

Use of Ligasure Sealing Versus Conventional Suture - Ligation in Total Thyroidectomy

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Abstract: Introduction: Effective vessel haemostasis can be achieved by suture knot tying technique or newer techniques of vessel haemostasis 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. The objective of this randomized study was to compare the outcome of ligasure versus conventional clamping and tie in total thyroidectomy for benign thyroid diseases. **Patients and Methods:** A total of 200 patients diagnosed to have bilateral BMNG were subjected to primary total thyroidectomy and divided into two main groups Ligasure (L) and Suture-Ligation (SL). For detection of laryngeal nerves status, vocal cords were checked immediately postoperatively by laryngoscope and at the day 10 of postoperative period to assess the status of both laryngeal nerves. The function of the parathyroids was checked by detecting the serum calcium concentration and parathyroid hormone level. The following parameters were measured to compare the effect of ligasure versus conventional suture-ligation technique in decreasing the operative blood loss, operative time, securing laryngeal nerves and parathyroids, postoperative drainage and postoperative wound infection. **Results:** There was no statistical difference between the two groups regarding age, sex and body mass index and also there was no operative mortality. As regard the operative time, in ligasure group it was 115.54±15.35 minutes while in suture-ligation group was 127.1±7.95 minutes and intraoperative blood loss in group A was 62.06± 7.34 and in group B was 75.84± 9.21. Temporary RLN injury was detected in 3 patients (3%) in group A and in 5 patients in group B (5%). No permanent hypoparathyroidism was seen in group A patients but in one patient (1%) of group B, transient hypoparathyroidism occurred in 2 patients (2%) of both groups. The amount of fluid drained in group A was 54.16±9.21 and 66.28±8.99 in group B. **Conclusion:** The use of the Ligasure sealing system in total thyroidectomy is proved safe and effective in reducing the operative time, intraoperative blood loss together with reduction in postoperative fluid drainage. Owing to the ability to reduce energy spread profile, use of Ligasure sealing system is accompanied with better outcome regarding the function of laryngeal nerves and parathyroids.

Keywords: Ligasure, Suture-Ligation, Total Thyroidectomy, Outcome

1. Introduction

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 [1-3]. The Ligasure instruments utilize a high current, low-voltage

bipolar radiofrequency energy, in combination with a feedback-controlled response system that automatically delivers and disrupts the power according to the composition and impedance of the tissue between the jaws of the instrument [4].

Total thyroidectomy has been accepted as current surgical therapy for benign and malignant thyroidal disorders but

extensive resection might increase the risk of postoperative complications [5]. During thyroidectomy bleeding may obscure the operative field making safe dissection of recurrent laryngeal nerve and parathyroid gland difficult and prolonging the operation time. Thyroid surgery involves meticulous devascularization of the thyroid gland, which has one of the richest blood supplies of all organs, with numerous blood vessels and plexuses entering its parenchyma. Therefore, hemostasis is of paramount importance when dividing the various vessels before excising the gland [6]. Effective vessel haemostasis can be achieved by suture knot tying technique or newer techniques of vessel haemostasis like ligasure as an alternative bipolar surgical diathermy system [7]. Postoperative bleeding complications and hematoma formation are observed slightly more in case of total than subtotal thyroidectomy due to the extensive resection performed [5,8]. The objective of this randomized study was to compare the outcome of ligasure versus conventional clamping and tie in total thyroidectomy for benign thyroid diseases.

2. Patients and Methods

A total of 200 patients diagnosed to have bilateral BMNG were enrolled to this prospective analytic study conducted in Port Fouad General Hospital, Port-Fouad, Egypt from April 2008 to December 2014. Patients were subjected to primary total thyroidectomy due to compression symptoms and/ or huge neck swelling without previous neck surgery or radiotherapy. All patients data were collected such as demographic data (age at diagnosis, gender, occupation and residence), and presenting symptoms (dysphagia dyspnea, hoarseness, and others). Our patients were divided into two main groups Ligasure (L) and Suture-Ligation (SL). Written consent was obtained from all patients or first-degree relatives before the management procedure and the local ethics committee approved the study.

2.1. Randomization

Randomization was performed prior to study commencement as follows: opaque envelopes were numbered sequentially from 1 to 200. A computer-generated table of random numbers was used for group assignment; if the last digit of the random number was from 0 to 4, assignment was to group A (L group), and if the last digit was from 5 to 9, assignment was to group B (SL group). The assignments were then placed into the opaque envelopes and the envelopes sealed. As eligible participants were entered into the trial, these envelopes were opened in sequential order to give each patient his or her random group assignment. The envelopes were opened by the operating surgeon after patient consent and just prior to the surgery

2.2. Preoperative Workup

The status of vocal cords for all patients was checked in the preoperative period our otorhinolaryngologist using direct

rigid laryngoscope (rigid laryngeal endoscope, Storz 70° with video monitor was used for laryngeal evaluation) during maximum phonation and maximum inspiration (full adduction and full abduction) to ensure intact both superior laryngeal nerve (SLN) and RLN. The preoperative preparation for thyroidectomy for the BMNG patients included the following investigations: neck ultrasound, determination of free T3, free T4, thyroid stimulating hormone and serum calcium concentration, and fine-needle aspiration cytology.

2.3. Postoperative Period

For detection of laryngeal nerves status, vocal cords were checked immediately postoperatively by laryngoscope and at the day 10 of postoperative period to assess the status of both laryngeal nerves. Temporary RLN paralysis after 6 months was considered permanent. Clinical evidence of SLN injury was considered as breathy voice or diminished vocal frequency range, especially with regard to raising pitch. Using direct laryngoscope, signs of bowing, and inferior displacement of the affected cord on examination were diagnostic [5]. The function of the parathyroids was checked immediately in the postoperative period by detecting the serum calcium concentration and parathyroid hormone level. Postoperative hypocalcaemia was considered when calcium level was lower than 8.0 mg/dL (reference range 8.2 - 10.2 mg/dL). Temporary hypocalcemia was defined as a calcium level lower than 8.0 mg/dL in at least two consecutive samples (twice daily for 3 days). In these patients, hypocalcemia resolved within days. Conversely, in patients who were symptomatic and required vitamin D with or without calcium supplementation, we considered temporary hypocalcemia to be severe when calcium levels remained lower than 8.0 mg/dL for more than 3 days. In these patients, hypocalcemia resolved within 6 months. In patients who required vitamin D and calcium supplementation for more than 6 months, we considered hypoparathyroidism to be permanent [5].

2.4. Outcome Parameters

The following parameters were measured to compare the effect of ligasure versus conventional suture-ligation technique in decreasing the operative blood loss, operative time, securing laryngeal nerves and parathyroids, postoperative drainage and postoperative wound infection.

2.5. Statistical Analysis

Data collected were processed using SPSS version 15 (SPSS Inc., Chicago, IL, USA). Quantitative data were expressed as means \pm SD while qualitative data were expressed as numbers and percentages (%).

3. Results

There was no statistical difference between the two groups regarding age, sex and body mass index and also there was

no operative mortality in our patients as shown in table 1. The mean age was 42.25± 9.5 years in patients of group A and was 40.19± 9.6 years in patients of group B with insignificant distribution.

Table 1. Showing patients distribution regarding sex.

Group	Male	Female	Total
A	41	59	100
B	39	61	100
total	80	120	200

As regard the operative time, in ligasure group it was between 90-120 minutes with a mean value of 115.54±15.35 minutes while in suture-ligation group, the operative time was between 110-140 minutes with a mean value of 127.1±7.95 minutes and this difference is considered to be extremely statistically significant [t = 5.0148, df = 198, P ≤ 0.0001].

The amount of intraoperative blood loss using the standard absorptive gauze measuring 30 cm X 30 cm was 50-75 ml in group A (mean 62.06± 7.34) and 60-90 in group B (mean 75.84± 9.21) respectively and this difference is considered to be extremely statistically significant [t = 11.7007, df = 198, P ≤ 0.0001] as shown in figure 1.

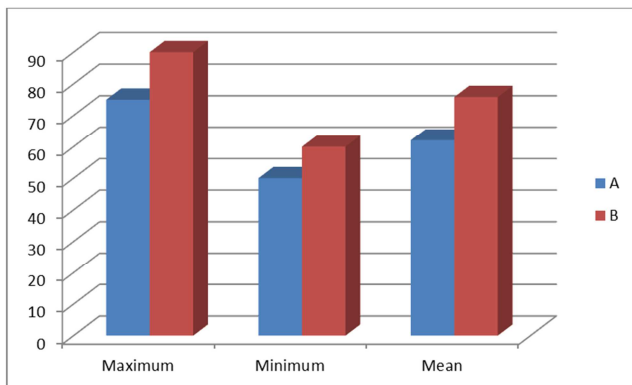


Figure 1. Showing the maximum, minimum and mean amounts of intraoperative blood loss.

No permanent or bilateral recurrent laryngeal nerve injuries occurred for patients in both groups. Temporary RLN injury was detected in 3 patients (3%) in group A and in 5 patients in group B (5%) . No permanent hypoparathyroidism was seen in group A patients but in one patient (1%) of group B, transient hypoparathyroidism occurred in 2 patients (2 %) of both groups.

The amount of fluid drained in group A was 40-70 ml { 54.16±9.21} and 50-80 ml { 66.28±8.99} respectively and this difference is considered to be extremely statistically significant [t = 9.4170, df = 198, P ≤ 0.0001].

4. Discussion

An accurate dissection and hemostasis is essential in order to provide a clear surgical field during total thyroidectomy, minimize the risk of structural damage, prevent post-surgical hemorrhage and avoid the need for surgical drains; however,

the safest, most efficient and cost-effective way to achieve these goals is still under debate [9]. In the present study, we used the ligasure sealing system in order to achieve proper intraoperative haemostasis and allow good field visualization. The use of Ligasure sealing system at the experimental level [4] and in clinical studies [10] allows the surgeon to improve vessel sealing with minimal thermal spread to the surrounding tissue and these instruments can seal vessels of up to and including 7 mm in diameter [4,8,10].

Regarding the operative time, our data came in concordance with those reported in previous studies and the authors of these studies found significant difference in operative time reduction in case of ligasure [6,11,12,13]. The conventional suture knot tying technique requires a large number of surgical ties and this maneuver is time consuming and requires good exposure [7]

Estimation of intra-operative blood loss is governed by visual method [14] and the clinical assessment with collaboration with the anesthetist [15]. Regarding visual estimation of blood loss; the authors in this present study relied on the standard absorptive gauze measuring 30 cm X 30 cm. When it was soaked by 50 % the means that it contains about 25 ml of blood and if totally soaked; 100% this means that it contains 75 ml of blood [16]. Many researchers reported significant reduction of intra-operative blood loss by the use of ligasure system in total thyroidectomy when compared with the conventional suture-ligation technique [6,17,18,19] and our data came in agreement with those reported results. The ligasure vessel sealing system can apply control, sealing vessels up to 7 mm in diameter and facilitates surgery by achieving the efficient haemostasis of blood vessels encountered during dissection, and allowing the rapid and secure division of vascularised tissues, while minimizing thermal injury to adjacent tissues [20]. Ligasure created less thermal damage to the media of the vessels [4] and utilizes both electrical and elastin in vessel walls and tissue to provide haemostasis [8].

In total thyroidectomy using the conventional suture-ligation technique, the overall laryngeal nerve injury was reported in our previous studies to be around 5.8% and transient hypoparathyroidism occurred in 3.3 % [5,21,22]. Laryngeal nerve dysfunction and hypoparathyroidism are well-recognized important complications of thyroid surgery and the overall complication rates of thyroidectomy have a varying range for both RLN injury up to 1-14% and permanent hypoparathyroidism up to 1-11% [23] and these complications can be prevented with appropriate surgical technique during total thyroidectomy [24,25]. However, using the ligasure sealing system these figures are much more reduced in our data and in previous studies of same interest that compared ligasure versus conventional titanium clips and surgical ties during thyroidectomy and found that Voice Handicap Index scores significantly lower with ligasure compared to conventional surgery [26,27]. The accepted explanation of this reduction rate in nerve and parathyroid injury is that ligasure has the ability to reduce energy spread profile (< 2 mm) when compared with

unipolar cautery, with a potential decreased risk of injury to adjacent structures [28,29]. Khafagy and Abdelnaby [13] stated that standard vessel ligation, involving use of ties and suture ligatures, although being a highly efficient technique for vessel bleeding control, it is time consuming and can endanger adjacent structures such as the recurrent and superior laryngeal nerves.

The duration and total volume of postoperative drain discharge were significantly reduced in ligasure versus conventional group [30] and the incidence of seroma formation was fewer when ligasure is compared with the conventional suture- ligation technique [31].

The rates of infection after thyroidectomy have significantly decreased with improvements in technology and aseptic technique and the usual presentation is a superficial cellulitis with warmth, erythema, and tenderness surrounding the surgical incision. Other signs of infection, such as fever and leukocytosis, without an overlying cellulitis, may point to a deep space neck infection or abscess [32]. Postoperative wound infection was observed a bit higher following total thyroidectomy than lobectomy due to more tissue trauma [33] and the surgical site infection rate was detected in the conventional suture knot tying technique group and there was no infection sign in the ligasure group in another study [6]. The accepted explanation of this reduction rate is that the conventional suture knot tying technique requires a large number of surgical ties and is time consuming ,decreases healing as well as increases wound infection, requires good exposure, injury to neighboring structures and foreign body reaction [7]

5. Conclusion

The use of the Ligasure sealing system in total thyroidectomy is proved safe and effective in reducing the operative time, intraoperative blood loss together with reduction in postoperative fluid drainage. Owing to the ability to reduce energy spread profile, use of Ligasure sealing system is accompanied with better outcome regarding the function of laryngeal nerves and parathyroids.

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