highly effective and safe primary treatment modality. Initial thrombosis rates exceeded 90% and no serious complications were observed in this series despite a high rate of concomitant antiplatelet and antithrombotic therapy.

TCT-404
Efficacy and Safety of Total Percutaneous Femoral Closure Following Stent Graft Implantation Using Preclose Technique
Won Ho Kim1, Sanghoon Shin2, Byeong-Keuk Kim2, Young-Gak Ko2, Myeong-Ki Hong2, Yangsou Jang2, Donghoon Choi2
1Edui University Hospital, Edui University School of Medicine, Daejeon, Korea, Republic of, 2Yonsei Cardiovascular Hospital, Yonsei University College of Medicine, Seoul, Korea, Republic of

Background: The preclose technique with the 6 F Proglide for complete percutaneous endovascular aortic repair have not been sufficiently evaluated. We investigated the efficacy and safety of the preclose technique in a sufficient and large cases.

Methods: The medical records of 367 patients with 599 preclose techniques for various aortic repairs were reviewed. Procedural success was defined as hemostasis achieved by the preclose technique, without the need for surgical or endovascular procedures. Access related major adverse event (ARMAEs) were considered as those event, such as infection, bleeding, new onset ischemia of the lower leg, hematoma, pseudoaneurysm, arteriovenous fistula, embolization, laceration, femoral artery thrombosis, nerve injury, or death by access site injury.

Results: Procedural success was achieved in 359 of 367 patients (97.8%) and 591 of 599 left or right femoral sites (98.7%). All cases of procedural failure were treated by immediate surgical repair of femoral arteries. The preclose technique was more successful in the smaller sheath. ARMAEs developed in 25 of 367 patients (6.8%) and 26 of 599 sites (4.3%). Access site hematoma was the most frequent adverse events (16 of 367 patients (4.4%) and 17 of 599 sites (2.8%), followed by puncture site pseudoaneurysm (7 of 367 patients (1.9%) and 7 of 599 sites (1.2%). Bleeding after arterial closure occurred in 6 of 367 patients (1.6%) and 6 of 599 sites (1.0%). In 2 of 367 patients (0.5%), there was an infection at the puncture site. There were two cases of distal embolization, one case of acute femoral thrombosis, and one case of a vascular laceration at the puncture site. There were no access site related nerve injury, arteriovenous fistula or death complicated by access site.

Conclusions: The preclose technique can be used to achieve hemostasis for stent graft procedure successfully, with a high rate of procedural success and an acceptable rate of adverse event, the most common being puncture site hematoma formation.

TCT-405
Transradial approach decreases in-hospital mortality in patients with cardiogenic shock. A single-center experience
Oriel Rodriguez-Leor1, Eduard Fernandez-Noferias1, Xavier Carrillo1, Josepa Maury1, Carolina Oliete1, Carmen Rival1, Antoni Bayes-Genis1
1HU Germans Trias i Pujol, Badalona, Spain

Background: Transradial approach (TRA) in percutaneous coronary intervention (PCI) has increased over the past few years. Its use has been shown to decrease mortality compared with the transfemoral approach (TFA) in patients with acute coronary syndrome (ACS). Comparative studies have systematically excluded patients with cardiogenic shock (CS).

Methods: We carried out a prospective, observational registry study of consecutive patients undergoing emergent revascularization between February 2007 and January 2012. An analysis of the clinical evolution of patients with CS during hospitalization was performed according to the approach used in the PCI.

Results: Of 1,400 emergency procedures, 122 had CS, 80 underwent PCI by TFA (65.6%) and 42 by TFA (34.5%). The main reason for choosing TFA was the absence of radial pulse (54.9%). Mortality (64.3% vs. 32.5%, p=0.0001), serious access site complications (11.9% vs. 2.5%, p=0.003) and MACE (combination of death, infarction, stroke, serious bleeding, and postoperativeencephalopathy) (73.8% vs. 43.8%, p=0.0001) were greater in TFA patients. In the multivariate analysis, TFA was a predictor of mortality (OR 0.39 [0.15-0.97]; other predictive factors were age=75 [3.47 [1.35-9.82]), previous treatment with diuretics [3.67 [1.21-11.12]) and the success of the procedure (0.08 [0.02-0.24)]).

Conclusions: In centers with experience, TRA approach for PCI is possible and safe in patients with CS in up to two thirds of the patients. The main cause that prevented the use of TRA was the absence of radial pulse. In the multivariate analysis, TRA was associated with a lower risk of mortality.

TCT-406
Trans-radial balloon aortic valvuloplasty
Steven Goldberg1, Creighton Don2
1University of Washington Medical Center, Seattle, WA, 2University of Washington, Seattle, WA

Background: Balloon aortic valvuloplasty can be useful for palliation of symptoms in pts not eligible for surgical or transcatheter aortic valve replacement, or a bridge to AVR. Occasionally transfemoral access is impossible or challenging, due to vascular disease or morbid obesity. We present our experience with transradial access for balloon aortic valvuloplasty in pts not candidates for transfemoral approach.

Methods: 5 pts presented with critical aortic stenosis without femoral access. Transradial access was successfully obtained in all pts. In 1 pt a vascular loop prompted a change from the right to the left radial approach - the others were done via right radial access. Internal jugular venous access was used for PA catheter and pacing. After crossing the aortic valve using 6Fr amplatz 1 catheter with straight wire, and changing out for a dual lumen pigtail. Over an exchange length wire, the 6 Fr sheath was exchanged for an 8 Fr, and a 22 mm Tyshack balloon was advanced across the aortic valve and dilated during rapid pacing. Due to inadequate hemodynamics, in 1 case the 8 Fr sheath was exchanged for a 9 Fr, and a 25 mm Tyshack balloon used.

Results: Of the 5 pts aortic valvuloplasty was attempted and successfully performed. In 1 pt with morbid obesity vigorous diuresis was instead successful in treating his CHF and one year later he underwent successful surgical AVR. 1 of the pts with successful balloon valvuloplasty had occlusive lower extremity arterial disease and need for warfarin for a mechanical mitral valve, the other had morbid obesity (mean weight 168 kg). All pts had hemodynamic improvement, mean AV gradient decreased from 47 to 36 (23%), and AVA increased from 0.85 to 1.1 (29% increase). The pt with 9 Fr sheath had small amount of tissue removed with removal of the 9 Fr sheath, but no clinical complications in any pt.

Conclusions: Radial artery access is a feasible option for the performance of balloon aortic valvuloplasty in patients with poor femoral artery access.

TCT-407
Vascular Hemostasis Devices: Food And Drug Administration Perspective On Reported Risks
Robertta Sullivan1, Deborah Yoder2
1FDA/CDRH, Silver Spring, MD

Background: Vascular Hemostasis Devices (VHD) are regulated by FDA as high-risk Class III medical devices requiring Pre-Market Approval (PMA). First approved in 1995, these devices have evolved and been broadly adopted for hemostasis use, with current use estimates up to 50% of all coronary procedures. FDA databases were searched to provide a regulatory summary and device profile overview.

Methods: The PMA, Adverse Event, Recall, Registration and Inspection databases were searched using the device product code and years 2007 through 2011. Statistical testing used t-test and X2, as appropriate for proportions or means, with significance level of 0.05.

Results: The FDA registration and listing database identified 8 different manufacturers and 11 different devices. FDA approval of the 11 devices occurred from 1995 through 2011, 10 of the 11 listed devices are made in the US by US manufacturers. Two manufacturers represented 95% of the VHDs reported in adverse events. The number of annual adverse events reports increased 300% from 1,402 in 2007 to 4,243 in 2011, with a five year total of 14,120 reports received. Geographically, 72% of the adverse events occurred in the US and 27% in 53 other countries. Females were disproportionately represented (p<0.001, 44% vs. 34% expected). Patient age ranged from 4 to 98 years, with women found to be older than men (65.8 vs. 64.7, p<0.001). A total of 164 reports for death as the patient outcome were received. For women, deaths were present in 3.38% of the reports compared to 1.28% for men (p=0.001, odds ratio 2.7 [1.908, 3.802]). During the timeframe there was one US recall for a compromised sterility issue and one foreign recall for increased failure rates. US Manufacturer and contractor inspections included four cases of FDA citations requiring actions.

Conclusions: Reasons women experience higher risks are not known but appear to persist despite product experience and design changes. More research on gender differences and device design is recommended. Increased overall numbers of VHD adverse event reports to FDA likely parallels temporal increases in use. Limitations relate to missing data for patient age and gender, and known underreporting of adverse events.

TCT-408
Sheathless Guide Catheters in complex Transradial PCI. A Single Center Experience
Raúl Valdesuso1, Francisco Lacunza1, Juan Gimeno1, Juan García de Lara1, Jose Hurtado1, Eduardo Pinar1, Mariano Valdes1
1Hospital Universitario Virgen de la Arrixaca, Murcia, Spain

Background: The Sheathless Guiding Catheter (SOC) (Sheathless Eucath, Asahi Intec Co, Japan) has Hydrophilic coatings that enhances catheter tractability through tortuous vessels and allow PACing with radial spasm and performing Percutaneous Coronary Intervention (PCI) by radial approach in complex cases. We reported our experience in 91 patients (pts) with complex transradial approach in whom SGC was used to avoid femoral cross over to complete the procedure.