Comparison of the Cognivue® quantitative assessment tool and SLUMS to classify the risk of cognitive impairment

Diego Cahn-Hidalgo, MD 1; Raina Benabou, MD, PhD 1; Sarah Kewin 2
1Internal Medicine of Brighton, 300 White Spruce Blvd, Rochester, NY 14623; 2Cognivue Inc., 7911 Rae Blvd, Victor, NY 14564

ABSTRACT
Background: Cognivue® was developed based on clinical experience and NIH-funded laboratory research into the neural mechanisms of functional impairment in aging and dementia. The computerized testing tool that provides an automated brain functional assessment tool not based on traditional question & answer testing. Cognivue® consists of 3 sub-batteries of 10, selected to be representative of the SLUMS and Cognivue tests. Optimal performance of cognitive impairment. Method: Adults (age 55-95) at risk for age-related cognitive decline or dementia were invited to complete the SLUMS and Cognivue tests. Optimization analyses by positive percent agreement (PPA) and negative percent agreement (NPA) as well as by accuracy and biases were carried out. Results: 92 subjects, at 3 sites, completed SLUMS reference standard and Cognivue tests. Based on SLUMS score, 50% were not impaired (21-50), 26% were intermediate (21-26), and 24% were impaired (<21). Analyses using 2 measures of objective function (memory and error bias) showed that Cognivue® cut-off score of ≥75 (impaired) corresponded to a Cognivue® score of 54.5 (NPA = 0.92; PPA = 0.64). The Cognivue® cut-off score of ≥75 (no impairment) corresponded to a Cognivue® score of 78.5 (NPA = 0.5; PPA = 0.79). Based on the results of 2 separate analysis techniques, researchers showed that Cognivue® scores between 55-74 corresponded to SLUMS scores for no impairment. Conclusions: Cognivue® scores 100 provide a conservative standard for high risk of impairment to avoid misclassification of 1% of the population. Cognivue® scores ≤50 provide a conservative standard for low risk of impairment that will avoid misclassification of an individual as impaired. Cognivue® is FDA-cleared for use as an adjunctive tool to aid in assessing cognitive impairment. Cognivue® is an easy to use, computerized cognitive assessment aid, which provides a useful adjunctive part of a full medical work-up for cognitive impairment.

METHODS
Subjects: Cognivue® quantitative assessment tool is FDA approved for use as an adjunctive tool to aid in assessing cognitive impairment. Cognivue® was developed based on clinical experience and NIH-funded laboratory research into the neural mechanisms of functional impairment in aging and dementia. Cognivue® is a computerized testing tool that provides an automated brain functional assessment tool not based on traditional question & answer testing. Cognivue® consists of 3 sub-batteries of 10, selected to be representative of the SLUMS and Cognivue tests.

Methods: Cognivue® quantitative assessment tool includes (Table 1): 1) a 10-minute automated sequence; 2) motor & visual ability (visuomotor ability, perceptual processing, & memory processing) presented in an automated sequence over 10 minutes. RESULTS: 92 subjects, at 3 sites, completed both SLUMS and Cognivue® tests. Conclusions: Cognivue® scores ≤50 provide a conservative standard for high risk of impairment to avoid misclassification of an individual as impaired. Cognivue® scores ≤50 provide a conservative standard for low risk of impairment that will avoid misclassification of an individual as impaired.

METHODS (CONT.)
Tests (cont.)
• SLUMS (reference standard)
  - 11-item questionnaire with scores ranging from 0-30
  - Designed to measure orientation, memory, attention, & executive functions
• Cognivue®
  - 10 minute automated sequence
  - Motor & visual ability (visuospatial ability, motor & visual discrimination, & memory processing)

Methods: Adults (age 55-95) at risk for age-related cognitive decline or dementia were invited to complete the SLUMS and Cognivue tests. Optimization analyses by positive percent agreement (PPA) and negative percent agreement (NPA) as well as by accuracy and biases were carried out. Results: 92 subjects, at 3 sites, completed SLUMS reference standard and Cognivue tests. Based on SLUMS score, 50% were not impaired (21-50), 26% were intermediate (21-26), and 24% were impaired (<21). Analyses using 2 measures of objective function (memory and error bias) showed that Cognivue® cut-off score of ≥75 (impaired) corresponded to a Cognivue® score of 54.5 (NPA = 0.92; PPA = 0.64). The Cognivue® cut-off score of ≥75 (no impairment) corresponded to a Cognivue® score of 78.5 (NPA = 0.5; PPA = 0.79). Based on the results of 2 separate analysis techniques, researchers showed that Cognivue® scores between 55-74 corresponded to SLUMS scores for no impairment. Conclusions: Cognivue® scores 100 provide a conservative standard for high risk of impairment to avoid misclassification of 1% of the population. Cognivue® scores ≤50 provide a conservative standard for low risk of impairment that will avoid misclassification of an individual as impaired.

RESULTS
1st analysis: 92 subjects, at 3 sites, completed both SLUMS and Cognivue® tests. Conclusions: Cognivue® scores ≤50 provide a conservative standard for high risk of impairment to avoid misclassification of an individual as impaired. Cognivue® scores ≤50 provide a conservative standard for low risk of impairment that will avoid misclassification of an individual as impaired.

RESULTS (CONT.)
1st analysis
• SLUMS impairment cut-off score (<21) minimal 0.267 at Cognivue® score of 65.5 (NPA = 0.68; PPA = 0.79)
• SLUMS impairment cut-off score (<21) minimal 0.264 at Cognivue® cut-off of 73.5 (NPA = 0.68; PPA = 0.67)

Conclusions: Cognivue® scores 50 and 75 correspond with conservative standards for high risk of impairment and no risk of impairment, respectively.

Cognivue® is an easy to use, computerized cognitive assessment aid, which provides a useful adjunctive part of a full medical work-up for cognitive impairment.
Validation, reliability, and psychometric properties of Cognive®, a quantitative assessment of cognitive impairment

Diego Cahn-Hidalgo, MD1; Reina Benabou, MD, PhD2; Sarah Kewin2
1Internal Medicine of Brighton, 300 White Spruce Blvd, Rochester, NY 14623; 2Cognive Inc., 7911 Rae Blvd, Victor, NY 14564

Objective

To further validate the reliability and psychometric properties of Cognive®, and to demonstrate the safety and effectiveness of Cognive as an adjunctive tool to be used by licensed practitioners.

Method

401 subjects ages 55-95 who were at risk for age-related cognitive decline or dementia were given the Cognive test, SLUMS, and a series of other neuropsychological tests (RAVLT, TMT-A, TMT-B). They were each tested twice within 2-4 weeks.

Key Findings

• Cognive demonstrated significant correlation between the scores of Cognive and the SLUMS test.

• Good test-retest reliability of Cognive test results.

• The psychometric properties of the Cognive test battery compared to traditional neuropsychological tests.

Cognive is easy to use and provides a useful part of a full medical work-up for cognitive impairment.

ABSTRACT

Background: Many tests for assessing decline in cognitive function have limitations due to issues of accuracy, testing bias, and uptake among clinicians. Cognive® is a brief, easy-to-use, FDA-tested tool for the adjunctive assessment of risk of cognitive impairment.

Objective: To clinically validate Cognive® via agreement analysis of impairment risk classifications, retest reliability assessment, and psychometric property comparison.

Methods: Adults (age 55-95) at risk for age-related cognitive decline or dementia completed Cognive®, SLUMS, and other neuropsychological tests including Bay Auditory, Verbal Learning Test, Trail Making Test, WAIS III, TMT-A, TMT-B, HVCS, JOLO, PPB, GDS (15-item) & SLUMS-Animal Naming.

Results: Data were available for 401 subjects who completed 10 different tests; 205 in 1 session and 236 in 2 sessions. Previously determined Cognive® classifications were validated, demonstrating good agreement with SLUMS (κ = 0.87; 95% CI = 0.80–0.94). The test-retest reliability showed similar scores across retesting for Cognive® (κ = 0.81; 95% CI = 0.71–0.89), SLUMS (κ = 0.88; 95% CI = 0.81–0.94), and the other cognitive tests. Analyses included: regression analyses for agreement and re-test reliability of Cognive® test results; and validated the psychometric property comparison.

Conclusions: The Cognive® validation study demonstrated good agreement, re-test reliability, and very strong psychometric properties of Cognive® test results, and validated the psychometric properties of the Cognive test battery compared to traditional neuropsychological tests.

METHODS

Purpose: Clinically validate (1) Cognive® test

• Agreement analysis of previously defined impairment risk classifications

• Assessment of re-test reliability

• Comparison of psychometric properties of Cognive® vs. other neuropsychological tests

Subjects: Adults (55-95 y) from independent-living communities, at risk for age-related cognitive decline or dementia, invited to participate in study.

• Inclusion: Indoors, stable lighting

• Exclusion: Clinical or living setting, or visual disabilities, unable to provide informed consent

Tests: Cognive®, SLUMS, & other neuropsychological tests (Table 1)

• Need pre-existing subject to determine cut-off scores

• Cognive® (scores ≤ 51-74 = SLUMS 21-26 (intermediate), ≤ 0.50–0.63 = no impairment, ≤ 0.72-0.89 = low risk, ≤ 0.93-0.99 = high risk)

• SLUMS: adjusted linear R2 = 0.65

• Regression lines, the lines' parameters, and intraclass correlation (ICC) of tests 1 & 2 = 0.99 (p<0.001)

Retest reliability analyses: 30% subjects repeated Cognive® & SLUMS testing in 2 sessions 1-2 weeks apart

• In this validation analysis, low-risk score was defined as ≤ 0.71, low-moderate 0.71–0.81, moderate 0.81–0.90, high 0.90–1.00

Analyses: Regression analysis for agreement & re-test reliability, factor analysis for psychometric comparison (Table 1)

RESULTS (CONT.)

Table 1. Components of FDA pivotal clinical trial of Cognive®

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<thead>
<tr>
<th>Component</th>
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<tbody>
<tr>
<td>Cognive®</td>
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<td>SLUMS</td>
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<td>RAVLT</td>
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<td>HVCS</td>
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<td>GDS (15-item)</td>
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<td>SLUMS-Animal Naming</td>
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Validation analyses

• Cognive® agreement analysis revealed strong correlation between subject classification by 1st & 2nd Cognive® tests

• SLUMS analysis also showed strong agreement between subject classification by 1st & 2nd SLUMS tests

• Cognive® classifications of high, low-moderate, and no risk of impairment did not differ significantly across repeated testing

• Analysis of 3 classifications separately: 89% PPA for high, 93% for intermediate, 91% for unimpaired

Psychometric analyses

• Agreement analysis: tested Cognive®’s ability to classify subjects correctly across repeated testing

• Correlation analysis: Pearson correlation coefficients

• Inter-rater correlation: Landis & Koch agreement

• Validity analysis: Cognive® vs. SLUMS (regression fit: R2 = 0.67; r = 0.82)

Table 2. Proportion of subjects classified in each risk category by 1st and 2nd Cognive® tests

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Total</th>
<th>1st TEST</th>
<th>2nd TEST</th>
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<tbody>
<tr>
<td>High</td>
<td>27%</td>
<td>26%</td>
<td>28%</td>
</tr>
<tr>
<td>Low-moderate</td>
<td>43%</td>
<td>42%</td>
<td>45%</td>
</tr>
<tr>
<td>No risk</td>
<td>30%</td>
<td>32%</td>
<td>29%</td>
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Figure 1. Scatterplot showing Cognive® 1st & 2nd test scores (subject classification by 1st & 2nd Cognive® tests)

Figure 2. Scatterplot showing regression standardized predicted values for SLUMS and Cognive® (regression fit: R2 = 0.88, y = 0.88x + 1.6, r = 0.99)

Cognive® test scores or (B) SLUMS test scores

CONCLUSIONS

• FDA pivotal clinical trial demonstrated validity, reliability, and psychometric properties of Cognive®

• Validation study confirmed agreement between SLUMS & Cognive® classifications of risk of impairment

• Cognive® can inform an impression that patient is or is not impaired

• Retest reliability study demonstrated Cognive® repeated testing of older adults resulted in similar scores, and similar test subject classifications

• Psychometric profile of Cognive® most closely correlated with verbal processing, manual dexterity & speed, visual acuity, visuospatial function, and speed & sequencing, and was in general agreement with that of SLUMS

• Cognive® is an easy-to-use, computerized cognitive assessment aid, which provides a useful adjunctive part of a full medical work-up to detect early signs of cognitive impairment in patients 55-95 years of age.

For INDICATIONS FOR USE: Cognive® testing is intended as an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 y. It is not intended for monitoring cognitive state in the intensive care unit, for assessing cognitive impairment in patients ≤ 55 y, or for monitoring cognitive state before or after general anesthetic procedures.