Long-term Comparative Analysis from an All-Comers Cohort of Coronary Patients Treated Using First and Second Generation Drug Eluting Stents

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Disclosure
NONE

Background

The long term comparative safety and effectiveness of the different stents in clinical use is still a topic of major interest.

We aim of to establish potential differences in safety and efficacy between the different stents used in our clinical practice.

Methods

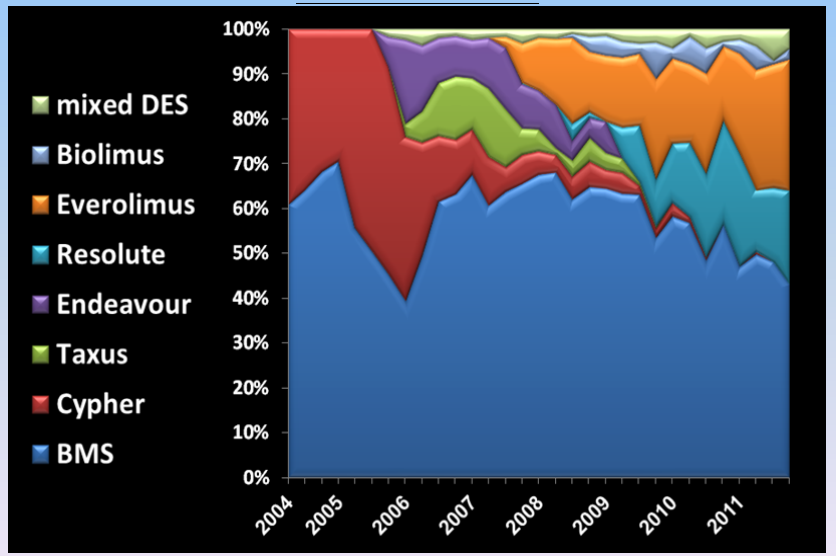
- A large cohort of patients with CAD (n=9,584), treated with angioplasty, in the Rabin Medical Center, were follow up for 3 years; mean f/u was 2.8 years.
- Patients treated with BMS 5,599 (58.4%) were compared to 3,985 (41.5%) DES counterparts (un-matched comparison).
- Then, the sirolimus eluting stent (Cypher) was taken as the prototype DES and compared to BMS and other DESs, using propensity matching score.
- Primary outcome was the rate of a composite endpoint of All-cause Mortality, MI, need for TVR or CABG.

Results

	BMS (n=5,599)	DES (n=3,985)	p-value
Male Gender (%)	4,221 (75.4)	3,048 (76.5)	0.245
Age	68.2 ±12.4	66.82 ±11.4	<0.001
Diabetes mellitus (%)	2,243 (40.1)	1,719 (43.1)	0.003
Hypertension (%)	4,084 (72.9)	2,930 (73.5)	0.528
Smoking history (%)	2,110 (37.6)	2,930 (33.2)	<0.001
Prior congestive heart failure (%)	486 (8.8)	245 (6.1)	<0.001
Moderate/severe LV dysfunction (%)	739 (13.2)	426 (10.7)	<0.001
Prior coronary bypass surgery (%)	838 (14.9)	564 (14.1)	0.278
Prior dementia (%)	104 (1.8)	38 (0.95)	<0.001
Prior malignancy (%)	481 (8.6)	267 (6.7)	<0.001
Prior anticoagulation (%)	150 (2.7)	66 (1.6)	<0.001
Proximal Left anterior descending (%)	616 (11.1)	1239 (31.1)	<0.001
Proximal main vessel (%)	202 (36.1)	2,233 (56.0)	<0.001
Unprotected LM (%)	63 (1.1)	121 (3.0)	<0.001
Acute case (MI or ACS) (%)	3,623 (64.7)	2,196 (55.1)	<0.001
Emergent PCI for STEMI (%)	1,135 (20.2)	292 (7.3)	<0.001
Critical state (%)	136 (2.4)	12 (0.3)	<0.001
Prior creatinine (mg/dl)	1.1 ±0.8	1.0 ±0.7	<0.001
Prior GFR per MDRD (ml/min/1.73 m2)	81.3 ±28.1	84.17 ±27.3	<0.001

Different brands of DESs used	
SES	37.5%
PES	8.7%
ZES	11.7%
ZES-R	10.6%
EES	20.1%
BES	3.0%
mixed	8.1%

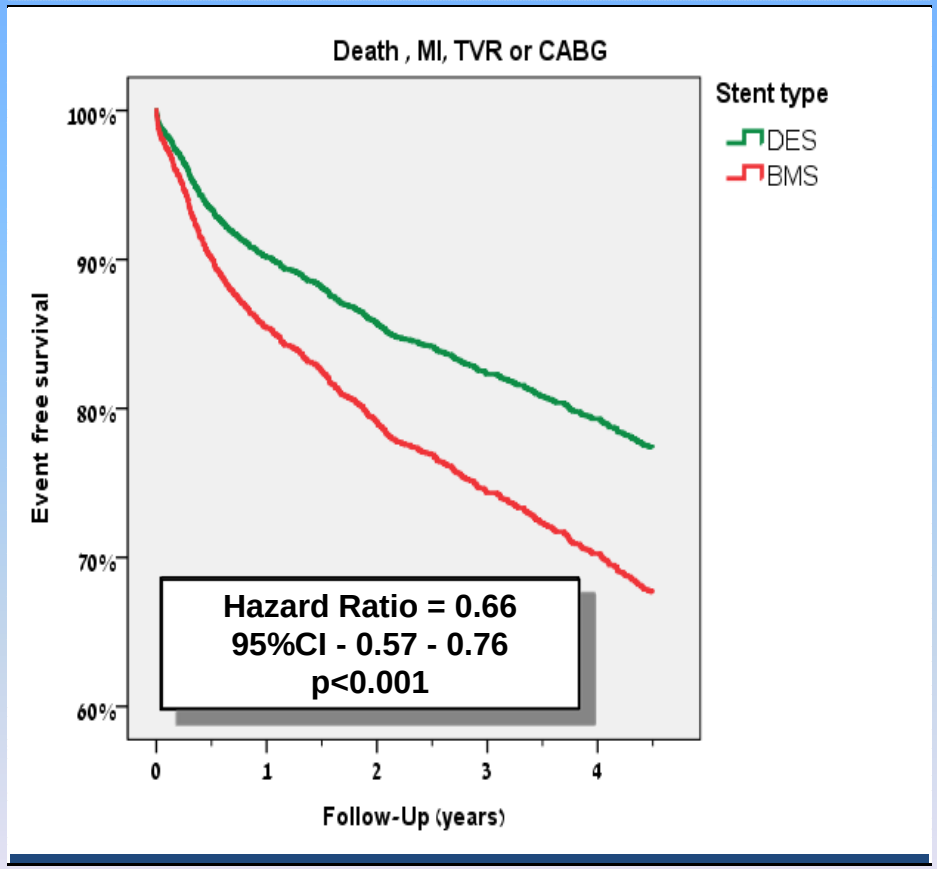
Relative distribution of the different stents in use over time



Results: BMS vs. DES and Sirolimus Eluting Stent

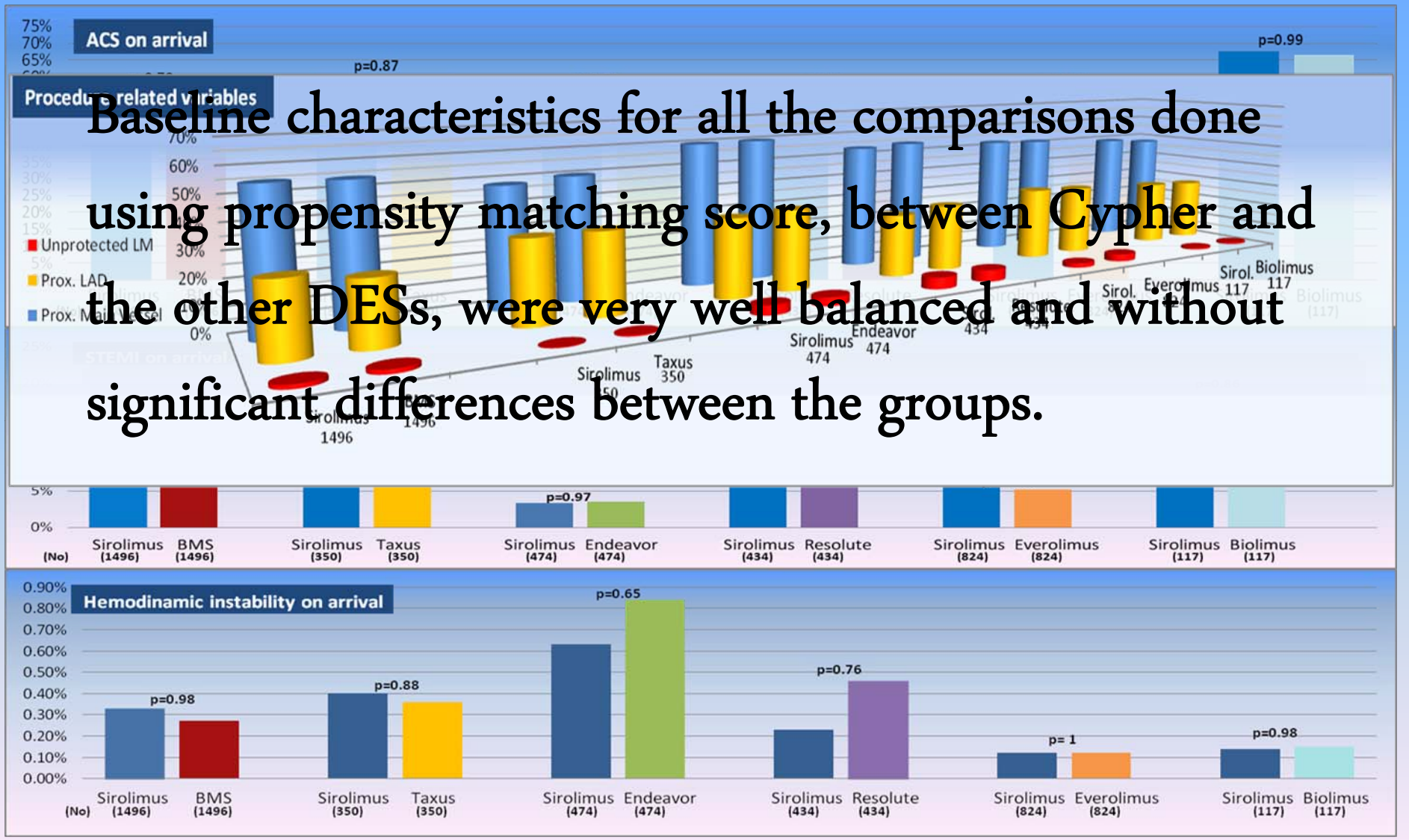
Outcomes of BMS vs. All-DESs (unmatched comparison)			
	BMS (n=5598)	All DESs (n=3985)	P value
Death			
6 month	5.34%	2.15%	
1 year	7.15%	3.25%	
2 years	10.27%	5.41%	
3 years	13.33%	7.62%	<0.001
Death/MI	16.10%	9.26%	<0.001
TVR			
6 month	4.51%	2.56%	
1 year	6.82%	4.34%	
2 years	8.15%	6.68%	
3 years	9.13%	8.47%	0.038
TVR/CABG	11.68%	10.37%	0.002
MACE	25.32%	17.92%	<0.001

Outcomes of BMS vs. SES (matched comparison)



Results: SES vs. Other brands of DES

Baseline characteristics for all the comparisons done using propensity matching score, between Cypher and the other DESs, were very well balanced and without significant differences between the groups.



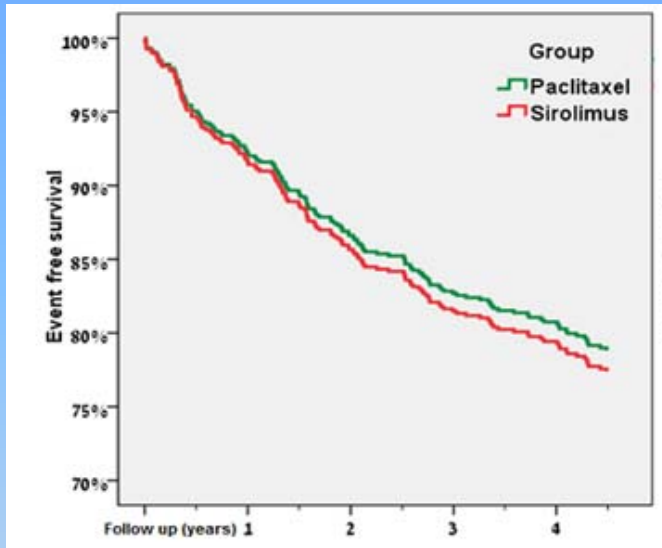
Results: SES vs. Other brands of DES

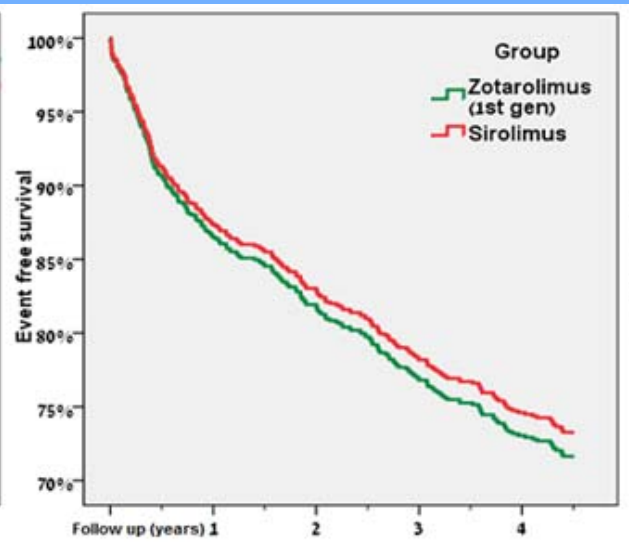
Propensity matching score comparison of Death, Death or MI, TVR, TVR or CABG and MACE rates between SES and each of the other DESs brands

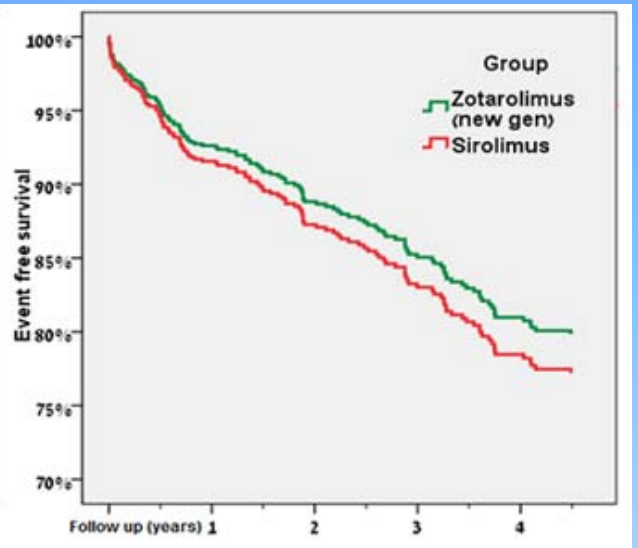
	Cipher	Taxus	P val.	Cipher	Endeavour	P val.	Cipher	Resolute	P val.	Cipher	Everolimus	P val.	Cipher	Biolimus	P val.
	(n=350)	(n=350)		(n=474)	(n=474)		(n=434)	(n=434)		(n=824)	(n=824)		(n=117)	(n=117)	
Death			0.9024			0.4554			0.5549			0.4226			0.3345
3 years	5.74%	6.59%		10.59%	12.87%		7.46%	5.92%		4.76%	5.01%		6.00%	2.05%	
Death/MI	8.32%	8.02%	0.601	14.18%	14.98%	0.8904	8.84%	6.71%	0.8623	6.70%	5.88%	0.9756	7.71%	2.05%	0.1454
TVR			0.2158			0.4045			0.4791			0.9296			0.6383
3 years	10.37%	8.31%		9.95%	7.59%		9.06%	5.70%		7.57%	7.04%		6.01%	10.49%	
TVR/CABG	11.80%	10.30%	0.3528	10.80%	10.76%	0.7545	9.75%	6.21%	0.4306	8.91%	9.14%	0.7261	6.86%	11.53%	0.6053
MACE	18.12%	17.74%	0.6979	21.81%	23.21%	0.3576	16.90%	11.76%	0.7364	14.28%	14.16%	0.6132	13.72%	13.45%	0.6607

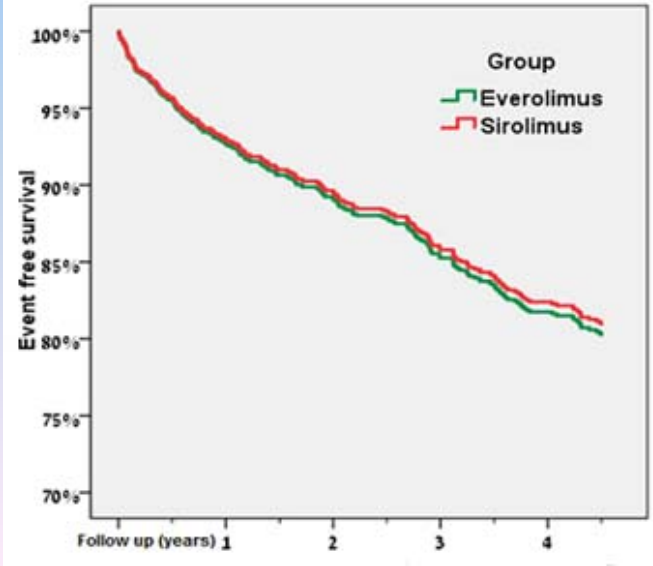
Results: SES vs. Other brands of DES

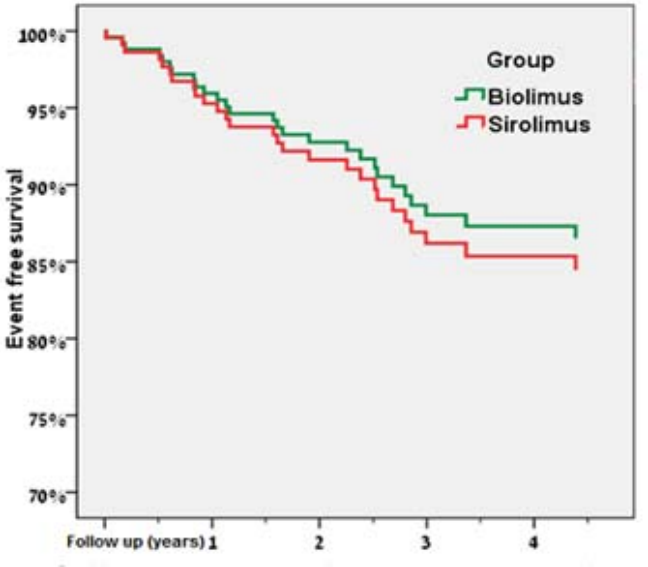
Comparison using propensity matching score of MACE (All-cause mortality, MI, TVR and CABG) rates between SES and PES, ZES, ZES-R, EES and BES.

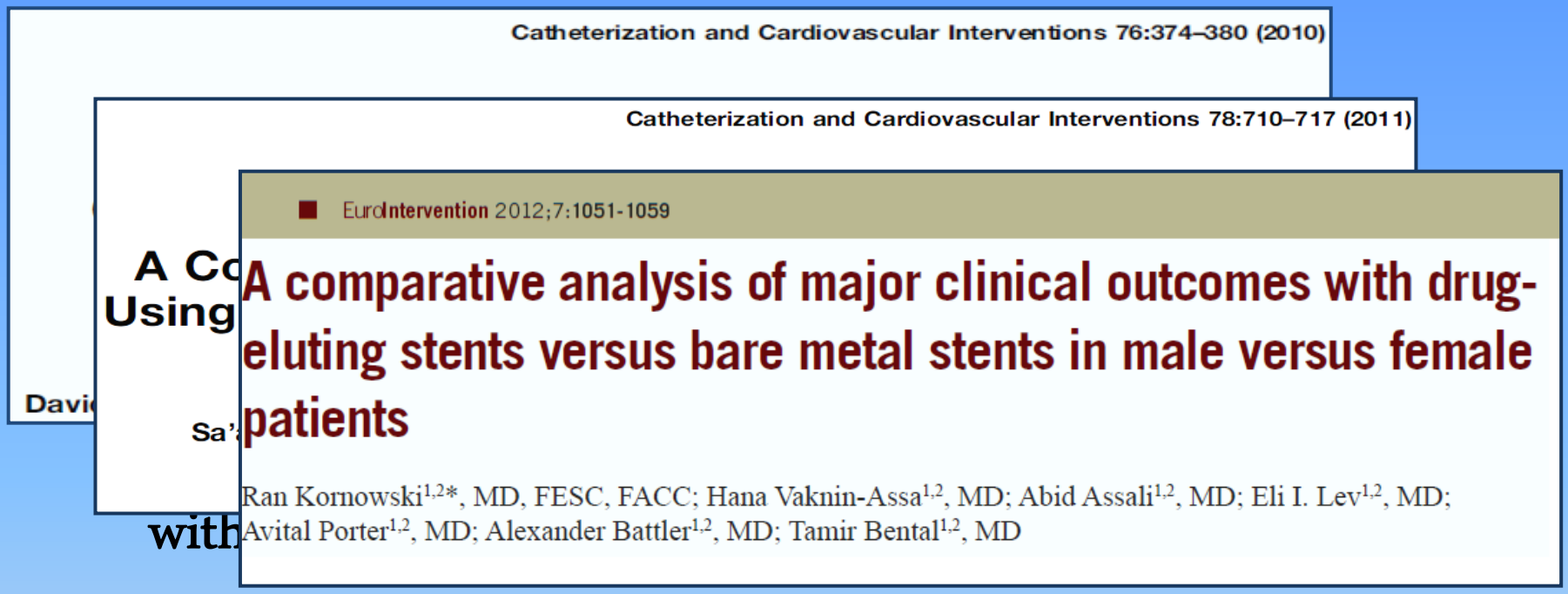












- In the current report we confirmed and reinforced our prior findings that the use of DES improves the long term outcomes by reducing rates of all-cause mortality, need for TVR or CABG and MACE compared to BMS treated patients.
- The prognostic advantage of DES was evident in both the unmatched and the propensity matched comparisons.

Summary

- The main finding of the current investigation is the lack of significant differences between the various DES treated sub-groups in comparison to SES.
- This was true for any of the studied endpoints.
- Among our patients we did not find any added prognostic benefit in favor of the use of additional 1st generation or newer 2nd generation DESs over SES.
- Our findings seem to be robust as the DES sub-groups were very well balanced.

Limitations

- We report the experience of a single center.
- Our study is **not a randomized prospective trial.** We approached this potential bias by using a propensity-matching scheme that balanced all known confounders.
- Data regarding long- term pharmacological medical treatment is not provided.
- We could not present data regarding stent thrombosis, as the definitions have evolved over the years and reporting in the electronic medical record was not homogenous.

Conclusion

- From the analysis of this large cohort of "real world" coronary patients, DES implantation, either 1st generation or 2nd generation, showed a significant reduction in the rates of deaths, myocardial infarction and need for target vessel revascularization in comparison to BMS.

- No further benefits in the studied outcomes were achieved with the use of the newer 2nd generation DES in comparison to the 1st generation Sirolimus eluting stent.

- This study encourages the widespread use of DES for the revascularization of coronary artery disease, when clinically indicated.

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