

Interventional Cardiology



NEWS



RESEARCH HIGHLIGHTS



Use of a vascular closure device may reduce major access bleeding in acute coronary syndrome patients

A recent trial suggests promising results for patients fitted with a vascular closure device following invasive surgery

Acute coronary syndrome patients (ACS) undergoing early invasive management by the femoral approach who are fitted with a vascular closure device (VCD) have a reduced risk of major access site bleeding (ASB), the recent Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) trial demonstrated.

Timothy Sanborn and colleagues (University of California, CA, USA) studied 11,602 ACS patients who were undergoing invasive surgery, in the ACUITY trial. A total of 4307 of these patients were fitted with a VCD following invasive surgery and the other 7314 patients received manual compression.

The study found that the risk of major ASB was significantly decreased in patients who received a VCD compared with the risk in patients who did not. The rate of major ASB in VCD receiving patients was 2.5 versus 3.3% in patients receiving manual compression, giving a relative risk of 0.76.

Since bleeding has previously been found to act as a powerful independent predictor of 30-day mortality in ACS patients receiving invasive surgery, the results from this study suggest the use of a VCD could improve the invasive management of ACS. However, Sanborn cautions that owing to the nonrandomized nature of the trial and any potential bias associated with this design, the findings should be used primarily in order to generate hypotheses for further investigation.

In this study, major ASB was defined as bleeding requiring interventional or surgical correction and hematoma of 5 cm or more at the puncture site. Other definitions of major ASB (e.g., retroperitoneal bleeding, oozing

blood, prolonged bleeding at the access site, hemoglobin drop ≥ 3 g/dl with ecchymosis, or hematoma < 5 cm) did not differ between the VCD and non-VCD groups.

It is worth noting that the timing of the major ASB was not recorded in the trial and consequently it is possible that in some patients the occurrence of major ASB during angiography may have influenced the decision to use a VCD and so led to an apparent increased rate of bleeding in the non-VCD group.

Further analysis by Sanborn and colleagues found that the lowest rate of ASB ($< 1\%$) was observed in patients who were participating in the bivalirudin monotherapy arm of the trial and also received a VCD.

"The present findings suggest that the combined use of bivalirudin and a VCD may reduce major ASB in patients with ACS managed with an early invasive strategy from the femoral approach", summarizes Sanborn.

However, the authors caution that there have been no large-scale, randomized trials to support a reduction in bleeding associated with the use of VCDs. Observational studies suggest a better outcome for patients receiving VCDs than for those who do not, but prior meta-analyses have suggested that the outcome is worse with a VCD. It is not clear whether the findings of the current study truly reflect better outcomes with VCDs or merely suggest an inability to adjust for confounding factors.

Source: Sanborn TA, Ebrahimi R, Manoukian SV et al.: Impact of femoral vascular closure devices and antithrombotic therapy on access site bleeding in acute coronary syndromes. *Circ. Cardiovasc. Interv.* 3, 57–62 (2010).

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Clinical trial to evaluate Duo 12 port open irrigated catheter ablation system for atrial fibrillation has been announced

The US FDA has granted an Investigational Device Exemption to St Jude Medical Inc. (MN, USA) in order to allow them to begin enrolment for the Irrigated Ablation System Evaluation (IRASE) trial, which will evaluate a new cardiac ablation catheter system for the treatment of atrial fibrillation (AF).

St Jude Medical Inc. have announced that they will carry out a multicenter, randomized, single-blind study evaluating the safety and efficiency of their Duo 12 port open irrigated catheter ablation system.

The study's Principal Investigator Andrea Natale (Texas Cardiac Research Foundation, TX, USA) explained that, "With the IRASE AF trial, we hope to learn more about how safe and effective St Jude Medical's Duo 12 port tip irrigated ablation catheters are as part of an ablation strategy to treat atrial fibrillation." The

Duo 12 port open irrigated catheter ablation system, whose 12 ports are designed to improve cooling of the ablation tip, will be compared with an irrigated ablation system already approved by the FDA for treatment of paroxysmal AF. The trial will take place in the USA and international markets and is expected to last approximately 3 years. The company intends to use 324 patients, who will be randomly assigned on a 1:1 basis to either the Duo 12 port open irrigated catheter ablation system or the previously approved system.

The IRASE trial will evaluate both safety and efficiency of the new system. The primary efficiency end points will be targeted pulmonary vein isolation and freedom from atrial fibrillation for 12 months after the procedure is carried out. The safety end points have been cited as freedom from acute major

adverse events within 7 days of the procedure and absence of any chronic major adverse events within the first 12 months following the procedure. Jane Song, President of the St Jude Medical Atrial Fibrillation Division, noted "The IRASE AF trial marks an important milestone for St Jude Medical because it could result in the company's first atrial fibrillation indication for a catheter ablation system in the USA."

"The trial reflects our ongoing commitment to funding research relevant to the electrophysiology medical community and to the development of innovative technologies and devices to treat atrial fibrillation", Song concluded.

Source: St Jude Medical; <http://phx.corporateir.net/phoenix.zht?ml?c=73836&p=irolnewsArticle&ID=1382377&highlight>

Early invasive strategy shows no benefit according to 5-year follow-up of the ICTUS trial

Follow up results from the Invasive versus Conservative Treatment in Unstable Coronary Syndromes (ICTUS) trial suggest that early invasive strategy provides no long-term benefit for reducing mortality or myocardial infarction in non-ST-segment elevation acute coronary syndrome patients with elevated troponin T.

The results of the 5-year clinical follow-up of the ICTUS trial have been reported by Robbert de Winter and colleagues (Academic Medical University of Amsterdam, The Netherlands) in the *Journal of the American College of Cardiology*.

The trial compared early invasive strategy and selective invasive strategy in 1200 patients. The 1- and 3- year follow-up had previously shown no benefit of

early invasive strategy on the composite of death, myocardial infarction or angina symptoms requiring rehospitalization.

The 5-year follow-up study examined 604 patients in the early invasive group and 596 patients in the selective invasive group. Revascularization rates were found to be 81% in the early invasive group and 60% in those who had been treated with the selective invasive strategy. No difference between the two groups was observed for either death or myocardial infarction.

The results of the ICTUS trial suggest that it would be safe for patients with non-ST-segment elevation myocardial infarction, who stabilize on medical therapy, to wait for an invasive evaluation. However, it remains to be seen whether this wait

would be beneficial to patients, and until further work is completed angiographic approaches are expected to prevail.

"In the new era of comparative effectiveness research, however, cost and quality metrics will be measured alongside hard clinical outcomes to ultimately define how various strategies reduce resource utilization and achieve optimal benefits for patients with NSTEMI", concludes John Bitl (Munroe Regional Medical Center, FL, USA) who wrote the accompanying editorial.

Source: Danman P, Hirsch A, Windhausen F, Tijssen J, de Winter R: A randomized comparison of an early invasive versus selective invasive management in patients with non-ST-segment elevation acute coronary syndrome. *J. Am. Coll. Cardiol.* 55, 858–864 (2010).



First percutaneous heart valve has been approved by the US FDA

The Medtronic (MN, USA) Melody® Transcatheter Pulmonary Valve and Ensemble Delivery system has been approved by the US FDA. The Melody valve is the first heart valve to be implanted through a catheter and guided to the heart from a vein in the leg.

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The Melody valve can delay the need for open-heart surgery and is intended to provide an alternative option to conduit replacement. Conduits are implanted to treat congenital heart defects of the

pulmonary valve. Pulmonary valve defects impede the blood flow from the heart to the pulmonary artery, which is vital in returning blood to the lungs for oxygenation. Although the Melody valve does not cure the heart condition and over time may wear and need replacing, clinical trials of 99 patients in the USA and 68 patients in Europe have demonstrated that the Melody valve improves heart function. The majority of participants in the trials also reported improvements in their clinical symptoms. It is thought that the Melody valve will be particularly beneficial to pediatric patients with right-sided valvular heart disease, who are likely to face several surgeries throughout their lifetimes. The Melody valve will act to hold open that patients weak pulmonary valve, keeping blood flowing in the correct direction and prolonging the time between surgeries.

The FDA's approval is conditional upon agreement by Medtronic Inc. to carry out two post-approval studies that will assess the long-term risks and benefits as well as determining the physician specialization required to conduct the implantation procedure. Medtronic will also maintain a database of Melody recipients.

"The FDA's approval of Melody allows patients to undergo a much less invasive procedure to treat their heart condition," noted Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health. "Congenital heart defects represent the number one birth defect worldwide and this approval represents a new, first-of-a-kind treatment option for some of those patients."

 Source: US FDA press release; www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm198597.htm

Stentys announce that their drug-eluting and bare-metal stents show promising results in recent trial

Results of the complete 'OPEN-I' clinical study were presented at the Joint Interventional Meeting 2010 in Rome this February. Medical device pioneer Stentys (Paris, France) announced that their stents demonstrated superior results in the trial.

"We are actively pursuing our clinical program ... to also prove the superiority of the Stentys technology in this additional group of patients."

Stefan Verheye (Middelheim Hospital, Belgium) presented the results to the meeting, stating that "These clinical results suggest very promising benefits for patients."

The study involved a 6-month angiographic follow-up of 60 patients, 27 of which received Stentys drug-eluting stents and 33 received Stentys bare-metal stents.

"We had already demonstrated that the self-expanding and disconnectable Stentys platform ensured optimal wall apposition and easy access to side branches. We can now confirm that the addition of a drug coating eliminates the need for reintervention", Verheye explained.

The medical device company Stentys develops devices with the aim of making the treatment of blocked coronary artery bifurcations as simple and effective as a conventional stenting procedure.

Gonzague Issenmann, the CEO and cofounder of Stentys added, "These data fortify our conviction of the indisputable superiority of Stentys self-expanding and drug-eluting stents over balloon-expandable

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"We are actively pursuing our clinical program, particularly in the treatment of acute myocardial infarction, to also prove the superiority of the Stentys technology in this additional group of patients."

 Source: Medical News Today: Stentys drug-eluting self-expanding coronary stent shows 4% restenosis in complex lesions; www.medicalnewstoday.com/articles/179284.php