Transcatheter Aortic Valve Replacement With Percutaneous Coronary Intervention: Results From A Federal Facility

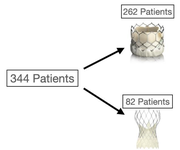
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ABSTRACT

Transcatheter aortic valve replacement (TAVR) has become the predominant treatment for patients with severe aortic stenosis of any surgical risk. Randomized clinical trials addressed isolated aortic stenosis treated by TAVR vs surgical aortic valve replacement (SAVR). However, patients with significant coronary artery disease are recommended for SAVR and coronary artery bypass grafting (CABG) over TAVR and percutaneous coronary intervention (PCI). We examined the outcomes of the subset of patients who underwent TAVR/PCI at a federal facility. Veterans Affairs Medical Centers (VAMC) are not required to submit TAVR outcomes to the Society of Thoracic Surgeons Transcatheter Valve Therapy registry, but instead report to VA databases for surgery and interventional cardiology. Therefore, limited TAVR/PCI data is available from VAMC. Using Valve Academic Research Consortium-3 (VARC-3) consensus statements, our objective was to evaluate outcomes of TAVR/PCI at a VA facility.

METHODS

As the 4th VAMC approved for TAVR, we retrospectively evaluated 335 TAVR patients since November 2013 for concomitant TAVR/PCI vs staged PCI. Standardized criteria of TAVR outcomes were used from the Valve Academic Research Consortium-3 (VARC-3) consensus statements. 344 patients evaluated, 262 Balloon-expandable valves, 82 self expanding valves.



VARC-3 Definitions Used, Outcomes within 30 days

-**Bleeding:**
- Type 1: Minor, noted by medical professional, no more than 1 u PRBC
- Type 2: Overt bleeding, 2-4 units or Hb drop 3-5 g/dL
- Type 3: Bleeding in critical organ (brain, spine, eye, pericardium, IM with compartment syndrome), of causing shock/ hypotension, or requiring reoperation/ intervention, transfusion 5 or more units, or >5 g/dL
- Type 4: bleeding that causes death (none in our cohort)

- CNS Injury:
- New criteria define as acute or subacute; we can group them together
- NeuroArc Type 1: All strokes, ischemic/ hemorrhagic or hypoxic-ischemic
- NeuroArc Type 2: Covert without signs/ symptoms (we can say no data for this)
- NeuroArc Type 3: Delirium or TIA (also no systematic data on delirium)

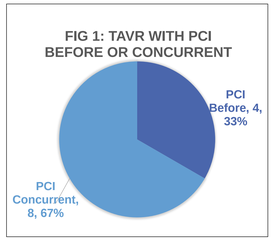
- AKI:
- Stage 1: Increase in Cr more than 1.5 – 2x baseline within 7 days, or increase of Cr > 0.3 within 48 hours.
- Stage 2: Increase in Cr 2 – 3 x baseline in 7 days
- Stage 3: Cr > 3x or Cr > 4.0 with increase of >0.5
- Stage 4: Already coded in our existing dataset; requiring HD.

- Vascular complications:
- Major: complications resulting in loss of limb, visceral ischemia, or permanent neurologic impairment or death
- Minor: injury not resulting in death or major impairment, unplanned Endovascular or surgical intervention, closure device failure

RESULTS

TABLE 1

	All Patients (n=344)	TAVR (n=332)	TAVR/PCI (n=12)
Age at TAVR (Yrs)	78	77.8	79
Male	336	329	12
Body Mass Index (Kg/m²)	28	28.8	27.5
STS Risk Score	3.93%	3.90%	4.60%
Hypertension	312 (90.7%)	300 (89.2%)	12 (100%)
Diabetes Mellitus	149 (43.3%)	145 (43.2%)	4 (33%)
Prior Myocardial Infarction	87 (25.3%)	82 (24.4%)	5 (42%)
Prior Percutaneous Coronary Intervention	108 (31.4%)	99 (29.8%)	9 (75%)
Chronic Lung Disease			
None	270 (78%)	200 (60%)	10 (83%)
Mild	37 (10.8%)	68 (20.5%)	2 (17%)
Moderate	32 (9.3%)	37 (11.1%)	0
Severe	4 (1.1%)	32 (9.6%)	0
Previous Cerebrovascular Accident	26 (7.6%)	23 (6.9%)	3 (25%)
Peripheral Artery Disease	71 (20.6%)	67 (19.9%)	3 (25%)
New York Heart Association Class			
III	284 (82%)	273 (82%)	11 (92%)
IV	19 (5.5%)	18 (5.4%)	1 (8.3%)



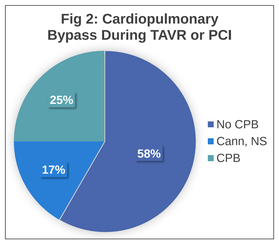


TABLE 2

Patient	PCI Timing (Days Prior to TAVR)	PCI Targets	CPB	Valve	Hospital Stay
1	54	LAD	NO	Balloon Exp.	6
2	3	RI	NO	Balloon Exp.	2
3	6	LAD, RCA	NO	Balloon Exp.	2
4	49	LM, LCX, Diag, OM	YES	Balloon Exp.	5
5	0	LM, LCX.	YES	Self Exp.	8
6	0	LM-LAD, RCA, LCX	YES	Self Exp.	6
7	0	LM	Not Supported	Balloon Exp.	3
8	0	LM, LAD	Not Supported	Balloon Exp.	3
9	0	LCx	NO	Balloon Exp.	2
10	0	LAD	NO	Balloon Exp.	5
11	0	LCx	NO	Self Exp.	13
12	0	RCA	NO	Self Exp.	3

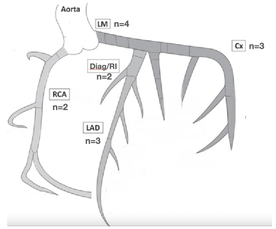
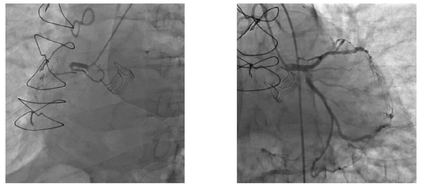


Fig 3: Total number of targets for percutaneous coronary interventions.

TABLE 3

	% (n=12)
STS Score (Mort %)	4.6%
STS Low <4	50% (6)
STS Int 4-8	41.7% (5)
STS Hi >8	8.3% (1)
VARC-3 Bleeding	66.7% (8)
Bleeding 1	25% (3)
Bleeding 2	41.7% (5)
Bleeding 3	0% (0)
VARC-3 AKI	16.7% (2)
AKI 1	16.7% (2)
AKI 2	0% (0)
AKI 3	0% (0)
AKI 4	0% (0)
VARC-3 Vasc-Minor	8.3% (1)
Major CVA	0% (0)
Average LOS (days)	4.8



RCA LCA

Fig 5: A representative coronary angiography from a patient with a RCA CTO and occluded SVG to RCA, who underwent CPB supported PCI to LM-LCx during TAVR procedure.

RESULTS

- There were no major bleeding, AKI or vascular complications with TAVR/PCI
- Average LOS was 4.8 days
- No 30 day mortality was associated with TAVR and PCI

CONCLUSIONS

- Patients with PCI to LM tended to be cannulated for CPB, but not all required support
- CPB tended to be used with multi-vessel PCI including LM and/or LAD

CONCLUSIONS

- Multiple PCI can be safely performed concomitantly with TAVR
- Cardiopulmonary bypass can be safely used in complex PCI and TAVR

FUTURE DIRECTIONS

- Understanding the complexities of TAVR with PCI will help guide future decision making between TAVR/PCI vs. SAVR/CABG
- Additional data collection will help determine which TAVR/PCI patients most benefit from cardiopulmonary bypass support

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DISCLOSURES

Elaine Tseng and Liang Ge: Founders and major shareholders of Revalve Med, Inc.
RR, AG, KS, JZ: No disclosures