

Potential conflicts of interest

Speaker's name: MISCHIE Alexandru Nicolae

☐ I do not have any potential conflict of interest











Endothelial Dysfunction: Prognosis

A Swardia et al. (B) Schachinger et al. (19) 2000 Routine commangraphy+/- PTCA for the evaluation of chest pain 147 7.7 y 14 14 14 14 14 15 14 14	Author / Method	Year of publication	Target Population	Number of patients	Median follow-up period	Conclusions
Al Swaidi et al (18) 2000 CAD Cad Schackings et al (19) 2000 Routine coronarography 4 PTCA for the evaluation of chest pain 147 7.7 y	Coronary angiography	puntation		рацень	periou	
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Targonskier al (22) 2003 CAD Clinical indication for coronarography (females) 163 16 mo (Maringet al (21) 2004 Clinical indication for coronarography (females) 185 48 mo 185 48	Hollenberg et al (47)	2001		73	a CAV or cardiac	Predictive of CV events
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Kithrich efal (48) 2009 2009 Post-cardiac transplant 147 25+/-33 mo 1ndependent predictor of CV events 1ndependent 1ndependent predictor of CV events 1ndependent predictor of C						
Sanchez et al (49) 2009 Post-cardiac transplant Coronary syndrome x 147 25+i-33 mo 7 Independent predictor of CV events, mainly hospital readmissions for worsening angina 147 25+i-33 mo 7 Independent predictor of CV events, mainly hospital readmissions for worsening angina 148 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149 149						
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Impedance Plefhysnography Perticore et al (43) 2001 Untreated young (<54 y) hypertensives 225 31.5 mo Heitzer et al (22) 2001 CAD 281 4.5 y 198 47.77±15.1 mo Heitzer et al (25) 2005 Heart failure (early-stage) 289 4.8 y 4.8 y Response to Ach predictive of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach predictive of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response to Ach was an indepent predictor of events Response	Sánchez et al (49)	2009		147		
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Shechter et al (25) Rossi et al (38) Corrado et al (39) Suzuki et al (37) Takase (26) Consecutive healthy and cardiac patients Asymptomatic post-menopausal females 2264 45+/-13 mo 2264 45+/-13 mo 2264 45+/-13 mo 24 mo 81+/-21 mo 81+/-21 mo FMD predictive of CV events beyond traditional risk factors FMD predictive of CV events beyond traditional risk factors FMD and IMT predictive of CV events FMD and IMT predictive of CV events FMD and metabolic syndrome predictive of higher CV events than those with either one of them alone FMD and exercise stress ECG predictive of CV events, whereas IMT less						FMD predictive of CV events beyond traditional risk factors
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Corrado et al (39) Suzuki et al (37) Suzuki et al (37) 2008 Asymptomatic Asymptomatic free of stroke or MI Takase (26) 2008 Clinically suspected CAD Asymptomatic free of stroke or MI 103 50+/- 15 mo FMD and IMT predictive of CV events FMD and metabolic syndrome predictive of higher CV events than those with either one of them alone FMD and exercise stress ECG predictive of CV events, whereas IMT less					45+/-13 mo	FMD predictive of CV events beyond traditional risk factors
Takase (26) 2008 Clinically suspected CAD 103 50+/- 15 mo either one of them alone FMD and exercise stress ECG predictive of CV events, whereas IMT less				84		
Takase (26) 2008 Clinically suspected CAD 103 50+/- 15 mo FMD and exercise stress ECG predictive of CV events, whereas IMT less	Suzuki et al (37)	2008	Asymptomatic free of stroke or MI	819	81+/-21 mo	FMD and metabolic syndrome predictive of higher CV events than those with
	Takase (26)	2008	Clinically suspected CAD	103	50+/- 15 mo	
powerful in predicting CV events	17.1 1 . 1.025	2000	4	2014	_	powerful in predicting CV events
Yeboah et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Kitta et al (33) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (33) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Sitta et al (35) Zero Asymptomatic multi-ethnic (61.2+/-9.9 y) Zero Asymptomatic multi-ethnic multi-ethnic (61.2+/-9.9 y) Ze						Provide a first of the control of th
event independent predictor of CV evens	Kitta et al (33)		CAD and FMD <5.5% after medical freatment	251		independent predictor of CV events
Corrado et al (28) 2009 CAD after PTCA 58 10 mo IMT, glycemia, and a lower FMD predictive of stent restenosis						
Takishima et al (46) 2011 Ischaemic heart failure and FMD <5.5% after 245 36 mo or 1" cardiac Persistent impairment of FMD despite optimized therapy to reduce RF-	Takishima et al (46)	2011		245		
medical treatment event independent predictor of CV evens			medical treatment		event	independent predictor of CV events
Reactive hyperemia Nichall and 1/40 CURE house and for the FMD		2004	Assessment and and DE #1 =>	20.45	3	CC DII -1-1 - CU DE 11-1- 6- CC DII1-1- EMD
Mitchell et al (40) Huang et al (30) Asymptomatic with moderate RF (61 y) PAD before elective vascular surgery 2045 SS-RH related to CV RF, lesser correlation for SS-RH incorporated into FMD RH and FMD independent predictors of CV events beyond traditional RF			PAD before elective rescular surrors		300 days	PH and FMD independent predictors of CV events beyond traditional PF
Philpott et al (43) 2009 Asymptomatic men without CV disease 1477 - SS-RH and vti-RH better associated with CV RF than FMD					Jus uays	
Anderson et al (13) Asymptomatic men without CV disease (49.4 1574 5 y vti-RH (but not FMT and CRP) and IMT predictive of CV events			Asymptomatic men without CV disease (40.4		5 v	
y)			1	-2	- "	











Endothelial Dysfunction: Prognosis

Author /	Method	Year of publication	Target Population	Number patients		Median follow-up period		Conclusions
Al Suwa Schachii	ry angiography idi et al (18) ngeret al (19) erg et al (47)	2000 2000 2001 2001	CAD Routine coronarography +/- PTCA for the evaluation of chest pain Post-cardiac transplant With and without CAD	157 147 73		28 mo 7.7 y a CAV or cardiac		Predictive of increased rates of myocardial events Independent predictor of increased rates of myocardial events Predictive of CV events
voi Kü Sá	Author / Me	thod	Target Population	I	Medi: perio	an follow-up d	Co	onclusions
Im Ple Ple Fit He Fit Mit Go Br Ch Pa Xyo Sh Ye Ro	Coronary an Al Suwaidi e Schachinger Hollenberg e Halcox et al. Targonski et von Mering Kübrich et a Sånchez et a	et al. et al. et al. t al. et al. al.	CAD Routine coronarography +/- PTC for the evaluation of chest pain Post-cardiac transplant With and without CAD CAD Clinical indication for coronarography (females) Post-cardiac transplant Coronary syndrome x	CA	death 46+/3 16 mo 48 mo	V or cardiac months	Inc my Pr Inc Inc eve Inc	redictive of increased rates of myocardial events dependent predictor of increased rates of yocardial events dependent predictor of CV events dependent predictor of cerebrovascular events esponse to Ach was an indepent predictor of ents dependent predictor of CV events dependent predictor of CV events, mainly spital readmissions for worsening angina
Co Su	Plethysmogi	aphy						h
Ta Ye Ki	Flow-mediat	ted						
Co Ta	Reactive hyp	eremia .						
	et al (30) et al (43) n et al (13)	2007 2009 2011	PAD before elective vascular surgery Asymptomatic men without CV disease Asymptomatic men without CV disease (49.4 y)	267 1477 1574		309 days - 5 y		D RH and FMD independent predictors of CV events beyond traditional RF SS-RH and vti-RH better associated with CV RF than FMD vti-RH (but not FMT and CRP) and IMT predictive of CV events











PCR Endothelial Dysfunction: DES

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Author	2007	Number	Aledian tollowup	Score dilber	Techniq sneeked and doonge	Evaluated registers	Conclusions Observations
I		of subject	period	procedure			
Carrageer	1999	39	> 0 mo	BMS (n=12)	Acety lehic line (10-6, 10-5, 10-4 mol./L)	Mean aggment diameter et LAD	EMS-c-ED increased vs. EA/DCA
i i				BA (n=15)		•	
et al.				DCA (n= 12)			
Aymong	2002	48	30 man after	BMS (8-20)	Acetylcheline (107, 10-6 met/L)	5 and 10 mm data to the stem	Supener Acho-CEF in Abeliumab group.
	2002	70				3 and 10 mm data to the stem	Superior Activi-Car in Additional group.
et al.			atenting	BMS+ Abeiximab (n= 20)	Nitroglycerin (200 meg)		
l					Adenosine (24meg)		
Ho hera	2004	15	At the	Stent (n= 7)	Acetylcheline, CFR,	Distal to the steet	Irradiation did not affect the EP acutely or at 0 me. Irradiated argments had less negative
et al.			intervention/6 mp	Stent + imadiation(n=8)	IVUS.		remodeling but higher glague burden than the controls did.
Togas	2004	27	104/-3 mo (B303)	BMS (n=14)	Exercise	5 to 15 mm grox/mal and distal to the	
et al.			94/-1 ma	Brachy T (n=13)		atent	, , , , , , , , , , , , , , , , , , , ,
95 AL.		l .		Emeny's (n=15)		315315	
			(Brachy T)				
Togas	2005	25	6+(-1 mo	B505 (n=11)	Extreme	5 to 10 mm proximal and distal to	SES-4-ED in the presumal and distal segments vs. ENS
et al.				SES (n= 14)	Nitrates	atent	
Ho tena	2005	12	0 me	BMS (n= 5)	Acctylcholane (10-8, 10-7, 10-6 mal./L)	2 to 17 mm distal to the stent	SESED in the presumal and data! segments vs. EMS
et al.				SES (n - 7)	Nitrates		· · ·
Togai	2007	27	641-2 mp	BMS 76-121	Exercise	3 to 10 mm moximal and distal to	VES-0-ED in the presumal and distal segments vs. EMS
	2007		CHINE THE	PES (n=15)	Nitrates	atent	Parameter in the presental and datas adjusted 15, 2012
et al.			_				
Fulls	2007	33	0 mo	BMS (n= 12)	Acetylcholine (10-8, 10-7 mel/L)	3 mm proximal and datal to the stent	SES-4-ED in the presumal and data! segments vs. EMS
et al.				SES (n = 21)			
Sain	2007	22 77	0-V mo	BMS (n= 5)	Acctylcholane (10-6 mol./L)	 10 and 20 mm proximal and distal 	SES and VESED in the datal and far-dutal argments vs. EMS
et al.				SES (n = 9)	Nitrates	to the atent	
				PES (n - 8)			
Kares	2008	83	0 ma	B315 7a - 101	Assistable tractill all and till man beaut		SES and VESED expecially in the datal segments vs. BMS
et al.	2000		V 1120	SES (n= 30)	Nitrate (200 meelmin)		ses are resourced expensely in necessary parties of
ec al.					Natrate (200 meg man)	atent	
				PES (n = 36)			
Hamadalo:	2008	83	9-12 mo	B515 (n=13)	Atnal pacing	10 mm preximal and 10 mm datal to	SES and VES4-ED in the proximal and datal segments vs. EMS/ZES/bAVES
et al.				ZES (n=10)		the atent	
l				SES (n = 21)			
l				PES (n= 11)			
l				bA9ES (n-28)			
Hamulot	2008	34	y mo	BMS (n= 19)	Atnal pacing	to 11 mm movemel and district to be	SESED in the proximal and distal argments vs. EMS
et al.			*	SES (n=15)	Action yourses	atent	The state of the s
						•	
Sain	2008	23	6-9 mo	ZES (n=11)	Acetylcheline (10-6 mel/L)	5, 10 and 20 mm groxemal and datal	SESED in the datal and far datal argments vs. ZES.
et al.				SES (n - 12)	Nitrates	to the stent	
Bases	2009	30	0 mo	BMS (n=10)	Acetylcheline (10, 20, 30 and 100	3 mm groximal and 3 mm diable to the	Progressive ED to incremental doses of Acetylcheline for ZES and 3ES vs. EMS. Sugenor
et al.				ZES (n = 20)	mez/min)	atent	SES-i-ED in distal segments vs. ZES
				SES (n - 20)	Nitrate (200 meg/min)		
Obses	2009	33	2 weeks/ 6 me	BMS (n= 18)	Acetylcheline(10 meg/min)	15 to 20 mm dastal to the stent	SESED in the digital segments vs. BMS EF recovery of BMS at 0 mg vs. 2 weeks.
et al.	2000		nest-STEMI	SES (n=15)	Nitrates		Impaired anterior LV-RWM in SES vs. BMS at 6 mg, even though LV EF between the 2
ec at.			Bost-2 (Eps)	5E5 (R= 13)	Name of the last o		
							groups was similar at any time points.
Incommo	2010	40	12 me gest Nee-	TES (n= 20)	Atnal pacing	•	Study in grogica, parloimed in Non-STEMI setting, Tatenta per patient.
et al.			STEMI	PES (n= 20)			
Perin	2010	160	1 mg/ 18 mg	B345 (n= 80)	Extensise attentatent	Climical evaluation and follow-up.	At 1 mg, increased goattive exercise stress test rate in DES vs. EMS probably due to DES-
et al.				DES (n= 74)			FD
ar ar.				(4 - 7 - 7			At 18 me. DES patients had lower rate of TVR but a higher rate of MI.
110							
100	2011	42	Angiography at	DES (Cypher and Taxus)			DES-4-ED in distal segments. Steril length proportionally with ED degree.
et al.			follow-up after		Nitrates (2-5 mg isosorbide dinitrate)	20 mm distal to the stent	
I			DES				
Altockie	2011	14	0 mo	BMS (n=14)	Acetylcholane (10-5 meg fram)	10 and 3 mm groximal to the stent.	Stents implanted in pairs in each gatient, SES-4-ED in the growmal and especially distal and
et al.				SES (n=14)	Nitrate (200 meg/min)	5. 10 and 20 mm distal to the ratest.	far-distal acgments via BMS. Severe ED in athreseleratic SES distal arteries subgroup via
						Proximal, distal and total mean	the same BMS subgroup. ED correlated with SES length and diagno-portional with SES
l						segment dimeters.	diameter. Mean scement diameters more adoptate for ED studies involving stents.
						regment simeers.	enaments, where significan diameters more adoptate for all student in the ting stores.











Endothelial Dysfunction: DES

Author	Year	Number	Steding to lower	Stead of Bell	Techniq smethod and distage	Evaluated registers	Conclusions Observations
		ofsubject	period	procedure			
Carrageer	1999	39	> 0 mo	BMS (n=12)	Acetylcheline (10-6, 10-5, 10-4 mel./L)	Mean argment diameter of LAD	EMS-0-ED increased vs. EA/DCA
i				BA (n=15)			
et al.				DCA (n=12)			
Aymong	2002	48	30 man after	BMS (n= 20)	Acetylcheline (10-7, 10-6 mel/L)	5 and 10 mm datal to the stent	Sugener Achi-CEP in Aberranab group.
et al.			stenting	BMS+ Abeisimab (n= 20)	Nitroglycerin (200 meg)		
			•		Adenosine (24meg)		
Ho tera	2004	15	At the	Stent (n=1)	Acetylcholine, CFK,	Distal to the steri	Irradiation did not affect the EP scutchy or at 0 mo. Irradiated argments had less negative
et al.			intervention/6 mp	Stent + imadiation(n=8)	IVUS.		remodeling but higher glaque burden than the controls did.
Togas	2004	27	104(-3 mo (BMS)	BMS (n=14)	Exercise	5 to 15 mm groximal and distal to the	Bracky 4-ED in the groximal and distal segments vis. BMS
et al.			9+/-1 mo	BrackyT (n=13)		atent	

Togar et al. Hotera et al. Togar et al. Fuke et al. Skin

et al.

Most of these studies conclude that SES and PES induce ED proximal and especially distal to stent edges, but comparison was made in different persons with different risk factors.

et al.		ı	ı	445 (n= 10)	ı	ting attent	
l				SES (n= 21)			
l				PES (n= 11)			
l				6A9ES (n-28)			
Hamalor	2008	34	y mo	B345 (n= 19)	Atnal pacing	3 to 13 mm groximal and distal to the	SES-4-ED in the presumal and distal segments vs. EMS
et al.				SES (n = 15)	* *	atent	
Ship	2008	23	6-V mo	ZES (n=11)	Acetylcheline (10-6 mel/L)	5, 10 and 20 mm proximal and datal	SES-4-ED in the datal and far datal segments vs. ZES.
et al.				SES (n=12)	Nitrates	to the stent	•
Kint	2009	50	0 me	BMS (n= 10)	Acetylcholane (10, 20, 50 and 100	3 mm proximal and 3 mm distal to the	Progressive ED is incremental doses of Acetylcheline for ZES and SES vs. EMS. Supener SES-ED in distal segments vs. ZES.
et al.				ZES (n = 20)	mcg/min)	stent	SES-i-ED in distal segments vs. ZES
				SES (n = 20)	Nitrate (200 meg/min)		
Ubaca	2009	33	2 weeks/ 6 me	B305 (n= 18)	Acety lehe line (10 meg/min)	15 to 20 mm datal to the stent	SES-4-ED in the datal segments vs. BMS EF recovery of BMS at 0 mo vs. 2 weeks.
et al.			post-STEMI	SES (n= 15)	Nitrates		Impaired anterior LV-RWM in SES vs. BMS at 6 ma, even though LV EF between the 2
							groups was similar at any time points.
Incommo	2010	40	12 me gest Nen-	1ES (n= 20)	Atnal pacing		Study in gragical, patermed in Non-STEMI setting, Tatenta per patient.
et al.			STEMI	PES (n = 20)			
Nerta	2010	160	1 mo/ 18 mo	B345 (n = 86)	Exercise stress test	Clinical evaluation and follow-up.	At 1 me, increased positive exercise stress test rate in DES vs. EMS probably due to DES-
et al.				DES (n= 74)			ED.
							At 18 mo, DES patients had lower rate of TVR but a higher rate of ML
100	2011	42	Anguagraphy at	DES (Cypher and Taxus)	Acetylcholane (20, 50 and 100 meg man)	3 to 10 mm groxsmal and distal; 10 to	DES-0-ED in distal segments. Steet length proportionally with ED degree.
et al.			follow-up after	1	Nitrates (2-5 mg isosorbide dinitrate)	20 mm distal to the stent	
			DES				
Minchie	2011	14	6 me	B305 (n=14)	Acetylcholane (10-3 meg/min)	10 and 3 mm groxamal to the stent.	Stents implanted in pairs in each patient, SES-4-ED in the preximal and expecially dark and
et al.			l	SES (n= 14)	Nitrate (200 meg/min)	5, 10 and 20 mm distal to the stent.	far-distal segments vs. BMS. Severe ED in athret seleratic SES distal arteries subgroup vs.
l			l			Proximal, distal and total mean	the same BMS subgroup. ED correlated with SES length and disproportional with SES diameter. Mean segment diameters more adequate for ED studies involving stents.
						segment dimeters.	diameter. Mean segment diameters more adequate for ED studies involving stents.











The **CREDENTIAL** study

Authors: Alexandru Nicolae Mischie, M.D., Marco Stefano Nazzaro, M.D., PhD, Rosario Fiorilli, M.D., Francesco De Felice, M.D., Carmine Musto, M.D., Carla Boschetti, M.D., Crina Sinescu, M.D., PhD, FESC, Roberto Violini, M.D., PhD, FESC.

The study was performed at the Interventional Cardiology Unit, Ospedale San Camillo (Roma, Italy), Direttore Prof. Roberto Violini, from from January to September 2009.











The **CREDENTIAL** study

The aim of our randomized study was to provide the best accuracy regarding the effects of SES and BMS over ED in the same patient. To date, no study has investigated this issue in a prospective randomized fashion and by using a pair-stenting concept which overcomes the different risk factors of each patient.

Study Design:

In this monocentric study, we compared the ED of SES vs. BMS, both implanted in the same patient with multiple de novo coronary artery lesions undergoing elective percutaneous coronary intervention (PCI). Patients, data analyst and statistician were masked to treatment allocation.

Inclusion criteria:

- stable angina pectoris and/or a positive stress test
- presence of at least two de novo significant angiographic stenosis in different native coronary vessels or in the same vessel but in different ramifications with similar diameter.











The **CREDENTIAL** study

Exclusion criteria:

- acute coronary syndrome in the last 3 months
- coronary vasospasm, coronary angiographic findings of a fresh thrombus at the initial angiography (filling defect proximal to or involving the stenosis)
- coronary anatomy unsuitable for intracoronary Ach infusion (left main coronary artery disease >30%, surgical diffuse three vessel disease or other anatomical considerations that make it unsafe to perform intracoronary studies)
- target vessel diameter <2,50 mm and lesion length <10 and >30 mm
- target vessel diameter difference >0,5mm and difference of the length of the stenosis >50%
- severe LV dysfunction
- bifurcation/ostial lesions
- presence of a dissection
- any contraindication/nontolerance to the use of aspirin, heparin and/or clopidogrel
- chronic renal failure requiring dialysis
- lack of consent to participate
- survival expectancy < 1 year
- angiographic restenosis at follow-up
- patients with severe risk factors for ED: uncontrolled diabetes mellitus (DM), uncontrolled hypertension (systolic blood pressure >180mmHg), refuse to discontinue smoking, persistent hypercholesterolemia (total cholesterol >240mg/dl)



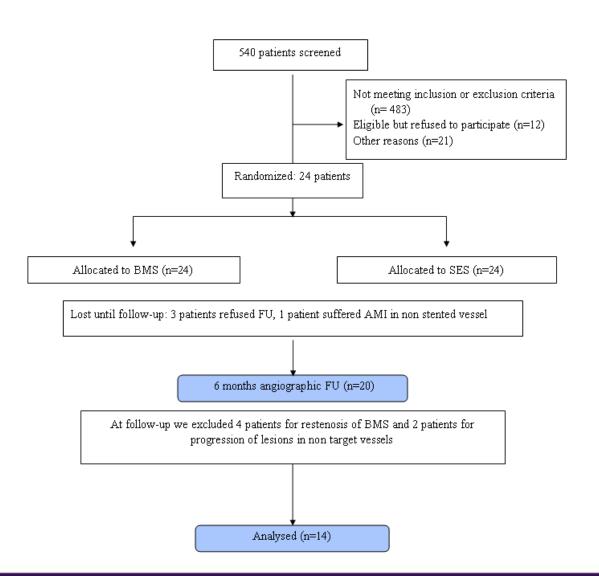








The **CREDENTIAL** study



Study protocol











The **CREDENTIAL** study

Table 1. Baseline characteristics.

70.8 ± 7.1
1.879 ± 0.117
9 (64.2%)
4 (28.5%)
8 (57.1%)
13 (92.8%)
6 (42.8%)
5 (35.7%)
2.857 ± 0.363
1.50 ± 0.65

*HD= heart disease; †CCS= Canadian Cardiovascular Society;

±NYHA= New York Heart Association.

Table 2. Blood samples results at 6 moths follow-up.

C-Reactive Protein (mg/dl)	0.09 ± 0.04
Creatinin (mg/dl)	0.94 ± 0.27
HbA1C (%)	6.043 ± 0.696
Homocysteine (microm/l)	9.95 ± 2.59
Hemoglobin (gr/dL)	13.5 ± 1.3
Total Cholesterol (mg/dl)	155.9 ± 29.7
Low Density Lipoprotein (mg/dl)	78.8 ± 19.1
High Density Lipoprotein (mg/dl)	45.9 ± 13.8
Triglyceride (mg/dl)	112.1 ± 64.2
Fibrinogen (mg/dl)	302.6 ± 45.9







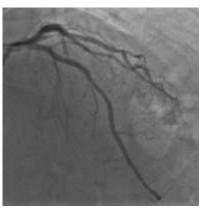




The **CREDENTIAL** study

Table 3. PCI Characteristics.

Mean BMS length (mm)/ (range)	16.1 ± 2.9	(12.00-19.00)
Mean BMS diameter (mm)/ (range)	3.2 ± 0.4	(2.50-4.00)
Mean SES stent length (mm)/ (range)	19.29 ± 7.28	(13.00-30.00)
Mean SES stent diameter (mm)/ (range)	2.86 ± 0.39	(2.50-4.00)
BMS Artery		
Right Coronary Artery	5(35.7%)	
Circonflex Artery	5 (35.7%)	
Left Anterior Descendent Artery	4(28.5%)	
SES Artery		
Left Anterior Descendent Artery	5 (35.7%)	
Right Coronary Artery	4 (28.5%)	
Circonflex Artery	3 (21.4%)	
Ramus Intermedius	2 (14.2%)	



Baseline



Ach infusion









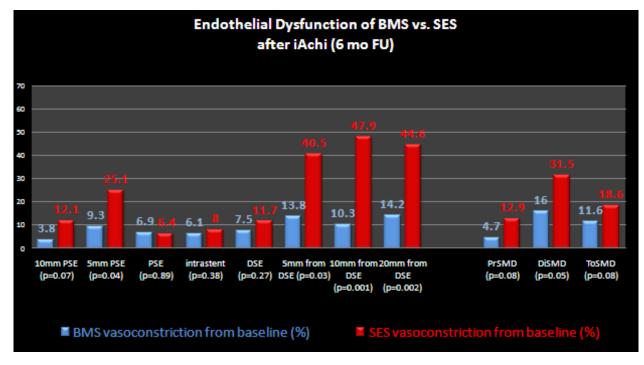


The **CREDENTIAL** study

Results (1):

For the overall population SES produce:

- •a 3.5 fold vasoconstriction of SES vs. BMS calculated for distal diameters (mean value for the 3 distal diameters)
- •a 1.9 fold vasoconstriction of SES vs. BMS calculated for DiSMD.



BMS = bare metal stents:

FU = follow-up;

SES = sirolimus eluting stents;

iAchi = intracoronary acetylcholine infusion;

mo = month;

PSE = proximal (to) stent edge;

DSE = distal (to) stent edge;

PrSMD = proximal segment mean diameter- mean diameter calculated from 10 mm PSE to PSE:

DiSMD = distal segment mean diameter- mean diameter calculated from DSE to 20 mm after DSE;

ToSMD = total segment mean diameter - mean diameter from 10 mm PSE to 20 mm from DSE









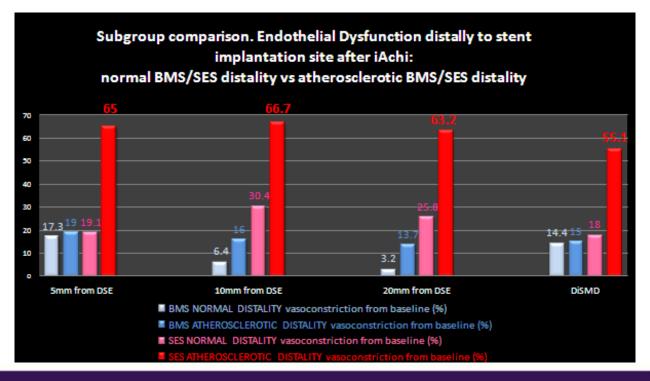


The **CREDENTIAL** study

Results (2):

For the subgroup with diffuse distal atherosclerotic coronary segments, SES produce:

- •a 4.0 fold vasoconstriction vs. BMS calculated for distal diameters (mean value for the 3 distal diameters)
- •a 3.6 fold vasoconstriction vs. BMS calculated for DiSMD.



BMS = bare metal stents:

SES = sirolimus eluting stents;

iAchi = intracoronary acetylcholine infusion;

DSE = distal (to) stent edge;

DiSMD = distal segment mean diameter- mean diameter calculated from DSE to 20 mm after DSE







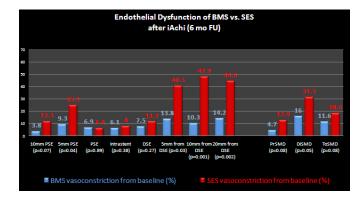


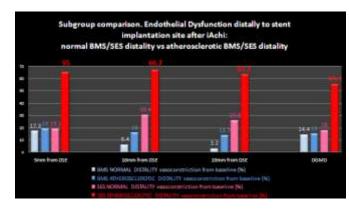


The **CREDENTIAL** study

Possible mechanisms of SES-induced-ED:

- the drug (sirolimus normally eluted after 60 days)
- •the polymer (decreased ED with 2nd-Gen-DES)
- vasa vasorum involvement
- •mechanical injury during PCI...
- •SES-i-ED could be time-limited (could dissapear after 1 or more years)













The **CREDENTIAL** study

Limitations:

- small number of enrolled patients
- high rate of drop-out at the angiographic follow-up
- no Ach infusion for EF evaluation before stent implantation
- •short period of follow-up (6 months)











The **CREDENTIAL** study

Conclusions:

- •In comparison to BMS, SES implantation produce an increased vasoconstrictive response after Ach infusion. The effect is more severe in the subgroup with distal atherosclerotic coronary disease.
- •These findings could have implications regarding the type of stent we choose (BMS, 1st-genDES or 2nd-genDES), the duration of double antiplatelet treatment and other medical interventions to improve EF.
- •We suggest <u>a possible new gold-standard</u> in evaluating stent-induced ED by measuring mean segment diameters, which are more accurate than measuring predefined punctual diameters.
- •So, if a SES should be implanted in a vessel with diffuse distal atherosclerosis, aggressive medical treatment should be administered to decrease the ED and atherosclerosis.











The **CREDENTIAL** study

What stent to choose for best results?













The **CREDENTIAL** study

What stent to choose for best results?













The **CREDENTIAL** study

What stent to choose for best results?













The **CREDENTIAL** study

Thank you for your attention!













The **CREDENTIAL** study

Additional slides











The **CREDENTIAL** study

Additional slides: BASKET study

Outcome	Sirolimus- Eluting Stent (N=775)	Everoli mus- Eluting Stent (N = 774)	Bare-Metal Stent (N=765)	Sirolimus-Eluti vs. Bare-Met		Everolimus-Elut vs. Bare-Met:		Sirolimus-Eluting Stent vs. Everolimus-Eluting Stent	
	35.00	(8.5-/5-7.)		Haz ard Ratio (95% CI)	PValue	Hazard Ratio (95% CI)	PValue	Hazard Ratio (95% CI)	P Value
	n	o. of pasients (%)						
Death									
From any cause	28 (3.6)	25 (3.2)	34 (4.4)	0.82 (0.50-1.35)	0.71	0.73 (0.43-1.22)	0.46	1.13 (0.66-1.94)	0.85
From cardiac causes	13 (1.7)	13 (1.7)	22 (2.9)	0.59 (0.30-1.18)	0.38	0.58 (0.29-1.14)	0.37	1.03 (0.48-2.23)	0.93
Nonfatal my ocardial infarction	7 (0.9)	13 (1.7)	20 (2.6)	0.37 (0.15-0.87)	0.13	0.67 (0.33-1.36)	0.51	0.54 (0.22-1.36)	0.43
Death from cardiac causes or nonfatal myocardial infarction									
Total	20 (2.6)	25 (3.2)	37 (4.8)	0.54 (0.31-0.93)	0.13	0.66 (0.40-1.10)	0.37	0.82 (0.45-1.47)	0.78
0-6 mo	11 (1.4)	10 (1.3)	21 (2.7)	0.52 (0.25-1.08)	0.31	0.47 (0.22-1.01)	0.22	1.10 (0.47-2.59)	0.92
7–24 mo	9 (1.2)	15 (1.9)	16 (2.1)	0.56 (0.25-1.27)	0.42	0.90 (0.44-1.82)	0.90	0.63 (0.27-1.43)	0.51
Farget-vessel revascularization									
Arry	33 (4.3)	29 (3.7)	79 (10.3)	0.47 (0.31-0.72)	0.005+	0.41 (0.27-0.65)	0.002†	1.13 (0.68-1.88)	0.85
Not related to myocardial infarction	29 (3.7)	24 (3.1)	68 (8.9)	0.46 (0.30-0.73)	0.007†	0.39 (0.24-0.63)	0.002†	1.18 (0.69-2.04)	0.82
Related to myocardial infarction	4 (0.5)	5 (0.6)	11 (1.4)	0.40 (0.13-1.28)	0.37	0.49 (0.17-1.44)	0.43	0.82 (0.22-3.04)	0.90
De ath, myocardial infarction, or target- vessel revascularization	61 (7.9)	59 (7.6)	99 (129)	0.59 (0.43-0.82)	0.009†	0.56 (0.41-0.78)	0.005†	1.05 (0.74-1.51)	0.90
Stent thrombosis									
Definite	3 (0.4)	2 (0.3)	6 (0.8)	0.50 (0.13-2.02)	0.59	0.33 (0.07-1.62)	0.42	1.54 (0.26-9.23)	0.85
Definite or probable	6 (0.8)	5 (0.6)	9 (1.2)	0.75 (0.26-2.18)	0.85	0.62 (0.20-1.88)	0.67	1.23 (0.37-4.02)	0.90
Definite, probable, or possible	11 (1.4)	12 (1.6)	13 (1.7)	0.92 (0.41-2.10)	0.92	0.96 (0.43-2.15)	0.93	0.96 (0.42-2.18)	0.93

* Patients may have had more than one event. All Pvalues have been adjusted for multiple comparisons.









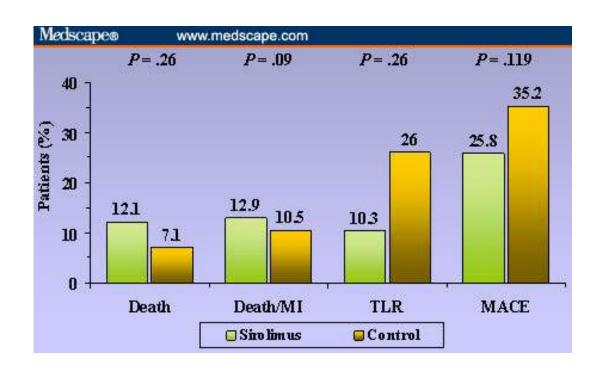
DRUG-ELUTING VS. BARE-METAL STENTS IN LARGE ARTER

[†]The difference between groups is significant after adjustment for multiple comparisons by means of the step-up procedure.



The **CREDENTIAL** study

Additional slides: RAVEL study







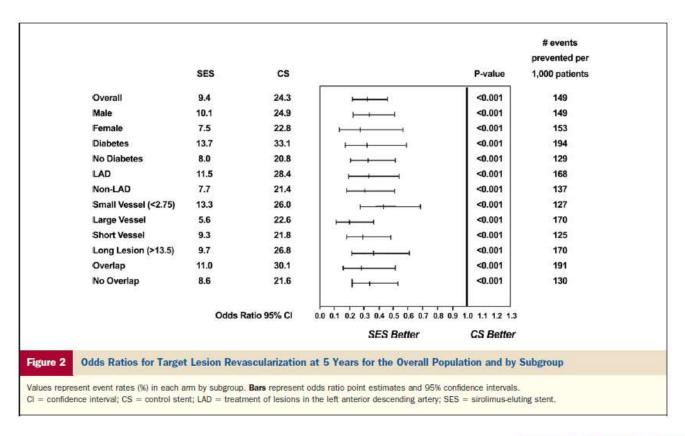






The **CREDENTIAL** study

Additional slides: SIRIUS study













The **CREDENTIAL** study

Additional slides: SIRIUS study

	SES (n = 533)	BMS (n = 525)	Difference (95% CI)	p Valu
All events at 1 yr	***************************************			
Death	7 (1.3)	4 (0.8)	0.6% (-0.7% to 1.8%)	0.55
Cardiac	3 (0.6)	2 (0.4)	0.2% (-0.6% to 1.0%)	1.00
Noncardiac	4 (0.8)	2 (0.4)	0.4% (-0.5% to 1.3%)	0.69
MI (all)	16 (3.0)	22 (4.2)	-1.2% (-3.4% to 1.1%)	0.33
Q-wave	4 (0.8)	4 (0.8)	-0.0% (-1.1% to 1.0%)	1.00
Non-Q-wave	12 (2.3)	18 (3.4)	-1.2% (-3.2% to 0.8%)	0.27
Death or any MI	23 (4.3)	25 (4.8)	-0.4% (-3.0% to 2.1%)	0.7
Death or Q-wave Mi	11 (2.1)	8 (1.5)	0.5% (-1.1% to 2.1%)	0.64
TLR	26 (4.9)	106 (20.2)	-15.3% (-19.2% to -11.4%)	< 0.00
TL CABG	5 (0.9)	9 (1.7)	-0.8% (-2.2% to 0.6%)	0.30
TL PCI	23 (4.3)	102 (19.2)	-15.1% (-18.9% to -11.3%)	< 0.00
All TVR	38 (7.1)	120 (22.9)	-15.7% (-19.9% to -11.5%)	< 0.00
TVR (non-TL)	20 (3.8)	34 (6.5)	-2.7% (-5.4% to -0.1%)	0.00
MACE	44 (8.3)	122 (23.2)	-15.0%(-19.3% to -10.7%)	<0.0
TVF	52 (9.8)	130 (24.8)	-15.0%(-19.5%to -10.5%)	< 0.0
VI events at 5 yrs	0.0040.003			
Death	45 (8.4)	44 (8.4)	0.1% (-3.3% to 3.4%)	1.0
Cardiac	22 (4.1)	19 (3.6)	0.5% (-1.8% to 2.8%)	0.7
Noncardiac	23 (4.3)	25 (4.8)	-0.4% (-3.0% to 2.1%)	0.7
MI (all)	33 (6.2)	34 (6.5)	-0.3% (-3.2% to 2.7%)	0.9
Q-wave	8 (1.5)	6(1.1)	0.4% (-1.0% to 1.7%)	0.7
Non-Q-wave	26 (4.9)	28 (5.3)	-0.5%/-3.1% to 2.2%)	0.7
Death or any MI	74 (13.9)	70 (13.3)	0.6% (-3.6% to 4.7%)	0.8
Death or Q-wave MI	51 (9.6)	49 (9.3)	0.2% (-3.3% to 3.8%)	0.9
TLR	50 (9.4)	127 (24.2)	-14.8% (-19.2% to -10.4%)	< 0.0
TL CARG	12 (2.3)	18 (3.4)	-1.2% (-3.2% to 0.8%)	0.2
TL PCI	43 (8.1)	121 (23.0)	-15.0% (-19.3% to -10.7%)	< 0.0
All TVR	88 (16.5)	160 (30.5)	-14.0% (-19.0% to -8.9%)	<0.0
TVR (non-TL)	55 (10.3)	68 (13.0)	-2.6%/-6.5% to 1.2%)	0.2
MACE	108 (20.3)	176 (33.5)	-13.3% (-18.5% to -8.0%)	< 0.0
TVF	120 (22.5)	182 (34.7)	-12.2% (-17.6% to -6.8%)	<0.0
All events between 1 and 5 vm		102 (04.7)	-122%(-17.6%to -6.8%)	<0.0
Death	38 (7.1)	40 (7.6)	-0.5% (-3.6% to 2.7%)	0.8
Cardiac	19 (3.6)	17 (3.2)	0.3% (-1.9% to 2.5%)	0.8
Noncardiac	19 (3.6)	23 (4.4)	-0.8% (-3.2% to 1.5%)	0.5
			0.9% (-1.1% to 2.9%)	0.4
MI (all) O-wave	17 (3.2) 4 (0.8)	12 (2.3) 2 (0.4)	0.9% (-1.1% to 2.9%) 0.4% (-0.5% to 1.3%)	0.6
		100000000000000000000000000000000000000		0.5
Non-Q-wave Death or any Mi	14 (2.6)	10 (1.9)	0.7% (-1.1% to 2.5%) 1.0% (-2.5% to 4.5%)	
	51 (9.6)	45 (8.6)		0.5
Death or Q-wave Mi	40 (7.5)	41 (7.8)	-0.3% (-3.5% to 2.9%)	0.9
TLR	24 (4.5)	21 (4.0)	0.5% (-1.9% to 2.9%)	0.7
TL CABG	7 (1.3)	9(1.7)	-0.4% (-1.9% to 1.1%)	0.6
TL PCI	20 (3.8)	19 (3.6)	0.1% (-2.1% to 2.4%)	1.0
All TVR	50 (9.4)	40 (7.6)	1.8% (-1.6% to 5.1%)	0.3
TVR (non-TL)	35 (6.6)	34 (6.5)	0.1% (-2.9% to 3.1%)	1.0
MACE	64 (12.0)	54 (10.3)	1.7% (-2.1% to 5.5%)	0.3
TVF	68 (12.8)	52 (9.9)	2.9% (-1.0% to 6.7%)	0.1

Values are number of cases (%). Events at 1 year were reported previously (4)

BMS – bars-metal steriţis); CABC – coronary aftery typass graft surgery; CI – confidence Internati, MACE – major adverse cardiac eveniţis); M – myocardal infection; PCI – percultansecu coronary functioneribles; SES – actionius situating steriţis); TL – target lassion; TLR – target existent invascularization; VR – larget vessel faiture; VR – target existent envascularization.











The **CREDENTIAL** study

Additional slides: RESOLUTE study

Clinical Evaluation of the Resolute Zotarolimus-Eluting Coronary Stent System in the Treatment of De Novo Lesions in Native Coronary Arteries

The RESOLUTE US Clinical Trial

Methods

Results

Conclusions

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Objectives The RESOLUTE US (R-US) trial is a prespective, observational study designed to evaluate the clinical effectiveness of the Resolute adarolimus-sluting start (R-ZES) in a U.S. population.

Background The R-ZES releases autorolimus over a 6-month period in order to achieve optimal clinical effectiveness and

The RUS trial recruited patients with de nove native coronary lesions salitable for 1- or 2-vessel treatment with stants from 2.55 to 4.0 mm in diameter. In the main analysis cohort (2.5- to 3.5 mm stants and stegle-lesion treatment), the primary endpoint was 12-month target lesion failure (ILF) defined as the compassis of cardiac death, myocardial inflatotion (MI), and dimically-driven target lesion revasculatation (ILIP), compared with data from Endeavor adamnimus-eluting stant (E-ZES) trials, adjusting for baseline covariates through propersity scores.

Overall, 1,402 patients were emotived with a mean reference visited diameter of 2.59 ± 0.47 mm and diabetes providence of 34.4%, in the main analysis cohort, TLF was 3.7% at 12 months compared with historical E-255 tessits (TLF = 6.5%). The PLZES met the 3.3% margin of noninteriority (rate difference = -2.8%, upper 1.sided 95% conflictness interval: -1.3%, p < 0.001). The overall TLF rate was 4.7%, and rates of cardiac death, MI, and TLR were 0.7%, 1.4%, and 2.8%, respectively. The 12-month rate of stent thrombosis was 0.1%.

The R-ZES achieved a very low rate of clinical restances while maintaining low rates of important clinical safety events such as death, MI, and stant thrombosis at 1-year follow-up. (The Meditionic RESOLUTE US Clinical Trial [R-US]; NCT00726453) (J Am Coli Cardiol 2011;57:1778-83) @ 2011 by the American College of Cardiology Foundation











The **CREDENTIAL** study







