Patient Responsibility for Medical Decision Making and Risky Treatment Options

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Objective. Studies have shown that increasing patient participation in decision making decreases utilization of risky procedures. It has been demonstrated that risk perception is increased under conditions that emphasize volition, or the act of choosing. The objective of this study was to examine whether emphasizing volition increases patients’ risk perception and decreases their willingness to accept risk.

Methods. Consecutive patients attending outpatient clinic appointments viewed a video in which a physician described the availability of a new medication associated with a rare risk of a serious side effect. Patients’ willingness to accept treatment and worry about the risk of the serious side effect were measured under 2 different conditions: one that minimized patient involvement and the one that maximized patient involvement in the decision-making process.

Results. The willingness of the subject to take the proposed medication was lower (mean ± SD 4.2 ± 3.7 versus 5.3 ± 3.7; P < 0.001) and their worry about the risk of the adverse event was greater in the high compared with the low involvement condition (mean ± SD 6.1 ± 3.7 versus 5.5 ± 3.8; P < 0.001).

Conclusion. Increasing patient responsibility in medical decision making may decrease the patient’s willingness to accept risky treatment options.

INTRODUCTION

Significant efforts are currently being made to increase patient participation in decision making. Several studies have found that patients who ask questions and express concerns during clinical encounters have better outcomes than their more passive counterparts (1–4). For example, Ward et al (3) reported that women with systemic lupus erythematosus who participate more actively in their visits have less morbidity compared with women who were more passive. Although patient participation in health care is generally known to have positive effects on patient satisfaction and disease-specific outcomes, less is known regarding the effects of shifting the burden of responsibility in decision making to the patient.

There are data demonstrating that promoting patient involvement in decision making via the use of decision aids leads to improved knowledge and decreased decisional conflict (5). Fewer studies have reported the effects of decision aids on changes in health care utilization. Nonetheless, a recent systematic review found that, despite some variability, controlled trials have found stronger preferences for conservative versus major surgical interventions among patients randomized to a decision aid compared with those receiving usual care (5). The accepted explanation for this finding is that patients are more likely to choose conservative measures when empowered to make informed, value-concordant decisions (6,7). However, a recent study from the basic decision-making literature by Nordgren et al (8) suggests a different possibility. In this study, the authors demonstrated that risk perception is increased under conditions that emphasize volition, or the act of choosing whether or not to engage in a risky activity. For example, city dwellers living on a bus route perceive greater risk associated with driving compared with rural dwellers. This difference occurs because city dwellers have a choice over whether or not to engage in the risky activity. For example, city dwellers living on a bus route perceive greater risk associated with driving compared with rural dwellers. This difference occurs because city dwellers have a choice over whether or not to engage in the risky activity, whereas the act of driving is imposed for rural dwellers who have few, if any, alternative forms of transportation. This study suggests that patients’ worry about risks related to proposed treatment options might be amplified when the responsibility for making a decision is shifted from the physician to the patient.

Considering these findings, we conducted a proof-of-concept study to determine whether the decreased will-
MATERIALS AND METHODS

We created 2 videos (A and B) of a physician (LF) seated at a desk describing the availability of a new medication associated with a rare risk of an adverse event (jaw necrosis in video A, progressive multifocal leukoencephalopathy in video B) relevant to patients with rheumatic diseases. We chose to develop 2 videos in order to examine the willingness to accept risk for primary prevention as well as for symptom control. Scenarios were developed to ensure that patients were not presented with adverse events related to the medications they were currently taking. Video A discussed a new medication to prevent heart disease and video B discussed a new medication to treat chronic pain. In both videos, the medication was described as being a very effective, small pill taken once a day, which would not interfere with any other medications, was completely covered by the subject’s insurance, and was very well tolerated except for the extremely rare risk of a serious side effect. Subjects were told that the medications were hypothetical. The video scripts are provided in Supplemental Appendix A (available in the online version of this article at http://www3.interscience.wiley.com/journal/77005015/home).

Eligibility criteria for video A included age ≥50 years and currently taking ≥1 prescription medication for a chronic disease. Patients with known heart disease, osteoporosis or osteopenia, or who were currently taking a bisphosphonate were excluded. To be eligible to view video B, subjects had to be age ≥18 years and currently taking ≥1 prescription medication for a chronic, painful condition.

Six formats including combinations of quantitative (1 in 100,000), qualitative (extremely rare), and common examples (number of people that can be seated in a major college stadium) were used to describe risk. The risk formats varied for the purpose of a separate study on risk communication and were treated as covariates in the current study. A random number sequence was used to determine which risk format each subject viewed.

Consecutive subjects were approached in a university hospital-affiliated outpatient clinic serving general medicine and subspecialties. Following their clinical consultation, the subjects were asked to view either video A or B, depending on their eligibility criteria. Subjects eligible for both were randomly assigned to view 1 of the videos. After viewing the videos, each subject was exposed to 2 consecutive sets of instructions. The first set of instructions, designed to minimize volition, contained the following statement: “The doctor decides that you should take this medication and she writes you a prescription for it.” The second set of instructions was designed to maximize volition: “The doctor tells you that it is completely up to you whether or not you take this medication and then asks you to make a decision.” After reading each set of instructions, subjects rated (on 11-point numeric scales, where 0 = the lowest value and 10 = the maximum value) their willingness to take the medication and their worry about developing the rare complication described on the video. The order of presentation was systematically varied to ensure balance, and order was treated as a covariate. To determine whether this manipulation was successful, we asked subjects to rate (using an 11-point numeric scale) how responsible they would feel if they developed the complication that was described in the respective condition. Mean ± SD scores for the high and low volition conditions were 6.6 ± 3.8 and 4.8 ± 3.8, respectively, and the difference was statistically significant (P < 0.001, using Wilcoxon’s 2-tailed signed rank test).

We first examined whether there were any significant differences in willingness and worry across both volition conditions using Wilcoxon’s 2-tailed signed rank test. We then sought to determine whether the observed difference in willingness across the low and high volition conditions was associated with a corresponding difference in worry after controlling for age, sex, education, health status, clinical scenario, and risk format using a linear regression model. In this model, difference in willingness across both conditions (i.e., willingness to take the medication when “the doctor decides that you should take this medication and she writes you a prescription for it” or willingness to take the medication when “the doctor tells you that it is completely up to you whether or not you take this medication and then asks you to make a decision”) was treated as the dependent variable. The study protocol was approved by the Human Investigations Committee at Yale University School of Medicine.

RESULTS

A total of 832 subjects were approached, of whom 418 were eligible. Of these 418, 11 refused to enroll and 191 could not stay after their appointment to be interviewed because of time constraints, leaving a total of 216 participants. The mean age of the study sample was 59 years (range 21–88 years), 62% were women, 70% were white, 65% had at least some college education, and 28% reported their overall health status as being excellent or very good. Demographic data were not available for nonparticipants.

As predicted by Nordgren et al (8), subjects’ worry about the risk of the adverse event was greater in the high volition condition compared with the low (mean ± SD 6.1 ± 3.7 versus 5.5 ± 3.8; P < 0.001). Willingness to take the proposed medication was lower in the high volition condition compared with the low (mean ± SD 4.2 ± 3.7 versus 5.3 ± 3.7; P < 0.001). There was no main effect of scenario on patient willingness (P = 0.6). In the regression model, worry remained significantly associated with willingness to take the proposed medication after adjusting for age, sex, education, and health status, clinical scenario, and risk format (Table 1).
Table 1. Association between differences in patient willingness and worry under high and low volition conditions*

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>SEE</th>
<th>R² change</th>
<th>F change</th>
<th>P for F change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order, risk format, video</td>
<td>0.14</td>
<td>0.02</td>
<td>−0.003</td>
<td>2.36</td>
<td>0.019</td>
<td>0.87</td>
<td>0.460</td>
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<tr>
<td>Order, risk format, video, sex, education, age</td>
<td>0.27</td>
<td>0.07</td>
<td>0.028</td>
<td>2.32</td>
<td>0.052</td>
<td>2.43</td>
<td>0.068</td>
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<tr>
<td>Order, risk format, video, sex, education, age, difference in worry†</td>
<td>0.37</td>
<td>0.14</td>
<td>0.092</td>
<td>2.25</td>
<td>0.067</td>
<td>10.07</td>
<td>0.002</td>
</tr>
</tbody>
</table>

* Dependent variable is the difference in willingness to take the medication associated with the rare risk of an adverse event under high and low volition conditions. \( \text{SEE} \) = standard error of the estimate.
† Predictor (difference in worry) is entered into the model after the 6 covariates.

**DISCUSSION**

In this proof-of-concept study, we found that highlighting the perception of having a choice increases patients’ worry about the risks of adverse events and decreases their willingness to accept treatment. These results are consistent with a recent article by Nordgren et al demonstrating that situations that maximize volition increase risk perceptions (8).

The strengths of this study include the use of a video format that more closely resembles an actual patient-physician encounter than the usual paper-and-pencil format used to study risk perception, and the experimental design that allowed us to examine the consequence of manipulating volition on patients’ decision making. However, this study was designed as a proof-of-concept project and used extremes of volition. In clinical practice, the extent of patient involvement varies greatly, and would be expected to be strongly related to the patient-physician relationship, the specific clinical context, and the physicians’ recommendation. Moreover, given the fact that worry and risk aversion vary according to clinical context, it is likely that the relationship of volition and risk perception may also vary by context. Future research is needed to test this hypothesis. A further limitation is the participation rate. Although few patients refused to participate, many could not remain after their appointment due to time constraints. In addition, given that this was a cross-sectional, hypothetical study, we cannot know whether the difference in willingness observed would translate into clinically significant differences in patient behaviors.

Having more knowledgeable and engaged patients making informed decisions is requisite to decreasing unwarranted variability in the distribution of health care services and ensuring high-quality health care. However, the effects of greater patient involvement in decision making are not well understood. The results of this study suggest that the worry and concern that patients experience in contemplating treatment decisions is influenced not only by the actual risks posed by treatments, but by the responsibility they feel for making the decision. Future studies are needed to identify whether this observation is restricted to patients who are unprepared to participate in decision making.

While this study used hypothetical scenarios and presented extremes of patient involvement, given previous work demonstrating the effect of voluntary appraisals on risk perception, clinicians should be aware that promoting increased patient responsibility for decisions involving their health care may be associated with lower uptake of risky procedures or interventions.

**AUTHOR CONTRIBUTIONS**

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Fraenkel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study conception and design.** Fraenkel.

**Acquisition of data.** Fraenkel.

**Analysis and interpretation of data.** Fraenkel, Peters.

**REFERENCES**