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Research Article

Utilization of KINDL R Scale to Assess HRQoL among Pediatric Patients with Epilepsy: A Prospective Interventional Study

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ABSTRACT

Epilepsy, a neurological disorder characterized by abnormal brain electrical activity leading to recurrent seizures, affects approximately 1% of the Indian population, with a higher prevalence in rural (1.9%) compared to urban (0.6%) settings. This interventional study conducted at a tertiary care hospital aimed to assess health-related quality of life (HRQoL) among pediatric epilepsy patients using KINDL R questionnaires. Baseline data was collected from 110 pediatric patients, with two follow-up assessments conducted after interventions were implemented after the first follow-up. HRQoL was evaluated across three age groups: 3 to 6 years, 7 to 13 years, and 14 to 17 years. The study enrolled 110 patients and collected baseline data. Two follow-up assessments were conducted, and interventions were provided after the first follow-up. Following the intervention, HRQoL revealed positive changes in different age groups: 3 to 6 years (score changed from 17.37 + 2.31 to 20.79 + 4.10), 7 to 13 years (score changed from 53.29 + 3.96 to 58.88 + 5.68), and 14 to 17 years (score changed from 63.35 + 6.18 to 74.70 + 8.10). This study concludes the positive impact of pharmacist interventions on HRQoL among pediatric epilepsy patients. The findings underscore the effectiveness of pharmacist involvement in enhancing medication management and overall wellbeing. Further research could explore long-term effects and optimal strategies

INTRODUCTION

Recurrent seizures are caused by an abnormality in the brain's electrical patterns in epilepsy. Sudden coordinated electrical energy bursts can momentarily impair awareness, mobility, and feeling in people experiencing seizures by disrupting normal electrical rhythms. [1] Epilepsy affects approximately 1% of children and can result in long-term cognitive impairment, mental health issues, and functional limitations if left untreated or if seizures begin early. It is considered the most prevalent chronic and serious neurological disorder globally, impacting around 65 million individuals worldwide. In India, it is estimated that over 10 million people are affected by epilepsy, with a prevalence of about 1% in our demographic. Rural areas exhibit a high prevalence at 1.9% compared to urban areas at 0.6%. [2]

Epileptic syndromes that begin in childhood fall into three categories. (1) Self-limited focal epilepsy (2) Generalized epilepsy (3) Developmental and/or epileptic encephalopathy.

Children with epilepsy (CWE) face an increased risk of poor psychosocial outcomes, even without comorbidities, emphasizing the importance of assessing health-related Qol. [3] The growing prevalence of chronic childhood health conditions underscores the significance of health-related quality of life (HRQoL) assessment in pediatric care. HRQoL encompasses a person's perspective of life, including physical health, mental state, social relationships, and environmental factors. Factors affecting CWE's quality of life include seizure frequency, poly pharmacy, AED side effects, and epilepsy duration. Tailored pediatric HRQoL scales for epilepsy offer accurate tools for assessing its impact. [3,4]

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One helpful instrument used to evaluate health-related quality of life (QoL) of pediatric epilepsy patients is the KINDL-R questionnaire. [5] Widely-used KINDL questionnaire, incorporating both positive and negative items, helps mitigate response bias. Research has linked self-esteem with HRQoL when measured with KINDL. [6] The KINDLR questionnaire, with 24 Likert scale items across six dimensions, enables comprehensive HRQoL evaluation. Clinicians are urged to integrate outcome measures like KINDL into routine practice for effective assessment. [6] Henceforth current study focused on the assessment of the KILDL R questionnaire among the pediatric population.

The International League against Epilepsy Commission on Epidemiology views HRQoL as a crucial metric for assessing the effectiveness of treatment.^[7] In the present scenario, where the focus on patient-reported outcomes is increasing, assessing HRQoL using validated instruments like the KINDL R questionnaire can provide pharmaceutical companies with valuable data to support the development and marketing of new antiepileptic drugs (AEDs). By demonstrating the impact of their AEDs on HRQoL, pharmaceutical companies can differentiate their products from competitors and provide healthcare professionals with evidence-based information to guide treatment decisions. Additionally, incorporating HROoL assessments into clinical trials can help identify the most effective and well-tolerated AEDs, ultimately improving patient outcomes and quality of life.^[7]

The growing prevalence of chronic childhood health conditions, such as epilepsy, underscores the significance of HRQoL assessment in pediatric care.

MATERIALS AND METHODS

The primary objective of this study was to assess the HRQoL among pediatric epilepsy patients using the KINDL R questionnaire. Conducted at a tertiary care hospital over a period of 10 months, this prospective interventional study aimed to evaluate the impact of pharmacist interventions on HRQoL in this patient population. The study enrolled a sample size of 110 pediatric epilepsy patients. Data collection involved administering the KINDL R questionnaire at baseline, followed by two additional assessments after interventions were implemented after the first follow-up. The results were analyzed using SPSS software for descriptive analysis, includes *p-value* and T-test. The study site, being a tertiary care hospital, provided an ideal setting for the comprehensive evaluation and management of pediatric epilepsy cases, facilitating both data collection and intervention implementation.

Study Eligibility Criteria

This study focuses on patients aged 3 to 17 years with a history of epilepsy, forming the target population. Those diagnosed with psychiatric disorders, cognitive impairment or who have undergone kidney transplantation will be excluded from the study. This ensures a specific and defined participant group, allowing for a focused investigation into the impact of epilepsy within the chosen age range.

Schematic Representation

The study was conducted in the paediatric oncology department, where patients were screened and those meeting the inclusion criteria (ages 3–17, both genders, diagnosed with epilepsy) were enrolled. The KINDL R questionnaires, well-designed and validated, were used to assess HRQOL. Baseline data were collected, followed by pharmacist intervention through counselling with educational tools. The study included a first and second follow-up, each with a one-month interval. Appropriate statistical analyses were then performed to extract and measure the study outcomes. (Fig. 1).

RESULTS

Demographic Data

Throughout the study duration, a screening process was conducted on 247 pediatric patients diagnosed with epilepsy. Among these, 123 patients met the criteria for participation & were enrolled in the study. Out of those enrolled, 110 patients consented to take part, while 13 were excluded. Among the excluded individuals, 8 declined participation, and five were unreachable. Ultimately, the study included 110 patients who successfully completed the 2-month follow-up period.

The gender distribution of participants revealed a predominance of males, constituting 70.90%, while females accounted for 29.09%. Participants were categorized into different age groups: 36.36% fell within the 3 to 6 age range, 43.63% within the 7 to 13 range, and 20% within the 14 to 17 range. The educational attainment of participant parents varied: 36.36% had primary education, 33.63% had secondary education, 20.90% had

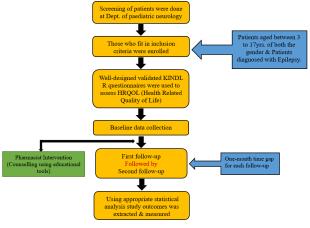


Fig. 1: Study methodology



Table 1: Distribution of demographic details among the study population

population								
S. No	Characteristics	Category	Frequency (n = 110)	Percentage (%)				
1		Male	78	70.90				
	Gender	Female	32	29.09				
		3-6	40	36.36				
2	Age	7-13	48	43.63				
		14-17	22	20				
	Parents education	Primary	40	36.36				
		Secondary	37	33.63				
3		Graduation	23	20.90				
		Post graduate	02	1.81				
		Illiterate	08	7.27				
	Parents occupation	Farmer	33	30				
4		Business	33	30				
4		Private sector	30	27.27				
		Government sector	14	12.72				
	Socio- economic status	Upper (More than 50,000)	00	00				
5		Upper middle (21,000- 50.000)	51	46.36				
		Lower middle (11,000-20.000)	46	41.81				
		Lower (less than 10,000)	13	11.81				
	Age of onset of seizures	Early infancy (Birth- 1 Year)	55	50				
		Toddlerhood (1–3 Years)	30	27.27				
6		Preschool age (3-6 Years)	12	10.90				
		School age (6-12 Years)	10	9.09				
		Adolescence (12-18 Years)	03	2.72				
7	Types of epilepsy/seizure)	Generalized seizures	67	60.90				
		Focal seizures	11	10				
		Temporal lobe epilepsy	18	16.36				
		Occipital lobe epilepsy	10	9.09				
		Frontal lobe epilepsy	03	2.72				
		Lennox gaustat syndrome	01	0.90				

graduated, 1.81% had post-graduation degrees, and 7.27% were illiterate. Occupationally, participant parents were engaged in diverse sectors: 30% were farmers, 30% were involved in business, 27.27% worked in the private sector, and 12.72% were employed in the government sector. Regarding socio-economic status, none of the participants belonged to the upper-income bracket (earning more than 50,000 INR). The distribution was as follows: 46.36% were classified as upper-middle class (earning between 21,000-50,000 INR), 41.81% as a lower-middle class (earning between 11,000--20,000 INR), and 11.81% as a lower class (earning less than 10,000 INR). The onset of epilepsy varied among participants: 50% experienced it since early infancy (birth to 1 year), 27.27% during toddlerhood (1-3 years), 10.90% during preschool age (3-6 years), 9.09% during school age (6-12 years), and 2.72% during adolescence (12-18 years). Participants exhibited various types of seizures, with the majority experiencing generalized seizures (60.90%), followed by temporal lobe epilepsy (16.36%), focal seizures (10%), occipital lobe epilepsy (9.09%), frontal lobe epilepsy (2.72%), and Lennox-Gastaut syndrome (0.90%) (Table 1).

Health-related Quality of Life

The HRQoL of the patients significantly influences the treatment of pediatric epilepsy. In this study, we conducted a comprehensive assessment of the QoL among 110 patients diagnosed with epilepsy. The evaluation of HRQoL was performed at multiple time points, starting from the beginning of the study. Baseline data were collected during the recruitment phase of the patients, and recommendations were provided to improve their quality of life. Following the recruitment, two follow-up assessments were scheduled. The first follow-up examination occurred after 1-month, during which patient counseling was offered to further enhance their quality of life. A second follow-up visit was conducted 1-month later to evaluate the final quality of life outcomes.

The interventional gap significantly influenced QoL across different age groups. Between baseline and first follow-up (BF-FF), mean differences were 17.37 \pm 2.31 (p < 0.0001), 53.29 \pm 3.96 (p < 0.0001), and 63.35 \pm 6.18 (p < 0.0001) for ages 3 to 6, 7 to 13, and 14 to 17 years, respectively. BF-SF and FF-SF also showed significant variation across age groups (p <0.0001). Overall, the results suggest that

Table 2: Statistical analysis of QoL (KINDL R) to compare means by using paired- t test

Variables	Interventional gap	3–6 years			7–13 years			14–17 years		
		Mean ± SD	Mean Diff	p-value	Mean ± SD	Mean Diff	p-value	Mean ± SD	Mean Diff	p-value
QOL	BF - FF	17.37 ± 2.31	1.71	0.0001*	53.29 ± 3.96	3.35	0.0001*	63.35 ± 6.18	6.09	0.0001*
	BF – SF	19.08 ± 3.70	3.42	0.0001*	56.65 ± 4.86	5.58	0.0001*	69.43 ± 7.27	11.35	0.0001*
	FF - SF	20.79 ± 4.10	1.71	0.0001*	58.88 ± 5.68	2.23	0.0001*	74.70 ± 8.10	5.26	0.0001*

BF - Baseline follow-up, FF - First Follow-up, SF - Second Follow-up

Table 3: Summary of QoL and its components in three groups at different treatment times

					-					
Variables	Treatment times	3–6 years			7–13 years			14–17 years		
variables		Mean ± SD	Mean Diff	p-value	Mean ± SD	Mean Diff	p-value	Mean ± SD	Mean Diff	p-value
Physical	BF - FF	3.26 ± 0.89	6.09	0.2623	8.83 ± 1.43	0.46	0.0001*	10.13 ± 1.32	0.61	0.0098*
wellbeing	BF – SF	3.34 ± 0.97	11.35	0.0018*	9.29 ± 1.38	0.79	0.0001*	10.74 ± 2.09	1.17	0.0004*
	FF - SF	3.63 ± 1.22	5.26	0.0004*	9.63 ± 1.67	0.33	0.0001*	11.30 ± 2.30	0.57	0.0001*
Emotional	BF - FF	3.32 ± 0.93	0.21	0.0033*	9.10 ± 1.79	0.35	0.0424*	10.13 ± 1.74	0.57	0.0062*
wellbeing	BF - SF	3.11 ± 0.95	0.05	0.6235	9.46 ± 1.66	0.69	0.0012*	10.70 ± 2.22	1.22	0.0002*
	FF - SF	3.37 ± 1.24	0.26	0.0008*	9.79 ± 1.81	0.33	0.0036*	11.35 ± 2.52	0.65	0.0006*
Self-	BF - FF	2.26 ± 0.55	0.42	0.0095*	7.21 ± 1.15	0.42	0.0271*	8.70 ± 1.26	1.17	0.0054*
esteem	BF - SF	2.68 ± 0.81	0.63	0.0004*	7.52 ± 1.54	0.63	0.0016*	9.87 ± 1.98	1.87	0.0003*
	FF - SF	2.89 ± 0.92	0.21	0.0188*	7.81 ± 1.78	0.21	0.0020*	10.57 ± 2.11	0.70	0.0002*
Family	BF - FF	3.47 ± 0.73	0.87	0.0001*	9.90 ± 1.51	0.46	0.0002*	11.17 ± 2.17	1.30	0.0001*
	BF - SF	4.34 ± 1.36	1.11	0.0001*	10.35 ± 1.77	0.90	0.0001*	12.48 ± 2.43	2.35	0.0001*
	FF - SF	4.58 ± 1.41	0.24	0.0106*	10.79 ± 2.13	0.44	0.0003*	13.52 ± 2.48	1.04	0.0001*
Friends	BF - FF	2.76 ± 0.82	0.21	0.0500*	8.00 ± 1.37	0.71	0.0006*	11.04 ± 2.48	1.13	0.0001*
	BF - SF	2.97 ± 1.13	0.61	0.0001*	8.71 ± 1.79	1.08	0.0001*	12.17 ± 2.71	2.61	0.0001*
	FF - SF	3.37 ± 1.17	0.39	0.0001*	9.08 ± 2.25	0.38	0.0003*	13.65 ± 2.82	1.48	0.0001*
School	BF - FF	2.29 ± 0.46	0.34	0.0009*	10.25 ± 1.55	1.06	0.0001*	12.17 ± 1.23	1.30	0.0001*
	BF – SF	2.63 ± 0.79	0.66	0.0001*	11.31 ± 1.76	1.52	0.0001*	13.48 ± 1.27	2.13	0.0001*
	FF - SF	2.95 ± 0.87	0.32	0.0002*	11.77 ± 1.94	0.46	0.0001*	14.30 ± 1.46	0.83	0.0001*

BF - Baseline follow-up, FF - First Follow-up, SF - Second Follow-up

longer intervention gaps are associated with greater improvements in QoL (Table 2).

The analysis reveals significant improvements in physical wellbeing across all age groups and treatment times. Notable enhancements were seen between BF and FF (6.09, p = 0.2623), BF and SF (11.35, p = 0.0018*), and FF and SF $(5.26, p = 0.0004^*)$ for 3 to 6 years age group. For 7 to 13 years age group, improvements were observed between BF & FF (0.46, $p < 0.0001^*$), BF and SF (0.79, $p < 0.0001^*$), and FF and SF (0.33, $p < 0.0001^*$). Similarly, in the 14 to 17 years age group, notable differences existed between BF and FF (0.61, $p = 0.0098^*$), BF and SF (1.17, $p = 0.0004^*$), and FF and SF (0.57, $p < 0.0001^*$). Emotional wellbeing also significantly improved across all age groups and treatment times. In the 3 to 6 years age group, enhancements were observed between BF and FF (Mean Diff = 0.21, p = 0.0033*), while for the 7 to 13 years age group, improvements were noted between BF and FF (Mean Diff = 0.35, p = 0.0424*) and BF and SF (Mean Diff = 0.69, p = 0.0012*). In the 14 to 17 years age group, improvements were seen between BF and FF (Mean Diff = 0.57, p = 0.0062*) and BF and SF (Mean Diff = 1.22, p = 0.0002*). Self-esteem showed significant improvement among pediatric epilepsy patients across all age groups, with notable enhancements seen in the 3 to 6 years (mean difference = 0.42, p = 0.0095*), 7 to 13 years (mean difference = 0.42, p = 0.0271*), and 14 to 17 years (Mean difference = 1.17, p = 0.0054*) age groups. Significant improvements were observed in family QoL

across all age groups and treatment times, with notable enhancements seen between BF and FF (mean difference = 0.87, $p = 0.0001^*$), BF and SF (mean difference = 0.24, $p = 0.0106^*$), and FF and SF (mean difference = 0.24, $p = 0.0106^*$). The analysis of the Friends component in the QoL across different age groups and treatment times revealed notable improvements in social relationships among pediatric patients with epilepsy, with significant enhancements seen in all age groups (p < 0.05). Overall, the study findings indicate significant improvements in various aspects of quality of life among pediatric epilepsy patients across different age groups and treatment times, underscoring the effectiveness of intervention strategies in enhancing the wellbeing of these patients (Table 3).

DISCUSSION

Recent studies have shown that pediatric patients suffering from epilepsy experience a significantly compromised quality of life compared to the general population. This is not only due to the seizures themselves but also to medical, psychiatric, and psychosocial comorbidities. Assessing the QoL can provide valuable insights for treatment planning, including identifying factors that contribute to QoL in epilepsy. The study by Riechmann $et\ al.$ identified several factors that correlated with poorer QoL in children and adolescents with epilepsy and their caregivers. In children and adolescents, missing seizure freedom (p = 0.046), concomitant diseases (p = 0.007), hospitalization



(p = 0.049), recent status epilepticus (p = 0.035), living in a nursing home or with foster parents (p = 0.049), and relevant degree of disability (p = 0.007) were associated with poorer QoL.^[5, 8] In the present study, there were 32 female participants and 78 male participants. Comparable findings were observed in the research conducted by Aycan Ünalp et al., where males (31) outnumbered females (29). [9] We analyzed these changes using paired t-tests, differing from the approach of Aycan Ünalp et al., who employed the Mann-Whitney U test applied to the KINDL Kids questionnaire compared QoL in pediatric epilepsy patients (n = 60) and controls (n = 51), Epilepsy patients had significantly lower total QoL scores (p = 0.006) but similar physical wellbeing (p = 0.217) and school-related QoL (p = 0.509), lower scores in emotional wellbeing (p= 0.001), self-esteem (p = 0.053), family (p = 0.045), and friends (p = 0.032) domains highlight epilepsy's impact. [9] In the current study, there were 48 participants in the 7 to 13 age group. Identical results were noted in study by Asia Alnaamani et al., where 54 participants fell within the 8 to 12 years of age range. Parallel to the current findings, 55 patients experienced seizures during early infancy (1-year). Similar findings were reported in the study by Asia Alnaamani et al., where 45 patients aged between 4 and 7 years old exhibited similar characteristics.^[10] Correspondingly, there were 67 cases of generalized seizures and one case of Lennox-Gastaut syndrome. In contrast, Nora Faved et al. observed 176 patients with generalized tonic-clonic seizures, indicating a predominance of this type over others.^[11] Moreover, a study by Wirastuti et al. compared the quality of life between well-controlled epileptic children and nonepileptic children using the PedsQL questionnaire. The results showed that well-controlled epileptic children had significantly lower total PedsQL scores compared to nonepileptic children (37.67 \pm 1.52 vs. 8.45 \pm 0.63, p < 0.01), indicating poorer quality of life.^[12]

This finding emphasizes the substantial impact of epilepsy on various aspects of a child's life, even in well-controlled cases. To investigate the impact of pharmacist intervention on QoL, we conducted an interventional study. During the evaluation of HRQoL, we observed that pharmacist intervention led to an improvement in QoL among children with epilepsy. To compare the improvement in HRQoL, the mean and standard deviation were computed. The resulting values for p indicated statistically significant results. We measured the overall HRQoL of epilepsy patients at two follow-up visits, with baseline data collected during patient enrolment. Based on the underlying data, we provided counseling to the patients. Subsequently, we observed an improvement in their HRQoL after the second follow-up visit compared to baseline. Furthermore, a study by Wirastuti et al. compared the quality of life between well-controlled epileptic children and nonepileptic children using the PedsQL questionnaire. [12] The results showed that well-controlled epileptic children had significantly lower total PedsQL scores compared to non-epileptic children (37.67 \pm 1.52 vs. 8.45 \pm 0.63, p < 0.01), indicating poorer quality of life. The present study provides a comprehensive assessment of HRQoL, considering family, friends, school, self-esteem, and physical and emotional wellbeing. Our findings indicate an improvement in quality of life over time. Specifically, in the 3 to 6 years age group, HRQoL scores increased from 17.37 \pm 2.31 to 20.79 \pm 4.10. Among participants aged 7 to 13 years, scores rose from 53.29 \pm 3.96 to 58.88 \pm 5.68. In the 14 to 17 years age group, scores improved from 63.35 \pm 6.18 to 74.70 \pm 8.10. These improvements were statistically significant. The study emphasized the importance of patient counseling in enhancing the quality of life for individuals with epilepsy.

These findings emphasize the necessity of guidance and counseling to improve the standard of living for individuals with epilepsy, highlighting the crucial role of healthcare professionals in prioritizing patient QoL in epilepsy management. From our study, we can conclude that appropriate guidance and counseling are necessary to help enhance the standard of living for those who have epilepsy. Physicians, pharmacists, and other healthcare professionals should prioritize the patient's quality of life and educate patients about the importance of QoL in epilepsy management.

CONCLUSION

Study findings infer a positive impact on HRQoL in pediatric patients as time progresses. Pharmacist-led counseling and education programs can target specific domains identified, such as emotional wellbeing, self-esteem, family, and social interactions. Interventions may include medication adherence support, mental health counseling referrals, and community resources linkage to enhance overall HRQoL. Pharmacist involvement can improve patient understanding, coping strategies, and treatment adherence, ultimately contributing to a better quality of life for individuals managing chronic conditions like epilepsy.

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