

# Comparison of surgical outcomes of Ultrasonic technique (Harmonic Focus™) with Conventional technique in open hemithyroidectomy.

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## ABSTRACT

**Background:** The option for dissection and haemostasis during thyroid surgery include either the modern ultrasonic technology (Harmonic Focus™) or the conventional technique using knot and ties, monopolar or bipolar electrocautery. Comparison between the surgical outcomes of open hemithyroidectomy using these two modalities was done.

**Objective:** To compare the surgical outcomes of ultrasonic technique using Harmonic Focus™ (HS) with Conventional technique (CT) in open hemithyroidectomy.

**Method:** Twenty consecutive patients undergoing open hemithyroidectomy for benign solitary thyroid nodule of  $\leq 3$  cm were randomly assigned into two groups; group HS (n=10) and group CT (n=10). Analysis of surgical outcomes performed by these two techniques, particularly: operative time, intra-operative blood loss, post operative pain, incision size, complications and hospital stay were done.

**Results:** The age, sex and pathologies were comparable in both the groups. For the group HS, mean operative time was (mean  $\pm$  SD=55  $\pm$  5 min) 15 minutes shorter than group CT (mean  $\pm$  SD= 70  $\pm$  10 min) (P<0.01). Mean operative blood loss was (mean  $\pm$  SD=20  $\pm$ 10 ml) 16 ml less in group HS than CT (mean  $\pm$  SD= 36  $\pm$ 12 ml) (P<0.01). The group HS experienced less post operative pain (mean  $\pm$  SD=4  $\pm$  0.94 VAS) than CT (mean  $\pm$  SD= 7  $\pm$  0.81 VAS) (P<0.001). The incision size at the time of skin closure was 1.6 cm shorter in group HS ((mean  $\pm$  SD= 3.95  $\pm$ 0.61 vs. 5.5  $\pm$  0.78 cm) (P<0.01). Hospital stay (mean  $\pm$  SD= 2.30  $\pm$  0.48 vs. 4.20  $\pm$ 0.42 days) was statistically significant (P<0.01) in group HS than CT. There were no major complications.

**Conclusion:** In patients undergoing open hemithyroidectomy, HS is a faster, better cosmetic, safe and less morbid tool than CT. Its use reduces operative time, blood loss, post operative pain, scar size, along with hospital stay.

**Key words:** Haemostasis, Harmonic Focus™, Hemithyroidectomy, Conventional technique.

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## INTRODUCTION:

The thyroid gland is one of the most vascularized organs in the human body<sup>1</sup>. The principles of safe and efficient thyroid surgery consist of three basic phases: identification and ligation of vessels, identification and preservation of laryngeal nerves, and parathyroid glands. Bleeding remains one of the major post operative complications of thyroid surgery, with potential to cause life threatening airway obstruction. During thyroidectomy, bleeding can obscure the operative field, leading safe dissection difficult<sup>2</sup>.

Basic surgical instruments are not significantly changed; the main innovations are new methods of coagulation and vascular section<sup>2</sup>. Conventional flap elevation is done either by monopolar cautery or by scalpel and scissors where as conventional hemostasis is performed by clamp and tie technique, and monopolar or bipolar electrocautery for small vessels<sup>3</sup>. This technique is the gold standard for thyroid surgery<sup>4</sup>.

Since development of the harmonic scalpel (HS) in the early 1990s, it has been used as a newer technique in thyroid surgery to ensure a bloodless surgical field. The synchronous action of the HS for simultaneous cutting and coagulation of blood vessels is beneficial in shortening operating time and reducing blood loss during flap elevation as well as vascular section, compared to CT while retaining a good safety profile<sup>2,5-9</sup>.

The aim of this prospective comparative study was to compare the surgical outcomes of HS with CT in open hemithyroidectomy as it was a recently introduced tool in our setting. The primary objectives were to compare the operative time, blood loss and post operative pain in hemithyroidectomy with the use of the HS and CT. The secondary objectives were to compare the incision size, hospital stay and surgical complication between the groups.

## METHODS

With Institutional Ethical Committee approval, this prospective comparative study was carried out at the Department of ENT-HNS in Kathmandu Medical College Teaching Hospital (Kathmandu, Nepal) from May 2011 to April 2012. All the patients were blinded to the surgical technique used and well explained about the advantages and disadvantages of each technique. Those patients who gave signed informed consent were enrolled in the study. Twenty three patients were assessed for eligibility. Three of them were excluded from the study because they had papillary carcinoma (n=2) diagnosed preoperatively by fine needle aspiration cytology and one had hyperthyroidism. Remaining 20 consecutive patients undergoing open hemithyroidectomy for benign solitary thyroid nodule of  $\leq 3$  cm were randomly assigned into two groups. The patients were randomly assigned to a group by picking a paper (number one or two) from a box containing 20 papers (10 for each group). In the group

HS, 10 patients were operated entirely using the Focus Ultracision Harmonic Scalpel (Ethicon Endo-Surgery Inc, Cincinnati, Ohio, USA) and no other haemostatic tool. Likewise, other 10 patients in group CT were operated by classical technique, ligating bigger vessels and cauterizing smaller vessels using monopolar and bipolar diathermy. Those with medical contraindications for surgery including deranged thyroid function test, thyroid malignancy, and previous neck surgery, history of neck irradiation and coagulation disorders were excluded from the study. A complete preoperative assessment apart from thyroid function tests, neck ultrasound and fine needle aspiration cytology were done.

The surgery was performed under general anesthesia. The smallest possible incision was made in both the groups and was extended if it was really required to ensure a safe surgery. Subplatysmal flaps were elevated and strap muscles were separated at midline by the Harmonic Scalpel in the group HS whereas by monopolar cautery in the group CT. The inferior, middle and superior thyroid vessels were then identified and divided either with HS or with conventional technique. In the group HS, haemostasis was achieved at low power for named vessels and at high power for small vessels and soft tissue for easy cutting. In the group CT, hemostasis in the small vessels and soft tissues were done by monopolar electrocautery (except near the laryngeal nerves where bipolar was used) whereas conventional knot and tie ligation for named vessels. Careful dissection was performed for identification and preservation of recurrent laryngeal nerve (RLN) and parathyroids with its intact vascular supply. Every attempt was made to identify and preserve the superior laryngeal nerve (SLN) while dissecting upper pole. The wound was irrigated and an idea to put a drain or not was entirely based on how the surgical field appeared at the end. It was used in all the cases in the group CT. Finally the wound was closed in layers and length of the incision measured. The drain, if was kept removed when it was  $\leq 25$  ml in 24 hours. Intraoperative blood loss was measured by weighing the gauge piece (1 gram =1 ml) before and after its use. It was done by a highly sensitive digital weighing machine. Patients were given Ibuprofen tablets 400 mg per oral three times a day for post operative pain management and injection Diclofenac 75 mg intramuscularly if needed. A visual analog scale (VAS) (0-10) was applied to assess the pain every six hours throughout the hospital

stay using a linear scale between zero (no pain) and 10 (severe pain)<sup>10</sup>. The VAS for pain was graded as mild (2-5), moderate (6-7) and severe (8-10). Preoperative, operative and post operative data were taken and filled in a pre designed performa by one of the residents on duty who was not involved in the study.

Analysis of following variables was done: age, sex, pathology, operative time, intra operative blood loss, post operative pain, incision size, complications and hospital stay.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 17.0 software for windows. The mean and standard deviation (SD) were computed. Results were compared using Student's *t*-test. *P* value was considered statistically significant when it was less than 0.05.

## RESULTS

The clinicopathological data were comparable in both the groups (Table 1). The mean operative time for group HS was 15 minutes shorter than for group CT ( $p < 0.01$ ). Mean operative blood loss was 16 ml less in group HS than CT ( $P < 0.01$ ). The group HS experienced only mild post operative pain where as CT experienced moderate to severe pain in VAS ( $P < 0.001$ ). The parathyroids, recurrent laryngeal nerve and external branch of superior laryngeal nerves were identified and preserved in all the cases. The incision size at the time of skin closure was 1.6 cm shorter in group HS ( $P < 0.01$ ). The mean hospital stay was 2.3 days for group HS and 4.2 days for group CT ( $p < 0.001$ ). The overall satisfaction was assessed with visual analogue scale (VAS) after the suture removal in sixth post operative day and was found to be statistically significant in group HS over CT ( $P < 0.01$ ). The surgical field was almost dry in group HS, so no drain was kept in any of the cases operated by this technique. The mean amount of the drain in the group CT till the time of its removal was 60 ml. Conventional antibiotic regime was not followed for the group HS apart from a stat dose of injection ampicillin and cloxacillin 1 gram intravenously at the time of induction. But the group CT received the same dose of antibiotic four times a day for seven days. Intraoperative and postoperative period was uneventful in all the cases and their characteristics tabulated (Table 2).

**Table 1: Clinicopathological data between the groups.**

Group	CT (n=10)	HS (n=10)
Age in years (Mean $\pm$ SD)*	30.90 $\pm$ 3.872	29.50 $\pm$ 5.40
Sex (M/F)	2/8	2/8
Pathology	Colloid goitre	Colloid goitre

*p* value 0.51

**Table 2: Intraoperative and Postoperative outcomes between the groups.**

Outcome variable	Group	Mean	SD	P value
Intraoperative blood loss (ml)	HS	20	10	0.004
	CT	36	12	
Operative time (min)	HS	55	5	0.005
	CT	70	10	
Incision size (cm)	HS	3.95	0.61	<0.001
	CT	5.5	0.78	
Post operative pain (VAS)	HS	4	0.94	<0.001
	CT	7	0.81	
Hospital stay (day)	HS	2.30	0.48	<0.001
	CT	4.20	0.42	

## DISCUSSION

The Harmonic Scalpel was originally developed for its application in laparoscopic abdominal surgeries but has found a successful application into otolaryngology speciality<sup>11</sup>. Traditionally thyroid surgery has been performed using knots and ties, bipolar and monopolar electrocautery. After the introduction of Harmonic Scalpel in 1990s, it has gained worldwide reputation as a newer technique during thyroidectomies. It is a system composed of three parts: a generator, a hand piece and a scalpel. An ultrasonic frequency is used to generate mechanical energy at 55.5 kHz over a distance of 80  $\mu$ m and denatures protein by breaking the hydrogen bonds in tissue<sup>2,12</sup>. This forms the endovascular coagulum, that tamponades blood vessels<sup>2,7</sup>. The Ultracision HS has been approved by the United States Food and Drug Administration for the ligation of the vessel up to 3 mm diameter<sup>13</sup>. The lateral thermal damage is limited to 0-2 mm beyond the tissue grasped and is less than that of bipolar or monopolar diathermy<sup>13,14</sup>. The last generation of the HS (Harmonic Focus) was implicated in this study which is even more appropriate since it is approved for closing vessels up to 5 mm in diameter<sup>15</sup>.

Harmonic hemithyroidectomy using the Harmonic Focus was 15 minutes faster than the conventional hemithyroidectomy in our study. The time saving aspect of HS has been suggested by many studies ranging from 6 to 78 minutes reduction in total thyroidectomy or other head and neck surgeries<sup>16-18</sup>. But this was the first study to show that harmonic focus can decrease the operative time even while performing hemithyroidectomy. The quickness of the operation may be explained by the fact that harmonic scalpel combines haemostasis and vascular sectioning by a single instrument, thus avoiding time loss while manipulating several instruments and while tying knots.

The Harmonic Focus was found to be more effective haemostatic tool than the conventional technique. Intraoperative blood loss was significantly less in the group HS and surgical field was almost dry. So no suction drain was kept in any of the cases operated by this technique. No patient required second surgery because of bleeding or haematoma. This was in accord with previous studies<sup>1,19,20</sup>. Tabaqchali et al<sup>21</sup> noted no difference in the incidence of postoperative bleeding or airway obstruction between the patients who had drains and those who did not during thyroid surgeries and concluded that drains were more likely to develop wound infection and the exit point of it actually deteriorates the cosmetic outcome, therefore not necessary.

Hemithyroidectomies performed with Harmonic Focus generated less pain (mild) as compared to CT (moderate) in this series. This might be due to a well known fact that the harmonic hemostasis is performed at a lower temperature of 50°C to 100°C compared to 150°C to 400°C for bipolar and monopolar electrocautery. Hence, hemostasis performed using lower energy and at a low temperature will definitely yield less post operative pain and quicker healing of the tissues. This might be due to reduced operating time which in turn reduces cephalagia and neck pain, which are the principal cause for pain after thyroid surgery<sup>1,7</sup>.

The incision size measured at the end of skin closure was smaller in the group HS. This observation was similar to other reports<sup>22,23</sup>. This might be due to avoidance of using multiple instruments at a time as single Harmonic Focus was enough to achieve haemostasis and vascular section.

The avoidance of drain resulted in 1.9 days shorter hospital stay for the group HS. All the patients of this study were admitted to the hospital, the day before the surgery and were discharged when they started normal diet, wound was healthy, pain was minimal or none with use of analgesics and the drains, if any, were removed. Those who were not having drain could be discharged at the day or next of surgery. This was the reason of shorter hospital stay in the group HS. The decision regarding the discharge was solely made by a team of three surgeons belonging to the head and neck unit. No patients developed wound infection, even though routine course of antibiotics were not prescribed, for those who were operated using Harmonic Focus. There were no other major complications like nerve palsy or haematoma as well in any of the cases in this group.

This is how the group HS achieved the objective of the cosmetic thyroid surgery<sup>23</sup> because of faster recovery, reduced post operative pain, decreased hospital stay and smaller scar size. Hence, the hemithyroidectomies performed in this group of patients eventually became minimal invasive surgery (Mini Thyroidectomy<sup>22</sup>) in this study. Probably these were the factors which led to better patient satisfaction in the group HS which was assessed by visual analog score (VAS) at the sixth post operative day after suture removal. Keeping a suction drain in all the cases seems to be unnecessary if the Harmonic Focus in hemithyroidectomies is employed. These observations are similar to Hopkins et al<sup>24</sup> who has concluded that patients with small solitary nodules undergoing harmonic hemithyroidectomy are candidates for selective use of drains, or where used, early removal of the drain and same day discharge was possible. Though antibiotics were not prescribed in the group HS post operatively, none of them developed wound infection. This shows that the routine use of post operative antibiotic seems unnecessary which is in accord with another study<sup>25</sup>.

The major criticism of ultrasonic device (Harmonic Scalpel) comes from its cost. This technology is recently available in authors' operating room which has been shared by other surgical disciplines as well eg. General Surgery, Urology and Gynaecology. The accessory what is needed for thyroidectomy is the Focus Harmonic Shears which is disposable. The added cost will be compensated by the reduction in operative time so as to buy some busy hours of operating room and cost of

sutures or ties, the suction drain, antibiotics and bed charges. But more précised studies have to be planned to analyze the cost effectiveness of this technology.

This study had several limitations. The sample size was relatively small and only the benign cases were included. As we were using this ultrasonic technology for the first time in Nepal during thyoid surgery, we wanted to increase the learning curve before approaching more challenging cases. That is why in this study; only small goiters were selected for hemithyroidectomy. A randomized control trial with a good number of cases has to be planned to establish the role of this technology during thyroidectomy in this present setting.

## CONCLUSION

Harmonic Scalpel (HS) is a faster, better cosmetic, safe

and less morbid tool than Conventional technique (CT) in patients undergoing open hemithyroidectomies. Its use reduces operative time, blood loss, post operative pain, scar size, along with hospital stay. Post operative antibiotics and suction drain seem unnecessary if ultrasonic technique during open hemithyroidectomies is employed.

## ACKNOWLEDGEMENT

The authors acknowledge Prof. Babu Raja Shrestha for reviewing this manuscript and giving his valuable suggestions. We are very thankful to Associate Prof. Sunil Kumar Joshi for his constant help and Asst. Prof. Umesh Raj Aryal for statistical analysis. The cooperation of all the faculties and residents belonging to Department of ENT- Head and Neck Surgery is highly appreciable.

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