Quality of Life after On-Pump and Off-Pump Coronary Artery Bypass Grafting Surgery

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Summary

Background: **Coronary artery bypass grafting techniques without using cardiopulmonary bypass (off-pump CABG) result in less systemic damage, less clinical complications, less time spent in the intensive care unit, and shorter hospital stays, thereby raising the perspective of improved quality of life (QOL) for patients.**

Objective: **To assess quality of life in patients who underwent on-pump and off-pump CABG.**

Methods: **The Short-Form Health Survey (SF-36) Questionnaire was administered to patients with stable multivessel coronary artery disease (CAD) and preserved ventricular function before and at six and 12 months after surgery.**

Results: **Between January 2002 and December 2006, a total of 202 patients were randomized to either on-pump or off-pump CABG. Demographic, clinical, laboratory, and angiographic characteristics were similar in both groups. One hundred and five patients underwent off-pump CABG and 97 underwent on-pump CABG. In the postoperative course, 22 patients had myocardial infarction, 29 reported angina, one was reoperated, and three experienced stroke. No patient died. Quality of life, as measured by the SF-36 questionnaire, was shown to be similar in both groups regarding physical and mental components. However, male patients showed a significant improvement in physical functioning and role limitations due to physical problems. Also, a large number of patients in both groups returned to work.**

Conclusion: **Progressive enhancement in quality of life and early return to work were observed for all patients, regardless of the surgical technique used. Save for a greater improvement in physical functioning and role limitations due to physical problems experienced by male patients, no statistically significant differences were found in the other domains between groups. (Arq Bras Cardiol 2008;91(4):217-222)**

Key words: **Quality of life; myocardial revascularization; coronary arteriosclerosis; extracorporeal circulation.**

Introduction

Coronary artery bypass grafting surgery using cardiopulmonary bypass (on-pump CABG) is effective for treating symptoms of coronary artery disease (CAD) and preventing myocardial infarction and cardiovascular death in some subgroups of patients[1-3]. It also allows patients to enjoy a better quality of life (QOL) compared with other treatment methods[4-6].

However, the incidence of postoperative complications remains a great challenge, and there are currently few possibilities of short-term solution. These are caused by a systemic response, due to the non-physiological nature of cardiopulmonary bypass (CABG), which induces a systemic inflammatory reaction mediated by autoimmune substances, such as interleukins and their complements[7,8]. Moreover, the use of CABG with an arrested heart may result in myocardial dysfunction and, in some patients, hibernating myocardium, hemorrhagic diathesis, neurological impairment, tissue edema, and renal failure[9,10]. Cardiopulmonary bypass is also associated with significant cerebral morbidity, ranging from cognitive decline to stroke[11,12]. Recently, a number of studies have demonstrated that CABG surgery can be safely performed off-pump, yielding satisfactory clinical outcomes[13-16]. These studies have shown better preservation of ventricular and mitochondrial functions, as compared with patients undergoing on-pump surgery[17] Off-pump CABG surgery, therefore, emerges as a promising alternative for reducing the primary complications related to on-pump surgery. By achieving these objectives, and especially by minimizing the adverse effects associated with the intervention, this technique is thought to improve patients' postoperative quality of life.

Yet, there are few studies in the literature comparing quality of life of patients randomized to either on-pump or off-pump CABG. Thus, the aim of this study is to compare the quality of life of patients with stable coronary artery disease and preserved ventricular function undergoing elective CABG using these two surgical techniques.

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Methods

This study was performed at the *Hospital das Clínicas* Heart Institute (InCor) of the University of São Paulo Medical School (FMUSP), involving the Chronic Coronary Heart Disease Unit and other interlinked units for tests and procedures. The study was approved by the Scientific Committee of InCor under nº 1926/01/114 and by the Institutional Research Ethics Committee of the Hospital das Clínicas and University of São Paulo Medical School under nº 698/01, and conducted in accordance with the Helsinki Declaration.

Patient selection

Patients with documented CAD, more than 70% stenosis in at least two major coronary arteries and symptoms of stable angina were considered eligible for the study. Anginal symptoms were reported in the anamnesis or identified by exercise stress testing. Angina pectoris was graded according to the Canadian Cardiovascular Society (CCS) (class II or III)[18]. Study inclusion and randomization were performed if there was a consensus among surgeons that myocardial revascularization could be safely and similarly achieved with both surgical techniques. All angiograms were reviewed by the study surgeons, and an operative plan was documented before randomization. Only patients for whom myocardial revascularization was the sole surgical indication, with no other cardiac corrections, such as valve replacement, ventricular aneurysms, among others, were considered eligible for the study. Patients with unstable angina requiring emergency surgery or ventricular dysfunction were also excluded, as were those who refused to sign an informed consent form.

Surgical and anesthetic techniques

In this study, operations were performed by surgeons experienced in both techniques, on-pump and off-pump CABG, who were instructed to perform the most complete myocardial revascularization possible according to good surgical practice. On-pump CABG was performed using cold cardioplegia solution for myocardial protection, while off-pump CABG was performed using the "Octopus" tissue stabilizer. This device has been fully described elsewhere[14]. The anesthetic technique was standardized for all patients at the Heart Institute, regardless of randomization. Patients randomized to on-pump surgery were given 300 U/kg of heparin, and one-half that dose was given to those randomized to off-pump surgery. Only in the on-pump group was protamine used to reverse heparin effects. All anastomoses were hand-sutured.

Quality of life assessment instrument

Quality of life was measured using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), a generic questionnaire developed by Ware and Sherbourne[19] and validated for Brazilian Portuguese by Ciconelli[20]. It can be administered to people aged 12 and older to measure physical and mental health status both in individual clinical practice and in the general population as a whole. This questionnaire consists of 36 questions, 35 of which cover eight health domains (or dimensions) divided into two broad components: the physical component, including physical functioning, bodily pain, general health, and role limitations due to physical problems; and the mental component, including mental health, role limitations due to emotional problems, social functioning, and vitality. The remaining question compares the current health status with that of the previous year. The purpose of the questions was to transform subjective measures into objective data capable of allowing specific, global, and reproducible analyses. (Table 1)

Each question was given a score, with a low value reflecting poor health perception, loss of function, and the presence of pain, and a high value reflecting good health perception, preserved function, and absence of pain.

The SF-36 was designed to be self-administered, but it can also be administered in interviews. In this study, the interview format was used, since educational levels of our patients varied.

Interviews were conducted at baseline and at six and twelve months of follow-up, and were recorded as TP1, TP2, and TP3, respectively.

All interviews were conducted face-to-face by the same investigator. Nevertheless, no differences were reported by a previous study when the SF-36 was applied by telephone interview, face-to-face interview or self-administration[21].

A demographic questionnaire was administered to collect information on schooling, marital status, professional life, and relationship with work. The occurrence of disease-related changes in the work environment, economic situation, and professional outlook was also investigated. In addition, the influence of these changes from the patent's standpoint was evaluated.

Statistical analysis

All variables were initially analyzed descriptively. For quantitative variables, the mean, median, standard deviation, minimum and maximum values were calculated, and for qualitative variables, absolute and relative frequencies. The Student's t-test was used to compare means between two groups. When the normality assumption was rejected, the nonparametric Mann-Whitney test was used. The chi-square test or Fisher's exact test was performed for homogeneity of proportions when expected frequencies were less than five.

Table 1 – Domains (dimensions) and their respective ranges

	Domain	Range
CPhysical Component	Physical functioning	Presence of physical limitation
	Role physical	Limitations in daily activities
	Bodily pain	Severity and limitations
	General health	Severity and limitations
Mental Component	Vitality	Energy and fatigue
	Social functioning	Relationships
	Role emotional	IEmotional interference
	Mental Health	Depression and anxiety

Friedman's nonparametric test was used to assess group behavior, since the normality assumption was rejected. The nonparametric Mann-Whitney test (with Bonferroni's correction) was used to compare two groups (at each time point), the nonparametric Kruskal-Wallis test (with Bonferroni's correction) was used to compare four groups, and the Dunn test was used for multiple comparisons. The significance level was set at 5%.

Results

Between January 2002 and December 2006, a total of 252 patients were randomized to surgical treatment. Of these, 202 were followed-up for quality of life assessment and demographic profile. The remaining 50 patients were lost to follow-up, refused to participate in the study, had difficulty in completing the questionnaire, or died. Of the 202 patients comprising this sample, 97 underwent on-pump CABG and 105, off-pump CABG. Randomization produced balanced treatment groups with respect to important prognostic characteristics of the disease. Distribution of patients with anginal symptoms graded by the Canadian Cardiovascular Society was similar in both groups. Mean age of patients referred for on-pump CABG was 59 years, compared with 61 years for those referred for off-pump CABG. In the population studied, 61 patients (30%) were diabetic and 89 (44%) reported history of myocardial infarction.

The number of obstructed arteries and the degree of obstruction were similar in both groups. Demographic, laboratory, clinical, and angiographic characteristics are summarized in Table 2. Patients' vital status was determined in December 2007. The total duration of the study was one year for all patients.

Off-pump CABG

After one year of follow-up, of the 105 patients who underwent off-pump CABG, 18 (17%) had angina and 10 (9.5%) experienced acute myocardial infarction. No patient in this group sustained a stroke, was reoperated, or died.

On-pump CABG

In this group, 97 patients (11%) had angina, 12 (12.5%) had acute myocardial infarction, three had a stroke, and one (1%) was reoperated. No patient died, as described in Table 3.

Quality of Life

In regard to quality of life, there were significant changes in both the physical and mental components of the SF-36. Significant improvements were noted in all domains of both components. However, no significant differences were detected when both treatment groups were compared, as shown in Tables 4 and 5.

When the eight domains were analyzed according to gender, the scores for bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health were found to be similar. However, regarding physical functioning, improvement was significantly greater in male patients in the three interviews conducted. The same was true for physical health perception during the first six months of follow-up, as compared with female patients.

No significant differences were found in seven domains when patients below 65 years of age were compared with those above 65 years, except for mental health perception, which was significantly greater among patients younger than 65 ($p<0.005$). A considerable proportion of patients returned to work early: 65% and 75% in the on-pump and off-pump group, respectively, but without statistical significance between groups.

Table 2 – Clinical and Demographic Characteristics

Characteristics	(n = 97)	(n =105)	p
Demographic profile	On-pump CABG	Off-pump CABG	
Age (years)	59	61	NS
Female (%)	21	30	NS
Smoking (%)	66	64	NS
Medical history			
Acute myocardial infarction (%)	44	44	NS
Hypertension (%)	57	70	NS
Diabetes mellitus (%)	27	33	NS
Angina Pectoris II or III (%))	85	88	NS
Laboratory data			
Total cholesterol	224 ± 6	226 ± 4	NS
LDL cholesterol	140 ± 12	38 ± 14	NS
HDL cholesterol	38 ± 8	39 ± 7	NS
Triglycerides	166 ± 10	170 ± 8	NS
Blood glucose	102 ± 15	100 ± 12	NS
Stress-induced ischemia (%)	82	80	NS
Angiographic data			
Two-vessel disease (%)	26,18	24,16	NS
Three-vessel disease (%)	73,82	75,84	NS
Ejection fraction (mean)	65,68	64,58	NS

P - Level of significance; NS - Non-significant

Table 3 – Frequency of major events in the postoperative course

Variables	On-pump	Off-pump	p
	(n= 97)	(n=105)	
Angina (N and %)	11 (11.3%)	18 (17%	NS
AMI (N and %)	12 (12.5%)	10 (9.5%)	NS
Stroke (N and %)	03 (3%)		NA
Reoperation (N and %)	01 (1 %)		NA
Death (N and %)	-		NA

On-pump - with CABG; Off-pump - without CABG; AMI - acute myocardial infarction; P - level of significance; NS - Non-significant; NA - non-applicable;

Table 4 – **Physical component**

Domain	On-pump X Off-pump				
Physical functioning	**TP1**	**TP2**	**TP3**	**p**	**p**
On-pump	55 ± 29	80 ±19	84 ± 18	< 0.05	P =0.32; 0.06; 0.14
Off-pump	53 ± 28	76 ± 17	82 ± 16	< 0.05	
Role physical					
On-pump	28 ± 37	59 ± 42	66 ± 40	< 0.05	P = 0.65; 0.09; 0.16
Off-pump	26 ± 35	48 ± 42	56 ± 43	< 0.05	
Bodily pain					
On-pump	59 ± 29	74 ± 24	76 ± 24	< 0.05	P = 0.58; 0.07; 0.87
Off-pump	55 ± 31	69 ± 24	75 ± 24	< 0.05	
General health					
On-pump	68±23	79±20	79±20	< 0.05	P = 0.11; 0.17; 0.27
Off-pump	63±23	75±20	75±22	< 0.05	

On-pump - with CABG; Off-pump - without CABG; TP1, TP2, TP3 - time points 1, 2, and 3; p - level of significance.

Table 5 – **Mental component**

Domain	On-pump X Off-pump				
Vitality	**TP1**	**TP2**	**TP3**	**p**	**p**
On-pump	64 ± 26	77 ± 21	79 ± 21	< 0,05	P = 0,24; 0,22; 0,22
Off-pump	61 ± 25	75 ± 19	76 ± 20	< 0,05	
Social functioning					
On-pump	70 ± 28	83 ± 23	84 ± 24	< 0,05	P = 0,54; 0,43; 0,86
Off-pump	70 ± 29	81 ± 21	86 ± 19	< 0,05	
Role emotional					
On-pump	50 ± 44	74 ± 39	77 ± 38	< 0,05	P = 0,78; 0,20; 0,53
Off-pump	46 ± 45	65 ± 46	74 ± 40	< 0,05	
Mental Health					
On-pump	71 ± 23	77 ± 19	78 ± 20	< 0,05	P = 0,08; 0,67; 0,68
Off-pump	66 ± 24	75 ± 21	77 ± 21	< 0,05	

On-pump - with CABG; Off-pump - without CABG; TP1, TP2, TP3 - time points 1, 2, and 3; p - level of significance

Discussion

Instruments to assess physical or mental health status are used to measure possible changes in quality of life associated with some medical interventions in both controlled and population-based studies[22]. A growing number of clinical trials have been specifically designed to evaluate the safety and effectiveness of different procedures, techniques[23], or pharmacological tests incorporating quality of life instruments[24]. It is necessary that models used in these measurements be appropriate to each type of population, treatment or intervention, since the concept of quality of life can be specifically applied to measure the multiple aspects of physical or mental health. Most clinical trials of drugs or interventional therapy use self-administered questionnaires for specific purposes[25] and other questionnaires for a wide range of conditions, particularly chronic diseases[26-28].

By using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), this study has shown improvements in all physical and mental components. This improvement, however, was progressive and similar in patients undergoing either technique. When the eight domains were analyzed according to gender, the scores for bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health were found to be similar. However, regarding physical functioning, improvement was significantly greater in male patients in the three interviews conducted. This may have been a serendipitous finding, since our study was not specifically designed to address this issue.

Moreover, physical health perception improved significantly in male patients in the first six months of follow-up, compared with female patients. In fact, earlier studies comparing the outcomes of myocardial revascularization between genders have shown that women required longer ICU stays, longer postoperative care, longer mechanical ventilation, and longer hospital stay, in addition to presenting cognitive decline[29-31]. Nevertheless, he incidence of adverse events did not differ between male and female patients[29]. In the study by Kurlanski et al[32], the SF-36 was administered to patients undergoing CABG using only internal mammary arteries, and a significant improvement was found in groups operated with and without CABG. There were no differences between groups. The same result was reported by Otso Järvinen et al[33] using the RAND-36 Health Survey questionnaire. Although hypertension may influence postoperative outcomes, there were no significant differences when both techniques were compared. Quality of life studies using the MOS-(SF-36) in hypertensive outpatients undergoing two different therapeutic modalities have found no significant differences[34]. In our study, not only did quality of life improve, but also a considerable number of patients in both groups returned to work. Our results, therefore, are better than those reported by Daniel Mark et al[35] In their study, which followed up 449 patients undergoing CABG, a significant number of patients have retired from the work force.

Final Remarks

The above-mentioned studies were either multicenter or multinational trials. Given the sociocultural differences among research centers, different samples of patients, and different instruments used for measuring quality of life, some degree of bias may have affected the results of these studies. On the other hand, the homogeneity of our sample, which was made up of stable patients and also appropriate for any type of surgical technique, had a positive impact on the final result of the study. Moreover, patients' follow-up, performed by the same medical team throughout the study, as well as QOL interviews, conducted by the same investigator, contributed to lend more credence to our results. Therefore, the greater clinical status and quality of life achieved by all patients should be considered in the context of continuous follow-up and multiprofessional care, including specific rehabilitation programs. The significant improvement in quality of life, in its two major components and also in several domains, experienced by patients undergoing both surgical techniques, should be analyzed considering all clinical variability, comorbidities, physical and emotional aspects, plus expectations before the intervention, as well as the randomized therapy considered by the patient as effective and definitive.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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