The safety of MRI in patients with implanted sacral neuromodulation systems: RF-induced heating

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Background

Sacral neuromodulation (SNM), an important therapy in a variety of lower urinary tract and bowel dysfunctions, requires the surgical implantation of at least one pulse generator and one electrode lead. To date, despite an encouraging preliminary clinical safety study [1], the presence of these implants is widely considered to be a contraindication for MRI. Advice from the device manufacturer specifically supports this view [2]. While appearing superficially similar to deep brain stimulation (DBS) instrumentation, for which MRI safety has been more extensively explored [e.g. 3,4], these implants may have different internal design, lead lengths, and orientation due to their location in the sacral region. These factors may critically alter electromagnetic interactions during MRI. To investigate this we measured, in an anatomically appropriate test object, temperature rises produced during MRI with a SNM system, as the scanner bed was moved through a number of positions.

Methods

An implantable pulse generator (IPG, InterStim® Model 3023, Medtronic Inc, Minneapolis, MN, USA) and quadripolar SNM lead (tined lead Model 3093, Medtronic Inc, Minneapolis, MN, USA) were positioned on an artificial pelvis (figure 1) immersed in an aqueous gel (polyacrylic acid 8g/litre and NaCl 0.70 g/litre) with electrical and thermal characteristics similar to those of human tissue [5]. MRI was performed using a Siemens 3Tesla Tim Trio VB15 system in body-coil transmit mode for all measurements. Temperature was measured continuously at 4 positions (the most distal electrode contact [electrode 0], a medial electrode contact [electrode 1], the IPG case and a reference position), using an optical-florescence thermometer (Luxtron). A 6min 33s duration turbo-spin echo sequence was used and measurements performed first with the scanner landmarked on the phantom head position (table position 0), and then moving the table through successive 200mm intervals. The -800mm acquisition was approximately centred on the IPG. At each position a standard 4-slice protocol was first acquired (i.e. constant time-averaged B_1 at each position) then the number of slices was increased with the aim of achieving a scanner-reported whole-body SAR ≈ 2W/kg at each position (i.e. constant whole body SAR at each position). When the scan was centred close to the head (0 and -200mm positions) the maximum achievable whole-body SAR was reduced due to lower scanner-imposed restrictions on head SAR. To investigate the influence of the implant on the scanner-reported SAR, the implant was removed from the phantom and the prescan repeated at each position. All experiments were performed with the IPG amplitude set to 0V and the output set at "off".

Results

bed position (mm)	number of slices	whole-body SAR (W/Kg)	transmit-gain (scanner units)	maximum temperature rise (°C)		
				distal electrode contact	medial electrode contact	IPG case
0	4	0.1	200.07	0.1	0.1	0.1
-200	4	1.4	682.5	0.1	0.1	0.1
-400	4	1.1	215.5	0.3	0.2	0.1
-600	4	1.0	328.6	0.7	0.7	0.2
-800	4	0.7	356.9	0.6	0.6	0.1
-1000	4	0.5	292.8	0.1	0.1	0.1
0	19	0.6	200.07	0.1	0.1	0.1
-400	7	1.9	215.5	0.1	0.1	0.1
-600	7	1.8	328.6	1.2	0.9	0.3
-800	11	1.9	356.9	1.7	1.6	0.4
-1000	16	2.0	292.8	0.5	0.4	0.1

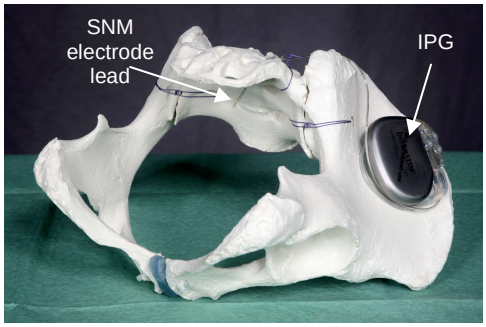

Figure 1 The IPG and SNM lead positioned on a model human pelvis prior to immersion in the gel phantom.

The scanner-reported SAR for the same 4-slice protocol varied widely with bed position, as did the concomitant maximum temperature rises (ΔTs) during each acquisition. For the acquisition centred on the head position, ΔTs were less than 0.1°C. At other positions, ΔT time-courses were qualitatively similar to those reported previously for DBS implants [3,4]. ΔT was greatest at the most distal electrode contact, while ΔTs at the IPG were relatively small. ΔT at the reference position was always ≤ 0.2°C. The maximum ΔT at any position for SARs ≈ 2W/kg was 1.7°C. On repeating the prescans in the same phantom with the implant removed the scanner-reported SARs changed by 1% or less.

Discussion

The ΔTs obtained at bed position 0mm suggest that SAR-restricted MRI examinations centred on the brain are likely to be safe with regard to RF heating in SNM patients. However, for MRI examinations centred upon the cervical, thoracic, lumbar and sacral regions, both the scanner-reported SAR and ΔTs may vary widely with bed position. Removing the implant had little effect on scanner-reported SAR hence we conclude that this variability was caused predominantly by position-dependent differences in loading of the body-coil by the simulated patient. These results further emphasize the difficulties of using scanner-reported SAR as a safety measure in patients with this type of implant [6]. However, since ΔTs in all bed positions remained modest in physiological terms, it is possible that MRI may be safely performed in SNM patients if a reliable, possibly scanner-specific, metric for controlling RF heating can be determined.

References: 1. Elkelini, M; Eur. Urol. 50; p311, 2006 **2.** Medtronic Inc., 2006 **3.** Carmichael, D; Neuroimage. 37; p508;2007 **4**. Bhidayasiri,R; Magn Res Imag 24; p677; 2005 **5.** Park, S; IEEE Trans Magn 9; p3367;2005 **6.** Baker, K; J. Mag Res Imag 20; p315; 2004