Use of Bipolar Vessel Sealing Device(Ligasure) Versus Conventional Suture Ligation in Thyroid Surgery

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ABSTRACT:

BACKGROUND:

Effective vessel hemostasis can be achieved by knot tying or newer techniques like ligasure as an alternative bipolar surgical diathermy system. Various diathermy techniques have been proposed to reduce intraoperative blood loss in surgery and the new electrothermal bipolar tissue sealing system (Ligasure) has been applied in various specialties of surgery.

OBJECTIVE:

To compare the outcome of ligasure versus conventional suture ligation in thyroid surgery.

METHODS:

This study was conducted in Al–Imamein Alkadhmein Medical City over 2 years period from the first of October 2016 to the first of October 2018.A Total of 110 patients were operated upon by the same surgical Team, using ligasure in 55 and conventional suture ligation in 55 patients for hemostasis. The medical records of the patients enrolled were reviewed and compared regarding age, sex, histopathological diagnosis, types of thyroidectomy, operating time, estimated intraoperative blood loss, postoperative complications, hospital stay , postoperative pain and outcome evaluation.

RESULTS:

There was no statistical difference between the two groups regarding age, sex and histopathological Data**.** The mean operating time was significantly shorter in the Ligasure group compared with the conventional group. Transient hoarseness of voice was detected in 2 patients (3.6%) of both groups. no permanent complication was seen in LVSS group but EBSLN injury (1.8%) was the only permanent complication occurred in conventional group.

CONCLUSION:

The use of LigaSure Vessel Sealing System for thyroid surgery is proved safe and effective as conventional suture ligation Technique, with the benefit of reducing intraoperative blood loss, reduced operating time, and postoperative pain severity.

KEYWORDS: Thyroid, LigaSure Vessel sealing system, Conventional suture ligation.

INTRODUCTION:

Thyroid surgery has been performed since ancient times. Albucasis the 11th century surgeon of corodoba (Spain) explained extirpation of the gland, two setons were inserted at right angles into the gland and tightened twice daily until the Lobes separated. The open wound was treated with caustic powder and left to heal .These methods were published by Roger Frugardi in 1170. Technical improvements did not occur until the middle of the 19th century.[1,2] With the advent of antiseptic techniques and antibiotics the mortality due to sepsis has disappeared. So also, the refinement in surgical techniques, recognition of the parathyroid gland, RLN, and need to protect the external branch of the superior laryngeal nerve (EBSLN) resulted in lesser morbidity. [3].

In the recent years several novel instruments have been developed and implemented in both open and laparoscopic surgery. These instruments utilize the properties and the effects of different energy sources, including radiofrequencies and ultrasound.[5,6]

The LigaSure enables simultaneous selective sealing and division of a vessel up to 7mm in diameter without dispersion of the electric power, and with less heat production, by denaturing collagen and elastin within vessel wall and surrounding connective tissue.[4,7] The energy from ligasure reaching the surrounding tissues is less than 1 mm.[8]

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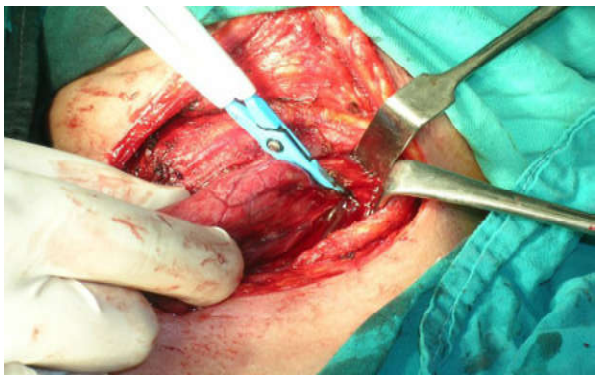

Figure 1: Division of superior thyroid vessels.

METHODS:

A prospective case matched study conducted on 110 patients admitted in the general surgical unit of Al–Imamein Alkadhmein Medical City over 2 years period from the first of October 2016 to the first of October 2018.

Patients were randomly allocated into two equal groups ,each of 55 patients: Group C included patients assigned for conventional thyroidectomy using suture ligation for hemostasis and Group L included patients assigned for thyroidectomy using covidien curved, small jaw, open sealer divider 16.5mm ligasure for hemostasis.

Inclusion criteria

After obtaining fully informed written patients'consent,all patients who sustained Lobectomy, near total thyroidectomy and Total thyroidectomy were included in the study.

Exclusion criteria

- Prior cervical surgery.
- Recurrent goiter.
- Thyroiditis.
- Operation need thoracic approach.
- Locally advanced malignancy.
- Patient with preoperative vocal cord paralysis secondary to malignancy or other causes.
- Bleeding tendency.
- Severely comorbid patients.

All patients underwent a routine preoperative investigation for their isease (T3,T4,TSH,S.calcium);neck ultrasound from suspicious nodules and c.t.scan for neck for malignant cases.

vocal cord function was evaluated in all Patients by an otolaryngologist and the patients were admitted the night before surgery. All procedures were performed using endotracheal intubation under general anesthesia. With the purpose of standardization, all the operations were performed by the same team, specifically by the senior and fifth stage resident. No prophylactic antibiotics were used in any surgery.

The same surgical approach was performed in both groups(neck collar incision, division of the platysma muscle and preparation of the flaps, division of upper and lower pedicles by ligasure, excision of thyroid gland by combination of scissors and ligasure).

The parameters that have been evaluated in each of 55 patients were:

Preoperatively:

Age,Gender,diagnosis(MNG,Graves'disease, malignancy).

Postoperatively:

Complications: such as hypocalcemia(presence of symptoms and signs and by measuring serum calcium) and, presence or absence of change in the voice(hoarseness pitched sound) and hospital stay.

All patients with postoperative s. calcium levels below the lower limit of normal range (8 mg/dL) were considered as hypocalcemia and treated with

oral calcium carbonate tablet and activated vitamin D3 supplementation. Clinical hypocalcemia was defined as ionized calcium below 1.14 mmol/l, associated with patient complaint of paresthesia and positive Chvostek sign.

Vocal cords assessment was done intraoperatively by anesthetist at time of extubation and post operatively by otolaryngologist (either by indirect or fiberoptic laryngoscopy). patients who developed signs and symptoms of recurrent laryngeal nerve injury were managed accordingly and had been followed by attending our hospital ENT clinic for serial examination every 4 weeks over 6-12 months period. We depended in calculating Operative time on the resident of Anesthesia.

Intraoperative blood loss was calculated by visual method. We relied on the standard absorptive packs measuring 30 x30 cm.when it is soacked by 50% this means that it contains about 25 ml of blood and if totally soacked 100% this means that it contains 75 ml of blood.[33].

Postoperative pain was assessed for the first 24 hours post operation, using the visual analogue scale (VAS) .The chart was graded from 0 to 10, marked at one end as no complain of the pain and at the other end as the worst pain has been felt. We depended on three visits to the patient in assessing the pain, first one in early post-operative 1-2 hours, second visit in the night tour of day zero and the last one in the next morning. Patients collecting scores of 3 or less were considered as having mild pain, those with score of 7 or more were defined as having severe pain and those from 3.1 to 6.9 as having moderate pain. Also, the amounts of analgesic drugs needed to relieve pain were assessed, depending on the use of 3 types of Analgesia available in our hospital starting with (paracetamol vial, diclofenac ampule , pethidine ampule) respectively according to the severity of pain and response of the patient.

Statistical Analysis:

Statistical analysis was performed using non parametric test for comparison. For qualitative data, Chi-square or Fisher's exact probability test (2 samples, unpaired) was used. For the quantitative data, Wilcoxon's signed Rank test (two samples, paired) with correction for ties was used. Two sided values ≤ 0.05 were considered significant.

RESULT:

Group C: consist of (43 female and 12 males) with a mean Age 44 ±11.4 year.

Group L: consist of (41 female and 14 male) with a mean age of 43.8 ±10.7 years.

There was no significant difference regarding age and gender between the Two groups(Table 1).

Table 1:Age and Sex.

GENDER	Conventional group	Ligasure group	P value
Male	12(21.8%)	14(25.5%)	0.268
Female	43(78.2%)	41 (74.5%)	0.897
Age(years) Means	37.84 _ 8.60	38.96 _ 7.21	0.367

we divided the patients into Two equal groups (C and L):
There was no significant difference between the numbers of patients
Sharing the same pathology in both groups(Table 2).

Table 2: Histopathological Data.

Pathological finding	Conventional group NO%	Ligasure group NO%
Benign pathology	51(93.8%)	52(94.6%)
Toxic MNG	8(14.5%)	9(16.3%)
Euthyroid MNG	36(65.4%)	34(61.8%)
Graves' disease	1 (1.8%)	1 (1.8%)
Toxic adenoma	zero	1(1.8%)
Follicular adenoma	6(10.8%)	7(12.6%)
Malignant pathology	4(7.3%)	3(5.4%)
Papillary c.	3(5.3%)	2(3.7%)
Follicular c.	1(1.8%)	1(1.8%)

Table 3:Types of operation.

Type of operation	Ligasu re	conventional
Total thyroidectomy	14(26.4%)	15(27.4%)
Near total thyroidectomy	28(53.7%)	27(52.7%)
Lobectomy	13(20.0%)	13(20.0%)

Table 4: Comparison of postoperative complications, hospital stay and analgesic Intake.

Types of complications	Conventional group	LigaSure group	P value
Transient complications	8 (14.5%)	6 (10.9%)	0.087
Transient hypocalcaemia	3 (5.4%)	2 (4.6%)	
Wound seroma	3 (5.4%)	2 (3.6%)	
Hoarseness	2 (3.6%)	2 (3.6%)	
Permanent complications	1 (1.8%)	0 (0%)	0.098
External laryngeal nerve	1 (1.8%)	0 (0%)	0.098
Hospital stay (days)	1	1	
RLN palsy	0(0%)	0(0%)	
Hypocalcemia	0(0%)	0(0%)	
analgesic intake(no.)	2.5±0.5	1.1±0.3	0.03
Visual analogue scale	5.1 ± 1.4	3.1± 1.2	0.008

There was no significant difference between the two groups regarding the postoperative complications. In the LigaSure group, two patients presented with transient hypocalcemia(4.6%), two patients developed transient hoarseness of voice(3.6%) and two patients developed wound seroma(3.6%). There was no permanent complication in this group. In the conventional group, three patients suffered transient hypocalcaemia(5.4%), three patients developed wound seroma(5.4%), and two patients developed transient hoarseness(3.6%), and all were resolved within 2 months. external laryngeal nerve injury was the only permanent complication occurred in this group.

we measured the amount of intraoperative blood loss in both groups and we found that there was a significant difference between both groups (132.72 ± 28.38 ml for conventional group vs. 65.60±14.79 ml for LigaSure group; P = 0.000).We noticed that there was a significant reduction in operating time in the LigaSure group vs. conventional group. The mean operating time for lobectomy in the conventional group was 67.25 ± 4.49 min vs. 37.65 ±4.68 min in LigaSure group (P =<0.0001).

Also, similar results were obtained for near total thyroidectomy (101.20 ± 7.51 min vs. 66.80 ±4.56 min; P = <0.0001) and total thyroidectomy (132.13 ± 7.50 min vs. 93.16 ± 5.68 min; P = <0.0001).

DISCUSSION:

ligaSure diathermy system constitutes a novel hemostatic method that produces a consistent permanent autologous seal to veins, arteries, and tissue bundles up to 7mm in diameter. Both groups have shared the same thyroid pathologies and Demographics. Moreover , the rates of the three types of thyroidectomy (Total, near total and Lobectomy)were nearly the same in both groups.

Regarding the operative time, our results were compatible with those reported in other studied[18,20,21] and the researchers of these studies noted a significant reduction in operative time in ligasure group, except for Andreas study[21] which concluded no significant difference in operative time .

Table 5:Comparison of operating time

Operating Time(min)	Conventional group	Ligasure group	P value
Lobectomy	67.25 ± 4.49	37.65±4.68	<0.0001
Near total thyroidectomy	101.20±7.51	66.80±4.56	<0.0001
Total thyroidectomy	132.13 ± 7.5	93.16 ± 5.68	<0.0001

Table 6:Summarize our operative time results and compare it with other studies.

study	operative time(min)		
	Ligasure group	conventional group	p value
our study	93.16 ± 5.68	132.13 ± 7.5	<0.0001
Wael(18)	115.54±15.35	127.1±7.95	≤0.0001
vaasna(20)	78.3±34.4	104.8±28.5	<0.0001
Andreas(21)	84±6	89±7	0.60

This is probably attributed to a specific vessel sealing characteristics of the ligasure device in reducing the time consumed in conventional blood vessel ligation.
Owing to the availability of several sizes of handpieces for the LigaSure generator, we were able to use it even with the small thyroid vessels. This was reflected on the statistically significant reduction in intraoperative blood loss in the LigaSure group.
This difference in Andreas study from other studies was attributed to the fact that Thyroid surgery is a microsurgical technique requiring precise tissue handling and dissection and the tip of the LigaSure is large for use with the small thyroid vessels.

Table 7 :summary of our intraoperative blood loss results and compare it with other studies.

study	intraoperative blood loss(ml)		
	Ligasure group	conventional group	p value
our study	66.60±14.79	130.72±27.37	<0.0001
Wael(1^)	62.06± 7.34	75.84± 9.21	≤ 0.0001
vassilios(22)	82±33.4	106±8.2	<0.0001
Andreas(21)	30±5	35±8	P=0.36

Moreover, we noticed a significant difference between the two groups regarding the reduction in the amount of analgesic needed and the severity of postoperative pain in ligasure group, which is compatible with other studies . This could be attributed to proper field visuality that enabled meticulous dissection and minimal tissue damage and subsequently reduced release of nociceptive mediators.

In contradiction with the results of a recent study(Ioanis study) [21] which showed a significant decrease in transient nerve palsy with Ligasure system use in thyroidectomy (0.7% VS 4% , p value <0.05, our results are comparable with the results of other studies(vassana,khafagy).[19,20]

Table 8: Summarize our RLN palsy results and compare it with other studies.

study	Temporary RLN palsy			permanent RLN palsy		
	LG	CG	p value	LG	CG	P value
our study	0(0%)	1(1.8%)	0.8	0%	0%	
vassana	2(1.0%)	1(0.5%)	>0.999	0%	0%	
Khafagy	1(6.7%)	2(13.3%)	0.087	0%	0%	
Ioannis	0.7%	4%	<0.05	0%	0%	
LG :ligasure group,CG :conventional group						

CONCLUSION:

1.The use of the Ligasure sealing system in Thyroid surgey is proved safe and effective as conventional knot Tying for thyroidectomy, with the benefit of decreasing intraoperative blood loss ,operative Time,post operative pain and Analgesic intake.

2.Post operative complications in both Groups of our study are within the Range of other similar studies.

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