Prevalence and Outcomes of Isolated Tricuspid Valve Surgery Among Medicare Beneficiaries

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We sought to characterize the clinical outcomes and to identify predictors of mortality undergoing isolated tricuspid valve surgery in the United States. We identified 5,164 patients undergoing isolated tricuspid valve surgery from the Centers for Medicare and Medicaid Services Medicare Provider Analysis and Review data between January 2003 and December 2014. The primary outcome was all cause 1-year mortality. A backward elimination method was performed to identify predictors of 1-year mortality. Tricuspid valve repair was performed in 2,494 (48.3%) patients and tricuspid valve replacement was performed in 2,670 (51.7%) patients. Perioperative and 1-year mortality rates were 9.9% and 24.1%, respectively. Predictors of 1-year mortality were age ($p < 0.001$), chronic heart failure ($p = 0.001$, cirrhosis ($p < 0.001$), carcinoid syndrome ($p < 0.001$), chronic kidney disease ($p = 0.001$), secondary pulmonary hypertension ($p = 0.023$), endocarditis ($p = 0.005$), decubitus ulcer ($p < 0.001$), malnutrition ($p < 0.001$), replacement ($p = 0.013$), emergency procedure ($p < 0.001$), and preprocedural shock ($p < 0.001$). The C-statistic for 1-year mortality was 0.70 (95% confidence interval, 0.67 to 0.73). In conclusion, isolated tricuspid valve surgery is infrequently performed in the United States, and is associated with high 1-year mortality. Patients at higher risk for mortality can be identified based on the presence of a number of comorbidities at the time of surgery. **(Am J Cardiol 2019;123:132−138)**

Moderate or severe tricuspid regurgitation may affect over one million patients in the United States,[1,2] and is a common condition in patients with left sided heart valve disease, particularly those with right heart dysfunction and dilation.[1] Tricuspid regurgitation is primary due to functional annular dilation and distortion of leaflet coaptation,[3] but may also occur from leaflet distortion following pacemaker or implantable defibrillator placement.[4] Severe tricuspid regurgitation is associated with an untoward prognosis[5,6] and is manifest by signs of right heart failure such as edema, liver congestion, and renal venous congestion.[7] Medical therapy for tricuspid regurgitation remains the mainstay of therapy in patients with tricuspid regurgitation,[8] but is limited in altering prognosis or improving symptom status in many cases.[1,9] Current guidelines recommend tricuspid repair or replacement in patients with tricuspid annular dilation and significant regurgitation who are undergoing left heart surgery.[1,10] These guidelines have provided limited recommendations for the management of patients with isolated tricuspid regurgitation, likely owing to the uncertain prognosis of surgery in these patients.[10] Single center reports following isolated tricuspid valve surgery have provided variable operative mortality rates, and only a few have provided comprehensive insight into the predictors of late mortality.[11−17] The objectives of this analysis are to characterize the clinical outcomes and to identify predictors of mortality undergoing isolated tricuspid valve surgery in the United States from the Centers for Medicare and Medicaid Services (CMS) Medicare Provider Analysis and Review (MedPAR) data.

Methods

The MedPAR files include administrative billing claims for all hospitalizations of Medicare fee-for-service beneficiaries, and have been used to study national patterns of procedure utilization in the United States.[18] After exclusion of other concomitant valve and coronary artery bypass graft surgeries (Supplementary Table 1), we identified 5,164 patients from 841 US sites undergoing tricuspid valve surgery with a procedure code "3504, 3514, 3527, and 3528" from MedPAR files between January 2003 and December 2014.

The primary outcome was all-cause 1-year mortality. It was determined through linkage of the MedPAR files to the CMS denominator file which includes information on a patient's vital status. Time to death was calculated as the

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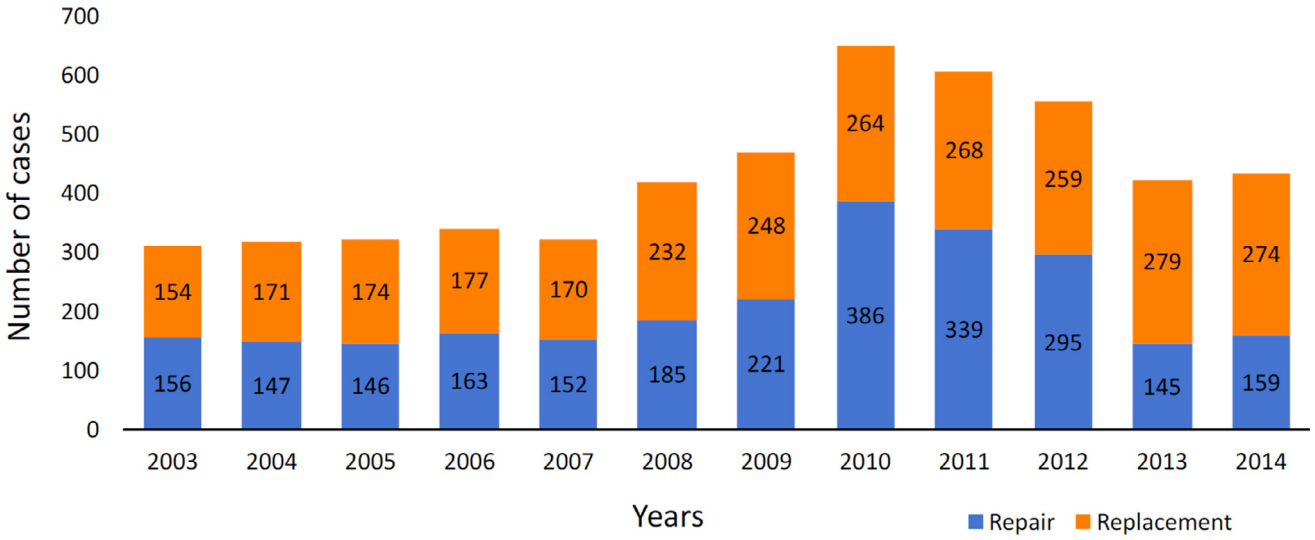

Figure 1. Number of tricuspid valve repair and replacement by year.

time between the procedure date and death date. A total of 33 variables were defined as possible risk factors for 1-year mortality after isolated tricuspid valve surgery, and corresponding ICD-9 diagnosis codes were used to identify these variables in the dataset (Supplementary Table 1). We collected operative adverse events including stroke, major bleeding, wound infection, sepsis, mechanical complications, pulmonary thromboembolism, acute renal failure, shock, and operative mortality, using the procedure date, discharge date, and ICD-9 complications codes (Supplementary Table 1). The distribution of the number of patients undergoing tricuspid repair or replacement and number of cases according to hospitals were plotted using bar graphs.

Analysis cohort and prediction model

A backward elimination method was performed to identify predictors of 1-year mortality and a model was constructed using the frailty model that incorporates random hospital effects. The significance level thresholds for entry and exit of independent variables were set at $p = 0.05$. After development of the model, Harrell's C-statistics were used to assess the capability of model to predict 1-year mortality in the entire cohort. Kaplan-Meier plots were also used to construct survival curves for the time-to-death analysis and then stratified based on repair, mechanical replacement or biologic replacement.

Continuous variables were presented as means with standard deviations (SD) and categorical variables were presented as counts and percentages. p Values < 0.05 were considered significant. All statistical analyses were performed in STATA software version 15.0 (Stata Corporation, College Station, TX).

Results

Between January 1, 2003 and December 31, 2014, 5,164 patients were treated with tricuspid valve surgery. The average number of cases performed per year was 433.3 (Figure 1), and 87.1% of hospitals performed 10 or fewer during the entire study period. In addition, only a few ($< 1\%$) surgical centers performed more than 5 isolated tricuspid valve surgeries per year (Figure 2).

Baseline characteristics of the patients are presented in Table 1. Mean age was 68.2 ± 12.8 years and were more frequently (58.3%) women. In additional to conventional

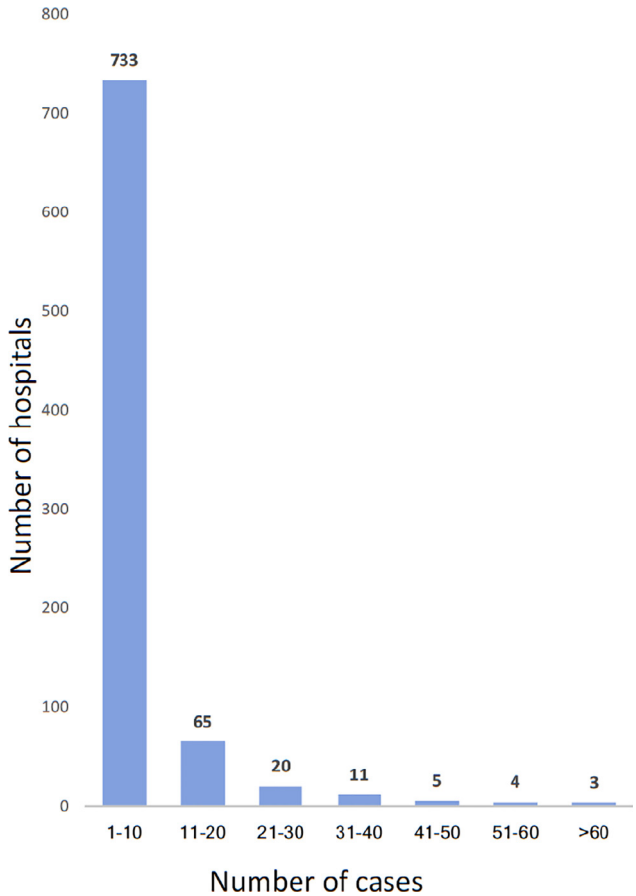

Figure 2. Number of cases by hospital.

Table 1
Baseline findings in patients undergoing tricuspid valve surgery

	Overall (n = 5,164)	Alive (n = 3,919)	One-year mortality (n = 1,245)	p Value
Age, mean (years)	68.2 ± 12.8	67.6 ± 13.0	69.8 ± 12.3	< 0.001
Men	2,151 (41.7%)	1,589 (40.5%)	562 (45.1%)	0.004
Chronic heart failure	2,387 (46.2%)	1,700 (43.4%)	687 (55.2%)	< 0.001
Prior stroke	62 (1.2%)	45 (1.1%)	17 (1.4%)	0.54
Prior coronary artery bypass graft surgery	229 (4.4%)	182 (4.6%)	47 (3.8%)	0.19
Hypertension	2,180 (42.2%)	1,758 (44.9%)	422 (33.9%)	< 0.001
Diabetes mellitus	905 (17.3%)	730 (18.6%)	175 (14.1%)	< 0.001
Prior myocardial infarction	366 (7.1%)	259 (6.6%)	107 (8.6%)	0.017
Peripheral vascular disease	356 (6.9%)	267 (6.8%)	89 (7.1%)	0.68
Atrial fibrillation	2,498 (48.4%)	1,991 (50.8%)	507 (40.7%)	< 0.001
Prior aortic surgery	50 (1.0%)	44 (1.1%)	6 (0.5%)	0.044
Infective endocarditis	479 (9.3%)	333 (8.5%)	146 (11.7%)	< 0.001
Prior valvular surgery	389 (7.5%)	312 (8.0%)	77 (6.2%)	0.039
Pacemaker	386 (7.5%)	305 (7.8%)	81 (6.5%)	0.14
Chronic obstructive pulmonary disease	749 (14.5%)	574 (14.6%)	175 (14.1%)	0.61
Secondary pulmonary hypertension	849 (16.4%)	654 (16.7%)	195 (15.7%)	0.40
Primary pulmonary hypertension	31 (0.6%)	23 (0.6%)	8 (0.6%)	0.82
Home O_2	47 (0.9%)	32 (0.8%)	15 (1.2%)	0.21
Chronic kidney disease	1,220 (23.6%)	821 (20.9%)	399 (32.0%)	< 0.001
Cirrhosis	328 (6.4%)	171 (4.4%)	157 (12.6%)	< 0.001
Carcinoid syndrome	59 (1.4%)	35 (0.9%)	24 (1.9%)	0.003
Anemia*	703 (13.6%)	556 (14.2%)	147 (11.8%)	0.033
Malnutrition	341 (6.6%)	167 (4.3%)	174 (14.0%)	< 0.001
Decubitus ulcer	150 (2.9%)	78 (2.0%)	72 (5.8%)	< 0.001
Difficulty in walking	16 (0.3%)	13 (0.3%)	3 (0.2%)	0.62
Depression	45 (0.9%)	33 (0.8%)	12 (1.0%)	0.69
Coagulopathy	859 (16.6%)	594 (15.2%)	265 (21.3%)	< 0.001

* Iron, other deficiency, and unspecified anemia.

cardiology risk factors including chronic heart failure (46.2%), hypertension (42.2%), and atrial fibrillation (48.4%), patients had chronic kidney disease (23.6%), cirrhosis (6.4%), malnutrition (6.6%), and decubitus ulcers (2.9%).

Tricuspid valve repair was performed in 2,494 (48.3%) patients and tricuspid valve replacement was performed in 2,670 (51.7%) patient**s.** A mechanical heart valve was used in 933 (34.9%) of patients undergoing replacement. Periprocedural findings and hospital course in patients undergoing tricuspid valve repair and replacement group are shown in Table 2. Tricuspid valve replacement was associated with longer intensive care unit days ($p < 0.001$), longer hospitalization days ($p < 0.001$), and higher hospital charges ($p < 0.001$). Perioperative adverse events in patients undergoing tricuspid valve replacement and repair are found in Table 3. Major bleeding, mechanical complications, and postoperative renal failure ($p < 0.001$) occurred more often in patients undergoing tricuspid valve replacement compared with those undergoing tricuspid valve repair.

Overall mortality was 9.9% in the perioperative period, and 24,1% at 1-year (Table 3). Multivariable predictors of 1-year mortality are found in Table 4. The strongest predictors of 1-year mortality included older age ($p < 0.001$), chronic heart failure ($p = 0.001$, cirrhosis ($p < 0.001$), carcinoid syndrome ($p < 0.001$), chronic kidney disease ($p = 0.001$), decubitus ulcer ($p < 0.001$), malnutrition ($p < 0.001$), emergency procedure ($p < 0.001$), and preprocedural shock ($p < 0.001$). Discrimination (C-statistics) for 1-year mortality of the model with an area under the curve

Table 2
Operative findings and hospital course

	Repair (n = 2,494)	Replacement (n = 2,670)	p Value
Nonrheumatic etiology	305 (12.2%)	400 (15.0%)	0.004
Mechanical replacement	-	933 (34.9%)	-
Preprocedural shock	211 (8.5%)	238 (8.9%)	0.56
Emergent procedure	470 (18.8%)	353 (13.2%)	< 0.001
With atrial septal defect repair	42 (1.7%)	14 (0.5%)	< 0.001
With ventricular septal defect repair	13 (0.5%)	10 (0.4%)	0.43
Intensive care unit stay (days)	8.15 ± 11.10	9.59 ± 13.70	< 0.001
Hospitalization (days)	15.60 ± 14.27	18.01 ± 18.72	< 0.001
Total all charges ($)	208,045 ± 198,793	248,267 ± 249,775	< 0.001

Table 3
Adverse events after isolated tricuspid valve surgery

	Overall (n = 5,164)	Repair (n = 2,494)	Replacement (n = 2,670)	p Value
Stroke	41 (0.8%)	24 (1.0%)	17 (0.6%)	0.19
Major bleeding	392 (7.6%)	157 (6.3%)	235 (8.6%)	< 0.001
Wound infection	43 (0.8%)	23 (0.9%)	20 (0.7%)	0.49
Sepsis	409 (7.9%)	206 (8.3%)	203 (7.6%)	0.38
Mechanical complications	93 (1.8%)	26 (1.0%)	67 (2.5%)	< 0.001
Pulmonary thromboembolism	107 (2.1%)	50 (2.0%)	57 (2.1%)	0.74
Acute renal failure	453 (8.8%)	184 (7.4%)	269 (10.1%)	< 0.001
Shock	100 (1.9%)	40 (1.6%)	60 (2.2%)	0.094
Mortality				
Operative	510 (9.9%)	249 (10.0%)	261 (9.8%)	0.80
1-year	1,245 (24.1%)	554 (22.2%)	691 (25.9%)	< 0.001

was 0.70 (95% confidence interval, 0.67 to 0.73). Kaplan-Meier plots based on repair, mechanical replacement or biologic replacement are shown in Figure 3. As shown in this figure there was no difference between mechanic and biologic replacement, however, repair was better than replacement ($p < 0.001$).

Discussion

Our study demonstrates that isolated tricuspid surgery was infrequently performed in the United States among Medicare fee-for-service beneficiaries over the past 10 years. Periprocedural complications after tricuspid valve surgery were acceptable given the overall health status of patients selected for surgery, albeit with more bleeding, acute renal injury, longer hospital stays, and higher 1-year mortality rates in patients undergoing tricuspid valve replacement than repair. Whereas the operative mortality was low (9.9%), the 1-year mortality rate of 24.1% was largely predicted by baseline co-morbid factors and disabling conditions.

Symptomatic tricuspid regurgitation is associated with a poor prognosis.[5,6] In an echocardiographic series of 5,223 patients, 1-year survival was 91.7% with no tricuspid regurgitation, 90.3% with mild tricuspid regurgitation, 78.9% with moderate tricuspid regurgitation, and 63.9%; severe tricuspid regurgitation, pulmonary hypertension, and left ventricular function were independent predictors of mortality.[5] In another series of 353 patients with isolated tricuspid regurgitation, severe isolated tricuspid regurgitation (adjusted hazard ratio: 1.78), and an effective regurgitant orifice (ERO) ≥ 40 mm^2 (adjusted hazard ratio: 2.67) were independently predictive of mortality.[6] The 10-year survival rate was lower with an ERO ≥ 40 mm^2 (38%) compared with an ERO < 40 mm^2 (70%; $p < 0.0001$). Cardiac surgery for severe isolated TR was rarely (16.5%) performed in this series, despite the relatively poor prognosis associated with medical therapy.[6]

Tricuspid valve surgery is most commonly performed in patients undergoing concomitant left-sided valve surgery, particularly in the settling of tricuspid annular dilation. Both tricuspid repair and replacement have been used for tricuspid surgery depending on the underlying pathology of the tricuspid valve.[13,14] A prior series evaluated 28,726 patients undergoing tricuspid valve repair or replacement captured in the National Inpatient Sample over 10 years ending in 2008[19]; isolated tricuspid valve surgery accounted for 20% of the total tricuspid patients.[19] The total number of tricuspid procedures more than doubled over the 10-year period ending in 2008, and relatively more repair than replacement was performed.[19] Overall hospital mortality was 10.6% and decreased over time.[19]

Our series documents the frequency of tricuspid surgery continued to peak among Medicare beneficiaries until 2010

Table 4
Predictors of 1-year mortality

	Hazard ratio (95% CI)	Coefficients	p Value
Age	1.02 (1.01-1.03)	0.021	< 0.001
Chronic heart failure	1.22 (1.09-1.38)	0.210	0.001
Cirrhosis	2.08 (1.74-2.49)	0.748	< 0.001
Carcinoid syndrome	1.87 (1.25-2.82)	0.631	0.002
Chronic kidney disease	1.35 (1.19-1.54)	0.312	< 0.001
Secondary pulmonary hypertension	0.82 (0.70-0.97)	-0.184	0.023
Infective endocarditis	1.31 (1.08-1.59)	0.237	0.005
Decubitus ulcer	1.64 (1.29-2.10)	0.511	< 0.001
Malnutrition	1.66 (1.40-1.98)	0.536	< 0.001
Surgical replacement	1.15 (1.02-1.30)	0.148	0.013
Emergent procedure	1.54 (1.33-1.76)	0.437	< 0.001
Preprocedural shock	2.76 (2.38-3.21)	1.041	< 0.001

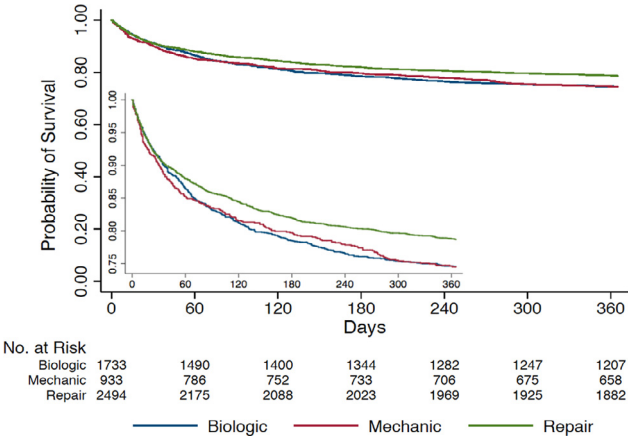

Figure 3. One-year survival after tricuspid valve replacement or repair.

Table 5
Outcomes after tricuspid valve surgery

Adverse events	Current study (n = 5,164)	Hwang et al[20] (n = 54)	Moraco et al[21] (n = 315)	Ejiofor et al[13] (n = 57)	De Bonis et al[22] (n = 96)	Chang et al[23] (n = 334)	Kim et al[17] (n = 51)
Acute renal failure	453/5,164 (8.8%)		N/A		1/96 (1%)	N/A	
Repair	184/2,494 (7.4%)	3/22 (14%)		2/18 (11%)			
Replacement	269/2,670 (10.1%)	3/31 (10%)		6/39 (15%)			N/A
Biologic	173/1737 (10.0%)						
Mechanic	95/933 (10.2%)						
Stroke	41/5,164 (0.8%)		N/A		1/96 (1%)		N/A
Repair	24/2,494 (1.0%)	1/22 (5%)		0/18 (0%)		3/334 (0.9%	
Replacement	17/2,670 (0.6%)	0/31 (0%)		0/39 (0%)			
Biologic	10/1737 (0.6%)						
Mechanic	7/933 (0.8%)						
Wound infection	43/5,164 (0.8%)		N/A		1/96 (1%)	N/A	1/51 (2%)
Repair	23/2,494 (0.9%)	1/22 (5%)		1/18 (5.6%)			1/37 (3%)
Replacement	20/2,670 (0.7%)	0/31 (0%)		0/39 (0%)			0/14 (0%)
Biologic	13/1737 (0.7%)						
Mechanic	7/933 (0.8%)						
Bleeding	392/5,164 (7.6%)				7/96 (7%)		5/51 (10%)
Repair	157/2,494 (6.3%)	2/22 (9%)		1/18 (6%)		13/334 (3.9%)	3/37 (8%)
Replacement	235/2,670 (8.6%)	1/31 (3%)		0/39 (0%)			2/14 (14%)
Biologic	172/1737 (9.9%)		6/29 (21%)				
Mechanic	56/933 (6.0%)		1/9 (11%)				
Operative mortality	510/5,164 (9.9%)				7/96 (7%)		1/51 (2%)
Repair	249/2,494 (10.0%)	3/22 (14%)	36/222 (16.2%)	3/18 (17%)		8/334 (2.4%)	0/37 (0%)
Replacement	261/2,670 (9.8%)	3/31 (10%)	12/93 (13%)	2/39 (5%)			1/14 (7%)
Biologic	161/1737 (9.3%)						
Mechanic	66/933 (7.1%)						
1-year mortality	1,245/5,164 (24.1%)	N/A			N/A	N/A	N/A
Repair	554/2,494 (22.2%)		32/175 (18.3%)	2/12 (17%)			
Replacement	691/2,670 (25.9%)		13/72 (18%)	3/35 (9%)			
Biologic	448/1737 (25.8%)		12/55 (21%)	N/A			
Mechanic	241/933 (25.8%)		2/18 (%9)	N/A			
Late-term mortality	1,344/5,164 (26.0%)	9/47 (%19)			13/89 (15%)		9/51 (18%)
Repair	598/2,494 (24.0%)		20/69 (29%)	2/9 (23%)		18/295(6.1%)	
Replacement	746/2,670 (27.9%)		23/67 (34%)	4/33 (12%)			
Biologic	481/1737 (27.7%)						
Mechanic	263/933 (28.2%)						

but has then declined each year with an increase in the number of tricuspid replacement compared with repair. A limited (<1%) number of centers performed more than 5 tricuspid surgeries per year. This finding underscores the complexity of patients selected for isolated tricuspid surgery. Our results based on the use of administrative coding of perioperative complications in our series provided comparable complication rates to those reported in the surgical series based on clinical review, including development of acute renal failure (8.8%), stroke (0.8%), wound infection (0.8%), and bleeding (7.6%)[13,17,20–23] (Table 5). We also found that the early complications were higher, the perioperative stay was longer, and the 1-year mortality rate was higher in patients undergoing tricuspid valve replacement than repair, although the reasons for the choice of repair versus replacement were not identified in this study.

Isolated tricuspid valve surgery has been associated with 2.0% to 20.6% perioperative mortality, and a 17% to 18% 1-year mortality.[13,17,22–26] Our series documents an overall mortality of 9.9% in the perioperative period, and 24.1% at 1-year. Importantly, we identified 12 independent predictors of 1-year mortality after isolated tricuspid valve surgery using administrative criteria. The overall predictive ability was good for this model, with a Harrell's C-statistic of 0.70 for these variables. Similar to prior clinical reports (Supplementary Table 2), age, chronic heart failure, cirrhosis,[24] carcinoid disease, chronic kidney disease, decubitus ulcer, malnutrition, malnutrition, pre-procedural shock, and endocarditis[11] were predictors of mortality. Other surgical series have also found that preoperative heart rhythm, and Euroscore were independent predictors of mortality after isolated tricuspid valve surgery.[10] These factors may have important implications for the selection of patients who undergo isolated tricuspid valve surgery. Currently, multiple novel transcatheter devices for tricuspid valve are being developed that may ultimately provide an alternative treatment for patients who require interventions. Our findings might be useful to compare outcomes with future trials in patients undergoing transcatheter tricuspid therapies.

There are several limitations to the current series. The indications and criteria for patient selection for isolated tricuspid valve surgery are not available. Administrative coding may miss co-morbidities and complications compared with prospective collection of these factors using standard clinical trial definitions. We are not able to identify the reasons that surgical tricuspid valve replacement or repair was performed. Because the study population was limited to Medicare beneficiaries, we did not have information on all patients younger than 65 years of age who might have undergone tricuspid valve surgery in the US, and those patients younger than 65 who were included in the study may not be representative of younger patients overall.

In conclusion, our report documents the experience with isolated tricuspid valve surgery among Medicare fee-for-service beneficiaries in the United States over the past 10 years. Isolated tricuspid surgery was infrequently performed and only a few (<1%) surgical centers performed more than 5 isolated tricuspid valve surgeries per year. We identified a number of independent predictors of 1-year mortality after isolated tricuspid valve surgery that largely related to underlying co-morbidities and disabilities rather than operative complications.

Supplementary Data

Supplementary Data associated with this article can be found, in the online version, https://doi.org/10.1016/j.amjcard.2018.09.016.

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