

# Feasibility and conspicuity of the MRWire in MRI- guided navigation of catheters in a porcine model at 1.5 Tesla.

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## Conspicuity and maneuvering the MRWire to 3 anatomical sites

### Purpose

To test the feasibility, conspicuity and safety of the CE certified MRWire guidewire in an animal model mimicking human vasculature

### Methods

- Guide wires were used by 2 independent interventionalists to guide a catheter to reach several targets.
- Three anatomical sites (aortic arch, common carotid, vena cava) in each of 4 swine.
- Five repetitive manipulations using the wire to place SoftVue non-braided catheters (6F, 7F) in a Siemens 1.5 Tesla platform

### Outcomes

Animal ID	Tip	Attempt	Score					Comments
			1	2	3	4	5	
F1000	straight	Aortic Arch	1	1	1	1	1	No difficulty in moving the wire through the vascular system Wire moved to the wrong anatomical part due to pig's anatomy
		Common Carotid	1	1	1	1	1	
		Vena Cava	1	1	1	1	1	
F1032	Straight	Aortic Arch	1	1	1	1	1	Wire too big for the pig anatomy
		Common Carotid	2	2	2	4	4	
		Vena Cava	1	1	1	1	1	
F1082	Angled	Aortic Arch	2	2	2	2	2	Difficult to move within catheter.
		Common Carotid	2	2	2	2	2	
		Vena Cava	2	2	2	2	2	
F1083	Angled	Aortic Arch	1	1	1	1	1	Difficult to move within catheter.
		Common Carotid	1	1	1	1	1	
		Vena Cava	2	2	2	1	1	

Animal ID	Wire Tip	Start Time	End	Total (h)	Performer
1	Straight	12:15	15:30	3:15	1
2	Straight	11:30	16:35	5:05	2
3	Angled	15:15	18:30	3:15	1
4	Angled	11:00	14:30	3:30	2
				Average	3:46
				SD	0:41

Score	Descriptive
1	Easy, no problems and replicates in all 5 replicates per target
2	Careful operation needed, minor problems in 2 or more replicates
3	Difficult to handle, requires special training
4	Very difficult to handle, high risk procedure, problems encountered in 2 or more replicates

### Conclusions

- Aortic arch and vena cava were well reached in all animals tested
- We were able to reach the carotid in 50 % of cases due to animal anatomy
- No remarkable pathology was seen in any animal after MRI.

### Ongoing PMCF in Europe (German Heart Centre- Munich):

- See oral presentation dr Meierhofer (this symposium)
- 17 patients with congenital heart disease included

## Images of real-time manipulation of guide wire in animal model



**Fig 1.** MRI images of guidewire with passive markers (arrows) in the same Animal (F1000). Left panel: carotid artery, middle panel: aortic arch, right panel: inferior vena cava.



**Fig.2** MRI images of guide wires in different target organs in the same animal (F1032). The arrows show the voids in the omages corresponding to the passive markers inside the guide wire. Left panel: carotid artery, middle panel: aortic arch, right panel: inferior vena cava.

### Essential details

Real-time imaging was performed using the Siemens product "turf-interactive". This is A bright blood TrueFISP, using the following parameters: 152 ms per image, TR= 2.28, Pixel size: 1.56 x 1.56 mm, slice thickness 6 mm, flip angle: 60 degrees, bandwidth 977 Hz, FOV 240 x 400.

Vital signs, including blood pressure and heart rate were monitored throughout the study. Blood samples were drawn at beginning of study, immediately post- MRI intervention and Prior to recovery and euthanasia for pathology No statistical changes in blood parameters Were seen between pre- and post-procedure.

Average time for procedure was 3:15 hours

### Interventional MRI in 5 years

- Our guide wire is first to market in Europe and FDA 510 K is pending. However. It is just a first step towards use of MRI guided procedures.
- More instruments are needed to enable widespread MRI guided procedures.
- Both radiology and cardiology need to collaborate to enable transfer of current cathlab procedures to MRI. Functional measurements (volume/flow) in MRI can be combined with real-time pressure evaluation.
- Passive markers are well suited to guide interventional and diagnostic procedures in animal and man.

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