Cluster of naphazoline and phenylephrine intoxications in children due to a compounding pharmacy error.

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Objectives – Introduction.
Compounding pharmacy error

- Cluster of intoxications due to inadvertent use of a nasal decongestant solution to reconstitute antibiotic solutions

- Alert given by a pharmacist
  - based on symptoms (pallor, somnolence) in a 1 year old boy
  - 4 times 4 ml, over the last 24 hours
  - Solution composition
    - Naphazoline 1 mg/ml
    - Phenylephrine 2.5 mg/ml
  - Same mistake for 6 other children

- Pharmacist asked to immediately contact the parents to refer the children to the hospital for medical assessment
Cases report - Details

Patient characteristics, doses received, quantity of naphazoline (Naph) and phenylephrine (PE), symptoms and duration of medical observation

<table>
<thead>
<tr>
<th>ID</th>
<th>Gender</th>
<th>Age</th>
<th>Weight</th>
<th>Nbr of doses</th>
<th>Vol. (ml) / dose</th>
<th>Naph (total, mg)</th>
<th>Naph mg/kg/dose</th>
<th>PE (total, mg)</th>
<th>PE mg/kg/dose</th>
<th>Somnolence</th>
<th>Pallor</th>
<th>Bradycardia</th>
<th>Heart rate (bpm)</th>
<th>Vomiting</th>
<th>Diaphoresis</th>
<th>Headache</th>
<th>Photophobia</th>
<th>Ataxia</th>
<th>Duration (days)</th>
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<td>4</td>
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</table>

Total (by symptom) | 5 | 5 | 5 | - | 2 | 2 | 1 | 1 | 1 |

\(a\) Index case

\(b\) Elder sister (unknown age, weight, exposure level) with similar symptoms

Estimated toxic dose (oral)
- \(< 2\) yrs \(\rightarrow 0,1\) mg/kg
- \(\geq 2\) yrs \(\rightarrow 0,3\) mg/kg

Toxic threshold : 1 mg/kg
Conclusions
(α- adrenergic vasoconstrictors)

Naphazoline
- Narrow therapeutic index - Probably the most toxic.
- Toxic by nasal & oral route.
- Contra-indicated under the age of 7 (BE)
- Main features: sleepiness, pallor, bradycardia
- Symptom severity according to age, to dose?
  - Single vs repetitive doses? T½: 2 to 4 hours
  - Threshold: 0.1 mg whatever the age?

Phenylephrine, relatively less toxic
- First pass metabolism by the oral route


