The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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ALERT: Interruption of Epoprostenol (Flolan) Infusion Leads to Patient's Death

This alert shares information learned from review of an incident that led to the death of a patient with severe pulmonary arterial hypertension. The death occurred after interruption of a continuous intravenous (IV) infusion of the short-acting drug epoprostenol (Flolan). This bulletin is intended to heighten awareness among all facilities and practitioners about this life-sustaining drug and to provide recommendations to prevent recurrence of this type of incident.

Background

Idiopathic pulmonary arterial hypertension (previously known as primary pulmonary hypertension), and pulmonary arterial hypertension associated with connective tissue diseases such as scleroderma are chronic and progressive diseases characterized by elevated pulmonary arterial pressure, which causes increasing pulmonary vascular resistance and ultimately right-side heart failure.[1,2] Symptoms may include shortness of breath, tiredness, swollen legs, and chest pain. About 2000 to 5000 Canadians are known to have some form of this disease, but the condition remains undiagnosed in thousands more because the symptoms often do not appear until the later stages of the disease.[3]

Pharmacologic treatment, with medications causing vasodilation of the pulmonary vessels, is the mainstay of therapy.[1,2] Epoprostenol, one of the drugs used for this purpose, is a prostaglandin analogue with two major pharmacologic actions: vasodilation of the pulmonary and systemic vascular system and inhibition of platelet aggregation.[4] Epoprostenol is administered as a continuous IV infusion via an ambulatory infusion pump and a long-term central venous access device, such as a Hickman catheter. Because epoprostenol has a very short half-life (2.7 minutes), the medication must be administered continuously at a specified rate.[4] Problems in the delivery system resulting in an abrupt interruption in administration of the drug or inadvertent administration of a bolus have been associated with serious consequences, including death.[4]

Incident Report

A patient with severe pulmonary arterial hypertension was being treated with a continuous infusion of epoprostenol delivered via an infusion pump through a Hickman catheter. The treatment was initiated by a specialist while the patient was in hospital. Both the patient and family were taught how to manage the ambulatory infusion pump, including how to change the cassettes containing the drug. In addition, at the time of discharge, the patient and family were given the telephone number of the hospital's pulmonary arterial hypertension "hotline", in case they experienced any problems.

A few weeks after discharge, the patient was unwell, an ambulance was called. Because of the urgency of the situation, the patient was taken to another hospital, the one closest to the patient's home. Rapid atrial fibrillation was diagnosed, and the patient was treated and sent home the same day. Later that day, the patient felt unwell again and was returned by ambulance to the closest hospital (i.e., the same hospital where treatment had been given that day). While in the emergency department, the patient initiated a scheduled change of the drug cassette in the infusion pump. At some point during this procedure, blockage of the Hickman catheter was noted. The staff in the hospital's emergency department attempted numerous times to reach the hotline, without success. During this time, staff withdrew the medication from another cassette and attempted to inject it through the peripheral line. The patient again experienced rapid atrial fibrillation, for which treatment was required. Although the atrial fibrillation resolved, the patient's oxygenation rapidly deteriorated, and cardiopulmonary arrest occurred. During resuscitation, the Hickman catheter was unblocked, and the epoprostenol drip was restarted with a new cassette. The patient's oxygenation improved, and cardiac rhythm was restored. The patient was transferred to the intensive care unit but died the following day.

During follow-up of this case, the cause of death was determined to be a complication of primary pulmonary arterial hypertension subsequent to blockage of the Hickman catheter (for epoprostenol administration).

Recommendations

After a review of this critical incident, a number of changes have been implemented at the facility where treatment with epoprostenol was initiated. The following recommendations are provided for consideration by facilities that administer epoprostenol by IV infusion and also facilities and emergency services that may provide care to patients who are receiving this drug by infusion.

Discharging Patients Home on Epoprostenol Infusion

- Review the critical points of potential failure from multiple perspectives, including patient, family, healthcare providers, equipment and supplies.
- Ensure that written instructions provided to the patient include emergency and alternate contact numbers. For example, the hospital where the patient was initiated on the epoprostenol infusion now uses a single-service pager, which is carried by the pulmonary hypertension physician on call, and includes the number of the pager in the patient's emergency instructions. A back-up plan, with alternate contacts, is also now in place.
- Because calls may be routed through a switchboard or "locating" service, ensure that all locating staff know how to manage these high-priority calls, including a back-up plan if a pager goes unanswered.
- Conduct tests to ensure that the emergency processes work as expected and to identify any failures that need to be addressed.
- Identify the supplies and instructions that the patient needs to have readily accessible at all times. Advise patients to carry supplies whenever they leave home. Consider giving the patient a travel bag with a checklist of items for this purpose.
- Provide clear, concise, and understandable instructions to accompany the ambulatory infusion pump. Remember that these instructions may be needed by individuals (including healthcare providers) who are unfamiliar with the medication and/or the infusion device.
- Consider working with a human factors engineer to assist with the design of instructions for patients and their families, and healthcare providers who do not have experience with this medication or the ambulatory infusion pump.

Providing Care to Patients Who Are Receiving Epoprostenol

- Ensure that staff are aware that maintaining the continuous infusion rate for epoprostenol is critical because of the drug's short half-life (2.7 minutes). Share this bulletin widely, particularly with staff who work in emergency departments and those who work for emergency services.
- Ensure close monitoring of patients who are receiving epoprostenol. Encourage staff to call the contact number to enhance understanding of steps needed to assist with provision of care and to ensure they are prepared in case difficulties arise.
- *In the event that the central access device for the epoprostenol infusion becomes blocked, transfer the ambulatory pump to another IV site immediately.*
  - Connect the tubing so that the drug reaches the patient in a timely manner (e.g., avoid attaching the tubing at a Y site).
  - Do *not* mix epoprostenol with any other parenteral medications or solutions before or during administration. [4]
- Avoid bolus injections of epoprostenol, as this can also lead to severe harm or even death.[4] (Refer to product monograph for additional information including technical requirements of infusion devices for an epoprostenol drip.)

It is hoped that the sharing of this information provokes thought and discussion about the safeguards needed to support patients who are receiving life-sustaining continuous infusions with drugs such as epoprostenol.

References

1. McLaughlin VV, Archer SL, Badesch DB, Barst RJ, Farber HW, Lindner JR, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension: a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association. J Am Coll Cardiol. 2009;53(17):1573-1619.
2. Mubarak KK. A review of prostaglandin analogs in the management of patients with pulmonary arterial hypertension. Respir Med. 2010;104(1):9-21.
3. About pulmonary hypertension. Vancouver (BC): Pulmonary Hypertension Association of Canada; 2011 [cited 2011 Jan 25]. Available from: http://www.phacanada.ca/index.php/en/patients
4. Flolan for injection: epoprostenal sodium 0.5 or 1.5 mg per vial. Vasodilator [product monograph]. Mississauga (ON): GlaxoSmithKline Inc.; 2010 Aug 3 [cited 2011 Mar 7]. Available from: http://www.gsk.ca/english/docs-pdf/Flolan_2010.pdf

ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

Medication Incidents (including near misses) can be reported to ISMP Canada:
(i) through the website: http://www.ismp-canada.org/err_report.htm or (ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.
ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

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