Use of a collagen hemostatic closure device to achieve hemostasis after arterial puncture: a cost-effectiveness analysis

Bos J J, Hunink M G, Mali W P

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
Collagen hemostatic closure device after arterial puncture.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing diagnostic or therapeutic cardiac and radiologic procedures who require arterial access which is usually obtained via the common femoral artery.

Setting
Hospital. The economic study was carried out in Groningen, the Netherlands.

Dates to which data relate
Effectiveness data was derived from studies conducted between 1992 and 1994. Resource and cost data were mainly derived from 1992-1994 sources. Resources were measured in 1994 values.

Source of effectiveness data
Probabilities of developing various complications were derived from a review of previous studies.

Modelling
A decision tree model was used to address the question of whether a collagen closure device provides a safe and cost-effective means of achieving hemostasis compared with manual compression after diagnostic angiography and interventional procedures performed by radiologists.

Outcomes assessed in the review
The outcomes assessed were the probabilities of developing various complications (hematoma, transfusion for hematoma, false aneurysm, stenosis or occlusion and closure device failure).

Study designs and other criteria for inclusion in the review
Previously completed studies. The exclusion criterion for studies was a low percentage of patients treated with a
Sources searched to identify primary studies
MEDLINE was searched for primary studies.

Criteria used to ensure the validity of primary studies
Randomized controlled trials (RCTs) and other clinical trials.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
7 studies for manual compression and 20 studies for collagen closure devices were included in the review.

Methods of combining primary studies
Data pooling.

Investigation of differences between primary studies
The results were reported for RCTs only and for all studies reviewed.

Results of the review
The baseline probabilities used for the decision tree were:

- hematoma = 0.077 (all trials) and 0.069 (RCTs) (range = 0.02-0.33) for manual compression
- hematoma = 0.048 (all trials) and 0.063 (RCTs) (range = 0-0.25) for the closure device;
- transfusion = 0.011 (all trials) and 0.003 (RCTs) (range = 0-0.19) for manual compression
- transfusion = 0.004 (all trials) and 0.002 (RCTs) (range = 0-0.1) for the closure device;
- false aneurysm = 0.02 (all trials) and 0.015 (RCTs) (range = 0-0.18) for manual compression
- false aneurysm = 0.012 (all trials) and 0.021 (RCTs) (range = 0-0.1) for the closure device;
- stenosis or occlusion = 0.002 (all trials) and 0 (RCTs) (range = 0-0.06) for manual compression
- stenosis or occlusion = 0.002 (all trials) and 0.002 (RCTs) (range = 0-0.02) for the closure device;
- closure device failure = 0.011 (all trials) and 0.021 (RCTs) (range = 0-0.1).

No statistical differences were found between the two methods for both RCT results only and all clinical trials.

Measure of benefits used in the economic analysis
The measure of benefits was a decrease in rate of puncture-site complications which required treatment.

Direct costs
Direct medical costs incurred by reimbursing the patient or directly paying the provider were included. The quantities were analysed separately from prices and included the cost of manual compression, closure device, blood transfusion (1-3 units of red cells), percutaneous transluminal angioplasty and one extra hospital day. Costs were not discounted. The quantity/cost boundary adopted was that of the health-care system.

**Statistical analysis of costs**
Not undertaken.

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis was carried out on alternative estimates for the probabilities of developing various complications and on the combined results of all the clinical trials. The method used was not stated. In the first case, manual compression was shown, by assuming equivalent length of stay, to be more effective and cost saving than use of the closure device. In the second case, the closure device, by assuming equivalent length of stay, was shown to be more costly than using manual compression. By allowing the closure device to reduce the length of stay by 1 day, the closure device was shown to be more effective and less costly.

**Estimated benefits used in the economic analysis**
Use of a collagen closure device was estimated to decrease the number of puncture-site complications from 31:1,000 to 16:1,000.

**Cost results**
The average cost of using the device was $177 per patient compared with $42 per patient for manual compression.

**Synthesis of costs and benefits**
The estimated benefits and costs were not combined. An incremental analysis was performed. The incremental cost of averting one complication exceeded $9,000 and rose to $37,000 per complication averted in the sensitivity analysis.

**Authors' conclusions**
Use of a collagen closure device to achieve hemostasis after an arterial puncture may reduce the complication rate, but the additional cost per complication averted is very high.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparator is clear. Hemostasis of arterial puncture site is normally achieved by means of manual compression. An alternative hemostatic closure device is the Vasoseal collagen plug which has the main advantage of reducing the time required to achieve hemostasis and therefore to increase physical productivity and decrease labour time and costs. You, as a user of this database, should consider whether these are widely used health technologies in your setting.

**Validity of estimate of measure of benefit**
The estimate of measure of benefit used in the economic analysis is likely to be internally valid. The data have not been used selectively and a systematic review of the literature was undertaken in determining baseline probabilities. The modeled solutions were tested using sensitivity analysis to test the robustness of the findings.
Validity of estimate of costs
Adequate details of methods of quantity/cost estimation were given. Important cost items were not omitted.

Other issues
The authors’ conclusions are likely to be justified, given the uncertainties in the data. The issue of generalisability to other settings was not addressed but appropriate comparisons were made with other studies. The results do not appear to have been presented selectively.

Implications of the study
The authors indicated that a large scale RCT would be needed to validate these results, but that the numbers required to show a statistical difference would be prohibitively high. As such this modeled solution is a suitable alternative.

Source of funding
Supported by a PIONIER award from the Netherlands Organization for Scientific Research.

Bibliographic details

PubMedID
8855523

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Aneurysm, False /economics /etiology /therapy; Angiography /adverse effects; Arteries; Arteriovenous Fistula /economics /etiology /therapy; Blood Transfusion /economics; Collagen /administration & dosage /economics /therapeutic use; Cost-Benefit Analysis; Costs and Cost Analysis; Decision Trees; Evaluation Studies as Topic; Hematoma /economics /etiology /therapy; Hemostatic Techniques /economics /instrumentation; Hemostatics /administration & dosage /economics /therapeutic use; Humans; Pressure; Punctures /adverse effects; Radiography, Interventional; Safety; Sensitivity and Specificity

AccessionNumber
2199600843

Date bibliographic record published
30/11/1998

Date abstract record published
30/11/1998