

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of thrombin injection for pseudoaneurysm

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared by Bazian Ltd in December 2002.

Procedure name

Thrombin injection for pseudoaneurysm

Specialty society

British Society of Interventional Radiology

Indication(s)

A pseudoaneurysm is a collection of blood and blood clot that has formed outside a blood vessel, usually after an injury. The collection is connected to a channel to the blood vessel so blood flows through it. A pseudoaneurysm may rupture and bleed.

Pseudoaneurysms (also called false aneurysms) 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 pseudoaneurysm is femoral artery puncture during cardiac catheterisation. About 100,000 cardiac catheterisations are performed in England each year (source: Department of Health Hospital Episode Statistics, ungrossed for missing data, 2000/2001). Up to 2% of cardiac catheterisations lead to pseudoaneurysm formation. Pseudoaneurysms may also occur following other procedures that involve puncture of an artery, including removal of an arterial blood pressure line or intra-aortic balloon pump, or following accidental trauma.

Summary of procedure

Many pseudoaneurysms resolve spontaneously (by thrombosis) and need no treatment. The traditional treatment for an unresolved pseudoaneurysm is surgical repair under general anaesthetic. This may be dangerous in people with cardiac disease. Other options include prolonged compression, which is time consuming and painful, and packing the pseudoaneurysm with metal coils, which leaves a lump in the groin.

Thrombin is an agent that causes clotting. It is injected under ultrasound guidance into the pseudoaneurysm to clot the blood inside it. The clot is gradually reabsorbed. The procedure may be performed under local anaesthetic. It is claimed to be faster and less painful for the patient than surgery or compression.

Literature review

Appraisal criteria

We included studies with clinical outcomes describing thrombin injection for pseudoaneurysm of any cause.

List of studies found

We found six controlled studies. The four largest are described in the table.¹⁻⁴

We found 15 case series including 30 or more people. The largest case series,⁵ and one case series with long term follow up⁶ are described in the table.

References to smaller studies are provided in the annex.

Summary of key efficacy and safety findings (1)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability and validity issues
<p>Khoury M¹ Historical controlled study Detroit, USA Dates not provided, published 2002</p> <p>n=320</p> <ul style="list-style-type: none"> • 189 compression, mean age 67, mean aneurysm size 2.8 cm • 131 thrombin injection, mean age 70, mean aneurysm size 3.3 cm <p>Follow up length not stated, assumed to be to hospital discharge</p>	<p>'Success':</p> <ul style="list-style-type: none"> • Compression: 75% • Thrombin injection: 96% <p>Time to achieve 'success':</p> <ul style="list-style-type: none"> • Compression: average 44 mins • Thrombin injection: thrombosis achieved 'in minutes' 	<p>Groin tenderness</p> <ul style="list-style-type: none"> • Compression: 34% • Thrombin injection: 0% <p>Major complications:</p> <ul style="list-style-type: none"> • Compression: none • Thrombin injection: intra-arterial thrombin injection 2% • pseudoaneurysm rupture after thrombosis (patient died 1 day postoperatively due to a cardiac arrest that occurred during surgery for treatment of rupture) 1% 	<p>Historical controls</p> <p>Thrombin injection and compression groups similar in age, sex and pseudoaneurysm size</p>
<p>Szendro G² Historical controlled study Israel 1992 to 1999</p> <p>131 people</p> <ul style="list-style-type: none"> • n=107 compression between 1992 and 1998 • n=24 patients thrombin injection between 1998 and 1999 	<p>'Success' rate (not defined in abstract):</p> <ul style="list-style-type: none"> • compression: 95% • thrombin injection 100% 	<p>No complications reported</p>	<p>Paper published in Hebrew</p> <p>Data extracted from English abstract</p> <p>Historical controls</p> <p>Success not defined in abstract</p>

<p>Weinmann EE³ Historical controlled study Israel 1997 to 2001</p> <p>66 people with pseudoaneurysm >1.5cm</p> <ul style="list-style-type: none"> n=33 compression, 1997 and 1999, mean age 66 years n=33 thrombin injection, 1999 and 2001, mean age 65 years <p>Follow up length not stated, assumed to be to hospital discharge</p>	<p>'Successful obliteration':</p> <ul style="list-style-type: none"> Compression: 87% Thrombin injection: 100% <p>Duration of treatment:</p> <ul style="list-style-type: none"> Compression: 75 minutes Thrombin injection: 25 minutes <p>Median hospital stay:</p> <ul style="list-style-type: none"> Compression: 2 days (range 1-5 days) Thrombin injection: 1 day (range 1-2 days) 	<p>Superficial skin infection:</p> <ul style="list-style-type: none"> Compression 7% Thrombin injection: 3% <p>Subsequent surgery:</p> <ul style="list-style-type: none"> Compression: 20% Thrombin injection: 0% 	<p>Historical controls</p> <p>Groups comparable on age, sex, size of aneurysm and underlying medical conditions</p>
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Summary of key efficacy and safety findings (2)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability and validity issues
<p>Taylor BS⁴ Retrospective cohort study Pittsburgh, USA 1996 to 1999</p> <p>n=69</p> <ul style="list-style-type: none"> 40 compression, 1996 to 1999 29 thrombin injection, 1998 to 1999 <p>Follow up length not stated, assumed to be to hospital discharge</p>	<p>'Successful obliteration':</p> <ul style="list-style-type: none"> Compression: 63% Thrombin injection: 93% <p>Time to obliterate pseudoaneurysm:</p> <ul style="list-style-type: none"> Compression: 'average' 37 mins Thrombin injection: 'seconds' <p>p<0.01</p> <p>'Average' vascular laboratory time:</p> <ul style="list-style-type: none"> Compression: 59 mins Thrombin injection: 16 mins 	<p>Severe pain:</p> <ul style="list-style-type: none"> Compression: 3 people Thrombin injection: none 	<p>From 1998 to 1999, people received thrombin injection according to preference of surgeon</p> <p>Comparison of characteristics in compression and thrombin injection groups not presented</p>
<p>Paulson EK⁵ Case series Durham, USA 1998 to 2001</p> <p>114 people Follow up 48 hours</p>	<p>'Success': 90% after one procedure, a further 6% at the second procedure</p> <p>Mean thrombosis time: 12 seconds (range 3 to 90 seconds)</p> <p>No recurrence at 24 hour follow up</p>	<p>Complications:</p> <ul style="list-style-type: none"> 1 blue toe resolved spontaneously 1 groin abscess 1 leg ischaemia resolved spontaneously 1 buttock pain resolved spontaneously 	<p>Uncontrolled case series</p> <p>Follow up short</p> <p>'Success' defined by ultrasound appearance</p>

<p>Calton WC⁶ Case series Pennsylvania, USA Published 2001</p> <p>52 people Mean length of follow up: 9 months (range 3 to 17 months)</p>	<p>Immediate 'success': 94%</p>	<p>Subsequent surgery: 3 people</p> <p>At follow up (32 people):</p> <ul style="list-style-type: none"> • recurrences: none • arteriovenous fistulas: none • distal circulatory problems: none 	<p>Paper not available</p> <p>Completed from abstract</p> <p>Follow up long</p> <p>Losses to follow up large</p> <p>'Success' defined by ultrasound appearance</p>
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Validity and generalisability of the studies

The studies were all carried out in settings applicable to the UK.

Three of the controlled studies examined outcomes in people who had thrombin injection compared with historical controls who had been treated with compression before thrombin injection was available.¹⁻³ In the other controlled study, people received thrombin injection or compression according to physician preference. Both of these study designs are susceptible to confounding.

One of the controlled studies¹ and the larger case series⁵ were fairly large so provide some useful information on the incidence of complications.

Follow up was short in all studies except the smaller case series.⁶

Bazian comments

Most authors report that thrombin injection has become their treatment of choice.

Specialist advisor's opinion / advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- technique is now in fairly common use
- bovine thrombin may be controversial
- a technique of isolating a sample of the patient's own thrombin has been developed

References

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6. Calton, W. C., Jr., Franklin, D. P., Elmore, J. R., and Han, D. C. Ultrasound-guided thrombin injection is a safe and durable treatment for femoral pseudoaneurysms. *Vascular Surgery* 2001; 35: 379-383

Annex: References to studies not described in the table

Reference	Number of study participants
Comparative studies	
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Case series	
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Grewe, P. H., Deneke, T., Fadgyas, T., Germing, A., Lemke, B., Muller, K. M., von Dryander, S. [Minimally invasive percutaneous contrast-ultrasound guided thrombin occlusion of iatrogenic pseudoaneurysm]. [German] <i>Zeitschrift fur Kardiologie</i> 2001; 90: 737-744	33
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Kang, S. S., Labropoulos, N., Mansour, M. A., Baker, W. H. Percutaneous ultrasound guided thrombin injection: a new method for treating postcatheterization femoral pseudoaneurysms. <i>Journal of Vascular Surgery</i> 1998; 27: 1032-1038	30
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