Nerve sparing sutureless total thyroidectomy
Preliminary study

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Nerve sparing sutureless total thyroidectomy. Preliminary study

AIM: *In the present study the Authors assess the advantages of new technologies in thyroid surgery: to prevent nerve injury by using an intra-operative continuous nerve-monitoring techniques and to compare the real advantages of advanced coagulation devices*
MATERIALS AND METHODS: *Among a series of 440 thyroidectomies (jan 2004-feb 2006) the Authors reviewed charts from two groups:*
1) 240 total thyroidectomies performed using the traditional monopolar electrocautery, non-absorbable stitches for the principal vascular pedicles.
2) 140 total thyroidectomies performed using dedicated small bipolar electro thermal coagulator (Ligasure-Precise®).
3) Since 2006 in a double blind group selection of 70, we've performed Sutureless Thyroidectomy with continuous intra-operative nerve monitoring using dedicated endotracheal tube.
Mean operative time, post-operative bleeding, post-operative stay, incidence of transient or definitive laryngeal nerve lesions, incidence of permanent or transient hypocalcaemia, costs of the procedures were analyzed
RESULTS: *Major complications in the first two groups compared with the data of the literature are absolutely over-imposable, except a reduction of incidence of transient hypocalcaemia in the Precise group, but if we compare data of the 3rd group (NIM), we find a significative reduction of transient and permanent laryngeal nerve palsy incidence.*
DISCUSSION AND CONCLUSION: *This new technology offers several advantages: (1) atraumatic; (2) easy to use; (3) continuous monitoring and audio feedback to the surgeon (4) works outside the operation field (5) high sensitiveness. Cost-analysis confirm that NIM + Ligasure have same or less cost and time and probably less complications than traditional Total Thyroidectomy.*

KEY WORDS: Bipolar Vessel Sealing System, Intraoperative Nerve Monitoring, Total Thyroidectomy.

Introduction

The principal complication of thyroid surgery have always been after L-thyroxine discover, haemorrhage, hypocalcaemia and recurrent laryngeal nerve palsy. T. Kocher was maybe the first one to feel the importance of the problem (thyroid is the second most vascularised part of our body), experimenting an innovative klemmer that, still today, brings his name; year by year, a lot of device have been proposed for haemostasis in thyroid surgery, until the last year when most of surgeons divide preferences from Ultrasound Dissection and Bipolar Vessel Sealing System [1]. Hypocalcaemia is a difficult complication to prevent: a lot of factors act in post-opera-

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tive pathogenesis and not only transient or permanent p.o. hypoparathyroidism [2,3]. Finally Recurrent Laryngeal Nerve (RLN) injury after total thyroidectomy is a dreaded complication (m. 2,2% temporary paralysis, m. 1,6% permanent paralysis). Most of the reports in literature suggest that the rate of transient and permanent vocal fold immobility (VFI) after thyroid surgery is 4% to 7% and 1% to 4% [4], but the Recurrent Palsy can vary from 2 to 13% [5] increased by malignancy [6,7], secondary operations, anatomic variability, anomaly and distortion [8,9] and the injury for external branch of the superior laryngeal nerve (EBSLN) vary from 9 to 14% [10].Injury to cranial nerve represents in U.S.A., 5% of negligence litigation against general surgeons and of all malpractice jury verdicts in endocrine surgery 60% accounts for recurrent nerve injuries and 15% for anoxic brain injuries from RLN injuries, unrecognized post-operatively. During Total Thyroidectomy is reported an incidence of failure to find the nerve in 5-18% of cases [11]; routine identification of the RLN during thyroid surgery has reduced the injury rate from 10% to less than 4% [12,13] and Mountain et al. showed that the incidence of nerve paralysis was 3 to 4 times greater in cases where the nerve was not exposed than in cases where was routinely exposed, thus makes us to understand the importance of a clear identification during every thyroid dissection [14]. At the beginning of 70's years, Flisberg and Lindholm were the first to study the electrophysiology of Inferior Laryngeal Nerve during major neck surgery. In 1979 Rea et al found out a new electrode (tack), using TECA-EMG for laryngectomy and Davies et al for thyroidectomy. Time was ready for Nerve Integrity Monitor (NIM): Rice and Cone-Wesson followed by Beck and Mayes in 1992 started to investigate clinical applications. Thyroid surgery has to wait until 1996 when David W and Eisele M.D. introduced a laryngeal surface electrode to enable another form of non-invasive monitoring of the RLN; electrode-imbedded endotracheal tubes allowed continuous intraoperative assessment of vocal cord function when connected to an electromyographic (EMG) response monitor [15]. Hemmerling T.M. in 2001 proposed a adhesive stitch electrode to apply over the orotracheal tube. A new age in thyroid surgery was beginning [16].

Objective

In the present study the Authors assess the advantages of new technologies in thyroid surgery: The first objective is to prevent nerve injury by using an intra-operative continuous nerve-electrophysiological monitoring techniques; the second objective is to compare the real advantages of advanced coagulation devices in thyroid surgery, comparing surgical techniques, results and costs, but also the efficacy in preventing some complications like RLN.

Patients and Methods

Among a series of 440 Total Thyroidectomies all performed by the same equipe (V Division of General Surgery of the Second University of Naples, during the last 2 years, since Jan 2004 until Dec 2006, (305 F, 135 M; mean age 46.7 years old, range 16-89). All patients were examined pre and postoperatively (1-6 months after) by direct laryngoscopy or laryngofiberoscopy to check vocal cord mobility (medium follow up 20,5 months range 1-48 months). The Authors reviewed charts from two groups, selected by a double blind, statistically designed study and again compared in a multivariate analysis (Stat 2004 ltd):

– 240 total thyroidectomies, performed during the previous year using the traditional monopolar electrocautery,non-absorbable stitches for the upper and lower vascular pedicles and absorbable sutures for all other vascular knots.

Fig. 1: Bipolar Vessel Sealing System – Ligasure Precise®.

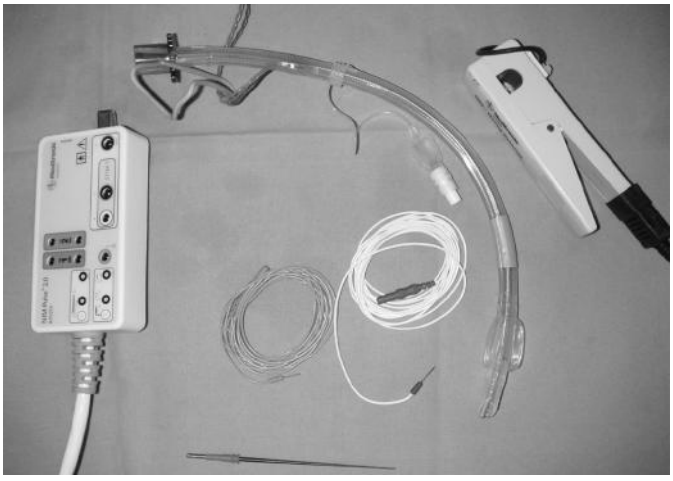

Fig. 2: Nerve Integrity Monitor – Pulse II®.

– 140 total thyroidectomies: performed by the conventional surgical technique, but absolutely suture-less by using a dedicated small bipolar electro thermal coagulator (Bipolar Vessel Sealing System, Ligasure–Precise®).
The Authors analyzed the incidence of major and minor complications, in order to evaluate the advantages of ligasure coagulation.
Sixty cases were not taken into account, because mixed techniques of haemostasis were used.
– Since 2006, in a statistical over-imposable group of 120 pts, (82 F, 38 M, a.a. 48 years old, range 20-82), in the same Institute, the same equipe, performed Sutureless Total Thyroidectomies with continuous intraoperative nerve monitoring using dedicated endotracheal tube with a last generation Nerve Integrity Monitor Pulse II (N.I.M. pulse II®) and avoiding the use of neuromuscular blocking agents during anaesthesiology procedure (only induction). We had necessity of 2 months to learn the new methodology and 50 cases were not taken into account, because of procedure, interpretation of signal and other technical problem and of course for the learning curve
For evoked electromyography (EMG), an initial "searching" current was delivered at 0.70 mA and then decreased to a value of 0.35 mA, which reliably elicited RLN stimulation with a minimal incidence of false-positive results like Pearlman RC and Shah A. suggest [17] Following this searching parameters, the nerve could be stimulated from a mean distance of 1.5 cm (range 0.9-2.5 cm) The average minimum amperage required for stimulation on first identification of all nerves was 0.50 mA (±0.55 mA). After completion of the procedure a mean threshold level of 0.35 mA (±0.45 mA) was obtained during direct RLN stimulation. Post-dissection stimulation threshold of the RLN was 0.78 mA (±0.70 mA). The following parameters were analyzed: mean operative time, post-operative bleeding, seromas, post-operative stay, incidence of transient or definitive laryngeal nerve lesions, uni- or bilateral, incidence of permanent or transient hypocalcaemia, costs of the different procedures and of course evoked response profiles of RLN electrical spreading by different coagulation procedures.

Results

There were no statistically significative difference between the groups for distribution of age, sex, epidemiological characteristics, type of pathology etc. The incidence of major complications in thyroid surgery in the first two groups (total Thyroidectomy performed by Traditional Technique and by Advanced Devices - Precise), as well as compared with the data of the literature are absolutely over-imposable; only significative difference is a reduction of incidence of transient hypocalcaemia in the Precise group, but if we compare data of the 3rd group (NIM), we find a significative reduction (too poor casistic to be validate by statistic analysis) of transient and permanent laryngeal nerve palsy incidence. The reliability of the NIM signal (correlation between postoperative vocal cord function and intraoperative signal interpretation) was reflected by a specificity of 88.5% (62/70 pts with intraoperatively unchanged neuromonitoring signals and p.o. normal vocal cord function) not as high as shown by German multicenter studies (98.2%) [18] and when the neuromonitoring signal was changing during operation 8 cases, 12,5% of the patients, suffered from transient vocal cord immobility and nobody had permanent loss of vocal cord function. There was one case of temporary RLN paralysis probably secondary to thermal spread that resolved 9 weeks postoperatively (temporary paralysis rate: 1.4% of patients).
With regard to the duration of the operations, the middle operating time of the exeresis with Bipolar Vessel

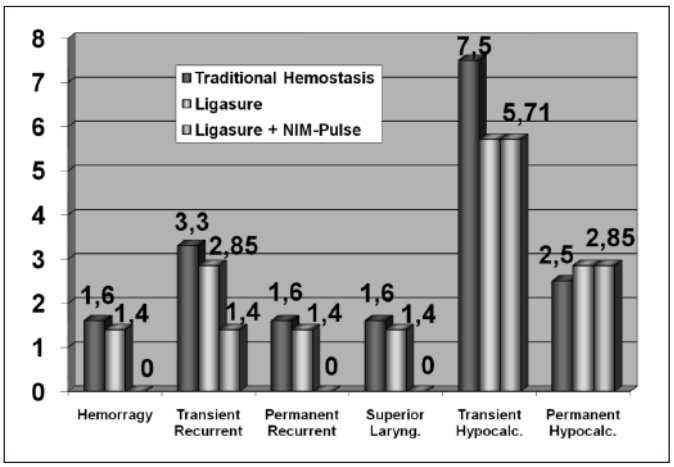

Fig. 3: Mayor complications in Thyroid Surgery (Total Thyroidectomy) [19].

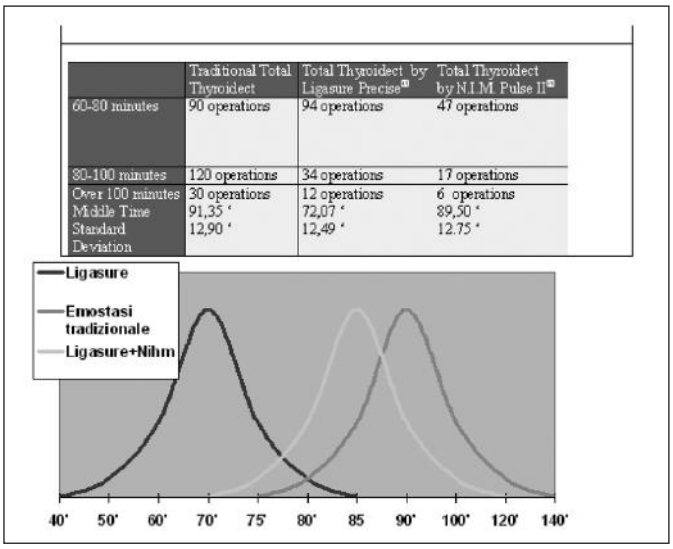

Fig. 4: Operating middle times.

Sealing System, Precise® in comparison to the conventional exeresis has been, certainly, reduced, in average, of 20 minutes around, time that the 3rd group (NIM II®) spend almost completely to search, to test and to monitor the nerve.

Discussion and Conclusion

Fortyfive years ago H. Bauer described the first case of recurrent laryngeal nerve palsy caused by intubation [20]. Systematic analyses regarding the incidence of RLN palsies due to intubation are scarce. Even if the damage caused by intubation may only account for a minority of cases, currently data justify the assumption that not every RLN palsy following thyroidectomy is due to surgeons malpractice. It's not easy to make a differential diagnosis of p.o. RLN injury. In cases of irregular preoperative (post anaesthesiologist procedures) in pts with normal pre-operative motility of the vocal cord, NIM could have a very important role, documenting anaesthesiologist negligence in case of litigation. Since the laryngeal palpation test is not a particularly useful method for predicting the level of RLN function after thyroidectomy [21].

After 20 years of Nerve Sparing Surgery, the utility and the role of Nerve Monitoring during Thyroidectomy is still debated: surely the pig-surgery prove that recurrent laryngeal nerve monitoring may be successfully during neck surgery [22], surely we can assert that indirect stimulation of the RLN is superior to direct stimulation and that an intact acoustic EMG signal is highly predictive of intact postoperative RLN function [23], and of course it's a feasible and reliable technique, that can be used to avoid nerve injury and to increase the surgeon's confidence but not to replace a systematic nerve identification and a careful dissection [24]. Literature data seems to suggest a very low incidence of nerve injury: Randolph GW et al. report a temporary paralysis rate of 0.2% of patients with nerves at risk [25], Otto RA and Cochran CS report a RLN injury rate of 4.94%. with high sensitivity and specificity, rispectively 75% and 92.2% and with a positive predictive value of 33.3% and negative predictive value of 98.6%.[26]. Recently some authors have reported doubts about utility of a so expensive and time consuming device: Hermann M et al. says that neuromonitoring does not reliably predict postoperative outcome [27] and seems that there are no statistically significant differences in RLN paralysis, paresis, or total injury rates between control and NIM groups [28] and at least NIM cannot necessarily prevent RLN transaction [29]. Those are probably the reason to develop more simple and cheap devices [30] that actually, we don't think will help to standardize a methodology. The high variability of the procedures, different kinds of EMG, different types of electrodes and of course different skill and experience of the surgeons make impossible to compare literature data until a multicenter research will not be planed. Our preliminary data seem to suggest the necessity of a minimum of 50 cases for planning correctly the methodology and for the learning curve. Although the poor casuistic doesn't agree statistical analysis, our data confirm a useful application of NIM in thyroid dissection nerve prevention. We don't believe that NIM can be useful for learning thyroid gland surgery [31], because NIM can't preserve from an accurate dissection and nerve identification technique, but can only support in nerve-at-risk thyroidectomy or during dissection can support expert surgeon's decision, having a clear pre-operative (post-anesthesiologist) and post-operative predictive value. This new technology offers several advantages: (1) atraumatic; (2) easy to use; (3) continuous monitoring and audio feedback to the surgeon (4) works outside the operation field (5) high sensitiveness

It's anyway an expensive and a time consuming procedure, but…analysis of costs, must be performed, therefore, in relationship to the operating duration: in our experience if the cost of the haemostasis with traditional technique can oscillate between 50 and 75 €, the general expense amounts, in this group, to a cost inclusive among 5000 and 7500 €, clearly inferior to the cost of the haemostasis in the "Innovative Devices Group" in which, besides the start-up cost of the source (20000-25000 €), we've to consider the cost of the hand piece (200-250 €), for a general cost of the haemostasis inclusive among 45000 and 57250. If we consider that the D.R.G. for a Total Thyroidectomy can vary among 2000 and 3500 € (variability of regional D.R.G.), executing every year, in the 2nd group, at least 25 interventions in more, we can esteem a profit inclusive among 50000 and 87500 €: in conclusion that signifies a net gain oscillating among 10000 and 37750 €, working off, therefore, the cost of the source entirely. The economical advantages performed by the time reduction with advanced haemostatic device are completely lost by the lack of time required by neuromonitoring setting and testing procedures and of course by the cost of this technology (30000 € for the E.M.G. system and almost 250 € for each dedicated endotracheal tube). So NIM+Ligasure have the same cost (something less), almost the same time (something less) and very probably less complications then traditional Total Thyroidectomy. Anyway we trust that this lack of money and time will surely paid back by an increased customer satisfaction and much less number of injury verdicts against surgeons.

Riassunto

In questo studio gli autori valutano i vantaggi di una nuova tecnologia nella chirurgia della tiroide al fine di prevenire i danni al RLN usando una tecnica di monitoraggio continuo intra-operatorio del nervo (NIM) e

comparando i reali vantaggi di nuovi device per la coagulazione. Sono state analizzate 440 tiroidectomie (Gennaio 2004 – Febbraio 2006) divise in due gruppi:
– 240 Tiroidectomie totali eseguite usando il tradizionale coagulatore monopolare e legature non assorbibili per i peduncoli vascolari principali;
– 140 Tiroidectomie eseguite usando un piccolo coagulatore bipolare (Ligasure-Precise®);
– Dal 2006 in un gruppo di 70 pazienti abbiamo eseguito una tiroidectomia senza suture con monitoraggio intra-operatorio continuo del nervo mediante un tubo endotracheale dedicato.
I parametri analizzati sono: tempo operatorio medio, sanguinamento post-operatorio,sieromi, degenza post-operatoria,incidenza di lesioni permanenti o temporanee dei nervi laringei,uni o bilateralmente,incidenza di ipocalcemia temporanea o permanente, costi delle differenti procedure. Le maggiori complicazioni nei primi due gruppi sono assolutamente sovrapponibili ai dati della letteratura, eccetto una riduzione della incidenza di ipocalcemia temporanea nel gruppo del Precise,ma se analizziamo i dati del 3° gruppo, noi troviamo una significativa riduzione della incidenza delle paralisi definitive e temporanee dei nervi laringei.
Questa nuova tecnologia offre diversi vantaggi: 1) traumatica; 2) facile utilizzo; 3) monitoraggio continuo e feedback acustico al chirurgo; 4) lavora al di fuori del campo operatorio; 5) alta sensibilità. L'analisi dei costi confermano che NIM + Ligasure ha gli stessi o anche minori costi e tempi e probabilmente meno complicazioni che la tiroidectomia totale tradizionale

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