Sirolimus - Versus Paclitaxel-Eluting Stents: Long-Term Clinical Results in Acute Myocardial Infarction

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Background: Recent trials indicate that drug-eluting stents (DESs) can be used in primary percutaneous coronary intervention (PCI). However, the efficacy of the two most common DESs, the sirolimus-eluting stent and the paclitaxel-eluting stent, has not been compared in this setting.

Objectives: The aim of the study was to investigate the clinical outcome of patients treated with primary PCI using a DES and to compare the efficacy of the sirolimus- and paclitaxel-eluting stents.

Methods: Primary PCI with a DES was performed in 151 patients: 82 treated with sirolimus-eluting stents and 69 with paclitaxel-eluting stents. The sirolimus-eluting stent group was characterized by higher rates of anterior myocardial infarction and ejection fraction lower than 40% (Table). Death, reinfarction, and need for repeated revascularization were assessed.

Results: The rate of major adverse cardiac events in the whole cohort was 11.2%. There was a trend towards higher mortality at 6 months in the paclitaxel-eluting stent group, but that trend decreased on longer follow-up. Patients treated with sirolimus-eluting stents needed more revascularizations, but the difference between the groups was not statistically significant.

Conclusions: The use of a DES in primary PCI yields excellent clinical results. Outcome appears to be equally good for treatment with sirolimus- or paclitaxel-eluting stents, though the latter may be associated with a small trend towards higher mortality.

	Sirolimus-Eluted Stents (n=82)		Paclitaxel-Eluted Stents (n=69)	
Age (yrs)	58±12		60±10	
Male	85%		90%	
Anterior AMI	76%*		52%*	
Diabetes mellitus	26%		22%	
2/3-vessel disease	62%		58%	
Post-PCI TIMI 3	94%		97%	
EF < 40%	51%*		34%*	
Follow-up	**6-month**	**12-month**	**6-month**	**12-month**
Death	0%†	2.4%	2.9%†	6.4%
Re-AMI	0%	0%	0%	0%
TVR	4.9%	7.3%	1.5%	2.1%
CABG	2.4%	3.7%	1.5%	2.1%
MACE	7.3%	12.2%	5.9%	10.4%
*p<0.05, †p=0.05-0.10				

Transradial Access for Coronary Procedures in a Moderate Volume Hospital: a Potential for Eliminating Serious Access Site Complications?

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Background: Numerous studies have demonstrated the feasibility and increased safety of transradial approach (TRA) over transfemoral approach (TFA) for coronary iprocedures in carefully selected patients. However the penetration of TRA in routine practice is still low. We sought to compare TRA with TFA for elective and emergency procedures in unselected patients in a hospital with moderate procedure volume.

Methods: We studied 100 consecutive patients who underwent cardiac catheterization iin October-November 2007. The patients were randomly assigned to TRA or TFA iaccording to the day of the week on which the procedure was performed. There were no exclusion criteria. Patients in TRA group with prior CABG or ischemic Allen test in the right hand underwent catheterization from the left radial access. The primary iend point was the incidence of access site complications (hematoma >10cm, pseudoaneurysm, arterio-venous fistula, need for blood transfusion or surgery).

Results: There were 52 patients in TFA group and 48 patients in TRA group. Coronary angioplasty (PCI) was performed in 25/52 (48%) patients in TFA group and 35/48 (73%) patients in TRA group ($P< 0.05$). The access failure rate was 1/52 (2%) and 4/48 (8%) in TFA and TRA group respectively (P=NS). The PCI was successful in all patients in TFA group and in 34/35 (97%) patients in TRA group (P=NS). The mean (±SD) contrast use and fluoro time in patients who underwent PCI was 259±85 cc and 13.5±8.8 min versus 223±88 cc and 13.6±7 min for TFA and TRA group respectively (P=NS). 6/52 (11.5%) patients in TFA group and 0/48 (0%) patient in TRA group had at least one vascular complication ($P<0.05$). The rate of complications excluding hematomas was 3/52 (5.8%) and 0/48 (0%) in TFA and TRA group respectively (P=NS).

Conclusions: The TRA for coronary procedures is a safe alternative to TFA in unselected patients in a moderate volume hospital. The routine implementation of TRA has a potential to reduce or even eliminate serious access site complications.

Drug Eluting Stents – Pattern of Restenosis and Outcome Impact

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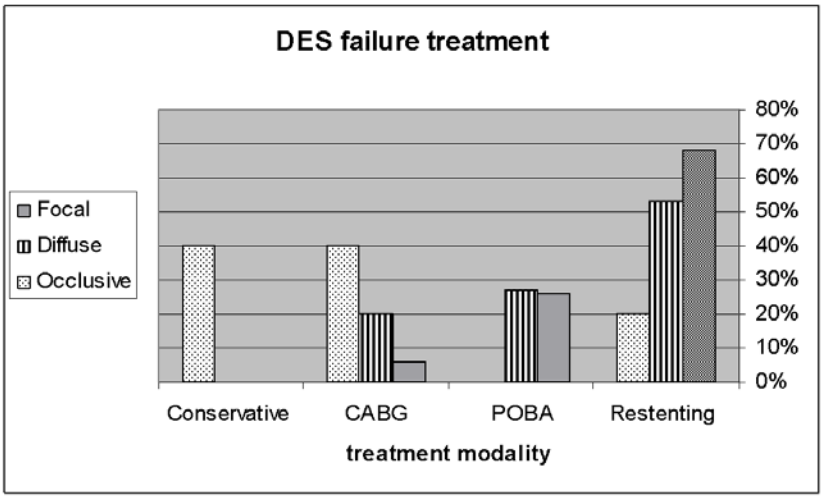
Obejectivs- We sought to identify the Drug eluting stent (DES) restenosis pattern and outcome at six month

Background – The in stent restenosis (ISR) pattern (according to Mehran classification) in bare metal stent (BMS) is known as prognostic factor. Little is known whether this remains in DES.

Methods – Between January 2004 and February 2007 we identified 71 patients with DES related ISR: 75% Cypher stent, 14% Endeavor stent and 11% Taxus stent.

ISR pattern was classified according to Mehran classification as: Focal, Diffuse or Occlusive. Major adverse cardiac events were obtained at Six month follow up.

Results – During the study period, DES failure was presented in 2.9% of treated patients. Mean age was 65±11 years, 75%-male. 68%-DM (20% Insulin treated), 41%-after CABG, and chronic renal failure (Create. ≥1.5 mg/dl) was encountered in 18% of pts. Multi-vessel disease was presented in 80%, and 44% had previous MI. Unstable angina was the clinical presentation in 52 (73%) of patients. Focal ISR was found in 71%, diffuse-ISR in 22% and 7% presented with stent occlusion. Restenting was more often used for focal and diffuse pattern (68% & 53% respectively) followed by POBA (26% & 27% respectively) as compared to CABG or medical therapy in the occlusive pattern (Fig.1)



Six month outcomes according to ISR type were available in 67 pts.

The incidence of recurrent PCI increased in the diffuse restenosis type compare to the focal group ,as well as MACE of 14.6% versus 42% p=0.05. There was no increment in mortality or myocardial infarction.

Conclusions - Although focal restenosis pattern is described in the majority of the pts, treatment modalities varied and remain to be defined. The pattern of DES is a predictor of the need for reintervension. The overall intermediate-term prognosis is favorable.

In-Stent Restenosis : Different Time Course of Clinical Presentation between Drug Eluting Stents and Bare Metal Stents

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Background: In-stent restenosis (IRS) of drug eluting stents (DES) is relatively infrequent . The timing and clinical presentation of IRS following implantation of DES is not well characterized.

Aim: To evaluate the clinical presentation of IRS after DES implantation .

Methods. Retrospective study of 78 pts (age: 65±10 y.) out of 1418 pts who had PCI between 4/04 and 10/06 and required a second procedure for IRS. Patient data was prospectively recorded in a computerized database. Demographic, clinical, angiographic and angioplastic characteristics were studied. We compared the clinical presentation and its timing after the initial procedure between patients initially given BMS (N=69) and those given DES patients (N=9).

Results: Patients initially treated with DES or BMS who later developed ISR had similar baseline clinical, angiographic and angioplasty characteristics during the initial procedure.

The time to the second procedure was 226 ± 172 days for the whole group. The clinical presentation of ISR was similar in BMS and DES : STEMI: 3% vs 22% , NSTEMI: 22% vs 26% ; unstable angina 49% vs. 33% and stable angina in 10% vs. 22%,. A trend for differences in the timing of the presentation of ISR was observed. ISR presented clinically during the initial six months in 58% of BMS pts vs 11% in DES, between 6 to 12 months in 26% of BMS and 33% in DES and after twelve month ISR presented in 56% of patients treated with DES in comparison with 16% in patients receiving BMS (p=0.08).

Conclusion: The clinical presentation of instent restenosis is similar in DES and BMS. However, there is a significant delay in the timing of clinical presentation of ISR in patients treated with DES. Whether this observation is an additional expression of the delayed healling of the arterial wall observed in drug eluting stents should be further investigated .

Long Term Results of Drug Eluting Stenting of Bifurcation lesions: A Systematic Approach Towards Stenting

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Background: The optimal stenting strategy in coronary artery bifurcation lesions is unknown. Recent studies suggest that, independent of stenting strategy; excellent clinical and angiographic results were obtained with percutaneous treatment of de novo coronary artery bifurcation lesions with drug-eluting stents [DES]. A systematic coronary stenting approach for bifurcation lesion using DES is needed. A strategy of using two DES may be preferred if the side branch is of adequate size and heavily diseased, while in other cases a 'simpler' approach of stenting the main vessel only, with optional (provisional) stenting of the side branch may be appropriate.
Objective: The strategy of systematic coronary stenting in bifurcation lesions was evaluated in a large single-center observational study during a two-year inclusion period.
Methods & Results: The study included 170 patients with a mean age of 63±12 years, 78% male, 52% with acute coronary syndromes. The LAD/diagonal bifurcation was involved in 63.5% of cases. Anti GP 2b/3a drugs were used in 72% of cases. In 78% of cases sirolimus-eluting stents [Cypher] were used. Initial two stents strategy was used in 63 pts [37%], while in 107 pts the strategy was stenting of the main branch with provisional stenting of the side branch, of whom 7 crossed to side branch stenting also due to procedural indications [dissection or unsatisfactory angiographic results].

	Six months [n=170]	One year [n=170]	Two years [n=85]
Death	1.2%	1.8%	3.5%
MI	4.7%	4.7%	8.2%
Stent thrombosis	1.8%	1.8%	3.5%
TVR	5.3%	7.1%	14%
CABG	4.1%	4.7%	8.2%
MACE	10%	13%	27%

Conclusions: Our results would indicate that a systematic approach towards PCI in bifurcation lesions with careful attention to procedural technique and using DES is associated with favorable long-term clinical results.

Procedural and Clinical Results of Percutaneous Patent Arterial Duct Closure in Adults

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Background: Patent arterial ducts (PDA) of clinical importance are rare in adults. They may require percutaneous device closure.

Aim: To examine the procedural and clinical outcomes of patients with PDA closure at the adult congenital heart unit in-order to characterize this relatively uncommon patients' group.

Results: We studied 28 pts. (20 female) who had PDA closure over a 13 years period; mean age at catheterization was 41±16 yrs (range 18-72) and mean age at diagnosis was 30±21 yrs. NYHA FC was I in 9 pts., II in 12, III in 6 and IV in one. In 19 pts. there was a continuous murmur. Echocardiography showed LV diastolic diameter 55±6 mm and left atrial area 24±5 cm^2. LV systolic function was good in 21, lower limit in 2, mild dysfunction in 2 and mild-moderate dysfunction in 3 pts. Diastolic function was normal in 16, delayed relaxation in one, restrictive in 5 and unknown in 6 pts. Two patients each had mild-moderate and moderate mitral regurgitation. Duct diameter by echo was 4.5±1.3 mm and by angiography 3.7±1 mm. Hemodynamics: Qp/Qs=1.6±0.4, mean pulmonary artery pressure 22±9 mmHg, mean right atrial pressure 6±2 mmHg, LVEDP 17±6 mmHg, cardiac index 3.2±0.8 l/min m^2 and pulmonary vascular resistance 1.8±1.2 Woods x msq. **Devices used:** 3 were closed with 17 mm Rashkind umbrella, 8 with Gianturco coils and 17 with Amplatzer PDA occluders (sizes 6/4 n=4, 8/6 n=9, 10/8 n=2, 12/10 n=1, 14/12 n=1). **Procedural success and complications:** None of the Rashkind and Amplatzer devices had a residual leak. One Amplatzer device was pulled through a very short duct, and another one was implanted on a later session. One patient had two coils with a very mild residual leak. One patient had hemolysis due to post coil residual leak and had a second coil implanted. One coil embolized to the pulmonary artery and was successfully retrieved. There were no late complications. On follow up echocardiograms, the LV diastolic diameter decreased to 50±13 mm (p=0.01), left atrial area to 21±5 cm. In 3 patients, echocardiogram on the day post procedure showed decrease in diastolic diameter, increase in wall thickness and a new abnormal relaxation pattern, presumably due to the abrupt reduction of preload. **Clinical outcomes:** Of the 19 patients who were in NYHA FC II or worse before PDA closure, 11 improved by one FC, 6 did not improve and in 2, FC post procedure is not known. One patient died 3 years post procedure from worsening mitral regurgitation and severe LV dysfunction despite initial improvement.

Conclusions: Percutaneous PDA closure is feasible in all ages, with a very high success rate and very low rate of minor and transient complications, mostly related to coils. In recent years, Amplatzer devices have been used successfully, without complications or residual leaks, even in relatively large ducts. Post procedure there is a significant decrease of LV size and in many also an improved functional capacity.

Referring Patients for Coronary Angiography Solely by the Internist: The CAFAIN-D Project.

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Background Increased demands of internal departments (ID), persistent growth in catheterization activities and short medical staff enforced us to develop on line interactive computerized flow chart for referring pts for coronary angiography (CA) without involving cardiac consultant.

Aim: Testing a model of referred pts from ID to CA using on-line interactive computerized data supplied by the ID directly into the catheterization laboratory (CL).

Methods: After each round in every ID, authorized physician asked to fill clinical, ECG, GXT, and laboratory data related to every potential candidate for CA. The clinical data are: pts age, angina type, previous CA and iodine allergy. ECG changes, GXT results, troponin, hemoglobin, platelet count and urea levels are also described. Using this type of model we examined: mean waiting time for CA, the rate of normal angiogram (NCA) and PCI during one month in two different periods: 10/2006 using cardiac consultant versus 10/2007 using internist.

Results:

October	2006 Cardiac Consultant	2007 Internist	p-value
Total N of CA	92	130	
Number of CA from ID	42 (46%)	69 (53%)	0.12
Waiting for CA. (days)	3.1±0.2	2.8±0.2	ns
Total N. of NCA	19 (20%)	24 (18%)	ns
NCA'from ID	4/42 (9%)	10/69 (14%)	0.22
PCI from ID	12/42 (30%)	32/69(46%)	0.032

In 10/2007 only 1 patient was rejected from CA due to atypical angina, anemia and renal failure and CA was delayed for 7 days due to end stage renal failure in other one. By this model we shorted waiting time for CA and noticed increased rate of PCI's from ID's.

Conclusions: Referring pts for CA by the internist using computerized flow chart data is easy, feasible and comparable to the task undertaken by cardiac consultant.

A model for Measuring Guidelines Implementation

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Background: There is a "treatment gap" between the clinical guideline recommendations and actual performance. As a result, many patients do not reach target goals. Dyslipidemia monitoring provides a good example for evaluating this phenomenon. A common definition of compliance with dyslipidemia monitoring is having one lipid profile test per year (AMA, 2005). Such an approach does not comply with guideline recommendations that relate to changes of treatment and LDL-C levels over time.

Aim: To Develop an appropriate system to measure guidelines implementation.

Methods: We built a flexible model to define compliance with dyslipidemia monitoring, depending on LDL levels, change of treatment and guideline recommended for monitoring interval.

Participants: Cardiovascular patients aged 40-80 who had been hospitalized for CABG, PTCA, Coronary catheterization, or any ACS or ACS beginning on 1/2000 until 1/2004 (n= 3435).

Results: According to the traditional definition of compliance, one lipid profile a year compliance rate was 85.9%. However, using our flexible model, only 65.8% of patients actually complied with lipid monitoring guidelines ($p<0.0001$).

Conclusions: A flexible model for measuring compliance is far more sensitive than present orthodox systems and it enables detecting a larger portion of the population at risk that do not comply with guidelines of risk monitoring. The flexible model is generic and can be adjusted for monitoring other risk factors, since the parameters of target goal, medication and recommended monitoring intervals can be changed readily.

Smoking History : A Predictor of Right Coronary Artery Narrowing

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Background: Smoking history is a major predictor for premature coronary atherosclerosis. Its association with narrowing of the right coronary artery (RCA), although guessed, was not studied systematically. We conducted a retrospective analysis of our data base and hospital records in order to clarify this issue.

Methods: Among patients aged <65 years subjected to coronary angiography during **2006,** demographic and pertaining clinical data of those identified as harboring single vessel coronary artery (CAD) disease were analyzed.

Results: A) Among smokers, myocardial infarction and diabetes were observed in 42(22%) and 39 patients (20%), respectively. Four patients were afflicted with both conditions. Obesity was observed in 32(17%) patients.

B) An overall difference in the distribution of disease location was observed between smokers and non-smokers ($p<0.0001$). This significant difference permitted the pairwise comparison of specific locations by smoking status, as shown below:

	RCA	LCX	LAD	LMCA	Total
Non-Smokers	46 (14%)	59(18%)	214(66%)	7(2%)	326
Smokers	82 (42%)	39(20%)	65(34%)	7(4%)	193
All	**128(25%)**	**98(19%)**	**279 (54%)**	**14(24%)**	**519**

Comparisons	p value
1) RCA vs LCX	0.02
2) RCA vs LAD	<0.0001
3) RCA vs LMCA	0.13 (NS)
4) RCA vs others	<0.0001
5) RCA vs each other	<0.0001

Conclusion: Among single vessel CAD patients, **smoking history** predicted a **threefold** incidence of **RCA** narrowing.

Comparative Analysis of Quantitive Fibrinogen, hsCRP and the Number of Diseased Vessels in Patients with Coronary Artery Disease

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Introduction

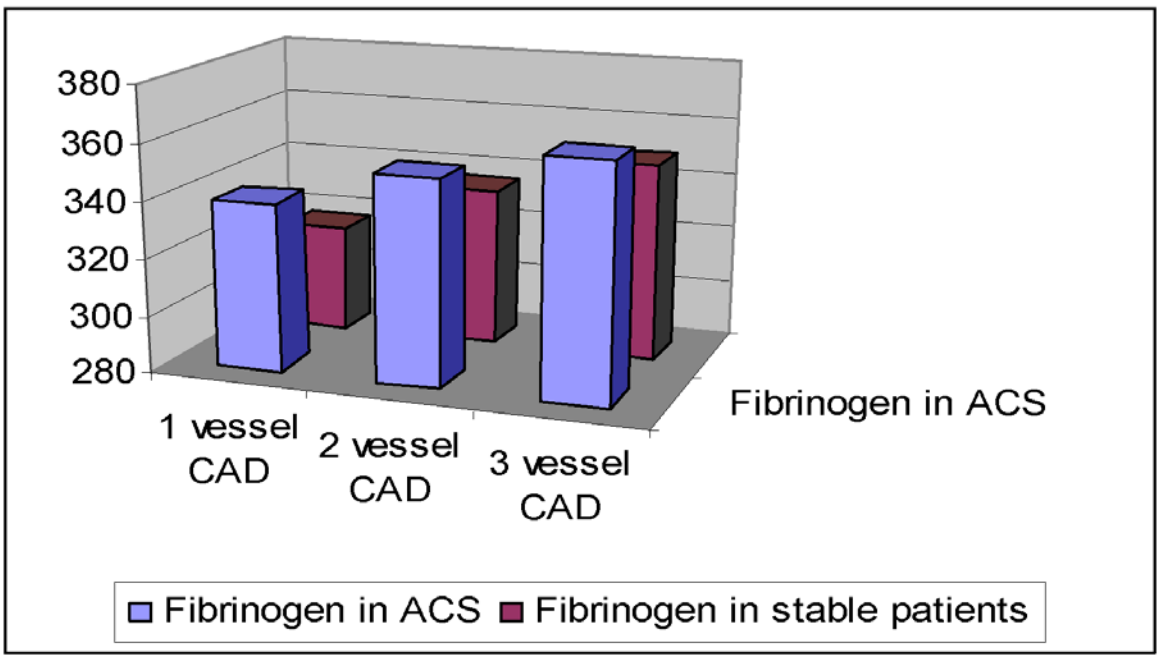
HsCRP and fibrinogen are relevant biomarkers in atherothrombotic cardiovascular diseases. We have conducted a prospective study to reveal the correlation between these biomarkers and the number of diseased vessels in patients with stable and unstable coronary artery diseases.

Methods

Patients with stable and acute coronary syndromes who underwent coronary angiography at the Tel Aviv Sourasky Medical Center were prospectively collected. A blood sample was taken for fibrinogen and hsCRP levels.
All patients gave their informed consent in accordance to the local ethics committee.

Results

We have collected 199 stable and 545 acute coronary syndrome patients undergoing angiography. The patients were divided according to their coronary artery disease status (1,2, or 3 vessels). The correlation between fibrinogen and the number of diseased vessels was significant in acute coronary syndrome (r=0.1, p=0.01) and borderline in stable patients (r=0.14, p=0.053). CRP was not correlated to the severity of CAD in both clinical scenarios. Figure 1 displays the fibrinogen values of the different groups.



Conclusion

Quantitative fibrinogen could be a useful biomarker to reveal the presence and extent of CAD.