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Aortic Paravalvular Regurgitation after TAVI Is Associated with Higher Mortality

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Background: Aortic stenosis (AS) is increasing in incidence with the aging of the population. Transcatheter Aortic Valve Implantation (TAVI) provides a therapeutic option for patients with severe AS who are high risk surgical candidates. Paravalvular aortic regurgitation (PAR) is frequent after TAVI but is usually mild. Moderate-to-severe regurgitation occur and may have clinical consequences.
Objective: The purpose of this study was to assess the clinical and prognostic significance of paravalvular regurgitation after TAVI.
Methods: Seventy six patients who underwent TAVI at our center from 9.2008 to 10.2011 were studied retrospectively. Echocardiography before the procedure and following the procedure but prior to discharge were reviewed. Aortic regurgitation was assessed using semi quantitative methods.
Results: Among seventy six patients who underwent TAVI seventeen (22%) had significant (moderate and more) APR and fifty nine (78%) had non-significant (less than moderate) APR. There was no significant difference in the baseline characteristics of the two groups (age, sex, EF, AVA, AV gradient, IHD, pre-procedural AR). The mortality rate was higher in the group with significant APR as compared to patients without APR (35% versus 8%, p-0.009).
Conclusions: Significant paravalvular aortic regurgitation after TAVI is associated with increased mortality. Long term follow up is critical to further define the impact of AR on clinical outcome. Until these data become available every effort should be made to prevent and treat this complication.

Contrast Media Induced Nephropathy in Renal Failure Patients - Maybe Not as Frightening as Expected

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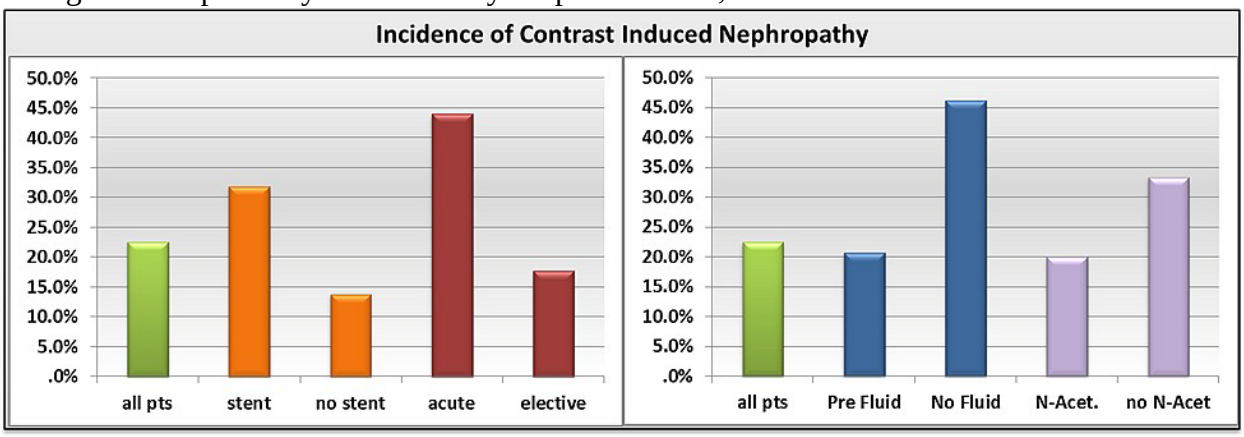
Contrast media induced nephropathy (CIN), defined as a 25% or 0.5mg/dL raise in creatinine, increases the risk for extended hospital stay, death and dialysis. The prominent known risk factors are: prior kidney disease, diabetes, type and quantity of contrast media used, heart failure, volume depletion and age.

Different preventive strategies have been suggested and implemented. In our medical center we used hydration with normal saline and N- acetyl cysteine. We retrospectively reviewed the incidence of CIN and need for dialysis in patients with severe chronic kidney disease, defined as calculated GFR less than 30 ml/min (chronic kidney disease- CKD- stage 4-5), who underwent coronary angiography and received preventive measures (GFR calculated by abbreviated MDRD formula). We further collected data to define risk factors and the effect of preventive measures.

Results: Data from 6 years was reviewed. 182 patients were identified with CKD 4-5. Overall 23% suffered CIN. In elective cases the incidence of CIN was 17% while in emergency coronary angiography it was 44%. Only 12 patients (6.5%) of this severe CKD population needed dialysis during their hospital stay. 7 of the dialyzed patients died, 5 of whom were acute cases.



Conclusions: while the incidence of CIN in this severe CKD population is 23%, only 6.5% needed dialysis support. From our data major risk factors for CIN are emergency coronary angiography, need for vasoactive amine therapy, stent placement, and diabetes treated with insulin. Normal saline prior to the angiography conveys prevention.

Gender Related Atherosclerosis Patterns in STEMI Patients Undergoing Angiography

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Aim: Gender related coronary disease outcome disparities are poorly understood. We hypothesized that gender induces different pattern of atherosclerosis, which in turn may lead to outcome disparities.

Methods: The coronary angiography of a cohort of 100 match-controlled ST-elevation myocardial infarction (STEMI) patients (50 men+50 women) was blindly and independently analyzed by 3 cardiologists. We have calculated the atherosclerotic burden of each lesion as the square root of (reference diameter (mm)*% narrowing*length (mm)). The lesions were summed to a personal "atherosclerotic burden" (ASB). We analyzed ASB for subcategories- proximal/distal lesions and specific coronary artery. A student t-test was utilized for comparison between the ASB's of men versus women.

Results: The average age for men and women was 64.42±12.90 and 65.78±12.90 respectively (p=0.6). The two groups baseline characteristics were well balanced in terms of demographics and risk factors except for a lower body surface area in women (1.92±0.14 vs. 1.75±0.15;p<0.001). Compared with men (Table-1), women had a significantly lower ASB. As opposed to women, men had significant ASB in proximal segments and segments involving the LAD and LCX. Multivariate analysis have demonstrate that in women, the addition of each risk factor adds 0.685 to the ASB (p<0.05).

Conclusion: This study demonstrates a significant difference in both the total atherosclerotic burden and distribution of atherosclerosis between men and women undergoing coronary angiography for STEMI which intuitively should translate to a more favorable outcome. As opposed to men, multiple risk factors are associated with higher ASB. The low total ASB in women, together with low incidence of ASB in the proximal and left system may indicate either increased vulnerability of atherosclerosis in women or the existence of eccentric/non-epicedial disease which may cause the actual less favorable outcome.

Table-1 Angiographic patterns disparities

Angiographic Data	Women	Men	p
Total ASB±SD	10.27±3.44	12.06±3.44	<0.05
ASB in LMA	2.55±1.55	3.3±1.15	0.246
ASB in LAD	7.02±2.56	8.38±2.51	<0.05
ASB in LCX	3.16±2.75	4.61±2.79	<0.05
ASB in RCA	5.45±3.67	5.9±3.72	0.531
Proximal ASB	5.22±2.92	7.10±2.92	<0.05
Distal ASB	8.14±3.92	9.26±3.57	0.138

One Stent for Bifurcation Lesions: Predictors and Clinical Outcome after Crossing into 2-Stents

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Background: A 'simplified' approach, e.g. stenting of the main branch with or without provisional stenting of the side branch, is currently implemented in the majority of bifurcation PCI cases.

Objective: To investigate the causes and clinical outcomes of crossing to 2 stents strategy during PCI of bifurcation lesions in our "real world" practice.

Methods & Results: The study included 540 consecutive patients with bifurcation lesions who were planed for single stent strategy. In 77 pts [14.3%] the plan was changed and crossed side branch stenting as well (due to dissection or unsatisfactory angio result).

	One stent [n=463]	Crossed to 2 stents [n=77]	P-value
Age [year]	64±12	61±13	0.4
Male	78%	77%	0.8
ACS	58%	77%	0.05
LAD/DIAG	57%	56%	0.99
True bifurcation	78%	88%	0.1
DES stenting	63%	41%	0.01
SB-Dilatation	38%	75%	0.001
One month MI	1.9%	5.2%	0.08
One month Stent thrombosis	1.3%	5.2%	0.02
6 month MI	3.9%	10.5%	0.01
6 month Stent thrombosis	1.3%	5.2%	0.02
6 month TVR	7.3%	18%	0.001

Conclusions: Our data indicate that ACS presentation, BMS stenting of the main branch and pre-dilatation of the side branch are altogether factors that predict and/or cause the need for 2 stents in bifurcation stenting. Crossing into 2 stents was associated with worse clinical outcomes. Thus, carful procedure planning is highly recommended.

Reducing Drug Related Problems in the Cathlab: An Interventional Study

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Background: Drug-related problems (DRP) are major causes of morbidity and mortality. Patients undergoing coronary angiography are often treated with complex therapy and are prone to DRP. We studied the frequency and different types of DRPs in cathlab patients and examined an interventional approach to reduce DRP occurrence.
Methods and Results: Routine screening of patient files for DRP was commenced in our cathlab on 2009 by a clinical pharmacist. A total of 340 DRPs were detected in 207 patients (54.6%) of which 9.2% were considered major errors. The most common DRP was lack of a prescribed drug with unequivocal indication (37 %)., Documentation errors were present in 24.4%. Patients with DRPs were significantly older (64.7±10.8 vs. 60.2±10.0 y.) and treated with poly-pharmacy (6.48±2.8 vs 5.8±2.3 drugs/patient, $p<0.05$). Patients with DRPs suffered more from renal failure (15 vs. 5.5%), diabetes mellitus (58 vs. 26.5%) and hypertension (76 vs. 49%, all $p<0.05$). DRP occurence decreased significantly during the monitoring period (53.7% vs 46.3%, $p<0.05$). To further reduce DRP occurrence we changed the format of the cathlab post-procedural orders and included common drugs checklist. Following the introduction of the new format we observed a significant reduction in DRPs. Lack of GI protection was decreased from 23.7 to 9.4%, missed prescription was reduced from 5% to none for aspirin, 11.8 to 5.6% for statins and 6.7 to 3.7% for ACE inhibitors.
Conclusions: DRPs are common in the cathlab. Risk factors for DRP are poly-pharmacy and advanced age. Screening for DRPs is simple, and with prompt intervention may be valuable in reducing drug-related morbidity and mortality.

Retroperitoneal Bleeding after Cardiac Catheterization - A Single Center Report

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Background: Retroperitoneal bleeding (RPB) is an unusual but potentially fatal vascular complication occuring after cardiac catheterization (CC). Current data of the predisposing factors and the clinical management of RPB in the era of dual anti-aggregant therapy and vascular closure devices are lacking.
Methods: We retrospectively examined all RPB cases that occured in the catheteriztion laboratory in Rabin Medical Center between the years 2005-2011.
Results: Out of 26,855 patients who underwent CC, a total of 51 patients (mean age 61± 15 years, 55% female) with RPB were identified (overall prevalence 0.19%). The etiology for CC was acute coronary syndrome (39%), myocardial infarction (33%), stable angina pectoris (10%), valve surgery (10%) and transcutaneous aortic valve implantation (6%). Coronary intervention was performed in 34 patients and closure device was used in 31% of patients. Seventy five percent of the patients were treated with clopidogrel, 20% with IIbIIIa inhibitors and 16% with anticoagulation. The median time to bleeding differed between patients with and without a closure device (12 hours vs. 5 hours, respectively). Computed tomography was the method of diagnosis in 92% of the patients. The clinical presentation of RPB was hemmhoragic shock in 42% of patients and 45% have received blood transfusion. Patients were managed either by conservative treatment (78%), angiography stenting (17%) and vascular surgery (8%). A total of 2 patients died of which RPB was the etiology in 1 patient (2%).
Conclusions: RPB is a rare but serious complication of CC occuring predominantly in female. Time to onset of bleeding can be delayed in patients treated with vascular closure devices. Mortality is not necessarily prevented when treating the bleeding source.

Is There a Gender Difference in Outcomes Following TAVI?

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Background: TAVI is emerging as the standard of care for patients with severe symptomatic aortic stenosis (AS) who are sub-optimal surgical candidates. We aimed to assess the potential gender differences in outcomes following TAVI procedure at our center.

Methods: 123 TAVI pts (50 males and 73 females) were treated and analyzed using various access approaches (TF, TA, TAx) and the 2 devices (Edwards and CoreValve) were used. Outcomes data were collected at 1 month follow up.

Results: Baseline characteristics did not differ between women and men including: age, clinical presentation (CHF, angina or syncope), CAD, CVA, COPD, and/or renal failure (p=NS for all comparisons). Male had more diabetes (46% vs. 22%) and prior CABG (38% vs. 19%) while female had more porcelain aorta (10% vs. 2%), ($p<0.05$ for all comparisons). Both groups were equally at high surgical risk (Euroscore and STS score: male 24±13 and 10.5±6.5 vs. female 22±11 and 9.3±5, P=NS). On average, female had lower aortic valve area by echocardiography (p=0.01), no significant differences were observed regarding the aortic valve gradients before TAVI. Procedural approach did not differ between genders. Procedural success was 98% in males and 96% in females with similar post TAVI gradients. Stroke was 4% in males and 0% in females (p=0.12). Importantly, one month mortality was 2% in males and 5.5% in females (p=0.3)

Conclusion: Baseline characteristics and short term outcomes of female AS patients undergoing TAVI was not different from males and both genders sustained favorable clinical outcomes.

Safety and Feasibility of Transradial Approach for Coronary Bypass Graft Angiography & Intervention

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Selective catheterization of coronary artery bypass grafts (CABG) might be more difficult and time-consuming from the radial artery as compared to the femoral route. This special patient subset has been either excluded or underrepresented in previous studies.
Objectives: To analyze the feasibility and safety of transradial catheterization in patients with previous CABG.
Methods: Single center, case series study. Catheterization data and outcomes during and post catheterization were collected prospectively from November 2005 through October 2011. The access site determined by the operator preference and patient suitability.
Results: We performed 1059 catheterizations in patients with previous CABG during the last 6 years: 572 (54%) via the transradial (TRA) and 487(46%) transfemoral approach (TFA). Mean age 66.4±10.3, female 21.9% and baseline characteristics were similar in both groups. Angioplasty (47.4% vs. 45.4%), including saphenous vein graft intervention (14.9% vs. 16.2%), were similar. Total procedural time (39.7±22.4 vs. 37.3±23.9 min), fluoroscopy time (18.1±13.9 vs.15.3±11.7 min), dye volume (135.3±68.2 vs. 128.6±59.6 ml) and used catheters/patient (3.4±1.3 vs. 3.3±1.1) were similar in both groups. Procedural failure and crossover to alternative access site were 4.4% in the TRA and 0.8% in TFA (p=0.002). Significant vascular access site complications (0.2% vs. 1.4%) were significantly lower (p= 0.02) in the TRA. There was no periprocedural stroke or death in both groups. The duration of hospitalization was shorter (1.2±0.9 vs. 1.9±1.2 days, p<0001) in the TRA.
Conclusion: TRA for coronary bypass graft angiography and intervention is safe and feasible with similar outcome compared TFA. However less vascular complications and early discharge are the edit values of TRA.

Diffuse In-Stent [BMS] Restenosis in Diabetes Mellitus is a Preventable "Malignant" Disease

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Background: Diabetes mellitus [DM] is a powerful predictor of adverse events in patients undergoing percutaneous coronary intervention. Bare metal instent restenosis [ISR] can be focal or diffuse.
Objectives: compare the clinical outcomes of BMS ISR according to ISR type [Focal versus Diffuse] in patients with DM treated with DES.
Methods: A series of 189 consecutive DM patients with ISR lesions treated with DES implantation were evaluated. Major adverse cardiac events (MACE) were defined as death, myocardial infarction, and the need for target lesion revascularization were analyzed at 24 months.
Results: The mean age was 64±10 years and 66% were males. 25% were insulin treated DM, and 63% presented as acute coronary syndrome. The clinical outcomes were compared according to ISR type.

Outcome	Focal ISR [n=71]	Diffuse ISR [n=118]	P-value
12 month death	1.5%	3.9%	0.4
12 month MI	0%	6.8%	0.02
12 month Stent thrombosis	0%	1.7%	0.5
12 month TVR	2.8%	16%	0.003
12 month CABG	1.4%	5.1%	0.2
12 month MACE	5.6%	19.5%	0.005

Conclusions: Diffuse BMS ISR in DM patients is associated with worst one year clinical outcomes even if treated successfully with DES. This worst outcome can be prevented by the use of DES during the index (i.e. first) PCI.

Corevalve-Accutrak Delivery System Improves the Deployment and Outcome of TAVI

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Objective: Transcatheter aortic valve implantation (TAVI) is a novel technology for the treatment of patients with severe and symptomatic aortic stenosis that are at high surgical risk. Implantation of the self-expandable Medtronic-Corevalve valve system is associated with a considerable risk of conduction defects that often warrant the implantation of permanent pacemaker. The Accutrak is a new delivery with an additional stability layer that allows accurate positioning of the corevalve system. We studied whether Accutrak use is associated with favorable deployment and lower risk of pacemaker implantation.
Methods and Results: We compared two consecutive cohorts of patients, each consisting of 24 patients that underwent TAVI with the Medtronic-Corevalve system, prior to and following the introduction of the Accutrak system. There were no significant differences in baseline characteristics including age, gender, co-morbidites, logistic euroscore or aortic stenosis severity. Implantation in both groups was performed via the transfemoral approach in 79% and via subclavian or direct aortic approach in 21%. The mean depth of implantation was 6.7±3 mm below annulus, with 50% of the cases implanted below 6 mm in the pre-Accutrak cohort and 4.7±2.6 mm below annulus ($p<0.05$) with 25% implanted below 6 mm in the Accutrak cohort. No differences were observed in the need for post-dilatation, post procedural aortic regurgitation nor the days to discharge (6.3±2 in both groups). In each cohort there was single mortality in 30 days.Permanent pacemaker was implanted in 42% of the pre-Accutrak cohort and 25% of those implanted with Accutrak (p=).
Conclusion: TAVI with Medtronic-Corevalve system is an effective and safe therapy of high-risk aortic stenosis patients. The new Accutrak delivery system allows accurate deployment, less conduction defects and a lower need for post procedural pacing.