



## Comparison between Outcome of Harmonic Scalpel and Conventional Hemostasis Method for Removal of Thyroid Gland in Total Thyroidectomy

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### Declaration

#### Authors' Contribution

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### ABSTRACT

**Objective:** To compare the outcomes of harmonic scalpel and conventional suture ligation hemostasis method in patients who underwent total thyroidectomy in terms of intraoperative blood loss, operative time, length of hospital stay and RLN injury. **Study Design:** Randomize controlled trial. **Place and Duration of the Study:** Department of General Surgery, Sheikh Zayed Hospital, Rahim Yar Khan, from February 2025 to June 2025. **Methodology:** Patients scheduled for total thyroidectomy were divided randomly into two groups. In Group A, thyroidectomy was performed using a Harmonic scalpel, and in Group B, hemostasis was accomplished using conventional methods. Baseline demographic data were collected for all subjects. The main operative variables measured were duration of surgery, estimated intraoperative blood loss, length of hospital stay, and occurrence of recurrent laryngeal nerve (RLN) injury. Categorical variables were tested for statistical significance using Chi-square test or Fisher's Exact test when necessary. Continuous variables were assessed using the independent sample t-test for normally distributed data and the Mann-Whitney U test for non-normally distributed data. The statistical analysis was performed with SPSS version 26.0 and a p value less than or equal to 0.05 was considered as statistically significant. **Sample Size:** This study was conducted on 60 patients, both male/female, aged 20-60 years, whose total thyroidectomy was planned. **Results:** Two patients from the harmonic group were excluded intraoperatively due to distorted anatomy requiring conventional hemostasis, leaving 58 patients for analysis (Group A: n=28; Group B: n=30). Mean blood loss was lower in Group A than Group B ( $69.32 \pm 7.37$  mL vs  $80.60 \pm 10.40$  mL;  $p < 0.001$ ). Mean operative time was shorter in Group A ( $118.07 \pm 12.76$  minutes vs  $132.13 \pm 10.35$  minutes;  $p < 0.001$ ). Median hospital stay was 2 days in both groups, but the harmonic group showed a statistically shorter stay ( $p = 0.047$ ). RLN injury occurred in 1 (3.6%) patient in Group A and 3 (10.0%) patients in Group B ( $p = 0.612$ ). **Conclusion:** Harmonic scalpel thyroidectomy resulted in lower blood loss and shorter operative time compared with conventional hemostasis. Hospital stay was slightly shorter, while RLN injury rates were comparable between groups

### INTRODUCTION

Total thyroidectomy is frequently undertaken for a wide spectrum of thyroid diseases, including carcinoma, hyperthyroidism, and benign nodular enlargement [1]. The procedure demands careful hemostatic control due to the gland's dense vascular supply and the close anatomical relationship of the operative plane to the recurrent laryngeal nerves and parathyroid tissue, making bleeding control a key determinant of surgical safety [2, 3]. The conventional hemostasis in thyroidectomy is typically achieved using the clamp-tie-divide method, with electrocautery used as needed. Although effective, particularly in experienced hands, monopolar cautery may be associated with unwanted lateral thermal spread and less controlled coagulation near delicate structures [4]. To

address these limitations, advanced energy devices such as the Harmonic Scalpel have been adopted, allowing simultaneous tissue dissection and vessel sealing, with the potential to shorten operative time and improve postoperative recovery [5]. Nonetheless, the risk of complications after surgery cannot be completely eliminated. The complications may vary in severity and frequency by hypocalcemia, recurrent laryngeal nerve (RLN) palsy, and postoperative bleeding, to much less frequent occurrences such as chylothorax. Although these complications are frequently encountered, their persistence in a permanent form can have a profound and lasting impact on a patient's quality of life [6, 7].

Benign multinodular goiter remains one of the most prevalent endocrine disorders, particularly in regions

where iodine deficiency is common [8]. Surgical intervention is usually considered when patients develop pressure-related symptoms such as difficulty in swallowing, significant retrosternal extension of the goiter, suspicion of malignancy, uncontrolled hyperthyroidism, or cosmetically unacceptable enlargement that does not respond to medical treatment [9]. While the most effective surgical procedure for goiter is total thyroidectomy but the discussion continues as to which of the harmonic scalpel and conventional hemostasis is the method that provides the greatest safety and effectiveness while remaining cost-efficient [10]. The rationale of this study is to compare outcome of harmonic scalpel and conventional suture ligation hemostasis method for removal of thyroid gland in total thyroidectomy in our local population. In busy tertiary care hospitals, reducing operative time has become increasingly important because of the heavy patient load. As a result, there is a growing inclination toward techniques that help shorten surgical duration without compromising safety. The harmonic Scalpel is one such modern tool, recognized for providing reliable hemostasis while maintaining a favorable safety profile. There is lack of local data regarding safety and efficacy of harmonic scalpel in our local population. This study will help patients by early discharge from hospitals and help surgeons by reducing operating time.

This study has been designed is to compare the outcomes of harmonic scalpel and conventional suture ligation hemostasis method for removal of thyroid gland in total thyroidectomy in terms of intraoperative blood loss, operative time, hospital stay and RLN injury presenting in surgical department of SHZ hospital, Rahim-Yar Khan. By undertaking a systematic examination of key parameters such as intraoperative blood loss, operative time, hospital stay and RLN injury this study aspires to contribute substantively to the current body of knowledge.

## METHODOLOGY

In this Randomize controlled trial, both male and female patients aged 20 to 60 years scheduled for total thyroidectomy presenting in the Department of General Surgery Shaikh Zayed Hospital, Rahim Yar khan, Pakistan, from February 2025 to June 2025 were included. Thyroid disease was diagnosed on the basis of clinical assessment, thyroid function tests, neck ultrasonography, and FNAC in patients with nodular thyroid disease, with cytology reported according to the Bethesda classification. By using a WHO calculator, the sample size was calculated to be 60. Patients were selected using a simple randomization method facilitated by computer software. Patients with benign pathologies, such as multinodular goiter, and Graves' disease (all stabilized preoperatively) were included. FNAC results in nodular thyroid disease were predominantly Bethesda II. Patients with incidental, early-stage DTC (pT1–T2) without clinically or radiologically suspicious lymph nodes (cN0) discovered on final histopathology were retained in the study, as their surgical management (e.g., total thyroidectomy) remained

identical to the benign protocol. While patients with history of neck surgery, recurrent goiter, and coagulopathy, pre-operative hoarseness of voice and high-risk patients (ASA  $\geq$  III) were excluded.

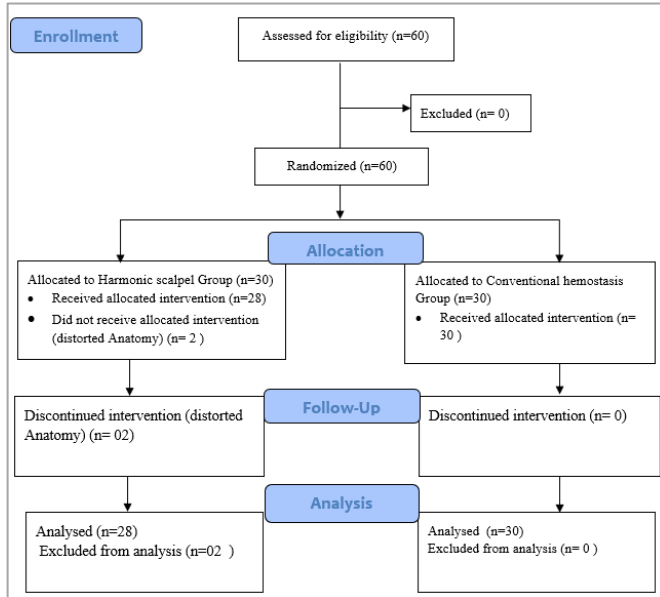
Participants were randomly assigned to one of two groups— Harmonic scalpel or Conventional hemostasis— through a computer-generated allocation system (

Figure 1). Each patient was thoroughly informed about the surgical procedure to be undertaken, and written informed consent was obtained. The Institutional Review Board (IRB) granted ethical clearance for this study. Power analysis was conducted to compare outcomes such as intraoperative blood loss, operative time, hospital stay and RLN injury between harmonic scalpel and conventional hemostasis. Sample size estimation was performed using the WHO sample size calculator, considering a significance level ( $\alpha$ ) of 0.05, and a power of 80%. Based on these parameters, a total of 60 patients were enrolled, with 30 assigned to the Harmonic scalpel group (A) and 30 to the Conventional hemostasis group (B).

A standardized preoperative protocol was applied to all study participants. We began by taking a meticulous clinical history, charting the onset and evolution of neck swelling while checking for obstructive signs like dysphagia or shortness of breath. We also screened specifically for metabolic cues of thyroid imbalance and evaluation of symptoms of hyperthyroidism (palpitations, weight loss, and heat intolerance) and hypothyroidism (constipation, lethargy, and cold intolerance) to judge the thyroid status. We also focused on checking the thyroid gland's size, consistency, and any nodularity during the physical exam and tracheal deviation and if there were signs of retrosternal extension. A thorough clinical examination was done for each patient and one of the aspects was looking for the presence of cervical lymphadenopathy, thus getting the clinical picture complete prior to the surgery. Two patients in the harmonic scalpel group were excluded after intraoperative identification of distorted anatomy with close proximity of the recurrent laryngeal nerve, necessitating the use of conventional hemostasis for nerve protection.

Neck ultrasonography was also performed for all patients to examine the goiter, identify nodularity and evaluate any retrosternal extension. Fine needle aspiration cytology (FNAC) was carried out to confirm benign pathology, and only patients with Bethesda II cytology were included. Patients whose cytology was indicative of malignancy or atypia (Bethesda III–VI), or those necessitating surgery more extensive than total thyroidectomy, were excluded from the study. There was also a small number of cases with early stage (T1, T2) differentiated thyroid carcinoma (DTC) that were included in the study. These tumors were strictly limited to the thyroid gland; therefore, the surgical procedure was the same as for benign goiters. This way, a comparison of the hemostatic techniques would not be influenced by more extensive oncological procedure.

**Figure 1**  
Flowchart of the patient randomization



Surgical candidates were cleared only after confirming a euthyroid state via preoperative thyroid profiles. In cases of hyperthyroidism, we initiated carbimazole therapy, deferring the procedure until biochemical euthyroidism was established. Standard preoperative workup for anesthetic clearance included baseline renal and liver function tests to ensure medication safety and fitness for general anesthesia. Vocal cord mobility was another priority; we performed indirect laryngoscopy on every participant at baseline. Anyone presenting with pre-existing hoarseness or cord palsy was excluded from the study.

As originally described by Megahed *et al.*, All procedures were carried out under general anesthesia. A transverse skin incision was placed along a natural skin crease, approximately one finger breadth below the level of the cricoid cartilage. Skin and subcutaneous tissue were divided and subplatysmal flaps were developed. The superficial layer of the deep cervical fascia was then opened and the strap muscles were separated and retracted. Strap muscle division was not routine and was only performed in cases of large goiter where exposure was otherwise inadequate. In Group A, hemostasis, including control of major vessels was achieved using the harmonic scalpel. In Group B, bleeding was controlled by the conventional clamp-and-tie technique with 3/0 Vicryl sutures.<sup>11</sup> In both groups, the superior laryngeal nerve and recurrent laryngeal nerve were identified during dissection, and the parathyroid glands were carefully preserved. A suction drain was placed in all patients and maintained for 24 hours postoperatively. All patients received standardized postoperative analgesia. Diclofenac 75mg was given to the patients every 12 hours for the first 24 hours after the surgery.

Data on age, gender, duration of disease, underlying thyroid pathology, as well as the American Society of Anesthesiologists (ASA) score, were documented for all patients. Patients were followed till discharge and hospital stay was documented in days. Intraoperative blood loss was noted in both groups. For every patient, data

regarding the length of the procedure was also collected. In terms of safety, the number of cases with recurrent laryngeal nerve (RLN) injuries also recorded. Indirect Laryngoscopy was performed preoperatively to document baseline cord movement and repeated within 24 hours after surgery. All data was entered in an especially designed proforma.

Baseline characteristics of the study groups were summarized using descriptive statistical methods. The normality of the data was assessed using the Shapiro-Wilk test. Quantitative data were expressed as mean  $\pm$  Standard deviation or medians accompanied by their respective interquartile ranges, while qualitative variables were presented as frequency (n) and percentages (%). The Chi-square test or Fisher's Exact test was applied to assess associations between categorical variables, and the comparison between independent groups A and B was performed using the independent t-test or Mann-Whitney U test. A p-value of less than 0.05 was considered statistically significant. All statistical analyses were carried out using IBM SPSS Statistics, version 26 (IBM Corp., Armonk, NY, USA).

## RESULTS

A total of 60 patients scheduled for total thyroidectomy were randomized into two groups. Group A: Harmonic scalpel technique (n=30) and Group B: Conventional hemostasis technique (n=30). Two patients in the harmonic scalpel group were excluded after intraoperative identification of distorted anatomy with close proximity of the recurrent laryngeal nerve, necessitating the use of conventional hemostasis for nerve protection. The demographic characteristics including age and duration of disease were comparable between both groups (mean age: 40.11 years vs 39.57 years,  $p=0.769$ ; mean duration: 20.50 months vs 18.17 months,  $p=0.207$ , Table 1). There was no significant difference in gender distribution ( $p=0.308$ , Table 1) or ASA score classification ( $p=0.432$ , Table 1) between the two techniques. The underlying thyroid pathology included multinodular goiter, Graves' disease, and differentiated thyroid carcinoma, with a comparable distribution between the two groups ( $p=0.715$ ).

The Sociodemographic characteristics including educational status, place of residence and socioeconomic classes were comparable between both groups thus the outside social factors were unlikely to affect the surgical recovery outcomes. Educational status was almost similar in both groups as there was no statistically significant difference in the distribution of illiterate, primary, secondary, and graduate categories ( $p=0.945$ , Table 2). There was also no significant difference in the place of residence ( $p=0.306$ , Table 2). The proportions of low, middle, and high socioeconomic classes were also comparable between Group A and Group B ( $p=0.743$ , Table 2).

Considerable differences were shown when the surgical and recovery data in Table 3 were analyzed. According to the intraoperative blood loss results, the use of Harmonic technique (Group A) led to a great decrease in blood loss ( $69.32 \pm 7.37$ ml vs.  $80.60 \pm 10.40$ ml,  $p<0.001$ , Table 3). Group A showed a remarkable improvement in

efficiency since the operating time was about 14 minutes shorter in Group A than in Group B on average ( $p < 0.001$ , Table 3).

In general, both groups needed only two days for recovery after surgery, but the total length of the hospital stay in the harmonic group was statistically shorter ( $p = 0.047$ , Table 3). In terms of safety, the number of cases with recurrent laryngeal nerve (RLN) injuries was less in Group A (3.6%) as compared with Group B (10%); however, there was no statistical significant difference in both groups ( $p = 0.612$ , Table 3).

**Table 1**  
*Clinical characteristics of patients according to surgical technique*

Parameters	Techniques		p-value
	Group A Harmonic (n=28)	Group B Conventional (n=30)	
Age	40.11 ± 6.74	39.57 ± 7.166	0.769 <sup>a</sup>
Gender			
Male	14(50)	12(40)	0.308 <sup>b</sup>
Female	14(50)	18(60)	
ASA SCORE			
ASA 1	19(67.9)	22(73.3)	0.432 <sup>b</sup>
ASA 2	9(32.1)	8(26.7)	
Duration of disease	20.50 ± 6.07	18.17 ± 7.69	0.207 <sup>a</sup>
Diagnosis			
Multinodular Goiter	12(42.9)	16(53.3)	0.715 <sup>b</sup>
Differentiated Thyroid carcinoma	3(10.7)	3(10)	
Graves' disease	13(46.4)	11(36.7)	

<sup>a</sup> The data are presented as mean ± Standard deviation. p: Independent Sample t-test. p-value is significant at the 0.05 level.  
<sup>b</sup> Data are presented as frequency (%). p: Chi square test. p-value is significant at the 0.05 level. ASA score= American Society of Anesthesiologists risk score.

**Table 2**  
*Comparison of socio-demographic profiles between harmonic scalpel and conventional group patients.*

Parameters	Techniques		p-value
	Group A Harmonic (n=28)	Group B Conventional (n=30)	
Education			
Illiterate	7(25.0)	8(26.7)	0.945 <sup>c</sup>
Primary	6(21.4)	5(16.7)	
Secondary	6(21.4)	8(26.7)	
Graduate	9(32.1)	9(30.0)	
Residence			
Urban	17(60.7)	14(46.7)	0.306 <sup>c</sup>
Rural	11(39.3)	16(53.3)	
Socioeconomic status			
Low	6(21.4)	8(26.7)	0.743 <sup>c</sup>
Middle	14(50.0)	12(40)	
High	8(28.6)	10(33.3)	

<sup>c</sup> Data are presented as frequency (%). P= Chi square test. p-value is significant at the 0.05 level.

**Table 3**  
*Comparison of intraoperative Blood loss, Operative time, Hospital stay (days), RLN injury between group A and B*

Parameters	Techniques		p-value
	Group A Harmonic (n=28)	Group B Conventional (n=30)	
Blood loss	69.32 ± 7.37	80.60 ± 10.40	<0.001 <sup>c</sup>
Operative Time	118.07 ± 12.76	132.13 ± 10.35	<0.001 <sup>c</sup>
Hospital stay(days)	2.00(0)	2.00(1)	0.047 <sup>d</sup>
RLN Injury	1(3.6)	3(10)	0.612 <sup>e</sup>

<sup>c</sup> The data are presented as mean ± Standard deviation. p: Independent Sample t-test. p-value is significant at the 0.05 level.  
<sup>d</sup> The data are presented as median (IQR). p: Mann-Whitney U test. p-value is significant at the 0.05 level.  
<sup>e</sup> Data are presented as frequency (%). P= Fisher's Exact test. p-value is significant at the 0.05 level. RLN Injury = Recurrent Laryngeal Nerve injury.

**DISCUSSION**

The present randomized trial compared the harmonic scalpel with conventional hemostasis in patients undergoing total thyroidectomy. We found that the Harmonic technique significantly reduced intraoperative blood loss and shortened operative time. A modest reduction in hospital stay was also observed. Although recurrent laryngeal nerve (RLN) injury was numerically lower in the Harmonic group, the difference was not statistically significant.

Reduction in blood loss is a consistent advantage reported with ultrasonic energy devices in thyroid surgery. In thyroidectomy, even small differences in bleeding can influence operative clarity and the need for repeated suctioning, which may prolong dissection. In the current study, the Harmonic Scalpel produced a measurable reduction in mean blood loss compared with conventional ligation. Arija D. et al. reported markedly lower blood loss with the Harmonic Scalpel (approximately 40 mL) compared with traditional hemostasis (124 mL), with improved operative field visibility [12]. Similarly, Bangash et al. observed significantly reduced blood loss in the harmonic group (47.10 ± 4.35 mL) compared with the conventional group (91.21 ± 6.16 mL) [13].

Operative time was significantly shorter in the Harmonic Scalpel group. The observed reduction is likely attributable to the ability of ultrasonic energy to achieve vessel sealing and tissue division in a single step, thereby minimizing repeated clamping, ligature placement, and instrument exchanges. Similar reductions in operative time have been reported in recent literature. A 2023 comparative study demonstrated a statistically significant decrease in mean operative time with the Harmonic technique compared with conventional hemostasis [14]. A 2024 regional study also reported shorter operative duration in the Harmonic group than in the conventional group, supporting the time-saving advantage of ultrasonic dissection in routine thyroidectomy practice [15].

Although the absolute difference in hospital stay between groups in this study was modest, it reached statistical significance. In modern thyroid surgery,

uncomplicated cases are typically discharged within 24–48 hours, so any reduction in length of stay may be subtle. Length of hospitalization is not only a reflection of pain and recovery but is also influenced by local practices, including routine drain use and institutional discharge policies. In our cohort, suction drains were placed in all patients for the first 24 hours, which likely constrained opportunities for earlier discharge and may have attenuated differences between groups. Similar observations have been reported in recent surgical series. A 2024 prospective comparative study observed somewhat shorter hospital stays in patients undergoing Harmonic scalpel thyroidectomy compared with conventional techniques, although both groups remained within the typical 1–3 day discharge window [16]. A 2022 randomized comparative study also found reduced mean hospital stay with Harmonic scalpel use ( $2.18 \pm 0.72$  days) compared with conventional hemostasis ( $3.41 \pm 1.12$  days), reinforcing the potential for shorter postoperative recovery with ultrasonic devices, particularly when drain and discharge protocols allow earlier mobilization [17].

Damage to the recurrent laryngeal nerve (RLN) is still one of the most serious complications after total thyroidectomy as even temporary paralysis can considerably impair voice and swallowing. In our study, there were fewer cases of RLN injury in the Harmonic Scalpel group compared to the conventional one; however, this difference was not statistically significant, probably because of the small sample size and the low overall number of events. Several recent pieces of research have also demonstrated that there is no difference in safety regarding RLN when using ultrasonic or conventional methods [18]. Kala et al. (2024) determined that the postoperative RLN palsy rate showed very little fluctuation between the Harmonic and the standard method [19]. On the other hand, a 2024 study also revealed that switching to alternative cautery sources, such as ultrasonic devices, is not linked to a higher risk of RLN injury when compared to the use of conventional methods [20].

One of the strengths of our work was that vocal cord mobility was objectively evaluated through laryngoscopy not only before the operation but also less than 24 hours after the procedure, thus allowing for a certain silent palsy

to be missed. Existing evidence comparing hemostatic techniques in total thyroidectomy remains variable, the studies have several limitations, for instance, most of them are non-randomized clinical trials, the cases are selectively included, or the surgical procedures are mixed, which makes it difficult to compare them directly. Notably, there is a lack of local studies carried out in high volume tertiary care settings, although changes in patient load, operative workflow, and discharge practices can affect the outcomes. By directly comparing the Harmonic Scalpel with conventional clamp-and-tie hemostasis in a randomized design, this study provides context-specific evidence on operative efficiency and safety in our population. The findings have practical value for surgeons working in busy units where even modest reductions in blood loss, operative time, and hospital stay can be translated into meaningful improvements in theatre turnover and patient care.

However, the study's limitations must be acknowledged. A major drawback of this study is its single center nature, which may limit the generalization of the findings. Besides, long term effects like transient versus permanent RLN dysfunction were not looked at and require further studies. Moreover, the results may have been affected by surgeon skill and selection bias even though the study was randomized.

## CONCLUSION

This randomized trial concluded that patients with total thyroidectomy using the Harmonic Scalpel had less blood loss during surgery and a shorter operation time as compared to the clamp and tie method of hemostasis. Besides, to some extent, the duration of hospital stay was shorter in the Harmonic group, but most patients in both groups were discharged at the same time after the operation. There were very few cases of recurrent laryngeal nerve injury and the rate of occurrence of such damage was not different significantly between the two methods. In general, the Harmonic scalpel appears to be a safe and efficient method for hemostasis in total thyroidectomy and its use can be very beneficial especially at high volume surgical centers where the operating time and workflow are of great importance.

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