Background: Women more often incur access site bleeding complications after cardiac catheterization compared to men. Vascular closure devices have been introduced into clinical practice with the aim of increasing procedural efficacy and safety of coronary angiography. Thus, vascular closure devices might be especially useful in women. The gender-specific value of vascular closure devices versus manual compression has not been assessed prospectively.
Methods: The Instrumental Sealing of ARterial puncture site – CLOSURE device versus manual compression (ISAR-CLOSURE) study is a multicenter, randomized, open-label clinical trial comparing FemoSeal, Exoseal and manual compression for arteriotomy closure in patients undergoing coronary angiography via the common femoral artery (random sequence 1:1:1). Primary endpoint is access site related vascular complications, i.e. the composite of hematoma $\geq$ 5cm, pseudoaneurysm, arteriovenous fistula, access site related bleeding, acute ipsilateral limb ischemia, need for vascular surgery/interventional treatment or local infarction at 30 days after randomisation. This analysis will focus on gender specific aspects of the comparison of arteriotomy closure with two different vascular closure devices versus manual compression. A second comparison will be performed between the two vascular closure devices. Outcomes examined will be stratified by gender. The trial is registered with ClinicalTrials.gov Identifier NCT01389375.
Results: From April 2011 until Mai 2014 a total of 4,524 patients have been enrolled in the ISAR-CLOSURE trial, among them 1,395 women. The present analysis will be gender-specific and will be available in August 2014. On the other hand, the primary results of the trial will also be submitted as late breaking clinical trial at this year TCT meeting.
Conclusions: The trial will help to assess the gender-specific role of two vascular closure devices versus manual compression in patients undergoing cardiac catheterization via the common femoral artery.

TCT-841

Comparative Efficacy of Bleeding Avoidance Strategies by Preprocedural Risk for Access Site Hematoma in Patients Undergoing Peripheral Vascular Interventions

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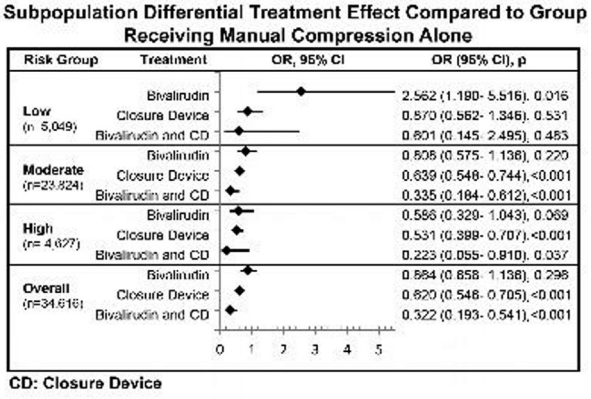
Background: The comparative effectiveness of bleeding avoidance strategies (BAS) in reducing access site hematomas (ASH) after peripheral vascular interventions (PVI) remains unclear.
Methods: 34,616 PVI from more than 100 centers included in the Vascular Quality Initiative (VQI) Registry were analyzed. Preprocedural risk for ASH was predicted by a model previously developed and validated based on data from the VQI registry.
Results: ASH complicated 1,116 procedures (3.22%). ASH rates differed by predicted preprocedural risk (low risk 1.81%; moderate risk 3.13%; high risk 5.16%). Manual compression (MC), bivalirudin, vascular closure device (VCD) and dual bleeding avoidance strategy (BAS) with bivalirudin plus VCD were used in 33%, 5%, 30% and 3% of patients, respectively. Overall, ASH was less frequent in patients who received VCD (2.51%, p< 0.001) and dual BAS (1.32%,p< 0.001) compared to patients who had MC alone (3.98%), but of similar frequency in patients receiving bivalirudin alone (3.46%, p=0.295). Patients at high predicted risk had the greatest risk reduction (RR) from the use of VCD (RR 0.548, 95% CI 0.417- 0.721; p < 0.001) and from dual BAS (RR 0.235, 95% CI 0.059- 0.938; p< 0.040), however they were less likely to receive VCD (39% vs. 45% in low risk and 44% in moderate-risk groups, p< 0.001).
Conclusions: VCD use, especially in conjunction with bivalirudin, was associated with lower ASH rates among patients at moderate and high preprocedural risk; however, high risk patients were less likely to receive VCD. Bivalirudin used alone was not associated with lower ASH rates.



TCT-842

The use of closure devices in peripheral endovascular interventions: The Leipzig real-world report

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Background: We report our single center experience using closure devices in different types of endovascular interventions, using various and eventually multiple access sites, between October/2012 and December/2013 in order to investigate their safety and effectiveness, and to identify trigger decision-making features helping to guide their use.
Methods: A retrospective analysis of consecutively treated patients in our department was performed. Demographic, clinical/periprocedural ,post-operative data, complications and re-interventions due to the use of closure devices were analyzed. Puncture site was routinely checked with Duplex ultrasound 24 h after operation and under clinical suspicion.
Results: 2393(1409(72,2%) men; 543(27,8%) women) patients were included. Among 3206 closure devices used, Perclose Proglide®(Abbott Vascular, CA,USA) was employed 2806 times(87,52%), Angio-SealTM(St. Jude Medical Inc.,MN,USA) 298(9,3%) and 102(3,18%) Exoseal®(Cordis,NJ,USA). More than one type was used in 55 patients(2,4%). Patients were 70±11 years old. Vascular access sites (1.845 retrograde(77,1%), 548 antegrade(22,9%)) with sheath size ranging from 5F to 24F. The overall success rate was 95,3% and did not significantly vary according to the device used(p< 0,05). Mild calcification was significantly unfavorable to Proglide's use when compared to Angioseal(p< 0,05). Severe calcification related to unsuccessful use of closures devices. High puncture site were prone to more significant bleeding complications, with no statistical difference among the devices, whereas low punctures were more prone to occlusive complications, with a lower incidence among proglide patients(p>0,05). Major complications occurred in 10 patients(0,5%). Morbid obesity, previous anticoagulation, mild/severe calcification, dislodge puncture site and $\geq$9F sheath resulted in higher complication risk.
Conclusions: Closure devices were safe and effective in this study. Higher complication rates were related with important vessel calcification, larger sheaths and dislodged puncture sites. Further prospective randomized studies should be performed.

TCT-843

Substantial decrease in access complications of femoral route coronary intervention with the sheathless guiding catheters

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Background: Haemmoragic local complications of femoral route coronary interventions decrease with the reduction of the introducer size.Sheathless guiding catheters developped by ASAHI* for radial approach combine an inner tubing equivalent to standard 6 F guidings with a 4.5 F external diameter size which represents the true dimension of the arterial hole. The objective of the study was to evaluate for the first time the feasibility and safety of these new guidings through femoral artery in a large variety of coronary interventions.
Methods: 303 consecutive patients (pts), 76% male,BMI:27.1 ±3.5 kgm2,mean age:68±1.7 years,31% diabetic,excluding acute myocardial infarction with GIIb3a,- were enrolled. PCI was performed immediately after diagnostic angiography through 4 F arterial sheath in 99 unstable patients or was progammed in 204 patients. Anticoagulation was obtained by injecting a mean dose of 4000±860 ui heparin . Immediately after PCI sheathless catheter was removed , manual compression was performed and time monitored. No arterial closure devices were used.In Hospital and 30 days local complications were also evaluated.
Results: In 285 single vessel PCI pts ,due to the excellent torque of the system with the dilator inside,only 303 sheathless catheters were utilised.In 18 pts with right and left coronary angioplasty during the same procedure 18 sheathless catheters were exchanged to controlateral curve catheter without bleeding. Exchange for 6 F standard guiding catheters was necessary in only two patients. Coronary interventions with 375 stents ,including 11 non protected left main stenting were successful in 99,3% of the cases. Mean haemostasis time was shortened to 316±174 seconds. 30 days minor complications included 2 small hematomas without any transfusion and one small false aneurysm spontaneously thrombosed at day 4. Compared to 6F procedures with closure device,in hospital cost was reduced by 80 Euros.
Conclusions: This first clinical study shows that Sheathless "4.5F" guiding catheters can be used succesfully through femoral artery in a large variety of patients with an extremely low groin complication rate (1%). Direct comparison with radial approach needs to be investigated in the future.