

Radial Artery Versus Femoral Artery Access Options in Coronary Angiogram Procedures

Randomized Controlled Trial of a Patient-Decision Aid

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Background—Vascular access options in coronary angiography can be considered a preference-sensitive decision, where the benefits/risks have different levels of significance, depending on the individual patient. For preference-sensitive healthcare options, patient decision aids (PtDA) significantly improve the process of decision-making. The purpose of this trial was to evaluate the effectiveness of an evidence-based PtDA compared with usual care in patients eligible for radial and femoral artery access.

Methods and Results—We conducted a single-center, nonblinded, randomized controlled trial with patients eligible for both femoral and radial access as per their treating physician. The PtDA was designed to guide patients to make an informed choice, consistent with their preferences and values. The primary outcome, decisional conflict, was assessed using the validated decisional conflict scale. One hundred fifty patients were randomized (vascular access PtDA=76 versus usual care=74). The intervention group had a significantly reduced decisional conflict scale compared with control (unadjusted 14.8 versus 19.5, $P=0.04$) and were significantly more knowledgeable regarding risks/benefits associated with each vascular access (mean knowledge score 3/5 (95% confidence interval, 2.6 to 3.3) versus 2/5 (95% confidence interval, 1.7 to 2.3, $P<0.01$). PtDA patients had better informed value congruence with their vascular access received (47.3% versus 25.7%, $P<0.01$). There were no significant differences in procedural success or safety between the 2 groups.

Conclusions—A vascular access PtDA for eligible patients undergoing coronary angiogram procedures reduces decisional conflict and improves value congruence and the patients' knowledge of their healthcare options; however, a multicenter study, powered to confirm these benefits and evaluate differences in procedural success or complications, is required.

Clinical Trial Registration—URL: <http://www.clinicaltrials.gov>. Unique identifier: NCT01032551.

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Key Words: patient decision aid ■ angiogram ■ radial ■ femoral ■ vascular access ■ patient preferences

Coronary angiography (CA), with or without percutaneous coronary intervention (PCI), is accomplished primarily with vascular access obtained via the radial artery or the femoral artery. Currently, a debate regarding the optimal vascular access site for CA procedures has flourished. Both radial and femoral artery vascular access have their advantages and disadvantages, but neither has yet been proven to have superior health outcomes, as outlined in a recent large randomized controlled trial and meta-analysis.^{1,2} Vascular access for CA procedures thus falls into the gray zone, close call, or preference-sensitive decision, where the benefits and harms of each healthcare option (femoral versus radial) may have different levels of significance depending on the patient's preferences and values.³

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CA procedures accomplished through the femoral artery have a longer history of use and have been shown to be more technically straightforward to perform compared with procedures conducted through the radial artery.⁴ The femoral approach also allows for the use of larger diameter catheters and sheaths, when necessary. Compared to the radial approach, CA procedures via the femoral artery consistently demonstrate reduced volume of contrast, shorter procedural times, and less x-ray exposure.¹

A recent randomized controlled trial and meta-analysis, however, suggests that radial artery access is associated with fewer major bleeding events compared with femoral vascular access.^{1,2}

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Moreover, vascular access through the radial artery requires the patient to lie flat for a significantly shorter period of time and has a shorter bed rest period following the procedure when compared with the femoral approach. This has significant implications for patients with chronic back pain. The radial approach may also be associated with earlier discharge compared with vascular access through the femoral artery.^{5,6}

Currently, usual care regarding vascular access options before CA procedures involves a brief discussion between the patient and the cardiologist performing the procedure; however, in general terms, usual care involved in the decision-making process for healthcare options has 3 key problems: (1) physicians are poor judges of patients' values; (2) the decision quality from standard counseling between physician and patient has been demonstrated to be inadequate; and (3) patients have unrealistic expectations of potential treatment benefits and harms.⁷

Given the difficulties surrounding the decision-making process in preference-sensitive healthcare options, the concept of shared decision-making and, more specifically, the use of patient decision aids (PtDA) to supplement physician-patient counseling have been developed, evaluated, and implemented. Furthermore, the US Patient Protection and Affordable Care Act has placed a significant emphasis on shared decision-making.⁸

WHAT IS KNOWN

- Vascular access options in coronary angiography can be considered a preference-sensitive decision, where the benefits/risks have different levels of significance, depending on the individual patient.
- For preference-sensitive healthcare options, patient decision aids significantly improve the process of decision-making.

WHAT THE STUDY ADDS

- A vascular access decision aid for patients undergoing coronary angiography was created, implemented, and tested in 150 patients at a single center.
- Use of the decision aid was associated with reduced decisional conflict, value congruence between desired and chosen treatment strategy, and improved patient knowledge of healthcare options.
- A vascular access decision aid would be a useful addition to cardiac centers that provide both femoral and radial access options for coronary angiography and intervention.

There is a significant body of evidence supporting the use of PtDAs. A meta-analysis of 55 randomized controlled trials comparing PtDAs versus usual care clearly demonstrated their benefit.⁹ More specifically, PtDAs improve the quality of decision-making by significantly improving knowledge of the patient's healthcare options, improving the patient's accurate risk perception, improving value congruence with the chosen healthcare option, and reducing decisional conflict. Unresolved decisional conflict often results in patients verbalizing uncertainty about their choices, vacillating between choices, feeling

distress, and delaying decision-making.¹⁰ PtDAs have also decreased unwarranted practice variation in preference-sensitive healthcare options.⁹

Given vascular access for CA procedures can be considered a preference-sensitive medical decision, implementation of an effective PtDA that guides eligible patients through the decision-making process regarding their vascular access options and improves the decision-making process and subsequent decision quality is warranted. The purpose of this trial was to evaluate the effectiveness of an evidence-based vascular access PtDA compared with usual care on decision quality and the process of making the decision about vascular access in eligible patients undergoing CA procedures.

Methods

Study Design

We conducted a single-center, nonblinded, randomized controlled trial. Between June 2010 and December 2010, all eligible patients undergoing CA procedures at a high-volume, tertiary care institution, who were appropriate candidates for both vascular access sites, were approached to participate in the study by research personnel independent of the operator (Figure). The randomization schedule was created with a computerized random number generator. Simple randomization was used. Concealment of the randomization list was performed with the use of sealed envelopes. The patients and physicians were not blinded to the study allocation. This study was approved by the local research ethics board (REB approval No. 09-340) and registered (NCT01032551).

Patient Population

The inclusion criteria were: participants ≥ 18 years of age, English-speaking, able to provide informed consent, and candidates for both femoral and radial access as defined by the pre-assessment checklist and subsequently approved by their treating physician. The pre-assessment checklist included the following features: palpable radial artery, palpable femoral artery and distal pedal pulses, no significant abdominal obesity or pannus, and no prior cardiac catheterization. Although it is standard practice to confirm dual circulation to the hand with the Allen test using pulse oximetry, this was not a strict inclusion criterion. Eligibility for radial access was left to the discretion of the treating physician.

Patients were excluded if they were emergent or hemodynamically unstable. A patient was deemed ineligible if the interventional cardiologist scheduled to perform the procedure did not feel comfortable or believed the patient was ineligible for either access (may include reasons not specifically outlined in the pre-assessment checklist). All 11 full-time interventional cardiologists practicing at the tertiary care hospital are experts in both radial and femoral access and participated in the recruitment of patients for this study.

Development of the Intervention (PtDA)

The development of the vascular access PtDA was based on the Ottawa Decision Support Framework and the International Patient Decision Aid Standards.^{11,12} The process involved a systematic review, consideration of patient experiences, consultation with experts, and a pilot study evaluating its feasibility of use and potential impact on practice patterns.¹³ The content in the PtDA was primarily based on a recent high-quality meta-analysis.¹ Wherever possible, published results of frequencies of complication rates and risks were used.

Intervention Group

Patients arrived at least 90 minutes prior to their scheduled CA procedure to allow appropriate intake by the nurses and assessment by their treating cardiologist. The intervention group received a 3-page booklet PtDA addressing vascular access at least 30 to 60 minutes before the start of their CA procedure. The PtDA was reviewed by the patients during this time. The PtDA is a brief lay

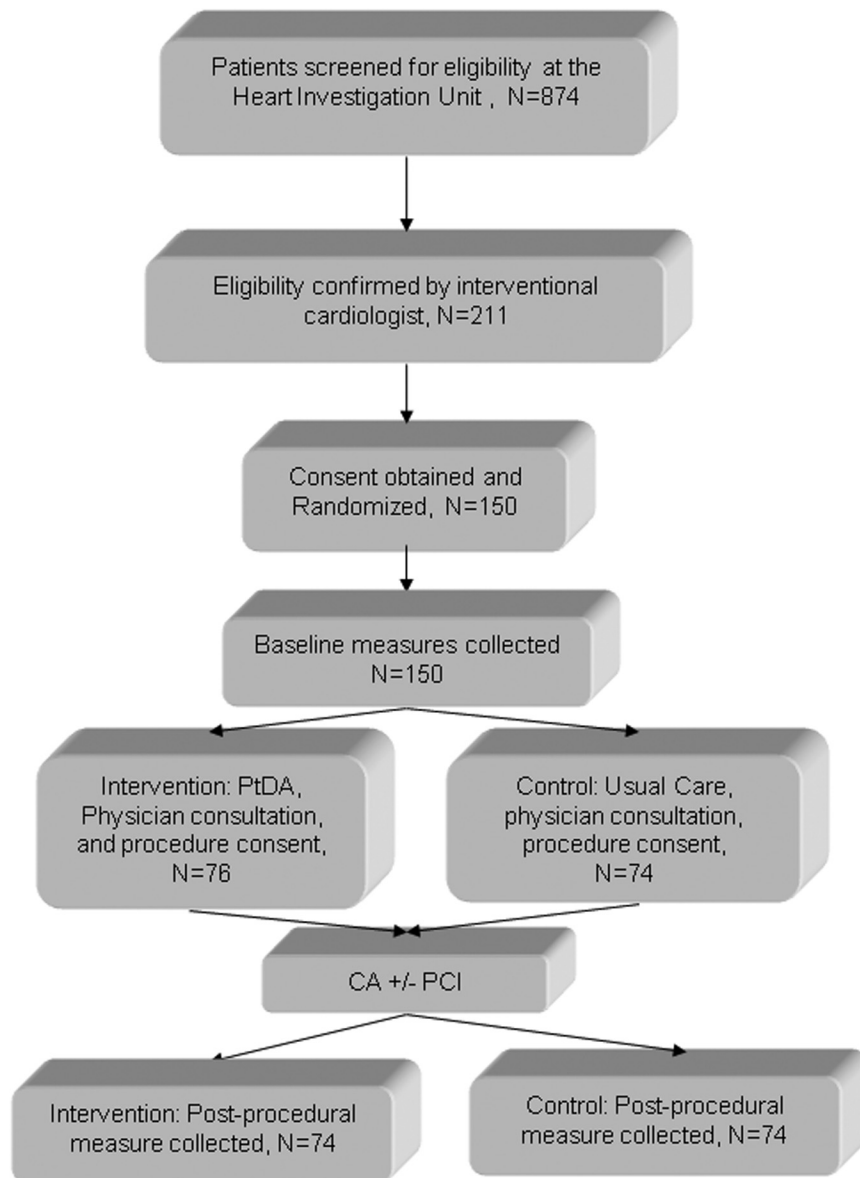


Figure. Schedule of study assessments. CA indicates coronary angiogram; PtDA, patient decision aid; PCI, percutaneous coronary intervention.

summary that outlines 5 steps, (1) the purpose of the PtDA; (2) a description of the options (femoral versus radial approaches for CA procedures); (3) what to expect from both options; (4) the known risks/benefits of each access site presented as probabilities using event rates (including grading of the evidence); and (5) an explicit values clarification exercise. This exercise asked patients to explicitly state which features, risks, and benefits of each option were important to them (online-only Data Supplement Appendix A). The PtDA was structured using 5 steps to guide patients in the process of decision-making. The completed PtDA could be shared with the treating physician.

Control Group

The control group received usual care. Usual care involved a brief discussion, just before CA, with the treating physician, regarding the patient's eligibility for both vascular access sites, followed by the advantages and disadvantages of both. The details and duration of the discussion were left to the discretion of the treating physician, as per their individual standard of care. There was no access to a formal PtDA in this group.

Outcome Measures and Measurement Procedures

Measures were collected in 4 ways: a screening log, assessment of baseline patient characteristics and procedure characteristics, PtDA

values assessment, and predischARGE questionnaire. The predischARGE questionnaire for the intervention and control only differ with respect to the inclusion of the values assessment in the control group's predischARGE questionnaire, as the interventions group has the values assessment imbedded within the PtDA. The values assessment was included in the PtDA, as this has been demonstrated to more effectively guide patients through the decision-making process, per the Ottawa Health Research Institute's validated PtDA format.¹⁴

The primary outcome was assessed using the 16-item decisional conflict scale (DCS), which is a validated scale that measures personal perceptions of: (1) uncertainty in choosing options; (2) modifiable factors contributing to uncertainty, such as feeling uninformed, unclear about personal values, and unsupported in decision-making; and (3) effective decision-making, such as feeling the choice is informed, values-based, likely to be implemented, and expressing satisfaction with the choice (online-only Data Supplement Appendix B).¹⁰ Reliability has been demonstrated: Cronbach alpha ranging from 0.78 to 0.92 for the total scale and 0.58 to 0.92 for the subscales; and test-retest reliability is 0.81 for both the total scale and the uncertainty subscale.¹⁰ Decisional conflict can be lowered with decision-supporting interventions such as a PtDA.¹⁵ The DCS was embedded into the follow-up questionnaire of the control and PtDA groups.

Secondary outcomes include knowledge, risk perceptions of the patient's healthcare options, informed value congruence with the patient's chosen option, and impact of patients choosing their vascular access (vascular access success rate, PCI success rate, procedural time, volume of contrast, and major vascular access-site complications before discharge). Major vascular access-site complications include pseudoaneurysms requiring ultrasound compression, thrombin injection or surgical repair, large hematomas requiring prolonged hospitalization, arteriovenous fistulae, limb ischemia, or damage to adjacent nerve. Secondary outcomes were assessed before discharge from the heart investigation unit, following the CA procedure.

Sample Size

The sample size was based on a significant effect size of 0.655, common standard deviation of 0.4 for the overall DCS, with a power of 90%, and a 2-tailed alpha of 0.05.¹⁰ This effect size was judged clinically important because effect sizes observed between those who make and delay decisions have ranged between 0.43 and 0.82.¹⁰ The anticipated sample size was 50 patients in each arm, for a total of 100. Given follow-up is performed immediately following the procedure, the attrition rate was expected to be negligible.

Statistical Analysis

Data from the Microsoft Excel database was analyzed using SAS version 9.2 (SAS Institute Inc). Unadjusted comparisons across randomized groups were assessed using a *t* test for continuous variables and given the adequate sample size of each group and χ^2 test for categorical variables. (The Fisher Exact test was used when cell counts were <5.) All subjects were included in the analysis, with the exception of 2 subjects in the Intervention Arm who did not have the DCS completed. An Analysis of Covariance with the dependent-variable DCS score was entertained to adjust for significant differences in baseline characteristics between the control and treatment groups.

The primary outcome variable was the DCS total score. Responses were transformed to standardized units on a 0-to-100 scale by summing all items, dividing by 16, and then multiplying by 25 for the total DCS score and subscale scores. Scores ranged from 0 [no decisional conflict] to 100 [extremely high decisional conflict].

Knowledge scores are displayed as a number (percent) of correctly answered responses and mean score with standard deviation.

The relationship among the vascular access value questions (see online-only Data Supplement Appendix A) pertaining to the wrist approach (3 questions on a scale of 0 [value of no importance] to 5 [value of great importance]) and leg approach (3 questions on a scale of 0 [value of no importance] to 5 [value of great importance]) and the outcome of vascular access received (radial or femoral) was assessed. For strength of values, a composite total-value wrist score was derived from the 3 value questions relating to the wrist approach (ranging from scores of 0 [not important] to 15 [extremely important]), similarly, a composite total-value leg score derived from the 3 value questions relating to the leg approach (ranging from scores of 0 to 15). Based on the composite total scores for wrist and leg, patients were classified as a "responder" if vascular access received was "radial," and composite total value score for wrist \geq composite total value score for leg, or vascular access received was "femoral," and composite total value score for leg \geq composite total value score for wrist; otherwise, the patient was classified as a "nonresponder." The proportion of patients in each group that were considered "responders" and had a knowledge score $\geq 3/5$ were compared to evaluate the outcome of informed values-based decision.

Results

Between June 2010 and December 2010, 874 patients undergoing CA at the tertiary hospital were screened for eligibility. Overall, 663 (75.9%) patients were deemed ineligible (316 [47.7%] had a prior angiogram, 180 [27.2%] had a LIMA graft, 129 [19.5%] were deemed inappropriate for either

Table 1. Characteristics of Participants

Characteristic	Intervention* (N=76)	Control* (N=74)	P Value
Age	63.4 (11.5)	63.0 (10.8)	0.60
Female	29 (38.2)	22 (29.7)	0.28
BMI	28.6 (4.1)	28.8 (4.3)	0.65
Cardiac history			
CHF	5 (6.6%)	2 (2.7%)	0.44
CVA/TIA	9 (11.8%)	1 (1.4%)	0.02
Diabetes	14 (18.4%)	17 (23%)	0.49
Hypertension	51 (67.1%)	44 (59.5%)	0.33
Hyperlipidemia	59 (77.6%)	52 (70.3%)	0.30
Smoking (current or former)	44 (57.9%)	42 (56.8%)	0.88
Prior MI	11 (14.5%)	6 (8.1%)	0.22
Indication for angiogram			
Stable angina	36 (47.4%)	43 (58.1%)	0.36
Unstable Angina/NSTEMI	18 (23.7%)	16 (21.6%)	
Other	22 (28.9%)	15 (20.3%)	

*Data are mean (SD) or No. (%).

BMI indicates body mass index; CHF, congestive heart failure; CVA, cerebrovascular accident; TIA, transient ischemic attack; MI, myocardial infarction; NSTEMI, non-ST-segment-elevation myocardial infarction.

radial or femoral access by the treating cardiologist, and 38 [5.7%] had a significant language barrier); 61 (9.2%) patients refused to provide consent; 150 (17.2%) patients provided informed consent, with 76 patients randomized to the intervention group and 74 patients to the control group (Figure). Table 1 outlines the baseline patient characteristics in the intervention and control groups. Although there were some baseline characteristics that differed between the groups, CVA/TIA was the only statistically significant variable (11.8% intervention versus 1.4% control, $P=0.0176$).

Unadjusted analysis demonstrates that patients in the intervention group had a significantly reduced total decisional conflict scale when compared with the control (mean scores: 14.8 versus 19.5, $P=0.04$, range 0 to 37.5 for intervention, 0 to 70.3 for control). Three of the 5 subscore categories of the DCS (Informed, values clarity, and effective decision) were significantly lower in the intervention group (Table 2); however, after adjusting for the baseline differences in CVA/TIA between the 2 groups, the treatment group was no

Table 2. Decisional Conflict Scale Outcome

Question	Intervention (N=76) Mean (SD)*	Control (N=74) Mean (SD)*	P Value
Uncertainty sub-score	18.0 (18.8)	19.6 (19.9)	0.61
Uninformed sub-score	15.7 (13.5)	22.3 (20.5)	0.02
Under values clarity sub-score	18.0 (15.3)	26.0 (24.2)	0.02
Unsupported sub-score	12.2 (15.2)	14.9 (16.9)	0.31
Ineffective decision sub-score	11.3 (11.4)	15.9 (15.9)	0.04
Total score†	14.8 (10.5)	19.5 (16.7)	0.04

*Median score for intervention group is 16.4 and for control group is 21.9.

†0 DCS indicates no decisional conflict; 100 DCS, highest decisional conflict.

Table 3. Procedural Characteristics

Characteristic	Intervention* (N=76)	Control* (N=74)	P Value
Vascular access chosen by			
Patient	58 (76.3%)	29 (39.2%)	<0.01
Physician	18 (23.7%)	45 (60.8%)	
Vascular access selected			
Radial	56 (73.7%)	58 (78.8%)	0.50
Femoral	20 (26.3%)	16 (21.6%)	
Vascular access received			
Radial	52 (68.4%)	56 (75.7%)	0.32
Femoral	24 (31.6%)	18 (24.3%)	
Vascular access success			
Referred for CABG	11 (14.5%)	10 (13.5%)	0.87
Major vascular access site complications	0 (0%)	0 (0%)	1.00
Mean diagnostic angiogram procedural time (min)	13.9 (6.5)	13.2 (5.0)	0.39
Mean contrast volume (ml)	118.6 (70.3)	107.4 (55.2)	0.28
Ad-hoc PCI	18 (23.7%)	18 (24.3%)	0.93
PCI success	18 (100%)	17 (94.4%)	0.92
Mean procedural time if PCI (min)	30.2 (17.9)	23.4 (7.7)	0.16

*Data are mean (SD) or No. (%).

CABG indicates coronary artery bypass graft; PCI, percutaneous coronary intervention; min, minutes; mL, milliliters.

longer a statistically significant predictor of the DCS score ($P=0.08$).

Table 3 outlines the procedural characteristics. The radial approach was the predominant access selected in both groups (74% intervention and 79% control, $P=0.5$). Despite 76.3% of patients actively selecting their access route of choice in the intervention group as compared with 39.2% in the control group ($P<0.01$), there was no significant differences in vascular access success (95% intervention versus 97% control, $P=0.68$), PCI success, contrast volume, procedural time (diagnostic angiogram and ad-hoc PCI), and major vascular access site complications. Four patients in the intervention group versus 2 patients in the control group in which the radial access was chosen had to cross over to femoral access ($P=0.68$); however, 2 of the 4 patients in the intervention group that crossed over to femoral access had the access site either selected by the physician or were influenced by the physician. Reasons for crossover include recurrent radial loop (33%), severe radial spasm (50%), and radial artery calcification (17%). Mean contrast volume and mean PCI procedural time trended toward an increase in the PtDA group; however, this was explained by 2 outliers involving complex procedures for a chronic total occlusion. Therefore, the differences in median contrast volume (90 mL and 80 mL) and PCI procedural time (26 minutes versus 23 minutes) in the PtDA and control groups, respectively, were less.

Furthermore, patients in the intervention group were significantly more knowledgeable regarding the risks and benefits associated with each vascular access, with a mean score of 3 out of 5 (95% confidence intervals (CI), 2.6 to 3.3) versus 2.0 (95% CI, 1.7 to 2.3, $P<0.01$), Table 4.

Table 4. Knowledge Scores

Question	Intervention (N=76) n (%)	Control (N=74) n (%)	P Value
Which option has the lowest chance of bleeding?	47 (61.8%)	37 (50.0%)	0.15
Which option has the highest chance of the procedure being unsuccessful?	46 (60.5%)	21 (28.4%)	<0.01
Which option requires you to lie flat the longest following the procedure?	65 (85.5%)	54 (73.0%)	0.06
Which option has the shortest procedure time?	20 (26.3%)	7 (9.5%)	<0.01
Which option is considered more technically challenging?	48 (63.2%)	29 (39.2%)	<0.01
Mean Score (SD)	3.0/5 (1.5)	2.0/5 (1.3)	<0.01

A significantly greater proportion of patients in the intervention group had better-informed value congruence with their vascular access site as compared with the control group (47.3% versus 25.7%, $P<0.01$).

An additional questionnaire was administered to the last 26 patients randomized to the intervention and 27 patients randomized to the control to address concerns of bias. Five patients receiving the additional questionnaire in the intervention group reported influence regarding the selection of the vascular access site (2 from their general cardiologist and 3 from family/friends). Nine patients receiving the additional questionnaire in the control reported influence regarding the selection of the vascular access site (4 from their general cardiologist, 3 from family/friends, 1 from a nurse, and 1 from the Internet).

Discussion

This study is novel for 3 key reasons. First, the concept and evaluation of formally involving patients in the healthcare decision regarding vascular access for CA procedures has never been reported. Second, this study supports that a vascular access PtDA for eligible patients undergoing CA procedures is not only feasible but reduces decisional conflict and improves the patients' knowledge and value congruence with their healthcare options, without affecting procedural success or complications. Finally, this PtDA was introduced to eligible patients during the same hospital visit for their CA procedure. The implementation of this PtDA did not negatively impact the flow of patients or procedures in this tertiary care cardiac center.

This study suggests the improvement in the process of decision-making regarding vascular access for CA procedures using a PtDA, as the unadjusted DCS is lower in the intervention group compared with control. Decisional conflict can significantly increase the probability of a patient to change his or her mind, delay decision-making, increase patient regret, and decrease patient performance on knowledge tests. Finally, decisional conflict can increase the likelihood of patients to blame their physician for bad outcomes.^{16,17}

Adjusted analysis, accounting for significant differences in baseline characteristics between the 2 groups, demonstrate that the vascular access PtDA no longer significantly predicts the outcome (DCS); however, the reduction in decisional conflict in patients receiving the vascular access PtDA was consistent with trials of other PtDAs.^{15,18} Therefore, its benefits cannot be discounted, but further studies are required.

This study also demonstrates that patients receiving a vascular access PtDA have better knowledge regarding the benefits and risks of each access site than patients exposed to usual care. Given patients who receive the decision aid score better than patients receiving usual care, the vascular access PtDA could be a means to supplement the pre-CA consultation and consent process.¹⁹

PtDAs have been demonstrated to improve the match between values and choice, as compared with usual care.⁹ It must be understood that value congruence is only important if patients understand the risks and benefits of each option, and they are, thus, making an informed values-based decision. Patients receiving the PtDA had a significantly better match between informed values and vascular access received as compared with the control group.

Although this study was not powered to demonstrate a difference in procedural characteristics and vascular access complications between the 2 groups, no significant differences or signals were noted.

PtDAs have been demonstrated to impact unwarranted practice variation for discretionary surgeries in previous studies.⁹ Although this study failed to demonstrate a significant difference in the rates of radial versus femoral access between the 2 groups, the overall rates of radial procedures increased compared with this tertiary care center's usual practice patterns (72% radial in the study cohort versus 41.6% radial access in all patients). This increase in radial access has the potential to decrease the incidence of local vascular access complications and potentially shorten duration of hospital stay, while still actively involving the patients in the decision process.^{1,5,6} Since completion of the study, this vascular access has been successfully implemented into practice in this tertiary cardiac care center.

This PtDA did not include the results of the recently published RIVAL study, as it was not completed before the completion of this vascular access study¹; however, the RIVAL study failed to demonstrate a significant difference between radial and femoral access with respect to the primary outcome of death, myocardial infarction, stroke, or noncoronary artery bypass graft-related major bleeding at 30 days.¹ A lower rate of local vascular complications was evident in the radial group, however, this was not inconsistent with a recent meta-analysis that was used to develop the PtDA.^{1,2} Prespecified subgroup analysis of RIVAL study patients with ST-segment-elevation myocardial infarction (STEMI) suggested that the radial group had a significant reduction in the primary outcome¹; however, this result would not alter the application of a vascular access PtDA in real world practice, as patients with STEMI would not be eligible for a PtDA, given the strict time constraints of the procedure. The RIVAL trial did demonstrate that the radial approach was preferred by pa-

tients for subsequent procedures. Future iterations of a vascular access PTDA could incorporate this information. Even when the results of the RIVAL study are considered, vascular access in CA procedures can still be considered a preference-sensitive medical decision. This vascular access PtDA and its content are not perfect nor are they fixed, but, despite these limitations, they provide a vehicle for discussion to involve the patient in this preference-sensitive decision process.

Limitations

Although this paper presents a novel approach to include patients in the decision process regarding vascular access for CA procedures, it also has several limitations to consider. First, healthcare worker bias has been raised as a potential limitation of this study. Although in-services educating both nurses and cardiologists, with respect to the impact of their personal opinions on the selection of vascular access, were conducted, this bias could not be completely removed from the study environment. To further address the issue of bias, a questionnaire was administered to the last third of patients randomized to the intervention and control groups. The results of this questionnaire demonstrate that, of the 20% to 30% of patients who were exposed to external influences regarding their options for vascular access, the majority of this influence did not come from nurses or physicians working in the tertiary care center.

Second, only 17.2% of the 874 patients screened for eligibility provided informed consent. Although this recruitment percentage seems low, it does not reflect the generalizability of this PtDA in everyday practice. Patient eligibility for this trial was more conservative than real world practice, as we deemed all patients with a prior CA procedure (36% of screened patients) to be ineligible for study participation in order to reduce the bias of a prior access site. Furthermore, only 129 patients (14.8% of all those screened) were deemed ineligible for both access sites, per their treating physician. Therefore, based on the screening at the tertiary care center, >60% of patients presenting for a CA procedure would be eligible to receive a vascular access PtDA.

Third, the use of this PtDA is restricted to patients of cardiologists who can competently perform CA procedures from both the radial and femoral approaches. Previously, the femoral artery approach was generally considered the access site of choice in 90% of cases worldwide²⁰; however, with surmounting evidence demonstrating the benefits of the radial approach, more centers are making available this access for CA procedures. Recent editorials highlight "the requirement for operators to employ both (access sites) and an obligation of the catheterization laboratory trainers to teach both techniques."²¹ Therefore, with more cardiologists and centers offering both radial and femoral approaches, a vascular access PtDA is highly relevant to the current era of CA procedures.

Conclusion

A vascular access PtDA for eligible patients undergoing CA procedures reduces decisional conflict and improves value congruence and the patients' knowledge of their healthcare

options; however, a multicenter study, powered to confirm these benefits and evaluate differences in procedural success or complications, are required. The vascular access PtDA would be a useful addition to any cardiac center that has invasive and interventional cardiologists proficient in both access sites to ensure an informed consent process for patient-centered care. Given increasing pressures to actively involve patients in their healthcare decisions, an evidence-based vascular access PtDA would be an essential tool for translating evidence to enable safe and effective patient involvement.

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Disclosures

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References

- Jolly SS, Yusuf S, Cairns J, Niemela K, Xavier D, Widimsky P, Budaj A, Niemela M, Valentin V, Lewis BS, Avezum A, Steg PG, Rao SV, Gao P, Afzal R, Joyner CD, Chrolavicius S, Mehta SR. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. *Lancet*. 2011;377:1409–1420.
- Jolly SS, Amlani S, Hamon M, Yusuf S, Mehta SR. Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: a systematic review and meta-analysis of randomized trials. *Am Heart J*. 2009;157:132–140.
- Wennberg JE. Unwarranted variations in healthcare delivery: implications for academic medical centres. *BMJ*. 2002;325:961–964.
- Agostoni P, Biondi-Zoccai GG, de Benedictis ML. Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures: systematic overview and meta-analysis of randomized trials. *J Am Coll Cardiol*. 2004;44:349–356.
- Bertrand OF, Rodés-Cabau J, Larose E, Nguyen CM, Roy L, Dety JP, Courtis J, Nault I, Poirier P, Costerousse O, De Larochelliere R. One-year clinical outcome after abciximab bolus-only compared with abciximab bolus and 12-hour infusion in the Randomized EARly Discharge after Transradial Stenting of Coronary Arteries (EASY) Study. *Am Heart J*. 2008;156:135–140.
- Ziakas A, Klinke B, Fretz E. Same-day discharge is preferred by the majority of the patients undergoing radial PCI. *J Invasive Cardiol*. 2004;16:562–565.
- Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? *Soc Sci Med*. 1997;44:681–692.
- The Patient Protection and Affordable Care Act. *Public Law* 111–148. March 23, 2010.
- O'Connor AM, Bennett C, Stacey D, Barry MJ, Col NF, Eden KB, Entwistle V, Fiset V, Holmes-Rovner M, Khangura S, Llewellyn-Thomas H, Rovner DR. Do patient decision aids meet effectiveness criteria of the International Patient Decision Aid Standards and Collaboration? A systematic review and meta-analysis. *Med Decis Making*. 2007;27:554–574.
- O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15:25–30.
- O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, McPherson R, Bunn H, Graham I, Drake E. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Couns*. 1998;33:267–279.
- Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thomson R, Barratt A, Barry M, Bernstein S, Butow P, Clarke A, Entwistle V, Feldman-Stewart D, Holmes-Rovner M, Llewellyn-Thomas H, Mournjid N, Mulley A, Ruland C, Sepucha K, Sykes A, Whelan T. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333:417–422.
- Schwalm JD, Raco M, Velianou JL, Natarajan MK. Letting patients decide: a vascular access decision aid feasibility trial. *Catheter Cardiovasc Interv*. 2010;75(S2).
- Ottawa Health Decision Centre. Evaluation measures of patient decision support. November 20, 2009. <http://decisionaid.ohri.ca/eval.html>.
- O'Connor AM, Bennett CL, Stacey D, Barry M, Col NF, Eden KB, Entwistle VA, Fiset V, Holmes-Rovner M, Khangura S, Llewellyn-Thomas H, Rovner D. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2009;8:CD001431.
- Gattellari M, Ward JE. Will men attribute fault to their GP for adverse effects arising from controversial screening tests? An Australian study using scenarios about PSA screening. *J Med Screen*. 2004;11:165–169.
- O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, McPherson R, Drake E, Hopman W, Mackenzie T. Randomized trial of a portable, self-administered decision aid for postmenopausal women considering long-term preventive hormone therapy. *Med Decis Making*. 1998;18:295–303.
- Stacey D, Bennett CL, Barry MJ, Col NF, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Légaré F, Thomson R. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2011;CD001431.
- Brehaut JC, Fergusson DA, Kimmelman J, Shojania KG, Saginur R, Elwyn G. Using decision aids may improve informed consent for research. *Contemp Clin Trials*. 2010;31:218–220.
- Hamon M, Mehta S, Steg PG, Faxon D, Kerkar P, Rupprecht HJ, Tanguay JF, Afzal R, Yusuf S. Impact of transradial and transfemoral coronary interventions on bleeding and net adverse clinical events in acute coronary syndromes. *EuroIntervention*. 2011;7:91–97.
- Kerns MJ. Cardiac Catheterization on the Road Less Traveled: Navigating the Radial Versus Femoral Debate. *JACC Cardiovasc Interv*. 2009;2:1055–1056.