Pedersen M Fog (2005). A Review of Evidence Based Research on Laryngeal Remobilisation for Bilateral Paralysis. *XVIII World Congress, Rome Italy (Published on CD).*

A REVIEW OF EVIDENCE BASED RESEARCH ON LARYNGEAL REMOBILISATION FOR BILATERAL PARALYSIS

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ABSTRACT

A scientific search of papers was made for the round table that included the topic of laryngeal remobilisation for bilateral paralysis. A survey of some papers is given.

One protocol was found in the Cochrane evidence based library for unilateral recurrent nerve palsy (Lowe DA and Hoare TJ, 2003).
But bilateral immobilisation was excluded due to the complex etiology of the disorder. This argument is not acceptable from an ethical point of view, when treatment effect is expected to be evaluated.

On that basis a suggestion for a structure for future evidence, and an eventual protocol for an evidence based study has been made, the adequate statistical number of patients in the different groups for a reasonable power of the study is not the problem, because evidence based pilot studies also have to be made, the ethical aspects are that without controls the treatments will always be doubted.

Key words: paralysis- bilateral- vocal cords- remobilisation- voice- respiration- communication- quality of life

INTRODUCTION

A search was made in the Cochrane Database for evidence based voice studies of laryngeal remobilisation for bilateral paralysis, as it earlier was done in other connections of laryngology (Pedersen M and McGlashan J, 2000, Hopkins C, Yoysaf U, Pedersen M, 2004).
None were found using the traditional Cochrane search strategies, one Cochrane protocol was found related to unilateral recurrent nerve palsy, bilateral palsy was not taken into account, the argument was the many sided aspects of etiology.

The other studies found were mostly related to SURGERY, which was found to give better respiration possibilities, and this surgical approach has been refined over the later years e.g. in the United States at the Mayo Clinic, a certain aggravated voice situation was accepted by patients and surgeons but not documented.

Respiration related quality of life measurements were not found in the literature.
Quality of Life scores were seldom found and without evidence.
Voice related Quality of Life and objective measure of the voice were seldom given.

MATERIAL AND METHOD

We have suggested that clinical voice laboratories in the European Union should include a standard clinical equipment, an optimal clinical equipment, and for research clinics also further equipments, the following settings should be required including medical doctors, physicists, statisticians, psychologists and eventually others first introduced by Pedersen M and Benini A (2001):

Physiological area	
Standard equipment:	Stroboscopy, Airflow measurement, Mean Flow Rate, Phonation time, Videokymography
Optimal equipment also:	Electroglottography, Respiratory measurements (long and short time) Air pressure, Electromyography, Articulatory measurements (three-dimensional magnetic sensor)
Further research equipment:	Videostroboscopy with quantitative computing, Instrumentation for brain stem, brain flow and other brain activity measurements, ultra sound, stem cells and genetics. Evidence based approaches.

Acoustical area

Standard equipment:	Recording procedure: Audio tape (analogue recording), Fundamental Frequency with jitter%, Intensity with shimmer %, Signal to noise ratio, signal to harmonics ratio, nasality, spectral analysis (FFT,LTAS power spectrum)
Optimal equipment also:	Recording procedure (digital recording) Phonetograms (2- or 3- dimensional) for speech, singing and shouting Phonation index, Diplophonia, Voice breaks, Simultaneous video- and Sound recording (for analysis)
Further research equipment:	Stroboscopy combined with glottography and phonetography. Motor speech profile measurements, evidence based efficiency measurements based upon air pressure, air flow and acoustic signal

Perceptual and Psychological area:

Standard methods:	Listening tests including the GRBAS test Quality of life tests, test for nasality Standard methods for registration of patients´ subjective statements of illness, the Voice Handicap index (VHI), Voice Related Quality of Life (VRQOL).
Optimal methods also:	Objective evidence based speech acoustics related perception and music acoustics related perception (Wøldike test of musicality, (Pedersen M)), video-and acoustic recording (e.g. by stuttering and spasmodic dysphonia)
Further research equipment:	Objective registration at the physiological and acoustical level of moods. Evidence based approaches, scores being evaluated. Advanced statistical methods for scores, making them usable in meta analysis.

RESULTS OF SEARCH

In the Cochrane library by double search only one protocol for surgery for vocal cord paralysis and paresis was found (Lowe DA and Hoare TJ, 2003) as earlier mentioned. Surgery for bilateral vocal cord paralysis was excluded in the protocol due to considerable differences in the management, surgical techniques and aim of the treatment. In addition patients with vagal rather than recurrent nerve palsy were excluded because vagal palsy often is more difficult to treat.

No reviews were found.

In the Cochrane library (only) 4 controlled clinical trials on laryngeal immobilisation of one vocal cord were found, all focusing on the use of EMG in unilateral paralysis. None were found for aspects of bilateral immobilisation.

Due to the ***evidence related results of EMG on vocal cords in the Cochrane Library,*** the EMG studies are presented, the use of EMG is stressed:

Mostafa, (2004)

Mostafa BE, Gadallah NA, Nassar NM, AL Ibiary HM, Fahmy HA, Fouda NM., from Ain-Shams University in Cairo examined 35 patients prospectively with a control group of 10 normals.

This means that a case-control study was made: The specificity of EMG was 100% detecting vocal fold immobility. The sensitivity was 65.7%. 26% had isolated recurrent nerve lesion, 74% combined superior laryngeal nerve and recurrent nerve lesions. After 6 months 40% were recovered, the specificity of EMG was 100% in predicting recovery.

Wahl (1998)

Wahl RA and Rimpl I, from Germany in a consecutive series of 1143 first operations for benign nodular goiter with1928 “nerves at risk” found that the rate of permanent recurrent laryngeal nerve palsy was higher after non-identification of the nerve (0.6% vs. 0%).

As a rule the nerve should be identified, especially in conventional subtotal resection, when possible without further mobilizing manipulations.

Hayashi (1997)

Hayashi M, Isozaki I, Oda M, Tanabe H and Kimura J, from Tokio Metropolitan Neurological Hospital examined 6 patients with multiple system atrophy compared with 6 normals. In multiple

system atrophy the small myelinated fibres innervating the vocal cord are affected first without obvious clinical signs.
The patient develops vocal cord palsy only after loss of the large myelinated fibres which mostly comprise the alpha motor axons that innervate the intrinsic laryngeal muscles.

Koch (1996)
Koch B, Boettcher M, Huschitt N and Hülsewede R from Germany prospectively compared two groups of subtotal resections of the thyreoid (382/413) with "nerves at risk", in each group two patients had transient vocal cord paralysis that recovered within 4 months.
The demand for obligatory intraoperative identification of the recurrent nerve seemed not to be tenable

A total search of the literature included 194 papers focusing on aspects for ***subgroups, non-evidence based of ethiology, diagnosis, treatment and swallowing.***

ETHIOLOGY
The papers focused on post goitre operation, trauma, malignancy, virus, neurological, metabolic and toxic disorders.
It can be commented that a very good GENERAL medical knowledge of aspects of:
Endocrinology
Malignancy
Trauma
Virus
Neurology
Metabolic disorders
Toxic disorders
is necessary prophylactically also in the area of remobilisation of the vocal cords, because with such knowledge many cases can be treated without surgery and eventual remobilisation. The ethical aspects of the society in this area must be taken into account.
A survey of tests to be made is given e.g. by Ernster JA et al.(2002). A differentiation to precancer situations is suggested by Arens C, Schöberlein S, and Glanz HK, (2005)

DIAGNOSIS

included EMG, evaluation of mobilisation of the arytenoids, scars especially in the interarytenoid region, evaluation of decline of respiratory function including spirometry, peak flow, and also physiological analysis with stroboscopy and acoustical voice analysis:

(e.g. phonation time, mean flow rate and voice intensity were analysed after the operation (Remacle M et al. 1996))

It can be commented that a good GENERAL knowledge with – also ethical - aspects of

EMG

Mobilisation of the arytenoids

Scars also between the arytenoids

Respiration function

Spirometry

Peak flow

Videostroboscopy

Voice analysis

Voice treatment

General health (SF 36)

Subjective voice related complaints (Voice Handicap Index, Voice Related Quality Of Life)

is necessary prophylactically, again because with such knowledge many cases can be treated without surgery and eventual remobilisation, taking care of intermediate exacerbations that are not immobilisation related, and which could also happen after remobilisation.

SURGICAL / NONSURGICAL TREATMENT

Focused on indications for tracheostomy, arytenoidectomy, cordectomy, and cordopexy.

The reinnervation techniques and electric pacing are considered to be experimental.

The works by Tucker HM and Ogura JH in animals (1971) and Fex S (1970) conclude that the phrenic nerve implantation in the posticus muscle, for reinnervation of abduction at inspiration is the better choice.

Zealear DL et al. (2003), and others have tried reanimation techniques and electric pacing of the posterior cricoarytenoid muscle out of 5 patients, 3 were decanulated. Crumley RL (1990) has made a protocol for management of the injured recurrent nerve.

Some new perspectives about human laryngeal muscle: single fibre analysis and interspecies comparison were made by Wu YZ, Crumley RL, Armstrong WB and Caiozzo VJ (2000). MedTronic has manufactured a number of prototype devices, but there are technical problems with the electrodes in the muscle. The research of electric pacing is ongoing, like in other fields the future is promising.

Genetic research of effects of denervation on cell cycle regulation of the posterior cricoartenoid muscle is also promising for new aspects of treatment as suggested by Vincent J et al. (2004).
Till prospective randomised clinical studies have been carried out we have to accept that the reinnervation studies are experimental.
The use of systemic corticosteroids and systemic antibiotics as well as antivirus treatment has to be validated.

SWALLOWING

The swallowing mechanism can be evaluated very specifically and gives information of further nerve involvement (Ludlow CL, 2004).

FOLLOW-UP

Spontaneous recovery can be expected in half of the patients. Care of complications must be made (Tucker HM, 1983). Decannulation can be tried up to four weeks after surgery.
The follow-up in the future has to be planned ahead by statistical advice as is usual done in prospective clinical trials. Till now no suitable statistically based follow-ups have been made.

DISCUSSION

In the future it is suggested that a prospective randomised set-up with very well defined inclusion criteria of quality of life are made for patients for surgery and remobilisation.
It is necessary to use evidence based clinical science to measure well defined inclusion groups of patients within a protocol, based on statistical calculations of difference between groups (power of study) and a control group statistically confirmed as for amount of patients in groups to measure difference, and a relevant follow up (Pocock SJ. Clinical Trials, 1983).
The choice of questions to be answered are related to the inclusion criteria and eventual
co-work with people that are related to funding, because the evidence based research is expensive.

Once the protocol is made, the carrying out should not wait for approval, because prospective randomised pilot studies with control groups are relevant also, and they can be the basis for clinical studies carried out later.

There does not seem to be excuses for not making evidence based documentation of surgical and non-surgical intervention.

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