Repair of Large Traumatic Tympanic Membrane Perforation with a Steri-Strips Patch

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Abstract

Objective. To investigate the effects of the Steri-Strips patch (3M) on the treatment of large traumatic tympanic membrane perforations (TMP).

Study Design. Prospective, randomized, controlled.

Setting. Tertiary university hospital.

Subjects and Methods. A randomized prospective analysis was performed between February 2009 and January 2011 for the treatment of traumatic TMP larger than 50% of the entire tympanic membrane. The results of closure rate, closure time, hearing gain, and rate of otorrhea between conservative observation, paper patching, and Steri-Strips patching groups were compared.

Results. In total, 87 patients were analyzed in this study. The closure rates of the perforations in the Steri-Strips patching, paper patching, and observation groups were 93.3%, 84.2%, and 78.9%, respectively. There was no statistically significant difference in tympanic membrane closure rate between the 3 groups. The Steri-Strips technique decreased the need for repeat procedures. Overall, the Steri-Strips and paper patching groups showed shorter healing times compared with the observation group. However, there was an increased rate of otorrhea in the Steri-Strips group compared with the observation group.

Conclusion. Steri-Strips patching reduced the healing time and need for repeat procedures in patients with large traumatic TMPs. However, the occurrence of otorrhea was significantly more common in patients treated with the Steri-Strips technique.

Keywords

tympanic membrane perforation, trauma, outcome, Steri-Strips

Received February 7, 2011; revised April 12, 2011; accepted April 18, 2011.
Subjects were excluded if there was granulation tissue or persistent otorrhea in the ear, severe vertigo or profound hearing loss, facial palsy, temporal bone fracture, or ossicular disruption suspected by physical examination or imaging study.

Patients were randomized to 3 groups: Steri-Strips treatment, paper patch treatment, or observation only. Randomization was performed using a table of random numbers and SPSS software (version 11.0 for Windows; SPSS, Inc, an IBM Company, Chicago, Illinois). In the Steri-Strips and paper patching groups, patients underwent Steri-Strips or paper patching via a transcanal approach under local anesthesia. In the observation group, there was no intervention, but the patients underwent regular follow-up.

Age, gender, date of injury, cause of traumatic injury, size of TMP, presence or absence of otorrhea, presence of temporal bone fracture or ossicular disruption, and associated clinical findings, such as hearing loss, vertigo, tinnitus, perilymph leak, and facial nerve palsy, were recorded at each visit.

Pure-tone audiograms were obtained using a GSI 10 audiometer (VIASYS Healthcare, Inc, Conshohocken, Pennsylvania) in a quiet room at the initial, postprocedure and final visits or 3 months after traumatic injury or patching. The 4-dimensional method was used at 0.5, 1, 2, and 4 kHz to obtain the pure-tone average.

All patients were examined with an otomicroscope, and the site and size of perforation were documented. A large perforation was defined as a perforation that exceeded 50% of the entire tympanic membrane when viewed using the ImageJ software (version 1.35; Wayne Rasband; National Institute of Health, Rockville, Maryland). After the cerumen or blood clot was carefully cleaned from the external auditory canal with a cotton bud soaked in hydrogen peroxide or alcohol, the perforated edge of the tympanic membrane was approximated by a small suction tip or ear pick. In the observation group, the patients were regularly followed, every 2 or 4 weeks up to 3 months postinjury, without surgical intervention. In the paper or Steri-Strips patching groups, the patients were initially followed 1 week after patching and then regularly every 2 or 4 weeks for 3 months. To reduce bias by the clinician, clinical events, such as detachment of patching, closure of the tympanic membrane, and the occurrence of otorrhea, were photodocumented using color slides at all follow-up visits.

In all groups, if complete closure of the perforation had not taken place after 3 months, tympanoplasty was performed under local or general anesthesia. Otorrhea was controlled by removing the patch and treating with antibiotics. After the otorrhea had resolved, the same patch technique was repeated if the tympanic membrane had not closed.

Surgical Techniques

Under the otomicroscope, the external auditory canal was injected with 2% lidocaine and 1:100,000 epinephrine at the bony cartilaginous junction. A small piece of cigarette paper moistened with saline or a Steri-Strips was trimmed to provide a 1- or 2-mm overlapping margin around the perimeter of the perforation. The paper patch or Steri-Strips, with the sticky side of the Steri-Strips facing the tympanic membrane, was laid over the perforation of the tympanic membrane using microforceps or an ear pick. If the patch detached before complete healing of the TMP, the procedure was repeated. No ear drops or packing of the auditory canal were used in either group.

Statistical Methods

For calculation of the sample size, the study was powered at 80% and a type I error of 5% (α = 0.05) was used. A 10% difference of closure rates between the treatment groups was predicted. Using these values for the calculation, it was determined that 17 patients were needed for each group. Assuming a loss of 10%, the number of patients needed for each group was 19, for a total of 57 patients.

Results are given as mean ± standard deviation or as a percentage. For statistical analysis of the results of the 3 groups, 1-way analysis of variance or Kruskal-Wallis testing was performed for continuous data, and the χ² test was used for categorical data. A 2-sample t test or the Mann-Whitney U test was used to compare the results of 2 groups. The rate of otorrhea between the Steri-Strips and observation groups was compared by Fisher exact test. A P value of <.05 was considered to indicate statistical significance. Statistical analyses were carried out using SPSS software (version 11.0 for Windows; SPSS, Inc).

This study was approved by the Soonchunhyang University Bucheon Hospital Institutional Review Board.

Results

In total, 120 patients were randomized into the study. The patients were divided into 3 groups: treatment with Steri-Strips patching, treatment with paper patching, and observation alone. Eight patients in the Steri-Strips group and 18 patients in the observation-alone group did not receive the allocated intervention after enrollment in the study; they elected to receive another treatment, such as paper patching or tympanoplasty. Six patients were lost to follow-up (Figure 1).

Final analysis was performed on 87 patients (52 men, 35 women) with a diagnosis of large traumatic TMP. The mean patient age was 36.9 (range, 18-73) years. Demographic data for the 3 groups are shown in Table 1. There was no statistically significant difference among the 3 groups with regard to age, gender, duration, or hearing levels. There was no serious complication in the Steri-Strips or paper patching groups.

Treatment outcomes of the 3 groups are shown in Table 2. The mean number of procedures was 1.1 ± 0.30 in the Steri-Strips group and 1.34 ± 0.48 in the paper patching group. Paper patching had to be repeated more often than Steri-Strips patching (P = .02).

The closure rates of perforation in the Steri-Strips patching, paper patching, and observation groups were 93.3%, 84.2%, and 77.2%, respectively. The closure rates among the 3 groups were not statistically different (P = .33).

The mean perforation closure times were 46.4 ± 16.6, 44.7 ± 19.9, and 56.42 ± 16.2 days for the Steri-Strips patching, paper patching, and observation groups, respectively. The closure times among the 3 groups were not statistically different.
However, there was a statistically significant difference between the patching and observation groups with regard to closure time ($P = .007$). There was no statistically significant difference between the Steri-Strips and paper patching groups with regard to closure time ($P = .706$).

The mean hearing improvement after 3 months was $13.5 \pm 2.6$ dB for the Steri-Strips patching group, $13.5 \pm 2.7$ dB for the paper patching group, and $12.8 \pm 2.7$ dB for the observation group. Differences in hearing improvement rates among the 3 groups were not statistically significant ($P = .85$).

Otorrhea was observed in 7 (23.3%) patients in the Steri-Strips group, 2 (5.3%) patients in the paper patching group, and 1 (5.3%) patient in the observation group. Otorrhea was more common in patients in the Steri-Strips patching group than in patients in other groups. Otorrhea in all patients resolved after removing the patch and treating with oral or topical antibiotics. Repatching was performed in 3 of 7 patients in the Steri-Strips group and 2 of 2 patients in the paper patching group. The tympanic membrane was closed in 4 of 7 patients in the Steri-Strips patching group after otorrhea had resolved. Closure time of patients with otorrhea was $\leq .05$ was considered statistically significant.


\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|c|}
\hline
Group & Steri-Strips Patch & Paper Patch & Observation \\
\hline
No. & 30 & 38 & 19 \\
Sex, male:female & 16:14 & 28:10 & 10:9 \\
Age, y & $38.7 \pm 14.3$ & $37.9 \pm 14.4$ & $34.6 \pm 15.1$ \\
Duration, d & $3.1 \pm 2.0$ & $2.17 \pm 1.5$ & $3.4 \pm 2.1$ \\
Hearing level, dB & $32.7 \pm 9.0$ & $32.7 \pm 8.3$ & $30.5 \pm 6.5$ \\
\hline
\multicolumn{4}{|c|}{PValue} \\
\hline
\end{tabular}
\caption{Demographic Data of Patients in the Steri-Strips Patching, Paper Patching, and Observation-Alone Groups}
\end{table}

\(^a\)One-way analysis of variance.

\(^b\)χ² test.

\(*P < .05 was considered statistically significant.

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\(\chi²\) test.

\(*\)One-way analysis of variance.
Table 2. Outcomes of Steri-Strips Patching, Paper Patching, and Observation-Alone Groups

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Steri-Strips Patch</th>
<th>Paper Patch</th>
<th>Observation</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closure rates, %</td>
<td>93.3 ± 84.2</td>
<td>78.9 ± 33</td>
<td>84.2 ± 33</td>
<td>.02-.022</td>
</tr>
<tr>
<td>Closure time, d</td>
<td>44.7 ± 19.9</td>
<td>12.8 ± 2.7</td>
<td>56.4 ± 16.2</td>
<td>.066c</td>
</tr>
<tr>
<td>Hearing gain, dB</td>
<td>13.5 ± 2.6</td>
<td>13.5 ± 2.7</td>
<td>13.5 ± 2.7</td>
<td>.85c</td>
</tr>
<tr>
<td>Otorrhea, %</td>
<td>23.3 ± 5.3</td>
<td>12.8 ± 2.7</td>
<td>12.8 ± 2.7</td>
<td>.048b</td>
</tr>
</tbody>
</table>

P < .05 was considered statistically significant.

aTwo-sample t test and Mann-Whitney U test.
bχ² test.
cOne-way analysis of variance.

47.2 ± 18.6 days and was not significantly different from that in the other groups (P = .75).

Discussion

In this study, we showed that Steri-Strips patching resulted in a reduced healing time compared with observation alone and a reduced number of repeat procedures compared with paper patching. However, the hearing gain and closure rates between 3 groups were not different, and Steri-Strips patching increased the incidence of otorrhea compared with paper patching and observation alone.

Observational studies have shown a high spontaneous closure rate and improved hearing without complications.8 However, some patients prefer more immediate improvement of hearing and rapid healing of the perforation if they are involved in water sports or to avoid infection. In some cases, regular follow-up can be more expensive than patching because watchful observation needs longer term follow-up. In addition, there are some risks for middle ear infection when a TMP remains unhealed.

Patching is an effective alternative to observation and provides immediate hearing gain and rapid healing. Patching can also provide a bridge to prevent ingrowth of squamous epithelium over the advancing rim of the perforation. The variety of techniques available for TMP include gentamicin ointment plugs, paper patches, tape patches, silk patches, water-soluble chitosan patches, allograft, urinary bladder matrix, growth factor combined patches, and tympanoplasty using fat or temporalis fascia.

Paper patching is one of the most common alternatives to observation in treatment of TMP.13 Paper patching shows a significant healing rate, even for acute, large perforations and chronic small perforations.14 However, paper patches can quickly fall away from the perforation site during yawning or swallowing. In addition, paper patching shows unfavorable closure rates for large perforations.

Tympanoplasty is recommended when the TMP remains unhealed after observation.2 The results of tympanoplasty for large TMPs are usually good. However, tympanoplasty is an invasive procedure and can induce related complications, such as facial nerve or chorda tympanic nerve injury, damage of the ossicular chain, infection, retraction of the tympanic membrane, and auditory canal stenosis. Tympanoplasty is also a more expensive procedure and sometimes requires general anesthesia.

Steri-Strips are adhesive strips that are used instead of sutures to treat small skin wounds and to treat wounds following early postsurgical suture or staple removal.15-17 Steri-Strips are coated with an adhesive, so when used to treat large traumatic TMP, they are not easily detached from the perforation margin; thus, they decrease the need for repeated patching. They may also be removed from the healed site without injuring the intact tympanic membrane. The adhesive has no potential health effects on the eye, skin, or breathing.15 It has also been demonstrated that Steri-Strips patching is useful to promote healing and prevent persistent TMP after removal of long-term ventilation tubes in children.18

In this study, Steri-Strips patching showed a relatively increased rate of otorrhea. No difference has been found between Steri-Strips and sutures or tissue adhesives in terms of infection in closure of surgical incisions.19 However, Steri-Strips may have a tendency to trap moisture, and this can induce bacterial infection in the middle ear. In addition, foreign bodies can easily attach to the sticky side of the Steri-Strips. In rare cases, otorrhea can be induced by an allergic response to Steri-Strips. In this study, the TMP closed in 4 of 7 Steri-Strips patching patients after otorrhea stopped. This may have occurred as a result of angiogenesis induced by infection. In this study, closure rates and closure times in patients with otorrhea were not different from closure rates and closure times in patients without otorrhea.

Limitations of this study include the small number of patients and relatively short-term follow-up. In addition, spontaneous healing of a TMP may be possible even 3 months after injury. Longer term, larger studies comparing Steri-Strips and observation for large traumatic TMP are needed.

Conclusions

Steri-Strips and paper patching are more efficient than observation alone for the treatment of large traumatic TMP patients who desire more rapid healing and immediate hearing gain. The Steri-Strips technique decreased the need for repeat procedures. However, the physician must be cautious about the possibility of otorrhea occurring when using Steri-Strips patching to treat large traumatic TMP.

Author Contributions

Moo Kyun Park, writer, data collection; Kyu Hoon Kim, writer, data collection; Jong Dae Lee, surgical procedure; Byung Don Lee, study design, writer.

Disclosures

Competing interests: None.
Sponsorships: None.
Funding source: None.

References