Medicinal mishap

Dosing errors with Donnalix Infant Drops

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Case 1

Parents of a three-month-old boy, weighing 5 kg, phoned the Victorian Poisons Information Centre for advice. The child had just woken up from a big sleep; he was now flushed, cranky and unsettled. Three hours earlier he had been given 5 mL of Donnalix Infant Drops instead of 0.5 mL. The parents were advised to take the child to the nearest hospital.

Case 2

A two-month-old boy, weighing 4 kg, was brought to a hospital emergency department. He had dilated pupils, a dry mouth, a heart rate of 200 beats/minute and was a little sleepy. Ninety minutes earlier, he had been given 2 mL of Donnalix Infant Drops, instead of the correct dose of 0.4 mL. The child required overnight admission for observation.

Case 3

A one-year-old girl, weighing 10 kg, was given three 10 mL doses of Donnalix Infant Drops instead of the correct dose of 1 mL. She presented to hospital with dilated pupils slowly reacting to light, a heart rate of 150 beats/minute, and difficulty feeding. The child required observation, with cardiac monitoring, and supportive care until her symptoms resolved.

Comment

Donnalix Infant Drops contain the anticholinergic compounds hyoscyamine, atropine and hyoscine. The product is used to relieve colic in infants, although evidence supporting its effectiveness is lacking. The drops can be purchased from pharmacies without a prescription. The recommended dose is 0.1 mL/kg of the infant's body weight before troublesome feeds, with a maximum of four doses in 24 hours.

In the last five years, the Victorian Poisons Information Centre has received 26 calls involving a dosing error made by parents or carers administering this product (Table 1). These errors occurred despite clear dosing instructions on the bottle and on the outer packaging and the inclusion of a graduated administration dropper in the pack.

In 22 of these calls, the infant had already been taken to hospital or the caller was advised to take the infant to hospital. Symptoms at the time of the call were noted in seven cases. They included drowsiness, floppiness, facial flushing, tachycardia, dry mouth, dilated pupils and poor feeding.

Toxicity in colicky infants given anticholinergic drugs is well documented.[1,2] Neurological manifestations of excessive dosing range from sedation to irritability, agitation, seizures and coma. Features of the anticholinergic syndrome may be seen, such as dry/warm skin, hyperthermia, thirst, dry mouth, dilated pupils, tachycardia, urinary retention, delirium and hallucinations. The range of toxicity is variable and unpredictable. Its effects may be delayed and cyclical. Physostigmine is an antidote for pure anticholinergic toxicity, but this is not without risk and indications for its use are limited.[3]

Recommendations

Medical, nursing and pharmacy staff need to be aware that dosing errors can occur with Donnalix Infant Drops, particularly giving 10 times the correct dose. Members of the public often assume that because over-the-counter medicines are not regulated by prescription, they are safe, even in overdose.[4]

In view of the potential for toxicity and the absence of a compelling clinical indication we believe Donnalix Infant Drops should be withdrawn from the market. As this is unlikely to happen, parents or carers should be shown the correct dose at the time of purchase. A boxed warning about the importance of measuring the correct dose and a reduction in the 'strength' of the drops would further decrease the risk of mistakes. Restricting access by rescheduling Donnalix Infant Drops to a 'pharmacist only' or 'prescription only' medicine may further decrease the risk of dosing errors.

Table 1

Dosing errors involving Donnalix Infant Drops

Dosing error	Number of calls
Double dose	3
Two and a half times correct dose	3
Three times correct dose	2
Five times correct dose	3
Seven and a half times correct dose	1
Ten times correct dose	14
Total	**26**

References

1. Myers JH, Moro-Sutherland D, Shock JE. Anticholinergic poisoning in colicky infants treated with hyoscyamine sulfate. Am J Emerg Med 1997;15:532-5.
2. Pickford EJ, Hanson RM, O'Halloran MT, Fenwick D, Noble P, McDonald JD. Infants and atropine: a dangerous mixture. J Paediatr Child Health 1991;27:55-6.
3. Tarabar AF, Hoffman RS. Pediatric toxic syndrome (toxidromes). In: Erickson TB, Ahrens WR, Aks SE, Baum CR, Ling L, editors. Pediatric toxicology: diagnosis and management of the poisoned child. 1st ed. New York: McGraw-Hill; 2005. p. 75-83.
4. Cranswick N, McGillivray G. Over-the-counter medication in children: friend or foe? Aust Prescr 2001;24:149-51.