

**SND** Svensk Nationell Datatjänst



## **Antioxidants during stapedotomy**

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# Metadata Production

**Metadata** Swedish national data service

**Producer(s):**

**Production Date:** December 19 2014

**Identification:** SND0974-001

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## Antioxidants during stapedotomy

### *Antioxidanter vid stapedotomi*

#### Overview

**Identification** SND0974-001

**Version** 1.0

#### Abstract

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

**Kind of Data** Measurement data: Physical measurements

**Unit of Analysis** Individual

#### Scope & Coverage

**Keywords** hearing loss, hearing, ear diseases, otosclerosis, antioxidants, stapedotomy, prevention

**Topics** HEALTH

**Time Period(s)** 2007-2007

#### Countries

#### Geographic Coverage

Stockholm, Uppsala

#### Universe

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

#### Producers & Sponsors

**Primary Investigator(s)** Fridberger, Anders Linköping University, Department of Clinical and Experimental Medicine, IKE

**Other Producer(s)** Linköping University, Department of Clinical and Experimental Medicine, IKE

#### Sampling

##### Sampling Procedure

Probability sample: Stratified sample

## Data Collection

**Data Collection** start 2007-12-01

**Dates** end 2013-04-30

**Time Period(s)**

**Data Collection** Physical measurements and tests

**Mode**

**Data Collector(s)** Karolinska University Hospital and Uppsala University Hospital

## File Description(s)

Dataset contains 1 file(s)

### 0974-001 Antioxidants in stapedotomy

Cases	2030
Variable(s)	12

# Variables List

Dataset contains 12 variable(s)

## File 0974-001 Antioxidants in stapedotomy

	Name	Label	Question
1	<a href="#">SND_study</a>	SND-study 0974	-
2	<a href="#">SND_dataset..</a>	SND-dataset 0974-001	-
3	<a href="#">SND_version..</a>	SND-version 1.0	-
4	<a href="#">id</a>	ID number (range 1-145, unique for each patient)	-
5	<a href="#">medicin</a>	Type of treatment given (possible values are "N-Acetylcysteine" or "Placebo")	-
6	<a href="#">beta</a>	Steroid betametason was given before surgery (Yes or No)	-
7	<a href="#">gender</a>	Gender	-
8	<a href="#">weight</a>	Each patient's weight in kg	-
9	<a href="#">age</a>	Age (in years, at the time of surgery)	-
10	<a href="#">freq</a>	Type of measurement performed. There are several possible values. For more information, see the codebook.	-
11	<a href="#">air1</a>	Measurements acquired 6 - 8 weeks after surgery.	-
12	<a href="#">air2</a>	Measurements acquired 1 year after surgery.	-

## Variables Description

Dataset contains 12 variable(s)

### File : 0974-001 Antioxidants in stapedotomy

#### SND\_study: SND-study 0974

**Definition:** SND-study 0974: Antioxidants during stapedotomy

Value	Label	Cases	Percentage
974	SND-studie 0974	2030	100.0%

**Information:** Type: discrete, Format: numeric, Range: 974-974, Missing: \*

**Statistics (NW/ W):** Valid: (2030 / -) Invalid: (0 / -)

#### SND\_dataset: SND-dataset 0974-001

**Definition:** SND-dataset 0974-001: Antioxidants during stapedotomy

Value	Label	Cases	Percentage
1	Dataset 001	2030	100.0%

**Information:** Type: discrete, Format: numeric, Range: 1-1, Missing: \*

**Statistics (NW/ W):** Valid: (2030 / -) Invalid: (0 / -)

#### SND\_version: SND-version 1.0

**Definition:** SND-version 1.0, December 2014

Value	Label	Cases	Percentage
1	Version 1.0	2030	100.0%

**Information:** Type: discrete, Format: numeric, Range: 1-1, Missing: \*

**Statistics (NW/ W):** Valid: (2030 / -) Invalid: (0 / -)

#### id: ID number (range 1-145, unique for each patient)

**Definition:** "id" is a number with range 1 - 145, unique for each patient

**Information:** Type: continuous, Format: numeric, Range: 1-145, Missing: \*

**Statistics (NW/ W):** Valid: (2030 / -) Invalid: (0 / -) Mean: (73 / -) StdDev: (41.867 / -)

#### medicin: Type of treatment given (possible values are "N-Acetylcysteine" or "Placebo")

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

Value	Label	Cases	Percentage
N-Acetylcysteine		1036	51.0%
Placebo		994	49.0%

**Information:** Type: discrete, Format: character, Missing: \*



**File : 0974-001 Antioxidants in stapedotomy****medicin: Type of treatment given (possible values are "N-Acetylcysteine" or "Placebo")**

Statistics (NW/ W): Valid: (2030 / -) Invalid: (0 / -)

**beta: Steroid betametason was given before surgery (Yes or No)**

**Definition:** "beta" denotes whether the steroid betametason was given before surgery

Value	Label	Cases	Percentage
No		1428	70.3%
Yes		602	29.7%

**Information:** Type: discrete, Format: character, Missing: \*

Statistics (NW/ W): Valid: (2030 / -) Invalid: (0 / -)

**gender: Gender**

**Definition:** "gender" is "f" for female patients and "m" for males

Value	Label	Cases	Percentage
f	Females	1344	66.2%
m	Males	686	33.8%

**Information:** Type: discrete, Format: character, Missing: \*

Statistics (NW/ W): Valid: (2030 / -) Invalid: (0 / -)

**weight: Each patient's weight in kg**

**Definition:** "weight" is each patient's weight in kg

**Information:** Type: continuous, Format: numeric, Range: 48-131, Missing: \*

Statistics (NW/ W): Valid: (2030 / -) Invalid: (0 / -) Mean: (73.203 / -) StdDev: (14.435 / -)

**age: Age (in years, at the time of surgery)**

**Definition:** "age" is the age (in years, at the time of surgery)

**Information:** Type: continuous, Format: numeric, Range: 21-74, Missing: \*

Statistics (NW/ W): Valid: (2030 / -) Invalid: (0 / -) Mean: (49.579 / -) StdDev: (11.522 / -)

**freq: Type of measurement performed. There are several possible values. For more information, see the codebook.**

**Definition:** "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.

**File : 0974-001 Antioxidants in stapedotomy**

**freq:** Type of measurement performed. There are several possible values. For more information, see the codebook.

Value	Label	Cases	Percentage
1000		145	7.1%
2000		145	7.1%
250		145	7.1%
3000		145	7.1%
4000		145	7.1%
500		145	7.1%
6000		145	7.1%
8000		145	7.1%
disk		145	7.1%
dizziness		145	7.1%
hearq		145	7.1%
surgery		145	7.1%
tinnitus		145	7.1%
tmv		145	7.1%

**Information:** Type: discrete, Format: character, Missing: \*

**Statistics (NW/ W):** Valid: (2030 / -) Invalid: (0 / -)

**air1: Measurements acquired 6 - 8 weeks after surgery.**

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

Value	Label	Cases	Percentage
-1		36	1.8%
-10		31	1.6%
-12		3	0.2%
-13		1	0.1%
-14		1	0.1%
-15		17	0.9%
-16		2	0.1%
-2		52	2.7%
-20		10	0.5%
-25		6	0.3%
-3		24	1.2%
-30		4	0.2%
-35		2	0.1%
-4		54	2.8%
-42		1	0.1%
-46		1	0.1%
-5		59	3.0%
-55		1	0.1%
-6		23	1.2%

**File : 0974-001 Antioxidants in stapedotomy****air1: Measurements acquired 6 - 8 weeks after surgery.**

Value	Label	Cases	Percentage
-7		9	0.5%
-8		8	0.4%
-85		1	0.1%
-9		2	0.1%
0		276	14.1%
1		41	2.1%
10		164	8.4%
11		3	0.2%
12		4	0.2%
13		2	0.1%
14		2	0.1%
15		156	8.0%
16		7	0.4%
17		7	0.4%
18		6	0.3%
19		2	0.1%
2		23	1.2%
20		140	7.2%
21		4	0.2%
22		4	0.2%
23		6	0.3%
24		5	0.3%
25		163	8.3%
26		4	0.2%
27		6	0.3%
28		4	0.2%
29		3	0.2%
3		15	0.8%
30		116	5.9%
31		5	0.3%
32		2	0.1%
33		6	0.3%
34		2	0.1%
35		80	4.1%
36		2	0.1%
38		1	0.1%
39		1	0.1%
4		25	1.3%
40		48	2.5%
42		3	0.2%
43		1	0.1%

**File : 0974-001 Antioxidants in stapedotomy****air1: Measurements acquired 6 - 8 weeks after surgery.**

Value	Label	Cases	Percentage
45		39	2.0%
46		1	0.1%
5		116	5.9%
50		11	0.6%
55		7	0.4%
6		14	0.7%
60		2	0.1%
7		9	0.5%
8		41	2.1%
9		26	1.3%
NA		77	

**Information:** Type: discrete, Format: character, Missing: \*/NA

**Statistics (NW/ W):** Valid: (1953 / -) Invalid: (77 / -)

**air2: Measurements acquired 1 year after surgery.**

**Definition:** "air2" contains measurements acquired 1 year after surgery.

Value	Label	Cases	Percentage
-1		30	1.5%
-10		22	1.1%
-11		1	0.1%
-12		1	0.1%
-14		2	0.1%
-15		15	0.8%
-16		4	0.2%
-2		47	2.4%
-20		6	0.3%
-25		7	0.4%
-26		2	0.1%
-3		36	1.8%
-30		2	0.1%
-36		1	0.1%
-4		45	2.3%
-42		1	0.1%
-45		1	0.1%
-5		53	2.7%
-50		2	0.1%
-54		1	0.1%
-55		2	0.1%
-6		26	1.3%
-60		4	0.2%

**File : 0974-001 Antioxidants in stapedotomy**

**air2: Measurements acquired 1 year after surgery.**

Value	Label	Cases	Percentage
-7		12	0.6%
-70		1	0.1%
-8		9	0.5%
-9		2	0.1%
0		244	12.5%
1		31	1.6%
10		158	8.1%
11		2	0.1%
12		2	0.1%
14		3	0.2%
15		156	8.0%
16		4	0.2%
18		6	0.3%
19		7	0.4%
2		34	1.7%
20		142	7.3%
21		6	0.3%
22		6	0.3%
23		5	0.3%
24		6	0.3%
25		165	8.5%
26		4	0.2%
27		5	0.3%
28		6	0.3%
29		4	0.2%
3		21	1.1%
30		114	5.9%
31		7	0.4%
32		4	0.2%
33		5	0.3%
34		3	0.2%
35		99	5.1%
36		1	0.1%
37		3	0.2%
38		2	0.1%
4		22	1.1%
40		64	3.3%
42		2	0.1%
43		1	0.1%
45		48	2.5%
46		1	0.1%

**File : 0974-001 Antioxidants in stapedotomy****air2: Measurements acquired 1 year after surgery.**

Value	Label	Cases	Percentage
48		1	0.1%
5		98	5.0%
50		27	1.4%
54		1	0.1%
55		7	0.4%
56		1	0.1%
57		1	0.1%
6		9	0.5%
60		3	0.2%
65		1	0.1%
7		13	0.7%
8		31	1.6%
88		1	0.1%
9		23	1.2%
96		1	0.1%
NA		84	

**Information:** Type: discrete, Format: character, Missing: \*/NA

**Statistics (NW/ W):** Valid: (1946 / -) Invalid: (84 / -)