

Study of Using Ligasure Small Jaw versus Traditional Clamp and Tie technique in Thyroidectomy: A Comparative Study

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ABSTRACT

Background: The ligasure (LS) system is a bipolar diathermy device used to close blood arteries with minimal heat damage to surround tissue. For both benign and malignant thyroid problems, total thyroidectomy is now the standard surgical treatment. **Objective:** The aim of the current study is to evaluate the effectiveness of the Ligasure small jaw approach versus the standard Clamp and tie method in thyroidectomy.

Patients and methods: Our study is a randomized controlled clinical trial was conducted in the General Surgery Department at Zagazig University Hospital on a sample of 30 cases. The patients were divided into 2 groups; Group A includes 15 patients underwent thyroidectomy using Ligasure small jaw technique, and Group B includes 15 patients underwent thyroidectomy by using traditional Clamp and tie technique.

Results: Drainage volume (ml) among the study groups that ranged from 60 to 110 with mean 81.06 (SD 20.12) in Ligasure group and ranged from 80 to 140 with mean 100.33 (SD 23.48) in Clamp and tie technique group. Group A had significantly smaller drainage volume than Group B (P value 0.024). Postoperative complications occurred more with traditional Clamp and tie technique than Ligasure technique, with no statistically significant difference.

Conclusion: When compared to the more common Clamp and tie method, the Ligasure technique reduces surgical time, blood loss during the procedure, the need for postoperative drainage or hematoma, the risk of parathyroid damage, and the risk of recurrent laryngeal nerve injury.

Keywords: Ligasure small jaw, Clamp and Tie technique, Thyroidectomy.

INTRODUCTION

Thyroid gland is a highly vascularized endocrine gland. For this reason, a good hemostasis is of utmost importance in thyroid surgery. Hemostasis of blood vessels can be performed using the time-tested Clamp and tie method or more modern methods like Ligasure, a form of bipolar surgical diathermy. The novel electrothermal bipolar tissue sealing device (Ligasure) has been used in many different surgical specialties, and other diathermy approaches have been presented to limit intraoperative blood loss⁽¹⁾. Thyroid surgery necessitates precise and reliable hemostasis because of the proximity of the thyroid to vital structures such the carotid artery, jugular vein, and recurrent laryngeal nerve (RLN). The extent to which laryngeal nerves and parathyroid glands are injured during surgery may be influenced by the efficacy of hemostasis⁽²⁾.

A number of recent tools, including as the Harmonic Focus Scalpel and the Ligasure vascular sealing device, have contributed to the development of thyroid surgery. When it comes to thyroid surgery, the newest iteration of the Ligasure (LS) is the small jaw. In thyroid surgery, the ability to dissect and cut with this instrument improves hemostasis and decreases the amount of time needed for the procedure⁽³⁾. LS system is a bipolar diathermy device used to close blood arteries with minimal heat damage to surrounding tissue. The device has been offered as a new approach for hemostasis during thyroidectomy after its successful application in abdominal surgery⁽⁴⁾.

Since the LS's electrode tips are insulated with rubber, they don't transfer as much heat to the surrounding tissue, making them ideal for dissecting near sensitive blood veins. An additional benefit of the LS is its unique ability to switch off after the tissue seal cycle

is complete, which lessens the risk of collateral tissue injury⁽⁵⁾.

Vocal cord palsy and hypocalcemia are the most prevalent and potentially fatal consequences of thyroid gland surgery. Bleeding during a thyroidectomy can delay the procedure and make it more difficult to safely dissect the recurrent laryngeal duct and the parathyroid glands. In this way, excellent hemostasis is most beneficial for preserving surgical visibility and avoiding harm to structures like the parathyroid glands and the laryngeal nerves⁽⁶⁾.

The aim of the current study is to evaluate the effectiveness of the Ligasure small jaw approach versus the standard Clamp and tie method in thyroidectomy.

PATIENTS AND METHODS

Our study is a randomized controlled clinical trial was conducted in the General Surgery Department at Zagazig University Hospital on a sample of 30 cases. The patients were divided into 2 groups; Group A includes 15 patients underwent thyroidectomy using Ligasure small jaw technique, and Group B includes 15 patients underwent thyroidectomy by using traditional Clamp and tie technique.

Inclusion criteria: Age 15 - 65 year, patients with diagnosis of multinodular goiter, patients with diagnosis of retrosternal goiter, patients with diagnosis of thyroid cancer, and any other cases indicated for thyroidectomy.

Exclusion criteria: Age less than 15 years and above 65year, those who had previously undergone neck surgery or who needed another thyroidectomy, and patients taking calcium supplements who also have underlying parathyroid disease.

All patients were subjected to:

A. History taking: Full clinical history taking will be obtained from each patient with special emphasis on the presenting symptoms.

B. Clinical Examination: Both general and local examinations were performed to every patient:

C. Laboratory investigation: Including thyroid function tests (TSH, T3 and T4 to assess the functional status of the gland and to render the patients with thyroid dysfunction euthyroid. All routine preoperative investigations for any major surgery were done including CBC, LFT, KFT, Coagulation profile, RBG, ECG, etc.

D. Imaging procedures: All cases were submitted to neck and thyroid US to confirm their diagnosis. It also provides data about site, size and character of the nodules moreover, the presence or absence of lymph nodes. CT scan of the neck was only done when retrosternal extension presented, invasion of the surrounding structures were suspected or assessment of cervical lymph nodes in cases suspected to be malignant. No MRI study was done for our patients.

E. Cytology: Fine needle aspiration cytology was done for all nodules at Clinical Pathology Department at Zagazig University Hospitals and in some specialized centers for pathological examination. The FNA reports were classified according British Thyroid Association (BTA) guidelines as class 1 (normal), class 2 (benign), class 3 (indeterminate or equivocal), class 4 (suspicious of malignancy) or class 5 (malignant cytology)⁽⁷⁾. A routine preoperative Internal Medicine and Cardiology consultations were done for all patients, in addition to Anesthesia consultation.

Operative measures:

All patients were admitted the day before operation after completion of all consultations (Cardiology, Internal Medicine and Anesthesia) and the patients were documented as fit for surgery. All patients were informed to be fasting for 6-8 hours before surgery time. A written consent for patient's acceptance of the operation and the possible complication of surgery was taken.

Operative technique: Endotracheal intubation and general anesthesia were used for all procedures, which were performed with the patients in supine position with their necks stretched using a cushioned sandbag between their scapulae and their head ring. Ligasure small jaw was used for cases of *Group A*, while, we used traditional Clamp and tie technique for cases of *Group B*. All patients underwent thyroidectomy in the following steps:

- Preparation of the skin from chin above to mid chest below and bilaterally as far as possible to include the entire neck and shoulders.
- Draping of the incision site by four towels.
- Transverse skin incision was made about 2 finger breadth above the sternal notch along Langer lines then division of platysma and formation of the upper flap till thyroid notch and lower flap till sternoclavicular joints.
- Vertical division of the midline raphe between the strap muscles then the muscles separated and

retracted laterally to expose thyroid lobes.

- Thyroidectomy hemostasis methods were used to classify patients into one of two groups: Ligasure (*Group A*, n=15) or traditional Clamp and tie technique (*Group B*, n=15).

For cases of Group A, we used Ligasure small jaw as the following steps:

All middle thyroid veins were sealed by the Ligasure and divided by scissors (**Figure 1**).

Exposure of the superior thyroid pole and the superior thyroid vessels were identified and sealed with preservation of EBSLN (**Figure 2**).

Inferior thyroid vessels were sealed and divided using Ligasure close to the gland to avoid injury of RLN (**Figure 3**).

Dissection of the gland from its posterior capsule was done using Ligasure with preservation of RLN and parathyroid glands.



Figure (1): Sealing of middle thyroid vein (Lt. Side) using Ligasure small jaw.



Figure (2): Sealing of superior thyroid pole and vessels using Ligasure small jaw.

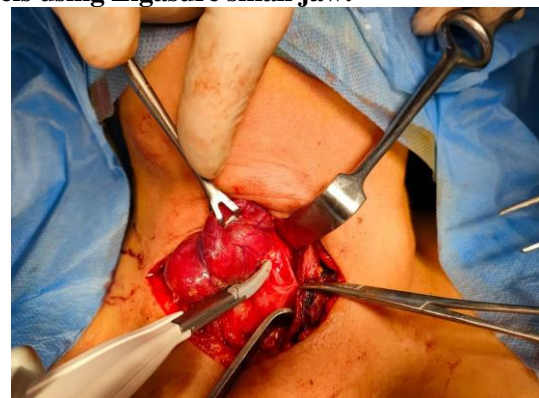


Figure (3): Sealing of inferior thyroid vessels using Ligasure small jaw.

For cases of group B, we used traditional Clamp and tie technique as the following steps:

- Retraction of the strap muscles to one side and the middle thyroid vein identified, clamped, divided then tied with vicryl 3/0.
- Exposure of the upper pole of the thyroid and the superior thyroid vessels are identified, clamped, divided and doubly tied near the upper pole with preservation of EBSLN (**Figure 4**).
- Ligation and division of branches of the inferior thyroid vessels to avoid injury of RLN by division of them at the capsule with preservation of the blood supply of parathyroid glands.
- The lobe dissected from the posterior capsule.
- The same steps were repeated for the other lobe in cases of total thyroidectomy.
- The gland dissected from the trachea and removed after its gross exam to ensure no removal of parathyroid glands.
- Ensure absolute hemostasis of the field then insertion of suction drain or rubber drain in thyroid bed (**Figure 5**).
- Closure of fascia of the strap muscles by interrupted sutures then approximation of platysma and finally subcuticular sutures by proline 3/0 or absorbable vicryl sutures.
- Light dressing of the incision site and the drain.
- Asking the anesthesiologist to check the mobility of the vocal cords.
- Excised thyroid gland specimen was sent for histopathological evaluation (HPE).
- Operative time was calculated and reported for each case.
- Intraoperative blood loss was estimated.



Figure (4): Exposure of the upper thyroid pole and vessels in Clamp and tie technique.



Figure (5): Ensure good hemostasis and insertion of rubber drain.

Postoperative measures:

Postoperative follow up; all cases at the inpatient department with near source of oxygen beside the patient bed. Regular check of the vital signs every 2hours and observation of dressing and the drains regarding the amount and nature of the discharge.

Oral fluids are allowed 2 hours after recovery and soft diet allowed at the evening if the patient tolerates the oral fluids. In the next day, serum calcium is estimated and calcium supplementation is started for a month.

Follow-up:

The patients are instructed for follow up at the outpatient clinic 1week later, then after 2weeks and monthly. The histopathology report usually interpreted at the first post-operative visit.

Ethical consent:

The study was approved by the Zagazig University Research Ethics Committee (IRB number: 7040/25-7-2021). After explaining our research objectives, written informed consent was obtained from all study participants. The World Medical Association's Helsinki Declaration established principles for conducting research involving human subjects.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 20 for Windows® (IBM SPSS Inc, Chicago, IL, USA). In order to convey the findings, tables and graphs were employed. Qualitative data were described using number and percent.

Quantitative data were described using median (minimum and maximum) and inter quartile range for non-parametric data, and mean and standard deviation (SD) for parametric data after testing normality using Kolmogrov-Smirnov test.

Student's t test (T) was used to assess the data while dealing with quantitative independent variables. Pearson Chi-Square and Chi-Square for Linear Trend (X²) were used to assess qualitatively independent data. P value ≤ 0.05 was considered significant.

RESULTS

When comparing the ages of participants in each group, there was no statistical significant difference. Table 1 compares Group A and Group B regarding age and gender.

Table (1): demographic data between the two studied groups

Variable			Group (A)	Group (B)
Age (year)	Mean± SD		39.60±11.37	37.33±11.31
	Range		27-60	25-58
Gender	Male	N	2	4
		%	13.33%	26.67%
	Female	N	13	11
		%	86.67%	73.33%
Total	N		15	15
	%		100.0%	100.0%

Table 2 summarizes the diagnosis of the 2 studied groups.

Table (2): Comparison between the two studied groups regarding diagnosis.

Variable			Group	
			Group (A)	Group (B)
Diagnosis	Differentiated thyroid carcinoma	N	2	1
		%	13.33%	6.67%
	Graves' disease	N	1	2
		%	6.67%	13.33%
	Toxic multinodular goiter	N	1	2
		%	6.67%	13.33%
	Multinodular goiter (MNG)	N	11	10
		%	73.33%	66.67%
Total	N		15	15
	%		100.0%	100.0%

In terms of operative time, there was a statistically significant difference between the two groups. Group A who had undergone thyroidectomy using Ligasure had significantly lower operative time than Group B using traditional method (Table 3).

Table (3): Comparison of operative time between the two studied groups.

Variable		Group (A)	Group (B)	T	P value
Operative Time (Min)	Mean ± SD	88.56 ± 8.6	116.58 ± 25.15	8.45	0.0002
	Range	60-100	90-150		

Thyroidectomies performed utilizing the ligature technique had much less blood loss than those performed using the conventional method (P=0.012) (Table 4).

Table (4): Comparison of amount of intraoperative blood loss between the two studied groups.

Variable		Group (A)	Group (B)	T	P value
Blood loss (ml)	Mean ± SD	70.0 ± 17.41	103.33 ± 23.96	2.732	0.012*
	Range	50-100	80-150		

No statistically significant difference in length of hospital stay could be found between the two groups (Table 5).

Table (5): Comparison of duration of hospital stay between the two studied groups

Variable		Group (A)	Group (B)	T	P value
Hospital stay/ days	Mean ± SD	1.05 ± 0.24	1.5 ± 0.8	1.620	0.116
	Range	1.6-2.8	1.9-4		

There was a statistically significant difference in the amount of postoperative drainage between the two groups (Table 6).

Table (6): Comparing means of postoperative drainage volume between the two studied groups

Variable		Group (A)	Group (B)	T	P value
Drainage (ml)	Mean ± SD	81.06 ± 20.12	100.33 ± 23.48	2.390	0.024*
	Range	60-110	80-140		

Regarding post-operative bleeding or hematoma, only one (6.7%) patient from *Group B* (Clamp and tie technique group) had experienced post-operative bleeding and was managed via surgical exploration. There was a change in vocal cord function associated with a lower vocal tone in five individuals (2 in the Ligasure group, or 13.3%, and 3 in the traditional group, or 20%); temporary laryngeal nerve palsy.

Systemic cortisone treatments, as well as nebulizer cortisone treatment, have been used to alleviate this condition. In neither group did patients experience any long-term or bilateral RLN palsy. Neither group experienced significantly more postoperative bleeding, or a higher rate of transient RLN palsy, than the other (Table 7).

There is no permanent hypocalcemia was seen in both groups but temporary hypocalcemia was occurred in 4 (26.7%) patients in both groups equally (26.7% of each group).

Post-operative wound infection occurred in 1 (6.7%) patient from Group A (Ligature group) and 3 (20%) patients from Group B (Clamp and tie group). Group A had a lower rate of wound infection than Group B, although the difference was not statistically significant (P value 0.28) (Table 7).

Overall, post-operative complications occurred more with traditional clamp and tie technique than Ligasure technique, with no statistically significant difference.

Table (7): Complications among two studied groups

Variable			Group		X ²	P value
			Group (A)	Group (B)		
Bleeding	-VE	N	15	14	1.03	0.309
		%	100%	93.3%		
	+VE	N	0	1		
		%	0.0%	6.7%		
Wound infection	-VE	N	14	12	1.15	0.28
		%	93.3%	80%		
	+VE	N	1	3		
		%	6.7%	20%		
Permanent hypocalcemia	-VE	N	15	15	0.0	1.0
		%	100%	100%		
	+VE	N	0	0		
		%	0.0%	0.0%		
Transient hypocalcemia	-VE	N	11	11	0.0	1.0
		%	73.3%	73.3%		
	+VE	N	4	4		
		%	26.7%	26.7%		
Permanent laryngeal nerve palsy	-VE	N	15	15	---	---
		%	100%	100%		
	+VE	N	0	0		
		%	0.0%	0.0%		
Temporary laryngeal nerve palsy	-VE	N	13	12	0.24	0.64
		%	86.7%	80%		
	+VE	N	2	3		
		%	13.3%	20%		
Death	Survived	N	15	15	---	---
		%	100%	100%		
	Died	N	0	0		
		%	0.0%	0.0%		
Total		N	15	15	---	
		%	100%	100%		

DISCUSSION

LS is a tool for closing blood arteries as small as 7 mm in diameter. Low voltage and high current are used to seal the tissue. The sealing process works because of the synergy between pressure energy and electric current. By applying intense force while the tissue is being heated, the hydrogen cross links are first broken and subsequently denatured, producing a seal with exceptional tensile strength. The typical seal life cycle lasts between two and four seconds⁽⁸⁾.

In our study, we found that the mean age was 39.60 years and 37.33 years among Groups A and B respectively. When comparing the ages of participants in each group, there was no discernible difference. Group A consisted of 86.67% women, while Group B was composed of only 73.33% women. Between Groups A and B, male representation was 13.33% and 26.67%, respectively. Neither group showed a statistically significant difference in gender. Nearly the same results was found in a previous study done by **AlJuraibi et al.**⁽⁵⁾, to compare between using Ligasure versus conventional suture-ligation in total thyroidectomy, found that In terms of age, sex, and other demographics, neither group statistically differed from the other. Patients in the Ligasure group had a mean age of 42.25 years, while those in the conventional suture -ligation group had a mean age of 40.19 years, with no statistically significant difference between the two groups.

In our study, the operative times for the two groups were significantly different. These findings were consistent with the result of a previous study held by **Bhattani et al.**⁽⁹⁾ showed that when comparing the two groups, Group A (Ligasure group) had a considerably shorter mean operation time (92 min) than Group B (traditional suture tie technique) (123 min). There was a statistically significant (P value 0.01) disparity between the groups' mean operative times. These results also came in concordance with those reported in previous studies performed by **Saint et al.**⁽¹⁰⁾, **Yao et al.**⁽¹¹⁾ and **Khafagy & Abdelnaby**⁽¹²⁾ found that using Ligasure in thyroidectomy result in a significant reduction in operative time.

Regarding intraoperative blood loss, Blood loss during surgery is estimated using the visual approach and the clinical assessment in conjunction with the anesthesiologist. Calculating blood loss via visual method, we relied on the standard surgical sponge measuring (4x4 inches). When a dry 4x4 sponge containing 10 ml of blood, it will appear completely saturated. For example, 5 completely soaked surgical 4x4 sponges will contain approximately 50 ml of blood⁽¹³⁾.

We found that Intraoperative blood loss differed significantly between the two groups (P =0.012). In the same direction, a study performed by **Bhattani et al.**⁽⁹⁾ found that the estimated mean intraoperative blood loss was 51.73 ml in the ligature group and 139.42 ml in the

non-ligature group (conventional suture tie technique). The difference between the two groups was statistically significant (P <0.01). Another study done by **Grøndal et al.**⁽¹⁴⁾ found that Using Ligasure in complete thyroidectomy instead of the more traditional suture ligation approach significantly decreased intraoperative blood loss. The same results were also obtained in a study performed by **Akram et al.**⁽¹⁾ found that mean intraoperative blood loss was recorded to be 57.28 ml in the Ligature technique group and 70.854 ml in the conventional technique group, with a P-value of 0.0001, indicating a significant difference between the two groups.

Regarding postoperative drainage volume, we found that a statistically significant difference existed between the two groups (P value =0.024). These findings came in concordance with a previous study held by **AlJuraibi et al.**⁽⁵⁾ found that Group A (Ligasure group) had significantly less fluid drained compared to Group B (traditional suture ligation group). These findings align with those of our research.

Regarding to postoperative complications, we found that there were 5 patients (2 (13.3%) from Ligasure group and 3 (20%) from traditional group) decreased vocal tone and altered vocal cord function were reported (temporary laryngeal nerve palsy). Systemic cortisone treatments as well as nebulizer cortisone treatment have been used to alleviate this condition. In neither group did patients experience any long-term or bilateral RLN palsy. As far as transitory RLN palsy was concerned, there was no discernible difference between the two groups. These findings were consistent with the result of a previous study performed by **Coiro et al.**⁽⁴⁾ who found Voice tone decreased and vocal function was altered in six cases (3 from group CT and 3 from group LSJ). The same results also showed by **AlJuraibi et al.**⁽⁵⁾ who found no individuals in either group suffered from bilateral irreversible damage to their recurrent laryngeal nerves. In Group A, 3% of patients and 5% of patients in group B experienced transient RLN damage.

Regarding post-operative bleeding or hematoma, only 1 (6.7%) patient from Group B (Clamp and tie technique group) had experienced post-operative bleeding and was managed via surgical exploration. In terms of postoperative hemorrhage, neither group differed significantly from the other. The same result was obtained from a previous study held by **Mosalam et al.**⁽¹⁵⁾ who found that 1 (10%) case in Group A (group of traditional method) was complicated by hematoma, while no cases developed that complication in the other group (P =0.372).

In our study, **Post-operative wound infection** occurred in 1 (6.7%) patient from Group A (Ligasure group) and 3 (20%) patients from Group B (Clamp and tie group). Wound infection was lower in Group A than Group B but this difference was not statistically significant (P value =0.28). **Mosalam et al.**⁽¹⁵⁾ found

that superficial surgical site infection was diagnosed in 1 (10%) case in each group, and they were managed by antibiotics in both cases. Post-operative seroma was lower in Ligasure group than traditional group as it was found in 1 (10%) case in Ligasure group and 2 (20%) cases in traditional group but this difference was not statistically significant ($P=0.248$).

In conclusion, Ligasure technique is superior to traditional clamp and tie technique in terms of lowering operation time, intra operative blood loss, postoperative drainage or hematoma, parathyroid damage and RLN injuries.

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