Coronary angiography through the radial or the femoral approach: the CARAFE study
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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 health interventions examined in the study were transradial versus transfemoral approaches for coronary angiography. The transfemoral procedure was performed in accordance with the Seldinger technique with a 5 Fr introducer, a 0.035 inch wire, 1.45m in length, and left and right Judkins catheters without heparin. Left and right transradial procedures were performed with radial artery puncture with a short bare 19-gauge needle into which a straight 0.025 inch Teflon-coated 1.5-m long wire was inserted and a 5 Fr tapering introducer was then placed on the 0.025 inch wire after skin incision. All approaches were performed with analgesia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing coronary angiography with a normal Allen test. Patients were excluded for clinical conditions (acute myocardial infarction), angiographic characteristics (previous bypass grafting), or technical conditions (known difficulty with the femoral approach, right heart catheterisation, simultaneous renal or aortic angiography, and absence of indication for ventricular angiogram).

Setting
The setting was a hospital. The economic study was carried out in France.

Dates to which data relate
Randomisation took place between November 1998 and April 1999 and data on both effectiveness and resource use were likely to have been collected over that six-month period, although the date of collection was not reported. No price year was reported.

Source of effectiveness data
The effectiveness evidence came from a single study.

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

Study sample
No power calculations were reported and no evidence was provided that the initial study sample was appropriate for the
clinical study question. The method of sample selection was not reported. A total of 442 coronary angiograms were performed over the study period. A number were excluded from the study population as described above. A number of eligible patients declined to participate. Thus the final study sample comprised 210 patients, who were allocated to three study groups:

70 patients with a mean age of 64.5 (+/- 13.1) years (77.1% men; 44.3% with hypertension) in the femoral group,

70 patients with a mean age of 60.9 (+/- 11.2) years (78.6% men; 47.1% with hypertension) in the right radial group, and

70 patients with a mean age of 61.4 (+/- 11.2) years (77.1% men; 42.9% with hypertension) in the left radial group.

Study design
This was a randomised controlled trial. The method of randomisation was not stated, but the authors reported that randomisation was performed taking into consideration the learning curve of two operators with experience. One operator with experience in the left radial approach (more than 1,000 procedures) randomised patients into left radial approach and femoral approach, while the second operator with experience in the right radial approach (more than 1,800 procedures) randomised patients into right radial and femoral approach. This was done at a ratio of 2:1 for the radial group versus the femoral group so that each group ended up with 70 patients. The number of centres where the study took place was not reported. Patients were followed-up until discharge from hospital and it appears that there was no loss to follow-up. No blinding was used for outcome assessment.

Analysis of effectiveness
The basis of the clinical analysis appears to have been intention to treat as all patients included in the final sample were taken into account in the effectiveness study.

The major health outcomes used in the analysis were:

- angiographic quality data (assessed on a scale of one to five by an interventional cardiologist not involved in the study);
- procedure duration;
- X-ray time;
- number of digital acquisitions;
- bed confinement (hours);
- time to discharge;

and patient comfort (estimated on a scale ranging from 0 to 5 prior hospital discharge).

Patients who had already undergone an angiogram were also asked their preferred approach. Other outcomes included a number of procedural success measures including failures, complications failures and selective catheterization. The authors stated that study groups were generally comparable at baseline in terms of demographic characteristics and indications for coronary angiography.

Effectiveness results
Vascular complications were observed in the following percentages of patients: femoral 5.9%, right radial 2.8%, and left radial 1.4%.

Left coronary angiographic quality was as follows: femoral 4.4 (+/- 0.7), right radial 3.9 (+/- 0.8), and left radial 4.3 (+/- 0.8), (the difference was statistically significant);
Right coronary angiographic quality was as follows: femoral 4.7 (+/- 0.6), right radial 4.7 (+/- 0.6), and left radial 4.8 (+/- 0.5); Procedure duration was: femoral 11.2 (+/- 3.3) minutes, right radial 12.4 (+/- 5.8) minutes, and left radial 14.2 (+/- 3.3) minutes, (statistically significant); X-ray time was: femoral 3.1 (+/- 1.7) minutes, right radial 3.8 (+/- 2.2) minutes, and left radial 4.2 (+/- 1.7) minutes, (statistically significant); The number of digital acquisitions was: femoral 12.1 (+/- 2.1), right radial 13.2 (+/- 2.3), and left radial 11.2 (+/- 1.6), (statistically significant); Bed confinement was: 9.9 (+/- 11.1) hours in the femoral group and 4.9 (+/- 3.9) hours in the radial groups, (statistically significant); Time to discharge was 42 (+/- 44.8) hours in the femoral group and 31.4 (+/- 22.5) hours in the radial groups, (statistically significant). There was one failure in the right radial group with subsequent cross-over in the left radial group.

Patient comfort was higher in the transradial groups (4.3 +/- 0.7) than in the femoral group (4.1 +/- 0.7) and the difference reached the threshold of statistical significance, (p=0.05).

Of the 51 patients who had already undergone an angiogram, 58% preferred the radial approach, 21% preferred the femoral approach, and 21% had no preference.

Clinical conclusions
The effectiveness study showed that the transradial approach was safe, successful, of high-quality, and associated with a low complication rate in comparison with the femoral procedure. Patient satisfaction with the transradial approach was high.

Measure of benefits used in the economic analysis
Health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis, thus the study was categorised as a cost-consequences analysis.

Direct costs
No discounting was performed due to the very short time horizon of the analysis. Unit costs were not reported separately from quantities of resources. The health services costs included in the economic evaluation were those for disposable equipment, medication (all drugs except anaesthetics, and contrast media), hospitalisation, medical fees (anaesthetist, operator, and clinical cardiologist), additional diagnostic tools (Doppler), monitoring (blood count), and treatment of vascular or coronary complications. The cost/resource boundary adopted was not stated, but it could have been that of the hospital. It was not clear whether charges or costs were used. The estimation of resource consumption was conducted alongside the clinical trial. The source of cost data was not reported, but it is likely to have been based on actual hospital data as some costs, such as hospitalisation, were derived from hospital invoices. No price year was reported.

Statistical analysis of costs
Costs were reported as means and standard deviations and standard statistical analyses were performed to test for statistical significance of estimated total costs.

Indirect Costs
Indirect costs were not included.

Currency
French francs (Ffr).

Sensitivity analysis
No sensitivity analyses were performed.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported above.

Cost results
Overall costs were Ffr 5,213 (+/- 2,672) in the femoral group, Ffr 4,745 (+/- 1,332) in the right radial group and Ffr 4,508 (+/- 991) in the left radial group. There was no statistically significant difference between total costs in the femoral and right radial groups, while total costs in the left radial group were significantly lower than in the femoral group. As regards cost components, hospitalisation costs and medical fees were significantly lower in the left radial group compared to the femoral group, while medication costs in both the right and left radial groups were higher than in the femoral group.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
The authors concluded that the transradial approach proved to be as safe as the standard femoral procedure for coronary angiography, but was associated with lower costs and earlier discharge and was preferred by the majority of patients. However, the success of the intervention was strictly related to the level of the operator's experience.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The authors stated that the transradial approach represented an alternative to the standard femoral approach used to perform coronary angiography. You, as a user of this database, should decide whether they represent widely used health interventions in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on a randomised controlled trial, which was appropriate for the study question. Details on the randomisation process were not reported, but the authors stated that operator experience was considered when randomly allocating the patients to the three study groups. It was not clear whether this procedure may have introduced some bias into initial concealment. The authors claimed that the results did represent differences in interventions rather than the operators' experience as the only significant difference in the femoral patients between the operators was the number of digital acquisitions. The number of sites where the study took place was not stated, but it was likely to have been only one hospital.

Despite the high initial refusal rate (26.5%), the authors stated that the characteristics of those who were excluded from the initial study sample were not statistically different from the characteristics of those who were considered in the effectiveness analysis. Thus the authors considered the study sample to be representative of the overall study population of patients undergoing coronary angiography at the authors' institution. Study groups were shown to have been comparable at baseline, thus further enhancing the internal validity of the analysis. No blinded assessment was performed, but an independent assessor was employed when measuring some of the study outcomes. Power calculations
were not performed to determine the appropriate sample size for the study question.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study (see validity of effectiveness comments above).

**Validity of estimate of costs**
The perspective adopted was not stated, but it could have been that of the hospital. Thus it was not possible to assess whether all relevant categories of costs were included in the economic evaluation. The authors commented that the costs of anaesthetists and analgesics drugs, invoiced costs of X-ray equipment, and nursing staff were not included in the analysis and the potential impact of their exclusion on the total costs of the two procedures was not clear. Indirect costs were not included. Discounting was not relevant and, appropriately, was not performed. No price year was reported, thus making reflation exercises in other settings difficult. Similarly, unit costs were not reported separately from quantities of resources used. It was not clear whether charges or true costs were used. A detailed breakdown of costs was not provided. Such issues may limit the internal validity of the economic analysis. Costs were treated deterministically.

**Other issues**
The authors did not explicitly compare their findings with those from previously published studies, but stated that their findings, both on the effectiveness and the economic sides, were similar to the results of other studies. The authors did not address the issue of the generalisability of the study findings to other settings and did not perform sensitivity analyses, thus the external validity of the analysis was low.

**Implications of the study**
The main implication of the study is that the transradial procedure for coronary angiography may be safely and efficiently performed. However, caution is required when interpreting such conclusion, due to the limitations of the analysis described above.

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None given.

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