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Patient Safety Tip of the Week

February 21, 2023

Tranexamic Acid Errors Just Won't Go Away

Tranexamic acid has become fairly widely used as an intervention for post-partum hemorrhage in obstetric patients. As a result, it is showing up in locations where it can lead to inadvertent spinal injection of this substance that is toxic to the nervous system. We've done columns on the devastating consequences of inadvertent spinal injection of tranexamic acid (see our Patient Safety Tips of the Week for June 4, 2019 "Medication Errors in the OR – Part 3", July 9, 2019 "Spinal Injection of Tranexamic Acid", and June 14, 2022 "Spinal Tranexamic Acid Again!"). A key contributing factor in all cases is the similarity between vials of tranexamic acid and vials of anesthetic drugs.

A recent review (Moran 2023) after they found 3 additional cases in South Africa notes that. "in anticipation of its use at cesarean delivery, tranexamic acid ampoules are now frequently kept in the anesthetic drug trolley in the operating room, creating a risk of tranexamic acid being mistaken for a spinal anesthetic drug and injected intrathecally before cesarean delivery." It also notes that the risk of this drug error is heightened by the similarity in shape and size of the ampoules containing tranexamic acid and those containing drugs used for spinal anesthesia (eg, bupivacaine).

Moran et al. go on to point out that in some cases the drug error may not be recognized because anesthetic practitioners may be unaware of the acute neurotoxic effects of intrathecal tranexamic acid. They cite an example, from 1 of the 3 recent cases they became aware of, that the presentation of convulsions and cardiovascular instability after administration of the spinal anesthetic was ascribed to eclampsia.

They cite a 2022 World Health Organization alert (WHO 2022) and a 2020 US Food and Drug Administration alert (FDA 2020) on the issue. While they note the importance of disseminating information about tranexamic acid accidents, they acknowledge that is not enough and that more needs to be done.

They recommend the following steps:

- Store tranexamic acid injection vials separately from other drugs, in a way that makes the labels visible to avoid reliance on identifying drugs by the vial cap color
- Add an auxiliary warning label to note that the vial contains tranexamic acid
- Check the container label to ensure the correct product is selected and administered
- Utilize barcode scanning when stocking medication cabinets and preparing or administering the product

Our June 14, 2022 Patient Safety Tip of the Week "Spinal Tranexamic Acid Again!" discussed a case published by ISMP Canada (ISMP Canada 2022) in which both tranexamic acid and bupivacaine were stored in the same drawer of the drug cart.

The ISMP Canada case also highlights the potential flaws in double checks. The hospital's investigation found that a form of confirmation bias ("seeing what you expect to see") likely contributed even though a double check had been performed.

A key point we always make is "Don't store dangerous medications in a location where someone might inadvertently pick it up, prepare it, and administer it". We learned that lesson many years ago when concentrated potassium chloride was sometimes inadvertently given IV to patients, resulting in fatalities. We also stressed it in our columns on the mistaken administration of methylene blue instead of the intended trypan blue in ophthalmology cases (May 20, 2014 "Ophthalmology: Blue Dye Mixup" and September 2014"Another Blue Dye Eye Mixup"). So, **don't keep tranexamic acid in locations where you don't need it**.

But you may need tranexamic acid in obstetric cases. However, it is not needed so urgently that you need to keep it where an anesthetist might inadvertently pick it up. Tranexamic acid **should always be stored separately from anesthetic drugs** used in the operating room. It should be stored in a secure container away from the anesthetic drugs cart. And it should never be put on the table set up in preparation for administering a spinal anesthetic.

Barcoding is an obvious technological solution to help avoid such misadministration. But, as we pointed out in see our June 2022 What's New in the Patient Safety World column "Where Are You Barcoding?", many OR's have yet to implement barcoding. ISMP (ISMP 2022) noted that Crystal Clinic Orthopaedic Center, which adopted barcode scanning technology in all perioperative and procedural settings prior to medication administration, requires some anesthesia-provider medications to be scanned and documented on the medication administration record (MAR). Tranexamic acid was specifically mentioned as one of those medications.

It is worth reiterating recommendations from the 2020 NAN (National Alert Network) Alert (NAN 2020):

- Separate or sequester tranexamic acid in storage locations and avoid storing local anesthetics and tranexamic acid near one another.

- To prevent reliance on identifying the drug by viewing only the vial caps, never store injectable drug vials in an upright position, especially when stored in a bin or drawer below eye level. Store them in a way that always makes their labels visible.
- Minimize look-alike vials (caps) by purchasing these products from different manufacturers.
- Consider purchasing labels that state, "Contains Tranexamic Acid" to place over the vial caps.
- Utilize barcode scanning prior to dispensing as well as when accessing the drug in surgical and obstetrical areas.
- Consider NRFit syringes and connectors for local anesthetics used for regional anesthesia administered via the neuraxial route. NRFit connectors are incompatible with Luer connectors, thus preventing misconnections with drugs intended for IV use, such as tranexamic acid.
- Consider the use of pharmacy-prepared or commercially available premixed containers of tranexamic acid, which would be less likely to be confused with local anesthetic vials. Pharmacy preparation and labeling of syringes or infusions would help alleviate these errors. A premixed container of IV tranexamic acid in a sodium chloride solution for injection, 1 g/100 mL (10 mg/mL), is commercially available. While the only approved indication for tranexamic acid is to reduce or prevent hemorrhage for patients with hemophilia undergoing tooth extraction, this product could be used off-label to treat other forms of bleeding. However, vials of tranexamic acid may still be needed since loading doses may be required prior to infusion (or a smart infusion pump loading dose feature could be used that automatically switches to a continuous infusion once the loading dose has been delivered). Also note: local anesthetics may be available at some locations in premixed containers or prepared by pharmacy for use in regional anesthesia.

And it's worth your while to review the recommendations from ISMP Canada (ISMP Canada 2022) discussed in our June 14, 2022 Patient Safety Tip of the Week "Spinal Tranexamic Acid Again!".

Moran et al. in the current review point out that regulatory bodies, suppliers, and manufacturers also have an important role in resolving this problem. They suggest those entities could help ensure that tranexamic acid drug ampules carry clear warning labels about the correct route of administration. They stress that a coordinated international effort is required to prevent inadvertent intrathecal tranexamic acid administration.

But, until industry gets it act together and packages tranexamic acid in a safer manner, the following recommendations are crucial:

- Don't store tranexamic acid in areas where it is not needed
- Always segregate tranexamic acid from anesthetics in areas where it is sometimes needed
- Use any method you can to flag vials of tranexamic acid as being potentially dangerous

- All syringes must be clearly labeled
- Implement barcoding in the OR or any other area where tranexamic acid might be used

If your facility uses tranexamic acid, it would be wise to perform a FMEA (failure mode and effects analysis) to identify and mitigate any current vulnerabilities you find.

Some of our prior columns on inadvertent spinal administration of tranexamic acid:

June 4, 2019 "Medication Errors in the OR – Part 3"
July 9, 2019 "Spinal Injection of Tranexamic Acid"
June 14, 2022 "Spinal Tranexamic Acid Again!"

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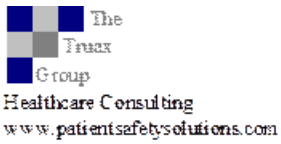

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