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The safety of the Harmonic® FOCUS in open thyroidectomy: A prospective, randomized study comparing the Harmonic® FOCUS and traditional suture ligation (knot and tie) technique

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ABSTRACT

Since Kocher and Billroth refined an acceptable technique, the thyroidectomy has become one of the most frequent procedures in endocrine surgery and bilateral total thyroidectomy is performed in the majority of thyroid diseases.

This work evaluated the use of the Harmonic® FOCUS and traditional suture ligation (knot and tie) technique in a prospective, randomized study of open thyroidectomy.

Eighty two patients were randomized and divided into two similarly sized groups: the Harmonic® FOCUS group (F group) and traditional group (T group).

The use of the harmonic FOCUS shows some statistically significant advantages limited to a few intraoperative parameters: surgical time and volume of blood loss.

The surgical time was significantly shorter in F group than in the T group (105 ± 27 min vs 143 ± 32 respectively; $p < 0.05$).

Intraoperative volume blood loss was significantly more in the T group than in the F group (36 ± 23 ml vs. 24 ± 18; $p < 0.05$).

The postoperative parameters (volume of drainage fluid, serum calcium at 12 and 48 h, hypocalcemia, wound complication, RLN palsy, postoperative pain and length of hospital stay) showed no statistical difference.

The Harmonic Focus may provide a cost-effective option only in high volume centers where reducing operative time may balance the number of daily procedures.

1. Introduction

Before 1872, year in which Kocher performed his first thyroidectomy, the mortality rate related to surgical intervention reached about 75%. The most frequent complications included damage of the recurrent laryngeal nerve and post operatory tetany due to removal of parathyroid glands.

By 1912, Kocher had performed about 5000 thyroidectomies with only 0.5% of mortality [1].

Since Kocher and Billroth refined an acceptable technique, the thyroidectomy has become one of the most frequent procedures in endocrine surgery, and bilateral total thyroidectomy is performed in the majority of thyroid diseases.

Because the thyroid gland has an extensive vascular network, an effective hemostasis is a crucial part of the procedure: ensure a dry surgical field is advisable not only to avoid potentially fatal hemorragies but also to avoid inadvertent damage to adjacent vital structures (superior and inferior recurrent laryngeal nerves and the parathyroid glands).

Nowadays the two most significant complications with incidences are permanent recurrent laryngeal nerve (RLN) palsy and hypoparathyroidism with an incidence reported in literature of up to 14 percent and four percent, respectively [2].

With advances in technology, using new energy devices such as ultrasonic coagulation (Harmonic Scalpel, Ethicon) and bipolar

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energy (LigaSure, Valleylab) for cutting and hemostasis during thyroidectomy has become a common practice.

Some institutions have adopted it as the preferred technique over the conventional technique of classic suture ligation with knot-and-tie maneuvers, metal clips, or by monopolar electrocoagulation: suture ligation is a time consuming procedure and togheter with clips carries the risk of slipping, monopolar electrocautery carries the potential risk of injuring surrounding tissues from dispersion of heat (150 °C–400 °C).

New techniques to achieve a safe and faster hemostasis with less thermal spread to reduce both operating time and complications have been researched and developed.

HS (Harmonic scalpel, formerly named UltraCision; Ethicon Endo-Surgery, Cincinnati, OH), developed in the early 1990s, controls bleeding by sealing it with a protein coagulum at temperatures ranging from 50 to 100 °C.

It allows simultaneous cutting and coagulation of blood vessels denaturing proteins by mechanically breaking the hydrogen bonds in protein molecules when the blade vibrates at 55.5 KHz.

The thermal injury induced by ultrasound appears to be reduced 10-fold when compared with electrocoagulation [3].

Moreover, the ability to cut and coagulate simultaneously helps in reducing the operating time and, according to some authors, could reduce total operating cost as more operations could be performed.

Ligasure is a closed-loop instrument and occludes blood vessels and lymphatics by delivering controlled electrical energy in combination with applied physical pressure to produce a collagen seal derived from fusion of the vessel walls.

To date, several prospective, randomized, trials have been reported in recent literature comparing the harmonic scalpel in thyroid surgery with other methods in terms of operating time, complications, costs and other outcomes.

Some studies demonstrated that using energy devices reduces the rate of hypoparathyroidism after total thyroidectomy. However, despite the overwhelming evidence supporting the use of an energy device in thyroidectomy, it remains unclear if the 2 different energy devices, namely ultrasonic coagulation and bipolar energy, produce similar outcome.

The objective of our study is to analyze our experience, based on prospectively acquired data, comparing the harmonic scalpel with other hemostatic techniques in thyroid surgical patients and to assess relevant outcomes such as operating time, blood loss, volume of drainage fluid, complications, postoperative pain, and length of hospital stay and, if feasible, to compare our results with prospective, randomized trials.

2. Materials and methods

This work evaluated the use of the Harmonic® FOCUS and traditional suture ligation (knot and tie) technique in a prospective, randomized study of open thyroidectomy.

This study was carried out from January 2010 to December 2011: 83 patients affected by multinodular nontoxic goitres, undergone open thyroidectomy in the Department of Surgery – University of Catania within this period, were included in this prospective study.

The patients were randomized and divided into two similarly sized groups: the Harmonic® FOCUS group (F group) and traditional group (T group).

The group F comprised 41 patients in whom the thyroidectomy were performed using the ultrasonically activated scalpel technology (Harmonic – Ethicon Endo Surgery INC – Johnson & Johnson Medical SPA, Somerville, NJ). The application of ultrasound to tissues was performed during the entirely procedure, to obtain three purposes synergistically: coagulation, cutting, and cavitation.

Even the dissection of Zuckerkandl tuberculum was performed using a sutureless technique. The temperature obtained and the lateral energy spread are lower than those detected when the monopolar hook is used, thus reducing the risk of tissue damage (RLN and parathyroid).

The group T consisted of 42 patients in whom dissection and hemostasis were performed using conventional materials (Vicryl, Ligapak 3-0, stitches, titanium hemostatic clips and monopolar or bipolar electrocautery).

All procedures were performed under general anesthesia by the same surgeon.

The clinical endpoints of this study included intraoperative and post-operative parameters. Intraoperative parameters included operating time (between skin incision and the end of wound closure) and blood loss (blood loss was measured from the increase in weight of the bloodied swabs or measured from intraoperative drainage).

Postoperative parameters included volume of drainage fluid (expressed in milliliters), serum calcium values (mg/dl) at 12 and 48 h, hypocalcemia (temporary or permanent), wound complication (such as seroma and hematoma), RLN palsy (temporary or permanent), postoperative pain and length of hospital stay.

Hypocalcemia was defined as permanent when it was associated with a need for calcium replacement after six months.

The preoperative evaluation and the postoperative follow-of vocal cord mobility was obtained via laryngoscopy performed by 1–2 days prior to the surgery and 1–2 days after the surgery.

Any reduction in vocal cord movement was recorded as postoperative cord paralysis. Recurrent laryngeal nerve palsy was considered permanent when it persisted more than 6 months after surgery. For patients with documented postoperative cord palsy, repeated examinations were performed periodically until a full functional vocal recovery had been confirmed.

The pain is valued through a visual analogue scale (VAS, scale of 1–10), stratifying pain into (a) the neck/back/cervical region, (b) wound pain and (c) pain/discomfort while swallowing.

3. Statistical analysis

An accurate analysis of data collected has been performed. For continuous variables, descriptive statistics were calculated and reported as mean + SD. Categorical variables were described using frequency distributions. The Student's *t* test for paired samples was used to detect differences in the means of continuous variables, and chi-square test was used in cases with low expected frequencies ($p < 0.05$ was considered to be significant).

4. Result

Intraoperative and postoperative findings of both groups are shown in Table 1.

4.1. Intraoperative parameters

The surgical time was significantly shorter in the harmonic group than in the traditional group (105 ± 27 min vs 143 ± 32 respectively; $p < 0.05$).

Intraoperative volume blood loss was significantly more in the traditional group than in the Focus group (36 ± 23 ml vs. 24 ± 18; $p < 0.05$).

4.2. Postoperative parameters

The mean amount of postoperative drainage was not significantly different among the two group (10 ± 3 vs. 11 ± 4 ml Focus group and Traditional group, $p > 0.05$).

Table 1
Clinical and pathological data of patients.

	F group (41)	T group (42)	*P*
Intraoperative parameters			
Operating time (min)[a]	105 ± 27	143 ± 32	<0.05
Blood loss (ml)[a]	24 ± 18	36 ± 23	<0.05
Post-operative parameters			
Volume of drainage fluid (ml)[a]	10 ± 3	11 ± 4	NS
12 h calcemia (mg/dl)[a]	7.62 ± 0.61	7,87 ± 0.56	NS
48 h calcemia (mg/dl)[a]	8.16 ± 0.31	8.13 ± 0.28	NS
Temporary hypocalcemia	5 (12.2%)	6 (14.28%)	NS
Permanent hypocalcemia	–	1 (2.3%)	NS
Wound complication			
- Seroma	1 (2.3%)	–	NS
- Hematoma	–	1 (2.3%)	NS
Temporary RLN palsy	2 (4.87%)	1 (2.3%)	NS
Permanent RLN palsy	–	–	
Postoperative pain (VAS)			
- Neck/back/cervical region[a]	2.37 ± 0.50	2.41 ± 0.67	NS
- Wound pain[a]	2.23 ± 0.71	2.51 ± 0.73	NS
- Pain/discomfort while swallowing[a]	3.33 ± 1.01	3.47 ± 0.99	NS
Length of hospital stay (h)[a]	51 ± 3	50 ± 3	NS

$p \leq 0.05$ was considered statistically significant.
NS – non significant.
[a] Mean value ± standard deviation.

The serum calcium levels at 12 h and 48 h showed no statistically significant differences in to two groups (respectively 7.62 ± 0.61 and 8.16 ± 0.31 group F vs 7.87 ± 0.56 and 8.13 ± 0.28 in the group T, $p > 0.05$).

Eleven (11) cases of temporary hypocalcemia have been reported, 5 in the A group and 6 in the T group. One case of permanent hypocalcemia has been reported in the T group without statistically significant between two groups.

There were 2 cases of wound complication: a seroma in the F group and an hematoma in the T group.

No significant difference for temporary RLN palsy rate was found between groups (4.87% –2 cases and 2.3% – a case respectively). We experienced no case of permanent RLN paralysis.

The assessment of postoperative pain showed a modest reduction in discomfort in Group F even in the absence of statistically significant differences between the two groups. The length of hospital stay was similar in the two groups.

5. Discussion

The Harmonic Focus is the latest ultrasonic device designed for thyroid surgery, offering significant benefits in the size and weight of its hand piece, hand-activated trigger system, and versatility.

The results of this prospective randomized trial on the Harmonic Focus device clearly show significant advantages of its use in total thyroidectomy in terms of reduced surgical time, intraoperative bleeding.

The ability of the FOCUS to reduce the operative time by several minutes compared to traditional technique has been longly demonstrated. In the published literature, it ranges from 15% up to 30%, and is more apparent when surgical procedures are long and complex [4,5]. A relative reduction of 27% in surgical time was observed in the current study.

Because the thyroid is a highly vascularized organ, the hemostasis in thyroid surgery remains a real challenge. The results of this study are coherent with the latest literature. We experienced a reduction near to 34%. This value appears to be within other data from published randomized trials that showed a relative reduction in intraoperative bleeding ranging from 13% to 61% [5,6]. In line with previously reported data [5–10], the present study showed no deleterious effect in terms of a temporary or permanent hypocalcaemia and abnormalities of the vocal cords using the Harmonic Focus. Reported cases of hypocalcemia, in both groups, can be attributed to the complexity of thyroidectomy: we found no statistically significant difference in the incidence rate in the two groups.

Some controversies still persist with regard to postoperative pain. There was no impact on postoperative pain in relation to hemostatic technique in our study, such as also dimostrated by other authors [8]. Conversely, other investigators have reported a reduction in postoperative pain evaluated by visual analogue scale scores using Harmonic scalpels [4,10].

The relationship between the type of hemostasis applied during thyroid surgery and of hospital stay remains unclear: we found a mean length of 2 days in both groups. Conversely, a very recent study showing a shorter hospital stay in patients undergoing an Ultracision procedure [10].

6. Conclusion

This work compares two groups of patients undergoing open thyroidectomy, with the aim to identify, among techniques, the one that shows greater benefits for the patients. The use of the harmonic FOCUS shows some statistically significant advantages limited to a few intraoperative parameters: surgical time and volume of blood loss. In contrast, the postoperative parameters (volume of drainage fluid, serum calcium at 12 and 48 h, hypocalcemia, wound complication, RLN palsy, postoperative pain and length of hospital stay) showed no statistical difference.

The cost remains a major concern and needs to be evaluated in terms of cost-savings made because of the reduced duration of surgery and compared to the conventional materials for traditional hemostasis [11–20].

The Harmonic Focus may provide a cost-effective option only in high volume centers where reducing operative time may balance the number of daily procedures.

These observations lead us to conclude, that a wider use of harmonic scalpel not offers such advantages to make it the reference technique.

Ethical approval

None.

Conflict of interest/financial support

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Author contribution

Antonio Zanghì: Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

Andrea Cavallaro: Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

Paolo Di Mattia: Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

Maria Di Vita: Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

Francesco Cardì: Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

Gaetano Piccolo: participated substantially in the drafting and editing of the manuscript.

Giuseppina Barbera: participated substantially in the drafting and editing of the manuscript.

Mario Urso: participated substantially in the drafting and editing of the manuscript.

Alessandro Cappellani: Participated substantially in conception, design, and execution of the study and in the analysis and interpretation of data. Also participated substantially in the drafting and editing of the manuscript.

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