Who needs “Super Statin” and What are the Recommendations?

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Outline:

1. Introduction
2. Lipid and Lipoproteins
3. CVD Risk categories
4. Lipid lowering medications including Super Statins
5. Evidence based Recommendations

Introduction:

- Atherosclerotic cardiovascular disease (ASCVD) - still a major cause of morbidity and mortality
- Responsible for just under 2.2 million deaths in females and just over 1.9 million deaths in males in the most recent year of available data in Europe
- Approximately 20.1 million persons in the United States live with Chronic Coronary Disease, 11.1 million Americans have chronic stable angina pectoris symptoms
- Main causal and modifiable ASCVD risk factors:
  - Blood apolipoprotein-B-containing lipoproteins, of which (LDL-C) is most abundant
  - Diabetes
  - Hypertension
  - Smoking

ESC 2023 guideline for management of ACS

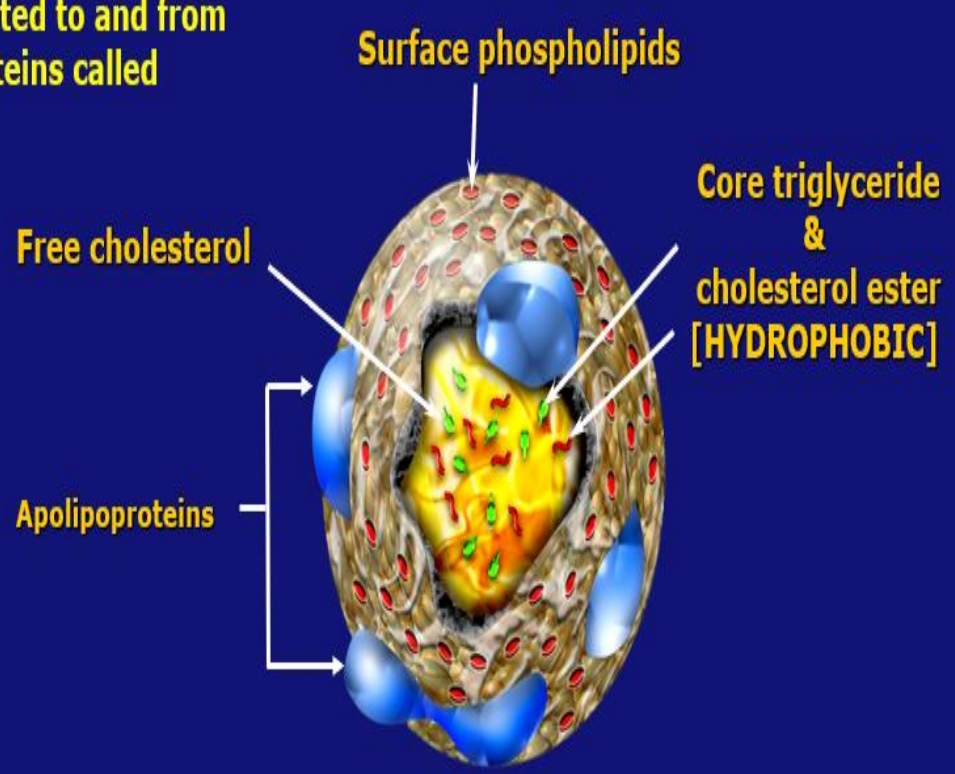
Introduction:

- Key initiating event in atherogenesis- Retention of LDL-C and other cholesterol-rich ApoB containing lipoproteins within the arterial wall
- The lower the achieved LDL-C values, the lower the risk of future cardiovascular events, with no lower limit for LDL-C values
- The relative reduction in CVD risk is proportional to the absolute size of the change in LDL-C
- Small absolute reduction in LDL-C is beneficial in a high- or very-high-risk patient on absolute risk reduction of ASCVD

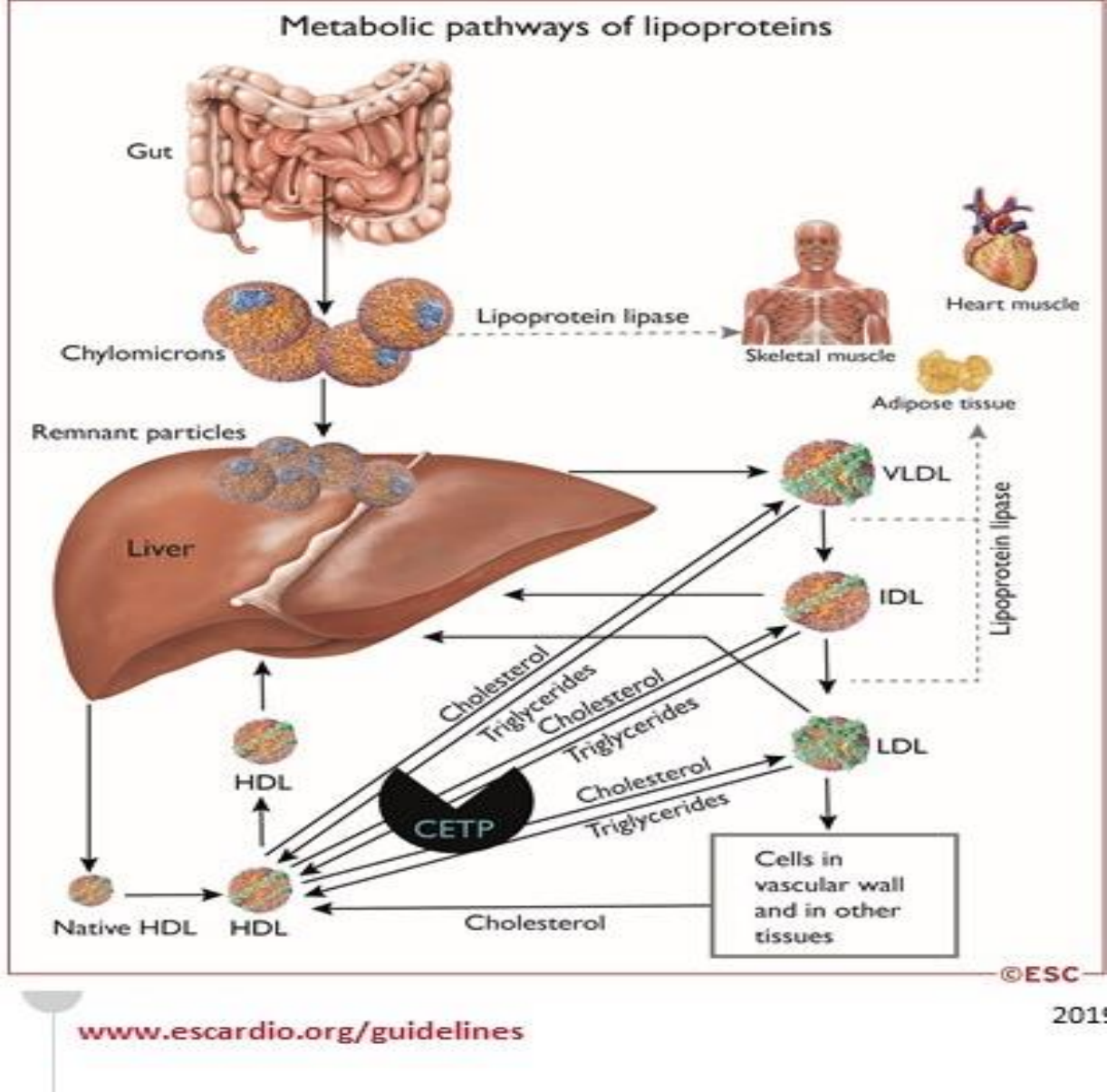
European Heart Journal (2020) 41, 111-188

Lipid and Lipoproteins

Cholesterol, due to its hydrophobic nature, **cannot dissolve in the blood**, and is instead **transported to and from the liver by carrier proteins called lipoproteins.**



Lipoproteins act as a "fuel delivery" vehicle in order to deliver the "cargo" (the lipids) to the periphery



Lipoproteins in plasma transport lipids to tissues for energy utilization, lipid deposition, steroid hormone production and bile acid formation

Physical and chemical characteristics of human plasma lipoproteins

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	Density (g/mL)	Diameter (nm)	TGs (%)	Cholesteryl esters (%)	PLs(%)	Cholesterol (%)	Apolipoproteins	
							Major	Others
Chylomicrons	<0.95	80-100	90-95	2-4	2-6	1	ApoB-48	ApoA-I, A-II, A-IV, A-V
VLDL	0.95-1.006	30-80	50-65	8-14	12-16	4-7	ApoB-100	ApoA-I, C-II, C-III, E, A-V
IDL	1.006-1.019	25- 30	25- 40	20- 35	16- 24	7- 11	ApoB-100	ApoC-II, C-III, E
LDL	1.019-1.063	20- 25	4- 6	34- 35	22- 26	6- 15	ApoB-100	
HDL	1.063-1.210	8-13	7	10-20	55	5	ApoA-I	ApoA-II, C-III, E, M
Lp(a)	1.006-1.125	25-30	4-8	35-46	17-24	6-9	Apo(a)	ApoB-100

Lipid and Lipoproteins

- ApoB-containing lipoproteins - Cross the endothelial barrier/dysfunction
- Trapped after interaction with extracellular structures such as proteoglycans
- Retained in the arterial wall → lipid deposition and initiation of atheroma
- Continued exposure to ApoB → growth and progression of atherosclerotic plaques

- Size of plaque burden - determined by both the concentration of circulating LDL-C and other ApoB-containing lipoproteins and by the total duration of exposure to these lipoproteins

- A person's total atherosclerotic plaque burden - proportional to the cumulative exposure to these lipoproteins

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Lipid and Lipoproteins

- Increased plaque burden + changes in the composition → disruption of plaque → overlying thrombus → obstructs blood flow → unstable angina, myocardial infarction (MI), or death

- Risk of acute ASCVD event - rises rapidly as more ApoB-containing lipoproteins become retained and the atherosclerotic plaque burden increases

- Encouraging a healthy lifestyle &
- Maintain low levels of ApoB-containing lipoproteins throughout life to progression of atherosclerosis

- Recommend treatment to lower LDL-C and other ApoB-containing lipoproteins, for both the primary & secondary prevention of CV events

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CVD Risk Categories

- All current guidelines on the prevention of ASCVD in clinical practice recommend the assessment of total CVD risk
- Provides information for tailored intervention on an individual level
- The higher the risk, the more intense the action should be
- Treatment goals can be individualized in a stepwise approach

- Residual CVD risk - defined as the risk estimated after initial lifestyle changes and risk factor treatment, mostly used in patients with established ASCVD

- Lifetime CVD risk and benefit estimation of risk factor treatment - to facilitate the communication of CVD risk and treatment benefits in apparently healthy people

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Cardiovascular risk categories: Very-high-risk

- People with any of the following: Documented ASCVD, either clinical or unequivocal on imaging

- Documented ASCVD includes:
  - previous ACS (MI or unstable angina), stable angina, coronary revascularization (PCI, CABG, and other arterial revascularization procedures)
  - stroke and TIA
  - peripheral arterial disease

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Cardiovascular risk categories: Very-high-risk

- Unequivocally documented ASCVD on imaging includes:
  - Findings known to be predictive of clinical events:
  - Significant plaque on coronary angiography or CT scan (multivessel coronary disease with two major epicardial arteries having >50% stenosis)
  - Carotid ultrasound

- DM with target organ damage, or at least three major risk factors
- Early onset of T1DM of long duration (>20 years)

- Severe CKD (eGFR<30)

- A calculated SCORE ≥10% for 10-year risk of fatal CVD

- FH with ASCVD or with another major risk factor.

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Cardiovascular risk categories: High-risk

- People with:
  - Markedly elevated single risk factors
    - TC >8 mmol/L (>310 mg/dL)
    - LDL-C >4.9 mmol/L (>190 mg/dL)
    - BP >_180/110 mmHg
- FH without other major risk factors
- DM without target organ damage, with DM duration ≥10 years or another additional risk factor
- Moderate CKD (eGFR 30-59 mL/min/1.73 m2)
- A calculated SCORE ≥5% and <10% for 10-year risk of fatal CVD

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Cardiovascular risk categories: Moderate-risk

- **Young patients (T1DM <35 years; T2DM <50 years) with DM duration <10 years, without other risk factors**

- **Calculated SCORE ≥1 % and <5% for 10-year risk of fatal CVD**

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Cardiovascular risk categories: Low-risk

- **Calculated SCORE <1 % for 10-year risk of fatal CVD**

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Patient categories and associated cardiovascular disease risk

Patients with type 2 diabetes mellitus

Patients with type 1 DM above 40 years of age may also be classified according to these criteria	Patients with well controlled short-standing DM (e.g. <10 years), no evidence of TOD and no additional ASCVD risk factors	**Moderate-risk**
	Patients with DM without ASCVD and/or severe TOD, and not fulfilling the moderate risk criteria.	**High-risk**
	Patients with DM with established ASCVD and/or severe TOD: • eGFR <45 mL/min/1.73 m² irrespective of albuminuria • eGFR 45-59 mL/min/1.73 m² and microalbuminuria (ACR 30 mg/g – 300 mg/g) • Proteinuria (ACR >300 mg/g) • Presence of microvascular disease in at least 3 different sites (e.g. microalbuminuria plus retinopathy plus neuropathy)	**Very high-risk**

2021 ESC Guidelines on cardiovascular disease prevention in clinical practice (European Heart Journal 2021 – doi:10.1093/eurheartj/ehab484)

Patient categories and associated cardiovascular disease risk

Patients with established ASCVD		
Documented ASCVD, clinical or unequivocal on imaging. Documented clinical ASCVD includes previous AMI, ACS, coronary revascularization and other arterial revascularization procedures, stroke and TIA, aortic aneurysm and PAD. Unequivocally documented ASCVD on imaging includes plaque on coronary angiography or carotid ultrasound or on CTA. It does NOT include some increase in continuous imaging parameters such as intima–media thickness of the carotid artery.		Very high-risk

2021 ESC Guidelines on cardiovascular disease prevention in clinical practice (European Heart Journal 2021 – doi:10.1093/eurheartj/ehab484)

Cholesterol-Lowering Drug Therapy

- Cholestyramine (Bile acid sequestrants)
  - Colestipol
  - Colesevelam
- Fibrates
  - Gemfibrozil
  - Fenofibrate
  - Clofibrate
- Nicotinic Acid
- Ezetimibe

- HMG CoA Reductase Inhibitors
  - Lovastatin
  - Simvastatin
  - Pravastatin
  - Atorvastatin
  - Rosuvastatin
  - Pitavastatin
- PCSK9 inhibitors (anti-proprotein convertase subtilisin/kexin type 9)

Wish list of Super Statin properties

- **High efficacy at start dose**
- **Potent HMG-CoA inhibition**
- **Lowers LDL, VLDL, Lp(a), remnants**
- **Raises HDL**
- **Anti-inflammatory, anti-thrombotic**
- **Good safety profile**
- **Selective for target organ – liver**
- **Minimal potential for drug interactions**
- **Useful in a wide range of patients**
- **Cost effective**

High and Moderate-Intensity Statin Therapy

High-intensity

Lowers LDL-C on average ≥50%

Atorvastatin 40–80 mg *
Rosuvastatin 20–40 mg*

*Administer any time of day

Moderate-intensity

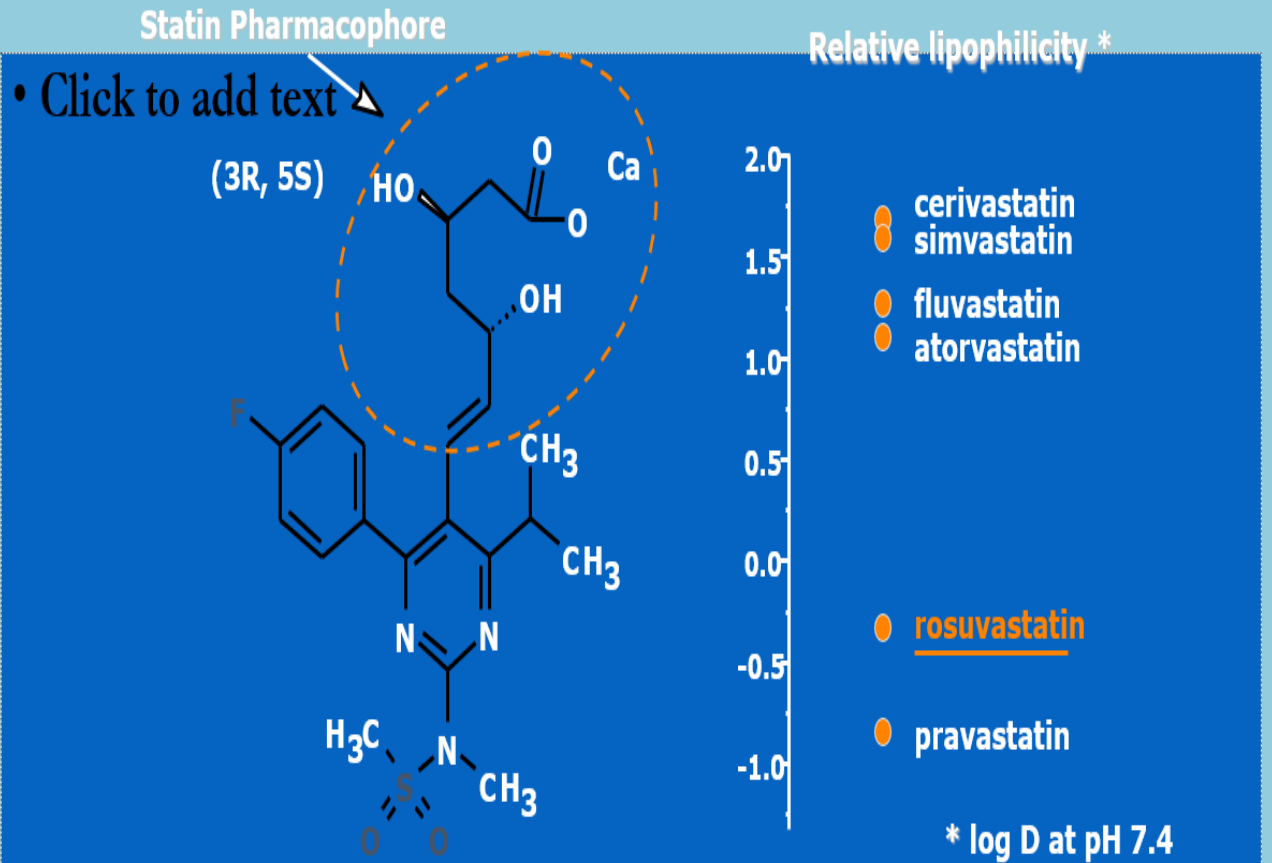
Lowers LDL-C on average 30 to 49%

Atorvastatin 10–20 mg*
Rosuvastatin 5–10 mg*
Simvastatin 20–40 mg
Pravastatin 40–80 mg
Lovastatin 40–80 mg
Fluvastatin XL 80 mg*
Fluvastatin 40 mg bid
Pitavastatin 1–4 mg*

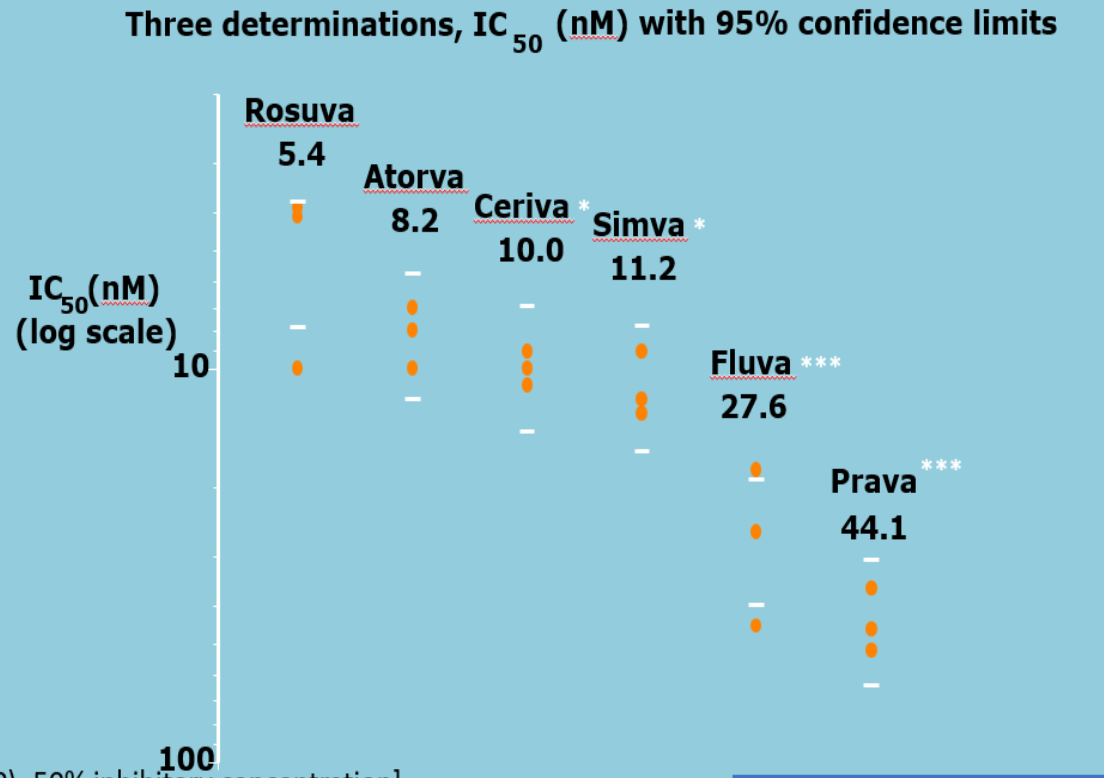
Grundy SM, et al. 2018 AHA/ACC Cholesterol Guideline. *Circulation*. 2019;139:e1082–e1143.

Rosuvastatin

Unique member of the class of statins due to its high hydrophilicity which increases hepatic uptake at the site of action, low bioavailability, and minimal metabolism via the Cytochrome P450 system



Potent inhibitor of HMG-CoA reductase

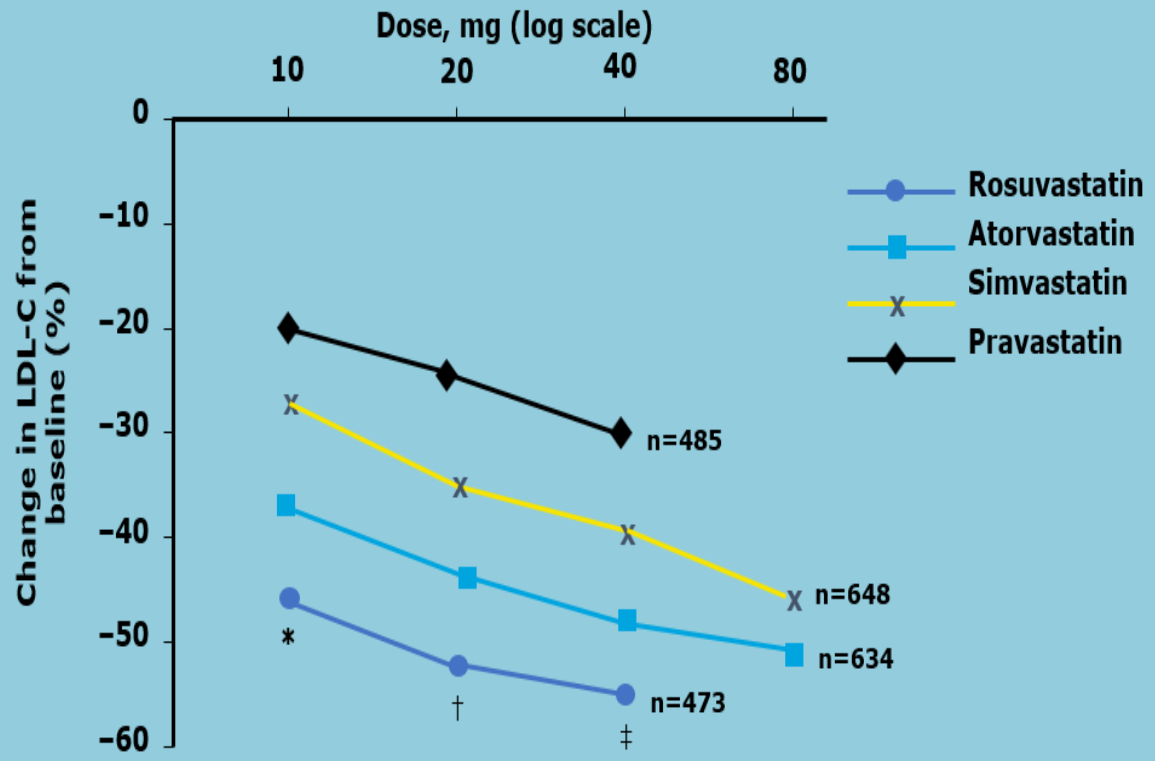


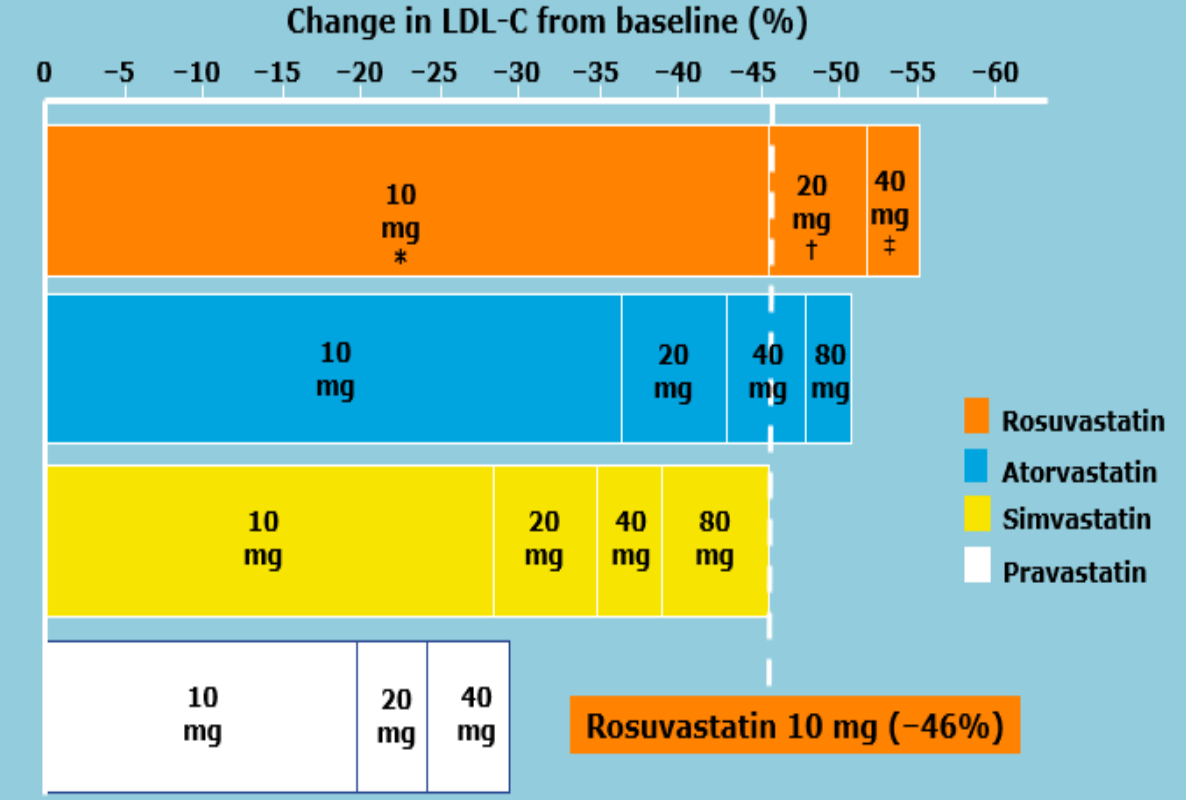
[IC50) -50% inhibitory concentration]

* P<o.o5 vs Rosuvastatin ***P<0.001 vs Rosuvastatin

McTaggart et al., (2001)

STELLAR –Rosuvastatin versus Comparators: LDL-C Efficacy Across the Dose Range (The STELLAR Study)





*p<0.002 vs ATV 10 mg; SIM 10, 20, 40 mg; PRA 10, 20, 40 mg
†p<0.002 vs ATV 20, 40 mg; SIM 20, 40, 80 mg; PRA 20, 40 mg
‡p<0.002 vs ATV 40 mg; SIM 40, 80 mg; PRA 40 mg

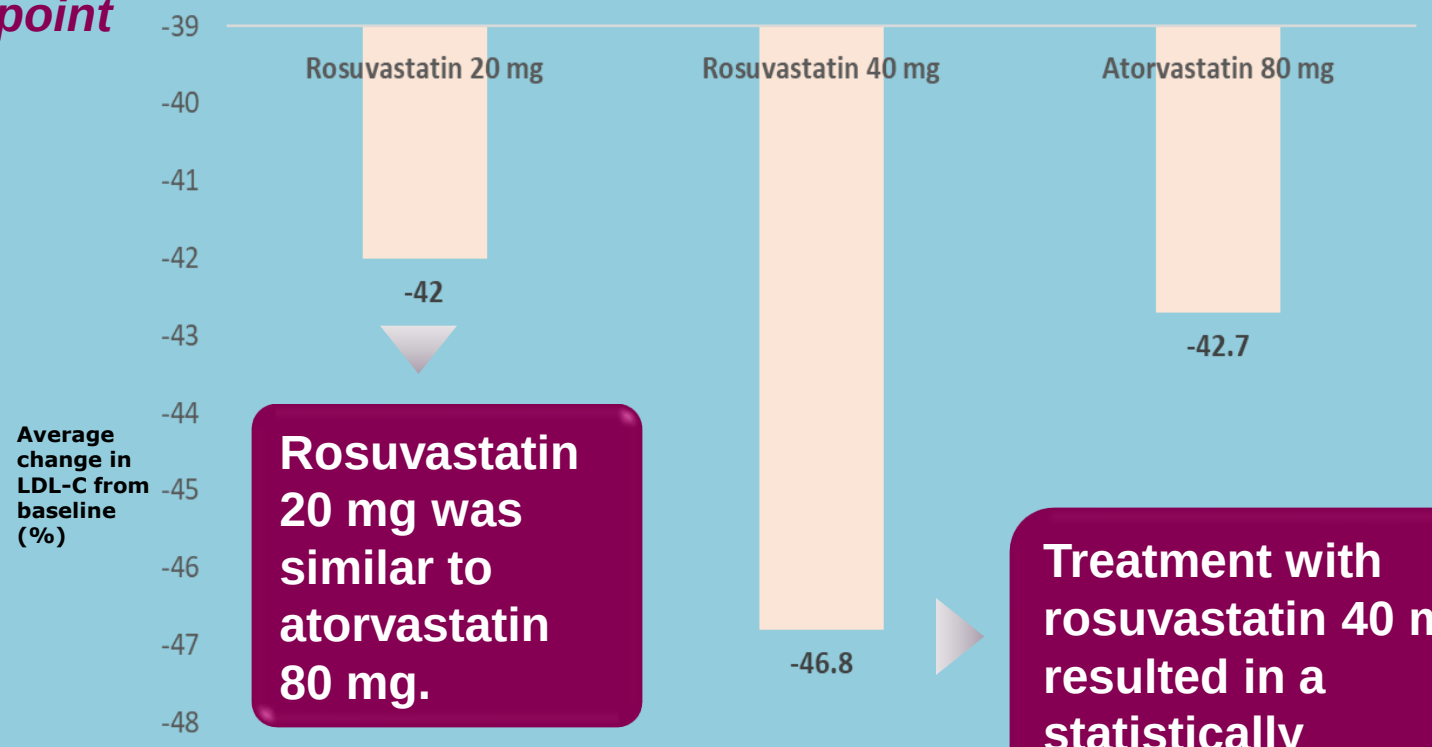
*p<0.002 vs atorvastatin 10 mg; simvastatin 10, 20, 40 mg; pravastatin 10, 20, 40 mg
†p<0.002 vs atorvastatin 20, 40 mg; simvastatin 20, 40, 80 mg; pravastatin 20, 40 mg
‡p<0.002 vs atorvastatin 40 mg; simvastatin 40, 80 mg; pravastatin 40 mg

Adapted from Jones PH et al. *Am J Cardiol* 2003;92:152–160

Jones PH et al. *Am J Cardiol* 2003; 92: 152–160

The objective was to compare the efficacy of once-daily regimens of RSV20 and RSV40 with ATV80 in reducing LDL-C levels in patients with ACS

LUNAR *Primary Endpoint*



Rosuvastatin 20 mg was similar to atorvastatin 80 mg.

Treatment with rosuvastatin 40 mg resulted in a statistically significant greater reduction in LDL-C levels compared with atorvastatin 80 mg (average of Week 6 and Week 12 data).

*p< 0.05 versus atorvastatin 80 mg

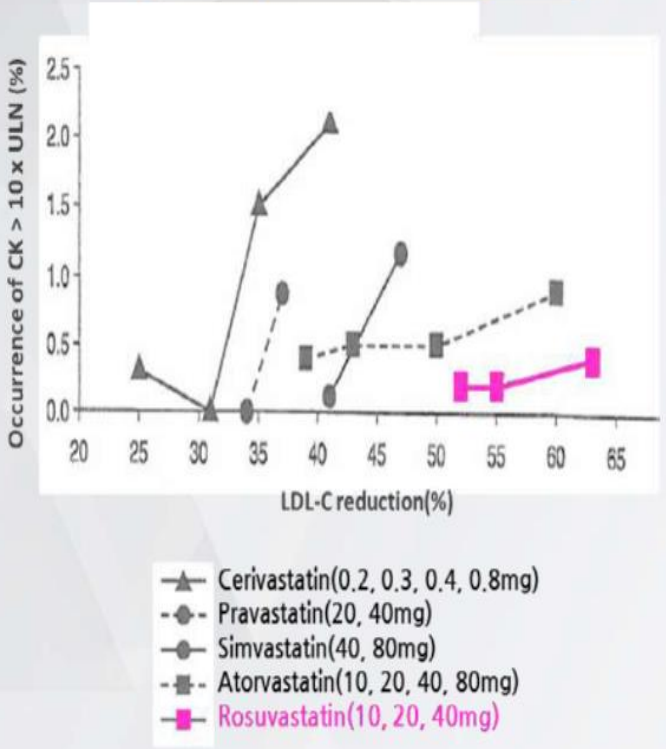
Similar results were achieved in all subcategories of ACS (unstable angina, non-STEMI, and STEMI)

Pitt B et al. *Am J Cardiol* 2012; 109 (9): 1239-46

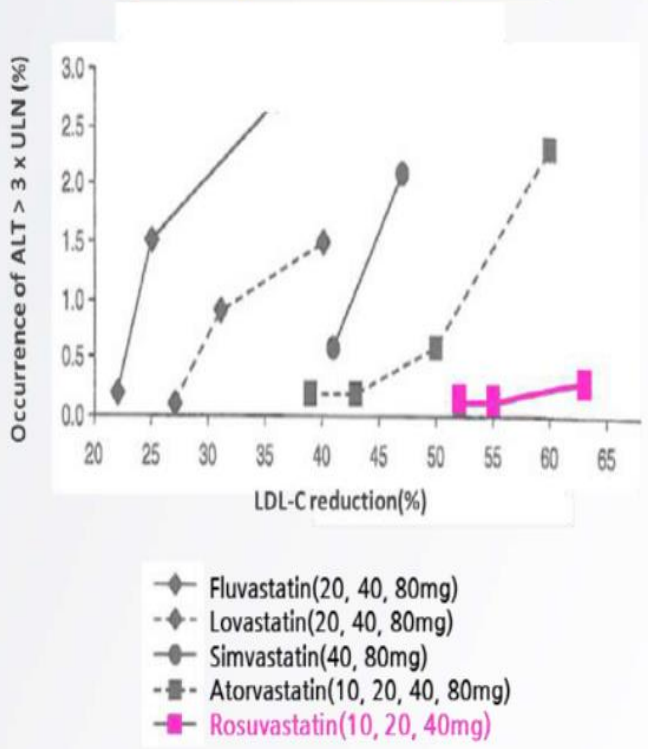
Concern about High Dose Statin

Highest doses statin was associated with increased muscle injury and LFT abnormalities.

Myopathy/Muscle injury (CK > 10X ULN)



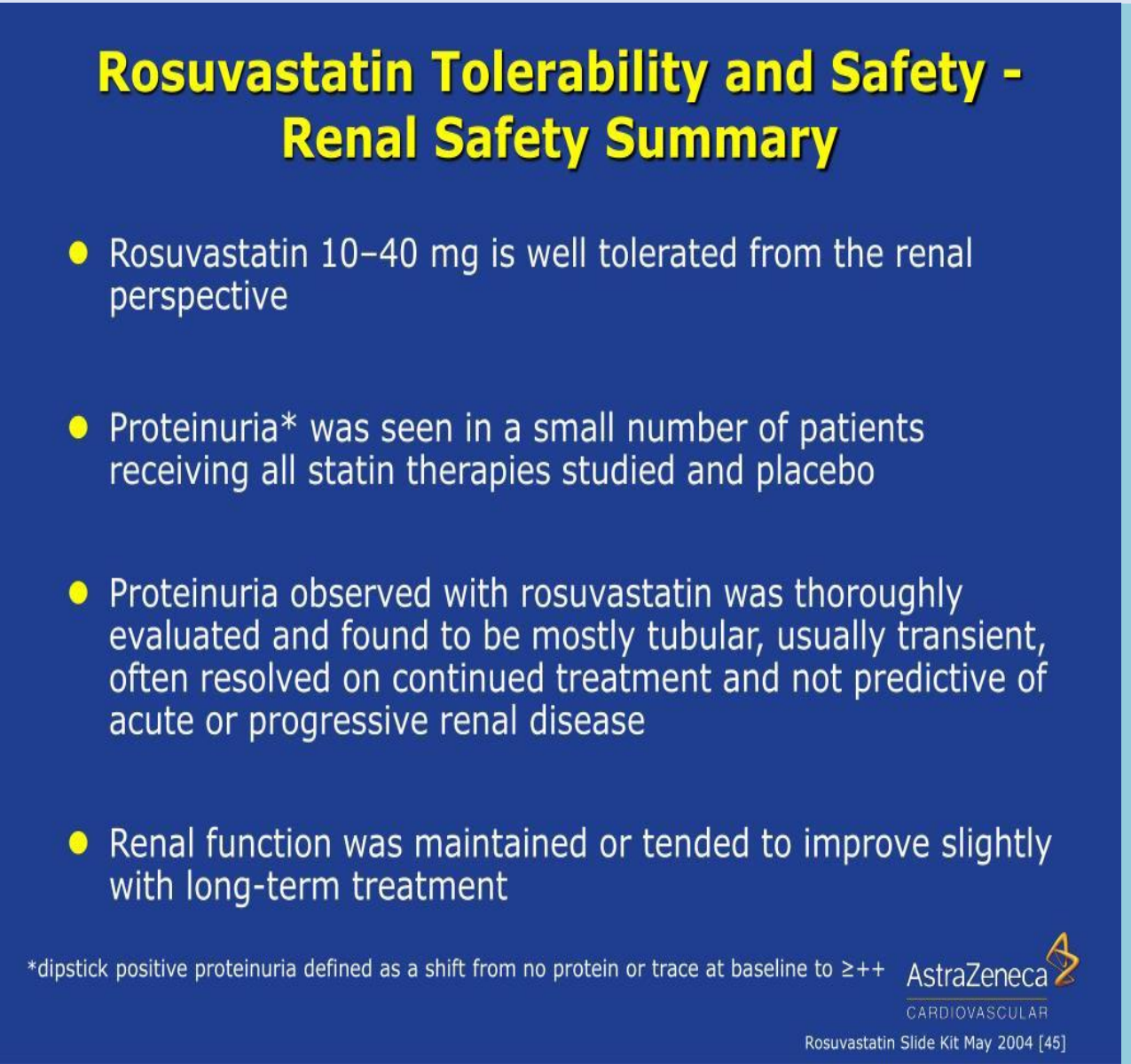
LFT abnormalities (ALT >3X ULN)



Ref.> Brewer HB Jr. *Am J Cardiol*. 2003;92(4B):23K-29K.

- **Effect of rosuvastatin on CK elevations and on the liver is certainly no worse than other statins up to 40 mg, and is combined with better effects on LDL-C reduction**

Rosuvastatin safety - Reanl



- Proteinuria observed with Rosuvastatin was Tubular in origin– Reduced reabsorption of normally filtered proteins
- Consequence of inhibition of HMG-CoA reductase in renal tubular cell

Intervention strategies as a function of total cardiovascular risk and untreated low-density lipoprotein cholesterol levels (1)

Total CV risk (SCORE)%	Untreated LDL-C levels					
	<1.4 mmol/L (55 mg/dL)	1.4 to <1.8 mmol/L (55 to <70 mg/dL)	1.8 to <2.6 mmol/L (70 to <100 mg/dL)	2.6 to <3.0 mmol/L (100 to <116 mg/dL)	3.0 to <4.9 mmol/L (116 to <190 mg/dL)	≥4.9 mmol/L (≥190 mg/dL)
Primary Prevention						
< 1 Low-risk	Lifestyle advice	Lifestyle advice	Lifestyle advice	Lifestyle advice	Lifestyle intervention, consider adding drug if uncontrolled	Lifestyle Intervention and concomitant drug intervention
Class[a]/Level[b]	I/C	I/C	I/C	I/C	IIa/A	IIa/A
≥1 to <5, or moderate-risk	Lifestyle advice	Lifestyle advice	Lifestyle advice	Lifestyle intervention, consider adding drug if uncontrolled	Lifestyle intervention, consider adding drug if uncontrolled	Lifestyle Intervention and concomitant drug intervention
Class[a]/Level[b]	I/C	I/C	IIa/A	IIa/A	IIa/A	IIa/A

2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk (European Heart Journal 2019 -doi: 10.1093/eurheartj/ehz455)

Intervention strategies as a function of total cardiovascular risk and untreated low-density lipoprotein cholesterol levels (2)

≥5 to <10, or high-risk	Lifestyle advice	Lifestyle advice	Lifestyle intervention, consider adding drug if uncontrolled	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention
Class[a]/Level[b]	IIa/A	IIa/A	IIa/A	I/A	I/A	I/A
≥10, or at very-high risk due to a risk condition	Lifestyle advice	Lifestyle intervention, consider adding drug if uncontrolled	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention
Class[a]/Level[b]	IIa/B	IIa/A	I/A	I/A	I/A	I/A
Secondary Prevention						
Very-high-risk	Lifestyle intervention, consider adding drug if uncontrolled	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention	Lifestyle Intervention and concomitant drug intervention
Class[a]/Level[b]	IIa/A	I/A	I/A	I/A	I/A	I/A

www.escardio.org/guidelines

2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk (European Heart Journal 2019 -doi: 10.1093/eurheartj/ehz455)

Central Illustration Upper panel Treatment goals for low-density lipoprotein cholesterol (LDL-C) across categories of total cardiovascular disease risk

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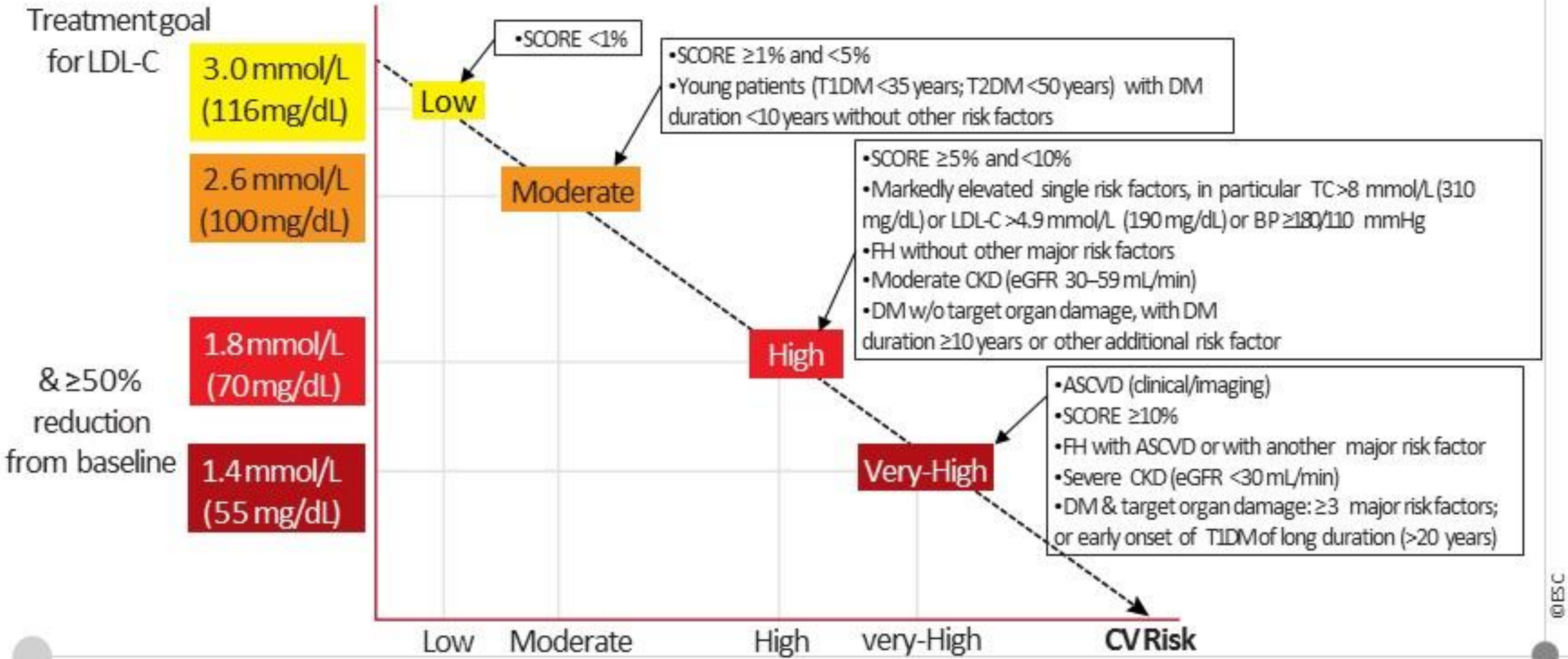

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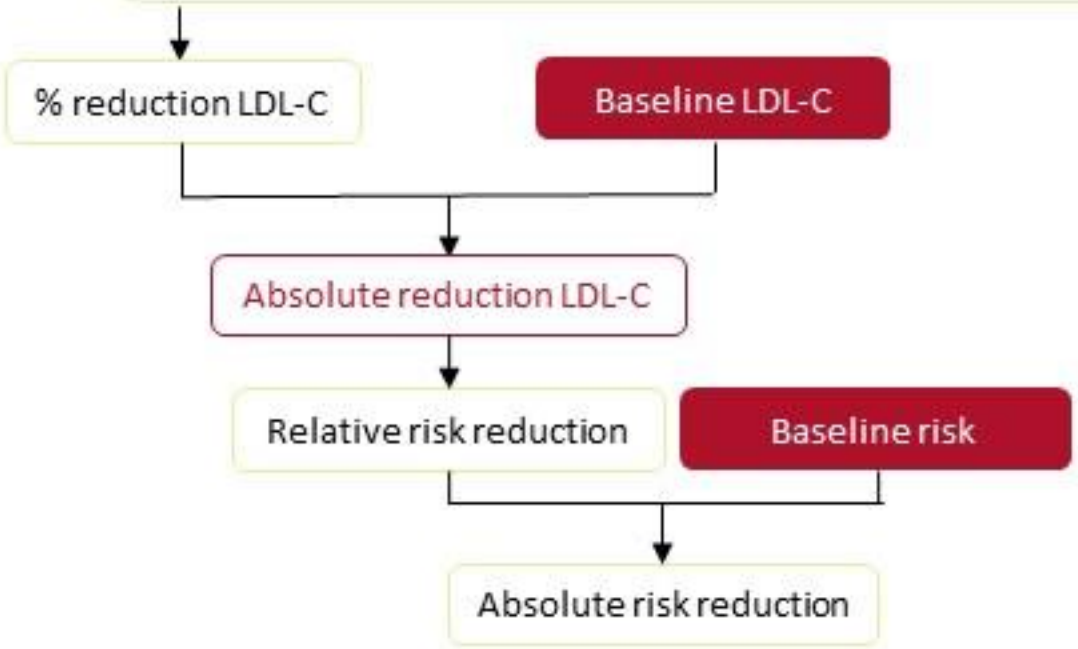
Expected clinical benefit of low-density lipoprotein cholesterol lowering therapies

Intensity of lipid lowering treatment

Treatment	Average LDL-C reduction
Moderate intensity statin	≈ 30%
High intensity statin	≈ 50%
High intensity statin plus ezetimibe	≈ 65%
PCSK9 inhibitor	≈ 60%
PCSK9 inhibitor plus high intensity statin	≈ 75%
PCSK9 inhibitor plus high intensity statin plus ezetimibe	≈ 85%



LDL-C = low-density lipoprotein cholesterol;
PCSK9 = proprotein convertase subtilisin/kexin type 9.

2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk (European Heart Journal 2019 -doi: 10.1093/eurheartj/ehz455)

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Treatment targets and goals for cardiovascular disease prevention (1)

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Smoking	No exposure to tobacco in any form.
Diet	Healthy diet low in saturated fat with a focus on whole grain products, vegetables, fruit and fish.
Physical activity	3.5–7 hours moderately vigorous physical activity per week or 30–60 min most days.
Body weight	BMI 20–25 kg/m^2, waist circumference <94 cm (men) and <80 cm (women).
Blood pressure	<140/90 mmHg[a]

[a] Lower treatment targets are recommended for most treated hypertensive patients, provided that the treatment is well tolerated.

2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk (European Heart Journal 2019 -doi: 10.1093/eurheartj/ehz455)

Treatment targets and goals for cardiovascular disease prevention (2)

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LDL-C	**Very-high-risk in primary or secondary prevention** A therapeutic regimen that achieves at least a 50% LDL-C reduction from baseline[b] and an LDL-C goal of <1.4 mmol/L (<55 mg/dL). No current statin use: this is likely to require high-intensity LDL-lowering therapy. Current LDL-lowering treatment: an increased treatment intensity is required. **High risk:** A therapeutic regimen that achieves at least a 50% LDL-C reduction from baseline[b] and an LDL-C goal of <1.8 mmol/L (<70 mg/dL).

[b]The term 'baseline' refers to the LDL-C level in a person not taking any lipid lowering medication, or to the extrapolated baseline value for those who are on current treatment.

Treatment targets and goals for cardiovascular disease prevention (3)

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LDL-C	**Moderate risk:** A goal of <2.6 mmol/L (<100 mg/dL). **Low risk:** A goal of <3.0 mmol/L (<116 mg/dL)
Non-HDL-C	Non-HDL-C secondary goals are <2.2, 2.6 and 3.4 mmol/L (<85, 100 and 130 mg/dL) for very-high-, high- and moderate-risk people, respectively.
Apolipoprotein B	ApoB secondary goals are <65, 80 and 100 mg/dL for very-high-, high- and moderate-risk people, respectively.
Triglycerides	No goal but <1.7 mmol/L (<150 mg/dL) indicates lower risk and higher levels indicate a need to look for other risk factors.
Diabetes	HbA1c: <7% (<53 mmol/mol).

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2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk (European Heart Journal 2019 -doi: 10.1093/eurheartj/ehz455)

Corresponding non–high-density lipoprotein cholesterol and apolipoprotein B levels for commonly used low-density lipoprotein cholesterol goals

LDL-C	Non-HDL-C	Apolipoprotein B
2.6 mmol/L (100 mg/dL)	3.4 mmol/L (131 mg/dL)	100 mg/dL
1.8 mmol/L (70 mg/dL)	2.6 mmol/L (100 mg/dL)	80 mg/dL
1.4 mmol/L (55 mg/dL)	2.2 mmol/L (85 mg/dL)	65 mg/dL

Central Illustration Lower panel: Treatment algorithm for pharmacological LDL-C lowering (1)

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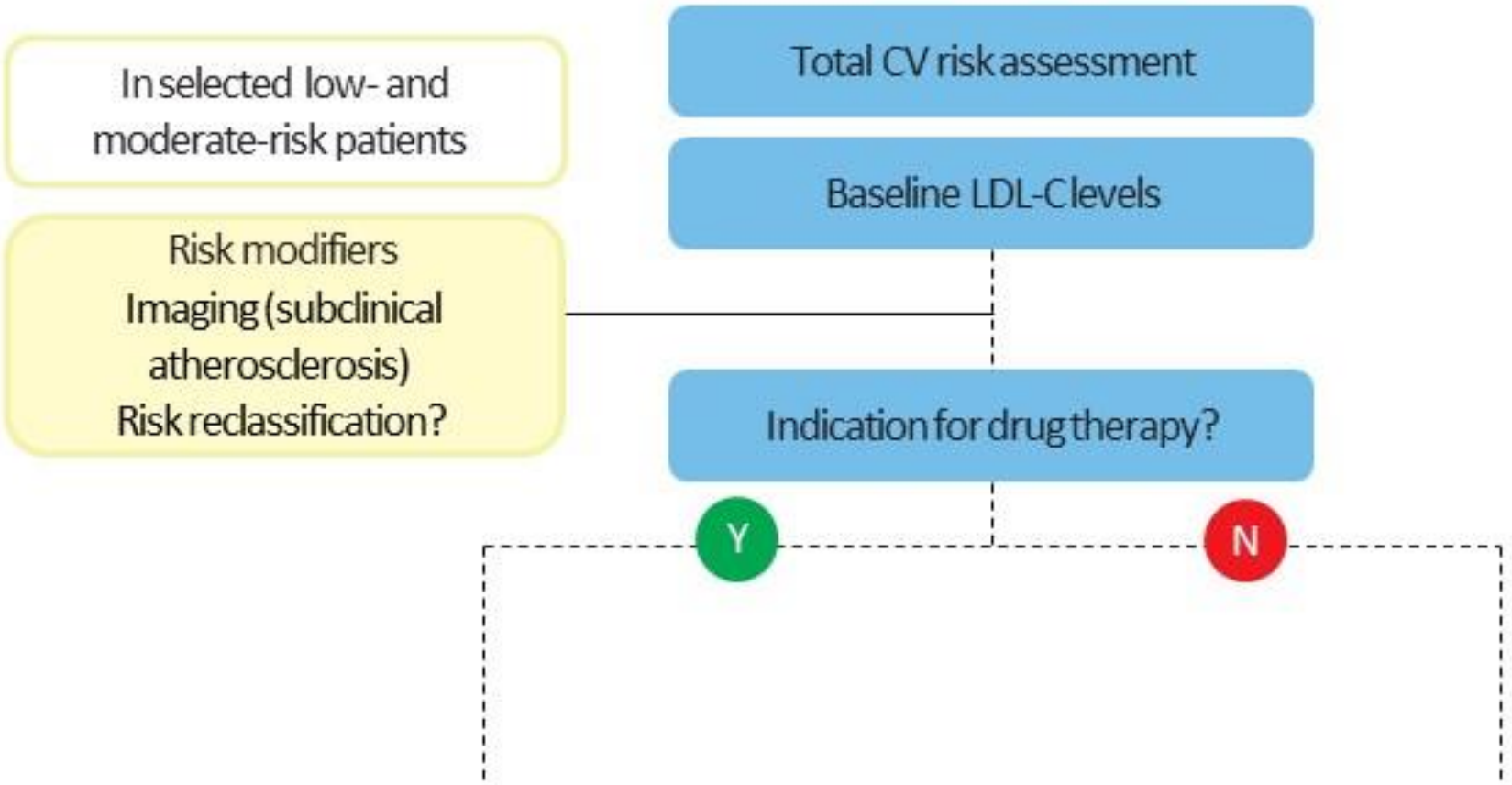
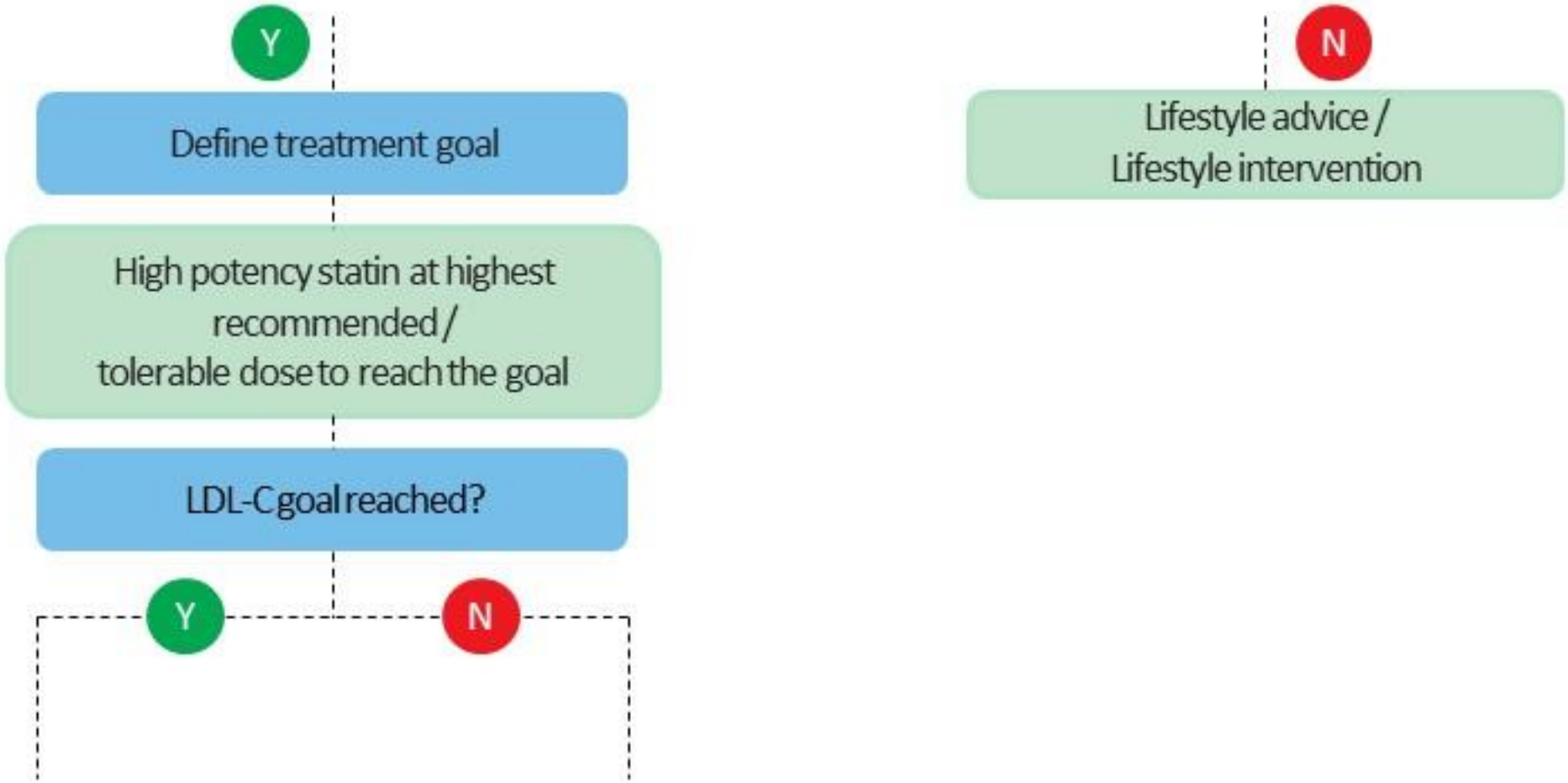


2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk (European Heart Journal 2019 -doi: 10.1093/eurheartj/ehz455)

Central Illustration Lower panel: Treatment algorithm for pharmacological LDL-C lowering (2)



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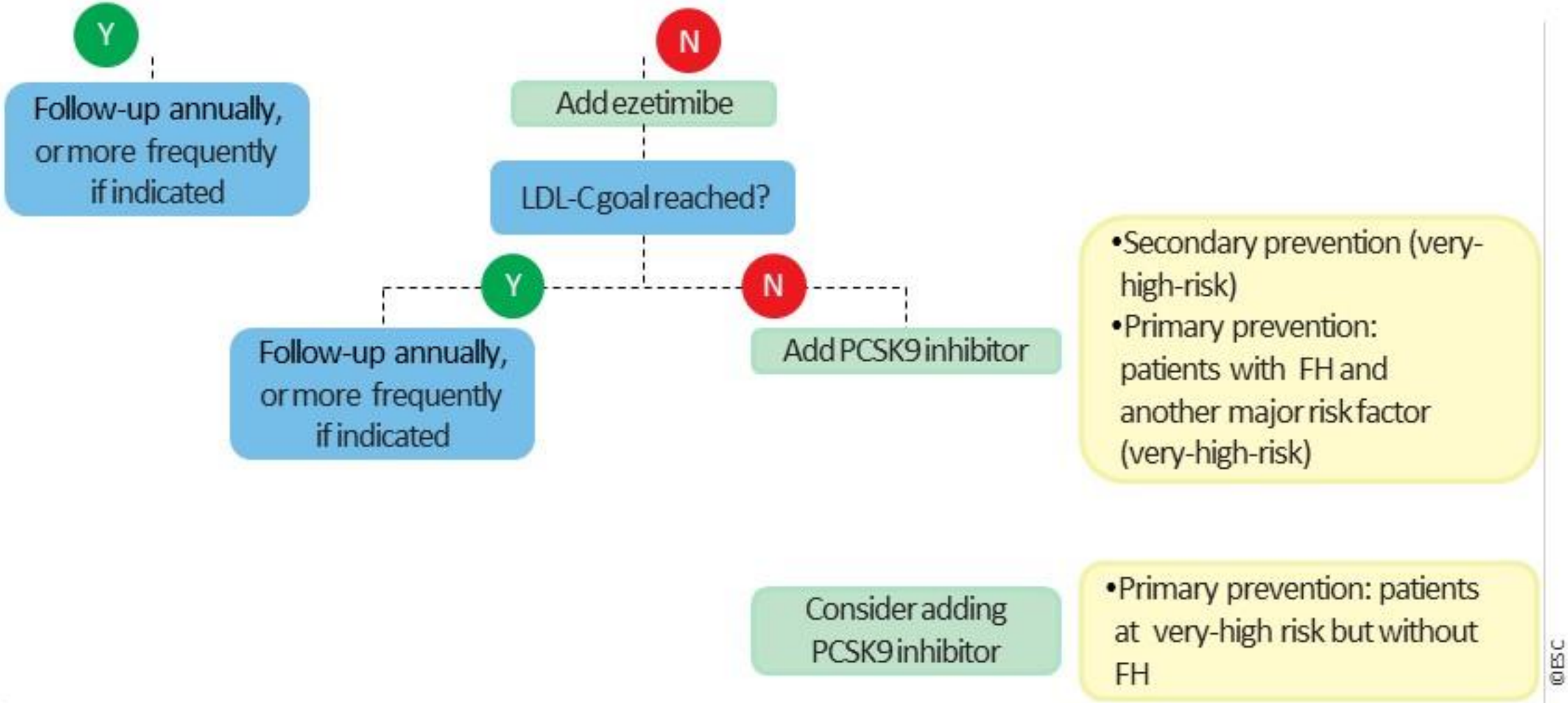
Central Illustration Lower panel: Treatment algorithm for pharmacological LDL-C lowering (3)



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Achievable reductions of low-density lipoprotein cholesterol as a function of the therapeutic approach (1)

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Starting LDL-C, mmol/L (mg/dL)	Achievable LDL-C levels with different therapeutic strategies				
	Moderate-intensity statins		High-intensity statins		PCSK9 inhibitor plus high- intensity statin
		Plus ezetimibe		Plus ezetimibe	
4.5 (175)	3.2 (123)	2.5 (96)	2.3 (88)	1.6 (61)	0.9 (35)
4.3 (165)	3.0 (116)	2.4 (91)	2.2 (83)	1.5 (58)	0.9 (33)

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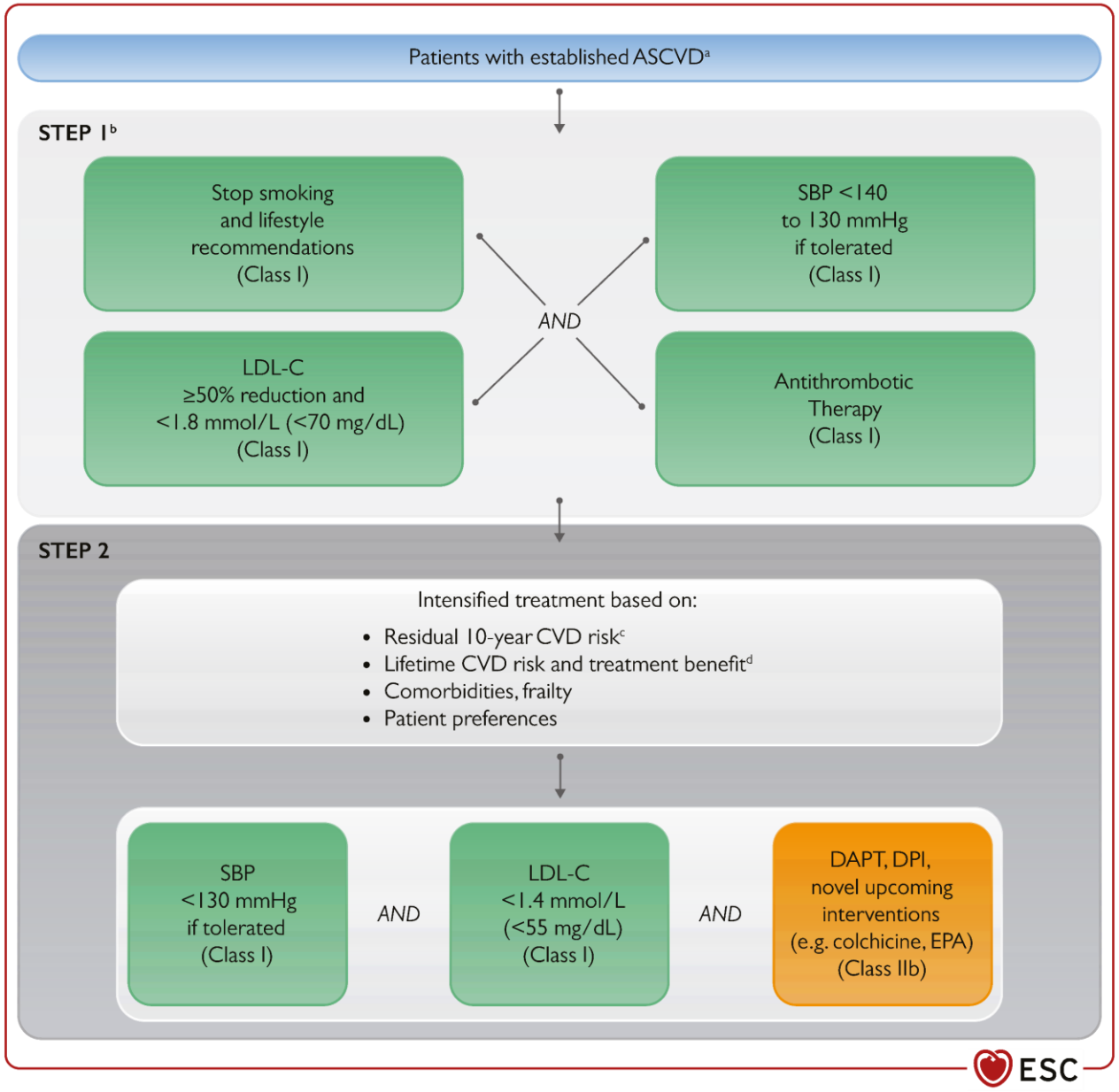
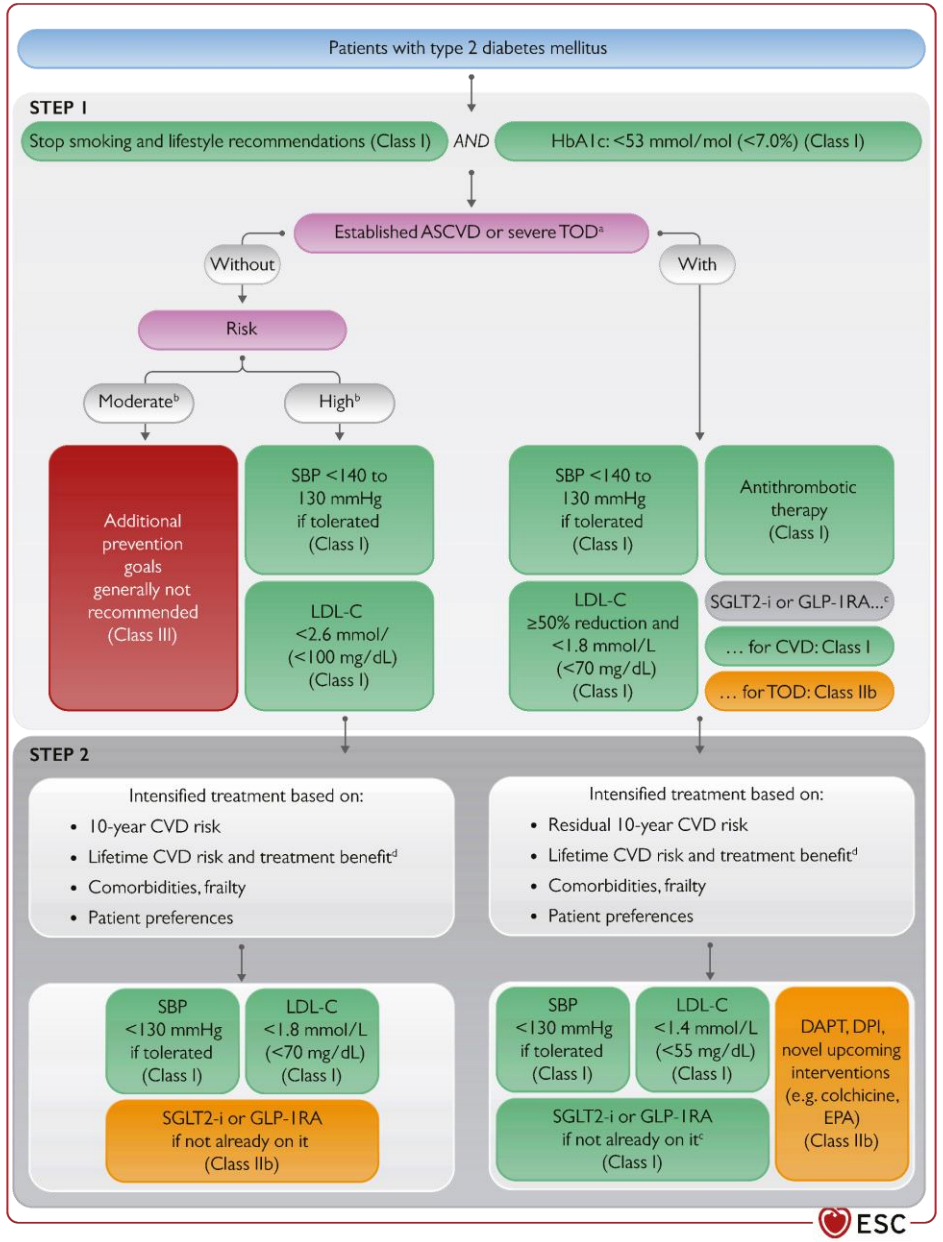


Cardiovascular risk and risk factor treatment in patients with established cardiovascular disease

2021 ESC Guidelines on cardiovascular disease prevention in clinical practice (European Heart Journal 2021 – doi:10.1093/eurheartj/ehab484)



Cardiovascular risk and risk factor treatment in patients with type 2 diabetes mellitus

2021 ESC Guidelines on cardiovascular disease prevention in clinical practice (European Heart Journal 2021 – doi:10.1093/eurheartj/ehab484)

Treatment goals for different patient categories

Patient category	Prevention goals (STEP 1)	Intensified/additional prevention goals[a] (STEP 2)
People with type 2 DM		
Well-controlled short-standing DM e.g. <10 years), no evidence of TOD and no additional ASCVD risk factors	Stop smoking and lifestyle optimization	
Without established ASCVD or severe TOD (see *Table 4* for definitions)	Stop smoking and lifestyle optimization SBP <140 down to 130 mmHg if tolerated[b] LDL-C <2.6 mmol/L (100 mg/dL) HbA1c <53 mmol/mol (7.0%)	SBP <130 mmHg if tolerated[b] LDL-C <1.8 mmol/L (70 mg/dL) and ≥50% reduction SGLT2 inhibitor or GLP-1RA
With established ASCVD and/or severe TOD (see *Table 4* for definitions)	Stop smoking and lifestyle optimization SBP <140 down to 130 mmHg if tolerated[b] LDL-C <1.8 mmol/L (70 mg/dL) HbA1c <64 mmol/mol (8.0%) SGLT2 inhibitor or GLP-1RA CVD: antiplatelet therapy	SBP <130 mmHg if tolerated[b] LDL-C <1.4 mmol/L (55 mg/dL) and ≥50% reduction SGLT2 inhibitor or GLP-1RA if not already on *May additionally consider novel upcoming treatments: DAPT, dual pathway inhibition, colchicine, icosapent ethyl, etc.*
Patients with established ASCVD	Stop smoking and lifestyle optimization SBP <140 down to 130 mmHg if tolerated[b] Intensive oral lipid-lowering therapy aiming at LDL-C <1.8 mmol/L (70 mg/dL) and ≥50% reduction Antiplatelet therapy	SBP <130 mmHg if tolerated[b] LDL-C <1.4 mmol/L and ≥50% reduction (55 mg/dL) *May additionally consider novel upcoming treatments: DAPT, dual pathway inhibition, colchicine, icosapent ethyl, etc.*

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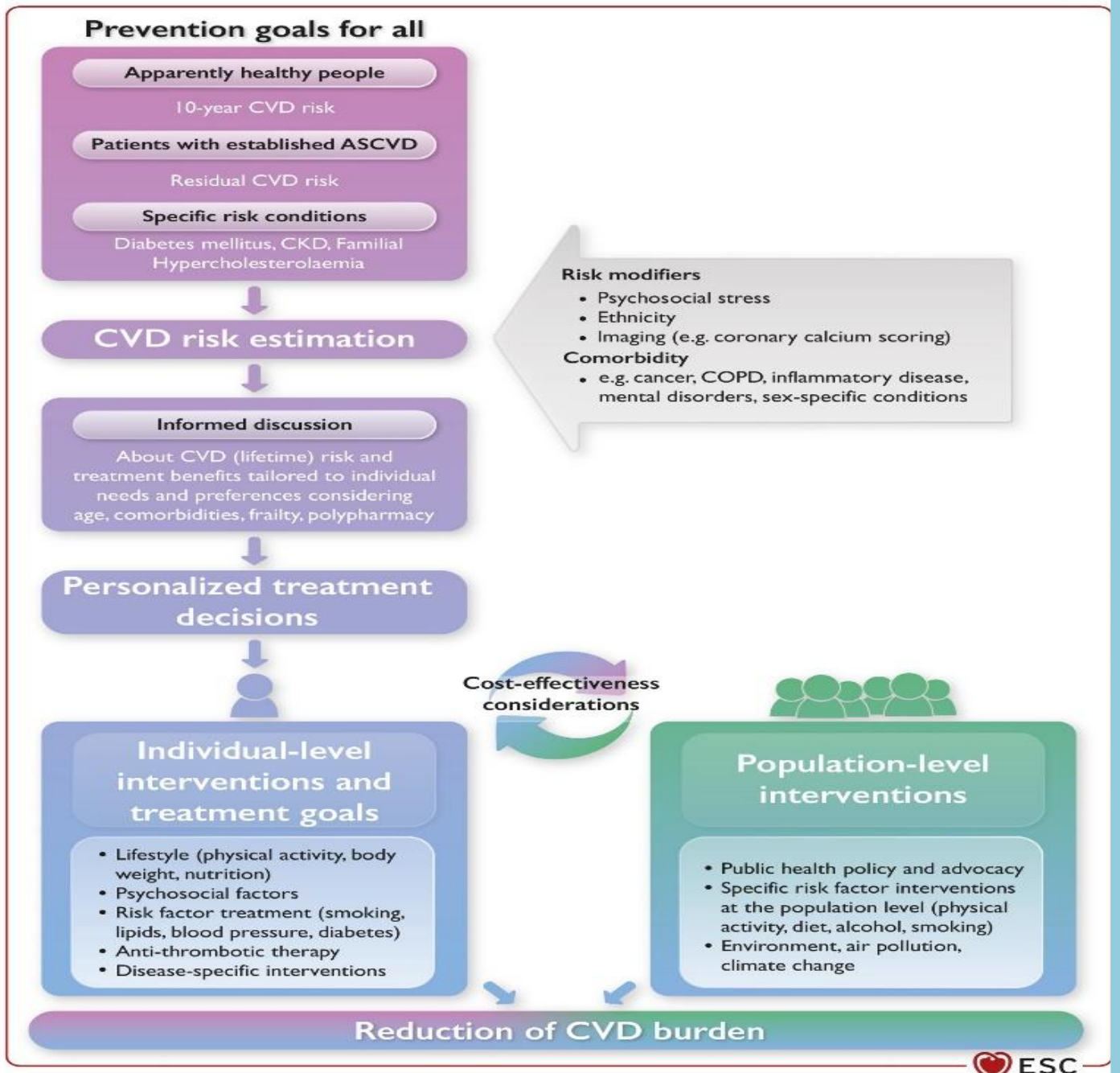
Prevention of CVD



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Take Home Message

- Emphasize Heart-Healthy Lifestyle
- Lower is better LDL-C with no lower threshold
- No known adverse effects of very low LDL-C <40mg/dl
- Treatment of Highest-risk patients achieves Largest LDL-C reduction
- Intensification of treatment Goals with High-Intensity Super Statin Therapy

THANK YOU