Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison

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
Transradial catheterisation (TRC) (catheterisation through the radial artery) for diagnostic cardiac catheterisation.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Stable patients with palpable femoral and radial pulses and a normal Allen's test, who were not expected to require other procedures during follow-up. The exclusion criteria were as follows: known or suspected vascular disease precluding access, unstable coronary symptoms, need for additional procedures during the same hospitalisation, or being unable or unwilling to give informed consent.

Setting
Hospital. The economic study was carried out in Ohio, USA.

Dates to which data relate
Effectiveness and resource use data corresponded to ICU patients screened for participation between 4 March 1996 and 6 February 1997. The price year was not explicitly stated.

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

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

Study sample
Power calculations were used to determine the sample size, based on a hypothesised absolute difference in bodily pain, measured with the SF-36, of 10 points, an alpha of 0.05, a 2-tailed comparison, and a power of 80%. 89 patients were required in each group. 896 of the 993 patients screened for participation had normal Allen's test. 503 of these patients were excluded, leaving 393 patients eligible for inclusion in the study. Of these patients 193 refused to participate. The final 200 patients were randomised to either the TRC group (n=101) with a mean (SD) age of 60(1) years or to the TFC group (n=99) with a mean (SD) age of 60(1) years.
**Study design**
This was a randomised controlled trial, carried out at a single site. The duration of the follow-up was 7 days after catheterisation. The study had no loss to follow-up. Randomisation was performed by coin toss. The performing physicians had to have carried out a minimum of 50 transradial catheterisations and were required to have extensive experience with transfemoral procedures. Judkin’s catheters were used for coronary angiography through 5F or 6F arterial sheaths in both groups.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was intention to treat. The main health outcomes were procedural outcomes (the number of successfully performed procedures; major vascular complications defined as pseudoaneurysm formation, blood transfusion, or limb ischemia resulting in the need for vascular surgery; total procedure time, fluoroscopy time, contrast volume, and length of hospital stay); quality of life as measured by the Medical Outcomes Study Form 36-item health status questionnaire (acute SF-36), and a series of procedure-specific questions (0 to 10 visual analog scales assessing overall discomfort, back pain, ability to use the bathroom, ability to feed or care for oneself, and walking); and patient preference. The measurement times were before catheterisation, then at 1 day and at 1 week thereafter. A further assessment of preference was made on 44 patients who underwent types of procedure. The questionnaires were self-administered. The patient groups were found to be well matched in terms of baseline characteristics. Patients in the TRC group had somewhat higher baseline SF-36 scores for mental health, role limitations as the result of emotional problems, and social function; the study groups were not significantly different in terms of other measures of quality of life at baseline.

**Effectiveness results**
The number of successful procedures was 98 in the TFC group and 99 in the TRC group; one patient in the TFC group and 2 in the TRC group crossed over to the alternative access sites. One patient in the TFC group had a minor stroke. No other major significant complications were observed.

The mean (SD) total procedure time was 47.6 (2.7) minutes in the TFC group versus 31.4 (1.70) minutes in the TRC group, (p<0.001).

No differences were found between the study groups in terms of fluoroscopy time or contrast volume.

The TFC group had a median length of stay of 10.4 hours versus 3.6 for the TRC group, (p<0.001).

The TRC group had better outcomes over the first day after the procedure in terms of measures of bodily pain, back pain, and walking ability (p<0.05 for all comparisons).

Over the week after the procedure, the same group had better results with respect to changes in role limitations caused by physical health, bodily pain, and back pain (p<0.05 for all comparisons).

As assessed at both 1 day and 1 week after the procedure, the majority of patients (p<0.0001) preferred the transradial method. The majority (80%) of the 44 patients who underwent both methods, strongly preferred the transradial method, 7% moderately preferred it, with only 2% (1 patients) favouring the transfemoral method.

**Clinical conclusions**
The current study demonstrates that transradial catheterisation can be performed with equal safety and procedural success as compared with the traditional transfemoral approach. Furthermore, it was associated with improved indices of quality of life after the procedure, and was strongly preferred by patients.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were
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 reported separately. Cost analysis covered bed costs inclusive of nursing utilisation, catheterisation laboratory costs, pharmacy costs, and all other costs. The perspective adopted in the cost analysis appears to have been that of the hospital. A hospital cost accounting system, calculating fixed and variable hospital costs on a per-patient basis, was used to calculate costs. Average daily cost was used to compute bed costs for outpatients. The price year was not explicitly specified. The costs associated with physician fees were not included in the cost analysis since they were deemed common to both alternatives.

Statistical analysis of costs
The statistical analysis performed on costs appears to have been based on the Mann-Whitney U test.

Indirect Costs
Not included.

Currency
US dollars ($).

Sensitivity analysis
Not conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The TRC group had a median (interquartile) cost of $2,010 (range: $1,758 - $2,669) versus $2,299 (range: $1,992 - $3,214; p<0.0001); bed and pharmacy costs were significantly lower with TRC.

Synthesis of costs and benefits
Costs and benefits were not combined since the use of TRC was the dominant strategy.

Authors' conclusions
The authors conclude that for patients undergoing diagnostic cardiac catheterisation, transradial access leads to improved quality of life after the procedure, is strongly preferred by patients, and reduces hospital costs.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (the strategy of performing TFC). It was the traditional method used in the context in question. 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
Although, as the authors state, patients could not be blinded to the method of catheterisation potentially affecting the
response to the quality-of-life measures, the effectiveness results are likely to be internally valid in view of the randomised design of the study and the power calculations performed. With the exception of the fact that the TRC group had somewhat higher baseline SF-36 scores for mental health, the study groups were found to be comparable in terms of baseline characteristics, most baseline quality-of-life measures, role limitations as the result of emotional problems, and social function. The patient sample (stable patients undergoing diagnostic catheterisation) appears to be representative of the study population.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit and the economic analysis may therefore be regarded as being of cost-consequences design.

**Validity of estimate of costs**
Some quantities were reported separately from the costs. Adequate details of methods of cost estimation were given. It appears that exclusion of physician fees does not affect the internal validity of the cost analysis. Statistical analysis was performed on some components of the resource use data and cost data. The price year was not specified. The effects of different procedures on indirect costs were not discussed; although it could be argued that, since the study sample had a mean age of 60 years, the relevance of indirect costs (lost productivity) may be open to question. The use of average costs from a hospital microaccounting system instead of true variable costs was stated to be one of the limitations of the cost analysis. The cost results may not be generalisable to other settings or countries.

**Other issues**
The authors' conclusion appears to be justified given uncertainties in the data. The issue of generalisability to other settings or countries was not directly addressed, although appropriate comparisons were made with other studies. The study sample consisted of stable patients undergoing diagnostic catheterisation and the authors' general comments appear to reflect this.

**Implications of the study**
Although the widespread use of transradial catheterisation would require some retraining on the part of invasive cardiologists, the findings of the study suggest that such an investment may be worthwhile given the substantial reductions in morbidity and cost that are possible.

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**Other publications of related interest**

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