ARE PATIENTS AND THE GENERAL PUBLIC LIKE-MINDED ABOUT THE EFFECT OF ERECTILE DYSFUNCTION ON QUALITY OF LIFE?

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ABSTRACT

Objectives. To substantiate claims for treatment, patients may overestimate treatment effects. Consequently, in funding debates, the question becomes whether the general public agrees on the value of a treatment. Unfortunately, little is known about the social values for treatments of erectile dysfunction (ED). To solve this problem, we compared the values of patients and the general population for ED.

Methods. One hundred six ED patients and a representative sample of 169 individuals of the general population valued 28 health states of ED using time tradeoff. A hesitation to reveal preferences for this taboo subject or unawareness of the quality-of-life effects of ED may bias the social values. To explore the validity, we compared the factor structure of the valuation space of patients’ and social values using a multivariate analysis of variance repeated measure analysis. Furthermore, we analyzed whether social values were related to demographic or sexual variables.

Results. Patients valued ED lower than the general public, but the factor structure was the same. This evidence suggests that patients and the general public valued the health states of ED in the same way, although the overall level of appreciation differed slightly. Values were not systematically related to any other background variable.

Conclusions. Both patients and the general population consider erectile function an important aspect of quality of life. Therefore, funding for ED treatment might be considered. Moreover, because the value for erectile function was equivalent in different age groups, there is no convincing argument to limit funding to young patients.


Shortly after the release of sildenafil in Europe in 1998, the popularity of this drug became clear—no other drug has been prescribed so often in the first months after its introduction. Furthermore, trucks filled with sildenafil tablets were reported stolen, stories were told that elderly men left their wives to explore their renewed sexual abilities, and many public figures gave their opinion on the desirability of this treatment for erectile dysfunction (ED). However, the popularity of this drug also has a negative spin. The high sales figures go with the fear of misuse of this medicine; for example, recreational use by men without ED. Furthermore, some comments suggest that sildenafil should be classified as a lifestyle intervention rather than a medical treatment. In addition, with the high societal costs of funding this treatment, it may not be surprising that the desirability of funding of sildenafil is debated.

Usually, the severity of the health problem is an important consideration in reimbursement decisions. Interventions that target severe health problems are more likely to be reimbursed than treatments for relatively mild conditions. In the case of sildenafil, however, it is difficult for healthcare policy makers to determine whether funding of sildenafil is appropriate, because opposing views on the value of treatment with sildenafil have been expressed and scientific evidence is lacking to validate the different claims. Studies into the quality-
of-life effects of ED present ambiguous results. The results of some studies have suggested that men value their erectile function highly and that the quality of life in patients with ED is impaired, but other studies have indicated the opposite, and in public debates the value of treatment for ED has been doubted. The contradictory results of the quality-of-life studies might simply reflect variances in peoples’ values for erectile functioning, but also biases in the patient values may explain these outcomes. For example, upward biases might have influenced the results of Blanker et al. In the pre-sildenafil era, no noninvasive treatment was available. Patients’ values collected in that time might therefore reflect coping strategies, resulting in an overestimation of their quality of life. Upward biases may have also occurred as a consequence of the taboo on pleasure derived from erectile function; men might have hesitated to reveal their real preferences for this taboo subject. In other studies, downward biases may have distorted the values for treatments of ED. Patients could have strategically underestimated their quality of life, because it is in their personal interests to value treatment highly to substantiate their claim for (funding of) treatment. Furthermore, selection bias might have occurred: only patients who attribute low values to ED seek treatment.

For healthcare decision makers, the source of these contradictory results is important, because they might not want to fund this treatment if no agreement exists of its value. Circumstances such as this therefore call for systematic research into the values for ED. In our study, we compared the values of patients and the general public for health states of ED. Additionally, we assessed the impact of demographic and sexual background variables on the values of the general public to determine whether different subgroups of society have different values.

### MATERIAL AND METHODS

#### Respondents

Three hundred fifty-four people were invited by telephone to attend a session of health state valuation. This sample was representative for the Dutch population for sex and age. They were offered about 14 Euro plus travel expenses. To avoid selection bias, the invitation was made without referring to ED. Participants were allowed to withdraw from the valuation sessions without financial consequences after they were informed about the subject of the study.

Patients were recruited in two hospitals that participated in a Phase IV clinical trial of sildenafil: the University Medical Center St. Radboud in Nijmegen and Hospital St. Antonius in Leidschendam. Both hospitals included 75 patients; one half had a history of ED treatment, and one half were new starters of ED therapy. If patients agreed, the interview was administered at the hospital after one of the scheduled visits to the urologist. The medical ethics committees of the two hospitals approved the study.

#### Determining Values for ED

Participants valued 28 ED states on a scale from 0 (death) to 1.0 (perfect health) using time trade-off (TTO), a preferred method in quality-of-life assessment for use in societal decision making. The health states in the valuation exercise (Table I) were based on questions 3, 4, and 7 of the International Index of Erectile Function. Questions 3 and 4 describe the two primary endpoints of ED treatment as the ability to attain and maintain an erection sufficient for satisfactory sexual performance. Because each question has five response levels, together they describe 25 ED states (5 × 5). The five ED states defined by question 7, about the satisfaction of intercourse in general, were entered into the valuation exercise independently. Of these 30 ED states, 28 were valued. The others describe normal erectile function and were set at a value of 1.0.

In the TTO, respondents were asked to imagine that they suffered from a disease that could be cured, but at the cost of life years. The subjects were asked how many life years they were willing to tradeoff. The ED states were thereby valued in terms of the proportion of a year in perfect health, equivalent to 1 year of life with ED. For example, if a respondent traded

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
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</table>
| 3. When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner? | 0 = Did not attempt intercourse
1 = Almost never or never
2 = A few times (much less than half of the time)
3 = Sometimes (about half of the time)
4 = Most times (much more than half of the time)
5 = Almost always or always |
| 4. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner? | |
| 7. When you attempted sexual intercourse, how often was it satisfactory for you? | |

* For a complete description of the questionnaire see Rosen et al.
† The time frame of the questions was “during the past 4 weeks.”
‡ Not included in our survey because this answer gives no information about problems with erectile function.
off 20% of his remaining life expectancy, the health state was valued at 0.80.

The tradeoff was measured relative to the life expectancy of the subjects. For example: “If during the past 4 weeks, your condition was such that you were sometimes able to attain an erection, and you were (almost) never able to maintain your erection, how many years would you be willing to tradeoff to restore your erectile function?” The underlined parts of the question varied, corresponding with the different gradations of ED. The subjects gained experience in the TTO method using health states defined by the EQ-5D questionnaire, a standardized and internationally validated generic quality-of-life questionnaire.9 As this exercise was also intended to provide reference points for the valuation, mild, moderate, and severe EQ-5D states were included, categorized in the EQ-5D as health states 11211, 11122, and 21232.

Respondents had to value the ED states “for a person like themselves.” Thus, older subjects gave values from an aging perspective, and persons without a sexual active partner could incorporate this circumstance in their values. The exception was gender: women had to imagine that they were men with ED. The ED states were presented on cards in random order; the TTO outcomes were self-administered. The interviews of patients and the general public were the same, except that the general public was interviewed in group sessions and the patients individually. The validity of the group sessions had been established in a previous investigation.10,11

Invalid Responses

Responses were excluded when a respondent left more than four questions unanswered, clearly did not understand the task, or used a lexicographic response mode for the EQ-5D states. A lexicographic response mode means that when a respondent is faced with an option, the person always prefers one particular alternative, no matter how favorable the other might be. In TTO, this usually means that the subject is not willing to tradeoff any life years, no matter how severe the health state. No tradeoff in time could also mean that the respondent does not see the particular health state as such a big problem, which might apply to ED. Therefore, exclusion of lexicographic responses was based on the EQ-5D states only: if a respondent did not make any tradeoff for ED states, the responses were considered valid, as long as the responses for the EQ-5D states were valid and not lexicographic.

Statistical Analysis

Differences between subject groups (patients or general public) and differences within the general population as a result of background characteristic (having a partner, age, having children, the frequency of intercourse, and the satisfaction of intercourse in general) were univariately and multivariately tested. For the univariate analysis, the t test was used. The multivariate analysis was performed using multivariate analysis of variance repeated measure analyses.

The repeated measure analysis will reveal if an overall difference is present between the respondents; for instance, patients might give, on average, lower values than the general public. In addition to this overall “between subjects” effect, the repeated measure analysis will also reveal if the factor structure of the responses of patients and the general public is the same. For instance, this analysis might reveal that question 3 is more important than question 4 in patients compared with the general public. To perform this analysis, we labeled questions 3 and 4 as two “within subjects” factors in the repeated measure multivariate analysis of variance. A similar factor structure should result in small or nonsignificant interaction effects between the subgroups and the two “within subjects” factors (questions 3 and 4).

The purpose of the analysis of the factor structure was to explore the validity of social values. After all, the general public might be unaware of the way in which ED affects a person’s quality of life, because ED is a taboo subject. We assumed that the validity of social values could be doubted if the factor structure differed between the patients and the general public.

RESULTS

Of the 150 patients in the trial, 106 were interviewed. The others discontinued participating in the trial because of unsatisfactory treatment effects before we were able to interview them. In the 106 interviews, we collected 90 valid responses (85%). Of the 354 invited subjects from the general population, 169 attended the interview, and 150 gave valid responses (89%). In both patients and the general public, most invalid responses were the result of a lexicographic response mode (52%). The mean age of persons with valid responses was 56.74 years (SD 11.59) in patients and 45.81 years (SD 15.44) in the general population. In the sample of the general population, the sex distribution was close to expected, but the distribution over age differed from the distribution in the general population.12

For the 24 ED states defined by International Index of Erectile Function questions 3 and 4, the social values ranged from 0.74 to 0.93, and patients’ values ranged from 0.68 to 0.91 (Table II). The values for question 7 ranged from 0.75 to 0.95 in the general public and from 0.68 to 0.91 in patients. The mean difference between patients’ values and those of the general public was 0.06 (P = 0.004, tested multivariately). Univariately, the observed difference was statistically significant for 18 of the 28 ED states, mostly moderate to severe ED states. The repeated measure analysis showed that no statistically significant interaction was present between the two within-subject variables and the between-subject variable “respondents” (question 3: P = 0.150 and question 4: P = 0.134). In both patients and the general public, the values increased if performance on questions 3 and 4 improved. The analysis also revealed that the patients’ values and those of the general public had the same factor structure given the valuation space as defined by questions 3 and 4 of the International Index of Erectile Function. That is, no statistically significant interactions were found between the two “within subjects” variables (questions 3 and 4) and the “between subjects” variable “respondent” (P = 0.454). Thus, the validity of the social values was confirmed. This means that on average the general public considered the problems of ED to be less bothersome, but this finding cannot be explained by unawareness of the general population for the problems associated with ED.
The multivariate repeated measure analysis showed that the background variables of age ($P = 0.962$), gender ($P = 0.381$), having a partner ($P = 0.328$), frequency of intercourse ($P = 0.621$), and satisfaction derived from intercourse ($P = 0.911$) were not related to the values for the ED states. The only background variable related to the values for ED was having children: subjects with children considered ED less a problem than did subjects without children ($P = 0.000$).

**COMMENT**

On average, patients valued ED lower than the general public, but the factor structure was the same. This evidence suggests that patients and the general public valued the health states of ED in the same way, although the overall level of appreciation differed slightly. Compared with other illnesses, the values indicate a moderate quality-of-life impairment with complete ED and milder impairments for less severe ED states. For example, moderate benign prostatic hyperplasia is valued at 0.90, moderate rheumatoid arthritis is valued between 0.60 and 0.70, and disseminated prostate cancer is valued between 0.35 and 0.50. Although the difference between the patients' values and social values was statistically significant, the values were of the same magnitude, suggesting that the general public and patients were like-minded about the value of ED.

Patients valued ED lower than the general public. Often, the opposite result is found, first because patients tend to marginalize their problems if no treatment is available (coping) and second because healthy people generally underestimate the quality of life because they do not anticipate that they will adapt to health problems. Our patients,

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**TABLE II. Values of patients and the general public for erectile dysfunction**

<table>
<thead>
<tr>
<th>Q3—Ability to Penetrate?</th>
<th>General Public (n = 123)</th>
<th>Patients (n = 93)</th>
<th>Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>0.74 ± 0.18</td>
<td>0.68 ± 0.26</td>
<td>0.06</td>
<td>0.043*</td>
</tr>
<tr>
<td>A few times</td>
<td>0.77 ± 0.17</td>
<td>0.70 ± 0.26</td>
<td>0.07</td>
<td>0.025*</td>
</tr>
<tr>
<td>Sometimes</td>
<td>0.79 ± 0.16</td>
<td>0.71 ± 0.25</td>
<td>0.07</td>
<td>0.014*</td>
</tr>
<tr>
<td>Most times</td>
<td>0.80 ± 0.16</td>
<td>0.73 ± 0.24</td>
<td>0.09</td>
<td>0.003*</td>
</tr>
<tr>
<td>Always</td>
<td>0.82 ± 0.16</td>
<td>0.74 ± 0.25</td>
<td>0.08</td>
<td>0.006*</td>
</tr>
<tr>
<td>A few times</td>
<td>0.80 ± 0.16</td>
<td>0.73 ± 0.25</td>
<td>0.07</td>
<td>0.022*</td>
</tr>
<tr>
<td>Most times</td>
<td>0.86 ± 0.14</td>
<td>0.80 ± 0.23</td>
<td>0.08</td>
<td>0.005*</td>
</tr>
<tr>
<td>Always</td>
<td>0.87 ± 0.14</td>
<td>0.81 ± 0.22</td>
<td>0.07</td>
<td>0.012*</td>
</tr>
<tr>
<td>Most times</td>
<td>0.82 ± 0.15</td>
<td>0.75 ± 0.22</td>
<td>0.05</td>
<td>0.008*</td>
</tr>
<tr>
<td>Always</td>
<td>0.85 ± 0.16</td>
<td>0.79 ± 0.22</td>
<td>0.07</td>
<td>0.016*</td>
</tr>
<tr>
<td>Sometimes</td>
<td>0.86 ± 0.14</td>
<td>0.81 ± 0.23</td>
<td>0.06</td>
<td>0.025*</td>
</tr>
<tr>
<td>Most times</td>
<td>0.88 ± 0.14</td>
<td>0.85 ± 0.21</td>
<td>0.03</td>
<td>0.175</td>
</tr>
<tr>
<td>Always</td>
<td>0.91 ± 0.13</td>
<td>0.85 ± 0.18</td>
<td>0.05</td>
<td>0.026*</td>
</tr>
<tr>
<td>Always</td>
<td>0.82 ± 0.15</td>
<td>0.77 ± 0.24</td>
<td>0.05</td>
<td>0.068</td>
</tr>
<tr>
<td>A few times</td>
<td>0.86 ± 0.15</td>
<td>0.81 ± 0.22</td>
<td>0.05</td>
<td>0.051</td>
</tr>
<tr>
<td>Most times</td>
<td>0.90 ± 0.13</td>
<td>0.84 ± 0.19</td>
<td>0.06</td>
<td>0.012*</td>
</tr>
<tr>
<td>Always</td>
<td>0.94 ± 0.12</td>
<td>0.91 ± 0.16</td>
<td>0.03</td>
<td>0.172</td>
</tr>
<tr>
<td>Always</td>
<td>0.94 ± 0.12</td>
<td>0.91 ± 0.17</td>
<td>0.04</td>
<td>0.071</td>
</tr>
<tr>
<td>Most times</td>
<td>0.84 ± 0.15</td>
<td>0.79 ± 0.22</td>
<td>0.06</td>
<td>0.036*</td>
</tr>
<tr>
<td>Always</td>
<td>0.89 ± 0.14</td>
<td>0.84 ± 0.20</td>
<td>0.04</td>
<td>0.104</td>
</tr>
<tr>
<td>Most times</td>
<td>0.91 ± 0.13</td>
<td>0.87 ± 0.18</td>
<td>0.04</td>
<td>0.064</td>
</tr>
<tr>
<td>Always</td>
<td>0.95 ± 0.13</td>
<td>0.91 ± 0.16</td>
<td>0.02</td>
<td>0.303</td>
</tr>
<tr>
<td>Q7—Satisfactory intercourse</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Data presented as the mean ± SD.

*Significant ($P < 0.05$).
however, participated in a trial, which makes it unlikely that they would marginalize their problems. Rather, they would overemphasize them to motivate their participation in the trial. Also the dropout of the nonresponders may have biased our results. It is, however, difficult to discern whether this dropout would have introduced an upward or a downward bias, if any. Given that the ED of the nonresponders turned out to be untreated, coping might have pushed their values upward. However, coping usually only concerns the value for the current health state of the patient and not for other health states. Because patients valued not only their own health state, but other health states as well, the strategic bias described above was probably of greater importance than the dropout rate.

Other biases may have affected both patient and social values. First, respondents might have given socially desirable answers. We were afraid that the taboo would result in values that were too high, but social pressure may actually have introduced a downward bias as a result of the popularity of sildenafil. Second, response spreading may have biased our results. Values may partly depend on the number of health states underpinning it that are preferred and less preferred. To scrutinize our results, we, therefore, repeated our measurement of the value for a health state of complete ED in the general public 1 year later. This time, the general public (n = 170) valued complete ED at 0.80, which suggests that the initial values were indeed a bit low. Nevertheless, because the values were of the same magnitude, the general conclusion that the general public also considered ED a substantial problem still stands.

A surprising finding was the large level of agreement about the quality-of-life effects of ED across subgroups of society. Although the robustness of the values for background variables may have been anticipated on the basis of published data, we did not expect this to hold for sexual functioning as well, because this subject seems surrounded by taboos and strictures imposed by society. The congruence between the values of men and women might have been induced by our method, because we asked women to imagine being men and not for their own values. It is harder to explain the robustness for the other background characteristics. It was not a power problem, because the power was strong enough to pick up differences based on having children. Thus, perhaps our hypothesis was wrong. In that respect, it should be noted that a number of studies have already proven false the stereotyped assumption that sexual activity and interest decrease in the elderly. Bretschneider and McCoy and Diokno et al. found that 60% of the older men and 30% of the women (older than 60 years) are sexually active. According to their research, decreasing sexual activity in the elderly depends on current physical and social factors, such as the availability of a partner, and not so much on a lack of interest, as is often assumed.

CONCLUSIONS

The results showed that both patients and the general public considered ED to have a mild to moderate impact on quality of life. The agreement about the importance of sexual functioning for a person’s life suggests that funding could be considered. The next question then becomes whether the impact on the quality of life is severe enough to substantiate a claim for treatment.

REFERENCES


