

Use of a Diathermy System in Thyroid Surgery

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Hypothesis: New hemostatic methods have been widely used in open and laparoscopic surgery. The LigaSure Precise diathermy system (Valleylab, Boulder, Colo) has been recently used in thyroid surgery. We hypothesized that its use could lead to reduced operative time and fewer complications compared with conventional knot tying in total or near-total thyroidectomy.

Design: Prospective case-controlled study.

Setting: Tertiary care private hospital.

Patients: Eighty patients underwent total or near-total thyroidectomy by 1 surgeon.

Interventions: Forty patients underwent thyroidectomy with the conventional knot tying technique and 40 patients with the LigaSure diathermy system.

Main Outcome Measures: Demographics, histopathological diagnosis, operative time, intraoperative blood loss, complications, and cost, using χ^2 test and Wilcoxon rank sum test.

Results: The study groups had similar demographic and histopathological characteristics. The mean \pm SD operative time was nonsignificantly reduced in the LigaSure group compared with the conventional knot tying group (84 ± 6 vs 89 ± 7 minutes, $P = .60$). The mean \pm SD intraoperative blood loss was less for the LigaSure group (30 ± 5 vs 35 ± 8 mL, $P = .36$). There was 1 case of transient recurrent laryngeal nerve palsy in the LigaSure group. One patient from this group and 2 patients from the other group exhibited transient hypocalcemia; permanent postoperative hypocalcemia was not encountered in either group. The cost of the LigaSure diathermy system was significantly greater than that of conventional knot tying.

Conclusion: Use of the LigaSure in thyroid surgery did not significantly reduce operative time, blood loss, or complication rates compared with conventional knot tying, but it increased operative cost.

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THYROID SURGERY INVOLVES meticulous devascularization of the thyroid gland, which has one of the richest blood supplies among the organs, with numerous blood vessels and plexuses entering its parenchyma. Therefore, hemostasis is of paramount importance to control and divide the various vessels before excision of the gland.

The principles of safe and efficient thyroid surgery were established some 60 years ago and are still valid.¹⁻⁴ Recently, some innovative methods of hemostasis in thyroid surgery have been tested, with promising results.⁵⁻⁸

The LigaSure Precise diathermy system (Valleylab, Boulder, Colo) is a new surgical technology that has been used to secure hemostasis in various open and laparoscopic procedures.⁹⁻¹² The system produces a consistent permanent autologous seal to veins, arteries, and tissue

bundles up to 7 mm in diameter, melting the tissues' collagen and elastin. It is associated with reduced thermal spread and minimal tissue charring compared with existing bipolar instruments. Moreover, it incorporates "intelligent sensors" within the diathermy forceps that provide audible tones once a complete seal cycle is accomplished. The combination of effective localized coagulation with minimal collateral thermal spread seems to be the most useful characteristic for thyroidectomy.

This prospective case-controlled study compares the use of conventional knot tying vs LigaSure by 1 surgeon in patients undergoing total or near-total thyroidectomy.

METHODS

PATIENTS

From January 1, 2003, to August 31, 2003, 80 patients underwent total or near-total thy-

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Figure 1. LigaSure Precise diathermy system used in this study (Valleylab, Boulder, Colo).

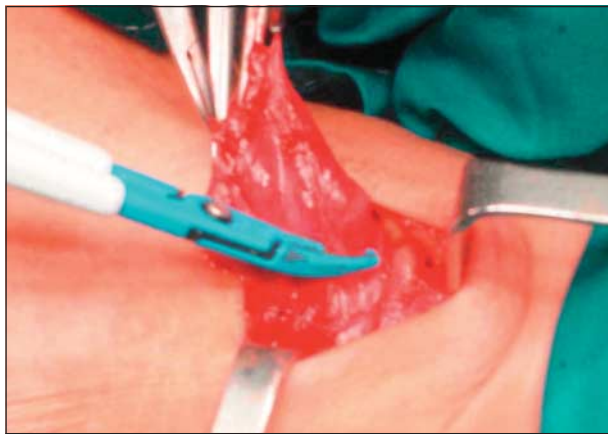


Figure 2. Double-ligation technique for the division of the upper thyroid vessels. The instrument is applied across the vascular bundle until the vessels are sealed. It is then moved several millimeters away from the initial site and a second seal cycle is applied. Division of the vessels is accomplished between the seals.

roidectomy performed by 1 surgeon (L.D.) using conventional knot tying (n=40) or the LigaSure (n=40) for hemostasis. The LigaSure diathermy system is shown in **Figure 1**. For a given patient in one group, a patient with similar demographic and thyroid disease characteristics was enrolled in the other group to create a uniform study population, for optimal interpretation of the outcome measures. Patients were enrolled into the study based on preoperative thyroid pathologic findings determined by ultrasound examination, thyroid scanning, possible fine-needle aspiration, and serum thyroid hormone values. After a careful examination of these variables, one of us (L.D.) chose the method of hemostasis to form operative groups with similar pathologic conditions and technical difficulty.

PROCEDURE

All patients had a routine preoperative workup and were admitted on the morning of the scheduled operation. They received the same anesthetic and hospital care regardless of the method of hemostasis. All patients underwent total or near-total thyroidectomy. The surgical technique included the development of subplatysmal flaps, separation of the strap muscles at the midline, and lateral reflection of the thyroid gland. The inferior, middle, and superior thyroid vessels were then divided with the LigaSure (**Figure 2**) or with conventional knot

tying. After medial rotation of the thyroid gland, various vessels in the ligament of Berry were divided in both groups. During this step, every effort was made to identify and protect the recurrent laryngeal nerves. The same steps were repeated for the contralateral lobe. Finally, after irrigation of the wound, the strap muscles and the platysmal layer were approximated using continuous 3-0 polyglactin suture in an interrupted manner. Small-sized closed-suction drainage was used and removed on the first postoperative day. The skin was closed using subcutaneous 4-0 nonabsorbable suture, which was removed on the first postoperative day, the day of discharge for all patients. Operative time was calculated by a surgery nurse, beginning with the skin incision until the placement of the suture. Intraoperative blood loss was calculated by using a small suction device and by weighing the sponges at the end of the operation. It is well-known that the size of the thyroid gland does not necessarily affect the degree of operative difficulty. Small thyroid glands can be more difficult and bloody than larger ones, and vice versa.

PATIENT DATA

Patients with previous neck surgery and those undergoing an accompanying procedure such as parathyroidectomy or lymph node dissection were excluded from the study. The medical records of the patients enrolled were reviewed and compared regarding age, sex, histopathological diagnosis, operative time, estimated intraoperative blood loss, and postoperative complications using χ^2 test and Wilcoxon rank sum test. Statistical significance was set at $P < .05$.

RESULTS

DEMOGRAPHIC AND HISTOPATHOLOGICAL DATA

Eighty patients were enrolled in the study, 40 into the conventional knot tying group and 40 into the LigaSure group. The mean \pm SD age of the patients was 46.4 ± 8.2 years in the former and 48.2 ± 7.8 years in the latter. The female-male ratio was 31:9 in the conventional group and 33:7 in the LigaSure group. Twenty-six patients in the conventional group and 25 in the LigaSure group had multinodular goiter, whereas 8 patients in each group had hyperthyroidism. Six patients in the conventional group (5 with papillary cancer and 1 with medullary thyroid cancer) and 7 patients in the LigaSure group (6 with papillary and 1 with medullary thyroid cancer) had malignant tumors (**Table**).

ANALYSIS OF OUTCOME MEASURES

The mean \pm SD operating time was 89 ± 7 minutes (range, 74-102 minutes) with conventional knot tying and 84 ± 6 minutes (range, 62-94 minutes) with the LigaSure diathermy system. The mean decrease in operating time with the LigaSure was thus 5 minutes ($P = .60$), and the relative decrease was 6.0% (**Figure 3A**). Because the patients of the groups were allocated with similar thyroid pathologic conditions, the difference in gland weight was insignificant and thus had no effect on operative time.

The mean \pm SD amount of intraoperative bleeding was 35 ± 8 mL (range, 28-60 mL) in the conventional knot tying group and 30 ± 5 mL (range, 25-40 mL) in the LigaSure group ($P = .36$) (Figure 3B). Reoperation for persistent bleeding was not required in either group. Postoperative drainage was minimal, although these results were inconclusive because of the differing methods of hemostasis.

One patient from the LigaSure group with multinodular goiter developed transient postoperative recurrent laryngeal nerve palsy that lasted 3½ months. The frequency of recurrent laryngeal nerve palsy was thus 1 (2.5%) in 40 patients in the LigaSure group vs 0% in the other group.

Postoperative clinically apparent hypocalcemia was found in 2 patients in the conventional knot tying group and in 1 patient in the LigaSure group. The overall incidence of postoperative transient hypocalcemia was thus 3 (3.8%) in 80 patients. All patients received prophylactic oral calcium supplementation for 2 weeks after surgery.

The mean cost of hospitalization was €1850 per patient. In the LigaSure group, there was an additional cost of €600 per patient for the disposable tip of the instrument used.

COMMENT

Hemostasis is of utmost importance in thyroid surgery. Use of conventional hand-tied ligatures for control of the 2 ends of a vessel before division is the standard method that has stood the test of time. Monopolar electrocautery was incorporated as an acceptable means of achieving vessel control, whereas bipolar electrocautery, clips, staplers, and lasers, each with disadvantages, never gained widespread acceptance in thyroid surgery.

The development of ultrasonically activated shears in the early 1990s provided an alternative to conventional methods of hemostasis. The device converts ultrasonic energy to mechanical action between the instrument blades. This mechanical action disrupts protein hydrogen bonds at a low temperature, causing less tissue injury compared with electrocautery. Moreover, the tissue proteoglycans and collagen fibers become denatured and mix with intracellular fluids to form a glue-like substance. The clinical efficacy of this method of hemostasis has been well documented in series of prospective nonrandomized studies^{5,7} and in a few prospective randomized trials.^{6,8}

The LigaSure diathermy system constitutes a novel hemostatic method that produces a consistent permanent autologous seal to veins, arteries, and tissue bundles up to 7 mm in diameter. It is associated with reduced thermal spread and minimal tissue charring. The combination of effective localized coagulation with minimal collateral thermal spread seems to be its most useful characteristic for thyroidectomy.

In this study, the LigaSure diathermy system seemed to be simple, easy to learn, and technically straightforward in its use. Given its similarity with other ultrasound hemostatic devices, the learning curve of the LigaSure was considered minimal.

Nevertheless, assessing the effect of this new technology on total operative time was challenging. Secure

Histopathological Data in the Study Groups

Pathologic Finding	Conventional Knot Tying Group (n = 40)	LigaSure* Group (n = 40)
Multinodular goiter	26	25
Graves disease	5	6
Toxic adenoma	2	2
Diffuse toxic goiter	1	0
Tumors	6	7
Papillary	5	6
Medullary	1	1

*LigaSure Precise; Valleylab, Boulder, Colo.

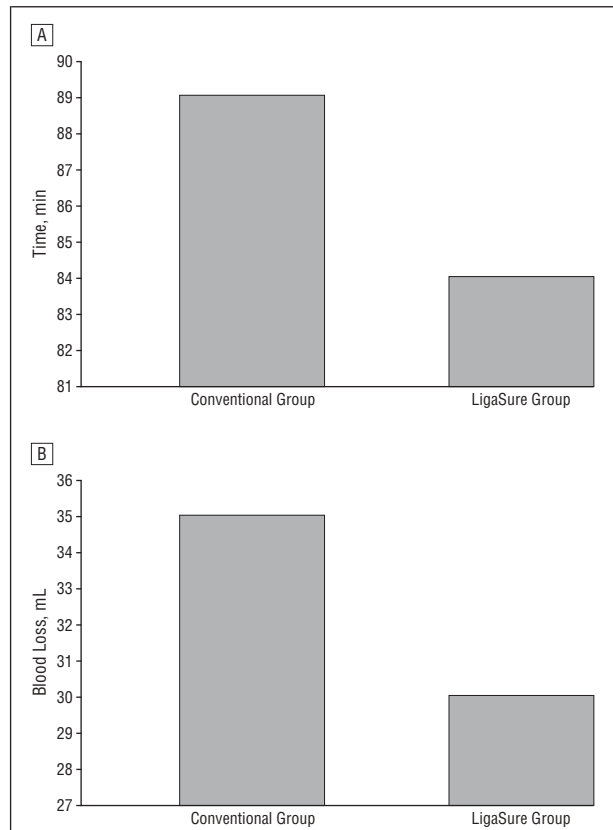


Figure 3. A, Operative time: conventional knot tying vs LigaSure (LigaSure Precise; Valleylab, Boulder, Colo). B, Intraoperative blood loss: conventional knot tying vs LigaSure.

and safe thyroidectomy involves the ligation of 3 major vessel groups and multiple miniature vessels and tissue bundles. The latter comprise the time-consuming steps of the procedure, and use of the LigaSure did not meet our expectations in time reduction. Although ligation of the upper thyroidal vessels seemed to be easier and at least as fast as conventional knot tying, meticulous ligation of numerous small vessels with the LigaSure did not statistically significantly reduce operative time. The use of similar study populations and 1 surgeon ensured the comparability and validity of our results. Although some recent series found a statistically significant reduction in operating time using ultrasonically activated shears in thyroid surgery⁵⁻⁸ or the LigaSure in other disease entities,⁹⁻¹⁶ our study fails to support a similar conclusion.

Another area of concern was the size of the instrument tip and the precision of the various intraoperative manipulations. Thyroid surgery is a microsurgical technique requiring precise tissue handling and dissection. The tip of the LigaSure is large for use with the small thyroid vessels. This is reflected in the statistically insignificant difference in the mean intraoperative blood loss and operative time compared with conventional knot tying.

Moreover, thermal spread from the tip of the instrument to the surrounding tissues can be dangerous in the occasional wet operative field during thyroid surgery. In our study, recurrent laryngeal nerve palsy observed in 1 patient was attributed to thermal injury from the LigaSure, although this was not proven. Another area of concern is the increased cost of the LigaSure, with a capital cost of €17 500 for the unit and €600 per patient for the disposable tip.

Given the increased cost and the good but not exceptional results associated with the use of this novel hemostatic method, we cannot advocate routine addition of this surgical device in thyroid surgery.

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