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Early-Onset Schizophrenia: Exploring the Contribution of the Thought Disorder Index to Clinical Assessment

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Abstract

Background: Differentiating diagnostically between schizophrenia and emotional and personality disorders with psychotic or psychotic-like symptoms is a challenging task. It is especially difficult when working with adolescent patients, because their symptoms tend to manifest at lower levels as compared with adult patients. Thought disorder is a core symptom of schizophrenia, and the Rorschach Inkblot Method is widely used for the assessment of formal thought disorder.

Objective: In this study, which is situated within ongoing clinical practice, we investigated whether the Rorschach test is helpful for assessing early-onset schizophrenia due to its ability to detect thought disorder. We also wanted to examine whether the Thought Disorder Index (TDI) is superior to the Comprehensive System (CS) for differentiating between patients with early-onset schizophrenia and non-psychotic patients experiencing auditory and visual hallucinations. An additional aim was to examine whether the TDI correlated with the Positive and Negative Syndrome Scale (PANSS).

Methods: Twenty-three subjects between the ages of 12 and 18 years were examined with the use of the Rorschach test, and the protocols were scored according to both the TDI and the CS. All subjects were also assessed with the Positive and Negative Syndrome Scale. The sample included 14 subjects who fulfilled the criteria for schizophrenia and 9 subjects who were experiencing hallucinations that emanated from severe emotional and relational problems but who had different non-psychotic disorders.

Results: Although the two groups could not be distinguished with regard to their total scores for thought disorder, the identification of specific thought disorder types proved useful for differential diagnosis. Verbalizations that were categorized by the TDI as "absurd responses," "fluidity," "contamination," "autistic logic," and "word-finding difficulty" were only given by patients who had been diagnosed with schizophrenia. When patients' responses were scored with the use of the CS, the "contamination" score was the only one found to be specific to schizophrenia.

Conclusions: Although the sample size limits the conclusions that can be drawn, the results indicate that the TDI may be superior to the CS for the identification of thought disorder specific to—but not always present in—adolescents with schizophrenia. In other words, the absence of severe thought disorder is not synonymous with the absence of severe psychopathology, but the presence of the most severe thought disorder types (i.e., "absurd responses," "fluidity," "incoherence," "contamination," and "autistic logic") seems to be a strong indicator of schizophrenic psychopathology.

Keywords: Early onset schizophrenia; thought disorders; Rorschach; TDI

Introduction

Schizophrenia is an invalidating psychiatric disorder, and early detection and treatment are crucial to an affected patient's prognosis (1). However, the

assessment of early-onset schizophrenia is a challenging and time-consuming task, which is why assessment instruments that are characterized by high sensitivity and specificity to schizophrenia symptoms are such important tools for the diagnostic process (2).

Schizophrenia in children and adolescents is usually associated with an insidious onset and with premorbid social, motor, and language impairments (3). A particularly challenging task is distinguishing between psychotic experiences in children and adolescents with early-onset schizophrenia and similar experiences in patients with other psychiatric disorders. Differential diagnosis with regard to schizophrenia and borderline personality disorder is particularly difficult due to the frequency of psychotic or psychotic-like symptoms in patients with borderline personality disorder when they are under stress (4).

Rating scales like the Present State Examination (5) and the Positive and Negative Syndrome Scale (PANSS) (6) are currently regarded as the gold standard for the assessment of psychotic symptoms in children with schizophrenia. These diagnostic interviews focus on patient descriptions of subjective phenomena like delusions and hallucinations. However, they are not designed to elicit formal thought disorder, which may often go unnoticed due to the structured dialogue offered by the interviews. Thought disorder is regarded as an endophenotypic marker of schizophrenia as a result of Bleuler's identification of the "loosening of associations" in these patients, and it is considered a core symptom of schizophrenia (7,8). The use of the Rorschach Inkblot Method (9) often reveals thought disorder: the patient is required to organize the unstructured stimuli of the inkblots and to verbalize what he or she sees to the clinician, thereby explicating the characteristics of his or her perception and thinking. Formal thought disorder can be observed objectively by the clinician, whereas symptoms such as hallucinations must be self-reported (8).

Assessment of thought disorder using the Rorschach approach

The Comprehensive System (CS) (9) is the most commonly used Rorschach approach. A recent international study found that approximately 96% of clinicians administer, score, and interpret the Rorschach tests using the CS (10). The special scores of the CS consist of four major categories of thought disorder that are scored on two levels of severity (Table 1) and then converted into a weighted sum of all special scores (WgtSum6). Exner's special scores are based on the work of Rapaport, who through the introduction of a nuanced system of thought disorder categories made thought disorder scoring a central aspect of the Rorschach test (11). Exner picked and synthesized the most reliable and valid variables from existing Rorschach systems and created an evidence based comprehensive Rorschach

scoring system. The virtue of Exner's scoring system is its simplicity (11,12).

TABLE 1. Comprehensive System (CS): Special scores and severity levels

Special score	Severity level
Deviant verbalization	1
Incongruous combination	
Deviant response	
Fabulized combination	
Deviant verbalization	2
Incongruous combination	
Deviant response	
Fabulized combination	
ALOG (autistic logic)	
Contamination	

The WgtdSum6 is calculated by using this formula: Weighted Sum6 = (1)xDV + (2)xDV2 + (2)xINCOM + (4)xINCOM2 + (3)xDR + (6)xDR2 + (4)xFABCOM + (7)xFABCOM2 + (5)xALOG + (7)xCONTAM

However, simplicity may come at the expense of sensitivity. According to Kleiger, Exner either condensed or left out discrete types of pathological verbalizations of particular diagnostic significance (12). In the clinic, Rorschach testing involving the CS often fails to distinguish between the different qualitative aspects of disordered thinking in patients with schizophrenia and other conditions (e.g., borderline pathology). Another and more nuanced approach to scoring thought disorder that is also based on Rapaport's work is the Thought Disorder Index (TDI) (12). The TDI comprises 23 different categories of thought disorder that are classified according to four levels of severity (0.25, 0.50, 0.75 and 1.0). The TDI is calculated on the basis of the total amount of thought disorder (Table 2).

The TDI has proved useful for identifying subtle differences in thought disorder and for differentiating between different types of psychosis (13,14). Originally, the TDI was developed as a research instrument. With its larger number of categories of thought disorder, learning to use the TDI is more difficult, and it is more difficult to achieve high inter-rater reliability. This may be the reason that the TDI has made few inroads into clinical assessment practice.

Validity of the TDI for assessing thought disorder during childhood and adolescence

Arboleda and Holzman (15) studied children with psychotic disorders, at-risk children, children with behavioral disorders, and normal control children. (The group with psychotic disorders was very heterogenic, however.) Significantly higher TDI

TABLE 2. Thought Disorder Index	(TDI): Thought disord	ler categories and	l severity level
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Severity levels	0.25	0.50	0.75	1.0
Thought disorder categories	Inappropriate distance Flippancy Vagueness Peculiar verbalizations Word-finding difficulty Clangs Perseveration Incongruous combinations Relationship verbalization Idiosyncratic symbolism	Queer responses Confusion Looseness Fabulized combinations, (impossible or bizarre) Playful confabulations Fragmentation	Fluidity Absurd responses Confabulations Autistic logic	Contaminations Incoherence Neologisms

The total TDI is calculated by using this formula:

 $TDI = (\sum [0.25 (A) + 0.50 (B) + 0.75 (C) + 1.0 (D)] \times 100) / Total R$

A = number of responses at the 0.25 level

B = number of responses at the 0.50 level

C = number of responses at the 0.75 level

D = number of responses at the 1.0 level

R = total number of Rorschach responses

scores were reported in the children with psychotic disorders and the at-risk children. The control group had total TDI scores that ranged from 5.34 to 9.30, whereas the psychotic and at-risk groups often had TDI total scores of more than 16. Furthermore, they had more pathological responses at severity levels of 0.75 or 1.0 that involved categories such as "fluidity," "confabulation," "autistic logic," "incoherence," and "neologisms."

With the use of the TDI, Makowski and colleagues (16) examined whether thought disorder in patients with early-onset schizophrenia is similar to that seen in patients with adult-onset schizophrenia. Their sample comprised 95 adolescents between the ages of 12 and 18 years. They compared 20 patients who had been diagnosed with schizophrenia with 46 psychiatric patients with major depression (with and without psychotic features) and 29 patients with non-life-threatening somatic illnesses. researchers found elevated levels of thought disorder in all patients with psychiatric illnesses. The patients in the schizophrenic group had the largest amount of thought disorder, and the qualitative features of the disordered thinking observed in adolescents with schizophrenia were distinct from the disordered thinking seen in the adolescents with psychotic depression. The types of thought disorder found in the schizophrenic group resembled those found in adults with schizophrenia and were characterized by "idiosyncratic word usage, illogical reasoning, perceptual confusion, loss of realistic attunement to the task, and loosely related ideas" (16). In the patients schizophrenic group, 12 antipsychotic medication and had lower total TDI scores than the unmedicated part of the group (16). This is in line with the dampening effect on schizophrenic thought disorder found by Spohn when he compared a group of adult patients with

schizophrenia whose medication had been discontinued with a group of patients with schizophrenia who were still receiving medication (17). Antipsychotic medication reduced the manifestation of more severe thought disturbance but had little effect on milder thought disorder (17). Twenty-five percent of the patients in the schizophrenic group did not have responses at the 0.50 level, and 45% did not have responses at the 0.75 level. Thus, some of the patients with schizophrenia only had minimal thought disorder. However, it is not clear to what extent medication accounted for those results.

Nielsen (18) used the TDI to analyze the prevalence of formal thought disorder in first-time hospitalized psychiatric patients between the ages of 18 and 38 years. The sample consisted of 146 patients: 48 patients were diagnosed schizophrenia, 48 were diagnosed with schizotypal disorder, and 50 had other diagnoses (12 of which were borderline personality disorder). Due to their rare occurrence, the following thought disorder categories were excluded: "flippancy," "word-finding "clangs," "confusion," "looseness," difficulty," "playful confabulation," "fragmentation," "fluidity," "contamination," "incoherence," and "neologisms." The remaining scores were collapsed into two categories according to severity: "idiosyncratic speech" and "autistic logic." Nielsen found that the 12 patients who had been diagnosed with borderline personality disorder had overall TDI scores of 17.38 and levels of severe thought disorder of 11.0; these results were similar to those of the schizophrenic group, which had scores of 16.8 and 8.1, respectively

Another study also suggested that schizophrenia and borderline personality disorder cannot be distinguished on the basis of the overall amount of thought disorder (19). By comparing 51 patients with

borderline personality disorder and 30 patients with schizophrenic disorder, Edell found that the two groups did not differ significantly with regard to overall TDI scores and were thus indistinguishable on that measure (19). The mean TDI score for the schizophrenic group was 17.9 (range, 0.0 to 83.8), whereas the mean TDI score for the borderline group was 12.3 (range, 1.5 to 78.0). However, the most disorganized responses (1.0 level) were largely restricted to the schizophrenic group (19). The "contamination" category was only chosen for five patients with schizophrenia and for 1 patient with mixed borderline and schizotypal characteristics.

The TDI is considered a valid and reliable coding system for the assessment of formal thought disorder, and its use has yielded significant contributions to the clinical assessment and diagnosis of early-onset schizophrenia. Groups of patients on the schizophrenia spectrum have more thought disorder overall in addition to thought disorder that falls into specific categories. To our knowledge, the TDI has never been used to assess thought disorder in a Danish child and adolescent sample, which makes this study the first to do so. The present study has the overall aim of exploring how the use of the Rorschach approach—and the coding of thought disorder using the TDI and the CS in particular may contribute to the clinical assessment of earlyonset schizophrenia. We also aim to examine whether the TDI is superior to the CS for the identification of formal thought Specifically, we will test the following hypotheses:

- 1) Patients who fulfill the criteria for a diagnosis of schizophrenia will a) have higher total amounts of thought disorder; b) have more severe thought disorder; and c) have specific types of thought disorder (e.g., "fluidity," "confabulation," "autistic logic," "incoherence," "contamination," "neologisms").
- Patients' TDI scores will correlate with their PANSS scores.

Methods

Subjects

The sample was comprised of 23 adolescents (9 males, 14 females) between the ages of 12 and 18 years (mean, 16.4 years). Fourteen patients met ICD-10 criteria for schizophrenia (8 males, 6 females). Of the nine remaining patients (1 male, 8 females), five had been diagnosed with other childhood emotional disorders (F93.8), two had unspecified behavioral and emotional disorders with onset usually occurring during childhood and adolescence (F98.9), one had mixed personality disorder (F61.0), and one had anxious (avoidant) personality disorder (F60.6). Subjects were recruited from the Region of Southern

Denmark at the Child and Adolescent Psychiatric University Clinic in Odense from 2012 to 2014. All subjects were referred to the clinic because of psychotic or psychotic-like symptoms, such as visual and auditory hallucinations and paranoid ideation. Patients with mental retardation (i.e., intelligence quotient <70) and patients with drug-related psychosis, organic psychosis, or neuropsychiatric disorders were excluded from the study.

When referred for assessment, five of the 14 patients from the schizophrenia group and six of the nine patients from the mixed group were prescribed antipsychotic medication. The majority of the patients had been seen by psychiatrists in other psychiatric units in the Region of Southern Denmark before their referral to the University Clinic in Odense.

Procedures

The diagnoses followed the criteria of the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, and they were made by an experienced child and adolescent psychiatrist (AS). The diagnoses were based on the admission clinical interviews with the patients and their parents and on clinical interviews that involved the PANSS (6). All 23 patients were tested with the Rorschach test, which formed part of the standard assessment routine. The study was situated within the ongoing clinical practice of the University Clinic. Thus, for cases in which the differential diagnoses were particularly challenging, the CS formed part of the diagnostic assessment. The Rorschach test was part of the diagnostic assessment of seven patients from the schizophrenia group and six patients from the mixed group.

Patients who had not been assessed cognitively before their referral were tested with the Wechsler Intelligence Scale for Children, Fourth Edition (20), or the Wechsler Adult Intelligence Scale, Fourth Edition (21), depending on their ages. The mean total intelligence quotient was 90 (range, 74 to 109) in the schizophrenic group and 88.2 (range, 82 to 98) in the mixed group.

Thought disorder was assessed with the use of both the CS and the TDI. The Rorschach tests were administered and transcribed verbatim by the first author (DBA), who also did the initial interpretation according to the CS and the TDI. The 23 Rorschach protocols were further interpreted according to the CS by a senior colleague and according to the TDI by one of the co-authors (DLV), who is an experienced child psychologist; both were blinded to the diagnostic status of the patients. The ratings made by the raters, who had been blinded to the patients' diagnoses, were used in the final analysis. DBA and DLV were trained and supervised in the

use of the TDI on five TDI protocols not included in the study by one of the co-authors (MV), who is an experienced child psychologist. Inter-rater reliability (R=0.9076) was calculated for five of the project protocols.

Measures

The PANSS is a rating scale that measures positive and negative psychotic symptoms and general psychopathology. It consists of three scales: a positive scale, a negative scale, and a general psychopathology scale. Inter-rater reliability is reported to range between 0.83 and 0.87, and criterion-related validity is reported to be 0.77 as compared with similar rating scales (6).

The TDI is reported to have inter-rater reliability that ranges from 0.74 to 0.93 across studies (13). The validity of the instrument is described earlier in this article.

The CS has been demonstrated to have inter-rater reliability that ranges between 0.82 and 0.97 (22). Severe thought disturbance (Critical Special Scores, Severe) are significantly related to bipolar disorder, high risk for psychosis, and psychosis (r = 0.35) (10).

Statistics

The following statistical tests were used: the chi-squared test (Fisher's exact test), independent sample T-tests (parametric), and the Mann-Whitney U-test (non-parametric) as per data type and distribution for the descriptive analyses of demographic data and for the comparison of the outcomes of the two groups. Pearson's correlation coefficient (r) was used for correlation tests. A P value of .05 was considered to be statistically significant. All analyses were conducted with the use of SPSS software version 21.0.

TABLE 3. Descriptive statistics

Total N=23	Schizophrenia group ¹ (N=14)		Mixed group ² (N=9)		<i>p</i> -value
Male gender – number (%)	8 (57.1)	-	1 (11.1)	-	p=0.04
Age (mean ± SD, range)	16.3 ± 1.7	12-18	16.0 ± 1.1	15-18	Ns
IQ³ (mean ± SD, range)	90 ± 10.8	74-109	88 ± 6.4	80-98	Ns
PANSS (mean ± SD, range)	73.3 ± 18.5	40-101	43.7 ± 6.3	36-53	<i>p</i> <.001
TDI_score (mean ± SD, range)	31.1 ± 26.8	3-96.4	18.8 ± 13.8	5.4-41.7	Ns
WgtSum6 (mean ± SD, range)	35.6 ± 30.9	3-109	14.1 ± 8.3	2-33	p=0.062

Note. PANSS=Positive and Negative Syndrome Scale, TDI=Thought Disorder Index, WgtSum6=Weighted sum for six special scores

¹ The schizophrenia group = Schizophrenia (F20.x)

²The mixed group = 93.8: Childhood emotional disorders (n=5); 98.9: Unspecified behavioural and emotional disorders (n=2); 61.0 and 60.6: Personality disorders (n=2)

³ IQ was assessed using WISC-IV and WAIS-IV

TABLE 4. Correlations

		PANSS1	PANSS2	PANSS3	TDI_score	PTI_score	WgtSum6
PANSS1	Pearson Correlation Sig. (2-tailed) N						
PANSS2	Pearson Correlation Sig. (2-tailed) N	.804** .000 23					
PANSS3	Pearson Correlation Sig. (2-tailed) N	.726** .000 23	.848** .000 23				
TDI_score	Pearson Correlation Sig. (2-tailed) N	.267 .218 23	.286 .186 23	.330 .124 23			
PTI_score	Pearson Correlation Sig. (2-tailed) N	.238 .275 23	005 .981 23	.211 .334 23	.589** .003 23		
WgtSum6	Pearson Correlation Sig. (2-tailed) N	.335 .118 23	.351 .100 23	.536** .008 23	.804** .000 23	.633** .001 23	

Note. ** Correlation is significant at the 0.01 level (2-tailed)

WgtSum6=Weighted sum for six special scores, TDI=Thought Disorder Index, PANSS=Positive and Negative Syndrome Scale, PANSS1= Positive syndrome scale, PANSS2= Negative Syndrome scale, PANSS3= General psychopathology scale

Results

The two groups did not differ significantly with regard to age or intelligence level, but the mixed group had a large majority of girls, whereas the group with schizophrenia was 57.1% boys; this represented significantly different gender proportions in the two groups per Fisher's exact test (p = .04). The total TDI discriminate scores did not between schizophrenic group and the mixed group (schizophrenia group, 31.1± 26.8; mixed group, 18.8 \pm 13.8; p = .31). The WgtSum6 was also not able to discriminate between the groups (schizophrenia group, 35.6 ± 30.9 ; mixed group, 14.1 ± 8.3 ; p = .062) (Table 3).

The total amount of thought disorder measured with the CS correlated with the PANSS general psychopathology score, whereas the total TDI score did not. There were no other correlations between the PANSS measures and the WgtSum6 or the TDI. The measure of the total amount of thought disorder as measured by Exner's CS system, the WgtSum6, and the total TDI score were all correlated (Table 4).

Most pathological responses (0.75 and 1.0) were largely restricted to being given by patients with schizophrenia (Table 5). However, six patients from

the schizophrenic group had no pathological responses, which means that no significant differences were found between the groups for these overall measures. This seems to be a result of the small sample size and thus a problem of power. However, specific types of severe thought disorder were restricted to the schizophrenic group: verbalizations that were categorized by the TDI as "absurd responses," "fluidity," "incoherence," "contamination," and "autistic logic" were only given by patients in this group.

In addition, the milder thought disorder represented by "word-finding difficulty" was only seen in the patients from the schizophrenic group. One patient from the mixed group gave responses that were scored as "confabulation" and "neologism." When the responses were scored using Exner's special scores, "contamination" was the only special score found to be specific to the group with schizophrenia.

TABLE 5. TDI level 0.75 and 1.0 scores

	Schizophrenia Group ¹	Mixed Group ²
≥ 1 level 0.75 in TDI	7	1
≥ 1 level 1.0 in TDI	3	1
No level 0.75 or 1.0 in TDI	6	8
<i>p</i> -value = 0.098		

Note. ¹The schizophrenia group = Schizophrenia (F20.x)

²The mixed group 0 93.8: Childhood emotional disorder 8n=5);
98.9: Unspecified behavioural and emotional disorders (n=2);
61.0 and 60.6: Personality disorders (n=2)

Discussion

We expected that the use of the Rorschach test would prove helpful for the clinical assessment of early-onset schizophrenia, and we expected that the TDI system would be superior for the identification of more types of thought disorder as compared with the CS. More specifically, we predicted that patients who had been diagnosed with schizophrenia would have a higher total amount of thought disorder and more severe thought disorder as compared with patients from the mixed group. Moreover, we expected that specific types of severe thought disorder (e.g., "fluidity," "confabulation," "autistic logic," "incoherence," "contamination," "neologisms") would be evident in patients with schizophrenia but not in patients from the mixed group. We found that patients with schizophrenia had higher total amounts of thought disorder; however, the difference between the groups was not significant. The most severe types of thought disorder identified by the TDI (i.e., "absurd responses," "fluidity," "incoherence," "contamination," and "autistic logic") were specific to patients with schizophrenia, which is in line with results from similar studies. A correlation between the TDI and the PANSS positive syndrome scale was expected, because the PANSS includes conceptual disorganization (among 6 other items). However, such a correlation was not found. One explanation could be that delusions, grandiosity, and hostility which are included in the PANSS positive scale—are rarely seen in patients with early-onset schizophrenia, although they are often found in patients in whom the illness has been present for several years or in whom it had a later age of onset.

In the group of patients with schizophrenia, five of the patients received antipsychotic medication; two of them still gave pathological responses, but none of the medicated patients with schizophrenia were among the 6 patients with the highest overall TDI scores. According to Spohn, antipsychotic medication has a dampening effect on thought

disorder (17). However, two patients from the schizophrenic group who were plagued by psychotic symptoms and who received high scores on the PANSS displayed almost no thought disorder, despite not being medicated. This could be explained by the fact that not all schizophrenic patients have thought disorder, not even during the acute phase of the disease (8,23). Andreasen's research on thought disorder offers an alternative explanation (24,25). Andreasen differentiates formal thought disorder by distinguishing between positive and negative thought disorder. Positive thought disorder is characterized by "incoherence, derailment, tangentiality, illogicality," and negative thought disorder is characterized by "poverty of speech and poverty of content' (25). Negative thought disorder is understood to be state-independent and considered an endophenotypic marker schizophrenia (26); it is predictive of a more invalidating course of illness (27). The CS and the TDI focus mainly on positive thought disorder and thus fail to identify negative thought disorder. However, it seems important to also take negative thought disorder into account during the clinical assessment.

Limitations

The small sample size of this study limits the interpretation of results. The fact that the Rorschach tests were part of the assessment is another limitation of this study. However, only the CS scores were used during the diagnostic process. This could result in an association between Rorschach scoring and diagnosis that is artificially high due to the a priori assumption that severe thought disorder is specific to schizophrenia.

Conclusion

The total amount of thought disorder was highest in the group of patients with schizophrenia. In contrast with the TDI, the WgtSum6 correlated with the PANSS, but neither the WgtSum6 nor the TDI was able to discriminate between the schizophrenic group and the mixed group. The most detailed and nuanced assessment of thought disorder can be found when using the TDI system. Word-finding difficulties and the most severe levels of thoughtdisordered responses (0.75 and 1.0) were largely restricted to—but not always shown by—patients with schizophrenia. In other words, the absence of severe thought disorder does not rule out the possibility that a patient has schizophrenia, but the presence of the most severe thought disorder categories (i.e., "absurd responses," "fluidity," "incoherence," "contamination," and "autistic logic") seems to be a strong indicator of schizophrenic psychopathology. The strength of the TDI is its ability to detect these qualitative nuances of thought disorder, so we therefore argue that the TDI is superior to the CS when using the Rorschach test for the clinical assessment of early-onset schizophrenia. Our findings suggest that specific types of thought disorder may be specific to schizophrenia. If these findings are replicated by larger studies, there are implications for other assessments and for the subtyping of schizophrenia. In addition, such findings may help to define the underlying mechanisms of the disorder itself.

To draw more definitive conclusions about the individual strengths and limitations of the CS and the TDI for the assessment of schizophrenia and of a possible combination of these scoring systems, a much larger study is necessary.

Ethics

The data presented in this article were collected as part of the standard clinical assessment of patients at the Child and Adolescent Psychiatric University Clinic in Odense. Data have been anonymized, and there are no ethical issues associated with this project. The project has been reported to the Danish Data Protection Agency. No ethical research committee approval was needed, because the data were obtained during the course of standard clinical care.

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