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## The Hypogonadism Screener: Psychometric Validation in Male Patients and Controls

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**Introduction and Objective:** Hypogonadism (HG) is a clinical disorder consisting of reduced testosterone (T) levels in addition to characteristic signs and symptoms of low T. Current instruments commonly used to assess HG in men lack adequate measurement properties. In this study, we present the quantitative validation of a new self-report instrument to identify male HG.

**Methods:** A total of 131 men were enrolled; 82 patients (47 with T levels <240 ng/dL, 35 with T levels 240-300 ng/dL) and 49 controls with T levels > 300 ng/dL. Subjects were selected in 2 age groups (21-49 y, 50-75 y) and recruited from 16 sites in the United States. Patients and controls completed a paper-and-pencil questionnaire packet consisting of a new HG Screener along with 7 validated questionnaires at Visit 1. At Visit 2 approximately half of the subjects (N=82) completed the HG Screener and another questionnaire and a cognitive debriefing interview was conducted on 71 of the 82 subjects at Visit 2. Analyses were conducted to evaluate the psychometric properties (factor structure, reliability, construct validity) of the new HG Screener in relation to previously validated questionnaires. Finally, cognitive debriefing interviews were used to confirm the content validity of the scale.

**Results:** The results of a factor analysis identified an 18-item scale, separable into five functional factors. The 5-factor solution yielded adequate eigenvalues (4.171 to 1.674), strong factor loadings (>0.627) and few cross-loadings between the factors, providing evidence for five relatively independent domains. Additionally, seven items which discriminated well between patients and controls but did not load strongly onto any of the five factors were selected to form a symptoms checklist. The resulting scale is a 25-item questionnaire consisting of 18 functional items in 5 core domains (sexual function, mood, memory, sleep function, and fatigue), in addition to 7 physical symptom items. Overall, the new scale was found to have strong psychometric properties, including a coherent factor structure consistent with our conceptual model, and acceptable discriminant, construct, and content validity as well as internal consistency and test-retest reliability.

**Conclusion:** A new screening tool (HG Screener) for identifying men at risk for HG has been developed and validated according to FDA standards. This new questionnaire is available for clinical or research use in the identification of men with HG.

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**Disclosure Statements:**

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