

Peer Review File

Article Information: <https://dx.doi.org/10.21037/ajo-22-13>

Reviewer A:

The American Academy of Otolaryngology and a review by Cochrane recommend against strict water precautions following ventilation tube insertion. No data exists from an Australian perspective with regards to water related otorrhea in children with grommets. This survey of predominantly otolaryngology consultants in Australia demonstrates that despite these published guidelines, advice regarding water precautions are variable. Clinicians in northern states are more cautious than their counterparts in colder climates.

His paper explores these issues.

Comment 1: The authors are recommended to use line numbering when submitting papers. This assists the reviewer when responding.

Reply 1: Thank you for your feedback and apologies, must have missed this end bit of author instructions. Line numbering has been added to assist review and editing – see manuscript

Comment 2: Remember to read the author instructions, tables and graphs should not be embedded in the document but be placed at the end.

Reply 2: Tables and graphs have been added on individual pages at end of the document – see page 14-18. They are also submitted as a separate document of ‘Tables’ and ‘Figures’.

Comment 3: With regards to references, only 1st 3 names and then et al as per author instructions.

Reply 3: As advised, we have modified our references to be in Vancouver style with first 3 author names – see page 19 and 20

Abstract:

Comment 4: Results; I would suggest using % rather than raw numbers within the abstract ie 77/168 - 46% etc

Reply 4: We have modified the abstract as advised – see page 3, line 14 and 15

Comment 5: Key words - ventilation tube insertion isn't a mesh head - alternative - tympanostomy tube insertion

Swimming and water are both mesh terms

Grommet tube is mesh heading

Suggest using this resource:

<https://meshb.nlm.nih.gov/MeSHonDemand>

Reply 5: Keywords have been modified as advised – see page 4, line 5 and 6

Introduction

Comment 6: Paragraph 4 - references 3,4,6,7,8 - papers 3 and 4 published before the American academy paper therefore expect they are within its references so not additional evidence. Perhaps worth making that clear rather than implying that they are additional evidence.

Reply 6: Reference 4 article by Carbonell and Ruiz-Garcia was included in the 2013 American guidelines so I have removed this reference to eliminate possible confusion, and to add only additional evidence. Reference 3 article by Salata et al. was not included in the American academy paper, nor was it used in systematic review in the Cochrane review so I have left this reference – see page 6, line 5

Comment 7: Reference 6 is a current opinion paper which reviews the current literature and references 2 new papers

1) Subtil J, Jardim A, Peralta Santos A, et al. Water protection after tympanostomy (Shepard) tubes does not decrease otorrhea incidence - retrospective cohort study. *Braz J Otorhinolaryngol* 2018; 84:500–50

Which looks remarkably similar to your reference 7 with the same 1st 2 authors. But the reference 2 paper is randomised controlled - I would suggest you look at both these papers, are they truly 2 different studies ?? If so can reference both.

2) Steele DW, Adam GP, Di M, et al. Prevention and Treatment of tympanostomy tube otorrhea: a meta-analysis. *Pediatric* 2017; 139:e20170667.

This is a comprehensive review including data on both prevention (including randomized as well as nonrandomized studies) as treatment (with a network meta-analysis). However I'd be surprised if it has any additional evidence not picked up by the American academy or Cochrane. Would suggest you read and see how it differs from American academy.

So although the current opinion piece is a nicely written piece I think you are better to reference the source material rather than review articles.

Reply 7: This 2018 retrospective study by Subtil J, Peralta et al. was indeed a different study to their 2019 randomised control study so I have referenced both as advised – see page 6, line 5. Review paper by Steele was focused on both prevention as well as treatment of tympanostomy related otorrhea. All the references used to review prevention of otorrhea overlapped with that captured in the Cochrane review, hence this paper is not included as a separate reference.

Comment 8: Reference 8 is also just a review so you would want to see if it has any new source material or just rehashing the American academy document (published the same year)

Reply 8: Once again, although not using the same references as the American guidelines, Cochrane review covered these articles in the systematic review. Therefore, it has been removed to present only additional evidence that is already not covered in

the Cochrane review or the American guidelines. See page 6, line 5.

Comment 9: I found this study which seems to be the only other RCT:

Miyake MM, Tateno DA, Cançado NA, Miyake MM, Tincani S, Sousa Neto OM. Water protection in patients with tympanostomy tubes in tympanic membrane: a randomized clinical trial. *Einstein (Sao Paulo)*. 2019 Mar 7;17(2):eAO4423. doi: 10.31744/einstein_journal/2019AO4423. PMID: 30843995; PMCID: PMC6394998

See my comments below in the discussion section.

Reply 9: I have included this article in the introduction, and will further discuss in discussion – See page 6, line 11-16.

Comment 10: Your referee 9 is one of the 2 RCT on which Cochrane is based, Given there were only 2 probably worth referencing both and stating that Cochrane based on just these 2 studies. (when you look closely there doesn't seem to be as much true evidence as perhaps suggested, but lots of opinion)

Reply 10: As advised, have referenced the two studies that Cochrane review is based on – see page 6, line 7

Method;

Comment 11: Was there any ethics application? It might have been approved by the ASOHNS board.

Reply 11: Ethics exemption was granted by Royal Brisbane and Women's Hospital Human Research Ethics Committee as this study was seen as quality assurance and evaluation activity, and it has been approved by the ASOHN survey ethics committee prior to distribution. This information has been included in page 8, line 10-12

Comment 12: Paragraph 2 - part of this paragraph is results rather than methods.

Reply 12: As advised, has been moved under Results – see page 8, line 17, 18

Results

Comment 13: What percentage of asohns members responded and was this equally broken down across the country?

Reply 13: As advised, percentage of response has been added – see page 8, line 17 – and distribution between states are available on Table 1

Comment 14: In order to allow readers to analysis the results themselves, all results should be presented as raw numbers as well as % - as the reviewer I have no means of confirming your results.

Reply 14: As advised, raw numbers and % have been added in all the tables and figure – see tables and figure

Comment 15 NB tables and graphs should all have been at the end, not embedded within the body of text

Reply 15: Noted and moved as advised

Comment 16 Table 2 is the same as graph 1?? Labelling needs correcting.

Reply 16 Figure 1 is a graphical representation of the percentage of **all** participants advising water precautions according to different water activity. This was then further analysed to see if there was difference in practice according to experience level (> or <10 years) which is shown on Table 2. I have modified both the figure and table in hope of reducing confusion – see table 2 and figure 1

Comment 17 Table 2 - the diving component is confusing. The table is labelled as % advising restrictions but table includes no restrictions. What is surface swimming - how does this correspond to ocean and pool swimming - needs tidying up.

Reply 17 As advised, table 2 has been modified to reduce confusion – see table 2

Comment 18 Table 3 like table 2 needs tidying up - not clear

Reply 18 As advised, table 3 has been modified to reduce confusion – see table 3

Discussion:

Points that may be worth including within discussion (and or within the introduction)

Comment 19: The avoidance of grommet insertion in indigenous children is often explained by the concerns over poor adherence to water precautions. This deserves discussion in light of guidelines and findings from this study.

Reply 19: As advised, discussed in Page 11, line 16-24

Comment 20: What is the rate of otorrhea in Australia post grommet? If no data this is an area for recommended research. This paper recently from Melbourne quotes around 9% in first 6 weeks.

Wang LC, Giddings CE, Phyland D. Predictors of postoperative complications in paediatric patients receiving grommets - A retrospective analysis. *Int J Pediatr Otorhinolaryngol.* 2021 Mar;142:110601. doi: 10.1016/j.ijporl.2020.110601. Epub 2020 Dec 30. PMID: 33412341.

Reply 20: As advised I have added this background information to the introduction – see page 5, line 10-11. There was no other local data that I could find, and have suggested this as an area of recommended future research – see page 13 line 23 – page 14 line 3

Comment 21: Although we shouldn't doubt the findings and recommendations from the American academy and the Cochrane review it is worth noting that only 2 RCT were found to answer this question. Since then there has been 1 further RCT from Portugal (see below) . American guidelines are based on these 2 studies and other less

rigorous studies.

The 2 RCT on which Cochrane is based are from USA, may not be comparable to Australia and in particular tropical regions.

- One out of Pittsburgh - climate more like southern Australian states, less swimming over colder months

- Swimming rates in USA are lower than Australia (would need data to support this).

What is the rate of home swimming pools in Pittsburgh vs Old?

- Majority of children under 3 - how much time really spent with head submerged??

- Swimming only occurred in 4-5% of days - which would be expected to be significantly lower than in Australian population, especially those in tropical regions.

- Bathing no difference but what is bathing? Bath or shower? - how much water submerging is happening??

- Pittsburgh no beach

- Second study also out of usa Cincinnati - unable to access -swimming vs no swimming likely similar - Cincinnati similar climate to Pittsburgh and also land locked.

This paper from Portugal probably is similar to Australia climatically and with regards to its coastal location. Children in this paper were swimming in 60% of cases. Like the USA studies showed no significantly increased risk of otorrhea.

Miyake MM, Tateno DA, Cançado NA, Miyake MM, Tincani S, Sousa Neto OM. Water protection in patients with tympanostomy tubes in tympanic membrane: a randomized clinical trial. *Einstein (Sao Paulo)*. 2019 Mar 7;17(2):eAO4423. doi: 10.31744/einstein_journal/2019AO4423. PMID: 30843995; PMCID: PMC6394998.

Reply 21 RCT by Goldstein et al was based in Pittsburg, that by Parker et al was based in Portsmouth. RCT by Miyake was based in Brazil. I appreciate the points that you have highlighted. Changes made as advised – see page 13 line 14-24, page 14 line 1-4.

Comment 22: Pseudomonas and staph are the organisms associated with water related otorrhea. Pseudomonas thrives in warmer water which may play a role in the recommendations of northern otolaryngologists to advise water precautions given their experience in this regard. Authors may be able to find further evidence surrounding this. Pseudomonas outbreaks in pools occurs even in the setting of chlorination and perhaps heated indoor pools which are often used for younger children in cooler states for swimming lessons in the winter months may be causative of otorrhea.

Other organisms may also be present within the pool water, resulting in children catching URTI's independent of water entering the middle ear via the grommet.

This reference may be useful. - *discussion*

Mena KD, Gerba CP. Risk assessment of *Pseudomonas aeruginosa* in water. *Rev Environ Contam Toxicol*. 2009;201:71-115. doi: 10.1007/978-1-4419-0032-6_3. PMID: 19484589

Reply 22: As advised, this information has been introduced in introduction (see page

5, line 12-18) and further explored in discussion – see page 12, line 6-8

Comment 23 Guidelines for Australia require further local research examining the rates of otorrhea across the country. Although RCT are gold standard, cohort studies comparing rates between surgeons may be helpful. More specific water exposure records would also assist in the generation of future guidelines. ASOHNS to date has not seen its role as a publisher of guidelines. The recent development of audit databases by ASOHNS may assist in collecting prospective data particularly looking at quality of life and outcomes of children requiring grommets.

Reply 23 Agree that there is paucity in local data in context of grommet insertion including quality of life, hearing outcomes, and incidence of otorrhea – further research has been suggested, see page 14, line 9, 10

References:

Comment 24: Ensure following author instructions with regards to style - 1st 3 authors only, then et al, using Vancouver style

Reply 24: Changes made as advised – see page 20, 21

Reviewer B:

Thank you for an interesting case series which is very relevant to most ENT's

Comment 1 It is important to establish the relevance of your sample please inform us, of the 174 replies, how many emails were sent and / or how many ASOHNS members were eligible to respond? One would like to see at least 30% of the Membership responded

Reply 1 There were 498 surveys distributed to all ASOHNS members as of Sep 2021 (excluding members stated as based overseas) with response rate of 34.9% with 174 responses. This information was added as advised – see page 8, line 19, 20

Comment 2 Define Diving - was this diving into water OR scuba/ free diving ie descending deep?

Reply 2 Diving was implied as submersion of head deeper than what would usually constitute ocean or pool swimming, often at least 1 meter below water surface. This question was added to ascertain whether clinicians have different precaution advice for deeper head submersion which is associated with increased hydrostatic pressure. This seemed to be the case as in the free text boxes, multiple participants did comment that they usually do have different water precaution advice if going more than 1m under water surface. We admit the wording of this particular survey question is vague and is a potential limitation of the study which will be added to the discussion – see page 13, line 2-4.

Comment 3 Why did you choose 10yrs experience? Please justify. Why not new grad regs + 5 yrs experience, 5-15yrs and senior > 15

Reply 3 Experience level of less and greater than 10yrs experience was chosen to identify if there is a significant difference in practice according to years of clinical experience. 10 years was seen as appropriate time to become established in practice and gain greater anecdotal experience of degree and location of water activity of local community, which could influence their water precaution advices. This 10 year timeframe also corresponded to when the first AAOHNS guideline was published in 2013 which could also influence the water precaution advice given by otolaryngologist according to years of experience – see page 9, line 9-13

Comment 4

Why did you choose this State breakdown ?? Why NOT analyse:

NSW + ACT

Queensland + NT

SA + Tasmania

Victoria

WA

Doesn't WA have similar feature in the north to Queensland and NT?

Also even though there were fewer responses from SA and WA compared to NSW and Victoria there are also fewer ENTs overall and as a proportion they may be similar and therefore as significant a representation of the members in the state

Reply 4 This breakdown of states was chosen to identify potential differences in water precaution advice given between warmer tropical northern states and cooler southern states. Although northern parts of WA do have similar features to QLD and NT, WA was included as 'southern' state as majority of WA population are located in southern parts of the state, where a large proportion of these post grommet patients are presumed to be based. Thus, water conditions (including temperature, microbiome, humidity) and amount of time spent doing water activity was thought to be comparable to that of other southern states of Australia. However, as suggested in discussion, an area of future research would be to explore different water precaution advice given according to rurality of clinician's practice to acknowledge the large geographical variation that is present in managing patients in Australian setting – see page 12, line 1-7, and page13, line 3-6

Comment 5 Where there any free text comments?

Reply 5 As advised, further details of free text comments have been added – See page 11 line 7-9, page 11 line 20-21, appendix 2