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Percutaneous or Surgical Revascularization in Patients with Severe Left Main Coronary Artery Disease in Latin America: A GRADE Clinical Practice Guideline.

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ABSTRACT

Background: Severe left main coronary artery disease (LMD) poses a major treatment challenge in Latin America, where both percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) are used.

Methods: This guideline was developed de novo using the GRADE approach. A multidisciplinary panel reviewed evidence from a systematic review of randomized trials comparing PCI and CABG, incorporating a comprehensive literature search of patient values and preferences and outcome utilities. Thresholds were assigned for each clinical outcome, from small to large effect.

Results: Five randomized trials enrolling 4,612 patients were included. At 30 days, PCI resulted in a large reduction in major bleeding and a small reduction in strokes. At 5 years, PCI was

associated with a small to moderate increase of spontaneous myocardial infarction and a moderate to large increase in repeat revascularization. No important differences in short- or long-term mortality were observed between PCI and CABG. The overall certainty of evidence was rated low. There was a notable variability in patient values and a close call on the balance of effects.

Conclusions: For patients in Latin America with severe left main coronary artery disease, the guideline panel suggests either PCI or CABG. This is a conditional recommendation, based on low certainty in the evidence ($\oplus\oplus\bigcirc\bigcirc$). It applies when both procedures are clinically and anatomically appropriate and can be performed at centers meeting acceptable standards. The decision should be made through a shared decision-making process involving the patient and the multidisciplinary care team.

Keywords: PCI; CABG; CAD.

RATIONALE:

Severe left-main coronary artery disease (LMD) is present in 5% of patients undergoing cardiac catheterization.[1] This condition is associated with poor survival with medical treatment alone.[2] Coronary artery bypass surgery (CABG) has demonstrated to be superior to medical therapy alone and remains as the standard of care.[3] However, with the development of modern interventional techniques and pharmacology, LMD PCI can be considered a less invasive alternative.[4,5]

Although several trials compared CABG with PCI for LMD, international clinical guidelines do not provide a consistent decision pathway.[6,7] In addition to the variability in the interpretation

of the body of the evidence, the implementation of these guidelines in Latin America is challenging due to limited resources and variability of PCI and CABG outcomes across the region. Therefore, there is a need for high-quality guidelines to aid in the decision-making process for revascularization in patients with LMD living in Latin America. We developed a guideline document following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method, a standardized and transparent approach for the formulation of trustworthy recommendations.

GUIDELINE METHODS

Development of a new guideline justification

Although revascularization guidelines from North America (ACC/AHA/SCAI) and Europe (ESC/EACTS) address similar clinical questions, we determined that developing a new guideline de novo was necessary.[6,7] Existing guidelines lack explicit absolute effect estimates and quantified thresholds for benefit/harm of the body of the evidence, do not integrate existing evidence of patient values and preferences, and did not account for contextual factors critical in Latin America such as resource variability, access limitations, and health equity concerns (more information is presented in the supplemental material under “New guideline development justification using the ADOLOPMENT procedure”).[8] Therefore, the development a new GRADE-based guideline tailored to the Latin American setting was warranted.

Setting

This guideline is specifically intended for people living and receiving treatment in Latin America. This population is mostly composed of middle-income countries with more constraints in resources and staff training compared to higher-income regions. Furthermore, the impact of both PCI and CABG on clinical outcomes is heterogeneous, varying from similar to substantially worse compared to real-world higher-income country reports.[9] Therefore, this recommendation focuses on centers offering both procedures at adequate standards.

Scope

This guideline focuses on the role of PCI as compared with CABG in treating patients with severe LMD considered for revascularization. For this purpose, we choose a scenario that

represents a common clinical situation in which both alternatives are considered reasonable: patients with severe LMD who can be considered for PCI or CABG by the treating team. Patients in which medical treatment alone is the preferred course of action by the treating team are not included in this guideline and nor are patients in which one modality is clearly preferred over the other due to patient profile or local expertise. Although technical details are mentioned as considerations for implementation and minimum standards description, this clinical practice guideline does not provide formal recommendations for technical aspects more properly covered in state-of-the-art articles.[10]

Audience

This document is targeted to health professionals participating in the decision of revascularization modality in patients with LMD including, at least, a clinical cardiologist, a cardiac surgeon, and an interventional cardiologist. The guideline is also targeted to decision-makers and public health policymakers in the ministries of health and other national, regional and local regulatory bodies, and healthcare system managers. The recommendations should be of interest to non-governmental and other organizations and professional societies involved in the planning and management of LMD. Although the guideline is meant to be used in Latin America, due to its thorough and transparent development process it can also be adapted to other regions, especially in those with lower- and middle-income healthcare systems.

Guideline team and roles

Different groups with specific roles participated in the guideline development process, including a steering committee, a guideline panel, a methodological team, and subgroup of topic experts.

Two methodologists with extensive experience implementing the GRADE approach performed systematic evidence reviews, developed summary of findings tables, and coordinated the panel meetings. The number of interventional cardiologists and cardiac surgeons were balanced in both the steering group and the guideline panel. The steering committee and the methodological team drafted the first version of the manuscript which was then shared with the panel and topic experts for approval. The latest version of the manuscript was submitted for external review. Guideline team roles are detailed in the supplemental material (Table S1), while the role of the remaining authors is detailed below under “Contributions”.

At the time of inception, both the steering committee and methodological team invited societies from Latin America to fund and endorse the guideline. The Sociedad Interamericana de Cardiología (SIAC) and the Sociedad Latino Americana de Cardiología Intervencionista (SOLACI) accepted the invitation. Both SIAC and SOLACI funded the guideline and appointed eligible clinical cardiology and interventional cardiologist panelists, respectively. The Latin-American Association of Cardiac and Endovascular Surgery (LACES) board of directors did not accept the proposal. Therefore, the steering committee approached cardiac surgeons to participate as panelists, topic expert, and external review to assure balance between cardiac surgeons and interventional cardiologists.

Conflict of interest management and role of the sponsor

All guideline participants completed an extensive conflict of interest form including material or financial interests, non-financial interests (personal beliefs, previously published opinions, research, institutional, career advancement, advocacy and policy positions, and expected

interests). Panelists were interviewed and screened to assure they had no important conflict of interest before they were formally invited to participate, which was confirmed by completing and reviewing the form (details in the supplemental material under “Conflict of interests’ specifications”). Authorities from both endorsing societies were not involved in the process of developing the guideline development. One panelist (AM) was appointed as elected SIAC vice-president during the process of the guideline. Both endorsing societies funded a dedicated methods team to generate the systematic review, meta-analysis, create a summary of findings and evidence for decision tables, and coordinate meetings with the guideline panel.

Guideline process

We used the GRADE approach to summarize and assess the certainty of the evidence and to move from evidence to recommendations. Additionally, we followed the RIGHT statement for reporting.[11,12] To facilitate completion of assigned tasks explicit instructions and reasonable timeframes were provided to the panel members. The final version of the guideline underwent an external review process, including a cardiac surgeon and an interventional cardiologist.

Guideline question

As the scope of the guideline was very specific, there was no need for question prioritization. The methods team agreed on the population and interventions to be considered, and this was confirmed with the panel before initiating the review. Severe LMD was defined as a left main coronary artery stenosis $\geq 50\%$. This guideline addresses clinical scenarios where, a priori, patient characteristics, professional skills, and individual medical center outcomes are compatible with either PCI or CABG being viable options. Patients with clinical characteristics

that strongly favors one treatment strategy over the other are not considered, such as PCI for patients at increased surgical risk, or CABG for patients with extensive or complex three-vessel coronary artery disease with high SYNTAX Scores.

For PCI we included studies that used drug-eluting stents. Bare-metal stents have been associated with increased risk of restenosis that can be life threatening after LMD PCI. In addition, bare-metal stents have already been replaced by drug-eluting stents in clinical practice around the globe. We did not make specific considerations for bilateral vs single thoracic artery bypass graft or off- vs on-pump surgery since clinical randomized trials do not clearly demonstrate that one strategy is superior to the alternative.[13,14]

An analytical framework was created to select the clinical outcomes of interest. These were presented to the panel which completed the outcome list. Panelists rated outcomes using a standardized questionnaire as critical (7 to 9 points), important (4 to 6 points), or not important (1 to 3 points) for decision-making by the panel following the GRADE approach.[15] Critical and important outcomes were used for the rest of the guideline process.

In recent years there has been a lack of consensus between interventional cardiologists and cardiac surgeons in regards to the clinical relevance of periprocedural myocardial infarction for clinical decision making.[16] Both the methodological team and panelists were uncertain about the inclusion of periprocedural myocardial infarction as a clinical outcome. A meeting dedicated to debate this aspect was coordinated with external key opinion leaders in the field, including a cardiac surgeon, interventional cardiologists, and research methods experts. During the meeting

all participants reviewed clinical evidence and research methodology related to the GRADE approach. Periprocedural myocardial infarction was found to independently correlate with other patient-important outcomes (such as cardiovascular mortality, heart failure, and readmissions), but evidence demonstrating a direct impact in patient-valued health states (or utility) is lacking.[17] In other words, patients unlikely perceive or report a meaningful decline in quality of life or health preference scores solely due to the periprocedural myocardial infarction, since most of them are clinically silent or transient. Therefore, most of the time periprocedural myocardial infarction behaved more like a surrogate rather than an independent patient-important outcome. This may not hold true in large periprocedural myocardial infarctions, but these are infrequent and the impact on heart failure, quality-of-life and survival is captured in those clinical outcomes already. Since short- and long-term mortality, the most patient-important outcomes that periprocedural myocardial infarction correlate with, was included in the research synthesis we decided not to include this outcome in the guideline process.

Systematic review and meta-analysis

Eligible primary studies were randomized trials comparing PCI using drug eluting stents with CABG in patients with LMD. The methods team identified a systematic review in which a comprehensive search published in 2020, and a decision was made to update that search.[18] A new comprehensive search was executed using Ovid MEDLINE, EMBASE, and CENTRAL databases in April 2022 (see supplemental material under "Literature search strategy") and was limited to studies published since 2020. Two methodologists (AI, MR) with the advice of the steering committee developed the search, and screened titles/abstracts and duplicate full text

publications. Outcomes were abstracted using the Academic Research Consortium definitions, when available.[19]

An individual patient data meta-analysis of four of the main clinical randomized trials was identified in the literature search.[20] Individual patient data meta-analysis tackles some limitations of conventional study-level meta-analysis, allowing a more accurate time-to-event analysis for long-term outcomes and subgroup analyses.[21] Therefore, we decided to include estimates from the identified individual patient data meta-analysis when available to the summary of findings table.

The methods team also developed and executed a comprehensive search for outcome values and patient preferences regarding PCI and CABG. The outcome utilities were used to guide panelists to establish thresholds for all patient-important outcomes. Utilities are a measure of how much people value an outcome or health state, presented on a scale from 0 as being dead and 1 for a perfect state of health.

To establish thresholds for interpreting the body of evidence and rating certainty in each patient-important outcome the methodological team prepared a document describing markers of health states, utilities from a literature overview (see supplemental material under “Values and preferences overview”), and the baseline risk with CABG for each of the outcomes identified by the panel. Two landmark outcomes were selected by the oversight committee and the methodological team and were sent to panelists to independently determine which change in each of these outcomes corresponds to a small important effect and a large effect. Panelists were

blind to the estimates of the effect summarized by the methods team when they gave their responses. The relation between utilities and thresholds for those two outcomes was used to model the thresholds for the rest of the outcomes.[22] Finally, small and large effect thresholds were validated by panel surveys using questionnaires with the following data: markers of states, utilities from a literature overview, the baseline risk with CABG and the modelled thresholds. Moderate effect thresholds were established as the equidistance between small and large thresholds. The final thresholds used for each outcome are detailed in Figure 1 and in the supplemental material under “Outcomes utilities and thresholds for Evidence to Decision judgments”.

Evidence certainty

Certainty of the body of evidence was evaluated using the GRADE approach by the methodological team for all outcomes.[11] The results of critical and important outcomes were presented to the panel as a summary of findings table including relative risk (RR) and absolute risk differences with 95% confidence intervals, number of participants and studies, the certainty of evidence, and interpretation.[23] The language used along these estimates, such as, “increases” or “reduces”, “probably”, or “may” are based on the evidence certainty of each outcome as suggested by the GRADE approach.[11] Risk of bias was assessed using the risk of bias tool 2 from the Cochrane Collaboration (see supplemental material under “Risk of bias assessment”).[24] Bias due to missing outcome data was assessed using sensitivity analysis based on GRADE Working Group guidance.[25,26]

Evidence to decision framework

The panel discussed all relevant domains pertaining to decision-making for the question assessed following GRADE guidance.[27,28] We completed an evidence to decision framework using GRADE GDT software to capture discussions and judgments.[29]

For costs and resource allocation, the panel discussed the potential economic implications of implementing PCI as opposed to CABG considering information on local direct costs for both interventions. We did not pursue a formal economic evaluation given the heterogeneity of health systems across Latin America, which is substantially different not only between- but also within-countries which would have limited applicability.

Consensus and voting

Guideline panelists (n= 9) were the only guideline members with voting rights. This was composed by two internists, three clinical cardiologists, two cardiac surgeons, and two interventional cardiologists. The experts debated on every domain of the evidence to decision framework aiming for consensus. When consensus was not reached by discussion, definitive judgments were made by voting based on simple majority (>50%). The meeting chair (MR, internist and research methodologist) managed disagreements and recorded minutes or relevant aspects of the discussion (available in the evidence to decision network in the supplemental material "Evidence to decision framework"). Panel members who did not attend the online meeting to debate these steps were asked to watch the full video recording, provide feedback, vote if needed, approve the content, or express disagreement if necessary.

Once panel judgments for every individual domain of the evidence to decision framework were defined panelists were asked to review a short summary on how to vote for the final

recommendation. Every panelist voted recommendation's direction and strength independently but not anonymously. Voting included three aspects: in favor or against PCI, its strength (conditional or strong), and the main reason for their decisions. To support a strong recommendation the methods team pre-established that 80% or more of panel votes should be strong, otherwise the recommendation would be defined as conditional (or weak).

RESULTS

Summary of the Evidence

We identified 218 citations in addition to those cited in the original systematic review. No new trials were identified in the updated systematic search. which did not add any additional trials. Three additional reports were included.[20,30,31] We identified five randomized trials including 4,612 patients, 2,303 treated with PCI and 2,309 treated with CABG (supplemental material, Figure S1 and Table S2).[20,32–35] Two of these trials were sponsored by industry.[33,34] The literature search on outcomes utilities identified 10 studies including 1,942 participants.

Outcome rating

The median value of outcome rating from the panel was 9 for all-cause or cardiovascular mortality, 7 for stroke with unspecified severity, 8 for major or life-threatening bleeding, 8 for spontaneous myocardial infarction, 6 for new revascularization, and 6 for 30-day health-related quality-of-life. Therefore, critical outcomes were all-cause mortality at 30 days, stroke at 30 days, major or life-threatening bleeding at 30 days, long term cardiovascular mortality, and spontaneous myocardial infarction, whereas 30-day quality-of-life and long-term repeat revascularization were rated as important, but not critical outcomes for decision making.

Benefits and harms

A summary of absolute risk differences from the meta-analysis with its corresponding certainty of the evidence and outcome-specific magnitude of effect is presented in Figure 2.

At 30 days

Compared to CABG, PCI probably result in little or no impact on mortality (Relative Risk [RR] 1.09, 95% confidence interval [CI] 0.60 to 1.97; 0.1% more, from 0.4% less to 1.0% more), but may reduce stroke slightly (RR 0.38, 95% CI 0.16 to 0.89; 0.6% less, from 0.9% less to 0.1% less). PCI results in a large reduction in major or life-threatening bleeding (RR 0.24, 95% CI 0.18 to 0.31; 9.1% less, from 9.9% less to 8.3% less), and may result in a trivial or slight increase in quality-of-life improvement (RR 1.07 for a 10-point improve, 95% CI 1.01 to 1.14; 5.0% more, from 0.7% more to 10.0% more).

At 5 years

PCI may no increase cardiovascular mortality (RR 1.07, 95% CI 0.83 to 1,37; 0.4% more, from 1% less to 2,1% more), probably increases spontaneous myocardial infarction (RR 2.02, 95% CI 1.52 to 2.70; 3.3% more, from 1,7% more to 5,5% more), and probably result in a moderate to large increase in the need for new revascularization (RR 1.73, 95% CI 1.49 to 2.02; 8.1% more, from 5,4% more to 11,3% more).

Certainty of the evidence

Each outcome's certainty of evidence is presented in the summary of findings table (Table 1).

The overall certainty of evidence was considered low primarily due to imprecision and attrition bias detected by sensitivity analysis in the critical outcome of 5-year cardiovascular mortality.

Values and acceptability

The panel considered that there was a possibly important uncertainty or variability of patient outcome values. They also considered that both interventions are acceptable by relevant stakeholders in the majority of the scenarios where revascularization is needed as far as center results are comparable to the studies informing this guideline.

Balance of effects

There was no consensus on the balance of effects. A simple majority of the panelists (5 out of 9 panelists) determined that, on balance of health effects, CABG was favored over PCI because most informed patients may likely believe that the reduction in long term myocardial infarction and need for repeat revascularization is more important than the short-term benefits of PCI. The rest of the panel determined that, on balance of health effects, neither intervention was favored over the other. This close balance between effects was a key determinant of the recommendation.

Resources, equity, and feasibility

The panel judged that costs for PCI and CABG in patients with LMD living in Latin America may vary at national and subnational levels, making the comparative costs uncertain. Uncertainty may be even more related to indirect health outcomes cost. Based on those inputs, they judged the cost-effectiveness very uncertain. The panel judged that equity will likely be increased by

using PCI in settings where surgery is not available, because it may be less complex to implement for some health systems. This gives an opportunity for patients to receive timely revascularization, while there is no relevant impact of equity in settings where both procedures are available. No feasibility problems arise in settings where PCI and CABG are suitable alternatives and are available when considering professional skills and center outcome results. However, the panel considered that even in this scenario, center outcomes, timely access, catheterization laboratory and operating room facilities, and health insurance could affect the implementation of PCI and CABG.

Main recommendation

Main recommendation: For patients in Latin America with severe left main coronary artery disease, the guideline panel suggests either percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). This is a conditional recommendation, based on low certainty in the evidence ($\oplus\oplus\bigcirc\bigcirc$). It applies when both procedures are clinically and anatomically appropriate and can be performed at centers meeting acceptable standards. The decision should be made through a shared decision-making process involving the patient and the multidisciplinary care team. A summary of the main recommendation is presented in Figure 3 and the summary of judgements driving this recommendation in Table 2. Most of the panel members voted this recommendation [6 panelists supported this recommendation, 2 panelists voted conditional for CABG over PCI and 1 panelist voted conditional for PCI over CABG].

The panel judged that the balance of desirable and undesirable consequences for the use of PCI or CABG in this setting are balanced considering the short-term health benefits of PCI (less

morbidity and better quality-of-life) and the long-term benefits of CABG (less new revascularizations and less myocardial infarctions). The panel considers that the best course of action is highly sensitive to patient's values and preferences for which a shared decision-making process is necessary. During this process the panel suggests integrating key subgroup characteristics for a more personalized recommendation (see below under "Population").

Remarks

This recommendation applies to patients who are candidates for both procedures. The recommendation does not apply to patients with clinical characteristics strongly favoring one procedure over the other, such as those at increased surgical risk favoring PCI, or extensive or complex multivessel coronary artery disease (high SYNTAX Score) favoring a cardiac surgery. The recommendations apply to centers that can perform both procedures with adequate standards, meeting quality metrics and institutional volumes, including experienced staff and the availability of required equipment. Individual centers should consider their own outcomes for both procedures.

The conditional nature of this recommendation means that most patients can be offered surgical or percutaneous revascularization. For clinicians, this means they must be familiar with the evidence supporting this recommendation. It also means that they need to assist each patient make a management decision. The multidisciplinary team discussion should be aligned with patient's values and preferences. Patients need to be adequately informed about the positive and negative aspects of each strategy through a shared process before a decision can be made.

Considerations for implementation

This recommendation applies to settings where PCI and CABG are suitable alternatives considering patient characteristics, professional skills, and individual center outcomes. The panel considered that candidates should be assessed by a multidisciplinary team involving at least one clinical cardiologist, a cardiac surgeon, and an interventional cardiologist. The conclusions or main comments from team discussion should ideally be documented in medical records.

Population

This guideline does not apply to patients in which one treatment is strongly favored or those in which medical treatment alone is the preferred management strategy. Patients should be considered candidates to both interventions and preferably resemble those included in the studies informing this document. Patients enrolled in randomized clinical trials had a mean age of 66 years (95% CI 59 - 73; age ≥ 65 years 56.8%), a EuroSCORE of 3.0% (95% CI 1.0 - 4.0), 25% were diabetic, and the mean SYNTAX score was 25 points (95% CI 18.0 - 31.0), with SYNTAX score ≤ 22 in 40.8%, 23 to 32 in 37.3%, and ≥ 33 in 21.9% of patients. LMD and three vessels disease was present in 20.8%, and LMD in bifurcation in 74.0% of patients.[20] Evidence from subgroup analysis does not suggest significant heterogeneity for 5-year all-cause mortality across sex or diabetes status.[20]

For implementation, the panel suggests assessing the following criteria in each candidate to aid the decision to recommend PCI or CABG to patients (Table 3): Older patients and those with shorter life expectancy usually favor a less invasive treatment, while younger patients may place more value on long term durability in terms of myocardial infarction and repeat revascularization

procedures. The calculation of surgical risk can be performed with local or regional calculators when available (for example, the ARGENSCORE), but it is reasonable to use the STS or EuroSCORE II risk tools in those centers with surgical results comparable to North America and Europe.[36–38] The presence and magnitude of comorbidities not appropriately captured by surgical scores (like thorax radiation or porcelain aorta, among others) should also be considered to better inform about the perioperative risk and rapid recovery. Although patient frailty can be perceived subjectively by observing the patient, is advisable to use validated scores.[39] Objective tools, such as the SYNTAX Score, can help to determine coronary disease extension and complexity, and should be integrated into decision making according to local team expertise and clinical outcomes.[40] The risk of bleeding both in the short- and the long-term should be judged by the treating team using validated scores.[41] The need and feasibility of complete coronary revascularization should also be considered as a key consideration, especially in younger patients. The presence and magnitude of these aspects should also be conveyed to the patient, highlighting how these factors may influence the efficacy and safety of both alternatives in the short and the long-term. Patient- and context-specific treatment cost and coverage should be assessed by the local treating team when deciding between PCI and CABG.

Adequate standards, professional skills, and local applicability

The treating team should demonstrate sufficient experience to apply this recommendation. Latin America is a large region with significant variability in center volumes and professional skills. Most the countries do not provide or provide limited public universal healthcare coverage. This leads to the proliferation of a large diversity of private practice centers with variable volumes and quality of care, between and within countries. To be eligible to apply this guideline

recommendation, the practice at individual centers should resemble the practice of centers that participated in randomized clinical trials. In these studies, the use of intravascular imaging was 67.6%, and some received guidance and training on how to perform LMD PCI. Among patients treated with CABG, left-internal mammary artery was used in 95.6%, and one study mandated at least 750 heart surgeries per year, of which 400 had to be coronary revascularizations. The panel considered that equipment availability, as well as technical ability are strong factors to apply this recommendation, with special emphasis on intravascular imaging, calcium modification devices, and hemodynamic support for PCI.

We provide the suggested minimum standards the centers should adhere to implement this recommendation (available in the supplemental material under "Suggested minimum standards for centers offering left main PCI or CABG"). To aid in the decision making of future patients, we encourage centers to implement quality improvement processes and audit their short- and long-term outcomes for both PCI and CABG, using dedicated registries. In addition, centers should systematically review their complications. In scenarios where local data is lacking or not available, judgement of the team assessing the patient is needed and patients should be informed. Imbalanced results (for example, centers with excellent CABG outcomes but sub-optimal PCI results, or vice versa) should also be considered by the team when implementing this recommendation favoring the strategy with better outcomes. Centers that do not provide acceptable patient outcomes for either procedure should consider transferring the patient to centers with adequate standards. It should be noted that center registry analyses should not include patients who were never candidates to the other treatment, such as LMD PCI in those with increased risk of cardiac surgery or CABG in those with diffuse three-vessel disease.

Shared decision-making process

Shared decision-making is a collaborative process in which clinicians and patients work together to make healthcare decisions that align with the patient's values, preferences, and clinical needs. Unlike the paternalistic or "best agent" approach—where decisions are made by clinicians on behalf of patients without fully incorporating their individual goals—shared decision-making emphasizes partnership and informed choice. This process should be ideally led by the clinical cardiologist in close collaboration with the patient and their family. Shared decision-making typically involves three key steps: first, making patients aware that a decision exists and that their input is important; second, presenting the options along with their risks, benefits, and uncertainties; and third, supporting patients as they consider their values and preferences to arrive at an informed choice. To do this effectively, clinicians must be familiar with the magnitude of the expected differences between PCI and CABG, using evidence from the summary of findings table complemented by the expected local results to provide contextually relevant estimates.

Patients should understand that CABG is an open-heart surgical procedure that generally offers more durable long-term outcomes and lower rates of repeat revascularization, particularly in cases of complex or diffuse coronary disease. However, it involves a longer recovery period, greater initial procedural risk, and potential surgical complications. PCI, on the other hand, is less invasive, offers faster recovery, and may be more appealing to patients seeking to avoid surgery, but it is associated with higher rates of repeat procedures and myocardial infarction. It is the responsibility of the cardiologist to ensure that patients and their families are fully informed

about these trade-offs, understand the evidence, and are supported in making a decision that aligns with their health goals and values.

EXECUTIVE SUMMARY

Main recommendation: For patients in Latin America with severe left main coronary artery disease, the guideline panel suggests either percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). This is a conditional recommendation, based on low certainty in the evidence ($\oplus\oplus\bigcirc\bigcirc$). It applies when both procedures are clinically and anatomically appropriate and can be performed at centers meeting acceptable standards. The decision should be made through a shared decision-making process involving the patient and the multidisciplinary care team.

Remarks:

- This recommendation applies only to those centers that perform both procedures with adequate standards.
- Patients should be assessed by a multidisciplinary team involving at least one clinical cardiologist, a cardiac surgeon, and an interventional cardiologist.
- The guideline recommendation applies to patients considered adequate candidates for both revascularization procedure types given clinical and anatomical characteristics assessed by the local treating team.
- This recommendation does not apply to:
 - Patients with clinical characteristics strongly favoring one procedure. For example, older adults or patients with high surgical risk that would favor the use of PCI, or patients with extensive multivessel coronary artery disease (for instance, a high SYNTAX Score) that would favor CABG.
 - Those considered for medical treatment alone.

Implications of the Conditional Recommendation:

- For patients: Both options are reasonable. Patients should receive clear, balanced information about the potential benefits and downsides of each procedure and be supported in making a decision that aligns with their values and preferences. We provide guidance to enhance this process.
- For clinicians: Familiarity with the supporting evidence is essential. Shared decision-making should integrate:
 - Clinical and anatomical assessments,
 - Input from the multidisciplinary team,
 - The patient's informed preferences.

Table 1: Summary of findings

Outcome N participants (studies)	Relative effect (95% CI)	Anticipated absolute risk (95% CI)			Certainty of the evidence	Interpretation
		With CABG	With PCI	Difference		
All-cause mortality at 30 days from individual patient data meta-analysis № of participants: 4394 (4 randomized controlled trials)	HR 1.09 (0.60 to 1.97)	1.0% ^b	1.1% (0.6 to 2)	0.1% more (0,4 less to 1 more)	⊕⊕⊕○ Moderate ^c	PCI probably results in little to no difference in 30 days mortality
CV mortality at 5 years from individual patient data meta-analysis № of participants: 4394 (4 randomized controlled trials)	HR 1.07 (0.83 to 1.37)	5.9% ^{5,b}	6.3% (4.9 to 8)	0.4% more (1 less to 2,1 more)	⊕⊕○○ Low ^{d,e}	PCI may not increase CV mortality at 5 years
Stroke at 30 days № of participants: 3957 (4 randomized controlled trials) ^f	RR 0.38 (0.16 to 0.89)	1.0% ^a	0.4% (0.2 to 0.9)	0.6% less (0,9 less to 0,1 less)	⊕⊕⊕⊕ High ^{g,h}	PCI does not increase 30 days stroke risk (HIGH certainty). PCI may reduce 30 days stroke slightly (LOW certainty)
Quality of life improvement at 30 days using SAQ QoL (0-100; higher the better); minimally important difference 8-10 № of participants: 1538 (1 randomized controlled trial)	RR 1.07 (1.01 to 1.14)	71.6% ^{13,i}	76.6% (72.3 to 81.6)	5.0% more (0,7 more to 10 more)	⊕⊕○○ Low ^{j,k}	PCI may result in a trivial or slight increase in quality of life improvement at 30 days
Major or life-threatening bleeding at 30 days № of participants: 3271 (3 randomized controlled trials) ^m	RR 0.24 (0.18 to 0.31)	12.0% ^a	2.9% (2.2 to 3.7)	9.1% less (9,9 less to 8,3 less)	⊕⊕⊕○ Moderate ^{l,n,o}	PCI probably results in a large reduction in 30 days major or life-threatening bleeding
New revascularization (new PCI or CABG) at 5 years № of participants: 4037 (4 randomized controlled trials)	RR 1.73 (1.49 to 2.02)	11.0% ^a	19.1% (16.5 to 22.3)	8.1% more (5,4 more to 11,3 more)	⊕⊕⊕○ Moderate ^{p,q}	PCI probably results in a moderate to large increase in new revascularization (PCI or CABG) at 5 years

Spontaneous myocardial infarction at 5 years № of participants: 4037 (4 randomized controlled trials) ^r	RR 2.02 (1.52 to 2.70)	3.2% ^a	6.5% (4.9 to 8.7)	3.3% more (1,7 more to 5,5 more)	⊕⊕⊕○ Moderate ^{s,t}	PCI probably increases spontaneous 5 years myocardial infarction
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- a. Median incidence in the control arm of randomized control trials.
- b. Incident rate in the individual patient data meta-analysis.
- c. 30-day mortality. Small effect threshold 0.5%, large effect threshold 2%. Estimate cross the small effect threshold, so we rate down one level for imprecision.
- d. Sensitivity analysis in study level meta-analysis considering plausible assumptions related to lost to follow up (3 to 1): RR 1.22 [CI95% 0.85, 1.75; RD 1.3% more 95%CI 0,9 fewer to 4,5 more): certainty range crosses a moderate threshold (as opposed to complete case analysis) so we rate down one level for risk of bias.
- e. 5-year mortality. Small effect threshold 1%; large effect threshold 4%. Assumed moderate effect threshold at 2.5%. Considering confidence interval crosses a small threshold we decide to rate down 1 level for imprecision.
- f. Definitions: SYNTAX: A focal, central neurological deficit lasting >72 hours which resulted in irreversible brain damage or body impairment; PRECOMBAT: A sudden onset of vertigo, numbness, aphasia, or dysarthria resulting from vascular lesions of the brain, including hemorrhage, embolism, thrombosis, or rupturing aneurysm, and persisting for >24 hours; NOBLE: Ischemic or haemorrhagic cerebrovascular event verified by brain computed tomography (CT) or magnetic resonance imaging (MRI); EXCEL: The rapid onset of a new persistent neurologic deficit attributed to an obstruction in cerebral blood flow and/or cerebral hemorrhage with no apparent non-vascular cause (e.g., trauma, tumor, or infection). A vascular neurologist or stroke specialist will determine whether a stroke has occurred and determine the stroke severity using the NIHSS TIA/Stroke questionnaire. Available neuroimaging studies will be considered to support the clinical impression and to determine if there is a demonstrable lesion.
- g. Some concerns of bias arising from the randomization process for NOBLE and Boudriot et.al trial representing 16% of meta-analysis weight, p value for interaction 0.34. Sensitivity analysis considering plausible assumptions related to lost to follow up (3 to 1): RR 0.38 [CI95% 0.16, 0.90; RD 0.6% fewer (CI95% 0,9 fewer to 0,1 fewer). We decide not to rate down for risk of bias.
- h. 30-day stroke. The small effect threshold is 0.5%, the large effect threshold is 2%. We decide to downgrade 2 levels for certainty in a small reduction in stroke considering both limits of confidence interval and the proximity of point estimate to small benefit threshold.
- i. Proportion of patients with an improvement equal to or greater than minimally important difference at follow up.
- j. Unblinded, at high risk of bias in measurement of the outcome.

- k. 30-day quality-of-life. Small effect threshold 5%, large effect threshold 10%. We downgrade one level as moderate effect threshold (assumed at 7.5% was crossed).
- l. 30-day major or life threatening bleeding. Small effect threshold 2%, large effect threshold 6%. Optimal information size for life threatening bleeding considering CABG risk 12% and large threshold for PCI 6%: 356 per arm. We nor rate down for imprecision.
- m. Defined as: BARC Type 2–5 en EXCEL. Blood transfusion in NOBLE. Resternotomy for bleeding requiring blood transfusion in Boudriot et. al.
- n. One or more concerns in the three trials that reported results. Some concerns in randomization process and selection of the reported results for NOBLE and Boudriot et.al. High risk of bias due to deviations from the intended intervention in NOBLE; some concerns in measurement of the outcome in EXCEL.
- o. Little overlap in point estimates and confidence intervals in meta-analysis may be related to the definition, but all report a large relative effect. We decide not to downgrade for inconsistency.
- p. Open label trials. Unblinded, deviations from intended interventions might had significant impact in the decision of revascularization. Sensitivity analysis considering plausible assumptions related to lost to follow up (3 to 1): RR 2.04 [CI95% [1.76; 2.35]; RD 11.5% more (8,4 more to 14,9 more). We did not downgrade our certainty for risk of bias for deviations from intended interventions considering that range estimate suggest harm and sensitivity analysis confidence interval estimate is above moderate harm threshold which we choose as our certainty target (moderate to large harm).
- q. 5-year revascularization. Small effect threshold 4%, large effect threshold 10%. We rate our certainty in a moderate to large harm (estimate above moderate increase in revascularization with PCI). Although confidence interval cross multiple thresholds we rate down only one level for imprecision considering 5-year estimate and certainty.
- r. Defined as: SYNTAX: MI was defined in relation to intervention status as follows i) after allocation but before treatment: Q-wave (new pathological Q-waves in ≥ 2 leads lasting ≥ 0.04 seconds with CK-MB levels elevated above normal), and non-Q-wave MI (elevation of CK levels > 2 times the upper limit of normal [ULN] with positive CK-MB or elevation of CK levels to > 2 times ULN without new Q-waves if no baseline CK-MB was available); ii) > 7 d after intervention: new Q- waves or peak CK-MB/total CK $> 10\%$ or plasma level of CK-MB 5x ULN or plasma level of CK 5x ULN. PRECOMBAT: MI was defined as new Q waves or an increase in creatine kinase MB concentration to greater than the upper limit of the normal range, plus ischemic symptoms or signs, if occurring more than 48 hours after the procedure. NOBLE: A rise in biochemical markers exceeding the decision limit for myocardial infarction (99th percentile including $< 10\%$ CV) with at least one of the following; (1) ischemic symptoms, (2) ECG changes indicative.
- s. Open label trials. Some concerns in relation to consistent but fragile estimations between mask and unmask trials considering meta research evidence. Sensitivity analysis considering plausible assumptions related to lost to follow up (3 to 1): RR 2.40 [CI95% [1.84; 3.15]; RD 4.2% more (2,5 more to 6,4 more). We did not downgrade our certainty for risk of bias in measurement of the outcome

considering that range estimate suggest harm and sensitivity analysis confidence interval estimate is above small harm threshold which we choose as our certainty target (important harm).

- t. 5-year myocardial infarction. Small effect threshold 2%, large effect threshold 5%. We rate our certainty in an important harm (estimate above small but important increase in myocardial infarction with PCI). As confidence interval cross that threshold to null effect, we rate down one level for imprecision.

Table 2: Judgements from evidence to decision framework

	SUMMARY OF PANEL JUDGEMENTS						
	<<< Favors CABG			Favors PCI >>>			
PROBLEM PRIORITY	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

Table 3: Variables to consider by treating team to aid decision making

Favors CABG	Favors PCI
Young age, longer life expectancy	Older age, shorter life expectancy
Low surgical risk	Increased risk of cardiac surgery
No major comorbidities	Presence of multiple comorbidities
No frailty	Presence of fragility
Complex LMD anatomy	Poor quality of bypass landing zone, or ostial LMD
PCI not accessible or covered	CABG not accessible or covered
Long-term high risk of bleeding, contraindication for dual antiplatelet therapy	Increased risk of perioperative bleeding
Extensive multivessel coronary disease, high SYNTAX score	Isolated LMD
Moderate or severe left ventricular function	Normal or mild ventricular dysfunction

Figure 1: Outcome thresholds

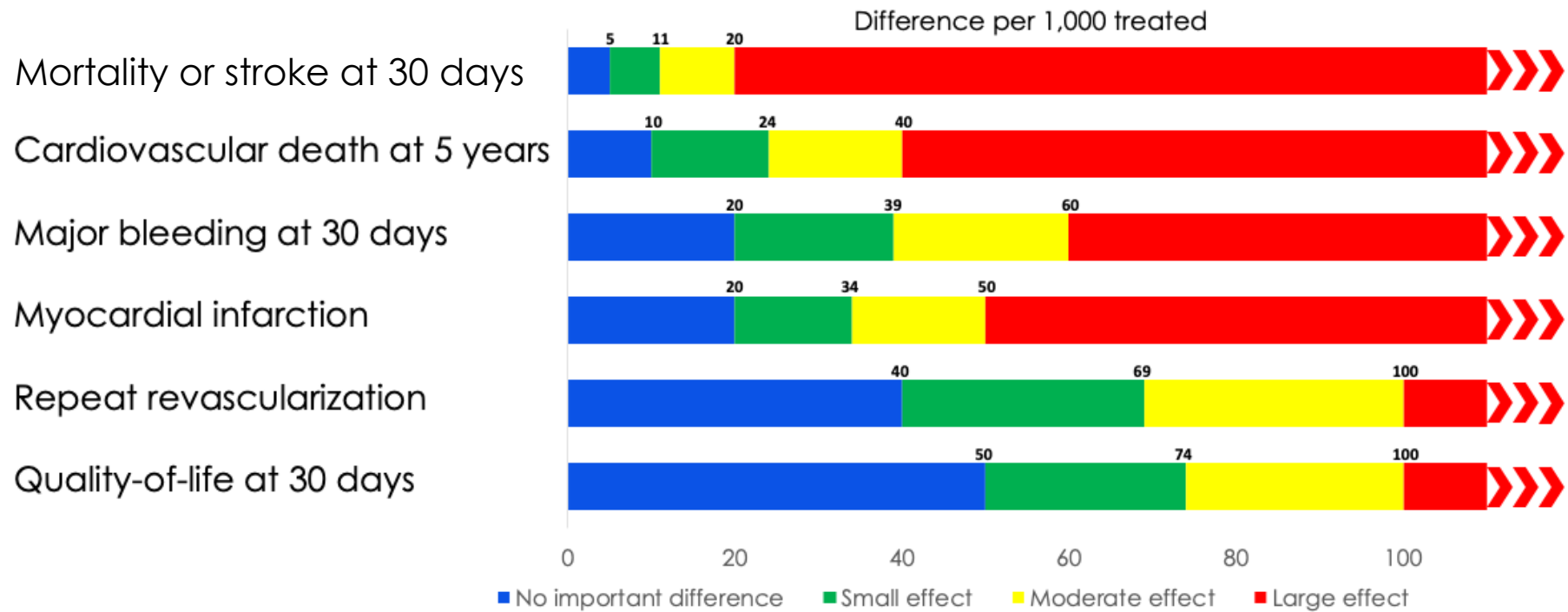


Figure 2: Summary of absolute risk differences between PCI and CABG from meta-analysis

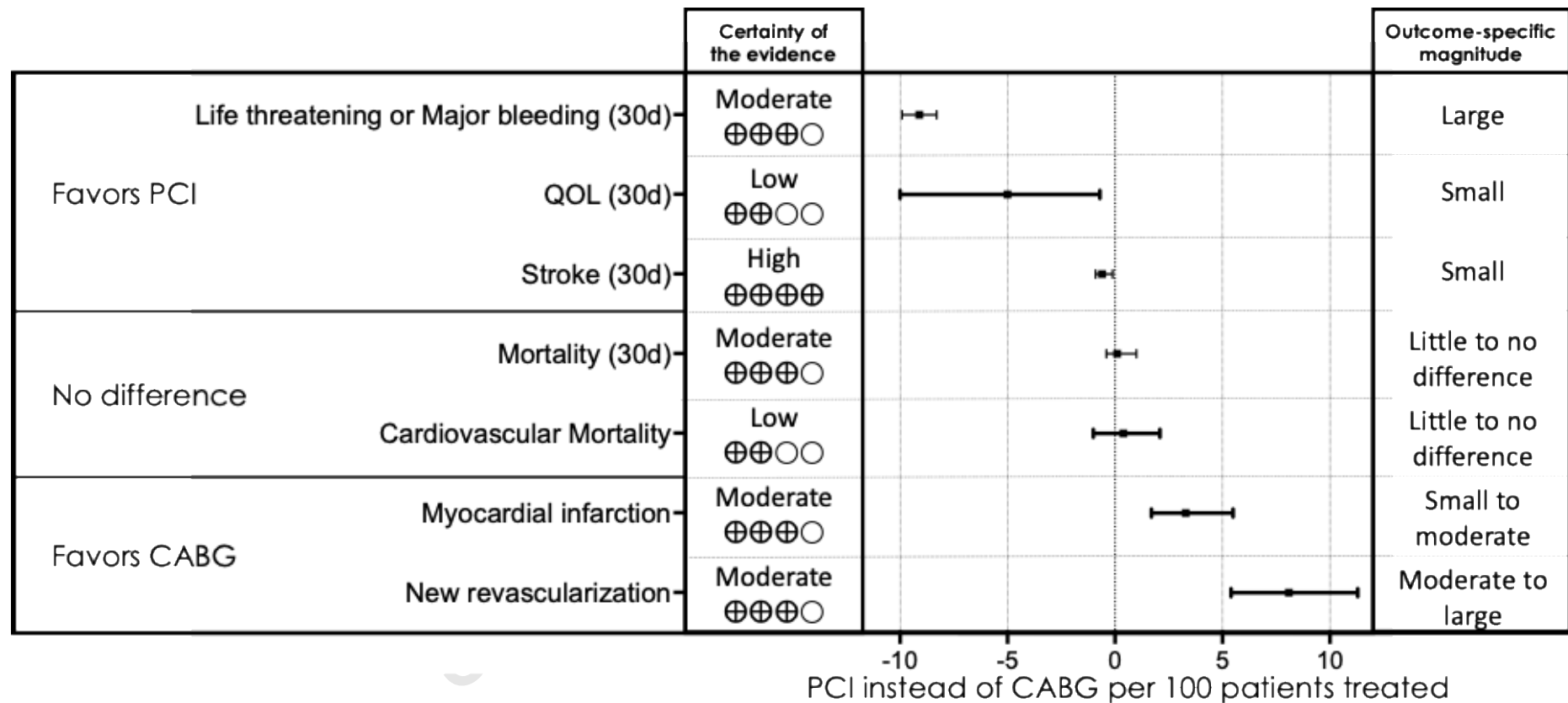
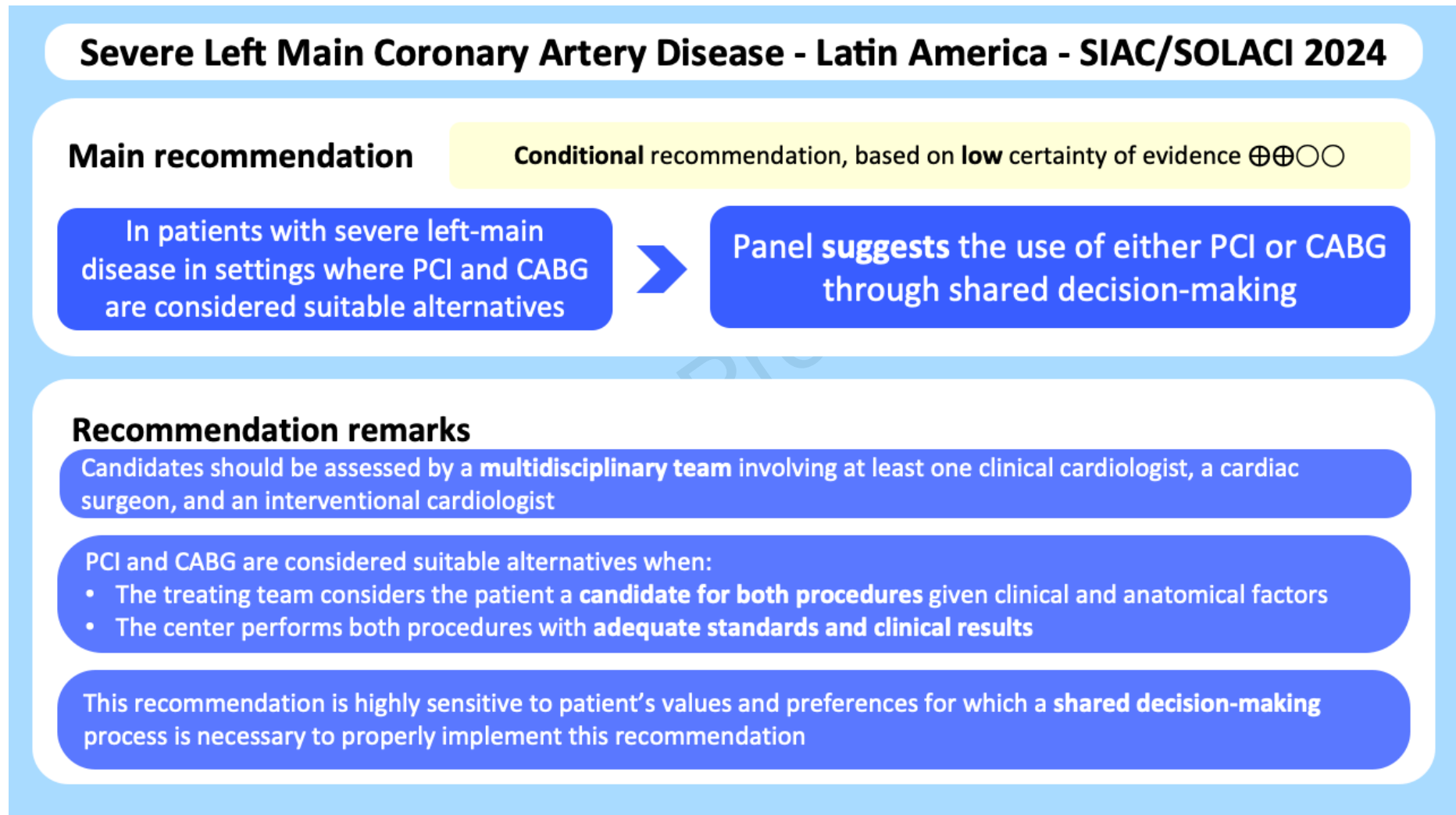


Figure 3: Main guideline recommendation



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Contributions

PL, MPS developed and oversight the whole process of the guideline. MR, AI composed the methodology team. FB, MTB, MISL, FL, OM, MZ, PA, AM, JCR collaborated as panelists. All authors contributed to the review of, and critical revisions to, the manuscript; PL and MPS wrote the first draft of the manuscript and revised the manuscript based on the authors' suggestions, contributed to drafting and verifying details about overall guideline processes, organizational oversight, and policies. MR and AI contributed sections to the first draft, revisions of subsequent drafts, and the revision after peer review; MR summarized the evidence, elaborated and executed the strategy to establish outcome thresholds, gathered information for panelists, and composed evidence to decision tables. RB, RW, DC, HGG, MM, MC, OM, AA composed the consultant topic expert team. AR and TC participated as external reviewers. MA, RC, OS, PH, and AB participated as quality assurance group.

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Highlights

- There is a need to develop region-specific high-quality clinical guidelines to guide decision making.
- For patients in Latin America with severe left main coronary artery disease, the guideline panel suggests either percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). This is a conditional recommendation, based on low certainty in the evidence (⊕⊕○○).

- It applies when both procedures are clinically and anatomically appropriate and can be performed at centers meeting acceptable standards. The decision should be made through a shared decision-making process involving the patient and the multidisciplinary care team.