SLN monitoring and Continuous Vagal monitoring

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Disclosure Elements

• Relevant Financial Disclosures
  -- None

Name of Presenter Gregory W. Randolph
Monitoring 2015

1- SLN-100% ID

2- CIONM -Prevention

3- IONM -Professional Voice
RLN Neural Monitoring
Electrophysiologic Recurrent Laryngeal Nerve Monitoring During Thyroid and Parathyroid Surgery: International Standards Guideline Statement

Gregory W. Randolph, MD; Henning Dralle, MD, with the International Intraoperative Monitoring Study Group*: Hisham Abdullah, MD; Marcin Barczynski, MD; Rocco Bellantone, MD; Michael Brauckhoff, MD; Bruno Carnaille, MD; Sergii Cherenko, MD; Fen-Yu Chiang, MD; Gianlorenzo Dionigi, MD, FACS; Camille Finck, MD; Dana Hartl, MD; Dipti Kamani, MD; Kerstin Lorenz, MD; Paolo Miccoli, MD; Radu Mihai, MD, PhD, FRCS; Akira Miyauchi, MD, PhD; Lisa Orloff, MD, FACS; Nancy Perrier, MD, FACS; Manuel Duran Poveda, MD; Anatoly Romanchishen, MD; Jonathan Serpell, MD, FRACS, FACS; Antonio Sitges-Serra, MD; Tod Sloan, MD, MBA, PhD; Sam Van Slycke, MD; Samuel Snyder, MD, FACS; Hiroshi Takami, MD; Erivello Volpi, MD; Gayle Woodson, MD
The Non Recurrent Laryngeal Nerve: Anatomic and Electrophysiologic algorithm for reliable identification

Dipti Kamani, Andre Potenza, Claudio Cernea, Gregory Randolph
Clinical Practice Guideline: Improving Voice Outcomes after Thyroid Surgery

Sujana S. Chandrasekhar, MD, Gregory W. Randolph, MD,
Michael D. Seidman, MD, Richard M. Rosenfeld, MD, MPH,
Peter Angelos, MD, PhD, Julie Barkmeier-Kraemer, PhD, CCC-SLP,
Michael S. Benninger, MD, Joel H. Blumin, MD, Gregory Dennis, MD,
John Hanks, MD, Megan R. Haymart, MD, Richard T. Kloos, MD,
Brenda Seals, PhD, MPH, Jerry M. Schreibstein, MD,
Mack A. Thomas, MD, Carolyn Waddington, MS,
FNP, Barbara Warren, PsyD, Med, and Peter J. Robertson, MPA
Statement 7.

**INTRAOPERATIVE EMG MONITORING:** The surgeon or their designee may monitor laryngeal electromyography (EMG) during thyroid surgery. *Option based on one RCT and observational studies with a balance of benefit versus harm*

**Action Statement Profile**
- Aggregate Evidence Quality: Grade C
- Benefit: Added information regarding neurophysiologic status of the RLN (specifically when the nerve is injured), potential improved accuracy in nerve identification, avoiding transient/temporary nerve paresis in one RCT (number needed to treat 33)

**AAOHNS guidelines 2013:** special utility in cases
1. bilateral thyroid surgery
2. revision thyroid surgery
3. surgery in the setting of existing RLN paralysis
2014 American Thyroid Association Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer

The American Thyroid Association (ATA) Guidelines Taskforce on Thyroid Nodules and Differentiated Thyroid Cancer

[B13] Intraoperative Voice and Parathyroid Management

RECOMMENDATION 41

A) Visual identification of the recurrent laryngeal nerve (RLN) during dissection is required in all cases. Steps should also be taken to preserve the external branch of the superior laryngeal nerve (EBSLN) during dissection of the superior pole of the thyroid gland. (Strong recommendation, Moderate-quality evidence)

B) Intraoperative neural stimulation (with or without monitoring) may be considered to facilitate nerve identification and confirm neural function. (Weak recommendation, Low-quality evidence)
Monitoring 2015

1- SLN - 100% ID
2- CIONM - Prevention
3- IONM - Professional Voice
Statement 6.

PROTECTION OF SUPERIOR LARYNGEAL NERVE: The surgeon should take steps to preserve the external branch of the superior laryngeal nerve(s) when performing thyroid surgery.

*Recommendation based on preponderance of benefit over harm*

**Action Statement Profile**

- Aggregate Evidence Quality: Grade C
- Benefit: Preserves vocal projection and high frequencies, may improve airway in extreme circumstances
- Risk, Harm, Cost: May leave superior pole thyroid tissue
- Benefit-Harm Assessment: Preponderance of benefit
- Value Judgments: None
- Intentional Vagueness: The steps taken to preserve the nerve are purposefully not specified in the statement to emphasize the important issue is preserving the nerve, which may or may not be identifiable during surgery. Therefore, it is the attention to the nerve that is important
- Role of Patient Preferences: None
- Exclusions: None
- Policy level: Recommendation
“the surprising voice is gone forever. The sad specter of a ghost replaces the velvety softness”
Normative Intra-operative Electrophysiologic Waveform Analysis of Superior Laryngeal Nerve External Branch and Recurrent Laryngeal Nerve in Patients Undergoing Thyroid Surgery

Andre S. Potenza · Eimear A. Phelan · Claudio R. Cernea · Cristian M. Slough · Dipti V. Kamani · Ashlie Darr · David Zurakowski · Gregory W. Randolph
Laryngeal head of the sternothyroid muscle
POTENTIALS EVOKED BY STIMULATION OF THE EXTERNAL BRANCH OF THE RIGHT SUPERIOR LARYNGEAL NERVE

EMG Amplitude in Millivolts

ENDOTRACHEAL ELECTRODE
RIGHT SIDE

Time in Milliseconds Relative to Stimulus
SLN amplitude: 34% of ipsilateral RLN amplitude

Nerve

RLN

Amplitude of EMG response in microvolts

p<0.0001

SLN: 269.9

RLN: 782.2
EBSLN and Cricothyroid muscle twitch
Superior Laryngeal Nerve Quantitative Intraoperative Monitoring is Possible in all Thyroid Surgeries

E. Ashlie Darr M.D.¹, Ralph P. Tufano, M.D., MBA, FACS², Suleyman Ozdemir, M.D.², Dipti Kamani, M.D.¹, Shelley Hurwitz, PhD³, Gregory Randolph M.D.¹,⁴

¹ Division of Thyroid and Parathyroid Surgery, Department of Laryngology and Otology, Massachusetts Eye and Ear Infirmary, Harvard Medical School

² Division of Head and Neck Endocrine Surgery, Department of Otolaryngology-Head and Neck Surgery, Johns Hopkins University School of Medicine

³ Division of Endocrinology, Department of Medicine, Brigham and Women’s Hospital, Harvard Medical School

⁴ Division of Surgical Oncology, Department of Surgery, Massachusetts General Hospital, Harvard Medical School
(Above) Tri-Vantage NIM endotracheal tube. (Center) Monopolar (Prass) stimulator probe. (Below) Bipolar stimulator probe.
Results: In 100% of cases, external branch of the superior laryngeal nerve was identified as well as quantifiable EMG response was observed. EMG amplitude did not change despite extensive nerve dissection and multiple nerve stimulations. External branch of the superior laryngeal nerve amplitude was similar for left and right sides, for patients under age 50 and aged 50 or older, for both genders and with monopolar and bipolar stimulators.

Table 1. Overall amplitudes for EBSLN, RLN, and VN using monopolar and bipolar stimulator probes

<table>
<thead>
<tr>
<th>Stimulator probe</th>
<th>Nerves at risk (n)</th>
<th>Minimum Amplitude (uV)</th>
<th>Maximum Amplitude (uV)</th>
<th>Mean Amplitude (uV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monopolar</td>
<td>EBSLN initial</td>
<td>29</td>
<td>100</td>
<td>272.2±202.9</td>
</tr>
<tr>
<td></td>
<td>EBSLN final</td>
<td>17</td>
<td>49</td>
<td>263.8±184.7</td>
</tr>
<tr>
<td></td>
<td>RLN</td>
<td>16</td>
<td>391</td>
<td>1041.4±542</td>
</tr>
<tr>
<td></td>
<td>VN</td>
<td>10</td>
<td>236</td>
<td>699.1±331.8</td>
</tr>
</tbody>
</table>
Contemporary Review

External Branch of the **Superior Laryngeal Nerve** Monitoring During Thyroid and Parathyroid Surgery: International Neural Monitoring Study Group Standards Guideline Statement

Marcin Bareysnäski, MD; Gregory W. Randolph, MD; Claudio R. Cernea, MD; Henning Dralle, MD; Gianlorenzo Dionigi, MD; Piero F. Alesina, MD; Radu Mihai, MD; Camille Finck, MD; Davide Lombardi, MD; Dana M. Hartl, MD; Akira Miyauchi, MD; Jonathan Serpell, MD; Samuel Snyder, MD; Erivelto Volpi, MD; Gayle Woodson, MD; Jean Louis Kraimps, MD; Abdullah N. Hisham, MD; with the International Neural Monitoring Study Group
TABLE II

The Mnemonic Formula of EBSLN Facilitates Recall of the Steps Necessary for Safe Dissection and Identification of the EBSSLN.

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
<th>Aim(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>Expose of the space harboring the EBSSLN</td>
<td>Exposure of the EBSSLN can be improved by transverse division of the laryngeal head of the sternothyroid muscle and gentle traction of the superior thyroid lobe towards the lateral and caudal direction.</td>
</tr>
<tr>
<td>B</td>
<td>Bluntly dissect tissues</td>
<td>Blunt dissection within the avascular space between the cricothyroid muscle and medial aspect of the superior thyroid pole allows for visual identification of the EBSSLN lying on the inferior constrictor muscle before its termination within the cricothyroid muscle.</td>
</tr>
<tr>
<td>S</td>
<td>Stimulate tissues during dissection</td>
<td>Stimulation of tissues during blunt dissection should be undertaken in order to facilitate visual identification of the nerve.</td>
</tr>
<tr>
<td>L</td>
<td>Look for cricothyroid twitch</td>
<td>Looking for a positive cricothyroid twitch is recommended during gentle dissection of tissue with the tip of the stimulation probe rather than expecting a positive EMG response on the monitor.</td>
</tr>
<tr>
<td>N</td>
<td>Navigate your dissection using the technique of nerve mapping</td>
<td>Navigation of the dissection should be continued once the nerve is identified to assure functional nerve preservation. In cases when the nerve is not seen but mapped out in the operative field, this navigation should allow for optimizing the level of the superior thyroid artery ligation to ensure intact functional integrity of the EBSSLN provided by electrical nerve testing. One obtains positive stimulation medially and then only divides tissue in the superior pole dissection, which stimulates negatively.</td>
</tr>
</tbody>
</table>

EBSSLN = external branch of the superior laryngeal nerve; EMG = electromyography.
Monitoring 2015

1- SLN-100% ID

2- CIONM -Prevention

3- IONM -Professional Voice
Why Continuous Vagal Nerve Monitoring (CIONM) ?

1-Standard IONM- stim is intermittent

Stimulation-injury-stimulation

2-Passive traumatic (non-evoked) responses are poorly related to nerve injury

Standard IONM has great utility but CIONM brings the potential of preventing injury
Mechanism of injury

Snyder 08 and Chiang 08 IONM mapping studies 75% RLN injuries are stretch injury at LOB
Vagal Electrode configuration

Closed
• Medtronic
• Saxophone

Open
• Inomed
• Langer
Initial CIONM studies during thyroidectomy-Safety

- **Lamade 00,07, 11 Ulmer 08**: saxophone and cuff <1mA, stim ~ 1-1/2 hrs
- **Schneider 09**: 45 pts, Anchor < 1hr
- **Jonas 10**: V3 inomed 100 pts-LOS
- **Ulmer 11**: studied HRV-parasympathetic predominance w/o cardiac arrhythmia, hemodynamic instability
- **Dralle, Randolph 12**

Safe-neural, cardiac, pulmonary
CIONM EMG Injury Construct

Type, amount and speed of onset of injury

Nature of EMG change-Ampl, latency, etc...

Slope of EMG changes

The absolute EMG non recovery point

LOS

AXIS AMPLITUDE

AXIS TIME

Transection
Cautery
Compression
Stretch
CIONM Electrode Image
APS Electrode on Vagus Nerve
Case 4 - RLN Recovery Post Manipulation

- Vocalis Left: 11 μV, 73 μV/6.63mS
- Vocalis Right: 6 μV, 320 μV/7.38mS
Case 37 - Mild Combined Event

1. Vocalis Left
   - 9 \mu V
   - 290 \mu V/8.00 mS

2. Vocalis Right
   - 21 \mu V
   - 139 \mu V/7.13 mS
Continuous Intraoperative Vagus Nerve Stimulation for Identification of Imminent Recurrent Laryngeal Nerve Injury

Rick Schneider¹*, MD, Gregory W. Randolph²*, MD, Carsten Sekulla¹, PhD, Eimear Phelan², MD, Phuong Nguyen Thanh¹,MD, Michael Bucher³, MD, Andreas Machens¹, MD, Henning Dralle¹, MD, Kerstin Lorenz¹, MD

¹ Department of General, Visceral, and Vascular Surgery, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany;
² Department of Otolaryngology, Division of Thyroid and Parathyroid Surgery, Massachusetts Eye and Ear Infirmary, Harvard Medical School, Boston, Massachusetts, USA.;
³ Department of Anesthesiology and Intensive Care Medicine, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany
Superposition of the EMG tracing from 4 patients.

A. Complete loss of signal resulting in postoperative recurrent laryngeal nerve palsy;
Schematic representation of the EMG changes preceding loss of signal and postoperative recurrent laryngeal nerve palsy
153x153mm (300 x 300 DPI)
Continuous Vagal IONM Prevents Recurrent Laryngeal Nerve Paralysis by Revealing Initial EMG Changes of Impending Neuropraxic Injury: A Prospective, Multicenter Study

Continuous Vagal IONM (CIONM):

**Amplitude and latency changes:**

1. **Mild Combined Event (mCE)-**
   - amplitude decrease of $>50–70\%$ with a concordant latency increase of $5-10\%$

2. **Severe Combined Event (sCE)-**
   - amplitude decrease of $>70\%$ with an concordant latency increase of $>10\%$

3. **Loss of Signal (LOS) –**
   - complete loss of recognizable RLN signal (amplitude $<100\ \mu V$) intraoperatively
Table 2.
Vocal Cord Paralysis Group vs. No Vocal Cord Paralysis Group: Combined Events and Loss of Signal

<table>
<thead>
<tr>
<th>Vocal Cord Palsy (VCP)</th>
<th>Severe CEs % occurring/average #</th>
<th>LOS % occurring</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCP (N = 6)</td>
<td>Occurring 83%</td>
<td>83%</td>
</tr>
<tr>
<td></td>
<td>Average # 29.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(range 0 – 124)</td>
<td></td>
</tr>
<tr>
<td>No VCP (N = 96)</td>
<td>Occurring 20%</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>Average # 3.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(range 1 – 79)</td>
<td></td>
</tr>
</tbody>
</table>

sCE (>7) Sensitivity 66.7% Specificity 91.7% for VCP
PPV 33% NPV 97%

LOS Sensitivity 83% Specificity 99% for VCP
PPV 83% NPV 98%
Adverse but nascent EMG outcome parameter: severe CE

Receiver Operator Curve for Severe Combined Events

(Area under ROC curve = 0.8368)
Continuous Vagal IONM (CIONM):

Figure 7: Clinical Implication of Continuous Vagal Monitoring for the Surgeon

- Total Study Patients N=102
- 1 or more Severe Combined Events N=22
- Surgical Maneuver Adjusted in Response to EMG Changes
- EMG Changes Resolved N=16
- EMG Changes Persistent N=6
- LOS N=6
- Temporary VCP N=5

~72%
~17%
LOS – an evolution

CIONM:
- amp, latency in isolation without utility
- severe Combined Events: $p = 0.001$ -VCP
  - sens 67% spec 91% NPV 97% PPV 33%
  - reversible in $>70\%$

- LOS: $p < 0.001$ –VCP
  - sens 83% spec 99% NPV 98% PPV 83%
  - reversible in $<20\%$

sCE multiple sCE 72% LOS 17% VCP
Monitoring 2015

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Normal Singing Voice
Thyroidectomy in the Professional Singer – Neural Monitored Surgical Outcomes
• Methods
  – Prospective database of 30 professional voice users undergoing thyroid surgery with IONM between August 2002 – March 2014
  – Pre- and post-operative vocal cord function was normal in all patients
• Methods
  – I. Surveys to collect pre & post-operative voice instrument data
  • Voice Handicap Index (VHI)
  • Singing Voice Handicap Index (SVHI)
  • Evaluation of the Ability to Sing Easily (EASE)
  – II. Additional questions formulated by our laryngologist team
  • Vocal parameters affected during ‘recovery phase’
  • Time to return to performance
**VOCAL GENRE**

- **Motown**: 4%  
- **Other b**: 7%  
- **Musical Teacher**: 7%  
- **Musical Theater**: 7%  
- **Country & Blues/Folk**: 11%  
- **Religious a**: 19%  
- **Pop/Rock**: 25%  
- **Classical/Operatic**: 44%

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**PERCENTAGE**

- a Includes Gospel, Jewish Cantor and Church/Choir  
- b Includes a voice over artist and television meteorologist
• Results
  – Average age 44.81 (range 17 – 76)
  – 100 % return to performance
  – Mean time of 2.26 months (range 0.5 – 8 months)
• Results

  – Vocal instrument mean scores showed no statistically significant difference in pre-operative to post-operative comparisons

<table>
<thead>
<tr>
<th>Vocal Instrument</th>
<th>Pre –Op</th>
<th>Post -Op</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VHI</td>
<td>4.15</td>
<td>4.04</td>
<td>0.9301</td>
</tr>
<tr>
<td>SVHI</td>
<td>11.26</td>
<td>12.07</td>
<td>0.8297</td>
</tr>
<tr>
<td>EASE</td>
<td>6.19</td>
<td>6.00</td>
<td>0.9348</td>
</tr>
</tbody>
</table>
VOCAL PARAMETERS

- **Range (low)**: 22%
- **Amplitude/loudness**: 52%
- **Projection**: 55%
- **Pitch control/modulation**: 74%
- **Strength**: 81%
- **Range (high)**: 89%
- **Fatigue**: 89%

**PERCENTAGE**
• Conclusion
  – Neural monitored thyroid surgery in professional voice users is safe
  – Key elements are:
    • Strict adherence to INMSG with respect to RLN & EBSLN
    • pre and post-operative laryngeal assessment (in compliance with the AAO-HNS voice guidelines)
    • specific intra-operative surgical techniques to maximize vocal integrity
Monitoring 2015

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Invitations
Surgery of the Thyroid and Parathyroid Glands

Harvard Medical School, Boston

October 2016

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617 –573- 4115
September 17-19 2015

FIRST WORLD CONGRESS OF NEURAL MONITORING IN THYROID AND PARATHYROID SURGERY

INTERNATIONAL ORGANIZING COMMITTEE:

Marcin Barczyński, Poland
Feng-Yu Chiang, Taiwan
Gianlorenzo Dionigi, Italy
Henning Dralle, Germany
Gregory Randolph, USA

TOPICS:

- Prevalence of IONM
- Why IONM?
- Technique
- Anesthetic perspective
- SLN monitoring
- c-IONM
- Loss of signal and what to do?
- Safety analysis
- Limits of IONM
- IONM in endoscopic thyroidectomy
- Neurophysiology of the RLN
- Staged thyroidectomy
- Cost-effectiveness analysis
- Informed consent and legal issues
- Update of INMSG Guideline Statements

For more information please visit: http://www.neuromonitoring.com.pl/
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Boston, Massachusetts

A global multi-disciplinary meeting of all specialists involved in the field of Thyroid Cancer and Thyroid Nodules.

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