



Efficacy of LigaSure[®] Use during Total Thyroidectomy for Multinodular Goitre: A Prospective Randomized Study

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Abstract

Background: Thyroid surgery commonly carried out by surgeons is generally achieved by thread-tying technique which lengthens the operation period. Therefore, new technologies are needed to decrease the operation time without increasing complications. LigaSure[®] Precise[™] is a new vascular sealing system with an integrated active feedback control. The aims of the present study are to assess the efficacy of LigaSure[®] in total thyroidectomy and compare the clinical outcomes with traditional technique.

Methods: This prospective randomised study included a total number of 80 patients, underwent a total thyroidectomy for multinodular goitre. The patients were operated either with LigaSure[®] (Group L; n=40) or conventional technique (Group C; n=40). These were assessed and compared within the groups: demographics, peroperative (length of incision, amount of bleeding, operative period, necessity of drain use) and postoperative (calcium levels, pain, drainage volume, complications) data.

Results: Length of incision (7.7±1.9 vs. 6.7±1.5 cm in Group C vs. Group L; p< 0.05) and operation time (92.2±26.4 vs. 79.1±30.9 minutes in Group C vs. Group L; p< 0.05) were significantly shorter in Group L. Other parameters were similar within the groups.

Conclusion: LigaSure[®] may shorten the operation time and the length of the incision during total thyroidectomy for multinodular goitre.

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Keywords: LigaSure[®]; Multinodular goitre; Total thyroidectomy

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Introduction

Thyroidectomy may be sometimes troublesome operation due to the excessive vascularization of the thyroid, and the control of the bleeding may be difficult or even harmful. Although a “thread tying” technique combined with a bipolar electro-cauterization process has become a gold standard, multiple knots may lengthen the duration of the procedure [1]. Thus, multiple devices have been investigated in order to shorten the operation time without any increase in complications, particularly in the safety of the operation by risking a secure bleeding control.

LigaSure[®] device has been presented as an alternative to the conventional knotting technique, and has been effectively used for thyroid surgery [1-3]. The aim of this prospective randomized study was to evaluate the outcomes of LigaSure[®] device use by comparing to conventional technique in total thyroidectomy. The LigaSure[®] Precise[™] (Valleylab, Tyco International Healthcare, Boulder, CO, US) is a new vascular sealing system with an integrated active feedback control. It consists of an electro-surgical generator and hand piece device. The tissue is grasped and compressed by the instrument and the response generator senses the density of the tissue bundle. In turn, the generator's computer automatically adjusts the amount of energy to be delivered. When sealing is completed, the microprocessor-controlled feedback automatically terminates the pulse. Then the semi-transparent window can be safely divided [4-6]. This device has been approved by USA Food and Drug Administration (FDA) to seal vessels up to 7 mm in diameter while experimental histological studies of vessels sealed with a LigaSure[®] demonstrated 1,5 to 3,3 mm thermal spread, beyond the tissue within the forceps' jaw [7]. The effectiveness and safety of the device have been proven especially for laparoscopic surgery [8] and may reduce the period of the operation [9]. Recent studies have revealed that LigaSure[®] may be also safely used in thyroid surgery.

The aim of this prospective randomized study was to evaluate the outcome of using LigaSure[®]

Table 1: Demographic and preoperative clinical characteristics of the groups.

Variables		Group C (%)	Group L (%)	P
Gender	Female	25 (62.5)	23 (57.5)	0,64
	Male	15 (37.5)	17 (42.5)	
Age		46,9 ± 13,2	50,9 ± 12,9	0,17
Preoperative Diagnosis	Non-Toxic MNG	23 (57.5)	22 (55)	0,82
	Toxic MNG	17 (42.5)	18 (45)	

Table 2: Preoperative and postoperative findings of Group C and Group L.

Variables	Group C	Group L	p
Length of incision (cm)	7.7 ± 1.9	6.7 ± 1.5	0.01
Preoperative amount of bleeding (cc)	108.2 ± 96.7	80.7 ± 98.1	0.21
Operation period (Minute)	92.2 ± 26.4	79.1 ± 30.9	0.04
Duration of hospitalization (Day)	1.15 ± 6	1.13 ± 5	0.85
Post op. 6.h Ca	8.5 ± 0.5	8.4 ± 0.9	0.53
Post op. 72.h Ca	8.7 ± 0.8	8.6 ± 0.6	0.33
Post op. Drainage	95.0 ± 46.5	98.0 ± 48.5	0.83
Number of cases undergone drainage	24	20	0.36
post op. Pain 3.h	2.9	2.8	0.8
post op. Pain 6.h	2.1	2.6	0.25
post op. Pain 12.h	2.1	2.6	0.25

device by comparing to conventional technique in total thyroidectomy.

Materials and Methods

A prospective, randomized study was conducted between July 2013 and September 2014, and 80 consecutive patients operated for benign multinodular goitre at our institution were included. Prior to study, hospital ethic committee had approved the design of the study, and a written consent was obtained from all patients before the operations. Patients with thyroid cancers, Graves' disease and those had history of previous thyroid surgery were excluded from the study. However, patient with toxic multi nodular goitre included to the study, and operated after the regulation of hormone levels. All patients were preoperatively evaluated with ultrasonographic and fine needle aspiration biopsy and if clinically necessitated, scintigraphic examinations and indirect laryngoscope were performed in order to rule out the malignancy and vocal cord immobility.

The patients were randomized into 2 groups with the use of a computer-generated randomization schedule. They were operated either with LigaSure® (Group L; n=40) or conventional technique (Group C; n=40). In the Group L, LigaSure® was used for sealing the vessels including superior and inferior thyroid vessels and medial vein. In Group C, all stages were completed with knotting and using bipolar or unipolar cautery. The necessity of the drain use was decided by the surgeon at the end of the procedure. All patients were operated by a surgeon (S.V.) who dedicated primarily to thyroid surgery.

These were assessed and compared within the groups: demographics (age and gender), preoperative (length of incision, amount of bleeding, duration of operation, necessity of drain use) postoperative (pain, drainage volume, complications, hospitalization) data. All operations were begun with a 5 cm incision and if necessitated, the incisions were lengthened. The duration of operation was defined as the duration between the incision and dermal closure. The amount of preoperative bleeding was estimated with the total blood in the

Table 3: Postoperative Complications of Group C and Group L.

Complications	Group C (%)	Group L (%)	P	
Hematoma	0 (0)	1 (2.5)	1	
RLN Injury	Temporary	2 (5)	2 (5)	1
	Permanent	0 (0)	0 (0)	NA
Hypoparathyroidism	Temporary	3 (7.5)	4 (10)	0.69
	Permanent	0 (0)	0 (0)	NA

operative sponges at the end of the operation. The pain level was postoperatively evaluated with a visual analog scale (VAS) ranging 1 to 5 at 3, 6 and 12 hours. The calcium level was assessed in all patients 6 and 24 hours after the operation. Patients were discharged from the hospital the day after the operation unless any suspicion for complication including hypocalcemia or laryngeal nerve palsy. If the nerve palsy or hypoparathyroidism extent more than 6 months, it was defined permanent.

A SPSS 15 for Windows software was used for statistical analysis. Data were presented as means and standard deviations or percentages, and the comparisons were made by using a student t or chi-square test. A p value less than 0.05 were considered significant.

Results

A total of 80 patients (48 [60.0%] female, 48.9±13.1 years old) were included to the study. Gender (25 [62.5%] vs. 23 [57.5%] females in Group C and Group L, respectively; p=0.64) and age (46.9±13.2 vs. 50.9±12.9 years in Group C and Group L, respectively; p=0.17) were similar within the groups. Elevated hormone levels were determined and preoperative treatment were necessitated in 17 (42.5%) and 18 (45.0%) patients in Group C and Group L, respectively (p=0.82) (Table 1).

Perioperative data were presented in Table 2. Length of incision (7.7±1.9 vs. 6.7±1.5 cm in Group C vs. Group L; p<0.01) and operation time (92.2±26.4 vs. 79.1±30.9 minutes in Group C vs. Group L; p<0.04) were significantly shorter in Group L. Other parameters were similar within the groups.

The complication ratio was 15% (n=12) in our study (Table 3). A hematoma observed in the Group L was treated conservatively, and none of the complications was permanent. As these results no difference between both groups was observed significantly.

Discussion

Multinodular goitre is the most frequently encountered thyroidal pathology. Among therapeutically options, surgical intervention is still the most important route of therapy [10-12]. Total thyroidectomy may be the best choice for the treatment of multinodular goitre as it is also an adequate surgical option for thyroid cancer which may be incidentally noticed in the specimen. If total thyroidectomy is adequately performed, no recurrence will be seen. A standard

thyroidectomy operation depends on a meticulous anatomical dissection, and secure and effective hemostasis [13]. Conventional knotting techniques with the use of cautery have been used and accepted as a gold standard in thyroidal surgery. In fact, this method may extend the duration of the operation and may necessitate a larger incision in order to secure the knots especially located to the poles. Therefore, new devices have been investigated.

Ligasure is a new vascular sealing system of which the effectiveness and safety have been proven especially for laparoscopic surgery [9] and reduces the period of the operation [14,15]. Recent studies have revealed that LigaSure[®] may be also safely used in thyroid surgery, however the effect of LigaSure[®] use on operation time is controversial [14-16]. In the present study, we evaluated the outcomes in patients underwent total thyroidectomy for multinodular goitre using either conventional knotting techniques or LigaSure[®]. Demographics and perioperative data were similar within the groups. Our data suggested that the operation time significantly decreased when LigaSure[®] was used. The shorter operation time is expected in LigaSure[®] group, since multiple knots take more time in the conventional technique. Furthermore as the thread is a foreign substance we will also recover from the rest. Additionally, in conditions where the upper pole is placed at the high position we are able to close vessels more safely by the LigaSure[®]. In addition, present data has revealed that LigaSure[®] use may decrease the length of incision, which has never been evaluated in the previous studies. This advantage may be due to the requirement of a larger space for knotting in conventional technique.

The most important complications in thyroidal surgery are recurrent laryngeal nerve (RLN) injury and hypoparathyroidism. Many current studies have indicated that there are no any difference in complications between conventional knotting and LigaSure[®] sealing. In literature, complications stated above have been observed lesser in patients in the LigaSure[®] groups [17]. In our series permanent RLN palsy and hypoparathyroidism were not noticed, and the hypocalcemia ratios at postoperative 6th and 72nd hours were found lower in the LigaSure[®] group, even though the differences were not statistically significant. The peroperative bleeding amount does not have a statistically significant importance between groups. Number of patients needed drainage and postoperative amount of blood loss of these patients was similar between groups. According to Visual Analog Pain Scale (VAS), no significant difference was observed. The duration of hospitalization is also similar within the groups. Most importantly, the similar complication rates within the groups suggest the safety of LigaSure[®] use.

Conclusion

LigaSure[®] does not jeopardize the safety of the procedure during total thyroidectomy for multinodular goitre. The use of the device may statistically shorten the operation time and the length of the incision.

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