

Patient Preference for Radial versus Femoral Vascular Access for Elective Coronary Procedures: The PREVAS Study

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Objectives: To explore patient preference for vascular access site in percutaneous coronary procedures, the perceived importance of benefits and risks of transradial access (TRA) and transfemoral access (TFA) were assessed. In addition, direct preference for vascular access and preference for shared decision making (SDM) were evaluated. **Background:** TRA has gained significant ground on TFA during the last decades. Surveys on patient preference have mostly been performed in dedicated TRA trials. **Methods:** In the PREVAS study (Clinicaltrials.gov: NCT02625493) a stated preference elicitation method best-worst scaling (BWS) was used to determine patient preference for six treatment attributes: bleeding, switch of access-site, postprocedural vessel quality, mobilization and comfort, and over-night stay. Based on software-generated treatment scenarios, 142 patients indicated which characteristics they perceived most and least important in treatment choice. Best-minus-Worst scores and attribute importance were calculated. **Results:** Bleeding risk was considered most important (attribute importance 31.3%), followed by length of hospitalization (22.6%), and mobilization (20.2%). Most patients preferred the approach of their current procedure (85.9%); however, 71.1% of patients with experience with both access routes favored TRA ($P < 0.001$). Most patients (38.0%) appreciated SDM, balanced between patient and cardiologist. **Conclusions:** Patients appreciate lower bleeding risk and early ambulation, factors favoring TRA. Previous experience with a single access route has a major impact on preference, while experience with both routes generally resulted in preference for TRA. Most patients prefer balanced SDM. © 2017 The Authors Catheterization and Cardiovascular Interventions Published by Wiley Periodicals, Inc.

Key words: catheterization; patient preference; medical decision making; transradial access; transfemoral access

INTRODUCTION

During the last decades, transfemoral access (TFA) has been the predominant access route for coronary angiography and percutaneous coronary intervention

(PCI) [1–3]. Recently, there has been a substantial shift toward transradial access (TRA), which reduces entry site bleeding and adverse clinical outcome, in particular in patients treated for acute coronary syndromes [4–7]. While TRA is related to lower bleeding risk, it

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is associated with limitations such as the sometimes more difficult intubation of the guiding catheter, limited back-up of guiding catheters in challenging anatomies, higher incidence of switching to another access route, and a higher risk of vascular occlusion at the access site [1,8,9].

In clinical practice, the choice of the primary access route is a decision sensitive to preference, and frequently made solely by the interventional cardiologist, who considers clinical guidelines, personal experience, and characteristics of the individual patient (i.e., obesity; peripheral artery disease; arterial pulsation; collateral perfusion) [9–12]. Nevertheless, patients may rate the benefits and risks of the different access routes differently [13,14]. In an era of patient-centred care with a trend toward shared decision making (SDM), a more systematic involvement of the patient's values and preferences in the choice of vascular access is desirable, but so far data on SDM in interventional cardiology are scarce [15].

Previous studies focused more on technical and clinical perspectives of TRA versus TFA. Meanwhile, surveys on patient satisfaction have mostly been performed in participants of dedicated TRA trials or in patients of centres that are known for performing most coronary interventions via TRA [16], which might have had an impact on the results that suggested a broad patient preference for TRA. Therefore, in the present study, in patients who had undergone routine elective coronary angiography or PCI, we used established statistical instruments for the assessment of patient preference to evaluate: (1) the preference for specific treatment characteristics (i.e., importance of risks and benefits) with regard to vascular access; (2) the direct patient preference for TRA or TFA; and (3) the valuation of participation in decision making on the choice of vascular access together with the interventional cardiologist.

MATERIAL AND METHODS

Study Population

We performed a patient preference study on vascular access (PREVAS) in a consecutive series of patients who, between June and August 2014, underwent elective coronary procedures at Thoraxcentrum Twente, a tertiary PCI centre with wide use of both TRA and TFA. After the intervention, patients were invited to participate. During the study period, 240 patients underwent elective coronary procedures, of which 22 were not eligible due to limited knowledge of the Dutch language or low literacy, and another 15 patients were not approached for logistic reasons. Of the 203 eligible patients, 153 indicated they were willing to participate in the study and to

deliver the questionnaire prior to discharge; 142 (92.8%) of these patients returned a correctly filled in questionnaire prior to discharge. A total of five of all 203 (2.5%) patients refused study participation. Another 45 patients indicated that they wanted to use a postal return option but the vast majority did not return a correctly filled in questionnaire, which was interpreted as a concealed refusal to participate. Therefore, the PREVAS study team unanimously decided to perform the final analysis on data from the 142 patients (70.0% of all 203 eligible patients), who had returned the questionnaires prior to discharge from the ward.

The PREVAS study complied with the Declaration of Helsinki and was approved by the institutional review board. The medical ethical committee Twente approved the final design of the PREVAS questionnaire. According to Dutch law, it was not required to obtain a written informed consent; patients indicated by returning the filled-in questionnaire that they agreed with the use of anonymous data for the research purposes of the PREVAS study.

Procedural Details

By standard protocol in this centre all patients treated via TFA received a collagen-based vascular closure device. TFA patients were instructed to stay in bed for 4 hr after a diagnostic coronary angiography and for the duration of 6 hr after a PCI procedure. All patients treated via TRA received a dedicated radial pressure device (Radistop). Following TRA procedures, patients were free to walk around in the ward and were not obliged to stay in bed. The length of hospital stay was determined by the treating physician and dependent on several factors including length and type of procedure, comorbidities and possible complications. All procedures were carried out by experienced interventional cardiologists in both the radial and femoral approach (each operator had a total experience of >1,000 PCI procedures).

Patient Preference Questionnaire

The patient preference questionnaire (PPQ) was designed by the PREVAS study team and consisted of questions on: patient baseline characteristics; preference for specific treatment characteristics (ranking of risks and benefits) with regard to vascular access; direct patient preference for TRA or TFA; and the valuation of participation in decision making on the choice of vascular access with the interventional cardiologist (i.e., decision ownership). Methodological and clinical experts from the PREVAS study team validated the content and construct of the questionnaire that was first pilot-tested in 10 subjects. An independent

research assistant informed all patients included in this study by use of a standardized text. The text was generated by the study committee, which comprised an interventional cardiologist, a methodologist, and research nurses. The research assistant followed careful instructions and a script to make the manner as standardized as possible.

Assessment of preference for specific treatment characteristics. The characteristics of TRA and TFA relevant to the patients were identified from literature, clinical guidelines, and consultation of expert clinicians. The method of best-worst scaling [17] (BWS) was used to assess patient preference for specific treatment characteristics, which will be addressed as “attributes.” These attributes comprised: risk of periprocedural bleeding with or without need for transfusion; risk of switching access site during the same procedure; need for choosing another access site for the next procedure; need for overnight stay; postprocedural comfort; and postprocedural mobilization. To construct treatment scenarios, two or three levels were assigned to each attribute, which described the variation in possible outcomes, depending on the choice of access route. The full factorial design generated all 216 possible combinations of attributes and levels. Then the fractional design selected a subset of these scenarios, based on balancing the opportunity for attribute selection and each attribute level appearing an equal number of times; a fractional set of 32 scenarios was designed, and distributed over four different versions of the questionnaire.

Eight hypothetical treatment scenarios were presented to each patient; for each scenario patients were asked to indicate the best (most desirable) and worst (least desirable) characteristic of the procedure (Supporting Information). The scenarios were unlabelled, meaning that it was not explicitly mentioned to the patients whether the scenario presented concerned TRA or TFA.

Assessment of direct preference. To assess direct patient preference for vascular access, patients were first informed that the TFA and TRA are effective and safe access routes, and a detailed overview with characteristics of both access routes was presented. Patients were then asked to indicate which of the two access routes they preferred.

Assessment of valuation of participation in decision making. Patients were asked about the perceived and desired decisional power in the choice for vascular access. Patient could choose the current decision maker and desired decision maker, using a 5-option answer scale ranging from “only the cardiologist” to “only me.”

STATISTICS

Data were reported as frequencies and percentages for dichotomous and categorical variables. Continuous variables were expressed as mean \pm standard deviation (SD). Data analysis was performed using IBM SPSS 20.0 and StataCorp STATA 13. Descriptive analyses and nonparametric Chi-square tests were used to evaluate the direct choice for vascular access, the relation between preference and baseline characteristics, and relationship between stated preferences for vascular access route and history of previous procedures. *P*-values < 0.05 were considered statistically significant. For the BWS survey, a scatterplot showed the distribution of best and worst counts for the attributes of access routes. The mean best-minus-worst score was estimated, to account for the total number of times an attribute was shown in the survey and could be chosen by a respondent. This mean score can range from -1 (always chosen as worst) to $+1$ (always chosen as best). If the mean score approaches zero, this can either mean that the level was often not chosen by patients or the patients as a group were indifferent (about as many patients chose it as the best or the worst). Best-minus-worst scores determine the part-worth utility of the attribute levels, while the normalized within attribute level difference was used to estimate attribute importance. Conditional logit analysis was used to determine the relative preference for each attribute level; a high positive coefficient indicates that the attribute was more often chosen as best rather than worst.

RESULTS

Characteristics of the Study Population

Among the 142 patients were 100 (70.4%) men and 42 (29.6%) women, with a mean age of 64.1 ± 9.6 years (Table I). More than half of the patients ($n = 81$, 57.0%) indicated that they had experience with at least one previous coronary procedure (prior to the current procedure): 71 of these patients had experience with TFA only, 1 with TRA only, and 9 with both TRA and TFA. The current procedure was performed in 51 (35.9%) patients via TRA and in 89 (62.7%) via TFA; cross-over from TRA to TFA was required in 2 (1.4%) patients. Based on previous and current procedures, 38 patients (26.8%) in the study population had experience with both vascular access routes. Eligible patients who did not participate in the present study showed no significant difference in age, gender, procedure type, or vascular access route as compared to the study population.

Most and Least Preferred Characteristics of Treatment

As shown in Fig. 1, major bleeding (coded as E-L3) was perceived as the worst possible outcome of the

TABLE I. Characteristics of the Patient Population

	Total <i>n</i> = 142	TRA <i>n</i> = 51	TFA <i>n</i> = 91
Patient characteristics			
Age (years)	64.1 ± 9.6	63.0 ± 9.7	64.8 ± 9.5
Men	100 (70.4)	39 (76.5)	61 (67.0)
Nationality			
Dutch	134 (94.4)	47 (92.2)	87 (95.6)
Foreign	8 (5.6)	4 (7.8)	4 (4.4)
Educational level ^a			
Low	61 (43.9)	23 (45.1)	38 (41.8)
Middle high	51 (36.4)	17 (33.3)	34 (37.4)
High	28 (19.7)	11 (21.6)	17 (19.1)
Hypertension ^a	49 (34.8)	17 (33.3)	32 (35.6)
Diabetes mellitus	33 (23.2)	14 (27.5)	19 (21.1)
GFR (mL/min/1.73 m ²)	74.3 ± 17.3	74.4 ± 15.0	74.2 ± 18.6
Previous myocardial infarction	43 (30.3)	17 (33.3)	26 (28.9)
Previous CABG	16 (11.3)	1 (2.0)	15 (16.7)
Procedural characteristics			
Baseline procedure			
Angiography	80 (56.3)	30 (58.8)	50 (54.9)
Percutaneous coronary intervention	62 (43.7)	21 (41.2)	41 (45.1)
Current vascular access route			
TRA, primary approach	51 (35.9)	51 (100)	0 (0)
TFA, primary approach	89 (62.7)	0 (0)	89 (97.8)
TFA, crossover after TRA failure	2 (1.4)		2 (2.2)
Previous experience			
With TRA	81 (57.7)	31 (60.8)	50 (54.9)
With TFA	1 (0.7)	0 (0)	1 (1.1)
With TFA	71 (50.0)	26 (51)	45 (49.5)
With TRA and TFA	9 (6.3)	5 (9.8)	4 (4.4)
Total experience with TFA and TRA ^b	38 (26.8)	31 (60.8)	7 (7.7)
Length of hospital stay			
<24 hr	75 (53.2)	31 (60.8)	44 (48.9)
≥24 hr	66 (46.8)	20 (39.2)	46 (51.1)
Bleeding of puncture site	5 (3.5)	1 (2.0)	4 (4.4)

Data are *n*(%) or mean ± SD.

^aData available of 141/142 patients.

^bBased on previous and current procedure. There was only a statistically significance found on previous CABG between the TRA and TFA group ($P = 0.008$) and between total experience with TFA and TRA ($P < 0.001$). CABG = coronary artery bypass grafting; GFR = glomerular filtration rate; TFA = transfemoral access; TRA = transradial access.

procedure by all patients: it has the highest score on worst outcome (*y*-axis) and the lowest score on best outcome of treatment (*x*-axis). A procedure performed in day care (coded A-L1) was perceived as the best possible outcome of treatment. In Fig. 1, characteristics of treatment that are either close to the *x* or close to the *y*-axis were perceived similarly by all patients; in contrast, levels located in the middle were perceived differently. An example of the latter is overnight hospital stay (coded A-L2), which was perceived equally often as being desirable and undesirable. Figure 2 shows the relative preference for each attribute level; a high positive coefficient indicates that the attribute was more often chosen as best rather than worst

The relative importance of characteristics of treatment were: risk of periprocedural bleeding (31.3%); length of hospital stay (22.6%); postprocedural mobilization (20.2%); risk of switch in access site (17.9%);

and need to change access site for next procedure (7.7%; Fig. 1B). Age or educational levels did not have an impact on attribute importance. Men considered bleeding risk to be the most important characteristic of treatment, while women considered the risk of a switch in access site during the procedure to be most important, followed by bleeding risk.

Direct Preference for Vascular Access

When directly asked, slightly more patients preferred TFA ($n = 86, 60.6%$). Preference for TFA was stronger in women (76.2% vs. 54.0%, $P = 0.014$). The majority of patients preferred the access route that they experienced during the current procedure ($n = 122, 85.9%$). Of the 38 patients with experience in both vascular access routes, the vast majority ($n = 27, 71.1%$) preferred TRA over TFA (28.9%, $P < 0.001$).

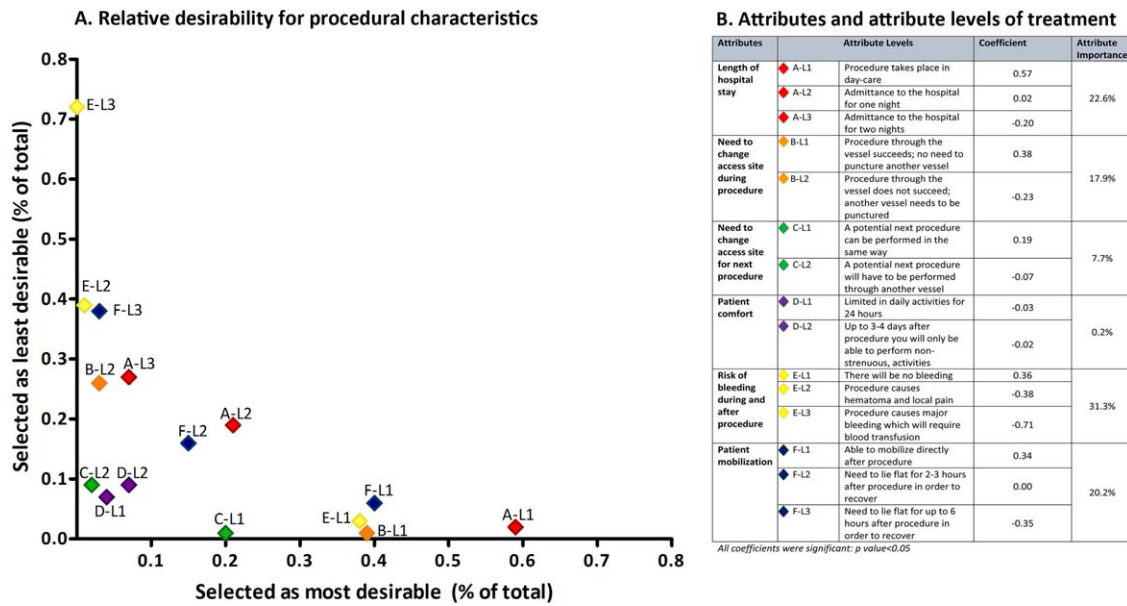


Fig. 1. A: Relative desirability for procedural characteristics. Characteristics of treatment that are either close to the x or close to the y-axis were perceived similarly by all patients; in contrast, levels located in the middle were perceived differently. B: Attributes and attribute levels of treatment. Definitions of the individual labels. [Color figure can be viewed at wileyonlinelibrary.com]

Decisional Power

When patients were asked who decided on the access route in their current coronary procedure, almost two-thirds of the patients indicated that the decision was made either by the cardiologist alone (n = 49, 34.5%) or mainly by the cardiologist in consultation with them (n = 42, 29.6%; Fig. 3). When asked about the desired decision owner, fewer patients indicated that the cardiologist should make the decision alone (n = 30, 21.1%) while more patients indicated that the cardiologist should consult the patient (n = 54, 38.0%) or take the decision together with the patient as equal partners (n = 54, 38.0%; Fig. 3). During the current procedure, one in four patients received less decisional power than desired, while one in nine patients received more decisional power than desired.

DISCUSSION

Main Findings of This Study

The present study in patients who underwent elective diagnostic or therapeutic coronary procedures is the first to examine patient preference for vascular access by use of a stated preference elicitation method (BWS). Patients showed a significant preference for the individual characteristics of TRA, such as low bleeding risk and early ambulation. However, when given the direct choice between TRA and TFA, patients more often preferred TFA. This is

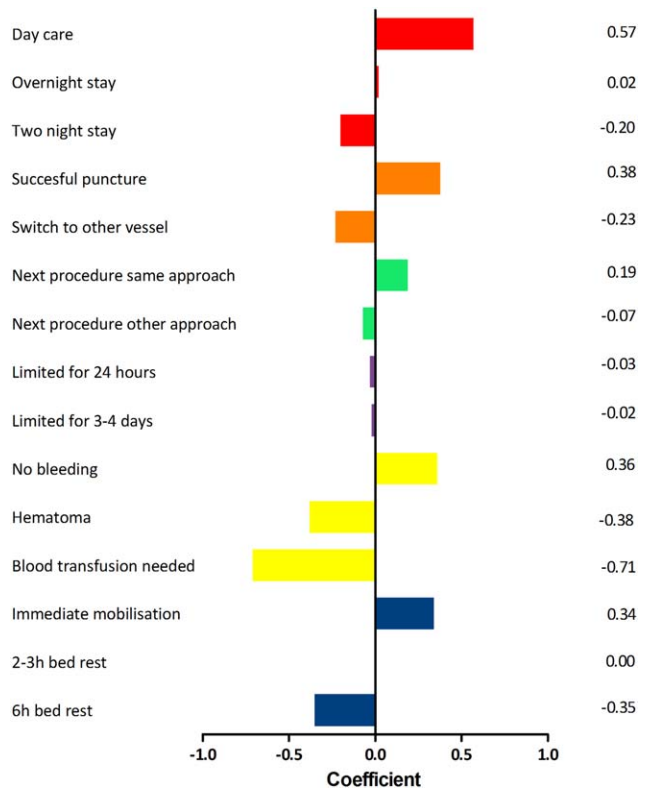


Fig. 2. Conditional logistic regression of attributes. A high positive coefficient indicates that the attribute was more often chosen as best rather than worst, and thus likely to be preferred relative to other combinations of attributes. [Color figure can be viewed at wileyonlinelibrary.com]

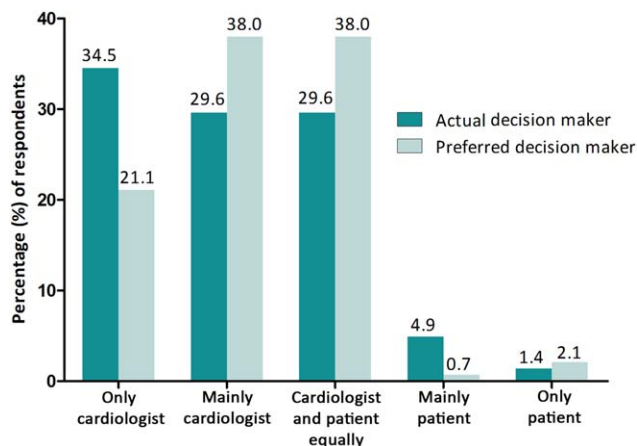


Fig. 3. Actual and preferred decision maker. The actual decision maker in the current procedure is depicted by dark bars; the desired decision maker is depicted by light bars. [Color figure can be viewed at wileyonlinelibrary.com]

most likely the result of the patient's personal experience with an access route, as in the present study 86% of all patients indicated preference for the same access route as used during their current procedure. While experience appears to greatly influence the preference of patients with personal knowledge of a single route of vascular access, patients with experience in both TRA and TFA preferred TRA over TFA significantly more often (71.1% vs. 28.9%, $P < 0.001$). The group with broader experience in vascular access options should be able to provide the most well-founded preference. Finally, the vast majority of patients appreciated SDM on vascular access, which for most patients should ideally be balanced between patient and cardiologist. Nevertheless, a minority of patients favored a decisive attitude of the cardiologist and not being involved in the decision-making process.

Previous Preference Studies

Research that previously demonstrated a preference for TRA was very often performed at interventional centres that are publicly known to prefer and promote procedures via TRA, and/or were primarily designed to assess the potential advantage of TRA [16,18,19]. However, in a study in which patients were randomly assigned to TRA or TFA, most patients in the TRA-group preferred TRA after the procedure, while in patients in the TFA-group postprocedural preference for TRA and TFA was almost evenly distributed [16]. In contrast to previous studies [9,16,18], somewhat more of our patients preferred the TFA when directly asked, which most likely reflects personal experience, as the current procedure was performed via TFA in more than 60% of patients.

Previous Safety Studies

Previous studies that compared safety and efficacy of TRA and TFA in both elective patient populations and patients with acute coronary syndromes have demonstrated a reduction in major access site complications, mostly driven by reductions in bleeding [5–7,20,21]. The first reports and observational studies did not suggest a clinical benefit for TRA in terms of major adverse cardiovascular events (MACE), or suggested only a slight potential advantage. However, most of these studies did not have a sufficient sample size to accurately estimate potential effects on death and ischemic outcomes [2,3,22].

The large randomized MATRIX Access trial [19] compared TRA and TFA in patients with acute coronary syndromes and performed an updated meta-analysis, showing that radial access reduces major bleeds, MACE, as well as all-cause mortality, but not myocardial infarction or stroke.

Despite various results that favor TRA and the significant increase of TRA use over time, there is still a wide interhospital and geographical variability in the use of TRA [7]. In the ACUTY trial, which recruited over 10,000 patients from 600 centres in 10 countries, radial access was used in no more than 6.2% of patients [7]. This wide variability in choice of access is explained by several challenges that are still to be met: TRA is technically more demanding and requires a longer learning curve from the operator [8,19,20,23,24]. Nevertheless, TRA procedures performed by experienced operators are believed to outweigh these disadvantages and should become the default for patients undergoing invasive diagnostic assessment or treatment [19,25].

Factors Underlying Patient Preference of Vascular Access

The results of our present study identify the factors that underlie the patient preference. We measured patient appreciation for or aversion toward specific treatment attributes, such as characteristics of procedural risks and benefits. Importantly, this assessment was performed without telling the patient to which approach of vascular access the individual characteristics could be attributed.

An important attribute to patients was the length of hospital stay. However, there was considerable disagreement among patients about the desirable length of stay: while a procedure performed in day-care was among the most preferred, confirming the results of previous studies [26,27], equal numbers of patients perceived an overnight stay after the procedure as either most desirable or least desirable. We can only hypothesize that elderly patients might prefer the overnight stay, as this patient group is known to more often have

difficulty in coping with postprocedural stress and lack of adequate help at home [28].

Another important attribute was mobilization, while postprocedural supination up to 6 hr was perceived undesirable. Previous studies also indicated the importance of a rapid postprocedural mobilization to patients who preferred the TRA [1,9].

If patients desire more involvement in the process of decision making, as indicated by our present study, the use of a patient decision aid for vascular access can help tremendously in reducing decisional conflict, improving patient knowledge on procedural options, and improving the value agreement between the desired and actually chosen approach [13].

Limitations

We recognize that the present study has limitations. The questionnaire was somewhat complex for certain patients. Difficulties with understanding the instructions were generally resolved by additional verbal explanation by a dedicated research nurse. Due to the laborious nature of the present study, we had to limit the number of study participants. Nevertheless, the participation rate in this survey was high, as our study population represented 70% of all eligible patients. Future studies using a simplified stated-preference technique in larger patient populations may be of value. In the present study a significant share of the procedures were performed via TFA, while in current practice the number of radial procedures has increased significantly, resulting in more patients having experience with TRA, or both TFA and TRA.

Implications

The findings of the present study imply that patients tend to choose the procedure they are familiar with, but in fact may appreciate individual aspects of another procedure when being presented to them in a more factual way. More research is recommended to further investigate potential unidentified treatment attributes. With these attributes, a preference-elicitation instrument could be developed to measure stated preferences for vascular access. In addition, a patient decision aid, as previously suggested in other studies, might be a helpful tool in incorporating patients' preferences and opinions in the process of decision making [13,25]. Currently, there is an increasing interest in patient preference and self-reported outcomes [28–30] Future research should also focus on the readiness and willingness of patients to take responsibility in decision making. Finally, in clinical practice it is important for clinicians to realize that a small but considerable proportion of patients do not appreciate being involved in

the process of decision making. In addition, many of our patients prefer TRA when familiar with both TRA and TFA.

CONCLUSIONS

Patients appreciate lower bleeding risk and early ambulation, factors that favor TRA procedures. Previous experience with one vascular route has a major impact on direct patient preference, but experience with both TRA and TFA often results in a preference for TRA. Most patients appreciate SDM on vascular access, which for the majority should be balanced between patient and cardiologist.

Impact on Daily Practice

The results of this study support a more patient-centred approach toward the choice of vascular access for percutaneous coronary procedures. If patients have experience with only one of the two vascular access routes, particular attention should be paid to providing detailed information on the alternative route. This is important, as patients otherwise tend to choose the route that is familiar to them, even if it may not reflect their general treatment preferences (e.g., low bleeding risk or early ambulation). Information on existing preferences and perspectives of individual patients may help to balance SDM.

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