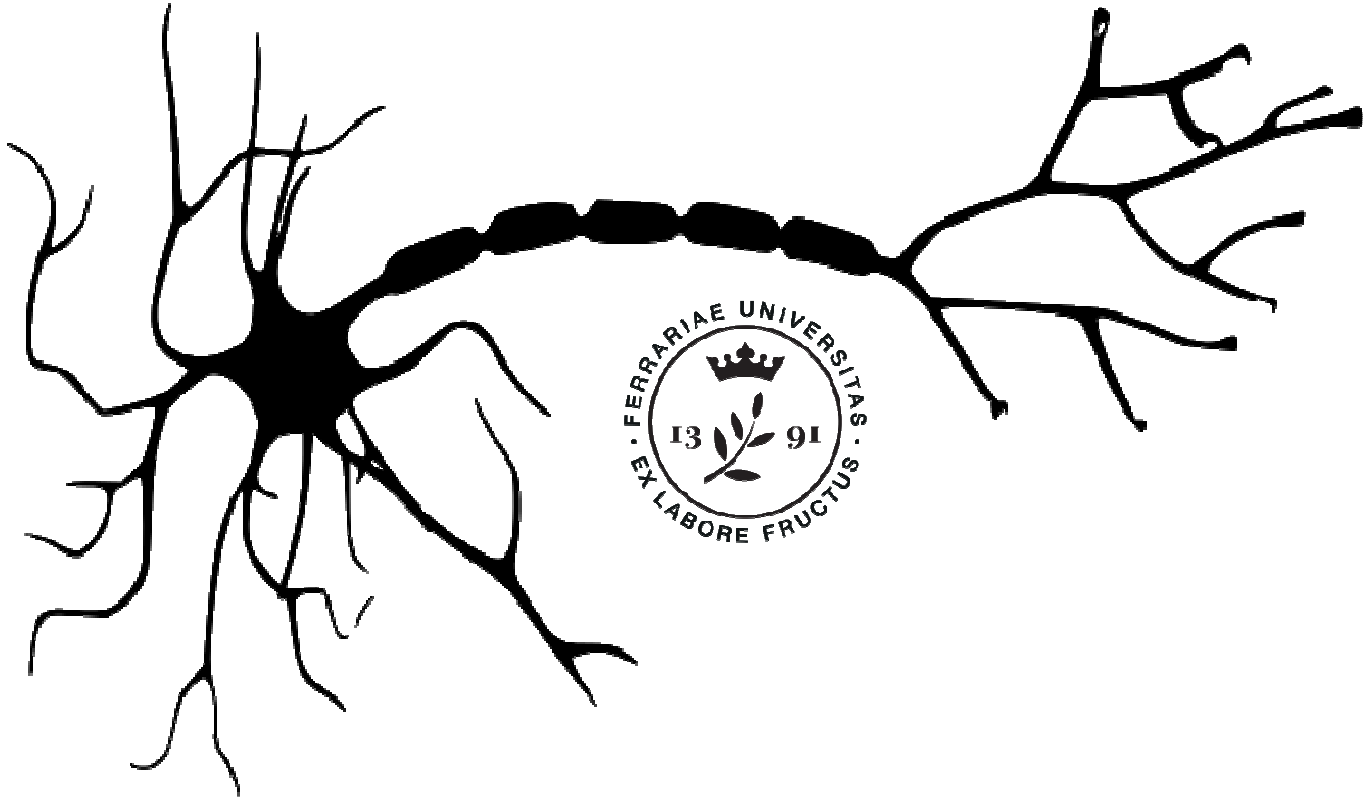
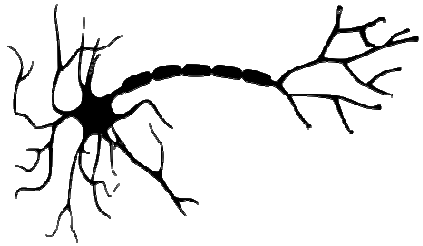



# Intraoperative Nerve Monitoring (IONM) during thyroid surgery

Mattia Portinari



# RLN injury

*Systematic review and Meta-analysis of 20 studies*
*23,512 patients and 35,513 nerves at risk*

**Transient recurrent laryngeal nerve injury (<6 months) 4,5%**

**Permanent recurrent laryngeal nerve injury (<6 months) 1,5%**

Pisanu A. *J Surg Research. 2014;188:152-161.*

# Malpractice litigations

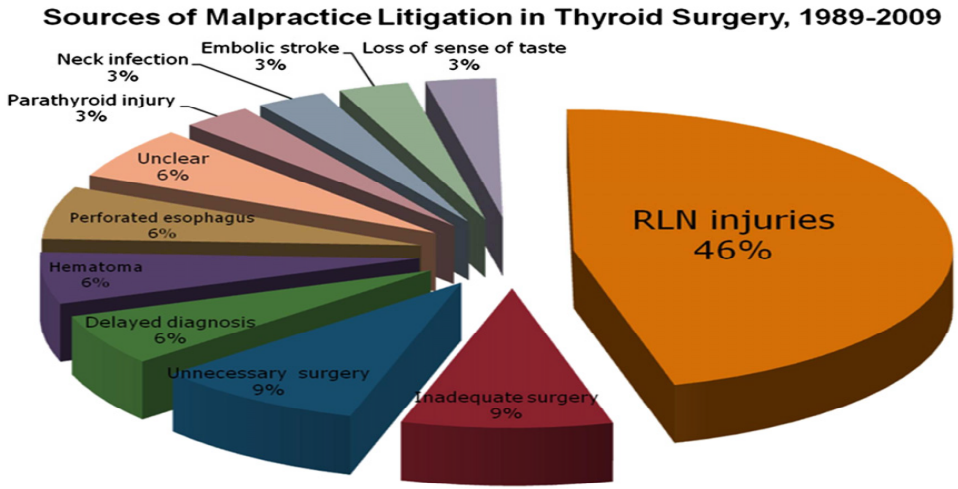



**Fig 2.** Sources of malpractice litigation in thyroid surgery, 1989–2009.

**Recommendations against malpractice litigations:**

1.RLN visualization

2.Record in the operative note a statement on RLN visualization and its intact anatomy

3.Clearly discuss with the patients the possibility of RLN injury and other complications

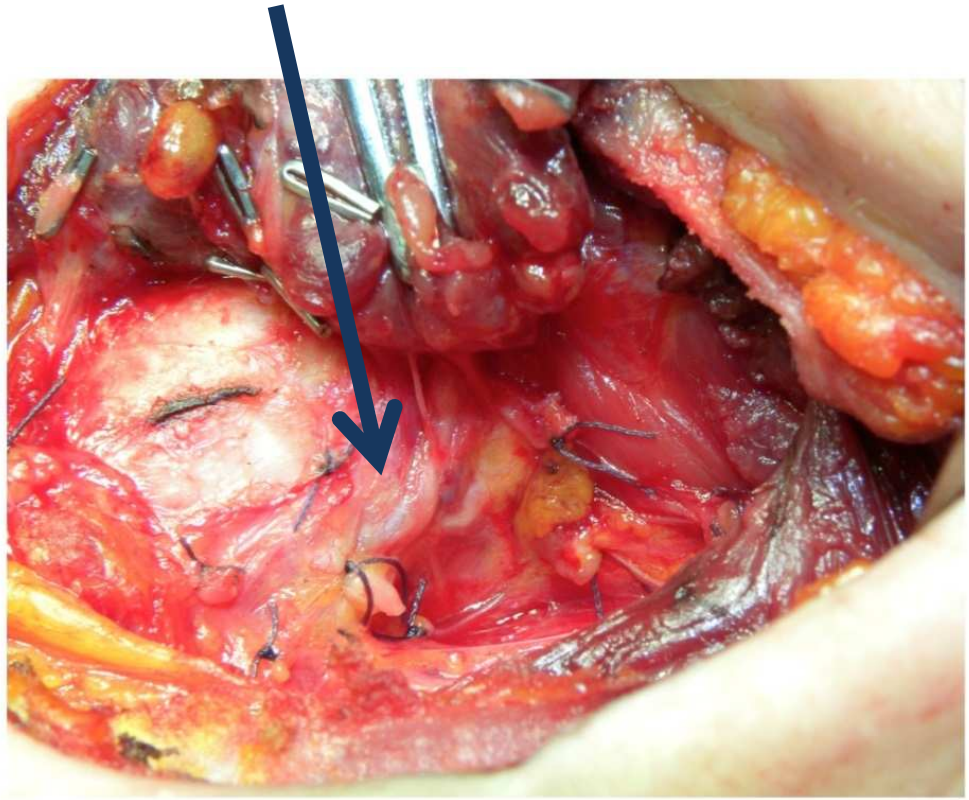
4.Preoperative laryngoscopy

*Abadin SS. Surgery 2010;148:718-723*

# RLN injury prevention

## Gold Standard

## Recurrent laryngeal nerve visualization



**Ann Surg. 2002 Feb;235(2):261-8**.
Laryngeal recurrent nerve injury in surgery for benign thyroid diseases: effect of nerve dissection and impact of individual surgeon in more than 27,000 nerves at risk.
Hermann M, Alk G, Roka R, Glaser K, Freissmuth M.

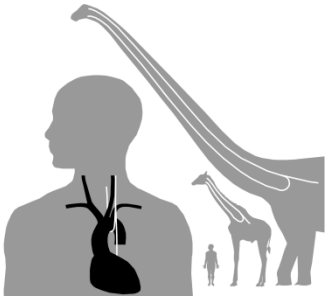
**Laryngoscope. 2002 Jan;112(1):124-33**.
Advantages of recurrent laryngeal nerve identification in thyroidectomy and parathyroidectomy and the importance of preoperative and postoperative laryngoscopic examination in more than 1000 nerves at risk.
Steurer M, Passler C, Denk DM, Schneider B, Niederle B, Bigenzahn W.

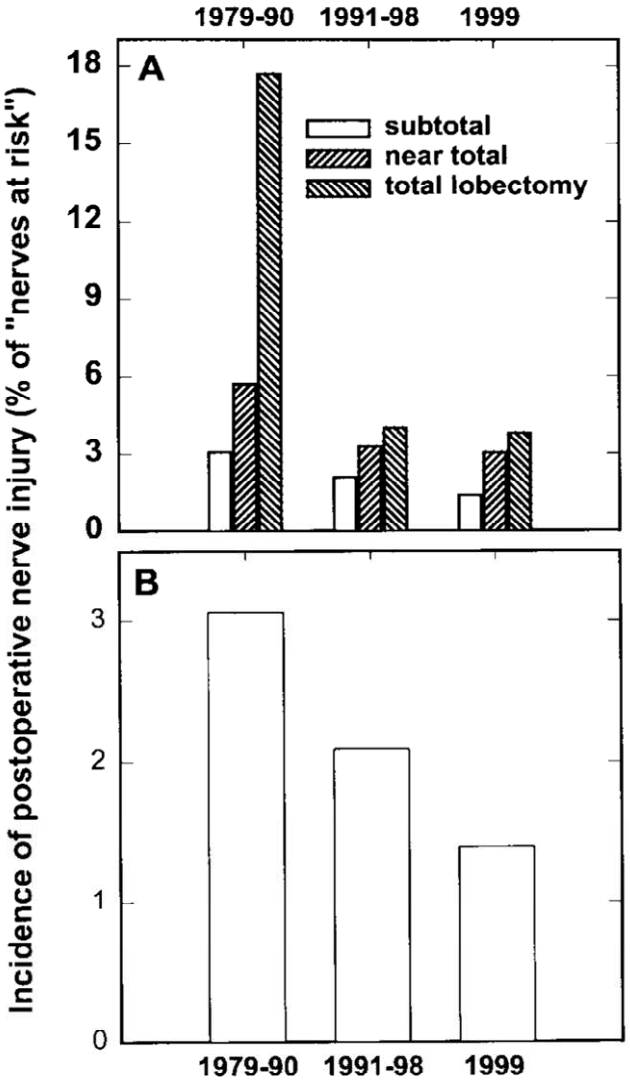
**World J Surg. 2008 Jul;32(7):1358-66**.
Intraoperative monitoring of the recurrent laryngeal nerve in thyroid surgery.
Dralle H, Sekulla C, Lorenz K, Brauckhoff M, Machens A; German IONM Study Group.

**Br J Surg. 2009 Mar;96(3):240-6**.
Randomized clinical trial of visualization versus neuromonitoring of recurrent laryngeal nerves during thyroidectomy.
Barczyński M, Konturek A, Cichoń S.

# RLN injury prevention

## *Visualization*






## 27,000 nerves at risk

**Incidence of postoperative recurrent nerve injury without nerve exposure (period 1, 1979–1990) and with nerve exposure (period 2, 1991–1998, and period 3, 1999).**

(A)In all types of resections, the incidence of recurrent nerve injury declined significantly ($P < .01$) if period 1 (no nerve exposure) was compared with period 2 (surgery with nerve exposure).

(B)The data for subtotal resections have been redrawn with an expanded y-axis to illustrate the significant effect of nerve exposure ($P < .001$, period 1 vs. 2).

**"Exposure of the recurrent nerve significantly reduced the global rate of transient and permanent RLN injury"**

*Hermann M. Ann Surg 2002 Feb;235(2):261-8.*

# Standardized IONM technique

**L1** – Preoperative laryngoscopy

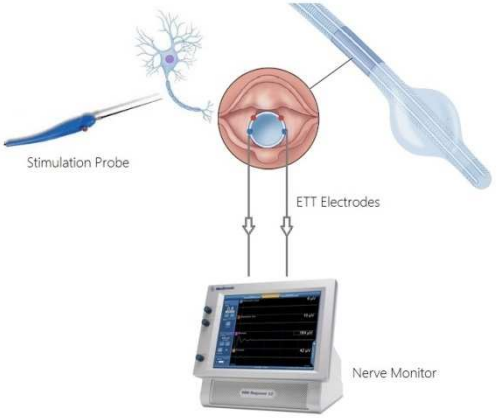
**V1** – Vagal nerve (VN) stimulation before dissection

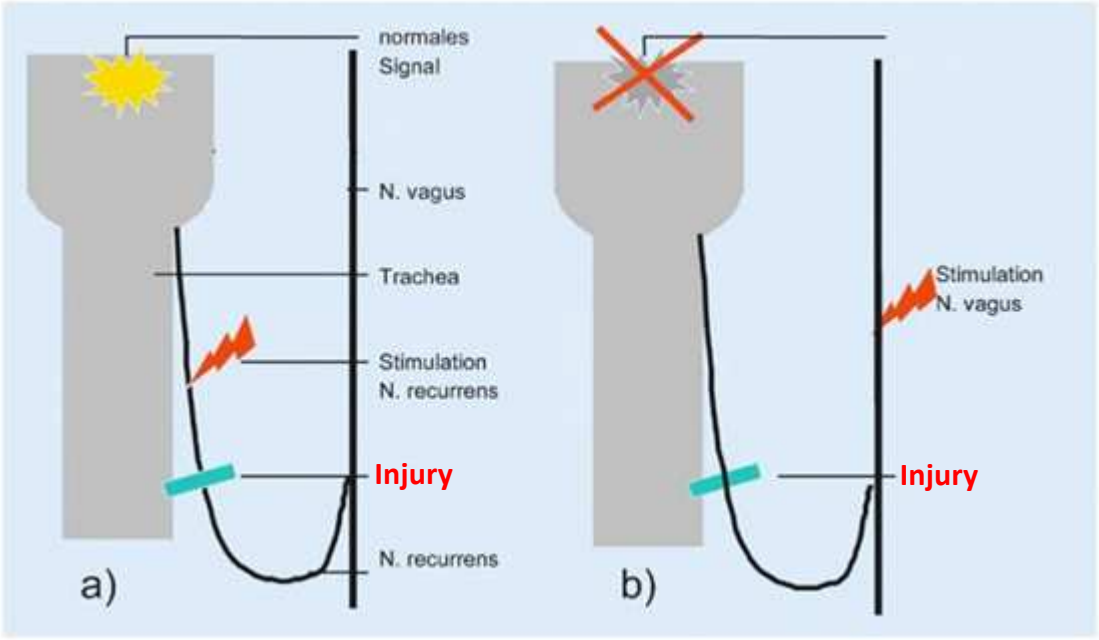
**R1** – Recurrent laryngeal nerve (RLN) stimulation at initial identification

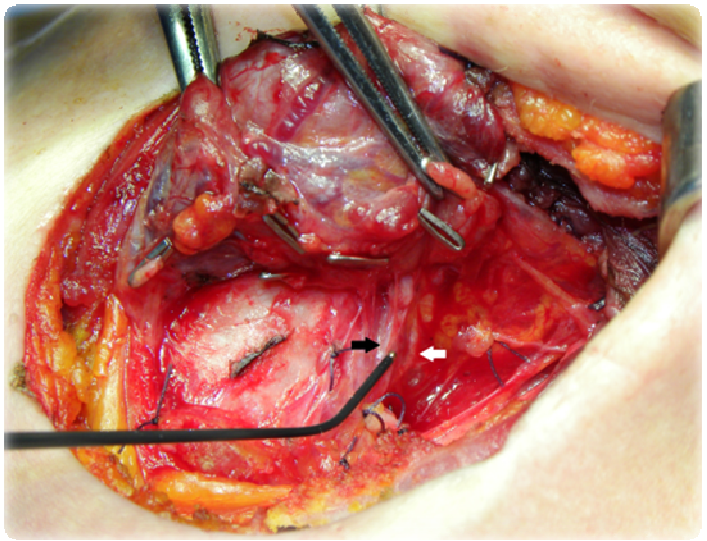
**R2** – Recurrent laryngeal nerve (RLN) stimulation at the end of dissectior

**V2** – Vagal nerve (VN) stimulation after complete thyroidectomy

**L2** – Postoperative laryngoscopy



# Malpractice litigations

ORIGINAL ARTICLE

## Verdicts on malpractice claims after thyroid surgery: Emerging trends and future directions

**75 malpractice claims**
**RLN palsy: 57.3%**

Henning Dralle, MD,* Kerstin Lorenz, MD, Andreas Machens, MD

Department of General, Visceral and Vascular Surgery, University Hospital and Medical Faculty, University of Halle–Wittenberg, Halle/Saale, Germany.

*Accepted 7 September 2011*
*Published online 20 March 2012 in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/hed.21970*

**ABSTRACT:** *Background.* Few investigations have addressed malpractice litigation after thyroid surgery. The purpose of this medico-legal review was to provide a more comprehensive picture of medico-legal trends in thyroid surgery.

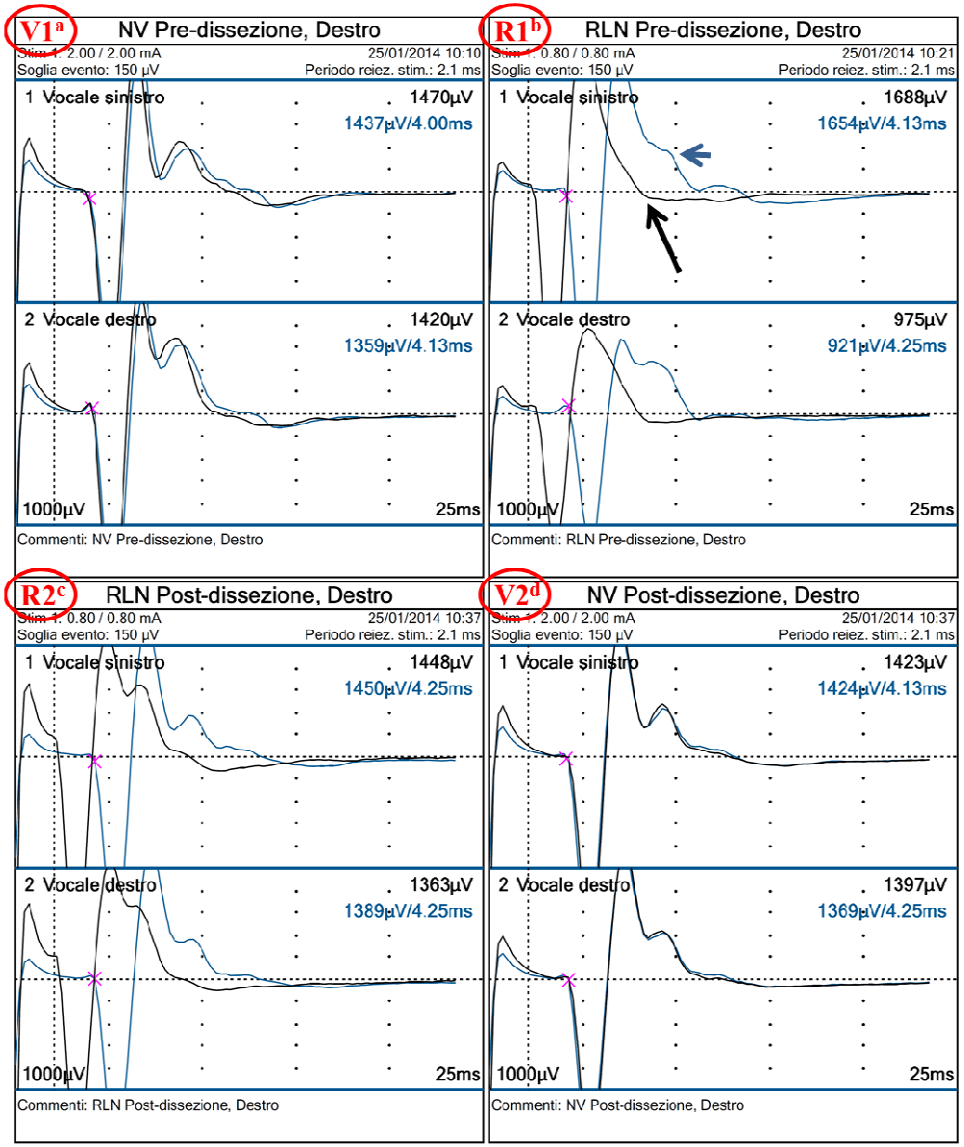
*Methods.* Reviewed were all expert opinions on claims of malpractice after thyroid surgery, commissioned between 1995 and 2010 at 1 tertiary center, and their corresponding verdicts.

*Results.* Forty-three of 75 malpractice claims involved recurrent laryngeal nerve (RLN) palsy (21 unilateral and 22 bilateral palsies), with a 45% tracheostomy rate for bilateral RLN palsy. Twenty-one claims concerned permanent hypoparathyroidism. Since 2007, intraoperative nerve monitoring (IONM) has become the subject of pleading in 4 of 7 malpractice claims involving unilateral or bilateral RLN palsy. In none of these cases did IONM follow international standards, resulting in 3 plaintiff verdicts.

*Conclusion.* The growing appreciation that standardized IONM can prevent bilateral RLN palsies after signal loss on the initial side of resection may become increasingly relevant to malpractice litigation.
 *Head Neck* **34:** 1591–1596, 2012

**KEY WORDS: thyroidectomy, recurrent laryngeal nerve palsy, hypoparathyroidism, medico-legal litigation, civil court, medical arbitration board, malpractice claim, intraoperative nerve monitoring**

# Neuromonitoring documentation



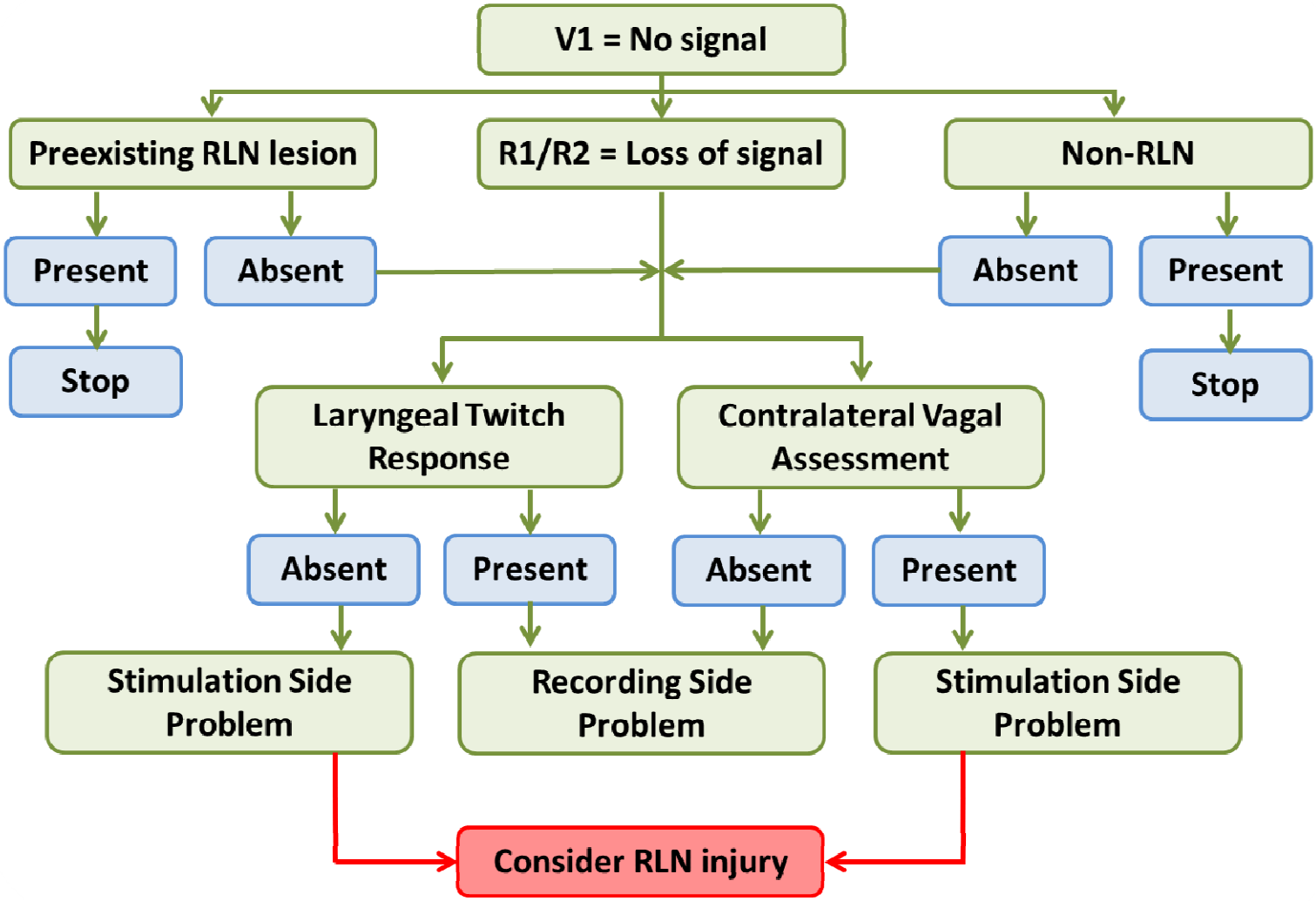

**EMG report at the end of total thyroidectomy and central lymph node dissection.**

[a]**V1**= EMG signal of the vagus nerve (VN) before thyroid dissection;
[b]**R1**= EMG signal of the recurrent laryngeal nerve (RLN) at initial identification;
[c]**R2**= EMG signal of the RLN at the end of thyroid dissection and CLND;
[d]**V2**= EMG signal of the VN after complete thyroidectomy and CLND.

**Short arrow** = stimulation through APS electrode;
**Long arrow** = stimulation through monopolar electrode.

# Troubleshooting algorithm

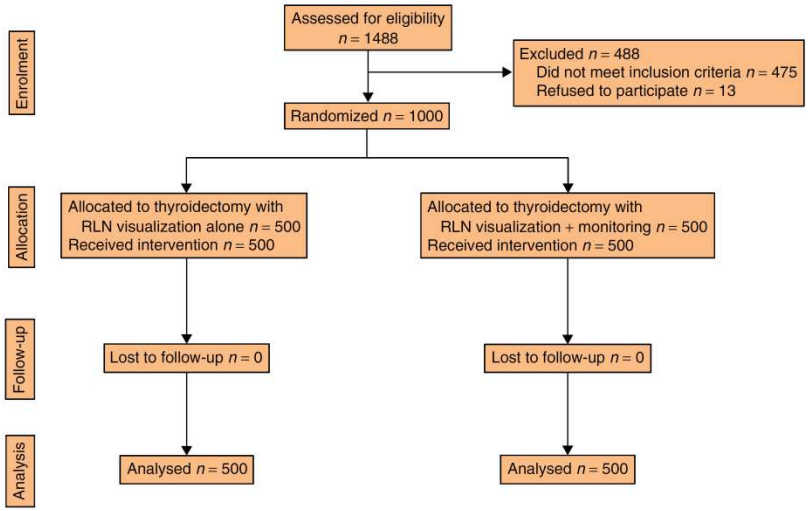
**Loss of Signal (LOS) Amplitude <100µV | RLN lesion *versus* IONM System malfunction**



# RLN injury prevention

## *I-IONM*

***Randomized clinical trial of visualization versus neuromonitoring of recurrent laryngeal nerves during thyroidectomy (1000 nerves at risk)***




In patients with RLN visualization plus neuromonitoring the prevalence of RLN injury and transient RLN palsy were respectively 2,3% (p = 0,007) and 1,9% (p = 0,011) lower than with visualization alone

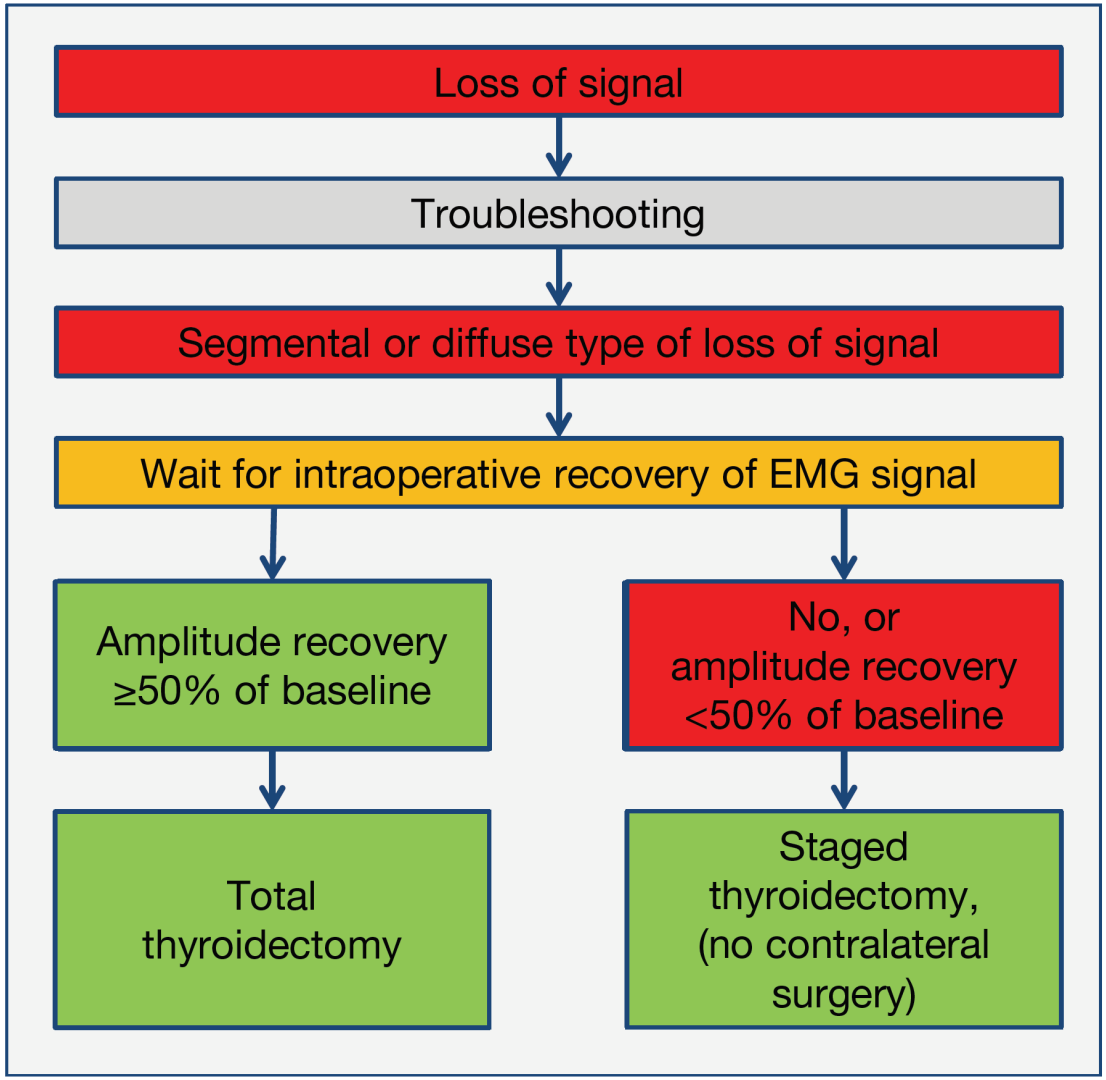
**"Intermittent nerve monitoring decreased the incidence of transient but not permanent RLN palsy compared with visualization alone"**

**NPV 98,4%**

**PPV 37,8%**

Barczyński M. *Br J Surg. 2009 Mar;96(3):240-6.*

# Two stage thyroidectomy




*Management algorithm after loss of signal (LOS) during continuous neural monitoring in thyroid surgery without, with incomplete or complete intraoperative recovery of electromyographic (EMG) signal*

Schneider R. *Gland Surg. 2016;5:607-616.*

# RLN injury prevention

## *I-IONM*

**Table 3 – Postoperative morbidity in terms of overall, transient and permanent RLN palsy per patient and per nerve at risk.**

| Study type | Author (y) | No. of patients | | Nerves at risk | | Overall | | Total transient | | Total permanent | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | IONM | VA | IONM | VA | IONM | VA | IONM | VA | IONM | VA |
| RCS | Calò *et al.* 2013 [13] | 751 | 942 | 1493 | 1844 | 20 | 28 | 14 | 21 | 6 | 7 |
| RCS | Alesina *et al.* 2012 [16] | 89 | 157 | 128 | 161 | 8 | 4 | 8 | 4 | 0 | 0 |
| RCS | Gremillion *et al.* 2012 [18] | 31 | 88 | 41 | 121 | 2 | 4 | 2 | 3 | 0 | 1 |
| PCS | Stevens *et al.* 2012 [1] | 39 | 52 | 62 | 81 | 5 | 5 | 4 | 3 | 1 | 2 |
| PCS | Barczynski *et al.* 2011 [29] | 151 | 151 | 302 | 302 | 5 | 10 | 3 | 8 | 2 | 2 |
| PCS | Duclos *et al.* 2011 [17] | 475 | 211 | 878 | 382 | 36 | 10 | – | – | – | - |
| RCS | Frattini *et al.* 2010 [30] | 76 | 76 | 152 | 152 | 3 | 7 | 2 | 5 | 1 | 2 |
| RCT | Sari *et al.* 2010 [11] | 123 | 114 | 210 | 199 | 3 | 3 | 3 | 3 | 0 | 0 |
| RCS | Atallah *et al.* 2009 [21] | 112 | 149 | 181 | 240 | 16 | 22 | 9 | 13 | 7 | 9 |
| RCT | Barczynski *et al.* 2009 [7] | 500 | 500 | 1000 | 1000 | 27 | 50 | 19 | 38 | 8 | 12 |
| RCT | Dionigi *et al.* 2009 [31] | 36 | 36 | 55 | 57 | 1 | 3 | 1 | 3 | 0 | 0 |
| RCS | Agha *et al.* 2008 [32] | 18 | 41 | – | – | 1 | 4 | – | – | – | - |
| PCS | Netto *et al.* 2007 [33] | 104 | 100 | 169 | 158 | 12 | 12 | 6 | 7 | 6 | 5 |
| RCS | Shindo *et al.* 2007 [20] | 427 | 257 | 671 | 372 | 25 | 17 | 16 | 9 | 2 | 1 |
| PCS | Terris *et al.* 2007 [34] | 73 | 64 | 92 | 84 | 4 | 5 | 4 | 5 | 0 | 0 |
| PCS | Chan *et al.* 2006 [9] | 316 | 323 | 501 | 499 | 21 | 26 | 17 | 20 | 4 | 6 |
| RCS | Witt *et al.* 2005 [35] | 54 | 83 | 83 | 107 | 6 | 4 | 4 | 3 | 2 | 1 |
| PCS* | Dralle *et al.* 2004* [4] | – | – | 17,832 | 5517 | 626 | 193 | 483 | 144 | 143 | 49 |
| RCS | Robertson *et al.* 2004 [12] | 82 | 83 | 116 | 120 | 5 | 8 | 4 | 5 | 1 | 3 |
| RCS | Yarbrough *et al.* 2004 [36] | 52 | 59 | 72 | 79 | 11 | 11 | 9 | 8 | 2 | 3 |
| | Total per patient at risk | 3509 | 3486 | – | – | 211 (6.0%) | 233 (6.7%) | 125 (3.5%) | 158 (4.5%) | 42 (1.2%) | 54 (1.5%) |
| | Total per nerve at risk | – | – | 24,038 | 11,475 | 837 (3.5%) | 426 (3.7%) | 608 (2.5%) | 302 (2.6%) | 185 (0.8%) | 103 (0.9%) |

*Overall 16,517 patients not divided per group, but identified per absolute numbers of nerves at risk.

***3 RCT***

***High volume surgeons***

*Systematic review and Meta-analysis of 20 studies*
*23,512 patients and 35,513 nerves at risk*

**"No significant difference in the incidence of transient and permanent RLN palsy"**

Pisanu A. *J Surg Research. 2014;188:152-161.*

# RLN injury prevention

## *I-IONM (PPV)*

**Table 2** Review of the literature on prediction of early postoperative recurrent laryngeal nerve palsy, and rates of early and permanent recurrent laryngeal nerve palsy by intraoperative nerve monitoring in thyroid surgery

| Reference | Year | No. of nerves at risk | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) | Early postop. vocal fold palsy | Permanent vocal fold palsy |
|---|---|---|---|---|---|---|---|---|
| IIONM | | | | | | | | |
| Hamelmann *et al.*[22] | 2002 | 428 | 23·5 | 98·5 | 40·0 | 96·8 | 19 (4·4) | 1 (0·2) |
| Thomusch *et al.*[23] | 2004 | 12 486 | 33·0 | 98·3 | 36·7 | 97·9 | 413 (2·7)* | 104 (0·7)† |
| Beldi *et al.*[24] | 2004 | 429 | 40 | 98 | 67 | 91 | 37 (8·6) | 6 (1·4) |
| Hermann *et al.*[6] | 2004 | 475 | 57·1 | 99·3 | 87·0 | 96·6 | 43 (8·9)‡ | 15 (3·1)‡ |
| Chan *et al.*[25] | 2006 | 271 | 53 | 94 | 35 | 97 | 15 (5·5) | 2 (0·7) |
| Tomoda *et al.*[26] | 2006 | 2197 | 69·3 | 99·7 | 92·1 | 98·5 | 80 (3·6) | 21 (1·0) |
| Barczyński *et al.*[27] | 2009 | 1000 | 63·0 | 97·1 | 37·8 | 98·9 | 27 (2·7) | 8 (0·8) |
| Melin *et al.*[28] | 2014 | 3426 | 85·4 | 99·0 | 68·0 | 99·6 | 82 (2·4) | n.a. |
| Calò *et al.*[29] | 2014 | 2068 | 91·3 | 99·4 | 77·8 | 99·8 | 23 (1·1) | 6 (0·3) |
| De Falco *et al.*[30] | 2014 | 600 | 83·3 | 99·5 | 62·5 | 99·8 | 5 (0·8) | 4 (0·7) |
| Present study | 2015 | 965 | 73·9 | 99·5 | 77·3 | 99·4 | 23 (2·4) | 4 (0·4) |
| CIONM | | | | | | | | |
| Present study | 2015 | 1314 | 90·9 | 99·7 | 88·2 | 99·8 | 33 (2·5) | 0 (0) |

Values in parentheses are percentages; based on *15 403, †15 340 and ‡481 nerves at risk with follow-up information. PPV, positive predictive value; NPV, negative predictive value; IIONM, intermittent intraoperative nerve monitoring; n.a., data not available; CIONM, continuous intraoperative nerve monitoring.

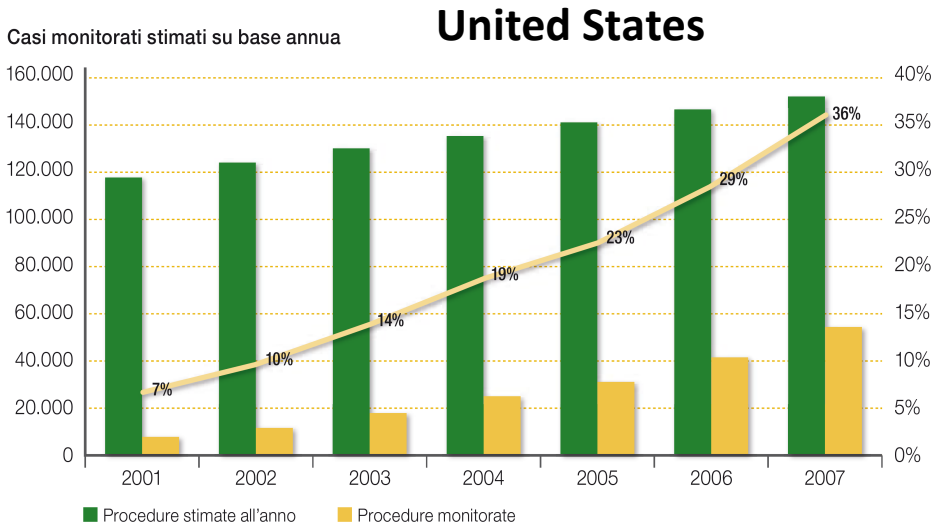
**IIONM – mean PPV: 61,9%**

**CIONM – PPV: 88,2%**

C-IONM: **0,4%** reduction in permanent vocal cord palsy (p = 0,019)

Schneider R. *Br J Surg. 2015;102:1380-1387.*

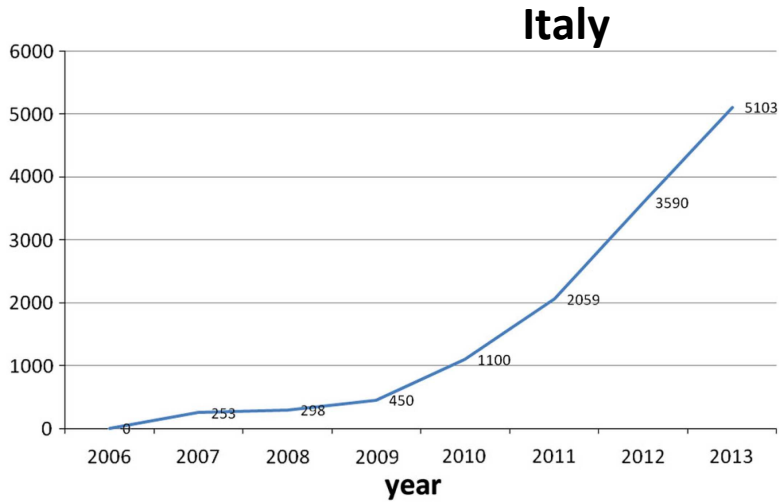
# Prevalence of neuromonitoring




*Gianlorenzo Dionigi.*
*Tiroidectomia con monitoraggio dei nervi laringei. Editore: Edra, 2014*

The value of IONM information for surgeons is highlighted by its **prevalent use in high volume centers by surgeons performing >100** thyroid and parathyroid surgeries per year

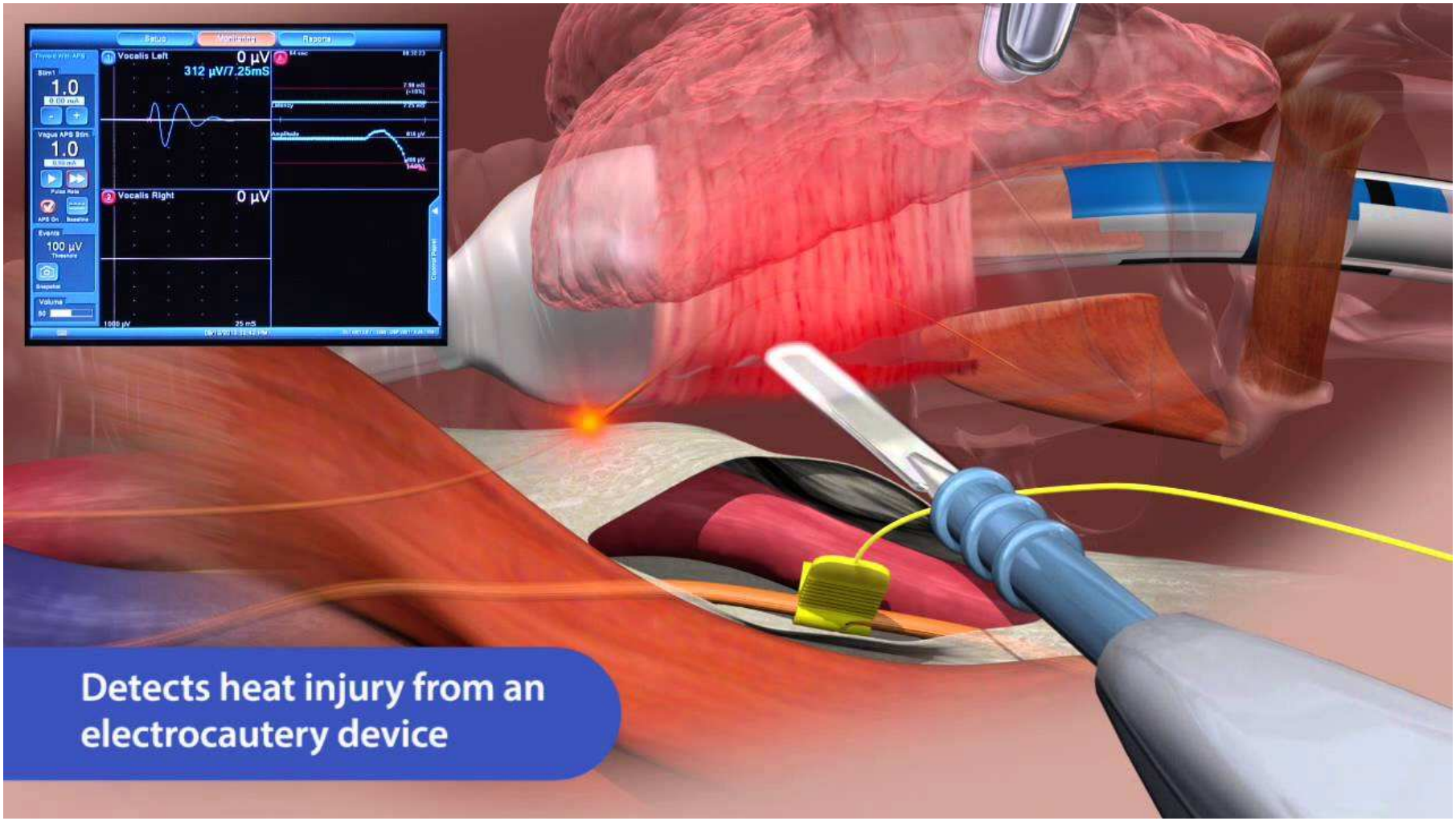
*Sturgeon C. World J Surg. 2009;33:417-425.*




*Trends of recurrent laryngeal nerve monitoring device use in thyroid and parathyroid surgery in Italy from 2007 to 2013*

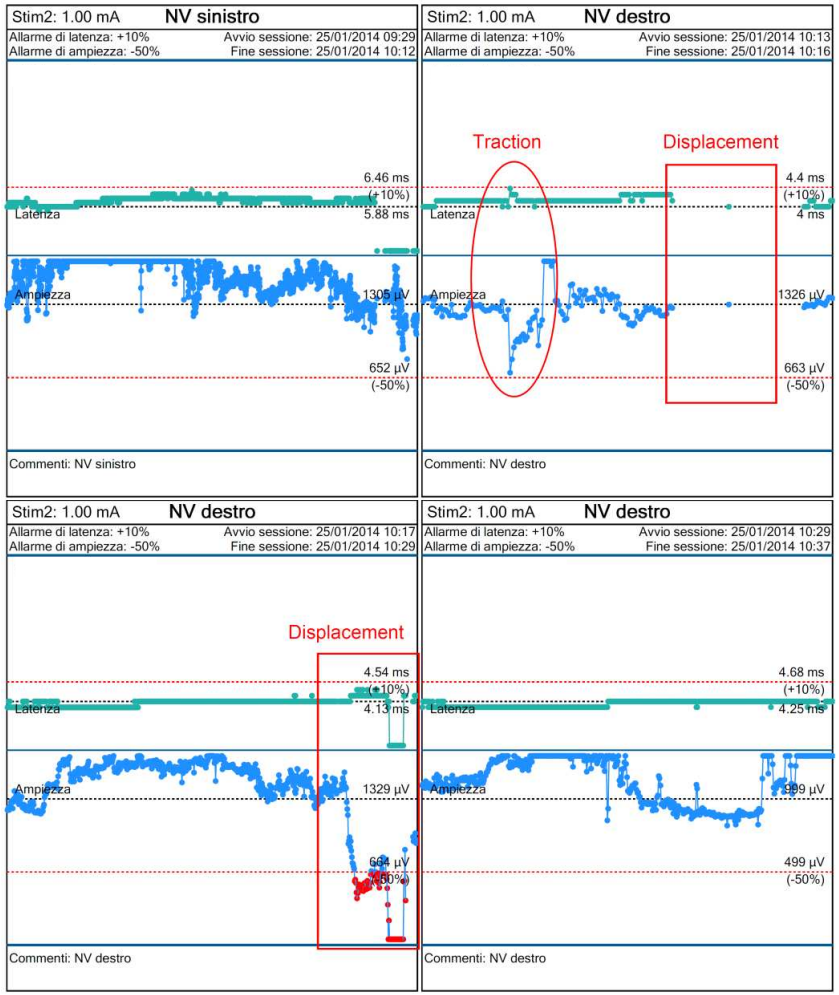
*Dionigi G. Updates Surg. 2014;66:269–276.*

# Continuous Intraoperative Nerve Monitoring (C-IONM)



# RLN injury prevention

## *C-IONM*

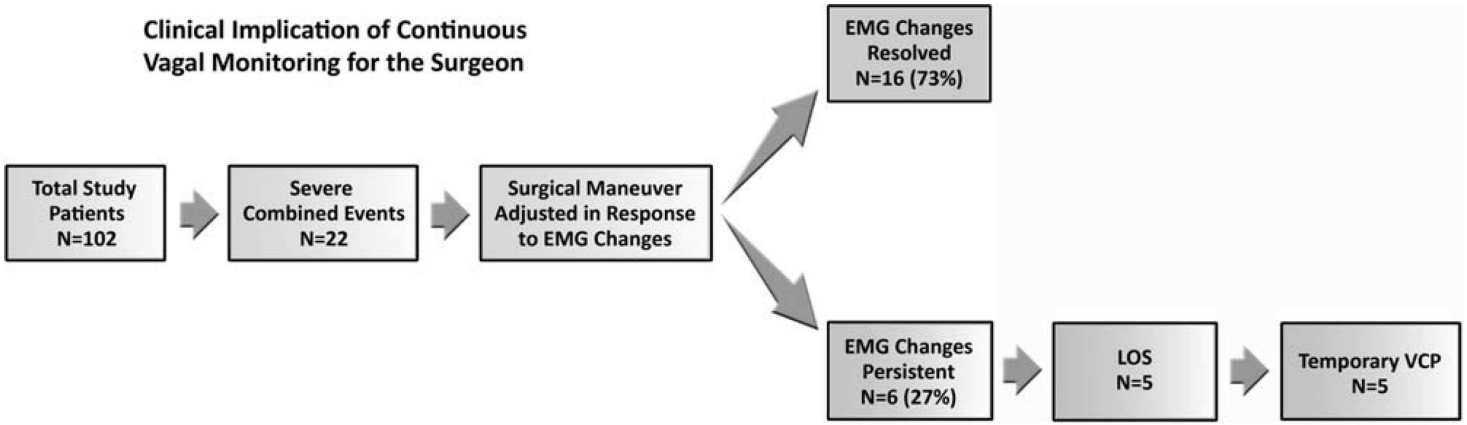



**C-IONM comprises automatic periodic stimulation of the vagus nerve**

"For CIONM, **combined EMG events** indicative of imminent nerve injury were defined as an **EMG amplitude decrease of 50%** or more and a **latency increase of 10%** relative to baseline values"

# RLN injury prevention

## *C-IONM*




**Severe combined event**
(Amplitude decrease > 70% | Latency increase > 10%)
**Reversible in 73%**

**NPV 97,0%**

**PPV 33,0%**

**Loss of signal** (amplitude <100 µV)
**Reversible in 17%**

**NPV 98,0%**

**PPV 83,0%**

*Phelan E. Laryngoscope. 2014;124:1498-1505.*

# Pros and Cons of Neuromonitoring

## I-IONM

### PROS

**1.Nerve identification before visualization** resulting in a significant decrease in the prevalence of RLN temporary paresis

**2.Identification of anatomic variants of RLN** with a reduction in injuries of the anterior motor branch

**3.Verification of RLN functional integrity** of a visually intact nerve to aid intraoperative decision making

**4.Definition of the site of a nerve injury** in the event of loss of signal

### CONS

**1.The RLN palsy is usually identified after it has occurred**

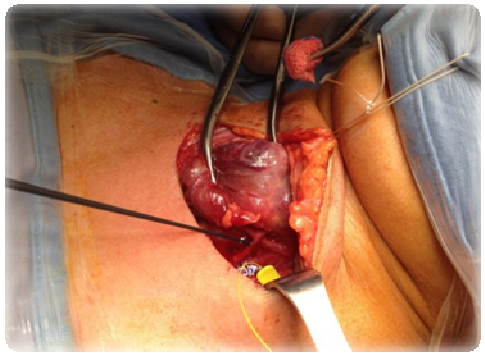
## C-IONM

### PROS

**1.Real-time detection of an impending RLN injury** with early modification of the intraoperative strategy, thus avoiding nerve damage

### CONS

**1.360° vagus nerve dissection** to place the electrode



# Conclusions

**RLN visualization remain the gold standard to reduce transient and permanent nerve injury**

**The use of I-IONM associated to C-IONM with a standardized technique is suggested to:**

—improve RLN identification and verify RLN function;

—modify the surgical maneuver and strategy;

—provide documentary evidence of RLN functional integrity at the end of surgery

**A documentation of RLN visualization in the operative note and the neuromonitoring report are recommended to demonstrate that the operation met the standard of practice**