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Differences in Thyroidectomy Outcomes Based on Surgical Method: A Comparison of LigaSure Precise, Harmonic Focus, and Traditional Methods

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New surgical devices have been developed to improve haemostatic control and vascular closure in thyroid surgery. Here, we compare the efficacy and clinical outcomes of 3 surgical methods, Harmonic Focus, LigaSure Precise, and the traditional suture-ligation method, in patients undergoing total thyroidectomies. This retrospective study compared total thyroidectomies performed between July 2008 and August 2012. Thyroidectomies were performed in 243 patients using Harmonic Focus (n = 81), LigaSure Precise (n = 81), and traditional suture-ligation (n = 81). No significant differences were observed among groups in terms of patient demographics, thyroid weight, pathological diagnoses, pre- and postoperative calcium levels, postoperative complications, length of hospitalization, and clinical outcomes. The Harmonic Focus approach showed an ∼15% shortening in operating time relative to the suture-ligation group; no statistically significant differences were detected between the LigaSure and traditional suture-ligation groups. All 3 methods were found to be both safe and effective. Operating time was significantly shorter in the Harmonic Focus group; no differences in terms of postoperative complications were observed among groups.

Key words: Thyroidectomy – Operating time – Complications

Total thyroidectomy is a common practice, even in cases of benign histopathology following biopsy,[1] and has resulted in a large number of surgical procedures. Given the frequency with which these operations are performed, standardization of techniques is necessary to minimize compli-

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cations, with particular attention paid to hemostatic control, as well as the superior and recurrent laryngeal nerves and the parathyroid glands.

In recent years, a large number of commercial devices have been developed to improve the outcomes of laparoscopic surgeries. These devices rely heavily on high-energy sources, including radio waves and ultrasound, with specialized instruments now available specifically for thyroid surgery.[2–5] Recent studies have suggested that the Harmonic Focus method is associated with higher complication rates, whereas the LigaSure Precise method prolongs the operating time.[6] New scissors have also been introduced to increase efficacy and intraoperative safety.[7] However, despite the widespread implementation of these surgical devices, no direct comparison of surgical outcomes has been performed. In this retrospective study, we examined clinical outcomes associated with three thyroidectomy techniques, an electrothermal bipolar vessel sealing system (LigaSure), harmonic curve scissors (Harmonic Focus), and the traditional suture-ligation method.

Patients and Methods

Two hundred forty-three patients were treated for benign thyroid disease in the general surgery department of Safa Hospital, Istanbul, Turkey, between July 2008 and August 2012. This retrospective study included all nonemergency cases of thyroidectomy performed during this time period, with patients divided into 3 groups according to the hemostatic technique used: (1) traditional suture and ligation (group T), (2) Harmonic Focus (group H), and (3) LigaSure Precise (group L). The Harmonic Focus device was produced by Focus Ethicon Endosurgery (Johnson & Johnson, Cincinnati, Ohio) and the LigaSure Vessel Sealing System (LigaSure Precise) was produced by Valley Lab (Tyco International Healthcare, Boulder, Colorado). The physical principle of the Harmonic Focus is the use of ultrasonic energy, whereas the LigaSure Precise uses high-energy radio waves. All procedures were performed by the same surgical team. We did not use neuromonitoring for the recurrent laryngeal nerve.

The following parameters were evaluated for each of the 243 patients: age, sex, preoperative histologic diagnosis, thyroid hormone levels [thyroid stimulating hormone (TSH), T3, T4], parathyroid hormone (PTH), and calcium. During the operation, operating time, surgical complications, and weight of the removed thyroid gland were also recorded. Postoperative parameters included surgical complications, body temperature, calcium levels on postoperative days 1, 2, and 3, length of hospitalization, and hoarseness of voice. Retrosternal multinodular goiter was defined as a goiter $\geq$2 cm in diameter that remains with the mediastinum when the patient's neck is in the hyperextended position.[6]

All patients, including those with Graves' disease, were treated pharmacologically until they become euthyroid (TSH, T3, T4, and PSH levels were within normal ranges), after which they were cleared for surgery. Routinely, all patients underwent total thyroidectomy for benign thyroid disease, with a focus on recognition and preservation of the laryngeal nerves, along with at least 3 parathyroid glands. A drain was placed after thyroidectomy and removed within 24 hours.

The removed thyroid glands were weighed before fixing in formalin. After the operation, patients underwent periodic examinations at 15 days, 3 months, 6 months, and 2 years. Vocal cord movements were examined laryngoscopically, both pre- and postoperatively, with the exception of 14 patients in whom laryngoscopy was tolerated poorly.

Postoperative calcemia

Ionized calcium levels were monitored in patients until discharged from the hospital. All patients with calcium levels $<$8 mg/dL were considered hypocalcemic and were treated with oral calcium carbonate and vitamin D_3 replacement. Clinical hypocalcemia was defined as the presence of a numbness complaint or positive Chvostek sign together with ionized calcium levels $<$1.14 mmol/L.

Statistical analyses

Quantitative variables (age, calcium levels, operating times, thyroid gland weight, and hospitalization length) were expressed as means $\pm$ standard deviation. Qualitative variables (sex and diagnosis) were expressed as frequencies and percentages. The results were reported separately for each group. Nonparametric tests were used for the statistical analyses, because the distribution was not normal. Where appropriate, χ^2 or Fisher's exact test was used to evaluate differences between qualitative variables. The Kruskal-Wallis test was used to compare quantitative variables between groups.

Table 1 Patient demographics and laboratory findings

Variable	Harmonic Focus (n = 81)	Traditional (n = 81)	LigaSure (n = 81)	*P* value
Age	50.3 ± 11.9	50.9 ± 11.9	51.3 ± 13.5	0.957[X]
Sex (%)				
Male	21	17	20	0.802[Y]
Female	60	64	61	
Preoperative calcaemia (mg/dL)	9.2 ± 0.1	9.3 ± 0.3	9.1 ± 0.3	0.264[X]
Preoperative TSH (pmol/L)	1.0 ± 1.0	1.0 ± 0.6	1.0 ± 0.8	0.978[X]
Preoperative T3 (pmol/L)	3.7 ± 1.5	3.6 ± 0.8	4.8 ± 1.4	0.006[X]
Preoperative T4 (pmol/L)	4.2 ± 5.0	2.0 ± 2.8	5.9 ± 5.5	0.016[X]

$P < 0.05$ was considered statistically significant. X, Kruskal-Wallis test; Y, χ^2 test.

Kruskal-Wallis *post hoc* test was used to compare groups P and H with the control group. $P < 0.05$ was considered statistically significant, and all analyses were performed using SPSS advanced statistical software (SPSS Inc, Chicago, Illinois).

Results

Total thyroidectomy was achieved in all patients, with no reports of mortality, intra- or postoperative bleeding, cervical hematoma, or infection. Patient groups were well matched for sex, age, histopathologic diagnosis, and thyroid weight, with no statistically significant differences detected in terms of age, sex, histopathologic diagnosis, or thyroid weight (Tables 1 and 2; $P > 0.05$). Similarly, no significant differences were detected in terms of calcium levels or postoperative hypocalcaemia among groups (Table 1); postoperative hospitalization length was also similar across groups (mean = 2 days).

Group H consisted of 14 patients with retrosternal multinodular goiters, 60 with multinodular goiters, and 7 with Graves' disease. Group T contained 15 retrosternal multinodular goiters, 56 multinodular goiters, and 10 Graves' disease cases. All patients with hypocalcemia recovered within 30 days of medical treatment.

Total operating time was 15% shorter in group H compared with group T (63.1 ± 13.9 versus 73.1 ± 13.9 minutes, respectively; $P < 0.05$). Intermediate operating times were seen for group L (69 ± 7.5 minutes), with no statistically significant differences observed relative to the other 2 groups (Table 2).

Transient hypocalcaemia was observed in 24.4% of patients, with no significant differences in terms of incidence among groups. Despite the frequency of hypocalcemia in these patients, clinical symptoms were detected in only 8 of 60 patients diagnosed with hypocalcemia. Of these 8 patients, 3 (1.2%) exhibited symptoms of hypocalcemia for as long as 6 months (2 patients from group T and 1 from group H).

Transient recurrent laryngeal nerve palsy occurred in 10 patients (4.1%), including 4 from group H, 3 from group L, and 3 from group T, although all patients recovered within 3 months. No cases of persistent laryngeal nerve palsy were observed in this study, reflecting the accuracy of all 3 techniques used by our surgical team in the protection against intraoperative surgical injuries.

Discussion

Total thyroidectomy is a delicate procedure requiring extreme care to avoid damage to neighboring anatomical structures. Strict hemostatic control is

Table 2 Diagnoses and findings (operative time and weight of excised thyroid gland)

Variable	Harmonic Focus (n = 81)	Traditional (n = 81)	LigaSure (n = 81)	*P* value
Diagnoses				
Retrosternal				
Multinodular goitre	14	15	18	0.868[Y]
Multinodular goitre	60	56	53	
Graves' disease	7	10	10	
Operative time (min)	63.1 ± 13.9	73.1 ± 13.9	69.0 ± 7.5	0.018[X]
Weight of excised thyroid gland (g)	96.4 ± 46.4	76.7 ± 25.6	90.8 ± 26.6	0.123[X]

$P < 0.05$ was considered statistically significant. X, Kruskal-Wallis test; Y, χ^2 test.

essential for limiting the risk of serious complications, including recurrent laryngeal nerve and parathyroid gland injuries, and for decreasing the incidence of other postoperative complications. Given the importance of hemostatic control, the use of devices to dissect and close vessels during thyroid surgery is not uncommon.[8–10] The aim of our study was to provide a direct comparison of clinical outcomes associated with each of 3 techniques used for total thyroidectomy: LigaSure, Harmonic Focus, and the traditional suture-ligation technique.

Harmonic Focus facilitates dissection of tissues and improves handling due its unique ergonomic design, whereas LigaSure necessitates a separate blade for cutting. In cases in which the use of Harmonic blades is difficult, the LigaSure method may be used to aid dissection. LigaSure can be used to close vessels up to 7 mm in diameter, with a range of 2 to 3 mm for thermal injury; the Harmonic scalpel can close vessels up to 5 mm in diameter, with a safety measure of 2 mm for thermal injury.[11,12] Although these devices offer shorter overall operating times compared with the traditional suture and ligation approach,[13] they have not been shown to improve complication rates.[14] These devices do not replace careful surgical practices but do serve to enable a more streamlined process. In fact, experienced surgeons have an easier learning curve using these devices, with no associated increase in complication rates.[15,16]

No differences were detected among groups in terms of histopathologic diagnosis, age, sex, or thyroid gland weight; no hemorrhagic complications occurred in any patient. The most frequently reported hemorrhagic complication is related to cleavage of the superior thyroid artery, which can be serious even in cases in which the Harmonic Scalpel was used.[14]

No statistically significant differences in terms of complication rates were observed among groups. Hypocalcemia is the most frequently encountered complication of total thyroidectomy, although contradictory results have also been reported. Fremen *et al*[17] reported a lower incidence of hypocalcemia associated with the Harmonic Scalpel Pons.[18] Only 3 patients in this study experienced symptoms of hypocalcemia lasting as long as 6 months.

Ten of our patients had transient recurrent laryngeal nerve palsy, all of whom recovered in 2 months; no cases of persistent laryngeal palsy were reported. When the Harmonic Scalpel was first introduced, it was accompanied by an increase in surgical complications.[19] Our experiences were also unfavorable due to disadvantages associated with its long handle and difficulty in dissection, limiting our use to only minimal invasive thyroid surgery.[17–20] However, as surgeons have become more experienced with the capabilities and limitations of this device, complication rates have declined, enabling use in a more diverse array of conditions.[21] In contrast, the LigaSure Precise is a safe, user-friendly device, with an easier learning curve relative to other ultrasonic hemostatic devices.[15]

Early studies examining the efficacy of Harmonic Focus were often limited to a small number of patients. These studies were suggestive of shorter operative times, although no statistically significant differences were identified, likely reflective of the limited experience of surgeons with the device, along with the small sample size of the studies.[22] Our findings showed a significant reduction in operative times (~15%) in group H compared with group T. Although average operative times were also shorter in group L relative to group T, this difference was not statistically significant. The shorter operative times associated with Harmonic Focus are likely due to its unique ultrasound-based technology, which enables simultaneous cutting and coagulation.

Previous studies comparing the cost of these new techniques have not provided conclusive data, with many studies providing contradictory results.[23,24] This variability is likely the result of inconsistencies in terms of the objective parameters used by hospitals and medical centers to analyze cost; this is particularly true of specialized centers where the operating room is under heavy use, and prolongation of operative time is a considerable factor.

Many surgeons continue to abstain from using advanced surgical devices in noncomplicated thyroidectomies, as the difference in operative time is likely negligible relative to the traditional suture and ligation method, particularly when considering that many surgeons have more experience with traditional endocrine surgeries. Instead, it may be reasonable to prefer these kinds of advanced devices for more complex thyroidectomies, such as those for gross goiters and/or those embedded behind the mediastinum. The relatively high cost of new devices, such as these, supports this tendency, with most devices requiring additional positive criteria to justify use. These data are consistent with the use of traditional suture and ligation in relatively straightforward cases, whereas large goiters, as well as

those that may require longer operation times, are more likely to benefit from use of the new devices.

Our data and experience strongly support both the safety and efficacy of the Harmonic Focus and LigaSure vessel sealing system for routine and complicated thyroidectomies. The only real advantage of these devices in thyroid surgery is the associated time savings, making implementation of these techniques an issue of balance between cost and efficiency. Despite recent reports of a decrease in postoperative hypocalaemia associated with these devices,[25] our study revealed no improvement in the rate of postoperative hypocalcaemia. Indeed, no statistically significant differences in terms of postoperative complications were detected among the 3 groups.

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