Impact of swimming on chronic suppurative otitis media in Aboriginal children: a randomised controlled trial

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Abstract

Objectives: To measure the impact of 4 weeks of daily swimming on rates of ear discharge among Aboriginal children with a tympanic membrane perforation (TMP) and on the microbiology of the nasopharynx and middle ear.

Design, setting and participants: A randomised controlled trial involving 89 Aboriginal children (aged 5–12 years) with a TMP, conducted in two remote Northern Territory Aboriginal communities from August to December 2009.

Intervention: 4 school weeks of daily swimming lessons (45 minutes) in a chlorinated pool.

Main outcome measures: Proportions of children with ear discharge and respiratory and opportunistic bacteria in the nasopharynx and middle ear.

Results: Of 89 children randomly assigned to the swimming or non-swimming groups, 58 (26/41 swimmers and 32/48 non-swimmers) had ear discharge at baseline. After 4 weeks, 24 of 41 swimmers had ear discharge compared with 32 of 48 non-swimmers (risk difference, − 8% (95% CI, − 28% to 12%). There were no statistically significant changes in the microbiology of the nasopharynx or middle ear in swimmers or non-swimmers. *Streptococcus pneumoniae* and non-typeable *Haemophilus influenzae* were the dominant organisms cultured from the nasopharynx, and *H. influenzae*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* were the dominant organisms in the middle ear.

Conclusions: Swimming lessons for Aboriginal children in remote communities should be supported, but it is unlikely that they will substantially reduce rates of chronic suppurative otitis media and associated bacteria in the nasopharynx and middle ear. However, swimming was not associated with increased risk of ear discharge and we found no reason to discourage it.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12613000634774.

Rates of chronic suppurative otitis media (CSOM) among Aboriginal children living in remote areas in Australia are the highest in the world.[1,2] A survey of 29 Aboriginal communities in the Northern Territory found that 40% of children had a tympanic membrane perforation (TMP) by 18 months of age.[3] About 50%–80% of Aboriginal children with CSOM suffer from moderate to severe hearing loss.[4,5] This occurs while language and speech are developing and may persist throughout primary school.

There is evidence suggesting that the recommended treatment for ear discharge (twice-daily cleaning and topical ciprofloxacin) can produce cure rates of 70%–90%.[6-8] However, a study of Aboriginal children with CSOM in the NT found that less than 30% of children had resolution of ear discharge after 8 weeks of similar treatment.[9] This study suggested that ongoing treatment for long periods was difficult for many Aboriginal families living in underresourced and stressful conditions. When children in high-risk communities do not receive appropriate medical treatment for ear disease, using swimming pools to limit levels of ear discharge and possibly reduce bacterial transmission becomes an attractive option.

Traditionally, children with perforated eardrums have been restricted from swimming because of fears of infection. However, it is hypothesised that swimming helps cleanse discharge from the middle ear, nasopharynx and hands and that this benefit may outweigh the risk of introducing infection. Several observational studies have examined the relationship between swimming and levels of skin and ear disease among Aboriginal children.[10-14] In a cross-sectional survey, close proximity to a swimming area was associated with reductions of up to 40% in otitis media.[10] Two systematic reviews have found that swimming without ear protection does not affect rates of recurrent ear discharge in children with tympanostomy tubes (grommets).[15,16] Despite these findings, surveys indicate uncertainty among clinicians regarding water precautions for children with grommets.[17-19]

Our aim was to conduct a randomised controlled trial (RCT) to better understand the impact of swimming on children with CSOM, and to address a lack of data on ear discharge in older Aboriginal children (aged 5–12 years) with CSOM. We also aimed to obtain microbiological profiles of the nasopharynx and middle ear to help elucidate the cleansing hypothesis.

Methods

Study design

Between August and December 2009, we conducted an RCT examining the impact of 4 weeks of daily swimming in a chlorinated pool on TMPs in Aboriginal children. The Human Research Ethics Committee of the Northern Territory Department of Health and Families and the Menzies School of Health Research approved the study.

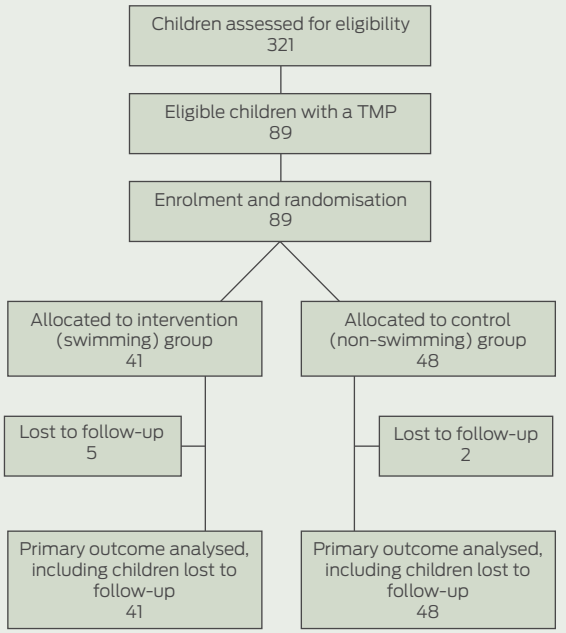
Participants and setting

Participants were from two remote Aboriginal communities in the NT. Resident Aboriginal children aged 5–12 years who were found at baseline ear examination to have a TMP were eligible for the trial. Children with a medical condition that prohibited them from swimming were excluded.

Randomisation and blinding

A random sequence stratified by community and age (< 8 years or ⩾ 8 years) was generated using Stata version 8 (StataCorp). The allocation sequence was concealed from all investigators. The clinical assessment was performed without knowledge of the group allocation, and laboratory staff were also blinded to group allocation and clinical data.

1 Flowchart of participants through the trial



TMP = tympanic membrane perforation. ◆

Intervention

Children in the intervention group swam in a chlorinated pool for 45 minutes, 5 days a week, for 4 weeks. Swimmers did not wear head protection (cap or earplugs) and went underwater frequently. Children in the control group were restricted from swimming for 4 weeks.

Clinical assessments

Participants' ears were examined in the week before and the week after the intervention using tympanometry, pneumatic otoscopy and digital video otoscopy. Criteria for diagnosis were:

- Otitis media with effusion: intact and retracted non-bulging tympanic membrane and type B tympanogram
- Acute otitis media without perforation: any bulging of the tympanic membrane and type B tympanogram
- Acute otitis media with perforation: middle ear discharge, and perforation present for less than 6 weeks or covering less than 2% of the pars tensa of the tympanic membrane
- Dry perforation: perforation without any discharge
- CSOM: perforation (covering > 2% of the pars tensa) and middle ear discharge.

Children with a perforation were examined a second time with a video otoscope. The degree of discharge was graded as nil, scant (discharge visible with otoscope, but limited to middle ear space), moderate (discharge visible with otoscope and present in ear canal), or profuse (discharge visible without otoscope). Drawings of the eardrum and perforations were made, with estimates of the position and size of the perforation as a percentage of the pars tensa. Examiners reviewed the videos in Darwin to confirm the original diagnoses of perforations.

Swab collection and microbiology

Swabs were taken from the nasopharynx and middle ear at both the baseline and final ear examinations. All swabs were cultured on selective media for respiratory bacteria. The bacteria specifically targeted were *Streptococcus pneumoniae*, non-typeable *Haemophilus influenzae*, *Moraxella catarrhalis* and *Staphylococcus aureus*. Ear discharge swabs were also cultured for *Streptococcus pyogenes* (Group A *Streptococcus*), *Pseudomonas aeruginosa* and *Proteus* spp.

Swabs stored in skim-milk tryptone glucose glycerol broth[20] were thawed and mixed, and 10 μL aliquots were cultured on the following plates: full chocolate agar, 5% horse blood agar containing colistin and nalidixic acid, and chocolate agar with bacitracin, vancomycin, and clindamycin (Oxoid Australia). Ear discharge swabs were also cultured on MacConkey agar plates. Blood plates were incubated at 37°C in 5% CO_2, and MacConkey plates at 35°C in air. Bacterial isolates were identified according to standard laboratory procedures.

The density of each of the bacteria on each plate was categorised as: 1) < 20; 2) 20–49; 3) 50–100; 4) > 100 or confluent in the primary inoculum; 5) as for 4, but colonies also in second quadrant of the plate; 6) as for 5, but colonies also in third quadrant; 7) as for 6, but colonies also in fourth quadrant. Dichotomous measures for bacterial load were categorised as low density (< 100 colonies) or high density (≥ 100 colonies).

Outcome measures

Clinical measures

The primary outcome measure was the proportion of children with otoscopic signs of ear discharge in the canal or middle ear space after 4 weeks. Final ear examinations took place 12 hours to 2.5 days after the participants' last scheduled swim. Prespecified subgroup comparisons were: younger (5–7 years) versus older (8–12 years) children; children who had been prescribed topical antibiotics versus those who had not; degrees of discharge; and smaller (< 25%) versus larger (≥ 25%) perforations.

Microbiological measures

For the nasopharynx, we determined the proportions of children with *S. pneumoniae*, *H. influenzae*, *M. catarrhalis*, any respiratory pathogen (*S. pneumoniae*, *H. influenzae*, *M. catarrhalis*) and *S. aureus*. For the middle ear, we determined the proportions of children with *S. pneumoniae*, *H. influenzae*, *M. catarrhalis*, *S. aureus*, Group A *Streptococcus*, *P. aeruginosa* and *Proteus* spp.

Statistical methods and analyses

All participants allocated to a group contributed a clinical outcome for analysis, including children lost to follow-up, whose diagnoses were assumed not to have changed from baseline. Children lost to follow-up were excluded from assessments of microbiological outcomes. Risk differences (RDs) between the study groups were calculated with 95% confidence intervals. The Mann–Whitney *U* test was used to compare median perforation sizes of the study groups.

Sample size

We hypothesised that 90% of children not swimming would have ear discharge at 28 days and that swimming could reduce this proportion. We specified that a 25% difference between the two groups would be clinically important. Our aim was to recruit a sample of 100 children to provide 80% power to detect a substantial difference of 25% between the two groups.

Results

Parental consent was obtained for 89 eligible children: 41 children in the swimming group and 48 children in the non-swimming group (Box 1). At 4-week follow-up, final ear examinations were conducted on 82 children (36 swimmers and 46 non-swimmers).

2 Participant characteristics at baseline and 4-week follow-up

	Baseline		Follow-up		
	Swimmers (*n* = 41)	Non-swimmers (*n* = 48)	Swimmers (*n* = 41)	Non-swimmers (*n* = 48)	Risk difference (95% CI)*
Mean age in years (SD)	8.9 (2.4)	8.6 (1.9)	—	—	
Male	27 (66%)	31 (65%)	—	—	
Ear diagnosis	*n* = 41	*n* = 48	*n* = 41†	*n* = 48†	
Bilateral closed tympanic membranes	—	—	1/41 (2%)	6/48 (13%)	−10% (−23% to 2%)
Unilateral dry TMP	11/41 (27%)	11/48 (23%)	11/41 (27%)	5/48 (10%)	16% (0 to 33%)
Bilateral dry TMPs	4/41 (10%)	5/48 (10%)	5/41 (12%)	5/48 (10%)	2% (−12% to 17%)
Unilateral wet TMP	12/41 (29%)	13/48 (27%)	10/41 (24%)	12/48 (25%)	−1% (−18% to 18%)
Wet TMP and dry TMP	2/41 (5%)	2/48 (4%)	5/41 (12%)	5/48 (10%)	2% (−12% to 17%)
Bilateral wet TMPs	12/41 (29%)	17/48 (35%)	9/41 (22%)	15/48 (31%)	−9% (−27% to 10%)
Median size of TMP as percentage of pars tensa (IQR)	20% (8%–38%)	18% (6%–40%)	15% (4%–32%)	20% (5%–49%)	*P* = 0.39
Any ear discharge (primary outcome)	26/41 (63%)	32/48 (67%)	24/41 (59%)	32/48 (67%)	−8% (−28% to 12%)
Moderate or profuse discharge	16/41 (39%)	19/48 (40%)	20/41 (49%)	25/48 (52%)	−3% (−24% to 17%)
Nasopharyngeal bacteria	*n* = 41	*n* = 46‡	*n* = 35‡	*n* = 41‡	
Streptococcus pneumoniae	28/41 (68%)	33/46 (72%)	19/35 (54%)	27/41 (66%)	−12% (−33% to 1%)
Non-typeable *Haemophilus influenzae*	17/41 (41%)	28/45 (62%)	21/35 (60%)	30/41 (73%)	−13% (−34% to 8%)
Moraxella catarrhalis§	17/40 (43%)	17/46 (37%)	6/35 (17%)	14/41 (34%)	−17% (−36% to 3%)
Any respiratory pathogen	28/41 (68%)	41/46 (89%)	24/35 (69%)	37/41 (90%)	−22% (−40% to −4%)
Staphylococcus aureus	8/41 (20%)	5/46 (11%)	9/35 (26%)	4/41 (10%)	16% (−1% to 34%)
At least one high-density respiratory pathogen§	17/35 (49%)	23/43 (53%)	16/35 (46%)	16/41 (39%)	7% (−15% to 28%)
Middle ear bacteria	*n* = 24‡	*n* = 30‡	*n* = 23‡	*n* = 32‡	
Streptococcus pneumoniae§	1/24 (4%)	4/30 (13%)	0/23	2/32 (6%)	−6% (−20% to 9%)
Non-typeable *Haemophilus influenzae*	8/23 (35%)	14/28 (50%)	16/23 (70%)	20/31 (65%)	5% (−21% to 29%)
Moraxella catarrhalis§	0/22	0/29	1/21 (5%)	0/31	5% (−4% to 14%)
Staphylococcus aureus	8/24 (33%)	5/30 (17%)	8/23 (35%)	4/32 (13%)	22% (0 to 45%)
Group A *Streptococcus*	3/24 (13%)	1/30 (3%)	5/23 (22%)	2/32 (6%)	15% (−3% to 37%)
Pseudomonas aeruginosa	3/24 (13%)	10/30 (33%)	10/23 (43%)	10/32 (31%)	12% (−13% to 37%)
Proteus spp.	3/24 (13%)	2/30 (7%)	2/23 (9%)	2/32 (6%)	2% (−13% to 22%)

TMP = tympanic membrane perforation. IQR = interquartile range. * Unless otherwise indicated. † Includes children lost to follow-up, whose diagnoses were assumed not to have changed from baseline. ‡ Denominators are reduced due to children lost to follow-up, children refusing to have swab taken, or swab being damaged in transportation. § Some plates were contaminated by *Proteus* spp. ◆

At baseline, the study groups were similar in age, sex, perforation size, the presence and degree of ear discharge, and the prevalences of ear diagnoses (Box 2). Although there were no statistically significant differences in the baseline prevalence of bacteria in the nasopharynx or middle ear, swimmers had lower rates of *H. influenzae* in the nasopharynx and higher rates of *S. aureus* in both the nasopharynx and middle ear. Of the 89 children, 58 (26 swimmers and 32 non-swimmers) had ear discharge at baseline.

At 4-week follow-up, 56 children had ear discharge: 24 of 41 swimmers compared with 32 of 48 non-swimmers (RD, −8%; 95% CI, −28% to 12%). Excluding children lost to follow-up, 21 of 36 swimmers had ear discharge compared with 31 of 46 non-swimmers (RD, −9%; 95% CI, −30% to 12%).

Between baseline and 4-week follow-up, there was no statistically significant change in the prevalence of bacteria in the nasopharynx (Box 2). *P. aeruginosa* infection in the middle ear increased in swimmers, compared with no change in non-swimmers. Non-typeable *H. influenzae* isolated from ear discharge increased in both groups. Overall, the dominant organisms were *S. pneumoniae* and *H. influenzae* in the nasopharynx, and *H. influenzae, S. aureus* and *P. aeruginosa* in the middle ear.

Per-protocol analysis of swimmers attending >75% of swimming classes and non-swimmers adhering to swimming restrictions >75% of the time indicated that 16 of 24 swimmers had ear discharge at 4-week follow-up, compared with 29 of 44 non-swimmers (RD, 1%; 95% CI, −23% to 23%).

Rates of discharge were significantly lower in children who were prescribed ciprofloxacin and in children with smaller perforations (Box 3).

Of the 89 children, 65 had no change from their original diagnosis (by child's worst ear) at 4-week follow-up. Ear discharge failed to resolve in 31 of the 35 participants with moderate to profuse ear discharge at baseline (Box 3). Seven of the 89 children had a perforation that healed (Box 4).

Discussion

We found that regular swimming in a chlorinated pool for 4 weeks did not aid resolution of ear discharge in Aboriginal children with CSOM. At the end of the trial, rates of ear discharge were similar between swimmers and non-swimmers. Our microbiological data also suggest that swimming is unlikely to be effective in removing discharge from the middle ear and nasopharynx, with rates and

3 Children with ear discharge at final ear examination, by subgroup at baseline

	Overall	Swimmers	Non-swimmers	Risk difference (95% CI)
All children with ear discharge at final ear examination	56/89 (63%)	24/41 (59%)	32/48 (67%)	−8% (−28% to 12%)
Subgroup				
Aged 5–7 years	14/24 (58%)	6/11 (55%)	8/13 (62%)	−7% (−44% to 31%)
Aged 8–12 years	42/65 (65%)	18/30 (60%)	24/35 (69%)	−9% (−31% to 15%)
Not prescribed topical ciprofloxacin	46/67 (69%)	20/30 (67%)	26/37 (70%)	−4% (−26% to 18%)
Prescribed topical ciprofloxacin	10/22 (45%)	4/11 (36%)	6/11 (55%)	−18% (−54% to 23%)
Nil discharge	9/31 (29%)	3/15 (20%)	6/16 (38%)	−18% (−47% to 15%)
Scant discharge	16/23 (70%)	5/10 (50%)	11/13 (85%)	−35% (−66% to 4%)
Moderate or profuse discharge	31/35 (89%)	16/16 (100%)	15/19 (79%)	−21% (−1% to 44%)
Small (< 25%) perforation	19/49 (39%)	9/24 (38%)	10/25* (40%)	−3% (−29% to 24%)
Large (≥ 25%) perforation	35/38 (92%)	15/17 (88%)	20/21 (95%)	−7% (−31% to 13%)

* Perforation size was not estimated for two children in the non-swimming group at baseline. ◆

densities of organisms generally comparable between swimmers and non-swimmers, with little change during the study. Among swimmers, there was an increase in *P. aeruginosa* middle ear infection, but this was not correlated with new episodes of ear discharge.

Our study is the first RCT to examine the effects of swimming on Aboriginal children with CSOM and also addresses the need for more RCTs examining the impact of swimming on children with grommets. Further, the microbiological data enabled an assessment of the effect of regular swimming on infection in the nasopharynx and middle ear. Other strengths include the blinding of examiners, prespecified subgroup analysis and a follow-up rate of more than 90%.

Our study also has some limitations. We planned to randomly assign 100 children and anticipated that 90% of participants would have ear discharge at follow-up, but we had only 89 participants and 63% with discharge at follow-up, meaning the study was underpowered. Some difficulties were encountered in recruiting children who did not attend school in one community. The possibility of contamination among non-swimmers was also a concern. Parents and school and pool staff assisted in ensuring that non-swimmers did not swim at the pool or at any other water sites, and alternative activities were provided for non-swimmers after school, as this was a popular swimming time. Attendance at swimming and activity classes were monitored, and two portable media players were offered as incentives to children with the highest attendance.

The lack of objective measures for the degree of discharge, perforation size and bacterial density may have contributed to measurement error. It is unlikely that these limitations would prevent a large clinical effect being identified. However, our small sample size means that modest benefits or harms associated with daily swimming may still be possible.

4 Change in diagnosis (by child's worst ear) from baseline to final ear examination

Outcome	Overall (*n* = 89)	Swimmers (*n* = 41)	Non-swimmers (*n* = 48)
Dry TMP to closed tympanic membrane	4 (5%)	1 (2%)	3 (6%)
Dry TMP to dry TMP	18 (20%)	11 (27%)	7 (15%)
Dry TMP to wet TMP	9 (10%)	3 (7%)	6 (13%)
Wet TMP to closed tympanic membrane	3 (3%)	0	3 (6%)
Wet TMP to dry TMP	8 (9%)	5 (12%)	3 (6%)
Wet TMP to wet TMP	47 (53%)	21 (51%)	26 (54%)
Improved	15 (17%)	6 (15%)	9 (19%)
Same	65 (73%)	32 (78%)	33 (69%)
Got worse	9 (10%)	3 (7%)	6 (13%)

TMP = tympanic membrane perforation. ◆

Our results are not consistent with research from two remote communities in Western Australia, which found that rates of TMPs among Aboriginal children halved from about 30% to 15% after swimming pools were installed.[11] The potential to improve on our results with longer exposure to swimming is possible. However, the WA study did not follow individual children, and after 5 years the reductions were sustained in only one community.[14] Further, the likelihood of significant clinical improvements over a longer period is not supported by our microbiological data. A recent South Australian study also found that the installation of swimming pools in six communities did not affect rates of TMPs among children.[12]

While swimming may remove some ear and nasal discharge, there is evidence to suggest that cleansing practices alone will not cure CSOM. A Cochrane review of studies conducted in developing countries found that wet irrigation or dry mopping was no more effective than no treatment in resolving ear discharge in children with CSOM (odds ratio, 0.63; 95% CI, 0.36–1.12).[21] The review recommended that aural cleansing should be conducted in conjunction with topical antibiotic therapy.[21] Future studies could look at the effectiveness of swimming in combination with the application of topical antibiotic therapy.

Over the 4 weeks of our intervention, rates of *H. influenzae* middle ear infection substantially increased in both swimmers (from 35% to 70%) and non-swimmers (from 50% to 65%). Previous topical antibiotic trials

of Aboriginal children (aged 1–16 years) have reported lower baseline rates of *H. influenzae* in the middle ear, ranging from 5% to 25%.[6,9] In contrast, a vaccination trial of Aboriginal infants aged < 24 months found *H. influenzae* in 85% of new perforations.[22] The high levels of *H. influenzae* ear and nasopharyngeal infection may mean that there is a role for the use of oral antibiotics in combination with topical antibiotics to treat Aboriginal children with CSOM. There may also be benefits from vaccines against *H. influenzae* in Aboriginal children at high risk of progressing to CSOM.

Simultaneous hand contamination and nasal carriage of *S. pneumoniae* and *H. influenzae* is a reliable indicator of TMP in Aboriginal children under 4 years of age.[23] Future research could examine rates of hand contamination in relation to swimming, particularly targeting younger children (aged 2–5 years), who are most likely to transmit otitis media bacteria to infants.

In conclusion, it seems unlikely that regular swimming in pools will resolve ear discharge and heal TMPs in the short term. We also found no clear indication that swimming reduces rates of respiratory and opportunistic bacteria in the nasopharynx or middle ear. However, we did not find swimming to be associated with an increased risk of ear discharge. We would not support the practice of restricting children with a TMP from swimming unless it was documented that ear discharge developed directly after swimming (for that particular child). More RCTs are needed to assess more modest (or longer-term) effects of swimming on middle ear disease in Aboriginal children. The combination of swimming and ciprofloxacin treatment may also produce better clinical outcomes and should be investigated.

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