Proximity arteriography: cost-effectiveness in asymptomatic penetrating extremity trauma

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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
The use of delayed (next morning) proximity arteriography, a diagnostic instrument, to evaluate asymptomatic patients with penetrating extremity trauma near a major vessel with no obvious signs of vascular injury.

Type of intervention
Diagnosis.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients presenting at the trauma unit with penetrating extremity trauma near major arteries. Patients with soft or hard signs of vascular injury were excluded.

Setting
The study was set in an urban trauma unit. The economic study was carried out at the Departments of Radiology and Surgery of the Cook County Hospital, Chicago (IL), USA.

Dates to which data relate
The effectiveness evidence and resource use data were derived from studies published between 1975 and 1998. The price year was 1998.

Source of effectiveness data
The effectiveness data were derived from a review of published studies, and assumptions from the authors’ institution.

Modelling
A decision-tree analytic model was used to analyse and evaluate the costs and the outcomes of the two possible strategies. In the observation branch (comparator) of the decision tree, patients would have been discharged after 24 hours’ observation if there were no signs or symptoms of injury, and asked to return if there were symptoms. In the arteriography branch (intervention), all patients would have undergone the diagnostic procedure and only patients achieving a normal outcome would have been discharged.

Outcomes assessed in the review
The outcomes assessed in the review were:

a series of disutility values from arteriography, exploratory surgery and surgical repair;
limb loss following occult vascular injury (amputation);

permanent limb injury following occult vascular injury (claudication);

the probability of a patient with an injury missed on physical examination returning for early surgical repair to restore a normal outcome;

the amputation rate for patients returning late for surgical repair;

the prevalence of a missed injury for asymptomatic proximity trauma requiring surgical repair;

the probability of a patient with a misread arteriogram returning in time for operative repair to normal; and

the sensitivity and specificity of arteriography.

**Study designs and other criteria for inclusion in the review**
Not reported.

**Sources searched to identify primary studies**
Not indicated.

**Criteria used to ensure the validity of primary studies**
Not reported.

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

**Number of primary studies included**
The effectiveness evidence was derived from 21 primary studies.

**Methods of combining primary studies**
When estimations were not obtained from a single study, "half of the average" value from a review was used for the amputation rate for late repair.

**Investigation of differences between primary studies**
Not carried out.

**Results of the review**
The disutility values were -0.15 for arteriography, -0.5 for exploratory surgery, and -2.0 for surgical repair.

The disutility values were -60 for limb loss following occult vascular injury (amputation), and -27 for permanent limb injury following occult vascular injury (claudication).

The probability of a patient with an injury missed by physical examination returning for early surgical repair to a normal outcome was 70%.

The probability that patients returning late for repair would have amputation was 6.7% (overall amputation rate of 2%).
A range of values from 0.7% to 16% was also obtained for the prevalence of missed injury for asymptomatic proximity trauma requiring surgical repair.

The sensitivity of arteriography was 99% and the specificity was 97%.

The probability of a patient with a misread arteriogram returning in time for operative repair to normal was 83%.

**Methods used to derive estimates of effectiveness**

Further effectiveness data were obtained from a retrospective review of the hospital records for 1997, from the authors' institution. Data were obtained for the 147 patients (160 proximity arteriograms) the authors had encountered. The authors also made some assumptions about the effectiveness.

**Estimates of effectiveness and key assumptions**

The prevalence rate for occult injury was estimated as 2.5%. The authors assumed that if a patient with an occult injury returned early, the outcome was early surgical repair to normal. If, on the other hand, the patient returned late, the outcome was late surgical repair to an outcome equivalent to amputation or a permanent injury equivalent to intermittent claudication. The authors also assumed that a false negative arteriogram would not miss an injury leading to amputation.

**Measure of benefits used in the economic analysis**

The health benefit measure used in the economic analysis was the number of quality-adjusted life-years (QALYs). This was computed for both of the treatments analysed.

**Direct costs**

Discounting was irrelevant due to the short time horizon adopted in the analysis. The quantities and the unit costs were reported separately for capital, labour (by type of personnel), housekeeping and supplies. The resource/cost boundary reflected the perspective adopted in the study. The costs were for capital, labour and supplies. In particular, the analysis considered the costs of hospitalisation (daily cost), surgical exploration, surgical repair (immediate, early, and late), the arteriogram, the operating room, supplies, and labour (attending, resident, technician, and nurse personnel). The labour and capital costs for the angiography suite were amortised assuming that the suite was used 50 hours per week. The analysis also included the extra costs relating to the first year of rehabilitation, or prosthesis after amputation.

The costs were estimated from actual data obtained from the purchasing and pharmacy departments, and from data derived from the literature. All the costs were converted into 1998 US dollars using the medical component of the US consumer price index.

**Statistical analysis of costs**

No statistical analysis of the costs was reported.

**Indirect Costs**

The indirect costs were relevant to the perspective adopted and were included in the analysis. The authors calculated the present value of 50% of the estimated annual public disability payment because almost half of traumatic amputees returned to work. Since the average age of the patients undergoing proximity arteriography at the authors' institution in 1997 was 26.7 years, it was assumed that they could live for an additional 50 years. A 3% discount rate was therefore used. The liability costs for bad outcomes from missed injury were also included, although in the base-case they amounted to $0. The cost of lost productivity was not included.
Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses and a threshold analysis (at $50,000/QALY) were carried out. These were conducted to
investigate the robustness of the model, and the uncertainty around the data obtained from the literature. The following
parameters were varied:

- the utility values for amputation (range: 20 - 60) and claudication (range: 60 - 85);
- the rate of early return (range: 50 - 90%);
- the amputation rate (range: 0 - 20%);
- the prevalence rate (range: 0 - 10%);
- the sensitivity (range: 95 - 100%) and the specificity (range: 95 - 100%) of arteriography;
- the complication rates (range: 0.05 - 0.25);
- the cost of the arteriogram (range: $40 - $1,500); and
- the costs of rehabilitation (range: $0 - $500,000), disability (range: $0 - $500,000) and liability (range: $0 - $500,000).

Estimated benefits used in the economic analysis
The estimated QALYs associated with the treatments were not reported. However, the authors reported that the
incremental utility of proximity arteriography over observation was 0.041, which amounts to 3.08 QALYs for 150
patients.

Cost results
The total costs of each intervention, obtained from the decision model, were not reported. However, the incremental
cost was $37,400 for 150 patients.

Synthesis of costs and benefits
The costs and the benefits were combined using an incremental cost-utility analysis. The incremental cost per QALY
gained of proximity arteriography, relative to observation, was $12,100.

The sensitivity analyses indicated that the results were robust to changes in the outcome values for amputation, the
sensitivity and specificity of arteriography, and the costs of rehabilitation and disability. Observation became the
dominant strategy if the value assigned to claudication was greater than 80, if early return was greater than 75%, and
when the prevalence of occult injury was varied from 0 to 2%. Between a prevalence of 2.5% and 5%, the cost-
effectiveness ratio for arteriography was below $50,000. At or above a 5.5% prevalence, arteriography dominated
observation. Arteriography would be cost-effective (at this level) if the prevalence was greater than 1.0%, only if the
complication rate was assumed to be 0.4% and the disutility of amputation was -90.

Authors' conclusions
From the perspective of the taxpayer, proximity arteriography was a cost-effective strategy for the treatment of
patients with penetrating extremity trauma near major arteries, given an incremental cost-effectiveness ratio lower than
a common cut-off value of $50,000. The authors stated that the prevalence of injury had to be greater than 1.0%.
CRD COMMENTARY - Selection of comparators
The reason for the selection of the comparator was clear. The procedure based on observation for 24 hours and discharge was selected because it represented the basic intervention for the patients. Therefore, proximity arteriography appeared to be a "further step", whose impact was under investigation. You should consider whether the observation and discharge strategy represents a commonly used procedure in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence was derived from studies published in the literature, but the authors did not state that a systematic review of the literature had been undertaken. The methodology and conduct of the review were not reported satisfactorily. In particular, search modalities were not indicated, and the methods used to select and assess the quality of the studies were not described. In addition, when average estimates were obtained from the primary studies, the weighting scheme to reflect differences in, for example, sample sizes of the primary studies, was not reported. Finally, the authors' experience with a sample of 147 patients, partially supported by the literature, was used to select a base prevalence rate, which became one of the most crucial variables in the model.

Validity of estimate of measure of benefit
QALYs were used as the benefit measure in the economic analysis. However, the source of the utility values was unclear, for example, patients suffering from the same disease, physicians, experts' panel, and the general public. In addition, the total number of QALYs determined by each intervention was not indicated.

Validity of estimate of costs
The perspective of the taxpayer adopted in the study also permitted the inclusion of indirect and intangible costs. Hence, this almost approximated to a societal perspective, which best reflects the amount of resources consumed. This could have been used for alternative interventions, although no account of productivity loss was taken. The estimation of the costs was quite specific to the authors' institution, although numerous sensitivity analyses (including threshold analyses) were conducted. Also, the resource quantities and the unit costs were given.

Other issues
The issue of the generalisability of the study to other settings was not explicitly addressed. However, sensitivity analyses were conducted on the major variables in the model. The authors made several comparisons of their findings with those from other studies. The authors' conclusions, as reported in the paper's summary, were misleading, stating that the intervention was cost-effective as long as the prevalence was greater than 1.0%. In fact, as the sensitivity analysis demonstrated, this would only be the case if extreme values of low arteriography complication rate and high amputation disutility were assumed. In fact, this complication rate lay outside the range that the authors stated was used for the one-way analysis.

Implications of the study
The authors recommended the adoption or maintenance of proximity arteriography, a cost-effective diagnostic procedure, at trauma centres. This recommendation should be treated with caution, given the misleading claim relating to the threshold analysis and the authors' evidence concerning the likelihood of the prevalence of injury being sufficiently low to make arteriography not cost-effective, or even dominated by the observation strategy.

Source of funding
None stated.

Bibliographic details
PubMedID
11435537

Indexing Status
Subject indexing assigned by NLM

MeSH
Angiography /economics; Cost-Benefit Analysis; Decision Support Techniques; Extremities /injuries; Humans; Retrospective Studies; Sensitivity and Specificity; Wounds, Penetrating /economics /radiography

AccessionNumber
22001001403

Date bibliographic record published
31/07/2002

Date abstract record published
31/07/2002