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Abstract

Research to date in mainland China has mainly focused on children with autistic disorder rather than Autism Spectrum Conditions and the diagnosis largely depended on clinical judgment without the use of diagnostic instruments. Whether children who have been diagnosed in China before meet the diagnostic criteria of Autism Spectrum Conditions is not known nor how many such children would meet these criteria. The aim of this study was to evaluate children with a known diagnosis of autism in mainland China using the Autism Diagnostic Observation Schedule and the Autism Diagnostic Interview–Revised to verify that children who were given a diagnosis of autism made by Chinese clinicians in China were mostly children with severe autism. Of 50 children with an existing diagnosis of autism made by Chinese clinicians, 47 children met the diagnosis of autism on the Autism Diagnostic Observation Schedule algorithm and 44 children met the diagnosis of autism on the Autism Diagnostic Interview–Revised algorithm. Using the Gwet's alternative chance-corrected statistic, the agreement between the Chinese diagnosis and the Autism Diagnostic Observation Schedule diagnosis was very good (AC1 = 0.94, p < 0.005, 95% confidence interval (0.86, 1.00)), so was the agreement between the Chinese diagnosis and the Autism Diagnostic Interview–Revised (AC1 = 0.91, p < 0.005, 95% confidence interval (0.81, 1.00)). The agreement between the Autism Diagnostic Observation Schedule and the Autism Diagnostic Interview–Revised was lower but still very good (AC1 = 0.83, p < 0.005).

Introduction

Autism Spectrum Conditions (ASC) are neurodevelopmental disorders, characterised by impairments in social interaction and communication, and the presence of repetitive and stereotyped behaviours, interests and activities (WHO, 1993). Defined by the *International Classification of Disease, 10th revision* (WHO, 1993), the most severe subtype of ASC is Childhood Autism. The most recent *Diagnostic and Statistical Manual of Mental Disorders, 5th edition* (DSM-V) adopted a single diagnosis of ASC to replace separate diagnostic subtypes (Association Psychiatric Association, 2013).

The most recent prevalence estimate of ASC in the US was 147 per 10,000 in 2014 (Centers for Disease Control and Prevention, 2014). In the East, the prevalence of ASC in South Korea was 264 per 10,000 in 2011, suggesting Eastern estimates may be higher than those from the West (Kim et al., 2011). A recent review of prevalence studies of ASC in mainland China suggested the prevalence of Autistic Disorder was around 12 per 10,000(Sun et al., 2013). It is difficult to compare those estimates directly due to various reasons. One reason is the different methods for case identification between Western and Chinese studies. Recent prevalence studies in the West adopted a two-phase procedure for case confirmation: screening in a large population, and further diagnostic assessment in a proportion of screened population. In most Western studies, the *Autism Diagnostic Observation Schedule* (ADOS; (Lord, Rutter, DiLavore, & Risi, 2001) and the *Autism Diagnostic Interview-Revised* (ADI-R; (Rutter, LeCouteur, & Lord, 2003) have been used in the diagnostic assessment. This diagnostic approach has been referred as research quality, gold standard assessment method for the diagnosis of ASC (Levy, Mandell, & Schultz, 2009). Both instruments have not been adopted in epidemiological study in mainland China (Tang, Guo, Rice, Wang, & Cubells, 2010). In previous Chinese studies (Sun & Allison,

2009), the diagnosis depended on clinical judgement based on *the Chinese Classification of Mental Disorders, the 3rd editi*on (Chinese Society of Psychiatry, 2001), ICD-10 or *the Diagnostic and Statistical Manual Fourth Edition* (American Psychiatric Association, 1994). The CCMD-3 is only used in mainland China (Appendix 1). The diagnostic process for autism in mainland China has been relatively short without multidisciplinary assessments (Sun, Allison, Auyeung, Baron-Cohen, & Brayne, 2012). The terminology for the diagnosis of autism in mainland China was "Autism", "Autistic Disorder/Childhood Autism" or "Autism Tendency" (Sun, Allison, Auyeung, Baron-Cohen et al., 2012). So far, whether the diagnosis of ASC or autism made by Chinese clinicians is comparable to the diagnosis made in developed countries is still unknown (W. Mandy, Charman, Puura, & Skuse, 2014). Another reason is that application of Western developed instruments to Eastern culture is not without difficulty (Chuthapisith, Taycharpipranai, Ruangdaraganon, Warrington, & Skuse, 2012). A further question, whether the ASC presents differently in different cultures has been discussed more frequently nowadays (W. Mandy et al., 2014; W. P. Mandy, Charman, & Skuse, 2011). Literatures on Autism Quotient (AQ) in different cultures provided evidences of similarity of autistic traits across cultures (Baron-Cohen, Wheelwright, Skinner, Martin, & Clubley, 2001; Hoekstra, Bartels, Cath, & Boomsma, 2008; Wakabayashi, Baron-Cohen, Wheelwright, & Tojo, 2006; Wakabayashi, Tojo, Baron-Cohen, & Wheelwright, 2004). However, a number of studies also found possible different autistic features between Asian and UK samples (Hoekstra et al., 2011; Wakabayashi et al., 2007). It would be valuable to know how these standardised instruments work in Chinese population. Thus, this study was to verify the existing diagnosis of autism in mainland China and to explore whether the existing cases of autism are mainly children on the more severe end of the autism spectrum, such as Autistic Disorder. A pilot evaluation of the existing diagnosis of

autism in mainland China was conducted using standardised diagnostic instruments, the ADOS and the ADI-R.

Method

Participants and procedures

Ethical approval for this research was sought from the Ethics committee at university. Fifty children who had a diagnosis of autism made by Chinese clinicians were randomly recruited from the database of Beijing China Disabled Persons' Federation (BCDPF) (n=29) and the Elim Intervention Centre for Chinese with Autism in Qingdao (n=21). BCDPF is a local branch of the China Disabled Persons' Federation (Wikipedia, 2012), which is responsible for the rehabilitation of residents with disabilities in Beijing area. Children who registered in the BCDPF have official records of disability in the healthcare system and can receive allowance from the government. Since the fact that, not all children with an existing diagnosis of autism would have been registered with CDPF, children were also recruited from private intervention centre. This situation may be partly due to that some parents do not want their children to have a record of disability in their files. The Elim centre is one of the most well-known private intervention centres specifically for autism in mainland China. Children who have enrolled in Elim centre for autism may not have records in the CDPF. The records of all the children aged 4 to 11 years old who had a diagnosis of autism in the database the two institutions were obtained. Each child within these two institutions had a unique ID number within its system. A number of 29 children were randomly selected from BCDPF and a number of 21 children were randomly selected from Elim centre. The invitation for participation was sent out to these 50 children and their families by the two institutes. After the confirmation of a copy of the child's diagnosis made by Chinese clinicians, all of the 50 children and their

families were sent the consent for a diagnostic assessment. All of them agreed to participate and provided their consent.

Instruments

A combination of the ADOS (Lord et al., 2001) and the ADI-R (Rutter et al., 2003) were adopted as the assessment instruments. The ADOS is a semi-structured, standardised, play-based observational play and activity assessment of the child, which usually takes about 40 minutes to complete (Lord et al., 2000). The ADOS has been developed to detect the borderline spectrum of ASC and has five comparable models for administration with different individuals according to their chronological age and expressive language level (Aldridge, Gibbs, Schmidhofer, & Williams, 2011; Berument et al., 2005). Regarding coding, there are around 30 behaviours coded and most items are coded from 0 indicating no impairment with respect to the behavioural definition for each item to 3 indicating severe impairment for the individual under evaluation (Le Couteur, Haden, Hammal, & McConachie, 2008). In this study, module 2 was generally used except for when the child was non-verbal or only spoke in single words, in which case module 1 was chosen. For children with fluent language, module 3 was used. There are four domains on the ADOS algorithm: communication (A), reciprocal social interaction (B), imagination/creativity (C), and stereotyped behaviours and restricted interests (D). There are two diagnoses of ADOS including autism (Childhood Autism) and ASC. In this study, module 2 was generally used except for when the child was non-verbal or only spoke in single words, in which case module 1 was chosen. For children with fluent language, module 3 was used. The diagnostic cut-offs for autism and ASC in ADOS are different for each module. For module 1, the cut-off for autism is $A+B \geq 12$, with $A \geq 4$ and $B \geq 7$. The cut-off for ASC is $A+B \geq 7$, with $A \geq 2$ and $B \geq 4$. For module 2, the cut-off for autism is $A+B \geq 12$, with $A \geq 5$ and $B \geq 6$. The cut-off for ASC is $A+B \geq 8$, with $A \geq 3$ and $B \geq 4$. For

module 3, the cut-off for autism is A+B≥12, with A≥3and B≥6. The cut-off for ASC is A+B≥7, with A≥2 and B≥4.

The ADI-R is a standardised, face-to-face semi-structured diagnostic protocol for interviews with parents or caregivers of individuals referred for a possible ASC. The coding of the ADI-R is similar to that of the ADOS with most items scored from 0 to 3. The diagnosis in the ADI-R only has two categories, autism or not autism. On the ADI-R algorithm, the three domains include reciprocal social interaction (A: cut-off≥10), communication (B1: cut-off≥8 for verbal and B2: cut-off≥7 for non-verbal), and restricted, repetitive and stereotyped patterns behaviour (C: cut-off≥3). In order to meet the ADI-R criteria of autism, the score of the subject needs to be equal to or higher than the cut-offs of all three domains, and the child's development had been concerned before 36 months (D: cut-off≥1) (Moss, Magiati, Charman, & Howlin, 2008). The assessments of the ADOS and the ADI-R were conducted by the first author, who is medically trained and also trained in the administration of the ADOS and the ADI-R. The first author met the research reliability of the two instruments and is an independent trainer of the ADOS. Reliability of the assessments was also checked by consulting with an experienced examiner in Cambridge on a weekly basis. The ADI-R tapes and videos of the ADOS assessments were reviewed twice to ensure their accuracy.

The Raven's Progressive Matrices (RPM) was used as an IQ test for primary school children. The RPM was developed in 1938 which is a commonly used test in clinical neuropsychology for general intellectual abilities (Raven, 1938). The Chinese version of RPS was validated in 1989 and can be applied to individuals from 5 to 75 years old (Li, 1989). The cut-off of a low IQ is below 70, borderline normal IQ is 71-79, normal IQ is 80-129, and extraordinary IQ is 130 or higher. After the

ADOS, the child was given the RPM to complete on his/her own. Each child was given at most 1.5 hours to complete the test.

Statistic analysis

The proportion of children who met the cut-offs on the ADOS and the ADI-R for autism was calculated. The agreement between the existing diagnosis by Chinese clinician, the ADOS and the ADI-R was examined using the Gwet's inter-rater reliability test. Gwet's inter-rater reliability test has been suggested to be less affected by the trait prevalence in the population under consideration. It provides a reliable estimate of agreement when the sum of the marginal classification probabilities is very different from 1 (Gwet, 2002). Gwet's agreement test uses an alternative chance-corrected statistic to the kappa statistic (Cohen, 1968), which is more robust (Gwet, 2001). The new chance-agreement probability, $e(\gamma)$, is calculated using equation (1) at footnote. The approximate chance that a diagnostic method (A or B) classifies a child into category 1 (autism) is calculated by equation (2) at footnote (Table 1). The alternative Gwet's statistic is referred as the AC1-statistic is generated by equation (3) at footnote with $p=(A+D)/N$ (Gwet, 2002).

The interpretation of the Gwet's agreement is the same as the Cohen's kappa as follows (Altman, 1991): 1) Poor: less than 0.20; 2) Fair: 0.21 to 0.40; 3) Moderate: 0.41 to 0.60; 4) Good: 0.61 to 0.80; 5) Very good: 0.81-1.00.

In addition, the sensitivity and the positive predictive values (PPV) of the ADOS and the ADI-R when using clinical diagnosis as reference were calculated. Due to the study design, no children without an existing diagnosis of autism were included in this sample. The examiner was not blind to the clinical status of the children participated in this study. Thus, the specificity and the negative predictive values (NPV) of both instruments were not calculated.

Results

All the 50 children and their families invited participated in this study. In total, 50 assessments of ADOS and ADI-R were conducted. The participation rate was 100%. Within 50 ADOS assessments, 18 assessments (36%) used Module 1, 23 (46%) used Module 2 and 9 (18%) used Module 3. The mean age of the children was 6.3 years (SD=1.6) with 44 boys (88%) and 6 girls (12%). The IQ tests were completed by 25 children (50%), the mean IQ of whom was 97.3 (SD: 14.56). When used the diagnostic category ASC of the ADOS as the final diagnosis, all children within this sample met this cut-off. When used the autism category on the ADOS and the ADI-R, most children (48 out of 50) had been given a diagnosis of autism by Chinese clinicians. Two had an existing diagnosis of High-functioning Autism or Asperger Syndrome. The mean scores on domains of the ADOS and the ADI-R was given in Table 1. After the assessment, most children met diagnostic level of both instruments. Only a small number of children failed, whose results are listed in Table 24. The assessment results of all children are provided in Appendix 2.

[insert Table 1, Table 2, Table 3 and Table 4 here]

Using the Gwet's alternative chance-corrected statistic, the agreement between the Chinese diagnosis and the ADOS diagnosis was very good (AC1=0.94, $p<0.005$, 95% CI (0.86, 1.00)). So was the agreement between the Chinese diagnosis and the ADI-R (AC1=0.91, $p<0.005$, 95%CI (0.81, 1.00)). The agreement between the ADOS and the ADI-R was lower but still very good (AC1=0.83, $p<0.005$).

When using clinical diagnosis as reference, the sensitivity of the ADOS was 97.9% (95%CI: 88.9%, 99.9%), while the sensitivity of the ADI-R was 91.7% (95%CI: 80.0%, 97.7%). The PPV of the ADOS was 95.9% (95%CI: 86.0%, 99.5%), and the PPV of the ADI-R was 100% (95%CI: 92.0%, 100.0%).

Discussion

Children with an existing diagnosis of autism made by Chinese clinicians were assessed using the standardised diagnostic instruments, the ADOS and ADI-R. Of 50 children, 47 children were given a diagnosis of autism by the ADOS and 44 were given a diagnosis of classic autism (Autistic Disorder) by the ADI-R. This study verified previous suggestion that most of the children that have been diagnosed as autism in mainland China also met the Western diagnostic methodology and most of them were children with classic autism (Autistic Disorder). The agreement between the ADOS, ADI-R and the original diagnosis was very good.

The results from this small pilot study should be interpreted with caution. The sample was opportunistic and the sample size was small. However, the sample is recruited from the children who already had a diagnosis of autism from both public supported and private intervention settings. The participation rate of this study is 100% which ensured the, representativeness of this sample to the children in intervention settings in general population. However, the purpose is not to understand ASC from the general population but to understand which subtypes within ASC the existing diagnosis of autism in mainland China would be categorized into. Thus, the sample was randomly selected from the general population records of Beijing area and one of the most-well-known intervention centres for autism. It is possible that other subtypes within the autism spectrum may not have been well identified in mainland China (Sun, Allison, Auyeung, Matthews et al., 2012). In order to improve the representative of the sample, the sources of cases included both health authority and intervention settings. Further study should explore a complete random selected sample with a larger sample size and more children having varied diagnosis on the autism spectrum. Another limitation was that all ADOS and ADI-R assessments were conducted by a single researcher in a relatively short time. The researcher was not blind to the existing diagnostic status of the participants. The researcher was a trained,

research-reliable examiner of the two instruments and had technical support from senior examiners at Cambridge during the assessment phase. Future research should employ an assessment team to ensure that the protocol includes regular consensus-coding meetings to establish reliability throughout the assessment phase through regular supervision and discussion. There was a time lag between the Chinese diagnosis and the assessment using the ADI-R. As the timing of the first manifestations of autistic features is important in the assessment of ADI-R, the results may be influenced by some difficulties in remembering the timing of developmental milestones. However, as the ADI-R focuses on the meaningful time periods, with the help from the examiner, the time lag should not have significant impact on the results.

Previous literatures on the healthcare of ASC in mainland China suggested that the concept of ASC has not been fully established in clinical settings (Sun, Allison, Auyeung, Baron-Cohen et al., 2012; Sun, Allison, Auyeung, Matthews et al., 2012). The findings from this small pilot study provide evidence that the clinical diagnoses of autism in mainland China seem to be valid according to the ADOS and the ADI-R. Most of the children that have been diagnosed as autism in this sample are cases of Autism Disorder. The children that have been diagnosed as having Asperger Syndrome or high functioning autism are also given a diagnosis of autism by the ADOS but not the ADI-R. The agreement between the clinical diagnosis and the two instruments was better than the agreement between the two instruments. This finding also suggested the possible conflict between the ADOS and the ADI-R, which was in line with previous studies. It was reported the agreement between the ADOS and the ADI-R was approximately 75% in Western population (Mazefsky & Oswald, 2006). These findings suggest that the profile of children with autism in mainland China share similarities with children with autism in the West. However, there may be some disagreement between the ADOS and the ADI-R which has been reported before (Le

Couteur et al., 2008; Leyfer, Tager-Flusberg, Dowd, Tomblin, & Folstein, 2008). As mentioned before, the difference in the methods of case identification between mainland China and developed countries was one of the obstacles for the comparison of study results and research development. This study also provides evidence that the ADOS and the ADI-R can be applied to the Chinese population for case detection of autism, which lays important groundwork for further adoption of standardised diagnostic instruments for case identification to improve the capacity of autism research in mainland China.

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Table 1 Mean assessment scores on domains of the ADOS and the ADI-R

Instrument	Domain	Mean score	Standard deviation
ADOS	Communication (A)	5.7	1.95
	Reciprocal Social Interaction (B)	11.2	2.61
	A+B	16.8	4.04
	Imagination (C)	1.8	1.47
	Stereotyped Behaviours and Restricted Interests (D)	2.2	1.88
ADI-R	Reciprocal Social Interaction (A)	21.2	5.68
	Communication (B-verbal)	15.3	4.12
	Communication (B-nonverbal)	11.5	1.87
	Restricted, Repetitive, and stereotyped patterns of Behaviour (C)	6.2	2.76
	Abnormality of Development Evident at or Before 36 Months	3.9	1.33

Table 2 Results of diagnosis by Chinese clinicians and the ADOS

Diagnostic method B:	Diagnostic method A: ADOS		
Chinese clinicians	1 (Autism)	2 (Non-autism)	Total
1 (Autism)	47 (A)	1 (B)	48 (B1=A+B)
2 (Non-autism)	2 (C)	0 (D)	2 (B2=C+D)
Total	49 (A1=A+C)	1 (A2=B+D)	50 (N)

Table 3 Results of diagnosis by Chinese clinicians and the ADI-R

Diagnostic method B:	Diagnostic method A: ADI-R		
Chinese clinicians	1 (Autism)	2 (Non-autism)	Total
1 (Autism)	44	4	48
2 (Non-autism)	0	2	2
Total	44	6	50

Table 4 Results of diagnosis by the ADOS and the ADI-R

Diagnostic method B:	Diagnostic method A: ADOS		
ADI-R	1 (Autism)	2 (Non-autism)	Total
1 (Autism)	42	2	44
2 (Non-autism)	5	1	6
Total	47	3	50