RESEARCH PAPER

Diagnostic Accuracy of International Epidemiology Network (INCLEN) Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD) in Comparison with Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5)

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Objective: To compare the diagnostic accuracy of INCLEN Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD) against Diagnostic and Statistical Manual of Mental Disorders – 5 (DSM-5) for the diagnosis of Autism Spectrum Disorder (ASD). **Methods**: 118 children aged 2-9 years with symptoms suggestive of ASD were assessed by INDT-ASD and DSM-V by trained personnel. ASD diagnosis by INDT-ASD was compared against the expert's DSM-5 diagnosis. **Results**: INDT-ASD had a sensitivity and specificity of 100% and 75%, respectively against DSM-5 for the diagnosis of ASD; specificity for Autistic Disorder was 87%. **Conclusion**: The INDT-ASD has a good sensitivity and specificity against DSM-5, and can continue to be used for the diagnosis of ASD even after the adoption of DSM-5 criteria.

Keywords: *Autism, Diagnosis, Evaluation, Pervasive developmental disorders.*

Autism Spectrum Disorders (ASD) are a highly heterogeneous group of disorders with wide variation in symptom severity, intellectual level, and functional disability [1]. Clinical diagnosis is made based on the presence or absence of specific behaviors. The Diagnostic and Statistical Manual of Mental Disorders (DSM) is conventionally used as a gold standard, but each time the nomenclature and criteria are revised, the new definition inevitably subtly changes the nature of how the conditions are construed [2,3]. DSM-IV used the term Pervasive Developmental Disorders (PDD), which included Autistic disorder, Asperger's disorder, Pervasive developmental disorder–not otherwise specified (PDD-NOS) along with Rett syndrome and Childhood Disintegrative Disorder (CDD). However, DSM-5 has done away with the five subtypes and gives only unitary diagnosis of Autism Spectrum Disorder (ASD) [3].

The International Clinical Epidemiology Network (INCLEN) had developed an indigenous instrument named the INCLEN-Diagnostic Tool for Autism Spectrum Disorder (INDT-ASD), which is suited to the Indian sociocultural milieu, and is freely available in five Indian languages [4]. At the time of its development, DSM-IV was in use and the tool was based on and validated against DSM-IV. The present study aimed to assess the diagnostic accuracy of INDT-ASD against DSM-5, the new gold standard.

METHODS

This hospital-based diagnostic accuracy study was conducted at the Child Development Center of Maulana Azad Medical College in New Delhi, India from February 2014 to February 2015, after obtaining Institutional Ethical Committee approval. Children aged between 2-9 years who were referred with parental concern regarding any of the following – delayed/deviant speech, poor eye contact, poor social skills, repetitive movements, delayed milestones, poor school performance, or hyperactivity –were enrolled consecutively after written informed parental consent. Children with primary caregivers who could not communicate in either English or Hindi were excluded. The sample size calculated was 100, assuming a sensitivity of 95%, absolute precision of 10%, confidence interval of 95%, and an ASD prevalence of 30% amongst the population attending the center [5].

The INDT-ASD has two sections: Section A includes items corresponding to DSM-IV triad, responses are recorded as Yes, No or Unsure; and Section B comprises of items that assess for delays or abnormal functioning in social interaction, communication and imaginative play to identify the subtype of disorder. An algorithmic approach is used to classify children as Autistic disorder, Asperger disorder, PDD-NOS, Rett syndrome or CDD. As DSM-5 excludes Rett syndrome and CDD, only

children diagnosed as Autistic disorder, Asperger syndrome and PDD-NOS were classified as ASD. Rett syndrome and CDD were classified as non-ASD [3,4,6].

The study population was randomly allocated to two groups with one undergoing INDT-ASD (index test) by a trained researcher, followed by an expert evaluation by a developmental pediatrician with over two decades of experience in evaluation of ASD and a thorough knowledge of DSM-5 (gold standard), and the other undergoing the sequence in reverse. Both assessments were done within five days of each other. Sensitivity, specificity, positive and negative predictive values of INDT-ASD were calculated by comparing diagnostic outcome with the DSM-5 results using Microsoft Excel.

RESULTS

We consecutively enrolled 118 eligible children, of which, 100 completed both evaluations (mean (SD) age 56 (23.3) mo; 71 boys). The distribution of primary presenting symptoms were delayed/repetitive speech in 71%, developmental delay in 43%, hyperactivity in 26% and poor scholastic performance in 21%. According to the expert evaluation, ASD was diagnosed in 60 children, Global developmental delay in 24, Intellectual disability in 9, ADHD in 5 and Social Communication Disorder in 2. Other baseline variables of the participants are detailed in ***Table* I.**

TABLE I CHARACTERISTICS OF THE STUDY POPULATION (*N*=100)

Characteristics	*Number (%)*
Age	
2-3 years	22 (22%)
3-4 years	22 (22%)
4-6 years	42 (42%)
6-9 years	14 (14%)
Mother's Education	
Graduate and above	23 (23%)
Secondary schooling (6-10 y)	37 (37%)
Primary schooling (1-5 y)	23 (23%)
No schooling	17 (17%)
Socio-economic status (Modified Kuppuswamy Scale)	
Upper	3 (3%)
Upper Middle	12 (12%)
Middle/Lower Middle	64 (64%)
Lower/Upper Lower	19 (19%)
Lower	2 (2%)
DQ/IQ	
<20	3 (3%)
20-35	14 (14%)
36-50	26 (26%)
51-70	42 (42%)
>70	15 (15%)

INDT-ASD diagnosed 70 of the children as having ASD and 30 as non-ASD. The sensitivity of INDT-ASD using DSM-5 as gold standard was 100% while the specificity was 75% for ASD as a group but was 87% for Autistic Disorder specifically. The Positive predictive value of the test was 85.7% while negative predictive value was 100%.

DISCUSSION

This diagnostic accuracy study in children (age 2-9 y) with symptoms suggestive of ASD found the sensitivity and specificity of INDT-ASD for a diagnosis of ASD to be 100% and 75%, respectively, when compared with the gold standard.

The sensitivity and specificity of INDT-ASD in its validation study in a similar-aged population and hospital setting was 98% and 95%, respectively [4]. The lower specificity of INDT-ASD found in our study could be due to the modifications in DSM-5 criteria itself. Other recently published studies have also reported a reduction in diagnosis of ASD ranging from 10%-33% when using DSM-5 criteria compared to DSM-IV [7-12]. The higher specificity of INDT-ASD for the subgroup of children diagnosed as Autistic Disorder as per the tool could be because this group could meet the stringent DSM-5 criteria for ASD as they usually have a more severe phenotype.

This study was conducted in a tertiary-care hospital, where the participants had been specifically referred with concerns suggestive of autism. They may not be representative of the children with autism in the general population, which could have influenced the predictive value of the tool. The assessment by a single trained evaluator for the tool in all the children is a major strength of the study.

The INDT-ASD, developed as an operationalization tool for DSM-IV criteria, is still able to identify majority of the children with signs and symptoms of ASD as per DSM-5 even though it does not address some of the new additional symptoms *e.g.*, sensory issues related to pain and touch. In the Indian scenario, where the awareness for ASD is low amongst health professionals because of which large number of these children often remain undiagnosed, the tool remains a suitable diagnostic modality given its previously described positive features [4]. This tool has also been approved by the Government of India for diagnosing autism for the purpose of disability certification [13].

WHAT THIS STUDY ADDS?

- INCLEN Diagnostic tool for Autism Spectrum Disorder (INDT-ASD) has a high sensitivity (100%) and good specificity (75%) for an ASD diagnosis as per DSM-5, and retains its acceptable diagnostic accuracy despite change in nomenclature and criteria.

Contributors: PV: acquisition, analysis, interpretation of data for the work and drafting the work; MJ: concept of the study and its methodology, and acquisition and analysis of data; DM: critical review of intellectual content and study methodology.
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