doses. The aim of our study was to determine the ORD during TRCA performed to OP.
Methods: Prospective observational study. From January 2014 to March 2014, ORD of 5 expert operators were measured during TRCA performed to 107 patients. Operators were equipped with 4 real-time dosimeters placed at eyes level, left wrist, thorax outside the lead apron, and left inguinal region outside the lead apron. Operator effective dose (ED) was calculated using the data collected from the 4 dosimeters. Right radial access was used during all procedures and patients with prior CABG were excluded. Obesity was defined as body mass index (BMI) ≥ 30 kg/m2.

Results: Mean age was 72.1±10 years, 67 (62.6%) were male and 28 (26.2%) were OP. Baseline characteristics were similar in non-obese patients (NOP) and OP except BMI (26.0±2.8 vs 34.0±3.8, respectively; p<0.001). Dose area product was higher in OP (29.0±11.6 Gycm2) than in NOP (17.2±9.0 Gycm2; p<0.001) with similar fluoroscopy time between both groups (23.5±1.1 minutes in NOP vs 27.1±2.1 minutes in OP; p=0.015). ORD measured at eyes (3.6±1.0 mSv in NOP vs 1.3±0.9 mSv in OP; p=0.001), at wrist (18.2±14.9 mSv in NOP vs 27.5±19.0 mSv in OP; p=0.01), and at thorax level (11.2±9.3 mSv in NOP vs 20.3±14.4 mSv in OP; p=0.004) were higher in OP compared with NOP, without significant difference at inguinal region (35.5±26.8 mSv in NOP vs 47.1±32.7 mSv in OP; p=0.073). There was a positive correlation between BMI and ED (correlation coefficient 0.36; p<0.001). During TRCA, ED was 1.8-fold higher in OP compared with NOP (95% CI: 1.2 to 2.8), with 1.2±0.9 mSv in NOP and 1.8±1.1 mSv in OP (p=0.006).

Conclusions: TRCA in OP are accompanied with higher ORD compared with procedures in NOP. Efforts should be made to reduce ORD during TRCA, and general recommendations regarding best practice for radiological protection must be followed, with broader adoption of techniques and protection devices in addition to standard protection, particularly when performing in OP population.

Vascular Access and Intervention - Femoral (includes closure devices)

**Washington Convention Center, Lower Level, Hall A**

Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 840-851
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, Exosseal and manual compression for arteriotomy closure in patients undergoing coronary angiography via the common femoral artery (ISAR-CLOSURE 1:1:1). Primary endpoint is access site related vascular complications, i.e., the composite of hematoma ≥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 randomization. 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 NCT01398375.

Results: From April 2011 until May 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 closing access site hematoma (ASH) after peripheral vascular interventions (PVI) remains unclear.

Methods: 34,616 PVI from more than 100 centers included in the Vascular Quality Improvement (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 (3.2%). 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%, 3%, 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 0.548, 95% CI 0.417-0.721; p < 0.001) and dual BAS (1.32%, p < 0.001). Severe calcification related to unsuccesful deployment of closures devices was more significant in bleeds, with no statistical difference among the devices, whereas low punctures were more prone to elusive complications, with a lower incidence among proligele patients (< 0.05). Major complications occurred in 10 patients (0.5%). Morbid obesity, previous anticoagulation, mild/severe calcification, dislodged puncture site and ≥98 sheath resulted in higher complication rate.

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: Haemorrhagic local complications of femoral route coronary interventions decrease with the reduction of the introducer size.Sheathless guiding catheters developed 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 the radial access site in a large variety of coronary interventions.

Methods: 303 consecutive patients (pts), 76% male,BMI:27.1 ± 3.5 kg/m²,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 programmed in 204 patients. Anti-cogulation 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 contralateral 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 successfully through femoral artery in a large variety of patients with an extremely low groin complication rate (1%). Direct comparison with radial access needs to be investigated in the future.