Local versus General Anesthesia in Stapes Surgery for Otosclerosis: A Systematic Review of the Evidence

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What is This?
Local versus General Anesthesia in Stapes Surgery for Otosclerosis: A Systematic Review of the Evidence

Inge Wegner, MD1, Arnold J. N. Bittermann, MD1,2, Margitta M. Zinsmeester1, Geert J. M. van der Heijden, PhD1,3, and Wilko Grolman, MD, PhD1,2

Abstract

Objective. To assess hearing results following primary stapes surgery in patients with otosclerosis, comparing local and general anesthesia.

Data Sources. PubMed, Embase, the Cochrane Library, CINAHL, and Scopus.

Review Methods. A systematic search was conducted, followed by assessment of directness of evidence and risk of bias. Studies reporting original data on the effect of local anesthesia, compared to general anesthesia, on closure of air-bone gap in patients undergoing stapes surgery for otosclerosis were included.

Results. A total of 257 unique studies were retrieved, of which 3 (including 417 procedures) satisfied the eligibility criteria. Assessment showed that all studies carried high risk of bias, and only 1 study provided direct evidence.

Conclusion. There is no difference in postoperative air-bone gap, worsening of sensorineural hearing loss, and postoperative vertigo between the 2 groups. A statistically significant increased risk of immediate dead ear following stapes surgery performed under general anesthesia was reported in 1 study.

Keywords
otosclerosis, stapes surgery, local anesthesia, general anesthesia, hearing recovery, pure-tone audiometry

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Clinical Question
A 50-year-old female is referred to the ENT department with progressive hearing loss. Otological examination shows left-sided conductive hearing loss, which is confirmed by pure-tone audiometry (PTA). CT images show bony deposits around the oval window. The diagnosis of otosclerosis is made. The ENT-surgeon suggests treating the patient with stapes surgery. However, the patient has a fear of general anesthesia and would rather have the surgery done under local anesthesia.
out the answer to the following clinical question: “What is the effect of local anesthesia, compared to general anesthesia, on recovery of hearing loss as measured by postoperative air-bone gap at 1 year follow-up in patients undergoing primary stapes surgery for otosclerosis?”

Methods
A systematic search in PubMed, Embase, the Cochrane Library, CINAHL, and Scopus was conducted, using synonyms for stapes surgery and anesthesia and relevant MeSH terms (see Table 1). Two independent assessors (IW and MZ) screened the titles and abstracts of the retrieved records for inclusion, and duplicates were excluded. Only records reporting original study data on the effect of both local anesthesia and general anesthesia in patients undergoing stapes surgery for otosclerosis were included (see Figure 1 for selection criteria). Systematic reviews, opinion papers, animal studies, and case reports were excluded. Related publications were searched in PubMed, while Scopus and Web of Science were used for cross-reference checking for studies not identified by the initial literature search. Selected articles, related reviews, meta-analyses, and guidelines were hand searched for relevant cross-references.

Predefined criteria were used for assessment of the directness of evidence and risk of bias of the selected articles (see Table 2). Initial discrepancies were discussed until consensus was reached. All studies with both low directness of evidence and high risk of bias were excluded for further review. Studies were classified as having high, moderate, or low directness of evidence if they complied with all 3, 2, or 1 of these criteria, respectively. If studies complied with all, 2, or 1 criteria used to assess risk of bias, they were classified as having a low, moderate, or high risk of bias, respectively.

Outcome data of the included studies were extracted and calculated by 2 independent authors (IW and MZ). The primary outcome measure was closure of the air-bone gap to within 10 decibels or less, which is generally considered a successful outcome of stapes surgery in the literature.4-7 According to the Committee on Hearing and Equilibrium, follow-up should be at least 1 year for this outcome measure since results change over time and long-term results provide a more realistic prognosis.8 Secondary outcome measures were worsening of sensorineural hearing loss, defined as changes in pure-tone audiometry exceeding 5 decibels or more; vertigo; and other complications. Preferably absolute risks were extracted or calculated. If these were not given or could not be calculated, the outcome measure as used in the article was reported.

Results
A total of 597 titles were retrieved, of which 257 were unique studies (see Figure 1; date of last search was March 11, 2013). After selection based on title and abstract and subsequent full-text screening, 3 articles9-11 were considered eligible for answering our question. Of 4 articles that could not be excluded based on their titles,12-15 no abstracts or full-texts were available, despite an extensive search in the available literature databases, university networks, and Google Scholar. We judge it highly unlikely that original study data are reported in these articles. Cross-reference checking revealed no additional articles. The selected studies included in total 417 procedures in 397 patients. All studies were case series. Assessment of their reported methods showed that only 1 study9 provided direct evidence (see Table 2). Important limitations in the directness of evidence were found in the other 2 studies, notably inclusion of patients who had undergone revision stapes surgery10,11 or stapes surgery for other reasons than otosclerosis.10 Revision stapes surgery is associated with an increased risk of postoperative sensorineural hearing loss, and hearing outcome is less favorable when compared to primary surgery.16 Furthermore, revision is technically far more challenging than primary stapes surgery, and the technique of repair is usually determined by the surgical findings at the time of revision.16 Therefore, studies reporting the results of revision stapes surgery do not provide direct evidence for answering the clinical question. These 2 studies were included for further analysis nonetheless. The risk of

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Table 1. Search for studies on the effect of local anesthesia, compared to general anesthesia, in patients undergoing primary stapes surgery for otosclerosis (date of search: March 11, 2013).

<table>
<thead>
<tr>
<th>Database</th>
<th>Search</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>PubMed</td>
<td>(stapedect* OR stapedot* OR poststapedect* OR poststapedot* OR otoscler* OR otospongiosis OR stapes OR stapedial OR ossicular OR footplate) AND (anast* OR anest* OR anaeast* OR sedat* OR narco*)</td>
<td>Title/abstract</td>
</tr>
<tr>
<td></td>
<td>(stapedectomy OR otosclerosis OR stapes) AND (anesthesia)</td>
<td>MeSH terms</td>
</tr>
<tr>
<td>Embase</td>
<td>(stapedect*:ti,ab OR stapedot*:ti,ab OR poststapedect*:ti,ab OR poststapedot*:ti,ab OR otoscler*:ti,ab OR otospongiosis*:ti,ab OR stapes*:ti,ab OR stapedial*:ti,ab OR ossicular*:ti,ab OR footplate*:ti,ab) AND (anast*:ti,ab OR anest*:ti,ab OR anaeast*:ti,ab OR sedat*:ti,ab OR narco*:ti,ab)</td>
<td>Title/abstract</td>
</tr>
<tr>
<td></td>
<td>(stapedectomy/exp OR stapedotomy/exp OR otosclerosis/exp OR otospongiosis/exp OR stapes/exp) AND (anesthesia/exp OR anaesthesia/exp OR sedation/exp OR narcosis/exp)</td>
<td>Entree</td>
</tr>
<tr>
<td>The Cochrane Library</td>
<td>(stapedect* OR stapedot* OR poststapedect* OR poststapedot* OR otoscler* OR otospongiosis OR stapes OR stapedial OR ossicular OR footplate) AND (anast* OR anest* OR anaeast* OR sedat* OR narco*)</td>
<td>Title/abstract</td>
</tr>
<tr>
<td>CINAHL</td>
<td>OR otospongiosis OR stapedial OR ossicular OR footplate) AND (anast* OR anest* OR anaeast* OR sedat* OR narco*)</td>
<td></td>
</tr>
<tr>
<td>Scopus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Table 2. Assessment of reported methods showed that only 1 study provided direct evidence (see Table 2). Important limitations in the directness of evidence were found in the other 2 studies, notably inclusion of patients who had undergone revision stapes surgery or stapes surgery for other reasons than otosclerosis. Revision stapes surgery is associated with an increased risk of postoperative sensorineural hearing loss, and hearing outcome is less favorable when compared to primary surgery. Furthermore, revision is technically far more challenging than primary stapes surgery, and the technique of repair is usually determined by the surgical findings at the time of revision. Therefore, studies reporting the results of revision stapes surgery do not provide direct evidence for answering the clinical question. These 2 studies were included for further analysis nonetheless. The risk of
bias was high in all studies. None of the studies were performed in a randomized fashion, nor was treatment allocation concealed. No information was provided regarding blinding or standardization of treatment in all studies. It is unlikely that both audiometrists and interpreters were blinded for the used anesthesia method, since audiometric results are often interpreted by the surgeon performing the procedure.

The extracted data of the included studies are described in Table 3 and Table 4. There are major dissimilarities between studies regarding type of surgery, type of surgeon, and follow-up duration. As to be expected, there are large differences in the size of the reported absolute effects of both local and general anesthesia between studies reporting on effects in (mainly) patients undergoing primary stapes surgery compared to...
patients undergoing revision surgery.\textsuperscript{11} The difference in postoperative air-bone gap between local and general anesthesia is minimal in all studies with statistically insignificant risk differences of around 1%. The percentage of sensorineural hearing loss in both groups is similar. However, Vital et al did report a statistically significant difference in the occurrence of immediate dead ear; 3 patients (1.9%) in the general anesthesia group versus 0 (0%) in the local anesthesia group.\textsuperscript{9}

Data on potential adverse effects of local and general anesthesia, other than sensorineural hearing loss, were systematically collected by Vital et al.\textsuperscript{9} Mild postoperative vertigo was reported in both groups with a risk difference slightly in favor of local anesthesia. No other adverse effects of either or both local and general anesthesia were reported.

### Translating Evidence into Practice

The amount of available studies on the effect of local anesthesia compared to general anesthesia on postoperative air-bone gap in patients undergoing stapes surgery is limited. Most of these studies provide indirect evidence and carry high risk of bias. They all show no difference in hearing in both groups, except for a statistically significant difference in incidence of dead ear favoring local anesthesia in 1 study.\textsuperscript{9} Since there is only a small difference in clinical effect, it would be interesting

\begin{table}
\centering
\begin{tabular}{|l|l|l|l|l|l|l|}
\hline
& \textbf{Local Anesthesia} & \textbf{General Anesthesia} & \textbf{Type of Stapes Surgery} & \textbf{Type of Surgeon} & \textbf{Pure-Tone Audiometry} & \textbf{Follow-Up Duration} \\
\hline
\textbf{Vital et al (2008)}\textsuperscript{9} & 1% lidocaine with 1:100,000 epinephrine \((n = 160)\) & Method unknown \((n = 108)\) & Primary stapedectomy \((n = 268)\) & ENT specialist \((n = 1)\) & Air and bone conduction pure-tone thresholds at 500 Hz, 1, 2, and 3 kHz & Postoperative PTA showing best hearing within one year of surgery \\
\hline
\textbf{Mathews et al (1999)}\textsuperscript{10} & 1% or 2% lidocaine with 1:100,000 epinephrine, augmented by intravenous sedation and analgesia \((n = 38)\) & Endotracheal intubation, intravenous narcotic agents, and inhaled agents \((n = 33)\) & Primary stapedectomy \((n = 60)\) & Resident surgeons in fourth or fifth postgraduate year \((n = 10)\) & Air and bone conduction pure-tone thresholds at 500 Hz, 1 and 2 kHz & Between 6 and 12 weeks postoperatively \\
\hline
\textbf{Babighian and Albu (2009)}\textsuperscript{11} & Method unknown \((n = 35)\) & Method unknown \((n = 43)\) & Revision stapedotomy following primary stapedotomy \((n = 78)\) & ENT specialist \((n = 1)\) & Air and bone conduction pure-tone thresholds at 500 Hz, 1, 2, 3, and 4 kHz & 1 month, 3 months and every 6 months after revision surgery. Last hearing test available was used in this study. \\
\hline
\end{tabular}
\caption{Study descriptives of studies on the effect of local anesthesia, compared to general anesthesia, in patients undergoing primary stapes surgery for otosclerosis.\textsuperscript{a}}
\end{table}

\begin{table}
\centering
\begin{tabular}{|l|l|l|l|l|l|l|}
\hline
& \textbf{Local Anesthesia} & \textbf{General Anesthesia} & \textbf{Follow-Up Duration} & \textbf{Air-Bone Gap Closure to within 10 dB} & \textbf{Secondary Outcome Measures} & \\
\hline
\textbf{Vital et al (2008)}\textsuperscript{9} & \text{Best PTA within 1 year} & \text{93.2 (90.2-96.2)} & \text{91.7 (88.4-95.0)} & 1.5 (0.04-3.0) & SNHL & 5.4 (2.7-8.1) \text{–} 6.2 (3.3-9.1) \text{–} 1.2 (0.1, 2.5) \\
& \text{n = 160} & \text{n = 108} & \text{–} & \text{–} & Dead ear & 0 \text{–} 1.9 (0.3-3.5) \text{–} 1.9 (0.3-3.5) \\
& \text{–} & \text{–} & \text{–} & \text{–} & Vertigo & 3.7 (1.4-6.0) \text{–} 4.4 (1.9-6.9) \text{–} 0.7 (0.3-1.7) \\
& \text{–} & \text{–} & \text{–} & \text{–} & SNHL & 0 \text{–} 0 \text{–} 0 \\
\hline
\textbf{Mathews et al (1999)}\textsuperscript{10} & \text{n = 38} & \text{n = 33} & \text{6-12 weeks} & \text{86.8 (78.9-94.7)} & \text{87.9 (80.3-95.5)} & –1.1 (–3.5, 1.3) \\
& \text{–} & \text{–} & \text{–} & \text{–} & SNHL & 0 \text{–} 0 \text{–} 0 \\
\hline
\textbf{Babighian and Albu (2009)}\textsuperscript{11} & \text{n = 35} & \text{n = 43} & \text{Every 6 months} & \text{54.3 (43.3-65.4)} & \text{53.5 (42.4-64.6)} & 0.8 (–1.2, 2.8) \\
& \text{–} & \text{–} & \text{–} & \text{–} & SNHL & 0 \text{–} 0 \text{–} 0 \\
\hline
\end{tabular}
\caption{Results of studies on the effect of local anesthesia, compared to general anesthesia, in patients undergoing primary stapes surgery for otosclerosis.\textsuperscript{a}}
\end{table}

\textsuperscript{a}n = number of procedures/surgeons.

\textsuperscript{b}Shows percentage (95% confidence interval).

\textsuperscript{c}P value < .05.

\textsuperscript{d}When risk difference is positive, this favors local anesthesia. n = number of procedures; PTA, pure-tone audiometry; SNHL, sensorineural hearing loss.

\textsuperscript{e}Shows percentage (95% confidence interval).

\textsuperscript{f}P value < .05.
to compare the benefits and costs of both types of anesthesia. Unfortunately, no data were available on the cost-effectiveness of any of the treatment options, and it was not possible to perform a cost-benefit analysis.

As mentioned previously, local anesthesia enables the surgeon to test hearing and recognize vertigo during the procedure. The surgeon can act accordingly immediately, thereby minimizing major complications. This anesthesia method seems to be safer and more beneficial to the patient when compared to general anesthesia. However, the available evidence shows no difference in hearing outcome between the 2 groups. On the other hand, the use of general anesthesia provides substantial advantages during teaching of residents. The patient is immobile and there is no limitation in the duration of anesthesia, enabling the surgeon to operate at a more relaxed and controlled pace and thereby making it possible for residents to complete the entire procedure. Furthermore, the patient is not disturbed by verbal communication among staff and residents during the surgery.

The following needs to be taken into consideration when interpreting these findings. First, the risk of bias is high in all studies. None of the studies were performed in a randomized fashion, nor was treatment allocation concealed. No information was provided regarding blinding or standardization of treatment. Second, the sample sizes are rather small, with the exception of 1 study. In total we were able to report on 417 procedures. Third, the designs of the included studies largely differed in their approach to the surgical intervention, amount and experience of surgeons, and follow-up duration. Therefore, the reported effects cannot simply be compared between studies.

To date the evidence is weak, and therefore no evidence-based recommendations can be provided. Based on the evidence, patients can be informed that it seems as though there is no difference in hearing outcome between local and general anesthesia and there seems to be an increased risk of immediate dead ear following stapes surgery under general anesthesia. The decision will be largely based on patient preference and experience of both surgeons and anesthesiologists with either method.

Conclusion and Recommendation

The available studies on the effect of local anesthesia, compared to general anesthesia, on postoperative air-bone gap in patients undergoing stapes surgery carry substantial high risk of bias. This precludes firm conclusions. All of the studies show no difference in postoperative air-bone gap, sensorineural hearing loss, and postoperative vertigo between the 2 groups. One study, with high directness of evidence and high risk of bias, reported an increased risk of immediate dead ear following stapes surgery under general anesthesia. Taking into consideration the risk of immediate dead ear and the patient’s wishes, it was decided to perform stapes surgery under local anesthesia in this patient.

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Author Contributions

Inge Wegner, writing, data collection, data analysis, interpretation, drafting and revision, approval final version; Arnold J.N. Bittermann, question, design, interpretation, drafting and revision, approval final version; Margitta M. Zinsmeester, writing, data collection, data analysis, interpretation, approval final version; Geert J.M. van der Heijden, design, interpretation, drafting and revision, approval final version, supervision; Wilko Grolman, design, drafting and revision, approval final version, supervision.

Disclosures

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