

Redesigning Informed Consent: Enhancing Risk Communication Through a Novel Risk Visualization Tool

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Abstract

Background: The communication of risk is a difficult task, with evidence to suggest that doctors perform poorly in the attempt to convey it. Consent forms should be designed to assist in informing patients of these risks, and encourage their comprehension. The authors present a pilot study into a novel risk visualization tool (RVT) for the informed consent process, which provides probabilistic and severity information in a single graphical form.

Methods: This is a prospective, randomized study of adult volunteers. One hundred volunteers were taken through a mock consent process for a laparoscopic appendectomy, with either the RVT or standard institutional form.

Results: There was greater recall of surgical risks in the group that utilized the RVT (4.94/8.0, 61%) compared to the standard consent form (3.52/8.0, 44%) ($P \leq 0.005$). Participants who were given the RVT were also more likely to recall the most common risk and the most severe risk. Participants who were given the RVT also reported greater satisfaction with the informed consent process than those patients given the standard consent form.

Conclusion: The results of the study suggest that a patient's ability to comprehend the risks of a surgical procedure and satisfaction with the consenting process can be improved with the use of the RVT.

Keywords: Consent; Surgery; Communication

Introduction

Informed consent for a surgical procedure involves the dis-

closure, and subsequent comprehension, of a number of risks. Consent forms should be designed to inform patients of these risks, and encourage their comprehension. Evidence suggests in practice this is not that case. Paasche-Orlow et al found a significant number of institutional review boards of medical schools in the US failed to produce consent forms for clinical trials that meet their own minimum readability standards [1]. If readability suffers, can we assume that some patients are not even reading their consent forms? This is certainly what some studies have suggested, with 60-70% of patients either "admitting to not reading the consent form" or not reading it "carefully" [2]. Such forms disempower and dissociate patients from the decision making process.

We present a pilot study into a novel risk visualization tool (RVT) for the informed consent process, which provides probabilistic and severity information in a single graphical format. The objective of this study was to assess whether the RVT was able to improve the comprehension and retention of the surgical risks of a laparoscopic appendectomy. Doing so serves to improve patient safety and satisfaction by enhancing understanding of the risks involved in undergoing a surgical procedure.

Material and Methods

Ethics approval for this study was obtained by our institutions human research review committee. Adult volunteers were recruited from public areas of a major tertiary hospital. Subjects were approached to be part of the study. Those who have had previous abdominal surgery were precluded from participation in the trial.

Participants were taken through a mock informed consent for a laparoscopic appendectomy. Participants were randomized to either receiving the RVT or the standard consent form in an alternate fashion (Fig. 1 and 2). The consent form was presented to the subject, and the information was read through twice. Subjects were then given a distraction task, to diminish their immediate recall ability. The consent form was withdrawn, they were presented with a generic picture of an abdomen and asked five questions related to the picture.

Subjects were asked a series of questions to assess their recall of the surgical risks (Table 1), and their answers were recorded.

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Laparoscopic Appendicectomy

Facility: _____

(Affix identification label here)

URN: _____

Family name: _____

Given name(s): _____

Address: _____

Date of birth: _____ Sex: M F I

A. Interpreter / cultural needs

An Interpreter Service is required? Yes No

If Yes, is a qualified Interpreter present? Yes No

A Cultural Support Person is required? Yes No

If Yes, is a Cultural Support Person present? Yes No

B. Condition and treatment

The doctor has explained to you that you have the following condition: (Doctor to document in patients own words)

Appendicitis-----

The condition requires the following procedure/treatment/investigation. (Doctor to document -- include site and/or side where relevant to the procedure.)

Laparoscopic Appendicectomy-----

A laparoscopic appendicectomy is a keyhole procedure to remove a person's appendix. It is often used to treat appendicitis. A camera will be inserted into the abdomen. The operation involves three small incisions in the abdomen, the abdomen is expanded with gas and a camera and instruments inserted to remove the appendix.

C. Risks of this procedure

As with any operation there are a number of risks to be aware of. It's important to remember that complications are uncommon, but should be taken into account before undergoing any operation. They include but are not limited to the following.

- Infection can occur, requiring antibiotics. Collections may occur in the abdominal cavity, requiring surgical treatment.
- Not all operations can be performed with keyhole surgery. Your procedure may need to be performed with a larger cut,

- A weakness in the wound can occur, with development of a hernia.
- Deep bleeding from the wound, or deep inside the abdomen may occur. This may require fluid replacement, blood transfusion, or further surgery.
- Adhesions (or scar tissue) may form and cause a bowel obstruction. This may require further surgery.
- Damage to other organs, such as bladder or bowel, which may need further surgery.
- Blood may clot in the leg causing pain and swelling (DVT). In rare cases part of the clot may break off and go to the lungs.
- Heart attack or stroke could occur due to strain on the heart. Death, although very rare, may result from any procedure.

D. Significant risks and procedure options

(Doctor to document in the space provided. Continue on the medical record if necessary.)

E. Risks of not having this procedure

(Doctor to document in the space provided. Continue on the medical record if necessary.)

PROCEDURAL CONSENT FORM

Figure 1. Standard institutional consent form.

Subjects were then asked to appraise three statements via a five-point Likert scale. Participants utilizing the RVT were asked to respond to the questions in Table 2a.

Participants utilizing the standard consent form were

Table 1. Questions on Frequency and Severity of Risks

Q1	What are the risks or potential adverse events that can occur when undergoing a laparoscopic appendicectomy?
Q2	Which of these adverse events are the most likely to occur?
Q3	Which of these adverse events are the most serious?

asked to respond to the questions in Table 2b.

Answers were collated and underwent statistical assessment by an independent biostatistician using SPSS v21.

Results

The means for all response variables among the two study sub-groups were statistically compared using independent samples *t*-tests. Since these response variables deviate slightly from the assumptions of normality, we confirmed our results by performing non-parametric comparison of medians. A P-value of

LAPAROSCOPIC APPENDICECTOMY

A laparoscopic appendicectomy is a keyhole procedure to remove a person's appendix. It is often used to treat appendicitis. A camera will be inserted into the abdomen. The operation involves three small incisions in the abdomen, the abdomen is expanded with gas and a camera and instruments inserted to remove the appendix.

As with any operation, there are a number of risks you should be aware of. It's important to remember that complications are uncommon, but should be taken into account before undergoing any operation.



Around 1 in 20 patients will have a complication. Of those complications, some are more common and some are very rare

The diagram below represents the major risks of this operation. In general, the risks to the left are more common, but less severe, and the risks on the right are less common, but more severe.

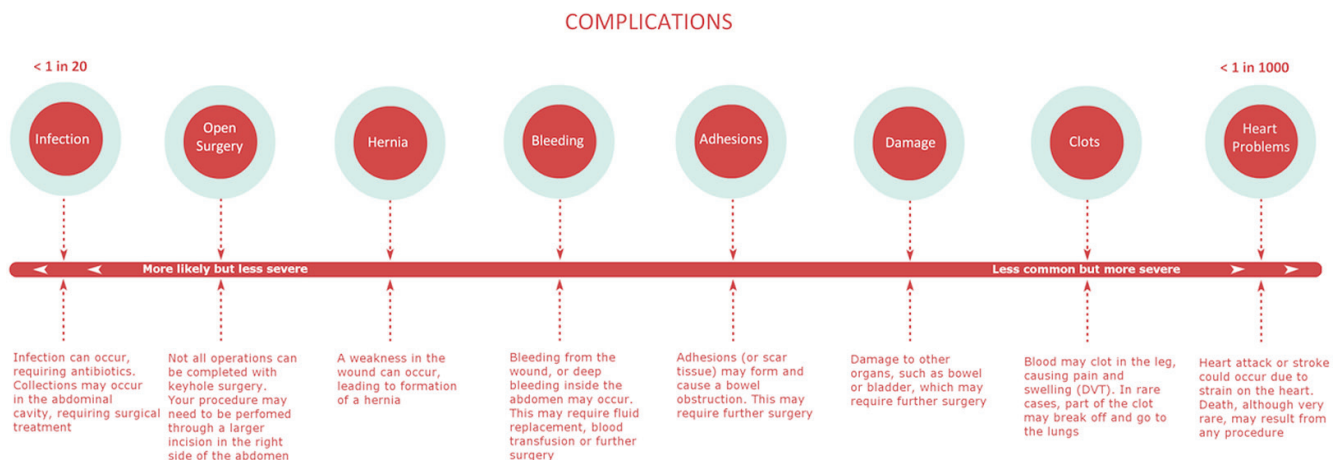


Figure 2. Risk visualization tool.

< 0.05 was considered statistically significant.

Subject profile

Thirty-nine percent of respondents were aged 18 - 24 years, 24% between 25 and 35 years, 22% between 35 and 55 years, and 15% over 55 years.

Recall

Participants who received the RVT were able to recall an aver-

age of 4.94 of the eight risks mentioned on the consent form. Those who received the standard consent form were only able to recall 3.52 of the eight risks on the consent form. This difference was statistically significant (P = 0.005).

Most common and most severe risk

Forty-two of the participants given the RVT were able to recall "infection" as the most common risk, compared to 34 participants who utilized the standard form (P = 0.05). Forty-six of the participants given the RVT were able to recall "heart problems" as the most severe risk, compared to 43 who utilized the

Table 2. Statements on Self-Reported Comprehension Assessed via 5-Point Likert Scale

a. RVT	b. Control
Q1. The use of a "risk visualization tool" made learning about the procedure and its risks easier to understand.	Q1. The informed consent process made learning about the procedure and its risks easy to understand.
Q2. The use of a "risk visualization tool" made learning about the procedure and its risks easier to remember.	Q2. The informed consent process made learning about the procedure and its risks easier to remember.
Q3. If you were to undergo a laparoscopic appendicectomy, the use of a "risk visualization tool" would make it easier to understand and remember the risks of having the procedure.	Q3. If you were to undergo a laparoscopic appendicectomy, the use of an extra visual information such as this (show RVT to participant) would make it easier to understand and remember the risks of having the procedure.

standard form. This was not statistically significant ($P = 0.36$).

Self-reported understanding and integration

Subjects given the RVT were more likely to report that the risks were easier to understand (RVT 4.5/5, non-RVT 3.62/5, $P \leq 0.001$) and easier to remember (RVT 4.34/5, non-RVT 3.24/5, $P \leq 0.001$), than if given the standard institutional form.

Utility of the RVT

Participants shown the RVT after undergoing the mock consent with the standard institutional form rated the use of “extra visual information” highly as a possible adjunct to aid in the consenting process (4.56/5). Patients who solely used the RVT also rated the instrument highly (4.46/5).

Time

Time taken to consent participants utilizing the standard consent form was 3 min 50 s. Time taken to consent participants utilizing the RVT was 4 min and 5 s. This difference was not statistically significant ($P = 0.1$).

Discussion

The risks in the RVT are presented in a visual form, in what may be described as an information graphic. Visual aids have been used as an adjunct to the presentation of data in medicine for many years - the ubiquitous pie chart was first popularized by Florence Nightingale to describe causes of mortality of soldiers during the Crimean War. The usefulness of graphical presentation of information has been explored previously in making informed consent a more informed process. Methods explored include graphs and tables [3], pictograms [4], videotapes [5], and interactive multimedia programs [6]. Altering the style and substance of consent forms has shown mixed results in improving patient comprehension [7].

The RVT differs from previous attempts in that it combines the graphical representation of risk and the consent form in one paper instrument. Videotapes and interactive web programs in particular require specialized equipment to consent the patient. The RVT requires no more resources, nor time to use, compared to a standard consent form. This is of obvious importance in time-sensitive fields such as surgery, where one has little time to take a patient through a complex interactive multimedia programme or video.

Participants who were taken through the mock consent process with the RVT were able to recall more risks than those who used the standard consent form. This is despite the fact that the core information on each consent form was almost entirely identical. Humans have a remarkable capacity for remembering visual information. Standing et al showed 10,000 images to individuals for a few seconds each, and found they were able to recall which

pictures they had previously seen with 84% accuracy [8]. Visual recognition has been proven to be “systematically superior” to auditory recognition [9]. Despite the evidence for the superiority of visual recognition and memory, standard consent forms often persist to be text-based and presented in a plain fashion.

The RVT differed from the standard consent form not only visually, but also by the inclusion of probabilistic and severity information. It is possible that this in itself may have improved participants’ recall of risk. The levels-of-processing effect described by Craik and Lockhart in 1979 proposes that the provision of context may enhance the encoding of memory [10]. The comprehension of each risk may have been facilitated in providing context related to its relative frequency and severity.

The instrument not only resulted in an improvement in the recall of risks, but individuals also self-reported greater integration of the information provided to them when utilizing the RVT. This suggests that the instrument improves patient satisfaction with the informed consent process when utilizing the RVT, as compared to the standard form.

One problem in formulating the RVT was prioritizing whether a risk was “more likely” or “more severe” than another. This is a difficult task, as reported complication rates vary widely, as will the severity of a complication. Infection was placed at the most common and least severe end of the scale; however, a severe infection can be just as life-threatening as a heart attack. Published data on complication rates were used to assist in ascertaining the frequency of each complication [11, 12]. Severity of a complication was rated subjectively by the authors. An individual’s assessment of whether a complication is more severe than another will depend on their own value system. The RVT included a caveat to advise that the frequency/severity scale was to be utilized in general terms, rather than prescriptively.

The results of this pilot study would have been strengthened if the health literacy levels of the participants was ascertained and controlled for. The distraction task could have been an opportunity to assess this, with a scoring of the participants’ answers to simple health questions serving as a surrogate for their health literacy. Younger volunteers (18 - 24) are over-represented in the sample; however, the peak incidence of appendicitis is between the ages of 10 and 30 years [13].

The RVT created is intended as an alternative to the traditional consent form. Participants who utilized the RVT had greater recall of risks, and greater self-reported uptake of information, than those who utilized the standard consent form. It is the aim of the authors to further explore the utility of the RVT in a hospital inpatient setting. The findings of this study suggest that the RVT may be a valuable adjunct to the decision making process for patients undergoing surgical operations.

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