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Outcomes of Bovine versus Porcine Surgical Aortic Valve Replacement

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Abstract

Introduction: There are no guidelines regarding the use of bovine pericardial or porcine valves for aortic valve replacement, and prior studies have yielded conflicting results. The current study sought to compare short- and long-term outcomes in propensity-matched cohorts of patients undergoing isolated AVR with bovine versus porcine valves. *Methods:* This was a retrospective study utilizing an institutional database of all isolated bioprosthetic surgical aortic valve replacements performed at our center from 2010 to 2020. Patients were stratified according to type of bioprosthetic valve (bovine pericardial or porcine), and 1:1 propensity-score matching was applied. Kaplan-Meier survival estimation and multivariable Cox regression for mortality were performed. Cumulative incidence functions were generated for all-cause readmissions and aortic valve reinterventions. *Results:* A total of 1,502 patients were identified, 1,090 (72.6%) of whom received a bovine prosthesis and 412 (27.4%) of whom received a porcine prosthesis. Propensity-score matching resulted in 412 risk-adjusted pairs. There were no significant differences in clinical or echocardiographic postoperative outcomes in the matched cohorts. Kaplan-Meier survival estimates were comparable, and, on multivariable Cox regression, valve type was not significantly associated with long-term mortality (HR 1.02, 95% CI: 0.74, 1.40, p=0.924). Additionally, there were no significant differences in competing-risk cumulative incidence estimates for all-cause readmissions (p=0.68) or aortic valve reinterventions (p=0.25) in the matched cohorts. *Conclusion:* The use of either bovine or porcine bioprosthetic aortic valves yields comparable postoperative outcomes, long-term survival, freedom from reintervention, and freedom from readmission.

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ABSTRACT

Introduction: There are no guidelines regarding the use of bovine pericardial or porcine valves for aortic valve replacement, and prior studies have yielded conflicting results. The current study sought to compare short- and long-term outcomes in propensity-matched cohorts of patients undergoing isolated AVR with bovine versus porcine valves.

Methods: This was a retrospective study utilizing an institutional database of all isolated bioprosthetic surgical aortic valve replacements performed at our center from 2010 to 2020. Patients were stratified according to type of bioprosthetic valve (bovine pericardial or porcine), and 1:1 propensity-score matching was applied. Kaplan-Meier survival estimation and multivariable Cox regression for mortality were performed. Cumulative incidence functions were generated for all-cause readmissions and aortic valve reinterventions.

Results: A total of 1,502 patients were identified, 1,090 (72.6%) of whom received a bovine prosthesis and 412 (27.4%) of whom received a porcine prosthesis. Propensity-score matching resulted in 412 risk-adjusted pairs. There were no significant differences in clinical or echocardiographic postoperative outcomes in the matched cohorts. Kaplan-Meier survival estimates were comparable, and, on multivariable Cox regression, valve type was not significantly associated with long-term mortality (HR 1.02, 95% CI: 0.74, 1.40, p=0.924). Additionally, there were no significant differences in competing-risk cumulative incidence estimates for all-cause readmissions (p=0.68) or aortic valve reinterventions (p=0.25) in the matched cohorts.

Conclusion: The use of either bovine or porcine bioprosthetic aortic valves yields comparable postoperative outcomes, long-term survival, freedom from reintervention, and freedom from readmission.

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Keywords: bovine pericardial, porcine, bioprosthetic, aortic valve

Highlights:

- Postoperative clinical and echocardiographic outcomes are similar with bovine and porcine aortic valves
- Long-term survival after aortic valve replacement does not differ between bovine and porcine valve use

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- All-cause readmission and aortic valve reintervention rates after aortic valve replacement do not differ between bovine and porcine valve use

INTRODUCTION

Aortic valve replacement (AVR) continues to be the mainstay of therapy for severe valvular disease, and surgeons remain faced with a wide array of prosthetic valve options. Broadly, prosthetic valve types can be subdivided into mechanical or bioprosthetic, with bioprosthetic valves being further subdivided into stented and stentless valves. With the advantages of avoiding anticoagulation and the option of future valve-in-valve transcatheter aortic valve replacement (TAVR), bioprosthetic valve use has been increasingly favored over mechanical valve use in the elderly and middle-aged populations.[1,2] While there are guidelines regarding the use of bioprosthetic versus mechanical aortic valves in certain patient populations, there is no consensus on the use of bovine pericardial versus porcine bioprosthetic valves.[3] As such, the choice of bioprosthetic valve type continues to be left to surgeon preference. Recent studies suggest that bovine valves are used more commonly than porcine valves, comprising roughly two thirds of all bioprosthetic AVRs.[4,5,6]

Prior studies comparing bovine and porcine valves in the aortic position have had conflicting results, with some studies demonstrating differences in survival and reintervention rates, and other studies showing no differences between the two valve types. Due to the lack of consensus and inconsistent findings in the available literature, we performed a propensity-matched study of patients at our center who underwent isolated aortic valve replacement with either a bovine or a porcine valve. This study sought to evaluate the specific impact of valve type on both short-term and long-term outcomes.

METHODS

This was a retrospective, observational study utilizing a prospectively maintained institutional database. All isolated bioprosthetic surgical aortic valve replacements (SAVRs), performed at our center using either a bovine or porcine valve, from 2010 to 2020 were included. Patients who underwent mechanical aortic valve replacement (AVR) were excluded. Patients with a history of prior AVR were also excluded, as were patients who underwent concomitant operations such as coronary artery bypass grafting (CABG) or mitral valve repair/replacement. Definitions and terminology were consistent with the Society of Thoracic Surgeons (STS) database. This study was approved by the Institutional Review Board of the University of Pittsburgh on 4/17/2019 (STUDY18120143), with written consent being waived.

The primary aim of the study was to compare long-term survival between patients who underwent SAVR using a bovine versus porcine bioprosthetic valve. Secondary outcomes of interest included postoperative clinical outcomes, echocardiographic data, all-cause readmission rates, and aortic valve reintervention rates. Follow-up data was obtained from the clinical warehouse that contains all long-term survival data for patients undergoing cardiac surgery at the University of Pittsburgh Medical Center. Vital status data from the clinical warehouse was cross-referenced with the Social Security Death Index.

Primary stratification was between the bovine valve group and the porcine valve group. Continuous variables were presented as mean $\pm$ standard deviation for normally distributed data, or median and interquartile range (IQR) for non-normally distributed data. Categorical data were reported by frequency and percentage. Normally distributed continuous variables were analyzed using the student's t-test, while non-normally distributed continuous variables were analyzed with the nonparametric Mann-Whitney U test. The Chi-squared or Fisher's exact test was used to compare categorical variables between groups, as appropriate. A 1:1 propensity-score matched analysis was performed using greedy nearest-neighbor matching, incorporating baseline characteristics. The quality of the match was determined by standardized mean differences (SMD), with <0.1 considered indicative of an adequate balance.[7] Postoperative outcomes in the matched cohorts were compared. Survival estimates were generated using Kaplan-Meier methods and compared between the two matched cohorts using log-rank statistics. Stratified Cox proportional hazards regression was used for the multivariable analysis of mortality in propensity-matched pairs. Cumulative incidence functions were calculated for all-cause readmissions and for aortic valve reinterventions. Death was treated as a competing risk for both readmissions and reinterventions. All statistical analyses were performed using either STATA,

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version 16.1 (Stata Corporation, College Station, TX) or R programming language version 4.1.0 (R Foundation for Statistical Computing, Vienna, Austria). All tests were 2-sided with an alpha level of 0.05 designated to indicate statistical significance.

RESULTS

A total of 1,502 patients who underwent isolated surgical aortic valve replacement with a bioprosthetic valve were identified, 1,090 (72.6%) of whom received a bovine prosthesis and 412 (27.4%) of whom received a porcine prosthesis. Patients who received bovine valves were significantly more likely to have chronic lung disease and peripheral vascular disease when compared to patients who received porcine valves (Table 1). Those who received bovine valves also had significantly higher STS Predicted Risk of Mortality scores than those who received porcine valves. Rate of elective vs urgent vs emergent surgical status differed significantly between the two groups. Implanted valve size was significantly smaller in the bovine group than in the porcine group.

To account for differences in baseline and operative characteristics, propensity score matching was utilized to create similar groups. Matching yielded 412 risk-adjusted pairs, with an adequate balance indicated by SMDs <0.1 for 23 out of the 24 variables that were matched on (Table 2).

Postoperative outcomes of the matched study population are reported in Table 3. There were no significant differences in operative mortality, length of stay, blood product transfusion, reoperation for bleeding, duration of intubation, pneumonia, stroke, renal failure requiring dialysis, 30-day readmission rates, or aortic valve reintervention rates in the matched cohorts (p>0.05). The mean interval from surgery to the time of postoperative echocardiogram was 0.69±1.47 years in the bovine group and 0.58±1.33 years in the porcine group. There were no significant differences in postoperative mean aortic valve gradient or ejection fraction in the matched cohorts.

Kaplan–Meier estimates demonstrated comparable survival in propensity-matched cohorts of patients who received bovine versus porcine aortic valves (Figure 1, p=0.99, log-rank). On multivariable Cox proportional-hazards regression, valve type was not significantly associated with long-term mortality (HR 1.02, 95% CI: 0.74, 1.40, p=0.924, Table 4). Variables which were significantly associated with long-term mortality after bioprosthetic SAVR included age, chronic dialysis, history of cerebrovascular accident, prior cardiovascular intervention, atrial fibrillation, and urgent surgical status (Table 4).

There were no significant differences in competing-risk cumulative incidence estimates for all-cause readmissions (p=0.68, Figure 2) or aortic valve reinterventions (p=0.25, Figure 3) in the matched cohorts.

DISCUSSION

This single-center propensity-matched study of over 1,500 isolated bioprosthetic surgical aortic valve replacements demonstrates comparable short-term and long-term outcomes of bovine and porcine prostheses. There were no significant differences in postoperative clinical outcomes, echocardiographic data, readmission rates, reintervention rates, or long-term survival between the propensity-matched groups.

Notable differences between bovine and porcine valves have been hitherto established. Importantly, we know that the mode of structural valve deterioration (SVD) differs between these two valve types; porcine valves tend to fail via leaflet tears, while bovine pericardial valves tend to degenerate via fibrosis/calcification.[8]Interestingly, despite these respective modes of SVD, previous prospective and/or randomized studies have demonstrated higher transprosthetic gradients for porcine valves, with smaller indexed effective orifice areas (despite larger implanted valve sizes) when compared to bovine prostheses.[9,10,11] Bovine valves have been found to have more favorable hemodynamics in general across the majority of these studies. Our study, on the other hand, found comparable gradients between the two xenograft materials, though this finding may not have persisted at 5 or 10 years.

How bovine and porcine valves compare with one another regarding short-term and long-term clinical outcomes remains unclear. In an effort to answer these questions, several comparative studies have been performed to-date, though most have included concomitant operations and have not accounted for differences in baseline characteristics with propensity matching. Moreover, data from these studies have yielded conflicting results.

One such study, involving roughly 13,000 patients in Sweden, found a long-term survival benefit with porcine prostheses, though with a higher need for reoperation when compared to bovine prostheses.[6] A study of almost 40,000 patients in England and Wales demonstrated no difference in long-term survival or need for reintervention among patients who received bovine or porcine aortic valves, as did another study from Duke.[4,12]Importantly, all of these studies included patients who received concomitant CABG, and none of them utilized propensity matching to account for baseline differences. A recent meta-analysis of studies published from 2010-2015 also demonstrated no difference in long-term survival in patients who underwent AVR with a bovine or porcine prosthesis, though these studies also included patients who underwent concomitant operations and did not match on baseline characteristics.[13] Our study, which included only isolated AVRs and which incorporated propensity matching to adjust for confounders, may help to clarify and adjudicate prior findings.

As valve-in-valve TAVR becomes more popular, suitability for this subsequent intervention, should it be necessary, also becomes an important consideration when choosing a surgical prosthesis. Prior studies have not found specific differences in feasibility or outcomes of valve-in-valve TAVR according to use of bovine or porcine surgical valves, though it has been demonstrated that residual stenosis following valve-in-valve TAVR is more common with surgical valves that have an inner diameter of < 20 mm.[14] Thus, it is not so much the type of surgical valve, but rather the size of the implanted valve, that seems to carry the most importance.

Another important question that has been investigated is the comparison between stented and stentless bioprosthetic aortic valves.[15,16,17,18] A randomized controlled trial was performed to compare clinical outcomes and hemodynamic performance between these two valve types. In comparison to stented prostheses, this trial found stentless valves to have greater effective orifice areas, as well as greater improvement in postoperative left ventricular function when used in patients with small annuli or left ventricular dysfunction.[19] A recent meta-analysis has adjudicated this finding of superior short-term hemodynamic outcomes with stentless valves in patients who have small annuli.[20]

Outcomes of valve-in-valve TAVR following stented versus stentless prostheses have also been investigated. In a study using the Valve-in-Valve International Data registry, stentless valve-in-valve TAVR was associated with more periprocedural complications such as device malposition, coronary obstruction, and paravalvular leak.[21] Thus, while long-term outcomes of stented versus stentless AVR appear to be comparable, and stentless valves confer better hemodynamics in patients with small annuli, these valves may also complicate the performance of future valve-in-valve TAVR.

This study is inherently limited by its retrospective, observational design. Moreover, multiple valve types were included, and the performance of a particular valve model could have impacted outcomes. We did not include data on indexed effective orifice area; however, we matched on implanted aortic valve size to adjust for this potential confounder. Serial, longitudinal echocardiographic data at set time-points was not available but would have been very useful in evaluating changes in hemodynamic performance of these two valves over time. The study also incorporated longitudinal data with varying follow-up times, with some patients being lost to follow-up. Finally, the data is from a single high-volume center, which may limit generalizability of the findings.

The use of either bovine or porcine bioprosthetic aortic valves yields comparable postoperative outcomes, long-term survival, freedom from reintervention, and freedom from readmission.

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Variable	**Bovine valve (n=1090)**	**Porcine valve (n=412)**	**p value**
Age (years)	70.81 ± 11.11	71.21 ± 9.71	0.519
Sex (female)	452 (41.5%)	156 (37.9%)	0.226
Race Caucasian African American Other	1,056 (96.9%) 27 (2.5%) 7 (0.6%)	391 (94.9%) 12 (2.9%) 9 (2.2%)	0.030
Body mass index (kg/m^2)	29.65 ± 6.23	29.59 ± 6.09	0.855
Diabetes mellitus	369 (33.9%)	125 (30.3%)	0.218
Dyslipidemia	806 (73.9%)	312 (75.7%)	0.522
Hypertension	910 (83.5%)	350 (85.0%)	0.542
Preoperative creatinine	1.10 ± 0.78	1.07 ± 0.38	0.564
Chronic dialysis	18 (1.7%)	3 (0.7%)	0.266
Chronic lung disease	263 (24.1%)	71 (17.2%)	0.005
Peripheral vascular disease	189 (17.3%)	50 (12.1%)	0.017
Cerebrovascular disease	207 (19.0%)	74 (18.0%)	0.702
Family history of coronary artery disease	154 (14.1%)	46 (11.2%)	0.155
Ejection fraction	56.07 ± 10.66	56.45 ± 10.53	0.537
Immunosuppression	73 (6.7%)	29 (7.0%)	0.905
Smoking history	153 (14.0%)	50 (12.1%)	0.381
Atrial fibrillation	192 (17.6%)	89 (21.6%)	0.090
Prior myocardial infarction	180 (16.5%)	63 (15.3%)	0.620
Prior cerebrovascular accident	70 (6.4%)	36 (8.7%)	0.147
Prior cardiovascular intervention	286 (26.2%)	106 (25.7%)	0.893
Prior percutaneous coronary intervention	148 (13.6%)	53 (12.9%)	0.781
STS predicted risk of mortality score	3.00 ± 4.00	2.00 ± 2.00	<0.001

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Variable	Bovine valve (n=1090)	Porcine valve (n=412)	p value
Status Elective Urgent Emergent/salvage	824 (75.6%) 258 (23.7%) 8 (0.7%)	323 (78.4%) 79 (19.2%) 10 (2.4%)	0.006
Cardiopulmonary bypass time (min)	100.00 ± 36.65	100.64 ± 47.85	0.783
Aortic cross clamp time (min)	76.65 ± 28.77	75.42 ±33.69	0.478
Implanted aortic valve size	23.61 ± 2.32	25.07 ± 2.52	<0.001

Table 1. Baseline and Operative characteristics in the entire cohort

Table 2. Baseline and Operative Characteristics in propensity-matched pairs

Variable	Bovine valve (n=412)	Porcine valve (n=412)	SMD
Age (years)	71.77 ± 10.00	71.21 ± 9.71	0.057
Sex (female)	159 (38.6%)	156 (37.9%)	0.015
Race Caucasian African American Other	394 (95.6%) 13 (3.2%) 5 (1.2%)	391 (94.9%) 12 (2.9%) 9 (2.2%)	0.076
Body mass index (kg/m^2)	29.49 ± 5.78	29.59 ± 6.09	0.017
Diabetes mellitus	121 (29.4%)	125 (30.3%)	0.021
Dyslipidemia	319 (77.4%)	312 (75.7%)	0.040
Chronic dialysis	3 (0.7%)	3 (0.7%)	<0.001
Hypertension	360 (87.4%)	350 (85.0%)	0.070
Smoking history	47 (11.4%)	50 (12.1%)	0.023
Chronic lung disease	80 (19.4%)	71 (17.2%)	0.056
Immunosuppression	27 (6.6%)	29 (7.0%)	0.019
Preoperative creatinine	1.05 ± 0.64	1.07 ± 0.38	0.046
Peripheral vascular disease	59 (14.3%)	50 (12.1%)	0.065
Cerebrovascular disease	74 (18.0%)	74 (18.0%)	<0.001
Family history of coronary artery disease	44 (10.7%)	46 (11.2%)	0.016
Prior cerebrovascular accident	30 (7.3%)	36 (8.7%)	0.054
Prior cardiovascular intervention	113 (27.4%)	106 (25.7%)	0.038
Prior percutaneous coronary intervention	56 (13.6%)	53 (12.9%)	0.021
Ejection fraction	56.03 ± 10.20	56.45 ± 10.53	0.040
Atrial fibrillation	81 (19.7%)	89 (21.6%)	0.048
Prior myocardial infarction	64 (15.5%)	63 (15.3%)	0.007
Status Elective Urgent Emergent/salvage	323 (78.4%) 86 (20.9%) 3 (0.7%)	323 (78.4%) 79 (19.2%) 10 (2.4%)	0.141
STS predicted risk of mortality score	2.00 ± 2.00	2.00 ± 2.00	0.039

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Variable	Bovine valve (n=412)	Porcine valve (n=412)	SMD
Implanted aortic valve size	24.85 ± 2.31	25.07 ± 2.52	0.090

SMD = standardized mean difference

Table 3. Postoperative outcomes in propensity-matched cohorts

Variable	Bovine valve (n=412)	Porcine valve (n=412)	p value
Operative mortality	7 (1.7%)	4 (1.0%)	0.544
Length of stay (days)	7.44 ± 4.62	7.11 ± 4.36	0.303
Blood product transfusion	128 (31.1%)	112 (27.2%)	0.250
Reoperation for bleeding	10 (2.4%)	17 (4.1%)	0.240
Duration of intubation (hours)	15.28 ± 59.09	14.69 ± 45.59	0.871
Prolonged ventilation > 24 hours	27 (6.6%)	30 (7.3%)	0.784
Pneumonia	5 (1.2%)	10 (2.4%)	0.297
Stroke	6 (1.5%)	6 (1.5%)	1.000
Renal failure requiring dialysis	7 (1.7%)	6 (1.5%)	1.000
30-day readmission	24 (5.8%)	16 (3.9%)	0.257
Mean aortic valve gradient (mmHg)	9.39 ± 5.24	9.31 ± 5.59	0.828
Ejection fraction	56.80 ± 7.18	56.78 ± 7.82	0.972
Aortic valve reintervention	17 (4.1%)	10 (2.4%)	0.240

Table 4. Cox Proportional Hazards Regression for Long-term Mortality in propensity-matched cohorts

Variable	Hazard Ratio	95% CI	p-value
Porcine (ref: Bovine)	1.02	0.74, 1.40	0.924
Age (years)	1.04	1.02, 1.05	<0.001
Female sex (ref: male)	1.24	0.84, 1.80	0.280
Diabetes	1.32	0.94, 1.85	0.109
Dyslipidemia	0.73	0.51, 1.07	0.093
Chronic dialysis	3.51	1.19, 10.30	0.023
Smoking history	1.55	0.92, 2.68	0.103
Chronic lung disease	1.40	0.97, 2.02	0.074
Peripheral vascular disease	1.35	0.92, 1.98	0.128
Prior cerebrovascular accident	1.89	1.20, 2.97	0.006
Prior cardiovascular intervention	1.54	1.09, 2.15	0.014
Atrial fibrillation	1.72	1.21, 2.46	0.003
Status (ref: elective) Urgent Emergent/salvage	1.78 1.01	1.27, 2.50 0.24, 4.25	<0.001 0.989
Implanted aortic valve size	0.97	0.89, 1.00	0.385

***C-index: 0.71**

Figure 1. Kaplan-Meier Survival curves in propensity-matched cohorts

Figure 2. Cumulative Incidence Function for All-cause Readmissions in propensity-matched cohorts

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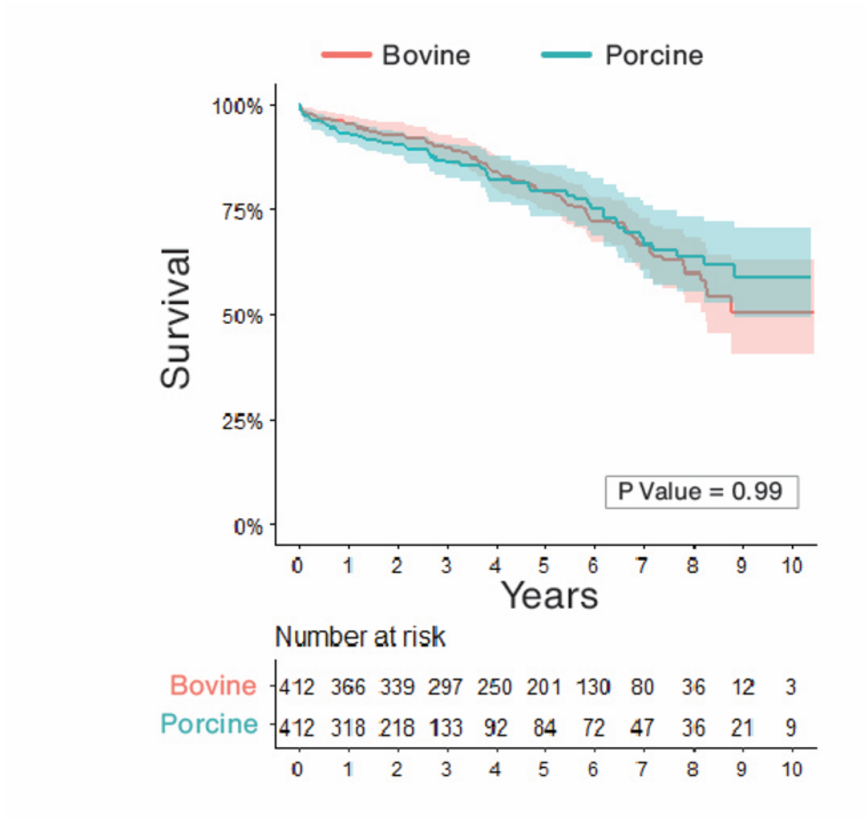
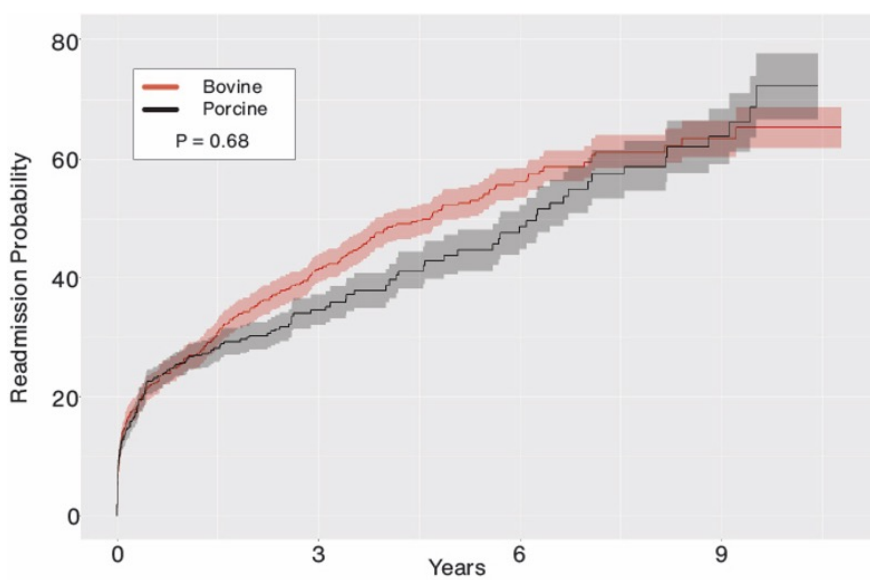
Figure 3. Cumulative Incidence Function for Aortic Valve Reintervention in propensity-matched cohorts





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