

# **SURGICAL VERSUS NON-SURGICAL INTERVENTIONS FOR VOCAL CORD NODULES**

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**Cochrane review updated 2012, first 2001**

# ABSTRACT

- **Background**

This is an update of a Cochrane Review first published in *The Cochrane Library in 2002*. Vocal cord nodules are bilateral, benign, callous-like growths of the mid-portion of the membranous vocal folds. They are of variable size and are characterised histologically by thickening of the epithelium with a variable degree of inflammation in the underlying superficial lamina propria. They characteristically produce hoarseness, discomfort and an unstable voice when speaking or singing.

- **Objectives**

To assess the effectiveness of surgery versus non-surgical interventions for vocal cord nodules.

- **Search methods**

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; *mRCT and additional* sources for published and unpublished trials. The date of the most recent search was 25 November 2009, following a previous update search in January 2007.

- **Selection criteria**

Randomised and quasi-randomised trials comparing any surgical intervention for vocal cord nodules with non-surgical treatment or no treatment.

- **Data collection and analysis**

No suitable trials were identified.

- **Main results**

No studies fulfilled the inclusion criteria.

- **Authors' conclusions**

**There is a need for high quality randomised controlled trials to evaluate the effectiveness of surgical and non-surgical treatment of vocal cord nodules.**

# BACKGROUND

- 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.

# SYMPTOMS, PREVALENCE AND AETIOLOGY

- **Vocal nodules** cause hoarseness, throat discomfort or pain which varies with the amount of voice use. This results in an unstable and unpredictable voice, which can affect quality of life, particularly in professional voice users such as singers.
- The **prevalence of nodules** in the general population is not known but it has been reported as being the cause of hoarseness in up to 23.4% of children. The prevalence of nodules in female teachers was found to be 43% of 218 cases with dysphonia, in a population of 1046 female teachers in a study in Spain. It has been reported that teachers speak for an average of 102 minutes per eight hours. Nodules were found in 25% of hoarse singers.
- The **aetiology of vocal nodules** is not known, but they are thought to be due to 'voice abuse' and psychological factors, especially in children.
- Other **medical conditions**, such as infection, allergy and reflux may also play a role. In a study of 20 adult females, voice abuse was considered to be the cause of vocal nodules. The abuse was characterised by strain in the neck and shoulder region, hard glottal attack, loud voice in the chest register and singing above the individual's range.
- The **definition of vocal** abuse is however subjective, although attempts have been made to define objective deviations. The impact stress of phonation appears to be important both clinically and in laboratory models of vocal cord nodules. In boys it is recognised that nodules resolve spontaneously at puberty

# DIAGNOSIS

- The accepted method for the diagnosis of nodules is endoscopic laryngeal examination (allowing visualisation of the vocal cords during phonation and respiration).
- Examination with a stroboscope gives additional information about the vibratory and closure patterns of the vocal cords and helps exclude other vocal cord pathology, for example intracordal cysts. Stroboscopy is considered a necessary preoperative examination in adults and in children it is also desirable but not always possible.
- Acoustic and aerodynamic criteria alone cannot be used for diagnosis, although improvements in certain parameters, with return towards normal values, can be taken as a sign of response to intervention.

As many patients will not have had surgery, a clinical diagnosis may not have been confirmed by histological examination.

# MANAGEMENT OPTIONS

- There is considerable controversy over the role of surgery in the management of vocal cord nodules.
- Historically, nodules were excised, but with better understanding of vocal function, more conservative non-surgical techniques have been developed and are now considered by many to be the primary treatment of choice.
- Rates of surgical intervention vary widely and the exact criteria for surgery are not clearly defined.

- Vocal cord nodules are treated either by speech therapy techniques or by surgery. Exacerbating factors, such as infection, allergy and reflux, may also be treated with medical/pharmacological interventions. Non-surgical treatments are based on behaviour modification. They include vocal hygiene measures, 'abuse' reduction and vocal retraining.
- Occasionally no intervention is indicated and observation alone is recommended, either because the symptoms are not severe enough or because there is a strong expectation of spontaneous improvement.

- A systematic review is warranted to compare the effectiveness of surgical removal of nodules with more conservative treatments.

# OBJECTIVES

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

# METHODS: CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

## *Types of studies*

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

## *Types of participants*

- Children and adults with visually confirmed vocal cord nodules. We planned to include studies where the clinical diagnosis had been reached by examination of the vocal cords by indirect laryngoscopy, rigid or fibre-optic endoscopy or micro-laryngoscopy. Stroboscopy was not considered mandatory.

## *Types of interventions*

Non-surgical versus surgical interventions.

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

1. medical/pharmacological treatment of infections, allergy and gastroesophageal 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.

# METHODS: *TYPES OF OUTCOME MEASURES*

## ○ *Primary outcomes*

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

## ○ *Secondary outcomes*

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, one month; medium-term, six months; long term, one to five year.

# ASSESSMENT OF RISK OF BIAS IN INCLUDED STUDIES

- The two authors will independently undertake assessment of the risk of bias of the included trials with the following to be taken into consideration, as guided by the *Cochrane Handbook for Systematic Reviews of Interventions* ([Handbook 2011](#)):
  1. sequence generation;
  2. allocation concealment;
  3. blinding;
  4. incomplete outcome data;
  5. selective outcome reporting; and
  6. other sources of bias.
- We will use the Cochrane 'Risk of bias' tool in RevMan 5 ([RevMan 2011](#)), which involves describing each of these domains as reported in the trial and then assigning a judgment about the adequacy of each entry: low, high or unclear (or unknown) risk of bias. We will resolve differences by discussion.

# EFFECTS OF INTERVENTIONS

- No studies were found which satisfied the inclusion criteria for this review, out of the around 600 studies evaluated.

- See: [Characteristics of excluded studies](#); [Characteristics of studies awaiting classification](#).
- We retrieved a total of 244 references from the 2012 searches, which dropped to 179 after removal of duplicates. Following first-level screening for clearly irrelevant references we were left with 17 references, none of which met the inclusion criteria for the review. We added one study to the '[Characteristics of excluded studies](#)' table (a randomised controlled trial comparing vocal therapy with vocal hygiene in patients with voice disorders including nodules). One reference is awaiting assessment as no abstract was available and we are currently unable to obtain the full text of the paper ('[Characteristics of studies awaiting classification](#)').
- From the 2009 update searches a total of 356 references were retrieved: 312 of these were removed in first-level screening (i.e. removal of duplicates and clearly irrelevant references), leaving 44 references for further consideration. We identified no studies which met the inclusion criteria for the review. We added a further three studies to the '[Characteristics of excluded studies](#)' table. All were randomised controlled trials which comprised or included a proportion of vocal cord nodules patients, however none compared a surgical with a non-surgical intervention.
- In 2007 a total of 295 studies were identified through electronic searching for the previous update of this review. For the original review, handsearching of more than 250 pre-1966 papers was also carried out. From the full search results, we obtained 18 full-text papers for further evaluation. Of these 10 were not relevant to the review, and the remaining eight were excluded. Details of the excluded studies, with reasons for exclusion, can be found in the table of '[Characteristics of excluded studies](#)'. Again all excluded studies were randomised controlled trials and all, or a proportion of, the participants in each trial had vocal cord nodules.
- The studies were excluded because they compared different surgical techniques (e.g. microspot CO<sub>2</sub> laser versus excision), different regimens of voice therapy (e.g. traditional voice therapy versus transnasal flexible laryngoscopy assisted voice therapy) or other interventions for nodules (e.g. acupuncture). We identified no randomised controlled trials which compared surgical with non-surgical interventions and therefore no studies met the inclusion criteria for this review.

# DISCUSSION

- We used a comprehensive search strategy for the review. We excluded no studies due to language.
- While we made several attempts to identify unpublished works, it is still possible that some studies will have been missed. However, the absence of eligible studies for review was not due to restricted selection criteria.

# DISCUSSION

- We identified around 600 studies describing either the etiology, methods for diagnosis or treatment of vocal cord nodules.
- A major problem highlighted by these descriptive studies is **the lack of consensus on the definition of vocal cord nodules** and relationship with possible aetiological factors.
- Not all patients with vocal nodules are symptomatic and some may like the quality of voice that the nodules give them. Out of 65 asymptomatic singing students Lundy found two with nodules diagnosed with video-stroboscopy.
- Malmgren et al did not find a strong association between the patient's and speech therapist's perception of the voice after treatment and the size or change in size of the vocal nodules.
- **This raises the question of whether the endoscopic appearance of vocal cords is actually an appropriate outcome measure in spite of it being one of the most widely used.**

# DISCUSSION

- A variety of other outcome measures were used to assess the effectiveness of the interventions, many of which were subjective and there was often no reference to validation.
- Some studies used psychological and quality of life measures, and a few used perceptual measures and objective voice measurements.
- There were problems with many of the studies considered for this review in that they had methodological and statistical errors such as inconsistent definitions of key variables, inadequate sample size, no confidence limits, short or missing follow-up, too many separate endpoints and missing data.

# DISCUSSION

- Although it is taught that vocal cord nodules form as a result of 'voice abuse', this is increasingly recognized as being a rather simplistic view.
- Nodules have a heterogenous appearance ranging from diffuse swellings where the histological abnormality seems to be more concentrated in the superficial lamina propria to tiny discrete whitish lesions representing focal epithelial thickening.
- These various types **may not necessarily have the same aetiology or prognosis** and further studies need to be performed to determine the causative factors now that the lesions can be better visualized with newer imaging techniques.

# DISCUSSION

- The point at which nodules become pathological may depend on the individual's perception of their voice and the demands on their voice.
- As with any organ it is possible to improve its physical performance with training and optimization of the environment in which it is expected to function.
- However, there are likely to be physical limits to the sound production (in terms of stamina, pitch range, loudness, timbre and fine control) based on the anatomical and physiological limitations of the individual's vocal apparatus.
- It may be necessary to recognize that the vocal demands are in fact too great for the individual, or the individual's larynx, in their chosen working environment (the amount of background noise or vocal cord irritation from a pollutant). These factors may be as important as, if not more important than, the intervention itself in determining the success of a treatment.

# DISCUSSION

- There are no gold standards in objective outcome measures of voice treatment and often there is **poor correlation between the more objective and subjective measures of assessment.**
- The aims of treatment need to be carefully defined, e.g. resolution of nodules on endoscopic examination, improvement in levels of impairment, activity and participation, acoustic, perceptual and aerodynamic measurements.
- Whatever measurements are chosen they must be as objective as possible, but also have real relevance to patients.

# DISCUSSION

- There is evidence from non-randomized intervention studies that both speech therapy techniques and surgery are effective. However it is not clear how patients should be selected.
- There is no consensus as to which of the techniques employed by speech therapists are most effective nor for how long they should be used.
- The techniques range from improving vocal hygiene, behaviour modification and 'abuse' reduction, to vocal retraining and psychological support.
- It is likely that more than one factor usually requires intervention and that this should be individualized.
- Future studies would benefit from attempts at quantifying or at least defining each of these factors.

# DISCUSSION

- There is a general consensus that surgical treatment of the nodules should aim at removing the minimum amount of mucosa from the vocal cord.
- Whether cold surgical techniques are better than laser treatment has not been determined with certainty but with newer instruments the surgical result is more likely to be dependent on the skill and experience of the surgeon rather than the tool.

# DISCUSSION

- The role of postoperative voice therapy is unclear with some claiming that recurrence is more likely without it.
- The chance of recurrence is likely to depend on compliance with pre-operative instructions in speech therapy techniques, anatomical, physiological, environmental and psychological factors.
- Some are likely to be cured with or without postoperative voice therapy and some will suffer further recurrence in spite of it.

# DISCUSSION

- There is no doubt that vocal nodules are a difficult condition to study and treat when the aetiology is not fully understood.
- In addition there are no robust objective measures of vocal function and there are many variables that can affect the outcome of an intervention.
- More patient-orientated outcome measures are being developed and their value is being slowly defined.

# AUTHORS' CONCLUSIONS

## **Implications for practice**

- There is no evidence from randomised controlled trials on which to base reliable conclusions about the comparative effectiveness of surgical versus non-surgical interventions for the management of patients with vocal cord nodules.

# AUTHORS' CONCLUSIONS

## **Implications for research**

- There is a need for a carefully designed prospective randomised controlled study to determine which patients should be selected for primary voice therapy and which would benefit from surgery or other treatments.
- Although voice therapy is usually chosen as treatment it may not necessarily be the most cost-effective way of managing this condition. Voice therapy usually requires a prolonged period of treatment while surgery potentially removes the causative lesions restoring the anatomical configuration of the vocal folds.
- However, there are potential risks of surgery and failures have been reported if the underlying causative factors are not addressed.
- In addition, it may be that patients would rather explore conservative approaches before submitting themselves to surgery.
- It may be important to determine patient views before investing in such a study.

# THANK YOU FOR YOUR ATTENTION

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