Extracts from The Cochrane Library: Topical Anaesthetic or Vasoconstrictor Preparations for Flexible Fibre-optic Nasal Pharyngoscopy and Laryngoscopy

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Otolaryngology -- Head and Neck Surgery 2012 146: 694 originally published online 9 April 2012
DOI: 10.1177/0194599812444060

The online version of this article can be found at:
http://oto.sagepub.com/content/146/5/694

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>> Version of Record - May 1, 2012
OnlineFirst Version of Record - Apr 9, 2012

What is This?
Flexible endoscopy is one of the most common procedures performed by otolaryngologists. Resident physicians are expected to become proficient in flexible laryngoscopy and nasal endoscopy at an early stage of training because these procedures offer important diagnostic information in the inpatient, outpatient, and emergency room settings. As Sunkaraneni and Jones\(^1\) state bluntly in their Cochrane Review, the procedure is “at best uncomfortable and at worst intolerable for the patient.” Therefore, topical anesthetic and decongestant preparations are often used to improve the patient’s experience. Few clinicians question this dogma or seek the underlying evidence; however, the trials in this review should prompt a new look at an old and routine practice.

## Cochrane Abstract: Topical Anaesthetic or Vasoconstrictor Preparations for Flexible Fibre-optic Nasal Pharyngoscopy and Laryngoscopy, by Sunkaraneni VS and Jones SEM\(^1\)

### Disclaimer

This is an abstract of a Cochrane Review published in the Cochrane Library 2011 Issue 3 (see www.thecochranelibrary.com for information). Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the Cochrane Library should be consulted for the most recent version of the review.

### Background

Nasal pharyngolaryngoscopy (NPL) is performed as an outpatient and inpatient procedure on a daily basis, for a variety of indications. It frequently causes some degree of discomfort to the patient. Various different topical agents, which are intended to reduce this discomfort, are in common use. This review aimed to assess the effectiveness of the various agents.
Objectives
To assess the effectiveness of topical preparations used to reduce discomfort and facilitate NPL in adults.

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; ISRCTN and additional sources for published and unpublished trials. The date of the most recent search was April 14, 2010.

Selection Criteria
Randomized controlled trials (RCTs) looking at the effect of topical anaesthetic or vasoconstrictor agents used reduce discomfort and facilitate NPL in adult patients.

Data Collection and Analysis
Two review authors independently selected studies, extracted data, and assessed risk of bias. We contacted trial authors for further information where necessary. The primary outcome measured was pain/discomfort. Secondary outcomes that were looked at included side effects of the topical medications, ease of the procedure and the quality of the view from the operator’s perspective.

Main Results
We included 8 RCTs (746 participants) in the review. The risk of bias in the studies was generally low. Five studies did not demonstrate any advantage in using a topical treatment prior to endoscopy. One study suggested that a vasoconstrictor alone should be used to reduce the general level of unpleasantness. Two studies did not compare treatment against placebo or no treatment, so it was not possible to draw meaningful conclusions from them. There may be some unpleasant side effects from the use of topical preparations, such as unpleasant taste. There was variation in the format of the outcome data and a lack of complete data; none of the included studies reported their results in a way that would allow pooling and we could not therefore perform meta-analysis.

Authors’ Conclusions
The included studies do not demonstrate any evidence to support the use of topical treatments prior to the use of a fiberoptic nasal endoscope. Some go as far as to suggest that these agents should not be used due to cost and unpleasant side effects. Five studies did not demonstrate any advantage in terms of reducing pain or discomfort when using a topical treatment prior to endoscopy. The absence of demonstrable effect may be due to relatively small patient groups. It is therefore possible that there is a small effect of using these sprays. Further research using standardized reporting methods is needed.

Comments on Cochrane Review
Comments by Altman
I have been very impressed with the Cochrane Reviews, taking a systematic approach to identifying pertinent studies and critically analyzing the utility of the subject based on level of evidence. These reviews are most pertinent with high-risk or high-cost medical and surgical interventions. The present review on the use of topical anesthetic or vasoconstrictor preparations seeks to apply the Cochrane approach for flexible nasopharyngolaryngoscopy (NPL), with the objectives to assess (1) relieving pain, (2) minimizing side effects, (3) improving passage of the endoscope, and (4) maximizing the chance of an adequate examination. Eight studies were included in the analysis, and one of the excluded studies examined the use of lubrication.

Although the results of this exercise do not show any meaningful benefit from the various interventions tested, there are a number of limitations. The most prominent is that the primary outcome measure was patient satisfaction, being discomfort from the examination and unpleasant side effects. Unlike more objective outcomes measures in most RCTs, patient satisfaction is highly variable and may not reflect a true measure of their comfort. In fact, the act of being studied may enhance their perception of quality of care.

Further variations not highlighted in the 8 studies included the individual effects of patient anatomy, procedure length, and pathology requiring closer inspection. There are also distinct differences between the pathologies associated with rhinitis, sinusitis, nasopharynx disorders (including evaluations for sleep apnea), and laryngeal disorders. And the examinations target different aspects of the anatomy with varying scrutiny. For example, the benefit of a nasal decongestant in a patient with obstructive sinusitis may make the difference between observing purulent drainage or not. Reviewing the concept of anesthetic or vasoconstrictor preparations for all these transnasal procedures together limits the completeness, and the authors themselves recognize “their applicability to clinical practice may be regarded as limited.”

Discomfort from visualizing intranasal anatomy may be mitigated by the brevity of the procedure; however, all otolaryngologists are familiar with patients who have a prominent gag reflex that limits visualization of the larynx. These patients clearly, although anecdotally, require topical anesthetic to conduct the procedure. A prolonged laryngoscopy exposes the patient to the added risk of laryngospasm, and this has been shown to be suppressed with topical anesthetic. One would have a difficult time imagining slightly more invasive procedures such as fiberoptic intubation, bronchoscopy, and transnasal esophagoscopy without topical anesthetic.

This review does not address a high-risk or high-cost medical or surgical intervention, but there is still some benefit from this information. Patient satisfaction has become one of the driving forces in measuring the value of health care, and patients themselves emphasize the overall experience as much
as the medical outcome. Individualizing which patients require topical anesthetics or vasoconstrictors would certainly enhance their perception of care. We may also benefit from better anesthetics and vasoconstrictors that provide quicker onset, shorter duration of action, and better taste than what is currently used.

**Comments by Burton**

The choice of appropriate outcome measures is critical in evaluating any intervention. Whether one is undertaking a primary study (an individual RCT, for example) or a systematic review, it is obviously important that the correct outcomes are evaluated. But who is to say what those outcomes are? We know that historically, well-meaning physicians have measured the effects of interventions using outcomes that are not always directly related to the patients’ own experience. How useful is it to use an outcome that can be easily measured and seen to change but is not associated with any change in the patient’s symptoms, experience, or disease progression?

Those undertaking RCTs are encouraged to specify a single primary outcome measure that has been defined as “the pre-specified outcome considered to be of greatest importance to relevant stakeholders (such as patients, policy makers, clinicians, funders).” Although this allows for the possibility that an outcome of interest to clinicians might be appropriate, the inclusion of patients first in the list reflects the importance that must be attached to patient preferences. Trialists—and systematic reviewers—should ask the following question: which outcome is of most importance to patients?

It is always easier to undertake a systematic review when the intervention in question has been evaluated in a number of different studies using a “standard” set of outcomes. The COMET (Core Outcome Measures in Effectiveness Trials) Initiative “brings together people interested in the development and application of agreed standardized sets of outcomes, known as ‘core outcome sets’.” These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition. Some of our colleagues in other disciplines are already well ahead in this venture. For example, the OMERACT (Outcome Measures in Rheumatology) is “an informal international network of working groups and gatherings interested in outcome measurement across the spectrum of rheumatology intervention studies,” which has been one of the leaders in involving patients in this process. Another example is the Harmonizing Outcome Measures for Eczema (HOME) group.

So if patient’s views are so important, how about measuring “patient satisfaction”? As Dr Altman says, this may be highly variable and subject to measurement biases. But does that make it something not worthwhile measuring?

He also highlights some of the variations between patients. Luckily, the process of randomization is specifically designed to ensure that factors that may affect outcomes—both known ones such as those he mentions and unknown ones—are balanced across the intervention groups. But the amount of variation may mean that an underlying benefit that might have been found if one specific subgroup had been studied is “lost” in the process of including and combining different types of patients within and between studies.

I agree that this review does not address a high-risk or high-cost intervention. But something of low cost, undertaken many tens of thousands of times a day all over the world, undoubtedly consumes a significant amount of increasingly precious health care resource. And given the number of procedures undertaken, it should not be difficult to answer this question: who benefits, by how much, and at what cost—human and financial?

**Comments by Rosenfeld**

I suspect that most readers at this point will still be somewhat confused about reconciling the “negative” findings of this Cochrane Review with an intuitive and logical practice used daily by many otolaryngologists. Perhaps some clarity will emerge if we consider the studies in terms of technique, outcomes, and generalizability.

Most included studies (Table 1) used saline as a control spray, which may offer some benefits by lubricating the nasal mucosa and facilitating passage of the endoscope. The potential confounding effect of lubrication was deemed so important by the authors of this review that they excluded 1 study (Sadek 2001, Table 1) from data pooling because all patients received a lubricant in addition to topical medication. Whether or not saline spray could also confound results is unknown, but this possibility must at least be considered. Also, whereas most studies allowed 10 minutes between spray and procedure, some did not specify the interval, and 1 study (Leder 1997, Table 1) waited only one minute, which was likely insufficient for efficacy.

Most important, the choice of outcome measure in these trials may not have had adequate sensitivity to detect meaningful differences in treatment groups. Both Drs Altman and Burton comment on patient satisfaction, which includes diverse constructs such as waiting time, access to care, interpersonal skills, and technical expertise. None of the studies in this review, however, measured outcomes using patient satisfaction (Table 1). What most studies did use were visual analog scales (VAS), which have appealing simplicity to researchers but are often confusing to patients, have serious drawbacks relating to the wording of end points and limits, and have poor reliability as a single-item test compared with longer measures. Moreover, several studies used small ordinal scales or dichotomized data, further reducing sensitivity.

Last, it is difficult to generalize these studies to patients in diverse settings because all were conducted in the United Kingdom. This is not to suggest that patients from the United Kingdom necessarily are different from all others, but there are clear national variations in how physicians interact with patients, how patients perceive subjective symptoms, and the values assigned by the health care system to specific outcomes.

What this Cochrane Review should do is promote reflection on a common practice that rarely has merited much scrutiny. Perhaps saline spray or lubricants work just as well as active treatment. Perhaps the right outcome measure and
proper control of confounders could show efficacy. Perhaps this low-risk, low-cost decision will never reach the level of truly evidence-based care. Nonetheless, we may wish to question our own certainty about the value of routine topical therapy and engage patients in decisions as to whether or not it should be used.

Author Contributions
Martin J. Burton, writer; Kenneth W. Altman, writer; Richard M. Rosenfeld, concept, writer, critical revision.

Disclosures
Competing interests: Kenneth W. Altman has received a speaker honorarium from Nestle Nutrition Institute and is on the Risk Management Board at Watermark Research Partners for Stryker.

Sponsorships: None.

Funding source: None.

References

Table 1. Studies Included in the Cochrane Review

<table>
<thead>
<tr>
<th>Author</th>
<th>Site</th>
<th>No.</th>
<th>Interventions</th>
<th>Outcome Measures</th>
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<tr>
<td>Cain 2002</td>
<td>UK</td>
<td>90</td>
<td>Lidocaine + phenylephrine vs saline vs no spray</td>
<td>VAS: procedural pain and overall discomfort</td>
</tr>
<tr>
<td>Frosh 1998</td>
<td>UK</td>
<td>82</td>
<td>Lidocaine vs saline, vs no spray</td>
<td>VAS: unpleasantness of procedure, taste, and overall experience; procedural pain</td>
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<td>Geogalos 2005</td>
<td>UK</td>
<td>98</td>
<td>Lidocaine + phenylephrine vs saline</td>
<td>VAS: unpleasantness of taste; procedural pain; overall discomfort</td>
</tr>
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<td>Leder 1997</td>
<td>UK</td>
<td>152</td>
<td>Tetracaine vs ephedrine vs saline</td>
<td>Ordinal scale: discomfort score</td>
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<tr>
<td>Lennox 1996</td>
<td>UK</td>
<td>80</td>
<td>Lidocaine + phenylephrine vs lidocaine</td>
<td>VAS: procedural pain</td>
</tr>
<tr>
<td>Sadek 2001</td>
<td>UK</td>
<td>100</td>
<td>Lidocaine + phenylephrine vs xyloglucose vs lidocaine vs no spray</td>
<td>VAS: procedural pain, bad taste, burning, choking, numbness, dysphagia, overall unpleasantness</td>
</tr>
<tr>
<td>Singh 1997</td>
<td>UK</td>
<td>60</td>
<td>Cocaine vs saline</td>
<td>VAS, dichotomized into 2 levels: apprehension, gag, discomfort/pain</td>
</tr>
<tr>
<td>Smith 2002</td>
<td>UK</td>
<td>84</td>
<td>Lidocaine + phenylephrine vs lidocaine</td>
<td>VAS: discomfort/pain score</td>
</tr>
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Abbreviation: VAS, visual analog scale. Adapted from Sunkaraneni and Jones.