

SAFETY AND EFFICACY OF THE BIPOLAR RADIOFREQUENCY ABLATION DEVICE FOR HEMOSTASIS IN THYROIDECTOMY IN COMPARISON WITH THE CONVENTIONAL KNOT-TYING TECHNIQUE

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Abstract

The conventional method of hemostasis by using knot-tying technique is safe and effective in thyroid surgery but it is time consuming. A new energy devices like ultrasonic scalpel and advanced bipolar electro-surgical cautery have been proven to be safe and effective in shortening the length of thyroid surgery but the high cost of these advanced generators that designed to work only with an expensive disposable hand pieces, make its use difficult to justify in some hospitals. Radiofrequency ablation device is a refined type of electro-surgical cautery that utilizes a wave of electrons at a frequency between 2 and 4MHz to seal and divide the targeted tissue and the ablation property of this device act as an extra vessel sealing effect, it can be used with conventional reusable bipolar electro-surgical cautery hand pieces.

The aim is to evaluate the safety and efficacy of a simple bipolar radiofrequency ablation device for hemostasis in thyroidectomy in comparison with the conventional knot-tying technique.

This study was conducted in Alshiffa General Hospital following the approval of the local ethical committee. Fifty patients with different thyroid gland pathologies underwent total thyroidectomy in which hemostasis was achieved mainly with bipolar radiofrequency ablation device. The results of this group were compared with results of conventional knot-tying technique by the same surgical team at an earlier period.

This study showed that bipolar radiofrequency ablation device significantly reduced; mean operative time, amount of foreign suture material, significant reduction in the mean volume of postoperative drainage, early patient discharge from hospital, and less complications.

In conclusion, the use of the bipolar radiofrequency ablation device with conventional reusable bipolar cautery forceps for hemostasis in thyroidectomy is a safe, simple technique and effective in reducing the operative time in comparison with the conventional knot-tying technique.

Introduction

The thyroid gland is a highly vascularized structure, located adjacent to a very vital structures in the anterolateral aspect of the neck, so that hemostasis during thyroidectomy is a very important step to avoid

complications. Intraoperative bleeding if occur will obscures important anatomical structures such as the laryngeal nerves and parathyroid glands and increases the risk of their injury and the rate of morbidity. Postoperative bleeding may

cause airway compression and respiratory distress, as a result of laryngopharyngeal edema secondary to the impairment of venous and lymphatic drainage¹.

The conventional method of hemostasis by using knot-tying technique is safe and effective in thyroid surgery but it is time-consuming and the frequent clamping and tie may causes injuries to the adjacent vital structures, knot tie may slip leading to life threatening bleeding and the sutures that used in this technique are foreign materials may increase the incidence of wound infection².

In recent years, time-saving techniques are becoming a very important issue, especially for the turnover of patients in theatres and for using up less anesthesia time. Therefore, there is an interest in devices or techniques that reduce the need for conventional knot-tying or suture ligation for hemostasis³.

Recent advances in surgical technology included the use of new energy devices for hemostasis during surgery like advanced bipolar electro-surgical cautery and ultrasonic scalpel, these devices has been designed to seal blood vessel up to 7 mm in diameter⁴.

Recently these devices has been used in thyroid surgery for suture less thyroidectomy and there were several studies reported the successful use of these energy devices in shortening the length of thyroidectomy and reducing blood loss^{5,6}.

The standard conventional bipolar electro-surgical cautery is design to utilize electrical current in a frequency of less than 1 MHz, with this frequency the device is able to coagulate and seal a small vessels, with a diameter up to 3 mm but unable to divide the sealed vessel at the same firing so that there is a need to another instruments like the surgical scissor to divide the vessel, the newly published studies; proved the safety and cost effectiveness of the conventional bipolar cautery for sealing of the branches

of superior and inferior thyroid vessels during thyroidectomy with operative time still comparable to that of conventional knot-tying technique^{7,8}.

The bipolar radiofrequency ablation device is a refined type of electro-surgical cautery that utilizes an electrical current at a frequency between 2–4 MHz, with this frequency there is minimal tissue resistance to the passage of electrical current in the target tissue leading to agitation and friction movement between tissue ions leading to heat production, the tissue temperatures stay localized within a (60-100°C) leading to the fusion of collagen and elastin in the walls of the vessel with the creation of a permanent sealed zone without carbonization. In addition to that, the ablation property of radiofrequency current act as an extra vessel sealing effect by decreasing the diameter of blood vessel due to shrinkage of the collagen fibers in the vessel wall^{9,10}.

In this study, we evaluate the safety and efficacy of a simple bipolar radiofrequency ablation device for hemostasis in total thyroidectomy in comparison with the conventional knot-tying technique.

Patients and Methods

This study was conducted in Alshiffa General Hospital, Basrah, Iraq during the period from January 2016 to January 2018 and following the approval of the local ethical committee. Fifty patients with different thyroid gland pathologies underwent total thyroidectomy in which the hemostasis was achieved mainly with bipolar radiofrequency ablation device (BR group). The results of this group were compared with results of another selected group of fifty patients that underwent total thyroidectomy in which the hemostasis was achieved completely with the conventional knot-tying technique by the same surgical team at an earlier period (CT group). Patients with

previous thyroid surgery, very large or retrosternal goiter and patients with postoperative follow up period less than 8 weeks were excluded from the study.

All thyroidectomies had been done with Theodor Kocher procedure. Under general anesthesia 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 another, creation of sub-platysmal flaps, vertical incision of pretracheal fascia and separation of strap muscles, mobilization of thyroid lobes, all tributaries of middle thyroid vein and all terminal branches of superior thyroid artery, inferior thyroid artery and other unnamed vessels were sealed and divided near the capsule of thyroid gland with bipolar radiofrequency ablation device (Radiosurg 2200, ENT Version, 2.2 MHz, Meyer Haake, Germany, Figure 1) in BR group. In this group, the superior thyroid pedicle has been ligated proximally with an absorbable suture material then by using conventional reusable bipolar

cautery forceps that connected to this generator, each vessel was identified and dissected from surrounding tissues, then separately grasped gently with bipolar cautery forceps and coagulated and sealed in two proximal and one distal site. The sealed vessel was divided by grasping the vessel again in a midpoint between distal and proximal coagulated sites but with more mechanical pressure force on the jaws of the bipolar cautery forceps during firing of the radiofrequency generator and each vessel that re-bleed after division, will grasped with artery forceps and ligated with absorbable suture as an extra safety measure. In the conventional knot-tying technique group (CT group), all thyroid vessels has been double ligated with absorbable sutures and divided with surgical scissor.

Recurrent laryngeal nerve was identified on both sides and preserved, parathyroid glands were identified at least on one side and preserved in all possible conditions, vacuum drain has been used in all cases and the wound was closed in layers.



Figure 1: Bipolar Radiofrequency Ablation Device (Radiosurg 2200, ENT Version, 2.2 MHz, Meyer Haake, Germany,) with the small conventional reusable bipolar cautery forceps.

During operation; the operative time was calculated from start of skin incision to the end of skin closure and after completion of the operation; the anesthesiologist examined the vocal cord for documentation of any abnormality. following recovery from anesthesia, patients were transferred to the surgical

ward for observation and follow-up. The drain was removed when the drainage volume was less than 30ml after 24 hours. Patients were discharged from hospital after removal of the drain. All patients were re-examined at the end of the 1st week, 4th week and 8th week of postoperative follow-up period.

Perioperative data were recorded that's included; the patients characteristics in terms of gender, age, clinical diagnosis, thyroid ultrasound findings, histopathology results, results of ENT vocal cord examination before and after operation and the surgical procedure details involving the number of suture ligations that used to seal the thyroid blood vessels and the outcome of surgery in term of; duration of surgery, postoperative drainage volume, time of drain removal and the length of hospital stay. Also the complications in term of; postoperative recurrent laryngeal nerve palsy, symptoms of hypocalcemia (paraesthesia, muscle spasm, Chovstek's or Trousseau's signs) confirmed by serum Calcium <2.1 mmol/ml, hematoma formation, postoperative bleeding need for blood transfusion and/or reoperation and any intraoperative or postoperative mortality. Statistical Package for social science (SPSS. Statistics Version 20) was

used for data analysis. The results were directly compared between the two groups using the two-tailed t-test for quantitative variables and related samples Mc Nemar test for qualitative variables. Statistical significance was considered at $P < 0.05$.

Results

In this study; the patient's age, duration of surgery, number of suture ligations that used to seal thyroid blood vessels, duration of hospital stay, the volume of drainage and the time of drain removal were expressed in mean \pm SD, other patients characteristics like gender and the complications were expressed in frequencies.

There were no significant statistical differences in the patient's characteristics of both groups in term of the age, gender and the perioperative diagnosis as shown in table I.

Table I: Patients' age, gender and the diagnosis.

Characteristics	CT group (50 patients)	BR group (50 patients)	P-Value
Mean age (y) \pm SD	40.46 \pm 9.74 SD	40.27 \pm 10.05 SD	0.460
Gender (%)			
Male	10 (20%)	11 (22%)	0.125
Female	40 (80%)	39 (78%)	0.500
Total	50 (100%)	50 (100%)	
Diagnosis (%)			
Toxic goiter	14 (28%)	13 (26%)	0.250
Nontoxic goiter	36 (72%)	37 (74%)	0.450
Total	50 (100%)	50 (100%)	
Multinodular goiter	35 (70%)	36 (72%)	0.350
Diffuse goiter	14 (28%)	13 (26%)	0.250
Solitary nodule	01 (2%)	01 (2%)	1.000
Total	50 (100%)	50 (100%)	
Benign	48 (96%)	49 (98%)	0.650
Papillary ca.	01 (2%)	01 (2%)	1.000
Follicular ca.	01 (2%)	00 (00%)	0.500
Total	50 (100%)	50 (100%)	
Large goiter	12 (24%)	11 (22%)	0.200
Moderate goiter	31 (62%)	33 (66%)	0.320
Small goiter	07 (14%)	06 (12%)	0.720
Total	50 (100%)	50 (100%)	

The outcome of the procedure in terms of; mean duration of surgery, mean number of suture ligations, mean duration of hospital stay, mean duration of drain

removal and the mean volume of postoperative drainage per-drain are shown in table II.

Table II: The outcome of procedure in both groups.

The outcome factors	CT (50 patients)	BR (50 patients)	P-value
Duration of surgery Mean±SD (min)	98.13±14.16 SD	56.10 ± 14.16 SD	0.001
Number of suture ligations Mean±SD	18.12 ± 6.11 SD	2.18 ± 1.18 SD	0.001
Duration of hospital stay Mean±SD (hrs)	39.75 ± 14.13 SD	24.73 ± 14.19 SD	0.001
Duration of drain removal Mean±SD (hrs)	38.95 ± 18.22 SD	25.22 ± 14.82 SD	0.001
Volume of postoperative drainage Mean±SD (ml)	70.56 ± 12.27 SD	20.46 ± 12.37 SD	0.001

The frequency of complications of both procedures are shown in table III; five patients (10%) in CT group developed symptoms of temporary hypocalcaemia in comparison to 4 patients (8%) in BR group with no significant statistical difference (p-value 1.000); these cases were confirmed by serum Calcium <2.1 mmol/ml and treated with oral calcium

and Vit.D3 and resolved within few weeks. The other complication is the temporary RLN palsy which developed in one patient (2%) in each group, that was confirmed by ENT examination and treated conservatively and resolved within less than 8 weeks. No other complications were reported in our study.

Table III: The frequency of the complications in both groups.

Complications	CT (50 patients)	BR (50 patients)	P-value
Wound hematoma	0%	0%	
Temporary hypocalcaemia	5 (10%)	4 (8%)	1.000
Permanent hypocalcaemia	0%	0%	
Temporary RLN palsy	1 (2%)	1 (2%)	1.000
Permanent RLN palsy	0%	0%	
Postoperative bleeding that needs blood transfusion and/or reoperation	0%	0%	
Mortality	0%	0%	

Discussion

The bipolar radiofrequency ablation device with conventional reusable bipolar forceps significantly reduces mean operative time of total thyroidectomy to (56.10 ±14.16 minutes) in comparison to

(98.13±14.16 minutes) that reported in conventional knot-tying technique. With this device we are saving about (42 minutes) from the operative time for total thyroidectomy, these results were similar

to published result^{10,11}. This reduction in the operative time may be due to in part to the ablation effect of the radiofrequency current that leading to a rapid and secured sealing of blood vessels without the need for the time consuming excessive suture ligations which are significantly reduced by using bipolar radiofrequency ablation device to (2.18±1.18) vs (18.12±6.11) for conventional knot-tying technique. the other factor that reduce operative time may be due to the use of the same bipolar cautery forceps for the dissection, sealing and division of the blood vessels and thyroid tissue without the need to use another instruments to dissect or to divide the coagulated tissues.

The other benefits of using bipolar radiofrequency ablation device for hemostasis in this study, is the significant reduction in the mean volume of postoperative drainage per drain (20.46±12.37 ml) vs (70.56±12.27 ml) for conventional knot-tying technique, this result leading to an early removal of drain in bipolar radiofrequency group (25.22±4.82 hrs) vs (38.95±18.22 hrs) for conventional knot-tying group and also early patient discharge from hospital in bipolar radiofrequency group; (24.73±14.19 hrs) vs (39.75±14.13 hrs) for conventional knot-tying group, the published studies also reported similar findings^{11,12}. This significant reduction in the amount of postoperative drainage

may be due to the ablation property of bipolar radiofrequency device that seal even the micro blood vessels in the raw area after excision of thyroid gland.

With respect to the postoperative complications; the only complications that reported in this study are the temporary hypocalcaemia and the temporary recurrent laryngeal nerve palsy and there were no significant difference in the rate of these complications between both groups; 5 patients (10%) in bipolar radiofrequency group developed symptoms of temporary hypocalcaemia vs 4 patients (8%) in conventional knot-tying technique group, while 1 patient (2%) in each group developed symptoms of temporary RLN palsy, these results goes with the published data^{13,14}.

No cases of permanent hypocalcaemia, permanent RLN palsy, postoperative bleeding or hematoma were reported in this study. The absence of these complications in our study; may be due to the relatively small number of patients and to the very low incidence of these complications in the published studies^{1,15}.

In conclusion, the use of the bipolar radiofrequency ablation device with conventional reusable bipolar cautery forceps for hemostasis in thyroidectomy is a safe, simple and effective technique in reducing the operative time in comparison with the conventional knot-tying technique.

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