APERTO DCB "superior" for AV fistulae lesions in new RCT

Professor Dr Qizhuang Jin (Peking University First Hospital Nephrology Department, China) spoke to *LINC Today* about the recently published results of the first randomised controlled trial (RCT) comparing the APERTO® drug-coated balloon (DCB) with high pressure angioplasty balloon in the treatment of arteriovenous fistulae (AVF) lesions[1].

APERTO OTW (over-the-wire) DCB achieved better primary patency rates (peak systolic velocity rate, PSVR≤2.0) at six months in treating patients with AVF lesions than high pressure angioplasty balloons (DCB 65% vs. control 37%, rate difference 28%, 95% CI 13–43%, p<0.001), the trial revealed. APERTO OTW also achieved statistically superior results at 12 months compared to the control group in terms of target lesion intervention-free survival (DCB 73% vs. control 58%, p=0.04) and target shunt intervention-free survival (DCB 73% vs. control 57%, p=0.04). The average degree of target lesion stenosis at six months was not significantly different between the two groups (DCB 44% ± 16% vs. control 49% ± 18%, p=0.09). There were no significant differences in major adverse events or in device, technical, clinical, or procedural success rates between the groups at one year.[1]

The study included 161 haemodialysis patients with fistulae dysfunction in ten centres in China. Subjects were randomly assigned in two groups, from which 78 patients received the APERTO OTW and the other 83 patients received high pressure balloon. All patients were followed up at one, three, six and 12 months with echo-Doppler ultrasound. This study was promoted by Cardionovum Zhuhai, the Chinese subsidiary of Cardionovum GmbH, a German company with headquarters in Bonn manufacturing drug-coated balloons and drug eluting stents, including the APERTO OTW and other innovative medical devices.

> "Results clearly demonstrate the superiority of APERTO OTW versus a high pressure balloon."
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> **Qizhuang Jin**

Professor Jin told *LINC Today*: "The main purpose of the APERTO AVF RCT China was to evaluate the safety and efficacy of APERTO OTW versus a high-pressure angioplasty balloon in the treatment of autologous AVF lesions in haemodialysis patients. Results clearly demonstrated the superiority of APERTO OTW."

"The incidence of death and stroke in the study group and the control group were comparable, meaning that the safety of the

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APERTO OTW is not statistically different from a high-pressure uncoated angioplasty balloon."

"Considering these clinical data on the APERTO OTW high-pressure DCB, this novel technology will be an essential therapy to treat AV stenosis and other complications. I believe that combining standard angioplasty with high pressure and paclitaxel will offer a higher rate of success post procedure, and prolonged patency compared to common therapies."

These findings contributed to the CFDA's approval of the APERTO OTW in China, making it the first DCB approved for treating AVF lesions. "The APERTO AVF RCT China results are a step towards the acknowledgement of paclitaxel DCBs (and specifically the APERTO OTW) as a safe and effective first-line treatment for AVF stenosis," commented Professor Jin.

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Stenosis is the most common complication after AV access creation, he added, with AVF maturation failure ranging from 20–60% in observational studies. Venous stenosis is often the result of neointimal hyperplasia and leads to several serious sequelae in both AVF and arteriovenous grafts (AVGs).

"Stenosis also causes dysfunction in mature AVFs resulting in inadequate haemodialysis clearance, thrombosis, and eventual abandonment. AVFs are also susceptible to stenosis developing at the graft-vein junction, leading to thrombosis in 80% of AVFs."

"Percutaneous transluminal angioplasty (PTA) is the first-line treatment for stenosis in the access circuit. Although this generally remains the case in the modern era of vascular access, several important clinical trials (including APERTO AVF RCT China) and device innovations may alter the indications for angioplasty and the types of balloons and stents to be used for treatment of stenosis."

The next step for APERTO OTW, explained Professor Jin, is the launching of a real world, large scale study to evaluate the safety and effectiveness of AV stenosis treatment with the APERTO OTW. "Furthermore, we hope to answer how the APERTO OTW high-pressure DCB will perform without predilation, to reduce the number of procedural steps."

The APERTO AVF RCT China is the first trial comparing APERTO OTW DCB against high-pressure angioplasty balloon, he noted, while the IN.PACT AV IDE Trial[2] compared DCB against a standard angioplasty balloon. According to the results of another RCT published in the *New England Journal of Medicine* a few months ago, treatment of haemodialysis arteriovenous fistulas with a drug-coated balloon provide primary patency, including freedom from clinically driven target-lesion revascularization, that was superior to that provided by standard balloon angioplasty.

"Moreover, the primary patency in APERTO RCT is based not only on CD-TLR, but also on echo-Doppler ultrasound quantitative measurement of PSVR, evaluating patency reduction even before symptoms occur. In the APERTO RCT, 80% of subjects receiving DCB had a longer intervention-free period (DCB 262 days vs. control 172 days, a 34% reduction), showing clinical benefits for the patients. The clear evidence provided by these two RCTs could be the basis for updating international guidelines on the treatment of AVF lesions in haemodialysis patients."

APERTO OTW (Cardionovum, Bonn, Germany) is the first high-pressure DCB specifically designed for the management of AV fistula stenosis. The device is designed with one side possessing a short shaft, which makes handling easier (40 cm for AV fistula and 80 cm for central venous stenosis), and a unique coating technology consisting in a matrix of 3.0 mg/mm² paclitaxel and ammonium salt excipient (called SAFEPAX®), exclusively designed to keep the lowest drug wash off rate during the whole procedure while guaranteeing the drug release on the site lesion.

References

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