



Quality of life after coronary revascularization in the elderly

Michelle M. Graham^{1*}, Colleen M. Norris^{1,2}, P. Diane Galbraith⁶, Merrill L. Knudtson^{3,5}, and William A. Ghali^{3,4,6} for the APPROACH Investigators[†]

¹Division of Cardiology, Department of Medicine, University of Alberta Hospital, 8440-112 Street, Edmonton, Alberta, Canada T6G 2R7; ²Faculty of Nursing, University of Alberta, Alberta, Canada; ³the Department of Medicine, University of Calgary, Calgary, Canada; ⁴Community Health Sciences, University of Calgary, Calgary, Canada; ⁵The Libin Cardiovascular Institute, University of Calgary, Calgary, Canada; and ⁶Centre for Health and Policy Studies, University of Calgary, Calgary, Canada

Received 14 July 2005; revised 31 March 2006; accepted 28 April 2006; online publish-ahead-of-print 22 May 2006

See page 1642 for the editorial comment on this article (doi:10.1093/eurheartj/ehl111)

KEYWORDS

Aging;
Revascularization;
Coronary disease;
Morbidity

Aims To describe health status outcomes at 4 years for a cohort of elderly patients with cardiac disease. **Methods and results** Using the Alberta Provincial Project for Outcomes Assessment in Coronary Heart Disease, an outcomes initiative capturing all patients undergoing cardiac catheterization in Alberta, Canada, health status was measured using the Seattle Angina Questionnaire (SAQ) and crude and risk-adjusted outcomes were determined and compared for patients treated with percutaneous coronary intervention or coronary artery bypass surgery (CABG) vs. medical therapy. Response rates among surviving, consenting patients were 64.8% for patients <70 years ($n = 7883$), 77.3% for patients aged 70–79 years ($n = 2940$), and 77.7% for patients ≥ 80 years of age ($n = 439$). For patients aged <70 years, and those aged 70–79 years, for all dimensions of the SAQ, scores were significantly better for patients treated with revascularization procedures than with medical therapy. For patients over the age of 80 years, scores for patients treated with CABG in particular were significantly better, with the exception of exertional capacity. At 3 years, all scores remained stable or improved, and continued to favour revascularization.

Conclusion Elderly patients undergoing revascularization have better health status at 4 years than do those in the same age group who do not undergo revascularization. These findings suggest that age should not deter against revascularization given the combined survival and quality-of-life benefits.

Introduction

The high burden of coronary artery disease (CAD) in the elderly combined with reports of poor outcomes following coronary artery bypass graft surgery (CABG) or percutaneous coronary intervention (PCI) have led to some uncertainty as to whether these procedures should be routinely offered to elderly patients.¹ More recently, however, significantly improved outcomes associated with revascularization procedures have been noted in both a small, randomized trial² and a large observational study.³

The impact of a revascularization procedure on health status is as (or more) important than survival, particularly with elderly patients. In the only randomized trial of revascularization vs. medical therapy in the elderly (the TIME trial), significant improvements were noted in terms of both symptom relief and quality-of-life at 6 months following a revascularization procedure.² Although TIME is important, it remains a small randomized trial with uncertain

general applicability. Findings from a large, population-based cohort can complement the TIME results by demonstrating robust conclusions in a usual-care setting. We recently reported the long-term survival outcomes of a large series of 21 573 patients treated with PCI, CABG, or medical therapy.³ Among these, 6181 patients were over the age of 70. We found that these elderly patients have greater absolute risk reductions associated with revascularization than do younger patients.³ The large, population-based clinical registry used to evaluate the mortality benefit of revascularization also contains health status outcome assessments that are completed over the duration of follow-up. The purpose of the present investigation was to examine the detailed health status outcomes at 4 years following cardiac catheterization in this same cohort of patients.

Methods

The Alberta Provincial Project for Outcomes Assessment in Coronary Heart Disease (APPROACH) is a clinical data collection initiative capturing all patients undergoing cardiac catheterization in the

* Corresponding author. Tel: +1 780 407 1590; fax: +1 780 407 1496.

E-mail address: mmgraham@cha.ab.ca

[†]APPROACH Project Office (PDG), Calgary, Edmonton, Canada.

province of Alberta, Canada since 1995.⁴ APPROACH contains detailed clinical information including patients' age, sex, ejection fraction (EF), and the presence or absence of previous myocardial infarction (MI), congestive heart failure, diabetes, cerebrovascular disease, peripheral vascular disease, chronic pulmonary disease, elevated creatinine, dialysis, hyperlipidaemia, hypertension, liver or gastrointestinal disease, or malignancy. Furthermore, the APPROACH registry tracks therapeutic interventions such as previous thrombolytic therapy and previous or subsequent revascularization by CABG or PCI. Coronary anatomy is also recorded. Follow-up mortality is ascertained through semi-annual linkage to data from the Alberta Bureau of Vital Statistics.

Health status data in APPROACH are collected by means of a self-reported questionnaire that includes the Seattle Angina Questionnaire (SAQ). The SAQ is a 19-item self-administered disease-specific questionnaire measuring five dimensions of health status: exertional capacity, anginal stability, anginal frequency, quality-of-life, and treatment satisfaction, generating five independent scales. Each question is measured on an ordinal scale from 1 to 5 (6 for the anginal frequency scale), with 1 indicating the lowest/poorest response. On the basis of the results of validity, responsiveness, and reliability testing, the SAQ has been judged to be a valid, responsive, and reliable instrument. The SAQ is sensitive to clinical changes in a patient's cardiac status, in which it focuses on symptoms and impairments in health that are unique to coronary disease.^{5,6}

Patients registered in APPROACH who have CAD documented at the time of index catheterization and who consent to being contacted are sent the follow-up survey around the 1, 3, and 5 year anniversaries of their index cardiac catheterization. The completed questionnaire can be returned by mail, or patients may call a toll-free line and respond to the verbally administered questionnaire, which is recorded and transcribed daily. A second questionnaire is sent to non-respondents, 14 months post-catheterization with the same options for completion. Finally, at 16 months post-catheterization, a third reminder is sent to non-responders. Similar efforts are used to ensure response to the 1- and 3-year surveys.

Statistical analysis

This cohort consisted of all patients undergoing cardiac catheterization from 1 January 1995 to 31 December 1998, excluding those undergoing investigation for valvular heart disease, those without CAD on angiography, and those who did not consent to follow-up. For the purposes of these analyses, patients were divided into three age categories: <70 years, 70–79 years, and ≥80 years of age. Patient characteristics among the three age groups were compared using χ^2 tests.

The SAQ is scored by assigning each response an ordinal value, beginning with 1 for the response that implies the lowest level of functioning, and ending with 5 (6 for the anginal frequency scale) for the response that implies the highest level of functioning. The responses are then summed across items within each of the five-dimensional scales. As suggested by the developers, scale scores are then transformed to a 0–100 range by subtracting the lowest possible score, dividing by the range of the scale and multiplying by 100.⁶ As each of the scales monitor a unique dimension of CAD, no summary score is generated. The crude mean SAQ dimensional scores were compared between age groups using analysis of variance, and illustrated using box plots by treatment strategy. Treatment received is defined as the occurrence of any revascularization procedure within a year after catheterization. Procedures occurring after 1 year were not considered to be the 'assigned' therapy, as those would generally tend to be procedures occurring beyond a typical waiting period, and thus representative of a new treatment decision taken after, typically, new problems arise. Three-year results were also analyzed according to initial treatment received.

General linear modelling was used controlling for the patients' sex, coronary anatomy, EF, and the presence or absence of previous myocardial infarction (MI), congestive heart failure, diabetes, cerebrovascular disease, peripheral vascular disease, chronic pulmonary disease, elevated creatinine, dialysis, hyperlipidaemia, hypertension, liver or gastrointestinal disease, or malignancy. Treatment modality was then used to compare adjusted mean-dimensional SAQ scores between age groups.⁷ A previous methodological comparison of potential multivariable modelling strategies for ordinal derived quality-of-life data has revealed that linear regression performs well despite the non-linear distribution of health status scores.⁸ This technique was therefore used for this multivariable analysis, with separate models developed for each of the five SAQ dimensions at 4 years. Two-sided tests were used for comparisons between groups.

We also performed a sensitivity analysis for which we used an ordinal regression analysis to compare quality-of-life scores between revascularization and medical therapy groups, while controlling for baseline severity of illness.

Results

A total of 21 573 patients underwent catheterization for CAD between 1 January 1995 and 31 December 1998. Of these, 15 392 patients were <70 years, 5198 patients were between 70 and 79 years, and 983 patients were ≥80 years of age. As described in the flowchart seen in *Figure 1*, by 1 year there were 7883 respondents <70 years, 2940 between 70 and 79 years, and 439 ≥80 years of age after exclusion of deaths, non-consenting patients and those without documented CAD. Total survey response rates among surviving, consenting patients were thus 64.8% for eligible patients <70 years, 77.3% for patients aged 70–79 years, and 77.7% for patients ≥80 years of age. *Table 1* provides a summary of the clinical characteristics of the three age groups, according to treatment strategy. Elderly patients were more likely to have associated comorbidities such as cerebrovascular disease, peripheral vascular disease, hypertension, and diabetes. Older patients also had more urgent indications for catheterization and had more severe CAD. Patients who did not respond to the survey were more likely to be male, have diabetes, and be treated with medical therapy.

Figure 2 presents the box plots that depict the unadjusted 1 year SAQ score distributions by age category and treatment strategy. For patients <70 years of age and those aged 70–79 years, patients treated with PCI or CABG tended to have better crude SAQ scores than those treated medically, as evidenced by higher median scores in revascularized patients. For patients aged ≥80 years of age, crude scores were significantly better for CABG.

Table 2 shows risk-adjusted SAQ dimensional scores at 1 year for the three age groups, according to first treatment received (medical therapy, CABG, or PCI). For patients aged <70 years, and those aged 70–79 years, for all dimensions of the SAQ, scores were significantly better for patients treated with revascularization procedures than with medical therapy. For patients over the age of 80 years, scores for patients treated with CABG in particular were significantly better, with the exception of exertional capacity. In addition, for all the three ages groups, scores were generally better for patients treated with CABG than with PCI ($P < 0.001$ for all pair-wise PCI vs. CABG comparisons, with the exception of exertional capacity in the two older age groups).

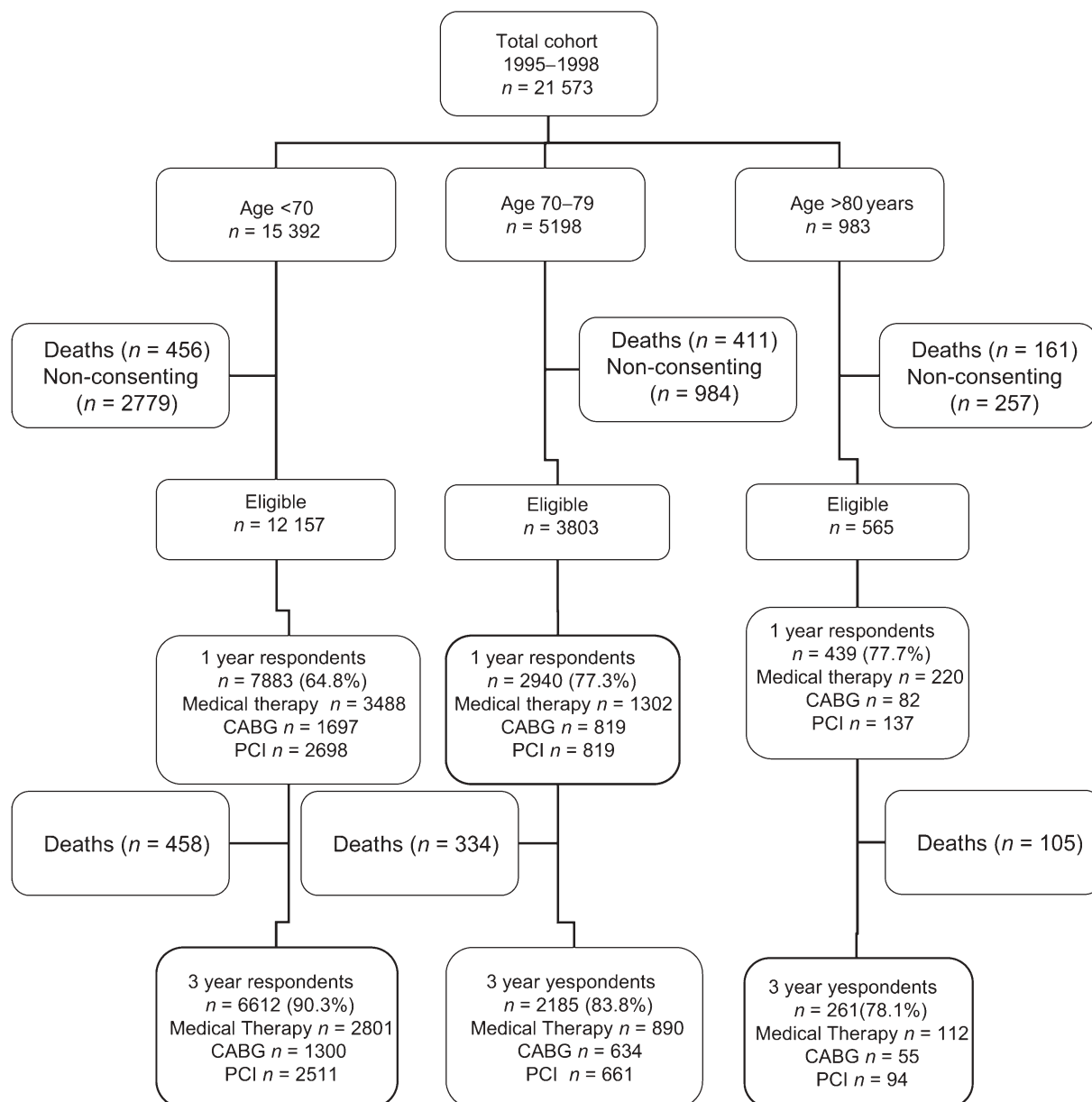


Figure 1 Flowchart illustrating the final cohort of patients at 1 year.

By 3 years, questionnaires were available for 6612 patients of <70 years, 2185 patients of 70–79 years, and 261 patients of ≥ 80 years of age. Of these, only 143 patients aged <70 years, 44 patients aged 70–79, and none of the patients ≥ 80 years of age who were initially treated medically, subsequently received revascularization procedures. In addition, 31 patients aged <70 years, 21 patients aged 70–79 years, and none of the patients ≥ 80 years of age who were initially treated with revascularization underwent repeat revascularization procedures. Figure 3 presents the boxplots of the unadjusted 3-year SAQ scores. Crude scores were superior for both CABG and PCI when compared with medical therapy in the two younger age groups, but only CABG was superior in the oldest age group. Table 3 demonstrates the risk-adjusted SAQ scores for these patients, and shows that comparisons of revascularization

procedures vs. medical therapy favoured revascularization in patients aged <70 years, and those 70–79 years of age, and CABG in particular in those aged >80 years, with CABG patients again having higher scores than PCI patients in all dimensions except exertional capacity.

Repeat multivariable analysis of the SAQ scores using ordinal regression yields qualitatively similar findings, as shown in Table 4. Proportional odds ratios (OR) above 1.0 reflect a better odds of having higher scores on the ordinal rating scales that comprise the SAQ. The consistent finding of proportional OR above 1.0 for all subscales and across all age groups indicates that revascularization is associated with better health status as defined by the SAQ subscales. (The wider CI seen in those aged >80 years reflect the smaller number of patients in that age group, but the magnitude of the OR is comparable across age groups.)

Table 1 Baseline characteristics

	Age <70				Age 70–79				Age ≥80			
	Med n = 3488	CABG n = 1697	PCI n = 2698	P	Med n = 1302	CABG n = 819	PCI n = 819	P	Med n = 220	CABG n = 82	PCI n = 137	P
Median Age (years)	59.2	61.6	59.1		73.9	73.6	73.9		82.4	81.8	82.1	
Sex (% Female)	31.1	16.1	21.6	<0.001	37.3	22.8	31.9	<0.001	34.5	25.6	43.8	0.022
EF (%)				<0.001				<0.001				0.673
<20	1.8	0.4	0.3		1.2	0.4	1.0		0.5	0	0.7	
20–34	5.8	7.2	3.0		9.2	7.8	5.4		11.4	6.1	5.8	
35–50	18.1	25.6	18.5		19.7	28.9	19.5		18.2	20.7	20.4	
>50	61.7	56.0	64.5		55.1	50.1	61.5		50.9	57.3	54.0	
LV not done	0.6	0.8	1.1		1.2	0.5	1.0		1.4	1.2	0.0	
Unknown	12.1	9.8	12.6		13.6	12.3	11.6		17.7	14.6	19.0	
CHF (%)	12.0	10.4	6.3	<0.001	19.4	18.2	15.0	0.034	21.4	26.8	25.5	0.505
PVD (%)	5.9	6.6	4.0	<0.001	8.8	11.2	8.7	0.117	13.2	13.4	8.8	0.403
COPD (%)	7.6	6.5	5.2	0.001	9.8	11.0	10.0	0.665	13.2	6.1	11.7	0.225
CVD (%)	4.4	4.2	3.6	0.245	7.4	9.5	6.7	0.081	12.7	12.2	8.0	0.370
Creatinine >200 mmol/L	1.5	2.1	1.3	0.099	1.6	2.7	1.7	0.160	4.1	1.2	2.2	0.345
Diabetes (%)	15.8	21.7	14.0	<0.001	17.2	19.4	17.0	0.337	20.5	19.5	19.7	0.977
Hypertension (%)	47.1	52.5	47.1	0.001	43.8	42.1	43.7	0.784	55.9	58.5	50.4	0.280
Hyperlipidaemia (%)	42.5	53.2	51.0	<0.001	33.4	40.9	36.9	0.002	22.3	24.4	29.9	0.265
Malignancy (%)	2.5	2.2	2.5	0.840	5.1	5.3	6.3	0.421	9.5	4.9	5.8	0.262
Previous CABG (%)	9.3	4.8	6.0	<0.001	16.6	8.7	10.4	<0.001	11.4	3.7	14.6	0.041
Previous PCI (%)	10.4	10.1	13.5	<0.001	11.5	9.9	17.6	<0.001	9.5	8.5	15.3	0.170
Previous MI (%)	42.8	49.6	54.9	<0.001	47.7	54.7	57.4	<0.001	53.2	46.3	63.5	0.034
Prior lytic (%)	9.2	10.3	16.8	<0.001	6.3	7.4	15.6	<0.001	5.9	3.7	14.6	0.004
Indication (%)				<0.001				<0.001				0.170
Stable angina	39.1	38.6	27.6		37.0	31.9	26.0		32.7	30.5	19.0	
Unstable angina	23.4	31.3	31.0		28.1	35.8	34.2		32.7	36.6	40.1	
MI	16.1	22.2	35.4		16.5	21.2	32.8		24.5	15.9	31.4	
Other	20.6	7.9	6.0		17.8	11.1	7.0		10.02	17.1	9.5	
Coronary anatomy (%)				<0.001				<0.001				<0.001
Minimal CAD	40.2	0.8	0.8		25.8	0.7	0.5		17.4	0.0	0.0	
1–2 vessel	19.25	2.5	32.9		19.1	2.9	21.2		13.7	1.5	13.0	
2 vessel + pLAD	19.3	19.1	42.1		21.5	16.2	43.9		18.6	16.2	36.6	
3 vessel	9.9	23.3	14.9		15.2	22.8	18.7		19.9	23.5	20.3	
3 vessel + pLAD	7.2	28.5	7.1		12.4	28.2	12.5		16.1	25.0	26.0	
LM	2.7	24.4	1.6		4.9	27.3	2.2		11.8	32.4	3.3	
Unknown	1.5	1.4	1.0		1.1	1.8	0.9		2.5	1.5	0.8	

P-values refer to differences across groups.

Discussion

We have demonstrated significantly better health status (as measured by the SAQ in our population of elderly patients) associated with revascularization procedures when compared with medical therapy, at both 1 and 3 years following catheterization. Although improvements in health status parameters at 3 years following cardiac catheterization are also noted in those patients initially treated medically (particularly in the oldest subgroup), in general, revascularized patients continue to report better health status scores relative to those treated medically.

The initial 6-month results from the TIME trial demonstrated that elderly patients treated with an invasive approach had significantly greater improvements in quality-of-life as measured by the SF-36, the Duke activity score index (DASI), and the Rose questionnaire for angina. Major adverse cardiac event rates were also reduced when compared with those treated with optimized medical therapy.² By 1 year, however, there were improvements in quality-of-life for both patient groups, and the early

difference favouring the invasive treatment arm disappeared. The incidence of death or non-fatal myocardial infarctions were also similar, but overall major adverse cardiac event rates (primarily driven by rehospitalization and need for late revascularization) were higher in medically treated patients. Improvements in quality-of-life in the group receiving optimized medical therapy were felt to be due to late revascularization procedures, which occurred in 46% of these patients.⁹ In our patient population, however, only 44 patients aged 70–79 years (and none of those patients 80 years or older) who were initially treated medically were subsequently revascularized. Therefore, any improvements in health status noted after 1 year may be associated with medical therapy, rather than a 'cross-over' effect (to revascularization) noted in the TIME follow-up analysis.⁹

A number of studies have reported significant improvements in quality-of-life in elderly patients undergoing CABG or PCI.^{10–13} However, few studies have also evaluated quality-of-life over time. Yun *et al.* followed 604 patients over the age of 65, administering the Health Status

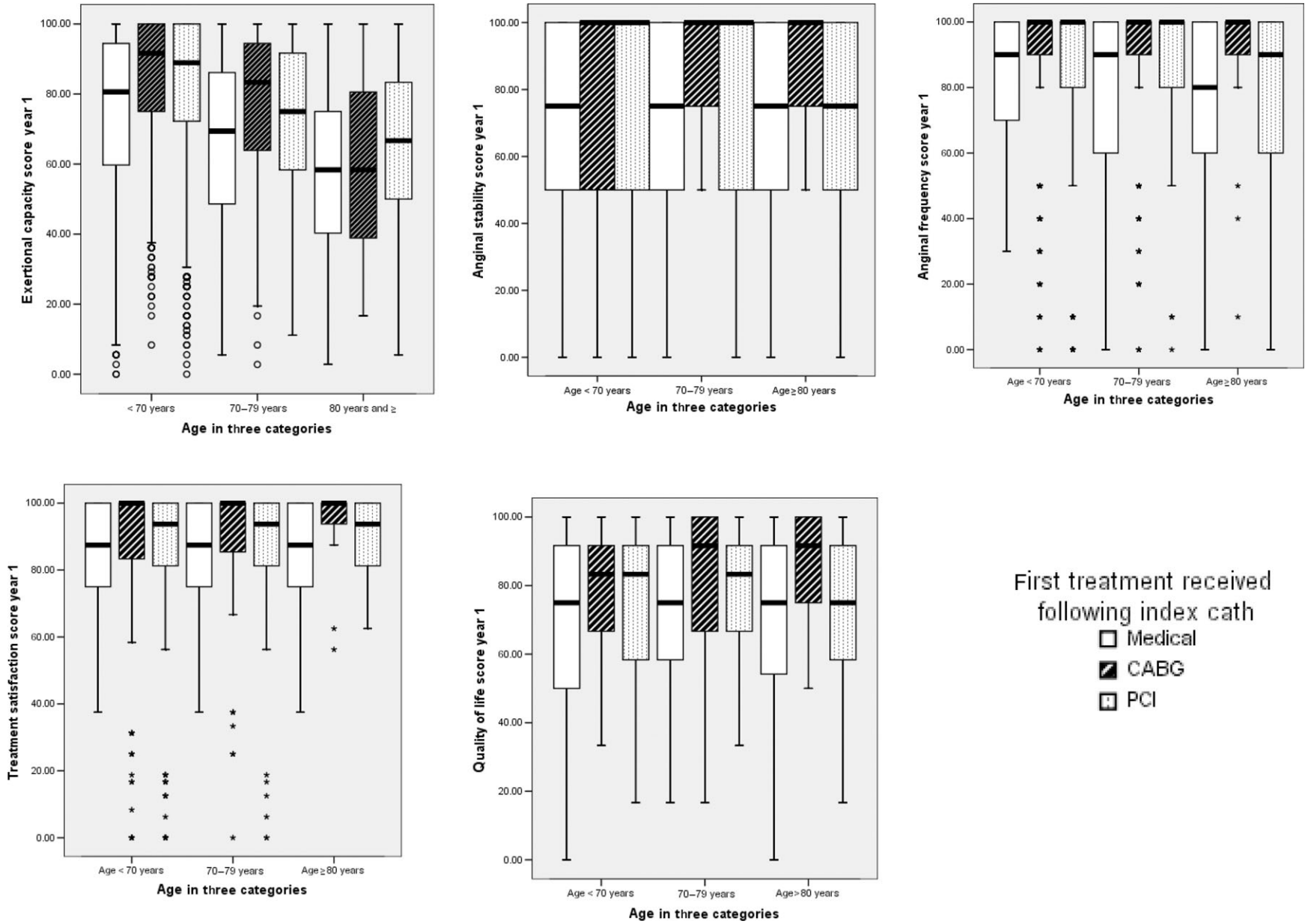


Figure 2 Boxplots illustrating the distributions of 1 year crude SAQ scores, by age and treatment category. The central line of the box plot presents the median, whereas the end of the box indicates the 25th and 75th percentile values. The extending stem indicates the 5th and 95th percentiles, and additional points present outlier observations.

Table 2 Risk-adjusted Seattle Angina Questionnaire Dimensional Scores and 95% CI at 1 year for the three age groups

	Exertional capacity	Angina stability	Angina frequency	QoL	Treatment satisfaction
Age <70 years (n = 7883)					
Medical therapy	72.8	75.3	84.1	71.1	84.4
(n = 3344)	72.4, 73.1	75.1, 75.4	83.9, 84.3	70.9, 71.2	84.3, 84.5
CABG	74.2	78.6	86.2	73.3	86.9
(n = 1529)	73.7, 74.7	78.4, 78.8	85.9, 86.4	73.5, 73.9	86.8, 87.0
PCI	74.9	76.7	85.4	72.5	85.5
(n = 2826)	74.5, 75.3	76.6, 76.9	85.2, 85.6	72.4, 72.7	85.4, 85.6
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Age 70–79 years (n = 2940)					
Medical therapy	62.1	77.0	83.0	74.9	86.3
(n = 1085)	61.4, 62.8	76.7, 77.3	82.7, 83.3	74.6, 75.2	86.2, 86.5
CABG	63.3	80.5	85.5	77.3	88.6
(n = 731)	64.4, 64.2	80.2, 80.9	85.7, 83.7	76.9, 77.6	88.4, 88.8
PCI	63.2	78.2	84.0	75.8	87.1
(n = 782)	62.4, 64.1	77.9, 78.6	83.6, 84.4	75.5, 76.1	86.9, 87.3
P	0.040	<0.0001	<0.0001	<0.0001	<0.0001
Age ≥80 years (n = 439)					
Medical therapy	51.9	75.0	79.9	73.5	87.9
(n = 152)	50.0, 53.9	74.4, 75.7	79.1, 80.7	72.8, 74.2	87.5, 88.3
CABG	53.7	78.1	82.2	75.3	89.6
(n = 66)	50.7, 56.7	77.1, 79.2	81.0, 83.4	74.3, 76.4	89.0, 90.2
PCI	51.9	74.7	79.3	72.9	88.0
(n = 118)	49.9, 54.0	73.9, 75.5	78.4, 80.2	72.1, 73.8	87.6, 88.5
P	0.590	<0.0001	0.001	0.003	<0.0001

P-values refer to differences across groups.

Questionnaire (HSQ) at 3, 12, and 24 months following elective CABG. There were significant quality-of-life improvements in all eight categories assessed by the HSQ, which peaked at 12 months. By 2 years, measures relating to physical health and health perception had declined. Scores for mental attributes, however, increased over time.¹⁴ In a study of high-risk patients with medically refractory ischaemia randomized to PCI or CABG, Rumsfeld *et al.* noted no difference in quality-of-life between these groups at 6 months.¹⁵ However, in a prospective Swedish study of 601 chronic stable angina patients with one- or two-vessel coronary disease, Brorsson *et al.* administered questionnaires at 6, 21, and 48 months following PCI or CABG. Functional status and well-being improved for all patients throughout the study, generally to a greater extent in those patients treated with CABG.¹⁶ This study was not specific to elderly patients, but it is consistent with our findings of better SAQ dimensional scores in patients treated with revascularization procedures, particularly CABG.

In our study, approximately 32% of the overall patient cohort did not respond to the 1 year follow-up survey. In all three age groups, but particularly among the oldest patients, non-responders were more likely to have received medical therapy (age <70 = 54.9%; age 70–79 = 50.3%, age >80 = 59.6% of non-responders). While it is possible that they failed to respond because their quality-of-life was excellent, previous research suggests that non-responders may in fact be more ill and less willing to complete the questionnaire.^{17,18} Therefore, had they responded, our results favouring improved quality-of-life with revascularization might have been even more marked than was seen. This would also be the case if we had included those patients

who died in the analysis, as we have previously shown that survival was better in elderly patients undergoing revascularization procedures.³ However, the SAQ is not designed to include death in the assessment of health status.

In the population of patients aged 70–79 at 3 years after the index catheterization, and those aged 80 years or more, at both 1 and 3 years, there was no difference in the perception of exertional capacity. The SAQ scores the exertional capacity dimension with a series of nine questions, with the final three questions relating to running or jogging; ability to lift or move heavy objects; and participating in strenuous sports such as swimming or tennis. Similar to the observations of Garratt *et al.*,¹⁹ we found that these three questions had a large number of patients who either failed to complete the question or responded that they were 'limited or did not do for other reasons'. This response is treated as missing data in the computation of the scale score, resulting in a relatively large number of respondents without a cumulative score for the exertional capacity dimension. Furthermore, there was a significant association between the respondents' age category and the percentage of missing data for the final three questions of the exertional capacity dimension. These questions were not typically answered by the very elderly patients in our cohort, who check instead the 'limited for other reason or do not do activity' category (Running = age <70 years 27.2% missing, age 70–79 years 34.7% missing, and age ≥80 years 36.4% missing, $P < 0.001$). This dimension, then, will only represent the results of the 'healthiest' (most active) group of elderly patients, regardless of treatment, and therefore may underestimate the true difference between the medical therapy and revascularization groups.

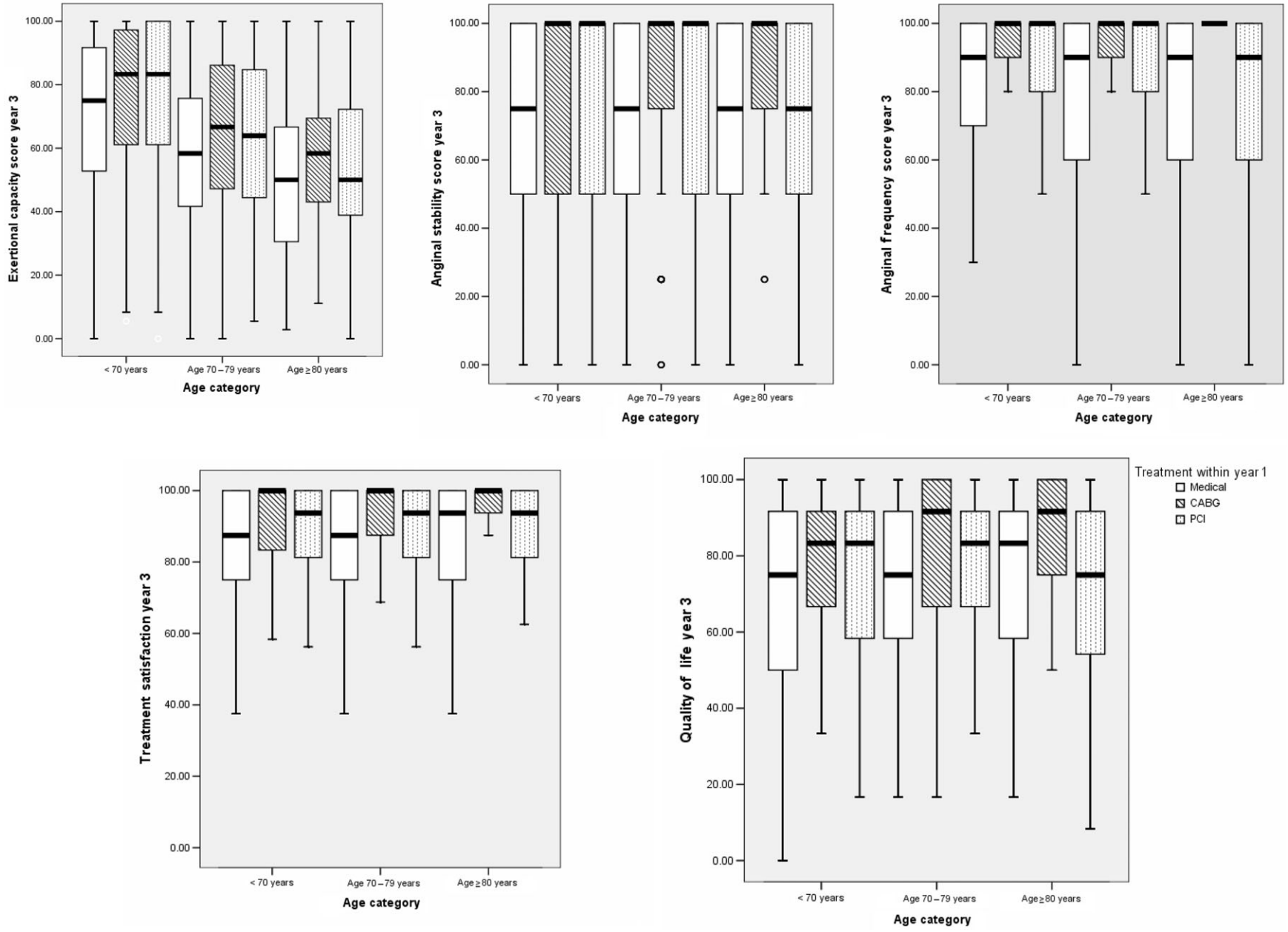


Figure 3 Boxplots illustrating the distributions of 3 year crude SAQ scores, by age and treatment category. The central line of the box plot presents the median, whereas the end of the box indicates the 25th and 75th percentile values. The extending stem indicates the 5th and 95th percentiles, and additional points present outlier observations.

Table 3 Risk-Adjusted Seattle Angina Questionnaire Dimensional Scores and 95% CI at 3 years for the three age groups

	Exertional capacity	Angina stability	Angina frequency	QoL	Treatment satisfaction
Age <70 years (n = 6612)					
Medical therapy	73.5	74.9	84.6	71.6	84.8
(n = 2801)	73.1, 73.8	74.7, 75.0	84.4, 84.7	71.5, 71.8	84.7, 84.9
CABG	74.7	78.1	86.6	74.0	87.1
(n = 1300)	74.2, 75.3	77.9, 78.3	86.3, 86.8	73.8, 74.2	87.0, 87.3
PCI	75.5	76.2	85.8	73.0	85.9
(n = 2511)	75.2, 75.9	76.1, 73.4	85.7, 86.0	72.8, 73.1	85.8, 86.0
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Age 70–79 years (n = 2185)					
Medical therapy	62.2	76.7	83.6	75.1	86.6
(n = 890)	61.4, 63.0	76.4, 76.9	83.3, 83.9	74.8, 75.4	86.5, 86.8
CABG	62.9	80.0	85.9	77.4	88.9
(n = 634)	62.0, 63.9	79.7, 80.4	85.5, 86.3	77.0, 77.7	88.7, 89.1
PCI	63.1	77.8	84.5	76.0	87.4
(n = 661)	62.2, 64.0	77.5, 78.1	84.1, 84.9	75.6, 76.3	87.2, 87.6
P	0.261	<0.0001	<0.0001	<0.0001	<0.0001
Age ≥80 years (n = 261)					
Medical therapy	53.8	76.8	81.2	74.2	88.3
(n = 112)	51.5, 56.4	76.1, 77.6	80.4, 82.1	73.5, 75.0	87.8, 88.7
CABG	54.2	80.3	83.8	76.2	90.1
(n = 55)	50.9, 57.4	79.3, 81.3	82.6, 85.0	75.1, 77.4	89.5, 90.8
PCI	53.3	76.9	81.0	73.9	88.7
(n = 94)	50.9, 55.7	76.1, 77.7	80.1, 81.9	73.1, 74.8	88.2, 89.1
P	0.893	<0.001	0.001	0.004	<0.001

P-values refer to differences across groups.

Table 4 Results of ordinal regression sensitivity analysis with proportional OR and 95% CI for Seattle Angina Questionnaire Dimensions for Revascularization compared with medical therapy

	Age <70 years	Age 70–79 years	Age ≥80 years
Exertional capacity	1.48 (1.32, 1.66)	1.45 (1.20, 1.76)	1.79 (1.04, 3.10)
Anginal frequency	1.70 (1.51, 1.90)	1.97 (1.63, 2.40)	2.03 (1.24, 3.32)
Anginal stability	1.80 (1.64, 1.99)	2.16 (1.82, 2.55)	1.86 (1.19, 2.88)
Quality of life	1.56 (1.41, 1.73)	1.69 (1.42, 2.02)	1.70 (1.07, 2.71)
Treatment satisfaction	1.77 (1.55, 2.02)	1.96 (1.53, 2.50)	1.62 (0.79, 3.36)

There are limitations to this study. This is not a randomized trial capable of providing an unbiased assessment of treatment effects. It is possible that unmeasured factors such as mental status, nutritional status, other diseases adversely affecting surgical risk, and patient refusal influenced the choice of treatment strategy. Also, we lack baseline health status assessments collected at the time of cardiac catheterization, a limitation made clear by recent work demonstrating that baseline health status (as measured by the SAQ) is an important predictor of outcomes at 1 year in patients with coronary disease.²⁰ For practical reasons, however, it has not been possible to gather baseline QoL data in the large collective of patients captured in the APPROACH database. This is because patients frequently arrive to the catheterization laboratory in urgent circumstances that make it difficult or impossible to collect health status information prior to catheterization. Furthermore, for many of these urgent cases, the concept of 'baseline health status' as measured by the SAQ is difficult to characterize given that a substantial proportion (specifically, those presenting with *de novo* acute coronary

syndromes) will have had no coronary disease history and no related coronary disease symptoms prior to the onset of the acute coronary syndrome that precipitates urgent catheterization. Meanwhile, many elective 'non-urgent' patients are catheterized as outpatients, and are thus not 'captive' patients who can be approached later in a hospital room to complete QoL questionnaires. The most notable strength of our study (the inclusion of data on a geographically representative and unselected collective of patients) is thus accompanied by a limited feasibility for attempting to gather baseline health status data on such a dynamic group of patients.

A caveat to our results is that we present a number of stratified analyses by age and treatment strategy, with many corresponding statistical comparisons. We intentionally do not make a formal declaration in the paper on a P-value cut-point for judging significance, because 'significance' should not be judged dichotomously based on P-values being just below or above an arbitrarily set threshold. This is particularly true in the analysis of large databases like ours, where our statistical power is such

that even small differences (i.e. small from a 'clinical' perspective) can be significant at extremely low *P*-values when tested statistically. For this reason, our emphasis is on descriptive presentation of SAQ scores, along with corresponding *P*-values for comparisons that permit readers to reflect on both the clinical importance of differences, and the *P*-value that indicates the probability of the observed difference arising from chance alone.

Weighing against these limitations and caveats are a number of strengths. First, our data include repeated assessments over time, with relative lack of 'cross-over' to revascularization providing a more accurate assessment of the health status outcomes associated with both therapeutic strategies. Second, our health status assessments at 1 year serve as a 'baseline' assessment of sorts for the subsequent health status assessments performed at 3 years. The resulting year 3 to year 1 comparisons provide valuable insights. Future work will include an analysis of the 5 year outcomes of these patients.

In conclusion, observation of the long-term outcomes of a large cohort of elderly patients with ischaemic heart disease shows that older patients undergoing revascularization procedures have better health status at 1 and 3 years than do those in the same age group who do not undergo revascularization. The differences by treatment strategy persisted with adjustment for severity of illness differences between groups, and are of similar magnitude to those seen in younger patients. These findings imply that the benefits of revascularization procedures performed in appropriately selected elderly patients extend not only to clinical outcomes, but also to long-term enhancement of quality-of-life.

Acknowledgements

APPROACH was funded in 1995 by the Weston Foundation, with ongoing support from Merck Frosst Canada Inc.; Monsanto Canada Inc., Searle; Eli Lilly Canada Inc.; Guidant Corporation; Boston Scientific Ltd.; Hoffmann-La Roche Ltd.; Johnson&Johnson Inc., Cordis; and the Province-Wide Services Committee of Alberta Health and Wellness. We appreciate the assistance of the Calgary Health Region and the Capital Health Authority in supporting data entry by cardiac catheterization laboratory personnel. APPROACH receives support from industry sponsors. W.A.G. is supported by a Health Scholar Award from the Alberta Heritage Foundation for Medical Research, Edmonton, Alberta and by a Government of Canada Research Chair. C.M.N. is supported by a New Investigators Award from Canadian Institute of Health Research.

Conflict of interest: none declared.

Appendix

APPROACH Clinical Steering Committee

Edmonton—S Archer, MM Graham, W Hui, A Koshal, RT Tsuyuki (Chair), and CM Norris; Calgary—LB Mitchell, MJ Curtis, WA Ghali, ML Knudtson, A Maitland, M Traboulsi, and PD Galbraith. Dr Ghali is a Health Scholar of the Alberta Heritage Foundation for Medical Research, Edmonton, Alberta, and a Government of Canada Research Chair in Health Services Research. Dr Norris is supported by a Population Health Investigator Award from the Alberta Heritage Foundation for Medical Research, and by a New Investigators Award from Canadian Institute of Health Research. Ms Galbraith was supported during part of this work by: (i) Canadian Cardiovascular Outcomes Research Team (www.ccort.ca)

student fellowships, funded by an operating grant from the Canadian Institutes of Health Research and the Heart and Stroke Foundation; and (ii) TORCH—Tomorrow's Research Cardiovascular Health Professionals (www.torch.ca) student fellowship.

References

- MacDonald P, Johnstone D, Rockwood K. Coronary artery bypass surgery for elderly patients: is our practice based on evidence or faith? *CMAJ* 2000;**162**:1005–1006.
- The TIME Investigators. Trial of invasive vs. medical therapy in elderly patients with chronic symptomatic coronary artery disease (TIME): a randomized trial. *Lancet* 2001;**358**:951–957.
- Graham MM, Ghali WA, Faris PD, Galbraith PD, Norris CM, Knudtson ML for the APPROACH Investigators. Survival after coronary revascularization in the elderly. *Circulation* 2002;**105**:2378–2384.
- Ghali WA, Knudtson ML for the APPROACH Investigators. Overview of APPROACH—The Alberta Provincial Project for Outcomes Assessment in Coronary Heart Disease. *Can J Cardiol* 2000;**16**:1225–1230.
- Spertus JA, Winder JA, Dewhurst TA, Dayo RA, Fihn SD. Monitoring the quality of life in patients with coronary artery disease. *Am J Cardiol* 1994;**74**:1240–1244.
- Spertus JA, Winder JA, Dewhurst TA, Deyo RA, Prodzinski J, McDonell M, Fihn SD. Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease. *J Am Coll Cardiol* 1995;**25**:333–341.
- Lezzoni LI. *Risk Adjustment for Measuring Healthcare Outcomes*. 2nd ed. Chicago: Health Administration Press; 1997.
- Norris C, Ghali W, Saunders L, Brant R, Galbraith PD, Faris P, Knudtson ML. Comparison of four different statistical analysis strategies for analyzing health related quality of life data from the Seattle Angina Questionnaire quality of life data. *J Clin Epidemiol* 2006;**59**:448–456.
- Pfisterer M, Buser P, Osswald S, Allemann U, Amann W, Anghern W, Eckhout E, Erne P, Estlinbaum W, Kuster G, Mocetti T, Naegeli B, Rickenbacher P. Trial of invasive vs. Medical therapy in Elderly patients (TIME) investigators. Outcome of elderly patients with chronic symptomatic coronary artery disease with an invasive vs. optimized medical treatment strategy: 1 year results of the randomized TIME trial. *JAMA* 2003;**289**:1117–1123.
- Guadagnoli E, Ayanian J, Cleary PD. Comparison of patient-reported outcomes after elective coronary artery bypass grafting in patients aged \geq and $<$ 65 years. *Am J Cardiol* 1992;**70**:60–64.
- Fruitman DS, MacDougall CE, Ross DB. Cardiac surgery in octogenarians: can elderly patients benefit? Quality of life after cardiac surgery. *Ann Thorac Surg* 1999;**68**:2129–2135.
- Kahler J, Lutke M, Weckmuller J, Koster R, Meinertz T, Hamm CW. Coronary angioplasty in octogenarians: quality of life and costs. *Eur Heart J* 1999;**20**:1791–1798.
- Seto TB, Taira DA, Berezin R, Chauhan MS, Cutlip DE, Ho KK, Kuntz RE, Cohen DJ. Percutaneous coronary revascularization in elderly patients: impact on functional status and quality of life. *Ann Intern Med* 2000;**132**:955–958.
- Kl Yun, Sintek CF, Fletcher AD, Pfeffer TA, Kochamba GS, Mahrer PR, Khonsari S. Time related quality of life after elective cardiac operation. *Ann Thorac Surg* 1999;**68**:1314–1320.
- Rumsfeld JS, Magid DJ, Plomondon ME, Sacks J, Henderson W, Hlatky M, Sethi G, Morrison DA. Health-related quality of life after percutaneous coronary intervention vs. coronary bypass surgery in high-risk patients with medically refractory ischemia. *J Am Coll Cardiol* 2003;**41**:1732–1738.
- Brorsson B, Bernstein SJ, Brook RH, Werko L. Quality of life of chronic stable angina patients 4 years after coronary angioplasty or coronary artery bypass surgery. *J Int Med* 2001;**249**:47–57.
- Staquet MJ, Hays RD, Fayes PM. *Quality of Life Assessment in Clinical Trials. Methods and Practice*. Oxford: Oxford University Press; 1998.
- Bert S. *Quality of Life and Pharmacoeconomics in Clinical Trials*. 2nd ed. Philadelphia: Lippincott-Raven; 1996.
- Garrett A, Hutchison A, Russell I. The UK version of the Seattle Angina Questionnaire (SAQ-UK): reliability, validity and responsiveness. *J Clin Epidemiol* 2001;**54**:907–915.
- Spertus JA, Jones P, McDonell M, Fan V, Fihn SD. Health status predicts long-term outcomes in outpatients with coronary artery disease. *Circulation* 2002;**106**:43–49.