A Canadian Winter indirectly inactivates a deep brain stimulation system.

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Keywords:

Deep brain stimulation
Implantable pulse generator
Electromagnetic interference
Movement disorders

Running head: Winter effects on IPG

Title characters: 73

Word counts: 1016

Author number: 2

References: 7

Deep brain stimulation (DBS) technology has evolved over time, yet pulse generators remain vulnerable to electromagnetic interference (EMI). Precautions pertaining to EMI are extensive[1], making it difficult for patients to identify the EMI source easily. This happened to one of our patient whose DBS would inadvertently shut off every time he would stepped out of the house into the cold Canadian winter.

Mr. RT was a left-handed 67 year-old male suffering from medically refractory disabling essential tremor involving his upper extremities, predominantly his left. A DBS electrode was implanted in the right ventrointermediate nucleus and connected to a Soletra (Medtronic, Minneapolis, MN, USA) implantable pulse generator (IPG) in his right chest. At the time of the incident, his DBS system had provided him with six months of excellent tremor control through the summer and autumn. The coming winter, he reported tremor recurrence every time he stepped out in the frigid cold. Afflicted by tremors once outside the house, he would need assistance to turn his IPG back on using his controller. However, until he returned inside and opened his winter coat, his IPG would again turn off spontaneously. Interrogation of the IPG in the clinic did not reveal any abnormalities or battery failure.

Although EMI was the obvious suspect, our problem remained identifying the source of this EMI. For two months, our patient investigated the environment around his house for any device emitting an electromagnetic field, initially blaming his neighbor's newly installed dog perimeter fence. One day, after inserting his reading glasses into his winter coat chest pocket, he realized that his glasses stuck tightly to two small magnets hidden underneath the fabric. His winter coat had an inside pocket equipped with a magnetic closure positioned at the level of his implanted IPG. Only when our patient would fully zip up his winter coat would these magnets be close enough to inactivate his IPG, explaining the IPG inactivation noticed mainly on frigid winter days. Removing the magnets from his coat solved the problem.

Neodymium magnets are polyvalent in the fashion and technology industries. In our patient, small hidden fashion magnets caused his IPG to inactivate but only once positioned in very close proximity, complicating our search for an EMI device. Miniature magnets (8 mm) can interfere with implantable cardioverter-defibrillators if positioned within 3 cm of the generator[2]. Magnets from tablet computers can also modify programmable shunt valve settings[3]. As illustrated by this case, education about EMI alerted our patient to the possibility of interference but did little to help him rapidly resolve his problem.

The literature on adverse events from EMI on IPG is scarce compared to that of cardioverter-defibrillator. A search for: (DBS (MeSH term) AND (electromagnetic field)) OR (DBS (MeSH term)

AND equipment failure (MeSH term)) OR (electromagnetic interference (keyword) AND deep brain stimulation (keyword)) was performed. The results were screened for publications that focused on adverse events secondary to EMI. Seven publications were retrieved for revision and only three investigated the effects of EMI on DBS systems. Blomstedt et al.[4], reported a retrospective chart review of 172 patients with DBS who experience an adverse effects from EMI. Twenty patients (12%) experienced an unintended deactivation of their IPG, the majority secondary to theft detectors or airport security gates. The cohort was composed of 16 Itrel-II, 1 Soletra and 3 Kinetra IPGs. Dustin[5] performed a review of the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database in 2008 looking at reported EMI adverse events. Seventy-six events were found, nine for DBS and 67 for spinal cord stimulators. Adverse events included a change of stimulation settings, shock or pain or tingling, unintended deactivation, or local burning at the IPG site. IPG models involved in these events included Soletra and Itrel II-IV. And Kain et al.[6], investigated the effects of GSM mobile phones in vitro on Itrel-III IPGs. GSM mobile phones did not cause interference with the pulse generator.

Our case report involved a Soletra IPG. The newer Medtronic model, Activa, available since 2006, has been advertised as being less affected by EMI. A search of the literature using the following terms: (medtronic Activa deep brain stimulation) OR (medtronic dbs) OR (medtronic Activa) OR Activa, did not reveal any publication specifically addressing EMI with the Activa IPG. One publication reported rates of unexpected IPG switching off to be 18.7% in Soletra / Kinetra but only 3.4% in Activa RC[7]. This unexpected switch off could be from EMI although this was not confirmed in the publication. A search of the FDA MAUDE database for all Medical Device Reports (MDR) associated with Medtronic Activa, Kinetra or Soletra neurostimulators and classified under (Electromagnetic Interference (EMI) OR Electromagnetic Compatibility OR Electromagnetic Interference (EMI): Compatibility / Incompatibility) was performed on October 1st 2016. The total EMI reports were: Soletra 93, Kinetra 45, Activa 110. The number of reports with confirmed or highly suspected EMI based on the report description included: Soletra 76, Kinetra 35, and Activa 66. The number of reports clearly describing a magnet as the cause of the EMI included: Soletra 9, Kinetra 2, and Activa 6. A Chi-square analysis showed no statistically significant difference ($p = 0.40$) between the groups after normalization for the 10-year span of MDR for Soletra and Kinetra IPGs, and 6-year span for the Activa.

The lack of integrated diagnostic resources available to interrogate an IPG makes troubleshooting problems like EMI difficult for both patients and physicians. Diagnostic applications have been available for electronic devices such as computers and cellphones for years but are not available for IPGs. DBS systems are implanted for improving patient quality of life. In our opinion, IPG software should be designed with the same focus in mind. Patient anxiety increased once faced

with what seems to them to be an unstable device. While newer devices such as the Medtronic Activa provide the patient with some data, such as residual battery voltage, these data are limited. A user-friendly interface providing diagnostic and troubleshooting functions such as time-equivalent residual battery power, electrode integrity, and malfunction codes, would go a long way in supporting patient quality of life.

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