ISCoS The International Spinal Cord Society

www.nature.com/scsandc

CASE REPORT

Interaction between a smartphone and intrathecal baclofen pump case report

Francesca Filipetto[1], Judith Walden[2] and Michelle Trbovich[1,2]✉

INTRODUCTION: Intrathecal Baclofen (ITB) is used for the treatment of spasticity. Pump complications are most commonly related to surgical implantation or catheter dysfunction. Less common complications include catheter access port dysfunction, motor failure from excessive wear on motor gear shafts, or a complete stall of the motor.

CASE PRESENTATION: 37-year-old with T9 motor complete paraplegia with ITB presented in baclofen withdrawal. Workup revealed that the pump's motor was not turning, requiring pump replacement. Questioning revealed that he had not undergone any MRI studies within the past six months, but that he recently purchased a new iPhone. The phone was 2–3 inches away from the pump for up to twelve hours a day, carried in a fanny pack around his waist.

DISCUSSION: We present a case of motor pump failure from long term exposure to a magnetic field from a new iPhone. The ability of iPhones to overpower an ITB pump magnet is not widely known. In 2021, the Food and Drug Administration published a report regarding the effects of magnets in consumer electronics on implanted medical devices, recommending that such electronics should be kept at least 6 inches from the device. Providers should be aware of the ability of new models of commonly used electronic devices to stall the ITB motor to avoid life-threatening complications of baclofen withdrawal.

Spinal Cord Series and Cases (2023)9:5 ; https://doi.org/10.1038/s41394-023-00563-9

INTRODUCTION

Intrathecal Baclofen (ITB) pump therapy was approved by the FDA in 1992 for the treatment of muscle hypertonia of spinal and supraspinal origin [1]. Complications of ITB therapy occur in approximately 10.5–37% of implants [2–4]. Such complications breakdown into categories of catheter dysfunction, pump failure, battery failure, errors in medication dosage, CSF leakage, infection, and skin breakdown over the implantation site [5].

Intrinsic motor/pump failure is far less frequent than catheter dysfunction. In 2008, the Swiss Paraplegic Center conducted a chart review of patients with intrathecal drug systems from 1992 to 2003 [4]. They found the annual rate for complications requiring surgical measures was 10.5%, and of those 65% were catheter related and 35% were motor related. In 2010, Stetkarova et al. published a systematic review of procedure and device related complications of 1,362 ITB pumps, 27% were related to surgical procedures, 66% catheter malfunction, and 7% motor failure [6]. In 2021, the U.S. Food and Drug Administration (FDA) published a report regarding the effects of magnets in consumer electronics on implanted medical devices, recommending that such electronics be kept 6 inches or more from the medical device [7].

Diagnosing the exact cause of ITB system failure requires a systematic and methodical assessment to identify patterns suggestive of system failure or another explanation for the patient's symptoms. This begins with a clear understanding of the patient's medical history, disease progression, and presentation, and is followed by a systematic interrogation of the ITB system [5, 8, 9].

CASE PRESENTATION

The patient was a 37-year-old with a T9 sensorimotor complete (AIS A) spinal cord injury (SCI) (per the ASIA/ISCoS International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)) due to T10-L1 herniated discs and spinal compression requiring emergent T10-12 decompression via laminectomy in 2015. The patient's SCI resulted in significant lower limb spasticity that was uncontrolled with oral baclofen. One year post injury, the patient received a Medtronic (Minneapolis, MN, USA) Synchromed II Model (40 ml) ITB therapy system.

Over the next five years, the pump was refilled with intrathecal baclofen approximately every 10 weeks. Throughout the duration of his ITB therapy, the patient had one episode of a low reservoir alarm being set off when he exceeded the low reservoir date after missing a refill appointment, otherwise no other alarms or alerts were ever recorded since implant. Over the year prior to presentation, he had asked for higher doses to achieve the same therapeutic effect, with a Modified Ashworth Scale (MAS) score of the bilateral hamstrings of 1. Efficacy plateaued at a simple continuous rate of 940 mcg of baclofen per day.

The patient presented to the clinic for acutely worsening lower extremity spasticity that started the night prior and did not

[1]Department of Rehabilitation Medicine, University of Texas Health Science Center at San Antonio, San Antonio, TX, USA. [2]Audie L. Murphy Veteran's Administration Hospital, San Antonio, TX, USA. ✉email: mbrand.md@gmail.com

Received: 18 November 2022 Revised: 13 February 2023 Accepted: 23 February 2023
Published online: 06 March 2023

improve with clonazepam. He also endorsed itching around the T12 dermatome and poor sleep the past 12 h. He denied trauma, falls, recent MRI studies (last was 4 years prior) or being near security machines in the past 6 months, constipation, urinary retention, hematuria, lower extremity swelling, fever, or irritability. Vital signs were normal. On examination, he was noted to have a flushed face, bilateral hamstring MAS increased to 2, and continuous spontaneous spasms while lying in semi-fowlers position.

The ITB system was systematically evaluated per clinic protocol as follows: [1] pump interrogation revealed that no log alerts or alarms had been triggered [2]; aspiration of the reservoir volume was as anticipated when calculated from his previous refill date [3]; catheter access port aspiration demonstrated no resistance with ease of aspiration of catheter volume (0.25 ml) plus an additional cerebrospinal fluid volume for a total of 2.0 ml; followed by [4] motor roller study performed under fluoroscopy, which showed no movement of the motor rollers over a 5-minute period.

Given the motor failure with potential life-threatening symptoms of baclofen withdrawal, Neurosurgery was consulted for emergent pump replacement. Oral baclofen was given to prevent severe withdrawal symptoms until pump replacement was performed the following day. During the procedure, the catheter port was aspirated, and again a total of 2.0 ml was removed without resistance, confirming an intact and uncompromised catheter. The old pump was removed, and a new pump (Medtronic Synchromed II Model 8637-40) was connected to the original catheter, after which CSF was again aspirated from the catheter port without difficulty. One day post op, the patient reported complete resolution of his symptoms with spasticity back to his prior baseline.

Given the rarity and prematurity of pure motor failure and a desire to avoid recurrent motor stall in the new pump, the physician inquired to causes of pure motor stall. The patient was asked about pump exposure to electronic devices. The patient stated that when he initially became wheelchair bound six years ago, he began wearing a fanny pack around his waist to carry his smartphone and other personal items. He stated he wore the fanny pack for approximately 12 h during the day, with the iPhone approximately 2–3 inches away from the ITB pump. He purchased an iPhone 10 in November 2017, and later an iPhone 12 in October 2020, which he had for approximately 1 year prior to the motor stall.

The pump was sent to Medtronic for evaluation where the device was subjected to a series of standard tests that include visual inspection, alarm output, motor function, and dispense testing. Destructive analysis identified residue in the motor gear train and battery, as well as wearing on the upper shaft of gear number two [10].

DISCUSSION

The goal in presenting this case study was twofold: [1] review the systematic approach to identifying the cause of baclofen withdrawal for patients with implanted intrathecal drug infusion systems and [2] discuss how prolonged exposure of ITB pumps to magnets used in new smartphone models can lead to motor stall causing potentially life-threatening acute baclofen withdrawal.

Complications with intrathecal infusion therapies arise from human error, medication, or mechanical system failure [8]. Baclofen withdrawal symptoms include fever, nausea, dizziness, hyperthermia, itching, insomnia, altered mental status, hallucinations, seizures and/or worsened spasticity [11]. Once ITB withdrawal is diagnosed, the ITB system integrity should be evaluated.

Investigating the cause of ITB system failure begins with listening for alarms and interrogating the pump logs for motor stall/alerts. The non-critical alarm (single beep) repeats once every hour to indicate a low amount of medication in the pump, or if the pump needs to be replaced within 90 days indicating limited battery life. The critical alarm (two-tone beep) will sound when medication is no longer flowing due to an empty reservoir, blocked catheter, or stalled motor [1, 9]. For this patient, in 2019 he heard and responded to the non-critical alarm that the pump's medication reservoir was low, and a refill was required. In 2021, when he developed withdrawal due to motor stall, unexpectedly, no alarms were heard, and no alerts were noted during interrogation.

The next step of the investigation should focus on evaluating catheter integrity by comparing the calculated expected volume of medication in the reservoir to the actual volume removed [5, 8]. Catheter involvement is suspected if the medication reservoir is significantly different from the expected volume. Low reservoir volume indicates leakage due to a tear or displacement of the catheter, for which a patient may endorse spinal headaches and a fluid-filled mass along the catheter [8]. Unchanged or higher than expected reservoir volume may indicate occlusion or kinking, which results in an inability to aspirate 2–3 mL of CSF from the catheter port [8, 12, 13]. In this case study, the clinician determined that the volume of baclofen in the reservoir was equal to the amount expected based on the infusion rate and the time since the last refill. Further, 2.0 ml of fluid, which is greater than the volume of the 0.25 ml catheter, was aspirated without resistance both at the initial diagnosis and at the time of pump replacement, indicating no catheter dysfunction.

If the catheter is not the source of the changed baclofen infusion, then the pump motor requires assessment [14]. Pump malfunction is rare and has declined with continued improvement of pump technology. In most cases, pump malfunction is due to unexpected battery depletion, component or motor failure, or catheter access port failure [15]. Average life expectancy of battery for the SynchroMed II drug infusion system is 5–7 years and dependent on the complexity of the drug infusion algorithm (multiple drugs, dosages, and timing, versus a simple constant rate) [1, 8, 15]. The more complex the infusion algorithm, the more demand for power and thus a shorter battery life. For this case study, at the time of pump failure the battery was 5 years old and operating with a simple constant infusion rate with one medication the entire duration of pump life. Given this simple drug infusion algorithm and rate, intrinsic battery failure at 5-years was premature. Furthermore, the fact that the pump failed suddenly with no warning via pump alarm was unusual.

Motor failure, such as excessive wear on the motor gear shafts can occur if there is unusual or abnormal stress on the mechanism [15]. To evaluate the motor and rollers, serial x-rays or fluoroscopy is used to confirm that the rollers are moving at the expected rate or to see if they have come to a full stop [8]. Fluoroscopy of this patient's pump revealed that the motor rollers did not move over a 5-minute period, indicating failed motor rotation, thus requiring a new pump.

A case describing ITB motor stall due to gear assembly wear and corrosion was described by Riordan and Murphy in 2015, in which the patient experienced a total of 3 stalls over 3 days [16]. With each motor stall, the event was recorded, alarm sounded, and automatically restarted after 9 h, before failing completely on the third day. In their case, the battery was functional as an alarm sounded, the stall recorded, and the motor restarted. Destructive analysis of their pump indicated corrosion on the motor gear box as the cause of the motor stalls, similar to the destructive analysis of the pump in our case [10, 16]. Although, the patient's pump in our case did not record any alerts/alarms and given the state of his withdrawal symptoms the night before and day of presentation, the pump likely ceased operating 12–24 h before evaluation. The cause of battery failure in our case is unknown, however, given that intrinsic battery/alarm failure is so rare, we question whether the recurrent exposure to a strong external force of a magnetic field could have drained power from the battery.

The definitive cause of a pump's failure is typically performed by full destructive analysis of the pump by the manufacturer [9]. Prior to 2017, 59% of SynchroMed II infusion pumps returned to Medtronic for motor stall analysis were due to excessive gear shaft wear, 2% with corrosion of a drive gear, and 14% with internal power shorting; all product improvements based on these findings were implemented by August 2017 [17]. This patient's pump was placed in 2016, prior to these improvements. In this case study, analysis of this patient's explanted pump identified residue in the motor gear train, as well as wearing on gear shaft two [10]. These findings suggest that the reason for the motor/roller stall was due to gear shaft wear.

A full stall of the motor/rollers may be caused by the influence of a magnetic field greater than 20 Gauss such as an MRI, various commercial magnets (including cell phones) and being in proximity of high voltage regions, microwave, or radio towers [1]. When exposed to magnetic fields of at least 20 Gauss, the SynchroMed II pump can be temporarily stalled, alarm after detecting a stall, and automatically recover [9]. Various widely used consumer products contain strong permanent magnets, for example some cell phones, smart watches, magnetic name tags, and magnetic therapy bracelets. Consistent with recommendations from consumer product manufacturers and the FDA, Medtronic recommends that patients implanted with a SynchroMed II pump keep magnetic products a minimum of six inches away from the pump [7, 9]. Apple also includes such a warning on their website regarding iPhone generations 12 and older, as all have an array of magnets used to support wireless charging and peripherals known as "MagSafe" [18, 19]. In 2021, Seidman et al. measured the actual level of Gauss produced by the iPhone 12 [20]. For the iPhone 12 Pro Max, iPhone 12 Pro, iPhone 12, and iPhone 12 mini, at 1 mm the level of Gauss ranged from 190.07 G to 113.48 G; at 11 mm, 19.03 G to 16.18 G; at 21 mm, 8.76 G to 7.77 G; and at 31 mm, 4.17 G to 3.51 G. From these measurements, it was determined that keeping these devices at least 6 inches away from an implanted infusion pump will not cause a motor stall.

In this patient's case, he wore a fanny pack around his waist to hold his iPhone 12 directly over his SynchroMed II infusion pump for approximately twelve hours a day. Thus, it is very likely that the phone came within a quarter to half-inch away from the pump recurrently, exposing it to more than 20 Gauss of magnetism multiple times per day. Given these factors, we suspect that beginning in 2020 when the patient purchased his iPhone 12 with MagSafe, the proximity of the magnets was not enough to bring the pump to a full motor stall, but enough to 1) cause recurrent motor stall/recovery with a high frequency and/or 2) influence the pump's alarm and recording system —not unlike placing a simple magnet on a floppy disk. We hypothesize that the damage to the gear shaft and train that may have caused the motor to stall was further compounded by recurrent motor stall & recovery and/or an exhausted battery & a failed alarm/alert system likely caused by the close proximity of the iPhone 12. The degree that the motor stall was due to normal wear & tear versus recurrent motor stall/recovery & battery failure from the influence of the iPhone magnet is difficult to differentiate. Nonetheless, it is imperative that patients with ITB therapy and providers managing ITB are aware of the potential interference of such widely utilized personal technological devices with ITB drug delivery.

Smartphones are known to have magnets stronger than 20 Gauss, which exceeds the magnet strength within the ITB pump. If such devices are within 6 inches of an ITB pump, they can cause motor stall. While ITB pump motors are programmed to restart after magnet exposure, repeated exposure to these devices multiple times per day has the potential to lead to excessive wear on the pump motor. Eventually, recurrent motor stall from repeated device exposure may permanently damage the motor beyond its ability to recover. Motor failure causes acute baclofen withdrawal, which can be life-threatening. Before now, the impact of smartphones on ITB pump motors in persons with SCI has not been reported. It is imperative that providers managing patients with ITB therapy are aware of the ability of such commonly used devices to stall the pump motor. Awareness of this potential interference should be added to the education of risks of ITB therapy so life-threatening complications of ITB withdrawal can be avoided.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author, [MBT], upon reasonable request.

REFERENCES

1. Medtronic Pump Management—ITB Therapy. https://www.medtronic.com/us-en/patients/treatments-therapies/drug-pump-severe-spastici1qty/living-with-itb-therapy/pump-management.html.
2. Borrini L, Bensmail D, Thiebaut JB, Hugeron C, Rech C, Jourdan C. Occurrence of adverse events in long-term intrathecal baclofen infusion: a 1-year follow-up study of 158 adults. Arch Phys Med Rehabil. 2014;95:1032–8.
3. Taira T, Ueta T, Katayama Y, Kimizuka M, Nemoto A, Mizusawa H, et al. Rate of complications among the recipients of intrathecal baclofen pump in Japan: a multicenter study. Neuromodulation. 2013;16:266–72.
4. Fluckiger B, Knecht H, Grossmann S, Felleiter P. Device-related complications of long-term intrathecal drug therapy via implanted pumps. Spinal Cord. 2008;46:639–43.
5. Delhaas EM, Huygen F. Complications associated with intrathecal drug delivery systems. BJA Educ. 2020;20:51–7.
6. Stetkarova I, Yablon SA, Kofler M, Stokic DS. Procedure- and device-related complications of intrathecal baclofen administration for management of adult muscle hypertonia: a review. Neurorehabil Neural Repair. 2010;24:609–19.
7. FDA In Brief: FDA Continues to Monitor the Effects of Magnets in Consumer Electronics on Implanted Medical Devices. US. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-brief-fda-continues-monitor-effects-magnetsconsumer-electronics-implanted-medical-devices.
8. Jones RL, Rawlins PK. The diagnosis of intrathecal infusion pump system failure. Pain Physician. 2005;8:291–6.
9. Medtronic Inc. Intrathecal Baclofen Therapy Systems—SynchroMed II. Medtronic. www.medtronic.com/us-en/healthcare-professionals/products/neurological/intrathecal-baclofen-therapy-systems/synchromed-ii.html.
10. Medtronic. Neuroscience Customer quality—SynchroMed II SN: N644097001 motor stall analysis In: Michelle Trbovich M, editor. Medtronic; 2021.
11. Ross JC, Cook AM, Stewart GL, Fahy BG. Acute intrathecal baclofen withdrawal: a brief review of treatment options. Neurocrit Care. 2011;14:103–8.
12. Taha J, Favre J, Janszen M, Galarza M, Taha A. Correlation between withdrawal symptoms and medication pump residual volume in patients with implantable SynchroMed pumps. Neurosurgery. 2004;55:390–3. discussion 3-4
13. Rigoli G, Terrini G, Cordioli Z. Intrathecal baclofen withdrawal syndrome caused by low residual volume in the pump reservoir: a report of 2 cases. Arch Phys Med Rehabil. 2004;85:2064–6.
14. Francisco GE, Saulino MF, Yablon SA, Turner M. Intrathecal baclofen therapy: an update. PM R 2009;1:852–8.
15. Noon KP, Poree LR, Ike K, Jones RCW. Intrathecal Pump Malfunction: Flipped, Expired, Stalled, and Malfunctioned Valves and Rotors Leading to Under- and Over-Infusion. Challenging Cases and Complication Management in Pain Medicine: Cham: Springer; 2018. p. 7.
16. Riordan J, Murphy P. Intrathecal Pump: An Abrupt Intermittent Pump Failure. Neuromodulation. 2015;18:433–5.
17. Medtronic. Intrathecal Baclofen Therapy Systems—SynchroMed II: Design Changes. https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/intrathecal-baclofen-therapy-systems/synchromed-ii.html.
18. Apple. About potential magnetic interference with medical devices - Apple Support November 9, 2021. https://support.apple.com/en-us/HT211900.
19. Maring J Does iPhone 13 Have MagSafe? Here's What You Should Know. https://screenrant.com/iphone-13-magsafe-does-it-support-explained-apple/.
20. Seidman SJ, Guag J, Beard B, Arp Z. Static magnetic field measurements of smart phones and watches and applicability to triggering magnet modes in implantable pacemakers and implantable cardioverter-defibrillators. Heart Rhythm. 2021;18:1741–4.

ACKNOWLEDGEMENTS

This material is the result of work supported with resources and the use of facilities at the Audie L. Murphy Veteran's Affairs Hospital in San Antonio, Texas. We would like to thank Medtronic for their technical assistance, which contributed to the final

manuscript. We would also like to thank Dr. Cristian Gragnaniello and Dr. Daniel Smerin, who replaced the baclofen pump.

AUTHOR CONTRIBUTIONS

FEF was responsible for writing the case presentation and contributed to writing the abstract, introduction, and discussion. JGW was responsible for finding references and contributed to writing the introduction and discussion. MBT provided feedback on the manuscript, and contributed to writing the abstract, introduction, case presentation and discussion.

COMPETING INTERESTS

The authors declare no competing interests.

ETHICAL APPROVAL

Our local IRB considers this exempt human subject research. The patient provided informed written consent.

ADDITIONAL INFORMATION

Supplementary information The online version contains supplementary material available at https://doi.org/10.1038/s41394-023-00563-9.

Correspondence and requests for materials should be addressed to Michelle Trbovich.

Reprints and permission information is available at http://www.nature.com/reprints

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.