

Real-time CMR guidance for intracardiac and great vessel pressure mapping in patients with congenital heart disease using an MR conditional guidewire—results of 25 patients

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Background: The aim of this study was to test a CE-certified MR-conditional guidewire to facilitate blood pressure measurement in cardiovascular magnetic resonance (CMR) using fluid-filled catheters in patients with congenital heart disease (CHD). The main purpose was to determine procedural success in a post market clinical follow-up (PMCF) for routine procedure in a diagnostic and interventional workflow. Real-time CMR provides high quality imaging without the risk of exposing the patient to X-rays, especially for patients with irregular heart anatomy and patients who are susceptible to radiation and iodinated contrast media. To date, the assessment of blood pressure gradients is not a common feature of CMR, as these gradients cannot be accurately evaluated in routine CMR.

Methods: Twenty-five CHD patients who were planned for combined clinical CMR and diagnostic and/or interventional catheterization were enrolled in the trial. Prior to inclusion, a specific procedure for catheterization in CMR was defined, encompassing the assessment of pressure and pressure gradients in the heart and great vessels.

Results: By the use of an MR-conditional guidewire we successfully measured specific pressure and pressure gradients in up to 92% of cases with liquid-filled catheters which were guided exclusively under CMR guidance. There were no guidewire-related adverse events, and guidewire guidance and manipulation of catheters were successful.

Conclusions: Using a MR-conditional guidewire assists in easily reaching targets in the heart and great vessels and makes the catheter itself visible, so that invasive blood pressure assessment by CMR guidance with liquid-filled catheters can be improved.

Keywords: Cardiovascular magnetic resonance (CMR); congenital heart disease (CHD); cardiac catheterization; magnetic resonance; pressure; guidewire

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Introduction

Cardiovascular magnetic resonance (CMR) is an established instrument for measuring heart volume and blood flow using standardized methods and is increasingly replacing diagnostic cardiac catheterization, although pressure and pressure gradients cannot be accurately assessed with routine CMR (1-3). The determination of invasive pressure gradients using liquid-filled catheters in MRI studies has been rarely used in clinical settings in so-called hybrid MR fluoroscopy suites (4-6).

Thus, we aimed to test a CE-certified conditional MR guidewire to facilitate blood pressure measurement by interventional CMR (iCMR) guidance using liquid-filled catheters in CHD patients without the need for a hybrid MR fluoroscopy suite. The primary objective was to define the success of the procedure in our diagnostic and interventional workflow. The trial itself was also designed to serve as a post-market clinical follow-up (PMCF) of the guidewire.

The application of fluoroscopic techniques with the use of ionizing radiation to drive cardiac diagnostic and interventional procedures is not optimal for sensitive, especially young patients and for procedures that are time-consuming and may even induce an enhanced risk of cancer occurrence (7,8). While current imaging technologies offer many options for dose minimization, they require careful customization. Hence, real-time iCMR could offer a radiation-free option to radiographic imaging and assist in bringing diagnostic and interventional methods from the traditional catheter lab to iCMR. In addition to radiation reduction by fluoroscopy, better visibility of the specific soft tissue architecture can also improve the success of the technique (9).

In humans, MR-guided interventions have been limited by the absence of MR-compatible and safe devices, such as MR-guided guidewires. In spite of all the promising advancements made over the last decade, the iCMR community continues to need certified devices and guidewires that are appropriate for diagnostic and therapeutic purposes and allow iCMR to more effectively extend to human cardiovascular areas (6,10).

There are attempts to use conventional, MR non-conditional guidewires in the MR environment by testing the equipment for heating or using low specific absorption rate. Moreover, a dedicated low gradient MR system can be used (11,12).

Earlier versions of the guidewire and its markers used in this trial were evaluated in experimental animal

studies and phantoms for vena cava filter positioning in the inferior vena cava and stenting in regions such as the renal arteries by magnetic resonance (13,14). Lately, in studies with phantoms, similar guide wires equipped with discrete markers have been used to show that percutaneous angioplasty can also be performed under MR guidance (15). We present the following article in accordance with the MDAR reporting checklist (available at <http://dx.doi.org/10.21037/cdt-20-575>).

Methods

Twenty-five patients (12 women; age median 28.3 years, range 14.1 up to 79.0 years, mean age 37 years) with congenital heart disease were scheduled for diagnostic or interventional cardiac catheterization by fluoroscopy and CMR and were included into this trial. The study was designed to be a prospective, single center (initiated as a multi-center), open label trial.

Subsequent to a standard CMR examination, invasive blood pressure and pressure gradients were assessed. The target regions were defined during the enrollment process in the clinical trial. An assessment using conventional catheterization by fluoroscopy was considered on the very same day following completion of iCMR, since most patients required interventional procedures under fluoroscopic guidance. After iCMR investigation, 22 of 25 individuals had undergone standard cardiac catheterization and fluoroscopic procedures. For 3 out of 25 cases, no separate cath lab intervention was required because all clinical issues could be resolved by iCMR and there was no need for intervention based on iCMR results. Two very skilled interventionists carried out cardiac catheterization in iCMR.

Ethics approval

The trial was accepted by the ethical committee of the Technical University of Munich. The study is documented at [ClinicalTrials.gov](https://clinicaltrials.gov) under identifier NCT02493634. All patients and parents gave their written consent to the study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) (16).

Inclusion criteria

Included were CHD patients with clinical indicators for CMR and standard diagnostic or interventional heart

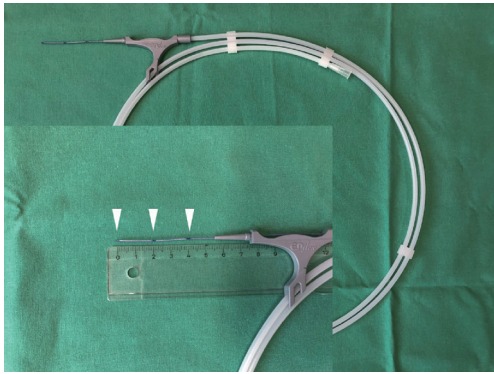


Figure 1 MRWire[®]. Photograph of MRWire[®] and MRWire[®] tip construction with the three markers.

catheterization. A total body weight of ≥ 40 kg was necessary to enable the insertion of an introducer of ≥ 5 French.

Exclusion criteria

Excluded were all patients with a medical history of major bleeding disorder, a major surgical procedure in the last 6 weeks, a contraindication for CMR, contraindications for guidewire procedures such as signs of active infection or a current pregnancy.

Duration of the trial

Postprocedural follow-up was 30 days.

Blood pressure and pressure gradient mapping using liquid-filled catheters

We were using a proprietary standard 1.5 Tesla MR scanner (Avanto, Siemens, Erlangen, Germany) to carry out the imaging for assessing pressure and pressure gradients using liquid-filled catheters.

After covering the patient with sterile drapes and puncturing the femoral artery and/or vein with a Luer lock needle (Luer lock needle REF 219.09 and REF 219.14, Vygon, Écouen, France) on the scanner table in the scanner room, an introducer sheath (Radiofocus Introducer II, 6 Fr, Terumo Europe, Leuven, Belgium) was inserted using the Seldinger method prior to placing the patient into the bore of the scanner. A 6F-Berman angiography balloon catheter (length 90 cm, Arrow International Inc., Reading, PA) and an MR-compatible guidewire (specifications, see below) were then used. Patients were examined in a supine

and head-first position using a 12-element cardiac phased array multi-channel coil (Siemens Healthcare, Erlangen, Germany) with a real-time sequence for visualization.

The liquid-filled catheters were attached to a pressure transducing device (CODAN Xtrans, CODAN pvb Critical Care GmbH, Forstinning, Germany) and a digital monitor (Precess Invivo, Gainesville, FL) for pressure monitoring and measurement. However, a special pressure registration device, as proposed by the NIH research group (<https://icmr.nhlbi.nih.gov>), was not readily available for this trial. All catheters were utilized off-label for iCMR.

Guidewire

The study was designed to demonstrate the efficacy and overall safety of the MR-conditional guidewire (MRWire[®], Nano4Imaging, Düsseldorf, Germany). The guidewire has three passive markers at the tip.

The wire was developed and certified for use in the MR field (in line with standards ASTM F2182, F2052, F2053 and F2213; standard test method for medical equipment in the magnetic resonance field) and is designed as a one-piece core-shaft-tip assembly of fiber-reinforced composite material with a Pebax outer sleeve. The guidewire had a straight tip, diameter 0.89 mm/0.35 inch, length 180 cm, with 3 marks at 0, 2 and 4 cm (*Figure 1*). The distinctive marks on the tip produce the desired artifacts, which are tested according to ASTM 2119 (standard test method for evaluation of MR image artifacts of passive implants). Additionally, the guidewire incorporates BaSO₄ for X-ray visibility. The guidewires were delivered sterile and non-pyrogenous and complied with the current product norm ISO/DIS 11070:2013.

Preinterventional CMR analysis and real-time iCMR

For preinterventional assessment, vascular and cardiac morphology and function was measured using appropriate CMR sequences as previously described (1,17). Catheter and guidewire were navigated using real-time iCMR, with the alignment slices defined individually for each patient.

We used a dedicated real-time sequence (Beat-IRT, Siemens Healthcare, Erlangen, Germany) with the parameters below: Field of view 300 mm, slice thickness 10–15 mm, TR 157.20 ms, TE 1.31 ms, flip angle 70°, image read out SSFP, acceleration factor 2 (GRAPPA), echo encoding steps 95, echo train length 1, averages 1,

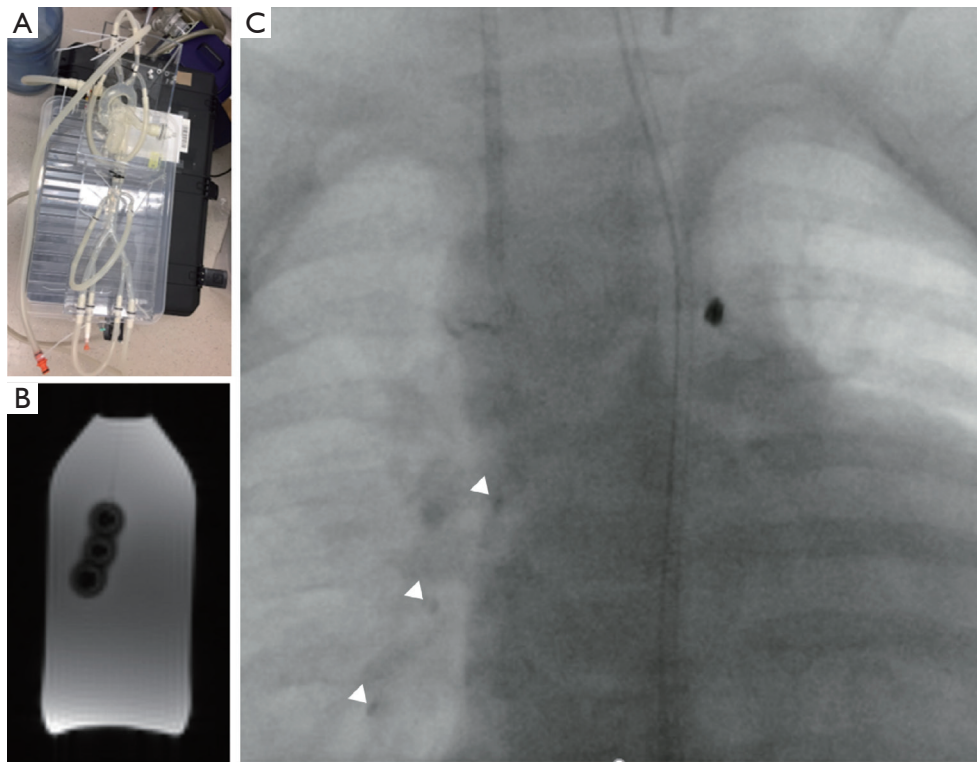


Figure 2 (A) Phantom for guidewire retrieval testes. (B) MR phantom with guidewire; signal void by the three markers on the guidewire. (C) Fluoroscopic image in an infant with partial cavo-pulmonary anastomosis; visualization of the three markers at the tip of the guidewire (white arrows).

bandwidth 1,488 Hz per pixel, temporal resolution 6.36 images per second and partial Fourier off.

Endpoint of the PMCF trial

The primary objective of the trial was to assess the device's safety and effectiveness in the intended procedures. Thus, the primary endpoint was defined as the success of the procedure achieved in the absence of device-related adverse events. The success was divided into three aspects, namely adequate handling, steerability and visualization. Success of the procedure implies that all three aspects mentioned above must be rated “yes” and no guidewire-related adverse events as damage to the vessel walls or other device-related events such as device failure, catheter obstruction by the guidewire, or non-visibility occurred. A positive evaluation of structural integrity of the guidewire was needed at the end of iCMR.

As a safety precaution, retrieval of the guidewire was trained in a phantom model (Elastrat, Geneva, CH) using

fragments that were intentionally cut from the wire. Typical conventional snares were used for the procedure and retrieval times in the phantom were about 1–2 minutes. Such procedures can be performed under X-ray control, as the tip of the wire is visible in the X-ray image (*Figure 2*).

Results

A summary of all procedures is shown in *Table 1* with diagnosis, regions of interest for cardiac catheterization by iCMR and the success of iCMR.

Twenty-five patients were recruited into the trial (52% male, 48% female). Median age was 28.3 years; range 14.1–79.0 (mean age 37 years; *Table 2*). Duration of the procedure was defined as the initial insertion of the guidewire into the patient until the guidewire was finally withdrawn from the individual. Procedure time on average was 19.0 minutes (median 15.0 minutes; range 2.0–45.0 minutes). In three out of 25 (12%) of the patients, no further examination in the standard cath lab was indicated as all relevant clinical

Table 1 Description of the participants and the success of the study

Patient	Age (years)	Sex	Diagnosis	Clinical question, target pressure	Overall success
# 1	38	Male	Tricuspid atresia after modified Fontan-operation, RA-RVOT homograft	RVP	Yes
# 2	28	Male	CoA, arterial hypertension	Pressure CoA	Yes
# 3	14	Male	valvular AS and AR, Ross procedure, allograft, allograft stenosis	Pressure gradient RVOT	Yes
# 4	18	Male	Pulmonary atresia, ASD II, BTA, AP-Shunt, PCPC, TCPC (extracardiac conduit), severe AR	Pressure gradient TCPC	Yes
# 5	55	Female	Chronic pulmonary embolism, PAPVR upper left PV	Pressure RA	Yes
# 6	36	Male	TOF, residual VSD, Shelhigh, Shelhigh stenosis, VSD	RVP, pressure gradient RVOT	Yes
# 7	55	Male	Outlet VSD, PAPVR/ASD II, atrial fibrillation, arterial hypertension	RVP, pressure PA	Yes
# 8	19	Male	PS, ASD II, valvuloplasty, transannular patch repair, ASD closure, severe PR and RV dilation	RVP	Yes
# 9	28	Female	Situs inversus, azygos continuation, PAPVR, PAH	Pressure PA	No (complex morphology, PAH)
# 10	45	Male	Ebstein's anomaly, TVR (bio), re-TVOR (bio), VSD-closure, paroxysmal atrial fibrillation, RBBB; TV (mean 7 mmHg), residual VSD; TVR (interventional repair with Sapien valve)	Pressure RA and RVP	Yes
# 11	78	Female	TOF; late VSD-closure, RV-PA-Conduit (bioprosthesis), coronary artery disease, CABG, atrial fibrillation, RV-PA Stenosis	RVP, pressure PA	No (high degree IVC stenosis)
# 12	49	Female	Aortic valve disease with AS and AR, Ross procedure; now slight obstruction of the RVOT and regurgitation (3rd degree, RV enlargement)	RVP	Yes
# 13	28	Male	Severe valvular PS	RVP	Yes
# 14	39	Male	Pulmonary atresia with VSD, PDA, Waterston-anastomosis, Rastelli operation; now: moderate allograft-stenosis and -regurgitation, severe AR, LV severely enlarged, LVEF (40%), ectasia of the aortic bulb and AoA	RVP	Yes
#15	26	Female	DORV (Taussig-Bing), TGA, CoA, PAB, Dilatation of re-CoA. Kawashima operation, VSD-closure, ventricular tachycardia, now: re-CoA	Pressure CoA	Yes
#16	28	Female	TAC, RPA- and LPA- stenosis; allograft, Infective endocarditis, allograft replacement, angioplasty of RPA and LPA, RPA- and LPA-stent; Now: intima proliferation in the stent	RVP	Yes
#17	24	Male	AS; Ross-Procedure, now: enlarged RV, severe PR	RVP	Yes
#18	25	Female	Ebstein's anomaly, severe TR	Pressure RA	Yes
#19	79	Female	PDA, CoA	Pressure CoA	Yes
#20	20	Female	Ebstein's anomaly, Cone procedure, Now: Stenosis of "Cone valve"	Pressure gradient RV/RA	Yes

Table 1 (continued)

Table 1 (continued)

Patient	Age (years)	Sex	Diagnosis	Clinical question, target pressure	Overall success
#21	46	Female	ASD II	Pressure RA and RVP	Yes
#22	17	Male	DILV, PAB, pulmonary hypertension	Pressure RA and RVP	Yes
#23	33	Female	Tricuspid atresia, Fontan-operation, conversion to TCPC (extracardiac conduit)	Pressure gradient TCPC	Yes
#24	25	Female	VSD	Pressure RA and RVP	Yes
#25	63	Male	Ebstein's anomaly, TR, PFO, arterial hypertension	Pressure RA and RVP	Yes

AoA, ascending aorta; AP, aorto-pulmonary; AR, aortic regurgitation; AS, aortic stenosis; ASD, atrial septal defect; BTA, Blalock-Taussig anastomosis; CABG, coronary arterial by-pass graft; CoA, coarctation of the aorta; DILV, double inlet left ventricle; LPA, left pulmonary artery; PA, pulmonary artery; PAB, pulmonary artery banding; PAH, pulmonary arterial hypertension; PAPVR, partial anomalous pulmonary venous return; PCPC, partial cavo-pulmonary connection; PFO, persistent foramen ovale; PR, pulmonary regurgitation; PS, pulmonary stenosis; RA, right atrium; RPA, right pulmonary artery; RV, right ventricle; RVOT, right ventricular outflow tract; RVP, pressure right ventricle; TAC, truncus arteriosus communis; TCPC, total cavo-pulmonary connection; TGA, transposition of the great arteries; TOF, tetralogy of Fallot; TR, tricuspid regurgitation; TVR, tricuspid valve replacement; VSD, ventricular septal defect.

Table 2 Demographics of the study population and target region

Parameter	Quantity: absolute and percentage
Age (median, range)	28.3; 14.1–79.0
Female/Male	12/13 (48%/52%)
Pressure measurement (primary target region)	
Right atrium	8 (32%)
Right ventricle	17 (68%)
Pulmonary artery	5 (20%)
Coarctation of the aorta	3 (12%)
Total cavo-pulmonary connection (TCPC)	2 (8%)
Patients reached primary endpoint	23 (92%)

queries and pressure assessments were addressed by iCMR. In all other patients, a sophisticated interventional cath lab catheter procedure was performed afterwards, which was not considered to be done by iCMR. The target of pressure monitoring for all subjects is presented in Table 2. It shows that most measurements were taken in the right ventricle (n=17) and in the right atrium (n=8).

Pressure data are not shown because single pressure measurements are not particularly relevant to the objective of this trial, which concentrates on the effectiveness and overall safety of the technique.

Twenty-three out of 25 subjects (92%) successfully completed iCMR; in only two of 25 individuals could the

target anatomical region not be reached with the catheter-guidewire assembly because of complex anatomy, high pulmonary pressure and unknown stenosis of the inferior vena cava.

One patient (#9), for example, had presented with complex CHD with situs inversus, partially abnormal pulmonary venous return, continuation of the azygos vein, and pulmonary arterial hypertension. Due to the complex anatomy and the high pulmonary pressure even with catheterization under fluoroscopy, there had been great advantages for cardiac catheterization. The main reason for the lack of success of the technique in this case was the complexity of the anatomy.

The second patient (#11) presented with tetralogy of Fallot, late closure of a ventricular septal defect, bioprosthesis of the right ventricle to the pulmonary artery (RV-PA) with conduit stenosis, coronary artery disease after coronary bypass grafting and atrial fibrillation. During the procedure, a previously unknown advanced stenosis of the inferior vena cava was found, which couldn't be cleared with the catheter in iCMR due to an unfavorable angle of the inferior vena cava to the right atrium.

General anesthesia was only applied to the very first four of the 25 enrolled patients in this trial. As a result of the improvements in expertise and practice in the iCMR trial, the patients did not require sedation to complete the procedure.

Figures 3-5 illustrates the guidewire markers in various positions in three patients. The Berman catheter is imaged

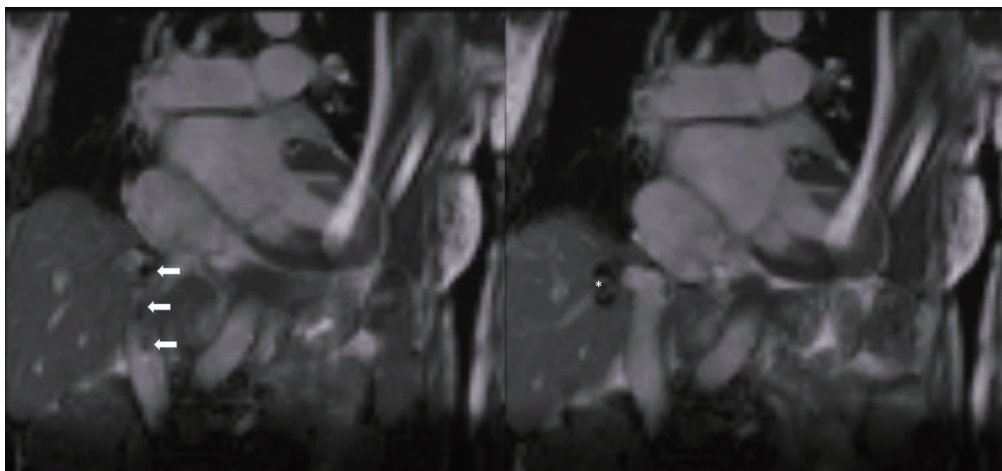


Figure 3 Case #11, 78 years, female, tetralogy of Fallot, right ventricular to pulmonary artery conduit, late VSD-closure, coronary artery disease with coronary arterial bypass graft, RV-PA stenosis and atrial fibrillation; Target of iCMR: pressure of the right ventricular, pressure in the pulmonary artery; No success due to severe degree of stenosis of inferior vena cava at the level of the entrance to the right atrium. The three marks on the tip of the guidewire are located in the inferior vena cava (white arrows); balloon of Berman catheter inflated with CO₂ in a liver vein (white asterix).

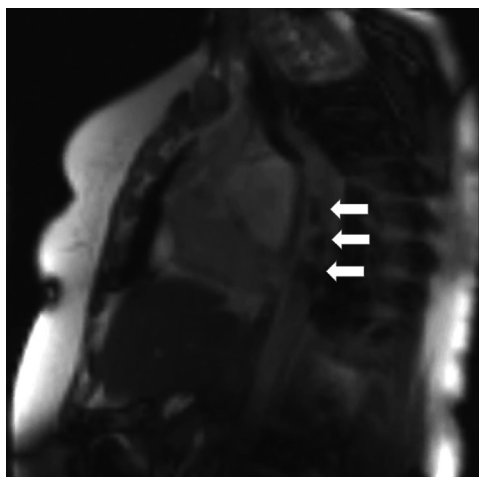


Figure 4 Case #15, 26 years, female, double outlet right ventricle (DORV, Taussig-Bing), coarctation of the aorta (CoA), transposition of the great arteries, CoA-repair, pulmonary artery banding, re-CoA with balloon dilatation. Corrective surgery (Kawashima), closure of the VSD, ventricular tachycardia. Now: re-CoA. Target of iCMR procedure: aortic arch with pressure measurement for pressure gradient assessment over the coarctation; Success: yes. Markers on guidewire in the descending aorta (white arrows).

separately by inflating the balloon with carbon dioxide (Figure 3).

The cumulative outcome of the procedures was 92%.

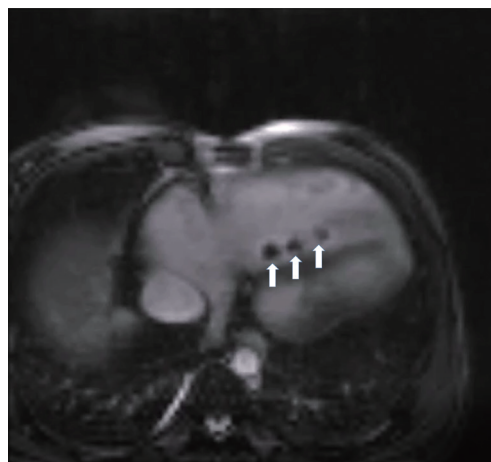


Figure 5 Case #17, 24 years, male, aortic stenosis; Ross-surgery, now: right ventricle enlargement, severe pulmonary insufficiency. Target of iCMR: pressure in the right ventricle; Successful iCMR procedure. The tip of the guidewire with its markers is located in the right ventricle (white arrows).

No severe adverse events were reported in any of the 25 patients during the procedure, prior to their discharge or after 30 days of follow-up. Adverse events occurred in 11 of 25 patients (44%) that were related to their disease status or to the procedure, but none of these events were related to the devices (catheter or guidewire) (Table 3).

Table 3 Overview of adverse events, patient's reference number and the association with the procedure

Adverse event	Patient's reference number (as in Table 1)	Association to the procedure
Hematoma in groin	2, 10, 14, 25	Yes
Atrial fibrillation	1	No, pre-condition of patient
Pain in the groin	18	Yes
Pseudo aneurysm groin, femoral artery	25, 2	Yes
Pruritus	8	No
Diarrhea	20	No
Abdominal pain	7	No
Hypotension	16	Yes
Bradycardia	16	Yes
Sore throat	16	No
Vocal cord palsy	16	No

Discussion

The study demonstrated that invasive blood pressure and pressure gradients can be successfully assessed with liquid-filled catheters alone under iCMR guidance and with no need for a hybrid MR fluoroscopy suite. In the last decade, a number of research groups have performed these techniques using a hybrid suite. Tzifa *et al.* first reported on congenital interventions in men (6), Pushparajah *et al.* reviewed the 10 year experience of a single institution at Kings' College London (18) and Rogers *et al.* conducted a similar evaluation for the clinical work at the National Heart Lung and Blood Institute; National Institute of Health (NIH) (19). Pushparajah *et al.* also showed that pulmonary vascular resistance measured by iCMR catheterization allows accurate stratification for intervention in patients with CHD in a high volume study (20). Clinical work in these sites has opened the door for the creation of instruments for techniques such as right heart catheterization, MRI-guided biopsy, ablation and pressure assessment (5,11,12,21-25). An MR-certified guidewire could be useful for most of these catheterization procedures. The availability of certified equipment has long been a major bottleneck in the iCMR community (10,26). Recently Rogers *et al.* published a study of right heart catheterization by CMR fluoroscopy in 102 patients (25) and Ratnayaka *et al.* published 50 cases of right heart catheterization by CMR fluoroscopy with

focus on feasibility and safety (27). Knight *et al.* showed that CMR-right heart catheterization can be incorporated into clinical practice for testing of pulmonary hypertension (24). In respect of these new promising studies we provide additional data of feasibility of iCMR by using a MR-conditional guidewire.

The CE-marked guidewire evaluated in this trial was designed on the basis of a long process of development. It features a passive marking system with a set of discrete marks based on paramagnetic iron particles that have been optimized and applied to a different wire that has been used in animal studies for the placement of vena cava filters and renal and aortic stenting (13,14).

The guidewire is a one body core-shaft-tip design as a safe-by-design follow-up of previously used guidewire (28). The findings demonstrate that the marks allow good visibility and dynamic control of the wire positioning, whereas the catheter tip can be additionally visualized by carbon dioxide (CO₂) inflated in the catheter balloon. It might also be possible to use balloons filled with gadolinium or using an alternate saturation pre-pulse in the real-time sequence that has been shown by different working groups (5,29,30). Using a CO₂-filled balloon that generates a signal void at the tip of the Berman catheter might be helpful, even when the guidewire markers itself also produce a signal void, since size and shape of the signal voids were of different shape.

Because we used straight-tipped guidewires according to the study design, we were unable to test the angled tip guidewires, which may have been beneficial for targeting more specific regions and may have been effective in the two cases in which the target region could not be accessed due to anatomical constraints. The balloon inflated with CO₂ at the tip of the Berman catheter was also chosen to enhance overall visibility, as the guidewire markers often pass through the imaging slice faster than the inflated balloon tip at a slice thickness of 10 to 15 mm. The closed tip Berman catheter was chosen only for safety reasons in this trial. Advanced iCMR procedures are only possible by pushing the tip of the guidewire outside of the catheter and to guide the catheter into the target region. One of the more promising advances of using a guidewire was the stiffening of the catheters in any required situation, as the catheters would become very smooth and floppy in the warm blood surrounding during the more advanced procedure duration. Using a real-time sequence, we were able to obtain an acceleration factor of 6 (GRAPPA), leading up to 11 frames per second (TR 94.32 ms), but with

reduced images quality.

Carrying out the vascular access in the MR room improved the overall procedure time and general acceptance of the study design. The total procedural time has improved as all study personnel have been increasingly customized with all of the steps in the MR setting over the course of time. The procedure time for the iCMR itself varied from 2 to 45 minutes, which was more dependent on the various anatomical and hemodynamic conditions and the selected target region for pressure assessment and not on the gain of experience during the trial.

We found procedural success in 92%. No success of iCMR catheterization was only found in two patients (#9, #11), due to anatomic conditions. Despite the fact that the catheter examination was not successful, a solid basic examination could be performed by standard MRI. Three patients out of 25 did not need an additional cathlab procedure, since all of the clinical questions could be answered by iCMR. Most of the patients had an additional procedure in the conventional cathlab, even when all questions could be answered by iCMR, because most of the additional procedures had an interventional focus under fluoroscopic guidance. Failing to reach the target region in two of 25 patients was also due the circumstance that we did not want to force catheterization over a stenotic region or in a complex cardiac condition. In general, other regions for vascular accesses are also possible, so that in patients with congenital heart defects, access via the radial artery or via the jugular vein may also be an option. For this study, only an access via the femoral vein/artery was chosen. For this purpose, however, the patients must be positioned differently in the MRI scanner. The study was designed to provide highest safety condition for the patients involved. The experience gained during the study may guide further examinations.

For a successful future of cardiac catheterization in the MR-scanner for advanced interventions, the problem of how to treat severe unwanted complications in complex interventions must also be solved. First and foremost, heavy bleeding after a vessel or heart perforation by the catheter or guidewire is an essential problem, since the solution to this problem is often extremely time-critical in conventional cardiac catheterization laboratories. First of all, a good and fast visualization of the perforation site is essential, where MRI is limited by the current temporal resolution. Higher temporal resolution can only be bought by a worse image quality. Even for simple cardiac catheter examinations, there must always be a plan for handling a complication

or a backup must be possible in the conventional catheter laboratory or by the heart surgeons. Furthermore, the right MR-compatible equipment must be available for these complications. With the further development of the iCMR, we hope to have more working tools at our disposal.

Study limitations

Although iCMR offers an inherent benefit in visualizing the position of the target chambers and vessels as well as the guidewire markers, only the catheter tip with its three markers could be visualized so far.

However, we believe that with safe MR guidewires and equipment, iCMR driven procedures may take their next step. Additional MR safe equipment as different safe catheter types and even more guidewires with different length, diameter and moreover different stiffness will hopefully follow. In the meantime, the next generation MR-compatible guidewire (Emery Glide™, Nano4Imaging, Düsseldorf, Germany) with Teflon coating and advanced gliding characteristics was released, but clinical data from this guidewire are still pending.

CMR and cardiac catheterization has been performed on a high level since years. Using the MR safe guidewire will help to steer the catheter to the region of interest. Simultaneous measurement of pressure/flow, pressure/volume relationship and vascular resistance in CHD and pulmonary hypertension as a standard procedure in several centers will be feasible and may take iCMR to the next level of clinical routine and for new applications.

Conclusions

A MR-conditional guidewire assists in reaching targets in the heart and great vessels easily and at a high success rate. Therefore, invasive blood pressure measurement by CMR guidance by using fluid-filled catheters may be improved and interventional CMR may advance for a more routine procedure in future.

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Footnote

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ClinicalTrials.gov under identifier NCT02493634. All patients and parents gave their written consent to the study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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