# Radiation Dose Reduction in Preprocedural CT Imaging for TAVI/TAVR Using a Novel 3-Phase Protocol: A Single Institution's Experience

Strahlendosisreduktion der präprozeduralen CT-Bildgebung für TAVI/TAVR mittels eines neuartigen 3-Phasen-Protokolls

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### Key words

computed tomography, CT angiography, radiation dose, cardiac-gated imaging techniques, transcatheter aortic valve implantation, transcatheter aortic valve replacement

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#### Bibliography

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### ZUSAMMENFASSUNG

**Ziel** Diese retrospektive Studie untersuchte die Wirksamkeit eines neuen 3-Phasen-Protokolls für die präprozedurale Computertomografie (CT) vor einer Transkatheter-Aortenklappenimplantation (TAVI; engl.: TAVR) in Bezug auf die Strahlenbelastung und diagnostische Bildqualität.

**Material und Methoden** 107 nichtrandomisierte Patienten (81 ± 7,4 Jahre) erhielten vor der geplanten TAVI/TAVR eine präinterventionelle CT an einem 80-Zeilen-Gerät. Davon wurden 55 Patienten mit einem kombinierten EKG-synchronisierten und nicht EKG-synchronisierten Spiral-CT-Protokoll entsprechend der Empfehlungen der Society of Cardiovascular Computing Tomography (SCCT) untersucht, während 52 Patienten die CT-Bildgebung nach dem neuen, aktualisierten 3-Phasen-Protokoll (vHP3; variabler Pitch-Faktor 3) erhielten. vHP3 kombiniert eine nicht EKG-synchronisierte Spiral-CT des oberen Thorax mit einer anschließenden EKG-synchroni sierten Spiral-CT des Herzens und einer nicht EKG-synchronisierten Abdomen/Becken-Spiral-CT. Die Strahlendosis wurde anhand eines automatisch generierten Protokolls basierend auf dem CT-Dosisindex (CTDI) bestimmt. Die objektive Bildqualität in Bezug auf Gefäßkontrastierung und Bildrauschen wurde gemessen und SNR und CNR berechnet. Die subjektive Bildqualität wurde unter Verwendung einer 4-Punkt-Skala bewertet und mittels Cohens-Kappa-Koeffizienten (κw) auf Interrater-Reliabilität überprüft. Alle Daten wurden verglichen und statistisch ausgewertet.

**Ergebnisse** Die Verwendung des neuartigen 3-Phasen-vHP3-Protokolls reduzierte das Dosislängenprodukt (DLP) von 1256,58 ± 619,05 mGy<sup>\*</sup> cm auf 790,90 ± 238,15 mGy<sup>\*</sup> cm, die effektive Dosis (E) von 21,36 ± 10,52 mSv auf 13,44 ± 4,05 mSv und die größenspezifische Dosisabschätzung (SSDE) von 20,85 ± 7,29 mGy auf 13,84 ± 2,94 mGy (p < 0,001). Hierunter zeigten sich keine signifikanten Unterschiede in der objektiven und subjektiven Bewertung der Bildqualität zwischen beiden Gruppen.

Schlussfolgerung Das neue 3-Phasen-vHP3-Protokoll ermöglicht die Durchführung einer präprozeduralen CT vor TAVI/ TAVR mit einer signifikanten Reduzierung der Strahlendosis ohne Minderung der Bildqualität.

#### Kernaussagen:

- Die Verwendung eines neuartigen 3-Phasen-Protokolls für die präprozedurale TAVI-CT reduziert die Strahlendosis um 37% verglichen mit einem kombinierten EKG-synchronisierten und nicht EKG-synchronisierten Spiral-CT-Protokoll.
- Die objektive Bildqualität bleibt unbeeinträchtigt, da Bildrauschen, SNR und CNR keinen signifikanten Unterschied zwischen beiden Protokollen aufweisen und die durchschnittliche Gefäßkontrastierung der Aorta jeweils 450 HU übersteigt.
- Die subjektive Bildqualität wird f
  ür beide Protokolle mit fast perfekter bis zu erheblicher Interrater-Reliabilit
  ät als gut bis ausgezeichnet bewertet.

### ABSTRACT

**Purpose** To retrospectively investigate the effectiveness of a novel 3-phase protocol for computed tomography (CT) before transcatheter aortic valve implantation/transcatheter aortic

valve replacement (TAVI/TAVR) in terms of radiation dose and image quality.

Materials and Methods A total of 107 nonrandomized patients (81 ± 7.4 years) scheduled for TAVI/TAVR underwent preprocedural CT on an 80-row CT scanner. 55 patients underwent a combined ECG-synchronized spiral scan of the chest and non-ECG-synchronized spiral scan of the abdomen/pelvis as recommended by the Society of Cardiovascular Computed Tomography (SCCT). 52 patients underwent an updated 3-phase variable helical pitch (vHP3) protocol combining a non-ECG-synchronized spiral scan of the upper thoracic aperture, followed by a prospective ECG-synchronized spiral scan of the heart, and a non-ECG-synchronized abdominal/pelvic spiral scan. The radiation dose was determined from an automatically generated protocol based on the CT dose index (CTDI). Objective image guality in terms of vessel attenuation and image noise was measured, and the signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR) were calculated. Subjective image quality was evaluated using a 4-point scale and compared for interrater agreement using Cohen's weighted kappa coefficient (kw). All data were compared and statistically analyzed.

**Results** Use of the novel 3-phase vHP3 protocol reduced the dose-length product (DLP) from  $1256.58 \pm 619.05 \text{ mGy}^{\circ} \text{ cm}$  to  $790.90 \pm 238.15 \text{ mGy}^{\circ} \text{ cm}$ , reducing the effective dose (E) from  $21.36 \pm 10.52 \text{ mSv}$  to  $13.44 \pm 4.05 \text{ mSv}$  and size-specific dose estimates (SSDE) from  $20.85 \pm 7.29 \text{ mGy}$  to  $13.84 \pm$ 

2.94 mGy (p < 0.001). There were no significant differences in objective and subjective image quality between the two protocols and between the two readers.

**Conclusion** The novel 3-phase vHP3 protocol significantly reduces the radiation dose of preprocedural TAVI/TAVR CT without a loss of image quality.

#### **Key Points:**

- The use of a novel 3-phase protocol for preprocedural TAVI/TAVR CT reduces radiation dose by 37 % compared to a combined ECG-synchronized and non-ECG-synchronized spiral CT protocol.
- Objective image quality remains unaffected as image noise, SNR, and CNR did not differ significantly between the two protocols. The average attenuation of the aortic root and abdominal aorta exceeded 450 HU in both protocols.
- The average subjective image quality ratings were good to excellent for both protocols with almost perfect to substantial interrater agreement.

#### **Citation Format**

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# Introduction

Aortic stenosis (AS) is the most common acquired valve defect [1]. Although surgical aortic replacement is the predominant therapeutic procedure [2, 3] and is considered the most effective treatment [4], nearly one-third of patients cannot undergo surgery due to high surgical risk [5]. For these patients, transcatheter aortic valve implantation/transcatheter aortic valve replacement (TAVI/TAVR) may be a potential therapeutic alternative [6, 7].

While contrast-enhanced computed tomography (CT) was initially used for peripheral access route imaging, it is now primarily used for annular sizing and co-planar fluoroscopic angle prediction [6]. Furthermore, CT provides useful additional information, including an estimate of aortic valve calcification [6, 7].

The most recent recommendations for preprocedural CT scanning issued by the Society of Cardiovascular Computed Tomography (SCCT) require a contrast-enhanced, ECG-synchronized CT scan that should at least cover the aortic root [8]. Other body parts can be imaged without ECG synchronization. There are two main options for combining both in a single CT protocol: 1) ECGsynchronized scan of the chest followed by a non-ECG-synchronized abdominoiliac CT angiography (CTA); 2) ECG-synchronized scan of the heart, followed by non-ECG-synchronized thoracoiliac CTA [8].

In our center, we perform preprocedural TAVI/TAVR CT according to the first option with the use of variable helical pitch (vHP). This is a specific feature of Canon Medical Systems (Otawara, Japan) CT scanners, and allows a seamless change of parameters during one continuous acquisition, thus enabling the combination of ECG and non-ECG synchronization with different pitch settings in a single spiral scan [9]. Recently, the technique has been updated to enable the acquisition of images in three distinct phases (renamed vHP3). This 3-phase vHP3 software update allows the combination of a non-ECG-synchronized spiral scan of the upper thoracic aperture at a high pitch, an ECG-synchronized spiral scan of the heart at a lower pitch, and a non-ECG-synchronized spiral abdominal/pelvic scan at a high pitch into one acquisition (see  $\succ$  Fig. 1).

The purpose of this study was to investigate preprocedural TAVI/TAVR CT using the novel 3-phase vHP3 protocol in terms of diagnostic performance regarding radiation exposure as well as objective and subjective image quality.

# Methods

### **Study Population**

A total of 163 patients suffering from AS who were referred from our cardiology department for preprocedural CT for TAVI/TAVR over a period of 21 months were considered for inclusion in this non-randomized retrospective study. 56 patients with severe cardiac arrhythmia were excluded as they were scanned with a non-



► Fig. 1 Variable helical pitch allows a seamless change in scan pitch during one continuous acquisition, thus enabling combination of ECG-synchronized and non-ECG-synchronized acquisitions in one scan.

▶ Abb. 1 Variabler Pitch-Faktor ermöglicht eine nahtlose Änderung des Pitches und gestattet so eine Kombination aus EKG-synchronisierter und nicht EKG-synchronisierter Bildakquise innerhalb 1 Scans.

ECG-synchronized, high-pitch protocol that differed from both the vHP and the vHP3 scanning protocols. Therefore, a total of 107 patients were included in the study. These patients were categorized into two consecutive groups: Group A (n = 55) with images acquired using the vHP protocol examined within the first 9 months and Group B (n = 52) with images acquired using the novel vHP3 protocol examined within the following 12 months. Our local ethics committee approved this study (approval number EA4/140/17). The CT examinations were clinically indicated, and informed consent was not required.

### **CT** Protocol

All imaging was performed on an 80-detector-row CT scanner (Aquilion PRIME, Canon Medical Systems, Otawara, Japan) with a temporal resolution of 175 ms using half-scan reconstruction. The scan parameters were as follows: automated tube voltage selection (min = 80 kV in Group A, min = 100 kV in Group B), automated tube current modulation based on two scanned projection radiographs (ATCM, min = 40 mA, max = 600 mA, with selected image noise of pixel values in the reconstructed image serving as image quality reference parameter, i. e., 40 in Group A and 12.5 in Group B), 0.5 mm thickness, 0.5 mm increment,  $40 \times 0.5$  collimation, 0.35 s rotation time, 400 mm FOV,  $512 \times 512$  matrix. Axial images were reconstructed from the raw data using Canon's integrated adaptive iterative dose reduction (AIDR-3 D) reconstruction algorithm at a slice thickness of 0.5 mm in axial images and 3.0 mm in coronal and sagittal images. A full field of view (FOV) was used for annulus assessment.

For Group A, a pitch of 0.235 was set for the retrospective ECGsynchronized chest scan and a pitch of 1.388 for the non-ECGsynchronized abdominal/pelvic scan, which followed the chest acquisition after a short switchover time. For Group B, a pitch of 0.813 was set for the non-ECG-synchronized scan of the upper

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quisition after a short switchover time. For Group B, a pitch of 0.813 was set for the non-ECG-synchronized scan of the upper thoracic aperture, followed by prospective ECG-synchronized acquisition of the heart with a pitch of 0.267 and a subsequent non-ECG-synchronized abdominal/pelvic scan with a pitch of 0.813 without delay. The single acquisitions were reconstructed as one volume.

All patients were administered an intravenous contrast agent (CA) bolus of iomeprol (400 mg iodine/ml; Imeron<sup>®</sup>-400 MCT, Bracco, Milan, Italy) followed by a saline flush of 60 ml using an automatic power injector (Accutron CT-D, Medtron AG, Saarbrücken, Germany). Patients with an estimated glomerular filtration rate (eGFR) <35 ml/min/1.73 m<sup>2</sup> received a 60 ml CA bolus at a rate of 3.0 ml/s, patients with an eGFR between 35–45 ml/min/1.73 m<sup>2</sup> received a 80 ml CA bolus at a rate of 4.0 ml/s, patients with an eGFR between 45–60 ml/min/1.73 m<sup>2</sup> received a 100 ml CA bolus at a rate of 4.0 ml/s and patients with an eGFR >60 ml/min/1.73 m<sup>2</sup> received a 120 ml CA bolus at a rate of 4.0 ml/s. CT acquisition was started automatically with a delay of 3 s after vessel attenuation in a region of interest (ROI) placed in the ascending thoracic aorta reached 200 Hounsfield units (HU).

No premedication for heart rate control was added to the patient's baseline medication before the CT scan.

### Radiation Dose

To evaluate radiation dose exposure, the dose-length product (DLP) in mGy\*cm, effective dose (E) in mSv and size-specific dose estimates (SSDE) in mGy were compared. The DLP was recorded from an automatically generated protocol, based on the CT dose index (CTDI). E was calculated from the DLP according to the method and conversion coefficients (k) presented in the European Guidelines on Quality Criteria for Computed Tomography [10, 11]: we used a k of 0.017, which is the mean of the k of the chest (0.017 mSv/mGy\*cm), abdomen (0.015 mSv/mGy\*cm), and pelvis (0.019 mSv/mGy\*cm), and the following formula:  $E = k \times DLP$ . SSDE was calculated, as described in another study [12], by multiplying conversion coefficients as a function of the sum of the lateral and anteroposterior dimensions with CTDI.

### **Objective Image Analysis**

For quantification of objective image quality, circular ROIs were placed in the aortic lumen and the closest adjacent muscle at two anatomical levels in axial images: 1) the aortic root and 2) the abdominal aorta just proximal to the aortic bifurcation. The following parameters were measured: a) CT attenuation number of the artery and b) image noise, defined as the SD of the CT attenuation number of the artery. The following parameters were calculated: c) SNR, defined as the mean attenuation of the artery divided by the image noise of the CT attenuation value of the artery and d) CNR, defined as the difference between the mean attenuation of the artery and the mean attenuation of the closest adjacent muscle, divided by the image noise of the CT attenuation value of the artery [10, 13–16]. All aortic ROIs were drawn as large

**Table 1** Demographic and imaging data of the patients included in the two groups. The Mann-Whitney U-test was used to test for statistically significant differences in age, BMI, scan time, kV and administered volume of CM, Student's t-test for differences in HR and eGFR, and the chi-squared test for differences in sex distribution and the distribution of administered CM.

**Tab.1** Demografische und Bildgebungsdaten der Patienten, die in die beiden Studiengruppen eingeschlossen wurden. Der Mann-Whitney-U-Test wurde zur Überprüfung der Signifikanz von Unterschieden bezüglich Alter, BMI, Scanzeit, kV und Kontrastmittelvolumen angewendet, der T-test für Unterschiede in der Herzfrequenz und eGFR und der Chi-Quadrat-Test für Geschlechtsverteilung und Verteilung der Kontrastmittelvolumina.

	total (mean)	group A	group B	p-value
number of patients	107	55	52	
age (years)	81±7.4	81±7.9	80±6.9	0.696 (n. s.)
BMI (kg/m²)	27.3 ± 7.0	27.4 ± 7.9	27.2 ± 6.0	0.333 (n. s.)
sex (♂/♀)	63/44	32/23	31/21	0.880 (n. s.)
heart rate (bpm)	70±13.0	73 ± 14.8	68±10.7	0.213 (n. s.)
eGFR (ml/min/1.73 m <sup>2</sup> )	57.4±18.4	53.8±18.6	59.7±17.8	0.331 (n. s.)
scan time (s)	14.8±1.8	15.7 ± 1.7	13.9±1.25	< 0.001
kilovoltage (kV)	100.9±10.8	101.4±14.9	100.4 ± 2.8	0.857 (n. s.)
CM volume (ml)	102.4 ± 20.4	99.3 ± 22.6	105.5 ± 17.6	0.337 (n. s.)
CM volume distribution 60/80/100/120 ml	12/18/26/51	7/10/12/26	5/8/14/25	0.645 (n. s.)

as possible while avoiding calcifications or metallic artifacts to exclude partial volume effects. Muscle ROIs were made the same size as the corresponding vessel ROIs.

### Subjective Image Analysis

Two medical doctors with different levels of experience (rater 1: 15 years; rater 2: 3 years) rated the image quality of the aortic root and the aortoiliac pathway with respect to the following features: 1) clear identification of the annulus plane; 2) clear depiction of valve leaflets; 3) arterial wall sharpness; and 4) conspicuity of arterial wall calcifications. Image quality was rated on a 4-point Likert scale (1: excellent, 2: good, 3: sufficient, 4: poor). Image datasets of both groups were blindly evaluated in random order using a hanging protocol on RA1000 PACS (GE Healthcare, Wauskesha, USA) with a preset bone window (W: 1800 L: 400 HU) and 1 mm slice thickness. Raters only used axial images for reading but were allowed to change window settings.

### **Statistical Analysis**

All data was tested for normal distribution using the Shapiro-Wilk test. Differences in heart rate (HR) and eGFR were tested for significance with an unpaired Student's t-test. To compare the distribution of male and female patients and the distribution of CM administered, a chi-squared test ( $\chi^2$ ) was used. Differences in patient age, body mass index (BMI), scan time, administered CM volume, kilovoltage (kV), radiation dose, artery attenuation, image noise, SNR, CNR and subjective image quality scores between the two groups were tested for significance using the Mann-Whitney U-test. Interrater agreement of subjective image quality scores between the two readers was compared using Cohen's weighted kappa coefficient ( $\kappa_w$ ).  $\kappa_w$  was interpreted as follows: <0.00: poor, 0.00–0.20: slight, 0.21–0.40: fair, 0.41–0.60: moderate, 0.61–

0.80: substantial and 0.81–1.00: almost perfect agreement [17, 18]. A p-value below 0.05 was considered statistically significant. Values are presented as mean ± SD unless specified otherwise. SPSS (SPSS<sup>®</sup> Mac, v. 20.0; IBM Corp., New York, NY) was used for all statistical analyses.

# Results

### **Patient Characteristics**

Patient characteristics are summarized in  $\triangleright$  **Table 1**. There was no significant (n. s.) difference between the two groups with respect to age (p = 0.696), BMI (p = 0.333), sex (p = 0.880), HR (p = 0.213), eGFR (p = 0.331), kV (p = 0.857), volume of CM administered (p = 0.337) and the distribution of CM administered (p = 0.645). The scan time was significantly shorter in Group B with 13.9 ± 1.25 s compared to Group A with 15.7 ± 1.7 s (p = < 0.001).

### **Radiation Dose**

The mean DLP in Group A was  $1256.58 \pm 619.05 \text{ mGy}^{*}\text{cm}$  compared to a mean of  $790.90 \pm 238.15 \text{ mGy}^{*}\text{cm}$  in Group B. Using the methods described in other studies [10-12], we calculated a mean E of  $21.36 \pm 10.52 \text{ mSv}$  for Group A and  $13.44 \pm 4.05 \text{ mSv}$  for Group B as well as a mean SSDE of  $20.85 \pm 7.29 \text{ mGy}$  for Group A and  $13.84 \pm 2.94 \text{ mGy}$  for Group B. Differences were statistically significant (p = < 0.001). Results are summarized in **> Table 2**, **> Fig. 2**.

### **Objective Image Analysis**

The results are summarized in  $\triangleright$  **Table 3**. There was no significant difference in artery attenuation measured in HU in the aortic root and abdominal aorta (aortic root p = 0.153; abdominal aorta

**Table 2** Summary of dose parameters. The Mann-Whitney U-test was used to test for statistically significant differences.

► Tab.2 Zusammenfassung der Dosisparameter. Der Mann-Whitney-U-Test wurde zur Überprüfung der Signifikanz der Unterschiede angewendet.

	group A	group B	p-value
DLP (mGy*cm)	1256.58±619.05	790.90 ± 238.15	< 0.001
E (mSv)	21.36±10.52	13.44±4.05	< 0.001
SSDE (mGy)	20.85±7.29	13.84±2.94	< 0.001

p = 0.195) between the two groups. Likewise, attenuation values for background muscle did not differ significantly (muscle at the level of aortic root p = 0.643; muscle at the level of abdominal aorta p = 0.898). Furthermore, there was no significant difference in image noise, SNR, and CNR between Group A and B (image noise: aortic root p = 0.727; abdominal aorta p = 0.550; SNR: aortic root p = 0.212; abdominal aorta p = 0.643; CNR: aortic root p = 0.207; abdominal aorta p = 0.682).

### Subjective Image Analysis

No significant difference was observed in image guality ratings of the two readers between Group A and B. The mean scores of the first reader were  $1.90 \pm 0.83$  for image guality of the aortic root and  $1.05 \pm 0.22$  for image quality of the aortoiliac pathway in Group A and 1.53 ± 0.61 for image quality of the aortic root and 1.11 ± 0.46 for image quality of the aortoiliac pathway in Group B (p = 0.146 and 0.914). The mean scores of the second reader were  $1.90 \pm 0.77$  for image guality of the aortic root and  $1.10 \pm 0.44$  for image guality of the aortoiliac pathway in Group A and  $1.47 \pm 0.61$ for image quality of the aortic root and  $1.05 \pm 0.23$  for image quality of the aortoiliac pathway in Group B (p = 0.914 and 0.973). The  $\kappa_w$  value for the interrater agreement was almost perfect in Group A and B for the aortic root and substantial in Group A and B for the aortoiliac pathway. Sample images of the aortic root and the aorta are shown in > Fig. 3, 4, and the results are summarized in ► Table 4.

# Discussion

In this study, we have demonstrated that the updated 3-phase vHP3 protocol can produce a complete preprocedural TAVI/TAVR CT by switching between a non-ECG-synchronized acquisition of the upper thoracic aperture, an ECG-synchronized cardiac acquisition, and a non-ECG-synchronized abdominal/pelvic acquisition within a single spiral scan. Thus, the updated vHP3 protocol can significantly reduce the radiation dose compared to a combined ECG-synchronized spiral scan of the chest and a non-ECG-synchronized spiral scan of the chest and a non-ECG-synchronized spiral scan of the abdomen/pelvis. The fact that TAVI/TAVR is generally performed in an elderly population, with a mean patient age of 79.8–83.6 years in high- and intermediate-risk trials and 79.1 years in the NOTION trial [19], might suggest that radia-



▶ Fig. 2 Box-and-whisker plots graphically depict significant (\*) radiation dose difference in dose-length product between the two groups (p = <0.001).

► Abb. 2 Kastengrafik-Diagramme zeigen grafisch einen signifikanten (\*) Unterschied in der Strahlungsdosis im Dosislängenprodukt zwischen beiden Gruppen (p = < 0,001).



**Fig.3** Sample images of the aortic valve of representative patients examined in Group A (left) and Group B (right).

► Abb.3 Exemplarische Bilder der Aortenwurzel repräsentativer Patienten in Gruppe A (links) und Gruppe B (rechts).

tion dose reduction is of low clinical relevance. However, improvements in the design of TAVI/TAVR and an increase in operator experience have improved procedure safety, leading to an expansion of indications for the procedure into low-risk groups without age restriction, such as in the PARTNER 3 trial [19–23]. As a result, the need to minimize radiation exposure during preprocedural TAVI/TAVR CT while ensuring diagnostic image quality is gaining importance. Besides, the ALARA (as low as reasonably achievable) principle is not restricted to a particular age group.

The 37 % dose reduction achieved with the vHP3 protocol, calculated as DLP, E, and SSDE ( $1256.58 \pm 619.05 \text{ mGy}^{*}$  cm vs. 790.90 ± 238.15 mGy<sup>\*</sup> cm, 21.36 ± 10.52 mSv vs. 13.44 ± 4.05 mSv, and 20.85 ± 7.29 mGy vs. 13.84 ± 2.94 mGy), compared to vHP is in line with a recent 2020 study by Ippolito et al., who reported a dose

**Table 3** Summary of objective image parameters measured in the aortic root and the abdominal aorta. The Mann-Whitney U-test was used to test for statistically significant differences.

**Tab.3** Zusammenfassung der Parameter der objektiven Bildqualität. Der Mann-Whitney-U-Test wurde zur Überprüfung der Signifikanz der Unterschiede angewendet.

region	parameter	group A	group B	p-value
aortic root	vessel (HU)	571.88	464.23	0.153 (n. s.)
	muscle (HU)	44.38	43.53	0.643 (n. s.)
	image noise (SD)	36.11	34.43	0.727 (n. s.)
	CNR	14.61	12.22	0.207 (n. s.)
	SNR	15.84	13.48	0.212 (n. s.)
abdominal aorta	vessel (HU)	544.00	449.05	0.195 (n. s.)
	muscle (HU)	51.85	49.95	0.898 (n. s.)
	image noise (SD)	45.83	44.49	0.550 (n. s.)
	CNR	10.74	8.97	0.682 (n. s.)
	SNR	11.87	10.09	0.643 (n. s.)



**Fig. 4** Sample images of the aorta and the right iliac artery of representative patients examined in Group A (left) and Group B (right).

► Abb.4 Exemplarische Bilder der Aorta und der rechten Iliakalarterie repräsentativer Patienten in Gruppe A (links) und Gruppe B (rechts).

reduction from  $1600.3 \pm 340.7 \text{ mGy}^{\circ} \text{ cm}$  to  $672.3 \pm 317.16 \text{ mGy}^{\circ} \text{ cm}$ and  $27.55 \pm 5.95 \text{ mSv}$  to  $11.54 \pm 5.23 \text{ mSv}$  by using a low-kV (80 kV) protocol with a single continuous ECG-synchronized acquisition with iterative model-based reconstruction (IMR) compared to a 100 kVsetting [24]. We achieved a greater dose reduction than reported in a recent 2018 study by Talei Franzesi et al., who achieved a dose reduction from 2044.53  $\pm 130.22 \text{ mGy}^{\circ} \text{ cm}$  to  $1600.29 \pm$  $340.65 \text{ mGy}^{\circ} \text{ cm}$  and  $28.82 \pm 2.21 \text{ mSv}$  to  $22.56 \pm 5.8 \text{ mSv}$  by using a 100 kV tube voltage setting compared to a 120 kV standard protocol [25]. Nonetheless, our radiation exposure with vHP3 is still higher than the exposure found in a 2016 study by Bittner et al., who used a dual-source CT scanner with prospective ECG synchronization, low CM volume of 38 ml of a 350 mg iodine/ml CM in a high-pitch (3.2) 100 kV setting. They reported a dose of  $210 \pm 21 \text{ mGy}^{*}$  cm and  $2.9 \pm$ 0.3 mSv [26]. However, Bittner et al. also reported much lower attenuation values at the aortic root ( $285 \pm 60$  HU) and at the iliac bifurcation (289 ± 74) compared to our values in both groups. This difference is attributable to the high pitch and low CM dose, which led to a repeat acquisition in 1 of the 40 study patients due to poor image quality. Finally, while one group of researchers previously conducted a study investigating the effectiveness of preprocedural TAVI/TAVR CT using vHP and reported a radiation dose of 1281.6 ± 195.7 mGy\*cm [19], to the best of our knowledge, our study is the first to demonstrate the usefulness of the novel 3-phase vHP3 in patients scheduled for TAVI/TAVR.

Compared to the studies by Ippolito et al., Talei Franzesi et al., and Bittner et al., a possible concern regarding our study is that we administered higher volumes of CM (99.3 ± 22.6 ml in Group A and 105.5 ± 17.6 ml in Group B). This is especially relevant because TAVI/TAVR is generally performed in patients who typically have chronic kidney disease [25]. Furthermore, a recent 2019 consensus document by the European Society of Cardiovascular Radiology (ESCR) states that a 50 ml CM volume at a flow rate of 3–4 ml/s is often sufficient for diagnostic imaging [4]. Combining three different phases into a single acquisition, vHP3 would allow a reduced single contrast injection. Nonetheless, we believe that, if parameters of renal function are adequate, higher CM doses are reasonable to ensure adequate image guality and prevent repeated acquisition. A recent review published by The New England Journal of Medicine indicates that severe acute kidney injury with a substantial reduction in kidney function or the need for renal replacement therapy appears to be very infrequent after intravascular contrast administration [27]. Furthermore, a recent consensus **Table 4** Summary of subjective image quality parameters measured using a 4-point scale and compared for interrater agreement using Cohen's weighted kappa coefficient ( $\kappa_w$ ). The Mann-Whitney U-test was used to test for statistically significant differences.

**Tab.4** Zusammenfassung der Parameter der subjektiven Bildqualität unter Verwendung einer 4-Punkt-Skala und Vergleich der Interrater-Reliabilität mittels Cohens-gewichteter Kappa-Koeffizienten (κ<sub>w</sub>). Der Mann-Whitney U-test wurde zur Überprüfung der Signifikanz der Unterschiede angewendet.

region	rater 1	rater 2	
aortic root			
group A vs. group B	1.90 ± 0.83 vs 1.53 ± 0.61	1.90 ± 0.77 vs 1.47 ± 0.61	
p-value	0.146 (n. s.)	0.914 (n. s.)	
κ <sub>w</sub> group A (p-value)	almost perfect: 0.888 (< 0.001)		
κ <sub>w</sub> group B (p-value)	substantial: 0.644 (0.002)		
aortoiliac pathway			
group A vs. group B	1.05 ± 0.22 vs 1.11 ± 0.46	1.10 ± 0.44 vs 1.05 ± 0.23	
p-value	0.914 (n. s.)	0.973 (n. s.)	
κ <sub>w</sub> group A (p-value)	almost perfect: 0.912 (< 0.001)		
$\kappa_w$ group B (p-value)	substantial: 0.787 (< 0.001)		

statement from the American College of Radiology and the National Kidney Foundation concludes that the risk of administering modern intravenous iodinated CM in patients with reduced kidney function has been overstated. Therefore, lowering the CM volume below a diagnostic threshold and a loss of diagnostic accuracy should be avoided [28].

Regarding objective and subjective image quality, our study found no statistically significant difference between the two protocols. Nonetheless, our results show a tendency towards a loss of vessel attenuation in the aortic root as well as the abdominal aorta on the order of 100 HU in Group B. Since the only statistically significant difference between both protocols is the acquisition time  $(15.7 \pm 1.7 \text{ s in Group A vs. } 13.9 \pm 1.25 \text{ s in Group B})$ , we can only guess that we may have overtaken or not reached the maximum contrast bolus at the measuring sites. Another explanation could be that minimum automated tube voltage was 80 kV in Group A and 100 kV in Group B. Although the mean kV value did not reach a statistically significant difference, 10 of 55 patients (18%) in Group A were examined with a kV of 80 compared to none in Group B. The use of low tube voltages might have provided greater contrast enhancement as iodine attenuation increases at lower tube potentials [29]. This effect might have been strong enough to be a confounding factor.

Our study has some limitations. First, vHP was acquired using retrospective ECG synchronization, while vHP3 was acquired using prospective ECG synchronization. Furthermore, the vHP3 software update has restrictions regarding choices for pitch, automated tube voltage for ATCM, and image noise as an image quality reference parameter for ATCM. Therefore, there is a mismatch of pitch values between the two protocols (for example, 1.388 in the abdominal spiral scan in Group A vs. 0.813 in Group B). Likewise, although lower tube voltages are generally recommended [4, 30], we could choose a minimum of 80 kV in automated tube voltage in Group A but not in Group B, as this would lead to a deactivation of tube current modulation in vHP3, even though this did not result in a statistically significant difference in mean kV. Furthermore, image noise as an image quality reference parameter for ATCM is set lower in vHP3 at 12.5 vs. 40 in vHP. Interestingly, this should result in a higher dose [31]. Nonetheless, it seems that the dose-reducing qualities of vHP3 counterbalance this effect. Thus, it is not fully clear which specific parameter contributes most to the dose reduction we observed. However, we believe it is a combination of all factors. After all, we used the same CT scanner with unchanged iterative reconstruction algorithms in all patients to ensure the comparability of the two protocols. Therefore, the reported differences in radiation exposure between the two groups reflect the real change resulting from the protocol selection.

Apart from Canon Medical Systems, there is currently no other vendor offering the vHP3 software update. Therefore, the diagnostic performance we found in our study may not be generalizable to other acquisition protocols and CT systems. Furthermore, we believe that dose reduction using vHP and 3-phase vHP3 does not yet fully exhaust the overall dose reduction potential. For instance, we observed that the ATCM is deactivated for a specific time during switching between the different phases in vHP. At the same time, the switchover process occurs at the end of the cardiac scan in vHP3. We believe that optimization of ECG synchronization and ATCM can further reduce radiation exposure without a loss of objective image quality.

Finally, we did not have the opportunity to compare vHP3 with a protocol that combines a prospective ECG-synchronized cardiac scan with a subsequent non-ECG-synchronized thoracoiliac spiral scan. This could be a starting point for further investigations. In this study, we show that an affordable novel 3-phase vHP3 protocol update significantly reduces the dose in preprocedural TAVI/TAVR CT imaging without a loss of image quality. This is of clinical relevance as TAVI/TAVR is increasingly being offered to a broader spectrum of patients, including younger ones.

### **Conflict of Interest**

S. Shnayien: nothing to disclose.

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### References

- Masci PG, Dymarkowski S, Bogaert J. Valvular heart disease: what does cardiovascular MRI add? Eur Radiol 2008; 18: 197–208. doi:10.1007/ s00330-007-0731-x
- [2] Baumgartner H, Falk V, Bax JJ et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J 2017; 38: 2739– 2791. doi:10.1093/eurheartj/ehx391
- [3] Webb JG, Wood DA. Current status of transcatheter aortic valve replacement. J Am Coll Cardiol 2012; 60: 483–492. doi:10.1016/ j.jacc.2012.01.071
- [4] Francone M, Budde RPJ, Bremerich J et al. CT and MR imaging prior to transcatheter aortic valve implantation: standardisation of scanning protocols, measurements and reporting-a consensus document by the European Society of Cardiovascular Radiology (ESCR). Eur Radiol 2019. doi:10.1007/s00330-019-06357-8
- [5] Bach DS, Siao D, Girard SE et al. Evaluation of patients with severe symptomatic aortic stenosis who do not undergo aortic valve replacement: the potential role of subjectively overestimated operative risk. Circ Cardiovasc Qual Outcomes 2009; 2: 533–539. doi:10.1161/ circoutcomes.109.848259
- [6] Leon MB, Smith CR, Mack M et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010; 363: 1597–1607. doi:10.1056/NEJMoa1008232
- [7] Smith CR, Leon MB, Mack MJ et al. Transcatheter versus surgical aorticvalve replacement in high-risk patients. N Engl J Med 2011; 364: 2187– 2198. doi:10.1056/NEJMoa1103510
- [8] Blanke P, Weir-McCall JR, Achenbach S et al. Computed Tomography Imaging in the Context of Transcatheter Aortic Valve Implantation (TAVI)/Transcatheter Aortic Valve Replacement (TAVR): An Expert Consensus Document of the Society of Cardiovascular Computed Tomography. JACC Cardiovasc Imaging 2019; 12: 1–24. doi:10.1016/ j.jcmg.2018.12.003
- [9] Hofmann NP, Schuetz M, Bekeredjian R et al. Image quality and contrast agent exposure in cardiac computed tomography angiography prior to transcatheter aortic valve implantation procedures using different acquisition protocols. Eur J Radiol Open 2017; 4: 75–83. doi:10.1016/ j.ejro.2017.06.001
- [10] Wielandner A, Beitzke D, Schernthaner R et al. Is ECG triggering for motion artefact reduction in dual-source CT angiography of the ascending aorta still required with high-pitch scanning? The role of ECG-gating in high-pitch dual-source CT of the ascending aorta. Br J Radiol 2016; 89: 20160174. doi:10.1259/bjr.20160174
- [11] Christner JA, Kofler JM, McCollough CH. Estimating effective dose for CT using dose-length product compared with using organ doses: consequences of adopting International Commission on Radiological Protection publication 103 or dual-energy scanning. Am J Roentgenol 2010; 194: 881–889. doi:10.2214/ajr.09.3462
- [12] American Association of Physicists in M. Size-specific dose estimates (SSDE) in pediatric and adult body CT examinations. Task Group 2011; 204: 1–26
- [13] Beitzke D, Wolf F, Edelhauser G et al. Computed tomography angiography of the carotid arteries at low kV settings: a prospective randomised trial assessing radiation dose and diagnostic confidence. Eur Radiol 2011; 21: 2434–2444. doi:10.1007/s00330-011-2188-1
- [14] Apfaltrer P, Hanna EL, Schoepf UJ et al. Radiation dose and image quality at high-pitch CT angiography of the aorta: intraindividual and interindi-

vidual comparisons with conventional CT angiography. Am J Roentgenol 2012; 199: 1402–1409. doi:10.2214/ajr.12.8652

- [15] Asano Y, Tada A, Shinya T et al. Utility of second-generation single-energy metal artifact reduction in helical lung computed tomography for patients with pulmonary arteriovenous malformation after coil embolization. Jpn J Radiol 2018; 36: 285–294. doi:10.1007/s11604-018-0723-6
- [16] Wang R, Schoepf UJ, Wu R et al. Diagnostic accuracy of coronary CT angiography: comparison of filtered back projection and iterative reconstruction with different strengths. J Comput Assist Tomogr 2014; 38: 179–184. doi:10.1097/rct.000000000000005
- [17] Mandrekar JN. Measures of interrater agreement. J Thorac Oncol 2011; 6: 6–7. doi:10.1097/JTO.0b013e318200f983
- [18] Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1977; 33: 159–174
- [19] Matsumoto S, Yamada Y, Hashimoto M et al. CT imaging before transcatheter aortic valve implantation (TAVI) using variable helical pitch scanning and its diagnostic performance for coronary artery disease. Eur Radiol 2017; 27: 1963–1970. doi:10.1007/s00330-016-4547-4
- [20] Mack MJ, Leon MB, Thourani VH et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med 2019; 380: 1695–1705. doi:10.1056/NEJMoa1814052
- [21] Leipsic J, Bax JJ, Webb JG et al. Trials Testing the Value of Imaging Use in Valve Disease and in Transcatheter Valvular Interventions. JACC Cardiovasc Imaging 2017; 10: 286–295. doi:10.1016/j.jcmg.2016.09.031
- [22] Overtchouk P, Prendergast B, Modine T. Why should we extend transcatheter aortic valve implantation to low-risk patients? A comprehensive review. Arch Cardiovasc Dis 2019; 112: 354–362. doi:10.1016/ j.acvd.2019.03.004
- [23] Rogers T, Thourani VH, Waksman R. Transcatheter Aortic Valve Replacement in Intermediate- and Low-Risk Patients. J Am Heart Assoc 2018; 7: doi:10.1161/jaha.117.007147

- [24] Ippolito D, Riva L, Talei Franzesi C et al. Computed Tomography Angiography Combined With Knowledge-Based Iterative Algorithm for Transcatheter Aortic Valve Implantation Planning: Image Quality and Radiation Dose Exposure With Low-kV and Low-Contrast-Medium Protocol. J Comput Assist Tomogr 2020; 44: 13–19. doi:10.1097/ rct.000000000000965
- [25] Talei Franzesi CR, Ippolito D, Riva L et al. Diagnostic value of iterative reconstruction algorithm in low kV CT angiography (CTA) with low contrast medium volume for transcatheter aortic valve implantation (TAVI) planning: image quality and radiation dose exposure. Br J Radiol 2018; 91: 20170802. doi:10.1259/bjr.20170802
- [26] Bittner DO, Arnold M, Klinghammer L et al. Contrast volume reduction using third generation dual source computed tomography for the evaluation of patients prior to transcatheter aortic valve implantation. Eur Radiol 2016; 26: 4497–4504. doi:10.1007/s00330-016-4320-8
- [27] Mehran R, Dangas GD, Weisbord SD. Contrast-Associated Acute Kidney Injury. Reply. N Engl J Med 2019; 381: 1296–1297. doi:10.1056/ NEJMc1908879
- [28] Davenport MS, Perazella MA, Yee J et al. Use of Intravenous Iodinated Contrast Media in Patients with Kidney Disease: Consensus Statements from the American College of Radiology and the National Kidney Foundation. Radiology 2020; 192094: doi:10.1148/radiol.2019192094
- [29] Meyer M, Haubenreisser H, Schoepf UJ et al. Closing in on the K edge: coronary CT angiography at 100, 80, and 70 kV-initial comparison of a second- versus a third-generation dual-source CT system. Radiology 2014; 273: 373–382. doi:10.1148/radiol.14140244
- [30] Kok M, Turek J, Mihl C et al. Low contrast media volume in pre-TAVI CT examinations. Eur Radiol 2016; 26: 2426–2435. doi:10.1007/s00330-015-4080-x
- [31] Merzan D, Nowik P, Poludniowski G et al. Evaluating the impact of scan settings on automatic tube current modulation in CT using a novel phantom. Br J Radiol 2017; 90: 20160308. doi:10.1259/bjr.20160308