Palatal Surgery for the Management of OSA

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Disclosures
The following personal financial relationships with commercial interests relevant to this presentation:

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Apnex Medical
ReVENT Medical
Inspire Medical Systems
Split Rock Scientific
Berendo Scientific
Magnap
Overview

Palate Procedures

UPPP

Expansion Sphincter Pharyngoplasty
--Singapore (Pang), US (Woodson), and Italy (Campanini/Sorrenti)

Lateral Pharyngoplasty
--Brazil (Cahali), version 4/5

Palate Surgery and Outcomes
The Efficacy of Surgical Modifications of the Upper Airway in Adults With Obstructive Sleep Apnea Syndrome

An American Sleep Disorders Association Review

Aaron E. Sher¹, Kenneth S. Schechtman² and Jay F. Piccirillo³

Summary: This paper, which has been reviewed and approved by the Board of Directors of the American Sleep Disorders Association, provides the background for the Standards of Practice Committee’s parameters for the practice of sleep medicine in North America. The intent of this paper is to provide an overview of the surgical treatment of obstructive sleep apnea syndrome, to provide the basis for the American Sleep Disorders Association’s practice parameters on this subject and to share our findings of meta-analysis of previously published studies regarding uvulopalatopharyngoplasty. We searched MEDLINE from January 1996 through April 1992, with an update in February 1993, to provide a review of the application of surgical modifications of the upper airway to treat adults with obstructive sleep apnea syndrome. Operations to treat obstructive sleep apnea syndrome include nasal septal resection; uvulopalatopharyngoplasty; uvulopalatopharyngoplasty + laser midline glossectomy; lingualplasty; inferior sagittal mandibular ostectomy and genioglossal advancement, with hyoid myotomy and suspension (the entire process is referred to as GAMS); maxillomandibular ostectomy and advancement; and tracheotomy. Papers included in meta-analysis provided prospective and retrospective polygraphic data on a total of 463 patients treated with uvulopalatopharyngoplasty for their obstructive sleep apnea. Analysis of the uvulopalatopharyngoplasty papers revealed that this procedure is, at best, effective in treating less than 50% of patients with obstructive sleep apnea syndrome. The site of pharyngeal narrowing or collapse, although identified by different and unvalidated methods, has a marked effect on the probability of success of uvulopalatopharyngoplasty. Patients who present with a nasopharyngeal site of obstruction tend to have better results than those who do not. For patients who demonstrate retrofingual narrowing or collapse, other surgical modifications have been described, such as lingualplasty, GAMS, and maxillomandibular ostectomy and advancement. The studies to support the use of the surgical treatment of obstructive sleep apnea syndrome contain biases related to small sample size, limited follow-up and patient selection.

Sher, Sleep 1996;19:156-177

http://sleep-doctor.com/blog
Table 8—Response rates correlated to definition of response based on location of pharyngeal narrowing or collapse

<table>
<thead>
<tr>
<th>Variable used to measure response</th>
<th>Type I (n = 111)</th>
<th>Type II or III (n = 57)</th>
<th>Unknowns location (n = 177)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% Decrease in AI</td>
<td>65/109 (60.7)</td>
<td>42/11 (36.4)</td>
<td>60/67 (89.6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>50% Decrease in RDI</td>
<td>47/109 (67.1)</td>
<td>9/18 (50.0)</td>
<td>56/67 (84.8)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>50% Decrease in either AI or RDI</td>
<td>83/109 (76.1)</td>
<td>12/11 (109.1)</td>
<td>100/177 (58.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>50% Decrease in RDI and a postopera-</td>
<td>57/109 (52.3)</td>
<td>35/7 (53.3)</td>
<td>77/177 (45.0)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

137/337 = 40.7%
Palate Surgery Helps: Palate vs. Tongue Obstruction

Adapted from Table 7

Sher et al. SLEEP 1996;19:156-177

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Modified Expansion Sphincter Pharyngoplasty

http://sleep-doctor.com/blog
Modified Expansion Sphincter Pharyngoplasty

Hard Palate (Bone)
Soft Palate
Palatopharyngeus m.
Palatoglossus m.
Superior Pharyngeal Constrictor m.

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Modified Expansion Sphincter Pharyngoplasty

http://sleep-doctor.com/blog
Modified Expansion Sphincter Pharyngoplasty

http://sleep-doctor.com/blog
Expansion Sphincter Pharyngoplasty
Pang and Woodson 2007

RCT; n=45 (23 ESP, 22 UPPP)
Tonsil 1+ or 2+
BMI < 30
“Type I Fujita and lateral wall collapse on [Muller's m.]”

Results: decreased lateral wall collapse with Muller’s m.

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Modified ESP + TORS
Vicini Head Neck 2013

Case series (n = 12 v. 12)

UPPP + TORS
Modified ESP + TORS

Decrease in AHI in both
Bigger decrease with modified ESP

http://sleep-doctor.com/blog
Lateral Pharyngoplasty

http://sleep-doctor.com/blog
Lateral Pharyngoplasty: Outcomes

Cahali SLEEP 2004 (version 1)

RCT: LP (15) vs. UPPP (12)

MMP 3/4, + tonsils, FOE suggesting palate only

<table>
<thead>
<tr>
<th></th>
<th>BMI</th>
<th>AHI Pre</th>
<th>AHI Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>LP</td>
<td>29.3</td>
<td>42</td>
<td>16*</td>
</tr>
<tr>
<td>UPPP</td>
<td>30.1</td>
<td>35</td>
<td>30</td>
</tr>
</tbody>
</table>

Improvement in airway dimensions (awake CT neck before and after surgery)

Pillar Procedure

Insertion of three polyethylene terephthalate (PET, same as Dacron) implants into soft palate

Premise: implants and fibrosis create stiffening that decreases airway compromise and snoring

FDA Clearance (2003):
Primary snoring and mild-moderate OSA
Pillar Procedure—Mild to Moderate OSA

Friedman et al., Otolaryngology—HNS 2008
62 patients randomized to placebo vs. Pillar

AHI 5-40; MMP I/II/III; BMI ≤ 32; soft palate 2-3.5 cm
--careful patient selection, similar to other studies

AHI 24 to 16 in treatment group; 20 to 21 in placebo
Meaningful AHI improvement: 41% (Pillar) vs. 0%
ESS and subjective snoring improved

http://sleep-doctor.com/blog
**Pillar Procedure—Mild to Moderate OSA**

Steward et al., Otolaryngology—HNS 2008
100 patients randomized to placebo vs. Pillar

AHI 10-40; MMP I/II; BMI ≤ 32; tonsils 0-2+
--careful patient selection, similar to Friedman 2008

AHI increased (17 to 20, but NS); Placebo greater increase (17 to 26; p < 0.001)
Meaningful AHI improvement: 26% (Pillar) vs. 10%
ESS, FOSQ, and subjective snoring improved

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**Palate Surgery and Clinical Outcomes**

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CPAP and Palate Surgery Effectiveness: Mortality

Marti et al., Eur Resp J 2002

Research Questions:
Is OSA associated with increased mortality?
Does treatment of OSA reduce mortality?

Cohort study (n=444 OSA; AHI ≥ 10)
Baseline AHI 55 ± 27
Treatments: none (98), dietary changes/weight loss (134), CPAP (124), UPPP (88)
Age- and gender-matched controls (1:1)

Table 5. — Observed and expected overall mortality, adjusted for age and sex, rate ratio (RR) and 95% confidence interval (CI)

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Expected</th>
<th>RR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nontreated SAHS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>25</td>
<td>5.46</td>
<td>4.58</td>
<td>3.09–6.78</td>
</tr>
<tr>
<td>Females</td>
<td>5</td>
<td>0.62</td>
<td>8.07</td>
<td>2.00–31.19</td>
</tr>
<tr>
<td>Age in males</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17–50 yrs</td>
<td>4</td>
<td>0.25</td>
<td>16.66</td>
<td>6.03–42.80</td>
</tr>
<tr>
<td>51–60 yrs</td>
<td>8</td>
<td>1.35</td>
<td>5.95</td>
<td>2.07–11.89</td>
</tr>
<tr>
<td>&gt;60 yrs</td>
<td>13</td>
<td>3.87</td>
<td>3.36</td>
<td>1.95–5.79</td>
</tr>
<tr>
<td>Test for trend</td>
<td></td>
<td></td>
<td></td>
<td>p&lt;0.05</td>
</tr>
<tr>
<td>Treated SAHS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>17</td>
<td>13.20</td>
<td>1.29</td>
<td>0.80–2.07</td>
</tr>
<tr>
<td>Females</td>
<td>2</td>
<td>1.81</td>
<td>1.11</td>
<td>0.16–7.70</td>
</tr>
<tr>
<td>Age in males</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17–50 yrs</td>
<td>1</td>
<td>1.42</td>
<td>0.71</td>
<td>0.10–5.01</td>
</tr>
<tr>
<td>51–60 yrs</td>
<td>6</td>
<td>4.45</td>
<td>1.35</td>
<td>0.61–3.00</td>
</tr>
<tr>
<td>&gt;60 yrs</td>
<td>10</td>
<td>7.33</td>
<td>1.36</td>
<td>0.73–2.53</td>
</tr>
<tr>
<td>Test for trend</td>
<td></td>
<td></td>
<td></td>
<td>p&gt;0.20</td>
</tr>
</tbody>
</table>

SAHS: sleep apnoea/hypopnoea syndrome.

Untreated OSA (mainly severe OSA) associated with increased mortality

Fig 3. — Kaplan-Meier estimate of the survival curve for sleep apnoea/hypopnoea syndrome patients, according to whether they were treated (—) or not treated (—).
OSA Treatment Effectiveness: Mortality (Marti 2002)

OSA treatment is associated with lower mortality

Diet/weight loss

CPAP

UPPP

Adjusted for AHI, gender, smoking, comorbidity

Table 3.—Cox regression: overall mortality

<table>
<thead>
<tr>
<th>Variable</th>
<th>Original model</th>
<th>Added variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;60 y</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>BMI &gt;25 kg/m²</td>
<td>1.10</td>
<td>1.10</td>
</tr>
<tr>
<td>AHI history</td>
<td>1.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>

CPAP and Palate Surgery Effectiveness: Mortality

Weaver E et al., Oto—HNS 2004

Research Question: Is providing CPAP associated with better survival than UPPP (with or without other OSA surgeries)?

All VAMCs FY 1998-2001

18,754 CPAP

2,072 UPPP (39 trach, 32 tongue procedures)

Adjustment: age, gender, race, comorbidity, tx year

No adjustment: OSA severity, CPAP compliance

http://sleep-doctor.com/blog
CPAP and Palate Surgery Effectiveness: Mortality

Unfair comparison
Palate surgery alone may not be adequate surgical treatment for many OSA patients
CPAP benefits vary dramatically based on compliance

Palate surgery not better than effective CPAP, although definition of compliance unclear
Key is having effective treatment (requires use of CPAP and SDB improvement for surgery)

Adjusted CPAP hazard ratio: 1.31 (1.03-1.67)
## What Do I Do?: Structure-Based Approach

<table>
<thead>
<tr>
<th>Area</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Velum/Palate</td>
<td>UPPP ± tonsillectomy—tissue bulk</td>
</tr>
<tr>
<td></td>
<td>ESP—normal/thin palate, lateral walls</td>
</tr>
<tr>
<td>Oro LW</td>
<td>LP—thick lateral walls</td>
</tr>
<tr>
<td>Tongue</td>
<td>? Hyoid suspension, ESP, LP, MAD/MMA</td>
</tr>
<tr>
<td>Epiglottis</td>
<td>Genioglossus advancement</td>
</tr>
<tr>
<td></td>
<td>Tongue RF</td>
</tr>
<tr>
<td></td>
<td>Tongue stabilization</td>
</tr>
<tr>
<td></td>
<td>Tongue resection (BMI &gt;30/32)</td>
</tr>
<tr>
<td>Maxillofacial</td>
<td>Hyoid suspension vs. Partial epiglott</td>
</tr>
</tbody>
</table>

## Summary

- UPPP improves AHI and mortality
- Newer palate procedures appear to have better outcomes, at least in selected populations
- Pillar Procedure generally not for OSA
- Goal: improving matching of palate procedures to anatomy