

Comparative Study between Ligasure and Conventional Vessel Ligation in Thyroidectomy “Randomized-Controlled Study “

Ammar SA ¹, Moataz Ahmed Altayb ², Ashraf Ahmed Helmy¹, Abadeer Rafaat Marsis^{1*}

¹General Surgery, ² Pediatric Surgery, Faculty of Medicine - Assuit University

*Corresponding author: Abadeer Rafaat Marsis, Email: Dr.abadeermarsis@gmail.com, Mobile: 01289028410

ABSTRACT

Background: Remarkable increase in incidence of thyroid cancer over previous decade has resulted in increased need for thyroid surgery.

Aim and objectives: Goal of research was to evaluate safety and efficacy of using vessel sealing device ligasure (COVIDIEN®) in terms of intraoperative and postoperative complications, comparing to standard vascular ligation in open thyroid surgery.

Patients and methods: A randomized-controlled trials that was conducted at Department of General Surgery of Assiut University Hospitals. A total of 80 patients were scheduled for thyroidectomy participated in the research. Those patients were randomly subdivided into 2 categories. Category 1 included cases who underwent conventional vessel ligation (n= 40 patient) and category 2 included cases who underwent ligasure vessel sealing (n=40 patients). The study was conducted in the period between 2019 and 2021.

Results: Both groups had insignificant difference regarding overall recorded complications (8 (20%) vs. 7 (17.5%); $p=0.51$). One patient in each group developed hoarseness while recurrent transient laryngeal nerve damage was recorded in two patients in each category. The most frequent complication was transient hypocalcaemia (12.5% of conventional ligation and 10% of ligasure sealing group).

Conclusion: Ligature was superior to conventional approach in terms of lowering operation time, perioperative and postoperative blood loss, and parathyroid damage. RLN injuries, on the other hand, were comparable in both categories. Although shorter operative periods led to lower operating room occupancy expenses, overall cost of surgery was considerably greater in ligasure category.

Keywords: ligasure; conventional vessel ligation; thyroidectomy; hemostasis.

INTRODUCTION

Given thyroid gland's substantial vascularity and fairly limited operating field, thorough hemostasis will always be key prerequisite for successful result in thyroid surgery ⁽¹⁾.

Tying and cutting of blood arteries is cornerstone for attaining hemostasis in thyroid surgery, both of which are effective but time-consuming approaches. Given current state of healthcare constraints and long waiting lists, any strategy that can cut surgical time while maintaining acceptable standards and complication rates merits further consideration ⁽²⁾.

So-called laparoscopic revolution in surgical procedures occurred in 1990s, when many operations were adjusted from classical open surgery to minimally invasive techniques. Minimally invasive surgeries consequence in less surgical trauma, less pain, and shorter hospital stay ⁽³⁾. Since it offers better cosmetic outcomes without increasing risk of surgical problems, approach has proven particularly appealing for thyroidectomy surgeries ⁽²⁾.

New technology have been developed because minimally invasive surgical methods have improved, between them vessel sealing device (LigaSure COVIDIEN®) ⁽⁴⁾.

Vessel sealing device seals vessels by fusing inner layers of vessel wall with little thermal dispersion, burning, and tissue friction, lowering likelihood of unintentional burns. due to these advantages, vascular

sealing tool has increased in popularity among head and neck surgeons, particularly for thyroid procedures ⁽⁵⁾.

PATIENTS AND TECHNIQUES

A randomized-controlled trial was conducted at Department of General Surgery of Assiut University Hospitals.

Inclusion criteria:

Any patient was scheduled for lobectomy, subtotal thyroidectomy, or total thyroidectomy was enrolled in the study.

Exclusion criteria:

Studied case undergoing re-operation, including whole thyroidectomy, studied case undergoing concurrent operations such as cervical lymphadenectomy and par-thyroidectomy, and studied case refusal.

Sample size and randomization:

All cases that fulfilled the selection criteria during the study period were recruited. The expected number of patients during study period was 80 patients. Computer-generated database of random numbers was utilized to allocate studied cases to different treatments in 1:1 ratio. Studied cases were assigned to appropriate therapy category in numerical

order after agreeing to enroll at time of enrollment. Permuted blocked randomization was done online to generate the randomization list. So, we had two groups in the study; category 1 included studied cases underwent conventional vessel ligation (n= 40 patient) and category 2 included studied cases underwent ligasure vessel sealing (n=40 patients).

Methodology

Preoperative assessment:

Studied cases were subjected to thorough history taking (age, sex, symptoms and duration of symptoms) and full clinical evaluation.

Neck ultrasound was done to all patients. Baseline laboratory investigations (complete blood count and coagulation profile) was ordered in all patients. Indirect laryngoscopy to assess mobility of both vocal cords was performed.

Operative procedure:

All procedures were carried out by surgical resident and senior writer. Operative procedure was divided into 3 stages: 1) Kocher's skin incision, separation and undermining of strap muscles, sealing of middle thyroid veins, 2) ligation of upper thyroid pole vessels and ima veins, dissection of lateral part of gland to isthmus, and midline cleavage, and 3) hemostasis and closure (Figure 1). Measuring intraoperative blood loss was hard, where gauze absorbs majority of blood. Adoption of visual analogue may improve blood loss estimation accuracy and reduce implications of excess or underestimation of blood loss. Removal suction pump was placed across thyroid fossa.

To close strap muscles and platysma layer, incision was closed with discontinuous 2-0 polyglactin sutures (Vicryl, Ethicon). Monocryl 3-0 subcuticular sutures were used to seal skin.

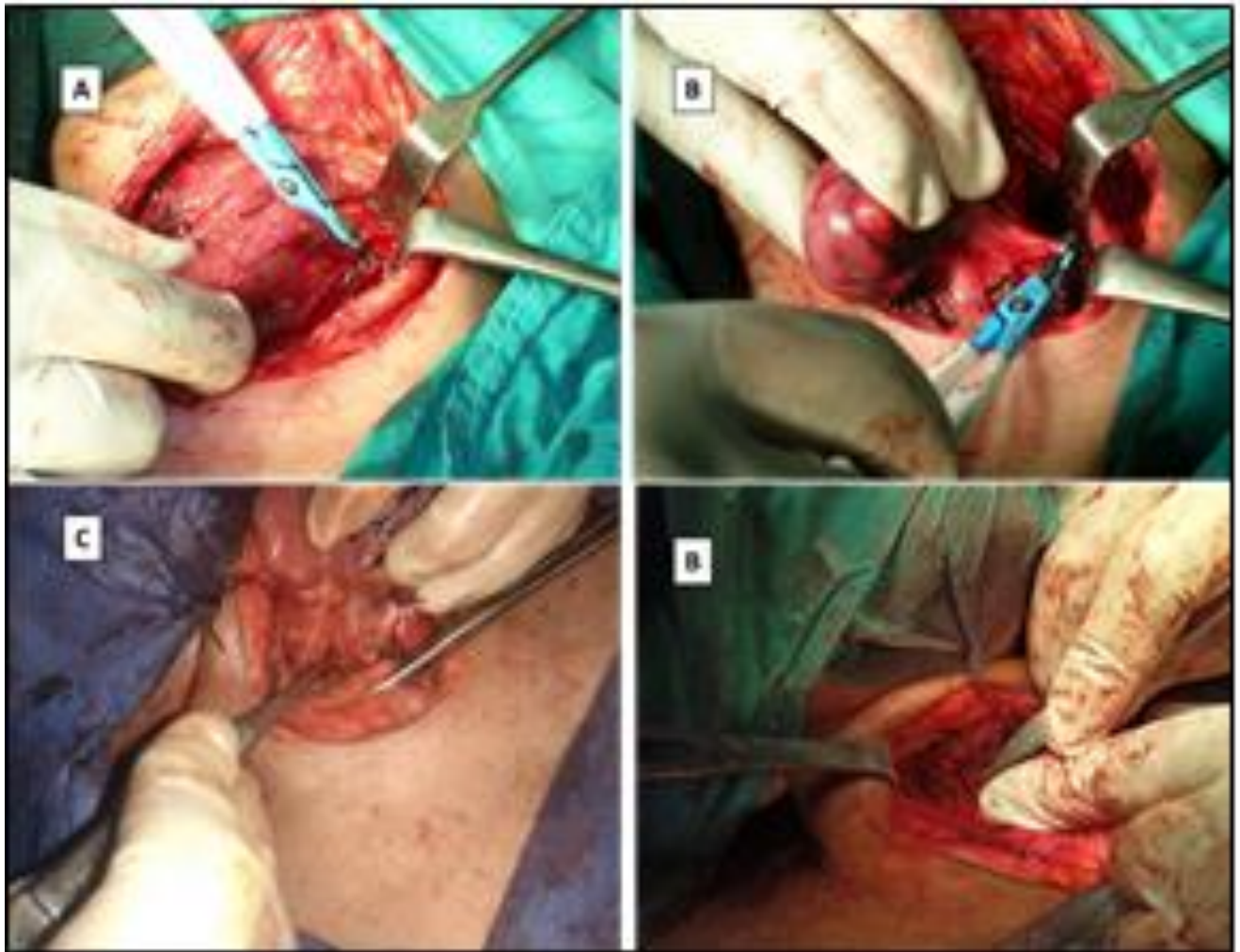


Figure 1: A, B) ligasure sealing system; C, D) Conventional vessels ligation

Postoperative follow up:

During the postoperative period the patients were assessed carefully for the clinical symptoms and signs of hypocalcaemia, symptoms of recurrent laryngeal nerve (RLN) injury, postoperative wound hematoma, postoperative drainage and thyroid storm. When the drainage volume was less than 20 ml/24 hours, the suction device was removed and the patient was discharged. The patients were observed closely regarding respiration and any change in their voice. Any patient who had any of the previous complaint underwent laryngoscope examination for evaluation of both vocal cords.

Outcomes: Primary outcome was decrease of operative time and volume of discharge. 2 categories in terms of hospital stay and surgical complications like hypocalcemia and RLN palsy were the secondary outcome.

Ethical considerations:

The study was approved by the Faculty's Ethics Committee, Assuit University. All the patients were informed about the surgery and the auto transplantation technique, value and possible complications. Informed written consents were taken from all patients. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

The collected data were examined with package for social sciences, version 20.0. (SPSS Inc., Chicago, Illinois, USA). Student t test was used to compare quantitative data given like mean ± SD. Chi square test was used to compare qualitative data expressed like frequency and percentage. P ≤ is significant.

RESULTS

Both groups of studied cases had insignificant differences as regards age (39.55 ± 13.08 vs. 41.20 ± 10.96 years) and body mass index (25.52 ± 2.74 vs. 26.34 ± 3.98 kg/m²). Majority (82.5%) of group I and 87.5% of group II were females (Table 1).

Table (1): Baseline characteristics of studied cases

	Category 1 (n= 40)	Category 2 (n= 40)	p value
Age (years)	39.55 ± 13.08	41.20 ± 10.96	0.54
Sex			0.37
Male	7 (17.5%)	5 (12.5%)	
Female	33 (82.5%)	35 (87.5%)	
Body mass index (kg/m ²)	25.52 ± 2.74	26.34 ± 3.98	0.41

Data expressed as frequency (percentage) and mean ± SD. Category 1 had studied cases who

underwent conventional vessel ligation Category 2 included patients who underwent ligasure vessel sealing

Multinodular goiter was frequently present in both groups (60% of category1 and 70% of category 2) where eight patients in each group had thyroid nodule. Toxic goiter was present in 5 (12.5%) and 2 (5%) patients of group I and II, respectively. Three patients (7.5%) of category 1 and 2 (5%) patients of category 2 had thyroid cancer. Only four patients in the current study had hyperthyroid pattern while the other patients had euthyroid pattern. Both groups had insignificant differences as regards diagnosis and pattern of thyroid function (p > 0.05) as shown in table (2).

Table (2): Diagnosis among studied patients

	Group I (n= 40)	Group II (n= 40)	P value
Diagnosis			0.61
Multinodular goiter	24 (60%)	28 (70%)	
Thyroid nodule	8 (20%)	8 (20%)	
Toxic goiter	5 (12.5%)	2 (5%)	
Thyroid cancer	3 (7.5%)	2 (5%)	
Pattern of thyroid function			0.30
Euthyroid	37 (92.5%)	39 (97.5%)	
Hyperthyroid	3 (7.5%)	1 (2.5%)	

Category 1 had studied cases underwent conventional vessel ligation Category 2 had studied cases underwent ligasure vessel sealing

It was found that operative time was significantly lower among patients who underwent ligasure vessel sealing (132 ± 31.71 vs. 108.75 ± 30.14 minutes). Also, patients who underwent ligasure vessel sealing had significantly lower intraoperative blood loss (96.50 ± 23.38 vs. 143 ± 59.71 and post-operative blood loss (17.50 ± 5 vs. 95.56 ± 16.56 ml). In the same time, postoperative calcium was significantly higher among those who underwent ligasure vessel sealing (8.61 ± 0.34 vs. 8.14 ± 0.82 mg/dl) (Table 3).

Table (3): Perioperative data of cases

	Category 1 (n= 40)	Category 2 (n= 40)	p value
Operative time (minute)	132 ± 31.71	108.75 ± 30.14	< 0.001
Intraoperative blood loss (ml)	143 ± 59.71	96.50 ± 23.38	< 0.001
Post-operative blood loss (ml)	95.56 ± 17.50	16.56 ± 5	< 0.001
Post-operative calcium (mg/dl)	8.14 ± 0.82	8.61 ± 0.34	0.03

Category 1 had cases underwent conventional vessel ligation Category 2 had cases underwent ligasure vessel sealing

Studied cases who underwent ligasure vessel sealing had shorter hospital stay (2.1 ± 0.71 vs. 3.45 ± 2.47 day). Both groups had insignificant difference as regards overall recorded complications (8 (20%) vs. 7 (17.5%), $P= 0.51$). One patient in each group had hoarseness while transient RLN injury was recorded in two patients in each category.

The most frequent complication was transient hypocalcaemia (12.5% of conventional ligation and 10% of ligasure sealing group). Each of neck hematoma and wound infection was reported in one patient in conventional ligation group. There were no significant differences between both groups concerning all complications and they were conservatively managed (Table 4).

Table (4): Hospital stay and post-operative complications among studied categories

	Category 1 (n= 40)	Category 2 (n= 40)	p value
Hospital stay (day)	3.45 ± 2.47	2.1 ± 0.71	0.03
Neck hematoma	1 (2.5%)	0	0.50
Wound infection	1 (2.5%)	0	0.50
Transient hypocalcaemia	5 (12.5%)	4 (10%)	0.60
Transient RLN injury	2 (5%)	2 (5%)	0.69
Hoarseness	1 (2.5%)	1 (2.5%)	0.75
Overall complications	8 (20%)	7 (17.5%)	0.51

RLN: recurrent laryngeal nerve Category 1 had studied cases underwent conventional vessel ligation Category 2 had studied cases underwent ligasure vessel sealing.

It was found that mean cost of ligasure vessel sealing was significantly higher in comparison with conventional vessel ligation (1245.25 ± 111.98 vs. 46.25 ± 4.77 LE) (Table 5).

Table (5): Mean cost among each group of cases

	Category 1 (n= 40)	Category 2 (n= 40)	p value
Cost (LE)	46.25 ± 4.77	1245.25 ± 111.98	<
Range	40-55	111.98-1800	0.001

Category 1 had studied cases underwent conventional vessel ligation Category 2 had studied cases underwent ligasure vessel sealing.

DISCUSSION

Remarkable rise in incidence of thyroid cancer over last decade has led in increase in need for thyroid surgery. Several energy devices with hemostatic purposes were designed and frequently used in surgical sectors. Several surgeons use them in conjunction with electric cautery and ligation (6,7).

A total of 80 patients scheduled for thyroidectomy participated in this research. Those patients were randomly subdivided into categories. Category 1 included cases underwent conventional vessel ligation (n= 40 patient) and category 2 included cases underwent ligasure vessel sealing (n=40 patients). In terms of baseline information, there were no differences between the two groups, and the majority of studied cases were females. In line with the current study, a previous one was conducted on 118 patients (60 patients in group conventional ligation and 58 patients in ligasure sealing group) (8). Similar to our research, **Ahmed et al.** (9) enrolled 66 women cases (94.3%) and just 4 men cases in research at Pakistan Emirates Military Hospital (5.7%). In research, mean age of studied cases was 39.4 ± 6.7 years with no differences between standard suture ligation category and ligasure category. In addition, **Shaikh et al.** (10) evaluated fifty five studied cases, twenty four in conventional method category and thirty one in ligasure method category. Average age of research cases was 33.25 ± 10.60 years in traditional method category and 35.16 ± 07.96 years in the ligasure method category, with no change (p-0.448). Almost 80% of research participants were women in both categories.

Most diagnosis in research was multinodular goiter. There were only five patients in the study had thyroid cancers. Regarding diagnosis and histopathology both had insignificant differences. In agreement with these results, previous study enrolled 102 patients scheduled for thyroidectomy, up to 66.7% had multinodular goiter. There was only 1 studied case who had been diagnosed with differentiated thyroid cancer preoperatively (11). In contrast, **Back et al.** (12) studied 75 patients who underwent thyroidectomy. The authors found that majority (88%) of patients had thyroid cancers and only 9 (12%) patients had benign thyroid lesions. This discrepancy was attributed to different selection bias and different population.

Our study found that operative time was significantly lower among patients who underwent ligasure vessel sealing (132 ± 31.71 vs. 108.75 ± 30.14 minute). Also, patients who underwent ligasure vessel sealing had significantly lower intraoperative blood loss and post-operative blood loss. In the same time, postoperative calcium was significantly higher among those underwent ligasure vessel sealing (8.61 ± 0.34 vs. 8.14 ± 0.82 mg/dl). Similarly, a previous study stated that mean operative time in ligasure group was significantly lower than conventional category. Also, mean intraoperative blood loss in ligasure group was significantly lower in ligasure group (12). Meta-analysis by **Zhang et al.**, (13) also reported reduction in operative time in ligasure category versus conventional suture ligation method (10). Cases have reported an average operative times ranging from 58 to 115.54 minutes for total thyroidectomy using ligasure machine and 75 to 153.45 minutes for conventional vascular ligation

method^(9,11). Another study concluded that traditional method category had substantially longer average operative time of 113.62 ± 11.50 minutes than ligasure method category of 85.90 ± 15.40 minutes⁽¹⁰⁾. These results are also consistent with results of **Saint Marc et al.**⁽¹⁴⁾ who found 41.5 ± 11.2 minutes as average operative time in ligasure category and 48.86 ± 8.8 minutes in traditional category.

Our study found that patients who underwent ligasure vessel sealing had significantly shorter hospital stay (2.1 ± 0.71 vs. 3.45 ± 2.47 days). In consistence with the current results, many previous studies reported that use of ligasure decreased surgical time and hospital duration considerably^(10, 11, and 14).

Both groups in our study had insignificant difference as regards overall recorded complications [8 (20%) vs. 7 (17.5%)]. One patient in each group had hoarseness while in every category, 2 individuals experienced transient RLN damage. The most frequent complication was transient hypocalcaemia (12.5% of conventional ligation and 10% of ligasure sealing group). Each of neck hematoma and wound infection was reported in one patient in conventional ligation group. A study reported that ligasure approach allows for easier dissection of thyroid lobes and decreases surgery time. They also suggested that ligasure reduced need for lateral skin retraction, shorter incision length and decreased postoperative pain⁽¹⁵⁾. In comparable to our results, **Bhattani et al.**,⁽¹¹⁾ stated that in traditional arterial ligation category, there was only 1 occurrence of postoperative hematoma development (0.9%), but none of studied cases in ligasure collective suffered hematoma formation. **Dehal et al.**⁽¹⁶⁾ reported 1.5% incidence of postoperative hematoma after thyroid surgery in their retrospective study.

In our study, usage of ligasure did not enhance risk of RLN palsy and hypocalcemia. These findings are consistent with a study reported that use of ligasure in thyroid surgery reduces likelihood harmful vascular and nerve damage dramatically. When compared to traditional thyroidectomy, ligasure vessel sealing method has been shown to decrease operative time and RLN, and parathyroid damage⁽¹¹⁾.

In the current study, the mean cost of ligasure vessel sealing was significantly higher in comparison with conventional vessel ligation (1245.25 ± 111.98 vs. 46.25 ± 4.77 LE). Similarly, **Bhattani et al.**⁽¹¹⁾ concluded that despite benefits of reduced operative time cost of surgery was much greater in ligasure category due to cost of device. Although operative time is reduced significantly, cost savings is likely offset by cost of devices themselves.

The main strength of the current study included being randomized-controlled trials. Also, our study discussed special issue in such situation that was cost of each procedure. The main limitations of our study were modest sample size and being performed in single location.

CONCLUSION

Ligasure was superior to conventional approach in terms of lowering operation time, perioperative and postoperative blood loss, and parathyroid damage. RLN injuries, on the other hand, were comparable in both categories. Although shorter operative periods resulted in lower operating room occupancy expenses, cost of surgery was considerably greater in ligasure category.

Declarations:

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Availability of data and material: Available

Competing interests: None

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