CORONARY ARTERY STENTS FOR THE TREATMENT OF ISCHEMIC HEART DISEASE (REVIEW OF NICE TECHNOLOGY APPRAISAL GUIDANCE No 71)

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Drug eluting stents reduce the relative risk of requiring a repeat procedure following index PCI by approximately 50%. This has been demonstrated in multiple randomised controlled trials. The absolute risk reduction is significantly affected by whether or not these trials included mandatory angiographic follow up. This is not a feature of normal clinical practice and the absolute risk reduction in patient cohorts not subjected to mandatory angiographic follow up varies across the trials from less than 5% to approximately 10%. This is critical as it drives the cost effectiveness calculations for drug eluting stents. The second component driving the cost effectiveness calculations is of course the price premium between drug eluting and bare metal stents. This has come down significantly over the last two to three years and I would expect it to continue to fall. Finally there is the critically important issue of safety. The randomised control trials of Cypher and Taxus show no statistically significant excess incidence of stent thrombosis from the point of randomisation to the end of four years of follow up. This data has been published in the New England Journal of Medicine. However, if the data is censored at one year there is a small excess incidence of late stent thrombosis in the drug eluting stent arm compared to bare metal stents from year one to year four. This does not translate into an excess incidence of death on myocardial infarction. This could be due to the trials being underpowered to detect this end point. Alternatively there is evidence to suggest that any excess death or myocardial infarction due to stent thrombosis is offset by less death or myocardial infarction related to a reduced need for repeat revascularisation. Again this has been published in the literature. Observational registries have suggested that drug eluting stent use is associated with an increased risk of late stent thrombosis but patients who receive drug eluting stents have more complex disease than patients receiving bare metal stents and despite sophisticated statistical analysis it is not possible to control for all the potentially confounding factors in these non-randomised patient cohorts. The response of the cardiological community to a perceived increased risk of late stent thrombosis with drug eluting stents has been to recommend dual anti-platelet therapy for twelve months rather than six or three months in patients receiving drug eluting stents. This is associated with some cost and a small excess incidence of bleeding, but twelve months dual anti-platelet therapy is in any event a NICE recommendation for patients who present with non ST elevation acute coronary syndrome based on the results of the CURE Trial. The high risk group in the CHARISMA Trial also benefited from prolonged dual anti-platelet therapy. As such it's not difficult to justify twelve months of dual anti-platelet therapy in patients whose coronary disease is so severe that they have required percutaneous revascularisation.

Full compliance with original NICE guidance equated to a rate of drug eluting stent use of around 70% and not 30% as indicated in the original document. In the West of Scotland, for financial reasons, we reduced the reference vessel diameter indication for the use of a drug eluting stent from 3mm to 2.75mm. This resulted in a drug eluting stent use of around 45 – 50% which I believe is entirely appropriate. I

also believe that drug eluting stents should be used during PCI in diabetic patients who have a significantly increased risk of re-stenosis with bare metal stents.

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