Patient Comprehension of an Interactive, Computer-Based Information Program for Cardiac Catheterization

A Comparison With Standard Information

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Background: Several studies suggest that standard verbal and written consent information for treatment is often poorly understood by patients and their families. The present study examines the effect of an interactive computer-based information program on patients' understanding of cardiac catheterization.

Methods: Adult patients scheduled to undergo diagnostic cardiac catheterization (n=135) were randomized to receive details about the procedure using either standard institutional verbal and written information (SI) or interactive computerized information (ICI) preloaded on a laptop computer. Understanding was measured using semistructured interviews at baseline (ie, before information was given), immediately following cardiac catheterization (early understanding), and 2 weeks after the procedure (late understanding). The primary study outcome was the change from baseline to early understanding between groups.

Results: Subjects randomized to the ICI intervention had significantly greater improvement in understanding compared with those who received the SI (net change, 0.81; 95% confidence interval, 0.01-1.6). Significantly more subjects in the ICI group had complete understanding of the risks of cardiac catheterization (53.6% vs 23.1%) ($P=.001$) and options for treatment (63.2% vs 46.2%) ($P=.048$) compared with the SI group. Several predictors of improved understanding were identified, including baseline knowledge ($P<.001$), younger age ($P=.002$), and use of the ICI ($P=.003$).

Conclusions: Results suggest that an interactive computer-based information program for cardiac catheterization may be more effective in improving patient understanding than conventional written consent information. This technology, therefore, holds promise as a means of presenting understandable detailed information regarding a variety of medical treatments and procedures.

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Beauchamp and Childress[1] describe 3 required elements of informed consent: the threshold, information, and consent elements. Unfortunately, several studies suggest that the components of the information element (ie, disclosure, recommendation of a plan, and understanding) are often not successfully communicated owing to poor disclosure on the part of the physician and/or a lack of patient understanding of the material.[2-5] This is important because a lack of understanding might cause patients to misinterpret the risks and benefits of a treatment or procedure and impair their ability to follow a prescribed treatment regimen.

See Invited Commentary at end of article

To improve the communication of important medical information to patients, several alternative strategies have been explored with mixed success.[6] Such strategies include the use of modified consent forms with improved readability and processability (formatting),[7,8] inclusion of graphics,[9,10] extended discussions,[11] teaching aids,[12] and video technology. Video presentations have shown promise in improving patients' knowledge of treatments and procedures, including colonoscopy,[13] knee arthroscopy,[14] hormone therapy,[15] and the use of intravenous contrast media.[16] However, video presentations are limited in that they do not promote active participation in learning and decision making and, like written information, tend to be targeted to groups of patients rather than tailored to the learning ability and information needs of the individual patient.

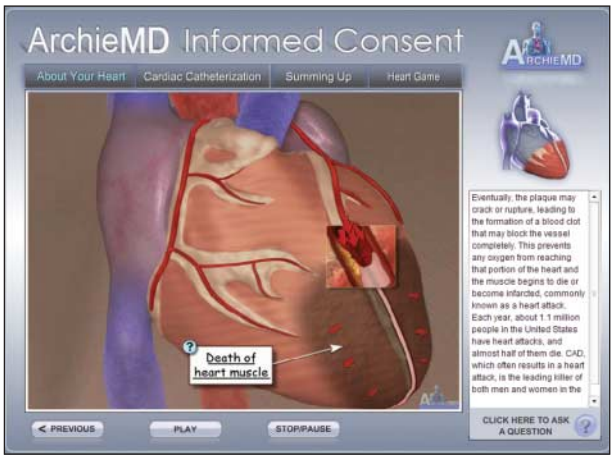

Figure 1. A screenshot from the interactive computer program highlighting the consequences of coronary artery blockage. During the presentation, the graphics are dynamic, and the virtual heart actively "beats."

Interactive computer-based technologies offer the potential to overcome some of the passivity limitations of video by promoting active participation in learning and allowing subjects to access information in a manner consistent with their learning styles and health literacy. However, the effectiveness of this approach in meeting the requirements for informed consent and patient understanding is relatively unknown.[17,18] The present study, therefore, was designed to test the hypothesis that use of an interactive computer-based information program for cardiac catheterization would result in improved patient understanding compared with standard verbal and written information. The primary outcome measure was the change in understanding from baseline (ie, before information was given) to just after completion of cardiac catheterization (early understanding).

METHODS

POPULATION

This study was approved by the University of Michigan's institutional review board with a waiver of written informed consent because the study constituted no more than minimal risk and did not deny subjects information that they would normally receive. Consecutive adult patients (age >18 years) were solicited for participation in the study as they arrived at our medical facility, in each case approximately 1 hour prior to scheduled elective diagnostic cardiac catheterization. Patients who had undergone a catheterization within the past 3 years and those undergoing emergency catheterization were excluded. Eligible patients were randomized (tables of random numbers) to receive information about cardiac catheterization in 1 of 2 ways: verbal and written information per the institution's standard information protocol (SI), or interactive computerized information (ICI) preloaded on a laptop computer. All subjects were told that they would be asked later for their cardiac catheterization consent signature by a member of the cardiology team who was not part of the study.

BASELINE ASSESSMENT

Subjects were given a short, semistructured, open-ended, preintervention interview to elicit their baseline understanding of 6 core elements of the cardiac catheterization procedure: (1) medical indication, (2) purpose, (3) protocol, (4) risks, (5) benefits, and (6) alternative treatments (baseline test) (eFigure, http://www.archinternmed.com). The responses to each of the core element questions were written down verbatim by trained research assistants who were allowed to clarify questions and prompt the subjects for additional information but did not offer any specific details of the procedure. The interview process and measurement of understanding have been presented previously.[8,19]

Subjects were also asked what information they had reviewed prior to this procedure. In our setting, patient education regarding cardiac catheterization is available as a brochure mailed by the Department of Cardiology, information on the hospital Web site, and verbal information provided by the patient's primary care provider or person scheduling the catheterization procedure.

INTERVENTION

After the baseline assessment, subjects were given information about cardiac catheterization using either the SI or ICI.

SI Protocol

In our setting, consent for cardiac catheterization is routinely obtained on the day of the procedure by a cardiology fellow or a physician's assistant who provides verbal information regarding the procedure, risks and benefits, and options for treatment. The consent document is a generic institutional form used for all surgical and other procedures customized to include the risks and benefits of the specific procedure to be performed.

ICI Protocol

The ICI for cardiac catheterization (ArchieMD Inc, Boca Raton, Florida) was developed using advanced 2-dimensional (2-D) and 3-dimensional (3-D) graphics technology to create a virtual patient animated to simulate a variety of dynamic physiologic functions (eg, the beating of the heart). The program content was based on a review of existing consent documents, review of the extant literature, and expert opinion (cardiologists and computer graphics designers). Prior to the study, the program underwent final review for content, visual interface, and ease of navigation by a panel of experts and lay persons (ie, cardiologists, informed consent experts, nurses, students, and patients). Sequential information on cardiac catheterization was provided through dynamic 2-D and 3-D graphics, text, and narrative. Additional information could be accessed as needed by clicking on specified underlined items. At any time while navigating the program, subjects could type in questions that they had about the procedure. These questions were accessed at the end of the program and relayed to the cardiologist.

The program included 3 modules. The first module, "About Your Heart," included subsections on the healthy heart, heart disease, and treatment options. Each screen was presented in sequence and none could be skipped. Information was presented using 3-D animation of the beating heart with zoom-in features to detail items such as coronary artery blockage and ischemia (**Figure 1**). Information was further enhanced by a voice-over narrative and by scrollable text on the screen.

The second module, "Cardiac Catheterization," described details of the cardiac catheterization procedure, including catheter placement and introduction of the contrast dye. The patient was also shown how a blockage appears on an actual angiogram. The module also described angioplasty and stent placement and other treatment options as potential conse-

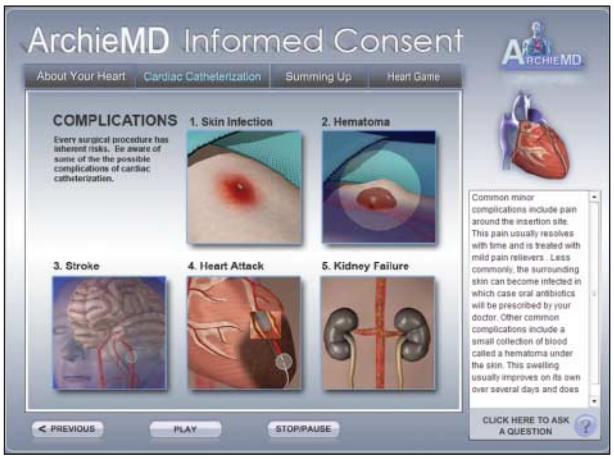

Figure 2. A screenshot from the interactive computer program highlighting the risks of cardiac catheterization.

quences of an identified blockage in a coronary artery. Subsequent screens described the risks and benefits of cardiac catheterization (**Figure 2**).

The third and final module, "Summary and Optional Quiz," comprised a summary of all the ICI information together with a short optional quiz to ascertain the subjects' understanding of the key elements of the procedure. The quiz consisted of 11 questions: 7 required subjects to identify certain items on the simulated graphics (eg, plaque buildup), and 4 were multiple-choice questions.

One computer preloaded with the ICI was used. An ancillary speaker was added to ensure that subjects who were hard of hearing could hear the narrative. A research assistant was present during the subject's navigation through the program to ensure completion and to offer assistance as needed. Completion of the core modules and summary took approximately 10 to 12 minutes, after which time the cardiology caregiver obtained the subject's signature to undergo cardiac catheterization using the institutional consent document for procedures.

POSTPROCEDURE INTERVIEWS

Once the subjects had fully recovered from the cardiac catheterization procedure and prior to discharge, they were interviewed again using the same semistructured interview to determine their new understanding of the information (early understanding). Subjects also completed a short questionnaire to assess the clarity and amount of information, effectiveness of the message delivery, and overall satisfaction with the information on a scale from 0 to 10 (10 being the highest rating). In addition, demographic information was obtained including age, sex, education level, socioeconomic status, and race or ethnicity.

Subjects also completed the shortened versions of the Rapid Estimate of Adult Learning in Medicine (REALM)[20] reading test and Need for Cognition test.[21] Need for cognition (NFC) refers to an individual's tendency to engage in and enjoy effortful cognitive endeavors. Subjects were categorized as having low or high NFC based on the median split. A third interview was administered via telephone 2 weeks after the procedure to measure long-term knowledge retention (late understanding).

SCORING UNDERSTANDING

The transcribed responses to questions regarding the risks and benefits and other aspects of cardiac catheterization were scored independently by 2 assessors who were blinded to the subjects' group assignment. Guidelines for scoring were determined a priori. Scores of 0 (no understanding), 1 (partial understanding), and 2 (complete understanding) were assigned for each core element, and scores were combined to provide an overall score of understanding (range, 0-12; 12 indicates complete understanding). The scoring system used was based on the Deaconess Informed Consent Comprehension Test[22] and has been described previously.[8,19]

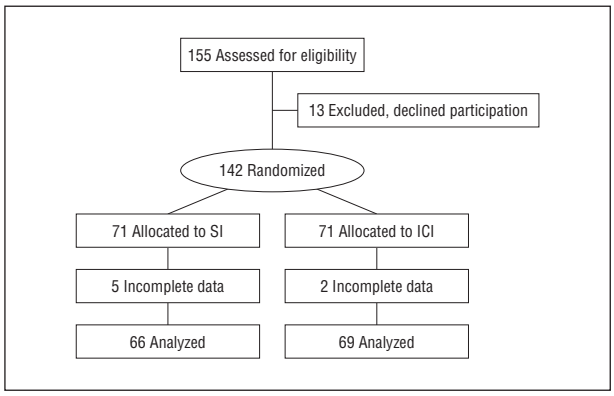

Figure 3. Flow diagram of participant progress through the phases of the study. ICI indicates interactive computerized information preloaded on a laptop computer; SI, standard institutional verbal and written information.

STATISTICAL ANALYSIS

Sample size determination was based on the findings of a previous study in which the mean (SD) score for understanding of a standard consent form was 6.4 (1.4) on a scale from 0 to 10 and that the understanding score for a modified form with improved processability (format and graphics) was 7.2 (1.5).[8] Accepting this difference as the smallest that we believed to be clinically important to detect, we required a sample of 66 subjects per group ($\alpha = .05$; $\beta = .1$; 2-sided test). Data were analyzed using U, χ^2, Fisher exact, and unpaired t tests, as appropriate. Subject-specific changes between baseline and early and/or late understanding were compared between groups. Interrater agreement between the 2 assessors were performed using the κ statistic. Kappa values of ≥ 0.7 were considered to represent acceptable levels of agreement. Independent factors found to be associated with early understanding by univariate analysis ($P < .10$) were subsequently entered into a multivariate regression with stepwise selection. Statistical analyses were performed using SPSS statistical software, version 16.0 (SPSS Inc, Chicago, Illinois).

RESULTS

A total of 155 adult patients were solicited to participate in this study over a 7-month period (June through December 2008). Of these, 13 declined and 7 were excluded owing to incomplete information or withdrawal from the study. Data are thus presented for 135 subjects (**Figure 3**). Subjects who declined to participate in the study were similar demographically to participants but tended to be more anxious. Reasons for nonparticipation were "too nervous" (54%; n=7), "didn't want to watch a video" (46%; n=6), "didn't want to be told about the procedure" (23%; n=3), and "didn't want to be bothered with anything extra before the procedure" (39%; n=5).

Table 1. Demographic Characteristics of Subjects by Message Delivery Method[a]

Characteristic	Message Delivery Method	
	SI (n=66)	ICI (n=69)
Age, mean (SD), y	59.4 (12.8)	61.6 (13.3)
Female to male sex ratio	30/32 (48/52)	34/34 (50/50)
Race or ethnicity		
White	52 (84)	62 (91)
African American	8 (13)	3 (4)
Hispanic	1 (2)	0
Other	1 (2)	3 (4)
Level of education		
≤High school diploma	16 (27)	20 (31)
Some college and/or trade school	18 (30)	13 (20)
≥Bachelor's degree	26 (43)	32 (49)
Catheterization procedure		
Right heart	1 (2)	4 (6)
Left heart	43 (65)	44 (64)
Right and left heart	22 (33)	21 (30)
Admission type		
Outpatient	48 (73)	62 (90)[b]
Inpatient	18 (27)	7 (10)[b]
English as primary language	59 (95)	61 (90)
Preprocedure anxiety score, mean (SD)[c]	5.6 (2.9)	5.9 (3.1)
REALM literacy score, mean (SD)	64.1 (2.7)	63.3 (7.4)
NFC score, mean (SD)	22.5 (3.0)	22.2 (2.7)

Abbreviations: ICI, interactive computerized information preloaded on a laptop computer; NFC, Need for Cognition test[21] (0-35 scale, where 35 indicates a high need for cognition); REALM, Rapid Estimate of Adult Literacy in Medicine[20] (0-66 scale, where 66 indicates a high literacy level); SI, standard institutional verbal and written information.

[a] Unless otherwise indicated, data are reported as number (percentage) of subjects.

[b] $P=.01$ vs SI.

[c] Scale ranged from 0 to 10, with 10 indicating the highest anxiety level ("extremely anxious").

Table 2. Comparison of Changes From Baseline to Early and Late Understanding Between the ICI and SI Groups[a]

Tests	Message Delivery Method		Mean Difference (95% CI)
	SI	ICI	
Baseline understanding, before ICI or SI	6.8 (2.4)	6.9 (2.9)	0.16 (–0.07 to 1.1)
Early understanding, after ICI or SI	8.1 (2.3)	9.3 (2.2)[b]	1.2 (0.4 to 1.9)
Complete early understanding, No. (%) of subjects			
Medical indication for catheterization	44 (68)	53 (77)	NA
Purpose of catheterization	46 (71)	57 (84)	NA
Catheterization protocol	27 (42)	37 (54)	NA
Risks	15 (23)	37 (54)[b]	NA
Benefits	31 (48)	34 (49)	NA
Options for treatment	30 (46)	43 (63)[b]	NA
Late understanding, 2 wk after ICI or SI	7.9 (2.2)	8.6 (2.7)	0.65 (–0.4 to 1.7)
Understanding score change			
Baseline to early	1.3 (2.5)	2.2 (2.1)[b]	0.81 (0.01 to 1.6)
Baseline to late	1.2 (1.9)	1.4 (2.3)	0.24 (–0.7 to 1.1)
Early to late	–0.2 (2.6)	–0.6 (1.8)	–0.44 (–1.4 to 0.5)

Abbreviations: CI, confidence interval; ICI, interactive computerized information preloaded on a laptop computer; NA, not applicable; SI, standard institutional verbal and written information.

[a] Unless otherwise indicated, data are reported as mean (SD) scores (range, 0-12, where 12 indicates complete understanding).

[b] $P<.05$ vs SI.

Of the 7 patients who did not complete the interviews or were withdrawn from the study, 4 had been randomized to the SI and 3 to the ICI. Reasons for withdrawal included postponement of the procedure for medical reasons (n=2), loss to follow-up (n=3), patient could not hear the computer narrative (n=1), and "too many questions" (n=1).

The demographic characteristics of the study sample are summarized in **Table 1**. There were no differences in demographics between the 2 experimental groups, and while the ICI group had significantly more outpatients than the SI group ($P=.01$), this difference had no effect on understanding. A similar number of subjects in each group spoke English as their primary language. There were no differences between groups with respect to information sought or accessed prior to cardiac catheterization. Only 1 subject reported receiving no information prior to the procedure. Most patients (73.1%) obtained information from a physician or nurse, 23.1% from a family member or friend, 13.4% from the internet, 50.7% from a book or magazine, and 3.0% from television or radio. Many subjects obtained information from more than 1 of these sources.

Subjects who received the ICI reported having "average" comfort with using computers (mean [SD] score of 5.8 [3.6] out of 10, where 10 indicates "extremely comfortable"). Although most ICI subjects did not require help with the computer program (74%; n=49), 18% required "some help" (n=12) and 8% needed a "lot of help" (n=5). There were, however, no differences in understanding between those who needed help (score, 8.6 [2.2]) and those who did not (score, 9.3 [2.2]). Interrater reliability between the assessors' scores of subject understanding showed excellent agreement. Kappa statistics for each of the core elements (eg, risks and benefits) ranged from 0.71 to 1.00 ($P<.001$).

The net change in early understanding from baseline between the SI and ICI groups (primary outcome) was 0.81 (95% confidence interval, 0.01-1.6) (**Table 2**). There were no differences in baseline understanding of cardiac catheterization between the 2 groups. However, subjects who received information using the ICI had a significantly greater improvement in early understanding than patients receiving the SI ($P=.002$). There was a trend toward greater early understanding of all the individual information elements (eg, risks, options, purpose, and protocol) among patients who received the ICI. However significance was achieved only for understanding of the risks and options for treatment (Table 2). Late understanding (ie, 2 weeks post procedure) decreased slightly in both groups but was not significantly different between them. The effect of age, education, literacy, and NFC on early understanding by groups is summarized in **Table 3**. Overall, subjects who were younger and had higher literacy had significantly greater understanding of the material. **Table 4**

Table 3. Comparison of Early Understanding by Message Delivery Method[a]

Characteristic	Message Delivery Method		Mean Difference (95% CI)
	SI	ICI	
Age, y			
18-59 [Reference]	8.3 (2.3)	9.9 (1.7)[b]	1.7 (0.7 to 2.7)
≥60	7.9 (2.3)	8.7 (2.4)[c]	0.8 (–0.4 to 1.9)
Education			
<Bachelor's degree [Reference]	7.9 (2.2)	8.9 (2.3)	1.0 (–0.07 to 2.1)
≥Bachelor's degree	8.5 (2.0)	9.6 (2.1)[b]	1.1 (0.01 to 2.2)
REALM literacy score			
Low [Reference][d]	6.3 (2.9)	7.7 (1.6)	1.4 (–1.8 to 4.7)
High[e]	8.1 (2.3)	9.8 (2.0)[b,c]	0.9 (0.02 to 1.9)
NFC score			
Low [Reference][f]	8.8 (2.1)	9.4 (2.3)	0.6 (–0.8 to 1.9)
High[g]	7.6 (2.1)[c]	9.3 (2.1)[b]	1.7 (0.7 to 2.7)

Abbreviations: CI, confidence interval; ICI, interactive computerized information preloaded on a laptop computer; NFC, Need for Cognition test[21] (0-35 scale, where 35 indicates a high need for cognition); REALM, Rapid Estimate of Adult Literacy in Medicine[20] (0-66 scale, where 66 indicates a high literacy level); SI, standard institutional verbal and written information.

[a] Unless otherwise indicated, data are reported as mean (SD) scores (range, 0-12, where 12 indicates complete understanding).

[b] $P<.05$ vs SI.

[c] $P<.05$ vs reference group.

[d] Low literacy score, 0 to 60 (third to eighth grade equivalence).

[e] High literacy score, 61 to 66 (ninth grade equivalence or higher).

[f] Low NFC, 0 to 21.

[g] High NFC, 22 or higher; cutoff based on median split.

Table 4. Perceptions of the Message Delivery

Characteristic	Message Delivery Method[a]	
	SI	ICI
Quality of information	9.2 (1.5)	9.4 (1.2)
Ability to follow information	9.5 (0.9)	9.4 (1.3)
Effectiveness of presentation	9.5 (1.1)	9.5 (1.0)
Overall satisfaction	9.5 (1.0)	9.5 (1.3)

Abbreviations: ICI, interactive computerized information preloaded on a laptop computer; SI, standard institutional verbal and written information.

[a] Data are reported as mean (SD) scores (range, 0-10, where 10 indicates best score).

Table 5. Multiple Regression of Factors Predictive of Improved Change in Early Understanding

Characteristic	β Coefficient	*P* Value
Baseline understanding	0.634	<.001
Younger age, 18-60 y	0.246	.002
ICI group	0.239	.003

Abbreviation: ICI, interactive computerized information preloaded on a laptop computer.

summarizes the subjects' perceptions of, and satisfaction with, the quality and effectiveness of the information between groups. As indicated, there were no differences observed.

Of those who received the ICI, 17 attempted the quiz at the end (30%), 23 "did not want to" (40%), and 17 "would have liked to but did not have time" (30%). Eighty-eight percent of patients who attempted the quiz found it to be helpful (n=15). However, there was no difference in understanding of the information between those who took the quiz and those who did not. Only 3 patients typed in questions on the computer. The low utilization of this function may reflect the patients' perceived high level of understanding, or it may represent a perceived lack of time or added burden.

Factors that were found to be associated with early understanding by univariate analysis ($P<.10$) were entered into a multivariate regression model with stepwise selection. These factors included the intervention group and the subjects' baseline understanding, age, literacy, NFC, education level, perception of the quality of the information, and satisfaction. Factors determined to be predictive of improved understanding are summarized in **Table 5**.

COMMENT

The results of this study show that subjects who received information about cardiac catheterization using the ICI demonstrated significantly greater improvement in overall early understanding from baseline than those receiving SI. Although the difference in overall early understanding was relatively modest, the effect of the ICI on understanding of the core information elements was clinically significant. For example, of those who received the ICI, almost twice as many had complete understanding of the risks, and a third more had complete understanding of the options for treatment compared with those receiving the SI. This is particularly important because studies have shown that understanding of risk is one of the most important determinants of informed decision making.[23,24] These findings reinforce the need for improved diligence and strategies to ensure that patients understand these critical elements.

Traditionally, information about medical treatments or procedures is presented in written and/or verbal formats. However, studies suggest that this standard approach often results in poor patient understanding of the material.[2,4,5,8,25,26] In one study, only 18% of patients with cataracts could recall the risks immediately after giving their "informed" consent to undergo a cataract procedure,[2] and in another study, 88% of patients could not recall specific information regarding the risks of blood transfusions.[26] The reasons for this lack of understanding and/or retention include the inability of patients to read and understand material written above the recommended eighth grade reading level and incomplete and/or expedited disclosure on the part of the persons providing the information as well as use of unfamiliar medical terminology and variability in the clarity and amount of information.

The results of the present study show that information provided by the ICI on the day of cardiac catheterization resulted in improved understanding compared with that gained from the SI. We had some initial concern about presenting detailed information of risks and benefits just before surgery, but we were encouraged to find that the vast majority of patients responded positively to the ICI. Although we cannot conclude this from the present study, it is possible that presenting information prior to the day of catheterization would result in even better understanding. However, a previous study found that patient understanding of consent information was similar regardless of whether the information was presented on the day of surgery or several days prior.[27]

Computer-based technologies for communicating health information offer several potential advantages over standard methods by providing a media-rich interface that encourages participation in learning.[17] Systematic reviews of the literature reveal that computerized educational interventions for chronic conditions such as diabetes mellitus, asthma, and arthritis are positively received by patients and elicit a greater sense of control and understanding of their conditions.[18,28] Despite the apparent usefulness of these technologies, however, there is a paucity of data related to their use as a means to provide consent information. In a study by Shaw et al,[17] a multimedia computer-assisted instruction for colonoscopy was shown to improve overall patient understanding compared with standard education, although comprehension of certain items was not affected by the message format. Furthermore, in a survey of patients' perceptions of a preoperative computer-based program for cholecystectomy, over two-thirds of the respondents ranked the clarity of both the text and the illustrations as excellent.[29]

The computer program used in the present study was unique in that it was interactive and utilized 2-D and 3-D animation to produce a virtual patient. To our knowledge, there are very limited data on the effect of this type of technology on patient understanding of medical information. In a German study, 3-D technology describing surgical thyroidectomy resulted in improved overall understanding and lowered anxiety compared with standard text.[30]

A potential advantage of interactive computerized systems is the ability to tailor the information to the learning style and information preferences of the individual. Indeed, the concept of tailoring has been shown to be extremely effective in helping individuals change health-related behaviors such as smoking, diet, and physical activity.[31-33] The program used in this study allowed for some degree of tailoring in that patients were able to access additional information based on their individual needs. However, given that the ICI was shown to improve understanding to a greater extent among those who were younger and had higher literacy, further tailoring of the information using this type of technology may be necessary to ensure that those who are older or have different information needs are equally well informed.

Although short-term understanding of the information was improved among patients receiving the ICI, longer-term retention (2 weeks) was independent of the method of information delivery. However, in both groups, retention of information decreased slightly over the 2 weeks following presentation of the information. This is consistent with the results of previous studies that showed a decline in retention of medical information over time.[34] There was a slightly larger lack of information retention in the ICI group than in the SI group, but the difference was not significant. The reason for the difference is unclear, particularly because we could not determine if additional information had been communicated in the postoperative period that might have disproportionately affected one group over the other.

There were no differences in the subjects' satisfaction or perceptions of the quality of the information between the 2 groups, which suggests that patients were usually satisfied with the information they were given even if they did not completely understand it. Unfortunately, due to time constraints, we were unable to have the subjects directly compare the 2 methods of message delivery, which comparison might have revealed differences in perception and satisfaction.

Our study had several limitations. First, the study involved elements of survey research and so was subject to the potential biases of nonresponse and self-reports. However, given that very few subjects declined participation, the potential for nonresponse bias was likely minimal. Likewise, since the questionnaires contained no identifying information, the chance for self-report bias was also low.

Second, this study represents 1 intervention among 1 population at 1 institution and thus may not be generalizable to other situations or populations. Third, we recognize that since the sample size was based on expected differences in early understanding between groups, the sample may not have been sufficiently powered to detect differences in all univariate and multivariate comparisons.

Finally, while the ICI resulted in improved understanding of the information, it remains unknown whether or how its use affected the decision to undergo cardiac catheterization. Previously, we showed that subjects with greater understanding were more likely to participate in a research study,[19] but no such conclusions can be drawn

from the present study. No patient in the study refused cardiac catheterization after being informed by either SI or ICI. However, it was part of the study design that the patient's initial decision to undergo the procedure was already made prior to study recruitment. Unfortunately, data regarding any patient refusal to undergo catheterization were not available. Further studies to examine the effect of this technology on decision making may be warranted.

In summary, results of this study showed that an interactive computer program for cardiac catheterization was more effective in improving patient understanding than conventional written and verbal information. As such, computer-based technologies hold promise as a means of presenting understandable detailed information regarding a variety of medical treatments and procedures.

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INVITED COMMENTARY

Quandaries of Informed Consent

Although widely accepted as ethically essential, obtaining meaningful informed consent with good consistency has proven difficult. The report by Tait and colleagues in this issue of the *Archives* illustrates some of the challenges and provides glimpses of a promising approach to the task of conveying understandable information to patients about cardiac catheterization. The authors describe a carefully constructed study of a computer-based interactive educational program for patients presented shortly before a physician asks for informed consent for cardiac catheterization. Referencing an early edition of a classic book on biomedical ethics by Beauchamp and Childress,[1] Tait et al note 3 key elements of informed consent: threshold, information, and consent. They conduct their study to address the information element, specifically whether a particular computer program can convey information to patients more effectively than the standard informed consent procedure at their hospital.

This study used a careful educational research design, and it produced important results: patients who completed the computer-based educational program showed significantly greater understanding than those who experienced only the standard informed consent procedure. Although neither group of patients fully retained the information 2 weeks later, at the time the patients signed consent forms, greater gain of information occurred for those who had used the computer-based program. The fact that the study showed a significantly higher level of overall understanding after patients completed the computer-based educational program represents an important accomplishment—perhaps more important than whether patients increased their understanding of risks but not benefits, or options for treatment but not medical indications for catheterization. Very likely, patients came to the computer-based program with varying amounts of knowledge about different aspects of cardiac catheterization, and one would not expect equal growth in knowledge on each topic. Furthermore, informed consent requires a patient to have an understanding of all relevant aspects of a procedure, not just 1 or 2, so a measure of overall understanding has practical meaning in this context. These authors have made an important contribution to the literature by demonstrating a significantly higher overall understanding of cardiac catheterization in a carefully implemented study.

Despite these significant results, however, much work remains to determine whether this educational program leads to meaningful outcomes in the context of informed consent. The study addresses patient satisfaction and patient acquisition of knowledge—levels 1 and 2 of Kirkpatrick's 4 levels of program evaluation.[2] The third and fourth levels require exploration to determine the effectiveness of this computer-based educational program. Does acquisition of information by patients influence patients' or physicians' behavior around informed consent (Kirkpatrick's third level)? Can use of this educational program affect outcomes across a health care program (Kirkpatrick's fourth level)? Put in a more straightforward way, can this interactive computer-based educational program effectively inform patients in a practice setting, which lacks the controls of a research setting? More importantly, if informed by this program, would patients more effectively engage in informed consent, which requires more than informed patients? Would meaningful outcomes change across a health care system if this program were consistently available to patients who would decide whether to consent to the procedure after completing the program?

RECONSIDERING INFORMED CONSENT

A great deal of work has gone into developing and testing various methods of conveying information to patients to help prepare them to make decisions or provide consent. Many approaches to informing patients have been shown to accomplish the task of conveying information.[3,4] Many decision aids have shown higher-level outcomes as well, such as less decisional conflict, more active involvement in decision making, and greater clarity about personal values that relate to a treatment or screening decision.[5] Beyond the task of effectively conveying information, even beyond the challenges of addressing different learning styles among patients and different levels of literacy and health literacy, informed consent harbors additional complexities. For example, in the study by Tait and colleagues, it could be argued