

Interventional Cardiology



NEWS



RESEARCH HIGHLIGHTS



Results of COMFORTABLE AMI trial suggest lower complication rates in patients treated with biolimus stents

A large clinical study assessing major adverse cardiac events following primary percutaneous coronary intervention (PCI) has added to mounting evidence that the use of drug-eluting stents (DES) can lead to lower complication rates than bare-metal stents (BMS) following ST-segment elevation myocardial infarction (STEMI).

Lower rates of 1-year revascularization and target-vessel reinfarction for the biolimus stent group were thought to drive the results, supporting the increasing use of DES in STEMI and raising the question of whether most patients should now be treated with DES.

Although PCI is now accepted as one of the primary treatment for STEMI, the type of stent that should be used is still controversial. Stents that secrete antiproliferation drugs such as sirolimus or paclitaxel have been developed in order to limit the growth of scar tissue and are said to reduce the level of complications. Newer-generation DES such as the biolimus-eluting stent contain biodegradable polymers

that degenerate to form a BMS-like surface, reducing long-term inflammation-related complications.

The recent COMFORTABLE AMI trial published in *JAMA* compared the 12-month outcomes for 1161 patients presenting with STEMI randomized to receive a biolimus-eluting stent ($n = 575$) or BMS ($n = 582$). While cardiac mortality was not different, the rate of major adverse cardiac events (a composite of cardiac death, target vessel-related reinfarction and ischemia-driven target-lesion revascularization after 1 year) were lower in patients receiving biolimus-eluting stents with a biodegradable polymer (24 [4.3%]) than observed in patients receiving BMS (39 [8.7%]).

The results were thought to be due to lower rates of target vessel-related reinfarction and ischemia-driven target-lesion revascularization in patients receiving biolimus-eluting stents compared with those receiving BMS. Stent thrombosis was also more common in patients treated with BMS (12 compared with five patients in the biolimus-eluting stent group).

The results led some in the field to begin contemplating whether the results may mean that DES should become the preferred treatment choice in patients following primary PCI for STEMI.

In an accompanying editorial appearing in *JAMA*, Salvatore Cassese and Adnan Kastrati (Deutsches Herzzentrum, Munich, Germany) stated, "The trial offers positive signals that, along with previous findings indicating the excellent 4-year safety of biodegradable polymer DES, form a good basis to believe that these new DES may belong to the

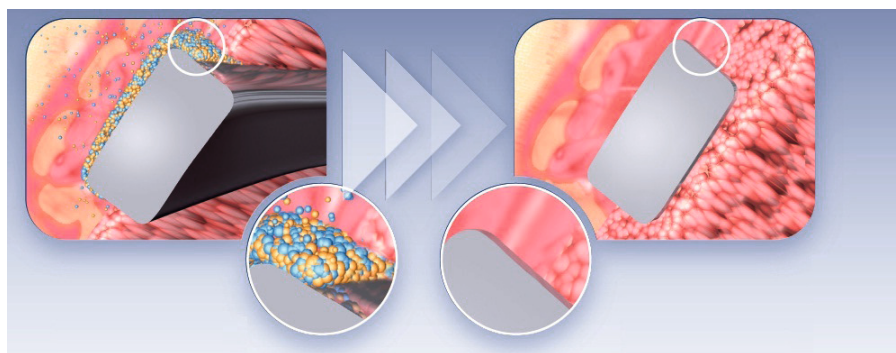


Figure 1. Biolimus-eluting stent. The abluminal polymer coating (left panel) elutes the drug biolimus A9 and dissolves into water and carbon dioxide within 6–9 months after implantation, rendering the stent into a bare-metal stent (right panel). Courtesy of Biosensors Europe, Switzerland.



‘first-choice’ devices in patients with STEMI.”

Speaking to *Interventional Cardiology*, first author Lorenz Räber of Bern University Hospital (Bern, Switzerland) supported the use of the new-generation DES for most patients but illustrated some exceptions, “The results of COMFORTABLE AMI, in conjunction with the data of EXAMINATION, indicate that newer generation DES reflect the preferred treatment strategy in most patients suffering from STEMI. Exceptions may still exist and mainly regard patients who have contraindication against dual antiplatelet

therapy (e.g., allergy against aspirin or relevant bleeding disorders).”

Although direct comparisons between DES and BMS may no longer be considered necessary Räber identified the need to develop PCI therapies, listing the following directions for the field:

- Conduct long-term follow-up of COMFORTABLE AMI population throughout 5 years to assess long-term outcomes both in terms of safety and efficacy;
- Identify whether the reduction in rates of target rate reinfarction with DES could be confirmed in “an adequately designed trial with adequate primary end point and a large number of patients;”
- Investigate new improved stent platforms under development “that will use biodegradable polymers with shorter

degradation time, a thinner coating and less drug.”

– Written by Louise Rishton

Sources: Räber L, Kelbæk H, Ostojic M et al. Effect of biolimus-eluting stents with biodegradable polymer vs bare-metal stents on cardiovascular events among patients with acute myocardial infarction: the COMFORTABLE AMI randomized trial. *JAMA* 308(8), 777–787 (2012); Ielasi A, Latib A, Colombo A. Current and future drug-eluting coronary stent technology. *Expert Rev. Cardiovasc. Ther.* 9(4), 485–503 (2011); Casese S, Kastrati A. New-generation drug-eluting stents for patients with myocardial infarction. *JAMA* 308(8), 814–815 (2012); Byrne RA, Kastrati A. No country for old stents? Improving long-term patient outcomes with biodegradable polymer drug-eluting stents. *Expert Rev. Cardiovasc. Ther.* 10(4), 429–432 (2012); JAMA press release: <http://media.jamanetwork.com/news-item/use-newer-generation-drug-releasing-stent-results-lower-rate-adverse-cardiac-events-for-heart-attack-patients>

MRI-guided right heart catheterization shown to be feasible and safe

A preliminary study of 16 patients lead by Robert Lederman (NIH, MD, USA) has shown that MRI-directed transfemoral right heart catheterization is feasible, exhibiting similar success rates and procedural durations to traditional x-ray guidance. The technique could one day become an alternative to the current x-ray-directed methods, allowing reduced radiation exposure.

The study is the first to examine this type of catheterization using MRI guidance entirely and is the only paired comparison of x-ray and MRI catheterization in the same patients. Researchers also compared MRI-guided catheterization, using an air-filled balloon with the procedure using a balloon containing a 2% solution of diluted gadolinium.

Sixteen unselected patients scheduled for comprehensive transfemoral right heart catheterization underwent the procedure three-times: first, using standard x-ray guidance; second, using real-time MRI guidance with an air-filled balloon; and third, using real-time MRI guidance with a gadolinium-filled balloon. The MRI-directed catheterizations took place in an adjoining room to the x-ray-directed interventions, and procedures were carried

out without using a guidewire due to the current lack of MRI-safe versions.

Authors compared success rate, time to perform key steps and catheter visibility between types of guidance.

All three image-guidance techniques produced a similar success rate for all chamber-entry tasks. A high success rate was observed – the team successfully performed 15 out of 16 catheterizations without a guidewire. The one procedural failure occurred in a patient with a large secundum atrial septal defect with large pulmonary arteries and moderate pulmonary hypertension. Both x-ray- and MRI-guided catheterization failed in this patient without a guidewire.

Overall, it did not take significantly longer to perform the MRI-guided procedures compared with the x-ray-guided version and navigation tended to be fastest using MRI guidance with gadolinium-filled catheters when entering the left pulmonary artery from the main pulmonary artery. A further encouraging finding was that operator confidence was reportedly equivalent over the three different image-guidance techniques, although there appeared to be a learning curve under the less familiar MRI-guidance: these procedures tended

to be quicker in the second eight patients compared with the first eight.

x-ray guidance demonstrated the highest catheter visibility, with both the tip and shaft continually visible. Only the catheter tip was visualized in MRI-guided procedures, but using a gadolinium-filled balloon proved more consistently conspicuous compared with their air-filled equivalents. This was thanks to the specific enhancement of the gadolinium using a ‘saturation preparation’ MRI mode.

While MRI-directed catheterization is a long way from broad clinical adoption, researchers hope that future use of this alternative image-guidance technique could reduce radiation exposure and allow interventionalists to benefit from improved tissue visualization. The study authors cite improved devices and workflows as essentials for making this patient investigational technique one day become reality.

–Written by Sarah Miller

Source: Ratnayaka K, Faranesh AZ, Hansen MS et al. Real-time MRI-guided right heart catheterization in adults using passive catheters. *Eur. Heart J.* doi:10.1093/eurheartj/ehs189 (2012) (Epub ahead of print).



Adherence to radiation reduction methods found to reduce exposure by 40% in cardiac procedures

Adherence to new radiation reduction measures by a team of researchers from the Mayo Clinic's cath laboratory (MN, USA) has been found to reduce radiation exposure by 40% over a 3-year period, reinforcing the achievability of targets to reduce risks to patients and staff during cardiac interventions.

The results, reported in the *Journal of the American College of Cardiology: Cardiovascular Interventions*, were following technical modifications to the use of standard x-ray equipment coupled with intensive radiation safety training.

"Through our efforts, we were able to quickly cut the overall radiation exposure to patients by nearly half using simple but effective methods," reported Charanjit Rihal, chair of Mayo's Division of Cardiovascular Diseases. "We think this

program could serve as a useful model for other cath laboratories in the USA."

x-rays are increasingly used in the cath laboratory to aid with diagnosis and guide procedures; however, exposure to excessive amounts of radiation can raise the risk of certain cancers and skin damage.

In the effort to reduce radiation during cardiac intervention, the Mayo Clinic instituted a program of technical changes such as establishing standard x-ray imaging protocols, increasing the use of x-ray beam spectral filters, reducing the detector target dose for certain imaging techniques and reducing the fluoroscopy frame rate. Recognizing that practice changes can also be used to reduce exposure, they also put in place intraprocedure radiation dose announcements; the reporting of

procedures of high air-kerma, including procedure air-kerma in the clinical report; and starting compulsory radiation safety training for investigators.

Comparing the cumulative skin dose after a total of 18,115 procedures performed by 27 staff cardiologists and 65 fellows-in-training over 3 years, the researchers found a 40% reduction from the end of the period compared with the beginning.

– Written by Louise Rishton

Sources: Fetterly KA, Mathew V, Lennon R. Radiation dose reduction in the invasive cardiovascular laboratory: implementing a culture and philosophy of radiation safety. *JACC Cardiovasc. Interv.* 5(8) 866–873 (2012); Newswise press release: www.newswise.com/articles/mayo-clinic-cardiologists-dramatically-cut-patient-radiation-exposure-from-x-rays

To stent or not to stent? New study shows similar outcomes in diabetics and nondiabetics

A recently published meta-analysis from the University of Ulsan College of Medicine (Seoul, Korea) comparing the effect of PCI versus coronary artery bypass surgery (CABG) in diabetic and nondiabetic patients has revealed similar outcomes in both patient groups. However, PCI was associated with an increased risk of revascularization, regardless of diabetic status.

The relative treatment effects of CABG and PCI in patients with different diabetic statuses is the subject of great investigation and a definitive answer remains elusive. This most recent study has been published in *Circulation: Cardiovascular Interventions*.

A total of 5775 patients from three clinical studies (the MAIN-COMPARE, Asan-Multivessel and ASAN-MAIN registries) were used. Individuals with

complex multivessel or left main coronary artery disease underwent PCI (n = 2789) or CABG (n = 2986). The authors compared adverse outcomes (death; a composite outcome of death, stroke or Q-wave myocardial infarction; and repeat revascularization) in diabetic versus nondiabetic patients.

Median follow-up at 5.5 years revealed no significant differences in risk-adjusted adverse outcomes between diabetic and nondiabetic patients. In both patient groups, PCI was associated with a higher risk of repeat revascularization.

These recent results may come as a surprise and the authors note that the observational studies to date comparing PCI and CABG in diabetic and nondiabetic patients have been unable to provide a clear

answer. Such studies also lacked long-term data for drug-eluting stents.

Authors of this recent study propose that their findings could be due to improvements in PCI devices and adjunctive pharmacology boosting positive PCI outcomes in diabetic patients, reducing the relative benefits of CABG over PCI in this population. Conducting large randomized trials should help provide increased clarity in the ongoing debate of PCI versus CABG in diabetic patients.

– Written by Sarah Miller

Source: Park DW, Kim YH, Song HG et al. Long-term outcome of stents versus bypass surgery in diabetic and nondiabetic patients with multivessel or left main coronary artery disease: a pooled analysis of 5775 individual patient data. *Circ. Cardiovasc. Interv.* 5(4), 467–475 (2012).

About the News and Views

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