The use of the harmonic scalpel in thyroid surgery

Our experience

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The use of the harmonic scalpel in thyroid surgery. Our Experience

The aim of this study was to evaluate the potential advantages of the use of Harmonic Scalpel in thyroidectomies in terms of operative time and complications.
Between May 2007 and June 2010 1151 patients were submitted to total thyroidectomy. In 681 thyroidectomies were performed using harmonic scalpel FOCUS® (group A), in 470 without it (group B).
Mean operative time was 97 minutes in group A and 114 in group B with a mean difference of 17 minutes (14.9%). 554 patients in group A (81.35%) and 345 in group B (73.4%) were discharged in second postoperative day. In group A, hypoparathyroidism was present in 348 patients at discharge (48%), in 23 at 6 months (3.38%) and in 10 at 12 months (2.13%), in group B, in 255 at discharge (54.26%), in 61 at 6 months (12.98%) and in 28 at 12 months (5.96%).
The major benefit of Harmonic Scalpel used during thyroidectomy is the reduction in the time of operation. All studies but one to date have reported reductions in operative time, ranging from 6 to 78 minutes with a 10% to 35% savings in operative time and this was confirmed in our study. A reduction of hypoparathyroidism, particularly transitory, and in length of hospital stay was reported in some studies and confirmed in our experience.
The use of Harmonic Scalpel in thyroid surgery is safe and effective and is associated with a significant reduction in operative time, postoperative hypocalcaemia and hospital stay, without increasing complications rate.

KEY WORDS: Harmonic Scalpel, Thyroidectomy, Thyroid surgery.

Introduction

Thyroidectomy is one of the most frequently performed operations in general and endocrine surgery [1-3].
Hemostasis is extremely important in thyroid surgery to provide a dry operative field and to avoid intraoperative and postoperative complications such as bleedings and damages to the superior and recurrent laryngeal nerves and the parathyroid glands [2,4,5].
Conventional haemostatic techniques in thyroidectomy include ligation and electrocoagulation [2,3]. In conventional thyroid surgery, most surgeons use a large number of ligatures or clips, which is time consuming, bearing the risk of knot slipping [3,6-10]. Various devices have been introduced in clinical practice to achieve a safe and faster hemostasis: electrosurgical devices use heat energy to denature proteins and the heating of the surgical field due to lateral dispersion may easily damage vital structures [2,3,8]. The parathyroid glands and the laryngeal nerves lie very close to the dissection plane and can be damaged by thermal energy [11].

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Ultrasonic coagulator was developed in early 1990s [3,12,13] and laparoscopists were the first to adopt it widely [6,13-14]. In addition, this new technology has been widely used in several fields of surgery, including otorhinolaryngologic, gastrointestinal, vascular, and obstetric and gynecological surgery [15].

The Harmonic Scalpel is a device that uses ultrasonic energy to produce vibrations which cut and coagulate tissues at the same time [6,9,11]. It is a system composed of three parts: a generator, a hand piece, and the scalpel [16]. The generator produces acoustic waves at a frequency of 55,500 Hz [1,2,6,13,16-19]. By transmitting the vibration, a rupture of hydrogen bonds of the tissue proteins is provoked, and thus proteins are denaturated to form an endovascular coagulum, which seals the vessels and assures hemostasis at low temperatures [1,6,16,20]. This technology can coagulate vessels that have a diameter less than or equal to 5 mm [16,21]. It allows reliable, safe, and rapid hemostasis and division to be achieved with a single tool [22]. Harmonic Scalpel is associated with a considerably lower production of thermal energy thus causing significantly less damage to the adjacent tissue [19]. The Harmonic Scalpel causes lateral thermal injury 1-3 mm wide, approximately half that caused by bipolar systems, less smoke formation, no neuromuscular stimulation, and no electrical energy to or through the patient [15,18]. Furthermore, no foreign bodies are left behind [23]. In an experimental pig model, the ultrasonically activated coagulating shears, while providing effective hemostasis in transecting uterine horn and small bowel, caused a lateral thermal injury that was half of the injury caused by bipolar systems [10]. For surgeons, the Harmonic Scalpel could represent advantages in terms of a reduction in operative time and intraoperative bleeding, with a comparable efficiency in patient morbidity [15]. The use of harmonic scalpel reduces operative time for thyroid surgery by between 20 and 40 minutes [12,17,20]. On the other hand, the extent to which the use of Harmonic Scalpel adjacent to the recurrent laryngeal nerve affects this nerve remains unclear [24]. An innovative technical improvement of the device has been made available recently for thyroidectomy [5].

The aim of this study was to evaluate the potential advantages of the use of Harmonic Scalpel in thyroidectomies in terms of operative time and complications in a large retrospective comparative study.

Material and method

Between May 2007 and June 2010 1151 patients (928 female and 223 male) were submitted to total thyroidectomy. In 681 patients (547 female and 134 male) thyroidectomies were performed using harmonic scalpel FOCUS® (group A), in 470 patients (381 female and 89 male) without it (group B). Patient's characteristics were similar for the 2 groups.

In group A 613 patients were submitted to total thyroidectomy; in 59 cases a VI level lymphectomy and in 9 cases a II-III-IV-V-VI level lymphectomy was associated. In group B 435 patients were submitted to total thyroidectomy; in 30 cases a VI level lymphectomy and in 5 cases a II-III-IV-V-VI level lymphectomy was associated.

In group A, histologic diagnosis was differentiated carcinoma in 236 cases, medullary carcinoma in 7, multinodular goiter in 260, toxic goiter in 59, autoimmune thyroiditis in 118, secondary neoplasm in 1 case. In group B, histologic diagnosis was differentiated carcinoma in 179 cases, medullary carcinoma in 3, multinodular goiter in 183, toxic goiter in 36, autoimmune thyroiditis in 69.

Mean glandular weight was 42,62 g in group A (range 14-210) and 41.71 in group B (range 14-160).

No significant differences for type of surgery, histologic diagnosis or glandular weight were observed in the two groups.

The statistical significance of categorical variables was evaluated by the χ^2 test, whereas the Student's *t* test was used for the evaluation of continuous variables. A value of $p<0.05$ was considered to indicate significance.

Results

Mean operative time was 97 minutes in group A and 114 minutes in group B with a mean difference of 17 minutes (14.9%) (Table I).

Operative time was 96 minutes for carcinomas, 95 for multinodular goiters and 112 for toxic goiters in group A, 118 minutes for carcinomas, 109 for multinodular goiters and 120 for toxic goiters in group B.

The difference was 22 minutes for carcinomas (18.6%), 14 minutes for multinodular goiters (12.8%) and 8 minutes for toxic goiters (6.6%) (Table I).

TABLE I - *Differences in operative time between the two groups*

Diagnosis	Operative time (group A)	Operative time (group B)	Savings in operative time
Carcinoma	96 min	118 min	22 min (18.6%)
Multinodular goiter	95 min	109 min	14 min (12.8%)
Toxic goiter	112 min	120 min	8 min (6.6%)
Total	97 min	114 min	17 min (14.9%)

TABLE II - *Amount of drainage in the two groups*

Group	Drainage (first postoperative day)	Drainage (second postoperative day)	p
Group A	40 cc	25 cc	p=0.4709
Group B	45 cc	30 cc	

The drainage was 40 cc in first postoperative day and 25 cc in second for group A and 45 cc in first and 30 cc in second for group B. These differences were not statistically significant (p=0.4709) (Table II).
In group A 554 patients were discharged in second postoperative day (81.35%), 107 in third (15.71%), 14 in fourth (2.06%) and 6 after (0.88%); in group B 345 patients were discharged in second postoperative day (73.4%), 110 in third (23.4%), 11 in fourth (2.3%) and 4 after (0.9%). Comparing patients discharged in second postoperative day and after the difference was statistically significant (p=0.0017) (Table III).
In group A, hypoparathyroidism was present in 348 patients at discharge (48%), in 52 at 3 months (7.64%), in 23 at 6 months (3.38%), in 18 at 9 months (3.36%), in 10 at 12 months (2.13%); in group B, hypoparathyroidism was present in 255 patients at discharge (54.26%), in 108 at 3 months (22.98%), in 61 at 6 months (12.98%), in 33 at 9 months (7.02%), in 28 at 12 months (5.96%). Hypoparathyroidism was defined as calcemia < 8.0 mg/dl or PTH < 10 pg/dl. Difference was statistically significant (p=0.0000000235 at 6 months and 0.0048 at 12 months) (Table IV).
In group A transitory recurrent laryngeal nerve injury was observed in 12 patients (1.76%) and definitive in 6 (1.27%). In group B transitory recurrent laryngeal nerve injury was observed in 7 patients (1.60%) and definitive in 5 (1.06%). Recurrent injury was classified as definitive if present 12 months after operation. These differences were not statistically significant (Table V).
Bleedings were observed in 6 patients in group A (0.88%) and in 3 patients in group B (0.63%). These differences were not statistically significant (p=0.5) (Table VI).
In group A seromas were observed in 8 patients (1.17%), wound infection in 3 (0.44%), thoracic duct injury in 1 and Bernard-Horner syndrome in 1; in group B we observed 1 seroma (0.21%) and 1 wound infection (0.21%) (Table VII).
No significant difference was observed in relation to postoperative pain or postoperative analgesic use.

TABLE III - *Hospital stay in the two groups*

Discharge	Group A	Group B
II postoperative day	554 (81.35%)	345 (73.4%)
III postoperative day	107 (15.71%)	110 (23.4%)
IV postoperative day	14 (2.06%)	11 (2.3%)
>IV postoperative day	6 (0.88%)	4 (0.9%)

N.B. p=0.0017 (comparing patients discharged in second postoperative day and after).

TABLE IV - *Incidence of hypoparathyroidism in the two groups*

Hypoparathyroidism *	Group A	Group B
At discharge	348 (48%)	255 (54.26%)
At 3 months	52 (7.64%)	108 (22.98%)
At 6 months	23 (3.38%)	61 (12.98%)
At 9 months	18 (3.36%)	33 (7.02%)
At 12 months	10 (2.13%)	28 (5.96%)

*Hypoparathyroidism was defined as calcemia < 8.0 mg/dl or PTH < 10 pg/dl.
N.B. p=0.0000000235 at 6 months and 0.0048 at 12 months

TABLE V - *Incidence of recurrent laryngeal nerve injury in the two groups*

Recurrent laryngeal nerve injury	Group A	Group B
Transitory	12 (1.76%)	7 (1.60%)
Definitive	6 (1.27%)	5 (1.06%)

N.B: P = ns

TABLE VI - *Incidence of bleedings in the two groups*

Bleedings (Group A)	Bleedings (group B)	P
6 patients (0.88%)	3 patients (0.63%)	0.5

TABLE VII - *Incidence of seromas in the two groups*

Seromas (group A)	Seromas (group B)	p
8 patients (1.17%)	1 patient (0.21%)	0.1386

Discussion and commentary

Adequate hemostasis and keeping the operative field dry is of utmost importance during thyroid surgery due to the need to avoid damage to the superior and recurrent laryngeal nerves and parathyroid glands. Suture ligations are time-consuming and carry the risk of knot slipping [1,2].

Sinchronous cutting and coagulation functions of the harmonic scalpel make the instrument practical and time saving because cutting and coagulation occur at lower temperatures than does electrocautery, and thermal damage is minimal [18]. Thermal injury induced by ultrasound is reduced 10-fold when compared with electrocoagulation [6,25].

The major benefits of Harmonic scalpel used during open thyroidectomy are the reduction in time of operation (between 15 and 35 minutes) and decreased blood loss [1]. All studies but one to date have reported reductions in operative time, ranging from 6 to 78 minutes [26] with a 10% to 35% savings in operative time [15]. In our study the mean reduction in operative time was 17 minutes with a 14.9% saving in operative time; the reduction was more relevant in thyroidectomies for malignant neoplasms.

The mean intraoperative blood loss and the drainage volume were significantly lower in the experience of some authors [1-3,6,10,15,18,19,25,27], but this was not confirmed in our study: the amount of postoperative drainage and the incidence of postoperative bleedings, in fact, were similar in the two groups.

Some authors suggested an increased danger of the recurrent laryngeal nerve injury and a higher chance for hypoparathyroidism in operations performed with the use of Harmonic Scalpel [1,8,20]. Other authors report a reduction of hypoparathyroidism, particularly transitory one, and no difference in recurrent laryngeal nerve injuries [15,21,25,28]. In our experience we have no statistically significant difference in recurrent laryngeal nerve injuries while transitory and permanent hypoparathyroidism were significantly reduced; hypoparathyroidism was present in 3.38% of patients in group A and 12.98% in group B at 6 months. The reduction in post-operative hypocalcaemia may occur as a consequence of less injury to the parathyroids and surrounding structures through lateral dispersion of heat [15,21]. Excellence in haemostasis may also permit a better view of these structures to preserve when operating [21].

Some authors report a reduced analgesic use for patients who had ultrasonic dissection [6,9,15,16,25]. This may be explained by decreased production of phlogogenic substances, the absence of foreign materials and the reduced tissue injury with no neuromuscular stimulation or the decreased operating time in which the head position is in hyperextension that is a well-known source of postoperative pain [7,15,16,25]. Our study did not confirm this reports.

Length of stay was slightly reduced in the experience of some authors [6,7] and this was confirmed in our experience. In group A 81.35% of patients were discharged in second postoperative day and 18.65% after, in group B 73.4% in second postoperative day and 26.6% after. This effect was probably due to the reduced incidence of hypoparathyroidism and the reduced operative time.

A disadvantage of the use of Ultrasonic Activated Shears is the cost of the instrument, which is disposable [27]. However, with regard to cost, there will be the absence of metal clips, sutures or ties, a quicker turnaround time permitting on average another case to be done per list, less hospital stay and less expense relating to the correction of hypocalcaemia [21].

In the experience of Lombardi [13] the global charges of the hospitalization were slightly lowered in the Harmonic Scalpel group. The significant higher cost of disposable materials in the Harmonic Scalpel group was counterbalanced by significant higher costs of drugs, personnel and operative room charges in the knot tying group related to the longer operative time and operative room utilization time. In addition clips, legatures and bipolar coagulation were not used. The shorter operative time implies the possibility to treat more patients in the same operative sessions. This results were confirmed by other authors [14,16].

In our study a precise evaluation of costs was not possible; however, our experience confirms a reduced hospital stay associated to a reduced incidence of hypoparathyroidism and a reduced operative time; so, in line with the experience of Lombardi, we believe that the cost of disposable materials can be counterbalanced by less use of drugs, less operative room utilization time, shorter hospital stay and less expense relating to the correction of hypocalcaemia; in addition reduction in operative time has permitted, in our experience, to add at least one intervention for operative session.

Shorter incision length resulting in better cosmesis has been cited as a significant advantage of use of the ultrasonic dissector in some published series [1,13,15,18,26]. Mean incision length was found to be reduced and patient satisfaction in relation to cosmetic result was found to be significantly increased in the experience of some authors [18-19,29]. We did not observe differences in length of incision in our experience in traditional thyroidectomies; however, we always use Ultrasonic Scalpel in minimally invasive and video-assisted thyroidectomies.

Conclusions

The use of Harmonic Scalpel in thyroid surgery is safe and effective and is associated with a significant reduction in operative time, postoperative hypocalcaemia and hospital stay, without increasing complications rate.

Riassunto

Lo scopo di questo studio è stato quello di valutare i potenziali vantaggi dell'uso del bisturi ad ultrasuoni in corso di tiroidectomia totale in termini di tempi operatori e incidenza delle complicanze in un ampio studio retrospettivo.
Tra maggio 2007 e giugno 2010 1151 pazienti sono stati sottoposti a tiroidectomia totale nel nostro Dipartimento. In 681 pazienti la tiroidectomia è stata effettuata con l'utilizzo del bisturi ad ultrasuoni FOCUS® (gruppo A), in 470 senza (gruppo B).
Il tempo operatorio medio è stato di 97 minuti nel gruppo A e 114 nel gruppo B con una differenza media di 17 minuti (14.9%). 554 pazienti nel gruppo A (81.35%) e 345 nel gruppo B (73.4%) sono stati dimessi in seconda giornata postoperatoria. Nel gruppo A,un ipoparatiroidismo è stato riscontrato in 348 pazienti alla dimissione (48%), in 23 a 6 mesi (3.38%) e in 10 a 12 mesi (2.13%), nel gruppo B, in 255 alla dimissione (54.26%), in 61 a 6 mesi e in 28 a 12 mesi (5.96%).
Il maggiore beneficio nell'uso del bisturi ad ultrasuoni nella tiroidectomia è sicuramente la riduzione dei tempi operatori. Tutti gli studi pubblicati in letteratura tranne uno mettono in evidenza una riduzione dei tempi operatori dai 6 ai 78 minuti con un risparmio di tempo del 10-35%; questi risultati sono stati confermati nel nostro studio. In alcuni studi è stata riportata una riduzione dell'ipoparatiroidismo, in particolare transitorio, e della lunghezza della degenza ospedaliera e anche questi dati sono stati confermati nella nostra esperienza.
L'utilizzo del bisturi ad ultrasuoni si rivela sicuro ed efficace, consentendo una riduzione dei tempi operatori, dell'ipoparatiroidismo e delle degenze ospedaliere senza un incremento del tasso di complicanze.

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