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FOCUS ON TRICUSPID INTERVENTIONS

ORIGINAL RESEARCH: STRUCTURAL

Incidence, Predictors and Outcomes of Bleeding Following Transcatheter Tricuspid Valve Repair

The TriValve Registry

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ABSTRACT

BACKGROUND Bleeding remains among the most common complications following catheter-based structural heart procedures. Its clinical implications following transcatheter tricuspid valve interventions have yet to be systematically evaluated.

OBJECTIVES The aim of this study was to evaluate the incidence of bleeding and its predictors and prognostic implications following transcatheter tricuspid valve repair.

METHODS TriValve (International Multisite Transcatheter Tricuspid Valve Therapies Registry; NCT03416166) is an international multicenter registry capturing a range of transcatheter tricuspid valve interventions. Bleeding events were classified according to the Bleeding Academic Research Consortium (BARC). For this analysis, BARC bleeding events type 2, 3, and 5 occurring within 1 year of transcatheter tricuspid valve repair were retrospectively evaluated.

RESULTS A total of 440 patients (mean age 76.6 ± 8.9 years, 57.7% women) were included. The BARC major bleeding incidence was 11.4% (50 patients). Postprocedural tricuspid regurgitation severity (adjusted ORl]: 1.83; 95% CI: 1.12-3.01; $P = 0.02$), higher systolic pulmonary artery pressures (adjusted OR: 1.61; 95% CI: 1.16-2.24; $P = 0.0048$), and increasing procedure duration (adjusted OR: 1.49; 95% CI: 1.00-2.22; $P = 0.049$) were associated with bleeding, whereas concomitant oral anticoagulation was not (adjusted OR: 1.51; 95% CI: 0.74-3.10; $P = 0.30$). Major bleeding was associated with a markedly increased risk for in-hospital death (adjusted OR: 106; 95% CI: 1.31-8,553; $P = 0.04$). Likewise, bleeding was significantly associated with a 1-year composite of death or all-cause hospital readmission (adjusted HR: 2.41; 95% CI: 1.39-4.19; $P = 0.002$), all-cause death (adjusted HR: 3.55; 95% CI: 1.75-7.21; $P = 0.0004$), and cardiovascular death (adjusted HR: 3.72; 95% CI: 1.62-8.52; $P = 0.002$).

CONCLUSIONS BARC major bleeding occurs in about 11% of patients following transcatheter tricuspid valve repair and is a major determinant of in-hospital and 1-year death. Enhanced patient selection and procedural optimization (with shorter procedural times) may help curb bleeding risk. (JACC Cardiovasc Interv. 2026;19:711-722) © 2026 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

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ABBREVIATIONS AND ACRONYMS

aHR = adjusted HR

aOR = adjusted OR

BARC = Bleeding Academic Research Consortium

EuroSCORE II = European System for Cardiac Operative Risk Evaluation II

OAC = oral anticoagulation

sPAP = systolic pulmonary artery pressure

TEE = transesophageal echocardiographic

TR = tricuspid regurgitation

TTVI = transcatheter tricuspid valve intervention

Transcatheter tricuspid valve interventions (TTVIs) have evolved over the past decade as a reliable treatment option in patients with severe tricuspid regurgitation (TR), alleviating symptoms and reducing the incidence of heart failure hospitalization in appropriately selected individuals.[1,2] If TR is left untreated, patients with severe TR often experience reduced cardiac output, leading to heart failure and poorer quality of life.[3] As a result, there is considerable demand for a transcatheter toolbox of severe TR solutions.[4,5] However, patients undergoing TTVI frequently represent a multimorbid cohort, with ubiquitous oral anticoagulation (OAC) use with or without concomitant antiplatelet therapy, thus contributing to both an increased bleeding and thrombotic risk.[6,7] Although bleeding is a well-recognized major complication in transcatheter valve therapies per se, limited data exist on bleeding rates following TTVI, a patient cohort that notionally exhibits greater bleeding risk both as a result of periprocedural transesophageal imaging and during large-bore vascular access. In addition, data are limited as to whether bleeding following TTVI is linked to adverse outcomes. Therefore, the aims of the present analysis were to describe the incidence of bleeding in a large multicenter, international registry of patients undergoing transcatheter tricuspid valve repair and to evaluate predictors of bleeding and its association with death and hospital readmission.

METHODS

STUDY DESIGN. The details of the TriValve (International Multisite Transcatheter Tricuspid Valve Therapies Registry) international registry have been previously described.[8] Briefly, TriValve is a multicenter registry including data on patients with symptomatic, at least severe TR undergoing TTVI with multiple devices. The registry includes the following devices: MitraClip and TriClip (Abbott Cardiovascular); Trialign, Cardioband, Forma, and PASCAL (Edwards Lifesciences); TriCinch (4Tech); TricValve (Products & Features); TRICENTO (NVT Biosensors); and NaviGate (NaviGate Cardiac Structures). All patients enrolled in the registry were discussed by the local multidisciplinary heart team. Clinical and echocardiographic data were collected at baseline. Follow-up events and echocardiographic findings were collected whenever available from the respective centers. Procedural success was defined as successful device implantation with residual TR ≤2+. Grading of TR severity was based on the integration of semiquantitative and quantitative measures, as described in the American Society of Echocardiography and European Association of Cardiovascular Imaging guidelines.[9,10] A total of 22 centers in Europe, the United States, and Canada contributed to the registry. The TriValve registry is registered at ClinicalTrials.gov (NCT03416166).

Of 688 subjects in the full TriValve registry, 203 patients with missing data on bleeding characteristics were excluded from the present analysis. Given the dominance of transcatheter tricuspid repair

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therapies in TriValve, the present analysis excluded orthotopic and heterotopic replacement procedures (n = 45). All patients included in the study were enrolled between March 2015 and March 2024. As part of the TriValve registry, hemoglobin was measured at least twice for each patient: before the procedure and at least once after the procedure prior to discharge. In case of multiple measurements available for a single patient, the minimal values were used for the definition of bleeding. The measurement of hemoglobin levels was performed in local laboratories, and the values are reported as grams per deciliter. The study was approved by the Institutional Review Boards of the participating centers, and the requirement to obtain informed consent was waived given the retrospective nature of the study.

ENDPOINT DEFINITION. Available information on bleeding and cardiovascular outcomes as well as rehospitalization and death of any cause was collected from participating centers, with the latest follow-up updated in March 2024. Bleeding events were classified according to the Bleeding Academic Research Consortium (BARC). For this analysis, BARC bleeding events type 2, 3, and 5 occurring within 1 year after interventional tricuspid valve therapy were included.[11,12] The primary outcome was the composite of death or any hospital readmission at 1 year. In addition, in-hospital death, cardiovascular death, and the components of the primary outcome were assessed.

STATISTICAL ANALYSIS. Categorical variables are expressed as numbers and percentages and were compared using the Fisher exact test or chi-square test. Continuous variables are expressed as mean ± SD when normally distributed and median (Q1-Q3) when not normally distributed and were compared using the unpaired Student's *t*-test or Wilcoxon rank test, stratifying by patients with and without bleeding events. Evaluation of the distribution of continuous measures was performed using histograms, together with assessment of skewness and kurtosis.

Predictors of bleeding were evaluated using univariable and multivariable logistic regression analysis. For multivariable analysis, the model contained all variables with significant difference in baseline or procedural characteristics. The final model included dialysis, European System for Cardiac Operative Risk Evaluation II (EuroSCORE II), prior NYHA functional class, prior systolic pulmonary artery pressure (sPAP), TR severity following the procedure, anticoagulation with vitamin K antagonists, procedural duration, and procedural success. Logistic cubic spline models were used to evaluate the dependence of bleeding events on the duration of procedure. Similarly, the association of bleeding with in-hospital death was evaluated using multivariable logistic regression analysis. Adjustment controlled for age, gender, baseline EuroSCORE II, baseline hemoglobin level, baseline rhythm, history of cardiovascular disease, baseline NYHA functional class, post-procedural TR severity, baseline left ventricular ejection fraction, baseline sPAP, baseline anticoagulation, and procedure duration. Associations with incident all-cause death, cardiovascular death, or a combined composite of all-cause death or any hospital readmission were evaluated using a multivariable Cox regression model adjusted with the same covariates used for the evaluation of in-hospital death. Kaplan-Meier analyses depicted the difference in outcome measures, stratifying by patients with vs without BARC type 2, 3, or 5 bleeding. Differences were evaluated using the log-rank test. Endpoints occurring after the start of the procedure up to a follow-up period of 1 year were included the Kaplan-Meier and Cox regression analyses. All analyses were performed using SAS version 9.4 (SAS Institute) and R version 4.3.2 (R Foundation for Statistical Computing) for Windows. *P* values <0.05 indicated statistical significance.

RESULTS

STUDY POPULATION. Baseline characteristics of the study population (n = 440) are presented in **Table 1**. The mean age was 76.6 ± 8.9 years, and 58% were women. Over the 1-year follow-up period, 50 patients (11%) experienced BARC major bleeding (type 2, 3, or 5). Of 50 patients who developed BARC bleeding events during 1 year of follow-up; 2 patients experienced intracranial bleeding; 4 patients had fatal bleeding; any bleeding leading to hospitalization or intervention or prompting evaluation was present in 43 patients; and clinical overt bleeding requiring transfusion occurred in 31 patients. Six patients had more than 1 bleeding event (1 patient had ≥3 BARC bleeding events). The median duration between intervention and bleeding events was 5 days (Q1-Q3: 5-36.5 days) (Supplemental Figure 1). Patients with BARC major bleeding had higher EuroSCORE II, were more likely to be in NYHA functional class III or IV, and were more likely to be hemodynamically unstable at hospital presentation. sPAP was also greater among patients with bleeding. Likewise, patients with bleeding events were more likely to have experienced longer procedure duration.

TABLE 1 Baseline Characteristics of the Overall Cohort and Patients Who Did and Did Not Experience BARC Major Bleeding Within 1 Year of Follow-Up

		BARC Bleeding (Type 2, 3, or 5)		
	Overall (N = 440)	No (n = 390)	Yes (n = 50)	*P* Value
Clinical and biochemical				
Age, y	76.6 ± 8.9	76.4 ± 9.1	77.6 ± 7.5	0.3
Female	254 (57.7)	223 (57.2)	31 (62.0)	0.5
Body mass index, kg/m^2	26.0 ± 4.8	26.2 ± 4.9	24.8 ± 4.3	0.06
STS risk score, %	5.9 ± 5.8	5.7 ± 5.6	7.8 ± 7.1	0.057
EuroSCORE II, %	9.1 ± 9.4	8.6 ± 7.7	13.1 ± 9.5	0.02
Prior CVD	136 (31.1)	115 (29.6)	21 (42.9)	0.06
Prior AMI	66 (15.9)	56 (15.2)	10 (21.3)	0.3
Prior pacemaker or ICD	110 (25.2)	99 (25.6)	11 (22.0)	0.6
Diabetes mellitus	123 (28.1)	105 (27.1)	18 (36.0)	0.2
Dialysis	23 (5.3)	21 (5.4)	2 (4.1)	0.7
COPD	83 (19.0)	74 (19.1)	9 (18.0)	0.9
History of atrial fibrillation/flutter	250 (57.2)	218 (56.3)	32 (64.0)	0.6
Extracardiac atherosclerosis	63 (14.5)	56 (14.6)	7 (14.0)	0.9
eGFR, mL/min	46.7 ± 19.7	47.0 ± 19.6	44.2 ± 20.3	0.3
AST, U/L	32.7 ± 18.8	32.0 ± 18.4	38.5 ± 20.7	0.03
ALT, U/L	24.2 ± 24.7	24.0 ± 25.2	25.7 ± 19.9	0.7
GGT, U/L	137.7 ± 134.3	134.8 ± 129.5	162.0 ± 168.9	0.4
Prothrombin time	47.5 ± 28.6	47.6 ± 28.4	47.0 ± 29.8	0.9
Hemoglobin, g/dL	10.7 ± 2.4	10.8 ± 2.4	10.2 ± 2.6	0.1
Peripheral edema	298 (74.1)	263 (74.1)	35 (74.5)	0.9
Ascites	80 (19.9)	64 (18.0)	16 (34.0)	0.01
Hemodynamic instability	15 (3.4)	9 (2.3)	6 (12.5)	0.0003
NYHA functional class				0.04
II	31 (7.1)	29 (7.5)	2 (4.0)	
III	295 (67.5)	267 (69.0)	28 (56.0)	
IV	111 (25.4)	91 (23.5)	20 (40.0)	
Echocardiographic findings				
LVEF, %	50.4 ± 13.3	50.3 ± 13.5	51.3 ± 11.2	0.6
LVEDD, mm	50.2 ± 8.7	50.2 ± 8.8	50.0 ± 7.8	0.8
Left atrial volume, mL	110.2 ± 50.8	108.3 ± 47.2	124.9 ± 71.6	0.17
Right atrial volume, mL	105.1 ± 58.5	103.9 ± 60.7	114.2 ± 35.9	0.25
TAPSE, mm	17.0 ± 4.6	17.0 ± 4.5	17.0 ± 5.1	0.98
sPAP, mm Hg	40.2 ± 15.6	39.5 ± 15.5	45.3 ± 15.6	0.02
Tricuspid regurgitation etiology				0.5
Functional	381 (87.2)	341 (87.7)	40 (83.3)	
Degenerative	19 (4.4)	15 (3.9)	4 (8.3)	
Mixed	31 (7.1)	28 (7.2)	3 (6.3)	
Other	6 (1.4)	5 (1.3)	1 (2.1)	
Tricuspid regurgitation severity				0.06
2	11 (2.5)	11 (2.9)	0	
3	186 (42.8)	171 (44.3)	15 (60.6)	
4	238 (54.7)	204 (52.9)	34 (69.4)	
Baseline medications				
Aspirin	90 (22.4)	81 (22.7)	9 (20.5)	0.7
$P2Y_{12}$ inhibitor therapy	31 (7.8)	29 (8.2)	2 (4.6)	0.4
Dual antiplatelet therapy	15 (3.1)	14 (3.9)	1 (2.7)	0.4
Anticoagulation				0.2
Warfarin/phenprocoumon	149 (37.3)	127 (35.7)	22 (50.0)	
DOAC	184 (46.0)	169 (47.5)	15 (34.1)	
Type of transcatheter TV repair				0.5
Edge to edge	398 (90.4)	355 (91.0)	43 (86.0)	
Annuloplasty	29 (6.6)	24 (6.2)	5 (10.0)	
Forma/other	13 (3.0)	11 (2.8)	2 (4.0)	
Procedure duration, min	129.5 ± 59.7	122.9 ± 53.4	175.3 ± 85.0	0.002

Values are mean ± SD or n (%).

ALT = alanine aminotransferase; AMI = acute myocardial infarction; AST = aspartate aminotransferase; BARC = Bleeding Academic Research Consortium; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; DOAC = direct oral anticoagulant agent; eGFR = estimated glomerular filtration rate; GGT = gamma-glutamyl transferase; ICD = implantable cardioverter-defibrillator; LVEDD = left ventricular end-diastolic diameter; LVEF = left ventricular ejection fraction; sPAP = systolic pulmonary artery pressure; STS = Society of Thoracic Surgeons; TAPSE = tricuspid annular plane systolic excursion; TV = tricuspid valve.

TABLE 2 Postprocedural Characteristics of the Overall Cohort and Patients Who Did and Did Not Experience BARC Major Bleeding Within 1 Year of Follow-Up

	Overall (N = 440)	BARC Major Bleeding		P Value
		No (n = 390)	Yes (n = 50)	
Echocardiographic findings				
LVEF, %	49.5 ± 13.5	49.4 ± 13.8	50.3 ± 10.8	0.5
LVEDD, mm	50.7 ± 8.9	50.7 ± 9.1	51.1 ± 7.5	0.8
TAPSE, mm	16.1 ± 4.6	16.2 ± 4.7	15.1 ± 3.7	0.2
sPAP, mmHg	39.0 ± 13.0	38.2 ± 12.9	45.3 ± 12.4	0.002
Tricuspid regurgitation severity				<0.0001
0	2 (0.5)	2 (0.6)	0	
1	134 (34.2)	129 (36.9)	5 (11.9)	
2	165 (42.1)	149 (42.6)	16 (38.1)	
3	64 (16.3)	52 (14.9)	12 (28.6)	
4	27 (6.9)	18 (5.1)	9 (21.4)	
Medications				
Aspirin	108 (27.0)	97 (27.2)	11 (25.6)	0.7
$P2Y_{12}$ inhibitor therapy	62 (15.3)	4 (9.3)	58 (16.2)	0.5
Dual antiplatelet therapy	62 (15.5)	58 (16.3)	4 (9.3)	0.2
Anticoagulation				0.1
Warfarin/phenprocoumon	145 (36.3)	122 (34.0)	23 (53.5)	
DOAC	200 (50.0)	184 (51.3)	16 (37.2)	
Anticoagulation + ASA/$P2Y_{12}$ inhibitor	78 (19.5)	69 (19.3)	9 (20.97)	0.8
Acute procedural success device	273 (79.1)	254 (83.3)	19 (47.5)	<0.0001
Dialysis	14 (3.2)	11 (2.8)	3 (6.0)	0.3

Values are mean ± SD or n (%).
Abbreviations as in Table 1.

Postprocedural characteristics are displayed in Table 2. The severity of residual TR and sPAP were greater among patients with bleeding. Patients with bleeding events were also more likely to have unsuccessful procedures. At baseline, aspartate aminotransferase was higher in patients with bleeding events compared with those without bleeding. In contrast, alanine aminotransferase and gamma-glutamyl transferase did not differ between groups. At 30 days, no differences in liver enzymes were observed for patients with vs without bleeding (aspartate aminotransferase, 30.2 ± 12.2 vs 30.7 ± 8.1 U/L [$P = 0.8$]; alanine aminotransferase, 20.7 ± 10.9 vs 20.2 ± 10.4 U/L [$P = 0.8$]; gamma-glutamyl transferase, 126.5 ± 129.4 vs 122.2 ± 96.4 U/L [$P = 0.9$]). Comparing early vs late bleeding vents (<5 days vs ≥5 days after the procedure), at least moderate to sever residual TR was present in 56% of patients with early bleeding events and in 41% of patients with later bleeding events.

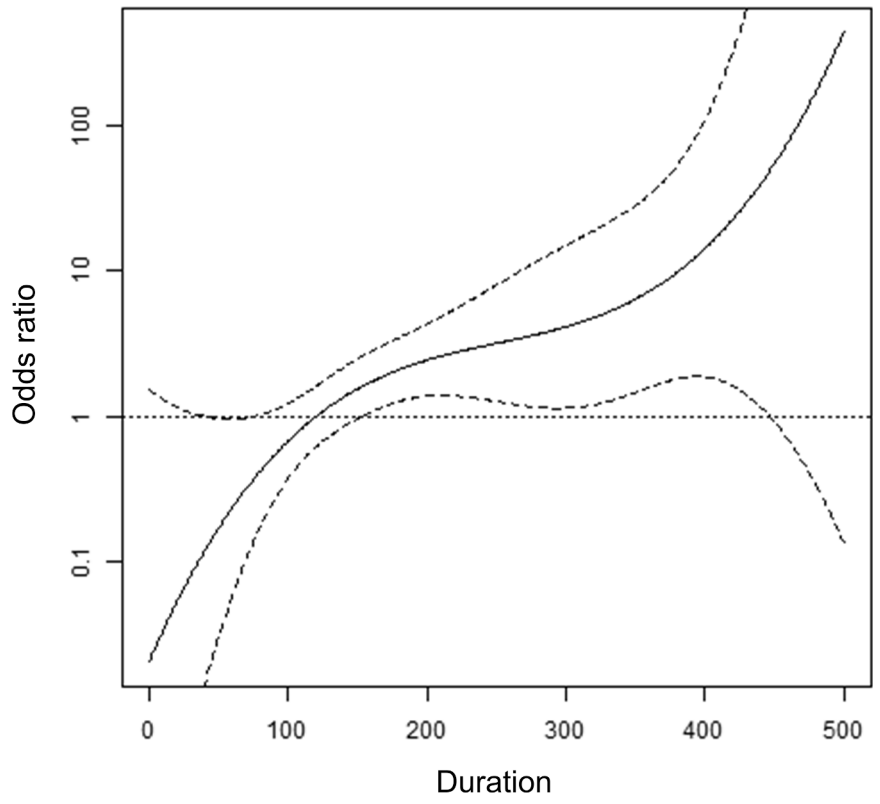
PREDICTORS OF BLEEDING. Table 3 shows predictors of BARC bleeding events. In univariable analysis, postprocedural EuroSCORE II, NYHA functional class, preprocedural sPAP values, the severity of residual TR, procedural duration, and procedural success were associated with bleeding. Following multivariable adjustment, associations remained statistically significant for sPAP values preprocedure (adjusted [aOR] per 1-SD increase: 1.61; 95% CI: 1.16-2.24; $P = 0.0048$), the severity of residual TR (aOR: 1.83; 95% CI: 1.12-3.01; $P = 0.02$), and procedural duration (aOR per 1-SD increase: 1.49; 95% CI: 1.00-2.22; $P = 0.0492$). Notably, OAC use was not associated with bleeding. Cubic splines analysis showed that bleeding rates increased if procedural duration exceeded 100 minutes (Figure 1).

TABLE 3 Univariate and Multivariable Predictors of Bleeding Academic Research Consortium Bleeding (Type 2, 3, or 5)

	Univariate		Multivariable	
	OR (95% CI)	P Value	OR (95% CI)	P Value
Dialysis[a]	2.20 (0.59-8.17)	0.2	1.71 (0.37-7.85)	0.5
EuroSCORE II[b]	1.41 (1.02-1.94)	0.04	1.14 (0.84-1.53)	0.4
Prior NYHA functional class	1.97 (1.14-3.41)	0.015	1.84 (0.96-3.50)	0.07
Prior sPAP[b]	1.43 (1.02-1.99)	0.004	1.61 (1.16-2.24)	0.0048
Postprocedural TR severity	2.25 (1.57-3.23)	<0.0001	1.83 (1.12-3.01)	0.02
Warfarin/phenprocoumon	2.34 (0.97-5.66)	0.057	1.51 (0.74-3.10)	0.3
Procedure duration[b]	2.01 (1.10-3.68)	0.02	1.49 (1.00-2.22)	0.0492
Procedural success	0.20 (0.07-0.52)	0.001	0.63 (0.22-1.76)	0.4

[a]Hemodialysis status in the post-procedural setting. [b]Per SD.
EuroSCORE II = European System for Cardiac Operative Risk Evaluation II; TR = tricuspid regurgitation; other abbreviations as in Table 1.

FIGURE 1 The Effect of Procedural Duration on Bleeding Academic Research Consortium Bleeding (Type 2, 3, or 5) Risk



Restricted cubic spline plot for OR with 95% CI, using median duration as a reference.

ASSOCIATION OF BLEEDING EVENTS WITH OUTCOMES. Patients who experienced BARC bleeding had higher adjusted rates of in-hospital death (aOR: 106; 95% CI: 1.31-8553; $P = 0.04$). At 1-year follow-up, the incidence of death or all-cause rehospitalization was higher among patients who experienced BARC bleeding (46.0% vs 20.7%; $P < 0.001$) (Table 4). This was driven primarily by differences in the rates of all-cause death (33.3% vs 10.1%; $P < 0.001$). Likewise, patients with incident bleeding were more likely to die of a cardiovascular cause (25.6% vs 8.3%; $P = 0.0004$). Kaplan-Meier analysis confirmed the higher survival rate of patients without major BARC bleeding (Central Illustration, Figure 2). In Cox regression analysis, BARC bleeding type 2, 3, or 5 was independently associated with increased 1-year death or rehospitalization (adjusted HR [aHR]: 2.41; 95% CI: 1.39-4.19; $P = 0.002$), driven by increased all-cause death (aHR: 3.55; 95% CI: 1.75-7.21; $P = 0.0004$). Major BARC bleeding was

TABLE 4 Association Between Bleeding Academic Research Consortium Bleeding Within 1 Year (Type 2, 3, or 5) an Clinical Outcomes

	Unadjusted OR (95% CI)	*P* Value	Adjusted OR (95% CI)	*P* Value
In-hospital death	52.1 (6.13-443)	0.0003	106 (1.31-8553)	0.04
1 y	Unadjusted HR (95% CI)		Adjusted HR (95% CI)	
Death	3.67 (2.07-6.50)	<0.0001	3.55 (1.75-7.21)	0.0004
Cardiovascular death	3.15 (1.57-6.31)	0.0012	3.72 (1.62-8.52)	0.002
Composite of death or all-cause readmission	2.65 (1.65-4.23)	<0.0001	2.41 (1.39-4.19)	0.002

Adjusted for age, gender, baseline European System for Cardiac Operative Risk Evaluation II, baseline hemoglobin, baseline rhythm, history of cardiovascular disease, baseline NYHA functional class, baseline left ventricular ejection fraction, baseline systolic pulmonary artery pressure, baseline anticoagulation, postprocedural tricuspid regurgitation severity, and procedure duration.

CENTRAL ILLUSTRATION **Bleeding Events Within 1 Year of Transcatheter Tricuspid Valve Repair**

Occurrence and Outcome of Bleeding in TriValve Registry

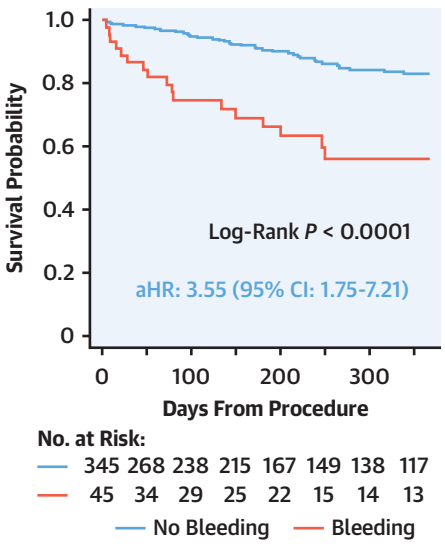
Patients undergoing transcatheter tricuspid valve repair (N = 440)

- No bleeding events within 1 year n = 390 (89%)
- BARC Type 2, 3, or 5 bleeding event within 1 year n = 50 (11%)

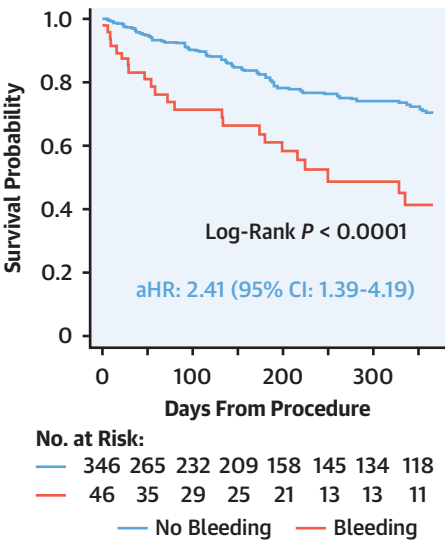
Predictors of Bleeding	aOR (95% CI)
• SysPAP	1.61 (1.16-2.24), *P* = 0.005
• Residual TR severity	1.83 (1.12-3.01), *P* = 0.017
• Procedure duration	1.49 (1.00-2.22), *P* = 0.049
• Vit K antagonist	1.51 (0.74-3.10), *P* = 0.257

Endpoints

All-Cause Death



All-Cause Death and Readmission



- BARC 2, 3, or 5 bleeding events occur in 11% of patients within 1 year after transcatheter tricuspid valve repair.
- SysPAP, residual TR severity, and procedure duration are predictors of bleeding.
- Bleeding is a strong predictor (aHR: 2.41) of all-cause death and hospital readmission.

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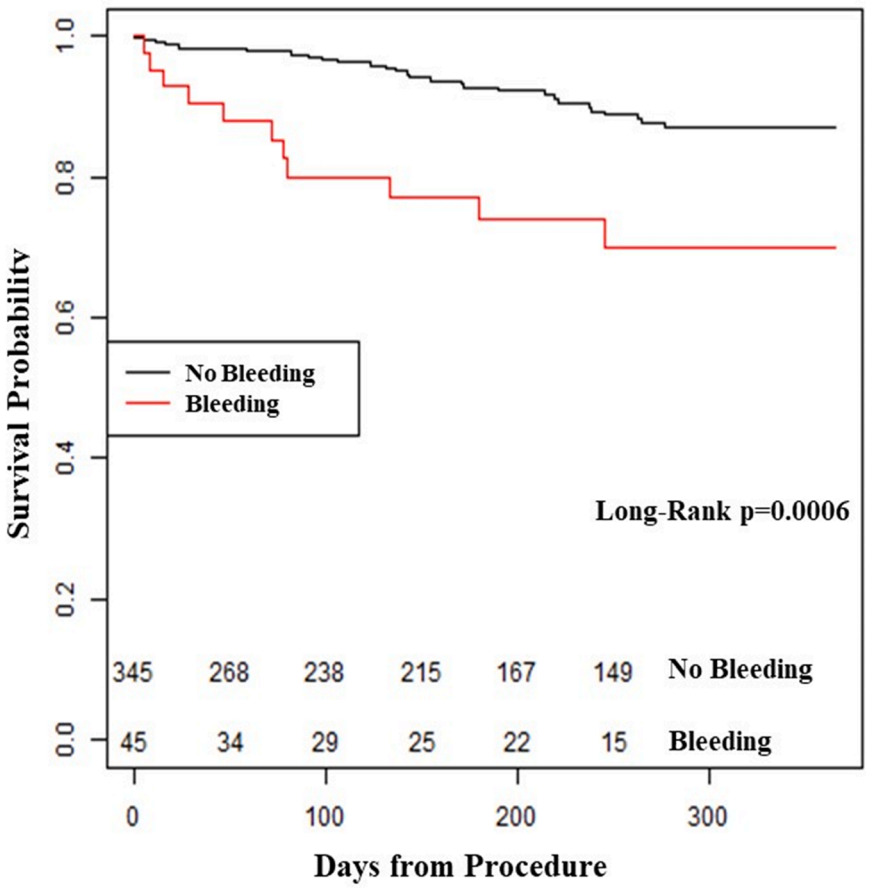
Study cohort, predictors of bleeding and outcomes in the TriValve (International Multisite Transcatheter Tricuspid Valve Therapies Registry) registry. aHR = adjusted HR; aOR = adjusted OR; BARC = Bleeding Academic Research Consortium; SysPAP = systolic pulmonary artery pressure; TR = tricuspid regurgitation; Vit K = vitamin K.

FIGURE 2 Association of Bleeding Academic Research Consortium Bleeding (Type 2, 3, or 5) With Cardiovascular Death



independently associated with a more than 3.5-fold increase in cardiovascular death (aHR: 3.72; 95% CI: 1.62-8.52; $P = 0.002$).

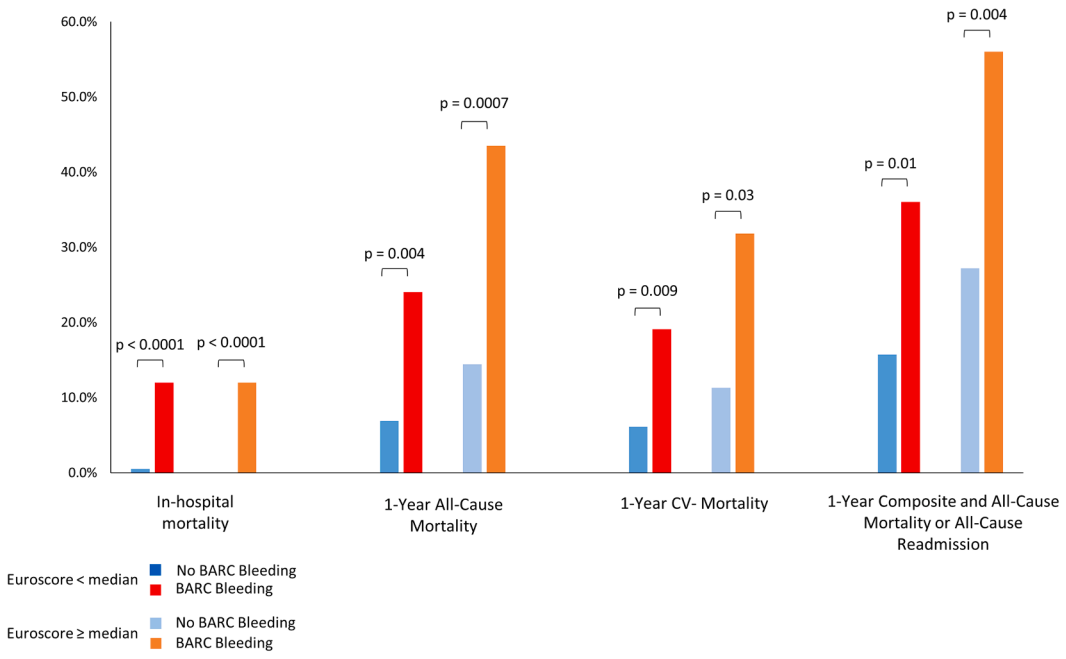
Stratifying by EuroSCORE II at baseline, the incidence of in-hospital death, all-cause death, cardiovascular death, or the combined endpoint of all-cause death and all-cause rehospitalization was higher among patients who experienced major BARC bleeding irrespective of whether their EuroSCORE II was greater than or equal to or less than the median (Figure 3). For all major adverse cardiovascular events, BARC type 2, 3, or 5 bleeding led to a better stratification of events than EuroSCORE II being greater than or equal to vs less than the median.

The incidence of all-cause and cardiovascular death was not different among groups with early vs later bleeding events (all-cause death, 35.7% vs 30.0% [$P = 0.68$]; cardiovascular death, 29.6% vs 18.8% [$P = 0.43$]).

DISCUSSION

The present analysis, based on a multicenter, international registry of patients undergoing transcatheter tricuspid valve repair, demonstrates that 11% of individuals developed type 2, 3, or 5 BARC bleeding within the first year postprocedure. Elevated sPAP, the severity of residual TR, and longer procedural duration were independently associated with bleeding. Early bleeding was associated with a markedly increased risk for in-hospital death. In addition, elevated risk for all-cause death, cardiovascular death, and a composite endpoint of death or hospital readmission persisted to 1 year of follow-up. Bleeding, which typically occurred within 5 days postprocedure, was a stronger determinant of both in-hospital and 1-year death than EuroSCORE II. Surprisingly, neither concomitant vitamin K antagonist nor direct OAC treatment was associated with

FIGURE 3 **Outcomes According to Subgroups of Less Than vs Greater Than or Equal to Median EuroSCORE II as Well as Presence vs Absence of BARC Bleeding (Type 2, 3, or 5)**



BARC = Bleeding Academic Research Consortium; CV = cardiovascular; EuroSCORE II = European System for Cardiac Operative Risk Evaluation II.

bleeding risk. These findings highlight the critical impact of bleeding for patients undergoing transcatheter atrioventricular valve repair, underscoring the importance of optimized patient selection and procedural times to minimize short and longer term death risk.

Bleeding remains among the most common complications following transcatheter heart valve therapy, yet very little is known regarding the incidence, predictors, and implications of bleeding in patients undergoing various transcatheter tricuspid valve therapies. In TRILUMINATE, major bleeding at 1 year defined according to BARC type ≥3a occurred in 5.2% in those randomized to the TriClip.[2] Using Mitral Valve Academic Research Consortium bleeding criteria, bleeding rates of up to 21% were reported from a 2-center analysis of patients undergoing transcatheter tricuspid valve repair.[13] The present TriValve analysis is unique in elucidating predisposing factors promoting bleeding. It was surprising to note the absence of an association between OAC use and bleeding, despite the ubiquitous presence of atrial fibrillation and OAC use in the severe TR population. Rather, higher pulmonary artery pressures were a notable patient-related factor that correlated with bleeding. Of note, liver function at 30 days did not significantly differ between patients with and those without BARC bleeding.

A novel finding was the strong link between procedural duration and bleeding, with procedural duration >100 minutes significantly increasing bleeding risk. This may relate to prolonged and repeated transesophageal echocardiographic (TEE) probe manipulation, shown to cause esophageal or gastric injury in 86% of patients undergoing TEE imaging during structural heart interventions.[14] Prolonged TEE imaging is likely to also be a result of anatomical complexity and/or suboptimal TEE views. The 2-fold greater risk for bleeding with respect to procedural duration should alert operators wishing to pursue transcatheter repair solutions to consider using adjunct imaging techniques (such as intracardiac echocardiography, or intracardiac echocardiography) that can shorten procedure times and minimize esophageal-gastric echocardiographic probe manipulation. Alternatively, nonrepair solutions such as heterotopic caval valve implantation that require mostly fluoroscopy and limited surface echocardiography with much shorter procedural times could be considered for treating patients with

severe TR. In addition, longer procedural duration may reflect the complexity of the procedure, also mirrored by lower rates of TR reduction and procedural success.

A striking observation from the present TriValve analysis was the significant impact of bleeding upon longer term (1-year) hospitalization and death. Although the median time of bleeding from the procedure was 5 days (which explains why early mortality was increased in those who bled), the fact that 1-year hospitalization and death were significantly affected by early postprocedural bleeding speaks to the notion of a detrimental legacy effect of not only bleeding per se but perhaps the medium- to longer term ramifications of managing bleeding (kidney injury, potential thromboembolism from halting OAC, anemia, etc). Others have shown that only one-half of early bleeding events following transcatheter tricuspid valve procedures, similarly to other interventional valve therapies, relate to vascular access site-related complications.[15-18] The significant comorbid nature of the severe TR population (which may include hepatic synthetic dysfunction and thrombocytopenia) clearly predisposes this population to spontaneous delayed bleeding. These observations underscore the need for more intense postprocedural surveillance. In the TRISCEND II trial, the 1-year cumulative severe bleeding rate was 15.4% (10.4% within 30 days).[19] Giving the high prognostic implications of bleeding in this multimorbid cohort, our results support a repair-first strategy over replacement in suitable anatomies.

The present findings relate to mostly those patients with severe TR who underwent transcatheter tricuspid edge-to-edge therapy (90% of the population). Therefore, comparisons between orthotopic and heterotopic transcatheter tricuspid valve replacement recipients, who typically harbor a more advanced TR/right heart failure substrate, and tricuspid transcatheter edge-to-edge therapy recipients may not be valid.[2,19-21] Replacement technologies are also more prone to device-related thrombosis, necessitating lifelong OAC. On the flip side, some of these emerging orthotopic and heterotopic replacement technologies have shorter procedural times and less involved periprocedural TEE imaging. Dedicated bleeding analyses in the orthotopic and heterotopic tricuspid valve replacement population will need to be performed to better understand the nuances related to bleeding tendency in the tricuspid valve repair vs replacement populations.

STUDY LIMITATIONS. We undertook a retrospective analysis of data from 22 high-volume centers in the United States and Europe, thus limiting somewhat the generalizability of our data. Given the retrospective design, not all bleeding events, especially during follow-up, may have been recorded adequately by the centers. Moreover, because of the information provided in the registry, we were unable to describe other nonmajor bleeding endpoints and the choice of vascular closure at the puncture site. The present analysis may be somewhat limited by sample size. In addition, the registry included early device experience and a more advanced heart failure population than current studies. Larger studies are needed to confirm our results and extend the analysis of potential predictors of bleeding.

CONCLUSIONS

In the present TriValve multicenter registry of patients undergoing transcatheter tricuspid valve repair, BARC bleeding type 2, 3, and 5 within 1 year of the procedure occurred in 11%. Elevated sPAP, residual TR severity, and procedural duration were independently associated with bleeding. Bleeding was associated with a markedly increased risk for in-hospital death but also significantly associated with 1-year cardiovascular death, all-cause death, and hospital readmission. Therapeutic strategies designed to minimize bleeding risk both during and following transcatheter tricuspid valve repair are warranted to improve outcomes in this high-risk patient cohort.

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Dr Dykun has received speaker fees from and/or has participated on advisory boards for Daiichi-Sankyo, Novartis, and Sanofi. Dr Russo has received a fellowship training grant from the European Association of Percutaneous Cardiovascular Interventions, sponsored by Edwards Lifesciences. Dr Mahabadi has received speaker fees from and/or participated on advisory boards for Amgen, Daiichi-Sankyo, Edwards Lifesciences, Novartis, and Sanofi; has received research funding from Daiichi-Sankyo and Edwards Lifesciences. Dr Andreas is a proctor, consultant, and speaker for Edwards Lifesciences, Abbott Laboratories, Medtronic, Boston Scientific, and Zoll; and has received institutional research grants from Edwards Lifesciences, Abbott Laboratories, Medtronic, and LSI Solutions. Dr Estevez-Loureiro is a consultant for Abbott Cardiovascular, Boston Scientific, and Edwards Lifesciences. Dr Nickenig has received honoraria for lectures or advisory board membership from Abbott Laboratories, Boston Scientific, Edwards Lifesciences, and Medtronic. Dr Hahn has received speaker fees from Abbott Structural Heart, Baylis Medical, Edwards Lifesciences, and Philips Healthcare; has institutional consulting contracts for which she receives no direct compensation with Abbott Structural Heart, Boston Scientific, Edwards Lifesciences, Medtronic, and Novartis; has stock options with NaviGate;

and is chief scientific officer for the echocardiography core laboratory at the Cardiovascular Research Foundation for multiple industry-sponsored trials, for which she receives no direct industry compensation. Dr Maisano is a consultant for Abbott Cardiovascular, Medtronic, Edwards Lifesciences, Perifect, Xeltis, Transseptal Solutions, Magenta, and Cardiovalve; has received grant support from Abbott Cardiovascular, Medtronic, Edwards Lifesciences, Biotronik, Boston Scientific, NVT, and Terumo; has received royalties from Edwards Lifesciences and 4Tech; and is a cofounder and shareholder of Transseptal Solutions,4Tech, Cardiovalve, Magenta, Perifect, Coregard, and SwissVortex. Dr Rassaf has received research funding from Abbott Laboratories; and has received honoraria for lectures or advisory board membership from AstraZeneca, Bayer, Berlin Chemie, Bristol Myers Squibb, Boehringer Ingelheim, Daiichi-Sankyo, Medtronic, Novartis, and Pfizer. Dr Adamo has received personal fees from Abbott Cardiovascular, Medtronic, and Novartis. Dr Sievert has received study honoraria to the institution, travel expenses, and consulting fees from 4Tech Cardio, Abbott Laboratories, Ablative Solutions, Adona Medical, Akura Medical, Ancora Heart, Append Medical, Axon, Bavaria Medizin Technologie, BioVentrix, Boston Scientific, Cardiac Dimensions, Cardiac Success, Cardimed, Cardionovum, CeloNova Biosciences, Contego, Coramaze, CroíValve, CSL Behring, CVRx, Dinova, Edwards Lifesciences, EndoBar, Endologix, EndoMatic, Esperion Therapeutics, Hangzhou Nuomao Medtech, Holistick Medical, InterShunt Technologies, Intervene, K2, Laminar, Life Tech Care, Magenta, Maquet Getinge Group, Metavention, Mitralix, Mokita, Neurotronic, NXT Biomedical, Occlutech, Recor, Renal Guard, Shifamed, Terumo, Trisol, Vascular Dynamics, Vectorious Medtech, Venus, Venock, Vivasure Medical, Vvital Biomed, and WhiteSwell. Dr Tang has received speaker honoraria from and served as a physician proctor, consultant, advisory board member, transcatheter aortic valve replacement publications committee member, RESTORE study steering and screening committee member, APOLLO trial screening committee member, and IMPACT MR steering committee member for Medtronic; has received speaker honoraria from and served as a physician proctor, consultant, advisory board member, ENVISION trial screening committee member, and TRILUMINATE trial anatomical eligibility and publications committee member for Abbott Structural Heart; has served as an advisory board member for Boston Scientific; has served as a consultant for Shockwave Medical, Anteris, Philips, Edwards Lifesciences, Peija Medical, and Shenqi Medical Technology; and has received speaker honoraria from Siemens Healthineers. Dr Stolz has received speaker honoraria from Edwards Lifesciences. Dr Taramasso has received consultancy fees from Abbott Cardiovascular, Edwards Lifesciences, 4Tech, Boston Scientific, CoreMedic, Mitraltech, and SwissVortex (outside the submitted work). All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

WHAT IS KNOWN? Bleeding events after transcatheter aortic and mitral valvular procedures are associated with increased morbidity and mortality, but the clinical implications of bleeding after transcatheter tricuspid valve repair are unclear.

WHAT IS NEW? In the present multicenter registry of patients undergoing transcatheter tricuspid valve repair, BARC major bleeding (type 2, 3, or 5) within 1 year postprocedure occurred in 11% of patients and was a strong determinant of in-hospital and 1-year death. Higher sPAP, procedural duration, and postinterventional TR severity were independent predictors of bleeding.

WHAT IS NEXT? Greater efforts are needed to further mitigate hemorrhagic complications of transcatheter tricuspid repair procedures, including strategies to minimize procedure time and delivery system size, all while optimizing residual TR severity.

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KEY WORDS BARC, bleeding, transcatheter tricuspid valve repair, TriValve registry

APPENDIX For the supplemental figure, and a video of the interactive Central Illustration, please see the online version of this paper.