

M. Pedersen · A. Beranova · S. Møller

## Dysphonia: medical treatment and a medical voice hygiene advice approach. A prospective randomised pilot study

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**Abstract** For many years all patients with dysphonia referred to in the literature as resulting from non-organic (functional) voice disorders were sent to speech therapy. *Medical diagnoses* were not taken into account. In our earlier Cochrane review on vocal cord nodules we discovered that *evidence-based research* in the area of benign voice disorders with dysphonia, and with or without slight benign swellings including nodules on the vocal cords, was lacking at that time. Therefore, a prospective randomised pilot study based on our Cochrane review has been made on dysphonic patients with non-organic (function provoked?) voice disorders as the basis for further evidence-based studies.

Medical treatment was based on the scientific approach that once a micro-organic disorder caused by reflux, infection, allergy or environmental irritants (e.g., dust or noise in the workplace) was discovered by very careful anamnesis and systematic objective routine analyses and was treated effectively, with documentation, the non-organic voice disorder disappeared, as, e.g., in the case of a diagnosis and treatment of helicobakter pylori. The reason is that the mucosal swelling/dysfunction of the vocal cords is secondary.

In order to try to understand why the recommendation to all these patients for many years was only voice therapy, which the speech therapists “felt to be effective”, updated voice-hygiene advice (for posture, accents of the diaphragm, intonation pattern and resonance) was given by experienced laryngologists, randomised with the updated medical diagnosis/therapy in order to elucidate what effect the *training* might have. No evidence-based studies in the literature document any effect. The crucial point seemed

to be that doctors mostly did not examine any other diagnoses other than the “dysphonia” and did not dig down to any of the medical reasons when the vocal fold diagnosis of “non- organic disorders” was made. This should be changed in the future. This pilot study was based on a comparison of ten dysphonic patients with stroboscopic non- organic (functional) voice disorders, where a micro-organic diagnosis was searched for and treated systematically in a medical regime (for infections, allergies, gastroesophageal reflux and environmental irritants such as dust, noise, etc.) versus ten dysphonic patients with stroboscopically confirmed non-organic (functional) voice disorders, having only the traditional but optimal voice advice, which we can call medical voice-hygiene advice, including the use of the Accent method. A retrospective group of ten patients treated medically was included, too. A demand cannot be made that the functional group being treated by randomisation with voice advice should also be medically treated at once, the medical approach being the new one. On the other hand, it is strange that no evidence-based research was made before. All patients were measured two times with stored videostroboscopy, a quality-of-life questionnaire and phonetograms with 1-month intervals. All patient groups improved. There was no statistical improvement in favour of the medical group with the voice-related quality-of-life score, also not for the group who received voice-hygiene advice. The geometrical mean values of the phonetogram areas in decibels times semitones were better in all groups, but a statistical difference was not found between the medically treated group and the voice-hygiene advice group. The pilot study showed that both medical treatment and medical voice-hygiene advice had a positive effect on dysphonia in non-organic (functional) voice disorders. There is need of an extensive prospective randomised trial on dysphonia including vocal cord nodules to find out which treatment should be used for this group of patients. It is suggested that an eventual randomisation for microsurgical treatment or regular voice therapy should be made after a period of systematic medical diagnosis and treatment including medical voice-hygiene advice.

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M. Pedersen (✉) · A. Beranova · S. Møller  
Voice Unit, The Medical Centre,  
Østergade 18-3, 1100 Copenhagen, Denmark  
Tel.: +45-33-159600, Fax: +45-33-137705,  
e-mail: m.f.pedersen@dadlnet.dk

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## Introduction

The aim of the prospective randomised single-blinded pilot study was to evaluate the role of the medical approach in the treatment of dysphonic patients, in the literature referred to as having non-organic (functional) benign vocal fold disorders. We assumed that medical micro-organic disorders caused by allergies, infections, reflux or environmental irritants (dust, noise, etc.) were the reason for the dysphonia. Therefore, the medical approach was compared with medical voice advice (voice-hygiene, advice about positioning, training of the diaphragm, intonation patterns and resonance) carried out by experienced laryngologists, training having been the only recommendation made to this kind of patient for many years. It was often made by more or less experienced therapists and without objective documentation. Patients with non-organic (functional) voice disorders diagnosed with indirect laryngoscopy or stroboscopy were routinely referred to voice training by voice or singing therapists. No evidence was found concerning the results of this training.

So, the ethical problem of offering medical diagnosis and treatment combined with medical voice-hygiene advice should be seen in the light of the problems that include: (1) those cases where a speech or singing therapist does not refer the patient to the qualified laryngologist for diagnosis of eventual micro-organic diagnoses; (2) those cases where, once micro-organic disorders caused by infections, allergies and intolerances, gastrooesophageal reflux, environmental irritants (e.g., dust and noise) and other medical disorders were treated, qualified laryngologists and allergists think that there is no need for speech or singing therapy, because normal organs and functions have been restored; (3) the surgical option that surgery for benign functionally caused swellings, e.g., for vocal cord nodules, is necessary, without taking micro-organic disorders or training into account.

Since no prospective studies were found in our Cochrane Review on vocal cord nodules [1], we thought that it would be interesting to follow the regular outpatients in a voice clinic during 1 month together with a research fellow from Prague (A.B.) as a part of preparing the protocol for a multinational prospective study of vocal-cord nodules [2].

The randomised prospective single-blinded pilot study of the quality of life focused on the role of either (1) systematic medical diagnoses of micro-organic diagnosis and therapy or (2) adequate medical vocal hygiene advice given at the first consultation.

It must be remembered that the medical approach is new, and that until now only voice therapy (+/- surgery) was the recommendation to these patients. It seemed necessary for us to compare the systematic medical approach to micro-organic disorders, which in these cases included the vocal folds and medical voice-hygiene advice in a ran-

domised way to elucidate the role of each approach for dysphonia of "macroscopic" non-organic (functional) voice disorders, which excluded patients with polyps, papilloma, tumors and paralysis of the vocal cords. A differentiation of the medical diagnoses was not the aim of the study. Further evidence-based studies should be made in the future (the disorders referred to could be called micro-organic instead of non-organic/functional voice disorders).

## Materials and methods

### Material

The pilot study was based on a comparison of 30 consecutive patients in the clinic with the primary complaint of persistent hoarseness/dysphonia with a non-organic (functional) disorder lasting for more than 2 weeks. This was the number of patients attending the voice clinic during May 2002, when there was mostly no waiting period for voice disorders. Because of this fact, no ethical problems were found for the procedures, the waiting time for any diagnosis and treatment in most other centres being more than 1 month. Clients were excluded if an organic voice disorder of polyps, papilloma, tumors or paralysis of the vocal cords was found. Age under 18 years, malignancy, pregnancy and neurological or psychiatric disorders were also reasons for exclusion. For all patients, an informed consent including intention to treat was made. Randomisation was made for the patients by a blinded throw of the dice after the consent was signed in the clinic. Twenty outpatients were new, and ten had been medically treated earlier and were treated medically again. The 20 new patients were randomised in a group of ten for only medical treatment and ten for only medical voice-hygiene advice (by M.P. and A.B., [3]) for 1 month. The mean ages in the groups were 38.9 years in the medical group, 40.7 in the voice-hygiene group and 48.9 in the retrospective group. The mean duration of complaints was 19.6 weeks in the medical group, 27.3 weeks in the voice hygiene group and 20.2 months in the retrospective group.

### Methods

A general ear, nose and throat anamnesis and objective analysis were made on all new patients. On all 20 new patients a computed stored videostroboscopy was made (Atmos Medizin Technik), and they completed a quality-of-life questionnaire with mean scores for the social, emotional domain, physical functioning domain and overall voice quality [4]. Computed phonetograms were stored, also of the ten patients that had been in the clinic before (by A.B. [5]). After 1 month, videostroboscopy, the quality-of-life questionnaire and computed stored phonetograms were repeated.

The statistical analysis was made with SAS systems. The McNemar test was used for the videostroboscopy and *t*-tests for the quality-of-life questionnaires. In the results of the phonetograms, the lowest and highest tones in semitones (Hz) and the area in decibels times semitones were computed, one-way analysis of variance was made, geometric means were computed and the differences from before and after were presented as a ratio, after/before.

The patients in the medical group of new patients did not have complaints that they connected to allergy, infection, reflux or environmental irritants (e.g., dust or noise). But the group of the ten new patients had a systematic and careful anamnesis, and in all cases, one of the referred to diagnoses was found and they were treated for (1) allergy by counselling and related medication at once, diagnoses being made from testing blood samples after 1 week, (2) infections caused by bacteria and/or viruses diagnosed after 3–5 days and treated with antibiotics and relevant counselling, (3) gastrooesophageal reflux, diagnosed by gastroscopy and X-rays (no acid measurements were available) and treated with counselling, diet and acid pump inhibitors, (4) environmental irritants (from dust,

**Table 1** Voice-related quality of life questionnaire, results of the randomised prospective pilot study of the new patients with follow-up after 1 month

Mean score	Medical group			Medical voice-hygiene group				
	No. 9	Before therapy	After therapy	Difference	No. 7	Before	After	Difference
Social emotional domain		74.3	87.5	13.2	69.6	76.8	7.1	
Physical functioning domain		63.9	84.7	20.8	64.9	73.8	8.9	
Overall voice related quality of life		68.1	85.8	17.8	66.8	75.0	8.2	

noise, etc.); however, these patients were not removed from dusty or noisy surroundings, all being dependent on working to earn their wages. They were carefully informed about avoiding dust and noise, etc. Their confidence representatives were informed. Other disorders were scarce.

The other group of ten new patients with non-organic (functional) voice disorders was only given what could be called the traditional "old-fashioned" medical voice-hygiene advice for 1/2 h of posture correction, accents of the diaphragm (abdominal respiration during speech), intonation patterns and resonance training; most of them studied themselves, too [3]. A supplemental history of the new aspects of infections, allergies, reflux, environmental irritants, etc., was of course not made for this group in this randomised study. The ethical problem was that speech therapists did not work together with scientifically qualified laryngologists till recently to get evidence-based results. The group of ten previously medically treated patients received supplementary medical treatment.

## Results

There were nine females and one male in the new patients' medical group; nine patients were seen at the follow-up. Seven females and three males were in the medical voice hygiene advice group; seven patients were seen at the follow-up. Eight females and two males were in the group of previously treated patients who all came in for the follow-up after 1 month. The patients followed the medical treatment and the medical voice-hygiene advice conscientiously, and all admitted that they felt better after 1 month. All were working. No psychogenic aetiology of voice abuse/misuse was found in this group of adult working patients.

The McNemar test for videostroboscopy showed no changes for the worse or better of slight abnormalities of the vocal cords (e.g., prenodular edema, nodules, diffuse slight laryngeal edema, posterior glottal gap, mucosal wave, amplitude, closure and symmetry of right/left movement) of the patients who came for the control.

There was an effect on the voice-related quality-of-life score after medical treatment for all three parameters and also after medical voice-hygiene advice (mean score difference: 17.3 versus 8.0) (Table 1). The better results for both groups were not statistically different. The phonetograms were better after 1 month than before treatment for the new patients who were treated medically. The maximum dynamic range changed from 18.7 to 22.8 dB, the difference being 4.1 dB. This was also the case for the mean phonetogram area in decibels times semitones, which changed from 257.7 to 380.9.

There was an improvement, too, of the maximum dynamic range in the medical voice-hygiene advice group.

When the examination before treatment was compared with the results 1 month after the advice, the maximum dynamic mean range improved with 2.4 dB, the phonetogram area improvement was 135.5 dB times semitones.

In the previously medically treated out-patient group that came in for supplementary medical treatment, the improvement of mean dynamic range was 2.9 dB; the mean improvement of the phonetogram area was 86.4 dB times semitones. All calculations were made on the groups that returned for the follow-up. No statistical difference between the group treated medically and the one with medical hygiene therapy was found. All patients improved.

## Discussion

The design of the pilot study is based on the old, well-known lack of evidence concerning voice therapy for non-organic (functional) voice disorders in prospective randomised blinded studies with adequate follow-up compared with the new knowledge of medical disorders caused by allergy, infections, reflux and environmental irritants distorting the microwaves of the vocal folds, which move up to many hundreds per second. These kinds of systematic diagnoses and treatments should be made routinely by laryngologists treating dysphonic patients when the stroboscopy reveals no other pathology than dysfunction (change of amplitude, mucosal wave, irregular fluctuation of the vocal folds or insufficient closure and eventual slight deviations of the form of the vocal cords). Improvement was found in the pilot study for a voice-related quality-of-life score after medical treatment of non-organic (functional) voice disorders of adult patients with complaints of dysphonia for more than 2 weeks, nine out of ten completing the study. This was underlined by better maximum dynamic range and phonetogram areas in semitones times decibels. The blinded prospective randomisation of patients for medical treatment (for allergy, infection, gastrointestinal reflux, environmental irritants, etc.) was made with a comparison to ten patients receiving only updated medical voice-hygiene advice.

Nine out of ten completed the *medical treatment* (for infection, allergy, reflux, environmental irritants, hormonal disorders and others). Seven out of ten treated with *medical voice-hygiene* advice completed the study. No statistical difference was shown comparing the groups with follow-up based on the voice-related quality-of-life score and the phonetograms. All improved. The groups with follow-

up were comparable for stroboscopy and phonetograms. All patients were working, so for this important parameter for quality of life they were comparable. The videostroboscopies showed no changes for the better or the worse.

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## Conclusion

Based on the results of the pilot study careful medical diagnosis and treatment seems to improve the dysphonic (hoarse) patients' quality of life at least as much as the previously used voice training. A combination of medical voice hygiene advice at the first visit of patients with "non-organic" voice disorders and a scientifically based treatment of "micro-organic" disorders such as allergy, infection, reflux, etc., of the upper airways has possibly a better effect than one of them alone. Still, there seems to be a need for further evidence in prospective randomised studies also of the psychological aspects of non-organic (functional) voice disorders, which include vocal fold nodules [6]. In a larger prospective randomised study of vocal fold nodules based on the Cochrane review [1, 2] medical treatment of concomitant related upper airways disorders has been planned. Stroboscopy alone cannot be used without acoustical measurement for the diagnosis of a "functional" voice disorder; as shown in the pilot study, a supplementary acoustical measurement of phonetograms and a quality-of-life questionnaire is advisable [7].

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