PA PSRS
Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

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Skin Integrity Issues Associated with Pulse Oximetry

Pulse oximeters, devices which estimate the oxygen saturation of arterial blood, have been in wide use since the 1980's[1] because this modality is non-invasive, convenient to use, and often portable.[2] In 1986, the American Society of Anesthesiologists endorsed pulse oximeters as a standard of care whenever anesthesia was used.[1] Initially, pulse oximeters were used in the Operating Room by anesthesiologists and nurse anesthetists, or by respiratory care practitioners in critical care settings.[3]

Over the past 15 years, however, use of pulse oximetry has expanded to a variety of settings including: monitoring patients during ambulance transport; spot-checking on general medical-surgical units and in outpatient areas/centers; during sleep studies; while exercise testing; home monitoring of infants at risk for sudden infant death syndrome or patients receiving respiratory therapy treatments; and in dental offices during anesthesia.[1]

Because they are non-invasive, pulse oximeters are considered a safe medical technology.[4] While the sensor emits a small amount of heat into the skin, testing indicates that the sensors are considered safe up to a temperature of 43°C on well perfused skin for up to 8 hours.[5]

However, reports submitted to PA-PSRS indicate that patients have sustained injuries from this modality. There have been at least eight occurrences of skin integrity problems including: cuts/lacerations, skin discoloration, blanched pressure areas/necrosis, induration, burns, and blisters.

While, to date, the injuries reported to PSRS appear to be minor, the clinical literature indicates that irreparable injury may occur during pulse oximetry in both infants and adults. Some case reports of pulse oximetry-related injuries in the literature include:

- Full thickness burn of an adult's distal phalanx that required amputation and skin grafting.[6]
- Thermal burns of an adult post-CABG patient with poor circulatory perfusion.[7]
- Third degree burn on the anterior and posterior aspects of a finger, requiring debridement and full-thickness skin grafting.[8]
- A neonate developed second degree burns of a finger and third degree of an ear where a pulse oximeter sensor had been placed.[9]
- A premature infant sustained burns to the dorsum of a foot, leading to gangrene and loss of 4 toes.[2]

Mechanisms of Injury

Equipment

Injuries may occur due to problems/malfunctions of the device.[10] The wiring of sensors and pulse oximeter monitors from different manufacturers may be incompatible.[1] In older equipment, this incompatibility may not be readily apparent because the sensor cable from one manufacturer may easily fit into an oximeter unit from another manufacturer. However, the incompatibility may overheat the sensor, causing burns when the sensor is applied to the skin.[2,9,11-13] Design changes in the connections of newer sensors and oximeter base units often prevent the connection of incompatible equipment.

Sensor overheating can also occur due to short circuits between wires in the sensor lead.[14] If insulation over the light-emitting diode (LED) portion of the sensor is damaged or missing, the sensor's electrical components may contact the patient's skin. An electrochemical burn at the site may result, caused by low-voltage direct-current tissue electrolysis.[15] Further, the protective cover over the LED may become damaged, allowing the sensor to overheat.[2,4,14] These problems are more likely with repeated use of a disposable one-patient sensor.[14] Skin injury has also been reported associated with pressure from a fold that may develop in the inner surface of a flexible pulse oximetry sensor.[16]

Patient Condition

The condition of the patient may contribute to the risk of pulse oximetry injury. Decreased blood flow to the area where the sensor is applied (usually a distal extremity) increases the risk of burn injury. The heat generated by the LED may not be dissipated from the

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site because of inadequate blood flow. Therefore, temperature increases in the area, and the area is in contact with the heat over a length of time. Shock, hypothermia, and ischemia of the extremity used for monitoring could all result in this type of injury.[5]

The thinness of the patient's skin increases the risk of more severe injury.[5] Toes and fingers, where sensors are usually placed, may have thinner skin than other areas of the body.[5] Infants (particularly premature infants) and the advanced elderly have delicate, more friable/fragile skin and may also have poor peripheral perfusion. Compression of the skin by the sensor may further decrease blood flow, reducing the body's ability to dissipate sensor-generated heat.[2] Among oximetry-related skin injury reports submitted to PA-PSRS, 50% were aged 3 months or younger, 25% were aged 13 to 24 months, and the remaining 25% were over age 80.

Persons at higher risk for severe skin injuries are those unable to communicate or perceive noxious stimuli such as skin heating: persons with insensate limbs, communication impairments, altered mental status; infants; unconscious/obtunded patients; and those under general anesthesia or local anesthesia to the area where the sensor is applied.[6]

Technique

Decreased blood flow can occur by mechanical means, such as the pressure exerted by wrapping or taping the sensor around the finger/toe.[12] This may result in a tourniquet-like effect.[5] The duration of skin contact with the sensor increases the risk of skin discoloration and burn injury.[5] For example, in a case reported in the literature, ultraviolet tanning of an infant's foot occurred after a sensor was on the same site for five days.[17]

Diagnostic/Treatment Modalities

Severe burns associated with pulse oximetry have occurred in patients undergoing Magnetic Resonance Imaging (MRI).[1,6] Most healthcare workers are aware of such contraindications to MRI as metallic aneurysm clips, cardiac pacemakers, and intraocular metal fragments. However, the potential for thermal or electrical burns associated with electrical monitoring devices may be less well known.[6]

During MRI, electrical currents are induced in all conductive materials exposed to the radio-frequency and gradient magnetic fields used during imaging.[18] The current generated in such conductive materials can produce enough heat to cause a burn.[1,8] The potential

Limitations of Pulse Oximetry

A 1994 study of what nurses and doctors in medical surgical units understood about pulse oximetry found that 97% did not know how pulse oximetry worked or what factors affected the readings.[1] Today, pulse oximetry use has expanded and is no longer used in only ORs and ICUs. The following limitations of pulse oximetry may be overlooked in common situations.

Patient Factors

The accuracy of pulse oximetry measurements requires normal hemoglobin. Abnormal hemoglobins, such as methemoglobin or carboxyhemoglobin, may cause great inaccuracies in pulse oximetry measurements of oxygen saturation.[2,3] For example, carbon monoxide has a stronger affinity for hemoglobin than oxygen, and pulse oximetry cannot differentiate between oxygen and carbon monoxide combined with hemoglobin. Therefore, patients with carbon monoxide poisoning, smoke inhalation, or cigarette smoking may have inaccurately increased SaO_2 readings that reflect the sum of oxyhemoglobin and carboxyhemoglobin saturations.[3] Such patients may be suffering from hypoxemia (lack of oxygen in the blood) without producing abnormal readings on pulse oximetry.[2]

Pulse oximetry does not measure the actual content of oxygen in the blood. Pulse oximetry estimates the percent of oxygenated hemoglobin present in the total of reduced and oxygenated hemoglobin. Therefore, a patient with anemia or polycythemia will have less oxygen content than a person with normal hemoglobin levels, even though their pulse oximetry measurements of oxygen saturation may be comparable.[2] Severe forms of anemia (hemoglobin less then 5mg/dL) prevent accurate pulse oximetry measurement.[2-4]

Although pulse oximetry may reflect oxygenation of the blood, it does not evaluate the patient's ability to ventilate. Partial pressure of carbon dioxide (pCO_2) is an appropriate measurement of ventilation.[2] Pulse oximeters also do not measure pH, which assesses acid-base status.[3]

Pulse oximetry does not evaluate whether oxygen present in the blood is available for use at the tissue or cellular level. Conditions such as acidemia, hyperthermia, or hypercapnea (increased pCO_2) decrease oxygen affinity, making oxygen more available to the cells. In contrast, in situations of increased oxygen affinity, such as alkalosis, hypothermia, or hypocapnea (decreased pCO_2) oxyhemoglobin is less able to release the oxygen molecules at the tissue level.[2]

Pulse oximeter oxygen saturation measurements are based on pulsating arterial blood. If the arterial pulse is not stronger than the surrounding venous blood/tissue, the oximeter cannot accurately reflect arterial oxygenation. Causes of low perfusion include hypothermia, hypotension, vasoconstrictive drug therapy, low cardiac output, and peripheral vascular disease.[2-4]

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Limitations of Pulse Oximetry (Continued)

External Factors

External factors that can affect the accuracy of pulse oximetry include:

- Lighting (e.g., surgical lights, bilirubin lights, infrared radiant warmers).[3] Patient movement/motion artifacts.
- Non-pulsatile substances that absorb light: (e.g., nail polish, false nails, dried blood, heavy skin pigmentation/ tattoos).
- Intravascular compounds that absorb light at the same wavelengths as hemoglobin (e.g., dyes like methylene blue, indocyanine green, or indigo carmine).[2-4]

Electrosurgical units (ESUs) can interfere with pulse oximetry by generating high-frequency currents which can radiate to the oximeter sensor. Some models freeze the SpO_2 display during ESU activation, which may lead clinicians to mistakenly rely on an inaccurate measurement of oxygen saturation. There have also been reports of the magnetic field of Magnetic Resonance Imaging systems affecting pulse oximeter circuitry and performance. Pulse oximetry is ineffective/inaccurate if intravenous infusions, blood pressure cuffs, or tourniquets are used on the same extremity.[3]

The most common reasons for inaccurate pulse oximetry readings are: movement, loss of pulse signal, and disconnection between the sensor and the patient.[4] Other issues affecting the accuracy of pulse oximetry measurements include: failing to use a sensor that is appropriate to the age of the patient; placing a transmittance sensor on a flat body surface, or a reflectance sensor on a digit; or securing the sensor too loosely or too tightly on the body.[5]

Pulse oximetry is a useful tool to monitor a patient's condition, but pulse oximetry measurements don't substitute for a full, direct, and comprehensive patient assessment. Education concerning indications, proper use, and limits of this technology can help to ensure accurate interpretation of pulse oximetry readings and prevent life-threatening or even fatal mistakes.

Notes

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for burns is greater if monitor cables are looped or if cables are in direct contact/taped to the skin.[8,18]

A review of the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database reveals a recent report pertaining to the use of a dye for a clinical purpose. A patient admitted to undergo parathyroidectomy for adenoma received 65 ml of IV methylene blue. A pulse oximeter sensor was attached to the fingertip. Surgery lasted 1.5 hours, followed by 2 hours' recovery. On the eighth post-operative day in the physician's office, the surgeon noted a healing circular brown blister on the patient's finger where the pulse oximeter sensor had been applied. The biomedical department did extensive testing on the equipment but could not find a source for this problem.[19]

Methylene blue can profoundly affect SpO_2 because of its ability to absorb light emitted from the pulse oximeter sensor LED.[20] Combined with poor perfusion, this might contribute to heat build-up at the sensor site, increasing the risk for burn.

Photodynamic therapy can also increase the risk of pulse oximeter-related injury. This therapy is used to treat cancers by combining the effects of a photosensitizing drug activated by visible light.[10,21] The photosensitized drug is retained in greater concentrations in malignant tissue than in normal tissue.[21] This modality is increasingly becoming an adjunctive cancer treatment because it is minimally invasive, with low morbidity, and high efficacy.[21] Cancers treated by this method include those of the bladder, lung, gynecologic system, abdomen, brain, head, neck, gastrointestinal system, and skin.[10,21]

However, the photosensitized drug remains in the skin for 6 to 8 weeks.[10,21] As a result, the patient must be protected from bright light.[21] A photosensitizing drug such as Photofrin may be activated by the red light emitted by the pulse oximeter sensor.[21] One case in the clinical literature indicated that a second degree burn of the index finger and subsequent loss of the finger nail occurred. A pulse oximeter was in use during photodynamic therapy, and the sensor was on the finger for three hours.[10]

Prevention/Risk Reduction

Several interventions can help to reduce the potential for pulse oximeter-associated injury.

Equipment

- Standardizing the makes and models available throughout the organization.
- If a facility uses oximeters and sensors from

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more than one company, checking the equipment to determine whether incompatibilities can occur—both mechanical and/or functional.[9]

- Not connecting pulse oximetry sensors and machines from different manufacturers—even when their electrical connectors are mechanically compatible—unless manufacturers' manuals/packaging instructions indicate that this is safe.[9]
- Ensuring that warning labels about incompatibilities are on sensor cables and pulse oximetry units.[22]
- Inspecting sensors and wires for cracks/breaks in insulation, and exposed electrical connections/wires, before application and each time the site is changed.[5,12,14]
- Reusing disposable one-patient-use pulse oximeter sensors only in accordance with manufacturers' recommendations.[14,15]
- Investigating any instance of freezing of the pulse oximetry monitor display, which can indicate short circuits in the sensor cable wiring.[14]
- Not allowing damaged sensors with exposed electrical connections to come in contact with the patient.[15]
- Removing from service and clearly labeling damaged sensor/cable/oximeters and sending them to biomedical engineering staff for evaluation.[15]
- Assessing the patient population served by the healthcare facility and using pulse oximetry equipment that effectively addresses those patients' needs.
- If appropriate, considering newer pulse oximetry technologies that might reduce the risk of skin integrity problems. For example, some newer models include flat reflectance sensors that can be used on more central body locations when poor peripheral perfusion is an issue.[1]
- Securing equipment so that it will not fall on patients.

Patient Condition

- Changing the sensor site more frequently (such as hourly), especially in conditions of decreased skin perfusion[14] or for unconscious patients,[23] critically ill premature infants,[2] and ICU patients.

Technique

- Frequently changing the sensor site to avoid prolonged skin contact,[12,14] at least every 2-4 hours.[7,14,17]
- Not wrapping flexible sensors tightly around the end of the finger/toe; avoiding wrapping sensors with elastic adhesive tape.[17]
- Assessing sensor sites frequently—at least whenever the site is changed.[10,14,17]

MRI

- Using only specially trained personnel to institute precautions and monitor pulse oximeter apparatus during MRI.[6,8]
- Ensuring that oximeter leads contact the patient at only one point,[6,8] as far away as possible from the imaging site.[18,23]
- Positioning cables from monitoring devices coming into contact with the patient so that no conductive loops are formed.[8,18,23]
- Keeping dry any skin surfaces coming in contact with leads.[6]
- Immediate removal of monitoring equipment that malfunctions during MRI.[6,8]
- Removing unused, clinically unnecessary sensors, cables, and surface coils from the MRI system/bore of the magnet/area.[18,23]
- Instructing patients to call out if they experience heat/discomfort.[23]
- Installing intercoms to check on patients frequently during procedures.[23]
- Frequently inspecting oximetry sites of insensate/unconscious patients.[23]
- Placing insulation (e.g., a blanket) between wires or cables and the patient's skin.[18,23]
- When possible, selecting monitoring equipment with electrically non-conducting paths or high-resistance paths, if clinically appropriate.[6,23] Some pulse oximeters use nonconductive fiber-optic cables that will not cause radio-frequency burns.[1]
- Considering MRI-compatible alternatives to pulse oximeters to evaluate respiratory function (such as end-tidal CO_2 or capnometers), which may use non-conductive tubing.[8,23]
- Using all devices according to the manufacturer's instructions.[23]

Photosensitized Drugs/IV Dyes

- Including a question in the history and physical that explicitly addresses these interventions in patients who may receive pulse oximetry.
- If pulse oximetry is clinically required, moving the sensor frequently to prevent prolonged contact with one area of the skin.

Education

- Educating staff to ensure that they understand the following: purpose, limitations (See Sidebar), proper use/protocols, maintenance/inspection, dangers/risk reduction strategies.[3]

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- Developing criteria concerning what categories of healthcare providers can use pulse oximetry.[3]
- Having available written materials, including manufacturer's operating manuals, for healthcare worker reference.[3]
- Instructing staff to follow manufacturer directions/protocols concerning site assessment, changing sensor locations, and equipment inspection.[15]
- Heightening awareness about pulse oximetry and skin integrity problems.[15]
- Developing pre- and post-training tests, and using competency skills checklists to confirm knowledge and affirm safe practice pertaining to use, reading, and interpretation of pulse oximeters.[3]
- Ensuring that new employees and independent contractors receive orientation to the proper use of pulse oximetry.[3]
- Reinforcing to clinicians that oxygen saturation as determined by pulse oximetry is not necessarily equal to arterial blood oxygen saturation.[3] (See Sidebar)
- Emphasizing that pulse oximetry is not a substitute for direct assessment of the patient.[3]
- Warning staff not to use a damaged sensor or cable.[15]

General

- Developing and implementing clinical protocols concerning the use of pulse oximetry equipment.[15]
- Investigating problems related to the use/misuse of pulse oximetry and taking appropriate action.[3]
- Tracking/analysis of such problems to identify opportunities for improvement.[3]
- Reporting such occurrences to the Patient Safety Officer and/or others who may determine whether further reporting is indicated[15] (e.g., Administration, PA-PSRS, FDA).
- Remaining current concerning regulatory standards for the use of pulse oximetry.[3]

Notes

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The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's website at www.psa.state.pa.us.

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