Quality of Life in Patients with Stable Coronary Artery Disease Submitted to Percutaneous, Surgical and Medical Therapies: A Cohort Study

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Abstract

Background: Clinical, surgical and percutaneous strategies have been shown similar effectiveness in the prevention of major cardiovascular events in patients with stable coronary artery disease (CAD). The possibility that these strategies have differential effects over health-related quality of life (HRQoL) has been debated, particularly in patients treated outside clinical trials.

Methods: 454 patients diagnosed with coronary artery disease during an elective diagnostic coronary angiography were assigned to Coronary Artery Bypass Grafting (CABG), Percutaneous Coronary Intervention (PCI) or optimal medical treatment (OMT), and followed on average for 6.0 ± 1.9 years. HRQoL was assessed by a validated Brazilian version of the 12-Item Short-Form Health Survey (SF-12) questionnaire. The association between therapeutic strategies and scores of QoL were tested by ANOVA and adjusted for confounding in a general linear model.

Results: There was no difference in the Mental Component Summary (MCS) scores in the follow-up evaluation by therapeutic strategies: 51.4, 53.7 and 52.3, respectively, for MT, PCI, and CABG. Physical Component Summary (PCS) scores were higher in the PCI group, when compared to the CABG and MT (46.4 vs. 42.9 and 43.8, respectively), but these differences were no longer different after adjustment for confounding variables.

Conclusion: In a long-term follow-up of patients with stable CAD, HRQoL was not different in patients treated by medical, percutaneous or surgical treatments.

Background

Coronary artery disease (CAD) is expected to persist as the major cause of death worldwide at least until 2030.¹ Clinical, surgical and percutaneous strategies have demonstrated effectiveness to relieve its clinical manifestations and to prevent the recurrence and fatalities, particularly in acute events². The identification of the best therapeutic strategy in patients with stable CAD, however has been controversial.

Randomized controlled trials³⁻⁴ and their meta-analyses⁵⁻⁶ have demonstrated that there is no evidence of superiority of interventional treatments over clinical treatment in the prevention of major cardiovascular events in patients with stable CAD. Recently, the ISCHEMIA and ISCHEMIA-CKD Trials, reported that in patients with stable CAD, and moderate or severe ischemia, an invasive strategy (CABG or PCI), compared with a conservative strategy (OMT only) did not reduced the incidence of cardiovascular events or death after a follow-up of approximately 3 years.⁷⁻⁸

Most of the clinical trials evaluating strategies for management of chronic CAD, however, have compared patients submitted to CABG and PCI, but not medical treatment. Overall, these trials demonstrate that there is no significant difference in the incidence of mortality or myocardial infarction in patients treated with either one of the invasive options. However, surgical patients have lower rates of new revascularization procedures during follow-up.⁹⁻¹¹

On the other hand, observational studies comparing CABG with PCI have suggested that the former can be more effective to prevent major CV (cardiovascular) events¹²⁻¹⁴. In studies that included patients treated clinically, however, the incidence of CV events has not been substantially different than in patients treated by CABG or PCI, as we demonstrated in a cohort study recently reported.¹⁵

Independently of the effectiveness of therapies in the prevention of major CV outcomes, it is important to investigate if patients treated with different strategies have better outcomes in regard to the frequency of symptoms and quality of life. Studies that have addressed this issue, as the COURAGE Trial¹⁶ and the Ischemia Trial¹⁷. These trials have demonstrated better health-related quality of life (HRQoL) in patients treated with invasive strategies, when compared to conservative strategies with optimized MT only. In the comparison of the effects of invasive strategies, CABG may have a more durable benefit over HRQoL, than PCI¹⁸, as demonstrated in a sub-analysis of the SYNTAX Trial.

Observational studies with all comers could offer insightful information in relation to the effect of different therapies over HRQoL. To our knowledge, there are a few observational studies comparing the effect of different strategies of treatment in participants submitted to OMT, CABG or PCI.¹⁹⁻²² These studies had small sample sizes, high rates of losses during follow-up,¹⁹⁻²⁰ short follow-up,^{19,22} used different scales for the assessment of HRQoL, and were not adjusted for confounding²⁰⁻²². A meta-analysis identified these and other 30 observational studies assessing the effect of different treatments over HRQoL.²³ In the total, six studies compared HRQoL in patients treated with PCI or CABG,^{19-22; 24-25} and the remaining reported the effect of individual therapies over HRQoL (after treatment of all participants). This meta-analysis²³ was not preceded by a systematic review, and compared findings of different study arms without the methods recommended for network meta-analysis, separating arbitrarily for analysis studies with and without outliers. Herein we report the comparison of quality of life in cohort of patients with stable CAD treated contemporarily by clinical, percutaneous or surgical strategies.

Methods

Details of the study protocol have been described previously.¹⁵ In summary, patients for this analysis were referred by cardiologists and clinicians for elective diagnostic coronary angiography to a reference tertiary university-affiliated hospital. All comers with a documented diagnose of CAD were included in the study irrespectively of the type of treatment that they were assigned (OMT, PCI or CABG). The option of the therapeutic strategy was taken by the attending physician and, in more complex cases, after a discussion with a cardiovascular surgeon and an interventional cardiologist. Patients with acute coronary syndromes, valvular heart disease, aortic diseases, previous coronary revascularization, class III or IV heart failure, chronic renal disease (previous medical diagnosis or serum creatinine greater than 1.5 mg/dL), history of cancer, or severe psychiatric illness were excluded.

A standardized questionnaire was applied immediately before the coronary angiography. This was considered the baseline interview, and evaluated demographic information, educational history, lifestyle

characteristics and past medical history.

The follow-up of patients was done through telephone interviews medical records review death certificates and interviews with next-of-keen. A combination of strategies was adopted to minimize losses, which included contact patients by registered letters and interview the attending physicians.

The outcome in this analysis was HRQoL, assessed by a validated Brazilian version of the 12-Item Short-Form Health Survey (SF-12) questionnaire,²⁶ which uses 12 questions to assess the influence of eight health domains to score physical and mental health dimensions in the four weeks before the interview. Physical health-related domain investigated General Health (GH), Physical Functioning (PF), Role Physical (RP), and Body Pain (BP), while Mental health-related scales included Vitality (VT), Social Functioning (SF), Role Emotional (RE), and Mental Health (MH). Two scores were calculated: the Physical Component Summary (PCS) and the Mental Component Summary (MCS).^{27–29}

All data were evaluated by at least two authors independently, with control of quality on data entry to verify amplitude and consistency. For quality control of the team's performance, 20% of the protocols were randomly selected to be reviewed by a senior investigator (SCF).

The report of this study was based on the STROBE guidelines (Strengthening the Reporting of Observational Studies in Epidemiology).³⁰

Statistical Analysis

Results are expressed as mean $\pm$ standard deviation (SD) or number (percentage) for continuous and categorical variables, respectively. Continuous and dichotomous variables were analyzed using the Student t-test, one-way ANOVA or chi-square test, as appropriate. When necessary Bonferroni test was applied to identify differences in multiple comparisons. The association between therapeutic strategies and scores of HRQoL were tested by ANOVA and adjusted for confounding using a general linear model. Variables included in the model were those theoretically associated with worse clinical outcomes in patients with coronary heart disease and, therefore, with potential to confound the association of the interventions with scores of HRQoL. Statistical analyses were performed using SPSS, Version 18.0 (SPSS, Inc., Chicago, IL, USA).

Ethical Aspects

The study protocol was approved by the hospital's Ethics Committee, which is accredited by the Office for Human Research Protections as an Institutional Review Board, registered under no. 13–0171. All participants provided informed consent to participate in the investigation.

Results

Among 1028 patients referred to elective diagnostic coronary angiography at our institution during the study period, 454 patients had a confirmed diagnosis of coronary artery disease and were treated by

clinical, surgical, or percutaneous interventions. A total of 402 patients (88.5%) completed the HRQoL questionnaire in an average follow-up of 6 ± 1.9 years and were included in the present analysis. Of these, 112 received OMT alone, 224 were submitted to PCI and 66 were submitted to CABG; (Fig. 1). Participants were, on average, aged 60.8 years and most were men ($n = 258$; 64%).

Table 1 shows that characteristics of the study population, according to treatment groups, were relatively similar. Differences that should be highlighted are the higher prevalence of women in the medical therapy alone group, when compared with PCI and CABG (46.4% vs. 31.2% and 33.3%, respectively). Also, participants who reported a previous myocardial infarction were more often submitted to interventional treatment (60.6% and 48.7% vs. 31.3%, for CABG, PCI and OMT alone, respectively). Patients treated by CABG had higher SXscores in comparison to PCI and OMT alone groups (20.5, 9.3 and 6.6, respectively).

Table 1
Baseline clinical and angiographic characteristics

Baseline characteristics	MT alone (n = 112)	PCI (n = 224)	CABG (n = 66)	P value
Age (years)	61.2 ± 10.0	60.6 ± 9.1	61.3 ± 8.1	0.79
Male	60 (53.6%)	154 (68.8%)	44 (66.7%)	0.02
Race white	77 (68.8%)	156 (69.6%)	54 (81.8%)	0.13
Years at school (years)	6.1 ± 4.0	6.9 ± 4.3	6.8 ± 4.1	0.21
BMI (kg/m^2)	29.2 ± 4.8	28.1 ± 4.3	27.8 ± 4.2	0.07
SBP (mmHg)	140.4 ± 22.5	141.6 ± 24.1	141.9 ± 19.8	0.88
DBP (mmHg)	79.3 ± 11.7	81.6 ± 13.1	81.6 ± 11.6	0.26
Glucose (mg/dL)	103.5 ± 32.4	105.7 ± 27.2	116.3 ± 49.3	0.03
HDL-C (mg/dL)	41.8 ± 10.6	39.7 ± 10.1	40.6 ± 11.4	0.24
Triglycerides (mg/dL)	140.2 ± 81.4	148.8 ± 124.3	156.9 ± 130.6	0.63
Diabetes mellitus	36 (32.1%)	60 (26.8%)	26 (39.4%)	0.13
Hypertension	103 (92.0%)	213 (95.1%)	63 (95.5%)	0.46
Previous myocardial infarction	35 (31.3%)	109 (48.7%)	40 (60.6%)	< 0.001
HF	14 (12.5%)	30 (13.4%)	14 (21.2%)	0.22
Creatinine (mg/dL)	0.68 ± 0.18	0.69 ± 0.18	0.72 ± 0.22	0.44
Current smoking	13 (11.6%)	30 (13.4%)	3 (4.5%)	0.14
SXscore	6.6 ± 8.6	9.3 ± 6.9	20.5 ± 9.7	< 0.001
* Variables were described as mean $\pm$ SD or number (percentage)				

The mean unadjusted values of PCS and MCS scores according to treatment strategy are shown in Table 2. There was no difference in MCS between the three groups, with mean MCS for OMT alone, PCI and CABG of 51.4, 53.7 and 52.3, respectively. PCS scores in patients treated by OMT alone, PCI and CABG were 43.8, 46.4 and 42.9, respectively, (Fig. 2) and the score was significantly higher in the PCI group compared to CABG and OMT alone. The statistically significant differences showed in Table 2 were no longer significant after adjusting for confounding factors (Table 3)

Table 2
Unadjusted Mean for Quality of Life Scores after CAD treatment in 402 patients undergoing elective coronary angiography

Treatment	PCS *	MCS
	Mean $\pm$ SD (95%CI)	Mean $\pm$ SD (95%CI)
OMT alone	43.8 $\pm$ 10.5 (41.8–45.8)	51.4 $\pm$ 10.8 (49.4–53.4)
PCI	46.4 $\pm$ 11.2 (45.0–48.0)	53.7 $\pm$ 9.4 (52.5–54.9)
CABG	42.9 $\pm$ 11.7 (40.0–45.8)	52.4 $\pm$ 10.4 (49.8–54.9)
PCS, physical component summary score; MCS, mental component summary; Score of the SF-12		
* Between groups ANOVA P value = 0.02		

Table 3
Mean Quality of Life Scores after CAD treatment in 402 patients undergoing elective coronary angiography after adjustment for confounding

Treatment	PCS *	MCS
	Mean (95%CI)	Mean (95%CI)
OMT alone	44.3 (42.1–46.4)	51.4 (49.5–53.3)
PCI	46.2 (44.8–47.7)	53.8 (52.4–55.1)
CABG	42.2 (39.1–45.2)	52.4 (49.8–55.2)
PCS, physical component summary score; MCS, mental component summary score of the SF-12		
*The differences between groups were not significant after adjustment for age, mean SBP, Syntax score, years at school and BMI		

Discussion

In this cohort study of patients with stable CAD treated clinically or by invasive strategies, we identified that all treatment options had similar effect over HRQoL after an average follow-up of 6.0 ± 1.9 years. A trend for better QoL in patients treated through PCI was no longer significant after adjustment for the baseline severity of disease and other confounders.

Health-related quality of life is a multidimensional concept, subjectively perceived, which embraces physical, social, emotional and functional health.³¹ Traditional outcomes of randomized controlled trials and cohort studies may not capture the impact of the intervention on patient's HRQoL. Therefore, assessment of HRQoL has become increasingly important in the management patients with coronary artery disease, which is a chronic disease that classically impairs functional capacity and quality of life,^{32–33}. Sometimes patients consider the quality of the additional life years gained as important as length of life.³⁴

The COURAGE Trial was one of the first studies conducted in patients with stable CAD that evaluated HRQoL changes according to treatment strategies (PCI x OMT alone). In this trial, the initial improvement in HRQoL in patients treated with PCI was no longer detected after 12 months.¹⁶ A benefit of invasive strategies compared to OMT on HRQoL was reported in other study.³⁵ In another report, patients submitted to revascularization by CABG had a longer improvement in HRQoL than patients treated with PCI.³⁶ The effect of treatments over angina-related health status, assessed by the Seattle Angina Questionnaire (SAQ) and HRQoL, assessed by European Quality of Life–5 Dimensions (EQ-5D) in the Ischemia trial, were a priori sub analysis specified by protocol. Participants treated by CABG or PCI had higher SAQ summary scores than patients treated clinically during a follow-up of 36 months.¹⁷ HRQoL, however, improved similarly along this period of follow-up.¹⁷ The loss of beneficial effects of invasive approaches over HRQoL at longer follow-up in the Courage and at the Ischemia trials suggest that the short-term effects may be at least in part explained by a placebo effect. Our findings also suggest that any eventual benefit of PCI and CABG at short-term follow-up in the real-world care of patients also vanishes in a longer follow-up.

Our findings are hardly comparable to the observational studies that assessed the effect of OMT, PCI or CABG. In addition to the limitations of a few studies that compared the three strategies in contemporary cohorts,^{19–22} they had short follow-up. As far we know, there is only one recent systematic review with meta-analysis addressing this topic,²³ but non-adherence to the core methods of doing meta-analysis threatens its internal validity.

Our study has limitations that deserve mention. We did not assess the quality of life at the baseline, what could be a bias in the assessment of quality of life in the follow-up. Nonetheless, the underlying reasons for differences in QoL at the baseline were controlled in the multivariate analysis. Limited statistical power due to the sample size may have concealed a beta error. The study was carried out in only one center, which may reduce its external validity. In any case, the characteristics of patients and the diagnostic and therapeutic practices used in our service do not differ substantially from those of other centers. The study of all comers, without the limitations for participation in clinical trials, the comparison of three strategies of treatment, and the long follow-up, can be recognized as strengths of our study.

Conclusion

In conclusion, we demonstrated that HRQoL of patients with stable CAD is not different after treatment by CABG, PCI or OMT alone after a relatively long period of follow-up. Considering that these strategies have similar effectiveness in the prevention of major CV outcomes, the option for OMT alone seems to be adequate as the first option for the management of patients with stable CAD.

Abbreviations

CABG: Coronary Artery Bypass Grafting

CAD: Coronary artery disease

CV: cardiovascular

EQ-5D: European Quality of Life–5 Dimensions

HRQoL: Health-related quality of life

MCS: Mental Component Summary

OMT: Optimized Medical Therapy

PCI: Percutaneous Coronary Intervention

PCS: Physical Component Summary

SAQ: Seattle Angina Questionnaire

SD: standard deviation

SF-12: 12-Item Short-Form Health Survey

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

SXscores: Syntax Scores

Declarations

Ethics approval:

The study protocol was approved by the Hospital das Clínicas de Porto Alegre Ethics Committee, registered under no. 13-0171, which is accredited by the Office for Human Research Protections as an Institutional Review Board.

Consent to participate:

All participants provided informed consent.

Consent for publication:

All the authors have consented for the publication of this version of the article.

Availability of data and material :

All data relevant for this work is available for the community upon reasonable request to the corresponding author.

Conflicts of interest:

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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Authors' contributions:

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Lucas Molinari Veloso da Silveira, Adriana Silveira Almeida, Aline Gonçalves Silva, Marcelo Balbinot Lucca and Samuel Scopel. The first draft of the manuscript was written by Lucas Molinari Veloso da Silveira and all authors commented on previous versions of the manuscript. All authors read and approved the final version of the manuscript.

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Figures

Figure 1

Study Flowchart

Figure 2

Mean Quality of Life Scores after CAD treatment in 402 patients undergoing elective coronary angiography after adjustment for confounding