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PATIENT RESPONSIBILITY FOR MEDICAL DECISION MAKING AND RISKY TREATMENT OPTIONS

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Abstract

Background: Some studies have shown that increasing patient participation in decision making decreases utilization of risky procedures. A recent paper demonstrated that risk perception is increased under conditions which 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 two different conditions: one minimizing patient involvement and the second maximizing patient involvement in the decision making process.

Results: Subjects' willingness to take the proposed medication was lower (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 to the low involvement condition (6.1 ± 3.7 versus 5.5 ± 3.8, $p<0.001$).

Conclusions: Increasing patient responsibility in medical decision making may decrease patients' willingness to accept risky treatment options.

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) found that women with lupus who participate more actively in their visits have less morbidity compared to women who are more passive. While 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 onto 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 healthcare 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 to those receiving usual care. The accepted explanation for this finding is that patients are more likely to choose conservative measures when empowered to make informed, value-concordant, decisions (7). However, a recent study

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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 which 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 to 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 in effect 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 willingness to accept risky interventions observed in studies designed to increase patient participation in decision making, is in part due to an emphasis on volition and a corresponding increase in patients' concerns related to risk.

Methods

We created two 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 relevant to patients with rheumatic diseases: jaw necrosis in Video A and progressive multifocal leukoencephalopathy in Video B. We chose to develop two videos in order to examine 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 included a new medication to prevent heart disease and Video B 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, that does not interfere with any other medications, is completely covered by the subject's insurance, and is very well tolerated except for the extremely rare risk of a serious side effect. Subjects were told that the medications were hypothetical. The scripts for the videos are included in Appendix A.

Eligibility criteria for Video A included being 50 years or older and currently taking at least one prescription medication for a chronic disease. Patients with known heart disease, osteoporosis or osteopenia, or currently taking a bisphosphonate were excluded. For Video B subjects had to be 18 years or older and currently taking at least one 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 they were asked to view either Video A or B, depending on their eligibility criteria. Subjects eligible for both were randomly assigned to view one of the videos. After viewing the videos, each subject was exposed to two 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, ranging from 0=lowest value to 10=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 scores and standard deviations 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 a 2-tailed Wilcoxon Signed-Rank test).

We first examined whether there were any significant differences in willingness and worry across both volition conditions using a 2-tailed Wilcoxon 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, gender, education, and 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 – 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 our institution.

Results

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

As predicted by Nordgren et al's paper, subjects' worry about the risk of the adverse event was greater in the high compared to the low volition condition (6.1 ± 3.7 versus 5.5 ± 3.8, $p<0.001$). Willingness to take the proposed medication was lower in the high compared to the low volition condition (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, gender, education, and health status, clinical scenario and risk format (Table 1).

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 paper demonstrating that situations which maximize volition increase risk perceptions (8).

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 which 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 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 healthcare 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.

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Appendix: Script used in Video A

Hello, my name is Dr. Smith – and I know we have never met before – but for the next few minutes – try and pretend that I am your regular doctor. For this exercise you need to pretend that you are a patient with a high risk for heart disease. In this video I am going to be telling you about a new medication. Ok let's start:

- As you know heart disease is the number one cause of death in the US.
- Your heart beats 100,000 times every day and so taking care of your heart is extremely important.
- There is a medication available that dramatically decreases your risk of developing heart disease.
- This medication is completely covered by your insurance.
- It is a small pill taken once a day and it does not interfere with any of your other medications.
- The medication is very well tolerated and it does not cause any side effects except:

1 in 100,000 people, which is extremely rare, develop a severe form of damage to the jawbone that is very difficult to treat. This jaw problem is painful and potentially disfiguring. It can be associated with a jaw infection and portions of the jawbone may become exposed inside the mouth. But it is important to remember that of the thousands of patients taking this medication, only 1 in 100,000 people will develop this complication, which is extremely rare.

Script used in Video B

Hello, my name is Dr. Smith – and I know we have never met before – but for the next few minutes – try and pretend that I am your regular doctor. In this video I am going to be telling you about a new medication. Ok let's start:

- I understand that you have a condition that causes pain that is severe enough to interfere with the quality of your life so you can still make it through your day but you can't always do the things you used to do.
- There is a new medication available that dramatically reduces pain. It works quickly and provides lasting relief.
- This medication is completely covered by your insurance.
- It is a small pill taken once a day and it does not interfere with any of your other medications.
- The medication is very well tolerated and it does not cause any side effects except:

1 in 100,000 people, which is extremely rare, develop a brain disorder that can cause confusion, dizziness, difficulty talking or walking, and vision problems. This disorder gradually destroys a person's memory, ability to learn, and ability to carry out daily activities. But it is important to remember that of the thousands of patients taking this medication, only 1 in 100,000 people will develop this complication, which is extremely rare.

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Table 1

Association between differences in patient willingness and worry under high and low volition conditions

Model	R	R^2	Adjusted R^2	Std. Error of the Estimate	R^2 Change	F Change	P value for F Change
Order, risk format, video	.14	.02	−.003	2.36	.019	.87	.460
Order, risk format, video, gender, education, age	.27	.07	.028	2.32	.052	2.43	.068
Order, risk format, video, gender, education, age, *difference in worry*	.37	.14	.092	2.25	.067	10.07	.002

In this model the 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. The predictor, difference in worry, is entered into the model after the six covariates.