



Roma, 8-11 novembre 2018



ITALIAN CHAPTER



Aula Leptis 2

Simposio 1

Danni ricorrenti nella chirurgia della tiroide

## Cosa può fare il chirurgo

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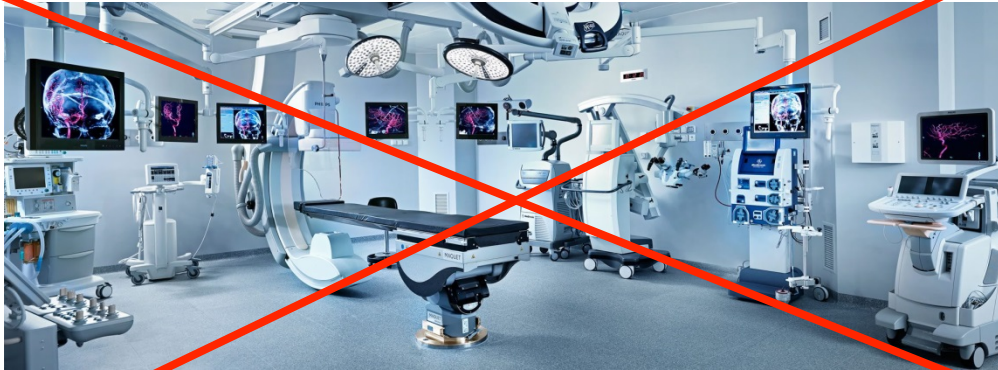
**Presidente eletto SIUEC**





## Cosa può fare il chirurgo

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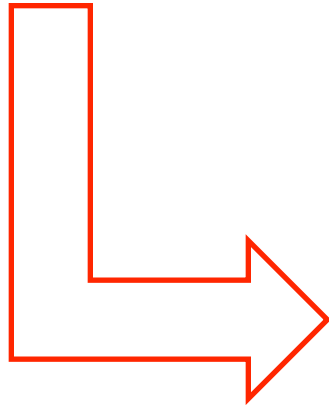


# NON OPERARE !



## Cosa può fare il chirurgo

# Imparare ad operare



**BENE**



# Danno ricorrenziale 0.2% - 20%



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Thomusch O, 2000; Dralle H, 2004; Rosato L, 2004

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**Rappresenta un indicatore di qualità che risente di diverse variabili:**

- **tipo di chirurgia** (*primo intervento o reintervento*)

0.6% vs 3.6%



6 VOLTE

- **estensione della resezione** (*subtotale / totale*)

0.7% vs 1.3%



RADDOPPIA

- **esperienza del chirurgo**

0.6% vs 1.4%



PIU' DI 2 VOLTE

Thomusch O, 2000; Dralle H, 2004

## Complicanza temibile

- Peggioramento della **qualità di vita**
- Impatto negativo sulla **performance lavorativa**



Responsabile, da sola, di circa il **79%** del contenzioso medico-legale in chirurgia endocrina

Kern KA, 1993







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# LESIONI RICORRENZIALI



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## Duplice problema

- *L'integrità anatomica del nervo non ne implica l'integrità funzionale*
- *Incertezza dell'outcome post-operatorio*



## INTRAOPERATIVE NERVE MONITORING



Per la valutazione funzionale del **nervo ricorrente e della sue branche**  
**prima, durante e dopo** la tiroidectomia

# Nerve Monitoring in Chirurgia Tiroidea

Randomized clinical trial: NIM vs Identificazione del nervo

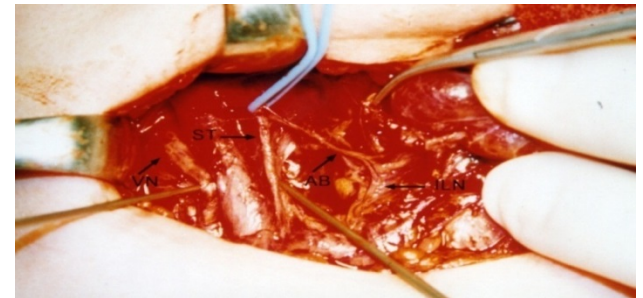
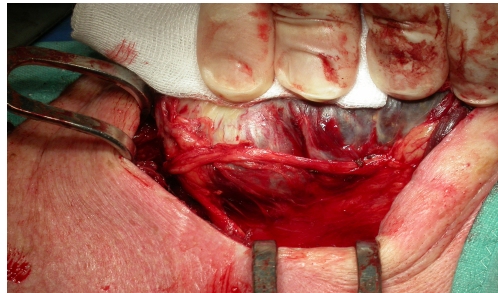
Barczynski M. et al

**1000** nerves-at-risk in each groups



|                  | RLN visualization alone |                        |          | RLN visualization + monitoring |                        |       | P value† |
|------------------|-------------------------|------------------------|----------|--------------------------------|------------------------|-------|----------|
|                  | Low risk<br>(n = 508)   | High risk<br>(n = 492) | P value* | Low risk<br>(n = 494)          | High risk<br>(n = 506) | P*    |          |
| <b>Paralysis</b> |                         |                        |          |                                |                        |       |          |
| Transient        | 14 (2.8)                | 24 (4.9)               | 0.080    | 9 (1.8)                        | 10 (2.0)†              | 0.858 | 0.011    |
| Permanent        | 3 (0.6)                 | 9 (1.8)                | 0.072    | 3 (0.6)                        | 5 (1.0)                | 0.499 | 0.368    |
| Overall          | 17 (3.3)                | 33 (6.7)               | 0.014    | 12 (2.4)                       | 15 (3.0)§              | 0.601 | 0.007    |
| Total            | 50 (5.0)                |                        |          | 27 (2.7)                       |                        |       | 0.007    |

L'uso del NIM riduce le lesioni ricorrenti temporanee



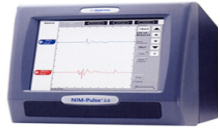


# Nerve Monitoring in Chirurgia Tiroidea



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Il NIM è uno strumento che può essere **utile**, per il **controllo dell'integrità funzionale del nervo**: ?



## **Valore Predittivo Negativo**

**Elevato 92-100%**

*la presenza del segnale all'EMG esclude la presenza di lesioni ricorrentziali*

## **Valore Predittivo Positivo**

**Variabile 10-90%**

*l'assenza del segnale all'EMG non necessariamente implica lesioni ricorrentziali (**non univoca interpretazione dei dati**)*

... può diventare uno **strumento pericoloso** in mani INESPERTE !!!

*L'identificazione convenzionale del RLN  
rimane il "gold standard" di trattamento ...*



# Nerve Monitoring in Chirurgia Tiroidea

## Indicazioni all'uso del NIM



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### Nervi ad alto rischio

- Carcinoma + eventuale linfadenectomia
- Patologia recidiva
- Gozzo immerso

### Nervi a basso rischio

- Uso professionale della voce



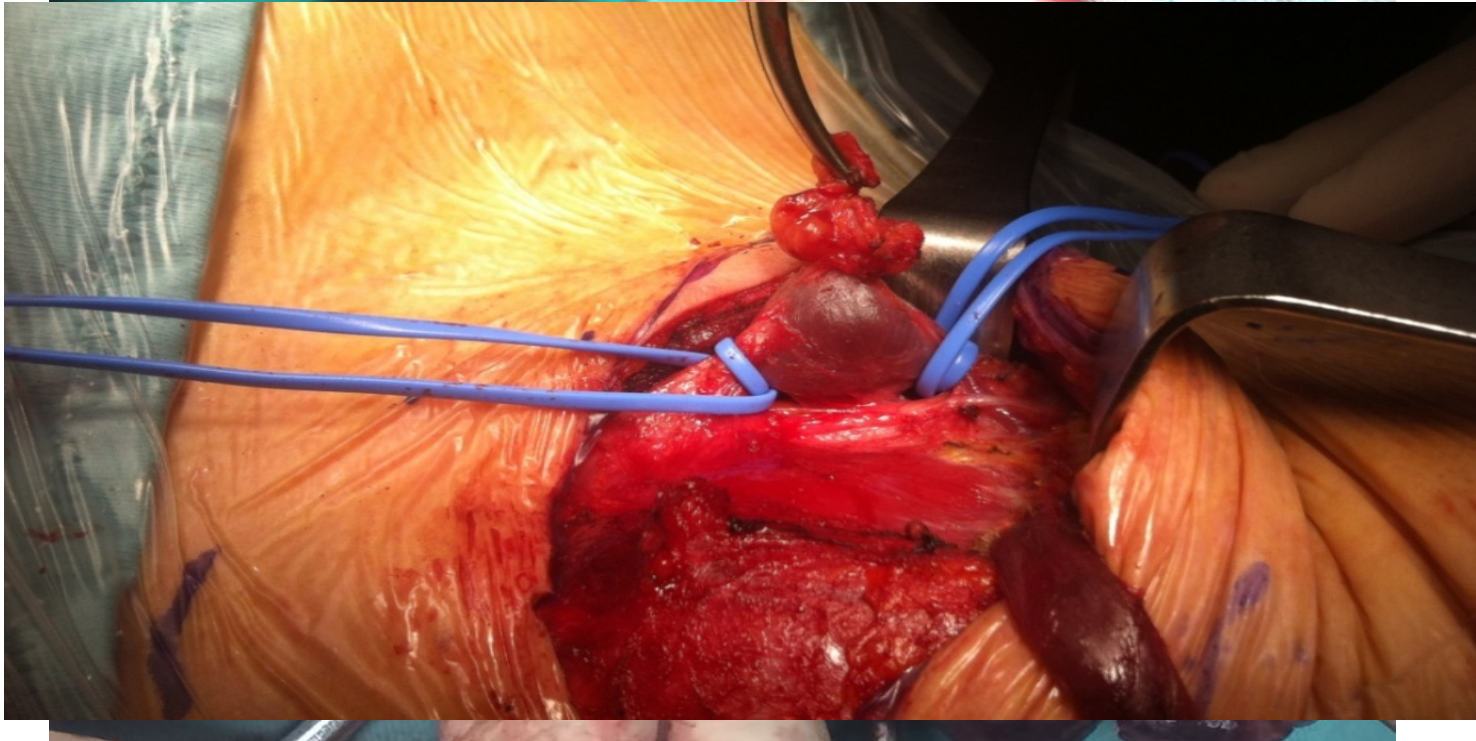


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# Nerve Monitoring in Chirurgia Tiroidea *... utile in casi particolari ...*



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# Nerve Monitoring in Chirurgia Tiroidea



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Hermann et al

328 pazienti



**Sensibilità nerve monitoring:** 86% per patologia benigna  
25% per reinterventi per patologia maligna

11 pazienti (0.3%): paralisi post-operatoria con normale risposta NIM

14/21 pazienti con paralisi pre-operatoria: risposta NIM normale (**falso negativo**)

*“Il fattore più importante che influenza i risultati finali è l’esperienza del chirurgo”*



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# Nerve Monitoring in Chirurgia Tiroidea



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Surg Endosc (2012) 26:2601–2608  
DOI 10.1007/s00464-012-2239-y



## Recurrent laryngeal nerve injury in video-assisted thyroidectomy: lessons learned from neuromonitoring

G. Dionigi · P. F. Alesina · M. Barczynski ·  
L. Boni · F. Y. Chiang · H. Y. Kim · G. Materazzi ·  
G. W. Randolph · D. J. Terris · C. W. Wu

*Conclusions* RLN palsy still occurs with routine endoscopic identification of the nerve, even combined with LNM. LNM has the advantage of elucidating the mechanism of RLN injury. Traction and thermal RLN injuries are the most frequent lesions in VAT.





# Nerve Monitoring in Chirurgia Tiroidea



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## Systematic review with meta-analysis of studies comparing intraoperative neuromonitoring of recurrent laryngeal nerves *versus* visualization alone during thyroidectomy

Adolfo Pisanu, MD, PhD,\* Giulia Porceddu, MD, Mauro Podda, MD, Alessandro Cois, MD, and Alessandro Uccheddu, MD



**Conclusions:** The current review with meta-analysis showed no statistically significant difference in the incidence of RLN palsy when using IONM *versus* VA during thyroidectomy. However, these results must be approached with caution, as they were mainly based on data coming from non-randomized observational studies. Further studies including high-quality multicenter, prospective, randomized trials based on strict criteria of standardization and subsequent clustered meta-analysis are required to verify the outcomes of interest.





## Clinical Review

2016

“The final countdown”: Is intraoperative, intermittent neuromonitoring really useful in preventing permanent nerve palsy? Evidence from a meta-analysis

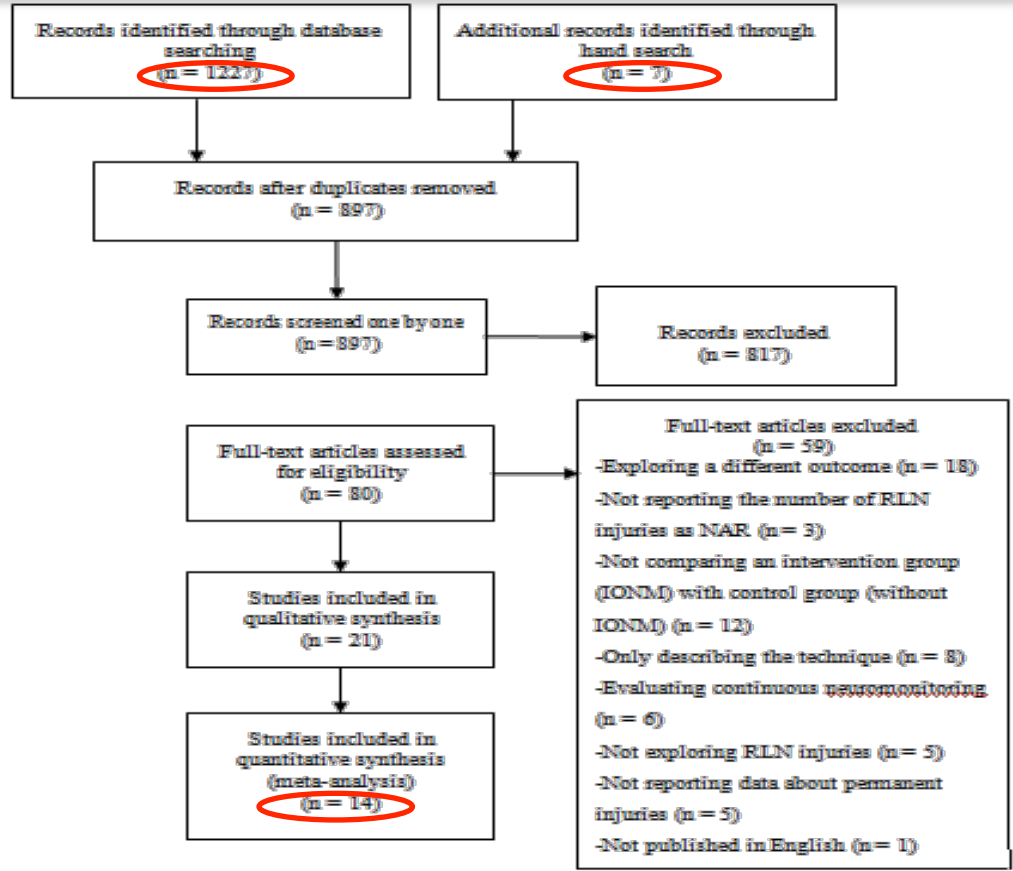


Celestino Pio Lombardi, PhD,<sup>a</sup> Giulia Carnassale, MD,<sup>a</sup> Gianfranco Damiani, MD,<sup>b</sup> Anna Acampora, MD,<sup>b</sup> Marco Raffaelli, PhD,<sup>a</sup> Carmela De Crea, MD,<sup>a</sup> and Rocco Bellantone, PhD,<sup>a</sup>  
*Rome, Italy*

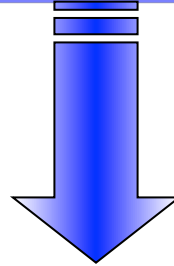




Identification  
Screening  
Eligibility  
Included



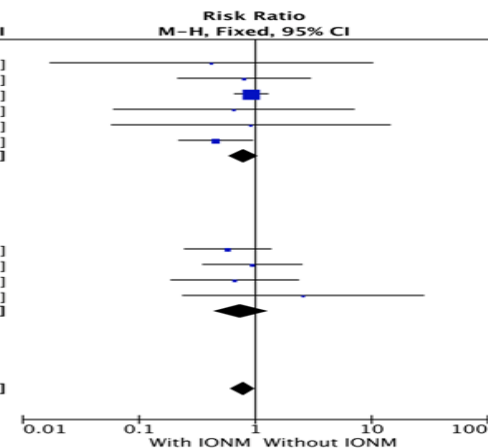
1234 selected articles



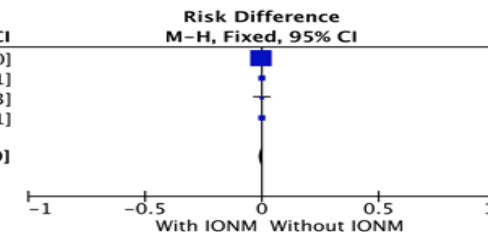
14 included



| Study or Subgroup  | With Neuromonitoring |              | Without Neuromonitoring |              | Weight        | Risk Ratio         |                     |
|--|----------------------|--------------|-------------------------|--------------|---------------|--------------------|---------------------|
|  | Events               | Total        | Events                  | Total        |               | M-H, Fixed, 95% CI | M-H, Fixed, 95% CI  |
| <b>Permanent RLN injuries after 6 month</b>  |                      |              |                         |              |               |                    |                     |
| Alesina 2012   | 0                    | 128          | 1                       | 161          | 1.0%          | 0.42               | [0.02, 10.19]       |
| De Falco 2014  | 4                    | 600          | 5                       | 600          | 3.6%          | 0.80               | [0.22, 2.96]        |
| Dralle 2004  | 143                  | 17832        | 48                      | 5517         | 53.0%         | 0.92               | [0.67, 1.28]        |
| Stevens 2012   | 1                    | 62           | 2                       | 81           | 1.3%          | 0.65               | [0.06, 7.04]        |
| Terris 2007  | 1                    | 92           | 1                       | 84           | 0.8%          | 0.91               | [0.06, 14.37]       |
| Thomusch 2001  | 9                    | 2483         | 37                      | 4650         | 18.6%         | 0.46               | [0.22, 0.94]        |
| <b>Subtotal (95% CI)</b>   |                      | <b>21197</b> |                         | <b>11093</b> | <b>78.2%</b>  | <b>0.79</b>        | <b>[0.60, 1.05]</b> |
| Total events   | 158                  |              | 94                      |              |               |                    |                     |
| Heterogeneity: $\text{Chi}^2 = 3.24$ , $\text{df} = 5$ ( $P = 0.66$ ); $I^2 = 0\%$                 |                      |              |                         |              |               |                    |                     |
| Test for overall effect: $Z = 1.59$ ( $P = 0.11$ )   |                      |              |                         |              |               |                    |                     |
| <b>Permanent RLN injuries after 12 months</b>  |                      |              |                         |              |               |                    |                     |
| Barczynski 2014  | 7                    | 500          | 20                      | 826          | 10.9%         | 0.58               | [0.25, 1.36]        |
| Calò a 2014  | 8                    | 2068         | 8                       | 1946         | 6.0%          | 0.94               | [0.35, 2.50]        |
| Chan 2006  | 4                    | 501          | 6                       | 499          | 4.3%          | 0.66               | [0.19, 2.34]        |
| Witt 2004  | 2                    | 83           | 1                       | 107          | 0.6%          | 2.58               | [0.24, 27.95]       |
| <b>Subtotal (95% CI)</b>   |                      | <b>3152</b>  |                         | <b>3378</b>  | <b>21.8%</b>  | <b>0.75</b>        | <b>[0.43, 1.30]</b> |
| Total events   | 21                   |              | 35                      |              |               |                    |                     |
| Heterogeneity: $\text{Chi}^2 = 1.63$ , $\text{df} = 3$ ( $P = 0.65$ ); $I^2 = 0\%$                 |                      |              |                         |              |               |                    |                     |
| Test for overall effect: $Z = 1.02$ ( $P = 0.31$ )   |                      |              |                         |              |               |                    |                     |
| <b>Total (95% CI)</b>  |                      | <b>24349</b> |                         | <b>14471</b> | <b>100.0%</b> | <b>0.79</b>        | <b>[0.61, 1.01]</b> |
| Total events   | 179                  |              | 129                     |              |               |                    |                     |
| Heterogeneity: $\text{Chi}^2 = 4.92$ , $\text{df} = 9$ ( $P = 0.84$ ); $I^2 = 0\%$                 |                      |              |                         |              |               |                    |                     |
| Test for overall effect: $Z = 1.88$ ( $P = 0.06$ )   |                      |              |                         |              |               |                    |                     |
| Test for subgroup differences: $\text{Chi}^2 = 0.03$ , $\text{df} = 1$ ( $P = 0.86$ ), $I^2 = 0\%$ |                      |              |                         |              |               |                    |                     |



| Study  | With Neuromonitoring |             | Without Neuromonitoring |             | Weight        | Risk Difference    |                      |
|--|----------------------|-------------|-------------------------|-------------|---------------|--------------------|----------------------|
|  | Events               | Total       | Events                  | Total       |               | M-H, Fixed, 95% CI | M-H, Fixed, 95% CI   |
| Barczynski 2009  | 8                    | 1000        | 12                      | 1000        | 68.4%         | -0.00              | [-0.01, 0.00]        |
| Barczynski 2012  | 0                    | 200         | 0                       | 202         | 13.8%         | 0.00               | [-0.01, 0.01]        |
| Dionigi 2009   | 0                    | 55          | 0                       | 57          | 3.8%          | 0.00               | [-0.03, 0.03]        |
| Sari 2010  | 0                    | 210         | 0                       | 199         | 14.0%         | 0.00               | [-0.01, 0.01]        |
| <b>Total (95% CI)</b>  |                      | <b>1465</b> |                         | <b>1458</b> | <b>100.0%</b> | <b>-0.00</b>       | <b>[-0.01, 0.00]</b> |
| Total events   | 8                    |             | 12                      |             |               |                    |                      |
| Heterogeneity: $\text{Chi}^2 = 0.73$ , $\text{df} = 3$ ( $P = 0.87$ ); $I^2 = 0\%$ |                      |             |                         |             |               |                    |                      |
| Test for overall effect: $Z = 0.84$ ( $P = 0.40$ )                                 |                      |             |                         |             |               |                    |                      |



Inferior laryngeal nerve palsy is one of the most feared complications in thyroid surgery

The most important reason for malpractice litigation in thyroid surgery ~ 46%

Shabirhusain et al- Malpractice litigation after thyroid surgery: the role of recurrent laryngeal nerve injuries, 1989-2009 - Surgery 2010

Still in the 1970s, the earliest devices for neuromonitoring began to be employed

FlisbergK et al. 1970 – Acta Otolaryngol - Electrical stimulation of the human recurrent laryngeal nerve during thyroid operation

Intermittent intraoperative neuromonitoring (IONM) is a common method in use:

a technique employing endotracheal tube surface electrodes placed in contact with the mucosa of the vocal cords.

Once the ILN is identified, stimulation is delivered by applying a bipolar probe (electric current range: 0.5-1.5 mA; with a frequency of 30 Hz).

The identification of the healthy nerve is confirmed by the electromiography waveform.



# In our opinion ...



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- ✓ Intraoperative **visual identification** of the nerve together with preoperative and postoperative laryngoscopic assessment of vocal cord function **remain the gold standard** of ILN management in thyroid surgery
- ✓ Cases associated with increased **difficult dissection** (revision surgery, substernal goiters, thyroid cancer, significant lymph node resection, Graves' disease/thyroiditis) may **benefit from IONM**

Moreover ...

In literature the role of IONM during thyroid surgery is still under debate

No consensus exists concerning the prevention of ILN injury

Over the years, many authors concluded that there are no real differences in complication rates between the operations performed with or without the use of IONM



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# Conclusion



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**For these reasons IONM should not be considered the standard care**



# CIONM



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*The Laryngoscope*  
© 2014 The American Laryngological,  
Rhinological and Otological Society, Inc.

## 2014

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### Continuous Vagal IONM Prevents Recurrent Laryngeal Nerve Paralysis by Revealing Initial EMG Changes of Impending Neuropraxic Injury: A Prospective, Multicenter Study

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Eimear Phelan, MD; Rick Schneider, MD; Kerstin Lorenz, MD; Henning Dralle, MD;  
Dipti Kamani, MD; Andre Potenza, MD; Niranjan Sritharan, MD; Jenifer Shin, MD;  
Gregory W. Randolph, MD, FACS

**Conclusions:** Continuous vagal monitoring is safe and provides real-time RLN evaluation during surgical maneuvers. Combined events and LOS, both easily identifiable intraoperatively, are related to the development of VCP. A combined event represents a largely reversible electrophysiologic change when the associated surgical maneuver is aborted. If allowed to continue, it can advance to LOS (which typically is significantly less reversible) and to postoperative VCP. Continuous vagal monitoring has utility in identifying real-time adverse concordant amplitude and latency changes (combined events), which can prompt modification of the associated surgical maneuver and may prevent RLN paralysis during thyroidectomy.

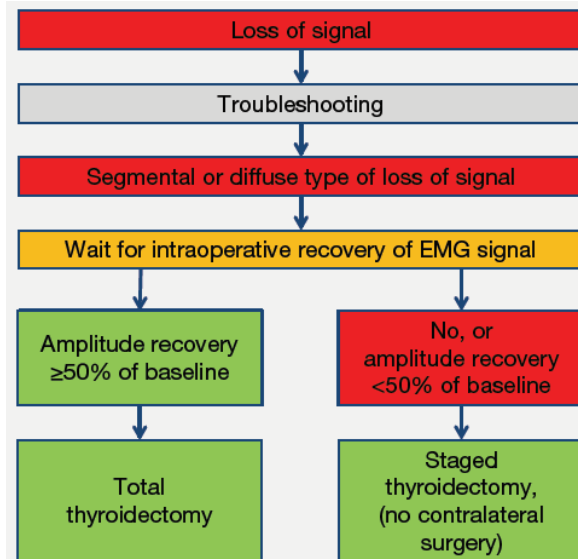


## Continuous intraoperative neural monitoring of the recurrent nerves in thyroid surgery: a quantum leap in technology

2016



Rick Schneider<sup>1</sup>, Gregory W. Randolph<sup>2</sup>, Marcin Barczynski<sup>3</sup>, Gianlorenzo Dionigi<sup>4</sup>, Che-Wei Wu<sup>5</sup>, Feng-Yu Chiang<sup>5</sup>, Andreas Machens<sup>1</sup>, Dipti Kamani<sup>2</sup>, Henning Dralle<sup>1,6</sup>



With the 5 years of experience with CIONM, permanent VCP rate is lower with CIONM and accuracy in predicting intact or non-intact early postoperative vocal cord function is superior to IIONM. Also, procedure-related false positive (unnecessary staged thyroidectomy) and false negative (risk of bilateral VCP) results can be reduced by CIONM.





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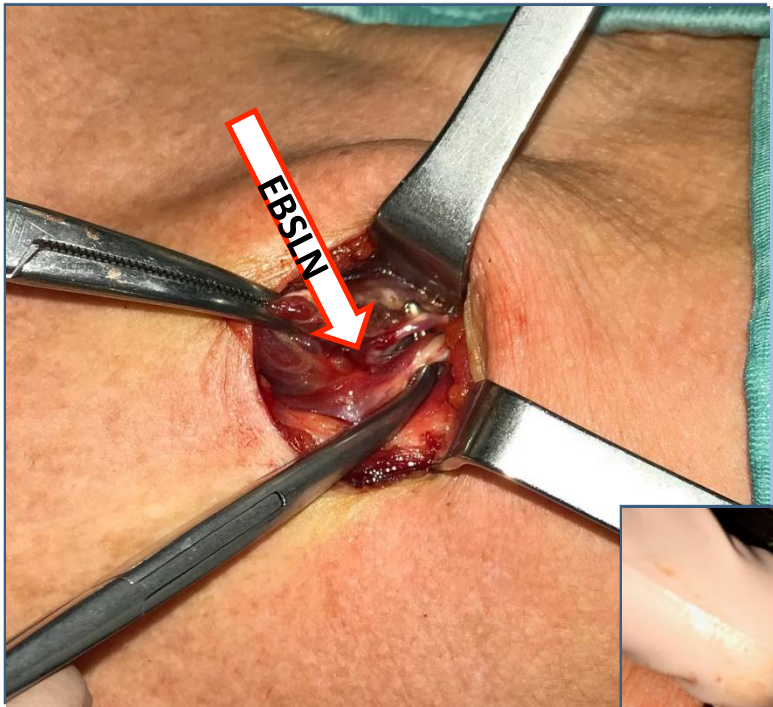
Danni ricorrenziali nella chirurgia della tiroide

## Cosa può fare il chirurgo

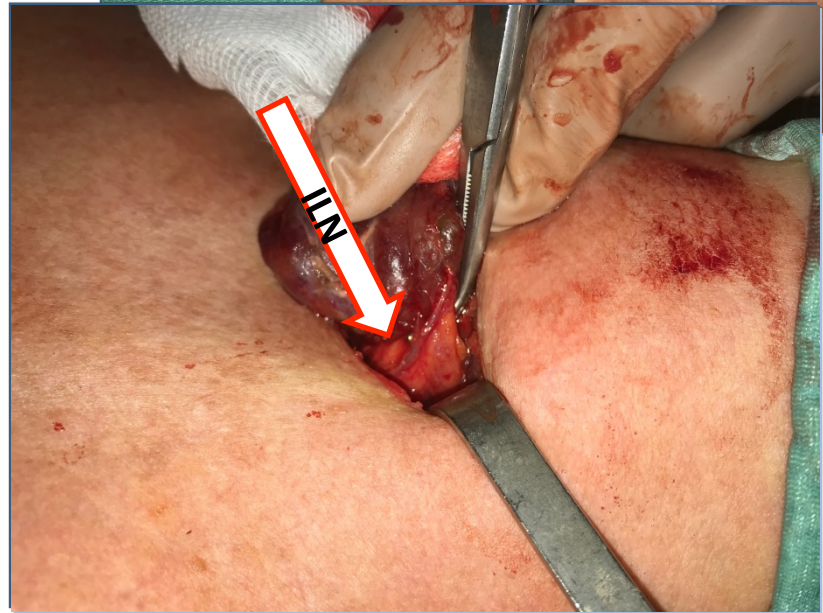
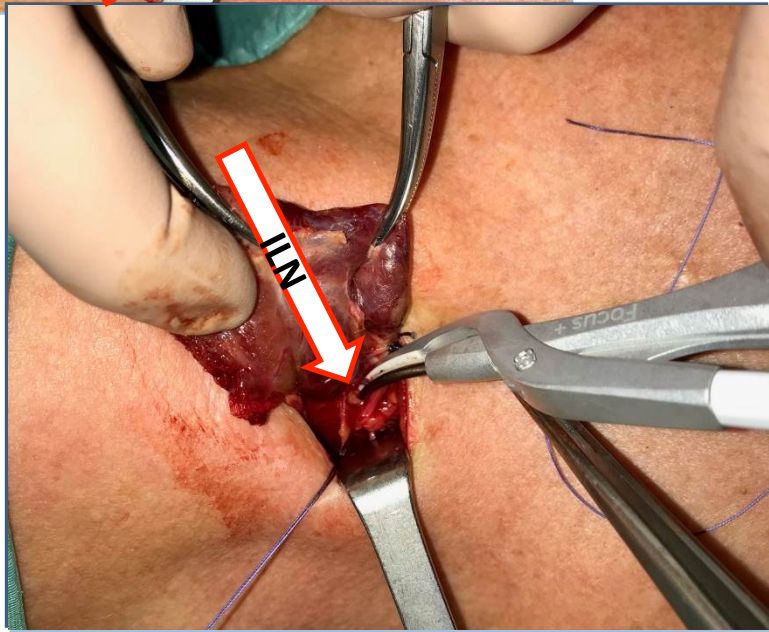
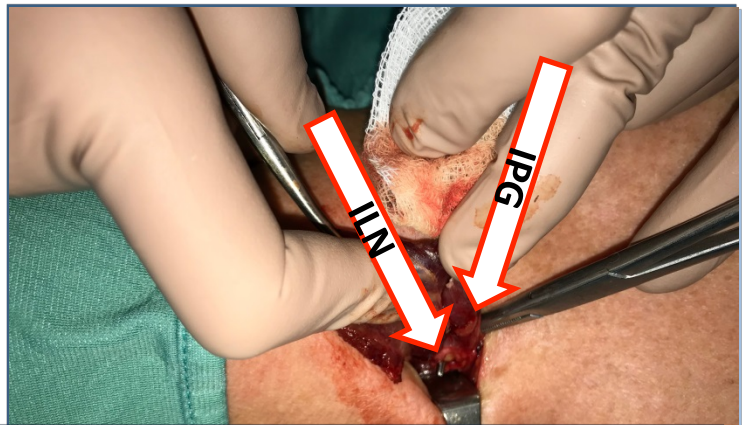


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MARCEL PROUST

**ALLA RICERCA  
DEL TEMPO PERDUTO**

Credere alla medicina sarebbe la follia suprema, se non crederle non fosse una follia ancor più grande, perché da quel mucchio di errori poco a poco è venuta fuori qualche verità.





# Gemelli



Fondazione Policlinico Universitario Agostino Gemelli IRCCS  
Università Cattolica del Sacro Cuore



*Thanks!*