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Original research

Total thyroidectomy with harmonic scalpel combined to gelatin-thrombin matrix hemostatic agent: Is it safe and effective? A single-center prospective study

Giovanni Docimo [a], Salvatore Tolone [a], Roberto Ruggiero [a, *], Gianmattia del Genio [a], Luigi Brusciano [a], Angela Pezzolla [b], Gianpaolo Jannelli [a], Alfonso Bosco [a], Domenico Parmeggiani [a], Cosmo Cosenza [a], Paolo Limongelli [a], Ludovico Docimo [a]

[a] Department of General Surgery, Second University of Naples, Via Pansini 5, 80131 Naples, Italy
[b] Surgical Unit, University of Bari, Italy

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ABSTRACT

Introduction: Hemostasis during thyroidectomy is essential; however, the safest, most efficient and cost-effective way to achieve this is unclear. The aim of this study was to evaluate the outcome of total thyroidectomy (TT) performed with combination of harmonic scalpel (HS) and Floseal.
Methods: Patients undergone TT were divided into two groups: HS + Floseal and traditional hemostasis groups. The primary endpoint was 24-h drain output and blood-loss requiring reintervention. Secondary endpoints included surgery duration, postsurgical complications and hypocalcemia rates.
Results: Between September 2012 and January 2014, 165 patients were enrolled (100 to HS + Floseal, 65 to standard hemostasis); 80.5% female; mean age 42.3 years. The 24-h drain output was lower in the HS + Floseal group compared with standard TT. HS + Floseal also had a shorter mean surgery time ($p < 0.0001$) vs standard TT. No differences in post-surgical complications and in hypocalcemiarates between groups.
Conclusion: combination of Floseal plus the HS is effective and safe for TT and it provides a complementary hemostatic approach.

1. Introduction

Total thyroidectomy (TT) is the preferred option for the management of benign multinodular goiter and the standard treatment for cancer [1–4]. An accurate dissection and hemostasis is essential in order to provide a clear surgical field during TT, minimize the risk of structural damage, prevent post-surgical hemorrhage and avoid the need for surgical drains; however, the safest, most efficient and cost-effective way to achieve these goals is still under debate. Besides the traditional surgical hemostatic techniques, different hemostatic approaches which further minimize the risk of bleeding and complications during thyroidectomy have become available. These include ultrasonic coagulation, bipolar coagulation and modern topical hemostatic agents.

The Harmonic Scalpel (HS), a device that uses ultrasonic coagulation via high frequency mechanical vibration (in the range 55,500 Hz) to allow both a cutting and hemostatic effect simultaneously [5], has been shown to be an effective surgical device which decreases operative time, complications and bleeding in a variety of surgical procedures [6–14]. The hemostatic effect is achieved via protein denaturation rather than heat used in electrosurgical hemostatic devices, which uses a high electric current to produce the heat required for the hemostatic effect [15].

Floseal Hemostatic Matrix (Floseal; Baxter Healthcare Corporation, USA), a gelatin-thrombin matrix topical hemostatic agent that has been on the market in the US and in Europe since 1999 [16], is a combination of bovine-derived cross-linked gelatin granules and topical human thrombin. It has been proven to reduce blood loss in a variety of surgical procedures [17–26] including thyroid surgery [27].

The aim of this study was to evaluate the outcome of these two hemostatic approaches in combination, with their different and potentially complementary mechanisms, in patients undergoing TT.

* Corresponding author.
E-mail address: roberto.ruggiero@unina2.it (R. Ruggiero).

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2. Methods

2.1. Study design

This single-center, prospective study investigated the hemostasis efficacy and safety of Floseal + HS (Harmonic Focus; Ethicon Endo-Surgery, Norderstedt, Germany)in patients undergoing TT. Two groups were assessed: patients receiving Floseal + HS, and patients receiving traditional hemostatic procedures alone (gauze, ligature, electrocauterization) during TT.

The protocol was reviewed and approved by local Independent Ethics Committee/Institutional Review Board. The study was conducted in accordance with the Declaration of Helsinki and according to local and regional ethical standards. Written informed consent was obtained from all patients.

2.2. Patients

Patients were included if they were ≥18–70 years of age and were planning to undergo total thyroidectomy due to thyroid disease. Patients were excluded from the study if they had diabetes, chronic renal disease or other metabolic diseases, had received previous neck irradiation or surgery, had cervico-mediastinal goiters, required lymphadenectomy, had a planned video assisted thyroidectomy (minimally invasive) or one lobe pathology where only hemi-thyroidectomy was planned, had known coagulopathy, had active or past history of malignant systemic disease, were pregnant or lactating females, had a known allergy to the components of Floseal, were known to abuse drug or alcohol, or were receiving chronic cortisone or platelet inhibitors.

2.3. Treatments and surgical technique

Total thyroidectomy was performed using institutional guidelines by experienced surgeons [28,29]. A 4–6 cm Kocher incision was made at the lower neck crease two fingers above the suprasternal notch with a scalpel. Traditional hemostatic procedure was performed as follows: after division of the platysma, the cervical linea alba is opened without division of the strap muscles. The thyroid lobe is dissected progressively from the strap muscles. Thyroid vessels were ligated and divided, rotating the thyroid lobe medially before dividing vessels in the ligament of Berry, supervising and saving the recurrent laryngeal nerve, and the thyroid lobe is removed. The procedure was repeated for the contra lateral lobe. After a check for hemostasis, a drain is placed in the thyroid bed. The cervical linea alba and platysma are sutured with absorbable sutures, and the skin is closed by an intracutaneous running suture.

In patients undergoing TT with HS + Floseal, dissection and ligation of vascular pedicles was done using the HS, with surgical hemostasis used if additional hemostasis was deemed necessary and Floseal was used for bleeding not responding to surgical hemostasis, in particular in the Gruber and Sappey ligaments, avoiding electrocautery injuries to recurrent nerves.

In all patients a suction surgical drain was placed for the first 24 h, as part of this study, in order to better objectivize and quantify blood loss, although some centers did not longer consider drainage useful after thyroidectomy.

All patients received the same postoperative protocol. Surgical drain was removed after 24 h; a neck ultrasonographic evaluation was performed 48 h after surgery to verify the presence of seroma or blood collections. All patients in the study were discharged on postoperative day 3 (72 h after surgery) for better evaluation of the postoperative course. The postoperative follow-up care included indirect laryngoscopy to check vocal cord mobility. An indirect laryngoscopy was performed on postoperative day 2 to assess transitional or permanent paralysis of laryngeal nerve; in case of incidence of dysphonic voice, laryngoscopy was also reconsidered after 1 week and 3 months.

The serum calcium level also was measured for all patients at 6, 12, 24, 48 h. In case of symptomatic hypocalcemia, intravenous calcium was administered; in asymptomatic hypocalcemic patient, oral calcium was given.

2.4. Study endpoints

The primary endpoint was the drain output (ml) after 24 hours and the presence of a significant blood loss (if patient needed to return to OR). Secondary endpoints included presence of seroma, the duration of surgery, post-surgical complications and post-surgical serum calcium level.

2.5. Statistical analysis

Qualitative and quantitative descriptive analyses were performed for all the variables collected. Qualitative variables were analyzed using frequencies and percentages. Quantitative variables were studied through the mean, standard deviation (SD), median and interquartile (IQR) range (25 percentile – 75 percentile). Parametric (analysis of variance [ANOVA]) and nonparametric tests (Wilcoxon) were used for comparisons of numerical variables. For the primary endpoint a Bonferroni adjustment was performed to account for multiplicity. Fisher's exact test was used for comparison of categorical variables. In all statistical hypotheses, the significance level was set at $\alpha = 0.05$. All analyses were performed with the SPSS software version 17.0.

3. Results

3.1. Baseline characteristics and patient disposition

Between September 2012 and January 2014, 165 patients were enrolled (100 to HS + Floseal, 65 to standard hemostasis). Of the 165 patients, 80.5% were female and the mean age was 42.3years.There were no meaningful differences between the two treatment groups with respect to demographic or baseline characteristics (Table 1). However, the type of thyroid disease in each group varied slightly between the treatment groups.

Table 1
Baseline characteristics/demographics and surgical parameters.

Characteristic/demographic	HS + Floseal TT ($n = 100$)	Standard TT ($n = 65$)
Mean age, years	49.3 ± 12.2	48.7 ± 12.2
Range	30.1–71.8	23.2–69.4
Gender, *n* (%)		
Male	28 (28)	15 (23)
Female	72 (72)	50 (77)
BMI, kg/m^2	23.7 ± 2.8	23.4 ± 3.3
Pulse rate, bpm	73.0 ± 6.89	73.6 ± 7.75
BP, mmHg		
Systolic	123.7 ± 10.7	125.0 ± 12.4
Diastolic	77.9 ± 6.6	78.8 ± 6.2
Thyroid disease, *n* (%)		
Goiter	79 (79)	48 (73.9)
Hyperthyroid goiter	9 (9)	7 (10.7)
Carcinoma	12 (12)	10 (15.4)
Thyroid weight, g	32.8 ± 3.3	45.9 ± 27.3

All data is presented as mean ± standard deviation (SD) unless otherwise stated. BMI, body mass index; BP, blood pressure; bpm, beats per minute; CS, clinically significant; ECG, electrocardiogram; HS, harmonic scalpel.