BREAKFAST KOL ROUND TABLE – PICS-AICS 2018 LAS VEGAS

MRI guided Cardiac Catheterization Procedures in Congenital Heart Disease

Organizer: Nano4Imaging, Aachen, Germany
Moderator: Prof. dr. Paul Borm
Speakers:
» Prof. Peter Ewert, MD
» Dr. Suren Reddy, MD
» Prof. Henry Halperin, MD

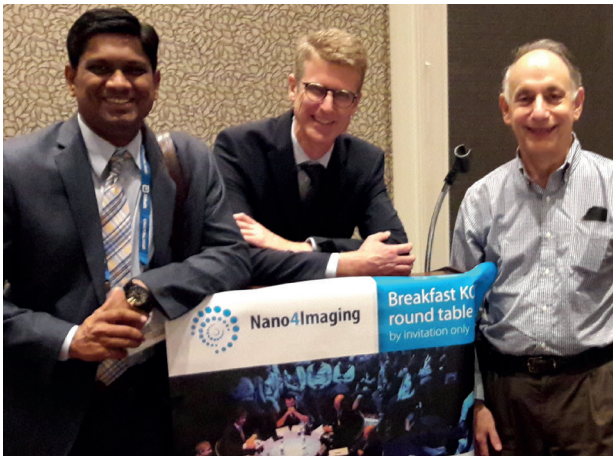
Abstract

On September 6th 2018, Nano4Imaging organized and moderated a workshop during the Pediatric Interventional Cardiological Symposium (PICS) in Las Vegas (USA). During the KOL workshop, key-reference labs in the USA (Dallas Children's/UTSW, Johns Hopkins) and Europe (German Heart Centre Munich) shared their experience and vision regarding MRI guided procedures to an audience of 30 invited pediatric cardiologists and representatives of medical device industry (BBraun, Numed, PFM). After more than 15 years of complicated start-up in hybrid scanner environment, their centers have now established MRI guided procedures as routine in their expert centers. Acquisition of accurate flow data from MRI combined with simultaneous pressure measurement provides a robust assessment of patient hemodynamic status. Real interventions are also now coming close, if tools are made available by industry. The round table delivered several priorities and actions, such as formation of a task force with a clinical branch to define clinical indications and needs on the one hand, and an industry branch to communicate and explore conversion into products. The workshop has put clear landmarks for the perspective of MRI guidance in pediatric cardiology, created new connections between academia and industry and will have follow-up by the task force and a next meeting at the SCMR conference in Seattle 2019.

Breakfast KOL Round Table - PICS 2018 Las Vegas

Introduction

While participants enjoyed breakfast and coffee, Paul Borm, clinical director of N4I, briefly summarized the vision of Nano4Imaging to enable a transfer of invasive diagnostics and future interventions in pediatrics to the MRI. Avoidance of repetitive radiation to a susceptible group, visibility of abnormal structures and combination into functional assessment were specifically mentioned by him and later in session by the clinical experts.



From left to right: Dr. Suren Reddy, M.D | Prof. Peter Ewert | Prof. Henry Halperin

A peaceful co-existence

Prof. Peter Ewert from the German Heart Centre in Munich (DHZM) was the first of clinical speakers. As an experienced interventional cardiologist, and head of his institute he notes that there is currently "a peaceful co-existence" of the people working in the cathlab and the cardiologists running the CMR. He stresses that the fact that the cathlab is a well-equipped machine does not mean one should not explore and innovate procedures, especially when concerning patients who are susceptible to the effects of radiation. Prof. Peter Ewert states that it is time that both groups step out of their bubbles and start to learn from each other. There are many centers that have already made this step.

Munich has conducted clinical work including a postmarketing study with the new MRWire in 2017; so far 27 patients have been investigated at a 92 % success rate, reaching different targets in the heart to measure hemodynamic properties. The Munich approach guided by Prof. Peter Ewert has always been pragmatic. MRI should be able to function as a stand-alone cathlab and hybrid suites will only inhibit further routine use. Munich uses a 1.5 T Siemens system, an In Vivo in room monitor and has now a beamer and screen installed to allow better vision during intervention.

iCMR: From diagnostics to interventions

Dr. Suren Reddy, MD, a pediatric and adult congenital heart disease interventional cardiologist at UT Southwestern/Children's Health in Dallas, provided an extensive outlook as to what the future MRI guided cathlab procedures can deliver. Dr. Suren Reddy stated that while safety and utility of MRI guided diagnostic cardiac catheterizations has been established over more than a decade, the field of MRI guided interventions (interventional MRI – iCMR) has lagged behind.

Dr. Suren Reddy was the first to use the MRWire in the United States in March 2018 and has since used the MRWire for a multitude of applications in close to 20 pediatric patients with congenital heart disease with increasing complexity. After initial pressure measurements in various regions in the heart, he has challenged the MRWire to cross ASDs to left atrium and reach pulmonary veins and cross fenestrations and test occlude fenestrations in Fontan patients, perform retrograde left heart catheterization, cross severely stenotic coarctation of aorta site. After MRI guided diagnostic procedures, Dr. Suren Reddy then systematically studied the MRWire in patients to evaluate its candidacy to be used as a guidewire for performing interventional procedures:

- The MRWire was used in the cath lab to exchange diagnostic catheters to pigtail catheters.
- The guidewire was used in the cathlab to exchange short to long sheaths to prepare for stent angioplasty procedures.
- The MRWire was used as a guidewire to advance balloon angioplasty catheters both on the right and left heart side to perform balloon angioplasty of the RV-P conduit stent and coarctation of the aorta.

Dr. Suren Reddy presented 8 clinical cases with increasing complexity thereby showing what can be done in MRI at the same time indicating the need for additional equipment to perform radiation free interventions in the MRI space and avoid transferring patient back to the cath lab. Finally, he summarized the additional equipment needed (more features of the guidewire, long sheaths, catheters, balloons and stents) in a wish-list that was the start of the round table discussion.

Table 1: Dr. Suren Reddy's wishlist for iCMR devices

Immediate	Next years
MRI access introducer kit (needle, dilator, introducer wire)	MR compatible angioplasty balloons (e.g. Tyshak and BIB)
Sheaths- long sheaths	Stents- CP stent (BBraun)
Catheters- Balloon tip, curved, JR and JL Multipurpose type, pigtail	Bioptome (heart transplant follow-up)
MRWire (Nano4Imaging): - Additional sizes - Modifications for conspicuity (also cathlab)	Trans-septal needle (EP procedures)
	Contrast agents (selective angiograms)

Prof. Henry Halperin (Johns Hopkins) who is a professor in medical engineering and cardiology provided a brief review of the advances in MRI guided ablation and recent developments in the EP field. His presentation was an eye-opener to many clinicians to present as to what is already technically feasible and available (as Pre-IDE) in cardiac ablation. In addition, he explained a number of practical approaches for MRI compatible solutions and estimated consequences for workflow and recurrence rate of cardiac ablation.

Prof. Henry Halperin has an engineering and test lab in-house and offers his services and know-how to resolve both theoretical and practical questions from industry.

Task force to convert vision into actions

The round table discussion was started with the wish list that was presented by Dr. Suren Reddy during his presentation, giving industry participants a clear indication of clinical needs and benefits. Subsequently, the discussion focused on the devices that would deserve priority in development. With this respect it was interesting to note that the companies present (NuMed, PFM, Nano4Imaging) can provide solutions by amendments to existing devices, that would take minimal effort with regard to marking (visibility in MRI) and labelling of the products. The industry partners are also interested to hear more on more complex procedures such as defect closures (ASD, VSD) and doing MRI guided biopsies. The information exchange during the discussion is very useful on all levels, both practical/operational and for strategic planning. Therefore, it is decided to create a task-force with two main sections: an industrial-device section and a clinical-academia section. The clinical section will be led by Dr. Suren Reddy, Prof. Peter Ewert, Prof. Henry Halperin, Kanishka Ratnayaka and Henri Justino). Paul Borm (Nano4Imaging) will connect and coordinate the activities of both sections. The clinical section will prepare a questionnaire to be sent to SCMR and PICS participants to make an inventory of their potential use of MRI guidance, their clinical indications and estimated numbers over the next 2, 5 and 10 years. The outcome will be presented and discussed by the same group during SCMR in Seattle early February 2019. Nano4Imaging will explore opportunities to line up with the interventional CMR symposium day in Seattle and try to involve more industrial stakeholders.

Studio A: Location Breakfast KOL Round Table

Participants

- Prof. Peter Ewert (DHZM)
- Dr. Reddy (UTSW/Dallas Children's)
- Prof. Henry Halperin (Johns Hopkins)
- Henri Justino (Texas Childrens)
- Kanishka Ratnayaka (San Diego)
- Gianfranco Butera (Milan)
- Marc Gewillig (Leuven)
- Christian Jux (Giessen)
- Alan Nugent (Chicago Lurie Childrens)
- Darren Bermann (Nationwide)
- Akansha Thakkar (Houston Methodist)
- Thomas Forbes
- Thomas Fagan
- Sara Trucco (Pittsburgh Children's)
- Ziyad Hiyazi (Sidra)

- Dave Mittl (BBraun)
- Pete Flosdorf (BBraun)
- Jennifer Gotto (BBraun)
- Allen Tower (Numed)
- Ted Dominy (Numed)
- Rolf Pfeil (PFM)
- Jens Nikelski (PFM)
- Sonny Joyce (PFM)
- Michael Barilla (N4I)
- Christoph Manegold (N4I)

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