femoral venous and arterio venous Loop was created with the help of Terumo wire. PDA Sheath was passed through RA, RV and then into Aorta with Kissing technique sheath was positioned in LV. PDA device was loaded in sheath. Device was positioned on LV side first and then on RV side. Position was checked on 2D-Echo which was found to be accurate. Wire and catheter was removed. Post procedure treatment with steroids was advised as per standard treatment. Antiplatelet aspirin was recommended for one month.

RESULTS Procedure was done successfully in 66 without any complications. In 15 cases Transient BBB was developed on during procedure. In 1 case complication of CHB occurred during procedure in which temporary pace maker (TPM) was implanted for 3 days. In another case, complication of CHB occurred in ICU after 3 hours in which TPM was done for 2 days. In 2 cases device was embolized, 1 device successfully retrieved with help of the basket snare and continued procedure with bigger size device, another 1 case went to surgery. 1 case of death was observed on 5thday, which was due to stroke. At 1 year follow up no shunt was noted in ECHO and ECG remained same with no additional conditional defect.

CONCLUSION Transcatheter closure is safe and efficacious in selected cases of perimembranous and muscular VSD using PDA device. Trascatheter closure of ventricular septal defect using PDA devices is gaining acceptance in selected cases as compare to surgical closure which is associated with morbidity and mortality. Potential advantages of the transcatheter closure over conventional surgery include a smaller incision, shorter stay and fewer complications.

TCTAP A-055

Transcatheter Closure of Large PDA with Custom Made Devices: Useful Alternative to Surgery

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BACKGROUND Transcatheter closure of patent ductus arteriosus (PDA) is a simple, safe and effective procedure, being done throughout the world. Since the first use of Ivalon plugin 1967 (1), no other shunt lesion has seen so much advancement in the development of device technology as PDA, the latest being the second generation Amplatzer vascular plugs (St Jude Medical, Plymouth, IN, USA). However, the maximum sizes available amongst the commonly used devices are 16/14 mm for Amplatzer duct occluder I (AGA Medical corporation, Golden Valley, MN, USA), 22mm for Amplatzer vascular plug II and 24/22 mm for Cera PDA occluder (Lifetech Scientific, Shenzhen, China).

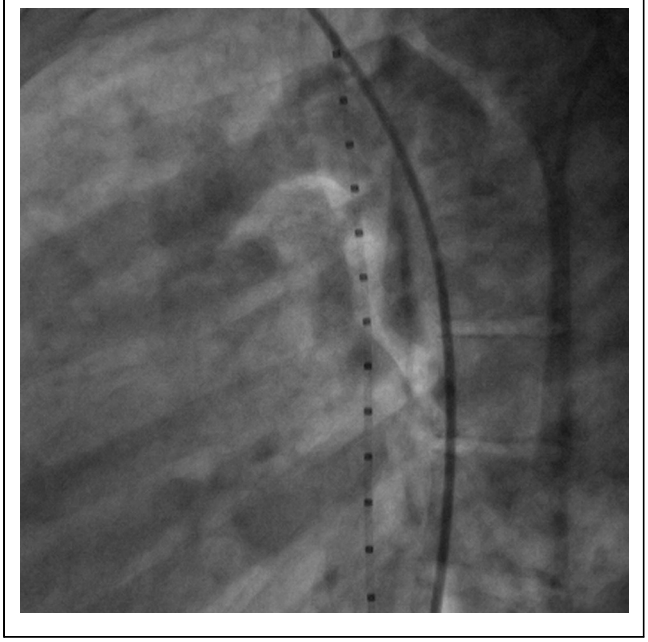
In developing countries, many patients with large PDA present late in life. In the absence of large size devices, the only option left for these patients is surgical ligation. Here we report four patients with large PDA, and their transcatheter closure with custom made large PDA occluder or muscular ventricular septal defect (VSD) occluder.

We are presenting six cases of large PDA measuring 14-16 mm in young adolescent & adult where in in four cases were closed with 30/28 mm PDA from life tech china & in two cases 24mm muscular VSD device was used. PDA device used was two times the size of PDA. In two children on 12 years PDA 30/28 was too large & was changed to 24 mm muscular VSD device successfully.

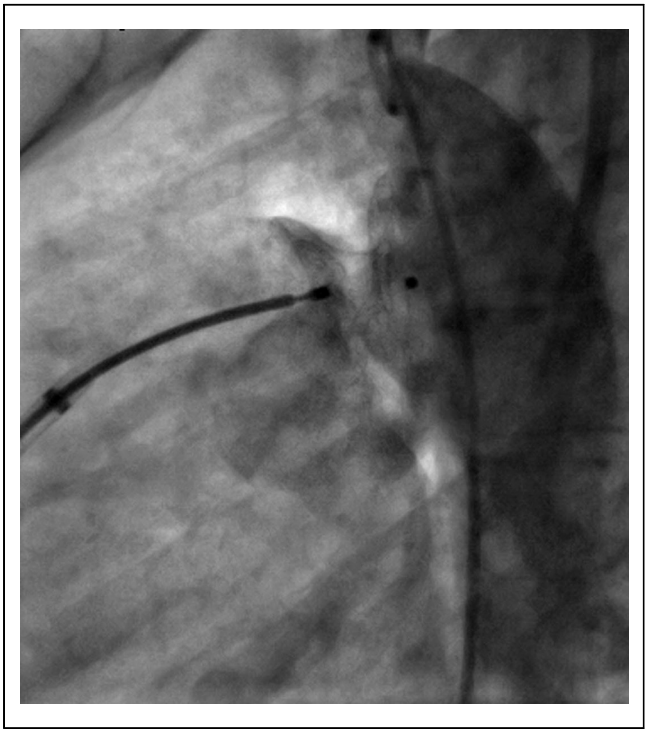
CONCLUSIONS Patients with large PDA diagnosed late in life are commonly seen in developing countries. Dedicated custom-made transcatheter devices can be used successfully for transcatheter closure of these PDA without significant complications instead of using expensive muscular VSD occluders or surgery.

METHODS Case 1

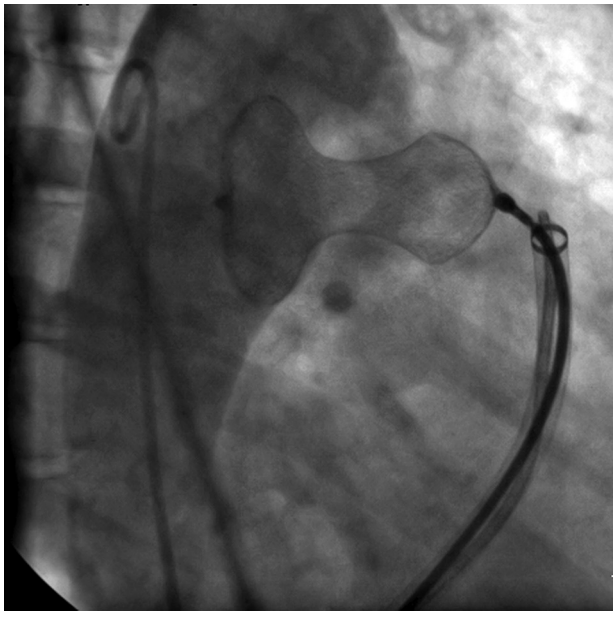
A 16 years old patient was referred with an incidentally detected murmur. On examination, she had a continuous murmur in the left first and second intercostal spaces. Echocardiography showed a large PDA with enlarged left atrium (LA) and left ventricle (LV) and preserved left ventricular systolic function. After an informed consent, she was taken up for cardiac catheterization and device closure. Both femoral artery and vein were accessed after giving local anaesthesia. Hemodynamic study revealed pulmonary artery systolic pressure (PSAP) of 48 mmHg, systemic systolic pressure of 130 mmHg, Qp/Qs of 2.83 and PVR/SVR of 0.09. Descending aortogram was done using a 6F pigtail catheter (Cordis corporation, Florida, USA) and ductus size was measured to be 15 mm in lateral view.



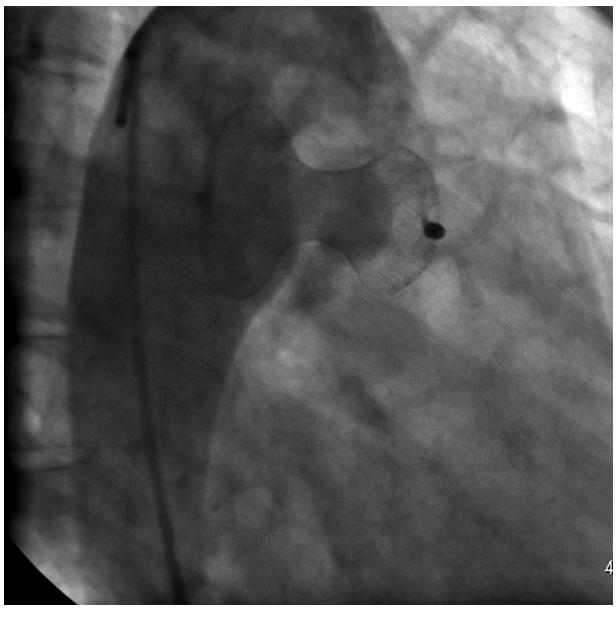
After crossing the PDA from pulmonary artery side using a Multipurpose catheter (Cordis corporation, Florida, USA), a 0.035 inch, and 260cm Amplatzer extra stiff guide wire (AGA Medical Corporation, Golden Valley, MN, USA) was introduced. A 14F cook delivery sheath (Cook, Bloomington, IN) was inserted over the guidewire and a 24 mm atrial septal defect occluder (AGA Medical corporation, Golden Valley, MN, USA) was positioned across the PDA. A check angiogram showed substantial flow across the device.



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.



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



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 mm 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

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.