Spontaneous closure of traumatic tympanic membrane perforations: observational study

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Abstract

Background: The treatment of traumatic tympanic membrane perforations varies in different investigations, ranging from observation to early surgical repair. The present study aimed to focus on the closure rate and the closure time in a group of patients treated with a watchful waiting policy.

Methods: The study comprised 133 consecutive patients with a total of 137 perforations. Data were evaluated in terms of aetiology, location and size of perforation, audiometric findings, closure rate, and closure time.

Results: The overall closure rate was 97 per cent. For patients with a known closure time within three months, the median closure time was between three and four weeks. The probability of spontaneous closure over time was further analysed with Kaplan–Meier plots, for those perforations with known closure times and for all perforations including those with unknown closure times. Perforation size was the only significant determining factor for closure time.

Conclusion: Small perforations had a high probability of spontaneous closure within three to four weeks, justifying a watchful waiting policy. Larger uncomplicated perforations might warrant early surgical repair, depending on the patient's needs and the availability of surgery.

Key words: Tympanic Membrane Perforation; Trauma; Rupture, Spontaneous; Observation

Introduction

The treatment of traumatic tympanic membrane perforations over the last few decades has ranged from observation only to early surgical repair.

An overview study from 1992, which included 16 studies, showed a spontaneous perforation closure rate of 80 per cent in 760 different cases of perforations. Subsequent studies showed similar findings, with spontaneous closure rates ranging from 80 to 97 per cent. For cases of large perforations and blast injuries, spontaneous closure rates have been observed to range from 56 to 82 per cent. 6,7

Studies comparing outcomes after observation only versus different active surgical interventions using various techniques have shown spontaneous closure rates between 53 and 86 per cent in the observation only groups, and closure rates between 88 and 100 per cent in the operated groups. However, different observation times were used in the various studies.

The present study investigated closure rates and closure times in a group of patients treated with a watchful waiting policy. It aimed to evaluate the importance of different parameters for prognostic

outcome estimates of spontaneous traumatic tympanic membrane perforation closure.

Materials and methods

A total of 166 traumatic tympanic membrane ruptures in 162 consecutive patients were observed in the general ENT practice of one of the authors over an 18-year period. A watchful waiting policy was applied as the general treatment modality, with intended clinical control and otomicroscopy performed every week until spontaneous closure of the tympanic membrane within the first three months was observed.

At the first visit after the trauma, the patient's history was taken, and otomicroscopy was performed to determine the size and location of the perforation, presence of infection, and any sign of other possible complications. An audiogram with air and bone conduction was performed in all patients that were able to participate. The tympanic membrane was left untouched. In cases of infection, antibiotics were prescribed. Audiometry was repeated at the time when closure of the tympanic membrane was observed.

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Twenty-nine patients, each with one traumatic tympanic membrane perforation, were lost to follow up, mainly because of a missed appointment or because they lived in a foreign country. The type and cause of tympanic membrane perforation, and demographic data of these patients, did not differ from the remaining population under investigation.

The study comprised 133 patients with a total of 137 traumatic tympanic membrane perforations. There were 87 males and 46 females. The distribution of patient age is shown in Figure 1. A Kaplan–Meier analysis, log-rank test and test for trend were used to analyse tympanic membrane closure time. The influences of different parameters on closure time were analysed with a Cox regression. A *p*-value of less than 0.05 was regarded as significant.

Ethical standards

All procedures contributing to this work complied with the ethical standards of: the regional committee on health research ethics, the institutional guidelines and the Helsinki Declaration of 1975 (as revised in 2008). Data collection was approved by the local data protection agency.

Results

Aetiology

The 137 tympanic membrane ruptures were related to sport in 25 per cent of cases, accidents in 57 per cent of cases and violence in 18 per cent of cases. In order of decreasing frequency, the ruptures were caused by: blows and slaps to the ear, a ball to the ear, water skiing, diving, bathing or swimming,

manipulating cotton buds in the ear canal, syringing, welding (one case), and an explosion (one case).

Patients attended for treatment on the day or the day after the rupture in 44 per cent of cases. Fifty-three per cent waited between 2 and 14 days, and 3 per cent waited more than 14 days.

Perforation location and size

The numbers of observed perforations at different locations of the tympanic membrane are presented in Figure 2. The size of the perforation at the first visit was graded from 1 to 5, depending on the perceived percentage of tympanic membrane involved: grade 1 = pinhead-sized perforation, grade 2 = less than 25 per cent, grade 3 = 25-49 per cent, grade 4 = 50-74 per cent and grade 5 = 75-100 per cent.

Closure rate

The study population was divided into 3 groups: a group that showed spontaneous closure within 3 months (109 patients with 111 perforations of the tympanic membrane (81 per cent)); a group with known spontaneous closure after more than 3 months but with uncertain closure time (21 patients with 22 perforations (16 per cent)); and a group with no spontaneous closure (3 patients with 4 perforations (3 per cent)). Two patients had bilateral perforations, and two patients had two perforations on two separate occasions affecting each ear one at a time.

Findings on the relationship between perforation size and the number of perforations with known or unknown healing times or unhealed perforations are presented in Table I. Overall, there was spontaneous closure in 133 out of 137 perforations (97 per cent).

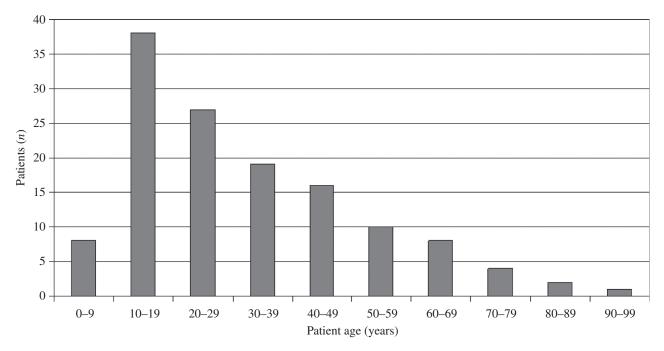


FIG. 1
Age distribution of all 133 patients.

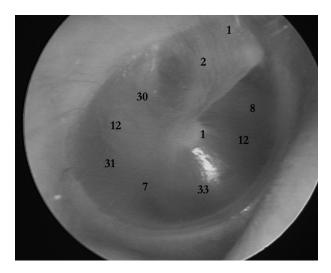


FIG. 2
Numbers of perforations at different locations of the tympanic membrane

One of the unhealed perforations was treated with myringoplasty. The other three patients with unhealed perforations were offered surgery, but this was not performed because of the patients' desires or other reasons. Two of the perforations that did not heal were grade 1 size and two were grade 3 size.

Closure time

Closure time was defined as the time from diagnosis of the tympanic membrane perforation to observation of membrane closure. Obviously that means the closure time reported might be longer than the real closure time, as clinical visits were scheduled on a weekly basis. The median and range of closure times were calculated for different grades of perforation size among the patients with a known closure time; these data are presented in Table I.

A Cox regression analysis was performed to evaluate whether patient age or the presence of discharge from the ear were co-factors, together with perforation size, for the observed closure time. There were 23 patients with ear discharge during the clinical course. Multivariate analysis showed that perforation size was the only significant factor determining closure time (p < 0.05). The probability of a closed tympanic

membrane related to closure time was examined with a Kaplan–Meier plot for different grades of perforation size, as presented in Figure 3.The log-rank test showed a significant difference (p < 0.05) between the three grades of perforation compared. The test for trend was also significant (p < 0.05) when perforations sized as grade 1, grade 2 or grade 3–4 were compared.

A Kaplan–Meier plot was used to examine all healed perforations together, to estimate the probability of spontaneous perforation closure related to time, including the upper and lower 95 per cent limits, thus including censored data (Figure 4).

No signs of cholesteatomas or perilymphatic fistula were observed at the time of final otomicroscopy.

Audiometric findings

The mean hearing level for the middle frequencies, 0.5, 1.0 and 2.0 kHz, was used to compare changes in hearing from the time of diagnosis to follow up, after spontaneous healing. A flow diagram of the findings is presented in Figure 5.

Sixteen ears had a hearing level above 20 dB at follow up. Six of these had a final hearing level between 22 and 27 dB, including one from the group with initial hearing within 20 dB. In eight ears, hearing loss of mixed conductive and neurogenic origin within 30 to 63 dB was unchanged. Two of the non-healed ears had hearing levels of 33 dB and 52 dB. Eight of the patients with no final audiogram were not able to participate in formal audiogram, while the remaining 17 patients had missing data because of other reasons. In 39 ears, there was a change of the hearing level to within 20 dB after spontaneous healing, an improvement from a mean of 30 dB (range, 22–52 dB).

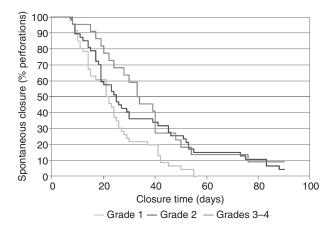
Discussion

The age distribution of the population in the present study corresponds to that of other studies, showing a peak in patients aged 10–30 years. This age group might represent the more active individuals who have the highest risk of developing ear lesions associated with a general urban lifestyle.

Although most perforations were located in the two lower and the upper posterior quadrants of the tympanic membrane, this cannot be interpreted as a sign

TABLE I NUMBER OF PERFORATIONS AND MEDIAN CLOSURE TIME BY PERFORATION SIZE				
Size grade	Healed perforations (with known closure time) (n)	Closure time (median (range); days)	Healed perforations (with unknown closure time) (n)	Non-healed perforations (n)
1	46	22.5 (7–88)	6	0
2	45	24 (7–83)	9	2
3	17	28.3 (9-54)	6	2
4	2	(Included in grade 3*)	0	0
5	0		0	0
Unknown	1	_	1	0
Total	111	_	22	4

^{*}Size grade 3 and 4 perforations were regarded as one group for this comparison, as mentioned in the Closure time section in the main text.



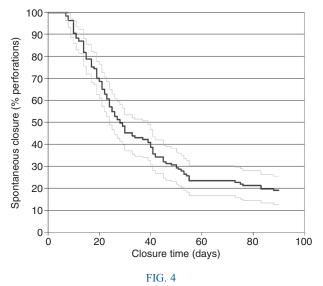
Kaplan–Meier plot showing the probability of spontaneous closure by time for perforations graded as size 1, 2 and 3–4 in patients with a known closure time (100 per cent indicates that all perforations are open).

FIG. 3

of genuine weakness in these parts of the membrane. It might just as well be explained by weak parts of the tympanic membrane as a result of previous middle-ear disease. Most perforations were relatively small, as shown in Table I.

The study revealed a high spontaneous closure rate, reaching 97 per cent overall, which was unrelated to closure time. This indicates a tendency for spontaneous closure in most cases of perforation, if one waits long enough. The spontaneous closure rates and closure times in the present study are in accordance with results from other studies. ^{1-3,5}

Several factors might be important determinants of closure time, such as age, ear discharge and perforation size. With multivariate analysis, we found that perforation size was the single determining factor related to closure time, a finding also reported in some other studies.^{2,4} In addition, some authors have stressed the



Kaplan—Meier plot showing the probability of spontaneous closure by time for all 137 perforations, including censored data with unknown closure times. The upper and lower 95 per cent limits are given (100 per cent indicates all perforations are open).

negative influence of ear discharge and increasing age on closure time. ^{3,4} We found no obvious importance of perforation location, a finding supported by others. ⁴ Previous reports of the importance of inverted and everted edges are contradictory, ^{3,5} but it has been stated that the type of epithelial migration has importance for closure time but not for closure rate. ⁵

In order to describe perforation closure time in more detail, a Kaplan-Meier plot was applied in two ways. Firstly, it was applied to the patients with a known closure time, with a comparison between the different grades of perforation size, as presented in Figure 3. This showed a significant difference between the perforation grades. From the figure, it can be estimated that between 50 and 80 per cent of perforations are likely to be closed within a month, depending on the size of the perforation. Secondly, a Kaplan-Meier plot was applied to all data, including censored data with unknown closure times. These data are presented in Figure 4 with 95 per cent limits, which give an overall view of the probability of having a closed perforation by time. This might provide the clinician with a more realistic prognostic judgement, which has implications regarding the choice of therapy, made in co-operation with the individual patient.

- Spontaneous closure rate of traumatic tympanic membrane perforations is high
- Perforation size was the only determining factor for closure time
- Closure rates and closure times for perforations involving less than 25 per cent of the membrane justify a watchful waiting policy

Evaluation of any hearing deterioration caused by a traumatic tympanic membrane perforation can be a difficult task when prior hearing level is unknown. Whenever possible, an audiogram should be performed at the first clinic visit to allow comparisons with follow-up outcomes, for medicolegal reasons and to rule out any sign of complication. The flow diagram in Figure 5 gives an overview of

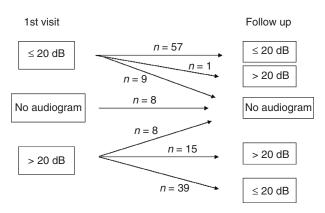


FIG. 5

Changes in hearing for all 137 ears (based on mean air conduction hearing levels at 0.5, 1.0 and 2.0 kHz) at first and follow-up visits.

the hearing status for the 137 cases of perforations investigated in the present study.

Conclusion

The present study shows a high spontaneous closure rate of traumatic tympanic membrane perforations. The size of the perforation was the only determining factor for closure time. Perforations involving less than 25 per cent of the tympanic membrane have a high probability of spontaneous closure within three to four weeks, justifying a watchful waiting policy in these cases. For larger perforations, early surgical repair might be considered, depending on the patient's needs and the availability of surgery.

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References

- 1 Kristensen S. Spontaneous healing of traumatic tympanic membrane perforations in man: a century of experience. *J Laryngol Otol* 1992;**106**:1037–50
- 2 Lou ZC, Lou ZH, Zhang QP. Traumatic tympanic membrane perforations: a study of aetiology and factors affecting outcome. Am J Otolaryngol 2012;33:549-55
- 3 Lou ZC, Tang YM, Yang J. A prospective study evaluating spontaneous healing of aetiology, size and type-different groups of traumatic tympanic membrane perforation. *Clin Otolaryngol* 2011;36:450–60

- 4 Orji FT, Agu CC. Determinants of spontaneous healing in traumatic perforations of the tympanic membrane. *Clin Otolaryngol* 2008;**33**:420–6
- 5 Lou ZC. Spontaneous healing of traumatic eardrum perforation: outward epithelial cell migration and clinical outcome. *Otolaryngol Head Neck Surg* 2012;147:1114–19
- 6 Lou Z. Healing large traumatic eardrum perforations in humans using fibroblast growth factor applied directly or via gelfoam. *Otol Neurotol* 2012;33:1553-7
- 7 Sridhara SK, Rivera A, Littlefield P. Tympanoplasty for blast-induced perforations: the Walter Reed experience. *Otolaryngol Head Neck Surg* 2012;**148**:103–7
- 8 Amadasun JE. An observational study of the management of traumatic tympanic membrane perforations. *J Laryngol Otol* 2002;**116**:181–4
- 9 Hempel JM, Becker A, Müller J, Krause E, Berghaus A, Braun T. Traumatic tympanic membrane perforations: clinical and audiometric findings in 198 patients. *Otol Neurotol* 2012;33: 1357–62
- 10 Sayin I, Kaya KH, Ekizoglu O, Erdim I, Kayhan FT. A prospective controlled trial comparing spontaneous closure and Epifilm® patching in traumatic tympanic membrane perforations. Eur Arch Otorhinolaryngol 2013;270:2857–63

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