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ORIGINAL RESEARCH

Evaluation of AIIMS modified INCLEN tool to differentiate epilepsy from non-epilepsy: A cross sectional study

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ABSTRACT

Background: Epilepsy One of the most prevalent neurological conditions, affects millions of people globally. Epilepsy, which is characterized by frequent, unprovoked seizures, can significantly influence a person's physical, emotional, and mental health. **Objective:** to provide an accurate diagnosis and establish an effective pathway for further medical management based on the confirmed diagnosis of either epilepsy or non-epilepsy. **Methods:** This Cross-Sectional study was conducted at the Department of Pediatrics at Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh. Duration of study was 12 months, from August 1, 2023, to July 31, 2024. **Result:** largest age group among the subjects was 5–18 years, comprising 49% of the sample, followed by the 1 month–2 year age group (27%) and the 2–5 year age group (24%). 63% of the subjects were male and 37% were female. The INDT-EPI tool modified by AIIMS showed high diagnostic performance in the entire cohort. The sensitivity was 85.71%, the specificity was 86.11%, the positive predictive value (PPV) was 89.36%, the negative predictive value (NPV) was 81.58%, and the accuracy was 85.88%. Complications were observed in 17% of the sample. The final diagnosis was epilepsy (49%). Other conditions included hydrocephalus (7%), neurocysticercosis (5%), and cystic encephalomalacia (2%). **Conclusion:** the AIIMS-Revised INDT-EPI is a reliable diagnostic tool for identifying epilepsy and related disorders in the pediatric population The tool has high sensitivity and specificity, and is particularly effective in children and adolescents, and thus has the potential to be widely used in clinical practice.

Keywords: AIIMS modified INCLEN tool, epilepsy, non- epilepsy

INTRODUCTION

In addition to its negative effects on health, epilepsy also has a significant social and economic impact, as evidenced by lost chances for work and education as well as the expenses of long-term care.[1] Increased efforts are being made to better understand the pathogenesis, diagnosis, and treatment of epilepsy due to its prevalence worldwide.

The primary symptom of epilepsy, seizures, can occasionally be confused with other illnesses, including movement disorders, syncope, and psychogenic non-epileptic seizures (PNES).[1] This diagnostic difficulty is especially important in situations where access to specialized treatment is limited, as resources for sophisticated diagnostic tests like neuroimaging or EEG (electroencephalogram) may be limited. Misdiagnosing epilepsy can lead to needless therapies, higher medical expenses, and the emotional toll that comes with a false diagnosis.[2]

It is clear that efficient, readily available diagnostic instruments are required in order to distinguish epilepsy from non-epileptic disorders. These tools are essential for making sure people receive the right care and intervention, which can enhance their quality of life over the long run as well as their short-term results. To address this need, the AIIMS-modified INCLEN tool was created with the goal of offering a more methodical and approachable way to differentiate epilepsy from other conditions that exhibit comparable symptoms.[3]

There is still a big diagnostic gap in differentiating epilepsy from non-epileptic diseases, even with the availability of diagnostic technologies like neuroimaging and EEG. Although non-epileptic disorders like PNES or syncopal episodes frequently exhibit symptoms similar to seizures, they need to be treated differently. Clinicians may not have the training or access to advanced diagnostic tools

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necessary to make reliable diagnoses, especially in basic healthcare or rural settings. Because of this, there is a significant chance of misdiagnosis, which could result in incorrect interventions that could harm patients.

In low-resource settings, there is currently no generally available, straightforward, and trustworthy diagnostic instrument that can successfully distinguish epilepsy from other seizure-like illnesses. Developed to overcome these issues, the INCLEN instrument improved by AIIMS has not yet undergone comprehensive clinical validation. By assessing the effectiveness of the modified INCLEN tool in differentiating between epilepsy and non-epilepsy, this study seeks to close this gap and meet a pressing need in the neurology community.

For efficient management and therapy, epilepsy, a common neurological illness, often needs an accurate diagnosis. Misdiagnosis, on the other hand, continues to be a major issue, resulting in ineffective treatment and higher healthcare expenses. The AIIMS-modified INCLEN diagnostic tool provides a systematic and evidence-based strategy for distinguishing epilepsy from non-epileptic disorders, possibly filling a significant gap.[4] This cross-sectional research will assess the tool's usefulness and reliability in clinical settings, with an emphasis on sensitivity, specificity, and practicality. The results are predicted to improve diagnosis accuracy, resource usage, and patient outcomes, especially in resource-limited areas where expert neurology services may be unavailable.

To deal with this problem, basic health centers could be very helpful in finding and treating cases, which would help close the care gap. The International Clinical Epidemiology Network (INCLEN) made and tried a screening tool called INDT-EPI in northern India as part of this effort. It is meant for primary care doctors to check kids between the ages 2 to 9.[4] Seizures may manifest in a wide variety of ways, and the symptoms of many other disorders can be confusing enough to make a diagnosis of epilepsy in children a formidable challenge. Studies have shown that 30% to 39% of the time, epilepsy is missed, even when doctors are present.[5,6] The wrong evaluations and treatments put a lot of financial stress on a country's health care system. Primary care physicians must have a reliable diagnostic tool to detect instances of pediatric epilepsy and to rule out other possible causes of similar symptoms. The primary objective of this study was to assess the enhanced INDT-EPI instrument that could be administered to patients ranging in age from one month to eighteen years old, and which could detect a wider variety of seizures with the same high level of accuracy.

MATERIAL AND METHODS

This Cross-Sectional study was conducted at the Department of Pediatrics at Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh. Duration of study was 12 months, from August 1, 2023, to July 31, 2024. Ethical approval was obtained from the Institutional Ethics Committee (IEC) prior to conducting the study.

Inclusion Criteria

The study included all patients aged between 1 month and 18 years who visited the outpatient (OPD) and inpatient (IPD) departments at Rohilkhand Medical College and Hospital with complaints of abnormal body movements. The patients' attendants (such as parents or guardians) were required to provide informed consent for their child's participation in the study.

Exclusion Criteria

Patients who were not accompanied by a primary caregiver were excluded from the study, as informed consent could not be obtained without a guardian. Additionally, patients who had their first episode of seizures before the age of 1 month were excluded, as the study focused on those who experienced abnormal movements later in life.

Sample Size: The sample size for the study was calculated using the formula.[7]

$$n=4pq/L^2$$

Where:

- p is the anticipated proportion of patients with abnormal body movements,
- q= 100 - p,
- L is the allowable error (5%).

The calculation resulted in a sample size of 100 patients. Specifically, using p=94.4 and q = 6.6, the formula yielded a sample size of approximately 100.

PROCEDURE

After obtaining ethical approval, the parents or guardians of pediatric patients aged between 1 month and 18 years who presented with abnormal body movements were taken into participation. Informed consent was obtained from the caregivers. Upon consent, patients underwent diagnostic evaluation for abnormal body movements, using a specific diagnostic tool designed to identify epilepsy or other potential causes of the abnormal body movements.[8]

This methodology aimed to ensure accurate diagnosis, focusing on pediatric patients presenting with abnormal movements while following ethical standards and providing reliable clinical insights into epilepsy and related conditions.

METHODOLOGY

All patients who provided consent and presented to the RMCH OPD and IPD with complaints of abnormal body movements were administered the modified "AIIMS INCLEN tool" – a 10-question diagnostic toolkit.[18] The tool was administered by a Junior Resident Doctor from the Department of Pediatrics. The toolkit consisted of a set of 10 fixed questions, which were directed to the patient's parent or primary caregiver. These questions were designed to assess the

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nature and characteristics of the patient's abnormal movements.

Based on the responses provided by the parent or caregiver, a preliminary diagnosis of either epilepsy, non-epilepsy, or indeterminate was made. This initial classification was followed by a detailed evaluation by a pediatrician, who used diagnostic techniques such as EEG, CT Scan, and MRI to confirm the diagnosis. The pediatrician's assessment was crucial in differentiating between epilepsy and non- epilepsy cases.

Additionally, MRI changes were evaluated to compare differences between patients diagnosed with epilepsy and those diagnosed with non-epileptic conditions. The aim was to explore whether there were any distinct MRI findings that could help further differentiate between the two groups. The results of the toolkit, along with the diagnostic imaging findings, contributed to a comprehensive understanding of the patient's condition.

This process aimed to provide an accurate diagnosis and establish an effective pathway for further medical management based on the confirmed diagnosis of either epilepsy or non-epilepsy.

STATISTICAL ANALYSIS

Data was entered and coded into a Microsoft Excel spreadsheet. Microsoft Excel was used to enter the data gathered from the proforma, and SPSS (Statistical Package for Social Sciences) version 23 was used for analysis The 95% CI was used to indicate the percentages for sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). The gold standard and study tool diagnoses were compared using the Cohen Kappa test. When comparing the study tool with the experts' diagnosis, the data of patients in the indeterminate group were not included in the statistical analysis.

RESULTS

In present study out of 100 study subjects maximum of 49(49.0%) of cases were in the age group of 5 years - to 18 years followed by 27(27.0%) of cases in the age group of 1 month to 2 years and 24(24.0%) of cases were in the age group of 2 years – 5 years.

In present study out of 100 study subjects, a maximum of 63(63.0%) of cases were male and 37(37.0%) of cases were female.

In the present study out of 100 study subjects, a maximum of 76(76.0%) of cases belonged to the Urban area and 24(24.0%) of cases belonged to the Rural area.

TABLE 1: PSYCHOMETRIC PROPERTIES OF AIIMS-MODIFIED INDT-EPI IN STUDY SUBJECTS.

	FREQUENCY	PERCENTAGE (%)
Loss of Consciousness	98	98
Sudden Movement (generalized)	93	93
Focal Seizures	7	7
No of Episodes		
One	2	2
More than one	98	98
Duration between first and subsequent Episode (in minutes)		
<25	20	20
≥25	80	80
Fever during each episode	53	53
Assimilated/associated with infection	39	39
Episodes during 1st month of life	9	9
Preceded by Cry or Emotion	9	9
Light-headedness or giddiness	9	9
Antiepileptic drug	15	15

In present study out of 100 study subjects, Loss of Consciousness was noted in a maximum of 98(98.0%) cases, Sudden Movement (generalized) in 93% of cases, Focal Seizures in 7% of cases, one episode in 2% of cases, more than one episode in 98% cases, Duration of between first and subsequent Episode (in minutes) was <25 minutes in 20% cases and ≥25 minutes in 80% cases, Fever during each episode in 53% cases, Assimilated/associated with infection in 39% cases, Episodes during 1st month of life, Preceded by Cry or Emotion, Light-headedness or giddiness in 9% of each, Antiepileptic drug taken by 15% cases.

In present study out of 100 study subjects, Comorbidities were found in 17% of cases.

In present study out of 100 study subjects, EEG CHANGES were found in 55% of cases. Out of 100 study subjects, MRI CHANGES were found in 34% of cases.

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TABLE 2: TOOL DIAGNOSIS

TOOL DIAGNOSIS	FREQUENCY	PERCENTAGE%
Epilepsy	47	47
No Epilepsy	38	38
Indeterminate	15	15

In the present study out of 100 study subjects, EPILEPSY was found in 47% of cases according to Tool diagnosis, NO- EPILEPSY was found in 38% of cases, and INDETERMINATE in 15% of cases according to Tool diagnosis.

TABLE 3: FINAL DIAGNOSIS

FINAL DIAGNOSIS	FREQUENCY	PERCENTAGE (%)
Epilepsy	49	49
Febrile Seizure	20	20
AES	4	4
CP	8	8
Dyselectrolytemia	1	1
Neuro Cysticercosis	5	5
Cystic Encephalomalacia	2	2
Hydrocephalus	7	7
Pyogenic Meningitis	2	2
Tubercular Meningitis	2	2

In present study out of 100 study subjects, EPILEPSY was found in 49% of cases as a final diagnosis, FEBRILE SEIZURE was found in 20% of cases, NEURO CYSTICERCOSIS was found in 5% of cases, AES in 4% of cases, CP in 8% of cases and DYSELECTROLYTEMIA in 1% of cases, CYSTIC ENCEPHALOMALACIA, PYOGENIC MENINGITIS, and TUBICULAR MENINGITIS in 2% in each of cases.

In the present study out of 100 study subjects, the study tool showed a sensitivity of 85.71%, Specificity of 86.11%, Positive predictive value of 89.36%, Negative predictive value of 81.58%, and Accuracy 85.88%.

TABLE 4: PSYCHOMETRIC PROPERTIES OF AIIMS-MODIFIED INDT- EPI IN STUDY SUBJECTS IN AGE GROUP OF (1 month -2 year (n=27).

VALUE	1 MONTH - 2 YEARS (N=27)
Sensitivity	87.56%
	(72.71% to 99.86%)
Specificity	81.81%
	(71.46% to 94.57%)
Positive predictive value	72.90%
	(57.25% to 85.70%)
Negative predictive value	96.28%
	(84.22% to 99.59%)
Accuracy	87.36%
	(77.43% to 95.18%)

In present study out of 100 study subjects,27(27.0%) of cases in the age group of 1 month to 2 years, the study tool showed a sensitivity of 91.66%, Specificity of 82.42%, Positive predictive value of 72.90%, Negative predictive value of 96.28%, and Accuracy 87.36%.

TABLE 5: PSYCHOMETRIC PROPERTIES OF AIIMS-MODIFIED INDT- EPI IN STUDY SUBJECTS IN AGE GROUP OF *2 years - 5 years (n=24).*

VALUE	2 YEARS - 5 YEARS (N=24)
Sensitivity	77.42%
	(58.90% to 90.41%)
Specificity	96.00%
	(79.65% to 99.90%)
Positive predictive value	96.00%
	(77.70% to 99.40%)
Negative predictive value	77.42%

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	(64.00% to 86.86%)
Accuracy	85.71%
	(73.78% to 93.62%)

In the present study out of 100 study subjects,24(24.0%) of cases in the age group of 2 years to 5 years, the study tool showed a sensitivity of 77.42%, Specificity of 96.0%, Positive predictive value of 96.0%, Negative predictive value of 77.42%, and Accuracy 85.71%.

TABLE 6: PSYCHOMETRIC PROPERTIES OF AIIMS-MODIFIED INDT- EPI IN STUDY SUBJECTS IN AGE GROUP OF 5year -18 year (n=49).

VALUE	5 YEARS - 18 YEARS (N=49)
Sensitivity	90.62%
	(80.70% to 96.48%)
Specificity	70.37%
	(49.82% to 86.25%)
Positive predictive value	87.88%
	(80.13% to 92.87%)
Negative predictive value	76.00%
	(58.72% to 87.57%)
Accuracy	84.62%
	(75.54% to 91.33%)

In present study out of 100 study subjects,49(49%) of cases in the age group of 5 years to 18 years, the study tool showed a sensitivity of 90.62%, Specificity of 70.37%, Positive predictive value of 87.88%, Negative predictive value of 76.0%, and Accuracy 84.62%.

DISCUSSION

The present study indicates that the AIIMS-modified INDT- EPI tool has acceptable psychometric properties for the diagnosis of epilepsy in children. The psychometric properties of the questionnaire will help to assess the usefulness of the questionnaire as a diagnostic screening tool at the primary care level in settings where diagnostic facilities at the tertiary level are not available. Previous investigators have attempted to investigate the utility of questionnaire-based diagnostic or screening tools for epilepsy. Most of the previous epilepsy screening questionnaires have focused solely on the diagnosis of tonic-clonic seizures.[10] However, the modified AIIMS INDT-EPI includes questions to identify a range of seizure types, including myoclonic seizures, epileptic seizures, atonic seizures, syncope, and focal seizures.[7,9] The epilepsy diagnostic questionnaire used in previous studies was developed based on expert experience rather than on standard international definitions or seizure classifications. The modified AIIMS INDT-EPI is based on the ILAE classification, which may explain the higher sensitivity of this survey tool compared to most of the previously studied tools.[7,11] A second reason for the higher sensitivity in our study is related to the ability of our study tool to diagnose a wide range of epileptic seizures, whereas previous studies focused on specific seizure types. Similarly, our study showed higher specificity compared to previous studies, owing to the ability of the tool to diagnose more types of non-epileptic events, such as respiratory arrest and syncope. The high specificity of the study instrument results in a high positive predictive value and a low false positive rate. We observed a lower sensitivity of the study instrument compared to previous studies. This may be due to the different types of populations involved in the study, which included children at higher risk for seizures. Parents of these children may be more familiar with the terminology, which may increase the likelihood of a positive response and thus the sensitivity of the study questionnaire.[8] In our study, children with a history of abnormal body movements and admitted to general pediatric and neurology outpatient clinics were enrolled. Similarly, the lower specificity of the diagnostic questionnaire in this study compared to previous studies may be due to the different types of study populations. Unlike other studies, this study did not include healthy children as a control group.[7] In general, the participation of healthy individuals increases the specificity of the test.

This study is a comprehensive analysis of 100 subjects diagnosed with epilepsy, focusing on various factors such as age distribution, gender, comorbidities, and performance of the AIIMS-modified INDT-EPI tool for diagnosing epilepsy and related disorders. The results highlight important trends and provide insight into the diagnostic reliability of the tool and the distribution of epilepsy-related disorders. The majority of the subjects were in the age group of 5-18 years (49%), followed by the age group of 1 month-2 years (27%) and the age group of 2-5 years (24%). These findings are consistent with previous studies suggesting that seizures are more common in infancy and adolescence, especially for generalized seizures seen in epilepsy or febrile seizures. The higher incidence in the age group of 5-18 years may be related to the increasing prevalence of diseases such

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as epilepsy in this age group, especially in children with genetic predisposition or brain damage. Regarding gender distribution, there was a higher proportion of males (63%) compared to females (37%), which is consistent with other literature on epilepsy. The study found a slightly higher prevalence of epilepsy in males, which may be due to differences in genetic or environmental exposure, but further studies are needed to fully understand this gender imbalance. The AIIMS modified INDT-EPI tool showed strong diagnostic properties in the study population. Overall, the tool had a sensitivity of 85.71%, a specificity of 86.11%, a positive predictive value (PPV) of 89.36%, a negative predictive value (NPV) of 81.58%, and an accuracy of 85.88%. These results indicate that the tool is highly effective in identifying both true-positive and true-negative cases, making it a reliable tool for diagnosing epilepsy in the study population. When analyzing the age data, the tool showed good results in all age groups. In the age group of 1 month to 2 years, the tool showed high sensitivity (87.56%) and accuracy (87.36%). This is noteworthy, as the diagnosis of epilepsy in very young children can be difficult due to the nonspecific nature of the initial seizure symptoms. In the age group of 2 to 5 years, the sensitivity decreased to 77.42%, but the specificity and positive predictive value remained high, confirming that the tool has the ability to correctly identify epilepsy cases despite the low sensitivity in this age group. In the age group of 5 to 18 years, the device showed the highest sensitivity (90.62%), which once again confirms its effectiveness in diagnosing epilepsy in older children and adolescents. However, the specificity was relatively low (70.37%), which may indicate a higher false positive rate in this age group. This may be associated with other symptoms resembling epilepsy, such as febrile convulsions or psychogenic nonepileptic seizures, which are relatively common in this age group. In this study, 17% of subjects had a comorbid condition, which is a relatively low rate compared with other studies that have reported a higher rate of comorbid conditions in children with epilepsy. This may reflect the specific population selected in this study, which may not have included patients with severe comorbidities or more complex seizure disorders. EEG changes were observed in 55% of cases, and MRI changes were detected in 34% of cases. These findings are consistent with the pathophysiology of epilepsy, where EEG abnormalities (e.g., epileptiform discharges) are common and MRI changes (e.g., structural brain abnormalities) may be particularly present in patients with focal seizures. However, the importance of clinical diagnosis is highlighted by the absence of EEG or MRI abnormalities in a significant number of cases (45% for EEG and 66% for MRI), as neuroimaging and EEG findings may sometimes appear normal in patients with epilepsy. With regard to diagnostic classification, the AIIMS modified INDT-EPI tool detected epilepsy in 47% of the subjects, which was almost consistent with the final diagnosis of epilepsy (49%). This suggests a strong correlation between the diagnostic ability of the instrument and clinical diagnosis. However, a significant number of subjects (38%) were classified as ‘no epilepsy’ by the tool, and 15% were unclassified, suggesting that the tool cannot always distinguish between epileptic-like seizure disorders such as febrile seizures and other neurological disorders such as neurocysticercosis. Final diagnosis revealed a wide range of other disorders, including, in addition to epilepsy, febrile seizures (20%), neurocysticercosis (5%), hydrocephalus, and cystic encephalomalacia. The presence of these symptoms in the study subjects suggests that seizures in children are not always easy to diagnose and may have a variety of underlying causes, emphasizing the importance of careful clinical evaluation. The study found that epilepsy accounted for 49% of all cases, which is consistent with literature showing that epilepsy is the leading cause of seizure disorders in children. The study found that febrile seizures, common in young children, accounted for 20% of all cases. Other notable conditions included hydrocephalus (7%), neurocysticercosis (5%), and cystic encephalomalacia (2%). These findings highlight the importance of accurate diagnosis, as febrile seizures, neurocysticercosis, and other structural brain abnormalities can present with similar seizure symptoms. Although this study provides valuable information, it also has some limitations. The sample size of 100 may not be representative of the entire pediatric population, and the study did not investigate long-term outcomes or the effectiveness of the treatment provided to the subjects. In addition, because the study relied on the AIIMS modified INDT-EPI instrument, there is a possibility of diagnostic errors, especially when non-epileptic seizures or other disorders were involved. Future studies could investigate a larger and more diverse population and study clinical outcomes in patients diagnosed using the AIIMS modified INDT-EPI instrument. Longitudinal studies could also provide information on the progression of epilepsy and the impact of early diagnosis and intervention on long-term neurodevelopment.

CONCLUSION

In conclusion, this study demonstrates that the AIIMS-modified INDT-EPI tool is effective in diagnosing epilepsy and related seizure disorders in the pediatric population. The tool demonstrated high diagnostic validity with high sensitivity, specificity, and accuracy across a wide range of age groups, especially in the 1-month to 2-year and 5-18-year age groups. These results highlight the potential of this instrument as a reliable tool for detecting epilepsy even in challenging clinical situations such as seizure diagnosis in very young children and adolescents.

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However, the study also identified some limitations, such as relatively low sensitivity in the 2-5- year age group and a high false positive rate in the 5-18-year age group. These results suggest that although the tool is effective in many cases, it may not be able to differentiate epilepsy from other seizure-related disorders, such as febrile seizures or psychogenic non-convulsive seizures. Moreover, the presence of comorbidities and abnormal EEG or MRI findings in a significant proportion of the study subjects highlights the difficulty in diagnosing seizure disorders with multifactorial etiology. The findings highlight the importance of combining the AIIMS-modified INDT-EPI instrument with other diagnostic approaches such as careful clinical evaluation, neuroimaging, and electroencephalography (EEG). These tools should not be used in isolation but as part of a comprehensive diagnostic process to accurately differentiate between different seizure disorders.

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