouras A, Markogiannakis H, Koutras AS, Antonakis PT, etal. Thyroid surgery: comparison between the electrothermal bipolar vessel sealing system, harmonic scalpel, and classic suture ligation. Am J Surg. 2008;1:48–52.

4. Kilic M, Keskek M, Ertan T, Yoldas O. A prospective randomized trial comparing the harmonic scalpel with conventional knot tying in thyroidectomy. Adv Ther. 2007:24:632–8.

5. Shen WT, Baumbusch MA, Kebebew E, Duh QY. Use of the electrothermal vessel sealing system versus standard vessel ligation in thyroidectomy. Asian J Surg. 2005;28:86-9.

6. Chamberlain RS, Korvick D, Mootoo M, Story S, Dubiel B, Sharpnack D Can harmonic focus curved shear effectively seal the pancreatic ducts and prevent pancreatic leak? Feasibility evaluation and testing in ex vivo and in vivo porcine models Surg Res. 2009;157:279-83.

7. Takagi K, Hata Y, Sasamoto S, Tamaki K, Fukmori K, Otsuka H, et al. Late onset postoperative pulmonary fistula following pulmonary segmentectomy using electoro- cautery or harmonic scalpel. Am Thorac Cardiovasc Surg. 2010;16:21-5.

8. Prgoomet D, Janjanin S, Bura M, Bilic M, Prstacic R, Katic V. The use of harmonic scalpel in head and neck surgery a report of 161 patients. 2008;130:178- 82.

9. Karvounaris DC, Antonopoluos V, Psarras K, Sakadamis A. Efficacy and safety of ultrasonically activated shears in thyroid surgery. Head& Neck. 2006;28:1028–31.

10. Koch C, Friedrich T, Metternich F, Tannapfel A, Reimann H-P, Eichfeld U. Determination of temperature elevation in tissue during the application of the harmonic scalpel. Ultrasound Med Biol. 2003;29:301–9.

11. Nduka CC, Poland N, Kennedy M, Dye J, Darzi A. Does the ultrasonically activated scalpel release viable airborne cancer cells? Surg Endosc. 1998;12:1031–4.

12. Foreman E, Aspinall S, Bliss RD, Lennard TW The use of harmonic scalpel in thyroidectomy.´beyond the learning curve´ Ann R Coll Surg Engl. 2009;91:214-6.

13. Koh YW, Park JH, Kim JW, Lee SW, Choi EC. Clipless and sutureless endoscopic thyroidectomy using only the harmonic scalpel Surg Endosc. 2010:24:1117-25.

14. Koutsoumanis K, Koutras AS, Drimousis PG, Stamou KM etal, Theodorou D, Katsaragakis S et al. The use of a harmonic scalpel in thyroid surgery: report of a 3-year experience. Am J Surg. 2007;193:693–6.

15. Papavramidis TS, Sapalidis K, Michalopoulos N,Triantafillopoulou K, Gkoutzananis G, Kesisoglou I, Papavsamidis Ultracision hasrmonic scalpel versus clamp- and –tie thyroidectomy , clinical trial. ST Head Neck. 2010;32:723-7.

16. Konstantinos K, Athanasios S, Panagiotis G, Konstantinos M, Dimitrios T, Stylianos K, The use of a harmonic scalpel in thyroid surgery: report of a 3-year experience. The American Journal of Surgery. 2007;193:693–6.

17. Randolph GW, Kobler JB, Wilkins J. Recurrent laryngeal nerve identification and assessment during thyroid surgery: laryngeal palpation. World J Surg. 2004;28:755–60.

18. Ortega J, Sala C, Flor B, Lledo S. Efficacy and Cost-Effectiveness of the UltraCision harmonic scalpel in thyroid surgery: an analysis of 200 cases in a randomised trial. J Laparoendosc Adv Surg Tech A. 2004;14:9–12.

19. Ordón C, Fajardo R, Ramírez J, Herrera MF. Arandomised, prospective, parallel group study comparing the harmonic scalpel to electrocautery in thyroidectomy. Surgery. 2005;137:337–41.

20. Iccoli P, Berti P, Dionigi Gian L, D'Agostino J, Orlandini C, Donatini G Randomized controlled trial of harmonic scalpel use during thyroidectomy. Arch Otolaryngol Head Neck Surg. 2006;132:1069–73.

21. Viapiano J, Wards DS. Operating room utilization: the need for data. Int Anesthesiol Clin. 2000;38:127–40.