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Analysis of percutaneous coronary intervention outcomes in unprotected left main coronary artery lesions

Análise dos desfechos em intervenção coronária percutânea de tronco de coronária esquerda não protegido

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ABSTRACT – **Background:** Significant lesions in the left main coronary artery are found in approximately 5% of patients undergoing coronary angiography, with most cases involving multiple vessels and affecting the distal bifurcation. A coronary artery bypass graft surgery is considered the preferred treatment for unprotected left main coronary artery lesions. However, with the advancement of techniques and the introduction of new drug-eluting stents, percutaneous coronary intervention has been considered a viable strategy, with favorable results. The objective of this study was to analyze the outcomes in patients with unprotected left main coronary artery lesions undergoing percutaneous coronary intervention. **Methods:** Electronic data from patients undergoing percutaneous coronary intervention between December 2017 and January 2020 at a single center were analyzed to assess clinical and angiographic characteristics and clinical outcomes. **Results:** A total of 103 patients with significant unprotected left main coronary artery lesions were included; in that, 66% were male, 88.3% were hypertensive, and 87.4% had normal ventricular function. Lesions involving the bifurcation were identified in 73.8% of patients, 36.9% had concomitant lesions in the three major epicardial vessels, and 42.7% had an intermediate SYNTAX score (23 to 32 points). Angiographic success was achieved in 100% of cases, with four (3.9%) adverse cardiac and cerebrovascular events, with 2.9% mortality. **Conclusion:** Hospital results support percutaneous coronary intervention as a safe procedure, with excellent angiographic results and low rates of adverse cardiac and cerebrovascular events. We concluded that PCI is an option to coronary artery bypass graft surgery and is a very viable option for surgical treatment of unprotected left main coronary artery lesions.

Keywords: Coronary angiography; Coronary artery disease; Percutaneous coronary intervention; Myocardial revascularization; Drug-eluting stents

RESUMO – **Introdução:** Lesões significativas no tronco de coronária esquerda são encontradas em aproximadamente 5% dos pacientes submetidos à coronariografia, sendo a maioria dos casos multiarteriais e com envolvimento do tronco distal. A cirurgia de revascularização do miocárdio é considerada o tratamento preferencial para lesões de tronco de coronária esquerda não protegido. No entanto, com o avanço de técnicas e a introdução dos novos stents liberadores de fármacos, a intervenção coronariana percutânea tem sido considerada estratégia viável, apresentando resultados favoráveis. O objetivo deste estudo foi analisar os desfechos em pacientes com lesões de tronco de coronária esquerda não protegido submetidos à intervenção coronariana percutânea. **Métodos:** Foram analisados dados eletrônicos de pacientes submetidos à intervenção coronariana percutânea entre dezembro de 2017 e janeiro de 2020 em um único centro, com o objetivo de avaliar características clínicas, angiográficas e os desfechos clínicos. **Resultados:** Foram incluídos 103 pacientes portadores de lesões significativas de tronco não protegido, 66% eram do sexo masculino, 88,3% eram hipertensos, e 87,4% possuíam função ventricular normal. Lesões envolvendo a bifurcação foram identificadas em 73,8% dos pacientes, 36,9% apresentavam lesões concomitantes nos três grandes vasos epicárdicos e 42,7% com escore SYNTAX intermediário (23 a 32 pontos). O sucesso angiográfico foi obtido em 100% dos casos, com quatro (3,9%) eventos cardíacos e cerebrovasculares adversos, sendo 2,9% de mortalidade. **Conclusão:** Os resultados hospitalares sustentam a intervenção coronariana percutânea

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como um procedimento seguro, de excelente resultado angiográfico e eventos cardíacos e cerebrovasculares adversos comparáveis aos da cirurgia de revascularização do miocárdio, configurando opção bastante viável em relação ao tratamento cirúrgico.

Descritores: Angiografia coronária; Doença da artéria coronariana; Intervenção coronária percutânea; Revascularização miocárdica; Stents farmacológicos

INTRODUCTION

Left main coronary artery (LMCA) lesions are always relevant, due to the risk of serious clinical repercussions due to the large myocardial area involved. They are considered severe when the obstruction is greater than 50% of the coronary lumen or the angiographic appearance indicates a high probability of acute occlusion (dissection, ulcer, or thrombus). Left main coronary artery is classified as protected when the patient has a patent bypass graft to the left circumflex artery or to the left anterior descending artery.[1] Significant lesions in the LMCA are found in approximately 5% of patients with coronary artery disease (CAD) undergoing coronary angiography: 11% to 29% are isolated lesions, and 52% to 81% with involvement of the distal segment of the LMCA (bifurcation or trifurcation).[2]

Historically, coronary artery bypass grafting (CABG) has always been the preferred treatment for unprotected LMCA lesions, and considered superior to an optimized drug treatment.[3,4] Up until recently, percutaneous coronary intervention (PCI) was not considered as a treatment option, due to technical difficulties, the high prevalence of associated lesions in other coronary vessels, and the high risk of restenosis, which can lead to catastrophic outcomes.[4]

However, with the evolution of techniques for the treatment of bifurcation lesions, intracoronary imaging, and the introduction of new generations of drug-eluting stents (DES), the PCI approach has become a viable strategy, especially for patients with low complexity lesions (SYNTAX score ≤22).[2,5,6] Recent American and European guidelines on revascularization take into account some factors, such as patient preference, comorbidities and lesion complexity when choosing between PCI and CABG. It is important to clarify the risks and potential benefits of each technique to patients and offer both as treatment options.[1]

The present study aimed to analyze the results obtained in the treatment of unprotected LMCA lesions by PCI, performed in a single center, evaluating demographic variables, the technique used, adjunct devices and clinical and angiographic outcomes in the hospital phase.

METHODS

This was a descriptive, retrospective study involving patients with significant unprotected LMCA lesions undergoing PCI, between December 2017 and January 2020, at *Hospital Encore*, in the city of Aparecida de Goiânia (GO). Patients with acute coronary syndrome (ACS) due to an LMCA lesion at hospital admission were excluded. After the identification of eligible patients, previous clinical and angiographic characteristics, procedure-related technical data, and clinical and angiographic outcomes during the hospital phase were analyzed, using the electronic medical records. Cardiac catheterization images were reviewed by an experienced interventional cardiologist, and the SYNTAX score was used as a tool to stratify the angiographic complexity of the lesions. In addition, the occurrence of adverse events after hospital discharge was monitored by telephone follow-up.

Clinical outcomes were analyzed using major adverse cardiac and cerebrovascular events (MACCE) that occurred during the hospital phase, defined as death from any cause, non-fatal acute myocardial infarction (MI), stroke, or need for further emergency intervention (CABG or PCI). Angiographic success was defined as a successful stent implantation, with <20% residual stenosis and final Thrombolysis in Myocardial Infarction (TIMI) 3 flow, whereas intervention success was defined as angiographic success with no MACCE during the period of hospitalization.[7,8]

In addition, in the post-PCI telephone follow-up, patients were asked about the absence or presence of symptoms (chest pain or shortness of breath), physical exercise, a return visit to a cardiologist, and the need for further intervention (PCI or cardiac surgery).

The tabulation and the descriptive statistical analysis were performed in Microsoft Excel®. Quantitative variables were expressed as means and standard deviations. Qualitative variables were described in absolute numbers and proportions.

The Research Ethics Committee of the *Hospital de Urgências de Goiânia* approved this study (CAAE: 32731420.3.0000.0033).

RESULTS

The records of 157 patients were analyzed, of which 103 (65.6%) met the eligibility criteria and were selected to comprise the sample: the patients had a >50% unprotected LMCA lesion, associated or not with other lesions. The remaining 54 (34.4%) were excluded because they did not meet the inclusion criteria or there was a failure during the angiographic images recording.

The demographic characteristics are shown in table 1. The mean age was 69 years, with 68 (66%) male patients, 91 (88.3%) hypertensive patients, and 81 (78.6%) dyslipidemia patients, and the most common clinical presentation was stable angina (49.5%).

Table 2 shows the technical and angiographic characteristics of the procedure. Seventy-six patients (73.8%) had bifurcation lesions and 38 (36.9%) had lesions

Table 1. Clinical characteristics

Characteristics	
Age, years	69±9.9
Male	68 (66)
HTN	91 (88.3)
Dyslipidemia	81 (78.6)
Diabetes mellitus	47 (45.6)
Smoking habit	
Prior	43 (41.7)
Active	14 (13.6)
Creatinine clearance <60mL/min/1.73 m^2	33 (32)
LVEF <50%	13 (12.6)
Clinical presentation	
Stable angina	51 (49.5)
Asymptomatic	26 (25.3)
Unstable angina	15 (14.6)
MI	11 (10.6)

Results expressed as mean ± standard deviation or n (%).
HTN: hypertension; LVEF: left ventricular ejection fraction; MI: myocardial infarction.

Table 2. Technical and angiographic data

Characteristics	
Location of the lesion in the LMCA	
Ostium/body	17 (16.5)
Bifurcation	76 (73.8)
Trifurcation	10 (9.7)
Affected vessels	
Isolated LMCA	12 (11.7)
LMCA + 1 vessel	24 (23.3)
LMCA + 2 vessels	
LMCA + 3 or more vessels	38 (36.9)
Calcified LMCA	26 (25.2)
SYNTAX score, points	
<23	41 (39.8)
23-32	44 (42.7)
>32	18 (17.5)
Mean ± SD	25.1±8.9
Classification of bifurcation lesions (Medina)	
1,1,1	41 (39.8)
1,1,0	17 (16.5)
1,0,1	9 (8.7)
1,0,0	4 (3.9)
0,0,1	2 (1.9)
0,1,1	2 (1.9)
0,1,0	1 (1.0)
Not applicable	27 (26.3)
Technique used	
Single stent	65 (63.1)
Mini crush	17 (16.5)
TAP	14 (13.6)
T-stenting	4 (3.9)
Culotte	2 (1.9)
Double kissing crush	1 (1)
Adjunct devices	
Intravascular ultrasound	37 (35.9)
Rotational atherectomy	10 (9.7)
Vascular access	
Radial	22 (21.4)
Femoral	78 (75.7)
Brachial	3 (2.9)
Catheter diameter, F	
5	3 (2.9)
6	35 (34.0)
7	60 (58.2)
8	5 (4.9)
Vascular occlusion devices	
Proglide	19 (18.4)
Angio-Seal	20 (19.4)

Results expressed as n (%) when not stated otherwise.
LMCA: left main coronary artery; SD: standard deviation; TAP: T and protrusion.

involving the three major epicardial vessels. Complex lesions, with SYNTAX above 32, were found in 18 (17.5%) cases. The single stent technique was performed in 65 patients (63.1%), and in only 17 the lesion was restricted to the ostium and/or body. In 38 cases of distal lesions, two or more stents were needed, and the most used technique was mini-crush (16.5%), followed by T and protrusion (TAP; 13.6%), T-stenting (3.9%), culotte (1.9%), and DK-crush (1%). The drug used in the stent was everolimus in 96% of cases. The most commonly used adjunct device was intravascular ultrasound (IVUS) in 37 (35.9%) patients, followed by rotational atherectomy (Rotablator™) in ten (9.7%) cases. The total mean length and diameter of the implanted stents were 3.8mm and 80.3mm, respectively. Angiographic success was achieved in 100% of cases, and the mean length of hospital stay was 4.9 days.

During the in-hospital period (Table 3), three deaths were recorded, and these patients had high SYNTAX and high risk for CABG – two patients were diabetic and had a compromised ventricular function, and the treatment option was PCI, after discussion by Heart Team. Intra-aortic balloon counterpulsation was used in one patient, who died from cardiogenic shock. Myocardial infarction requiring reintervention was diagnosed in a patient on the fifth day of hospitalization due to in-stent thrombosis in the left circumflex artery, treated with abciximab, at the intensive care unit, with a good clinical course.

There were also eight cases of minor complications, six related to the puncture site and two acute stent thrombosis. Bleeding from the arterial access route occurred in two cases, one of which required transfusion of blood product.

Data on late clinical follow-up, in a period of up to 3 years after the procedure, were obtained through telephone contact and are shown in table 4. Calls were successful in 71.8% of cases, and 22 patients required additional intervention; 17 underwent cardiac recatheterization, and five were operated on.

Table 3. Clinical outcomes and complications in the hospital phase

Events	
MACCE	
Cardiovascular death	3 (2.9)
Need for further intervention (CABG or PCI)	1 (1.0)
Non-fatal MI	0
Stroke	0
Complications	
Hematoma on access site	2 (1.9)
Bleeding	2 (1.9)
Femoral pseudoaneurysm	2 (1.9)
Stent thrombosis	2 (1.9)
Total	12 (11.6)

Results expressed as n (%).
MACCE: major adverse cardiac and cerebrovascular events; CABG: coronary artery bypass graft surgery; PCI: percutaneous coronary intervention; MI: myocardial infarction.

Table 4. Telephone follow-up after percutaneous coronary intervention

Characteristics	
Successful calls	74 (71.8)
Alive	66 (89.2)
Chest pain	7 (9.4)
Shortness of breath	11 (14.8)
Asymptomatic	50 (67.5)
Follow-up with cardiologist	61 (82.4)
Recatheterization	17 (22.9)
Underwent heart surgery	5 (6.7)
Does regular physical activity	16 (21.6)
Frequency of physical activity, times/week	3.9±1.5

Results expressed as n (%) or mean ± standard deviation.

DISCUSSION

The present study reports the experience in the treatment of unprotected LMCA lesions by PCI performed in a single cardiology center. More than half of the cases had a low or intermediate SYNTAX score, and the immediate results were promising, with angiographic success in all of them and low MACCE (4; 3.9%). Therefore, this is a safe and effective treatment option, with low rates of in-hospital complications.

The population studied was predominantly composed of elderly patients, with multiple comorbidities and high risk for coronary heart disease. Hypertension was the most prevalent risk factor, followed by dyslipidemia, both of which were increased when compared to the general population for the same age group.[9] A total of 45.6 % of patients in the sample had diabetes, which is a higher risk factor, tending to worse prognosis and progression to unfavorable outcomes when compared to non-diabetic patients.[10]

Over a quarter (25.3%) of patients underwent treatment for LMCA lesion and were previously asymptomatic, and diagnosis was established after routine outpatient examinations. Hence, the data reinforce the importance of individualized investigation of ischemic disease in patients at high risk of cardiovascular events.

Aiming to compare the primary and secondary outcomes of PCI revascularization *versus* CABG, a meta-analysis of five studies, published in 2016, evaluated the clinical safety in the treatment of LMCA. The included studies were PRECOMBAT, SYNTAX, NOBLE, EXCEL, and Boudriot et al., with a total of 4,594 patients followed up for a period of 12 to 60 months. There was no difference in the rates of mortality from all causes, infarction, or stroke, although patients undergoing CABG had significantly lower rates of revascularization (OR 1.85; 95%CI 1.53-2.23; p<0.001).[2,11]

In 2020, the 10-year extended follow-up results of the 600 patients studied in PRECOMBAT were published. Despite limited by the sample size, the non-inferiority remained.[12]

The success in the treatment of LMCA lesions is directly related to the angiographic characteristics of the lesions. Most subjects in the sample (82.5%) had low to intermediate complexity lesions when stratified by SYNTAX, involving at least one vessel in addition to the LMCA (88.3%). Patients with complex lesions represented 17.5% of population. In these cases, considering the SYNTAX score (>32) as an isolated factor, CABG may be of greater benefit to the patient. However, the score is limited because it does not consider other important factors, such as surgical risk, contraindications, patient's preference and socioeconomic aspects, and it should not be the only aspect taken into account for decision making.[8]

In addition to the angiographic aspects, the intravascular anatomical assessment using IVUS and the functional assessment using fractional flow reserve (FFR), and/or the new non-hyperemic physiological rates have proved to be a valuable tool in decision making. By determining characteristics of the lesions and the dimensions of the artery with high accuracy, IVUS contributes to the adequate selection of the stent and technique to be used, in addition to evaluating the need for additional balloon expansion, or the use of rotational atherectomy in lesions with severe calcification.[7,13,14]

Results of the study by Fujii et al. demonstrated that inappropriate expansion and residual segmental stenosis were independent risk factors for post-procedure restenosis and stent thrombosis.[15,16] In this study, the thrombosis rate was 2.9%, and two thromboses occurred during an intervention performed with IVUS, and one thrombosis occurred 5 days after a stent implantation in the left circumflex artery, a procedure performed without IVUS. In the records of the NOBLE, PRECOMBAT and EXCEL studies, PCI was guided by IVUS in 47%, 91%, and 77% of patients, respectively, whereas in the present service, it

was performed in 35.9% of patients. This difference is due to its high cost and the difficulties found for the exam to be approved by supplemental healthcare services. FFR has been indicated for borderline lesions (40% to 50%) and concerns about side branch entrapment.[7] Throughout this series, no FFR was available in this service, and such an assessment was not possible. As to rotational atherectomy, the Rotablator™ was used in 9.7% of procedures, a value above the general average when compared to the treatment of any other vessel, which reaches 2.5%, as reported by Seca et al., indicating greater complexity and calcifications of LMCA lesions.[17]

The average number of total stents implanted per patient was 3.2, a value above those reported in other published studies, which were roughly 2.5.[2] The most used technique in bifurcation lesions was the provisional technique, up until then considered the most adequate one, according to BBC ONE and NORDIC studies, which demonstrated this technique was superior to the double stent technique, with lower mortality in a 5-year follow-up. The results of the EBC MAIN randomized study have been recently published, comparing the provisional technique and the double stent technique for the treatment LCMA lesions, and concluded there is no significant difference between the two approaches, and the provisional technique should be used as the standard treatment in LMCA bifurcation interventions.[18]

Vascular occlusion devices were used for hemostasis in 39 patients. A systematic review published by Cox et al. showed shorter bed rest and hospital stay, but with similar complication rates when compared to manual compression.[19]

The average length of stay was approximately 5 days, which is considered high when compared to other similar studies, in which the approximate length of stay did not exceed 2 days. This discrepancy can be explained by the fact that few patients had severe complications, requiring prolonged hospitalization. However, most patients remained hospitalized for 3 days. On the other hand, this can be considered an advantage, if compared to the length of stay of patients undergoing CABG, which was approximately 9 days, according to data shown in the NOBLE study.[20]

In this study, angiographic success was achieved in the treatment of LMCA lesions in 100% of cases. Four (3.9%) MACCE and eight minor adverse events were reported, with an in-hospital mortality rate of 2.9%, values comparable to those found in the DELTA study (6.8% for MACCE and 2.0% of all-cause mortality).[21]

Continuing the analysis, the late follow-up was carried out through telephone contact, and 71.8% of calls were successful. Despite the barriers, among the successful calls, 10.8% of patients died within a period of up to 3 years after the procedure, and 25.8% needed cardiac recatheterization, a superior finding when compared to the results shown in the most relevant studies comparing PCI and CABG treatments. However, the data must be interpreted with caution, considering the gaps that make the analysis difficult, such as 28.2% of failed phone calls, impossibility of defining the cause of non-hospital deaths and the fact that, in some cases, the information was transmitted by third parties, which may result in information bias and overestimation of negative results for the evaluated period.

The higher recatheterization and mortality rates after hospital discharge can be explained, in part, by the high number of patients undergoing the procedure who had highly complex lesions, with potentially greater risk of an unfavorable clinical course. Therefore, the data support the need to expand knowledge regarding probable causes of worse late outcomes for the development of intervention and management strategies.

CONCLUSION

In this study, the treatment of unprotected left main coronary artery lesions by percutaneous coronary intervention in an unselected population (all-comers) proved to be safe and effective, with low rates of in-hospital complications. The choice between percutaneous coronary intervention or coronary artery bypass graft surgery should be performed after discussion by the Heart Team and in conjunction with the patient's preferences, weighing the risks and the benefits, as well as the technique to be used.

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CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: FPB and GG; data collection: HLG; data interpretation: DRS, MWN, FZ, FHF, AMJ, AGA, DFRR, FLO and MLP; text writing: HLG, GG, MLP and FPB; approval of the final version to be published: HLG, GG, DRS, MWN, FZ, FHF, AMJ, AGA, DFRR, FLO, MLP and FPB.

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