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# The Structured Interview for Insight and Judgment in Dementia: Development and validation of a new instrument to assess awareness in patients with dementia

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**Abstract**

**Introduction:** Poor insight about their cognitive and functional deficits is highly prevalent in patients with Alzheimer's disease (AD); however, there is a lack of reliable, valid instrumentation to measure this construct. The aim of this study was to develop and validate a semistructured interview to assess insight and judgment in patients with AD and to provide information regarding the assessment of competency and risk in this population.

**Methods:** We validated the Structured Clinical Interview for Insight and Judgment in Dementia (SIJID) in a consecutive series of 124 patients with probable AD. The following psychometric properties were evaluated: internal consistency, test-retest reliability, interrater reliability, and convergent and predictive validity.

**Results:** The SIJID demonstrated high test-retest, interrater reliability and also showed strong discriminant and convergent validity. It showed good predictive validity based on 1-year follow-up information of the patient's clinical outcomes, with a significant association between higher SIJID total scores at baseline, and more severe neuropsychiatric symptoms and more severe caregiver distress at follow-up. Moreover, higher scores of dangerous behaviors at baseline were significantly correlated with a higher frequency of hospitalization and placement in residential care 1 year later.

**Conclusion:** The SIJID is a reliable and valid instrument to assess insight and judgment in patients with AD and is a valuable tool for assessing presence and severity of dangerous behaviors, determining risk, and providing critical information for the assessment of competency.



*Keywords:* Dementia; Insight; Judgment; Assessment; Anosognosia

## 1. Introduction

A large proportion of patients with Alzheimer's disease (AD) have anosognosia (i.e., poor insight) about their cognitive deficits, functional limitations, and behavioral changes [1,2]. Prevalence of anosognosia in AD varies between 20% and 80%, depending on different factors such as the assessment method used, sample characteristics, and severity of dementia [3]. Anosognosia is present in the early stages of AD [4] and has been associated with more severe paranoid ideation, irritability, behavioral disinhibition, agitation [5], dangerous behaviors [6], lack of treatment compliance, and caregiver distress, as compared to AD patients without anosognosia [7]. Dangerous behaviors are particularly important as they represent a potential risk for patients and others and may limit the patient's capacity to

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live independently. In a series of 278 patients with probable AD, our group found that 16% had dangerous behaviors and 84% of this group explicitly denied these behaviors, most having anosognosia [6].

Caregivers are often faced with the dilemma of whether to allow patients to engage in activities with potentially harmful consequences or whether to restrict their autonomy. Furthermore, poor insight is among the most powerful predictors of negative outcomes [7] and may contribute to caregiver burden over and above dementia severity and functional impairment. Thus, the assessment of insight in AD has high clinical relevance, when considering not only the impact of this problem on patients and their family but also the social implications of increased need for medical support, and social, legal, and financial services as well [8].

Current clinical practice rarely includes semistructured interviews for psychological and behavioral problems of AD. The paucity of reliable and valid instruments to assess insight and judgment focusing on risk is a limitation in the clinical care of AD patients [9–11].

During the past 30 years, more than 50 instruments have been designed to assess anosognosia in patients with AD, but many of these lack adequate psychometric information [12–14]. Although most instruments measure insight of deficits for specific cognitive functions, usually memory, they do not provide information regarding more global functioning and/or risks [13,15]. Some instruments are very brief [12,16,17] and do not allow for a sound diagnosis of deficits on insight and judgment. Others were originally designed to assess insight in disorders other than dementia, and the validity of these instruments for use in AD remains unknown [18–20]. The main instruments currently used to assess insight/anosognosia in AD, along with their psychometric attributes, are presented in Table 1.

We developed the Structured Interview for Insight and Judgment in Dementia (SIJID) to examine the patient's performance on a range of basic and instrumental activities of daily living, to assess their current mood and affect, to identify aberrant behaviors, and detect the presence and severity of dangerous behaviors. The SIJID is a semistructured interview that includes questions for both patients and informants and considers information from additional sources such as the patient's clinical records and general practitioner's reports. The aim of the SIJID was to provide reliable and valid information on the patient's level of insight for their physical, psychological, cognitive, and behavioral problems, as well as judgment regarding their capacity to perform basic and instrumental activities of daily living, and the presence and severity of dangerous behaviors, all of which may assist in the assessment of competency. The main aim of this study was to determine the validity and reliability of the SIJID for use in AD and to discuss its potential contribution to the assessment of competency and risk in this patient population.

## 2. Methods

### 2.1. Conceptual framework, structure, and scoring method of SIJID

The SIJID was conceived as an evaluative and predictive instrument to assess insight, judgment, and capacity in patients with AD and to also estimate the risk to the patient as a result of engagement in current or potentially dangerous behaviors. Insight of illness was defined as the ability to acknowledge the presence of symptoms of the illness and the subsequent impact on the patient's physical capacity, emotions, and cognition. Judgment was defined as

Table 1
Summary of psychometric properties of instruments to assess awareness in AD

| Name | Sample | Content validity | Internal consistency | Construct validity | Reliability | |
|---|---|---|---|---|---|---|
| | | | | | Test-retest | Interrater |
| AQ-D [21] | $N = 750$, reliability: 10 | + | + | + | ? | ? |
| AII [22] | $N = 23$ | + | + | ? | 0 | 0 |
| ASPIDD [23] | Pilot study, $N = 10$; total sample, $N = 201$ | + | + | 0 | 0 | 0 |
| AC [24] | Pilot study = 40; reliability, $N = 12$ | + | ? | + | − | ? |
| AMIS [25] | Baseline, $N = 203$; control, $N = 40$ | + | + | 0 | ? | 0 |
| CIRS [26] | $N = 50$; interrater reliability = 25 | ? | + | 0 | 0 | ? |
| DDS [27] | Total sample, $N = 201$ | + | + | + | ? | ? |
| GRAD [28] | Sample, $N = 170$; interrater reliability, $N = 20$ | ? | + | 0 | 0 | ? |
| MARS [29] | Normative data = 236 AD patients and 80 controls | + | + | + | ? | ? |
| MIC [30] | Sample, $N = 79$; reliability = 12, controls = 20 | + | + | ? | 0 | ? |
| SCQ [31] | $N = 45$, reliability = 18 | ? | 0 | 0 | ? | ? |
| SED-11Q [32] | $N = 107$ | ? | 0 | ? | 0 | 0 |

Abbreviations: AD, Alzheimer's disease; AQ-D, Anosognosia Questionnaire for Dementia; AII, Assessment of Impaired Insight; ASPIDD, Assessment Scale of Psychosocial Impact of the Diagnosis of Dementia; AMIS, Awareness of Memory Impairment Scale; CIRS, Clinical Insight Rating Scale; DDS, Dementia Deficit Scale; GRAD, Guidelines for the Rating of Awareness Deficits; MARS, Memory Awareness Rating Scale; MIC, Memory Inventory for Chinese; SCQ, Self Consciousness Questionnaire; SED-11Q, Symptom of Early Dementia–11 Questionnaire.

NOTE. + = positive, ? = indeterminate (i.e., doubtful design or method; lacking of a clear description of the design or methods of the study, sample size for reliability smaller than 50 subjects, or using Pearson or Spearman correlation coefficients to assess reliability, or no specific hypothesis was formulated to test construct validity or responsiveness, or any important methodological weakness in the design or execution of the study), 0 = no information available [33].

the ability to judge the capacity of coping with daily life activities, whereas capacity was defined as the ability to avoid risks that may arise from the individual's cognitive deficits. The final version of SIJID consists of two assessment sections and three scoring sections. Section 1 (patient's form) and section 2 (informant's form) assess insight (module A), judgment (module B), and capacity (module C) and include the dangerous behavior checklist (DBC). This is a subscale assessing the patient's engagement in a variety of impulsive and disinhibited behaviors carrying the potential for danger. The scoring sections of the SIJID result in the generation of the following measures: discrepancy score (informant minus patient score for individual module items) and DBC total score (informant minus patient DBC total score − discrepancy score) from section 3 (scoring sheet), a rating of Insight, Judgment and Capacity from section 4 (rating), and level of risk generated by a specific algorithm from section 5 (classification of level of risk). Detailed information about the development process and structure of SIJID is provided in the Supplementary Methods. The final version of SIJID including the scoring method is provided in Supplementary File 1. SIJID total score (sum of discrepancy scores from modules A, B, and C), module total score (sum of discrepancy scores from module), and section total score (sum of "a" scores from modules A, B, and C) were generated solely for examining SIJID reliability and validity.

### 2.2. Design, settings, and inclusion/exclusion criteria

The final version of the SIJID was validated in a cross-sectional study that included 124 patients with AD attending the Fremantle Hospital Memory Clinic and Rehabilitation Services (affiliated with the University of Western Australia) and patients admitted to the geriatric ward at Fremantle Hospital. Patients met the following inclusion criteria: (1) NINCDS-ADRDA criteria for probable AD [34]; (2) clinical dementia rating (CDR) global score for very mild, mild, or moderate dementia [35]; (3) fluent in English; (4) a Hachinski ischemic score of 4 or lower [36]; (5) no history of closed head injuries with loss of consciousness or neurodegenerative disorders other than dementia; (6) normal results on laboratory tests to rule out reversible causes of dementia; and (7) living at home and having at least 1 person meeting the criteria for "informant." The criteria for being an appropriate informant was as follows: (1) first- or second-degree relative or friend currently responsible for, or in regular contact with the participant, at least twice a week for no less than 4 hours per week, for at least 6 months before the assessment and (2) a Mini–Mental State Examination (MMSE) [37] score of 24 or higher. All participants had neuroimaging (computed tomography [CT] or magnetic resonance imaging [MRI]) as part of their dementia protocol assessment. Patients meeting criteria for vascular dementia, Lewy body dementia, or frontotemporal dementia were excluded from the study. Diagnoses of dementia were carried out by geriatricians specialized in dementia management and confirmed by an experienced neuropsychiatrist (S.E.S.).

#### 2.2.1. Baseline assessment

After written informed consent was provided by the patient and the informant, background information was obtained from them both. All patients were assessed by a trained rater with the following instruments: (1) MMSE [37]: an 11-item examination found to be valid and reliable in assessing a limited range of cognitive functions in a global way; (2) CDR scale [35]: a global assessment instrument that yields a global and Sum of Boxes (SB) score, with the global score used to stage dementia severity; and (3) The Anosognosia Questionnaire–Dementia (AQ-D) [21]: a 30-item scale measuring awareness of functional deficits and behavioral changes. We previously demonstrated the validity and reliability of this instrument for use in AD [38].

Informants were asked to provide information about the patient with the following instruments: (4) The Neuropsychiatric Inventory (NPI) [39]: a standardized interview to obtain information on the presence of psychopathology. The NPI was assessed on 51 patients only, as this instrument was included in the research protocol after the study had started, to complement the study of neuropsychiatric symptomatology; and (5) the Mini-International Neuropsychiatric Interview (MINI) [40]: a structured psychiatric diagnostic interview. Informants were asked to provide information about themselves with (1) the MMSE and (2) the Zarit Burden Interview (ZBI) [41]: the most widely referenced scale in studies of caregiver burden. Finally, all patients and their respective informants were assessed with the SIJID. Use of antidepressant medication among patients was measured using the unipolar composite antidepressant rating, a quantitated standardized measure of antidepressant use [42]. Neuroleptic and benzodiazepine equivalents were calculated based on standardized methods [43].

#### 2.2.2. One-year follow-up assessment

Informants were assessed 12 months after baseline with the (1) Zarit Burden Interview and about the patient with the (2) Neuropsychiatric Inventory, and (3) the consequences of loss of insight (CLI): this is a semistructured interview which was specifically designed for this study to collect information about the patient's negative outcomes such as admissions to hospital for any medical condition, use of emergency medical services, medical treatment for any injury, outpatients visits to psychogeriatric services, commencement of legal procedures (e.g., power of attorney, guardianship, etc.), placement in respite care, admission to a residential care facility, incurrence of financial losses, and complaints to local government authorities against the patient. Each negative outcome was assigned 1 point. Higher scores indicate a higher number of negative outcomes. The CLI demonstrated adequate internal consistency (Cronbach $\alpha = 0.71$; this instrument is provided in the Supplementary File 2).

### 2.3. Statistical analysis

All analyses were performed using IBM SPSS Statistics version 22.0 for Windows [44]. Demographic and disease-related variables have been presented descriptively. Normal distribution was checked with Kolmogorov-Smirnov statistics [45]. Acceptability was calculated using missing responses, with less than 5% considered acceptable [46]. Distribution was based on observed means versus median scores, and a difference of <10% of the maximum possible scale score was considered acceptable. For floor and ceiling effects, 15% was taken as the maximum acceptable [33]. For skewness, the accepted limits were −1.0 to +1.0 [47]. Internal consistency and all the remaining statistical comparisons were carried out considering the discrepancy between patient and carer ratings, except for items B4 and C3 which were rated by the examiner. Cronbach α provided a measure of internal consistency. A Cronbach α of 0.70 or greater was considered acceptable. Interrater and test-retest reliability were calculated with the intraclass correlation coefficient (ICC, two-way mixed-effect model, average measures, absolute agreement) and kappa statistics. A kappa or ICC ≥ 0.70 was considered satisfactory [33]. To assess whether informants provided reliable and valid information, we explored correlations between informant's ratings on patient's basic activities of daily living and patient's CDR-SB and MMSE scores. Convergent validity of the SIJID with the AQ-D and discriminant validity with the MINI-hypomania module (MINI-HM) were assessed with Spearman rank correlation coefficients. Analyses of covariance were calculated to predict negative outcomes. Group differences were analyzed with means and standard deviations, *t* tests, and one-way analyses of variance (ANOVA) with post hoc tests using Tukey honest significant difference (HSD) test. All *P* values were two tailed.

## 3. Results

### 3.1. Demographic and clinical data

One hundred and thirty three AD patient/informant dyads were screened for participation between June 2006 and March 2015, with 92% completing the baseline assessments. Nine patients were withdrawn from the study: four informants declined participation, one informant could not be contacted, two patients were too physically unwell, one patient refused to answer questions, and one patient died soon after inclusion. There were no significant differences between completers and noncompleters for age, education, duration of illness, CDR-SB score, or MMSE score (see Supplementary Table 1). The average time to assess the full SIJID was 21 minutes for patients (range 12–34 minutes for section 1) and 16 minutes for informants (range 10–22 minutes for section 2). One hundred twenty-four AD patients were included in the study, and the summary of the demographic and clinical data of the sample is shown in Table 2.

Table 2
Baseline characteristics of the study sample

| | |
|---|---|
| Number of patients | 124 |
| Age, mean ± SD (range), years | 78.0 ± 7.7 (55–94) |
| Female, *n* (%) | 57 (46) |
| Education, mean ± SD (range), years | 10.8 ± 2.8 (3–18) |
| Duration of illness, mean ± SD (range), years | 1.2 ± 1.4 (1–7) |
| Patient MMSE score, mean ± SD (range) | 21.9 ± 5.1 (8–30) |
| Informant MMSE score, mean ± SD (range) | 28.3 ± 1.7 (24–30) |
| CDR global score—very mild | 39% |
| CDR global score—mild | 41% |
| CDR global score—moderate | 20% |
| Informant—spouse | 57% |
| Informant—children | 29% |
| Informant—others | 14% |
| Living with the patient | 62% |
| Daily contact | 15% |
| Contact more than once per week | 23% |
| Relationship length, mean ± SD (range), years | 45.4 ± 14.6 (6–77) |

Abbreviations: SD, standard deviation; MMSE, Mini–Mental State Examination; CDR, clinical dementia rating.

### 3.2. Psychometric attributes of the SIJID

#### 3.2.1. Internal consistency

The SIJID was found to be highly reliable (15 items; Cronbach α = 0.83). Analysis showed good internal consistency for modules A (Insight) (nine items; Cronbach α = 0.73) and B (Judgment) (five items; Cronbach α = 0.79). Cronbach α was not calculated for module C (Capacity) because it only included 2 scored items.

#### 3.2.2. Test-retest reliability

Eighteen patients were assessed by the same examiner on two occasions, with a mean interval of 9.8 ± 9.1 days (range 1–33 days). There was excellent agreement for module A, B, and C total scores (ICC = 0.91, 0.91, and 0.97, respectively). For both the classification of level of risk and DBC total score, the test-retest reliability was good (kappa = 0.77 and ICC = 0.85, respectively).

#### 3.2.3. Interrater reliability

Twenty-one patients were assessed by two raters during the same session, with one of the raters asking the questions and the second rater scoring the answers blind to the other examiner's scores. There was excellent interrater reliability for modules A, B, and C total scores (ICC = 0.86, 0.96, and 0.96, respectively), classification of level of risk (kappa = 0.93), and DBC total score (ICC = 0.95).

#### 3.2.4. Validity of informant's reports

There was a significant correlation between informants ratings on instrumental activities of daily living as assessed by the basic ADL question of the SIJID (B1a) and both the CDR-SB score (r = 0.50, $P < .001$) and patient's MMSE score (r = −0.41, $P < .001$), suggesting that the information provided by informants about patients was consistent with patients functional and cognitive status.

*3.2.5. Acceptability and distribution*

Missing data from any part of sections 1 (patient's form) and 2 (informant's form) was less than 1%, demonstrating good acceptability. The mean and standard deviation (mean ± SD) for section 1 was 8.4 ± 4.7 and 19.4 ± 8.8 for section 2. Skewness values were 1.0 and 0.3, respectively. For both sections, the difference between observed mean and median scores was <10% of the maximum section score, demonstrating acceptable distributions. Kolmogorov-Smirnov test for normality were $D$ (124) = 0.79, $P$ = .005 for section 1 total score and $D$ (124) = 0.77, $P$ = .005 for section 2 total score, indicating that these scores were not normally distributed.

*3.2.6. Floor and ceiling effect*

Neither floor nor ceiling effects were present. The lowest possible SIJID total score was achieved by 5.2% of the sample.

*3.2.7. Convergent validity, known-group validity, and discriminant validity*

Convergent validity was examined with the baseline AQ-D assessment. There was a significant correlation between SIJID total score and AQ-D total discrepancy score (r = 0.71, $P$ < .001), the AQ-D section A (anosognosia for deficits on basic and instrumental activities of daily living; r = 0.68, $P$ < .01), and the AQ-D section B (anosognosia for behavioral and emotional problems; r = 0.62, $P$ < .01). Using the AQ-D algorithm to diagnose anosognosia [48], we found that patients with anosognosia ($N$ = 66) had significantly higher scores on the SIJID total score, modules A and B total score, and DBC total score, than patients without anosognosia ($N$ = 57) (see Supplementary Table 2), demonstrating significant known-group validity (i.e., SIJID total scores were able to differentiate patients grouped by diagnosis of anosognosia). Correlations with module C were not explored given that the AQ-D does not assess dangerous behaviors. To assess discriminant validity, we examined the association between insight/judgment and hypomania, given the lack of conceptual relationship between the domains. No significant correlation was found between MINI-HM score and the SIJID total score (r = 0.005, $P$ = .95), module A total score (r = 0.05, $P$ = .57), module B total score (r = −0.009, $P$ = .91), DBC total score (r = 0.06, $P$ = .49), or classification of level of risk (r = 0.078, $P$ = .39).

*3.2.8. Sensitivity to anosognosia*

Based on the SIJID algorithm for classification of level of risk, 23% of the patients were classified as level 0 (no risk), 41% as level 1 (mild risk), 20% as level 2 (moderate risk), and 16% as level 3 (severe risk). Demographic and clinical data for each level are shown in Table 2. A one-way ANOVA showed significant between-group differences for AQ-D total discrepancy scores [F(3,124) = 13.3, $P$ = .0001]. Post hoc Tukey HSD test demonstrated that AQ-D total discrepancy scores were significantly lower ($P$ < .05) for the group with no risk (M = 3.1, SD = 17.4), when compared with mild- (M = 18.4, SD = 18.5), moderate- (M = 21.1, SD = 17.2), and severe-risk (M = 34.7, SD = 15) groups. For the classification of level of risk, the percentage of patients diagnosed with anosognosia based on the AQ-D was 17% for the no-risk group, 50% for the mild-risk group, 73% for the moderate-risk group, and 90% for the severe risk group.

*3.2.9. Dangerous behaviors and risk levels*

Patients with severe risk based on the SIJID algorithm showed significantly higher scores on the DBC, indicating that this group had a higher frequency of dangerous behaviors than the other groups. The severe group also showed significantly lower MMSE scores than the group with no risk. Informants of patients in the severe risk group scored significantly higher scores on the ZBI than informants for patients with lower level of risk, indicating greater caregiver burden for the severe risk group. Finally, no significant between-group differences were found for age, education, duration of illness, or intake of psychoactive medication (see Table 3).

*3.2.10. Predictive validity*

Predictive validity of the SIJID was examined based on a 1-year follow-up assessment on 108 of the 124 patients assessed at baseline. Of the remaining 16 patients, 13 had the baseline assessment less than 1 year before the study was completed, and three patients could not be contacted. After adjusting for severity of dementia assessed by CDR global score and NPI total scores at baseline, age, duration of illness, and gender, the SIJID total score at baseline was a significant 1-year predictor of NPI total score [$R^2$ = 0.50, F(1,51) = 2.50, $P$ = .021], NPI severity score [$R^2$ = 0.58, F(1,51) = 2.84, $P$ = .011], and NPI distress score [$R^2$ = 0.66, F(1,51) = 4.23, $P$ < .001]. Analysis of individual NPI domains showed that "agitation" and "disinhibition" accounted for the majority of the variance, [$R^2$ = 0.38, F(5,51) = 5.74, $P$ < .0001] and [$R^2$ = 0.27, F(5,51) = 3.41, $P$ < .01], respectively. The SIJID total score at baseline was also a significant 1-year predictor of DBC total score [$R^2$ = 0.54, F(5,51) = 10.3, $P$ < .001] and the CLI total score [$R^2$ = 0.21, F(4,108) = 0.56, $P$ < .001], indicating that poor insight of dangerous behaviors at baseline was significantly associated with poor outcomes 1 year later. Analysis of individual CLI items showed that admissions to hospital [$R^2$ = 0.27, F(5,108) = 3.42, $P$ < .01] and placement in residential care [$R^2$ = 0.17, F(5,108) = 4.43, $P$ < .001] accounted for 37% of the variance.

There were significant unadjusted correlations between SIJID total scores and NPI total scores (r = 0.55, $P$ < .001), NPI severity scores (r = 0.52, $P$ < .001), NPI distress scores (r = 0.46, $P$ < .001), DBC total score (r = 0.68, $P$ < .001), and CLI total scores (r = 0.47, $P$ < .001). Additionally, there were no significant changes on DBC total score over the 1-year follow-up [baseline

Table 3
Demographic and clinical data of sample categorized by SIJID levels

| | Classification of level of risk, mean (SD) | | | | | |
|---|---|---|---|---|---|---|
| Level of risk | None (0) | Mild (1) | Moderate (2) | Severe (3) | F (df), *P* value | Group comparison |
| *N* | 29 | 50 | 24 | 21 | | |
| Age (years) | 76.8 (8.5) | 78.2 (7.6) | 80.7 (5.9) | 76.2 (8.7) | 1.73 (3123), $P = .16$ | NS |
| Education, (years) | 10.9 (2.6) | 10.3 (2.7) | 12 (3.2) | 10.2 (1.3) | 2.54 (3123), $P = .06$ | NS |
| Duration of illness, (years) | 1.1 (1.3) | 1.2 (1.3) | 1.1 (1.1) | 1.5 (1.9) | 0.26 (3123), $P = .85$ | NS |
| CDR-SB score | 6.9 (4.7) | 9.2 (4.5) | 10.4 (5.0) | 13.4 (3.5) | 8.62 (3124) $P = .0001$ | L3 > L0, L1 |
| MMSE | 24.0 (5.1) | 21.6 (4.7) | 21.7 (4.4) | 19.4 (5.5) | 3.85 (3123), $P = .01$ | L0 > L3 |
| Zarit Burden Interview | 8.2 (7.5) | 9.9 (7.8) | 11.9 (8.1) | 18.0 (11.6) | 4.77 (3123), $P = .004$ | L3 > L0 |
| DBC total score | 0.9 (2.3) | 3.2 (3.4) | 5.2 (5.1) | 14.4 (6.4) | 54.2 (3123), $P = .0001$ | L3 > L0, L1, L2 |
| UCAR | 0.3 (0.8) | 0.2 (0.5) | 0.7 (1.6) | 0.5 (0.9) | 1.41 (3,97), $P = .22$ | NS |
| Benzodiazepine | 0.5 (2.2) | 0.4 (1.7) | 0.0 | 0.2 (1.1) | 1.53 (3,97), $P = .20$ | NS |
| Neuroleptic | 1.8 (8.1) | 7.8 (23.9) | 7.1 (27.5) | 15.2 (35.7) | 0.83 (3,97), $P = .41$ | NS |

Abbreviations: SIJID, Structured Interview for Insight and Judgment in Dementia; SD, standard deviation; NS, not significant; CDR-SB, Clinical Dementia Rating Sum of Boxes; MMSE, Mini–Mental State Examination; DBC, dangerous behavior checklist; UCAR, unipolar composite antidepressant rating.

mean = 9.7, SD = 9.2; follow-up mean = 9.2, SD = 8.2; $t(44) = 4.2$, $P = .67$].

*3.2.11. Additional findings*

A baseline ANOVA with NPI scores as the independent variable showed significantly higher scores for the group with severe risk as compared to patients with mild or no risk [severe-risk group (M = 5.5, SD = 1.8), moderate-risk group (M = 3.6, SD = 1.3), mild-risk group (M = 2.6, SD = 1.8), and no-risk group (M = 2.3, SD = 1.5; $F(3,50) = 7.2$, $P = .0001$)]. There was a significant correlation between NPI scores at baseline and NPI scores at follow-up [$R^2 = 0.16$, $F(1,50) = 9.6$, $P < .001$]. Finally, there were significant correlations between modules A (Insight) and B (Judgment), and module C (Capacity) ($r = 0.39$, $P < .0001$; and $r = 0.71$, $P < .0001$, respectively).

## 4. Discussion

The aim of this study was to develop and validate a semi-structured clinical interview to assess insight and judgment in AD, and there were several important findings. First, the SIJID showed strong psychometric attributes including good test-retest and interrater reliability and adequate convergent and discriminant validity. Second, there was a significant association between severity of anosognosia measured with the AQ-D and classification of level of risk demonstrating strong convergent validity. Third, level of risk based on the SIJID algorithm at baseline was a significant predictor of rate of institutionalization during the 12 months following the assessment. Moreover, there were significant correlations between baseline SIJID total scores and the frequency of hospital admissions and placement in residential care 1 year later, demonstrating clinically relevant predictive validity. Taken together, our findings suggest the SIJID is a useful instrument to assess insight and judgment in AD, as it predicts the presence of risk regarding behavioral problems, caregiver distress, medical complications, and rate of institutionalization.

Before further discussion, several limitations of our study should be pointed out. First, our sample consisted of referrals to memory and rehabilitation clinics and may not represent patients with AD living in the community. It is highly likely that we failed to recruit AD patients with severe anosognosia, who usually refuse to attend memory clinics or participate in research studies. Second, there is no "perfect" approach to measure deficits of awareness in dementia because the assessment is relative to the measure used as gold standard. Different strategies have been developed to assess insight in dementia, and all of them have relevant limitations [3]. Our study used information provided by informants as the gold standard, which may provide biased information due to confounders, such as depression or cognitive deficits in the informant, or not spending enough time with the patient to obtain accurate responses. We tried to control for these important confounders by screening informants for depression and cognitive deficits and only including those that had been in contact with the patient at least twice a week for no less than 4 hours per week, for at least 6 months. Significant positive correlations between informant's ratings on patient's basic ADLs and CDR-SB score, as well as patient's MMSE scores in ours and other studies [27,49,50], provide validation for this strategy, as does the finding of significant positive associations between reports from informants and those of clinicians [27]. Third, our statistical analyses used the DBC total score, but it is possible that this scale may consist of different factors, and this should be explored in future studies. The algorithm to classify patients into different risk groups was initially created on an ad hoc basis and later refined based on findings on our pilot studies leading to the final version of the SIJID. The present results provide preliminary validation to the algorithm, but future studies are needed for further validation. Fourth, we designed the CLI to collate outcome information in a standardized way. The CLI showed

adequate internal consistency; however, future studies should examine the psychometric attributes of this instrument in greater detail. Fifth, a limitation of the SIJID is the relatively long assessment time and the need for an informant to provide information across different domains. Hence, the SIJID may be suitable for specialized clinics or in-patient services but not for busy outpatient clinics. Finally, it is important to clarify that the acceptable level of reliability of a test varies according to its proposed application. Thus, for group-based inference, a reliability of 0.70 is acceptable, whereas a reliability of 0.90 or higher is necessary for making inferences about individual patients [49,51].

It is well known that patients with AD may minimize or fully deny the presence of cognitive problems and functional deficits. The assessment of insight is of great relevance in AD given its influence on the patient's ability to interact successfully and safely within their environment. Given the increasing complexity of decision making in contemporary life, competency assessment among patients with dementia is becoming more frequently demanded, and consequently, there is a great need for valid and reliable instruments.

The SIJID is different from the usual tools used to assess anosognosia in AD, since to our knowledge, this is the first semistructured interview to assess insight and judgment, and measure the presence and severity of dangerous behaviors. The SIJID was primarily designed to assess deficits of insight as they relate to risk to the patient or others. The rationale behind this decision is that this risk is one of the most relevant clinical outcomes in AD. We demonstrated that one of the main attributes of the SIJID is the capacity to predict negative outcomes 1 year after baseline. A regression analysis that adjusted for age, gender, severity of dementia, and duration of illness showed that SIJID total scores at baseline were significant predictors of NPI total and caregiver distress scores, more frequent admission to a general hospital, and more frequent placement in residential care. Thus, the SIJID is the first instrument to show predictive validity of insight and judgment in terms of relevant medical outcomes 12 months after baseline.

Lack of competence has been considered to result from the dual inability to make choices and to appreciate consequences [50]. In AD, whenever insight is impaired, competence is also affected, with a concomitant increase in the frequency of dangerous behaviors. The SIJID was developed with the aim of assessing deficits of insight and judgment and the capacity to live safely using a specific conceptual framework (see Supplementary Methods). It assesses insight and judgment about performance on basic and instrumental activities of daily living, mood and behavioral changes, as well as the presence of dangerous behaviors. The SIJID demonstrated strong psychometric attributes such as strong test-retest and interrater reliability, strong convergent and discriminant validity, and significant predictive validity for negative outcomes. Relevant attributes such as relatively short duration and simplicity of use make the SIJID a useful tool for specialized clinical practices. The SIJID is a semistructured interview that offers flexibility when obtaining information about the patient as well as flexibility to deepen in specific areas when required. Although further validation studies will be useful, we believe the SIJID is currently a highly effective instrument to assist in the assessment of competency of patients with AD, in terms of risk to themselves or others. Future studies should examine the utility of the SIJID in other dementias and compare this instrument with other measures of capacity and risk in AD.

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The authors declare that they have no conflict of interests.

## Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.dadm.2016.12.012.

## RESEARCH IN CONTEXT

1. Systematic review: Deficits of insight and judgment are frequent in dementia. These deficits are usually measured with scales with unknown validity providing information that is difficult to include when assessing competency. Furthermore, none of these instruments have proven predictive validity. We present the Structured Interview for Insight and Judgment in Dementia (SIJID), a semistructured interview that focuses not only on assessing poor awareness of cognitive and behavioral deficits, but also on dangerous behaviors as well.
2. Interpretation: The SIJID not only showed strong psychometric attributes, but to our knowledge, this is the first instrument demonstrating significant predictive validity for negative outcomes due to deficits of Insight and Judgment in Alzheimer's disease.
3. Future direction: We are currently assessing the long-term predictive validity of the SIJID among patients with early Alzheimer's disease, as well as its usefulness on a new structured method for conducting comprehensive competency assessments in dementia. Furthermore, we are exploring the usefulness of the SIJID in other dementias, such as the behavioral variant of frontotemporal dementia.

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