

Quality of Life after Surgical Myocardial Revascularization, Angioplasty or Medical Treatment

Myrthes Emy Takiuti, Whady Hueb, Shirley Borghetti Hiscock, Célia Regina Simoes da Rocha Nogueira, Priscyla Girardi, Fabio Fernandes, Desiderio Favarato, Neuza Lopes, Jorge Chiquie Borges, Aécio Flávio Teixeira de Góis, José Antonio Franchini Ramires

Instituto do Coração HCFMUSP – São Paulo, SP - Brazil

Summary

Background: Although the clinical benefits of coronary interventions seem to be confirmed, their effects on quality of life (QoL) are still scarcely studied.

Objective: To assess the QoL in multivessel coronary disease in patients randomly undergoing surgery, angioplasty or medical treatment.

Methods: The Short-Form Health Survey (SF-36) questionnaire was answered by 483 patients. Of these, 161 underwent surgical revascularization, 166 underwent angioplasty, and 153 were medically treated.

Results: At baseline, 86% of the patients referred angina, 34% referred infarction, and 32% were smokers. Medical Treatment: 12 patients (7.7%) had AMI, 24 (15.3%) underwent surgery, and 19 (12.1%) died. In addition, 5 (3.2%) had stroke, and 40 (25.6%) had angina. As regards the mental component, 64.1% and 30.8% had their condition improved and worsened, respectively. As regards the physical component, 70.5% and 27.6% had their condition improved and worsened, respectively. Surgery: 13 patients (8.1%) had AMI, 2 (1.2%) underwent surgery, and 12 (7.4%) died. Also, 9 (5.6%) had stroke and 30 (18.6%) had angina. As regards the mental component, 72.7% and 25.5% had their condition improved and worsened, respectively. As regards the physical component, 82.6% and 16.1% had their condition improved and worsened, respectively. Angioplasty: 18 patients (10.9%) had AMI, 51 (30.7%) underwent interventions, and 18 (19.9%) died. Additionally, six (3.6%) presented stroke and 35 (21%) reported angina. As regards the mental component, 66.9% and 26.5% had their condition improved and worsened, respectively. As regards the physical component, 77.1% and 20.5% had their condition improved and worsened, respectively.

Conclusion: Improvement was observed in all domains and in the three therapeutic modalities. Comparatively, surgery had provided a better quality of life after a four-year follow-up.

Key words: Quality of life, coronary artery disease, angina pectoris, angioplasty, myocardial revascularization.

Introduction

Recent studies on quality of life (QoL) have been conducted in patients with several morbid conditions, with the purpose of assessing the different therapeutic measures aimed at improving the patients' medical conditions, as well as their quality of life¹. Included in this condition, coronary artery disease (CAD), which is considered one of the major causes of morbidity and mortality in the adult population, has a scenario that will probably not change in the coming years².

A disease based on risk factors such as dyslipidemia, smoking, diabetes mellitus and hypertension, which are subject to changes, the CAD may undergo interventions throughout its progression, with a consequent reduction in the risk of a coronary event, and, therefore, improvement of

the patients' quality of life (QoL)³.

On one hand, these interventions contribute to an increase in survival and, on the other hand, to the progression of possible comorbidities triggered by this disease^{4,5}. Thus, these interventions will interfere with the emotional, physical and social status, and mainly with the quality of life as a whole. Also, the continuous use of medications such as acetylsalicylic acid, beta-blockers, statins, and angiotensin-converting-enzyme inhibitors is an example of an intervention able to interfere with the progression of possible cardiovascular comorbidities⁶⁻⁸. Thus, with the growth of the elderly population and increase in longevity, diseases of the circulatory system will continue to lead the progressive development of different forms of therapeutic and pharmacological interventions aimed at changing these statistics^{9,10}.

Randomized studies with the objective of comparing the effects of CAD treatment on the survival and incidence of cardiovascular events, as well as on the long-term quality of life, resulted in conflicting conclusions¹¹⁻¹³. These differences were mainly due to the different moments when the studies were conducted and to the therapeutic resources available,

Mailing address: Neuza Lopes •

Av. Dr. Enéas Carvalho de Aguiar 44 ab sala 114 – 05403-000 – São Paulo, SP - Brazil

E-mail: mass@incor.usp.br

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as well as to the different tools used to assess the patients' quality of life.

With the purpose of comparing the three therapeutic modalities available for the control of CAD symptoms and their respective interference on the patients' quality of life, the MASS II (The Medicine, Angioplasty or Surgery Study II) was developed to evaluate the outcomes of the major clinical events, of long-term survival, and of the quality of life of patients undergoing medical treatment, surgery or angioplasty¹⁴.

Methods

Details of the Mass II study design, study protocol, patient selection and inclusion criteria have been previously published¹⁴. Briefly, patients with symptomatic multivessel CAD documented with angiograms, and myocardial ischemia identified by symptoms or exercise test were considered eligible for inclusion. Angina pectoris was classified according to the Canadian Cardiovascular Society (CCS) (class II or III)¹⁵.

This study has been conducted in the *Instituto do Coração (InCor) do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (FMUSP)*, and also in the Medical Unit of Chronic Coronary Artery Disease and other units interlinked for tests and procedures, with approval by the *Instituto do Coração's* Scientific Commission under no. 946/94/56, and by the *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo's* Ethics Committee under no. 264/94/11.

Patient selection - From May, 1995 to May, 2000, 20769 patients undergoing coronary angiography due to a clinical suspicion of CAD were registered in a database. Of these, 18693 patients were excluded because they did not meet the specific protocol criteria. Of the remaining 2076 who were eligible for the three usual treatment modalities, 1465 patients were not included for not accepting to participate in a randomized study. Thus, the present study sample is comprised by the remaining 611 patients. The patients would be included and randomized if surgeons, hemodynamicists and clinicians simultaneously agreed on the possibility of any of the treatment modalities. Thus, 203 patients were assigned to surgical myocardial revascularization, 205 to angioplasty, and 203 to medical treatment. Awritten informed consent was obtained from all patients after they received detailed information on the study and had their questions answered.

Instruments - We used the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), a generic questionnaire for quality of life assessment conceived by Ware and Sherbourne¹⁶ with the Portuguese version validated by Ciconelli¹⁷. This questionnaire is a tool that may be administered to persons from 12 years of age, and its objective is to assess the physical and mental health in the clinical practice both individually and in the general population.

The questionnaire comprises 36 questions addressing eight domains (or dimensions) in two major components: the physical component that includes physical functioning, bodily pain, general health, and role physical; and the mental component that encompasses mental health, role emotional, social functioning, and vitality, and is assessed through 35 questions. Also, there is one additional question comparing

their current health with that of the previous year. The purpose of the questions was to turn subjective measures into objective data that could be analyzed in a specific, global and reproducible manner (Table 1).

Table 1 - Domains (dimensions) and their respective range

	Domains	Range
Physical component	Physical functioning	Presence of physical limitation
	Role physical	Problems with daily activities
	Bodily pain	Intensity and limitations
	General health	Self-perception of health
Mental component	Vitality	Weakness and tiredness
	Social functioning	Relationships
	Role emotional	Emotional interference
	Mental health	Depression and anxiety

A specific score for each question was used to analyze the results. A low numeric score reflected a poor perception of health, loss of function, and presence of bodily pain, whereas a high numeric score reflected a favorable perception of health, preserved function, and absence of bodily pain.

The SF-36 was constructed to be a self-administered instrument; however it can also be administered in the interview format, which was used in our study with the purpose of standardizing the management, since a variation in the educational attainment was detected among our patients. The interviews were administered at baseline and at six, 12, 24, 36, and 48 months of follow-up.

All interviews were conducted interpersonally and by the same investigator. However, in a previous study, when the SF-36 was administered via phone calls or interviews, or was self-administered, no differences were observed between the results obtained¹⁸.

The demographic profile investigation questionnaire included questions on educational attainment, marital status, professional life, and relationship with work. We also sought to evaluate the occurrence of changes in the work environment related to the disease; of the economic situation in the professional prospects; and also of the influence of these changes from the patient's point of view.

Statistical analysis - The variables measured at more than one time point (baseline, 6, 12, 24, 36, 48 months) are shown in graphs containing means and standard error. The means were evaluated using analysis of variance for repetitive measures, where the following basic hypotheses were tested:

Ho1: The mean profiles are parallel, that is, the groups have the same behavior;

Ho2: The mean profiles are coincident, that is, there is no group effect;

Ho3: There is no time effect, that is, the profiles are parallel

to the abscissa axis.

The generalized linear model was used to evaluate the scores at the 48-month time point. P values < 0.005 were considered statistically significant.

Results

Of the 611 randomized patients comprising this study sample for long-term clinical follow-up, 483 were followed up for quality of life assessments and demographic profile questionnaire. These patients comprised the following therapeutic groups: surgical myocardial revascularization (SMR), 161 patients (33.3%); percutaneous coronary angioplasty (PCA), 166 patients (34.3%); and medical treatment (MT), 153 patients (32.4%), periodically followed up. The remaining 128 patients were excluded for finding it difficult to understand the questionnaire, for refusing to participate in this study, or for dying during follow-up, among other reasons. The vital status of all patients was concluded in May, 2004. The minimum duration of the research was 4 years for all patients. The therapeutic groups had well-balanced clinical and demographic characteristics related to significant prognostic factors of the disease. Thus, the patients in the three therapeutic modalities were similar as regards medical conditions, angiographic conditions, medication use, laboratory tests, and others. At baseline, 86% of the patients followed-up presented with class II or III (CCS) anginal symptoms, 34% reported previous myocardial infarction, and 32% were smokers, as shown in Table 2. All patients were using specific medications for their heart conditions and other comorbidities.

Medical treatment - After the four-year follow-up, of the 153 patients assigned for medical treatment, 12 (7.7%) had acute myocardial infarction, 24 (15.3%) underwent surgical myocardial revascularization, and 19 (12.1%) died. Also, five patients (3.1%) had a stroke and 40 (25.6%) reported symptoms of angina pectoris. Regarding quality of life, we observed significant changes both in the physical and in the mental components. Thus, as for the physical functioning domain, 104 patients (68%) improved, 13 patients (8.5%)

remained unchanged, whereas 36 (23.5%) worsened. As for the role physical domain, 74 (48.5%) patients improved, 54 (35%) remained unchanged, and 25 (16.5%) worsened. In relation to bodily pain, 68 patients (44.5%) reported improvement, 48 (35.5%) reported worsening, and 37 (24%) remained unchanged. In the assessment of the general health, 90 patients (59%) improved, 44 patients (28.5%) worsened, and 19 patients (12.5%) remained unchanged.

Also, the vitality assessment showed improvement in 87 patients (55.7%), worsening in 20 patients (13%), and an unchanged condition in the remaining 46 patients (30%). The social functioning improved in 74 patients (49%), worsened in 40 patients (25.5%), and remained unchanged in 39 patients (25.5%). The role emotional domain improved in 63 patients (41%), worsened in 33 patients (21.5%), and remained unchanged in 57 patients (37.5%). Finally, as regards mental health, improvement was observed in 101 patients (66%), worsening in 42 patients (27.5%), and unchanged condition in 10 patients (6.5%).

Surgical treatment - During the follow-up period, of the 161 patients referred for surgical treatment, 13 (8.1%) had myocardial infarction, five (3.1%) underwent myocardial revascularization, and 12 (7.4%) died. Also, nine (5.6%) patients had a stroke, and 30 (18.6%) reported anginal symptoms. Changes in quality of life regarding the physical and mental components were also observed. Regarding the physical functioning domain, 130 patients (83.5%) showed improvement, eight patients (5%) remained unchanged, whereas 18 (11.5%) worsened. Regarding the role physical domain, 102 patients (65.5%) showed improvement, 38 (24.5%) remained unchanged, and 16 (10%) worsened. In relation to bodily pain, 87 patients (56%) reported improvement, 41 (26%) reported worsening, and 28 (18%) remained unchanged. In the assessment of general health, 116 patients (74.5%) showed improvement, 31 patients (20%) reported worsening and nine patients (5.5%) remained unchanged. Also, the assessment of vitality revealed improvement in 109 patients (70%), worsening in 36 patients (23%), and an unchanged condition in the

Table 2 - Patient demographics and clinical characteristics

Characteristics	Angioplasty (n = 166)	Medical (n = 153)	Surgical (n = 161)	P value
Demographic profile				
Age (years)	59 ± 9	59 ± 10	59 ± 8	0.925
Female gender (%)	35	31	28	0.419
Smoking (%)	27	37	34	0.015
Medical history				
Myocardial infarction (%)	50	37	42	0.049
Arterial hypertension (%)	58	52	59	0.321
Diabetes mellitus (%)	32	37	39	0.317
Angina pectoris (%)	91	82	87	0.053

p - descriptive probability level; n - number of patients.

remaining 11 patients (7%). Social functioning improved in 94 patients (60%), worsened in 31 patients (20%), and remained unchanged in 31 patients (20%). The changes in the emotional role domain revealed improvement in 82 patients (52.5%), worsening in 25 patients (16%), and an unchanged condition in 49 patients (31.5%). Finally, in relation to mental health, improvement was observed in 105 patients (67.5%), worsening in 40 patients (25.5%), and no change in the 11 remaining patients (7%).

Angioplasty - During the four-year follow-up of the 166 patients undergoing angioplasty, 18 (10.9%) had acute myocardial infarction, 15 (9.0%) underwent surgical myocardial revascularization, 36 (21.7%) underwent repeat angioplasty, and 18 (10.9%) died. Also, six (3.6%) had stroke, and 35 (21%) referred symptoms of angina pectoris. Changes in quality of life regarding the two components analyzed – the physical and the mental components, were also observed. Thus, in the physical functioning domain, 119 patients (73.5%) showed improvement and 13 patients (8%) remained unchanged, whereas 30 (18%) worsened. In the role physical domain, 92 patients (57%) showed improvement, 49 (30%) remained unchanged, and 21 (13%) worsened. As regards bodily pain, 79 patients (48.5%) reported improvement, 41 (25.5%) reported worsening, and 42 (26%) remained unchanged. In the general health assessment, 102 patients (63%) showed improvement, 42 patients (26%) reported worsening, and 18 patients (11%) remained unchanged.

Also, the assessment of vitality showed improvement in 94 patients (58%), worsening in 45 (28%), and no change in the 23 (14%) remaining patients. Social functioning improved in 90 patients (55.5%), worsened in 32 patients (19.5%), and remained unchanged in 40 patients (25%). The changes in the role emotional domain showed improvement in 76 patients (47%), worsening in 19 patients (11.5%), and no change in 67 patients (41.5%). Finally, in relation to mental health, improvement was observed in 108 patients (67%), worsening in 40 patients (24.5%), and no change in the 14 remaining patients (8.5%). When the major clinical events were analyzed during the 4-year follow-up, a significant increase in the need for repeat interventions in patients undergoing angioplasty and need for angioplasty in the patients of the medical group, as well as a significant number of patients with anginal symptoms in all treatment groups were observed (Table 3).

The analysis of the changes in all domains as observed

at baseline and end of the follow-up comparing the three treatment modalities are shown in Figure 1. Also, the comparison between medical treatment and both intervention treatments (surgery and angioplasty) showed a significant improvement in the role emotional, physical functioning, mental health, and general health domains (Figure 2). When the results of the two major components (the physical and the mental components) - each with their four domains- were analyzed within these treatment groups, we found a significant improvement of these components with the intervention treatments. Comparison between the medical and the surgical treatment showed marked improvement of the eight domains in the patients undergoing surgery (Figure 3). Improvement of the two major components was also observed in the surgical patients. Also, when the surgical treatment was compared with angioplasty, we observed a significant advantage of the surgical treatment in all but the emotional domain (Figure 4). The same occurred in relation to the physical and mental components when these two treatments were compared. Finally, the comparison between medical treatment and angioplasty showed a significant improvement in the patients undergoing angioplasty in all but the bodily pain domain (Figure 5). Significant improvement was also observed in the two major components (physical and mental) among the patients undergoing angioplasty in comparison with those undergoing medical treatment. The multivariate analysis of comorbidities as well as of the demographic data corrected for variables such as age, educational attainment, gender, smoking, diabetes, hypertension, infarction and angina status showed that, except for the mental health domain, a significant improvement was observed at the end of the three treatment modalities used.

Discussion

Physical or mental health assessment instruments are used to measure possible changes in quality of life resulting from certain medical interventions in controlled studies and also in population-based studies¹⁹. We currently observe the increasing frequency of clinical trials designed to specifically evaluate the safety and effectiveness of different procedures or techniques²⁰, or pharmacological tests incorporating quality of life instruments²¹. The models used in these measurements have to be adequate to each type of population, treatment, or intervention, since the concept of quality of life may be

Table 3 - Frequency of major events during follow-up

	Angioplasty n = 166	Medical n = 156	Surgical n = 161	Total n = 483
MI (n%)	18 (10.9%)	12 (7.7%)	13 (8.1%)	43 (8.9%)
Stroke (n%)	6 (3.6%)	5 (3.1%)	9 (5.6%)	20 (4.1%)
MR (n%)	15 (9.22%)	24 (15.3%)	1 (0.6%)	40 (8.2%)
PCA (n%)	36 (21.7%)	40 (25.6%)	4 (2.5%)	80 (16.5%)
Angina (n%)	35 (21.0%)	40 (25.6%)	40 (25.6%)	115 (23.8%)

n - number; MI - Myocardial infarction; MR - Myocardial revascularization; PCA - Percutaneous coronary angioplasty.

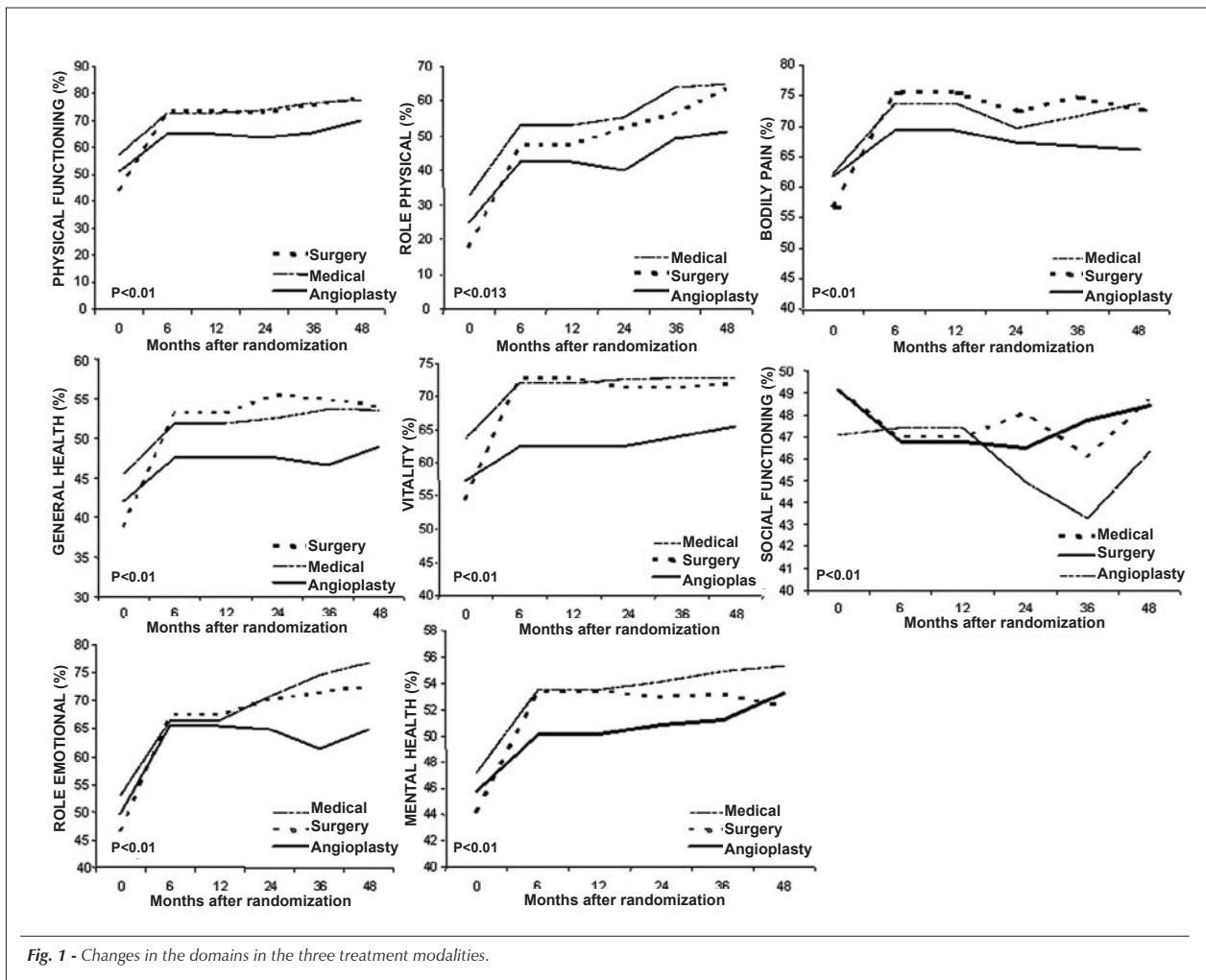


Fig. 1 - Changes in the domains in the three treatment modalities.

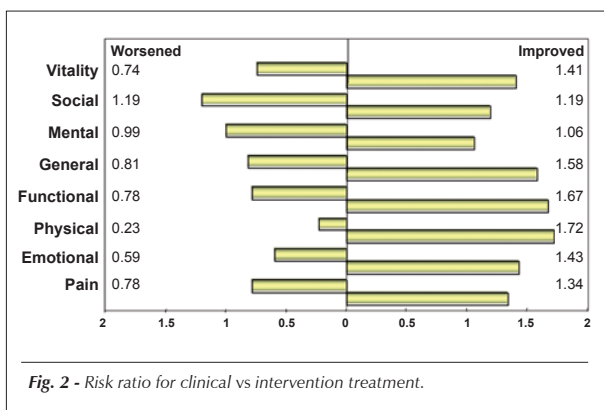


Fig. 2 - Risk ratio for clinical vs intervention treatment.

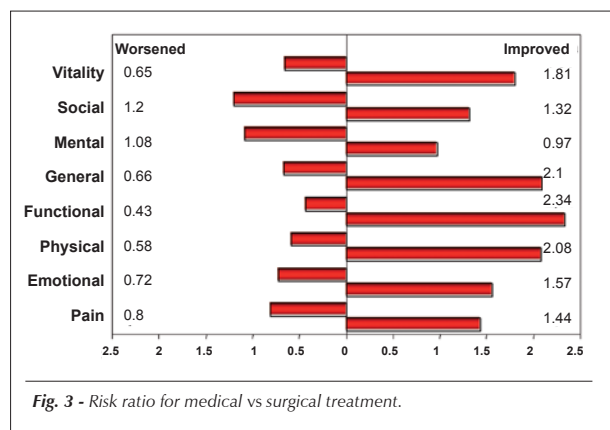
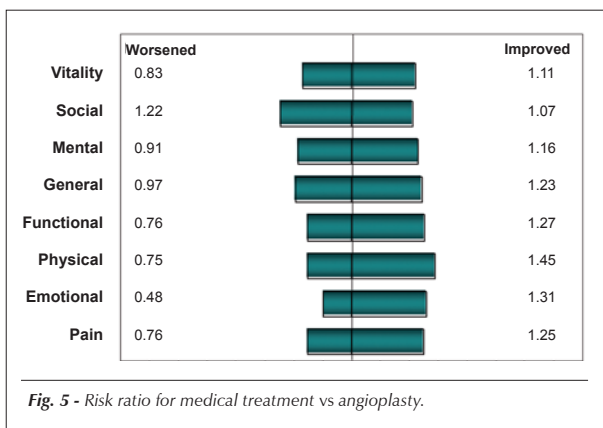
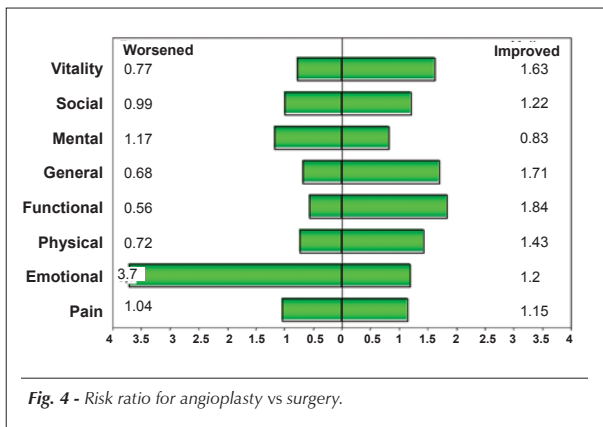


Fig. 3 - Risk ratio for medical vs surgical treatment.

specifically applied to measure the multiple aspects of physical or mental health. Most of the clinical trials using drugs or intervention treatments use self-administered questionnaires available for specific purposes²², and others for a great variety of diseases, mainly the chronic ones²³⁻²⁵.

By administering the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), we observed improvement

of all components, both physical and mental, at the end of the present study. This improvement, however, was more significant among patients undergoing surgery. The analysis of the different domains of the physical or mental components at baseline showed that the patients assigned for surgical treatment had a worse evaluation for these items in relation to the patients assigned for the other types of treatment.



On the other hand, the surgical group was the one with the best quality of life at the end of the study. This result directly corroborates the better results of surgery in the progression of anginal symptoms, in the incidence of reinfarction, and in the need for additional interventions. On the other hand, although patients undergoing angioplasty required a significantly greater number of additional interventions in relation to the other types of treatment, they presented improvement in their quality of life at the end of the study when compared to patients of the medical group. Finally, patients who underwent medical treatment only also experienced improvement in their quality of life at the end of the study. It is important to point out that the continued periodic patient follow-up, the intense administration of drugs, and the strict control of risk factors in patients with potentially severe conditions may have contributed to these results. In this context, the maintenance of the same multiprofessional team had a key role in the favorable outcome of the patients in this study. Also, it is also worth pointing out that the instrument was administered using interviews, always by the same investigator, which provides a higher stability in the relationship between the patient and the health professional. Studies assessing the quality of life of patients undergoing intervention treatment (surgery vs. angioplasty) that used the same quality of life instrument (SF-36), although in a self-administered form, showed that by the end of three years of follow-up the angina status

and return to work had a significant improvement in both forms of treatment. Anginal symptoms were less significant in the patients undergoing surgical treatment than in those undergoing angioplasty¹³. However, return to work was faster among the patients treated with angioplasty. In conclusion, similar improvement in the quality of life was observed in both treatment modalities. These studies that assessed patients undergoing medical treatment or angioplasty using the self-administered SF-36 showed that the angioplasty group had a significant improvement in the quality of life especially as regards vitality and the physical component, in comparison to the medical group. These results were attributed to the higher frequency of anginal symptoms and dyspnea reported by the patients of the medical group at the end of the study¹¹. On the other hand, another study aiming at comparing the quality of life of patients assigned to medical or surgical treatment during a 10-year follow-up showed that the improvement in quality of life, decrease in anginal symptoms, increase in physical activity, and reduction in the use of anti-angina drugs were higher among the patients treated with surgery only in the first few years of follow-up. At the end of the study, patients in the surgical group had a recurrence of the anginal symptoms, which affected their quality of life²⁶. In this study, not the SF-36, but a generic questionnaire was administered. A non-specified self-administered questionnaire assessing physical activity and general well being was administered in patients undergoing angioplasty and medical treatment. In this study, the patients treated with angioplasty had a significant improvement of their physical and mental performances. This improvement was related to the patients who had a better performance in the exercise tests²⁷. We have to consider that the patients in this study had single-vessel coronary disease, stable angina, and preserved ventricular function, which provide an excellent clinical prognosis in the long term. Using the Nottingham Health Profile²⁸, a self-administered assessment instrument, the Coronary Angioplasty versus Bypass Revascularization Trial (CABRI) did not show differences in quality of life between the two treatment modalities; however, after one year of follow-up, improvement in the vitality perception was observed between the two groups of patients studied²⁹.

Final considerations - Some of the studies previously mentioned were conducted in multiple centers whereas others, in several countries. Given the social and cultural differences of each research center, the different patient samples studied, and also the different quality of life instruments used, some degree of bias in the results obtained in these studies has to be considered. On the other hand, the homogeneity of our sample, deemed as comprised of stable patients, and simultaneously appropriate for any type of treatment or intervention, had positive implications in the final result of the study. Also, the follow-up of these patients performed by the same medical team that started the treatment, as well as the quality of life interviews conducted by the same researcher, contributed to a better reliability of the results. Thus, the clinical and quality of life improvement experienced by all patients should be considered within a context of continuous follow-up and multiprofessional care, including specific rehabilitation programs. The significantly higher quality of

life in its two major components and also in various domains observed among the patients undergoing surgery in relation to those of the other treatment groups should be analyzed considering the whole clinical variability, comorbidities, physical and emotional aspects, expectations prior to the intervention, as well as the randomized treatment indication

deemed by the patients as effective and definitive.

Potential Conflict of Interest

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

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