REVIEW PAPER

DOI: https://doi.org/10.5114/kitp.2024.141149

Left main coronary artery disease: percutaneous coronary intervention or coronary artery bypass grafting? A critical review of current knowledge and contemporary debates

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Kardiochirurgia i Torakochirurgia Polska 2024; 21 (2): 108-112

Abstract

Significant unprotected left main (ULM) disease is the highest-risk coronary artery lesion, carries high morbidity and mortality related to a large amount of myocardium supplied, and should undergo prompt revascularization. Among recent randomized controlled trials (RCTs), NOBLE failed to demonstrate non-inferiority of percutaneous coronary intervention (PCI) versus coronary artery bypass grafting (CABG). However, all the other RCTs have shown comparable outcomes. While CABG is associated with higher stroke rates at 30 days and 1 year, PCI is associated with increased spontaneous myocardial infarction (MI) events and the need for repeat revascularization. Furthermore, the benefit of CABG is more evident with the increased complexity of coronary artery disease. In current European and American guidelines, CABG is the standard of care for ULM disease. PCI is considered a reasonable alternative in selected patients (2a B-NR). There is still a great need for carefully designed RCTs with longer follow-up times to validate the role of recent technological and pharmacological regimens.

Key words: coronary artery bypass grafting, percutaneous coronary intervention, left main coronary artery disease, contemporary debates.

Introduction

The left main coronary artery arises from the left sinus of Valsalva, below the sinotubular junction, and, after a short course (average length: 10 mm), it splits into anterior descending and circumflex or trifurcates (1/3 of cases) due to the presence of the intermediate branch. It is divided into three parts: the ostium, middle, and distal part (bifurcation). The ostium lacks an outer coat and has many smooth muscle cells and many elastic fibers, the most in the entire coronary network. This property should be taken into consideration when planning an intervention via angioplasty (PCI), as it provides greater flexibility and support, making it technically advantageous for PCI at this location. The rest of the sections have standard architecture (inner/middle/outer coat), identical to the epicardial coronary arteries [1].

Historically, it was quickly understood that patients with unprotected left main disease (ULMD) face a very high mortality risk (> 50% in 5 years) and morbidity, higher than expected for other locations of coronary artery disease (CAD), because the vessel is responsible for 84% of the blood flow to the left ventricle, and irrigates about 70% of its mass. Given the predictive severity of ULMD in contemporary clinical practice, interventional treatment

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Received: 25.06.2023, **accepted:** 5.05.2024, **online publication**: 30.06.2024.

is strongly recommended for stenoses (> 50%) [2–4]. Left main disease (LMD) is not rare in patients with acute coronary syndrome and multivessel CAD [5]. Therefore, the term LMD seems to include a large and heterogeneous population: with/without disease in the rest of the coronary network, with various locations (ostium, etc.), with/without comorbidities (DM, etc.), with different age distributions, etc. The hemodynamic data of the area play a primary role in the development of atherosclerotic plaque in the left main coronary artery, with the regions of low shear stress being more vulnerable (e.g., on the lateral walls of the bifurcation) and the areas of high shear stress being considered relatively resistant [6].

Also, the length of the vessel seems to play a role in the position where the atheromatous plaque will develop; in short stems, the lesion tends to develop near the ostium, while in larger stems, the lesion tends to be located in the bifurcation area and be more calcified [7]. The interventional methods (coronary artery bypass grafting – CABG, PCI) differ in the mechanisms by which they improve blood flow to the myocardium: PCI directly opens the stenosis, dilates and stabilizes the lumen but does not affect in any way the progression of the atherosclerotic plaque in other parts of the diseased vessel. CABG restores blood flow to the under-perfused myocardium and, by protecting the peripheral vessel from the progression of CAD (due to secretion of vasodilatory factors from the graft), seems to reduce the likelihood of subsequent myocardial infarction (MI) [8].

The developments in imaging methods are crucial in the modern approach to the disease: intravascular ultrasound (IVUS) provides information about the hemodynamic impact and the precise morphological characteristics of the lesion, allowing the selection of the optimal strategy, facilitates stent placement and reveals possible periprocedural complications. Similarly, fractional flow reserve (FFR) measurement evaluates the functional consequences of borderline angiographic lesions, setting or lifting in this way, often playing a pivotal role in patient stratification in favor of interventional treatment [6–8].

The superiority of surgery over conservative treatment was documented in the 1970s and 1980s. Hence, CABG was considered the intervention of choice in LMD [9–11]. However, the developments in interventional cardiology, in combination with the not negligible long-term rate of failure of venous grafts, fueled the research interest for newer treatment options and highlighted PCI as an alternative proposal from the early 2000s.

Randomized controlled trials and meta-analyses for the treatment of left main coronary artery disease

A comprehensive review of the literature was performed via a search in the Medline database. The most relevant articles related to the treatment of patients with left main CAD disease, comparing PCI with open-heart surgery, were selected for discussion:

1) PRECOMBAT: (2004–2009, Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left-Main CAD): A non-inferiority trial, where PCI (first-generation DES) was proven non-inferior to CABG in the endpoints (mortality/MI/stroke/reintervention), at 1 year/5 years/10 years. However, the expanded non-inferiority margins made the study not helpful clinically or at the level of guidelines [12].

2) SYNTAX: (2005–2007, first-generation paclitaxel-eluting-stents) included patients with three-vessel disease and left main coronary artery disease (LMCAD). CABG was enormously superior in the population's endpoints at the follow-up (10 years) [13]. In a posthoc analysis of patients with LMD, the major adverse events were comparable between the two groups: similar mortality at 1–5 years, increased stroke in the CABG group, and increased need for reintervention in the PCI group. Further analysis showed identical effects of the methods in the intermediate/low but clear superiority of surgery in the high SYNTAX scores [14].

3) EXCEL: (2010–2014, Evaluation of Xience Everolimus-Eluting Stent vs. CABG Surgery for Effectiveness of Left-Main Revascularization) included patients with intermediate/low SYNTAX scores. At 3 years, the results were comparable in terms of major endpoints. PCI was associated with fewer bleeding events, infections, and MI in the periprocedural period. These results are confirmed at 5 years. Nevertheless: a) the results of CABG endure and develop over time (the favorable effects of PCI are maintained until 36 months, then CABG evolves better), b) reintervention is more frequent after PCI [15–17].

4) NOBLE: (2008–2015, Nordic-Baltic-British Left-Main Revascularization, 2^{nd} generation biolimus-eluting or 1^{st} generation sirolimus-eluting stents): At 5 years, the major complications were significantly higher for the PCI group, and therefore the hypothesis of non-inferiority was not confirmed. The mortality may have been similar, but CABG was associated with significantly lower stroke, MI, and reintervention rates. Also, stent thrombosis occurred more frequently in NOBLE than in EXCEL, which is attributed to using different stents per study. Finally, the superiority of CABG was confirmed in the whole population, regardless of the SYNTAX score [18].

5) LE MANS: (2008, 2009, 2016, Left Main Coronary Artery Stenting Trial): The initial outcomes showed that patients treated with PCI for unprotected left main coronary artery (ULMCA) disease exhibited more favorable early outcomes than those who underwent CABG. By the 1-year mark, left ventricular ejection fraction (LVEF) had significantly improved in the PCI group alone. Beyond 2 years, the rates of survival without major adverse cardiac and cerebrovascular events (MACCE) were comparable between both groups, although there was a trend towards better long-term survival rates following PCI, which was however statistically not significant [19]. Over a 10-year period, patients who underwent stentingfor revascularization of the ULMCA, showing low tomedium complexity in coexisting coronary artery disease, demonstrated a trend toward improved ejection fraction-

compared to those who underwent surgery. This trend was however still not supported statistically by significant difference. While mortality and MACCE rates did not differ significantly between the stenting and surgery groups, numerical trends favored stenting. There were also no significant differences in the occurrence of myocardial infarction, stroke, and the need for repeated revascularization. The probability of surviving up to 14 years was similar between PCI and CABG, but a trend suggested higher MACCE-free survival in the PCI group. In summary, stenting presented a numerically favorable, though not statistically significant, long-term safety and efficacy outcome up to 10 years, offering a viable alternative to CABG for patients with ULMCA stenosis and low to medium disease complexity [20].

Recently (2017–2021), seven meta-analyses concluded that PCI with DES and CABG have similar efficacy that, depending on the case, extends up to 10 years [21]. The EXCEL and NOBLE studies seem to be the most selective, with a lower risk of bias and thus higher generalizability. However, despite their prospective nature and careful design, they yielded conflicting results. Indeed, while EXCEL proved the non-inferiority of PCI, with NOBLE, this was not possible, reflecting the design heterogeneity between the studies, the different efficacy of alternative types of stents, the other surgical practices in the material (off-pump CABG, on-pump, arterial revascularization), and different effectiveness of each method over time [22].

Also, the selected statistical methods are essential in highlighting and interpreting the results. For example, the Bayesian analysis of EXCEL does not confirm the hypothesis of non-inferiority of PCI. According to this analysis, practices should be individualized. PCI in LM should only concern a strictly selected population with minimal life expectancy (2–3 years) and patients with very high surgical risk [17]. In any case, the results of randomized studies need to be supplemented with longer follow-ups to enhance their reliability. Regardless of any differences, some findings are consistently repeated in randomized studies: i) The 5-year survival is similar, regardless of the method of treatment; ii) reintervention and late MI are higher after PCI; iii) stroke and periprocedural MI are more common in CABG; and iv) the benefit that emerges from the less invasive nature of PCI seems to fade over time.

On the other hand, the entry of patients into the protocols of randomized studies is often a rigorous and restrictive process because a set of criteria must be met simultaneously, both for inclusion and exclusion from the study. This raises concerns about to what extent the results of the studies can be generalized and should guide the decisions of everyday clinical practice. Patients in "real life" usually, in addition to the fundamental cardiological problem, have a set of comorbidities and anatomical peculiarities, which must be taken seriously into consideration in the design and treatment, and such patients are traditionally excluded from extensive studies.

From this point of view, the conclusions from the study of large databases should be taken seriously precisely because they emerge after analyzing the entire population, without exceptions, and unapproved, often categorizations. Thus, the very recent report from the analysis of the Swedish database for angiographically confirmed LMD, excluding patients with non-ST myocardial infarction (Swedish Coronary Angiography and Angioplasty Registry – 10 254 patients, PCI:5391, PP:4863), reached the following conclusions: a) CABG is associated with significantly lower mortality than PCI. b) The favorable effects of CABG are more significant and more evident the longer the patient's life expectancy is. c) PCI should be preferred in elderly patients with LMD (aged > 80 years) [23].

Risk factors related to higher risk for LMD

There is a wealth of evidence concerning the increased risk for progressive atherosclerotic disease, and it merits an individualized approach concerning treatment options. Moreover, diabetic patients are likely to have extensive and diffuse CAD with a high atherosclerotic burden, and diabetes mellitus (DM) is a risk factor for CABG interventions. The recommendation for CABG in diabetic patients with three-vessel CAD is known. However, no specific guidelines exist for patients with LMD and DM because no randomized studies have been done on this question. The data come from subgroup analyses of extensive studies and do not differ, in general, from those of the general population, indicating that the presence of DM has a limited effect on the respective treatment method. Thus, DM patients with LMD and uncomplicated CAD can be treated with PCI [21, 24]. Long-term LMD, when untreated, is often complicated with heart failure (HF). A recent publication highlighted the results of CABG in patients with HF as clearly better than those of PCI, mainly due to the possibility of achieving complete revascularization. Therefore, the functional status of the myocardium is a factor that must be considered when planning the intervention [25]. The optimal treatment for people aged > 70 years is still being determined, given that these patients are usually more vulnerable, with more comorbidities and complex CAD. It seems that elderly (> 70 years) patients with three-vessel CAD ± LMD have a 10-year mortality, a 5-year incidence of significant complications, and a 5-year quality of life that are comparable between PCI and CABG, so PCI probably constitutes a good, effective, safe, and less invasive alternative, the desired outcome, for this group of patients [26].

Finally, the exact topographic location of LMD is a factor of decisive importance in the choice of method. Isolated ostial or trunk lesions are treated equivalently with CABG and PCI [27]. However, bifurcation lesions are more technically demanding, so the results of PCI are inferior to CABG in this position. Before making decisions, a careful study and evaluation of the lesions should be done with all available imaging methods (Angiography/IVUS/FFR) [28].

Lastly, it is essential to consider that CABG techniques differ in efficacy and long-term outcomes. In more detail, achieving total arterial revascularization (TAR) for CABG has been controversial. Although a wealth of evidence has solidified it as the treatment gold standard, it is underused in contemporary clinical practice, with usage rates ranging from 56% to 2%. Thus, there is an increasing need for well-designed studies that compare endovascular treatment methods and TAR. Despite what we know, many of the questions still need to be answered: What is the long-term effectiveness of the most advanced stents, primarily when the intervention is performed under the guidance of modern imaging tools? (For now, we know from the FAME 3 study that FFR-guided PCI is not "non-inferior" to CABG for the same disease.) [29]. What is the long-term effectiveness of methods in patients with high clinical (DM, HF) and anatomical risk (bifurcation lesions)? When can we accept incomplete revascularization? What is the optimal PCI strategy for peripheral bifurcation lesions? What is the optimal antiplatelet/antithrombotic drug therapy for complex PCI?

Review of guidelines for treatment of LMD

In the last decade, the guidelines strongly recommend (Class I) CABG as the method of choice for treating LMD. In agreement with the European Guidelines of 2014, the guidelines of 2019 maintained the strong recommendation for CABG in LMD (Class I), with the highest degree of evidence (A) and regardless of the anatomical complexity [24, 30]. After the publication of the results of EXCEL and NOBLE, however, PCI is considered an appropriate alternative to CABG for patients with low/medium SYNTAX scores, combined with upgrading the degree of evidence from B to A for where it is proposed. Thus, PCI is recommended in SYNTAX scores ≤ 22, receives indication IIa in SYNTAX scores 23–32, and is not recommended in lesions of high complexity (SYNTAX score ≥ 33, III B). In comparison with the European Guidelines of 2014, the American guidelines of the same year take into consideration clinical data in their recommendations [31]: IIa for PCI, when: high surgical risk (STS-score > 5%) and low-risk PCI with high probability for good long-term outcomes (e.g., SYNTAX score ≤ 22 and ostial LMD) are documented; IIb for PCI, when: there is low/intermediate risk, medium/high probability for good long-term outcomes, and increased surgical risk (COPD, REDO, stroke, STS score > 2); III: patients with inappropriate anatomy for PCI but good candidates for CABG. In the most recent American guidelines: CABG has a recommendation 1 B-R for LMD and is preferred. PCI has an indication IIa B-NR in selected patients, provided that it can ensure revascularization similar to CABG [32]. At this point, we should emphasize the role of the Heart Team in making decisions and shaping the treatment strategy because the respective guidelines, no matter how accurate they are, only provide a general outline in which one must move. In many cases, they legitimize the gray areas that undoubtedly exist. Each patient is unique, requiring individualized diagnostic and therapeutic requirements. From this perspective, in specialized cases, the Heart Team is the one that will answer the following questions: Which method ensures complete revascularization? What is the risk of each intervention? What long-term benefits does each method offer? What is the experience of the department in treating the disease? All of the above must be communicated to the patient, who, being informed, must participate in the final decision.

Conclusions

LMD should be treated surgically. CABG is the treatment of choice, reflected over time, up to the most recent guidelines. The developments of interventional cardiology at the level of materials, techniques, imaging, and drug therapy and the new profile of cardiac patients (increased life expectancy, comorbidities) have highlighted PCI as a reliable, less invasive alternative to CABG. Both methods have evolved rapidly in recent years, as evidenced by the results of EXCEL and NOBLE: mortality < 1% at 30 days for a disease that previously had very high mortality/morbidity. What we know: CABG offers complete revascularization, even in anatomically special conditions, has a low rate of reoperation, and protects from sudden MI in the long term. On the other hand, PCI is less invasive and offers immediate recovery, short hospitalization, and low perioperative morbidity. Both methods have comparable short/medium-term outcomes in low- to medium-risk patients. Thus, and given that patients need to be individualized, as general rules, the following could be considered: CABG will be preferred in patients with HF, concomitant heart surgery disease that will be treated simultaneously, inability to receive dual antiplatelet therapy for long-term stent support, DM with multivessel disease and, of course, complex CAD, as reflected in the SYNTAX score. On the other hand, in stable clinical disease, PCI will be preferred in patients with significant comorbidities, high surgical risk, limited life expectancy, disease of low to moderate anatomical complexity, and, depending on the case, in lesions purely ostial or on the trunk of the LM.

Acknowledgments

Ioannis Panagiotopoulos, Francesk Mulita and Georgios-Ioannis Verras – equal contribution.

Funding

No external funding.

Ethical approval

Not applicable.

Disclosure

The authors report no conflict of interest.

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