

Computer Information Program Improves Patient Understanding in Informed Consent for Cardiac Catheterization

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Study Overview

Objective. To examine the effect of an interactive computer-based information program on patients' understanding of cardiac catheterization.

Design. Randomized controlled trial.

Setting and participants. Consecutive adult patients (age > 18 years) scheduled to undergo elective diagnostic cardiac catheterization were recruited for participation as they arrived at the facility, approximately 1 hour prior to the procedure. Patients who had undergone a catheterization in the past 3 years and patients undergoing emergency catheterization were excluded. Eligible patients were randomly assigned (using a table of random numbers) to receive information about the procedure either via the institution's standard information procedure (SI) or via an interactive computerized information program (ICI). The SI protocol included verbal information about the procedure, risks, benefits and options for treatment provided by the cardiology fellow or physician's assistant and a generic institutional consent form customized to include the risks and benefits of cardiac catheterization. The ICI protocol included information modules about the healthy heart, heart disease, treatment options, and the details, risks and benefits of cardiac catheterization provided through sequential 2-D and 3-D graphics, text, and narrative on a laptop computer. Additional information could be accessed by patients as needed by clicking on specified underlined items. At any time, patients could type in questions they had about the procedure, which were then relayed to the cardiologist. The final section included a summary of all information and an optional quiz. An ancillary speaker was used for patients who were hard of hearing. A research assistant was present to ensure completion and assist with program navigation. Completion of the ICI protocol took approximately 10–12 minutes, after which time patients were asked to sign the institutional consent form.

Main outcome measures. Patient understanding of cardiac catheterization was measured via a short, semistructured, open-ended interview. Six core elements of understanding

were assessed: (1) medical indication, (2) purpose, (3) protocol, (4) risks, (5) benefits, and (6) alternatives. The interview was administered at 3 time-points: prior to receipt of information about the procedure (baseline), prior to discharge (early understanding), and 2 weeks after the cardiac catheterization (late understanding). Interview responses were scored independently by 2 blinded assessors, with scoring guidelines determined a priori. Scores of 0 (no understanding), 1 (partial understanding), and 2 (complete understanding) were assigned for each core element, and combined for an overall score (range, 0–12 with 12 indicating complete understanding). The primary outcome measure was the change from baseline to early understanding.

Main results. Of the 155 patients assessed for eligibility, 13 declined to participate and 7 were excluded due to incomplete data or withdrawal. Data were analyzed for 135 patients (66 in SI group and 69 in ICI group). There were no differences in demographics between the 2 study groups. The ICI group had significantly more outpatients, but this difference did not affect understanding. Baseline understanding did not differ between the 2 groups (SI group mean, 6.8 ± 2.4 ; ICI group mean, 6.9 ± 2.9). Both groups showed improvements from baseline to early understanding (SI group mean understanding score change, 1.3 ± 2.5 ; ICI group mean understanding score change 2.2 ± 2.1). However, improvement from baseline to early understanding was significantly greater among patients in the ICI group than among patients in the SI group (mean difference 0.81; 95% CI, 0.01–1.6; $P = 0.002$). Patients in the ICI group had significantly greater early understanding of risks ($P = 0.001$) and options for treatment ($P = 0.048$) than patients in the SI group. There was a trend toward greater early understanding of other information elements in the ICI group. Late understanding decreased slightly in both groups and did not differ significantly between them. In multivariate models, factors predictive of improved change in early understanding included baseline understanding ($P < 0.001$), younger age ($P = 0.002$), and ICI group ($P = 0.003$). Of those who received ICI, 30% attempted the quiz at the end. There was no difference in understanding between those who took the quiz and those who did not. Only 3 patients typed in

questions on the computer. Satisfaction with the quality and effectiveness of information was high in both the SI and ICI groups and did not differ between them.

Conclusion. This study found that an interactive computer-based information program was satisfactory to patients and more effective in improving patient early understanding of cardiac catheterization than standard verbal and written information alone. Computer-based technologies hold promise for improving patient understanding in informed consent for medical and surgical procedures.

Commentary

Valid informed consent prior to invasive medical and surgical procedures requires patient understanding of the proposed intervention, including potential risks, benefits, and alternatives [1–3]. Informed consent is a legal and ethical requirement and widely recognized as a key component of safe, high-quality, and patient-centered health care. Yet informed consent in clinical practice is frequently inadequate [4,5]. Physicians receive little training in how to give information to patients prior to procedures, and the time pressures and competing demands of clinical medicine may hinder the informed consent process. Many standard consent forms do not contain key elements of information about the proposed procedure or are written in a language too complex for many patients to understand [6,7]. Perhaps not surprisingly, patient understanding in informed consent is often poor [8,9].

Recognition that the process of informed consent falls far short of its stated goals has led to a search for interventions to augment standard informed consent procedures and improve patient understanding. A wide range of interventions have been proposed and evaluated, including additional written information, extended informed consent discussions, test-feedback techniques, and audiovisual/multimedia programs. However, consensus regarding the comparative effectiveness of such interventions and the optimal method for delivering information about informed consent has not been reached.

The current study evaluates an interactive computer information program for cardiac catheterization developed by ArchieMD, Inc, a corporation led by Dr. Levine, the study's senior author. The study is notable for its rigorous methods (including adequate randomization, high response and participation rates, blinded outcome assessments, and consideration of multiple potential confounders in the interpretation of results) and for its significant findings. The computer program resulted in overall improved patient understanding of cardiac catheterization when compared to a standard informed consent process, and this improvement was judged to be clinically significant. For example, almost twice as many patients in the ICI group as compared to the

SI group had a complete understanding of the risks of the procedure. It is also noted that Dr. Levine, while responsible for development of the computer program, had no involvement in subject recruitment, data collection, analysis, or interpretation of the data.

Several limitations should be considered in the interpretation of these results. First, while the computer program improved patient understanding, it is not known whether it affected patient decision making about whether or not to undergo cardiac catheterization. Full informed consent involves not only an exchange of information but a process of shared decision making [10]. The computer program was administered to patients as they arrived at the facility, on average only 1 hour prior to the scheduled catheterization. It could be argued that by this time most patients had already made up their minds to undergo the procedure. Second, while the authors carefully consider education and literacy as potential confounders, no information is provided about the literacy level of the intervention. In presentation of the stratified results, significant improvements in understanding with the computerized information program are noted only for patients with bachelor's degrees or higher and for those with higher literacy scores. Further work is needed to evaluate this computer program in broader populations, and future informed consent interventions should be designed and evaluated with particular attention to patients at greatest risk for poor understanding.

Applications for Clinical Practice

This study provides evidence that a brief computer-based information program improves patient understanding of cardiac catheterization. Computer-based information programs may be an effective tool for augmenting traditional verbal and written informed consent. Future work should evaluate feasibility, acceptability, and comparative effectiveness of such programs in broader populations and for different procedures, as well as their impact on patient decision making and clinical outcomes.

—Review by Yael Schenker, MD

References

1. Whitney SN, McGuire AL, McCullough LB. A typology of shared decision making, informed consent, and simple consent. *Ann Intern Med* 2004;140:54–9.
2. Matiasek J, Wynia MK. Reconceptualizing the informed consent process at eight innovative hospitals. *Jt Comm J Qual Patient Saf* 2008;34:127–37.
3. American Medical Association. Informed Consent. Accessed 27 Apr 09 at www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml.

4. Braddock CH 3rd, Fihn SD, Levinson W, et al. How doctors and patients discuss routine clinical decisions. Informed decision making in the outpatient setting. *J Gen Intern Med* 1997; 12:339-45.
5. Schenker Y WF, Selig SJ, Ng R, Fernandez A. The impact of language barriers on documentation of informed consent at a hospital with on-site interpreter services. *J Gen Intern Med* 2007;22:294-9.
6. Bottrell MM, Alpert H, Fischbach RL, Emanuel LL. Hospital informed consent for procedure forms: facilitating quality patient-physician interaction. *Arch Surg* 2000;135:26-33.
7. Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *N Engl J Med* 2003;348:721-6.
8. Mark JS, Spiro H. Informed consent for colonoscopy. A prospective study. *Arch Intern Med* 1990;150:777-80.
9. Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. *BMJ* 1993;306:885-90.
10. Lo B. *Resolving ethical dilemmas: a guide for clinicians*. 2nd ed. Philadelphia: Lippincott Williams & Wilkins; 2000.

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