

Thrombin injections for pseudoaneurysms

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www.nice.org.uk/guidance/ipg60

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

2.1.1 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

2.2.1 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% (27/29 patients) and 100% (24/24 patients) using thrombin injection, and between 63% (25/40 patients) and 95% (102/107 patients) using compression. For more details, refer to the 'Sources of evidence' section.
- 2.3.2 The Specialist Advisors did not note any concerns regarding the efficacy of this procedure.

2.4 Safety

2.4.1 In the studies identified, the main complications reported were: intraarterial thrombin injection necessitating thrombectomy for artery occlusion (2%, 3/131 patients); pseudoaneurysm rupture after thrombosis (1%, 1/131 patients); groin abscess (1%, 1/114 patients); leg ischaemia (1%, 1/114 patients); blue toe (1%, 1/114 patients); and buttock pain (1%, 1/ 114 patients). For more details, refer to the 'Sources of evidence' section.

2.4.2 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).

Andrew Dillon Chief Executive May 2004

Further information 3

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of thrombin injections for pseudoaneurysms', December 2002.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance 4

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and

Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a <u>summary of this guidance for patients and carers</u>. Information about the evidence it is based on is also <u>available</u>.

Changes since publication

28 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

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