## **Original Research Article**

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# Prospective randomised study using focus harmonic scalpel versus conventional hemostasis for vessel ligation in open thyroid surgery

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## **ABSTRACT**

**Background:** The objective was to compare operative factors, postoperative and surgical complications of open thyroidectomy by using FOCUS harmonic scalpel (HS) versus conventional hemostasis.

**Methods:** A prospective randomised study in which 34 patients with benign/malignant thyroid disease patients underwent open thyroidectomy, patients were randomised into two groups, Group -1(HS) - included 19 patients which FOCUS Harmonic scalpel was used exclusively, Group -2(CH) included 15 patients in which conventional hemostasis was used exclusively. We recorded operative time, postoperative blood loss and drain output, postoperative complications and duration of hospital stay, patients were watched for 48-72 hours following surgery. The results were analysed by using student's t-test.

**Results:** Mean operative time for hemithyroidectomy was 53.40±9.07 minutes in HS group versus  $85.25\pm17.03$  minutes in CH group (p-value -0.004) mean operative in patients who underwent near total thyroidectomy is  $67.21\pm10.36$  in HS group v/s  $109.60\pm29.35$ ml in CH group (p-value 0.001), postoperative drain output in patients who underwent hemithyroidectomy in HS group is  $16.00\pm15.16$  v/s  $36.25\pm4.78$  ml in CH group (p-value 0.008), postoperative drain output in patients who underwent near total thyroidectomy in HS group is  $28.21\pm16.36$ ml v/s  $45.50\pm8.95$ ml in CH group(p-value 0.006),length of hospital stay is  $3.28\pm1.06$  days in HS group v/s  $4.20\pm1.39$ days in CH group,(p-value-0.083), complications like temporary hypocalcemia was present in 1 patient in HS group v/s 3 patients in CH group ,temporary RLN palsy was present in 2 patients in each group, there were no cases of permanent RLN palsy in either group, neither were the cases of permanent hypoparathyroidism in either group.

**Conclusions:** FOCUS Harmonic scalpel will reduce operative time, reduces the incidence of symptomatic hypocalcemia but not temporary hypocalcemia, reduces postoperative drain output, reduces the duration of hospital stay, and shows no significance on incidence of temporary/permanent RLN palsy. FOCUS harmonic scalpel supposed to be more reliable and safe instrument that can be used instead of conventional hemostasis techniques in open thyroidectomy.

**Keywords:** Conventional hemostasis, Harmonic scalpel, Multinodular goitre, Recurrent laryngeal nerve palsy, Solitary nodule of thyroid

## **INTRODUCTION**

Theodor Kocher and Theodor Billroth, the pioneers of thyroid surgery, developed an acceptable technique of standardized thyroid surgery between 1873 and 1883. By 1920, the principles of safe and efficient thyroid surgery were already established. This consist of three basic

steps: identification and ligation of vessels, identification and preservation of laryngeal nerves, and parathyroid glands. Technical aspects of thyroid surgery had few developments since the approach described by Kocher in thyroid surgery greater than a century ago.<sup>2</sup> Given the significant vascularity of the thyroid gland and the relatively small operative field, meticulous hemostasis

will always be an important prerequisite in thyroid surgery for a successful outcome.<sup>3</sup> The mainstay for achieving hemostasis in thyroid surgery is tying and/or clipping of blood vessels, both being effective at the same time its time-consuming techniques. In the current trend of healthcare constraints and long waiting list, any method that can reduce operative time while maintaining acceptable standards and complication rates warrants investigation.

Almost two decades ago, the harmonic scalpel (Ethicon Endo-surgery, Cincinnati, Ohio) was introduced into the surgeon's armamentarium. This device can cut and coagulate tissue simultaneously by using mechanical vibrations at frequency of 55.5 kHz. The advantages of using Harmonic Scalpel over traditional electrocautery include minimal lateral thermal tissue injury, lack of neuromuscular stimulation. and avoidance transmission electrical energy either to or through the patient.<sup>4</sup> Since the adoption of the harmonic scalpel (HS) into modern surgical practice, its utility for a wide variety of operations has been well documented. For example, a randomized prospective clinical trial demonstrated its ability to diminish blood loss as well as operative time for laparoscopic Nissen fundoplication.<sup>5</sup>

Over the last decade, there have been many reports that have evaluated the utility of HS for thyroid surgery and most these studies have been carried out at European centers. The investigators have shown similar results regarding reduced operative times with its utilization, but conflicting results regarding other postoperative outcomes such as transient postoperative hypocalcemia and recurrent laryngeal nerve dysfunction (RLND). These complications are relatively uncommon and the number of cases reported in individual studies is limited.

The present prospective randomized study was designed to evaluate the efficacy and safety of using Harmonic Scalpel (HS) compared with conventional haemostasis (CH) in open thyroid surgery. The primary objectives of this study were the reduction of operative time, and reduction in drainage volume in thyroid surgery with the use of the HS. The secondary objectives were the comparison between groups in terms of hospital stay and surgical complications in thyroidectomy, such as hypocalcemia and RLN palsy.

## **METHODS**

Between May 2016 to Nov 2016, at the Department of General Surgery, Krishna Rajendra Hospital, Mysore, India 34 patients with benign / malignant thyroid disease had undergone open thyroidectomy performed by the same surgeon. Patients were randomly assigned to either the HS group (group I of 19 patients in which the surgery was performed solely using the HS with no other haemostatic tool) or the CH group (group II of 15 patients in which the surgery was performed using conventional

hemostasic tools such as the classic knot tying technique, re-absorbable ligature and bipolar diathermy).



Figure 1: Focus Ultracision Harmonic Scalpel (Ethicon Endo-Surgery, Inc, Cincinnati, Ohio, USA).

We used the focus ultracision harmonic scalpel (Ethicon Endo-Surgery, Inc, Cincinnati, Ohio, USA) (Figure 1). The harmonic scalpel system consists of a generator, a blade and a hand piece. The hand piece contains an ultrasonic transducer that consists of a stack of piezoelectric crystals sandwiched between two metal cylinders under pressure. The transducer is attached to the blade through a mount. The 110-volt generator is a high-frequency switching power supply controlled by a microprocessor that pulses the transducer in the hand piece with AC current. This current allows the transducer to vibrate at its natural harmonic frequency of 55.5 kHz. The blade used most frequently in most procedures looks like a curved paddle with a sharp inner bevelled side for cutting and a blunt outer radius for coaptive coagulating (Figure 2). The generator has adjustment from a level of 1 to 5 for increasing cutting speed and decrease coagulation by increasing the blade's lateral excursion <sup>6-9</sup>.



Figure 2: The curved blade and the clamp arm with Teflon pad of the Focus Ultracision Harmonic scalpel.

All patients were randomly assigned to the surgical technique used and all patients before enrollment in the study signed an informed consent. The patients were divided to generate homogeneous groups per preoperative diagnosis, age and thyroid size.

## Inclusion criteria

- Age>18years
- Scheduled near total thyroidectomy for multinodular goiters and differentiated carcinoma.

#### Exclusion criteria

- Preoperative medication including analgesics, corticosteroids or NSAIDS.
- Coagulation disorders
- Pregnancy
- Cervicomediastinal goiters
- History of neck irradiation

A total thyroidectomy for malignant thyroid disease (papillary carcinoma) and near total or hemithroidectomy for benign thyroid diseases was performed under general anesthesia and with endotracheal intubation in all cases. A complete preoperative assessment (thyroid profile, ultrasonography to evaluate gland volume and nodule size, and FNAC of swelling) was obtained for all patients; they were positioned, painted and draped in conventional manner.

A 4 to 6 cm incision (depending on size of the gland) was made over the thyroid isthmus. Subplatysmal flaps were raised, and the strap muscles separated in the midline and reflected laterally. The middle, superior and inferior thyroid vessels identified and were then divided either with the conventional hemostatis (CH) technique or with harmonic scalpel (HS). Thyroid lobe was then rotated medially, and the vessels in ligament of Berry, were divided with the RLN under direct vision with HS in group I and were clamped and tied in group II. The similar steps repeated for removal of contralateral lobe. Romovac suction drain kept over the thyroid fossa and secured in position. Finally, the wound was closed using interrupted 2-0 polyglactin sutures (Vicryl, Ethicon) to close the strap muscles and platysmal layer. Skin closed by subcuticular sutures using Monocryl 3-0.

Outcome of the study include operative time, output and content in the suction drain (drainage volume) during first 48-72 hours after surgery, duration of hospital stay, and incidence of complications (RLN injury and hypocalcemia). The drains were removed 48-72hours after surgery. Preoperative RLN status was determined by indirect laryngoscopy and postoperative RLN status was checked by direct laryngoscopy. Any reduction in vocal cord movement was recorded as postoperative cord paralysis. Recurrent laryngeal nerve palsy was considered permanent when it persist for more than 6 months after surgery.

Patients who underwent near total or total thyroidectomy or patients in whom more traumatisation to parathyroid glands is suspected or patients who are having symptoms of hypocalcemia, serum calcium level estimation was done on post-operative day 7, serum calcium is less 8.5mg/dl was diagnosed as hypocalcemia. Hypocalcemia can be temporary or permanent, when need for calcium replacement is less than 6 months is temporary and is defined as permanent when it was associated with a need for calcium replacement more than six months. Hypocalcemia is treated with oral calcium carbonate

1000-1500mg/day in divided doses. IV replacement is recommended in symptomatic or severe hypocalcemia with cardiac arrhythmias or tetany. 10 mL of calcium gluconate in 50-100 mL of 5% dextrose in water (D5W) should be given over 5-10 minutes.

## **RESULTS**

In present study of 34 cases there were 5 male (14.70%) and 29 female (85.30%) patients with M:F ratio 1:5.4. Most of the patients who had undergone thyroid surgeries are under the age group of 30-50 (70.36%) years. 33 (97.10%) cases were benign and 1 (2.90%) was malignant condition. 9 (26.4%) cases were solitary nodule of thyroid, 24 (70.58%) cases were multinodulargoiter.

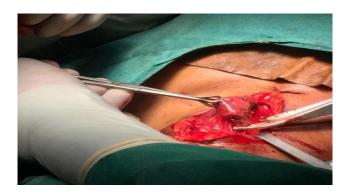


Figure 3: Superior pole ligation using FOCUS Harmonic Scalpel.

One patient had Papillary Carcinoma of Thyroid with level II, III, IV and VI Lymph nodes involvement and had undergone Total Thyroidectomy with Functional Neck Dissection

**Table 1: Indications for surgery.** 

Indication	Number of cases
Multinodular Goiter	24
Solitary nodule	9
Thyroid cancer (papillary carcinoma)	1

Table 2: Type of operation.

Туре	Number	Percentage
Total		
Thyroidectomy+functional	1	2.9
neck dissection		
Near total thyroidectomy	24	70.58
Hemithyroidectomy	9	26.4
Total	34	100

## Pre-operative parameters

Operative time in patients who underwent near total thyroidectomy is 67.21±10.3 min in HS group v/s

109.60±29.35 min in CH group which is statistically significant with P-value of 0.001 with a difference of 42 minutes. Operative time in patients who underwent hemithyroidectomy is 53.40±9.07 min in HS group v/s

85.25±17.03 min in CH group which is statistically significant with p-value of 0.004 with a difference of 30.42 minutes.

Table 3: Student's t-test in MNG.

Group statistics					
	Groups	N	Mean	Std. deviation	Std. error of mean
Operative time in min	HS in MNG	14	67.2143	10.36398	2.76989
	CH in MNG	10	109.6000	29.35302	9.28224
Drain output in ml	HS in MNG	14	28.2143	16.36214	4.37297
	CH in MNG	10	45.5000	8.95979	2.83333
Hospital stay in days	HS in MNG	14	3.2857	1.06904	.28571
	CH in MNG	10	4.2000	1.39841	.44222



Figure 4: Inferior pole ligation using FOCUS Harmonic Scalpel.

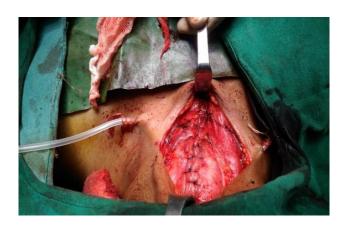


Figure 5: Closure of strap muscles by interrupted sutures using Vicryl 2-0.

## Postoperative parameters

The post-operative Drain output in patients underwent near total thyroidectomy in HS group is  $28.21\pm16.36$  ml v/s  $45.50\pm8.95$  ml in CH group (t=3.021, p=0.006),

which is statistically significant with p value <0.05 with a difference of 17.28ml. The post-operative Drain output in patients who underwent hemi thyroidectomy in HS group is  $16.00\pm~15.16$  ml vs  $36,25\pm4.78714$  ml in CH group (t=3.62, p=0.008), which is statistically significant with p value <0.05 with a difference of 13.85ml.

Table 4: Independent samples test in MNG.

t-test for equality of means					
		t	df	Sig. (2-tailed)	Mean difference
Operative time	Equal variances assumed	-5.020	22	0.001	-42.38571
Drain output	Equal variances assumed	-3.021	22	0.006	-17.28571
Hospital stay	Equal variances assumed	-1.818	22	0.083	91429

The length of hospital stay was shorter in the HS group v/s CH group in patients who underwent near total thyroidectomy ( $3.28 \pm 1.06$  days vs. $4.20\pm1.39$ , t=1.81, p =.083) though there was difference of 1.39 days but is not

statistically significant as p-value >0.05. There is no difference in both groups in means of hospital stay in patients who underwent hemi-thyroidectomy. The serum calcium levels showed no statistically significant

differences in the two groups. In either group, there were no cases of permanent postoperative hypocalcemia. In 4 cases, temporary hypocalcemia has been reported, 1 in the HS group and 3 in the CH group.

No significant difference for temporary RLN palsy rate was found between groups (only 1 case in each group which resolved after 48 hours). We experienced no case of permanent RLN paralysis.

Table 5: Student's t -test in SNT.

Group statistics					
	Groups	N	Mean	Std. deviation	Std. error mean
Operative time in min	HS in SNT	5	53.4000	9.07193	4.05709
	CH in SNT	4	85.2500	17.03673	8.51836
Drain output in ml	HS in SNT	5	16.0000	15.16575	6.78233
	CH in SNT	4	36.2500	4.78714	2.39357
Hospital stay in days	HS in SNT	5	3.0000	.00000a	.00000
	CH in SNT	4	3.0000	.00000a	.00000

A. cannot be computed because the standard deviations of both groups are 0.

Table 6: Independent samples test in SNT.

Independent sam	iples test				
t-test for Equality of Means					
		T	Df	Sig. (2-tailed)	Mean Difference
Operative time	Equal variances assumed	-4.452	7	0.004	-30.4278
Drain output	Equal variances assumed	-3.626	7	.008	-13.85000
Hospital stay	Equal variances assumed	-2.540	7	.06	-20.25000

**Table 7: Post-operative complications.** 

Postoperative complications	HS group (n = 19)	CH group (n = 15)
Transient hypocalcemia	1	3
Permanent hypoparathyroidism	0	0
Transient recurrent laryngeal nerve injury	2	2
Permanent recurrent laryngeal nerve palsy	0	0

### **DISCUSSION**

The thyroid is highly vascularized gland which receives blood from the superior and inferior thyroid arteries. Therefore, careful hemostasis is essential in order to avoid complications such as haematoma and/or seroma that sometimes may cause potentially fatal asphyxia (Rosato et al). The use of conventional hemostasis technique entail more time to achieve adequate haemostasis.

Over the years various new equipments were introduced, such as bipolar or monopolar electrocoagulation, they have revealed the disadvantage of the thermal diffusion that would damage adjacent vital structures especially the recurrent laryngeal nerve. The FOCUS harmonic scalpel is the modern ultrasonic device utilized in thyroid surgery, contributing significant benefits in terms of its size and light weight of its hand piece and hand-activated trigger system, and versatility.



Figure 6: Skin wound after 48hrs of surgery.

Shemen has largely demonstrated the effectiveness of the Harmonic scalpel in thyroidectomy analysis of 105 cases. 11 Siperstein et al has successfully used Harmonic Scalpel to attain hemostasis and also describing the strategy of "double bind" which consists of double coagulation of two consecutive areas of the vessel. The advantages of using Harmonic scalpel have been revealed also in our study, as narrated above. 12 In our study of 34 cases there were 5 males (14.70%) and 29 female

(85.30%) patients with M: F ratio 1:5.4. There is slight female preponderance. This is in accordance with most of the studies.

71% of patients lie in the age group of 30-50 years. 33 (97.10%) cases were benign conditions. 9 (26.4%) cases were solitary nodule, 22 (70.58%) cases multinodulargoiter, 2 (5.8%) Hashimotos thyroiditis. One (2.9%) patient had papillary carcinoma of thyroid with level II, III, IV, V and VI lymphnodes involvement.

Mean operating time for hemithyroidectomy in group I on a average was 63 min vs 92 min in group II and near total thyroidectomy on a average was 80 min in group I vs 130 min group II, and total thyroidectomy with modified radical neck dissection was 180 min as such procedure of total thyroidectomy was over by 80 min, rest 100 min required for modified radical neck dissection.

According to our study it was noticed a difference in the operative time (about 30 - 40 minutes shorter in the HS group). Manouras et al found that compared with the classic technique, surgical time was reduced significantly by about 20% when the bipolar vessel sealer or harmonic scalpel was used (93.3 $\pm$ 12.5 vs. 74.3 $\pm$ 14.2 and 73.8 $\pm$ 13.8 min, P = 0.001, and P = 0.001, respectively. <sup>13</sup> The 48 hours drain output in group I was 32ml vs 46 ml in group II, Petrakis et al in their study found intra-operative total blood loss was similar between the two groups, but postoperative drain volume was less in harmonic scalpel group than in other (21 $\pm$ 15 mL; p <0.01). <sup>14</sup>

The use of drainage after thyroidectomy is still a source of debate, in fact Papavramidis et al in his scientific study has concluded that there is no advantage or disadvantage in the use of drainage after thyroid surgery.<sup>15</sup> The incidence of haematoma will not change with both the drainage and that without drainage, and also in cases where there is a relative increase in the incidence of hematoma this is attributable to the size of the gland. It is also seen that the onset of hematoma after 24 hours occurs mostly in patients who have undergone resection of a substernal goiter or with cardiac co-morbidities. So in conclusion it was found that the drainage only gives discomfort to the patient and which is used for the serenity of the surgeon. In our study drain was not kept in 5 patients who underwent surgery through harmonic scalpel as there was no ooze from the thyroid bed and post operatively all patients had uneventful course.

In our study, postoperative complications were observed in 8 (23.52%) cases, out of which 3 (37.5%) were in group I vs 5 (62.5) were in group II. Saint Marc et al in their study found the postoperative complication rate of 35% overall, including all transient postoperative disturbances. In present study 1 patient of group I had transient hypocalcemia and 3 patients of group II had transient hypocalcemia (5.26% vs 20%), none of the patients from either group had permanent hypocalcemia.

In our study 2 patients from each group had transient RLN palsy (10.52 vs 13.33). In our series, there were no statistically significant differences in calcium level between group I and group II. But the symptomatic hypocalcemia of group I were lower than group II, which indicated that the FOCUS Harmonic scalpel may be helpful in protecting parathyroid.

Shorter length of hospital stay, as also demonstrated by Papavramidis et al, likely due to lower amount of blood loss collections when compared to the conventional technique.<sup>15</sup>

## **CONCLUSION**

FOCUS Harmonic scalpel will reduce operative time, reduces the incidence of symptomatic hypocalcemia but not temporary hypocalcemia, reduces postoperative drain output, reduces the duration of hospital stay, and shows no significance on incidence of temporary/permanent RLN palsy. FOCUS harmonic scalpel supposed to be more reliable and safe instrument that can be used instead of conventional hemostasis techniques in open thyroidectomy.

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Ethical approval: The study was approved by the

institutional ethics committee

## **REFERENCES**

- 1. Becker WF. Pioneers in thyroid surgery. Annals Surg. 1977;185(5):493-504.
- 2. Delbridge L. Total thyroidectomy: the evolution of surgical technique. ANZ J Surg. 2003;73(9):761-8.
- 3. Wiseman P, Tomljanovich, Rigual N. Thyroid lobectomy: operative anatomy, technique, and morbidity. Operative Techniques Otolaryngology Head Neck Surg. 2004;15(3):210-9.
- 4. Roye GD, Monchik J, Amaral JF. Endoscopic adrenalectomy using ultrasonic cutting and coagulating. Surgical Technology International. 2000;9:129-38.
- Laycock WS, Trus TL, Hunter JG. New technology for the division of short gastric vessels during laparoscopic Nissen fundoplication a prospective randomized trial. Surgical Endoscopy. 1996;10(1):71-3.
- 6. Walker RA, Syed ZA. Harmonic scalpel tonsillectomy versus electrocautery tonsillectomy: a comparative pilot study. Otolaryngology Head Neck Surgery. 2001;125(5):449-55.
- 7. Carus SD. Physiologic mechanism of the ultrasonically activated scalpel. Journal Am Association Gynecologic Laparoscopists. 1996;3(4):601-8.
- 8. Landman J, Kerbl K, Rehman J. Evaluation of a vessel sealing system, bipolar electrosurgery, harmonic scalpel, titanium clips, endoscopic

- gastrointestinal anastomosis vascular staples and sutures for arterial and venous ligation in a porcine model. J Urology. 2003;169(2):697-700.
- 9. Wiatrak BJ, Willging JP. Harmonic scalpel for tonsillectomy. Laryngoscope. 2002;112(8):14-6.
- 10. Rosato L, Avenia N, Bernante P, Palma M, Gulino G, Nasi PG. Complications of thyroid surgery: analysis of a multicentric study on 14,934 patients operated on in Italy over 5 years. World J Surg. 2004;28 (3):271-6.
- 11. Shemen L. Thyroidectomy using the harmonic scalpel: analysis of 105 consecutive cases. J Am Acad Otolaryngol Head Neck Surg. 1999;127(4):284-8.
- 12. Siperstein AE, Berber E, Morkoyun E. The use of the harmonic scalpel vs conventional knot tying for vessel ligation in thyroid surgery. Arch Surg. 2002;137(2):137-42.
- 13. Manouras A, Markogiannakis H, Koutras AS. Thyroid surgery: comparison between the electrothermal bipolar vessel sealing system, harmonic scalpel and classic suture ligation. Am J Surg. 2008;195(1):48-52.

- 14. Petrakis IE, Kogerakis NE, Lasithiotakis KG, Vrachassotakis N, Chalkiadakis GE. Liga sure versus clamp-and-tie thyroidectomy for benign nodular disease. Head Neck. 2004;26(10):903-9.
- Papavramidis TS, Pliakos I, Michalopoulos N, Mistriotis G, Panteli N, Gkoutzamanis G. Classic clamp-and-tie total thyroidectomy for large goiters in the modern era: to drain or not to drain? World J Otorhinolaryngol. 2014;4(1):5.
- 16. Marc SO, Cogliandolo A, Piquard A, Famà F, Pidoto RR. Liga surevs clamp-and-tie technique to achieve hemostasis in total thyroidectomy for benign multinodular goiter: a prospective randomized study. Arch Surg. 2007;142(2):150-6.

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