access may increase the time required, patient discomfort, risk of arterial spasm, and the need for cross-over to other access sites. Ultrasound (US) guidance has been demonstrated to facilitate vascular access and reduce vascular complications in multiple sites and locations, but has not been tested in a multicenter fashion in transradial access.

Methods: We conducted a multicenter randomized controlled trial of 473 patients undergoing transradial cardiac catheterization. Four centers (6 hospitals) and 16 operators trained in US guidance participated in the study. Patients were randomized to needle insertion with either palpation (P) or real-time US guidance (237 P, 236 US). Primary endpoints were the number of forward attempts required for access, first pass success rate, and time to sheath insertion.

Results: The mean number of attempts was reduced with US guidance (1.65 ± 1.2 vs. 3.05 ± 3.4, p < 0.0001) and the first pass success rate improved (64.8% vs. 43.9%, p < 0.0001). The mean time to sheath insertion was reduced (83 ± 78 vs. 113 ± 102 seconds, p < 0.0016) and was the median time to insertion (60 [IQR 42-91]) vs. 75 [50-119], p < 0.005. Ten patients in the control group required cross-over to US guidance after 5 minutes of failed palpation attempts with 9/10 (90%) having successful sheath insertion with US. The number of difficult access procedures was decreased with US guidance (6 vs. 44 for > 5 attempts, p < 0.001; 6 vs. 15 for > 5 min, p = 0.07). There was no significant difference in the rate of operator-reported spasm (4.2% P vs. 5.5% US, p = 0.53), crossover to other access sites (2.5% P vs. 1.3% US, p = 0.34), mean patient pain scores (range 0-10) following the procedure (0.7 P vs. 0.89 US, p = 0.29), or bleeding complications (1.7% P vs. 2.1% US, p = 0.75).

Conclusions: Ultrasound guidance improves the success and efficiency of radial artery cannulation in patients presenting for transradial catheterization. NC101605292

TCT-279
Use Of 4 French Systems For Treating Fem-Pop Lesions: Advantages And Disadvantages: Lessons From The 4EVER Trial Using Astron Pulsar Stents And No Closure Devices
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Background: One of the more recent treatment options for femoro-popliteal, atherosclerotic lesions, is the application of self-expanding nitinol stents. The use of 4 French systems, can reduce access site related complications. Although there are clear indications of the benefits of 4F devices for peripheral applications, scientific evidence to support this thesis is still lacking today. The 4EVER trial attempts to investigate the long-term results (up to 24 months) in patients presenting with intermittent claudication or critical limb ischemia by use of 4 French systems.

Methods: The 4EVER trial is a prospective, non-randomized, multi-center, multi-national, controlled trial conducted in 5 sites in Belgium and Germany. Between June 2010 and May 2011, 120 patients were enrolled. The primary endpoint was primary patency at 12 months, defined as freedom from >50% restenosis at 12 months as indicated by an independently verified duplex ultrasound peak systolic velocity ratio (PSV) >2.5 in the target vessel with no reintervention.

Results: Of the 120 patients enrolled, 82 (68.33%) were men and the mean age was 71 (47-90; ±9.70) years. 83.33% had intermittent claudication and 16.67% presented with critical limb ischemia. For lesion treatment, 70 (58.33%) patients received an Astron Pulsar stent, 46 (38.33%) were treated with Pulsar-18 stent placement and 4 (3.33%) received mixed stent use. The mean lesion length was 43.50mm in the Astron Pulsar group, 105.44mm in the Pulsar-18 group and 145.00mm in the mixed stent group. Kaplan Meier estimation reported a 6-month primary patency rate of 90.0% and a 6-month freedom of target lesion revascularization of 95.4%. Primary patency rates for the Astron Pulsar group, Pulsar-18 group and mixed stent group at 6 months were 92.2%, 85.3% and 100% respectively. For 103 patients, compression time was recorded with a mean compression time of 6.12 (2.00-15.00) minutes.

Conclusions: With a high primary patency at 6 months and a low compression time, this first analysis indicates the benefits of treatment with 4 French systems. As these first preliminary 6-month data show promising results, full 12-month data will be presented at TCT 2013.

TCT-280
Impact of catheter sheath insertion into radial artery on vascular endothelial function as assessed by reactive hyperemia peripheral arterial tonometry
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Background: The transradial approach has been accepted as an alternative entry method for coronary angiography and angioplasty. However, this procedure carries a risk of injury to the endothelium in the radial artery. Flow-mediated dilation (FMD) has often been used to investigate vascular endothelial function, and some reports have examined the impact of catheter sheath insertion on vascular function using this method. However, the assessment is limited in that the focus is on only one point of the brachial or radial artery. Reactive hyperemia peripheral arterial tonometry (RH-PAT) has recently been developed for the assessment of endothelial function in peripheral arteries, offering higher reproducibility and easier manipulation. The aim of this study was to examine vascular dysfunction caused by catheter sheath insertion into a radial artery using RH-PAT and to compare differences in injuries according to the size of sheath.

Methods: RH-PAT was measured using an Endo-PAT2000 system. Forty-three patients receiving transradial catheterization with 6-Fr sheaths (n=17) or 4-Fr/5-Fr (n=26) sheaths underwent Endo-PAT2000 before and the day after catheterization. RH-PAT was assessed in the arm of sheath placement and in the other arm as a control. Thirteen subjects in the 6-Fr group were reassessed using RH-PAT at 6 months after catheterization.

Results: RH-PAT values decreased from 2.42±0.67 before catheterization to 2.08±0.41 the day after catheterization in the 6-Fr group (p<0.05), while the change in the non-6-Fr (4-Fr/5-Fr) group was not significant (from 2.22±0.56 to 2.08±0.61; p=0.24). In both groups, RH-PAT of the non-catheterized arm was unchanged. At 6 months after catheterization, RH-PAT values had not returned to baseline (2.59±0.68 before catheterization and 2.24±0.47 at 6 months after catheterization; p=0.138).

Conclusions: Insertion of a 6-Fr catheter sheath into the radial artery impairs vascular endothelial function as assessed by RH-PAT. In addition, such injuries do not recover completely within 6 months. These findings suggest that smaller sheaths (<6-Fr) should be used to prevent severe endothelial dysfunction in the radial artery during transradial catheterization.

TCT-281
Usefulness of a systematic “Crossover wire Technique” to improve percutaneous treatment of vascular complications in Transfemoral Transcatheter Aortic Valve Implantation
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Background: Access site difficulties are a major cause of complications following TAVI procedures. Different techniques have been proposed to optimize the femoral hemostasis, advancing an angioplasty wire from the ipsilateral or contralateral femoral artery in cases of vascular complications. However, once the complication is in place, it may be difficult to cross the bleeding point with a wire. This study sought to evaluate the usefulness of a systematic “Crossover wire Technique” advanced from the contralateral femoral artery at the beginning of the procedure, to manage potential vascular complications and to improve the hemostasis during TAVI procedures.

Methods: Retrospective analysis of 159 patients undergoing TAVI with 18F introducer and percutaneous closure with Prostar device were analyzed. Patients were divided into 2 sequential groups: group I (“without wire”, n=57, treated up to July 2010) and group II (n=112), including patients since August 2010 that underwent the “Crossover wire technique”. Pre-procedural variables, complications (VARC-2 criteria) and treatment were compared.

Results: Results: are expressed in the table. Total number of vascular complications was similar in both groups. Prostar closure failure resulted the most frequent complication. Life threatening bleedings (3 vs 12%, p=0.04), major vascular complications (7 vs 18%, p=0.04) and mortality (6 vs 18%) were lower in group II. Surgical repair was undertaken more frequently in group I (7 vs 1%, p=0.06) while a percutaneous management with covered stent implantation was preferred in group II (21 vs 9%, p=0.05).

Conclusions: The “Crossover wire technique” does not reduce the incidence of vascular complications but decreases their severity and clinical impact, facilitating a percutaneous resolution. The team experience might have influenced in the results.

JACC Vol 62/18/Suppl B | October 27–November 1, 2013 | TCT Abstracts/POSTER/Vascular Access and Closure B91