RESEARCH PAPER

Pediatric-Friendly Oral Drug Delivery Systems for Chronic Kidney Disease Management

Dr Reenoo Jauhari*[1] Dr Apparanjitha V Ramana [2] Dr Ankit Sharma[3] Amandeep Singh[4] Dr. Hemant Kumar Singh[5]

*[1]School of Pharmacy, Graphic Era Hill University, 24807, Dehradun, India. Specialization: Pharmacy Practice
ORCID ID: 0000-0001-8508-3113Email ID: reenoojauhari1309@gmail.com
[2]Senior Resident, Sree Balaji Medical College And Hospital, ChennaiSpecialization: Paediatrics
Email ID: apparanjitha1998@gmail.com
[3]Assistant Professor, Department of Pediatrics, Subharti Medical College, Swami Vivekanand Subharti University, Meerut, Specialisation - Pediatrics. Email ID - drankit.sharma10@gmail.com
ORCID ID - 0009-0009-7296-227X
[4]Assistant Professor, School of Allied Health Sciences (AHS), CGC University, Mohali -140307, Punjab, India
Email ID: Star.Amandeep@gmail.com
[5]Assistant Professor, School of Pharmacy and Paramedical Sciences, K K UNIVERSITY, Biharsharif, Nalanda, Bihar-803115 Email ID: hemantkumarsingh57@gmail.com
ORCID ID: 0009-0009-5658-3675

Abstract
Chronic kidney disease (CKD) in pediatric populations requires long-term pharmacotherapy, where medication adherence plays a critical role in achieving optimal clinical outcomes. However, conventional dosage forms often present challenges such as poor palatability and swallowing difficulties, leading to reduced compliance among children. To evaluate the impact of pediatric-friendly oral drug delivery systems on medication adherence and clinical outcomes, and to compare adherence between conventional and pediatric-friendly formulations in pediatric CKD patients. A retrospective observational study was conducted involving 80 pediatric CKD patients. Data were collected from medical records, including demographic characteristics, drug formulation type, adherence status, and clinical parameters such as eGFR, serum creatinine, and blood pressure. Statistical analysis included descriptive statistics, chi-square test, Pearson correlation, and logistic regression. Pediatric-friendly formulations demonstrated higher adherence scores compared to conventional dosage forms. A significant association was observed between formulation type and adherence ($p = 0.003$). Improved adherence was positively correlated with better clinical outcomes, including enhanced eGFR and blood pressure control. Logistic regression identified pediatric-friendly formulations as a significant predictor of good adherence. Pediatric-friendly oral drug delivery systems significantly improve medication adherence and clinical outcomes in children with CKD. Optimizing formulation design is essential for enhancing treatment compliance and achieving better disease management in pediatric populations.

Keywords: Pediatric CKD, drug delivery systems, medication adherence, oral formulations, clinical outcomes

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1. Introduction

Pediatric patients with chronic kidney disease (CKD) is a chronic disease with high morbidity levels, which impairs growth, development, and long-term health outcomes. Children with CKD have to be under pharmacological treatment to be able to regulate the disease progression and the related factors like hypertension, anemia, and metabolic disruptions (Reis et al., 2018; Emma et al., 2019). The development of the pediatric care has prolonged the lifespan, which has led to the necessity of developing prolonged therapeutic approaches that address the needs of children (Khandros and Kwiatkowski, 2019). Moreover, pediatric pharmacokinetics is also complicated; this fact makes the optimization of treatment even more complicated (Engle et al., 2015). CKD imposes a significant burden in both physiological and psychological and social difficulties, which affect the treatment compliance. The longevity and multiple prescriptions are the characteristics of the way pediatric patients have to follow treatment, and the adherence is a critical predictor of the outcomes in the clinical setting (Eiland et al., 2018). The growing importance of precision therapeutics raises the concern of customized and patient-centered treatment practices in children (McLaughlin et al., 2019).

There are special difficulties in the drug delivery to the child population in comparison with adults. The difficulties in digesting conventional tablets and capsules are some of the reasons why the users do not get the complete dosage or refuse to take the medications, especially among young children (Galande et al., 2020). Aversion to taste and low palatability also increase the lack of compliance, since children are more

*Author for Correspondence: reenoojauhari1309@gmail.com

inclined to the unpleasant taste (Nadeem, 2021). These difficulties are even made more complicated in chronic disorders that involve long term treatment. The other major problem is dose flexibility, whereby the children need to be provided with specific doses according to body weight and stages of development. Alteration of adult dosage forms is frequently needed, which can undermine the stability and accuracy of drugs (Li et al., 2020). Moreover, the intervention of parents in the administration of medications brings in new complications, such as proper management of drugs and storing them (El Edelbi, 2021). All of these impose on the poor compliance and inefficient therapeutic outcomes.

In order to address these barriers, there has been significant advancements in the development of oral delivery of drugs, which are pediatric friendly. Syrups and suspensions are very common liquid formulations that are easily administered, and they are more palatable. Orodispersible and dispersible tablets also have more benefits since they dissolve quickly in the oral cavity, which avoids the challenge of swallowing (Adepu and Ramakrishna, 2021). Recent technologies in drug delivery, mini-tablet, granules, and cellulose based hydrogel drugs have shown the possibility of controlled and sustained release (Ciolacu et al., 2020). Even more, patient acceptability and adherence can be achieved with the help of flavoring formulations and taste-masking (Lavradorinho, 2021). Innovations in pharmaceutical research remain focused on the need to develop child-formulations to enhance the outcome of therapy (Lee et al., 2021).

In spite of these developments, there is still a deficit of clinical evidence that assesses the clinical usefulness of pediatric friendly formulations in enhancing treatment adherence and outcomes in CKD patients. The majority of available literature revolves around the development of the formulations, or disease-specific treatment in other childhood diseases, including pancreatitis, HIV, or radiation-related disorders (Abu-El-Haija et al., 2018; Gittus and Roach, 2016; Kaur et al., 2017). On the same note, the new treatments of infectious disease emphasize the relevance of individualized delivery of drugs in patients with renal failure (Adamsick et al., 2020). Thus, a retrospective study is needed to determine the impact of various oral drug delivery methods on the adherence and clinical outcomes in CKD children. This real-life data can be useful in the optimization of pharmacotherapy, as well as in enhancing patient-centered care.

Objectives of the study

1. To evaluate the impact of pediatric-friendly oral formulations on medication adherence and clinical outcomes in pediatric CKD patients.
2. To compare adherence between conventional and pediatric-friendly oral dosage forms.

2. Methodology

2.1 Study Design

The study was carried out as a retrospective observational study to determine the effects of pediatric-friendly oral drug delivery system on the medication adherence and clinical outcome of children with chronic kidney disease (CKD). The available medical records were used to retrieve patient data. The retrospective design allowed exploring the actual practises of treatment, adherence behaviour, and clinical outcomes without interfering with the current therapeutic interventions and prescribing patterns.

2.2 Study Population

The study included 80 pediatric patients who had CKD. Eligible patients were patients aged (0-18) years that were on oral pharmacotherapy. Those who had incomplete medical registers or acute renal diseases were excluded. Overall, both male and female patients in the groups of diverse CKD stages were included in the study population, which made it possible to assess adherence dynamics and clinical outcomes in a representative group of children with CKD.

2.3 Data Collection

Electronic medical records were analyzed to obtain a structured form of data. Age category, sexual orientation, CKD stage, oral medication type of formulation, adherence status, and clinical indicators (eGFR, serum creatinine and blood pressure) were some of the information collected. There were also scores in adherence. This helped to provide consistency and achieve a detailed analysis of how relationships between the type of formulation, adherence, and clinical outcomes developed.

2.4 Classification of Drug Delivery Systems and Outcomes

The oral drug formulations were classified into conventional (tablets and capsules) and pediatric-friendly formulations (syrups, suspensions, dispersible tablets and granules). Clinical documentation was used to determine medication performance as either good or poor. The main outcomes were the levels of adherence, whereas secondary ones were the alteration of eGFR, serum creatinine, and blood pressure. This categorization helped to make comparisons of the effectiveness of therapeutic application between various types of formulation.

2.5 Statistical Analysis

The analysis through statistical analysis was conducted on the standard analytical software. Demographic characteristics and adherence scores were summarized by descriptive statistics. Formulation type and adherence were measured using the chi-square test to determine their correlations. The correlation was used to assess the relationships between adherence and clinical outcomes. Predictors of good adherence were identified after the use of regression. A p-value of below0.05 was regarded as significant in the whole analysis.

3. Results

3.1 Demographic Characteristics

Eighty pediatric patients with chronic kidney disease (CKD) were used in this retrospective study. Most of the patients belonged to the (6 to 10) years old bracket (35.0%), then (11 to 15) years (31.3%). The population of the male patients was 57.5% of the total population. The most common one was CKD Stage III (37.5%), which means moderate severity of the disease. The representative pediatric CKD cohort is demonstrated in demographic distribution (Table 1).

Table 1. Demographic Characteristics

Variable	Category	Frequency (n)	Percentage (%)
Age Group (years)	0–5	12	15.0
	6–10	28	35.0
	11–15	25	31.3
	16–18	15	18.7
Gender	Male	46	57.5
	Female	34	42.5
CKD Stage	Stage I–II	18	22.5
	Stage III	30	37.5
	Stage IV	20	25.0
	Stage V	12	15.0

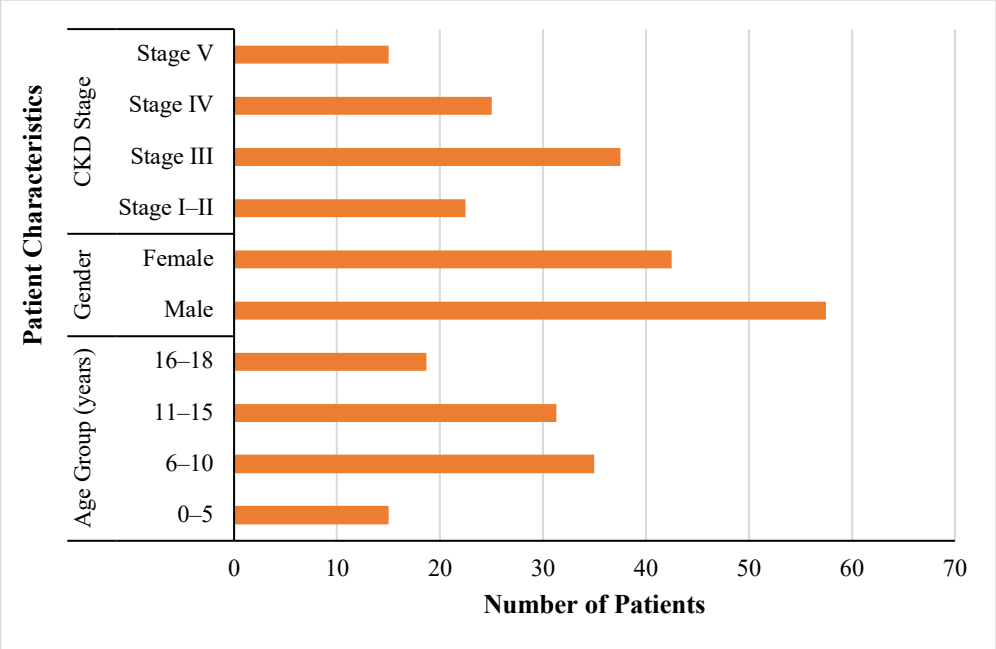

Figure 1. Demographic Characteristics

Figure 1 indicates the distribution of the pediatric patients by the age, gender, and chronic kidney disease stages. It presents differences among demographic classes and severity of the disease, which gives a picture of the population under study. The visualization is based on the general trend of patient characteristics that were represented in the retrospective analysis.

3.2 Distribution of Drug Delivery Systems

Systems of drug delivery that are pediatric friendly showed a higher adherence rate as compared to the traditional formulations. The mean adherence scores were greatest in syrups and suspensions (8.3 ± 1.2), then in dispersible tablets (8.1 ± 1.4) and then granules (8.0 ± 1.3). Traditional dosage forms demonstrated a relative low adherence (6.1 +1.8) which means lower acceptability by the pediatric patients (Table 2).

Table 2. Mean Scores Across Drug Delivery Systems

Formulation Type	Mean Adherence Score ± SD
Conventional	6.1 ± 1.8
Syrups/Suspensions	8.3 ± 1.2
Dispersible Tablets	8.1 ± 1.4
Granules/Mini-tablets	8.0 ± 1.3

Overall Pediatric-Friendly	8.2 ± 1.3

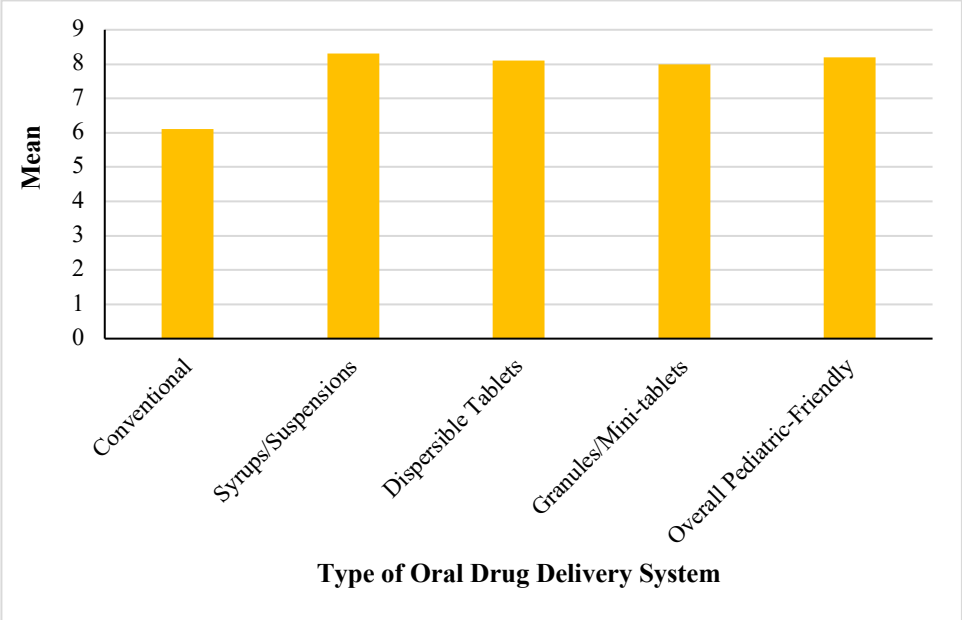

Figure 2. Mean Scores Across Different Oral Drug Delivery Systems

Figure 2 depicts the correlation between the mean scores of the adherence to different oral drug delivery systems in pediatric CKD patients. Pediatric friendly formulations exhibit better adherence rates than standard dosage forms used. The graphical representation shows that the differences in patient compliance are those that are related to the type of formulation, and the need to utilize child-friendly delivery methods of drugs.

3.3 Adherence Outcomes

The drug formulation type and medication adherence were found to have a statistically significant relationship. There were 36 patients with good adherence and 14 with the conventional group among the pediatric-friendly formulation users. The non-adherence was of a higher frequency among patients treated with traditional dosage forms. Chi-square analysis established a significant difference (2 = 8.64, p = 0.003), which demonstrated that pediatric-friendly formulations have a considerable effect on the increase in adherence (Table 3).

Table 3. Association Between Formulation Type and Adherence

Formulation Type	Good Adherence (n)	Poor Adherence (n)	Total
Conventional	14	18	32
Pediatric-Friendly	36	12	48
Total	50	30	80

3.4 Clinical Outcomes and Correlation Analysis

There were strong associations between medication adherence and clinical outcomes. The compliance was found to have a strong positive relationship with eGFR changes (r = 0.62, p = 0.0001), and serum creatinine had a strong negative relationship (r = -0.58, p = 0.0002). The control of the blood pressure was moderately positively correlated (r = 0.49, p = 0.002), so the clinical outcomes were better with the increased adherence levels (Table 4).

Table 4. Correlation Between Adherence and Clinical Outcomes

Variables Compared	Correlation Coefficient (r)	p-value
Adherence vs eGFR improvement	+0.62	0.0001
Adherence vs Serum Creatinine	−0.58	0.0002
Adherence vs Blood Pressure Control	+0.49	0.002

3.5 Predictors of Medication Adherence (Regression Analysis)

Pediatric-friendly formulations were found by logistic regression analysis to be a strong independent predictor of good adherence. The patients who got such formulations were 3.45 times more probable to show good adherence (p = 0.002). The predictor of younger age was weak (p = 0.041), but CKD stage and gender were statistically insignificant. These results show the

essence of type of formulation in enhancing adherence outcomes (Table 5).

Table 5. Regression Analysis

Variable	Odds Ratio (OR)	95% Confidence Interval	p-value
Pediatric-friendly formulation	3.45	1.52 – 7.82	0.002
Age (younger)	1.28	1.01 – 1.62	0.041
CKD Stage	0.76	0.52 – 1.10	0.148
Gender	1.12	0.58 – 2.16	0.730

4. Discussion

The study revealed that oral medication delivery systems that were child-friendly had a greater effect on enhancing the adherence to medicines among children with chronic kidney disease. The scores of adherence were higher with syrups, dispersible tablets and granules; this means that the acceptance of these forms of administration is better than traditional dosage forms. Favorable clinical outcomes, such as improved renal functioning and improved blood pressure control were also linked to improved adherence which underscores the relevance of the formulation design in the pediatric therapeutic success. Statistically substantial correlation was established between the type of formulation and adherence to prove that child friendly dosage form is essential in the long term adherence to treatment. The results also revealed that compliance had a direct effect on such clinical parameters as eGFR and serum creatinine, which implies that the enhanced compliance leads to the improved management of the disease. Pediatric friendly formulations were also found through regression analysis to be an independent predictor of good adherence, as they support their clinical significance.The results are aligned with other research works that have highlighted the significance of pediatric-specific preparations in enhancing the results of treatment and adherence in chronic diseases (Siafaka et al., 2021). The presence of pharmacokinetic variability in pediatric CKD additionally requires the custom-made approaches to drug delivery to achieve therapeutic outcomes (Schijvens et al., 2020). The age-appropriate formulations are also supported by developmental aspects of pediatric pharmacology (Stancil et al., 2021). Moreover, new developments in minimally invasive treatments in children emphasize the necessity to adjust clinical practice to the physiology of children and their comfort (Sheth et al., 2018). Nanostructured formulations and fast-dissolving films are some of the innovative delivery systems that have demonstrated potential in improving drug bioavailability and compliance (Uddin et al., 2019; Voltan et al., 2016). Moreover, with the emergence of new technologies of personalized drug delivery, such as sophisticated fabrication methods, there are prospects of improving therapeutic accuracy and effectiveness in children (Wang et al., 2020).This study has clinical implications. The findings demonstrate the necessity to consider pediatric-friendliness of formulations by prescribing chronic diseases, including CKD, to children. Not only do improved adherence improve the outcomes of the therapeutic process but also minimizes the chances of developing a disease further and experiencing complications. Furthermore, pharmaceutical development ought to be aimed at coming up with formulations that are palatable, adjustable in dosage and appropriate as long term use in children. The study has a number of limitations in spite of the strengths. The retrospective design can be biased because of missing or irregularly documented data. The evaluation of adherence was based on clinical record instead of observing the patient behavior directly, which might be inadequate in measuring the real behavior of the patient. Moreover, the research was performed in a small clinical environment, which can impact the applicability of the results.The future literature needs to include future, multicentric research to confirm these results and investigate the outcomes in the long term related to pediatric-friendly formulations. Further studies should involve the incorporation of new technology in drug delivery such as nanotechnology and personalized medicine strategies. Moreover, the introduction of caregiver and patient perspective could give further insight about the behavior of adherence and further the process of developing more effective pediatric drug delivery system.

5. Conclusion

The study has indicated the importance of oral drug delivery systems that are friendly to children in enhancing medication compliance and clinical outcomes in children with chronic kidney disease. The results proved that formulations could be used in the form of syrups, dispersible tablets, and granules, which were more likely to be adhered to than traditional tablets and capsules. Better compliance was also associated with improved clinical outcomes such as improved renal functioning and good blood pressure regulation, and therefore, the significance of the patient-centered design of the formulation. The statistical significance of the relationship between the formulation type and adherence as well as the regression analysis that the systems are pediatric-friendly highlight their clinical relevance. In addition, the research offers practical evidence that is useful in the real world on the need to integrate child-friendly drug delivery methods into normal clinical practice. Pediatric-friendly formulations can also help to achieve better treatment outcomes and a decrease in disease burden by solving such challenges as

palatability, dosing flexibility, and administration benefits. Altogether, the effort to streamline oral drug delivery systems in children is an important process that may help improve the adherence rate of children to treatment and guarantee the effective management of the disease. The future developments in designing formulations and personalized medicine methods should also enhance the health outcomes and the quality of living of the children.

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