Duration of Patency of Laser-Assisted Tympanic Membrane Fenestration

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Background: Laser-assisted tympanic membrane fenestration (LTMF) provides intermediate-duration middle ear ventilation, which benefits selected children with acute otitis media (AOM) and otitis media with effusion (OME).

Objective: To evaluate clinical and technical factors that may affect duration of LTMF patency.

Design: Prospective clinical cohort effectiveness trial.

Setting: Four tertiary care children’s hospitals.

Patients: Volunteer sample of 251 children (430 ears) followed up at 1, 2, 3, 4, 8, and 12 weeks; time to fenestration closure was evaluable in 201 ears, and assessment of cure at study conclusion was evaluable in 128 ears.

Interventions: Laser-assisted tympanic membrane fenestration for prospectively defined AOM or OME. The surgeon determined spot size, wattage, and concurrent adenoidectomy based on clinical judgment.

Main Outcome Measures: Cure of AOM/OME with effusion at 90 days and duration of LTMF patency relative to spot size (1.8-2.8 mm), fenestration location on tympanic membrane, power (7-22 W), concurrent adenoidectomy, age, diagnosis (AOM vs OME), type of effusion, and preoperative tympanogram characteristics. Results are based on the number of ears that could be evaluated at each data collection interval.

Results: Fenestrations remained patent for 2 to 4 weeks (mean = 2.52, median = 2.0, SD = 1.4, n = 201); 97.4% were closed at 6-week follow-up. Spot sizes of 2.4 and 2.6 mm had a higher rate of patency than the 2.0-mm spot size at 3 weeks following LTMF. Cure at 90 days was related to fenestration patency for all patients combined and for patients treated for AOM and OME, but not for those undergoing adjunctive adenoidectomy. Cure at 90 days was related to larger spot size for all patients combined and those treated for AOM. Other investigated factors did not achieve statistical significance.

Conclusions: Spot size of 2.4 mm or greater results in improved duration of LTMF patency, persisting for up to 3 weeks after LTMF, especially for treatment of AOM. Increased duration of LTMF patency correlates with greater incidence of cure of middle ear effusion at 90 days. Additional investigation is indicated to determine optimum spot size and optimum duration of patency for disease- and severity-adjusted populations.

Arch Otolaryngol Head Neck Surg. 2003;129:825-828
Laser-assisted tympanic membrane fenestration may be superior to myringotomy in children with clinical treatment failure of acute OM (AOM). The Centers for Disease Control and Prevention suggests performing tympanocentesis in children who demonstrate a lack of clinical improvement in signs and symptoms of AOM after 3 days of therapy to identify the etiologic agent and test for antibiotic susceptibility.1 Obtaining a culture is particularly important if a child has recently received multiple courses of antimicrobial therapy and is therefore more likely to harbor a multiple-resistant strain of bacteria.1 In this situation, LTMF provides access to obtain middle ear culture material but may also provide immediate pain relief and hasten recovery. Laser-assisted tympanic membrane fenestration can be performed in an office setting on an urgent basis using topical anesthesia.

Fenestration creates a round opening in the TM within a fraction of a second and is usually bloodless. The carbon dioxide laser system (OtoLAM; ESC/Sharplan, Yokneam, Israel) equipment required and the characteristics of the opening in the TM are different from those associated with incisions made with a scalpel or with conventional carbon dioxide laser. Fenestration generally lasts 2 or 3 weeks, while the duration of patency of cold-knife myringotomies is typically 48 to 72 hours,2 and middle ear ventilation tubes frequently remain patent for months to years.

For these reasons, LTMF is being investigated for treatment of AOM unresponsive to medical management, recurrent AOM, and for treatment of OME, with or without adenoidectomy. This study addresses the optimum duration of middle ear fenestration for the treatment of OM and factors that may affect duration of LTMF patency, as well as correlates duration of fenestration patency with incidence of cure of OM at 90 days.

METHODS

PATIENTS

Three hundred three children (519 ears) with OM with effusion (OME) or AOM were prospectively enrolled in a multisite clinical cohort trial of LTMF by 4 hospital-based pediatric otolaryngology groups from June 1998 through March 1999. Children who underwent simultaneous ventilation tube placement were excluded from further analysis. The remaining 251 children (+30 ears) who underwent LTMF without ventilation tube placement comprise the study population. Time to fenestration closure was evaluable in 201 ears, and assessment of cure at study conclusion (90 days) was evaluable in 128 ears. Patients underwent LTMF for treatment of AOM unresponsive to medical management, recurrent AOM, and OME, with or without adenoidectomy. Institutional review board approval and informed consent were obtained.

INTERVENTION

Patients underwent LTMF using an OtoLAM device, a carbon dioxide Flashscanner laser (ESC/Sharplan), that creates a round fenestration in the TM. The surgeon determined spot size, power, and need for concurrent adenoidectomy (with or without tonsillectomy) based on individual patient characteristics and clinical judgment. The design of the laser allows precise selection of spot size and power. Spot size ranged from 1.8 to 2.8 mm and power from 7 to 22 W. In general, thicker tympanic membranes required higher power or more than 1 laser discharge.

Topical anesthesia, consisting of 8% to 16% tetracaine, was used for patients undergoing LTMF in an office setting. General anesthesia was used for patients undergoing LTMF in the operating room.

DATA COLLECTION

Duration of LTMF patency was evaluated by examination at 1, 2, 3, 4, 8, and 12 weeks. Cure of AOM or OME, defined as both normal pneumatic otoscopy examination findings and a type A or C1 tympanogram, was assessed at 12 weeks.

Data collected included spot size in millimeter increments, location of fenestration by TM quadrant, power (watts), concurrent adenoidectomy, age (≤24, 25-48, >48 months), diagnosis (AOM, OME, or OM treated in conjunction with adenoidectomy), type of effusion (none, serous, mucoid, bloody, purulent, mixed, or other), and preoperative tympanogram characteristics.

STATISTICAL ANALYSIS

The χ² test was used to detect statistically significant differences between frequency or rates. P<.05 was considered significant.

RESULTS

Laser fenestrations generally remained patent for 2 or 3 weeks (mean [median] ±SD, 2.52 [2.00] ±1.4 weeks; n=201). At 1- and 2-week follow-up, 2.4- and 2.6-mm spot size resulted in a greater percentage of patent fenestrations than 2.0-mm spot size (week 1: t199=3.00 and 3.27 for 2.4- vs 2.0-mm and 2.6- vs 2.0-mm spot size, respectively [P<.01]; week 2: t199=2.01 for 2.4- and 2.6-mm vs 2.0-mm spot size [P<.05]; Figure 1). While 2.2-mm spot size resulted in a greater percentage of patent fenestrations than 2.0-mm spot size and a smaller percentage than 2.4- or 2.6-mm spot size at weeks 1 and 2, these differences were not statistically significant. No significant differences were found for patent fenestration rates at any follow-up period thereafter.

Meaningful statistical analysis could not be accomplished on (1) the single TM treated with a spot size of 1.8 mm, which closed at 1 week; (2) the single TM treated...
with a spot size of 2.5 mm, which closed at 4 weeks; and (3) the 3 TMs treated with a spot size of 2.8 mm, one of which closed at 8 weeks and the other two at 12 weeks (all 3 achieved cure at 90-day follow-up).

Two TMs that were treated with spot sizes of 2.4 and 2.6 mm remained patent at the end of the study period. One closed by the 6-month follow-up and one closed after paper patch myringoplasty. Other investigated factors did not achieve statistical significance as predictors for duration of fenestration patency: age of patient, primary indication for LTMF, type of fluid, wattage, preoperative tympanogram, or quadrant of TM undergoing fenestration. At the time of fenestration, fluid was found in the mesotympanum in 87.3% of 430 ears.

Cure, defined as normal findings from pneumaticotony and type A or C tympanograms at the 90-day follow-up, was accomplished in 68.8% of 128 ears evaluable at 90 days (including 63.2% of 38 ears with AOM), 65.0% of 60 ears with OME, and 83.3% of 30 ears that underwent fenestration in conjunction with adenoidectomy. Longer duration of fenestration was associated with higher 90-day cure rates for all patients combined ($\chi^2 = 221.3; P < .001$), patients with AOM ($\chi^2 = 77.6; P < .001$), and patients with OME ($\chi^2 = 120.6; P < .001$; Table 1 and Figure 2). Duration of fenestration did not correlate with 90-day cure rate for patients undergoing LTMF in conjunction with adenoidectomy, but the incidence of cure in this group was greater than in the other groups.

Larger spot size correlated positively with higher 90-day cure rates for all patients combined ($\chi^2 = 50.2; P = .01$) and for patients treated for AOM ($\chi^2 = 31.6; P = .002$), but not for patients treated for OME or patients undergoing LTMF in conjunction with adenoidectomy (Table 2 and Figure 3).

**COMMENT**

The duration of LTMF patency is affected by spot size, but not by other patient or laser characteristics addressed in this study. Increased duration of patency was accomplished with spot sizes of 2.4 and 2.6 mm compared with smaller spot sizes. It is conceivable that further increases in spot size may further increase the duration of patency, but this potential must be balanced against the presumed risks of persistent perforation and damage to adjacent structures such as the external ear canal and ossicles. Other fenestration shapes may also provide increased duration of patency. Valtosen et al demonstrated in an animal model that the geometry of laser fenestration affects the duration of patency, with kidney bean–shaped and semicircular openings remaining patent longer than circular openings.

In the present study, the incidence of cure at 90 days for AOM and OME is greater than 60%, and the incidence of cure for OM treated in conjunction with adenoidectomy is greater than 80%. It is difficult to compare these results with historic data for several reasons. This study included children younger than 2 years and children with severe disease; in many studies of outcome or resolution of AOM and OME, these groups are excluded. In addition, in our study group, patients were enrolled only after medical management had failed, so this study population may represent children with more severe or more recalcitrant disease. This analysis also does not address which children received benefit, evidenced by resolution of signs and symptoms of disease, during the period when the fenestrations were patent.

Many of the study participants were children who could otherwise have qualified for placement of middle ear ventilation tubes. Ventilation tubes have provided tremendous benefit for children with both AOM and OME, but for some children they may continue to function longer than necessary and can cause concomitant problems. Often, children with upper airway obstruction from adenotonsillar hypertrophy are incidentally found to have middle ear effusions and hearing loss of uncertain duration. Laser-assisted tympanic membrane fenestration at the time of adenoidectomy (with or without tonsillectomy) may provide a period of middle ear ventilation that would otherwise be provided by ventilation tubes.

**Table 1. Data Demonstrating Incidence of Cure at 90 Days by Duration of LTMF Patency and Diagnosis**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>8</th>
<th>12</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ears</td>
<td>3/14 (21.4)</td>
<td>38/54 (70.4)</td>
<td>28/33 (84.8)</td>
<td>17/22 (77.3)</td>
<td>2/3 (66.7)</td>
<td>0/2</td>
<td>88/128 (68.8)</td>
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<tr>
<td>AOM</td>
<td>1/6 (16.7)</td>
<td>17/23 (73.9)</td>
<td>2/4 (50.0)</td>
<td>3/3 (100)</td>
<td>1/1 (100)</td>
<td>0/1</td>
<td>24/38 (63.2)</td>
</tr>
<tr>
<td>OME</td>
<td>1/5 (20.0)</td>
<td>13/22 (59.1)</td>
<td>16/19 (84.2)</td>
<td>8/12 (66.7)</td>
<td>1/1 (100)</td>
<td>0/1</td>
<td>38/60 (63.3)</td>
</tr>
<tr>
<td>OME + A</td>
<td>1/3 (33.3)</td>
<td>8/9 (88.9)</td>
<td>10/10 (100)</td>
<td>6/7 (85.7)</td>
<td>0/1</td>
<td>0/0</td>
<td>25/30 (83.3)</td>
</tr>
</tbody>
</table>

Abbreviations: A, adenoidectomy; AOM, acute otitis media; LTMF, laser tympanic membrane fenestration; OM, otitis media; OME, otitis media with effusion.

*Data are number cured/number of LTMFs (percentage).
Larger spot size (≥2.4 mm) and longer duration of fenestration patency resulted in an increased incidence of cure for OM patients with AOM, and increased duration of patency correlated favorably with increased incidence of cure for patients with OME. These findings suggest that LTMF can have a beneficial impact in the treatment of AOM and OME.

Table 2. Data Demonstrating Incidence of Cure at 90 Days by Spot Size and Diagnosis*

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>2.0</th>
<th>2.2</th>
<th>2.4</th>
<th>2.6</th>
<th>2.8</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ears</td>
<td>6/8 (75.0)</td>
<td>14/30 (46.7)</td>
<td>31/39 (79.5)</td>
<td>35/49 (71.4)</td>
<td>2/2 (100)</td>
<td>88/128 (68.8)</td>
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<tr>
<td>AOM</td>
<td>2/3 (66.7)</td>
<td>5/15 (33.3)</td>
<td>12/14 (85.7)</td>
<td>5/6 (83.3)</td>
<td>0/0</td>
<td>24/30 (80.0)</td>
</tr>
<tr>
<td>OME</td>
<td>4/5 (80.0)</td>
<td>8/14 (57.1)</td>
<td>15/19 (78.9)</td>
<td>11/21 (52.4)</td>
<td>1/1 (100)</td>
<td>39/60 (65.0)</td>
</tr>
<tr>
<td>OM+A</td>
<td>0/0</td>
<td>1/1 (100)</td>
<td>4/6 (66.7)</td>
<td>19/22 (86.4)</td>
<td>1/1 (100)</td>
<td>25/30 (83.3)</td>
</tr>
</tbody>
</table>

*Data are number cured/number of LTMFs (percentage).

The duration of ventilation is related to laser spot size; fenestrations created with spot sizes of 2.4 and 2.6 mm generally remained patent for 2 to 3 weeks. Larger spot size (≥2.4 mm) and longer duration of ventilation tubes. When treatment of AOM or OME is necessary in the spring, intermediate-duration middle ear ventilation may obviate the need for water precautions during the summer swimming season.

Both larger spot size (≥2.4 mm) and longer duration of fenestration patency are associated with greater incidence of cure of OM at 90-day follow-up. Increased duration of patency and larger spot size correlated favorably with increased incidence of cure for patients with AOM, and increased duration of patency correlated favorably with increased incidence of cure for patients with OME. These findings suggest that LTMF can have a beneficial impact in the treatment of AOM and OME.

CONCLUSIONS

Laser-assisted tympanic membrane fenestration using the OtoLAM device provides intermediate-duration middle ear ventilation. The duration of ventilation is related to laser spot size; fenestrations created with spot sizes of 2.4 and 2.6 mm generally remained patent for 2 to 3 weeks. Larger spot size (≥2.4 mm) and longer duration of fenestration patency resulted in an increased incidence of cure for OM. Additional investigation is indicated to determine optimum spot size and optimum duration of fenestration to achieve the best incidence of cure accompanied by the lowest incidence of complications in the treatment of OM for disease- and severity-adjusted populations.

Submitted for publication May 25, 2000; final revision received November 21, 2002; accepted November 26, 2002.

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We wish to thank Charles Bower, MD, Patrick Brookhauser, MD, David Chait, MD, Mark Nagy, MD, Michael Pizzuto, MD, Christopher Poje, MD, Gordon Siegel, MD, and Milton Waner, MD, for their valuable contributions to this multicenter study.

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