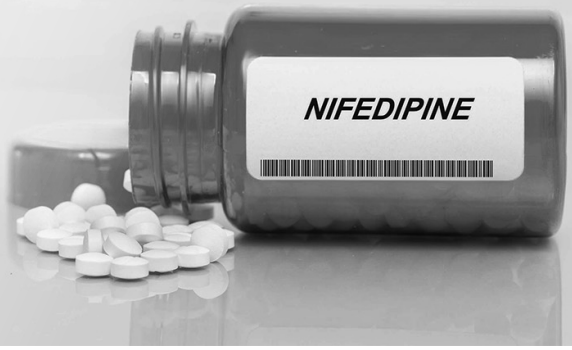
Nifedipine Errors and Serious Patient Harm: Insights From the Pennsylvania Patient Safety Reporting System and Potential Mitigation Strategies



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The Patient Safety Authority (PSA) has received multiple reports in recent years via the Pennsylvania Patient Safety Reporting System (PA-PSRS) describing serious events involving nifedipine that resulted in serious patient harm, including death. Nifedipine is a dihydropyridine calcium channel blocker that dilates cardiac and smooth muscles to reduce peripheral vascular resistance, decrease systemic blood pressure, and increase oxygen delivery to the heart.[1-3]

Immediate-release (IR) formulation of nifedipine (e.g., Procardia) is currently available but no longer commonly used due to its potential to cause excessive reductions in blood pressure and other serious adverse events such as change in neurological status, myocardial infarction, and death.[1,4-6] The U.S. Food and Drug Administration (FDA) and its committee have issued multiple warnings over the years about its potential adverse cardiovascular effects and recommended against its use to lower blood pressure.[6,7] Currently, nifedipine IR is available in capsules and FDA-approved only for the treatment of vasospastic angina and chronic stable angina.[1]

To mitigate the adverse effects associated with the IR formulation, the extended-release (ER) formulation (e.g., Procardia XL) was designed for a more sustained drug delivery and once-daily administration. Currently, nifedipine ER is available in tablets, which should not be crushed, divided, or chewed.[2,8] Inappropriate crushing of nifedipine ER, which rapidly releases the total daily dose, is associated with documented fatality.[9] In 2018, PSA described a patient who experienced hypotension and lethargy, and required intubation and resuscitation after receiving inappropriately crushed nifedipine ER.[10]

The following examples of medication errors involving nifedipine have been reported to PA-PSRS in recent years.[a]

- Inappropriate prescribing, ordering, or administration of the IR formulation

  Patient who was taking 30 mg [milligrams] *of nifedipine ER for chronic hypertension presented to L&D* [labor and delivery] *triage and was inadvertently given 30 mg of nifedipine IR. Due to the onset of tachycardia and the patient's past medical history, the patient was treated with activated charcoal and fluids, and required admission for further monitoring.*

  Patient was inadvertently ordered 30 mg of nifedipine IR instead of nifedipine ER. Patient subsequently experienced a drop in blood pressure and change in neurological status necessitating treatment with calcium gluconate and fluids.

  Patient who was on nifedipine ER 90 mg daily at home had the medication regimen erroneously changed to nifedipine IR 30 mg three times daily. Patient experienced drops in blood pressure that correlated with the administration times of nifedipine IR doses.

- Inappropriate alteration (crushing, splitting, dividing, chewing) of the ER formulation

  Nifedipine ER 90 mg was erroneously crushed, mixed in apple sauce, and administered to the patient. It was not recognized that this was an extended-release formulation that should not be crushed. A rapid response was called when the patient was found obtunded. Despite pharmacological interventions, transfer to ICU, and cardiac resuscitation, the patient passed away.

  After intubation, patient's nifedipine ER 60 mg was not changed to accommodate the new route of administration via gastric tube. A nurse then crushed the ER tablet and administered it through the gastric tube despite the administration instructions "do not crush." The patient became severely hypotensive with systolic blood pressure in the 60s and required norepinephrine infusion.

Facilities can mitigate the risk of nifedipine-related errors by implementing the following safety strategies.

- Restrict the accessibility, ordering, and dispensing of nifedipine IR exclusively to patient care areas with approved protocols (e.g., obstetric units).[11]
- Implement mandatory educational initiatives to educate and remind the providers that the IR formulation of nifedipine should never be substituted for the ER formulation to treat hypertension.[1]
- Mandate the use of full drug names by spelling out "Immediate-Release" and "Extended-Release" in the electronic health record (EHR) and automated dispensing cabinet (ADC).[12] Consider adding descriptions such as "SHORT acting" or "LONG acting" to the product names to minimize confusion between formulations.[12]
- Require pharmacy verification of all nifedipine orders prior to dispensing and administration.[11]
- Implement multilayered warnings and alerts throughout the EHR and ADC to caution the user that nifedipine ER tablet should not be crushed, divided, or chewed.[10,11]
- Establish a standardized procedure to identify and document patients with existing feeding tubes and those with newly inserted enteral feeding tubes to minimize the risk of inappropriate alteration and administration of nifedipine ER.[10]
- Review the facility's formulary and implement procedures to ensure that modified-release dosage forms, such as the extended-release and delayed-release dosage forms, are never altered before they are administered to patients.[8,10,13]
- Mandate the use of barcode medication administration (BCMA) technology to confirm the details of the medication prior to administration.[10]
- Consider formally designating nifedipine product(s) as high-alert medication(s) based on facility-specific risk assessment findings and implement corresponding practices to prevent patient harm resulting from medication errors (e.g., preventing the override capability).
- Provide ongoing education to both providers and patients regarding the safe use of nifedipine and potential risks associated with it.[10,11]

The use of nifedipine IR in current practice is limited due to its potential to cause fluctuations in blood pressure and other adverse effects. To mitigate these risks, facilities should restrict access to nifedipine IR and reserve its use for specific, facility-approved indications and designated clinical areas. Furthermore, it is important to note that inappropriate alteration of nifedipine ER, such as crushing, splitting, or chewing, can result in the rapid release of the entire dose and increase the risk of severe patient harm. We encourage facilities to reassess their processes, implement risk mitigation strategies, and take proactive steps to prevent medication errors and improve patient safety related to the use of nifedipine.

[a]The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

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