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Comparison between MGuard and Bare-Metal Stents in Patients with ST-Elevation Myocardial Infarction

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Background: The MGuard stent (bare metal stent wrapped externally with a polymer mesh sleeve) is designed to prevent distal embolization by reducing thrombus and plaque fragments released during and post percutaneous coronary intervention (PCI). The aim of this study was to compare the outcomes of the MGuard stent vs bare-metal stents (BMS) in the setting of primary PCI for STEMI.

Methods: A total of 275 patients (MGuard: 47 and BMS: 228) who underwent primary PCI in the setting of STEMI < 12 hours were enrolled in this single center registry. We evaluated TIMI flow grade, peak troponin T release, left ventricular ejection fraction before discharge and MACE (Cardiac death, MI, TLR, stent thrombosis) during 6 months follow-up. Patients with cardiogenic shock were excluded.

Results: TIMI flow grade 2-3 was achieved during PCI with MGuard stent in 95.7% of patients vs 91.1% in BMS group ($p=0.2$). Improvement from initial to post-procedural TIMI flow grade ≥ 2 points was higher in the MGuard group than in BMS, 68.1% vs 48.2% respectively ($p=0.026$). Peak release of troponin T at 48 hours was similar in two groups, MGuard 4.38 ± 3.6 ng/ml vs BMS 4.59 ± 4.2 ng/ml ($p=0.8$). Severely reduced LV ejection fraction before discharge was detected in 10.5% of patients in MGuard group compared to 18.7% in BMS ($p=0.06$). MACE rates at 6 months in the MGuard and BMS groups were 8.5% vs 10.1% ($p=0.7$). The rates of TLR at 6 months were similar (MGuard: 8.5% vs BMS: 9.6%, $p=0.85$).

Conclusions: This registry shows that among STEMI patients undergoing primary PCI, there was a tendency for better post-procedural TIMI flow grade in group of the MGuard stent. Patients treated with the MGuard stent compared to BMS had similar clinical outcomes during 6 months follow-up. There was no difference in TLR rates between the MGuard stent and BMS. There is a need for a randomized trial to evaluate the efficacy and safety of the MGuard stent in STEMI.

εLeft Ventricular Mass: A Strong Predictor of Death in Stented Renal Artery Patients

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Background: Percutaneous dilation and stenting of Renal Artery Stenosis (RAS) has been applied as a complementary invasive method to cope with (ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease 2006): hypertension refractory to drug therapy (class IIa, loe B), anticipating recurrence of pulmonary edema (class I, loe B) or deterioration of kidney function. (class IIa, loe B).

Objective: Evaluate outcomes of RAS patients stented in our cath lab.

Population & Methods: 126 patients (aged 72.9± 9.0, 71 males) , were stented between 2004-7 ; bilateral RAS in 40 patients (16 of the 40 bilateral RAS patients underwent both lesions stent implantation). Most (94%) patients had lesions >90% stenosis.

Results: Twenty eight patients were dead in December 31, 2010. Table A presents variables associated with death. Neither LVEF<35% nor ECG-LVH predicted death.

	Survivors n=98	Dead n=28	p
Baseline Creatinine (mg%)	1.3±0.56	1.72±1.3	0.006
Diabetes Mellitus (%)	35(36)	16(57)	0.042
Triglycerides (mg%)	152.3±61.5	181.5±75.8	0.04
Contrast Dose (ml)	139.9±62.5	181.2±83.2	0.007
Prior MI (%)	38(39)	17(61)	0.039
LV-Mass (gr)ε	183.05±47.5	226.8±62.45	0.009

ε49 cases only, ξ LV mass(gr) = 0.8[1.04{(pwt+lvid+swt)³ - lvid³}] +0.6 (Devereux RB, Reichek N . Circulation 1977 , 55:613-618

By multi variable analysis (Table B)

Variable	Odds Ratio	Confidence Interval	p value
LVmass (gr%)	1.012	1.002-1.022	0.014
DM	2.36	0.848-6.566	0.1

Conclusions: Death was related to Echo-determined LVH but not to ECG-LVH or depressed LVEF. We are unable to comment on effect of renal stenting on mortality; Compared to ASTRAL trial (n=806 , mean age-71 years, 33.6 month f/u , 26 % death) although our cohort was sicker (not shown), still death rate at 55.6 month f/u was lower - 22% only.

Single Center Experience using Drug Eluting Balloons

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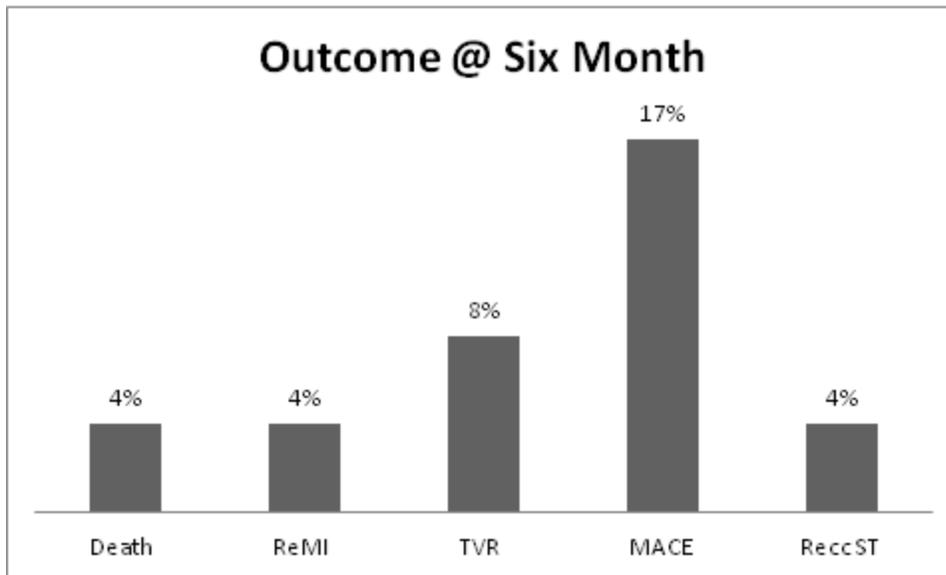
Background: Drug Eluting Balloon (DEB) has emerged as an alternative treatment for In Stent Restenosis (ISR).

Objectives: The aim of this study was to investigate the efficacy of DEB for the treatment of ISR.

Methods: We analyzed the clinical and angiographic data of 50 consecutive patients with ISR using DEB (5 X SeQuent-Please, 45 X De-Lux DEBs) between 2/2010-4/2011.

Results: The mean age was 69 ± 13 years with high risk features of Diabetes-53%, Dyslipidemia-84% and Hypertension of 78 %. The majority presented with Acute Coronary Syndrome (71%). Angioplasty with DEB were mostly used for DES ISR, DES Stent type restenosis: Cypher-9%, Endeavor 4% Xience 3% and Taxus, 32% of cases were BMS ISR. Focal Restenosis was the presentation of 54% according to Mehran Classification. Time to Restenosis 22 ± 24 month and Recurrent ISR occurred 1.4 ± 2.4 month (mean 1-6). The mean Balloon diameter and Length were 3.1 ± 0.4 mm and 16.4 ± 13.3 mm respectively. At six month One patient had stent thrombosis presented as acute myocardial infarction and had target vessel revascularization, and another patient had restenosis ten days after Drug eluted balloon angioplasty. The overall mace (Death, MI, TVR) was 17 %.(Fig.1).

Conclusions: The treatment of in-stent restenosis (2/3 within DES) using drug eluting balloons showed good intermediate term clinical results. Expanded long-term data are awaited.



Culprit Only Versus Complete Coronary Revascularization during Primary PCI

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Background: Current guidelines for management of patients with ST elevation myocardial infarction (STEMI) recommend treating only the culprit vessel in multivessel disease and that other vessels be addressed at a later procedure. Acute multivessel PCI (MVPCI) is recommended during the index procedure only for patients with hemodynamic compromise.

Objectives: The purpose of this study was to examine differences in in-hospital clinical outcomes as well as short term and 1 year mortality for STEMI patients with multivessel disease as a function of whether they underwent culprit vessel or MVPCI.

Methods: STEMI patients with multivessel disease undergoing primary PCIs between January 2001, and September 2010, were divided into those who underwent culprit vessel PCI (CVPCI) alone and those who underwent MVPCI during the index procedure. In-hospital adverse outcomes and mortality rates were compared.

Results: A total of 453 patients had multivessel disease. In 318 (70.2%) of them MVPCI was performed during the index procedure, in 135 (29.8%) patients CVPCI only was done, the rest of the revascularization was completed in the same hospitalization in 29 patients, and 1 to 3 months after in 106 patients. MVPCI during the index procedure was associated with a shorter hospitalization (4.4 ± 1.27 vs 7.6 ± 2.3 days, $P = 0.01$), reduced incidence of in-hospital major adverse cardiac events (recurrent ischemia, reinfarction, acute heart failure and mortality (16.1 vs 35.5%, $P = 0.01$). There was a significantly lower rate of recurrent ischemic episodes (7.2% vs 25.9%, $P = 0.02$), myocardial reinfarction (3.1% vs 9.6%, $P = 0.01$), and reintervention (9.4% vs 29.9%, $P = 0.001$). Transient renal dysfunction was more common in MVPCI (8.4% vs 4% $P = 0.01$). In-hospital and one year mortality rates (4.1% vs 4.4% $p=0.9$, 6.9% vs 7.4% , $p=0.5$) were similar in both groups.

Conclusion: MVPCI in STEMI is feasible, safe and can result in improved clinical outcomes in select cases.

Impact of Gender on Outcomes in Diabetic Vs. Nondiabetic Patients Undergoing Primary PCI for STEMI

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Background: Diabetic patients(pts) and women with acute myocardial infarction(AMI) have a worse clinical outcomes compared with men.The aim of this study was to evaluate impact of gender on outcomes in diabetic versus nondiabetic pts undergoing primary percutaneous coronary intervention(PCI) for AMI.

Methods: We used our clinical database from 1/2000 to 9/2010 consisting of all pts treated by primary PCI (unlaot 12 hours) for AMI excluding pts with cardiogenic shock. The clinical and angiographic results of pts were evaluated in two groups of pts: group "A"- male and group "B"- female according to diabetes mellitus status.

Results: The study cohort consisted of 304 diabetic pts; 993 nondiabetic pts in group "A" and 115 diabetic pts;177 nondiabetic pts in group "B".Diabetic pts in both groups were with higher rates of hyperlipidemia($p<0.008$).Renal failure was more frequent in diabetics female group and in nondiabetics male group($p<0.003$).6 months mortality in male group was 4.6% in diabetic pts and 3.7% in nondiabetic pts($p=0.5$) compared with female group mortality of 15% in diabetic pts and 6.8 % in nondiabetic pts($p=0.03$).12 months mortality in male group was 6% in diabetic pts and 4.7% in nondiabetic pts($p=0.4$) compared with female group mortality of 18% in diabetic pts and 8.5 % in nondiabetic pts($p=0.02$).Multivariate analysis showed in diabetic female a trend toward increased 6 and 12 months mortality [Odds Ratio(OR)=2.1; confidence intervals(CI)=0.9-5.0; $P=0.08$] and not in male. CADILLAC Risc Score was found independent risc factor for 6 and 12 months mortality in male(OR=1.4; CI= 1.2-1.5; $P=0.0001$) and for 12 months mortality in female OR=1.4;CI= 1.2-1.5; $P=0.0001$).

Conclusion: Diabetic females sustain higher mortality following STEMI treated using primary PCI. The etiology might be related to advanced age and/or co-morbidities rather than gender and/or diabetic status per se.

Endovascular Therapy of Intracerebral Posterior Circulation: Early Results and Mid Term Follow Up

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Background: Symptomatic vertebrobasilar ischemia despite antiplatelet or anticoagulation therapy deserved endovascular therapeutic approach.

Aim: To report our initial experience of intracranial vertebral and basilar endovascular therapy by invasive cardiology team.

Methods: During last 6 month 7 pts (4M , 3F, mean age 67 ± 9 years) underwent therapeutic endovascular intervention secondary to atherosclerotic intracerebral posterior circulation (PC) disease. All pts had 3-4 major atherosclerotic risk factors. Four had concomitant coronary and peripheral vascular diseases. Main symptoms were recurrent syncope or dizziness and 2 reported on TIA related to PC. All were symptomatic under antiplatelet , lipid lowering and antihypertensive agents. All underwent either CTA or MRA before intervention. All procedures were undertaken under awake status; 5/7 via the femoral approach , and 2/7 via the ipsilateral radial approach. All procedures performed using regular coronary interventional equipment.

Results: One mid basilar (90%), and 6 V4 vertebral narrowing (70-80%) were treated. One pts had left sided tandem lesion in V2 and V4 segment and other had bilateral V4 significant lesions. 5/7 intracranial vertebral narrowing were treated by DES, whereas basilar lesion and type C V4 lesion were treated initially by balloon only, adopting the submaximal angioplasty approach. All procedures were technically successful. Post dilatation residual narrowing was 10% for stenting and 30-50% for balloon angioplasty. Dual antiplatelet was recommended for 1 year. During mean follow up of 4 moths no symptoms reoccur. CTA during follow up didn't show restenosis in the treated segments.

Conclusions: Safe and beneficial endovascular therapy in symptomatic pts with intra cranial PC narrowing's can be handled by experience interventional cardiologists.

How To Use 3D Imaging To Decrease Complications of TAVI with the Edwards “Sapien” Balloon Expandable Aortic Valve

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One of the most frequent not solved complications at TF-, and TA-TAVI with the balloon expandable Edwards “Sapien” Valve is the paravalvular leakage causing aortic valve regurgitation. It can cause, if relevant, aortic valve malposition, migration during the implantation and by the time serious left or right heart failure and even death.

The reason of the leakage is mostly the different stiffness, morphology, and the size of the aortic valve annulus, and the leaflet-plaques and the different grad of resistance to the balloon and to the stented valve during the valve insertion.

We want to demonstrate here by our precisely and detailed valvular and subvalvular TEE and multi-sliced CT measurement and methods for effective positioning, how to avoid valve embolisation, relevant paravalvular aortic regurgitation and valve oversizing and malpositioning. We operated transapical successfully in the last 2 years 81 patients /EUROSCORE: 30,7 +/-12,7; STS Score . 15,4 +/- 7,8 /.

By these method we reduced significantly our perioperative morbidity and mortality:

Coronary Occlusion : 0,0 %

AV Annulus Rupture : 0,0 %

Permanent Arrhythmia : 0,0 %

AV Block : 0,0 %

Postop. Pacemaker : 0,0 %

Periop. Heart Insuff. : 0,0%

AR Grad I. : 3,6 %

AR-Grad II. : 9,6%

AR-GRAD III. : 0,0 %

Perioperative Mortality: in 3days : 3.6 % (81 Patients)

30 days : 9,6 % (81 Patients)

1 Y. Mortality:14,8 % (81 Patients)

Aortic valve regurgitation after TAVI is still an important issue that must be solved. By our precise annulus, leaflet and subvalvular detailed anatomical measurements and slightly different, deeper positioning and the reduced sizing of the valve, we could partly compensate the protective isolating function of the missing “Outer-coat” of these balloon expandable stented valve and reach a reasonable survival rate.

Analysis of Early Vs. Late Drug Eluting Stent Thrombosis

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Background: The risk of stent thrombosis (ST) following drug eluting stent (DES) implantation may extend very long time beyond the initial period after successful implantation.

Objective: To evaluate the clinical outcomes of patients who presented with DES-related, old, early (<30 days) and late (>30 days) angiographic ST.

Methods: Between 2004 and 2011, 52 patients underwent PCI with DES implantation at our institution. Patients readmitted with confirmed diagnosis of ST were included in and were followed. Clopidogrel therapy was prescribed for 3 to 12 months following the index procedure. Clinical follow up was obtained and adjudicated at one and six month following any ST event.

Results: Angiographically documented stent thrombosis occurred in all 52 patients. Early stent thrombosis was noted in 10 (19%) patients, and late stent thrombosis in 42 (81%) patients. The time interval to early thrombosis was 6.4 ± 3.8 days [median 5-range 3.9-100 days] as compare with time interval to late ST of 873 ± 541 days [median 720- range 480-1080 days]. At 6 months the subsequent major adverse cardiac event rate (including death, re-infarction, recurrent ST or need for emergent CABG) was 30% in the early group and 19% in the late ST group ($p=0.9$).

Overall cardiac mortality rate was higher in the early ST group 20% and lower in the late ST group 2.4% ($p<0.05$).

Conclusions: Following DES implantation at our center, the majority of patients developed late ST (>30 days) and beyond the period recommended for dual anti-platelet pharmacotherapy. We noticed greater mortality rate following early vs. late ST event, while MACE rates did not differed between the groups.

LAD/RCA as Culprit Arteries in AMI (n-2011) in Changing Physical Environment. PCI Data, 2000-2010

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Percutaneous Coronary Intervention (PCI) is one of the principal treatments of Acute Coronary Syndrome (ACS), including Acute Coronary Infarction (AMI). This treatment largely expanded our knowledge about the pathophysiology of AMI and related coronary pathologies. Recent studies found significant relationship of the timing of ACS with environmental physical activity- Solar (SA), Geomagnetic (GMA), Cosmic Ray (CRA) activity.

The aim of this study was to check the interrelationship of two most often involved as culprit arteries- LAD and RCA in the development of AMI in different daily levels of GMA and CRA.

Patients and methods: patients undergoing PCI for AMI at the day of disease (n-2011, 79.9% men) in Rabin Medical Center in years 2000-2010 were studied. The culprit arteries –LAD and RCA, related to AMI in Zero and I0-IV0 of daily GMA and inverse to GMA related CRA (measured by Neutron activity on the Earth surface.) were studied and their ratio compared.

Results: LAD in 45.0% and RCA in 35.7% were the culprit arteries in the AMI. The LAD/RCA ratio rose inverse to GMA (zero – IV0 , $r=0.94$, $p=0.017$) and in correlation with daily Neutron activity for LAD $r=0.97$, $p=0.03$; RCA, $r=0.95$; $p=0.04$. LAD/RCA ratio was 1 in IV0 of GMA and steady rose to 1.62 (62% difference) at zero GMA ($r= -0.94$, $p=0.0117$), and raising Neutron activity accompanied by rising LAD involvement as culprit artery in AMI.

Conclusion: high daily Neutron activity and low GMA are accompanied by rising LAD as culprit artery in AMI. The possible mechanisms of this finding are discussed.

Superficial Femoral Artery Recanalization by Coronary Equipment: From Concept Towards Daily Practice

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Backgrounds:Chronic total occlusion (CTO) of superficial femoral artery (SFA) carries bad clinical outcome. Micro and Macroscopic neo channels are part of this vascular pathology whereas wire crossing and equipment delivery are the main obstacles related to.

Aims: Reporting our experience of SFA recanalization by using coronary equipment after failure with the ordinary peripheral tools.

Material & Methods: Balloon angioplasty and stenting using the contra lateral approach is our standard technique for SFA recanalization. Stiff hydrophilic guide wire (Terumo .035") with an angled tip is our first choice. Seventeen CTO lesions were attempted for recanalization during the last 2 years. Main reasons for initial technical failure were either wire crossing inability or failed peripheral balloon propagation despite wire crossing. After failure of recanalization using the ordinary tools we switched to coronary dedicated wires and balloons. The edit value of this technical approach is described in the following table.

Results:

year	no of pts	missing segments	initial success	after using coronary equipment	total success
2010	10	8 ±4	4/10(40%)	3/10(30%)	70%
2011	7	10±3	3/7(43%)	2/7(28%)	71%

All technically successful procedures terminated with self expandable stent implantation. Using this approach no periprocedural complications were recorded

Conclusions: Coronary balloons and wires may increase the success rate of SFA recanalization by improving penetration and dilatation of the tiny CTO vascular neo channels.