

No increased risk with drug eluting stents -- but late stent thrombosis remains a concern

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Several large observational data sets have convincingly shown that there is no overall safety issue with drug eluting stents (DES) vs. bare metal stents (BMS). In fact, most registry studies suggest a lower risk of death or myocardial infarction with drug eluting stents. However, late occurring stent thrombosis still remains higher and seems to be uniquely associated with these stents. Late stent thrombosis is a rare but very serious event and all possible efforts should be made to avoid the complication by improving patient selection, optimizing the implantation technique and enhancing anti thrombotic treatment. With highly effective anti thrombotic treatments and novel drug eluting stent designs without potentially toxic polymers a clear reduction of death and myocardial infarction rates is highly probable.

The original SCAAR study published 2007 indicated a higher mortality after the initial six months in patients with drug eluting stents and we concluded that a generalized use of DES should be avoided until large randomized studies with long term follow-up had ruled out any increased risk.

Two years later, a five year follow-up of all patients treated with drug-eluting compared to bare-metal stents in Sweden, shows similar rates of death or myocardial infarction and an important improvement in the rate of restenosis in high risk patients. Among patients at highest risk for restenosis, there was an over 70% relative risk reduction with drug eluting stents compared to bare metal stents. This is a unique presentation of the entire experience of the long-term outcome of

treatment with different types of stents in an entire country comprising almost 50.000 patients. Was the original study incorrect?

When the original cohort of patients treated 2003-2004 were followed up to 5 years the increased risk among the patients treated initially in 2003 remained unchanged. With inclusion of new patients treated 2005-2006 there was no increased risk. Also in subgroups of patients at higher risk such as patients with diabetes and ST elevation myocardial infarction the safety of drug eluting stents is now confirmed.

Other large observational studies such as the United States national cardiovascular database that included 260,000 elderly patients from the Medicare program have indicated a lower risk of death or [myocardial infarction](#) with drug eluting stents with a surprisingly low reduction in revascularization rates. Similar reassuring safety results were found in a recently published meta analysis of over 30 observational studies.

However, all observational data comparing treatment options should be interpreted with caution because of possible concealed confounders and there is no registry study that can replace any large well performed randomized trial with long term follow-up. The importance of large scale registries has prompted the SCAAR registry to start performing all-comers randomized trials within the registry.

Source: European Society of Cardiology ([news](#) : [web](#))

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