THERAPEUTIC DRUG MONITORING OF AMIKACIN IN NEONATES: ABOUT A NEW PROTOCOL

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Background and Importance

Amikacin is a widely used antibiotic in neonates. An adequate dosing regimen is essential for effective and safe therapy; however, many patients do not achieve adequate plasma concentrations due to high interindividual variability in this population.

Aim and Objectives

The aim was to compare the amikacin plasma concentrations in neonates according to the administered 15mg/kg/24h dosing regimen, a previously established protocol, versus the amikacin 12mg/kg/24h new protocol, to establish best initial dosing regimen, as well as analyzing differences between subpopulations (preterm or term).

Materials and Methods

- Retrospective observational study , between January-July 2023.
- Inclusion criteria:

  Neonates from neonatal unit or neonatal intensive care unit

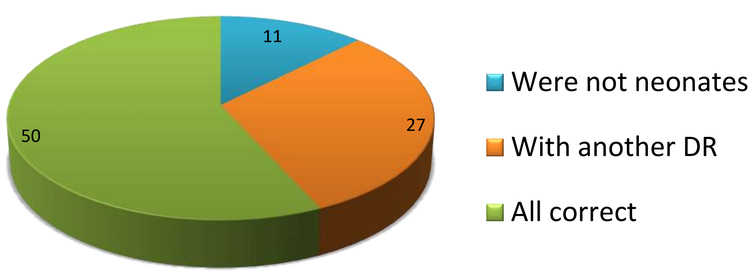
  Treated with amikacin

  Dosing regimen (DR): 12 mg/kg/24h or 15 mg/kg/24h

- Variables: gender, age, weight, preterm/term, DR, first level Cmin and Cmax plasma concentrations.
- Target levels: Cmin <5 µg/mL and Cmax 20-30µg/mL
- Quantitative variables are expressed as mean and standard deviation(SD) and qualitative variables as number and percentage(%). The chi-square test was used to compare qualitative variables.

Results

88 patients were selected



50 neonates included

26 (52.0%) male
7.6 (1.7) days
2.9 (1.0) kg
35 (70.0%) at term

Total patients (%)	Within range(%)	Out of range(%)	Mean Cmin (µg/mL)	Mean Cmax (µg/mL)	Protocol
24 (48.0)	18 (75.0)	6 (25.0)	1.4 (0.2)	26.0 (0.9)	**12 mg/kg**
26 (52.0)	7 (2.9)	19 (73.1)	2.3 (0.3)	33.5 (1.3)	**15 mg/kg**

Chi-square	P-value
11.5	$6.8*10^{-4}$

Conclusion and Relevance

This study demonstrates that **amikacin 12mg/kg/24h dosing regimen** guarantees better results in terms of optimal plasma concentrations in our study population in neonates, which allows us to establish this dosage regimen as the initial dose in our patients.

Clinical pharmacokinetics is essential for improving outcomes in neonates.