

EARLY DIAGNOSIS OF AUTISM SPECTRUM DISORDER USING M-CHAT R/F SCREENING TOOL AMONG TODDLERS IN PEDIATRIC OUTDOOR CLINIC - A CROSS SECTIONAL STUDY



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ABSTRACT

INTRODUCTION

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder characterized by impairments in reciprocal social communication and a tendency to engage in restrictive, repetitive stereotyped patterns of behaviors. Early identification allows for timely interventions that can significantly improve outcome. This study aims to estimate the prevalence of ASD among low-risk young children who attend the pediatric outpatient clinic of a tertiary care center in Pune.

METHODS

This cross-sectional study was conducted over children aged 16 to 30 months who visited the immunization clinic and pediatric outdoor clinic of a tertiary care center in Pune, Maharashtra.

All children were screened for ASD using the internationally validated 2-stage parent reporting M-CHAT-R/F screening tool. All screened-positive toddlers underwent a confirmatory test based on DSM-V, specifically the AIIMS-modified (INCLIN) diagnostic tool for Autism Spectrum Disorder (INDT-ASD). The collected data was analyzed, and the prevalence was determined.

RESULTS

400 children were screened using the 2-stage parent reporting M-CHAT R/F tool, with a median age of 20.5 months (range: 16–30 months). The M-CHAT R scale identified 391 children (97.75%) as low risk and 9 (2.25%) as medium risk. Of the 9 medium-risk children, M-CHAT R/F confirmed 7 as positive (77%) and 2 as negative (23%). ASD diagnosis using INDT-ASD found 6 of the 7 M-CHAT R/F-positive cases (85.5%). Overall, 6 out of 400 children were diagnosed with ASD, indicating a 1.5% prevalence.

CONCLUSION

This study again confirms that M-CHAT R/F is very useful screening tool and may be adopted by policy makers to use as epidemiological survey tool to early anticipate and take remedial measures after confirming diagnosis

KEYWORDS; Autism Spectrum Disorder (ASD), M-CHAT R/F, Neurodevelopmental Disorder, ASD screening, Modified INCLIN diagnostic tool

INTRODUCTION

Autism Spectrum Disorder (ASD) is a neurodevelopmental condition characterized by difficulties in socialization, communication impairments, and restricted, repetitive behaviors. [1] Western literature estimates ASD prevalence at 1% in the UK, 1.5% in the US, and 1.8% as reported

by the CDC. [2-5] Developed countries generally report a prevalence of 1 in 100, with slightly lower rates in developing nations. [5,6]

In India, ASD prevalence is estimated at 12 to 14 per 10,000, lower than figures reported in the US and UK. The INCLIN study in India places the prevalence at 1.12 (0.74–1.68) per 100 children. [7-11] Given

its significant economic implications—requiring healthcare, educational support, and rehabilitative services—early identification is crucial, as timely interventions improve outcomes.

Recently, an increasing number of children have been brought for pediatric consultations due to erratic behavior or poor social communication, often suggesting ASD. This underscores the need for continuous monitoring through standardized screening tools to track prevalence trends. This screening can be conducted on a small scale in outpatient clinics or as part of large-scale epidemiological surveys.

To contribute this, the present study aims to estimate ASD prevalence in children aged 16 to 30 months attending the pediatric outdoor clinic of a tertiary care center in Pune. The study employs a highly internationally validated two-stage parent-report screening tool, utilizing the Modified Checklist for Autism in Toddlers, Revised with Follow-Up (M-CHAT-R/F)[12,13] and INDT-ASD to confirm the all screen positive children. [8]

METHODOLOGY

This Cross-Sectional Study was conducted in a hospital setting on young children attending the Pediatric outdoor clinic (OPD). Toddlers between 16 and 30 months of age attending the immunization clinic and Pediatric OPD of tertiary care hospital in Pune was screened for ASD.

Sample Size - Using OpenEpi (version 3), an open-source calculator and the sample size formula $n = [DEFFNp(1-p)] / [(d^2/Z^2 - \alpha/2(N-1) + p(1-p))^{**}]$, the required sample size for a population of 100,000 was determined taking a screen-positive frequency of 9.1% for M-CHAT R/F, as reported [14], with a 99.9% confidence level, the calculated sample size was 359. Considering a 10% dropout rate, the adjusted sample size was 394.9, which was rounded to 400 for the study.

Children aged 16 to 30 months visiting the immunization clinic and pediatric OPD were screened for ASD using the internationally validated M-CHAT-R/F tool after obtaining informed consent. [11,12] Children with serious medical or neurological conditions were excluded.

Eligible toddlers underwent ASD screening using the two-stage M-CHAT-R/F tool, consisting of 20 questions. In the first stage, parents received the M-CHAT-R questionnaire, which assigns one point per question for a total score of 20. Trained medical personnel assisted parents in completing the forms, ensuring they understood the questions before proceeding. For all M-CHAT-R/F questions, except 2, 5, and 12, a 'NO' response indicates ASD risk, while for these three items, 'YES' indicates risk. Each positive response scores 1 point. Cutoff value was taken 3 or more.

- **Low Risk (Score 0-2):** No further action required.

- **Medium Risk (Score 3-7):** Follow-Up (M-CHAT-F) administered by trained medical personnel to gather additional details on at-risk responses.

- **High Risk (Score 8-20):** Immediate referral for diagnostic evaluation and early intervention, bypassing Follow-Up.

The 2nd stage M-CHAT-R/F was administered only to children who scored between 3 and 7. This Follow-Up included 20 flowcharts, one for each question, to confirm ASD risk based on initial positive responses. After Follow-Up, children scoring 2 or higher were classified as screened positive and referred for evaluation and intervention.

All toddlers screening positive via M-CHAT-R/F underwent definitive ASD diagnosis using the AIIMS-modified INCLIN test based on DSM-V criteria. Data were analyzed using OpenEpi online software version 3.0 and Mid-P exact test and Conditional maximum likelihood estimate of Odds Ratio (CMLE OR) were calculated to find statistical significance between non-parametric independent (demographic variables) and dependent variables (frequency of ASD). Ethical committee approval was obtained.

RESULTS

A total of 400 young children from general population who attended pediatric outdoor clinic, aged 16 to 30 months (Median age 20.5 months) were screened using M-CHAT R. Of the 400 screened young children, 226 (56.5%) were male, and 174 (43.5%) were female. 65 children (16.25%) were born pre-term and rest other demographic data depicted in Table 1.

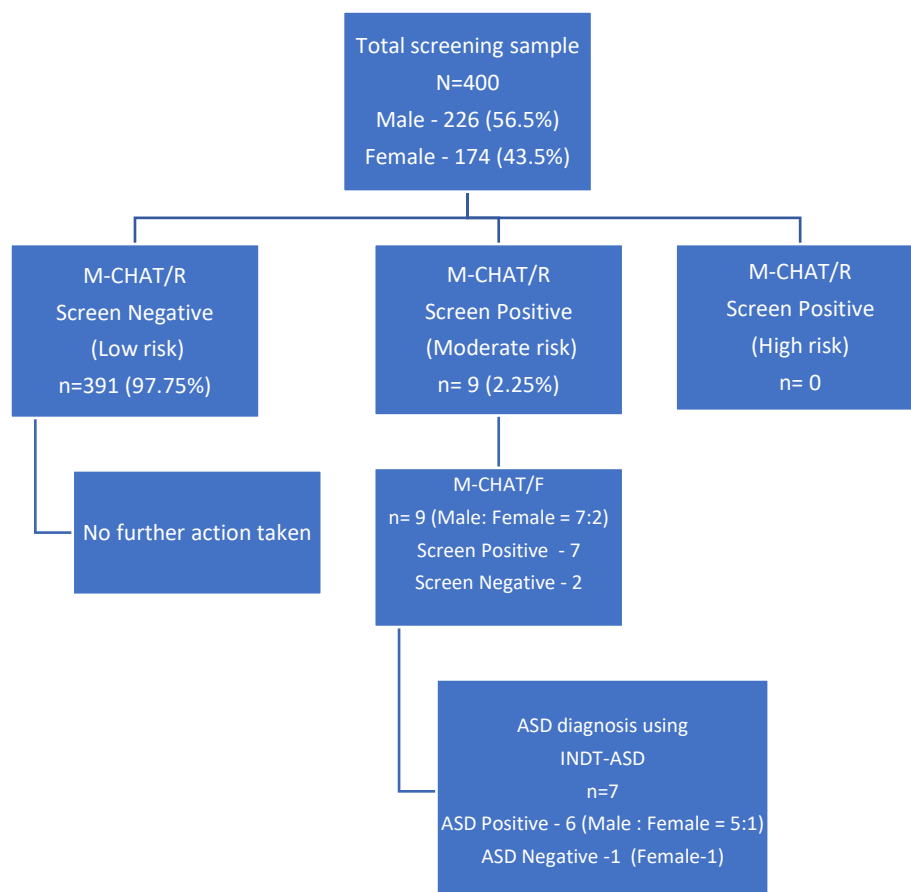
Among 400 study participants 391 (97.75%) children classified as low risk whereas 9 were categorized under medium risk and none fall under high risk group. Children classified as low risk were reassured and not followed up further but instructed to report back if any concern arises. Median age in screen positive children was 25.5 months with age range of 20 - 28 months. Out of total 9 children 07 (77%) found positive when M-CHAT F administered in follow up. Figure 1

Further, these 07 screen positive children for ASD by M-CHAT R/F, evaluated by using AIIMS modified INCLIN diagnostic tool for Autism spectrum disorder and found 06 children positive (85.5%).

Finally, out of total 400 children, 06 were diagnosed as ASD and found the prevalence of 1.49% (95%CI - 0.55% to 3.21%) in the study population.

Table 1: Study Population Demographic Data

Participants Demographics (N= 400)	
Characteristics	
Median Age in months at the time of screening (Range)	20.5 months (16-30 months) N= 400
<i>Gender Distribution</i>	
Male	226 (56.5%)
Female	174 (43.5%)
<i>Gestational Age</i>	
Preterm	65 (16.25%)
Term	333 (83.25%)
Post term	2 (0.50%)
<i>Born by mode of Delivery</i>	
Normal delivery	298 (74.5%)
LSCS	102 (25.5%)
<i>Place of Birth</i>	
Institutional delivery	356 (89%)
<i>Breastfeeding pattern</i>	
Exclusive breastfeeding minimum 6 month	346 (86.5%)
Formula feed	54 (13.5%)
<i>Immunization Pattern</i>	
Vaccinated as per schedule	385 (96.25%)
Partially Vaccinated	15 (3.75%)
<i>Parental Education (minimum 10+2 std)</i>	
Both parent	336 (86%)
One of two	51 (12.75%)
None	13 (3.25%)

**FIGURE 1**

Study participation flowchart. Three staged screening and confirmatory procedure follows. First 2 stage were with M-CHAT R/F screening tool thereafter ASD was confirmed with INDT-ASD (AIIMS Modified INCLEN Diagnostic tool for ASD). No participant was categorized under high risk screen positive on M-CHAT/R.

Table 2. Bivariate analysis among demographic variables & ASD

Characteristics	N=400	Normal (Screen Negative)	ASD (INDT- ASD)	Mid P Exact test (p)	CMLE* Odds Ratio(95% CI)
Median Age in months at the time of screening (Range)	20.5 months (16-30 months) N= 400		25.5 months (20-28 months)		
Gender Distribution					
Male	226 (56.5%)	221	5	0.1062	3.903 (0.5345-93.63)
Female	174 (43.5%)	173	1		
Gestational Age					
Preterm	65 (16.25%)	61	4	0.004054	0.093.4 (0.0117-0.5356)
Term	333 (83.25%)	331	2		
Post term	2 (0.50%)	2	0	See Note#	
Mode of Delivery					
Normal delivery	298 (74.5%)	298	0	0.0001229	0 (0.0-0.21)
LSCS	102 (25.5%)	96	96		
Breastfeeding pattern					
Exclusive Breastfeeding	346 (86.5%)	342	4	0.1113	0.3054 (0.5287-2.435)
Top feed	54 (13.5%)	52	2		
Immunization Pattern					
Vaccinated as per schedule	385 (96.25%)	380	5	0.1121	0.1859 (0.02368-4.683)
Partially Vaccinated	15 (3.75%)	14	1		

Table 2: Study population characteristic association analysis with Autism Spectrum Disorder (ASD). *Conditional maximum likelihood estimate of Odds Ratio; Lower section caesarean section (LSCS); AIIMS modified INCLEN diagnostic tool for ASD (INDT-ASD). # Note: not considered for association analysis since no ASD case falls under this category

On bivariate analysis as shown in Table 2, no statistically significant association was found between gender and confirmed ASD cases ($p = 0.1062$). However, the conditional maximum likelihood estimate of the odds ratio (CMLE OR = 0.093; 95% CI: 0.0117–0.5356) suggests a potential male predilection, as the confidence interval remains below 1.

In contrast, ASD was significantly associated with preterm birth ($p = 0.004$) and delivery by LSCS ($p = 0.0001229$), as presented in Table 2. The CMLE odds ratios for these associations were 0.093 (95% CI: 0.0117–0.5356) for preterm birth and 0.3054 (95% CI: 0.5287–2.435) for LSCS delivery.

On the other hand, breastfeeding patterns and immunization status showed no statistical significance, with p -values exceeding 0.5."

DISCUSSION

ASD is a significant developmental disability worldwide. The estimated prevalence is 1% in the UK and 1.5% in the US, similar to 8.3 per 10,000 children aged 3–12 years in China [2-6]. In India, with a population of 1.3 billion, over 2 million individuals may be affected. A systematic review of South Asia (Bangladesh, India, Sri Lanka) reports ASD prevalence ranging from 0.09% to 1.07% among children aged 0–17 years. According to CDC

data, ASD prevalence has risen to 1 in 54 children (1.8%). The INCLEN study estimates India's ASD prevalence at 1.12 per 100 children [4, 7-11]. Estimated Prevalence in this study is 1.5% which is almost similar to other studies.

Mean age of diagnosis of ASD in this study population was 25.50 months with range of 20 – 28 months in the study population. In a study by Harshini Manohar et al, 2018 early identification of ASD symptoms were at an average age of 22.22 ± 9.47 months [21].

Gender distribution in this study shows Male: Female ratio is 5:1. Other studies also showed the same results. Autism is more common among male children with M: F ratio of 4:1. Studies from clinical samples report higher M: F ratio (4–6 to 1) while lower ratios (2–3 to 1) are reported in community samples. A large-scale epidemiological study report that M:F ratio is lower in the range of 2-5:1. According DSM-V ASD prevalence in gender distribution male and female ratio is 4:1 [15-18]. However, on bivariate analysis, this study showed no significant statistical association, though CMLE Odds ratio being less than 1 suggest a potential male predilection.

In this study, all the 06 positive cases were delivered by LSCS delivery (100% LSCS delivery), which is statistically significant. Other studies also show caesarean section delivered children were more affected by ASD than Normal vaginal delivered children. Caesarean sections delivered children were more prone to develop ASD due to most of low birth weight and anomalies babies delivered by LSCS [19,20].

Children with suboptimal breastfeeding are more vulnerable to ASD compared with their siblings [78]. Gut microflora acts as pivot role in developing immune system and neural development. Breastfeeding pattern in children also may have a role but there was no statistical association was established in present study. Although other studies showed exclusive breastfeeding significantly affect prevalence of ASD [21]

ASD was significantly associated with preterm birth ($p=0.004$) with CMLE Odds ratio 0.093 (95%CI: 0.0117, 0.5356). Similarly, other studies also showed Preterm and Low birth weight act as a marker for development of later psychiatric and neurodevelopmental conditions [19,20].

Immunization pattern of this study population shows that five children were fully immunized (83 %) as per national Immunization schedule. There is no direct role of immunization in Autism spectrum disorder (Wendy Roberts, 2002). There is no association between receiving MMR vaccination and Autism (Jain A et al, 2015, DeStefano F, 2019) [22-24].

CONCLUSION

The prevalence of Autism Spectrum Disorder (ASD) in this study was 6 out of 400 children (1.5%), which is consistent with findings from other studies within the Indian population. The mean age at which ASD symptoms were identified in this study population was 25.50 months, suggesting that early screening between 16 to 30 months facilitates timely diagnosis and intervention.

Males were more affected than females. Additionally, children born through LSCS delivery, preterm births, and those with low birth weight had a higher prevalence of ASD, underscoring the importance of comprehensive antenatal and perinatal care.

LIMITATION OF STUDY

A limitation of this study is that the collected sample was derived from a single center and lacked randomization. This issue could have been mitigated if the study had been multicentric, encompassing various regions of India to reduce selection bias, particularly regional bias. Additionally, children who screened negative using the M-CHAT-R but were not

further evaluated were assumed to have true-negative results for analysis. However, there remains a possibility that some cases were overlooked.

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