

“Does the size matter?” – A small manufacturing defect causing big problems in an epidural minipack

Dear Editor,

As a part of the manufacturing process, medical equipment passes through various quality assurance tests. Still, manufacturing defects are common in various medical equipment.^[1,2] Epidural minipacks used for providing epidural anesthesia are no different in this context.^[3,4] Here, we share an observation of a small manufacturing defect in an epidural catheter adapter, causing major difficulty in establishing the epidural catheter.

Epidural analgesia was planned in a 45-year-old patient undergoing radical cystectomy. A Medikit Epidural Minipack was used (Lot 22E1053; Global Medikit Limited, Dehradun, India). An 18-gauge epidural needle was inserted at T10–T11 intervertebral space via midline approach. After confirming the epidural space via the loss of resistance technique, we connected the epidural catheter adapter to the hub of Touhy needle and attempted to thread a 20-gauge epidural catheter

via it. Upon advancing the initial 12 cm of the catheter via the adapter (catheter reaching the Huber tip), some resistance was felt. It was observed that the catheter adapter was too wide to hold the catheter in place [Figure 1]. This led to curling of the catheter within the adapter [Figure 2]. This further led to easy kinking of the catheter just outside the adapter. Upon this observation, the catheter adapter was exchanged for a new catheter adapter available (Mercury+™ Epidural Kit, Lot EK2022-09; St. Stone Medical Devices Private Limited, Manipur, India). This adapter had a narrow lumen to direct the epidural catheter into the Touhy needle. The same epidural catheter was threaded easily via this adapter. The case proceeded uneventfully.

The observation can be explained by the near-axial forces acting in the cylinder of the Touhy needle by the epidural catheter. As the adapter becomes wide, the angle of force transmitted by the pushing action of the catheter in the adapter deviates from the near-axial direction. This leads to the reactionary forces against the resistance of the path to become unbalanced, leading to curling of the catheter within the adapter. The same is avoided in the narrow adapter as the forces are transmitted linearly in near-axial direction, resulting in balanced reactionary forces and easy threading of the epidural catheter clinically.^[5]

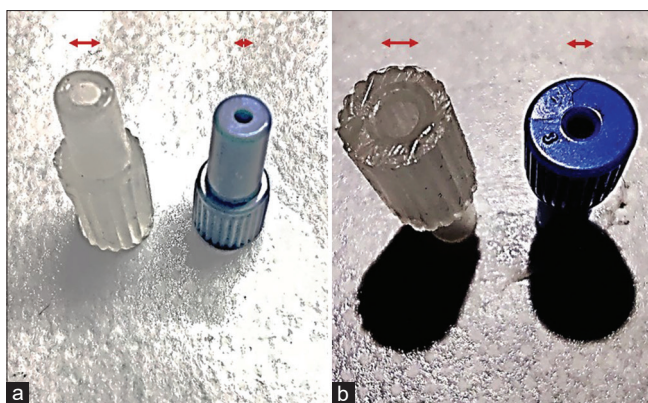


Figure 1: Width differences between the lumens of the two catheter adapters: (a) hub end of the adapters, (b) free end of the adapters (double-headed arrows depicting the width of adapter openings) (white adapter – Medikit Epidural Minipack, Global Medikit Limited; blue adapter – Mercury+™ Epidural Kit, St. Stone Medical Devices Private Limited)

This shows that even a defective small component like a catheter adapter can cause big problems during establishment of an epidural catheter. If a similar problem would have occurred during a combined spinal epidural application, the difficulty and delay in catheter insertion would have led to an undesirable saddle block. Therefore, the importance of careful manufacturing of even the smallest components of procedural kits cannot be undermined.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Sonali Turki, Abhishek Arya¹, Kamal Kajal, Sanjay Kumar

Department of Anaesthesia and Intensive Care, Post Graduate Institute of Medical Education and Research, Chandigarh,

¹Department of Anaesthesiology, Pain Medicine and Critical Care, All India Institute of Medical Sciences, New Delhi, India

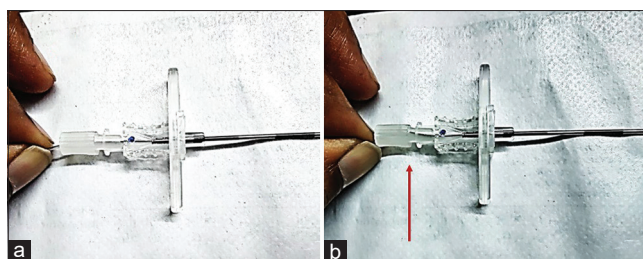


Figure 2: (a) Epidural catheter seen in the lumen of the wide adapter before threading distal to the Huber tip; (b) epidural catheter seen curling within the wide adapter (single-headed arrow) upon attempting to negotiate it through the Huber tip

Address for correspondence: Dr. Abhishek Arya, Senior Resident, Department of Anaesthesiology, Pain Medicine and Critical Care, All India Institute of Medical Sciences, New Delhi - 110 029, India.
E-mail: arya.abhishek95@gmail.com

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Quick Response Code:	Website: https://journals.lww.com/joacp
	DOI: 10.4103/joacp.joacp_249_22

How to cite this article: Turki S, Arya A, Kajal K, Kumar S. "Does the size matter?" – A small manufacturing defect causing big problems in an epidural minipack. *J Anaesthesiol Clin Pharmacol* 2023;39:680-1.

Submitted: 15-Jul-2022 **Accepted:** 06-Aug-2022 **Published:** 24-Nov-2022
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