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 up\(^6\) are described in the table.

References to smaller studies are provided in the annex.
### Summary of key efficacy and safety findings (1)

<table>
<thead>
<tr>
<th>Authors, location, date, patients</th>
<th>Key efficacy findings</th>
<th>Key safety findings</th>
<th>Key reliability and validity issues</th>
</tr>
</thead>
</table>
| **Khoury M**<sup>1</sup>  
Historical controlled study  
Detroit, USA  
Dates not provided, published 2002  
n=320  
- 189 compression, mean age 67, mean aneurysm size 2.8 cm  
- 131 thrombin injection, mean age 70, mean aneurysm size 3.3 cm  
Follow up length not stated, assumed to be to hospital discharge | *Success*:  
- Compression: 75%  
- Thrombin injection: 96%  
Time to achieve ‘success’:  
- Compression: average 44 mins  
- Thrombin injection: thrombosis achieved ‘in minutes’ | Groin tenderness  
- Compression: 34%  
- Thrombin injection: 0%  
Major complications:  
- 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% | Historical controls  
Thrombin injection and compression groups similar in age, sex and pseudoaneurysm size |
| **Szendro G**<sup>2</sup>  
Historical controlled study  
Israel  
1992 to 1999  
131 people  
- n=107 compression between 1992 and 1998  
- n=24 patients thrombin injection between 1998 and 1999 | *Success’ rate (not defined in abstract):  
- compression: 95%  
- thrombin injection 100% | No complications reported | Paper published in Hebrew  
Data extracted from English abstract  
Historical controls  
Success not defined in abstract |
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| Taylor BS4 Retrospective cohort study Pittsburgh, USA 1996 to 1999 | ‘Successful obliteration’:  • Compression: 63%  • Thrombin injection: 93%  
Time to obliterate pseudoaneurysm:  • Compression: ‘average’ 37 mins  
  • Thrombin injection: ‘seconds’ p<0.01  
‘Average’ vascular laboratory time:  • Compression: 59 mins  
  • Thrombin injection: 16 mins  | Severe pain:  • Compression: 3 people  
  • Thrombin injection: none  | From 1998 to 1999, people received thrombin injection according to preference of surgeon  
Comparison of characteristics in compression and thrombin injection groups not presented  |
| Paulson EK5 Case series Durham, USA 1998 to 2001 | ‘Success’: 90% after one procedure, a further 6% at the second procedure  
Mean thrombosis time: 12 seconds (range 3 to 90 seconds)  
No recurrence at 24 hour follow up  | Complications:  • 1 blue toe resolved spontaneously  
  • 1 groin abscess  
  • 1 leg ischaemia resolved spontaneously  
  • 1 buttock pain resolved spontaneously  | Uncontrolled case series  
Follow up short  
‘Success’ defined by ultrasound appearance  |
| Calton WC<sup>c</sup>  
Case series  
Pennsylvania, USA  
Published 2001 |
|------------------|
| 52 people  
Mean length of follow up: 9 months  
(range 3 to 17 months) |
| Immediate ‘success’: 94% |
| Subsequent surgery: 3 people  
At follow up (32 people):  
• recurrences: none  
• arteriovenous fistulas: none  
• distal circulatory problems: none |
| Paper not available  
Completed from abstract  
Follow up long  
Losses to follow up large  
‘Success’ defined by ultrasound appearance |
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 studies\(^1\) and the larger case series\(^5\) 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


### Annex: References to studies not described in the table

<table>
<thead>
<tr>
<th>Reference</th>
<th>Number of study participants</th>
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<tr>
<td><strong>Comparative studies</strong></td>
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<tr>
<td>Lonn, L., Olmarker, A., Getterud, K., Klingenstierna, H., Delle, M., Grip, L., Risberg, B.</td>
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<td>McNiel, N. L. Clark, T. W.</td>
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<td><strong>Case series</strong></td>
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</tr>
<tr>
<td>Therapeutic thrombin injection of pseudoaneurysms: a multicenter experience. Vascular Medicine 2001; 6: 241-244</td>
<td></td>
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<td>La Perna, L., Olin, J. W., Goines, D., Childs, M. B., Ouriel, K.</td>
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<td>Sheiman, R. G. Brophy, D. P.</td>
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<td>Ramsay, D. W. Marshall, M.</td>
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<td>Chattar-Cora, D., Pucci, E., Tulsyan, N., Cudjoe, E., James, K. V., Resnikoff, M.</td>
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<td>Friedman, S. G., Pellerito, J. S., Scher, L., Faust, G., Burke, B., Safa, T.</td>
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<td>Ultrasound-guided thrombin injection is the treatment of choice for femoral pseudoaneurysms. Archives of Surgery 2002; 137: 462-464</td>
<td></td>
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<td>Morrison, S. L., Obrant, D. A., Steinmetz, O. K., Montreuil, B.</td>
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<td>Grewe, P. H., Deneke, T., Fadgyas, T., Germing, A., Lemke, B., Muller, K. M., von Dryander, S.</td>
<td>33</td>
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<tr>
<td>Duplex-guided thrombin injection for iatrogenic femoral artery pseudoaneurysm is effective even in anticoagulated patients. British Journal of Surgery 2000; 87: 796-801</td>
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