Innovation and Guidelines – Does the one exclude the other?

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### Definitions of Clinical Guidelines

- Systematically developed statements to assist practitioner and patient on appropriate decisions for health care in specific clinical circumstances
- Consensus of experts interpreting the best available scientific evidence
- .... to assist practitioner and patient decisions .... not fixed protocols that must be followed, but are intended for health care professionals and providers to consider

# Topics

- Classes of recommendations and levels of evidence
- Patient information / patient involvement
- Educational value
- Gaps in evidence, future studies and innovations



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#### **Classes of recommendations**

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommmended/ is indicated.
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered.
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered.
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended.



#### **Levels of evidence**

Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.



## Clarity

#### be careful with the grading and exact wording of the recommendations

Recommendation 102Iliac artery aneurysm	Class	Level
The threshold for elective repair of isolated iliac artery aneurysm (common	llb	С
iliac artery, internal iliac artery and external iliac artery, or combination		
thereof) may be considered at a minimum of 3.5 cm diameter.		

Recommendation 92EVAR follow-up	Class	Level
Patients considered at low risk for endovascular aortic repair fai	lure after IIb	С
their first postoperative computer tomography angiography, ma	y be	
<b>considered</b> to be stratified to less frequent imaging follow-ups.		

Recommendation 116Saccular aortic aneurysm		Class	Level
Early treatment may be considered for saccular abdominal aortic aneurysm	IS,	llb	С
with a lower threshold for elective repair than for standard fusiform			
abdominal aortic aneurysms.			



## **Clinical applicability and flexibility**

leave some room for individualized decision making

'The decision when and how an AAA is to be operated on is extremely complex, with multiple variables that should be considered. It is therefore not possible to provide very detailed recommendations, and important to allow some degree of freedom for individualised decision making, respecting patient choice whenever possible'

Recommendation 60 Elective AAA repair	Class	Level
In patients with suitable anatomy and reasonable life expectancy,	lla	В
endovascular abdominal aortic aneurysm repair should be considered as the		
preferred treatment modality.		

Recommendation 61	Class	Level
In patients with long life expectancy, open abdominal aortic aneurysm repair	lla	В
should be considered as the preferred treatment modality.		



## Lack of evidence

Expert opinion

Recommendation 23 Threshold for repair in women	Class	Level
In women with acceptable surgical risk the threshold for considering elective	llb	С
abdominal aortic aneurysm repair <b>may be considered</b> to be ≥5.0 cm		
diameter.		
Recommendation 58 New techniques	Class	Level
New techniques/concepts (such as endovascular aneurysm sealing with	Ш	С
endobags) are not recommended in clinical practice and should only be		
used with caution, preferably within the framework of studies approved by		
research ethics committees, until adequately evaluated.		

Recommendation 108 Mycotic AAA	Class	Level
It is recommended to repair mycotic aneurysms irrespective of aneurysm	I	С
size.		



Parachutes appear to reduce the risk of injury but ... their effectiveness has not been proved with randomised controlled trials



Joint 2010 ESC - EACTS Guidelines on Myocardial Revascularisation





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# Antithrombotic treatment options in myocardial revascularisation

STEMI			
Antiplatelet therapy		Class	Level
	ASA	1	В
	Clopidogrel (with 600 mg loading dose as soon as possible)	I	с
	Prasugrel	- I	В
	Ticagrelor	I	В
	+ GPIIb-IIIa antagonists (in patients with evidence of high intracoronary thrombus burden)		
	Abciximab	lla	А
	Eptifibatide	lla	В
	Tirofiban	llb	В
	Upstream GPIIb-IIIa antagonists	Ш	В

Depending on drug approval and availability.

EUROPEAN SOCIETY OF CARDIOLOGY\*

www.escardio.org/guidelines

Joint 2010 ESC - EACTS Guidelines on Myocardial Revascularisation



Steg G et al. Oral presentation AHA 2009

# PLATO

#### **Cardiovascular death**

18,624 ACS UA/NSTEMI or STEMI (if primary PCI) All receiving ASA; clopidogrel-treated or -naïve



Wallentin L, et al. N Engl J Med. 2009;361:1045-57.

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# Recommendations for decision making and patient information

	Class	Level
It is recomminformed? ts be adequately in potential benefits and showing-term risks of a revascularisation procedure. Enough time should be spared for informed decision making.	I	C
The appropriate revascularisation strategy in patients with MVD should be discussed by the Heart Team.	I	С



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#### 24 h post CABG



#### 24 h post multivessel PCI



#### Four principles of medical ethics

• The "four principles plus scope" approach provides a simple, accessible, and culturally neutral approach for the thinking about ethical issues in health care

- It is based on four common, basic prima facie moral commitments:
  - respect for autonomy,
  - beneficence,
  - non-maleficence,
  - justice,

plus concern for their scope of application

Gillon et al. BMJ. 1994;309:184-8.



Joint 2010 ESC - EACTS Guidelines on Myocardial Revascularisation

#### **Respect for autonomy**

• Demands for agreement before action

Demands for communication

- Participation in medical decision making
- Demands for informed consent

Gillon et al. BMJ. 1994;309:184-8.



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Joint 2010 ESC - EACTS Guidelines on Myocardial Revascularisation

# Patient information document: content

- What is significant about coronary artery disease (CAD)?
- How is CAD treated?
  - 1. Medical treatment.
  - 2. Percutaneous Coronary Intervention (PCI) or angioplasty.
  - 3. Coronary artery bypass grafting (CABG) or bypass surgery.
- Angioplasty: advantages and disadvantages at a glance.
- Bypass surgery: advantages and disadvantages at a glance.

Document available in the Appendix of the online version of the Guidelines.

European Heart Journal (2010) 31, 2501-2555 European Journal of Cardio-thoracic Surgery (2010) 38, S1-S52

> Joint 2010 ESC - EACTS Guidelines on Myocardial Revascularisation





#### **Anatomical representation**



Wijns W & Kolh Ph. Eur Heart J. 2009;30(18):2182-5.



www.escardio.org/guidelines

Joint 2010 ESC - EACTS Guidelines on Myocardial Revascularisation

# esvs

### Information for patients (AAA GL) patient's perspective

- Patient engagement improves the validity of clinical guidelines
- Lay review process;
  - Information for patients was drafted for each subchapter plain English summary
  - Read and amended by a vascular nurse specialist and at least one layperson or patient
  - Finally reviewed by the Leicester patient focus group (PFG)
- Leicester PFG:
  - 8 men with small AAA under surveillance in Leicester (UK)
  - Previously attended a patient education on the clinical management of small AAA and the background to the ESVS guideline development process.

#### KOMPETENZ ENTSCHEIDET.



# esvs

### Information for patients (AAA GL) patient's perspective

- Resulted in clarity, consistency and simplicity in the presentation of facts and recommendations in the plain English summaries
  - > What happens if I am diagnosed with an AAA?
  - If I have an AAA what is the risk of it bursting?
  - What happens if I have a small AAA and it gets bigger?
  - How is an operation to repair an AAA performed?
  - What are the main advantages and disadvantages of an open and an endovascular AAA repair?
  - > What happens if I am not fit enough to have an operation to repair my AAA?
  - What happens if an AAA bursts?
- → Development of Core Outcome Sets (COS)

#### KOMPETENZ ENTSCHEIDET.





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#### CORE CURRICULUM (2015-2022)

- 2015 Chronic Venous Disease
- 2017 Descending Thoracic Aorta
- 2017 Mesenteric Arteries and Veins
- 2018 Carotid and Vertebral Arteries
- 2018 Vascular Access
- 2019 Abdominal Aorto-Iliac Artery Aneurysms
- 2020 Acute Limb Ischaemia
- 2020 Vascular Graft and Endograft Infection
- 2021 Venous Thrombosis
- 2022 Chronic Venous Disease
- 2022 Carotid and Vertebral Arteries

**ESVS Clinical Practice Guidelines App** 

#### CORE CURRICULUM - JOINT GUIDELINES

2018 – ESC/ESVS Guidelines on Peripheral Artery Diseases
2019 – SVS/ESVS/WFVS Guidelines on Chronic Limb Threatening Ischaemia
2019 – ESVS/EACTS on Aortic Arch - position paper

#### PLANNED: ESVS GUIDELINES (2023-2025)

2023 – Radiation Protection
2023 – Antithrombotic Therapy in Vascular Surgery
2023 – Descending Thoracic Aorta

2024 – Peripheral Artery Disease 2024 – Abdominal Aorto-Iliac Artery Aneurysm 2024 – Diabetic Foot (Joint GLs with SVS/IWGDF)

- 2025 Vascular trauma
- 2025 Visceral Vessels
- 2025 Vascular Malformations (with VASCERN)

2025 – Chronic Limb Threatening Ischemia (with SVS & WFVS)

# Rationale for a GVG in CLTI

- Growing global prevalence of disease and risk factors
- High patient and public health costs
- Diverse specialties/providers and care settings
- Highly variable utilization of vascular interventions
- Wide disparity in outcomes, unclear standard of care
- Continuously evolving technology, shifting practice patterns
- Lack of consensus definitions and disease staging a major limitation to evidence-based medicine and clinical/outcomes research
- Define Key Research Questions
- Foster Improved Care and Quality Outcomes for Patients







# **Guideline Sections**

- 1. Definitions and nomenclature
- 2. Epidemiology and risk factors
- 3. Diagnostic evaluation
- 4. Medical management
- 5. Anatomic staging
- 6. Strategies for revascularization
- 7. Non-revascularization treatments of the limb
- 8. Biologic and regenerative approaches
- 9. Role of amputation
- 10. Post-procedural care and surveillance
- 11. Study designs and clinical trial endpoints
- 12. Interdisciplinary Team in CLTI
- 13. Global implementation



ESVS, SVS, WFVS Working Together to Improve Patient Care

# **Revascularization Decision Matrix in CLTI**





FP grading: SFA: no significant stenosis Popliteal: no significant stenosis **FP grade = 0** 

IP grading: TAP = peroneal artery Peroneal: CTO 3-10cm IP grade = 3

#### **GLASS Stage = II**

	INFRAINGUINAL GLASS STAGE					
FP	4	111		111	- 111	ш
Grade	3	Ш	II	Ш	ш	ш
	2	I	II	Ш	II	ш
	1	I	I	Ш	II	ш
	0	NA	I	- I	Ш	ш
		0	1	2	3	4
			IP Gr	ade		



# EUROPEAN SOCIETY FOR VASCULAR SURGERY (ESVS) 2022 CLINICAL PRACTICE GUIDELINES ON THE MANAGEMENT OF CHRONIC VENOUS DISEASE OF THE LOWER LIMBS

esvs



# Topics

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#### Surgical techniques in aortic disease

Recommendations	Class	Leve
Cerebrospinal fluid drainage is recommended in surgery of the thoracoabdominal aorta to reduce the risk of paraplegia.	I	В
Aortic valve repair using the reimplantation technique or remodelling with aortic annuloplasty is recommended in young patients with aortic root dilatation and tricuspid aortic valves.	I	с
For repair of acute type-A aortic dissection (AD), an open distal anastomotic technique avoiding aortic clamping (hemiarch/complete arch) is recommended.	I	с
In patients with connective tissue disorders requiring aortic surgery, the replacement of aortic sinuses is indicated.	I	с
Selective antegrade cerebral perfusion should be considered in aortic arch surgery to reduce the risk of stroke.	IIa	В
The axillary artery should be considered as first choice for cannulation for surgery of the aortic arch and in aortic dissection.	IIa	с
Left heart bypass should be considered during repair of the descending aorta or the thoracoabdominal aorta to ensure distal organ perfusion.	IIa	с



#### **Treatment of aortic dissection**

Recommendations	Class	Level
In all patients with AD, medical therapy including pain relief and blood pressure control is recommended.	I	с
In patients with type-A AD, urgent surgery is recommended.	I	B
In patients with acute type-A AD and organ malperfusion, a hybrid approach (i.e. ascending aorta and/or arch replacement associated with any percutaneous aortic or branch artery procedure) should be considered.	IIa	в
In uncomplicated type-B AD, medical therapy should always be recommended	I	с
In uncomplicated type-B AD, TEVAR should be considered.	IIa	B
In complicated type-B AD, TEVAR is recommended.	I	-
In complicated type-B AD, surgery may be considered.	IIb	С



#### Interventions of thoracic aortic aneurysm (TAA)

Recommendations	Class	Level
Interventions on ascending aorta		2
Surgery is indicated in patients who have aortic root aneurysm, with maximal aortic diameter ≥50 mm for patients with Marfan syndrome.	I	С
Surgery should be considered in patients who have aortic root aneurysm, with maximal ascending aortic diameter: ≥45 mm for patients with Marfan syndrome with risk factors. ≥50 mm for patients with bicuspid valve with risk factors. ≥55 mm for other patients with no elastopathy.		c
Lower thresholds for intervention may be considered according to body surface area in patients of small stature or in the case of rapid progression, aortic valve regurgitation, planned pregnancy, and patient's preference.	IIP	с
Interventions on aortic arch aneurysms		
Surgery should be considered in patients who have isolated aortic arch aneurysm with maximal diameter ≥55 mm.		С
Aortic arch repair may be considered in patients with aortic arch aneurysm who already have an indication for surgery of an adjacent aneurysm located in the ascending or descending aorta.		c

#### Aortic root support



Personalised External Aortic Root Support

PEARS





In 2007 Camilla Allen became the ninth person with Marfan's syndrome to have an external aortic root support wrapped around her dilated aorta. She has since become the first woman with an exostent to become pregnant and give birth. C. Allen, J. Pepper, **External aortic support for people with Marfan's syndrome** *BMJ* 2010; 340

# Case: Arch aneurysm treated with branched arch graft

(thanks to Pr Verhoeven, EJVES associated editor for complex endovascular surgery)

- 74 YO Male
- Distal aortic arch aneurysm
  - Dmax: 6.2cm
- Pararenal AAA
  - Treated with FEVAR in 2012





#### Left L Car-LSA bypass



#### Cook arch device

#### 2 inner branches





Stent-graft positioning & deployment





Innominate branch deployment



Left CCA branch deployment



#### Final Result





# Conclusions

- Guidelines (as the word states) are a guiding principle, but the care given to a single patient is always dependent on
  - the individual patient (symptom variability, comorbidities, age, level of activity...),
  - the treatment setting (availability of techniques),
  - other factors.
- Guidelines should be part of the Core Curriculum of every cardiac/vascular surgeon
- Guidelines set the standard of optimal care but also pave the way for future innovations and trials.