

Evaluation of the quality of the parenteral nutrition prepared at the neonatal unit

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Background

Parenteral nutrition (PN) is crucial for hospitalized premature infants. The **quality of the preparations** has a direct impact on the patient's safety.

In our hospital, individualized PN bags for preterm infants are prepared until now partially in the central pharmacy (~2500 per year) and partially at the neonatal unit (~6000 per year).

Purpose

Evaluation of the physicochemical and microbiological quality of the **bags prepared on the ward**.

Material and Methods

1. Test for bacterial **endotoxin** by kinetic coloration of LAL (limulus ameobocyte lysate)
2. Test for **sterility** according to Ph.Eur.(2.6.1)
3. Assay of **electrolytes** (K^+ , Na^+ , Ca^{2+} , Mg^{2+}) by capillary electrophoresis and **glucose** by UV (enzymatic method of hexokinase)¹

Results

No perfusion among the 110 PN tested contained **endotoxins** (limit: 2.25 EU/ml).

All 78 PN tested were **sterile**.

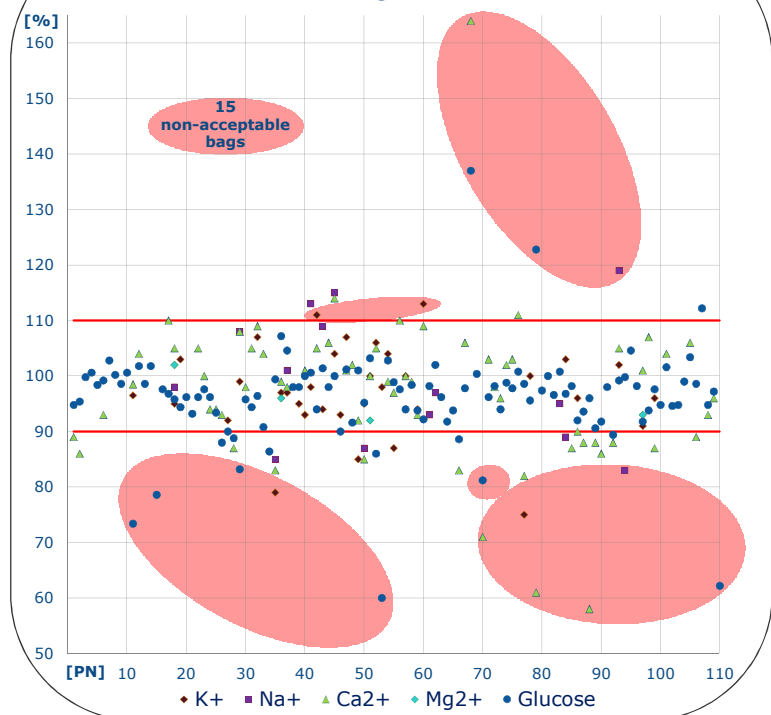
34% (37 PN) were **not conform** to their medical prescription (90% - 110%).

14% (15 PN) from these 34% were **not acceptable** from a clinical perspective.

Conclusions

- PN bags compounded by nurses of the neonatal unit were quite frequently **not accurate** on electrolyte or glucose concentrations (**14% ≈ 840 bags per year**)
- PN bags were sterile and nonpyrogenic
- The **preparation of PN bags** at the **pharmacy** with physicochemical controls before administration seems **unavoidable**

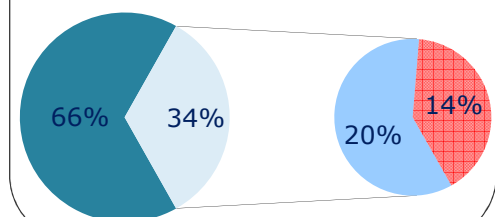
Dosage of electrolytes and glucose of 110 PN



Parameter	Number of analysis	Mean value	± SD	Range measured	Internal Acceptable Range
K^+	34/110	97.2%	± 8.0%	75-113%	85-110%
Na^+	14/110	99.4%	± 11.7%	85-115%	85-115%
Ca^{2+}	66/110	97.5%	± 13.7%	71-164%	81-120%
Mg^{2+}	4/110	95.8%	± 4.5%	92-102%	81-120%
Glucose	110/110	96.3%	± 8.6%	60-137%	85-120%

Conformity of 110 PN

- Conform
- Non-conform
- Non-acceptable



References

J Pharm Biomed Anal. 2010 Oct 10;53(2):130-6: "Determination of potassium, sodium, calcium and magnesium in total parenteral nutrition formulations by capillary electrophoresis with contactless conductivity detection" Nussbaumer et al.

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No conflict of interest