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MAPS; acute safety data of the St Jude accent - tendril IPG system during prolonged max power CMR scanning

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Background

Until recently, the use of MRI in patients with PPM's was prohibited. The lifetime probability of a patient with a cardiac device requiring an MRI is 50-75%. Serious adverse events occurring during MRI of patients with cardiac devices are rare, but include asystole, VF and death. There is a clinical need to develop knowledge of MR safe devices and safe scanning protocols.

This study specifically address these issues in the SJM Accent MR PPM System, undergoing a dedicated CMR scan at 1.5 T, with a long scan duration at max power.

Methods

Patients were recruited into the MAPS trial and implanted with a SJM Accent ppm and 2 tendril MR leads. All patients were PPM dependent. CMR was performed more than 6 weeks following implant. Pacing capture thresholds, impedances and battery voltages were assessed prior to, between and immediately following the CMR scan. The scans were performed on a Siemens Avanto 1.5T scanner. All patients were placed in an MR pacing mode. Each scan duration was over 90 mins.

Results

Between February 2012 and February 2014, 50 patients were implanted with the SJM MR ppm. The mean age of the patients was 67.3±8.1 years, 30 male. All 50 patients had at least 1 CMR.

There were no significant adverse events reported during any of the scans and no loss of capture was seen in any scan.

Pacing thresholds

The mean pacing threshold for RVOT lead at implant was 0.67±0.22V and at 2 week check was 0.73±0.21V. Pacing thresholds prior to the 1st CMR scan, between the lead switch over and following the scan were 0.66 ±0.16V, 0.66±0.16V and 0.69±0.27V respectively, p=0.34.

The mean pacing threshold for the apical lead at implant was 0.71±0.29V and at 2 week check was 0.74±0.26V. Pacing thresholds prior to the 1st CMR scan, between the lead switch over and following the scan were 0.69±0.17V, 0.69±0.16V and 0.69±0.16V respectively, p= 1.

Impedance

The mean pacing impedance for the RVOT lead at implant was 739±168Ω and at 2 week check was 655±251Ω. Pacing impedances prior to the CMR scan, between the lead switch over and following the scan were 601±123Ω, 595±114Ω and 579±141Ω respectively, p=0.008.

The mean pacing impedance for Apical lead at implant was 631±130Ω and at 2 week check was 616±81Ω. Pacing impedances prior to the CMR scan, between the lead switch over and following the scan were 612±81Ω, 611±80Ω and 574±69Ω respectively, p=0.004.

Battery

The mean battery voltage prior to, between and following every CMR scan did not alter acutely. CMR scan 1 was at 2.99±0.03V.

Specific absorption rate

The max SAR of 4 w/kg was never exceeded. See Fig 1.

Tendril leads 5 control patients had the MR system but no CMR scans. Table 1 compares the parameters between cohorts over 12 months. A similar trend in

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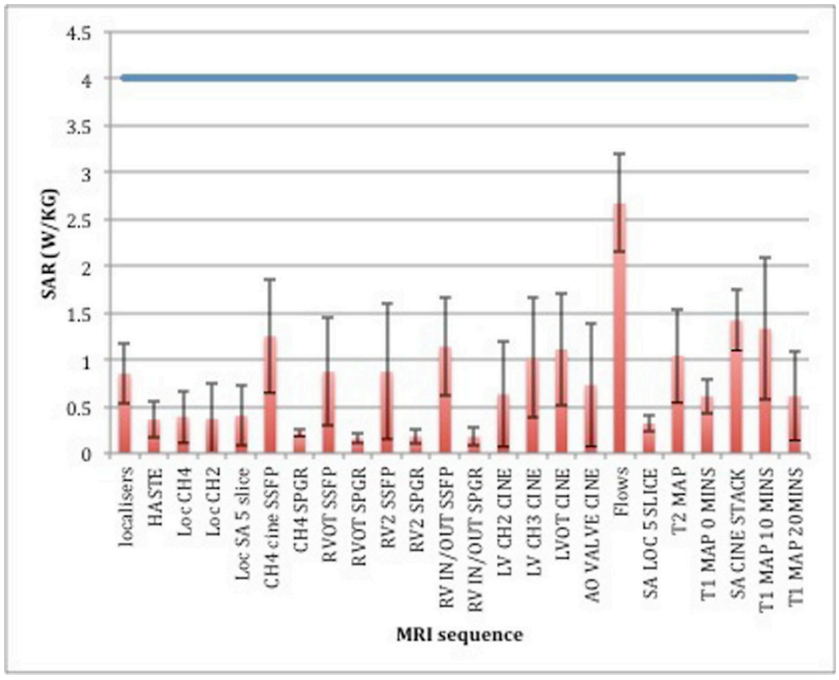

Figure 1 illustrates the Mean SAR of the different MR sequences for 10 scans.

Table 1 Control group of 5 patients with MR system but no CMR scans compared to study group.

		0 months	2 months	12 months
Threshold (V)	Control	0.625 +/-0.14	0.6±04	0.65±0.3
	CMR group	0.67±0.16	0.67±0.2	0.7±0.48
Impedance Ω	Control	698±135	568±85	537±92
	CMR group	739±167	585±108	558±154
Battery (V)	Control	2.99	2.99	2.96
	CMR group	3	3	2.96

parameter changes was observed between the CMR and non-CMR pacing cohort.

Conclusions

Prolonged max power CMR scanning of the St Jude Accent - Tendril IPG system at 1.5 T is safe and has no clinically relevant effects on PCT, voltage and Battery power.

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