Pedersen M (2006). Evidenz in der Gesang-Forschung *XVIII. Bundesverband Deutscher Gesangpaedagogen-Jahreskongress Kassel.*

Bundesverband Deutscher Gesangpädagogen 2006 Kassel

Evidenz in der Gesang Forschung

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Musikalische Ausbildung

1954-57 Permanente Gesang Soloistin im Gymnasium
1957-65 Jolanda Rodio; private Gesang Unterricht
1975-80 Karen Heerup; private Gesang Unterricht
Master Klasses
1949-57 Private Piano Unterricht, E. Munk
1958-61 Private Piano Unterricht, Teddy Teirup

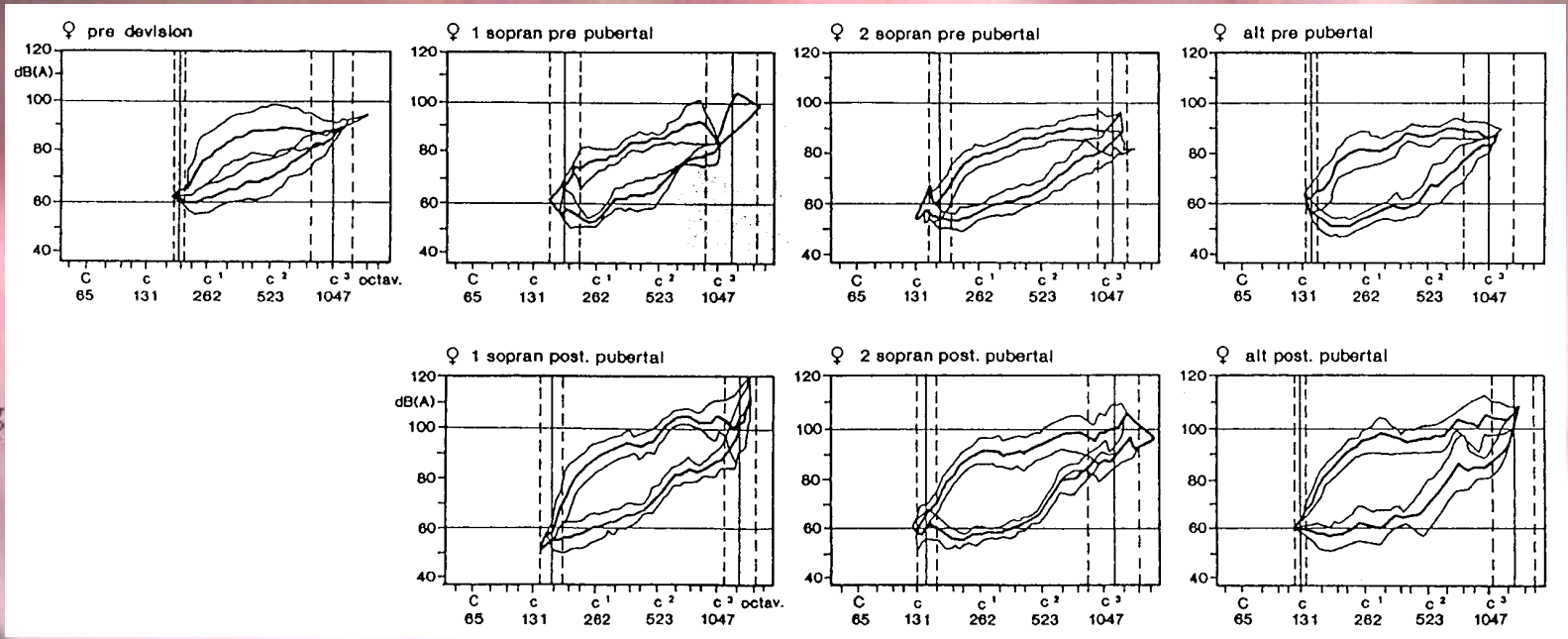
Repertoire:

Gesang:
Müllerlieder and Wintereise (Schubert)
Dichterliebe (Schuman)
Vier ernste Gesänge (Brahms)
Verdi-Arien
Usw.

Piano:
Beethoven Sonaten
Bach pieces, incl. Italian Konzert.
Schuman, Kinderscenen
Usw.

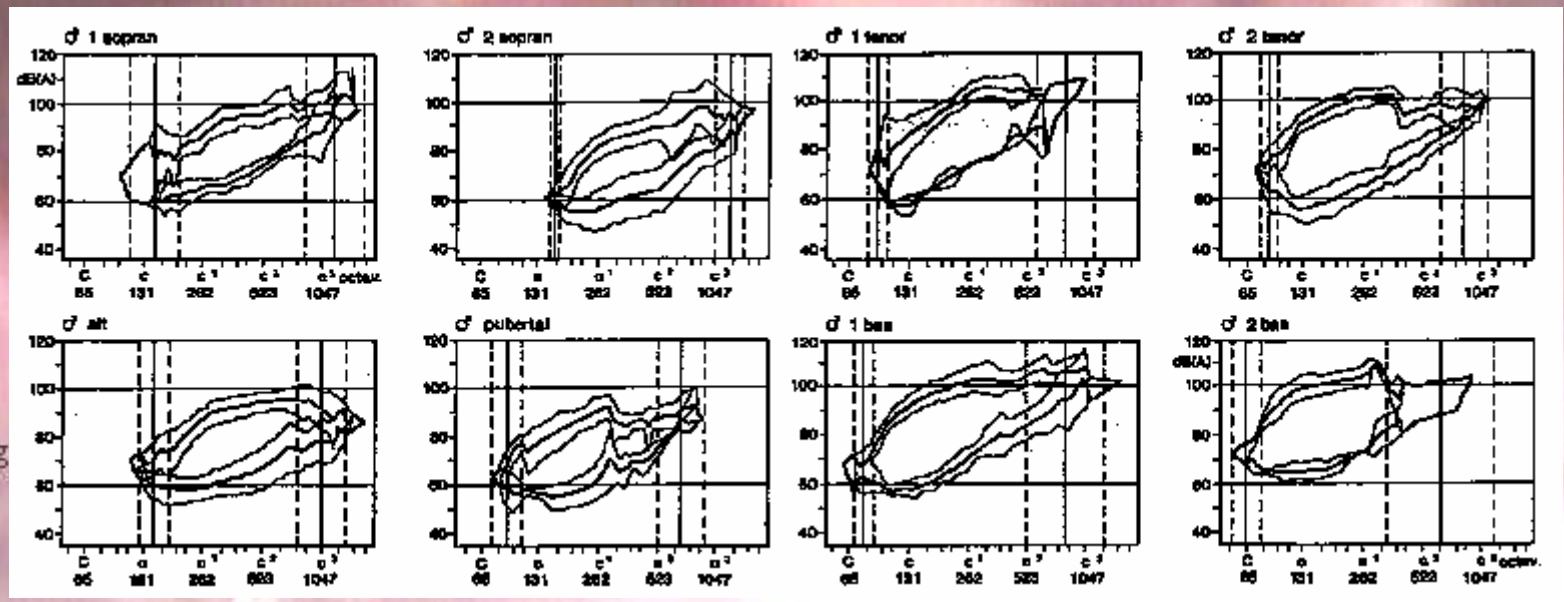
Geräte, notwendig für das Verstehen der Stimmen

Phonetogramme der Knaben Entwicklung:



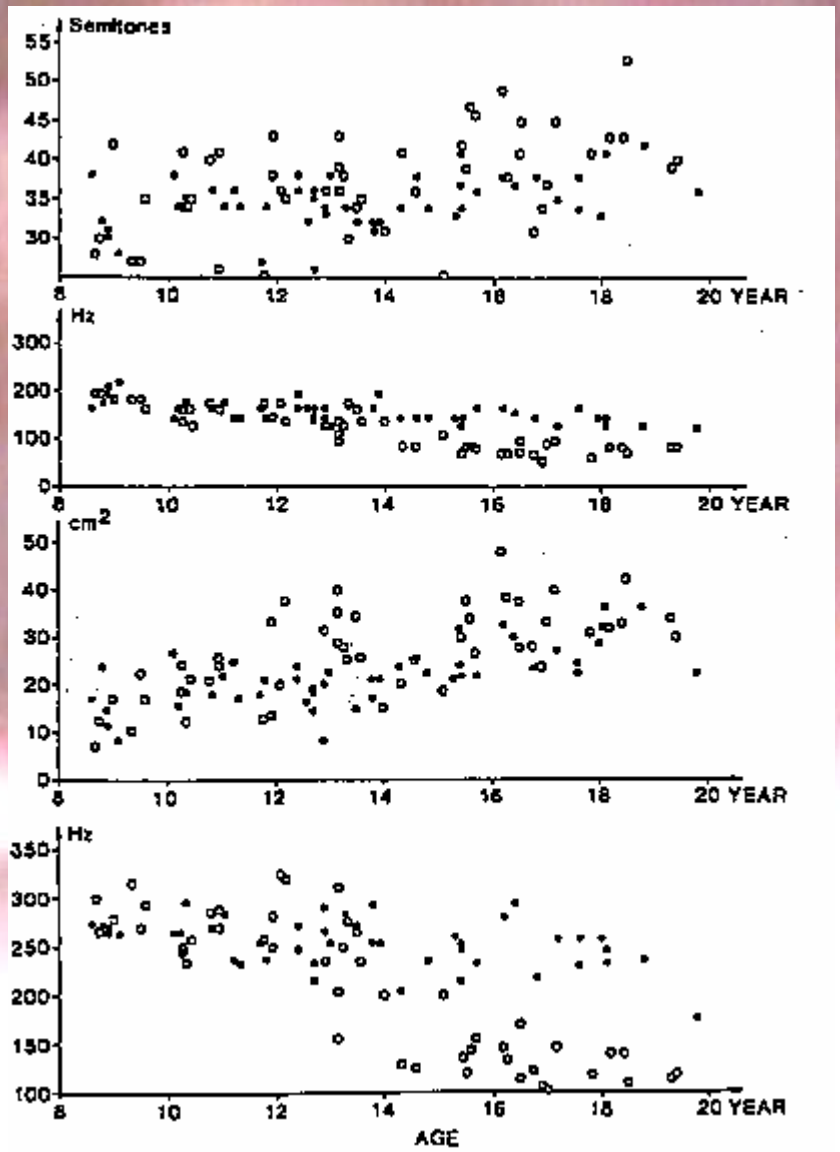
Geräte, notwendig für das Verstehen der Stimmen

Phonetogramme der Mädchen Entwicklung:



Geräte, notwendig für das Verstehen der Stimmen

Mädchen und Knaben:



Tonumfang

Niedrige Ton

Grundfrekvenz Areal
Semitöne x dB(A)

Grundfrekvenz
des Sprechens

Lx 0Deg 138.7Hz 67.4dB

Keine Evidenz in der Stimmforschung (zwei Cochrane Übersichten auf Englisch)

ACID REFLUX TREATMENT FOR HOARSENESS [REVIEW]

Hopkins C, Yousaf U, Pedersen M

SURGICAL VERSUS NON-SURGICAL INTERVENTIONS FOR VOCAL CORD NODULES

Pedersen M, McGlashan J

ACID REFLUX TREATMENT FOR HOARSENESS [REVIEW]

A recent study of reflux and voice disorders suggests that up to 55% of patients with hoarseness (dysphonia) have laryngo-pharyngeal reflux.

The aim of the review was to assess the effectiveness of anti-reflux therapy for patients with hoarseness, in the absence of other identifiable causes, whether or not a definitive diagnosis of laryngo-pharyngeal and gastro-oesophageal reflux has been made. This was assessed by evaluation of **prospective randomised controlled studies** that were identified by a systematic review of the literature. Both medical and surgical treatments were evaluated.

Search strategy

We searched the Cochrane ENT Group Specialised Register and the Cochrane Central Register of Controlled Trials (The Cochrane Library, Issue 3, 2005). Additional studies were searched for using MEDLINE (1951 to 2005) and EMBASE (1974 to 2005), CINAHL (1982 to 2005), Biological Abstracts and review articles. *Handsearching* of the authors' own files was carried out as well as searches of databases of theses. The date of the last search was September 2005.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All randomised and quasi-randomised, controlled, double-blinded trials. Controlled clinical trials (trials using a control group but no adequate randomisation procedure) and quasi-randomised trials were also identified.

Types of participants

All adult (aged 18 or over) patients with hoarseness (dysphonia). The participants should have had the symptom for at least six weeks (to differentiate between acute and chronic hoarseness). The participants will be included whether or not there is a definitive diagnosis of gastro-oesophageal reflux disease. All patients should have undergone *laryngoscopy* to exclude other identifiable causes of hoarseness including malignancy, vocal cord paralysis and vocal cord nodules.

Types of interventions

The interventions will be divided into non-surgical and surgical.

Non-surgical treatments include:

1) Lifestyle modification and patient education
2) Pharmacological treatment:
    - Proton pump inhibitors (PPIs)
    - Antacids
    - H2-receptor antagonists
    - Prokinetic agents
    - Erythromycin

Surgical treatments include:

1) Fundoplication repair:
    - Nissen fundoplication
    - Rossetti fundoplication
    - Toupet fundoplication (partial fundoplication)
    - Bore fundoplication (partial fundoplication)
    - Collis gastroplasty followed by fundoplication

2) Non-fundoplication repairs:
    - Hill repair (gastropexy)
    - Bilsey MK-4

Anti-reflux therapy will be compared with placebo or no medication where possible since the spontaneous improvement without any medication and the placebo response have been reported as being substantial.

Results

No randomised controlled trials met the inclusion criteria of the review.

Discussion

The studies which were excluded could be divided into three groups:
1. Randomised controlled trials of proton-pump inhibition in patients with symptoms of laryngo-pharyngeal reflux, including hoarseness
 (too small materials)
2. Prospective studies without control group
3. Retrospective studies

SURGICAL VERSUS NON-SURGICAL INTERVENTIONS FOR VOCAL CORD NODULES

Definition:

Vocal cord nodules are bilateral swellings of variable size found at the mid-part of the membranous vocal cords. They are characterised mainly by thickening of the epithelium with a variable degree of inflammatory reaction in the underlying superficial lamina propria (Nagata 1983).

Objective

To assess the effectiveness of surgical versus non-surgical treatment in the management of vocal cord nodules.

Types of studies

All randomised or quasi-randomised controlled comparisons. Controlled clinical trials (trials using a control group but no adequate randomisation procedure) and quasi-randomised trials were sought for the review, no randomised controlled trials considering the treatments of interest having been found.

Types of intervention

Treatment which was non-surgical or surgical.

Non-surgical measures included one or more of the following:

1. Medical/pharmacological treatment of infections, allergy, and laryngo-pharyngeal acid reflux
2. Vocal hygiene advice (including alterations in working environment)
3. Reduction of 'voice abuse'
4. Voice re-training
5. Voice rest
6. Observation alone

Surgical treatment was removal of the nodules by:

1. Direct microsurgical techniques
2. Indirect microsurgical techniques
3. Laser excision
4. Laser ablation

Description of studies

A total of 659 studies were identified through electronic searching. Handsearching of more than 250 pre-1966 papers was carried out. No randomised controlled trials were identified by the search and therefore data collection and synthesis was not performed. The studies which were selected for evaluation were the only ones with systematically given diagnoses and treatment

Types of outcome measures

The primary outcome measures of interest were:

1. Perceptual scoring of voice quality (both by the patient and the investigator)
2. Quality of life, for example, return to singing career or other vocally demanding profession

We were also interested in:

1. Assessment of conditions associated with nodules (see under non-surgical types of interventions)
2. Objective assessment of the vocal cords and of vocal function in individuals with nodules:

--a. Visual appearance of the vocal cords

--b. Scoring of roughness, breathiness and overall hoarseness of the voice with perceptual measures

--c. Acoustic measures of continuous speech or sustained vowels and phonetograms

--d. Fundamental frequency with jitter and shimmer

--e. Aerodynamic measurements

Desirable time points of outcome assessment were: short-term, 1 month; medium-term, 6 months; long-term, 1-5 years.

Results

No studies were found which satisfied the inclusion criteria for this review.

Discussion

The twenty (18 retrospective and two prospective) studies on intervention that had a methodological structure could roughly be divided into three groups:

1. Microsurgery and postoperative voice therapy (Wendler 1971; Motta 1986; Bouchayer 1988; Cornut 1989; Kleinsasser 1991; Keilmann 1997)
2. Voice therapy alone (Böhme 1969; Lacina 1972; Yamaguchi 1986; Yotsukura 1988; McFarlane 1990; Koufman 1991; Fex 1994; Benninger 1995)
3. Voice therapy combined when evaluated necessary (without inclusion criteria) with microsurgery (Nagata 1983; Lancer 1988; Murry 1992; Krecicki 1993; Ford 1994; Remacle 1999).

No control groups were mentioned:

The six studies describing microsurgery and postoperative voice therapy included **644** patients with good result in 613. Eleven had recurrence out of 163 patients that had responded to the request for follow-up evaluation.

The eight studies concerned with voice therapy alone included **465** patients 282 of which had a good result. However 25 out of 134 responding to the request for follow-up evaluation had recurrence.

Voice therapy and eventual secondary microsurgery was carried out in six studies. Out of the **895** patients 666 had good results. There were 37 recurrences out of the 348 patients followed up.

A few trends were noted with the studies over time. In the later studies:

1. stroboscopy is used for confirming the diagnosis
2. researchers are more likely to identify compounding factors such as infections, allergy, acid reflux and environmental factors
3. pre- and post treatment quantitative voice analysis was more likely to have been performed.

Letter from The Danish Research Committee, reply on application for research funds

Forskningsstyrelsen
Ministeriet for Videnskab Teknologi og Udvikling

Danish Research Agency
Ministry of Science Technology and Innovation
Statens Sundhedsvidenskabelige Forskningsråd

26. november 2003

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Medical specialist
Mette Katharina Pedersen
Medicinal Medical specialist Centre
Østergade 18, 3
1100 Copenhagen C

The Research Committee has reviewed your application of 29th September 2003 in support of your project

A multicentre 2x2 factorial designed observer blinded randomised clinical trial (vocal nodules (VONOD)).

The committee regrets to inform you that the request could not be met.

The Research Committee regrets that the request could not be met, the Committee finds that the project is **worthy of support** due to following criteria:

- The quality and originality of the project, comprising its scientific and societal perspectives.
- The projects' problem formulation, theoretical application and the suggested methods appropriateness.
- The projects' feasibility (timetable, work location, access to scientific guidelines and facilities etc.)
- The applicant'/applicants' scientific qualifications.
- The project's ethical aspects.

The Committee's funds are too limited to accommodate all the qualified applications. SSVS can only finance 14% of the requested means. In this situation the Committee regrets to inform you that other applications have a higher priority.

Best regards

Signature

Mette Pedersen
Administrative officer

VONOD

Eksempel für Projekte:

Hinsicht:

English:

The VONOD group finds it to be of greatest importance to examine the effect of the different treatment possibilities. It is necessary to complete a randomized clinical trial, in which the 4 most applied treatments are being tested and compared. A successful trial could make basis for future recommendations of which treatment to offer the patients. The purpose of VONOD trial is to establish whether the four treatments are different with regard to reducing the nodules and normalizing the voice.

Hintergrund

To bring clarity over the current knowledge, the initiators of VONOD have conducted a Cochrane Review on the subject (1). In the review no randomised studies were found, but instead used 20, only observatory epidemiological studies (n = 2004). These studies were evaluated the effect of treatment on vocal nodules. All studies were conducted without a control group. The 20 studies can roughly be divided into 3 main groups

- Microsurgery without logopedic treatment
- Logopedic treatment without surgery
- Logopedic treatment combined with microsurgery whenever estimated as indicated though indications were vague.

Modellierung und Messung

VONOD trial is an international, Danish initiated and conducted, medical science project. A cohort on approximately 2000 patients with symptomatic vocal cord nodules, undergo careful examination based on international recommendations. The patients are first offered medical treatment for three months. The treatment is customized to the individual based on the results of a series of trials. The patients who do not achieve contraction of symptoms and/or vocal cord nodules during the three months period – estimated to be 700 patients – will in VONOD trial be offered a randomized selection of following treatments:
Continuing medical treatment
Speech therapy and continuing medical treatment
Microsurgery to remove the nodules and continuing medical treatment
Combined speech therapy with microsurgery and medical treatment

The following procedures are international recognized means for measurement of vocal cord nodules, dysphonia, voice quality and quality of life. They will be referred to in abbreviated form in the text:

GRBAS overall severity score:	Consensus Auditory Perceptual Evaluation of Voice
Video-stroboscopy:	Laryngo -stroboscopy images
VHI:	Voice Handicap Index
Quality of Life:	Voice -related Quality of Life (V -RQOL)
	Short Form 36 Quality of Life measure (SF 36)

Effect

The **primary target of effect** will be evaluated through use of digital images obtained from video-stroboscopy, where the vocal cord nodules will be categorized as: unchanged, decreased or cured. On top of that there is being recorded a digital tape of their sound for measurement of dysphonia (GRBAS test). Images and voice recordings are being evaluated by an external committee, blinded for the chosen character of treatment.
There is also a series of **secondary targets of effect** which concern the patient's own evaluation of the treatments effect and life quality, the practitioner's evaluation of the patient's voice quality and job situation and finally possible side effects to the treatment are evaluated.

Materiale

Inclusion criteria for phase 1 (for initial medical treatment and instruction on voice hygiene):
Dysphonia according to the patient, meaning VHI Total Score > 10
Vocal cord nodules diagnosed as a result of centralized blinded on laryngo-stroboscopical image of the vocal cords during phonation and respiration
GRBAS Overall Severity Score >33% by a centralized blinded evaluation of a digital voice recording on at least 600 Kilobytes recorded on the terms provided by the GRBAS instructions. Age over 18 years.

Signed informed declaration of consent on participation in both phase 1 and phase 2.
Exclusion criteria for phase 1 (for initial medical treatment and instruction on voice hygiene): Earlier surgical treatment of vocal cord nodules
Neurological diseases including upper airways
Malignant diseases in larynx
Notable communication difficulties
Notable difficulties participating in the tria l
Professional user of the voice, demanding acute intervention
Participation in clinical trials on vocal cord nodules within the last six months
Lack of informed consent.

Patients suffering from dysphonia (VHI >10) and vocal cord nodules (GRBAS) Severity Score >33%) diagnosed with a new video -stroboscopy after the three months period will be offered randomization providing that they fulfill following inclusion criteria and none of the exclusion criteria

Inclusion criteria for phase 2:
Dysphonia and reduced voice
function for more than three months despite optimal medical
treatment
Vocal cord nodules diagnosed by a centralized blinded evaluation of a laryngo -strobosopical image of the vocal cords during phonation and respiration
GRBAS Overall Severity Score >33% by a centralized blinded evaluation of a digital voice recording on at least 600 Kilobytes recorded on the terms provided by the GRBAS instructions Signed informed consent

Exclusion criteria for phase 2:
- Same as for phase 1 only including not “Participation in clinical trials on vocal cord nodules within the last six months”

Clinical centers

Research plan

Hypothesis

Statistical calculations

Randomization

Ethical considerations

The trials feasibility and economy

References:

1) Pedersen M, McGlashan J. Surgical versus non -surgical intervention for vocal cord nodules (Cochrane Review). The Cochrane Library, Issue 2, 2001.

2)Pedersen M, McGlashan J, Surgical versus non -surgical intervention for vocal cord nodules (Updated Cochrane Review). 2003 (posted)

3) MacKenzie K, Millar A, Wilson J, Sellars C, Deary IJ. Is voice therapy an effective treatment for dysphonia. A randomised controlled trial. BMJ 2001; 323: 658 -61.

Danke