

Thrombin injection for pseudoaneurysms

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

May 2004

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called thrombin injection. 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 thrombin injections are safe enough and work well enough for them to be used routinely for the treatment of pseudoaneurysms.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of thrombin injections and how well they work
- 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 thrombin injections

NICE has looked at thrombin injections for pseudoaneurysms. A pseudoaneurysm is a build up of blood and blood clot outside a blood vessel. It happens if a blood vessel gets damaged and blood leaks out – this can happen in an accident or if a blood vessel is damaged during an operation. Pseudoaneurysms are sometimes dealt with by the body's own natural processes, so they go away without any treatment. But because there's a risk that a pseudoaneurysm can bleed into the body, a medical procedure such as a thrombin injection is sometimes needed.

Thrombin is a naturally occurring substance that makes blood clot. It's made in the body when a person cuts themselves – it makes a clot form, which helps to stop the bleeding. The procedure NICE has looked at involves injecting thrombin into the pseudoaneurysm. The aim is to form a small clot to plug the 'hole' in the artery where the blood is leaking out into the pseudoaneurysm. The doctor uses ultrasound images to make sure that the injection is going into the pseudoaneurysm. The clot that is formed breaks up naturally once the body has repaired the damaged artery.

Another way of treating a pseudoaneurysm involves putting pressure on the artery to stop the bleeding – this is called ‘compression’. Or sometimes the pseudoaneurysm is plugged in another way – this is called ‘embolisation’. In some cases, a surgeon repairs the damaged artery directly.

How well it works

What the studies said

NICE found four studies that compared what happened in patients who had thrombin injections with what happened in patients who had compression. All these studies showed that thrombin injection was more successful than compression in treating the pseudoaneurysm. In one study using thrombin injection, the pseudoaneurysm was treated successfully in nine out of ten patients, and it worked for all the patients in a second study. When compression was used, between six and nine out of ten patients were successfully treated.

What the experts said

The experts did not have any concerns about how well thrombin injections worked.

Risks and possible problems

What the studies said

In the studies, the main problems in patients who had thrombin injections were:

- thrombin being accidentally injected into the artery so that a blood clot formed that had to be removed surgically: this affected 3 out of 131 patients
- the pseudoaneurysm burst and bled after the clot had been formed: this affected 1 person out of 131
- an abscess (an infected pus-filled area) formed in the groin: 1 person out of 114 had this
- lack of blood flow to the legs: 1 person out of 114 had this
- poor blood circulation in a toe: 1 person out of 114 had this
- pain in the buttock: this affected 1 person out of 114.

What the experts said

The experts said that one of the most likely problems was that a blood clot could form in the damaged artery. Also, if a thrombin injection was used for a pseudoaneurysm that was actually infected, bleeding could happen again some time afterwards (infection makes re-bleeding more likely).

What has NICE decided?

NICE has considered the evidence on thrombin injections. It has recommended that when doctors use them for people with a pseudoaneurysm, they should be sure that:

- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

What the decision means for you

Your doctor may have offered you a thrombin injection for a pseudoaneurysm. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless you should understand the benefits and risks of a thrombin injection before you agree to it. Your doctor should discuss the benefits and risks 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.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on thrombin injection for pseudoaneurysms is on the NICE website (www.nice.org.uk/IPG060guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0577. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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