Initial experience with reuse of coronary angioplasty catheters in the USA

Browne K F, Maldonado R, Telatnik M, Vlietstra R E, Brenner A S

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 reuse of percutaneous transluminal coronary angioplasty (PTCA) balloon catheters in patients with coronary artery disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with coronary artery disease undergoing PTCA.

Setting
Hospital setting. This study was carried out at the Watson Clinic, Lakeland, Florida, USA.

Dates to which data relate
Not stated. The study was published in 1997.

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

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

Study sample
All patients scheduled for coronary angioplasty were considered for enrolment in this trial, including patients experiencing acute myocardial infarction. 107 patients underwent PTCA using restored catheters and 108 received new catheters. The study was designed to have an 80% probability of detecting a 5% difference in the failure rates of new and reused balloons (i.e. alpha 0.05, delta 0.05, beta 0.20).

Study design
This was a retrospective cohort study carried out at a single centre. All patients were followed until hospital discharge. No long-term follow-up was performed.
Analysis of effectiveness
The analysis of the clinical study was based on treatment completers. The primary health outcomes used included lesion outcomes, procedure time, fluoroscopy time, dye volume, and number of balloons/lesion. The age of patients in the experimental group was 64 (+/- 12) years and 56% were male. The indication for PTCA in the experimental group was stable coronary insufficiency in 69, unstable angina in 22 and acute MI in 16. Between the two groups, there was no significant difference in frequency of fever (11 versus 12) or WBC (12 versus 14).

Effectiveness results
For the experimental group, 108 of 110 lesions approached were crossed and dilated. 64 lesions required no further procedures. 29 patients had planned stenting and 8 required bailout stenting. In two lesions, a restored balloon catheter initially failed to cross a stenosis. This represented 2% of restored catheters used as initial devices. In 12 lesions, restored catheters were used after a new device. The mean procedure time was 67 (+/- 30) minutes compared with 83 (+/- 49) minutes in the comparison group. The mean fluoroscopy time for the procedures was 13 (+/- 10) minutes compared with 18 (+/- 15) minutes in the comparison group. The mean dye volume was 275 (+/- 125) ml compared with 307 (+/- 157) ml in the comparison group. An average of 1.5 (+/- 0.7) balloons/lesion was used in the study, compared with 1.6 (+/- 0.6) balloons/lesion in the comparison group.

Clinical conclusions
When restoration is performed in a very high quality fashion, performance of restored balloon angioplasty catheters can be expected to be similar to that of new devices.

Modelling
No modelling was undertaken.

Measure of benefits used in the economic analysis
The primary measure of benefit used was the rate of angiographic failure.

Direct costs
Discounting was not applicable. Quantities and costs were not reported separately. Direct costs consisted of the acquisition costs of catheters. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. The source of cost data and the price year were not reported.

Statistical analysis of costs
No statistical analysis of costs was undertaken.

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.
Estimated benefits used in the economic analysis
The angiographic failure rate was 7% for reused catheters (10 of 108, 95% CI: 2% - 12%), comparable with the 10% failure rate seen with new balloons in other studies.

Cost results
It was expected that reusing catheters would permit the institution to save 40% of the original invoice costs of the product to the hospital. Reusing 1,000 catheters with savings of $160 each, would thereby save the hospital laboratory $160,000.

Synthesis of costs and benefits
Costs and benefits were not combined into a cost-effectiveness ratio.

Authors’ conclusions
Restoration of disposable coronary angioplasty catheters using a highly controlled process appears to be safe and effective, with success rates similar to those of new products and no detectable sacrifice in performance. Hence, the reuse of disposable equipment may offer cost savings to US hospitals, without sacrifice of quality.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear.

Validity of estimate of measure of benefit
The measure of benefit would appear to be valid. However, the angiographic failure rate was not reported for the control group. The effect of reusing catheters on long-term outcomes was not assessed. The authors did not distinguish between restored catheters used after a new device and restored catheters used as an initial device. It is unclear if and how this would affect the results.

Validity of estimate of costs
A more extensive costing could have been undertaken. Cost consequences of differences in procedure time, fluoroscopy time and dye volume between the two groups were not assessed. No statistical analysis or sensitivity analysis was undertaken.

Other issues
The results are likely to depend on the restoration process used and the number of times catheters are restored, but neither of these factors were assessed in the study. Not all balloon sizes, lengths and catheter types were studied. Hence, it is difficult to assess the generalisability of the results to other settings or countries.

Implications of the study
A larger trial should evaluate, in a double-blinded, randomised manner, new versus restored angioplasty catheters in a multi-institution format. This trial should take into account the characteristics of the restoration process.

Source of funding
None stated.

Bibliographic details
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Other publications of related interest


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MeSH
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