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PC202. Evolution of Vascular Complications in Transfemoral Transcatheter Aortic Valve Replacement

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Evolution of Vascular Complications in Transfemoral Transcatheter Aortic Valve Replacement

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Background

Vascular complications (VCs) following transfemoral transcatheter aortic valve replacement (TF-TAVR) have historically been common and associated with significant morbidity and mortality.[1,2] We evaluated our large multicenter experience to provide new insight on the incidence, predictors, management, and clinical impact of VCs after TAVR.

Methods

- Retrospective TVT registry and chart review were performed for 1,573 patients undergoing non-clinical trial TF-TAVR across 7 centers within our hospital network between January 2012 through December 2016.
- Vascular and bleeding complications were defined by Valve Academic Research Consortium-2 definitions.[3]
- Incidence of 30-day vascular complications, treatment strategy, and outcomes were reported. Between-group differences were analyzed by t-test, Fisher exact, Chi-square, ANOVA, or Wilcoxon rank sum.
- Mixed effect model with hospital as a random effect was used to assess predictors of major VC.
- Kaplan-Meier survival analysis and log-rank test were used to compare 1-year survival for minor, major, and no VC groups. Cox proportional hazards model was used to assess predictors of mortality at 1-year, for those who survived >30 days.

Results 1

Table 1: Vascular and Bleeding Complications

Vascular Complications	Bleeding Complications				Overall
	None	Minor	Major	Life Threatening	
None	1396	0	3	1	1399 (89.0%)
Minor	57	20	0	0	77 (4.9%)
Major	6	1	46	43	96 (6.1%)*
Overall	1459 (92.8%)	21 (1.3%)	49 (3.1%)	44 (2.8%)	1573

Data presented as n (%) of patients; highest severity of complication was counted
* One patient had two major VCs

Table 2: Patient Demographics

Variable	All Patients (n=1573)	No VC (n=1399)	Minor VC (n=77)	Major VC (n=96)	P-value
Age, years	83.0 (77.0, 87.8)	82.9 (77.0, 87.7)	84.9 (76.8, 88.2)	83.1 (77.9, 89.1)	0.435
Female	713 (45.3%)	603 (43.1%)	46 (59.7%)	64 (66.7%)	<0.001
BMI, kg/m^2	27.2 (23.8, 32.2)	27.2 (23.8, 32.1)	27.1 (23.8, 30.8)	28.8 (24, 34.9)	0.249
Diabetes	623 (39.6%)	558 (39.9%)	32 (41.6%)	33 (34.4%)	0.533
Chronic lung disease	658 (41.8%)	568 (40.6%)	40 (51.9%)	50 (52.1%)	0.016
Smoker	88 (5.6%)	80 (5.7%)	3 (3.9%)	5 (5.2%)	0.896
Hypertension	1357 (86.3%)	1206 (86.1%)	67 (87%)	84 (87.5%)	0.915
Immunosuppression	248 (15.8%)	214 (15.3%)	13 (16.9%)	21 (21.9%)	0.222
Prior PCI	558 (35.5%)	492 (35.1%)	21 (27.3%)	45 (46.9%)	0.02
Prior CABG	360 (22.9%)	339 (24.2%)	9 (11.7%)	12 (12.5%)	0.002
Prior MI	372 (23.6%)	328 (23.4%)	18 (23.4%)	26 (27.1%)	0.716
Prior shock*	18 (1.1%)	16 (1.1%)	0 (0%)	2 (2.1%)	0.462
Prior cardiac arrest*	6 (0.4%)	6 (0.4%)	0 (0%)	0 (0%)	>0.999
Prior aortic valve	172 (10.9%)	153 (10.9%)	12 (15.6%)	7 (7.3%)	0.221
Prior stroke	224 (14.2%)	204 (14.6%)	9 (11.7%)	11 (11.5%)	0.564
Prior PAD	478 (30.4%)	413 (29.5%)	27 (35.1%)	38 (39.6%)	0.076
STS risk of AVR mortality, %	6.0 (4.2, 8.6)	6.0 (4.2, 8.5)	6.1 (3.8, 9.4)	7.1 (4.8, 9.4)	0.062

* Within 24 hours
Data presented as n (%) of patients or median (IQR)
BMI = body mass index, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft, MI = myocardial infarction, PAD = periphery artery disease, INR = international normalized ratio, STS = society of thoracic surgery, AVR = aortic valve replacement.

Results 2

- Ninety-seven major vascular complications occurred in 96 patients (6.1%); majority of major VC patients also experienced major or life-threatening bleeding (89 cases, 93%) (Table 1)
- Minor and major VC groups had a higher percentage of female and CLD, with lower rates of prior CABG; rates of prior PCI also differed between groups (Table 2)
- Fifty percent of major VCs occurred at the TAVR access site, 53% occurred intra-operatively, and 74% required treatment, of which 48% had open surgery as the primary treatment method (Table 3)
- Rates of location, timing, and treatment of major VC were similar across the years (Table 3)

Table 3: Temporal Trends in Major Vascular Complications

Variable	Overall	2012	2013	2014	2015	2016	P-value
# procedures, # (%) major VC	1573, 97* (6.1%)	40, 5 (12.5%)	73, 5 (6.8%)	222, 15 (6.8%)	460, 29 (6.3%)	778, 43 (5.4%)	0.434
Site							0.870
Access, contralateral (small) sheath	23 (23.7%)	2 (40%)	2 (40%)	3 (20%)	7 (24.1%)	9 (20.9%)	
Access, TAVR side	49 (50.5%)	3 (60%)	2 (40%)	7 (46.7%)	16 (55.2%)	21 (48.8%)	
Non-access	25 (25.8%)	0 (0%)	1 (20%)	5 (33.3%)	6 (20.7%)	13 (30.2%)	
Timing							0.936
Intra-op	51 (52.6%)	3 (60%)	2 (40%)	7 (46.7%)	15 (51.7%)	24 (55.8%)	
Post-op	46 (47.4%)	2 (40%)	3 (60%)	8 (53.3%)	14 (48.3%)	19 (44.2%)	
Received treatment	71 (73.2%)	4 (80%)	4 (80%)	11 (73.3%)	19 (65.5%)	33 (76.7%)	0.898
Treatment method							0.861
Open	34 (47.9%)	2 (50%)	2 (50%)	8 (72.7%)	7 (36.8%)	15 (45.5%)	
Endo	18 (25.4%)	1 (25%)	1 (25%)	2 (18.2%)	6 (31.6%)	8 (24.2%)	
Hybrid	6 (8.5%)	1 (25%)	0 (0%)	0 (0%)	2 (10.5%)	3 (9.1%)	
Pericardial drain	9 (12.7%)	0 (0%)	0 (0%)	1 (9.1%)	3 (15.8%)	5 (15.2%)	
Thrombin injection	4 (5.6%)	0 (0%)	1 (25%)	0 (0%)	1 (5.3%)	2 (6.1%)	

Data presented as n (%) of complications.
* One patient had two major VCs

Table 4: Outcomes for Patients with Vascular Complications

Variable	All Patients (n=1573)	No VC (n=1399)	Minor VC (n=77)	Major VC (n=96)	P-value
ΔHgb, pre vs post	2.1 ± 1.3	1.9 ± 1.2	2.3 ± 1.2	4.0 ± 1.5	<.001
RBC Transfusion	165 (10.5%)	96 (6.9%)	16 (20.8%)	53 (55.8%)	<.001
RBC units	0.3 (1.3)	0.2 (0.8)	0.7 (2.0)	2.2 (3.1)	<.001
ICU hours	31.2 ± 41	28.4 ± 34.6	43.6 ± 61.1	61.3 ± 77.9	<.001
Post-op LOS	3.6 ± 3.8	3.4 ± 3.1	4.5 ± 6.8	6.6 ± 7.2	<.001
Significant cardiac event‡	26 (1.7%)	2 (0.1%)	1 (1.3%)	23 (24.0%)	<.001
Stroke	29 (1.8%)	22 (1.6%)	2 (2.6%)	5 (5.2%)	0.028
Post-op wound infection	3 (0.2%)	1 (0.1%)	0 (0%)	2 (2.1%)	0.017
30-d all-cause readmit	162 (10.3%)	145 (10.4%)	9 (11.7%)	8 (8.3%)	0.753
30-d readmit for vascular reason	13 (0.8%)	3 (0.2%)	6 (6.5%)	5 (5.2%)	<.001
30-d mortality	42 (2.7%)	25 (1.8%)	2 (2.6%)	15 (15.6%)	<.001

Data presented as mean ± SD or n (%) of patients
* During index hospitalization, unless otherwise indicated
‡ Procedure-related significant cardiac event includes coronary compression or obstruction, annular dissection, aortic dissection or cardiac perforation
Hgb = hemoglobin, RBC = red blood cell, ICU = intensive care unit, LOS = length of stay, SD = standard deviation

Results 3

- VC patients had higher rates of blood transfusion, longer ICU and post-operative LOS, higher rates of significant cardiac event, stroke, wound infection, and 30-day mortality (Table 4)
- 30-day all-cause readmission was similar between VC groups, however 30-day readmission for a vascular reason was higher in the major and minor VC groups. (Table 4)
- 1-year survival was lower for patients with major VC. Majority of the death happened within 30-day of procedure. For patients who survived >30 days, 1-year survival did not differ between groups (Figure 1)
- Female gender, Hispanic ethnicity, prior PCI, prior PAD, CLD, TAVR access on right side and date of surgery were predictors of major VC. Every 90-day increase in the procedure date decreased the odds of having a major VC by 6% (p=0.012). (Table 5).
- For patients who survived >30 days, the predictors of one-year mortality were male gender, BMI <18.5, CLD, current home oxygen use, immunocompromised, and STS mortality risk score of surgical AVR. After adjusting for the above factors, experiencing a major or minor VC did not impact long-term survival (p=0.129 for minor VC vs. no VC; p=0.698 for major VC vs. no VC).

Table 5: Risk Factors for Major Vascular Complications

Major VC: multivariable regression model		
Variable	**OR (95% CI)**	**p-value**
Female	3.00 (1.91, 4.72)	<.001
Hispanic	3.04 (1.07, 8.69)	0.037
Prior PCI	2.14 (1.38, 3.31)	0.001
Prior PAD	1.65 (1.06, 2.55)	0.025
CLD, moderate or severe	1.61 (1.05, 2.46)	0.027
Laterality of TAVR access sheath, right	2.10 (1.26, 3.50)	0.004
Date of surgery, per 90-day increase	0.94 (0.90, 0.99)	0.012

* For patients who survived >30 days
‡ Immunosuppressive medication therapy, including systemic steroid therapy, inhaled steroid therapy, or preoperative protocol, within 30 days preceding the operative procedure
OR = odds ratio, CI = confidence interval, PCI = percutaneous coronary artery disease, PAD = periphery artery disease, CLD = chronic lung disease, HR = hazard ratio, STS = society of thoracic surgeons

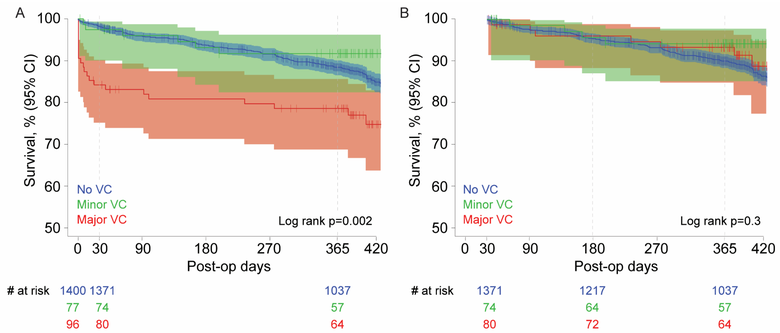

Figure 2 – Survival: One-year survival for all patients (A) and patients who survived greater than 30 days after TAVR (B).

Conclusions

Despite a reduction in the incidence of VCs in our multicenter experience, major VCs continue to be associated with significant perioperative morbidity and mortality. These findings reinforce the importance of patient and anatomic selection for TF-TAVR, as well as consideration of TAVR with alternative access for those with challenging iliofemoral access.

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