

Surgical Outcomes of LigaSure Bipolar Device versus Conventional Technique in Total Thyroidectomy

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Abstract

LigaSure® (LS) is an energy-based surgical hemostasis device recently introduced in thyroid surgeries. This study aimed to compare the outcomes of using the LS system and conventional clamp-and-tie (CT) technique for total thyroidectomy in terms of surgical time, hospitalization, blood loss and complications. In this prospective controlled study, a total of 104 patients with benign goiter disorders were enrolled. During the period between January 1, 2018 and December 30, 2020, all participating patients underwent thyroidectomy in the surgical wards of the Baqubah and Kirkuk hospitals, northern Iraq. These study subjects were subdivided into 2 groups each comprising equal number of patients. LigaSure diathermy system was applied to the patients in first group i.e. LS group whereas, conventional ligation was used in the other group i.e. CT group. Surgical outcomes were compared between both groups and the results showed considerable differences regarding the time of surgery, hospital stay, blood loss during and after surgery, hematoma, and laryngeal nerve paralysis ($p < 0.05$). Thus, the study concluded that performing thyroidectomy using the Ligasure system is safe with least possible complications involved. **Keywords:** Catalase, Autologous platelets, Glutathione peroxidase, Malondialdehyde, Iraq

Keywords: Total thyroidectomy, benign goiter, diathermy system.

INTRODUCTION

Generally, thyroidectomy is the treatment of choice for many thyroid disorders, so it can be considered as the most common endocrine surgery.^[1] Thyroidectomy was first described by Halstead and Kocher and since then, it has not changed markedly and is still widely performed.^[2] Because of high vascularity of the thyroid gland and its presence near the main lateral cervical vessels, surgeons should use caution while performing thyroid surgery to achieve speedy and efficacious hemostasis.^[1,3] Intraoperative hemorrhage may cause more serious complications, such as injuries to the laryngeal nerve.^[4] In the past two decades, energy-based devices (EBDs) have been developed to achieve surgical hemostasis. These devices have been able to minimize operation time by ligating the blood vessels without suturing and therefore, reducing the postoperative complications.^[5,6] In addition, surgery with EBDs has proven their efficiency when compared to traditional methods in

terms of hospital stay, postoperative drainage and pain.^[7] LigaSure diathermy (LigaSure vessel sealing system) is among these newly developed technical devices which has achieved promising results in thyroid surgery.^[8,9] Complications related to its surgery can occur because of uncontrolled bleeding, both during and after the surgery.^[10] This sealing device (helps prevent this complication to occur by dissecting tissues in planes, coagulating and cutting vessels with minimal lateral damage to adjacent anatomical structures.^[11-13] As thyroid surgery with EBDs is becoming more common these days, hence, there is an ample need to conduct studies which can analyze the results of this approach towards surgery. Therefore, this comparative

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study aims to evaluate the efficiency of LigaSure device for total thyroidectomy by comparing it with the conventional method in terms of outcomes.

METHODOLOGY

Patients and study design

The current prospective analytic study included 104 patients with goiter and who underwent total thyroidectomy. The procedure was performed in the surgical departments of Baqubah Teaching Hospital, and Kirkuk General Hospital, Iraq. The current study was conducted from January 1, 2018 to December 30, 2020 after getting approval from the ethics committee for scientific research in the local health directorates. In addition, an informed consent was obtained from all participants. According to the type of surgery, the patients were divided into two groups i.e. LS and CT with 52 patients in each group. Patients in former group underwent LigaSure diathermic device while later group patients had conventional clamp-and-tie surgery.

Inclusion and exclusion criteria

All patients with goiter who were assigned total thyroidectomy for benign cases and who agreed to participate in the study were included in this research. In

addition, patients from both genders with age 18 years and above were included. In contrast, patients with recurrent goiter, previous thyroid surgery, cancerous goiter, vocal cord paralysis and thyroiditis were excluded.

Surgical procedures

All patients underwent the necessary preoperative laboratory tests and were admitted in the hospital one night before surgery. Prior to surgery, the patients received appropriate antibiotics in the morning. All procedures were performed using endotracheal intubation under general anesthesia. An upper and lower flap under the platysma was performed through a collar incision, followed by determination of the middle thyroid vein to be controlled either by LigaSure vessel sealing or conventional clamp-and-tie according to the techniques of surgery. Studies have shown that while using LigaSure system, vessels up to 7mm in diameter are sealed,^[14] while lateral thermal diffusion is limited to 1-3mm.^[15] By applying high current and low voltage, closure and division of the vessels are achieved simultaneously. The sealing process occurs by denaturation of collagen and elastin in the vessel wall^[16] as shown in figure 1. A suction vacuum (Redivac) drainage system was installed on the thyroid bed of each patient, which was removed in the next morning.

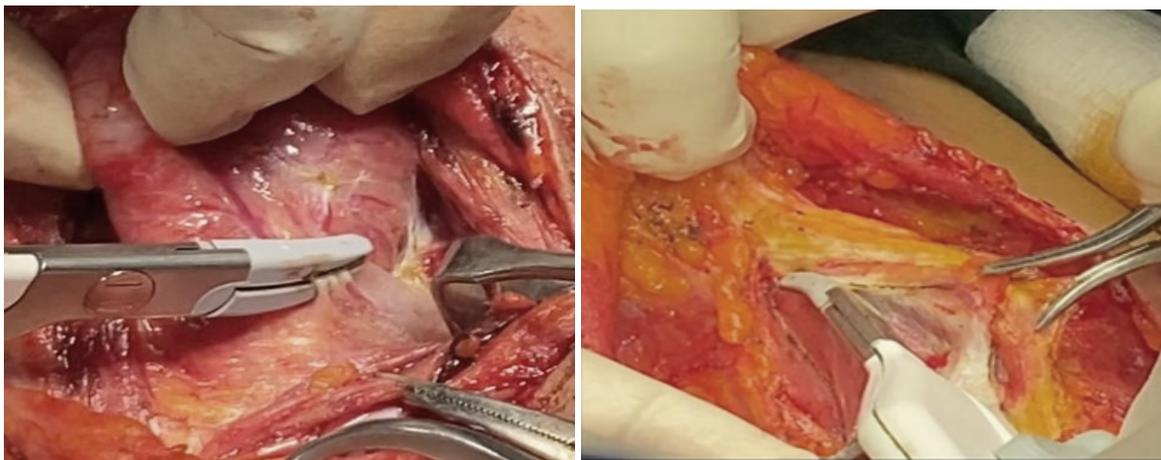


Figure 1: Total thyroidectomy with LigaSure® energy-based device.

After performing the procedure, skin was closed with a subcuticular suturing with prolene 2/0. Following extubation in the operating room, patients underwent direct laryngoscopy to assess the integrity of the RLN. Intraoperative blood loss was measured by calculating the blood collected in the suction device, weighing the blood-soaked gauze and measuring the difference in their weight between wet and dry state. Postoperative blood loss was recorded by measuring the amount collected in a Redivac bag during the first 24 hours.

Outcome measurements

To compare the competence of LigaSure system with that of conventional technique in total thyroidectomy, surgical outcomes were estimated in terms of operation time

(based on the anesthesia assessor), duration of hospital stay, intra and post-operative blood loss, hematoma and wound infection. Additionally, recurrent laryngeal nerve (RLN) palsy was also recorded by postoperative follow-up of twelve months.

DATA ANALYSIS

The data as analyzed using SPSS statistical software (IBM), version 26. The descriptive data was expressed in the form of frequencies and percentages while quantitative variables, were presented as mean and standard deviation. Differentiation between surgical groups was made by independent t-test and chi-square, The p-value less than 0.05 was considered statistically significant.

RESULTS

The mean age±SD of patients in LS group was 41.99±10.56 and that of patients in CT group was 42.77±12.03 whereas, the overall mean age ± SD of all patients was recorded to be 42.38 ± 11.27. With respect to the gender distribution, 72.1% of the patients were females and rest were male. The distribution of age and gender of all patients is shown in table 1.

Table 1: Baseline variables for both surgical groups

Variables	LS N=52 (50%)	CT N=52 (50%)	Total N=104 (100%)
Age(M±SD)	41.99±10.56	42.77±12.03	42.38±11.27
Gender	Male	11 (10.6%)	29 (27.9%)
	Female	41 (39.4%)	75 (72.1%)

No operative deaths were recorded among the participants. The operation time and hospital stay for patients in LS group were remarkably less ($p=0.0001$) than those in group CT (0.018) as illustrative in table 2.

Table 2: Comparison of operation time and hospital stay between surgical groups

Operation time (minutes)	LS N=52	CT N=52	P-value
	89.23±5.12	114.16±7.51	0.0001
Hospital stay (days)	1.19±0.487	1.52±0.852	0.018

The mean amount of intraoperative blood loss in the LS group was found to be (49.64 ± 17.92 ml) which was significantly lower as compared to the blood loss in conventional group i.e. 64.42 ± 20.72 ml. Likewise, the postoperative blood loss was also found to be remarkably lower in the LS versus CT group (table 3).

Table 3: Blood loss during and after the operation in both groups

Intra-operation blood loss (ml)	LS N=52	CT N=52	P-value
	49.64±17.92	64.42±20.72	0.000
Post-operation blood loss (ml)	33.75±6.02	74.67±12.91	0.000

Regarding the infection, only 1 patient in the LS group and 3 patients in CT group got infection at the surgical site. Moreover, no hematoma was observed in LS group, while it was observed in 5 cases (4.8%) of the CT group. Besides, 10.6% of all the patients (n=11) had transient RLN palsy with 1.9% (n=2) in the LS group and 8.7% (n=9) in the CT group ($P=0.026$). Results are shown in table 4.

Table 4: Post-operative complications in both surgical groups

Complications	LS N=52	CT N=52	Total N=104	P-value
Surgical site infection	1 (1.0%)	3 (2.9%)	4 (3.8)	0.308
Hematoma	0 (0.0%)	5 (4.8%)	5 (4.8%)	0.022
Transient RLN palsy	2 (1.9%)	9 (8.7%)	11 (10.6%)	0.026

DISCUSSION

Thyroidectomy is one of the most common operations performed in countries with a high incidence of goiter.^[17] In general, the purpose of surgical intervention for thyroid problems is to eliminate the disease with fewer complications.^[18-20] Besides traditional methods, thyroidectomy surgery has changed over time with the advent of hemostasis techniques including LigaSure diathermy system.^[21] It is mainly characterized by low operation time, so it is extensively used in numerous surgeries.^[22,23] In the present study, LigaSure surgical system was found to significantly reduce the operation time for all patients as compared to patients who underwent conventional method. This is in accordance with other studies including a meta-analysis study which reported not only reduction in operation time with LigaSure device as compared to conventional hemostasis but also significantly less intraoperative blood loss ($P=0.023$).^[24] Similarly, a retrospective study reported lowering of the operation time, risk of complications and perioperative and postoperative blood loss with LigaSure diathermic system in thyroid surgery as compared to the traditional technique.^[11] Because LS system is more effective and achieves hemostasis in thyroidectomy faster as compared to the traditional clamp and ligation manner, thus it decreases the total surgical time and intraoperative blood loss also.^[25] The use of the LigaSure device not only improves the efficiency of the sealing but also it allows the overlapping closure of the target tissues which significantly reduces the incidence of postoperative bleeding.^[26] In the current study, 4.8% cases (n=5) in conventional group suffered from hematoma and 8.7% (n=9) had RLN palsy. On the other hand, no case of hematoma was found in LS group while RLN palsy was observed in only 2 patients in this group. Infection at the surgical site is usually represented by superficial cellulitis, erythema and tenderness surrounding the surgical incision, fever and leukocytosis. Sometimes the infection reaches an abscess in the deep space of the neck.^[27] Studies have reported the incidence of surgical site infection in patients with the CT technique and absence of any sign of infection in the LS group.^[28] The traditional suture technique requires multiple surgical ties and a long time, which reduces healing, increases the infection of the wound and allows the opportunity to infect neighboring structures as well.^[29] The incidence of wound infection after traditional thyroidectomy is around 2 - 7% which is found to be decreased significantly after using advanced technological tools in thyroid surgery.^[30] Hematomas are considered among the worse postoperative outcomes of thyroidectomy. As they can cause airway pressure and venous congestion which results in hypoxia and occlusion, therefore, they may require surgical decompression and evacuation. Around 0.3% to 4.4% of patients suffer from hematomas after thyroid surgery. Although postoperative hematoma is a rare complication, yet it is life-threatening, hence it requires emergency re-operation to prevent external compression in the airway.

[31,32] Another critical postoperative complication is RLN paralysis which is also called as a transient complication because it may not exceed the sixth month after surgery. However, if this paralysis continues until the sixth month, it is termed as permanent. In general, the incidence of laryngeal nerve palsy ranges from 5% to 10%, the transient incidence of this paralysis is estimated to be 5%.^[33] Damage to the recurrent laryngeal nerve can most commonly cause hoarseness or aphonia.^[34] Conventional hemostasis methods are time consuming and may not be suitable for large vessels of the thyroid gland. On the other hand, diathermy systems including LS devices, offer an alternative to these traditional methods. They not only provide strict control of hemostasis but also reduce common postoperative complications. It should be noted that postoperative hypocalcemia is a common complication after traditional thyroidectomy. Around 25%-68% of the patients suffer from this complication which can be temporary or permanent.^[35]

Another similar study depicted the ability of LS system to perform a completely non-suture thyroidectomy and better outcomes in terms of postoperative hematoma and RLN palsy, when compared to the conventional technique.^[36] Likewise, other studies have also shown that energy-based vessel sealing devices meritoriously serve as a safe and effective alternative to the traditional ligation method in the thyroid surgery approach, conferring reduced operating time without increasing RNL injury rates.^[37] Another study found an association of LS regimen with reduced risks of both bleeding and drainage after operations with a slight reduction in operation time and intraoperative blood loss.^[38]

CONCLUSIONS

The results of present study depicted LicaSure system to be a safe choice for total thyroidectomy. Moreover, it was found to have superior outcomes in terms of shorter operation time, hospital stay, less intra and postoperative bleeding and other complications compared to the conventional hemostasis and ligation technique.

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