



Bologna, 10-11 febbraio 2017



ITALIAN CHAPTER



# TERAPIA IPOLIPEMIZZANTE

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SSD Diabetologia e Endocrinologia

Ospedale di Biella



Bologna, 10-11 febbraio 2017

# Conflitti di interesse



ITALIAN CHAPTER



Ai sensi dell'art. 3.3 sul conflitto di interessi, pag 17 del Regolamento Applicativo Stato-Regioni del 5/11/2009, dichiaro che negli ultimi 2 anni non ho avuto rapporti diretti di finanziamento con soggetti portatori di interessi commerciali in campo sanitario



Bologna, 10-11 febbraio 2017

# TERAPIA IPOLIPEMIZZANTE



ITALIAN CHAPTER



- Quali target
- Quali terapie
- Situazioni particolari



Bologna, 10-11 febbraio 2017

# TERAPIA IPOLIPEMIZZANTE



ITALIAN CHAPTER

- Quali target
- Quali terapie
- Situazioni particolari



# DAL 2011 (PRECEDENTI LINEE GUIDA ESC EAS) al 2017



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ITALIAN CHAPTER

## NUOVE EVIDENZE

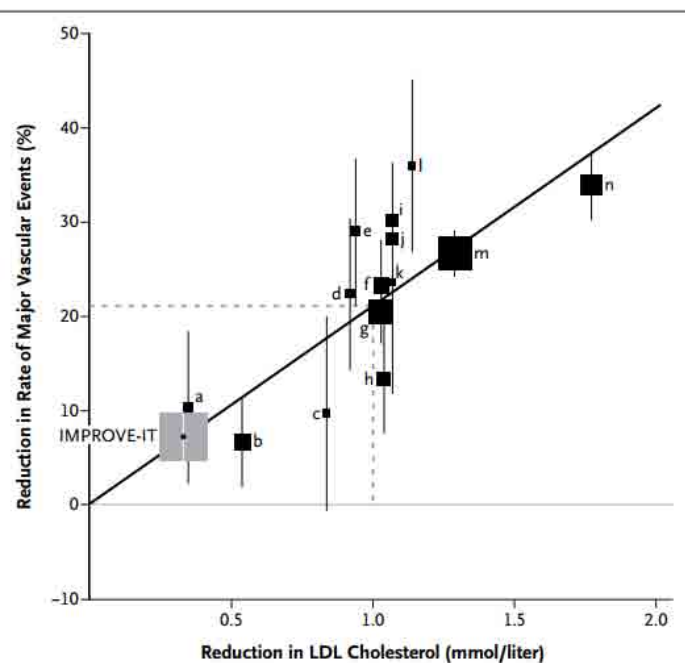


Figure 2. Plot of the IMPROVE-IT Trial Data and Statin Trials for Change in Low-Density Lipoprotein (LDL) Cholesterol versus Clinical Benefit.

## NUOVI FARMACI



## UN SERENO CONFRONTO



The NEW ENGLAND  
JOURNAL of MEDICINE

ESTABLISHED IN 1812      JUNE 18, 2015      VOL. 372 NO. 25

Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes



Bologna, 10-11 febbraio 2017

# CI SONO NOVITA'?



## Qualcuna.....

Volume 17 - Suppl. 1 al n. 6  
Giugno 2016  
www.giornalediardiologia.it

### GIORNALE ITALIANO DI CARDIOLOGIA

Documento di consenso intersocietario ANMCO/ISS/AMD/ANCE/ARCA/FADOI/GICR-IACPR/SICI-GISE/SIBioC/SIC/SICOA/SID/SIF/SIMEU/SIMG/SIMI/SISA

#### Colesterolo e rischio cardiovascolare: percorso diagnostico-terapeutico in Italia



### Standard italiani per la cura del diabete mellito 2016

Questo testo è disponibile, in forma elettronica e interattiva, presso il website di riferimento: [www.standarditaliani.it](http://www.standarditaliani.it), raggiungibile anche dai website di AMD e SID

Data di rilascio: 20 giugno 2016

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### Position paper ANMCO: Gestione clinica dell'ipercolesterolemia dopo sindrome coronarica acuta

Furio Colivicchi<sup>1</sup> (Coordinatore), Michele Massimo Gulizia<sup>2</sup> (Coordinatore), Marcello Arca<sup>3</sup>, Maurizio Giuseppe Abrignani<sup>4</sup>, Gian Piero Perna<sup>5</sup>, Gian Francesco Mureddu<sup>6</sup>, Federico Nardi<sup>7</sup>, Carmine Riccio<sup>8</sup>

AMERICAN DIABETES ASSOCIATION

## STANDARDS OF MEDICAL CARE IN DIABETES—2017



### 2016 European Guidelines on cardiovascular disease prevention in clinical practice

The Sixth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of 10 societies and invited experts)

European Heart Journal Advance Access published August 27, 2016

ESC/EAS GUIDELINES

### 2016 ESC/EAS Guidelines for the Management of Dyslipidaemias

The Task Force for the Management of Dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS)

AAACE/ACE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM—2017

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Samuel Dagogo-Jack, MD, FACE	Yehuda Handelsman, MD, FACP, FNLA, FACE	

### National Lipid Association Annual Summary of Clinical Lipidology 2016

Harold E. Bays, MD, FNLA\*, Peter H. Jones, MD, FNLA, Carl E. Orringer, MD, FNLA, W. Virgil Brown, MD, FNLA, Terry A. Jacobson, MD, FNLA

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### EXPERT CONSENSUS DECISION PATHWAY

### 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statins Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk

A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents Endorsed by the National Lipid Association

### Clinical Review & Education

JAMA | US Preventive Services Task Force | RECOMMENDATION STATEMENT

### Statin Use for the Primary Prevention of Cardiovascular Disease in Adults

US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force

JAMA. 2016;316(19):1997-2007. doi:10.1001/jama.2016.15450

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### AAACE 2017 Guidelines

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF DYSLIPIDEMIA AND PREVENTION OF ATHEROSCLEROSIS

EXECUTIVE SUMMARY



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# CONSENSO INTERSOCIETARIO RISCHIO CARDIOVASCOLARE



ITALIAN CHAPTER



Volume 17 – Suppl. 1 al n. 6  
Giugno 2016  
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## GIORNALE ITALIANO DI CARDIOLOGIA

Documento di consenso intersocietario  
ANMCO/ISS/AMD/ANCE/ARCA/FADOI/  
GICR-IACPR/SICI-GISE/SIBioC/SIC/SICOA/  
SID/SIF/SIMEU/SIMG/SIMI/SISA

**Colesterolo e rischio cardiovascolare:  
percorso diagnostico-terapeutico in Italia**

Rischio	Condizioni	Target C-LDL
Alto	<ul style="list-style-type: none"><li>• Pazienti con dislipidemie familiari o ipertensione severa, diabetici senza fattori di rischio cardiovascolare e senza danno d'organo e pazienti con insufficienza renale cronica moderata (GFR 30-59 ml/min/1.73 m<sup>2</sup>), Punteggio secondo le carte del rischio SCORE ≥5% e &lt;10%.</li></ul>	<100 mg/dl
Molto alto	<ul style="list-style-type: none"><li>• Pazienti con malattia cardiovascolare documentata (da coronarografia, ecocardiografia da stress, imaging con radionuclidi, evidenza ultrasonografica di placca carotidea), pregresso infarto miocardico, pregressa SCA, pregresso intervento di rivascularizzazione coronarica (con BPAC o PCI) o periferica, pregresso ictus ischemico e arteriopatie periferiche, diabetici con uno o più fattori di rischio cardiovascolare e/o marker di danno d'organo (es. microalbuminuria) e con insufficienza renale grave (GFR &lt;30 ml/min/1.73 m<sup>2</sup>), Punteggio secondo le carte del rischio SCORE &gt;10%.</li></ul>	<70 mg/dl



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# STANDARD ITALIANI PER LA CURA DEL DIABETE MELLITO 2016



ITALIAN CHAPTER



**Tabella 21. Obiettivi terapeutici per il trattamento della dislipidemia in pazienti con diabete**

Parametro	Obiettivo	
Colesterolo LDL	<100 mg/dl	<70 mg/dl in pazienti con pregressi eventi CV o fattori di rischio multipli
Trigliceridi	<150 mg/dl	
Colesterolo HDL	>40 M >50 F	

M, maschi; F, femmine; CV, cardiovascolari.







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ESC/EAS2016



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ESC/EAS GUIDELINES

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JOINT ESC GUIDELINES

2016 European Guidelines on cardiovascular disease prevention in clinical practice

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## RISCHIO MOLTO ALTO

- Patologia cardiovascolare documentata
- Diabete mellito con danno d'organo

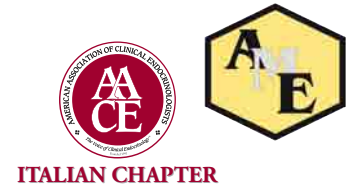
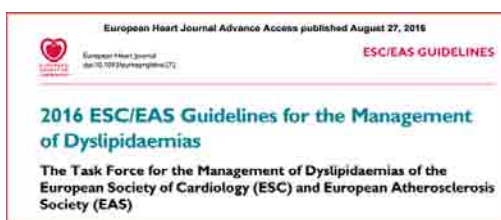
### Very high-risk

Subjects with any of the following:

- Documented CVD, clinical or unequivocal on imaging. Documented clinical CVD includes previous AMI, ACS, coronary revascularization and other arterial revascularization procedures, stroke and TIA, aortic aneurysm and PAD. Unequivocally documented CVD on imaging includes significant plaque on coronary angiography or carotid ultrasound. It does NOT include some increase in continuous imaging parameters such as intima-media thickness of the carotid artery.
- DM with target organ damage such as proteinuria or with a major risk factor such as smoking or marked hypercholesterolaemia or marked hypertension.
- Severe CKD (GFR <30 mL/min/1.73 m<sup>2</sup>).
- A calculated SCORE ≥10%.



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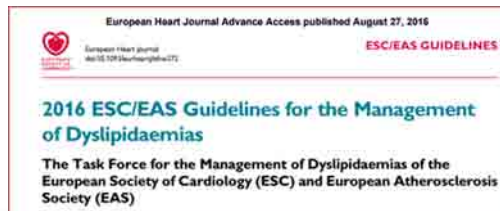
## RISCHIO MOLTO ALTO

- target C-LDL <70mg/dl
- o una riduzione di C-LDL almeno del 50% rispetto al basale se fra 70 e 135mg/dl
- Per C-HDL e trigliceridi non target ma livelli indicativi di rischio minore

Lipids LDL-C is the primary target <sup>b</sup>	<b>Very high-risk: LDL-C &lt;1.8 mmol/L (70 mg/dL)</b> or a reduction of at least 50% if the baseline <sup>b</sup> is between 1.8 and 3.5 mmol/L (70 and 135 mg/dL).
	<b>High-risk: LDL-C &lt;2.6 mmol/L (100 mg/dL)</b> or <u>a reduction of at least 50%</u> if the baseline <sup>b</sup> is between 2.6 and 5.2 mmol/L (100 and 200 mg/dL).
	<b>Low to moderate risk: LDL-C &lt;3.0 mmol/L (115 mg/dL).</b>
	Non-HDL-C secondary targets are <2.6, 3.4 and 3.8 mmol/L (100, 130 and 145 mg/dL) for very high-, high- and moderate-risk subjects, respectively.
	HDL-C: no target, but >1.0 mmol/L (40 mg/dL) in men and >1.2 mmol/L (48 mg/dL) in women indicates lower risk.
	TG: <u>no target</u> but <1.7 mmol/L (150 mg/dL) indicates lower risk and higher levels indicate a need to look for other risk factors.



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## Recommendations for the treatment of dyslipidaemia in diabetes

In all patients with type 1 diabetes and in the presence of microalbuminuria and/or renal disease, LDL-C lowering (at least 50%) with statins as the first choice is recommended irrespective of the baseline LDL-C concentration.

I

C

In patients with type 2 diabetes and CVD or CKD, and in those without CVD who are >40 years of age with one or more other CVD risk factors or markers of target organ damage, the recommended goal for LDL-C is <1.8 mmol/L (< 70 mg/dL) and the secondary goal for non-HDL-C is <2.6 mmol/L (< 100 mg/dL) and for apoB is <80 mg/dL.

I

B

## OBIETTIVI SECONDARI

- C-non HDL <100 mg/dl
- ApoB <80 mg/dl



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2017



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ASCVD RISK FACTOR MODIFICATIONS ALGORITHM

RISK LEVELS	HIGH	VERY HIGH	EXTREME	<b>RISK LEVELS:</b>  <b>HIGH:</b> DM but no other major risk and/or age <40  <b>VERY HIGH:</b> DM + major ASCVD risk(s) (HTN, Fam.Hx, low HDL-C, smoking, CKD3,4)*  <b>EXTREME:</b> DM plus established clinical CVD
	DESIRABLE LEVELS	DESIRABLE LEVELS	DESIRABLE LEVELS	



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# AAACE 2017



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## ASCVD RISK FACTOR MODIFICATIONS ALGORITHM

RISK LEVELS	HIGH	VERY HIGH	EXTREME
	DESIRABLE LEVELS	DESIRABLE LEVELS	DESIRABLE LEVELS
LDL-C (mg/dL)	<100	<70	<55
Non-HDL-C (mg/dL)	<130	<100	<80
TG (mg/dL)	<150	<150	<150
Apo B (mg/dL)	<90	<80	<70

**RISK LEVELS:**

- HIGH:** DM but no other major risk and/or age <40
- VERY HIGH:** DM + major ASCVD risk(s) (HTN, Fam.Hx, low HDL-C, smoking, CKD3,4)\*
- EXTREME:** DM plus established clinical CVD



<b>Table 11</b>	
<b>Lipid Goals for Patients at Risk for Atherosclerotic Cardiovascular Disease</b>	
<b>Lipid Parameter</b>	<b>Goal (mg/dL)</b>
TC	<200
LDL-C	<130 (low risk) <100 (moderate risk) <100 (high risk) <70 (very high risk) <55 (extreme risk)
Non-HDL-C	30 above LDL-C goal; 25 above LDL-C goal (extreme risk patients)
TG	<150
Apo B	<90 (patients at high risk of ASCVD, including those with diabetes) <80 (patients at very high risk with established ASCVD or diabetes plus $\geq 1$ additional risk factor) <70 (patients at extreme risk)
See text for references and evidence levels. Abbreviations: apo, apolipoprotein; ASCVD, atherosclerotic cardiovascular disease; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; TC, total cholesterol; TG, triglycerides.	

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**EXECUTIVE SUMMARY**



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# TERAPIA IPOLIPEMIZZANTE



ITALIAN CHAPTER

- Quali target
- Quali terapie
- Situazioni particolari

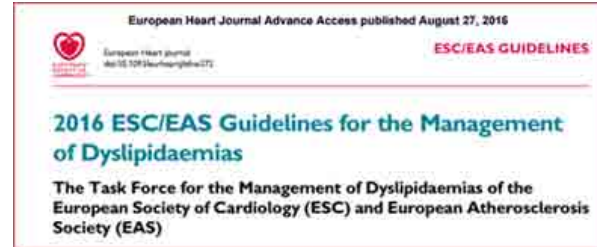


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# QUALI TERAPIE (considerando solo quanto disponibile in fascia A e nota 13)



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## OBIETTIVI DELLA TERAPIA

- C-LDL: evidenza di benefici clinici forte
- TRIGLICERIDI: evidenza di benefici clinici modesta
- C-HDL: manca evidenza diretta di benefici clinici con la terapia farmacologica







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# TERAPIE PER C-LDL



ITALIAN CHAPTER



European Heart Journal Advance Access published August 27, 2016



European Heart Journal  
doi:10.1093/eurheartj/ehw022

ESC/EAS GUIDELINES

## 2016 ESC/EAS Guidelines for the Management of Dyslipidaemias

The Task Force for the Management of Dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS)

## EFFICACI SU C-LDL

- **Stile di vita** (alimentazione e attività fisica)
- **Statine**: di prima scelta per efficacia clinica evidente, dimostrata da trial clinici e metanalisi: -23% di eventi coronarici maggiori per ogni riduzione di C-LDL di 40mg/dl, -20% mortalità per malattia coronarica, -10% mortalità per tutte le cause
- **Inibitori dell' assorbimento del colesterolo (EZETIMIBE)**: efficacia clinica in aggiunta alla statina dimostrata, è il farmaco da usare quando le statine risultano insufficienti o non tollerate. In monoterapia riduce C-LDL del 15-22%, in associazione a una statina determina una ulteriore diminuzione del 15-20%
- **Sequestranti degli acidi biliari (COLESTIRAMINA)**: non ci sono trial clinici pubblicati con terapia combinata (anche se si è evidenziata una riduzione di aterosclerosi valutata con coronarografia), spesso mal tollerati per effetti gastroenterici, interferiscono in modo importante con molti altri farmaci



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# STATINE



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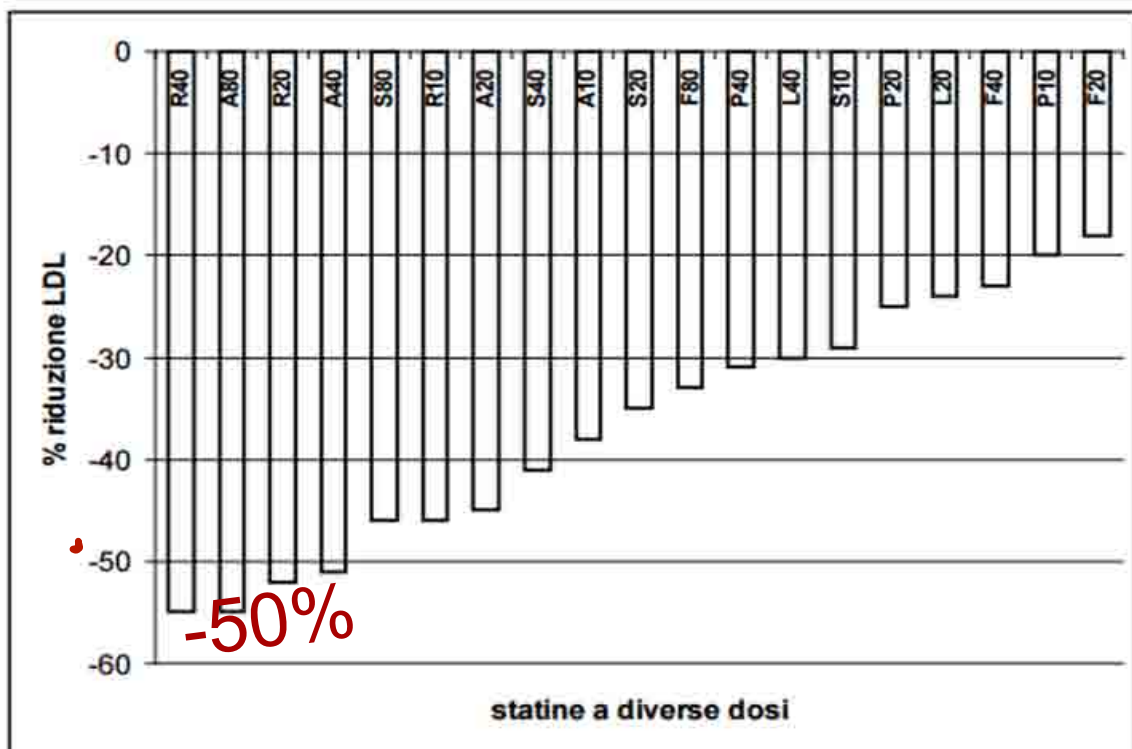


## NOTA 13

## Allegato 1

La seguente figura presenta l'entità della riduzione del colesterolo LDL ottenibile con le diverse statine ai diversi dosaggi disponibili in commercio.

**Grafico della riduzione percentuale del colesterolo LDL adattato dal documento del NHS Foundation Trust "Guidelines on statin prescribing in the prevention of cardiovascular disease" (2006).**



NB: raddoppiando la dose di una statina si ottiene una riduzione ulteriore di C-LDL pari al 4-7%, mentre gli effetti collaterali aumentano in modo rilevante con l'aumentare della dose di ciascuna statina

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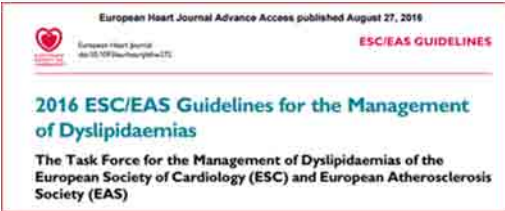
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Colesterolo e rischio cardiovascolare:  
percorso diagnostico-terapeutico in Italia

I principi attivi più efficaci sono sulla sinistra del grafico (A=atorvastatina F=fluvastatina P=pravastatina R=rosuvastatina S=simvastatina L=lovastatina. La dose è indicata dopo la lettera che indica il farmaco)



# TERAPIE PER IPERTRIGLICERIDEMIA

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- Vanno considerate le cause di ipertrigliceridemia legate a obesità, abitudini alimentari, patologie, farmaci
- E' desiderabile un livello di Tg a digiuno < 150 mg/dl
- L' evidenza di benefici clinici sul piano della prevenzione cardiovascolare con la terapia per ridurli è ancora modesta, maggiore nei pazienti con TG elevati e ridotto C-HDL
- Variare lo stile di vita (attività fisica e alimentazione) contribuisce a migliorare il profilo lipidico



# TERAPIE PER IPERTRIGLICERIDEMIA

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ITALIAN CHAPTER



**Table 18**

Recommendations for drug treatments of hypertriglyceridaemia.

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
Drug treatment should be considered in high-risk patients with TG >2.3 mmol/L (200 mg/dL).	<b>IIa</b>	<b>B</b>	261, 262
Statin treatment may be considered as the first drug of choice for reducing CVD risk in high-risk individuals with hypertriglyceridaemia.	<b>IIb</b>	<b>B</b>	263, 264
In high-risk patients with TG >2.3 mmol/L (200 mg/dL) despite statin treatment, fenofibrate may be considered in combination with statins.	<b>IIb</b>	<b>C</b>	261–264

CVD = cardiovascular disease; TG = triglycerides.

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>Reference(s) supporting recommendations.

European Heart Journal Advance Access published August 27, 2016

ESC/EAS GUIDELINES

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The Task Force for the Management of Dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS)

**Table 19**

Summary of the efficacy of drug combinations for the management of mixed dyslipidaemias.

A combination of statins with fibrates can also be considered while monitoring for myopathy, but the combination with gemfibrozil should be avoided.

If TG are not controlled by statins or fibrates, prescription of n-3 fatty acids may be considered to decrease TG further, and these combinations are safe and well tolerated.

TG = triglycerides.



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# TERAPIE PER BASSI LIVELLI DI C-HDL



ITALIAN CHAPTER



- Le variazioni dello stile di vita sono efficaci
- Non c'è chiara evidenza diretta che aumentare il C-HDL porti a prevenzione di patologia cardiovascolare

**Table 20**

Recommendations if drug treatment of low high-density lipoprotein cholesterol is considered.

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
Statins and fibrates raise HDL-C with a similar magnitude and these drugs may be considered.	<b>IIb</b>	<b>B</b>	262, 292
The efficacy of fibrates to increase HDL-C may be attenuated in people with type 2 diabetes.	<b>IIb</b>	<b>B</b>	261, 262

HDL-C = high-density lipoprotein cholesterol.

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>Reference(s) supporting recommendations.



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# TERAPIA IPOLIPEMIZZANTE



ITALIAN CHAPTER



- Quali target
- Quali terapie
- **Situazioni particolari**



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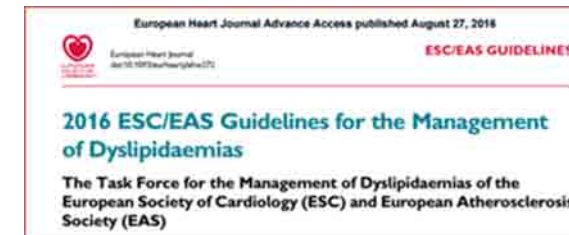
# INSUFFICIENZA RENALE



ITALIAN CHAPTER



Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
Patients with stage 3–5 CKD have to be considered at high or very high CV risk.	I	A	388–392
The use of statins or statin/ezetimibe combination is indicated in patients with non-dialysis-dependent CKD.	I	A	393, 394, 397
In patients with dialysis-dependent CKD and free of atherosclerotic CVD, statins should not be initiated.	III	A	395, 396
In patients already on statins, ezetimibe or a statin/ezetimibe combination at the time of dialysis initiation, these drugs should be continued, particularly in patients with CVD.	IIa	C	
In adult kidney transplant recipients treatment with statins may be considered.	IIb	C	



Nota 13:

- I scelta: simvastatina+ezetimibe
- II scelta: altre statine a minima escrezione renale



# SINDROME CORONARICA ACUTA E ANGIOPLASTICA CORONARICA



**Table 27**

Recommendations for lipid-lowering therapy in patients with acute coronary syndrome and patients undergoing percutaneous coronary intervention.

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
It is recommended to initiate or continue high dose statins early after admission in all ACS patients without contra-indication or history of intolerance, regardless of initial LDL-C values.	<b>I</b>	<b>A</b>	64, 358–360
If the LDL-C target is not reached with the highest tolerable statin dose, ezetimibe should be considered in combination with statins in post-ACS patients.	<b>IIa</b>	<b>B</b>	63
If the LDL-C target is not reached with the highest tolerable statin dose and/or ezetimibe, PCSK9 inhibitors may be considered on top of lipid-lowering therapy; or alone or in combination with ezetimibe in statin intolerant patients or in whom a statin is contra-indicated.	<b>IIb</b>	<b>C</b>	115, 116
Lipids should be re-evaluated 4–6 weeks after ACS to determine whether target levels of LDL-C <1.8 mmol/L (<70 mg/dL) or a reduction of at least 50% if the baseline is between 1.8 and 3.5 mmol/L (70 and 135 mg/dL) have been reached and whether there are any safety issues. The therapy dose should then be adapted accordingly.	<b>IIa</b>	<b>C</b>	
Routine short pretreatment or loading (on the background of chronic therapy) with high-dose statins before PCI should be considered in elective PCI or in NSTEMI-ACS.	<b>IIa</b>	<b>A</b>	363–365

ACS = acute coronary syndrome; LDL-C = low-density lipoprotein-cholesterol; NSTEMI-ACS = non-ST elevation acute coronary syndrome; PCI = percutaneous coronary intervention; PCSK9 = proprotein convertase subtilisin/kexin type 9.

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>Reference(s) supporting recommendations.





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# SCOMPENSO CARDIACO



ITALIAN CHAPTER



**Table 28**

Recommendations for the treatment of dyslipidaemia in heart failure or valvular disease.

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
Cholesterol-lowering therapy with statins is not recommended (but is not harmful either) in patients with heart failure in the absence of other indications for their use.	III	A	373, 374
n-3 PUFAs 1 g/day may be considered for addition to optimal treatment in patients with heart failure.	IIb	B	376
Cholesterol-lowering treatment is not recommended in patients with aortic valvular stenosis without CAD in the absence of other indications for their use.	III	A	243, 377, 378

**Nota:** nello studio GISSI Prevenzione la terapia con n-3 PUFA ha ridotto la mortalità cardiovascolare anche nel post-infarto, apparentemente per un effetto antiaritmico

CAD = coronary artery disease; PUFAs = polyunsaturated fatty acids.

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>Reference(s) supporting recommendations.



# ANZIANI



**Table 24**  
Recommendations for the treatment of dyslipidaemia in older adults.

<b>Recommendations</b>	<b>Class<sup>a</sup></b>	<b>Level<sup>b</sup></b>	<b>Ref<sup>c</sup></b>
Treatment with statins is recommended for older adults with established CVD in the same way as for younger patients.	<b>I</b>	<b>A</b>	334, 337
Since older people often have co-morbidities and have altered pharmacokinetics, lipid-lowering medication should be started at a lower dose and then titrated with caution to achieve target lipid levels that are the same as in younger subjects.	<b>IIa</b>	<b>C</b>	
Statin therapy should be considered in older adults free from CVD, particularly in the presence of hypertension, smoking, diabetes and dyslipidaemia.	<b>IIa</b>	<b>B</b>	62, 64, 65



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ITALIAN CHAPTER



**Grazie per  
l'attenzione!**