Editorial

Comments on the 2018 ESC/EACTS Guidelines for Myocardial Revascularization

Comentarios a la guía ESC/EACTS 2018 sobre revascularización miocárdica

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INTRODUCTION AND COMMENTARY ON THE METHODOLOGY

The Spanish Society of Cardiology endorses the clinical practice guidelines (CPG) published by the European Society of Cardiology (ESC). As part of this policy, ESC guidelines are translated into Spanish and published in the online version of *Revista Española de Cardiología*, with the aim of increasing their accessibility and facilitating their implementation.[1] The translated articles are accompanied by an editorial authored by a panel of Spanish experts that highlights the most important content of each CPG document, details changes and innovations introduced since the previous edition, and discusses the more contentious aspects and possible limitations. The editorial also seeks to evaluate and adapt the recommendations to the context of health care organization and clinical practice in Spain.

The latest ESC guidelines for myocardial revascularization[1] update the previous CPG published in 2014.[2] It should be noted that a major effort has been made to maintain coherence with previous guidelines.

DIAGNOSTIC TOOLS TO GUIDE MYOCARDIAL REVASCULARIZATION

Noninvasive diagnostic tools

For patients with angina symptoms, the guidelines recommend a noninvasive imaging test as an initial diagnostic measure. In patients undergoing coronary angiography by computed tomography (CT), regional ischemia can be revealed by myocardial perfusion or the determination of fractional flow reserve (FFR-CT).

Patients with advanced heart disease (HD) and maintained myocardial viability should be revascularized before being considered for mechanical circulatory support or heart transplant.

Invasive diagnostic tools

The most notable change in this section concerns the introduction of the instantaneous wave-free ratio (iFR), a new measure that does not require adenosine induced hyperemia. In the new guidelines, iFR is included in the class I A recommendation for assessing the functional impact of intermediate-grade lesions. The guidelines consider FFR and iFR as equivalent, and the cutoffs for defining a lesion as hemodynamically significant are iFR ≤ 0.89 and FFR ≤ 0.8.

For the use of FFR to guide percutaneous treatment of multivessel disease, the new CPG document maintains the recommendation established previously (IIa B).[2]

The new guidelines place great value on pressure-derived functional indices (FFR and iFR), whose use in clinical practice has increased sharply. A clear example of this is provided by experience in Spain, where data from 2017 reveal a 23% increase compared with the previous year.[3]

A separate section is devoted to the assessment of stenosis severity in the left main coronary artery (LMCA), mostly involving ostial lesions. Functional assessment by FFR or iFR can be technically complex, and the evidence supporting their use in this setting is scarce. Consequently, intravascular ultrasound (IVUS) is a class IIa B recommendation, and revascularization should be excluded when the minimal luminal area is > 6 mm^2. For all lesions outside the LMCA, functional assessment is preferable to intracoronary imaging.

PROCESS FOR DECISION-MAKING AND PATIENT INFORMATION

In line with the 2014 guidelines,[2] the new CPG document emphasizes the importance of giving patients up-to-date evidence-based information about treatment options. The guidelines stress the need for treatments to be decided by a multidisciplinary Heart Team. This decision-making process is designed not only to ensure routine adherence to guideline recommendations, but also to establish defined decision-making algorithms, the measurement and short-term and long-term communication of results, and the consideration of patient preferences.

The recommended timing of revascularization (ad hoc vs deferred) depends on the clinical presentation. For patients with acute coronary syndrome (ACS) or shock, it is acceptable to perform ad hoc revascularization according to a protocol established by the multidisciplinary Heart Team. In contrast, delayed revascularization

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is recommended for most patients with stable angina, with a deferral period of 2 to 6 weeks depending on the clinical and anatomical characteristics and ventricular function. In general, ad hoc revascularization (within the same procedure as the angiographic diagnosis) is not recommended for patients with stable angina and complex coronary anatomy.

For a number of reasons, fewer coronary artery bypass grafting (CABG) procedures are performed in Spain than in comparable countries, which is reflected in a lower rate of CABG relative to percutaneous coronary intervention (PCI), according to data from the Organisation for Economic Co-operation and Development.[4]

REVASCULARIZATION FOR STABLE CORONARY ARTERY DISEASE

Important changes have been introduced in this section, which now incorporates discussion about the assessment of surgical risk and anatomical complexity. A new figure (Figure 3 in the CPG document) summarizes the clinical and anatomical factors influencing the decision between CABG and PCI, and the guidelines also evaluate the benefits of complete revascularization. The CPG document evaluates the alternative definitions of complete revascularization, and the preferred strategy is complete revascularization based on the functional rather than the anatomical definition. Moreover, the probability of complete revascularization is given priority in decision-making between CABG and PCI (class IIa B). Despite the benefits of this recommendation, it can conflict with the indication for revascularization in specific anatomical situations that require CABG or PCI independently of the possibility of complete revascularization.

Recommendations according to the extent and anatomical complexity of coronary artery disease (CAD) remain unaltered except for diabetes patients with 3-vessel CAD and a SYNTAX score ≤ 22, for whom the recommendation for PCI has been downgraded from IIa B in 2014 to IIb B in the current CPG. This change is somewhat surprising because 3-vessel CAD and a SYNTAX score ≤ 22 indicates low anatomical complexity and a low future rate of revascularization and thrombosis. CABG remains an optimal treatment for LMCA and 3-vessel disease. PCI and CABG are both class I A recommendations for LMCA disease with a SYNTAX score ≤ 22 and for 3-vessel CAD without diabetes and a SYNTAX score ≤ 22. For most other patients with LMCA or 3-vessel disease, PCI is contraindicated if CABG is possible; the exception is LMCA patients with an intermediate SYNTAX score, for whom PCI retains a class IIa recommendation.

Compared with the previous guidelines,[2] the new guidelines give less weight to the EuroSCORE II in the prediction of surgical mortality (IIa B in 2014 vs IIb B in 2018), whereas the STS and SYNTAX scores maintain a class I B recommendation. The logistic EuroSCORE and other scores are no longer considered, and the use of the SYNTAX-II score is not recommended. The ESC Task Force members acknowledge the major limitations of the SYNTAX score, but nonetheless still regard it as a basic tool in the choice of revascularization method, a conclusion supported by data from a recent collaborative individual patient pooled analysis of randomized trials.[5] To date, only 1 study has compared CABG and PCI specifically in relation to the SYNTAX score.[6] The new guidelines reduce the left ventricular ejection fraction (LVEF) cutoff for indicating revascularization in patients with multivessel disease and documented ischemia; the cutoff was previously ≤ 40% and is now ≤ 35% (I A). The new guidelines add the possibility of revascularization of lesions with FFR < 0.75 (I B).

This section of the CPG document addresses the controversial issue of the possible placebo effect of PCI, indicated by the ORBITA study.[7] The Task Force members conclude that, despite its elegant design, the ORBITA study has major limitations that make it unsuitable for guiding changes to clinical practice. Nevertheless, the ORBITA study underlines the importance of optimal medical treatment for patients with stable CAD.

The new ESC guidelines incorporate data from a network meta-analysis of 100 studies confirming that new-generation drug-eluting stents (DES) improve survival compared with medical treatment, although this has not been demonstrated in any individual study.[8]

REVASCULARIZATION IN NON–ST-ELEVATION ACUTE CORONARY SYNDROME

The invasive strategy remains the standard treatment for most patients with non–ST-segment elevation acute coronary syndrome (NSTEACS). The early invasive strategy (intervention in the first 24 hours) is recommended for most NSTEACS patients, including those with elevated troponins, repolarization changes, or a GRACE score > 140. The debate about the basis for intervention within 24 hours is an old one, and this strategy has well-known logistic and procedural implications that may significantly contribute to its incomplete implementation in Spain. Therefore, in Spain, the decision on whether to use the early invasive strategy should be informed by consideration of regional health care organization and the type of hospital to which the patient is admitted.

Radial access and the use of new-generation DES are recommended for all patients. The guidelines highlight the usefulness of FFR for identifying functionally significant lesions in NSTEACS patients, although the prognostic value of this approach is unknown.

Complete revascularization is recommended for patients with multivessel disease and should be carried out in a single procedure except in patients with cardiogenic shock.

CABG is required in only 5% to 10% of NSTEACS patients, and the ideal timing of intervention should be carefully determined for each individual. The guidelines give no specific recommendation for preoperative antiplatelet therapy; however, they do remind readers that, whereas the incidence of preoperative ischemic events is < 0.1%, the incidence of perioperative bleeding is above 10%. Even so, dual antiplatelet therapy does not justify delaying surgery in patients with active ischemia and hemodynamic instability. There is no evidence favoring a choice between PCI or CABG for patients with stable NSTEACS, and physicians should therefore apply the same criteria used for patients with stable CAD.

REVASCULARIZATION IN ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

This section introduces several changes compared with the previous CPG document. The most important changes include the promoted recommendations for radial access and DES use (both of which are now class I A); the recommendation against the systematic use of thrombus aspiration (relegated from class IIa A to III A), while allowing for its use in selected patients; and the use of unfractionated heparin as the anticoagulant of choice (class I C), with enoxaparine and bivalirudin as alternatives in decreasing order of preference (class IIa and class IIb, respectively). Another major change compared with the 2014 guidelines relates to the treatment of severe stenosis in nonculprit vessels in STEACS patients. For stable patients, the recommendation is to revascularize nonculprit vessels before hospital discharge (class IIa A). The basis for recommending revascularization during hospitalization is that this is the procedure used in trials; however, there is no reason to expect that results would be different if revascularization were performed after hospital discharge. For patients in shock, the new guidelines advise against the systematic practice of multivessel PCI in this setting (class III B).

MYOCARDIAL REVASCULARIZATION IN PATIENTS WITH HEART FAILURE

Chronic heart failure

CABG is the preferred revascularization procedure for HD patients with reduced LVEF or multivessel disease and acceptable

surgical risk (class I B). PCI is recommended as an alternative to CABG (IIa C) for patients with 1-vessel or 2-vessel disease when complete revascularization can be achieved. PCI is similarly recommended for patients with 3-vessel disease based on the Heart Team's assessment of the surgical risk (comorbidities), coronary anatomy, the predicted completeness of revascularization, and above all diabetes status. PCI should also be considered for elderly patients with diabetes when complete revascularization can be achieved, whereas CABG is recommended for younger patients with extensive CAD and for patients with diabetes. There has been no trial comparing CABG and PCI in heart failure patients with reduced LVEF, and the evidence gap in this area should to some degree influence the application of these recommendations.

Acute heart failure and cardiogenic shock

The most notable feature of this section is the maintenance of the low recommendation for short-term mechanical circulatory support (class IIb C) and its restriction to a set of defined patient characteristics. The document includes no recommendations about the use of intra-aortic balloon pumps in patients with shock in the peri-infarct period and mechanical complications.

The CPG document mentions that extracorporeal membrane oxygenation support appears to provide superior clinical benefit vs intra-aortic balloon pumping in observational studies; in contrast, no such advantage has been reported for percutaneous left ventricular assist devices (Impella and TandemHeart).

Revascularization in special patient groups

Patients with diabetes

The only specific recommendation in this section retained from the previous guidelines is to check renal function if patients have taken metformin immediately before angiography and to suspend metformin if renal function deteriorates. Other recommendations for diabetes patients are included in the general sections of the document. The discussion of the evidence favoring revascularization in diabetes patients has been simplified, and concludes that the recommendations for this patient group are similar to those for the general population in light of a meta-analysis showing no significant interaction between diabetes and the benefits of revascularization. The guideline authors note that this meta-analysis included only patients with ACS and that the largest study designed to compare revascularization and medical treatment in diabetes patients showed no benefit.

CABG remains the recommended revascularization method for multivessel disease in diabetes patients. As previously mentioned, the guidelines recommend PCI for diabetes patients with a SYNTAX score ≤ 22 (class IIb A), based on several studies in a variety of clinical contexts. New studies are needed to explore whether functional revascularization and new-generation DES also provide a benefit in patients with low anatomical complexity.

Patients with chronic kidney disease

Like previous editions, the new guidelines highlight the underrepresentation of this patient group in clinical trials. The need to prevent contrast-induced nephropathy in all patients is addressed by raising the recommendation class for preoperative risk assessment (from class IIa C in 2014 to class I C in the new CPG document) and ensuring adequate hydration (class I C). For patients with moderate or severe chronic kidney disease, the guidelines recommend prehydration and posthydration with isotonic saline if the expected contrast volume is > 100 mL (IIa C).

Patients requiring valve interventions

There are no major changes in this section. Coronary stenosis severity can be assessed with FFR or iFR in patients with severe aortic stenosis; however, the current evidence in insufficient to support the use of these approaches in this setting.

For patients with moderate aortic stenosis/regurgitation undergoing CABG, the Heart Team should carefully assess the potential for transcatheter aortic valve implantation on a case-by-case basis. The guidelines introduce a new indication for mitral valve repair at the time of CABG in patients with concomitant severe primary mitral regurgitation. However, a general recommendation for mitral valve repair applies only if the effective regurgitant orifice area (EROA) is > 0.4 cm^2, and the decision to combine mitral valve repair with CABG should be individualized for patients with an EROA between 0.2 and 0.4 cm^2. A class IIa C recommendation has been added for mitral valve repair in patients with severe mitral regurgitation and LVEF < 30% accompanied by evidence of myocardial viability.

Patients with peripheral artery disease

The myocardial revascularization guidelines endorse the 2017 ESC peripheral arterial diseases guidelines.[9] The current CPG authors note the higher incidence of stroke in patients undergoing CABG and discuss the causes and available preventive strategies. The new guidelines do not tackle the frequent problem of myocardial revascularization in patients who also require surgical or percutaneous vascular intervention, the evidence for which is well established.

REPEAT REVASCULARIZATION

Clinically apparent early graft failure after CABG is a rare event (≈3%). For patients with suspected severe myocardial ischemia immediately after CABG, perioperative angiography is recommended to detect the cause and inform joint decision-making between the surgeon and the catheterization specialist. In this situation, it is better to target treatment to the native vessels or the internal mammary artery (IMA) and avoid the occluded saphenous veins.

Repeat CABG increases the mortality risk between 2 and 4 times relative to the initial surgery, and therefore patients with early graft failure should always be considered for PCI. However, PCI in saphenous vein bypass grafts is associated with a high risk of complications. Although procedures to prevent distal coronary embolization are effective, the current recommendation for the systemic use of PCI in this situation is class IIa B, reduced from I B in the previous guidelines. In venous bypass grafts, DES produce superior initial results to metallic stents and are therefore recommended; however, the relative benefit of DES over the very long-term (5 years) has not been confirmed. When repeat revascularization surgery is indicated, the IMA should be used whenever possible.

Patients treated by PCI can develop angina during follow-up due to restenosis, incomplete revascularization, or disease progression, with disease progression being the most frequent cause in the long-term. In patients with restenosis, repeat PCI remains the strategy of choice. Both DES and drug-coated balloon angioplasty are recommended for patients with restenosis of a bare-metal stent or a DES (class I A).[10] Intracoronary imaging provides useful information about the mechanism of stent failure caused by restenosis or thrombosis and aids decision-making about optimal treatment (IIa C).

ARRHYTHMIAS

Coronary revascularization should always be considered for CAD patients with LVEF < 35% before they are fitted with an implantable

cardioverter-defibrillator for primary prevention. CABG reduces 10-year mortality in patients with reduced LVEF. Irrespective of the ECG pattern, survivors of out-of-hospital cardiac arrest with no obvious noncardiac cause of the arrhythmia should undergo early coronary angiography (IIa C). Patients who develop atrial fibrillation (AF) as a complication of PCI or CABG should be assessed for anticoagulation. Beta-blocker therapy should be considered as a measure to prevent the appearance of AF after CABG (I B).

PROCEDURAL ASPECTS OF CORONARY ARTERY BYPASS GRAFTING

The new guidelines omit recommendations on perioperative medication and the handling of periprocedural blood products in favor of a focus on surgical techniques. Regarding the selection of the second coronary graft, the CPG document recommends bilateral IMA grafts in patients younger than 70 years, stating that "a second arterial graft should be considered" depending on patient characteristics and other factors. The recommendation for the skeletonized IMA harvesting technique is limited to patients with a high risk of infection. Hybrid revascularization (CABG and PCI performed consecutively as part of the same procedure or sequentially in separate operating environments) retains a low recommendation (IIb) for selected patients treated in experienced centers; nonetheless, the evidence level has been changed from C in 2014 to B in the current document.

The recommendations for fully arterial revascularization (with no saphenous vein grafts) are based exclusively on the 5-year results of the Arterial Revascularization Trial.[11]

Spain has a low per capita rate of CABG, and it is therefore difficult for Spanish centers to follow the recommendation to assemble specialist teams in minimally invasive revascularization, surgery without extracorporeal circulation, or endoscopic dissection.

PROCEDURAL ASPECTS OF PERCUTANEOUS CORONARY INTERVENTION

The use of balloon angioplasty is now relegated to vessels unsuitable for stent implantation due to technical difficulties or because they are too narrow. As already mentioned, radial access has been upgraded to a class I A recommendation, and is already used in 88% of procedures in Spain.[3]

The maximum recommendation (class I A) is maintained for the use of DES in all clinical contexts and for all lesion types. However, implementation of this recommendation could be limited by spending restrictions in the health care sector. Despite this concern, DES are very widely used in Spain.[3] The guidelines discuss the polymers used or their absence in the different types of DES available; studies published to date have shown no significant clinical differences between the new-generation DES devices. This applies even to the high bleeding risk and the subsequent reduction in dual antiplatelet therapy duration, although the evidence in this area is limited to specific types of DES.[12] The use of bioresorbable scaffolds is not recommended (class III C) except in clinical trials.

The use of IVUS and optical coherence tomography (OCT) is recommended to optimize stent implantation (class IIa B). The 2014 guidelines already included this recommendation for IVUS, and now OCT has been upgraded to the same recommendation class (from IIb C in the previous guidelines). Reclassification to a firmer recommendation (class I) is impeded by the predominance of observational studies.[13]

Regarding specific lesion subsets, the guidelines increase the recommendation for main branch-only stenting with provisional stenting of the side branch (class IIa A in 2014; upgraded to I A in the new guidelines). In the specific case of true distal LMCA bifurcation lesions, the double-kissing crush technique is recommended (class IIb B) in preference to the provisional T-stent strategy. Although only class IIb, the recommendation of a specific method for true distal LMCA bifurcation lesions is contentious given the complexity and operator dependency of the double-kissing crush technique; moreover, the cited trial used lesion profiles unsuitable for provisional T-stenting, and the results in this treatment branch were worse than those obtained in other studies.

The guidelines maintain the class IIa B recommendation for the treatment of chronic total occlusions in patients with refractory chest pain or a large ischemic area near the occluded vessel. No distinction is made between anterograde and retrograde access. Since the evidence for a benefit associated with PCI mostly derives from registry data, the recommendation is lower than class I.

ANTITHROMBOTIC TREATMENTS

Recommendations for antiplatelet therapy have undergone no major changes with respect to the previous guidelines. The $P2Y_{12}$ receptor inhibitors of choice for ACS are ticagrelor and prasugrel, except in patients with a high bleeding risk or other contraindications. For patients with stable CAD treated by PCI, clopidogrel remains the preferred medication; however, for patients at high ischemic risk, more potent $P2Y_{12}$ receptor inhibitors should be considered (IIb C). A weak recommendation (IIb A) is made for cangrelor as an alternative medication for patients undergoing PCI and who have no history of $P2Y_{12}$ receptor inhibitor therapy, independently of their clinical presentation. This option is unavailable in Spain until this drug is commercialized. Recommendations for the duration of dual antiplatelet therapy after PCI retain the starting points of 6 months for stable CAD and 12 months for ACS; however, the guidelines stress the need to individualize treatment duration according to ischemia and bleeding risk.

Regarding anticoagulant treatment during PCI, the only major change is the relegation of bivalirudin to a class IIb A recommendation for STEACS and NSTEACS patients.

The new CPG document updates recommendations regarding the use of platelet function testing to guide antiplatelet therapy. These changes include a class IIb B recommendation to consider "downscaling" $P2Y_{12}$ receptor inhibitor therapy in ACS patients to less potent drugs. Moreover, the use of platelet function testing to guide antiplatelet therapy interruption in patients undergoing cardiac surgery has been downgraded from a class IIa recommendation to class IIb. Thus in both cases, the recommendation is weak.

For nonvalvular AF patients requiring simultaneous antiplatelet therapy, nonvitamin K oral anticoagulants (NOAC) are preferred over vitamin K antagonists and should be used at the minimum dose shown to prevent stroke. Moreover, NOACs are recommended in triple therapy (aspirin, clopidogrel, and an oral anticoagulant), although none of the published trials of triple therapy used NOACs at an appropriate dose for stroke prevention. This recommendation has major cost implications in Spain, where the current level of NOAC prescription is low and varies between the different autonomous communities.

VOLUME-OUTCOME RELATIONSHIP FOR REVASCULARIZATION PROCEDURES

The new guidelines maintain the previous recommendation that surgical revascularization be performed in centers with an annual volume of ≥ 200 patients (IIa C). A new recommendation has been introduced for periodic monitoring of performance measures to promote continuous improvement (class I C). There is no standard European training program in CABG; however, the guidelines recommend that trainee surgeons perform at least 200 procedures under supervision before working independently. Because of the fragmented organization of cardiac surgery centers

in Spain, it is difficult for our cardiac surgeons to achieve these numbers.

The guidelines also maintain the recommendations for training in PCI, both for ACS (≥ 75 procedures per operator in centers with at least 400 PCI procedures per year and a 24-hour on-call service) and for stable CAD (≥ 75 procedures per operator in centers with at least 200 PCI procedures per year). For the first time, the guidelines recommend that PCI treatment of LMCA disease be carried out by experienced operators (IIa C), defined in the article cited by the guidelines as those who treat at least 15 patients per year.[14] An especially notable modification has been introduced into the recommendation regarding the treatment of elective PCI patients considered complex. The guidelines maintain the requirement for PCI in these patients to be performed by experienced operators, with access to circulatory support and intensive care treatment; however, the requirement in the previous guidelines for an on-site surgical team has been eliminated.

For training in interventional cardiology, the guidelines propose a standardized program based on that put forward by the European Association of Percutaneous Cardiovascular Interventions (EAPCI). This program stipulates a minimum of 200 procedures as lead operator in a center performing more than 800 angioplasty procedures annually and an established 24-hour angioplasty service. This proposal provides support for the accreditation scheme run by the SEC Working Group on Cardiac Catheterization and Interventional Cardiology and should strengthen moves to give it legal standing.

MEDICAL THERAPY, SECONDARY PREVENTION, AND FOLLOW-UP STRATEGIES

Recommendations for cardiac rehabilitation are strengthened in the new guidelines for all patients treated for ACS with CABG or PCI, rising from class IIa in 2014 to class I A currently. This is a challenging recommendation in Spain because some centers lack a cardiac rehabilitation unit, and efficient implementation of these programs is impeded due to limited funds and a lack of infrastructure, patient care time, and multidisciplinary teams. Nonetheless, adherence to this recommendation may be improved with the advent of supervised telematic cardiac rehabilitation programs available to patients in their own homes.

Although the restenosis rate has decreased with the use of DES, it is important to check for the recurrence of ischemia symptoms, together with other secondary prevention measures. These concerns require clearly defined follow-up strategies, but there are numerous evidence gaps in this area.

Finally, the guidelines do not recommend systematic invasive or noninvasive screening for ischemia in asymptomatic patients.

CONFLICTS OF INTEREST

None declared.

APPENDIX: AUTHORS

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