Ultrasound scalpel in thyroidectomy.
Prospective randomized study

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OBJECTIVE: *The ultrasonic scalpel is a surgical shear that uses high-frequency mechanical energy to enable simultaneous vessel sealing and tissue coagulation at the same time. We conducted a prospective randomized study to compare the outcome of total thyroidectomy using the ultrasonic scalpel versus standard clamp and tie (CT) procedure in terms of safety, operative time, overall drainage volume, complications, hospital stay.*
METHODS: *Between January 2008 and December 2010, 200 patients (130 women, 70 men; mean age 46 years) undergoing thyroidectomy were randomized into two groups: group A, where CT technique were used, and group B, where the ultrasonic device was used.*
RESULTS: *There was no significant differences between the two groups in terms of age, gender, indication for thyroidectomy, thyroid gland weight and diameter, histopathologic diagnosis, preoperative and postoperative serum calcium levels, postoperative complications and reoperative thyroid surgery. In group B there is a statistically significant reduction of the operative times (63 ± 9' vs 85 ± 15', P<0.001) and overall drainage volume (50 ± 20cc vs 70 ± 25cc, P<0.001) .*
CONCLUSIONS: *The ultrasonic scalpel is safe, effective, useful, and time-saving alternative to the traditional suture ligation technique for thyroid surgery. They simplified total thyroidectomy, eliminating the need for clamp-and-tie maneuvers while achieving efficient hemostasis. Our study shows that the use of ultrasound in thyroid surgery reduces significantly surgical time and overall drainage volume. Furthermore, we also verified a decrease in hospitalization time, postoperative pain and blood loss, without increasing complication rates, for patients who underwent total thyroidectomy with the ultrasonically activated shear.*

KEY WORDS: Hemostasis, Thyroidectomy, Ultrasonic device.

Introduction

Total thyroidectomy (TT) is the most performed operation in endocrine surgery, representing the most appropriate therapeutic choice for the surgical treatment of many thyroid disorders [1,2].

Being the thyroid a richly vascularized organ, the control of hemostasis is a priority to avoid also hard complications such as bleeding, laryngeal nerve palsy and hypoparathyroidism [3,4].
An exhaustive hemostasis makes it possible to prevent blood loss and bleeding in the operating field, allowing a good view of the operating field and thus significantly reducing the possibility of potential lesions of the parathyroid glands and laryngeal nerves, as well as potential dangerous post-operative bleeding. Hemostasis obtained with traditional methods, such as clamp and tie, use of clips or electrocautery, is time consuming and carry the risk of knot slipping, dislodgment and thermal damage [5-7].

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Recently, innovative vessel sealing devices have been recommended in order to give a valuable contribution in terms of accuracy of hemostasis, reducing of operative time and postoperative pain, safety, knowing that the reduction of surgical times is a necessity in terms of cost-effectiveness [8-10].

The ultrasonically activated shear is among the first devices for surgical simultaneous cutting and tissue coagulation which allows to obtain dissection and hemostasis by direct application of ultrasound and allows minimally invasive surgical procedures with minimal lateral thermal spread and, thus, minimal adjacent tissue destruction [11].

Ultrasonic shear is a really innovative device for many aspects and it is already widely used in laparoscopic surgery implying surgical time-saving and low incidence of complication rates [12-14].

The first reference about the use of the ultrasonic scalpel in thyroid surgery dates back to 2000[15]. Then numerous studies have confirmed the validity of this innovative technology [5,6,16-26].

Moreover, during the last ten years, on the based-experience of the surgeons who used the ultrasonic scalpel, both ergonomic and technical changes were made to improve the dissection and hemostasis of tissue [18,27,28].

The aim of the study was to evaluate the use of ultrasonic scalpel in thyroid surgery compared to the traditional technique in a significant number of patients (200). We conducted a prospective randomized study to identify particularly: analysis of complications, surgical time, overall drainage volume and duration of the hospital stay [29].

Materials and methods

Between January 2008 and December 2010, 230 patients, with thyroidal disease requiring surgical treatment, were selected and 200 of them were enrolled in our study. Some of the reasons of the exclusion of the 30 patients enrolled in the study were: age over 70 years, need for central or lateral compartment lymphadenectomy, recurrent goiter, previous neck irradiation or radioiodine ablation.

The 200 patients undergoing total thyroidectomy surgery gave informed consense of the study and were randomly divided into 2 groups (A and B) of 100 patients each. The average age of patients was 46 years (range 16-70 years) with a numerical prevalence of women (130/200).

In group A patients underwent total thyroidectomy surgery with the traditional vessel sealing techniques, while in group B patients underwent total thyroidectomy surgery by ultrasonic scalpel on all vessels including the superior thyroid artery, reducing the use of the electrocautery and suture ligations significantly.

The comparative pre-operative data between the two groups included: age, gender, preoperative serum calcium and thyroid pathology (Table I).

TABLE I - *Comparative preoperative data*

	Total	Group A	Group B
Number of patients	200	100	100
Mean age (years)	46 (16-70)	44	47
Female patients	130	60	70
Male patients	70	40	30
Preoperative calcium level (mg/dl)	9	9.3	9.3
Benign disease	173	85	88
Malignant disease	27	15	12

The duration of surgery was estimated in minutes from skin incision to skin closure.

The postoperative evaluation included analysis both of complications (laryngeal nerve palsy, hypoparathyroidism, blood loss, hematoma, seroma, wound infection) and the features of the pre and post-surgery (size of the thyroid specimen, postoperative serum calcium levels, overall drained, pain medications – paracetamol –, histopathologic diagnosis, reoperations, length of hospital stay, final outcome).

In both groups, a suction drain for each thyroid side was placed after surgical procedure and removed between the 1st and 3rd post-operative day. Serum calcium levels was monitored on the 12, 24, 48 hours postoperatively and patients were discharged between the 2nd and 4th post-operative day.

Statistical analysis were performed using dedicated statistical software (SPSS, version 17.0); unpaired T test and Fischer's exact test with a two sided P value <0.05 were used when appropriated.

Results

In 200 performed total thyroidectomy operations, histology revealed a benign disease in 162 cases (multinodular goiters, Hashimoto's thyroiditis, Basedow desease) and in 38 cases malignancy (papillary and follicular carcinoma).

There were no significant differences between the two groups regarding age, sex, serum calcium values pre-and post-surgery, reoperations, weight and diameter of the thyroid specimen, final histopathologic diagnosis.

With regard to operative time the average value of the group B was significantly lower (63 ± 9 min.) than in group A (85 ± 15 min.) ($P <0.001$).

The amount of drainage was lower in group B (50 ± 20 cc) than group A (70 ± 25 cc) ($P <0.001$).

The average hospital stay was lower in group B than group A (2.3 vs 2.8 days) (Table II).

Regarding complications observed in both groups 1 patient (1%) with recurrent transient paralysis, regressed over 6-8 weeks and 1 patient (1%) reoperated for

TABLE II - *Postoperative evaluation*

	Total	Group A	Group B	P
Number of patients	200	100	100	
Operative time (min)	74 ± 6	85 ± 15	63 ± 9	<0.001
Post-operative calcium level (mg/dl)	8.6	8.4	8.1	NS
Drainage volume (cc)	60 ± 20	70 ± 25	50 ± 20	<0.001
Paracetamol post-operative (g)	3	3.5	2	NS
Hospital stay (days)	2.5	2.8	2.3	NS
Reoperation	2	1	1	NS
HISTOPATHOLOGIC DIAGNOSIS				
Multinodular goiter	134	66	68	
Hashimoto thyroiditis	20	11	9	
Basedow disease	8	5	3	
Papillary cancer	31	14	17	
Follicular cancer	7	4	3	

TABLE III - *Complications*

	Total	Group A	Group B	P
Number of patients	200	100	100	NS
Hemorrhage	2	1	1	NS
Seroma	5	3	2	NS
Hematoma	2	1	1	NS
Wound infection	0	0	0	NS
Transient hypocalcaemia	38	18	20	NS
Transient recurrent nerve palsy	2	1	1	NS

incurred bleeding during the first 2 hours post-surgery.
In group A, transient hypocalcaemia has been observed in 18 (18%) patients of whom 9 (9% of total) asymptomatic, however normalized in 3 months by medical therapy with oral calcium and vitamin D.
In group B, the incidence of transient hypocalcemia was 20% (20 patients) with 5 asymptomatic patients (5% of total), regressed by treatment with calcium supplements and vitamin D analogues in the next 4 months in all patients.
There were no infections, the seromas and hematomas were resolved by conservative treatment (Table III).

Discussion

Technological innovation allowed us to use ultrasonic mechanical energy to improve the methods of dissection and coagulation, thereby facilitating the surgical act in terms of adequacy of hemostasis and reduction of operative times [22-25,30].
The ultrasonically activated shear is a device using high frequency ultrasonic energy to be able to determine a coagulative seal of the vessels and of the tissue with a cut in correspondence of the point of impact at 55.5 kHz, with temperatures below 100 degrees which lead to a reduced thermal damage on adjacent tissues[18,30,31].
The application of ultrasound technology is already known in cardiac, thoracic, urological, gynecological surgery safely and effectively. Even in thyroid surgery several studies have shown that the use of ultrasonic scalpel is safe and effective [16,17,19-21].
The ultrasonic scalpel, in fact, compared to the traditional technique, provide benefits at several levels: for the patient, for the surgeon and for the healthcare facility where it is used.
In particular, the literature confirms there is less blood loss (–45%)[30], less postoperative pain (–40.5%)[8,32], lower consumption of pain medication (–38%)[20], less drainage volume (–50.5%), smaller and better aesthetic scars[20], significant reduction in operative time (–47% on average)[8,14], rapid and effective hemostasis with minimal tissue damages19, a significant reduction of time also in terms of use of the operating room (–24 minutes)[8,19], reducing use of economic resources by the medical insitution[19].
The suggestions for using of ultrasonic scalpels initially were for vessels not exceeding 3 mm. The technological development with provided and ergonomic tools has led to the use on vessels up to 5 mm in diameter offering a precise and accurate surgical dissection, such as the thyroid surgery, with a great saving of surgical times. [8,13,27]
Lateral thermal damage is limited up to 2 mm beyond the tissue grasped within the forceps of the device [6]. This is an important property in thyroid surgery because it allows safe vascular ligation with minimal risk for damage to the recurrent laryngeal nerve, the external branch of the superior laryngeal nerve, and the parathyroid glands.
Moreover there have been several studies that prove the safety and efficiency of the this device for the superior thyroid artery [23,26] .

Conclusion

About the technical feature we found that the use of ultrasonic scalpel is effective both in the hemostasis of the all vessels and in dissection at the course of the laryngeal nerves, respecting the safety margins, and Berry's and Gruber's ligaments.
Keep in mind that heat loss irradiates around the area of synthesis for about 3 mm, so with a remarkable advantage over the high temperatures achieved with mono-or bipolar electrocautery, especially near to the recurrent nerve, to the external branch of the superior laryngeal nerve, to the parathyroid glands.
Also important is the correct use of the device since the temperature may rise above 100 degrees in case of prolonged activation (over 10 sec.) or high frequency use (levels 4 and 5). However keeping the correct parameters and precautions, such low power setting (level 3), short application time (less than 10 sec) and an suitable distance from structures to be preserved (3-5 mm), the tool grants a safe and efficacy use [33,34].
The detected complications (transient recurrent palsy, transient hypoparathyroidism) were similar in both the groups, in line with the literature data [12,13,35].
The hypocalcaemia is subsequent to parathyroid glands damage during thyroidectomy. The transient hypocalcaemia was slightly higher, even though not statistically significantly, in group B. This suggests a greater caution near the parathyroid glands to preserve blood supply, as stated in other studies too [16,36].
The amount of draining, higher in the group treated with conventional hemostasis, has shown that the utilization of ultrasonic scalpel permit also to reduce lymphorrea depending on ligations and sections, so giving the opportunity of anticipated dimission. In fact, if the removal of the drainage is delayed, the discharge is delayed too, so if the ultrasonic scalpel is not used, even slightly, the length of stay will be longer.
Nowadays operative time is perhaps the most significant feature in all comparative studies, demonstrating the real advantage of using a system of hemostasis and dissection alternative to traditional ones. Moreover, the reduction of operative times might allow to decrease operating room occupancy costs.
Probably the only disadvantage of ultrasonic device is the cost of the single-use devices.
Other studies analyzing and comparing costs, confirm that the expenditure for the device can be easily amortized if surgical operative times will be saved, provides a better and greater utilization of operating rooms, increases the number of programmable surgical procedures in the same surgical session and reduces the anesthesia costs, pain medication and hospital stay and eliminates the cost of clips and suture ligation, therefore decreasing the overall hospital costs [8,9,11,37,38].
In conclusion, our study shows that the use of ultrasound in thyroid surgery reduces significantly the surgical time and the overall drainage volume. Furthermore, we also verified a decrease in hospitalization time, postoperative pain and blood loss, without increasing complication rates, for patients who underwent total thyroidectomy with the ultrasonically activated shear.

Riassunto

Il bisturi ad ultrasuoni è tra i primi dispositivi chirurgici per taglio e coagulazione che consente di ottenere simultaneamente dissezione ed emostasi mediante applicazione diretta degli ultrasuoni e che permette di effettuare manovre chirurgiche poco invasive e nel rispetto della struttura dei tessuti da trattare.
Scopo del nostro lavoro è stato quello di valutare l'impiego del bisturi ad ultrasuoni in chirurgia tiroidea rispetto alla tecnica tradizionale in un significativo numero di pazienti (200). Abbiamo condotto uno studio prospettico randomizzato per identificare soprattutto: analisi delle complicanze, dei tempi chirurgici, della entità del drenato e della durata della degenza.
Tra Gennaio 2008 e Dicembre 2010 sono stati selezionati 230 pazienti con patologia tiroidea che richiedeva trattamento chirurgico e di questi 200 sono stati arruolati nel nostro studio.
Nel gruppo A i pazienti sono stati sottoposti ad intervento chirurgico di tiroidectomia totale con tecniche di emostasi tradizionale (legature, bisturi elettrico) mentre nel gruppo B i pazienti sono stati sottoposti ad intervento chirurgico di tiroidectomia totale utilizzando il bisturi ad ultrasuoni su tutti i peduncoli vascolari, riducendo in maniera significativa il ricorso a legature ed al bisturi elettrico.
Abbiamo valutato tutti i dati raccolti con indagine statistica (P value), considerando non significativi (NS) quelli in cui $P>0.05$.
Per quanto riguarda i tempi chirurgici il dato medio del gruppo B è stato significativamente più basso (63±9 min.) rispetto al tempo del gruppo A (85±15 min.) ($P<0.001$).
L'entità del drenato è stata più bassa nel gruppo B (50+/-20 cc) rispetto al gruppo A (70±25cc) ($P<0.001$).
Le complicanze osservate (paralisi ricorrenziale transitoria, ipoparatiroidismo transitorio) sono state percentualmente simili nei due gruppi osservati, in accordo con i dati riportati in letteratura.
L'ipoparatiroidismo transitorio è risultato leggermente superiore, anche se non in maniera statisticamente significativa, nel gruppo B. Questo dato suggerisce una maggiore cautela in prossimità delle paratiroidi, come segnalato anche in altri studi.
L'entità del drenato, maggiore nel gruppo trattato con emostasi tradizionale, ha dimostrato che ritardando la rimozione del drenaggio è ritardata anche la dimissione, quindi non impiegando il bisturi ad ultrasuoni aumentano, anche se di poco, i tempi di degenza.

Il nostro studio conferma che l'impiego degli ultrasuoni in chirurgia tiroidea riduce in maniera statisticamente significativa i tempi chirurgici, l'entità del drenato e la durata della degenza.

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