Shared Decision Making in Cardiovascular Disease in the Outpatient Setting

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ABSTRACT

The authors developed a patient decision aid (PDA) to educate patients regarding CAD. Patients were randomized to standard of care or a PDA. PDA group had increased medical knowledge of CAD and decreased decisional conflict. Patients presenting in an outpatient setting with symptoms may benefit from the use of a PDA. (Level of Difficulty: Beginner.) (J Am Coll Cardiol Case Rep 2019;1:261–70) © 2019 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

LEARNING OBJECTIVES

- Selection of further cardiovascular testing for prevention of coronary artery disease development in patients with cardiovascular risk factors must consider several clinical factors, including the patient's values and preferences.
- A patient presenting with symptoms concerning for coronary artery disease should be made aware of their likelihood of developing the disease and the pros and cons of each individual testing option that they may undergo.
- It is important to discuss the available options with patients who have risk factors for coronary artery disease.
- Although this is a relatively small study (n = 100), larger studies have also demonstrated the effectiveness of utilizing a PDA tool to increase patient knowledge and reduce decisional conflict.
- Longer-term follow up of patients enrolled in this study can be used to determine whether patients received further cardiovascular testing and whether they developed coronary artery disease. We can then compare outcomes in the control group versus the group that received the PDA.

It is estimated that 8 million patients present each year for the evaluation of chest pain or other symptoms related to underlying coronary artery disease (CAD) (1). Clinical evaluation combined with diagnostic testing is used to risk stratify and diagnose patients. The decision to undergo cardiovascular testing, and the type of testing used, is dependent upon the health care provider, institution, and patient. Furthermore, within cardiology, testing may be invasive in nature, carrying an even higher risk. Information regarding potential risks, benefits, and possible alternatives may not consider patient preferences or values. The shared decision-making model is a collaborative process in which patients and providers make health care decisions together after discussing options, potential benefits and harms, and considering the patient's personal values, preferences, and financial considerations (2).

The concept of shared decision making has gained increasing traction over the last few decades. With shared decision making, patients are empowered to take an active role in their health care treatment and management plans, with an increase in patient comprehension and engagement (3). Patient decision aids (PDAs) are evidence-based tools designed to support patients in the shared decision-making...
PDAs are meant to supplement, as opposed to replace, health care providers’ counseling about options. In general, PDAs provide: 1) a statement on the decision that needs to be considered; 2) evidence-based information about a health condition, including treatment options, associated benefits, harms, probabilities, and scientific uncertainties; and 3) recognition of the values to consider when deciding between options and to clarify the value patients may place on the potential benefits and harms (4).

PDAs in cardiovascular disease have been developed to help patients with decisions regarding treatment options, such as whether or not to undergo certain revascularization procedures (percutaneous coronary intervention or bypass surgery) (5) or heart failure patients deciding whether or not to have a left ventricular assist device (6). The goal of this pilot study was to develop a web-based PDA and evaluate its effectiveness to educate symptomatic patients presenting for cardiovascular disease regarding various testing for CAD. This is important in this patient population because results from initial diagnostic testing may lead to a more invasive procedure with higher risk and solidifying this shared decision is important. We hypothesize that the use of this PDA for cardiovascular testing in the evaluation of symptomatic patients for CAD will increase patient knowledge, increase engagement in decision making, reduce decisional conflict, and increase satisfaction for patients with regard to their health care.

METHODS

STUDY DESIGN. This was a single-center, randomized controlled pilot study performed at the MedStar Georgetown University Hospital outpatient cardiology clinic. Participants were randomized in a 1:1 fashion to a web-based PDA or standard of care without use of a PDA. Randomization was performed by a random number generator with assignment blinded in a sealed folder before enrollment. The primary endpoint was increased in patient knowledge, increase engagement in decision making, reduce decisional conflict, and increase satisfaction for patients with regard to their health care.

PARTICIPANTS. Between 2014 and 2019, new patients presenting to the MedStar Georgetown University Hospital outpatient cardiology clinic for the evaluation of chest pain or other symptoms concerning for underlying CAD were evaluated for enrollment in the study. Inclusion criteria was defined as new patients, over the age of 18 years, with no known history of CAD or prior CAD evaluation. Patients were excluded if they did not meet these criteria. Enrolled patients needed to be able to read and understand basic English, because the PDA was only available in English. Finally, if the patient was unwilling or unable to sign the informed consent, they were excluded from the study.

Patients who met inclusion criteria were approached by a research staff member during their time in the waiting room and asked whether they would be amenable to participating in the research study. Patients who agreed and signed the informed consent were then randomized to either the PDA group or the standard of care group. Assignment to a specific group was determined by a random number generator before the start of the study. The treating health care provider was blinded to randomization, and patients were advised not to discuss randomization with the provider. Patients who were randomized to the PDA group were given an iPad (Apple, Cupertino, California) that was linked to the PDA website. Patients who were randomized to standard of care received standard evaluation and treatment from their health care provider (Figure 1).

INTERVENTION. The PDA is an interactive, web-based tool providing information about CAD, as well as various tests used in its clinical evaluation, that was designed for use on a desktop or laptop computer, but was also functional on a tablet or iPad. The PDA was hosted on a website developed and securely maintained by Georgetown University. It was created by a multifaceted team at Georgetown University involving a steering group consisting of health care professionals, research personnel, and a web designer. Clinicians were consulted to determine what information they believed patients needed in order to improve their understanding when making a decision about cardiovascular testing. An early prototype of the PDA was then evaluated by health care professionals and research personnel to assess the design and data presented. It was then tested by nonclinical administrative staff to assess acceptability and usability, with further adjustments on design based on feedback. Study subjects were exposed to the final version of the PDA after adjustments had been performed.

Section I of the PDA includes basic introductory information on American Heart Association recommendations for CAD testing, including commonly used screening and diagnostic tests. Section II provides information on the definition, symptoms,
natural history, prevalence, and mortality related to CAD, including questions that health care providers may ask patients to diagnose and treat CAD. Section III goes over the various types of cardiovascular testing that may be used for the diagnosis of CAD including a description (with pictures) of what is involved, results to expect, potential risks and benefits (with graphical representation), as well as limitations for each test, including a comparison table of the various tests (Figures 2 and 3).

Section V provides the opportunity for patients to input their own information to calculate their personal risk estimate for having significant CAD and/or having a cardiac event. Furthermore, patients can also recalculate their personal risk estimates depending on positive or negative results for different cardiac tests (Figure 3).

This provides personalized information they can use to help determine which test they would like to undergo if further testing is indicated. An interactive slider toolbar allowed patients to record personalized preferences and values with regard to specific decisions that may need to be made. Patient testimonials were also included to provide context and relevance. The PDA was written at an eighth-grade reading level.
**QUESTIONNAIRES.** Patients enrolled in the study were asked to complete 4 to 6 questionnaires (depending on randomization) after their office visit. The first questionnaire was a 10-item quiz designed to assess the patient’s knowledge of CAD and testing for CAD (Supplemental Table 1). The second questionnaire evaluated the possible decisional conflict faced by patients when making decisions during their office visit (Supplemental Table 2) (7). The third questionnaire assessed the extent to which the patient felt there was shared decision making between themselves and the health care provider (Supplemental Table 3) (8). The fourth questionnaire determined how much trust the patient had in the provider during their office visit (Supplemental Table 4) (9). The last 2 questionnaires were only given to those subjects who were randomized to using the PDA and assessed the acceptability of the PDA and how prepared the patient felt for making decisions about his or her health after use of the PDA (Supplemental Tables 5 and 6).

When calculating totals from the survey questions, questionnaires 3 to 5 (Supplemental Tables 3 to 5) had several questions that had to be reweighted due to an inconsistent scale. In questionnaire 3, questions 1, 2, 7, 10, and 11 were reweighted so that a low number corresponded with higher certainty and a high number corresponded with uncertainty. In questionnaire 4, questions 1, 5, 7, and 11 were reweighted so that a low number corresponded to high trust and a high number corresponded with low trust. In questionnaire 5, questions 4 and 5 were reweighted so that a score of 7 signified “yes” and 1 signified “no.” The questionnaires were reweighted to ensure the scales were consistent for numerical values low to high. This reweighting had no impact on changing the results or

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**FIGURE 2** Overview of PDA

Enrolled patients randomized to use of the PDA were provided an iPad with the website before their office visit. The PDA provided basic introductory information on American Heart Association recommendations for CAD testing, including commonly used screening and diagnostic tests. Patients were also provided information on the definition, symptoms, natural history, prevalence, and mortality related to CAD. Abbreviations as in Figure 1.
introduced any new bias into the study. The reweighting just allowed for easier statistical comparison.

Patients enrolled in the study were also informed that if they had any feedback on the PDA or the questionnaires, they would be able to inform the research personnel once they had seen their health care provider and completed all appropriate forms.

**STATISTICAL ANALYSIS.** We used a 10-item questionnaire for assessment of patient knowledge, the primary endpoint (Supplemental Table 1). We assumed that patients in the standard of care group would, on average, answer 4 of the 10 questions correctly. A sample size of 100 provided 90% power to detect a >20% increase in mean knowledge for the PDA group, assuming equal variances between the 2 arms and $\alpha = 0.05$. Comparisons between additional outcome variables were tested using Wilcoxon rank sum test for continuous variables and Pearson’s chi-square tests for categorical or proportional variables.

**RESULTS**

Between 2014 and 2019, a total of 115 eligible patients were approached for enrollment with 15 declining to participate. The median age of enrolled patients was 52 years with slightly more female (50.5%) and white (56.6%) participants. Study participants were also more likely to be single (42.4%) and employed full-time (33.3%) (Table 1). Of the 100 patients enrolled, 92 successfully completed all questionnaires, 7 patients submitted incomplete questionnaires, and 1 patient withdrew before randomization. Forty-nine patients were randomized to standard of care and 43 patients to the PDA group. The most common chief complaint was chest pain ($n = 28$) followed by hypertension ($n = 11$) and “irregular heart beat” ($n = 11$) (Table 2). On average, each participant who was randomized to using the PDA spent an average of 25 min looking through the information and answering the corresponding questions. Participants in the
standard of care group spent slightly less time completing the questionnaires, averaging approximately 15 min.

Participants in the PDA group averaged 81% (mean 8.05 ± 1.29) correct on the quiz testing medical knowledge of CAD, whereas participants in the standard of care group averaged 70% (mean 6.94 ± 1.44) correct. When compared with the standard of care group, participants in the PDA group had statistically significant increased medical knowledge of CAD (p < 0.001) as well as decreased decisional conflict (p < 0.001). Both groups reported high patient satisfaction (p = 0.42) and trust in the provider (p = 0.26), with no statistically significant difference between the groups (Figure 4). Participants in the PDA group reported high acceptability of the decision aid tool (range 1 to 7, mean 5.2 ± 0.49) and increased preparedness for making decisions (range 1 to 5, mean 3.8 ± 0.14).

Upon retrospective chart review of the 99 patients who enrolled and completed the study, there were 99 primary diagnoses recorded following their office visit, which were referenced when determining whether to undergo additional cardiac testing. Of these 99 diagnoses, the most common were chest pain/discomfort (20%) and hypertension (17%), and the patients with these diagnoses were more likely to undergo additional cardiac testing (Table 3).

A total of 64 of the 99 patients (64.6%) underwent further cardiac testing after their initial consult, whereas 36 (36.4%) did not undergo further testing. Some patients also underwent >1 cardiac test. Of the 119 additional cardiac tests performed after the initial office visit, 42 (35.3%) were transthoracic echocardiogram, 25 (21.0%) were stress echocardiogram, 6 (9.0%) were cardiac magnetic resonance imaging/magnetic resonance angiography, 6 (9.0%) were computed tomography scans of the heart/chest, and 5 (7.5%) were computed tomography angiography of the chest (Figure 5). Interesting to note, none of the patients were directly referred for invasive coronary angiography. This finding may reflect an inherent selection bias of patients who are referred to outpatient cardiology clinic in general. These patients may be lower risk overall and less likely to be referred for the highest-risk test: invasive coronary angiography.

### DISCUSSION

Patient-centered care, and specifically PDA tools, have become increasingly prevalent in clinical practice because there has been renewed emphasis on shared decision making between clinicians and

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**Table 1: Patient Enrollment Demographics**

|                | Total (N = 99) | Standard Care (n = 49) | PDA (n = 50) |
|----------------|---------------|------------------------|-------------|
| Age, yrs       | 51.5 (37-65)  | 53.1 (38-67)           | 49.9 (35.3-64.5) |
| Men            | 49.5          | 50.0                   | 50.0        |
| Women          | 50.5          | 50.0                   | 50.0        |
| Race           |               |                        |             |
| White          | 56.6          | 55.0                   | 58.0        |
| Black          | 27.3          | 26.5                   | 28.0        |
| Asian          | 1.0           | 0.0                    | 2.0         |
| Other          | 7.7           | 6.1                    | 8.0         |
| Prefer not to answer | 8.1 | 12.2                   | 4.0         |

**Table 2: Chief Complaints of Enrolled Patients**

| Chief Complaint                              | Count |
|----------------------------------------------|-------|
| Chest pain                                   | 28    |
| Hypertension                                 | 11    |
| Irregular heart beat                         | 11    |
| Abnormal cardiac testing                     | 9     |
| Shortness of breath                          | 8     |
| Pre-operative cardiac consult                | 7     |
| Syncope                                      | 4     |
| Postural orthostatic tachycardia syndrome    | 3     |
| Medication adjustment/refill                 | 2     |
| Procedure follow-up                          | 2     |
| Heart failure                                | 2     |
| Diastolic dysfunction                        | 2     |
| Stroke                                       | 2     |
| Myocarditis                                  | 1     |
| Heart murmur                                 | 1     |
| Ischemia                                     | 1     |
| Edema                                        | 1     |
| Sudden cardiac death                         | 1     |
| Endocarditis                                 | 1     |
| Family history of coronary artery disease    | 1     |
| Cough                                        | 1     |

Patients presented to the outpatient cardiology clinic with multiple varying chief complaints. The most common complaint was chest pain (n = 28) followed by hypertension (n = 11) and irregular heart beat (n = 11).
patients. Clinical evaluation, combined with diagnostic testing, is utilized to risk stratify and diagnose patients. The decision to undergo additional testing, and the type of testing utilized, is dependent upon the health care provider, institution, and patient. Information regarding potential risks, benefits and possible alternatives may not consider patient preferences or values. Studies implementing PDAs have demonstrated improved patient knowledge of their options and outcomes, reduced decisional conflict, and more realistic and often conservative treatment choices when concerning major elective surgeries (10). It has also been shown that PDAs enable patients to clarify what matters most to them and choose a decision more in line with their own values (4). Shared decision making allows for more open lines of communication and greater understanding between health care providers and patients, thus eliciting improved clinical outcomes.

Some of these PDAs have focused on topics such as end-of-life care, percutaneous coronary intervention (PCI), and cancer screening tailored to a specific patient population (11–13). In 1 study using a web-based decision aid for surrogate decision makers of patients with prolonged mechanical ventilation, there was improved surrogates’ understanding of physicians’ prognostic beliefs and reduced decisional conflict after using a decision aid (11). In an alternate study, researchers aimed to improve patient understanding that PCI for stable CAD does not significantly reduce heart attack and death (12). This improvement was seen to a greater extent in the group that was provided with a decision aid during their visit. In a final study, a decision aid was developed to determine whether providing additional information about colon cancer screening would support informed choice and reduce decisional conflict about screening decisions in patients with low health literacy. The study found that use of a decision aid promoted increased knowledge leading to a more informed choice, as well as reduced decisional conflict (13). To our knowledge, our study, which highlights the importance of outpatient cardiovascular testing for CAD, is the first PDA to focus on this aspect of cardiovascular disease. This PDA goes beyond simply being an educational pamphlet or brochure by incorporating interactive,
personalized information that patients can adjust to determine different outcomes.

To this end, we created a web-based PDA developed specifically for adult cardiology patients who present with initial symptoms suggestive of CAD for use at the MedStar Georgetown University Hospital outpatient cardiology clinic. Around 8 million patients present each year for evaluation of chest pain or other symptoms related to underlying CAD (1). These data aligned with our patient population, in which the most often reason for their visit was chest pain (28%). It is important to ensure that these patients receive adequate information to guide their clinical decision making, as chest pain is the most common sign of underlying CAD, which could result in increased myocardial infarction and cardiovascular mortality if left untreated. Although there was no effect on patient satisfaction or trust in the health care provider with regards to the decision-making process; the patients in the PDA group rated highly both the acceptability of the PDA and their preparedness for making a medical decision, showing the benefit they received by using the PDA. Although no invasive intervention was offered, screening and diagnostic tests can still lead to anxiety, and education on their risks and benefits is important for patients. By allowing patients to take a more active role in their care, in this case with the use of a PDA, shared decision making regarding cardiovascular care can be made in a patient-centered manner.

**Patient Education and Preferences.** The main findings from our pilot study are that a web-based PDA focused on cardiovascular testing for CAD is associated with increased medical knowledge of CAD and decreased decisional conflict as it relates to a patient’s cardiovascular care. There was no effect on patient satisfaction or trust in the health care provider with regard to the decision-making process, specifically whether to undergo cardiovascular testing.

Throughout the course of the study, there was various feedback from patients on the use of the PDA. Women in particular reported that they thoroughly enjoyed using the PDA and felt that they learned a lot. They were also more likely to ask if they could check if their answers were correct for questionnaire #1 (Supplemental Table 1). There was a select group of patients who asked if the decision aid website was available for public use at home, thus re-emphasizing its value to this patient population. In terms of critical feedback, patients reported that they wished there were fewer questions to fill out after seeing the provider.

This web-based PDA lends itself to numerous possibilities for further application. Due to its online nature, it has the ability to be transformed into an app that patients would have access to on their smartphones. More outpatient clinics are moving in-line with technological advances, including digital check-in for patients on electronic tablets. If patients were able to check-in, choose their primary symptom/reason for the visit via a drop-down menu, and then get a link sent to their phone with the relevant PDA—which they could access while they wait—the results could be highly favorable for both patient and clinician.

**Study Limitations.** First, all patients were seen at a single institution, MedStar Georgetown University Hospital, located in a particularly affluent part of...
Washington, DC. This could have led to the patient population being comprised of higher socioeconomic groups, thus lending more access to education and internet resources on CAD, with resultant, higher-than-expected scores on the knowledge of CAD questionnaire #1 (Supplemental Table 1). Despite the higher baseline knowledge, our study did show an increase in knowledge with use of the PDA.

A second limitation of the study is that the PDA was distributed electronically on an iPad. Because the average age of patients enrolled in the study was 52 years, some of the older patients reported difficulty going through the PDA due to a general lack of prior experience with using an iPad and the small screen and text size. This could have affected the knowledge they were able to gain through use of the PDA.

A third limitation of the study was the variable time availability for use of the PDA for those randomized to the PDA group. Because patients were enrolled in the study at the time of their clinic visit, the available time allotted to using the PDA was dependent on the clinic workflow of the day, which was unpredictable and could range between 20 and 30 min. Despite this, patients who used the PDA still felt that adequate time was available to go through all the information offered.

Another limitation of the study was that although health care providers were blinded to enrollment and randomization, some unintentional unblinding may have occurred because patients enrolled in the study may have had their study folder and iPad with them in the patient room in order to maximize their time with using the PDA and completing the questionnaires. This may have biased providers in their interaction with patients who they suspected were enrolled in the study than they otherwise would be. As discussed in the preceding text, a selection bias was also present in our study due the fact that in general patients who are referred to outpatient clinic are overall a lower risk patient population and less likely to undergo a higher risk test such as invasive coronary angiography. Lastly, we had a prolonged enrollment period of 5 years due to the lack of support staff in the middle of our enrollment period.

**CONCLUSIONS**

Patients presenting with symptoms related to CAD in an outpatient setting may benefit from the use of a web-based PDA to increase medical knowledge and decrease decisional conflict as it relates to decisions regarding cardiovascular testing without affecting overall patient satisfaction or trust in their physician. A larger study is needed to confirm whether these results are applicable to other, more diverse patient populations.

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**KEY WORDS** coronary artery disease, decision aid, management, pilot program

**APPENDIX** For supplemental tables, please see the online version of this paper.