Comparison of Surgical Outcomes between Patients Treated with The Harmonic Scalpel and Ligasure Device During Total/ Near Total Open Thyroidectomy

Aseel Mahmood Jawad

F.I.C.M.S ,MRCS ,DGS, College of Medicine, General Surgery Department ,Bagdad ,Iraq.

Abstract

Over the last few years many surgeons have begun to utilize the LigaSure device or Harmonic scalpel to perform thyroid surgery. Several papers have demonstrated the benefits of these devices over traditional hand-tying techniques. The purpose of this study was to examine our institution's experience with the LigaSure device and Harmonic scalpel during thyroid surgery and to compare mean operative times and complications associated with each device.The aim of the study was to compare surgical time,postoperative complications and other parameters between ligasure device and harmonic scalpel in the open thyroidectomy procedure. We choose to examine our institution's experience with the LigaSure and Harmonic scalpel during total/near total thyroidectomy.

Key Words: *Thyroid ,Harmonic Scalpel, Ligasure*

Introduction

With blood supply from four to five vessels, the thyroid gland represents one of the most vascularized organs of the human body.Its close proximity to neighboring structures, especially the recurrent[1,2] laryngeal nerves (RLN) and the parathyroid glands, leaves limited room for surgical manipulation.Therefore hemostasis and injury to neighboring structures are of concern(Peter CA and Dirk 2016)[3]

Surgery is one of the standard therapies for numerous thyroid diseases.A total of 80,000 thyroidectomies per year are performed in the United States alone(Bhattacharyya and Fried 2002)[4] . The thyroid is the highly vascularized gland and hemostasis is one of the key limiting factors in morbidity and mortality in thyroid surgery[5] .Similar to bleeding, other possible sources of postoperative morbidity include dysphonia and dysphagia due to recurrent and/or superior laryngeal nerve injury, hypocalcemia due to parathyroid ischemia or unintended deprivation, postsurgical hemorrhage, wound infection and postoperative pain.However, the risk of perioperative mortality or major disability[6, 7] is extremely low(Chiang et al 2004.,Shindo et al 2000). Harmonic scalpel is manufactures and marketed by Ethicon.The HS is a high power system which works at a frequency of 55.5 KHz or 55,500 vibrations/sec. Dissection by ultrasonic is called ultracision[8,9] .The ultrasound(US) transducer located in the handpiece is composed of piezoelectric crystal sandwiched under pressure among metal cylinders.The US generator converts ultrasonic energy into mechanical[10] energy(Slakey 2008).The sealing of the vessels is achieved due to denatured protein coagulum which occurs due to tamponade and coaptation. It can coagulate[11,12] vessels up to 5 mm(Meurisse et al 2000.,Macario et al 2008).

Patients and Method

The study was carried out between 1/10/2015 and 30/8/2017, in which 120 patients having various thyroid diseases were operated in our institution, all were scheduled for total / near total thyroidectomy for different indications they were divided into two groups according to the hemostatic techniques .

One hundred twenty patients were enrolled in this study,55patients(54.2%) using ligasure vessel-sealing system (LVSS) ,\65 (45.8 %) patients using harmonic scalpel(HS). All the operations were performed by surgical teams after consent the patients.

To eliminate confounding factors the following exclusion criteria adopted .

Those are patients:

1.with preoperative low serum ca.

2.with vocal cord palsy on preoperative assessment.

3.with need for cervical lymph node dissection.

4.with previous thyroid surgery (recurrence, completion thyriodectomy).

5.with history of neck irradiation.

6.with coagulopathy and bleeding disorders.

7.Pendred 's syndrome.

The study domains were:

1.Operative time in minutes.

2.postoperative hoarseness.

3.Post-operative bleeding(drainage volume in ml).

4.Recurrent laryngeal nerve(RLN) status.

5.Total serum calcium level.

In addition to the baseline pre-operative work up ,patients were investigated for:

1.Thyroid function test(T3,T4, and TSH).

2.Pre-operative indirect laryngoscopy for vocal cords assessment.

3.Pre-operative total serum calcium.

4.neck Ultrasound.

5.Fine needle aspiration for cytology.

All hypothyroid and thyrotoxic patients, including those with Graves' disease, were treated pharmacologically until they became euthyroid (TSH,T3,T4 levels were within normal ranges),after which they were cleared for surgery. Routinely, patients underwent total/near total thyroidectomy for benign thyroid disease, with a focus on recognition and preservation of the laryngeal nerves, along with at least 3 parathyroid glands. The patients had general anesthesia with endotracheal intubation with collar incision 2-3 cm above suprasternal notch.We used ligasure small jaw sealer(Covidien ,L 1212 A) (fig.1) was used in one group and for the other group, harmonic scalpel(ethicon:Johnson & Johnson) for cutting and coagulation where the generator machine can be adjusted from level 1 to 4 to increase cutting speed and decrease coagulation by increasing the blade's lateral excursion. Closed suction system(Redivac) drain was used to drain post-operative blood over next 24-48 hrs. Vocal cords were checked during recovery by the anesthetist and if any kind of immobility or malfunction was found, the patient was followed up at 1 monthly intervals till 6 months. Patients were assessed for complaint of paresthesia, perioral tingling ,examined for chvostek's sign, trousseau's sign and Serum calcium was measured during the first and second post-operative days. A level of 8 mg/dl (2mmol/l) was considered as a cut-off value for hypocalcemia. If it was found, the patient would be given calcium and vitamin D3 preparations. Hypocalcemia and RLN palsy were regarded transient if resolved within first 6 months and permanent if they continued after 6 months.

Quantitative domains(serum calcium ,operative time and postoperative bleeding volume were expressed as mean ± Standard deviation(SD) and qualitative domains(gender, diagnosis,RLN palsy ,transient hoarseness) was given as frequency and percentage. Statistical significance between the two devices for qualitative domains ,was assessed using Fischer ,s Exact test while for quantitative domains, simple descriptive statistic tests were used .the data were entered ,coded and analyzed using SPSS version 22 and p-value of 0.05 was considered significant.

Figure.1:The LigaSure used and the Harmonic Device

Results

A total of 120 patients were enrolled in this study ,95 females (79.2%) &25 males(20.8%) (Table.1), ♀:♂ (3.8:1). (Table.1):The mean age at surgery 43.89±11.17(minimum 22 and maximum 66years).Hemostasis achieved by harmonic device in 65 patients(54.2%) and by ligaSure vessel–sealing system in 55 patients(45.8 %). Of the harmonic group 12 out of 65 patients were male,while in ligasure group 13 out of 55 patients were male, Various thyroid pathologies included in our study sample were diagnosis confirmed by histopathological examination(Table.1).

Table(1): Distribution and Frequency Data of Sample

Distribution of gender in sample				
Gender	Frequency		Percent	
Female	95		79.2	
Male	25		20.8	
Total	120		100.0	
Distribution of patients per device				
Device	Frequency	Percent	Gender	
			♀	♂
harmonic device	65	54.2	53	12
ligasure device	55	45.8	42	13
Total	120	100.0	95	25
Frequency of different thyroid pathologies in study				
Pathology	Frequency		Percent	
Simple MNG	65		54.2	
Toxic MNG	20		16.7	
Grave›s disease	11		9.2	
Papillary carcinoma	11		9.2	
Hashimoto›s thyroiditis	8		6.7	
Follicular carcinoma	3		2.5	
Reidels thyroiditis	1		0.8	
Hürthle cell cancer	1		0.8	
Total	120		100.0	

The patients were matched for age and gender(male ,female),no statistically significant difference between the two groups were detected as reported in table(p-value 0.35, 0.51, 0.32 respectively).,The mean surgical time with harmonic hemostasis was shorter (56.6±5.8min) than in ligaSure hemostasis(70.3 ±5.4min).Statistically the difference was highly significant(P-value 0.001).,When complications rate were examined there was no significant differences in the mean volume of post-operative blood loss between harmonic device(102.8 ±16.5 ml) and ligasure(101.5 ±16.4 ml), the p- value was(0.63).,The average serum calcium for patients operated with HS was 8.78 and with ligasure 8.81.,Postoperative hypocalcemia was observed in(12/65)pateints which represent 18.46 % of harmonic scalpal group and(11/55)patients which represent (20%) of ligaSure group ,the result was statistically non significant,(p-value 0.78), 4out of 12(6.1%) patients continue to have hypocalcaemia beyond 6 months in harmonic group and 3out of 11 (5.4%) patients in ligasure group(p-value 0.70),(Table.2)

Table(2): Comparison, Demographic data demonstrate no differences of gender and age distribution for use of each device

Demographic data demonstrate no differences of gender and age distribution for use of each device				
		Device		P-value
		harmonic device	ligasure device	
Gender	female	53	42	0.32
	male	12	13	0.51
Age	Mean ± SD	41.9(10.9)	46.3(10.9)	0.35
Comparison of operative time between the use of two hemostasis devices				
Operative time		Device		P-value
		harmonic device	ligasure device	
Operative time in min (±SD)		56.6(5.8)	70.3(5.4)	0.001
Differences in Blood loss between the use of two devices				
Blood loss/Device		Device		P-value
		Harmonic device	ligasure device	
Blood loss in ml(±SD)		102.8(16.5)	101.5(16.4)	0.63
The differences in frequency of hypocalcaemia in each device				
Hypo ca^{+2} /Device		Device		P-value
		Harmonic device	Ligasure device	
		No. %	No. %	
Hypocalcaemia		12 18.4	11 20	0.78
Frequency of permanent Hypocalcaemia in devices used				
Hypo ca^{+2} /Device		Device		P-value
		Harmonic device	Ligasure device	
		No. %	No. %	
Hypocalcaemia		4 6.1	3 5.4	0.70

Twenty three patients experienced postoperative hoarseness from the total(120) patients.,Postoperative hoarseness was indifferent between the two devices,with(12/65) patients of harmonic group(18.46%) experiencing hoarseness compared to(11/55) patients (20%) in ligaSure group (p-value 0.83).Of the 23 patients with hoarseness ,5 patients (4.16%) reported permanent RLN palsy(beyond 6 months) in harmonic group 4/65 (6.15%) while in ligaSure group1/55(1.81%) which was statistically significant, p-value (0.001).,(Table.3)

Table(3):frequency of postoperative hoarseness in our study(total)

frequency of postoperative hoarseness(total)		
postoperative hoarseness	Frequency	Percent
No	97	80.8
Yes	23	19.2
Total	120	100.0

The differences in frequency of postoperative hoarseness(in each device)			
Device/postoperative hoarseness	Device		P value
	Harmonic device	Ligasure device	
hoarseness	12	11	0.83

Frequency of permanent RLN palsy(total)		
RLN palsy	Frequency	Percent
NO	115	95.8
Yes	5	4.16
Total	120	100.0

The differences in frequency of permanent RLN injury(in each device)			
RLN palsy/ Device	Device		P-value
	harmonic device	Ligasure device	
RLN palsy	4	1	0.001

Discussion

Total thyroidectomy is a very delicate procedure requiring extreme care to avoid injury to neighboring anatomical structures. Strict hemostatic control is fundamental for limiting the risk of serious complications,including recurrent laryngeal nerve and parathyroid gland injuries, and for decreasing the incidence of other postoperative complications[13,14] .Given the importance of optimizing hemostatic control, the use of devices to dissect and close vessels during thyroidectomy is not uncommon(Takao et al 200.,Siperstein et al 2000)[15,16].

The aim of study was to provide a direct comparison of clinical outcomes associated with each of two hemostatic techniques used for total thyroidectomy:LigaSure,and Harmonic device.

The mean surgical time in total thyroidectomy with harmonic hemostasis was shorter (56.6±5.8) than in ligaSure hemostasis(70.3±5.4) Statistically the difference was highly significant(P-value 0.001).Our result consistent with that of Arun Upadhyaya et al who reported that the surgical time was significantly decreased in the HS group compared with the LS instrument group,and in agreement with that of McNally et al which was a retrospective analysis of prospectively maintained database, they compare the effectiveness and safety of ultrasonic dissection(UD) and electronic vessel sealing(EVS) in patients undergoing thyroidectomy between January 1, 2007 and January 25, 2008 ,they

found significantly decreased operative time with UD versus EVS. Contin et al published[14] a systematic review and meta-analysis comparing HS,LS and a conventional technique in 2013.The study compared HS and LS with the conventional technique,and HS and LS separately.The study concluded that HS and LS were significantly different when compared to conventional hemostasis in terms of shorter surgical time. It also concluded that HS was faster in comparison to LS.This was contrary to study by Kwak HY et al to evaluate the safety and efficacy of thyroidectomy using the Harmonic scalpel(HS) or the LigaSure Precise(LS) instrument in 320 patients(HS group, N=164; LS instrument group, N=156) who demonstrate no statistically significant differences in the operative times between the two techniques.our result was inconsistent with that of Macario et al who[18] reported that The operation time of LigaSure electro surgical bipolar sealing system is less than that of the ultrasonic device.The HS is unique in the fact that it combines hemostasis and cutting in a single instrument, thus avoiding the loss of time when associated with the manipulation of several instruments. By contrast, the LS instrument can only be used for hemostasis, and sectioning was performed with another instruments such as scissors after withdrawal of the device.The shorter operative time may be attributed to the fact that LS is a more time-consuming multiple-sealing approach at the same vessel but HS divides the tissue at the same time of coagulation.Regarding RLN palsy,we found a statistically significant differences between[15] the two techniques where incidence was higher with harmonic,which inconsistent with the fact that LigaSure had a range of 2 to 3 mm for thermal injury; the Harmonic scalpel had safety measure of 2 mm for thermal injury.Our result contrary to many studies which reveal that HS has less damage to nearby vital structures like the RLN and the parathyroid glands(Obonna and Mishra 2014)[17] .

On 2016 Dequanter et al investigated the extent of heat injury, ultrasonic dissection did not cause any immediate damage of the nerve even close to the RLN(1 mm away from the RLN).They concluded that the use of harmonic scalpel for thyroid surgery is safe for the surrounding structures (nerves). Careful tissue applications of the device near the RLN(1 mm) did not cause any lesion histologically.On 2013 George et al published[16] a study comparing HS,LS and clamp and tie technique in thyroid surgery demonstrating that ultrasounic coagulation showing the highest risk of RLN palsy

Our result may be due to the fact that 2 of the 4 patients in the harmonic group were having obscured anatomy and dense adhesions of Hashimoto ,s and Reidels thyroiditis . Five patients had recurrent laryngeal nerve palsy 1 of LigaSure group and 4 of HS group ,all of whom were unilateral; no cases of bilateral laryngeal palsy were reported. Following traction injury, thermal injury is the second most common mechanism of RLN damage during thyroidectomy. Intra operative RLN thermal injuries are believed to be mostly related to the Energy based devices EBDs tip thermal effect, which is used for dissection or bleeding control near the RLN. The degree of lateral thermal spread depends on the type of instrument, the power settings used and the duration of application. Nikica et al demonstrated that harmonic scalpel application times of more than 5 seconds presented a risk of lateral thermal damage, especially near sensitive tissues or organs(Milson et al 2012.,Norman et al 2012) like the common bile duct or ureter. studies suggest that after 5 seconds of application, a 5-second pause should be made, followed by an additional 5 seconds if necessary to allow device to cool .Lateral thermal damage produced by the Harmonic scalpel at an output power of 5 was greater than that at an output power of 3.Regarding the morbidity of thyroidectomy, no significant differences observed in rate of hypocalcemia,postoperative hoarseness and postoperative blood loss between the two devices. Several studies showed that the postoperative morbidity was not different between the two techniques.

A study by D'Ajello F demonstrated that transient hypoparathyroidism was more in the harmonic scalpel group.While Foreman et al reported a lower incidence of hypocalcemia associated with the Harmonic Scalpel.Pons.Kiriakopoulos and Oussoultzoglou reports of a decrease in postoperative hypocalcemia[16] associated with these device.More recently(Rosato et al 2004.,Francis et al 2015) a newer version of ligasure has been developed with an integrated cutting blade into the instrument(Goretzki et al 2009.,Cordon et al 2005) which overcomes the need for manipulating several[17,18] instruments(Dionigi et at 2016., Gabriele et al 2017).

Conclusions

In this study,there was no difference in the rate of complications between the two devices except for RLN palsy.However, the use of the Harmonic

scalpel significantly decreased operative time for thyroidectomies when compared to the LigaSure device. They are safe and effective advantageous for sealing medium-sized vessels,however a scrupulous and careful care of the surgical technique and hemostasis should always be observed.

Conflict of Interest:There is no any Conflict of Interest

Ethical Clearance:Ethics committee refer that there is no plagiarism and there is no mistakes or wrong results in this work.

Source of Funding:Self funding.

References

1. Peter CA ,Dirk RW. Is sutureless thyroid surgery safe in the hands of surgical trainees. A single study .BMC Res Notes. 2016;9:118.
2. Bhattacharyya N, Fried MP. Assessment of the morbidity and complications of total thyroidectomy. Arch Otolaryngol Head Neck Surg. 2002;128:389–392.
3. Chiang FY, Lee KW, Huang YF. Risk of vocal palsy after thyroidecitomy with identification of the recurrent laryngeal nerve. Kaohsiung J Med Sci. 2004;20:431–436
4. Shindo M, Stern A. Total thyroidectomy with and without selective central compartment dissection:A comparison of complication rates. Arch Otolaryngol Head Neck Surg. 2010;136:584–587.
5. Slakey DP. Laparoscopic liver resection using a bipolar vessel-sealing device:LigaSure. HPB Oxf. 2008;10:253–255
6. Meurisse M, Defechereux T, Maweja S. Evaluation of the Ultracision ultrasonic dissector in thyroid surgery. Prospective randomized study. Ann Chir. 2000;125:468–472.
7. Macario A, Dexter F, Sypal J, Cosgriff N. Operative time and other outcomes of bipolar vessel sealing system(LigaSure) versus other methods for surgical:A meta-analysis. Surg Innov. 2008;15:284–291.
8. Takao S, Shinchi H, Maemura K, Aikou T.Ultrasonically activated scalpel is an effective tool for cutting the pancreas in biliary-pancreatic surgery: experimental and clinical studies. J Hepatobiliary Pancreat Surg. 2000;7:58-62.
9. Siperstein AE, Berber E, Engle KL, Duh QY. Laparoscopic posterior adrenalectomy: technical considerations. Arch Surg.2000;135:967-971.
10. Obonna GC, Mishra RK. Differences between Thunderbeat ,LigaSure and Harmonic Scalpel Energy System in Minimally Invasive Surgery. World J Lap Surg 2014;7(1):41-44.
11. Milson J, Trencheva K, Monette S, Pavoor R, Shukla P. Evaluation of the safety, efficacy, and versatility of a new surgical energy device (thunderbeat) in comparison with harmonic ACE, LigaSure V in a porcine model. J Laparoendosc Advanced Surg Tech 2012;4:378-386.
12. Norman S. Williams ,Christopher J.K. Bulstrode. Connell. Bailey and Love, s Short Practice Of Surgery ,26th ed. Chapter 51;2012:741-777
13. Francis CB, Dana kA, Timothy RB, David LD ,John GH, Jeffrey BM ,Raphael EP .Schwartz,s principle of surgery ,10th ed.Chapter 38;2015:1521-1556.
14. Goretzki PE, Schwarz K, Lammers BJ. Implementing the general use of dissection devices in thyroid surgery from prospective randomized trial to daily use. Surg Technol Int 2009;18:86–92.
15. Franco J, Kish KJ, Pezzi CM, Pak H, Kukora JS. Safely increasing the efficiency of thyroidectomy using a new bipolar electrosealing, device (LigaSure) versus conventional clamp and tie technique. Am Surg .2006;72(2):132–136
16. Dionigi G, Wu CW, Kim HY, Rausei S, Boni L. Severity of Recurrent Laryngeal Nerve Injuries in Thyroid Surgery. World J Surg. 2016;40(6):1373-81.
17. Gabriele M, Carlo EA, Lorenzo F, Luigi DN. Prevention and management of bleeding in thyroid surgery .Gland surg.2017;6(5):510-515.
18. Arun U, Tianpeng H, Zhaowei M, Xue L, Xianghui H. Harmonic versus LigaSure hemostasis technique in thyroid surgery: A meta-analysis. Biomed Rep. 2016;5(2):221–227.