The costs and quality-of-life outcomes of drug-eluting coronary stents: a systematic review

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**CRD summary**
This review assessed differences in quality-of-life (QoL) measures between people who had, or did not have revascularisation procedures following coronary stenting. The authors concluded that there was a QoL benefit in avoiding revascularisation, but also recommended further research. However, since relevant studies might have been missed and it is difficult to assess the reliability of the results, caution is advised.

**Authors' objectives**
To assess the quality-of-life (QoL) effects of reducing restenosis and target vessel revascularisation as part of a review assessing the costs of drug-eluting stents (DES).

**Searching**
MEDLINE, ISI Web of Science and the Cochrane Library were searched from 1995 to 2006; the search terms were given. The search was limited to papers reported in English and to papers where abstracts were available within the database. The reference lists of identified articles were checked. Grey literature, non peer-reviewed studies, and those that only appeared in meeting abstracts were excluded.

**Study selection**

**Study designs of evaluations included in the review**
No inclusion criteria were given in relation to the study design.

**Specific interventions included in the review**
Studies assessing the effects of reducing restenosis following percutaneous coronary intervention (PCI) with DES or bare metal stents (BMS) were eligible for inclusion.

**Participants included in the review**
Studies of people undergoing coronary artery stenting were eligible for inclusion. No other details were given.

**Outcomes assessed in the review**
Studies that included QoL differences between people who did, or did not, experience restenosis and target vessel revascularisation (TVR) were eligible for inclusion. The QoL instruments in the included studies were the Seattle Angina Questionnaire (SAQ), the EuroQol-5D (quality-adjusted life-years, QALYs), the Hospital Anxiety and Depression Scale, the Impact of Event Scale, and the Medical Outcomes Study/Short Form-36. In addition, one study assessed the participants' willingness-to-pay to reduce the risk of TVR. Follow-up ranged from during initial hospitalisation, to 12 months post-PCI.

**How were decisions on the relevance of primary studies made?**
Two reviewers independently assessed studies for inclusion.

**Assessment of study quality**
Two reviewers independently assessed validity. Any differences were resolved through discussion. Final quality scores were calculated by averaging the scores of the individual reviewers. The scores were based on the internal validity of the study (study design, including use of validated QoL instruments), appropriateness and completeness of follow-up, statistical analyses and external validity (generalisability). The scoring ranged from 1 to 5, with 5 representing the highest quality.
Data extraction
Two reviewers independently extracted the data and conferred in order to reconcile any differences. The data extracted included methods of assessing QoL and measure of statistical significance. QoL scores and percentage values appear to have been extracted as reported in the original studies.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative discussion and in tabular format.

How were differences between studies investigated?
Differences between the studies were discussed within the narrative.

Results of the review
Eight studies (6,158 participants) were included. These included cohorts of people from five randomised controlled trials (RCTs), one registry and two single-centre studies.

Average quality scores were 3 or above. The studies were too heterogeneous for formal meta-analyses.

In all studies, those people who developed restenosis and needed TVR had measurably significant QoL losses.

In three studies, those with clinically driven TVR had worse angina frequency and QoL subscale scores measured on the SAQ at 6 months after initial PCI (range of decrease: 4 to 12 points on a 100-point scale). One study found these differences to be resolved at 12 months, but a second found consistent differences between those who did or did not receive TVR.

Cost information
In one study lower QALYs were measured in those undergoing TVR (0.86 versus 0.80 QALYs, p=0.003). Another study indicated that QALYs averaged 0.08 higher in non-TVR people. This difference persisted across age and diabetes status strata.

One study that assessed acceptance of a dollar cost, by participants, found that the median acceptable prices were $363 for a 10% reduction in restenosis risk, $486 for a 20% reduction and $1,544 for a 30% reduction. There was unexplained heterogeneity in price response, and higher income predicted a greater willingness-to-pay.

Four randomised controlled trials assessed costs. DES had higher initial costs than BMS, with total initial hospitalisation costs ranging from $1,600 to $3,200. However, because of higher revascularisation procedures, the follow-up costs were higher in the first year with BMS than with DES. There was disagreement in such costs between the studies: $1,437 to $2,886 higher with BMS, although an additional study found higher costs of $408 at the 6-month follow-up.

Authors' conclusions
There is agreement on the QoL benefits of avoiding revascularisation; the average QALY benefit of an avoided revascularisation is 0.04 to 0.08.

CRD commentary
The aims of this review were only partially stated in that no criteria were given for the study design. The review aimed, first, to assess the costs and cost-effectiveness of DES; and second, to evaluate the QoL effects of lower revascularisation and restenosis rates as a result of DES. The search was limited by language and type of publication, and it is therefore likely that studies were missed. This could result in publication and/or language bias. The methods of the review were appropriate for minimising the introduction of bias, and quality was assessed. However, little information was given about the included studies and their participants, and this could affect the generalisability of the
review.

The decision to combine the results in a narrative review seemed appropriate given the differences between the studies. The studies included a variety of patients, outcome measures and study designs, and none of the studies were rated as being of a high quality; the reliability of the results is therefore unclear. Although the authors' conclusions appear to be supported by the data presented, they should be interpreted with caution given the aforementioned concerns.

**Implications of the review for practice and research**

*Practice:* The authors did not state any implications for practice.

*Research:* The authors stated that more research is needed into the QoL effects of restenosis in people with DES, including longer term assessment. This should include assessments of direct QoL effects of restenosis as compared with concomitant disease (e.g. diabetes or complex coronary lesions).

**Funding**

Health Technology Studies (InHealth).

**Bibliographic details**


**PubMedID**

17300390

**DOI**

10.1111/j.1540-8183.2007.00214.x

**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

Angioplasty, Balloon, Coronary /economics; Coronary Artery Disease /therapy; Coronary Restenosis /economics /prevention & control; Cost-Benefit Analysis; Drug Delivery Systems /economics; Health Care Costs; Humans; Outcome Assessment (Health Care); Quality-Adjusted Life Years; Stents /economics; United States

**AccessionNumber**

12007000697

**Date bibliographic record published**

31/12/2007

**Date abstract record published**

31/12/2007

**Record Status**

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.