ATC code: J01 - Antibacterials for systemic use



# THERAPEUTIC DRUG MONITORING OF GENTAMICIN IN NEONATES



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# BACKGROUND AND IMPORTANCE

Peak (maximum plasma concentration)/MIC> 8-15 is pharmacokinetic (PK)/pharmacodynamic (PD) parameter that best correlates with effectiveness of aminoglycosides. A peak between 8-15 mg/L is necessary to achieve it. In neonates, doses between 3-5 mg/kg/day the first week and 7,5 mg/kg/day from the second to the fourth week of life, are recommended.

### AIM AND OBJECTIVES

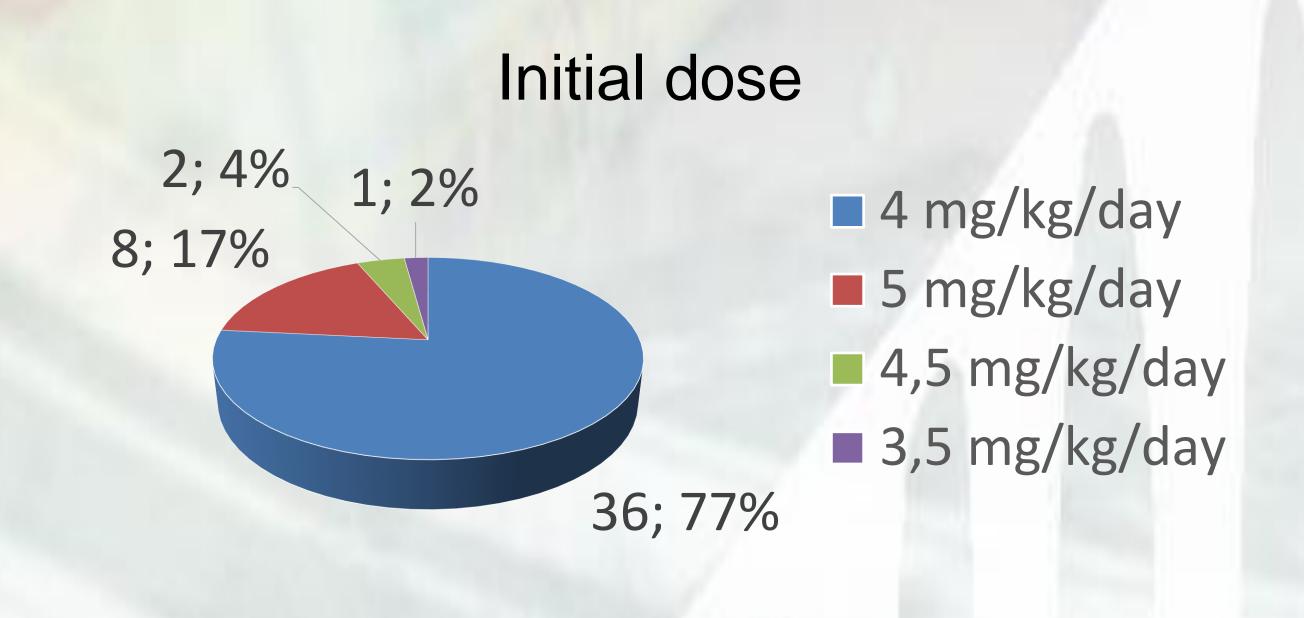
Evaluate the degree of adequacy of the initial dose with current recommendations and whether therapeutic drug monitoring (TDM) allows optimization of treatments.

## MATERIALS AND METHODS

Retrospective study from 1-1-2016 to 02-29-2020, in a general universitary hospital. Patients 0-35 days old treated with gentamicin and with plasma concentrations (Cp) were reviewed. The descriptive analysis was performed with SPSSv.24 program.

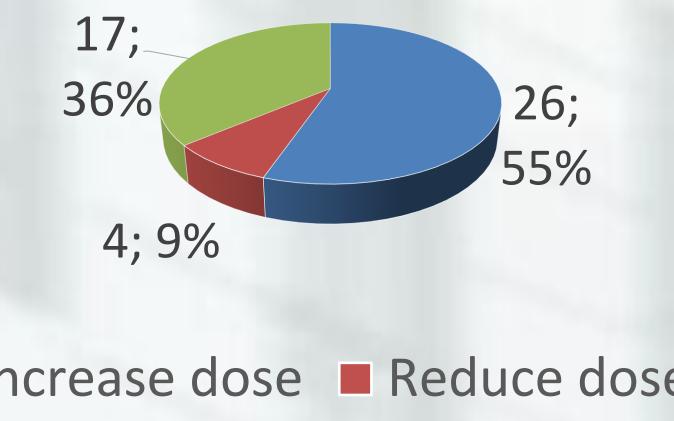
#### RESULTS

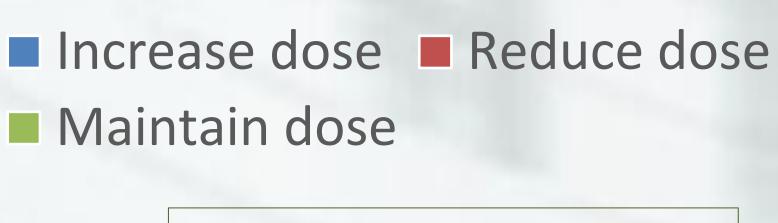
| TDM                   | 47 neonates       |                         |
|-----------------------|-------------------|-------------------------|
| Age                   | 3 (0-33) days     | 26 (55,3%) < 7 days old |
| Gender                | 33 (70%) men      |                         |
|                       | Neonatal sepsis   | 35 (72,3%)              |
| Type of infection     | Urinary infection | 7 (14,9%)               |
| Ampicilin             | 45 (95,7%)        |                         |
| Empiric               | 34 (72,3%)        |                         |
| Duration of treatment | 6 (2-9) days      |                         |



# First recommendation (TDM in 47 neonates):

Cp were extracted with a median of 2 days (1-4) after start, the median of peak was 7,5 mg/L (3,5-21,6), 29 (62%) had a peak< 8 mg/L. The through was <0,2 mg/L in 26 patients and of those that was quantified, the median was 0,4 mg/L (0,2-1,3), being higher than 1 mg/L only in a case.

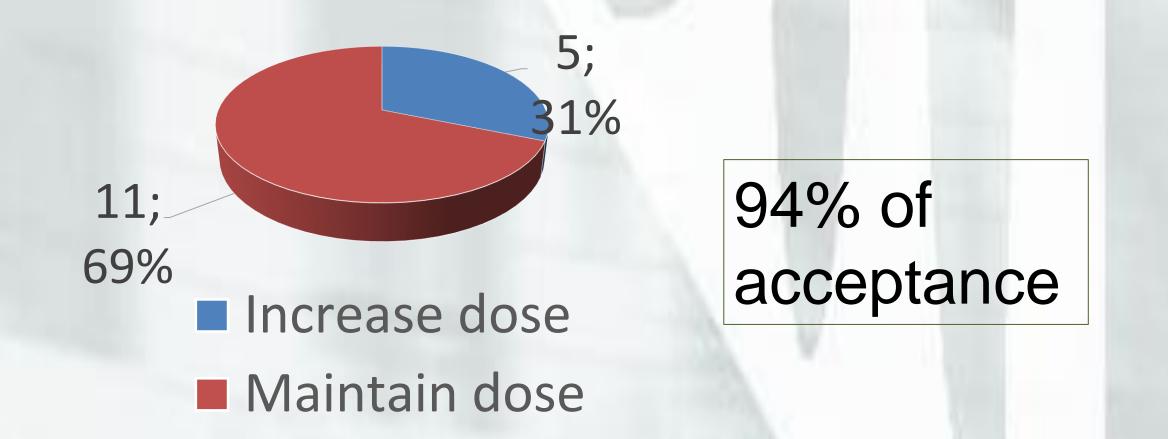




90% of acceptance



Median peak of 9 mg/L (6-12) and through always less than 0,5 mg/L



#### **CONCLUSION AND RELEVANCE**

The dose prescribed has been lower than recommended in neonates > 1 week old. Cp let to detect and correct deviations from the recommended peak or throug in 64% of cases, mainly due to low peak, with a high acceptance of TDM. Plasma determination and TDM of gentamicin continues to be an essential tool to achieve the recommended PK/PD.

#### REFERENCES

- 1. Fuchs A, Bielicki J, Mathur S et al. Reviewing the WHO guidelines for antibiotic use for sepsis in neonates and children. Paediatr Int Child Health 2018;38(sup1):S3-S15.
- 2. Bijleveld YA, van Den Heuvel ME, Hodiamont CJ, et al. Population pharmacokinetics and dosing considerations for gentamicin in newborns with suspected or proven sepsis caused by Gram-negative bacteria. Antimicrob. Agents Chemother 2016; 61(1): e01304–e01316.