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Psychopathology: education, evidence and translation. The 23rd Congress of the Italian Society of Psychopathology

Dear Colleagues,

The XXIII Annual Meeting of the Italian Society of Psychopathology will deal psychopathology in its 3 aspects of education, evidence and translation. These 3 topics are inspired by the need to deal with the growing amount of biological, medical, psychological and social knowledge, from the psychopathological viewpoint.

Professional training in psychiatry and mental health has become an increasingly complex challenge, combining professional areas such as physicians or psychologists and others with consolidated practice in mental health. All these must be kept up to date to deal with complex social and economic shifts.

Psychopathology, as a science and discipline that describes and assesses anomalies of subjective psychological experience, has seen levels of interest vary widely over the last century. Teaching and training in psychopathology need a more central place in clinical practice, as sometimes clinical manifestations are only judged superficially, using terms that do not convey the real characteristics of the suffering person.

Young psychiatrists are not satisfied with their formal and practical training in psychopathology, and some even consider it of little clinical utility. This attitude risks leading to excessive simplification of the description and analysis of symptoms, which can 'dilute' psychopathology down to plain psychiatry, hence to mental health, with little more than an ancillary role. The consequence of this tendency is that on the diagnostic level too psychological descriptors get lost in 'nominalistic' categories. Aspects like perplexity, autistic withdrawal, expansivity or impulsivity call for careful analysis of the subjective findings in a person with a mental disorder. The prophecy that then comes true is that hasty, generic descriptions serve no useful purpose.

One of the reasons for contradictions between clinical and neurobiological findings is often inadequate psychopathological evaluation. The clinical variable may not necessarily add up to a 'diagnosis', or a clear nosological entity, but may consist of psychopathological constructs or endophenotypes. The construct of 'aberrant salience' seems a useful definition or psychopathologic model to describe the passage from a high-risk condition on the one hand, to overt psychotic manifestations on the other. This construct is not necessarily associated with a single diagnosis, but may comprise more than one and may link phenomenology to neurobiology of delusion formation.

Evidence-based clinical practice and care must clearly be combined with practice based on experience and values. Social complexity, economic

variables, religious diversity, sexual orientation, and technological innovation are all factors that can influence the interventions and outcomes in mental health. They have therefore to be managed with an approach integrating evidence-based medicine (EBM) and good clinical practice.
The MBE approach can help the clinician in making a decision, but in psychiatry it is harder to meld the different psychological, psychosocial and neurobiological disciplines involved in deciding the treatment. EBM has therefore to work alongside practice based on experience and values, and in this direction psychopathology is a pivotal, irreplaceable tool.
The translation heading refers to how, how much, and where to apply knowledge and evidence responding to the principles of clinical utility, ethical compatibility and – last but not least – the economic aspects and sustainability of the national health service. Scientific societies, universities, mental health departments and all others concerned must establish close contacts with national and local health agencies with a view to selecting the most appropriate interventions, but also to organize controlled trials of innovative interventions in order to verify the utility of the knowledge acquired.
The 23rd SOPSI Congress, 2019, will examine these questions, bearing in mind that training, evidence and translation are all increasingly 'global' issues, that need to be tackled from this viewpoint – critically but open to knowledge and innovation.

I hope you enjoy the Congress

Alessandro Rossi

President of the Italian Society of Psychopathology

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Original article

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Reliability and validity of the Structured Clinical Interview for DSM-5-Clinician Version (SCID-5-CV) Attention Deficit/Hyperactivity Disorder Criteria: preliminary evidence from a sample of 217 Italian adolescents

Summary

Objectives

The aim of this study was to evaluate the psychometric properties of the Italian translation of the Structured Clinical Interview for DSM-5 Clinician Version (SCID-5-CV) Attention Deficit Hyperactivity Disorder (ADHD) module in a community sample of male adolescents.

Methods

217 male adolescents with problem behavior/poor performance at school were administered the SCID-5-CV ADHD module by trained clinicians during school time. Participants received also the Italian translations of the Adult ADHD Self-Report Scale, the Wender Utah Rating Scale, and the Personality Diagnostic Questionnaire-4+ Conduct Disorder Scale. Official school behavior and subject grades were collected.

Results

Our findings suggested that DSM-5 adult ADHD diagnostic criteria may be reliably assessed using the SCID-5-CV ADHD module, at least in a community sample of male adolescents with problem behavior/performance at school. More than 6% of the participants qualified for a DSM-5 ADHD diagnosis; this finding was consistent with the available literature and supported the usefulness of adult ADHD diagnosis. All convergent validity coefficients were large (i.e., ≥ .50). A confirmatory bi-factor model proved to be the best fitting model of the SCID-5-CV ADHD symptom items.

Conclusions

We feel that our data provide first support to the reliability and validity of the SCID-5-CV ADHD module, at least among community male adolescents.

Key words
SCID-5-CV • ADHD • Adolescence • Reliability • Validity

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Attention-deficit hyperactivity disorder (ADHD) is classified in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (5th edition; DSM-5) as a childhood-onset neurodevelopmental disorder, defined by the presence of developmentally inappropriate and impairing levels of inattention, hyperactivity, and impulsivity [1]. Epidemiological studies showed that 5-6% of children meet diagnostic criteria for ADHD [2-4]; although the behavioral manifestations of the disorder are known to vary with subject's gender, the ADHD prevalence has been consistently found to be higher in boys than in girls [5], with a ratio of approximately 2:1 in children and 1.6:1 in adults [1].

Meta-analysis of follow-up studies of children with ADHD found that 15% of children retained the full diagnostic criteria by the age of 25 years, with a further 50% of those meeting subthreshold criteria with persistence of ADHD symptoms causing continued impairments [6]. Recently, this evidence has been consistently replicated in two follow-up studies showing high persistence of ADHD symptoms from childhood to young adulthood, with approximately 80% still meeting criteria for ADHD [7 8]. Moreover, Agnew-Blais and colleagues [9] documented both high persistence rate of childhood-onset ADHD into adulthood and late-onset ADHD.

These considerations lead the DSM-5 task force on ADHD to recognize the importance of diagnosing ADHD in adults, reducing from six to five criteria the number of criteria to meet the diagnostic threshold for ADHD diagnosis [1]. Moreover, an attempt to improve the criteria by including more age-appropriate descriptions has been included in DSM-5 [2].

The Structured Clinical Interview for DSM-5 (SCID-5) is a semi-structured interview for making the major DSM-5 diagnoses [10]; it is administered by a clinician familiar with the DSM-5 classification and diagnostic criteria (American Psychiatric Association 2013). Work on revising the SCID for DSM-5 began in 2012; changes in the DSM-5 criteria sets [1] required the development of many new SCID questions, as well as adjustments to the SCID algorithm. Interestingly, the final version of the Structured Clinical Interview for DSM-5-Clinician Version (SCID-5-CV) [10] included an ADHD section. The ADHD presentation types (i.e., predominantly inattentive, predominantly hyperactive/impulsive, and combined) are included in the SCID-5-CV because they are required to determine the diagnostic code. Recently, the SCID-5-CV has been translated into Italian [11], using a backtranslation approach to ensure both translation accuracy and translation correspondence to the original US version [10]. One intriguing aspect of the SCID-5-CV is that its language and diagnostic coverage make it appropriate for use both with adults (age 18 and over) and adolescents [10]. Although the Diagnostic Interview for ADHD in Adults [12 13] represents the most widely used instrument for assessing ADHD in adults, the availability of an ADHD section in a general semi-structured interview for DSM-5 mental disorders may prove helpful to improve the assessment of ADHD in the transition from adolescence to adulthood and may be useful to increase clinician's awareness towards ADHD in adolescent and adult subjects.

Starting from these considerations, we aimed at testing the basic psychometric properties of the SCID-5-CV ADHD scale in a sample of male adolescents who were attending high school while showing problem behaviour according to their teachers' reports (e.g., poor school behaviour, truancy, high rates of failure, drug abuse, temper tantrums, anger outbursts etc.). We preferred relying on a community sample of adolescents because clinical samples are known to be poorly representative of the population of interest (the so-called Berkson's bias; Berkson, 1946) [14]. Male participants with poor school behaviour/performance were chosen as potential candidates for this study to maximize the likelihood to detect ADHD symptoms.

Methods

Participants

The sample was composed of male adolescents who were attending a vocational school in Northern Italy. Although 219 subjects originally agreed to participate in the study, 2 participants (0.9%) yielded incomplete questionnaires. The small number of participants with missing values prevented from missing value analysis. Participants' mean age was 17.63 years, *SD* = 1.50 years. All participants gave their informed assent to participate in the study; for participants of minor age, the written informed consent form was signed by their parents/legal guardians after detailed description of the study. To prevent linguistic bias, all participants were asked to be native Italian speaker. None of the participants received an incentive for participating in the study. After obtaining approval from the school principal, adolescents were contacted for their initial assent to participate in the study.

All participants were assessed anonymously by trained clinical psychologists during school time; an alphanumeric code was used to allow matching adolescent's graded with his/her corresponding test scores. All measures were administered individually in random order. SCID-5-CV ADHD was administered blind to self-reports and school grade scores. In the present study, time considerations allowed for testing only SCID-5-CV ADHD module.

Measures

Structured Clinician Interview for DSM-5-Clinician Version Attention-deficit/Hyperactivity Disorder Module (SCID-5-CV ADHD) [10]. The SCID-5-CV ADHD is a semi-structured interview for assessing DSM-5 ADHD criteria. It provides at least one question for each DSM-5 ADHD criteria and impairment and exclusion criteria are explicitly tested. The assessment for ADHD begins with two screening questions that are designed to determine whether or not to proceed with the full assessment of the 18 ADHD items; then, questions concerning the nine inattention symptoms and the nine hyperactive/impulsive symptoms are asked [10].

Adult ADHD Self-Report Scale (ASRS-6) [15]. The ASRS is a 6-item Likert-type screening measure designed to assess the presence of ADHD symptoms in adult popu-

lations. It showed adequate psychometric properties [15], also among Italian adolescents [16].

Wender Utah Rating Scale (WURS) [17]. The WURS is a self-report questionnaire designed to retrospectively assess the severity of ADHD symptoms during childhood. Adequate reliability and validity were reported for the WURS; moreover, it significantly predicted the treatment outcome of subjects with adult ADHD, and the WURS, together with the CAARS, showed the best psychometric properties among 14 scales for adult ADHD [18]. The Italian translation of the WURS showed adequate reliability and validity [19].

Personality Diagnostic Questionnaire-4+ (PDQ-4+) Conduct Disorder Scale [20]. The PDQ-4+ is a 99 true/false item self-report questionnaire designed to assess the diagnostic criteria of personality disorders (PDs) included in DSM-IV Axis II. It includes a scale for Conduct Disorder (CD) assessment. In the present study, participants were administered only the PDQ-4+ CD scale; the higher the total score, the higher the number of CD criteria reported by a given participant. The psychometric properties of the Italian translation of the PDQ-4+ were detailed elsewhere [21].

School grades were obtained from official school records.

Data analysis

Cronbach's α was used to evaluate the internal consistency reliability of SCID-5-CV ADHD criteria for the DSM-5 ADHD diagnosis, as well as for the two sub-subscales – namely, Inattention and Hyperactive/Impulsive; Cronbach's α values were expected to be adequate (i.e., > .70) [22].

The convergent validity of the SCID-5-CV ADHD scores (i.e., number of symptoms) was assessed by computing the Pearson r values with two self-report measures of ADHD, namely, the six-item version of the ASRS-6 and the WURS. To provide further evidence of the SCID-5-CV ADHD module validity, we computed correlations (i.e., Pearson r value) between the SCID-5-CV ADHD scores and the number of self-reported conduct disorder symptoms on the PDQ-4+ corresponding scale and with official school grades for participants' behaviour at school and subjects' performance, respectively.

The factor validity of the SCID-5-CV ADHD criteria was assessed using weighted least square mean and variance adjusted (WLSMV) confirmatory factor analysis (CFA); the following models were tested: a) a unidimensional model, with a single latent factor underlying the 18 SCID-5-CV ADHD items; b) a two-factor model, with SCID-5-CV Inattention items defining the Inattentive factor and SCID-5-CV Hyperactivity/Impulsivity items loading on the Hyperactive factor; a second-order ADHD factor was hypothesized to explain the correlation between the two first-order factors; c) a CFA bi-factor model, with all SCID-5-CV ADHD criteria loading on the general factor, and two specific factors corresponding to the Inattentive factor and the Hyperactive factor, respectively. We used several measures to identify model fit, including the χ^2 goodness-of-fit statistic, Browne and Cudeck's [23] root mean square error of approximation (RMSEA), the Tucker-Lewis index (TLI), and comparative fit index (CFI). Following Hu and Bentler's [24] suggestions, TLI and CFI values ≥ .95, RMSEA values close to .06, and SRSMR < .08 were considered as indicating good model fit, whereas TLI and CFI values of .90 and higher, and an RMSEA of .08 and lower were considered as suggestive of an adequate fit. In bi-factor models, observable indicators are thought to measure all the same latent dimension (i.e., the general factor), while specific factors are hypothesized to explain only residual covariation [25]. The reliability of the factors was assessed by computing omega-hierarchical and omega-specific coefficients [25].

Results

Participants were 217 male adolescents who were attending a vocational school in Northern Italy; participants' mean age was 17.63 years (*SD* = 1.50 years). Seventy-three (33.6%) participants previously experienced one or more school failures; 45 (20.7%) adolescents manifested severe behavior problem at school. Descriptive statistics, reliability (Cronbach α) coefficients, and Pearson r values for all measures used in the present study are listed in Table I.

Based on SCID-5-CV ADHD module, 14 (6.5%) participants met DSM-5 criteria for adult ADHD diagnosis. Participants who met DSM-5 criteria for adult ADHD diagnosis received on average significantly lower behavior (7.50 *vs* 8.14, t(215) = -2.28, p < .05, d = -0.31) and school (6.4 *vs* 6.8, t(215) = -2.03, p < .05, d = -0.28) grades than participants who did not meet DSM-5 criteria for ADHD. Previous school failures were not significantly associated with adult ADHD, t(215) = 0.74, p > .40, d = 0.10.

Goodness-of-fit indices for the CFA models of the SCID-5-CV ADHD module are listed in Table II. According to Hu and Bentler [24] the bifactor model was the besting model for SCID-5-CV ADHD symptom criteria. Standardized factor loadings and omega-hierarchical/-specific coefficients for the best-fitting model (i.e., confirmatory bi-factor model of SCID-5-CV ADHD criteria) are listed in Table III. The general omega coefficient value was .88; the general ADHD factor explained 81.0% of the SCID-5-CV ADHD criteria reliable score variance, whereas the Inattentive and Hyperactive/Impulsive specific factors explained 66.5% and 4.6% of the reliable score variance that was independent from the general ADHD factor, respectively.

TABLE I. *Structured clinical interview for DSM-5-Clinician Version Attention-Deficit/Hyperactivity Disorder Scale: descriptive statistics, internal consistency reliability (Cronbach α values are listed on the main diagonal), convergent validity (i.e., Pearson r) coefficients with the adult ADHD Self-Report Scale-6 Item Version and the Wender Utah Rating Scale Total Scores, and external validity (i.e., Pearson r) coefficients with the Personality Diagnostic Questionnaire-4+ Conduct Disorder Scale Score and School Grades (n = 217).*

	M	SD	1	2	3	4	5	6	7	8
1. SCID-5- CVADHD Total Score (number of Symptoms)	6.00	3.67	.85							
2. SCID-5- CVADHD Hyperactivity Score (number of symptoms)	2.64	2.22	--	.82						
3. SCID-5- CVADHD Inattentive Score (number of symptoms)	3.36	2.12	--	**.44**	.73					
4. ASRS-6 Total Score	8.42	4.39	**.55**	**.43**	**.49**	.74				
5. WURS Total Score	23.95	15.04	**.54**	**.50**	**.43**	**.57**	.91			
6. PDQ-4+ Conduct Disorder Total Score	2.24	2.28	**.37**	**.40**	**.22**	**.29**	**.50**	.73		
7. School Behavior Grade	8.10	1.02	**-.23**	-.11	**-.28**	-.17	**-.23**	-.20	--	
8. School Subjects Average Grade	6.77	0.79	-.07	-.01	-.11	-.11	-.14	-.16	**.36**	--

Note. SCID-5-CV ADHD: Structured Clinical Interview for DSM-5-Clinician Version Attention-Deficit/Hyperactivity Disorder Module; ASRS-6: Adult ADHD Self-Report Scale-6 Item Version; WURS: Wender Utah Rating Scale; PDQ-4+: Personality Diagnostic Questionnaire-4+. Since a total of 26 correlations were computed, the nominal significance level was corrected according to the Bonferroni procedure and set at p <.0019. Pearson r coefficients greater than |.21| are significant at Bonferroni-corrected nominal p-level. Bold highlights significant r coefficients.
--: Statistic not computed.

TABLE II. *Structured clinical interview for DSM-5 Clinician Version Attention Deficit Hyperactivity Disorder Module: confirmatory factor analysis models and confirmatory bifactor model Goodness-of-Fit indices (n = 217).*

Factor Models of SCID-5-CV ADHD Criteria	WLSMV $\chi 2$	*df*	RMSEA	RMSEA 90% CI	CFI	TLI
a) 1 factor	223.343***	135	.055	.042 - .067	.891	.876
b) 2 correlated factors with one second-order ADHD factor	191.788***	134	.045	.029 - .058	.928	.918
c) Confirmatory bifactor model: 1 general factor and 2 specific factors	140.068	116	.031	.000 - .048	.970	.961

Note. SCID-5-ADHD: Structured Clinical Interview for DSM-5 Clinician Version Attention Deficit Hyperactivity Disorder module; WLSMV: weighted least square mean and variance adjusted; $\chi 2$: WLSMV goodness-of-fit chi-square; df: degrees of freedom; TLI: Tucker-Lewis index; CFI: Comparative fit index; RMSEA: root mean square error of approximation; CI: Confidence interval for RMSEA.
** p < .05; ** p < .01; *** p < .001.*

Discussion

To our knowledge, the present study represents the first attempt at evaluating the psychometric properties of the ADHD module of the Italian translation of the SCID-5-CV in a sample of adolescents. Consistent with our hypotheses, our findings suggested that DSM-5 adult ADHD diagnostic criteria may be reliably assessed using the SCID-5-CV ADHD module, at least in a community sample of male adolescents with problem behavior/performance at school. These findings may be important for the assessment of ADHD; indeed, structured interviews (i.e., SCID-5-CV ADHD module) have been specifically designed to improve on the limitations of unstructured clinical interview. The SCID-5-CV ADHD module represents a user-friendly instrument which can be used to enhance the reliability and validity of ADHD diagnostic assessment, particularly in clinical settings. Moreover, the User's Guide for the SCID-5-CV [10 11] represents an important instrument for clinicians who seek to integrate time-tested interview questions corresponding to the DSM-5 criteria into their DSM-5 diagnostic assessment process. Indeed, the User's Guide provides comprehensive instructions on how to use the SCID-5-CV accurately, describes the rationale and usage of the SCID-5-CV, and discusses in detail how to interpret and apply the specific DSM-5 criteria for each ADHD criterion [10 11]. According to SCID-5-CV ADHD module assessment, the internal consistency reliability estimates of the DSM-

TABLE III. *Confirmatory bifactor model of SCID-5-CV ADHD criteria: standardized factor loadings and omega-hierarchical/-specific coefficients (n = 217).*

SCID-5-CV ADHD criteria	General ADHD factor λ	Inattentive specific factor λ	Hyperactiviy/impulsivity specific factor λ
H2. Missed details	.20*	.31**	---
H3. Had trouble staying focused	.49***	.35**	---
H4. Mind was elsewhere	.56***	.45***	---
H5. Started and dropped things	.10	.57***	---
H6. Had trouble organizing things	.16	.40***	---
H7. Avoided/disliked tasks	.33**	.50***	---
H8. Lost or misplaced things	.29**	.24	---
H9. Easily distracted by things	.37***	.31*	---
H10. Been very forgetful	.12	.53***	---
H12. Fidgeted/squirmed/tapped	.66***	---	-.60***
H13. Left seat	.66***	---	-.28
H14. Physically restless	.61***	---	-.61***
H15. Unable doing things quietly	.49***	---	.09
H16. Uncomfortable being still	.74***	---	-.43*
H17. Often talked too much	.43***	---	.14
H18. Finished people's sentences	.51***	---	.17
H19. Trouble waiting for "turn"	.37***	---	-.10
H20. Often interrupted	.88***	---	.45*
Omega-hierarchical/-specific	.71	.50	.04
Explained common variance	.60	.22	.18
Construct replicability (H index)	.90	.68	.64

Note. SCID-5-CV: Structured Clinical Interview for DSM-5 Clinician Version; ADHD: Attention Deficit Hyperactivity Disorder; λ: Standardized factor loading.
**p <.05; **p < .01; ***p <.001.*

5 ADHD criteria were adequate both for the full set of criteria and for the two sub-sets (i.e., Hyperactivity/Impulsivity and Inattentive). In our sample of community youngsters, 6.5% of the adolescents qualified for a DSM-5 diagnosis of ADHD. This finding was pretty consistent with prevalence estimates of adult ADHD in community samples [26], and further stressed the importance of assessing ADHD also in adolescence and later age [9]. Indeed, our school-based interview assessment prevented us from testing the inter-rater reliability of the SCID-5-CV ADHD module, as well as from administering the full interview. Although this method issue may represent a major limitation of our study, it should be observed that in our sample the SCID-5-CV ADHD scores (i.e., number of DSM-5 ADHD criteria met by each participant) showed significant associations with self-report measures of ADHD whose effect size would be considered large by conventional standards [27]. This finding could be hardly compatible with poor consistency of ADHD criteria ratings between independent interviewers. Interestingly, the number of ADHD symptoms (particularly, Hyperactivity/Impulsivity symptoms) based on SCID-5-CV assessment was significantly associated with the number of self-report CD criteria; this finding was consistent with previous longitudinal studies documenting that ADHD may represent a risk factor for antisocial behavior in adolescence/adulthood [9]. Consistent with our expectations, the association between SCID-5-CV ADHD symptoms and PDQ-4+ self-reports of CD was somewhat smaller than the convergent validity correlations with self-report measures of ADHD, further stressing the validity of the SCID-5-CV module as a measure of ADHD. Interestingly, our data suggested that the number of SCID-5-CV ADHD symptoms (as well as the WURS total score) was significantly associated with adolescents' current poor behavior at

school. Adolescents who qualified for a DSM-5 ADHD diagnosis based on the SCID-5-CV interview showed significantly poorer behavior at school and school performance than non-ADHD adolescents, although the effect size estimates for these differences were small. Of course, we do not mean not to say that poor academic performance in adolescence is always related to ADHD. Rather, we feel that our findings stress the importance of identifying ADHD in adolescence to prevent early drop-out from school [9 28].

Our WLSMV CFA results suggested that the tetrachoric correlations among the 18 SCID-5-CV ADHD symptom items are best explained by a bi-factor model hypothesizing a general ADHD factor, and two specific factors corresponding to the a priori DSM-5 Hyperactivity/Impulsivity and Inattentive dimensions. With the exception of three (16.7%) of SCID-5-CV ADHD symptom items, all other ADHD symptoms significantly loaded on the ADHD general factor, with an omega-hierarchical value that may be considered adequate by conventional standards [29]. When this general ADHD dimension was held constant, the majority of SCID-5-CV ADHD Inattentive symptom items showed positive, significant loadings on the Inattentive specific factor. Rather, none of the SCID-5-CV Hyperactivity/Impulsivity symptom item loaded positively and significantly on the Hyperactivity/Impulsivity specific factor.

In our study, the explained common variance and the omega-hierarchical coefficient values for the ADHD general factor were .60 and .71, respectively. Under these conditions, Reise and colleagues [30] suggested that the presence of some multidimensionality may not be severe enough to disqualify the interpretation of the instrument – i.e., the SCID-5-CV ADHD module – as primarily unidimensional. However, the Inattentive specific factor showed a non-trivial omega-specific value; moreover, the proportion of reliable score variance in the Inattentive factor sub-scale that was independent from the general ADHD factor was .665. In other terms, in our sample a non-negligible amount of reliable score variance in SCID-5-CV Inattentive symptoms was independent from the general ADHD factor; this finding was consistent with studies suggesting that attention problems are heterogeneous in nature and are not wholly captured by the inattention symptoms used to assess, diagnose, and treat ADHD [31 32].

Of course, our findings should be considered in the light of several limitations. The sample size was moderate and included only community male participants; this limits the generalizability of our findings clinical samples as well to samples including female adolescents and to community adult samples. We were not able to provide full assessment of DSM-5 mental disorder diagnoses included in the SCID-5-CV, thus not providing data on ADHD co-morbidity. As we mentioned above, we were not able to provide data on the inter-rater reliability of the SCID-5-CV ADHD criteria; however, the pattern of associations that we observed for the SCID-5-CV ADHD module was hardly compatible with poor rater agreement. Further studies on this topic are badly needed before accepting our conclusions. The reduced number of participants who met DSM-5 criteria for ADHD diagnosis prevented us from sub-typing the disorder. It might be claimed that relying on CFA for testing the latent structure of the SCID-5-CV ADHD symptom items may not be consistent with the categorical nature of the DSM-5 ADHD diagnosis. However, available evidence clearly supports the dimensional latent structure of ADHD [33].

Even keeping these limitations in mind, we feel that our data provides first support to the reliability and validity of the SCID-5-CV ADHD module, at least among community male adolescents.

Conflict of Interest

The authors have no conflict of interests.

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Original article

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The relationship between difficulties in emotion regulation and dysfunctional technology use among adolescents

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Summary

Objectives

Since two decades scientific research is studying excessive and dysfunctional new technologies use and its influences on people's lives, in terms of personal, relational, scholastic and work functioning impairment. The objectives of the present study are to investigate gender differences in problematic new technologies use as well as to examine the relationship between problematic new technologies use, emotional regulation and its specific dimensions.

Methods

280 italian adolescents (51.1% males) aged 11 to 18 years (mean age = 13.31; SD = 2.33) were recruited from two italian secondary public schools and involved in this study. Data were collected using the Internet Addiction Test, the Video Game Dependency Scale, the Brief Multicultural Version of the Test of Mobile-Phone Dependence and the Difficulties in Emotion Regulation Scale.

Results

Results indicate significant association between emotion dysregulation and problematic internet ($r = .504$; $p < .001$), videogame ($r = .372$; $p < .001$), mobile-phone ($r = .424$; $p < .001$) use. These results support hypothesis that adolescents with greater emotion dysregulation are more likely to experience problematic new technologies use. Additionally, stepwise multiple regression analysis pointed out that the lack of effective emotion regulation strategies is a common risk factors between the problematic new technologies use, but regression analysis highlighted specific risk factors for some of the investigated dependent behaviors.

Conclusions

Findings of this study highlight a link between problematic new technologies use, emotion dysregulation and its specific dimensions. The results are discussed considering scientific advances and the role of emotional dysregulation in determining problematic new technologies use in adolescence. Further research with larger sample sizes is needed to confirm our data.

Key words

Internet Gaming Disorder • Internet Addiction • Problematic Mobile-Phone Use • Emotion Regulation • Adolescence

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Introduction

The term "addiction", was traditionally used to explain symptoms deriving from the use and abuse of substances. In the current literature, it

refers to dysfunctional behaviors and negative consequences associated to the repetition of typically socially accepted activities (e.g., gambling, internet use and videogames) [1]. In recent years, scientific research has shown interest in the problematic use of or addiction to new technologies including Internet Addiction [2-4], Internet Gaming Disorder [5-7] and Mobile-Phone Addiction [8-10]. These behaviors have been conceptualized in different ways. On the one hand, they may be considered along an impulsive-compulsive spectrum (with some classified as impulse control disorders). On the other hand, which does not exclude the former, they may also be conceptualized as Behavioral Addictions [11 12].

In a recent review study, Grant and colleagues [13] point out that behavioral addictions resemble substance addictions in diverse domains, including natural history, phenomenology, tolerance, co-morbidity, overlapping genetic contributions, neurobiological mechanisms and response to treatment. These findings concern pathological gambling exclusively and, only in part, extend to internet and videogame addictions, while there is not enough data to draw conclusions regarding other behavioral addictions.

Concerning neurobiological findings, recent research highlighted that problematic internet use is associated with structural or functional impairment in the regions of brain implicated in the process of reward, motivation, memory and cognitive control [2]. Specifically, the orbitofrontal and the prefrontal cortex [3] resulted involved in the development of internet addiction, suggesting that adolescence represents a specific risk phase due to the yet incomplete maturation of the development of these specific brain regions [3].

The publication of the fifth version of the DSM 5 represents a fundamental innovation on this topic. Indeed, Pathological Gambling has been recategorized within the "Substance-Related and Addictive Disorders" section and renamed Gambling Disorder. With this change, gambling disorder has become the first recognized non substance behavioral addiction. Furthermore, Internet Gaming Disorder (IGD) is included in Section III, as a condition warranting more clinical research before it may be considered for inclusion as a formal disorder.

IGD is defined as the persistent and recurrent use of internet-based games, often with other players, that leads to clinically significant impairment or distress, as indicated by the presence of at least five criteria among those reported in the DSM-5, during the last 12 months [5]. However, the DSM-5 does not include an Internet Addiction Disorder diagnosis and no shared diagnostic criteria for this condition are available. Data on the prevalence of internet addiction is limited by methodological difficulties concerning both the diagnosis and the heterogeneity of diagnostic tools, making it difficult to compare prevalence rates among different countries [14]. These concerns also regard the study of IGD 7 and mobile-phone addiction [14-16].

Another important aspect to keep in mind is related to the complexity of technologies their diverse uses and applications. The latest generation of mobile phones allows easy accessibility and usability of internet and videogames. Griffiths [17] distinguishes between addiction "to" the internet and "on" the internet, to clarify how some individuals may be Internet addicted but not necessarily addicted to the internet per se, since they use it only as a medium to satisfy other addictions. Similarly, Billieux [18] considers dysfunctional use of mobile phones that implies involvement in specific online activities (e.g., videogames, gambling and other addictive behaviors). In other words, a videogamer who uses the internet or mobile-phone primarily to play could be addicted to videogames but may not be addicted to the internet per se (similar to pathological gamblers who use the internet or mobile-phones only to bet). The distinction between these different behaviors should be considered. The risk is to confuse the different modalities of technology usage (internet, videogame, mobile-phone).

Addiction and emotion (dys)regulation

Difficulties in emotional regulation, in particular the regulation of negative and painful emotions, plays an important role in increasing the risk of developing or maintaining an addiction [4 19-22]. Emotion regulation refers to how an individual sustains, intensifies, or inhibits ones emotions, according to ones purposes [23]. Some studies highlight the relationships between emotion regulation and addiction including internet addiction [4]. In particular, faced with the inability to tolerate intense and unpleasant emotional states, individuals resort to substances and/or behaviors in order to experience temporary relief. There are still very few studies that have investigated the relationship between emotional dysregulation and addictions to new technologies in adolescence, for example, problematic videogame and internet usage [24]. Research has suggested that internet and technology use can be a way to escape and get away from reality as well to cope with stress, depression, loneliness and worry [4 26]. Indeed, motivations reported more frequently by problematic gamers include the use of videogames to relieve tension and escape from reality [27].

The apparent benefits of addictive behavior (e.g. changes in mood and subjective experience, relaxation and pleasure, coping strategy social anxiety, fear, tension and painful emotions) reinforce the behavior, representing a temporary solution or coping strategy to managing developmental tasks. However, the dysfunctional and disorganizing nature of the addiction has been shown to have an impact on adolescent's psycho-physical health.

In light of the above, the present study adds to the existing knowledge on the link between emotion regulation and technology use and is based on the conceptualization of emotion regulation as proposed by Gratz and Roemer [28]. In particular, the following dimensions have been included to define the concept: a) awareness and understanding of emotions; b) acceptance of emotions; c) the ability to control impulsive behaviors and behave in accordance with desired goals when experiencing negative emotions; and d) the ability to use strategies to regulate emotions appropriate to the situation and in a flexible way, in order to modulate the emotional responses as desired, so as to achieve individual goals and situational requests.

Objectives

The current study aimed to explore the relationships between difficulties in emotion regulation and adolescents' problematic internet use (PIU), problematic videogame use (PVU) and problematic mobile-phone use (PMPU). This studys' objectives include the following:

- to evaluate the prevalence of PIU, PVU, PMPU, gender and age groups differences;
- to analyze the relationship between problematic technology use (internet, videogame and mobile-phone) and emotion dysregulation, exploring in particular potential associations with the emotion dysregulation dimensions;
- finally, the predictive effect of the emotion dysregulation dimensions (Nonacceptance, Goals, Impulse, Strategies, Awareness and Clarity) on problematic technology use (including PIU, PVU and PMPU) will be investigated through stepwise multiple regression analysis. The aim was to examine which specific dimensions of emotion dysregulation better predict problematic technology use. The stepwise multiple regression was employed in order to identify the independent variables that have stronger associations with the dependent variable. This procedure involves analysis at each step to analize the specific contribution of the predictor variable entered previously in the equation in order to understand the contribution of the previous variables when the new independent variable has been added.

Materials and methods

Subjects

This study was conducted on a sample of 280 Italian students (M = 143, F = 137) aged 11-18 (M = 13.31, SD = 2.33) attending two secondary schools in central Italy. A written informed consent was obtained from the parents before inclusion in the study. Collective administration of the self-report questionnaires took place during school time in the classrooms. Anonymity of participants was ensured. This study was approved by the Ethics Committee of the Department of Dynamic and Clinical Psychology, Faculty of Medicine and Psychology, Sapienza University of Rome (Italy).

Measures

All participants in the research completed the questionnaires described below:

- the *Internet Addiction Test* (IAT) (Young) [4 29] is a 20 item self-report questionnaire assessing the level of psychopathological risk associated with the internet, examining the degree of concern and compulsiveness, as well as the impact on the individual's life. Participants responded on a Likert scale ranging from 1 (*never*) to 5 (*always*). A higher total score reflects a high level of PIU. Based on the IAT total score, Young [30] distinguishes the following internet users: a score between 0 and 30 points is considered below the average and does not indicate any problem related to the use of the internet; a score between 31 and 49 points suggest an average use of the Internet, the individual can sometimes surf the web a little too long, without losing control of the situation; a score between 50 and 79 points is above the average score that implies occasional problems related to use, a condition at risk for addiction development; finally, a score between 80 and 100 points indicates that internet use is intense causing significant problems and is suggestive of an Internet Addiction (IA). The psychometric evaluation of the IAT Italian version demonstrated good internal consistency (Cronbach's α values range from .83 to .86) and convergent validity [31]. In the present study, the scale showed good internal consistency (Cronbach's α of .85);
- the *Video Game Dependency Scale* (CSAS) [7] is a self-report questionnaire including 18 items evaluating PVU, both online and offline. This instrument covers all nine DSM-5 criteria for the IGD diagnosis and reflects a first estimate of the risk of developing the condition. Students were instructed to respond based on their gaming behavior within the last 12 months and rated each item on a four-point scale from 1 (*strongly disagree*) to 4 (*strongly agree*). The CSAS demonstrated very good reliability in Rehbein et al.7 (Cronbach's α = 0.93). In the present study, the scale showed a very good internal consistency (Cronbach's α of .93). For research purposes, the CSAS total score was used as a dimensional indicator of the degree of PVU;
- the *Brief Multicultural Version of the Test of Mobile Phone Dependence* (TMD brief) [32] is a self-report questionnaire consisting of 12 items that investigate

problems related to PMPU. The first three items are answered on a scale ranging from 0 (*never*) to 4 (*frequently*). The nine remaining items use a scale ranging from 0 (*completely disagree*) to 4 (*completely agree*). This instrument was adapted from a previous instrument (TMD) [10] initially developed according to the DSM-IV-TR criteria for dependence disorder. The authors [32] reported that the questionnaire exhibits good reliability (Cronbach's α = 0.88). They outline four dimensions: Abstinence; Abuse and Interference with other activities; Tolerance; and Difficulty of control: These are representative of the addictive process. In the present study, the scale demonstrated good internal consistency (Cronbach's α of .87);

- the *Difficulties in Emotion Regulation Scale* (DERS) 28 is a 36 item self-report measure developed to assess clinically relevant difficulties in emotion regulation. Items are scored on six subscales: Non acceptance of Emotional Responses (Non acceptance, 6 items); Difficulties Engaging in Goal-Directed Behavior (Goals, 5 items); Impulse Control Difficulties (Impulse, 6 items); Lack of Emotional Awareness (Awareness, 6 items); Limited Access to Emotion Regulation Strategies (Strategies, 8 items); and Lack of Emotional Clarity (Clarity, 5 items). Participants respond on a Likert scale ranging from 1 (*almost never*) to 5 (*almost always*). High scores reflect greater difficulties in emotion regulation. The DERS and its subscales have strong psychometric properties [22]. In the Italian context, the DERS has been shown to be a valid and reliable tool (Cronbach's α = .90) [33]. In the present study, the scale showed good internal consistency (Cronbach's α of .87) as well as all six subscales (Cronbach's α from .66, Awareness, to .80, Strategies).

Statistical analysis

Data were analyzed using the Statistical Package for Social Science (SPSS) 25.0 for Windows. The sample (n = 280) was divided in 3 subgroups based on age: group 1: aged 11-12 years (n = 138); group 2: aged 13-15 years (n = 77); and group 3: aged 16-18 years (n = 65). Descriptive statistics were used to evaluate sample characteristics (frequency, means and standard deviations). Thee zero-order correlations between the variables were initially calculated in order to analyze the relationships between the variables of this study. Subsequently, analysis of univariate variance (ANOVAs) were used to investigate the main differences according to gender and the three age groups. Stepwise multiple linear regression analysis was conducted in order to determine whether there were any predictive effects of the emotion regulation dimensions on PIU, PVU and PMPU.

Results

The total sample's (n = 280) mean score on the IAT was 42.09 (SD = 11.32). No statistically significant differences emerged between males and females (F(1,279) = 2.42; p = .35).

On the basis of the cut off set by Young [30], 15.4% (n = 43) of the participants did not report any problems related to the internet use with a total score below the average on the IAT (from 0 to 30); 58.8% (n = 165) of participants reported a total score range (from 31 to 49) that suggests an average use of the internet indicating that the individual can sometimes surf the web a little too long, without losing control of the situation; 25.7% (n = 72) of participants obtains a score above the average (from 50 to 79) that implies occasional problems related to internet use, a condition at risk for addiction development. No participant obtained a test score between 80 and 100 points indicating significant problems and an internet addiction.

The total sample's (n = 280) mean score on the CSAS was 27.17 (SD = 10.14). Statistically significant differences in relation to gender emerged (F(1,279) = 39.59; p < .001) indicating that males (M = 30.71, SD = 11.01) consistently scored higher than females (M = 23.47, SD = 7.57) on PVU, both online and offline.

As outlined by Rehbein and colleagues [7], the item scores that are based on the DSM-5 criteria were calculated. Approximately three percent (n = 9, aged 11-13) of participants appeared to meet the diagnostic criteria for IGD, including eight males and one female.

Finally, the total sample's (n = 280) mean score on the TMD brief was 19.89 (SD = 10.54). No statistically significant differences emerged between males and females (F(1,279) = 3.02; p = .08).

Significant positive correlations between PIU and PVU (r = .520; p < .001), between PIU and PMPU (r = .688; p < .001), as well as between PVU and PMPU (r = .397; p < .001) were found. Significant positive correlations between emotion dysregulation and PIU (r = .504; p < .001), PVU (r = .372; p < .001) and PMPU (r = .424; p < .001) also emerged (Tab. I).

Additionally, stepwise multiple regression analyses showed that the "Strategies" factor of the DERS appears to be the best predictor of PIU, PVU and PMPU (Tabs. II-IV). Regarding PVU, "Strategies", male gender and "Non acceptance" explained 29% of the variance in CSAS scores. With respect to PIU, "Strategies" and "Goal" explained 25% of the variance in IAT scores. Finally, in terms of PMPU, "Strategies" explained 18% of the variance in TMD brief scores.

Furthermore, findings highlighted statistically significant differences between the three subgroups (group 1: aged 11-12; group 2: aged 13-15; and group 3: aged 16-18) in IAT, CSAS and DERS scores (Tab. V).

TABLE I. *Pearson correlation among psychological test scores.*

	CSAS	IAT	TMDbrief
DERS	0.372***	0.504***	0.424***
NonAcceptance	0.373***	0.411***	0.334***
Goal	0.217***	0.344***	0.305***
Impulse	0.276***	0.346***	0.319***
Awareness	-0.034	-0.004	-0.025
Strategies	0.409***	0.489***	0.429***
Clarity	0.093	0.261***	0.182***

*Note. CSAS: Video Game Dependency Scale; IAT: Internet Addiction Test; TMDbrief: Test of Mobile Phone Dependence Brief Version; DERS: Difficulties in Emotion Regulation Scale; * p < .05; **p < .01; *** p < .001.*

Group 2 obtained a higher mean score than the other two age groups on both the IAT and the DERS. Group 1 demonstrated a higher mean score than the other two groups on the CSAS. No statistically significant differences emerged between the groups on the TMD brief. Regarding the DERS subscales, the limited access to emotion regulation strategies ("Strategies") was significantly different between groups: group 2 reported a higher mean score than the other two groups.

Discussion and conclusions

Excessive and problematic use of the internet [16 14 25], videogames [24 7] and mobile-phones [18], can have a negative impact on the psychophysical and social-relational well-being of the individual. In accordance with Young [30], no research participant met the diagnostic criteria for Internet Addiction, as measured by the IAT. These results are in contrast to with other studies carried out in Europe. In particular, findings from a Greek study [2] revealed a 6.2% prevalence rate of IA in adolescents aged 14 to 18 years. Conversely, our results are in line with other studies carried out in Italy among adolescent non-clinical populations which have reported a low prevalence rate ranging from 0.79% [34] to 1.2% [16] for IA. Similarly, a recent study [35] on a sample of Italian adults, showed that no participant scored between 80 and 100 on the IAT (indicating IA).

In our sample, 25.7% (n = 70) of participants received a score between 50 and 79, with occasional problems related to internet use, reflecting a risk condition for the development of IA [30]. This finding is in accordance with other Italian studies in which the prevalence of those at risk of developing IA has ranged from 5% [34] to 49% [16]. On the one hand, the increase of subjects "at risk" could refer to "a new normality" considering PIU a temporary

TABLE II. *Stepwise multiple regression analysis for risk factors predicting CSAS total scores in study participants.*

Dependent variable: CSAS				
Indipendent variable	**Beta**	**R2**	**R2 adjusted**	**F**
Strategies	0.27***			
Genere	-0.33***			
Nonacceptance	0.17*	0.30	0.29	37.24***

*Note. CSAS: Video Game Dependency Scale; * p < .05; **p < .01; *** p < .001.*

TABLE III. *Stepwise multiple regression analysis for risk factors predicting IAT total scores in study participants.*

Dependent Variable: IAT				
Indipendent variables	**Beta**	**R2**	**R2 adjusted**	**F**
Strategies	0.42***			
Goal	0.14*	0.25	0.25	45.25***

*Note. IAT: Internet Addiction Test; * p < .05; **p < .01; *** p < .001.*

TABLE IV. *Stepwise multiple regression analysis for risk factors predicting TMDbrief total scores in study participants.*

Dependent Variable: TMDbrief				
Indipendent variable	**Beta**	**R2**	**R2 adjusted**	**F**
Strategies	0.43***	0.18	0.18	60.45 ***

*Note. TMDbrief: Test of Mobile Phone Dependence Brief Version; * p < .05; **p < .01; *** p < .001.*

TABLE V. *Analysis of variance (ANOVA) comparing the three age groups.*

Variable	Group 1 (11-12 years), mean (± SD)	Group 2 (13-15 years), mean (± SD)	Group 3 (16-18 years), mean (± SD)	F	P-value
CSAS	29.36 (± 10.60)	27.74 (± 10.37)	26.99 (± 10.05)	16.90	0.000
IAT	41.46 (± 10.95)	47.22 (± 11.49)	42.03 (± 11.37)	15.05	0.000
TMDbrief	18.87 (± 11.31)	21.82 (± 10.83)	19.54 (± 8.03)	1.88	0.154
DERS	85.80 (± 18.98)	89.30 (± 18.42)	85.59 (± 18.79)	3.58	0.029
Nonacceptance	12.17 (± 4.88)	13.23 (± 4.99)	12.25 (± 4.76)	2.89	0.057
Goal	14.56 (± 4.69)	14.96 (± 4.71)	14.54 (± 4.73)	.73	0.481
Impulse	13.77 (± 5.22)	14.40 (± 4.83)	13.72 (± 5)	1.75	0.176
Awareness	17.27 (± 4.70)	17.04 (± 4.39)	17.10 (± 4.64)	.21	0.814
Strategies	17.14 (± 6.45)	17.93 (± 6.22)	16.87 (± 6.19)	4.07	0.018
Clarity	10.89 (± 4.26)	11.74 (± 4.11)	11.11 (± 4.29)	1.09	0.337

Note. CSAS: Video Game Dependency Scale; IAT: Internet Addiction Test; TMDbrief: Test of Mobile Phone Dependence Brief Version; DERS: Difficulties in Emotion Regulation Scale.

phenomenon connected to the specific adolescent period of life and to the fact that it is necessary to adapt to the new online environment. Vice versa, on the other hand, it could indicate an expansion of problems related to internet use. In line with other studies on adolescent populations [16], our findings showed no statistically significant differences between males and females with respect to PIU and PMPU.

Approximately 3.2% (n = 9) of the this sample demonstrated PVU that is in agreement with a previous study in which the same tool was used to investigate PVU basing on the diagnostic criteria of the DSM-5 7. We observed that males were more at risk of developing IGD than females. Additionally, a higher PVU score characterized younger adolescents (aged 11-12). The results of the present study could be explained by referring to adolescence as a crucial period of life during which impulsivity and sensation-seeking play an important role in exposing adolescents to risky behaviors. Adolescence is characterized by a greater vulnerability to emotional dysregulation and to psychopathological risk due to different factors, including the non-homogeneous development of the cerebral, behavioral and cognitive systems, together with emerging emotional, intellectual and behavioral abilities, and the need to manage the different evolutionary tasks of this phase of life [36].

In accordance with the existing literature [8], the results of the present study demonstrate that the IAT, CSAS and TMD brief scores are positively and significantly correlated, underlining the strong associations between PIU, PVU and PMPU. The positive associations reported among problematic technology use may be due to one or more risk factors shared by the addictive behaviors investigated [8 18]. It is worth noting that difficulties in emotion regulation are associated with various forms of addiction. Specifically, emotion dysregulation is a critical factor for a variety of psychiatric and emotional disorders [22].

Similarly, findings of the present study confirm that emotion dysregulation is associated with the problematic use of new technologies [24 25]. In particular, PIU, PVU and PMPU correlated with emotional dysregulation dimensions, namely, non acceptance of emotional responses ("Nonacceptance"), difficulties engaging in goal-directed behavior ("Goals"), impulse control difficulties ("Impulse") when negative emotions are experienced and limited access to emotion regulation strategies ("Strategies"). The lack of emotional clarity ("Clarity") correlated with PIU and PMPU but not with PVU. This finding is in contrast with a recent study by Estévez and colleagues [1], who observed that the lack of understanding of the nature of emotional responses predicts PVU in a sample of Spanish adolescents. Furthermore, the lack of emotional awareness ("Awareness") was not associated with the problematic use of the new technologies investigated. Weinberg & Klonsky [22] obtained the same result with clinical variables theoretically associated with emotional dysregulation (such as depression, anxiety, suicidal ideation etc.). According to the authors, this result may be linked to the potential problematic nature of the "Awareness" subscale, in particular, the lack of validity or to the inappropriate and unclear language for an adolescent population. In Estévez and colleagues' (i.e., study [1] study, this scale predicted drug abuse but not the problematic use of technology (internet and videogames).

In our study, the limited access to effective emotion regulation strategies is central in predicting the problem-

atic use of the technologies explored (internet, videogames, mobile-phones). This DERS dimension together with non-acceptance of emotional responses ("Non acceptance") predicts PVU, while together with difficulties engaging in goal-directed behaviour ("Goals"), predicts PIU. In line with the findings observed by Kuss and colleagues [27] and Young [4], it is possible that adolescents with PIU, PVU and PMPU obtain relief from negative emotional states through a compulsive-impulsive behavior related to the use of technologies.

In sum, the results of this study add new knowledge to the literature and are in line with hypothesis regarding the existence of specific risk factors linked to different technological addictions, as well as shared risk factors [18].

It should be noted that this study is not exempt from limitations. First of all, the statistical analysis carried out does not allow conclusions to be drawn regarding any cause-effect directionality between the variables investigated; only longitudinal research would allow for the investigation of the causal relationship between the observed associations. Second, only self-report questionnaires were used. Third, the measures employed in this study did not evaluate information such as hours of use, favorite content and applications, motivations and purposes. The investigation of these additional aspects is needed to increase the clinical and theoretical validity of these results. Finally, the sample size influences the generalizability of the present findings.

This study demonstrates that difficulties in emotion regulation and, in particular, the "Strategies" dimension, appear to be associated with the problematic use of new technologies (i.e., internet, videogames, mobile-phones). Further studies, especially longitudinal ones, are needed to expand and better understand the various aspects related to the new technologies while additionally adopting a multidisciplinary perspective.

Conflict of Interest

The authors have no conflict of interests.

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Original article

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Which metacognitive components of insight in schizophrenia? The relationship between subjective and objective measures of metacognition and insight

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Summary

Objectives

It has been well documented that metacognition is compromised in people with a diagnosis of schizophrenia. Recent theories, concerning the roots of poor insight in schizophrenia, have proposed that it may result, in part, from impairments in metacognition, the capacity to think about thinking. Metacognition is a complex construct including both objective and subjective elements not necessarily overlapping. Aim of this study is to investigate the relationship of these elements with insight.

Methods

Metacognitive abilities were assessed using both objective [i.e. Wisconsin Card Sorting Test (WCST), metacognitive adaptation] and subjective measures [Subjective Scale to Investigate Cognition in Schizophrenia (SSTICS)] in 44 individuals with schizophrenia. The G12 item of the Positive and Negative Symptoms Scale (PANSS) was used for Insight evaluation. Functional performance was evaluated using Global Assessment of Functioning.

Results

Table I shows the means of symptoms, insight, metacognition and functional ability in the studied sample. Table II shows Pearson r correlations between metacognitive evaluations and symptomatology, insight, cognitive and functional variables. No relationship was found between objective and subjective measures of metacognition. Subjective metacognition, but not the objective one was related to PANNS depressive score. Lack of Insight did not correlate with objective metacognition, but was significantly related to subjective metacognitive complaints and positive, negative, disorganized and excited PANNS symptoms. Global functioning was related only to the PANSS Positive Factor.

Conclusions

Subjective and objective metacognitive measures in schizophrenia could be considered as distinct domains, supporting the hypothesis of the independence of cognitive functioning in schizophrenia from its subjective measures. Our results support the hypothesis of the lack of insight as a complex psychopathological construct related to phenomenology, cognition and psychotic symptoms.

Key words

Metacognition • Insight • Psychotic symptoms • Functional assessment • Schizophrenia

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Introduction

Metacognitive function concerns the ability to self-monitor and self-regulate knowledge about one's own cognitive abilities and real cognitive performance, which are fundamental determinants of a competent function-

ing in the real world: "knowing about knowing". Studies have consistently shown that metacognition is compromised in persons with schizophrenia [1], related to functionality, symptomatology [2 3] and insight of illness [4].
Lack of insight (LoI) is commonly observed in the persons with schizophrenia. It has been well documented that they have a specific LoI into their condition in comparison to other mental health disorders, both at early [5] and chronic [6] phases of the illness.
Several etiological models of LoI have been proposed that have led however to equivocal results. Since the predictive powers of symptoms [6 7] and neurocognition [8] on insight appear to be limited, some authors have hypothesized LoI as impaired metacognition [4 9]. From the metacognitive perspective, the development of insight requires an individual that not only notices and reflects upon historical events related to one's own illness, but also make sense of such experiences and develop a personally meaningful and consensually valid narrative of the illness. An individual, to develop insight, would need to construct a coherent and integrated account of his psychiatric state. Therefore, impaired metacognition is a promising potential contributor to LoI [4 10].
However, research on the relationship between metacognition and insight has yielded mixed results with some studies showing an association [9 11] while others no [12]. These contradictory results could be explained by many factors, such as the complexity of the insight construct, likely multidimensional, the use of different measures of insight and metacognition as well as differences in the diagnostic groups investigated in different studies [9].
Several assessment tools of metacognition have been put forward, usually self-administered instruments [13 14]. These instruments assess the capacity to self-monitor and self-regulate knowledge about one's own cognitive abilities and cognitive performance [15]. Therefore, the subjective cognitive impairments can provide additional information to tell about the severity of clinical and functional outcomes of the patient. The Subjective Scale to Investigate Cognition in Schizophrenia (SSTICS) [13] is a simple and ecological scale to assess patients' subjective experiences of cognitive impairment. Although several instruments have been used to measure self-perceived cognitive functioning, only SSTICS was designed to particularly measure subjective complaints regarding the cognitive deficits constantly reported in schizophrenia [16].
On the other hand, a direct objective measure of metacognition is also needed. An objective measure of metacognition has been elaborated by Koren et al. [17] based on the awareness of performance on the Wisconsin Card Sorting Test (WCST). The WCST is the mostly used task to investigate executive functions, whose impaired performance is significantly associated with functional disability [18 19].
This paradigm investigates two important aspects of metacognitive functioning: monitoring (i.e. the mechanism that is used to subjectively assess the correctness of potential responses) and control (the mechanism that determines whether or not to volunteer the best available candidate answer). Through this version of WCST it is possible obtain both efficiency quantitative indices of cognitive function and metacognitive ability [2].
Aim of the study is to explore the relationship between the subjective and objective metacognitive evaluations (SME and OME) in a sample of patients with schizophrenia spectrum disorders and their relationships with insight into illness, psychotic symptoms and functional ability.

Materials and methods

Participants

Participants in the study were persons hospitalized for an index episode of schizophrenic disorder at the Department of Mental Health of L'Aquila. Inclusion criteria were a diagnosis of schizophrenia according to the DSM-IV-TR, and an age between 18 and 65 years. Exclusion criteria were: neurologic disorders; substance abuse in the past 6 months or lifetime history of substance dependence; mental retardation; medical illnesses associated with neurocognitive impairment and inability to provide an informed consent.
The institutional ethics committee approved all recruitment and assessment procedures. All patients provided written informed consent after receiving detailed explanation of the study. This study adheres to the Declaration of Helsinki.

Measures and procedures

The evaluation was made during the illness episode remission, immediately before discharge. This stabilization level was chosen as a criterion for evaluating the subjects in order to minimize state-dependent effects and maximize testing validity.

Clinical assessment

The Positive and Negative Syndrome Scale (PANSS) is a 30-item scale designed to obtain a measure of positive, negative and general symptoms. We used the five-factor model proposed by Wallwork et al. [20] comprising a positive factor (items P1, P3, P5, G9), a negative factor (items N1, N2, N3, N4, N6, G7), a disorganized/concrete (cognitive) factor (items P2, N5, G11), an excited factor (items P4, P7, G8, G14) and a depressed factor (items G2, G3, G6), including a total of 20 items.

Insight assessment

The item "Lack of judgement and insight" (G12) from PANSS has been used for the insight assessment. Lack

of insight (LoI) was defined as impaired awareness or understanding of one's own psychiatric condition and life situation. The measure is a 7-point, clinician-rated item: from "1", no impairment, to a "7", emphatic denial of past and present psychiatric illness. This item did not enter into the Wallwork et al. [20] model.

Metacognitive functioning

Objective Metacognitive Evaluation (OME)

Objective Metacognitive abilities were assessed using the paradigm of Koren et al. [17], which is an adaptation of the 64-card WCST. In addition to the standard "forced responses", the procedure yielded a measurement of "free responses". To each participant was asked to rate his level of confidence in the answer on a scale of 0 (just guessing) to 100 (completely confident) and to decide whether he wanted the answer count toward his overall performance score. The metacognitive variables used were: 1) Accuracy score (the proportion of correct volunteered responses); 2) Free-response improvement (the difference between the free-response output-bound accuracy score and the forced-choice input-bound (quantity) score); 3) Global monitoring (the truthfulness of one's overall sense of knowledge, defined as the difference between the total number of correct responses and the total number of responses asked to be included); 4) Monitoring resolution (i.e. the extent to which the confidence judgments distinguished between correct and incorrect sorts; 5) Control sensitivity indexed by the gamma correlation calculated across all sorts between the level of confidence and the decision to venture the sort and 6) Gain (the score gain calculated as the overall difference between correct and incorrect responses) [17]. Perseverative errors have been also used as index of executive function performance.

Subjective Metacognitive Evaluation (SME)

The Subjective Scale to Investigate Cognition in Schizophrenia (SSTICS) was developed as a measure of self-appraisal cognitive deficit. The questionnaire contains 21 items focusing on memory, attention, executive functions and praxia. Sustained executive function, Memory of information, Consciousness of effort, Daily life, Distractibility and Alertness subscales were calculated [13]. Lecardeur and colleagues [16] demonstrated that the SSTICS is a good instrument for evaluating the subjective cognitive complaints of patients with schizophrenia and also revealed good concordance between cognitive impairments experienced by patients and cognitive disorders assessed by a clinical rater.

Community functioning ability

Functional performance was evaluated using Global Assessment of Functioning (GAF), a rating scale used to assess the social and occupational functioning of adults.

Statistical analyses

Descriptive statistics were computed for all variables of interest. Cronbach's alpha for subjective and objective metacognitive (SME and OME) evaluations was calculated. A factor analysis was done on the metacognitive measures using a principal components analysis with oblimin rotation using Kaiser's criterion for factor retention (i.e. eigenvalue > 1).

We examined potential bivariate relationships between insight, cognitive and metacognitive variables, clinical and functional assessment using Pearson's product-moment correlations.

All analysis yielding a p value of less than 0.05 were considered significant. Statistical analysis was performed using SPSS software (V 20.0).

Results

Forty-four persons (28 men and 16 women) were recruited: mean age of 40.16 years (SD 12.74), educational level 10.28 years (SD 3.20), 24.9% were married and 81.8% unemployed at the time when they were interviewed. The mean age at onset of illness was 26.65 (SD 10.82) and the mean duration of illness 13.68 (SD 10.73). All participants were on antipsychotic medication at the time of the evaluation and the mean chlorpromazine equivalent dose was 500 (SD 195.09) [21].Mean and SD of the studied variables are reported in Table I.

Cumulative scores for subjective and objective metacognitive evaluations (SME and OME respectively) were obtained through factor analysis. Firstly, Cronbach's alpha was calculated. Cronbach's alpha on the six SSTICS subscales was .85 with no items whose exclusion increased the overall reliability value. Cronbach's alpha on the six WCST metacognitive indexes showed 4 items (Accuracy score, Improvement due to free choice, Monitoring resolution, Control sensitivity) whose exclusion increased the overall reliability value. These items were then excluded from calculations and Cronbach's alpha on the 2 remaining items was .87.

Exploratory Factor Analysis performed on the 6 SME and the 2 OME items showed a Kaiser-Meyer-Olkin value of .748 and a Bartlett's test of Sphericity of 179.547, d.f. 28, $p < .0005$. Two factors had eigenvalues greater than 1 explaining the 70.39% of the total variance (46.98 and 23.41 respectively). All the items of the SSTICS highly loaded on the first cluster (all coefficients > .74), while the WCST metacognitive items very highly loaded of the second one (all coefficients > .95). The factorial scores obtained (regression method) were then considered in subsequent correlations.

No correlation was found between SME and OME. SME correlated with PANSS depressive factor ($r = .32$, $p < .05$, i.e. higher cognitive complaint – higher depression) and lack of insight ($r = -.37$, $p < .01$, i.e. higher

TABLE I. *Means (standard deviation) of symptoms, insight, metacognition and functional ability in the studied sample (n = 44).*

Five-factor model PANSS	Positive factor	13.74 (4.24)
	Negative factor	17.94 (8.38)
	Disorganized/concrete factor	9.59 (3.35)
	Excited factor	12.33 (4.67)
	Depressed factor	7.02 (2.18)
	Total	90.78 (20.19)
	LoI	4.51 (1.33)
WCST cognitive index	Perseverative errors	12.39 (8.39)
WCST metacognitive indexes	Accuracy score	.58 (.19)
	Improvement due to free choice	.02 (.04)
	Global monitoring	-23.40 (15.89)
	Monitoring resolution	.30 (.40)
	Control sensitivity	.36 (.55)
	Gain	9.02 (23.50)
SSTICS	Sustained executive function	4.79 (3.53)
	Memory of information	4.51 (3.36)
	Consciousness of effort	5.62 (3.35)
	Daily life	3.63 (3.26)
	Distractibility	3.49 (2.22)
	Alertness	.86 (1.17)
	Total score	23.67 (13.70)
GAF		44.08 (10.37)

Note. PANSS: Positive and Negative Syndrome Scale; Five-factor model PANSS (Wallwork et al.,2012); LoI: Lack of judgement and insight (Item 12 PANSS General Psychopathology); WCST: Wisconsin Card Sorting Test; SSTICS: Subjective Scale to Investigate Cognition in Schizophrenia; GAF: Global Assessment of Functioning

cognitive complaint – better insight). On the other hand, OME highly correlated with WCST perseverative errors ($r = -.62$, $p < .0005$, i.e. higher metacognitive performance – less perseverative errors) (Tab. II).

Lack of Insight item (G12) was correlated with PANSS positive symptoms ($r = .30$, $p < .05$), negative symptoms ($r = .35$, $p < .01$), Disorganized/Concrete Factor ($r = .49$, $p < .001$), Excited Factor ($r = .41$, $p < .01$) and total score ($r = .58$, $p < .0005$).

The GAF was related only to the PANSS Positive Factor ($r = -.50$, $p < .0005$).

Discussion

Our data revealed that the SSTICS subscales did not correlate with any of the WCST indexes, nor perseverative errors or metacognitive. Previous studies on subjective and objective measures of metacognition reported mixed results [22]. Correlations were found between SME and OME by some authors [14 23 24], while other ones reported only a small or no relationship [25]. These last findings are similar to our results, suggesting that the subjective evaluation of cognition in schizophrenia could be a specific dimension of cognition, which is independent from its objective measurements [4 18 26].

It would be hypothesized that the absence of correlation is due to cognitive impairment without awareness and, subsequently, complaints about it. This absence of awareness would be encompassed within a more general concept of lack of insight [26].

As a matter of fact we found a negative correlation between awareness of illness, measured by the item G12 of the PANSS and SME. Previous studies confirm this result [13 27 28], although not confirmed by others ones [16 28 29]. It is conceivable that more a patient lacks insight, less he perceives cognitive difficulties. As suggested by Medalia and Thysen [14], who compared insight into clinical symptoms *vs* insight into neurocognitive symptoms, patients have significantly less cognitive insight than clinical insight.

We found no correlation between insight and OME as far as concerned metacognitive and cognitive indexes of WCST. As emerged from the meta-analysis by Aleman et al. [8], some studies found associations between the WCST (cognitive or metacognitive indexes) and poor insight [17 30 31], while a number of studies failed to replicate such relationship [9 10].

On the other hand, OME highly correlated with WCST perseverative errors. The more there is higher metacognitive performance, the less perseverative errors are present confirming our previous findings [2 3].

A relevant aspect that emerged in our study is the relationship between SSTICS and depressive symptoms. Our findings are consistent with previous reports showing significant correlations [4 21 27-29]; however, contrasting

TABLE II. *Pearson r correlations between metacognitive evaluations and symptomatology, insight, cognitive and functional variables (n = 44).*

	Subjective metacognitive evaluation	Objective metacognitive evaluation
PANNS		
Positive factor	- .17	- .06
Negative factor	.01	- .21
Disorganized/concrete factor	- .24	- .10
Excited factor	- .06	- .05
Depressed factor	.32*	.07
Total	- .09	- .16
LoI	- .37**	- .10
WCST perseverative errors	.04	- .62***
GAF	.06	.10

*$p < .05$; **$p < .01$; ***$p < .0005$

reports do exist [32]. It could be possible to hypothesize a role of LoI as third variable that could mediate the relationship between SSTICS and depressive symptoms, i.e. an enhanced risk of depression could be present in patients more aware of their disability. Such a condition is well known as the "Insight paradox", with those persons with schizophrenia with higher levels of Insight showing increased levels of depression [33 34].

As far as the relationship between Lack of Insight with clinical symptomatology, we found significant correlation with PANSS positive, negative, disorganized, excited symptoms as well as with total score. These results confirm previous studies supporting the hypothesis of the lack of insight as a complex psychopathological construct related to phenomenology, cognition and psychotic symptoms [6 7 35].

Our study has significant strengths. We used objective and subjective metacognitive performance, which are thought to be dissociated in some psychiatric disorders, particularly in psychosis. Regarding the SME we used SSTICS [13] the only one designed to specifically measure subjective complaints regarding the cognitive deficits in schizophrenia [16]. About the OME, the adaptation of the 64-card Wisconsin Card Sorting Test (WCST), proposed by Koren et al. [17] is a good instrument that investigate both cognitive and metacognitive functioning.

Limitations however have to be considered. The main one is that the study is cross-sectional in a naturalistic clinical setting. A prospective study is needed to confirm the stability over time of the relationships identified herein.

We used one item only from PANSS to evaluate insight while other studies used more detailed measures. However, several studies employed single-item insight measures embedded in scales to assess symptomatology, such as the PANSS.

The sample size is relatively small reducing the power of the analysis; it however can be sufficient to heuristically investigate the relationship among the studied variables.

Conclusions

On the basis of our data subjective and objective metacognitive measures can be considered distinct domains. On the other hand, Insight is a complex construct interacting with neurocognitive, social-cognitive and metacognitive abilities [9].

Several studies suggested that metacognitive impairments, particularly self-reported/subjective metacognition may play a role in the development of poor insight [4]. Cognitive complaints are informative about the patient's own psychological status and long term symptom improvement. Indeed, self-perception of cognitive dysfunction has been found to be a good predictor of long-term symptomatic deterioration and it is a critical aspect in schizophrenia for implementing appropriate coping strategies [25].

The pattern of correlation between LoI, symptoms and self-perceived cognitive deficit that we found, suggests that Insight in schizophrenia may be better considered as a more global concept of "awareness" encompassing different constructs such as insight into clinical symptoms and insight into cognitive impairment [9 32].

Conflict of Interest

The authors do not have conflicts of interest about this article.

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Interrater reliability of the authorized Italian version of the Comprehensive Assessment of At-Risk Mental States (CAARMS-ITA)

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Summary

Objective

The Comprehensive Assessment of At-Risk Mental States (CAARMS) was specifically developed to detect and assess young individuals at Ultra-High Risk (UHR) of psychosis. Aim of the current study was to test the interrater reliability of the authorized Italian version of the CAARMS (CAARMS-ITA) in young adult help-seekers consecutively recruit through the "Reggio Emilia At-Risk Mental States" (ReARMS) project, an early detection and intervention infrastructure developed in the Reggio Emilia Department of Mental Health.

Methods

We included 51 young adults, aged 18-35 years, seeking help at the Reggio Emilia outpatient mental health services. Two trained raters were paired for each CAARMS interview, both simultaneously in the room with the subject. Interrater reliability of the CAARMS-ITA was tested measuring the Intra-Class Correlation (ICC) coefficients and the Cohen's kappa for interrater agreement on CAARMS-defined diagnosis criteria (i.e. UHR and First-Episode Psychosis [FEP]).

Results

The CAARMS-ITA showed an excellent interrater reliability. The Cohen's kappa for CAARMS diagnoses was 0.845 ($p < 0.001$). The ICC coefficients of the seven CAARMS subscale scores ranged from 0.965 and 0.990.

Conclusions

The CAARMS-ITA is a reliable instrument for detecting and assessing at-risk mental states in Italian clinical setting.

Key words

At-Risk Mental States • Ultra-High Risk • Early detection • Assessment • Prodrome • Psychosis • Schizophrenia

Introduction

Psychosis is a severe psychiatric condition, with schizophrenia being among the main leading causes of disability in young adults in Europe [1]. Since the evidence of improvement in patient's functioning is limited once the psychotic disorder is established [2], early intervention may delay or even avoid First Episode Psychosis (FEP) [3].

Within a clinical staging strategy of psychosis, McGorry and colleagues (2003) [4] proposed the notion of "At-Risk Mental State" (ARMS) to identify individuals at increased risk of developing FEP. The conceptualization of ARMS has to be understood as an early phase of the disease, viewed in perspective, and as the epistemological and nosological reversal of the retrospective concept of prodrome [5]. Within the variety of "ARMS", the so called "Ultra High Risk" (UHR) criteria were proven to be valid tools to

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identify individual with prospectively high (but not inevitable) imminent risk of developing psychosis [6]. Those are: a) Attenuated Psychotic Symptoms (APS), that are experiences of subthreshold positive psychotic symptoms during the past year; b) Brief Limited Intermittent Psychotic Symptoms (BLIPS), which are transient episodes of frank positive psychotic symptoms that have spontaneously remitted within one week, and c) vulnerability, a trait/state risk condition present in individuals who have a first-degree relative with a psychotic disorder or who have a schizotypal personality disorder, along with a significant decrease in functioning during the past year [7].

Over the years, the UHR criteria have gone through some slight modifications, but the core construct, such as the combination of socio-demographic risk feature (age range: 14-30 years), the state and trait factors (i.e. APS, BLIPS, and vulnerability) and help-seeking behavior, remained the same [8 9], with a particular focus on the help-seeking behavior, in order to mitigate the potential high number of false positives that might occur assessing large asymptomatic community samples [10]. Several studies tested the predictive strength of UHR criteria to identify individuals at risk of psychosis. The percentage of patients who matched the UHR criteria and subsequently presented a FEP within 12 to 30 months went from 40% in the yearly studies [6], to 15% in the most recent ones [11 12]. This decrease in the transition rate was detected also in a recent meta-analysis that provided as a possible explanation of this phenomenon the increased ability in the clinical services to recognize patient at risk and the effectiveness of intervention at an earlier stage [13].

Among the clinical interviews used to identify UHR/FEP individuals, the "Comprehensive Assessment of At-Risk Mental States" (CAARMS) is one of the most validated and reliable [14]. This instrument was explicitly developed at the PACE clinic in Melbourne to assist the early identification, risk stratification and longitudinal monitoring of ARMS [7]. The CAARMS has been adopted, besides Australia, also in many European, Asiatic, and Arabic countries, including UK, France, Spain, Germany, Denmark, Sweden, Greece, Japan, China, Korea, and Tunisia [15].

In this context, the "Reggio Emilia Departmental Group on Early detection and intervention on Psychosis" used the CAARMS in the clinical practice and, through a close collaboration with its Australian authors that granted the copyright in 2008, published the Italian version (CAARMS-ITA) (see supporting information in Pelizza et al., 2018) [16] under the aegis of the "Emilia-Romagna Regional Project on Early Detection in Psychosis" [17].

Aim of the present study was to assess the interrater reliability of the CAARMS-ITA in a sample of Italian young adult help-seekers.

Materials and methods

Participants

The interreater reliability was assessed in 51 young adult (aged 18-35 years) help-seekers consecutively recruited between September 2017 and March 2018 through the "Reggio Emilia At-Risk Mental State" (ReArms) project, an early detection and intervention infrastructure developed under the governance of the "Regional Project on Early Detection in Psychosis" in the Reggio Emilia Department of Mental Health [18]. In the ReARMS project, the participants are assigned to a multidisciplinary team, including a psychiatrist, a clinical psychologist and a case-manager for recovery-oriented early rehabilitation, generally within 2-3 weeks.

ReARMS inclusion criteria were: a) young individuals seeking the help of a specialist; b) age between 13 and 35 years; c) presence of UHR criteria defined by the CAARMS (i.e. APS, BLIPS, and/or Vulnerability), or d) a Duration of Untreated Psychosis (DUP) < 2 years in case FEP is detected in the initial assessment. The exlusion criteria were: a) history of past psychotic episodes either schizophrenic or affective, as specified in the Diagnostic and Statistical manual of Mental Disorders, Fifth Edition (DSM-5) [19]; b) history of previous exposure to antipsychotics; c) current substance dependence; d) known mental retardation (Intelligence Quotient < 70); and e) neurological disorders, head injury, or any other medical condition associated with psychiatric symptoms.

All participants entering the ReARMS protocol voluntarily agreed to participate to the study with written informed consent. All individuals assessed in this research were Italian native speakers. Relevant ethical and local NHS research and development approvals were sought for the study.

CAARMS

The CAARMS is a semi-structured clinical interview designed to study different aspects of attenuated psychopathology and functioning (via the integrated Social and Occupational Functioning Assessment Scale [SOFAS] module) [7]. The administration takes approximately 1-1.5 hours. CAARMS interview is made by 27 items, each one rated (0-6) in terms of intensity and frequency/duration. The items can be clustered in seven subscales: a) "Positive Symptoms" (disorders of thought content, perceptual abnormalities, disorganized speech); b) "Cognitive Change, Attention and Concentration" (subjective experience and observed cognitive change); c) "Emotional Disturbance" (subjective emotional disturbance, observed blunted affect, observed inappropriate affect); d) "Negative Symptoms" (alogia, avolition/apathy, anhedonia); e) "Behavioral Change" (social isolation, impaired role functioning, disorganizing/odd/stigmatizing behavior, aggressive/dangerous behavior); f) "Motor/Physical

Changes" (complaints of impaired motor functioning, impaired bodily sensation, and impaired autonomic functioning); and g) "General Psychopathology" (mania, depression, suicidality and self-harm, mood swings/lability, anxiety, obsessive-compulsive symptoms, dissociative symptoms, impaired tolerance to normal stress).
Among those subscales the "Positive Symptoms" one is used to determine both the UHR criteria and the threshold for psychosis, i.e. the presence of fully (positive) psychotic symptoms occurring for at least 1 week (either on a daily basis or more than three times a week) with each symptom continuing for more than 1 hour on each occasion [7]. UHR status is defined as follows: a) vulnerability group: schizotypal personality disorder in the individual or family history of psychosis in a first-degree relative combined with 30% drop in functioning for at least 1 month or chronic low functioning, as measured by the SOFAS (the decline in functioning is calculated by subtracting the current SOFAS score from the highest SOFAS score in the last year; scores range from 1 to 100); 2) APS group: sub-threshold positive psychotic symptoms within the past 12 months; and 3) BLIPS group: criteria for psychosis met for less than 7 day at a time and ceasing spontaneously (i.e. without antipsychotic medication) [7].
The Australian version of the CAARMS was translated into Italian by Andrea Raballo and back-checked by a team of experienced mental health professionals after obtaining permission from the original authors. This early version was then examined and judged as satisfactory by a staff member of the PACE clinic in Melbourne, who was fluent in Italian and familiar with the usage of the CAARMS [16].

Procedures

The interrater reliability of the CAARMS-ITA was tested by using data from consecutive joint interviews of 51 young adults entering the ReARMS protocol. Initially, three psychologists of the ReARMS project with clinical experience of psychotic disorders were trained on the usage of the CAARMS through collective supervision by the main author of the approved Italian translation [17], who was trained at Orygen, The National Centre of Youth Mental Health in Melbourne, Australia. Preliminary administration of the instrument to suspected ARMS individuals was conducted before the study. Of the three raters, two were paired for each interview, both simultaneously in the room with the subject. Interrater agreement was also assessed for the UHR/FEP criteria.

Statistical analysis

The interrater reliability is a method established to test the agreement among the various data collectors and it measures the extent to which raters assign the same score to the same variable. This method allows to know which extent the data collected in the study are correct representations of the variables measured [20]. To compute the data for the interrater reliability of the CAARMS-ITA, we used two different statistic tools: the Intra-Class Correlation (ICC) coefficients and the Cohen's kappa.
To assess the interrater reliability of the CAARMS-ITA subscale scores, we used the two-way, mixed effect, model of ICC, a tool commonly applied for ordinal, interval, and ratio variables [21]. In the current study, we also focused on the absolute agreement. Moreover, to generalize the reliability of multiple raters to the subjects rated by one coder, the ICC method here used was for single-measures [21].
The Cohen's kappa is used for a set of nominal ratings to measure the observed level of agreement between coders and allows to correct agreement that would be expected by chance [21]. In our study, the nominal variables were the three CAARMS-defined diagnoses: a) UHR- (i.e. participants below the UHR threshold to be considered at risk of developing psychosis); b) UHR+ (i.e. participants who met the UHR criteria), and c) FEP (participants who met the FEP criteria).
Data analysis was performed using the software Statistical Package for Social Science (SPSS) 15.0 for Windows [22].

Results

Sample

The interrater reliability of the CAARMS-ITA was assessed on 51 ReARMS young adult participants. Of these subjects, 26 (51%) were males. After distributions of all quantitative variables were examined for violations of normality assumption, descriptive analyses included median and interquartile range for not normally distributed parameters. The median was 25 years (interquartile range = 21-32 years) for age, 13 years (interquartile range = 10-15 years) for education, and 50 weeks (interquartile range = 15-56 weeks) for the Duration of Untreated Illness (DUI), defined as the interval (in weeks) between the onset of a psychiatric clinically relevant symptom and the administration of the first pharmacological/psychological treatment [23] (Tab. I).

Interrater reliability

The Cohen's Kappa for the three CAARMS diagnoses (i.e. UHR-, UHR+, and FEP) was 0.845 ($p < 0.001$), showing an almost perfect agreement between raters [24]. Similarly, the result of the overall ICC coefficient was 0.990, demonstrating an excellent interrater reliability. The analysis was also performed on the seven CAARMS subscores, on each item of the interview, and on the SOFAS score. Interrater reliability ranged from very good to excellent for all the scores. The results of the individual ICC coefficients are reported in Table II.

Discussion

The assessment of inter-rater reliability provides a way

TABLE I. *Sociodemographic and clinical characteristics of the total sample (n = 51).*

Variables	
Gender (males)	26 (51%)
Age	25 (21-32)
Education (in years)	13 (10-15)
DUI (in weeks)	50 (15-56)

Note. DUI: Duration of Untreated Illness. Frequency (and percentage), median and interquartile range are reported.

to quantify the level of agreement between two or more coders who make independent ratings on a variable. This analysis is necessary for research studies where data are collected through ratings provided by different coders. The presence of a good interrater reliability is one of the more relevant factor demonstrating the general reliability of an interview [20]. In the current study, reliability of the Italian version of the CAARMS was assessed with respect to interrater reliability. The overall ICC coefficient of the CAARMS-ITA was 0.990 and the coefficients for each subscale showed good to excellent reliability, in line with the original validation study by Yung et al. (2005) [7]. Moreover, in an Italian sample of 34 UHR+ young adults, the interrater reliability of the CAARMS had been previously assessed in a pilot study by Fusar-Poli et al. (2012) [25] using an unofficial and non-authorized version of the interview, which showed ICC scores comparable to ours. Finally, the CAARMS has been also validated in other different languages, such as Japanese [26], Greek [27], and Arabic [28], with an interrater reliability ranging from good to excellent.
Overall, these findings suggest that the interrater reliability of the CAARMS-defined UHR criteria were satisfactory, and that this instrument can be safely administered by trainer raters in clinical and research settings to assess the broad spectrum of prodromal and psychotic symptoms presented by young help-seekers referred to mental health services.

Limitations

There are several methodological limitations for the current study. Firstly, the group of raters was small and had considerable clinical experience with prodromal symptoms of psychosis. This can prevent the generalizability of our findings to primary care setting with no or less experience in the UHR assessment. Secondly, UHR+ sample size was limited. Thus, interrater reliability of the CAARMS-ITA must be studied in a larger UHR+ sample. Finally, our UHR+ participants were referred to the ReARMS program because considered potentially at risk for psychosis and thus the results might not be generalizable to help-seeking population in general mental health services.

TABLE II. *Intra-Class Correlation (ICC) coefficients of the CAARMS-ITA.*

CAARMS subscale	ICC
Overall	0.990
1. Positive symptoms	0.990
1.1 Unusual thought content	0.988
1.2 Non-bizarre ideas	0.978
1.3 Perceptual abnormalities	0.977
1.4 Disorganized speech	0.986
2. Cognitive change	0.973
2.1 Subjective cognitive change	0.955
2.2 Objective cognitive change	0.967
3. Emotional disturbance	0.987
3.1 Subjective emotional disturbance	0.952
3.2 Blunted affect	0.988
3.3 Inadequate affect	0.981
4. Negative symptoms	0.979
4.1 Alogia	0.947
4.2 Avolition/apathy	0.961
4.3 Anhedonia	0.948
5. Behavioral change	0.982
5.1 Social isolation	0.967
5.2 Impaired role functioning	0.936
5.3 Disorganized behavior	0.980
5.4 Aggressive behavior	0.968
6. Motor/physical change	0.966
6.1 Subjective motor functioning	0.997
6.2 Objective motor functioning	0.990
6.3 Subjective bodily sensation	0.939
6.4 Subjective autonomic functioning	0.923
7. General psychopathology	0.965
7.1 Mania	0.974
7.2 Depression	0.924
7.3 Suicidality/self-harm	0.957
7.4 Affective instability	0.956
7.5 Anxiety	0.937
7.6 OCD	0.985
7.7 Dissociative symptoms	0.965
7.8 Impaired subjective tolerance to normal stress	0.931
SOFAS score	0.974

Note. ICC: Intra-Class Correlation coefficients; CAARMS-ITA: the authorized Italian version of the Comprehensive Assessment of At-Risk Mental States; OCD: Obsessive-Compulsive Disorder; SOFAS: Social and Occupational Functioning Assessment Scale.

Conclusions

Despite these limitations, CAARMS-ITA demonstrated to have an excellent interrater reliability and to be a reliable tool to assess and detect ARMS in Italian clinical setting.

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Conflict of Interest

The authors declare to have no conflict of interest.

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Original article

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Healthcare resource utilization and direct medical costs in patients with dual diagnosis in Italy

Summary

Objectives

This study is aimed at analyzing the patterns of care and annual costs of services in patients with dual diagnosis treated in an Italian Mental Health and Pathological Dependency Department (MH-PDD).

Methods

In this retrospective prevalence-based study, healthcare accesses of 331 patients with dual diagnosis being treated at the MH-PDD were obtained through a linkage of 7 administrative databases (Tab. I). All adult patients with at least one contact with the MH-PDD are recorded in the database, which includes demographic characteristics, the ICD-9-CM diagnosis and information on each type of service provided. The ICD-9-CM are grouped into diagnostic categories, defined in Table II. Costs were assigned using different drivers and cost objects (national, regional tariffs and ad hoc estimated MH costs).

Results

The study population consisted of 331 patients with a diagnosis of substance abuse and a mental health disorder who had at least one contact with the MH-PDD in 2013. Patients were 68% male, with a mean age of 45 years and 93% Italian (Tab. III). A large proportion (n = 228, 68.6%) had a > 2 year duration of contact with MH-PDD. The substance of abuse or dependence was alcohol in the large majority (n = 196, 59.2%), followed by drugs (n = 99, 29.9%) and other substances (n = 16, 4.8%). Among the MH-PDD services that patients received, psychiatric-clinical treatment and initial assessment/reassessment and were the most frequent interventions, while vocational training, psychosocial rehabilitation and day center services were uncommon (Tab. IV). Total MH-PDD costs were 867,080€ and costs per patient ranged from 25€ (three psychiatric follow-up visits) to 239,125€ in one outlier patient with psychosis and alcohol use disorder, who received 1,100 MH services and 22 home visits (Tab. V). The median cost was 279€ and the mean cost 2,620€. The amount of non-MH-PDD costs almost equaled that of MH-PDD costs, and was largely ascribable to hospitalization in psychiatric and non-psychiatric wards (Fig. 1). Overall costs per patient ranged from 45€ (first MH-PDD assessment) to €239,287 (the same outlier patient, with 1,100 MH services, 22 home visits and 4 specialty services). Median cost was 1,423€, mean cost 5.381€ and the overall total was 1,780,958€. Classification of patients in cost tertiles revealed that one third of patients accounted for 88.1% of overall costs (Fig. 2). The costs borne by the MH-PDD increased from the first to the third tertile while the vice versa was true for non-MH-PDD costs. Median costs by psychiatric diagnosis ranged from 205€ for other mental disorders to 2,085€ for dementia (Tab. V, Fig. 3).

Conclusions

An integrated healthcare system based on outpatient management of patients with substance abuse/dependence costs less than other countries with different healthcare systems. In the absence of outcome data, cost-effectiveness studies are warranted.

Key words
Dual diagnosis • Substance use disorder • Costs • Drugs • Alcohol

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Introduction

Individuals with co-occurring mental illness and addiction (the so-called dual diagnosis, DD) comprise at least half of patients in most mental health treatment systems [1-4]. These patients present several challenges to health professionals because of their increased risk of psychiatric relapse, poor medication compliance, violence, suicide, legal problems, high utilization of emergency room or inpatient services, and HIV and HCV infection compared to those with either mental or substance use disorders alone [5-7]. Data reported by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) indicate that in Italy psychiatric comorbidity among drug users in treatment amounts to 22% [8]. No population surveys on this topic were conducted in Italy and available data refer to the treated prevalence in a Local Health Authority (LHA) or in a limited number of drug addiction services [9-12], except for two multicenter studies (ASSALT and CORRAL) focused on identifying prognostic factors associated with alcoholism treatment outcomes and on investigating the history of alcohol treatment and the socio-demographic and clinical variables of patients hospitalized in Italian residential alcohol abuse rehabilitation units for alcohol dependence or abuse [13].

Patients with DD consult both mental health and addiction services, according to the predominant problem, with a risk of treatment fragmentation [14].

The recommended organizational response for DD patients is nowadays an integrated and 'managed care' model, in which a single health professional acts as case manager, by translating the 'unique' needs of the patient and ensuring a good coordination of psychiatric and addiction services [7]. Although evidence on the efficacy of an integrated service model over standard and non-integrated ones is weak and inconsistent [15], the integrated model is widely accepted as an evidence-based practice for DD patients and is endorsed by clinicians and managers because it improves some outputs (e.g. lowers staff-to-patient ratios) [16]. Over the last three decades, innovative ways of liaison between psychiatry and drug addiction services have suggested that integrated care tailored on DD patients' needs may reduce ambulatory consultations, long-term care, and hospital admissions [17].

The complexity of this group of patients raises many questions regarding the effectiveness of the combination and intensity of the available interventions. The expected outcomes depend on patient characteristics and on the quality and amount of treatment they received. Although there is no consensus on the intensity of treatment that DD patients would require, some evidence exists regarding the determinants of intervention effectiveness. For instance, severity and duration of addiction are strong predictors of lower recovery rates. In fact, patients with moderate to high severity of illness have poorer health, social and legal outcomes [18]. Moreover, severe patients are more likely to receive inpatient care besides community care and drug treatment [19]. Despite the lack of clear evidence on a dose-response relationship, several studies suggest a strong positive association between severity of DD related problems and the total amount and intensity of care required. A review of interventions and their effectiveness is provided by the NICE guidelines [20].

Costs of illness studies on mental health and substance use disorders show higher annual and lifelong costs for DD patients, independently of the mental health financing policies [21-24]. The aim of this study is to estimate the direct medical costs of patients with dual diagnosis by quantifying the resource consumption and the costs borne by an Italian LHA to treat this special case mix. This will be done by analyzing both the patterns of access and the costs of services provided by the Mental Health and Pathological Dependences Department (MH-PDD) and those generated by the use of other services (hospital, emergency, outpatient services, domiciliary care, long-term rehabilitation and pharmacy) in a given year. The specific focus on DD patients is chosen because their access to care is voluntary, likely to involve several services due to complex health needs related to the psychiatric and substance abuse problems.

Material and methods

Overview

This is a retrospective, prevalence-based study consisting of patients with substance abuse/dependence who had at least one contact with MHS in 2013.

Population studied and services organization

We included all patients admitted to the MH-PDD in 2013 with a diagnosis of substance abuse and a co-occurring psychiatric condition or referred to the mental health services for a psychiatric assessment. The MH-PDD consists of two units: the MH unit provides services for patients with psychiatric disorders, and the PD unit, provides services for patients with pathological dependences. Usually, when patients have both conditions, the main clinical problem is a psychiatric disorder and the substance abuse or dependence does not require intensive management in PDD, patients are treated at the MH services. However, in order to ensure continuity of care and compliance of patients with co-occurring psychiatric disorders and substance abuse/dependence, the healthcare services in the study area have implemented a specific clinical pathway with a shared management of patients between MH and PDD services. Patients with complex clinical or social problems may receive specific treatments delivered in dedi-

cated facilities. Community day hospital interventions include drip, and parenteral or oral drug administration to patients in an acute illness phase, as an alternative to hospitalization. They are carried out in non-hospital facilities. Day center activities are daytime group rehabilitative therapeutic activities for patients with severe mental illness. Socio-rehabilitation consists of individual or group daytime activities, tailored to the needs of care or rehabilitation of patients with a high degree of disability / chronicity. Socio-rehabilitation activities are aimed at providing patients social and/or economic support, or helping them reacquire daily activity skills and interpersonal functioning. They are carried out outside day centers or day hospital [25].

Data source

Healthcare accesses to mental health services, outpatient care provided by other community services, hospital care, home care and drug supply were obtained through a record linkage of 7 administrative databases using the unique anonymous patient identifier. The data sources to calculate healthcare services utilization and costs are provided in Table I.

TABLE I. *Summary of cost objects by service domain, source of information and methodology.*

Service domain	Type of service	Costing unit	Monetary value	Method	Source
MH-PDD	MH unit services (45 services)	Per service	Unit Cost given number and type of health professionals involved	Av. Unit cost, bottom-up approach	SISM
Acute inpatient care by the Hospital Trust (SPDC)	Acute in patient care	Hospital episode (discharge)	Regional tariffs applied to specific DRG considering LOS	Charges	SDO
Community intensive hospitalization (public or private)	Sub-acute inpatient care and rehabilitation	Hospital episode (discharge)	Regional tariffs applied to specific DRG, for LOS (eventual integration pro die if hospitalization lasts longer)	Charges	SDO and SDRES
Inpatient acute	Hospital services (public/private)	Hospital episode (discharge)	DRG charge reported by the hospital (trimmed, adjusted per LOS, per type of hospital)	Charges	SDO and SDRES
Emergency	Public hospital emergency admissions	Per admission (short observation and discharge)	DRG charge reported by the hospital, only the episodes not followed by hospitalization were valuated	Charges	PS
Homecare*	Home care provided by GPs and LHA homecare nurses for health problems other than MH and SA	Per visit		Av. Unit cost Top-down approach 98,49€ per visit	Model LA for ADI services and ADI activity database
Out-patient ambulatory services	Non Mental Outpatient medical Service	Per consultation (visit, rehab session, therapy)	ASA regional charges 2013	Charges	ASA
Out-patient ambulatory services	Diagnostic services	Lab tests	ASA regional charges 2013	Charges	ASA
Pharmaceutical expenditure	Drug supply (direct supply and self-purchased)	Per prescription	Drug regional prices (different VAT, and wholesaler and retailer margins apply for FED and AFT)	Charges	FED and AFT

**This is estimated by taking the total COA cost for 'home care' and dividing it by the number of home visits delivered in 2013. This method was used as no reliable information on the length and type of visit was available. Once excluded the direct healthcare costs (drugs supplied at home are recorded in the FED) the average unit cost per visit is 98.49€ and it encompasses the payment provided to GPs for participating in this activity and the LHA costs to run and support this activity.*

TABLE II. *ICD-9-CM diagnostic categories included in the study.*

ICD-9-CM codes	Diagnostic cluster
295.xx, 297.xx, 298.xx, 299.1x, 299.9x	Psychotic disorders
296.0x, 296.1x,296.4x, 296.5x, 296.6x, 296.23, 296.24, 296.33, 296.34	Bipolar affective disorder
311 and residual 29	Depressive disorders
300.xx	Anxiety
301.xx	Personality disorders
	Substance abuse and dependence
291.xx, 303.xx	Alcohol
292.xx (excluding 292.8), 304.xx (excluding 304.1), 305.xx (excluding 305.4x)	Drugs
305.4x 304.1x, 292.8	Other substances
290.xx, 293.xx, 294.xx	Dementia
302.xx, 306.xx-310.xx, 312.xx, 316-319	Other mental health disorders
309.xx	Adjustment disorder

Note: the diagnostic category "Other mental health disorders" (ICD-9-CM codes 302.xx, 306.xx-310.xx, 312.xx, 316-319) includes intellectual disabilities, adjustment disorders and other miscellaneous disorders.

The mental health information system (SISM) was implemented in 2005 for administrative and epidemiological purposes. All adult patients with at least one contact with the MH-PDD are recorded in the database, which includes demographic characteristics, the ICD-9-CM diagnosis and information on each type of service provided. The ICD-9-CM are grouped into categories, defined in Table II.

The hospital discharge record (HDR) database includes demographic characteristics, admission and discharge dates, main diagnosis, up to five secondary diagnoses, up to six interventions (identified using the ICD-9-CM coding system) and discharge status. HDRs are sent by public and private hospitals to the Regional Authority and on a regular basis from the Regional Authority to the Ministry of Health after data quality control. Since 1995, the diagnosis-related group system has been systematically used to allocate funds to hospitals and to monitor quality of care and outcomes.

Residential mental healthcare discharge record database is active since 2008 and includes mandatory information on patients discharged from accredited non-profit or private facilities, that is, admission and discharge dates, main diagnosis and discharge status. Accredited facilities are private hospitals where fees are reimbursed by the Italian National Health Service if the patient is resident in Italy.

The outpatient pharmaceutical database includes information on patients' gender and age, prescriptions (substance name, ATC System code-V.2013, trade name, date of prescription filling and number of packages) and prescribers. This register includes drugs reimbursed by the healthcare system that are prescribed by the general practitioner or a specialist, or directly delivered by the hospital pharmacies. Each region tracks the drug prescriptions in the AFT (Outpatient Pharmaceutical Supply) and FED (Direct Supply Drugs) databases (Tab. I).

The emergency room database records accesses in Emilia-Romagna region, patients' gender and age, residence, citizenship, number and type of services provided to the patients, main and secondary diagnoses, waiting time, severity of patient, type of trauma, transfer to hospital unit (if applicable).

The specialist outpatient services database includes laboratory tests, diagnostic, therapeutic and rehabilitation services and specialty visits.

The home services database was established in 2002, and includes information on the care pathway for each patient: demographic characteristics, social and health characteristics, information about the episode of home care delivered, the total number of accesses to address made by the different professionals during the take-over period, the presence of social and health care protection, and patients' needs.

Demographic information was retrieved from the SISM database. The methods used to calculate costs are described in detail elsewhere [25]. In short, gross hourly cost was estimated for each service provided by the MH-PDD in 2013 up to a maximum of 4 health professionals involved in each activity, then multiplied by the duration of the service. The duration in minutes was set to the validated standard time when provided in the main setting, otherwise a weight varying between 1.25-1.50

was applied if provided in a secondary location (home, residential facility, prison).
The study was carried out in conformity with the regulations on data management of the Regional Health Authority of Emilia-Romagna, and with the Italian law on privacy (Art. 20-21, DL 196/2003) (http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1115480, published in the Official Journal no. 190 of August 14, 2004) which explicitly exempts the need of ethical approval for anonymous data (Preamble #8).
Data were anonymized prior to the analysis at the regional statistical office, where each patient was assigned a unique identifier. This identifier does not allow to trace the patient's identity and other sensitive data. As anonymized administrative data are used routinely for health-care management no specific written informed consent was needed to use patient information.

Costs

The ultimate cost unit in this study is any contact or access with the MH-PDD and any other LHA unit in 2013. The aggregation of contacts by user allows subsequently an estimation of aggregated costs per-case, per diagnostic cluster and MH-PDD clinical pathway. For outpatient 'accesses' occurred outside the MH-PDD, including laboratory tests, specialty visits and rehabilitation, regional tariffs are applied.
Hospitalization and day-hospital costs are based on regional tariffs applied to specific DRG and on the length of stay. The medication costs are borne by the National Health Service (NHS) (with a co-payment by patients with high income). The drug retail prices are the NHS list prices, which are the prices at which the pharmacies are reimbursed. Medication price is set through negotiations between the Italian Medicines Agency and pharmaceutical companies.

Data analytic procedures

Categorical data were summarized as absolute and percentage frequencies and continuous variables as mean ± SD or median and range. χ^2 was used to compare frequencies among groups and t-test to compare means between groups. Pooled df were used for t-tests comparing groups with unequal variance.

Results

Patient characteristics

The study population consists of 331 patients with an ICD-9-CM diagnosis of substance abuse and a mental health disorder, who had at least one contact with the MH-PDD in 2013. They comprise 4.4% of all patients recorded in the mental health services database in 2013.
Patients' characteristics are provided in Table III. They

TABLE III. *Patients' demographic and clinical characteristics (n = 331).*

Sex (n, %)		
Males	225	68.0
Females	106	32.0
Age (mean, SD)	45.3	13.3
Citizenship (n, %)		
Italian	308	93.1
Other	23	6.9
Education (n, %)		
Primary	167	69.9
Secondary	58	24.3
Tertiary	14	5.8
Missing	92	
Employment status (n, %)		
Unemployed	126	97.7
Employed	3	2.3
Missing	202	
Living arrangement (n, %)		
Own family or cohabiting	37	15.9
Alone	186	79.8
Health social housing	10	4.3
Missing	98	
Diagnosis (n, %)		
Psychosis	37	11.2
Bipolar disorder	6	1.8
Depression	54	16.3
Anxiety	25	7.6
Dementia	6	1.8
Personality disorder	123	37.2
Other MH disorders*	4	1.2
Adjustment disorder	21	6.3
Substance of abuse/dependence (n, %)		
Alcohol	196	59.2
Drugs	99	29.9
Barbiturates	16	4.8
Polysubstances	21	6.3
Contacts with MHS (Mean, SD)		
Years	8	7.1
Days	16	28.0

**The diagnostic category "Other mental health disorders" (ICD-9-CM codes 302.xx, 306.xx-310.xx, 312.xx, 316-319) includes intellectual disabilities, adjustment reactions and other miscellaneous disorders.*

were 68% male, with a mean age of 45 years and 93% Italian. A large proportion (n = 228, 68.6%) had a > 2 year durations of contact with MH-PDD, denoting an established relationship with mental health services. The substance of abuse or dependence was alcohol in the large majority (n = 196, 59.2%), followed by drugs (n = 99, 29.9%) and other substances (n = 16, 4.8%), including barbiturates, sedatives, hypnotics or anxiolytics. Twenty-one patients (6.3%) used multiple substances.
Compared with the rest of patients recorded in the 2013 SISM database 25, the 331 patients of the present study were more frequently male (68% vs 40.3%, $\chi 2$ = 99.9, df = 1, p < .001) younger (mean ± SD 45.3 ± 13.3 vs 51.9 ± 17.1, t-test = 8.6, pooled df = 381, p < .001), single (65% *vs* 53.7%, $\chi 2$ = 11.6, df = 1, p = .001), unemployed (25.7% *vs* 12.5%, $\chi 2$ = 90.0, df = 1, p < .001) and with a longer contact with mental health services.

Healthcare services use

The percentage of patients receiving each type of MH-PDD services, organized in broad categories is shown in Table IV. Psychiatric-clinical treatment and initial assessment/reassessment and were the most frequent interventions, while vocational training, psychosocial rehabilitation and day center services were uncommon. The pattern of the full range of healthcare services provided out of the MH-PDD (hospital, community, home, prison services and drug administration) is shown in Table V.
Outpatient medical services (such as specialty visits, diagnostic and laboratory services) were the most frequently provided (82% of patients). Nearly three quarters of patients received drug prescriptions and more than a half had an ER access. Only 90 patients were hospitalized, for a total of 1,524 days, mostly in non-psychiatric wards. Home visits were provided only to 8 patients, for a total of 402 accesses.

Costs of MH-PDD and of other health care services

Total MH-PDD costs were 867,080€ and costs per patient ranged from 25€ (three psychiatric follow-up visits) to 239,125€ in one outlier patient with psychosis and alcohol use disorder, who received 1,100 MH services and 22 home visits. The median cost was 279€ and the mean cost 2,620€, underscoring that the use of the mean may be misleading to summarize costs per patient, when the cost distribution is very skewed and includes important outliers, as is the case in the present study. Notably, the amount of non-MH-PDD costs almost equaled that of MH-PDD costs, and was largely ascribable to hospitalization in psychiatric and non-psychiatric wards (Fig. 1).
Overall costs per patient ranged from 45€ (first MH-PDD assessment) to €239,287 (the same outlier patient, with 1,100 MH services, 22 home visits and 4 specialty services). Median cost was 1,423€, mean cost 5.381€ and the overall total was 1,780,958€. Classification of patients in cost tertiles revealed that one third of patients accounted for 88.1% of overall costs (Fig. 2). The costs borne by the MH-PDD increased from the first to the third tertile while the vice versa was true for non-MH-PDD costs. Comparison of patients' characteristics among tertiles revealed that the gender and age distri-

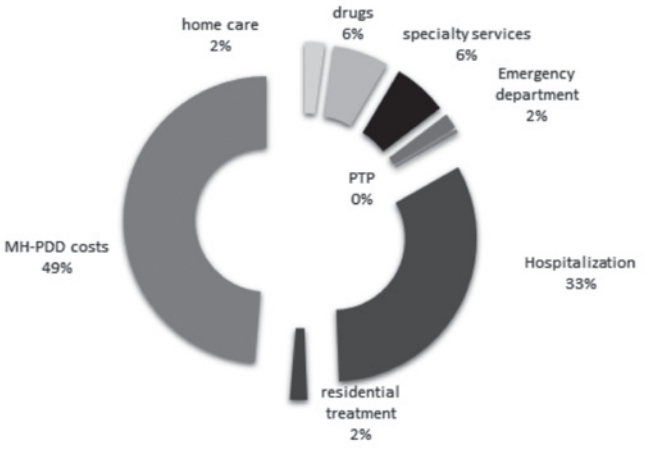


FIGURE 1. *Health care costs for MH-PDD and non-MH-PDD services.*

TABLE IV. *Patients receiving MH-PDD services by pathway.*

	N	%	Mean	SD	95% CI		Median	Min	Max
First contact/reassessment	175	52.87	2.33	2.04	2.02	2.63	2	1	13
Vocational training	11	3.32	6.58	5.37	3.17	9.99	5	1	18
Psychiatric treatment	217	65.56	27.45	34.32	22.88	32.02	18	1	329
Day center	14	4.23	246.57	328.65	56.81	436.33	119	20	1073
Community DH care	5	1.51	304.60	230.20	18.77	590.43	387	7	593
Socio-rehabilitation	17	5.14	40.06	60.00	9.21	70.91	23	2	248

bution was similar (data not shown). However, less costly patients had been in contact with MH-PDD for a median of 3.3 years vs 7.4 and 8.1 in the second and third tertiles (Kruskal-Wallis test 12.5, p = 0.002). Moreover, patients in the second tertile were more likely to have a diagnosis of psychosis (χ^2 = 8.8, p < 0.05) or bipolar disorder (Fisher exact test, p = 0.019) compared with those of the first tertile.
Median costs by psychiatric diagnosis ranged from 205€ for other mental disorders to 2,085€ for dementia (see Table V and Figure 3 for details).

Discussion

To our knowledge, this is the first study to investigate costs and utilization of services by patients with dual diagnosis in a large area of a country with a universal healthcare system. An Italian study carried out in Lombardy region and using administrative databases for the year 2010 reported a higher consumption of healthcare resources among patients with dual diagnosis compared with patients with mental health problems, but did not estimate the associated costs [26].

We used a previously applied methodology to estimate the direct costs of patients being treated by community mental health services [25].
Consistent with epidemiological data on substance use disorder, patients in our population were mostly male, unemployed and single, with a predominant diagnostic pattern including alcohol drug use associated with personality disorders [27,28].
Our results show that the annual costs of patients with dual diagnosis in Italy are lower than in other countries with similar healthcare systems. One study from Norway reported a median individual cost/year of 57,548€ in 2010, which is 40 times higher than ours (median = 1,423€, mean 5,381€) [29]. Other US studies reported adjusted means of 7,400$ per patient in 1998 and 4,757$ per patient in 1996 [28,30]. Our findings are consistent with previous reports that Italy's longstanding tradition of a community-based mental health management, integrating different services in a public-funded universal healthcare system, can lead to lower costs and high quality outcomes for patients [31].
In our study population, one third of patients generated

TABLE V. *Health care accesses and costs of patients.*

	Total patients	Total days/ accesses/ services	Costs (€)			
			Total	Mean	Median	Range
Days of hospitalization	90	1524	554,755	6,164	3952	320-39,125
Psychiatric ward	25	365	115,041	4,602	2,521	315-26,790
Other wards	72	1,159	439,714	6,107	3,891	220-38,810
DH accesses	12	146	25,772	2,148	1,385	125-9,750
ER accesses	186	478	30,591	185	101	23-1,479
Days in residential facilities	8	166	34,712	4,959	5,043	1,470-8,405
Personalized treatment plan (PTP)	110	110	6,768	61,53	60	36-120
Outpatient medical services	270		109,898	413	175	2-37,038
Specialty visits	210		16,458	82	46	18-3,712
Diagnostic serv.	191		25,762	139	83	13-852
Lab serv.	197		21,450	112	61	2-917
Rehabilitation	13		2,069	159	70	14-511
Treatment	76		44,159	581	50	4-33,082
Home visits	8	402	39,593	3.940	886	492-14,281
Prison	48	50				
Psychotropic drug prescriptions	243		55,127	227	98	0.06-2,502
Non-psychotropic drug prescriptions	249		56,671	228	55	1.46-10,756
MH services provided	331	12,168				
MH-PDD costs	331		867,080	2,620	279	25-239,125
Total costs	331		1,780,966	5,381	1,423	45-239,287

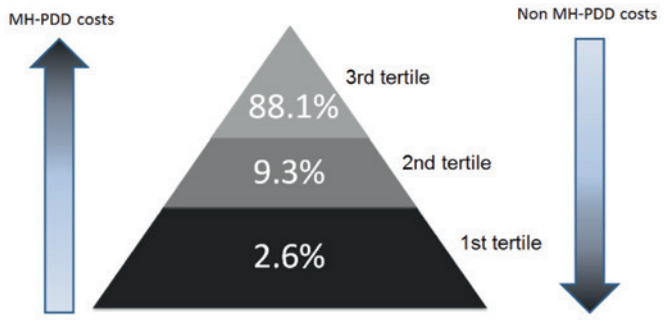
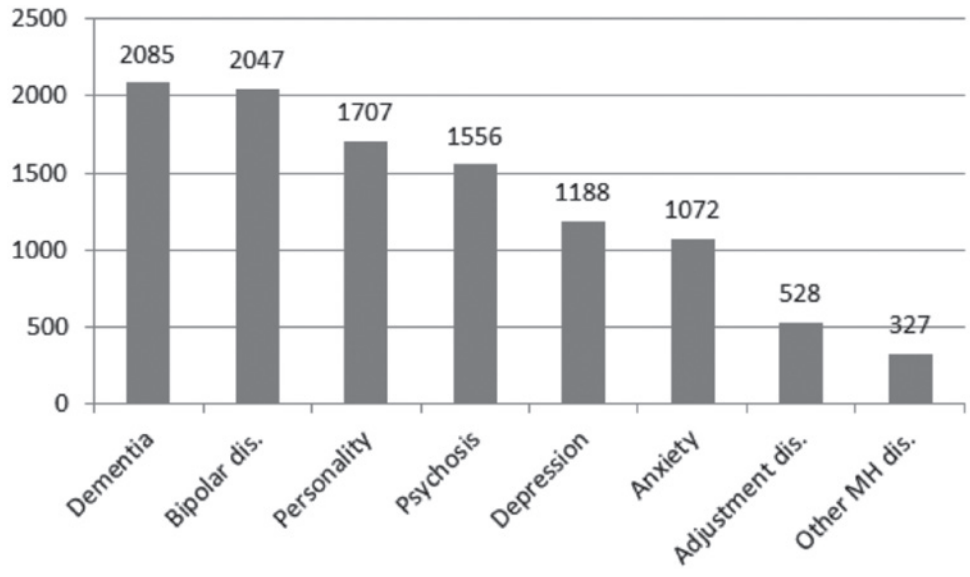


FIGURE 2. *Classification of patients in cost tertiles.*

88% of overall costs, while the bottom two thirds absorbed only 12% of costs. Interestingly, the proportion of the service use differ among the cost tertiles, with a higher use of MH-PDD services by patients in the top tertile. A recent US study, focused on high-cost patients with mental illness or substance use disorder, found that these patients had a more frequent use of non-MH-PDD services compared to patients with other mental disorders or without any mental illness [32].

The presence of an integrated system in Italy, where non-hospital services play a key role to manage patients with mental disorders, may explain in part why even more complex patients, such as the high-cost group, are treated more in MH-PDD than non-MH-PDD facilities, with a subsequent reduction in costs. About a half of costs were borne by the MH-PDD, with a predominance of initial and follow-up assessment visits and psychiatric treatment. One third of costs were due to hospitalizations in psychiatric or non-psychiatric wards, with median hospitalization costs higher in non-psychiatric than in psychiatric wards (3,818 *vs* 2,521€). Patients with at least 7 years of contact with MHS were more costly [25]. This is consistent with Jones et al. [33] who showed that previous psychiatric utilization (and therefore a longer contact with the services) can be an important predictor of costs. Our cost analysis highlighted a high variability across psychiatric diagnoses, with median costs ranging from 205€/year in patients with intellectual disabilities, adjustment reactions and other miscellaneous disorders and 2,085€/year in patients with dementia. Curran et al. [34] found that patients with substance abuse or dependence and dementia are particularly at increased risk of ED accesses, with a subsequent high increase in costs.

Studies from other countries describe a wide range of organizational models, showing that, unlike Italy, patients with DD are often not treated by the same organization. Trocchio et al. [35] report that in Sweden, the substance use treatment system is provided and paid for by municipal social services agencies and the mental health system is delivered through county-specific health care



Note: costs are reported in euro. The diagnostic category "Other mental health conditions" (ICD-9-CM codes 302.xx, 306.xx-310.xx, 312.xx, 316-319) includes intellectual disabilities, adjustment reactions and other miscellaneous disorders.

FIGURE 3. *Overall median costs by diagnosis.*

systems. In the UK drug dependences are treated by Drugs Action Teams or Drug and Alcohol Teams (DATs), while mental health systems provide treatment for patients with psychiatric disorders [36 37].

Recently, a new classification system has been developed for mental health with a primary focus on patient need and severity, in order to introduce a prospective provider payment system. Among the 21 clusters defined, the cluster of patients with DD costs 3.6 times more than that including patients with common mental health problems [38].

In the United States the treatment system for drug dependence and mental health problems is very fragmented and only 12% of people with coexisting mental health and substance use problems receive interventions for both [39]. In conclusion, our results underscore that 'dual diagnosis' is a label used to denote a highly heterogeneous group of patients and that separate approaches should be taken when drug dependence co-occurs with severe mental disorders rather than with common mental disorders, because interventions for these subgroups of patients have different goals, outcomes and costs.

This study has several limitations. First, the study sample is representative of patients with substance abuse who were seen at least once by community mental health services. Patients who sought treatment only at the PDD are not captured by the SISM database and could not be included in the present sample. Second, it is possible that some psychiatric diagnoses are underreported when the predominant problem is alcohol or substance abuse or dependence. This would potentially lead to an underestimation of costs for patients with co-occurring mental health disorders. However, it is unlikely that diagnoses for patients with severe mental illness are not recorded, thereby mitigating this possible bias. Third, the administrative databases used for the present study did not include outcome measures. Although efforts are currently ongoing in Emilia-Romagna region to encourage the collection of the Health of the Nation Outcomes Scales (HoNOS) for specific programs, the use of this outcome for cost-benefits analyses is yet to come. An alternative specific outcome measure for patients with dual diagnosis could be the Addiction Severity Index (ASI) [40]. This structured clinical research interview consisting of relevant problem areas (Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychiatric) has been successfully used in a US nationwide evaluation of the process and outcomes of care for VA patients [18]. In Sweden, ASI it is the key instrument for baseline assessments of individuals presenting with addiction related problems [41]. Still, criticism has been raised about its reliability and validity [42].

Conclusions

Our results indicate that an integrated healthcare system based predominantly on outpatient management of patients with substance abuse/dependence generates lower costs than in other countries with different healthcare systems and healthcare resources are mostly devoted to patients with complex needs. However, in the absence of outcome data, cost-effectiveness studies are warranted.

Conflict of Interest

The authors have no conflict of interests.

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Review

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Mortality in mental disorders: are we approaching to close the gap respect to other medical specialties? The case of schizophrenia

Summary

Objectives

To selectively review data on the effect of antipsychotic treatment on mortality in schizophrenia.

Methods

The authors performed a search of relevant registry-based and population-based studies, systematic reviews and meta-analyses, randomized controlled trials directly or indirectly assessing the impact of antipsychotic treatment on mortality in schizophrenia.

Results

Antipsychotics, particularly long-acting preparations such as paliperidone palmitate, might be beneficial in reducing mortality risk in schizophrenia.

Conclusions

Although data on the effect of antipsychotics on mortality are encouraging, the field of psychiatry is still far from achieving results in line with what observed in other areas of medicine (for instance in oncology and cardiology). Only the implementation of accurate clinical monitoring and a stronger engagement of the medical field in the care of people affected by mental disorders, will overcome the scandal of the underestimation of their physical health problems and the undeniable disparities they meet when specific treatments for physical disorders with an important impact on survival are needed.

Key words

Schizophrenia • Antipsychotics • Long-acting injectable • Mortality • Stigma • Treatment gap • Physical comorbidity

Schizophrenia is a severe and lifelong disorder characterized by periods of largely partial remission alternated with periods of relapse in approximately three-quarters of cases [1]. Approximately 80% of patients relapse within 5 years of the initial episode [2] and symptomatic remission rates, evaluated according to defined stringent criteria, are as low as 23% among chronic patients [3 4]. Schizophrenia is a cause of significant disability [5] due to a frequently impaired functioning [6]. The latter is explained by a highly complex interplay between illness-related variables, personal resources and contextual variables [7 8]. In turn, impaired functioning seems to be the main factor explaining the quite low rate of recovery (14%) found on average among patients affected by schizophrenia [9]. Taking into account these data, the tremendous human, economic and social costs of the illness are not surprising. Schizophrenia has a heavy socio-economic burden worldwide, being the 8th leading cause of disability-adjusted life years (DALYs) in the age group 15-44 years, and accounting for 1.1% of total DALYs and 2.8% of total years lived with disability (YLDs) [11]. The eco-

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nomic burden of the illness has been estimated to range from 0.02% to 1.65% of gross domestic product [12]. In Europe, the annual cost per patient ranges from €533 in Ukraine to €13,704 in the Netherlands [13]. In Italy, the total economic burden has been estimated at €2.7 billion, with 50.5% due to indirect costs and 49.5% to direct costs [14]. Although the economic impact of schizophrenia is remarkable and to some extent quantifiable, the so-called "humanistic burden" caused by subjective suffering, stigma, discrimination and poor quality of life of patients and families, is virtually inestimable [15]. In addition to these undoubtedly high and well-known illness-related problems, the reduction in life expectancy, an extremely serious burden of schizophrenia, seems to have been somewhat overlooked, if not by the scientific literature, certainly by the extended field of medicine and by the public opinion. Indeed, research data show a markedly high physical comorbidity and relevant premature mortality in individuals affected by schizophrenia, with a 15-20 year shorter life expectancy compared to the general population [16]. This gap has been prevalently attributed to natural causes of death, among which appear prominent those attributable, in particular, to cardiovascular diseases [17]. Unhealthy lifestyles, such as smoking, inadequate diet, sedentary habits, lower healthcare fostered by social stigma against people with mental illnesses, drug side effects, and biological factors such as genetic predisposition and accelerated aging have been indicated as determinants of the increasing mortality gap between people affected by schizophrenia and the general population. Indeed, in recent years a 37% increase of the standardized mortality ratio (SMR) has been observed in schizophrenia, with a rise from the 2.2 recorded in pre-1970s studies to the 3.0 of post-1970s reports [18]. At variance with schizophrenia, increased life expectancy has been observed for a number of severe medical conditions including breast cancer [19], HIV/AIDS20, and, in particular, ischemic heart disease and acute myocardial infarction, with mortality for the latter being reduced by 60-80% over the last 30 years in Europe [21 22]. The latter trends are highly impressive when compared to data specifically relating to schizophrenia and other severe mental disorders, which display a much lower decline in mortality from circulatory diseases (from 35% to 42%) than for the general population [23].

It is an acknowledged fact that mortality is the strongest outcome measure in medicine, hence representing a gold standard of clinical performance; however, psychiatry has invariably encountered difficulty in demonstrating the potential efficacy of the therapeutic methods applied in improving this end-point, with the sole exception of the lowering of suicide mortality in schizophrenia due to clozapine [24], and in mood disorders due to lithium salts [25]. The reduction of mortality has long represented a relevant indicator of outcome in mental health, a field where policies and services are evaluated, amongst other indicators, by their effectiveness in reducing suicide rates. Unnatural deaths, however, provide only a partial picture of the life expectancy of a vulnerable population, given that natural causes of death contribute prevalently to increased mortality. The possibility of reducing overall mortality in patients with severe mental disorders, and particularly schizophrenia, has long been questioned, with data collected in recent years (Tab. I) suggesting that psychiatry is gradually closing the gap with other medical specialties. Indeed, data from observational studies have shown that the use of antipsychotics is associated with a lower mortality in treated patients [26-34], compared to untreated individuals. Further, evidence emerging from meta-analyses and systematic reviews of randomized controlled trials (RCTs) shows lower mortality rates during antipsychotic treatment than during placebo [35-37]. Conversely, a recent meta-analytic study investigating long acting injectable antipsychotics (LAI) reported no difference versus placebo in the incidence of all-cause death and death due to suicide [38]. However, in a subgroup meta-analysis of only short duration RCTs (≤ 13 weeks), LAIs exhibited a lower incidence for all-cause deaths compared to placebo [38]. It should be noted that the increasing mortality gap observed in schizophrenia has been partly attributed to side effects of antipsychotics, with particular reference to induced weight gain and metabolic syndrome and the consequent increased of cardiovascular risk [39]. Strong support was provided to the notion of a beneficial effect of antipsychotic treatment on mortality by a very recent prospective study of more than 29.000 patients affected by schizophrenia followed for 5-7 years; the results revealed an approximately 40% lower mortality rate amongst schizophrenia patients taking antipsychotics compared to those who were not receiving these treatments [40]. Moreover, the use of LAI antipsychotics was associated with an approximately 30% lower risk of death compared with oral use of the same medication; extrapolation of these results would correspond to a difference of approximately 10% in absolute risk over a 15-20 year time span [40]. The latter finding suggests that the excessive mortality recorded for patients affected by schizophrenia is more likely associated with a lack of antipsychotic therapy rather than with the presence of antipsychotic treatment. Furthermore, the use of second generation LAIs, in particular paliperidone palmitate, might lower mortality rates in schizophrenia [40]. The time has arrived for psychiatry to overcome premature mortality of people suffering from severe mental disorders such as schizophrenia. Research data tell us that antipsychotics do not exert a

TABLE I. *Effect of treatments on mortality in schizophrenia.*

Authors, year of publication, country, (reference)	Study design	Sample	Main findings
Tiihonen J et al., 2009, Finland [26]	Registry based prospective cohort study	2,230 schizophrenic patients consecutively hospitalized for the first time	During an average follow-up of 3.6 years mortality was markedly raised in patients not taking antipsychotics (Adjusted RR 12.3, 95% CI 6.0 to 24.1) and the risk of suicide was high (37.4, 5.1 to 276).
Tiihonen J et al., 2009, Finland [27]	Registry based prospective cohort study	66,881 schizophrenic outpatients	Long-term cumulative exposure (7-11years) to any antipsychotic. Treatment is associated with lower mortality than is no drug use (HR 0.81, 95% CI 0.77-0.84)
Tiihonen J et al., 2011, Finland [28]	Registry based prospective cohort study	2,588 schizophrenic patients consecutively hospitalized for the first time	Use of any antipsychotic compared with no antipsychotic was associated with lower mortality (adjusted hazard ratio = 0.45, 95% CI = 0.31-0.67).
Tiihonen J et al, 2012, Finland [29]	Registry based prospective cohort study	2,588 schizophrenic patients consecutively hospitalized for the first time	Compared with antipsychotic monotherapy, concomitant use of 2 or more antipsychotics was not associated with increased mortality (HR, 0.86; 95% CI, 0.51-1.44). Antidepressant use was not associated with a higher risk of mortality (HR, 0.57; 95% CI, 0.28-1.16) and was associated with markedly decreased suicide deaths (HR, 0.15; 95% CI, 0.03-0.77). Benzodiazepine use was associated with a substantial increase in mortality (HR, 1.91; 95% CI, 1.13-3.22)
Tiihonen J et al., 2016, Sweden [30]	Registry based prospective cohort study	all individuals 16-65 years of age with a schizophrenia diagnosis (n = 21,492)	Compared with no exposure, both moderate (adjusted hazard ratio = 0.59, 95% CI = 0.49-0.70) and high (adjusted hazard ratio = 0.75, 95% CI = 0.63-0.89) antipsychotic exposures were associated with substantially lower overall mortality. Moderate antidepressant exposure was associated with a lower mortality adjusted hazard ratio (0.85, 95% CI = 0.73-0.98), and high exposure, even lower (adjusted hazard ratio = 0.71, 95% CI = 0.59-0.86). Exposure to benzodiazepines showed a dose-response relationship with mortality (hazard ratios up to 1.74 [95% CI = 1.50-2.03])
Torniainen M et al., 2015, Sweden [31]	Registry based prospective cohort study	All individuals with schizophrenia diagnoses before year 2006 (n = 21,492), aged 17-65 years, and persons with first-episode schizophrenia during the follow-up (n = 1,230)	The highest overall mortality was observed among patients with no antipsychotic exposure (hazard ratio [HR] = 6.3, 95% CI: 5.5-7.3), followed by high exposure (> 1.5 DDD/day) group (HR = 5.7, 5.2-6.2), low exposure (< 0.5 DDD/day) group (HR = 4.1, 3.6-4.6), and moderate exposure (0.5-1.5 DDD/day) group (HR = 4.0, 3.7-4.4) The highest excess overall mortality was observed among first-episode patients with no antipsychotic use (HR = 9.9, 5.9-16.6)
Baandrup L et al., 2010, Denmark [32]	Population-based nested case-control study	27,633 patients with ICD-8- and ICD-10-diagnosed schizophrenia or other mainly non-affective psychoses aged 18-53 years	Risk of natural death did not increase with the number of concurrently used antipsychotic agents compared with antipsychotic monotherapy (no antipsychotics: adjusted odds ratio[OR] = 1.48 [95% CI, 0.89-2.46]; 2 antipsychotics: OR = 0.91 [95% CI, 0.61-1.36]; 3 or more antipsychotics: OR = 1.16 [95% CI, 0.68-2.00])

continue

continue Table I.

Authors, year of publication, country, (reference)	Study design	Sample	Main findings
Crump C et al., 2013, Sweden [33]	Registry based prospective cohort study	8,277 patients with schizophrenia, followed for 7 years (2003-2009) for mortality and co-morbidities diagnosed in any outpatient or in-patient setting nation-wide	Patients affected by schizophrenia had an elevated mortality from ischemic heart disease (adjusted hazard ratio for women, 3.33 [95% CI = 2.73-4.05]; for men, 2.20 [95% CI = 1.83-2.65]) and cancer (adjusted hazard ratio for women, 1.71 [95% CI = 1.38-2.10]; for men, 1.44 [95% CI = 1.15-1.80]). Lack of antipsychotic treatment was associated with elevated mortality
Vanasse A et al., 2016, Canada [34]	Retrospective cohort study using administrative data	18,869 adult patients with SZ and starting antipsychotic drugs between January 1998 and December 2005	Quetiapine and not using any antipsychotics were associated with an increased risk of mental and physical health events as compared to other drugs
Baxter AJ et al., 2016, International study [35]	Meta-review of 16 systematic reviews of controlled studies		Antipsychotic and antidepressant medications had some protective effect on mortality, subject to treatment adherence
Khan A et al., 2007, USA [37]	Review of FDA safety data from clinical trials conducted from 1982 to 2002	16,791 adult patients with schizophrenia	The mortality rate for patients assigned to placebo treatment was significantly higher ($p < 0.05$) than for either the investigational antipsychotic (OR = 0.23, 95% CI = 0.13 to 0.45) or the active control group (OR = 0.19, 95% CI = 0.08 to 0.45)
Khan A et al., 2014, USA [38]	Review of FDA safety data from clinical trials conducted from 1990-2011	92,542 adult patients with a diagnosis of schizophrenia, depression, bipolar disorder, anxiety disorders, or attention-deficit/hyperactivity disorder	Compared with the general adult population, patients with schizophrenia had the highest mortality risk (3.8-fold increase), followed by patients with depression (3.15-fold increase) and bipolar disorder (3.0-fold increase). The mortality risk was not increased when patients were assigned to psychotropic agents rather than placebo except for heterocyclic antidepressants
Kishi T et al., 2016, Japan [39]	Categorical meta-analysis of 52 RCT	17,416 patients with schizophrenia	Neither pooled nor individual LAI-Aps differed from the placebo regarding the incidences of all-cause death (pooled LAI-APs: RR = 0.64, p = .37) and death due to suicide (pooled LAI-APs: RR = 0.98, p = .98). Only short-duration RCTs (≤ 13wk), pooled LAI-APs exhibited a trend toward lower incidence of all-cause death than placebo (RR = 0.29, p = .08)
Taipale H et al, Sweden, 2017 [40]	Registry based prospective cohort study	All patients aged 16-64years with schizophrenia in Sweden (n = 29,823 in total; n = 4,603 in the incident cohort)	The lowest cumulative mortality was observed for second generation (SG) long-acting injection (LAI) use (7.5%). Adjusted hazard ratios (aHRs) compared to SG LAI use were 1.37 (95%CI 1.01-1.86) for first generation (FG) LAIs, 1.52 (1.13-2.05) for SG orals, 1.83 (1.33-2.50) for FG orals, and 3.39 (2.53-4.56) for nonuse of antipsycotics. The lowest mortality was observed for once-monthly paliperidone LAI (0.11, 0.03-0.43), oral aripiprazole (0.22, 0.15-0.34), and risperidone LAI (0.31, 0.23-0.43). In pairwise comparison, LAIs were associated with 33% lower mortality than equivalent orals (0.67, 0.56-0.80)

class-specific effect on mortality. Indeed, it seems that Lai preparation of paliperidone might have a distinct impact on this relevant outcome. However, even if used optimally, antipsychotics alone are likely not sufficient in modulating mortality risk in schizophrenia. As clinicians we must pay a greater attention to prevention through interventions on lifestyles as well as through an accurate monitoring of the physical health of our patients. But, again, even this is not enough. Taking care of the health of people with mental disorders is not just the focus of psychiatrists. We do need help from specialists in the other areas of medicine. This implies that we should do our best to overcome their fears and prejudices toward the mentally ill. The new frontier is to engage the rest of the medical field in the care of people affected by mental disorders, in order to overcome the scandal of the underestimation of their physical health problems and the undeniable disparities they meet when specific treatments for physical disorders with an important impact on survival are needed [41-43].

Conflict of Interest

BC participated as a consultant in scientific boards and as a speaker in industry sponsored courses or symposia supported by Janssen Italy, Lundbeck Italy, Otsuka Italy, ACRAF Angelini ; FP participated as a speaker in Industry sponsored courses or symposia supported by Janssen Italy and Otsula Italy. MM and MGO declare no conflict of interest

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Autism spectrum disorder presenting with acute anorectic symptomatology: a diagnostic challenge

Summary

An increasing empirical evidence supports a relationship between autism spectrum disorder (ASD) and anorexia. Higher autistic traits are reported in anorexia and a subgroup of adolescent females with anorectic symptomatology could receive an ASD categorial diagnosis. In this case report of a 12-year-old female, we present clinical challenges in the recognition and diagnosis of ASD during hospitalization for anorectic symptomatology: ASD assessment during hospitalization did not support the diagnosis, while another ASD assessment one year later supported the diagnosis, reflecting a changing clinical picture in comparison with that predominant during the anorectic period. In conclusion, the phase of illness and the setting of assessment may influence the detection of a suspected underlying ASD in presence of an acute anorectic symptomatology.

Key words

Autism spectrum disorders • Anorexia • Hospitalization • Camouflage

Introduction

Given the higher prevalence of Autism Spectrum Disorders (ASD) in males [1], descriptions of clinical phenotypes of ASD may present a gender bias, with female phenotypical features possibly under-recognized and under-diagnosed [2]. In this perspective, two recent empirical evidences began to fill the gap on the clinical knowledge about specific phenotypic features of ASD females, especially in those high-functioning: 1) "social camouflaging", i.e. coping strategies for use in social situations, including explicit techniques to appear social competent and to prevent others from seeing own social difficulties [3 4]; 2) an association between ASD features and anorectic symptomatology, both at dimensional and at categorial levels: from a dimensional perspective, there is an emerging evidence that anorectic female subjects have more severe autistic traits in comparison with typical controls in relation to social skills, communication and flexibility [5], as resulting by a recent meta-analysis of the Autism-Spectrum Quotient in anorexia [6]; from a categorial perspective, there is also an emerging evidence that diagnostic tools adopted for ASD, as the Autism Diagnostic Observation Schedule, 2nd Edition (ADOS-2), in clinical samples of adolescent anorectic females may reveal previously unrecognized ASD, at least in measure of 10% of assessed subjects [7-9].

In this case report we present clinical challenges in the recognition and diagnosis of ASD presenting with an acute anorectic symptomatology, suggesting that the clinical course and a longitudinal assessment may facilitate this goal.

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Case report

NR, a 12-year old female, underwent attention at a secondary mental health service for children and adolescent due to an acute onset of restrictive eating behavior, that in few months caused a weight loss of about 10 kg. Lack of insight and of collaboration, and a life-threatening Body Mass Index (BMI) of 11.5 (weight: kg 23.2), indicated the need of hospitalization in a specific pediatric eating disorder ward. NR was hospitalized from March to June 2016 for a total of 99 days, with a BMI at discharge of 16.9 (weight: kg 33.9). The lack of collaboration with clinicians and of adherence to the specific eating program persisted during the first month of hospitalization; then, the introduction of a pharmacological therapy (fluoxetine 20 mg/die since day 31 plus olanzapine 2.5 mg/die since day 46) gradually induced a good adherence, in the second half of hospitalization. Despite its initial lack of collaboration, NR rapidly adjusted to hospitalization, without apparent suffering from being apart from parents.

The developmental history was suggestive of a possible unrecognized ASD: since infancy, repetitive rituals with dolls for falling asleep, rigid locations for toys in her room, and refusal of removing any stuff owned since early years (e.g. drawings, toys, clothes); at social level, poor eye contact, difficulties in socialization with peers and lack of close relationships. Growing up rituals of order were extended to the whole house, that was systematically tidy up when coming back from school; she also presented lack of interest for clothes and personal hygiene, with irritable mood and frequent temper tantrums. School achievement has always been on average, with a progressive increase of competitiveness. Considering improved collaboration, an assessment for ASD was performed during hospitalization with the ADOS-2 Module 3 [10] and the Autism Diagnostic Interview Revised (ADI-R) [11], but the diagnostic hypothesis was not confirmed by both instruments. After discharge, eating behavior progressively returned to premorbid usual habits, with maintenance of weight; at the same time behavioral features progressively changed in the subsequent year, with increasing distress in parents: in social contexts NR exhibited severe difficulties to grasp social rules and to manage relationship with peers. For these worsening features, a second assessment in a tertiary ASD service was performed in November 2017 (age 14) with both standard instruments (ADOS-2 Module 4 and ADI-R) and scales for high-functioning conditions: Krug Asperger's Disorder Index [12], score 107; Gilliam Asperger's Disorder Scale [13], score 103; Childhood Autism Rating Scale Second Edition – High Functioning Autism [14]: score 34.5): in this occasion, all instruments converged to support an ASD diagnosis.

Discussion

This clinical case presents hints about the phenomenology of adolescent females with high-functioning ASD. In this case we could consider that typical language development, mild expressions of restricted and repetitive patterns of behavior and activities (with absence of reported stereotypies) as well as average school achievement could have masked the underlying condition of ASD, whose phenotypic expressivity began to be more pronounced in terms of deficits in social interactions toward preadolescence. The increasing subjective distress induced by increasing difficulties in adjustment across multiple contexts, coupled with an ASD structure, may have facilitated a phenotypic expression in terms of an anorectic symptomatology. The acute and severe anorectic manifestation, characterized by a rapid weight loss associated with restrictive eating (with need of hospitalization) as well as by a rapid resolution, doesn't represent the common clinical course of anorexia; therefore, these atypical eating symptoms could be framed within a more general and unrecognized underlying psychopathological picture, as ASD [8 9] or schizophrenia spectrum disorders [15]. For example, ASD traits of perfectionism and rigid thinking, if associated to restrictive eating, could induce similar acute and severe manifestations, as well as imperative auditory hallucinations related to eating could have similar effects. The developmental history presented features suggestive of a possible ASD, while features suggestive of schizophrenia spectrum disorders were not evident. Interestingly, in this case, the assessment of ASD with the same instruments (except that for ADOS-2 modules: Module 3 in the first assessment, Module 4 in the second assessment) as inpatient and 16 months later as outpatient had different results in terms of scores and of final diagnosis: absence on ASD in the first case, evidence of ASD in the second case, also supported by other scales for high-functioning conditions (KADI, GADS, CARS-2-HF). Westwood and colleagues [8] reported a similar diagnostic approach (ADOS-2 with patients and the Developmental Dimensional and Diagnostic Interview Short Version for parents) in a sample of 40 females aged between 12 and 18, recruited in an inpatient and day-patient eating disorder center: 21 out of 40 patients score above cut-off on the ADOS-2 suggesting a possible ASD, but only in 4 cases (10% of the sample) also the developmental history as reported by parents was also suggestive of ASD. In our case, the diagnostic mismatch between the first and the second assessment reliably reflects the longitudinal change of the clinical picture, that during hospitalization was polarized on eating disturbance and on lack of insight and collaboration, while thereafter was progressively characterized by evident social deficits and bizarre imagi-

nation. Therefore, in case of a suspected unrecognized ASD condition underlying an anorectic symptomatology with acute and atypical onset, the setting and the timing of assessment may influence the diagnostic process. The assessment during hospitalization may hinder a diagnosis, probably being ASD symptomatic expression attenuated by the hospitalization, and being judgments of parents as well as of the same clinicians polarized (and therefore biased) on the life-threatening behavior of restrictive eating rather than on social deficits. Once returned to usual daily-life contexts, the phenotypic expression of ASD traits may "re-emerge", becoming more clinically evident especially in relation to social situations and social rules, that become more demanding in adolescence. In this perspective, a recent study [16] on young females with recent-onset anorexia reported that those who recovered from anorexia presented more severe impairments in the perception of social stimuli in comparison with those with first-episode anorexia, suggesting that social deficits may be differently expressed along the clinical course of the eating disorder, at least comparing clinical *vs* recovered states.

In conclusion, this clinical case suggests that the phase of illness and the setting of assessment may influence the detection of a suspected underlying ASD in presence of an acute anorectic symptomatology.

Conflict of Interest

The authors have no conflict of interests.

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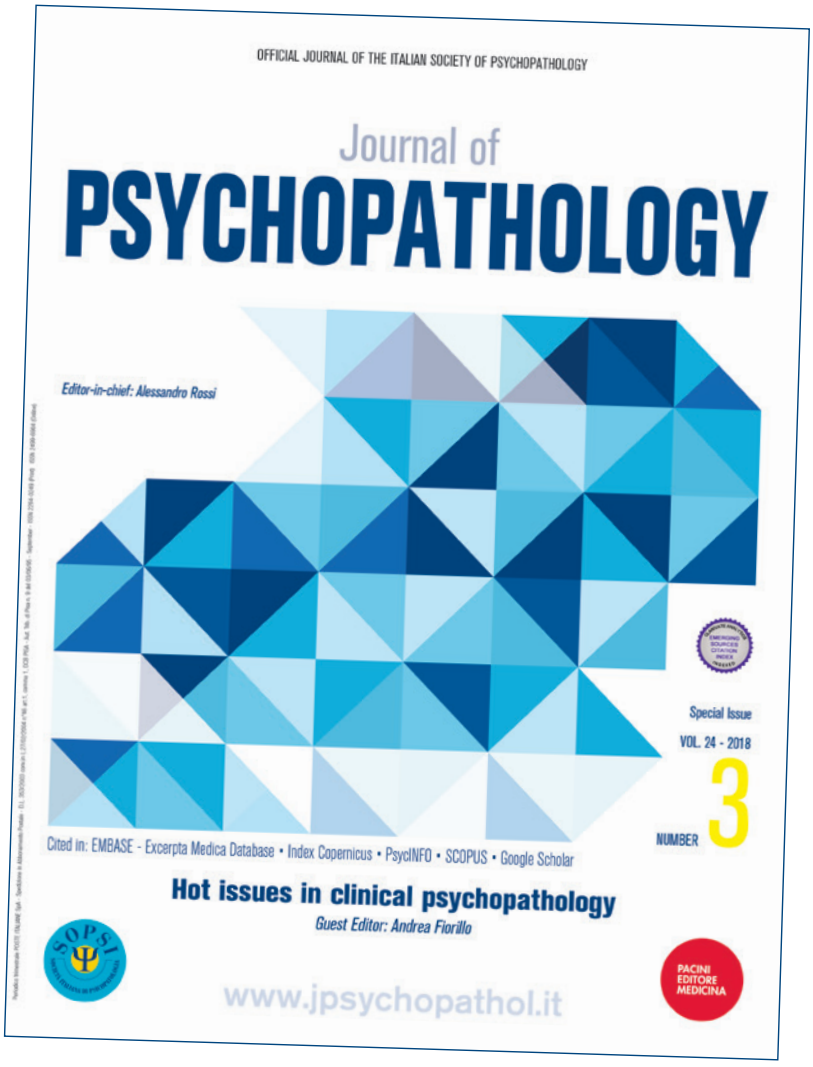

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I disturbi d'ansia in età evolutiva: basi biologiche, presa in carico e trattamento - L. Mazzone

13.00–15.30 **SIMPOSI**

15.45–19.30 **CERIMONIA DI APERTURA**

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Ricchezza, povertà, lavoro - D. De Masi

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10.30–11.15 *Fiducia e ingiustizia epistemica* - P. Fonagy

11.30–12.45 **SIMPOSIO** - MODERATORI: M. Maj, A. Siracusano

Risalire in superfice: Full Functional Recovery

Depressione e Full Functional Recovery - C. Niolu

Full Functional Recovery e nuove strategie terapeutiche - A. Tortorella

13.45–15.15 **SIMPOSIO** - MODERATORI: M. Maj, A. Siracusano

La gestione del paziente con schizofrenia: connessioni, culture, conflitti

Le connessioni dentro e fuori il Dipartimento di Salute Mentale - M. Vaggi

Atteggiamenti, pregiudizi e culture delle terapie long-acting - G. Maina

Conflitti, governance e appropriatezza terapeutica: verso una global mental health - S. De Giorgi

15.30–16.30 **SIMPOSIO** - MODERATORI: A. Rossi, A. Siracusano

Agitazione psicomotoria: inquadramento e strategie di intervento

Inquadramento clinico e psicopatologico dell'agitazione psicomotoria - M. Amore

Agitazione psicomotoria e nuove strategie di intervento - C.Niolu

16.40–17.50 **PRO E CONTRO** - MODERATORE: A. Fagiolini

L'impiego delle sostanze psichedeliche nel trattamento dei disturbi psichiatrici resistenti? - R. Carhart Harris, M. Di Giannantonio

16.40–17.50 **FORUM** - MODERATORE: E. Aguglia

I nuovi sistemi di connessioni e la psicoterapia - D. La Barbera, M. Biondi

18.00–19.30 **SIMPOSI**

Venerdì **23 febbraio**

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LETTURE PLENARIE

MODERATORI: M. Di Giannantonio, S. Galderisi

9.40–10.25 *Sessualità e cervello* - M. Craig

10.30–11.15 *Insight nella psicosi* - J. Parnas

11.30–12.40 **FORUM** - MODERATORE: P. Rocca

Traiettorie di sviluppo e stati a rischio - A. Bechdolf, P. Fusar Poli

11.30–12.40 **FORUM** - MODERATORI: M. Biondi, E. Sacchetti

Origine delle relazioni umane - M. Ammaniti, C. Niolu

13.45–15.15 **SIMPOSIO** - MODERATORI: A. Rossi, A. Siracusano

Efficacia, tollerabilità e funzionamento in schizofrenia: evidenze e implicazioni dalla pratica clinica

Dagli studi registrativi agli studi osservazionali: evidenze a confronto - A. Fagiolini

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15.20–16.50 **SIMPOSIO** - MODERATORI: A. Rossi, A. Siracusano

Schizofrenia: Aspetti di psicofarmacologia e nuove strategie di trattamento

Luci e ombre nella cura delle persone affette da schizofrenia - S. Galderisi

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Sabato **24 febbraio**

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