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ESC/EACTS GUIDELINES

2014 ESC/EACTS Guidelines on myocardial revascularization

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

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

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Councils: Council for Cardiology Practice, Council on Cardiovascular Primary Care, Council on Cardiovascular Nursing and Allied Professions.

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4. Process for decision-making and patient information

4.1 Patient information and informed consent

The process of medical decision-making and patient information is guided by the 'four principles' approach to healthcare ethics: autonomy, beneficence, non-maleficence, and justice.[31] The informed consent process should not be regarded as a necessary legal requirement but as an opportunity to optimize decision-making. Patient-related factors, institutional factors and referral patterns may impact the decision-making process.

Informed consent requires transparency, especially if there is controversy over various treatment options. Collaborative care requires the pre-conditions of communication, comprehension, and trust. Treatment decisions should not be based solely on research results and the physician's appraisal of the patient's circumstances, since active patient participation in the decision-making process may yield better outcomes. Patients are subject to bias by labels when considering coronary revascularization,[32] and patient preference may sometimes contradict evidentiary best practice. Patients may have limited understanding of their disease and sometimes unreasonable expectations with regard to the outcomes of a proposed intervention. As many as 68% of patients are not aware of an alternative revascularization strategy.[33] Short-term procedure-related and long-term risks and benefits—such as survival, relief of angina, quality of life, potential need for late re-intervention, and uncertainties associated with different treatment strategies—should be thoroughly discussed. Patients can only weigh this information in the light of their personal values and cultural background and must therefore have the time to reflect on the trade-offs imposed by the outcome estimates.

In order to seek a second opinion or to discuss the findings and consequences with referring physicians, enough time should be allowed—up to several days, as required— between diagnostic catheterization and intervention. Patient information needs to be unbiased, evidence-based, up-to-date, reliable, accessible, relevant, and

Table 4 Multidisciplinary decision pathways, patient informed consent, and timing of intervention

	ACS			Multivessel SCAD	SCAD with *ad-hoc* PCI indication according to predefined Heart-Team protocols
	Shock	STEMI	NSTE-ACS		
Multidisciplinary decision making	Not mandatory during the acute phase. Mechanical circulatory support according to Heart-Team protocol.	Not mandatory during the acute phase.	Not mandatory during the acute phase. After stabilization recommended as in stable multivessel CAD.	Required.	Not required.
Informed consent	Verbal witnessed informed consent or family consent if possible without delay.	Verbal witnessed informed consent may be sufficient unless written consent is legally required.	Written informed consent.[a]	Written informed consent.[a]	Written informed consent.[a]
Time to revascularization	Emergency: no delay.	Emergency: no delay.	Urgency: within 24 hours if possible and no later than 72 hours.	For patients with severe symptoms (CCS 3) and for those with high–risk anatomy (left main disease or equivalent, three-vessel disease or proximal LAD or depressed ventricular function), revascularization (PCI or CABG) should be performed within two weeks. For all other patients with SCAD, revascularization (PCI or CABG) should be performed within six weeks.	*Ad hoc*
Procedure	Proceed with intervention based on best evidence/availability. Non-culprit lesions treated according to institutional protocol or Heart Team decision.	Proceed with intervention based on best evidence/availability. Non-culprit lesions treated according to institutional protocol or Heart Team decision.	Proceed with intervention based on best evidence/availability. Non-culprit lesions treated according to institutional protocol or Heart Team decision.	Plan most appropriate intervention allowing enough time from diagnostic catheterization to intervention.	Proceed with intervention according to institutional protocol defined by Heart Team.

ACS = acute coronary syndromes; CABG = coronary artery bypass grafting; CCS = Canadian Cardiovascular Society; LAD = left anterior descending; NSTE-ACS = non—ST-segment elevation acute coronary syndrome; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease; STEMI = ST-segment elevation myocardial infarction.

[a]This may not apply to countries that legally do not ask for written informed consent. ESC and EACTS advocate documentation of patient consent for all revascularization procedures.

Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality

Recommendations according to extent of CAD	CABG		PCI		
	Class[a]	Level[b]	Class[a]	Level[b]	Ref[c]
One or two-vessel disease without proximal LAD stenosis.	IIb	C	I	C	
One-vessel disease with proximal LAD stenosis.	I	A	I	A	107,108,160, 161,178,179
Two-vessel disease with proximal LAD stenosis.	I	B	I	C	108,135,137
Left main disease with a SYNTAX score ≤ 22.	I	B	I	B	17,134,170
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B	17
Left main disease with a SYNTAX score >32.	I	B	III	B	17
Three-vessel disease with a SYNTAX score ≤ 22.	I	A	I	B	17,157,175,176
Three-vessel disease with a SYNTAX score 23–32.	I	A	III	B	17,157,175,176
Three-vessel disease with a SYNTAX score >32.	I	A	III	B	17,157,175,176

CABG = coronary artery bypass grafting; LAD = left anterior descending coronary artery; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.

during the second half of the 5-year follow-up. In the ASCERT registry of elective patients >65 years of age with two- or three-vessel CAD, 86 244 patients underwent CABG and 103 549 patients underwent PCI (78% with early-generation DES). Using propensity scores and inverse probability adjustment, mortality at 4 years—but not at 1 year—was lower for CABG than for PCI (16.4% vs. 20.8%; RR 0.79; 95% CI 0.76–0.82).[26] The observational nature of the studies does not permit assessment of how each patient was selected for each kind of treatment and, despite statistical adjustments, residual confounders cannot be excluded. Early-generation DES were used, which are devoid of the advantages of the newer generation.[125–131,133] There is notable consistency in the findings on the survival advantage of CABG over PCI for more severe three-vessel CAD.

7. Revascularization in non-ST-segment elevation acute coronary syndromes

Non-ST-segment elevation acute coronary syndrome (NSTE-ACS) is the most frequent manifestation of ACS, and mortality and morbidity remain high and equivalent to those of patients with ST-segment elevation myocardial infarction (STEMI) during long-term follow-up. The key objectives of coronary angiography and subsequent revascularization are symptom relief and improvement of prognosis. Overall quality of life, length of hospital stay, and potential risks associated with invasive and pharmacological treatments must also be considered when deciding on a treatment strategy.

Early risk stratification is important, in order to identify patients at high immediate- and long-term risk for death and cardiovascular events, in whom an early invasive strategy with adjunctive medical therapy may reduce that risk. Patients in cardiogenic shock, or after resuscitation, should undergo immediate angiography (within 2 hours) because of the high likelihood of critical CAD, but it is equally important to identify patients at low risk, in whom invasive and medical treatments provide little benefit or may even cause harm. Details on risk stratification, particularly with respect to the interpretation of troponins, are found in the ESC Guidelines on NSTE-ACS.[180]

7.1 Early invasive vs. conservative strategy

A meta-analysis of seven RCTs that compared routine angiography followed by revascularization against a selective invasive strategy, showed reduced rates of combined death and myocardial infarction [odds ratio (OR) 0.82; 95% CI 0.72–0.93; $P = 0.001$].[181] The routine revascularization strategy was associated with a risk of early death and myocardial infarction during the initial hospitalization; however, four of the seven trials included in this meta-analysis were not contemporary, due to marginal use of stents and glycoprotein (GP) IIb/IIIa receptor inhibitors. Another meta-analysis, covering seven trials with more up-to-date adjunctive medication, showed a significant reduction in risk for all-cause mortality (RR = 0.75; 95% CI 0.63–0.90; $P < 0.001$) and myocardial infarction (RR = 0.83; 95% CI 0.72–0.96; $P = 0.012$), for an early invasive vs. conservative approach at 2 years without excess of death and myocardial infarction at 1 month.[182] A further meta-analysis of eight RCTs showed a significant lower incidence of death, myocardial infarction, or rehospitalization for ACS (OR = 0.78; 95% CI 0.61–0.98) for the invasive strategy at 1 year.[183] The benefit was carried mainly by improved outcomes in biomarker-positive (high-risk) patients. In a gender-specific analysis, a similar benefit was found in biomarker-positive women, compared with biomarker-positive men. Importantly, biomarker-negative women tended to have a higher event rate with an early invasive strategy, suggesting that early invasive procedures should be avoided in low-risk, troponin-negative, female patients. A more recent meta-analysis, based on individual patient data from three studies that compared a routine invasive- against a selective invasive strategy, revealed lower rates of death and myocardial infarction at