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Optimizing Paediatric Paracetamol Dosing: Transitioning from Age-Based to Automated Weight-Based Calculations in Saudi Arabia

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Abstract—Introduction: **Paracetamol is one of the most commonly used over-the-counter (OTC) medications for managing conditions in paediatric patients.**

Objectives: **Evaluate paediatric paracetamol dosing by age versus weight, and propose automated solutions for OTC dosing.**

Methods: **A retrospective study compared weight-based (15mg/kg) to age-based dosing in children 0-12 years of age.**

Results: **A total of 352 paediatric patients were included, with a mean age of 5 years, 4.8 months (SD=48 months) and a median weight of 16.9 kg (IQR:10.4 to 25.75). We observed that 71.59% of patients (n=252) are likely to be underdosed when using age-specific dosages rather than their actual weight. Conversely, 27.56% (n=97) could be overdosed, and only 0.85% (n=3) received an accurate dose. The discrepancies between the age-based and weight-based doses ranged from 1 mg to 928.5 mg per dose. We noted a correlation between the patient's weight and the variation in dose between the two different methods of dosing; $r(350)=0.82$, $p<0.001$. The regression was significant [$F(1,350)=742.18$, $p<0.001$], with 67.2% of the variability in dose difference explained by the patient's weight. The average difference in dose was 6.9 mg for every kilogram of the patient's weight. A linear regression analysis revealed that the patient's age was also a significant predictor of dose difference ($F(1,350)=150.12$, $p<0.0001$), with age explaining 29.8% of the variance. On average, the dose of paracetamol differed by 1.5 mg for each additional month of patient age ($p<0.001$).**

Expected impact: **To optimise the dosing of OTC medication and enhance safety, we propose the use of supervised machine learning with Saudi growth charts, and the integration of a weight-based dosing calculator into the 'Sehaty' app.**

Index Terms—**Artificial Intelligence, Body Weight, Drug Dosage Calculations, Medication Errors, Paracetamol (Acetaminophen), Patient Safety, Paediatrics.**

I. INTRODUCTION

Paracetamol, known internationally as acetaminophen, is one of the most commonly used medications for treating fever and mild to moderate pain in paediatric patients. It is widely recognised for its efficacy, tolerability, and safety profile when administered correctly [1,2]. However, dosing paracetamol based on body weight is crucial to avoid adverse effects, such as underdosing, which can lead to ineffective treatment, or overdosing, which raises the risk of serious liver toxicity [1,3]. As a drug often used by caregivers at home and frequently prescribed in paediatric healthcare settings, the accuracy of its dosing is of paramount importance. Incorrect dosage, whether due to reliance on age-based estimates or errors in reading body weight, could contribute to suboptimal outcomes in children [4,5].

In paediatric care, the patient's body weight is a fundamental factor used by healthcare providers to calculate the correct dosage of many medications, including paracetamol. This weight-based dosing strategy is essential because drug clearance and the volume of distribution in paediatric patients differ from those in adults [2,5]. Any error in determining the actual weight of a paediatric patient could significantly impact the dosage and effectiveness of the medication they receive [6-8].

The challenge of accurately dosing paediatric patients is not unique to Saudi Arabia; it is a concern worldwide. Several studies have demonstrated the prevalence of errors in paediatric dosing, particularly when healthcare providers rely on age-based estimates or inaccurate body weight measurements

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[7,9,10]. These studies report discrepancies between the prescribed dose and the actual required dose based on the child's weight, emphasising the need for individualised calculations that capture accurate weight measurements in all paediatric healthcare settings [11-14].

In the case of OTC paracetamol, paediatric patients may receive a dose based on their approximate age or a 'one-size-fits-all' weight estimate printed on the medication bottle, rather than an accurate, up-to-date body weight measurement. This discrepancy can lead to suboptimal treatment outcomes, particularly in children who are significantly underweight or overweight for their age [15,16].

In the context of Saudi Arabia, there is limited research examining how closely prescribed paracetamol dosages align with actual body weight in paediatric populations. By comparing the doses of paracetamol based on age and general weight estimates with the ideal doses calculated according to actual body weight, this study aims to identify any discrepancies that may exist. Highlighting these discrepancies could encourage improvements in prescribing practices, ensuring that children receive the safest and most effective doses of paracetamol.

II. METHODOLOGY

Study design

This study is a retrospective, cross-sectional analysis conducted at a tertiary hospital in Saudi Arabia.

Study population and setting

The study included a random selection of Saudi Arabian paediatric patients aged 0-12 years. Data was collected over the period from August 2023 to October 2023.

Inclusion criteria

Paediatric patients aged 0–12 years, whose body weights were recorded during the treatment period, were included in the study.

Exclusion criteria

Patients were excluded if their charts were missing a recorded body weight.

Sample size estimation

The sample size was determined using a power analysis to ensure the clinical significance of any identified dose discrepancies. Assuming an effect size of 0.3, a significance level (alpha) of 0.05, and a power of 80%, the study included at least 352 patients. The final sample size depended on data availability and the inclusion of eligible patients within the study period.

Data collection

Data was extracted retrospectively from the hospital's electronic health record (EHR) system. The information collected for each patient included their age (in months/years), gender, and body weight (in kilograms), as recorded at the time of their hospital visit.

Calculation of ideal paracetamol dose

The ideal paracetamol dose was calculated according to the standard dosage of 15 mg/kg per dose, administered every 4-6 hours, with a maximum daily dose of 75 mg/kg. Each patient's actual body weight, as recorded in their health record, was used to calculate their ideal dose. The following formula was applied:

Ideal Dose (mg) = Body Weight (kg) × 15 (mg/kg)

For patients receiving multiple doses, the total daily dose was calculated and compared with the recommended maximum daily dose.

We then compared the calculated dose (in milligrams per dose and total daily dose) with the age-based dosage recommendations provided in the drug leaflets. The comparison was conducted using two different brand-name formulations.

Data analysis

Data was analysed using Stata Statistical Software: Release 17. Descriptive statistics were used to summarise demographic data, including age, gender, and body weight. We used the Pearson correlation, Fisher's exact test, and linear regression models in our analysis.

Ethical considerations

Ethical approval was obtained from the hospital's Institutional Review Board before the study commenced. Since this was a retrospective study, informed consent was not required from the patients; however, all patient data was anonymised to ensure confidentiality. Only authorised personnel had access to the data, and the analysis was conducted in accordance with the hospital's data protection policies.

III. RESULTS

Demographics

A total of 352 paediatric patients were included in the analysis. The mean age of the cohort was 5 years and 4.8 months (SD = 48 months), ranging from 3 days to 12 years. Males accounted for 55.9% (n = 197) of the sample. The median body weight was 16.9 kg, with an interquartile range (IQR) of 10.4 kg to 25.75 kg.

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Age-specific vs weight-specific dosage

We found that 71.59% of patients (n = 252) can be expected to be underdosed on the basis of age-specific dosage compared with that for their actual weight, while 27.56% (n = 97) will be overdosed, and only 0.85% (n = 3) will receive an accurate dose (Table 1).

An exploration of the median and maximum daily doses, assuming five doses per day, reveals that the median daily dose based on age is 1200 mg (IQR: 600 mg to 2000 mg), with the highest daily dose being 2400 mg, which remains below the maximum allowable dose. In contrast, the median daily dose based on weight is 1267.5 mg (IQR: 780 mg to 1931 mg), with a maximum daily dose of 1408.5 mg. Although the median age-based daily dose (1200 mg) is only slightly lower than the median weight-based daily dose (1267.5 mg), the majority of patients receive substantially lower doses using the age-based protocol. This discrepancy appears because a few age groups are assigned relatively high doses, skewing the upper end of the range (maximum: 2400 mg), while most patients fall into categories with lower-than-appropriate dosing.

The median difference between age-based and weight-based doses is 49.5 mg, with an IQR of 22.5 mg to 98.5 mg, and differences ranging from as little as 1 mg to as much as 928.5 mg.

Correlation between patient age and dose difference

The Pearson correlation between the patients' age and the dose difference reveals a moderate yet statistically significant association, $r(350) = 0.55$, $p < 0.001$. A linear regression analysis (Table 2) shows that patient age significantly predicts the difference between age-based and weight-based doses, $F(1,350) = 150.12$, $p < 0.0001$, with age explaining 29.8% of the variability in dose difference. On average, the difference in paracetamol dosage differs by 1.5 mg for each additional month of patient age, with this coefficient being highly significant ($p < 0.001$) (Figure 1). Based on the confidence interval, the slope relating dose difference to patient age is between 1.25 and 1.72 (95% CI). We used the regression equation: Dose difference = -1.62 + 1.49 (age).

Correlation between patient weight and dose difference

The Pearson correlation between the patients' weight and dose difference was $r(350) = 0.82$, $p < 0.001$, indicating a strong and statistically significant association. A linear regression analysis was conducted to assess the extent to which patients' body weight predicted the dose difference (Table 2). The regression was significant, $F(1,350) = 742.18$, $p < 0.001$, with body weight accounting for 67.2% of the variability in dose difference. With a coefficient of 6.86, the average difference in dose is 6.9 mg for each additional kilogram of body weight. This coefficient is also highly significant ($p < 0.001$) (Figure 2).

Based on our confidence interval, the slope relating dose difference to patients' weight is between 6.36 and 7.35 (95% CI).

We used the regression equation: Dose difference = -48.76 + 6.86 (weight).

Correlation between patient gender and dose difference

The Fisher's exact test did not reveal a significant association between gender and discrepancies in paracetamol dosing ($p = 0.112$), suggesting that gender does not play a substantial role in dosing accuracy.

IV. DISCUSSION

To our knowledge, this is the first study to explore and compare age-based dosing with weight-based dosing in paediatric patients. Our results showed significantly large discrepancies in these doses, with more than two-thirds of patients underdosed, 27.56% overdosed, and less than 1% dosed correctly. These results highlight shortcomings in paediatric medication practices, particularly in settings where weight-based dosing should be prioritised for medication safety. The implications are critical for paediatric healthcare in Saudi Arabia, where there is a scarcity of studies on this topic.

In paediatrics, correct dosage of paracetamol is key to both safety and effectiveness. While age-based dosage is simpler and more practical in busy clinical settings, it does not account for individual variations in body weight and can lead to under- or overdosing [17]. Weight-based dosage is more precise [18]; nonetheless, weight measurements are not always up to date and age-based guidelines are still used. Alomary et al reported that 29% of medication errors in a Saudi hospital were dose related; more than any other type of error [19]. Similarly, Al-Jeraisy et al also reported 22% of errors being dose-related in another Saudi hospital. Paracetamol, salbutamol, and amoxicillin were the most common drugs involved in medication errors [20].

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Underdosing in paediatric patients, as this study uncovered, can result in inadequate therapeutic effect, especially in cases where pain and fever management is required [21]. In Saudi Arabia, where there is an emphasis on improving paediatric care, underdosing may compromise treatment outcomes and increase the number of hospital visits. According to El- Egunsola et al. (2019), the inappropriate dosing of common medications like paracetamol and amoxicillin calls for more refined dosing to avoid therapeutic failure [22].

Although overdosing was observed in less than one-third of our sample, it raises significant concerns regarding the risk of hepatotoxicity. A study by Schillie et al. (2009) found that medication errors, including overdosing, are common in paediatric wards, paracetamol being one of the most common culprits usually leading to emergency department visits. This is alarming, as overdosing paracetamol can cause liver failure [23].

The positive correlation between age and dose difference means that age is a significant predictor of dosing errors. As paediatric patients get older, their weight might increase disproportionately to the age-based dosing guidelines, resulting in the dose discrepancy [24]. This was confirmed by our linear regression analysis, in which age accounted for 29.8% of the variation in dose difference. The implication is that reliance on age-based dosing becomes increasingly problematic as children grow older and their weight deviates further from that assumed in the drug leaflet.

It is noteworthy that age-based prescribing guidelines do not always take into account variations in body weight such as obesity and malnutrition. In their study in the Gulf Region, Adam et al. (2024) reported an increasing incidence of high body weight among Saudi children, particularly those living in urban areas [25]. In obese children, age-based dosing methods may result in significant underdosing and suboptimal therapeutic outcomes when using paracetamol.

Weight was found to be a stronger predictor of dose discrepancy ($r = 0.82$, $p < 0.001$), accounting for 67.2% of the variation in dosing errors. This means that weight is a better metric to determine correct paracetamol dosage in paediatric patients, as supported by the guidelines that recommend weight-based dosing as the gold standard. This being the case, patients' weight should be measured regularly, and a weight-adjusted dosing formula applied to minimise errors [26].

Gender differences in drug metabolism have been noted in some studies, especially during puberty, with its associated changes in body composition and metabolism. Nonetheless, we found no correlation between gender and paracetamol dose discrepancies in our paediatric population. Previous studies, such as that of Mohammed et al. (2012), found minimal difference in the pharmacokinetics of paracetamol between boys and girls, which supports our findings [27].

Over the last five decades, artificial intelligence (AI) has made significant strides in health care, driving transformative progress across numerous medical fields [28]. Advances in machine learning (ML) and deep learning (DL) have enabled personalised medicine, shifting from algorithm-centric approaches to tailored solutions. AI has revolutionised clinical decision-making, diagnostics, rehabilitation, surgical processes, and prognostic evaluations [29]. Researchers and analysts globally have integrated ML into diverse studies, leveraging its role in big data analysis. Supervised machine learning (SML) techniques, including Naïve Bayes, Logistic Regression, Random Forest, and Support Vector Machine (SVM), are pivotal for generating predictive outcomes from trained datasets [30].

Another machine learning technique is reinforcement learning, which is the foundation of deep reinforcement learning (DRL). It presents an innovative strategy for optimising drug dosage regimens by enabling a decision-making agent to learn through interaction with a simulated environment. DRL involves an agent receiving feedback—rewards or penalties—for its actions and learning a policy to maximise long-term rewards. For drug dosage optimisation, the agent selects appropriate dosages within a simulated patient model that captures dynamic physiological factors, including pharmacokinetics, pharmacodynamics, and potential side effects [31,32].

A customised AI/ML-based dose recommendation system that integrates information from several sources, including safety and efficacy metrics, electronic health records, growth charts for Saudi children and adolescents, treatment history, and patient input, might be beneficial for patients. The goal of such system is to reduce adverse effects while increasing therapeutic efficacy. Already, predicting and modifying doses for precision-based cancer therapy has been demonstrated to be possible with

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reinforcement learning systems [33]. Deep reinforcement machine learning presents a transformative method for personalised medicine by facilitating adaptive optimisation of drug dosages. Successful applications of DRL have been highlighted in various therapeutic areas, such as sepsis treatment, cancer chemotherapy, and diabetes management [31]. Although the availability and accessibility of such large databases may present a challenge, the cost of medication errors and their consequences justifies further investment in this area.

V. CONCLUSION

To optimise the dosing of over-the-counter (OTC) paracetamol and enhance the safety and accuracy of dispensing, we propose the use of reinforcement or deep reinforcement machine learning algorithms in conjunction with growth charts for Saudi children and adolescents. Additionally, we recommend integrating these algorithms into the national health application, '*Sehaty'*.

Overall, the implementation of this multifaceted strategy would optimise dosing of OTC medications, based on patients' body weight and tailored to the medication brands available in Saudi Arabia. Future research is needed into the paediatric dosing of other medications, such as ibuprofen. By following these recommendations, paediatric hospitals in Saudi Arabia can improve medication safety and therapeutic outcome for their patients.

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Table 1. Distribution of Dosing Accuracy (n = 352).

Dosing Category	Number of Patients (N)	Percentage (%)
Underdosed	252	71.59
Overdosed	97	27.56
Accurately dosed	3	0.85
Total	352	100

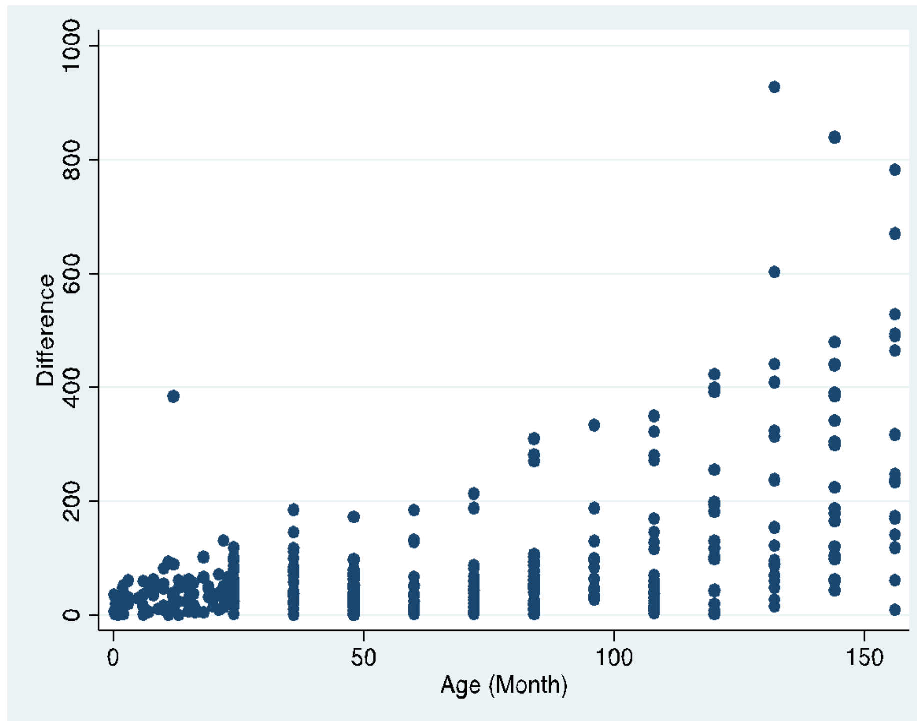

Figure 1. Scatter plot illustrating dose differences in relation to patients' age

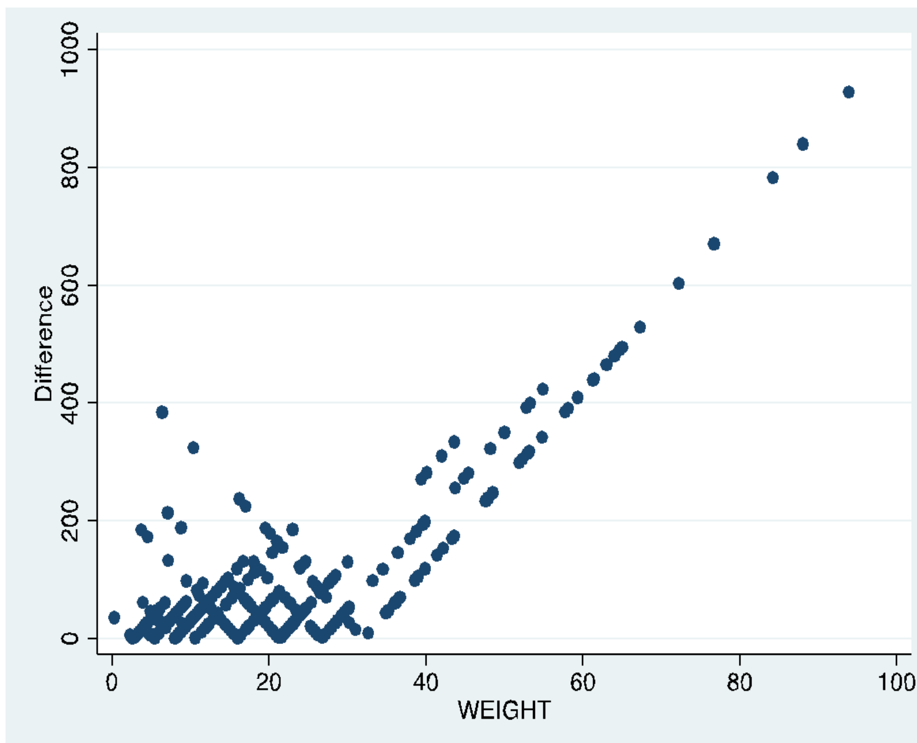

Figure 2. Scatter plot illustrating dose differences in relation to the patient weight

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Table 2. Linear regression analysis predicting factors that affect dose difference.

Predictor Variable	Coefficient (β)	95% Confidence Interval	R^2	F-statistic	P-value
Age (months)	1.5 mg	1.25 – 1.72	0.298	150.12	< 0.001
Weight (kg)	6.9 mg	6.36 – 7.35	0.672	742.18	< 0.001

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