

# Medicinal mishap

## Intravenous paracetamol in paediatrics: cause for caution

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### Case 1

A two-week-old 2.9 kg baby presented to a general hospital emergency department with acute bowel obstruction and underwent urgent laparotomy. Postoperatively the baby was given three doses of 290 mg intravenous paracetamol (instead of the prescribed 29 mg dose) over a 38-hour period. The error was detected 1–2 hours after the third dose, which was initially thought to be a single overdose. The preceding two overdoses were discovered six hours later and N-acetylcysteine was given, following the advice of a Poisons Information Centre toxicologist. The baby remained clinically stable and liver transaminases were normal throughout.

### Case 2

A 5.65 kg infant admitted to a general hospital was prescribed '80 mg paracetamol IV/PO/PR'. Poor legibility of the prescription led to interpretation of the dose as 280 mg. A 1000 mg vial of intravenous paracetamol was connected to an infusion pump set at 168 mL/hr for 10 minutes. The infusion continued beyond the intended duration and a total dose of 430 mg (75 mg/kg) was given.

### Comment

Paracetamol has a good safety record when used appropriately. Since intravenous paracetamol became widely available there have been multiple inadvertent 10-fold overdoses in infants.<sup>1,2</sup> A key contributing factor is the 10 mg/mL strength of intravenous paracetamol – health professionals mix up the mg and the mL dose. Ten-fold dosing errors occur regularly in paediatric patients and are a recognised source of significant harm, including deaths. A recent review examines contributing factors and recommends general strategies for harm prevention.<sup>3</sup>

The NSW Therapeutic Advisory Group (NSW TAG) has developed comprehensive, evidence-based guidance on the appropriate and safe use of intravenous paracetamol.<sup>1</sup> There are key recommendations for clinicians caring for paediatric patients in all hospital settings. Importantly, NSW TAG's guidance provides an up-to-date dose recommendation for intravenous paracetamol in infants; this differs from the current Australian product information for infants weighing less than 10 kg. The justification for this 'off-label' dose recommendation is discussed.

NSW TAG's guidance also includes advice about using paracetamol for fever in adults with stroke, dosing in underweight adults and frail older people, and more general advice for preventing hepatotoxicity in adults.

### Recommendations<sup>1</sup>

- Reserve intravenous paracetamol for acute, short-term treatment of mild–moderate pain when enteral administration is not possible.
- Undertake a comprehensive risk assessment before treatment and review daily – exercise particular caution in infants less than six months of age. General risk factors for paracetamol hepatotoxicity in paediatric patients (see Box) and for underweight adults and frail older people less than 50 kg are described in relevant sections of NSW TAG's guidance.
- Follow general principles for safe paediatric prescribing,<sup>4</sup> including:
  - always write legibly – printing in capitals is strongly recommended
  - check the basis for the dose calculation in a current paediatric prescribing reference or other up-to-date, evidence-based medicines information resource
  - calculate the dose using the patient's current, accurate (or, for overweight children, ideal) body weight (advice on how to estimate ideal body weight using paediatric growth charts is provided in the guidance)
  - independently double check the calculated dose (using a calculator) at the time of prescribing and at each administration

### Box Key risk factors for paracetamol hepatotoxicity \*

febrile illness  
younger age  
prolonged fasting  
vomiting or dehydration  
chronic undernutrition  
severe hepatic impairment

\* adapted from reference 1

- prescribe the dose in milligram (mg) units. Additional specification of the volume in millilitres (mL) and the strength of the solution may maximise the clarity of the intended dose for liquid medicines, but the primary order should always be expressed in dose units.
- Specify only one route of administration, as the appropriate dosing interval and recommended maximum daily dose differs for each administration route. Prescribing 'paracetamol IV/PO/PR' is inappropriate and unsafe.
- In small infants, the volume containing the required dose should be drawn up in a syringe (using a 5 or 10 mL syringe for infants less than 10 kg), diluted appropriately and administered using computerised infusion control.
- Ensure no other formulations of paracetamol are concurrently prescribed or administered and the

safe maximum daily dose (from all sources) is not exceeded.

- When prescribing 'paracetamol IV', specify the brand name in addition to the generic name to avoid confusion with other formulations.
- All health professionals prescribing and administering intravenous paracetamol for paediatric patients should be appropriately educated in the general principles of safe paediatric prescribing and medicines use as well as in the appropriate and safe use of intravenous paracetamol specifically.

*Conflict of interest: none declared*

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