TCT-417

Abstract Withdrawn

TCT-418

Doppler Control Of Radial Artery After Use Of TR Band Following Coronarography and/or Angioplasty : DRABAND study results

Methods: 574 patients were consecutively included in this European multicentric registry with 8 centers. All patients received a vasodilator and heparin <cocktail> and underwent cardiac catheterization using 5F or 6F introducer sheath and catheters. Hemostasis was achieved for all patients with a radial compression device (TR Band™), applied after sheath removal, with the same protocol for set up and removal allowing flow-limiting compression of the artery. The Radial Compression Device was removed 24 hours after the procedure.

Results: With a majority of right radial approach, coronary angiography was performed in 62% of cases. 6 Fr was used in 211 patients (37%) and a previous radial approach was done in 39% of cases. Comparison between treated radial and femoral patients revealed no significant difference (p=0.23) for compression pain (n=6.7 vs. 4.3, p=0.002) and compression residual hematoma per protocol (p=0.22). A periodical Doppler assessment of radial pulse was performed in 98.5% of cases throughout the triplicity (n=30). Univariate statistical analysis evidenced no significant predictors of RAO: no-use of antiplatelet/poor anticoagulation (p=0.1), need for rescue vascular surgery (p=0.2), and a procedure performed by a young radialist physician (p=0.02). RAO was more frequent with large sheath use and after previous radial approach, but not statistically significant.

Conclusions: Because one the most important RAO predictor factors is the maintain of radial pulse during hemostatic compression, TR Band™ device with its flow-limiting compression allows to avoid early radial occlusion as confirmed by DRABAND study, with only 3.8% incidence. We have also shown importance of quality shear choice avoiding radial occlusion complication.

TCT-419

Complete Percutaneous Approach For Arterial Access And Closure For Device Deployment In The Transfemoral Transcatheter Aortic Valve Replacement - A Comparison With Surgical Cut-down

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Background: Surgical cut-down has been a primary approach for arterial access to place large caliber 22 or 24 Fr sheath used for commercially available transfemoral (TF) transcatheter aortic valve replacement (TAVR) system in the US. The complete percutaneous arterial access and closure was recently introduced as an alternative approach for arterial access/closure with acceptable safety. However, there has been no study comparing these two approaches regarding acute clinical outcomes post TF TAVR.

Methods: In 230 patients who underwent TF TAVR using the Edwards-Sapien valve (23mm or 26mm diameter), Incidence of immediate major VC defined by VARC, its angiographic location and success rate of subsequent endovascular or surgical intervention was assessed.

Results: Major VC occurred in 14.4% of the patients (17 out of 118 cases). Dissection or perforation of iliac artery was the most common form of the major VA (53% of 17). Six cases developed major VC at the puncture site in common femoral artery (one perforation and 5 stenoses). Two of these cases also had dissection in the separate site (both at the bifurcation of external and internal iliac artery). All these were successfully treated with peripheral endovascular intervention. Two other cases required surgical intervention. One case with ruptured lower abdominal aorta was treated by both endovascular intervention and surgical repair, and the other that has difficulty of sheath removal underwent emergent iliofemoral bypass surgery. Compared to the patients without major VC, the patients with major VC received more frequent blood transfusion (28% vs 71%, p = 0.0008). However, there was no significant difference in mean length of hospital stay (4.6 ± 6.9 days vs. 4.8 ± 3.7 days) and 30-day mortality (3.0% vs 5.9% for no major VC vs. Major VC).

Conclusions: Biofemoral artery was the most common site of major VC in TF TAVR with percutaneous access/closure for device access for the first generation Edwards-Sapien valves. The majority of them can be successfully managed by immediate endovascular intervention and supportive therapy without affecting acute clinical outcomes.

TCT-421

Lower periprocedural quality of life in STEMI patients undergoing PCI with femoral access

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Background: Despite improved clinical outcomes with the transradial approach in STEMI, the data on health related quality of life (HRQoL) is still limited. The aim was to understand the HRQoL depending on the selected vascular approach.

Methods: 1000 STE/ACS individuals admitted for PCI in 2010 randomized to transradial (TF, n=48) or transfemoral (TR, n=52) approach. A EQ-5D, visual analog scale (VAS) and MacNew instruments were used to assess the HRQoL.

Results: The baseline HRQoL was indifferent (TF vs. TR). Two hours after PCI the HRQoL improved (VAS: 50.2 vs. 70.1, p<0.005). The mobility, self-care and pain were impaired in the TF vs. TR (p<0.01). Over next three days these domains improved and differences equalized between groups. There was no difference of the total HRQoL, on day three as by VAS (72.1 vs 69.0), EQ-5D and MacNew (5.3 vs. 4.5), despite for lower scores in emotional domain in the TF vs. TR (4.18 vs. 5.1, p=0.05).

Conclusions: The TF approach is associated with lower HRQoL early after PCI and improves within days after the procedure. An impaired emotional status noticed in TF group needs to be studied in larger trials. The TR access should be preferred when patients satisfaction is taken into account.

TCT-420

Major Vascular Complication And Its Management After Complete Percutaneous Arterial Access And Closure In Transfemoral Transcatheter Aortic Valve Replacement

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Background: The complete percutaneous access/closure has been introduced as an alternative approach for surgical cut-down for placement of large caliber sheath in transfemoral (TF) transcatheter aortic valve replacement (TAVR). However, incidence of associated major vascular complication (VC), its anatomic characteristics and management mode remains uncertain.

Methods: Using the pre-closeure technique by deployment of two PerClos Proglide devices (Abbott Vascular Inc., Santa Clara, California), 118 patients underwent complete percutaneous approach for placement of either a 22 or 24 Fr sheath for TF TAVR using the first generation Edwards-Sapien valves (23mm or 26mm diameter). Incidence of immediate major VC defined by VARC, its angiographic location and success rate of subsequent endovascular or surgical intervention was assessed.

Results: Major VC occurred in 14.4% of the patients (17 out of 118 cases). Dissection or perforation of iliac artery was the most common form of the major VA (53% of 17). Six cases developed major VC at the puncture site in common femoral artery (one perforation and 5 stenoses). Two of these cases also had dissection in the separate site (both at the bifurcation of external and internal iliac artery). All these were successfully treated with peripheral endovascular intervention. Two other cases required surgical intervention. One case with ruptured lower abdominal aorta was treated by both endovascular intervention and surgical repair, and the other that has difficulty of sheath removal underwent emergent iliofemoral bypass surgery. Compared to the patients without major VC, the patients with major VC received more frequent blood transfusion (28% vs 71%, p = 0.0008). However, there was no significant difference in mean length of hospital stay (4.6 ± 6.9 days vs. 4.8 ± 3.7 days) and 30-day mortality (3.0% vs 5.9% for no major VC vs. Major VC).

Conclusions: Biofemoral artery was the most common site of major VC in TF TAVR with percutaneous access/closure for device access for the first generation Edwards-Sapien valves. The majority of them can be successfully managed by immediate endovascular intervention and supportive therapy without affecting acute clinical outcomes.
TCT-422
Large 22 to 24Fr femoral vein hemostasis with a subcutaneous stitch or a double Perclose closure is effective and safe.

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Background: Various methods of hemostasis have been developed for large 22 to 24Fr femoral vein access for structural heart disease. Manual compression (MC) is uncontrollable whilst a subcutaneous stitch (SCS), which too is uncomfortable to remove, and a double Perclose (DPC; Abbott Vascular Devices, CA) closure enables immediate hemostasis. This study is to determine the effectiveness and safety of these methods.

Methods: 155 patients (mean age 70±17 years; 60.38% female) underwent 158 valvular procedures with the MitraClip device [n=147, 93%] (Abbott Vascular, Santa Clara, CA), Melody [n= 2, 1%] (Medtronic Inc., Minneapolis, MN) or Edwards SAPIEN [n = 9, 6%] (Edwards Lifesciences LLC, Irvine, CA) valves. There were 24(16%) SCS and 96(62%) MC and 35(22%) DPC.

Results: There were 8(5%) access site complications (ASC; 4/35(11%) in MC (2 hematoma ≥1 cm but <5 cm, 1 hematoma ≥5 cm requiring 2U of blood, 1 arterial venous fistula), 1/24(4%) in SCS (1 bleeding requiring 1U of blood), and 3/35(9%) in DPC (1 femoral vein thrombosis, 1 hematoma ≥1 cm but <5 cm, 1 hematoma ≥5 cm requiring 2U of blood). The frequency of ASC between methods was not significantly different (MC vs. SCS p = 0.33, MC vs. DPC p = 0.06, SCS vs. DPC p = 0.78). Median length of stay was 1.0±1.1 days and was similar to patients that developed ASC (p=0.09) and between groups (p=0.23). Procedural (median dose 30±13mg) use did not influence the frequency of ASC (28/50 patients ASC vs ASC w/o aspirin, p = 0.29). Post procedure hemoglobin and hematocrit drop was significant (1.4±1.0g/dL, and 4.2±3.5%; both p<0.01) and by comparison, this decline was significantly less for SCS (0.7±1.2g/dL and 1.9±3.9%; both p=0.01). DPC required additional injections (18/35 SCS) to attain immediate hemostasis more than SCS (26/99 (26%) vs. 12/45 (4%); p=0.02). Overall there were no in-hospital deaths, ASC related deaths and wound infections at follow-up (mean 20±18months).

Conclusions: Femoral vein closure for large 22 to 24Fr accesses, with either the SCS or DPC method enables immediate hemostasis and reduces patient discomfort, without compromising safety.

TCT-423
Profile, Safety, And 1-Year Outcome Of Patients With Same-Day Discharge After Percutaneous Coronary Intervention Using Different Vascular Access: A High-Volume Single-Center Experience.

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Background: Same-day discharge after elective percutaneous coronary interventions (PCI) allows a decrease in length of hospital stay, waiting list and costs with increased patient satisfaction, but data regarding clinical features of the population with potential benefit and safety are limited.

Methods: A consecutive group of patients who underwent elective PCI and considered suitable for same-day discharge over a period of 4 years were enrolled. Unstable patients with left main disease, left ventricular ejection fraction ≤35%, non-use of dual antiplatelet therapy, use of oral anticoagulants or inability to reach the PCI-center within 60 minutes were excluded. Patients were examined 6 hours post-PCI and discharged if 60 minutes were excluded. Patients were examined 6 hours post-PCI and discharged if no deaths or myocardial infarction within 7 days of discharge. The 1-year mortality rate was very low (0.2%, 1 patient).

Conclusions: Same-day discharge after elective PCI is feasible and safe with a remarkable 1-year outcome. Its application and benefits could be extended to a broader population of patients.

TCT-424
Trends in access site choice for PCI and influence on mortality - Observational data from the British Cardiovascular Intervention Society PCI database.

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Background: In the UK, there has been a significant change in choice of access site for PCI driven by the desire to reduce access site complications. This has become increasingly important with the shift to more acute PCI with the use of more potent anti-thrombotic agents. The aim of this large observational study, there is an association between TRA and lower 30 day mortality.

Methods: This study includes data collected by the British Cardiovascular Intervention Society under the auspices of the Central Cardiac Audit Database. We performed a retrospective analysis of the BCDS database between January 2006 and December 2010. The data was split into 2 cohorts based on access site: either radial or femoral (mixed access site use and other access sites were excluded from the analysis).

Results: Of the 370,238 procedures recorded, 223,476 (60.4%) used only transfemoral access (TFA) and 124,616 (33.7%) used only transradial access (TRA). Data was missing or mixed access was used in 22,146 (6%) of procedures. Between 2006 and 2010 TRA for PCI increased from 17.1% to 50.8%. Over the same period, PCI for ACS increased from 47% to 61% of procedures. 30 day mortality was 1.9% in the TFA group and 1% in the TRA group (p < 0.0001). The incidence of patients presenting with cardiogenic shock was significantly higher in the TFA group (2.1% vs 0.9%, p< 0.0001). With shocked and intra-aortic balloon pump (IABP) treated patients excluded, TRA remained independently associated with a reduction in 30 day mortality (HR 0.65, CI 0.60-0.70; p<0.0001) in a multivariate analysis.

Conclusions: The majority of PCI in the UK is now undertaken using radial access. In this large observational study, there is an association between TRA and lower 30 day mortality. The association persists even when shock and IABP treated patients are excluded.

TCT-425
Repeated Transradial Catherization: Feasibility, Efficacy and Safety.

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Background: Transradial approach is used as an alternative to transfemoral approach for coronary angiography (CA) and primary coronary intervention (PCI). Transradial approach results in less access site bleeding, immediate ambulation after the procedure, reduced length of stay and costs, less pain and improved patient comfort. However, it has been suggested that transradial approach can lead to increased incidence of radial artery occlusion, not allowing for repeated catheterizations from the same artery. There is limited data on the feasibility, safety and efficacy of repeated transradial (rTR) catheterization from the same artery. We evaluated the incidence of failure and major complications during rTR catheterization.

Methods: We performed 3,857 catheterizations with various indications and access sites at the American Heart Institute, in Nicosia-Cyprus, between Jan 2006 and Dec 2009. In our center, we established TR catheterization as the routine method for elective, urgent and emergency procedures (primary or rescue PCI). Baseline characteristics (e.g. sociodemographics, underlying disease, smoking, prior CABG), procedural success rates and major complications were recorded.

Results: Right rTR catheterization was attempted in 92 patients. Repeated access to the radial site was not possible in only 2 patients, due to poor pulse (n=1), and inability to advance the wire (n=1). In 84 patients right rTR was successfully performed twice, and in 6 patients 3 times. No major access site complications were noted in any of the above procedures.