Ultrasound guided stenting

The routine use of intracoronary stents to reduce acute complications and improve the clinical outcome of percutaneous coronary intervention is now well established, with a reduction in the complications of acute closure, myocardial infarction, and emergency surgery, as well as the six month restenosis rate by up to 50%. However, with the continued incidence of subacute stent thrombosis and the fact that a six month clinical restenosis rate of 10–20% still exists, this suggests that stenting, particularly in “non-Benestent” lesions, is less than perfect. Initial experience with coronary stent deployment was characterised by a high thrombosis rate despite aggressive anticoagulant regimens, which increased the risk of early vascular complications. Improvements in clinical outcomes followed from the use of antiplatelet rather than anticoagulant drugs, better stent designs, and the evidence from intravascular ultrasound (IVUS) of suboptimal stent expansion with lower pressure deployment. Studies using the latter technique showed that full stent expansion, complete apposition to the vessel wall, and full lesion coverage significantly reduced the incidence of stent thrombosis.

Most interventionists are confident in deploying intracoronary stents using angiographic guidance alone, given the small incidence of acute stent related problems. However, suboptimal stent deployment after final balloon dilatation has been observed in the majority of cases with IVUS despite a satisfactory angiographic appearance, which has implications for a higher restenosis rate at follow up. For this reason, several recent trials have investigated the use of IVUS to guide stent deployment to see whether its adjunctive use leads to better clinical outcomes at follow up compared to using angiography alone.

Intravascular ultrasound and stenting

The MUSIC trial was a prospective non-randomised observational study designed to examine the additional value of IVUS in determining optimal stent deployment in vessels with a reference segment larger than 3.0 mm, with the intention of reducing the need for antithrombotic medication. The “MUSIC criteria” for optimal expansion were: a minimum stent area (MSA) > 90% of the average of proximal and distal reference segments; an MSA > 100% of the smallest reference segment, as well as complete stent apposition to the vessel wall. These standards proved difficult to achieve in practice, and so they were subsequently revised to 80%, 80%, and 90%, respectively, if the MSA achieved was > 9 mm². A stent thrombosis rate of only 1.3% was reported after a mean follow up of 198 days in 155 patients treated with aspirin alone. Emergency bypass surgery was required in 0.6% of patients with an overall target lesion revascularisation of 4.5%. The MUSIC ultrasound criteria were achieved in 80% of lesions, and the six month angiographic restenosis rate was only 8.3% (which was half that reported in Benestent II).

In a smaller observational study of IVUS guided stent deployment, Moussa and colleagues found that an MSA > 9 mm² was associated with the lowest angiographic restenosis rate, while the only criterion associated with freedom from clinical restenosis was an MSA ≥ 55% of the average reference vessel (not lumen) cross sectional area.

In another study of 173 patients treated with a Palmaz-Schatz stent in Milan, where IVUS guidance was routine, the results were matched retrospectively with an equal number of patients treated in Hamburg with angiographic guidance only. In the initial phase of this study, when balloons were sized to the distal vessel diameter in the IVUS guided group, IVUS guidance led to a greater MSA (mean SD 9.5 (2.4) mm² v 7.5 (1.8) mm²). This also led to a lower angiographic restenosis rate at six months (9% in Milan v 22% in Hamburg). These studies all suggested that improved clinical outcomes might be expected if IVUS was used to optimise stent deployment, but this hypothesis required confirmation in randomised trials.

Randomised trials of ultrasound guided stenting

There have been three major multicentre randomised trials of ultrasound guided stenting. CRUISE, the ultrasound substudy of STARS, included nine centres in which stents were deployed using IVUS guidance. Patients treated in these centres were compared with seven centres in which stenting was guided by angiography alone followed by blinded IVUS assessment (IVUS documentary). A total of 499 patients were followed up from an initial 525 patients, with larger balloon sizing (3.88 (0.51) mm v 3.69 (0.59) mm, p < 0.001) and greater dilatation pressure (18.0 (2.6) atm v 16.6 (3.0) atm, p < 0.001) used in the IVUS guided and IVUS documentary groups, respectively. A total of 36% of patients in the IVUS guided group had a change in deployment strategy based on the ultrasound images. This was associated with superior stent expansion (MSA) in the IVUS guided group (7.78 (1.72) mm² v 7.06 (2.13) mm², p < 0.001). At nine month follow up, a 44% reduction in the clinical end point of target vessel revascularisation (TVR) was demonstrated (8.5% v 15.3%, p < 0.05). This was an encouraging clinical outcome although the apparent benefits of IVUS guidance could have been accentuated by other differences in treatment between the different centres, given the operators’ individual discretion regarding optimisation of final stent deployment. Also, a clinical restenosis rate (TVR) rather than angiographic restenosis rate was selected as a primary end point in CRUISE; yet a significantly greater number of multivessel disease patients were in the IVUS documentary group (44%) compared to the IVUS guided group (27%), although this was not an independent predictor of TVR by multivariate analysis.

In OPTICUS, the first randomised trial with angiographic follow up, 550 patients receiving one or two coronary stents were randomly assigned to ultrasound or angiography guided deployment in the same catheterisation laboratories, and restudied at six months. Optimal stent expansion according to the MUSIC criteria was achieved in 64% of IVUS guided lesions. The initial minimum lumen diameter (MLD) post-stent deployment was greater in the IVUS guided group, and this led to a small reduction in the need for early repeat angioplasty. However, there were no significant differences in the composite clinical or
angiographic primary end points. These data appeared disappointing given the earlier non-randomised studies suggesting benefit from ultrasound. In OPTICUS, however, a potential confounding variable was the fact the patients were randomised in each centre to either arm of the study, leading to the situation where the interventionists used to ultrasound guidance made decisions to up-size balloons for dilatation post-stent deployment in the angiography guided group. This was evident in the comparable MLD and balloon sizes used in the angiography guided group compared to IVUS guidance.

The initial results of the AVID trial, another multicentre comparison of ultrasound and angiography guided stent deployment, were reported in 1999. A total of 759 patients undergoing elective single or multiple stent placement in native vessels > 2.5 mm or saphenous vein grafts in 24 centres were included. Patients were randomised after optimal angiography guided stent deployment (<10% residual stenosis). In the angiography guided group, documentory IVUS was performed (with un-blinding only if significant dissection was noted (2.6%)). In the IVUS guided group, larger balloons or additional stents were required in 43% of cases to achieve the criteria of full stent apposition and MSA > 90% of the distal reference area. As a result, the final MSA was greater in the IVUS guided group (7.54 (2.86) mm² v 6.94 (2.46) mm², p < 0.01). After 12 months follow up, the primary clinical end point of target lesion revascularisation (TLR) was 8.4% in the IVUS guided group versus 12.4% in the angiography guided group (p = 0.08). When protocol violations such as the inclusion of vessels smaller than 2.5 mm were excluded, the difference achieved significance (4.9% v 10.8%, p = 0.02). The benefit of IVUS guidance was particularly evident in three subgroups: saphenous vein grafts (TLR 5.7% v 20.4%, p = 0.05); vessels with a diameter stenosis > 70% (TLR 3.5% v 14.9%, p = 0.003); and vessels with a distal reference diameter < 3.25 mm (TLR 7.9% v 14.6%, p = 0.04).

Clinical implications

In summary, ultrasound guided stenting leads to balloon upsizing in up to 40% of patients, which results in a greater initial minimum stent area with no increase in acute complications. Despite encouraging results from uncontrolled studies, the randomised trials have shown no difference in angiographic restenosis rate, though there appears to be a reduction in clinical restenosis, particularly in specific subgroups. In the current era of improved stent design, better antiplatelet treatment, and the knowledge gained from clinical IVUS studies, most interventionists believe that the benefits of routine IVUS guidance do not justify the investment in time and equipment. However, intravascular ultrasound is useful to define ambiguous angiographic appearances during stenting. Furthermore, certain subgroups may be identified as having particular benefit—saphenous vein grafts, more severe stenoses (implying a greater plaque load), and smaller vessels. In addition, specific subgroups such as diabetic patients, who have an increased risk of restenosis after coronary intervention, also appear to benefit from ultrasound guided stenting on retrospective analysis.

Given the current rate of coronary stenting, it would be difficult to recommend routine ultrasound for the majority of cases. However, in addition to its important role in clinical research, and its utility in defining unusual or ambiguous angiographic appearances, the evidence suggests that it is of additional benefit in improving the medium term clinical outcome in selected patients at increased risk of restenosis.

A L MCLEOD
D B NORTHRIDGE
N G UREN

Department of Cardiology,
Lothian University Hospitals NHS Trust,
Edinburgh, UK
nealuren@hotmail.com

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A L MCLEOD, D B NORTHRIDGE and N G UREN

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