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Research Article

QUALITY OF LIFE IN PEDIATRIC PATIENTS WITH EPILEPSY ON ANTIEPILEPTIC DRUGS: A CROSS-SECTIONAL STUDY USING QOLCE-55 TOOL IN NORTH INDIA

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ABSTRACT

Objective: The objective of this study is to assess the impact of epilepsy and antiepileptic medication on the quality of life (QoL) of children with epilepsy, particularly in the northern region of India.

Methods: This was a cross-sectional, hospital-based study that collected social demographic and clinical data from 100 children aged between ≥4 and ≤14 years. QoL was assessed using the QoL in Children with Epilepsy (QOLCE-55) questionnaire.

Results: The mean total QOLCE-55 score was 58.66±22.02, with the physical domain being the most affected. Age, seizure frequency in the last year, and schooling status showed significant associations with the mean QOLCE-55 score. However, there were no significant associations observed with gender, area of residence, socioeconomic status, type of epilepsy, type of antiepileptic drug, and family history of epilepsy.

Conclusion: The study emphasizes the significance of health-care providers focusing on the physical well-being of children with epilepsy, especially in resource-constrained developing countries, particularly in their rural areas. Age, seizure frequency, and schooling status showed significant associations with the QOLCE. These factors should be taken into account while designing treatment plans to ensure effective and equitable health care interventions.

Keywords: Quality of life domains, Pediatric patients with epilepsy, Quality of life questionnaire, QOLCE Scale, Antiepileptic drugs.

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INTRODUCTION

Epilepsy is a chronic neurological disorder that results in recurrent seizures and affects individuals of all ages. It is estimated that 50 million people worldwide have epilepsy, with nearly 80% of cases occurring in low- and middle-income countries, including an estimated 12 million individuals in India [1]. In North India, a study of children with epilepsy found prevalence rates of 6.99 for rural areas, 5.48 for urban areas, and 4.07 for active epilepsy per 1000 population [2]. These statistics highlight the significant burden of epilepsy in India, particularly in resource-constrained settings.

Quality of life (QoL) is a critical measure of well-being and satisfaction in children with epilepsy, encompassing physical, psychological, social, and environmental factors. Evaluating QoL can help assess treatment effectiveness, support health care policy and research, and provide a comprehensive evaluation of individual health [3,4]. Children with epilepsy often experience lower QoL due to seizure frequency and severity, cognitive and behavioral issues, social stigma, and adverse effects of antiepileptic drugs. Unfortunately, physicians may overlook under-reported symptoms or fail to address the physical, psychosocial, and educational effects of epilepsy and its therapies. Epilepsy-specific QoL questionnaires can supplement assessment by evaluating the effects of seizures and antiepileptic drugs. Studies indicate that children with epilepsy often have lower QoL compared to healthy children and those with other chronic conditions [5-9].

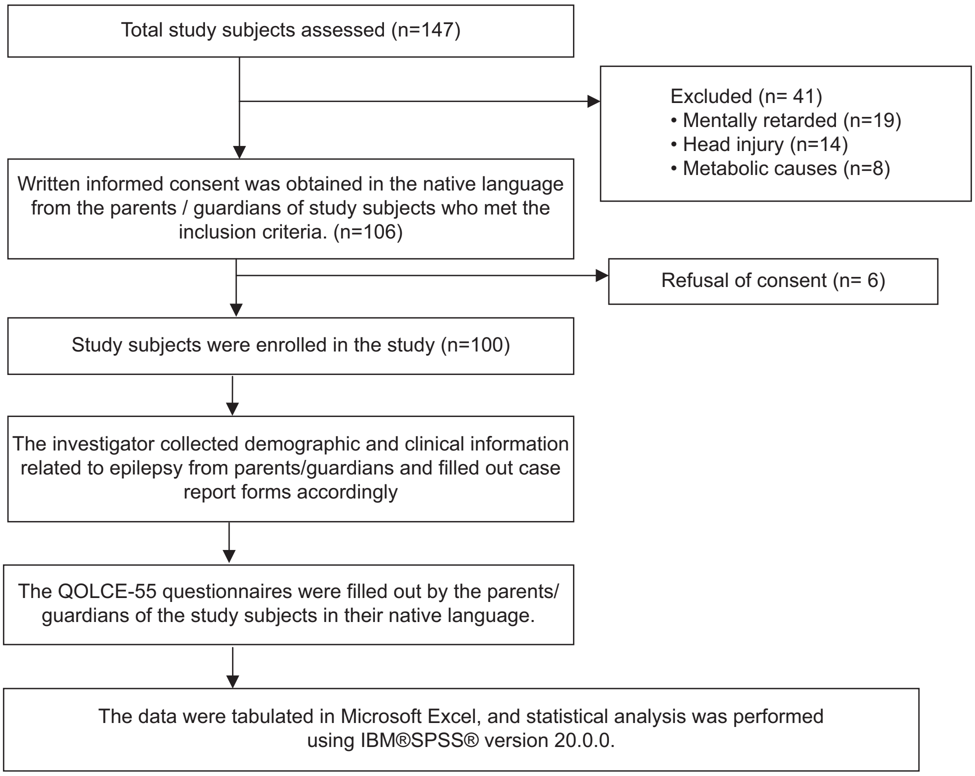
Multiple studies have demonstrated that epilepsy can have adverse effects on several aspects of a child's QoL, such as physical health, psychological well-being, self- esteem, anxiety, depression, memory and attention, independence, social stigma, and social well-being [7,10-12]. However, in India, particularly in the northern region, there is a paucity of data on the QoL of children with epilepsy (QOLCE). Studying QoL is important to understand the impact of epilepsy on the daily lives of these children and to improve the treatment plan. The availability of data on QoL in this region can also help raise awareness of the issues faced by children with epilepsy and encourage the efforts of physicians/caregivers to address these challenges. Therefore, the present study aims to evaluate the QoL of children on antiepileptic medication(s) in a tertiary care teaching hospital.

METHODS

This cross-sectional study was conducted at a government tertiary care teaching hospital in North India. Patient recruitment and data collection were carried out from November 2020 to December 2021.

The sample size was calculated using the formula $X = Z_{\alpha/2}^2 * \sigma^2/e^2$, where $Z_{\alpha/2}$ is the critical value of the normal distribution at $\alpha/2$, σ is the standard deviation, and e is the margin of error. Using a 95% confidence level and a power of 80% and employing the σ as 21.32 overall QOLCE-55 score, taking into account the previous study by Aggarwal *et al*. [13], the minimum calculated sample size was 70. Considering a 10% non-response/attrition rate, the overall sample size became 77. Therefore, a total of 100 subjects were included using the purposive non-probability sampling technique for this study.

This study included study subjects of either gender aged ≥4 and ≤14 years who had been taking antiepileptic drugs for at least 3 months. The type of epilepsy was diagnosed by the treating physician based on the patient's history, clinical examination, electroencephalogram, and neuroimaging. The epilepsy was classified as per the ILAE classification of the epilepsies 2017 [14], and although we did not conduct a formal Intelligence quotient assessment, the study included children who were studying in age-appropriate classes and had developmental levels similar to those of their typically developing siblings.



Total study subjects assessed (n=147)

Excluded (n= 41)
- Mentally retarded (n=19)
- Head injury (n=14)
- Metabolic causes (n=8)

Written informed consent was obtained in the native language from the parents / guardians of study subjects who met the inclusion criteria. (n=106)

Refusal of consent (n= 6)

Study subjects were enrolled in the study (n=100)

The investigator collected demographic and clinical information related to epilepsy from parents/guardians and filled out case report forms accordingly

The QOLCE-55 questionnaires were filled out by the parents/guardians of the study subjects in their native language.

The data were tabulated in Microsoft Excel, and statistical analysis was performed using IBM®SPSS® version 20.0.0.

Fig. 1: Study Flow chart. n: Number of study subjects, IBM: International Business Machines, SPSS: The Statistical Package for the Social Sciences, QOLCE-55: Quality of Life in Childhood Epilepsy

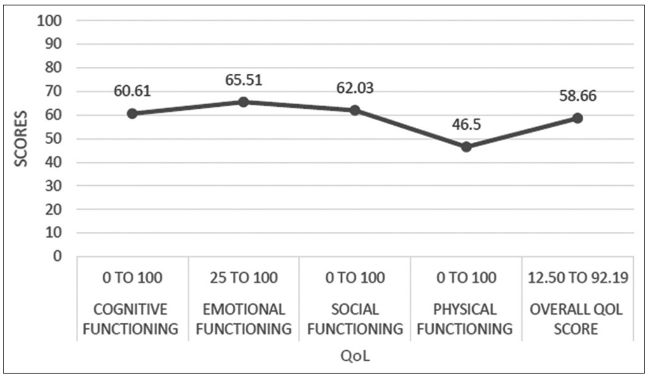


Fig. 2: Mean scores of QOLCE-55

Demographic and clinical information from patients/guardians of study subjects with epilepsy was collected and identified by an individual case number. To evaluate the QOLCE, the QOLCE-55 scale was used. This open-access tool has been recommended by the National Institute of Neurological Disorders and Stroke and has been validated for its intended use [15,16]. It has also been used in several studies conducted in India and abroad [17-21].

The QOLCE-55 questionnaire was administered in the native language of the parents or guardians of the study subjects and included four domains:
- Cognitive functioning domain had 22 questions that asked about problems the study subjects may have had with concentration, remembering, and speaking compared to other children their age.
- Emotional functioning domain had 17 questions that described the study subjects' general feelings and behavior in society.
- Social functioning domain had 7 questions that described the study subjects' social interactions and activities.
- Physical functioning domain had 9 questions that asked about the study subjects physical activity.

Scoring was performed according to the QOLCE-55 scale instructions, and the overall QoL score was calculated.

To ensure accurate completion of the questionnaire, a researcher was available to clarify any doubts. The questionnaire was translated into Punjabi by a bilingual pediatrician and then back-translated into English by a non-medical language expert. The translated version was compared with the original, and any discrepancies were corrected. To verify the accuracy of the translated version, a pilot study was conducted on 20 study subjects. The test-retest reliability of the translated version was established using Cronbach's alpha and Pearson correlation, which indicated good internal consistency and construct validity.

The data were organized in Microsoft® Excel® and analyzed using IBM® SPSS® version 20.0.0. Demographic and clinical variables were reported as frequency and percentage, while QoL scores were presented as Mean±SD. The statistical analysis involved the use of both parametric tests, including the unpaired T-Test and Analysis of variance, and non-parametric tests, such as the Kruskal–Wallis H test. A significance level of $p<0.05$ was considered statistically significant for this study.

Ethical approval

Before its commencement, the study received ethical approval from the Institutional Ethics Committee, as evidenced by the issued letter number BFUHS/2K22p-TH/7534.

CTRI registration

In accordance with standard guidelines, the study was registered on November 29, 2021 with the Clinical Trials Registry of India (CTRI Number: CTRI/2021/11/038327).

OBSERVATIONS AND RESULTS

Initially, a total of 147 study subjects aged ≥ 4 and ≤ 14 years were subjected to eligibility screening. Out of these, 106 subjects met the inclusion criteria, while 41 were excluded based on predefined criteria. Written informed consent was obtained from the parents or guardians

Table 1: Demographic and clinical data of study subjects

Variable	Study subjects (n=100)	Percentage
Age distribution		
Early Childhood (04–05 years)	14	14.00
Late Childhood (06–11 years)	41	41.00
Early Adolescent (12–14 years)	45	45.00
Gender distribution		
Male	71	71.00
Female	29	29.00
Residence		
Rural	68	68.00
Urban	32	32.00
Socioeconomic status of parents*		
Lower	97	97.00
Upper Lower	2	2.00
Lower Middle	1	1.00
Upper Middle	0	0
Upper	0	0
Type of epilepsy		
Generalized	87	87.00
Focal	13	13.00
Seizure frequency in last year		
>6 Episodes	4	4.00
5–6 Episodes	17	17.00
3–4 Episodes	36	36.00
1–2 Episodes	20	20.00
None	23	23.00
Type of antiepileptic drug therapy		
Monotherapy	61	61.00
Dual Therapy	29	29.00
Polytherapy	10	10.00
Schooling status of study subjects		
Normal	55	55.00
Delayed	28	28.00
Drop out	12	12.00
Never Joined	5	5.00
Family history of epilepsy in study subjects		
Yes	9	9.00
No	91	91.00

*As per Modified Kuppuswamy socioeconomic scale: 2022 update of India [22].

Table 2: QOLCE-55 score in study subjects (n=100)

Quality of life	Actual range	QOLCE-55 score observed	
		Mean score	SD
Cognitive functioning	0–100	60.61	25.68
Emotional functioning	25–100	65.51	17.71
Social functioning	0–100	62.03	24.07
Physical functioning	0–100	46.50	20.55
Overall QOLCE-55 score	12.50–92.19	58.66	22.02

of 100 eligible study subjects in their native language. Notably, six subjects were subsequently excluded from the study as their parents or guardians declined to provide written consent, as illustrated in Figure 1.

Demographic and clinical data of these 100 study subjects were collected and are summarized in Table 1. This data encompasses variables such as age distribution, gender distribution, residence, socioeconomic status of parents, type of epilepsy, seizure frequency, antiepileptic drug therapy, schooling status, and family history of epilepsy. The mean QOLCE-55 scores are depicted in the line graph presented in Figure 2. For a more detailed breakdown of the QOLCE-55 scores, refer to Table 2.

To investigate the associations between the demographic and clinical characteristics of the study subjects and their QOLCE-55 scores, we conducted a comprehensive statistical analysis. The results of these analyses, along with the corresponding p-values, are detailed in Table 3.

DISCUSSION

The study aimed to evaluate the QoL in children aged ≥4 and ≤14 years with epilepsy who had been taking antiepileptic drugs for at least 3 months. The study was conducted in a tertiary care hospital in North India and used the QOLCE-55 questionnaire to assess the impact of epilepsy on the physical, emotional, cognitive, and social functioning of these children. The results of the study have the potential to identify specific areas of life that are most affected by epilepsy and its treatment, which could lead to targeted interventions and improved health outcomes for these children. Overall, the study has significant implications for the management and care of children with epilepsy.

Among the 100 study subjects, 45 (45%) were early adolescents, and 71 (71%) were male. The majority of study subjects (68%) hailed from rural areas, and 97% belonged to lower socioeconomic strata. Generalized epilepsy was the most common type of epilepsy observed in 87% of the study subjects, and 36% had experienced 3–4 seizures in the past 1 year. Monotherapy was the preferred treatment option for 61% of the study subjects, and 55% had a normal schooling status. Furthermore, 91% of the study subjects had no family history of epilepsy.

The study observed that the overall mean QOLCE-55 score for the study subjects was 58.66±22.02, with the physical domain being the most affected. Age, seizure frequency in the last year, and schooling status were found to be significantly associated with the mean QOLCE-55 score, indicating that these factors have a significant impact on the QOLCE. However, there was no significant association observed between QOLCE-55 scores and gender distribution, area of residence, socioeconomic status, type of epilepsy, type of AED prescribed, and family history of epilepsy.

The study conducted by Nagesh *et al*. recruited 104 children aged 4–13 years with epilepsy from a tertiary care hospital in South India. They used the QOLCE-55 questionnaire and found that the mean overall QoL score was 46.82±10.90, indicating a comparatively weaker QOLCE. The study also revealed that several factors, including the type of epilepsy, seizure frequency, type of antiepileptic drug, and maternal education, significantly affected QoL. The study found that cognitive functions were the most severely affected, with a mean score of 37.99±18.35, while physical functions were relatively unaffected, with a mean score of 61.10±13.44. Furthermore, the study showed a statistically significant difference in seizure frequency, while the rest of the results were in contrast with this study [17].

The study conducted by Arya *et al*. in North India enrolled 40 children, aged 2–14 years, with active epilepsy, and their parents provided demographic and clinical information. The parent-reported (QOLCE-91) questionnaire was used to evaluate QoL. The study found that the overall QoL of these children was compromised, with the lowest scores observed in the self-esteem sub-scale and the highest scores in the control/helplessness, anxiety, and social stigma sub-scales. However, the study did not find significant effects of demographic factors such as parental education and socioeconomic status, or clinical factors such as seizure frequency and type of epilepsy, on the overall QoL of these children with epilepsy. Besides seizure frequency, demographic variables such as parental education and socioeconomic status were also found to be statistically non-significant, consistent with the results of this study [23].

The study conducted by Nadkarni *et al*. in central India aimed to measure the QOLCE and found that various factors negatively impact it. The study used the Quality of Life in Childhood Epilepsy (QOLCE-76) questionnaire to assess the QoL of 102 children with epilepsy aged 5–15 years. The study found that factors such as age, place of residence, socioeconomic condition, maternal education, seizure

Table 3: Association of demographic and clinical data of study subjects with their QOLCE-55 scores

Variable	QOLCE-55 scores	Statistical test	p-value
Age and QOLCE-55 Scores	Mean±SD		
Early Childhood (4–5 years)	51.97±22.69	ANOVA	0.001 *
Late Childhood (6–11 years)	51.56±19.27		
Early Adolescent (12–14 years)	67.22±18.59		
Gender Distribution and QOLCE-55 Scores	Mean±SD		
Male	58.42±20.51	Unpaired t-test	0.784
Female	59.25±21.79		
Residence and QOLCE-55 Scores	Mean±SD		
Rural	58.48±20.41	Unpaired t-test	0.941
Urban	59.05±21.88		
Socioeconomic Status and QOLCE-55 Scores	Median (IQR)		
Lower	58.38 (47.27–72.16)	Kruskal–Wallis H test	0.687
Upper Lower	56.93 (22.93–90.93)		
Lower Middle	76.61 (76.61)		
Upper Middle	0		
Upper	0		
Type of Epilepsy and QOLCE-55 Scores	Mean±SD		
Generalized	58.61±20.82	Unpaired t-test	0.971
Focal	59.00±21.35		
Seizure Frequency in Last Year and QOLCE-55 Scores	Median (IQR)		
>6 episodes	29.25 (27.04–43.81)	Kruskal–Wallis H test	0.001 *
5–6 episodes	35.92 (30.10–58.42)		
3–4 episodes	54.94 (48.04–71.73)		
1–2 episodes	67.92 (57.97–88.72)		
No seizures in the last 1 year	68.87 (48.77–75.53)		
Drug Therapy and QOLCE-55 Scores	Median (IQR)		
Monotherapy	59.97 (46.98–72.54)	Kruskal–Wallis H test	0.956
Dual Therapy	55.77 (47.65–73.41)		
Polytherapy	59.13 (53.15–63.29)		
Schooling Status and QOLCE-55 Scores	Median (IQR)		
Normal	68.63 (56.74–78.36)	Kruskal–Wallis H test	0.001 *
Delayed	52.73 (33.40–60.29)		
Drop out	32.92 (28.86–48.37)		
Never Joined	23.21 (19.56–35.74)		
Family History of Epilepsy and QOLCE-55 Scores	Mean±SD		
Yes	64.29±14.50	Unpaired t-test	0.519
No	58.11±20.89		

QOLCE-55: Quality of Life in Childhood Epilepsy, SD: Standard deviation, IQR: Interquartile Range, p-value of less than 0.05 was considered statistically significant

type and frequency, and the number of antiepileptic drugs affected the QoL in these patients. The study concluded that comprehensive care for children with epilepsy should address more than just seizure control. However, apart from age and seizure frequency, the rest of the parameters contrasted with the findings of the current study [9].

The study conducted by Aggarwal *et al*. in North India aimed to assess the QoL of 108 children aged between 6 and 15 years with epilepsy using the QOLCE-76 questionnaire. The study found that the overall score for QoL was 62.62±21.32, indicating a moderate level. In addition, the study revealed that several factors, including age, type of epilepsy, seizure frequency, and maternal education, significantly impacted the overall QoL of these children with epilepsy. Apart from maternal education, the rest of the findings are consistent with those of the present study [13].

Pachange *et al*. conducted a cross-sectional study to assess the QoL of school children in South India. The QoL of these children was assessed using the QOLCE-55, and physical functioning was found to have the lowest mean QoL score (mean=58.3, SD=20.66). The present age of the child, the age at the first seizure episode, and the time since the last seizure were found to have a significant relationship with QoL. The treatment gap was 70.4%. The study concluded that assessing QOLCE is important for effective and comprehensive management. The results of this study are consistent with the present study [21].

It is possible that the differences in previous study results can be attributed to variations in the study population and different cultural backgrounds. However, the present study found significant associations between age, seizure frequency in the last year, and schooling status with mean QOLCE-55 scores in children with epilepsy. Older age was associated with better QoL, possibly due to better adaptation and understanding of the condition. Higher seizure frequency was associated with lower QoL, indicating that the QOLCE-55 is sensitive to differences in seizure severity. Furthermore, delayed dropout and never joining school were linked to lower QOLCE-55 scores, perhaps because children may feel embarrassed by their condition. These results are consistent with previous studies.

The study's strength lies in its ability to capture the QoL of a heterogeneous population of children with epilepsy from rural areas in Northern India, most of who belonged to a lower socioeconomic status. The inclusion of subjects from various nearby regions also adds to the generalizability of the study findings. Overall, the study provides valuable insights into the QOLCE in resource-limited settings, which is an area of research that is often neglected.

A multicenter study with a larger sample size and longer follow-up duration would help to increase the generalizability of the results and provide a more comprehensive understanding of the factors that impact the QOLCE in rural areas.

CONCLUSION

This study highlights the impact of epilepsy and its treatment on the QoL of children aged ≥4 and ≤14 years. The physical domain was found to be the most affected, which indicates the need for more attention to be paid to the physical health of children with epilepsy. Age, seizure frequency in the last year, and schooling status were found to have a significant impact on the QoL of these children. Therefore, health-care providers should pay close attention to these factors/domains when designing treatment plans for children with epilepsy. Overall, the results of this study can help us improve the health outcomes of children with epilepsy. Further research is needed to better understand the long-term impact of epilepsy and its treatment on the QoL of children.

The study emphasizes the need for health-care providers to pay attention to the physical well-being of children with epilepsy, especially in resource-constrained developing countries, particularly in rural areas. Age, seizure frequency, and schooling status are significant factors that need to be considered when designing treatment plans to ensure effective and equitable health-care interventions. However, due to a scarcity of data, designing such interventions remains a challenge.

CONSENT TO PARTICIPATE

Before enrollment in the study, the legal parents or caregivers were provided with a patient information leaflet that explained the purpose of the study. The investigator resolved any queries or concerns they may have had. As the study subjects were minors between the ages of ≥4 and ≤14 years. Written informed consent was obtained from their legal parents or caregivers. For study subjects aged 7 and above, oral assent was taken, and for those aged 13 and above, written assent was also obtained before their final enrollment.

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AUTHOR CONTRIBUTION

Kanav Mehta was responsible for acquiring and curating the data, as well as drafting, reviewing, and editing the original manuscript. Raj Kumar conceptualized and designed the study, and also reviewed and edited the manuscript. Navneet Kaur made critical revisions to the manuscript to improve its intellectual content.

CONFLICT OF INTEREST DISCLOSURE

Neither of the authors has any conflict of interest to disclose.

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