

16:00 - 17:30 S22 - Outcomes following DES Utilization - a Broad Perspective Hall A
Chairs: **S. Banai**
R. Kornowski

- 16:00 **A Comparative Analysis of Major Clinical Outcomes Using Drug-Eluting Stents Versus Bare Metal Stents in Diabetic versus Non-Diabetic Patients.**
T. Bental, A. Assali, S. Fuchs, H. Vaknin-Assa, E.I. Lev, D. Brosh, I. Teplitsky, R. Kornowski
Petach Tikva
- 16:15 **Safety of Short-Term Discontinuation of Anti-Platelet Therapy in Patients with Drug-Eluting Stents**
K.B. Filion, P. Richard, D. Libersan, M.J. Eisenberg
Montreal
- 16:30 **In-stent Thrombosis in DES: Clinical Characteristics and Adverse Outcomes**
H. Vaknin-assa, A. Assali, S. Ukabi, D. Brosh, I. Teplitsky, E. Rechavia, S. Fuchs, R. Kornowski
Petach Tikva, Tel-Aviv
- 16:45 **Incidence ,Predictors and Outcome of Early and Late Stent Thrombosis and Premature Discontinuation of Thienopyridine Therapy after Successful Implantation of Drug Eluting Stents**
M. Blich, T. Zeidan Shwiri, S. Petcherski, A.B. Osherov, H. Hammerman, W. Markiewicz
Haifa
- 17:00 **A Comparative Analysis of Major Clinical Outcomes Using Drug-Eluting Stents versus Bare Metal Stents in Male versus Female Patients.**
T. Bental, A. Assali, S. Fuchs, H. Vaknin-Assa, E.I. Lev, D. Brosh, I. Teplitsky, R. Kornowski
Petach Tikva
- 17:15 **Long Term Results of Drug Eluting Stenting in Saphenous Venous Grafts**
A. Assali, H. Vaknin-Assa, E. Lev, I. Teplitsky, T. Bental, D. Brosh, S. Ukabi, D. Dvir, S. Fuchs, A. Battler, R. Kornowski
Petah-Tikva

A Comparative Analysis of Major Clinical Outcomes Using Drug-Eluting Stents Versus Bare Metal Stents in Diabetic versus Non-Diabetic Patients.

Tamir Bental, Abid Assali, Shmuel Fuchs, Hana Vaknin-Assa, Eli I Lev, David Brosh, Igal Teplitsky, Ran Kornowski

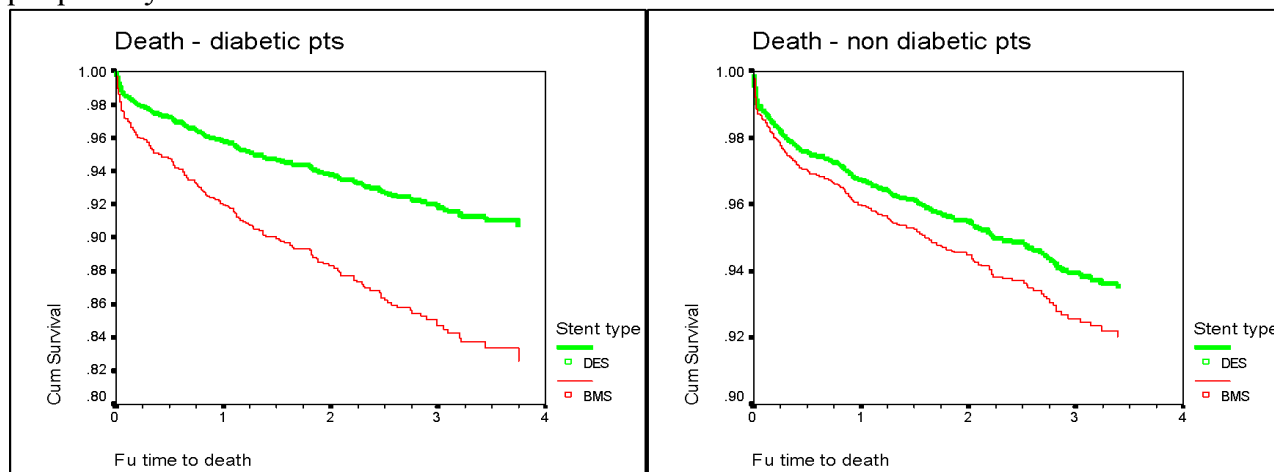
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Background: Diabetic patients have been defined as a preferential target population for the use of drug eluting stents (DES) by the Israeli reimbursement policy. We aimed to check the safety and possible benefit of DES use in diabetics versus non diabetics.

Methods: We compared risk-adjusted total mortality, myocardial infarction, repeat target vessel revascularization rates and event-free survival in a consecutive cohort of 4700 patients undergoing PCI at our institution between 1/4/2004 and 30/6/2007, of whom 1830 were diabetic and 2870 were non diabetic. Follow up time was 9 months to 4 years (mean 2.44 years).

Results: Drug eluting stents were used in 44.9% of diabetics vs. 40.4% of non-diabetics ($p=0.002$). Diabetic patients were older, had more hypertension, congestive heart failure, prior CABG, multivessel disease and had more lesions treated, with slightly longer stents. Diabetic patients had a lower 4 year cumulative mortality rate with use of a DES (9.7%) versus use of a BMS (18.3%) with a propensity score adjusted hazard ratio of 0.51 (CI-0.37-0.72; $p<0.0001$). Non diabetic patients had overall lower mortality rates but only a trend for benefit using DES (DES 6.61% vs. BMS 9.59%; $p=0.2$). This pattern was similar for other cardiac outcome measures.

Figures: Cox proportional hazards plots adjusted for stent type, diabetes mellitus and propensity score



Conclusions: Our risk-adjusted survival analysis would indicate a prognostic advantage for DES utilization *primarily* in diabetic patients which sustains up to 4 years following PCI, whereas non diabetic patients derive less prognostic benefit from DES coronary treatment.

Safety of Short-Term Discontinuation of Anti-Platelet Therapy in Patients with Drug-Eluting Stents

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Background: Anti-platelet therapy is often discontinued in patients with drug-eluting stents (DES) who are undergoing surgical procedures. However, the safety of short-term discontinuation of these agents remains unknown.

Methods: We systematically searched Medline for reported cases of late stent thrombosis (LST) published between January 2001 and February 2008. LST was defined as angiographically-confirmed cardiac events occurring ≥ 30 days following index percutaneous coronary intervention (PCI) with a DES. We restricted our study to reports that specified the time from discontinuation of antiplatelet therapy to LST.

Results: We identified 148 cases of LST from 76 articles. Patients had a mean age of 59 ± 13 years, and 89% were male. The median time from PCI to LST was 365 days (95% CI=278, 435). If patients stopped both agents simultaneously, the median time to event was 7 days. If patients had previously stopped their thienopyridine with no ill effect and subsequently stopped ASA, the median time to event was 7 days from ASA cessation. If the thienopyridine was stopped but ASA was maintained, the median time to event was 112 days. Among the 47 patients who stopped both agents, 35 cases of LST (74%) occurred within 10 days. Among the 84 patients who discontinued a thienopyridine but continued ASA, only 6 cases of LST (7%) occurred within 10 days ($p < 0.0001$).

Conclusion: If ASA therapy is maintained, short-term discontinuation of thienopyridine for < 10 days is relatively safe in patients with DES.

In-stent Thrombosis in DES: Clinical Characteristics and Adverse Outcomes

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Objective: To describe a consecutive group of patients' outcomes who developed drug-eluting stent (DES) in-stent thrombosis (ST) at our hospitals.

Methods: The rate of ST according to ARC definition and major adverse cardiac events (MACE a composite of cardiac death, myocardial infarction and Re-ST) was analyzed. Thirty consecutive patients have developed DES related ST, in a series of 4394 patients who were implanted between 2004 and 11/2008.

Results: The overall early and late definitive ST rate was 0.68% . Stents implanted were Cypher (2496), Endeavor (814), and Taxus (614), Xience V (472). ST rate was 24/2496 (0.96%) in Cypher, 1/814 (0.12%) in Endeavor and 3/614 (0.49%) in Taxus and 0/472 (0%) in Xience V. The time interval to thrombosis was 21 ± 43 months [median 24-range 0.1-48 months]. Six cases occurred within one month of stenting and 24 cases occurred later (early ST=0.14% and late/very late ST rate =0.54%).

Mean age was 61 ± 13 yrs, 79% were male, and 29% had diabetes mellitus. Lesion location was mostly in the LAD (15/30). The clinical presentation during the ST event was STEMI in 97% of cases. In two ST afflicted patients, we also noticed a stent fracture. During follow up, death occurred in 2 (9.5%) patients, recurrent myocardial infarction in one (4.8%), emergency CABG was needed in 3(14%), and recurrent ST occurred in one (4.8%) additional patient. The repeat MACE following ST was 24%.

Conclusions: According to our experience, DES-related ST is relatively infrequent but remains a major clinical problem. Major adverse cardiac events following ST are substantial at six month and thus deserve careful clinical attention.

Incidence ,Predictors and Outcome of Early and Late Stent Thrombosis and Premature Discontinuation of Thienopyridine Therapy after Successful Implantation of Drug Eluting Stents

Miry Blich, Tawfiq Zeidan Shwiri, Sirouch Petcherski, Azriel B Osherov, Haim Hammerman, Walter Markiewicz

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Background: Data regarding the risks and impact of thrombosis of drug eluting stents (DES) in Israel is limited.

Objectives: To evaluate the incidence, predictors and clinical outcome of stent thrombosis (STH) and premature discontinuation of thienopyridine after implantation of DES in an unselected Israeli population.

Methods: Data were collected prospectively from all consecutive patients who underwent DES implantation at our Center from February 2006 until January 2007. Follow-up was by phone interview or by collecting data from admission files. Confirmed and suspected STH were pooled together as defined in the medical literature.

Results: Three hundred fourteen patients were successfully treated with DES (413 lesions). At 20 ± 6.7 months follow up (median 22 months), 14 patients (4.4%) had STH. Two patients had acute thrombosis (within 48 hours, 0.6%) and 12 patients had non-acute thrombosis (3.8%). Among these 14 patients five died (case fatality rate, 36%). Predictors of STH were male gender ($p=0.05$), diabetes ($p=0.05$), history of thromboembolic event ($p=0.003$), reduced cardiac Canadian scale (CCS) functional capacity at implantation ($p=0.02$) and treatment with 2B3A inhibitors during the procedure ($p=0.048$). We found no correlation with the indication for stent implantation (acute myocardial infarction vs unstable vs stable angina pectoris). Risk factors for premature discontinuation of thienopyridine (3 month or less) were Arab ethnic origin ($p=0.001$), elementary education ($p=0.004$), receiving national insurance benefits ($p=0.003$), absence of cardiac follow up ($p<0.001$) and absence of explanation about the importance of thienopyridine therapy by the doctor ($p<0.001$). Seven of the 12 non-acute STH events occurred in patients receiving thienopyridine therapy. At one year follow-up, 184 patients were still receiving thienopyridine and 289 were receiving aspirin.

Conclusions: The incidence of STH at 22 month follow up in “real – world” Israeli patients was substantially higher than the rate reported in clinical trials. The medical community should be aware of risk factors for STH. Subsidizing the cost of thienopyridine, providing simple and clear explanation to the patient and encouraging cardiologist follow up may prevent premature discontinuation of thienopyridine after implantation of DES.

A Comparative Analysis of Major Clinical Outcomes Using Drug-Eluting Stents versus Bare Metal Stents in Male versus Female Patients.

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Background: Gender differences have not been addressed in the evaluation of drug eluting stents (DES). We aimed to check the safety and possible benefit of DES use in males versus females.

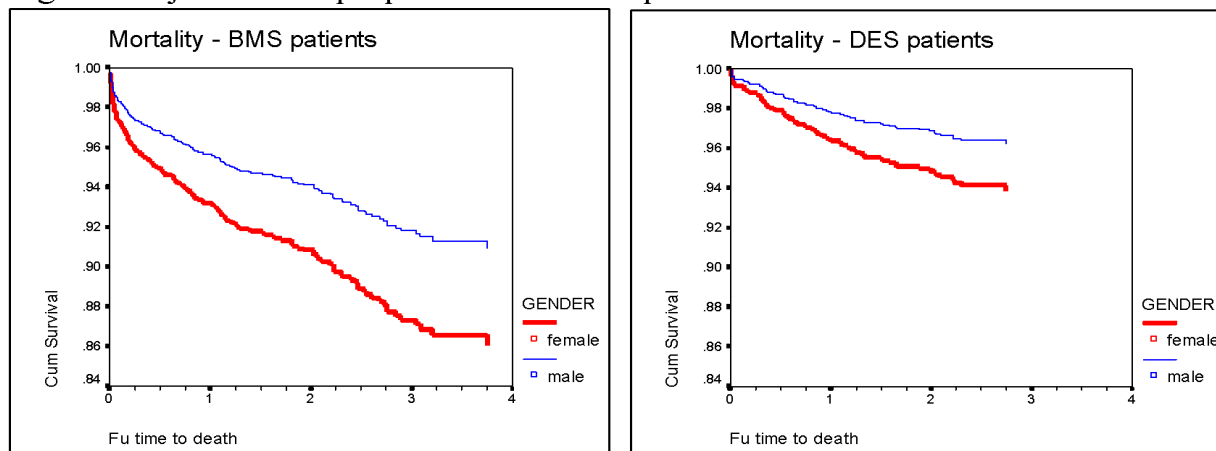
Methods: We compared risk-adjusted total mortality, myocardial infarction and event-free survival in a consecutive cohort of 4700 patients undergoing PCI at our institution between 1/4/2004 and 30/6/2007, of whom 3544 (75.4%) were male and 1156 (24.6%) were female. Follow up time was 9 months to 4 years (mean 2.44 years).

Results: Drug eluting stents were used in 42.0% of males vs. 42.6% of females (p=NS). Female patients were older, had more diabetes mellitus and hypertension, and were more likely to be treated for proximal main vessel disease. They had less 3 vessel disease and smoked less. The distribution of risk factors in males vs. females was equal in the DES and the BMS treated groups. Both males and females derived a significant benefit from use of DES vs. BMS (see table). Whereas female patients treated using BMS had a worse 4 year cumulative mortality compared to males (16.6% vs. 11.61% adjusted hazard ratio 1.58 CI-1.15-2.19; p=0.005), DES-treated patients had no gender-related mortality difference (9.47% vs. 7.39%; p=NS). This pattern was similar in other outcome measures.

Table: 4 year cumulative event rate

	males			females		
	BMS	DES	P value	BMS	DES	P value
Death	11.61%	7.39%	0.008	16.6%	9.47%	0.009
Death/MI	15.33%	9.25%	0.001	20.08%	13.27%	0.008

Figures: adjusted Cox proportional hazards plots



Conclusions: Both males and females benefit from DES use. The benefit of DES among females attenuates the gender difference in cardiac prognosis.

Long Term Results of Drug Eluting Stenting in Saphenous Venous Grafts

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BACKGROUND: Percutaneous coronary intervention (PCI) of saphenous vein graft (SVG) lesions is associated with worse outcomes and high incidence of in-stent restenosis compared with PCI of native coronary arteries.

OBJECTIVES: The purpose of the present report was to evaluate the long-term clinical and angiographic outcomes of DES implantation in SVG lesions.

METHODS: Data from consecutive patients who underwent PCI of SVG were imputed into a clinical Database. We evaluated the clinical outcomes up to three years after DES stenting. Included 90 patients [97-grafts] [89% male]. Major adverse cardiac events (MACE) including death, myocardial infarction, target lesion revascularization (TLR), and target vessel revascularization (TVR) were recorded.

RESULTS: The patients mean age was 69±9yrs and the mean age of SVG was 10.6±5.2yrs. The presenting diagnosis was ACS in 71% of patients. And 59% had DM and 14% of lesions were 'in-stent' restenotic. Distal protection device was used in 39% of cases and procedural success was achieved in all patients.

	Six months [n=90]	One year [n=90]	Two years [n=83]	Three years [n=51]
Death	1-1.1%	1-1.1%	6-7.2%	6-11.7%
MI	2-2.2%	4-4.4%	5-6%	6-11.3%
Definite Stent thrombosis	0-0%	2-2.2%	3-3.6%	3-5.9%
TVR/graft	7-7.2%	11-11.3%	22-24%	26-4.2%
TLR/graft	6-6.2%	9-9.3%	19-21%	23-38%
CABG	1-1.1%	3-3.3%	5-6%	5-9.8%
MACE	9-10%	15-16.6%	25-30%	28-47%

CONCLUSIONS: DES implantation in SVG lesions appears safe with favorable and improved short-term outcomes. Nonetheless, long-term results are limited by disease progression in degenerated SVGs and high rate of target lesions/vessel revascularization procedures.