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Portable Versus Mounted Fluoroscopic Imaging During Transcatheter Aortic Valve Replacement

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Abstract

Objectives: To compare outcomes of portable angiography system (PAS) versus mounted angiography system (MAS) in high-risk patients with severe symptomatic aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR).

Background: MAS is the preferred imaging modality for TAVR procedures. The role and safety of PAS have not been systematically studied in TAVR.

Methods: A retrospective study was conducted on 101 consecutive TAVR cases performed at our center from December 2014 to November 2016. Procedural, safety and clinical endpoints were compared at 30 days and 1 year.

Results: 24 patients were in the PAS group and 77 in the MAS group. There was no significant difference in all-cause mortality between the PAS and MAS group at 30 days (4.2% vs 2.6%, P = 0.56) or at 1 year (21.7% vs 16.0%, P = 0.54). The two study groups had comparable rates of ischemic stroke (PAS, 4.3% vs MAS, 1.3%, P = 0.42), life-threatening or major bleeding (16.7% vs 6.6%, P = 0.21), vascular complication requiring intervention (8.7% vs 5.3%, P = 0.62), pacemaker implantation (13.0 vs 6.7%, P = 0.39), rehospitalization (8.7% vs 18.7%, P = 0.35), improvement in New York Heart Association functional class (P = 0.17), and degree of paravalvular leak (P = 0.22). The PAS group more frequently underwent alternative vascular access (25.0% vs 1.3%, P = 0.001), which was associated with longer length of stay from procedure to discharge (3 days vs 2 days, P = 0.003). Total radiation exposure was significantly less in the PAS group (air kerma 371 mGy vs 683 mGy, P = 0.043).

Conclusions: PAS is a safe and effective imaging modality for TAVR procedures with less total radiation exposure than MAS.

Key Words

Aortic stenosis • Transcatheter aortic valve replacement • Fluoroscopy • Mobile C-arm • Air kerma

Introduction

Transcatheter aortic valve replacement (TAVR) is preferred over surgical aortic valve replacement (SAVR) in patients with severe symptomatic aortic stenosis (AS) who are high-risk surgical candidates [1-6]. In this cohort of patients, large, multicenter, randomized clinical trials have demonstrated the non-inferiority of TAVR to SAVR for mortality and major cardiovascular and cerebrovascular adverse outcomes, as well as its superiority for major bleeding events [1-4, 7-9]. More recently, in intermediate surgical risk patients, several studies have shown the superiority of TAVR compared to SAVR for mortality, stroke, and moderate or severe aortic regurgitation at 1 year [10-13]. As a result of these investigations, TAVR is now a class IIa recommendation in patients

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with severe symptomatic AS who are at intermediate surgical risk [14].

Traditionally, TAVR procedure has been performed using a high resolution, multifunction, mounted angiography system (MAS), often utilizing computed tomography (CT) overlay technology to optimize valve positioning. A portable angiography system (PAS)—defined as a mobile C-arm fluoroscopic system capable of obtaining high quality angiographic images with cineography, digital subtraction, and archiving abilities [15-17]—is an alternative imaging modality that has been less commonly used in structural heart interventions. Instead, PAS has more frequently been utilized in endovascular, urologic, orthopedic and gastroenterology procedures [15, 18]. In the past, PAS has been limited by poor image resolution, small field of view, longer procedure times with frequent system overheating, and potential breach of sterility from C-arm rotation [19-22]. As a result, it has not been seen as a feasible alternative to current mounted camera use during TAVR [20]. However, with the recent production of digital, high-resolution, liquid cooled PAS, the new generation of portable imaging addresses many of these perceived limitations.

While PAS has been used during TAVR in select institutions outside the United States [23], to our knowledge, the role and safety of PAS have not been systematically studied in TAVR. Herein, we propose that the new generation of high-powered, high-resolution PAS may be implemented as a safe and feasible alternative to MAS. In this study, we compare clinical and procedural outcomes of high-risk patients with severe symptomatic AS undergoing TAVR using a traditional MAS versus a new generation PAS.

Methods

Study design

A retrospective study was conducted on 101 consecutive TAVR cases performed at our center from December 09, 2014 to November 15, 2016. The study was approved and performed in accordance with the hospital institutional review board at United Health Services Hospitals (UHSH) Wilson Medical Center, Johnson City, NY. Patients underwent transcatheter valve replacement for the treatment of severe symptomatic AS. All candidates received standard preoperative evaluation by the institution's heart valve team, which consisted of cardiologists (valve specialists, imaging specialists, and interventionalists) and cardiothoracic surgeons. Operative risk was measured by the Society of Thoracic Surgeons (STS) predicted risk of mortality score, which was calculated using the online STS Adult Cardiac Surgery Risk Calculator [24]. Patients with a STS risk score of 3% or greater, or otherwise deemed at prohibitive risk for open surgical repair, were candidates for TAVR. The default vascular access route for transcatheter intervention was transfemoral. However, when the ileofemoral approach was unfeasible, an ideal alternative access (transaortic, transapical, or transsubclavian) was chosen based on individual patient anatomy.

TAVR procedures were performed using either a new generation PAS or a traditional MAS fluoroscopic camera, which were allocated in a randomized fashion based on hybrid operating room (OR) and camera availability. Pulsed fluoroscopy and cineography imaging modes were used in all cameras. Three cameras were used in the PAS group: Siemens Cios Alpha, Ziehm Vision RFD (RFD), and GE OEC 9900 Elite (GE9900). Three cameras were used in the MAS group: GE Advantx DLX, Philips Allura Xper FD20 (FD20), and Siemens Artis zee biplane. None of the systems were equipped with CT overlay functionality. Intraoperatively, transesophageal or transthoracic echocardiography (TTE) was performed adjunctively to guide fluoroscopic assessment of prosthesis implantation.

All patients received either a balloon-expandable (Edwards SAPIEN XT or SAPIEN 3, Edwards Lifesciences, Irvine, CA, USA) or self-expandable (Medtronic CoreValve Evolut, Medtronic, Minneapolis, MN, USA) prosthetic aortic valve, with a diameter of 23, 26, or 29 mm. The optimal valve type and size were selected based on patient specific anatomical and clinical factors.

Data collection and definitions

Baseline demographic and procedural characteristics were collected from the UHSH computerized health record. The STS risk score served as a proxy for coexisting medical conditions. Body mass index (BMI) was calculated using recorded height and weight. Baseline New York Heart Association (NYHA) heart failure class and left ventricular ejection fraction (LVEF)

Table 1. Patient demographics

Degree	Grade
None	0
Trace	I
Mild	II
Mild to Moderate	III
Moderate	IV
Severe	V

were defined from preoperative TAVR evaluation findings. Paravalvular leak (PVL) and postoperative LVEF ($LVEF_{1\text{-}day}$) reflect TTE findings on postoperative day 1. Using a previously described research-oriented PVL grading scheme [25], PVL was assigned a value according to Table 1. The 30-day LVEF ($LVEF_{30\text{-}day}$) was determined between 5 days and 3 months following TAVR. Postoperative NYHA class heart failure was defined by symptom burden at 30-day follow-up, which occurred between 21 days and 3 months following hospital discharge. When available, radiation exposure was quantified by dose area product (DAP), air kerma, and fluoroscopy time.

Definition of outcomes

Where appropriate, clinical outcomes were defined according to the Valve Academic Research Consortium-2 standardized definitions [26]. Mortality was assessed at 30 days and 1 year. All other outcomes were measured at 30 days, including ischemic stroke, life threatening or major bleeding, vascular complication requiring intervention, pacemaker implantation, and rehospitalization. Life threatening or major bleeding was defined using a packed red blood cell transfusion threshold ≥3 units during hospitalization, as previously described [26]. A vascular complication was noted to be any post-procedure access site intervention. The safety endpoint of excessive intraoperative radiation exposure was defined as a DAP greater than 1 standard deviation (SD) above the mean DAP for all patients (DAP > 13310 $cGy*cm^2$). The dichotomous composite safety outcome was defined as the occurrence of any of the above adverse events at 30 days, including excessive intraoperative radiation exposure or the presence of moderate or severe PVL.

Subgroups

Subgroup analysis was performed on selected demographic and procedural characteristics. Patients were categorized by BMI <20, 20 to <30, or ≥30$\ frac{\text{kg}}{m^{2}}$; STS risk score <3, 3 to 8, or >8%; and valve size implanted: small (23 mm Sapien XT/Sapien 3 or 23/26 mm CoreValve Evolut), medium (26 mm Sapien XT/Sapien 3 or 29 mm CoreValve Evolut), or large (29 mm Sapien XT/Sapien 3).

Statistical analysis

All statistical analysis was performed using SPSS software (25.0, SPSS Inc., Chicago, IL, USA). Normally distributed continuous variables were presented as mean ± SD, and compared using the two-tailed Student's t-test coupled with Levene's test for homogeneity of variance. Non-normally distributed continuous variables were presented as median (25^{th} to 75^{th} interquartile range), and were analyzed with the Mann-Whitney U test. Categorical variables were reported as frequency (%), and compared using the chi-square statistic, Fisher's exact test, or likelihood ratio, where appropriate. The Spearman's rank correlation coefficient was used in the univariate analysis of non-normally distributed continuous variables. Hazard ratios for the PAS group with two-sided 95% confidence intervals were generated using a Cox proportional-hazards model with the MAS group as the reference. In the subgroup analysis, hazard ratios were computed for the composite safety outcome of any adverse event at 30 days. Binary logistic regression was used to compute P-values for interaction between the subgroup variable and the composite safety outcome. Event free survival was compared between groups using the composite safety outcome of any adverse event at 30 days. Event free and cumulative survival curves were approximated using the Kaplan-Meier method, and event rates compared with the log-rank test. All tests were 2-sided, and a P-value <0.05 signified statistical significance.

Results

Baseline characteristics

Of the 101 TAVR cases reviewed, 24 patients were in the PAS group and 77 in the MAS group. Baseline characteristics were well balanced between groups

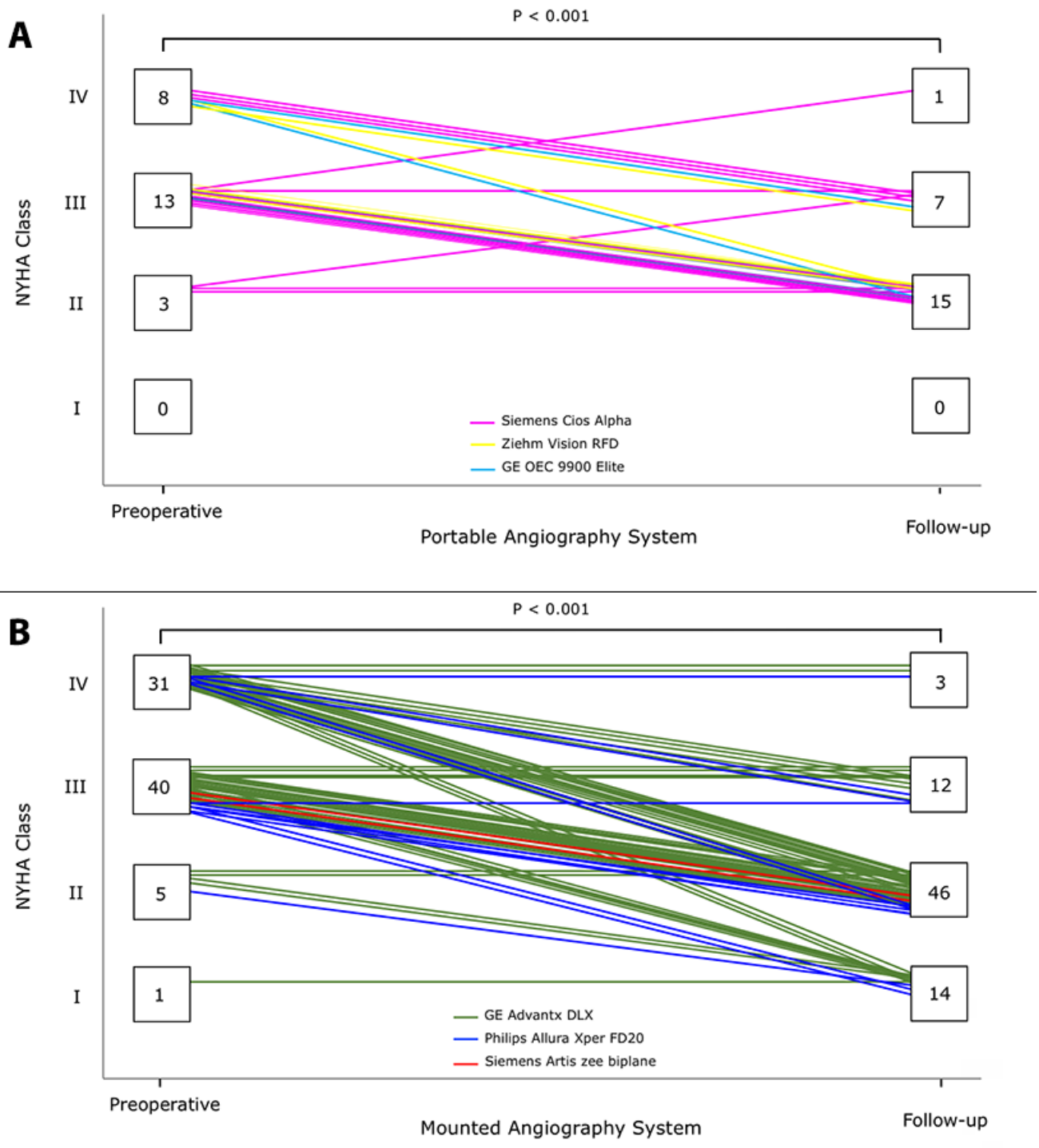


Figure 1. Cardiac Symptom Status. Changes in New York Heart Association (NYHA) functional class heart failure according to intraoperative fluoroscopic camera used (*Panel A, PAS group; Panel B, MAS group*). Boxes contain number of patients in each NYHA class. Lines depict symptom trajectory for each patient from preoperative baseline to 30-day follow-up, which occurred between 21 days and 3 months following hospital discharge.

Table 2. Baseline Patient Characteristics.

Characteristic	Portable Angiography System (n = 24)	Mounted Angiography System (n = 77)	P Value
Age, yrs	81 ± 8	81 ± 8	0.78
Male sex	12 (50.0)	38 (49.4)	0.96
BMI	31 ± 8	29 ± 6	0.15
STS risk score, %	7.7 ± 4.6	7.8 ± 3.5	0.87
NYHA functional class			
I	0 (0.0)	1 (1.3)	0.67
II	3 (12.5)	5 (6.5)	
III	13 (54.2)	40 (51.9)	
IV	8 (33.3)	31 (40.3)	
LVEF, %	51 ± 11	53 ± 14	0.58

(Table 2). The mean STS risk score was 7.7% and 7.8% in the PAS and MAS group, respectively, indicating high risk cohorts. Patients in both groups exhibited predominantly NYHA class III or IV symptoms, with an overall similar distribution of baseline symptoms (P = 0.67). There was no significant difference in LVEF (PAS, 51% vs MAS, 53%, P = 0.58).

Procedural characteristics and outcomes

Procedural characteristics are provided in Table 3. The most commonly used camera in the PAS and MAS group was the Siemens Cios Alpha (70.8%) and the GE Advantx DLX (80.5%), respectively. While balloon expandable valves were more frequently employed in both groups, the overall distribution of valve types across groups was not significantly different (P = 0.053). Similarly, the distribution of the three valve sizes across groups was comparable (P = 0.95).

A majority of patients in the two study groups underwent TAVR using a transfemoral approach; however, a significantly greater proportion of patients in the PAS group underwent alternative vascular access (25.0% vs 1.3%, P = 0.001). No patient was converted from a transfemoral approach to an alternative vascular route. Similarly, no patient needed conversion to open surgical repair. The TAVR procedure was not aborted in any case.

The air kerma in the PAS group was significantly lower than in the MAS group (371 mGy vs 683 mGy, P = 0.043). Additionally, there was a non-significant trend towards lower DAP and fluoroscopy time in the PAS group compared to the MAS group (6566 cGy*cm^2 vs 9016 cGy*cm^2, P = 0.27; and 17 min vs 21 min, P = 0.16, respectively).

Clinical and echocardiographic outcomes

Clinical outcomes are summarized in Table 4. No significant differences were found in $LVEF_{1\text{-day}}$ or $LVEF_{30\text{-day}}$ in the PAS vs MAS group (54% vs 56%, P = 0.50; and 52% vs 53%, P = 0.80, respectively). Patients in each group experienced marked improvement in heart failure symptoms on follow-up (P < 0.001 in PAS and MAS group, Figure 1, Panel A and B). Rates of NYHA class III or IV symptoms on follow-up were similar between the two study groups (P = 0.17). All patients in the PAS group and a majority of patients in the MAS group had grade II or less PVL on postoperative day 1. As shown in Figure 2, no significant difference was observed in the distribution of PVL grades across groups (P = 0.22). The hospital and post-procedural length of stay were longer in the PAS group than in the MAS group (3 days vs 2 days, P = 0.005; and 3 days vs 2 days, P = 0.003, respectively).

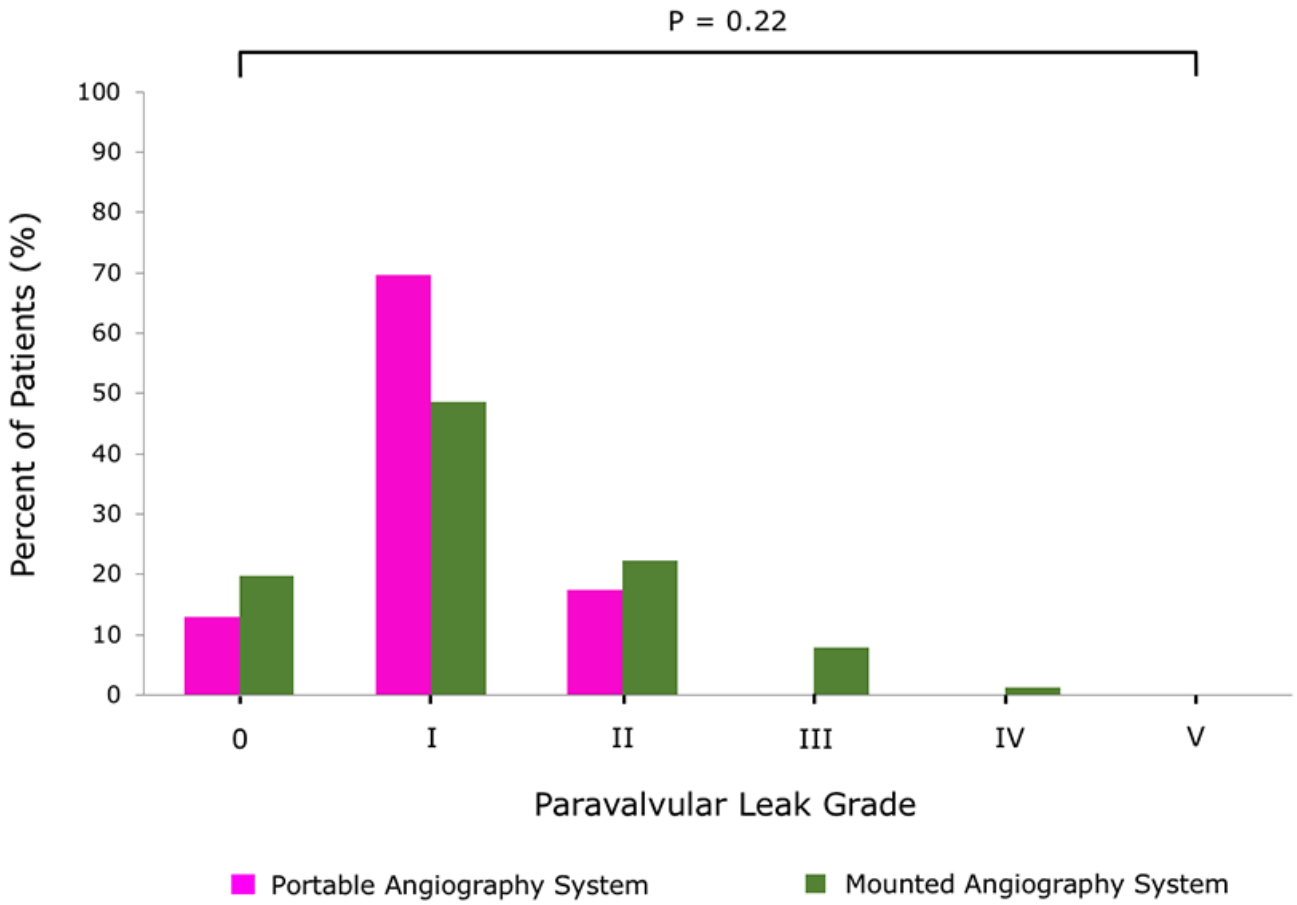


Figure 2. Frequency of Paravalvular Leak (PVL) Grade. Comparison of PVL grade frequency between groups on postoperative day 1. Grading scheme as in Table 1.

Most 30-day adverse event rates were low and comparable in the PAS and MAS group. No between group differences were observed in all-cause mortality (PAS, 4.2% vs MAS, 2.6%, P = 0.56) or cardiovascular mortality (4.2% vs 1.3%, P = 0.42). Rates of ischemic stroke (P = 0.42), life threatening or major bleeding (P = 0.21), vascular complication requiring intervention (P = 0.62), pacemaker implantation (P = 0.39), and rehospitalization (P = 0.35) were all similar in each group.

The two groups did not differ significantly in the 1-year rates of all-cause (PAS, 21.7% vs MAS, 16.0%, P = 0.54) and cardiovascular mortality (4.3% vs 5.3%, P = 0.85). The Kaplan-Meier estimate of cumulative survival shows no significant difference in mortality between the PAS vs MAS group from 30-days to 1-year (hazard ratio [HR] for mortality with PAS vs MAS, 1.41; 95% confidence interval [CI], 0.50 to 4.01; log-rank P = 0.51; Figure 3, panel B).

The rate of the composite safety outcome of any adverse event at 30 days was similar in the PAS group compared to the MAS group (41.7% vs 33.8%, respectively), with no significant difference in the event free survival curves (HR for composite safety outcome with PAS vs MAS, 1.39; 95% CI, 0.67 to 2.88; log-rank P = 0.36; Figure 3, panel A). This finding was consistent across all three subgroups (Figure 4).

Discussion

This study demonstrates that in patients with severe symptomatic AS at high risk for open surgical repair, TAVR procedures can be performed using a new generation PAS with comparable safety and effi-

Table 3. Procedural Characteristics.

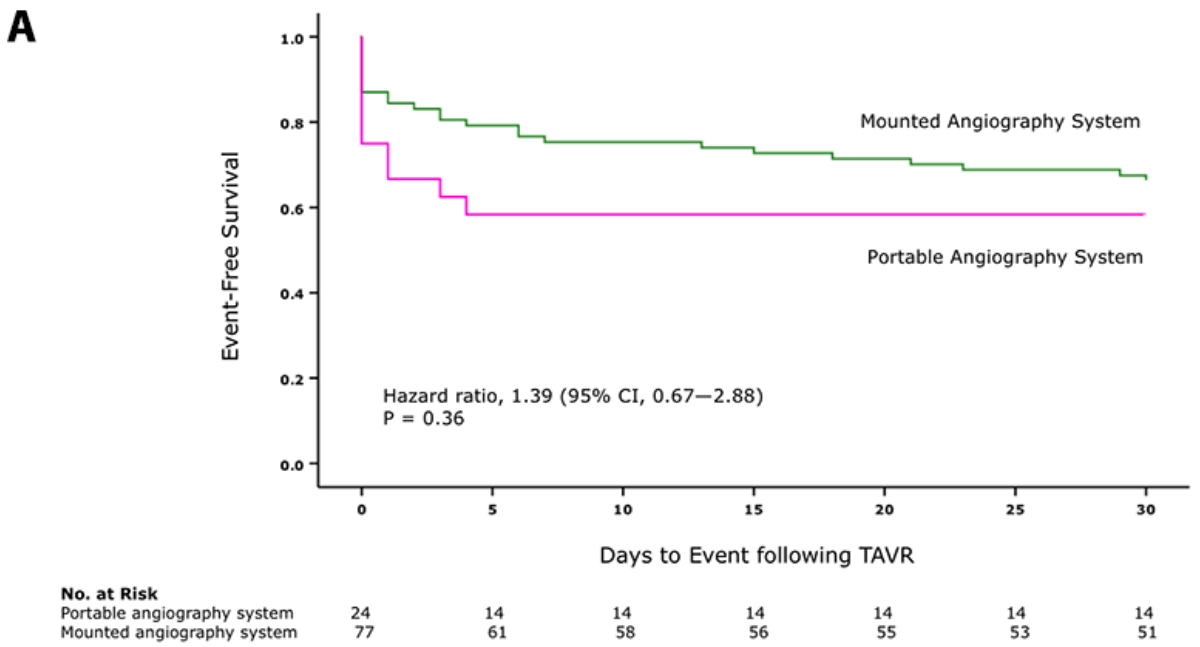
Characteristic	Portable Angiography System (n = 24)	Mounted Angiography System (n = 77)	P Value
Fluoroscopic camera			
Siemens Cios Alpha	17 (70.8)	-	
Ziehm Vision RFD	5 (20.8)	-	
GE OEC 9900 Elite	2 (8.3)	-	
GE Advantx DLX	-	62 (80.5)	-
Philips Allura Xper FD20	-	13 (16.9)	
Siemens Artis zee biplane	-	2 (2.6)	
Valve type			
Sapien XT	4 (16.7)	33 (42.9)	
Sapien 3	14 (58.3)	34 (44.2)	0.053
CoreValve Evolut	6 (25.0)	10 (13.0)	
Valve size, mm			
23	9 (37.5)	27 (35.1)	
26	7 (29.2)	25 (32.5)	0.95
29	8 (33.3)	25 (32.5)	
Alternative vascular access			
Transaortic	1 (4.2)	0 (0.0)	
Transapical	4 (16.7)	0 (0.0)	0.001
Transsubclavian	1 (4.2)	1 (1.3)	
Radiation dose			
DAP, cGy*cm^2	6566 ± 3335	9016 ± 7745	0.27
Air kerma, mGy	371 ± 145	683 ± 534	0.043
Excessive radiation exposure ★	1 (5.0)	4 (26.7)	0.14
Fluoroscopy time, min	17 ± 7	21 ± 13	0.16

Values are number (%) and mean ± SD.
★Defined as DAP > 13310 cGy*cm^2.
DAP = dose area product.

cacy to a traditional MAS. We observed no statistically significant differences in rates of mortality, ischemic stroke, life threatening or major bleeding, vascular complication requiring intervention, pacemaker implantation, or rehospitalization. Additionally, both groups had similar improvement in NYHA class symptoms and degree of PVL. For the composite safety outcome of any adverse event at 30 days and for mortality at 1 year, the two study groups had comparable event-free survival. As a result of these findings, we believe PAS can be used as an alternative to MAS during TAVR.

Overall, the features of new generation PAS fluoroscopic systems compare well to those of MAS systems, which may explain, in part, why the two study groups experienced similar clinical outcomes. The specifications of the PAS cameras and the newest MAS camera used in this study (the FD20) are compared in Table 5.

All three PAS cameras offer radiation dose monitoring and reduction features comparable to the FD20 ClarityIQ, Doseaware, SpectraBeam, and MRC-GS 0407 technologies [27-29]. Like the FD20, the GE9900 and RFD cameras offer high frequency X-ray generators, while the Cios Alpha generator uses a monoblock de-



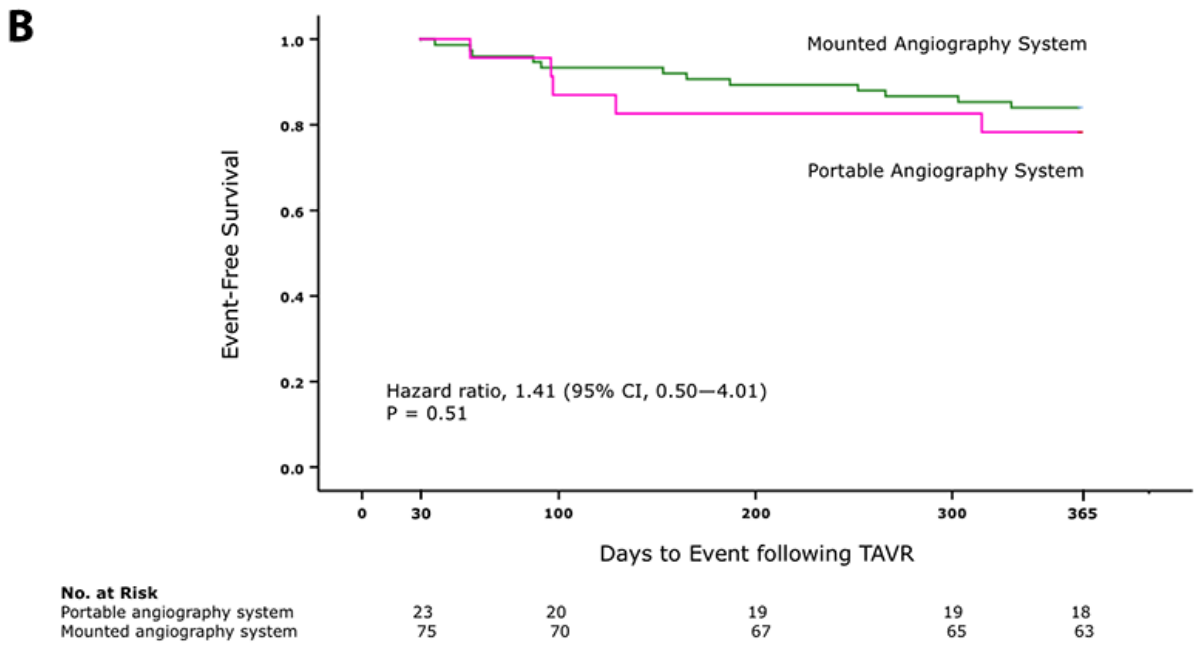


Figure 3. Survival Curves for the Composite Safety Outcome of Any Adverse Event at 30 Days, and All-Cause Mortality from 30-Days to 1-Year. Event-free survival curves for the composite safety outcome of any adverse event (mortality, ischemic stroke, life threatening or major bleeding, vascular complication requiring intervention, pacemaker implantation, rehospitalization, excessive intraoperative radiation exposure, or moderate or severe paravalvular leak) at 30 days *(Panel A)*. The number of patients in each group surviving without an event at each 5-day interval is shown. Cumulative survival curves from day 30 to 1 year *(Panel B)*. The number of patients in each group surviving at each interval (varies) is shown. Event rates were calculated using the Kaplan-Meier estimate and compared using the log-rank test.

Table 4. Outcomes.

Outcome	Portable Angiography System (n = 24)	Mounted Angiography System (n = 77)	P Value
$LVEF_{1\text{-day}}$, %	54 ± 12	56 ± 13	0.50
$LVEF_{30\text{-day}}$, %	52 ± 11	53 ± 12	0.80
NYHA functional class III or IV ★	8 (34.8)	15 (20.0)	0.17
Grade PVL†			
0	3 (13.0)	15 (19.7)	
I	16 (69.6)	37 (48.7)	
II	4 (17.4)	17 (22.4)	0.22
III	0 (0.0)	6 (7.9)	
IV	0 (0.0)	1 (1.3)	
V	0 (0.0)	0 (0.0)	
Length of stay, days ‡	3 (2-7)	2 (1-3)	0.005
Length of stay: procedure to discharge, days ‡	3 (2-4)	2 (1-2)	0.003
30 Days			
Mortality			
All-cause	1 (4.2)	2 (2.6)	0.56
Cardiovascular cause	1 (4.2)	1 (1.3)	0.42
Ischemic stroke	1 (4.3)	1 (1.3)	0.42
Life threatening or major bleeding	4 (16.7)	5 (6.6)	0.21
Vascular complication requiring intervention	2 (8.7)	4 (5.3)	0.62
Pacemaker	3 (13.0)	5 (6.7)	0.39
Rehospitalization	2 (8.7)	14 (18.7)	0.35
1 Year			
Mortality			
All-cause	5 (21.7)	12 (16.0)	0.54
Cardiovascular cause	1 (4.3)	4 (5.3)	0.85

Values are number (%), mean ± SD, and median (25th-75th percentile) for non-normally distributed variables.
★NYHA class symptoms at 30-day follow-up, which occurred between 21 days and 3 months following hospital discharge.
†Grading scheme as in Table 1.
‡Non-normally distributed variable.
LVEF1-day = LVEF on postoperative day 1; LVEF30-day = LVEF determined between 5 days and 3 months post-TAVR; PVL = paravalvular leak on postoperative day 1; other abbreviations as in Table 2.

sign. The PAS and FD20 cameras are all equipped with a pulsed fluoroscopy mode, which generally ranges from 1 to 30 fps, though the FD20 is capable of 60 fps. The contemporary PAS systems (Cios Alpha and RFD) offer fluoroscopic mA ranges similar to that of the FD20, and have housing heat storage capacities of 5.3 MHU and 10 MHU, respectively, which are similar to the FD20 capacity of 5.4 MHU. The comparable heat capacity of PAS cameras in conjunction with their liquid cooling technology reduce the risk of sys-

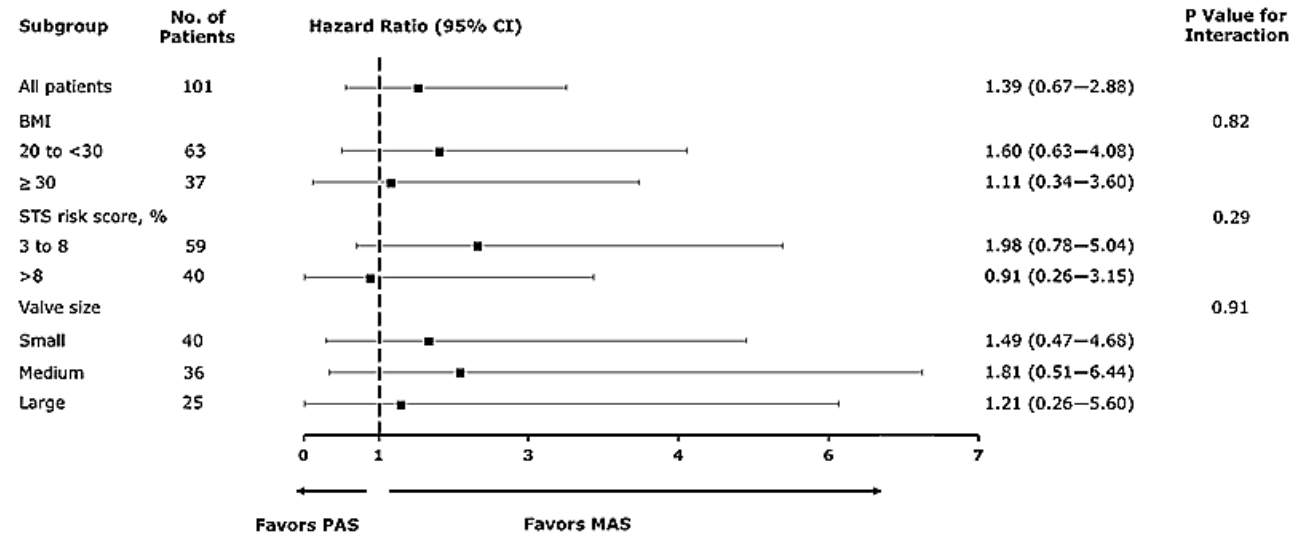


Figure 4. Subgroup Analysis for the Composite Safety Outcome of Any Adverse Event at 30 Days. Subgroup analysis for the composite safety outcome (defined as in Figure 3) at 30 days. Hazard ratios were generated using the Cox-proportional hazards model with the MAS group as the reference. Data markers indicate mean hazard ratios; lines represent 95% confidence interval. P values represent the likelihood of interaction between the subgroup variable and the composite safety outcome. Abbreviations as in Table 2. Valve size: small = 23 mm Sapien XT/Sapien 3 or 23/26 mm CoreValve Evolut; medium = 26 mm Sapien XT/Sapien 3 or 29 mm CoreValve Evolut; large = 29 mm Sapien XT/Sapien 3.

tem overheating, which is particularly advantageous during prolonged procedures.

The PAS cameras have power ratings ranging from 15 to 25 kW at 100 kVp, compared to the 100 kW at 100 kVp power rating of the FD20 [27-29]. Our analysis suggests that the increased power rating of the FD20 does not confer a procedural advantage during TAVR, and may in fact contribute toward higher radiation doses. In addition, the contemporary PAS cameras utilize a digital flat panel display, which is also employed by the FD20. Compared with image intensifiers, flat panels have the advantage of minimizing image distortion [30]. However, the PAS flat panel detectors are smaller than that of the FD20, which may additionally explain why the PAS group experienced less radiation.

The PAS group had a significantly longer hospital length of stay compared to the MAS group. Univariate analysis demonstrated a significant association between length of stay and alternative vascular access use (P = 0.004). Since the PAS group underwent significantly more alternative access, it is not unexpected then that they experienced a longer hospital stay.

Another important finding of this study was the trend toward lower radiation exposure in the PAS group. This likely represents a fundamental difference between PAS and MAS systems, whereby owing to their higher power rating and larger imaging field of view, MAS cameras accrue greater radiation doses, even when equivalent pulsed fluoroscopy settings are applied. This benefit of PAS over MAS appears to hold independently of fluoroscopy time, which was not significantly different between groups. Interestingly, the radiation doses observed in both the PAS and MAS group are lower than those reported in two prior studies investigating radiation exposure during TAVR [31, 32]. This discrepancy is largely attributed to lower fluoroscopy times used in our study, which reflect simplifications in TAVR procedure complexity over time.

While MAS remains the mainstay of intraoperative fluoroscopic imaging during TAVR procedures, PAS offers unique advantages. PAS cameras are versatile platforms which can complement existing MAS cameras, expanding the imaging armamentarium of institutions participating in complex fluoroscopy-guided subspecialty procedures (Figure 5). Furthermore, PAS

Table 5. Comparison of Camera Characteristics★

	PAS			MAS
Product name	Siemens Cios Alpha	Ziehm Vision RFD	GE OEC 9900 Elite	Philips Allura Xper FD20
FDA cleared, yr	2014	2009	2008	2013
Type	Mobile C-arm	Mobile C-arm	Mobile C-Arm	Ceiling mounted single plane
Radiation lowering/dose control features	Yes	Pulsed fluoroscopy; low-dose mode; object detected dose control; PreMag; removable grid	Pulsed fluoroscopy; low-dose mode; preview collimator; laser aimer	ClarityIQ
Radiation dose monitoring features (for staff and/or patients)	Yes	Calculated DAP; air kerma; measured DAP (option); structured dose report	Yes	DoseAware
X ray generator Type	Monoblock	Monoblock and high frequency	High frequency split block	High frequency
Power rating, kW at 100 kVp	25	20 / 25	15	100
Radiographic mA	10 - 250	Up to 20	Up to 75	1 - 1250
Radiographic kV	40 - 125	40 - 110	50 - 120	40 - 125
Fluoroscopic mA	3 - 250	1.5 - 180 (at 20 kW); 1.5 - 250 (at 25 kW)	Normal: 0.2 - 10; HLF: 1 - 20	60
Fluoroscopic kV	40 - 125	40 - 120	40 - 120	40 - 125
Focal spot size (mm)	0.3	Dual focus: 0.3 / 0.6	0.3 - 0.6	0.4 and 0.7 (MRC)
Pulsed fluoroscopy; Cine range (fps)	Yes; 0.5 - 30	Yes; 1, 2, 4, 8, 15, 30; Cine 1 - 25	Yes; 1, 2, 4, 8, 15; up to 30 fps	Yes; 3.25, 7.5, 15 and 30 fps; optional 60 fps
Housing heat storage capacity, MHU	5.3	Anode: 0.365; System: 10	0.3	Anode: 2.4; System: 5.4
Diameter of intensifier or dimensions of detector, cm	30x30; Cardiac 20x20	30x30 (a-Si); 20x20	31x23x15 image intensifier	30x38

★ Adapted from references 27-29.
kVp = peak kilovoltage; HLF = high level fluoro; a-Si = amorphous silicon; other abbreviations as in Table 3.

can simplify operative workflow, condense OR space allocation, and reduce resource consumption, all of which have the potential to reduce overall cost. PAS may also be used to facilitate conversion of a traditional OR to a hybrid OR, reducing the transition time for implementing a TAVR program. As TAVR procedures become more routinely performed in lower risk populations, PAS allows institutions seeking to initiate or expand TAVR programs to do so without further straining institutional resources.

Our study is limited by small sample size and single center, retrospective design. Though the same imaging mode was used in both fluoroscopic camera systems, there may have been differences in their calibrations, which could confound the observed differences in outcomes. Furthermore, the relatively small sample size increases the risk of a type II error. The limitation of sample size is further demonstrated in radiation measurements. Because the GE Advantx DLX camera did not monitor radiation exposure, there may have been insufficient power to detect a statistically significant difference in DAP. Similarly, while the subgroup analysis was consistent with the overall observations of the study, there may have been insufficient power to detect a statistically significant interaction be-

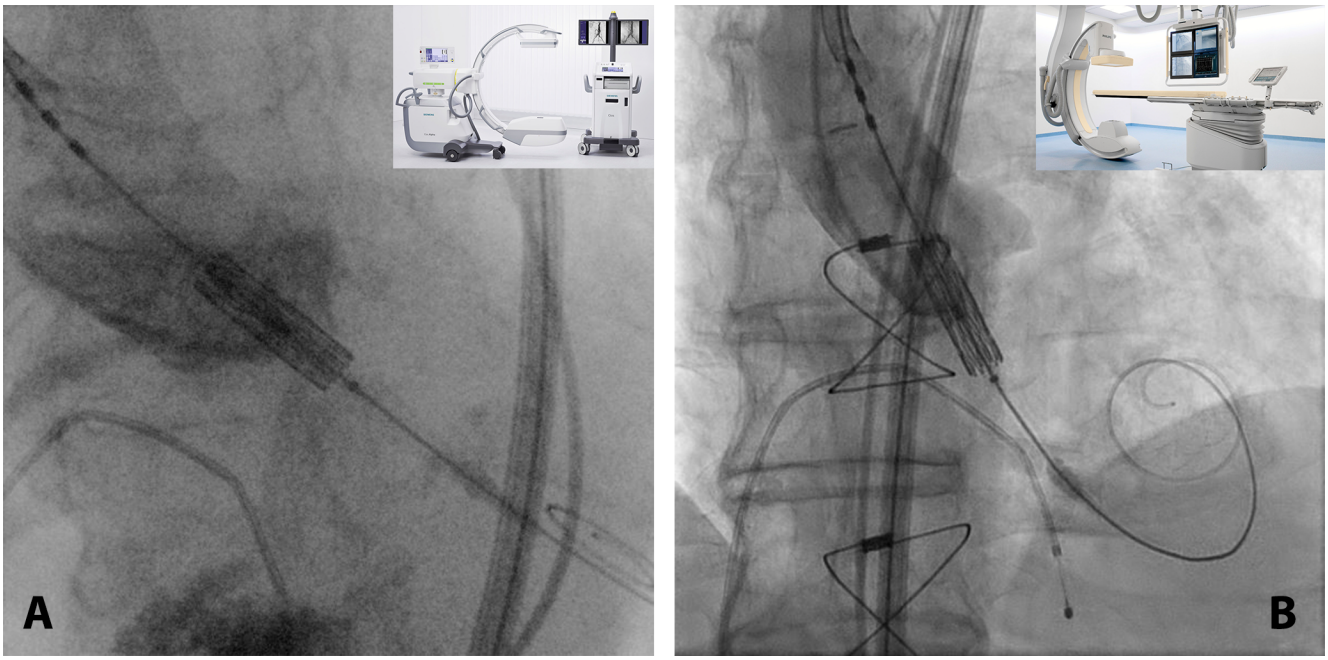


Figure 5. Aortic root angiogram confirming prosthesis positioning predeployment. Siemens Cios Alpha, PAS *(Panel A)*. Philips Allura Xper FD20, MAS *(Panel B)*. Inset, corresponding fluoroscopic camera.

tween subgroups and the composite safety outcome of any adverse event at 30 days.

In conclusion, our study demonstrates that PAS is a safe and effective imaging modality for TAVR procedures with less total radiation exposure than MAS. Future prospective studies with larger sample sizes are needed to clarify this finding.

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Conflict of Interest

The authors have no conflict of interest relevant to this publication.

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