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When brain devices go wrong: a patient with a malfunctioning deep brain stimulator (DBS) presents to the emergency department

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SUMMARY

A man in his 50s attended the emergency department with an acute deterioration in his Parkinson's symptoms, presenting with limb rigidity, widespread tremor, choreiform dyskinesia, dysarthria, intense sadness and a severe occipital headache. After excluding common differentials for sudden-onset parkinsonism (eg, infection, medication change), an error on the patient's deep brain stimulator was noted. The patient's symptoms only resolved once he was transferred to the specialist centre so that the programmer could reset the device settings. Due to COVID-19-related bed pressures on the ward, there was a delay in the patient receiving specialist attention—highlighting the need for non-specialist training in the emergency management of device errors.

BACKGROUND

A clinical cyber-crisis is a patient emergency that results from a failing medical device.[1] Over the last two decades, new medical technologies have developed at an exponential rate—from implanted cardiac devices to phone apps that can monitor blood glucose. While there is a significant volume of research highlighting the benefits of new devices, less focus is given to the impact of malfunctioning devices on patients. Most importantly, we lack educational and research material for clinicians who are faced with managing a patient in crisis due to a failing implanted device.

The performance of implanted medical devices may be compromised in several ways, such as hardware or software faults resulting from malicious or non-malicious hacks; or due to disrupted connectivity features affected by electromagnetic radiation (EM) from the environment.[2–6] Research by Rahimpour *et al* has found that performance of deep brain stimulators (DBS) can be affected by the EM radiation of common household appliances including hair dryers and security gates.[6] Furthermore, cybersecurity researchers have demonstrated the security limitations of implantable medical devices, which if exploited could have severe consequences for patients.[3 7 8] Existing case studies of telemetric device hacking have included the use of a radiofrequency transmitter to bypass the security of an insulin pump with conceivably lethal implications for a patient.[9]

Two years ago, Dameff *et al* designed the first 'cyber-crises' clinical training simulations, in which healthcare practitioners were tasked with treating patients suffering from clinical syndromes arising from errors in implanted hardware.[1] Their findings illuminated an absence in clinical understanding when faced with a device complication and an urgent need for improved awareness so that practitioners can integrate these considerations into their differentials.[1] Our paper focuses on a novel cyber-crisis that resulted from a failing DBS. Through our work we aim to improve awareness regarding these device errors and foster greater research and collaboration between the bioengineering and medical communities on the topic of biotechnological syndromes.

DBS technology

A DBS is an implant which sends electrical pulses to specific areas of the brain that have been affected by a disease process, therapeutically targeting a patient's symptoms (eg, tremor in Parkinson's disease).[2 10] The device consists of a pulse generator implanted in the upper chest from which an electrical current is transmitted through insulated wires, running under the skin of the neck and scalp, to a target site within the brain.[10]

In the 1980s, long-term brain stimulation emerged as an alternate treatment to surgery for patients with Parkinson's disease and has since been used in more than 100 000 patients.[10] In recent years, there has been a surge of interest in these forms of 'neurotechnology'—the overarching term that describes computational devices interfacing with neuroanatomy. Youngerman *et al* describe the growing adoption of Neurotechnologies in medicine for a range of 'emerging indications', including conditions such as bipolar disorder, depression and obsessive–compulsive disorder.[2] Under the BRAIN Initiative, the Defense Advanced Research Projects Agency—the research branch of the US military—developed brain implants to treat conditions such as post-traumatic stress disorder, anxiety and traumatic brain injury.[10] In recent years, neurotechnologies have proliferated beyond the healthcare space, with interfaces now being developed by companies in the consumer market, for example, within the neurogaming industry, and by initiatives such as neuralink.[11]

DBS errors

The societal proliferation of these technologies increases the likelihood that clinicians will encounter a patient suffering from a technological complication. Such complaints can present with a range of complex clinical phenomena, illustrated

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by the growing number of DBS errors described in the literature.[12–17] The introduction of inappropriate electrical signals into the brain has far-reaching effects, with the potential to manifest in any of a patient's physiological systems. Individual reports have described the impact of DBS complications on autonomic function, including the case of a patient who presented with fever and tachycardia, and was treated for sepsis until the DBS error was identified.[12] Further case reports have identified DBS complications resulting in loss of motor functions, blepherospasm, psychiatric phenomena and new clinical pictures such as 'Twiddler's syndrome' (the manipulation of wire systems by the patient).[13–17]

The acceleration in the adoption of DBS technology is largely related to the improved connectivity of these devices.[10] Since 2013, neurostimulators have been capable of reading neural signals in addition to directing simulating currents into the brain.[10] The connectivity of these devices provides opportunities to make long-term neural recordings of patients and improve individual care. However, the increased connectivity also opens new security vulnerabilities, including risks of 'Brainjacking'—a term coined by Pycroft *et al* to refer to the unauthorised control of an electronic brain implant—raising questions about the privacy of brain data.[3]

In their review of brain device cybersecurity, Pycroft *et al* report that malicious hacks do not have to be particularly sophisticated to induce harm; once neurosecurity has been breached, several mechanisms exist for brainjacking.[3] Manipulation of voltage/current, frequency, pulse width and electrode contact can all be altered to affect the patient.[3] Further, in their article the researchers provide a table of possible neurosecurity attack types on DBS technology, including battery drainage, overcharge stimulation, data theft and voltage manipulation.[3] Such targeted attacks may result in the impairment of motor function, alteration of impulse control, modification of emotions or affect, induction of pain and modulation of the reward.[3]

CASE PRESENTATION

The patient, a man in his 50s, presented to the emergency department in the middle of the night with an acute deterioration in his Parkinson's symptoms. The patient had been diagnosed with Parkinson's 15 years earlier and his symptoms of rigidity and tremor were usually well controlled by the combination of levodopa and a DBS that had been implanted 5 years earlier.

On the evening, the patient presented he reported that his medications were no longer effective, and his symptoms had intensified beyond his previous experience; he was exhibiting severe dyskinesia with violent shaking of all four limbs at around three per second. He was sweaty, struggling to speak and the dyskinesia was associated with widespread rigidity and tremor. The patient was also reporting an intense occipital headache, associated with nausea, and he expressed intense sadness and emotional distress during his presentation.

Examination of the patient's respiratory, cardiovascular and abdominal system did not demonstrate further pathology, however, the presence of the patient's neurostimulator in the patient's left pectoral region was noted. The neurostimulator sits beneath the skin and communicates with a remote device called the 'patient programmer'—a telemetric remote control which can synchronise with the neurostimulator and change the settings. Unfortunately, because we were not the patient's local team, we did not have access to his previous medical records and had no knowledge of the device's characteristics.

INVESTIGATIONS AND DIFFERENTIAL DIAGNOSIS

Initially, we considered common differential diagnoses that could account for the acute deterioration in his parkinsonism: levodopa-induced dyskinesia, underlying intercurrent illness (eg, COVID-19) or, given the severity of his new onset headache, an intracranial bleed. Our initial investigations offered little direction regarding these diagnoses, the patient's inflammatory and infective markers were within normal parameters and his additional bedside tests (COVID-19 swab, urine dip and ECG) were normal. The only abnormality was the patient's creatine kinase (1453), thought to be related to muscle breakdown relating to his extensive hyperkinesia. The CT brain scan did not demonstrate an acute event; however, it directed our attention to the bilateral DBS device in situ (figure 1).

The presence of largely normal blood tests and imaging results demonstrates that hardware faults may not be captured by usual physiological investigations. Furthermore, investigations may need to be interpreted differently when a device is present, especially regarding ECGs. Recording an ECG trace on a patient with a DBS can deactivate the neurostimulator in the chest, indicating that these patients require tailored work ups to ensure the performed assessments are appropriate given their device background. Additionally, the presence of a neurostimulator can introduce artefact on an ECG, distorting the trace and interfering with an effective evaluation of cardiac symptoms.

For biotechnological syndromes the investigations need to extend beyond the patient to the device itself. In an attempt to understand the device failure, the team performed a reverse-image search of the patient programmer on Google and found

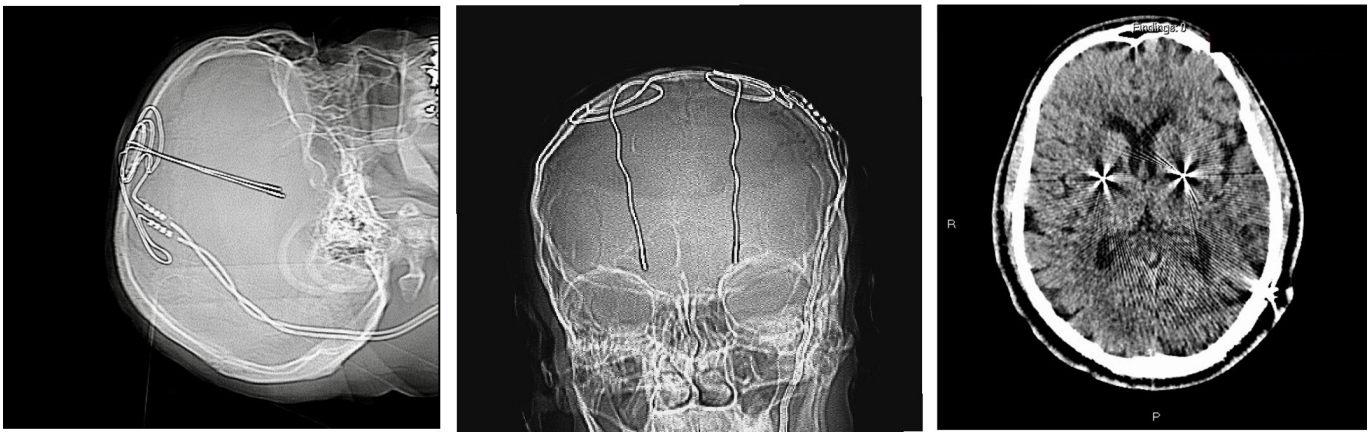

Figure 1 CT images demonstrating the position of the deep brain stimulator (DBS) wires in the brain.

the user manual for the device. On exploring the device user manual, we were able to interpret the error message on the device which indicated that the neurostimulator had desynchronised.

TREATMENT

Due to our patient presenting at 0200, we were limited in the specialist expertise we could access. We communicated directly with the specialist unit; however, the full team and technical expertise were not available during on-call hours. In the context of our acutely unwell patient the lack of appropriate medical and programming expertise was a significant limitation in the care we could provide. Our priority was to manage the patient in the intermittent period before specialist attention could be obtained, highlighting the importance of non-specialist emergency training in device failures.

Our first challenge was technical. Having not managed a similar case in the past, we were unfamiliar with the device and there were simple design issues that could be remedied. For example, the device controller had two power buttons sharing a similar appearance. Given that one button turns the programmer on, whereas the other terminates the therapy, simple improvements to the design that highlight the role of both buttons would be useful to non-specialists.

With the assistance of the specialist team over the phone, attempts were made to reconfigure the device using the patient programmer in the department. Unfortunately, these attempts failed, and we were unable to resolve the patient's symptoms. For intermediary management, he was treated with intravenous fluids, analgesics and benzodiazepines which had a limited effect on improving his symptoms. Due to bed pressures related to COVID-19, transferring the patient to the specialist hospital was delayed. Once this transfer was arranged and the programmer was available to attend to the patient, the correction of the DBS settings immediately resolved the patient symptoms.

OUTCOME AND FOLLOW-UP

The patient remained in the specialist hospital for a few days following the resolution of his symptoms, during which time causes for the device error were explored. On examination, it appeared that the DBS settings had been unintentionally reset and once the correct voltage and frequency settings were reinstated the patient improved immediately. The cause of the change in the DBS settings remains unclear, these settings can only be adjusted using the clinician's programmer as opposed to the patient's programmer which they have at home. As a result, it should not be possible for the parameters to change outside of the clinical setting. Once discharged, the patient returned to his previous functional baseline, his symptoms being controlled with his regular medications and reconfigured DBS hardware.

DISCUSSION

As much as patients require and deserve access to these technologies, they also need medical professionals who can assist them when devices fail and they present asking for help. At present, clinicians are rarely trained in the medical manifestations of malfunctioning implanted devices; an omission which needs urgent attention if we are to provide the best care for patients. Through the case of our patient, we highlight the importance of this area of research and present novel ethical questions raised by technologies that interact with our brains and minds.

Traditional history-taking does not encompass a digital history of the patient. Such a history could include information on patient access to consumer or prescribed healthcare technologies, exposure to sources of EM radiation (eg, have symptoms started following a visit to the radiology department, a flight or passing through airport security gates) or previous engagement with biohacking practices. In the case of our patient, a digital history would have involved details of the device model, possible faults and exposure to sources of EM radiation. At this stage, we could also consider digital 'red flags'. If our team had known the research that describes how DBS voltage changes can induce different emotional states, the patient's intense sadness may have been picked up as an indicative symptom of DBS failure.

Following our initial assessment of the patient, we found that the investigations provided little direction regarding the source of pathology. This is largely because medical investigations are tailored to investigating human physiology—we do not know how a man-made device error may materialise on our standard blood panels. We saw normal investigations—aside from the rising CK which related to the ongoing end-point symptoms of hyperkinesia. Symptoms and deterioration, in the absence of an explanation captured by traditional investigations, should increase clinical suspicion of implanted hardware faults. For example, chest pain and ECG changes in the absence of biochemical changes in cardiac enzymes, may indicate a faulty pacemaker. In addition, our investigations were limited by our technical skills and patient care would have been improved if an on-call programmer was available to address the device error. As clinicians, we lacked an understanding of the device, its mechanisms of failure, and the management options that were available to us.

There is a dearth of research describing biological syndromes arising from technical manipulation of human physiology and anatomy. Given the predicted expansion of the DBS market and the growth of the citizen biohacking community, we can expect biotechnological syndromes to become more prevalent.[18] In the case of neurotechnology, Denning *et al* discussed cases of self-hacking (patients who attempt to self-prescribe elevated moods or increased activation of reward centres) and malicious hacking in which hackers attempt to programme stimulation therapy maliciously.[19] At present, there is no definitive guidance on which treatment options are most effective for these patients, for example, will seizure medications be effective when the pathological source is a metallic implant? Our case highlighted this gap in current clinical knowledge as it relates to the emergency setting and the case of acutely unwell patients.

Learning points

- Biotechnological syndromes and cyber-crises can present with a range of clinical phenomena and device failures or hacks need to be added to diagnostic differentials.
- While the increasing connectivity of medical devices may improve personalised care, they also carry new risks due to the introduction of possible cybersecurity exploits.
- Emergency management of cyber-crises needs to be incorporated into medical education and clinical training.
- Symptoms and clinical deterioration, in the absence of an explanation captured by traditional investigations, should increase clinical suspicion of implanted hardware faults.
- Greater cross-disciplinary research into presentations arising at the intersection of computational devices and human physiology is urgently needed.

Following the case, our team reported the device error to both the United States 'Food and Drug Administration' (FDA) and the UK 'Medicines and Healthcare products Regulatory Agency' (MHRA) - the national regulatory bodies for pharmaceuticals and implanted devices -however, this is a voluntary process in which clinicians receive little training. While the prevalence of medical devices has grown exponentially over the last decade, our guidelines have not developed at a parallel pace. Healthcare practitioners would benefit from targeted teaching on biotechnological syndromes, through the integration of educational material into medical curricula and the introduction of technology-focused simulation sessions into training pathways. By educating clinicians on these issues, we can ensure these patients are not missed, wrongly diagnosed or subject to lacking medical care. To ensure best practice, we urgently require greater research into biotechnological syndromes, improvements to clinical training in cyber-crises, and comprehensive hospital policies that can effectively respond to such cases.

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