

EuroPCR 2014 examines vascular response and long-term safety of bioresorbable scaffolds

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At EuroPCR 2014 yesterday, experts discussed the development in evidence for bioresorbable vascular scaffolds, which represent an era of vascular restoration in interventional cardiology. The available data were analysed and participants heard that bioresorbable fixed strut vascular scaffolds are associated with increased acute thrombogenicity due to flow disturbances. This means that patients who are implanted with these devices need to receive ongoing dual antiplatelet therapy. The panellists also pointed out that endothelialisation is further delayed when these devices are used compared with when thin strut drug-eluting stents are used.

Tan Huay Cheem, National University Heart Centre, Singapore, said: "I think one of the greatest attractions of bioresorbable vascular scaffolds is the idea of eventual restoration of normal vasofunction. There is some evidence from imaging data to show that the plaque is modified alongside the stent dissolving. There is also positive remodelling taking place, and this [vascular response](#) is one of the most exciting aspects of the technology."

The diversity of devices that are approaching the market was also emphasised. Michael Joner, CEO, CVPath Institute, Gaithersburg, USA, said: "There is no uniformity in these devices and no class effect. Every device needs to be assessed carefully and individually. The inflammatory response associated with these devices depends on the pace of

degradation, so we need to assess how they degrade over time, and this has important implications for patient safety."

"The long-term safety of bioresorbable vascular scaffolds will depend on various things: if we can see that arterial healing occurs over time; if full degradation occurs in the absence of excess inflammation and if we do not see too much positive remodelling, then these devices can be very beneficial to patient care," Joner added.

"I think the technology is very interesting, but the bar that has been set by drug-eluting stents is very high and bioresorbable vascular scaffolds will need to match this, especially with regard to strut thickness and deliverability," said Prof Chaim Lotan, Head of the Cardiovascular Institute, Hadassah University Hospital, Jerusalem, Israel.

Lotan also commented on the lack of long-term safety data being available. "We need follow-up data of more than five years' duration, possibly up to 10 years, because our previous experience with [bare metal stents](#) and drug-eluting stents has shown that we still see changes up to seven years. So we await long-term data for bioresorbable vascular scaffolds with regard to device behaviour and degradation patterns. We have seen cases where the stent has not yet degraded after three years and this could pose a problem for [patients](#). Will the degradation occur as planned? Will the struts be apposed? Will we see late events such as thrombosis? All these are unanswered questions," he said.

Robert-Jan van Geuns, University of Rotterdam, The Netherlands, pointed to the potential advantages of using bioresorbable vascular scaffolds. "In general, the data emerging are in line with the theory behind these devices: that vascular restoration therapy is going to heal vessels better than metallic stents. The long-term data has been demonstrated in non-complex patients, and we see that these patients do very well. We still need more data in more complex patients; there are

now some non-randomised data available that are out to six-months, but we have to wait for the evidence in more complex patients before we can advocate the use of these devices in such patients," he said.

More information: Further information on press registration may be found at www.europcr.com/page/press/393-press.html

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