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ESC/EACTS GUIDELINES

2018 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)

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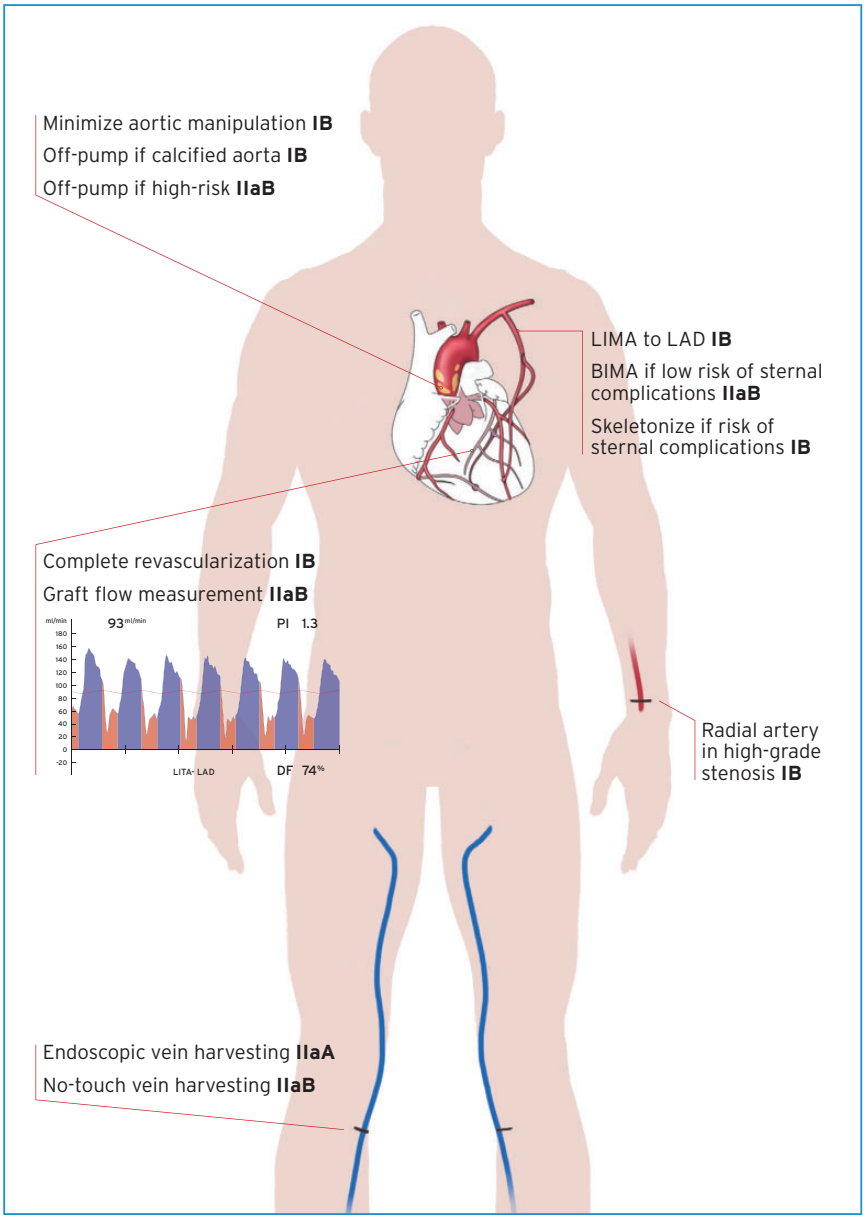

Figure 8 Technical aspects of CABG. BIMA = bilateral internal mammary artery; CABG = coronary artery bypass grafting; IMA = internal mammary artery; LAD = left anterior descending coronary artery.

16 Procedural aspects of percutaneous coronary intervention

16.1 Percutaneous coronary intervention devices

16.1.1 Balloon angioplasty

Plain balloon angioplasty has been superseded in the treatment of *de novo* coronary lesions after demonstration of the superiority of stenting in terms of the requirement for repeat revascularization.[564] Balloon angioplasty might be considered for the treatment of selected patients in whom implantation of stents is not technically feasible, or in a vessel that is considered to be too small to be stented. Balloon angioplasty is no longer preferred to stenting with DES for patients who require urgent non-cardiac surgery as short-duration DAPT may be reasonable with both strategies.[565,566]

16.1.2 Choice of coronary stents

Stenting with BMS results in an approximately 30% lower rate of restenosis in comparison with plain balloon angioplasty.[564] Although many efforts have been made to further reduce restenosis by the modification of stent designs and materials, reducing the thickness of stent struts has been the only proven modification capable of reducing restenosis of BMS.[567,568]

A major reduction in the risk of restenosis has been achieved with DES technology. Early-generation DES released sirolimus[569] or paclitaxel[570] from a permanent polymer matrix coating on a relatively thick-strut (120–140 μm) stainless steel backbone. These devices reduced angiographic and clinical restenosis by approximately 50–70%, but increased the risk of very late stent thrombosis compared with BMS.[336,571]

Early-generation DES have now been supplanted by new-generation DES. These stents represented an iterative development of early generation technology, including polymers with enhanced biocompatibility (permanent or biodegradable), exclusively sirolimus-analogue active drugs, and stent backbones with thin struts (50–100 μm) composed of stainless steel, cobalt chromium, or platinum chromium.[572–577] New-generation DES have higher efficacy and safety in comparison with both early-generation DES and BMS.[336,571,578] Although stenting with new-generation DES confers a similar risk of death or MI at mid- to long-term follow-up in comparison with BMS,[579] the risk of subacute and late stent thrombosis is significantly lower.[579,580] Moreover, the risk of very late stent thrombosis is at least comparable to that of BMS and lower than that of early-generation DES.[336,571,579,580] These observations were confirmed in a recent trial enrolling patients aged 75 years or older and demonstrating superior outcomes (composite of all-cause mortality, MI, stroke, or ischaemia-driven target lesion revascularization) with DES as compared with BMS with similar duration of intended DAPT (1 month or 6 months) in both treatment arms.[581] Similarly, there is no clear evidence of a difference between DES and BMS on the risk of stent thrombosis following unplanned disruption of DAPT.[565] Accordingly, new-generation DES should be preferred to BMS for routine use.

A large number of new-generation DES have received approval for use and CE mark in Europe.[578] Supplementary *Table 6* displays a list of new-generation DES with the CE mark and evidence from large-scale clinical trials powered for clinical primary endpoints.

Biodegradable polymer and polymer-free DES offer the potential to reduce late adverse events after PCI by eliminating inflammatory reactions to permanent polymer coatings. A number of large-scale trials showed comparable efficacy and safety compared with permanent polymer stents.[575,576,582–590] However, at the moment, there is no evidence of differential efficacy with new-generation biodegradable polymer DES in comparison with new-generation permanent polymer DES in large-scale randomized trials with follow-up out to 5 years.[591–594]

Regarding polymer-free DES, two large-scale trials with different devices showed comparable results with new-generation DES and superior results to BMS.[173,577] Long-term follow-up from randomized trials vs. new-generation permanent polymer DES is only available for a single device and shows comparable outcomes between the devices.[591]

The high clinical efficacy and safety of new-generation DES support their preferred use in patients with an indication for PCI, including patients with diabetes, CKD, multivessel and LMS disease, AMI, vein grafts, restenotic lesions, and chronic total occlusions. New-generation DES should therefore be considered as the default stent type for PCI regardless of clinical presentation, lesion subtype, concomitant therapies, or comorbidities.

16.1.3 Bioresorbable scaffolds

Completely bioresorbable scaffolds (BRS), which degrade to predominantly inert end products after fulfilling their scaffold function in the lesion site of the coronary vessel, have been developed with the goal of reducing or eliminating stent-related adverse events at long-term follow-up. Current scaffold platforms to have reached clinical testing are based on two different technologies: bioresorbable, polymer-based scaffolds (resorption up to 3–4 years) and resorbable, metallic (magnesium) scaffolds (resorption up to 1 year).[595] Although a number of devices have received approval for use in Europe (see Supplementary *Table 7*), randomized trial data are available only with the Absorb bioresorbable vascular scaffold (BVS) (Abbott Vascular).

The safety and efficacy profile of the Absorb BVS has been compared with contemporary DES in several trials. Findings of these trials as well as meta-analyses consistently indicate the inferior efficacy and safety of Absorb BVS compared with contemporary DES during long-term follow-up. Specifically, the Absorb BVS is associated with a significantly increased risk of target lesion revascularization and device thrombosis, with numbers needed to harm of 40–60.[596,597] Of note, commercial use of the Absorb BVS was stopped in 2017 (for additional details see the Supplementary Data).

Available evidence on the magnesium scaffold is limited to small observational studies. Initial results appear encouraging, but further evaluation is needed. Therefore, the Task Force endorses the recommendation of the recent ESC/European Association for Percutaneous Cardiovascular Interventions (EAPCI) document on bioresorbable scaffolds that any BRS should not be used outside well-controlled clinical studies. In patients who have been treated with BRS, prolonged-duration DAPT for 3 years or longer may be considered.

16.1.4 Drug-coated balloons

The rationale for using DCBs is based on the concept that with highly lipophilic drugs, even short contact times between the balloon surface and the vessel wall are sufficient for effective drug delivery. There are various types of DCB that are approved for use in Europe and their main characteristics are listed in Supplementary *Table 8*. Although specifically designed comparative randomized trials are lacking, a class effect for all DCBs cannot be assumed.[598] Randomized trial data supporting the use of DCB angioplasty are limited to the treatment of in-stent restenosis (see section 13.4). In terms of the use of DCB angioplasty for *de novo* disease, a number of small randomized trials have been reported with somewhat conflicting results.[599–601] At present, there are no convincing data to support the use of DCB angioplasty for this indication.

16.1.5 Devices for lesion preparation

Lesion preparation is critical for successful PCI. In addition to plain balloon angioplasty (with standard or non-compliant balloons), cutting or scoring balloon angioplasty or rotational atherectomy may be required in selected lesions—particularly those with heavy calcification—in order to adequately dilate lesions prior to stent implantation. However, studies investigating the systematic use of these adjunctive technologies, such as rotational atherectomy, have failed to show clear clinical benefit.[602]

16.2 Invasive imaging tools for procedural guidance

16.2.1 Intravascular ultrasound

The majority of the existing clinical trial data relate to the use of IVUS guidance during PCI. In the BMS era, several RCTs addressed the potential of IVUS in reducing restenosis and adverse events after

stenting, with somewhat conflicting results. Findings from one meta-analysis of randomized trials suggested better outcomes with IVUS guidance in terms of acute procedural results and reduced angiographic restenosis, repeat revascularization, and MACE, with no effect on death and MI.[603,604] In the DES era, meta-analysis of randomized and observational studies also suggests better clinical outcomes with IVUS-guided vs. angiography-guided PCI.[605,606] However, the contribution of findings from observational studies must be weighed against the likelihood of considerable residual confounding due to treatment selection bias. Similarly, findings of improved outcome in patients undergoing LM stem PCI with IVUS-guided PCI vs. angiography-guided PCI from a propensity score matched analysis must be interpreted with caution.[35]

In cases of stent failure, including restenosis and stent thrombosis, the use of IVUS should be considered in order to identify and correct underlying mechanical factors (see section 13).[386]

16.2.2 Optical coherence tomography

A number of studies have assessed OCT imaging for PCI guidance. Two observational studies show that while OCT imaging changes operator behaviour, its impact on clinical outcomes is unclear.[607,608] Indeed, OCT is more accurate than angiography or IVUS in detecting subtle morphological details including malapposition, residual thrombus, plaque prolapse, and residual dissections, although many of these additional findings may have a benign course.[609,610] A single randomized trial compared OCT with IVUS and coronary angiography, and showed that OCT-guided PCI was safe and resulted in a similar minimum stent area to that of IVUS-guided PCI.[611] However, OCT guidance was not superior to either IVUS or angiography alone. An additional randomized trial that enrolled patients with NSTE-ACS compared OCT-guided PCI with angiography-guided PCI and found no signal of impact on clinical outcomes.[612]

A number of observational studies have shown that OCT is feasible and safe in the assessment of stent failure due to thrombosis, and may yield information that may be clinically useful.[386,387,613,614] Likewise, in cases of in-stent restenosis, intrastent neointimal tissue may be characterized by OCT, enabling for example the detection of neoatherosclerosis.[386,615,616] In cases of stent failure, the use of OCT should be considered in order to identify and correct underlying mechanical factors (see section 13).

16.3 Specific lesion subsets

16.3.1 Bifurcation stenosis

A number of RCTs have investigated the optimal intervention strategy in patients with bifurcation lesions and showed no benefit for the systematic two-stent approach vs. main branch-only stenting with provisional stenting of the side branch in terms of clinical outcomes.[617] A recent pooled analysis of two RCTs showed lower 5 year survival in patients randomized to a systematic two-stent approach.[618] In addition, procedure time, contrast volume, radiation exposure, and cost are higher with a two-stent approach.[618] The EBC TWO (European Bifurcation Coronary TWO) trial found no difference between a provisional T-stent strategy and a systematic two-stent strategy (culotte technique) in terms of the composite endpoint of death, MI, and TVR at 12 months among 200 patients with large-calibre true bifurcation lesions (side branch diameter ≥2.5 mm) and significant ostial disease length (≥5 mm).[619] Thus, main branch-only stenting with provisional stenting of the side branch should be the preferred approach for most bifurcation lesions. Exceptions to this rule, where upfront side branch stenting may be preferable, include the presence of a large side branch (≥2.75 mm) with a long ostial side branch lesion (>5 mm) or anticipated difficulty in accessing an important side branch after main branch stenting, and true distal LM bifurcations. Recently, a multicentre trial conducted in China directly compared a double-kissing crush two-stent strategy with provisional stenting of the main branch in 482 patients with distal LM bifurcation disease. Double-kissing crush resulted in a lower risk of the primary endpoint target lesion failure at 1 year compared with provisional stenting.[620]

When a two-stent strategy is necessary, which two-stent technique should be preferred is debated. The three most widely used contemporary two-stent techniques are culotte, crush (classic or double-kissing crush), and T and protrusion (TAP).[621,622] Several RCTs have compared these techniques. In non-LM bifurcation lesions, there is no compelling evidence that one technique is superior to the others in terms of major clinical endpoints.[621,622] In LM true bifurcation lesions, double-kissing crush has the most favourable outcome data.[623]

Final 'kissing' balloon dilation is generally recommended when two stents are eventually required, with no advantage from final kissing with the one-stent technique.[624,625] Several stents, designed specifically for the treatment of bifurcation lesions, have undergone extensive evaluation with promising angiographic and clinical results, though RCTs against current recommended therapy are limited.[626] Further technical details relating to bifurcation PCI are described in the consensus document of the European Bifurcation Club.[627]

16.3.2 Chronic total coronary occlusion

Dedicated RCTs examining the outcomes of patients with chronic total occlusion (CTO) allocated to revascularization or conservative therapy are scarce. One trial randomized patients with STEMI and CTO in a non-culprit vessel to CTO-PCI vs. conservative therapy, and found no difference in the primary endpoint of LVEF and LV end-diastolic volume at 4 months.[628] More recently, the prospective randomized EUROCTO (Randomized Multicentre Trial to Compare Revascularization With Optimal Medical Therapy for the Treatment of Chronic Total Occlusions) trial showed symptomatic improvement by PCI of CTO.[629] This trial included 396 patients who were randomly assigned to PCI of CTO with optimal medical therapy, or optimal medical therapy alone. During the 12 month follow-up, the primary endpoint-the change in health status assessed by the Seattle angina questionnaire-showed significantly greater improvement of angina frequency and quality of life with CTO PCI as compared with optimal medical therapy alone. Yet, MACE were comparable between the two groups. A systematic review of 25 observational studies showed that at median follow-up of 3 years, successful CTO-PCI was associated with improved clinical outcomes in comparison with failed revascularization, including overall survival, angina burden, and the requirement for bypass surgery.[630] Broadly speaking, the treatment of CTOs may be considered analogous to the treatment of non-CTO lesions (see recommendations in section 5). In cases of regional wall motion abnormalities in the territory of the CTO, objective evidence of viability should be sought. The decision to attempt CTO-PCI should be considered against the risk of greater contrast volume, longer fluoroscopy time, and higher MACE rates in comparison with non-CTO PCI patients.[631] *Ad hoc* PCI is generally not recommended for CTOs, although it may be necessary in selected cases (e.g. acute bypass graft failure not amenable to recanalization of the bypass graft).

Recent developments in catheter and wire technology, and increasing operator expertise with both antegrade and retrograde approaches as well as wire escalation and dissection/re-entry techniques, have translated into increasing success rates of CTO-PCI with low rates of MACE.[631–633] Success rates are strongly dependent on operator skills, depending on experience with specific procedural techniques, and the availability of dedicated equipment, and vary from 60–70% to >90%.[631–633]

16.3.3 Ostial lesions

In ostial coronary lesions, additional judgement and caution is essential before proceeding to PCI. In particular, a catheter-induced coronary spasm must be rigorously excluded. Lesion assessment with IVUS may be helpful, particularly in LM ostial stenosis. FFR measurement may also be valuable in the assessment of ostial lesions of borderline significance,[634] taking special care to avoid a wedge position of the guiding catheter and using i.v., rather than intracoronary, adenosine. When performing an intervention, due to interaction between the guide catheter and the proximal stent edge, the risk of longitudinal stent deformation must be considered[635] and avoided with careful catheter manipulation. The accurate positioning of the stent, precisely in the coronary ostium, may be technically challenging and some specialized techniques that may help to achieve optimal stent placement have been described.[636,637]

16.4 Vascular access

A number of RCTs have compared radial access with femoral access for diagnostic angiography and PCI. The two largest were RIVAL (Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes) and MATRIX (Minimizing Adverse Haemorrhagic Events by Transradial access Site and Systemic Implementation of AngioX).[172,638] In the RIVAL trial, which enrolled 7021 patients, the primary outcome of death, MI, stroke, or non-CABG-related major bleeding at 30 days occurred at a similar rate in radial vs. femoral access (HR 0.92, 95% CI 0.72–1.17, P = 0.50).[638] In the MATRIX trial, 8404 ACS patients were randomly allocated to radial or femoral access.[172] In terms of the first co-primary endpoint of 30 day MACE, there was no significant difference between radial access and femoral access (RR 0.85, 95% CI 0.74–0.99, two-sided P = 0.031; non-significant at a pre-specified α of 0.025). The second co-primary outcome of 30 day net adverse clinical events [MACE or non-CABG BARC (Bleeding Academic Research Consortium (major bleeding] was significantly lower with radial access (RR 0.83, 95% CI 0.73–0.96; P = 0.009). Major BARC 3 or 5 bleeding was significantly reduced in the radial group (1.6 vs. 2.3%; RR 0.67, 95% CI 0.49–0.92; P = 0.013), and radial access was associated with a lower risk of all-cause mortality (1.6 vs. 2.2%; RR 0.72, 95% CI 0.53–0.99, P = 0.045). However, the benefit of radial over femoral access depends upon the operator's expertise in the radial technique.[639]

Treatment of restenotic and saphenous vein graft lesions are discussed in section 13.3.

Recommendations on choice of stent and access site

Recommendations	Class[a]	Level[b]
DES are recommended over BMS for any PCI irrespective of: • clinical presentation • lesion type • planned non-cardiac surgery • anticipated duration of DAPT • concomitant anticoagulant therapy.[100,578,579,640]	I	A
Radial access is recommended as the standard approach, unless there are overriding procedural considerations.[172,638,641]	I	A
BRS are currently not recommended for clinical use outside of clinical studies.[642–650]	III	C

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BMS = bare-metal stents; BRS = bioresorbable scaffolds; DAPT = dual antiplatelet therapy; DES = drug-eluting stents; PCI = percutaneous coronary intervention.
[a]Class of recommendation.
[b]Level of evidence.

Recommendations on intravascular imaging for procedural optimization

Recommendations	Class[a]	Level[b]
IVUS or OCT should be considered in selected patients to optimize stent implantation.[603,612,651–653]	IIa	B
IVUS should be considered to optimize treatment of unprotected left main lesions.[35]	IIa	B

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IVUS = intravascular ultrasound; OCT = optical coherence tomography.
[a]Class of recommendation.
[b]Level of evidence.

Recommendations on specific lesion subsets

Recommendations	Class[a]	Level[b]
Stent implantation in the main vessel only, followed by provisional balloon angioplasty with or without stenting of the side branch, is recommended for PCI of bifurcation lesions.[654–658]	I	A
Percutaneous revascularization of CTOs should be considered in patients with angina resistant to medical therapy or with a large area of documented ischaemia in the territory of the occluded vessel.[629,659–663]	IIa	B
In true bifurcation lesions of the left main, the double-kissing crush technique may be preferred over provisional T-stenting.[620]	IIb	B

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CTO = chronic total occlusion; PCI = percutaneous coronary intervention.
[a]Class of recommendation.
[b]Level of evidence.

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Supplementary Table 6 CE-approved new-generation drug-eluting stents recommended for clinical use based on randomized trials with a primary clinical endpoint (in alphabetical order)

DES	Stent platform	Polymer coating	Drug	References
Based on durable polymer coatings				
Promus element	Platinum–chrome	PBMA and PVDF-HFP	Everolimus	15,16
Resolute	Cobalt–chrome	PBMA, PHMA, PVP, and PVA	Zotarolimus	16–18
Xience	Cobalt–chrome	PBMA and PVDF-HFP	Everolimus	19–21
EluNIR (BioNIR)	Cobalt–chrome	PBMA and TSPCU	Ridaforolimus	22
Based on biodegradable polymer coatings				
Biomatrix	Stainless steel	PDLLA	Biolimus A9	23,24
Nobori	Stainless steel	PDLLA	Biolimus A9	25–27
Orsiro	Cobalt–chrome	PLLA	Sirolimus	28,29
Synergy	Platinum–chrome	PLGA	Everolimus	29
Ultimaster	Stainless steel	PDLLA/PCL	Sirolimus	30
Yukon Choice PC	Stainless steel	PDLLA	Sirolimus	31
Polymer-free				
BioFreedom	Stainless steel	–	Biolimus A9	32
Yukon Choice PF	Stainless steel	–	Sirolimus	33

DES = drug-eluting stent; PBMA = poly n-butyl methacrylate; PC = polymer-coated; PDLLA = poly(D,L)-lactic acid; PDLLA/PCL = poly (D,L)-lactide-co-caprolactone; PF = polymer-free; PHMA = polyhexyl methacrylate; PLGA = poly(d,l-lactide-*co*-glycolide); PLLA = poly-L-lactic acid; PVA = polyvinyl acetate; PVDF-HFP = poly(vinylidene fluoride-cohexafluoropropylene); PVP = polyvinyl pyrrolidone; TSPCU = thermoplastic silicone-polycarbonate-urethane.