Middle-ear pain and trauma during air travel

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ABSTRACT

INTRODUCTION: Changes in air pressure during flying can cause ear-drum pain and perforation, vertigo, and hearing loss. It has been estimated that 10% of adults and 22% of children might have damage to the ear drum after a flight, although perforation is rare. Symptoms usually resolve spontaneously. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical question: What are the effects of interventions to prevent middle-ear pain during air travel? We searched: Medline, Embase, The Cochrane Library and other important databases up to April 2007 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found four systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review we present information relating to the effectiveness and safety of the following interventions: nasal balloon inflation; oral pseudoephedrine; and topical nasal decongestants.

QUESTIONS

INTERVENTIONS

Key points

- Changes in air pressure during flying can cause ear-drum pain and perforation, vertigo, and hearing loss. Barotitis is inflammation of the ear drum as a consequence of air pressure changes.

  It has been estimated that 10% of adults and 22% of children might have damage to the ear drum after a flight, although perforation is rare.

  Symptoms usually resolve spontaneously.
- Nasal balloon inflation may reduce symptoms of barotitis in people during air travel.
- Oral pseudoephedrine may reduce symptoms in adults with previous ear pain during flights.

  We don't know whether oral pseudoephedrine is also beneficial in children, but it can cause drowsiness.
- We don't know whether topical nasal decongestants can prevent symptoms of barotrauma.

DEFINITION

The effects of air travel on the middle ear, as a result of changes in air pressure, can include ear-drum pain, vertigo, hearing loss, and ear-drum perforation.

INCIDENCE/ PREVALENCE

The prevalence of symptoms depends on the altitude, type of aircraft, and characteristics of the passengers. One point prevalence study found that, in commercial passengers, 20% of adult and 40% of child passengers had negative pressure in the middle ear after flight, and that 10% of adults and 22% of children had otoscopic evidence of damage to the ear drum. [1] We found no data on the incidence of perforation, which seems to be extremely rare in commercial passengers.

AETIOLOGY/ RISK FACTORS

During aircraft descent, the pressure in the middle ear drops relative to that in the ear canal. A narrow, inflamed, or poorly functioning Eustachian tube impedes the necessary influx of air. As the pressure difference between the middle and outer ear increases, the ear drum is pulled inwards.

PROGNOSIS

In most people, symptoms resolve spontaneously. Experience in military aviation shows that most ear-drum perforations will heal spontaneously. [2]

AIMS OF INTERVENTION

To prevent ear pain and trauma during air travel.

OUTCOMES

Barotrauma (includes incidence and severity of pain and hearing loss, and incidence of perforation of ear drum).

METHODS

Clinical Evidence search and appraisal April 2007. The following databases were used to identify studies for this systematic review: Medline 1966 to April 2007, Embase 1980 to April 2007, and The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials 2007, Issue 1. Additional searches were carried out using these websites: NHS Centre for Reviews and Dissemination (CRD) — for Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA), Turning Research into Practice (TRIP), and NICE. We also searched for retractions of studies included in the review. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the author for additional assessment, using pre-determined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews and RCTs in any language, at least single blinded, and containing more than 20 individuals of whom more than 80% were followed up (those studies with less than 80% follow-up but with intention-to-treat analysis were considered). There was no minimum length of follow-up required to include studies. We excluded all studies described as "open", "open label", or not blinded unless blinding was impossible. In addition, we use a regular surveillance protocol to capture harms alerts from organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA), which are added to the reviews as required. To aid readability of the numerical data in our reviews, we round many percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 9). The categorisation of the quality of the evidence (high, moderate, low, or very low) reflects the quality of evidence available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the Clinical Evidence population and outcome of choice may represent only a small subset of the total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com).

QUESTION Preventing middle-ear pain during air travel

OPTION NASAL BALLOON INFLATION

- For GRADE evaluation of interventions for Middle-ear pain and trauma during air travel, see table, p 9 .
- Nasal balloon inflation, p 2 may reduce symptoms of barotitis in people during air travel.

Benefits and harms

Nasal balloon inflation versus control:

We found one controlled trial comparing nasal balloon inflation during flight versus no nasal balloon inflation. [3]

Barotrauma

Nasal balloon inflation compared with no nasal balloon inflation Nasal balloon inflation during flights may be more effective at reducing barotitis compared with controls (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Barotitis					
[3] Controlled clinical trial	120 people	**Barotitis** 2/36 (6%) with nasal balloon inflation 10/69 (15%) with control Possible bias; for full details, see further information about studies	P <0.05 See further information on studies for methodological details	○○○	nasal balloon inflation

Adverse effects

No data from the following reference on this outcome. [3]

Further information on studies

[3] The intervention and control groups took different flights — which may lead to bias. The trial was of sufficient sample size and power to detect the efficacy of nasal balloon inflation in reducing the symptoms of barotrauma during flight among adults. 105 people who had negative middle-ear pressure after the flight performed a valsalva manoeuvre (forceful blowing of air while keeping the mouth and nose closed), after which 48/105 (46%) had equalised their middle-ear pressure. The remaining 57 underwent nasal balloon inflation. The study found that 36/52 (69%) were able to equalise their middle-ear pressure after nasal balloon inflation.

Comment: None.

OPTION PSEUDOEPHEDRINE (ORAL) IN ADULTS

- For GRADE evaluation of interventions for Middle-ear pain and trauma during air travel, see table, p 9 .
- Oral pseudoephedrine, p 3 may reduce symptoms in adults with previous ear pain during flights.

Benefits and harms

Oral pseudoephedrine versus placebo:

We found no systematic review. We found two RCTs in adult passengers with a history of ear pain during air travel. [4] [5]

Barotrauma

Oral pseudoephedrine compared with placebo Oral pseudoephedrine is more effective than placebo at reducing the symptoms of barotrauma during air travel — such as ear pain and hearing loss — in adults with a history of ear pain (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Symptoms of barotrauma					
[4] RCT **3-armed trial**	150 adults The remaining arm evaluated oxymetazoline nasal spray People with acute or chronic ear problems were excluded	**Proportion of people with symptoms of barotrauma (ear pain, blockage, hearing loss, dizziness/vertigo, and tinnitus; assessed by post-flight questionnaire)** 14/41 (34%) with pseudoephedrine 120 mg 29/41 (71%) with placebo Pseudoephedrine was given at least 30 minutes before flying	RR 0.48 95% CI 0.29 to 0.67	●●○	pseudoephedrine
[5] RCT	190 adults People with acute or chronic ear problems were excluded	**Proportion of people reporting ear pain (assessed by post-flight questionnaire)** 25/96 (26%) with pseudoephedrine 120 mg 43/94 (46%) with placebo Pseudoephedrine was given at least 30 minutes before flying	P = 0.007	○○○	pseudoephedrine
[5] RCT	190 adults People with acute or chronic ear problems were excluded	**Proportion of people reporting hearing loss (assessed by post-flight questionnaire)** 20/96 (21%) with pseudoephedrine 120 mg	P = 0.006	○○○	pseudoephedrine

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		38/94 (40%) with placebo Pseudoephedrine was given at least 30 minutes before flying			

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Drowsiness					
[4] RCT **3-armed trial**	150 adults The remaining arm evaluated oxymetazoline nasal spray People with acute or chronic ear problems were excluded	**Drowsiness** 4/41 (10%) with pseudoephedrine 120 mg 2/41 (5%) with placebo Pseudoephedrine was given at least 30 minutes before flying	Significance not assessed		
[5] RCT	190 adults People with acute or chronic ear problems were excluded	**Drowsiness** 7/96 (7%) with pseudoephedrine 120 mg 2/94 (2%) with placebo Pseudoephedrine was given at least 30 minutes before flying	Significance not assessed		
Dry mouth					
[4] RCT **3-armed trial**	150 adults The remaining arm evaluated oxymetazoline nasal spray People with acute or chronic ear problems were excluded	**Dry mouth** 4/41 (10%) with pseudoephedrine 120 mg 1/41 (2%) with placebo Pseudoephedrine was given at least 30 minutes before flying	Significance not assessed		
[5] RCT	190 adults People with acute or chronic ear problems were excluded	**Dry mouth and nausea** 4.2% with pseudoephedrine 120 mg 4.3% with placebo Absolute numbers not reported Pseudoephedrine was given at least 30 minutes before flying	Significance not assessed		
Nasal irritation					
[4] RCT **3-armed trial**	150 adults The remaining arm evaluated oxymetazoline nasal spray People with acute or chronic ear problems were excluded	**Nasal irritation** 1/41 (2%) with pseudoephedrine 120 mg 0/41 (0%) with placebo Pseudoephedrine was given at least 30 minutes before flying	Significance not assessed		

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Gastrointestinal symptoms					
[4] RCT **3-armed trial**	150 adults The remaining arm evaluated oxymetazoline nasal spray People with acute or chronic ear problems were excluded	**Stomach upset** 1/41 (2%) with pseudoephedrine 120 mg 0/41 (0%) with placebo Pseudoephedrine was given at least 30 minutes before flying	Significance not assessed		
Headache					
[4] RCT **3-armed trial**	150 adults The remaining arm evaluated oxymetazoline nasal spray People with acute or chronic ear problems were excluded	**Headache** 0/41 (0%) with pseudoephedrine 120 mg 1/41 (2%) with placebo Pseudoephedrine was given at least 30 minutes before flying	Significance not assessed		

Further information on studies

Comment: None.

OPTION PSEUDOEPHEDRINE (ORAL) IN CHILDREN

- For GRADE evaluation of interventions for Middle-ear pain and trauma during air travel, see table, p 9 .
- We don't know whether oral pseudoephedrine, p 5 is beneficial in children, but it can cause drowsiness.
- We found no clinically important results from RCTs about the effects of oral decongestants compared with topical decongestants in children with ear pain during air travel.

Benefits and harms

Pseudoephedrine (oral) in children versus placebo:

We found no systematic review. We found one RCT. [6] We found no RCTs comparing oral versus topical decongestants in children.

Barotrauma

Oral pseudoephedrine compared with placebo Oral pseudoephedrine may be no more effective at reducing ear pain at take-off or landing compared with placebo (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Ear pain					
[6] RCT	50 children aged 6 months to 6 years, total of 91 flights assessed	**Proportion of children reporting ear pain , take off** 2/50 (4%) with pseudoephedrine 2/41 (5%) with placebo	P = 1.0	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		Denominator is number of flights in analysis			
[6] RCT	50 children aged 6 months to 6 years, total of 91 flights assessed	**Proportion of children reporting ear pain , landing** 6/49 (12%) with pseudoephedrine 5/39 (13%) with placebo Denominator is number of flights in analysis	P = 1.0	⟷	Not significant

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Drowsiness					
[6] RCT	50 children aged 6 months to 6 years, total of 91 flights assessed	**Proportion of children reporting drowsiness , take off** 30/50 (60%) with pseudoephedrine 11/41 (27%) with placebo Denominator is number of flights in analysis	P = 0.003	○○○	placebo

Further information on studies

Comment: None.

OPTION NASAL DECONGESTANTS (TOPICAL)

- For GRADE evaluation of interventions for Middle-ear pain and trauma during air travel, see table, p 9 .
- We don't know whether topical nasal decongestants, p 6 can prevent symptoms of barotrauma.
- We found no clinically important results about the effects of topical decongestants compared with other topical nasal decongestants or oral decongestants in adults with ear pain during air travel.

Benefits and harms

Topical decongestants versus placebo:

We found no systematic review. We found one RCT. [4] The RCT did not directly compare topical versus oral decongestants. We found no RCTs comparing other topical nasal decongestants versus oral decongestants or versus placebo or during air travel.

Barotrauma

Nasal decongestant compared with placebo Nasal decongestant (oxymetazoline nasal spray) is no more effective than placebo at reducing symptoms of barotrauma in adults with a history of ear pain during air travel (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Barotrauma					
[4] RCT **3-armed trial**	150 people with a history of ear pain during air travel The remaining arm evaluated pseudoephedrine	**Proportion of people with symptoms of barotrauma (ear pain, blockage, hearing loss, dizziness/vertigo, and tinnitus; assessed by post-flight questionnaire)** 27/42 (64%) with oxymetazoline 0.05% 29/41 (71%) with placebo Oxymetazoline was given at least 30 minutes before flight	P = 0.695	⟷	Not significant

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Nasal irritation					
[4] RCT **3-armed trial**	150 people The remaining arm evaluated pseudoephedrine	**Nasal irritation** 6/42 (14%) with oxymetazoline 0.05% 0/41 (0%) with placebo Oxymetazoline was given at least 30 minutes before flight	Significance not assessed		
Drowsiness					
[4] RCT **3-armed trial**	150 people The remaining arm evaluated pseudoephedrine	**Drowsiness** 1/42 (2%) with oxymetazoline 0.05% 2/41 (5%) with placebo Oxymetazoline was given at least 30 minutes before flight	Significance not assessed		
Dry mouth					
[4] RCT **3-armed trial**	150 people The remaining arm evaluated pseudoephedrine	**Dry mouth** 1/42 (2%) with oxymetazoline 0.05% 1/41 (2%) with placebo Oxymetazoline was given at least 30 minutes before flight	Significance not assessed		
Gastrointestinal symptoms					
[4] RCT **3-armed trial**	150 people The remaining arm evaluated pseudoephedrine	**Stomach upset** 1/42 (2%) with oxymetazoline 0.05% 0/41 (0%) with placebo Oxymetazoline was given at least 30 minutes before flight	Significance not assessed		
Headache					
[4] RCT **3-armed trial**	150 people The remaining arm evaluated pseudoephedrine	**Headache** 1/42 (2%) with oxymetazoline 0.05% 1/42 (2%) with placebo	Significance not assessed		

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		Oxymetazoline was given at least 30 minutes before flight			

Further information on studies

[4] The RCT may have been too small to detect an effect of topical decongestants.

Comment: None.

GLOSSARY

Barotrauma Symptoms caused by changes of atmospheric pressure are called barotrauma. In the ear, these include ear drum pain, vertigo, hearing loss, tinnitus, and ear drum perforation.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Very low-quality evidence Any estimate of effect is very uncertain.

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GRADE **Evaluation of interventions for Middle-ear pain and trauma during air travel.**

Important outcomes									
			Barotrauma						
Studies (Participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
Preventing middle-ear pain during air travel									
1 (120) [3]	Barotrauma	Nasal balloon inflation versus control	4	–2	0	–1	0	Very low	Quality points deducted for sparse data and inclusion of controlled clinical trial. Directness point deducted for differences in flights taken between intervention and control
2 (272) [4] [5]	Barotrauma	Oral pseudoephedrine versus placebo	4	–1	0	0	0	Moderate	Quality point deducted for uncertainty about assessment of outcome
1 (91) [6]	Barotrauma	Pseudoephedrine (oral) in children versus placebo	4	–2	0	0	0	Low	Quality points deducted for sparse data and for analysis of a different measure than that randomised (children randomised but analysis based on number of flights)
1 (83) [4]	Barotrauma	Topical decongestants versus placebo	4	–1	0	0	0	Moderate	Quality point deducted for sparse data

We initially allocate 4 points to evidence from RCTs, and 2 points to evidence from observational studies. To attain the final GRADE score for a given comparison, points are deducted or added from this initial score based on preset criteria relating to the categories of quality, directness, consistency, and effect size. Quality: based on issues affecting methodological rigour (e.g., incomplete reporting of results, quasi-randomisation, sparse data [<200 people in the analysis]). Consistency: based on similarity of results across studies. Directness: based on generalisability of population or outcomes. Effect size: based on magnitude of effect as measured by statistics such as relative risk, odds ratio, or hazard ratio.