



Thrombin injections for pseudoaneurysms

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www.nice.org.uk/guidance/ipg60

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

1.1 Current evidence on the safety and efficacy of thrombin injections for pseudoaneurysms appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

2 The procedure

2.1 Indications

- A pseudoaneurysm (also called a false aneurysm) is a collection of blood and blood clot that has formed outside a blood vessel, usually after an injury. The collection is connected by a channel to the blood vessel, so blood flows through it. A pseudoaneurysm may rupture and bleed. Pseudoaneurysms differ from true aneurysms in that blood within a true aneurysm is contained by the weakened wall of the blood vessel. The most common cause of a pseudoaneurysm is femoral artery puncture during cardiac catheterisation. A pseudoaneurysm may also occur after other procedures that involve puncture of an artery, including removal of an arterial blood pressure line or an intra-aortic balloon pump, or after accidental trauma.
- 2.1.2 Many pseudoaneurysms resolve spontaneously by thrombosis and need no treatment. If treatment is required, treatment options include compression under ultrasound control, embolisation of the pseudoaneurysm with a variety of materials, or surgical repair.

2.2 Outline of the procedure

In this procedure, thrombin (a blood-clotting agent) is injected under ultrasound guidance into the pseudoaneurysm. This causes thrombosis of the pseudoaneurysm cavity, which seals the arterial puncture site. The resulting clot is gradually reabsorbed.

2.3 Efficacy

- 2.3.1 Three historically controlled studies and one retrospective cohort study were identified comparing thrombin injection with compression. All four studies reported greater success in treating pseudoaneurysms with thrombin injection. In these studies, success rates ranged between 93% (27 out of 29 patients) and 100% (24 out of 24 patients) using thrombin injection, and between 63% (25 out of 40 patients) and 95% (102 out of 107 patients) using compression. For more details, see the overview.
- 2.3.2 The Specialist Advisors did not note any concerns regarding the efficacy of this procedure.

2.4 Safety

- In the studies identified, the main complications reported were: intra-arterial thrombin injection necessitating thrombectomy for artery occlusion (2%, 3 out of 131 patients); pseudoaneurysm rupture after thrombosis (1%, 1 out of 131 patients); groin abscess (1%, 1 out of 114 patients); leg ischaemia (1%, 1 out of 114 patients); blue toe (1%, 1 out of 114 patients); and buttock pain (1%, 1 out of 114 patients). For more details, see the <u>overview</u>.
- The Specialist Advisors listed the main potential adverse events of this procedure as thrombosis of the damaged artery and treatment of a clinically infected pseudoaneurysm (because infection can cause late recanalisation and rupture).

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.