

Ligasure *versus* Clamp and Tie Technique to Achieve Hemostasis in Thyroidectomy for Benign Diseases

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Abstract

- Background** Occurrence of adverse effects and advantages of the Ligasure diathermy system (or Ligasure vessel sealing system) in thyroidectomy have not been tested in prospective randomized studies comparing its use with that of the time-saving clamp-and-tie technique to ligate and divide thyroid vessels. The effectiveness of Ligasure in achieving vessel division and hemostasis remains dependent on vessel diameter, and the risk of damage to adjacent structures cannot be completely excluded.
- Objective** To evaluate the operative time, hospital stay and postoperative complications that achieved by ligasure in versus with clamp-tie technique in subtotal and near total thyroidectomy.
- Methods** One hundred patients with benign multinodular goiter underwent subtotal and near total thyroidectomy. Subtotal and near total thyroidectomy was performed in 45 patients using ligasure and in 55 patients using the clamp-and tie technique.
- Results** Postoperative complication rate was 2.7-7% overall in ligasure group (group one) vs. 7-31% clamp-and-tie technique (group two) including all temporary postoperative disturbances. There are no permanent complications but statistically, there was difference in their incidence. The mean hospitalization time was 1.4 day in group one vs. 2.5 day in group two. Mean operative time was shorter in the Ligasure group with minimal time difference of 17 minutes.
- Conclusion** The use of Ligasure is safe and effective at vessel division and homeostasis than the clamp-and-tie technique, with a statistically significant decrease in mean operative time and hospitalization time. Because of that decrease in operative time and low complication rate, this would allow more patients to undergo thyroidectomy by this technique.
- Key words** Ligasure, clamp and tie, thyroidectomy, hemostasis

Introduction

Thyroidectomies for goitreous patients are known to be more blood spattered operations that requires careful and accurate hemostasis than other operations performed. The conventional technique by clamp and tie of vessels for hemostasis can be done safely but it is a time consuming. Recently, a vessel sealing system was developed and

started to be used in various fields of surgery including urological, gynecological, gastric, and laparoscopic and anorectal procedures⁽¹⁻⁶⁾. Hemostasis is extremely important in thyroid surgery to avoid post-operative complications, but it requires meticulous technique, various devices as electrosurgical devices use heat energy to denature proteins and heating of surgical field due to lateral dispersion may easily

damage vital structures. Research has been looking for new instruments with less thermal spread in the effort to reduce both operating time and complications^(7,8). Ligasure enable sealing and division of a vessel which disperses less heat to surrounding tissue than classical bipolar or monopolar electro coagulation methods. Ligasure system produces a consistent permanent autologous seal to veins, arteries and tissue bundles up to 7 mm in diameter, melting the tissue's collagen and elastin. It incorporates intelligent sensor within the diathermy forceps that provide audible tones once a complete seal cycle is accomplished⁽⁹⁻¹⁰⁾. The objectives were to evaluate the operative time, hospital stay and postoperative complications that achieved by ligasure in versus with clamp-tie technique in subtotal and near total thyroidectomy.

Methods

This cross sectional study on sample of 100 patients with multinodular goiter who were admitted to the first surgical unit in Baghdad Teaching Hospital at Medical City between first of June 2009 to first of June 2010. We divided the patients in to two groups, in group one a 45 patients were involved and underwent thyroidectomy by using a bipolar vessel ligation system (ligasure) and it was the choice of modality for hemostasis and group two as 55 patients involved and a clamp and tie suture technique was used for hemostasis. A thorough history and clinical examination were done and investigations were sent and the diagnosis of goiter was established, the surgery was done by using these two methods of hemostasis. According to pre-operative clinical, radiological and laboratory evaluations of 30 patients (30%) were hyperthyroid with diagnosis of toxic multinodular goiter.

Out of these 30 hyperthyroid patients a 14 patients (47%) were in ligasure group and 16 patients (53%) were in a clamp and group. All hyperthyroid patients had been receiving antithyroid medication pre-operatively to provide an euthyroid state. Treatment with propranolol tablet with initial dose of 40-60

mg/day and carbimazol tablet in dose of 10-30 mg/day, which were reduced gradually to maintain euthyroid state, as serum thyroid hormone concentrations declined. Patients received this treatment for a minimum of 2 weeks before operation. The indications for surgical treatment of these hyperthyroid patients were as follow, patients were inconvenienced for medical treatment (20 patients), large goiter (10 patients), while the main indications for surgery of all euthyroid patients (70 patients) were large goiters that caused compressive effects. None of these patients in the current study groups had been receiving either any medications known to have any side effects on coagulation, or any anti-coagulative drugs, and none of them had been diagnosed of any coagulopathic disorders formerly.

Patients were assessed for early post-operative complications as recurrent laryngeal nerve paralysis, hypoparathyroidism, hemorrhage, operating time and duration of post-operative hospital stay. Indirect laryngoscopic examination was applied to carry in all patients. Post-operative cord palsy was defined as the presence of an immobile vocal cord or decreased movements of cords during phonation. Classical thyroidectomy is done by performing a collar incision, the subcutaneous tissue and platysma were divided, and skin flaps were developed by monopolar electrocautery. The strap muscles were divided in the midline and retracted laterally, in group one all middle thyroid veins and vessels of superior and inferior thyroidal poles were sealed with ligasure regardless of their size, the ligasure was used only if the distance was wider than 2 mm between the tip of the device and recurrent laryngeal nerve., after bleeding control, suction drains were placed in all patients. After surgical intervention, Histopathological examinations were performed for all patients.

Patients were followed for 6 months post-operatively. In group two, we used a clamp and tie technique for hemostasis for superior and inferior poles. In all patients, thyroidectomy was

performed after identification of recurrent laryngeal nerves and at least one parathyroid gland on each side.

Statistical analysis

The data were analyzed using SPSS 11.0 for windows; comparisons of the data were done by wilcoxon and chi-square tests. The results were expressed as mean ± SD and *P* < 0.05 was accepted to be statistically significant.

Results

The mean age of the 100 patients was found to be 48 ± 11 years (range 18-69 years). The female/ male ratio was calculated to be 8.5/1.5 (n=85/15). Among all patients, 46 patients underwent bilateral near total thyroidectomy and 54 patients underwent bilateral subtotal thyroidectomy. Here was no mortality in both groups in this study. The evaluation of the patients with/ without ligasure usage, the operative time and duration of the hospital stay in group one was (58 min.), (1.4 days)

respectively were significantly lower than those in group two (75 min.), (2.5days) as *P* < 0.05 as shown in table 1.

The complication rates of ligasure group (group one) were significantly lower than those in clamp and tie technique (group two) (*P* < 0.005), permanent vocal cord palsy and permanent hypoparathyroidism were not encountered in this study. Patients had postoperative incidence of temporary hypoparathyroidism (n=3) 6.6% in group one while (n=5) 9% in group two. Temporary recurrent laryngeal nerve palsy (n=1) 2.2% in group one while (n=10) 20% in group two, seroma (n=2) 4% in group one while (n=5) 9% in group two, hemorrhage (n=0) in group one while (n=3) 6% in group two, wound infection (n=2) 4% in group one while (n=5) 9% in group two and cervical hematoma (n=1) 2.2% in group one while (n=3) 6% in group two as shown in table 2.

Table 1. Demographic features of ligasure group and clamp and tie surgical technique group

Feature	Group I N = 45	Group II N = 55	P Value
Age (years)	47 (21-69)	41 (18-67)	0.066
Mean operation time (minutes)	58	75	0.0001
Mean hospital stay (days)	1.4 (1-3)	2.5 (1-5)	0.001

Group I = Ligasure group, Group II = Clamp and tie technical group

Table 2. Postoperative complications that occurred in ligasure group and clamp and tie surgical technique group

Complication	Group I N = 45	Group II N = 55	P Value
Temporary hypoparathyroidism	3 (6.6%)	5 (9%)	0.004
Permanent hypoparathyroidism	0	0	-
Temporary recurrent Laryngeal nerve palsy	1 (2.2%)	10 (18.18%)	0.003
Permanent recurrent Laryngeal nerve palsy	0	0	-
Seroma	2 (4%)	7 (13%)	0.004
Hemorrhage	0	3 (6%)	0.003
Wound infection	2 (4%)	5 (9%)	ns
Cervical hematoma	1(2.2%)	3 (6%)	ns

Group I = Ligasure group, Group II = Clamp and tie technical group

The evaluation of patients according to thyroid hormone status is shown in table 3. Among all 100 patients, 30 patients (30%) were hyperthyroidism and 70 patients (70%) were euthyroid. Out of the 30 hyperthyroidic patients, 14 patients (46%) underwent thyroidectomy with ligasure, and clamp and tie technique was performed to remaining 16 patients (53%). Out of 70 euthyroidic patients, 31 patients (44.3%) were operated by use of ligasure and 39 patients (55.7%) underwent thyroidectomy with clamp and tie surgical technique. There was no significant difference due to age and gender, while there were significantly reduce in mean

operative time, mean hospital stay and complications rate in group one in comparison with group two ($P < 0.05$), in hyperthyroidism patients the mean operative time in group one was 60 min. while in group two was 80 min. , the mean hospital stay was 1.2 day in group one while it was 2.2 days in group two and complications rate was 2.7% in group one while it was 5.8% in group two regarding the euthyroid state while it was 7% in group one and 31% in group two regarding hyperthyroid state. Hospital stay between ligasure group and clamp and tie group was significant ($P < 0.05$) as shown in table 3.

Table 3. Demographic features of the patients according to thyroid hormone status

Feature	Hyperthyroid		P value	Euthyroid		P value
	Group I	Group II		Group I	Group II	
Number of patients	14 (46%)	16 (54%)	-	31 (44.3%)	39 (55.7%)	-
Mean age (years)	45 (24-61)	48 (18-65)	0.074	48 (18-65)	49 (20-69)	0.062
Female/male	11/3	12/4	0.460	32/4	30/4	0.920
Mean operative time (min.)	60	80	0.001	58	75	0.001
Mean hospital stay (days)	1.2 (1-3)	2.2 (1-4)	-	1.2 (1-3)	2.2 (1-5) 2/34	0.001
Complication rates	1/14 (7%)	5/16 (31%)	-	1/36(2.7%)	(5.8%)	0.002

Group I = Ligasure group, Group II = Clamp and tie technical group

The mean operating time for subtotal and near total thyroidectomy subgroups of ligasure group were significantly shorter when compared with that of clamp and tie group, 53.38 versus 65.8

minutes ($P = 0.005$) and 62.5 versus 84.89 minutes ($P = 0.001$) respectively as shown in table 4.

Table 4. Duration of operations according to the extent of procedure

Surgical Procedure	Duration of operation (minutes)				P value
	Ligasure group		Clamp and tie group		
	No.	Mean	No.	Mean	
Subtotal thyroidectomy	30 (66%)	53.38 min	38 (69%)	65.80 min	0.005
Near total thyroidectomy	15 (22%)	62.50 min	17 (31%)	84.89 min	0.001

Discussion

The ligasure technique enables surgeons to apply high current (4 A) and low voltage (200 V) to achieve simultaneous vessel sealing and division. The device acts through denaturation of the collagen and elastin in the vessel wall. The pressure applied by the scissors opposes the walls to allow the proteins to form a seal.

Microscopically, it is possible to verify that internal elastic lamina is preserved and collagen bundles form across the previous lumen⁽²⁾. The device has received acceptance worldwide in several surgical fields. It is claimed to be safe and effective because it allows vessel sealing and division without dispersion of electric power and with a little or no production of heat.

In thyroid surgery, there is an additional reason to use it in near or subtotal thyroidectomy⁽²⁾. Petrakis *et al*⁽¹¹⁾ in a retrospective case-control study reported fewer complications and shorter operative and hospitalization times in ligasure group. Other retrospective and prospective but not randomized studies did not find any differences between complication rates and hospitalization times^(2,3,10). Operative time was substantially reduced in studies by Kirdak and Shen *et al*^(2,3) but not by Kiriakopoulos *et al*⁽¹²⁾. In our study, the use of ligasure technique was safe, less time consuming, less hospital stay and less post-operative complications in comparison with clamp and tie technique.

The complication rate in our study was 7% in ligasure group (hyperthyroid) and 2.7% (euthyroid). In our study, 2.2% of patients in ligasure group and 9% of patients in the clamp and tie technique group had transient complications involving recurrent laryngeal nerves, and 6.6% of patients in ligasure group and 9% of patients in clamp and tie group had temporary hypoparathyroidism. Harold *et al*⁽¹³⁾ and Kahky *et al*⁽¹⁴⁾ had reported that temporary hypoparathyroidism may be noted in 13.4% of patients when only clinical symptoms are considered. In study of Delbridge *et al*⁽¹⁵⁾ in 20% of patients who underwent near total thyroidectomy required calcium supplementation for 3-6 weeks after surgery. Transient recurrent nerve paralysis has been observed in 8.7% to 39% of patients^(16,17) and is not completely avoidable even with systemic laryngeal nerve identification. There were no permanent complications after near total in our series including permanent hypocalcaemia and permanent recurrent nerve lesions with no statistical difference between the two study groups. The vessel sealing used to prevent inadvertent damage to recurrent nerve by systemic. Careful identification and minimized long term effects of inadvertent damage to parathyroid glands.

From the current study one may conclude that the usage of ligasure is a safe technique in thyroidectomy for benign diseases, and it is

recommended to use over the clamp and tie technique.

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