Critical analysis of the classic indications for myocardial revascularization

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SUMMARY

Treatment of stable coronary artery disease (CAD) relies on improved prognosis and relief of symptoms. National and international guidelines on CAD support the indication of revascularization in patients with limiting symptoms and refractory to optimal medical treatment, as well as in clinical situations where there is a prognostic benefit of interventional treatment. Most of the studies that support the guidelines for indication of revascularization date back to the 1980s and1990s of the last century. Recent studies have revisited the theme and brought a new breath. The present review provides a critical analysis of classic indications for revascularization, reviewing evidence from the studies of the 1970s to the recent controversial ORBITA study.

KEYWORDS: *Coronary artery disease. Myocardial Revascularization. Angina, Stable.*

INTRODUCTION

Once the diagnosis of stable coronary artery disease (CAD) is established and the optimal medical therapy (OMT) introduced, the clinical cardiologist is faced with the dilemma of whether or not coronary intervention (surgical or percutaneous) associated to the OMT is necessary. There is no doubt that the OMT is absolutely necessary and responsible for over 70% of the reduction in the relative risk of death or myocardial infarction in two years in the context of secondary prevention[1].

However, the dilemma is real. The evidence directs us to the lack of prognostic benefit of surgical or percutaneous revascularization when compared to exclusive OMT, when indicated routinely and generally[2,3]. This same evidence, however, identifies specific subpopulations, whose high risk of adverse outcomes could be reduced with myocardial revascularization[4]. The recognition of these subpopulations is an indispensable part of the therapeutic management of patients with stable CAD.

CLASSICAL INDICATIONS FOR REVASCULARIZATION

The identification of the spectra of stable CAD that benefit from revascularization procedures in addition to the OMT is based on the concept that the benefit of revascularization is greater the more severe is the CAD. The severeness is considered from a clinical (limiting symptoms), angiographic (lesions

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in the topography of poor prognosis), ischemic (extensive area at risk), or ventricular function (systolic dysfunction of the left ventricle) perspective.

Thus, the decisive elements for defining the indication of revascularization are focused on the patient: symptoms, anatomy, ischemia and left ventricular systolic function. Some of these variables, in addition to assisting in the indication of myocardial revascularization, also help in selecting the strategy of revascularization. However, it is necessary to differentiate the tools necessary for the best judgment of indication of those useful in the selection of the intervention strategy (Figure 1).

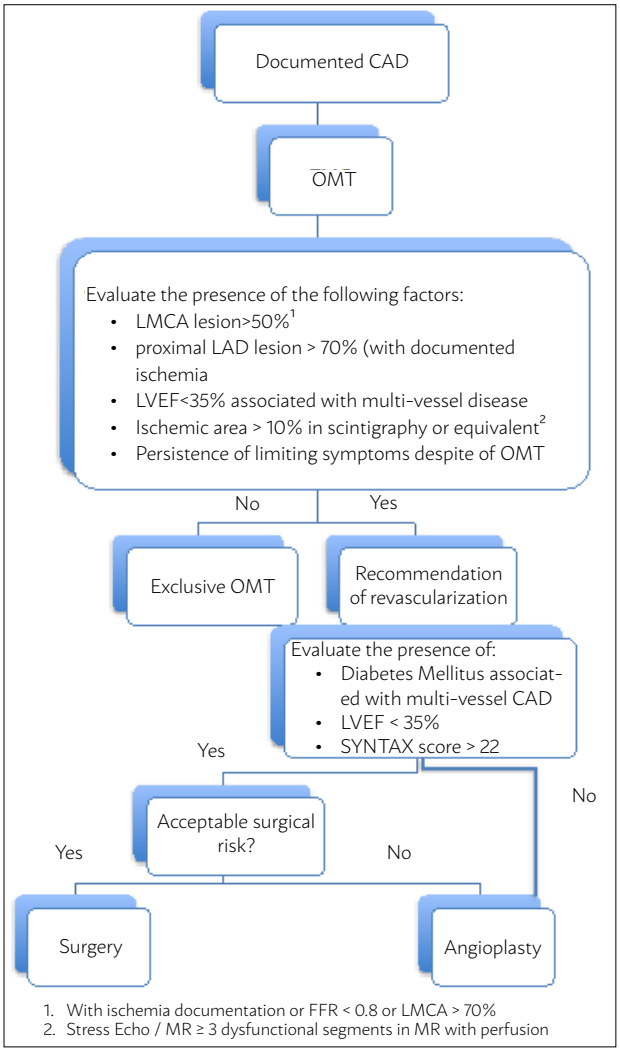
PRESENCE OF DOCUMENTED ISCHEMIA

Classically, the presence of moderate-to-severe ischemic burden constitutes as one of the indications for myocardial revascularization in chronic coronary artery disease (CAD). A retrospective study with observational data evaluated the relationship between the ischemic area detected by means of stress and resting scintigraphy and cardiovascular mortality[5]. Patients were randomly divided into two groups, clinical (9,956 individuals) or surgical (678 patients), in accordance with the established treatment after 60 days of the scintigraphy. In patients in which they identified an ischemic area of 1%-5%, there was a mortality rate of 1% in the clinical group and 1.8% in the surgical group. However, above 10%, there was a mortality rate of 4.8% in the group of drug therapy alone *versus* 3.3% in the group of surgical revascularization. Finally, for those with significant ischemia (> 20%), the mortality rate in the clinical group was more than three times higher than that of the intervention group (6.7% *versus* 2.0%). A careful analysis of these findings is necessary because this is a retrospective study in which the cause-and-effect association cannot be fully established.

A recent prospective and randomized study compared the angioplasty guided by FFR with drug-eluting stents, combined with pharmacological treatment, and the clinical treatment alone in patients with stable CAD[6]. The lesions with FFR < 0.8 were treated. There was a reduction of the composite outcome of mortality due to all causes, non-fatal myocardial infarction and unplanned hospitalization with new revascularization in two years. However, this reduction was due only to the decrease in additional revascularizations, without impact on myocardial infarction or mortality. On the other hand, in patients with lesions anatomically significant but without ischemia evidenced by FFR, there was an excellent prognosis with clinical treatment alone. There are also some limitations of this study that are noteworthy. The early interruption in the recruitment of patients after the analysis of a high rate of events in the control group may have reduced the power of the study. In addition, doctors and patients were not blinded regarding the group they belonged to. This fact may have influenced the decision-making process during the follow-up.

Conversely, it is worth mentioning the nuclear subanalysis of the Courage study[7], in which the treatment with percutaneous angioplasty (PCI) was superior to the clinical treatment in the reduction of ischemia assessed using myocardial scintigraphy (2.7% reduction *versus* 0.5%). However, this finding did not translate into improved survival after adjusted risk analysis.

FIGURE 1.



The moderate-to-severe ischemic burden seems to indicate the worst prognosis. However, the thresholds of both ischemic area and fractional flow reserve still need to be reviewed as indicators of intervention. In this perspective, the ischemia trial (ClinicalTrials.gov Identifier: NCT01471522), randomized, controlled, under development, will evaluate more consistently the prognostic impact of ischemia in stable CAD, as well as the role of myocardial revascularization in this context.

PRESENCE OF ANGINA

In addition to the prognostic improvement, symptomatic relief is one of the main objectives of the treatment of stable angina. Data from the literature demonstrate that the intervention treatments can be used in conjunction with a clinical treatment for this purpose. In this perspective, the quality of life analysis of the classic CASS study[2] showed that in patients with angina CCS I or II myocardial revascularization surgery, compared to clinical treatment alone, improved the quality of life, reduced angina more significantly, with a reduction of the daily need of beta-blockers and nitrates. A subanalysis of the STICH study[8] demonstrated that the presence of angina was not a predictor of a worse prognosis in patients with ventricular dysfunction and CAD and did not identify patients who could present better survival with surgical revascularization. Notwithstanding, surgery reduced angina more consistently than drug treatment alone. Percutaneous angioplasty with stent was also assessed for symptomatic control. Parisi et al.[9] demonstrated, in a prospective study of patients with angina and documented ischemia on cardiac stress testing and coronary lesions in main vessels above 70%, that drug therapy alone or its association with percutaneous angioplasty (PCI) were effective in reducing the incidence of symptoms, as well as increasing exercise time and improving the quality of life. However, these benefits were more significant in the group submitted to PCI.

The Orbita[10] study was the target of great controversy, since it demonstrated, randomly and blindly, the futility of the percutaneous treatment in the improvement of exercise tolerance in a population with univessel CAD by visual estimation. The selection of individuals (univessel, oligosymptomatic, approximately 25% without demonstrated ischemia), as well as the primary outcome selected (time of exercise tolerance, with objective ischemia or class of secondary angina outcomes) may explain the results of this study[11]. Thus, the Orbita study should not be generalized to the heterogeneous population with CAD.

Thus, it is recommended that clinical treatment be optimized as the initial strategy for angina control. If there is symptomatic resistance in its duration, both percutaneous and surgical treatment may be indicated, and the choice of each method depends on the anatomical complexity of comorbidities, functional status, and the preference of the patient.

ANATOMICAL COMPLEXITY OF CORONARY ARTERY DISEASE

Lesion in the proximal LAD

The most commonly used definition of the lesion in the proximal LAD consists in the stenosis between the end of the LMCA and the first great septal or first diagonal, whichever is nearest[12]. The prevalence of atherosclerotic involvement at this location can reach 41% in a population of patients in CAD assessment[13].

Classically, due to the large extension of myocardium at risk associated with stenosis of the proximal LAD, the interventionist approach is recommended in this scenario. In the European study, the subgroup of patients with stenosis above 50% in the proximal LAD showed higher mortality in the group submitted to drug treatment when compared to the surgical group, mainly in association with three-vessel disease[14]. Since then, the presence of a lesion in the proximal LAD has been associated with a worse prognosis in the long term, irrespective of the number of arteries affected. The two studies in question, however, were carried out in the period in which the clinical treatment for CAD consisted of symptomatic medications, with little or no impact on prognosis.

The Mass I[15] study, after comparing three therapeutic strategies (surgery, balloon angioplasty, or drug treatment alone) in a sample of 214 patients with isolated involvement of the proximal LAD and preserved left ventricular function, showed no difference in mortality or infarction among the three groups. In the surgical group, there was a reduction in the primary composite outcome at the expense of a lower rate of additional revascularization. In a subanalysis of the Courage study[16], the presence of a lesion in the proximal LAD, even in three-vessel patients, was not associated with the increase in the primary outcome composed of death, myocardi-

al infarction, and unstable angina. In the same way, when compared with the clinical treatment alone, revascularization was not proved to be beneficial in this subgroup of patients. Thus, in individuals who do not present angina that is limiting and resistant to optimal medical therapy, the initial therapeutic approach with regular clinical follow-up and optimization of medications is an acceptable strategy in this population in relation to survival. The guidelines that recommend revascularization in this scenario with prognosis benefit are based on reducing the need for additional revascularization during follow-up, with no change in mortality. On the other hand, when opting for myocardial revascularization in this context (indication of revascularization for improvement of symptoms, for example), the choice of the best interventionist strategy (surgical or percutaneous) is still a subject of debate in clinical practice.

In a meta-analysis including nine randomized studies that compared the strategies of revascularization in 1,210 patients with isolated involvement of the proximal LAD, Kapoor et al.[17] showed there was no difference in mortality between the groups, but there was less need for additional revascularization and greater symptomatic relief in the surgical group.

In the presence of stenosis of the proximal LAD, therefore, after an initial strategy of optimal clinical treatment, if there is a persistence of symptoms, the two options of interventionist approach may be considered. In the case of percutaneous treatment, however, there is a greater likelihood of a need for new revascularization procedures during outpatient follow-up, but without prognostic impact.

Lesion in the left main coronary artery disease

The lesion in the left main coronary artery (LMCA), among the many segments of the coronary tree, is the most feared because of its association with adverse events, given the magnitude of the territory irrigated by the left coronary system.

Conley et al.[18] followed-up patients who presented LCT lesion documented by cardiac catheterization and did not undergo myocardial revascularization surgery. The survival rate of 163 patients in clinical treatment with lesion ≥ 50% was 79% and 50% in 1 and 3 years, respectively. However, these data differ when comparing lesions between 50%-70% and lesions above 70%. Patients kept under clinical treatment with obstructions in the LCT above 70% presented lower survival in a three-year follow-up compared to those with lesions between 50%-70% (41% *vs.* 66%; $p < 0.05$). Thus, not only a significant lesion in the LMCA but also its severity, represent a prognostic value in this peculiar population of coronary heart disease patients.

The records of the CASS study[19] show 1,484 patients with LCT lesion ≥ 50% allocated to surgical and clinical treatment (MT). Coronary artery bypass grafting (CABG) was the initial treatment in 1,153 patients (78%), in accordance with the preferences of medical staff and patients. The population submitted to CABG had more angina, lesions of greater severity in the LCT, but better left ventricular function. In the greatest long-term follow-up ever published for this type of patients, 15 years, the median survival was of 13.3 years in the surgical group and 6.6 years in the clinical group ($p < 0.001$). However, it should be noted that this significant difference in survival rate between the groups disappears when analyzing only those with preserved ventricular function, even when in association with right coronary lesion greater than 70%. On the other hand, the surgical treatment proposed in the present study, as well as the clinical one, is far from the current standards. The left mammary artery graft, for example, was used in only 9.5% of the patients.

The Iris-Main[20] records are a contemporary study, non-randomized, multicenter, and observational of Asian hospitals, including consecutive patients with LCT lesion ≥ 50% submitted to clinical treatment, percutaneous or surgical. The results were interpreted according to the generation of *stents* used in pre-specified historic times. During all periods, the rates of combined events (death, myocardial infarction, and cerebrovascular accident) were greater in patients under clinical treatment alone in comparison with interventional therapy, regardless of the strategy used. However, they observed a gradual reduction in the rate of events in the population that was kept under the conservative treatment, possibly related to the growing use of statins and dual platelet antiaggregation therapy during the three periods. The rates of events in the group under surgical treatment remained stable, while a significant reduction of these outcomes was observed in patients undergoing percutaneous treatment, in the pre-specified historic times. When comparing the interventional therapies, higher rates of new revascularization always were identified in the percutaneous group (PCI). However, with the advent and development of

pharmacological stents associated with the use of functional revascularization and imaging tools (fractional flow reserve, intravascular ultrasound, and optical coherence tomography), we observed a gradual reduction in the difference for this outcome between the PCI and CABG groups[21].

The choice of clinical treatment alone in patients with a significant lesion in the LMCA is reserved for situations of fragility, low life expectancy, refusal to interventional therapy and anatomy unfavorable for revascularization. The current discussion focuses on the definition of the interventionist strategy more appropriate for this subgroup of patients.

Lesion in the single remaining patent coronary artery

It is defined as lesion in the single remaining patent coronary artery > 50% with the occlusion of all other coronary beds The indication for myocardial revascularization in patients with severe stenosis in the single remaining patent coronary artery consists of a class I recommendation in the major national and international guidelines[22,23]. However, this recommendation is based on physiopathology and not on clinical evidence. In fact, an event associated with this artery will most likely result in a fatal event. However, the selection of the best strategy of revascularization should be based on angiographic aspects, presence of comorbidities, and left ventricular function.

PRESENCE OF VENTRICULAR DYSFUNCTION

Coronary artery disease (CAD) is the most common etiology of heart failure with reduced ejection fraction. The presence of left ventricular dysfunction confers a worse prognosis for patients with chronic coronary disease. The objective of myocardial revascularization for this group of patients consists of contractile recovery after the coronary flow is reestablished, the reduction of cardiovascular events, and the improvement of symptoms and functional capacity[24].

The STICH study[25] (Surgical Treatment of Ischemic Heart Failure), in a sample of 1,212 patients with ventricular dysfunction (ejection fraction less than 35%) associated with multivessel coronary disease, compared the optimized clinical treatment with surgical myocardial revascularization. After a median follow-up of five years, there was no difference between the two therapeutic strategies with regards to the primary outcome of general mortality, but there was a trend of reduction of cardiovascular mortality in the surgical group. With the objective of better selecting individuals with ventricular dysfunction that could benefit from a surgical approach, Velazquez et al.[4], in a subanalysis of the STICH, study identified three predictors of prognostic benefit with revascularization surgery (three-vessel disease, ejection fraction lower than 27%, and indexed end-systolic volume greater than 79 ml/m2). In the presence of two or more of these factors, the patients had lower mortality when submitted to a surgical procedure in comparison with the sample with one or no predictor. Additionally, the results of the very long-term follow-up of the STICH study corroborate the indication for surgical revascularization for ischemic cardiomyopathy. In this analysis, the surgical group presented lower overall mortality rates and cardiovascular mortality when compared to patients undergoing clinical treatment alone.

In patients with left ventricular dysfunction secondary to multivessel CAD, therefore, current evidence suggests that the prognosis benefit of the surgical strategy should be prioritized in the therapeutic management, regardless of the documentation of myocardial viability. However, patients with high surgical risk, fragile and/or with less complex anatomy, can be eligible for percutaneous treatment, especially when undergoing complete revascularization[26].

PATIENTS WITH DIABETES MELLITUS

A patient with diabetes mellitus (DM) presents a higher risk of death and adverse events in the context of CAD. Due to angiographic (more extensive disease, affecting more coronary segments and/or more diffuse), plaque (a higher probability of plaques called “vulnerable”), and individual (greater association with other morbidities, kidney insufficiency, for example) peculiarities, the indication of an earlier intervention in the natural history of CAD is questioned in these individuals in an attempt to prevent more serious cardiovascular events. However, the evolution of the atherosclerotic disease in diabetic patients undergoing the various procedures of intervention is also marked by complications. Thus, we know that the diabetic population is more susceptible to thrombosis and restenosis of stents, as well as a higher rate of early (CVA, infections) and late (lower patency of grafts in the long term) surgical complica-

tions. Thus, the safety of keeping a diabetic patient with CAD in a drug treatment alone was researched in studies with long-term follow-up.

The BARI 2D[27] study, which included a population of 2,368 diabetic patients with multivessel CAD, showed no difference in the incidence of AMI, CVA, or death in the long-term follow-up, comparing the intervention (with surgery or conventional angioplasty with stent) and optimal medical therapy (OMT). However, there was a lower incidence of the combined primary outcome of AMI, CVA, and death in the subgroup submitted to surgery compared to the OMT group (22.4% *versus* 30.5%; p = 0.01).

In our environment, a subanalysis of the MASS study[28] compared three therapeutic modalities (surgery, angioplasty, and OMT) in 190 diabetic patients with stable multivessel CAD, out of the 611 included in the original study. After the first year of follow-up, a lower mortality rate among those submitted to interventionist procedures (surgery and angioplasty) was observed when compared to the OMT group (p = 0.039). These data were confirmed in a ten-year follow-up of the same population, with the benefit of the surgery over the clinical treatment alone among diabetics[29].

The indication of revascularization in diabetic patients with CAD without further formal indications of revascularization is controversial and lacks evidence. However, once the revascularization is indicated, there is the benefit of surgical treatment over the percutaneous treatment among patients with multivessel CAD[30].

CONCLUSION

The indications for myocardial revascularization are substantiated on more than 30 years of evidence and aspects that focus on symptoms, coronary anatomy, as well as the presence of extensive ischemia and left ventricular dysfunction. The variables that govern the indication of myocardial revascularization should be properly distinguished from those that assist in the selection of the best strategy of revascularization.

RESUMO

O tratamento da doença arterial coronariana estável (DAC) se baseia na melhora do prognóstico e alívio de sintomas. Diretrizes nacionais e internacionais sobre a DAC respaldam a indicação de revascularização em pacientes com sintomas limitantes e refratários ao tratamento medicamentoso, bem como em situações clínicas nas quais há benefício prognóstico do tratamento intervencionista. Grande parte dos estudos que norteiam as diretrizes de indicação de revascularização data das décadas de 1980 e 1990. Estudos recentes têm revisitado o tema e trazido novo fôlego. A presente revisão faz uma análise crítica das indicações clássicas de revascularização, revisando a evidência desde os estudos da década de 1970 ao recente e polêmico estudo Orbita.

PALAVRAS-CHAVE: *Doença da artéria coronariana. Revascularização miocárdica. Angina estável.*

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