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Risk factors for impaired health status differ in women and men treated with percutaneous coronary intervention in the drug-eluting stent era

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Abstract

Objectives: In patients treated with percutaneous coronary intervention (PCI) in the drug-eluting stent era, we compared women's and men's health status 6 and 12 months post-PCI and investigated whether predictors of poor health status at 12 months are similar for women and men. **Methods:** Consecutive patients (n=692; 28% women) treated with PCI completed the 36-item Short-Form Health Survey (SF-36) 6 and 12 months post-PCI. **Results:** There was a significant improvement in health status over time (P<.001), but women experienced a significantly poorer health status compared with men (P<.001) at 6 and 12 months, adjusting for differences in baseline characteristics and health status at 6 months. Predictors of impaired health status were generally different for women and men. In women, the predominant predictors were previous coronary artery bypass graft (CABG) surgery, renal impairment, and older age; in contrast, in men, older age was associated with better functioning. In women, previous CABG was associated with a 4-15 fold increased risk of impaired health status. Health status at 6 months was a predictor of all SF-36 domains at 12 months in both women and men. **Conclusions:** Women reported poorer health status compared with men 6 and 12 months post-PCI, and predictors of impaired health status generally differed for women and men. Further studies examining risk factors for adverse outcomes for women and men separately, which will lead to better risk stratification in research and clinical practice, are warranted.

Keywords: Health status; Percutaneous coronary intervention; Predictors; Sex; Sirolimus-eluting stent

Introduction

Despite advances in the diagnosis and treatment of cardiovascular disease, sex differences continue to exist in the pathophysiology, treatment, morbidity, mortality, and course of recovery [1–4]. The drug-eluting stent (DES) comprises a recent advancement in interventional cardiology that in randomized controlled trials has been shown to lead to a dramatic reduction in the restenosis rate and the need for repeat revascularization following percutaneous coronary intervention (PCI) [5,6]. In the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) registry, DES implantation was also shown to be superior to bare metal stent implantation in unselected patients [7]. However, the use of DES has not shown to confer any increased benefit on survival [8].

No study has examined whether women also are at risk of adverse health status compared with men in the DES era. Health status is an important outcome measure in its own right, but poor health status has also been identified as a risk factor for mortality [9,10]. Furthering our knowledge of the determinants of patient-centered health status has been proposed as an important step toward closing the gap between research and clinical practice [11]. In the pre-DES era, women with cardiovascular disease have been shown to

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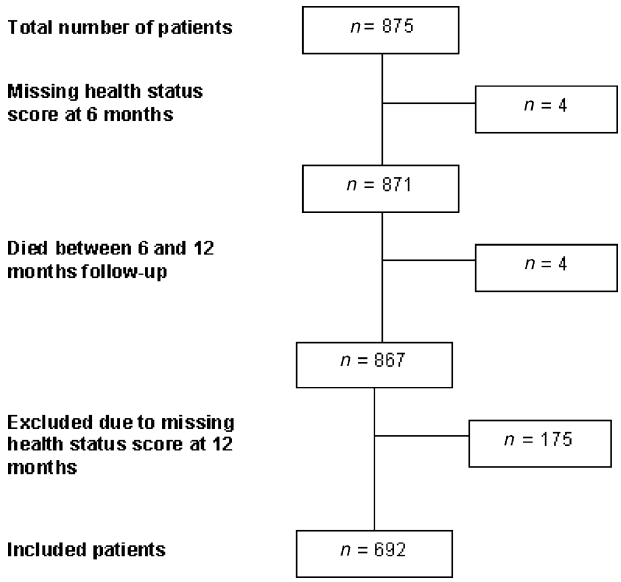

Fig. 1. Flowchart of patient selection.

report poorer health status compared with men [12–18]. These findings have generally been consistent irrespective of cardiac diagnosis [17] and disease severity [1,12]. Vaccarino et al. [12] also found that the absolute number of women experiencing a worsening in physical functioning and mental health 6 months post-coronary artery bypass graft (CABG) surgery was significantly higher than that of men.

Little also is known about predictors of adverse health status in women, although preliminary evidence suggests that predictors of poor health status may not be the same for women as those for men. In a recent study on a mixed group of cardiac patients, a sense of belonging was associated with emotional well-being in women but not in men [15]. Knowledge of predictors of adverse health status may provide indications for interventions, improve risk stratification in clinical practice, and, ultimately, lead to the enhancement of secondary prevention. The results of a recent substudy of the Enhancing Recovery in Coronary Heart Disease (ENRICHD) clinical trial emphasize this notion, as only White men experienced a positive effect on cardiovascular morbidity and mortality following a psychosocial intervention; a null effect was found for White women, whereas a negative effect was found for minority women [4].

The purpose of the current study was twofold: (1) to compare women's health status with that of men at 6 and 12 months post-PCI following implantation with either DES or conventional bare stents and (2) to investigate whether predictors of poor health status at 12 months post-PCI are similar in men and women.

Methods

Participants

Consecutive patients (N=875; response rate=71%) treated with PCI with either sirolimus-eluting stents or bare metal stent implantation between October 16, 2001, and October 15, 2002, as part of the RESEARCH registry who participated in the psychological substudy [19] comprised the patient group for the current study. The design of the RESEARCH registry has been published elsewhere [20]. In brief, the objective of the registry was to evaluate the impact of sirolimus-eluting stents on clinical adverse events in the "real world" of interventional cardiology. Therefore, no clinical and anatomical exclusion criteria were applied. Importantly, most patients (68%) included in the RESEARCH registry would not have been enrolled in clinical trials due to their more complex clinical profile [21]. Only patients (n=692) who had a score on the 36-item Short-Form Health Survey (SF-36) at 6 and 12 months post-PCI qualified for inclusion (Fig. 1). Nonresponders on the SF-36 at 6 or 12 months did not differ on demographic and clinical baseline characteristics, except that they were more likely to have had a previous PCI as compared with responders (32% vs. 23%; P=.03).

At 6 and 12 months postprocedure, letters were sent to the civil registries requesting information on the survival status of each patient. For the current substudy, all surviving patients were contacted by mail and asked to fill in a self-report questionnaire. After 7 weeks, a reminder was sent to patients who had not yet returned their questionnaire. Assessment at 6 months was chosen so as to represent patients in a stable medical condition. A similar approach has been adopted in other studies on PCI patients [22–24]. Clinical variables were also obtained at 6 months.

Table 1
Baseline characteristics (6 months post-PCI)

	Women (n=196)	Men (n=496)	P
Demographic factors			
Age [mean (S.D.)]	65 (11)	61 (10)	<.001***
Stent type			
Sirolimus-eluting stent (%)	43	40	.49
Clinical			
Previous MI (%)	29	40	.01*
Previous CABG (%)	11	13	.52
Previous PCI (%)	21	24	.43
Recent event (%)	9	9	1.00
Multivessel disease (%)	47	53	.21
Hypertension[a] (%)	47	34	.01**
Hypercholesterolemia[b] (%)	79	81	.67
Diabetes mellitus[a] (%)	17	12	.14
Renal impairment[c] (%)	44	27	<.001***
Current smoking[d] (%)	28	33	.21

Previous MI = MI prior to the index event; previous CABG = CABG prior to the index event; previous PCI = PCI prior to the index event; recent event = MI, CABG, or PCI between 0 and 6 months post-PCI.

[a] Present if being treated for the condition.

[b] Total cholesterol levels >240 mg/dl or on lipid-lowering medication.

[c] Indicated by creatinine clearance <60 ml/min.

[d] Based on self-report.

* P<.05.

** P<.01.

*** P<.001.

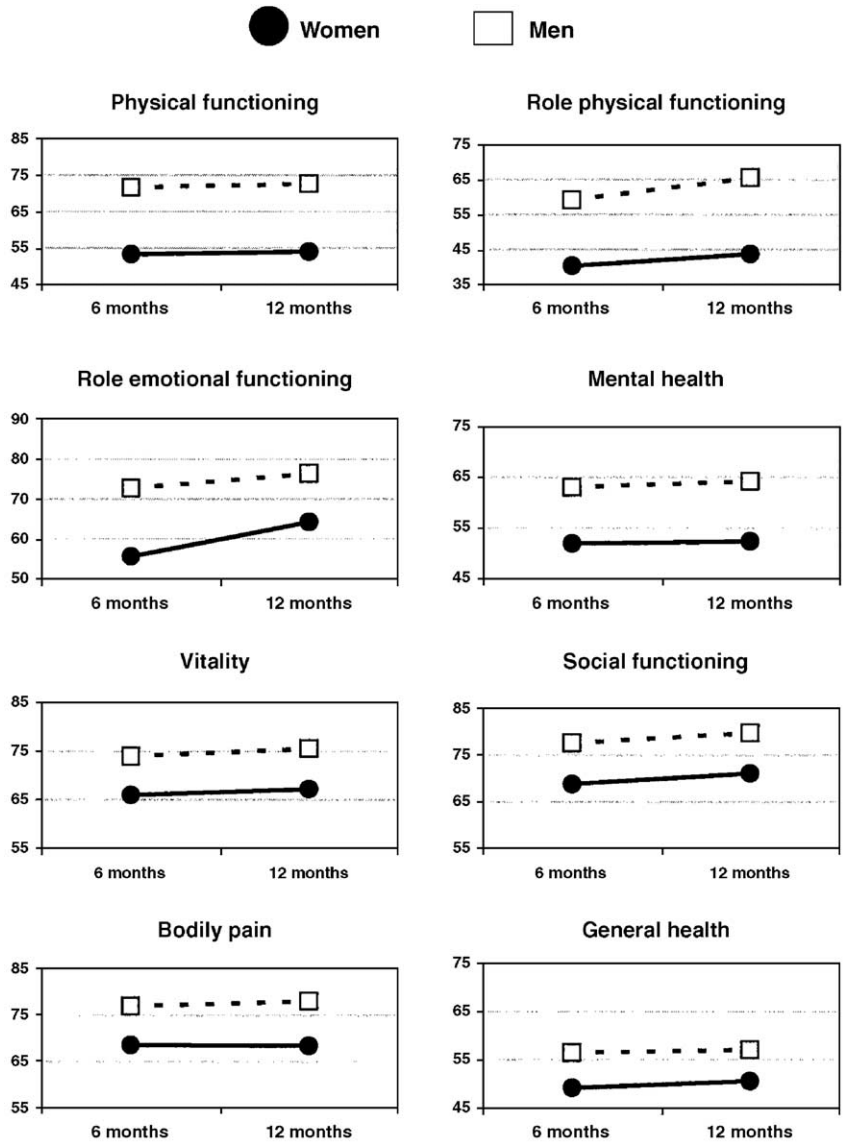

Fig. 2. Health status at 6 and 12 months stratified by sex. Analysis of variance for repeated measures (univariable analysis); effect of sex for all subdomains of health status at 6 and 12 months ($P<.001$). A high score indicates better health status, with a high score on bodily pain representing the absence of pain. S.D.'s for women ranged from 19.54 to 45.03; for men, 19.34 to 41.94.

The study was approved by the local medical ethics committee and was conducted in accordance with the Helsinki Declaration. Every patient provided written informed consent.

Measures

Demographic and clinical variables

Demographic variables included sex and age. Information on clinical variables [previous myocardial infarction (MI), previous CABG, previous PCI, recent events (MI, CABG, or PCI between 0 and 6 months post-PCI), multivessel disease, hypertension, hypercholesterolemia, diabetes mellitus, renal impairment, sirolimus-eluting or bare metal stent implantation, and smoking status] were prospectively collected at the time of the procedure and recorded in the institutional database.

Health status

Health status was measured with the SF-36 [25]. The SF-36 assesses eight health status domains (i.e., physical functioning, role physical functioning, role emotional functioning, mental health, vitality, social functioning, bodily pain, and general health). Scale scores are obtained by summing the items together within a domain, dividing this outcome by the range of scores and then transforming the raw scores to a scale of 0 to 100 [25]. A higher score on the SF-36 subdomains represents a better functioning; a high score on the bodily pain scale indicates freedom from pain. Based on the eight subdomains, physical (PCS) and

mental component summary (MCS) scores can be calculated according to an algorithm, with the subdomains physical functioning, role physical functioning, bodily pain, and general health being the primary contributors to the PCS and role emotional functioning, vitality, social functioning, and mental health being the primary contributors to the MCS [26]. The scale has good reliability, with Cronbach's α ranging from 0.65 to 0.96 for all subscales [27]. Patients were asked to complete the SF-36 6 and 12 months post-PCI.

Statistical analysis

Discrete variables were compared with the χ^2 test; continuous variables, with Student's *t* test. Univariable and multivariable analyses of variance for repeated measures were used to evaluate changes in health status between 6 and 12 months using sex as the between-subjects factor. In multivariable analyses, we adjusted for all baseline characteristics. Multivariable logistic regression analyses were used to identify predictors of impaired health status at 12 months in women and men separately. Prior to analyses, the health status domains were dichotomized with the lowest tertile indicating poor health status as compared with the other two tertiles indicating good health status. This dichotomization was done to enhance clinical interpretability, as advocated by others [28,29]. In the regression analyses, we adjusted for all baseline characteristics and health status at 6 months. All statistical tests were two tailed. $P<.05$ was used for all tests to indicate statistical significance. Odds ratios (ORs) with 95% confidence intervals (CIs) are reported. All statistical analyses were performed using SPSS Version 12.0.1 for Windows.

Results

Patient characteristics at 6 months are shown in Table 1. Women and men differed on a number of characteristics, with women being older, more likely to have hypertension and renal impairment, but less likely to have suffered a previous MI as compared with men. No other statistically significant difference was found between the two sexes on patient characteristics.

Health status in women compared with men at 6 and 12 months

There was a significant improvement in health status over time ($P<.001$); some but not all changes were clinically relevant based on the criterion that a score change of 1 S.E.M. is commonly regarded as clinically important [30]. We found a main effect for sex ($P<.001$), with women experiencing a significantly poorer health status than men (Fig. 2). These differences were substantial, ranging from 7 to 22 points depending on the health status domain in question and the time point (6 or 12 months). The effect of sex on health status was persistent over time, as indicated by the nonsignificant interaction effect for Time × Sex ($P=.99$). Because women and men differed on several baseline characteristics, we examined whether the main effect of sex remained significant in multivariable analyses. Women were still found to report poorer health status after adjusting for all baseline characteristics ($P<.001$).

Predictors of health status at 12 months in women and men

The predominant predictors of adverse health status in women were age ≥60 years, previous CABG, renal impairment, and poor health status at 6 months (Table 2). Of note, previous CABG was associated with a 4- to 15-fold increased risk of impaired health status depending on the

Table 2
Predictors of impaired health status in women and men 12 months post-PCI (multivariable analyses)[a]

	Women ($n=196$) [OR (95% CI)]	Men ($n=496$) [OR (95% CI)]
Physical functioning		
Age ≥60 years	3.51 (1.28–9.64)*	–
Hypercholesterolemia[b]	0.29 (0.10–0.83)*	–
6-month health status	37.04 (13.58–101.08)**	23.34 (12.93–42.12)**
Role physical functioning		
6-month health status	4.56 (2.35–8.85)**	8.11 (4.99–13.18)**
Role emotional functioning		
Age ≥60 years	3.07 (1.21–7.75)*	–
Recent event	–	2.32 (1.01–5.36)*
Renal impairment[c]	2.23 (1.05–4.77)*	–
6-month health status	8.38 (3.98–17.63)**	14.68 (8.49–25.40)**
Mental health		
Previous CABG	4.62 (1.39–15.27)*	–
Multivessel disease	–	0.48 (0.26–0.87)*
6-month health status	5.62 (2.74–11.54)**	19.24 (10.99–33.67)**
Vitality		
Renal impairment[c]	2.32 (1.10–4.88)*	–
6-month health status	8.38 (4.10–17.16)**	18.27 (10.77–31.01)**
Social functioning		
Renal impairment[c]	2.22 (1.05–4.70)*	–
6-month health status	9.82 (4.45–21.67)**	11.40 (6.63–19.59)**
Bodily pain		
Previous MI	–	0.53 (0.31–0.91)*
Previous CABG	4.56 (1.31–15.84)*	–
Renal impairment[c]	2.12 (1.03–4.37)*	–
6-month health status	4.54 (2.23–9.25)**	12.49 (7.46–20.91)**
General health		
Age ≥60 years	–	0.54 (0.33–0.87)*
Previous CABG	15.63 (3.10–78.79)*	–
Recent event	0.20 (0.04–0.90)*	–
Renal impairment[c]	2.70 (1.20–6.05)*	–
6-month health status	12.73 (5.45–29.75)**	6.87 (4.30–10.99)**

[a] Adjusted for all baseline characteristics and health status at 6 months; only significant independent predictors are shown.
[b] Total cholesterol levels >240 mg/dl or on lipid-lowering medication.
[c] Indicated by creatinine clearance <60 ml/min.
* $P<.05$.
** $P<.001$.

Table 3
Predictors of impaired PCS and MCS scores in women and men 12 months post-PCI (multivariable analyses)[a]

	Women (n=196) [OR (95% CI)]	Men (n=496) [OR (95% CI)]
Physical component		
Previous CABG	7.71 (1.34–44.31)*	–
6-month PCS score	9.74 (4.56–20.78)**	10.27 (6.25–16.86)**
Mental component		
Age ≥60 years	2.37 (0.99–5.60)*	0.50 (0.29–0.85)*
Recent event	–	2.64 (1.16–6.01)*
Hypertension[b]	0.41 (0.19–0.88)*	–
6-month MCS score	9.81 (4.64–20.71)**	15.13 (9.01–25.44)**

[a] Adjusted for all baseline characteristics and the component scale score at 6 months; only significant independent predictors are shown.
[b] Present if being treated for the condition.
* $P<.05$.
** $P<.001$.

SF-36 health status subdomain, and renal impairment was associated with a 2-fold increased risk. In men, age ≥60 years, previous MI, multivessel disease, and a recent event were predictive of impaired health status in addition to poor health status at 6 months (Table 2). Of note, age ≥60 years had a protective effect in men, whereas higher age was associated with impaired functioning in women. A similar pattern was found for a recent event, defined as MI, PCI, or CABG between 0 and 6 months post-PCI; in women, it was associated with better general health, whereas in men, it was a predictor of impaired role emotional functioning at 12 months.

In secondary analyses, we looked at predictors of the SF-36 component summary scores, PCS and MCS (Table 3). In women, previous CABG was associated with a 7-fold risk of impaired PCS at 12 months. In both women and men, a poor PCS score at 6 months was a predictor of poor PCS at 12 months. Similarly, a poor MCS score at 6 months was associated with a poor MCS score at 12 months in both sexes. In addition, in women, older age and hypertension were independent predictors of MCS at 12 months, with older age being associated with a lower MCS score and hypertension with better functioning. In contrast, in men, older age was associated with better functioning and the experience of a recent cardiac event with a lower MCS score at 12 months.

Discussion

This is the first study to examine sex differences in health status in post-PCI patients in the DES era. Although there was a significant improvement in health status over time, women reported a significantly worse health status at 6 and 12 months post-PCI compared with men regardless of age, stent type, and clinical risk factors. We also found that predictors of poor health status at 12 months post-PCI generally were different for women and men.

The overall improvement seen in health status in women and men at 12 months compared with 6 months is consistent with previous studies showing that health status generally improves over time [12,14,17]. These improvements were for some but not all subdomains of the SF-36 also clinically relevant [30]. Nonetheless, it is notable that women experienced significantly impaired health status at 6 and 12 months post-PCI compared with men, also when adjusting for baseline characteristics. This indicates that the persistent effect of female sex on health status over time was not a function of differences in demographic and clinical baseline characteristics. Nevertheless, it is possible that differences on health status between men and women already existed prior to the index PCI. However, because we had no information on health status at the time of the revascularization procedure, we cannot conclude whether women do not benefit from PCI on par with men—only that women generally report lower health status compared with men. Women have generally been reported to experience poorer health status in studies conducted in the pre-DES era, although most of these studies were conducted in a mixed group of cardiac patients or post-CABG patients rather than in pure PCI patients [12–18].

In addition, we found that predictors of impaired health status generally were different for women and men, with previous CABG, older age, and renal impairment comprising the most frequent predictors in women in addition to health status at 6 months. For men, older age, previous MI, a recent event, and multivessel disease were the only significant predictors in addition to health status at 6 months. However, in contrast to women, older age had a protective effect in men. Notably, there was little overlap in the demographic and clinical predictors of poor functioning in women and men apart from 6-month health status. In a recent study, social support was associated with emotional well-being in women but not in men, whereas social support had no impact on physical functioning in either sex [17]. Taken together, these findings underscore the importance of examining risk factors for adverse outcomes for women and men separately. This undoubtedly will lead to better risk stratification in research and clinical practice given that health status has been associated with an increased risk of mortality [9,10] and female sex with increased medical care costs at 10 years following revascularization [31]. The results of two clinical trials, the ENRICHD and the Montreal Heart Attack Readjustment Trial, that showed that only men benefited from a psychosocial intervention in terms of improved prognosis support this notion [4,32].

Finally, in the current study, disease severity as measured by means of multivessel disease was not associated with health status in women, but it was a predictor of improved mental health in men. This is different from the findings of Lane et al. [18] who identified severity of MI as a predictor of poor health status 4 and 12 months post-MI. Similarly, Sullivan et al. [33] found that disease severity was associated with physical functioning at the time of

catheterization, whereas anxiety and depression were the strongest predictors at 1 year. However, in a previous study comparing CABG with PCI, disease severity was not associated with health status [23].

The results of the current study should be interpreted with some caution. First, patients were not randomized to type of revascularization procedure; however, a strength of the study is that the population was representative of the real world of interventional cardiology as no exclusion criterion was applied. In fact, 68% of the patients included in the current study would not have qualified for inclusion in clinical trials due to their more complex profile [21]. Research conducted in real world settings has been advocated as a means by which to close the gap between research and clinical practice [11]. Second, health status was not assessed at baseline; therefore, we do not know whether the groups displayed initial differences on health status. However, assessment at 6 months post-PCI rather than at the index procedure has been adopted in other studies in order for patients to be medically stable [22–24]. In addition, health status was assessed twice, which allows for the evaluation of changes over time. Third, nonresponders on the SF-36 at 12 months differed from responders, with nonresponders being more likely to have undergone a previous PCI. Finally, men and women differed on several baseline characteristics, but these variables were controlled for in multivariable analyses.

In conclusion, the results of the current study show that despite advances in interventional cardiology, women still experience a significantly poorer health status compared with men. Predictors of adverse health status were also different for women and men. These findings have implications for research and clinical practice given that health status has been related to increased morbidity and mortality. Further studies examining risk factors for adverse outcomes for women and men separately, which will lead to better risk stratification in research and clinical practice, are warranted.

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