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PSYCHOMETRICS

Psychometric Evaluation of the Hypogonadism Impact of Symptoms Questionnaire Short Form (HIS-Q-SF)

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ABSTRACT

Background: The Hypogonadism Impact of Symptoms Questionnaire Short Form (HIS-Q-SF) is a patient-reported outcome measurement designed to evaluate the symptoms of hypogonadism. The HIS-Q-SF is an abbreviated version including17 items from the original 28-item HIS-Q.

Aim: To conduct item analyses and reduction, evaluate the psychometric properties of the HIS-Q-SF, and provide guidance on score interpretation.

Methods: A 12-week observational longitudinal study of hypogonadal men was conducted as part of the original HIS-Q psychometric evaluation. Participants completed the original HIS-Q every 2 weeks. Blood samples were collected to evaluate testosterone levels. Participants completed the Aging Male's Symptoms Scale, the International Index of Erectile Function, the Short Form-12, and the PROMIS Sexual Activity, Satisfaction with Sex Life, Sleep Disturbance, and Applied Cognition Scales (baseline and weeks 6 and 12). Clinicians completed the Clinical Global Impression of Severity and Change scales and a clinical form.

Main Outcome Measures: Item performance was evaluated using descriptive statistics and Rasch analyses. Reliability (internal consistency and test-retest), validity (concurrent and know groups), and responsiveness were assessed.

Results: One hundred seventy-seven men participated (mean age = 54.1 years, range = 23−83). Similar to the full HIS-Q, the final abbreviated HIS-Q-SF instrument includes five domains (sexual, energy, sleep, cognition, and mood) with two sexual subdomains (libido and sexual function). For key domains, test-retest reliability was very good, and construct validity was good for all domains. Known-groups validity was demonstrated for all domain scores, subdomain scores, and total score based on the Clinical Global Impression−Severity. All domains and subdomains were responsive to change based on patient-rated anchor questions.

Clinical Implications: The HIS-Q-SF could be a useful tool in clinical practice, epidemiologic studies, and other academic research settings.

Strengths and Limitations: Careful consideration was given to the selection of the final HIS-Q-SF items based on quantitative data and clinical expert feedback. Overall, the reduced set of items demonstrated strong psychometric properties. Testosterone levels for the participating men were not as low as anticipated, which could have limited the ability to examine the relations between the HIS-Q-SF and testosterone levels. Further, the analyses used data collected through administration of the full HIS-Q, and future studies should administer the standalone HIS-Q-SF to replicate the psychometric analyses reported in the present study.

Conclusion: Similar to the original HIS-Q, the HIS-Q-SF has evidence supporting reliability, validity, and responsiveness. The short form includes a smaller set of items that might be more suitable for use in clinical practice or academic research settings. **Gelhorn HL, Roberts LJ, Khandelwal N, et al. Psychometric Evaluation of the Hypogonadism Impact of Symptoms Questionnaire Short Form (HIS-Q-SF). J Sex Med 2017;14:1046−1058.**

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INTRODUCTION

Hypogonadism in men is often associated with a range of symptoms that can include poor libido, erectile dysfunction, irritability, fatigue, and psychological and relationship problems, among other symptoms.[1,2] Many of these symptoms are difficult for clinicians to evaluate accurately and might be best assessed through patient-reported outcome (PRO) measurements. Recent research has suggested that androgens have a measurable impact on functioning and health-related quality of life.[3,4] The Hypogonadism Impact of Symptoms Question (HIS-Q) is a recently developed 28-item PRO measurement designed to assess the full range of symptoms in men.[5] This instrument comprehensively captures important hypogonadal symptoms but, because of its length, it might be less practical for use in clinical, epidemiologic, or other research settings. There is increasing interest in including PRO measurements in electronic medical records to document outcomes from the patients' perspective.[6] In addition, relatively brief and psychometrically sound measurements are needed for hypogonadism-related epidemiologic studies. Therefore, there is a need for a shorter instrument to practically assess changes in hypogonadism symptoms over time to measure how patients respond to treatment in real-world clinical settings.

The HIS-Q is a self-report questionnaire designed to assess changes in symptoms in hypogonadal men in response to testosterone replacement therapy (TRT).[5,7] The 28-item instrument was developed primarily for use in clinical trial settings, has been developed in accordance with the Food and Drug Administration's (FDA) PRO guidance for industry,[8] and addresses the limitations of existing instruments. The developers sought to develop an abbreviated version of the original HIS-Q, the HIS-Q short form (HIS-Q-SF), for inclusion in clinical practice and academic settings (Appendix A, available online).[9] Because the HIS-Q-SF was developed concurrently with the original HIS-Q, it is composed of a subset of items from the original version with the same instructions and recall period. The goal was to align the items and scoring between the two forms so that the use of the HIS-Q and HIS-Q-SF would be meaningful to clinicians in clinical practice and in evaluating and interpreting results from clinical trials (Appendix B, available online).

The two versions of the HIS-Q were developed based on a literature review, extensive qualitative work, and input from expert clinicians.[5,9] The SF instrument contains 17 items assessing the following five domains and two subdomains: the sexual domain, including libido and sexual function subdomains; and additional domains for energy, sleep, cognition, and mood. The final 17 items in the HIS-Q-SF were initially selected based on qualitative research with patients to determine those most relevant for inclusion in a short form.[9] The item selections for the HIS-Q-SF were further supported by input from clinical experts, the instrument development team, and prior research conducted in the development of the original HIS-Q. The final step in the development of the HIS-Q-SF, reported in the present study, was to perform a psychometric evaluation of the reduced item set.

METHODS

Aims

In the development of the original HIS-Q, a 12-week prospective, observational, longitudinal study was conducted.[7] The present study used these existing HIS-Q data, and further analyses were conducted to confirm the item content, scoring algorithm, and psychometric properties (ie, reliability, validity and responsiveness) of the items and scales composing the HIS-Q-SF.

Participants

Twenty US clinical sites with specialties in urology and sexual medicine participated in the study. Eligible participants, who signed informed consents, included men who were at least 18 years old; diagnosed with hypogonadism (a clinical diagnosis based on historical laboratory results[s] of serum total testosterone concentration < 300 ng/dL by at least one laboratory test before enrollment in the study); switching TRT treatments or on maintenance therapy (currently on treatment with no change) or treatment naïve (new to treatment); and able to understand English. Diagnostic tests for patients who were currently taking treatment were required to have been conducted before initiating treatment. Patients were excluded if they had non-stabilized depression (stabilized depression was defined as being on the same antidepressant medication at the same dosage for $\geq$3 months), severe psychiatric illness, or addictions; history of or current obstructive sleep apnea; a clinically significant medical condition; or were taking a concurrent medication that would affect hormonal balance, sexual functioning (eg, phosphodiesterase type 5 inhibitors), or interfere with participants' participation in the study. The sample size for the study was driven by the estimation of the factor analytic models; the total of 177 participants and estimation of a factor model with 14 items yields more than 12 observations per item. Sample size recommendations for factor analysis indicate that there should be at least five subjects for each item included in the factor analysis.[10,11] The sample size in this study exceeded these recommendations.

Procedures and Measurements

The study protocol and procedures used were reviewed and approved by the appropriate institutional review committee (Ethical and Independent Review Services, September 25, 2013, protocol 13110-01). All study staff members at every site were