Methods: We included 827 consecutive patients who underwent primary PCI by femoral access in our institution between August 2009 to October 2013 with a 6 months follow-up. Primary end point was the presence of VC defined as a composite of hematoma> 6 cm, recurrent bleeding, pseudoaneurysm, arteriovenous fistula, arterial thrombosis or retroperitoneal bleeding.
Results: 404 (48.8%) patients received Angio-Seal® and 423 (51,2%) Exo-Seal®. 39 (4,7%) patients had a VC with a similar incidence of events between the 2 VCDs: 18 (4,4%) in Angio-Seal® and 21 (4,9%) in Exo-Seal® (p=0.7). Risk of VC was significantly associated with body mass index (p=0.01), sheath size (p=0.04), presence of chronic kidney disease (p=0.005) and peripheral arterial disease (p=0.03). There was no fatal complications. Most of the pseudoaneurysms were resolved with compression and/or thrombin, only 2 of them and 1 retroperitoneal bleeding required vascular surgery.
Conclusions: Although radial approach is increasing in recent years, femoral remains the most frequent in primary PCI. VC after femoral VCDs in patients undergoing primary PCI, have a low but not negligible incidence despite being implanted by interventional cardiologists experienced in femoral access. VC were significantly associated with individual (body mass index, chronic kidney disease, peripheral arterial disease) and procedure-related (sheath size) characteristics. Safety and efficacy of both (Angio-Seal® and Exo-Seal®) VCDs is similar after primary PCI.

TCT-848

Mynx™ Vascular Closure Device Achieves Reliable Closure and Hemostasis of Large Bore Percutaneous Trans-Femoral Venous Access in a Porcine Vascular Model: Acute and 30 Day Evaluation using Angiography, Ultrasound, and Histology

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Background: Vascular closure device (VCD) based venous closure has been anecdotally reported but systematic evaluation of the reparative response of the vessel wall to venous closure is lacking. The need to control groin complications, and minimize risks associated with postponed sheath removal under conditions of persistent anticoagulation, has generated interest in the role of vascular closure devices for venous access closure. We sought to characterize the vessel wall response to venous closure, both acutely and in delayed fashion at 30 days using angiography, ultrasound and histology.
Methods: Ten (10) venous 7F sheaths were deployed in the femoral veins of swine. Bilateral venous access sites were subsequently closed utilizing manual compression (control arm, n=4) or a closure device utilizing an extravascular polyethylene glycol sealant (MynxGrip Treatment arm, n=6). Acute (post-closure), 3-day and 30-day vascular ultrasound, as well as venography was used to assess outcomes. Gross pathology and histology were obtained at the 30 day endpoint for all femoral venous closure sites.Each animal was evaluated for venous thromboembolism to downstream tissues vena cava, heart, and lungs.
Results: Hemostasis was successfully achieved in all cases without access site complications. Venography and ultrasound confirmed normal ilio-femoral anatomy and flow at all study time points. Gross pathology and histopathology revealed no evidence of deep vein thrombosis, and no abnormalities were seen in the vena cava, heart or lungs. Histology (at 30 days) showed complete healing of the vein wall access site, with a small focus of chronic inflammation and fibrosis in the perivascular adventitial tissue of the access tract. There was no microscopic evidence of the sealant. The tissue tract showed mild discrete inflammation (foamy macrophages, lymphocytes, plasma cells) with micro-granulomas centered on residual red cells in both treatment and control groups.
Conclusions: This study provides novel insight into healing mechanisms following femoral vein closure and the bioresorptive role of MynxGrip™ extravascular sealant in achieving effective venous closure, while preserving long term vessel patency without thromboembolism.

TCT-849

Preclosure of vascular access site with the suture-mediated ProGlide system during transfemoral TAVI and MitraClip implantation

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Background: The ProGlide closure system is becoming popular for the percutaneous delivery of suture for closing the vascular access site of patients who have undergone structural interventional procedures using 5F to 21F sheaths. This study is intended to demonstrate the safety, effectiveness and feasibility of a suture-mediated ProGlide for access site closure after transfemoral transcatheter aortic valve implantation (TAVI) and transfemoral MitraClip.
Methods: ProGlide closure was used between 2010 and 2013 in 57 patients in our centre. The ProGlide sutures were deployed in a preclose technique before the insertion of the large caliber sheath. Achieving effective hemostasis and no further access site-related vascular or hemorrhagic complications during the whole hospital stay is considered success of the closure technique.
Results: Patients were 73+/-6.5 years old with a logistic EuroSCORE of 22.2+/-12.4. There were total of 57 patients deemed high risk as surgical candidates undergone percutaneous therapy for transfemoral TAVI with Edwards SAPIEN valves (n=31) and MitraClip procedure (n=26). The overall success rate of the ProGlide closure was 98.3%(one patient had diminished pulses distal to closure site that needed surgical intervention). The success rate remained at 100% among the patients on dual antiplatelet therapy (DAPT) or on anticoagulants. None of the patients that were examined with ultrasound demonstrated an AV fistula, aneurysm, hematoma or local thrombosis related to the ProGlide device.
Conclusions: This study demonstrated that the suture-mediated ProGlide system is a safe, simple and highly effective method to close the large arterial access site after transfemoral TAVI and large venous sites of 24Fr as needed in patients undergoing MitraClip procedure despite on platelet inhibitors or anticoagulation. Additionally, use of the ProGlide system can result in shorter procedure time, duration to achieve hemostasis and also shorter length of hospital stay.

TCT-850

Patients undergoing PCI via the femoral artery in a default radial centre have very high BARC bleeding rates and subsequent bleeding 30 day and 1 year mortality

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Background: Increasingly the trans-radial route (TR) is preferred over the trans-femoral route (TF) for PCI. However even in high volume default TR centres a small cohort of patients are required to undergo TF PCI. We examined the demographics, procedural and bleeding outcomes of patients undergoing PCI via the TF in a single high volume UK centre.
Methods: The patient demographics procedure and outcomes of 5379 patients undergoing PCI between 2009 and 2012 were examined. 559(10.4%) patients underwent PCI via the TF route reviewed for Hb drop 3g/dl or more, overt bleeding, Transfusion with in 7 days post PCI, Doppler US/ CT abdomen.
Results: 559(10.4%) patients underwent PCI via the TF route and these patients were more often female, older, lower body weight, shocked and undergoing complex procedures than patients in the TR cohort. In the TF group 79 patients (16.4%) experienced bleeding with 1 each BARC Type 5a and 5b bleed each, 3 BARC Type 3b bleeds, 17 Type 3a bleeds and 57 Type 2 bleeds. Within the TF cohort patients with bleeding when compared to TF patients without bleeding were less likely to have stable angina (13.9% vs. 38.5%, p< 0.0001), more likely to be undergoing primary PCI (30.4% vs. 9.4%, p< 0.0001), present with cardiogenic shock (24.1% vs. 3.5%, p< 0.0001), have sheath sizes greater than 6F used and have a lower BMI (26.0 vs. 32.3 in females and 27.2 vs. 30.0 in males). Mortality at 30 days (15.2% vs. 1.9%, p < 0.0001) and 1 year (25.3% vs. 5.2%, p< 0.0001) was significantly higher in the bleeding group. Major bleeding was an independent predictor of 30 day and 1year mortality.
Conclusions: In a high volume default TR centre the incidence of BARC-defined bleeding was extremely high in TF PCI patients with excess mortality at 30 days and 1 year. Therefore TF PCI cases undertaken in a default TR centre cases require meticulous peri-procedural and post-procedural care to minimise complications.

Demographics and procedural characteristics of the bleeding vs. no bleeding in the femoral cohort

VARIABLES	No bleeding n=480	Bleeding n=79	p value
Female %	35.4	39.2	NS
Female Age years	67.5	67.8	NS
Male Age years	62.8	65.3	NS
BMI	28.7±0.24	27.5±0.77	NS
Weight kg	81.4	75.2	NS
Stable Angina %	36.3	13.9	<0.0001
Acute coronary syndrome %	63.7	86.1	NS
Cardiogenic shock %	3.5	24.1	<0.0001
Previous PCI %	26.0	27.9	0.74
Previous CABG %	14.4	12.7	0.69
Chronic renal failure %	5.0	11.4	0.025
Gp2b3a used %	12.5	27.8	0.0004
Embolic protection device used %	2.0	0	0.219
Intra-aortic balloon pump used %	3.75	24.0	<0.0001
Diagnostic device used %	10.4	10.1	NS
Rotablation used %	3.9	8.9	0.042
Left Main Stem %	5.6	12.7	0.019
Non-LMS %	94.3	87.3	0.019
Graft(s) %	9.1	3.1	NS
CTO %	21.1	6.8	<0.0001
6Fr sheath %	84.0	60.8	<0.0001
7Fr sheath %	7.5	21.5	<0.0001
8Fr sheath %	6.7	13.9	0.03
No. of vessels attempted	535	93	0.0958
No. of lesions attempted	731	130	
Procedural success %	87.2%	92.4%	

TCT-851

A Propensity Score Analysis of Venous Access Closure Using Extravascular Closure Device In High Risk Patients

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Background: Recent advances in catheter techniques have resulted in an increased number of complex percutaneous cardiac interventions requiring large venous access and full anticoagulation. Manual compression (MC) has been the standard approach to hemostasis and has been associated with significant discomfort, delayed ambulation, more involved nursing care, overdue hospital discharge and groin complications. Extravascular closure devices (ECD) do not have any intraluminal components and use water-soluble, bioabsorbable, polyethyleneglycol matrix. ECDs, like Mynx [AccessClosure,CA] are therefore an excellent choice for venous access closure.
Methods: Between 2009 and 2012, 1521 patients underwent various cardiac interventions requiring femoral vein access and had immediate post-catheterization venous access site closure. We selected high risk patients for groin complications (≥8F and or ACT>200 sec at closure) who underwent venous access closure with either Mynx device (Mynx group, n= 277) or MC (control group, n=204). Propensity score analysis was used to control for confounding/bias. Bleeding Academic Research Consortium (BARC) definition used for bleeding. Access site complications evaluated at discharge and 4 weeks.
Results: A total of 481 veins were included in analysis. Baseline and procedural characteristics were similar between groups. At closure, average ACT was higher for Mynx group, 243 sec vs. 146 sec (p< 0.001). Failure to achieve hemostasis, converting to MC for Mynx group or requiring extended MC (>30 min) for control group, was significantly reduced for Mynx compared to control group (1.5% vs. 11%, p< 0.001). Mean time to ambulation was significantly shorter for Mynx group (3 hours vs. 7 h, p< 0.001). One hematoma noted in the Mynx group vs 9 for control group (p=ns). No episodes of significant bleeding were noted (BARC Type 2, 3 or 5) for the Mynx group while there was 1 patient in MC group who developed subcutaneous hematoma confirmed on venous ultrasound and required surgery.
Conclusions: In this propensity score analysis of high risk patients, Mynx device use for venous access site closure was associated with rapid hemostasis and early ambulation compared to manual compression.