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Clinical Science

Post-thyroidectomy complications. The role of the device: bipolar vs ultrasonic device Collection of data from 1,846 consecutive patients undergoing thyroidectomy

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Ultrasonic device;
Bipolar forceps;
RLN palsy;
Hypocalcemia

Abstract

BACKGROUND: Specific complications after thyroid surgery, such as recurrent laryngeal nerve injury (RLN) or hypoparathyroidism, are feared because they may give rise to a lifelong disability for the patient. The aim of this study was to evaluate the possible association between the types of device used (bipolar vs ultrasound-based harmonic scalpel defined Harmonic Focus) and major postoperative complications.

METHODS: During a 1-year period, between October 2010 and October 2011, Italian Endocrine Surgery Units affiliated with the Italian Endocrine Surgery Units Association collected data on all consecutive patients older than 18 years who had undergone primary total thyroidectomy, near total thyroidectomy, and completion thyroidectomy. The data were included in a dataset, listing demographic variables, details on the surgical procedure, and 2 major complications of the thyroid surgery: postoperative RLN palsy/hypomobility and hypocalcemia.

RESULTS: Our population comprised 1,846 subjects (78.6% women, median age 52 years). Six hundred four (32.7%) subjects underwent thyroidectomy by bipolar forceps and 1,242 (67.3%) by ultrasonic device. The risk of hypocalcemia in subjects undergoing thyroidectomy by ultrasonic device was similar to those undergoing thyroidectomy by bipolar after adjusting for sex, type of thyroidectomy, and central lymphadenectomy (odds ratio .94, 95% confidence interval .76 to 1.17). Subjects who underwent thyroidectomy by ultrasonic device had a lower risk of RLN paralysis compared with

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those undergoing thyroidectomy by bipolar forceps also after adjusting for central lymphadenectomy (odds ratio .39, 95% confidence interval .2 to .7).

CONCLUSION: This multicenter study acknowledges the value of the ultrasonic device as a protective factor only for RLN palsy, confirming nodal dissection as a risk factor for postoperative hypocalcemia and vocal folds disorders.

Thyroidectomy is the most common endocrine operation. The thyroid gland is highly vascularized, a feature that may cause bleeding complications. Different modalities can perform hemostasis in thyroid surgery.[1] Choosing the best procedure depends on evidence-based evaluation to the different intervention modalities.[2] Specific complications after thyroid surgery, such as recurrent laryngeal nerve (RLN) injury or hypoparathyroidism, are feared although unusual, because they may give rise to a lifelong disability for the patient. Hypocalcemia has been reported to occur transiently in 30% of the patients[3] and permanently in up to 2% of the patients.[4,5] In a recent multicentric study, the incidence of RLN lesions after total thyroidectomy (TT) was assessed at 4.3% (2.4% transient, 1.3% definitive), while the incidence of bilateral lesions was .6%.[6] One of the main challenges of thyroid surgery is therefore to cure the disease while keeping the complications to a minimum.[7]

The initial "clamp-and-tie" technique continues to be practiced in the present era with several modifications, including the use of ligatures, titanium vessel clips, or staples.[8,9] At present, the most widely used hemostatic tools are the bipolar forceps, ultrasound-based harmonic scalpel (Ethicon Endo-Surgery, Inc, Johnson & Johnson, Cincinnati, OH), and LigaSure system (Valleylab, Covidien, Boulder, CO). The last 2 devices deliver ultrasonic energy and combine pressure and energy to the vessel wall, respectively, to achieve homeostasis.[10,11] The aim of this study was to evaluate the possible association between the type of device used (bipolar vs ultrasound-based harmonic scalpel defined Harmonic Focus) and the 2 major complications of the thyroid surgery: postoperative RLN palsy/hypomobility and hypocalcemia.[5,6]

Patients and Methods

During a 1-year period, between October 2010 and October 2011, all consecutive patients older than 18 years undergoing primary TT, near total thyroidectomy (NTT), and completion thyroidectomy (CT) were prospectively followed up within 6 months from thyroidectomy, and underwent analysis regarding major postoperative complications. Data were collected from the Italian Endocrine Surgery Units affiliated with the Italian Endocrine Surgery Units Association where thyroid surgery is routinely performed and included in a dataset, listing demographic variables, details on the surgical procedure, and the major complications postsurgery. All the patients gave their informed consent to participate.

Outcomes of interest

We decided to use the following functional outcomes as primary endpoints: hypoparathyroidism and RLN injuries (vocal cord hypomobility, vocal cord monolateral paralysis).[4,12] The presence of RLN palsy/hypomobility was evaluated at the first postoperative day and hypocalcemia at day 1 and 2 postoperatively.

Hypocalcemia was defined as ionized calcium level less than 1.0 mM at day 1 or 2 postoperatively. All hypocalcemic patients received supplementation therapy in the form of oral calcium (Calcium-Sandoz Forte; Novartis Pharma SA, Orléans, France) 3 g per day (1 g every 8 hours) and also vitamin D (calcitriol [Rocaltrol]; Roche SpA, Milan, Italy) 1 mg per day (.5 mg every 12 hours) if symptomatic.

RLN injuries can be defined as unilateral and bilateral vocal cord hypomobility or paralysis. Video laryngoscopy examination was performed preoperatively, on the first postoperative day and after 6 months. Unilateral RLN injury can cause varying degrees of hoarseness, microaspiration, coughing, and other symptoms, seriously affecting the patients' quality of life. Bilateral RLN injuries may induce aphonia, dyspnea, and even asphyxia that are threatening to the life of the patient.

Statistical analysis

Categorical and continuous variables were expressed as frequency and median with range, respectively. Differences in frequencies between groups were calculated using the chi-square test. First, univariate logistic regression models were used to assess whether demographical and surgical variables (sex, age, type of histological diagnosis, type of surgery, central lymphadenectomy, and length of the cervicotomy) were related to the type of devices used (bipolar or ultrasonic) and to the complications postsurgery (hypocalcemia, vocal cord hypomobility, and vocal cord paralysis). Second, fully multivariate models were fitted that included the type of device, complication postsurgery, and the all-important confounders, significantly related to both the type of devices used and the complication postsurgery identified in univariate analysis using a statistical significance cut-off level of P less than .05. We considered treating "missing data" of a particular variable as a separate category only if their amount was greater than 5%, otherwise we chose to ignore it. All tests were 2 tailed with significance level set at P less than .05. STATA 12 software was used to analyze the data.