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EuroPCR issues statement on bioresorbable stent (BRS) technologies

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Ongoing development of bioresorbable stent (BRS) technologies that are bioresorbed after achieving vessel expansion in percutaneous coronary intervention procedures is an important option to optimise outcomes in patients whose needs are not adequately met with current devices, EuroPCR advised in a statement issued at the close of the 2017 annual course.

"We think it's important to make a statement because of the need to continue to develop this approach for the future, supporting the concept of a stent that disappears in patients with 30, 40, and even 50 years of life expectancy after undergoing a procedure," said EuroPCR 2017 Course Director William Wijns. He added, "The ideal of a stent that does its job and disappears is a valuable long-term goal, especially in young patients with long life-expectancy."

EuroPCR issued the statement to support future developments that can benefit patients after recent studies raised questions about the safety of a currently available BRS device. It is noted that current bioresorbable scaffolds are first-generation devices and show significant mechanical limitations compared to available thin strut metallic drug-eluting stents. Strut thickness and width (which together result in the scaffold footprint) are large to afford sufficient radial strength to BRS devices. As a result, the polymer load is high and lumenal dimensions can be restricted, particularly in vessels smaller than 2.5 mm or at overlap sites.

EuroPCR noted that the Absorb Bioresorbable Vascular Scaffold is the

only currently available BRS device that has been evaluated by randomised controlled trials with medium-term follow-up. Clinical outcomes did not quite match the outstanding results obtainable with state-of-the-art drug-eluting stents, with significantly increased risk of early and late definite and probable scaffold thrombosis, as shown by patient-level meta-analyses of randomised trials. However, post-hoc analysis according to vessel size and adequate procedural technique showed mitigation of scaffold thrombosis, as indicated by Course Director Jean Fajadet. In addition, data from large registries from several countries, including France, Italy and the UK, confirmed the decrease in thrombotic event rates in analysis of sequential data with improved case selection and implementation of pre-dilatation, proper sizing and post-dilatation.

EuroPCR considered that there is no class effect for BRS, because different technologies use different materials and scaffold architecture and have different bioresorption times. "Encouraging results for several first- and second-generation polymeric and metallic (magnesium-based) BRS devices currently being evaluated have been presented during EuroPCR 2017," said Dr Wijns. However, he noted that observational studies included relatively small numbers of patients, and that the data obtained with thinner strut polymeric BRS are encouraging but limited to short-term follow-up. "Until the concerns about bioresorbable stents can be assuaged, current-generation BRS should not be preferred to metallic drug-eluting stents in routine clinical practice," he concluded.

EuroPCR called for responsibility among interventional physicians to protect the potential of BRS as an innovation by avoiding its use in situations where poor results might be predicted. Dr Fajadet also noted the need for continued focus on the fundamentals of good procedural practice, including adequate sizing and good stent expansion to optimise outcomes for patients.

Provided by PCR