Vascular Complications Associated with Transfemoral Aortic Valve Replacement

George L. Hines, MD¹ Vita Jaspan¹ Brian J. Kelly, MD² Rose Calixte, PhD³

¹Department of Thoracic and Cardiovascular Surgery, Winthrop University Hospital, Mineola, New York

²Department of Surgery, SUNY-Stony Brook, Stony Brook, New York

³Department of Biostatistics, Winthrop University Hospital, Mineola, New York

Address for correspondence: George L. Hines, MD, Division of Vascular Surgery, Winthrop University Hospital, Mineola, NY 11501 (e-mail: ghines@winthrop.org).

Int J Angiol 2016;25:99–103.

Abstract

Background Transfemoral aortic valve replacement (TAVR) is a novel technique for treating aortic stenosis, yet vascular complications are yet to be delineated.

Objectives This study aims to study the vascular complications of TAVR with Edwards Sapien valves (Edwards Lifesciences Corp., Irvine, CA).

Methods We performed a retrospective evaluation of TAVR patients. Standard demographics, femoral vessel and sheath size, access type (femoral cut-down [FC], percutaneous access [PFA], and iliac conduit [IC]), and treatment method were recorded. Complications were defined by the Valve Academic Research Consortium Criteria. Logistic regression was used for statistical analysis.

Results A total of 99 patients underwent TAVR between February 15, 2012 and July 17, 2013 with an Edwards Sapien valve. Out of which, 48 were males with a mean age of 83 ± 7 years. Overall, 33 had FC, 58 had PFA, and 6 had an IC. A total of 17 major (2 aortic and 15 iliac) and 38 minor complications (36 access and 2 emboli) occurred. Aortic complications were managed by open repair (OR, 1) or percutaneous repair (PR, 1). Overall, 12 iliac injuries were managed by PR and 3 by OR. Out of the 33 groin complications in FC patients 8 (24%) were treated by OR, whereas 30 (52%) of the 58 groin complications in PTA patients were treated by PR. There were no differences in transfusion requirements or length of stay.

Conclusion Vascular complications of TAVR are common with most being minor, related to access site and causing no immediate sequelae. Iliac injury can be managed by PR or OR. Aortic injury is associated with significant mortality. These findings increase vascular surgeons' awareness of these complications and how to manage them.

Keywords

- aortic valve disease
- artery
- cardiovascular disease
- cardiac device
- dissection
- endovascular procedure
- percutaneous

Transfemoral aortic valve replacement (TAVR) was first used in man in 2002.¹ It was initially introduced as a less invasive procedure than open aortic valve replacement (AVR) in extremely high risk patients. Since then, multiple single-center studies, and both national and international registries have confirmed the efficacy of TAVR in high-risk patients.^{2–4} The placement of aortic transcatheter valves (PARTNER trial) cohort A + B trial has verified the efficacy of TAVR in patients

with severe aortic stenosis and a high or prohibitive surgical risk. Further studies have also suggested its effectiveness in less high-risk patients.⁵

Initially, TAVR was only possible through femoral or iliac artery access. This required the use of large sheaths placed through frequently diseased and tortuous iliac vessels. The incidence and definition of vascular injuries was initially not standardized. In 2011, the Valve Academic Research

Consortium (VARC) published guidelines to better define and standardize the various complications of TAVR.⁶ One set of criteria dealt with vascular injuries. Vascular injuries were defined as major or minor by VARC criteria. TAVR was first employed at Winthrop University Hospital in February 2012 when this procedure first became clinically available.

We reviewed our experience with the TAVR procedure with specific focus on vascular complications. Included in this review were overall complication rates, risk factors for vascular complications and survival with major and minor complications. Transapical TAVR was not available commercially during the time of this study.

Methods

We performed a retrospective review of a prospectively maintained database of all patients who underwent a transfemoral TAVR placement from February 2012 to July 2013. Data collected included age, sex, history of coronary artery disease, end stage renal disease, smoking, iliac artery size (mm), and sheath size. All patients, by protocol, underwent a computed tomographic scan angiogram of the thoracic, abdominal, iliac, and femoral arteries to determine size, tortuosity, and calcification of access vessels. Films were reviewed by an interventional cardiologist and cardiac surgeon to determine adequacy of vascular access. All procedures were performed in a hybrid cardiac catheterization laboratory. The access vessel for the procedure was chosen at the surgeon's discretion based on appropriateness for large sheath access.

All procedures were performed with Edwards Sapien (Edwards Lifesciences Corp., Irvine, CA) in this review. Sheath sizes varied from 22 to 24F. An attempt was made to use common femoral artery (CFA) access in all patients where appropriate. All procedures were performed under general anesthesia with intra-arterial and pulmonary artery monitoring. Anesthesia was given by "cardiac" anesthesiologists.

Early in this study, femoral access for the main body device was obtained through open access. A longitudinal skin incision was made by isolation of the CFA, superficial femoral, and profunda femoris arteries. A 4–0 Prolene purse-string suture (Ethicon Inc., Somerville, NJ) was placed and vascular access obtained. The purse-string suture was tied when the sheath was removed. If bleeding or loss of a distal pulse was present after sheath removal, a localized reconstructive procedure was employed to control bleeding or reestablished distal flow. If there was uncertainty as to the status of the CFA, an angiogram was performed via the contralateral femoral artery.

Later in our experience, percutaneous access was chosen when the vessel was deemed satisfactory for percutaneous closure. Closure was performed by using 3-proglide (Abbott Laboratories, Redwood City, CA) sutures placed before sheath placement. All sites closed percutaneously were imaged via the up and over the catheter. If there was extravasation, stenosis, or dissection, it was treated with a stent (either bare metal or covered).

In the subset of patients where the femoral artery was not considered compatible with safe access an iliac conduit, consisting of a separate graft being sewn onto the iliac artery and that graft being used as an access point, was used. Iliac conduits were performed utilizing a standard retroperitoneal incision. If an iliac artery or aortic injury occurred, an initial attempt at endovascular management was attempted. If this was unsuccessful, an open repair was performed. Patients were monitored postoperatively in a cardiothoracic surgical intensive care unit for at least 24 hours.

Vascular complications were graded as defined by the VARC. According to these criteria, major complications included any of the following: (1) thoracic aortic dissection, or (2) access site or access-related vascular injury leading either to death, greater than four units' transfusion requirement, or irreversible end organ damage and distal embolization from a vascular source requiring surgery or resulting in amputation or irreversible end organ damage.

Minor complications included the following: (1) access site or access-related vascular injury requiring less than two units transfusion, not requiring unplanned percutaneous or surgical intervention and not resulting in irreversible end organ damage. (2) Distal embolization treated by thrombectomy or embolectomy and not resulting in amputation or end organ damage. (3) Failure of percutaneous access site closure requiring either interventional or surgical correction but not associated with greater than four units of transfusion, death, or irreversible end organ damage.

Statistics

A logistic regression was used to test for an association between complications and patients' demographics and clinical characteristics. A *p* value of ≤ 0.05 was considered statistically significant. All analyses were done in SAS 9.2 (SAS Institute Inc., Cary, NC).

Results

A total of 99 patients underwent TAVR between February 15, 2012 and July 17, 2013. There were 48 males and 51 females. Mean age was 83 ± 7 years. Overall, 56 patients had a history of hypertension, 25 had a history of coronary artery disease, 35 had borderline renal insufficiency, 38 had chronic obstructive pulmonary disease, and 38 had diabetes mellitus. The Edwards Sapien valve was employed in all patients. The device was placed through an open femoral access in 33 patients, percutaneous access in 58 patients, and an iliac conduit in 6 patients.

A total of 55 vascular complications occurred, 17 major and 38 minor, in separate patients. The major complications included 2 aortic and 15 iliac injuries. Overall, 17% of the patients were affected by a major complication representing 31% of all the complications. Of the 38 minor complications, there were 36 femoral access site complications and 2 embolic complications.

The two aortic complications occurred in patients who had undergone an iliac conduit for access. Of the 15 iliac

complications, 6 were in patients who had an iliac conduit, 6 in patients who had percutaneous access, and 3 patients with open femoral access. Femoral complications occurred in 6 patients with open access (18%), 1 patient who had an iliac conduit, and 29 patients who had percutaneous access. The two embolic complications occurred in patients who had percutaneous access.

The aortic injury was treated with open repair in one patient and endovascular repair with a covered stent (CS) in one patient. Iliac injuries included both dissections and perforations. Three patients underwent emergent open repair, seven were treated with bare metal stents (BMSs), and five patients were treated with CSs. Eight patients developed access site complications after open access. Each of these patients was treated with open repair consisting of endarterectomy and patch angioplasty with bovine pericardium. A total of 30 patients developed complications after percutaneous access. These complications consisted of dissection, bleeding, or occlusion after percutaneous access. Each of these patients underwent endovascular repair with either CSs (20) or BMS (10). Several patients had more than one stent placed. There were a total of five perioperative deaths, deaths occurring within 30 days (5%). Two of these had no vascular injuries.

On univariate logistic regression, advancing age was the only predictor of vascular complications. A 1 year increase with age resulted in a 7% increase in the rest of complications (► **Table 1**). Iliac artery size in patients experiencing iliac complications was 8.1 ± 0.85 cm and was 8.5 ± 1.5 cm in those without complications. Percutaneous access predicted the development of femoral artery access complication ($p = 0.003$) by chi-square analysis.

The two patients with aortic injuries died perioperatively. One patient with an iliac injury expired perioperatively. No deaths were attributed to a groin complication.

Discussion

TAVR has been demonstrated to be an effective treatment modality for patients with severe aortic valve disease. Originally applied to patients thought to be too high risk for standard open surgery, its use is now being expanded to encompass less medically compromised patients.

Table 1 Association of risk factors with any vascular complication

Parameter	Patients (N)	p value
Hypertension	56	0.7673
Hypercholesterolemia		0.7909
Diabetes mellitus	38	0.8019
Chronic obstructive pulmonary	38	0.5427
Renal insufficiency	35	0.9347
Coronary artery disease	25	0.6504
Size of Iliac artery		0.5125

Vascular complications encountered during TAVR should be comparable to those encountered in other endovascular procedures where large sheaths are inserted into calcified, diseased, and tortuous access vessels.⁷

Généreux et al,⁸ in a review of vascular complications from the PARTNER trial, using VARC criteria, reported a major complication rate of 15.3% and a minor complication rate of 11.9% within 30 days in 419 patients. Major complications were associated with increased 30-day and 1-year mortality. The only predictor of major vascular complications was female gender.

Mwipatayi et al,⁹ in a single-center study reported on 100 TAVR patients recruited during the 3-year period (2009–2012). Overall, 81 of their patients underwent transfemoral approach and 18 transapical. In the transfemoral group, 16 vascular complications occurred (9 major and 7 minor). These included aortic dissection, femoral dissection, iliac artery rupture, distal embolization, and false aneurysms. Although, on their review, vascular injury was associated with increased transfusion requirements, length of stay and cost, it was not associated with an increase in either 30-day or 1-year mortality.

Ducrocq et al,¹⁰ reviewed their experience in 54 patients undergoing transfemoral Sapien valve implantation between 2006 and 2009. They experienced nine (16.7%) vascular complications. These included five ruptures (9.3%) which required open surgical repair and four iliac dissections, two of the iliac dissections were treated endovascularly and two required open repair.

Hayashida et al,¹¹ reported vascular complications 27.6% of the patients undergoing transfemoral TAVR (17.3% major and 10.2% minor). Major vascular complications, predicted 30-day mortality (22.7 vs. 7.6%, $p = 0.049$). Sheath-to-femoral artery ratio, center experience, and femoral calcification predicted major complications by multivariate analysis.

Percutaneous endovascular aneurysm repair (PEVAR) rather than open femoral exposure, was more recently introduced.^{12,13} The use of this technique requires the use of closure devices. Successful use of this technique requires accurate preoperative and intraoperative duplex assessment of the puncture site to determine the amount and location of calcium plaques.¹⁴

Manunga et al,¹⁵ reviewed percutaneous access in 391 arteries undergoing percutaneous access for endovascular aneurysm repair. Sheath sizes ranged from 12 to 24F. Patients with > 50% anterior femoral vessel calcification or prior femoral surgery were excluded from PEVAR. They had a technical success rate of 96.4%. There were 14 intraoperative failures managed with open femoral exposure requiring either primary repair (5 patients) or patch angioplasty (9 patients). They found that the extent of femoral artery calcification was the major determinant of failure.

Van Mieghem et al,¹⁶ reviewed the databases of 5 European centers to evaluate access site complications in 986 patients. Overall, 803 patients (81%) underwent percutaneous closure and 183 patients (19%) had open femoral exposures. In their entire series 14.2% of patients had major vascular complications, 11% life threatening bleeding, and

17.8% major bleeding. In the patient group, who underwent percutaneous access, most instances of major vascular complications and life-threatening or significant bleeding were due to closure device failure in 64 and 29% of patients. In their multivariate analysis, they determined female sex and sheath size to be important determinants of failure.

Kahlert et al,¹³ in 2009 reported on 101 patients who underwent TAVR. Overall, 33 patients underwent transapical repair, 8 transfemoral TAVR with surgical access or closure, and 60 patients had percutaneous transfemoral TAVR. Out of the 60 percutaneous patients 59 had successful deployment, but access site complications occurred in 19 patients (32%). These included retroperitoneal hematoma in 2, iliac or femoral dissection in 10, pseudoaneurysm formation in 3, and closure device vessel stenosis in 6. Six patients required open repair, five required no specific therapy, and eight were treated by contralateral endovascular methods.

The incidence of major vascular injuries reported in our series is similar to that reported in the literature. There were 2 aortic injuries and 15 iliac injuries.

With multivariate analysis, increasing age was the only factor associated with vascular injury.

The number of major injuries is most probably related to the fact that in this series, only transfemoral access was available as transapical valves were not commercially available. Therefore, patients who might have been suboptimal candidates for a transfemoral approach underwent the procedure and were treated via femoral access. The complications will probably decrease as the smaller sheath size is employed and more transapical procedures are used for patients with unfavorable anatomy.

There were significantly more minor complications with percutaneous access than with open access. Overall, 24% of open access and 52% of percutaneous access patients developed minor complications. The open group was treated by localized endarterectomy or patch repair. In the percutaneous group, all closures were angiographically visualized before completion of the procedure. Any evidence of localized dissection or extravasation was treated by a BMS or CS, respectively. In retrospect, it is not entirely clear that all patients with access complications in the percutaneous group, who were diagnosed radiographically, would have developed clinical findings. Furthermore, there is a well-documented learning curve in the utilization of percutaneous access in procedures requiring large endovascular sheaths. It is likely that the complication rates would decrease as with progression along the learning curve.

Patients found to have dissection and extravasation undergoing percutaneous access required insertion of BMS and CSs in the distal external iliac artery and the CFA. Although none of the patients in this group have developed clinically significant lower extremity ischemia because of stent stenosis, thrombosis, or embolization, long-term follow-up is not available. Further follow-up is required to determine the long-term effect of stents in the area of the inguinal ligament.

Conclusion

In our experience using the first commercially available transfemoral aortic valves, vascular complications occurred in a large percentage of patients. A total of 17 major (15 iliac and 2 aortic) and 38 minor complications occurred. Aortic injuries were associated with death. Minor complications were generally associated with femoral access issues and were most frequently seen after percutaneous access.

The introduction of smaller sheath sizes and the use of transapical valve insertion will probably decrease the number of vascular complications in patients with less favorable anatomy.

References

- 1 Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002; 106(24):3006–3008
- 2 Kodali SK, Williams MR, Smith CR, et al; PARTNER Trial Investigators. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med* 2012;366(18): 1686–1695
- 3 Généreux P, Head SJ, Van Mieghem NM, et al. Clinical outcomes after transcatheter aortic valve replacement using valve academic research consortium definitions: a weighted meta-analysis of 3,519 patients from 16 studies. *J Am Coll Cardiol* 2012;59(25):2317–2326
- 4 Leon MB, Smith CR, Mack M, et al; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363(17):1597–1607
- 5 Webb JG, Wood DA. Current status of transcatheter aortic valve replacement. *J Am Coll Cardiol* 2012;60(6):483–492
- 6 Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for Transcatheter Aortic Valve Implantation clinical trials: a consensus report from the Valve Academic Research Consortium. *J Am Coll Cardiol* 2011;57(3):253–269
- 7 Vandy FC, Girotti M, Williams DM, et al. Iliofemoral complications associated with thoracic endovascular aortic repair: frequency, risk factors, and early and late outcomes. *J Thorac Cardiovasc Surg* 2014;147(3):960–965
- 8 Généreux P, Webb JG, Svensson LG, et al; PARTNER Trial Investigators. Vascular complications after transcatheter aortic valve replacement: insights from the PARTNER (Placement of AoRTic TraNscatheter Valve) trial. *J Am Coll Cardiol* 2012;60(12):1043–1052
- 9 Mwiipatayi BP, Picardo A, Masilonyane-Jones TV, et al. Incidence and prognosis of vascular complications after transcatheter aortic valve implantation. *J Vasc Surg* 2013;58(4):1028–36.e1
- 10 Ducrocq G, Francis F, Serfaty JM, et al. Vascular complication of transfemoral aortic valve implantation with the Edwards SAPIEN prosthesis: incidence and impact on outcome. *EuroIntervention* 2010;5(6):666–672
- 11 Hayashida K, Lefèvre T, Chevalier B, et al. Transfemoral aortic valve implantation new criteria to predict vascular complications. *JACC Cardiovasc Interv* 2011;4(8):851–858
- 12 Hayashida K, Lefèvre T, Chevalier B, et al. True percutaneous approach for transfemoral aortic valve implantation using the Prostar XL device: impact of learning curve on vascular complications. *JACC Cardiovasc Interv* 2012;5(2):207–214
- 13 Kahlert P, Al-Rashid F, Weber M, et al. Vascular access site complications after percutaneous transfemoral aortic valve implantation. *Herz* 2009;34(5):398–408

- 14 Mousa AY, Campbell JE, Broce M, et al. Predictors of percutaneous access failure requiring open femoral surgical conversion during endovascular aortic aneurysm repair. *J Vasc Surg* 2013;58(5):1213–1219
- 15 Manunga JM, Gloviczki P, Oderich GS, et al. Femoral artery calcification as a determinant of success for percutaneous access for endovascular abdominal aortic aneurysm repair. *J Vasc Surg* 2013;58(5):1208–1212
- 16 Van Mieghem NM, Tchetché D, Chieffo A, et al. Incidence, predictors, and implications of access site complications with transfemoral transcatheter aortic valve implantation. *Am J Cardiol* 2012;110(9):1361–1367