

Thyroidectomy with ultrasonic dissector: a multicentric experience

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SUMMARY: Thyroidectomy with ultrasonic dissector: a multicentric experience.

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Introduction. We have conducted a clinical controlled trial (CCT) on patients who had undergone thyroidectomy for goitre or thyroid carcinoma. The endpoint of this study was to evaluate the benefits of ultrasonic dissector vs conventional technique (vessel ligation and tight) in patients undergoing thyroid surgery.

Patients and methods. Between January 2007 and December 2009 a CCT was conducted on 2.736 consecutive patients admitted to our clinical wards, who had undergone thyroidectomy for goitre or thyroid carcinoma. They were divided in two groups: 1.021 patients (203 male and 818 female) underwent thyroidectomy with ultrasonic dissector (UAS) and 1.715 patients (369 male and 1.346 female) underwent thyroidectomy with conventional technique (vessel ligation and tight) (CT).

Results. The operative time (UAS 80 minutes mean, 50 to 120 min., vs CT 120 minutes, 70 to 180 minutes) was much lower in the thyroidectomy with UAS group. The incidence of transient laryngeal nerve palsy (UAS 17/1.021 patients, 1.6%, vs CT 16/1.715 patients, 0.9%) was higher in the thyroidectomy with UAS group; the incidence of permanent laryngeal nerve palsy was similar in two groups (UAS 9/1.021 patients, 0.9%, vs CT 18/1.715 patients, 1%). The incidence of transient hypocalcemia (UAS 98/1.021 patients, 9.5%, vs CT 132/1.715 patients, 7.7%) was higher in the thyroidectomy with UAS group; there are no relevant differences in the incidence of permanent hypocalcemia (UAS 26/1.021 patients, 2.5%, vs 35/1.715 patients, 2%) which was similar in two groups. Also the average post-operative hospitalization was similar in two groups (2 days).

Conclusion. Actually, the only significant advantage shown from this CCT is represented in terms of cost-effectiveness (reduction of the usage of operating room and hospitalization) for patients treated with

RIASSUNTO: Tiroidectomia con dissettore ad ultrasuoni: uno studio multicentrico.

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Obiettivo. Abbiamo condotto uno studio clinico controllato (Clinical Control Trial - CCT) su 2.736 pazienti (pz) sottoposti a tiroidectomia per gozzo o carcinoma della tiroide. Obiettivo dello studio era valutare i benefici del dissettore ad ultrasuoni rispetto alla sola tecnica chirurgica convenzionale (legatura e sezione del vaso).

Pazienti e metodi. Tra gennaio 2007 e dicembre 2009 2.736 pz sono stati arruolati in questo CCT e suddivisi in due gruppi: 1.021 pz (203 M e 818 F) sottoposti a tiroidectomia con dissettore ad ultrasuoni (UAS) e 1.715 (369 M e 1.346 F) sottoposti a tiroidectomia con tecnica convenzionale (CT).

Risultati. La durata dell'intervento chirurgico (UAS 80 min in media, da 50 a 120 min, vs CT 120 min, da 70 a 180 min) è minore nel gruppo sottoposto a tiroidectomia con UAS. L'incidenza di paralisi transitoria del nervo laringeo ricorrente (UAS 17/1.021, 1,6%, vs CT 16/1.715, 0,9%) è risultata maggiore nel gruppo sottoposto a tiroidectomia con UAS; l'incidenza di paralisi permanente del nervo laringeo ricorrente è stata simile nei due gruppi (UAS 9/1.021, 0,9%, vs CT 18/1.715, 1%). L'ipocalcemia transitoria (UAS 98/1.021, 9,5%, vs CT 132/1.715, 7,7%) è risultata maggiore nel gruppo sottoposto a tiroidectomia con UAS; non vi sono differenze significative per l'ipocalcemia permanente (UAS 26/1.021, 2,5%, vs 35/1.715, 2%). La degenza media post-operatoria è stata simile (2 giorni).

Conclusioni. Questo CCT ha dimostrato un significativo vantaggio in termini di diminuzione dei costi per i pazienti trattati con UAS; ciò è conseguente alla riduzione dei tempi dell'intervento chirurgico. L'UAS non ha presentato vantaggi in termini di complicanze post-operatorie transitorie: ipocalcemia (UAS 9,5% vs CT 7,7%) e paralisi del nervo laringeo ricorrente (UAS 1,6% vs CT 0,9%). Non ci sono neppure differenze nell'incidenza di paralisi permanente del nervo larin-

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UAS, subsequent to the significant reduction of operative duration. Although the analysis showed that the patients who were treated with ultrasonic dissector don't present more favourable results in incidence of post-operative transient complications: transient laryngeal nerve palsy (1.6% in UAS vs 0.9% in CT) and transient hypocalcaemia (9.5% in UAS vs 7.7% in CT). There is no significant difference in the incidence of permanent laryngeal nerve palsy (0.9% in UAS vs in 1% CT) and permanent hypocalcaemia (2.5% in UAS vs 2% in CT). The experience of surgeon is the only important factor which can influence the appearance of these complications; the usage of Ultrasonic dissector can only help surgical action but can't replace the experience of the operator.

geo ricorrente (UAS 0,9% vs CT 1%) e di ipocalcemia permanente (UAS 2,5% vs CT 2%). L'esperienza del chirurgo è l'unico fattore significativo nella comparsa di complicanze. L'utilizzo del dissettore ad ultrasuoni può agevolare l'atto chirurgico, ma non si può sostituire all'esperienza dell'operatore. È necessario eseguire nuovi e più ampi RCT con il nuovo dissettore ad ultrasuoni Focus.

KEY WORDS: Thyroidectomy - Ultrasonic dissector - Harmonic scalpel - Hypocalcemia - Laryngeal nerve palsy.
Tiroidectomia - Dissettore ad ultrasuoni - Bisturi armonico - Ipocalcemia - Paralisi del nervo laringeo ricorrente.

Introduction

The bases of the thyroid surgery were founded by Theodor Billroth and Theodor Kocher at the end of XIX century (1). From the beginning of the XX century the innovations in this type of surgery were poor. In the last ten years MIVAT was introduced by Miccoli in 1999 (2) and some new instruments for the execution of section and more safe homeostasis of thyroidal vessels were also invented (LigaSure and ultrasonic dissector). LigaSure is a generator, which producing electric energy at high intensity and low voltage, coagulates vessels before their section (3, 4). Ultrasonic dissector cuts and coagulates using lower temperatures (50-100°C) compared with those used by electric energy at high intensity or by laser (100-400°C). Also lateral thermal diffusion is minor and is of approximately 2 mm. The first ultrasonic dissector which entered in the market was Harmonic ACE with scissors of 5 mm of diameter and 14 of length (5). Recently it became possible to use Harmonic Focus scissors (length of 9 cm), much more ergonomic than the first one (6). Both instruments have scissors with curved active blade and is of inert branch with the function of taking. The quality of homeostasis depends on the pressure of the instrument and also on the level of "power output" of the generator (level 3 for coagulation and level 5 for coagulation and cutting). It is extremely important to have attention not to use active blade near nervous structures and parathyroids. We have conducted a clinical controlled trial (CCT) on 2.736 patients who had undergone thyroidectomy for goitre or thyroid carcinoma. The endpoint of this study was to evaluate the benefits of ultrasonic dissector vs conventional technique (vessel ligation and tight) in patients undergoing thyroid surgery.

Patients

Between January 2007 and December 2009 a CCT was conducted on 2.736 consecutive patients admitted to our clinical wards, who underwent thyroidectomy for goitre or thyroid carcinoma.

Inclusion criteria were:

- absence of concomitant metabolic (diabetes), infective or hematological pathologies;
- patients not undergoing corticosteroid or immunosuppressive treatment.

Exclusion criteria were:

- presence of severe obesity;
- patients undergoing thyroidectomy and lymphadenectomy;
- patients undergoing secondary surgery in the cervical region;
- patients undergoing thyroidectomy for locally advanced tumors;
- patients with goitres submerged in the thorax.

All patients underwent a minimum ambulatory follow up of 30 days.

Methods

The 2.736 patients enrolled in this CCT were divided in two groups: 1.021 patients (203 male and 818 female) underwent thyroidectomy with ultrasonic dissector (UAS) and 1.715 patients (369 male and 1.346 female) underwent thyroidectomy with conventional technique (vessel ligation and tight) (CT).

Outcomes of interest

The following outcomes were used to compare the thyroidectomy group with UAS versus CT group:

- operative time (minutes);
- operative blood loss (mL);
- transient laryngeal nerve palsy (no. of patients);
- permanent laryngeal nerve palsy (no. of patients);
- transient hypocalcemia (no. of patients);
- permanent hypocalcemia (no. of patients);
- average post operative hospitalisation;
- infection of the wound.

Results

The operative time (UAS 80 minutes mean, 50 to 120 min., vs CT 120 minutes, 70 to 180 minutes) was much lower in the thyroidectomy with UAS group. The incidence of transient laryngeal nerve palsy (UAS 17/1.021 patients, 1.6%, vs CT 16/1.715 patients, 0.9%) was higher in the thyroidectomy with UAS group; the incidence of permanent laryngeal nerve palsy was similar in two groups (UAS 9/1.021 patients, 0.9%, vs CT 18/1.715 patients, 1%). The incidence of transient hypocalcemia (UAS 98/1.021 patients, 9.5%, vs CT 132/1.715 patients, 7.7%) was higher in the thyroidectomy with UAS group; there are no relevant differences in the incidence of permanent hypocalcemia (UAS 26/1.021 patients, 2.5%, vs 35/1.715 patients, 2%) which was similar in two groups. Also the average post-operative hospitalisation was similar in two groups (2 days)

Discussion

From our CCT the main advantage of UAS is shorter operation duration. The significant reduction of the operative time is consequent to the simultaneous coagulation/dissection of UAS, this technique is quicker once the need to have repetitive 'clip, cut and tie' (7); this advantage is present also by LigaSure usage. The reduction of operative time permits also significant reduction of costs of the usage of operating room (8).

The incidence of post-operative complications represents a disadvantage of UAS as far as transient complications are concerned (transient laryngeal nerve palsy: 1.6% in UAS vs 0.9% CT; transient hypocalcemia: 9.5% in UAS vs 7.7% in CT) and is similar in permanent complications (permanent laryngeal nerve palsy: 0.9% in UAS vs 1% in CT; permanent hypocalcemia: 2.5% in UAS vs 2% in CT).

Hypocalcemia, as a result of inadequate preparation during the surgical procedure, is the most common post-operative complication after thyroidectomy (9). Permanent recurrent laryngeal nerve palsy was observed in 1.4% in the total thyroidectomy (TT) group, 1.2% in the subtotal thyroidectomy (ST) group, and 0.9% in the hemithyroidectomy (HT) group; permanent hypocalcemia was observed in 3.5% in TT group, 2.5% in the ST group, in 1.4% in the HT group (10). Reoperation for recurrent goitre and central neck dissection for thyroid cancer increases the risk of parathyroidectomy ($p=0.001$); but there is no statistically significant difference in the incidence of post-operative hypocalcemia ($p=0.55$). (11). A systematic review of the adverse effects of thyroidectomy combined with central neck dissection compared with thy-

roidectomy alone doesn't evidence the increased permanent morbidity by performing the procedure at the same time as thyroidectomy (12). An other systematic review was undertaken for the diagnosis of recurrent laryngeal nerve palsy after thyroidectomy: the average incidence of temporary RLNP after thyroid operations is 9.8% and the incidence of permanent RLNP is 2.3%. The RLNP rate varied according to the method of examining the larynx and ranged from 26% to 2.3% (13).

In spite the fact that the new techniques are continuously proposed to avoid nervous lesions of larynx and parathyroid (intraoperative laryngeal nerve monitoring during thyroidectomy, routine intraoperative rapid parathyroid hormone monitoring) (14-17), the experience of surgeon and the choice of surgical technique represent the unique causes of hypocalcemia and laryngeal nerve palsy.

Kocher has already evidenced this problem: "Since we have adhered strictly to this procedure, the hoarseness, formerly so frequently observed after operation, has now become exceptional". Subsequently in 1919 Halsted wrote in "The Operative Story of Goitre": "Kocher, neat and precise, operating in a relatively bloodless manner, scrupulously removed the entire gland, doing little damage outside its capsule, Billroth, operating more rapidly, and, as I recall his manner, with less regard for the tissues and less concern for the hemorrhage, might easily have removed the parathyroids or at least have interfered with their blood supply, and have left fragments of the thyroid" (18).

Conclusions

Actually, the only significant advantage shown from this CCT is represented in terms of cost-effectiveness (reduction of the usage of operating room and hospitalization) for patients treated with UAS, subsequent to the significant reduction of operative duration. Although the analysis showed that the patients who were treated with ultrasonic dissector don't present more favourable results in incidence of post-operative transient complications: transient laryngeal nerve palsy (1.6% in UAS vs 0.9% in CT) and of transient hypocalcaemia (9.5% in UAS vs 7.7% in CT).

There is no significant difference in the incidence of permanent laryngeal nerve palsy (0.9% in UAS vs 1% CT) and permanent hypocalcaemia (2.5% in UAS vs 2% in CT).

The experience of surgeon is the only important factor which can influence the appearance of these complications; the usage of ultrasonic dissector can only help surgical action but can't replace the experience of the operator.

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