

A Safety-Based Comparison of Pure LigaSure Use and LigaSure-Tie Technique in Total Thyroidectomy

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Rezumat

Compararea gradului de siguranță al tehnicilor LigaSure și LigaSure-Tie în tiroidectomia totală

Scop: Tiroidectomia totală fără suturi, cu ajutorul dispozitivelor de etanșare a vaselor, se dovedește o metodă sigură conform studiilor recente. Cu toate acestea, unii chirurghi sunt în continuare îngrijorați cu privire la utilizarea acestor dispozitive de mare energie în apropierea nervului laringeal recurent și a glandelor paratiroide. Obiectivul acestui studiu a fost de a investiga efectele metodei LigaSure asupra complicațiilor post-operatorii și de a discuta pe baza literaturii de specialitate.

Materiale și metode: Am inclus în studiu un număr de 456 de pacienți ce au fost supuși tiroidectomiei totale între iunie 2009 și martie 2011. Datele au fost obținute și evaluate retrospectiv. Pacienții au fost împărțiți în două grupuri. Grupul L, alcătuit din 182 de pacienți pentru care s-a folosit doar LigaSure și grupul LT, alcătuit din 274 de pacienți în cazul cărora s-a utilizat ligaturarea în vecinătatea nervului laringeal recurent și a glandelor paratiroide, iar LigaSure pentru restul operației. Valorile calciului seric au fost măsurate postoperator, precum și la 24, 48 și 72 de ore de la operație. Grupurile au fost evaluate în funcție de caracteristicile demografice, patologia tiroidiană, durata intervenției și complicațiile postoperatorii.

Rezultate: Grupurile au fost asemănătoare din punct de

vedere al caracteristicilor demografice, duratei operației, patologiei de glandă tiroidă. Nu s-a înregistrat nici un deces. Incidența hipocalcemiei a fost mai ridicată în grupul L ($p < 0,003$), dar nu s-au înregistrat diferențe semnificative statistic între cele două grupuri în ceea ce privește hipocalcemia simptomatică. Nici unul dintre pacienții din cele două grupuri nu a prezentat hipocalcemie permanentă sau leziune de nerv laringeal recurent.

Concluzii: Metoda simplă LigaSure poate crește frecvența decelării în laborator a hipocalcemiei după tiroidectomie totală, dar nu și pe cea a hipocalcemiei simptomatice. Complicațiile legate de hemoragii au fost similare și în număr scăzut în cele două grupuri. Utilizarea ligaturii în zonele din vecinătatea structurilor anatomice sensibile nu a dus la prelungirea timpilor operatori și poate reprezenta o metodă mai sigură de efectuare a tiroidectomiei totale.

Cuvinte cheie: hipocalcemie, LigaSure, ligatură, leziune termică, nerv laringeal recurent, tiroidectomie

Abstract

Background and Aim: Sutureless total thyroidectomy by using vessel sealing devices has been shown to be safe in some recent clinical studies. However, some surgeons are still concerned about the use of these energy devices in the vicinity of the recurrent laryngeal nerve and parathyroid glands. The objective of this study was to investigate the effects of the use of pure LigaSure on postoperative complications and to discuss the pertinent literature.

Methods: A total of 456 patients having undergone a total thyroidectomy operation between June 2009 and March 2011

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were included in the study. Data were prospectively collected and retrospectively evaluated. Patients were separated into 2 groups. Group L comprised of 182 patients where only LigaSure was used, and group LT consisted of 274 patients where ligation was used in the vicinity of the recurrent laryngeal nerve and parathyroid glands, and LigaSure was used in all other parts of the surgery. Patient's blood calcium values were checked preoperatively and at postoperative 24, 48, and 72 hours. Groups were assessed in terms of demographic properties, thyroid pathology, duration of operation, and post-operative complications.

Results: Groups were similar in respect of demographic properties, operation duration, thyroid gland pathology. No mortality rate was recorded. Laboratory hypocalcemia rate was higher in group L ($P < 0.003$), but no significant difference was identified between groups in terms of symptomatic hypocalcemia. No permanent hypocalcemia or recurrent laryngeal nerve injury developed in any of the patients in the two groups.

Conclusions: Pure LigaSure for total thyroidectomy may increase laboratory hypocalcemia rate, but not symptomatic hypocalcemia. Hemorrhage related complications were similar and low in the two groups. Ligations in the places close to delicate anatomic structures did not cause longer operative times and may be a safer option in total thyroidectomy.

Key words: hypocalcemia, LigaSure, ligation, thermal injury, recurrent laryngeal nerve, thyroidectomy

Introduction

Thyroidectomy is one of the most frequently performed operations in general surgery. The thyroid gland is an organ which is quite rich in vascularization, as well as being adjacent to delicate anatomic structures like the recurrent laryngeal nerve and parathyroid glands. Accordingly, a good hemostasis is very important in terms of protection from complications (1,2). In recent years, advanced devices such as LigaSure™ Vessel Sealing System (LVSS) (Valleylab, Boulder, CO, USA) which enables a fast and safe hemostasis are used routinely. In the literature, there are many studies comparing LigaSure with the conventional method in terms of duration and complications. In the majority of these studies, it has been reported that the use of LigaSure shortens the operative time and does not increase the rate of permanent complications. However, in terms of hypocalcemia rates, quite different results were reported. In some studies, hypocalcemia and recurrent laryngeal nerve injury were attributed to the thermal effect of LigaSure; in some of them, on the contrary, the use of LigaSure was emphasized to decrease complications (3,4). Besides, some present studies also report that there is no difference between the two (5-10). The occurrence of these different results suggest that additional hemostasis methods may also be used at sites close to vital structures (recurrent

laryngeal nerve, parathyroid glands) in some LigaSure groups.

The objective of this study was to compare LigaSure group (L) and LigaSure-tie group (LT) in terms of complications and to discuss the effects of the use of pure LigaSure on post-operative complications in comparison with the literature.

Material and Methods

Patients

This clinical study was carried out in an endemic region for thyroid diseases. Patients scheduled for total thyroidectomy for the surgical treatment of benign and malignant thyroid pathologies between June 2009 and March 2011 were included in this study. Data were prospectively collected and retrospectively evaluated. Patients having a history of previous thyroidectomy, scheduled for cervical lymph node dissection, presenting with hoarseness or calcium metabolism disorder were excluded from the study. After obtaining informed consents, a total of 468 patients were included in the study. LigaSure is routinely used in the clinic where this study was performed, and thyroidectomies were performed by 4 surgeons who each had at least 10 years of experience in thyroid surgery.

Operative technique

Total thyroidectomy was applied with the same technique for all patients. After Kocher's collar incision, subplatysmal skin flaps were prepared. After strap muscles were separated from the mid-line, the thyroid gland was revealed. Hemostasis was achieved by taking tissue as thin as possible from the closest part to the thyroid in the upper, middle, and lower vessel pedicles. The hemostasis procedure was performed using LigaSure in group L, and LigaSure+Tie in group LT. The ligation procedure was performed using 4-0 absorbable suture material (polyglactine) only in areas close to the parathyroid glands and the recurrent laryngeal nerve. In almost all cases, bilateral recurrent laryngeal nerves and four parathyroid glands were revealed. Parathyroid glands were moved away by dissection from the thyroid tissue in a cautious manner. When ischemia developed or the parathyroid glands needed to be removed, auto-transplantation into the sternocleidomastoid muscle was performed. A suction drain was inserted in cases where it was considered necessary. Strap muscles and the platysma were closed with 4-0 absorbable suture, the skin was closed with subcutaneous 3-0 non-absorbable suture. Patient's blood calcium values were checked at postoperative 24, 48, and 72 hours. Patients with blood calcium values of ≤ 8 mg/dl (2 mmol/l) were considered as hypocalcemic. Patients developing postoperative hoarseness were evaluated with a laryngoscope. After operation, no calcium support was routinely initiated for any patient. Intravenous calcium was administered for patients whose clinical symptoms of hypocalcemia existed. Patients without complications were discharged on the 3rd postoperative day. Patients with complications were followed up until recovery. Data were recorded in terms of patient demographics, thyroid pathology, pre- and post-operative blood calcium levels,

operation duration, and postoperative complications (bleeding, recurrent laryngeal nerve injury, hypocalcemia).

Statistical analysis

For statistical assessment of data and results, Student *t* and Chi-square tests were used. The results were expressed as mean \pm SD, and $P < 0.05$ was accepted to be statistically significant.

Results

The L group consisted of a total of 182 patients, 134 females and 48 males. The mean age was 49.54 ± 10 (range from 27- 73 years). The LT group consisted of a total of 274 patients, 195 females and 79 males. The mean age was 48.95 ± 12 (range from 22- 80 years). When patients were compared in terms of age, gender, pathological results, and thyroid gland weight, there was no significant difference between the two groups. The operation duration in the group L was 71 ± 16 minutes, 73.4 ± 17 minutes in group LT, and no significant difference was detected between groups. Data is summarized in *Table 1*. Mean preoperative blood calcium values were 9.2 ± 0.6 in the group L and 9.1 ± 0.4 mg/dl in the group LT. In the early period after operation, 2 patients in the group L and 3 patients in the group LT were operated on again due to bleeding. Hoarseness emerged in 5 patients in group L and in 6 patients in group LT ($P < 0.05$). At laryngoscopic examination, unilateral vocal cord paralysis was identified in these patients. No permanent recurrent laryngeal nerve injury was encountered in any patients at 6 months. Parathyroid auto-transplantation

was performed in 17 patients in group L, 32 patients in group LT ($P < 0.05$). When assessing pathology reports, an accidentally-removed parathyroid gland was detected in 9 patients in the group L, in 14 patients in group LT. Biochemically, hypocalcemia (≤ 8 mg/dl) was identified in 95 patients in group L ($P < 0.003$), 104 patients in group LT. However, there was no significant difference between groups in terms of hypocalcemia (*Table 2*).

Discussion

LigaSure use in thyroidectomy provides a good hemostasis however risk of lateral thermal injury remains a concern. Therefore, there have been controversies regarding the undesirable effects of pure LigaSure use on recurrent laryngeal nerves and parathyroid glands. The extent of thermal injury has been reported as less than 1 mm (11), but some authors have stated that thermal injury might be as wide as 3 mm (12-14).

Despite similar results related to recurrent laryngeal nerve injury reported in numerous studies comparing LigaSure use and clamp-tie technique (4,7-9,15-18), varying results were reported regarding hypocalcemia (3,4,8,19) (*Table 3*). Highly variable hypocalcemia rates in studies may be explained by several factors such as extent of thyroidectomy (total, subtotal, lobectomy, addition of neck dissection) (7,13,16,20), whether postoperative calcium support was routinely performed or not (16), short hospitalization (24 hours) (5,9), and differences in the definition of hypocalcemia (blood calcium level, the presence of clinical symptoms, the need of calcium replacement) (5,7,9,15,16, 20,21).

In some studies comparing LigaSure and Clamp-tie

Table 1. Clinical and demographic characteristics of the patients

	LigaSure group (L) (n=182)	LigaSure-Tie group (LT) (n=274)	P value
Mean age (years \pm SD)	49.54 \pm 10	48.95 \pm 12	ns
Female /Male	134/48	195/79	ns
Thyroid gland weight (g \pm SD)	85 \pm 35	87 \pm 30	ns
Thyroid pathology (n)			
Nodular goitre	130	187	ns
Graves' disease	11	16	ns
Malignancy	41	71	ns
Operative time (min \pm SD)	71 \pm 16	73.4 \pm 17	ns

Table 2. Comparison of postoperative complications

	LigaSure group (L) (n=182)	LigaSure-Tie group (LT) (n=274)	P value
Postoperative hypocalcemia	95 (52.2%)	104 (38.0%)	$P < 0.003$
Symptomatic hypocalcemia	27 (14.8%)	39 (14.2%)	ns
Parathyroid autotransplantation	17 (9.3%)	32 (12%)	ns
Accidental parathyroidectomy	9 (4.9%)	14 (5.1%)	ns
Temporary RLN palsy	5 (2.7%)	6 (2.2%)	ns
Permanent RLN palsy	0 (0%)	0 (0%)	ns
Hematoma	2 (1.1%)	3 (1.1%)	ns

Table 3. Postoperative complication rates of the clinical trials comparing L and CT

References	Year	Type of Thyroidectomy	Number of Patients		Hypocalcemia %				P value	Recurrent Nerve Lesion %				P value
			L	CT	L		CT			L		CT		
					T	P	T	P		T	P	T	P	
Saint Marc et al. ⁹	2007	Total	100	100	21	1	18	2	NS	12	1	10	1	NS
Cipolla et al. ⁸	2008	Total	53	52	7.5	0	7.7	0	NS	1.9	0	1.9	0	NS
Lepner et al. ⁴	2007	Various	204	199	2.5	0	7	0	0.02	1	0	0.5	0	NS
Shen et al. ⁷	2005	Various	135	99	5	0	11	0	NS	3	0	1	2	NS
Musunuru et al. ¹⁷	2008	Lobektomi	51	99	-	-	-	-		4	0	1	0	NS
Petrakis et al. ³	2004	Total	270	247	1.1	0	4.8	0	<.05	0.7	0	4	0	<.05
Sartori et al. ¹⁹	2008	Total	50	50	44	0	20	0	<.05	2	0	2	0	NS
Manouras et al. ⁵	2008	Total	148	90	2.7	0	4.4	1.1	NS	1.4	0	1.1	0	NS

techniques in thyroidectomy it has been reported that surgeons feel safer when they perform ligation instead of LigaSure in close proximity to the recurrent laryngeal nerve and parathyroid glands (7,8,22). In these studies, no significant difference between postoperative recurrent laryngeal nerve and hypocalcemia was detected between groups (rates 1.9-2.6% and 7.5-7.6%, respectively). In their studies comparing LigaSure and conventional thyroidectomies, Musunuru et al observed 4% and 1% recurrent laryngeal nerve injury, respectively, and reported that LigaSure does not increase the risk of recurrent laryngeal nerve injury (17). However, particularly, they reported that they performed ligation in a site close to the recurrent laryngeal nerve in a group where LigaSure was used. In some other studies with similar design, the use of LigaSure in the vicinity of the recurrent laryngeal nerve and parathyroid glands was not suggested due to its thermal effect (8,16). As an opposing view, Petrakis et al reported that the use of LigaSure decreases hypocalcemia and recurrent laryngeal nerve injury (3). The rates of hypocalcemia and recurrent laryngeal nerve injury were found as 0.7%-1.1% in LigaSure group, and as 4%-4.8% in clamp-tie technique group in their study, respectively, both in favour of the LigaSure group. In their view, no additional instrument is required, because both grasping and coagulation can be achieved by LigaSure at the same time. In the present study, recurrent laryngeal nerve injury rates were similar in both groups. However, laboratory hypocalcemia was recorded in 52% of the patients in pure LigaSure group, whereas this rate was 38% in the LT group. Because both groups are similar in terms of risk factors the authors think that the higher laboratory hypocalcemia rate in the LigaSure group can be attributed to the thermal injury of the device. On the other hand, the authors have experienced that LigaSure device has revealed no contribution to meticulous dissection and manipulation of delicate tissues. In fact, many surgeons who prefer LigaSure device in thyroidectomy may also use ancillary hemostasis methods like ligation, clip, and a variety of hemostatic materials in practice, although it is not clearly indicated in relevant publications (7,8).

In the literature, symptomatic hypocalcemia has been

reported in quite different rates, even reaching up to 15%, laboratory detected hypocalcemia may develop in up to 80% of the cases (23-25). Although the mechanism of hypocalcemia seen after thyroidectomy may be secondary to several reasons, the most likely cause is hypoparathyroidism (26,27). Hypoparathyroidism depending on the impairment of blood circulation, direct injury, or involuntary excision of the parathyroid gland may develop during operation (28). Patients with retrosternal large goitre and recurrent goitre, undergoing more extensive surgery (total or near total thyroidectomy, central or lateral neck dissection) are at increased risk of hypoparathyroidism. In order to evaluate the thermal effect of LigaSure more effectively, the authors tried to minimize negative factors (demographic, histopathological ones, thyroidectomy type, surgical procedure, definition of hypocalcemia, follow-up period) affecting blood calcium values.

Parathyroid auto-transplantation increases the temporary hypocalcemia risk, but permanent hypocalcemia rates become less than 1% (29-31). Parathyroid cells can gain function by revascularization in the 2nd week of auto-transplantation (32). In the literature, parathyroid auto-transplantation during thyroidectomy has been reported in a range of 13%-100%, and permanent hypocalcemia rate has been recorded as 0%-6% (33-36). In the present study, parathyroid glands were routinely checked for delicate anatomy and vitality, but auto-transplantation was required in 17 patients (9%) in the L group, and 32 patients (12%) in the LT group. Temporary hypocalcemia rates were 76% and 47%, respectively. The difference in auto-transplantation rates of the two groups was not significant. Nevertheless postoperative laboratory hypocalcemia was significantly more frequent in the LigaSure group. Higher hypocalcemia rate in patients for which auto-transplantation was performed in the LigaSure group was suggestive of the thermal injury. In the present study, no permanent hypocalcemia was encountered in any patients for whom auto-transplantation was performed.

The maintenance of calcium hemostasis in early postoperative period after thyroidectomy is associated with the number of remaining parathyroid glands (26,37). Observing

only one parathyroid gland during operation increases the risk for hypocalcemia (27,28). On the other hand, Bergamaschi et al reported that there is no relationship between the parathyroid gland number seen during operation and hypoparathyroidism with postoperative calcium levels (38). In the literature, the rate of accidental parathyroidectomy rate is reported between 6.4%-31% (39-43). In the present study, according to the histopathological results of patients, accidentally-excised parathyroid gland was detected at the rate of 4.9% in the L group, at the rate of 5.1% in the LT group, and there was statistically no significant difference.

A rapid uptake of calcium to the bones (hungry bone syndrome) emerges in patients with hyperthyroidism due to thyrotoxic osteodystrophy after operation. Therefore, the postoperative hypocalcemia risk increases (44,45). In this study, 11 and 16 Graves' patients were present in the L and LT groups, respectively. Hypocalcemia was seen in 8 patients in the L group, and 4 of them were symptomatic. In the LT group, hypocalcemia was seen in 13 patients, and 7 of them were symptomatic. Statistically, there was no significant difference between groups.

In many studies performed with LigaSure, similar results relevant to recurrent laryngeal nerve injury were reported. According to these results, nerve injury was seen at the same rate in LigaSure and in the conventional method (Table 3). Only in a few studies, LigaSure was reported to decrease the recurrent laryngeal nerve injury rate (3,46,47). In this study, recurrent laryngeal nerve injury was seen at the rate of 3% in the L group, at the rate of 2% in the LT group, and these results are compatible with many studies in the literature. The authors consider that LigaSure does not increase the recurrent laryngeal nerve injury rate.

Symptoms in clinical hypocalcemia recover quickly with the proper treatment, and the patient tolerance is quite good. However, even though the recurrent laryngeal nerve injury is temporary, especially if bilateral, clinical symptoms after operation are severe and significantly impair the patient's quality of life. This situation is also frustrating for many surgeons. So, the authors consider that the sensitivity to the recurrent laryngeal nerve injury in thyroidectomy is higher than that to dissection of the parathyroid glands. Due to the parathyroid glands' close proximity to the recurrent laryngeal nerve with the thyroid capsule and localization at the rate of 49% inside the thyroid, it causes parathyroid gland injury to occur more frequently (40). As long as the surgical experience increases, the ability to identify parathyroid glands and recurrent laryngeal nerves will improve, which in turn will reduce the number of complications (48,49).

There are certain limitations of the present study. Although data were collected prospectively, the study design is not prospective randomized. Therefore our results may provide an opinion for the safety of LigaSure thyroidectomy, but the scientific evidence is not as strong as that revealed by a randomized double blind trial. Furthermore, all the patients in the LigaSure group were operated by a single surgeon, and the results might be influenced by personal experience.

Conclusions

Pure LigaSure for total thyroidectomy may increase laboratory hypocalcemia rate, but not symptomatic hypocalcemia. Hemorrhage related complications were similar and with low rates in the two groups. Ligations in the places close to delicate anatomic structures did not cause longer operative times and may be a safer option in total thyroidectomy.

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