

## Outcomes of comparative study between ultrasonic harmonic scalpel versus conventional haemostasis in open thyroidectomy

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### Abstract

**Introduction:** Open thyroidectomy is a surgical procedure that requires meticulous dissection, safe anatomical exposure, and effective hemostasis. Total thyroidectomy is the treatment of choice for many thyroid diseases. This operation is performed frequently, with no mortality and low morbidity.

**Objective:** To compare ultrasonic harmonic scalpel versus conventional hemostasis in open thyroidectomy.

**Study Design:** Randomized control trial

**Study Setting:** General Surgery ward, Jinnah Postgraduate Medical Centre (JPMC), Karachi

**Study Duration:** Six months commenced from 26-08-2013 to 25-02-2014

**Subjects and Methods:** All patients with age 18-70 years of either gender with benign multinodular goiter of more than 6 months duration and scheduled to undergo open thyroidectomy were included in this study. Two groups "HS" and "CH" were made by opaque sealed envelope method for ultrasonic harmonic scalpel group and conventional hemostasis respectively. Both groups compared in terms of mean duration of surgery, mean amount of blood loss and mean length of hospital stay. Data was analyzed using SPSS version 16 and for comparison of the two groups unpaired t test was used. P value less than or equal to 0.05 was taken as significant.

**Results:** Mean age of the patients was  $42.38 \pm 17.39$  years. Mean duration of disease was  $7.37 \pm 1.20$  months. Mean duration of surgery was  $102.27 \pm 43.61$  minutes. Mean amount of blood loss was  $63.14 \pm 45.01$  ml. Mean length of hospital stay was  $39.60 \pm 15.33$  hours. Female proportion was found to be higher, i.e. 42 (60%) whereas, male proportion was 28 (40%). Statistically significant evidence of significant association was observed for duration of surgery, Length of hospital stay and amount of blood loss in between HS group and convention group as p-value founds  $< 0.05$ .

**Conclusion:** There is a difference in the outcome of ultrasonic harmonic scalpel versus conventional haemostasis in open thyroidectomy.

**Key words:** Open Thyroidectomy, Conventional Haemostasis, Ultrasonic Harmonic Scalpel

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### Introduction:

Open thyroidectomy is a surgical procedure that requires meticulous dissection, safe anatomical exposure, and effective hemostasis. Open thyroidectomy is the treatment of choice for many thyroid diseases. This operation is performed frequently, with no mortality and low morbidity. The standardized thyroid surgery developed by Theodor Kocher and Theodor Billroth, the pioneers of thyroid surgery, has not undergone a major change in operative technique in the last century.<sup>1</sup> Although thyroidectomy is one of the most common surgical procedures, the safest, most efficient and cost-effective way to achieve hemostasis during thyroidectomy is debatable.<sup>2</sup>

The development of ultrasonic instruments in the early 1990s has provided an alternative to other methods of controlling blood vessels (e.g., Ligasure precise, lasers, clips, and staples).<sup>3,4</sup> The ultrasonically activated scalpel (harmonic scalpel) that uses high frequency mechanical energy makes it possible to cut and coagulate tissues and vessels simultaneously, without the need of knot tying.<sup>5</sup> Despite their safety and effectiveness in thyroid surgery, the previous harmonic scalpel instruments are considered large and cumbersome by some surgeons. The new harmonic scalpel (Focus) has been made available since 2008 and is now being used as an alternative to conventional hand-tied ligation for

hemostasis in thyroid surgery.<sup>6,7</sup>

The Harmonic Scalpel gave surgeons the versatility to perform several important functions (e.g., to dissect, cut, coagulate and grasp) without the need to exchange instruments.

Although multiple studies have been done on this topic but it seems that the sample was not calculated and has wide variation. Hence the present study is designed and keeping appropriate sample size so that the results can be generalized. The superior of the two techniques would be used in future.

### Methodology

This study was designed as a Randomized control trial and was carried out in General Surgery Ward 2, Jinnah Postgraduate Medical Centre (JPMC), Karachi during Six months from August 2013 to February 2014. We included 70 patients, 35 in each group i.e Harmonic Scalpel group and conventional hemostasis group. Non probability consecutive sampling was done. Patients of either gender from age of 18 upto 70 years with benign multinodular goiter of more than 6 month duration of ASA grade 1 and 2 were included. Patients with previous history of neck surgery or neck irradiation or ASA 3 and 4 and patients with coagulopathies were excluded. Patients who needed open thyroidectomy, and presented in Out Patient Department filling inclusion criteria were enrolled in the study. Prior permission from the institutional ethical committee was taken and informed consent for surgery and enrolment in the study was taken from patients. Two groups were made by opaque sealed envelope method. Patients picking up envelope bearing a chit in it of letter "HS" was placed in ultrasonic harmonic scalpel group and those picking up envelope bearing a chit in it of letter "CH" were placed in conventional hemostasis.

Patients were operated by a single General Surgeon having more than 15 years of experience of thyroid surgeries. Time from incision to last stitch of closure of skin was noted using a stop watch. The small and big gauze pieces were weighted prior to surgery. All the gauze pieces soaked with blood were weighted at the end of

the surgery and difference was calculated to assess blood loss during surgery. The usage of Visual analogue scale was explained to the patient before surgery and the mean pain score was assessed at 12 and 24 hours postoperatively. Same dose of 3rd generation Cephalosporin was given to all patients. Patients were followed postoperatively in the ward and the final outcome was measured at the time of discharge. Duration of hospital stay was noted in hours from the end of surgery till discharge.

Data was analyzed using software of Statistical package of Social Sciences (SPSS version 16). Mean + SD was presented for age of the patients, duration of disease, duration of surgery, amount of blood loss and hospital stay. Frequency and percentages was presented for gender, Unpaired t test was applied to compare the duration of surgery, mean hospital stay and the amount of blood loss between groups. Stratification of age, duration of disease and gender was done to control confounders/effect modifiers, t test was applied and  $P \leq 0.05$  was considered as significant.

### Result

Mean age of the patients was  $42.38 \pm 17.39$  years. Mean duration of disease was  $7.37 \pm 1.20$  months. Mean duration of surgery was  $102.27 \pm 43.61$  minutes. Mean amount of blood loss was  $63.14 \pm 45.01$  ml. Mean length of hospital stay was  $39.60 \pm 15.33$  hours. As shown in table 1.

Female proportion was found to be higher, i.e. 42 (60%) whereas, male proportion was 28 (40%).

Mean duration of surgery in HS group was  $61.14 \pm 1.28$  minutes while mean duration of surgery in conventional group was  $143.4 \pm 3.02$  minutes. (p-value 0.001).

Mean length of hospital stay in HS group was found to be  $26.4 \pm 4.87$  hours while mean length of hospital stay in conventional group was found to be  $52.8 \pm 9.74$  hours (p-value 0.001).

Mean amount of blood loss in HS group was found to be  $20.57 \pm 3.9$  ml while mean amount of blood loss in conventional group was found to be  $105.71 \pm 19.07$  ml (p value 0.001). (Table 2)

Stratification of age, duration of disease and

Table 1: Descriptive Statistics n=70

Author	Age (in years)	Duration of disease (in Months)	Duration of Surgery (in Minutes)	Amount of Blood Loss (in ml)	Length of Hospital stay (in Hours)
Mean	42.38	7.37	102.27	63.14	39.60
Std. Deviation	17.39	1.20	43.61	45.01	15.33
Minimum	23	6	53	19	24
Maximum	67	9	153	122	72

Table 2: Outcome in both groups

Mean	Harmonic scalpel group	Conventional hemostasis group	p-value
Duration of Surgery (min)	61.14	143.4	0.001
Hospital Stay(hours)	26.4	52.8	0.001
Blood Loss (ml)	20.57	105.71	0.001

gender was done to control the effect modifier. Statistically sufficient evidence of significant relationship was observed for age, duration of disease and gender as p-value was found to be less than level of significance.

### Discussion:

Open thyroidectomy is one of the most common surgical procedures. The thyroid gland has an extensive vascular network, thus meticulous hemostasis is essential to ensure a dry surgical field and avoid inadvertent damage to adjacent vital structure. Shemen L, conducted a study and the sample size was 105 patients in HS group and 20 in conventional group,<sup>12</sup> in another study there 17 patients in each of the two groups,<sup>13</sup> Hallgrimsson in 2008 carried out the same study having 27 and 24 patients.<sup>14</sup> In our study 35 patients were present in both HS and conventional group.

The Harmonic Focus gave surgeons the versatility to perform several important functions (e.g., to dissect, cut, coagulate and grasp) without the need to exchange instruments. The device divides tissue by using 55.5 kHz ultrasonic energy transmitted between the instrument blades. This mechanical action disrupts protein hydrogen bonds within the tissue, and functions at a

relatively low temperature (between 50°C and 100°C) to cause a lesser tissue injury compared with The harmonic scalpel provides high quality of dissection and haemostasis, minimized tissue injury, resulted in 35 percent reduction in operative time and reduced mean operative cost.

Several studies shows that the Harmonic Focus allow a one third time saving vs classic hemostasis.<sup>14</sup> In our study mean duration of surgery in HS group was 61.14±1.28 minutes while mean duration of surgery in conventional group was 143.4±3.02 minutes (p-value 0.001). Other study shows that the average operative time was significantly shorter in the HS group (44.9 ± 8.3 minutes) compared with the CH group (69.5 ± 10.7 minutes; P < .001).<sup>8</sup> The mean hospital stay was 2.2 ± 0.9 days in HS group; while 3.7 ± 1.3 days in CH group; (P > .05)<sup>8</sup>. In our study, Mean length of hospital stay in HS group was found to be 26.4±4.87 hours while mean length of hospital stay in conventional group was found to be 52.8±9.74 hours (p-value 0.001).

The use of the Harmonic scalpel would allow reduced traction and reduced manipulation of the thyroid. The Harmonic scalpel proved to be safe, with good control of the blood vessels and no bleeding after surgery. Mean amount of blood loss in HS group was found to be 20.57±3.9 ml while conventional group was found to be 105.71±19.07 ml (p value 0.001). Safety and efficiency of the HS is comparable to the tie-and-clip technique in thyroid surgery. The use of the HS in thyroid surgery allows for a significant reduction in the length of the procedure with a comparable cost.<sup>15</sup>

Even if the HS is expensive, the reduced operation time and hospital stay without increased postoperative complications actually might make it cost-effective.

### Conclusion

There is a difference in the outcome of ultrasonic harmonic scalpel versus conventional haemostasis in open thyroidectomy as Harmonic Scalpel use for hemostasis, saves time, reduces

blood loss and shortens hospital stay.

**Role and contribution of Authors:**

Dr M Naseem Baloch, Associate Professor, Department of Surgery, Ward2, Jinnah Postgraduate Medical Center, Karachi, did conceived and designed the original study

Dr Mariyah Anwer, Senior Registrar, Department of Surgery, Ward2, Jinnah Postgraduate Medical Center, Karachi, did manuscript writing

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**Conflict of Interest:** None

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