

Epidural Conduction Device Fractures and Complications of Retained Fragments

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During the past 3 years, the US Food and Drug Administration (FDA) has received a growing number of adverse event reports on the breakage or fracturing and retention of anesthetic conduction device tips with associated complications. Serious injuries and other problems such as spinal stenosis, nerve root compression, and subcutaneous effusion can result.

Several case reports demonstrate how the problems occur; some illustrate the severity of the problem. All cases are from adverse event reports in the FDA Center for Devices and Radiological Health (CDRH) Manufacturer and User Facility Device Experience database.

Frequently, in the interest of not causing patient harm, a device fragment might not be removed as long

as the patient is not neurologically compromised or at risk for infection or there is little potential for migration of the fragmented piece. On many occasions, the fragments remain in patients without their knowledge. The FDA wants to raise awareness of the problem and its potential impact in creating complications, encourage the practice of informing patients of the fragmented device, and promote reporting of such incidents to CDRH via the MedWatch reporting system. Based on a search of the current literature, recommendations for prevention are suggested.

Key words: Anesthesia, epidural catheter, fragment, retained, retention.

The Department of Health and Human Services, US Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) monitors adverse event reports submitted by manufacturers, importers, user facilities, and voluntary reporters. CDRH is concerned about deaths and serious injuries reported in adverse events related to the fracture of anesthetic conduction needles and catheters. Fractures seem to occur most frequently during insertion or withdrawal of the devices from patients during epidural procedures. Fractured tips from these devices can remain in patients and have the potential to cause serious complications. Complications may arise from fragment placement or migration, an inflammatory response, or damage caused by imaging in the area of the retained fragment. This article is intended to inform nurse anesthetists of the problem as understood from actual case reports, describe potential impacts of unretrieved device fragments, and educate providers on how to prevent problems and identify strategies that will help to prevent the occurrence of fragments. In addition, the need to inform patients from whom a device fragment has not been retrieved is highlighted as an important part of a prevention strategy, helping the patients to receive the best possible future healthcare.¹⁻³

Manufacturers, importers, and user facilities are required by federal law to report adverse events as they become aware of them, with submission of reports of device-related deaths, serious injuries, and malfunctions within 30 days.⁴ Adverse events may also be reported voluntarily by user facilities, distributors, and individuals. The FDA is aware that adverse events are often underre-

ported and that when they are reported, the information provided may not be complete or sufficient to determine causality and contributing factors.^{5,6} Although the majority of reports are submitted through manufacturers, healthcare providers are valuable reporters of these events. Healthcare providers treating the affected patients can provide the most accurate history of a patient injury and have access to product information that is not always available to other reporters. The following cases are actual examples of adverse event reports submitted by practitioners between January 1, 2001, and December 31, 2006, to the CDRH Manufacturer and User Facility Device Experience database.

Case Summaries and Analysis

• **Case 1.** An epidurolysis procedure was performed on a patient for postlaminectomy syndrome with radiculopathy. The catheter could not be pulled back after performing adhesiolysis. The healthcare practitioner attempted to confirm that the catheter was in good position. The concern was that the catheter was catching on the needle and that the needle would shear the catheter into 2 pieces. The practitioner removed the needle and completed the procedure without incident.

After the procedure, the catheter could not easily be pulled out. The patient was taken back to the procedure room and the catheter examined under fluoroscopy. There were no knots, kinks, or obvious reasons for obstruction. A neurosurgeon was consulted. The practitioner and neurosurgeon agreed to pull on the catheter sharply to withdraw it, which resulted in the catheter breaking and leaving the remaining catheter extending

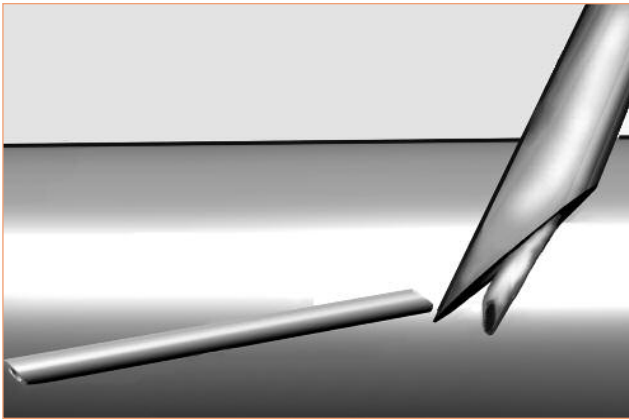


Figure 1. Slicing of an Epidural Catheter From Introducer Needle Bevel
(Original drawing by author.)

from the sacral cornu to just above the L5-S1 disk space. The decision was made to not retrieve the catheter. Antibiotic therapy was started, and follow-up was planned for the patient.

- **Analysis.** The catheter could not be pulled back after performing adhesiolysis, even after confirming that the catheter was in good position. The practitioner was concerned that the catheter was catching on the needle and that the needle would shear in 2 pieces. Under fluoroscopy, it was determined that the only choice was to pull the catheter straight out. The sharp pull on the catheter resulted in the catheter slicing in 2 pieces.

- **Case 2.** A patient was undergoing a caudal epidural steroid injection using an epidurolysis catheter. While the catheter was being advanced into position, there was resistance that was not relieved by repositioning the patient. The practitioner attempted to remove the catheter, but the plastic sheath sheared away from the metal part of the catheter and was retained in the spine. There were no plans to remove the fragment.

- **Analysis.** In this case, there seemed to be resistance when advancing the catheter. Resistance can be caused by technique, position, or anatomical obstacles that cause the catheter to be entangled in some way. Repositioning the patient did not relieve the resistance. The practitioner pulled on the catheter, and it broke. Undue pulling forces during removal can tear or snap an entangled catheter trapped against an obstacle.

- **Case 3.** The practitioner was completing an epidural pain management procedure. On catheter removal, he felt resistance, and a snap was heard. When the practitioner removed the catheter, he found the distal end to be sheared off and broken. After the Tuohy needle was withdrawn, the catheter tip was not found protruding from the site. A radiograph confirmed approximately 3 to 4 inches of tip remaining in the epidural space. The practitioner elected to leave the tip in place. The patient remained in stable condition and was discharged to home.

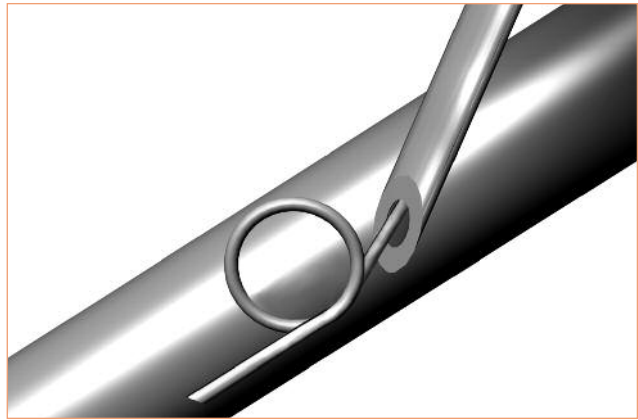


Figure 2. Looping of an Epidural Catheter
(Original drawing by author.)

- **Analysis.** In this case, the catheter was sheared or sliced in 2 pieces by a Tuohy needle. Radiographs confirmed that a segment remained in the patient. Radiographic imaging is not always possible because some catheters are not radiopaque.

As shown in these scenarios, catheter manipulation can result in fragmentation. Epidural catheter fragmentation can occur from shearing and tearing; increased insertion and/or withdrawal forces; looping, knotting and kinking; and decreasing catheter tensile strength from manipulation with devices.

Contributing Factors Further Explained

- **Shearing (slicing) or Tearing (ripping).** Shearing can be caused by withdrawing a catheter through a needle introducer, slicing the catheter in 2 pieces (Figure 1). The catheter may also tear as it catches the barbs of an unsharpened needle.

There are a number of explanations why a catheter may shear or tear. These include the application of undue force while removing a catheter, shearing of the catheter by the needle when attempts are made to withdraw the catheter through the introducer needle, nicking of the catheter by an imperfection on the bevel of the needle, shredding of the catheter when the needle is advanced over a previously placed catheter, weakness of the catheter produced by imperfections in manufacturing, and damage to a catheter occurring after placement.

- **Insertion and/or Withdrawal Forces.** Patient position can be a factor leading to increased force required to insert or remove an epidural catheter.^{7,8} The sitting position places more forces on the spine, creating increasing resistance on withdrawal.⁹ The force required to remove a lumbar catheter is 2.5 times more in the sitting position than in the lateral decubitus position.¹⁰ Morris et al⁸ suggested that the position used for insertion should be the position used for withdrawal.

Manufacturers provide precautionary warnings on their labels, including a warning that excessive or undue

withdrawal force should not be used. The maximal withdrawal force, in newton, is generally not listed in terms of exerted pressure or technique on manufacturer labeling. These pressures can be measured clinically by using a portable force gauge. Clinically, the average normal force required to remove an epidural catheter is 2.04 N (1 N is ~ 0.225 lb of force).¹⁰

- *Looping, Knotting, and Kinking.* A rare cause of a trapped epidural catheter is a looped or knotted catheter (Figure 2). An epidural catheter may be deflected by anatomical obstacles and can curl back on itself. A catheter can become entangled with nerve roots, blood vessels, lumbar fascia, posterior vertebral arches, vertebral processes, and facet joints.¹¹ Excessive catheter threading may increase the likelihood of entanglement. Kinking of an epidural catheter may occur at any point between the skin and the epidural space.¹²

- *Decreased Tensile Strength.* Nishio et al⁹ concluded that removal of epidural catheters with stainless steel hemostats decreased the tensile strength of the catheters, making them more vulnerable to breakage. The authors speculated that gripping with stainless steel hemostats caused microdamage to the catheter, resulting in decreasing tensile strength. It was also concluded that rubber-sleeved hemostats slightly increased tensile strength.⁹

What Are the Concerns and Impact of Retained Catheter Fragments?

In the vast majority of cases, epidural procedures are accomplished without incident. Occasionally, a fractured piece of a device remains in the patient and, for the most part, is a benign issue.

Should a device fracture, several issues should be considered. Is there a possibility of migration to areas of the body in which a fractured tip may cause problems? Will the fragment interfere with radiographic procedures or magnetic resonance imaging? Is the retained device biocompatible for an extended period?

There may be medical reasons to leave a fractured device in place. If an epidural catheter breaks during removal, surgery is frequently unnecessary because the catheter is inert and complications are rare.² When complications from retained epidural device parts occur, surgical intervention may be indicated.^{2,9,13,14} When attempting to remove a catheter in the intrathecal space under normal circumstances, Vallejo et al¹⁴ suggest that catheter removal should be abandoned if pain or paresthesia develops, and neurosurgical consultation with radiographic evaluation should be obtained. Radiographic evaluation, including a computed tomography scan and/or magnetic resonance imaging with injection of radiopaque dye, may prove useful in determining the location of the entrapped fragment.^{13,14}

Informing a patient of an unretrieved medical device fragment is an important ethical and quality of care issue.

Patients might not always be informed of the decision to leave the fragment in unless symptoms or sequelae occur. From a patient viewpoint, this omission of information may impinge on their right to be medically informed. To properly manage future treatment decisions and care, patients need to know about retained fragments and the potential for retention-related harm.

Strategies to Avoid Fragmentation

When the catheter cannot be removed using minimal traction, a number of maneuvers may facilitate removal. These maneuvers can include the following approaches:

1. Reposition the patient in a position that will cause the least spinal pressure for insertion and withdrawal. It has been suggested that this be the lateral decubitus position because it does not place the type of forces on the spine as does the sitting position.^{9,10}

2. An injection of sterile saline may help determine if the catheter is kinked or entangled. Gentle but firm traction can tighten a knot, thus decreasing its size and facilitating removal.¹⁵

3. Metal forceps and hemostats should be avoided to decrease the likelihood of the device breaking and a fragment not being retrieved.⁹

4. Waiting a few days to let back muscles relax may help in catheter removal. On rare occasions, if removal is still difficult with local anesthesia and intravenous sedation, Jongleux et al¹³ cautiously suggested general anesthesia with muscle relaxants as an alternative measure.³

5. When attempting to remove a catheter in the intrathecal space under normal circumstances, and pain or paresthesia develops, Vallejo et al¹⁴ suggest that catheter removal should be abandoned and neurosurgical consultation with radiographic evaluation be obtained. Radiographic evaluation may prove useful in determining retention location.¹⁴

Surgical removal may be reserved for patients who are symptomatic.^{2,13,14}

Conclusion

The purpose of this article is to raise awareness of the problem of retained epidural catheter fragments and identify the potential impact of complications. It also informs nurse anesthetists how to prevent potential problems through good practices, encourages the practice of recording catheter retention in medical records and informing patients of retained devices, and promotes the reporting of such incidents to CDRH via the MedWatch reporting system.

Confidential voluntary reporting of adverse events involving epidural devices or other medical devices can be accomplished through the FDA website: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>. As previously stated, adverse events are often underreported to the FDA, with incomplete reports and lack

of reporting contributing to incomplete knowledge of these events and their severity.

Healthcare providers and institutions can help to shed more light on the problem of retained device fragments by reporting events and providing sufficient information for the agency to assess the cause of the problem, whether related to manufacturing, human factors, and/or patient factors. The FDA will continue to monitor reports of retained fractured epidural devices. In the interim, it is important for practitioners and institutional risk managers to become aware of procedures to avoid the problem, report problems when they occur, and provide complete and accurate information in reports to the CDRH.

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