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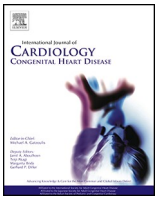

Percutaneous pulmonary valve implantation guided by three-dimensional rotational angiography

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STRUCTURED ABSTRACT

Objectives: To describe the workflow and value of three-dimensional rotational angiography (3DRA) in percutaneous pulmonary valve implantation (PPVI).
Background: 3DRA offers visualization of the entire topography in the chest and may enhance safety and reduce the risk for complications in PPVI through improved pre-procedural planning and per-procedural guidance.
Methods: All PPVI procedures with the use of 3DRA performed between August 2011 and December 2022 were reviewed. Success rate, complications and radiation dose were assessed. Radiation dose of the latest 3DRA protocol was compared to historical 3DRA data.
Results: PPVI was successful in 95 of 102 procedures. Seven procedures were aborted due to coronary compression after balloon testing (n = 3), main pulmonary artery (MPA) oversize (n = 3) and not passing of a Melody valve through a calcified Melody valve in situ (n = 1). PPVI was attempted in 61 homografts, 19 native right ventricular outflow tracts (including transannular patch), 4 previously implanted Melody valves, 2 in previously implanted Sapien valves and 16 in other bioprosthetic valves. A Melody valve was implanted in 43, a Sapien valve in 49 and a Pulsta valve in 1 patient. In 2 patients a Melody as well as a Sapien valve were subsequently implanted. Mean total dose area product (DAP) was 11813 mGycm^2 and 179 mGycm^2/kg for all attempted PPVI's. For successful PPVI 9835 mGycm^2 and 174 mGycm^2/kg. After optimizing the 3DRA protocols the mean dose reduced from 12677 mGycm^2 to 8551 mGycm^2 (200 mGycm^2/kg to 163 mGycm^2/kg). Four patients experienced one or more complications. There were no deaths peri-procedural or during follow-up. Complications were; need for cardiopulmonary resuscitation (n = 2), MPA paravasation (n = 1), valve dysfunction (n = 2).
Conclusions: The use of rotational angiography for the guidance of PPVI results in a high success rate, low number of complications with the use of a low amount of radiation.

1. Background

A substantial number of patients with congenital heart disease (CHD) with right ventricular outflow tract (RVOT) obstruction needs sequential pulmonary valve interventions during the course of their life. These defects include, Tetralogy of Fallot (ToF), isolated pulmonary valve stenosis (PS) and pulmonary atresia with ventricular septal defect (PA-VSD). Furthermore, patients post-Ross procedure for congenital aortic stenosis can require multiple pulmonary valve interventions. Percutaneous pulmonary valve implantation (PPVI) is performed in an increasing number of patients (currently over 11.000 procedures have been performed worldwide), reducing the need for repeat surgical procedures.

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Abbreviations

3DRA	Three-dimensional rotational angiography
CC	Coronary Compression
CHD	Congenital Heart Disease
CMR	Cardiac Magnetic Resonance
CTA	Computed Tomography Angiography
DAP	Dose Area Product
MPA	Main Pulmonary Artery
PPVI	Percutaneous Pulmonary Valve Implantation
RA	Rotational Angiography
RVOT	Right Ventricular Outflow Tract

PPVI is minimally invasive and has proven to be a safe and effective alternative to surgical procedures. Mid- and long-term survival and freedom from reintervention or surgery after PPVI are comparable to outcomes of surgical intervention [1]. However, the complication rate can be as high as 15 %. Complications include coronary compression (CC), aortic compression, conduit rupture, valve embolization, stent fracture and tricuspid valve damage [2–4]. Anticipated coronary compression (CC) is the most common contra-indication for performing PPVI [5], with an estimated risk between 1 and 6% [3,5–9]. The risk of CC is increased by an abnormal course of the coronary arteries, either due to congenital abnormalities or due to reinsertion during previous surgery (especially after the arterial switch or Ross operation) [5,10]. An abnormal coronary course makes risk stratification for CC challenging [10,11].

Risk stratification of CC and other complications using non-invasive techniques as cardiac magnetic resonance (CMR) or computed tomography angiography (CTA) can be cumbersome. Assessment of the chest topography at the landing zone is performed off-line (CMR + CTA) or has a lower spatial resolution (CMR).

Conventional biplane angiography for risk assessment of complications is suboptimal since coronary topography at the landing zone cannot be sufficiently visualized in all cases, even with multiple angiographies using various angulations.

Three-dimensional rotational angiography (3DRA) allows to evaluate the risk of CC in calcified conduits as well as in large RVOTs and can easily be applied during balloon interrogation. Furthermore 3DRA visualizes the entire chest topography to help understand RVOT morphology, pulmonary bifurcation stenosis, reduced retrosternal space and vessel-airway interactions.

The aim of our study was to examine how obtained topography can be used as a procedural roadmap, which in turn may enhance procedural safety and reduce the risk of complications. In this paper the authors describe a two-step workflow and the results of more than 10 years' experience with 3DRA in PPVI.

2. Methods

The peri- and post-procedural data of all 3DRA-guided PPVI procedures were retrospectively analyzed at the child- and adult catheterization laboratory between August 2011 and December 2022. Follow-up after PPVI consisted of all available information from the electronic patient file until the last outpatient clinic visit. The study received Institutional Ethics approval waiving the need for consent as it utilized anonynimized, clinically obtained data.

2.1. 3DRA workflow

2.1.1. Pre-procedure

Patients with a (possible) indication for pulmonary valve replacement are discussed in the multidisciplinary congenital heart disease team. Advise for percutaneous, surgical of conservative treatment is based on the patients history, previous treatments, transthoracic and/or transesophageal echocardiography. In most patients a preprocedural cardiac MRI or CTA is available during the team discussion. All patients who underwent percutaneous pulmonary valve replacement were included in this study.

2.1.2. Preparation for catheterization

All patients underwent PPVI under general anesthesia and central venous and arterial access, electrocardiography (ECG) and pulsoxymetry. An external defibrillator is connected to be able to convert ventricular rhythm disturbances potentially induced by rapid pacing. Medication during PPVI includes intravenous administration of antibiotic prophylaxis using Cephazoline and heparin 75–100 IU/kg with a target ACT >200 s in children and >250 s in adults.

2.1.3. Hardware

The DynaCT Artis Zee system (Siemens Healthcare, Erlangen, Germany) is used for 3DRA in both adults and children. This system has a large detector of 42 × 48 cm, which covers twice the size of a normal coronary angiography surface and allows for acquisition of the entire chest. The frontal plane is used for acquisition of the rotational angiography and rotates 200° from RAO 100° (right anterior oblique) to LAO 100° (left anterior oblique) with a scan time of 5 s. The number of frames is set to 1 frame per 1,5° rotation and acquisition is non-ECG triggered. Radiation parameters including vertical collimation are optimized individually.

2.1.4. Rotational angiography

Rotational angiography (RA) - also called "cone beam computed tomography" - is the basis for the computed 3D reconstruction. The principle of RA is different from conventional angiography. In conventional angiography contrast is injected at the cavity of interest and flows with the pulswave of the bloodstream. The high contrast density propagates during the angiographic film from the proximal to the distal end of the cavity. Rotational angiography could be described as conventional angiography combined with a CTA. Contrast density has to be homogenous throughout the entire RA to enable for density-based tomography in all angulations (as if the bloodstream is standing still).

There are four elements to achieve homogeneous contrast density throughout the entire rotation. First of all, reduction of cardiac output is crucial to minimize contrast run-off. This can be achieved by rapid pacing or temporary obstruction of a cavity (i.e. RVOT). Second, contrast injection should be high flow with high volume. Third, contrast has to be injected in the cavity proximal of the region of interest to reduce washout. Fourth, timing of contrast injection and start of C-arm rotation is crucial. Right ventricular rapid pacing between 160 and 220/min is performed to decrease the cardiac output with an average blood pressure drop to 60 %. The contrast injection locations and amount depend on the protocol used (Fig. 1). The standard dilution used is 60 % contrast (Omnipaque (iohexol) 300, GE Healthcare, Chicago, IL, USA) with 40 % saline. Ventilation is paused during acquisition to reduce breathing related motion artifacts.

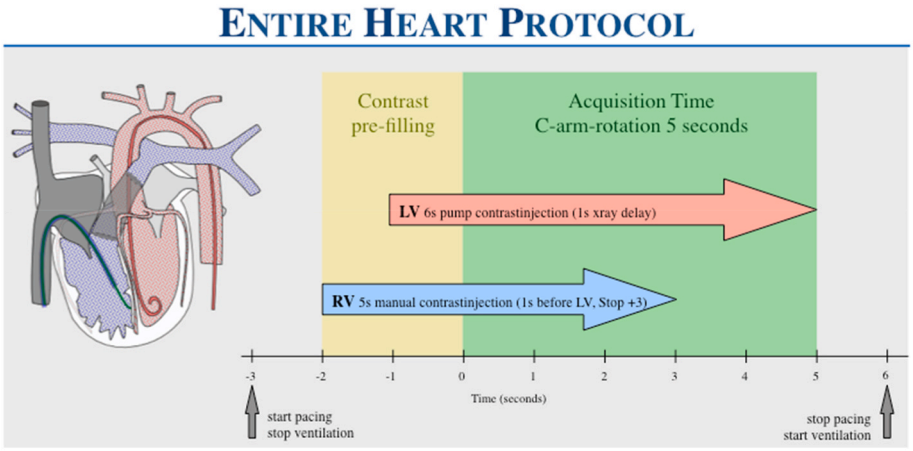
2.1.5. 3DRA and post-processing

The workstation automatically converts the rotational angiographic frames into Dicom stacks and creates a 3D volume rendered image by color-coding a specific range of Hounsfield units. The raw data consist of dicom stacks comparable to those known from CMR and CTA. A 3DRA capable angiographic system also enables the import of CMR or CTA dicom data to be used instead of or in combination with 3DRA datasets.

2.2. 3D rotational angiography protocols

During PPVI, the investigative team differentiated between two 3DRA protocols; one protocol is meant to understand the entire

a. "Entire Heart" protocol



b "Interrogation" protocol.

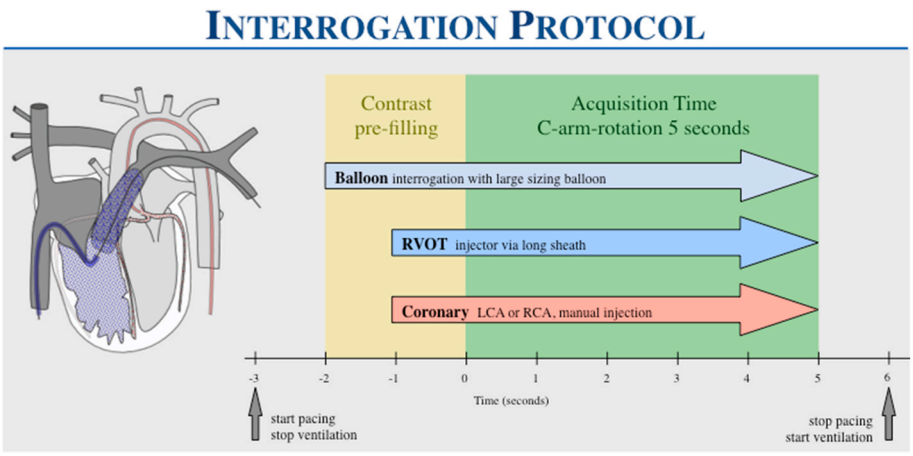


Fig. 1. a. "Entire Heart" protocol b "Interrogation" protocol.

topography ("Entire Heart protocol"), while the second protocol is executed to prepare for pre-stenting by balloon interrogation ("Interrogation protocol").

2.2.1. "Entire heart protocol"

The "Entire Heart protocol" (Fig. 1a) is used to visualize the entire right and left heart topography, including vessel-vessel, vessel-bone and vessel-airway interaction if not known from prior imaging. The protocol is performed by biventricular contrast injection. The obtained information includes RVOT dimensions, level and geometry of MPA, amount of calcification, the presence of right pulmonary artery (RPA) and left pulmonary artery (LPA) stenosis, interaction with the ascending aorta (AoAsc), coronary arteries and airway.

The contrast used in one RA equals the amount of contrast to visualize the same compartments with conventional angiography. The resulting 3DRA will allow to study the intrathoracic anatomy in unrestricted angulations. Whereas in conventional angiography every other angulation would demand another contrast injection. One "Entire Heart"-3DRA with simultaneous RV and LV contrast equals the amount of 4 biplane angiographies. The contrast used is 60 % diluted iodine contrast. For adults an average of 15 ml/s of diluted contrast is used during a 6 s interval (1 s prefill, 5 s rotation), resulting in 60 ml of pure contrast, equal to 2 conventional angiographies. If the maximum benefit of 3DRA is used, the iPilot will make multiple long sheath injections unnecessary to proof stent position right before implantation reducing contrast dose and radiation further.

2.2.2. "Interrogation protocol"

This protocol is used to assess coronary compression during balloon interrogation at landing zone level (Fig. 1b) in calcified conduits as well as in large RVOTs. The balloon is advanced over an ultrastiff guidewire and through a large long sheath which both are necessary for pre-stenting after 3DRA with balloon testing. Herewith, anatomic distraction caused by this stiff material is the same during the interrogation protocol and pre-stenting and allows to guide pre-stenting as well as valve placement. If risk of coronary compression is anticipated from the "Entire Heart protocol", the "Interrogation protocol" is performed. The interrogation protocol gives additive information opposed to conventional selective angiogram during balloon sizing. During 3DRA acquisition, progressive balloon inflation is performed with simultaneous selective coronary angiography. Inflation is halted when CC occurs or further inflation is not deemed safe. Rapid pacing is not necessary since total RVOT occlusion causes no-output hemodynamics. Ventilation-stop remains mandatory to reduce motion artifacts.

In native RVOT's the balloon diameter corresponds to the suitable valve size. Simultaneous RVOT contrast injection will be performed to prove total occlusion of the MPA. Push-and-pull maneuvers of the inflated balloon help to predict sufficient grip and stability of the landing zone for stenting.

In large RVOT's, interrogation with a 30 mm balloon (CBV Cristal Balt, BALT Extrusion SAS, France) is used to confirm or reject stability at stent- and valve position. If geometry is trapezoid or aneurysmatic the risk of incomplete sealing and paravalvular leakage can be assessed by simultaneous contrast injection in the RVOT (Fig. 1b "Interrogation

protocol").

2.2.3. Procedure guidance by "roadmap" (IPilot)

The 3D volume rendered dataset is post processed after acquisition to represent the image information necessary for anatomic understanding and for 3D guidance. 3D overlay – at the Siemens DynaCT called Ipilot – simplifies guidewire, catheter and device positioning, but at present doesn't compensate for movement (breathing, heart cycle). Anatomic shift can be corrected manually if necessary. The information obtained from both 3DRA protocols will identify the risk of CC, delineate MPA morphology (dimensions, calcification, bifurcation stenosis) and guide the procedure by providing a 3D roadmap. The post-processing is integrated in the catheterization laboratory system and can therefore be performed next to the patient. Alternatively, a separate workstation can be used. This post-processing takes about 10–15 min. Meanwhile the second operator can continue the procedure.

2.2.4. Fusion/merging with CMR/CTA data

Using previously acquired images (fusion or merging) can be helpful to reduce the contrast dose in selected patients, for example in case of renal insufficiency or contrast allergy. In these cases, the workstation will align bone structures from a CMR or CTA dataset with those from a low radiation non-contrast 3DRA ('empty rotation'), this is called 'registration'. The system uses boney structures or sternal wires to match pre-procedural images with live-images during the procedure. Patient position can be different and guidewires as well as a stiff sheath in situ can change the anatomy in a way that these off line imaging techniques become (severely) incongruent. However, periprocedural balloon interrogation cannot be substituted by procedural CTA or CMR.

3. Results

3.1. Baseline characteristics

One hundred two patients were scheduled for PPVI between August 2011 and December 2022. Baseline characteristics are depicted in Table 1. Mean age was 26 years (7–68), and ratio male versus female was 69/33. RVOT morphologies were 61 homografts (61 %), native RVOT's (including transannular patch) in 19 (19 %), previous implanted Melody valves in 4 (4 %), previous implanted Sapien in 2 (2 %) cases and other previous implanted bioprosthetic valves in 16 (16 %). The main lesion was pulmonary stenosis in 62 (61 %) patients, pulmonary regurgitation in 30 (29 %) patients, and 10 (10 %) patients had a combined lesion (see Table 1).

3.1.1. PPVI procedures

PPVI was successful in 95 of 102 attempted procedures (Table 1). Procedures were aborted because of an estimated high risk of CC (n = 3), an oversized landing zone (n = 3), or the inability to pass a Melody valve through a previous implanted calcified Melody valve (n = 1).

Pre-stenting was performed in all cases where a Melody valve was used. For procedures where a Sapien valve was used indication for pre-stenting was based on 3DRA. A challenging landing zone with a short stenosis or aneurysm were indications for pre-stenting. Pre-stenting was performed with Andra XXL (Andramed GmbH, Reutlingen, Germany), ev3 MaxLD (Medtronic, Minneapolis, MN, USA), or Cheatham platinum CP (covered) stents (B Braun, Melsungen, Germany) in most cases. In recent cases Sapien valves were implanted without pre-stenting in native RVOT's. Melody valves (Medtronic, Minneapolis, MN, USA) were implanted in 43 patients and Sapien valves (Edwards Lifesciences, Irvine, CA, USA) in 49 patients. Two patients were treated with two valves (see *'complications'-section for further details*). One patient was treated with a Pulsta 32 mm valve (TaeWoong Medical Co., Ltd., Gimposi, Gyeonggi-do, South Korea).

Table 1
Baseline characteristics.

Attempted PPVI's	(n = 102)
Male sex	69 (68 %)
Age	26 (7–68)
Weight	60 (21–125)
BSA	1,6 (0,77-2,50)
Diagnosis	
Tetralogy of Fallot	38 (37 %)
Isolated PS	6 (6 %)
PA with VSD	20 (20 %)
Truncus Arteriosus	4 (4 %)
Post-Ross	23 (23 %)
TGA with VSD	5 (5 %)
Other	6 (6 %)
Valve type	
Homograft	61 (61 %)
Native RVOT (including transannular patch)	19 (19 %)
Melody	4 (4 %)
Sapien	2 (2 %)
Other bioprosthetic valve	16 (16 %)
Indication for intervention	
PV Stenosis	62 (62 %)
PV Regurgitation	30 (30 %)
Mixed	10 (10 %)
Implanted valve	
Melody	43
Sapien	49
Melody + Sapien (implantation of a second valve in 2 patients)	2
Pulsta 32 mm *valve*	1
Radiation dose	
DAP (cGcm2)	11813 (286–131180)
DAP/kg (cGcm2/kg)	179
DAP (cGcm2) "old" protocol	12877
DAP/kg (cGcm2/kg) "old" protocol	200
DAP (cGcm2) "optimized" protocol	8551
DAP/kg (cGcm2/kg) "optimized" protocol	163

3.1.2. Morphology

The "Entire Heart" protocol visualized the entire right and left heart morphology in all patients within one run. Three-dimensional understanding of the anatomy was essential to choose the adequate position and length of the (covered) stent in patients with calcified RV-RA conduits. In patients with a large RVOT (native or after TAP) landing zone suitability was assessed using the interrogation protocol. After understanding the geometry of the landing zone, pre-stenting and valve implantation was performed safely in one session in these cases.

3.1.3. Roadmap

In multiple patients the roadmap described above was found to be helpful for guiding complex procedures by the operator. For instance, in several patients PA-bifurcation stenting or single PA-branch stenting with subsequent PPVI was performed, see Fig. 2.

3.1.3.1. Aborted procedures due to anticipated coronary compression. The "Interrogation" protocol identified three patients with high risk of CC. In all three patients CC was not anticipated on the basis of the pre-procedural MRA or CTA. In one patient the "Entire Heart" protocol showed the LAD close to the RVOT. Coronary angiography with simultaneous stepwise balloon inflation in the RVOT during the "Interrogation" protocol confirmed CC and the procedure was aborted. Fig. 3a shows a 10,3 mm distance between the landing zone and left coronary artery on the pre-procedural CTA. Selective angiography shows a non-obstructed left coronaory artery in Fig. 3b. With simultaneous balloon inflation a very fragile LAD with slow contrast filling is seen, Fig. 3c. Fig. 4 shows an inflated balloon (blue) and high resolution calcified tissue in the RVOT (yellow). A close relation to the LCA is visible and high risk for CC was estimated in this patient. Fig. 5. Shows proximal left main compression during balloon inflation in the RVOT.

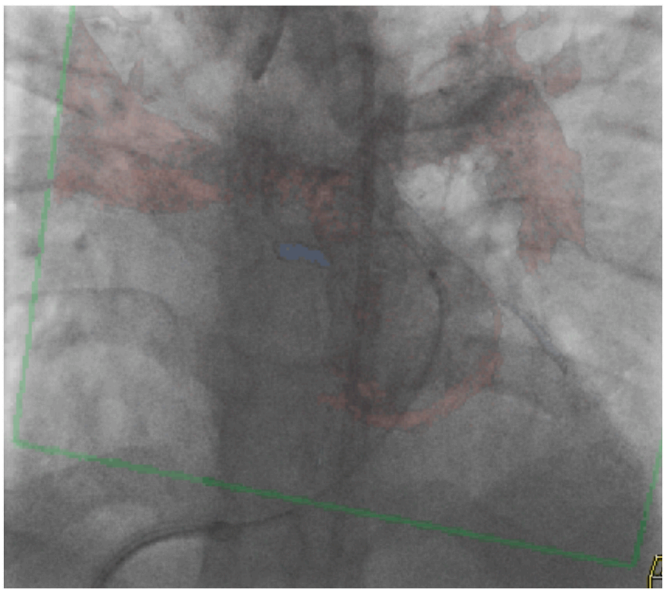


Fig. 2. Three-dimensional angiography in bifurcation stenting. Stents in situ; EV3 max LD stents, RPA 36 mm stent on BIB balloon 16 × 30mm; strut opening to LPA and stent through strut to LPA: EV3 mega LD 36 mm on BIB 16 × 30mm (Y-technique) Post-dilatation stents with Atlas 16x20mm. PPVI with a Melody 22 mm valve was performed in a second procedure.

In the second patient the "Entire Heart" protocol showed close proximity of the MPA to the left coronary artery (LCA). The "Interrogation" protocol demonstrated a distance of just 2–3 mm from MPA to LCA. Although there were no ST deviations or hemodynamic consequences of balloon inflation it was decided to abort the procedure and schedule a surgical homograft implantation in this patient who underwent just one previous surgery.

The third patient showed a 5 mm distance between the ostium of the LCA and the inflated balloon in the "Interrogation" protocol. The procedure was aborted and the patient underwent a surgical homograft implantation instead.

3.1.3.2. Aborted procedures due to very large MPA. In three patients the procedure was aborted due to a very large MPA, not anticipated from pre-procedural imaging. In one patient, pre-procedural transesophageal echocardiography suggested a MPA diameter of 18–21 mm, but measured 40 mm with the "Entire Heart" protocol. In the other two patients the inflated balloon in the "Interrogation' protocol did not seal the MPA. Fig. 6 shows paravalvular leakage assessed with RVOT interrogation with a balloon (CBV Crystal Balt) and simultaneous contrast injection in the RVOT.

Fig. 7a shows a pre-procedural CTA with a MPA of 25,3 mm. Fig. 7b shows a balloon interrogation in the same patient with a 30 × 40mm Altos balloon. In this still frame the contrast passing past the balloon is difficult to see. But, besides the contrast, there was no firm position during push-and-pull maneuver.

3.1.3.3. Aborted procedure due to not passing of a melody valve through a previously implanted melody valve. One patient had a history of interrupted aortic arch type B, Norwood/Rastelli procedure, and subsequent homograft implantation, multiple dilatations of re-coarctation, Contegra implantation, and Melody valve implantation. A dilatation and stenting of re-coarctation was performed four years after Melody implantation. Subsequently two Optimus XL 38 mm stents on BIB 18 × 35mm were placed in the calcified Melody valve with post-dilatation with an Atlas 20 mm balloon to 18 atm. In a now stable round geometry Melody valve implantation on 20 mm Ensemble was attempted. The Melody valve would not pass the 'old' Melody pre-stent despite 'buckle and twist'

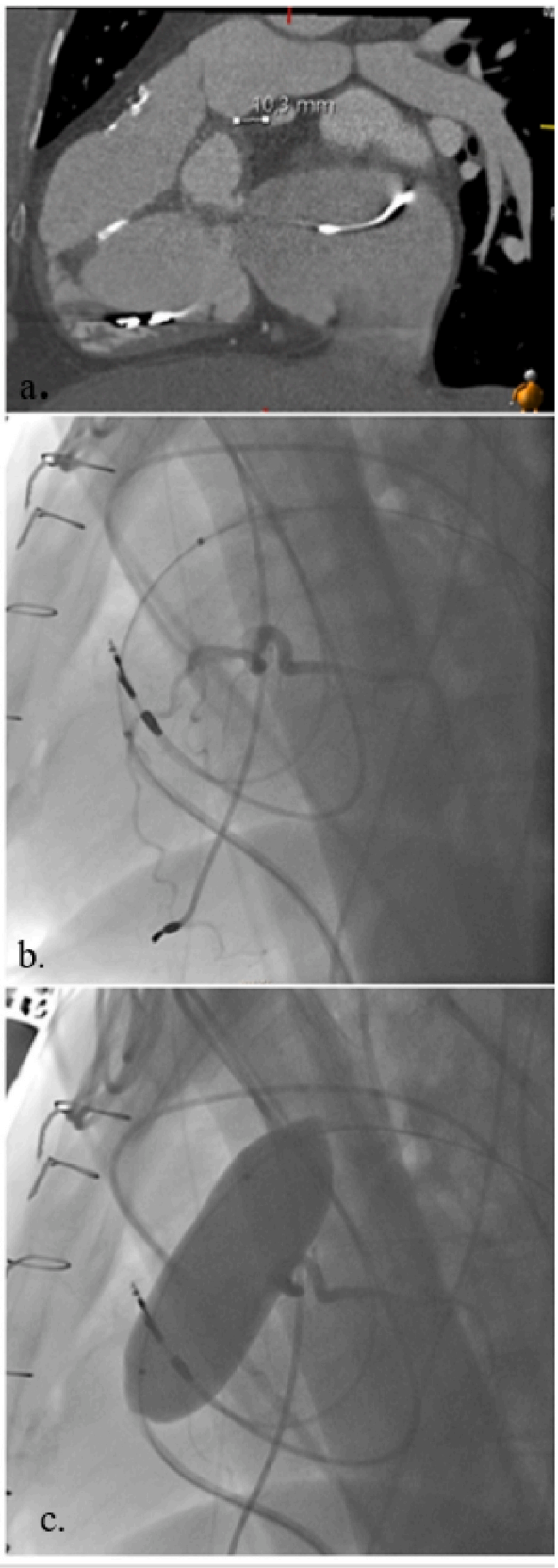


Fig. 3. Coronary compression not anticipated from pre-procedural CTA.

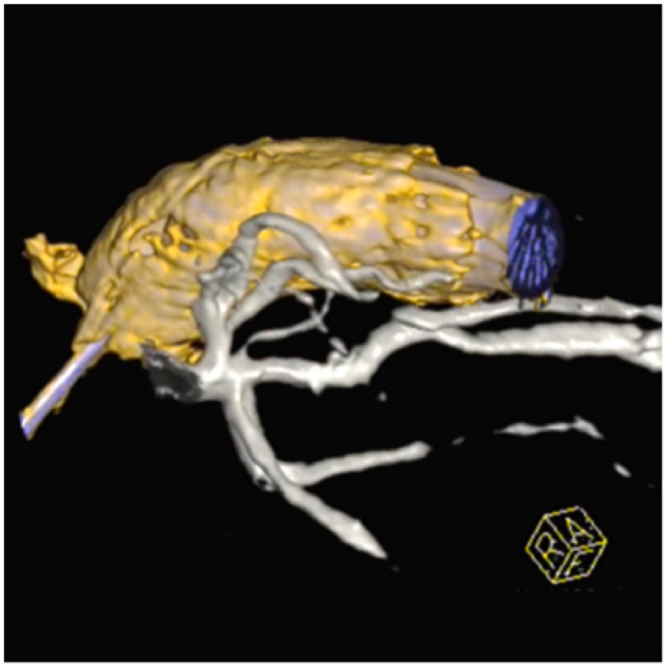


Fig. 4. "Interrogation protocol" shows an inflated balloon (blue) and high resolution calcified tissue in the RVOT (yellow). A close relation to the LCA is visible and high risk for CC was estimated in this patient. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

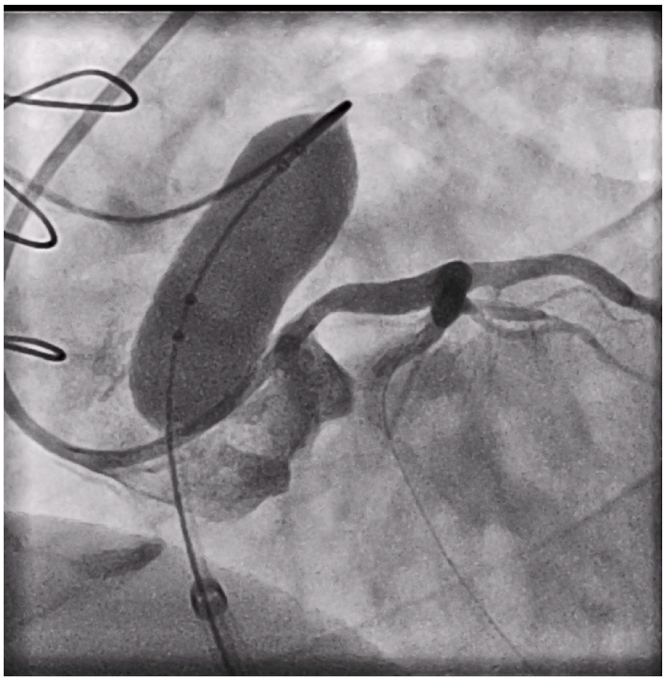


Fig. 5. Proximal left main compression during balloon inflation in the RVOT.

maneuvers. On retrieving the Ensemble, the Melody valve was lost hanging in the tricuspid valve. Retrieval was eventually successful with 18 Pink Cook in Dry Seal 24 French. Perforation of the septal tricuspid valve cusp occurred with moderate tricuspid insufficiency (mild tricuspid insufficiency pre-PPVI).

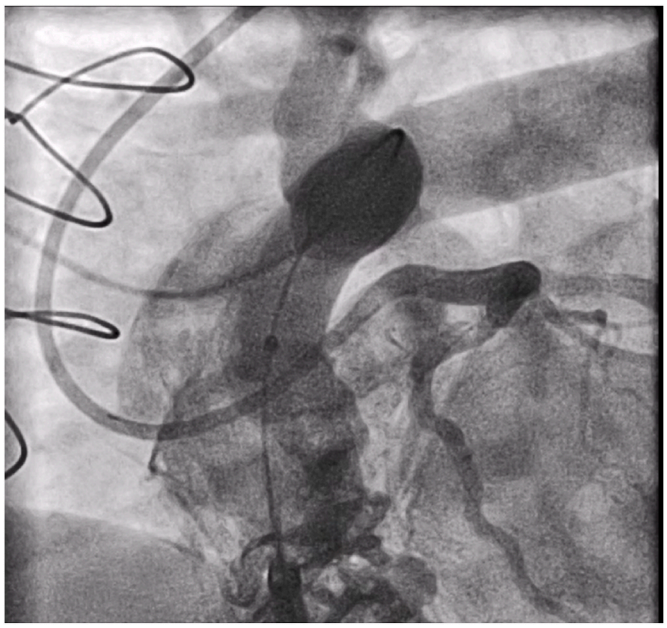


Fig. 6. Paravalvular leakage assessed with RVOT interrogation with a balloon (CBV Crystal Balt) and simultaneous contrast injection in the RVOT.

3.1.4. Radiation and contrast

Radiation dosages are depicted in Table 1. Mean total dose area product (DAP) was 11813 mGycm^2 and 179 mGycm^2/kg for all attempted PPVI's. For successful PPVI's mean DAP was 9835 mGycm^2 (IQR: 286–37869) and 174 mGycm^2/kg. After optimizing the 3DRA protocols the mean dose reduced from 12677 mGycm^2 to 8551 mGycm^2 (200 mGycm^2/kg to 163 mGycm^2/kg) [12]. There was no difference in radiation dose between the subgroups with predominantly a stenotic lesions and a regurgitation (12017 mGycm^2 and 187 mGycm^2/kg versus 12040 mGycm^2 and 177 mGycm^2/kg). Improvement of image quality and reduction of radiation and contrast dose was achieved by the use of diluted contrast, contrast injection in the pre-chamber location, use of rapid pacing and strict timing of the 3DRA. Post-processing was optimized by data duplication and setting two different threshold levels (another Hounsfield range) for left and right heart structures.

The contrast dose was available in a limited number of patients (n = 30). The mean contrast dose was 4 ml/kg (290 ml with SD 100 ml) for the total procedure.

3.1.5. Complications

Four patients experienced one or more complications. There were no deaths peri-procedural or during follow-up. Complications were; need for cardiopulmonary resuscitation (n = 2), MPA paravasation (n = 1), valve dysfunction (n = 2). See Table 3.

3.1.5.1. Cardiopulmonary resuscitation. In a 20-year-old female with rTOF and severe stenosis of a Freestyle valve a "diabolo phenomenon" occurred with a limited central deployment of a BeGraft Aortic stent graft 37 mm (Bentley InnoMed GmbH, Hechingen, Germany) mounted on a Balloon-in-Balloon (BIB; 24 × 45mm) catheter and rupture of the outer balloon. The BIB was stuck in the stent and retrieval was initially not possible. There was sufficient flow alongside the stent and BIB and the patient was hemodynamically stable. Emergency heart team discussion took place. Arteriovenous transfemoral extracorporeal life support was started to ensure safe retrieval of the BIB. This was ultimately possible with the use of a pink sheath with a launcher JR and MP 125, Terumo wire (Terumo medical, Tokyo, Japan), and subsequent deployment of the stent with an Atlas 12 mm and 18 mm balloon (Bard peripheral vascular, Tempe, AZ, USA), and an Amplatzer extra stiff wire

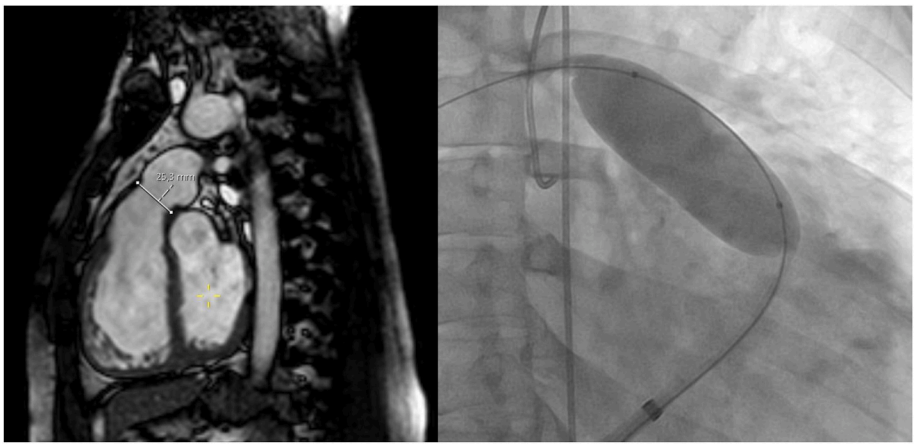


Fig. 7. a. Pre-procedural CTA with an MPA diameter of 25,3 mm. 7b. Unstable 30 × 40mm balloon in RVOT with passing of contrast (poorly visible in still frame).

(Cook medical, Bloomington, IN, USA). Subsequent Melody 22 mm implantation was performed inside the Bentley stent and the patient recovered without any sequelae.

A 33-year-old female with PA-VSD and a severe stenotic homograft became hemodynamic unstable due to severe paravasation at the proximal part of the RVOT stent and pericardial tamponade after Sapien 3 implantation. Cardiopulmonary resuscitation and percutaneous pericardial drainage was performed. The patient received protamin and blood transfusions and recovered without sequelae.

3.1.5.2. Valve dysfunction. In a 66-year-old post-Ross male patient with a severely stenotic homograft, which was implanted 19 years before, paravasation and severe valvular regurgitation arose after post-dilatation of a Melody 22 mm valve. This was treated by post-dilating with an Atlas 26 mm balloon and subsequent implantation of a Sapien XT 26 mm. After implantation of the Sapien valve no paravasation or dissection was visualized.

In a 19-year old female patient with a patched RVOT after repaired TOF and complete AVSD, the landing zone was located at the most distal aspect of a large trapezoid native MPA. Y-stenting from the distal MPA into the LPA and RPA (two stents ev3 MaxLD, 36 and 26 mm length) was performed 6 months earlier to treat severe bilateral branch stenosis. This procedure was also performed with the use of 3DRA and 3D roadmap-overlay. The "Interrogation protocol" confirmed a short landing zone (14 mm) and the critical proximity of the LCA 20 mm proximal of the branch ostia. A third ev3 MaxLD stent was placed to enhance mechanical properties. After placement of a Sapien 3 (23 mm) severe paravalvular leakage was demonstrated by PA angiography. The circumferential attachment of the stent and Sapien valve in the MPA were incomplete. The implantation of a Melody valve resulted in complete sealing and freedom from paravalvular leakage.

4. Discussion

This paper describes the single center experience in the use of 3DRA to guide PPVI. The application of this advanced peri procedural imaging technique in a retrospective study on 102 patients demonstrates the effectiveness and safety of a two-step workflow based on 3DRA. The initial high-resolution 3DRA of the entire heart is performed as start-up imaging to visualize the entire cardiovascular topography followed by 3DRA balloon interrogation with selective coronary angiography to delineate the coronary anatomy in relation to the intended landingzone of the pulmonary valve. Pre-procedural multimodality imaging can be merged with 3DRA for contrast and radiation reduction. The back-projection of the post processed 3DRA on the frontal black-white 2D screen offers 3D guidance of the entire procedure without the need for redundant conventional angiographies.Before the implementation of 3DRA in our center, multiple conventional angiographies in different angles were needed to assesses anatomy. This study demonstrates that the use of the 3DRA workflow is feasible and leads to enhanced procedural safety without significant increase of the radiation dose or contrast agent amount compared to conventional biplane angiography.

4.1. Contrast and radiation

Known arguments against the use of 3DRA are the supposed higher radiation and contrast dose compared to conventional angiography. This study shows that superior assessment of morphology and procedure guidance is possible with a similar amount of radiation and contrast dose (see Table 2 and references [12–16]).

Contrary to other recent reports [1,3,4,17,18], the majority of patients in this study had a predominantly stenotic lesion. There was no difference in radiation dose between the different subgroups.

The diagnostic advantages of 3DRA in CHD were also reported by other authors [13,14,19–21]. Aldoss et al. reported a 97,4 % superior image quality with 3DRA compared to conventional angiography [13]. A high detail of additional anatomical information with the use of 3DRA is reported by Aldoss et al. [13], Berman et al. [14], and Kapins et al [16].

The operators in our cohort did experience a learning curve in the adequate use of contrast and radiation. Timing of contrast injection, amount, concentration and location during a rotational angiography have little in common with a conventional angiography and had to be validated. In PPVI procedures the result was a two-step workflow for optimal anatomical understanding, procedural guidance and safety.

The purpose of the "Entire Heart"-3DRA protocol was to inform the operator about the morphology of the RV, LV, outflowtract interaction, coronary arteries, ascending aorta and PA bifurcation. With the "Interrogation"-3DRA protocol balloon interrogation at the PPVI target area and the risk of coronary compression can be assessed in every virtual

Table 2
Comparison of radiation dose.

	Mean DAP ($mGycm^2$)	DAP/kg ($mGycm^2$/kg)
Krings et al. (this paper) Attempted PPVIs.	11813	179
Krings et al. (this paper) successful PPVIs.	9835	174
Peters, Krings et al. [8] "old" protocol.	12877	200
Peters, Krings et al. [8] "optimized" protocol.	8551	163
Nguyen et al. [15]. PPVI with Melody valves.	8292	136

Table 3
Summary of complications.

Patient characteristics	Complication	Outcome
20 year old female with rTOF and severe stenosis of Freestyle valve	"diabolo phenomenon": limited central deployment of BeGraft Aortic stent after balloon rupture.	ECLS; retrieval of balloon and t deployment of the stent second balloon, and Melody 22 mm implantation. Patient recovery without sequelae.
33 year old female with PA-VSD and severe stenotic homograft	Hemodynamic unstable due to severe paravasation at proximal RVOT stent and pericardial tamponade	Cardiopulmonary resuscitation and pericardiocentesis. Administration of protamin and packed cells. Recovery without sequelae.
66 year old post-Ross patient with severe stenosis of homograft.	Paravasation and severe valvular regurgitation after post-dilation Melody valve.	Post-dilation with Atlas 26 mm and subsequent implantation of Sapien XT 26 mm. Recovery without sequelae.
19 year old female with patched RVOT after rTOF and complete AVSD. Now severe stenosis.	Severe paravalvular leakage after Sapien 3 implantation	Implantation of Melody valve Recovery without sequelae.

angulation not accessible during conventional angiography. The RA protocol is applied with a reduced 1,5° per frame setting and creates approximately 180 frames per 3DRA run, thus 360 frames for our 2 step 3DRA approach. The assessment of CC by conventional angiography usually needs 4 to 6 angulations, with 5–10 s in cine modus at 15 F/s, resulting in a total of 300–600 frames of biplane angiography (total 600–1200 frames). Alternatively, reducing the frame rate and acquiring shorter angiographies can reduce radiation if conventional angiography is used. Preprocedural CT and subsequent biplane imaging can also result in reduction of radiation.Thus when using rotational angiography up to half of frame number and up to half of the radiation of the corresponding number of conventional angiography is applied. Another advantage of rotational angiography is that the skin is exposed to radiation in 180-degree angles, whereas in conventional angiographymore or less AP/LAT and RAO/LAO angles are used. The lower variation of angles results in higher skin area dose. Opposite to TAVI procedures at high age, PPVI is in general the beginning of a recurrent intervention where cumulative effects of effective radiation dose (in mSv) in patients at relatively young age must be taken into account.

In 3DRA the available and virtually unrestricted 3D planes generate optimal orientation during pre-stenting and valve placement and herewith allows for overall reduction of fluoroscopy and cine angiographies. With high detail 3D imaging guidance the entire procedure can be performed with reduced fluoroscopy frame rates with 4 F/s without the need to search for optimal angulations and landmarks. For comparison, in most centers fluoroscopy framerate is set at 15–30 F/s. In electrophysiology with modern 3D non-contact visualization tools framerate is often decreased to a single frame. Analogue to this, the 3DRA protocol came down from 15 frames/s to 4 frames/s. Optimization of framerate and RA settings has led to more than 50 % reduction of overall radiation in the first years of 3DRA in our center [22]. In the company settings one 3DRA equaled 2–4 mSv, optimization of the protocol resulted in an average of 0,5 mSv per 3DRA, which is in the range of most modern CTAs. Now one 3DRA equals one 5 s biplane cine at framerate 15 F/s or monoplane cine of 10 s.

All patients who underwent PPVI with the use of 3DRA in our center were included in this study. This included a one year learning curve from 2012 to 2013 and resulted in inhomogeneous radiation and contrast amount within the first year of use. Table 3 shows a decrease in DAP over the learning curve which was achieved by careful adaptation of the radiation parameters. After optimization of the protocol and overall 3DRA workflow lower dosages were achieved ranging around 0,4-0,8 mSv per 3DRA comparable to those of a modern CTA.

Similar radiation dose was reported in other studies [13,14,19,20]. Nguyen et al. reported no difference between 3DRA and 2D angiography in Melody valve PPVI's [23]. Haddad et al. reported no difference in total procedural Air Kerma and DAP indexed to BSA in a group of complex 3DRA interventions versus two dimensional digital acquisition (2DDA). More contrast volume was used per 3DRA versus 2DDA but not for the entire procedure, probably due to the need for more 2DDAs to achieve the same detail of a single 3DRA (11 vs 7 per study; $p < 0.001$) [15].

Radiation and contrast dose reduction by fusion of live fluoroscopy with rendered 3D imaging from pre-procedural CT or MRI was reported by Goreczny [24–26]) and is also used in our institution.

4.1.1. *Balloon interrogation*

The "Interrogation protocol" is performed in calcified RV-PA conduits as well as in large RVOT's to delineate coronary proximity to the landing zone of the pulmonary valve and to prove coronary patency during balloon inflation. In large RVOT's the "Interrogation protocol" also predicts stent stability and RVOT occlusion with the aimed pulmonary valve diameter and helps avoiding potential para-stent leakage when implanting an undersized valve. There is an on-going discussion if balloon interrogation in calcified conduits is useful to demonstrate coronary patency or is contraindicated since displacement of calcification could already lead to irreversible coronary compression. Especially in heavily calcified homografts there is a significant risk of conduit rupture or irreversible CC if calcification is broken open. The right strategy in these cases remains an individual choice.

Recent reports demonstrate that the Sapien valve can be used for PPVI, even in native RVOTs without the use of a pre-stent without medium-term risk of frame fracture, paravalvar leak, or embolization [17,27].

4.1.2. *Coronary compression*

Fixation of a coronary artery to the MPA is anticipated to be suspect for an increased risk for CC. If the systolic-diastolic movement of the coronary artery is asynchronous to the MPA movement ("sign of the dancing coronary") the risk of CC most likely is lower. Since 3DRA is reduced to static information special attention should be paid to the potential information of the unprocessed rotational angiography. It offers 180-degree dynamic information on coronary flow during balloon interrogation. If CC still remains uncertain after 3DRA, selective conventional angiography of the suspected coronary artery at risk for compression is performed in the best angulation provided by the 3DRA images and using 3DRA as a roadmap.

4.1.3. *Rapid RV pacing during 3DRA*

Emphasis must be put on the rapid pacing protocol. In difference to CA contrast density enhancement at the region of interest is crucial during RA to enhance anatomical details by diminishing the cardiac output under rapid RV pacing. In combination with ventilation arrest it delivers optimal spatial resolution with reduced systolic-diastolic movement of the heart. Rapid RV pacing comes with the price of the loss of dynamic angiographic information, possible underestimation of vessel size and technical efforts linked to RV pacing. Also, other authors have posed the vulnerability of the myocardium as contra-indication for aggressive pacing. Ventricular tachycardias can be induced especially in patients after years of RV pressure overload (i.e. TOF with severe homograft stenosis). In our cohort we experienced Torsades de Pointes in one patient which was terminated by electrical cardioversion. In our experience the advantages of rapid pacing outweigh the acceptable risk of ventricular tachyarrhythmias. Noble et al. [28] have reported that rapid pacing is safe.

4.1.4. *Strength and limitations*

This retrospective study is limited by the lack of a same-center

control group to compare rotational angiography to conventional angiography. This is a single center study with use of single vendor equipment (Siemens Artis Zee) and describes only a limited number of patients. The number of patients studied are comparable to similar studies published on 3DRA in CHD [14,19–21,26]. Similar to using 3DRA with the Siemens system, techniques like Vessel Navigator (Philips) can be used as well as other periprocedural imaging techniques like (intracardiac) echocardiography to optimize safety and efficacy of the procedure [24].

5. Conclusion

A two-step 3DRA workflow in PPVI appears to be safe and efficient without significant increased radiation dose compared to conventional biplane PPVI. The use of 3DRA prevented PPVI in patients at risk for coronary compression Overall complication rate was lower than previously reported.

5.1. Summary

This retrospective, single-center study reports on the use of 3DRA for performing PPVI in 95 patients. A two-step workflow provides excellent topography of right and left heart structures. A systematic approach of the patient's anatomy including the use of 3DRA is safe and feasible; the risk of coronary compression can be adequately assessed and the RVOT landing zone can be assessed for valve size. These advantages are achieved with limited radiation dose. The authors recommend the use of 3DRA in all PPVI procedures.

5.2. Perspectives

What's known? 3DRA can be used as guidance for PPVI. Many centers do not use 3DRA due to the assumption of high radiation doses.

What's new? This study shows that 3DRA is safe and feasible with limited use of radiation.

What's next? The authors have had recent experience with 4DRA.

CRediT authorship contribution statement

Gregor J. Krings: Writing – review & editing, Writing – original draft, Supervision, Resources, Data curation, Conceptualization. **Bart W. Driesen:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Evangeline G. Warmerdam:** Writing – review & editing, Investigation, Data curation. **Mirella C. Molenschot:** Writing – review & editing, Data curation. **Gert-Jan T. Sieswerda:** Methodology, Investigation, Formal analysis, Conceptualization. **Pieter A. Doevendans:** Writing – review & editing, Supervision. **Arie P.J. van Dijk:** Writing – review & editing, Supervision, Methodology, Conceptualization. **M. Voskuil:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcchd.2024.100541.

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