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The Cost-Effectiveness of Sildenafil

[Articles]

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Abstract

Background: Coverage of sildenafil by health insurance plans is a contentious issue.

Objective: To evaluate the cost-effectiveness of sildenafil treatment for erectile dysfunction.

Design: A Markov decision model to estimate the incremental cost-effectiveness of sildenafil compared with no drug therapy.

Data Sources: Values for the efficacy and safety of sildenafil and quality-of-life utilities were obtained from the published medical literature. Base-case values were chosen to bias against sildenafil use.

Target Population: Men 60 years of age with erectile dysfunction.

Time Horizon: Lifetime.

Perspective: Societal and third-party payer.

Intervention: Sildenafil or no treatment in identical hypothetical cohorts.

Outcome Measures: Cost per quality-adjusted life-year (QALY) gained.

Results of Base-Case Analysis: The cost per QALY gained for sildenafil treatment compared with no therapy was $11 290 from the societal perspective and $11 230 from the third-party payer perspective.

Results of Sensitivity Analysis: From the societal perspective, the cost per QALY gained associated with sildenafil was less than $50 000 if treatment-related morbidity was less than 0.8% per year, mortality was less than 0.55% per year, treatment was successful in more than 40.2% of patients, or sildenafil cost less than $244 per month. The results were sensitive to variation of erectile dysfunction utilities, but cost per QALY gained was less than $50 000 if successful treatment increased utility values by 0.05 or more on a scale of 0 (death) to 1 (perfect health).

Conclusions: In an analysis biased against use of sildenafil, the cost-effectiveness of sildenafil treatment compared favorably with that of accepted therapies for other medical conditions.

Coverage of sildenafil (Viagra, Pfizer, Inc., New York, New York) by third-party payers is a contentious issue (1-4). Sildenafil treatment is effective for erectile dysfunction (5-7), but it is costly (1-3) and may lead to serious illness and death when used by men with cardiac conditions, particularly those with coronary artery disease who are taking nitrate medications (8-10). Because erectile dysfunction is not a life-threatening illness, some authors have questioned the appropriateness of insurance coverage for sildenafil given its costs and potential for harm and abuse (1, 3, 10-12). Some insurance plans in the United States and in other countries restrict coverage of sildenafil therapy to men who fall within strictly defined criteria, and some do not cover it at all (2, 13, 14).

Erectile dysfunction is estimated to occur in 30 million men in the United States (15). Other treatments for this condition involve penile injection (16), placement of intraurethral medication (17), use of vacuum devices, or surgical interventions (18). These methods, although useful, may not be acceptable to many men with erectile dysfunction (19). These men may find sildenafil, which is taken orally, to be a more acceptable intervention, even when the risks of treatment are considered (15, 19).

Although insurance companies consider many issues when making coverage decisions, it is not clear whether decisions about sildenafil coverage have been based on cost-effectiveness calculations. To clarify this issue, we performed a cost-utility analysis.

Methods

We used standard decision-analysis software (Decision Maker 7.01, Pratt Medical Group, Boston, Massachusetts) to construct a Markov decision model (20) that estimated the incremental cost-effectiveness of treating erectile dysfunction with sildenafil compared with no treatment. Our base-case analysis took the societal perspective, which considers both direct medical costs and indirect costs of obtaining care (21), and was designed to follow the reference-case recommendations of the Panel on Cost-Effectiveness in Health and Medicine (22). We also performed an analysis from the third-party payer perspective, using only direct medical costs (21). To account for potential changes in quality of life, morbidity, and mortality (22), incremental cost-effectiveness was calculated as cost per quality-adjusted life-year (QALY) gained. Costs and benefits were discounted at a rate of 3% per year (22).

Model

A schematic diagram of the Markov model is shown in the Figure. Sildenafil treatment and no treatment were tested in identical hypothetical cohorts of 60-year-old men. The Markov cycle length was 1 month. In either strategy, all men began the model in the erectile dysfunction state. Sildenafil-treated men could transition to the no erectile dysfunction state (on the basis of the rate of successful sildenafil therapy), have a morbid event or die because of treatment, remain in the erectile dysfunction state if treatment was unsuccessful, or die of natural causes (on the basis of data from standard mortality tables [23]). Unsuccessfully treated men were assumed to receive treatment for 1 month, during which they accrued 1 month's costs and risk for adverse events. After 1 month, sildenafil therapy was discontinued. In further cycles of the model, successfully treated men would continue to be at risk for morbidity and death due to sildenafil therapy or could revert to the erectile dysfunction state because of loss of treatment efficacy over time. Unsuccessfully treated men who had no morbid events remained in the erectile dysfunction state until they died of other causes.

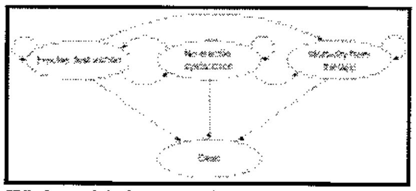


Figure. **The Markov model.**

[Help with image viewing]

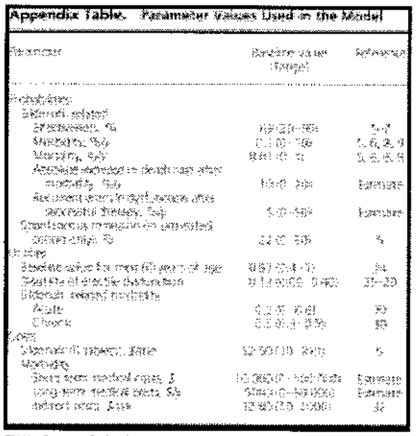
Untreated men remained in the erectile dysfunction state or had spontaneous remission of erectile dysfunction. They too were followed until they died of other causes.

Assumptions

The main simplifying assumption of the model was that treatments other than sildenafil for erectile dysfunction were not considered; that is, we modeled a situation in which other forms of treatment were not considered because they were unsuccessful or unacceptable for the patient. We also assumed that the effectiveness of sildenafil is not related to the success or acceptability of other treatments. Otherwise, assumptions biased the base-case analysis against sildenafil use. We assumed that morbidity and death due to sildenafil use occurred at rates significantly higher than those reported (5, 6, 8, 9). Men who had morbid events due to sildenafil were completely disabled for the remainder of their lives and died at high rates after those events. Untreated men could have spontaneous remission of erectile dysfunction, but unsuccessfully treated men with erectile dysfunction could not. We also modeled a loss of treatment effect over time for men who were successfully treated with sildenafil, which has not yet been described.

Parameter Values

Probabilities, utilities, and costs used in the base-case analysis of the model are listed in the Appendix Table. Spontaneous remission of erectile dysfunction occurred only in the untreated cohort, at a rate based on the remission rate seen in placebo-treated men (5). Utilities are represented on a scale of 0 to 1, in which 0 denotes death and 1 denotes perfect health. The utility for normal erectile function is based on the average utility for men 60 years of age as measured by using time-tradeoff methods from the Beaver Dam Health Outcomes Study (24). The disutility for erectile dysfunction is derived from an time-tradeoff utility value (0.74) for this condition obtained from men in the context of prostate cancer screening decisions (25). That value subtracted from the average utility from the Beaver Dam Health Outcomes Study (0.87) results in a disutility of 0.13, a value consistent with those from other studies in which disutility from erectile dysfunction ranged from 0.05 to 0.40 (26-29). Utilities for acute and chronic illness are based on utilities for short-term hospitalization and chronic disability (30).



Appendix Table. Parameter Values Used in the Model

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Costs are expressed in 1998 U.S. dollars. Sildenafil costs are the average wholesale prices (31) of six tablets per month (5). Costs of morbidity are estimates based on hospitalization and long-term treatment for cardiac conditions. Indirect costs for time spent obtaining care are based on the average hourly wage of non–farm workers in the United States (32). We assumed that disabled patients will spend 1 hour per week seeking care. Lost wages due to premature death or disability are not included in the model, following the reference-case recommendations of the Panel on Cost-Effectiveness in Health and Medicine (22).

Sensitivity Analysis

All parameters were varied through the ranges shown in the Appendix Table. In addition, we varied patient age from 40 to 80 years. Parameters that caused the cost-effectiveness ratio to increase above $50 000 were deemed sensitive to variation. These parameters were examined in several types of sensitivity analyses. It should be noted that no absolute threshold for cost-effectiveness exists (22); however, $50 000 per QALY gained is a commonly cited reference point in cost-effectiveness analyses (33).

Role of the Funding Source

Our study had no external funding.

Results

In the societal analysis, sildenafil-treated men gained 0.35 QALY more than untreated men at a cost of $3970; the resulting incremental cost-effectiveness ratio was $11 290 per QALY gained (Table 1). When only direct medical costs were considered from the third-party payer perspective, $3950 was spent for the same gain in QALYs, for an incremental cost-effectiveness ratio of $11 230 per QALY gained. We considered only the societal perspective in the sensitivity analyses.

Table 1. Results of the Base-Case Analysis*

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Sensitivity Analysis

Parameters whose variation caused the cost-effectiveness ratio to cross the $50 000 threshold are shown in Table 2. Morbidity rates, utilities, costs, excess mortality after morbid events, and patient age were not sensitive to variation. The incremental cost-effectiveness ratio increased to $27 800 then we modeled a patient 40 years of age who had an acute morbidity utility of 0.0 and cost of $100 000 and a chronic morbidity utility of 0.3 and cost of $50 000 per year (the values most unfavorable to sildenafil treatment). If successful therapy increased the utility by 0.05 or more, the cost per QALY gained remained less than $50 000 through a broad range of utilities.

Table 2. One-Way Sensitivity Analysis*

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* [illegible]

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Table 2. One-Way Sensitivity Analysis*

The effectiveness of and morbidity related to sildenafil, erectile dysfunction disutility, and baseline utility were varied simultaneously over the ranges shown in the Appendix Table by using a probabilistic sensitivity analysis (34). These parameters were entered as log-normal distributions (centered on the baseline value) and were randomly selected during each iteration of the model. In 1000 iterations, 98.2% had an incremental cost-effectiveness ratio of less than $50 000 per QALY gained for sildenafil treatment. The 25th percentile was $9040 per QALY gained, the 50th percentile was $11 500, and the 75th percentile was $15 600.

Discussion

In our analysis, the cost-effectiveness ratio of sildenafil compared favorably with those of commonly recommended interventions for other medical conditions, costing less than renal dialysis, cholesterol-lowering medication, and coronary artery bypass grafting (22). This result remained consistent even though we systematically biased the analysis against sildenafil use.

Utilities for erectile dysfunction and its successful treatment played a large role in our analysis, and the base-case disutility for erectile dysfunction that we used, 0.13, may be debatable. However, as long as successful treatment increases the utility by 0.05 or more, sildenafil treatment costs less than $50 000 per QALY gained. A potential limitation of our study is that we did not directly measure changes in utility due to sildenafil treatment. However, we varied utilities widely in sensitivity analyses, and the results were robust to variation in clinically plausible ranges.

It has been argued that because erectile dysfunction is not a life-threatening illness, sildenafil should not merit insurance coverage. However, treatment for many other non–life-threatening illnesses that affect only quality of life (for example, migraine, headaches) is covered by insurers. In addition, penile implantation surgery for erectile dysfunction, which incurs average costs of $6000 to $7000, is covered by insurance (35). Before sildenafil became available, expensive diagnostic evaluations for erectile dysfunction were also covered. Sildenafil treatment of erectile dysfunction may be treated differently by third-party payers because of the complex issues it raises (36). Cost-effectiveness analyses can be informative in this situation because they systematically distill medical decisions down to the amount of life, quality of life, or both that are gained by an intervention and how much the intervention and its effects cost. In this way, various treatments can be compared fairly by using accepted parameters.

When the economic aspects of sildenafil treatment are examined, this treatment is reasonable from a cost-effectiveness standpoint. Therefore, it seems that insurance companies that limit or deny coverage for sildenafil have not based their decisions on cost-effectiveness calculations. Clearly, however, other factors may override cost-effectiveness in making coverage decisions. The severe adverse effects of sildenafil—sudden death, myocardial infarction, and arrhythmia, among others—are influential. The pure cost of supplying sildenafil to a potentially large group of patients, the ethics of covering sildenafil when abuse is a possibility and other treatments may have higher priority, and the force of political pressure are also important components of this choice.

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Cost-benefit analysis; Sildenafil; Impotence; Insurance, health; Insurance, pharmaceutical services

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