Update on Hypopharyngeal and Base of Tongue Management in OSA

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Overview

Why hypopharyngeal surgery?
Evaluation techniques for procedure selection
Hypopharyngeal procedures and outcomes

OSA surgery review (Sher et al. Sleep 1996)
UPPP “successful” in 41% of all OSA patients
52% Fujita Type I
5% Fujita Types II and III
Conclusion: failure to identify site(s) of obstruction is principal factor in poor results for surgery

Friedman Stage (Friedman OtoHNS 2002)
Success of UPPP/T: Stage I 81%
Stage II 38%
Stage III 8%
Unfortunately, few patients Stage I

Why Hypopharyngeal Surgery?
Effective surgery directed at site(s) of obstruction
Nose
Palate
Hypopharynx
Fujita Classification
Type I Palate
Type II Combined
Type III Hypopharynx

Disclosures
The following personal financial relationships with commercial interests relevant to this presentation:
Medical Advisory Board Apnex Medical
Medical Advisory Board ReVENT Medical
Consultant Inspire Medical Systems
Consultant Split Rock Scientific
Intellectual Property Rights Berendo Scientific
Intellectual Property Rights Magnap
Expansion Sphincter Pharyngoplasty

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Lateral Pharyngoplasty

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Identifying the Sites: Drug-Induced Sleep Endoscopy

Developed in UK in 1991

Used in several centers around the world but less commonly in U.S.

Fiberoptic endoscopy of sedated, “sleeping” patient
Goal: reproduce SDB seen on sleep study

VOTE Classification system (Kezirian, Hohenhorst, de Vries Eur Arch Oto 2011)
--some standardization and comparison of findings/outcomes across centers

Velum/Palate

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Oropharyngeal Lateral Walls

http://sleep-doctor.com/blog

Tongue

http://sleep-doctor.com/blog
What is the Link between Obesity and OSA? Why is Obesity Associated with Worse Outcomes after Most Procedures?


Correlation of Percent Tongue Fat with BMI (Nashi et al, Laryngoscope 117:1467, 2007)

Factors and Outcomes

Examining case series studies, although some small Most randomized trials are pilot studies (sample size)

Factors: BMI, preop AHI, cephalogram measures
Outcomes: AHI and “success” “Success” = 50% reduction in AHI/AI to absolute level no greater than 20/15/5
Major oversimplification
Goal generally to improve OSA/AHI
Other outcomes (sleepiness, QOL)
However, AHI reported widely and enables comparison

Hypopharyngeal Procedures

Genioglossus advancement
Tongue radiofrequency
Tongue stabilization
Midline glossectomy
Hyoid suspension
Partial epiglottectomy
Hypoglossal nerve stimulation
Maxillomandibular advancement

Epiglottis

Site of Obstruction and Surgical Options

Current

Future?

Palate/Tonsils
Velum/Palate

Hypopharynx/
Oro LW

Retrolingual
Tongue

Epiglottis

Maxillofacial
Maxillofacial
**Genioglossus Advancement**

Rectangular osteotomy below incisor roots between canines
--GBAT: circular osteotomy

Capture genial tubercle and genioglossus muscle attachments

Advance bone fragment and muscle attachment to place genioglossus on tension

Risks: dental numbness, injury

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**Tongue Radiofrequency**

Many areas of the body
Heart, prostate, oncology
Turbinates, palate, tonsils, tongue

Energy delivered to create injury, then fibrosis

Multiple technologies
Monopolar (Gyrus/TCRF) vs. Bipolar (ArthroCare and Celon)

Less invasive
Can be done in clinic—titratable, snoring

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**Tongue Radiofrequency Outcomes**

Most have overweight BMI but not obese (highest mean BMI 32)
Wide range mean baseline AHI

Success rates 20-80% in different series
Randomized, placebo-controlled trial shows modest but real improvements in AHI and FOSQ (QOL)

Factors associated with outcomes
AHI (not universal)
BMI 29 or 30
Friedman Stage (II better than III)

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**Tongue Stabilization**

Marketed as Repose/Airvance system

Technique
Bone screw in mandible
Pre-attached suture passed through tongue base and secured to stabilize tongue base

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**Tongue Radiofrequency Improves UPPP/T outcomes**

<table>
<thead>
<tr>
<th>FS</th>
<th>UPPP/T Only</th>
<th>UPPP/T + RF Tongue</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>38%</td>
<td>55%</td>
</tr>
<tr>
<td>III</td>
<td>8%</td>
<td>33%</td>
</tr>
</tbody>
</table>

Palate surgery alone provides improvement

Addition of tongue RF improves outcomes for patient subgroups that would not be expected to have ideal outcomes after palate surgery

Friedman Otto—HNS 2003
Friedman Otto—HNS 2004

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**BMI Pre AHI Post AHI Success (AHI) Factors**

Riley 1994 39% (9/23)
Johnson 1994 59 14* 78% (7/9)
Lee 1996 53 15* 69% (4/6)
Miller 2004 (GBAT) 30.5 53 16* 63% (7/11)
Liu 2005 20.0 62 20* 52% (23/44)
Emara 2011 27.5 (24 + 36) 41 13* 87% (20/23)
Kim 2012 26.8 60 30* 41% (15/38)
Hendler 2001 (mortised genioplasty) 32.6 60 20* 48% (16/33)
dos Santos 2007 (genioplasty) 25.4 (all < 30) 12 4* 76% (7/10)

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**BMI and AHI (not universal)**

AHI 20-30, BMI >30 in sample

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Tongue Stabilization Case Series
Most have overweight BMI (highest mean 31)
Wide range mean AHI
Success rates 20-80% in different series
Factors associated with outcomes (limited eval)
AHI
BMI 29, graph
? Suture tightening

Source: Vicente Laryngoscope 2006 (n=54)

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Midline Glossectomy
Morbid procedure with CO2 laser, cautery
Robinson technique: Coblation (not FDA indication)

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Tongue Resection: Midline Glossectomy, SMILE, Hyoepiglottoplasty, and Lingual Tonsillectomy
Most series have mean BMI in obese range (29-36)
Mean baseline AHI wide range but higher than RF/TS
Success rates 25-100% in different series
Factors associated with outcomes
AHI
BMI (31 in responders vs. 38 in nonresponders)

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Hyoid Suspension
Rationale: Pharyngeal soft tissues attach to mobile hyoid bone
Advance hyoid, limit mobility
Mandible inferior border with fascia lata or sutures
(Repose/Airvance)--suture breakage?
Superior border of thyroid cartilage

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Hyoid Suspension in Combination with Other HP Procedures: Case Series
Wider range of mean BMI
Mean baseline AHI wide range but higher than RF/TS
Success rates 20-80% in different series, for different techniques
Factors associated with outcomes
AHI
BMI 30, 32
SNB angle on lateral cephalogram (normal 80±2 degrees; >78 degrees)
Age (one study; not examined much as a factor)
Partial Epiglottidectomy

Resection of portion of epiglottis

Below: central suprathyroid vs. central above vallecula
Others resect lateral portions

<table>
<thead>
<tr>
<th>BMI</th>
<th>Pre AHI</th>
<th>Post AHI</th>
<th>Success (AHI)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>36.0</td>
<td>73</td>
<td>47°</td>
<td>25% (3/12)</td>
<td>Mickelson 1997 (midline gloss)</td>
</tr>
<tr>
<td>42</td>
<td>8°</td>
<td>Selection by displacement of epiglottis from tongue base</td>
<td>Catalfumo 1998</td>
<td></td>
</tr>
<tr>
<td>23.4</td>
<td>45</td>
<td>14°</td>
<td>78% (21/27) Selection same as Catalfumo</td>
<td>Golz 2000</td>
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Hypoglossal Nerve Stimulation Technologies

Three companies in this area: Apnex Medical, ImThera, and Inspire Medical Systems.

Inspire Medical Pivotal Trial: Strollo NEJM 2014

- Single arm
- 12 centers: US, Europe
- Safety
- Efficacy
  - AHI
  - ODI
  - FOSQ
  - ESS
  - % sleep O2 <90%
- Key Entry Criteria
  - Failed CPAP
  - AHI 20-50
  - BMI < 32
  - Age: 20 - 70
  - Minimal central/mixed OSA
  - DISE: no CCC palate

Study Schematic and Timeline

Screening (PSG) → Implant → Therapy ON → Randomized Withdrawal (n = 46) → Long term Follow-Up

BL 0M 1M 12M 13M
Event Descriptions Outcomes

3 Device Explants
- 1 Infection/Hematoma
- 2 Elective Explants
  - Device explanted without sequelae
  - Underwent multilevel pharyngeal surgery and subsequently had an explant.
  - Second subject decided to withdraw before system activation and requested explant. Both underwent device explant without sequelae.

2 Cuff Dislodgements
- Occurred early in postoperative period. Surgical revision and re-placement required. Both subjects continued in the study with no further sequelae.

Inspire Medical: one explant for infection
ImThera: device and technical failures early (IPG, leads, external charger); no explants

Factors Associated with Outcomes

BMI: cutpoint of 30 or 32 kg/m²
AHI: more important than for palate surgery outcomes
Mandible/SNB: not as thoroughly studied (lack of cephalogram data?) but appears to be important
Structures: VOTE
Age?: very little data, but I believe important

Velum/Palate
- UPPP ± tonsillectomy
- Other palate procedures (ESP and LP)

Oro LW
- ? Hyoid suspension, ESP, LP, MAD/MMA

Tongue
- Genioglossus advancement
- Tongue RF
- Tongue stabilization
- Tongue resection (BMI >30/32)

Epiglottis
- Hypoglossal nerve stimulation
- Hyoid suspension vs. Partial epiglottectomy

Maxillofacial
- MMA

Counseling patients key: BMI, AHI, mandible (SNB), age
Conclusions

Selecting a hypopharyngeal surgery based on:

- Procedure technique (mechanism of action)
- Patient anatomy (evaluation)
- Factors associated with outcomes
- Surgeon training and experience
- Patient preferences

Poor outcomes have always been considered a failure of surgical technique/skill

Selection of appropriate procedure(s) may be just as important