

Elastomeric pump malfunction resulting in over-infusion of local anesthetic

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Abstract

A 70-year-old female patient presented for a right humeral head replacement. Preoperatively an interscalene catheter was placed and postoperatively connected to an elastomeric pump for continuous infusion at 8 mL/h of Ropivacaine 0.2% with an additional 5 mL patient activated bolus available every 30 min. About 17 h after the elastomeric pump was connected to the catheter, the 550 mL reservoir was found to be empty, indicating the pump's infusion rate was more than 32 mL/h despite the pump still being set at an infusion rate of 8 mL/h with a possible 5 mL bolus every 30 min. There was no visible damage or leak in the pump system, and the insertion site was dry. The patient denied any changes to the pump settings. She was alert and oriented and denied any signs of local anesthetic toxicity. The catheter was immediately pulled and the manufacturer notified. The manufacturer found a red tab broken inside the patient-controlled bolus remote resulting in the over-infusion. Despite the dependability of elastomeric pumps, healthcare providers must be aware of their possible complications and malfunctions.

Keywords

Elastomeric pump, interscalene catheter, pump malfunction

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Introduction

Continuous interscalene perineural infusions have been shown to provide excellent postoperative analgesia in patients undergoing shoulder surgery.^{1,2} A variety of infusion pumps, including elastomeric pumps, can be connected to perineural catheters and deliver a steady flow of local anesthetics to the targeted nerve structures. Perineural infusions have been shown to offer longer time to first pain and longer sleep time. Patients also experience less pain 1 week postoperatively and are able to be discharged home sooner when compared to general anesthesia alone. All of these benefits of perineural catheters can significantly reduce healthcare costs.^{1,3}

Elastomeric pumps are particularly popular due to their ability to be refilled, low cost, portability, independence from a power supply, disposability, as well as high patient satisfaction.^{3–5} However, it has been suggested that these pumps may deliver inconsistent volume which could lead to inadequate analgesia or unintended side effects.^{6,7} Such disadvantages can be caused by a multitude of factors such as temperature changes, viscosity of infused fluid, and even the

height of the elastomeric pump relative to the catheter site.^{8,9} Iliev et al.⁶ found that the On-Q pump (I-Flow Corporation, Halyard Health, Irvine, CA, USA) delivered 22%–65% higher volume than the set rate during the initial 8 h of the infusion, followed by volume infusion within 20% of the intended delivery rate thereafter. According to another study, the ACTION pump (Ambu USA, Columbia, MD, USA) was the only studied pump that tested within the acceptable flow rate ranges.⁷ Significant inaccuracies of elastomeric pumps resulting in total reservoir infusion in the first 24 h is extremely rare, and to our knowledge, only one reported case exists in the literature.¹⁰ We present a case of an On-Q Pump (I-Flow Corporation, Halyard Health, Irvine, CA, USA) malfunction resulting in complete administration of the 550 mL local anesthetic reservoir within 17 h.

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Figure 1. The red priming tab remaining inside the patient-controlled bolus remote keyhole.

Case

A 70-year-old female patient presented to our institution for a right humeral head replacement. Preoperatively, at 1445, with the patient in a semi-sitting position, a right interscalene catheter was placed as described by Antonakakis et al.¹¹ under ultrasound guidance. Incremental injections of 30 mL Ropivacaine 0.5% allowed visualization of the catheter at the appropriate location near the brachial plexus. The skin at the site of catheter insertion was sealed with DermaBond (Ethicon, Somerville, NJ, USA), and the catheter was secured with a Tegaderm (3M Company, St. Paul, MN, USA). The exposed end of the catheter was capped during the patient's surgery. The patient's surgical procedure was performed uneventfully with general anesthesia in the beach chair position. Postoperatively, at 1615, the catheter was connected to a primed On-Q Pump programmed to deliver 8 mL/h of Ropivacaine 0.2% with an additional 5 mL patient-activated bolus available every 30 min. Once the catheter and pump were securely connected, the pump's continuous line was unclamped. After achieving adequate postoperative anesthesia care unit (PACU) discharge criteria, the patient was transferred from the PACU to an inpatient room.

The following morning at 0930, the elastomeric pump's 550 mL reservoir was found to be empty, after approximately 17h, indicating the pump's infusion rate was more than 32 mL/h. There were no visible leaks in the pump system or moisture around the insertion site. The patient and her nurse denied any leakage or changes to the settings during the

night. She was alert and oriented, denied dizziness, lightheadedness, metallic taste, or other signs of local anesthetic toxicity. There were no arrhythmias noted on telemetry. The catheter was immediately removed without any damage noted to the catheter or the metallic tip. On further inspection of the pump, the rate was still set to 8 mL/h and the patient-activated bolus every 30 min at 5 mL as originally programmed. The manufacturer was notified and the pump delivered to them.

Discussion

Elastomeric pumps are composed of a distensible bulb inside of a protective bulb with a built-in filling port, delivery tubing, and a bacterial filter. When the pump is filled, it expands and generates potential energy from the strain of the elastomeric membranes. This potential energy then drives the pressure to infuse the fluid. Flow is controlled with flow restrictor tubing of a fixed diameter and length. Elastomeric pumps may have a variety of delivery options: a fixed flow rate that cannot be altered; a basal infusion with on-demand boluses; or an adjustable flow rate controller and bolus device.⁴ The pump in this case had an adjustable flow rate controller and bolus device.

Elastomeric pumps have gained wide acceptance because of their simple design and ease of use. A study by Weisman et al. evaluated five different elastomeric pumps for flow rate accuracy, consistency, and effect of positioning on output while controlling for temperature. It was found that five commonly available pumps were reliably accurate if utilized within the manufacturers' recommendations. However, there are various important factors that must be taken into account as it relates to pump output, such as height and temperature.⁷ Despite being at room temperature and near level with the patient's catheter insertion site, an over-infusion occurred with the presented pump.

In our case specifically, we utilized the I-flow On-Q PainBuster (I-Flow Corporation, Halyard Health, Irvine, CA, USA) postoperative pain relief pump system. We reviewed this specific device's manufacturer's adverse event reports for incidents of "fast flow," which demonstrated that in previous instances, the malfunction rested within the bolus remote itself. The On-Q pain relief system technical bulletin from Halyard Health states the volume of fluid in the pump, fluid temperature, and the relative height of the pump compared to the catheter site can affect flow rate accuracy, similar to what was described by Weisman et al.⁷

After eliminating obvious reasons for over-infusion such as patient or staff tampering, an investigation of the physical device took place. On inspection of the device, a remnant of the red priming tab remained inside its keyhole located in the side of the patient-controlled bolus remote (Figure 1). The red tab allows for continuous flow and tube priming during pump setup. After priming, the red tab should be pulled straight out while avoiding twisting or pulling in another

direction in order to avoid breaking it off in the keyhole. The manufacturer's instruction guide specifically states, "If red tab is not removed or breaks while removing, continuous delivery will occur." Possibly in the setup of the device, the red tab was incorrectly pulled upward while being removed. As a result, a small portion of the broken key remained inside the keyhole, permitting the continuous total flow of both the bolus and basal rate being infused into the patient. Fortunately, despite the resultant high flow rate, no harm befell the patient and appropriate steps were taken to rectify the situation. An incident report was created and the pump, along with the bolus device, was sent to Halyard who confirmed the red tab has broken during its removal.

Conclusion

Overall, elastomeric pumps have been shown to be reliable and consistent if operated within manufacturer recommendations and the appropriate steps followed.⁷ In one study, Remerand et al.⁹ suggest that nursing staff should weigh pumps before connecting the catheter and during the first hours of infusion to verify that their weights are decreasing and local anesthetic is being infused appropriately. In any incident involving malfunction of an elastomeric pump, cooperation between the primary regional anesthetic team, pharmacy, and manufacturer is of the utmost importance in maintaining safe and secure practices for continuous regional anesthesia.

At our institution, the pharmacy fills and primes these pumps with local anesthetics. Despite best practice instructions from the manufacturer, our department was unaware of this potential complication and have since learned how to prevent such an over-infusion. We are looking into the implementation of further safety mechanisms given the number of hands the pumps touch prior to being attached to the patient. Currently, we have developed a double check to ensure the key is undamaged and has been completely removed according to the manufacturer's instructions. This report underscores the importance of adequately training individuals involved in the preparation, placement, and follow up of elastomeric pumps, as well as strictly following manufacturer recommendations and checking for potential malfunctions, such as a broken and retained priming key.

Declaration of conflicting interests

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Ethical approval

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Informed consent

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