Magnetic resonance and computed tomography imaging fusion for live guidance of percutaneous pulmonary valve implantation

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Abstract

Introduction: Until recently, two-dimensional (2D) angiography was the mainstay of guidance for percutaneous pulmonary valve implantation (PPVI). Recent advances in fusion software have enabled direct fusion of pre-intervention imaging, magnetic resonance imaging (MRI) or computed tomography (CT) scans, to create a reliable three-dimensional (3D) roadmap for procedural guidance.

Aim: To report initial two-center experience with direct 2D–3D image fusion for live guidance of PPVI with MRI- and CT-derived 3D roadmaps.

Material and methods: We performed a prospective study on PPVIs guided with the new fusion imaging platform introduced in the last quarter of 2015.

Results: 3D guidance with an MRI- (n = 14) or CT- (n = 8) derived roadmap was utilized during 22 catheterizations for right ventricular outflow tract balloon sizing (n = 7) or PPVI (n = 15). Successful 2D–3D registration was performed in all but 1 patient. Six (27%) patients required intra-procedural readjustment of the 3D roadmap due to distortion of the anatomy after introduction of a stiff wire. Twenty-one (95%) interventions were successful in the application of 3D imaging. Patients in the CT group received less contrast volume and had a shorter procedural time, though the differences were not statistically significant. Those in the MRI group had significantly lower weight adjusted radiation exposure.

Conclusions: With intuitive segmentation and direct 2D–3D fusion of MRI or CT datasets, VesselNavigator facilitates PPVI. Our initial data show that utilization of CT-derived roadmaps may lead to less contrast exposure and shorter procedural time, whereas application of MRI datasets may lead to lower radiation exposure.

Key words: percutaneous pulmonary valve implantation, three-dimensional guidance, fusion imaging, VesselNavigator.

Summary

Until recently two-dimensional (2D) angiography was the mainstay guidance of percutaneous pulmonary valve implantation (PPVI). Introduction of three-dimensional rotational angiography enabled utilization of three-dimensional (3D) reconstruction to exclude coronary compression during balloon testing and/or to guide stent/valve placement. However, the specific C-arm setup and the need to process the three-dimensional dataset during the study may increase the procedure length. Direct 2D–3D fusion of pre-registered magnetic resonance (MR) or computed tomography (CT) datasets allows for shortening of the diagnostic phase of the procedure and facilitates PPVI. Initial data show that utilization of CT-derived roadmaps may lead to lower contrast exposure and shorter procedural time, whereas application of MRI datasets may lead to lower radiation exposure.

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Introduction

Over the recent years percutaneous pulmonary valve implantation (PPVI) has dramatically gained in popularity [1–3]. Promising results in patients with dysfunctional surgically placed grafts encouraged application of this treatment in those with native or patched right ventricular outflow tracts (RVOT) [4–7]. Moreover, new devices and refined techniques of implantation have been introduced to extend PPVI to patients previously deemed unsuitable [8, 9]. Despite these improvements, several potentially fatal complications, such as coronary artery compression, conduit rupture, valve or stent dislocation, are inherent to this treatment and require extensive pre- and intra-procedural imaging [10–12]. Attempts have been made to select patients at risk of complications on the basis of non-invasive imaging; however, until recently two-dimensional (2D) angiography was the mainstay of procedural guidance [1–14]. Even in typical cases, this technique requires repeated contrast administration to visualize the RVOT and pulmonary arteries, in order to position the stent(s) for a "landing zone" (pre-stenting) as well as assess the outcome. Multiplane visualization of the coronary arteries is indispensable before and during expansion of the "landing zone" particularly to rule out coronary compression. This relies on multiple filmed projections used to identify the left or right coronary course, which increases radiation and examination time. Introduction of three-dimensional rotational angiography (3DRA) has enabled the three-dimensional (3D) reconstruction to exclude coronary compression during simultaneous balloon testing and/or to guide stent/valve placement [15]. In the past, exposure to a relatively large contrast volume and higher radiation was the major drawback of this imaging modality. However, with use of modified study protocols and optimization of imaging settings the degree of exposure has been alleviated to some extent [16–18]. Unfortunately, the specific C-arm setup and the need to process the 3D dataset during the study may increase the procedure length.

Table I. Study protocol

The study protocol included collection of the following data:
• patient characteristics (age, weight, body surface area, diagnosis),
• type and quality of pre-intervention imaging, including radiation and contrast exposure for CT scans
• tools used for planning of the intervention: marking rings/points, measurements
• technique of 3D roadmap fusion: internal markers and/or angiography
• procedural data: RVOT balloon sizing or PPVI
• quality of the 3D overlay: initial and during the procedure
• need for intra-procedural realignment of the 3D roadmap
• complications related to 3D imaging
• overall success defined as stent and/or valve delivery with 3D roadmap guidance
• contrast usage and radiation exposure expressed as total air kerma and dose area product
• fluoroscopy and total study times

Recent advances in fusion software have enabled easy application of pre-intervention imaging, including computed tomography (CT) and magnetic resonance imaging (MRI) scans, to create a reliable roadmap for manipulating through complex cardiac anatomy [19–22]. This strategy has the potential to reduce the need for diagnostic angiographies while providing reliable guidance of stent/valve implantation without the need for repeated contrast injections. Moreover, it promises improvement of visualization, as well as a reduction of total contrast and radiation exposure.

Aim

In this report we describe an initial 9-month, two-center experience with novel image fusion software for live guidance of PPVI with MRI- and CT-derived 3D roadmaps.

Material and methods

We have performed a prospective study of PPVIs guided with VesselNavigator (Philips Healthcare) at two reference centers since its introduction in the last quarter of 2015. Inclusion criteria were as follows: availability of cardiac CT or MRI dataset, which was performed for clinical purposes only and according to the centre's or external radiology protocol, and use of VesselNavigator with integration of the CT or MRI dataset. Table I presents collected data according to the study protocol.

Application of VesselNavigator included four steps: segmentation, planning, registration and live guidance (Figure 1) [23]. DICOM data from the contrast CT or the

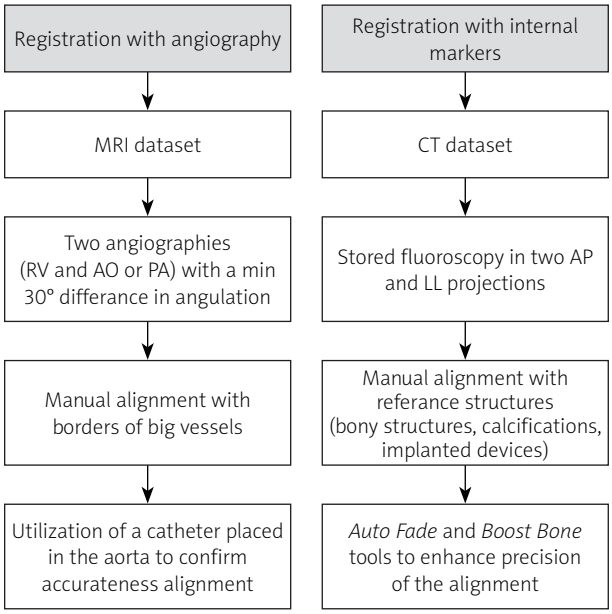

Figure 1. Step-by-step two-dimensional to three-dimensional (2D–3D) registration of magnetic resonance imaging (MRI) and computed tomography (CT) datasets with utilization of angiography or internal markers as reference points

3D whole heart or angiographic sequence MRI were uploaded into the VesselNavigator (Figure 2). The 3D image fusion software had been installed into the Allura XPer or Clarity (Philips Healthcare) platform on a separate computer. Segmentation of desired vessels was performed by highlighting and selecting the structures on automatically created 3D reconstructions or on one of the three orthogonal planes. The next steps consisted of placing marking rings/points, performing measurements and selecting the best angulations for the planned intervention.

The final stage before live guidance, and the first step requiring the patient to be prepared in the catheterization laboratory, is fusion of live fluoroscopy and the 3D roadmap. This is possible with 3D–3D or, a unique feature of this software, direct 2D–3D registration. The former requires a 3D data set derived from rotational spin, whereas the latter utilizes internal markers or 2D angiography as a reference.

Internal markers are mostly used for fusion of CT-derived 3D roadmaps. Easily visible bony structures such as the spine, vertebrae and sternum or calcifications, com-

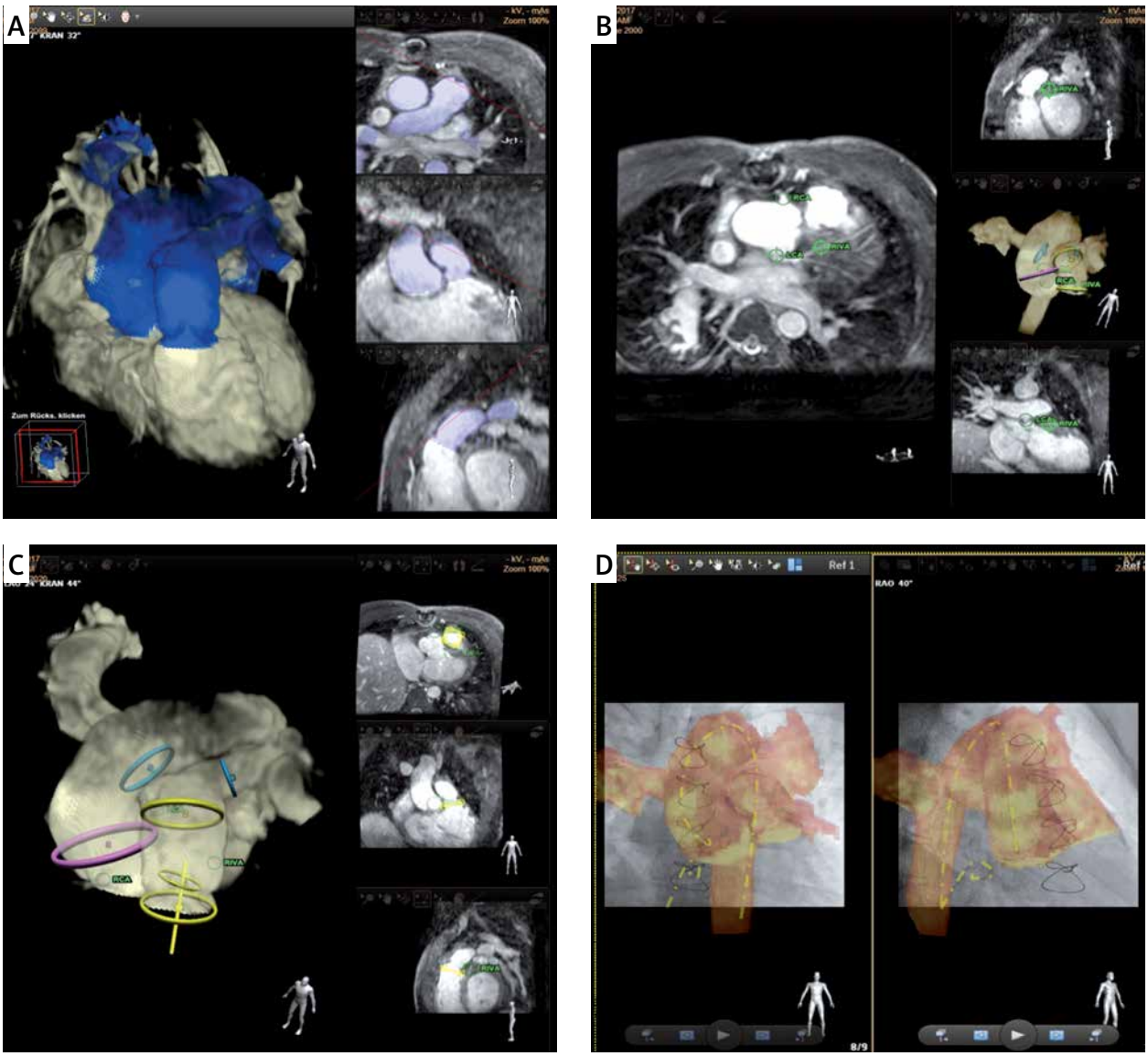

Figure 2. Percutaneous right ventricular outflow tract (RVOT) stenting and pulmonary valve implantation in 3-year-old male patient with pulmonary atresia (PA) and ventricular septal defect (VSD) with residual moderate stenosis and regurgitation of patch reconstructed RVOT. VesselNavigator assisted segmentation of magnetic resonance imaging 3D whole heart sequence without contrast (**A**). Green markers were placed to mark the right and left coronary artery (**B**). Additional yellow rings were placed to highlight the proximal, the narrowest and the distal part of the RVOT (**C**); origins of branch pulmonary arteries were marked with blue and the ascending aorta with a purple ring. Angiography and the position of two catheters placed in the aorta and the right atrium (yellow dotted line) were used for registration (**D**)

monly encountered in patients undergoing PPVI, serve as reference points for the alignment. Previously placed devices, for example mechanical valves, occluders or stents, also aid in the marking process [21–23]. This technique of registration included stored fluoroscopy in two projections, manual alignment, preferably with several reference structures, on the two planes, and utilization of "auto fade" and "boost bone" tools to enhance precision of the alignment.

For angiographic registration two acquisitions were needed with a minimum 30° difference in angulation of the anterior-posterior plane (Figure 2 D). This can be achieved by right ventricle, aortic or pulmonary artery angiography, which is routinely performed prior to PPVI in the majority of patients. These angiographies can also be performed by utilizing manual (10 ml total) injections, an approach aimed at reducing the total quantity of dye exposure. Apart from the use of dye, the catheter in the aorta can, itself, be used to help register the overlay properly.

Finally, live guidance of the intervention is performed with the 3D roadmap or sole marking rings/points overlaid on the fluoroscopy in an AP plane (Figure 3). The roadmap follows C-arm (A plane) and table movement; however, care must be taken not to move the patients on the table as this would result in misalignment of the 3D reconstruction.

Statistical analysis

Data analysis was performed using GraphPad InStat software (GraphPad Software, Inc., San Diego, CA, USA).

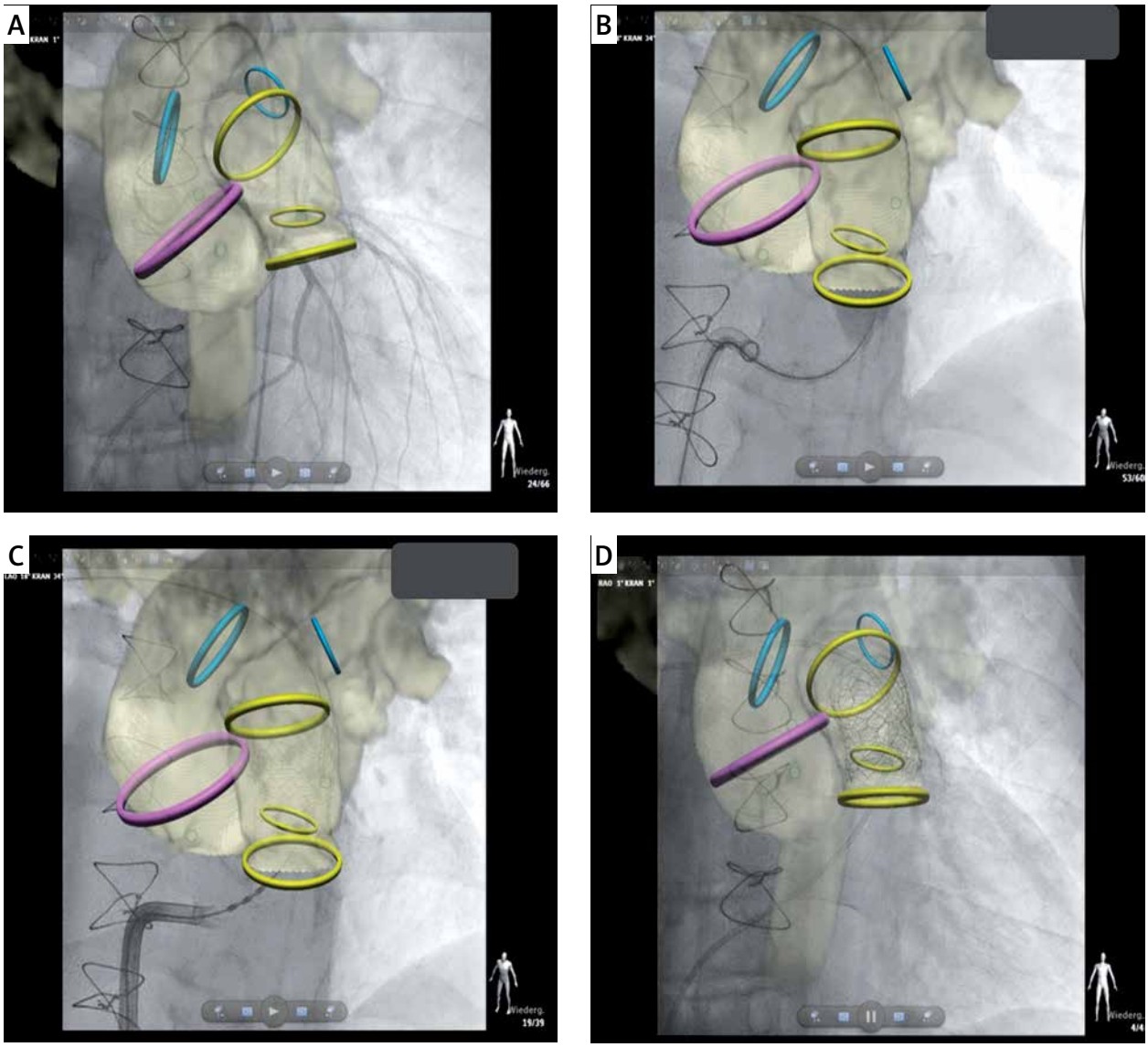

Figure 3. Live three-dimensional guidance of percutaneous pulmonary valve implantation. Magnetic resonance imaging derived three-dimensional roadmap (see Figure 2) was utilized to guide successive steps of the intervention: selective coronary artery angiography (**A**), pre-stenting with implantation of two covered stents (**B**), placement of a 26 mm Sapien 3 valve (Edwards) (**C**) and final angiography (**D**)

Data are presented as frequency with percentage of the total, median with range, or mean ± standard deviation, as appropriate. Student's *t*-test or the Mann-Whitney test, where indicated, was used for analysis. The level of statistical significance was set at $p \leq 0.05$.

Results

Patients and interventions

Fusion imaging with VesselNavigator was applied in 24 patients for planning (n = 4), suitability testing (n = 7) or live guidance during PPVI (n = 15) (Figure 4 A). In two patients VesselNavigator was used twice, during two separate sessions: for 3D guided RVOT balloon testing and PPVI respectively.

The median age was 15.9 (4.9–64) years and median weight was 46 (16.5–116) kg. Twenty-one (87.5%) patients had previous surgery with implantation of a right ventricle-to-pulmonary artery conduit and the remaining 3 (12.5%) patients had a patch repair for correction of a tetralogy of Fallot.

Pre-catheterization imaging and segmentation

A 3D roadmap was created either from existing contrast MRI (n = 14) or CT (n = 8) data sets (Figure 4 B). The imaging studies were performed at a median interval of 92 days (0–58 months) before catheterization or treatment planning with VesselNavigator.

In the case of MRI data sets either a 3D whole heart sequence (n = 8), contrast enhanced angiography (n = 3) or a 2D cine sequence (n = 1) was utilized. In three patients suboptimal quality of the 3D datasets limited the desired segmentation. In two patients MRI scans were performed elsewhere and 3D data were too fragmented for importing to VesselNavigator. In 1 patient with only 2D cine sequences available, an acceptable quality roadmap was obtainable in the corresponding projections, whereas all others presented poor resolution.

Two CT scans were of suboptimal quality for segmentation of the target structures. In one patient the scan was focused on the RVOT, resulting in poor visualization of coronary arteries. In another patient, poor contrast opacification of the RVOT led to suboptimal visualization of the graft and pulmonary arteries. The median dose length product for the CT scan and the median contrast volume injected were 92.5 (39–469) mGy·cm and 40 (20–80) ml or 0.9 (0.5–1.9) ml/kg, respectively.

Registration

During all 22 catheterizations successful 2D–3D registration was performed (Figure 4 B). For fusion of the overlay, fluoroscopy images were acquired in 2 projections with test angiography (n = 16), calcifications (n = 8), spine/vertebrae (n = 8) or a previously placed artificial valve (n = 2) serving as reference points for orientation of the 3D roadmap against live fluoroscopy. Accurate initial overlay, confirmed with soft wire and catheter movement within the borders of the 3D roadmap, was achieved in 21 (95%) patients. In 1 patient suboptimal manual alignment of the roadmap and a low volume contrast injection required readjustment at the beginning of the procedure.

Live guidance

3D guidance was utilized during 22 catheterizations including RVOT balloon sizing (n = 7) or PPVI (n = 15). In the former group four patients were disqualified due to a large RVOT (n = 3) or coronary compression (n = 1). Two patients underwent PPVI in separate sessions and one awaits a custom made stent.

Six (27%) patients required intra-procedural readjustment of the 3D roadmap due to distortion of the anatomy

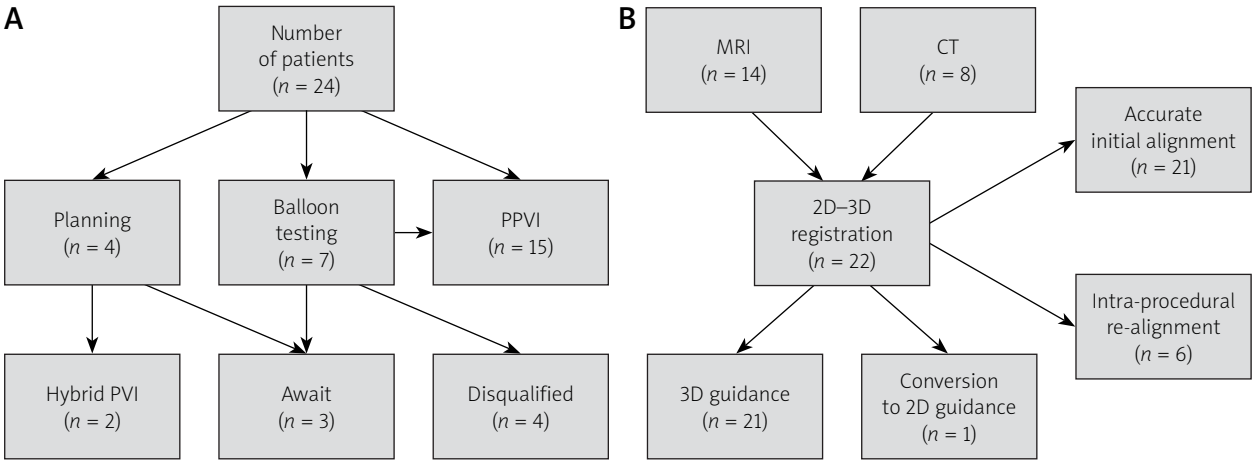

Figure 4. Fusion imaging with VesselNavigator for percutaneous pulmonary valve implantation (PPVI). VesselNavigator was used for planning, suitability testing and PPVI (**A**). Computed tomography (CT) and magnetic resonance imaging (MRI) datasets were used for two-dimensional to three-dimensional (2D–3D) registration (**B**)

after introduction of a stiff wire or sheath. One patient with bifurcation graft stenosis required repeat contrast injections due to significant distortion of the anatomy by large delivery sheath and balloon/stent assembly. The procedure, including graft and right pulmonary artery stenting with subsequent Melody valve implantation, was successfully finished with traditional 2D guidance.

Prestenting was performed in all patients followed by implantation of a Melody (n = 10) or Sapien valve (n = 5) within the same session. Excluding one PPVI finished with 2D imaging, the remaining 21 (95%) interventions were successful with no complications related to 3D guidance.

CT vs. MRI 3D guidance

Comparison of demographic data showed no difference between patients guided with CT- or MRI-derived 3D roadmaps (Table II). Patients in the CT group received less absolute and weight indexed contrast volume, yet the differences were not statistically significant. The absolute and weight adjusted dose area product was lower in the MRI group, with the latter being statistically significant. There were no differences in absolute and weight adjusted fluoroscopy time between the two groups. The total study time was shorter in the CT group, but without statistical significance.

Discussion

Pre-catheterization imaging with either MRI or CT is mandatory in patient qualification for PPVI [24, 25]. Despite variances among centers regarding the optimal imaging method, the size of the RVOT and the location of coronary arteries must be evaluated. In addition to the commonly used multiplanar reconstructions, 3D reconstructions or even 3D printed models allow better understanding of the anatomy and simulation of the intended intervention [26, 27]. Recently, several centers introduced 3DRA for balloon testing as a means to exclude coronary artery compression and/or to guide stent implantation to the RVOT [15–18]. Despite the availability of these 3D modalities, in the majority of catheterization laboratories the traditional 2D imaging remains the gold standard for PPVI guidance.

There is a growing body of literature evaluating the use of fusion imaging with CT or MRI datasets for congenital and structural interventions [28–32]. Most of the protocols rely on 3D–3D registration, which requires two sets of 3D data including the pre-intervention scan and a rotational spin. The latter may be performed without contrast administration and with low radiation exposure to reduce the burden for the patient. However, a specific setup of the C-arm is mandatory and data processing is performed during the study, adding to its length.

We utilized a simple 2D–3D registration protocol, which requires stored fluoroscopy in two projections, similar to setting up an isocenter at the beginning of the study with traditional 2D guidance [23]. A recent study compared this protocol of integration of CT datasets with 2D angiography and 3DRA for guidance of PPVI [33]. Application of pre-catheterization imaging led to reductions in contrast and radiation exposure and study time as compared with 2D guidance, and contrast usage as compared with 3DRA.

In this study we successfully applied this direct 2D–3D registration protocol for incorporation of MRI and CT datasets. Where available we used bony structures, calcifications and previously placed devices as reference

Table II. Comparison of selected demographic data, contrast usage, radiation exposure, fluoroscopy and study times between VesselNavigator guided catheterizations with CT- or MRI-derived 3D roadmap overlay

Parameter		Total (n = 22)	CT (n = 8)*	MRI (n = 14)**	P-value
Age [years]		16 (4.9–64)	12.7 (7.7–64)	21.7 (4.9–62)	NS
Weight [kg]		55 (16.5–116)	40.5 (29–80)	68 (16.5–116)	NS
BSA [m^2]		1.6 (0.7–2.35)	1.2 (1.05–2.0)	1.8 (0.7–2.35)	NS
Total contrast	[ml]	130 (18–374)	60.5 (40–315)	174 (18–374)	NS
	[ml/kg]	2.4 (0.4–7.5)	1.5 (1.1–3.9)	2.9 (0.4–7.5)	NS
Dose area product	[cGy·cm^2]	5480.4 (1507–24291.4)	6797 (1507–16694.1)	4418 (1598–24291.4)	NS
	[cGy·cm^2/kg]	125.4 (24.9–349.3)	162.3 (48.6–303.5)	57.6 (24.9–238.1)	0.014
Fluoroscopy time	[min]	23.3 (5.3–53.5)	23.3 (9.3–53.5)	22.5 (5.3–40)	NS
	[min × kg]	1176 (237.6–4640)	952.2 (288.3–3600)	1313 (237.6–4640)	NS
Study time [min]		150.5 (40–273)	127.5 (90–242)	161.5 (40–273)	NS

**All done on Xper, **9/14 done with Allura Clarity (Philips Healthcare).*

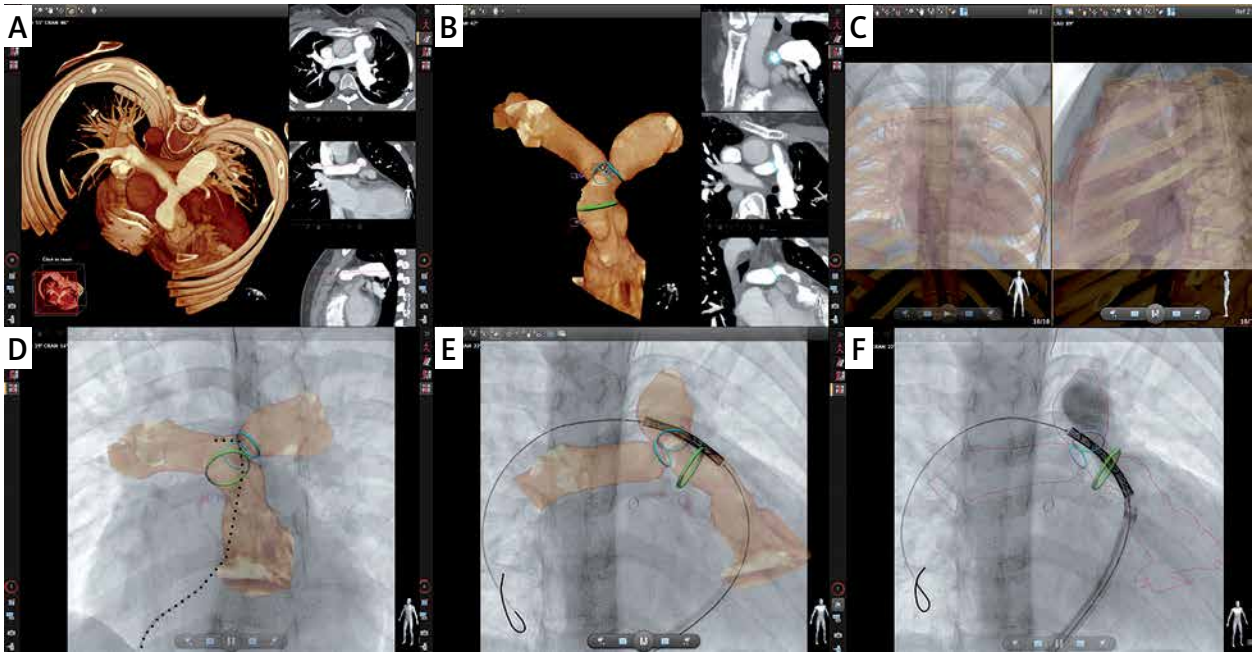

Figure 5. Percutaneous pulmonary valve implantation in a patient with distal conduit and bilateral proximal pulmonary artery stenosis. Automatic three-dimensional (3D) reconstruction and multiplanar reformats from pre-registered computed tomography (CT) were manipulated to outline the conduit and the proximal pulmonary arteries (**A**). The stent landing zone was marked with one green ring, and the origin of the right and left pulmonary artery with another two blue rings (**B**). Pink rings indicate ostia of the right and left coronary artery. Bony structures were utilized to enhance manual 3D image fusion with stored fluoroscopy in two perpendicular projections (**C**). Movement of a soft catheter (black dotted line) within the borders of the 3D roadmap confirmed satisfactory initial alignment (**D**). Introduction of a stiff wire and balloon/stent assembly resulted in distortion of the anatomy (**E**) and significant mismatch of the 3D roadmap (**F**) and actual position of the graft and pulmonary arteries. The remainder of the procedure was successfully conducted with traditional two-dimensional guidance

points. Although we have not yet objectively tested our theory, we feel that combination of all available reference structures improves the accuracy of the initial alignment. With such calibration it is possible to carry out the diagnostic phase of the procedure and, in select patients, even stent implantation to the RVOT, without angiography [34]. This is more likely with integration of the CT dataset. For fusion of the MRI dataset, angiography in two projections is necessary, as bony structures are not adequately visualized. This might be either routine pump injection or preferably low volume hand injection aimed only at delineating vessel borders. The latter approach allows reduction of the amount of dye, which may be further decreased when diluted contrast is used. Alternatively, some authors have reported utilization of airways for registration of MRI-derived 3D datasets [35, 36]. Typically, these protocols require specific MRI sequences to enhance visualization of the airways and are not routinely performed in current practice.

With the traditional 2D guidance the landmarks for stent implantation are typically set virtually with serial angiography. 3DRA may enhance positioning of the stent but comes with several disadvantages as previously mentioned. Application of fusion imaging allows highlighting of crucial structures or regions with marking rings or points. We commonly use marking rings for guidance of stent placement, as presented in Figures 2 and 5. The offline pre-planning process costs additional time yet it brings overall benefits, as stent length, balloon diameter and potential pitfalls can be better assessed before starting the procedure. During the catheterization, continuous visualization of the stents' landing zone marked with colored rings may limit or, according to the confidence of the operator, exclude the need for angiography during positioning of the stent.

In our experience, segmentation and registration of MRI and CT datasets did not greatly differ and required similar time and effort. Similarly, live guidance with 3D roadmaps obtained from different types of pre-catheter imaging modalities provided the same level of confidence for the operators. The only significant difference, inherent to our protocol, was the need for contrast injection to fuse the MRI-derived 3D roadmaps. This may partially explain higher contrast utilization and longer study time in those guided with MRI. However, these differences were not statistically significant. With growing

experience, we have adapted to using just a catheter position in the aorta or pulmonary artery for registration, which seems to prevent additional contrast exposure to the patients. This will be further analyzed in a recently established multicenter international registry of catheterizations guided with VesselNavigator.

The weight-adjusted dose area product was significantly lower in the MRI group. The majority of patients (9/14) in this group underwent catheterization with the AlluraClarity low X-ray dose system, in contrast to all patients in the CT group, who were treated with the older Xper angiographic system.

Due to the limited patient population we did not analyze subgroups of patients treated with different imaging platforms, different type of valves, or those with additional interventions. Further studies are warranted to explore the full benefits of the latest fusion imaging platform, especially with regard to the type of non-invasive imaging utilized.

Conclusions

With intuitive segmentation and direct 2D–3D fusion of MRI and CT datasets, VesselNavigator facilitates PPVI. Our initial data show that utilization of CT-derived roadmaps may lead to lower contrast exposure and a shorter procedural time, whereas application of MRI datasets may lead to lower radiation exposure. Further studies are warranted to explore the full benefits of the latest fusion imaging platform.

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Conflict of interest

The German Heart Center Berlin holds a research contract for the use and assessment of the VesselNavigator image fusion software and acts as a reference center for Philips, The Netherlands.

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