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Fact Finders for Patient Safety

OXFORD

CLINICAL PERSPECTIVES

Vial Coring

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Myth: When drawing up medication through a rubber vial top or glass ampule, coring or aspiration of unintended particles rarely occurs and cannot be prevented.

Fact: Evidence demonstrates that when drawing up medication through a rubber vial top or from a glass ampule, coring or aspiration of unintended particles happens frequently. Though the clinical risk of this event is unclear, multiple safeguards can be implemented.

The majority of, if not all, spinal injection procedures involve the insertion of a needle into a medication vial to administer injectate to a patient. Therefore, the risks of injecting "cored" particles or glass fragments must be considered when drawing up medications through a rubber vial top or from a glass ampule. This concern is further amplified given that these injections are performed in close proximity to vascular structures and in intra-articular spaces.

"Coring" of the Rubber Stopper

The process of inserting a needle through a rubber stopper to draw medication is a necessary step in most spine procedures. Analyses of this process have demonstrated that particles can be sheared off the stopper and appear in the syringe when inserting a needle through a rubber vial top to withdraw medication. A detection rate of up to 97% has been reported using microscopy for detection of particles in insulin vials, and 3% has been reported relying on naked eye detection. Theoretically, these particles can then be injected, inadvertently, into the patient.

The size of cored particles has also been investigated. A particle larger than 6–8 μm injected in a vessel would remain in the pulmonary capillary circulation. Red blood cells (RBCs) have an estimated diameter of 10 μm. Therefore, those particles smaller than an RBC are felt to be less likely to obstruct a vessel. Cored particle size can vary greatly, from as small as <70 μm to $>1{,}000$ μm. Potential consequences of injected particles could range from embolization to infarction to phlebitis if injected into a vessel.

Although the aforementioned theoretical risks are possibilities, no complication has been reported in relation to interventional spine procedures. However, implementing measures to reduce coring and prevent the transmission of cored particles to patients may be prudent.

Glass Ampules

Glass ampules remain an option for manufacturing small doses of single-use medications. However, the possibility of inadvertent aspiration of glass particles when withdrawing medications from glass ampules has been described. One study demonstrated that glass particles were found in 22% of 1-mL ampules and up to 56% of syringes when utilizing an 18-gauge needle to draw up medication from a 2-mL ampule. Use of a 21-gauge needle to draw up medication from a 1-mL ampule did not yield glass fragments; however, 39% of samples contained glass particles when withdrawing from a 2-mL ampule. This suggests that use of a larger-bore needle in a large ampule may increase the risk of aspirating glass particles. As with rubber stopper coring, the clinical consequences of inadvertent glass particle aspiration have not been clearly established. A case report noted the presence of glass fragments in a knee joint that were thought to have originated from a glass ampule. No complication was reported in relation to this event. Some experts suggest that filter needles may play a role in preventing the transfer of glass particles from an ampule to a syringe. A review found that filter needles could decrease transfer of particles 10 μm in size by 83%. The American Society of Health System Pharmacists recommends the use of filters whenever using glass ampules.

Safety Recommendations and Prevention

1. Needle insertion at a 45°–60° angle with the bevel facing up and away from the stopper has been shown to reduce the possibility of coring by approximately 50%. A small amount of positive

pressure can be applied to the syringe plunger at the point of entry into the stopper.
2. The prior puncture site should be avoided if a rubber stopper is penetrated more than once in the case of a multidose vial. The use of multidose vials is addressed in a separate FactFinder.
3. Sharp needles are preferred, as their use is associated with a lower incidence of coring compared with blunt-tip needles.
4. Aspiration of glass particles from ampules into the syringe can be reduced by using gauze to open the vial top, drawing up with the smallest-gauge needle necessary, and using a filter needle.
5. Safety measures to avoid intravascular needle placement should be implemented to prevent the injection of cored fragments or glass particles. These measures include the use of real-time fluoroscopy, digital subtraction, local anesthetic test dose, and microbore extension tubing to control flow rate if inadvertently placed in a vascular structure.

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Teaching Images

Intradural Adhesion at L3-4 Contributing to S1 Radiculopathy in Postlaminectomy Pain Syndrome

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Postlaminectomy pain syndrome refers to persistent leg and/or lumbar back pain after surgery for disc excision. Magnetic resonance imaging (MRI) in the assessment of postlaminectomy pain syndrome provides soft tissue resolution of common postsurgical pain generators, including recurrent posterior disc disease and associated narrowing of the spinal canal, lateral recess, or neural foramina. Much attention is paid to the epidural course of the exiting nerve roots in the setting of radiculopathy, with the intradural course of the traversing lumbar nerve roots often overlooked [1].

These images are from a 32-year-old woman with a history of prior right L4 hemilaminectomy presenting with left leg weakness and numbness consistent with a left S1 radiculopathy. Lumbar MRI with and without contrast was performed (Figure 1). These images suggest a "double-crush" syndrome with lesions involving the left S1 nerve root at both the intradural L3-4 level and the epidural L5-S1 level [2]. The intradural lesion was not recognized on a prior noncontrast lumbar MRI.

Physicians treating postlaminectomy pain should consider MRI with and without contrast and should review MRIs for possible symptomatic intradural adhesions. Such lesions, if recognized, should be considered in planning possible spine interventions, neuromodulation treatments, or further surgeries [3].

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