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Short Communication

Vice More than Virtue? Long Term Implications of the Coronary Stent

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Following the advent of coronary angioplasty by Gruntzig in 1977 [1], the early expansion of the new and explorative technique was limited by significant complication rates. Research and development was thus aimed at minimising the acute complications of acute vessel closure, recoil and vessel dissection or perforation. However, over the course of the next ten years, angiographic restenosis came to be recognised as a major long-term drawback, occurring in 30-40% of patients [2]. Coronary stents were introduced in 1986 in an attempt to ameliorate the acute complications of balloon angioplasty [2]. In due course, landmark studies demonstrated a reduction in the rate of repeat intervention for restenosis when employing a strategy of routine elective bare metal stent implantation as compared to balloon angioplasty (with a 5% cross over between the 2 arms) [3]. Routine stenting became the standard of care such that by 1999, 84.2% of all PCI involved coronary stents. This saw a reduction in acute complications, but angiographic restenosis remained problematic in up to 30% of cases [4].

In the subsequent 19 years, interventional cardiology research has been focussed on the reduction of PCI complications, particularly the rates of in-stent restenosis (ISR). From the first bare metal stents, to the currently ubiquitous drug eluting stent (DES), we have seen a progressive reduction in restenosis rates. Furthermore, as optical coherence tomography (OCT) enhances our understanding of the pathophysiological mechanisms behind stent restenosis, these rates of restenosis should continue on a downward trajectory. Indeed, the second generation DES are said to reduce ISR by 75% compared to bare metal stents (BMS) [5]. Despite this, reported ISR rates remain high in up to one third of patients up to 10 years [6]. The evidence from randomised controlled trials and meta-analysis is conflicting when comparing first generation and second generation DES. The first large meta-analysis reported a reduction in myocardial infarction (MI) and stent thrombosis (ST) but no significant difference between repeat coronary revascularisations [7]. Therefore, the problem of ISR remains significant.

In additional, despite the strong evidence base for stent technology reducing the need for repeated revascularisation due to restenosis, we have never been able to demonstrate that stents have any impact on mortality. Al Suwaidi., *et al*. performed a meta-analysis in 2004 comparing patients receiving PCI with stent versus those receiving balloon angioplasty only, finding no difference in mortality at 12 months between groups. Stents reduce the risk of major adverse cardiac events only when target revascularisation is included as an endpoint [8]. Other meta-analyses have failed to show a difference in mortality between conservative treatment and PCI in stable coronary artery disease [9,10]. Equally, despite the clear evidence supporting the use of drug eluting stents over bare metal stents with regards to rates of myocardial infarction, stent thrombosis, and to a degree ISR, there is no evidence of a difference in mortality between bare metal stents and drug eluting stents [11].

Based on the implication that drug eluting stents do not alter mortality and only have implications for major adverse cardiovascular events (MACE) when in-stent restenosis is incorporated, we question the necessity of drug eluting stent use for routine coronary angioplasty as the standard of care. The European Society of Cardiology (ESC) recommend the use of drug eluting stents for patients undergoing percutaneous coronary angioplasty based on comparative evidence with BMS as outlined above. However, BMS has not conclusively shown a reduction in mortality as compared to balloon angioplasty. We therefore hypothesise that an alternative strategy such as the use of the drug coated balloon (DCB) to reduce restenosis rates may be an attractive alternative to the use of permanent metallic implants.

The advantage of the DCB is that it features the positive remodelling effect of the vessel from localised drug treatment without leaving a permanent structure in situ, hence reducing the risk of target lesion restenosis. The use of DCBs are increasingly recognised both for small vessel disease and ISR [12-14], with the recent reports from the DARE trial indicating non-inferiority for DCB when compared to DES for ISR [15]. Many interventionalists prefer the use of DCBs in this scenario to prevent the unattractive proposition of multiple layers of metal. We suggest that DCB angioplasty should be increasingly utilised in routine PCI, not only in the case of ISR and small vessel disease. Nowadays, the acute complications previously seen with balloon angioplasty are much less common due to improved angioplasty tools and angiography, the availability of potent dual antiplatelet therapy and the availability of DES as a bailout option. With stents in our arsenal as a back-up strategy, there is much pointing towards the use of a DCB as first line treatment. There is a need for randomised controlled trials to compare the two strategies of routine elective DES and routine DCB with bail out or provisional DES.

In conclusion, we advocate the use of DCBs in all emergency and routine angioplasty where viable with the use of DES when required as a bail-out technique only. This is based on a lack of evidence to suggest coronary stents have any implication on mortality, an ongoing problem (despite advances in technology) with ISR and target lesion revascularisation and promising local data within our trust [16-18].

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