

NIM vs Neurosign in nerve sparing total thyroidectomy

Multicentric experience



Ann. Ital. Chir., 2012 83: 233-238
Published online 21 Dicembre 2011
(www.annitalchir.com)

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INTRODUCTION: Injury to cranial nerve represents 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 and if we think that routine identification of the RLN during thyroid surgery has reduced the injury rate from 10% to less than 4% and 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, then we understand the importance of a clear identification during every thyroid dissection

MATERIALS AND METHODS: 880 Total Thyroidectomies during the last 4 years, since January 2007 until December 2010, (610 F, 270 M; mean age 44,5 years old, range 14-83). All patients were examined pre and postoperatively (1-6 months after) by direct laryngoscopy or laryngofibroscope to check vocal cord mobility (medium follow up 25.5 months range 3-50 months). The Authors reviewed charts from two randomized groups, selected by a double blind, statistically designed study and again compared in a multivariate analysis (Stat 2004 ltd):

- 1) 480 total sutureless thyroidectomies, performed during the previous year with continuous intra-operative nerve monitoring using dedicated endotracheal tube with a last generation Nerve Integrity Monitor Pulse II (N.I.M. pulse II®)
- 2) 400 total sutureless thyroidectomies: performed with continuous intra-operative nerve monitoring using dedicated Laryngeal Electrode, a self-adhesive device designed to fit onto standard reinforced endotracheal tubes (Neurosign® 1040 – 4 Channel EMG)

RESULTS: There were no statistically significant difference between the two 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 NIM and by Neurosign), as well as compared with the data of the literature are absolutely over-imposable; only significant difference is a reduction of the costs in the second group (Neurosign).

The 1st group (NIM) specificity is 90.2% (433/480). There were 6 cases of temporary RLN paralysis (temporary paralysis rate: 1.25 % of patients), 3 true positive and 3 false negative. Finally there were 3 cases of permanent RLN paralysis (0.75%), 2 true-positive and 1 false-negative developed after 10 days (demyelination by thermal injury). The 2nd group (Neurosign) specificity of 89 % (356/400). There were 6 cases of temporary RLN paralysis (rate: 1.5 %, $p > 0.5$), 2 true positive, 1 false positive and 4 false negative. Finally 2 cases of permanent RLN paralysis (0.5% $p > 0.5$), 2 true-positive.

DISCUSSION AND CONCLUSION: Our data confirm a useful application of NIM and Neurosign in thyroid dissection nerve prevention. We don't believe that those procedures can be useful for learning thyroid gland surgery, because 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. Those procedures are anyway expensive and time consuming (25000-30000 € for the E.M.G. system and almost 200-250 € for each dedicated endotracheal tube in NIM group). So Neurosign group has over-imposable results in terms of complications specificity and accuracy (no statistically significant differences), but it's a much cheaper procedure!

KEY WORDS: Intraoperative Nerve Monitoring, Recurrent Laryngeal Nerve Palsy, Total Thyroidectomy.

Pervenuto in Redazione Maggio 2011. Accettato per la pubblicazione Luglio 2011

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Introduction

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%¹, but the Recurrent Palsy can vary from 2 to 13%² increased by malignancy^{3,4}, secondary operations, anatomic variability, anomaly and distortion^{5,6} and the injury for external branch of the superior laryngeal nerve (EBSLN) vary from 9 to 14%⁷. 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 cases⁸; routine identification of the RLN during thyroid surgery has reduced the injury rate from 10% to less than 4%^{9,10} 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 dissection¹¹. 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 Neuromonitoring: 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 endotra-



Fig. 1: Nerve Integrity Monitor – Pulse II®.

cheal tubes allowed continuous intraoperative assessment of vocal cord function when connected to an electromyographic (EMG) response monitor¹². Hemmerling T.M. in 2001 proposed a adhesive stitch electrode to apply over the oro-tracheal tube. A new age in thyroid surgery was beginning¹³.

Objective

In the present study the Authors assess the advantages of a new technologies in thyroid surgery. The first objective is to prevent nerve injury by using an intra-operative continuous nerve-electrophysiological monitoring techniques.

Patients and Methods

Among a series of 880 Total Thyroidectomies all performed by the same equip (V and VI Division of General Surgery of the Second University of Naples), during the last 4 years, since jan 2007 until dec 2010, (610 F, 270 M; mean age 44,5 years old, range 14-83), all patients were examined pre and postoperatively (1-6 months after) by direct laryngoscopy or laryngofibrosocopy to check vocal cord mobility (medium follow up 25,5 months range 3-50 months). The Authors reviewed charts from two randomized groups, selected by a double blind, statistically designed study and again compared in a multivariate analysis (Stat 2004 ltd):

- 1) 480 total sutureless thyroidectomies, performed during the previous year with continuous intra-operative nerve monitoring using dedicated endotracheal tube with a last generation Nerve Integrity Monitor Pulse II (N.I.M. pulse II®)
- 2) 400 total sutureless thyroidectomies: performed with continuous intra-operative nerve monitoring using dedicated Laryngeal Electrode, a self-adhesive device designed to fit onto standard reinforced endotracheal tubes.

In both groups we avoided the use of neuromuscular blocking agents during anaesthesiology procedure (only induction). We had necessity of 3 months to learn the new methodology and 60 cases were not taken into account, because of procedure, interpretation of signal and other technical problem and of course for the learning curve. We have excluded the first 70 cases of the first group performed in a preliminary phase in 2006. 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. suggest¹⁴ 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).

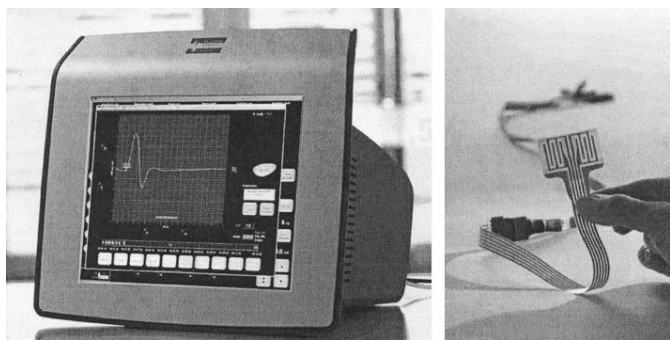


Fig. 2: Neurosign® 1040 - 4 Channel EMG.

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.

The Authors analyzed the incidence of major and minor complications, in order to evaluate the advantages of the two procedures.

Results

There were no statistically significant difference between the two 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 NIM and by Neurosign), as well as compared with the data of the literature are absolutely over-imposable; the only significant difference is a reduction of the costs in the second group (Neurosign). The reliability of the NIM signal (correlation between postoperative vocal cord function and intraoperative signal interpretation) was reflected by a specificity of 90.2% (433/480 pts with intraoperatively unchanged neuromonitoring signals and p.o. normal vocal cord function), not as high as shown by German multicenter studies (98.2%)¹⁵ and when the neuromonitoring signal was changing during operation 57 cases, 11.8% of patients, suffered from transient vocal deficit and nobody had permanent loss of vocal cord function. There were 6 cases of temporary RLN paralysis, probably secondary to thermal spread that resolved 4-9 weeks postoperatively (temporary paralysis rate: 1.25 % of patients), 3 true positive and 3 false negative. Finally there were 3 cases of permanent RLN paralysis (0.75%), 2 true-positive and 1 false-neg-

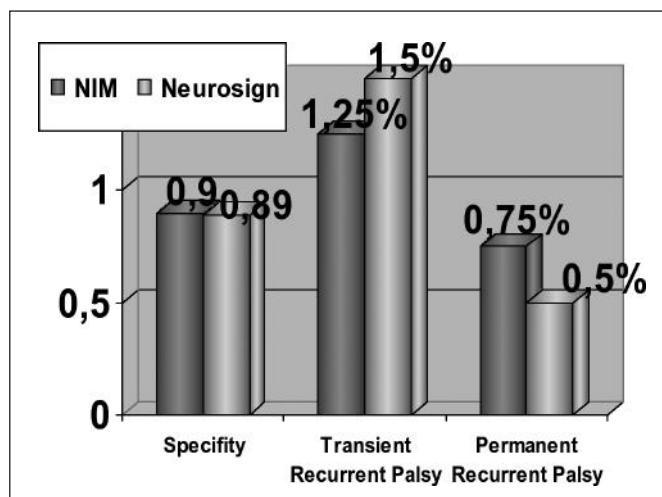


Fig. 3: Statistically no Significant differences¹⁶.

ative developed after 10 days (demyelination by thermal injury).

The Neurosign signal (correlation between postoperative vocal cord function and intraoperative signal interpretation) reflected a specificity of 89 % (356/400 pts with intraoperatively unchanged neuromonitoring signals and p.o. normal vocal cord function), lower than 1st group, but not statistically significant ($p > 0.5$) and with neuromonitoring signal changing during operation in 44 cases, 11.0 % of the patients suffered from transient vocal deficit and nobody had permanent loss of vocal cord function. There were 6 cases of temporary RLN paralysis probably secondary to thermal spread that resolved 4-9 weeks postoperatively (temporary paralysis rate: 1.5% of patients, $p > 0.5$), 2 true positive, 1 false positive and 4 false negative. Finally 2 cases of permanent RLN paralysis (0.5%, $p > 0.5$), 2 true-positive.

Discussion and Conclusion

Fortyfive years ago H. Bauer described the first case of recurrent laryngeal nerve palsy caused by intubation¹⁷. 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 pre-operative (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 thyroidectomy¹⁸.

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 surgery¹⁹, 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 function²⁰, 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 dissection²¹. 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 risk²², Otto RA and Cochran CS report a RLN injury rate of 4.94%. with high sensitivity and specificity, respectively 75% and 92.2% and with a positive predictive value of 33.3% and negative predictive value of 98.6%²³. 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 outcome²⁴ and seems that there are no statistically significant differences in RLN paralysis, paresis, or total injury rates between control and NIM groups²⁵ and at least NIM cannot necessarily prevent RLN transaction²⁶. Those are probably the reason to develop more simple and cheap devices²⁷ 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 planned. Our preliminary data seem to suggest the necessity of a minimum of 50 cases for planning correctly the methodology and for the learning curve. Our data confirm a useful application of NIM and Neurosign in thyroid dissection nerve prevention. We don't believe that those procedures can be useful for learning thyroid gland surgery²⁸, because 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. Those procedures are anyway expensive and time consuming, but analysis of costs, must be performed, therefore, in relationship to the operating duration. 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 (25000-30000 € for the E.M.G. system and almost 200-250 € for each dedicated endotracheal tube

in NIM group). So Neurosign group has over-impossible results in terms of complications specificity and accuracy (no statistically significant differences), but it's a much cheaper procedure! 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.

In conclusion we can agree that new technologies like nerve monitoring, as much as Mivat²⁹, can surely improve the traditional methodology of thyroidectomy, but they cannot avoid from the perfect knowledge of the anatomy, the correct surgical exposure and a careful research of all anatomical landmarks^{30,31}.

Riassunto

PREMESSA: Le lesioni dei nervi cranici rappresentano il 5% delle controversie legali per negligenza contro chirurghi generali, e di tutte le condanne per malasanità nell'ambito dell'endocrinocirurgia il 60% riguardano danni al nervo ricorrente, il 15% danni da anossia cerebrale per lesioni ad entrambi i nervi laringei. Nel corso delle tiroideomie si riferisce dal 5 al 18% di mancata localizzazione dei laringei e se si considera che la loro identificazione ha ridotto l'incidenza delle lesioni dal 10% a meno del 4%, e che l'incidenza della paralisi laringea era da 3 a 4 volte maggiore in caso di mancata esposizione del nervo, si comprende l'importanza di una loro chiara identificazione nel corso di ogni dissezione tiroidea.

ESPERIENZA PERSONALE: Su 880 casi di tiroideomie effettuate nell'arco di 4 anni (dal 2007 al 2012), con nessuna differenza statistica tra i due gruppi, analoghi per età, sesso, caratteristiche epidemiologiche e tipo di patologia, studiati pre e postoperatoriamente con laringoscopia diretta o fibrolaringoscopia per la mobilità cordale, gli Autori hanno ricontrollato le cartelle di due gruppi suddivisi a random in doppio cieco per compiere uno studio statistico comparativo con analisi multivariata.

– 480 casi trattati con tiroideomia *sutureless* monitoraggio continuo intraoperatorio mediante l'uso di uno specifico tubo endotracheale dotato di un Nerve Integrity Monitor Pulse II (N.I.M. pulse II®) di ultima generazione;

– 400 casi trattati con tiroideomia *sutureless* monitoraggio continuo intraoperatorio mediante l'uso di Elettrodo Laringeo, apparecchio autoadesivo adattato ad un tubo tracheale rigido (Neurosign® 1040 – 4 Channel EMG).

RISULTATI: L'incidenza di complicanze maggiori è risultata perfettamente sovrapponibile nei due gruppi e con i dati della letteratura, con soltanto una riduzione dei costi nel gruppo monitorizzato con Neurosign.

Nel primo gruppo 6 casi di paralisi laringee temporanee, suddivise al 50% tra vere positive e false negative, e 3 paralisi cordale permanente (2 vere positive e 1 falsa negativa) dovute ad un danno termico.

Nel secondo gruppo 6 casi di paralisi laringee temporanee (2 vere positive, 1 falsa positiva e 4 galse negative), e 2 casi veri di paralisi laringea permanente.

DISCUSSIONE E CONCLUSIONI: Si conferma l'utilità dell'uso del NIM e del Neurodign nella prevenzione di danni ai laringei nella chirurgia tiroidea, non tanto per apprendere la chirurgia della tiroide quanto piuttosto nelle tiroidectomie a rischio di danni.

Si tratta peraltro di procedure costose sia per l'economia che per il tempo, con netto vantaggio per il dispositivo Neurosign.

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