Does routinely collected patient-reported outcome data represent the actual case-mix of elective coronary revascularization patients?

Running title: Representativeness of PRO data

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ABSTRACT

Aims: Patient-reported outcomes (PROs) are valuable for effectiveness evaluation, but it is unknown whether the patient views obtained represent the actual case mix. We studied the representativeness of the responses obtained to a routinely administered health-related quality of life (HRQoL) questionnaire in a cardiology unit.

Methods and results: Elective coronary artery bypass grafting (CABG; N=404) and percutaneous coronary intervention (PCI; N=738) patients operated during 6/2012-8/2014 in the Heart Center, Kuopio University Hospital. The characteristics of the patients with a baseline (n=260 and 290 for CABG and PCI, respectively) or both baseline and follow-up HRQoL measurements (n=203 and 189 for CABG and PCI, respectively) were compared with those who did not respond (n=144 and 448 for CABG and PCI). Baseline questionnaires were less likely obtained from older CABG patients (OR, 95% CI 0.25, 0.28-0.91) and those with more severe disease (0.20, 0.05-0.79). Among PCI patients, women (0.69, 0.46-1.02), smokers (0.70, 0.49-1.02), and those with more severe disease (0.21, 0.08-0.52) or more hospital days were underrepresented.

Conclusion: Routinely collected PROs in cardiac patients may be biased towards younger and healthier patients. This needs to be recognised when evaluating the representativeness of such data. The routine collection of these data should be adequately resourced.

Keywords: Bias, Case mix, Health-related quality of life, Coronary Artery Bypass, Percutaneous Coronary Intervention

KEY MESSAGE

Routinely collected patient reported outcome datas in cardiac patients may be biased towards younger and healthier patients.

Introduction

One of the most important criterions when assessing the quality of health care is a patient's subjective experience of his/her health condition after treatment. Therefore, it is important to focus the evaluation of treatment effectiveness also on patient-reported outcomes (PRO) such as health-related quality of life (HRQoL), not only on life years gained(1). HRQoL can be measured by self-reported questionnaires, such as EQ-5D or 15D(2, 3).

It is rarely possible to convince all patients to respond to HRQoL surveys in practice, although obtaining a representative sample is necessary for unbiased estimation of effectiveness. If the patient characteristics affect the personnel's likelihood of administering the survey, or patient's decision or ability to respond, over- or underrepresentation of certain patient groups can lead to biased estimate of effectiveness if these differences are not accounted for, or, at least acknowledged when interpreting the results. It is known that HRQoL data are rarely missing at random, and several approaches for accounting for missingness have been proposed(4-8).

Pre- and postoperative 15D-data have been collected as a part of the admission process in the Heart Center of Kuopio University Hospital since 2012. In principle, the questionnaire should be administered to all elective patients, but as often occurs with routine data collection, data have not been obtained from all patients. Furthermore, the proportion of obtained questionnaires tends to vary between different treatments for the same condition, i.e. coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) for coronary artery disease.

The aims of this study were 1) to investigate whether the baseline and follow-up questionnaires were obtained from a representative sample of patients undergoing an elective CABG or PCI and 2) to study which participant characteristics were associated with loss to follow-up among those participants from whom only the baseline questionnaire was obtained.

Material and methods

Study population and data collection

The participants of this study were cardiac patients admitted for elective coronary revascularization therapy (coronary artery bypass grafting, CABG, or percutaneous coronary intervention, PCI) in the Heart Center, Kuopio University Hospital. All patients undergoing CABG or PCI were asked, as part of routine clinical practice, to fill in the 15D questionnaire at baseline and 12 months after the revascularization procedure. Patients who underwent CABG (N=404) or PCI (N=738) from June 2012 to August 2014 were included in this study. All patients were fluent in Finnish. The baseline questionnaires were distributed to the patients upon arrival to the hospital by staff nurses. The patients filled the questionnaires by pen or they used a tablet to answer the questions. After the patients had answered the questionnaires, the nurses transferred the data from the questionnaire to an electronic database. In addition to the paper format, the patients had an option to answer by using a tablet, and these replies were directly transferred to the database. The patients had a possibility to ask for help for technical issues (e.g. how to use the tablet) but the staff were instructed to refrain from advising the patients on how to answer the questions.

Follow-up was conducted by a postal or electronic survey, as chosen by the patient, 12 months after the operation. An e-mail reminder was sent to patients who opted to receive the follow-up questionnaire by e-mail, if they had not replied within one week of the deadline for answering that questionnaire . Reminders were not sent to persons who opted to receive a paper questionnaire. The average time lag between the responses was 367.3 days (SD 13.7) for PCI and 366.4 days (SD 9.2) for CABG. This average time was used to estimate the most likely return date for those from whom the follow-up questionnaire was not obtained when assessing whether they were alive or community-dwelling at that time.

The study was approved by the Ethical committee of the Kuopio University Hospital. Necessary approvals for register linkage were obtained from Statistics Finland and the National Institute of Health and Welfare.

Measurement of quality of life

The 15D instrument is a generic, self-administered questionnaire for measuring HRQoL(2). It consists of 15 dimensions (mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity) with five ordinal levels. The single index score of the 15D instrument ranges from 0 to 1. The 15D instrument can generate over 30 billion different health states. The valuation system of the 15D used in this study is based on a set of Finnish population-based preferences.

Patient characteristics

The demographic and preoperative characteristics (age, sex, disease severity, and body mass index; BMI) were extracted from electronic medical records. Disease severity was defined according to the classification systems by the New York Heart Association (NYHA) and the Canadian Cardiovascular Society (CCS). Data on all hospital admissions were obtained from the National Care Register for Health Care and date of death from Statistics Finland. The following comorbidities, with consequent ICD-10 codes, were identified: cancer (C*), diabetes (E10-E14), stroke (I60-64), asthma/COPD (J44-46), ischaemic heart disease (I20-25) and any mental or behavioural disorder (F*). To describe the overall comorbidity, the total number of hospital days and admissions five years before the operation was calculated and categorised as follows: 1-5 days, 6-12 days, 13-28 and 29 or more days for CABG patients.

The same categorisation, with an additional group of no hospital days, was used for PCI patients.

Statistical Analyses

Patient characteristics are presented as n (%). Associations between characteristics and likelihood of obtaining HRQoL data were investigated with logistic regression using three different comparisons (no data vs baseline data; no data vs baseline and follow-up data; only baseline data obtained vs baseline and follow-up data obtained. All statistical analyses were conducted by STATA12.0 (Stata Corp LP, Station, TX, USA)

Results

The proportion of obtained baseline and follow-up questionnaires, as well as reasons for loss to follow-up are described in Figure 1. Altogether 5 (1.2 %) CABG patients and 18 (2.4 %) PCI patients died before completing the follow-up questionnaire and 3 (0.7 %) CABG patients and 2 (0.3 %) PCI patients were hospitalised at that time and thus not able to return the follow-up questionnaire.

Associations between patient characteristics and likelihood of obtaining baseline and baseline and follow-up questionnaires in CABG patients are summarised in Table 1. Baseline questionnaires were less often obtained from older patients, those with more severe disease according to NYHA classification and those with more hospital stays prior to the operation. Individual comorbidities or sex were not associated with the likelihood of obtaining 15D data. Among persons with baseline and follow-up data, only the association of higher number of hospital stays remained significant while other determinants were attenuated towards null,

although the proportion of, for example, persons in NYHA IV class were 21.9% and 12.3% among those without and with baseline and follow up data, respectively. The likelihood of obtaining baseline data was similar in all years, but the proportion of patients with baseline and follow-up data was lower in 2014 when compared to the pilot phase of 2012 (data not shown, results available from authors by request). Cancer, diabetes, stroke, asthma/COPD or mental and behavioural disorders were not associated with likelihood of obtaining baseline and/or follow-up data (data not shown).

Associations between patient characteristics and likelihood of obtaining baseline and baseline and follow-up questionnaires in PCI patients are summarised in Table 2. Baseline questionnaires were more often obtained from men, overweight persons, those with less severe disease and those with less hospital days prior to revascularisation. In addition, smokers were underrepresented among in this group, but the confidence interval was wide and overlapped 1. Patients with the same characteristics were also overrepresented among those with baseline and follow-up data, except for BMI where the associations attenuated towards null. The likelihood of obtaining baseline data was higher in 2013 but returned to the same level than in 2012 in 2014. Cancer, diabetes, stroke, asthma/COPD or mental and behavioural disorders were not associated with likelihood of obtaining baseline and/or follow-up data (data not shown).

Tables 3-4 summarises the characteristics of CABG and PCI patients according to whether they were lost to follow-up. Provided that they had answered the baseline questionnaire, older CABG patients were more likely to return the follow-up questionnaire than younger ones. The loss to follow-up was higher in 2014 than in the previous years. Other characteristics were not associated with loss to follow-up among those who returned the baseline questionnaire.

Discussion

According to our results, routinely collected PRO data did not represent the actual patient case mix of patients undergoing coronary artery revascularisation procedure. Thus, if these kind of data would be directly applied for assessing treatment effectiveness or achieved outcomes, the results would be biased. If the intervention leads to larger improvements in patients suffering from more severe disease, the effectiveness is underestimated as healthier patients are overrepresented.

The 15D questionnaires were less often obtained from older patients, women, smokers and those with more severe coronary artery disease. The associations between patient characteristics and likelihood of obtaining 15D data were different between CABG and PCI patients, which may be due to differences in the admission process: CABG patients usually arrive to hospital on the previous day and thus they have more time to fill in the questionnaire. In comparison, the persons undergoing elective PCI often arrive on the same day, which means that they have less time to fill in the questionnaires. Further, if they require staff assistance in the preparation process, for example, because of their advanced age or lower functional ability (i.e. more severe disease), the staff may be less likely to administer the questionnaire to these patients. It is also possible that those with a more invasive operation are more likely to respond to these surveys. This may explain why the differences between respondents and non-respondents were more evident among PCI patients. Another possible explanation is the larger number of PCI patients.

The results of the current study are in line with previous studies that reported that patients with poor health status were less likely to respond to self-report questionnaires. This has been

observed in both cardiovascular patients and other patient populations including persons with diabetes, bilateral blindness, visual defiency and stroke(4, 9). Similarly, it has been previously shown that men and smokers are less likely to respond to self-reported questionnaires, compared to women and non-smokers. These associations were observed among cardiovascular patients but also in studies focusing on other diseases(4-6, 10). In our study, older patients were less likely to respond to the survey. Similar association was observed in a French population-based study,(4) while a study among persons undergoing elective surgery in England reported an opposite association (younger patients less likely to respond to survey),(5) and a Swiss study found no age difference between respondents and nonrespondents of a mailed health survey(10). Thus, the predictors of nonresponse may vary across different study populations and questionnaires.

Results from previous studies on factors associated with survey response rate among patients with myocardial infarction or unstable angina are comparable to ours, although there were some differences in study populations(6, 9). The first study, conducted in the Netherlands consisted of 548 aged men who had participated in a previous cardiovascular health study in 1985(9). They were asked to participate in a follow-up study by a mailed questionnaire and predictors of non-response to that questionnaire were assessed. In the other study, a HRQoL questionnaire was mailed to 2773 patients who had seven months earlier been diagnosed with acute coronary syndrome (including either acute myocardial infarction or unstable angina)(6). In both of these studies, patients with poor health status (chronic diseases such as stroke, dementia, depression, functional status and self-reported health status) were less likely to respond to the survey(6, 9). As observed in our study, one of these previous studies also showed that older patients and smokers were less likely to respond to the self-reported questionnaire(6).

The major strength of our study is the representative study population. We were able to identify all eligible patients from the electronic medical records, and the proportion of missing data on patient characteristics was small. Thus, it is unlikely that it affected the results. The Kuopio University Hospital is the only center performing revascularisations in its catchment area (covering populations of c. 250.000 and 800.000 for PCI and CABG, respectively; entire population of Finland is 5.4 million) and due to the current organisation of public health care, the patients were not selected on any basis. Thus, the results should be generalizable to other populations. One important limitation is that no data were available on which of the patients the baseline questionnaires were administered. Thus, it is not possible to evaluate whether the non-response was decided by the patient, or dependent on other factors.

These reasons for the observed biases in these data do not alter the main implication of our findings. If these kind of data are collected and utilized, it is essential to plan and resource the data collection adequately and perform regular check-ups to ascertain the data are representative of the actual patient population. The most obvious way would be to prevent non-response. Even though the 15D is a self-administered survey, non-response may be reduced by motivating the medical personnel to guide and assist the patients in the baseline process. In addition, adequate time should be reserved if the questionnaires are administered on the same admission as the procedure. Furthermore, reminding the patients to fill in the follow-up questionnaire is important but also this is unlikely to lead into a full data set. Thus, it is essential to use methods such as different weighting methods to account for nonresponse when possible, or at least acknowledge that the results may not be representative of all patients and consider how this affects the results.

Author contributions:

AMT planned the research project, JHA, MH, HM collected data, SO, AMT, JHE, RPR drafted the first version on the manuscript, SO and JHE performed statistical analyses and act as guarantors, all authors revised the draft version and accepted the final manuscript.

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Disclosures

JHE, AMT, RPR, JHA, MHI, and HMI have nothing to disclose. JM is a partner of ESiOR Oy, which carries out health economic and outcome research studies for pharmaceutical and food companies.

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Legends of Tables and Figures

Table 1 Distribution of characteristics among CABG patients according to whether the baseline or both the baseline and the follow-up questionnaires were obtained from them (N=404 unless otherwise indicated).

Table 2 Distribution of characteristics among PCI patients according to whether the baseline or both the baseline and the follow-up questionnaires were obtained from them (N=738 unless otherwise indicated).

Table 3 Association between patient characteristics and loss to follow-up among those CABG patients from whom the baseline questionnaire was obtained (N=260 unless otherwise indicated).

Table 4 Association between patient characteristics and loss to follow-up among those PCI patients from whom the baseline questionnaire was obtained (N=290 unless otherwise indicated).

Figure 1 Formation of study Cohort and loss

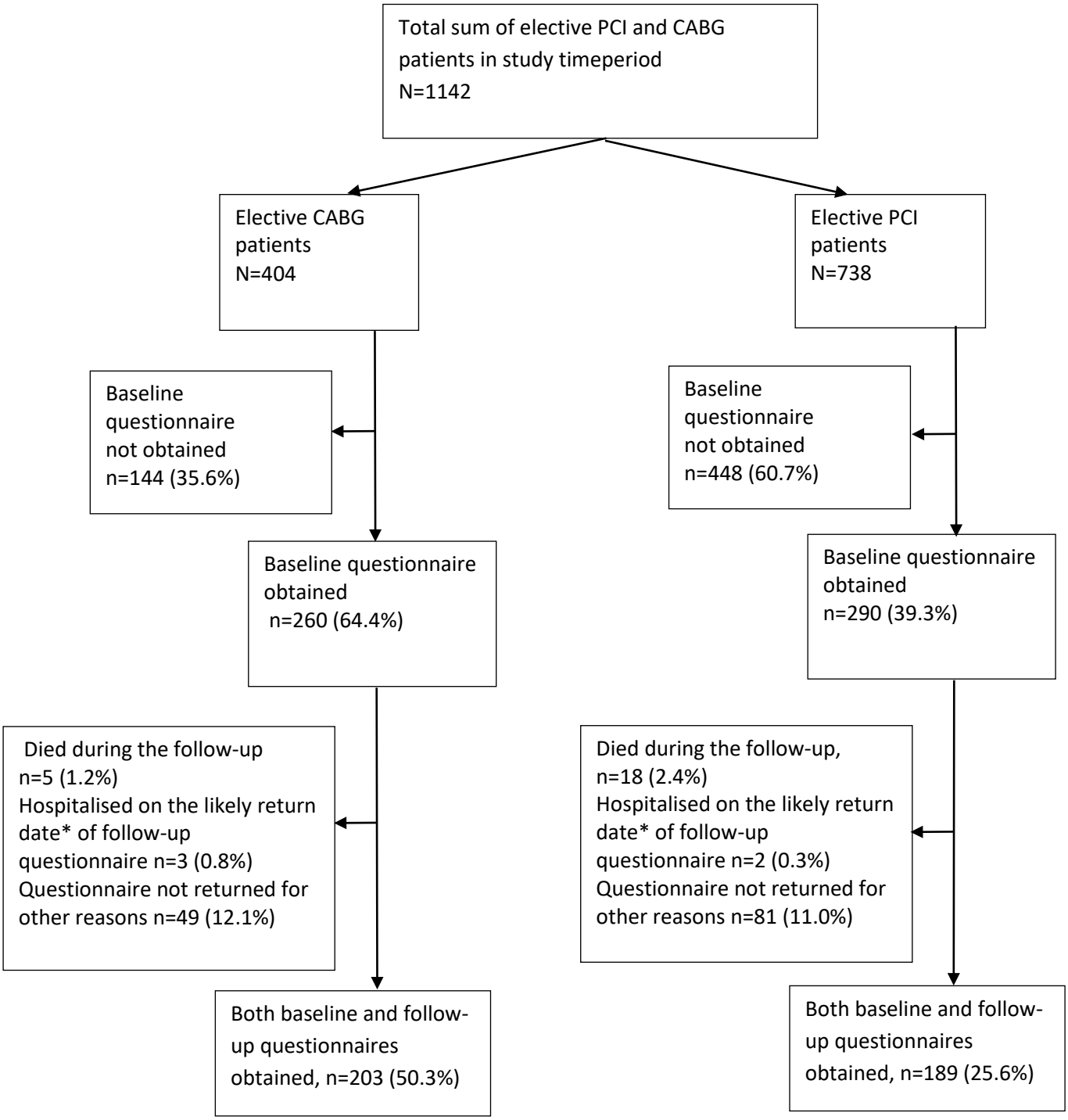

Figure 1 Formation of study Cohort and loss

* The average time lag between responses, 367.3 days (SD 13.7) for PCI and 366.4 days (SD 9.2) for CABG, was used to estimate the most likely return date.

Table 1 Distribution of characteristics among CABG patients according to whether the baseline or both the baseline and the follow-up questionnaires were obtained from them (N=404 unless otherwise indicated).

Variable	n	Baseline questionnaire obtained (%)	Baseline questionnaire not obtained (%)	OR (95 % CI) for baseline questionnaire return	n	Baseline and follow-up questionnaires obtained (%)	Baseline and follow-up questionnaires not obtained (%)	OR (95 % CI) for obtaining both questionnaires
Age								
35-65	164	113 (43.5)	51 (35.4)	1.00 (reference)	164	83 (40.9)	81 (40.3)	1.00 (reference)
66-75	172	111 (42.7)	61 (42.4)	0.82 (0.52-1.29)	172	87 (42.9)	85 (42.3)	1.00 (0.65-1.53)
76-86	68	36 (13.8)	32 (22.2)	0.51 (0.28-0.91)	68	33 (16.2)	35 (17.4)	0.92 (0.52-1.62)
Sex								
Men	329	217 (83.5)	112 (77.8)	1.00 (reference)	329	168 (82.8)	161 (80.1)	1.00 (reference)
Women	75	43 (16.5)	32 (22.2)	0.69 (0.42-1.16)	75	35 (17.2)	40 (19.9)	0.84 (0.51-1.39)
Body mass index (BMI), n=398								
<25	128	68 (26.4)	33 (23.6)	1.00 (reference)	101	54 (26.7)	47 (24.0)	1.00 (reference)
25-29.99	220	115 (44.6)	61 (43.5)	0.91 (0.54-1.54)	176	90 (44.6)	86 (43.9)	0.91 (0.56-1.49)
≥30	150	75 (29.0)	46 (32.9)	0.79 (0.45-1.38)	121	58 (28.7)	63 (32.1)	0.80 (0.47-1.36)
Smoking, n=395								
Never	232	158 (61.0)	74 (43.0)	1.00 (reference)	232	123 (61.8)	109 (55.6)	1.00 (reference)
Current/former	163	101 (39.0)	98 (57.0)	0.84 (0.58-1.20)	163	76 (38.2)	87 (44.4)	0.77 (0.52-1.16)
NYHA Class, n=403								
1	15	12 (4.6)	3 (2.1)	1.00 (reference)	15	8 (3.9)	7 (3.5)	1.00 (reference)
2	133	97 (37.3)	36 (25.2)	0.67 (0.18-2.53)	133	79 (38.9)	54 (27.0)	1.28 (0.44-3.74)
3	186	120 (46.2)	66 (46.2)	0.45 (0.12-1.67)	186	91 (44.9)	95 (47.5)	0.84 (0.29-2.41)
4	69	31 (11.9)	38 (26.6)	0.20 (0.05-0.79)	69	25 (12.3)	44 (22.0)	0.50 (0.16-1.53)
Hospital days before the operation								
1-5	62	48 (18.5)	14 (9.7)	1.00 (reference)	62	42 (20.7)	20 (10.0)	1.00 (reference)
6 -12	132	80 (30.8)	52 (36.1)	0.45 (0.23-0.89)	132	61 (30.1)	71 (35.3)	0.41 (0.22-0.77)
13-28	124	83 (31.9)	41 (28.5)	0.59 (0.29-1.19)	124	66 (32.5)	58 (28.8)	0.54 (0.29-1.03)
≥29	86	49 (18.8)	37 (25.7)	0.39 (0.19-0.80)	86	34 (16.7)	52 (25.9)	0.31 (0.16-0.62)
Baseline 15D index, n=260								

0.567-0.801	N.A	N.A	N.A	65	15 (26.3)	50 (24.6)	1.00 (reference)
0.802-0.860				65	16 (28.0)	49 (24.2)	0.94 (0.42-2.10)
0.861-0.925				65	14 (24.6)	51 (25.1)	1.07 (0.47-2.45)
0.926-1				65	12 (21.1)	53 (26.1)	1.33 (0.57-3.11)

Table 2 Distribution of characteristics among PCI patients according to whether the baseline or both the baseline and the follow-up questionnaires were obtained from them (N=738 unless otherwise indicated).

Variable	n	Baseline questionnaire obtained (%)	Baseline questionnaire not obtained (%)	OR (95 % CI) for baseline questionnaire return	n	Baseline and follow-up questionnaires obtained (%)	Baseline and follow-up questionnaires not obtained (%)	OR (95 % CI) for obtaining both questionnaires
Age, n=724								
37-65	316	136 (46.9)	180 (41.5)	1.00 (reference)	316	86 (45.5)	230 (43.0)	1.00 (reference)
66-75	249	97 (33.4)	152 (35.0)	0.84 (0.60-1.18)	249	63 (33.3)	186 (34.8)	0.91 (0.62-1.32)
76-92	159	57 (19.7)	102 (23.5)	0.74 (0.50-1.1)	159	40 (21.2)	119 (22.2)	0.90 (0.58-1.39)
Sex								
Men	548	230 (79.3)	318 (71.0)	1.00 (reference)	548	150 (79.4)	398 (72.5)	1.00 (reference)
Women	190	60 (20.7)	130 (29.0)	0.64 (0.45-0.91)	190	39 (20.6)	151 (27.5)	0.69 (0.46-1.02)
Body mass index (BMI) n=546								
<25	110	34 (19.0)	76 (27.9)	1.00 (reference)	110	26 (21.7)	84 (25.4)	1.00 (reference)
25-29.99	191	90 (50.3)	101 (37.2)	1.99 (1.22-3.27)	191	55 (45.8)	136 (41.1)	1.31 (0.76-2.24)
≥30	150	55 (30.7)	95 (34.9)	1.29 (0.77-2.18)	150	39 (32.5)	111 (33.5)	1.14 (0.64-2.01)
Smoking, n=578								
Non-smoking	309	136 (57.9)	173 (50.4)	1.00 (reference)	309	95 (59.7)	214 (51.1)	1.00 (reference)
Current/former	269	99 (42.1)	170 (49.6)	0.74 (0.53-1.04)	269	64 (40.3)	205 (48.9)	0.70 (0.49-1.02)
NYHA Class, n=729								
1	71	37 (12.9)	34 (7.7)	1.00 (reference)	71	23 (12.3)	48 (8.9)	1.00 (reference)
2	366	155 (53.8)	211 (47.9)	0.68 (0.41-1.12)	366	102 (54.5)	264 (48.7)	0.81 (0.47-1.39)
3	214	79 (27.4)	135 (30.6)	0.54 (0.31-0.92)	214	55 (29.5)	159 (29.3)	0.72 (0.40-1.29)
4	78	17 (5.9)	61 (13.8)	0.26 (0.13-0.52)	78	7 (3.7)	71 (13.1)	0.21 (0.08-0.52)
Hospital days before the operation								
0	58	35 (12.1)	23 (5.1)	1.00 (reference)	58	22 (11.6)	36 (6.6)	1.00 (reference)
1-5	166	67 (23.1)	99 (22.1)	0.44 (0.24-0.82)	166	44 (23.3)	122 (22.2)	0.59 (0.31-1.11)
6 -12	166	65 (22.4)	101 (22.6)	0.42 (0.23-0.78)	166	45 (23.8)	121 (22.0)	0.61 (0.32-1.14)
13-28	167	63 (21.7)	104 (23.2)	0.4 (0.22-0.73)	167	37 (19.6)	130 (23.7)	0.47 (0.24-0.89)
≥29	181	60 (20.7)	121 (27.0)	0.33 (0.18-0.60)	181	41 (21.7)	140 (25.5)	0.48 (0.25-0.90)

Baseline 15D index (n=290)							
0.605-0.773	N.A	N.A	N.A	73	51 (27.0)	22 (21.8)	1.00 (reference)
0.774-0.852				72	48 (25.4)	24 (23.7)	0.86 (0.43-1.74)
0.853-0.907				73	49 (25.9)	24 (23.8)	0.88 (0.44-1.77)
0.908-1				72	41 (21.7)	31 (30.7)	0.57 (0.29-1.13)

Table 3 Association between patient characteristics and loss to follow-up among those CABG patients from whom the baseline questionnaire was obtained (N=260 unless otherwise indicated).

Variable	n	Baseline questionnaire obtained (%)	Both questionnaires obtained (%)	OR (95 % CI) for follow-up questionnaire return
Age				
35-65	113	30 (52.6)	83 (40.9)	1.00 (reference)
66-75	111	24 (42.1)	87 (42.9)	1.31 (0.71-2.42)
76-86	36	3 (5.3)	33 (16.2)	3.98 (1.14-13.93)
Sex				
Men	217	49 (86.0)	168 (82.8)	1.00 (reference)
Women	43	8 (14.0)	35 (17.2)	1.28 (0.56-2.93)
Body mass index (BMI), n=258				
<25	68	14 (25.0)	54 (26.7)	1.00 (reference)
25-29.99	115	25 (44.6)	90 (44.6)	0.93 (0.45-1.95)
≥30	75	17 (30.4)	58 (28.7)	0.88 (0.40-1.97)
Smoking, n=256				
Non-smoking	158	35 (61.4)	123 (61.8)	1.00 (reference)
Current/former	98	22 (38.6)	76 (38.2)	0.98 (0.54-1.80)
NYHA Class				
1	12	4 (7.0)	8 (3.9)	1.00 (reference)
2	97	18 (31.6)	79 (38.9)	2.19 (0.60-8.09)
3	120	29 (50.9)	91 (44.9)	1.57 (0.44-5.59)
4	31	6 (10.5)	25 (12.3)	2.08 (0.47-9.29)
Hospital days before the operation				
1-5	48	6 (10.5)	42 (20.7)	1.00 (reference)
6 -12	80	19 (33.3)	61 (30.1)	0.46 (0.17-1.24)
13-28	83	17 (29.8)	66 (32.5)	0.55 (0.20-1.52)
≥29	49	15 (26.4)	34 (16.7)	0.32 (0.11-0.92)
Baseline 15D index, n=260				
0.567-0.801	65	15 (26.3)	50 (24.6)	1.00 (reference)
0.802-0.860	65	16 (28.1)	49 (24.2)	0.94 (0.42-2.10)
0.861-0.925	65	14 (24.5)	51 (25.1)	1.07 (0.47-2.45)
0.926-1	65	12 (21.1)	53 (26.1)	1.33 (0.57-3.11)

Table 4 Association between patient characteristics and loss to follow-up among those PCI patients from whom the baseline questionnaire was obtained (N=290 unless otherwise indicated).

Variable	n	Baseline questionnaire obtained (%)	Both questionnaires obtained (%)	OR (95 % CI) for follow-up questionnaire return
Age				
37-65	136	86 (45.5)	50 (49.5)	1.00 (reference)
66-75	97	63 (33.3)	34 (33.7)	1.08 (0.63-1.86)
76-92	57	40 (21.2)	17 (16.8)	1.37 (0.70-2.66)
Sex				
Men	230	150 (79.4)	80 (79.2)	1.00 (reference)
Women	60	39 (20.6)	21 (20.8)	0.99 (0.55-1.80)
Body mass index (BMI) n=179				
<25	34	26 (21.7)	8 (13.6)	1.00 (reference)
25-29.99	90	55 (45.8)	35 (59.3)	0.48 (0.20-1.19)
≥30	55	39 (32.5)	16 (27.1)	0.75 (0.28-2.00)
Smoking, n=235				
Non-smoking	136	95 (59.7)	41 (53.9)	1.00 (reference)
Current/former	99	64 (40.3)	35 (46.1)	0.79 (0.45-1.37)
NYHA Class, n=288				
1	37	23 (12.3)	14 (13.9)	1.00 (reference)
2	155	102 (54.6)	53 (52.5)	1.17 (0.56-2.46)
3	279	55 (29.4)	24 (23.7)	1.39 (0.61-3.17)
4	317	7 (3.7)	10 (9.9)	0.43 (0.13-1.38)
Hospital days before the operation				
0	35	22 (11.6)	13 (12.9)	1.00 (reference)
1-5	67	44 (23.3)	23 (22.8)	1.13 (0.48-2.65)
6 -12	65	45 (23.8)	20 (19.8)	1.33 (0.56-3.16)
13-28	63	37 (19.6)	26 (25.7)	0.84 (0.36-1.97)
≥29	60	41 (21.7)	19 (18.8)	1.28 (0.53-3.06)
Baseline 15D index				
0.605-0.773	73	51 (27.0)	22 (21.7)	1.00 (reference)
0.774-0.852	72	48 (25.4)	24 (23.8)	0.86 (0.43-1.74)
0.853-0.907	73	49 (25.9)	24 (23.8)	0.88 (0.44-1.77)
0.908-1	72	41 (21.7)	31 (30.7)	0.57 (0.29-1.13)