



New and Emerging Techniques - Surgical

Procedure Brief

Injection Snoreplasty

February 2003



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**

New and Emerging Techniques – Surgical
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**Royal Australasian
College of Surgeons**

NET-S Procedure Brief Summary

Injection Snoreplasty

- Primary snoring results from the vibration of the soft palate and the uvula.
- There are several procedures available to reduce primary snoring, including:
 - Uvulopalatopharyngoplasty (UPPP)
 - Laser-assisted uvulopalatoplasty (LAUP)
 - Cautery-assisted palatal stiffening operation (CAPSO)
 - Radiofrequency ablation (RFA) or somnoplasty
- Injection Snoreplasty is the injection of a sclerosing agent into the soft palate, which causes scarring and subsequent stiffening of the soft palate. This reduces the flutter of the soft palate, which is the cause of primary snoring.
- The short-term efficacy of Injection Snoreplasty, appears to be similar to the above mentioned procedures, but has the additional benefits of minimal postoperative pain and low cost.
- Long-term efficacy of Injection Snoreplasty is not known, and it is expected that snoring may resume as occurs with the other more invasive treatments.
- Injection Snoreplasty appears safe for the first one or two injections but the long-term safety of repeated scarring of the soft palate is unknown.
- There appear to be few specialists performing Injection Snoreplasty in Australia at this time, but as the materials are readily available it could be performed at any time. Appropriate care should be taken, as Injection Snoreplasty is still experimental, and lacks any long-term safety and efficacy data.

NET-S Classification

Injection Snoreplasty is currently on the short-term horizon of introduction into Australasian health care.

Background

Primary snoring results from the vibration of the soft palate and uvula in the roof of the mouth, caused by breathing during sleep. About 20% of all adults are chronic snorers.¹ Two to four percent of severe snorers suffer from sleep apnoea and 70% to 75% of snorers are overweight.²

Snoring is not only disruptive to sleep and family life, it may also serve as a precursor to hypertension, heart trouble and stroke.³ In five out of every 100 people, it is a symptom of obstructive sleep apnoea, in which patients frequently stop breathing during sleep for ten seconds or more at a time.³ This occurs when the airway at the back of the throat is sucked closed when breathing in during sleep.

Injection Snoreplasty is a new procedure aimed at reducing primary snoring, by injecting a sclerosing agent, Sotradecol, into the soft palate, causing it to stiffen. The stiffening stops the vibration that produces the snoring sound.

The Technology

Injection snoreplasty (IS) was developed by Brietzke and Mair.⁴ Firstly, the roof of the mouth is numbed with Lignocaine (Xylocaine 10%) spray and if additional numbing is required, Benzocaine gel can be applied. A test dose of 0.1 ml of sodium tetradecyl sulfate (Sotradecol 3%)ⁱ is injected into the soft palate to test for allergic reactions. If there is no allergic response in 15 to 20 minutes, the Injection Snoreplasty procedure is then carried out. During the first treatment Sotradecol is injected using a single needle penetration, into the midline soft palate (Figure 1) using a needle bent to a 30 to 45 degree angleⁱⁱ. Approximately two minutes after the injection the area turns purple indicating the sclerosing agent is having an effect. Over the course of a few weeks, this leads to the formation of scar tissue and stiffening, which stops the vibration of the soft palate that causes snoring.⁴

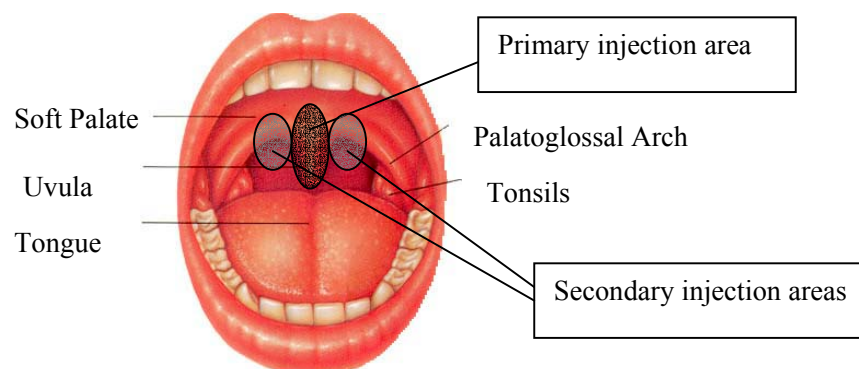


Figure 1. Anatomy of the mouth⁵

ⁱ In the initial study by Brietzke and Mair, initial injections used 1% Sotradecol. For patients undergoing re-injection 3% Sotradecol was used and the site of injection was modified to include the lateral (secondary injection area) areas of the soft palate (see Figure 1), as there was already significant stiffening of the midline (primary injection area). The authors used 3% Sotradecol for the initial treatment on the final two patients, and observed an apparent increase in efficacy with no increase in pain levels or mucosal breakdown. Australian practitioners have used 3% Sotradecol.

ⁱⁱ Actual Sotradecol concentrations and procedure method may vary between practitioners.

(Adapted to include site of injection⁴)

The procedure takes approximately 45 minutes and is performed in the doctor's office. Patients are then observed for 10 to 15 minutes before being allowed to return home. Mild painkillers may be necessary and paracetamol may be taken for any ensuing discomfort.

Patient Group

In 80% of cases, snoring is caused by palatal flutter and the remaining 20% may be due to obstruction caused by a thickening of the back of the tongue or a nasal obstruction.⁶ As Injection Snoreplasty only treats the soft palate, it will only be successful when the noise of snoring originates at this site.⁷

Current Treatment and Alternatives

Behavioural adjustments

Non-surgical alternatives, such as behavioural adjustments include: losing weight, avoiding alcohol and sleeping pills, getting more sleep or sleeping with the head of the bed elevated six inches or simply avoiding sleeping on the back.⁸

Devices

A custom-made adjustable oral appliance, made by an otolaryngologist or dentist, fits to the teeth and pulls the lower jaw forward while sleeping, to pull the tongue away from the palate and uvula.⁸

Surgical alternatives include:

Uvulopalatopharyngoplasty (UPPP) involves surgically trimming the throat tissues. The patient first undergoes a tonsillectomy, followed by the partial removal of the soft palate, uvula and pharyngeal arches.¹ This enlarges the throat allowing more airflow during breathing and there is also less tissue that can vibrate and cause snoring. It is carried out under general anaesthesia and requires a stay in hospital. In the short-term, this procedure stops most people from snoring. However, within a few years, snoring may recur. UPPP is often complicated by severe postoperative pain and is an expensive procedure.¹

Laser-assisted uvulopalatoplasty (LAUP) uses a laser to vaporise the uvula and a portion of the palate in an attempt to open up the airway and eliminate snoring. It is carried out under local anaesthetic and more than one session of treatment is required. However, severe postoperative pain makes patients less likely to return for treatment. In LAUP, less palatal tissue is removed as compared to UPPP and it costs only a fraction of UPPP.¹

Cautery-assisted palatal stiffening operation (CAPSO) is a procedure where the surgeon uses electrocautery equipment to remove part of the soft palate and uvula. It is carried out using local anaesthesia, on an outpatient basis in a doctor's office. There are no long-term efficacy data available at present.

Radiofrequency ablation (RFA) or somnoplasty (Somnus Medical Technologies Inc., Sunnyvale, CA, USA) is a relatively new treatment that uses radio waves to reduce the size of the uvula. It involves piercing the tongue, throat or soft palate with a needle connected to a radiofrequency generator. Heat applied to these tissues destroys cells beneath the surface of the soft palate. When the body absorbs these dead cells, the volume of living tissue is reduced. It is carried out using local anaesthesia, on an outpatient basis and several sessions of treatment are required. The advantage of RFA over UPPP and LAUP is that it is minimally invasive, the palatal mucosa is unaffected and thus the procedure should be significantly less painful.¹ The long-term efficacy of RFA is also unknown.

Characteristics of different snoring surgeries

All of the above mentioned procedures have a similar short-term efficacy, but no procedure continues to be as efficacious in the long-term. Snoring surgeries differ substantially when comparing postoperative pain and cost. Table 1 represents the short- and long-term efficacy, anaesthetic requirement, number of sessions required, apparent pain levels and cost for the four surgical alternatives for snoring.

Table 1¹

Procedure	UPPP	LAUP	CAPSO	RFA
Short-term efficacy	++++	++++	++++	+++
Long-term efficacy	++	++	Unknown	Unknown
Anaesthesia	General	Local	Local	Local
No. sessions	Single	Multiple	Single	Multiple
Pain	++++	+++	+++	+
Cost	\$\$\$\$	\$\$	\$	\$\$\$

Current Research Evidence

Safety

Issues have been raised⁹ concerning the safety of Sotradecol for injection into the soft palate, as it is recommended (in the Physicians Desk Reference) that Sotradecol is for intravenous use only such as for sclerotherapy of leg veins. It also states that there are possible side effects if the agent is injected non-intravenously. These include; severe local effects such as tissue necrosis; sloughing and necrosis after extravasation; allergic reactions including anaphylaxis. Four deaths have been reported with the use of Sotradecol. Briezke replied¹⁰ that, as mentioned in their article⁴, the use of Sotradecol has progressed to include several “off-label” uses which have been reported in almost 200 publications on Medline since 1973. In addition, Injection Snoreplasty with Sotradecol makes use of the local effects of the extravasation described in the Physicians Desk Reference, where the scarring and stiffening resulting from submucosal injection are a product of tissue necrosis.⁴ Allergic reaction causing death by anaphylactic shock may occur, as with most medicines. Briezke also stated that they have now treated over 100 cases and still find the procedure to be safe and efficacious.¹⁰

In the single published study⁴, Injection Snoreplasty appeared safe, at least in the short-term. Despite lack of evidence, it is likely to be safer than the more invasive techniques that require

general anaesthesia and removal of sections of the soft palate. However, the long-term safety of repeated scarring of the soft palate, by injection of a sclerosing agent, are unknown.⁷

Efficacy

In a study of 27 patients⁴ with a diagnosis of palatal flutter by sleep study, 25 patients (92%) reported a significant decrease in snoring. Most patients received more than one treatment (average, 1.8) in order to receive optimal palatal stiffening. There were no significant post injection complications and discomfort was minimal. Of these 25 patients that were successfully treated, 22 (88%) completed a survey with an average follow-up period of 19 months. Four patients (16%) reported a relapse of their snoring after treatment. Three were re-injected and their snoring improved.

At the same time, 15 new patients were prospectively treated. Thirteen (87%) patients reported subjective success with an average of 1.2 injections per patient. Eleven of 15 patients (73%) achieved improvements in palatal snoring and loudness.¹¹

All treatments for palatal flutter snoring have high relapse rates. For example, UPPP was reported to be 75% to 100% effective in eliminating or reducing snoring, but the long-term success rates ranged from 46% to 73%, and the largest long-term study revealed that only 46% of patients said that they had stopped snoring or that their snoring was markedly improved.¹ The efficacy of LAUP is reduced firstly due to a lack of patient compliance. LAUP requires multiple treatments, and the severe post-treatment pain causes a lot of patients to abandon treatment, hence affecting the short-term efficacy. Again, similar to UPPP, after 18 to 24 months, only 55% of patients reported that their bed partner was satisfied with the outcome.¹ CAPSO has shown a 92% short-term success rate and a 77% success rate after 12 months. Radiofrequency ablation has shown short-term success rates of between 77%¹² and 80%¹³, but at medium-term follow-up, the overall satisfaction rate was 69%.¹³ Short-term success was achieved in 92% of the first 27 patients to receive Injection Snoreplasty.⁴ A relapse rate of 16% was reported at follow-up at an average of 19 months and this appears to be comparable to other treatments for primary snoring.¹¹

No treatment for snoring has proven to be effective in the longer term. Even with the most aggressive surgical treatment, 50% of people are snoring again within four years. A simple scarring procedure, such as Injection Snoreplasty, cannot be expected to be successful in the long-term when even the most radical surgery is not.⁶

Cost and Availability

There appear to be few specialists performing Injection Snoreplasty in Australia at this time, but as the materials are readily available it could be performed at any time. This procedure should be approached with care, as the procedure is still in its experimental stages. There is also a lack of long-term follow-up data from the original patients studied by Brietzke and Mair.

An Australian (Sydney-based) ear, nose and throat surgeon charges approximately \$A500 per injection plus consultation fees. This procedure is not covered by Australian insurance funds at this time.

For more information, see <http://www.snoring.com.au>

Summary

Injection Snoreplasty appears to be simply performed in comparison with more invasive procedures such as uvulopalatopharyngoplasty, laser-assisted uvulopalatoplasty, cautery-assisted palatal stiffening operation and radiofrequency ablation. It is straightforward, lacks the risks associated with general anaesthesia, and does not require the purchase of expensive laser and radiofrequency equipment. Injection Snoreplasty appears to be as effective, in the short term, in reducing snoring, compared with other surgical treatments. Its long-term efficacy is unknown. It may be a suitable alternative to other treatment methods due to its minimal cost and minimal post-operative discomfort. Care must be taken as the long-term safety of repeated injections of a sclerosing agent is unknown.

Injection Snoreplasty is currently on the short-term horizon of introduction into Australasian health care.

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PO Box 688, North Adelaide, 5006, AUSTRALIA
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Fax: +618 8239 1244
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