Randomized comparison of rapid ambulation using radial, 4 French femoral access, or femoral access with AngioSeal closure

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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 study compared cardiac catheterisation techniques in rapid ambulation of patients. The techniques compared were femoral 6 Fr access with AngioSeal closure device (F+C), femoral 4 Fr access without a closure device (4 Fr alone) and radial access. It was assumed that the length of time to ambulation was the same for all techniques and was one hour.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients referred for cardiac catheterisation who were older than 18 years, and who had clear femoral and radial pulses and normal Allen's test. Patients with vascular disease of the upper or lower limbs that blocked the femoral or radial artery were excluded from the study, as were patients who had undertaken a femoral arterial graft surgery in the past. Also excluded were patients who had unsteady coronary syndromes, those with myocardial infarction who needed an intervention within 7 days, and those with further medical interventions scheduled at the same setting or during hospitalisation. Patients who did not provide informed consent were also not included in the study.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were collected between February 1999 and November 2001. The dates to which the cost data related were not reported. The price year was also not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Based on another published study, the sample size was determined using an effect size of 1.0 in back pain on the visual
analogue scale. According to power calculations performed with nQuery Advisor 4.0 software (Statistical Solutions, Saugus) a sample size of 25 patients in each group was adequate to reach a power of greater than 80%. It was reported that all of the patients who were referred for diagnostic cardiac catheterisation in the authors' setting, were screened for inclusion in the study. Further details of the sample selection method were not reported. Overall, 75 patients were recruited for the study and 25 patients were assigned to each of the three groups.

**Study design**
The analysis was based on a prospective single-centred randomised trial. The method of randomisation was not described. The patients were followed up at day 1 and 1 week after the procedure. Although 2 patients at day 1 and 5 patients at 1 week failed to provide complete data at the follow-up visits, no reasons for loss to follow-up were reported.

**Analysis of effectiveness**
The analysis was conducted on an intention to treat basis. The primary health outcomes used in the analysis were:

- the number of right heart catheterisations and percutaneous coronary interventions (PCIs) performed in each group;
- the success rate of each procedure;
- the duration of sheath insertion;
- the duration of catheterisation;
- haemostasis and fluoroscopy time;
- contrast usage (measured in mL); and
- the length of hospitalisation.

Postprocedural complications were also evaluated. The patients were shown to be comparable in terms of the baseline characteristics. Patients' values for QOL were evaluated using the Medical Outcomes Study Short Form 36-item health questionnaire (acute SF-36) and a self-administered questionnaire concerning the specific procedure.

Continuous variables were analysed using analysis of variance (ANOVA) and unpaired t-tests, while the Kruskal-Wallis statistic was used for non-normal variables (e.g. length of stay). The chi-squared test was used for categorical variables. A p-value less than or equal to 0.05 was considered to be statistically significant.

**Effectiveness results**
QOL, as evaluated by the self-administered questionnaire and the SF-36 item, did not differ in the three groups at day 1 and 1 week after the procedure.

The number of right heart catheterisations and PCIs performed did not vary between the groups.

The success rates of the procedures did not differ significantly.

Sheath insertion time was longer in the radial group (7.2 +/- 8.2 minutes) than the F+C group (3.0 +/- 1.7 minutes) and the 4 Fr group (3.6 +/- 3.0 minutes). The difference was statistically significant, (p<0.05).

The duration of catheterisation, fluoroscopy time, quantity of contrast used and duration of hospitalisation did not differ significantly between the groups.

Time until haemostasis was longer in the 4 Fr group (16.1 +/- 11.6 minutes) than in the F+C group (8.2 +/- 16.7 minutes) and the radial group (4.7 +/- 4.0 minutes). The difference was statistically significant, (p<0.01).
At day 1, 9 cases of haematomas occurred in each of the F+C and 4 Fr groups while none occurred in the radial group. The difference was statistically significant, (p<0.01).

One patient from the F+C group and one from the 4 Fr group were submitted for coronary artery bypass graft surgery.

**Clinical conclusions**
The authors concluded that all three procedures were equally effective in achieving 1-hour ambulation after cardiac catheterisation in terms of safety of the procedure and post-intervention clinical outcomes.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was used. In effect, a cost-consequences analysis was conducted.

**Direct costs**
Health care provider (hospital) costs were used in the economic analysis. Specifically, the analysis included drugs costs and costs of equipment used for cardiac catheterisation. Physician costs and hospital bed costs were omitted from the analysis since they were common to all three groups. The costs and the quantities were not analysed separately and the unit costs were not reported. The costs were derived from actual data while the quantities were obtained from the effectiveness analysis. Discounting was not relevant since all of the costs were incurred during less than 2 years. The price year was not reported.

**Statistical analysis of costs**
The Kruskal-Wallis statistic was used in the analysis of the costs. The median and interquartile range were reported.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The median total costs (equipment and supplies used) were reported per patient. These were $277.1 (range: 277.1 - 286.4) in the F+C group, $82.1 (range: 82.1 - 85.7) in the Fr 4 group and 85.7 (range: 85.7 - 90.6) in the radial group. The differences were found to be statistically significant, (p<0.0001).

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors’ conclusions**
Although femoral access with AngioSeal closure exhibits higher angiographic quality than Fr 4, it is a rather costly procedure. On the other hand radial access, although inexpensive and of high angiographic quality, depends heavily on the physician's experience and on the patient's anatomy.

**CRD COMMENTARY - Selection of comparators**
The authors justified their choice of the comparators used. You should decide if these represent widely used technologies in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a prospective randomised trial, which was appropriate given the study question. The study sample was representative of the study population and the patient groups were shown to be comparable at analysis. However, the method of randomisation was not reported. An appropriate statistical analysis was undertaken. Power calculations were reported and these confirmed that the sample size used was appropriate.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The perspective adopted in the economic analysis, although not explicitly stated, appears to have been that of the hospital. Given this assumption most, if not all, of the relevant costs were considered in the analysis. Some costs were omitted from the analysis as, according to the authors, they were common to all three procedures. The quantities used were derived from the effectiveness study and an appropriate statistical analysis was undertaken. The unit costs, resource quantities and the price year were not reported. This means that the analysis cannot be easily reworked for other settings.

**Other issues**
The authors compared their findings with those of published studies. They appropriately justified differences relating to QOL, but found consistency in other findings. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively. The study enrolled adult patients referred for cardiac catheterisation and this was reflected in the authors' conclusions. The authors acknowledged, as a limitation of the study, that the narrow sample size was inadequate to evaluate rates of vascular complications after the implementation of the procedures.

**Implications of the study**
The authors did not make any explicit recommendations for policy or practice changes, nor did they make any recommendations for further research.

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None stated.

**Bibliographic details**

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