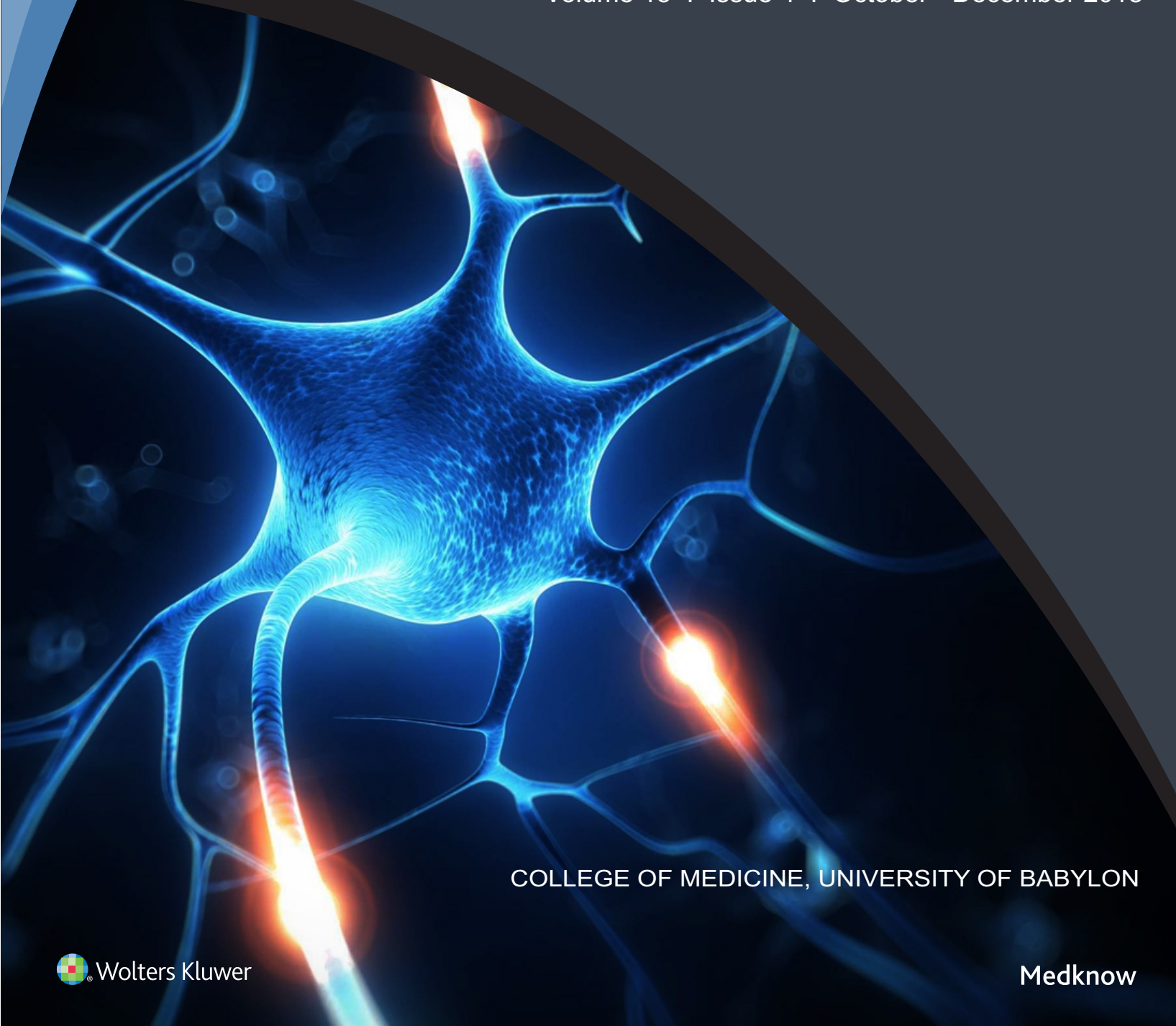


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Sutureless Focus Harmonic Thyroidectomy versus Conventional Clamping and Knot-Tying Technique

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Abstract

Background: Thyroidectomy is the most frequent procedure in endocrine surgery. Since thyroid is the highly vascular organ, therefore, prompt and meticulous hemostasis is extremely important. Although conventional thyroidectomy is used frequently with acceptable outcomes, it is time-consuming and resulted in significant intraoperative blood loss with possible risk of injury to parathyroid glands and laryngeal nerves. The advent of ultrasonically activated focus harmonic device in thyroid surgery was encouraging for improving safety, effectiveness, and reduction of operative time. **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 (clamping and suture ligation (knots tying) and electrocautery. **Patients and Methods:** This is a prospective, randomized study in which 64 patients with various types of goiters presented for thyroidectomy. The patients were divided into two comparable groups. Group A (32 patients) included patients who had focus harmonic thyroidectomy and Group B (32 patients) included patients who received conventional thyroidectomy. **Results:** Focus harmonic thyroidectomy showed significant reduction in operative time, intraoperative blood loss, volume of postoperative fluid drainage, and postoperative pain scores compared with conventional thyroidectomy. There were no significant differences in the incidence of postoperative hypocalcemia and laryngeal nerve injury between both the groups. The total cost of focus harmonic thyroidectomy and hospital stay were also less compared with conventional techniques. **Conclusions:** Focus harmonic thyroidectomy was a safe, effective, faster, and beneficial alternative to conventional technique since it reduces the time of surgery, blood loss, postoperative drainage, and pain with comparable postoperative complications.

Keywords: Conventional thyroidectomy, focus harmonic scalpel, sutureless thyroidectomy

INTRODUCTION

Thyroidectomy (lobectomy, subtotal, and total resection) is the most common endocrine operations performed in general surgical practice. It is indicated mainly for thyroid cancers, thyrotoxicosis, and obstructive symptoms and occasionally for cosmetic reasons.^[1] Although thyroidectomy is considered nowadays as a safe procedure, especially in the hands of expert surgeons, it carries potential complications mainly bleeding and injury to vital strictures such as recurrent laryngeal nerve. Thyroidectomy through the Kocher incision was the standard approach for many decades; bleeding was the most frightening complication responsible for most morbidity and reoperation. Since the thyroid gland is the highly vascular organ, thyroidectomy, therefore, necessitates meticulous hemostasis and delicate dissection to minimize intraoperative blood loss.^[2]

In conventional thyroidectomy, hemostasis is achieved by suture ligation (clamping and knots tying), clips, and

electrocautery in selected sites. These measures are liable for slippage or dislodgment and rebleeding postoperatively since hypotensive anesthesia is commonly used in thyroid surgery.^[3] Besides, these hemostatic measures are time-consuming that lengthen the operative time and hospital stay for observation and monitoring for any suspected complications which are cost-noneffective. Therefore, the need for more sophisticated and advanced alternative tools to control bleeding and better hemostatic measures was urgent and necessary.^[4]

The invention of ultrasonically activated focus harmonic device (shears and scalpel) in the mid of 1990s which simultaneously cauterize and cut tissue using ultrasonic mechanical vibrations instead of electronic current used in

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electrocautery causing minimal energy transfer and thus decreasing and limiting the damage to surrounding tissues.^[5]

The introduction of focus harmonic scalpel in thyroid surgery is deemed superior to conventional techniques since it dissects, coagulates, and cuts simultaneously. This new technique is safe, fast, effective in reducing the time of surgery, blood loss, postoperative pain, and complications.^[5,6]

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 (clamping and suture ligation [knots tying] and electrocautery).

MATERIALS AND METHODS

This is a prospective, randomized study conducted in one major hospital in Basrah between March 2014 and September 2017 in which 64 patients with various types of goiters (multinodular goiter, diffuse goiter, solitary nodule, and thyroid cancers) subjected to thyroidectomy.

The patients were divided randomly into two equal groups: the harmonic focus group (Group A, 32 patients) and the conventional group (Group B, 32 patients).

Patients with recurrent goiter, huge goiter, retrosternal goiter, and malignant goiter with cervical lymphadenopathy and those patients with previous neck surgery were excluded from the study.

Patients' characteristics and clinical presentation were similar and comparable in both groups. Female patients were predominant in both groups (56 females versus 8 males) with an age range between 23 and 63 years (mean 44.7 years).

Patients in both groups gave full information about both types of procedures, and their possible complications and informed consents were taken from all patients.

Complete preoperative assessment of all patients in this study was done, including complete blood count, thyroid function tests, and ultrasound examination. Fine-needle aspiration cytology was ordered for all nodular goiters to exclude malignancy. The results of indirect laryngoscopy from all patients were obtained to assess the vocal cord mobility preoperatively.

All procedures in both groups were done under general anesthesia with endotracheal intubation by the same single specialist surgeon. The patients were placed in supine position. A cotton roll or gel pad was placed beneath the shoulders to help extend the neck with head supported to maximize the exposure of surgical field. After proper scrubbing and draping, a traditional 6–8 cm collar incision 2 fingers breadths above the sterna notch was made, although smaller incision of 4 or 5 cm was occasionally used for small and unilateral enlargement of the thyroid. Upper and lower subplatysmal flaps by electrocautery followed by separation of strap muscles at the mid-line. Thyroid gland thus exposed

and mobilized; thyroidectomy proceeded by ligation of blood vessels according to each group. Group A included 32 patients offered for thyroidectomy using the focus harmonic scalpel (Harmonic–Ethicon Endo-Surgery Inc.) that coagulates and cuts simultaneously throughout the entire procedure, including ligations of all thyroid vessels and dissection of berry ligament off the trachea. Sutures were never used in these patients.

Patients presenting for conventional thyroidectomy (Group B, 32 patients) in whom thyroidectomy dissection and hemostasis were achieved by Kelly clamping and knot-tying using 0 silk and 0 vicryl sutures and clips or by monopolar and bipolar diathermy technique.

Identification and isolation of recurrent laryngeal nerve and parathyroid glands were routine in both types of procedures. At the end of the procedure, hemostasis was assured and a closed Redi-Vac suction drain was placed beneath the strap muscles, which then closed using 2/0 absorbable vicryl suture which also used to reapproximate the platysma muscle. Wound then closed using either subcuticular interrupted catgut 3/0 suture or titanium liga-clips. Drains were removed after 24–48 h postoperatively.

The surgical outcomes both intra- and post-operative parameters including operative time, blood loss, postoperative pain, amount of drainage, seroma and hematoma formation, injury to recurrent laryngeal nerve, hypocalcemia secondary to hypoparathyroidism, and length of hospital stay with total cost of both procedures were recorded, compared, and analyzed.

RESULTS

A total of 64 patients (8 males and 56 females) were included in this study. They were randomized into two equal groups of 32 patients each. Group A (focus harmonic thyroidectomy) consists of 28 female and four male patients whose mean age was 45.7 ± 12 years, and Group B (conventional thyroidectomy) consists of 26 female and six male patients with the mean age of 47.8 ± 9 years.

Simple nodular goiter was noted in 19 patients, toxic nodular goiter in 7 patients, thyroid cancer in 3 patients and Hashimoto's thyroiditis in 3 patients also proved by FNAC and histopathology. However, in conventional thyroidectomy group, simple nodular goiter was noted in 17, toxic goiter (nodular and diffuse) in six, thyroid cancer in five, and Hashimoto thyroiditis in four patients. Thyroid volumes measured by ultrasound were comparable in both groups (mean volume for focus harmonic group was 54.8 ± 4 [14–66] ml compared with 57.7 ± 3 [11–72] ml for conventional group).

The two groups, therefore, were similar in regard to age, sex, type of pathology, and volume of goiter as well as functional status. All patients were prepared to euthyroid status before surgery [Table 1].

The results of indirect laryngoscope were normal for all patients except in one patient in conventional group which revealed unilateral palsy with vocal cord polyp.

The length of incision in both types of procedure was 6–8 cm. The operative time measured from skin incision to skin closure, and dressing was significantly shorter in harmonic group than in conventional group (51.3 ± 12 min vs. 81.1 ± 9 min respectively; $P < 0.01$).

The intraoperative blood loss measured by weighing the blood-soaked gauze and by calculating the intraoperative drain was also significantly less in harmonic group than in conventional group (12 ± 4 ml vs. 28 ± 9 ml; $P < 0.01$). Consequently, the postoperative drainage volume was significantly less in harmonic group (10 ± 6 ml, mainly serous compared to 32 ± 4 ml of serosanguinous type).

The weight of thyroid specimen was comparable in both groups (56.2 ± 7 g for harmonic group vs. 61.5 ± 3 g for conventional group).

The main postoperative complications of thyroidectomy were observed and recorded in both groups.

Only one patient in conventional thyroidectomy group with large volume goiter developed unilateral recurrent laryngeal nerve palsy. This palsy, however, was transient and improved after 3 weeks. 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 this study.

Two patients in each group developed postoperative hypocalcemic symptoms secondary to hypoparathyroidism. All these patients were improved on conservative treatment in the form of calcium gluconate and Vitamin D3. The levels of serum parathyroid hormone and serum calcium were comparable in both groups.

The length of hospital stay was significantly shorter in harmonic thyroidectomy group compared with Group B of conventional thyroidectomy (26 ± 3 h vs. 39 ± 1 h; $P < 0.01$).

Postoperative pain among patients in both groups was assessed using the visual analog scale (VAS). There was significant reduction in pain score in harmonic group compared with conventional group both in the first 24 h and after 48 h (2.8 ± 12 vs. 4.7 ± 3 and 1.6 ± 5 vs. 3.1 ± 8 , respectively) [Table 2].

DISCUSSION

Thyroidectomy is the treatment of choice for many thyroid disorders and still the most commonly performed endocrine surgery. Since thyroid gland is a very vascular organ by their numerous blood vessels that are closely related to crucial structures, namely the laryngeal nerves which supply the

muscles of the larynx and vocal cords and parathyroid glands. Therefore, delicate dissection and meticulous hemostasis are very important during surgery to prevent intraoperative and postoperative bleeding which could be fatal and to avoid inadvertent injury to the laryngeal nerves and parathyroid glands.^[4,7]

The conventional thyroidectomy using either clamping and sutures ligation (knot-tying) or use of monopolar and bipolar electrocautery for dissection and coagulation had been used for many decades with acceptable outcomes with low morbidity and no mortality.^[8,9] This conventional thyroidectomy, however, is time-consuming and vulnerable to sutures slipping and dislodgment increasing the risk of hemorrhage and postoperative hematoma formation, while the use of electrocoagulation has a potential risk of injuring the nearby structures due to the lateral dispersion of heat.^[10]

In the late 1990, advanced technology has invented a new device which activated by ultrasonic wave in the form of shears and scalpel including the focus harmonic scalpel which utilizes high-frequency energy that can be used to cut and coagulate tissues and vessels at the same time with no further need for sutures ligations which is very important especially in a narrow and confined operative field like in thyroid surgery. Such harmonic scalpel seals blood vessels up to 5–7 mm in diameter with lateral thermal spread confined to 2 mm beyond the grasped tissues.^[8,11] The sealing effect of harmonic scalpel results from the formation of denaturated protein coagulum that clogs the blood vessels. The protein denaturation by harmonic scalpel occurs using ultrasound vibration that conveys mechanical energy that breaks the hydrogen bonds. The harmonic scalpel cuts by two mechanisms: mechanical cutting and cavitation fragmentation.^[9,12]

The present study has compared the use of focus harmonic ultrasonic scalpel to conventional techniques in thyroidectomy. We found that focus harmonic thyroidectomy was associated with significant reduction of operative time, intraoperative bleeding, and postoperative drainage compared with conventional thyroidectomy. We record a reduction of about 30 min in harmonic group compared with conventional technique. The use of focus harmonic scalpel in thyroid surgery had been shown by several previous literature to be associated with reduction in operative time by 15%–30%.^[13,14] Zanghi *et al.*^[15] observed a reduction of about 27% in surgical time and reduction near to 34% in the intraoperative bleeding when they used focus harmonic scalpel. Al-Dhahiry and Hameed^[16] found in their study that using harmonic scalpel for total thyroidectomy was associated with less blood loss, operative time, and postoperative drainage volume. Cheng *et al.*,^[17] in their systemic review and meta-analysis of using harmonic scalpel in thyroidectomy in comparison with 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. Regmi *et al.*^[18] showed that thyroidectomy by ultrasonic technique resulted in less intraoperative blood loss by 16 ml than in

conventional thyroidectomy. Di Rienzo *et al.*^[19] showed in their series that intraoperative blood loss was comparable when they used harmonic scalpel and LigaSure vessel sealing device and significantly less than in the conventional clamping and knot-tying technique. Operative time and postoperative fluid drainage were also less in harmonic thyroidectomy.

Effective and rapid hemostasis can be achieved using focus harmonic scalpel. Although postoperative bleeding and hematoma formation that necessitates re-exploration were not recorded in both groups in our study, the volume of drainage was significantly higher in conventional thyroidectomy (32 ml vs. 10 ml).

The reduction in the drainage volume has a role in the reduction and prevention of postoperative infection. Effective and meticulous hemostasis entails a clear surgical field which is very desirable and extremely important in thyroid surgery to avoid inadvertent injuries to laryngeal nerves and parathyroid glands which are the main complications after thyroid surgery. The incidence of these two complications in this study was comparable and showed no significant difference between the two groups. These findings could be attributed to the techniques adapted during thyroidectomy in both groups which

entails identification and preservation of recurrent laryngeal nerves and parathyroids during surgery. Several studies found that the symptoms of hypocalcemia and injury to laryngeal nerves were more frequent in the conventional group.^[20-23] Other researchers have claimed that the lateral thermal spread of harmonic excitation could result in injury to neighboring tissues.^[11,24,25] 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.^[26,27] Anandaravi *et al.*^[28] 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. Ferri *et al.*^[29] in their similar trial recorded the same findings, while Ciftici^[30] in their comparative study of using LigaSure precise, focus harmonic, and conventional technique showed no differences in terms of postoperative complications among the three groups. We believe that the limited thermal dispersion of harmonic scalpel (<2 mm) decrease the risk of impaired vascularity in the parathyroid glands.

The postoperative pain among patients in both groups has been studied and recorded. The results demonstrated significant differences between the two groups regarding the VAS scores both at 24 h and after 48 h postoperatively in favor of focus harmonic group. This reduction in postoperative pain could be explained by less tissues dissection, less neuromuscular excitations induced by minimum thermal spread and using sutureless hemostasis. Ferri *et al.*^[29] found in their similar trial that harmonic scalpel group recorded significantly less postoperative pain while Cordón *et al.*^[23] and Cannizzaro *et al.*^[31] showed that no significant difference between harmonic and conventional thyroidectomy regarding the postoperative pain.

The mean hospital stay in this study was significantly shorter in harmonic scalpel group compared with conventional technique (20 h vs. 32 h). Duan *et al.*^[32] demonstrated that in their series, focus harmonic scalpel can shorten the operative time and hospital stay. Cheng *et al.*^[17] in their systemic review

Table 1: Patients characteristics and diagnosis (n=32)

Patients characteristics and diagnosis	Group A (harmonic thyroidectomy)	Group B (conventional thyroidectomy)
Age (mean)	45.7±12	47.8±9
Sex (female:male)	28:4	26:6
Thyroid volume (mean)	54.8±4 (14-66)	57.7±3 (11-72)
Simple multi-nodular nodular goiter	19	17
Toxic multi-nodular goiter and Grave's disease	7	6
Thyroid cancers	3	5
Hashimoto thyroiditis	3	4

Table 2: Comparison of intra- and post-operative outcomes in both groups

Intra and postoperative parameters	Group A (harmonic thyroidectomy) (n=32)	Group B (conventional thyroidectomy)(n=32)	P
Operative time (min)	51.3±12	81.1±9	<0.01
Intraoperative blood loss	12±4 ml	28±9 ml	<0.01
Thyroid weight	56.2±7 g	61.5±3 g	NS
Postoperative drainage	10±6 ml	32±4 ml	<0.01
Postoperative bleeding (re-exploration)	0	0	NS
Postoperative pain (h)			
VAS in 24	2.8±12	4.7±3	<0.05
VAS after 48	1.6±05	3.1±8	<0.05
Recurrent laryngeal nerve injury	0	! (transient)	>0.01
Hypoparathyroidism	2	2	NS
Wound complications	0	0	NS
Hospital stay	20±3 h	32±1 h	<0.01
Total cost	less	more	<0.1

NS: Not significant, VAS: Visual analog scale

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).

The only concern regarding the use of harmonic scalpel results from its cost since the device and hand-piece are expensive and disposable; this concern, however, can be justified by short operative time and meticulous and ensured hemostasis which results in rapid turn-over of patients with decreased postoperative complications that either require re-exploration or lengthen the hospital stay. Sebag *et al.*^[33] reported an increased cost associated with the use of focus harmonic device for thyroidectomy. Furthermore, Blanchard *et al.*^[34] demonstrated in their large multicenter randomized controlled trial that despite the reduction in the operating time in almost all published researches, the total costs of focus harmonic thyroidectomy were higher than those of conventional techniques. Yoan *et al.*,^[35] on the other hand, found that thyroidectomy by this device is inexpensive procedure because of reduction in operative time, complications, and staff cost.

CONCLUSIONS

The use of focus harmonic scalpel in thyroid surgery is very effective and safe. It results in significant reduction in operative time, intraoperative blood loss, volume of postoperative drainage, and hospital stay compared with conventional techniques. The incidence of postoperative complications, namely hypocalcemia and recurrent laryngeal nerves injury, was comparable with no statistically significant differences between both groups. The added cost of focus harmonic device and the disposable hand-piece can be justified by rapid turnover of patients, decrease the number of surgical staff, and short hospital stay. Therefore, the total cost of focus harmonic thyroidectomy can be reduced especially in high-volume centers.

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Conflicts of interest

There are no conflicts of interest.

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