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Understanding the hidden risks of extravasation injuries

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A middle-aged woman was brought to a community emergency department (ED) hypotensive and unresponsive after an intentional calcium channel blocker overdose. The on-duty ED physician and two nurses immediately attended to the patient. Peripheral intravenous access was obtained during the initial resuscitative management. She subsequently declined into cardiopulmonary arrest, was intubated, and received standard emergency medical and advanced cardiac life support treatment for her overdose. The resuscitation was successful in large part due to an infusion of calcium chloride. Unfortunately, the patient also suffered a soft-tissue extravasation injury to her left arm from the calcium chloride, and complications of the injury led to the amputation of her arm above the elbow. The patient sued for damages from the infiltration injury and alleged the ED physician and hospital staff were negligent. The case settled out of court for a six-figure amount.

Although the injuries caused by the extravasation of calcium chloride represent a potential risk of treatment, this patient most certainly would have died without the lifesaving therapy. The nature of emergency medicine requires physicians to make rapid and sound judgments regarding therapeutic options, at times under intense pressure and extreme circumstances. Despite the fact that this patient's life was saved, she sustained a disabling injury due to her emergency care. Most would argue that the resultant outcome was

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acceptable under the circumstances. However, patients and family members may view such complications as both an avoidable and unacceptable consequence of medical treatment. The above case is not an isolated malpractice case. Numerous allegations of negligence have arisen from similar episodes of medications extravasating and causing injury. In at least two of these cases, large jury awards were awarded ($650,000 and $1,500,000).[1,2]

Extravasation (infiltration) is defined as a leakage of fluid from a vein into surrounding tissues. The cases discussed in this article involve these medication injuries and their legal ramifications. The specific treatment, injuries, and pathophysiology occurring from calcium channel blockers, phenytoin, dextrose, and vasopressor agents are discussed. The message from this article is simple: ED physicians and nurses must recognize the signs and symptoms of extravasation injuries and treat them immediately. When informed by a nurse that an IV has infiltrated, it is incumbent upon the physician to take the time to inspect the site, determine what drug was being infused, treat expectantly, and prepare for the worst.

General IV Site Infiltration

In *Goldstein v. Hauptman*,[3] the 6-week-old plaintiff suffered a severe chemical burn over the dorsum of his right foot when fluid from an IV infiltrated and caused severe soft-tissue necrosis. The plaintiff alleged that the nurses failed to properly monitor the IV and that Dr. Hauptman had departed from accepted medical standards in taping the IV needle to the baby's foot. The plaintiff claimed that by taping down the IV, it was difficult for the nurses to identify that the area was becoming swollen and irritated. The parents brought suit against the physician as well as the hospital for negligent nursing care.

There was testimony presented at trial that the nursing staff routinely checked IV sites every half hour between 8:30 a.m. and 12:30 p.m. The patient's infiltration was discovered during one of these exams. The procedure used to monitor the IV consisted of palpating the area where the needle was inserted and checking the color and temperature of the exposed foot area. The hospital chart contained only two entries pertaining to the actual checking of the IV. One was at noon, which read "IV infusing well," and another was at 12:30 p.m., which stated, "IV infiltrated."

Interestingly, there also was an entry indicating that the IV was still infusing between 1 and 2 p.m. The entry was crossed out, and a secondary notation read, "NO IV, discontinued at 12:30." Despite the taping that limited the nursing inspection and the scanty documentation of IV checks in the record, the court granted the hospital's motion for summary judgment. The court found that there was insufficient evidence showing the nurses had improperly monitored the IV. The jury then returned a verdict for Dr. Hauptman.

Case discussion: The nurses repeated checks of the IV site and prompt removal of the IV saved Dr. Hauptman in this case. It was very fortunate for both the physician and nurse involved that the jury did not pursue the error in the medical record. This case also demonstrates the importance of visual access of IV sites in order to facilitate rapid and repeated inspection. The use of clear tape is recommended. Ensure that all IV sites are inspected on a regular basis and any patient or family complaints about the

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IV are investigated immediately. Clearly document the timing and results of such inspections. If extravasation is suspected, stop the infusion and change the IV site. Consult the hospital pharmacy or specific protocols as necessary for any specific treatment measures pertaining to the extravasated substance, and document such consultations in the patient's chart.

Review and pathophysiology: It has been estimated that nearly 80% of patients receive some IV therapy during their hospitalization.[4,5,6] Approximately 50% of the IV lines placed in patients to deliver fluids fail at some point during a hospitalization.[7] This provides ample opportunities for an extravasation injury to occur. The overall incidence of IV extravasation in hospitalized patients has been documented as between 23%-28%.[8]

There are several theories regarding extravasation injury mechanism. Mechanical disruption of the IV site can occur by the catheter dislodging spontaneously from the vein, the initial venipuncture creating an additional opening through which fluid can leak, or patient manipulation of the catheter. Irritating intravenous solutions, such as solutions with extremes in pH or osmolality, can induce infusion thrombophlebitis, causing the vessel wall to rupture. In addition, backward flow of infused fluid through the initial insertion site also can induce extravasation.[9,10] Some research has suggested the primary mechanism for extravasation results from a reactive venoconstriction induced by infused intravenous solutions. This venoconstriction ultimately leads to an elevation of intravascular pressure, causing the medication to seep out from the insertion site into the surrounding tissues. Those fluids with an acidic or alkaline pH, hyperosmolar solutions, solutions with particulate matter or that precipitate easily, or infused drugs with irritant properties increase the risk of infusion thrombophlebitis and subsequent venoconstriction.[11]

There are many signs and symptoms of extravasation described in the literature. The "classic" signs of initial infiltration include: swelling, burning, tightness, blanching, and coolness surrounding the IV site. Pain, edema, and induration also can be present, but are unreliable diagnostic criteria. The more severe and later manifestations of extravasation injury can include blister formation, ulceration, skin necrosis, compartment syndrome, and reflex sympathetic dystrophy syndrome.[12-15]

The tourniquet test is an effective test to determine whether the catheter tip remains inside the venous lumen. A tourniquet or blood pressure cuff is placed proximal to the patient's IV site, and pressure is applied. If the catheter is still in the lumen, the IV flow rate will slow, but if the site has extravasated, the flow will not be affected.[16,17] A common misconception about IV extravasation is that once a catheter has been dislodged from the vein, the infusion rate will slow. In reality, infusion will continue into the subcutaneous tissue until the interstitial pressure overcomes the pressure of gravity driving the IV fluid.[18,19] Another misconception is that when an IV has infiltrated, blood will not be returned on aspiration. There can be blood return even if an extravasation has occurred, as the IV catheter tip still can be partially within the venous lumen, or a venous obstruction may exist, allowing blood to be aspirated back while infused fluids are exuded out of the vein.[20]

Recommendations: Currently, only limited and often noncontrolled studies of extravasation injury therapy have been performed. However, research and recommendations for reducing the general risk of an extravasation injury, as well as general treatment strategies, are well-documented. This article will address specific recommendations for individual medications in upcoming sections. Prevention of extravasation injury is the key initial step. When initially inserting an IV catheter, the health care practitioner should attempt to cannulate a larger vein and utilize a larger diameter IV catheter whenever possible. Flexible catheter tips are preferred, as rigid steel cannulas and butterfly needles markedly increase the risk of infiltration.[21,22] Once established, properly secure the IV with clear tape or adhesive; you may apply a commercially available transparent dressings and an arm board to decrease extremity movement. Ideally, perform hourly examinations during the infusion of medications, particularly those medications with a high risk of extravasation injury that are covered in this article. In addition, change the IV site every 48-72 hours to reduce the risk of infection as well as infiltration.

If an extravasation is suspected, immediately discontinue the infusion, and aspirate the remaining fluid in the tubing or catheter. Specific treatment will depend on the type of fluid or medication that has extravasated. There is conflicting evidence regarding conservative treatments, such as warm and cold

compresses, and their use should be tailored to the type of medication that caused the infiltrative injury.

Hyaluronidase (Wydase, Wyeth-Ayerst, Philadelphia) has been used since the 1950s to treat a variety of extravasation injuries.[23] It breaks down interstitial barriers and connective tissue surrounding the area of extravasation, which allows for rapid dispersal and reabsorption of the infiltrated medication. This drug can be used for a variety of medication extravasations including: calcium, total parenteral nutrition, many antibiotics, potassium salts, vinca alkaloids, sodium bicarbonate, and mannitol. It is most effective if administered within two hours of extravasation in a concentration of 15 units per mL, with 0.2 mL injected subcutaneously in five places around the site of the extravasation. There may be some benefit to injecting a portion of the hyaluronidase through the IV catheter, if it has not been removed already.[24,25]

Dextrose Solution Infiltration

In *Falkowski v. Maurus,*[26] the plaintiff was a diabetic who suffered an acute episode of hypoglycemia. Paramedics arrived at the scene and, after determining the plaintiff's serious condition, contacted the local ED for permission to use an established hypoglycemia protocol. The ED physician agreed, and the paramedics administered one ampule of 50% dextrose (D50) by intravenous bolus infusion. The patient soon complained of pain in his hand, where the IV was placed. Shortly thereafter, the paramedic removed the IV. On the following day, the plaintiff's hand and forearm became extremely swollen, and the plaintiff reported some loss of function in his hand. Subsequent examination revealed that the plaintiff had suffered a complete distal ulnar nerve palsy.

Under Louisiana law, a paramedic is liable only for acts that are intentional or grossly negligent. The plaintiff sued the paramedics, alleging gross negligence in the administration and supervision of the intravenous D50 bolus. The trial court found for the paramedics, and the plaintiff appealed. The appellate court affirmed the lower court decision based upon several points. The paramedic's compliance with established protocol, the constant observation of the IV site during transport, as well as the testimony of the ED physician indicating that no substantial swelling was found on the patient's arm, all indicated that the paramedics performed their job with respect to the IV in a reasonable fashion. The appellate court ruled that the paramedics clearly had not engaged in grossly negligent behavior. It is interesting to note that the plaintiff in this case was morbidly obese, weighing 320 pounds, which may have made swelling of the IV site more difficult to notice by the paramedics.

Case discussion: This case reflects the need to educate pre-hospital personnel about the risk of IV extravasation and the recognition of its signs and symptoms. The paramedics in this case rendered therapy that was within the standard of care. The care was not in any way grossly negligent, the standard under Louisiana law for holding a paramedic liable. The authors agree with the defendant's expert witness that, even if a patient suffers an infiltration injury from an intravenous venipuncture, this does not automatically imply negligence on the part of the medical provider. Other cases support the position that simply because an extravasation injury has occurred, negligence cannot necessarily be presumed.[27] In addition, in similar cases in other states where extravasation injuries were reported in the pre-hospital setting, defendants have prevailed.[28] These cases show promise that judge and jury will not allow a claim of negligence to succeed simply because a patient suffers an injury. As in all professional malpractice cases, the plaintiff must prove all four elements of the case: duty, a breach of the standard of care, proximate causation, and damages. An adverse outcome alone is not sufficient to establish that a physician or other health care provider was negligent.

Review and pathophysiology: Dextrose solutions, like many other crystalloid fluids, are mildly acidic with a pH of 3.5 to 6.5, but they also are markedly hyperosmolar.[29,30] It is presumed that the high osmolarity is the cause of skin necrosis with infiltration of dextrose solutions.[31,32] Other theories cite osmotic damage, which occurs through direct cellular injury from the disruption of the cellular transport mechanisms by hypertonic solutions. This results in intracellular dehydration and cellular death. The acidic nature of the dextrose solution also causes intracellular proteins to precipitate, leading to cell death and skin necrosis. Mechanical compression also may occur during a large dextrose extravasation and cause a pressure necrosis of tissues.[33]

Signs and symptoms of dextrose extravasation are

similar to injuries from other IV solution extravasations. Large bullae may appear within a few hours of extravasation, along with warmth, edema, erythema, and erosions.[34,35] Blistering has been shown to be a sign of serious skin injury from edema, but is not useful in predicting the extent of total tissue loss from an extravasation injury. The extent of the injury with dextrose solutions depends on the volume, composition, location, time period before the infiltration is discovered, and the treatment measures implemented after extravasation.[36]

Recommendations: Conservative management is the treatment of choice for dextrose extravasation injuries. Recommendations include a loose dressing, elevation of the extremity, and cold packs to the area. It also is advised to avoid warm soaks or compresses, as this may contribute to skin maceration. To reduce the risk of infiltration and extravasation, infuse dextrose solutions, like all hyperosmolar solutions, into a large vein using a flexible larger bore catheter. Stop the infusion at the first sign or symptom of an extravasation, and aspirate any remaining fluid within the IV tubing. There is limited evidence regarding the efficacy of hyaluronidase in dextrose extravasation injuries.

Calcium Infiltration

As early as 1965, cases of calcium chloride solution extravasation injuries were reported. In *Riley v. United States*,[37] the plaintiff suffered tissue necrosis of the forearm and hand near the site of an IV. In this case, the patient had a history of severe regional ileitis requiring a total colectomy and ileostomy at age 28, and she suffered from chronic hypocalcemia due to malabsorption. She presented to the ED with tetany in her arms and legs and was given IV as well as oral calcium replacement. Two days after admission, another physician noted erythema and impending necrosis of the right forearm and left hand where the calcium had been infused. The patient required two small skin grafts on her right forearm and left hand. She had no residual functional damages; however, there was obvious discoloration and scars around the grafted skin. The court ruled in favor of the defendant and emphasized that undesirable results stemming from a medical procedure are not, by themselves, conclusive proof of negligence.

In the similar but more recent case, *Odak v. Arlington Memorial Hospital*,[38] a child suffered injury after receiving an intravenous infusion containing 10% calcium gluconate. The IV infiltrated into the infant's leg and foot and caused pain, swelling, and blistering, as well as a large discolored scar. The plaintiff sued for damages. The defense moved for dismissal because of the plaintiff's failure to comply with Texas civil procedure. The procedural rules provided that, in medical malpractice cases, the plaintiff must certify that an expert has given the plaintiff a written report as to the negligence of the medical provider and posted a bond prior to trial. The plaintiff failed to comply with these requirements.

The plaintiff argued that this case was a *res ipsa loquitor* case and, therefore, no expert testimony was needed. ***Editor's note:*** *The doctrine of* res ipsa loquitor *("the thing speaks for itself") may be applied in situations where the mere fact that a particular type of injury occurred appropriately establishes, or tends to establish, a breach of duty. In such cases (e.g., an instrument left in the abdomen after surgery, amputation of the wrong extremity), the trier of fact may be permitted to infer the defendant's negligence based simply upon the fact that the event occurred. The precise procedural effect of the doctrine is beyond the scope of this article.* The plaintiff argued that persons do not suffer such burns in a hospital nursery absent negligence. The court disagreed and stated that this was not a *res ipsa loquitor* case. The court further stated that there was an issue as to whether the infusion had caused the injury. Finding for the defense, the court held that the placement and monitoring of a needle is not within a layperson's understanding, and thus expert testimony was required to establish a breach of the standard of care.

Case discussion: These cases have medical-legal significance as a general proposition in that these courts did not allow application of the *res ipsa loquitor* doctrine in this circumstance, and required expert testimony that the standard of care was breached. The majority of courts agree that application of the *res ipsa loquitor* doctrine in these cases (extravasation) is inappropriate and, in addition, that expert witness testimony is required as to the standard of care.[39-43] Prohibiting the application of the *res ipsa loquitor* doctrine bodes well for ED physicians. The majority of extravasation injury cases do not reflect malpractice, but rather an unavoidable adverse outcome of medication

infusion. ED physicians and nurses still need to be able to identify extravasation injuries and treat them promptly when injury occurs. Early recognition and treatment will build a strong defense for the practitioner if an allegation of malpractice arises.

At least one court has disagreed in extravasation injury cases.[44] The court found that *res ipsa loquitor* was applicable, and no expert testimony was required. It argued that laypersons would know that such injuries do not occur absent negligence. The court stated that the layperson has this knowledge from the common experience of receiving shots with needles. This case does contain a vigorous dissent in which it was argued that the *res ipsa loquitor* doctrine was allowed far too frequently whenever a medical procedure is performed and an unsatisfactory result occurred. The dissent argued that a layperson could hardly be expected to know that a medication will burn surrounding tissue if it escapes the vein.

Review and pathophysiology: Calcium is the most abundant mineral in the body and constitutes 10-20 g/kg of the average adult. It is 99% bound in bone as phosphate and carbonate with an intravascular and extravascular compartment ratio of 10,000:1.[45] Calcium can be administered intravenously as 10 mL of 10% calcium chloride solution (100 mg/mL or 27.3 mg/mL *elemental* calcium per 10 cc) or 10-30 mL of 10% calcium gluconate solution (100 mg/mL or 9 mg/mL *elemental* calcium), infused over 10-20 minutes. Although one 10 cc vial of either 10% calcium chloride or 10% calcium gluconate contains 1 gram of calcium solution, the calcium chloride solution contains three times the elemental calcium found in a similar volume of a calcium gluconate solution. When giving a calcium infusion, it should be diluted whenever possible in 1,000 mL of normal saline given over 12-24 hours, not exceeding 200 mg/min.[46]

Calcium gluconate and calcium chloride are weak acidic hypertonic solutions, and it is because of this characteristic that they are capable of precipitating protein, which produces cell death and skin necrosis.[47,48] There are many proposed mechanisms for calcium's destructive effect upon extravasation. Calcification has been attributed to massive collagen degeneration, soft-tissue necrosis, or an increase in mast cell production.[49,50] Other theories suggest that the lymphocytes, giant cells, and neutrophils seem to cause more damage than the mast cells alone.[51] Calcinosis cutis is a dermatologic condition of localized tissue calcification, and it occurs most commonly 13 days after a calcium infusion extravasation. The lesions appear as brown to white papules or nodules and may be associated with warmth, fluctuance, or even skin necrosis. Radiographic studies can demonstrate soft-tissue calcification.

Most patients with a calcium extravasation injury experience a burning sensation upon infiltration. Mild erythema and induration usually appear after three days.[52,53] Large ulcerations and nodules develop within two weeks, but by two months, most of the ulcerations will have healed and gradually disappeared.[54-56] However, some calcium solution infiltrations can cause localized calcification and soft-tissue necrosis.[57-59]

A variety of treatment options for calcium extravasation injury have been recommended. Most therapeutic regimens include elevation and cold compression for the edema.[60,61] It also has been recognized that surgical intervention and early skin grafting is neither indicated nor successful in most cases, because many lesions spontaneously resolve over time.[62,63] One case showed substantial reduction in full thickness skin loss when normal saline and hyaluronidase were injected subcutaneously up to one hour post initial injury.[64] Limited experimental data has shown that treating calcinosis cutis lesions in rabbits with a 0.5 cc subcutaneous injection of triamcinolone acetonide (10 mg/dL) reduced the histologic inflammatory response and resulted in earlier healing of the lesions.[65]

Recommendations: Recommendations to help avoid a calcium solution extravasation injury include using a stable and secure IV site, utilizing a flexible IV catheter rather than a needle, and a slow infusion of any calcium bolus. Inspection with diligence of IV sites during calcium infusion therapy may identify an IV infiltration before a significant amount of the solution extravasates. Except in rare emergency situations, small-caliber IV catheters placed in tenuous locations, such as the dorsum of the hand, are not appropriate for this irritating solution. Often, a calcium chloride bolus or infusion can be substituted with one or more calcium gluconate boluses or infusions. As 10 cc of calcium gluconate contains one-third the elemental calcium of a similar volume of calcium chloride, an extravasation will be less damaging, as local tissue damage directly correlates with

TABLE 1: Extravasation Protocol

Extravasated Drug	Antidote	Dilution	Administration	Warm/Cold
Sympathomimetics: Dopamine Epinephrine Norepinephrine (Levophed) Phenylphrine (NeoSynephrine) Vasopressin Metaraminol (Aramine)	Phentolamine (Regitine)	5-10 mg diluted in 10 mL normal saline. Must give at least 5 mg.	Prep area with povidone-iodine swab. With 25-gauge needle, inject site (hard, cold, pale area) intradermally or SQ with ½ to 1 mL along leading edge; then infiltrate the entire area, including approximately ½ inch around periphery.	Dry warm compresses for 15-20 minutes every 4-6 hours.
Hyperosmotic solutions: Calcium gluconate Calcium chloride Dextrose (10% or greater) Parenteral nutrition (TPN, PPN) Potassium (bolus or infusion) Radiocontrast media Sodium bicarbonate Mannitol	Hyaluronidase (Wydase)	Available as 150 units/mL vial. Withdraw 0.1 mL and dilute with 0.9 mL normal saline to yield concentration of 15 units/mL.	Cleanse area with povidone-iodine. With 25-gauge needle, inject 0.2 mL x 5 SQ or intradermally into leading edge in a circular pattern. Repeat dosing may be required for large extravasations. (Some sources recommend changing needle for each injection.)	Dry, cold compresses to affected area for 15-20 minutes every 4-6 hours for 24 hours. **Except** phenytoin, which is warm, dry heat.
Antibiotics/ Antimicrobials: Acyclovir Chloramphenicol Gentamicin Nafcillin Oxacillin Penicillin G potassium Vancomycin				
Miscellaneous: Aminophylline				

the amount of free calcium ion present in the offending solution that extravasates.[66] Only in rare, truly emergent situations, such as the previously mentioned hemodynamically unstable calcium channel blocker overdose is rapid bolus therapy of intravenous calcium indicated.

The Mosby's *Intravenous Medications* (15th ed., 1999) states that the dose of calcium chloride for adult cardiac resuscitation is 2-4 mg/kg, repeated as needed at 10-minute intervals, given as 0.5-1 mL of solution over one minute. It may be given undiluted; however, the preferred dilution is with equal amounts

of sterile water or normal saline (NS) to make a 5% solution. For administration of calcium gluconate in an adult cardiac arrest situation, 5-8 mg/kg is given every 10 minutes, as needed, either undiluted or diluted in up to 1,000 mL of normal saline. The rate of infusion for a direct undiluted IV bolus is 0.5 mL over one minute, not to exceed 2 mL/min.[67] When giving a calcium infusion, dilute it whenever possible with 1,000 mL of NS, given over 12-24 hours and not exceeding 200mg/min.

Once a calcium extravasation is identified, stop the infused solution and aspirate the catheter. Reference an established extravasation protocol immediately. **(See Table 1, p. 79.)** Elevate the extremity and place a cold pack onto the area. Inject hyaluronidase into the subcutaneous tissues surrounding the extravasation in five separate areas (15 units diluted in 1 mL of NS, with 0.2 mL in each injection). Some improvement in calcinosis cutis has been noted in an animal model with subcutaneous injection of triamcinolone acetonide; however, further investigation in humans is required before this can be supported as a standard of care. Calcium extravasations will require close clinical follow-up to assess for signs of skin necrosis or complications. Because of the lack of efficacy and these risks, calcium is no longer indicated during during resuscitations and should be used only for suspected hypocalcemia, hyperkalemia, and calcium-channel blocker overdose.[68]

Early tissue debridement of the extravasated soft tissue does not seem to improve cosmetic outcome, but any tissue necrosis that subsequently appears may require surgical debridement and possible skin grafting. If tissue necrosis occurs, the patient's primary care physician can coordinate consultation of a general or plastic surgeon as needed.

Phenytoin Infiltration

In *Kapadia v. Alief General Hospital*,[69] a diabetic patient visited her primary care physician, who recommended inpatient treatment for stabilization of her hyperglycemia. She refused to be admitted and left against medical advice. Three days later, she suffered several consecutive grand mal seizures at her home without regaining consciousness. Her family called 911, and the treating EMTs placed an IV in her hand. Upon arrival at the hospital, the ED physician attempted to place a central line to facilitate medication administration, but he reported he was unable to do so because of the patient's severe agitation and violent thrashing. The patient had another seizure in the ED and was transferred to the ICU. The consulting neurologist prescribed 1,000 mg IV phenytoin as a loading dose to prevent further seizures. Following the patient's CT scan and EEG, the phenytoin was administered. The nurse noted that approximately 1½ hours after the infusion was completed, the patient's hand became a bluish-purple color and was cool to the touch. The IV was stopped and moved to the right hand. Gangrene later developed that was refractory to medical treatment and ultimately required amputation of the left hand.

The nurse testified that the IV was given in 50 mg increments slowly; however, the terms "IV push" were used in the record. She stated that it took at least 30 minutes to give the medication. The family argued that they had noticed the injury occurring after 10-15 minutes of infusion, and that the nurse did not respond promptly to calls for help. A physician and nurse expert for the plaintiff argued that the dosage of phenytoin was too large and that the patient's physical restraints enabled fluid to remain in the tissues longer. Also at issue was whether the use of a gauze bandage rather than a transparent bio-occlusive dressing limited the visual inspection of the extremity. The jury returned a verdict for the defendant physician and hospital that was affirmed on appeal.

Case discussion: There were several issues in this case, which are common in extravasation injury claims. The first issue involves the plaintiff's claim of a delay in treatment, which was not substantiated. Another concern was the use of the gauze dressing, rather than a transparent dressing, to secure the patient's IV. This did not cause a delay in diagnosis of the patient's extravasation injury in this case because the injury was quickly noted by nursing staff. Finally, the dosage and infusion rate of phenytoin was questioned. In this case, the patient suffered from "Purple Glove Syndrome," a complication of intravenous phenytoin infusion. The majority of studies support a phenytoin infusion rate at no greater than 40-50 mg/min. with the infusion piggybacked on normal saline or diluted in saline.[70] However, the manufacturer recommends that the drug not be diluted. The recent introduction of the water-soluble preparation fosphenytoin provides an alternative to standard IV phenytoin loading. Fosphenytoin may be administered by the IV or IM route and is dosed as

phenytoin equivalents (PE). Clearly document in the chart the treatment and subsequent rechecks of the area once an extravasation has occurred, and employ liberal consultation of hospital pharmacists and plastic surgeons.

Cannulating large veins can reduce the risk of phenytoin infiltration, as well as using a slow infusion rate and allowing hemodilution to occur; however, a large vein may not be readily accessible. While many of the medications administered in the ED are urgent, few are immediately needed. The risk of delaying medication administration by 20 or 30 minutes while a suitable IV site is found and secured needs to be weighed upon a case-by-case basis. There certainly will be acceptable circumstances where the only IV access is a small peripheral vein. Some authors also encourage central IV administration rather than peripheral access to be used whenever possible for high-risk infusions, such as phenytoin.[71] The ED physician in this case attempted, but failed, to place a central line. A central line is not appropriate for all patients receiving phenytoin or other medications that may cause an extravasation injury. While the benefits of central access include improved hemodilution and a larger vein diameter, this may not be practical for most IV medications with a potential risk of infiltration. From a realistic standpoint, ED physicians often have a limited time for elective procedures and may be unable to initiate a central line on every patient requiring a potentially infiltrative medication. In addition, the associated risks with central line insertion, including pneumothorax, hemothorax, air embolism, catheter embolism, perforation or laceration of the vessel, perforation of the myocardium, and many others, all reflect the more invasive nature of this procedure.[72] Consider these risks prior to placement of a central line on any patient. Central line placement may be an essential procedure for a given patient's resuscitation or general treatment. However, universal central line placement simply for infusion of particular medications at high risk for extravasation is not indicated.

Another possibly safer and more cost-effective option is to dilute these medications and slow the rate of their infusion. Substituting fosphenytoin for phenytoin is an additional, but more costly, method to prevent extravasation injury. Collaborative discussion with a hospital pharmacist is advised. Most hospitals have protocols for IV rates and dilution of potentially harmful medications, particularly phenytoin. Courts will look at the hospital protocols to determine if the standard of care was met. It is therefore essential that these protocols be followed.

Review and pathophysiology: Phenytoin's chemical properties predispose it to cause extravasation injuries. It is a weak acid with limited aqueous solubility and subsequently is prone to precipitate.[73] The parenteral solution utilizes propylene glycol as a diluent that may produce cardiotoxicity

Table 2: Risk Management Tips

1. Institute a hospital intravenous extravasation policy that is accessible to all hospital staff. (**See Table 1, p. 79.)**
2. Physicians and nursing staff should be trained to recognize the signs and symptoms of extravasation injury and to institute the specific treatments as outlined in the protocol.
3. Cannulate larger veins with a larger flexible tip IV catheter whenever possible. Stable IV sites are preferred and reduce the chance of injury.
4. Carefully consider central lines for the infusion of high-risk medications on a case-by-case basis with an appropriate risk/benefit analysis.
5. Discuss with a hospital pharmacist the rate of infusion and possible dilution for any high-risk medications.
6. If a possible IV extravasation occurs, stop the infusion, attempt to aspirate back any solution, and remove the IV catheter. Coordinate specific antidotes and local site care with the substance extravasated.
7. All intravenous extravasations require close clinical follow-up. Although routine debridement and skin grafting is rarely required for most extravasation injuries, general or specialty surgical consultation is warranted for cases involving tissue necrosis, loss of function, neurological deficits, or possible compartment syndromes.
8. Document all exam findings, patient and consultant discussions, and therapies in the medical record.

and hypotension. The solution is adjusted to a pH of 12 by sodium hydroxide, which often causes a local phlebitis when administered. Phenytoin is supplied in a 50 mg/mL solution and typically dosed at 3-4 mg/kg/day, with a rate not to exceed 50 mg/min during IV infusion. Unlike other irritant drugs that may induce extravasation if not diluted, the manufacturer recommends that phenytoin be administered undiluted, as the drug has poor solubility in water and instability in normal saline and other normotonic IV fluids.[74] Contrary to the recommendations of the manufacturer, several sources recommend either dilution of the drug in a 0.45% or 0.9% saline solution, or IV "piggyback" administration into a normal saline infusion.[75,76]

Fosphenytoin sodium is a phosphate ester phenytoin pro-drug.[77] Due to the multiple adverse effects of IV phenytoin, fosphenytoin was developed as an effective alternative. After administration, the drug is rapidly hydrolyzed to phenytoin and bound to plasma proteins.[78] The standard doses for IV and IM fosphenytoin are 15-20 PE (phenytoin equivalents: equivalent to phenytoin mg/kg) infused at a rate of 100-150 PE/minute or 10-20 PE/kg IM injection. Before fosphenytoin is to be injected, it should be diluted in 5% dextrose or 0.9% sodium chloride.[79]

Fosphenytoin is very water-soluble, which eliminates the propylene glycol and ethanol used with phenytoin, and is buffered to a pH of 8.6-9. Therefore, it does not have many of the adverse effects of phenytoin administration.[80,81] Many studies have shown that fosphenytoin has less pain, burning, tenderness, and erythema at the infusion/injection site vs. phenytoin.[82,83] The manufacturer reports that injections of 5-20 mL in a single injection site have been well-tolerated by many patients. Fast infusion rates, up to 150 mg/min, have not shown any clinically significant hypotension or electrocardiographic changes in the healthy individual.[84] Most of fosphenytoin's side effects have been related to the central nervous system, such as nystagmus, headache, ataxia, and somnolence. Fosphenytoin is a safe and easily tolerated alternative to phenytoin administration in the seizure patient, but it has not been widely implemented at all institutions. A large barrier to fosphenytoin use is the cost of $60-$100 (U.S.) per standard dose, compared to a cost of $2-$3 for a comparable phenytoin dose.

Signs of possible phenytoin infiltration injury have been identified as a burning, painful tightness at the site of infusion, followed by the development of a cool and swollen extremity.[85] The degree of injury secondary to phenytoin infiltration ranges from minor injuries such as edema and partial or full-thickness tissue injury, to severe tissue necrosis, compartment syndrome, and amputation.[86]

In 1992, the "Purple Glove Syndrome" from intravenous phenytoin infusion was described.[87] It was noted to occur after infusion of the drug in the small dorsal veins of the hands. The syndrome has several stages of injury ranging from a dark purple indurated discoloration at the IV site, to edema and spreading of the discoloration to the forearm. The possibility of occlusion of arteries puts the patient at risk for ischemia and compartment syndrome. Often, the more extensive the discoloration, the more likely the skin is to blister and slough.

Of notable interest is that several injuries occurred even without actual extravasation of the drug. Several proposed theories for the mechanism of injury exist. Most studies contend that as phenytoin's highly alkaline solution is introduced into the more neutral environment of the bloodstream, a reflexive venoconstriction occurs, leads to a breakdown of vascular integrity, and allows the protein-bound phenytoin to freely flow into the soft tissues.[88-90] Once in this space, an osmotic pressure driven shift of fluids occurs, which leads to edema and discoloration. Additional theories contend that during the IV placement, a microtear in the vein is sustained, which leads to tissue extravasation of the drug, or that the phenytoin solution precipitates upon mixing with the patient's blood, which causes an obstruction that forces the medication into the surrounding tissues.[91-94]

Recommendations: Risk factors for sustaining a purple glove injury include age older than 60 years and a history of prior vascular disease.[95] Infusion rates should be no faster than 40 mg/min and even as slow as 20 mg/min in any patient with known risk factors. While studies have shown a decreased risk when phenytoin is piggybacked, this is not what the manufacture recommends. Either administration is acceptable until a consensus is established. Remember to consult your own hospital protocol and follow it.

Once an extravasation event is suspected, immediately discontinue the phenytoin infusion and aspirate all residual fluid in the tubing. Discontinue all use of that extremity until complete resolution of symptoms. Elevate and splint the extremity to reduce edema, and apply dry heat to help redistribute the

phenytoin throughout the forearm.[96-98] Moist heat is contraindicated, as it may contribute to skin breakdown, and cold packs also are contraindicated, as they will increase vasoconstriction and limit drug reabsorption.[99] Finally, continually re-evaluate the affected extremity for skin temperature, edema, discoloration, capillary refill, and peripheral pulses. If a compartment syndrome is clinically suspected or pulses are poorly palpated, obtain immediate surgical consultation to assess the need for fasciotomy.[100] The use of hyaluronidase solutions injected subcutaneously into a phenytoin extravasation injury site has shown promise for reducing injury, but it is based upon limited supporting evidence in the literature. If hyaluronidase is used, it appears to be most effective if therapy is instituted within one hour of the extravasation.[101]

Vasopressor Infiltration

In *Macon-Bibb County Hospital v. Ross*,[102] the plaintiff presented at 2:40 p.m. with hypertension (250/150 mmHg) and difficulty breathing. At 2:55 p.m., she suddenly deteriorated into respiratory arrest. She was given IV sodium nitroprusside at 2:58 p.m. The patient's blood pressure then dropped to 120/90. The sodium nitroprusside was discontinued at 3:31 p.m., after it was noted that the patient's blood pressure could not be auscultated. A dopamine infusion was started in a right wrist IV, the patient's blood pressure was stabilized, and she was transferred to the coronary care unit for further care.

At midnight, a nurse noted the IV site had developed some bruising and bluish discoloration. At 11 a.m. and 4 p.m. the following day, two nursing entries in the medical record noted that the extremity was swollen and painful, with a large blistered area surrounding the IV site. The attending physician was not contacted until 6:50 p.m. that day. The patient suffered pain, blistering, and permanent scarring of the arm.

At trial, the plaintiff presented expert testimony that indicated, according to the manufacturer's package insert, the drug should have been infused using a larger vein than the one chosen, and that the hospital staff's failure to promptly contact the doctor was negligent. The jury found for the plaintiff in the amount of $27,000.

Upon subsequent appeal, the court held that there was sufficient evidence presented to uphold the jury's verdict. The court further stated that not only did the manufacturer suggest using a large vein for infusing dopamine, it also recommended that, if that was not possible initially, (i.e., in an emergency situation), the infusion should be moved to a larger vein as soon as possible.

Case discussion: This case was decided against the defendant hospital for several reasons. First, there was time once the patient was stabilized to find a new IV site in a larger vein or to insert a central line. The failure to follow the manufacturer's suggested procedures was, in this case, sufficient evidence for the trier of fact to conclude that the standard of care had not been met. Second, the three nurses who repeatedly recognized and documented the discoloration should have immediately contacted the attending physician. The delay of seven hours was unacceptable. The nurses in this case appear to have lacked the education and training to properly identify an IV extravasation injury. In summary, this case was extremely difficult to defend based on the actions of the hospital staff. Education of physicians and nurses is a key in preventing such cases. Early recognition and treatment of extravasation will reduce permanent injury and provide for a more defensible case for all parties.

Pathophysiology and review: Extravasated alpha-adrenergic agonists, such as dopamine, dobutamine, epinephrine, and norepinephrine, induce soft-tissue injury by constricting smooth muscle around capillaries, which results in an ischemic tissue necrosis.[103] In addition, the acidic pH (3-4.5) of these solutions also may cause a chemical phlebitis during infusion.[104] Even at low doses (< 3ug/kg/min), where no appreciable alpha-adrenergic effect is expected, dopamine can cause severe vasoconstriction with extravasation.[105] While the time from extravasation to pharmacologic reversal is the most important factor associated with ischemic tissue damage, the presence of peripheral vascular disease, fluctuations in blood pressure, and the overall surface area involved can affect outcomes.[106]

Once an infiltration has occurred, immediately terminate the infusion and elevate the extremity. Treatment goals for vasopressor extravasation include promoting rapid absorption of the drug and decreasing local vascular constriction. Phentolamine, a short acting alpha-adrenergic blocking agent (Regitine, CibaGeneva Pharmaceuticals, Ciba-Geigy Corp., Summit NJ), competitively blocks alpha-receptors, causing the relaxation of vascular smooth muscle and

a hyperemic response. Phentolamine injected subcutaneously into experimental rat dopamine extravasations demonstrated decreased tissue injury as compared to blinded normal saline injections. Injection with either high-dose (1 mg/0.5 mL) or low-dose (0.5 mg/0.25 mL) phentolamine solutions was equally effective in reducing tissue damage.[107] The current therapeutic dose of phentolamine is 5-10 mg diluted in 10 mL of normal saline injected subcutaneously throughout the extravasation site.[108-110] Initiate the treatment as soon as possible, preferably within 12 hours of the injury. However, even up to 18 hours post-infiltration, you may use a trial of phentolamine to promote partial restoration of perfusion.[111]

Other treatment options include administering 2% topical nitrates and subcutaneously injected terbutaline. Topical 2% nitroglycerin ointment (Nitrobid Ointment 2%, Marion Merrell Dow, Kansas City, MO) reduces the damage from dopamine extravasation by dilation from relaxation of vascular smooth muscle.[112,113] The increased local blood flow dilutes the acidic solution being infused.[114] The hemodynamic effects are usually seen within seconds to minutes and can last from six to eight hours.[115,116] However, most of the studies using therapeutic nitroglycerin ointment have been conducted in a pediatric population. It is unclear whether topical nitroglycerin ointment will provide any additional benefit to phentolamine therapy in the adult population.[117] Since hypotension may occur, reserve its use for those patients who can tolerate a slight reduction in blood pressure.

Terbutaline, a selective B_2 agonist, has been successfully utilized in promoting peripheral vasodilation after vasopressor infiltration. After 1 mg of terbutaline diluted in 10 cc of normal saline is subcutaneously injected into an extravasation site, a reversal of peripheral vasoconstriction has been documented, presumably by B_2 receptor activation and relaxation of vascular smooth muscle.[118] Alternative, less successful treatments include amyl nitrite inhalations, metacarpal nerve blocks, intravenous chlorpromazine, intravenous nitroprusside, and warm water immersion.[119]

More important than the specific treatment of the vasopressor extravasation is its prevention. The manufacturer of dopamine has recommended it should be infused into a large vein whenever possible.[120] Some authorities recommend central access to avoid dopamine extravasation, as the risk for infiltration remains regardless of the volume, rate, operator skill level, catheter material, or IV site when infused peripherally.[121,122] If a peripheral IV is to be used, place a 5 cm angiocatheter, 20 gauge or larger, using the antecubital fossa or other large veins and avoiding the smaller hand or foot veins. Deliver a 20-30 cc bolus of intravenous fluids prior to the vasopressor being administered to assess the patency of the line, provide an adequate flush, and prevent medication mixing. If vasopressors are administered peripherally, carefully observe the IV site for any signs of extravasation.

Recommendations: The general treatment of vasopressor extravasation injury sites is similar to other infiltrative injuries. Specific local treatment includes dry warm compresses to the site for 15-20 minutes every four to six hours. Phentolamine, which competitively blocks the alpha-adrenergic receptors, is the treatment of choice for all vasopressor infiltrations. Phentolamine should be given as 5-10 mg diluted in 10 mL of normal saline and injected subcutaneously throughout the extravasation site. The use of transdermal glyceryl trinitrate patches may be beneficial in treating ischemic areas to increase perfusion after vasopressor extravasation.

Conclusion

ED physicians and nurses need to be able to recognize the signs and symptoms of IV infiltration and soft tissue extravasation injury. The risk of IV infiltration and subsequent extravasation injury can be reduced by using a large-caliber flexible tip IV catheter, utilizing larger veins, diluting the infused medication whenever possible, and slowing the rate of infusion. The extravasation of vesicants or irritants can result in tissue damage or necrosis and subsequent functional and cosmetic defects. Timely and appropriate management can reduce or eliminate any long-term complications. The risk of injury increases with the duration of exposure, the amount of extravasated fluid, and the substance extravasated.

Early recognition and treatment will reduce the injury and provide for a more defensible case if litigation ensues. Specific treatment and antidotes should be accessible and readily available within the hospital to avoid confusion and any delay in treatment. **(See Table 1, p. 79.)** Document all treatments clearly in the medical record. Always notify patients and family about the injury, as communication has

been shown to be the best defense in preventing subsequent litigation.

Endnotes

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CE/CME Questions

9. In dextrose infiltration, the following are true *except:*
   A. Loose dressings, elevation, and cold packs to the area are indicated.
   B. Warm soaks should be avoided.
   C. Injection of hyaluronidase at the site of extravasation has been shown to be harmful.
   D. Large veins should be used for the infusion when possible.

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The participant will be able to:

- identify a true statement about dextrose infiltration;
- identify the signs and symptoms of extravasation;
- identify what is included in the treatment of phenytoin extravasations injuries;
- identify what is included in the treatment for dopamine or other vasopressor extravasation injuries.

10. All of the following statements are true **except**:
    A. Extravasation rates vary from 23%-28% of all patients receiving IV therapy.
    B. The "classic" initial signs and symptoms of extravasation are swelling, burning, tightness, blanching, and coolness.
    C. The more severe and late manifestations of extravasation injuries are blister formation, ulceration, skin necrosis, compartment syndrome, and reflex sympathetic dystrophy syndrome.
    D. The IV should be properly secured with tape, covered with gauze, and wrapped in webroll or a gauze dressing.

11. Treatment of phenytoin extravasations injuries includes all of the following *except:*
    A. Immediate discontinuation of the infusion once detected, and aspiration of all residual fluid in the tubing and syringe.
    B. Discontinuation of all use of that extremity until complete resolution of symptoms.
    C. The extremity should be elevated and splinted to reduce edema, and dry heat should be applied to help redistribute the phenytoin throughout the forearm.
    D. Moist heat is indicated because it can reduce skin breakdown.

12. All of the following statements regarding the treatment for dopamine or other vasopressor extravasation injuries are true *except:*
    A. Phentolamine, which competitively blocks the alpha-adrenergic receptors, is the treatment of choice for vasopressors.
    B. Phentolamine at 0.5mg/mL is most effective if given within the first 12 hours of extravasation.
    C. The use of transdermal glyceryl trinitrate patches has been successful in treating ischemic areas to increase perfusion post extravasation.
    D. Subcutaneous hyaluronidase injection is the treatment of choice.

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Head Pain

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