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PICCOLETO II: More Support for DCB Safety and Efficacy in Small Coronaries

In-lesion late lumen loss was similar for a gel-based balloon versus an EES, but a trend was seen for more thrombosis with the stents.

By L.A. McKeown October 04, 2019

SAN FRANCISCO, CA—A new gel-based paclitaxel drug-coated balloon (DCB) outperformed an everolimus-eluting stent (EES) in terms of late lumen loss and resulted in comparable diameter stenosis, binary restenosis, and short-term clinical outcome in patients with small-vessel CAD, results from PICCOLETO II suggest.

Presenting here at TCT 2019, Bernardo Cortese, MD (Clinica San Carlo, Milan, Italy), said that although the study is small and not powered for hard endpoints, it adds to existing data hinting that drug delivery via a balloon may optimize outcomes better in small vessels than a stent.

"The best-in-class drug-eluting stents show a rate of target lesion failure

the superiority of DCB in terms of angiographic outcome," he told TCTMD.

PICCOLETO II is the latest trial to show DCB as a potential alternative to DES in patients with small-diameter lesions. At EuroPCR 2019, investigators from the BASKET-SMALL 2 trial presented new angiographic data showing similar late lumen loss with both treatments out to 1 year. Surprisingly, the angiographic data also showed eight cases of stent thrombosis in the DES group versus no complete thrombotic vessel occlusions in the DCB group. The PICCOLETO II data line up with those results.

"Similarly, we found a 1.8% rate of stent thrombosis in the EES arm, and no thrombosis in the DCB arm," Cortese told TCTMD. "We thus confirm the findings of BASKET-SMALL 2. The opportunity not to leave a stent in small vessels may protect from thrombotic events."

Gel May Improve Drug Delivery

PICCOLETO II is a follow up to the PICCOLETO study, in which patients with stable or unstable angina undergoing PCI of small coronary vessels (≤ 2.75 mm) were randomized to the Dior DCB (Eurocor) or Taxus DES (Boston Scientific).

As Cortese explained to TCTMD, the first study used a balloon that had paclitaxel sprayed onto the surface. The drug was lost during transit and manipulation, which the researchers believed prevented it from having the desired effect. For PICCOLETO II, they instead used the Elutax SV (Aachen Resonance), "a new-generation DCB with a gel which protects and mostly helps [paclitaxel] to be delivered to the vessel wall, and persist there for 4 to 6 weeks in order to obtain its effect," Cortese noted. The gel is hydrophilic, which is intended to help the drug stay on the balloon longer and prolong the absorption time. The paclitaxel dose on the balloon is 2.2 μg/мм^2 .

For the multicenter, open-label trial, 118 patients similar to those in the earlier PICCOLETO trial were randomized to the DCB and 114 to the Xience EES (Abbott Vascular). Predilatation was strongly recommended for both strategies, with at least a 30- to 60-second dilatation of the balloon but no specific advice for the EES.

Aside from a higher percentage of renal failure patients in the EES group, there were no significant baseline differences between the two arms. More than half of patients in each group had stable angina and about 20%

Predilatation was performed in 69% of the EES group and 84% of the DCB group, while postdilatation was performed in nearly 60% of the EES group and only 3% of the DCB group ($P = 0.001$). The number of devices used in the DCB group was lower than in the EES arm, but length of devices was a bit longer (8.2 mm vs 6.9 mm; $P = 0.04$).

At 6 months, in-lesion late lumen loss, the primary endpoint, was 0.17 ± 0.39 mm in the EES group and 0.04 ± 0.28 mm in the DCB group, meeting noninferiority criteria for the balloon ($P = 0.03$). There were no significant differences in clinical outcomes, although a trend was seen toward higher TLR in the DCB group ($P = 0.23$).

Minimum lumen diameter, a secondary endpoint, increased more in the DES group (from 0.83 mm before the procedure to 2.29 mm after the procedure) than in the DCB group (0.82 mm to 1.89 mm). Percent diameter stenosis changes, however, were similar in both arms. Other secondary endpoints of percent diameter stenosis and binary restenosis were similar between the treatment arms at 6 months (both in-stent and in-segment).

Smaller Lesions, Bigger Payoff With DCBs?

According to Cortese, the PICCOLETO II outcomes with regard to late lumen loss are among the best so far in small-vessel disease, a setting that includes studies such as PEPCAD SVD, BELLO, RESTORE SVD, and FASICO NATIVES.

Discussant Fernando Alfonso, MD, PhD (Hospital Universitario La Princesa. Madrid, Spain), said he was “nicely surprised” by the results of PICCOLETO II.

In theory, as you go smaller and smaller, the benefits of non-scaffold-based therapy might be even greater," added discussant Robert M. Bersin, MD (Swedish Heart & Vascular, Kirkland, WA). “Have you broken this down to the very small [lesion] subsets, like 2.22 mm and smaller to see whether or not you get a signal of superiority with DCB? Overall you have equivalence here, but you may even be superior the smaller you go.”

Cortese responded that the study is a proof-of-concept, and while that possibility does exist, it remains to be shown in future trials.

Given that the drug on the balloon is paclitaxel and that a meta-analysis recently turned the endovascular community on its head with suggestion that this drug may increase mortality when used to treat PAD, Cortese told TCTMD that long-term follow up of patients will be conducted “even if all the studies performed in the coronary arena till now never gave

Sources

Cortese B. Drug-coated balloon vs drug eluting stent for small coronary vessel disease: 6-mo primary outcome of the PICCOLETO II randomized clinical trial. Presented at: TCT 2019. September 27, 2019. San Francisco, CA.

Disclosures

Cortese reports consulting for Abbott Vascular, Astra Zeneca, Kardia, Innova, Stentys, Daiichi Sankyo, Philips-Spectranetics, Reva, Bayer, and Cardinal; honorarium from Amgen, Stentys, Sanofi, B. Braun, Servier, and Alvimedica; and institutional research/grant support from AB Medica, St Jude, and Abbott.