Comparative Outcomes of Alternative Access Site Versus Lithotripsy-Assisted Transfemoral Transcatheter Aortic Valve Replacement: A Single-Center Retrospective Study

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Abstract

Background: Transcatheter aortic valve replacement (TAVR) has emerged as a primary therapeutic option for patients with severe aortic stenosis across all surgical risk categories. Alternative access site (AAS) routes are often used in patients unsuitable for standard transfemoral (TF) approach, though intravascular lithotripsy (IVL) provides novel remedies to traditionally "unsuitable" patients. The objectives of our study were to compare outcomes between AAS TAVR placement and lithotripsy-assisted TF TAVR.

Methods: The authors analyzed 60 patients who underwent TAVR between 2019 and 2022 (41 with alternative access, 19 with lithotripsy) at a single US site. Primary outcomes included procedural success, adverse events at 1 month and 1 year, length of stay, and 3-year mortality.

Results: The data trended towards higher 1-month adverse outcomes in the alternative access patients compared to TF lithotripsy patients (17.1% (95% confidence interval (CI): 8.5% - 31.3%) vs. 0% (95% CI: 0.0% - 16.8%); P = 0.09), while 1-year adverse outcomes were similar (AAS 12.2% (95% CI: 5.3% - 25.5%) vs. IVL 15.8% (95% CI: 5.5% - 37.6%); P = 0.70), and 3-year mortality (19.5% vs. 21.1%) were similar between groups. Median length of stay was 3 days for both groups.

Conclusions: Lithotripsy-assisted TF TAVR demonstrated a statistically insignificant trend toward short-term major adverse events with comparable 1-year morbidity and 3-year mortality to alternative access approaches. These findings may support lithotripsy as a viable option for patients with challenging vascular anatomy rather than the more traditional use of AAS in these settings. However, more extensive research is necessary for appropriate statistical power to prove superiority rather than equivocality alone.

Keywords: TAVR; Alternative access; Lithotripsy; Vascular complications; Structural heart intervention

Introduction

Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of severe aortic stenosis, with the transfemoral (TF) approach preferred due to its established safety profile and superior outcomes compared to surgical aortic valve replacement [1-3]. However, severe peripheral artery disease, small vessel diameter, or excessive tortuosity can preclude TF access in roughly 5-15% of patients [4, 5]. Two strategies have emerged for these challenging cases: alternative access sites (AAS; transcarotid, transcaval, transapical, direct aortic, etc.) and intravascular lithotripsy (IVL) of the aortoiliac arterial system to preserve TF access [6, 7]. IVL uses sonic pressure waves to fracture calcified plaques, potentially restoring vessel compliance, facilitating large-bore access [8, 9].

Recent registry data demonstrate both approaches are feasible, with alternative access showing acceptable outcomes and lithotripsy enabling TF TAVR in over 90% of attempted cases [10, 11]. However, despite growing adoption of both techniques, no direct comparative data exist to guide clinical decision-making. A recent large US database study specifically identified the absence of direct comparative data and called for studies delineating optimal use criteria for IVL-TAVR versus alternative access [12]. This study provides the first head-to-head comparison of these approaches, offering real-world outcome data to inform multidisciplinary heart team decisions.

Materials and Methods

This single-center, retrospective study was conducted within

the Geisinger Health System. We reviewed data from patients who underwent TAVR between 2019 and 2022. Patients were included if they received either AAS TAVR or lithotripsy-assisted TF TAVR due to challenging iliofemoral anatomy that precluded standard TF access, following evaluation and procedural selection at discretion of the multidisciplinary heart team, consisting of interventional cardiology, cardiac surgery, advanced imaging, and anesthesiology.

Patients were categorized into two groups: 1) AAS group: patients who underwent TAVR via transapical, direct aortic, transcarotid, transaxillary, or trans-subclavian approaches; and 2) Lithotripsy group: patients who underwent TF TAVR after IVL preparation of the iliofemoral vessels. No crossover cases occurred where lithotripsy failed requiring bailout alternative access.

Procedural stratification and selection for IVL vs. AAS was individualized and performed following initial evaluation of suitability for surgical aortic valve replacement (SAVR) vs. TAVR, based on patient needs and characteristics. Salient anatomic findings of pre-procedural imaging were a primary stratification tool and included at least a standardized transthoracic echocardiography, contrast-enhanced, electrocardiogram (ECG)-synchronized computed tomography (CT) for annular sizing, coronary height and sinus dimensions, and iliofemoral access assessment, including minimum lumen diameter, calcium burden and distribution, and tortuosity, in accordance with professional-society guidance [13, 14]. These were taken alongside the results of routine assessment of frailty by experienced providers using validated tools, patient comorbidity, and patient preference.

Following selection for TAVR, patients underwent IVL-assisted TF access when CT showed focal or segmental, near-circumferentially calcified lesions that would otherwise preclude safe large-bore sheath passage without modification. TF access was preferred, and an alternative access method was chosen only when disease was diffuse or throughout a long vascular segment, tortuosity was severe, or the anticipated post-modification lumen was likely to remain below recommended sheath requirements, per professional-society guidance [6, 15]. Vessel diameter, calcification severity, and tortuosity were not abstracted empirically in this study. The study cohort and group allocation are illustrated in Figure 1.

Primary operators performing these procedures were board-certified and fellowship-trained interventional cardiologists working alongside cardiothoracic surgeons across the Geisinger Health System. collectively, the operator group has performed > 2,000 TAVR procedures. Programmatic standards and credentialing align with the operator and institutional recommendations of the American Association for Thoracic Surgery (AATS)/American College of Cardiology (ACC)/Society for Cardiovascular Angiography and Interventions (SCAI)/ Society of Thoracic Surgeons (STS) for the performance of TAVR [16].

Primary outcomes included procedural success (successful valve deployment without conversion to surgery), adverse outcomes at 1 month and 1 year post-procedure, length of stay (LOS, total and post-procedure), and all-cause mortality at 3 years. Total LOS was defined as admission-to-discharge. Post-procedure LOS was defined *a priori* as the time from the

TAVR procedure timestamp to discharge. Adverse outcomes were defined as myocardial infarction, stroke, transient ischemic attack, need for pacemaker implantation, major bleeding, endocarditis, or major vascular complications according to Valve Academic Research Consortium-2 definitions.

Categorical variables were described using frequencies and percentages. Continuous variables were described using means and standard deviations for normally distributed data and medians and interquartile range (IQR) for non-normally distributed data. Comparisons between groups were performed using Fisher's exact test or Chi-square test for categorical variables, as appropriate. For continuous variables, *t*-tests were used for normally distributed data and Wilcoxon rank-sum tests for non-normally distributed data. P values < 0.05 were considered statistically significant. For binary outcomes (30-day and 1-year adverse events, 30-day rehospitalization, and 3-year all-cause mortality), two-sided 95% confidence intervals (CIs) were calculated using Wilson score intervals with continuity correction to handle small samples and extreme proportions. Given the small sample and low event counts, multivariable or propensity modeling was considered underpowered and at risk of overfitting and was not performed. All analyses were performed using SAS Enterprise Guide (SAS Institute Inc., Cary, NC, USA).

This study was conducted in compliance with the ethical standards of the Helsinki Declaration and the responsible institution on human subjects. The Institutional Review Board (IRB) at Geisinger Medical Center approved the study and waived the requirement for individual patient consent due to the retrospective nature of the study.

Results

Patient characteristics

The study included 60 patients: 41 in the AAS group and 19 in the lithotripsy group. Mean age was similar between groups (AAS: 77.3 ± 7.83 years; lithotripsy: 78.1 ± 6.92 years; P = 0.69). Both groups showed a male predominance (AAS: 68.3%; lithotripsy: 73.7%). All patients were White. Baseline characteristics and outcomes are summarized in Table 1. The study cohort allocation is illustrated in Figure 1.

LOS

The median total LOS was 3 days for both groups (IQR: 2 - 6 days for AAS, 1 - 11 days for lithotripsy; P = 0.72). The median post-procedure LOS was 2 days for both groups (IQR: 1 - 3 days; P = 0.37).

Short-term outcomes

At 1 month post-procedure, the AAS group showed a trend toward higher adverse outcomes compared to the lithotripsy group (AAS 17.1% (95% CI: 8.5% - 31.3%) vs. IVL 0% (95%
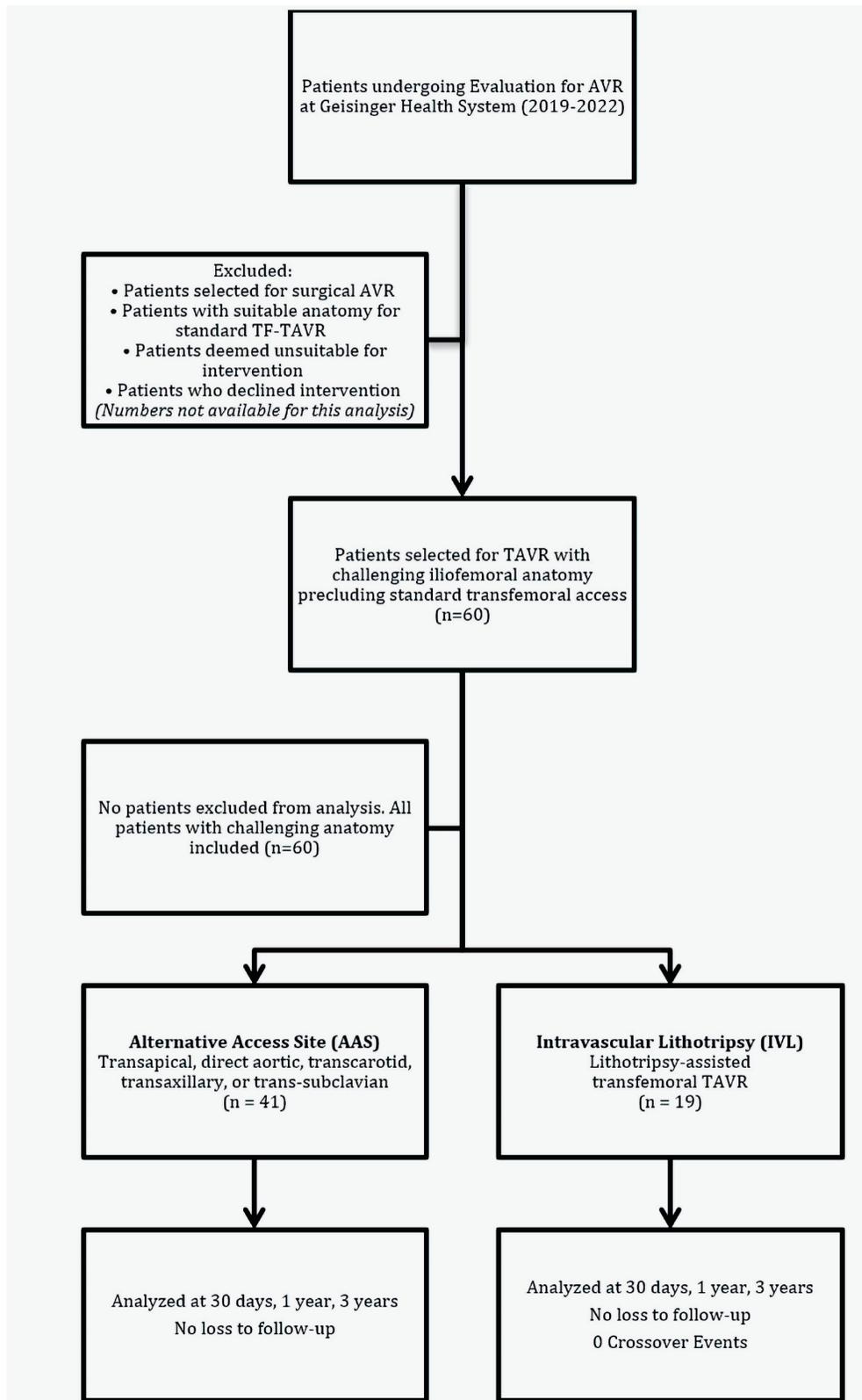
Figure 1. STROBE flow diagram demonstrating cohort derivation, group allocation, and follow-up completion for the comparative analysis of alternative access site versus lithotripsy-assisted transfemoral TAVR. TAVR: transcatheter aortic valve replacement; TF: transfemoral.

Table 1. Baseline Characteristics and Outcomes of Alternative Access Site (AAS) Versus Lithotripsy-Assisted Transfemoral TAVR

	Treatment		P value
	AAS (n = 41)	Lithotripsy (n = 19)	
Demographic information			
Age, mean (SD)	77.3 (7.83)	78.1 (6.92)	0.69[a]
Gender, n (%)			0.77[b]
Female	13 (31.7%)	5 (26.3%)	
Male	28 (68.3%)	14 (73.7%)	
Race, n (%)			
White	41 (100.0%)	19 (100.0%)	
Procedure location, n (%)			
GCMC	1 (2.4%)	8 (42.1%)	
GMC	31 (75.6%)	5 (26.3%)	
GWV	9 (22.0%)	6 (31.6%)	
Outcomes			
Total length of stay (days), median (IQR)	3 (2, 6)	3 (1, 11)	0.72[c]
Length of stay after procedure (days), median (IQR)	2 (1, 3)	2 (1, 3)	0.37[c]
Adverse outcomes, 1 month, n (%)			0.09[b]
No	34 (82.9%)	19 (100%)	
Yes	7 (17.1%)	0 (0.0%)	
Major vascular complication	1 (2.4%)	0 (0.0%)	
Major bleeding	2 (4.9%)	0 (0.0%)	
New pacemaker	2 (4.9%)	0 (0.0%)	
Paravalvular leak	1 (2.4%)	0 (0.0%)	
Stroke, major vascular complication	1 (2.4%)	0 (0.0%)	
Adverse outcomes, 1 year, n (%)			0.70[b]
No	36 (87.8%)	16 (84.2%)	
Yes	5 (12.2%)	3 (15.8%)	
MI	2 (4.9%)	2 (10.5%)	
Major bleeding	1 (2.4%)	1 (5.3%)	
New pacemaker	1 (2.4%)	0 (0.0%)	
Unknown	1 (2.4%)	0 (0.0%)	
Repeat hospitalization (30 days), n (%)			0.49[b]
No	34 (82.9%)	14 (73.7%)	
Yes	7 (17.1%)	5 (26.3%)	
Acute respiratory failure	1 (5.3%)	0 (0.0%)	
Aspiration pneumonia	0 (0.0%)	1 (10.0%)	
Clostridium difficile	1 (5.3%)	0 (0.0%)	
Chest pain (deemed noncardiac)	1 (5.3%)	0 (0.0%)	
Dyspnea related to worsening HF	1 (5.3%)	0 (0.0%)	
Endocarditis	0 (0.0%)	1 (10.0%)	
Femur fracture from osteoporosis	0 (0.0%)	1 (10.0%)	
GI bleed	0 (0.0%)	1 (10.0%)	
Hemorrhagic shock (GI)	1 (5.3%)	0 (0.0%)	
Pulmonary embolism	0 (0.0%)	1 (10.0%)	
Sepsis (pneumonia)	1 (5.3%)	0 (0.0%)	
Pseudoaneurysm from procedure, new AFIB	1 (5.3%)	0 (0.0%)	
Cause of death, n (%)			0.15[d]
Not cardiovascular	5 (12.2%)	0 (0.0%)	
Cardiovascular	3 (7.3%)	4 (21.1%)	
Alive	31 (75.6%)	15 (78.9%)	
Unknown	2 (4.9%)	0 (0.0%)	

[a]Unequal variance two sample *t*-test; [b]Fisher exact P value; [c]Wilcoxon rank sum P value; [d]Chi-square P value. IQR: interquartile range; TAVR: transcatheter aortic valve replacement; GCMC: Geisinger Community Medical Center; GMC: Geisinger Medical Center; GWV: Geisinger Wyoming Valley; HF: heart failure; MI: myocardial infarction; GI: gastrointestinal; AFIB: atrial fibrillation.

CI: 0.0% - 16.8%); P = 0.09). Adverse outcomes in the AAS group included significant vascular complications (2.4%), major bleeding (4.9%), new pacemaker insertion (4.9%), paravalvular leak (2.4%), and stroke with major vascular complication (2.4%). Event counts by category are shown in Table 1.

Long-term outcomes

At 1 year post-procedure, adverse outcome rates were similar between groups (AAS 12.2% (95% CI: 5.3% - 25.5%) vs. IVL 15.8% (95% CI: 5.5% - 37.6%); P = 0.70).These included myocardial infarction (AAS: 4.9%, lithotripsy: 10.5%), major bleeding (AAS: 2.4%, lithotripsy: 5.3%), and new pacemaker insertion (AAS: 2.4%, lithotripsy: 0%), as outlined in Table 1.

Mortality

Three-year all-cause mortality rates were similar (AAS: 19.5% (95% CI: 10.2% - 34.0%) vs. lithotripsy: 21.1% (95% CI: 8.5% - 43.3%)). In the lithotripsy group, all deaths were cardiovascular-related, while in the AAS group, only 37.5% of deaths were cardiovascular-related.

Repeat hospitalization

The 30-day repeat hospitalization rate was 17.1% (95% CI: 8.5% - 31.3%) for the AAS group and 26.3% (95% CI: 11.8% - 48.8%) for IVL (P = 0.49).

Discussion

This study represents the first direct comparison of AAS TAVR and lithotripsy-assisted TF TAVR, addressing a critical knowledge gap identified, but not previously addressed, in recent literature [12]. Our real-world analysis demonstrates that both approaches achieve excellent procedural success with comparable intermediate-term outcomes, while revealing interesting patterns in short-term complications.

The observation of fewer 30-day adverse events in the IVL-TF group (0% (95% CI: 0.0% - 16.8%)) versus the AAS group (17.1% (95% CI: 8.5% - 31.3%)) did not reach statistical significance and should be viewed as hypothesis-generating. These patterns are consistent with broader evidence that, when feasible, preserving TF access is associated with favorable early outcomes in meta-analyses comparing femoral versus non-femoral access [17, 18], and with registry data reporting low early-event rates after IVL-TF-TAVR [11]. Our 2.4% rate of major vascular complications in alternative-access cases mirrors early TF series that reported 3% to 4% vascular injuries despite smaller introducer sheaths [19]. However, it is important to note that the 30-day rehospitalization rate was numerically higher in the lithotripsy group (26.3% vs. 17.1%), suggesting a more complex short-term risk-benefit profile than initially apparent.

The convergence of outcomes at 1 year with similar event rates in both cohorts supports both strategies as viable long-term options for patients with challenging anatomy [18], though the level of confidence in calling the techniques equivalent prescriptively remains limited, given our investigation's limitations. In line with longer-term literature across device platforms and with comparisons of TAVR to SAVR, durable outcomes likely reflect multiple influences - including patient selection, anatomic considerations, and operator/program experience - rather than access strategy alone [20, 21]. In this context, IVL-assisted TF can be considered a reasonable strategy to preserve TF access in borderline anatomy, while larger, adjusted studies are needed to determine whether early differences translate into durable clinical benefit (and to define when non-TF access remains preferable). Preserving TF access aligns with established advantages of TF-TAVR in appropriate candidates [17].

Context from contemporary registries and implementation studies further underscores potential system-level implications. Peripheral non-TF strategies (e.g., transcarotid, transaxillary) have demonstrated outcomes comparable to or better than transthoracic access and, in multiple series, shorter LOS [22-24], while optimized TF pathways, like those put forth by FAST-TAVI and FAST-TAVI II, reproducibly reduce LOS and support earlier discharge in appropriate patients [25, 26]. These external data provide context for our finding of similar LOS across groups and suggest that center-level pathway implementation and access strategy may influence LOS and costs independent of device platform, generating important optimization-oriented insights for programs exploring feasibility of any or all of these strategies. Moreover, administrative and registry data also suggest that transapical access is associated with longer LOS and higher costs compared with non-transapical approaches [27]. It is important to note that, while LOS was similar between groups, there was a wider total LOS distribution in the IVL cohort (IQR 1 - 11 vs. 2 - 6 days for AAS). Given that post-procedure LOS did not greatly differ between groups, this increased distribution most plausibly reflects additional pre-procedure days and could reflect time accrued secondary to interfacility transfer, pre-procedural optimization, or scheduling rather than prolonged recovery after TAVR. Our dataset did not capture reasons for pre-procedure days, so these largely speculative inferences should be interpreted cautiously. Nevertheless, the similar LOS and readmission rates between groups indicate that neither approach offers a clear advantage in health-system resource utilization in our cohort, which, in addition to insights regarding efficiency of stay discussed above, may be an important consideration for programs planning or expanding TAVR programs [4]. However, the ability to maintain TF access through lithotripsy may offer other advantages not captured in our endpoints, such as procedural duration and complexity, anesthesia requirements, and post-procedural care involvedness at each level of the provider team, each of which were not collected for this cohort, warranting formal evaluation.

The difference in mortality etiology between groups warrants further study. Notably, all deaths in the lithotripsy group were cardiovascular-related, compared to only 37.5% in the AAS group. Whether this reflects selection bias or the natural history of lithotripsy-treated patients with severe peripheral arterial disease remains unclear and deserves investigation in larger cohorts,

much in the same way that differential outcomes in transcatheter vs. surgical valve replacement have been examined [21].

Study limitations

This pilot study has several important limitations. The single-center design and retrospective nature limit generalizability. The sample size, while providing the first comparative data in this field, limits statistical power for detecting differences between groups. Additionally, the statistical analyses employed were unadjusted, and only univariate comparisons were performed. Because the small sample size precluded robust multivariable or propensity-based adjustment, some amount of residual confounding is expected to influence these data. Detailed quantitative vessel characteristics were not systematically abstracted, which may limit direct reproducibility of our study. We acknowledge that the data not being reported hold back systems and providers from deriving functional cutoff values from this study; however, selection followed established professional society guidance for access strategy selection as is appropriate, alongside consideration of patient characteristics. The non-randomized design introduces potential selection bias, as selection for the approach employed was based on physician judgment and anatomical factors discussed above. It is important to note that all patients included in this analysis were White, which limits demographic representativeness and external generalizability. The study period (2019 - 2022) represents early experience with lithotripsy technology, and outcomes may improve with greater operator experience [16, 28]. Patient-level duration spent inpatient in pre- versus post-procedure was not captured, constraining interpretation of the wider total LOS range observed in the IVL group. Event rates should be interpreted with caution given wide CIs in small samples, and the study is underpowered to detect rare outcomes (e.g., stroke, cause-specific death). Anesthesia type, procedural duration, recovery metrics, and itemized costs were not collected, precluding efficiency and economic comparisons. These data are imperative for further investigations to provide comprehensive insights for health systems and operators, as they balance efficacy and outcomes data with health system- and patient-level cost incurred as they attempt to provide high-fidelity care to as many patients as possible. Long-term durability data beyond 3 years are not available.

Conclusions

This first comparative analysis of AAS TAVR versus lithotripsy-assisted TF TAVR demonstrates comparable procedural success and intermediate-term outcomes between approaches. The pattern of fewer short-term complications with lithotripsy, while not statistically significant in this pilot cohort, provides hypothesis-generating data supporting larger comparative studies. These real-world findings offer initial evidence to guide multidisciplinary heart team decision-making in patients with challenging vascular anatomy and highlight lithotripsy as a potentially viable strategy to expand TF TAVR eligibility.

Conflict of Interest

The authors declare no conflict of interest.

Informed Consent

The IRB at Geisinger Medical Center waived the requirement for individual consent due to the retrospective nature of the study.

Author Contributions

GR: study design, data collection, data analysis, validation, manuscript writing, manuscript review/editing. GD, RU, and AM: study design, data collection, data analysis, methodology. NI: study supervision, study design, procedure performance, manuscript review/editing. YN: study supervision, manuscript review.

Data Availability

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request and appropriate institutional approvals.

Abbreviations

AAS: alternative access site; GCMC: Geisinger Community Medical Center; GMC: Geisinger Medical Center; GWV: Geisinger Wyoming Valley; IQR: interquartile range; SAVR: surgical aortic valve replacement; IVL: intravascular lithotripsy; TAVR: transcatheter aortic valve replacement; TF: transfemoral

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