

Issue date: June 2005

Collagen injection for vocal cord augmentation

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG130

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0882 (full guidance)
- N0883 (information for the public).

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ISBN 1-84629-045-7

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely within the NHS. This guidance covers England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called collagen injection for vocal cord augmentation. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether collagen injection for vocal cord augmentation is safe enough and works well enough for it to be used routinely for the treatment of voice loss caused by problems affecting the vocal cords (see below).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of collagen injection for vocal cord augmentation and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About collagen injection for vocal cord augmentation

A person's voice comes from vibrations of the vocal cords, which are in the larynx (voice box) at the back of the throat. The vocal cords can become affected by problems such as scarring of the tissue or they can become small and weak, or slightly paralysed because the nerves that control the muscles in the area aren't working properly. These problems can lead to what's known as glottic insufficiency, and the person's voice is affected.

The options for someone with glottic insufficiency depend on the person's individual condition. They include voice exercises for people whose muscles could be strengthened, strengthening injections and surgery. Surgery can be used to reposition or reshape the vocal cords, and it may involve inserting a device to help. It's also possible to inject strengtheners into the vocal cords. These include fat taken from another place on the person's body, Teflon, silicone and collagen.

The new procedure that NICE has looked at involves injecting collagen into the affected vocal cord or cords. Collagen is a naturally occurring material that gives strength to tendons and cartilage in the body. It can be obtained from various sources. Usually a person has a sensitivity test before the procedure to check that they don't react to the collagen that would be used.

To inject the collagen into place in the vocal cord, the doctor puts the needle either through the person's mouth or through the skin under the vocal cord. The person may be offered antibiotics before the procedure to help reduce the risk of a bacterial infection.

How well the procedure works

What the studies said

One study involved patients whose condition was not suitable for other types of treatment for glottic insufficiency. Twelve months after the collagen injection, the maximum intensity (loudness) of patients' voices had increased by an average of 2.9 decibels (the difference in intensity between a whisper and a quiet conversation is about 10 decibels). But the increase in normal voice intensity was not significant.

In another study that involved 27 patients who'd had surgery on the larynx, there was a significant improvement in voice intensity and what's known as phonation time, which is the length of time that the person can make a sound using a single breath. In tests carried out in the 16 weeks after the injection, all the patients had an improvement in at least one assessment.

One study followed what happened in patients with vocal cord paralysis who had the collagen injection. There was a good improvement in the voices of 13 out of 14 people around 6 months after the treatment. The length of time that a person could make a sound was increased from 5.7 seconds before the injection to 8.6 seconds afterwards. When six patients were checked on again after 3 years, five still seemed to have stronger voices. Four patients were able to have tests and these people were able to make a sound for longer than they could before having the procedure (12.2 seconds compared with 4.2 seconds).

What the experts said

The experts said that the body may eventually absorb the collagen, so the injection may need to be repeated.

Risks and possible problems with the procedure

What the studies said

In a study that involved 27 patients, one person had a short-lived decrease in voice quality because too much collagen had been injected. In one person, the vocal cord became swollen with fluid for a short time.

In two studies that involved a total of 63 patients, there were no serious problems reported in the 12 months after the injection. There were no serious problems in six patients who had checks for 3 years after the injection (for example, there was no evidence that the collagen had moved out of the vocal cord).

What the experts said

The experts said that if collagen from cows (bovine collagen) was used in the injection then variant Creutzfeld–Jakob disease (vCJD) could be transmitted in theory, and allergic reactions were possible.

What has NICE decided?

NICE has considered the evidence on collagen injection for vocal cord augmentation. It has recommended that when doctors use it for people with glottic insufficiency, they should be sure that:

- the patient understands what is involved and the alternative treatment options that are available
- the patient understands that it's not clear how long the effects of collagen injections last
- the patient agrees (consents) to the treatment, and
- the results of the procedure are monitored.

Other comments from NICE

Different materials can be used for vocal cord augmentation and they have different risks and benefits. If a person wants long-term improvements, then surgery may be a more suitable option.

Not many good-quality studies have been carried out on collagen injections into the vocal cord, but NICE considers that there is enough evidence to support use of these injections in people who need short-term relief of problems affecting the vocal cords.

What the decision means for you

Your doctor may have offered you collagen injection for vocal cord augmentation. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough in the short term for use in the NHS. Nonetheless, you should understand the benefits and risks of having a collagen injection before you agree to it, and you should be told about the alternative treatments that are suitable for you. Your doctor should discuss the benefits and risks of all the options with you. Some of these benefits and risks may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on collagen injection for vocal cord augmentation that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.





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N0883 1P Jun 2005

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