

ORIGINAL ARTICLE

Demographic and Clinical Characteristics of Neonates at Risk of Gentamicin-induced Nephrotoxicity: A Single-Center Study in Sabah Women and Children Hospital

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ABSTRACT

Gentamicin is a clinically valuable aminoglycoside used empirically for the treatment of pneumonia, urinary tract infections, and neonatal sepsis. The recommended dosage for gentamicin in neonatal guidelines is 4 - 7 mg/kg at extended intervals of every 24, 36, or 48 hours, based on the subjects' gestational age. This study aimed to describe the demographic and clinical characteristics of neonates at risk of gentamicin-induced nephrotoxicity. This descriptive study was conducted among all neonatal patients receiving 5 mg/kg gentamicin with extended dosing intervals and had elevated blood gentamicin trough levels above 1 mg/L, indicating an increased risk of nephrotoxicity. Out of the total 44 subjects, 24 were preterm babies, and 27 had a body weight less than 2.5 kg. The subjects were categorized into two groups: the 24-hourly group and the 36-hourly group. There were 30 (68.2%) subjects in the 24-hourly group and 14 (31.8%) in the 36-hourly group. 20 out of 30 subjects in the 24-hourly group were term babies, whereas all subjects in the 36-hourly group were preterm babies. Of all 44 cases, gentamicin was administered during the first week of life in 31 cases, and after the first week of life in 13 cases. It appeared that the incidence of toxic gentamicin trough level was slightly lower in the 36-hourly group than in the 24-hourly group. It is recommended to use the 5 mg/kg 36-hourly regimen for all neonates in their first week of life when indicated.



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INTRODUCTION

Aminoglycosides, being an older class of antimicrobials, have continued to be clinically valuable in fighting infections. They are potent, broad-spectrum antibiotics covering aerobic organisms, including gram-negative bacteria and mycobacteria through the inhibition of protein synthesis. In general, aminoglycosides are indicated for both empirical and directed treatment (Block & Blanchard, 2024). Gentamicin, a member of the aminoglycoside class, was introduced in 1963 and commonly used for the treatment of pneumonia and urinary tract infections in pediatric practice (Kato et al., 2022). In neonates, gentamicin is routinely used with ampicillin or penicillin (cloxacillin if suspecting staphylococcal infection) for empirical treatment of neonatal sepsis (Hussain et al., 2018).

Despite over 60 years of clinical experience, gentamicin population pharmacokinetic studies are still lacking specifically for subpopulations, including pediatric, elderly and critically ill patients. Optimization of dosing strategy in these subpopulations require more fine tuning. Additionally, individualization of the dosage remains a challenge due to the narrow therapeutic range and substantial interindividual variability of gentamicin pharmacokinetics (Hodiamont et al., 2022).

In terms of dosing regimen, there is considerable variation between references, hence, selection of an initial dosing regimen can be challenging. The common dosage regimen used is 4-7 mg/kg every 24, 36 or 48 hours, depending on the gestational age (BNF for Children, 2022; Micromedex, 2024). Due to the potential for ototoxicity and nephrotoxicity, serum monitoring of gentamicin is recommended to ensure levels are within therapeutic range. Nephrotoxicity of gentamicin closely correlates with trough concentrations greater than 2 mg/L. However, some literature suggested to aim for a trough

concentration of less than 1 mg/L for extended-interval dosing since trough level of more than 1 mg/L suggests accumulation and potentially increases risk of nephrotoxicity (Darmstadt et al., 2008; Dersch-Mills et al., 2016).

In Sabah Women and Children Hospital, neonates with risk factors linked to neonatal sepsis such as maternal pyrexia, maternal Group B Streptococcus infection, septic blood counts, preterm or meconium aspiration syndrome are treated empirically with gentamicin alongside ampicillin or penicillin. The dosing of gentamicin commonly used in our setting is 5 mg/kg every 24 or 36 hours based on the gestational age (Table 1). Routine monitoring of serum trough level of gentamicin is done prior to the second or third dose due to the nephrotoxicity and ototoxicity risk. A therapeutic aim of serum gentamicin trough concentration of less than 1 mg/L was adopted as suggested in the Clinical Pharmacokinetics Pharmacy Handbook Malaysia (2019), a trough level above 1 mg/L is considered potentially toxic. Despite using recommended dosing, it was observed that over 30% of neonates treated with gentamicin experienced potential toxicity with gentamicin trough levels above 1 mg/L (Mustafa et al., 2022). Gonzalez et al. (2016) also found that 10% of neonates in their study experienced elevated initial trough gentamicin level. The objective of this study was to identify the demographic and clinical characteristics in neonates who are at risk of nephrotoxicity due to elevated gentamicin trough level despite application of recommended dosing regimen.

Table 1: Dosing of gentamicin in neonatal patients in Sabah Women and Children Hospital

Age Group		Dosing
Neonates	Gestational Age < 36 weeks, 1st week of life	5mg/kg 36 hourly
	Gestational Age < 36 weeks, after 1st week of life	5mg/kg 24 hourly
	Gestational Age ≥ 36 weeks	5mg/kg 24 hourly

METHODS

This was a single-center, cross sectional study conducted in the Sabah Women and Children Hospital. The Sabah Women and Children Hospital offers three levels of neonatal intensive care. Level 1 provides care for newborns with the least serious conditions, Level 2 is designed for those with moderately serious conditions, and Level 3 is reserved for neonates with the most serious conditions and requiring oxygen therapy. All patients who were prescribed intravenous gentamicin for more than one dose will be routinely checked for gentamicin trough level. The trough gentamicin serum level, which is associated with nephrotoxicity, will be measured within 30 minutes before the second or subsequent dose. Determination of gentamicin serum level was performed using the ABBOTT ALINITY I analyzer according to the instructions provided in the manufacturer's manual.

A non-probability sampling with purposive sampling method was employed. This study reviewed all neonates admitted to the Neonatal Intensive Care Unit (NICU) with at least one gentamicin serum level taken during admission from January till December 2019. Eligible patients were identified from the database of Therapeutic Drug Monitoring (TDM) records. TDM forms were screened for timing of blood samples taken and measured gentamicin levels. Only patients with blood samples taken within 30 minutes before second or subsequent gentamicin doses and had serum trough levels of above 1 mg/L were included.

The primary outcome of this study was to identify the demographic and clinical characteristics of neonatal patients who had elevated gentamicin trough level, hence, at risk of gentamicin-induced nephrotoxicity. Demographic data included gender, body weight, age, and ethnicity, whereas the clinical characteristics were described based on diagnosis, serum creatinine level, intubation

status and presence of concurrent nephrotoxic drug.

The demographic and clinical characteristics for eligible patients were extracted from the medical records. Data extracted include gender, body weight, age, ethnicity, diagnosis, dosing of gentamicin, serum creatinine level, intubation status and presence of concurrent nephrotoxic drug. Extracted data were recorded on a pharmacotherapy review form published by the Ministry of Health Malaysia.

This research was registered with the National Medical Research Registry (NMRR-20-1531-54586), and it was approved by the Malaysian Institutional Review Board/ Independent Ethics Committee (MREC) (Ref: KKM/NIHSEC/P20-1926(4)). Permission to waive informed consent was obtained from the MREC due to the study's retrospective design.

Data were initially transcribed into a Microsoft Excel 2021 Spreadsheet and later categorised based on demographic and clinical characteristics. Weights were grouped based on extremely low (less than 1kg), very low (1 to less than 1.5kg), low (1.5 to less than 2.5kg) and normal birthweight (2.5kg and above) as described by the World Health Organization (WHO). Age groups for neonates were categorised in regard to extremely preterm (less than 28 weeks), very preterm (28 to less than 32 weeks), moderate to late preterm (32 to 37 weeks) and term births (more than 37 weeks) as per WHO definition. Categorical data were summarized as frequencies and percentages. Descriptive statistics were performed to depict the demographic and clinical characteristics data.

RESULTS

In total, 632 TDM requests were reviewed. 82 cases met the inclusion criteria. Out of these 82 cases with serum trough levels of above 1 mg/L, 10 cases had elevated serum trough level above 5 mg/L. These cases were excluded

as the level is unlikely with 5 mg/kg extended interval regimen and the result could be due to sampling error. Another 28 cases were not included due to inability to locate the complete medical records. Only 44 cases were included for final data analysis.

Table 2 showed the demographic characteristics of patients with toxic gentamicin trough level. There were 34 male subjects and 10 female subjects. 61.4% of patients were from extremely low, very low and low birth weight groups. Majority of the patients (54.5%) were preterm neonates less than 37 weeks of gestational age.

Table 2: Demographic Characteristics of Patients with Toxic Gentamicin Trough Level

Characteristics	Frequency (Percentage)
Gender	
Male	34 (77.3%)
Female	10 (22.7%)
Body weight (kg)	
<1kg	2 (4.6%)
1-1.5kg	8 (18.2%)
1.5-2.5kg	17 (38.6%)
2.5kg and above	17 (38.6%)
Age group	
< 28 weeks	3 (6.8%)
28 to 31 weeks	8 (18.2%)
32 to 37 weeks	13 (29.5%)
> 37 weeks	20 (45.5%)
Ethnicity	
Malay	2 (4.6%)
Chinese	4 (9.1%)
Bajau	14 (31.8%)
Kadazandusun	12 (27.2%)
Brunei	3 (6.8%)
Murut	1 (2.3%)
Others	8 (18.2%)

On the other hand, the clinical characteristics of patients with elevated gentamicin trough level were depicted in table 3. 29 out of 44 patients (65.9%) were diagnosed with neonatal sepsis followed by meconium aspiration syndrome (15.9%). 23 out of 44 subjects (52.3%) had normal serum creatinine of less than 60 $\mu\text{mol/L}$. Majority of the patients were not intubated (61.4%) and not on concurrent nephrotoxic drugs (95.4%).

Dosing regimen wise, out of the total 44 subjects who had elevated blood

Table 3: Demographic Characteristics of Patients with Toxic Gentamicin Trough Level

Characteristics	Frequency (Percentage)
Diagnosis	
Group B Streptococcal (GBS) pneumonia	3 (6.8%)
Neonatal sepsis	29 (65.9%)
Meconium Aspiration Syndrome (MAS)	7 (15.9%)
Bronchopneumonia	2 (4.6%)
Others	3 (6.8%)
Serum creatinine ($\mu\text{mol/L}$)	
less than 60	23 (52.3%)
60-89	18 (40.9%)
more than 90	3 (6.8%)
Intubated	
Yes	17 (38.6%)
No	27 (61.4%)
Concurrent nephrotoxic drug	
Yes	2 (4.6%)
No	42 (95.4%)

gentamicin trough levels, there were 30 (68.2%) subjects in the 24-hourly group and 14 (31.8%) in the 36-hourly group. All subjects in the 36-hourly group were preterm neonates initiated with gentamicin in their first week of life. Whereas in the 24-hourly group, majority of the subjects (16 out of 30) were term babies prescribed with gentamicin in their first week of life (Table 4).

DISCUSSION

Gentamicin is mainly cleared via glomerular filtration and excretory renal function is more affected in neonates than in adults due to physiological and developmental factors (Pacifi, 2015). This study showed that the majority of the patients with toxic gentamicin trough level were premature neonates (<37 weeks) and with body weight of less than 2.5kg. These findings were consistent with a review by Llanos et al. (2017) that age and body weight were two main factors that influence gentamicin clearance. These two covariates were reported to have a positive relationship on clearance. Moreover, these findings were physiologically plausible, as neonatal nephrogenesis is not completed until 34 to 36 weeks of gestation (Gonzalez et al., 2016). Therefore, lower clearance in preterm neonates compared to term neonates resulted

Table 4: Distribution of Toxic Gentamicin Level Based on Age Group & Time of Gentamicin Initiation

Dosing	5mg/kg 36 hourly		5mg/kg 24 hourly	
Time of gentamicin initiation	Served in the first week of life	Served after first week of life	Served in the first week of life	Served after first week of life
Age	Frequency (Percentage)	Frequency (Percentage)	Frequency (Percentage)	Frequency (Percentage)
<28 weeks	2 (4.6%)	0	0	1 (2.3%)
28-31 weeks	5 (11.3%)	0	0	3 (6.8%)
32-37 weeks	7 (15.9%)	0	1 (2.3%)	5 (11.3%)
>37 weeks	0	0	16 (36.4%)	4 (9.1%)

in a higher possibility of elevated gentamicin trough level.

As gentamicin is primarily excreted via the renal pathway, renal function is the key component in gentamicin therapy (Ali et al., 2012). Clinically, serum creatinine values are the most convenient method to evaluate the renal function. However, in neonates and younger children, creatinine clearance and serum creatinine were often not identified as the influencing factors on gentamicin clearance, as they may not accurately reflect renal function in these populations. It is possible that a neonate may have significant renal injury with only slight serum creatinine increment since the muscle mass is small. For instance, a rise in serum creatinine from 1 mg/dl (88 umol/L) to 2 mg/dl (176 umol/L) as evident in renal injury in an adult may only result in an increment from 0.3 mg/dl (26.5 umol/L) to 0.6 mg/dl (53 umol/L) in a young infant (Llanos-Paez et al., 2017). In this study, majority of the patients (52.3%) with toxic gentamicin trough level had normal serum creatinine level of <60 umol/L. However, normal creatinine level in neonates might not necessarily reflect normal renal function (Llanos-Paez et al., 2017). Measurement of urinary volume may be another appropriate index for assessing renal function (Kato et al., 2022). But it was not evaluated in this study because not all neonatal patients receiving gentamicin had their urinary volume measured. In our hospital setting, all neonates from NICU Level 3 require strict input and output (I/O) charting, but this

is not applicable to neonates admitted to Level 2 and Level 1. Strict I/O charting typically required in neonates who are diagnosed with serious clinical condition like Persistent Pulmonary Hypertension of the Newborn (PPHN), Congenital Heart Disease (CHD), and Necrotizing Enterocolitis (NEC) or those undergoing surgical procedures (Constanza, 2022). Besides urinary volume, measurement of cystatin C which is directly related to glomerular filtration rate and not influenced by body mass, may be a valuable biomarker to assess the renal function in neonates (Baum, 2016). However, cystatin C is significantly more costly than serum creatinine thereby widespread measurements of cystatin C may not be feasible, specifically in resource-limited settings (Hundemer et al., 2024). In summary, the serum creatinine level should not be the sole indicator when deciding on the dosing of gentamicin, as it may not accurately reflect true renal function.

The ototoxicity of gentamicin was not investigated in this study, as gentamicin appears to have low ototoxicity rates in neonates when used with extended dosing intervals for a short duration (Ekmen & Doğan, 2021). This could be attributed to the less mature vestibular hair cells in neonates, and the maturation process may take a few weeks, resulting in reduced uptake of gentamicin into the cells and, consequently, less ototoxic effect. (Zaubitzer et al., 2024).

The use of TDM to optimize target

achievement and reduce toxicity is crucial, as the pharmacokinetic parameters of gentamicin can vary considerably in neonates. Clearance ranges from 0.49 to 6.3 L/h/70kg, and volume of distribution ranges from 26.6 to 63.7 L/70kg (Hollander et al., 2023). The trough serum level of gentamicin should be monitored in all patients receiving at least three doses, as the risk of nephrotoxicity increases with prolonged duration. On the other hand, peak levels are useful for evaluating the efficacy of gentamicin, as it is a concentration-dependent antibiotic. However, peak serum level monitoring was not routinely performed in our setting. In fact, peak levels are typically not required, as with extended interval dosing, the larger doses used are expected to yield concentrations sufficient for clinical efficacy (Mustafa et al., 2022). It has been reported that across the entire neonatal age and weight range, the gentamicin dosing regimens in the Dutch National Formulary for Children, the British National Formulary (BNF) for Children, Neofax, and the Red Book resulted in adequate peak but elevated trough concentrations (Pacifi, 2015). Model-based simulations also suggest that most neonates born at a gestational age above 34 weeks are expected to reach a peak level of at least 8 mg/L with a standard dose of 4 mg/kg once daily (Fuchs et al., 2014). Therefore, trough-only monitoring may be sufficient for neonatal patients prescribed gentamicin for empirical treatment.

Dosing of gentamicin is primarily initiated based on available guidelines, followed by serum level monitoring and subsequent dose adjustments. In view of the varied dosing recommendations across different neonatal guidelines and based on clinical practice, our hospital adopted the dosing regimen depicted in Table 1. Our study reported that 30 out of 44 subjects with toxic gentamicin trough levels received the drug at 24-hour intervals. In particular, 16 of these 30 patients were term babies receiving gentamicin during their first week of life. The dosing regimen in our setting for term

neonates requiring gentamicin in their first week of life is 5 mg/kg every 24 hours, similar to the recommendations in Micromedex (Micromedex Products: Gentamicin, 2024). Conversely, BNF for Children (2022) suggests administering gentamicin at a longer interval of every 36 hours in all neonates up to 7 days of life. Mustafa et al. (2022), who studied gentamicin serum levels in one-week-old neonates, also suggested that a prolonged dosing interval of 36 hours should be implemented in neonates weighing less than 2 kg, regardless of gestational age.

Theoretically, nephrogenesis is considered complete in term neonates; hence, administration of gentamicin at 24-hour intervals in term babies is acceptable. However, significant functional changes continue to take place during the first week of life as the neonate matures. Renal function only starts to stabilize by the 5th to 7th postnatal day and slowly progresses to eventually reach the adult state (Sulemanji & Vakili, 2013). Furthermore, a study by Hollander et al. (2023) found that 65.1% of term neonates on 5 mg/kg 24-hourly gentamicin had elevated trough levels of >1 mg/L, indicating an overestimation of clearance in term neonates. On the other hand, a prospective cohort study by Van Maarseveen et al. (2016) found that a gentamicin dosing regimen of 5 mg/kg every 36 hours led to the attainment of safe trough concentrations in all neonates >32 weeks gestation. Thus, these findings may warrant revising the gentamicin dosing interval to every 36 hours in term neonates during their first week of life due to maturational changes.

Our study has some noteworthy limitations. First, it was conducted at a single-center, which may limit the external validity of our findings, as they may not generalize well to other neonatal populations with different demographics and healthcare systems. The smaller sample size and the homogeneous environment of a single center could also introduce bias. Second, there is a lack of a

control group. This study only reviewed patients with elevated trough gentamicin levels; hence, there is no comparison group to evaluate possible risk factors that could be useful in predicting or preventing nephrotoxicity. Third, due to the retrospective design of our study, challenges such as missing or incomplete documentation encountered during data extraction from medical records may have resulted in inadequate data collection and potential biases. Missing data might mean that certain patient demographics or clinical characteristics are underrepresented, potentially impacting the generalizability and accuracy of the findings.

CONCLUSION

Gentamicin is a valuable aminoglycoside for treating infections in the neonatal population. Considering the significant variability in gentamicin pharmacokinetics within this population, serum level monitoring plays an essential role in ensuring adequate efficacy while minimizing toxicity. Gestational age and weight appear to be important demographic factors for predicting nephrotoxicity. Renal function in neonates should be assessed using multiple methods rather than relying solely on serum creatinine levels. In terms of dosing, the incidence of elevated gentamicin trough levels, which correlates with nephrotoxicity, was slightly lower in the 36-hourly group compared to the 24-hourly group. This study may serve as a basis for modifying prescribing patterns by recommending a 36-hourly regimen for all neonates during their first week of life and for neonates weighing less than 2 kg, regardless of gestational age. However, more in-depth studies are needed to confirm these findings. Future research could focus on validating these findings through multi-center studies to ensure broader applicability and reliability.

CONFLICT OF INTEREST

No conflict of interest was declared by the

authors

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