

INTRATHECAL CATHETER PUNCTURING FOLLOWED BY A POCKET FILL AFTER A PUMP REFILL: A CASE REPORT AND REVIEW OF THE LITERATURE

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Background: Refilling intrathecal drug delivery systems is a delicate procedure that can lead to serious complications. We report the first case of catheter damage during a refill.

Case Report: A patient implanted with a 20-mL reservoir pump for intrathecal baclofen infusion for severe spasticity-complained of spasticity increase after a complex refill. Despite increasing the drug dosage, the patient's symptoms did not improve, and, after another refill, he was hospitalized for deep sedation and unresponsiveness. Surgical revision demonstrated a catheter lesion close to the connection with the pump reservoir. We hypothesize that the catheter had been lesioned during the first refill and, after the last refill, a pocket fill occurred with a significant dose of baclofen reaching the intrathecal space.

Conclusion: Ultrasound or fluoroscopic guidance should be used when performing challenging pump refills to avoid potentially catastrophic adverse events such as catheter lesions or pocket fills.

Key words: Baclofen, case report, catheter, intrathecal therapy, pocket fill, spasticity

BACKGROUND

Intrathecal drug delivery systems (ITDDS) are a common intervention to manage chronic pain or spasticity (1). A reservoir is implanted in the subcutaneous tissue of the lower abdomen, and it is connected to a tunneled catheter reaching the intrathecal space. Baclofen, morphine, hydromorphone, clonidine, and ziconotide are the most frequently used drugs.

The reservoir must be emptied and refilled regularly. Usually, no guidance is needed for this procedure; the needle is placed in the reservoir through the silicone membrane of the refill port (RFP, located in the middle of the reservoir). Refilling the reservoir can be a tricky maneuver due to the patient's excess subcutaneous fat, spasticity, suboptimal positioning, pump rotation or inversion, and scar formation over the RFP.

In most pump models, the pressure inside the reservoir creates a typical sensation of the syringe piston being pushed away, which confirms the correct needle positioning for the clinician. Multiple attempts at refilling can result in infections or catheter lesion. Failing to fill the reservoir and injecting the drug in the surgical pocket (pocket fill) can result in loss of medication delivery to the intrathecal space, resulting in either a withdrawal syndrome or, in the case of sudden subcutaneous reabsorption, in an overdose (2-6). No reports of catheter lesioning during a refill have been published. We report a refill complication with both a catheter lesioning and a pocket fill.

The patient gave his written consent to use his personal data for scientific purposes.

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CASE PRESENTATION

We report the case of a 58-year-old patient who was implanted with a programmable pump (Prometra 2, 20 mL reservoir, Flowonix, Budd Lake, NJ) for intrathecal baclofen infusion. Baclofen infusion was set at 100 mcg/day. The pump was implanted subcutaneously in the left inferior abdominal quadrant in 2019. After 15 months of normal functioning and regular refills every 4 months, the patient reported an increase in spasticity in his lower limbs. Dosage was increased up to 250 mcg/day without beneficial effects.

A new refill was performed, which was reported as difficult due to the fatty tissue surrounding the pump reservoir; thus multiple attempts were required. As the spasticity symptoms were not improving after one month, a new refill was attempted, and it was reported as difficult; active aspiration was required to empty the reservoir (instead of having the syringe piston pushed by the reservoir pressure).

Three hours after the refill, the patient was at home and the caregiver contacted our center reporting deep sedation and unresponsiveness of the patient. The patient was urgently admitted in hospital with a Glasgow Coma Scale 1(E) 5(M) 2(V), bradypnea, blood pressure 90/40 mmHg and oxygen saturation 90%; the brain computed tomography scan was negative. The patient was admitted and monitored in the intensive care unit; only intravenous crystalloids and nasal oxygen were needed, and no ventilatory or hemodynamic supports were required. Progressively the patient gained full consciousness without any neurological deficit, the pump reservoir was evacuated, and he was discharged with prescription of surgical revision of the pump pocket.

We hypothesized a motor malfunctioning of the pump, which would have altered the drug flow causing a sudden bolus of baclofen and resulting in an overdose. However, pump interrogation reported no error messages or malfunctioning warnings. The abdominal x-ray did not suggest catheter kinking or reservoir displacement. The surgical revision was performed, and after the skin incision the reservoir pocket was fluid-filled; no signs of infection or bleeding were detected. During the surgical revision the reservoir was removed and analyzed. The refill port was intact and an attempt to refill the reservoir was performed without any problem. The catheter was visually analyzed and, close to the connection with the reservoir, a longitudinal 2-cm-long lesion was found in the catheter (Fig.1 and Fig. 2). The distal damaged part of the catheter was cut and a new

connection with a new reservoir was made. Baclofen infusion was resumed at 100 mcg/day, and after 2 days the patient started to report improved spasticity and reduced pain in his lower limbs. Subsequent refills were done with ultrasound guidance without issues.

DISCUSSION

The intrathecal drug delivery system catheter was inadvertently damaged after a complex refill performed under blind guidance. We hypothesize that after the catheter damage, baclofen flow was obviously reduced, therefore worsening the patient's spasticity.

Intrathecal drug delivery systems can present technical malfunctioning that results in drug over- or underdosage. Catheter kinking or even breakage have been reported as well. Catheter-related complications are far more frequent than pump-related adverse events (7). Haranhalli et al (8) reported an erosion of the suture at the catheter–pump connection site through the catheter. However, we found no reports of catheter damage after pump refills in our literature search. Pocket fill results in both a failure to deliver medications to the intrathecal space and a high amount of drug being reabsorbed through the subcutaneous tissue.

The exact incidence of pocket filling is unknown; however, Abd-Elsayed (4) reported 26 cases in 77,584 refills examined. Maino et al (5) reported symptoms of overdosing after a refill in 6 out of 221 refills; they related these events to partial pocket fills. From May 1996 through September 2010, 8 deaths and 270 events requiring medical intervention (serious or life-threatening injury) have been reported related to the occurrence of pocket fills (9).

Overdosing after pocket fills has been reported with hydromorphone and clonidine (2,3). Since the highest baclofen concentration for intrathecal treatment is 2000 mcg/mL, for a 20-mL reservoir the maximum amount of baclofen that could be systemically reabsorbed is 40 mg, an amount that, if administered subcutaneously or even intravenously, is unlikely to cause overdosing; therefore pocket fills with baclofen usually result in withdrawal syndrome. In a case report of 2 patients with baclofen overdosing syndrome after a pocket fill, the authors suggested that the pocket fills presumably tracked along the catheters and into the intrathecal space, delivering a large bolus of baclofen, causing overdoses (10). We hypothesize that in our patient a small but significant dose of baclofen entered the catheter through the tear and reached the intrathecal space, causing an overdose.

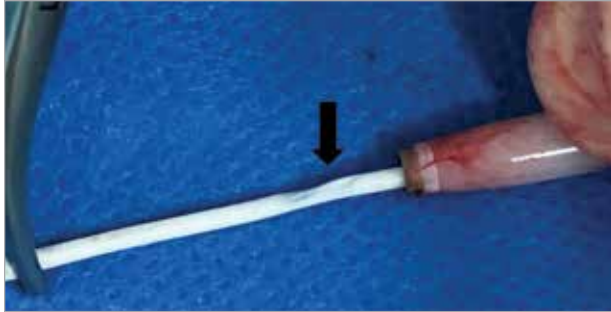


Fig. 1. Catheter tear (black arrow) at the connection between the catheter and the reservoir.

Ultrasound guidance has been proposed in order to reduce refill-related complications and improve patient comfort (11,12).

CONCLUSION

We report 2 complications of ITDDS associated with refills: lesion of the catheter and pocket fill. The pocket fill has been described by several authors and it represents an underestimated and potentially serious complication. Pocket fills with baclofen usually result in withdrawal symptoms, but overdosing cannot be ruled out. Catheter damage after refills has not been described before, but, as our case suggests, unexplained changes in symptoms after a refill should be promptly investigated and, after ruling out pump failures and pocket fills, a surgical revision to exclude catheter tearing should be planned. We advocate for a more extended use of ultrasound guidance to perform complex refills to improve patient safety.

Author Contributions

A.T, Wrote and reviewed the draft, edited images and collected patient's documents.

C.S. Edited and reviewed the draft, collected references.

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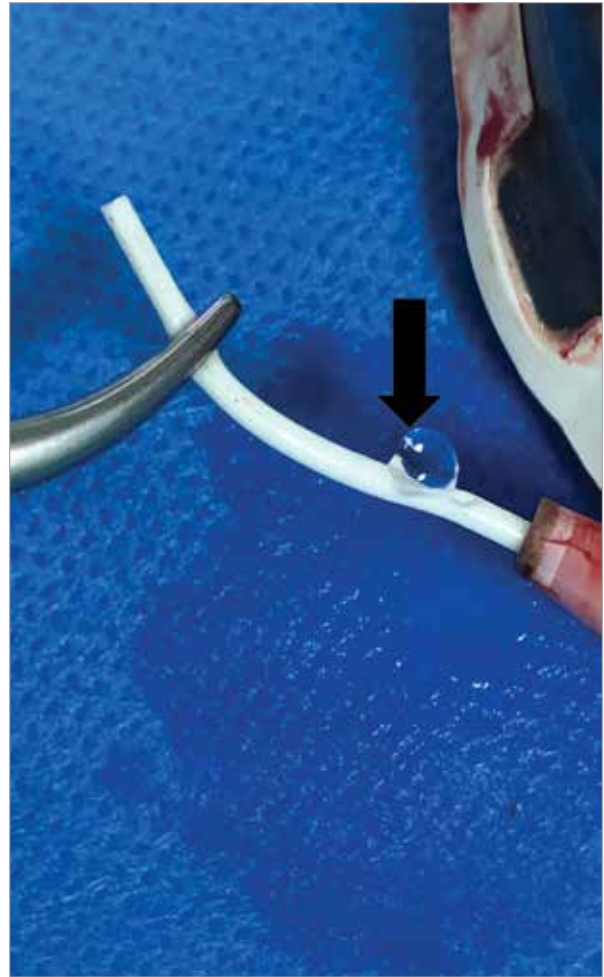


Fig. 2. Catheter tear (black arrow) with fluid spilling out after injection into the bolus port.

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