

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 ± 124 seconds, $p = 0.0016$) as 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 (0.82 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. NCT01605292

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 are 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, multinational, 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 (PSVR) < 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 8.12 (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.

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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.

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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.

	Group 1(57)	Group 2(112)	p
30-day complications in both groups (VARC-2 definitions) and mortality			
Bleedings	17 (30)	21 (19)	0.19
Life threatening bleedings	7 (12)	3 (3)	0.04 (*)
Major bleedings	1 (2)	6 (5)	0.42
Minor bleedings	9 (16)	12 (11)	0.47
Total vascular complications	23 (40)	31 (28)	0.54
Major vascular complication	10 (18)	7 (6)	0.04 (*)
Minor vascular complication	9 (16)	20 (18)	0.65
Closure device failure	4 (7)	5 (4)	0.72
Balloon angioplasty for complication management	8 (14)	8 (7)	0.21
Stent implantation for complication management	5 (9)	22 (20)	0.05 (*)
Surgical repair	4 (7)	1 (1)	0.06
Global mortality	10 (18)	6 (5.4)	0.02 (*)
Vascular complication mortality	3 (5)	0 (0)	0.05 (*)

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Feasibility and Safety of Transradial Coronary Intervention Using 6.5 French Sheathless Guiding Catheter during ST-segment Elevation Acute Coronary Syndrome (STEACS) in Patients with Small Radial Artery: A Multi Center Registry.

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Background: Transradial approach during STESCA is used more frequently and is associated with reduced rate of vascular complications and mortality. However, the small size of the radial artery is sometimes a limitation of this technique. A sheathless guiding catheter is available which is 2 french smaller than the sheath and has a hydrophilic coating along its entire length. The aim of this study is to investigate the feasibility and the safety of using this sheathless catheter during STEACS treatment in patients with small radial arteries.

Methods: From March 2009 to May 2013 in three french hospitals, 40 patients had a primary PCI through transradial approach using sheathless catheter after failure to introduce 6F sheath or severe frictions with 5F angiography catheter.

Results: The 40 patients were 65.62 ± 16.41 years old (40 to 91), 23 were women (57.5%). Patient baseline characteristics: 10 (25%) had a history of coronary artery disease, 18 (45%) were heavy smokers, hyperlipidaemia in 20 (50%), 15 (37.5%) had hypertension, diabetes in 7 (17.5%) and coronary family history in 5 (12.5%) patients. 12 (30%) patients had a lesion in the LAD, 22 (55%) in the RCA and 6 (15%) in the circumflex coronary artery. The average volume of product of contrast is 128.55 ml. The total number of 49 stents were used during these procedures (20 BMS, 29 DES) with 1.2 stents/patient. Door to Balloon average time was 35.25 minutes and the procedural time was 47.64 minutes. Adjunctive devices used in this cohort included thrombus-aspiration catheters in 32 patients (80%) and the technique of kissing balloon in 7 patients (17.5%) undergoing bifurcation PCIs. One patient had an acute intra stent thrombosis treated with thromboaspiration then angioplasty with balloon only. Rotablator atherectomy was implemented in one patient for very calcified lesion. The technical success rate of the procedures using the sheathless catheter was 100% without any conversion to femoral approach. There were no radial artery site complications.

Conclusions: The use of sheathless guiding catheter safely increases the feasibility of transradial approach for primary PCI.

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Balloon-Assisted Pseudoaneurysm Injection (BAPI) for Non-surgical Treatment of Complex Femoral Artery Pseudoaneurysm

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Background: PSA is a complication of femoral access occurring in 0.5-1.5% of diagnostic procedures and up to 6% after interventions. Current non-surgical strategies for management of PSA are limited by variable success rates, physical discomfort, and

risk of embolization. Complex anatomy (multilobar, short and wide necks, large PSA) is associated with more complications and decreased procedural success. Surgery is definitive, but can result in longer length of stay, incisional pain, and risk of wound infection. Moreover, surgery increases the risk of stent thrombosis after PCI due to DAPT cessation and prothrombotic state.

Methods: BAPI is an endovascular technique that isolates of the PSA from the arterial circulation in order to reduce risk of embolization and allows treatment of more complex PSA anatomy. Via the contralateral femoral approach, the PSA neck is identified via angiography and is occluded using balloon inflation. With the PSA isolated, thrombin injection is performed using ultrasound and fluoroscopic guidance. Once the PSA is thrombosed, the balloon is deflated and withdrawn. Complete obliteration of the PSA is confirmed via angiography and ultrasound.

Results: We report the largest series of BAPI to treat femoral artery PSA not amenable to standard thrombin injection. During 2008-2013, a total of 16 patients at our institution underwent BAPI for PSA after catheterization. All had anatomy that made them poor candidates for ultrasound-guided thrombin injection. 11 of these patients had just had coronary stenting, one had peripheral atherectomy/PTA, two had arrhythmia ablation, and two had diagnostic catheterization. 12 of the patients were on dual antiplatelet therapy at the time of the PSA repair. All patients had initial success of the procedure defined by thrombosis of the PSA by the end of the catheterization. Two of the patients required an additional procedure the following day for recurrent PSA. Both of these cases occurred early in our experience. No patients had femoral thrombosis, distal embolization, or access site infection.

Conclusions: BAPI is a safe and effective method to treat complex femoral artery PSA and when uninterrupted DAPT or anticoagulation is required.

TCT-284

Impact of female gender on bleeding complications and 1-year outcomes of transradial coronary intervention. A propensity score matched analysis: Korea TransRadial coronary Intervention registry

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Background: Besides poor clinical outcomes, female gender has been known high risk factor of bleeding complications. Transradial coronary Intervention (TRI) was associated with decreased bleeding complications compare to transfemoral coronary intervention. This study aimed to investigate the impact of gender on clinical outcomes and bleeding complications after TRI.

Methods: Korea TRI registry is a retrospective, multicenter, observational study with 4506 patients who underwent percutaneous coronary intervention from January to December 2009 in 12 centers. We performed a propensity score matched analyses in 1828 patients (63.2% men) who received TRI. The primary outcome was 1 year major adverse cardiac event (MACE) including cardiac death, myocardial infarction, target vessel revascularization and stent thrombosis. Secondary outcomes included bleeding complications, major bleeding (composite of bleeding requiring transfusion ≥ 2 units of packed cells or bleeding that was life-threatening) and vascular access site related bleeding.

Results: After propensity score matching (n=1358 total, 629 in each group), there was no difference in baseline characteristics between two groups. The proportion of MACE did not differ in both groups (6.1% vs. 5.7%, p=0.943). Women had higher incidence of bleeding complications (1.6% vs. 4.6%, p=0.016), major bleeding (1.4% vs. 3.8%, p=0.022) and vascular access site related bleeding (0 vs. 0.8%) than men. On multivariate analysis, female gender (odds ratio [OR] 3.36, 95% confidence interval [CI]; 1.31-8.62, p=0.012), age (OR 1.20, 95% CI; 1.04-1.16, p=0.001), diabetes (OR 2.28, 95% CI; 1.00-5.22, p=0.052), arterial sheath size (OR 2.82, 95% CI; 1.28-6.23, p=0.010) and chronic kidney disease (OR 5.29, 95% CI; 1.63-17.19, p=0.006) were independent predictors for bleeding complications. Female gender was also independent predictor for major bleeding (OR 2.87, 95% CI; 1.19-6.93, p=0.019).

Conclusions: Regardless of the access site, female gender showed higher incidence of bleeding complications than male gender without difference in clinical outcomes.

TCT-285

Procedural And Clinical Utility Of Transulnar Approach For Coronary Procedures Following Failure Of Radial Route.

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Background: Background and Objectives: Radial access for coronary procedures has gained sound recognition. However, it is not always successful. Few publications described ulnar route as a feasible approach for coronary intervention. The aim of this study is to assess whether transulnar approach is feasible and safe as an alternative to the transradial approach.