ESC Clinical Practice Guidelines -2011 Update Overview

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Clinical practice guidelines are intended to establish greater consistency of treatment and improve quality of care. To be most useful, guidelines should be updated regularly to include important data from clinical trials. Each year at its annual meeting, the European Society of Cardiology (ESC) releases several new or updated guidelines. This year, one new set of guidelines was issued and three others were updated.

Peripheral Artery Disease (PAD)

A substantial number of patients with coronary artery disease (CAD) also have cerebrovascular and/or lower extremity artery disease [Steg PG et al. *JAMA* 2007]. To aid in assessing patients with CAD for atherosclerosis at other sites, the ESC has issued its first set of guidelines for the diagnosis and treatment of PAD [Tendera M et al. *Eur Heart J* 2011]. The guideline overview was presented by Michal Tendera, MD, PhD, Medical University of Silesia, Katowice, Poland, and Victor Aboyans, MD, PhD, Dupuytren University Hospital, Limoges, France.

According to the new guidelines, a general diagnostic approach should include a complete medical history that focuses on a review of vascular beds and their specific symptoms, a systematic physical examination, and laboratory assessments to detect major risk factors of cardiovascular disease (CVD). The ankle-brachial index and duplex ultrasound are extremely useful diagnostic tools. Other noninvasive diagnostic modalities include computed tomography (CT) angiography and magnetic resonance angiography. Angiography, although considered the diagnostic gold standard in the past, is now used almost exclusively during endovascular procedures. The new guidelines stress that in all patients with PAD, secondary prevention should be implemented (Table 1). The major portion of the new guidelines is the site-specific section, which covers extracranial carotid and vertebral artery disease, upper extremity artery disease, mesenteric artery disease, renal artery disease, lower extremity artery disease, and multisite artery disease. For each condition, there is a detailed discussion of diagnosis and treatment modalities (medical therapy, surgery, and endovascular techniques). Differences in approaches for symptomatic and asymptomatic patients are also presented. The guidelines also provide direction for the management of patients with multisite artery disease.

Table 1. General Treatment Rules in Patients with PAD.

| Recommendations | Class | Level |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|
| All patients with PAD who smoke should be advised to stop smoking | I | В |
| All patients with PAD should have their LDL cholesterol lowered to <2.5 mmol/L (100 mg/dL), and optimally to <1.8 mmol/L (70 mg/dL) or ≥50% LDL cholesterol reduction when target level cannot be reached | I | C* |
| All patients with PAD should have their blood pressure controlled to ≤140/90 mm Hg | l I | А |
| β -blockers are not contraindicated in patients with LEAD, and should be considered in case of concomitant CAD and/or HF | lla | В |
| Antiplatelet therapy is recommended in patients with symptomatic PAD | I | C* |
| In patients with PAD and diabetes, HbA1C level should be kept at ≤6.5% | l I | C* |
| In patients with PAD, a multidisciplinary approach is recommended to establish a management stragegy | I | С |

*Evidence is not available for all sites. When evidence is available, accomodations specific for the vascular site are presented in responsive chapters; PAD=peripheral artery disease; LDL=low-density lipoprotein; LEAD=lower extremity artery disease; CAD=coronary artery disease; HF=heart failure; Reproduced with permission from the European Society of Cardiology.



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Acute Coronary Syndromes Without ST Elevation

The 2011 ESC Guidelines for the management of acute coronary syndromes (ACS) in patients who present without persistent ST-segment elevation [Hamm W et al. Eur Heart J 2011] were presented by Christian W. Hamm, MD, Kerckhoff Heart Center, Bad Nauheim, Germany. Important changes to the 2007 version of these guidelines involve diagnosis, risk stratification, medical treatment, and revascularization (Table 2). For the first time, it is recommended that patients with ACS be admitted, preferably to a dedicated chest pain or coronary care unit. The CRUSADE score is now recommended in addition to the GRACE score for prognostic assessment. The revised guidelines recommend that all patients receive an echocardiogram and that in certain patients, coronary CT angiography should be considered as an alternative to angiography to exclude ACS. Highly sensitive troponin (hsTn) tests are now included in the guidelines, and a new rapid rule-out protocol has been established for when these tests should be used (Figure 1). Under medical treatments, a proton pump inhibitor, in combination with dual antiplatelet therapy, is now recommended in selected patients, and both prasugrel and ticagrelor have been added to the treatment algorithm. Anticoagulation is recommended for all ACS patients in addition to antiplatelet therapy. The anticoagulation should be selected, based on both ischemic and bleeding risk and according to the efficacy-safety profile of the selected agent. Fondaparinux remains the preferred anticoagulant due to its favorable efficacy-safety profile. Enoxaparin is recommended when fondaparinux is not available. Bivalirudin plus provisional GP IIb/IIIa receptor inhibitors is recommended as an alternative to unfractionated heparin plus GP IIb/IIIa receptor inhibitors in patients with an intended urgent or early invasive strategy, particularly those who are at high risk of bleeding. The decision-making algorithm for invasive treatment has been modified from the 2007 guidelines to include the provision for an early invasive strategy in selected patients.

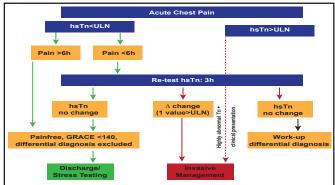


Figure 1. Rapid Rule-Out of ACS with hsTn.

hsTn=highly sensitive troponin; ULN=upper limit of normal. Reproduced with permission from the European Society of Cardiology.

Table 2. What's New in the 2011 Guidelines?

Diagnosis and Risk Stratification

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- ACS patients should be admitted preferably to chest pain units or coronary care units. (Class I: Level of Evidence C [LOE])
- It is recommended that established risk scores be used for prognosis and bleeding. (Class I: LOE B)
- A rapid rule-out protocol (0 and 3 hours) is recommended when highly sensitive troponin tests are available. (Class I: LÓE B)
- An echocardiogram is recommended for all patients to evaluate regional and global LV function and to rule in or rule out differential diagnosis. (Class I: LOE C)
- Coronary CT angiography should be considered as an alternative to invasive angiography to exclude ACS when there is a low to intermediate likelihood of CAD and when troponin and electrocardiogram are inconclusive. (Class IIa: LOE B)

Medical Treatment

- A PPI (preferably not omeprazole) in combination with DAPT is recommended in patients with a history of gastrointestinal hemorrhage or peptic ulcer, and appropriate for patients with multiple other risk factors (*H. pylori* infection, age ≥65 years, concurrent use of anticoagulants or steroids). (Class I: LOE A)
- Ticagrelor (180 mg loading dose, 90 mg twice daily) is recommended for all patients at moderate-to-high risk of ischemic events (eg, elevated troponins), regardless of initial treatment strategy and including those pre-treated with clopidogrel (which should be discontinued when ticagrelor is commenced). (Class I: LOE B)
- Prasugrel (60 mg loading dose, 10 mg daily dose) is recommended for P2T12-inhibitor-naïve patients (especially diabetics) in whom coronary anatomy is known and who are proceeding to PCI unless there is a high risk of life-threatening bleeding or other contraindications. (Class I: LOB B)
- GP IIb/IIIa receptor inhibitors are not recommended before angiography in an invasive treatment strategy. (Class III: LOE A)
- Bivalirudin plus provisional GP IIb/IIIa receptor inhibitors are recommended as an alternative to UFH plus GP IIb/IIIa receptor inhibitors in patients with an intended urgent or early invasive strategy, particularly in patients with a high risk of bleeding. (Class I: LOE B)

Revascularization

 An early invasive strategy (<24 hours) is recommended in patients with a GRACE score >140 or with at least one primary high-risk criterion. (Class I: LOE A)

ACS=acute coronary syndrome; LV=left ventricular; CAD=coronary arterv disease; PPI=proton pump inhibitor; DAPT=dual antiplatelet therapy; PCI=percutaneous coronary intervention; UFH=unfractionated heparin.

Cardiovascular Disease During Pregnancy

Between 0.2% and 4% of all pregnancies in industrialized nations are complicated by CVD. This number is rising due to older age in pregnancy and successful surgery for congenital HD. Hypertension (6% to 8% of pregnancies; serious complications infrequent), congenital HD (the cause of 75% to 82% of cardiac complications in the western world and only 9% to 19% outside Europe and North America), valvular HD (present in only 15% in industrialized countries but dominant in developing countries; mitral stenosis is most frequent), coronary HD (rare but increasing),



myocardial disease, and cardiomyopathy (rare but can cause severe complications; strong variation by country) are some of the CVDs that are seen during pregnancy. Vera Regitz-Zagrosek, MD, Deutsches Herzzentrum Berlin, Berlin, Germany, provided an overview of the ESC Guidelines on the management of CVD during pregnancy, which for the first time includes graded recommendations [Regitz-Zagrosek V et al. Eur Heart J 2011]. There are new recommendations in the guidelines concerning genetic testing, which should be performed if cardiomyopathy or channelopathies are suspected, if other family members are affected, or in the presence of dysmorphic features or other congenital abnormalities. The guidelines cover maternal diagnosis (including tests that can be modified by pregnancy and radiation doses for procedures that are needed for diagnosis), fetal assessment (by ECHO and biophysical profile), maternal interventions (percutaneous coronary intervention and cardiac surgery), infective endocarditis, contraception, termination of pregnancy, and in vitro fertilization. There are extensive recommendations on the timing and mode of delivery, general recommendations on risk estimation and high-risk states, and contraindications for pregnancy. Essential messages are summarized in Table 3.

Table 3. General Recommendations/Essential Messages.

| Start counselling and management by interdisciplinary teams before pregnancy. |
|------------------------------------------------------------------------------------------------------------------------|
| Refer high-risk patients, according the WHO scores, to specialized centers. |
| Maternal diagnosis: avoid radiation and prefer echocardiography, exercise testing and MRI. |
| Fetal diagnosis: Searching for congenital malformations in affected families by echocardiography may start in Week 13. |
| Surgical interventions in the mother are possible. |
| Mode of delivery (vaginal is preferred) should be decided by experienced teams; individualized strategy. |

Dyslipidemia

Željko Reiner, MD, University of Zagreb, Zagreb, Croatia, and Alberico L. Catapano, PhD, MD, University of Milan, Italy, presented the 2011 ESC/EAS guidelines for the management of dyslipidemia. Changes in plasma lipoprotein levels, whether alone or in combination with other CV risk factors, may affect the development of atherosclerosis; thus, optimal management of dyslipidemia is an essential and integral part of CVD prevention. In these guidelines, the prevention and treatment of dyslipidemia are considered within the broader framework of CVD prevention. There is less emphasis on target total cholesterol and more emphasis on low-density lipoprotein (LDL) levels, with a new lower target for LDL of <1.8 mmol/L(<70 mg/dL) that is recommended for patients who have the highest risk. Highdensity lipoprotein (HDL) is introduced as an important risk factor. Risk is assessed as being relative versus the more commonly used dichotomized approach (Table 4); thus, the level and timing of intervention and the targets (Table 5) are related to a particular combination of CV risk score and LDL level. Lifestyle changes, a major component of the approach at all levels, are also outlined, as are strategies to assist in medication compliance. The guidelines also provide specific recommendations for selected patient populations, including women, the elderly, and individuals with diabetes.

Table 4. LDL Target Recommendations.

| | In patients at VERY HIGH CV risk (established CVD, type 2 diabetes, type 1 diabetes with target organ damage, moderate to severe CKD or a SCORE level ≥10%) the LDL-C goal is <1.8 mmol/L (less than ~70 mg/dL) and/or ≥50% LDL-C reduction when target level cannot be reached. (Class I: LOE A) |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | In patients at HIGH CV risk (markedly elevated single risk factors, a SCORE level ≥5 to <10%) a LDL-C goal <2.5 mmol/L (less than ~100 mg/dL) should be considered. (Class IIa: LOE A) |
| | In subjects at MODERATE risk (SCORE level >1 to ≥5%), a LDL-C goal <3.0 mmol/L (less than ~115 mg/dL) should be considered. (Class IIa: LOE C) |

| Total CV | LDL-C Levels | | | | | | |
|----------------------------|---------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--|--|
| risk (SCORE) % | <70 mg/dL <1.8 mmol/L | 70 to <100 mg/dL 1.8 to <2.5 mmol/L | 100 to <155 mg/dL 2.5 to <4.0 mmol/L | 155 to <190 mg/dL 4.0 to <4.9 mmol/L | >190 mg/dL >4.9 mmol/L | | |
| <1 | No lipid intervention | No lipid intervention | Lifestyle intervention | Lifestyle intervention | Lifestyle intervention, consider drug if uncontrolled | | |
| Class/Level | I/C | I/C | I/C | I/C | Ila/A | | |
| ≥1 to <5 | Lifestyle intervention | Lifestyle intervention | Lifestyle intervention, consider drug if controlled | Lifestyle intervention, consider drug if uncontrolled | Lifestyle intervention, consider drug if uncontrolled | | |
| Class/Level | I/C | I/C | Ila/A | IIa/A | I/A | | |
| >5 to <10, or high risk | Lifestyle intervention, consider drug | Lifestyle intervention, consider drug | Lifestyle intervention and immediate drug intervention | Lifestyle intervention and immediate drug intervention | Lifestyle intervention and immediate drug intervention | | |
| Class/Level | Ila/A | Ila/A | Ila/A | I/A | I/A | | |
| ≥ 10 or very high risk | Lifestyle intervention, consider drug | Lifestyle intervention and immediate drug intervention | | |
| Class/Level | Ila/A | Ila/A | I/A | I/A | I/A | | |

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