

# Antioxidants in stapedotomy

**SND-ID:** snd0974-1. **Version:** 1.0. **DOI:** <https://doi.org/10.5878/002570>

## Download data

SND 0974-001-v1.zip (119.07 KB)

## Associated documentation

0974-001CB.pdf (103.75 KB)

## Download all files

snd0974-1-1.0.zip (~222.82 KB)

## Citation

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## Creator/Principal investigator(s)

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## Description

**Background:** Otosclerosis is a disorder that impairs middle ear function, leading to conductive hearing loss. Surgical treatment results in large improvement of hearing at low sound frequencies, but high-frequency hearing often suffers. A likely reason for this is that inner ear sensory cells are damaged by surgical trauma and loud sounds generated during the operation. Animal studies have shown that antioxidants such as N-Acetylcysteine can protect the inner ear from noise, surgical trauma, and some ototoxic substances, but it is not known if this works in humans. This trial was performed to determine whether antioxidants improve surgical results at high frequencies.

**Methods:** We performed a randomized, double-blind and placebo-controlled parallel group clinical trial at three Swedish university clinics. Using block-stratified randomization, 156 adult patients undergoing stapedotomy were assigned to intravenous N-Acetylcysteine (150 mg/kg body weight) or matching placebo (1:1 ratio), starting one hour before surgery. The primary outcome was the hearing threshold at 6 and 8 kHz; secondary outcomes included the severity of tinnitus and vertigo.

**Findings:** One year after surgery, high-frequency hearing had improved  $2.7 \pm 3.8$  dB in the placebo group (67 patients analysed) and  $2.4 \pm 3.7$  dB in the treated group (72 patients; means  $\pm$  95% confidence interval,  $p=0.54$ ; linear mixed model). Surgery improved tinnitus, but there was no significant intergroup difference. Post-operative balance disturbance was common but improved during the first year, without significant difference between groups. Four patients receiving N-Acetylcysteine experienced mild side effects such as nausea and vomiting.

**Conclusions:** N-Acetylcysteine has no effect on hearing thresholds, tinnitus, or balance disturbance after stapedotomy

## Purpose:

Otosclerosis is a disease of the middle ear that causes gradually increasing hearing loss. The stapes is gradually fixed inside the oval window, which leads to hearing impairment. The conventional treatment is surgical (stapedotomy): The stapes is partially replaced by drilling on its footplate and connecting a prosthesis. This results in great improvement of low-frequency hearing, but at frequencies above 4000 Hz, there is less improvement and in some cases even decline of hearing after surgery (see e.g. Meyer, 1999). This is considered a consequence of trauma to the high-frequency parts of the inner ear during drilling on the stapes footplate. During drilling, patients report loud sounds, often described as "the worst sound I ever heard".

In animals, antioxidants such as N-Acetylcysteine can protect the inner ear against noise-induced hearing loss. We will examine whether antioxidants lead to improved high-frequency hearing after stapedotomy. Our hypothesis is that antioxidants protect the inner ear against the trauma caused by the operation.

The dataset contains 9 variables:

"id" is a number with range 1 - 145, unique for each patient.

"medicin" denotes the type of treatment given (possible values are "N-Acetylcysteine" or "Placebo").

"beta" denotes whether the steroid betametason was given before surgery.

"gender" is "f" for female patients and "m" for males.

"weight" is each patient's weight in kg.

"age" is the age (in years, at the time of surgery).

"freq" denotes the type of measurement performed. There are several possible values. "Tinnitus" means that "air1" and "air2" contains the difference in tinnitus scores before and after surgery. "tmv" denotes that air1 contains the average hearing threshold across the frequencies 0.5 - 3 kHz.

"disk" means that "air1" contains the difference in discrimination scores before and after surgery

"dizziness" means that "air1" contains the difference in dizziness scores before and after surgery.

"hearq" means that "air1" contains the difference in hearing quality scores before and after surgery

"surgery" means that "air1" contains the patient's assessment of the outcome of the operation (10 is the best, 0 is the worst)

Numbers "250", "500", "1000", "2000", "3000", "4000", "6000" and "8000" means that "air1" contains the difference in hearing thresholds before and after surgery at this particular stimulus frequency.

"air1" contains measurements acquired 6 - 8 weeks after surgery.

"air2" contains measurements acquired 1 year after surgery.

## Language

[English](#)

## Unit of analysis

[Individual](#)

## Population

Patients who had surgery for otosclerosis at Karolinska University Hospital in Solna and Huddinge, and at Uppsala University Hospital.

## Study design

Double-blind randomised trial

**Sampling procedure**

[Probability: Stratified](#)

**Time period(s) investigated**

2007-12-01 – 2013-04-30

**Variables**

9

**Number of individuals/objects**

145

**Data format / data structure**

[Numeric](#)

**Data collection 1**

- Mode of collection: Physical measurements and tests
- Time period(s) for data collection: 2007-12-01 – 2013-04-30
- Data collector: Karolinska university Hospital and Uppsala University Hospital
- Source of the data: Population group

**Geographic spread**

Geographic description: Stockholm, Uppsala

**Responsible department/unit**

Department of Clinical and Experimental Medicine, IKE

**Ethics Review**

Stockholm - Ref. 2007/305-31

**Research area**

[Medical and health sciences](#) (Standard för svensk indelning av forskningsämnen 2011)

[Neurosciences](#) (Standard för svensk indelning av forskningsämnen 2011)

[Health](#) (CESSDA Topic Classification)

**Keywords**

[Hearing](#), [Hearing loss](#), [Ear diseases](#), [Antioxidants](#), [Otosclerosis](#), [Prevention](#), [Stapedotomy](#)

**Publications**

Fridberger A. A randomised, double blind trial of N-acetylcysteine for hearing protection during stapes surgery. PLOS One 2014, In press.

If you have published anything based on these data, [please notify us](#) with a reference to your publication(s). If you are responsible for the catalogue entry, you can update the metadata/data description in DORIS.

## **Accessibility level**

Access to data through SND  
Data are freely accessible

## **Use of data**

[Things to consider when using data shared through SND](#)

## **Versions**

Version 1.0. 2014-12-19

## **Download metadata**

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