Percutaneous Therapy for Aortic & Mitral Valve Disease

Ted Feldman, M.D., FSCAI FACC FESC

Evanston Hospital

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Evanston Hospital

Ted Feldman MD, FACC, FESC, FSCAI

Disclosure Information

The following relationships exist:

Grant support: Abbott, Atritech, BSC,
Edwards, St Jude, WL Gore
Consultant: Abbott, BSC, Coherex, Edwards, Intervalve,
Diiachi Sankyo-Lilly, WL Gore
Speaker: Boston Scientific

Off label use of products and investigational devices will be discussed in this presentation

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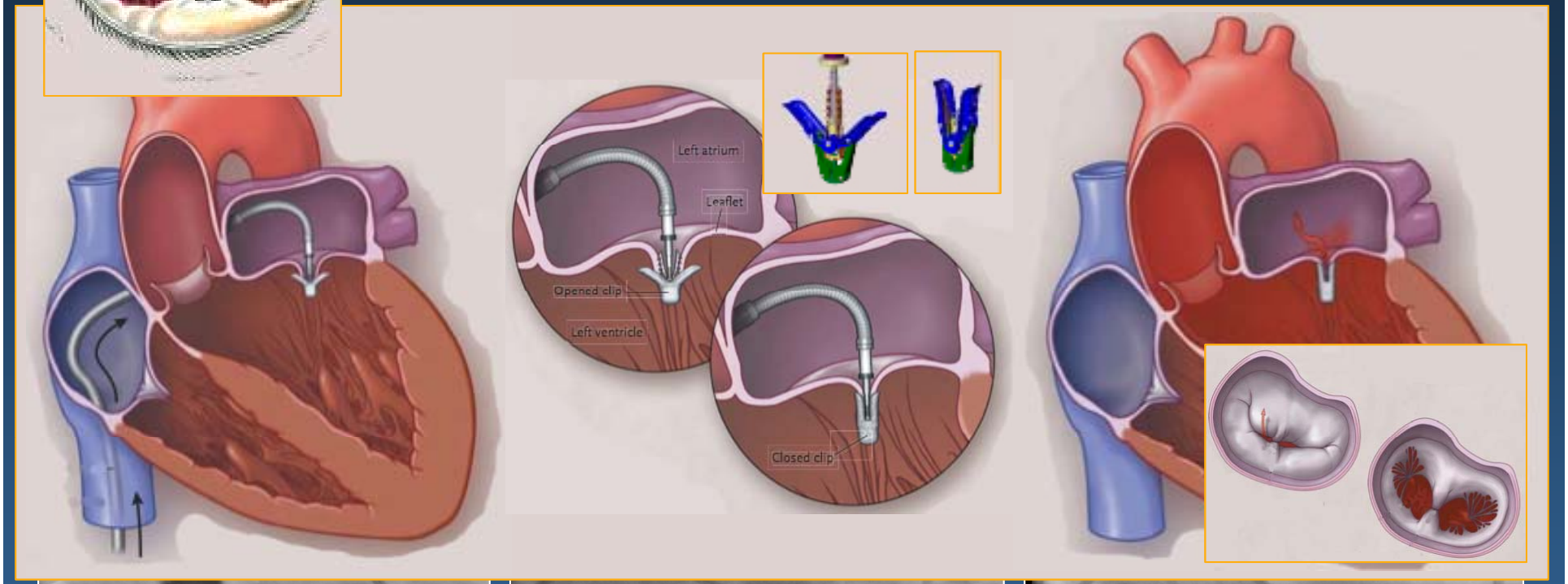
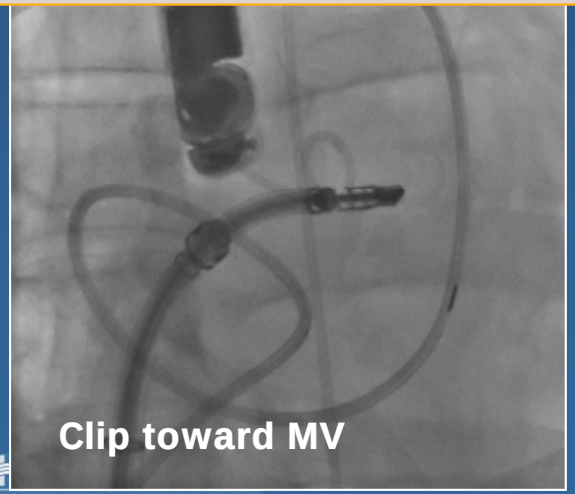
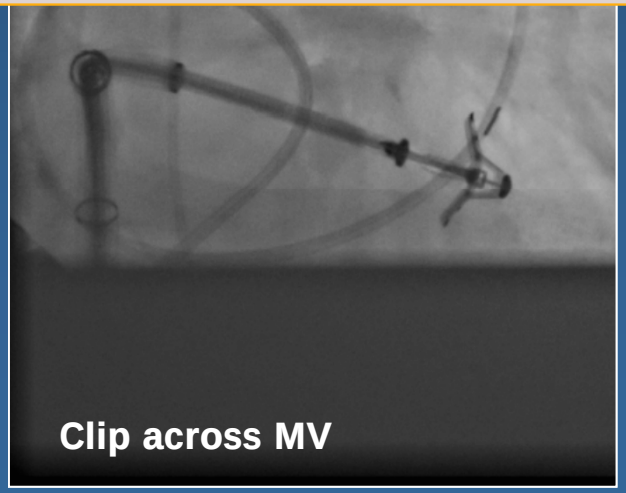
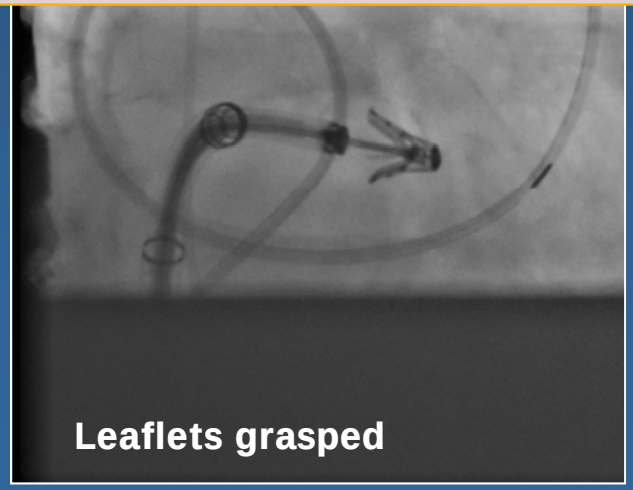
Catheter-Based Mitral Valve Repair

MitraClip System









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EVEREST II Randomized Clinical Trial

Demographics

	EVEREST II RCT	2008 STS Database		Isolated 1st Elective Operation for MR*
	n=279	Repair	Replace	High Volume Hospitals (>140/Yr)
Age yrs (mean)	68	60	61	59
≥65 yrs	58%	37%	45%	n/a
≥75 yrs	32%	n/a	n/a	0%
Male Gender	64%			
NYHA Class III or IV	50%	26%	45%	n/a
CHF	86%	41%	58%	n/a
Hypertension	75%	60%	67%	43%
Diabetes Mellitus	9%	13%	23%	6.5%
COPD / Chronic Lung Disease	15%	17%	29%	n/a
EF (mean)	60%	53%	55%	56%

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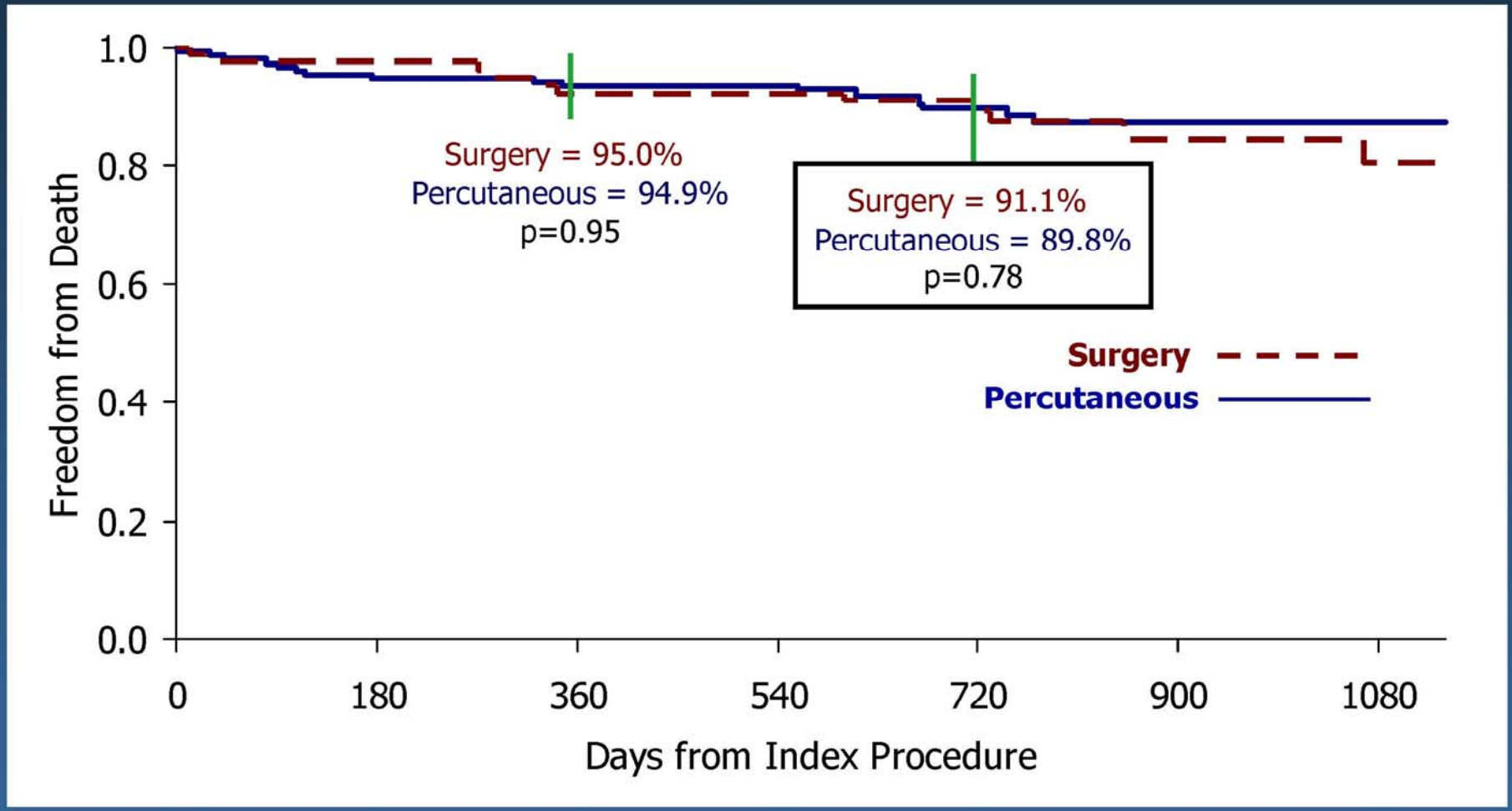
*Gammie JS et al Influence of Hospital Procedural Volume on Care Process and Mortality for Patients Undergoing Elective Surgery for Mitral Regurgitation. Circ 2007;115:881-887.

Safety Endpoint: 30 Day MAE
Intention to Treat

30 Day MAE	# (%) Patients experiencing event	
	Percutaneous (N=180)	Surgery (N=94)
Death	2 (1.1%)	2 (2.1%)
Major Stroke	2 (1.1%)	2 (2.1%)
Re-operation of Mitral Valve	0	1 (1.1%)
Urgent / Emergent CV Surgery	4 (2.2%)	4 (4.3%)
Myocardial Infarction	0	0
Renal Failure	1 (0.6%)	0
Deep Wound Infection	0	0
Ventilation > 48 hrs	0	4 (4.3%)
New Onset Permanent Atrial Fib	2 (1.1%)	0
Septicemia	0	0
GI Complication Requiring Surgery	2 (1.1%)	0
Transfusions ≥ 2 units	24 (13.3%)	42 (44.7%)
TOTAL % of Patients with MAE	**15.0%**	**47.9%**
	Difference (Percutaneous – Surgery) = -32.9%	
	p<0.001; (95% CI: -20.7%, -45.0%)	

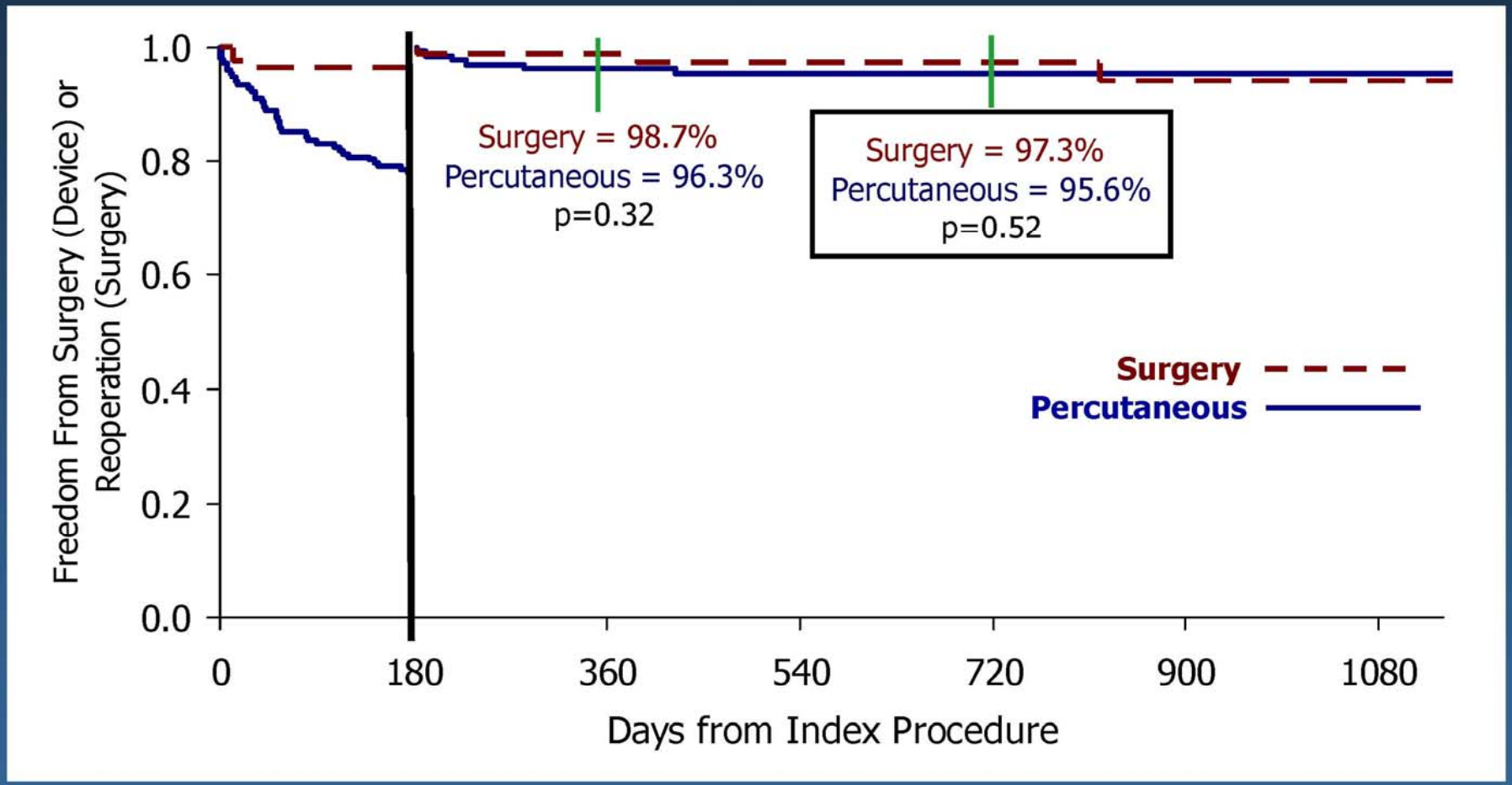
Kaplan-Meier Freedom from Death

Intention to Treat



At Risk:	0 Days	6m	1yr	1.5yr	2yr	3yr
Percutaneous	184	166	163	153	133	52
Surgery	95	78	74	71	63	25

Landmark Analysis of Kaplan-Meier
Freedom from MV Surgery (Percutaneous)/Re-operation (Surgery)
Intention to Treat



At Risk:	0 Days	6m	1yr	1.5yr	2yr	3yr
Percutaneous	184	138	131	124	109	44
Surgery	95	77	72	69	61	24

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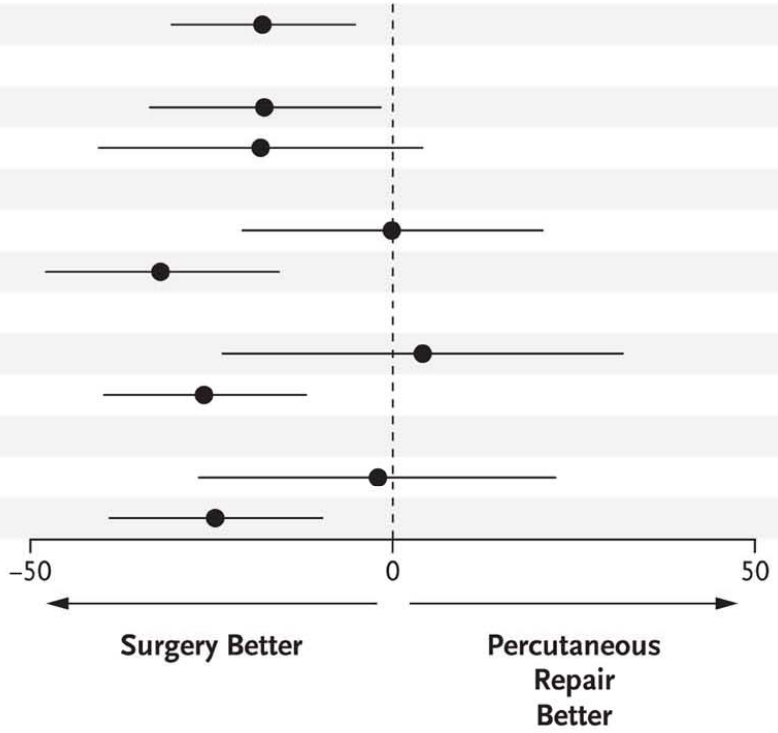
EVEREST II RCT – ACC 2011

EndovascularValveEdge-to-Edge REpairSTudy

Subgroup	Percutaneous Repair	Surgery	P Value for Interaction
	no. of events/total no. (%)		
All patients	100/181 (55)	65/89 (73)	
Sex			0.97
Male	63/114 (55)	43/59 (73)	
Female	37/67 (55)	22/30 (73)	
Age			0.009
≥70 yr	52/86 (60)	23/38 (61)	
<70 yr	48/95 (51)	42/51 (82)	
MR			
Functional	26/48 (54)	12/24 (50)	0.02
Degenerative	74/133 (56)	53/65 (82)	
LVEF			0.06
<60%	35/68 (51)	15/28 (54)	
≥60%	64/111 (58)	50/61 (82)	



Subgroup Analyses for the Primary End Point at 12 Months

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Feldman T et al. N Engl J Med 2011;364:1395-1406

Transcatheter Valve Therapy

First Generation Devices

Edwards Sapien™

CoreValve

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Transcatheter Aortic Valve Implantation for the Treatment of Severe Symptomatic Aortic Stenosis in Patients at Very High or Prohibitive Surgical Risk

Acute and Late Outcomes of the Multicenter Canadian Experience

Josep Rodés-Cabau, MD,* John G. Webb, MD,† Anson Cheung, MD,† Jian Ye, MD,†

Table 1 Baseline Characteristics of the Study Population (n = 339)

Variables	All Patients (n = 339)	Transfemoral (n = 162)	Transapical (n = 177)	p Value
Age (yrs)	81 ± 8	83 ± 8	80 ± 8	0.009
Male sex	152 (44.8)	91 (56.1)	61 (34.5)	<0.0001
BMI (kg/m^2)	26 ± 5	26 ± 5	26 ± 5	0.934
Diabetes	79 (23.3)	37 (22.8)	42 (23.7)	0.898
Dyslipidemia	241 (71.1)	104 (64.2)	137 (77.4)	0.020
Hypertension	252 (74.3)	102 (62.9)	150 (84.7)	<0.0001
Current smokers	20 (5.9)	8 (4.9)	12 (6.8)	0.645
NYHA functional class				

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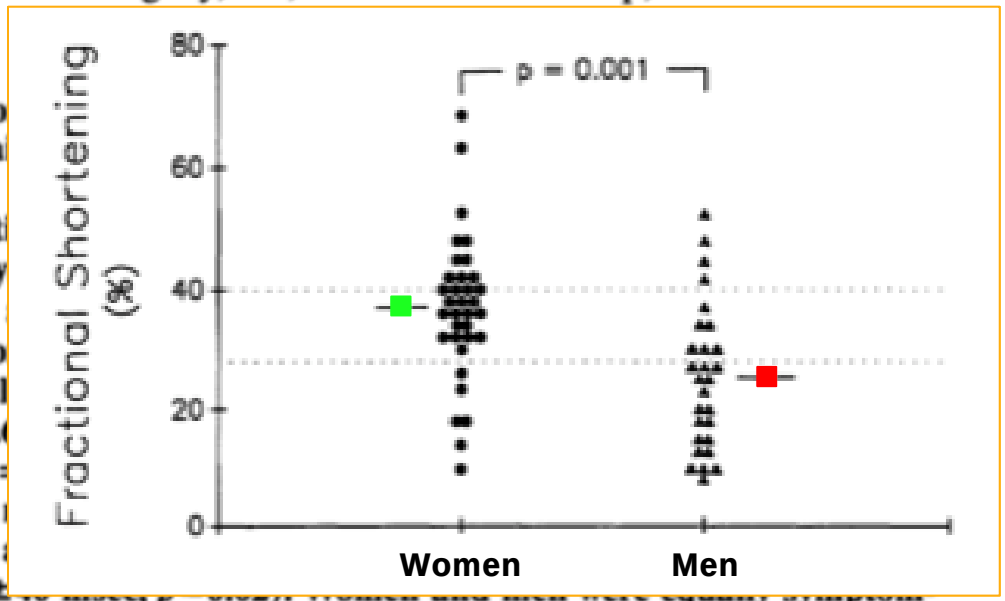
J Am Coll Cardiol 2010;55:1080–90

Patient Characteristics - 1

Characteristic	TAVI n=179	Standard Rx n=179	P value
Age - yr	83.1 ± 8.6	83.2 ± 8.3	0.95
Male sex (%)	45.8	46.9	0.92
STS Score	11.2 ± 5.8	12.1 ± 6.1	0.14
Logistic EuroSCORE	26.4 ± 17.2	30.4 ± 19.1	0.04
NYHA			
I or II (%)	7.8	6.1	0.68
III or IV (%)	92.2	93.9	0.68
CAD (%)	67.6	74.3	0.20
Prior MI (%)	18.6	26.4	0.10
Prior CABG (%)	37.4	45.6	0.17
Prior PCI (%)	30.5	24.8	0.31
Prior BAV (%)	16.2	24.4	0.09
CVD (%)	27.4	27.5	1.00

Sex-Associated Differences in Left Ventricular Function in Aortic Stenosis of the Elderly

John D. Carroll, MD; Eugenia P. Carroll, MD; Ted Feldman, MD; David M. Ward, BA; Roberto M. Lang, MD; Dean McGaughey, JD; and Robert B. Karp, MD



Background. **In aortic stenosis, the respo compensated hypertrophy to overt heart fa poorly understood.**

Methods and Results. **Left ventricular funct 29 men 60 years or older with both hemody aortic stenosis and no important coronary outflow obstruction in women versus men (ao ventricle of women had a greater fractional smaller end-systolic chamber size (1.82±0. pressure (210±35 versus 182±29 mm Hg, p= versus 1,595±384 mm Hg/sec, p=0.02). The l/min/m^2, p=0.02), higher mean pulmonary shorter ejection period (340±40 versus 370± atic. Supernormal left ventricular ejection performance was present in 41% of the women and only 14% of the men (p=0.002). This subgroup of women had a small, thick-walled chamber (end-diastolic radius to thickness ratio, 1.58±0.52 versus 2.45±0.51 in control women, p=0.01) with low end-systolic wall stress. Subnormal ejection performance was present in 64% of the men and only 18% of the women (p=0.002). This subgroup of men had an increased chamber size and high end-systolic wall stress compared with control men. Greater left ventricular mass was present in men compared with women (211±55 versus 179±55 g/m^2, p=0.03).**

Conclusions. **Sex is a factor in left ventricular adaptation to valvular aortic stenosis in adults 60 years or older. (*Circulation* 1992;86:1099–1107)**