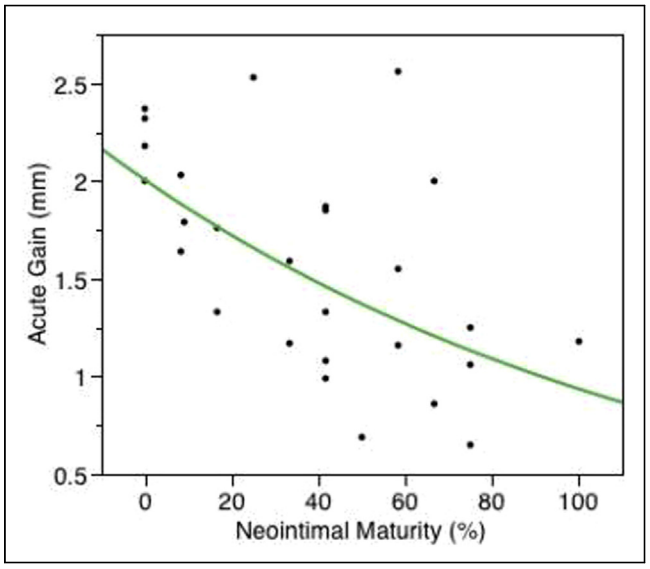

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Drug-eluting balloon, Optical coherence tomography, Restenosis, in-stent

TCT-416

Drug eluting balloon: a real world three centers experience

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BACKGROUND The use of drug-eluting balloons (DEB) for the treatment of in-stent restenosis (ISR) and lesions in small vessels has not been extensively investigated in the real-life clinical practice. According to the most recent guidelines, the use of DEB is indicated only for the treatment of ISR. We aim to report a three-centers "all comers" registry on the safety and efficacy of DEB in the treatment of ISR and de novo coronary artery disease.

METHODS Consecutive patients treated with the In.Pact Falcon™ (Medtronic Inc., Minneapolis, MN, USA) paclitaxel-eluting balloon between January 2012 and November 2014 in the centers of Verona, Mirano and Savona were retrospectively analyzed in our registry. The measured clinical end-points were cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), while procedural success was defined as the ability to reach, cross and dilate a lesion with the study device, with a residual stenosis <30% and a final TIMI 3 flow in the culprit vessel. Primary end point of the study was the occurrence of major adverse cardiac events (MACE), defined as combination of cardiac death, MI, and TLR, at 12 and 24 months of follow up.

RESULTS A total of 167 lesions were successfully treated in 143 patients. The mean age was 67±10 years, and 82.5% were males. The main risk factors were represented by hypertension and dyslipidemia while 39.4% of patients were diabetics. The 73.5% of the population had a prior PCI and the main indication for PCI was because of ACS (73.5% while 26.5% of patients suffered from stable angina). The predominant indication for DEB use was ISR (75%), mainly focal (34.1%), involving a DES in the 79% of cases. Procedural success was achieved in 97.6%. A mean of 1.1±0.18 DEB were used per patient. Bailout stenting was required in 2 lesions. No events were recorded during the hospitalization. Long term follow up was available for 100% of the study population. The overall incidence of MACEs at 12 months was 5.6%, while at 24 months was 9.1%, with an overall event free survival of 85%. Of interest, the primary endpoint occurred in 18% of patients treated for de novo lesions, against a 5.7% of ISR patients (p=0.01). Patients presenting with focal restenosis had an incidence of events comparable to those with more aggressive restenotic pattern (diffuse or proliferative, p=0.71).

CONCLUSIONS Our results confirm the safety and efficacy at short and long term follow up of DEBs, especially in patients presenting with ISR. On the contrary, the use of DEB in de novo lesions is associated with a poorer clinical outcome. Larger trials are needed to confirm our data.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Drug-eluting balloon, Restenosis, in-stent, Small coronary vessels

TCT-417

Treatment of coronary artery disease with a new-generation drug-coated balloon: preliminary results from the Italian Elutax SV Registry

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BACKGROUND drug-coated balloons (DCB) have shown to be a valuable alternative to stents for the treatment of in-stent restenosis, and there is some initial evidence of their efficacy for the treatment of small coronary vessels. Newer generation DCB were developed to overcome the reduced deliverability of the previous generation of devices, warranting an effective drug delivery to the vessel wall. However, the vast majority of such devices still lack of reliability due to paucity of clinical data.

METHODS between 2012-2014 all patients intended to be treated with this type of DCB at 9 italian centers were enrolled in this retrospective registry. We did not have specific exclusion criteria. Coronary interventions were performed following the Italian Position paper on DCB-PCI published in 2014. Primary outcome was the occurrence of target lesion revascularization (TLR) at the longest available follow up.

RESULTS we enrolled 247 consecutive patients/283 lesions, whose clinical, angiographic and procedural characteristics are depicted in Table. At the longest available clinical follow up (average 225 days, I.Q. ranges 67 days), 5 patients suffered a TLR, all but one managed with re-PCI (2 with another type of DCB, 2 with DES). We registered 2 cases of cardiac death (one for heart failure and one for fatal myocardial infarction related to another vessel), 4 non-cardiac deaths (2 malignancies and 2 intracranial hemorrhages) and no cases of target vessel myocardial infarction/thrombosis.

Table. Clinical, Angiographic and Procedural characteristics

Patients, n	247		
Lesions treated, n	283	Native vessel disease, %	59.0
Age, years	68.9±9.4	Small vessel disease, %	65.0
Males, %	72.4	Bifurcation (side branch), %	25.0
Diabetes Mellitus, %	31.8	Lesion length, mm	16±3.9
Hypertension, %	79.7	Average vessel diameter, mm±SD	2.7±0.42
History of smoke, %	36.9	Percent diameter stenosis, %±SD	85.9±9.5
LVEF, %±SD	53.2±7.2	Predilatation, %	92.2
Chronic Kidney disease, %	12.3	Pressure, atmospheres	9.4
Clinical Presentation: *Stable coronary artery disease, %*	43.3	Duration of balloon inflation, seconds	42.5±11.4
NSTEMI, %	50.6	Bailout stenting, %	12.3
STEMI, %	4.5	Final percent diameter stenosis, %	9.8±10.8
DES in-stent restenosis, %	28.0	Procedural success, %	97.5
BMS in-stent restenosis, %	13.0		

CONCLUSIONS In this consecutive series of patients, treatment with a new generation of DCB was found safe and effective in maintaining good vessel patency at mid-term follow up.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Drug-eluting balloon, Real world, Registries

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TCT-418

Comparative meta-analysis of transulnar and transradial cardiac catheterization

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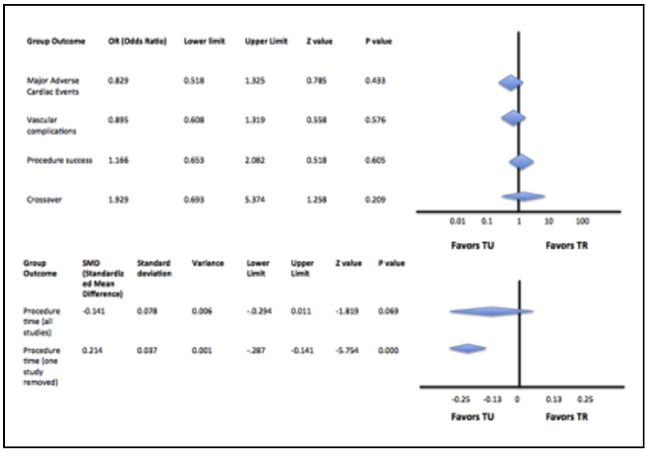
BACKGROUND Transradial (TR) catheterization has become popular as a first-line approach for coronary angiography due to less bleeding and access site complications. Recently, the transulnar (TU) approach has been getting attention as a possible substitute to TR access for repeat angiographic procedures and in cases of radial artery occlusion. It also preserves the radial artery for subsequent coronary artery bypass grafting. In this meta-analysis we attempt to compare safety and efficacy of TU and TR catheterization.

METHODS Electronic databases were searched for all studies comparing TU and TR catheterization. A total of 6 studies with 13,285 patients were identified to be included in this analysis. Outcomes of interest were major adverse cardiovascular events (MACE), vascular complications, procedure time, procedure success, and crossover rate. Odds ratio (OR) or standardized mean difference (SMD) along with 95% confidence intervals (CI) were computed for each outcome. Fixed and random effects models were used as found appropriate. Sensitivity analysis and bias assessment was done for each outcome.

RESULTS There was no significant difference between TR and TU for MACE [OR 0.83 (CI 0.52 to 1.33), p = 0.43], vascular complications [OR 0.9 (CI 0.61 to 1.32), p = 0.58], crossover rate [OR 1.93 (CI 0.69 to 5.37), p = 0.21], procedure success [OR 1.17 (CI 0.66 to 2.08), p = 0.61] and procedure time [SMD -0.14 (CI -0.29 to 0.011), p = 0.07]. Sensitivity analysis revealed that removal of one study (Geng et al) resulted in a significantly increased summary procedure time in TU catheterization [SMD -0.21 (CI -0.29 to -0.14), p <0.01]. This study (Geng et al) had shown a non-significant trend towards increase in procedure time in TR catheterization, which was incongruent with all other studies.



CONCLUSIONS Transulnar catheterization is a safe alternative to transradial approach and has many potential benefits with similar rates of procedure success. However, this approach may be associated with an increased procedure time.

CATEGORIES OTHER: Vascular Access: Transradial

KEYWORDS Meta-analysis, Transradial approach, Ulnar Access

TCT-419

Upper Extremity Dysfunction Post Transradial Percutaneous Coronary Intervention; Interim results

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BACKGROUND Transradial percutaneous coronary intervention (TR-PCI) is rapidly becoming the gold standard especially in primary percutaneous coronary intervention (PCI), where most benefit of the radial approach can be expected such as reduced major bleeding and mortality. However, transradial access and access-site complications could influence upper extremity function (UEF). The main objective of this study is to provide insight in the upper extremity morbidity after TR-PCI. Secondary objectives are to provide insight in the consequences for functional status, factors influencing UEF, financial costs, and to identify subjects who might benefit from early referral and treatment.

METHODS This study is a single center prospective cohort study with a minimum of 490 consecutive patients. All patients will, after baseline examinations, be treated with the intent of using the radial artery for PCI access. After the intervention patients will undergo follow-up after 24 hours, two weeks, one and six months. UEF consist of several parameters including anatomic integrity, strength, range of motion, coordination, sensory function and pain. In view of this, we created a primary endpoint which consists of a combination of parameters, resulting in a very sensitive binary score for upper extremity dysfunction (UED). This score was assessed after two weeks as compared to baseline, using validated examinations and questionnaires. Also, secondary endpoints including spasm, access-site bleeding and access-site hematoma were assessed.

RESULTS Interim results of 111 patients showed 63 patients (56.8%) had a positive score for (reversible) UED, of which after two weeks 7 patients (11%) had been referred to a hand rehabilitation specialist with at the time a Disabilities of Arm, Hand and Shoulder (DASH) score ranging from 0.9-37.9 points. Long term results need to be further determined. A multivariate binary logistic regression was performed to assess the impact of numerous factors on the endpoint. The strongest predictors were female gender (odds ratio (OR)=14.38, 95% confidence interval (CI):2.26-91.47,p=0.005), previous percutaneous coronary interventions ((OR)=7.15, 95%(CI):1.14-44.9, p=0.005), and number of skin punctures ((OR)=8.55, 95%(CI):1.85-39.6, p=0.006).