

IMPACT OF THE HARMONIC SCALPEL HEMOSTASIS IN TOTAL THYROIDECTOMY IN COMPARISON WITH CONVENTIONAL HEMOSTATIC TECHNIQUE

Sadq Ghaleb Kadem* & Raheem Sharhan Balasim@

*MB,ChB, FICMS. @MB,ChB, FICMS, Department of Surgery, Al-Shiffa General Hospital, Basrah, IRAQ.

Abstract

Traditional haemostatic technique in thyroidectomy may cause some damages to surrounding tissues and it is time consuming. It is believed that these damages and the time can be reduced using ultrasonic dissector devices like Harmonic Scalpel.

In this study, we investigate the benefits of harmonic Scalpel haemostasis (HS) versus conventional haemostatic techniques (CT) in total thyroidectomy.

Analysis of patient's data was done for cases with total thyroidectomies performed between 2011 and 2015 by the same surgeons using either the conventional technique (Clamp and Tie technique) or the harmonic scalpel for haemostasis. Gender, age, preoperative clinical information, histopathology results, and procedure type were analyzed. and according to the type of haemostatic techniques the collected patient's data was divided into two groups; conventional group (CT group) in which the haemostasis was done with Clamp and Tie technique and harmonic scalpel group (HS group) in which the haemostasis was done with Harmonic Scalpel (Sonicbeat Olympus). The outcome and the complications of the both procedures were analyzed statistically and compared.

The use of harmonic scalpel in total thyroidectomy significantly decreases mean operative time by (-37.635 min) 60.49 ± 7.78 SD for HS group vs 98.13 ± 14.165 SD for CT group with very significant P-value (0.0000). Statistical significant difference in the mean volume of postoperative drainage in (ml) through redivac drain observed between the two groups; 63.02 ± 19.91 SD for HS group and 72.50 ± 22.79 SD for CT group with significant P-value (0.0000). There were no significant difference in the other parameters of the outcome and complications after total thyroidectomy in both groups.

It is concluded from this study that main impact of harmonic scalpel in total thyroidectomy is the significant reduction in operative time and its use is safe and not associated with increase in the rate of the complications.

Introduction

Thyroidectomy is one of the frequent operation done over the world. In 952 AD, the first goiter excision had been done by Islam's medieval surgeon from Andalusia, Abu al-Qasim al-zahrawee as mentioned in his book "Al-Tasrif".

A thousand years later, Theodor Kocher "Father of Thyroid Surgery" describes a safe procedure for thyroidectomy and from that time till now this procedure still valid and considered as a gold standard procedure for thyroidectomy¹.

In recent years and despite the revolution in modern surgical procedures toward

minimal invasiveness, the original conventional (Theodor Kocher) thyroidectomy remain the only widely accepted procedure and the only accepted changes on this procedure is the method of haemostasis²⁻⁴.

The methods of haemostasis and ligation of blood vessels during conventional thyroidectomy involves using either frequent clamp and tie with sutures, metal clips or electrocautery, these conventional methods are time consuming and may be associated with complications; frequent clamp and tie may injure the nearby vital

structures and knot tie may slip leading to life threatening bleeding, metal clips also may dislodge leading to bleeding or erode into adjacent vital structures, sutures and clips are foreign materials may increase the incidence of wound infection, on other hand the use of conventional electrocautery for haemostasis might cause inadvertent injury to vital nearby structures by lateral thermal spread⁵.

Recently; ultrasonic energy devices like, harmonic scalpel was developed in early 1990s, this innovative device use ultrasonic energy to create mechanical vibration at a frequency of 55.5 kHz between the two jaws of the device, this friction mechanism produce 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 up to 5 mm at the same time with minimal lateral thermal spread⁶.

Although the initial use of the harmonic scalpel was in laparoscopic surgery, Published studies suggest that the function of harmonic scalpel in thyroid surgery is safe and effective in decreasing operative time⁷⁻⁸.

The objective of this study is to evaluate the outcome and the complications of the harmonic scalpel haemostasis in total thyroidectomy in comparison with the conventional haemostasis (clamp and tie with sutures) in term of operative time, duration of hospital stay, volume of postoperative drainage, time of drain removal and the postoperative complications like hypocalcaemia, recurrent laryngeal nerve palsy, postoperative haematoma or seroma, postoperative bleeding need blood transfusion and/or reoperation and any intraoperative or postoperative mortality.

Patients and Methods

This study was conducted in Al-Shiffa General Hospital and Surgeon Private Clinic in Basrah, Iraq; and following the approval of the local ethical committee.

Data sheets of patients underwent total thyroidectomies operated by same surgeons in the department of surgery from January 2011 until October 2015 were reviewed.

Perioperative data that was retrieved from surgeon's notes and surgical documentation sheets in the hospital and private clinic follow-up sheets, including the total number of patients, patients characteristics in term 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 and the outcome of surgery in term of; duration of surgery, postoperative drainage volume, time of drain removal and the length of hospital stay and the complications in term of; postoperative recurrent laryngeal nerve palsy, symptoms of hypocalcemia (paraesthesia, muscle spasm, Chovstek's or Trousseau's signs) confirm by serum calcium <2.1 mmol/ml, haematoma or seroma formation, postoperative bleeding need blood transfusion and/or reoperation and any intraoperative or postoperative mortality.

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 done midway between suprasternal notch and thyroid notch and extended from one sternomastoid muscle to another, creation of subplatysmal flaps, vertical incision of pretracheal fascia and separation of strap muscles, mobilization of thyroid lobes, closure of blood vessels supplying thyroid gland, dissection and excision of thyroid gland and closure of the wound in layers.

According to the method of haemostasis used to closed the blood vessels supplying thyroid gland and dissection of thyroid lobes during thyroidectomy, the cases of total thyroidectomies in this study were divided in to two groups; conventional group (CT group) in which the haemostasis was done with Clamp and Tie

technique and harmonic scalpel group (HS group) in which the haemostasis was done with Harmonic Scalpel (Sonicbeat Olympus), the selection of the technique for haemostasis depend on the availability of harmonic scalpel handpieces in our hospital.

Exclusion criteria includes: patients with history of previous thyroid surgery, patients with postoperative follow-up less than 8 weeks and patients with operative time not documented in the operative notes.

The Statistical Package of (IBM. 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

Two hundred cases of total thyroidectomies were included in this study with 96 (48%) procedures using conventional technique for haemostasis (CT group) and 104 (52%) procedures using harmonic scalpel for haemostasis (HS group).

The patient's age, duration of surgery (min), duration of hospital stay, the volume of drainage (ml) and the time of drain removal are expressed in mean \pm SD other patients characteristics like gender and the complications are expressed in frequencies.

The patient's age, gender and the diagnosis are summarized in table I.

No significant statistical differences were observed among the groups in terms of age, gender or diagnosis.

Table I: Patient's age, gender and the diagnosis.

Patients characteristics	HS group (n= 104)	CT group (n =96)	P-value*
Mean age (y) \pm SD	40.27 \pm 10.05 SD	40.46 \pm 9.74 SD	0.460 = NS
Gender (%)			
Male	25 (24.03%)	21 (21.87%)	0.500 = NS
Female	79 (75.96%)	75 (78.12%)	0.125 = NS
Total	104 (100%)	96 (100%)	
Diagnosis (%)			
Toxic goiter	35 (33.65%)	32 (33.33%)	0.250 = NS
Non toxic goiter	69 (66.34%)	64 (66.66%)	0.125 = NS
Total	104 (100%)	96 (100%)	
Multinodular goiter	73 (70.19 %)	67 (69.79%)	0.125 = NS
Diffuse goiter	28 (26.92%)	27 (28.12%)	1.000 = NS
Solitary nodule	3 (2.88%)	2 (2.08%)	1.000 = NS
Total	104 (100%)	96 (100%)	
Benign	100 (96.15%)	94 (97.95%)	0.630 = NS
Papillary ca.	2 (1.92%)	1 (1.04%)	1.000 = NS
Follicular ca.	2 (1.92%)	1 (1.04%)	1.000 = NS
Total	104 (100%)	96 (100%)	
Large goiter	27 (25.96%)	25 (26.04%)	0.500 = NS
Moderate goiter	53 (50.96%)	48 (50%)	0.630 = NS
Small goiter	24 (23.07%)	23 (23.95%)	1.000 = NS
Total	104 (100%)	96 (100%)	

* P-value < 0.05 = significant difference

The outcome of the procedures in both groups was shown in table II. Regarding the duration of surgery; the mean

operative time (min) for HS group was 60.49 ± 7.78 SD while for CT group was 98.13 ± 14.165 SD with significant

statistical difference P-value (0.0000)** ie (harmonic scalpel reduce operative time by 37.635 minutes) as shown in figure 1. Significant statistical difference in the mean volume of postoperative drainage in (ml) through redivac drain also observe between the two groups; 63.02±19.91SD

for HS group and 72.50 ± 22.79 SD for CT group with P-value of (0.0000)* ie (harmonic scalpel reduce volume of drainage by -9.48 ml) as shown in figure 2. There were no significant difference in the mean duration of hospital stay or the mean duration of drain removal.

Table II: The outcome of procedure in both groups.

Outcome factors	HS(n=104)	CT(n=96)	P-value
Mean duration of surgery (min)± SD	60.49±7.78SD	98.13±14.165SD	0.000*
Mean duration of hospitalization (hr) ±SD	24.25± 2.44SD	24.75 ± 4.197SD	0.320
Mean duration of drain removal (hr) ±SD	24.50± 3.44SD	25.00 ± 4.821 SD	0.417
Mean volume of postoperative drainage per drain (ml) ±SD	63.02±19.91SD	72.50± 22.79 SD	0.000*

*P- value <0.05=significant difference

Figure 1: Mean duration of surgery in both groups:

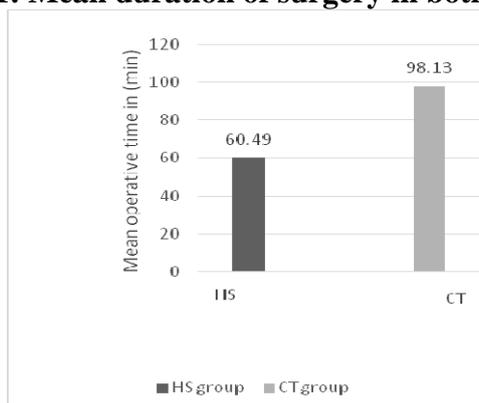


Figure 1: The mean operative time (min) for HS group was 60.49±7.78 SD while for CT group was 98.13±14.165 SD with significant statistical difference P-value (0.0000)* ie (the operative time for HS was shorter than that for CT by 37.635 minutes)

Figure 2: The mean volume of postoperative drainage (ml)

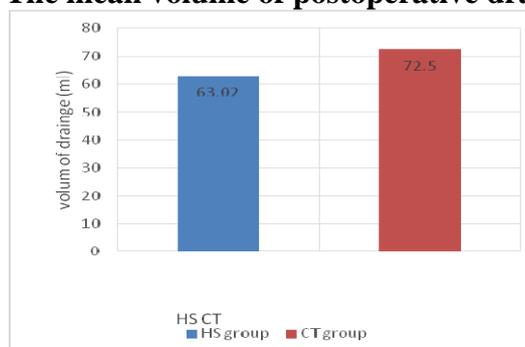


Figure 2: The mean volume of postoperative drainage (ml) was 63.02 ±19.91SD for HS group and 72.50 ±22.79 SD for CT group which is significant statistical difference, P-value (0.0000) *, ie (the volume in HS is 9.48 ml less than CT)

The frequency of complications of the procedures in both groups were shown in table III; two patients in each group developed mild postoperative seroma (1.9% for HS group vs 2.08% for CT group with no significant statistical difference P value=1.000), all cases in both groups were treated conservatively and resolved in few days. Ten patients (9.61 %) for HS group vs 9 patients (9.37 %) for CT group (with no significant statistical difference P value=1.000) developed symptoms of temporary hypocalcaemia and confirm by serum Calcium < 2.1 mmol/ml, were treated with

oral calcium and vit. D3 and resolved within few weeks. One patient in each group was developed temporary RLN palsy (0.96% for HS group vs 1.04% for CT group with no significant statistical difference P value =1.000) were confirmed by ENT examination and treated conservatively and recover within few weeks. In both groups; there were no intraoperative or postoperative mortality, no patients need blood transfusion or reoperation for postoperative bleeding, no patients complain of permanent hypocalcaemia or permanent recurrent laryngeal nerve palsy.

Table III: the complications in both groups:

Complications	HS (n=104)	CT (n=96)	P-value
Wound haematoma or seroma (%)	2 (1.9 %)	2 (2.08 %)	1.000 = NS*
Temporary hypocalcaemia (%)	10 (9.61 %)	9 (9.37 %)	1.000 = NS*
Permanent hypocalcaemia (%)	Zero	Zero	
Temporary RLN palsy (%)	1 (0.96 %)	1 (1.04 %)	1.000 = NS*
Permanent RLN palsy (%)	Zero	Zero	
Postoperative bleeding need blood transfusion and/or reoperation (%)	Zero	Zero	
Mortality (%)	Zero	Zero	

* P-value <0.05 =significant difference. NS* =not significant

Discussion

Our results reported significant reduction in the mean duration of surgery by proximately 37.635 minutes with the use of harmonic scalpel compared to the conventional technique, these results was similar to the international results that show significant reduction in the mean duration of thyroidectomy procedure with the use of harmonic scalpel. Regarding the mean duration of hospital stay and mean duration of drain removal, our study reported no significant difference between the use of harmonic scalpel and the use of the conventional technique, again these results goes with the results of the published studies⁸⁻¹¹.

With respect to the postoperative drainage volume, published studies reported significant reduction in the mean of the postoperative drainage volume with use of harmonic scalpels¹², our results also

report a small reduction in the mean volume of the postoperative drainage in the HS group in comparison with the CT group but this reduction has no clinical significant impact in the outcome in term of duration of hospital stay and duration of drain removal.

The most important complications of total thyroidectomy are the recurrent nerve palsy, hypocalcemia and postoperative haematoma with variable rate depend mainly on the surgeon experience¹³⁻¹⁵.

In our study, we found no permanent recurrent laryngeal nerve palsy, however, there were few cases in both groups develop transient recurrent nerve palsy with no significant statistical difference and both of these results are similar to published results^{16,17}.

Permanent hypocalcemia was not reported in our study, and the reported difference rate of the transient

hypocalcemia between the two groups was not statistically significant and this results was similar to the published results¹⁸⁻²².

According to the published literatures, the rate of postoperative haematoma and seroma was (0% and 2.5%)²³⁻²⁵, our results also reported same findings with no significant statistical difference between two groups; 2 patients (1.9% for HS group) and 2 patients (2.08% for CT group), the haematoma and seroma were absorbed spontaneously within few days without reoperation.

Harmonic scalpel has been approved by published studies to have better haemostatic effect in comparison to

conventional technique^{26,27}, our results does not report any cases of intraoperative or postoperative bleeding who need blood transfusion or reoperation in both groups.

No mortality was reported in our study while published data reported negligible mortality due to thyroidectomy²⁸.

Conclusion

The main significant impact of this ultrasonic energy device in total thyroidectomy is the significant reduction in operative time in comparison to conventional haemostatic technique and it's use is safe and not associated with increase in rate of complications.

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