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Validation and implementation of an analytical quality control method in preterm parenteral nutrition

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Background

Parenteral nutrition (PN) solutions are complex unlicensed medicines that cover essential needs in preterm infants. PN safety must be guaranteed by a proper quality control system.

Purpose

To evaluate the feasibiity of a routine analytical technique to measure glucose and electrolytes in plasma and urine as a quality control method for preterm PN solutions.

Material and methods

Emergency laboratory uses an automatic chemistry system (Dimension EXL) with spectrometry and indirect potenciometry technology for the analysis of glucose and electrolytes in plasma and urine. The technique was validated in front of standard solutions to study glucose, sodium, potassium, calcium and magnesium in a fat-free PN substrate.
Simultaneously, we studied the systematic error due to volumetric devices used in the compounding process.
Once we knew the inaccuracy of the technique, we discussed with clinics the clinical significance of differences among theoretical and measured values in order to establish acceptability ranges.

Results

- Glucose, potassium, calcium: inaccuracy <10%
- Sodium, magnesium: inaccuracy >15% (matrix interference)
- Systematic error due to volumetric devices: <5%

260 PN solutions
61 patients

← **Experience** (from May 2013) →

4 preparation errors detected

Mean time response: 55 minutes

Mean cost per unit analysed: 0,25€

Conclusion

The implementation of an analytical control of preterm PN solutions into the routine practice of the Emergency laboratory has provided a reliable quality control method that allows checking 100% of samples and knowing the results before PN administration at a very low cost.

Authors declare no conflict of interest