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Very Low Intravenous Contrast Volume Protocol for Computed Tomography Angiography Providing Comprehensive Cardiac and Vascular Assessment Prior to Transcatheter Aortic Valve Replacement in Patients with Chronic Kidney Disease

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Abstract

Background—Transcatheter aortic valve replacement (TAVR) is a lifesaving procedure for many patients high risk for surgical aortic valve replacement. The prevalence of chronic kidney disease (CKD) is high in this population, and thus a very low contrast volume (VLCV) computed tomography angiography (CTA) protocol providing comprehensive cardiac and vascular imaging would be valuable.

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Methods—52 patients with severe, symptomatic aortic valve disease, undergoing pre-TAVR CTA assessment from 2013-4 at Columbia University Medical Center were studied, including all 26 patients with CKD (eGFR<30mL/min) who underwent a novel VLCV protocol (20mL of iohexol at 2.5mL/s), and 26 standard-contrast-volume (SCV) protocol patients. Using a 320-slice volumetric scanner, the protocol included ECG-gated volume scanning of the aortic root followed by medium-pitch helical vascular scanning through the femoral arteries. Two experienced cardiologists performed aortic annulus and root measurements. Vascular image quality was assessed by two radiologists using a 4-point scale.

Results—VLCV patients had mean($\pm$ SD) age 86 ± 6.5 , BMI 23.9 ± 3.4 kg/m² with 54% men; SCV patients age 83 ± 8.8 , BMI 28.7 ± 5.3 kg/m², 65% men. There was excellent intra- and inter-observer agreement for annular and root measurements, and excellent agreement with 3D-transesophageal echocardiographic measurements. Both radiologists found diagnostic-quality vascular imaging in 96% of VLCV and 100% of SCV cases, with excellent inter-observer agreement.

Conclusions—This study is the first of its kind to report the feasibility and reproducibility of measurements for a VLCV protocol for comprehensive pre-TAVR CTA. There was excellent agreement of cardiac measurements and almost all studies were diagnostic quality for vascular access assessment.

Keywords

transcatheter aortic valve replacement; computed tomography angiography; chronic kidney disease; very low contrast volume

Introduction

Transcatheter aortic valve replacement (TAVR) has become a standard treatment option for patients with severe, symptomatic aortic stenosis considered high-risk for surgical AVR.(1,2) One of the many significant comorbidities in this patient population is chronic kidney disease (CKD), which negatively affects outcomes and also poses challenges for computed tomography angiography (CTA) evaluation, used to assess aortic root anatomy and arterial access.(3,4) A low contrast volume CTA protocol providing accurate cardiac-gated imaging and complete vascular access assessment while minimizing iodinated contrast volume would be of great clinical benefit.. No previous reports of CTA for pre-TAVR assessment in patients with CKD include both a complete, noninvasive cardiac and vascular assessment with the same low volume contrast bolus and quantitatively assesses both cardiac and vascular measurements with assessment of measurement reproducibility in comparison to a standard volume protocol.(5-8)

Technical Methods

Patient selection

52 patients with severe, symptomatic aortic valvular disease being evaluated for TAVR from March 25, 2013 through November 5, 2014 at Columbia University Medical Center were retrospectively evaluated. 26 consecutive patients with severe (class 4 or higher CKD, body-

mass index $<40\text{kg/m}^2$) underwent a novel low contrast volume comprehensive CTA for pre-TAVR assessment; 26 without CKD underwent our standard contrast volume protocol. The study was approved by the institutional review board

Imaging procedure

Using a 320-slice volumetric scanner (Aquilion One, Toshiba America Medical Systems, Otawara, Japan), the VLCV protocol included retrospective, single-heartbeat-duration ECG-gated volume scanning of the aortic root immediately followed by medium-pitch-helical (1.5) vascular scanning from aortic arch to femoral arteries using a single contrast bolus. Intravenous injection of 20 mL of iohexol 350 mg iodine/mL (Omnipaque, GE Healthcare, Princeton, NJ) was followed by 30 mL saline flush, both at 2.5 mL/s. During an inspiratory breath-hold, single-volume root acquisition was performed with prospective electrocardiographic triggering and 240-320 $\times$ 0.5 mm collimation, followed by vascular scanning with 100 $\times$ 0.5 mm collimation. The scanner required 5.5-6.3s delay between volumetric and helical scans. For control cases, 60 mL contrast was injected followed by 30 mL saline flush both at 3.5 mL/s. Tube current and potential were selected by either supervising physician or automated software with goal of maximizing image quality and reducing radiation exposure. Tube potential was equal for aortic root and vascular scans. Real-time bolus tracking in the descending thoracic aorta was used for scan timing. Breath-hold and scan were initiated at 80 and 130 Hounsfield Unit (HU) thresholds, respectively, for VLCV, and 130 and 180HU for SCV, with manual triggering if necessary.

Annular/Aortic and Vascular Imaging

For annular imaging, iterative image reconstruction used slice-thickness of 0.5mm and 5% phase intervals (maximum 20 phases) while vascular images reconstructed at 1mm. Reconstructed datasets were analyzed using 3mensio valve software (v5.1, Pie Medical Imaging, Netherlands) and Vitrea software (v6.5.3, Vital Images, Minnetonka, MN) for cardiac (9) and vascular analysis, respectively. Best systolic and diastolic phases were selected. Two blinded, experienced cardiologists (TCP, OKK) performed annular (area, perimeter, maximum/orthogonal minimum diameter, height), and root (annulus-to-coronary ostia distance, sinuses of Valsalva width/height, sinotubular junction diameters) measurements. One cardiologist (TCP) repeated measurements >2 weeks apart in randomly-selected case order. Two experienced, blinded radiologists (AR, GDNP) independently graded iliofemoral vascular image quality on a semiquantitative 4-point ordinal scale (1=non-diagnostic; 2=diagnostic but limited; 3=good, mild limitations; 4=excellent). Average luminal CT number was measured at annular and common femoral artery level for each patient. For 32 patients subsequently undergoing TAVR with intraprocedural 3-dimensional transesophageal echocardiography (3D-TEE), comparison of annular area and perimeter measurements were made to a previously-validated 3D-TEE approach.(10).

Statistical Analysis

Inter-observer and intra-observer agreement for aortic annular and aortic anatomic measurements were determined using intraclass correlation coefficients (ICCs). Vascular image quality score agreement was determined using weighted kappa. Clinical endpoints/adverse events were compared between groups using the log-rank test. Two-tailed *t*-tests

evaluated differences between groups. ($P<0.05$ significant). Analyses were performed using Stata (v12.1/13.1, StataCorp, College Station, Texas) and MedCalc (v15.4, Software Ostend, Belgium).

Technical Results

Aortic Root Measurements

Table 1 details baseline patient and imaging characteristics. Figure 1 shows examples of two excellent-image-quality VLCV cases.

There was excellent intra- and inter-observer agreement for cardiac and aortic root measurements (Figures 2-3, Table 2). For annulus measurements, area and perimeter had similar agreement. Standard aortic measurements all had excellent intra- and inter-observer correlation. Intra-reader differences were not statistically significant.

Mean DLP for the entire study was lower for VLCV studies ($846 \text{ mGy}\times\text{cm}$) than for SCV studies ($1226 \text{ mGy}\times\text{cm}$, $p=0.001$).

Mean annular areas were $444\pm 62 \text{ mm}^2$ for CT and $438\pm 61 \text{ mm}^2$ for 3D-TEE ($p=0.2$); mean perimeters were $76\pm 5 \text{ mm}$ and $75\pm 6 \text{ mm}$, respectively ($p=0.01$). For SCV patients ($n=16$), mean annular areas were 465 ± 67 and $476\pm 76 \text{ mm}^2$, respectively ($p=0.11$), and mean perimeters 78 ± 6 and $79\pm 6 \text{ mm}$, respectively ($p=0.22$). ICCs between CT and 3D-TEE for both groups were excellent ($r=0.92-0.96$).

Vascular Assessment

Figure 1 illustrates image quality of peripheral vasculature in a VLCV case.

Average vascular image quality score was 2.5 for VLCV and 3.8 for SCV patients ($p=0.0001$); however both observers found diagnostic quality in 96% of VLCV cases (1 study non-diagnostic) and 100% of SCV cases with excellent inter-observer agreement for absolute score ($\kappa=0.84$ for VLCV). Vascular image quality scores were not statistically comparable by kappa statistic for SCV due to the lack of variability in scores as all studies were scored as 3 (good) or 4 (excellent).

Clinical Outcomes

There were excellent clinical outcomes in both groups based on Valve Academic Research Consortium (VARC)-2 endpoints.⁽¹¹⁾ 19 (73.1%) VLCV and 18 (69.2%) SCV patients underwent TAVR ($p=0.76$). All had successful deployment of percutaneous aortic valve. 10 (53%) VLCV and 15 (83%) SCV patients had paravalvular leak (PVL) ($p=0.05$). Four (16%) VLCV and 5 (22%) SCV patients had VARC-2 PVL score of 2 (mild) ($p=0.69$). No patients had greater-than-mild aortic regurgitation (score >2), and average PVL score for VLCV and SCV patients were 0.68 and 1.1, respectively ($p=0.11$). Of the 37 patients undergoing TAVR, 4 (2 VLCV, 2 SCV) had minor vascular access site/access-related complications ($p=0.43$).⁽¹¹⁾

Discussion

CKD is a frequently-encountered comorbidity in patients evaluated for TAVR. Not only does CKD negatively affect outcomes, its presence can complicate the pre-procedural assessment of a potential TAVR patient due to increased risk of contrast-induced nephropathy.(12,13) While conflicting publications on the causative effect of contrast-induced nephropathy exist, Ahmed and Newhouse acknowledge its existence (14), though in reality no prospective study has focused on high-risk patients with severe CKD, severe aortic stenosis with heart failure and other high-risk comorbidities.

The VLCV and SCV patients displayed similar baseline characteristics (Table 1). Statistical differences in BMI are explained by a BMI cutoff of $< 40 \text{ kg/m}^2$ for the VLCV protocol.

A significant reduction in contrast volume did not seem to affect the accuracy or reproducibility of aortic annular or root measurements. We found a high level of intra- and inter-observer agreement of standard aortic annulus and aortic root measurements. In our group of 26 VLCV patients, all patients that underwent TAVR had successful valve deployment with excellent follow-up imaging noting minimal PVL with VARC2 scores < 1 . (11)

3D TEE has become a very important and accepted approach to both assessing necessary clinical aortic annular measurements as well as supporting intraprocedural placement of the TAVR device.(15) Compared to this previously-validated method(10), there was excellent agreement in measurements of both area and perimeter for both the VLCV and SCV. This, coupled with the desirable clinical outcomes in this group, suggests a high level accuracy of measurements in the VLCV group, in addition to the reproducibility shown from inter- and intra-observer agreement analyses.

There have been a few previous publications on the subject of a low-volume contrast protocol in the setting of CKD and TAVR evaluation. Zemedkun et al. reported on a protocol using direct intra-aortic access though did not permit assessment of both heart and thoracic aorta.(8) Another report of eight patients from Azzalini et al. did not assess annular image quality or annular/aortic measurements.(7) A recent study by Geyer et al used a low dose volume 60 mL protocol compared to our 20 mL.(5) Most recently, Spagnolo et al., describe high quality studies though using a complex injection protocol (5 separate and varying boluses without saline flush) with double to almost triple contrast volume (40-55mL compared to our protocol).(6) While feasible,, they do not report on blinded, intra- and inter-observer reliability of pertinent measurements, compare to their standard dose protocol, nor compare to an alternative measurement assessment such as 3D TEE.

Study Limitations

The number of patients studied was small. This VLCV protocol was developed for the Toshiba Aquilion One 320 slice CT scanner and vendor-specific variables should be taken into consideration. Currently two vendors offer a volumetric scanner. To perform this protocol, the scanner must scan an electrocardiographically-gated cardiac volume data set quickly followed by a non-electrocardiographically-gated helical scan. Another variable to

consider is patient body habitus as there is a relative cutoff at which a diagnostic study cannot be conducted for the VLCV protocol. Due to the retrospective nature of the study and referral to a quaternary center, follow-up of serum creatinine was limited.

Conclusion

A very low contrast volume CTA protocol (with 20mL of iodinated contrast in total) enabling comprehensive cardiac and vascular imaging in a high-risk pre-TAVR patient population with severe CKD, is feasible and allows for highly reproducible cardiac and aortic measurements. Although image quality is reduced compared to the SCV protocol, the VLCV protocol provides a very high likelihood of diagnostic vascular images with good outcomes.

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Abbreviations

BMI	body mass index
CKD	chronic kidney disease
CTA	computed tomography angiography
GFR	glomerular filtration rate
HU	Hounsfield Units
IV	intravenous
PVL	paravalvular leak
SCV	standard contrast volume
TAVR	transcatheter aortic valve replacement

VLCV very low contrast volume

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Figure 1. Aortic Annulus, Coronary Distance and Vascular Images

Very low contrast volume images demonstrating (A and B) 2 separate cases showing aortic annular measurements. C and D show annulus to coronary distance measurements for the left main coronary artery and right coronary artery (C and D from same patient). E and F demonstrate 2 separate cases of peripheral vessel opacification.

Figure 2. Scatter and Bland-Altman Plots Characterizing Inter- and Intra-observer Agreement in Area and Perimeter Measurements for Very Low Contrast Volume Protocol Patients

Scatter plots (top) and Bland-Altman plots (bottom) characterizing inter- and intra-observer agreement for area (left panels) and perimeter (right panels) measurements for VLCV protocol. Abbreviations: VLCV: Very low contrast volume.

Figure 3. Scatter and Bland-Altman Plots Characterizing Inter- and Intra-observer Agreement in Area and Perimeter Measurements for Standard Contrast Volume Protocol Patients
 Scatter plots (top) and Bland-Altman plots (bottom) characterizing inter- and intra-observer agreement for area (left panels) and perimeter (right panels) measurements for SCV protocol are shown. Abbreviations: SCV: Standard contrast volume.

Table 1
Baseline Characteristics and CT Scan Details

	VLCV Group (n=26)	SCV Group (n=26)	p Value
Age, years	85.7 +/- 6.5	83.2 +/- 8.8	0.26
Male, %	53.9 (14)	65.4 (17)	0.40
BMI, kg/m ²	23.9 +/- 3.4	28.7 +/- 5.3	0.0003
Coronary artery disease, %	61.5	56.0	0.69
Atrial fibrillation, %	38.5	36.0	0.86
STS score, %	9.8 +/- 4.1	9.1 +/- 5.4	0.58
LVEF, %	55.5 +/- 12.7	55.7 +/- 16.1	0.96
AVA, cm ²	0.65 +/- 0.17	0.78 +/- 0.14	0.009
AVA index	0.38 +/- 0.6	0.42 +/- 0.78	0.04
Tube potential, 80/100/120 kV	(5)/(19)/(2)	(0)/(17)/(9)	0.008
Mean tube current, aortic root study, mA	385	426	0.24
Mean CT number, aortic annulus, HU	288	450	0.0001
Mean tube potential, vascular imaging, kV	98	107	0.002
Mean tube current, vascular imaging, mA	314	304	0.72
Mean CT number, common femoral artery, HU	200	420	0.0001

Abbreviations: BMI= body mass index. STS=Society of Thoracic Surgeons. LVEF= left ventricular ejection fraction. AVA= aortic valve area. kV= kilovolts. mA= milliamperes

Table 2
Intra- and Inter-observer Agreement of Measurements Using a Very Low Contrast Volume Cardiac CTA Protocol and a Standard Contrast Volume Protocol

	VLCV Group						SCV Group					
	Intra			Inter			Intra			Inter		
	ICC	MD	ICC	ICC	MD	ICC	ICC	MD	ICC	MD	ICC	MD
Annulus Area	0.99 (0.99-1.0)	0.62	0.99 (0.98-1.0)	0.62	0.99 (0.98-1.0)	0.62	0.99 (0.99-1.0)	3.02	0.98 (0.96-0.99)	10.3	0.98 (0.96-0.99)	10.3
Annulus Perimeter	0.99 (0.99-1.0)	0.01	0.99 (0.98-1.0)	0.45	0.99 (0.98-1.0)	0.45	0.99 (0.98-1.0)	0.48	0.97 (0.89-0.99)	1.5	0.97 (0.89-0.99)	1.5
Annulus Maximum Diameter	0.96 (0.91-0.98)	0.09	0.98 (0.94-0.99)	0.38	0.98 (0.95-0.99)	0.38	0.98 (0.95-0.99)	0.20	0.97 (0.92-0.98)	0.06	0.97 (0.92-0.98)	0.06
Annulus Minimum Diameter	0.95 (0.89-0.98)	0.03	0.97 (0.93-0.99)	0.14	0.97 (0.93-0.99)	0.14	0.97 (0.93-0.99)	0.08	0.96 (0.91-0.98)	0.13	0.96 (0.91-0.98)	0.13
Left Coronary Height (oblique)	0.98 (0.97-0.99)	0.05	0.90 (0.78-0.96)	0.02	0.98 (0.96-0.99)	0.16	0.93 (0.84-0.97)	0.26	0.93 (0.84-0.97)	0.26	0.93 (0.84-0.97)	0.26
Left Coronary Height (perpendicular)	0.96 (0.92-0.98)	0.15	0.88 (0.74-0.95)	0.08	0.95 (0.90-0.98)	0.24	0.90 (0.77-0.95)	0.50	0.90 (0.77-0.95)	0.50	0.90 (0.77-0.95)	0.50
Right Coronary Height (oblique)	0.99 (0.99-1.0)	0.03	0.95 (0.88-0.98)	0.22	0.95 (0.89-0.98)	0.08	0.78 (0.51-0.90)	0.22	0.78 (0.51-0.90)	0.22	0.78 (0.51-0.90)	0.22
Right Coronary Height (perpendicular)	0.98 (0.97-0.99)	0.07	0.94 (0.87-0.97)	0.07	0.95 (0.89-0.98)	0.28	0.86 (0.67-0.94)	0.68	0.86 (0.67-0.94)	0.68	0.86 (0.67-0.94)	0.68
Left SOV Width	0.99 (0.98-1.0)	0.15	0.97 (0.93-0.99)	0.37	0.99 (0.97-0.99)	0.83	0.98 (0.95-0.99)	0.01	0.98 (0.95-0.99)	0.01	0.98 (0.95-0.99)	0.01
Right SOV Width	0.99 (0.97-0.99)	0.05	0.95 (0.87-0.98)	0.35	0.99 (0.97-0.99)	0.04	0.97 (0.94-0.99)	0.20	0.97 (0.94-0.99)	0.20	0.97 (0.94-0.99)	0.20
Non-Coronary SOV Width	0.98 (0.96-0.99)	0.18	0.97 (0.92-0.97)	0.05	0.99 (0.97-1.0)	0.05	0.96 (0.91-0.98)	0.02	0.96 (0.91-0.98)	0.02	0.96 (0.91-0.98)	0.02
Left SOV Height	0.99 (0.97-1.0)	0.12	0.90 (0.76-0.96)	0.25	0.92 (0.83-0.97)	0.36	0.92 (0.81-0.96)	0.10	0.92 (0.81-0.96)	0.10	0.92 (0.81-0.96)	0.10
Right SOV Height	0.99 (0.99-1.0)	0.05	0.98 (0.95-0.99)	0.22	0.96 (0.90-0.98)	0.02	0.89 (0.72-0.96)	0.92	0.89 (0.72-0.96)	0.92	0.89 (0.72-0.96)	0.92
Non-Coronary SOV Height	0.99 (0.98-1.0)	0.07	0.97 (0.90-0.99)	0.50	0.98 (0.95-0.99)	0.16	0.95 (0.89-0.98)	0.49	0.95 (0.89-0.98)	0.49	0.95 (0.89-0.98)	0.49
STJ Max Diameter	0.99 (0.98-1.0)	0.09	0.99 (0.97-0.99)	0.27	0.99 (0.97-0.99)	0.04	0.87 (0.72-0.94)	0.57	0.87 (0.72-0.94)	0.57	0.87 (0.72-0.94)	0.57
STJ Min Diameter	0.99 (0.99-1.0)	0.07	0.98 (0.96-0.99)	0.33	0.98 (0.95-0.99)	0.10	0.98 (0.89-0.99)	0.65	0.98 (0.89-0.99)	0.65	0.98 (0.89-0.99)	0.65

Abbreviations: ICC=intraclass correlation coefficient (95% confidence interval in parentheses). MD=mean difference. SOV= sinus of Valsalva. STJ= sinotubular junction.

* Coronary height obliquely measured from the inferior margin of the coronary artery ostium to the coronary cusp of the aortic annulus plane.

† Coronary height perpendicularly measured from the inferior margin of the coronary artery ostium to the continuation of the annular plane.