

## Original Research Article

# A comparative study between harmonic scalpel hemostasis and conventional hemostasis in total thyroidectomy

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## ABSTRACT

**Background:** Thyroidectomy is the most commonly performed procedure in endocrine surgery. Since the thyroid gland is highly vascular, therefore, rapid and absolute hemostasis is extremely required. Conventional thyroidectomy is commonly used with acceptable outcomes, however, it is time-consuming and resulted in significant intraoperative blood loss with the possible risk of postoperative hemorrhage, injury to parathyroid glands and laryngeal nerves. The advent of focus harmonic devices was encouraging for improving safety, effectiveness, and reduction of operative time, especially in thyroid surgery. Aim of this study: The purpose of this study was to analyze the effectiveness and surgical outcomes of using ultrasonic harmonic scalpel for thyroid surgery compared to conventional techniques.

**Methods:** This was a prospective, randomized study in which 60 patients with various types of goiters presented for thyroidectomy. The patients were divided into two comparable groups. Group A (30 patients) included patients who had focus harmonic thyroidectomy and Group B (30 patients) included patients who underwent conventional thyroidectomy.

**Results:** Focus harmonic thyroidectomy showed a significant reduction in operative time, intraoperative blood loss, volume of postoperative fluid drainage and meantime for hospital stay compared with conventional thyroidectomy. There were no significant differences in the incidence of postoperative hypocalcemia, seroma, hematoma, wound infection and laryngeal nerve injury between both groups.

**Conclusions:** Focus harmonic thyroidectomy was a safe, effective, faster, and appealing alternative to conventional technique since it reduced the operative time, intraoperative blood loss, postoperative drainage and hospital stay with comparable postoperative complications.

**Keywords:** Conventional thyroidectomy, Focus harmonic scalpel, Sutureless thyroidectomy

## INTRODUCTION

Goiter has been recognized since the earliest recorded history. The first mentioned goiter was in China as early as 2700 BC, and the first described thyroidectomy was done by Abulkasim Alzahrawi in 936 AD.<sup>1</sup> Early trials to treat thyroid enlargement and hyperactivity were associated with high mortality and morbidity due to asphyxia and hemorrhage. However, thyroid surgery continued with a high mortality rate (>40%); until the second half of the nineteenth century, as the first

acceptable technique of standardized thyroid surgery which led to decrease mortality and morbidity was described by Theodor Kocher (1841-1917 AD) and Theodor Billroth (1829-1894 AD).<sup>2</sup> Thyroid gland has rich blood supply, so proper hemostasis in thyroidectomy is crucial to avoid intraoperative bleeding, to obtain good surgical field, and to prevent injury to laryngeal nerves and parathyroid glands.<sup>3</sup> The conventional hemostasis technique in thyroid surgery relies on knot tying with or without electrocoagulation.<sup>4</sup> However, knot tying is time-consuming and carries the risk of knot slipping; on the

other hand, electrocautery implies the potential risk of injuring surrounding tissues because of the heat.<sup>5</sup> Harmonic scalpel devices use vibration at 55 kHz to simultaneously coagulate and cut tissue and seal 5 mm vessels. By transmitting the vibration to the tissue, this provokes hydrogen bonds of proteins rupture, and thus denatures protein to form a coagulum, which seals the vessels and provides hemostasis at low temperatures (about 80 °C) in comparison with electrocautery. So it is safer for dissection near vital structures due to minimal lateral thermal tissue damage, minimal smoke formation, no electrical energy to or through patient and no neuromuscular stimulation.<sup>6,7</sup> Sutureless thyroidectomy avoids leaving foreign bodies in the patient's body thus eliminating its complications, decreases the incidence of knot slippage, reduces the operative time by using one instrument in dissection, hemostasis, and cutting of tissues thus reducing patient's exposure to anesthesia, efficient in hemostasis decreasing intra-operative blood loss and safe, reducing postoperative drainage volume, provide a clean surgical field, and showed the greater capability of grasping delicate tissues.<sup>2,4,6</sup>

The study aimed at evaluating the advantages of harmonic scalpel in total thyroidectomy compared with conventional hemostasis (clamping and knot tying ± electrocautery) in terms of operative time, intraoperative blood loss nerve injury, postoperative blood loss, hematoma development, hypocalcemia and length of hospital stay.

## METHODS

In this study, 60 patients with different thyroid gland diseases or pathologies (multinodular goiter, toxic goiter i.e. nonmalignant goiters) were involved. They underwent total thyroidectomy at Tanta University Hospital from April 2018 to June 2019. Patients with a history of previous neck surgery, neck irradiation, preoperative vocal cord palsy, and those required lateral or central lymphadenectomy, hypocalcemia, recurrent goiter, patients underwent hemithyroidectomy or subtotal thyroidectomy, patients <25 years, those with severe cardiac or respiratory embarrassments and patients with coagulopathies were excluded from this study.

Patients were selected according to the technique of hemostasis and classified into two groups 30 patients included in the group of harmonic scalpel hemostasis (A) and 30 patients included in the group of conventional hemostasis (B). This study was performed after approval granted by the Institutional Medical and Ethics Committee. Written and informed consent was taken from all patients enrolled in this study. Patients were subjected to complete preoperative clinical evaluation to assess the nature of goiter. Pre-operative investigations including thyroid hormones and serum calcium. Preoperative radiological assessment included neck ultrasound and chest plain X-ray. Indirect laryngoscopy was routinely done to assess the mobility of vocal cords

in addition to routine laboratory investigations one day before surgery. Also, pre-operative fine needle aspiration cytology was done.

Surgery for all patients was done under general anesthesia with an endotracheal tube; all patients were positioned in reverse Trendelenburg and draped classically, collar neck incision 5-7 cm in length was made creating an upper and lower subplatysmal flap, an incision made in the midline of deep cervical fascia and thyroid gland was mobilized. In the group of conventional hemostasis, the middle thyroid vein was ligated first using vicryl 2/0, then superior thyroid vessels were ligated using double ligature of vicryl 0 or 2/0, inferior pedicle and all other vessels ligated using vicryl 2/0, with using of electrocautery for minimal oozing. In the harmonic group, the middle thyroid vein coagulated and dissected by the harmonic scalpel, and then the superior pedicle and other vessels were coagulated and dissected using harmonic scalpel from ethicon, (harmonic focus, ethicon endo-surgery, llc, guaynabo, puerto rico, 00969 USA) thyroid tissue was also dissected by the harmonic scalpel. Also in both groups care had been taken to identify and preserve the RLN and parathyroid glands.

In case the parathyroid glands were inadvertently sacrificed, it was chipped and harvested or transplanted to the ipsilateral sternomastoid muscle after histopathologic confirmation. A single suction drain was inserted and kept for 24-48 hours to calculate the amount of blood loss postoperatively. Wound was closed in all patients with the classic way; vocal cord mobility was checked directly following extubation by the anesthesiologist. The intra-operative parameters were recorded including operative time (from skin cutting to skin closure), recurrent laryngeal nerve (RLN) injury and intraoperative blood loss. Post-operative parameters were also recorded from the time that the patient discharged from the theater to the time of hospital discharge and included the development of hematoma, signs and symptoms of RLN injury (which include hoarseness of voice, shortness of breath, and checking of vocal cord mobility if there is any suspicion), serum calcium measuring for the patients that developed signs and symptoms of hypocalcemia and amount of blood collected in the drain for 24 or 48 hours. The drain was then removed when the drainage volume was less than 30 ml after 24 hours. Patients were discharged from the hospital after removal of the drain. All patients were re-examined at the end of the 1st week, 4th week, 3 months and 6 months of postoperative follow-up period. At follow-up, thyroid hormones and serum calcium levels were measured, and post-operative laryngoscopy was performed within 4 weeks after surgery in all patients to evaluate vocal cord function. Permanent nerve palsy considered when persisting more than six months after operation. Data were analyzed using SPSS software version 18. Continuous variables data were reported as mean and standard deviation (SD), while categorical variables reported using frequency distributions and chi-

square test used in cases of low expected frequencies (p value <0.05 was considered significant).

**RESULTS**

A total of 60 patients (15 males and 45 females) were included in this study. They were randomized into two equal groups of 30 patients each. Group A (harmonic thyroidectomy) consisted of 25 females and 5 males patients whose mean age was 44.7±12 years, and Group B (conventional thyroidectomy) consists of 20 females and 10 males patients with the mean age of 46.8±9 years. There was no statistical difference between the two groups regarding age, sex and also there was no operative mortality in our patients in either group as shown in Table 1 and 2.

**Table 1: Distribution of patients according to sex.**

Sex	Group A	Group B
	N (%)	N (%)
<b>Females</b>	25 (83)	20 (66.6)
<b>Males</b>	5 (17)	10 (33.3)
<b>Total</b>	30 (100)	30 (100)

**Table 2: Distribution of patients according to age.**

Age (years)	Group A	Group B
<b>Range</b>	32-60	35-58
<b>Mean</b>	44.7±12	46.8±9

Regarding the operative time, in Group A it ranged between 90-120 minutes with a mean value of 115.13±14.16 minutes. While in the suture-ligation group, the operative time was between 110-135 minutes with a mean value of 127.10±14.16 minutes and this difference is considered to be extremely statistically significant (p≤0.0001) (Table 3).

**Table 3: Operative time.**

Operative time (min)	Group A	Group B	P value
<b>Range</b>	90-120	110-135	≤0.0001
<b>Mean±SD</b>	115.13±14.16	127.10±14.16	≤0.0001

**Table 4: Intraoperative blood loss.**

Amount of blood loss (ml)	Group A	Group B	P value
<b>Range</b>	50-75	60-95	≤0.0001
<b>Mean±SD</b>	63.16±7.84	77.64±9.41	≤0.0001

**Table 5: The amount of post-operative fluid drained.**

Amount of drained fluid (ml)	Group A N (%)	Group B N (%)	P value
<b>Range (ml)</b>	40-60	50-90	≤0.0001
<b>Mean±SD</b>	50.17±7.21	67.38±9.99	≤0.0001

**Table 6: Postoperative complications.**

Variable	Group A	Group B	P value
	N (%)	N (%)	
<b>Hypocalcemia</b>			
Temporary	1 (3.3)	2 (6.6)	Non-significant
Permanent	0	0	Non-significant
<b>RLN palsy</b>			
Unilateral	1 (3.3)	2 (6.6)	Non-significant
Bilateral	0	0	Non-significant
<b>Reactionary hemorrhage</b>			
Yes	0	0	Non-significant
No	30	30	Non-significant
<b>Seroma</b>			
Yes	0	0	Non-significant
No	30	30	Non-significant
<b>Wound infection</b>			
Yes	0	0	Non-significant
No	30	30	Non-significant

The amount of intraoperative blood loss using the standard absorptive gauze measuring was 50-75 ml in group A (mean 63.16±7.84 ml) and 60-95 ml in group B (mean 77.64±9.41 ml) respectively and this difference is considered to be extremely statistically significant (p≤0.0001) (Table 4). Regarding the amount of post-

operative fluid drained in group A was 40-60 ml with a mean±SD of (50.17±7.21) and 50-90 ml for group B with a mean±SD of (67.38±9.99) and this difference is considered to be extremely statistically significant (p≤0.0001) (Table 5). As regards, the postoperative complications, no permanent or bilateral recurrent

laryngeal nerve injuries occurred for patients in both groups. Temporary RLN injury was detected in 1 patient (3.3%) in group A and 2 patients in group B (6.6%). No permanent hypoparathyroidism was seen in both groups, transient hypoparathyroidism occurred in 1 patient (3.3%) of group A and 2 patients (6.6%) in group B. None of the patients had wound infection, seroma or secondary hemorrhage. All the postoperative complications were not significant as shown in Table 6. The mean duration of hospital stay was shorter in group A (1.98±0.18 days) than group B (2.37±1.79 days); this difference was highly significant (p=0.001) (Table 7).

**Table 7: Duration of hospital stay.**

Duration of hospital stay	Group A	Group B	P value
Mean±SD (days)	1.98±0.18	2.37±1.79	0.001

## DISCUSSION

Total thyroidectomy is considered one of the most commonly performed surgical procedures. The thyroid gland is known to be a highly-vascularized organ so rapid and effective hemostasis is a critical step of the procedure.<sup>5</sup> An accurate dissection and hemostasis is essential to provide a clear surgical field during total thyroidectomy, minimize the risk of structural damage, prevent post-surgical hemorrhage and avoid the need for surgical drains; however, the safest, most efficient and cost-effective way to achieve these goals is still under debate.<sup>8</sup>

Since the evolution of sutureless surgery, the era of bloodless surgery, the use of HS constitutes a major advance in hemostasis. Sutureless thyroidectomy has been practiced widely and proved its efficacy; providing good hemostasis in a rather highly vascular surgical field and better safety than the conventional knot tying technique.<sup>4</sup> There is a saturation of evidence that suggest the superiority of sutureless thyroidectomy compared to the conventional knot tying technique.<sup>4,9,10</sup>

In the present study regarding the operative time, in group (A) it was between 90-120 minutes with a mean value of 115.13±14.16 minutes. While in the suture-ligation group, the operative time was between 110-135 minutes with a mean value of 127.10±14.16 minutes and this difference was considered to be extremely statistically significant. The results are similar and in concordance with the results of others as Mohamed et al reported that the operative time was 66 minutes in the sutureless group and was 97 minutes in the conventional group.<sup>11</sup> Also, Ali et al reported that operative time (min) (mean±SD) was 55.40±7.894 minutes in the sutureless group while it was 108.14±11.186 minutes in the conventional group. They also stated that the use of Harmonic FOCUS® significantly decreased the operative time compared with conventional knot tying technique in

a matter of 50% less.<sup>12</sup> Contin et al also reported the same results.<sup>13</sup> And with all authors, the difference was statistically significant. But Singhal et al reported that the mean operative time in Group A (sutureless) was 93.29 minutes whereas, in Group B (conventional), it was found to be 106.59; however, this was not statistically significant.<sup>14</sup>

Also in concordance with our results, Yener et al observed less operating time in hemithyroidectomy patients while using the ultrasonic device (47.2 min vs 79.2 min, p value: 0.001).<sup>15</sup> In a study by Aslam et al, they found the operative time to be 67.21 min in the ultrasonic group and 109.6 min in the conventional group, which was statistically significant.<sup>16</sup> Cirocchi et al found that operative time was less in ultrasonic group in total thyroidectomy (75 min vs 113 min).<sup>17</sup> In the present study, the amount of intraoperative blood loss using the standard absorptive gauze measuring was 50-75 ml in group A (mean 63.16±7.84 ml) and 60-95 ml in group B (mean 77.64±9.41 ml) respectively and this difference is considered to be extremely statistically significant (p≤0.0001).

Estimation of intra-operative blood loss was governed by visual method and the clinical assessment with collaboration with the anesthetist.<sup>18,19</sup> Regarding visual estimation of blood loss; the author in this present study relied on the standard absorptive gauze measuring 30 cm × 30 cm. When it was soaked by 50% this means that it contains about 25 ml of blood and if soaked; 100% this means that it contains 75 ml of blood.<sup>20</sup> Many researchers reported a significant reduction of intraoperative blood loss by the use of suture less techniques in total thyroidectomy when compared with the conventional suture ligation technique and study data came in agreement with those reported results.<sup>21-23</sup>

Al Juraibi et al also reported that the amount of intra-operative blood loss was 50-75 ml in sutureless group (mean 62.06±7.34) and 60-90 in the conventional group (mean 75.84±9.21).<sup>24</sup> Also, Noori et al reported in his study that the intraoperative blood loss measured by weighing the blood-soaked gauze and by calculating the intraoperative drain was also significantly less in the harmonic group than in conventional group (12±4 ml vs 28±9 ml, p<0.01).<sup>25</sup>

Mohamed et al in his study reported that the intraoperative blood loss was 27.41 ml in sutureless group whereas it was 70.37 ml in conventional group.<sup>11</sup> Also, Ali et al reported that intraoperative blood loss (Mean±SD) was 33.07±5.753 (ml) for the sutureless group and was 75.09±15.417 (ml) for the conventional group.<sup>12</sup> Regmi et al showed that thyroidectomy by ultrasonic technique resulted in less intraoperative blood loss by 16 ml than in conventional thyroidectomy.<sup>26</sup> Rienzo et al showed in their series that intraoperative blood loss was comparable when they used a harmonic scalpel and Liga Sure vessel sealing device and

significantly less than in the conventional clamping and knot-tying technique.<sup>27</sup> And all authors reported that the difference was statistically significant.

In the present study, the amount of post-operative fluid drained in group A was 40-60 ml with a mean±SD of (50.17±7.21) and 50-90 ml for group B with a mean±SD of (67.38±9.99) and this difference is considered to be extremely statistically significant ( $p \leq 0.0001$ ).

These results are similar and in agreement with other researchers' results as Al Juraibi et al that also reported that the amount of fluid drained in the sutureless group was 40-70 ml (54.16±9.21) and was 50-80 ml (66.28±8.99) in the conventional group and this difference was considered to be extremely statistically significant.<sup>24</sup> Also, Noori et al reported that the postoperative drainage volume was significantly less in the harmonic group (10±6 ml, mainly serous compared to 32±4 ml of serosanguinous type) in the conventional group.<sup>25</sup> Also, Mohamed et al in his study reported that the postoperative drainage volume was 12.67 ml in a sutureless group whereas it was 30.46 ml in the conventional group.<sup>11</sup> Also, Ali et al reported that the post-operative drainage volume (mean±SD) was 19.30±4.442 ml for the sutureless group and was 47.49±12.125 ml for the conventional group.<sup>12</sup>

Al-Dhahiry and Hameed found in their study that using harmonic scalpel for total thyroidectomy was associated with less blood loss, operative time, and postoperative drainage volume. Also, Cheng et al in their systemic review and meta-analysis of using harmonic scalpel in thyroidectomy in comparison with the conventional technique, showed that ultrasonic harmonic scalpel decreases the intraoperative blood loss by 45 ml and drainage volume by 29 ml and reduces the operative time by 29 min.<sup>29</sup>

In the present study, there were no permanent or bilateral recurrent laryngeal nerve injuries occurred for patients in both groups. Temporary RLN injury was detected in 1 patient (3.3%) in group A and 2 patients in group B (6.6%). No permanent hypoparathyroidism was seen in both groups, transient hypoparathyroidism occurred in 1 patient (3.3%) of group A and in 2 patients (6.6%) in group B. None of the patients had wound infection, seroma or secondary hemorrhage.

Noori et al reported that only one patient in the conventional thyroidectomy group with large volume goiter developed unilateral recurrent laryngeal nerve palsy and none of the patients in the focus harmonic group showed this complication.

Postoperative hemorrhage and hematoma or seroma formation that necessitates re-operation were not detected in both groups. Wound infection was not recorded also in any patient in his study. Two patients in each group developed postoperative hypocalcemia symptoms

secondary to hypoparathyroidism. But was transient and not permanent and responded to medications.<sup>25</sup> Mohamed et al in his study reported that the use of the harmonic focus significantly reduced postoperative transient hypocalcemia however, no significant difference regarding permanent hypocalcemia. About recurrent laryngeal nerve function, no significant difference between both groups was noted.<sup>11</sup> Ali et al in his study stated that regarding early postoperative complications, although reactionary hemorrhage did not occur in any patient of Group S (sutureless), it occurred in only one patient (2.85%) in Group C (conventional). Post-operative seroma, developed in 3 patients (8.57%) of Group C (conventional) compared to one patient (3.33%) in Group S (sutureless),  $p=0.745$ . Although superficial wound infection happened in 3 patients (4.61%) from Group C, and none in Group S. RLNP was only seen in 3 patients (8.57%) of Group C, 2 patients (5.72%) with unilateral RLNP, and one patient (2.85%) with bilateral RLNP, while it was not seen in Group S. Meanwhile post-operative transient hypocalcemia developed in 7 patients, one patient (3.33%) in Group S, and 6 patients (17.14%) in Group C, ( $p=0.025$ ). And only 2 patients (5.72%) from Group C developed post-operative permanent hypocalcemia, while there was not any in Group S (0%). P value was significant only for transient hypocalcemia.<sup>12</sup>

Several studies found that the symptoms of hypocalcemia and injury to laryngeal nerves were more frequent in the conventional group.<sup>30-32</sup> Other researchers have claimed that the lateral thermal spread of harmonic excitation could result in injury to neighboring tissues.<sup>4,33,34</sup> Several studies, however, found that the use of harmonic scalpel can be safely used in thyroid surgery with no increase in the incidence of such complications.<sup>35,36</sup> Anandaravi et al reported that the use of focus harmonic scalpel reduces the incidence of symptomatic hypocalcemia but showed no significance on the incidence of recurrent laryngeal nerve palsy.<sup>37</sup> Ferri et al in their similar trial recorded the same findings, while Ciftici in their comparative study of using Liga Sure precise, focus harmonic, and conventional technique showed no differences in terms of postoperative complications among the three groups.<sup>38,39</sup>

In the present study, the mean duration of hospital stay was shorter in Group A (1.98±0.18 days) than Group B (2.37±1.79 days); this difference was highly significant ( $p=0.001$ ). The results are similar to results of the other researchers as Noori et al who reported that the mean hospital stay in his study was significantly shorter in harmonic scalpel group compared with conventional technique (20 h vs. 32 h).<sup>25</sup> Also Duan et al demonstrated that in their series, focus harmonic scalpel can shorten the operative time and hospital stay.<sup>3</sup> Cheng et al in their systemic review and meta-analysis of 14 studies showed that the mean length of hospital stay was statistically significant reduced by 0.68 days, i.e., about 26.4% decrease in focus harmonic groups (focus harmonic 1.89 days vs. 2.58 days for conventional technique).<sup>29</sup>

Mohamed et al in his study reported that the hospital stay was 2.97 days in the harmonic group while it was 3.86 days in the conventional group.<sup>11</sup> Ali et al in his study stated that the mean duration of hospital stay was shorter in Group S (sutureless) (1.97±0.183 days) than Group C (conventional) (1.97±0.183 days); this difference was highly significant.<sup>12</sup>

## CONCLUSION

The use of a focus harmonic scalpel in thyroidectomy is effective and safe. It results in a significant reduction in operative time, intraoperative blood loss, volume of postoperative drainage, and hospital stay compared with conventional techniques. The incidence of postoperative complications in both groups was comparable with no statistically significant differences. The added cost of focus harmonic device and the disposable handpiece can be compensated by the rapid turnover of patients and short hospital stays.

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