

## Evaluation of Harmonic Scalpel vs Ligasure Device in Thyroidectomy: A Prospective Randomized Study in a Tertiary Care Center

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### ABSTRACT

*The harmonic scalpel HS (Johnson & Johnson®) and LigaSure LS (COVIDIEN®) are new technologies that have been introduced in the surgical treatment of thyroid diseases during recent years. The aim of this study is to evaluate the use of HS and LS in total thyroidectomy operation as regards the time of the operation, postoperative complications and duration of hospital stay. In the current study, 70 patients underwent total thyroidectomy for simple multinodular and toxic goitre in the period between June 2016 and June 2017. In all patients, total thyroidectomy was performed through a classic Kocher's incision. The harmonic scalpel was implemented on Group A (35 patients), while Group B (35 patients) were operated with Ligasure device. Both Groups were evaluated for the time of the operation, intra-operative and postoperative complications and the duration of hospital stay. The two Groups had similar demographics, thyroid pathology and type of operative procedure. In the present study, there was no statistically significant difference between the two Groups regarding the operative time, intra- and postoperative complications and duration of hospital stay. **Conclusion:** Both Harmonic scalpel and Ligasure device are safe and effective devices in total thyroidectomy operation for benign Goitre.*

**Keywords:** Harmonic Scalpel; Ligasure Device; Hypocalcaemia; hemostasis; total Thyroidectomy.

### INTRODUCTION

Between 1873 and 1883, Theodor Kocher and Theodor Billroth, developed a technique of the standard thyroid surgery, both considered as the pioneers of thyroid surgery. By 1920, the rules of safe and efficient thyroid surgery were already standardized<sup>(1)</sup>.

This consists of three basic principles: identification and ligation of vessels, identification and preservation of both laryngeal nerves, and the parathyroid glands. Techniques of thyroid surgery had little developments since the approach considered by Kocher and Billroth in thyroid surgery long time ago<sup>(2)</sup>.

The mainstay for achieving hemostasis in thyroid surgery is tying and/or clipping of blood vessels; both are effective but time-consuming techniques. New devices can reduce operative time while keeping acceptable standards and low complication rates<sup>(3)</sup>.

With the improvement of minimally invasive surgical techniques, new technologies have been

introduced, which called the vessel sealing devices among them the HS and LS.

The advent of ultrasonically activated shears in the early 1990s promised an alternative method for hemostasis. The conversion of ultrasonic energy to mechanical action is the physical basis for the operation of this instrument. The mechanical energy breaks down the hydrogen bonds of proteins with less heat generation, producing a glue like substance including denaturated tissue proteoglycans and collagen fibers mixed with intracellular fluids, thus leading to less tissue damage than electrocautery<sup>(4)</sup>.

The HS (Fig. 1) has been recommended when the aim is to control bleeding and minimize thermal injury (complementing or replacing electrocautery, laser or even the cold scalpel), and it allows simultaneous cutting and coagulation of vessels up to 5mm in diameter. Because HS does not use an electrical current, the harmonic scalpel reduces the risk of thermal injuries and it is easy to use, leading to reduce the operation time<sup>(4,5)</sup>.



**Fig. 1: Harmonic Scalpel (Focus shear)**

The Ligasure device (Fig. 2) is an advanced bipolar device that seals vessels by fusing the inner layers of the vessel wall with minimal levels of thermal dispersion, burning and tissue friction, thereby reducing the incidence of accidental burns <sup>(6)</sup>. It can be used for both open and laparoscopic surgical procedures that operates through permanently sealing vascular structures up to 7 mm in diameter <sup>(7,8)</sup>.



**Fig. 2: Ligasure Scalpel**

#### **Aim of the study**

This prospective cross sectional analytic study was designed to evaluate the efficacy and safety of using HS compared with the LS in total thyroidectomy operation in the period between June 2016 and June 2017.

#### **PATIENTS AND METHODS**

This study has been conducted at Assiut university hospital, General Surgery Department, in a period of 1 year (between June 2016 and June 2017) on 70 patients undergoing total thyroidectomy for treatment of benign goitre.

#### **Inclusion criteria:**

Patients with simple nodular and toxic goiter indicated for total thyroidectomy.

#### **Exclusion criteria:**

Patients with recurrent goiter, malignant goiter and patients with retrosternal extension of goiter.

According to the use of LS or HS, the patients were divided into two Groups:

- **Group A:** The harmonic scalpel Group (35 patients).
- **Group B:** The ligasure device group (35 patients).

The patients were randomly selected for the two Groups.

The method of randomization is the closed envelop technique.

All patients were equally assessed in the preoperative period (clinical, radiological assessment and laboratory assessment).

**Operative technique:** Preoperative informed consent was taken from all patients for the use of LS or HS, to ensure randomization. In each patient the same anesthetic regimen was used.

**Technique:** A 4 to 6 cm incision (depending on size of the gland) was made over the thyroid isthmus. Sub-platysmal flaps were raised, and the strap muscles separated in the midline and reflected laterally. The middle, superior and inferior thyroid vessels identified and were then divided either with the LS or with the HS (Fig. 3, 4). Thyroid lobe was then rotated medially, and the vessels in ligament of Berry, were divided with the recurrent laryngeal nerve under direct vision with HS or LS. The similar steps repeated for removal of the contra lateral lobe.



**Fig. 3: Ligation of middle thyroid vein with ligasure device**



**Fig. 4: Ligation of inferior vessels with Harmonic Scalpel**

Drain was placed in the thyroid fossa and secured in position. Finally, the wound was closed using interrupted 2-0 polyglactin sutures (Vicryl), to close the strap muscles and platysmal layer. The wound was closed by subcuticular sutures using Monocryl 3-0, or skin Glue.

**Postoperative management:** During the postoperative period, the patients were assessed carefully for the clinical symptoms and signs of hemorrhage, hypocalcaemia, symptoms of recurrent laryngeal nerve injury, thyroid storm and drain output.

All patients were observed closely as regarding respiration and any change in their voice, and any patient who had any of the previous complaint underwent laryngoscope examination for evaluation of both vocal cords.

A series of serum calcium levels were obtained every postoperative day until patients were discharged. All the patients with serum calcium level less than 8 mg /dL (reference range 9-11mg/dL) or have a symptomatic hypocalcaemia (fatigue, weakness, numbness around the lips or the tips of the extremities and positive chevostek or trousseau signs occurred with mild hypocalcaemia while the carpopedal spasm, convulsions occurred with advanced

hypocalcaemia) during the first 3 postoperative days were considered as have hypocalcaemia and received oral calcium carbonate and vitamin D3 supplementation.

If the serum calcium levels returned to normal within 6 months, hypoparathyroidism was classified as transient, and if hypocalcaemia persisted more than 6 months, it was classified as permanent.

#### **Statistical analysis:**

All statistical analyses were performed by SPSS software (version 10.00) (SPSS, Chicago, IL). Values of  $p < 0.05$  were considered statistically significant.

## **RESULTS**

Between June 2016 and June 2017, 70 patients underwent total thyroidectomy operations for treatment of benign goitre were included and distributed into HS and LS Groups.

#### **1-Demographic distribution:**

There was no statistically significant difference in age and gender between patients in the two Groups (Table 1 & 2).

**Table (1): Shows distribution of the studied patients according to age and the relation between age Groups and type of operation.**

Age	Operation				p-value
	Group A (n=35)		Group B (n =35)		
	No.	%	No.	%	
20-30 years	3	8.6	4	11.4	0.824
30-40 years	13	37.1	11	31.4	
40-50 years	8	22.9	10	28.6	
50 -60 years	11	31.4	10	28.6	

**Table (2): Shows distribution of the studied patients according to sex and the relation between sex and type of operation.**

Sex	Operation				p-value
	Group A (n=35)		Group B (n =35)		
	No.	%	No.	%	
Male	11	31.4	7	20	0.580
Female	24	68.6	28	80	

#### **2- The Pathological type of the Goitre:**

There were no statistically significant differences between the pathological type of the Goitre in both Groups (Table 3).

**Table (3): Shows the relation between the Goitre pathology in the two Groups**

Diagnosis	Operation				p-value
	Group A (n=35)		Group B (n =35)		
	No.	%	No.	%	
Controlled secondary toxic goiter	18	51.4	22	62.9	0.104
Primary toxic goiter	5	14.3	3	8.5	
Simple multinodular goiter	12	34.3	10	28.6	

**3- Complications:**

Three types of complications were focused upon in this study:

- Nerve injury (either superior laryngeal nerve or recurrent laryngeal nerve).
- Post operative hypocalcaemia.
- Post operative bleeding.

We found no statistically significant difference between the two devices as regards the postoperative complications (Table 4).

**Table (4): The relation between each type of the two devices and post operative complication.**

Complications	Operation				p-value
	Group A (n=35)		Group B (n =35)		
	No.	%	No.	%	
Nerve injury	1	2.9	1	2.9	0.781
Post-operative hypocalcaemia	0	0	2	5.7	0.202
Post-operative bleeding	2	5.7	1	2.9	0.586

**4- Duration of hospital stay:**

There was no statistically significant difference between the two Groups regarding the duration of hospital stay.

**Table (5): Shows distribution of the studied patients according to the duration of hospital stay.**

Hospital stay (Days)	Operation				p-value
	Group A (n=35)		Group B (n =35)		
	No.	%	No.	%	
1-2 days	32	91.4	31	88.6	0.264
3 days or more	3	8.6	4	11.4	

**5- Operative time:**

There was no statistically significant difference between the two Groups regarding the operative time (Table 6).

**Table (6): Shows distribution of the studied patients according to the duration of the operation.**

Operation time (Min.)	Operation				p-value
	Group A (n=35)		Group B (n =35)		
	No.	%	No.	%	
<70 Min.	3	8.6	1	2.8	0.370
70 -100 Min.	30	85.7	31	88.6	
>100 Min.	2	5.7	3	8.6	

## DISCUSSION

The rich blood supply of the thyroid glands with its numerous blood vessels, dictates meticulous hemostasis in thyroid surgery<sup>(9-10)</sup>.

In this prospective randomized study, we present our experience with the use of the LS and HS in total thyroidectomy. We compared 35 patients (Group A) who underwent thyroidectomy using HS with 35 patients (Group B) who underwent thyroidectomy using LS. The two Groups had similar demographics and thyroid pathologies.

As regarding operative time (the time between skin incision and skin closure), we found no statistically significant difference between the two Groups. In comparison, Bove in 2010<sup>(11)</sup>, Dionigi in 2013<sup>(12)</sup> demonstrate that surgical time between HS and LS is significantly different (P value 0.02) as HS was significantly shorter than LS. While Peker in 2014<sup>(13)</sup> indicated no significant differences was observed in the surgical time between both devices.

As regarding complications, we found no significant difference between the two Groups regarding the postoperative complications.

In Group (A), postoperative bleeding developed in 2 patients (5.7%) during the postoperative period. One of them was female, and the other was male. This hematoma did not require any intervention and resolved spontaneously. Transient hoarseness was observed in 1 patient (2.9%).

In Group (B), transient hypocalcaemia was developed in 2 (5.7%) patients. One of them was male and the other was female. Hoarseness occurred in 1 patient (2.9%) and hematoma developed in another patient (2.9%). This hematoma was small and required no intervention and resolved spontaneously.

Dionigi in 2013<sup>(12)</sup> and Rahbari in 2011<sup>(14)</sup> in their studies indicated no significant differences were observed between the serum calcium level in the two Groups (p = 0.80).

While Peker in 2014<sup>(13)</sup> reported in his study that transient hoarseness developed in 1 patient (0.79%) and hematoma developed in 1 patient (0.79%). During the postoperative period, permanent hypocalcaemia developed in 2 patients (1.6%) while transient hypocalcaemia was observed in 32 patients (25.4%) in the Group of patients that operated on by LS. On the other

hand, postoperative bleeding developed in 2 patients (15%) in the surgical cavity during the postoperative period. Also, transient hoarseness was observed in 1 female patient (0.7%). Transient hypocalcaemia was observed in 6 patients (4.4%) in the other Group operated on using HS.

As regarding postoperative hospital stay in the current study, no significant difference was observed between the two Groups. Also, Bove in 2010<sup>(11)</sup> and Dionigi in 2013<sup>(12)</sup> in their studies indicated that, there were no significant differences in the length of hospitalization between HS and LS.

Intra-operative comparison between the two devices, we found that the heat effect in the adjacent tissue is less in the Ligasure device, however the speed of coagulation and division is faster in harmonic device and also the ergonomics of its Focus shear is much easier and the dissection is much better because of the fine tips of its instrument.

## CONCLUSION

We found no statistically significant difference in the operative time and incidence of major or minor complications between the two devices. Both HR and LS are safe, effective and time consuming devices in total thyroidectomy operations for benign Goitre.

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