# Long-term Outcomes Associated with Bioprosthetic and Mechanical Valve Replacements in Hemodialysis Medicare Patients

Nimesh D. Desai MD PhD, Danielle Savino BS, Fenton McCarthy MD MHSP, Matthew Williams MD, Mary Siki BS, Chase Brown MD, Peter Groeneveld MD, Joseph E. Bavaria MD

Division of Cardiovascular Surgery and Leonard Davis Institute of Health Economics. University of Pennsylvania

Background

- ESRD is associated with advanced left-sided valvular degeneration due to calcium regulation differences
  - Secondary hypoparathyroidism
  - Adynamic bone disease

- 15 to 19 cases per 10,000 dialysed patients (dialysis rates vary by country)

- Increased risk of Infection from chronic indwelling catheters/dialysis access infections

- Same processes may be accelerated in Prosthetic Biologic Valve Tissue
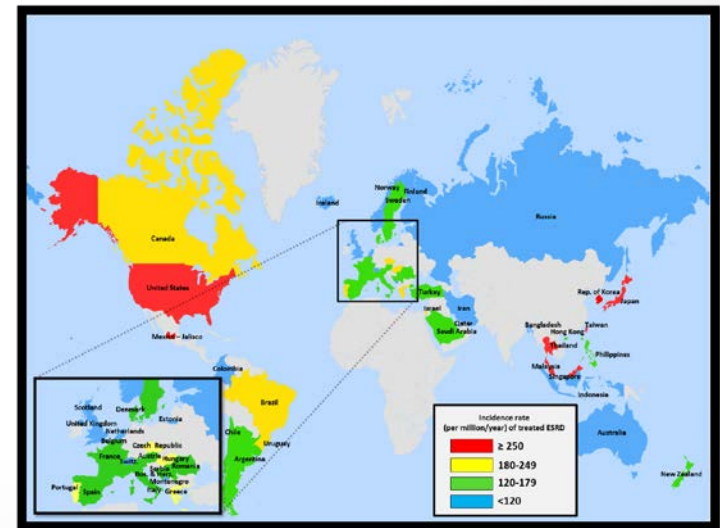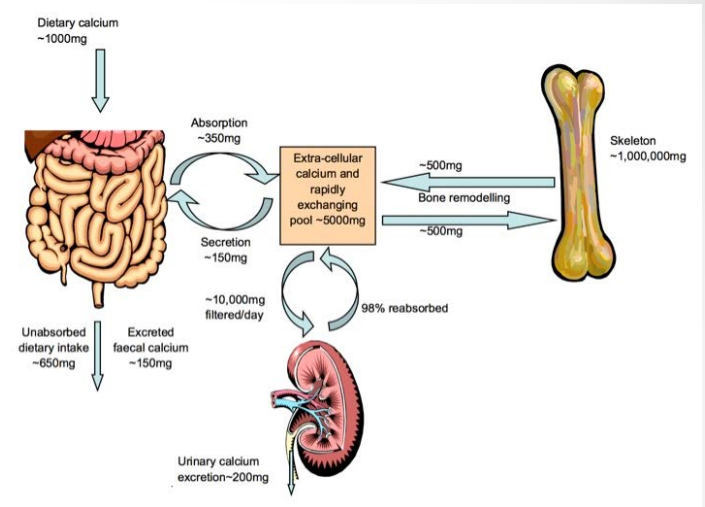
Background

Valve Selection in End-Stage Renal Disease: Should It Always Be Biological?

Matthew L. Williams, MD, Joseph E. Bavaria, MD, Michael A. Acker, MD, Nimesh D. Desai, MD, Prashanth Vallabhajosyula, MD, W. Clark Hargrove, MD, Pavan Atluri, MD, and Wilson Y. Szeto, MD

Division of Cardiovascular Surgery, Department of Surgery, University of Pennsylvania, Philadelphia, Pennsylvania

Table 2. Procedures

Procedure	Mechanical (n = 64)	Bioprosthetic (n = 151)
AVR ± CABG	16 (25)	62 (41)
MVR ± CABG	24 (38)	29 (19)
Two valves ± CABG	17 (27)	43 (28)
Three valves ± CABG	3 (5)	5 (3)
AVR + other*	1 (2)	6 (4)
MVR + other*	3 (5)	6 (4)

* Additional procedures included pulmonary valve replacement and reconstructions of abscesses in the aortic root or mitral valve annulus or both.

Values are n (%).

AVR = aortic valve replacement;   CABG = coronary artery bypass grafting;   MVR = mitral valve replacement.
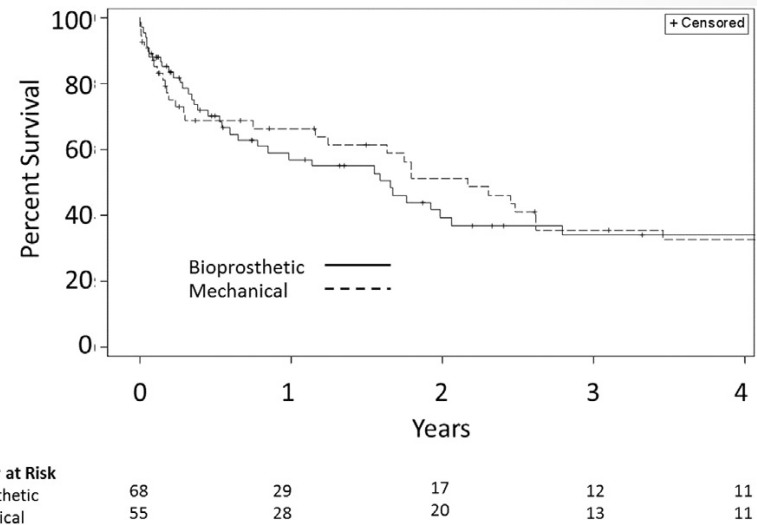
Table 6.4 Expected remaining lifetime (years) by age, sex, and treatment modality of prevalent dialysis patients, prevalent transplant patients, and the general U.S. population (2013), based on USRDS data and the National Vital Statistics Report (2016)

	Age	0-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85+
ESRD patients, 2013 — Dialysis	Male	22.6	21.6	18.5	16.2	14.3	12.6	11.0	9.2	7.9	6.6	5.5	4.5	3.8	3.2	2.6	2.2
	Female	23.3	19.0	16.4	14.3	13.0	11.6	10.4	8.9	7.8	6.6	5.7	4.8	4.0	3.5	2.9	2.4
ESRD patients, 2013 — Transplant	Male	60.1	47.9	43.4	39.2	35.1	31	27.2	23.4	19.9	16.7	13.8	11.4	9.5		7.7[a]	
	Female	59.8	48.5	44.2	40.2	36.4	32.8	28.9	25.2	21.7	18.3	15.3	12.6	10.4		8.7[a]	
General U.S. population, 2013	Male	70.7	59.7	55.0	50.3	45.7	41.0	36.4	31.9	27.7	23.7	19.8	16.2	12.8	9.8	7.1	3.7
	Female	75.4	64.4	59.5	54.6	49.7	45.0	40.3	35.6	31.1	26.8	22.6	18.5	14.7	11.3	8.4	4.4

Data Source: Reference Table H.13; special analyses, USRDS ESRD Database; and National Vital Statistics Report. "Table 7. Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2013 (2016)." Expected remaining lifetimes (years) of the general U.S. population and of period prevalent dialysis and transplant patients. [a]Cell values combine ages 75+. Abbreviation: ESRD, end-stage renal disease.

Methods

- All Medicare fee-for-service, January 2008 through December 2013

- Patients on hemodialysis undergoing either aortic valve replacement (AVR) or mitral valve replacement (MVR)(n=11850)

- Bioprosthetic and mechanical valves separated by ICD9 coding

- Bioprosthetic and mechanical valve patients *propensity matched* incl. age, gender, CAD, CABG, and endocarditis

# Preoperative Characteristics of Propensity Matched Bio vs. Mech AVR patients

|	All AVR Patients N=6660	Bioprosthetic AVR N=3330	Mechanical AVR N=3330	pval
Male	4329 (65%)	2154 (65%)	2175 (65%)	0.61
White	4230 (64%)	2159 (65%)	2071 (62%)	0.03
CHF	3870 (58%)	1974 (59%)	1896 (57%)	0.06
Valvular Disease	4841 (73%)	2412 (72%)	2429 (73%)	0.66
Pulmonary Hypertension	1388 (21%)	713 (21%)	675 (20%)	0.26
PVD	1423 (21%)	727 (22%)	696 (21%)	0.37
COPD	1602 (24%)	800 (24%)	802 (24%)	0.98
Diabetes	3136 (47%)	1574 (47%)	1562 (47%)	0.79
Anemia	3643 (55%)	1821 (55%)	1822 (55%)	1
Hypertension	6250 (94%)	3103 (93%)	3147 (95%)	0.03
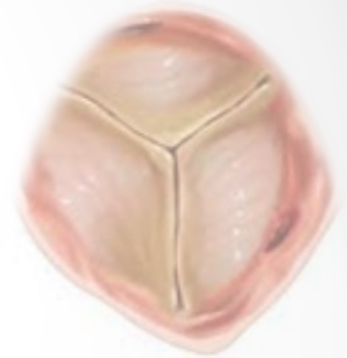
Kaplan Meier Survival for Bio vs. Mech AVR Hemodialysis Patients

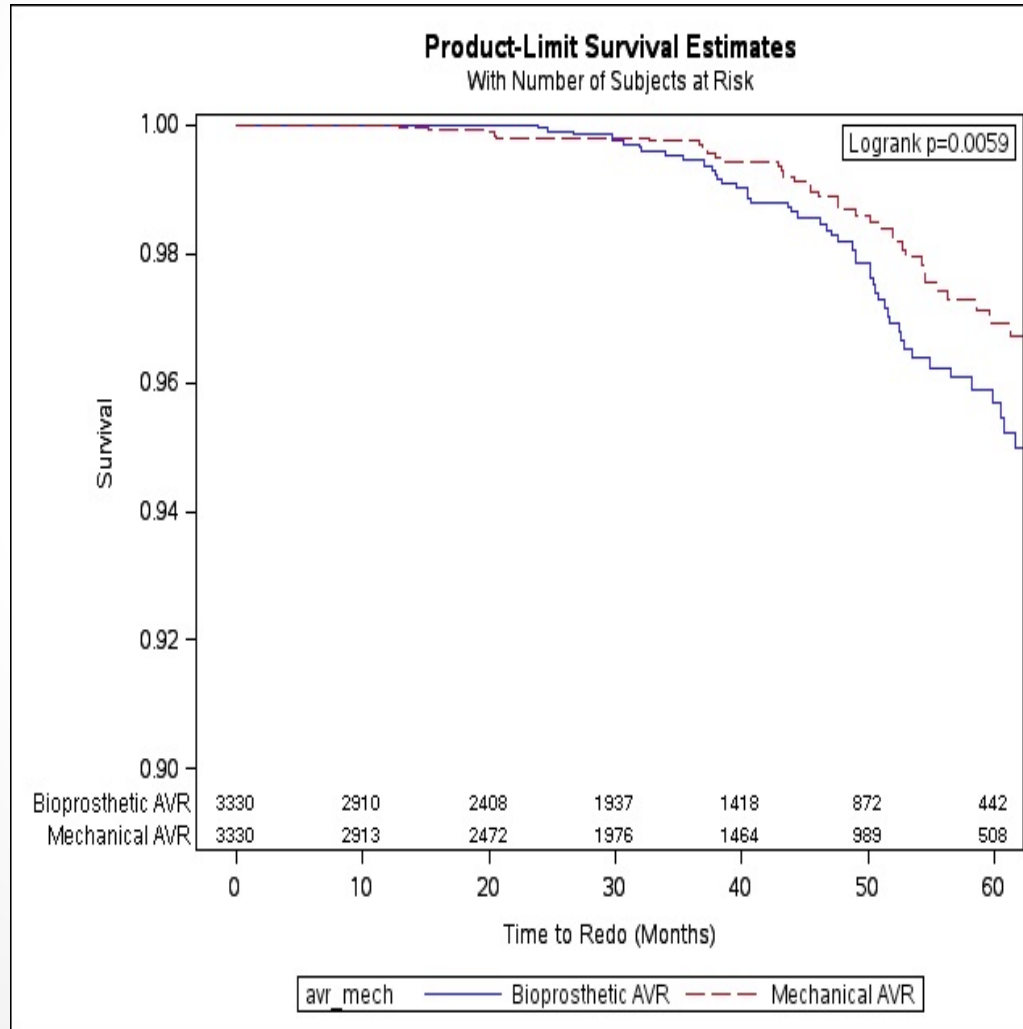All AVR Bio vs. Mech Hemodialysis Patients
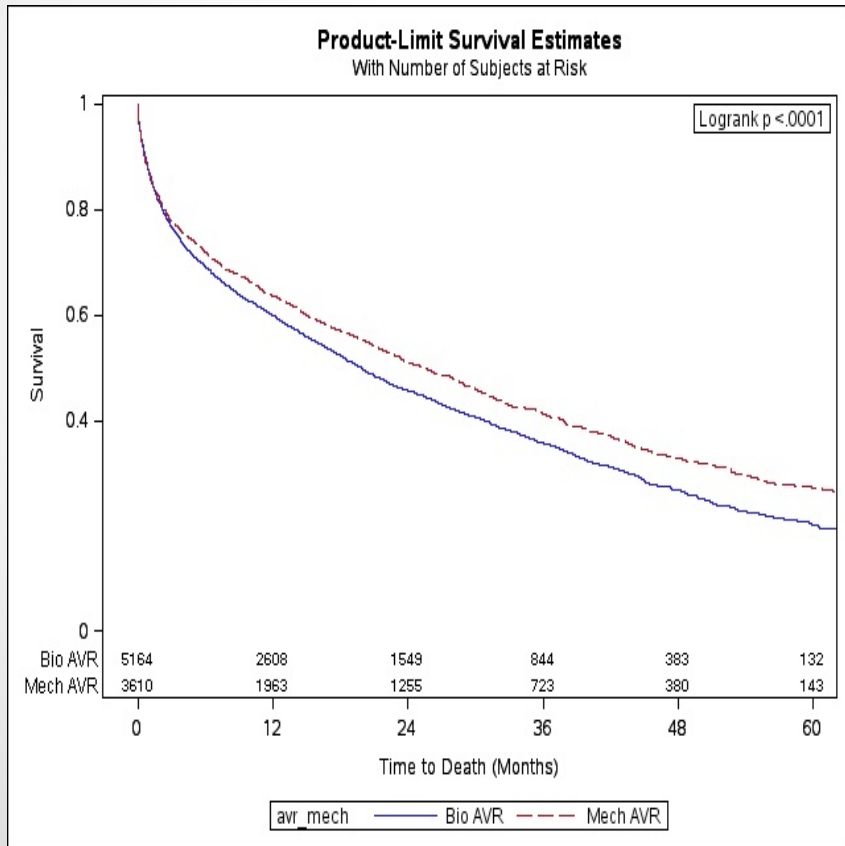
Propensity Matched AVR vs. Mech Hemodialysis Patients
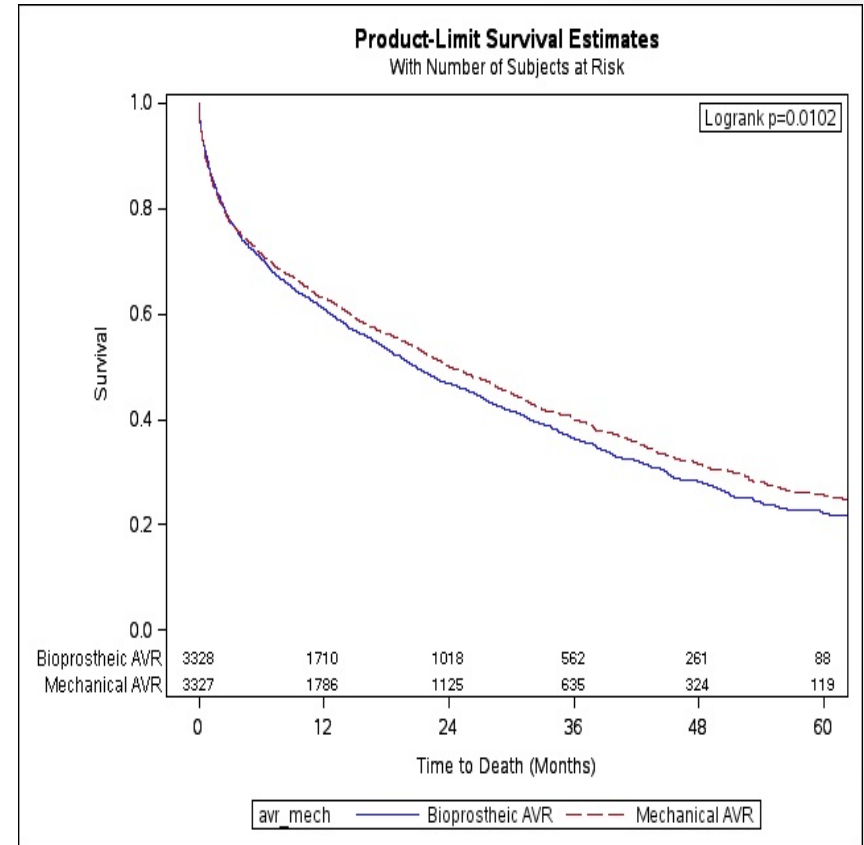
30 Day Mortality: Bioprosthetic 13%   Mechanical 13% p = 0.9
30 Day Stroke: Bioprosthetic 5%   Mechanical 6% p=0.2

Freedom from Redo AVR in Bio vs. Mech in propensity matched patients

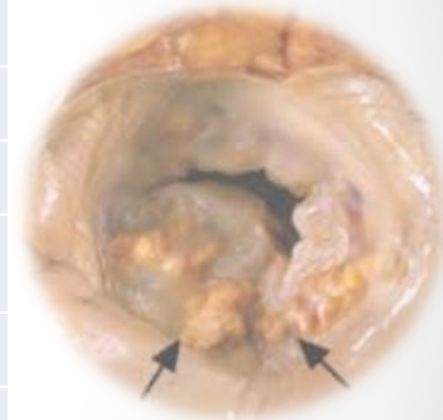*note y-axis range from 0.90 – 1.0

*competing risk of death

AVR Cox Long-term Survival Model

|	Hazard Ratio	95% CI		Pr > ChiSq
Male	0.918	0.859	0.981	0.0118
White	1.111	1.036	1.192	0.0033
Age	1.018	1.014	1.022	<.0001
CHF	1.232	1.152	1.319	<.0001
PVD	1.152	1.065	1.246	0.0004
Pulmonary Hypertension	1.114	1.027	1.207	0.0089
COPD	1.192	1.106	1.285	<.0001
Diabetes	1.131	1.059	1.208	0.0002
Liver Disease	1.362	1.174	1.581	<.0001
Anemia	0.901	0.843	0.963	0.0022
Hypertension	0.794	0.699	0.902	0.0004
Mechanical AVR	**0.934**	**0.876**	**0.995**	**0.0341**
CABG	1.122	1.045	1.205	0.0014
CAD	0.95	0.883	1.022	0.1692
Endocarditis	1.268	1.16	1.386	<.0001

Preoperative Characteristics of Propensity Matched Bio vs. Mech MVR

|	All MVR patients N=3492	Bioprosthetic MVR Patients N=1746	Mechanical MVR Patients N=1746	pval
Male	1685 (48%)	829 (48%)	856 (49%)	0.38
White	1985 (57%)	1027 (59%)	958 (55%)	0.02
CHF	2120 (61%)	1048 (60%)	1072 (61%)	0.43
Pulmonary Hypertension	951 (27%)	474 (27%)	477 (27%)	0.94
PVD	663 (19%)	344 (20%)	319 (18%)	0.3
COPD	953 (27%)	499 (29%)	454 (26%)	0.09
Diabetes	1644 (47%)	810 (46%)	834 (48%)	0.44
Renal Failure	3381 (97%)	1688 (97%)	1693 (97%)	0.7
Liver Disease	177 (5%)	104 (6%)	73 (4%)	0.02
Anemia	2027 (58%)	1016 (58%)	1011 (58%)	0.89
Hypertension	3260 (93%)	1626 (93%)	1634 (94%)	0.63

Kaplan Meier Survival for Bio vs. Mech MVR Hemodialysis Patients
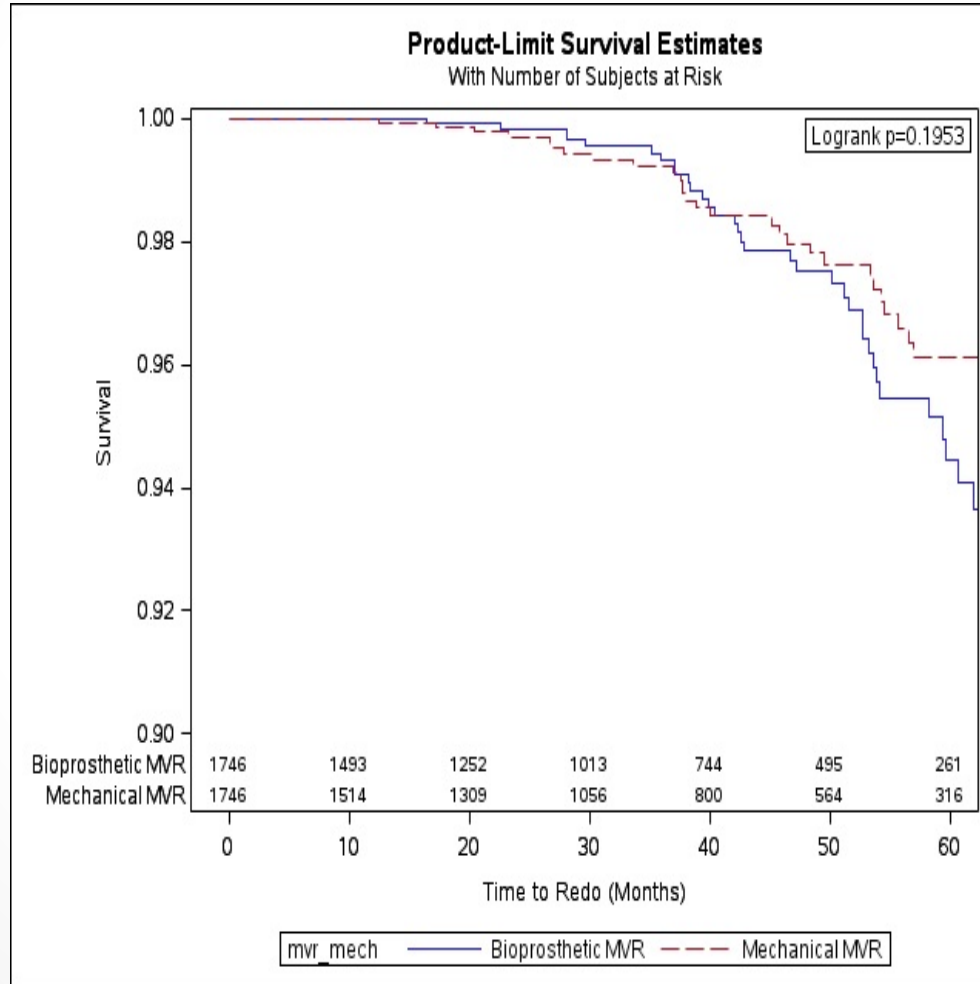
All MVR Bio vs. Mech Hemodialysis Patients
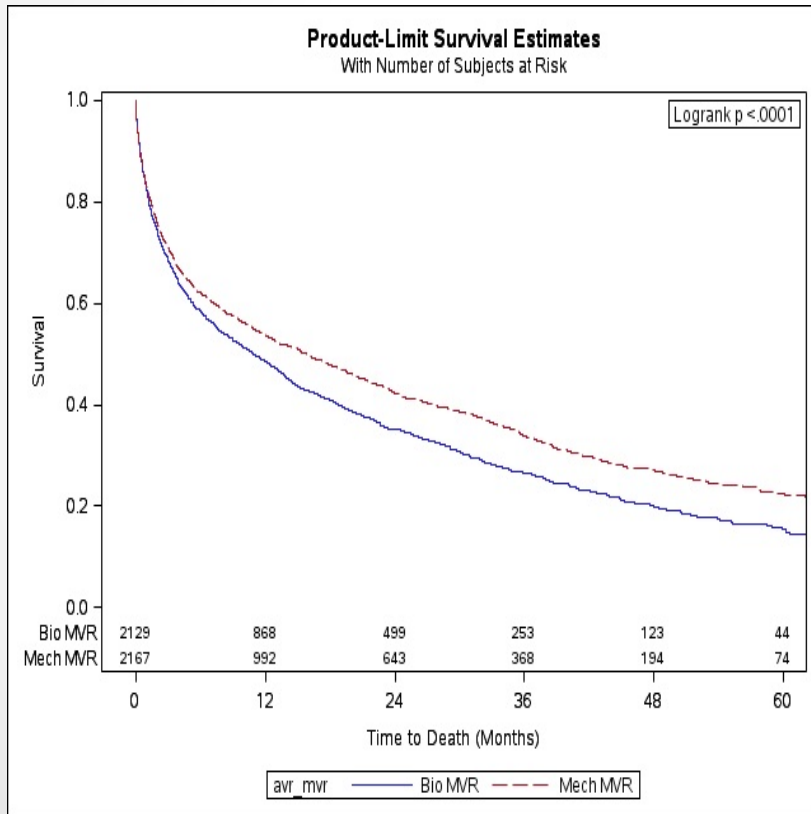
Propensity Matched Bio vs. Mech MVR Hemodialysis Patients
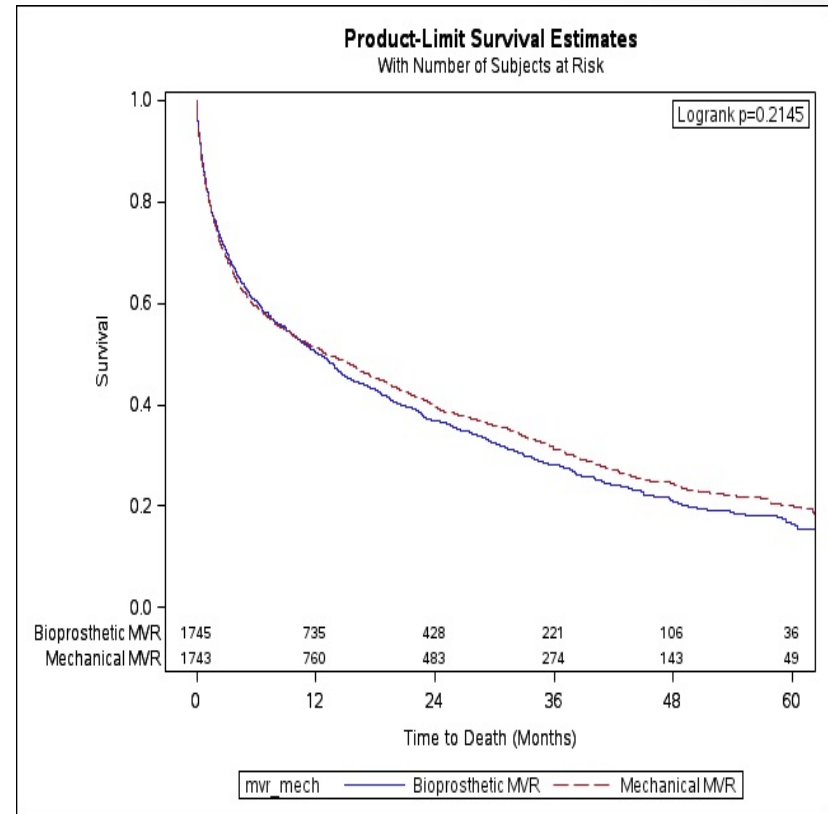
30 Day Mortality: Bioprosthetic 18%   Mechanical 17% p = 0.4
30 Day Stroke: Bioprosthetic 8.5%   Mechanical 8.6% p=0.7

Freedom from Redo MVR in Bio vs. Mech in propensity matched patients

*note y-axis range from 0.90 – 1.0

*competing risk of death

MVR Cox Long Term Survival Model

	Hazard Ratio	95% CI		P val
Male	1.05	0.966	1.142	0.2501
White	1.167	1.071	1.272	0.0004
Age	1.018	1.013	1.022	<.0001
CHF	1.071	0.978	1.171	0.1378
PVD	1.115	1.003	1.24	0.0448
Pulmonary Hypertension	1.047	0.95	1.153	0.3557
COPD	1.175	1.069	1.292	0.0008
Diabetes	1.107	1.016	1.207	0.0208
Liver Disease	1.152	0.955	1.391	0.1397
Anemia	0.887	0.813	0.968	0.0072
Hypertension	0.841	0.714	0.992	0.0397
Mechanical MVR	**0.965**	**0.889**	**1.047**	**0.3894**
CABG	1.122	1.02	1.234	0.0179
CAD	0.987	0.899	1.083	0.7763
Endocarditis	1.35	1.228	1.485	<.0001

Survival in Dialysis Patients
TAVR vs. SAVR
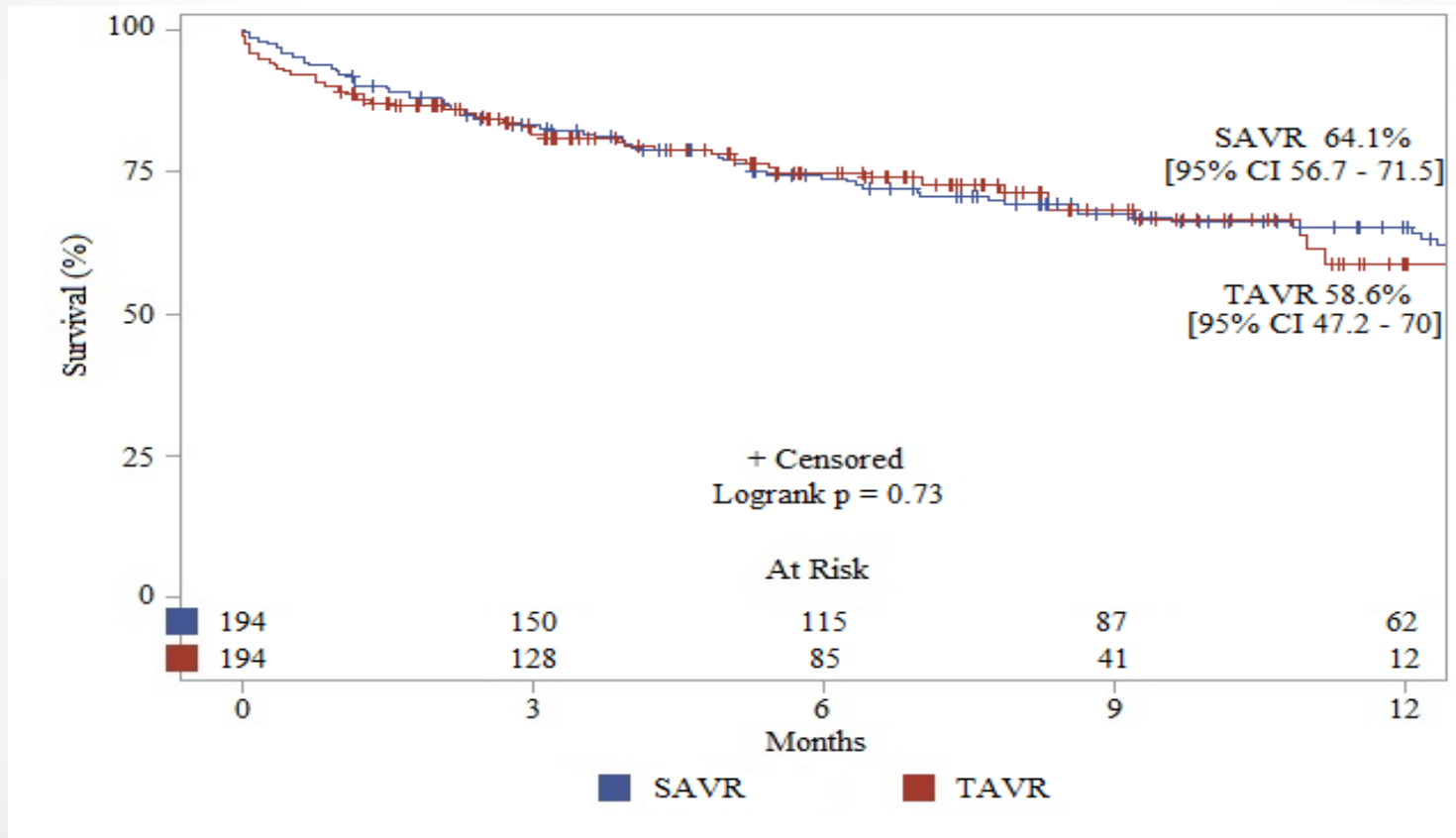
STS 2015, Kobrin, Desai ATS 2016

Conclusions

- There is no significant difference in survival or redo operation between bioprosthetic and mechanical valves in MVR patients

- Bioprosthetic valve AVR patients are significantly more at risk for death or redo operations

- Mechanical AVR offers a long-term survival benefit to patients on hemodialysis undergoing valve replacement surgery.