ORIGINAL ARTICLE

ULTRACISION HARMONIC SCALPEL VERSUS CLAMP-AND-TIE TOTAL THYROIDECTOMY: A CLINICAL TRIAL

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Abstract: Background. Hemostasis is important in thyroid surgery to avoid complications. Our aim was to evaluate the effectiveness of the harmonic scalpel in patients undergoing total thyroidectomy.

Methods. In this study, 90 patients were randomized into group A (classic technique of tying and knots) and group B (harmonic scalpel). We recorded the following: age, sex, pathology, thyroid weight, hemostatic technique, duration of operation, change in calcium (ΔCa), change in hematocrit (ΔHt), change in hemoglobin (ΔHgb), change in white blood cell count (ΔWBC), vocal motility, operative difficulty, postoperative vocal alteration, postoperative pain, complications, blood in the drains, operating time, mass of gland excised per minute, and hospitalization.

Results. Differences (p < .05) were observed concerning duration of surgery, operative difficulty, postoperative pain, hospitalization, ΔWBC, and quantity of gland removed per minute. No recurrent laryngeal nerve (RLN) palsies were observed.

Conclusions. Use of the Harmonic Scalpel in total thyroidectomy is more effective than the clamp-and-tie technique: the duration of surgery, intraoperative difficulty, postoperative pain, and hospitalization are reduced. Both techniques are equivalent concerning RLN injuries, postoperative vocal alterations, and blood loss. © 2009 Wiley Periodicals, Inc. Head Neck 32: 723–727, 2010

Keywords: thyroid surgery; harmonic scalpel; total thyroidectomy; nodeless thyroidectomy

Hemostasis is important in thyroid surgery to avoid intraoperative and postoperative complications. Traditionally, it requires a meticulous technique and is very often time-consuming because of the clamps and ties. Alternatively, in the last few years various devices (LigaSure [Valleylab, Boulder, CO] and harmonic scalpel [UltraCision, Ethicon Endosurgery, Cincinnati, OH]) have been introduced in clinical practice to achieve a safer and faster hemostasis.1–5

The aim of this randomized active comparator controlled study in patients undergoing total thyroidectomy was to evaluate the effectiveness of the harmonic scalpel, not only by measuring parameters such as duration of the surgery, blood loss, calcium variations, immediate postoperative complications, and hospitalization, but also by quantifying the intraoperative difficulty, the postoperative vocal alteration (without
recurrent laryngeal nerve damage), and the postoperative pain.

MATERIALS AND METHODS

From June 1, 2008, through November 30, 2008, 90 adult patients with benign or malignant thyroid disease scheduled for total thyroidectomy at the Third Surgical Department of AHEPA University Hospital of Thessaloniki were randomized into 2 groups according to the hemostatic technique used: conventional technique of tying and knotting (group A) or harmonic scalpel technique (group B). The study was approved by the ethics committee of AHEPA University Hospital. All patients included in the study were randomized by computer-generated tables.

The inclusion criteria were: (1) age >18 years, (2) acceptance to participate in the study (signed informed consent form), and (3) scheduled total thyroidectomy. The exclusion criteria were: (1) preoperative medication including opioid or nonopioid analgesics, corticosteroids, or nonsteroidal antiinflammatory drugs; (2) coagulation disorders; (3) pregnancy; (4) cervico-mediastinal goiters; (5) total thyroidectomy with lymph node dissection; and (6) neck reoperation. Figure 1 shows a patient flow diagram.

Total thyroidectomy was performed with patients in the supine position, with the head slightly hyperextended. All procedures were performed by a surgical team dedicated to thyroid surgery. All patients underwent preoperative direct laryngoscopy to assess vocal cord motility. Thyroidectomy was performed through a 4-cm cervicotomy. In group A, all ligatures were performed by tying/knotting with resorbable 4-0 vicryl ligatures, whereas in group B the harmonic scalpel was always used and the resulting thyroidectomy was sutureless. Both groups received 2 doses of 40 mg parecoxib sodium, 1 at the end of the operation and one 12 hours later.

Anesthesia was standardized following the protocol proposed by Andrieu et al.6 Patients were premedicated with hydroxyzine (1.5 mg/kg orally) 2 hours before surgery. General anesthesia was induced using propofol (2–3 mg/kg) and sufentanil (0.3 mg/kg). Tracheal intubation was facilitated by the administration of atracurium (0.5 mg/kg). General anesthesia was maintained with sevoflurane (0.5–1.8%) in an oxygen–nitrous oxide mixture (60/40%). The sevoflurane was adjusted to maintain a bispectral (BIS) index (AspectMedical Systems, Inc., Newton, MA) between 40 and 60. Additional doses of sufentanil (0.15 mg/kg) were administered for variations of systolic blood pressure and heart rate of >20% when compared with the values measured before operation.

Operative difficulty was assessed by a rating scale ranging from 1 (very easy) to 5 (very difficult). Postoperative pain was assessed by the visual analogue rating scale (VAS), ranging from 1 (no pain) to 10 (worst imaginable pain). Postoperative voice alteration was assessed by the VAS, ranging from 1 (no voice alteration) to 10 (worst imaginable alteration). Both pain and voice alteration were evaluated by the patient, whereas the operative difficulty was assessed by an observing surgeon. The observing surgeon was the same for all operations and was an emeritus professor who was performing thyroidectomies on a regular basis.

Ionized calcemia was drawn every postoperative day until hospital discharge to determine postoperative hypocalcemia. All patients with a postoperative calcium level below the lower limit of normal range (8.2–10.6 mg/dL) were considered as having hypocalcemia. Clinical hypocalcemia was defined as ionized calcium <8.2 mg/dL, associated with a positive Chvostek sign or patient complaint of paresthesia. Clinical
hypocalcemic patients received oral calcium carbonate and vitamin D₃ supplementation.

The following data were recorded: age, sex, pathology, thyroid weight, hemostatic technique, duration of the operation, ΔCa (postoperative – preoperative calcemia), ΔHt (postoperative – preoperative hematocrit), ΔHgb (postoperative – preoperative hemoglobin), ΔWBC (postoperative – preoperative white blood cell count), preoperative and postoperative vocal motility, operative difficulty, postoperative vocal alteration, postoperative pain, complications, blood in the drains, operating time, gram of gland excised per minute of the operation (weight of gland/duration of the operation), and length of hospital stay.

Continuous variables are reported as means (standard deviation [SD]). The differences between groups were examined using Student’s t test. A value of p < .05 was considered statistically significant. The epidemiologic characteristics of both groups are indicated in Table 1.

RESULTS
Statistically significant differences between groups were observed concerning duration of the surgery (p < .001), mean operative difficulty (p = .01), postoperative pain (p = .005), length of hospital stay (p = .01), ΔWBC (p = .02), and the quantity of gland removed per minute of operation (p = .01). The results concerning all the measured parameters in both groups are displayed in Table 2.

Additionally, clinical hypocalcemia was present in 4 and 5 patients for groups A and B, respectively (p = ns). It is important to notice that no recurrent laryngeal nerve (RLN) palsies were observed. Hematomas were not observed in either group.

DISCUSSION
Total thyroidectomy is a surgical procedure that requires meticulous dissection, safe anatomical exposure, and effective hemostasis. Hemostasis is of utmost importance to control and to divide the numerous vessels before excision of the gland. Even if the knot-and-tying technique is efficient in bleeding control, it is time-consuming; therefore, many devices have been introduced over the years, in clinical practice, to save time and to decrease postoperative complications.1–5,7 After the first introduction of harmonic scalpels to thyroid surgery, several prospective and retrospective studies have been performed, mainly evaluating duration of the surgery, blood loss, and complications.1–5,7,8 The present study additionally considers operative difficulty, postoperative pain, and vocal alteration with or without RLN injury.

Total thyroidectomy is the treatment of choice for many thyroid diseases. This operation is performed frequently, with no mortality and low morbidity. Morbidity mainly results from

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<th>Table 1. Epidemiologic characteristics.</th>
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<td>Factor</td>
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<td>Male/Female</td>
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<td>Mean age (SD), y</td>
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<td>Age range, y</td>
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<td>Weight of thyroid gland (SD), g</td>
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Abbreviations: ns, not significant.

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<th>Table 2. Operative and postoperative measurements.</th>
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<tr>
<td>Factor</td>
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<tr>
<td>Duration of surgery (SD), min</td>
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<tr>
<td>ΔCa (SD), mg/dL</td>
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<td>ΔHt (SD), %</td>
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<td>ΔHgb (SD), g/dL</td>
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<td>ΔWBC (SD), K/µL</td>
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<td>Mean operative difficulty</td>
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<td>Postoperative vocal alteration</td>
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<td>Postoperative pain</td>
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<td>Blood in the drains (SD), mL</td>
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<td>Length of hospital stay (SD), d</td>
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<td>Grams of thyroid per minute of the operation (SD), g/min</td>
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Abbreviations: ΔCa, difference of postoperative minus preoperative calcium; ns, not significant; ΔHt, difference of postoperative minus preoperative hematocrit; ΔWBC, difference of postoperative minus preoperative white blood cell count.
postoperative RLN palsy (transitory or definite) and hypocalcemia (clinical or nonclinical, transitory or definite). Incidence of RLN palsies varies from 0% to 23%, whereas transient asymptomatic hypocalcemia after total thyroidectomy may reach 63%. In the present series there were no RLN palsies (either in group A or in group B). On the other hand, clinical hypocalcemia ranged from 8.70% in group A (4 patients) to 11.71% in group B (5 patients). These percentages are considered to be among the lower in the international bibliography.

Intraoperative blood loss is a factor measured in several studies for evaluation of the effectiveness of the harmonic scalpel. However, in our practice the amount of blood lost during the operation was no more than 10 to 20 mL (rough estimate from the gauges used). This amount equals the quantity of blood taken during routine laboratory testing, and is thus clinically not significant and has no impact on clinical practice. We therefore preferred measuring the differences (preoperatively and on the first postoperative day) of Ht and Hgb, which indicate the overall blood loss (intra- and postoperatively). This study showed a decrease in Ht and Hgb in both groups. ΔHt and ΔHgb seem to correspond to the difference induced by the blood in the drains (~78 mL vs ~63 mL). We can conclude that hemostasis is equally effective with the harmonic scalpel and the classic clamp-and-tie technique and no blood transfusion was necessary.

Three parameters were used to evaluate the operative effectiveness of the harmonic scalpel: (1) duration of the surgery, (2) intraoperative difficulty, and (3) amount of gland removed by operative minute. The fact that the harmonic scalpel significantly decreases the duration of the surgery is the common variant among all studies comparing the classic hemostatic technique with the harmonic scalpel. Indeed, the present study also proves that use of the harmonic scalpel reduces the duration of the surgery by approximately 25 minutes. However, what this study is correlating for the first time is the intraoperative difficulty, as evaluated by an observing general surgeon. According to a 5-grade scale, the operations performed with the harmonic scalpel were easier compared with those performed with the classic technique (2.78 vs 3.09). Finally, the calculated amount of gland removed per minute showed that the harmonic scalpel was more efficient in removing thyroid in relation to operative time compared with the classic technique.

The present article used VAS scales to evaluate differences of postoperative pain and vocal alteration between the harmonic scalpel and the clamp-and-tie technique. The VAS used to evaluate vocal alteration showed no differences between the 2 groups. This seems very logical in that both groups had no RLN palsies. The fact that the VAS score was not null for both groups is probably explained by 2 mechanisms: (1) resulting from stretching, compression, or ischemia of the nerve, and (2) arising from injury or section of the superior laryngeal nerve that provides timbre to the voice. The VAS score that evaluated the postoperative pain showed that total thyroidectomy is an operative procedure that induces low levels of pain. However, a statistical difference was identified between the 2 groups. It seems that the clamp-and-tie technique is more painful than the harmonic scalpel technique. We believe a number of factors are responsible for the above-mentioned phenomenon. At first, in the clamp-and-tie technique, there is an abundance of foreign materials (the sutures used). Additionally, the harmonic scalpel uses high-frequency energy to cut and coagulate tissues. In that way, all minor nerve branches that were strangulated with the clamp-and-tie technique were cut and coagulated with the harmonic scalpel. A strangulated nerve continues to produce action potentials leading, at least for some hours, to increased pain, whereas a coagulated nerve produces no action potentials. In that way, we could probably explain the statistical difference in the VAS pain score between the 2 groups.

It is important to note that a statistically significant difference (p < .02) occurs between the 2 groups, concerning the WBC count, pre- and postoperatively. We observed that the harmonic scalpel group has a more elevated ΔWBC than that of the clamp-and-tie group. It is well known that the cellular events of acute inflammation are heralded by the tissue influx of large numbers of neutrophils. These cells have a well-established potential to injure tissues by a variety of mechanisms. However, it is also clear that acute inflammation has evolved as part of the beneficial host response to injury and infection that normally resolves with minimal residual tissue damage. In this perspective, we monitored WBC changes to roughly evaluate the acute inflammatory response. We consider that

the harmonic scalpel group has a more intense inflammatory response, indicating greater tissue destruction, greater host response, or even both. However, more detailed studies have to be planned to accurately describe the phenomenon.

Use of the harmonic scalpel in total thyroidectomy is more effective than the traditional clamp-and-tie technique. The duration of the surgery is shorter and the intraoperative difficulty is reduced; furthermore, the postoperative pain is less and the hospitalization period is diminished. Moreover, both techniques are equivalent concerning RLN injuries, postoperative vocal alterations, and blood loss.

REFERENCES


