PA PSRS
Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

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Standardization: Autonomy versus Consensus

On March 1, 2007, I had the privilege to be an invited speaker at the Wellspan Health System Quality Forum. I talked about standardization of medical care. As mentioned by Timmermans and Berg in their book, *The Gold Standard: The Challenge of Evidence-based Medicine and Standardization in Health Care*, there are four types of standards: standard designs, standard terminology, standards for performance, and standard procedures.[1] Standardized procedures produce reproducible outcomes. Standardizing procedures around best known practice produces optimal outcomes.

Having a single way of providing care for a single patient situation makes any deviation or variation from usual practice conspicuous and more likely to lead to correction of the error or, if warranted, refinement of the system. For most problems, the theoretical single best practice is not the same in the minds of every provider. Some consensus must be achieved, usually around the evidence in the literature and the opinions of the experts.

The resulting "best practice" may not be the very best in the minds of all. Physicians, in particular, value the autonomy to treat each patient situation individually. But their question should be "How should I go about providing treatment for 100 patients with the same clinical situation?," not "How should I go about providing treatment for patients with the same clinical situation 100 times?" The difference is subtle, but important. A protocol that is

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Airway Fires during Surgery

Airway surgeries that involve ignition sources to cut or coagulate tissue (e.g., electrosurgical units, lasers*) pose a significant and sometimes deadly risk of fire. Hazards exist when these ignition sources are used in the oxygen-enriched atmospheres (i.e., atmospheres containing more than 23% oxygen [O_2]) that are commonly present in the airway during surgery.[1]

PA-PSRS received three reports, described below, of airway fires in which electrosurgery or electrocautery was used during the reported events. Oftentimes the term electrocautery is used incorrectly to describe electrosurgery.

> *During the procedure to insert a "trach" tube, the surgeon stated "fire." The surgeon was using electrocautery at the time. A flame was noted coming out of the incision site. The surgeon tried to extinguish the flame with a dry sponge. The surgical tech immediately doused the site with sterile saline and wet sponges. Before the tracheal tube was removed, the skin was assessed and no change in skin integrity was noted compared to the preop assessment. The tracheal tube was removed and was noted to be blackened at the distal end. The patient was transported to the intensive care unit and a bronchoscopy was performed, which was negative.*

> *The doctor was opening the trachea with cautery. A flash fire occurred at the site and was immediately extinguished with the doctor's finger, followed by saline. Anesthesia also immediately turned off the gases. The procedure continued. The patient was transferred to SICU in stable condition. The doctor did check the patient with a flexible bronchoscope; no charring or other injury was noted.*

* Other sources of airway fires include electrocautery pencil tip, bronchoscope lights, and fiberoptic light sources.

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Office Location: 539 Forum Building
Harrisburg, PA 17120
Mailing Address: P.O. Box 8410
Harrisburg, PA 17105-8410
Telephone: 717-346-0469
Facsimile: 717-346-1090
Web site: www.psa.state.pa.us
E-mail: patientsafetyauthority@state.pa.us

Standardization: Autonomy versus Consensus (Continued)

designed to do something 100 times the same way should be more robust than a protocol that assumes you will do the same thing 100 times.

Physicians should not think about how they would provide treatment for *a* patient with a particular clinical situation, but about how they would set up a *system* to provide treatment for *every* patient with that same clinical situation. When they think this way, they see that their care will involve other health-care providers in the system. They will need to worry about more than their own behavior. They will need to involve themselves in how the system works to provide consistent care to their patients. They will need to work with the others who are trying to achieve the same objectives of consistently good care. To achieve that objective, they will need consensus, not autonomy.

Note

1. Timmermans S, Berg M. *The gold standard: the challenge of evidence-based medicine and standardization*. Philadelphia: Temple University Press; 2003.

John R. Clarke, MD
Clinical Director
Pennsylvania Patient Safety Reporting System

Query on Clostridium Difficile

PA-PSRS recently received a query from a reader about the article "Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use" that appeared in the June 2005 *PA-PSRS Patient Safety Advisory*. The query involved the efficacy of alcohol-based hand rubs in preventing the transmission of C. difficile (C. diff).

As stated in the article, according to the Centers for Disease Control and Prevention (CDC), gloves are worn when caring for patients with C. difficile (C. diff) diarrhea. After glove removal, hands can be washed with either of two methods: non-antimicrobial or antimicrobial soap and water, or disinfected with alcohol-based hand rub. Either handwashing approach is effective in reducing contamination by the vegetative state of C. diff. Because technique is important in the decontamination process, both handwashing techniques are presented in Figure 1 of the article.

Even during outbreaks of C. diff-related infections, the reason that CDC advises to wash with soap and water after removing gloves is that frequent use of alcohol-based hand rubs may dry the healthcare workers' skin, making it vulnerable to breakdown. However, as also specified in the article, no agent used in antiseptic handwash or antiseptic hand rub preparations is reliably capable of killing the spore form of C. diff. Spores can be physically removed by washing hands vigorously with non-antimicrobial or antimicrobial soap and water. Healthcare workers, therefore, may prefer to use this handwashing method rather than alcohol-based handwashes or hand rubs when C. diff is suspected or diagnosed.

The strategy referred to under the Cleaning/Disinfection section applies to environmental surfaces, rather than to provision of patient care. Environmental surfaces are inhospitable to microorganisms. C. diff., therefore, is more likely to form spores in order to survive on environmental surfaces. Alcohol-based environmental disinfectant cleaning products do not kill these spores.

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Albert L. de Richemond, MS, PE, Associate Director, Accident and Forensic Investigation, ECRI Institute

Michael L. Kay, MD, Kay & Tabas Ophthalmology Associates

Michael R. Rudnick, MD, Associate Professor of Medicine, University of Pennsylvania School of Medicine

Helping the Authority to Help You

In December 2006 and January 2007, the Patient Safety Authority hosted several small discussion groups of Patient Safety Officers (PSOs) from Pennsylvania healthcare facilities. Meetings were held across the state, and a representative group of 26 PSOs participated. The purpose of the meetings was to: give the Authority insight on how PA-PSRS can best help PSOs to improve patient safety, understand PSOs' needs and challenges, and seek feedback on the current and future direction of PA-PSRS.

The Authority benefitted tremendously from an open and thoughtful dialogue with participating PSOs, and the ideas and opinions offered at these meetings have informed the Authority's Board of Directors in their strategic planning. A full report on the discussions, *A Conversation with Patient Safety Officers*, is available on the Authority's Web site.

Among the topics PSOs raised as potential areas for the Authority's assistance are:

- Helping to educate senior administrators and Boards of Trustees in how they can demonstrate leadership in their facilities and promote patient safety
- Augmenting PSOs' limited time and resources by helping to educate front-line clinicians in patient safety
- Clarifying the reporting requirements in the Medical Care Availability and Reduction of Error (Mcare) Act and promoting greater standardization across facilities
- Providing guidance on disclosure of Serious Events to patients

The PSOs participating in these meetings also expressed interest in working with the Authority and with one another in workgroups and collaboratives to address a variety of patient safety initiatives. In a sense, PA-PSRS is itself a large, virtual collaborative. By continuing to report the adverse events and near misses that occur in your facility, you are helping to spread that knowledge through the *Patient Safety Advisory*. In our recent annual survey of PSOs, you and your colleagues throughout the state told us about hundreds of changes you had made as a result of articles in the *Advisory*. You also gave us high marks for the *Advisory*'s quality and relevance.

Yet, we also learned in these discussion groups that there is much more we could do to help you improve the safety of the care you provide. Over time, you should expect to see the Authority providing new opportunities for collaboration across facilities. One example is the PA-PSRS Workgroup on Pharmacy Computer System Safety, in which 32 hospitals tested their pharmacy computer systems against a set of unsafe medication orders, to see if their systems would detect them. Another example is the workshop "Failure Mode and Effects Analysis (FMEA) in Patient Safety," which the Authority is offering in May and June 2007.

We look forward to providing similar programs in the future, and we encourage you to participate in them. As one Patient Safety Officer stated in our discussion group meetings, "Patient safety is probably the one area where we would all agree that we should be cooperating and not competing."

Supplementary *Advisory*

Be sure to refer to the March 30, 2007, Supplementary *PA-PSRS Patient Safety Advisory* for information, resources, and more on the topic "Contrast-Induced Nephropathy: Can This Iatrogenic Complication of Iodinated Contrast be Prevented?" The Supplementary *Advisory* is available online at http://www.psa.state.pa.us.

Correction to the December 2006 *Advisory*

In the December 2006 *PA-PSRS Patient Safety Advisory*, a sentence in the article "Bone Cement Implantation Syndrome" omitted a key phrase. The correct sentence should read, "The process of cementing produces a transient but significant decline in cardiac output and reduction in stroke volume.[26]" The correct December 2006 *Advisory* issue is available online at http://www.psa.state.pa.us.

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Airway Fires during Surgery (Continued)

The patient was in the operating room (OR) for a tracheostomy and peg tube insertion. The incision was made using a scalpel. The physician instructed the anesthetist to remove the tracheal tube. At the point that the tracheal tube was above the carina, "bleeders" were noted by the surgeon. The "bovie" was used to cauterize the "bleeders." A spark was noted and the "bovie" was stopped. Smoke was noted coming out of the tracheal tube. Saline was used to douse the fire. A follow-up bronchoscopy was done. The patient was noted to have some minor redness in the airway.

Figure 1 shows an example of a tracheal tube blackened from an airway fire during a tracheostomy and, for comparison, an exemplar tube.

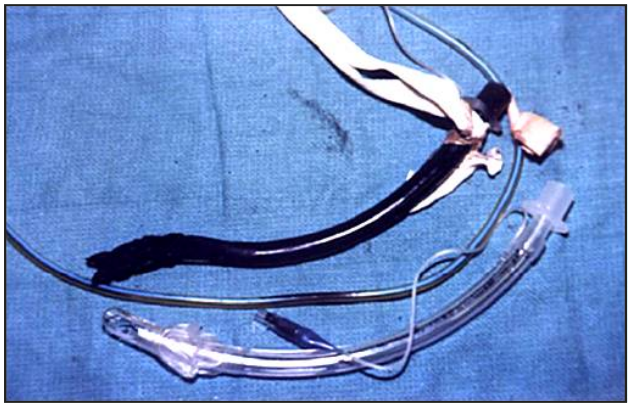

Figure 1. The top tracheal tube (blackened color) was ignited during electrosurgical use to enter the trachea during a tracheostomy. The tube damage is similar to that described in the PA-PSRS reports above, although the photo is not from the reported cases. The bottom tube is an exemplar tube for comparison. Image provided courtesy of ECRI Institute.

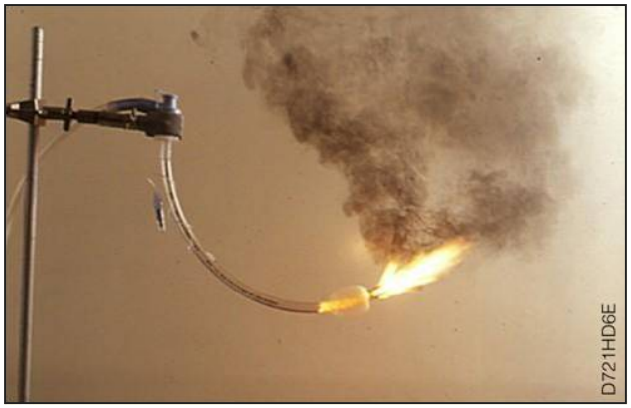

Figure 2. Demonstration of rocket-like flames shooting from a tracheal tube caused by laser ignition of the tube with 100% oxygen flowing. Image provided courtesy of ECRI Institute.

Mechanisms of Surgical Airway Fires

Ignition sources like electrosurgical units or lasers use energy to cut and coagulate tissue, which presents particular risks during airway surgeries. Airway surgeries frequently use oxygen and nitrous oxide to ventilate and anesthetize patients, respectively. Both gases support combustion and reduce the amount of energy (e.g., current, heat, friction) needed to ignite flammable substances. During airway surgery, those gases are present in the airway below a tracheal tube cuff, may leak around the cuff into the oropharynx, or may be present in high concentrations around the face of a patient receiving O_2 via a nasal cannula. This oxygen-enriched atmosphere creates an environment (i.e., lowers the temperature and energy at which fuels ignite) in which some fuels (e.g., tracheal tube) burn more readily and robustly than in room air (i.e., 21% O_2).[1]

Some flammable substances present in the airway during airway surgeries include tracheal tubes, catheters, and surgical sponges. In addition, a portion of tissue heated by an ignition source may turn to gas, especially gases evolved from fatty tissue, which will burn if made hot enough or if mixed with sufficient oxygen. Still other tissue may be reduced to embers. A flare of evolved gases or tissue ember can easily cause flammable substances to catch fire.[1]

A flame, sparking, or arcing is often observed at the surgical site prior to the fire. Usually, surgical staff believe that a malfunction occurred with the electrosurgical unit. However, the flame, sparking, or arcing is the result of accelerated burning of tissue and gases evolved from the electrosurgery. Additionally, an inactive but still hot electrosurgical active electrode or hot laser contact tip can, when in contact, ignite the tracheal tube or sponge leading to fire. In some cases, poor fiber preparation allows the laser energy to ignite the laser fiber sheath, which can then ignite other nearby fuels (e.g., tracheal tubes, bronchoscopes).

The ignition of a standard tracheal tube from a piece of incandescent material, nearby flaming tissue, or laser beam in an oxygen-enriched atmosphere can produce a rocket-like fire, smoke, and hot gases from the tube, which is being infused with gas continuously (see Figure 2). The result can be extensive damage to a patient's air passage and lungs.[2] An orange or red glow from the tracheal tube or a darkening of the breathing circuit is an indication that the tube is on fire.[3] ECRI Institute estimates, based on published accounts and

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Airway Fires during Surgery (Continued)

incidents reported to it, that approximately 21% of surgical fires occur in the airway.[4]

Reducing the Likelihood of Airway Surgery Fires
Ways to minimize airway fires during electrosurgery include the following:[1,4]

- Establish protocols for when electrosurgery will be removed from the surgical field because of risk of fire. For instance, some hospitals remove the electrosurgical unit when the tracheostomy tube is put on the surgical field.
- Do not use electrosurgical units to cut tracheal rings and enter the airway. A hot electrode tip or ember could contact the tube or tube cuff inside the trachea and ignite a fire. Instead, use a "cold" scalpel or scissors to avoid the risk of fire.
- If long, insulated electrosurgical electrode probes are needed to prevent mouth burns during procedures such as tonsillectomies, use only commercially available insulated probes. Do *not* use red rubber catheters or other materials to sheathe probes. The heat from the active electrode will ignite the rubber even in air.
- When operating in the oropharynx, scavenge around the surgical site with separate suction to catch leaking O_2 and nitrous oxide.
- Soak gauze or sponges used with uncuffed tracheal tubes to minimize gas leakage into the oropharynx, and keep them wet.

The delivery of laser energy may present a more serious airway fire risk than electrosurgery (see also the sidebar "Incidents of Airway Fires during Bronchoscopic Laser Surgery"). Laser energy is delivered as a collimated, coherent, monochromatic, directed beam of electromagnetic radiation to cut, coagulate, and vaporize tissue. The delivered power can range from tens of watts (W) to about 120 W for some lasers; however, the power density can be in the tens of thousands of W/cm^2 and, depending on spot size, focal length, and pulse duration, it can create intense heat within a very small area.

Ways to minimize airway fires during laser surgery include the following:[4]

- Limit the laser output to the lowest clinically acceptable power density and pulse duration. Place the laser in standby mode when not in use.
- Allow the laser to be activated only by the person wielding it to minimize inadvertent activation.
- Deactivate the laser and place it in standby mode before removing the laser from the surgical site.

Incidents of Airway Fires during Bronchoscopic Laser Surgery

Since mid 2006, ECRI Institute received six reports of airway fire during bronchoscopic laser surgery.[1] In each case, the fiber optic laser probe tip ignited in an oxygen-enriched atmosphere, and the resulting fire caused extensive airway injury.

A laser fiber is typically a slender glass fiber coated with a reinforcing plastic sheath. During use, the fiber tip may need to be refurbished because of damage or because of its initial condition. This refurbishment is called cleaving and stripping, and it involves several steps to insure a good fiber tip. The glass fiber must be scored and carefully broken at the score to produce a flat, circular fiber tip. The plastic sheath must be stripped from the fiber to expose several millimeters of the glass fiber and remove flammable material near the tip. The tip must be checked for proper transmission by either fiber calibration or aiming beam circularity; a round aiming beam spot without rays, commas, or halos indicates a good tip.

An improperly refurbished tip can cause the glass fiber to heat at the tip during laser emission. If the plastic sheath is close to the hot tip, the plastic will melt, ignite, and burn, especially in oxygen-enriched atmospheres. Should this occur, the burning plastic sheath can ignite the nearby bronchoscope components and tracheal tube. Rapid removal of all the burning materials can minimize the patient injury; delay or stepwise removal of the instruments can lead to severe patient injury or death.

Preventing such fires requires a properly prepared fiber tip and the lowest O_2 concentration possible at the point of laser use. This can be achieved by delivering air only for a short time before (e.g., 60 seconds) and during laser use. Elevated O_2 levels to maintain the patient can be delivered at other times when the laser will not be used.

Note
1. PA–PSRS. Conversation with: ECRI Institute. 2007 Feb 5.

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Airway Fires during Surgery (Continued)

- During lower-airway surgery, keep the laser fiber tip in view and make sure it is clear of the end of the bronchoscope or tracheal tube before laser emission.

- Use appropriate laser-resistant tracheal tubes during upper-airway surgery. Follow the directions in the product literature and on the labels, which typically include information regarding the tube's laser resistance, use of dyes in the cuff to indicate puncture, use of saline fill to prevent cuff ignition, and immediate replacement of the tube if the cuff becomes punctured.

Fighting Airway Fires

Under general anesthesia, a patient is mechanically ventilated and lacks sensation; as such, hot gases can be forced deep into the lungs, causing extensive damage or death. Immediate action is required by the surgical team to reduce the extent of the damage. The guidance below can help clinicians to develop a procedure for extinguishing airway fires.[4] (Note, perform steps 1a and b as rapidly and simultaneously as possible.) Such a procedure should be reviewed prior to each surgical intubation.

1a. Stop the gas flow.
   — Disconnecting the breathing circuit is the quickest way to stop the gas flow. By removing the source of oxygen and nitrous oxide from the airway, the fire's intensity is significantly reduced and may self-extinguish.

1b. Remove the tracheal tube, and maintain airway patency.
   — To minimize thermal and chemical damage to the airway, quickly remove the tracheal tube from the patient. The intense heat from the O_2-fed fire will remain in the mass of the tube and can still harm the patient even if the fire is out; the fire can reignite if oxygen flow is restored. Additionally, remove cuff-protective devices or any segments of burned tube that may remain smoldering in the airway.

2. Extinguish the fire.
   — A smoldering or glowing tube can ignite surgical drapes or gowns. OR personnel other than the anesthesiologist should extinguish the tube with water or saline in a basin or sink, or with a wet towel. Be wary of using any flammable liquids (e.g., alcohol) that may be near or in the surgical field to extinguish the fire. Liquids in the OR should be clearly labeled to avoid mix-ups. (For more information on labeling liquids see the article "Danger Associated with Unlabeled Basins, Bowls, and Cups" in the March 2005 *PA-PSRS Patient Safety Advisory*.) Save the tube and other relevant materials for later examination.

3. Care for the patient.
   — Reestablish the airway and resume ventilation with air until absolutely nothing is burning in the throat; then switch to 100% O_2. Some smoke and gases from the tracheal tube fire can cause chemical burns or toxic reactions. Examine the airway for the extent of damage and treat the patient accordingly. A rigid bronchoscope and forceps should be readily available during all tracheal surgery. Procedures such as lavage and suction to remove soot and particles in the airway, excision of burned tissue and melted material, or a tracheostomy may be necessary.

Visit the Patient Safety Authority Web site (http://www.psa.state.pa.us) to view or download a poster based on this article.

Click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Then, click on "Resources Associated with Patient Safety Articles."

Notes

1. ECRI Institute. Electrosurgical airway fires still a hot topic. *Health Devices* 1996 Jul;25(7):260-2.
2. ECRI Institute. Airway fires: reducing the risk during laser surgery. *Health Devices* 1990 Apr;19(4):109-10.
3. ECRI Institute. Fighting airway fires. *Healthcare Risk Control* 1996 Jan;4:Surgery and anesthesia 10:1-2.
4. ECRI Institute. Surgical fire safety. *Health Devices* 2006 Feb;35(2):45-66.

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Safety in Using Promethazine (Phenergan)

First approved by the U.S. Food and Drug Administration (FDA) in 1951, promethazine (Phenergan) is a medication in common use today. However, despite its familiarity, its use is not without risks. In particular, reports submitted to PA-PSRS illustrate that patients in Pennsylvania are being harmed when promethazine is prescribed intravenously.

The Drug

Promethazine is a phenothiazine derivative that possesses histamine H1-blocking, anti-muscarinic, sedative, antimotion sickness, anti-emetic and anticholinergic effects. Indications for promethazine include the amelioration of allergic reactions to blood or plasma or, after acute symptoms have been controlled, as an adjunct to epinephrine and other standard measures in anaphylaxis. Other uses include sedation, relief of apprehension, active treatment of motion sickness, and prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery. It is also used in surgical situations (e.g., repeated bronchoscopy, ophthalmatic surgery) with reduced amounts of meperidine or other narcotic analgesic as an adjunct to anesthesia and analgesia. Its clinical effects are apparent within five minutes of an intravenous (IV) injection.[1,2] The duration of action is 4 to 6 hours, although effects may persist up to 12 hours.

Promethazine is formulated with phenol and has a pH between 4 and 5.5.[3] Although manufacturers' product labeling refers to promethazine as an irritant drug, some sources consider it a lesser-known vesicant that can be highly caustic to the intima of blood vessels and surrounding tissue.[2,4-7] Although deep intramuscular injection into a large muscle is the preferred parenteral route of administration, promethazine's product labeling states that it may be given by slow IV push, which is the typical method of administration in most hospitals.[8]

The Risks

Because of its longstanding use, clinicians have grown comfortable with promethazine despite its serious risks.[3] There have been numerous reports submitted to PA-PSRS regarding severe, tragic or local injuries after infiltration or inadvertent intra-arterial injection. These types of injuries include the following: tenderness at intravenous site, burning, erythema, pain, induration, edema, severe spasm of vessels, venous thrombosis, nerve damage, paralysis, abscess, tissue necrosis, and gangrene.[5] Use of promethazine can result in severe tissue damage, regardless of the route of parenteral administration, although IV and inadvertent intra-arterial or subcutaneous administration results in more significant complications, including arteriospasm and the potential for gangrene.[8] There have been cases that required surgical intervention, including fasciotomy, skin graft, and even amputation.

While the extent of this problem is unknown, numerous reports submitted to PA-PSRS and the United States Pharmacopeia-Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (MERP); articles in professional literature; news of lawsuits in the media; and communications on various Internet listservs and message boards suggest that patient harm may be occurring more frequently than previously recognized.[8] Three examples from PA-PSRS include the following:

> *Following a dose of Phenergan for nausea, the patient voiced complaints of IV site pain, which was red upon inspection and very tender to touch. The follow-up call, one week after discharge, revealed continued pain at the site with darker discoloration and difficulty holding onto things.*
>
> *One hour following an IV injection of Phenergan, the patient stated her left arm felt tight. Upon inspection, the patient's left hand was larger than the right, and swelling and small blisters were noted on her hand seven hours later. The following morning, her entire arm was swollen. Patient was discharged but was readmitted three days later with edema and pain in her left arm and with blackened fingertips. Her treatment is ongoing.*
>
> *A postoperative patient returned to the inpatient unit with left-hand discoloration and complaints of tingling in her arm; her fingers and palm became purple and cool to touch, shortly after receiving Phenergan IV in the recovery room. Several days later, the hand swelling subsided; the hand was less tender, without tingling, and the patient improved.*

Similar cases have also been reported to MERP. In one example, a 19-year-old woman went to the emergency department (ED) with flu-like symptoms and received the branded drug Phenergan IV. During the injection, she complained of pain in the arm that received the medication, and was tempted to pull out her IV line. After the injection, she continued to experience arm pain and said that "something was wrong." Later, the patient's arm and fingers

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Safety in Using Promethazine (Phenergan) (Continued)

became purple and mottled (see Figure 1). The patient remained in the hospital for 30 days, during which she developed gangrene and required the amputation of several fingers.[8,9]

Another patient received 12.5 mg of promethazine into an IV site in the hand. During the injection, the patient complained of extreme burning, but the nurse continued administering the medication. The patient developed an area of necrosis on his hand, eventually requiring skin grafting and physical rehabilitation.[10] (See Figure 2.)

Figure 1. Woman Develops Gangrene after Receiving Phenergan IV. Image provided courtesy of ISMP.

Figure 2. Promethazine Extravasation Causes Gangrene in Man's Fingers. Image provided courtesy of ISMP.

Safe Practice Strategies

According to the promethazine package insert, "Proper IV administration of this product is well tolerated, but use of this route is not without some hazards."[4,10] It should be administered cautiously and it requires monitoring as some of its side effects may not be apparent for several days. To reduce the risk of these hazards, manufacturer labeling recommends the following:

- Give the drug in concentrations no greater than 25 mg/mL.
- Administer the drug at a rate no greater than 25 mg/minute.
- Inject the drug through the tubing of an infusion set that is running and known to be functioning satisfactorily.
- If the patient reports burning at the injection site, stop the IV immediately to evaluate for possible arterial placement or perivascular extravasation.

In April 2006, FDA issued an alert and black box warning for use of promethazine in children younger than two years of age, as it has been associated with cases of breathing problems, which sometimes resulted in death.[11] In addition, caution should be exercised in giving promethazine in any form to children age two and older. The labeling on all brand name and generic products has been changed to reflect these strengthened warnings. Promethazine is also contraindicated for patients in comatose states and those who have demonstrated an idiosyncratic reaction or hypersensitivity to promethazine or other phenothiazines.

Sharing the following safe practices in using promethazine with physicians, pharmacists, and nurses may facilitate discussion. While these suggestions may not be feasible in every facility, they can assist with the evaluation of current practices. Along with the manufacturer recommendations, the following strategies may help to prevent or minimize tissue damage when giving IV promethazine:[1,4,5,8,9-13]

- Do not stock promethazine in concentrations greater than 25 mg/mL, because this is

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Safety in Using Promethazine (Phenergan) (Continued)

the highest concentration of promethazine recommended by the manufacturer to be given IV.

- Limit the dose, especially for elderly patients, and consider 6.25 to 12.5 mg of promethazine as the starting IV dose. Hospitals have reported that these smaller doses have proven quite effective.

- During preparation, dilute the 25 mg/mL concentration to reduce promethazine's vesicants effects and enable slow administration. For example, dilute the drug in 10 to 20 mL of normal saline if it will be administered via a running IV, or prepare the medication in minibags containing normal saline if there is time for pharmacy to dispense them as needed for individual patients. Extravasation can also be recognized more quickly when promethazine is diluted than if the drug is given in a smaller volume.

- Administer the medication through large patent veins (i.e., preferably via a central venous access site, absolutely no hand or wrist veins).

- Check the means of administration. According to the package insert, aspiration of dark blood does not preclude intra-arterial placement of the needle because blood can become discolored upon contact with promethazine. Use of syringes with rigid plungers or small bore needles might obscure typical arterial backflow if this is relied upon alone.

- Administer IV promethazine slowly over 10 to 15 minutes.

- Revise preprinted order forms to ensure orders for promethazine reflect the safety measures listed above.

- Educate patients before administration of the drug. Request patients to immediately alert caregivers to burning or pain sensations during or after the injection.

- Build an alert to appear on computer-generated medication administration records (MARs), electronic MARs, and on automated dispensing cabinet screens for nurses to view each time they access and administer a dose of promethazine. This alert would serve to remind nurses that the drug is an irritant (lesser-known vesicant) and should be diluted and administered slowly through a running IV.

- Treat all promethazine extravasations and although the manufacturer notes there is no proven successful management of unintentional intra-arterial injection or perivascular extravasation, sympathetic block and heparinization have been employed during acute management of promethazine extravasations.

Alternatives	
Ondansetron (Zofran)	an antiemetic, 5HT3 receptor antagonist
Prochlorperazine (Compazine)	an antiemetic, phenothiazine
Metoclopramide (Reglan)	GI stimulant, an antiemetic
Dolasetron (Anzemet)	an antiemetic, 5 HT3 receptor antagonist
Granisetron (Kytril)	an antiemetic, 5HT3 receptor antagonist
Droperidol (Inapsine)	an antiemetic, anesthesia adjunct
Trimethobenzamide (Tigan)	an antiemetic
Alternative route of promethazine	i.e., suppository, IM, compounded topical gel
Diphenhydramine (Bendaryl)	an antihistamine, antidyskinetic, antiemetic, sedative-hypnotic
Hydroxyzine (Vistaril)	an antihistamine
Dexamethasone (Decadron)	an anti-inflammatory, antiemetic, immunosuppressant
H2-receptor antagonists	i.e., ranitidine (Zantac), famotidine (Pepcid)
Lorazepam (Ativan)	a benzodiazepine, sedative-hypnotic, antianxiety, antiemetic
Haloperidol (Haldol)	an antipsychotic, antiemetic
Nalbuphine (Nubain)	a narcotic analgesic, anesthesia adjunct
Zolmitriptan (Zomig)	an antimigraine, Serotonin Receptor Agonist, 5HT1

Table 1. Alternatives to IV Promethazine. The table lists alternatives to IV promethazine, in descending order of frequency, used by respondents to an Institute for Safe Medication Practices survey.[10]

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Safety in Using Promethazine (Phenergan) (Continued)

- Consider using safer alternatives with fewer drug interactions for the various conditions treated with IV promethazine. For example, 5-hydroxytryptamine type 3 (5-HT3) receptor antagonists may be used for both prophylaxis and as a rescue antiemetic. See "Table 1. Alternatives for IV Promethazine."

Conclusion

While all medications have risks and benefits, the safety of using promethazine must be considered. It should be administered and closely monitored for immediate and delayed side effects, which may not be visible for several days. It is very important that physicians, pharmacists, and nurses understand promethazine's risks because complications can be identified sooner and averted. Further, remedial interventions can be initiated so the extent of damage can be minimized. Incorporating these safe practice strategies proactively can help to reduce the risk of using promethazine.

Notes

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Abbreviation "Gotchas"

As discussed in previous *PA-PSRS Patient Safety Advisory* issues, PA-PSRS reports abound with occurrences involving misunderstanding of abbreviations. Here's another example of an abbreviation that caused a patient to receive an unintended intervention.

A physician wrote an order for "HCT," a common abbreviation for "hematocrit." The staff transcribed and entered hematocrit for the morning. The physician, however, wanted the patient to receive a CT scan of the head. Because the physician used what the factility's report identified as an unapproved abbreviation, the patient had blood drawn, but did not receive the CT scan.

If healthcare providers use facility-approved abbreviations, patients are more likely to receive interventions as intended on a timely basis.

Have you identified other abbreviations that have been open to misinterpretation or have multiple interpretations? If so, let us know by e-mailing your experience to PA-PSRS at support_papsrs@state.pa.us. PA-PSRS will publish these abbreviations in the "Abbreviation 'Gotchas'" box in future *Advisory* issues.

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Baxter Colleague Volumetric Infusion Pump: Product Recall Notifications

Bioengineering Corner

PA-PSRS has received reports describing stopped infusions of the Baxter Colleague series infusion pumps. Most reports did not indicate the cause of the stopped infusion. However, one report described a pump that was hot to the touch and that leaked clear fluid from the pump; two reports described pump failures during patient transport, specifically due to low or "dead" batteries; and two reports described pumps not infusing, possibly due to low battery conditions (for additional information, see the PA-PSRS reports below). There were no reported patient injuries.

While the causes of the unanticipated stopped infusions may be due to random malfunctions of the pumps or batteries that were not fully charged, Baxter has issued product recall notifications based on similar battery-related circumstances. The fact that PA-PSRS has received reports of previously documented problems related to the Colleague series pumps suggests that steps intended to address these problems may not have reached all clinical settings or facilities. Healthcare facilities experiencing repeated battery-related problems with the Colleague series infusion pumps may not associate the events with a potential systemic battery problem as outlined in the product recall notifications described below. Additionally, understanding proper battery management will help reduce some infusion pump failures.

This article focuses on the product recall notifications related to events reported to PA-PSRS; however, a number of product recalls have been issued for the Colleague pumps for other reasons, some of which led to the U.S. Food and Drug Administration (FDA) seizure of some Colleague infusion pumps. For more information, see the sidebar "Baxter Colleague Volumetric Infusion Pump Recall: Background behind FDA's Seizure."

Five PA-PSRS Report Event Descriptions

The pump alarmed failure and stopped. The roller clamp was closed on the tubing, (MSO_4 infusing), by nurse. The pump was hot to the touch, odor was present, and clear fluid was leaking from the machine. Once the pump was disconnected and removed, the odor went away. The IV tubing was examined for any leakage, but none was found. The patient was aroused easily. The patient was alert and oriented. Vitals were 110-120 systolic, PO was 98%, and no respiratory distress was noted. The pump was removed from service and sent to biomedical. A new pump was applied.

After unplugging the IV pump for patient transport, the pump failed. The battery for back up was dead.

The patient was to return from CT scan, the pump alarmed "Battery" upon disconnection from the wall outlet. The pump was plugged into the wall outlet while waiting for the elevator. The pump again alarmed "Battery" after getting off elevator. The patient was rushed to the room, and the pump was plugged in but it was not delivering medication. The patient was returned to baseline assessment with increased BP as medication was transferred to another IV pump.

Triple IV pump failure reading low battery upon being plugged in all day. The pump failure occurred while in use for patient care. [Shut off] would not turn back on.

Staff found IV integrilin not infusing on Baxter pump. The pump was not on or plugged in. The Baxter pump was low when turned on and plugged in.

Baxter Colleague Recall Notifications

The report describing fluid leaking from the pump may be related to a Baxter recall notification of long-term exposure to fluid. Fluid that enters Colleague monochrome-display infusion pumps either during cleaning or after spilling a significant amount of IV solution could contact the ribbon cable behind the keypad, degrading the cable and causing a malfunction of the power "on/off" circuitry.[1] On January 11, 2002, Baxter issued a recall by an Urgent Device Correction letter to Colleague users regarding unexpected "power on" or "power off" without a key press if fluid enters the main body of the pump after long-term exposure.

To remedy the problem, Baxter made available an insulator to be placed in the area of the ribbon cable to prevent fluid from contacting the cable. In the interim, Baxter provided the following information to users to prevent the malfunction from occurring:

- Do not spray cleaning fluid onto the body of the pump or submerge the pump for

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Baxter Colleague Volumetric Infusion Pump: Product Recall Notifications (Continued)

cleaning. Following the recommended cleaning instructions, cleaning fluid should not enter the pump.

- Use the panel-lockout feature as recommended in the Colleague user manual as a standard procedure during infusions. Pressing the panel-lockout button on the rear of the pump will enable this feature. When the panel lockout feature is enabled, all inputs from the on/off key are ignored, and the malfunction described above should not occur. If it does occur, an alarm will activate to notify the user. Alternatively, enabling the autolock feature in the configuration settings of the pump results in automatic setting of the panel-lockout two minutes after the start of an infusion.

- If a pump becomes exposed to excessive fluid, remove it from use and contact Baxter to schedule service.

- Remove from service any Colleague pumps that are reported to show this on/off problem or similar behavior.

- Install the protective insulator at the location of the ribbon cable. The insulator and instructions are provided at no charge to users. To obtain the insulator and instructions, contact your local Baxter representative. NOTE: Because the correction letter was issued in 2002, any affected pumps may already have the insulator installed. Contact your facility's Biomedical or Clinical Engineering departments or Baxter to determine if the insulator is installed in your pumps.

All of the aforementioned PA-PSRS reports may be related to battery issues described by Baxter in several of the following recall notifications:

January 21, 2003. Baxter issued an Important Product Information letter to Colleague users describing pumps that could become hot to the touch because the pumps' lead-acid batteries (i.e., two batteries per pump) swell as they near the end of their useful life. Batteries swelling could also cause internal pump damage.[2] In the letter, Baxter also provided the following information:

- The procedure for replacement, service life, and storage conditions of the sealed

Baxter Colleague Volumetric Infusion Pump Recalls: Background behind FDA's Seizure

Baxter has marketed the Colleague series volumetric infusion pumps since the late 1990s. Since 1999, the Colleague series pumps have encountered various problems requiring modifications. Early reported problems included software errors, pump motor failures, premature battery failures, failures of one channel in the triple channel Colleague pumps that would cause all three channels to stop operating, and random failure codes.[1] During the past few years, the Colleague series infusion pumps have been involved in a number of product recalls for various problems causing pumps to stop infusing. Due to continuing problems with the Colleague series pumps, in late 2005, the U.S. Food and Drug Administration (FDA) seized approximately 6,000 Baxter-owned Colleague infusion pumps.[2] The seizure did not affect customer-owned Colleague pumps.

On October 13, 2005, Baxter issued a press release regarding FDA's seizure of Colleague infusion pumps. FDA stated that the Colleague pumps have a design defect that may cause pumps to stop infusing, that the seized pumps were not manufactured under proper controls, and that Baxter failed to inform FDA of Colleague infusion pump failures. FDA believes that interruption in infusion therapy could result in serious injuries or death to critically ill patients dependent on continuous and/or life-sustaining medications.[2]

In a field correction letter dated July 20, 2005, Baxter identified a problem with the pump's clocking circuit as a source of the stopped infusions, which contributed to the FDA seizure. The clocking circuit can generate random failure codes, which could disrupt internal communications. Failure codes that could appear are 402, 403, 532, 533, 534, 535, 599, 702, 703, 704, 804:21, 804:22, 804:29, 804:34, 04:52, 804:58, and 12:303:xxx:0006. If any of these codes appear, the pump will alarm and stop infusing.[3]

Perspectives on the Colleague Recalls and Seizure

The effects of the above Colleague pump failures result in stopped infusion and alarm notification, which would alert clinicians to initiate an appropriate response. The result would be no different than a pump stopping an infusion and alarming because it detected a true air-in-line or occlusion condition; when a pump stops in such a manner, it is considered to be failing in a "safe" manner.

Additionally, the failure codes listed above are not exclusive to the clocking circuit failure. A pump exhibiting one of the related codes does not necessarily mean a clocking circuit failure occurred. Therefore, pumps with clocking circuit

(Continued on page 13)

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Baxter Colleague Volumetric Infusion Pump: Product Recall Notifications (Continued)

lead-acid batteries used in the pumps and indicated that for Colleague single-channel monochrome-display pumps with software below version 4.02, a software upgrade (version 4.02 or greater) was issued in September 2001—during a 2001 retrofit, a second battery was added to the pump's design—to allow the pumps to interface with the two-battery configuration. (Note: Since the product information letter was issued in 2003, your facility's pumps may already have been upgraded to software version 4.02 or greater. Checking with the facility's biomedical or clinical engineering departments or the local Baxter representative will help to determine if the upgrade has been completed.)

- Only the Yuasa NP2-12 (part no. UBAT1010.A) battery brand was approved by Baxter for use in the Colleague series pumps. Additionally, Baxter discovered that Ray-O-Vac batteries (Ray-O-Vac batteries were installed in Colleague pumps prior to September 2001) used in the pumps were more susceptible to swelling and recommended that all Ray-O-Vac batteries be removed from the pumps and replaced.

- Baxter also recommended replacing both batteries at the same time with two new batteries. Swelling could be prevented by replacing both batteries before their end of useful life and by following good battery-charging and pump-usage patterns. Baxter stated that a lead-acid battery has 68 or more full discharge/recharge cycles during its service life. The more often the battery is cycled, the sooner it needs to be replaced. Baxter also stated that normal ambient room conditions of 30°C/86°F or lower make for ideal storage conditions. Pumps that are plugged into AC power receptacles or batteries that are fully charged during storage in higher temperatures will reduce the likelihood of battery damage. Regardless of the ambient temperature, pumps should be plugged into AC power during storage to maintain the batteries at full charge. If any pumps are hot to the touch, remove the pumps from service and inspect the batteries as soon as possible.

Baxter Colleague Volumetric Infusion Pump Recalls: Background behind FDA's Seizure (Continued)

failures would not be any more unsafe than other pumps. An exception to this is a case in which the battery is damaged due to excessive deep discharges and the pump is operating on battery power. In this case, the pump may not have enough battery power to operate for as long as expected; for example, a pump operates for only 5 minutes after the first low-battery alarm activates instead of the 30 to 60 minutes expected from a properly operating pump. In this situation, a clinician might miss the alarm condition if he or she believes that the pump shut down without alarming.

In January 2006, Baxter issued a letter to Colleague users regarding ongoing corrective actions to address the clocking circuit problem. In May 2006, Baxter submitted an amended 510(k) package to FDA for a permanent hardware solution for the clocking circuit problem. In a June 2006 letter, Baxter announced a consent decree agreement with FDA on the sale of Colleague pumps in the United States (i.e., Baxter-owned pumps in the distribution system, not pumps in clinical use). Baxter agreed to stop manufacture and distribution of Colleague pumps in the United States until the firm can ensure that the devices comply with Good Manufacturing Practices (GMP) requirements. The agreement allows Baxter to continue to perform routine maintenance and to replace components, parts, and accessories for the pumps that were distributed to customers before October 12, 2005.[4] Subsequent to the consent decree, Baxter retracted the amended 510(k) submission.

In December 2006, Baxter announced that FDA issued conditional approval for the Colleague pump corrective action plan and that an updated 510(k) filing was submitted to FDA. On February 27, 2007, FDA and Baxter announced that Baxter received 510(k) clearance for the modified Colleague infusion pumps that addresses the problems that resulted in FDA seizure of the pumps.[5]

Notes

1. ECRI Institute. Baxter Colleague family of pumps has required numerous modifications [evaluation]. *Health Devices* 2002 Oct;31(10):377.
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4. ECRI Institute. Baxter—Colleague and Syndeo infusion pumps: following device seizures by FDA, Baxter signs consent decree. *Health Devices Alerts* 2006 Aug 11. [update] Action Item Accession No. A7510.
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Baxter Colleague Volumetric Infusion Pump: Product Recall Notifications (Continued)

February 25, 2005. Baxter issued an Important Product Information letter with supplemental information to the January 21, 2003, letter. According to the supplemental letter, Colleague infusion pumps with serial numbers 13120001CS, 13110181CC, 13120001CT, 13110338TC and higher were manufactured with an overcurrent protection circuit in the battery harness to help protect the batteries from overcurrent damage and swelling during charging. For pumps with serial numbers below those listed above, Baxter made the new battery harness available to replace harnesses without the overcurrent protection.[3] If applicable, checking with the facility's biomedical or clinical engineering departments or the local Baxter representative will help determine if the new harness was installed.

Baxter also offered the following information on excessive battery discharge:

- Damaging discharges may occur when the pump is left on battery power for an extended period after the "Battery Depleted" alarm occurs.
- When the batteries become damaged due to excessive discharge, the battery indicator will overstate the amount of charge remaining.
- While in "Battery Low" alert, a properly maintained battery will provide approximately 30 minutes of infusion time. Plugging the pump into an AC power receptacle when the "Battery Low" alert occurs will restore a battery's charge. Damaged batteries do not impact the pump's ability to function properly while operating on AC power, provided that no other failures or alarm conditions are present.
- The battery and pump history service screen will identify the number of discharges below the alarm threshold. If more than one excessive discharge is listed in the battery history log, Baxter recommends testing or replacing both batteries. Battery test and installation instructions can be found in the Colleague pump service manual.

December 13, 2005. In an Urgent Device Correction letter, Baxter identified a battery undercharging condition with the Colleague series pumps.[4] Baxter stated that if the batteries are not charged continuously for 12 hours after a "Battery Low" alert or a "Battery Depleted" alarm occurs, the remaining operating time of the pump after a subsequent "Battery Low" alert may be less than 30 minutes. The subsequent "Battery Low" alert will be followed by both an audible and visual notification of a "Battery Depleted" alarm stopping the infusion therapy. According to Baxter, following the charging instructions listed in the Colleague pump user manual will help avoid interruption or stoppage of therapy, loss of configuration memory, and/or device failure.

Maintenance Strategies

Without additional information, we cannot be certain the reports to PA-PSRS described above are directly related to these product recall notifications, but the potential connection warrants concern. Healthcare facilities may find the following general strategies useful in properly maintaining Baxter Colleague infusion pumps:

- Identifying whether the facility uses Baxter Colleague infusion pumps.
- Searching the facility's PA-PSRS reports to identify cases related to the Colleague pumps.
- Screening those cases to identify reported problems similar to the ones outlined in this article.
- If reported problems are similar to the ones outlined above, contacting the facility's biomedical or clinical engineering departments or the local Baxter representative to determine if any related product recall notifications exist and have been addressed for suspect pumps.
- If recall notifications have not been addressed, coordinating with the facility's biomedical or clinical engineering departments or Baxter to resolve the problem.
- Following the battery management guidelines discussed in this article and in the Colleague pump user manual.

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Baxter Colleague Volumetric Infusion Pump: Product Recall Notifications (Continued)

Notes

1. ECRI Institute. 13215 infusion pumps, general-purpose. *Health Devices Alerts* 2002 Feb 15. Action Item Accession No. A4598.
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What's New in MRI Hazards?

Two issues have recently come to light concerning magnetic resonance imaging (MRI) hazards. The U.S. Food and Drug Administration (FDA) has received reports of patients with second- and third-degree burns on skin under electrocardiogram (EKG) electrodes attached to cables. These burns were noted after the patients underwent MRI. Some burns were serious enough to require plastic surgery.[1]

Even if the EKG electrodes and cables are MRI compatible, radiofrequency fields occurring during MRI may heat the electrodes to the point where they produce burns on patients. This is more likely to occur when the electrodes are not in complete contact with the skin surface. The resulting air gap disrupts the electrical pathway, producing a build-up of heat at the electrode's center or a current arc from the electrode to the skin.[1]

Another hazard was identified in a report recently submitted to PA-PSRS. An MRI procedure was immediately discontinued when a metal artifact was noted on the images. Upon further patient interview, it was discovered that the patient had previously undergone a procedure involving ingestion of a PillCam™ (i.e., capsule endoscopy). The PillCam had not passed from the patient's gastrointestinal system prior to the MRI. The MRI was stopped before the patient sustained any injury.

Patient Safety Strategies

The following tips may reduce the risks associated with these hazards.

- Include on an MRI screening checklist questions concerning the following:
  - PillCams: date of use; date passed from gastrointestinal system
  - Electrodes/cables: whether MRI compatible; methods used to completely affix to skin
- During the MRI, closely observe the images for unexpected metal objects, and immediately stop the procedure if such objects are noted on the images.
- Use MRI-compatible electrodes and cables.[1]
- Do not use electrodes after their expiration date.[1]
- Search in clothing, sheets and covers, and on the patient for electrodes and cables and remove these devices when they are no longer needed for patient monitoring.[1]
- Affix electrodes completely to the skin surface by drying the area, removing excess hair, and avoiding air gaps.[1]
- Do not loop cables; keep a blanket between the patient's skin and cables.[1]
- After the MRI, assess the patient for skin integrity issues at electrode sites.[1]
- If a burn/injury occurs:[1]
  - Treat according to prescriber's orders.
  - Document the occurrence in the medical record.
  - Report to/notify appropriate departments of the occurrence.
  - Sequester the equipment involved, according to facility policy, for evaluation by biomedical engineering department and/or the manufacturer.

Note

1. U.S. Food and Drug Administration Center for Devices and Radiological Health. Cables and electrodes can burn patients during MRI. MRI Device Safety [online]. 2006 Nov 22 [cited 2006 Nov 22]. Available from Internet: http://www.fda.gov/cdrh/medicaldevicesafety/tipsarticles/electrodes.html.

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Take Steps to Avoid Inadvertent IV Administration of Nimodipine Liquid

Nimodipine (Nimotop), a calcium channel blocker, is indicated to reduce the incidence and severity of ischemic deficits in patients with subarachnoid hemorrhage from ruptured intracranial aneurysms.[1] It improves neurological outcome by relaxing cerebral smooth muscle vasculature and preventing vasospasm. The drug is available in a soft gelatin capsule and is normally given orally. However, the inadvertent intravenous (IV) administration of Nimotop has lead to serious patient harm and death.

The manufacturer notes in the nimodipine product labeling that for patients who are unable to swallow, doses can be prepared by extracting the liquid contents of the capsule into a syringe with an 18-gauge needle, administering it via the nasogastric (NG) tube, and flushing with 30 mL of 0.9% saline.[1] However, this procedure is potentially dangerous. Several reports have been submitted to PA-PSRS as well as national reporting programs documenting events in which the nimodipine was drawn into a parenteral syringe and accidentally given intravenously, resulting in severe hypotension, cardiovascular collapse, and cardiac arrest.

For example, a report submitted to PA-PSRS describes the following situation:

> *A patient presented to the hospital with hypertension, malaise, and a headache. A CT scan revealed a large sub-arachnoid bleed, but an angiogram did not demonstrate an aneurysm. Subsequently, the patient suffered a decreased level of consciousness and was intubated. The patient was ordered nimodipine to be administered via a NG tube. A nurse withdrew nimodipine from the capsule using a parenteral syringe and needle. The nurse gathered up this syringe with a collection of other syringes to take to the patient's bedside for administration. The nurse did not separate this syringe from the others and inadvertently administered the nimodipine IV push instead of via the NG tube. The patient suffered a hypotensive event, and his blood pressure fell from 170 to 70 before it slowly recovered to the 130s during the next half hour.*

Similar events have been reported to the United States Pharmacopeia-Institute for Safe Medication Practices Medication Errors Reporting Program (MERP). In one case, a patient was given the contents of a nimodipine capsule via the IV route, resulting in severe hypotension, cardiovascular collapse, and cardiac arrest.[2] Another report involved a pharmacy that dispensed nimodipine capsules to nursing units.[3] The pharmacists were unaware that the capsules were to treat patients who could not swallow and thus did not provide instructions on how to prepare the capsule contents for feeding tube administration. For one patient, a nurse softened the gelatin capsule in hot water and subsequently withdrew the medication into a parenteral syringe. In the chaos of the shift, the dose was administered IV instead of via the feeding tube. The nurse immediately noticed the error and tried unsuccessfully to withdraw the drug from the IV tubing. Unfortunately, the patient decompensated almost immediately and subsequently died.

Due to the number of harmful adverse drug events involving IV administration of nimodipine, the U.S. Food and Drug Administration (FDA) required the manufacturer to add a boxed warning to nimodipine's labeling to warn clinicians about medication administration errors with this product. In addition, FDA posted to its Web site a patient safety video titled "Caution on Accidentally Giving Nimodipine (NIMOTOP) Intravenously."[4] An alert on FDA's Web site and a "Dear Healthcare Professional" letter announced these changes.[5,6]

To prevent errors associated with the accidental injection of oral nimodipine in patients who are unable to swallow, facilities should consider some of the following:

- Use an oral syringe to administer the liquid contents of nimodipine capsules (and all other oral liquid medications) because oral syringes are typically incompatible with IV access ports. (While some NG tubes have a connection that is not compatible with an oral syringe, others are available with a suitable port that is compatible. Therefore, investigate the style of NG tube before implementing this procedure, or nurses may have to empty the oral syringe into a parenteral syringe, thus defeating this safety measure.) After administration, flush the NG tube with 30 mL of 0.9% saline.

- Consider having pharmacists prepare oral liquid nimodipine in oral syringes labeled "For ORAL use only." In the pharmacy, a parenteral syringe can be used initially to extract the liquid inside the capsule, but the liquid should always be transferred to an oral syringe before dispensing.

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Take Steps to Avoid Inadvertent IV Administration of Nimodipine (Continued)

- Consider having pharmacists prepare nimodipine oral syringes in batches. Nimodipine liquid extracted from capsules, stored in amber oral syringes and placed in light-protected bags is stable at room temperature for 31 days.[7] Each amber oral syringe can be given a "use by" date of 30 days from production and be stored in a light-resistant amber plastic bag with a sticker that reads "For ORAL use only."

- Notify pharmacists if patients cannot swallow so a process can be implemented to dispense nimodipine accordingly.

- Ask pharmacists to create a new drug entry in the pharmacy computer system for nimodipine 30 mg/mL and include default comments stating that doses given via NG tube be flushed with 30 mL of 0.9% saline after each administration.

- Place a reminder in the pharmacy computer systems, point-of-care bar-coding systems, and on the drug container to trigger an alert to warn practitioners of this potential problem.[3]

- Pharmacists may communicate the potential danger of inadvertent IV injection directly to the person responsible for administering the nimodipine. Because this error has occurred numerous times with fatal results, this communication may be helpful whenever nimodipine is dispensed.

Notes

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2. Institute for Safe Medication Practices. Nimotop safety brief. *ISMP Medication Safety Alert! Acute Care Edition* 1999 Aug 25; 4(17):1.
3. Institute for Safe Medication Practices. Take steps to avoid inadvertent IV administration of nimodipine [online]. ISMP Medication Safety Alert! Acute Care Edition 2005 Jul 28 [cited 2006 Nov 9]. Available from Internet: http://www.ismp.org/Newsletters/acutecare/articles/20050728_1.asp.
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If you have successfully implemented a program that has minimized or eliminated a particular complication or adverse event, the PA-PSRS Patient Safety Advisory *staff would appreciate information about what you did and how you did it. If you have completed a successful effort, please contact :*

John Clarke, MD, Clinical Director
Pennsylvania Patient Safety Reporting System
via e-mail at: jclarke@ecri.org

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Complications of Retrobulbar Blocks

Over two dozen reports of retrobulbar hemorrhages and at least three cases of respiratory arrest have been submitted to PA-PSRS since the program's inception in June 2004. These reports represent complications of the retrobulbar block, an anesthetic technique used for intraocular surgery that many practitioners are abandoning in place of topical anesthetics.

Declining Use of Retrobulbar Blocks

A recent survey indicates a move away from retrobulbar blocks, while topical anesthesia is gaining greater acceptance.[1] A 2003 survey of physician members of the American Society of Cataract and Refractive Surgery in the United States revealed this trend, presented in Table 1.[2] Whereas in 1985, 76% of survey respondents used retrobulbar blocks with facial block, in 2003 only 17% of respondents used this modality. The use of topical anesthesia has increased from 8% in 1995 to 61% in 2003. Interestingly, the use of topical anesthesia appears to be associated with the volume of cataract procedures performed. Those respondent surgeons performing one to five procedures per month used topical anesthesia in 38% of their cases while those doing more than 75 procedures monthly used it 73% of the time.

Each anesthesia modality, however, has unique benefits and risks. Table 2[3] displays this information for various anesthesia techniques used in ocular surgery.

Indications

If a retrobulbar block is considered, several factors will reduce the risk of complications.

Anesthesia	1985	1995	2000	2001	2003
Retrobulbar block without facial block					11%
Retrobulbar block with facial block	76%	32%	14%		9%
Peribulbar block		38%			17%
Topical Anesthesia		8%	51%		61%
– with intracameral lidocaine				81%	73%
– 1-5 cataract procedures/month					38%
– more than 75 procedures/month					73%

Table 1. Cataract Surgery Anesthesia Trends. Excerpted from Leaming DV. Practice styles and preferences of ASCRS members—2003 survey. *J Cataract Refract Surg* 2004;30:892-900, with permission from Elsevier.

Cooperation

The patient must be able to follow instructions and cooperate with the surgical team.[3,4] In order to follow directions, patients should not be hearing impaired or deaf, nor should there be a language barrier between the patient and surgical team.[3,5,6] Hearing aids, sign language interpreters, and/or foreign language interpreters may enhance cooperation.

Positioning

The patient must be able to lie flat on his/her back.[3,5] As a result, diagnoses that prevent such a position would be contraindications, such as severe back pain,[4] postural problems,[4] or chronic cardiac or respiratory problems.[6]

The ability to lie still is critical.[3] Therefore, conditions such as the following might make a patient an inappropriate candidate for the block: involuntary movements/tremors,[3,6,7] uncontrolled convulsive disorder,[5] unpredictable and uncontrolled cough,[6] excessive anxiety and claustrophobia.[5]

Patients should be older than 15 years, because young patients are not as likely to remain still throughout the block and surgical procedure.[5,6] Likewise, oriented patients, without significant mental impairment produced by psychiatric disorders or dementia, are more likely to stay still and follow instructions.[3,5] Moreover, oriented patients are more likely to be able to understand and tolerate the effects of a retrobulbar block on eye movement and vision during and for some time after surgery.[3]

Coagulation

This block is appropriate for patients with no significant bleeding or coagulation disorders.[5] There is a difference of opinion concerning whether anticoagulants, NSAIDS, aspirin, or clopidogrel bisulfate should be stopped prior to this block. One perspective is that patients receiving such medications are at greater risk of developing a retrobulbar hemorrhage.[8] Another perspective is that it is acceptable to perform a retrobulbar block if the patient's INR does not exceed twice the normal values.[9]

Globe

Anatomical abnormalities (e.g., a myopic axial length greater than 26 to 32mm) should not be present.[6,8] There must be enough room between the globe and the bony orbit to safely perform the block.[7] Normal intraocular pressure and absence of glaucoma are appropriate indications.[6] The block should not be completed if the globe is perforated.[5,6]

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Complications of Retrobulbar Blocks (Continued)

Allergy
The patient must have no known allergy/cross sensitivity to the local anesthetic to be used in the block.[6]

Co-morbidities
Because of the potential for significant complications, patients who receive retrobulbar blocks should not be blind in the non-operated eye.[6] Patients are less likely to sustain a retrobulbar hemorrhage if they do not have diseases that make the vasculature more fragile, such as acquired arteriosclerotic vascular disease, hypertension, coronary artery disease, peripheral or cerebral vascular disease, or diabetes mellitus.[10]

Length of Surgical Procedure
Retrobulbar blocks may be appropriate if the surgical procedure is expected to last less than 90 minutes.[5]

Anatomy
To understand the technique of retrobulbar block and its complications, one must understand the eye's basic anatomy and its relationship to surrounding/supporting structures.

The orbit is a pyramid-shaped cavity in the skull[1,7] with a posterior apex and an anterior base. The orbit is filled predominantly with adipose tissue, and the globe (eyeball) is in the anterior portion of the cavity.

Anesthesia	Benefits	Risks
General	• Excellent anesthesia, analgesia, akinesia • Duration of anesthesia can be varied to accommodate length of surgery	• Malignant hyperthermia • Hemodynamic fluctuation • Postoperative nausea and vomiting • Allergic reactions • Increased risk of cardiac complications • Ocular complications: – pressure fluctuation – Valsava retinopathy – corneal abrasions – chemical injury • Requires more medication, equipment, personnel, therefore most costly form of anesthesia • Inefficiency: time required for induction, intubation, extubation
Regional: retrobulbar, peribulbar, sub-Tenon's	• Excellent anesthesia, analgesia, akinesia • Duration of effect lasts for most cataract surgeries • Cost of medications and equipment less than general anesthesia • Injections take little time therefore more time- and cost-efficient than general anesthesia	• Patient may move, therefore not as controlled as general anesthesia • Localized swelling, bruising, subconjuntival hemorrhage • Allergic reactions • Brainstem anesthesia • Ocularcardiac reflex • Blind injection into orbit: – retrobulbar hemorrhage – globe perforation – optic nerve damage • Eye movement and vision affected for some time after surgery
– Peribulbar block	• Decreased likelihood of optic nerve and global perforation • Excellent akinesia and anesthesia	• Longer duration of onset
– Sub-Tenon's injection with blunt cannulas		• Lower risk of local complications
Topical	• Most cost-and time-efficient • Does not affect vision or motility therefore patients may have improved and useful vision almost immediately after surgery • Minimal cosmetic changes • Avoids systemic risks of general anesthesia and risk of local trauma • Shortest duration of action	• Rare local allergic reactions • Patients able to move eyes and other parts of the body • Patient may perceive pain or pressure • Patient may perceive visual phenomena

Table 2. Benefits and Risks of Ocular Surgery Anesthesia Types. Excerpted from Navaleza JS, Pendse SJ, Blecher MH. Choosing anesthesia for cataract surgery. *Ophthalmol Clin N Am* 2006 Jun;19(2):233-7, with permission from Elsevier.

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Complications of Retrobulbar Blocks (Continued)

Four rectus muscles are attached around the equator of the globe. These muscles come together at the apex of the orbit, affixed by the tendon of Zinn.[7] At this point, the optic nerve enters the orbit. The retrobulbar cone is defined by these four rectus muscles.

The following nerves innervate the globe.[1,7]

- The **ophthalmic nerve (V)** (i.e., the first branch of the trigeminal nerve), which controls sensory innervation of the globe.
- The **abducens nerve (VI)**, which regulates motor control to lateral rectus muscle.
- The **oculomotor nerve (III)**, which regulates motor control to all other extraocular muscles.
- The **trochlear nerve (IV)**, which regulates motor control to superior oblique muscles.

All of these nerves except the trochlear pass through the retrobulbar muscle cone. As a result, injecting a local anesthetic inside this cone provides anesthesia and akinesia of the globe, as well as the extraocular muscles.[1,7]

In addition to motor, sensory, and autonomic innervation of the globe, there are many other structures within the retrobulbar muscle cone that can be at risk during retrobulbar injection including the optic nerve and many arteries and veins of the orbit, including the optic artery.[1,7]

Technique

The goal of retrobulbar anesthesia is to direct the tip of the needle toward the orbital apex and into the retrobulbar muscle cone to diffuse the anesthetic within this space. This blocks the ocular motor nerves (III and VI) and sensory nerves (V), producing akinesia and anesthesia.[1]

To perform a retrobulbar block , a small amount of local anesthetic is injected inside the retrobulbar muscle cone (see Figure 1). The conventional technique[7] involves the following steps:

- Asking the patient to gaze in its primary position or a “downward and outward” position.[1]
- Introducing the needle through the skin below the inferior lid at a point between the lateral one-third and medial two-thirds of the inferior orbital edge.

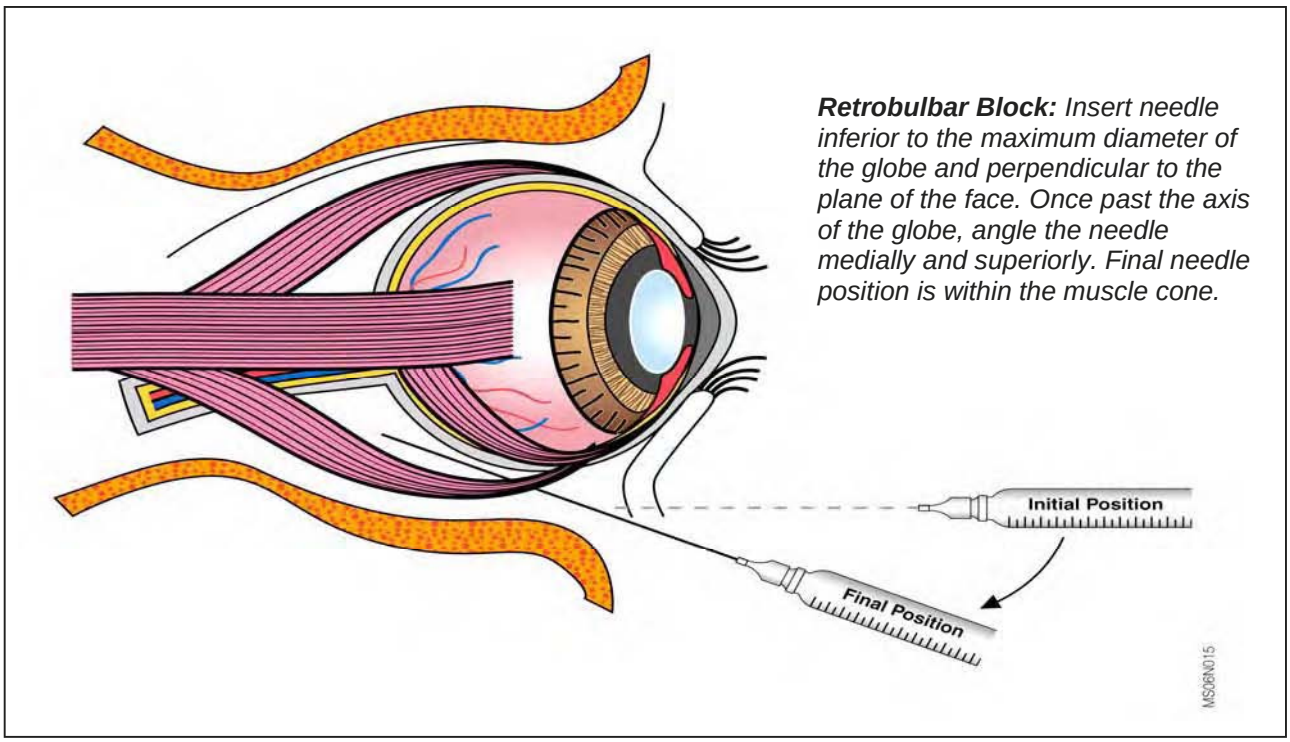

Figure 1. How the Retrobulbar Block is Performed

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Complications of Retrobulbar Blocks (Continued)

- Directing the needle to the apex of the orbit in a medial and cephalad direction
- Advancing the needle to a depth of 25 to 30mm
- Injecting 2 to 5cc of local anesthetic

Performing a facial block to prevent blinking. The technique most commonly used is the van Lindt block,[7] involving infiltration of local anesthesia in the areas of the terminal branches of the facial nerve (VII).[10]

Previously, Atkinson's "up and in" gaze was used for this block, but it is no longer advised because Liu et al. and Unsold et al. determined that this globe position increased the risk of optic nerve injury. Because the optic nerve passes near the path of the needle, it can be stretched or injured by the needle, rather than pushed aside as intended. This gaze position also places the needle near other structures such as the ophthalmic artery, superior orbital vein, and the posterior pole of the globe.[1,7] Unsold et al. recommends that the patient gaze with the globe in its primary position or in a down and outward position.[1] These positions place the optic nerve, blood vessels, and the inferior oblique muscle outside the needle's path.

Retrobulbar anesthesia is a blind technique. As a result, damage can result to the globe, orbital tissues, and neurovascular structures.[1] Near the apex, many structures are packed in a small area and fixed by the tendon of Zinn; therefore, the structures cannot move away from or be pushed aside by the needle.[7]

Complications

The literature describes several complications of retrobulbar blocks, including chemosis, bruising, retrobulbar hemorrhage, globe penetration and perforation, optic nerve damage and atrophy, extraocular muscle malfunction and injury, brain stem anesthesia, globe ischemia, and complications of nerve VII.[1,7,8] Table 3[8] displays these complications with information concerning mechanism of injury, risk factors, incidence, prevention, and treatment.

Two types of complications are evident in the PA-PSRS data: (1) central nervous system spread of anesthesia and (2) retrobulbar hemorrhages.

Central Nervous System Spread of Anesthesia

Unintentional intra-arterial injection of the anesthetic agent during retrobulbar block may result in reverse flow of the agent from the ophthalmic artery to the cerebral or internal carotid artery. Seizures can result from injection of as little as 4cc.[7] Rapid recovery occurs with symptomatic treatment.

The anesthetic can also be inadvertently injected under the dura mater sheath of the optic nerve or directly through the optic foramen, resulting in subarachnoid spread of the local anesthetic. The local anesthesia spreads directly to the brain from the orbit causing partial or complete brain stem anesthesia.[9] Symptoms include cranial nerve palsy or bilateral block, sympathetic activation, restlessness, confusion, total spinal anesthesia with tetraparesis, arterial hypotension, bradycardia, and respiratory arrest. Symptoms begin within about two minutes after injection and peak within 20 minutes. Recovery occurs in two to three hours.[9] Symptomatic treatment may include oxygen, vasopressors, tracheal intubation, and ventilation.[7]

There are at least three cases of respiratory arrest following retrobulbar blocks that have been reported to PA-PSRS.

Retrobulbar Hemorrhage

Over two dozen reports of retrobulbar hemorrhage have been reported to PA-PSRS. The overall incidence of this complication varies from between 0.1% to 3%.[1,3,8] Hemorrhage is caused by needle penetration of either the venous or arterial vessels in the orbit.[7,8]

Venous

Most retrobulbar hemorrhages are venous, and bleeding is slow.[1] Venous hemorrhages do not ordinarily threaten vision, the consequences are less severe than arterial hemorrages,[7] and they require no intervention other than postponing the surgery for which the block was administered.[1,7]

Arterial

Arterial hemorrhages, however, can be more serious. An arterial hemorrhage is evident within a few minutes; symptoms include proptosis and tight eyelids, ecchymosis, chemosis (i.e., conjunctival blood vessel engorgement), blood staining of periorbital tissues, lid swelling, and a dramatic increase in intraocular pressure.[1,8] Late optic atrophy may also result if the microvasculature of the optic nerve becomes occluded. A compressive retrobulbar hematoma may threaten retinal perfusion[2] by causing central retinal artery occlusion.[1]

The cause of retrobulbar hemorrhage is misplacement of the needle during this "blind" procedure. The risk of retrobulbar hemorrhage depends on the

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Complications of Retrobulbar Blocks (Continued)

experience of the person performing the block; for example, the complication is more likely if the person performing the retrobulbar block has limited experience.[7,9] Patient-related risk factors include elderly patients receiving anticoagulants, NSAIDS, aspirin or steroids.[8] However, it is considered acceptable to perform this block if the INR does not exceed twice the normal value.[9] Patients with acquired vascular disease are at risk,[1] as are those with diseases promoting arterial fragility such as diabetes or atheroma.[7] Hypertensive patients may also be at risk for this complication. Those at higher risk include patients with a history of previous eye surgery and those with pathological abnormalities of the globe, such as extreme myopia, myopic staphyloma, coloboma, or scleral buckle.[1,8]

Timely, effective treatment for retrobulbar hemorrhage can prevent permanent impairment of vision.[1] Most retrobulbar hemorrhages can be successfully treated conservatively.[8] Immediate oculocompression helps limit the extent and severity of the hemorrhage.[8] The goal of treatment is to reduce compartment pressure, thereby reducing intraocular pressure, which in turn reduces negative outcomes on retinal circulation.[8] The ophthalmologist will evaluate the extent of the hemorrhage and determine whether further interventions are necessary.[1,8] Interventions may include measuring intraocular pressure and checking retinal circulation.[8] Intraocular pressure can be lowered with acetazolamide.[8] Immediate lateral canthotomy/cantholysis may be required to relieve orbital pressure caused by the

Complications	Mechanism	Risk Factors	Incidence	Prevention	Treatment
Chemosis	Anterior spread of local anesthetic agent	Injection with smaller needles	Not known	Avoid anterior injection	Usually resolves on oculo-compression
Bruising	Damage to superficial blood vessels during injection	Elderly receiving steroids, NSAID, aspirin	1-2.75%	Avoid injection through visible blood vessels	Usually resolves and spread can be limited by oculocompression
Retrobulbar hemorrhage	Damage to arterial or venous blood vessels behind the globe	Elderly receiving steroids, NSAID, aspirin	0.1-3%	Limit insertion of needle to less than 31mm in the relatively avascular area	Immediate oculocompression, ophthalmologic opinion and decompression surgery
Globe penetration and perforation	Penetration of globe (wound of entry) and perforation (wounds of entry and exit)	Myopic eye, uncooperative patient, inexperienced user, poor technique, previous surgery	0-1%	Use of technique based on sound anatomical principles	Immediate senior ophthalmologic opinion
Optic nerve damage	Direct damage to nerve or compression of the nerve secondary to hemorrhage or vascular occlusion		Rare		Surgical decompression may be required
Optic nerve atrophy	Direct damage to nerve, central retinal artery or secondary to hemorrhage		Rare	Careful needle placement	Delayed complication
Damage to the motor nerve of the inferior rectus and inferior oblique muscles	Direct trauma to the nerve	Insertion of needle at the junction of medial 2/3 and lateral 1/3 of inferior orbital margin	Not known	Careful needle placement avoiding the nerve	
Inadvertent subarachnoid anesthesia (brain stem anesthesia	Subject to debate but spread through optic nerve sheath or through the orbital foramina	Placement of long needle into the apex	0.3-0.8%	Avoid using long needle	Extensive cardiorespiratory support
Globe ischemia	Interruption of blood flow	Prolonged oculocompression	Rare	Use pressure limiting oculocompression device	
Prolonged extraocular muscle malfunction	Prolonged exposure of fine muscle fibers, injection of local anesthetic agent into the muscle	May be associated with non-use of hyaluronidase	Not known	Proper placement of needle	
Complications of 7th nerve block	Direct damage to the nerve or neurogenic in origin		Rare		

Table 3. Complications of Akinetic Needle Block, Mechanism, Risk Factors, Incidence, and Their Prevention and Treatment. Source: Kumar CM, Dowd TC. Complications of ophthalmic regional blocks: their treatment and prevention. *Ophthalmologica* 2006;220:73-82. Reprinted with permission of S. Karger AG, Basel, Publisher.

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Complications of Retrobulbar Blocks (Continued)

retrobulbar hemorrhage.[1] Emergency orbital decompression surgery may be necessary if the optic nerve is compromised.[1,7]

Risk Reduction Strategies

Addressing the following issues can help achieve safe and successful retrobulbar blocks (and any akinetic block of the eye):[1,8]

- Education and competencies
  - Ensuring knowledge of anatomy and the relationship between the globe, orbit, and other ocular-related structures.
  - Having training and checking competencies in performing the technique.[12]
- Patient condition
  - Evaluating the globe for pathological abnormalities (e.g., abnormal axial length of the globe).
  - In severely hypertensive patients, consider postponing surgery until blood pressure is under greater control.[9]
- Technique
  - Using techniques based upon anatomical knowledge and existing ophthalmic pathology, including the following:
    - Using a small gauge needle (25 gauge) no longer than 31 mm in length.[9] (This reduces the risk of both retrobulbar hemorrhage and brain stem anesthesia.)
    - Inserting the needle when the eye is in primary gaze.
    - Placing the needle tangential to the globe.
    - Avoiding placement of the needle into the vascular quadrant or muscle belly by smoothly and gently inserting the needle into a relatively avascular area.
    - Aspirating before injecting the local anesthetic agent, to check for blood.
    - Consider repositioning the needle if resistance occurs during injection.
- Anesthesia/sedation
  - Considering other anesthesia modalities that may have fewer complications.[1]

Finger Index

The Finger Index (FI) is a grading system (0 to 3; see below) used in the Helsinki University Eye Hospital in Finland [6] that can determine the accessibility of the retrobulbar/peribulbar space in advance of needle injection. The tighter the globe is situated near the wall of the orbit, the more difficult the needle insertion. One finger palpates the space between the orbit and globe.

FI=0: Globe lies tightly on the rim of the orbit and cannot be lifted at all by the fingertip. (Retrobulbar/peribulbar blocks are contraindicated in such patients.)

FI=1: Only the tip of the finger fits between the globe and orbit. (Patients require an expert medical staff member to perform the block.)

FI=2: Finger easily fits between the orbit and globe. (Patients are suitable for retrobulbar/peribulbar anesthesia; the block may be administered by an appropriately educated and supervised physician in training.)

FI=3: Finger reaches the level beyond the equator of the globe. (Patients are suitable for retrobulbar/peribulbar anesthesia; the block may be administered by an appropriately educated and supervised physician in training.)

Further study is needed to determine whether this grading system can be scientifically validated. However, it may provide a supplemental screening method in addition to other risk reduction strategies to determine: (1) patients' appropriateness of such procedures and (2) the level of expertise required for the performance of the procedure.

Conclusion

The key to selecting the most appropriate anesthesia technique is for the surgeon, anesthesiologist, and the patient to work together during the anesthesia selection process, prior to surgery, and during anesthesia instillation.[5] Describing to the patient what he/she will experience before, during, and after surgery will reduce fear and anxiety and promote patient cooperation. While ophthalmologists routinely perform retrobulbar blocks, anesthesia staff can perform such blocks, as well as provide support to the patient by adjusting IV sedation to reduce discomfort.[3]

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Complications of Retrobulbar Blocks (Continued)

Resources

Resources concerning anesthesia alternatives for cataract surgery include:

- Schein OD, Friedman DS, Fleisher LA, et al. Anesthesia management during cataract surgery [evident report/technology assessment]. No. 16 (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 290-097-0006.) AHRQ Publication No. 01-E017. Rockville, MD: Agency for Healthcare Research and Quality. December 2001

- Navaleza JS, Pendse SJ, Belcher MH. Choosing anesthesia for cataract surgery. *Ophthalmol Clin N Am* 2006 Jun;19(2):233-7.

- Friedman DS, Bass EB, Lubomski LH, et al. Synthesis of literature on the effectiveness of regional anesthesia for cataract surgery. *Ophthalmology* 2001 Mar;108(3):519-529.

A review of complications of ophthalmic regional blocks includes:

- Kumar CM, Dowd TC. Complications of ophthalmic regional blocks: their treatment and prevention. *Ophthalmologica* 2006;220 (2):73-82.

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Follow Up on TASS

Toxic anterior segment syndrome (TASS) is a rare but serious complication of intraocular surgery that occurs when a non-infectious toxic agent enters the anterior segment of the eye and causes an inflammatory reaction. Since June 2004, ambulatory surgical facilities have submitted at least 15 reports of TASS to PA-PSRS, and at least three facilities have reported multiple cases. TASS incidence is difficult to pinpoint for several reasons, including that TASS is often confused with and treated as infectious endophthalmitis. (More information on TASS is included in the December 2006 *PA-PSRS Patient Safety Advisory*, available from the Patient Safety Authority Web site at http://www.psa.state.pa.us.)

"Get the Facts on Toxic Anterior Segment Syndrome," an educational program focusing on diagnosis, treatment, and prevention of toxic anterior segment syndrome (TASS), is available from http://www.tassfacts.com. The educational program, which is available either upon registration at the program's Web site or in a multimedia CD format, also includes discussion about TASS etiology, accounts of TASS cases, steps for proper care and treatment of surgical instruments, special considerations for sterilizers, and best practices for education and prevention.

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Skin Burns and Fires during Electroconvulsive Therapy Treatments

PA-PSRS has received five reports of patients experiencing skin burns or injuries from a fire during electroconvulsive therapy (ECT) treatments.

The first report described sparks but no fire; the anesthesiologist and RN observed this event at the time of the ECT device activation. The patient experienced erythematous skin on one side of the forehead and behind one ear. The second report described burns to the patient's hair and skin in the temporal area in front of one ear. In the third skin burn report, a post-anesthesia care unit nurse noted burn-like lesions on the patient's earlobe and forehead; however, according to the report, clinical staff believed the lesions were pre-existing to the ECT treatment. In the fourth report, a flash was noted at the electrode sites on both sides of the patient's temples. The flash occurred at the time a staff member turned the device off then on again because the display screen was blank (i.e., no illumination). According to the facility, although an oxygen (O_2) face mask was applied to the patient, no O_2 was flowing at the time of the flash.

Finally, in the report of a fire, a bright flash and flames were noted on the right side of the patient's head at the instant that the ECT shock was given. Though the flames were quickly extinguished, the patient experienced first- and second-degree burns on one ear and first-degree burns on the forehead above one eye. According to the event description, an O_2 face mask, with O_2 flowing, was on the stretcher near the patient's face during activation of the ECT device.

A search of the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database revealed 11 similar reports of burns and 1 report of fire during ECT treatments between 1992 and 2005. Of the 11 burn reports, 7 described burns to patients' skin at the electrode site without providing further details; 2 described no conductive gel or an inadequate amount of conductive gel between the electrode and skin; 1 described a flash at the electrode site during activation of the ECT device; 1 indicated that disposable electrodes were reused on the same patient several times; and 1 indicated the use of alcohol to clean the electrode site, which was against the electrode manufacturer's recommendations. The one MAUDE report of a fire during ECT also involved O_2 delivery on the face at the time of ECT shock delivery.

An ECT device generates a therapeutic pulsed electric current used to treat various psychiatric illnesses, especially severe depression.[1] The pulsed current causes brain nerve cells to fire in unison, which produces a seizure in the patient. The action of the seizure effect in treating the illness is not fully understood. Two theories include alteration of the brain's chemical messengers—neurotransmitters—by the seizure activity and adjustment of the stress hormone regulation in the brain.[2]

Prior to the procedure, the patient is anesthetized intravenously and given a drug (e.g., succinycholine) to minimize the severity of motor convulsions in the body, thereby reducing patient injury.[3] The therapeutic current passes through the patient's brain between two electrodes. Electrode placement methods for administering ECT include unilateral and bilateral. In unilateral ECT, one electrode is placed above the temple of the nondominant side of the brain and the other in the middle of the forehead or crown of the head. In bilateral ECT, one electrode is placed above each temple.

Of the five reports submitted to PA-PSRS, two did not indicate potential causes for the adverse events, one indicated that the apparent lesions may have been pre-existing, and one report described no patient discomfort following the event. The one report describing O_2 in use during ECT treatment indicated that at least one change the facility will make to this procedure is to remove O_2 flow from close proximity to the patient during ECT device activation.

Regarding the potential for fire, a spark at the electrode site in an oxygen-enriched environment immediately near the electrode may ignite the patient's hair or lingering alcohol vapors from skin prepping solutions. In the March 2006 issue of the *PA-PSRS Patient Safety Advisory* (see "Electrosurgery Safety Issues"), we discussed the three elements necessary for a fire: an ignition source, an oxidizer, and fuel. In the context of ECT, the ECT device is the ignition source, O_2 is the oxidizer, and fuel sources include hair, hair gel, skin, or alcohol, among others. While only one of the reports submitted to PA-PSRS described the use of O_2, O_2 was most likely in use during the other reported events. O_2 is typically administered to patients to prevent arterial desaturation during induction of general anesthesia (i.e., preoxygenation).[4] The third report of those described above indicated burns to the patient's hair and skin. Though the report does not indicate that alcohol was used to prepare the electrode site, hair can readily wick liquids such as alcohol and result in latent flammable alcohol vapors being present at the electrode area.

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Skin Burns and Fires during Electroconvulsive Therapy Treatments (Continued)

ECT Stimulus Electrodes

Various types of stimulus electrodes are available for use with ECT devices including stainless steel electrodes with holders, paddle electrodes and adhesive gel-pad electrodes. Stainless steel and paddle electrodes are held in place on the patient's skin by a clinician during ECT device activation. Adhesive-backed disposable gel-pad electrodes, when properly applied, stick to the patient's skin without being held in place. Poor electrode/skin contact during ECT procedures can lead to patient skin burns or fire. The electrode/skin interface beneath hand-held electrode types may be susceptible to gaps from clinician or patient movement during ECT activation. Conductive gels are used to minimize potential gaps between the electrode and skin and help to maintain an adequate conductive pathway for the therapeutic electric current.

Although it is less common than with hand-held electrodes, gaps may also occur with adhesive gel-pad electrodes. Creases created during placement of the adhesive electrodes or the pad lifting up from the skin during treatment can cause gaps between the electrode-skin interface. Those gaps may be sufficient to create electrical sparks, which in the presence of O_2 and a flammable substance may lead to burn or fire.

Electrode Site Preparation

Under the right conditions, skin burns during ECT treatment may occur readily due to poor electrode contact with the skin. Electrode site preparation is an important step in ensuring adequate electrode-to-skin contact. Hair, dead skin, and even cosmetic products between the electrode and skin could result in poor contact. Reducing the surface area contact between the electrode and skin disperses more therapeutic current over a smaller contact surface area. Concentrating the current in a smaller area generates greater heat dissipation from that area, which raises the skin temperature and could lead to a burn.

Isopropyl alcohol is often used to clean the skin of debris. Wiping the skin with a saline applicator is also sometimes used to clean the site.[5] If alcohol or alcohol-based solution is used and not given enough time to dry and the alcohol vapors are not given enough time to dissipate, a flash fire is possible in the presence of a spark.[6]

Understanding the potential risks associated with ECT procedures will help to promote a positive and safe treatment outcome. The mechanisms of action for the risks of patient skin burns include poor electrode site preparation, insufficient conductive gel between the electrode and skin, and reuse of single-use electrodes. Sparking from electrodes to the skin from poor site preparation can also cause fires due to alcohol vapor ignition from insufficient drying time for alcohol or alcohol-based solutions, from oxygen-enriched ignition of hair from O_2 delivery on the patient's face, or from an O_2 delivery device (e.g., nasal cannula or face mask) on the treatment bed during delivery of the ECT shock.

Minimizing patient or staff movement when using hand-held electrodes can reduce gaps between the electrode and skin, thereby, reducing the potential for sparks at the site. Adequate conductive gel also helps reduce or eliminate gaps and maintain good electrical conductivity between the electrode and skin.[7] However, too much gel may make the electrode slippery and prone to movement. Assessing the need for O_2 delivery to the patient during ECT device activation may help reduce the risks of burns or fires during ECT treatments. Off-label use of products (e.g., reuse of single-use accessories) may contribute to a negative patient outcome. Following manufacturer guidelines can greatly enhance the safety of the patient and lessen the chance of skin burns. However, no manufacturers caution about the risk of oxygen-enriched fire during ECT treatment. Fire prevention during ECT treatment may be guided by the information presented herein.

Notes

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Self Assessment Questions

The following questions about selected *Patient Safety Advisory* articles may be useful for internal education and assessment. You may use the following examples or come up with your own.

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Airway Fires during Surgery

1. Oxygen and nitrous oxide support combustion and
   A. increase the amount of energy needed to ignite flammable substances.
   B. decrease the amount of energy needed to ignite flammable substances.
   C. increase the temperature and energy at which fuels ignite.

2. Ways to minimize airway fires during electrosurgery include all EXCEPT which one of the following?
   A. Scavenge around the surgical site with separate suction to catch leaking oxygen and nitrous oxide.
   B. Use red rubber catheters to sheathe the electrosurgical probe to insulate the e patient's mouth from sparks during activation of the electrosurgical unit.
   C. Use a "cold" scissors or a scalpel instead of an electrosurgical unit to cut tracheal rings to enter the airway.
   D. Establish protocols for when electrosurgery will be removed from the surgical field.

3. The first step in stopping the flow of gas during an airway fire is to
   A. disconnect the breathing circuit.
   B. turn off the gas flow by shutting off the gas regulator(s).
   C. remove the tracheal tube from the airway.

Safety in Using Promethazine (Phenergan)

1. What is the maximum concentration that should be used when injecting promethazine?
   A. No greater than 25 mg/mL
   B. 6.25 to 12.5 mg/ml
   C. 50 mg/mL
   D. 10 to 20 mg/mL

2. In what age population is the use of all forms of promethazine contraindicated?
   A. The elderly
   B. Over 2 years of age
   C. Under 2 years of age
   D. 21 year olds with diabetes

3. All patients who experience local injury from IV promethazine infusions will have burning at the time of infusion.
   A. True
   B. False

4. Safe practices that may be considered to prevent or minimize tissue damage when giving IV promethazine include all EXCEPT which one of the following?
   A. Dilute the drug of the 25 mg/mL strength to reduce vesicants effects.
   B. Use large patent veins to administer IV promethazine.
   C. Consider safer alternatives.
   D. Dilute in bicarbonate.
   E. Consider administering IV promethazine slowly over 10 to 15 minutes.

Additional Assessment Questions

Self assessment questions on the topic "Contrast-Induced Nephropathy: Can This Iatrogenic Complication of Iodinated Contrast be Prevented?" are also available. in the March 30, 2007, Supplementary *PA-PSRS Patient Safety Advisory*. The Supplementary *Advisory* is available online at http://www.psa.state.pa.us.

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The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a non-punitive approach and systems-based solutions.

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