The (R)Evolution of Interventional MRI

Since the 1940s cardiac catheterization has been used to treat a variety of cardiac disorders using the power and visibility of X-ray and contrast agents (1). In the past decades, researchers and clinicians have become increasingly aware of the risks and challenges associated with traditional cath lab procedures (2). Therefore cardiac catheterization via MRI is gaining popularity as the next phase of evolution in cardiac care.

Clinical use of MRI for guidance during interventional procedures emerged shortly after the introduction of clinical diagnostic MRI in the late 1980s, but early applications of interventional MRI (iMRI) were limited due to the lack of dedicated iMRI magnets, pulse sequences, and equipment (3).

Over the course of the following three decades, significant advances in iMRI technology and the development of dedicated iMRI procedural suites have enabled expanded uses of iMRI procedures (4). Physicians have increasingly become aware of the advantages of iMRI for both diagnostic and interventional procedures, including superior soft-tissue resolution, ease of multiplanar imaging, lack of ionizing radiation, and capability to re-image the same section without the use of contrast agents. Such advantages, physicians have found, can make a huge difference in terms of patient outcomes as well as reduced physician exposure to radiation.

MR-Guided Cath Evolution in Human Subjects

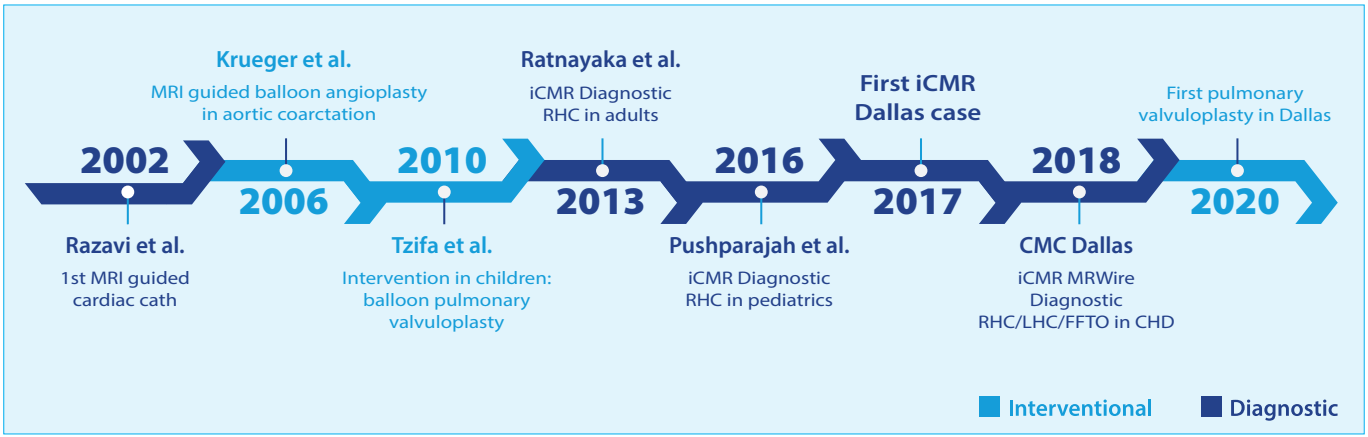


Figure 1. Between the discovery of X-ray in 1895 and its first cardiac use in a cathlab by Werner Forsmann in 1927 took 32 years. A 48 year interval elapsed between its invention in 1974 and first interventional use of MRI in 2006. It is anticipated that the incremental use of MRI will lead to a gradual decrease in X-ray in the next 40 years. The graph above shows the MRI guided cath evolution in human subjects over the past 25 years. Slide drafted on info of Dr. Greil (UT Soutwestern Dallas).

Cardiac Magnetic Resonance as a driver

One application of iMRI that has been gaining popularity in recent years due to these advantages include diagnostic and interventional cardiac procedures – in particular, cardiac catheterization. Numerous clinical centers have started interventional cardiovascular magnetic resonance (iCMR) programs to leverage the clear advantages of MRI tissue characterization, to quantify cardiac chamber function and flow, at the same time avoiding ionizing radiation exposure. While clinical implementation of more complex cardiovascular interventions has been challenging because catheters and other tools require re-engineering for safety in the iCMR environment, recent innovations in scanner and interventional device technology – in particular, the availability and re-introduction low-field MRI scanners, this time at high performance – could be the inflection point, enabling a new generation of iCMR procedures (5). Actually a worldwide survey among pediatric cardiologists conducted in 2019 (6) was conducted to understand the future use and application of interventional and diagnostic CMR by current and interested users. The results are shown in Table 1.

Table 1: An overview of most important indications in iMRI in 2019 and now in 2024, in which a trend to interventional procedures is visible. Actually among the main impediments to start interventional cardiovascular magnetic resonance imaging (iCMR), the instrumental needs ranked number two with 18 % of users. Other impediments included lack of infrastructure (26 %), need for training (13 %), team expertise (12 %), reimbursement (6%) and - last but not least- safety issues (5 %).

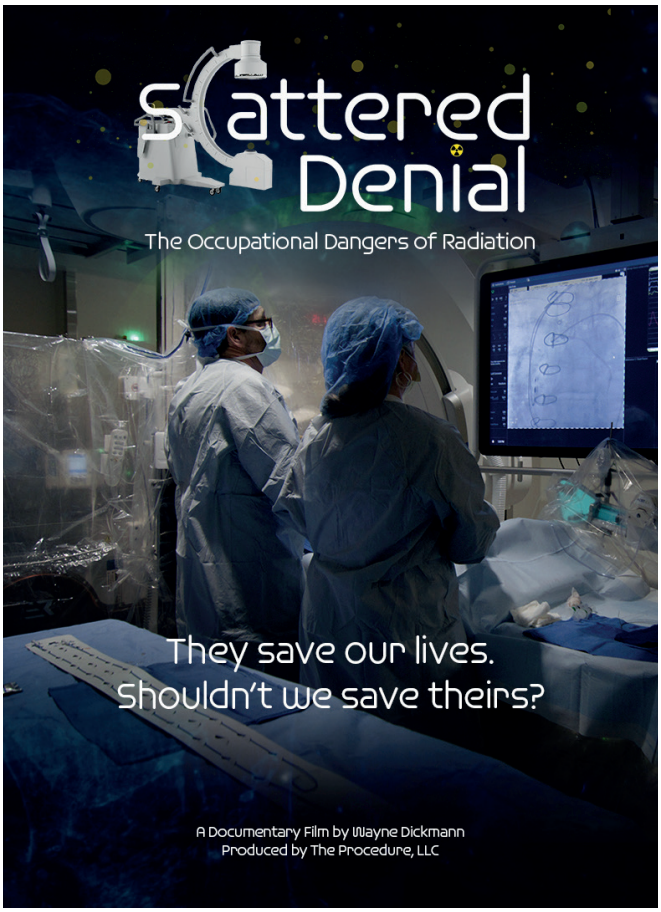
INDICATIONS 2019	INDICATIONS 2024
Evaluation of pulmonary hypertension (PHTN)	Balloon angioplasty of branch PA
Post-heart transplant patients	Myocardial biopsy
Diagnostic evaluation of post-Fontan/single-ventricle patients	Fontan fenestration test occlusion and device closure
Pre-Fontan surgical evaluation	Balloon angioplasty of RV-PA condult
Diagnostic RHC/LHC before shunt closure procedures	Balloon pulmonary valvuloplasty

Risks of radiation- the denial to overcome

While cath labs have long been the standard for performing diagnostic and interventional cardiac catheterizations, cath lab procedures are not without risks. Both staff and patients are at risk for injury due to chronic radiation in cath labs (5). Studies have also shown that clinicians who work in the cath lab are at risk for developing somatic DNA damage and chromosomal abnormalities at a higher frequency, as compared to clinical cardiologists who work outside the cath lab (7).

Additionally, there have been cases of brain tumors among physicians performing interventional procedures occurring disproportionately on the left side, because radiation exposure occurs two times more on the left side of the head compared to the right (8). Workers in cath labs also have a higher incidence of eye abnormalities such as and posterior subcapsular lens opacities than those nor working in cathlabs or not using fluoroscopy (9, 10). And it's not just cardiologists who are susceptible to the risks of traditional cath lab procedures: studies have found that anesthesiologists and nursing staff who work in an operating room setting are exposed to significantly less radiation than those working in the cardiac catheterization laboratory (11).

Last but not least, even the patients are at risk to chronic effects of radiation exposure during cath lab procedures. In fact, one study found that cardiac catheterization in the first year of life was associated with a significantly increased cancer risk in a population with congenital heart disease (12).



If you are interested to learn more about the harmful effects of radiation please check out the 6 episode documentary called **Scattered Denial**.

'The clinical benefits of iCMR are so obvious, it is not even a question'

- Dr. Gerald Greil MD, PhD, Professor of Pediatric Cardiology -

The early adaptors to use Interventional MRI

To further explore and understand the adoption and advantages of cardiac catheterization performed via interventional MRI, we spoke with leaders of hospitals in Europe and the USA who have implemented the procedure. Following is a summary of their firsthand experiences and insights.

Dr. Gerald Greil MD, PhD, Professor of Pediatrics
University of Texas Southwestern (UTSW) & Children's Health

The clinical benefits of iCMR are obvious

Dr. Gerald Greil joined Guy's and St. Thomas' NHS Foundation Trust and King's College London in London in 2006, pioneering the development of interventional cardiac MR (iCMR). Dr. Greil came to Children's Health in Dallas in 2015, where he established with his team the first cardiac catheterization laboratory at the University of Texas Southwestern/Children's Health in Dallas using MRI for catheter guidance. So far more than 150 cardiac catheterizations under MRI guidance have been performed safely there.

'The clinical benefits of iCMR are obvious, there's not even a question,' says Dr. Greil. 'There was strong interest from UTSW and Children's Health to establish this technology as a clinical tool, which we have done. Dallas was the right place for this program because we have a cath lab and MRI in close proximity to one another in the hospital, and because we have a large population of very complex, single-ventricle patients.'

Dr. Greil explains that as medical science advances, cardiologists are performing increasingly more complex and difficult procedures, with an increasing need for anatomical visualization during the procedure, as well as a need for precise and reproduceable anatomic and functional information before, during and after the intervention, to evaluate the effectiveness of the intervention.

The improved visibility of cardiovascular structures is a great advantage of iCMR, according to Dr. Greil. 'With X-ray cath, you're only seeing bones and very dense structures. With MRI, you can see the soft tissue, vessels, myocardium, and so on. In a traditional cath lab, we need to inject nephrotoxic contrast agent to make these structures visible. This is not needed using MRI.

Additionally, he says, longer, more complex procedures mean more time exposed to radiation in a cath lab, for both patients and physicians.

Yet despite the clear benefits, Dr. Greil says not everyone was immediately on board when he brought iCMR to Dallas. While the hospital leadership was enthusiastic about the program, 'Traditional' interventional cardiologists had reservations, he says. 'Much of the initial enthusiasm and support came from the younger, next generation of interventional cardiologists.'

Dr. Greil says he understands that some level of trepidation about any new technology or approach in medicine is to be expected. 'It's a common theme, regardless of where you are. It can be in any industry, not just medicine; people are almost never initially appreciative of innovation.'

However, he says, physicians were able to quickly see the advantages and benefits once they began performing the procedures. Now, Dr. Greil's team at Children's Health performs iCMR procedures as part of their clinical routine on a regular basis on pediatric patients.

'To me, the ultimate goal is to perform iCMR procedures as the standard of care around the globe, dr. Greil says.'

'There's no benefit to doing this only in Dallas,' Dr. Greil continues. 'I think this method needs to be widely available to the medical community. I very much hope this technology will have a major impact on healthcare around the world.'

Gianfranco Butera (MD)
Bambin Gesù Hospital (Rome, Italy)

Team training was a really pivotal moment for us

Gianfranco Butera began his career in cath labs in 1997 and has worked in Milan and then in London as director of the Cardiac Cath lab. Since 2021 he is director of the invasive cardiology at Bambin Gesu Hospital. Bambin Gesù is a 700-bed pediatric hospital with the largest pediatric cardiology department in Italy. Dr. Butera leads strategy at Bambin Gesù for the cath lab department, the adult congenital team, and the fetal and neonatal cardiology team. He is also heavily involved in mentoring and training staff in cardiology procedures in various societies such as AEPC and PICS.

Dr. Butera speaks highly of the increased level of detail in patient data that's available when performing cardiac catheterization via intervention MRI vs traditional cath lab procedures.

'We know there are several limitations in terms of evaluating the pulmonary vascular resistances in the cath lab. And we know that MRI is the gold standard for measuring pulmonary and systemic flows. So, by putting together this information – exact evaluation of flows plus the direct measurement of pressures –we can achieve very precise information in several groups of patients.'

The patients that benefit most from cardiac catheterization via iMRI include those with cardiomyopathy, pulmonary hypertension, and single-ventricle patients, he says. He notes that having this level of precise data for these patient groups can improve care following the procedure and have a positive impact on patient outcomes.

Dr. Butera also mentions the reduced risk for patients using iMRI vs cath lab. 'With MRI, patients and personnel are not exposed to X-rays. This is particularly important in patients, because many of them need to undergo multiple procedures during their lifetime. So, it would be an advantage to reduce the burden of X-ray exposure,' he says.

Radiologists and cardiologists at Bambin Gesù were 'very enthusiastic' about the shift to iMRI for cardiac catheterization, Dr. Butera says. He notes that referring physicians would often order both MRIs and catheterizations for their cardiac patients, and that there was an opportunity to educate physicians about the benefits of performing both procedures at once with interventional MRI. 'We were able to ask the physician to change the referral letter, and then schedule the patient for an MRI cath. 'My colleagues are very supportive of these new ways of doing things,' he says.

'This dual-procedure approach benefits not only the patient, in terms of convenience, but also the hospital, in terms of efficiency and cost savings,' Dr Butera explains.

The next step, now that MRI catheterization has been adopted at Bambin Gesù, says Dr. Butera, is broader education both within and outside the walls of that hospital. He's currently planning a department-wide meeting at the hospital to educate leadership and colleagues alike, sharing updates about what they're doing with iMRI and the benefits they have seen.

Peer-to-peer training from one hospital to another also plays an important role in wider adoption of cardiac cath via iMRI. For Bambin Gesù, this is a process that started with a core group of their cardiology team visiting a hospital in London where the procedure had already been implemented and was being regularly performed, so the Bambin Gesù team could observe and learn in a real-world setting.

'This was a really pivotal moment for us,' Dr. Butera says. 'The London team showed us some tips and tricks for performing cath procedures in MRI, and I really appreciated the support and enthusiasm from that team. When there's a big change to be implemented, it's so important to have a team of people who are fully motivated.'

And Dr. Butera plans on continuing that cycle of enthusiastic peer-to-peer training. 'I've contacted several colleagues in Rome who are treating patients for whom MRI cath would be helpful. I've told them that they can perform two procedures at once and get better physiological data to improve the care of their patients. We're planning to have those colleagues come to our hospital to see how we do what we do. Soon, there will be other hospitals in Italy using this approach.'

Overcoming Challenges to Innovation

It's clear from speaking with some of the leading experts in medicine around the world that iCMR procedures are the future of cardiac care, and that the future is imminent.

But there are a few things holding us back from that bright future; among these barriers are infrastructure, equipment and training. The magnetic force in most currently available MRIs is so great that non-metal equipment such as guidewires and surgical tools are necessary to ensure safety to the patient, and infrastructure of magnetic shielding is costly or caused the MRI scanner in hospital spaces were not patient surgery is performed.

The field of interventional CMR (ICMR) has been slow to advance, due to safety hazards from radiofrequency-induced heating of catheterization equipment during scanning, inability to visualize standard catheters with MRI, and large metallic artifacts from interventional wires that obstruct the imaging. Specific equipment was developed for catheterization to make wires and catheters safe and conspicuous in MRI. Nano4Imaging (Dusseldorf, Germany) has been a leader in this field and produced the first CE- and FDA-approved guidewire (EmeryGlide) by placing passive markers on the distal tip of a fibre-polymer composite wire. Others such Imricor have constructed complete MRI safe ablation catheters to support cardiac ablation. Aa complete overview of MRI safe devices and steering methods can be found in reference 13.

> 'We can achieve very precise information in several groups of patients.'
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> - Bambin Gesù Hospital (Rome, Italy) -

Low field MRI scanners: the missing piece in the puzzle?

In addition to this specialized equipment, the recent emergence of – and advancements in – low-field MRI scanners seems to be the final missing puzzle piece. While most MRI scanners have been built around a 1.5 Tesla (or T, a unit of measurement that measures magnetic flux density) magnet, and some have twice that strength at 3.0 T, Siemens Free.max low-field scanners use a magnet that's 0.55 T. This offers advantages in terms of the ability to safely use more traditional catheterization and surgical equipment as well as significantly lower costs to install and maintain the machine (significantly less cooling fluid needed, for instance), thereby eliminating most current concerns and barriers to the widespread adoption of iCMR procedures (14, 15).

With ongoing dedication to medical innovation, the passion and expertise of physicians like Dr. Butera and Dr. Greil, and the continued development of MRI-safe cardiac catheterization guidewires and other tools and equipment from industry leaders, interventional MRI is poised to transform the standard of care in cardiology and both the patient and physician experience – one step, one hospital, and one heartbeat at a time.

This white paper describes the rise of interventional MRI as an alternative to conventional cathlab guided by X-rays. Interviews and basic text were conducted and composed by Jen Ringler (ReadHealthy) and final version including graphics written by Dr Paul Borm (Nano4Imaging).

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