Initial TIMI 0-1 Flow is Associated with Worse 30-day Outcomes of Patients Undergoing Primary Percutaneuos Coronary Intervention for Acute Myocardial Infarction

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Background: Previous studies have shown that closed culprit vessel (TIMI 0-1 flow) following administration of thrombolytic therapy was associated with worse outcomes that were improved by rescue percutaneuos coronary intervention (PCI). Primary PCI is superior to thrombolytic therapy in acute myocardial infarction (AMI), and therefore it might have changed this association. However, the available data regarding this association at the PCI (with stents) and IIbIIIa era are limited. We sought to evaluate the association of initial TIMI 0-1 flow with 30-day outcomes in patients undergoing primary PCI for AMI.

Method and Results: We used our database of all pts (n=1336) undergoing primary PCI for AMI between 1/2001 and 7/2007, excluding those with cardiogenic shock and late arrivals (>12hrs from symptoms onset to 1st balloon inflation). Patients (n=1025) were allocated into 2 groups: 1st Group (n=646 pts) included those with initial TIMI 0-1 flow and 2nd Group (n=379 pts) included those with initial TIMI 2-3 flow. All patients were treated with stents. Patients' clinical and angiographic characteristics as well as 30-day outcomes are shown:

	Initial TIMI 0-1 Flow	**Initial TIMI 2-3 Flow**	P Value
N	646	379	
Age	60±13	60±13	0.99
Male (%)	82	81	0.7
Anterior AMI (%)	46	50	0.1
2-3 Vessel CAD (%)	55	58	0.5
DM (%)	24	25	0.9
CADILLAC score	4.4±3.5	3.7±3.6	**0.002**
Distal embolization (%)	14	5	**< 0.001**
Anti GP 2B/3A (%)	78	77	0.7
No/Slow Reflow incl. transient (%)	8	2	**< 0.001**
Myocardial Blush 3 (%)	78	90	**0.007**
Peak CK	2.5±2.1	1.4±1.6	**< 0.001**
LVEF < 40% (%)	47	35	**< 0.001**
30-day outcomes			
Death (%)	4.3	1.1	**0.001**
Re-MI (%)	3.7	1.6	**0.05**
Stent thrombosis (%)	2.6	0.8	**0.04**
MACE (%)	9.6	4.2	**0.002**

Conclusion: Initial TIMI 0-1 flow in patients undergoing primary PCI for AMI was associated with increased rates of distal embolization and no-reflow. It was also associated with increased infarct size and worse LV dysfunction, consequently resulted in worse 30-day outcomes.

Percutaneous Transluminal Renal Angioplasty, the Cardiologist Experience

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Background: Percutaneous transluminal renal angioplasty (PTRA) is used widely to treat hypertensive patients resistant to drug therapy and to alleviate deteriorating renal function. We present our experience with PTRA during the last years.

Methods: Patients with renal artery stenosis were either diagnosed non-invasively by nephrologists, or during coronary procedures. We retrospectively analyzed data of all patients who underwent PTRA between 1999-2006.

Results: Forty patients who underwent PTRA were included; 25% were referred by nephrologists and 75% were diagnosed during coronary angiography. Patients who were diagnosed primarily by the cardiologist were referred to a nephrologist for further assessment before PTRA. The indication for PTRA was uncontrolled HTN in 67.5%, flash pulmonary edema in 20%, and unexplained renal failure in 12.5%.

Stents were implanted in all patients. Guidewires, 70% of the balloon catheters and 40% of the stents were coronary equipment. Procedural success rate was 100% with no procedural complications.

At follow-up of 2.64±1.41 years, the average number of antihypertensive medications was reduced, episodes of flash pulmonary edema did not recur, and average renal function remained stable (table 1). One patient had in-stent restenosis and underwent balloon re-dilation. Six patients died from unrelated diseases at an average of 4.16±1.3 years post PTRA.

TABLE 1

	CREATININE	UREA	#ANTI HTN MEDS
Before PTRA	1.53±0.28	52.65±16.97	2.85±0.69
At F/U	1.54±0.76	52.60±25.13	1.66±0.81
P value	NS	NS	P<0.001

Conclusions: PTRA was performed successfully in the coronary catheterization laboratory with reduction of antihypertensive medications, disappearance of flash pulmonary edema and maintaining renal function The favorable outcome in this series may be attributed to cooperation between cardiologists and nephrologists and careful selection of patients.

Beneficial 2-years Results of Drug-eluting Stents in Saphenous Vein Graft Lesions

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Aims There are conflicting data regarding clinical outcomes of drug-eluting stents (DES) in saphenous vein graft (SVG) lesions compared to bare metal stents (BMS). We compared the outcomes of DES in *de novo* SVG lesions versus BMS using contemporary percutaneous coronary intervention (PCI) techniques.

Methods and Results We compared the one and two years outcomes in 68 patients (72 grafts) who underwent PCI of SVG lesions using DES and a control BMS group composed of 43 patients (46 grafts) who underwent angioplasty in *de novo* SVG lesions. Major adverse cardiac events (MACE) included death, myocardial infarction (MI), target lesion revascularization (TLR), and target vessel revascularization (TVR).

Results are shown in Table:

	BMS (Patients = 43) (Grafts = 46)	SES (Patients = 68) (Grafts = 72)	*P* value
One year outcomes			
Death / MI / TVR	4.7%/4.7%/23.3%	0%/4.4%/10.3%	0.1/0.9/0.1
Overall MACE	3.2%	11.8%	0.02
2 year outcomes			
Death / MI / TVR	4.7%/7%/32.6%	2.9%/8.8%/14.7%	0.6/0.9/0.03
Overall MACE	41.9%	20.6%	0.02

Between one to two years after PCI, no cases of angiographic stent thrombosis were recorded in either group

Conclusion According to our experiences, DES implantation in SVG lesions was safe and had better overall clinical outcomes after two years.

Side Branch Restenosis: Comparative Analysis of "T" Versus "Crush" Stent Techniques.

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Background: PCI treatment of coronary bifurcation lesions remains challenging. Although stent placement with dedicated techniques has been suggested to be a useful therapeutic modality for bifurcation lesions, restenosis of the side branch after drug eluting stent [DES] remain a problem. To overcome this limitation, the "Crush" technique has been proposed to provide optimal lesion coverage.

Objective: We compared clinical outcomes of the "Crush" versus the "T" technique in bifurcation lesions with drug eluting stents [82% using Cypher].

Methods & Results: We prospectively followed all patients who underwent PCI for symptomatic true bifurcation lesions at our center. Patients treated with two stents were included. Two techniques were used according to the operator's discretion:

	T technique (N=38)	**Crush (N=26)**	**P-value**
Age (years)	62±14	64±11	0.2
Male	84%	85%	0.9
Diabetes mellitus	26%	42%	0.1
ACS presentation	66%	61%	0.8
LAD/DIAGONAL	55%	81%	0.1
Final Kissing Balloon	90%	92%	0.7
Anti GP 2b/3a	84%	80%	0.5
6 month death	0%	0%	1.0
6 month Stent thrombosis	0%	0%	1.0
6 month TVR	0%	7.7%	0.1
6 month MACE	0	7.7%	0.1
12 month death	2.6%	0%	0.8
12 month Stent thrombosis	0%	0%	1.0
12 month MI	0%	3.9%	0.4
12 month TVR	0%	11.5%	0.4
12 month CABG	2.6%	3.8%	1.0
12 month MACE	5.3%	11.5%	0.4

Conclusions: Our results show that for the treatment of true bifurcation lesions with two stents, the use of DES (predominantly Cypher) is associated with improved one year patency regardless of whether "Crush" or "T" techniques were used. Restenosis of the side branch was not eliminated with the "Crush" technique.

Comparative Analysis of 1-year Outcome between Direct and Conventional Stent Implantation in Patients with ST Elevation Myocardial Infarction

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Background: In selected patients presented with ST elevation myocardial infraction (STEMI), direct stenting is associated with reduce procedural complications, duration and costs without compromising short-term outcome. Whether these short-term advantages are also sustained for 1-year has not been fully elucidated.

Methods: We compared procedural results, 30-day and 1-year outcomes between patients with non-cardiogenic shock STEMI who underwent primary percutaneous coronary intervention (PCI) within 12 hours of chest pains, using direct (n=233) versus conventional stenting (n=733) approaches.

Results: Patients who underwent direct stenting were younger (57±12 vs 61±13, p=0.0001), had more frequently single vessel disease (53% vs. 41%, p=0.003, admission TIMI 2\3 flow (63% vs 29%, p=0.0001), and less often calcified (5.6% vs. 16%, p=0.005) and bifurcation lesions (8.2% vs. 16%, p=0.005). CADILLAC score was also lower among patients who underwent direct stenting (3.2±3.4 vs. 4.4±3.5, p=0.0001). Plavix loading (46% vs. 46%, p=1.0) and use of IIb/IIIa antagonists (76% vs 79%, p=0.4) were similar between groups. Fluoroscopy time (10±8 vs 16±11 min, p=0.001), volume of contrast (150±63 vs 180±70, p=0.0001) and need for a second stent (15% vs. 31%, p=0.01) were lower in the direct stenting group. Post procedure TIMI III flow (98.7% vs. 96.2%, p=0.2) and blush 2/3 scores (83% vs. 83%, p=1.0) were similarly high although no-reflow rates (2.6% vs. 6.6%, p=0.01) were lower. 1-year MACE (death, MI, TVR-PCI, CABG, stent thrombosis) were similar between groups (19.9% vs. 22.2%, p=0.5) and no differences were noted in each of the individual endpoints.

Conclusions: Direct stenting is feasible and safe to perform in ~20-25% of *carefully* selected STEAMI patients, providing a reduction in procedural complications and costs, with similar clinical outcomes. Further studies to assess whether such approach is applicable to larger STEMI population are warranted.

Primary Percutaneous Coronary Interventions in Acute Myocardial Infarction in Diabetic Versus Non-diabetic Patients

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Background: Diabetes mellitus (DM) is an independent predicator of outcome after primary percutaneous coronary intervention (PCI) for acute myocardial infarction (AMI).
Objective*:* To compare the short and long term clinical outcome of AMI patients with DM to those without DM undergoing primary PCI.
Methods: We used our clinical database consisting of all patients treated using primary PCI for AMI between 1/2001-7/2007. Patients with cardiogenic shock were excluded. We compared the procedural and angiographic results and clinical outcome up to one-year in diabetic and non-diabetic patients.
Results*:* Of 1092 patients with AMI 273(25%) had DM, clinical characteristic, short and long-term outcome are summarized:

	No DM N=819	**DM N=273**	**P-value**
Age (years)	60±13	64±11	0.0001
Males (%)	84	71	0.0001
GFR (<60 mL/min/1.73 m^2) (%)	10.5	23	0.001
Killip class >1 (%)	15	16	0.3
Anterior MI (%)	46	52	0.3
2/3-vessel disease (%)	54	66	0.007
Ejection fraction <40% (%)	43	43	0.8
Successful PCI (%)$^{\tau}$	95	96	0.5
CADILAC risk score	4±3.4	5.1±3.9	0.0001
One year outcome N=706 N=259			
Death (%)	6.4	10.4	0.03
Re-AMI (%)	6.2	11.1	0.01
Target vessel revascularization (%)	12.6	17.7	0.04
Stent thrombosis (%)	3.4	4.6	0.4
CABG (%)	4.7	8.9	0.01
MACE^{+}	20.5	33	0.005

$^{\tau}$ TIMI 3 and residual stenosis <30%, $^{+}$MACE= Death, re-AMI, TVR
Multivariate logistic regression analysis identified CADILAC risk score (OR 1.4, CI 1.3-1.5, P = 0.001) and DM (OR 1.2, CI 0.7-2.2, P = 0.5) associated with one-year mortality
Conclusions*:* At one year following STEMI there were higher mortality and recurrent ischemic events among diabetic patients as compared to non diabetics.

Clinical Characteristics and Outcomes of DES Related 'Failures': A Comprehensive Single-Center Analysis

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Background: Limited data are available on drug eluting stent (DES) failure (i.e. characteristics and outcome management). We aimed to characterize the pattern, treatment and outcomes of DES in stent restenosis (ISR) in a large consecutive group of patients (pts) treated at our hospital.

Methods: We determined the incidence and major adverse clinical events (MACE) in 79 consecutive pts with DES failure: 71 pts had DES restenosis while 8 pts had DES thrombosis between the period of 1/2004 and 2/2007. We analyzed the clinical data, procedural parameters and outcomes of DES restenosis. ISR pattern was classified according to 'Mehran classification' as follow: focal (I), proliferative/diffuse (II/III) or occlusive (IV).

Results: DES failure was presented in 2.9% of treated patients (71 DES ISR patients out of 2473 DES implanted: cypher N= 1808, Endeavor N=421, Taxsus N= 319 treated patients). Mean age was 65±11 years, 75% were male. 68% of patients had diabetes mellitus (20% needed insulin treatment) and chronic renal failure (Creat. ≥1.5 mg/dl) was encountered in 18% of pts. MV disease was presented in 80% of patients 44% had previous myocardial infarction and 41% had previously CABG. Unstable angina was the clinical presentation in 52 (73%) of patients. Lesion location were mostly in the LAD (35%) followed by LCX (21%) RCA (20%) and bypass grafts (14%). Cypher stents were implanted in 53 pts while 10 pts had Endeavor stents and 8 pts had Taxus stent deployed. The index procedure stent length was 23.3±7.6 and stent diameter was 3.0±0.4. The mean time to restenosis was 11.3±9.9 months. One patient (1.4%) was previously treated using brachytherapy and 22% had prior ISR events. Six month clinical outcome were available in all patients. Three pts developed myocardial infarction (4.2%) of which stent thrombosis was the presentation in one pts (1.4%), restenosis at follow up were diagnosed in 8 pts (11.3%) the overall MACE was 18.3% (13 pts) and two pts died (2.8%).

Conclusions: According to our experience, DES related ISR is relatively infrequent but when encountered it remains a major clinical challenge. DES related restenosis is more frequently encountered in complex patients and lesions subsets (e.g. diabetics, patients with renal dysfunction and/or long lesions) but nonetheless the overall intermediate-term prognosis following repeat percutaneous treatment is favorable.

Results of Unprotected Left Main Coronary Stenting Distinguished by Drug Eluting vs. Bare Metal Stenting: A Single Center Clinical Outcome Analysis

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Background: Unprotected left main coronary artery (ULMCA) disease is considered a surgical indication in most centers. However, in some cases prohibited from surgery, there is a need for percutaneous coronary intervention (PCI) in ULMCA disease scenarios. Our study aimed at assessing the clinical outcomes among patients undergoing stent-based ULMCA angioplasty at our institution and compared the results of drug eluting stents (DES) vs. bare metal stents (BMS) utilization.

Methods: We identified 59 consecutive patients who underwent PCI in ULMCA between 1/2003 and 5/2007. Procedural and angiographic data and clinical outcomes were obtained for all patients (excluding infarction-related cardiogenic shock) and distinguished between DES vs. BMS groups. Clinical follow-up was obtained for all patients at 6 months following PCI.

Results: In the DES group, stent utilization included Cypher in 68%, Taxus in 9% and Endeavor in 24% of treated patients. Baseline characteristics and results of ULMCA stenting distinguished by stent group are shown in **Table**:

	BMS (n=25)	**DES (n=34)**
Age (yrs)	76±14	74±11
Male (%)	60	65
Diabetes (%)	20	38
LVEF >40% (%)	71	62
Hemodynamic unstable (%)	8	15
Distal LM bifurcation (%)	24	47
EuroScore*	8.2±3.1	6.6±3.9
6 month outcomes		
Death (%)	20	3.0
CABG (%)	8.0	3.0
TVR (%)	12.0	3.0
MACE (overall) *	28.0	9.0

** Statistical significant difference ($p \leq 0.05$)*

The six-month mortality rate [univariate] was correlated with the following parameters: DES utilization (r=0.3; p=0.03), EuroScore (r=0.5; p=0.004).

Conclusion: According to our experiences, overall clinical results of unprotected left main stenting are improved using DES.

Stepwise Combined Approach in Primary Percutaneous Intervention: Extensive Clot Extraction, IVUS Guided Focused Forced Predilatation, Stenting and Provisional Post Dilatation

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Background: Distal embolization and "no reflow" are common complications during primary PCI.

Aim: The aim of the study was to assess the impact of stepwise lesion preparation on acute angiographic and long term clinical outcomes in patients undergoing primary PCI.

Methods and results: A total of 30 consecutive patients (43 treated lesions) with acute STEMI scheduled for primary PCI were included in the analysis. All patients were systematically treated by extensive thrombus extraction (aspiration of 125±47 cc of blood), focused predilatation with a scoring balloon prior to stent insertion and finally, provisional post dilatation with a non compliant balloon. IVUS (grayscale and virtual histology) was essential to assess the culprit lesion and the adjacent vessel before predilatation and for result optimization.

Baseline and angiographic characteristics were as follow:

Patient baseline characteristics(n=30)		**Lesion characteristics**	
Age (mean±SD)	69±16	**In-stent occlusion**	7%
Male	66%	**SVG occlusion**	3%
Diabetes mellitus	31%	**Vessel diameter**	2.9±0.6
History of MI	43%	**Moderate or severe Calcification by IVUS**	38%
History of PCI	28%	**Initial TIMI-0 flow**	57%
History of CABG	3%		

Angioplasty and stenting were successfully performed with final TIMI-3 flow and without angiographic evidence of distal embolization in all 30 patients.

At 30-days, the rate of MACE (Death/reinfarction/TLR) was 3% (1/30) due to stent thrombosis in a patient with resistance to clopidogrel. At 6 months follow-up (97% of pts), the rate of MACE was 13% (4/30), one side branch occlusion and restenosis in two cases.

Conclusions: A systematic stepwise approach with extensive clot aspiration and lesion preparation by focused forced angioplasty during primary PCI is safe and associated with a very good short and long term clinical results. It is associated with a reduced rate of distal embolization or "no reflow". IVUS guidance is essential for accurate lesion coverage and optimal stent expansion. This approach should be tested in a randomized trial.

Treatment of In-Stent Restenosis: are Drug Eluting Stents Really the Best Solution?

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Background: In-stent restenosis (ISR) remains a serious challenge after stent implantation. Existing data support the use of drug eluting stents (DES) in these cases. However, few data exist comparing DES with other modalities of treatment.

Aim: To compare the clinical efficacy of DES and bare metal stents (BMS) in the treatment of ISR.

Methods: Retrospective analysis of 160 patients with ISR detected in the setting of clinically-driven coronary angiography between 04/2004 and 10/2006.We compared 129 pts treated with DES (mean age 65±12 y.) and 31 pts treated with BMS (mean age 65±11 y,p=ns). The patients were followed over a median period of 588 days. .Clinical and angiographic characteristics on admission, technical details of PCI and clinical events including all-cause mortality, myocardial infarction (MI), stroke and repeat angioplasty, as well as combined end point were compared. Data were obtained from computerized databases.

Results: Baseline demographic and clinical characteristics, including diabetes mellitus, left ventricular function and number of diseased vessels were similar in both groups. During angioplasty, the reference vessel diameter was smaller in the DES group (3±0.4 mm vs. 3.2± 0.6 mm, p=0.02). The stent diameter was smaller (3±0.4 mm vs. 3.2±0.6 mm; p=0.04) and stent length longer (28±14mm vs. 18±11; p=0.01) in the DES group. The angiographic success rate was 98% in both groups. The event rate for the DES and BMS groups was similar: All-cause mortality (8% vs. 13%), MI (8% vs. 10%); Stroke (5% vs. 0%) and repeat PCI (19% vs. 16%). A combined end point of all events was observed in 37% of DES pts and 35% of BMS pts (p=ns).

Conclusions: During long term follow up, instent restenosis is associated with an adverse clinical outcome. In this study, DES did not demonstrate superiority over BMS in the treatment of instent restenosis.