Venflon for Radial Artery Access (VERAA study)

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Transradial approach is an excellent alternative to the usual transfemoral route for both diagnostic and coronary interventions. Most operators use standard dedicated kits for port of accesses entry whereas in the literature there are few reports about other radial artery (RA) puncture techniques.

The aim of our study was to compare effectiveness and safety of much more chipper technique using simple Venflon and ordinary femoral sheath 5-6Fr (10$) compared to the standard trans radial kits (30$).

Methods: 913 pts (65.1% males, mean age 60, mean BMI 31.7) enrolled to our prospective, open label comparative study. In 61(7%) the RA was accessed by simple Venflon (17 GA) using ordinary 0.35" J-wire and 5-6Fr femoral sheath (1st group) and in others by standard trans radial kits (2nd group). There was a trend for more women in the 1st group, significantly more pts with peripheral vascular disease in the 1st group, without significant differences between two groups in other baseline characteristics.

Results:

Characteristics	1st group (Venflon) 61 pts	2nd group (Standard Kit) 852 pts	P value
Left RA puncture (%)	55.7	26.9%	<0.001
Failure of puncture (%)	4.5	4.7	ns
Crossover to brachial A. (%)	3.3	1.8	ns
Crossover to femoral A. (%)	3.3	4.5	ns
Crossover to ulnar or RA on 2nd arm (%)	0	1.2	ns
PTCA (%)	31.7	44.7	<0.01
Multivessel PTCA (%)	6.7	12.1	0.2
Radiation time (min)	7.9	10.8	0.079
No of nights to discharge	1.09	1.32	0.1
RA thrombosis (pts)	0	2	ns

Conclusions: Trans radial catheterization using Venflon technique for port of access entry is comparable, effective, safety and chipper alternative to the standard radial kit technique.

Comparison of Three Dimensional and Two Dimensional Coronary Angiography: Preliminary Results

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Background: Three-dimensional (3-D) coronary angiography was introduced recently as a promising technique in the coronary catheterization laboratories.
Aim: Comparison of three dimensional and two-dimensional (2-D) coronary angiography.
Methods: 10 consecutive patients were evaluated by 3-D angiography and were compared to 38 consecutive patients studied by the conventional technique by fluoroscopy time, radiation dose and the amount of contrast used.
Results: 3-D was superior to 2-D angiography in reducing volume of contrast agent used, 63.9+ 17.7 ml vs. 110+ 41.4 ml, $p<0.008$. We don't observed a significant difference in the fluoroscopy time (minutes), 4.77+ 1.45 for 3-D vs. 5.18+ 3.12 for 2-D angiography, p=ns, and radiation dose(mGy), 652.5+ 216.5 for 3-D vs. 739.2+ 267.2 for 2-D angiography, p=ns.
Conclusions: 3-D angiography is superior to 2-D angiography by significant reduction in the volume of contrast agent used, but a significant reduction in fluoroscopy time and radiation dose was not observed.

Safety and Feasibility of Transradial Primary Coronary Intervention in Patients with Acute Myocardial Infarction

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Intense anticoagulation or antiplatelet therapy potentially increases the risk of bleeding complications during primary percutaneous coronary intervention (PCI) in patients with acute myocardial infarction (AMI). The transradial approach to coronary interventions is associated with a lower incidence of vascular access site complications, although it is more demanding.
Objectives: To assess the efficacy and safety of radial versus femoral coronary catheterization in primary PCI for patients with AMI.
Methods: We studied 232 consecutive patients who underwent primary PCI for AMI in Killip class 1-3.

Results:

	Radial group (n=34)	Femoral group (n=198)	P value
Mean age	59.3±10.6	60.2±14.3	NS
Women	26%	18%	NS
Diabetes mellitus	36%	24%	NS
Body mass index	31.9±7.3	26.6±5.6	<0.0001
Significant peripheral vascular disease	21%	6%	0.005
Medical treatment before and during catheterization:			
- Aspirin and clopidogrel	94%	97%	NS
- Heparin	97%	96%	NS
- IIb/IIIa GP antagonist	84%	78%	NS
Procedural results:			
Crossover to alternative entry site	3%	1%	NS
Aspiration device	38%	29%	NS
Intra-aortic balloon pump	6%	7%	NS
Cannulation time (minutes)	1.9±0.6	1.7±0.7	NS
Total procedure time (minutes)	64±26	61±23	NS
Success rate	97%	98.5%	NS
In-hospital outcome and complications:			
MACE	6%	5%	NS
Significant access site complications	0%	2.5%	<0.0001
Blood transfusion	0%	1.5%	<0.0001

Conclusion: Transradial primary PCI is a safe and feasible with similar results to those with transfemoral approach, but with less vascular complications.

Angiographic Approach to Bifurcation Lesions in Patients with STEMI Undergoing Primary PCI

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Background: PCI to bifurcation lesions is technically challenging. This is particularly the case in patients with STEMI due to culprit lesion pathology and the time factor limitation. We compared different technical approaches for bifurcation lesions during 1° PCI and evaluated clinical outcomes.

Methods & Results: We analyzed our primary PCI database (1.2005 – 11.2007) for culprit bifurcation lesions with branch width ≥ 2 mm. Of 387 cases during
78 (20 %) culprit bifurcations were detected (52 LAD, 18 RCA, and 8 LCx). Double wire technique was used in 62 patients. All patients underwent stenting of the main vessel (4 DES), 63% had branch vessel balloon angioplasty and in 17% a stent was implanted. The patients were divided into two groups: A - PCI to main vessel only, B – PCI to both vessels. Angiographic analysis revealed significantly reduced branch patency in group A (90 vs. 17%, $p<0.01$). Mortality (mean 14 months) in patients with bifurcation culprit lesions was 2.1% as compared with 4.2% in the general primary PCI cohort. There were no differences in mortality between group A and group B.

Conclusions: Culprit bifurcation lesions during primary PCI are not associated with increased risk for mortality. Double branch treatment is associated with better final angiographic result that is not translated in our small series into clinical difference.

Drug Eluting Stents Restenosis Failures: Comparison between Cypher and Endeavor Stents

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Objective: We determined the different pattern and outcomes of limus-based DESs restenosis 'failures' according to stent type: e.g. Cypher vs. Endeavor stents.

Methods: We have identified all episodes of restenosis in 63 patients following Cypher (n= 53) or Endeavor (n=10) stenting in our institution between 1/2004 and 2/2007. Restenosis pattern was classified as focal, diffuse or proliferative.

Results: Cypher failure was observed in 53 pts: (age 64±11 years, 79% male) with 57 lesions, referred for coronary angiography mostly (77%) due to acute coronary syndrome. Ten patients had Endeavor failure (age 72±8.7 years, 80% male). Retenotic patients were often characterized as 'high-risk' in both group with diabetes (73.5% versus 80%), HTN (83% versus 100%), and dyslipidemia (89% versus 90%). Cypher stents length were 24±8mm vs. 19±6 mm for Endeavor stent (p=0.07) with stent diameter averaging 3.0±0.4mm (Cypher) vs. 3.2±0.5mm (Endeavor) respectively (p=0.1). Mean time to target vessel revascularization (TVR) was 12.5±10.6 mos for Cypher and 5.2±2.7 mos for Endeavor ($p<0.05$). The vast majority of restenotic lesions (71%) were focal in the Cypher group vs. diffuse (80%) in the Endeavor group (p=0.004). Accordingly, the incidence of diffuse restenosis was significantly higher in Endeavor compared to Cypher stent (12% vs. 80%, $p<0.0002$). The treatment of ISR in both groups is shown in **Table**:

Treatment of DES ISR	Cypher	Endeavor	P values
Re-stenting using DES	63%	60%	NS
POBA / Cutting balloon	26%	0%	p=0.05
CABG	7.5%	30%	NS
Conservative	3.5%	10%	NS

At six month follow up the overall MACE (death, MI, TVR) was 11.3% in the Cypher group and 50% in the Endeavor group (p=0.01).

Conclusions: Based on our experiences and compared to Cypher stent, Endeavor DES failure showed: 1) more diffuse restenotic pattern, 2) shorter time to restenosis, and 3) worse overall intermediate-term clinical outcome.

PRO-Kinetic: Results from an "All Comers" Clinical Registry

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Backround: The PRO-Kinetic stent combines the properties of Cobalt Chromium metal alloy with state-of-the-art design to deliver enhanced performances in all procedures. PRO-Kinetic's thin struts, low profile, exceptional deliverability and silicon carbide PROBIO® passive coating may ensure optimal clinical outcomes

Purpose: To conduct a retrospective registry of consecutive "real world" patients treated using PRO-Kinetic stents at Rabin Medical Center between January 2006 and March 2007.

Methods: With 40% DES utilization at our center, the PRO-Kinetic stent has been used in a wide variety of patients and clinical scenarios. Our study included 254 consecutive patients treated for 264 lesions. Patients were carefully followed by our Database team and all events were documented and adjudicated. We had 100% f/u rate by 6 months. Plavix administration was indicated for 3 months in stable patients and for 6 months or more following acute coronary syndrome events.

Results: The patients' characteristics are noted for 46% rate of diabetics and 18% renal insufficiency. Indications for angioplasty included patients with either stable of unstable clinical scenarios. 45% of lesions were of class B2/C and 23% of patients had reduced TIMI flow prior to interventions. The vast majority of these patients had acute or recent MI. The mean RVD was 2.8mm and lesions length was 10.4 mm prior to PCI and with angiographic success in all consecutively treated patients. The six month clinical outcome data were as follow: MACE rate of 5.5%, with 2.4% total mortality, 0.4% of any MI and TVR rate of 3.1% per treated patient and 3.4% per treated lesion and not a single case of stent thrombosis.

Conclusions: 1) The PRO-Kinetic clinical data shows excellent results on a group of coronary patients, treated consecutively. 2) The data should emphasize the remaining role of 'state of the art' non DES platforms for patients with a wide variety of characteristics and/or clinical syndromes.

Cypher Stenting: Focal Restenosis Pattern Treatment and Outcome

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Background: The preferred treatment strategy for drug eluting stent (DES) restenosis (balloon angioplasty vs. re-stenting) is yet unknown.
Objective: We aimed to compare those different treatment strategies with patients outcomes following focal ISR within Cypher stents.
Methods: We identified all episodes of Cypher restenosis in 53 consecutive patients with 57 lesions. Patients' demographics according to angiographic restenotic pattern (e.g. focal and diffuse) were obtained. Focal restenosis was investigated in term of treatment type: re-stenting, balloon/cutting (POBA) angioplasty, bypass surgery or conservative treatment. This cohort was followed for 6 month for major adverse cardiac event rate (MACE) according to the treatment strategy.
Results: Cypher failure was observed in 53 pts; 42 (79%) patients had focal in stent restenosis (age 65±11 years, 69% male) and 11 (21%) patients had diffuse restenosis (age 62±12 years, 82% male). The prevalence of diabetes (focal vs. diffuse) was 69% vs. 82%, respectively, hypertension (79% vs. 82%), and dyslipidemia (81% vs. 82%) and hronic renal failure was encountered in 12% vs. 36% of pts (p=0.07). Focal restenosis was observed in 42 pts with 45 lesions, 31 (69%) lesions were treated using stent deployment and in 12 (27%) lesions POBA (±cutting) was the preferred treatment option. Outcome of patients according to treatment types is shown in **Table**:

Pts N=42	**Re-Stenting**	**POBA**	**CABG**	
F/U pts	**N=28**	**N=11**	**N=2**	
Death	0	0	0	NS
MI	3.6%	0	0	NS
ST	3.6%	0	0	NS
TVR	16.7%	0	0	NS
MACE	18.0%	0	0	NS

At six month follow up, no death was encountered in any patient. One patient had stent thrombosis presented as AMI in the re-stented group.
Conclusion: Our experience showed that *focal* in stent restenosis pattern within Cypher stents had a tendency towards better clinical outcomes and especially when treated using POBA (±cutting) as compared to re-stenting sterategy.

Comparison of Drug Eluting Stents with Bare Metal Stents in Daily Practice for Bifurcation Lesions: One Year Results of Simple One Stent Strategy

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Background: The optimal stenting strategy in coronary artery bifurcation lesions is unknown. A simple approach, stenting of the main branch with provisional stenting of the side branch is currently implemented in the majority of cases when bare metal stenting [BMS] is used. Drug-eluting stents [DES] decreased the TVR rate in most lesions. The one year results of "simple approach" to these lesions comparing DES and BMS is not well documented.

Objective: compare the one year results of the "simple approach" using BMS versus DES in "real world" practice.

Methods & Results: The study included 192 patients with bifurcation lesions treated by single stent in the main branch.

	BMS [n=89]	DES [n=103]	P-value
Age [year]	64±12	63±12	0.5
Male	81%	74%	0.3
ACS	52%	49%	0.7
DM	31%	33%	0.8
Renal failure	13%	10%	0.6
LAD/DIAG	44%	64%	0.002
RVD [mm]	2.9±0.4	2.9±.5	0.6
One year			
Death	8%	1%	0.03
MI	9%	5.8%	0.4
Stent thrombosis	5.6%	2.9%	0.5
TVR	22.5%	8.7%	0.01
CABG	4.6%	4.9%	1.0
MACE	28%	15%	0.03

By multi-variate analysis the age, renal function and clinical presentation were significant independent predictors of one year mortality while DES use was not.

Conclusions: Our results would indicate that with "simple approach" of treating bifurcation lesion the use of DES is not associated with increased thrombotic complication. The TVR rate is significantly decreased.

The Impact of Culprit Lesions Morphology on Clinical Outcomes in Urgent Primary PCI for STEMI

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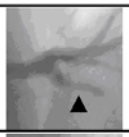
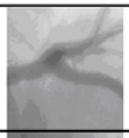
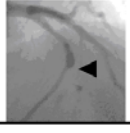
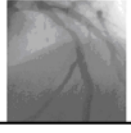
Background: Primary percutaneous coronary intervention (PCI) during STEMI is targeted at the culprit lesion. However, there are no studies classifying the different morphologic characteristics of culprit lesions on angiography or evaluating their possible prognostic significance.

Objectives: The aim of the study was to classify culprit lesions during primary PCI and to evaluate the long-term clinical results accordingly.

Methods: Images from 80 patients (81% men, mean age 62±13 years) undergoing primary PCI were evaluated. Culprit lesions were classified into morphologic subgroups according to their geometric characteristics. Findings were compared between 30 patients with major adverse-events up to one year (death, re-infarction or need for repeated revascularization) and a control group of 50 patients with no such adverse-events during follow-up.

Results: On long-term clinical evaluation, two morphologic types were significantly associated with adverse events ($p<0.05$). A slow tapering- down ("bird-beak") culprits were detected in 7 patients (23%) from the adverse-events group while in only 3 patients (6%) from the control group. Culprit lesions in the vicinity of a bifurcation were detected in 14 patients (47%) from the adverse- events group while in only 12 patients (24%) from the control group. The "cut-off" morphology, which was most prevalent in both groups, was less associated with the adverse- events group, although with a trend that did not reach statistical significance.

Conclusions: The culprit morphology during primary PCI might have a prognostic significance. The “bird-beak” morphology and near-bifurcation culprits are significantly associated with worse clinical outcomes and patients with such lesions should be regarded at higher prognostic risk.

culprit	before PCI	after PCI	adverse-events* group (n=30)	control group (n=50)	*p*
“bird-beak”			23%	6%	0.02
“cut-off”			50%	70%	0.07
bifurcation			47%	24%	0.04

*defined as death, re-infarction or need for repeat revascularization at 1 year follow-up.

Results of Urgent Percutaneous Coronary Intervention in Patients with Acute Myocardial Infarction and Significant Aortic Stenosis

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Background: Percutaneous coronary intervention (PCI) is associated with increased risk in the presence of severe aortic stenosis (AS). However, recently published data indicate that elective PCI is relatively safe in a subset group of severe AS patients with single-vessel coronary disease and good functional class. We sought to determine the safety of urgent PCI in patients with significant (at least moderate) AS.

Methods: We analyzed 18 consecutive patients with AS, who underwent urgent PCI (17 primary 1 rescue) for acute myocardial infarction at our medical center between 2001 and 2007. Data included demographic, clinical, angiographic and echocardiographic information. Aortic stenosis and ventricular function were graded by echocardiography criteria. The follow-up duration for post-procedure events was 6 months.

Results: The study group included 18 patients (12 males, mean age 75±8 years) with aortic stenosis (61% moderate, 39% severe, mean BSA indexed aortic valve area: 0.5±0.1 cm^2/m^2). All patients had AMI (17 had STEMI) with mean Killip score 1.4±0.9 (72% in Killip I). The mean CADILLAC score of the group was 8.5±4.1. Complete reperfusion (TIMI flow 3) was achieved in 13 patients (72%). There were no events of acute stent thrombosis and zero TVR rate at 1 and 6 months after PCI. Mortality rate was 22% (all during the first month but none during the procedure). Of the 4 deaths: 3 were females and >75 years old, respectively. Two patients had acute renal failure at the first month and one patient had CVA diagnosed at 6 months after PCI.

Conclusions: Urgent PCI in patients with significant AS and acute myocardial infarction is problematic form the standpoint of hemodynamic stability but if indicated it was shown to be feasible and relatively safe even in patients with concomitant LV dysfunction and significant co-morbidities.