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Original research

Effectiveness of an advanced hemostatic pad combined with harmonic scalpel in thyroid surgery. A prospective study

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ABSTRACT

Introduction: Hemostasis during thyroidectomy is essential; however the 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 the combination of harmonic scalpel (HS) and an advanced hemostatic pad (Hemopatch).

Methods: Patient undergone TT were divided into two groups: HS + hemopatch and HS + 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 2014 and March 2015, 60 patients were enrolled (30 to Hs + Hemopatch, 30 to Hs and standard hemostasis); 71.4% female; mean age 48.5 years. The 24-h drain output was lower in the HS + hemopatch group compared with standard TT. HS and hemopatch also had a shorter mean surgery time ($p < 0.0001$) vs standard TT.

Conclusion: combination of hemopatch plus HS is effective and safe for TT with 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 [5–15], bipolar coagulation and modern topical hemostatic agents [16–18].

2. Methods

2.1. Study design

This single-center, prospective study investigated the hemostasis efficacy and safety of Advanced Hemostatic Pad. The bovine collagen patch coated with a protein reactive pentaerythritol polyethylene glycol ether tera-succinimidyl glutarate (NHSPEG) is Hemopatch (Baxter AG, Vienna, Austria) (PCC).

When in contact with tissue, NHS-PEG forms covalent bonds between the collagen pad and tissue proteins, which seals the tissue and induces hemostasis in open and laparoscopic procedures.

Two groups were assessed: patients receiving Hemopatch, and

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patients receiving traditional hemostatic procedures alone (gauze, ligature, electrocauterization) during TT. 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, 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. 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. Surgical hemostasis is used if additional hemostasis was deemed necessary and Hemopatch was used for bleeding not responding to 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 h 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 postsurgical 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 e 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 a ¼ 0.05. All analyses were performed with the SPSS software version 17.0.

3. Results

3.1. Baseline characteristics and patient disposition

Between September 2014 and March 2015, 60 patients were enrolled (30 to Hemopatch, 30 to standard hemostasis). Of the 60 patients, 70% 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.

3.2. Surgical outcome

Surgery was uneventful in the majority of patients. Three patients standard TT had surgical complications, with one patient having dysfonia with a saturated O_2 of 98%.Compared with Hemopatch group, fewer patients who received standard hemostasis during surgery had a dry surgical field at the end of surgery and before placement of the drain according to the surgeon (100% vs 85.6%, $p < 0.001$). No other meaningful differences between the two treatment groups with respect to surgery were reported.

3.3. Efficacy outcomes

The mean of 24-h drain output was 50.1 ± 21.4 mL in Hemopatch group vs 90.3 ± 24.2 mL in standard TTgroup (95% CI _ 63.5, _32.3; $p < 0.0001$) (Table 2).

Incidence of post-operative seroma was higher in standard hemostasis group.

There was a statistically difference in the length of surgery: patients in the Hemopatch group had a shorter mean surgery time, compared with standard hemostasis ($p < 0.0001$) (Table 2). Only

Table 1
Baseline characteristic/demographics and surgical parameters.

Characteristic/Demographics	Hemopatch TT (N = 30)	Standard TT (N = 30)
Mean age, years	50.2 ± 11.7	49.5 ± 12.1
Range	22.1–70.5	22.8–68.8
Gender N (%)		
Male	8 (26.6)	10 (30.3)
Female	22 (73.4)	20 (69.7)
Thyroid disease, N (%)		
Goiter	26 (80.6)	24 (80)
Hyperthyroid goiter	2 (9.7)	3 (10)
Carcinoma	2 (9.7)	3 (10)