The Use of Drug Eluting Stents in Regular Clinical Practice did not Reduce the Clinical Restenosis Rate Compared to Bare Metal Stents.

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Background: Compared to BMS ,DES reduce the angiographic restenosis rate post PCI significantly in patients with ACS or stable angina. The effect of DES implantation ,in the usual indications, on symptomatic restenosis rate was not elucidated yet.

Hypothesis: In patients post PCI there is no effect of DES on clinical restenosis rate compared to BMS.

Methods and Results: We compared two periods of nine months each ,before and after the approval of the DES in regular clinical practice base.
We inserted DES in 20 percents of patients in the second group according to the regular indications ,instent restenosis and long lesions.
Three hundreds fifty eight patients were included in the BMS only group. Re-PCI was performed in 56 patients who suffered from clinical restenosis (16 percent). The DES plus BMS group included 413 patients and 58 patients suffered from clinical restenosis (14 percent). There was no significant difference in clinical restenosis rate between the two groups (P-0.54 ,RR-1.07 ,CI:0.9-1.3).

Conclusion : Compaired to BMS ,DES has no effect on the clinical restenosis rate post PCI .

The Impact of Diabetes Mellitus on Drug Eluting Stents Outcomes at One-year Following Acute ST Elevation Acute Myocardial Infarction

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Background: Little is known about the late outcome of patients with diabetes mellitus (DM) who receive DES during the course of STEMI.

Objective*:* We investigated the clinical outcomes of diabetic (DM) versus non DM patients with ST elevation AMI treated using DES.

Methods: We used our clinical database consisting of all pts treated with DES in primary PCI for STEMI. Patients with cardiogenic shock were excluded. We compared the procedural and angiographic results and clinical outcome at 1-year in DM versus non-DM pts.

Results*:* Of 162 patients with AMI 38(23.5%) had DM, clinical characteristic, short and long-term outcome are summarized in the **Table**:

	No DM N=124	**DM N=38**	**P-value**
Age (years)	58±12	60±12	0.4
Males (%)	90	79	0.06
GFR (<60 mL/min/1.73 m^2) (%)	8.9	13	0.002
Killip class >1 (%)	10	8	0.2
Anterior MI (%)	63	66	0.8
2/3-vessel disease (%)	56	71	0.01
Ejection fraction <40% (%)	41	50	0.4
Successful PCI (%)$^{\tau}$	95	97	0.7
CADILAC risk score	3.5±3	4.6±3.4	0.07
1 year outcome			
Death (%)	2.9	5.4	0.5
Re-AMI (%)	0.8	0	0.5
Target vessel revascularization (%)	7.7	0	0.08
CABG (%)	2.9	5.4	0.5
Stent thrombosis (%)	1	0	0.5
MACE^{+}	12.5	10.8	0.8

$^{\tau}$ TIMI 3 and residual stenosis <30%, $^{+}$MACE= Death, re-AMI, TVR

Conclusions*:* DES implantation inSTEMI in diabetic and non-diabetic appears safe with similar incidence of death, myocardial infarction and stent thrombosis up to1 year although target vessel revascularizationan (TVR), albeit low, appears to be concentrated among diabetic patients implanted using DES.

Urgent Coronary Catheterization in the Daily Practice: Indications and Changes Over 10 Years

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Increasing number of urgent coronary catheterizations (UCC) is performed over the last years. Primary percutaneous intervention (PPCI) for ST-elevation myocardial infarction (STEMI) is currently considered as the main indication for urgent catheterization.

Objectives: To assess the indications for UCC over the last 10 years.

Methods: Different rate of coronary intervention was noticed in two different periods: During January 1998 to December 1999 (old period) 587 PCI of 2414 cardiac catheterization (24%), and during November 2005 to October 2007 (new period) 1588 PCI of 3404 (47%) were performed.

Results:

UCC was performed in 72/2414 (3%) patients at the old period and in 241/3404 (7%) in the new period ($p<0.0001$). Patient's characteristics and the indications for UCC in both periods are presented in the following table:

	Old period (n=72)	New period (n=241)	P value
Mean age (years±SD)	60.1±13.7	62.2±14.3	<0.0001
Women	22%	19%	NS
Indications for urgent catheterization:			
- Primary PCI for STEMI (Killip 1-3)	49 (68%)	204 (85%)	0.0017
- Cardiogenic shock	12 (17%)	13 (5%)	0.002
- Treatment of stent thrombosis	4 (6%)	20 (8%)	NS
- Other indications	7(10%)	4(2%)	0.001
In-hospital major adverse cardiac events	9 (12%)	15 (6%)	0.08

Conclusion: The increasing number of urgent catheterizations in our institute over the recent years was due to primary PCI for STEMI and treatment of stent thrombosis.

Late Drug Eluting Stent Thrombosis: Clinical, Angiographic and Intravascular Ultrasound Characteristics

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Late stent thrombosis (LAST) after drug-eluting stent (DES) implantation has been the focus of intense interest because of its attendant morbidity and mortality. Its cause remains unknown.

Objectives: To describe the clinical, angiographic and intravascular ultrasound (IVUS) characteristics of patients who presented with LAST after DES implantation.

Methods: We studied 6 patients who were admitted to our institute in the last 2 years with LAST after DES implantation. All patients underwent immediate percutaeous coronary intervention (PCI) of whom IVUS was performed to 4 patients.

Results: Four males and 2 females, mean age 56.6±15.4 years, 5/6 (83%) diabetic.

In 3 patients the DES was implanted after ST-elevation myocardial infarction (STEMI) and 3 patients for stable angina pectoris. All primary lesions were de-novo, 4/6 (67%) type C. Mean period from stent implantation to thrombosis was 16.7±8.8 months. Thrombosis had occurred after 2 days and more than 1 month after clopidogrel cessation, in 1 and 5 patients respectively. All patients were stable on aspirin monotherapy.

Clinical presentations were STEMI in 4(67%) and non-STEMI in 2 patients. All patients had total thrombotic occlusion of the stented area. IVUS data demonstrated: incomplete stent apposition in 2 patients, underexpansion of the stent in 1 patient and normal apposition and expansion in 1 patient. One patient died during hospitalization.

Conclusion: LAST may appear when patients are stable on aspirin monotherapy more than one year after DES implantation. Incomplete stent apposition and underexpansion may contribute to stent thrombosis.

Management of Stable Coronary Disease Actual Practice and the Courage Trial

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Background: The COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial showed that coronary interventional procedures added little to optimal medical therapy with respect to the long-term outcome of patients with stable coronary disease when used as initial therapy.

Aim: To review the clinical and angiographic characteristics of patients undergoing elective cardiac catheterization in a large cohort of patients in Israel and to compare it to patients included in the Courage trial (C).

Methods: Catheter reports of patients undergoing elective cardiac catheterization at public and private hospitals were analyzed. Analysis was targeted to those patients having the "same" entry criteria as those (C).

Results: 1060 patients from private hospitals and 474 patients from public hospitals were included- Cohort

	Age (years)	Males (%)	Angina (%)	Previous PCI (%)	Previous CABG (%)	1VD (%)	Prox. Lad (%)
Cohort	63	86	72	40	20	36	23
Courage	61	85	88	15	11	31	31

Conclusions: 1. Asymptomatic patients are frequently catheterized. 2. Previously revascularized patients undergo a high rate of recatheterization. 3. Our patients have less severe coronary anatomy than in Courage.

Clinical implication: Many patients with stable coronary disease some asymptomatic are undergoing PCI as the first medical intervention, It is time to practice optimal medical therapy before referring stable patients to unnecessary and expensive invasive procedures.

Nitroglycerin Administration into the Left Main Coronary Artery: Immediate Hemodynamic Effects and Mechanism

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Background: Nitroglycerin (NTG) is administered frequently intracoronary during coronary angiography. We studied the hemodynamic effects of NTG injection into the left main coronary artery (LMCA).

Methods: NTG 150 micrograms was given as bolus into LMCA, ascending aorta (AA), right ventricle (RV), femoral artery (FA) and femoral vein (FV). Pulse and blood pressure (BP) were continuously recorded at the RV/PA and aorta. Cardiac output (CO) and stroke volume (SV) were calculated by simultaneous echocardiogram.

Results: Injection of NTG into AA and LMCA induced a similar and significant drop in systemic BP that started within1.54 and 1.2 sec and reached a trough low at 12.5 and 12.9 sec, respectively. Injection into RV and FV caused slower immediate (10.3 and 17.1 sec) and maximal (24.5 and 43.8 sec) response. Stroke volume decreased after injection to AA. CO and SV remained constant after injection to LMCA, FA and FV.

Inj site	LMCA		AA		RV	
	Base	NTG	Base	NTG	Base	NTG
SYS BP AO (mmHg)	142.3	126.1	131.8	103.9	135.7	115.4
	P=0.0001		*P=0.0001*			
Time to start of BP drop (sec)		1.2		1.54		10.3
Time to trough (sec)		12.5		12.9		24.5
SV (ml)	65	65	70.7	63.3	67.1	63.7
	P=NS		*P=0.047*		*P=0.154*	
CO (l/min)	4.07	4.01	3.98	3.76	4.38	4.12
	P=NS		*P=0.21*		*P=0.14*	

Conclusions: NTG injected into the AA and LMCA induced systemic BP reduction through different mechanisms. NTG injected into AA induced direct vasodilation and secondary (statistically significant) reduction in SV and (non-significant) reduction in CO. NTG administered into the LMCA induced immediate drop of BP that was not caused by either direct effect on systemic or pulmonary vascular bed, nor by decrease in SV and CO. A proposed mechanism might be reflex systemic vasodilation through coronary receptors.

A New Method for Femoral Sheath Withdrawal Using Elastic Bandage Compression

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Background: Hemostasis of femoral puncture by manual or mechanical devices is painful, and is time and effort consuming. We present a simple method for femoral artery puncture site hemostasis used in our department during the last 13 years.

Methods:

Femoral homeostasis: Upon sheath withdrawal gauzes folded to a cone shape are compressed by elastic bandage (EB) applied from the patient's left lower back (for right femoral puncture) towards the right groin, surrounding the right thigh to the patient's belly and then to his right lower back in an 8 shape. Bandage tension is adjusted to maintain pressure while keeping palpable peripheral pulse.

Method evaluation: The EB was used in 100 consecutive patients who underwent diagnostic coronary angiography or angioplasty. Conventional manual or mechanical pressure was then used in another 100 consecutive patients (CM group). All patients underwent femoral Duplex on the day after procedure.

Results: Ninety five percent of the arterial sheaths were 6F and 5% were 8F diameter. Compression in group CM included manual in 85%, Compressar (AVD ™) in 10%, and Femo-Pump in 5%. The median time needed was 90±35 seconds and 16±6 minutes in the EB and CM groups, respectively ($p<0.001$)). On duplex, 1 patient in each group had small pseudo-aneurysm resolved with local compression. Three patients in the EB group had hematomas – one small and two medium size, neither needed blood transfusion. Four patients in group CM had hematomas and one needed blood transfusion.

Conclusions: EB compression can be used for femoral homeostasis following coronary angiography and angioplasty, with comparable outcome to conventional compression. EB saves medical staff time and effort and seems to cause less discomfort to the patient.

Drug Eluting Stents in Diabetic Versus Non-diabetic Patients with Saphenous Venous Graft Occlusive Disease

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Background: The safety and efficacy of drug-eluting stent (DES) implantation for the treatment saphenous venous graft (SVG) lesions remains uncertain and the impact of diabetes mellitus (DM) on long-term outcomes is not well established

Objective*:* To evaluate clinical and angiographic outcomes of DES implantation in SVG lesions in diabetic versus non-diabetic patients.

Methods: Data from consecutive patients who underwent PCI of SVG were imputed into a dedicated clinical database. We compared the procedural and angiographic results and clinical outcome at 1-year in DM versus non- DM patients.

Results*:* Of 74 patients with SVG treated with DES 41 (55%) had DM, clinical characteristic, long-term outcome are summarized as follow:

	No DM (N=33)	**DM (N=41)**	**P-value**
Age (years)	72±8	69±9	0.01
Males (%)	91	88	0.7
Acute coronary syndrome (%)	70	75	0.8
Age of the grafts (years)	11.2±4.8	10±5.3	0.3
Degenerated vein grafts (%)	31	40	0.4
Slow/No- reflow (%)	0	7	0.1
Distal protection (%)	36	43	0.5
1 year outcome			
Death (%)	0	0	1
Re-AMI (%)	3	4.9	0.7
Target vessel revascularization (%)	6.3	9.8	0.7
Acute stent thrombosis	2.6	2	0.7
MACE^{+}	12.5	12.8	0.8

$^{+}$MACE= Death, re-AMI, TVR

Conclusions*:* DES implantation in SVG lesions in diabetic and non-diabetic appears safe with similar incidence of death, myocardial infarction, target vessel revascularization and stent thrombosis up to one year.

Comparison of Late Versus Early Stent Thrombosis: 5-Year Experience from a Large Unselected Population

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Background: It has been recently implicated that the risk for stent thrombosis (ST) extends for many months after stent implantation. We sought to investigate differences between early and late ST in a broad unselected population.

Methods: Data on all consecutive cases of angiographic ST from January 2003 to October 2007 was analyzed. During this period 8,849 stents (6,737 bare metal stents and 2,112 drug-eluting stents) were implanted in 5,141 patients. We compared early (0-30 days) versus late (>30 days) ST regarding the clinical attributes, angiographic findings, treatment and short-term outcome.

Results: Angiographic ST was reported in 63 patients (45 males, mean age 66±12): 44 (70%) early and 19 (30%) late cases. The median time (25-75% interquartile range) from stent deployment was 6 (2-87) days, with the last cases occurring more the 3 years after stent implantation. The majority of patients presented as ST-elevation MI in both late and early cases (84% vs. 93%, p=0.36), but late cases tended to be younger (62±12 vs. 68±11, p=0.06) , and to be in a worse clinical condition (Killip class III-IV 26% vs. 16%, p=0.08). Angiographically, in late cases the thrombosed stent tended to be more likely a drug-eluting stent (57% vs. 35%, p=0.14), and to less likely occur in the left anterior descending artery (53% vs. 71%, p=0.09). The need for additional stenting was much more frequent in early cases (42% vs. 5%, p=0.04). A few in-hospital fatalities were observed in both groups (2 early and 1 late).

Conclusions: Early and late stent thrombosis might be associated with different clinical and angiographic profiles. More early cases needed treatment with additional stenting, implying for different mechanisms for stent thrombosis.

One-Year Outcomes of Consecutive Patients Undergoing Percutaneous Corornary Intervention. Single Israeli center and European perspective- A Report from the PCI Registry, European Heart Survey

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Background: The European Percutaneous Coronary Intervention (PCI) registry is conducted to evaluate the current practice and outcomes of PCI for different indications in an unselected population in different centers and nations across the continent.

Aim: To compare the in-hospital and 1-year follow-up outcomes of patients undergoing PCI at Rambam medical to other participating European centers.

Methods and results: A total of 7894 consecutive patients underwent PCI in participating centers that provided 1-year follow up data. Of them, 7807 (99%) pts were discharged alive. Long term follow-up was available for 5666 (73%) patients. At Rambam medical center, the rate of follow-up was 90% (79/88 pts). Baseline characteristics, procedural data and one year follow up outcomes are presented in the table:

Baseline characteristics and procedural data			One year follow up		
	Rambam medical center	**European sites**		**Rambam medical center**	**European sites**
Number of pts	88	12 307	**Number of pts**	79	5666
Diabetes mellitus	30%	25%			
STEMI	27%	24%	**Alive at 1-y**	98.7%	95.9%
Acute coronary syndrome	61%	46%	**MACCE:** **Death** **Non-fatal MI** **Non-fatal stroke**	3.8% 1.3% 2.5% 0%	6.6% 4.1% 1.8% 0.9%
Drug eluting stent	46%	42%	**Hospital readmission**	19.2%	27.7%
Free from periprocedural complications	94%	94%	**CABG**	1.3%	1.9%
In hospital stent thrombosis	1.1%	0.6%	**PCI**	5.1%	10.1%
In hospital mortality	0%	1.5%	**Late stent thrombosis**	0%	1.1%
In hospital reinfarction	2.3%	1.8%	**NYHA III-IV**	5.1%	6.7%
			Medication at 1-y **Aspirin** **Clopidogrel** **Beta blockers** **ACE-I** **Statins**	 89.6% 20.8% 66.7% 37.3% 81.8%	 91.7% 37.5% 77.1% 59.9% 85.4%

Conclusions: By applying current guidelines, patients selected for treatment by PCI for all clinical indications have very good in-hospital and post discharge 1-year outcomes. With the reported penetration of drug eluting stents, the rate of MACCE, recurrent PCI and stent thrombosis are low.

Mechanical Facilitation of Primary Coronary Interventions – Is it Possible?

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Background: Primary coronary intervention is now the preferred strategy for the treatment of STEMI.

Given the pathophysiologic role of intra-coronary thrombus generation and occlusion, aspiration thrombectomy technique may be an attractive approach.

Purpose: To assess the mechanical yield of thrombus aspiration with the Pronto device in primary PCI.

Patients and methods: We reviewed the reports and digital data of all patients admitted to the cathlab with acute ST elevation coronary syndrome, who underwent urgent Primary PCI, with total occlusion of infarct related artery – TIMI 0 coronary flow on diagnostic coronary angiography. The use of aspiration thrombectomy (PRONTO technique) and implementation of different intravascular interventions such as balloon pre-dilatation as opposed to direct coronary intervention (direct stenting or PTCA-POBA), were investigated.

Results: Between June-November 2007, 66 patients with STEMI were treated.

Sixty four patients underwent primary coronary intervention, 2 were urgently transferred for surgery. 38 patients presented with total occlusion of the IRA with TIMI 0 coronary flow on diagnostic angiography. Aspiration thrombectomy was used in 24 cases (based on operator's discretion). In 21 cases aspiration was the first intravascular intervention performed – "Pronto-First" group. In 17 other cases aspiration was either not performed (14 cases) or was used later after another intravascular intervention had been performed (3 cases – all because distal embolization or non-reflow phenomenon) – "Non-Pronto" group.

In the Pronto-first group, pre-dilatation was performed in 7 (33.3%) cases and direct stenting became feasible in 14 (66.7%); in the "Non-Pronto" group, pre-dilatation was performed in 8 (47.1%) and direct stenting in 9 (52.9%) of cases.

Whenever aspiration technique was implemented – either as the first intervention or later during PCI, it resulted in mild improvement of TIMI flow, average from 0 to 1.7 in both groups. The resulting TIMI coronary flow was similar in both groups 2.86 in "Pronto-First" vs 2.78 in the second group.

Conclusion: The application of aspiration technique by Pronto in primary PCI, may reduce the need for balloon pre-dilatation, and may result in less intimal injury associated with the procedure.

Transient Rises in Serum Creatinine Following Coronary Angiography and the Risk of Long-Term Mortality

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Current data regarding the long-term implications of transient serum creatinine (SCr) rises following coronary angiography are limited. We prospectively followed-up, during a median period of 4.9 years, 78 patients with chronic renal insufficiency who underwent coronary angiography with or without intervention. All patients received intravenous 0.45% saline (1ml/kg of body weight per hour) 12 hours prior to and after coronary angiography, and were further randomly assigned to either acetylcysteine (600 mg orally t.i.d.) or placebo. There was a transient increase of ≥ 0.5 mg/dL in SCr concentration or >25% increase above baseline 48 hours after coronary angiography in 10 of the 78 patients (13%). All changes were no longer evident 7 days after coronary angiography. At 5 years of follow-up, the cumulative probability of death from any cause was significantly higher among patients who developed post-coronary angiography transient SCr rises (90%) as compared with those who did not (32%; p<0.001). In multivariate analysis, an older age (≥70 years: HR=2.68; p<0.001), a lower ejection fraction
(≤40%: HR=2.38; p=0.001), and transient SCr rises (HR=2.60; p<0.001) were identified as independent predictors of long-term morality, whereas administration of acetylcysteine at the time of coronary angiography was not associated with long-term outcome (HR=1.22; p=0.22). In conclusion, our findings suggest that transient short-term reductions in renal function following coronary angiography in patients with renal insufficiency are independently associated with a significant increase in the risk of subsequent long-term mortality. Careful follow-up of postcoronary angiography SCr levels is warranted for risk assessment in this population.