Thrombin injection versus compression of femoral artery pseudoaneurysms
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Ultrasound scan-guided thrombin injection, with dilute thrombin (100 U/mL), for femoral artery false aneurysm treatment.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study included patients with femoral artery pseudoaneurysms.

Setting
A large tertiary care hospital. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data corresponded to patients treated in the study institution between January 1996 and April 1999. The price year was not reported.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was retrospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. A review was conducted of 22 patients (with 22 pseudoaneurysms) with a mean age of 68.5 (range: 39 to 85) years, who underwent ultrasound scan-guided compression therapy as the primary treatment method in the period from January 1996 to April 1999. In the period between May 1998 and April 1999, corresponding to the period of evaluation of ultrasound scan-guided thrombin injection in the study institution, 39 patients were referred for the evaluation of 40 false aneurysms, of whom 23 patients with a mean age of 68.3 years (range: 22 to 84) underwent primary thrombin injection therapy and 16 patients with a mean age of 72 years (range: 56 to 82) years with 17 pseudoaneurysms underwent compression therapy.
Study design
This was a retrospective cohort study, carried out in a single centre. The choice of interventions was based on the attending surgeon's preference. The duration of the follow-up appears to have been until discharge from hospital. The follow-up ultrasound scans and the pulse examinations were performed 24 to 72 hours after the treatment to evaluate for thrombosis or recurrence.

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The clinical outcome measures were success rate, time to thrombosis, vascular laboratory time, severe pain, and complications. The study groups were comparable in terms of demographics and aneurysm sizes, (p>0.2).

Effectiveness results
The effectiveness results were as follows:

For the entire period, 25 of 40 pseudoaneurysms (63%) were treated successfully using the compression therapy (9 persistent aneurysms necessitated operation, and 6 were treated successfully with thrombin injection) versus 27 of 29 (93%) in the thrombin therapy.

The average time to thrombosis was 37 minutes for compression versus only seconds in the thrombin group (p<0.01).

The total vascular laboratory time for compression was 59 minutes per patient and 16 minutes per patient for thrombin injection.

Three patients in the compression group reported significant pain and requested that the procedure be aborted; no patients in the thrombin group had discomfort.

No complications were encountered in either form of treatment.

Clinical conclusions
The study found the percutaneous thrombin injection therapy to be a safe and more effective treatment method than compression. The authors believe that technical issues such as the localisation of the needle tip may limit the applicability of the thrombin injection to all patients.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only individual health outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs. Cost items were not reported separately. Cost analysis covered the costs of operative repair of femoral artery false aneurysms, hourly cost in the vascular laboratory, and cost of supplies. The perspective adopted in the cost analysis was that of the hospital. Average hospitalisation charges were reported for the study groups, but the average calculated cost per patient for treatment of a pseudoaneurysm was based on actual hospital costs in the study institution rather than charges. The price year was not given. The cost analysis did not cover physician fees.

Indirect Costs
Indirect costs were not included.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The average cost per patient for treatment of a pseudoaneurysm was $636 in the compression group versus $142 in the thrombin group.

Average charges for hospitalisation for those patients who underwent compression therapy were $51,897 and $50,971 for those who underwent thrombin injection.

Synthesis of costs and benefits
Costs and benefits were not combined since the intervention (thrombin therapy) was the dominant strategy.

Authors' conclusions
Ultrasound scan-guided thrombin injection is a safe, fast, and painless procedure that completely obliterates femoral artery pseudoaneurysms. The shift from compressive therapy to thrombin injection reduces vascular laboratory use and is less expensive, although it does not significantly impact hospital costs.

CRD COMMENTARY - Selection of comparators
The strategy of using ultrasound scan-guided compression therapy, as the comparator was justified as it was the standard practice before the use of thrombin injection. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results cannot be assured due to retrospective nature of the study design. The study groups were comparable in terms of demographics and aneurysm sizes, (p>0.2). Whether the study sample was representative of the study population cannot be objectively assessed as insufficient information was provided regarding the exclusion and inclusion criteria.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore one of cost-consequences in design.

Validity of estimate of costs
Positive aspects of the cost analysis were as follows: some quantities were reported separately from the costs; adequate details of methods of cost estimation were given; the perspective adopted in the cost analysis was reported; it was claimed that cost analysis was based on actual costs rather than charges. Some limitations of the cost analysis were as follows: cost items were not reported separately; some important direct cost items were omitted from the cost analysis (such as physician fees), as acknowledged by the authors; the methods used to calculate actual costs (such as using Medicare cost-to-charge ratios) were not reported; the effects of alternative procedures on indirect costs were not addressed; statistical analyses appear to have been performed on some resource consumption data, but not on cost data;
and the price year was not reported. The cost results may not be generalisable outside the study setting. It was noted that
the study was not able to show an overall significant cost saving in total hospital expenditures between the two groups
because of the large number of comorbid factors.

Other issues
Given the retrospective nature of the study design, and the lack of sensitivity analysis and statistical analysis of costs,
the study results may need to be treated with some degree of caution. The issue of generalisability to other settings or
countries was not addressed. Appropriate comparisons were made with other studies. The issue of the study sample
being representative of the study population was not addressed other than by noting that the study sample was associated
with a large number of comorbid factors.

Implications of the study
Ultrasound scan-guided thrombin injection therapy has become the authors' preferred initial treatment for all
pseudoaneurysms that appear suitable. The authors continue to use compression in the cases in which the cavity is small,
with an anterior simple neck, and in cases in which thrombin injection therapy fails. The authors thus believe that the
two therapeutic methods are complementary.

Source of funding
None stated.

Bibliographic details
Taylor B S, Rhee R Y, Muluk S, Trachtenberg J, Walters D, Steed D L, Makaroun M S. Thrombin injection versus

PubMedID
10587389

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Aged, 80 and over; Aneurysm, False /therapy /ultrasonography; Female; Femoral Artery /ultrasonography;
Hemostatic Techniques; Humans; Injections, Intra-Arterial; Male; Middle Aged; Pain Measurement; Pressure;
Retrospective Studies; Thrombin /administration & dosage; Treatment Outcome

AccessionNumber
22000000027

Date bibliographic record published
30/06/2001

Date abstract record published
30/06/2001