SCAAR registry provides reassurance on drug eluting stent safety

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A study published today in The *New England Journal of Medicine* (1), analysed the outcomes of 47,967 patients entered into the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) between 2003 and 2006.

Commenting on the results, interventional cardiology specialist, Professor Franz Eberli from the University Hospital Zurich (Switzerland) and official spokesperson for the European Society of Cardiology, said:

"To appreciate the significance of this paper you need to bear in mind the huge impact that data from the previous analysis of the SCAAR registry had when it was presented at the ESC in Barcelona in 2006, and published in the New England Journal of Medicine in 2007 (2). The initial paper, which showed that patients receiving drug eluting stents (DES) in Sweden between 2003 and 2004 had increased late mortality over those receiving bare metal stents (BMS), created a huge fire storm. The immediate impact was a decrease in the use of DES and a lot of scrutiny on safety, and the move for safety, cost effectiveness and durability of stents to be considered over efficacy," said Professor Eberli.

"This latest paper, looking at the same patient cohort, with the results extended to include all patients in Sweden receiving a stent between 2003 and 2006, (for whom there is more than one year of follow-up) found no increased risk of death between the two groups. The

conclusions are similar to many of the trials and registries already published in this area, and significant principally because they refute the previous findings of the SCAAR registry. The latest SCAAR data provides a lot of reassurance on the safety of DES," he said, adding that the study was probably the largest registry yet on stents with the longest follow-up.

Exploring possible reasons for the differences between the two SCAAR publications, Professor Eric Eeckhout, official spokesperson for the European Society of Cardiology, from the University Hospital of Lausanne, Switzerland, said: "The difference in outcome is likely to be a reflection of the way in which cardiology practice has evolved over time, leading to greater optimisation of the results of stenting. Significant changes include use of higher balloon pressures and the increased use of dual anti-platelet therapy."

He added that the field of DES was continually evolving, and that new devices with the potential to improve safety were arriving in the market. "For me this paper shows that there should now be no real concerns about the safety of DES and that the emphasis should shift back to considering the relative efficacy of BMS and DES."

Dr Steen Dalby Kristensen, from Aarhus University Hospital, Denmark, and Vice-President of the European Society of Cardiology, highlighted the inherent problems of registries, where there are dangers of inclusion bias.

"To draw definitive conclusions about the safety of drug eluting stents, what is really needed, is a large scale randomised controlled long term trial. Unfortunately there are challenges in getting public funding for such trials, which may also prove difficult to perform in countries that already have high uptakes of DES."

He added that data from the SCAAR registry suggesting that 39 patients would need to be treated with DES to prevent one case of restenosis, and that 10 patients in the higher risk groups would need to be treated to prevent one case, made a strong argument of the cost effectiveness of drug eluting stents. "What also needs to be remembered is that preventing restenosis also has an enormous influence on the patient's quality of life," he said.

More information:

1. James SK, Stenestrand U, Lindback J et al. Long-Term Safety and Efficacy of Drug-Eluting Versus Bare-Metal Stents in Sweden. N Engl J Med 2009; 360: 1933-45.

2. Lagerqvist B, James SK, Stenestrand U, et al. Long-Term Outcomes with Drug-Eluting Stents Versus Bare-Metal Stents in Sweden. N Engl J Med 2007; 356: 1009-19.

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