Validation of the Erection Hardness Score

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ABSTRACT

Introduction. Erection hardness is a fundamental component of erectile function, and is a very specific and easily monitored outcome. The Erection Hardness Score (EHS) is a single-item, patient-reported outcome (PRO) for scoring erection hardness.

Aims. The aim of this article is to report the psychometric validation of the EHS.

Methods. The dataset (N = 307) was from a multinational sildenafil trial (efficacy in the treatment of erectile dysfunction [ED]) with a 2-week screening phase, a 6-week double-blind, placebo-controlled treatment phase, and a 6-week open-label extension.

Main Outcome Measures. Test–retest reliability (intraclass correlation coefficient), quality and distribution of responses, known-groups validity (ability to differentiate between ED severity groups defined by the International Index of Erectile Function [IIEF] questionnaire), convergent validity (Pearson correlation coefficients with domain scores of the IIEF and the Quality of Erection Questionnaire [QEQ]), treatment responsiveness, and clinically important difference.

Results. The EHS demonstrated good test–retest reliability, acceptable quality and distribution of responses, known-groups validity against the IIEF (including clear differentiation between normal and impaired erectile function), moderate-to-strong convergent validity against the prespecified domains of the IIEF and QEQ, and high treatment responsiveness.

Conclusion. The EHS has desirable measurement properties, including being highly responsive to treatment. This one-item PRO is robust and easy to use for evaluating erection hardness. Psychometric analysis supports the use of the EHS as a simple, reliable, and valid tool for the assessment of erection hardness in clinical trials research.

Key Words. Erectile Dysfunction; Erection Hardness; Patient-reported Outcome

Introduction

In 2004, an international consensus panel of health specialists with experience in assessing and treating erectile dysfunction (ED) defined treatment efficacy as “... the ability of a pharmacologic agent to promote achievement and maintenance of firm or adequate erections,” and described a complete response as “... consistent achievement and maintenance of full erection ...” [1]. Erection hardness is a fundamental component of erectile function [2–6] and, before the development of the International Index of Erectile Function (IIEF), patient-reported or objectively measured hardness was the standard diagnostic criteria for ED.

From an engineering perspective, erection hardness is a reflection of axial penile rigidity, and is the erection quality that best characterizes the ability to overcome axial compression loads experienced during vaginal intromission and continued pelvic thrusting [4]. Inadequate erection hardness will result in penile buckling or curving of the erection column about its neutral axis, and
thus, failure of the penetration tool to achieve successful intercourse.

Objective measurement by an investigator of erection hardness and its role in successful penetration has been reported [2–5, 7–12]. A modified weight scale is applied to the tip of the erect penis in a downward direction either during sleep laboratory evaluation of nocturnal penile erections [7, 11], during dynamic pharmacocavernosometry [2–4], or during pharmacologic erection [8]. In one study, if erection hardness was able to support an axial loading force of 1 kg without any bending of the penile shaft, the erection hardness was considered to be sufficient, but if the erect shaft was deformed with an axial loading force of 1 kg, erection hardness was considered inadequate [8, 9].

Subjective measurement by the patient of erection hardness can be achieved by the Erection Hardness Score (EHS). This is a single-item patient-reported outcome for scoring erection hardness (Table 1). Beginning with the placebo-controlled clinical trials that established efficacy and supported regulatory approval of sildenafil citrate (Viagra, Pfizer Inc, New York, NY) in the 1990s, the EHS has been an integral part of the sildenafil clinical trials program [13, 14]. Use of the EHS in multiple clinical trials has shown that it is easy for the patient to complete and is a very specific patient outcome.

In 2006, the US Food and Drug Administration provided a draft guidance to the industry on the measurement of patient-reported outcomes to support labeling, including the development and use of questionnaires [15]. Rigorous assessment of patient-reported outcomes is necessary to ensure reliability, responsiveness, and discriminant and predictive validity [16]. These attributes ensure that the instrument measures what it states it measures, and that the results are reproducible and sensitive to change [17]. Our objective is to report the psychometric validation of the EHS, based in part on what has been learned from the FDA draft guidance [15] and accepted published recommendations for evaluating the validity and reliability of a patient-reported outcome [18–22].

**Methods**

**Dataset**

The dataset was derived from a multinational trial with a 2-week screening phase, a 6-week double-blind, placebo-controlled (DBPC) treatment phase, and a 6-week open-label extension (OLE) [23]. Inclusion criteria were a clinical diagnosis of ED confirmed by an IIEF erectile function domain score ≤25, six or fewer doses total of sildenafil or another phosphodiesterase type 5 (PDE5) inhibitor for treatment of ED and no dose within 4 weeks, and a stable sexual partner for the duration of the trial. The inclusion of men who had used a few doses of a PDE5 inhibitor was a compromise to enable completion of the trial within a realistic timeframe, given the difficulty in finding men with ED who have not tried a PDE5 inhibitor.

Flexible-dose sildenafil (25, 50, or 100 mg as needed) or matching placebo was to be taken 30 to 60 minutes before the anticipated sexual activity but no more than once daily. At the beginning of each phase (DBPC and OLE), study medication was initiated at 50 mg. At the next visit, the dose could be adjusted based on efficacy and tolerability. Patients were instructed to attempt sexual activity at least two times per week. Every time a sexual intercourse was attempted, the patient completed an 11-question event log that included the EHS. Written informed consent was obtained, and there was adherence to all appropriate regulations.

Psychometric analyses were conducted on EHS responses that were part of the event logs submitted by 307 men. Sildenafil (n = 154) and placebo (n = 153) groups were similar in age (mean 45 years [range 18–55]), race (>90% white), ED duration (mean 2 years [range <1–21]), and ED etiology. Comorbid medical conditions were common and included hypertension (sildenafil, 19%; placebo, 18%), diabetes (sildenafil, 12%; placebo, 11%), hyperlipidemia (sildenafil, 6%; placebo, 8%), benign prostatic hyperplasia (sildenafil, 5%; placebo, 3%), depression (3% in each group), and ischemic heart disease (sildenafil, 1%; placebo, 3%).

**Psychometric Analyses**

The EHS validation plan (Table 2) was formed prospectively (before conducting any analysis) and

<table>
<thead>
<tr>
<th>Table 1 Erection Hardness Score (EHS)</th>
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<tbody>
<tr>
<td>EHS*</td>
</tr>
<tr>
<td>0: Penis does not enlarge.</td>
</tr>
<tr>
<td>1: Penis is larger but not hard.</td>
</tr>
<tr>
<td>2: Penis is hard but not hard enough for penetration.</td>
</tr>
<tr>
<td>3: Penis is hard enough for penetration but not completely hard.</td>
</tr>
<tr>
<td>4: Penis is completely hard and fully rigid.</td>
</tr>
</tbody>
</table>

*“How would you rate the hardness of your erection?”

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followed key areas of analysis highlighted in the FDA draft guidance [15] and publications on the topic of validation for patient-reported outcomes [18–22]. Analyses were based on EHS data from event logs collected at baseline (including the 2-week screening period), at the DBPC interim visit (treatment week 2), at the DBPC end-of-treatment visit (treatment week 6), at the OLE interim visit (treatment week 8), and at the OLE end-of-treatment visit (treatment week 12).

### Reliability
To assess the test–retest reliability, the intraclass correlation coefficient (ICC) was estimated based on a repeated-measures analysis of EHS responses [24]. All pretreatment data collected during the 2-week period between the screening visit and the baseline visit were used. No postrandomization data were used in the analysis of reliability. The ICC of a single EHS response was estimated based on the relationship of the between-patients error variance ($e_1$) to the within-patients error variance ($e_2$) using the following formula:

$$ICC = \frac{e_1}{e_1 + e_2}$$

Then, the Spearman-Brown Prophecy formula [25] was used to calculate the average measure ICC (ICC($m$)):

$$ICC(m) = m \times ICC/(1 + (m - 1) \times ICC)$$

which estimates the reliability of the averaged responses where $m$ is the number of the responses averaged. A value $\geq0.7$ indicates acceptable reliability [26].

### Quality and Distribution of Responses
For the quality of responses, data were used from the screening visit to the baseline visit (2 weeks) and from the interim DBPC visit (treatment week 2) to the DBPC end-of-treatment visit (treatment week 6). The quality of response was calculated as

$$\text{Number of event logs with missing EHS scores}$$

$$\text{Number of event logs submitted per visit}$$

For the distribution of responses, all data collected at the baseline and DBPC end-of-treatment visit were used. However, for each patient, data were averaged across all responses that preceded a given visit. Floor and ceiling effects were defined as an endorsement $>50\%$ for EHS 0 and EHS 4, respectively.

### Validity
Convergent validity was evaluated by calculating Pearson correlation coefficients of the EHS with the domain scores of the IIEF and with the total score of the Quality of Erection Questionnaire (QEIQ, a one-domain instrument [27,28]) at the baseline and at the end of DBPC (treatment week 6). Because convergent validity demonstrates that end points are closely related (although not identical), the strongest convergent relationships ($r > 0.6$) for the EHS were expected to be with the IIEF erectile function domain and the QEIQ total score. Strong correlations with the EHS were also anticipated for the IIEF intercourse satisfaction and overall satisfaction domains. In contrast, correlations of the EHS with the IIEF sexual desire domain were expected to be poor.

Known-groups differences were evaluated by determining the ability of the EHS to differentiate between ED severity groups as defined by scores on the erectile function domain of the IIEF: 26–30 (no ED), 22–25 (mild ED), 11–21 (moderate ED), and 1–10 (severe ED); the mild-to-moderate group and moderate group established

### Table 2 Psychometric analyses

<table>
<thead>
<tr>
<th>Data Criteria Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening to baseline</td>
</tr>
<tr>
<td>Test–retest reliability</td>
</tr>
<tr>
<td>The intraclass correlation coefficient has been determined using a repeated-measures analysis of pretreatment event logs using estimated within-subject variability and between-subject variability</td>
</tr>
<tr>
<td>DBPC phase and OLE phase (from baseline to EOT)</td>
</tr>
<tr>
<td>Quality of response</td>
</tr>
<tr>
<td>Distribution of responses</td>
</tr>
<tr>
<td>An assessment of floor/ceiling effects according to the percent of responses that are “no erection at all” or “completely hard”</td>
</tr>
<tr>
<td>Convergent validity</td>
</tr>
<tr>
<td>EHS was expected to correlate most strongly with the erectile function, intercourse satisfaction, and overall satisfaction domains of the IIEF</td>
</tr>
<tr>
<td>Known-groups validity</td>
</tr>
<tr>
<td>EHS was expected to relate well to ED severity according to the IIEF erectile function domain</td>
</tr>
<tr>
<td>Treatment responsiveness</td>
</tr>
<tr>
<td>The effect size accounts for the difference between sildenafil and placebo averaged over the DBPC phase and the variability in EHS at baseline</td>
</tr>
</tbody>
</table>

DBPC = double-blind, placebo-controlled; OLE = open-label extension; EOT = end of treatment; EHS = Erection Hardness Score; IIEF = International Index of Erectile Function; ED = erectile dysfunction.
by Cappelleri et al. were combined into a single group labeled as “moderate” [29,30].

**Clinically Important Difference**

A repeated-measures, longitudinal, mixed-effects model was used on EHS and IIEF erectile function domain data from the baseline, the end of DBPC (treatment week 6), and the end of OLE to provide an estimate (least squares mean [95% confidence interval {CI}]) of the EHS difference between any two adjacent ED groups (i.e., no ED vs. mild ED, mild ED vs. moderate ED, and moderate ED vs. severe ED). The average estimate across all groups can be interpreted as the clinically important difference, i.e., how much an average EHS score should change to move a group of men from a particular ED status to an adjacent ED status.

**Responsiveness**

Responsiveness of the EHS to treatment was estimated with a repeated-measures, longitudinal, mixed-effects model using an unstructured covariance. The model included baseline, visit (two observations for the DBPC phase and two for OLE), treatment, center, and visit-by-treatment interactions. To distinguish between the DBPC phase and the OLE, the model assigned a “new” drug (open-label sildenafil) to every man who proceeded to OLE. This put all data in one model. Estimated treatment differences in EHS were calculated for sildenafil vs. placebo averaged over the DBPC phase. Effect size was calculated using standard deviation (SD) as estimated treatment difference in EHS score divided by SD of baseline mean EHS score. An effect size of 0.2 is considered “small,” 0.5 “moderate,” and ≥0.8 “large” [31].

**Results**

As previously reported, in the sildenafil group (n = 154), the least squares mean estimated percentage of occasions with EHS 4 erections (completely hard and fully rigid) was 58% (95% CI, 52–65%) [23]. Furthermore, improvement in function (erectile function domain of the IIEF), emotional well-being (Self-Esteem and Relationship [SEAR] questionnaire), and satisfaction (IIEF intercourse satisfaction domain, QEQ, and Erectile Dysfunction Inventory of Treatment Satisfaction [EDITS]) were greatest in men with EHS 4 erections, and correlated positively with other measures of hardness [23]. These outcomes support previous results [32].

**Test–Retest Reliability**

The between-subjects error variance estimate was 0.58, and the within-subject error variance estimate was 0.56. Based on these values, the estimated ICC of a single EHS response was approximately 0.51 (i.e., 0.58/[0.58 + 0.56] = 0.51) (Figure 1). However, reliability increased with the number of EHS responses, and the cutoff for acceptable reliability (≥0.7) was attained with three EHS responses, which gave an estimable reliability of 0.76. Furthermore, estimated ICC values continued to increase as the number of responses increased.

**Quality and Distribution of Response**

At baseline and DBPC end-of-treatment, 1,553 and 3,780 event logs, respectively, were submitted with EHS, and 16 and 27, respectively, were submitted without EHS (Table 3). Thus, the rate of missing responses to the EHS was 1.02%

**Table 3** Distribution of responses on the EHS

<table>
<thead>
<tr>
<th>Score</th>
<th>Number (%) of event logs submitted with an EHS*</th>
<th>Number (%) of event logs submitted with an EHS*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline visit Per EHS Cumulative Per EHS Cumulative</td>
<td>DBPC EOT visit Per EHS Cumulative Per EHS Cumulative</td>
</tr>
<tr>
<td>EHS 0</td>
<td>153 (9.9) 153 (9.9)</td>
<td>479 (12.7) 479 (12.7)</td>
</tr>
<tr>
<td>EHS 1</td>
<td>283 (18.2) 436 (28.1)</td>
<td>333 (8.8) 812 (21.5)</td>
</tr>
<tr>
<td>EHS 2</td>
<td>436 (28.1) 872 (56.2)</td>
<td>425 (11.2) 1237 (32.7)</td>
</tr>
<tr>
<td>EHS 3</td>
<td>594 (38.3) 1466 (94.4)</td>
<td>1159 (30.7) 2396 (63.4)</td>
</tr>
<tr>
<td>EHS 4</td>
<td>87 (5.6) 1553 (100)</td>
<td>1384 (36.6) 3780 (100)</td>
</tr>
</tbody>
</table>

*All data collected at the baseline and DBPC EOT visit were used.

EHS = Erection Hardness Score; DBPC = double-blind, placebo-controlled; EOT = end of treatment.
EHS Validation

Table 4  Distribution of averaged responses on the EHS

<table>
<thead>
<tr>
<th>Mean score</th>
<th>Baseline visit, N = 307</th>
<th>DBPC EOT visit, N = 289</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Per EHS</td>
<td>Cumulative</td>
</tr>
<tr>
<td>EHS &lt;0.5</td>
<td>14 (4.6)</td>
<td>14 (4.6)</td>
</tr>
<tr>
<td>0.5 ≤ EHS &lt;1.5</td>
<td>46 (15.0)</td>
<td>60 (19.5)</td>
</tr>
<tr>
<td>1.5 ≤ EHS &lt;2.5</td>
<td>122 (39.8)</td>
<td>182 (59.3)</td>
</tr>
<tr>
<td>2.5 ≤ EHS &lt;3.5</td>
<td>115 (37.5)</td>
<td>197 (66.7)</td>
</tr>
<tr>
<td>EHS ≥3.5</td>
<td>10 (3.3)</td>
<td>307 (100)</td>
</tr>
</tbody>
</table>

*All data collected at the baseline and DBPC EOT visit were used.
EHS = Erection Hardness Score; DBPC = double-blind, placebo-controlled; EOT = end of treatment.

Table 5  Correlations with the Erection Hardness Score

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>End of DBPC (week 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pearson's correlation coefficient (r value)*</td>
<td></td>
</tr>
<tr>
<td>IIEF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erectile function domain</td>
<td>0.69</td>
<td>0.86</td>
</tr>
<tr>
<td>Orgasmic function domain</td>
<td>0.39</td>
<td>0.63</td>
</tr>
<tr>
<td>Sexual desire domain</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>Intercourse satisfaction domain</td>
<td>0.54</td>
<td>0.74</td>
</tr>
<tr>
<td>Overall satisfaction domain</td>
<td>0.40</td>
<td>0.74</td>
</tr>
<tr>
<td>QEQ total score</td>
<td>0.56</td>
<td>0.84</td>
</tr>
</tbody>
</table>

*P < 0.0001 except for the correlations with the IIEF sexual desire domain at baseline (P < 0.0345).
DBPC = double-blind, placebo-controlled; IIEF = International Index of Erectile Function; QEQ = quality of erection questionnaire.

(16/1,569) at baseline and 0.71% (27/3,807) at DBPC end-of-treatment. The per-patient mean responses at the baseline visit were predominantly EHS 2 and 3 compared with responses during treatment that were predominantly EHS 3 and 4 (Table 4). There was no evidence of floor or ceiling effects (Tables 3 and 4).

Validity
As predicted, the strongest convergent relationships among the IIEF domains were with the erectile function domain, and the weakest were with the sexual desire domain (Table 5). For the QEQ, which assesses satisfaction with erection quality, the convergent relationship with the EHS was stronger during treatment than at baseline.

The least squares mean EHS followed the expected direction, being lowest in the men categorized as having severe ED, and increasing with each subsequent category (Figure 2). The difference of the mean EHS between any pair of ED severity categories was statistically significant (P < 0.0001), and the 95% CIs did not overlap. Thus, the EHS is able to differentiate between men without ED and men with ED, and between all groups categorized by ED severity, thereby demonstrating good known-groups validity.

Clinically Important Difference
The estimate of EHS difference averaged across all groups (e.g., how much an average EHS score should change to move a group of men from a particular ED status to an adjacent ED status) was 0.86.

**Figure 2**  Estimate (least squares mean, 95% CI), using a repeated-measures, longitudinal, mixed model, of the EHS difference between adjacent IIEF erectile function severity groups: no ED (IIEF erectile function domain score of 26–30), mild ED (score of 22–25), moderate ED (score of 11–21), and severe ED (score of 1–10). CI = confidence interval; ED = erectile dysfunction; EHS = Erection Hardness Score; IIEF = International Index of Erectile Function.
Responsiveness
The EHS was highly responsive to treatment. Over the DBPC period, the least squares mean (95% CI) estimated difference in EHS between sildenafil and placebo was 0.943 (0.79–1.10), which exceeded an estimated clinically important difference (0.86). Thus, the group of men who used sildenafil for their ED had erectile function that was more than one ED severity category better than that of men who used placebo. The effect size calculated using the SDs of the mean baseline EHS (0.836) for the estimated difference was large (1.13).

Discussion
The results show that the EHS has excellent psychometric properties. The low rate of missing items is consistent with what has been reported recently for the QEQ [27], indicating that the EHS is easy to use. It was estimated that acceptable reliability requires at least three EHS responses, which addresses the potential for variability in erection hardness at different sexual encounters. This reliability finding is important for the use of the EHS in nontrial settings, but is consistent with the design of most clinical trials, which require a minimum number of sexual encounters between visits. Furthermore, the finding is consistent with other questionnaires validated in men with ED (e.g., IIEF, QEQ, SEAR, EDITS), which ask for a response based on sexual activity across several encounters (e.g., over the previous 4 weeks) [33–42].

Known-groups validity of the EHS was demonstrated against the IIEF, a well-known and established standard for evaluating ED, indicating that the EHS has the ability to differentiate between all severity groups of ED categorized by IIEF erectile function domain scores and to clearly differentiate between functional men (no ED) and men with compromised erectile function (mild ED). The mild-to-moderate ED group (EF domain scores of 17–21) and the moderate ED group (11–16) were combined to create a broader moderate ED group (11–21) in order to facilitate interpretation and to increase sample size within groups. If the mild-to-moderate group were separated (giving five instead of four ED severity groups), the results and conclusions would remain similar and consistent with those reported in this article.

As anticipated, convergent validity of the EHS was strongest with the IIEF erectile function domain vs. the other IIEF domains, and with the QEQ during treatment vs. at baseline. The EHS was highly responsive to treatment, with the estimated differences in EHS between men treated with sildenafil and those treated with placebo exceeding the average change in EHS score needed to move a group of men from a particular IIEF erectile function domain severity category to an adjacent severity category.

As aforementioned, the EHS has been an integral part of the sildenafil clinical trials program. In the controlled clinical trials that supported regulatory approval, Goldstein et al. [13] reported that 80% of men with ED who received 50-mg sildenafil, and 85% of those who received 100-mg sildenafil, achieved EHS 3 or EHS 4, compared with 50% of men with ED who received placebo. Also, 80% of EHS 3 erections and 94% of EHS 4 erections resulted in successful sexual intercourse. More recently, relationships have been established between the EHS and the QEQ [32]; erectile function [43]; scores for the sexual satisfaction measures of the IIEF (i.e., the overall satisfaction domain, its component questions, and the intercourse satisfaction domain) [44,45]; emotional well-being such as self-esteem, confidence, and relationship satisfaction assessed by the SEAR questionnaire [32]; and satisfaction with ED treatment assessed by the EDITS [32]. A shift in most frequent erection from EHS 3 at baseline to EHS 4 at the end of treatment was shown to be accompanied by significant improvements in intercourse and relationship satisfaction, psychosocial benefits, and satisfaction with ED treatment [32].

In comparison with most other patient-reported outcomes for evaluating erections in men with ED, such as the IIEF [46], the QEQ [27], the Erection Quality Scale [47], the Treatment Satisfaction Scale [48], and the Sexual Encounter Profile (SEP) [49], only the EHS and the SEP assess erections at the time of the sexual encounter (rather than relying on patient recall), and only the EHS specifically and concisely assesses erection hardness. Erection hardness is a fundamental component of erectile function, and is a very specific and easily monitored outcome.

Given that the EHS has been in use for more than a decade, it was not possible to adhere strictly to the FDA draft guidance, which describes a prospective process of questionnaire development and validation [15]. However, the analyses that were conducted are consistent with the analytic criteria of the FDA draft guidance as well as with established conventions [18–22], and a scale developed de novo would be validated according to the same
psychometric criteria that were applied to the EHS.

The EHS is a robust, single-item, patient-reported outcome for scoring erection hardness. It is easy to use and highly responsive to treatment. It could be incorporated into clinical practice as both an in-office screening tool and as a monitoring tool for home use between office visits. Psychometric analysis supports the use of the EHS as a simple, valid, reliable, and responsive tool for the assessment of erection hardness in clinical trials research.

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Conflict of Interest: Dr. Mulhall receives research support from Astellas Pharma Inc and Pfizer Inc, and is a consultant to Auxilium Pharmaceuticals, Eli Lilly and Company, Johnson & Johnson, Mentor Corporation, and Pfizer Inc. Dr. Goldstein is a consultant to Auxilium Pharmaceuticals, Bayer HealthCare, Coloplast, Eli Lilly and Company, Pfizer Inc, Surface Logix Inc, Vivus, Inc, and Wyeth Pharmaceuticals. Kyle Hvidsten, Joseph C. Cappelleri, and Andrew Bushmakin are employees of Pfizer Inc.

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