Hardware-related Complications of Deep Brain Stimulation

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Abstract

Objective: To investigate the incidence of hardware-related complication of deep brain stimulation (DBS).

Methods: Forty patients receiving DBS were included for this study and there were 32 Parkinson diseases, 5 essential tremor, 3 post-stroke central pain. Forty patients received 69 permanent DBS electrode implants.

Results: Overall, 7 patients had hardware-related complications including 1 lead fracture, 2 infections and/or erosions and 4 IPG malfunctions. All IPG malfunctions were induced by electromagnetic wave including mobile phone, magnet, refrigerator and lightning.

Conclusion: Our study revealed that hardware-related complications of DBS therapy occur in a significant number of patients. The physician should be aware of the possibility of hardware related complications and understand the way of avoiding complications.

1. Introduction

Deep brain stimulation (DBS) or neurostimulation for the alleviation of movement disorders and pain is now an established therapy. The advantages that are intrinsic to such procedures are that they are nondestructive, the effects are reversible, and the parameters can be re-adjusted long-term. The main disadvantages are those of cost, the need for regular follow-up and programming, and the complications associated with implantation of foreign bodies. In multicenter United States and European Tremor Trials (n = 197 patients), adverse events related to the device included lead migration and/or dislodgment (1.0%), lead fracture (0.5%), infection (1.5%), erosion (2.5%), electrical short circuit or open circuit (1.0%), and component malfunction (1.5%). Furthermore such device related problems lead to significant patient mobility and increased cost of therapy in the form of prolonged antibiotics, in-patient hospitalization, repeat surgery, and device replacement. However there are few publications documenting hardware-related problems in any detail. We report our experiences of hard-ware failure related complications of neurostimulation.

2. Clinical materials and method

Forty patients underwent DBS procedure for movement disorder or central pain. These forty patients receiving DBS were consisted of 32 patients with Parkinson disease, 5 patients with essential tremor and 3 patients with post-stroke central pain. Overall, 40 patients had undergone implantations of 69 internal pulse generators (IPG).

The procedure were staged, with the first phase consisting of intracerebral electrode implantation and the second phase, usually 7 days later, involving the placement of an infraclavicular IPG. On the day of surgery, a preoperative MRI scan was performed for the CRW frame to obtain stereotatctic coordinates. The x,y, and z coordinates of the target were anatomically determined by anterior and posterior commissure. Intra-operative microelectrode recordings were performed to identify the target physiologically and then a DBS 3387 electrode (Medtronic, Inc, Minneapolis, MN) was implanted. The electrode was fixed to the cranium by use of the Medtronic burr hole ring and cap. Electrodes were connected to a Medtronic 7495 external cable, and the connector assembly and excess wire placed. The external cable was brought out through a separate stab incision lateral to the primary scalp incision, for further testing the ensuring week. The scalp incision was then closed in two layers. During the 1-week period of percutaneous electrode testing, several investigations including magnetic resonance imaging (MRI) scans, functional MRI scans and electrophysiological tests was performed in accordance with research protocols. In some patients, particularly those receiving DBS for pain, this period served as a trial to test the
efficacy of stimulation in symptom relief. After this period of percutaneous testing, all patients were placed under general anesthesia, and the IPG (Soletra or Itrel III) was implanted. A subcutaneous tunnel was made from the site of the externalized connector down to an infraclavicular subcutaneous pocket. The extension cable from the IPG was then subcutaneously passed up from the infraclavicular region and connected to the electrode. The distal end of the extension cable was connected to the IPG, which was secured to the pectoralis fascia with a single suture. All wounds were irrigated with tobramycin (antibiotics) and saline solution and then closed in one layer.

3. Results
Case one
52-year-old man with a 15-year history of L-DOPA responsive PD underwent bilateral STN-DBS because of fluctuation with severe and frequent off periods including severe freezing of gait. During test stimulation motor fluctuation and freezing gait alleviated dramatically, and SOLETREAs / Itrel III were implanted in both subclavicular regions one week later. The electrical parameters were 1.8 V, 90 sec, 135 Hz on the right electrode, and 1.8 V, 90 sec, 135 Hz on the left electrode. During the rehabilitation the patient noticed abnormal sensation when he moved his left upper limb. Further examination revealed the lead fracture at the joint of IPG and extension code in the left side (Fig 1.). The IPG was exchanged and the condition was improved.

Case two
73-year-old man with essential tremor underwent bilateral Vim-DBS 5 years ago. His tremor had been well controlled by stimulation. The patient noticed the erosion of the skin in the forehead and the lead was bared (Fig 2). The intracranial lead and the extension code were removed. The patient underwent implantation of DBS into the Vim 6 months later.

Case three
65-year-old woman with Parkinson disease underwent STN-DBS because of progression in gait disturbance. The electrical parameters were 1.5V, 120 sec, 135 Hz on the right electrode, and 1.8 V, 90 sec, 135 Hz on the left electrode. Her walking was improved by DBS, however, she was in poor health whenever she entered into the kitchen. The environment of kitchen was investigated and the refrigerator was doubted for the cause.

Case four
60-year-old man with Parkinson disease underwent bilateral STN-DBS because of progression in gait disturbance. The electrical parameters were 1.5V, 90 sec, 145 Hz on the right electrode, and 2.0 V, 90 sec, 135 Hz on the left electrode. He went to open-air concert one day and there was struck by lightning. His IPG had not worked well since then and unpredictable running was verified. Overall, 7 patients had hardware-related complications including 1 lead fracture, 2 infections and/or erosions and 4 IPG malfunctions induced by electromagnetic wave.

4. Discussion and conclusion
During the past decade, there has been a resurgence of interest in therapeutic brain stimulation spurred by its use in surgery for movement disorders or pain. Despite the proven benefit of this treatment, there are several reports of hardware-related complications of DBS1-3,5-11). Nonetheless, hardware-related complications can be more troublesome than stimulation-related side effects. To improve the risk to benefit ratio of DBS, the incidence of hardware-related complications must be known and efforts must be made to minimize these complications. In our series two patients had erosion complications and were associated with infection. These infections and erosions occurred at the burr hole site. Although we have used the silicone burr hole ring and cap supplied in the DBS lead kit to secure the electrode, in cases where there is an increased risk of lead dislodgment, the use of a microplate and screw fixation, as reported by authors at some centers4), may be useful. It was generally considered that infections and/or erosions occurred at the connector site. The size of the connector is probably an important factor. A smaller connector has been designed by Medtronic, Inc., but it is not yet commercially available10). There was lead fracture in one patient. The presence of this fracture was confirmed by precise X-ray. The precise X-ray in particular position should be considered whenever the patient complains of either abnormal sensation or no clinical change by stimulation. There are many sources of electromagnetic wave in our environment and these electromagnetic wave influences on the IPG. The possibility of IPG malfunction by mobile phone was issued in Pharmaceuticals and Medical Devices Safety Information.
No.179.2002 by the Ministry of Welfare and labor. Moreover the government roused the possibility that the IPG was influenced by patients’ surrounding electromagnetic wave including mobile phone, radio, IH rice cooker and antitheft devices etc. If the patient complains of abnormal behavior of the IPG, the physician should check the patient’s environment and advise the patients against approaching such doubtful devices.

Table 1 summarizes the reported rates of hardware-related complications of DBS1,2,5-11). In the twelve series, infectious complications were reported in 11 series and ranged from 2.7 to 23.4%. Lead breakages were reported in 7 series and ranged from 2.5 to 10.3%. Migrations were reported in 5 reports and ranged 1.8 to 14.2%. IPG malfunctions were reported in 7 series and ranged from 1.2 to 18.8%.

Our study revealed that hardware-related complications of DBS therapy occur in a significant number of patients. To maximize the therapeutic benefit and minimize the cost of these devices, hardware related complications must be identified and addressed. As experience is gained, novel ways of avoiding complications and treating patients with complications will be developed.

References

Fig 1: Lead fracture. When the patient elevated his upper limb, the breakage of lead was distinguished.

Fig 2: The lead was bared in the frontal region.

Fig 3: The abnormal activation of IPG was identified after thunder storm.

Table 1: summary of hardware related complications of deep brain stimulation.