Coronary stenting in routine interventional practice

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ABSTRACT - Background: Coronary stents have revolutionised interventional cardiology, providing a 'bail-out' option when angioplasty results are unsatisfactory, and reducing the risk of restenosis. However, despite the results of randomised trials, concerns have been expressed about whether stent insertion is cost-effective in routine clinical practice.

■ Methods: The notes of 356 patients who underwent stent insertion in Oxford between January 1996 and March 1997 were examined. Long-term follow-up information was obtained from questionnaires sent to general practitioners and patients.

■ Results: The procedure was successful in 327 (92%) cases. Eighteen (5.1%) patients suffered a serious coronary complication, and 13 (3.7%) a bleeding complication. Over the year following stent insertion, 238 (83%) of the 286 patients followed-up had suffered no coronary event, and 88% were in Canadian Cardiovascular Society (CCS) angina class II or below (slight limitation of normal daily activity at worst).

■ Conclusion: Whilst the initial cost of stent insertion is considerably greater than that of angioplasty alone, it reduces the need for high risk emergency bypass surgery or redo percutaneous intervention. Stent insertion thus represents a clear advantage for patients who have unsatisfactory angioplasties and may be a more cost-effective option.

Coronary stents were developed just over 10 years ago to manage early abrupt vessel closure after balloon angioplasty. Stents are coiled wire or slotted-mesh tubes which can be mounted on a balloon and deployed when the balloon is inflated. Their design ensures that, once expanded, they provide a rigid support to maintain vessel patency.

The initial experience with stents was disappointing, largely due to a high incidence of thrombotic complications1. However, the design of stents has progressively improved, and it is now well-recognised that high pressure balloon inflation is required for adequate stent deployment2. There have also been major improvements in the medical management of patients following stent insertion: the emphasis has shifted away from intensive anticoagulation towards improved antiplatelet regimens, which aim for better early stent patency with fewer haemorrhagic side-effects3.

Local dissection and abrupt vessel closure following balloon angioplasty are now routinely managed by stent implantation, which avoids subjecting a patient to a high-risk emergency bypass operation. The option to deploy a stent – the so-called 'bail-out' indication – has allowed interventional cardiologists to tackle a much wider range of coronary lesions than would be safe with balloon angioplasty alone. Moreover, elective stent placement reduces restenosis rates after angioplasty: angiographic rates of 22% were achieved (compared with 32% for angioplasty alone) in the Benestent clinical trial4. Thus, use of stents has increased dramatically worldwide: stents are now commonly deployed as a primary procedure at sites where the risk of restenosis with angioplasty alone is known to be particularly high, for example in the proximal left anterior descending artery and in vein grafts5,6.

The relevance of the results of the randomised controlled trials of stenting, which have been used to justify the rapid changes observed in routine interventional practice, has, however, been questioned. It has been suggested that the trials do not reflect everyday clinical practice and were based on an unrepresentative patient population7. The John Radcliffe Hospital in Oxford is a typical tertiary referral centre offering invasive cardiology and cardiac surgery. It serves a population of approximately two million, and provides both elective and emergency coronary intervention. In this paper we examine the short- and medium-term results of coronary stent implantation in an unselected population at our centre between January 1996 and March 1997, and compare them to both the results of a 1992 audit of angioplasty alone carried out in the same centre8, and the results of the Benestent clinical trial9.

Methods

Since April 1995, the number of stent insertions per month in Oxford has progressively increased, both in absolute terms and as a proportion of the total number of coronary interventions performed (2/31, 6% vs 53/80, 66%). The notes of 356 patients who underwent stent insertion between January 1996 and March 1997 were reviewed to obtain detailed information about the procedure and any procedural complications. Only first time interventions for a given coronary lesion were considered. A procedure was considered to be a stent implantation once a stent had been introduced into the guide catheter.

Technical expertise with stents had been improving rapidly in the centre since 1995, and changes had also occurred in post-stent management. Before the study period, the arterial sheath remained in situ for 24 hours, and patients received intensive anticoagulation with dipyridamole, dextran, heparin and warfarin. By January

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1996, however, high pressure balloon inflation at the end of the procedure had become routine, and for the majority of patients the arterial sheath was removed at four hours, intravenous heparin given for 36 hours, and the antiplatelet agent, ticlopidine, given for four weeks.

Long-term follow-up information on cardiac events and functional status was obtained from hospital notes and by sending a postal questionnaire to the general practitioner and, where appropriate, the patient. Events were defined as myocardial infarction, further angioplasty or stent insertion, bypass surgery, or death with a possible cardiac cause. Re-admission with chest pain but no subsequent coronary intervention was not included as it is our experience that the vast majority of such episodes represent non-cardiac chest pain.

Statistical significance was determined for continuous variables using an unpaired Student’s t test, and for categorical variables using a χ² test.

Results

The mean (SD) age of the 356 patients studied was 61 (±10) years, and 282 (79%) were male. Seventy-four (21%) patients had undergone a previous coronary intervention (bypass surgery or angioplasty). The majority of patients had presented acutely with either unstable angina or early post-infarct angina (67%). Fewer procedures involved the circumflex coronary artery (17%) than the left anterior descending (46%) or right coronary arteries (30%). More than one artery was stented in 3% of patients, the left main stem in <1%, and a bypass graft in 3%. Most stent insertions were performed non-electively following unsatisfactory results from balloon angioplasty (83%). Half of the stent procedures involved the use of at least 2 balloons, and more than one stent was deployed in 20%. The NIR stent was the most frequently used (in 38% of cases), and the majority of patients (96%) were treated with ticlopidine rather than intensive anticoagulation.

Table 1 shows the immediate results of stent insertion in our study compared with the 1992 Oxford angioplasty audit and the Benestent trial. Our overall in-hospital procedural success rate (angiographic success with no in-hospital coronary complication) was 327 (92%). The mean (SD) delay from procedure to discharge from hospital was 3.2 (3.3) days, and was shorter for elective cases compared to acute ones (2.5 (1.4) vs 3.5 (3.9) days; p=0.01). A fatal or serious coronary complication (death, emergency bypass surgery, emergency redo intervention or myocardial infarction) followed 18 (5.1%) procedures, and vascular access or bleeding complications occurred in 13 (3.7%). Our study group had a higher post-procedure mortality rate than observed in the 1992 angioplasty audit or the Benestent study (1.9% vs <1% vs 0%). However, four out of seven of these deaths occurred in patients with post-infarction cardiogenic shock, who died despite angiographically successful stent insertion.

Table 2 shows the outcome at one year for 286 survivors of stent insertion, compared with the results of the 1992 angioplasty audit and the Benestent trial. Of these, 238 (83%) patients remained free of major cardiac events (myocardial infarction, further angioplasty or stent insertion, bypass surgery, or cardiac death), and 88% remained in Canadian Cardiovascular Society (CCS) angina class II or below (slight limitation of normal daily activity at worst). For direct comparison with the other studies, at seven months 88% of patients were event-free (compared with 87% in the Benestent study), whilst at nine months 84% were event-free (compared with 71% in the angioplasty audit).

Of the 29 patients who did not have a successful stent insertion, seven died, six underwent successful emergency bypass surgery, and 16 were managed medically. Fourteen of the survivors were followed for at least one year:

Table 1. Immediate results for 356 coronary stent procedures carried out in Oxford between January 1996 and March 1997, compared with the 1992 Oxford angioplasty audit* and the Benestent trial.

|                        | Stent study | 1992 Oxford angioplasty audit | Benestent trial |
|------------------------|-------------|-------------------------------|-----------------|
| Number studied         | 356         | 236                           | 259             |
| Procedural success     | 327 (92%)   | 91%                           | 93%             |
| Procedure-to-discharge time (mean [SD]) | 3.2 (3.3) | days                         | 8.5 days        |
| Coronary/fatal complications: | 18 (5.1%) | 6.4%                         | 6.9%            |
| death in cath lab       | 0 (0%)      | <1%                           | 0%              |
| death on ward           | 4 (1.1%)    | 0%                            | 0%              |
| death peri CABG         | 3 (0.8%)    | 0%                            | 0%              |
| successful CABG         | 6 (1.7%)    | 4.6%                          | 3.1%            |
| redo intervention       | 1 (0.3%)    | 0.4%                          | 3.4%            |
| infarction              | 4 (1.1%)    | 0.8%                          | 3.4%            |
| Bleeding/access complications | 13 (3.7%) | 13.5%                        |                 |

*Results given as n (%) unless otherwise stated. CABG = coronary artery bypass grafting.
Discussion

In common with most other centres, the number of stent implantations performed in Oxford has increased dramatically over the past five years. This reflects increasing experience with the technique and technical advances, which together have made stent insertion an integral part of any percutaneous revascularisation strategy. The majority of procedures in our study were undertaken in patients presenting as emergencies, a high risk group, which reflects the increasingly acute nature of our catheter laboratory workload. This must be borne in mind when comparing our results with those of elective primary stenting in the randomised trials. The relatively small proportion of procedures involving the circumflex coronary artery is probably due to the greater technical difficulty in passing one of the first generation (less flexible) stents into this vessel compared to the left anterior descending or right coronary arteries. Nevertheless, in cases where stenting of the circumflex was attempted, the procedural success rate was equally good. Two or more balloons were usually necessary for stent deployment, the first for predilatation of the coronary stenosis, and the second for mounting the stent itself.

The vast majority of stent insertions in this survey were performed for unsatisfactory angiographic results following angioplasty, and therefore represent what would previously have been classed as unsuccessful angioplasties. It is therefore particularly gratifying that the procedural success rate was just as high as that for all angioplasties in the 1992 audit (Table 1), and comparable to that for relatively low risk elective stent insertions in the Benestent and STRESS trials.

The incidence of haemorrhagic complications in our study was lower than that in both the Benestent and STRESS trials, and our inpatient stay was shorter. This probably reflects the refinement of our post-procedure management, with early arterial sheath removal at four hours, and ticlopidine replacing intensive anticoagulation for most patients; routine discharge is currently 24-48 hours post procedure. The higher post-procedure mortality rate observed in our study was largely due to the treatment of certain critically ill patients, i.e. most of the deaths occurred despite rather than as a result of stent insertion.

Event-free survival during follow-up was comparable to that in the Benestent trial, and markedly better than that in the 1992 angioplasty audit. Only 13% of stented patients required a further revascularisation procedure within nine months, compared to 27% of those treated by angioplasty alone. This was despite the increasing number of patients with complex coronary disease being treated with a percutaneous strategy (including stents) rather than bypass surgery.

In planning modern healthcare, decisions about medical interventions need to reflect measures of cost as well as clinical benefit. The initial cost of stent insertion remains considerably higher than that of angioplasty alone, but is comparable to that of an emergency bypass operation. High risk emergency surgery was previously the only 'bail out' option following unsuccessful angioplasty. Stent insertion therefore represents a clear advantage for our patients, the majority of whom undergo the procedure for this indication. Over the nine months following the intervention, stent insertion reduces the need for bypass surgery by 7% and redo percutaneous intervention by 7% compared with successful angioplasty alone. This makes it a cost-effective option, and an increasingly indispensable part of percutaneous strategies.

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Background ■ Summary and recommendations ■ Methodology ■ The clinical problem ■ Prevention of osteoporosis ■ Treatment of osteoporosis ■ Management of osteoporotic fractures ■ Strategic considerations (including the economic perspective of treatment and guidelines for use of HRT) ■ Recommendations to commissioners of health care services

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