The device was retrieved and the patient was planned for a larger custom made Cera PDA occluder (Lifetech Scientific, Shenzhen, China). In the second setting, using the same hardware, a custom made 30/28 mm Cera PDA occluder was positioned across the PDA. A descending aortogram, done 15 minutes after positioning the device, showed some flow across the device.

Echocardiography done next day showed no flow across the PDA.

RESULTS Six patients with large PDA measuring 14-16 mm were taken up for percutaneous device closure. After failed attempt with 24 mm ASD device & 16 mm AGA PDA device in first cases all four cases were closed successfully with life tech 30/28 mm PDA device closure. In two cases children between 12-14 yrs PDA device of 30/28 was too big to obstruct aorta and was replaced with 24 mm muscular VSD device successfully. Two patients have had follow up cath angio which confirmed low PA pressure & no obstruction of aorta or LPA.

CONCLUSION In selected cases of large PDA measuring 14-16 mm
1) PDA device with life tech 30/28 mm is successful (PDA device is two times the size of PDA)
2) 30/28 mm PDA is too large for children of 12 years & below & it results in obstruction of aorta
3) this is more cost effective simple than surgery

A repeat angiogram, done 30 minutes later showed markedly reduced flow across the PDA. The device was released at this time, under fluoroscopic guidance.

DRUG-ELUTING STENTS (TCTAP A-056 TO TCTAP A-064)

TCTAP A-056
Long-Term Outcomes After Percutaneous Coronary Intervention with the 38mm Length Resolute Zotarolimus-Eluting Stent
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BACKGROUND The Resolute™ zotarolimus-eluting stent (R-ZES) demonstrates favorable outcomes in the treatment of coronary lesions across a range of patient and lesion complexity. However, limited long-term data is available on the treatment of long lesions. The RESOLUTE 38-mm substudy of the RESOLUTE Global Clinical Program was prospectively designed to include patients requiring treatment of de novo lesions in native coronary arteries with a 38-mm length R-ZES.

METHODS The RESOLUTE 38-mm substudy includes patients from the RESOLUTE US (R-US) and RESOLUTE Asia (R-Asia) prospective, observational, nonrandomized, multicenter trials that enrolled patients from 29 sites across the United States (U.S.) and 17 sites across Asia. Patients enrolled in these trials who received at least one 38-mm R-ZES in a lesion ≤35 mm in length and reference vessel diameter of 3.0 to 4.2 mm with up to two lesions (in separate vessels) were included in the 38-mm substudy. Target lesion failure (TLF) was defined as the composite of cardiac death (CD), target vessel myocardial infarction (TV-MI), or clinically driven target lesion revascularization (TLR). The RESOLUTE 38-mm substudy was a pre-specified analysis; a post hoc analysis by geography (Asia vs. US) was also conducted.

RESULTS A total of 223 patients (114 in R-US and 109 in R-Asia) were enrolled. Mean lesion length was 25.2 ± 8.8 mm (24.2 ± 9.1 in R-US vs. 26.3 ± 8.5 in R-Asia, p = 0.059). Compared with R-Asia patients, R-US patients were older (65 ± 10 mm vs. 57 ± 10 mm, p < 0.001), and more likely to have diabetes mellitus (44% vs. 31%, p = 0.051) and insulin dependent diabetes mellitus (15% vs. 6%, 0.021). Three-year follow-up was available in 221 (99.1%) patients demonstrating a low incidence of adverse clinical events (Figure, left). There was furthermore no difference at 3 years in the rates of TLR, CD, or TV-MI between R-Asia and R-US; however, TLF was lower in R-Asia (Figure, right).

CONCLUSION The 38-mm length R-ZES was associated with excellent and sustained clinical outcomes during long-term follow-up. Patients enrolled in Asia appeared to be less complex than those enrolled in the U.S., but clinical events remained similar other than for TLF.