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
A 'one balloon - one stent' strategy for elective, single vessel stent deployment.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing an elective, single-vessel coronary stent procedure. Seventy-five percent of patients were male and their average age was 60 years.

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

Dates to which data relate
The effectiveness and resource use data were collected during 1994-1995 (August 1994-April 1995, for the comparator, and April-September 1995 for the intervention). The price year was not clearly stated.

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

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

Study sample
Eighty-four patients were included in the study. Of these, 41 patients (74% male) underwent treatment by conventional means (CONV), whilst another 43 patients (76% male) subsequently underwent elective coronary stenting using a 'one balloon - one stent' approach (NEW). Power calculations to determine the sample size were not reported.

Study design
This was a single-centre, non-randomized study with historical controls. The duration of follow-up was 1 month. The loss to follow-up was not stated.
Analysis of effectiveness
The analysis of effectiveness is likely to have been based on treatment completers only. The primary health outcomes were procedural success rates, vascular events at follow-up, and balloon use. Groups were shown to be comparable in terms of patient/angiographic lesion characteristics.

Effectiveness results
The number of lesions stented was estimated to be 53 in the CONV group and 54 in the NEW group. The pre and poststent diameter were estimated to be 1.2 (+/- 0.4) and 3.4 (+/- 0.5) in the CONV group and 1.3 (+/- 0.2) and 3.3 (+/- 0.5) in the NEW group. The average numbers of balloon catheters were estimated to be 2.1 (+/- 1.1) in the CONV group and 1.3 (+/- 0.5) in the NEW group, (p<0.01). The procedural success rate was 100% in both groups, and no patient sustained subacute stent thrombosis or required target vessel revascularization during the follow-up period.

Measure of benefits used in the economic analysis
Since the strategies were shown to be comparable in terms of their clinical benefits, the economic analysis was based on the difference in costs only.

Direct costs
Quantities of resource use were analysed separately from the costs of device use. The quantity/cost boundary adopted was the hospital. The price date was not reported, although the authors stated that “individual component costs were calculated from direct acquisition costs during the study period (1994-95)”. The authors noted that a uniform price per balloon for both groups was used so as to adjust for the higher costs of perfusion balloons used for predilatation in the conventional strategy group of the clinical study. Contrast volume was omitted from the analysis because of the heterogeneous reporting methods in the clinical study.

Statistical analysis of costs
A Student t test was used in order to compare total costs between groups.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The total costs (minus stent) were estimated to be $1.093 (+/- 467) and $747 (+/- 401) in the CONV and NEW group, respectively (p<0.01). The total costs (plus stent) were estimated to be $3.955 (+/- 2.088) in the CONV group and $3.241 (+/- 1.110) in the NEW group, (p>0.05).

Synthesis of costs and benefits
Synthesis was not applicable as the principal benefit was reduction in costs.

Authors' conclusions
The use of a single Titan balloon catheter as part of an integrated cost-containment strategy for both lesion predilatation and poststent deployment, results in considerable cost savings when compared to a conventional strategy using nonintegrated components, while maintaining high procedural and clinical success rates.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparators is clear. The integrated system of catheter for both lesion predilatation and poststent deployment was considered as a means of reducing the costs associated with stenting in comparison with angioplasty (50-100% more costly as reported by the authors and other sources cited by them).

**Validity of estimate of measure of benefit**
As reported by the authors, the study is subject to limitations arising from its retrospective design, its single centre nature (which resulted in a small sample size), and the fact that a single cardiologist provided the majority of patients for the 'one balloon - one stent' group (from a total of three cardiologists). The validity of the study results, therefore, may require further confirmation by an experimental study such as an RCT.

**Validity of estimate of costs**
Adequate details of the methods of cost estimation were given. Important cost items were nevertheless omitted (the study did not attempt to address the total cost of revascularization). The price date was not clearly stated.

**Other issues**
The authors' conclusions are likely to be justified, given the uncertainties in the data. Due to the single-centre nature of the study, different cost results may be observed in other areas or institutions even within the US. The authors also remarked on the fact that comparisons with other clinical situations could not be made, given that the study enrolled only patients undergoing elective stenting. The results were not presented selectively.

**Implications of the study**
Prospective studies with concurrent controls are needed in order to validate the study results reviewed here in relation to a cost-containment strategy aimed at reducing direct stent procedure-related costs while maintaining quality of care.

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