

Shared Decision-Making in Femoral Versus Radial Cardiac Catheterization



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Shared decision-making is a strategy to assist with patient involvement in medical decisions. One of its pillars is patient knowledge and understanding of the risks and benefits associated with specific procedures. We studied patient knowledge about transradial (TRA) and transfemoral (TFA) cardiac catheterization. A prospective study was conducted in 100 patients hospitalized following diagnostic and therapeutic cardiac catheterization—TRA in 71% of patients and remaining TFA. All patients were presented a standard balanced informed consent outlining risks and benefits. Following catheterization, patients were verbally administered an 11-item open-ended questionnaire to assess knowledge of cardiac catheterization and the associated risks and benefits. A patient knowledge index (PKI) was developed with 1 point given for: identifying the procedure; correctly describing the procedure; identifying at least 1 risk of TRA; and/or TFA; and at least 1 benefit of TRA; and/or TFA. Maximum PKI score was 6. The mean PKI score was 2.6 ± 1.1 . A PKI score ≥ 4 was observed in 21% of patients with only 1 patient obtaining the maximum 6 points. Over 80% of patients were unable to recall procedure risks provided at the time of informed consent. The majority of patients were unable to discriminate between TRA and TFA risks and benefits, PKI 2.52 versus 2.60, respectively ($p = 0.718$). On multivariate analysis, higher education levels were correlated with increased PKI scores (odds ratio = 0.65, $p = 0.014$) whereas black race was associated with lower PKI scores (odds ratio = -0.48 , $p = 0.045$). In conclusion, patient retention of information from the informed consent was low. The majority of patients had no preference or deferred to their physician's expertise when deciding TRA compared with TFA. This study identifies challenges with implementing shared decision-making and the need for improved patient education and involvement regarding cardiac catheterization. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:190–194)

During the past decade, there has been a steady increase in the transradial approach (TRA) for cardiac catheterization.^{1,2} This trend is likely attributed to the decrease in access site complications and length of stay for TRA, without a corresponding increase in overall major adverse cardiovascular events when compared with the transfemoral approach (TFA).^{3–6} During this time, shared decision-making (SDM) has become a key component of patient-centered health care in which clinicians and patients collaborate to determine the optimal treatment methods for a given condition. With the increase in TRA, the decision of which approach to pursue must be made by the cardiologists and their patients. Traditionally, patients have relied on physicians to make their medical decisions. However, there has been an increasing shift away from this “paternalistic” model of patient care and toward a

“patient-centered” model, of which informed consent and SDM are the cornerstones.⁷ For SDM to occur, both the physician and the patient must weigh the advantages and disadvantages of each option from their respective perspectives. Physicians generally make decisions based on documented risks and benefits published in the literature, but there are real-world barriers that patients' experience that inform their own preferences and decisions.⁸ Further, SDM assumes a process of deliberation, where, before deciding, the patients weigh pros and cons whereas processing them both cognitively and emotionally.⁹ Currently, there is a lack of evidence on the extent to which patients who chose TRA or TFA in cardiac catheterization made an informed decision. The aim of this study is to examine SDM between physicians and patients when choosing TRA versus TFA in cardiac catheterization.

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See page 194 for disclosure information.

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Methods

We performed a prospective study from November 2017 to September 2018 at a large, urban tertiary academic medical center, where interventional cardiologists default to TRA as the access for cardiac catheterization. All English-speaking patients ages 18 years or older following catheterization either through the TRA or TFA who could provide written and verbal consent were included in the study.

With approval from the Institutional Review Board, we approached 113 patients and recruited 100 patients (88.5% response rate) who met the inclusion criteria and had recently (within 48 hours) underwent a diagnostic or interventional catheterization through the TRA or TFA.

Before undergoing cardiac catheterization, patients underwent the standard informed consent protocol with the cardiology fellows and attending physicians performing their procedures. This included a discussion of the procedure components, its risks and benefits, alternative options, and the risks of not performing the procedure. Following their catheterization and when the effects of any moderate sedation had worn off, patients were formally consented and enrolled in the study. A self-designed 11-item open-ended questionnaire was then verbally administered to assess the patient's knowledge of cardiac catheterization and the risks and benefits of TRA versus TFA. The questionnaire additionally assessed each patient's perceived involvement in deciding between TRA and TFA, as well as their preferred approach and level of satisfaction with the decision-making process. (Appendix A). The questionnaire was designed based on the CollaboRATE model developed by Glyn Elwyn and peers.¹⁰ Researchers recorded questionnaire responses verbatim, in addition to baseline medical history and cardiovascular risk factors.

Patient responses were coded as "correct," "partially correct," "wrong," or "do not know" by 2 coders. Discrepancies were resolved by consensus among the researchers. The accepted benefits and risks of TRA versus TFA are listed in Appendix B, against which patients' responses were compared. Patients' perceived level of involvement in the decision-making process was additionally assessed using a 10-point scale, with 1 representing no involvement and 10 representing maximum involvement. Patients' responses were analyzed for common themes regarding their answers to perceived involvement in the medical decision-making process and reasons for preferring TRA or TFA.

To assess a patient's decision-making, we emphasized the deliberation process by developing a patient knowledge index (PKI) score with 1 point given for each of the following: identifying the procedure; correctly describing the procedure; identifying at least 1 risk factor of TRA; and/or TFA; and at least 1 benefit of TRA; and/or TFA. The maximum PKI score was 6. Each response was given a full weighting of either 1 point or 0 points. Data were then summed among the 6 categories to yield an overall PKI score for each patient in the study.

The relation between various categories was assessed including Benefit to Own Procedure compared with Benefit to Other Procedure, Benefit to Own Procedure compared with Risk of Own Procedure, Benefit to Other Procedure compared with Risk of Other Procedure, and Risk of Own Procedure compared with Risk of Other Procedure. Corresponding *p* values were calculated for each of the 4 aforementioned comparisons. Univariate analysis was performed to summarize patient data. Continuous data are presented as a mean \pm SD and categorical variables are presented as a percent of total. *t* Tests were used to compare the aforementioned relations. All tests were 2-tailed, and a *p* value of <0.05 was considered significant

for all tests. To explore influence of patient and procedural factors on PKI, multivariate linear regression analyses using the least square estimation method were performed. The following covariates were included in the regression analysis—age, gender, race, education level, smoking history, hypertension, hyperlipidemia, past myocardial infarction, congestive heart failure, diabetes mellitus, previous percutaneous coronary intervention (PCI), previous coronary artery bypass grafting, hemodialysis, and patient preference.

Results

There were 100 patients who completed the study. The most common indication for receiving cardiac catheterization was unstable angina (32%). The majority (84.0%) of patients were able to correctly describe the purpose of their catheterization and 82.0% of patients underwent a TRAK. TRA was the preferred approach in 43% of patients whereas only 8% preferred TFA. Half the interviewed patients (49%) deferred access choice to the physician's decision or had no preference.

Baseline patient demographics are shown in Table 1. The majority of patients enrolled in the study were minorities (70%) and less than a quarter (23%) had received higher education training. The leading cardiovascular risk factor was hypertension followed by hyperlipidemia, diabetes mellitus, and smoking history.

The vast majority of patients (99%) knew the name of the procedure they had, and the purpose of their procedure (84%). However, patients' knowledge of the risks and benefits of the TRA or TFA approach were low. There were no significant differences between PKI scores amongst TRA and TFA (Table 2). The average PKI score was 2.6 ± 1.1 . Over 80% of patients were unable to recall procedure risks for either TRA or TFA provided at the time of informed consent (Figure 1). Only 31.0% of patients accurately described the benefit of the procedure they underwent compared with only 11% of the alternative procedure offered ($p < 0.001$). Understanding of procedure risk was similarly low—15% of patients accurately described the risk of their own procedure as compared with 19% of the other procedure ($p = 0.45$). The majority of patients were unable to

Table 1
Patient demographics (n = 100)

Characteristic	
Age, mean (Years)	57.4
Men	60.0%
Hyperlipidemia	46.0%
Smoker	30.0%
Hypertension	79.0%
Diabetes Mellitus	43.0%
White	30.0%
Black	54.0%
College \geq 4 years	23.0%
Previous PCI	36.0%
Weight, mean (kg)	86.8
Level of involvement	83.0%
Satisfied with level of involvement	96.0%

Table 2
Patient knowledge of TRA or TFA

Characteristic	Mean PKI score		p value
	TRA	TFA	
Overall	2.6	2.6	0.879
Male	2.4	2.6	0.601
Hyperlipidemia	2.6	1.8	0.167
Smoker	2.6	2.2	0.344
Hypertension	2.6	2.5	0.763
Diabetes Mellitus	2.5	2.7	0.779
White	3.1	3.2	0.942
Black	2.4	2.4	0.780
College education ≥ 4 years	3.2	2.8	0.459
Previous Percutaneous coronary intervention	2.7	2.7	0.960

discriminate between TRA and TFA risks and benefits, with corresponding PKI scores of 2.52 versus 2.60, respectively ($p = 0.718$). In multivariate analysis, black race was associated with lower PKI scores (odds ratio -0.48 , $p = 0.045$) whereas higher education level was associated with higher PKI scores (odds ratio 0.65 , $p = 0.014$; Table 3).

Although patients' knowledge of risks and benefits was low, 96% of patients still responded "Yes" to being satisfied with their level of involvement in the decision-making process. Of 10 points, with 10 representing maximum physician-patient collaboration, patients reported an average of 8.3 ± 0.5 . In addition, college-educated and noncollege educated patients reported feeling equally involved in the decision-making process and scored similar PKI scores (3.2 vs 2.8, $p = 0.459$).

Nearly half of all patients had no preference or deferred to their physician for the approach of the procedure. Of the patients that had a preference, 84% of those patients preferred TRA whereas the remaining 16% preferred TFA. There was no significant relation for patient satisfaction between patients that had a preference and those that did not likely due to the high satisfaction rate of the patients in

the study. Likewise, there was no significant relation between patient preference and PKI. Common reasons for TRA or TFA preferences among patients are listed in Table 4.

Discussion

In this prospective, single-center study, we have shown that (1) patient retention of risks and benefits of cardiac catheterization is low, (2) patient satisfaction levels with their involvement in the decision-making process remain high despite the low patient understanding of their procedure, and (3) implementation of SDM in the cardiac catheterization laboratory will require additional efforts.

We found a disconnect between a patient's understanding of the procedure (with its benefits and risks), their perceived level of involvement and their satisfaction with the procedure. Despite the high rates of satisfaction and perceived level of involvement, patients scored low overall in the PKI and had minimal retention of information following the informed consent. Patient knowledge regarding their procedure did not predict their preference for femoral or radial approach. Higher education level was associated with a greater understanding of the procedure whereas black race was associated with a decreased understanding of the procedure. These findings help describe the gap in the implementation of SDM in cardiac catheterization which must include more than medically documented risks and benefits of each procedure but should include a physician-patient conversation using decision-aid tools that are clear and comprehensive regarding their options for cardiac catheterization.^{11,12}

The informed consent process before cardiac catheterization procedures may fall short of effective content and delivery that is perceived as valuable by the patient. Key elements of an informed consent should include the impact of the procedure on the patient's lifestyle with emphasis put on treatment options that align with the patient's values.¹³ The patient's own preferences for PCI approach must be

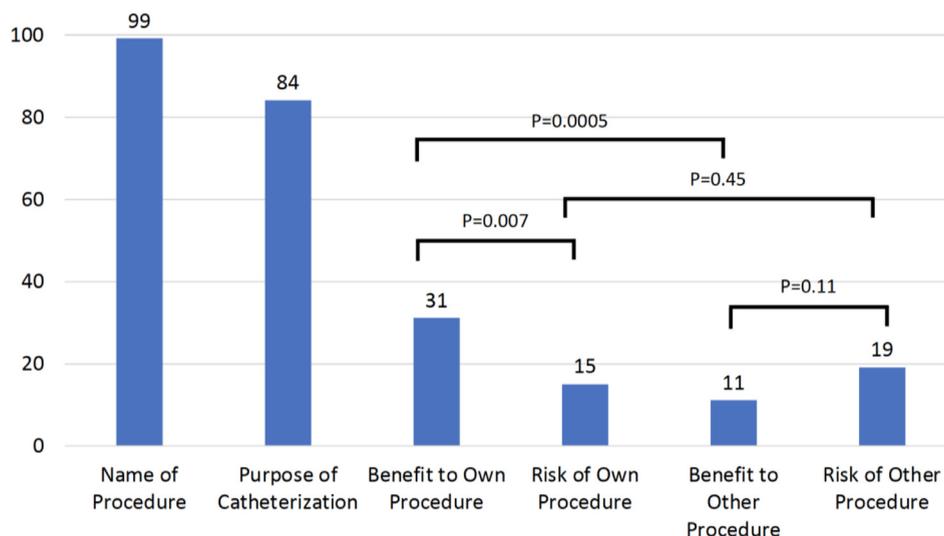


Figure 1. Percentage of patients able to identify key factors related to catheterization procedure.

Table 3
Multivariate regression

Patient characteristics	Estimate	Standard error	p value
Age	0.03	0.01	0.762
Sex	0.24	0.20	0.240
Race			
Black	−0.48	0.23	0.045
Hispanic	−0.54	0.35	0.125
Asian	−1.09	0.61	0.075
Other	−1.67	1.00	0.097
Bachelor's degree or greater	0.65	0.26	0.014
Smoker	−0.10	0.27	0.720
Hypertension	−0.18	0.29	0.539
Hyperlipidemia	−0.10	0.27	0.707
Past myocardial infarction	−0.59	0.36	0.107
Congestive heart failure	0.13	0.31	0.671
Past percutaneous coronary intervention	0.38	0.28	0.176
Past coronary artery bypass grafting	−0.25	0.45	0.584
Dialysis	−0.04	0.25	0.866
Diabetes mellitus	0.09	0.26	0.717

taken into consideration by the physician when discussing the risks and benefits associated with the procedure. An informed consent process that includes the aforementioned will result in greater patient compliance and participation during the decision-making process and the post-procedure follow-up.^{14–16} In cases where patient preference was not adhered to, we found that a clear explanation by the physician for the rationale was adequate to still maintain a high level of perceived patient involvement and overall satisfaction with the procedure. This aligns with findings showing that informational support prevents patients from feeling emotional distress, even when facing medical challenges.¹⁷ Effective involvement of the patient during the consenting process is vital to greater patient compliance and improved understanding of the risks and benefits of the procedure.

In addition to the consenting process, involvement of the patient during the cardiac catheterization procedure has been shown to improve patient understanding of their procedure.¹⁸ Among patients who observed PCI screens during the procedure with their physician's guidance, there was increased personal and treatment control perceptions which were further mediated by positive impacts on self-assessed health, risk perception, and overall health outcome.¹⁸ This evidence suggests that further patient involvement and greater implementation of SDM during cardiac catheterization might improve not just satisfaction, which we found to be already high, but also health outcomes.

Table 4
Common responses by patients

<i>Transradial approach preference reasons</i>	
Location was less sensitive compared with femoral region	
Decreased length of time in hospital	
Faster return to ambulation	
<i>Transfemoral approach preference reasons</i>	
Easier to access in femoral region	

SDM has become increasingly popular in medicine. In 2001, the Institute of Medicine encouraged physicians to collaborate more with patients to improve the quality of patient care. At the same time, it was recognized that some patients may not desire to be as involved in the decision-making process.¹⁹ This aligns with the preferences of our study participants in which roughly half of all participants had no preference regarding which procedure to have, or deferred to their physician's expertise. Multiple studies have found that patients want their physicians to make the final medical decision.^{20–22} Despite this, physicians should provide patients with the necessary information so that they make an informed decision regarding who will have the final medical decision during the procedure.²³

There are at least 2 proposed explanations as to why patients might prefer a more "paternalistic model" of care instead of a more "patient-centered model." With respect to ethnicity, Hispanics and Blacks, when compared with Whites, have been found to prefer leaving medical decision-making up to their physicians.²⁴ This could be explained in part by physicians' beliefs regarding different ethnic group's expectations, interpretation of their symptoms, interpersonal behavior, and the clinical decision-making.²⁵ One study suggested that physicians may engage Black populations less than they would White populations.²⁶ However, even when controlled for socioeconomic status and education, patients of minority racial groups were still more likely to prefer a physician-driven approach to their care, suggesting that cultural preferences may also be a factor.²⁴

One additional factor for influencing decision-making is the overall health of the patient. Previously published data has demonstrated that patients who report that they were in generally excellent health were less likely to defer to the physician in making medical decisions.²⁴ This may be due at least in part why patients who were more ill believed more dependent on their physicians.²⁷ Our data align with these findings as the majority of patients in our study had multiple comorbidities at the time of their procedure.

Whether knowledgeable or not of the risks or benefits of the TRA and the TFA, most patients were satisfied with their level of involvement in the decision-making process. We found that most patients tended to defer to the physician when choosing between TRA and TFA. Even in cases where a patient preferred a specific approach, they often deferred to the physician's expertise if their preferences were not followed. Patient's commonly cited trust in their physician and clear explanation by the medical team as the 2 most common reasons for deferral.

Lastly, we have identified a significant area for improvement of the patient consent process before cardiac catheterization. A thorough understanding of the risks and benefits of elective procedures is necessary before undergoing such procedures. Despite the current method for informed consent of patients, patient retention of this information remains low and further improvements can be made to better educate patients regarding TRA and TFA cardiac catheterization.

There were a number of limitations associated with our study. Given that this study was a survey that required patients to provide consent, there is a potential for sampling bias and voluntary response bias.²⁸ In addition, surveys are

more likely to elicit positive responses, and may not encourage patients to disclose specific issues in the quality of care.^{28,29} This study was conducted at a single center with a predominantly minority population that defaulted to TRA in cardiac catheterization. As such, results may have been driven by local demographics and biases which could limit the external validity of these results.²⁹ Further validation testing of the PKI score would help strengthen the efficacy of the scores. Lastly, in cases where patients had a preference, they often mentioned that they were not adamant if there was a satisfactory medical rationale. These cases were coded as their initial preference of radial or femoral, despite their initial preference.

In summary, patient retention of information from the informed consent was low despite a high patient satisfaction with their procedure. We identified an area for improvement of informed consent and patient understanding of the risks and benefits associated with cardiac catheterization. Patient preferences are not highly influenced by their respective knowledge of the risks and benefits of the procedure. During the SDM process, it is important to focus not only on the scientific evidence behind each procedure, but to also tailor patient education to each patient's perspectives and level of knowledge.

Disclosures

Dr. Mladen Vidovich discloses a research grant from Boston Scientific and royalties from Merit Medical.

Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.amjcard.2019.04.014>.

- Baklanov DV, Kaltenbach LA, Marso SP, Subherwal SS, Feldman DN, Garratt KN, Curtis JP, Messenger JC, Rao SV. The prevalence and outcomes of transradial percutaneous coronary intervention for ST-segment elevation myocardial infarction: analysis from the National Cardiovascular Data Registry (2007 to 2011). *J Am Coll Cardiol* 2013;61:420–426.
- Valle JA, Kaltenbach LA, Bradley SM, Yeh RW, Rao SV, Gurm HS, Armstrong EJ, Messenger JC, Waldo SW. Variation in the adoption of transradial access for ST-segment elevation myocardial infarction: insights from the NCDR CathPCI Registry. *JACC Cardiovasc Interv* 2017;10:2242–2254.
- Vorobcsuk A, Konyi A, Aradi D, Horvath IG, Ungi I, Louvard Y, Komocsi A. Transradial versus transfemoral percutaneous coronary intervention in acute myocardial infarction systematic overview and meta-analysis. *Am Heart J* 2009;158:814–821.
- Agostoni P, Biondi-Zoccai GG, de Benedictis ML, Rigattieri S, Turri M, Anselmi M, Vassanelli C, Zardini P, Louvard Y, Hamon M. 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.
- Brueck M, Bandorski D, Kramer W, Wiecezorek M, Holtgen R, Tillmanns H. A randomized comparison of transradial versus transfemoral approach for coronary angiography and angioplasty. *JACC Cardiovasc Interv* 2009;2:1047–1054.
- 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.
- Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Educ Couns* 2006;60:301–312.
- Ye S. Medical decision making and the counting of uncertainty. *Circulation* 2014;129:2500–2502.
- Elwyn Glyn, Miron–Shatz Talya. Deliberation before determination: the definition and evaluation of good decision making. *Health Expect* 2010;13(2):39–147.
- Elwyn G, Lloyd A, May C, van der Weijden T, Stiggelbout A, Edwards A, Frosch DL, Rapley T, Barr P, Walsh T, Grande SW, Montori V, Epstein R. Collaborative deliberation: a model for patient care. *Patient Educ Couns* 2014;97:158–164.
- Hargraves I, LeBlanc A, Shah ND, Montori VM. Shared decision making: the need for patient-clinician conversation, not just information. *Health Affairs* 2016;35(4):627–629.
- Spatz Erica S, Krumholz Harlan M, Moulton Benjamin W. Prime time for shared decision making. *JAMA* 2017;317(13):1309–1310.
- Blumenthal-Barby JS, Kostick KM, Delgado ED, Volk RJ, Kaplan HM, Wilhelms LA, McCurdy SA, Estep JD, Loebe M, Bruce CR. Assessment of patients' and caregivers' informational and decisional needs for left ventricular assist device placement: implications for informed consent and shared decision-making. *J Heart Lung Transpl* 2015;34(9):1182–1189.
- Spatz Erica S, Krumholz Harlan M, Moulton BW. The new era of informed consent: getting to a reasonable-patient standard through shared decision making. *JAMA* 2016;315(19):2063–2064.
- 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. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2009;319(7212):731–734.
- Grady Christine. Enduring and emerging challenges of informed consent. *N Eng J Med* 372.9 2015;372.9:855–862.
- Konheim-Kalkstein Yasmine L, Miron-Shatz Talya, Israel Leah Jenny. How women evaluate birth challenges: analysis of web-based birth stories. *JMIR Pediatr Parent* 2018;1(2):12206.
- Shiloh S, Drori E, Peleg S, Banai S, Finkelstein A. Mediation and moderation of the effects of watching the angiography screen on patients. *Psychol Health Med* 2016;21(7):806–818.
- Crossing the Quality Chasm: A New Health System for the 21st Century. Washington (DC), 2001.
- BeLue R, Butler J, Kuder J. Implications of patient and physician decision making: an illustration in treatment options for coronary artery disease. *J Ambul Care Manage* 2004;27:305–313.
- Deber RB. Physicians in health care management: 8. The patient-physician partnership: decision making, problem solving and the desire to participate. *CMAJ* 1994;151:423–427.
- Strull WM, Lo B, Charles G. Do patients want to participate in medical decision making? *JAMA* 1984;252:2990–2994.
- Brenner A, Malo T, Margolis M, Lafata J, James S, Vu M, Reuland D. Evaluating shared decision making for lung cancer screening. *JAMA Intern Med* 2018;178(10):1311–1316.
- Levinson W, Kao A, Kuby A, Thisted RA. Not all patients want to participate in decision making. A national study of public preferences. *J Gen Intern Med* 2005;20:531–535.
- van Ryn M. Research on the provider contribution to race/ethnicity disparities in medical care. *Med Care* 2002;40:1140–1151.
- Cooper-Patrick L, Gallo JJ, Gonzales JJ, Vu HT, Powe NR, Nelson C, Ford DE. Race, gender, and partnership in the patient-physician relationship. *JAMA* 1999;282:583–589.
- Quill TE. Partnerships in patient care: a contractual approach. *Ann Intern Med* 1983;98:228–234.
- Oterhals K, Hanestad BR, Eide GE, Hanssen TA. The relationship between in-hospital information and patient satisfaction after acute myocardial infarction. *Eur J Cardiovasc Nurs* 2006;5:303–310.
- Jenkinson C, Coulter A, Bruster S, Richards N. The coronary heart disease in-patient experience questionnaire (I-PEQ (CHD)): results from the survey of National Health Service patients. *Qual Life Res* 2002;11:721–727.