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Short Papers

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DOSING ACCURACY AND STABILITY OF ENTERAL NIFEDIPINE FOR PAEDIATRIC PATIENTS

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Administration of nifedipine, a short acting calcium channel blocker used to treat acute and chronic hypertension in paediatric patients, has been associated with large variations in treatment response to individual doses.¹ Currently, there is no licensed paediatric nifedipine formulation available in the UK. The aim of this project was to determine the accuracy and precision of methods used in clinical practice to prepare paediatric doses of enteral nifedipine.

Method Initially, qualitative data collection and observational studies using questionnaires to identify common preparation techniques used by nursing staff were performed at one children's hospital.

Weight and content uniformity of split and crushed modified release nifedipine tablets (Nifedipressâ MR 10), and an imported 20 mg/mL drop solution (Nifedipin-ratiopharmâ Tropfen), were analysed.

The accuracy and precision of three different doses of enteral nifedipine (5 mg, 1 mg and 0.5 mg) prepared using eight techniques identified in clinical practice were determined using High Performance Liquid Chromatography (HPLC). Stability over two hours of nifedipine solutions 5 mg/mL prepared from tablets and the drop solution was determined using HPLC.

Results Great variation in dose preparation methods was identified. Analysis of eight preparation techniques showed that doses between 50% and 264% of the intended dose were achieved.

For techniques using manipulated tablets only one technique, using split tablets dispersed in an oral syringe, produced an accurate and reproducible dose for 1 mg and 5 mg doses (97.9% [range 96–99.2%] and 94% [range 93.1–95.1%] respectively). For the 0.5 mg dose none of the techniques produced an accurate and reproducible dose.

Techniques using dilution of the imported liquid showed significant deviations and variability from the intended dose, particularly when the internal drop dosing device was used. Use of syringes to measure the dose improved accuracy and precision of the dose prepared, although significant carry-over of drug was seen if fresh syringes were not used at each dilution step.

Stability studies observed rapid decomposition of nifedipine when exposed to light, forming an unstable preparation within 30 minutes of tablet manipulation and within 60 minutes of liquid manipulation.

Conclusion A great variation of preparation techniques is employed by nursing staff to administer fractional doses of nifedipine to infants and children using the modification of either a licensed tablet or an imported drop formulation. Our small study investigating some of these techniques showed significant inaccuracy and imprecision of the doses delivered.

Preparation of paediatric doses of nifedipine require specific standardised preparation protocols to ensure accuracy and consistency of doses delivered to the patient.

Further studies should be performed to inform the development of these preparation protocols to identify methods which consistently deliver accurate doses across paediatric dosing ranges until more suitable licensed paediatric treatment alternatives become available in the UK.

REFERENCE

- 1 Khanderia S, Ryan RSM, Jordan B, (eds). BNF for children 2013/2014. London: BMJ Group, Pharmaceutical Press, RCPCH Publications; 2013.