Technology and thyroid surgery

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Surgical Department, Cagliari, Italy
Iasi, 06-08/05/2009

TECHNOLOGY AND THYROID SURGERY (Abstract): The main complications after total thyroidectomy are less and include bleeding, injuries of recurrent laryngeal nerves (RLN) and hypoparathyroidism. Modern technologies increase a quality of thyroid surgery. Accurate hemostasis is basic to prevent bleeding. Harmonic Focus is an ultrasonic scalpel that performs dissection, hemostasis and cut with small lateral thermic injuries. Harmonic Focus decrease operative time, hospital stay, postoperative drainage and postoperative hypoparathyroidism. Intraoperative RLN injury causes are section (mistake in surgical technique); ligature (without transection); mistake in hemostasis and dissection manoeuvers; stretch/traction; excessive traction during the medial traction of the thyroid lobe; excessive aspiration near to the nerve (suction); compression/confinement/pressure; thermal/electrical injury; diffusion by hemostatic devices; ischemia; ligation of the inferior pole vessels before identifying RLN; excessive dissection of the nerve with ischemia. Evolution of RLN monitoring was from intra-operative invasive techniques to non-invasive surface electrodes (endotracheal tube). Positive acoustic signal following stimulation of the vague nerve and the RLN always means: vocalis muscle is intact and positive acoustic signal only by RLN stimulation usually means: RLN paresis (nerve lesion distal to the stimulation site). The correlation between a positive acoustic signal and a postoperatively intact vocal function is very high (97%). The use of the nerve monitoring can be recommended as useful, but not generally demanded as obligatory.

KEY WORDS: THYROIDECTOMY, HARMONIC FOCUS, INJURIES OF RECURRENT LARYNGEAL NERVES

Complications

- Complications after total thyroidectomy are less than 2%
- Bleeding
- Injuries of laryngeal nerves
- Hypoparathyroidism

Modern technologies and quality of thyroid surgery

- **Bleeding (new devices)**
  - Reduction of postoperative complications
    - Recurrent laryngeal nerve paralysis (NIM)
    - Hypocalcemia (early iPTH measurement)

Devices

- **Ligasure®**
- **Ultracision®**
- **Electrocautery**
Harmonic Focus

- Harmonic Focus is an ultrasonic scalpel that performs dissection, hemostasis and cut.

Main Features:
- Hemostasis and cut with small tissue injury
- Simultaneous cut and hemostasis
- Small lateral thermic injuries
- Hemostasis and cut of vessels up to 5 mm
- Ergonomic scalpel

Harmonic Focus vs. traditional hemostasis

Operative time
Blood loss
P.o. drainage
Hospital stay (days)
Nerve palsy
Hypocalcemia
P.o. pain
Cost (euros)

<table>
<thead>
<tr>
<th></th>
<th>Ultracision</th>
<th>No Ultracision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cordon (60 Pt)</td>
<td>96 ± 23’</td>
<td>121 ± 34’</td>
</tr>
<tr>
<td>Ortega (200 Pt)</td>
<td>86 ± 20’</td>
<td>101 ± 16’</td>
</tr>
<tr>
<td>Manouras (234 Pt)</td>
<td>74 ± 14’</td>
<td>93 ± 12’</td>
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<td>Siperstein (171 Pt)</td>
<td>132 ± 39’</td>
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<td>Defechereux (34 Pt)</td>
<td>70 ± 18’</td>
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<tr>
<td>Hallgrimsson (51 Pt)</td>
<td>121’</td>
<td>172</td>
</tr>
<tr>
<td>Miccoli (100 Pt)</td>
<td>40 ± 6’</td>
<td>46 ± 10</td>
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<thead>
<tr>
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<th>Ultracision</th>
<th>Traditional hemostasis</th>
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<tbody>
<tr>
<td>Cordon (60 Pt)</td>
<td>35 ± 27 ml</td>
<td>54 ± 51 ml</td>
</tr>
<tr>
<td>Manouras (234 Pt)</td>
<td>24</td>
<td>32</td>
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<tr>
<td>Defechereux (34 Pt)</td>
<td>74 ± 50</td>
<td>134 ± 108</td>
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<tr>
<td>Yildirim (104 Pt)</td>
<td>25 ± 10</td>
<td>59 ± 33</td>
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### Harmonic Focus vs. traditional hemostasis

#### p.o. drainage

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<th>Traditional hemostasis</th>
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<tr>
<td>Cordon (60 Pt)</td>
<td>36 ± 22 ml</td>
<td>51 ± 48 ml</td>
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<tr>
<td>Miccoli (100 Pt)</td>
<td>40 ± 25</td>
<td>75 ± 43</td>
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#### Hospital stay (days)

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<td>2.1</td>
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<td>Ortega (200 Pt)</td>
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<td>1.15</td>
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<tr>
<td>Manouras (234 Pt)</td>
<td>1.4</td>
<td>1.6</td>
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#### RLN Palsy

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<td>Cordon (60 Pt)</td>
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<td>1</td>
</tr>
<tr>
<td>Ortega (200 Pt)</td>
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<td>2</td>
</tr>
<tr>
<td>Manouras (234 Pt)</td>
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#### Hypocalcemia

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<tbody>
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<td>Cordon (60 Pt)</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Ortega (200 Pt)</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Manouras (234 Pt)</td>
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<td>4</td>
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<tr>
<td>Defechereux (34 Pt)</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Miccoli (100 Pt)</td>
<td>5</td>
<td>16</td>
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#### p.o. Pain

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<tr>
<td>Cordon (60 Pt)</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Defechereux (34 Pt)</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Miccoli (100 Pt)</td>
<td>++</td>
<td>++</td>
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#### Cost (Euros)

<table>
<thead>
<tr>
<th></th>
<th>Ultracision</th>
<th>Traditional hemostasis</th>
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</thead>
<tbody>
<tr>
<td>Ortega (200 Pt)</td>
<td>985 ± 107</td>
<td>1148 ± 153</td>
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</tbody>
</table>
**Materials**

- Two groups:
  - "Harmonic Focus"
    - June 2008 - March 2009
    - 197 pts (157 F - 40 M)
  - "No Harmonic Focus"
    - January 2008 - June 2008
    - 197 pts (157 F - 40 M)

**Histopathologic diagnosis**

- "Harmonic Focus"
  - Differentiated tumor: 75
  - Medullary Carcinoma: 2
  - Goiter: 76
  - Hyperthyroidism: 13
  - Autoimmune thyroiditis: 31
  - Mean Weight: 46.15 gr
    (range: 14 - 308 gr)

- "No Harmonic Focus"
  - Differentiated tumor: 73
  - Medullary Carcinoma: 2
  - Goiter: 71
  - Hyperthyroidism: 15
  - Autoimmune thyroiditis: 36
  - Mean Weight: 41.24 gr
    (range: 11 - 160 gr)

**Hospital stay**

- "Harmonic Focus"
  - II p.o. 169 (85.8%)
  - III p.o. 25 (12.7%)
  - IV p.o. 2 (1%)
  - > IV p.o. 1 (0.5%)

- "No Harmonic Focus"
  - II p.o. 143 (72.6%)
  - III p.o. 46 (23.4%)
  - IV p.o. 6 (3%)
  - > IV p.o. 2 (1%)

**Operative Time**

- "Harmonic Focus"
  - Carcinoma: 98'
  - Goiter: 90'
  - Hyperthyroidism: 108'

- "No Harmonic Focus"
  - Carcinoma: 115'
  - Goiter: 107'
  - Hyperthyroidism: 118'
Hypoparathyroidism (*)

“Harmonic Focus”
- At discharge: 75/197 (38%)
- After 3 months: 21/186 (11%)
- After 6 m: 4/107 (3.7%)
- After 9 m: 4/107 (3.7%)

“No Harmonic Focus”
- At discharge: 103/197 (52%)
- After 3 months: 45/197 (23%)
- After 6 m: 23/197 (11.6%)
- After 9 m: 15/197 (7.6%)
- After 12 m: 4/90 (4.4%)

(*) Calcemia < 8.0 mg/dl

RLN Injury

“Harmonic Focus”
- 2 patients

“No Harmonic Focus”
- 2 patients

Bleeding

“Harmonic Focus”
- 2 patients

“No Harmonic Focus”
- 2 patients
Modern technologies and quality of thyroid surgery

- Bleeding (new devices)
- Reduction of postoperative complications
  - Recurrent laryngeal nerve palsy (NIM)
  - Hypocalcemia (early iPTH measurement)

### RLN injury

<table>
<thead>
<tr>
<th>Author</th>
<th>Evidence RLN injury</th>
</tr>
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<tbody>
<tr>
<td>No identification RLN</td>
<td>Localized RLN</td>
</tr>
<tr>
<td>Lacey FH, Ann Surg 1938</td>
<td>1.6% 0.3%</td>
</tr>
<tr>
<td>Riddell VH, Lancet 1956</td>
<td>3.5% 2.1%</td>
</tr>
<tr>
<td>Jazikoff, Surgery 1994</td>
<td>7.9% 1.2%</td>
</tr>
<tr>
<td>Wagner, Br J Surg 1994</td>
<td>21% 6.9%</td>
</tr>
<tr>
<td>Hermannet, Acta Eur 2002</td>
<td>2.1% 0.9%</td>
</tr>
<tr>
<td>Orsal H, Surgery 2004</td>
<td>1.16% 0.63%</td>
</tr>
<tr>
<td>Chiang, Surgery 2005</td>
<td>5.1% 0.9%</td>
</tr>
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</table>

### Intraoperative evidence of RLN injury

<table>
<thead>
<tr>
<th>Author</th>
<th>Evidence RLN injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bergenfelz A (2008)</td>
<td>1/10 11.3%</td>
</tr>
<tr>
<td>Chiang FY (2005)</td>
<td>3/40 7.5%</td>
</tr>
<tr>
<td>Lo CY (2000)</td>
<td>5/33 15%</td>
</tr>
<tr>
<td>Patlow CA (1986)</td>
<td>1/10 10%</td>
</tr>
<tr>
<td>Caldarelli D (1980)</td>
<td>1/10 10%</td>
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Intraoperative RLN injury causes

- Section (mistake in surgical technique)
- Ligature (without transection)
- Mistake in hemostasis and dissection maneuvers
- Stretch/traction
  - Excessive traction during the medial traction of the thyroid lobe
  - Excessive aspiration near to the nerve (suction)
- Compression/contusion/pressure
- Thermal/electrical injury
  - Diffusion by haemostatic devices
- Ischemia
  - Ligation of the inferior pole vessels before identifying RLN
  - Excessive dissection of the nerve with ischemia

Evolution of RLN Monitoring

- Intra-operative invasive techniques
  - Non-invasive surface electrodes (endotracheal tube)

Lamadé W
Transtracheal monitoring of the recurrent laryngeal nerve. Prototype of a new tube
Intraoperative monitoring of the recurrent laryngeal nerve. A new method
Chirurg. 1996 & 1997

In Europe, currently only about 5-10% of thyroidectomies are monitored (Germany 70%)

Materials and Methods

- February-April 2009:
  - 46 patients (92 Nerves at risk)
  - Total Thyroidectomy: 39
    - Plus limphectomy (VI level): 4
    - Plus limphectomy (II-III-IV-V-VI levels): 2
  - Recurrent carcinoma: 1

Operative technique

- Standard thyroidectomy
- No neuromuscular blocking agents
- NIM-Response 2.0 System (Medtronic Xomed, Jacksonville, Florida, USA)
- NIM Contact EMG Tube
- Single use pulse-generated monopolar stimulator probe
  - Stimulation level 0.5 mA-2.0 mA (mean 1mA)
  - Frequency of 30Hz, Impedance <5kOhm
- NIM requires bloodless field
- Haemostasis and dissection: vessel sealing system (Ultracision)
Operative technique

1. Test vagus nerve before identification of RLN.
2. Test RLN when it was identified at the tracheo-esophageal groove.
3. Test RLN after it was completely dissected from Berry's ligament.
4. Test vagus nerve after complete hemostasis.

Test vagus nerve before identification of RLN

Test of RLN

DIRECT RLN STIMULATION

INDIRECT VIA VAGAL STIMULATION

vagus nerve stimulation
Complications

- RLN Injuries: 0/92 nerves at risk
- Transient Hypoparathyroidism (*)
  - At discharge: 38%

(*) Calcemia < 8.0 mg/dl

Validity of NIM of the RLN in thyroid surgery

<table>
<thead>
<tr>
<th>Author</th>
<th>NAR (n, total)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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<tr>
<td>Thomusch 2004</td>
<td>12,486</td>
<td>33</td>
<td>98.3</td>
<td>36.7</td>
<td>99.7</td>
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<tr>
<td>(Transient RLNP)</td>
<td></td>
<td>49.6</td>
<td>97.6</td>
<td>11.6</td>
<td>99.5</td>
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<tr>
<td>(Permanent RLNP)</td>
<td></td>
<td>64.1</td>
<td>90.9</td>
<td>78.7</td>
<td>99.6</td>
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<tr>
<td>Hermann 2004</td>
<td>475</td>
<td>57.1</td>
<td>99.3</td>
<td>87</td>
<td>96.6</td>
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<tr>
<td>(Transient RLNP)</td>
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<td>64.5</td>
<td>90.9</td>
<td>77.1</td>
<td>99.8</td>
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<tr>
<td>(Permanent RLNP)</td>
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<td>64.5</td>
<td>90.9</td>
<td>77.1</td>
<td>99.8</td>
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<tr>
<td>Comoda 2006</td>
<td>2,197</td>
<td>62.1</td>
<td>97.3</td>
<td>95.1</td>
<td>99.8</td>
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<td>(Transient RLNP)</td>
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<td>97.3</td>
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<tr>
<td>(Permanent RLNP)</td>
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<td>62.1</td>
<td>97.3</td>
<td>95.1</td>
<td>99.8</td>
</tr>
</tbody>
</table>

German Multicentre Study

A. Positive acoustic signal following stimulation of the vagus nerve and the RLN always means: **vocalis muscle is intact**

B. Positive acoustic signal only by RLN stimulation usually means: **RLN paresis** (nerve lesion distal to the stimulation site)

<table>
<thead>
<tr>
<th></th>
<th>Positive predictive value</th>
<th>Negative predictive value</th>
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<tbody>
<tr>
<td>Transient paresis</td>
<td>30%</td>
<td>99%</td>
</tr>
<tr>
<td>Permanent paresis</td>
<td>11%</td>
<td>99%</td>
</tr>
</tbody>
</table>
When should RLN be monitored?

- Thyroid Cancer
- Significant Lymph Node Resection
- Graves Disease / Thyroiditis
- Large cervical or sub-sternal goiters
- Revision surgery
- Surgery after external beam radiation therapy

TRAINING

- Learning curve (50 procedures)
- Multidisciplinary team
- Standardization of technique

Conclusions

- Nerve identification is facilitated
- Visual nerve representation is the most important measure in preventing RLN paresis
- NIM detects exclusively neurogenically related vocal fold paresis
- NIM can predict postoperative vocal fold functional defect

Conclusions

- Adequate certainty there is only for the quality assessment of an unchanged positive signal but not for the qualities of weakened and missing signal
- Adequate experience with the technique is an indispensable prerequisite for safe utilization of NIM (minimum 100 operations)

Conclusions

- The correlation between a positive acoustic signal and a postoperatively intact vocal function is very high (97%)
  - By contrast
  - The correlation between a weakened or missing acoustic signal and postoperative RLN function is not particularly good (40%)

Conclusions

- Correct assessment of the nerve monitoring signal is possible only if one takes into account the vagus stimulation
- The use of the nerve monitoring can be recommended as useful, but not generally demanded as obligatory
- NIM can reduce the rate of RLN paresis in case of surgeons with little experience