



Total thyroidectomy: Conventional Suture Ligation technique versus sutureless techniques using Harmonic Scalpel or Maxium



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HIGHLIGHTS

- HS and MAX are safe useful and fast alternatives to conventional techniques in total thyroidectomy.
- These two devices facilitate surgical procedures and cancel any need for clips and suture ligations.
- They significantly reduce operative time without increases in the amount of blood losses and hospital stay.
- Probably the only disadvantage of these two devices is the cost of the single-use devices.

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ABSTRACT

Objectives: Harmonic Scalpel (HS) and Maxium (MAX) are surgical shears that enable simultaneous vessel sealing and tissue coagulation. This study compares the outcome of Total Thyroidectomy (TT) using Conventional Suture Ligation (CSL) technique versus (vs) two sutureless techniques; H S and MAX techniques in terms of safety, operative time, blood drainage volume, hospital stay and surgical complications.

Study design: This is a prospective observational cohort study.

Setting: This study was performed in AL-Karama Teaching Hospital/College of Medicine/University of Wasit/Iraq.

Patients and methods: This study was performed from June 2012 to 2015. A total of 80 patients, 60 patients were females and 20 patients were males (average/mean of age was 39/38 years). They underwent TT after been randomized into the following three groups: CSL group when Suture Ligation Technique was used, HS group when Harmonic Scalpel was used and MAX group when bipolar electro-surgery Maxium was used.

Results: The postoperative evaluation of operative time, blood drainage volume and surgical complications revealed no statistically significant differences between HS group & MAX group, but there were statistically significant differences between CSL group vs. HS and MAX groups. Operative time statistics showed significant differences between CSL vs. HS and MAX groups, 113 ± 10.9 minutes (min), 93 ± 13 min and 92 ± 10.6 min respectively, p -value < 0.001 and 95% confidence interval [CI] (92.3712, 101.6288). The postoperative blood drainage volumes were significantly different between the three groups: CSL group = 150 ± 12.7 ml, HS group = 89 ± 16.21 ml and MAX group = 118 ± 9.6 ml, P -value = 0.046 and 95% [CI] (89.9932, 99.6068).

Conclusions: HS and MAX are safe, effective, and time-saving techniques. They are also associated with low blood loss and low complication rates. HS and MAX are good alternative techniques to CSL for thyroid surgery.

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1. Introduction

TT is the commonest operation in the field of endocrine gland surgery. It is the most convenient therapeutic choice in the treatment of many thyroid disorders through surgical interference [1,2].

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A careful hemostasis is a priority for thyroid surgeons to avoid possible complications [3]. In addition to priority above, operative time-saving modulations became an increasingly significant factor [4]. A careful hemostasis prohibits bleeding in the site of surgery enabling the surgeon to have a clear and dry operative field. Hence, it decreases the potential trauma to parathyroid glands and laryngeal nerves, also it reduces potential risky postoperative bleeding [2]. Hemostasis achieved with classic methods such as tie and clamp, electrocautery, clips or glue of fibrin is time consumption and loaded with hazard of knot slipping, unsettlement and thermal trauma [5].

Vascular Sealing Devices (VSD), used during last decade seal vascular structures by coagulating them. The coagulated vessels will be ready to be safely transected without need for additional ligation. Although, VSDs are not appropriate for big and main vessels, they still able to coagulate all vessels faced intraoperatively for surgery of thyroid gland. They show an important reduction in time of operation [6]. Although, the cost is elevated, so it has been reported by some authors that this elevated cost is equiponderant with minimizing time of the operation [7].

VSD considerably assists endoscopic thyroid surgery [6]. Harmonic Scalpel (HS) is ultrasonically activated coagulation shear using ultrasound waves of a high-frequency (55 kHz) that can cut vessels of diameters up to 5 mm (mm). The active blade of HS vibrates in a longitudinal way against an inactive blade resulting in cutting and coagulation. It works at a comparatively low temperature (80 °C), hence there will be less thermal trauma to tissues in surrounding area than laser and electrocautery [8]. The innovation of Harmonic Scalpel is a great achievement as device for many views and now it is hugely used in laparoscopic surgery easing operations, time-saving and decreasing complications [9].

During last decade, many ergonomic and technical changes were made depending on experience of the surgeons who used HS, these changes led to improve hemostasis and dissection of tissue [10].

This study also used a new device Maxium which is a bipolar electro-surgical radiofrequency device with hemostatic mechanism causing a biologic seal that tightly closes the vessels.

1.1. Aim of the study

The study aims to compare use of both H S and Max versus CSL in thyroid surgery for 80 patients. This comparison was in terms of operative time, drainage volume, analysis of surgical complications and duration of hospital stay.

2. Patients and methods

The study started from 1st of June 2012 to 1st of June 2015. Eighty patients were complaining of thyroidal disease with need to surgical treatments. All 80 patients were enrolled in this study. This study was performed in AL-Karama Teaching Hospital/College of Medicine/University of Wasit/Iraq. The exclusion criteria of this study are the need for central or lateral compartment lymphadenectomy, previous neck irradiation, recurrent goiter, ablation with radioiodine and malignant goiters.

The study design: It was a prospective observational cohort study analyzing outcomes of TT using CSL technique vs. HS and MAX techniques.

Setting: This study was performed in AL-Karama Teaching Hospital/College of Medicine/University of Wasit/Iraq. Randomization was performed by Quasi random allocation using sequentially numbered patient in a parallel group way. Each patient was numbered either 1, 2, or 3 in order to allocate which technique was to be used for them, patient number 1 was treated by CSL

technique, patient number 2 was treated by sutureless technique using HS (produced by Soring, Germany) and patient number 3 was treated by sutureless technique using Max (produced by KLS martin group, Germany). Then patient number 4 was treated by CSL technique and so on, sequentially. The eighty patients who underwent TT signed and gave informed consent to be enrolled in the study. Preoperatively, the patients were clinically and biochemically evaluated, in addition to vocal cord mobility checking. All surgical procedures were performed under general anesthesia with endotracheal intubation. After division of platysma muscle, cervical linea alba was opened. Very large goiters necessitated division of strap muscles. The lobe of thyroid gland was progressively dissected away from strap muscles, its vascular pedicles were ligated with Vicryl 2/0 suture or coagulated and divided with HS or MAX. The thyroid lobe was progressively dissected off trachea after the recurrent laryngeal nerves and parathyroid glands were identified and dissected off the thyroid capsule (Fig. 1). After securing hemostasis, a suction drain was routinely put in the thyroid bed as a part of the study protocol to measure amount of blood loss during the first 48 h. The cervical linea alba and platysma muscle were closed with Vicryl 3/0 and the skin was closed by an intracutaneous running suture.

Preoperative data concerning age, gender, thyroid pathology and preoperative serum calcium were prospectively recorded. The surgical time was estimated in minutes from incision of skin to skin closure. The postoperative evaluation comprised analysis of both, the characteristics of preoperative and postoperative parameters (operative time, drainage volume, postoperative serum calcium levels, surgical complications (laryngeal nerve palsy, hypoparathyroidism, bleeding and wound infection), length of hospital stay, reoperations and histopathologic diagnosis. Serum calcium levels were monitored on the 1st, 2nd 10th and 30th days postoperatively. Hypocalcaemia was known as a serum calcium level below 8.0 mg/dL (2.00 mmol/L) (reference range, 8.0–10.5 mg/dL [2.00–2.60 mmol/L]) [11]. Hypoparathyroidism was known as a requirement for calcium or vitamin D administration. Regarding Recurrent Laryngeal Nerve (RLN) palsy, when there was no evidence of recovery within 6 months of follow up postoperatively, a

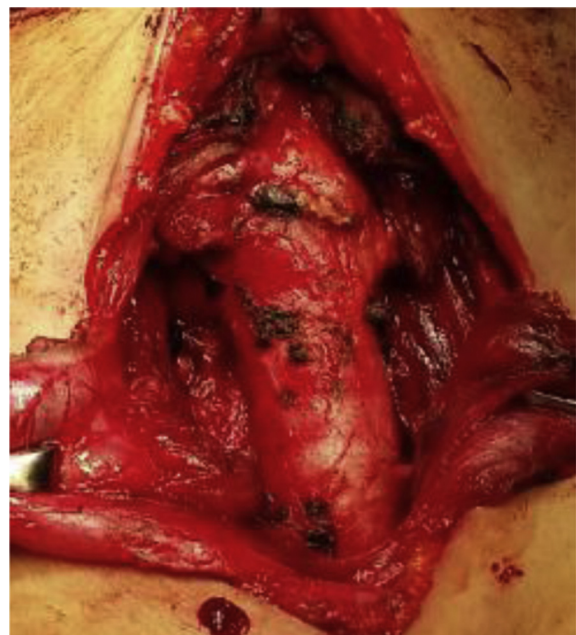


Fig. 1. Sutures less TT by Maxium.

permanent RLN palsy was recorded [12].

The patients were usually discharged on the 2nd or 3rd post-operative day.

2.1. Statistical analysis

The results were processed and analyzed by using SPSS, version 18; unpaired T test and Fischer's exact test. The level of significance was accepted at $P \leq 0.05$, highly significant at $P < 0.01$ and non-significant at $P > 0.05$.

3. Results

Eighty patients (60 women, 20 men) underwent TT. According to the surgical technique that has been used, the patients were randomized into 3 groups: 26 patients by CSL technique (CSL group), 26 patients by HS (HS group) and 28 patients by Maxium (MAX group). The patient's characteristics & preoperative evaluation between the three groups are shown in Table 1.

There were no significant differences between the three groups regarding age, sex and serum calcium levels. Twenty patients (25%) were males and 60 patients (75%) were females. Preoperative fibrotic examinations revealed that:

- Three out of 80 patients (3.7%) had unilateral Recurrent Laryngeal Nerve (RLN) palsy.
- Nine out of 80 patients (11.2%) had retrosternal goiters that were thyroidectomised through the cervical approach.
- Eight out of 80 patients (10%) had thyrotoxicosis medically converted to a euthyroid status.
- Six out of 80 patients (7.5%) had hypothyroidism medically converted to a euthyroid status. (Table 1)

Regarding the operative time, there was no significant difference (p -value > 0.05) between HS group and MAX group; mean and SD were (93 ± 13 m and 92 ± 10.6 m) respectively, but there was a significant statistical difference (p -value < 0.05) between CSL vs. HS and MAX groups; mean and SD were (113 ± 10.9 m vs. 93 ± 13 m, 92 ± 10.6 m) respectively, P -value < 0.001 with 95% confidence interval [CI] (92.3712, 101.6288). The postoperative drainage volumes were significantly different between the three groups, Mean and SD were; CSL group = 150 ± 12.7 ml, HS group = 89 ± 16.21 ml and MAX group = 118 ± 9.6 ml, P -value = 0.046, 95% [CI] (89.9932, 99.6068).

The average hospital stay was similar in the three groups CSL, HS & MAX; mean and SD were; 2.7 ± 0.6 day, 2.6 ± 1 day and 2.8 ± 0.7 day respectively, P -value = 0.268, 95% [CI] (2.42197, 2.77803). This study had neither reoperation nor mortality (Table 2).

Regarding types of RLN palsy, there were statistically no significant differences between groups HS & MAX, but there were statistically significant differences between CSL groups vs. HS & MAX groups.

Regarding transient and permanent hypocalcaemia, statistically, there were no significant differences between HS & MAX groups, but there was statistically a significant difference between CSL group vs. HS & MAX groups; transient hypocalcaemia: 8,4 and 5 respectively, permanent hypocalcaemia; 1,0 and 0 respectively, P -value < 0.01 . Most patients with transient hypocalcaemia improved within 3 weeks–6 months when they were kept on oral Calcium & Vitamin D. One patient developed permanent hypocalcaemia (1.2%).

Regarding postoperative bleeding, there were statistically no significant differences between HS and MAX groups but there was statistically a significant difference between CSL group vs. HS and MAX groups; 3, 1 and 1 respectively (P -value < 0.01). These bleeds spontaneously stopped (Table 3).

The histopathological examination of thyroidal specimens revealed, 76 patients (95%) had benign multinodular goiters, while 4 patients (5%) had unexpected thyroidal malignancies confined to the thyroid gland with no need for further surgical intervention. These 4 patients with unexpected malignancies one patient had lymphoma, one patient had follicular carcinoma and two patients had papillary carcinoma (Table 4).

4. Discussion

It is clear and self-evident that there was a difficulty in performing a randomized controlled trial in comparing surgical techniques. The outcomes of a novel technique can be confused by the learning curve phenomenon. Once the novel mechanism is set up, the interests may be seen, and at this point randomization becomes difficult [8].

Sutureless thyroidectomy not only reduces the operative time, but it also reduces the iatrogenic complications like neurovascular injuries around the thyroid gland [11].

HS uses high frequency mechanical energy with advantage of coagulating and cutting tissues simultaneously. It seals vessels up to 5 mm in diameter offering a precise and accurate surgical dissection as in the thyroid surgery with a great saving of operative times. Its lateral thermal damage is limited up to 2 mm beyond the tissue grasped within the forceps of the device [2].

Maxium is a diathermy system newly introduced as hemostatic system for both open and endoscopic surgical procedures that operates through permanently sealing vascular structures up to 7 mm in diameter [12].

This study showed operative times of CSL, HS & Max groups; a mean \pm SD were 113 ± 10.9 m, 93 ± 13 m and 92 ± 10.6 m

Table 1
Patient's characteristics & pre-operative evaluation.

Evaluation parameters	CSL group	HS group	MAX group	Total	%
Number of patients	26	26	28	80	
Mean of age (yr.)	35	41	38	38	
Males	6	6	8	20	25
Females	20	20	20	60	75
Preoperative calcium (mg/dl)	9.40	9.65	9.36		
Retrosternal goiter	3	2	4	9	11.2
Vocal cord status:					
Unilateral palsy	1	0	2	3	3.7
Bilateral palsy	0	0	0	0	0.0
Thyroid function:					
Thyrotoxicosis	2	2	4	8	10
Hypothyroidism	3	1	2	6	7.5

Table 2
Postoperative evaluation.

Postoperative parameters	CSL group	HS group	MAX group	Total	P-value
Patients	26	26	28	80	
Operative time (min)	113 ± 10.9	93 ± 13	92 ± 10.6	99 ± 14.9	0.000
Postoperative calcium (mg/dl)	7.68 ± 2.87	8.3 ± 0.62	8.16 ± 1.1	8.06	0.049
Drainage volume (mls)	150 ± 12.7	89 ± 16.21	118 ± 9.6	118 ± 6.2	0.046
Hospital stay (days)	2.7 ± 0.6	2.6 ± 1	2.8 ± 0.7	2.7 ± 0.8	0.268
Reoperation	0	0	0	0	
Mortality	0	0	0	0	

Table 3
Postoperative surgical complications.

Postoperative surgical complications	CSL group	HS group	MAX group	Total/%	P-value
Number of patients	26	26	28	80	
Transient RLNpalsy:					
Unilateral	2	1	1	4	5%
Bilateral	1	0	1	2	2.5%
Permenant RLNpalsy:					
Unilateral	2	0	1	3	3.7%
Bilateral	1	0	0	1	1.2%
Hypocalcemia:					
Transient	8	4	5	17	23.7%
Permanent	1	0	0	1	1.2%
Postoperative bleeding	3	1	1	5	6.03%
Wound infection	2	0	1	3	3.75%
Total	21	7	11	39	48.7%

Table 4
Histopathological distribution.

Patients/histopathology	CSL group	HS group	MAX group	Total	%
Patients	26	26	28	80	
Benign multinodular goiters	25	25	26	76	95%
Unexpected malignancy	1	1	2	4	5%

respectively with a mean ± SD of the total 99 ± 14.9 m. The operative times of HS and MAX groups were comparable, but they were shorter than that of CSL group with statistically significant difference, P-value < 0.001. The operative times of our three groups were longer than those of Peker et al. [12] study; Conventional Technique (CT), HS and LigaSure mean and SD were 92.92 ± 12.12, 60.13 ± 12.98 and 60.66 ± 11.90 respectively with P-value = 0.00. Peker et al. study agreed with this study results, and showed comparable operative times of Harmonic and LigaSure groups, but they were shorter than that of Conventional Technique (CT) group. Chang et al. [13] studied 1945 patients who underwent TT (1163 using a suturesless technique with Ligasure or Ultracision), and he observed no statistical difference in postoperative complications, but the mean of operative time was significantly lower in the suturesless groups. Nani Harlina – Md Latar [14] et al. study showed an average operative time of 121.29 m, while in this study the operative time was shorter; mean ± SD 99 ± 14.9 m. Allan E Seperstien et al. [15] study had longer operative time than this study; CT group, HS group; mean and SD 161 ± 42 m, 132 ± 39 m respectively with statistically significant difference P-value = 0.01. Zarebczan [16] in 231 patients observed no statistical difference in rate of complications between HS group and LigaSure group, but reduction of operative time in the HS group.

This study showed postoperative blood drainage volume for first postoperative 48 h; CSL, HS & MAX groups; mean ± SD, 150 ± 12.7 ml, 89 ± 16.21 ml and 118 ± 9.6 respectively with a mean ± SD of the total was 118 ± 6.2 ml. CSL group had the largest drainage volume, while HS group had the smallest drainage volume with statistically significant difference P-value = 0.046.

Peker et al. [12] study showed that the first 24 h postoperative drainage volumes; CT, HS and LigaSure; mean ± SD 48.18 ± 12.10, 47.45 ± 14.71 and 45.53 ± 10.87 respectively. These were much lower than ours because they were collected for the first 24 h. Statistically, there was no significant difference because P-value = 0.447.

Emanuele F et al. [11] study had a total drainage fluid volume lower in HS group than in CT group; mean ± SD 37.4 ± 2.4 versus 56.1 ± 4.2 respectively.

Regarding the hospital stay, the three groups; CSL, HS, MAX showed comparable hospital stays; mean ± SD 2.7 ± 0.6 day, 2.6 ± 1 day and 2.8 ± 0.7 day respectively with average of 2.8 ± 0.7 days with no statistically significant difference, P-value = 0.268, while Peker et al. [12] study showed comparable hospital stays in the three groups; CT, HS and LigaSure 1.7 ± 0.60 day, 1.7 ± 0.65 day and 1.8 ± 0.78 day respectively with no statistically significant difference P-value = 0.315. Nadim Khan et al. [17] reported average hospital stay of 3.1 day with a mean ± SD = 2.2 ± 0.9 days in HS group; 3.7 ± 1.3 days in CT group.

Regarding RLN palsy, this study had 10 out of 80 (1.25%) patients with RLN palsy; 4 patients (5%) had transient unilateral RLN palsy, 2 patients (2.5%) had transient bilateral RLN palsy, 3 patients (3.7%) had unilateral permanent RLN palsy and one patient (1.2%) had bilateral permanent RLN palsy. CSL group had 6 (60%) patients, HS group had one (10%) patient and MAX group had 3 patients (30%). CSL group had the highest RLN palsy (60%), while HS had the lowest RLN palsy (10%). G. Docimo et al. [6] study had a comparable transient RLN palsy; HS one patient, LigaSure one patient, while our study showed that HS group had one patient, MAX group had two patients, but CSL group had 5 patients with transient RLN palsy and one patient with permanent RLN palsy.

Regarding parathyroid function, postoperative mean ± SD of serum calcium levels among our three groups were CSL, HS and MAX, 7.68 ± 2.87, 8.3 ± 0.62 and 8.16 ± 1.1 respectively. The statistical difference was significant, P-value = 0.049. The means of postoperative calcium levels of HS and MAX groups were comparable, but that of CSL group was low. This study had 17 out of 80

patients (21.2%) with transient hypocalcaemia; CSL, HS and MAX; 8,4 and 5 respectively with statistical significance, P-value = 0.01. Only one patient from CSL group developed permanent hypocalcaemia, P-value = 0.349. Giovanni D et al. study [6] had comparable results with this study results; 38 out of 200 patients (19%) had transient hypocalcaemia; CT, HS groups; 20 and 18 respectively, P-value (NS). Matteo A C [18] study had 27 out of 265 patients (10.2%) with transient hypocalcaemia; CT, HS groups; 14, 13 respectively with no statistical significance, P-value (NS).

This study had 5 patients (6.3%) developed bleeding during the first postoperative 48 h; CSL, HS and MAX; 3, 1 and 1 respectively with statistically significant difference P-value = 0.01. Three patients (60%) were from the CSL group. These bleeds spontaneously stopped. E Foreman [8] et al. reported that reoperation for bleeding was one in HS group and one in CT group (2/183, 1.09%).

This study had 3 (3.75%) patients developed wound infection; two patients from CSL group and one from MAX group, this had no statistical significance, P-value = 0.331. They were conservatively treated.

Lang [19] in a systematic review of literature (8 studies with 963 patients) observed reduction of volume of blood loss and operating time in the HS group compared to LigaSure group. Bove [20] in a retrospective case-matched study about effectiveness and outcome in 240 total thyroidectomies by Harmonic Focus and LigaSure Precise observed a significant reduction of the operative time with Harmonic Focus with no statistically differences in postoperative complications.

This study showed that both suturless techniques, HS and MAX were superior to the CSL technique, and the results of the present study were comparable with most of the existing studies.

5. Conclusion

The results of this study showed that Harmonic Scalpel and Maxium, when being used in performance of a total thyroidectomy were safe, useful and fast alternatives to conventional techniques. The main advantage of these two devices is that they ease the surgical procedures, diminishing any need for clips and suture ligations and achieving efficient hemostasis. They significantly reduce the operative time, the amount of intraoperative and post-operative blood losses and length of hospital stay compared with conventional technique.

At present time, the operative time is the most significant factor in most comparative studies demonstrating the real advantage of using an alternative system of hemostasis and dissection to traditional methods. Reduction of operative time may facilitate a decrease in operating room occupancy costs. Probably, the only disadvantage of these two devices is the cost of single-use devices. Other studies that have analyzed and compared their costs have confirmed that the expenditure for the device could be easily amortized if surgical operative times were reduced, thus providing a better and greater utilization of operating rooms, and increasing the number of programmable surgical procedures in the same surgical session. They can also reduce costs associated with anesthesia, pain medication, hospital stay and eliminate cost of clips and suture ligation, so they decreasing the overall hospital costs [6,21–24].

Ethical approval

Ethical Committee of the Medical College/University of Wasit/Iraq approved the study.

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Author contribution

Assistant Professor Dr. Jawad Kadhim S. Al-Dhahiry: Participated substantially in conception, design, surgical performance, collection and analysis of data.

Assistant Professor Dr. Husam Majeed Hameed: Participated substantially in conception, design of the study, collection of data, preoperative & postoperative check of the vocal cords.

Conflicts of interest

Both authors have no conflict of interests.

Guarantor

Dr. Jawad Kadhim S. Al-Dhahiry.
Dr. Husam Majeed Hameed.

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