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# Corin Level as a Predictor of Major Adverse Cardiac Events Post PCI

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***Introduction*** : Corin is a Type II transmembran enzyme that cleaves Pro BNP and Pro ANP to the active natriuretic peptides. Natriuretic peptides confer multiple effects on the cardiovascular system.

***Hypothesis***: High level of corin is associated with reduced future cardiac events in CAD patients post PCI .

***Methods:*** One hundred thirty six consecutive patients with coronary artery disease that were admitted to the cardiology department between the years 2004 and 2006. Most of the patients were admitted for acute coronary syndrome; mainly NSTEACS .These patients underwent coronary angiography and PCI. Patients with normal coronaries or insignificant CAD were excluded from the study .Corin level in the serum was measured pre-PCI by ELISA assay. At the same period serum corin level was measured in 98 healthy volunteers in the same ages. The two populations were followed for MACE (MI, Death, Revascularization ,CVA/TIA, and Angina) between two and three years.
Data were analyzed with SAS statistical software, version 8 .
$P< 0.05$ was considered significant.
Continuous variables were reported as the mean value ± SD , and comparisons between groups were performed using t test .
Categorical data were compared by the chi square test.
Logistic regression analysis was used to determine predictors of MACE.

***Results:*** Mean corin level in healthy volunteers was 1125 ±640 pg/ml and 802±296 in the CAD patients ($P<0.0001$) .Patients that underwent PCI were followed for 2-3 years .Seventy patients suffered from MACE ( 51.4 percent).
Fifty two percent needed repeat PCI ,26 percent suffered from angina ,4 percent CABG ,7 percent suffered from stroke ,7 percent MI and 4 percent mortality .
Mean corin level in the whole study population was 802 ±296 pg/ml unit.
Mean corin level in the MACE group was 701±223 pg/ml unit ,and in the non-MACE group was 892±316 pg/ml unit ($P=0.0001$).
Using multivariate analysis to compare corin with known risk factors of CAD ,only corin was statistically significant as predictors of MACE ( $P=0.0007$ ,OR-0.85 ,95% CI -0.785-0.937).
Using corin level of 850 pg/ml or less we were able to predict MACE post-PCI with sensitivity of 83 percent ,specificity of 46 percent ,positive predictive value of 60 percent and negative predictive value of 73 percent.

***Conclusion:***
Patients with CAD have low serum corin levels compared to the general population. Low Serum corin level is an independent predictor of MACE following PCI.
In our cohort the risk factors of CAD were not proven to be predictors of MACE post-PCI.

# Trans Radial Approach for Coronary Procedures Performed by an Experienced Operator is Safe Regarding Fluoroscopy Time and Contrast Media Volume

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**Background:** Trans-radial approach (TRA) to coronary procedure, compares to the femoral approach (TFA), reduces the rate of major vascular and bleeding complications and allows a similar rate of success and MACE. On the other hand the TRA was criticized lately as less safe since it increases fluoroscopy time (FT) and contrast media volume (CM).
**Purpose:** To evaluate FT and CM in coronary procedures performed by a single, highly experienced, operator in our medical center and to compare these parameters in the TRA versus the TFA with a reference to worldwide experience (W).
**Methods:** We reviewed the FT and CM data for all consecutive procedures performed in the last 12 months by a single operator with 80% of procedures done by the TRA after a two year learning curve. World experience was obtained from published articles.
**Results:** during the mentioned period 374 procedures were performed by a single operator (AF) with the following distribution:

| | Total | PCI | PPCI | Post CABG | CTO | Bifurcation |
|---|---|---|---|---|---|---|
| TRA (%) | 300 (80) | 183 (49) | 25 (7) | 11 (3) | 22 (6) | 25 (7) |
| TFA (%) | 74 (20) | 46 (12) | 8 (2) | 63 (17) | 14 (4) | 6 (2) |
| Total (%) | 374 (100) | 229 (61) | 33 (9) | 74 (20) | 36 (10) | 31 (9) |

The safety profile of the above procedures regarding FT and CM compared to world experience (W) is summarized below:

| | TRA | TFA | TRA-W (range) | TFA-W (range) |
|---|---|---|---|---|
| FT (minutes) | 6.9±3 | 8.7±4 | 10-19 | 10-16 |
| CM (ml) | 114.8±25 | 142±32 | 134-224 | 127-182 |

**Conclusions:** The TRA is as safe as TFA for simple as well as complex coronary procedures regarding FT and CM when performed by an experienced operator with a high volume of TRA procedures.

# Is Drug Eluting Stent Better than Bare Metal Stent for the Treatment of Proximal Left Anterior Descending Stenosis ?

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Background: Stenosis in the proximal segment of the LAD ( pLAD) affects strategy treatment and has a major impact on clinical outcome .
Aims: To compare one year clinical outcome of DES implanted vs BMS at pLAD.
Methods: Retrospective analysis of 305 consecutive pts undergone to stenting of the pLAD with DES (162 pts) and BMS (143 pts) during 2004 to 2006. Demographic, clinical, angiographic and angioplasty characteristic of the patients as well one year mortality, myocardial infarction (MI) and repeated revascularization were studied.
Results: Baseline characteristics were of the same with the exception of a higher rate of smokers (51% vs.39%, p=0.04) and a previous stroke (13% vs 7%, p=0.05) in the BMS group. Pts receiving DES had less acute STEMI (43% vs 15%, p<0.01) and had more significant decrease of the LV function ( 44% vs.60%, p<0.06). DES lesions had lower rate of thrombus (21% vs 35%, p<0.04), smaller reference vessel diameter (3.2±0.3 vs. 3.3±0**.** 4, p<0.01) and longer lesion length (27±15 vs.19±8). Patients treated with DES had lower rates of one year mortality (1.2 % vs. 6.3 %, p<0.018), revascularization (7% vs 15%, p=0.04) and composite end point of death, myocardial infarction and revascularization (12% vs 22%, p=0.01). In a multivariate analysis DES implantation in pLAD was an independent predictor of lower mortality rate (HR=0.09 [0.01-0.7],p=0.02) and composite end point of death, MI and revascularization (HR=0.48 [0.25-0.91],p=0.02).
Conclusions: The implantation of DES in the proximal segment of the LAD in selected patients results in better clinical outcome. However selection bias may have just as major impact and should be controlled in randomized trail.

# Changing the Paradigm . Transradial Primary PCI Reduces Access Site Bleeding

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Background: Bleeding after PCI is associated with adverse outcomes. When PCI is performed as an urgent procedure for STEMI the risk of bleeding is particularly increased due to the use of intense antithrombotic therapy. Transradial primary PCI might improve outcomes by decreasing access site bleeding .

Aim: To investigate the feasibility, efficacy and risk of access site bleeding complication of transradial primary PCI .

Methods: Retrospective study of 327 consecutive STEMI patients (2007-2008) treated with ptransradial (171 pts) or transfemoral (137 pts) primary PCI artery. Clinical, angiographic and angioplasty characteristics were analyzed. The frequency of access site bleeding was compared.

Results. Radial pts were younger (58±12 vs. 62±14 y. ;$p<0.01$) and had more peripheral vascular disease (9% vs.5%, $p=0.05$). They more often had Killip class I-II (98% vs.88%; $p<0.02$) and normal or mildly decreased LV function (54% vs. 42%; $p=0.01$). IABP was used more frequently in the femoral group (11% vs 5%; $p=0.05$). No differences were observed in risk factors, number of diseased vessels , culprit artery, lesion complexity , number of stents, vessels and lesions treated and volume of contrast. IIb/IIIa inhibitors were used in 45% of the radial patients and 42% of the femoral patients (p=ns). Fluoroscopy time was longer in the radial group (12±8 vs.10±7;$p<0.03$) . The angiographic success rate was 91% and 88% in the radial and femoral groups, respectively (p=ns). The rate of access site bleeding was 6% in the radial group and 21% in the femoral group ($p<0.01$).

Conclusions: The efficacy of the transradial approach for primary PCI is similar to that of the transfemoral approach. Access site bleeding complications are significantly reduced using the radial approach. The impact of these findings on outcome should be further investigated.

# Changing the Paradigm: Radial Approach as the Main Access for Percutaneous Coronary Intervention

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Background: The radial approach for percutaneous coronary intervention (Rpci) is underused in Israel despite increased patient comfort and safety. Our aim was to describe a large center's experience with using the radial artery as the main access for PCI.

Methods: Retrospective comparison of 1961 consecutive patients who underwent PCI (2004-2006) via radial (1267 pts, 65%) or femoral artery (694 pts, 35%).

Results: Rpci pts were younger (63±12 vs. 65±12 years, $p<0.01$) and more frequently men (78% vs 70%, $p<0.01$). They had higher rates of dyslipidemia (83% vs. 74%,$p<0.01$); hypertension (71% vs 66%,$p<0.01$), and smoking (46% vs. 41%,$p<0.01$) and lower prevalence of renal failure (14% vs. 23%$p<0.01$).

Rpci was used less often in pts with STEMI,( 28% vs. 72%, $p<0.01$) or visible thrombus (13% vs. 30%, $p<0.01$) while patients presenting Killip class I-II (96% vs. 90%, $p< 0.01$) or normal to mildly decreased LV function (71% vs. 56%, $p<0.01$) were approached more frequently through the radial artery.

Rpci had a longer fluoroscopy time ( 15±10 vs. 13±9 min, $p<0.01$). The angiographic and angioplasty characteristics as well as PCI success were similar (99%) in both groups.

A multivariate analysis found that STEMI [OR:0.1 (0.05-0.18)], Killip III-IV [OR: 0.25 (0.07-0.5)]; age [OR: 0.96 (0.93-0.98)]; and renal failure [OR:0.36 (0.16-0.85)] were predictors for the not selection of the radial approach.

Conclusions: Radial PCI can be performed successfully in the majority of patients requiring coronary angioplasty. Hemodynamic disturbances, advanced age, renal failure and STEMI are still strong reasons for the selection of an alternative approach.

# Changing the Paradigm: The Impact of the Transradial Approach on One Year Survival after Percutaneous Coronary Intervention

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Background. Transradial coronary angiography is associated with a lower rate of bleeding. The impact of this approach on outcome following PCI has not been clearly established .

Aim: To compare survival of patients who had transradial or transfemoral PCI .

Methods: Retrospective analysis of 631 intensive care coronary unit patients ( 2004 to 2006) who underwent transfemoral (351 pts, 56%) or transradial (280 pts, 44%) PCI. Killip III-IV pts were excluded. Minimal follow up was one year. Demographic, clinical, angiographic and angioplasty characteristics, bleeding complications and mortality were compared. Multivariate analysis was performed to identify independent predictors of one year survival .

Results: Radial pts were younger (62±13y. vs.64±13y. ,$p<0.01$) and more frequently male (80% vs. 73%, $p=0.04$). They had a lower serum creatinine (0.9±0.3 vs.1.1±1.1 mg/dl, $p=0.02$) and higher Hb (13.3 ±1.7 vs. 12.7±1.8 gr/l ,$p<0.01$). Femoral pts presented more frequently with ST elevation myocardial infarction (80% vs.51%, $p<0.01$) and more often had primary PCI (59% vs. 23%, $p<0.01$) DES was more frequently used in radial PCI (26% vs.18%,$p<0.01$)
The transradial approach was associated with less access site bleeding complications (17% vs 36%,$p<0.01$), large hematoma (4% vs 10%,$p<0.01$) and total bleeding (19% vs.39%, $p<0.01$).No significant difference was seen in non access bleeding (2 % vs. 3%) but the need for transfusions tended to be lower with the radial approach ( 1% vs 4%, $p=0.06$). One year mortality was lower in radial vs. femoral pts ( 7% vs 16%, $p<0.01$).
A Multivariate analysis found that the selection of the radial approach was an independent predictor of one year survival after PCI ( hazard ratio 0.4 (95%CI: 0.1-0.9,$p=0.02$).

Conclusions. Transradial PCI is associated with a reduction of bleeding complications and one year mortality.

# Drug –Eluting Versus Bare Metal Stent Implantation for Unprotected Left Main Coronary Artery Stenosis

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**Objectives**
This study was designed to compare the clinical and angiographic outcomes of drug -eluting stent (DES) and bare metal stent (BMS) implantation for unprotected left main coronary artery (LMCA) stenosis.
**Background**
The safety and effectiveness of DES implantation for unprotected LMCA stenosis have not been ascertained.
**Methods**
One hundred and sixty two consecutive patients underwent unprotected LMCA stenting between January 2001 and May 2008 . The majority of the patients presented with acute coronary syndrome (88.9%), while the rest (11.1%) had stable angina. At least one year clinical follow up was available for all patients and angiographic follow up for 84%. Angiographic , interventions and follow up data of the 122 patients who received BMS were compared to those of the 40 patients who received DES.
**Results:**
The procedural success rate was 100% for both groups. There were no incidents of death, or emergent bypass surgery during procedure in either group.
Compared to the BMS group, the DES group had more bifurcation lesions (75% vs. 29.5%, p = 0.001), more multivessel involvement (58.4% vs. 10.7%, p = 0.001), a smaller stent diameter (3.25 ± 0.63 mm vs. 3.92 ± 0.71 mm, p = 0.001), and a longer stent length (21.6 ± 12.5 mm vs. 11 ± 5.3 mm, p = 0.001). Compared to BMS group, in the DES group more inteventions were performed to other arteries (45% vs 65% , p = 0.01).
The overall angiographic LM restenosis rate were significantly lower in the DES group than the BMS group (5.8 % vs. 13.7%, p = 0.01). At one year follow up acute myocardial infarction occured in low rates ( 2.5% vs 2.4%, p = 0.82). In hospital mortality was low and equal for both groups (2.5 vs 3.2 , p = 0.88 ) . At one-year follow-up, mortality rate was similar between the two groups ( 7.5% vs 7.3% , p = 0.78 ). Target lesion revascularization at one year was performed in two DES patients (5.8%) and 12 BMS patients (11.7%) (p = 0.01).
**Conclusions**
Drug-eluting stent implantation for unprotected LMCA stenosis appears safe with regard to acute and long term complications and is more effective in preventing restenosis compared to BMS implantation.

# Unprotected Left Main Coronary Artery Stenting in Hospital and Long Term Outcomes

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**BACKGROUND:** Revascularization with coronary bypass surgery has been generally recommended for treatment of left main coronary stenosis. Improvements in angioplasty and coronary stent techniques and equipment may result in the wider applicability of a percutaneous approach.

**OBJECTIVES:** To present the in-hospital and long term clinical and angiographic outcome of a consecutive group of patients undergoing stenting for unprotected left main coronary artery (LMCA) disease

**METHODS:** A total of 162 consecutive patients underwent unprotected LMCA stenting between January 2001 and May 2008 . The majority of the patients was presented with acute coronary syndrome (88.9%), while the rest (11.1%) had stable chronic angina. Patients were followed routinely in outpatient clinic for 1 , 3, 6 , 12 months. Later telephone , clinic, angiographic follow up was obtained either from the outpatient clinic records or by telephone interview. Control 6 months angiography was recommended to all patients and was performed in 84% of them.
**RESULTS:** The patients presented with acute ST elevation MI in 7.4%, non ST elevation MI 13.6% , unstable angina 67.9% , chronic stable angina 11.1% . The average left ventricular ejection fraction was preserved 54± 11%. The majority of the patients were in killip class I . The procedural success rate was 100%. The in hospital overall mortality was 3%. In the patients that were in stable hemodynamic condition at entry to catheterization laboratory the mortality rate was 0 % and none of the patients needed emergent CABG. In the long term follow-up (average 3 years) there were 12 deaths (8%), 3 patients required coronary artery bypass surgery and 14 patients required repeat target vessel revascularization .
**CONCLUSIONS:** Coronary stenting for LM stenosis can be performed safely with acceptable in hospital and long -term outcome. Our results show that PCI is a viable alternative to ACBG . Reconsideration of current guidelines shoud be considered .

# Percutaneous Implantation of the Self-Expandable CoreValve in Patients with Severe Aortic Stenosis: The Technique

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Objectives: The prevalence of aortic stenosis increases with advancing age. Once symptoms occur the prognosis in patients with severe AS is poor. The current treratment of choice for these patients is surgical aortic valve replacement (AVR). However, in a large portion of patients, mainly the very elderly and those with major co morbidities, the surgical risk is considered extreme and thus, these patients are decline of surgery. Recently, a percutaneous alternative for surgical AVR has emerged and two percutaneous heart valves are available. In this report we will describe in details the percutaneous technique involved in the implantation of self-expandable CoreValve.

From September-November 2008, 15 patients underwent percutaneous AVR in two Israeli centers. Briefly, the technique was performed under general anesthesia with TEE guidance in 13/15 patients. A temporary pacemaker is inserted. Both groins are punctured initially, one with 6Fr sheath for the insertion of a pigtail catheter to the aortic root and a second with 18Fr for valvuloplasty and valve insertion. A 9Fr sheath is initially inserted and a ProStar closure device (Abbot Vascular) is introduced. A super-stiff 0.035 guide-wire is inserted into the left ventricle and an aortic valvuloplasty performed with a dedicated balloon (Numend 22 or 25 mm) under rapid ventricular pacing (150-200/min.). Then, the valve is introduced and positioned using markers and the aortic valve calcifications. The valve is gradually deployed under fluoroscopy and position is verified by repeated aortic root injections. The catheter is carefully withdrawn and removed. The arteriotomy is closed by the ProStar device and finally an angiogram of the 18Fr punctured artery is performed to exclude perforation or residual stenosis. Patients are admitted to CCU for 3-5 days to monitor for the nonoccurrence of complete AV block requiring permanent pacemaker.

Conclusions: Percutaneous aortic valve replacement is a promising technique that warrants a skillful multidisciplinary approach. New protocols are implemented in the cathlab and the ICCU to assure successful procedure.

# SKICE – Skylor in real world practICE: Results from the Israeli Multi-Center Registry

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Background: Skylor (Invatec) is a cobalt-chromium, thin-strut, low profile closed-cell stent. The Skylor is considered a last-generation stent in terms of design and technology. Recent studies support a low major adverse cardiovascular events (MACE) rate with the use of modern bare metal stents. The Skylor registry studied MACE rate following Skylor implantation in a mixed population of patients and lesions.

Methods: During 2006, 81 patients were treated with 93 Skylor stents in 7 Israeli centers. Clinical follow-up at six months was achieved in all but one patient.

Results: Indications for angioplasty included silent ischemia, stable angina and acute coronary syndromes. 26% of the patients had acute myocardial infarction. 36% of the lesions were defined as class B2/C. Mean stent diameter was 3.1±0.27mm and mean length was 13.26±2.9mm. Direct stenting was performed in 36% of the cases. Angiographic success was achieved in all cases. MACE rate at six months was 3.8% (3/80) with one mortality case (1.2%) due to stent thrombosis at 5 days after and two cases of target lesion revascularization due to stent thrombosis (1 STEMI and 1 NSTEMI).

Conclusions: The Skylor Israeli multi-center registry clinical data shows favorable results in a mixed population of coronary patients. MACE rate at 6 months was extremely low. Modern bare metal stents should be considered "stents of choice" for a wide variety of clinical indications.

# Distal Vessel Contrast Injections for Characterization of the No Reflow Phenomenon

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The absence of distal flow during coronary intervention is an ominous phenomenon. This may occur at the commencement of the procedure, following wire passage, or following ballooning or stent deployment. A number of pathological processes can result in this phenomenon. A successful conclusion to the intervention is dependent upon the correct diagnosis and the institution of its appropriate treatment.

The Twin-Pass catheter is a microcatheter with a distal monorail lumen and an off-center slightly proximal over-the-wire lumen. This second lumen can be used for a second wire, pressure measurement or drug and contrast delivery. We assessed this catheter to determine the pathological process underlying the lack of distal flow, by performing distal vessel contrast injections and characterizing the angiographic response.

Methods: In 6 cases of lack of antegrade flow occurring following wire positioning or balloon inflation, the Twin-Pass was deployed distal to the occlusion and a diluted contrast injection performed.

Results: Four specific processes were defined, a proximal occlusive lesion (dissection or thrombus)(2), no reflow due to distal vascular bed plugging (2), a distal spiral dissection with the wire residing in the true lumen(1), a distal spiral dissection with the wire residing in the false lumen(1). In the presence of a proximal occlusive lesion, distal injection results in distal vessel filling only with rapid run off to the distal vascular bed. Distal injection with the absence of distal run off but unimpeded retrograde filling of the proximal artery is the hallmark of distal vascular plugging. When the wire resided in the true lumen of dissected vessel, progressively more proximal injections allowed for the clear definition of the inflow and outflow tracts of the dissection. Injection into the dissection plane demonstrated contrast stasis along the vascular wall.

Conclusions: In the presence of the "no flow" phenomena, distal vessel contrast injections using the Twin-Pass catheter allows for the characterization of four distinct pathological processes and provides the operator with the diagnostic information necessary to select the appropriate intervention.

# Prospective Comparison of Transfemoral and Transradial Approaches for Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction

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Background: Bleeding complications are increasingly recognized to portend increased mortality in patients with ST-elevation myocardial infarction (STEMI). Transradial approach (TRA) reduces bleeding from vascular access site complications in patients undergoing percutaneous coronary interventions (PCI) when compared with transfemoral approach (TFA). There is a concern that technical difficulties using TRA can delay achievement of reperfusion during primary PCI in patients with STEMI.

Methods: We prospectively studied 73 patients who underwent primary PCI for STEMI using TRA (49 patients) and TFA (24 patients). Statistical analysis was performed on intention to treat basis. Procedural success was defined as successful completion of PCI from the original access site. Time to reperfusion was defined as time from skin anesthesia to the first balloon inflation and total procedural time as time from skin anesthesia to the completion of procedure. Vascular complications were hematoma > 10 cm, psedoaneurism, AV fistula, need for blood transfusion or surgery.

Results: Baseline clinical characteristics were similar in both groups. Procedural success was achieved in 95.6% and 90.9% and angiographic PCI success in 95.6% and 95.5% of patients in TRA and TFA group respectively (p=NS). GP IIb/IIIa inhibitor was used in 68.9% of patients in TRA group and 59.1% of patients in TFA group (p=NS). Use of contrast media was 203±69 mL in TRA group and 202±51 mL in TFA group (p=NS). Fluoro time (min) was 13.5±6.9 vs. 12.1±6.6, time to reperfusion was 29.3±12.8 vs. 28.0±12.5, total procedural time was 48.3±18.9 vs. 56.1±23.9 in TRA and TFA groups respectively (p=NS for all comparisons). Five patients (20.8%) had at least one vascular complication in TFA group vs. none in TRA group (p=0.01). The rate of complications excluding hematomas was 2/24 (8%) in TFA group vs. 0/49 (0%) in TRA group (p=NS).

Conclusions: The use of TRA for primary PCI is as safe and effective as TFA. The primary PCI from TRA, when performed by experienced operator, is not associated with prolonged time to reperfusion, and leads to fewer vascular complications.

# Single Drug Eluting Stenting of Bifurcation lesions: Importance of Final Kissing Balloon Post-Dilation

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**Background**: previous studies revealed that stent deformation due to the opening of a strut is a constant phenomenon that must be corrected by final kissing balloon [FKB] inflation. Moreover, it was observed that the opening of a stent strut into a side branch may improve angiographic results of the side branch ostium.

**Objective:** explore the clinical benefits of FKB in bifurcation lesions stenting using one Drug eluting stent technique.

***Methods & Results:*** The study included 189 patients. 76% with acute coronary syndromes. In 56% of cases sirolimus-eluting stents [Cypher] were used.

| | No FKB [n=64] | FKB [n=125] | P-value |
|---|---|---|---|
| Age [y] | 64±12 | 63±11 | 0.9 |
| Male | 84% | 70% | 0.04 |
| DM | 30% | 34% | 0.6 |
| LAD/DIAG | 72% | 59% | 0.04 |
| 6 months Death | 0% | 0.8% | 0.5 |
| 6 months MI | 7.8% | 3.2% | 0.2 |
| 6 months Definite Stent thrombosis | 1.6% | 1.6% | 0.99 |
| 6 months TVR | 7.8% | 4% | 0.2 |
| 6 months CABG | 7.8% | 0.8% | 0.01 |
| 6 months MACE | 14.1% | 6.4% | 0.07 |

***Conclusions:*** Our results would indicate that a systematic final kissing balloon during PCI in bifurcation lesions using one drug eluting stent technique may be associated with favorable clinical results.

# Drug Eluting Stenting of Bifurcation Lesions: A Systematic Approach Towards Stenting

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***Background:*** 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 293 patients with a mean age of 63±12 years, 77% male, and 76% with acute coronary syndromes. The LAD/diagonal bifurcation was involved in 62% of cases. Anti GP 2b/3a drugs were used in 65% of cases. In 58% of cases sirolimus-eluting stents [Cypher] were used. Initial two stents strategy was used in 97 pts [33%], while in 196 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=293] | One year [n=273] | Two years [n=178] |
|---|---|---|---|
| Death | 3-1% | 8-2.9% | 11-6.2% |
| MI | 11-3.8% | 12-4.4% | 14-7.7% |
| Definite Stent thrombosis | 3-1% | 3-1.1% | 3-1.7% |
| TVR | 14-4.8% | 20-7.3% | 27-14.5% |
| CABG | 9-3.1% | 10-3.6% | 12-6.6% |
| MACE | 25-8.5% | 37-13.6% | 48-25.5% |

***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.

# Comparison of Sirolimus Versus Paclitaxel Eluting Stents for Treatment of Coronary In-stent Restenosis

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**Background**: In patients with in-stent restenosis (ISR) inside bare metal stents, drug-eluting stents [DES] reduce the recurrence of restenosis compared with balloon angioplasty. However, few data are available which compare the different stents in these cases.
**Aim:** To evaluate the immediate and mid-term outcome of sirolimus- [SES] and paclitaxel- [PES] eluting stent implantation in diffuse ISR and determine the predictors of clinical and angiographic restenosis recurrence.
**Methods:** A series of 253 consecutive patients with 261 ISR lesions [including 91 diffuse ISR lesions] treated with DES implantation were evaluated. Major adverse cardiac events were defined as death, myocardial infarction, and the need for target lesion revascularization.
**Results**: Table depicts results according to SES or PES.

| | **SES (N=216)** | **PES (N=37)** | **P-value** |
|---|---|---|---|
| Age (years) | 63±11 | 62±10 | 0.7 |
| Males (%) | 76 | 70 | 0.8 |
| DM (%) | 50 | 57 | 0.4 |
| Diffuse ISR (%) | 36 | 26 | 0.2 |
| RVD mm | 2.8±0.6 | 2.9±0.8 | 0.2 |
| Mean stents Diameter mm | 3.0±0.3 | 3.0±0.6 | 0.7 |
| **6 months outcome** | | | |
| Death (%) | 1.9 | 0 | 0.4 |
| Re-AMI | 1.4 | 2.9 | 0.5 |
| Stent thrombosis | 2.3 | 0 | 0.3 |
| Target vessel revascularization (%) | 6.9 | 5.4 | 0.7 |
| CABG | 1 | 2.9 | 03 |
| MACE | 8.9 | 8.6 | 0.9 |
| **12months outcome** | | | |
| Death (%) | 2.4 | 0 | 0.4 |
| Re-AMI | 2.9 | 6.5 | 0.3 |
| Target vessel revascularization (%) | 9.7 | 6.7 | 0.6 |
| CABG | 2.4 | 3.3 | 0.7 |
| MACE | 13.6 | 12.9 | 0.9 |

By multivariate analysis, post stenting MLD<2.5mm was confirmed to be the only independent predictor of recurrent restenosis (odds ratio 4.4, 95% confidence interval 1.4-14, p = 0.009).
**Conclusion:** Both SES and PES implantation for ISR is associated with acceptable clinical results. Small vessel is an unfavorable condition leading to a high risk of recurrence.

# Ovalum CiTopTM: A Novel Guidewire for crossing Chronic Total Occlusion in Coronary Artery Disease patients – First-in-Man Experience

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**Aims:** To evaluate the safety and efficacy of the CiTop™ Guidewire in attempting to cross through chronic total occlusion in CAD patients with various coronary dimensions and morphology. Although chronic total occlusions are encountered frequently in patients with coronary artery disease, an effective strategy to deal with them has yet to be devised. Various new guidewires have been designed in an attempt to negotiate chronic occlusions successfully. The aim of the CiTop™ guidewire is to improve the success rate of CTO recanalization.

**Methods:** Ten consecutive male or female patients between 21 and 80 years of age, with no significant co-morbidities and with angiographic documented Chronic Total Occlusion (> 1 month) showing distal TIMI flow 0, or a prior failed guidewire attempted CTO were included in the study. The end points analyzed were technical success (crossing of CTO by placement of CiTop™ distal to occlusion with no device related major complications), angiographic success (<20% residual stenosis and TIMI flow grade 3), and clinical success. The basic features of the novel guidewire and its assessment of compatibility with other cathlab equipments were also recorded.

**Results:** The mean (± SD) age of the all male patient group was 53.6±9 years. The mean (±SD) lesion diameter and length was 3.1±0.4 mm and 20.4±7.9 mm, respectively, while the mean (±SD) age of occlusion was 25.5±26.8 months. Technical and angiographic successes were obtained in 7 patients (70%). The dissection of the coronary artery was observed in 2 (20%) patients using other guidewire. No events were recorded within seven days and 30-days follow up after discharge.

**Conclusion:** The CiTop™ guide-wire was found to be efficacious and safe for use in recanalization of chronically occluded coronary arteries in this initial experience.

# The New 0.014" CiTop™ Guidewire for the Treatment of Chronic Total Occlusions in Peripheral Arteries: Results of the First-in-Man Randomized Clinical Study

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**Background:** Despite the development of novel interventional devices, chronic total occlusion (CTO) still remains a challenging problem in endovascular peripheral intervention, mostly due to inability to cross the lesion with the guide-wire. We describe herein the first in man randomized study comparing the new 0.0014" CiTop guide-wire to conventional wires in peripheral CTOs.

**Methods:** Nineteen patients with 24 peripheral CTOs were randomly assigned to the CiTop™ guide-wire or to conventional wires as a first wiring attempt to penetrate a total occlusion. Study endpoint was a successful crossing of CTO in distal true lumen without a device-related adverse event.

**Results:** CiTop™ guide-wire successfully crossed the CTO in 13 out of 14 occlusions (92.3%), whereas a standard wire was able to cross in 4 out of 10 occlusions (40%). From this group of patients, 5 CTOs were crossed over to CiTop™ guide-wire attempts where successful crossing was observed in 4 cases (80%). No technical problems or adverse events associated with the CiTop™ guide-wire usage were noted. **Conclusions:** Our preliminary results demonstrate that the new 0.014" CiTop™ guide-wire is safe and efficacious for the treatment of peripheral CTOs. The CiTop™ guide-wire may serve as an excellent first choice wire in attempting peripheral CTO re-canalization.