INCLEN Diagnostic Tool for Attention Deficit Hyperactivity Disorder (INDT-ADHD): Development and Validation

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Objective: To develop and validate INCLEN Diagnostic Tool for Attention Deficit Hyperactivity Disorder (INDT-ADHD).

Design: Diagnostic test evaluation by cross sectional design.

Setting: Tertiary care pediatric centers.

Participants: 156 children aged 65-117 months.

Methods: After randomization, INDT-ADHD and Connor's 3 Parent Rating Scale (C3PS) were administered, followed by an expert evaluation by DSM-IV-TR diagnostic criteria.

Main outcome measures: Psychometric evaluation of diagnostic accuracy, validity (construct, criterion and convergent) and internal consistency.

Results: INDT-ADHD had 18 items that quantified symptoms and impairment. Attention deficit hyperactivity disorder was identified in 57, 87 and 116 children by expert evaluation, INDT-ADHD and C3PS, respectively. Psychometric parameters of INDT-ADHD for differentiating attention deficit hyperactivity disorder and normal children were: sensitivity 87.7%, specificity 97.2%, positive predictive value 98.0% and negative predictive value 83.3%, whereas for differentiating from other neuro-developmental disorders were 87.7%, 42.9%, 58.1% and 79.4%, respectively. Internal consistency was 0.91. INDT-ADHD has a 4-factor structure explaining 60.4% of the variance. Convergent validity with Conner's Parents Rating Scale was moderate (r =0.73, *P*= 0.001).

Conclusions: INDT-ADHD is suitable for diagnosing attention deficit hyperactivity disorder in Indian children between the ages of 6 to 9 years.

Keywords: *Childhood neuro-developmental disorders, Resource limited settings, Psychometric evaluation.*

Attention Deficit Hyperactivity Disorder (ADHD) has 3-5% prevalence in school-aged children worldwide [1,2]. The diagnosis of ADHD is purely clinical and challenging as the developmental level and co-morbid disorders affect manifestations. Subjectivity arises in recognition of symptoms and degree of functional impairment. In the West, studies have shown that ADHD can be reliably diagnosed across clinicians [3]. This may not be true in India and other similar settings due to low levels of awareness and expertise about ADHD in community clinicians. Clinically, International Classification of Disease-10 (ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders- Text Revision (DSM-IV-TR) criteria are used to diagnose ADHD [4,5]. Both constructs are based on core symptom clusters of inattention and hyperactivity/impulsiveness. The American Academy of Pediatrics (AAP) guidelines for ADHD assessment advise DSM-IV-TR criteria, evaluating for co-morbid conditions, and a neurological examination [6].

Accompanying Editorial: Pages 448-50.

Appropriateness of construct of the DSM-IV-TR diagnostic criteria has not been studied in the Indian cultural context. Moreover, the uses of narrow band rating scales are limited by bias, cost, extensive training

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requirement, decreased availability and poor applicability. Some tools require the teacher's perspective of the child's behavior which may not be as reliable given the high student-teacher ratios. Appropriateness criteria are evidence-based guidelines developed to assist physicians and clinical psychologists in diagnosing conditions with wide variability in clinical decision in such settings. They are created by blending broad ranges of clinical experience with evidence-based information. The current study was planned to develop appropriateness criteria for ADHD in Indian children (6-9 years of age) and validate a diagnostic tool based on this criteria.

METHODS

Development of Appropriateness Criteria and Instrument

A panel consisting of 49 national experts from different parts of India and 6 international experts (pediatricians, child psychiatrists, pediatric neurologists, epidemiologists, pediatric otorhinolaryngologists, clinical psycho-logists, special educators, specialist nurses, speech therapist, occupational therapists and social scientist) developed the appropriateness criteria and diagnostic tool over three rounds of two-day workshops conducted during 2006-2008. Diagnostic modalities of ADHD in children were reviewed, and clinical expertise regarding personal practice was shared [7]. The former included ICD-10, DSM-IV-TR, ADHD Comprehensive Teacher Rating Scale-2nd edition, The Vanderbilt ADHD Teacher Rating Scale, Conner's Parent and Teacher Rating Scales-Revised (CPRS-R, CTRS-R), Swanson, Nolan, and Pelham-IV Questionnaire, and Attention Deficit Disorder Evaluation Scale-Second Edition [8-13]. A pool of items was selected by the panel using the modified Delphi technique. Appropriateness criteria comprising of 18 symptoms, based on parental interview and direct observation, were finalized based on clarity, importance and frequency of endorsement. The items were formulated in a construct similar to DSM-IV-TR criterion. The criteria were converted into symptom clusters for clinicians and psychologists to rate during diagnostic workup. The tool was named "INCLEN Diagnostic Tool for Attention Deficit Hyperactivity Disorder INDT–ADHD. The tool was translated forwards and backwards from *Hindi* to English and *Malayalam* by bilingual translators maintaining conceptual, content, semantic, operational and functional equivalence of the items, and validated. The tool was similarly prepared in *Odia, Konkani, Urdu, Khasi, Gujarati* and *Telugu*.

Section-A of INDT-ADHD consists of 18 items related to 'inattention' and 'hyperactivity/impulsiveness' symptoms (9 items each) while Section B consists of 8 items pertaining to onset, duration, functional impairment and a diagnostic algorithm to arrive at the diagnosis. Scoring is by parental endorsement with '1' for 'Yes' and '0' for 'No'. A score of six or more of the 9 items related to 'only inattention', 'only 'hyperactivity/impulsiveness' and 'both' indicate 'predominantly inattentive', 'predominantly hyperactive/impulsive', and 'combined subtypes', respectively. These are considered significant if the duration of symptom is ≥6 months, onset is before 7 years of age, and manifestation are in at least two settings. The instrument is given as *Web Appendix* **I**.
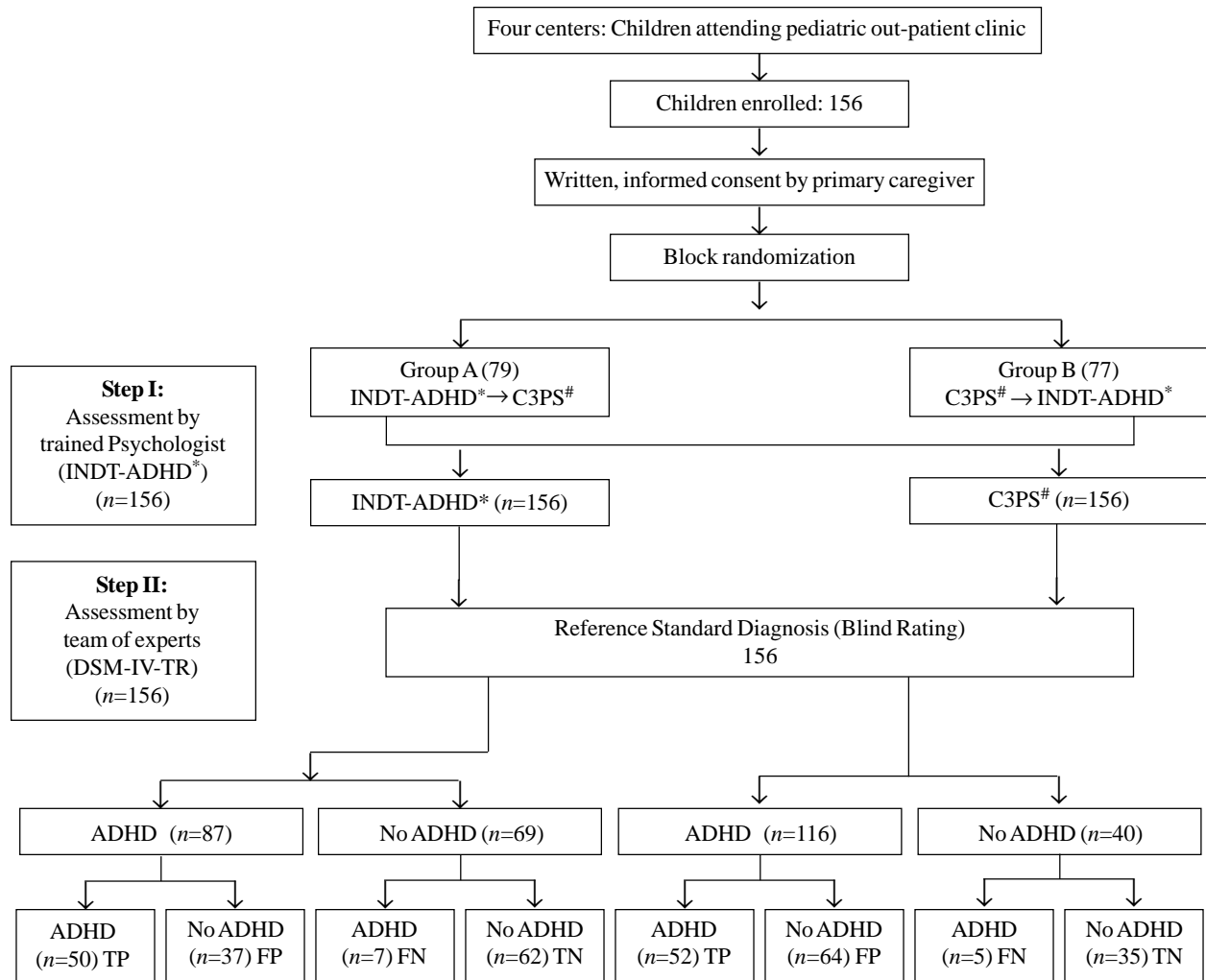
Psychometric Evaluation

The evaluation was conducted at four tertiary pediatric centers [All India Institute of Medical Sciences (AIIMS), Maulana Azad Medical College (MAMC), and Lady Hardinge Medical College (LHMC) in New Delhi, and Child Development Centre in Thiruvananthapuram] from June 2008 to April 2010.

Children 6-9 years of age with various Neurodevelopmental Disorders (NDDs) were recruited from the Child Development/Neurology outpatient clinics; those with typical development were recruited from the pediatric outpatient departments. Informed consent from the accompanying primary caregiver was obtained. The study was approved by the IndiaCLEN Review Board and individual Institutional Ethics Committees.

Enrolment and assessment

***Fig*.1** depicts the method for participant selection, assessment and interview. At every study site, the study coordinator, who was not part of any assessment, evaluated the children attending the clinic for eligibility and enrolled them in the study. The 156 participants were randomly allocated into group A (*N*=79) or B (*N*=77) by block randomization. In group A, INDT-ADHD was administered followed by Conner's 3 Parent Rating Scale-Short Form (C3PS) [14] whereas in group B, the sequence was reversed. This was done by independent psychologists to minimize rating bias. Thereafter, each child was assessed by a two member expert team (pediatric neurologist and child psychiatrist) who based their diagnosis on DSM-IV-TR criteria. This process took 3.5 hours over two consecutive days for each participant, comprising of interviews and direct observations. Each evaluator was blinded to original diagnosis and to the assessment by each other. After the expert evaluation, parents were counseled

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                    │ Four centers: Children attending pediatric out-patient clinic │
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                              │ Children enrolled: 156 │
                              └──────────────────────┘
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                    │ Written, informed consent by primary caregiver │
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                              │ Block randomization │
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Step I: Assessment by trained Psychologist (INDT-ADHD[*]) (*n*=156)	Group A (79) INDT-ADHD[*]→C3PS[#]	Group B (77) C3PS[#] → INDT-ADHD[*]
	INDT-ADHD* (*n*=156)	C3PS[#] (*n*=156)

| **Step II:** Assessment by team of experts (DSM-IV-TR) (*n*=156) | Reference Standard Diagnosis (Blind Rating) 156 | |

ADHD (*n*=87)	No ADHD (*n*=69)	ADHD (*n*=116)	No ADHD (*n*=40)
ADHD (*n*=50) TP	No ADHD (*n*=37) FP	ADHD (*n*=7) FN	No ADHD (*n*=62) TN	ADHD (*n*=52) TP	No ADHD (*n*=64) FP	ADHD (*n*=5) FN	No ADHD (*n*=35) TN

*INCLEN Diagnostic Tool for Attention Deficit Hyperactivity Disorder; #Connors 3 Parent Rating Scale; TP- True Positive; FP- False Positive; FN-False Negative; TN-True Negative

FIG. 1 *The flowchart for randomization, assessment and interviews.*

regarding the diagnosis and referrals were facilitated accordingly.

A sample size of 50 was calculated for each of the three groups (ADHD, children with other NDDs, and with normal development) assuming 85% sensitivity and specificity of INDT-ADHD to diagnose ADHD and 90% precision at 95% confidence. It was decided to enrol 60 children to account for drop-outs. This sample size was adequate to have an exploratory factor analysis during validation.

Training: The psychologists were trained in administration of INDT-ADHD and C3PS using a standardized operational manual in a 3-day structured workshop. Separate groups of psychologists were formed for INDT-ADHD and C3PS. Two pediatric neurologists and two child psychiatrists with over 10 years of professional experience were the trainers. Out of eight trainees, six were Masters in Psychology and two were Clinical Psychology graduates.

Data management and analysis

Participants' assessment details were entered in a predesigned instrument with unique identification numbers. Blinding was maintained by separate opaque, sealed envelopes and protected by reversible anonymity and restricted availability. Statistical analysis was done using SPSS (version 19) and MedCalc (version 12.2.1.0) after data was entered into Intelligent Character Recognition sheets (ICR). These were processed using ABBYY Form

Reader 4.0 software. Psychometric parameters of diagnostic accuracy, construct validity, criterion validity and internal consistency of INDT-ADHD were estimated. The performance of INDT-ADHD was compared with C3PS for convergent validity.

RESULTS

Mean (SD) age of enrolled children (*N*=156; 107 boys) was 89.1 (11.9) months. The diagnoses made by each method is depicted in ***Table* I**. According to expert team (gold standard), 57 children had ADHD (47 isolated and 10 with other co-morbid NDD); 26 were predominantly inattentive, 11 predominantly hyperactive/impulsive and 20 were combined ADHD. INDT-ADHD diagnosed ADHD in 87 children; 33 predominantly inattentive, 16 predominantly hyperactive/impulsive and 38 combined. C3PS made a diagnosis of ADHD in 116 cases without any differentiation into sub-types.

Psychometric parameters of INDT-ADHD are summarized in ***Table* II**. The receiver operating characteristic (ROC) curve for INDT-ADHD with a cut-off score of ≥ 8 against expert diagnosis gave an Area Under the Curve (AUC) of 0.98 [95% CI0.94, 0.99] [depicted as ***Fig*. 2**]. The diagnostic accuracy of INDT-ADHD against expert diagnosis calculated by AUC according to age (below and $\geq$7 years), gender and severity (no ADHD and ADHD) is presented in ***Table* III**. Inter-rater reliability and test-retest reliability were not assessed. The Cronbach's α coefficient for the whole construct showed high internal consistency (0.91) and good internal consistency separately for inattention (0.84) and hyperactivity/impulsiveness (0.87). Construct validity was demonstrated by exploratory factor analysis (principal component extraction and varimax rotation). Taking the critical Eigen value as 1, a 4-factor structure was derived [***Web Table* I**]. Factors 1, 2, 3 and 4 represented inattention, hyperactivity, communication related restlessness and distractibility, respectively. With loading factor cut off level of 0.4, 14 items loaded distinctively on to single factors, eight with inattention, three with hyperactivity, two with communication related restlessness and one with distractibility, whereas four symptoms cross-loaded on to more than one factor. This factor analysis explained 60.4% of the variance. When the performance of INDT-ADHD was compared with that of C3PS it was observed that the convergent validity was moderate (r = 0.73, *P*= 0.001).

DISCUSSION

In the present study, the diagnostic accuracy for INDT-ADHD for ADHD was high irrespective of age and gender. Sensitivity, specificity, positive predictive and negative predictive values were acceptable INDT-ADHD performed well in differentiating ADHD from normal children but could not effectively differentiate it from other NDD's, especially ASD.

Content validity refers to the extent to which a measure represents all facets of a given construct. In this tool it was inattention, hyperactivity, restlessness and distractibility. This was ensured during tool development as only those items in which >50% consensus was reached by the experts were considered. During validation this was substantiated as not a single item was assigned a score of '0' in > 50% of children with ADHD by expert diagnosis. Construct validity is the degree to which a test measures what it claims to be measuring that

TABLE I FINAL DIAGNOSES OF STUDY GROUP ACCORDING TO EXPERTS (*N*=156)

Evaluation by	Final Diagnosis					
	ADHD			Not ADHD		
	Total (Break-up)*	Isolated ADHD (Break-up)*	With co- morbid NDD (Break-up)*	Total	NDD/co morbidities other than ADHD	Normal development
Expert Team[$]	57 (26,11,20)	47 (15,14,18)	10 (4,3,3)	99	55[#]	44
INDT-ADHD	87 (33, 16, 38)	Not done by tool	Not done by tool	69	26	43
C3PS	116 (No sub-type possible)	Not done by tool	Not done by tool	40	12	28

* Inattention, hyperactivity/impulsiveness, combined. [#]ASD-Autism Spectrum Disorder; ID-Intellectual Disability; SLD-Speech and Language Disorder; HI-Hearing Impairment; VI-Vision Impairment; NMI-Neuro-motor Impairment; CP-Cerebral palsy; LD-Specific Learning Disorders. INCLEN Diagnostic Tool for Attention Deficit Hyperactivity Disorder (INDT- ADHD); Connors Parent Rating Scale (C3PS) and Diagnostic and Statistical Manual of Mental Disorders- IV-Text Revision (DSM-IV TR). [#](ASD -19, ASD + ID-5, ID-15, SLD- 2, HI-3/ VI-1, NMI/CP- 3, Epilepsy - 2, LD- 5); [$]Expert team: diagnosis with DSM-IV-TR Diagnostic criteria of ADHD.

TABLE II DIAGNOSTIC ACCURACY OF INDT-ADHD AGAINST THE EXPERT DIAGNOSIS

|	Sensitivity% (95% CI)	Specificity% (95% CI)	PPV (95% CI)	NPV (95% CI)	Positive LR (95% CI)	Negative LR (95% CI)
ADHD vs. other NDD	87.7 (78.6-94.2)	42.9 (34.6-48.7)	58.1 (52.1-62.4)	79.4 (64.1-90.2)	1.5 (1.2-1.8)	0.28 (0.12-0.61)
ADHD vs. normal	87.7 (81.1-89.4)	97.2 (86.7-99.9)	98.0 (90.6-99.9)	83.3 (74.3-85.6)	31.5 (6.0-610.8)	0.12 (0.10-0.21)
INDT-ADHD total score ≥8	87.7 (76.3-94.9)	95.9 (90.0- 98.9)	38.2 (34.9-43.7)	11.1 (0.04 - 0.2)	21.7 (19.5-24.1)	0.13 (0.04-0.4)

INDT- ADHD: INCLEN Diagnostic Tool for Attention Deficit Hyperactivity Disorder; Other NDD: Other Neuro-developmental disorder; LR: Likelihood ratio; PPV: Postive predictive value; NPV: Negative predictive value.

is assessed by factor analysis of the symptom clusters of ADHD. Variability in factor analysis results has been observed in studies with 2-factor, 3-factor and 4-factor structures being used to explain the construct, probably attributable to differences in study population and statistical approach [15-17]. The 4-factor structure of INDT-ADHD is similar to the model offered by Baumgaertel, *et al.* [17]. Moderate convergence of INDT-ADHD with C3PS implied that the construct of both were theoretically related to each other. The Cronbach's alpha coefficient of internal consistency is in agreement with a previous study [18].

The strength of this study was its multi-centric development and validation. Using appropriateness criteria as diagnostic tool has been successful previously [19]. However, validation was on a referral center based population where the prevalence of ADHD is expected to be high, and not representative of the general population. The total variance explained by the 4-factor model of 60% indicates that it could be due to missing information in the tool or a small sample size. The former may reflect absence of inclusion of symptoms of co-morbid disorders whereas in the latter a larger size may generate a more stable factor structure model and improve construct validity.

The implication of this study is the creation of qualitatively-derived and theory-guided appropriateness criteria-based tool for diagnosing ADHD with high accuracy, and adequate validity and internal consistency. It can be used for initial evaluation and assessment of post-intervention status in ADHD. Currently available tools for diagnosing ADHD are patented and need payment every time these are used. The INDT-ADHD

Area under curve = 0.98 (95% CI=0.94-0.99)
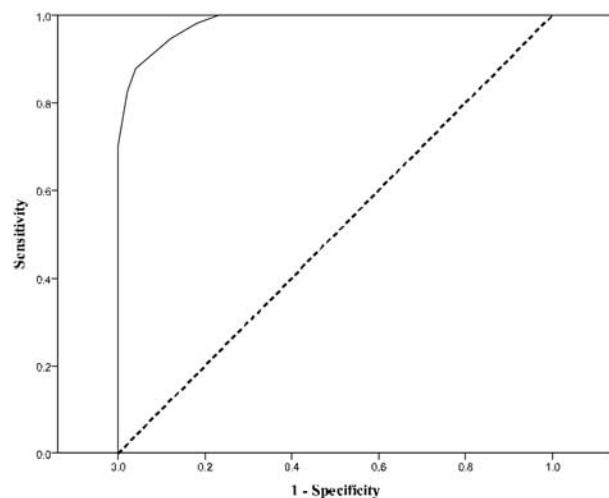
FIG. 2 *The Receiver Operating Curve characteristics of INCLEN Diagnostic Tool for Attention Deficit Hyperactivity Disorder (INDT-ADHD) total score against Diagnostic and Statistical Manual of Mental Disorders- IV-Text Revision (DSM-IV-TR) diagnosis (Expert Diagnosis).*

TABLE III PERFORMANCE OF INDT-ADHD AGAINST DSM-IV TR DIFFERENT AGE GROUPS, GENDER AND SEVERITY* OF ADHD

Groups	AUC (95% CI)
Age group	
Children < 7 years	0.98 (0.96-1)
Children ≥7 years	0.98 (0.96-1)
Gender	
Boys	0.97 (0.95-0.99)
Girls	0.99 (0.97-0.99)
*Severity of ADHD**	
No ADHD/Borderline	0.53 (0.42-64)
Severe	0.81 (0.69-0.93)

Severity of ADHD dichotomized into no ADHD/borderline (C3RS score of 0-56/57-63) and elevated scores (C3RS score of ≥64); DSM-IV TR: Diagnostic and Statistical Manual of Mental Disorder-IV- Text Revision.

WHAT IS ALREADY KNOWN?

• Diagnosis of ADHD necessitates evaluation by an experienced psychologist, psychiatrist, or developmental pediatrician.

WHAT THIS STUDY ADDS?

• The INDT-ADHD diagnostic tool for ADHD is a freely available tool, developed for the resource limited settings through expert consensus based on established DSM-IV-TR criteria.

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will be available in public domain and is likely to expand diagnostic access to populations in developing countries.

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