

Safety and Efficacy of Bipolar Radiofrequency Ablation Device in Hemostasis during Thyroidectomy in Comparison with Ultrasonic Scalpel: A Comparative Study

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Abstract

Aim: Ultrasonic scalpel is one of the recent advances in surgical technology. The main limitation of their use is the cost. However, radiofrequency ablation device is a refined type of electrosurgical cautery that can be used with conventional reusable bipolar cautery forceps. This study aims to compare the efficacy of bipolar radiofrequency ablation device that can be used with conventional reusable bipolar cautery forceps for hemostasis and dissection during thyroidectomy with that of ultrasonic scalpel. **Materials and Methods:** Sixty patients underwent total thyroidectomy were recruited at Alshiffa General Hospital, Basrah, Iraq from March 2016 to June 2017. The participants were divided into two equal groups: in the first group thyroid dissection was done with ultrasonic scalpel, and in the second group thyroid dissection was done with bipolar radiofrequency ablation device. Outcome and complications of both procedures were analyzed statistically and compared. **Results:** The bipolar radiofrequency ablation device significantly reduced the mean operative time by (-15.35 min) in comparison to ultrasonic scalpel. The Bipolar Radiofrequency Ablation Device (BRFA) group reported a mean operative time of 50.13 ± 14.16 compared to 65.49 ± 7.78 in the US group with, P value = 0.001. There was no statistically significant difference in the other outcome parameters and the rate of complications reported between the two devices during this study. **Conclusion:** The bipolar radiofrequency ablation device that can be used with conventional reusable bipolar cautery forceps is a simple, safe, and time-saving adjunct for thyroid surgeries and equally effective as compared to costly instruments like ultrasonic scalpel. **Clinical Significance:** The bipolar radiofrequency device can be used in thyroid surgery to secure hemostasis, save time, and cost.

Keywords: Bipolar radiofrequency ablation device, comparative study suture less thyroidectomy, new energy devices, ultrasonic scalpel

INTRODUCTION

The prompt and secure hemostasis in thyroid surgery is crucial to avoid bleeding, obtain good visualization of the surgical field, and prevent injury to structures such as the parathyroid glands and laryngeal nerves.^[1] Standard vessel ligation, involving the use of ties and suture ligatures, has been a conventional technique in most centers. Although being a highly efficient technique for vessel bleeding control, it is time consuming and can endanger adjacent structures such as the recurrent and superior laryngeal nerves.^[2,3] Time-saving operations are becoming an increasingly important issue, especially for the turnover of patients in high-volume operating theatres and for using shorter anesthesia time. Therefore, there is an interest in devices or techniques that reduce the need for conventional knot-tying or suture ligation for hemostasis.^[4]

The conventional energy devices, such as monopolar cautery, generate significant heat and result in inconsistent vessel sealing with substantial thermal spread and charring so that it is not recommended for hemostasis in thyroid surgery. However, the conventional bipolar cautery proved to have less thermal spread.^[5]

Recent advances in surgical technology include the use of new energy devices for dissection and hemostasis during surgery such as bipolar vessel sealing systems (LigaSure™), ultrasonic energy device (Harmonic ACE™), and bipolar

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radiofrequency ablation device (ENSEAL™). These devices have been designed to work with disposable hand pieces to seal blood vessel of about 5 mm in diameter and primarily founded to perform hemostasis in a remote places during laparoscopic surgery instead of sutures ligation.^[6,7] Ultrasonic energy devices were developed in early 1990s. These innovative devices use ultrasonic energy to create mechanical vibration at a frequency of 55.5 kHz between the two jaws of the device. This friction mechanism produces low heat energy (between 50°C and 100°C) transmitted to the tissue result in denaturation of protein and formation of coagulum with sealing and cutting out of vessel at the same time with minimal lateral thermal spread.^[8]

Radiofrequency ablation device is a refined type of electrosurgical cautery that utilizes a wave of electrons at a frequency between 2 and 4 MHz to incise, excise, or coagulate the targeted tissue. Furthermore, the ablation property of this device acts as an extra vessel sealing effect by decreasing the diameter of blood vessel because of the shrinkage of the collagen fibers.^[9] With radiofrequency (2–4 MHz), there is minimal tissue resistance to the passage of electrical current leading to agitation and friction movement between tissue ions leading to heat production. The targeted tissue temperatures stabilized within a 60–100°C range, and the tip of the probe or the forceps remains cold, thus limiting heat dissipation and damage to adjacent tissue. In contrast, conventional electrocautery or diathermy temperatures are significantly higher (750–900°C), and the tip of the forceps becomes hot that result in a very high heat propagation, which is far in excess of the desired therapeutic need.^[10]

Radiofrequency surgery has a lengthy documented history of use in oral, ophthalmic, plastic, gynecology, dermatology, cosmetology, cardiology, neurosurgery, hepatology, and ENT surgery.^[11,12]

Several studies have reported the successful use of ultrasonic energy device and the bipolar radiofrequency ablation device in shortening the length of thyroid surgery and reducing blood loss while retaining a good safety profile. However, these techniques do incur the cost of these advanced generators that designed to work only with an expensive disposable hand pieces, which may be difficult to justify in some hospitals.^[13,14] The new published studies proved the safety and cost effectiveness of the conventional bipolar cautery for sealing of the superior and inferior thyroid vessels during thyroidectomy with operative time shorter than that of conventional knot-tying technique.^[15-17]

This study aims to compare the efficacy of simple bipolar radiofrequency ablation device that can be used with conventional reusable bipolar cautery forceps for hemostasis and dissection during thyroidectomy with that of ultrasonic scalpel in term of operative time, intraoperative blood loss, duration of hospital stay, volume of postoperative drainage, time of drain removal, and the postoperative complications such as hypocalcemia, recurrent laryngeal nerve palsy, postoperative hematoma, postoperative bleeding which

necessitates blood transfusion and/or reoperation, and any intraoperative or postoperative mortality.

MATERIALS AND METHODS

This study was conducted in Alshiffa General hospital, Basrah, Iraq from March 2016 to June 2017 and was approved by a local ethics committee. Sixty patients with different thyroid gland pathologies who are candidate for total thyroidectomy were included in the study and divided randomly, by simple random sampling, into two groups. The first group (US group) included 30 patients in whom the hemostasis and thyroid dissection were done by ultrasonic scalpel (SONICBEAT, USG-400, Olympus Japan), and the second group (BRFA group) included 30 patients in whom the hemostasis and thyroid dissection were done with bipolar Radiofrequency ablation device that can be used with conventional reusable bipolar cautery forceps, (radioSURG 2200, Ear, Nose, and Throat (ENT) Version, 2.2 MHz, Meyer-Haake, Germany), [Figure 1]. Exclusion criteria includes patients who had thyroid surgery, patients who had visible large size goiter (grade 3 goiter according to World Health Organization goiter grading system^[18]), (any grade of retrosternal goiter^[19]), or with postoperative follow-up period less than 8 weeks were excluded from the study.

The following data were recorded perioperatively: patients' demographics, clinical diagnosis, thyroid ultrasound findings, histopathology results, and flexible fiberoptic laryngoscopy for vocal cord examination before and after operation. In addition, surgical procedure details and outcome such as duration (minutes), intraoperative blood loss (ml) (the difference in the weights of gauze before and after use in gram unit, converted to ml unit, and using gram to ml conversion chart), postoperative drainage volume (ml), time of drain removal (hour), and length of hospital stay (hour) were also documented. Postoperative complications such as recurrent laryngeal nerve palsy, symptoms of hypocalcemia (paraesthesia, muscle spasm, and Chvostek's or Trousseau's signs, confirmed by serum calcium <2.1 mmol/ml), hematoma formation, bleeding necessitates blood transfusion and/or reoperation, and any intraoperative or postoperative mortality were also documented.

All thyroidectomies have been done by the same surgeon with Theodor-Kocher procedure under general anesthesia



Figure 1: Bipolar radiofrequency ablation device

with endotracheal intubation and in supine position with neck extension. A collar skin incision was done midway between suprasternal notch and thyroid notch and extended from one sternomastoid muscle to the other creating subplatysmal flaps. Vertical incision of pretracheal fascia and separation of strap muscles are then performed followed by mobilization of the thyroid lobes. The hemostasis during thyroidectomy, dissection, and excision of thyroid tissue was done either with harmonic scalpel or with bipolar radiofrequency ablation device. Vacuum drain was used in all cases, and the wound was closed in layers.

Techniques of hemostasis and dissection

All tributaries of middle thyroid vein and terminal branches of superior thyroid artery, inferior thyroid artery, and other unnamed vessels were identified, sealed, and divided either with the ultrasonic scalpel in the first group of patients (US group) or with the bipolar radiofrequency ablation device in the second group of patients (BRFA group).

Recurrent laryngeal nerve was identified on both sides and preserved. Similarly, parathyroid glands were identified at least on one side and preserved in all possible conditions.

During operation the operative time was calculated from start of skin incision to end of skin closure. After completion of the operation, the anesthetist re-examined the vocal cord for documentation of any abnormality, and after recovery from anesthesia, the patients were transferred to the surgical ward for observation and follow-up. After being discharged from hospital, all patients were re-examined after 1, 4, and 8 weeks.

IBM SPSS Version 20 (IBM Corp., Armonk, NY, USA) was used for data analysis. Results were directly compared between the two groups using the two-tailed *t* test for quantitative variables and related samples. The McNemar test was used for qualitative variables. The statistical significance was considered at $P < 0.05$. Patients' age, surgery duration (min), hospital stay duration (hour), drainage volume (ml), and drain removal time (hour) were expressed in mean \pm SD. Other patient's characteristics such as gender and various complications were expressed in frequencies.

This study was ethically conducted in accordance with declaration of Helsinki.

RESULTS

Patients' age, gender, and diagnosis are summarized in Table 1. There were no statistically significant differences observed among the groups in terms of age, gender, or diagnosis.

Regarding the outcome of both procedures, the BRFA group reported a significant shorter mean operative time in comparison to US group (50.13 \pm 14.16 and 65.49 \pm 7.78 min), respectively, P value = 0.001. However, there was no statistically significant difference in the other outcome parameters between the two groups of patients [Table 2].

The only complication reported during this study is the temporary hypocalcemia, where two patients (6.66%) in each group developed symptoms of this complication, with no significant statistical difference (P value = 1.000). These cases were confirmed by serum calcium < 2.1 mmol/ml, treated with oral calcium and vitamin D3, and resolved within few weeks.

During this study, we observed the following technical and financial points for both devices. First, the ultrasonic scalpel generator is more expensive and designed to work only with an expensive disposable hand piece. Second, the jaw of the hand piece is relatively large, and therefore, it is not suitable for fine dissection and remains hot for a time even after stop firing [Table 3].

DISCUSSION

Most published studies reported that the main impact of ultrasonic scalpel and electrothermal bipolar vessel sealing

Table 1: Basic characteristics of patients

Patients characteristics	US group (n=30)	BRFAD group (n=30)	P
Mean age (y) \pm SD	40.27 \pm 10.05	40.46 \pm 9.74	0.460
Gender (%)			
Male	5 (16.66%)	6 (20%)	0.500
Female	25 (83.33%)	24 (80%)	0.125
Total	30 (100%)	30 (100%)	
Diagnosis (%)			
Toxic goiter	9 (30%)	8 (26.66%)	0.250
Non-toxic goiter	21 (70%)	22 (73.33%)	0.125
Total	30 (100%)	30 (100%)	
Multinodular goiter	17 (56.66%)	18 (60%)	0.125
Diffuse goiter	10 (33.33%)	10 (33.33%)	1.000
Solitary nodule	3 (10%)	2 (6.66%)	0.375
Total	30 (100%)	30 (100%)	
Benign	28 (93.33%)	28 (93.33%)	1.000
Papillary cancer	1 (3.33%)	1 (3.33%)	1.000
Follicular cancer	1 (3.33%)	1 (3.33%)	1.000
Total	30 (100%)	30 (100%)	
Large goiter	8 (26.66%)	7 (23.33%)	0.500
Moderate goiter	16 (53.33%)	17 (56.66%)	0.630
Small goiter	6 (20%)	6 (20%)	1.000
Total	30 (100%)	30 (100%)	

Table 2: The outcome of procedure in both groups

Outcome factors	US (n=30)	BRFAD (n=30)	P
Mean surgery length (min) \pm SD	65.49 \pm 7.78	50.13 \pm 14.16	0.001
Mean hospitalization stay (hr) \pm SD	24.25 \pm 2.44	24.75 \pm 4.197	0.320
Mean drain removal duration (hr) \pm SD	24.50 \pm 3.44	25.00 \pm 4.821	0.417
Mean postoperative drainage volume per drain (ml) \pm SD	63.02 \pm 19.91	62.50 \pm 22.79	0.330

Table 3: Technical and financial observations during the study

Technical and Financial Observations	BRFAD	US
Approximate cost of the generator ^a	\$11,000	\$30,000
Approximate cost of the hand piece*	\$100 (reusable)	\$900 (disposable)
Size of the jaw of the hand piece	Fine tip, suitable for fine tissues dissection	Relatively large tip, not suitable for fine tissues dissection
Heat at the jaw of the hand piece	Remain cold even during firing	Remain hot even after stop firing

^aAccording to the local sale price in Basrah, Iraq

system in thyroid surgery is the significant reduction in the operative time in comparison to the conventional technique.^[20-23] The results of our study are in line with these studies, where both procedures reported significant reduction in the operative time when compared to the operative time that published for conventional procedure. Furthermore, we reported a significant reduction in the operative time with the use of the BRFAD device (-15.35 min) in comparison to ultrasonic scalpel. This reduction in operative time may be because of the fine tip of the bipolar cautery forceps, which can be used for fine dissection, sealing, and division of tissues and blood vessels at the same time, and it may be because of the ablative property of this device which acts as an extra sealing effect leading to rapid hemostasis. There was no statistically significant difference reported between the two devices regarding the other outcome parameters such as intraoperative blood loss, volume of postoperative drainage, time of drain removal, and duration of hospital stay.

The only complication that reported in our study was the temporary hypocalcemia that was observed in two patients (6.66%) in each group. This rate is similar to what has been reported in literature.^[24-26]

No cases of hematoma or recurrent nerve palsy have been reported in this study which is similar to the results of other studies that reported very low incidence of these complications that depends mainly on the surgeon experience.^[27,28] The absence of these dangerous complications in this study may be because of the relatively small number of patients or may be because of the good hemostatic effect of both devices that maintained clear operative field and prevented postoperative bleeding.

Grajek ZW *et al.* compared three methods of hemostasis in thyroid surgery: monopolar, bipolar electro-surgical cautery, and ultrasonic scalpel. They suggested that the bipolar electro-surgical cautery is associated with less thermal effect leading to a significant reduction in the incidence of recurrent laryngeal nerve injury and postoperative hypoparathyroidism.^[29]

Although the financial and the technical comparison between the two devices are not the objective of this study, we observed that the BRFAD generator was simple with low-cost and designed to work with low-cost reusable hand pieces. While the ultrasonic scalpel generator has high cost because of its advanced technology and designed to work only with special expensive disposable hand piece. We observed the following

financial and technical points for both devices. According to the local sale price, the ultrasonic scalpel generator is more expensive, costs about (\$30,000), and designed to work only with an expensive disposable hand piece that costs about (\$900). While the BRFAD generator is less expensive, costs about (\$11,000), and designed to work with a less expensive reusable conventional bipolar cautery forceps that costs about (\$100). In addition, we observed that the fine tip of the BRFAD hand piece is more suitable for fine dissection than the relatively large jaws of the ultrasonic scalpel. Furthermore, the tip of the BRFAD hand piece remains cold even during firing unlike the ultrasonic scalpel hand piece which remains hot even after stopping firing for a significant time, which may cause an inadvertent burn injury to the patient and operating team.

These findings are in part in line with the results of Su L *et al.*, who compared the therapeutic effects of bipolar coagulation forceps with those of harmonic scalpel in open thyroid surgery. They suggest that, the low-cost, widely applicable bipolar coagulation forceps can decrease surgical expenses, have therapeutic effects similar to those of the harmonic scalpel, and also prevent complications.^[30]

Baldwin K *et al.* evaluated the application of bipolar radiofrequency ablation device (ENSEAL, Ethicon Endo-Surgery, Cincinnati, OH) for the hemostasis during thyroidectomy. They suggested that the function of this device is safe, effective in achieving secure hemostasis, and reducing operative time, with no increase in the rate of complications.^[31]

From the data above, we believe that the use of simple BRFAD with the conventional bipolar coagulation forceps for hemostasis in thyroid surgery in our study is novel in achieving significant reduction in operative time and in the cost of surgery, with no increase in the rate of complications. When compared with the current studies that either use the conventional electro-surgical cautery with conventional bipolar coagulation that can achieve the low-cost surgery but has a similar operative time to that of harmonic scalpel as in Su L *et al.*^[30] In another study, the investigators used an advanced BRFAD (ENSEAL, Ethicon Endo-Surgery, Cincinnati, OH) that is designed to work with an expensive disposable hand piece.^[31] This technique may achieve a significant reduction in operative time, but not in the cost of surgery in comparison to the conventional thyroidectomy. Furthermore, and up to our knowledge, there are no published clinical studies that directly compare the bipolar radiofrequency ablation device

with the ultrasonic scalpel in the hemostasis and dissection during thyroidectomy. Hence, our study may be the first small series in this topic.

Limitations of this study include the small sample size, short follow-up period, lack of blinding, and the fact that it was conducted in a single center.

CONCLUSIONS

The bipolar radiofrequency ablation device that can be used with conventional reusable bipolar cautery forceps is a simple, safe, and time-saving adjunct for thyroid surgeries and equally effective as compared to costly instruments such as ultrasonic scalpel.

CLINICAL SIGNIFICANCE

The bipolar radiofrequency device can be used in thyroid surgery to secure hemostasis, save time, and cost. It is a recent advance in thyroid surgery and may be considered as a suitable technique to be used by thyroid surgeons.

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Conflicts of interest

There are no conflicts of interest.

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