Validation, reliability, and psychometric properties of Cognivue®: a quantitative assessment of cognitive impairment

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ABSTRACT

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

Objective: To clinically validate Cognivue® 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 Cognivue®. St. Louis University Mental Status (SLUMS), and other neuropsychological tests including Rey Auditory Verbal Learning Test (RAVLT) & Trail Making Test A&B (TMT-A, TMT-B). Analyses included: regression analyses for agreement and retest reliability, and rank linear regression and factor analysis for psychometric comparisons.

Results: Data were available for 401 subjects who completed ≥1 testing session, and 358 who completed 2 sessions 1–2 weeks apart. Previously determined Cognivue® classification scores were validated, demonstrating good agreement with SLUMS (κ = 0.57, 95% CI 0.50–0.63). The study of test-retest reliability showed similar scores across repeated testing for Cognivue® (regression fit: R² = 0.81, r = 0.90), and SLUMS (regression fit: R² = 0.87, r = 0.92). The Cognivue® classifications of high, moderate, and no risk of impairment, did not differ significantly across repeated testing, however, for SLUMS, the relationship between scores and classifications across repeated testing was less robust. The psychometric validity of the Cognivue® cognitive test battery was demonstrated compared to traditional paper & pencil neuropsychological tests. Scores were most closely correlated with measures of verbal processing, manual dexterity/speed, visual contrast sensitivity, visuospatial/executive function, and speed/sequencing.

Conclusions: The Cognivue® validation study demonstrated good agreement between Cognivue® and the SLUMS test; good test-retest reliability of Cognivue® test results; and validated the psychometric properties of the Cognivue® test battery compared to traditional neuropsychological tests.

BACKGROUND

- Tools for assessing cognitive function decline are often limited by lack of validation & consistent retest reliability.
- Cognivue® was developed as a physiological & psychophysical computerized tool for automated assessment of brain functioning & cognitive function.

- It is a 10-minute test, FDA-cleared for use as an adjunctive tool to aid in assessing cognitive impairment risk in those 55–95 years of age. It is not intended to be used alone for diagnostic purposes.
- Cognivue® uses scores from a sequence of tasks to produce a page report & score

METHODS

Purpose: Clinically validate (Table 1) Cognivue® via:

- Agreement analysis of previously defined impairment risk classifications
- Assessment of retest reliability
- Comparison of psychometric properties vs. other neuropsychological tests

Subjects: Adults (55–95) from independent-living communities, at risk for age-related cognitive decline or dementia, invited to participate via posters & email.

Exclusion criteria: Limiting motor or visual disabilities, unable to provide informed consent.

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

- Previous clinical trial (n=25) to determine cut-off scores found:
  - Cognivue® scores ≥75 = SLUMS ≥27 (impaired)
  - Cognivue® scores 51–74 = SLUMS 21–26 (low-risk moderate)
  - Cognivue® scores 25 = SLUMS ≥27 (no impairment)

In the validation analysis, low-risk moderate was combined with impaired category for each test modality.

Analyses: Regression analyses for agreement & retest reliability; rank linear regression & factor analysis for psychometric comparison (Table 1)

RESULTS

- Agreement analysis revealed strong correlation between subject classification by 1st & 2nd Cognivue® tests
  - kappa = 0.89, N=93 (% correlation (ICC) of tests 1 & 2 0.09 (p=0.001)
  - SLUMS analysis also showed strong agreement between subject classification by 1st & 2nd SLUMS tests
    - Pearson's r = 0.67, N=93 (p<0.001)
  - Cognivue® classifications of high, low-risk, and no risk of impairment, did not differ significantly across repeat testing
  - Analysis of 3 classifications separately: 89% PPA for high-risk of impairment, 57% PPA for low-risk, and 87% PPA for no risk (Table 2)

- For SLUMS, relationships between scores & classifications across repeated testing were less robust than those for Cognivue®
  - Analysis of 3 classifications separately: 87% PPA for impaired, 55% PPA for intermediate, and 51% PPA for unimpaired

Psychometric analysis:
- 401 subjects completed ≥2 testing session, including Cognivue®, SLUMS, & other neuropsychological tests
  - Rank scores on each test were plotted against their ranks on Cognivue® scores and against their ranks on Cognivue® scores with linear regression lines, the lines’ parameters, and their 95% CIs (data not shown)
  - Data were condensed using factor analysis of neuropsychological test scores

Conclusions:
- FDA pivotal clinical trial demonstrated validity, reliability, and psychometric properties of Cognivue®
- Validation study confirmed agreement between SLUMS & Cognivue® classifications of risk of impairment
- Cognivue® can inform an impression that patient is or is not impaired
- Retest reliability study demonstrated Cognivue® repeated testing of older adults resulted in similar scores, and similar test subject classifications
- Psychometric profile of Cognivue® most closely correlated with verbal processing, manual dexterity & speed, visual acuity, visuospatial & executive function, and speed & sequencing, and was in general agreement with that of SLUMS
- Cognivue® is an easy-to-use, computerized cognitive assessment aid, which provides a useful alternative part of a full medical work-up to detect early signs of cognitive impairment in patients 55–95 years of age

INDICATIONS FOR USE: Cognivue® testing is indicated as an adjunctive tool for evaluating perceptual and memory function in individuals aged 55–95 y. It is not intended to be used as a stand-alone device to identify the presence or absence of clinical diagnoses. Cognivue® is intended to be used by medical professionals qualified to interpret the results of a cognitive assessment examination.

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