

## Main Article

Dr S Marzouk takes responsibility for the integrity of the content of the paper

**Cite this article:** Marzouk S, Al-lami A, Sykes R, Neumann C, Nixon IJ. Assessing ototoxicity and patients' satisfaction of topical local anaesthesia in myringotomy and ventilation tube insertion. *J Laryngol Otol* 2019;**133**: 285–288. <https://doi.org/10.1017/S0022215119000288>

Accepted: 1 December 2018  
First published online: 2 April 2019

### Key words:

Otitis Media With Effusion; Anaesthesia, Local; Hearing Loss; Patient Satisfaction

### Author for correspondence:

Dr Sherief Marzouk,  
Department of ENT,  
East Kent Hospitals University  
NHS Foundation Trust,  
William Harvey Hospital, Ashford TN24 0LZ, UK  
E-mail: [marzouksherief@googlemail.com](mailto:marzouksherief@googlemail.com)

## Abstract

**Objectives.** Animal studies have suggested that exposure of the middle ear to topical local anaesthesia may be ototoxic. This study aimed to report sensorineural hearing outcomes and patients' satisfaction in those who underwent myringotomy and ventilation tube insertion using topical local anaesthesia.

**Methods.** Twenty-nine patients (32 ears) were operated on. Pre- and post-operative audiology findings were compared. A Likert-type questionnaire on treatment satisfaction was completed at the end of the procedure.

**Results.** Median patient age was 55 years (range, 27–88 years). Pre- and post-operative bone conduction pure tone averages were 26.76 dB and 25.26 dB respectively (mean reduction of –1.22 dB, 95 per cent confidence interval of –5.91 to 8.13 dB;  $p = 0.7538$ ). One ear (3 per cent) had a reduction in pure tone average of 10 dB.

**Conclusion.** The results suggest that sensorineural hearing loss is not a complication of ear exposure to topical local anaesthesia during myringotomy and ventilation tube insertion. The procedure was well perceived.

## Introduction

Ventilation tube insertion procedures are among the most commonly performed operations in otolaryngology, with approximately 30 000 cases per annum performed in the UK.<sup>1</sup> The vast majority of these are carried out under general anaesthetic for various reasons, including a stable operative field, assumptions regarding patient acceptance and the fact that most cases are paediatric. Studies have demonstrated the feasibility of local anaesthetic ventilation tube insertion techniques.<sup>2,3</sup> However, unfamiliarity with the technique, questions over patient acceptance and concern regarding the findings of various animal studies, which have indicated potential ototoxicity, have been barriers to more widespread implementation.

This study aimed to assess patients' satisfaction and to report sensorineural hearing outcomes in a cohort of patients who underwent myringotomy and ventilation tube insertion using topical local anaesthesia.

## Materials and methods

A eutectic mixture of local anaesthetics cream was used as a topical local anaesthesia agent in this study. All patients underwent pre-operative pure tone audiometry performed by the hospital audiology department. One surgeon performed all the procedures.

The inclusion criteria for this study were: patients aged 18 years and over; and ventilation tube insertion indications of otitis media with effusion, tympanic membrane retraction and Eustachian tube dysfunction. Patients with Ménière's disease who previously had a ventilation tube inserted under topical local anaesthesia were excluded, as the underlying aetiology could cause fluctuations in bone conduction thresholds, independent of any intervention, which may confound analysis.

On the day of surgery, the patient's ear was microsuctioned and the topical local anaesthesia agent was instilled in the ear under the direct vision of a microscope using a blunt-ended needle (Medioplast® metal suction tip 17 G) and (2 ml) syringe in a clinic treatment room. The topical local anaesthesia was applied to the whole of the external auditory canal and lateral surface of the tympanic membrane. Care was taken to avoid air bubbles next to the tympanic membrane, as this would affect the topical local anaesthesia efficacy.

The patient was then asked to wait in the day surgery unit waiting area for at least 45 minutes, to allow the topical local anaesthesia to take effect. After transfer to the operating theatre, the topical local anaesthesia agent was microsuctioned, antero-inferior myringotomy was performed and a Shah ventilation tube was inserted. Topical antibiotic drops (Sofradex®) were then instilled.

The patient subsequently completed a questionnaire with a score range of 1 to 7 (with 1 being very unsatisfied and 7 being very satisfied). The questions addressed were the

following: (1) How satisfied were you with the waiting times involved?; (2) How satisfied were you with the explanation of the treatment?; (3) How did your experience of the procedure meet expectations following the explanation?; (4) If you required this again, how likely would you be to choose local anaesthetic?; and (5) How satisfied are you overall with your experience today?

All patients were discharged on the same day as surgery, and out-patient audiological review was arranged.

A pure tone audiogram with appropriate masking was performed within three months of the date of surgery. As all of the pure tone audiograms included hearing thresholds at frequencies 0.5, 1, 2 and 4 kHz, based on the National Institute of Clinical Excellence guidelines for the management of otitis media with effusion,<sup>4</sup> the averages of these frequencies were selected to measure bone conduction thresholds in order to assess for evidence of sensorineural hearing loss. Based on similar published literature to this study,<sup>5</sup> a drop of 10 dB in bone conduction thresholds was considered clinically significant for sensorineural hearing loss. For the purpose of statistical analysis, a student's *t*-test was used to compare mean pure tone audiogram results.

## Results

A total of 31 patients were included in this study over a 22-month period. Two patients were lost to follow up and did not have post-operative audiometric assessment. Those two patients were therefore excluded from the data analysis of bone conduction hearing loss but included in the patient satisfaction survey results. A total of 29 patients (32 ears) had a complete set of data.

Twenty-six ventilation tubes were inserted for otitis media with effusion (81.2 per cent), three ventilation tubes were inserted for tympanic membrane retraction management (9.4 per cent) and three ventilation tubes were inserted for Eustachian tube dysfunction (9.4 per cent). No procedures were abandoned because of patient discomfort. The median patient age was 55 years (range, 27–88 years). Sixty-five per cent of the patients were male. Pre- and post-operative bone conduction pure tone averages were 26.76 dB and 25.26 dB respectively (mean reduction of  $-1.22$  dB, 95 per cent confidence interval of  $-5.91$  to  $8.13$  dB;  $p = 0.7538$ ). One ear (3 per cent) had a reduction in pure tone average of 10 dB.

The mean patient satisfaction survey scores (Figure 1) were: 5.93 out of 7 for satisfaction with the waiting time involved (median = 6); 6.90 out of 7 for satisfaction with the treatment explanation (median = 7); 6.45 out of 7 for the patient's experience of the procedure meeting their expectations after the explanation (median = 7); 6.55 out of 7 for the likelihood of choosing to have local anaesthetic ventilation tube insertion again (median = 7); and 6.68 out of 7 for overall satisfaction with their experience (median = 7).

The following questionnaire responses were graded as 6 or 7, indicating patients' satisfaction: satisfaction with waiting times = 90 per cent; satisfaction with explanation = 100 per cent; meeting expectations following the explanation = 84 per cent; willingness to choose local anaesthetic again = 90 per cent; and overall satisfaction = 90 per cent.

## Discussion

The provision of safe and effective local anaesthetic to the external ear canal and tympanic membrane has been pursued since the end of the nineteenth century.<sup>6</sup> Those efforts began

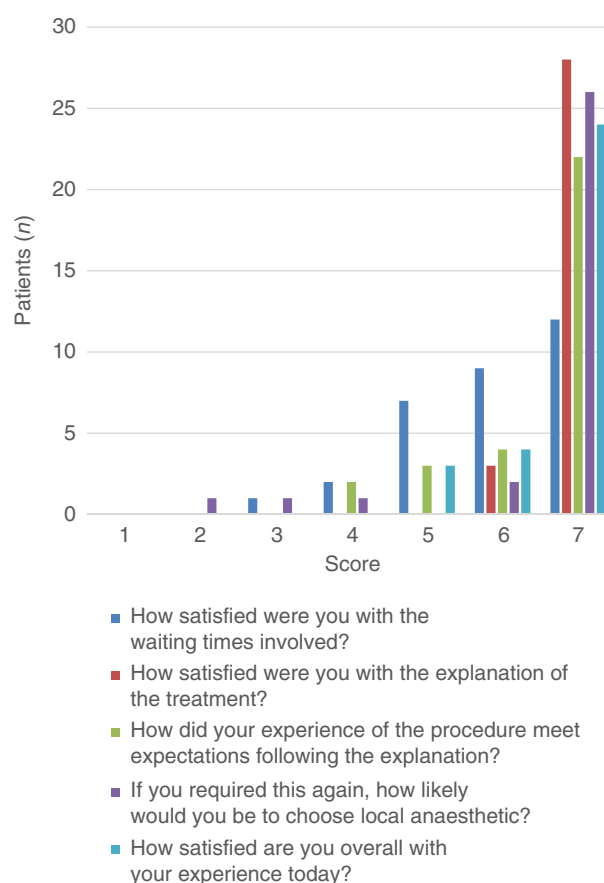


Fig. 1. Patients' satisfaction with the local anaesthetic ventilation tube insertion procedure (with a score of 1 indicating very unsatisfied and 7 reflecting very satisfied).

in 1884 with Zaufel, who anaesthetised the tympanic membrane with cocaine dissolved in alcohol after applying a macerating solution to the keratinised outer layer.<sup>6</sup> A similar approach was adopted with the advent of Bonain's solution, which combined cocaine with phenol and menthol; this would be used to necrotise the superficial layers of the tympanic membrane and anaesthetise deeper layers. Whilst being as effective as anaesthetic agents, their use carried significant risks, including tympanic membrane perforation, vestibulocochlear damage, facial nerve palsy and toxicity.<sup>6</sup> Despite this, they were adopted widely in the first half of the twentieth century. Some have attempted anaesthesia through a Eustachian tube route, but this is not popular given the risk of sensorineural hearing loss.<sup>6</sup>

Use of iontophoresis to anaesthetise the tympanic membrane was first described by Albrecht in 1911.<sup>7</sup> A direct electrical current was used to move the positively charged ions of an anaesthetic agent into the tympanic membrane. The method was effective in inducing anaesthesia, but was abandoned given the high risk of cochlear damage.<sup>7</sup> The method was modified in 1973 by Comeau *et al.*, who reduced the amperage and substituted cocaine for lidocaine.<sup>8</sup> However, it was a time-consuming and cumbersome procedure, and did not anaesthetise the skin of the canal wall due to the ions being transported directly across the tympanic membrane, this being the route of least electrical resistance.

Injection of local anaesthesia into the ear canal skin is a commonly performed part of many general anaesthetic otological procedures, but can cause as much pain as the procedure itself in the setting of a local anaesthetic grommet

insertion, necessitating prior topical anaesthetic use, which in itself would provide adequate anaesthesia.

In 1988, Anniko and Schmidt instilled a eutectic mixture of local anaesthetics into the tympanic cavities of guinea pigs.<sup>9</sup> They found severe morphological damage to the organ of Corti in the first 4 mm from the round window, with a clear demarcation between the normal and damaged areas. These changes were found to be independent of the frequency of administration.<sup>9</sup>

Further research by Anniko *et al.* (in 1989) centred on elucidating the effects of xylocaine, eutectic mixture of local anaesthetics and other substances on inner-ear function after 24 hours and at 6 months, and comparing them to pre-treatment conditions.<sup>10</sup> Each drug was instilled into the round window niche of the test animals, and repeat auditory brainstem response (ABR) testing was performed. Following this, the cochleae were examined with light microscopy morphologically. They found that xylocaine caused changes in ABR with no morphological changes. Eutectic mixture of local anaesthetics caused a functional impairment, with correlated morphological injury to the basal coil in the organ of Corti. Furthermore, they found outer hair cells to be more vulnerable to damage than inner hair cells.<sup>10</sup>

In 1990, Schmidt *et al.* conducted experiments to ascertain the effects of different topical anaesthetics on cochlear function in rats.<sup>11</sup> The round window niche was exposed to lidocaine, lidocaine-prilocaine and phenol. They tested ABRs at various frequencies from 2 kHz to 31.5 kHz, before application, and three weeks, two months and six months after exposure. Microscopic analysis of the rats' cochleae was then performed. All three tested agents caused severe impairment in ABR thresholds within 24 hours, with a slow recovery for the following 2 months; however, there were some effects lasting up to 6 months at the higher frequencies. The lower frequencies recovered. Microscopic examination showed no effect from lidocaine, but there was morphological damage from lidocaine-prilocaine and phenol.<sup>11</sup>

Eutectic mixture of local anaesthetics is a mixture of two local anaesthetic agents: lignocaine and prilocaine, with an emulsifying agent, Arlatone™.<sup>6</sup> It has been designed as a topical skin anaesthetic that achieves penetration by maintaining a high concentration of anaesthetic base with water.<sup>6</sup> An equal concentration of the two anaesthetics (1 g of eutectic mixture of local anaesthetics contains 25 mg each of prilocaine and lidocaine bases) with Arlatone would make an oil-water emulsion.<sup>6</sup> The resultant droplets of emulsion maintain an 80 per cent concentration of anaesthetic per droplet, with an overall 5 per cent concentration as a whole.<sup>6</sup>

A double-blind, randomised controlled trial conducted by Timms *et al.* in 1988 compared eutectic mixture of local anaesthetics cream to hand cream in anaesthetising the ear canal and tympanic membrane for electrocochleography in 15 patients (30 ears).<sup>6</sup> Analysis revealed that eutectic mixture of local anaesthetics provided adequate anaesthesia for the procedure.<sup>6</sup>

In 1989, Roberts and Carlin compared the efficacy of eutectic mixture of local anaesthetics versus prilocaine injection for tympanic membrane anaesthesia prior to ventilation tube insertion.<sup>12</sup> Eutectic mixture of local anaesthetics was found to be as effective as prilocaine injection in achieving anaesthesia of the tympanic membrane, but the former was preferred as patients found the discomfort of ear canal injection similar to that experienced when performing myringotomy with no anaesthesia.<sup>12</sup>

Bingham *et al.* conducted a trial in 1991 of ventilation tube insertion with eutectic mixture of local anaesthetics in 29

patients.<sup>13</sup> They reported good tolerance from all patients, with no evidence of ototoxicity at one-month follow up.

Patient selection is important to the success of such procedures; factors such as patient age, acceptance of local anaesthetic procedures and external ear canal anatomy are influential when selecting the most appropriate technique.

Limitations of the study include: biases in patient selection, based on age, patient acceptance and ear canal size associated with perceived ease of the procedure; the lack of long-term follow up to exclude late toxicity; and the relatively small sample size. Other barriers to more widespread implementation are the perceived risk to cochlear function based on the findings of previous animal studies, which suggested possible ototoxicity when anaesthetic agents penetrate the round window. However, there seems to be minimal risk of this occurring, as anaesthetic agents are applied onto an intact tympanic membrane and thoroughly suctioned before myringotomy is performed. Naturally, the presence of a perforation would render the insertion of a ventilation tube, and the preceding instillation of local anaesthetic, completely unnecessary.

- Myringotomy and ventilation tube insertion are very common ENT procedures
- Limited animal study data have shown some ototoxicity with local anaesthetic agents
- This study indicated that ototoxicity is not a complication of local anaesthetic ventilation tube insertion in humans
- Local anaesthetic is a viable alternative with correct patient selection

We report the findings of one of the largest series to date addressing the potential ototoxicity of topical local anaesthetic, and describing patients' satisfaction, for myringotomy and ventilation tube insertion. The one patient with a statistically significant reduction in bone conduction threshold had bilateral mixed hearing loss pre-operatively. The findings for this particular patient could have been due to the natural progression of the pre-existing sensorineural hearing loss component during the time interval between the pre- and post-operative pure tone audiograms during the study period. Our results therefore suggest that sensorineural hearing loss is not a complication of ear exposure to topical local anaesthetic during myringotomy and ventilation tube insertion. In addition, this technique provides a viable alternative to the established general anaesthetic technique that is well accepted by patients. This could result in significant savings in time and expense, for hospitals, clinicians and patients.

**Competing interests.** None declared

## References

- 1 NHS England. Commissioning Services for People with Hearing Loss: A Framework for Clinical Commissioning Groups. In: <https://www.england.nhs.uk/wp-content/uploads/2016/07/HLCF.pdf> [2 June 2016]
- 2 Nichani J, Camilleri AE, Broomfield S, Saeed S. Optimizing local anesthesia for grommet insertion: eutectic mixture of local anaesthetics versus Ametop. A randomized clinical trial. *Otol Neurotol* 2008;**29**:658–60
- 3 Hoffman C-L. Tetracaine topical anesthesia for myringotomy. *Laryngoscope* 2001;**111**:1636–8
- 4 National Collaborating Centre for Women's and Children's Health (commissioned by the National Institute for Health and Clinical Excellence). *Surgical*

- Management of Otitis Media with Effusion in Children*. London: RCOG Press, 2008;31
- 5 Han WW, Incesulu A, McKenna MJ, Rauch SD, Nadol Jr JB, Glynn RJ. Revision stapedectomy: intraoperative findings, results, and review of the literature. *Laryngoscope* 1997;107:1185–92
  - 6 Timms MS, O'Malley S, Keith AO. Experience with a new topical anaesthetic in otology. *Clin Otolaryngol* 1988;13:485–90
  - 7 Albrecht W. Anaesthesia for surgery of the ear [in German]. *Archiv Ohrenheilkde* 1911;85:198–215
  - 8 Comeau M, Brummett R, Vernon J. Local anesthesia of the ear by iontophoresis. *Arch Otolaryngol* 1973;98:114
  - 9 Anniko M, Schmidt SH. The ototoxic potential of EMLA. A new local anesthetic for the tympanic membrane. *Acta Otolaryngol* 1988;105:255–65
  - 10 Anniko M, Hellström S, Schmidt SH, Spandow O. Toxic effects on inner ear of noxious agents passing through the round window membrane. *Acta Otolaryngol Suppl* 1989;457:49–56
  - 11 Schmidt SH, Anniko M, Hellstrom S. Electrophysiological effects of the clinically used local anesthetics lidocaine, lidocaine-prilocaine and phenol on the rat's inner ear. *Eur Arch Otorhinolaryngol* 1990;248:87–94
  - 12 Roberts C, Carlin WV. A comparison of topical EMLA cream and prilocaine injection for anaesthesia of the tympanic membrane in adults. *Acta Otolaryngol* 1989;108:431–3
  - 13 Bingham B, Hawke M, Halik J. The safety and efficacy of Emla cream topical anesthesia for myringotomy and ventilation tube insertion. *J Otolaryngol* 1991;20:193–5