The Erection Hardness Score and Its Relationship to Successful Sexual Intercourse

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ABSTRACT

Introduction. The Erection Hardness Score (EHS), recently validated, was developed in 1998 as a simple (one-item) method to quantify erection outcome data. Although it is intuitive that erection hardness and successful sexual intercourse (SSI) are related, the link has not been directly established.

Objective. To evaluate the relationship between erection hardness (assessed by EHS) and SSI, establishing the EHS as a clinically useful tool.

Methods. The data set (N = 307) was from a multinational, double-blind, placebo-controlled trial (with open-label extension) of sildenafil citrate in men with erectile dysfunction.

Main Outcome Measures. Event-based modeling used every intercourse attempt and the EHS to estimate the odds ratio of SSI between adjacent EHS categories. Mean-based modeling used mean EHS per patient to determine its relationship to percentage of SSI. Mediation-based modeling used mean EHS and mean percentage of SSI over the double-blind phase to estimate the direct effect of sildenafil treatment on SSI and the indirect effect of sildenafil treatment on SSI via erection hardness.

Results. The odds of SSI for EHS 3 (hard enough for penetration but not completely hard) were 41.9 times (95% confidence interval [CI], 33.0–53.2; P < 0.0001) that for EHS 2 (hard but not hard enough for penetration), and the odds of SSI for EHS 4 (completely hard and fully rigid) were 23.7 times (95% CI, 19.5–28.9; P < 0.0001) that for EHS 3. The percentage of SSI increased approximately curvilinearly with the increase in mean EHS, from almost 60% at EHS 3 to 78.5% at EHS 3.5 and to 93.1% at EHS 4. The indirect effect of sildenafil treatment on SSI via erection hardness accounted for almost 90% of the total effect on SSI (P < 0.0001).

Conclusion. The close and direct relationship between erection hardness and SSI supports the broader use of the EHS—a simple, valid, reliable, and responsive measure—in clinical practice.


Key Words. Erection Hardness Score; Successful Sexual Intercourse; Sildenafil
Table 1  Erection Hardness Score

"How would you rate the hardness of your erection?"

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Penis does not enlarge</td>
</tr>
<tr>
<td>1</td>
<td>Penis is larger but not hard</td>
</tr>
<tr>
<td>2</td>
<td>Penis is hard but not hard enough for penetration</td>
</tr>
<tr>
<td>3</td>
<td>Penis is hard enough for penetration but not completely hard</td>
</tr>
<tr>
<td>4</td>
<td>Penis is completely hard and fully rigid</td>
</tr>
</tbody>
</table>

However, the scientific evidence-based link between erection hardness and SSI has not been directly established. Consequently, the objective of this report is to validate and quantify the relationship between the EHS and SSI through statistical modeling to determine whether erection hardness can be used as a proxy assessment of SSI. If such an association is found, the utility of the EHS as a clinical tool will be established.

Methods

Data Set

The data set, described previously [11], 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). The trial was conducted between May 2005 and January 2006 at 24 centers in Brazil, Italy, Germany, Poland, and Turkey [12]. Inclusion criteria were a clinical diagnosis of ED confirmed by an IIEF-Erectile Function domain score ≤25; ≤6 doses total and no dose within 4 weeks of sildenafil or another phosphodiesterase type 5 inhibitor for treatment of ED; and a stable sexual partner for the duration of the trial. Institutional Review Board approval was granted for each center, written informed consent was obtained, and there was adherence to all appropriate regulations.

Flexible-dose sildenafil (25, 50, or 100 mg as needed) or matching placebo was to be taken 30–60 minutes before 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 up or down based on efficacy and tolerability. The patients were instructed to attempt sexual activity at least two times per week.

Every time sexual intercourse was attempted or study medication was taken, the patient completed an event log consisting of items that queried study medication use (Q1: "Was the study medication taken?" and Q2: "If yes, how many tablets?") sexual stimulation (Q3: "Did you have any sexual stimulation?"), whether an erection was achieved (Q4: "Did you get an erection?"), erection hardness achieved (EHS [Q5: "How would you rate the quality of your erection?"]), whether sexual intercourse was attempted (Q6: "Did you attempt sexual intercourse?"), and whether sexual intercourse was successful (Q7: "Did your erection last long enough for you to have successful sexual intercourse?").
Data were 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).

**Data Analysis**

Every affirmative response to event log Q6 (sexual intercourse attempt) constituted an event (observation). The variable “SSI” was created based on affirmative answers to event log Q6 and Q7. If a patient answered “yes” to both Q6 and Q7, the outcome was assigned a value of 1. If the answer to either or both questions was “no,” the outcome was assigned a value of 0.

Because each patient had multiple events, data on the same patient over time are correlated. Consequently, several models were constructed to explore the relationship between EHS and SSI. The modeling methods are described briefly below; more details are included in the Appendix available online.

**Models**

The three models examined the odds ratio (OR) of SSI between adjacent EHS categories, the relationship of mean EHS per patient to per-patient percentage of SSI, and the effect of treatment on the per-patient percentage of SSI (directly and indirectly via erection hardness).

Event-based modeling (which uses every event of sexual intercourse as an observation) provides the probability of SSI for a given event. Mean-based modeling (which uses aggregate data on events of sexual intercourse over time) provides an overall picture of the relationship between a patient-averaged EHS and percentage of SSI. These two models are intended to provide complementary evidence to support the close correspondence between EHS and SSI.

The outcome of the mean-based modeling was used as an integral part of the subsequent mediation modeling, to postulate the functional relationship between EHS and SSI. A mediation model is one that seeks to identify and explain the mechanism that underlies an observed relationship between an independent variable (e.g., treatment) and a dependent variable (e.g., SSI) via the inclusion of a third explanatory variable (e.g., EHS), known as a mediator variable [13]. Rather than hypothesizing a direct causal relationship between the independent variable and the dependent variable, a mediation model hypothesizes that the independent variable causes the mediator variable, which in turn causes the dependent variable. The mediator variable, therefore, serves to clarify the nature of the relationship between the independent and dependent variables.

**Event-Based Modeling**

Every event (intercourse attempt) in every subject was a separate observation (i.e., SSI or not). The EHS was used as a categorical variable in this random-effects (random intercept) logistic regression model to estimate the OR (95% confidence intervals [CIs]) of SSI between adjacent EHS categories [14].

**Mean-Based Modeling**

All EHS data and SSI data that preceded a given visit were averaged per patient. Each man’s EHS was a continuous variable from 0 to 4. The per-patient percentage of SSI was used as an outcome, and each patient’s EHS was used as a predictor in longitudinal repeated-measures modeling [14]. The model did not impose any functional relationship between mean EHS and per-patient percentage of SSI.

**Mediation Modeling**

Mediation-modeling technique was used to estimate the effect of treatment on the outcome (per-patient percentage of SSI) directly (direct effect) and via erection hardness (indirect effect) [13].

**Results**

Analyses were based on event log and EHS data submitted by 307 men. The patients randomized to sildenafil (N = 154) or placebo (N = 153) were similar in age (mean, 45 years, range 18–55 years), ED duration (mean, 2 years, range <1–21 years), ED etiology, and race (>90% white) [12]. The patients commonly had comorbid medical conditions, including 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%) [12].

There were 14,131 events (observations) in the 307 men, for an average of 46 events per patient (maximum per patient, 95 events). In the last 4 weeks of the DBPC treatment phase, 87.6% (127/145) of sildenafil-treated men were using the 100-mg dose. In this period, EHS 3 predominated
Event-Based Modeling: The Relationship Between EHS and SSI

According to the random-effects logistic model, the odds of having SSI increased with each increase in EHS category. At increases between lower categories (EHS 1 vs. EHS 0 and EHS 2 vs. EHS 1), the increased odds of having SSI were relatively small (OR = 6). The largest ORs were those for EHS 3 (penis is hard enough for penetration but not completely hard) vs. EHS 2 (penis is hard but not hard enough for penetration) and for EHS 4 (penis is completely hard and fully rigid) vs. EHS 3. The odds of SSI for EHS 3 was 4.19 times (95% CI, 3.30–5.32; \( P < 0.0001 \)) that for EHS 2. The odds of SSI for EHS 4 (penis is completely hard and fully rigid) was 23.7 times (95% CI, 19.5–28.9; \( P < 0.0001 \)) that for EHS 3.

Mean-Based Modeling: The Relationship of Mean EHS to Percentage of SSI

The percentage of SSI increased approximately curvilinearly with the increase in mean EHS (Figure 1). In men with EHS 0.5 (i.e., mean between ≈0.25 and <0.75), fewer than 5% of intercourse attempts were successful, which did not differ significantly from the results in men with EHS 0 (i.e., mean <0.25). In men with EHS 3 (i.e., mean between 2.75 and 3.25), almost 60% of the intercourse attempts were successful. The percentage of SSI increased dramatically with EHS >3, to 78.5% in those with EHS 3.5 (i.e., mean between 3.25 and 3.75) and 93.1% in those with EHS 4 (i.e., mean ≥ 3.75).

Discussion

The results show a scientific, evidence-based, and direct relationship between erection hardness and SSI. The odds of having SSI increased with increasing EHS; the odds of SSI for EHS 4 (completely hard and fully rigid) were approximately 24
times that for EHS 3 (hard enough for penetration but not completely hard) and for EHS 3 were approximately 42 times that for EHS 2 (hard but not hard enough for penetration). The percentage of SSI increased approximately curvilinearly with the increase in mean EHS, from almost 60% at EHS 3 (i.e., mean between 2.75 and 3.25) to approximately 80% at EHS 3.5 (i.e., mean between 3.25 and 3.75) and >90% at EHS 4 (i.e., mean ≥ 3.75). The indirect effect of sildenafil treatment on SSI via erection hardness accounted for almost 90% (P < 0.0001) of the total effect of sildenafil on SSI.

Psychometric analysis supports the use of the EHS as a simple, valid, reliable, and responsive PRO [11]. From the perspective of researchers in sexual medicine, the EHS specifically addresses international consensus panel criteria defining ED treatment efficacy (“...the ability...to promote achievement and maintenance of firm or adequate erections”) [10]. From the perspective of patients, the EHS is easy to complete and is specific to an understandable and highly pertinent outcome. In fact, an international survey of more than 3,500 men with ED established that quality of erections, and specifically the capability to enable hard erections, is the primary attribute sought in a treatment for ED [15].

However, from the perspective of general practitioners and other physicians who are not specialists in sexual medicine, SSI may be a more meaningful outcome than erection hardness. The close and direct relationship between erection hardness and SSI indicates that erection hardness can be used as a proxy assessment of SSI. Incorporating the EHS into clinical practice is an easy way to assess erection hardness and, correspondingly, SSI.

A possible limitation to extrapolating the proxy relationship between EHS and SSI to clinical practice is that the data used in establishing the relationship were from a clinical trial. However, given that the patients in the clinical trial (based on their inclusion and exclusion criteria) are likely to be similar to those encountered in clinical practice, the extrapolation is expected to be reasonable and sound. Another possible limitation of these analyses is that, although the data set was geographically diverse (24 centers in Brazil, Italy, Germany, Poland, and Turkey), it was not geographically comprehensive. Regardless, the consistency of the response on the EHS and on SSI across different geographic regions [8,12,16] suggests that the inferences from our models are unlikely to differ substantially by region. In individuals with normal erectile function, it is assumed that the incidence of SSI would be high, but confirmation of our results would be useful.

Research on the EHS has established relationships, not just with the percentage of SSI [8,17], but with erection quality assessed with the Quality of Erection Questionnaire [12,16,18]; erectile function [12,16]; scores for the IIEF-Overall Satisfaction domain, its component questions, and the IIEF-Intercourse Satisfaction domain [19]; emotional well-being, such as self-esteem, confidence, and relationship satisfaction, assessed with the Self-Esteem And Relationship Questionnaire [12]; and satisfaction with ED treatment, assessed with the Erectile Dysfunction Inventory of Treatment Satisfaction [12]. 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 erectile function, intercourse and relationship satisfaction, emotional well-being, and satisfaction with ED treatment [19].

Conclusion
The EHS is easy to use and highly responsive to treatment. The relationship between erection hardness and SSI supports the use of the EHS as a proxy for SSI. This relationship also recommends a role for the EHS in clinical practice.

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Conflicts of Interest: Dr. Goldstein is a consultant to Alagin Research; Auxilium Pharmaceuticals; Bayer HealthCare; Coloplast; Eli Lilly and Company; Johnson & Johnson; Pfizer Inc; Slate Pharmaceuticals; and Vivas, Inc.

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.

Andrew G. Bushmakin, Joseph C. Cappelleri, Kyle Hvidsten, and Tara Symonds are employees of Pfizer.
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References

Appendix

Model Description

Event-Based Modeling
For a preliminary analysis to estimate the hardness effect, we disregarded the fact that the data were
collected as repeated measures. This approach gave us “crude” estimations of the odds ratios, which later were corrected using a random-effects model to account for the within-person correlation in the data.

**Effect of Erection Hardness Score on Successful Intercourse: “Crude” Odds Ratios**

<table>
<thead>
<tr>
<th>EHS</th>
<th>“Crude” odds of success (successful events/unsuccessful events)</th>
<th>“Crude” odds ratio [1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>7/1,243</td>
<td>OR (1 vs. 0) = 7.00</td>
</tr>
<tr>
<td>1</td>
<td>36/913</td>
<td>OR (2 vs. 1) = 2.85</td>
</tr>
<tr>
<td>2</td>
<td>162/1,444</td>
<td>OR (3 vs. 2) = 15.7</td>
</tr>
<tr>
<td>3</td>
<td>2,936/1,669</td>
<td>OR (4 vs. 3) = 11.8</td>
</tr>
<tr>
<td>4</td>
<td>5,457/264</td>
<td></td>
</tr>
</tbody>
</table>

A random-effects logistic model (more specifically, a random intercept logistic model) was constructed using all available data from all patients starting with the 2-week screening phase; through the 6-week double-blind, placebo-controlled treatment phase; and also through the subsequent 6-week open-label extension, such that every event (intercourse attempt) was used as a separate observation. EHS was used as a categorical variable.

**Mean-Based Modeling**

In mean-based modeling, all EHS data that preceded a given visit were averaged per patient, such that each man’s EHS was a continuous variable from 0 to 4. These mean data were subsequently divided into nine categories with half-category steps: EHS 0 (mean < 0.25), EHS 0.5 (0.25 ≤ mean < 0.75), EHS 1 (0.75 ≤ mean < 1.25), EHS 1.5 (1.25 ≤ mean < 1.75), EHS 2 (1.75 ≤ mean < 2.25), EHS 2.5 (2.25 ≤ mean < 2.75), EHS 3 (2.75 ≤ mean < 3.25), EHS 3.5 (3.25 ≤ mean < 3.75), and EHS 4 (mean ≥ 3.75).

Successful intercourse data that preceded a given visit were also analyzed per patient, such that the continuous variable was the per-patient percentage of successful sexual intercourse attempts over the time period. The curvilinear nature of the relationship was evident when successful intercourse was plotted against EHS. Therefore, when successful intercourse was plotted against EHS squared, a linear relationship surfaced as expected.

\[ R^2 = \text{coefficient of variation (i.e., the proportion of variation in the percentage of successful intercourse that is accounted for by variation in } x); x = \text{EHS squared.} \]

**Mediation Modeling**

In this model, which estimated the effect of treatment on successful intercourse directly (direct effect) and indirectly via erection hardness (indirect effect), treatment was represented by the binary variable (0 = placebo, 1 = sildenafil). EHS and percentage of successful intercourse attempts were averaged over the double-blind phase of the trial for every patient. The relationship between the mean EHS (X) and the mean percentage of successful intercourse attempts (Y) was postulated to be quadratic. Relationships between treatment (T) and mean EHS (X) and, separately, between treatment (T) and mean percentage of successful sexual intercourse attempts (Y) were postulated to be linear.