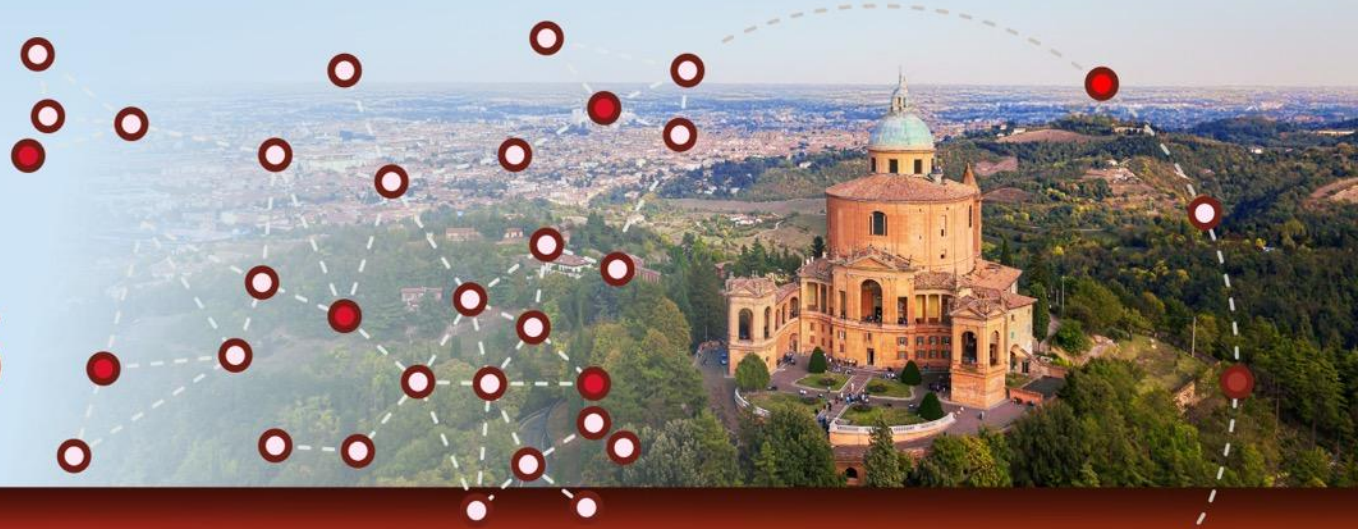
1ST INTERNATIONAL CONFERENCE ON

Ph+Leukemias



Bologna, Royal Hotel Carlton September 29-30, 2025

Treatment of CML patients with high cardiovascular risk

Giovanni Caocci

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Disclosures GIOVANNI CAOCCI

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
NOVARTIS	X				X	X	
INCYTE					X	X	
ABBVIE	X				X		
GSK					X		
SANOFI	X				X	X	
BE ONE	X				X		
ALEXION	X				X		
VERTEX						X	

ESC European Society of Cardiology

European Heart Journal (2022) **43**, 4229–4361
https://doi.org/10.1093/eurheartj/ehac244

ESC GUIDELINES

2022 ESC Guidelines on cardio-oncology developed in collaboration with the European Hematology Association (EHA), the European Society for Therapeutic Radiology and Oncology (ESTRO) and the International Cardio-Oncology Society (IC-OS)

Developed by the task force on cardio-oncology of the European Society of Cardiology (ESC)

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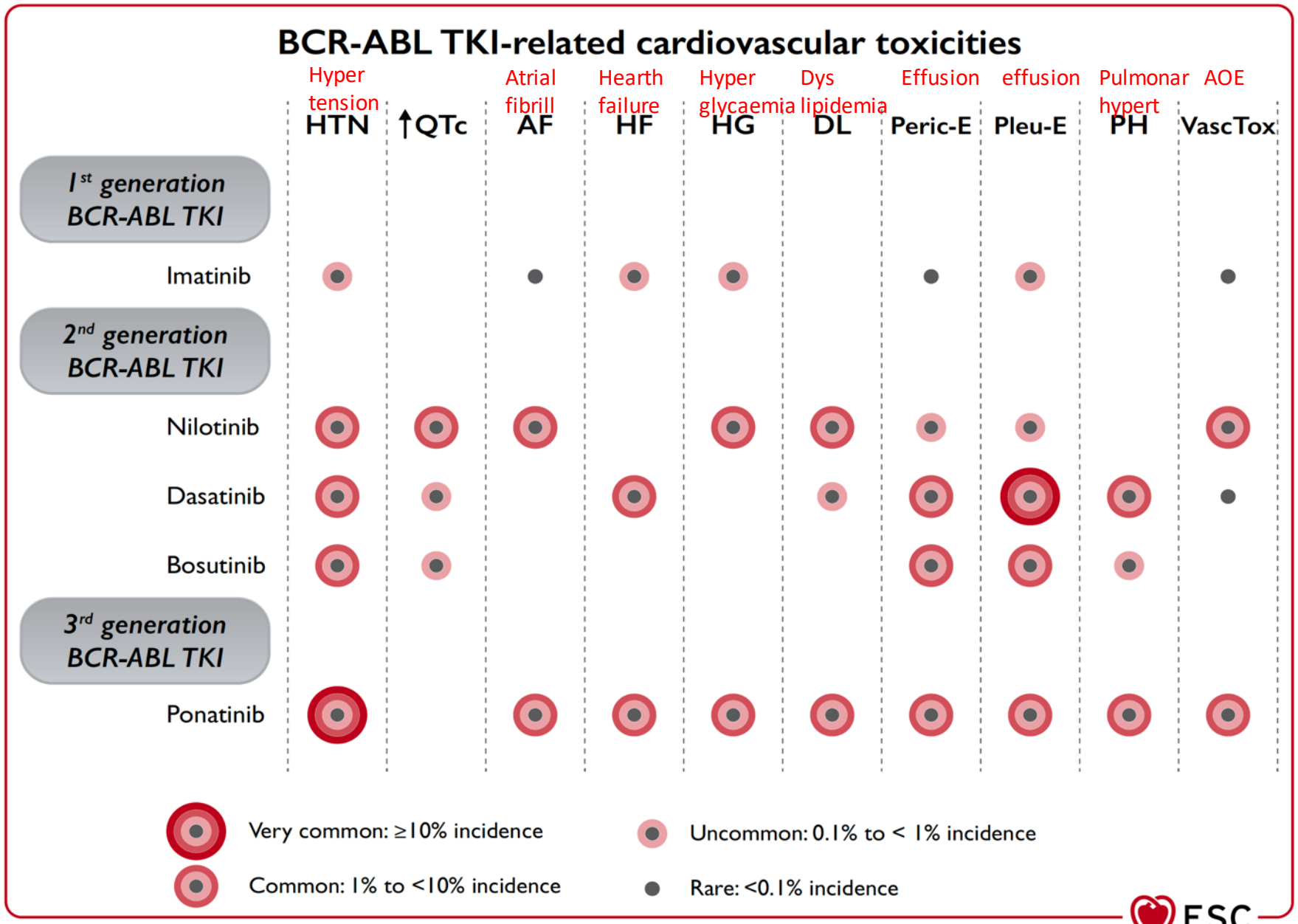

ESC

CML patients and cardiovascular risk:

1) Stress attention on CV patient history
2) Hard work on modifiable CV risk factors
3) Apply a CV risk score
4) Monitor as well as you can

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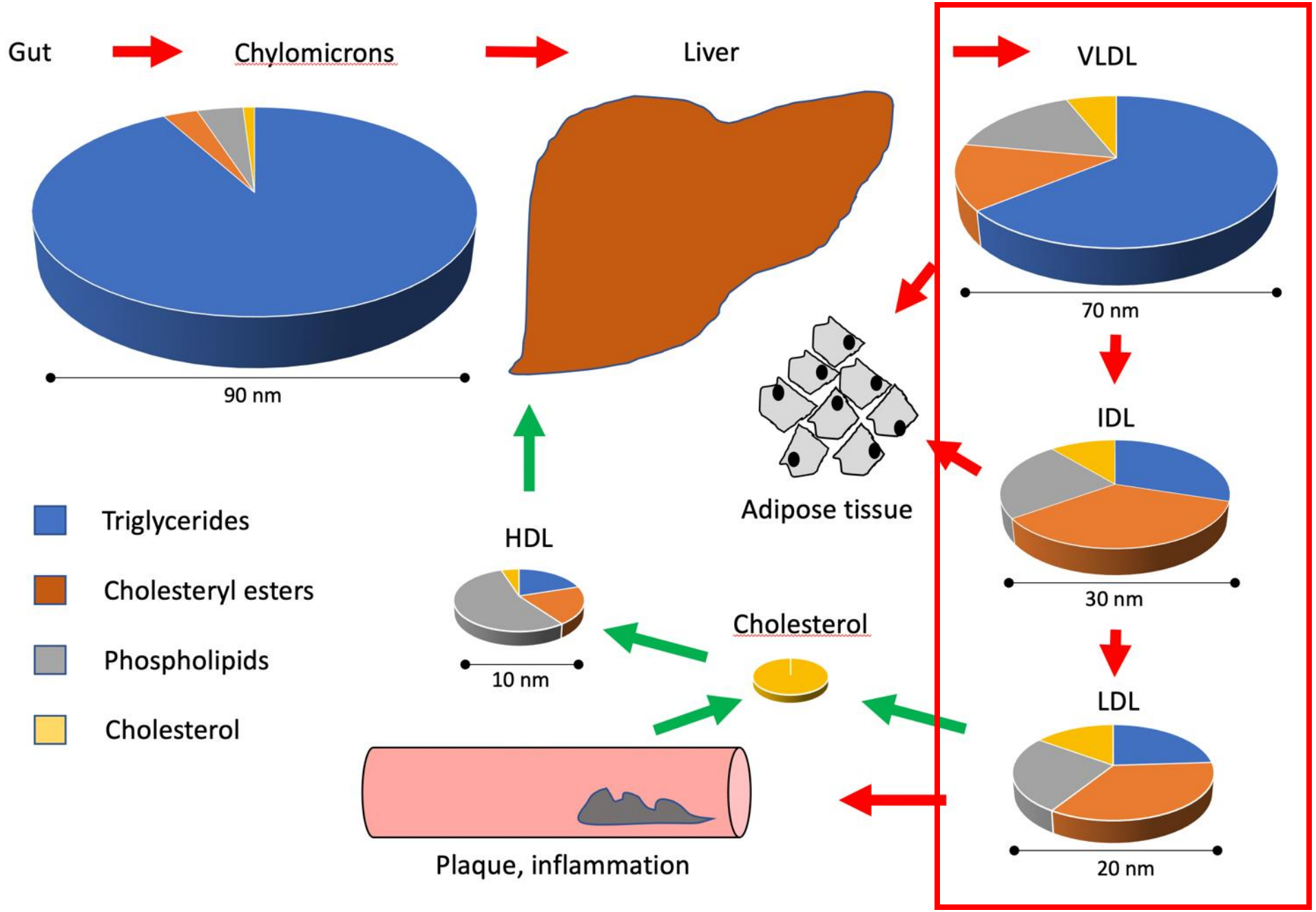
Optimal targets for the prevention of CVD

Risk Factor	evaluation	target
Hyperglicemia	HbA1c	< 7%
		7-8% pt with long lasting DM and personal history of CV events
Dyslipidemia	LDL - Cholesterol	< 100 mg/dL
	Triglycerides	< 150 mg/dL
	HDL – Cholesterol NON HDL c	> 40 mg/dL M; > 50 mg/dL F
Arterial Hypertension	SBP/DBP	< 140/90 mmHg
Smoke		Stop
Obesity	BMI	18.5 < BMI< 24.5

European Guidelines on cardiovascular disease prevention in clinical practice (version 2012)
European Heart Journal (2012) 33, 1635–170



NON HDL c

Caocci et al. Ann Hematol. 2021 Aug;100(8):2005-2014

Caocci et al. *Blood Cancer Journal* (2020)10:66
https://doi.org/10.1038/s41408-020-0333-2

Blood Cancer Journal

ARTICLE Open Access

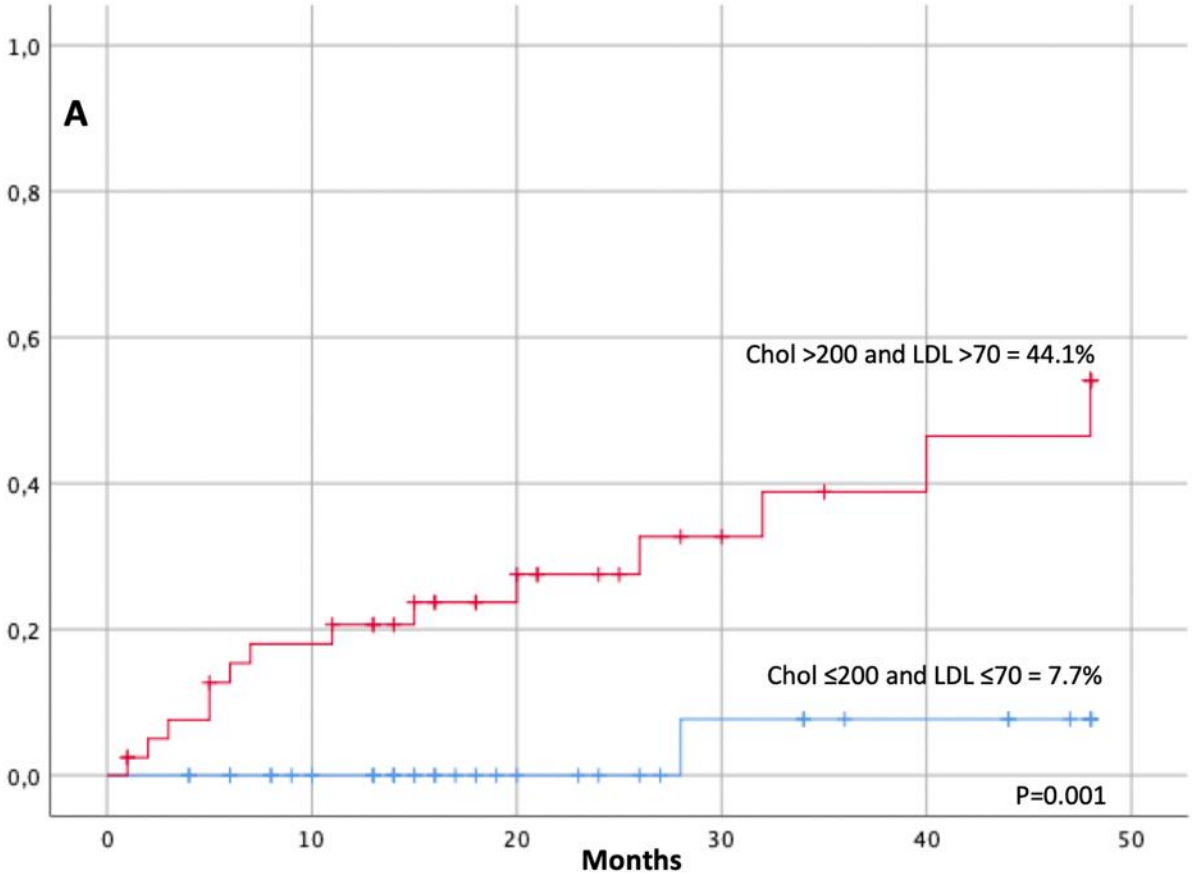
Low low-density lipoprotein (LDL), cholesterol and triglycerides plasma levels are associated with reduced risk of arterial occlusive events in chronic myeloid leukemia patients treated with ponatinib in the real-life. A *Campus CML* study

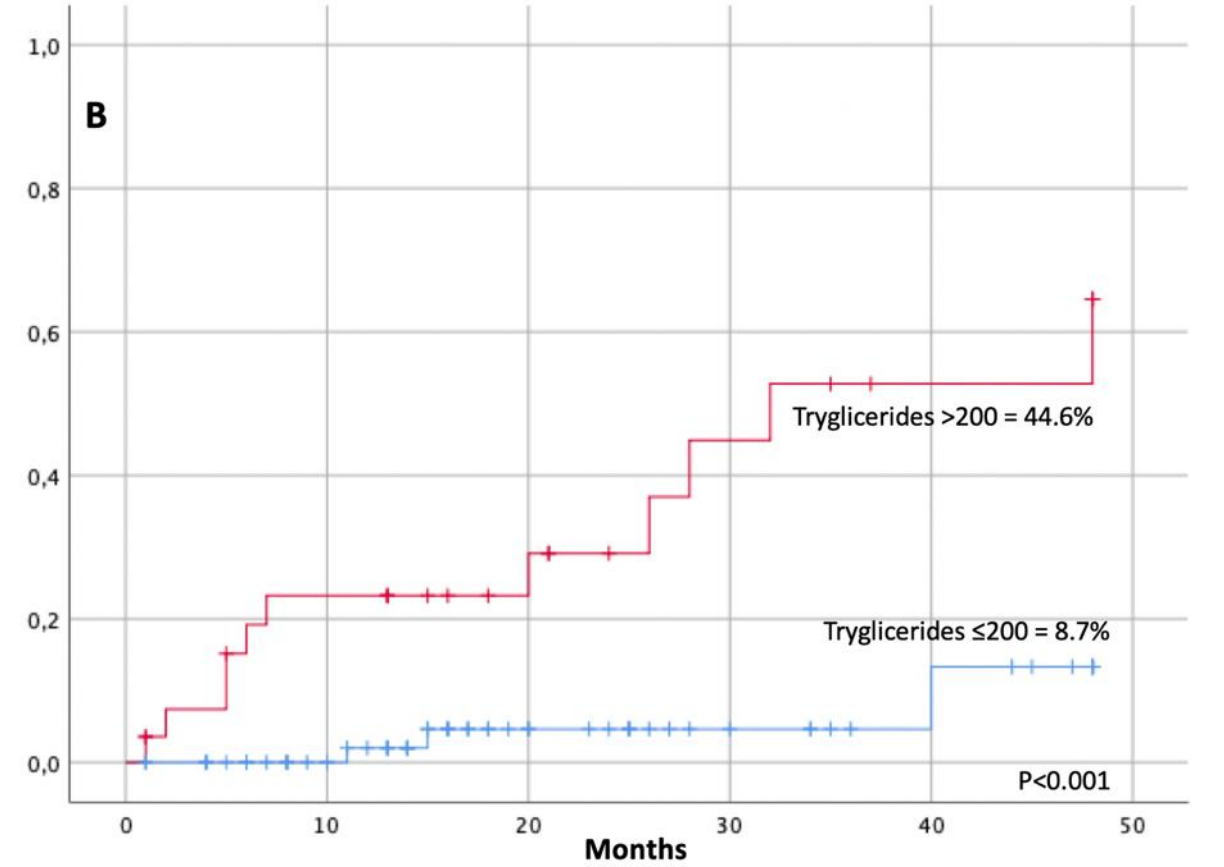
Giovanni Caocci[1], Olga Mulas[1], Isabella Capodanno[2], Elisabetta Abruzzese[3], Alessandra Iurlo[4], Luigiana Luciano[5], Francesco Albano[6], Mario Annunziata[7], Mario Tiribelli[8], Massimiliano Bonifacio[9], Sara Galimberti[10], Fausto Castagnetti[11], Nicola Sgherza[12], Fabio Stagno[13], Antonella Gozzini[14], Ester Maria Orlandi[15], Debora Luzi[16], Gianni Binotto[17], Patrizia Pregno[18], Claudio Fozza[19], Fabio Efficace[20], Maria Pina Simula[1], Malgorzata Monika Trawinska[3], Daniele Cattaneo[4], Fiorenza De Gregorio[5], Immacolata Attolico[6], Rossella Stella[8], Luigi Scaffidi[9], Claudia Baratè[10], Gabriele Gugliotta[11], Emilia Scalzulli[21], Chiara Elena[15], Francesca Pirillo[18], Robin Foà[21], Massimo Breccia[21] and Giorgio La Nasa[1]

Sex, N° (%)			CVD risk factors, N (%)		
Male	67	(58)	Hypertension	26	(22)
Female	49	(42)	Dyslipidemia	41	(35)
Age at diagnosis, mean years (range)	49	(23-81)	Obesity (BMI>24.5)	17	(15)
Median follow-up, mean years (range)	3.5	(1-5)	Severe renal insufficiency	1	(1)
Leukocyte x10^3/uL, mean value (range)	132	(7-515)	Diabetes	13	(11)
Hemoglobin g/dl, mean value (range)	12.3	(5-18)	SCORE* ≤5%	84	(72)
Platelet x10^3/uL, mean value (range)	383	(110-998)	SCORE >5%	32	(28)
Splenomegaly, N° (%)	68	(59)	CVD at baseline, N (%)		
Sokal score, N° (%)			Positive anamnesis for CVD	23	(20)
Low	28	(24)	Myocardial infarction/ angina	7	(6)
Intermediate	59	(51)	Arrhythmia	6	(5)
High	29	(25)	Other cardiac disease∞	9	(8)
Line of treatment, N° (%)			Peripheral arterial disease	1	(1)
Second line	42	(36)	Stroke	1	(1)
Third line	47	(41)	Peripheral venous disease	0	(0)
Fourth line	27	(23)	CV events following ponatinib, N (%)		
Reason of switch, N° (%)			Hypertension	15	(13)
Inefficacy	95	(82)	Myocardial infarction/angina	6	(5)
Intolerance	21	(18)	Peripheral arterial disease±	7	(6)
Ponatinib dose at baseline, N° (%)			Stroke	3	(3)
15mg	18	(16)	Primary prophylaxis	19	(16)
30mg	56	(48)	Secondary prophylaxis	6	(5)
45mg	42	(36)	Patient treated with statin/fibrate	10	(9)
Ponatinib dose at AOEs in 16 pts			Atorvastatin	6	(5)
15mg	5	(31)	Pravastatin	2	(2)
30mg	6	(38)	Lovastatin	1	(1)
45mg	5	(31)	Gemfibrozil	1	(1)

N=116

Arterial occlusive events (AOEs) in 82 CML patients according to cholesterol plasma level > 200 mg/dL and LDL >70 mg/dL after 3 months since starting ponatinib (A) and in 94 CML patients according to triglycerides plasma level > 200 mg/dL before starting ponatinib (B).





Caocci et al. Blood Cancer Journal (2020) 10:66

LDL target in dyslipidemia patients according to CV risk

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)
<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 (see *Table 4*)	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
≥5 to <10, or high-risk (see *Table 4*)	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 (see *Table 4*)	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

115

100

70

55

2019 ESC/EAS guidelines for the management of dyslipidaemias

Practical key issues in the management of dyslipidemia in CML patients starting ponatinib

- Evaluation of the cardiovascular risk, including the SCORE estimation and a complete lipid profile (cholesterol, LDL, HDL, triglycerides and, ideally, ApoB)
- In CV low-intermediate risk patients, lipid value should be maintained within normal range and specific lifestyle intervention on dietary habits and physical activity should be recommended
- In CV high-very-high risk patients, or patients with diabetes or other CV risk factors or aged ≥ 60 years or presenting plaque burden on arterial ultrasonography, LDL value should be maintained < 70 mg/dL
- In patients that do not reach the LDL target, the addition of a non-statin lipid-modifying agent such as ezetimibe to a maximally tolerated statin should be considered
- In patients with adverse events by statin, LDL lowering can be obtained using different dose schedule, such as every other day or twice weekly, with atorvastatin or rosuvastatin
- Prophylaxis with aspirin 100 mg/die should be considered in patients with CV risk factors, in particular if aged ≥ 60 years
- Dose adjustment of Ponatinib in CV high-very-high should be considered

Caocci et al. Blood Cancer Journal (2020) 10:66

CML patients and cardiovascular risk:

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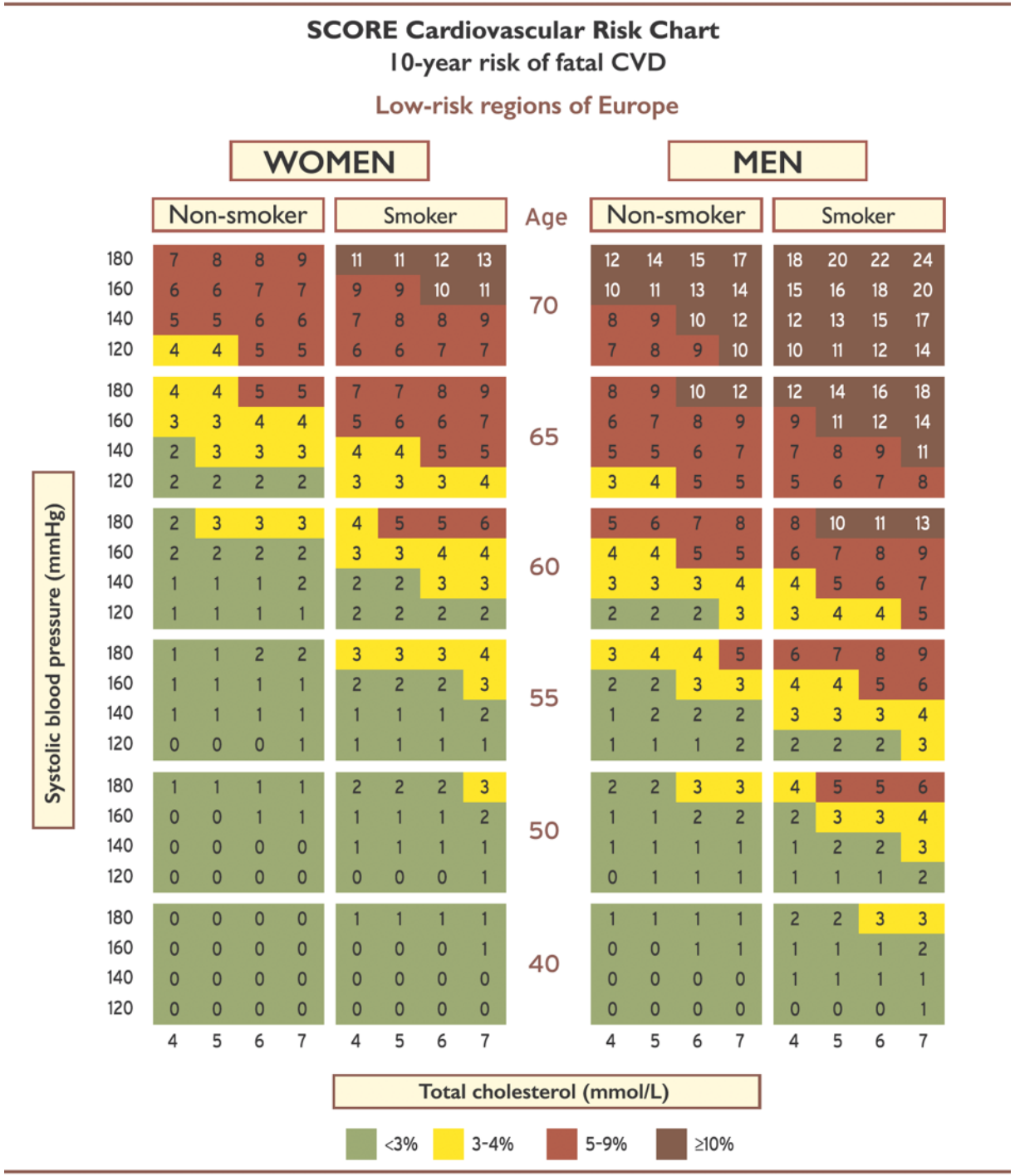


Authors/Task Force Members, ESC Committee for Practice Guidelines (CPG), ESC National Cardiac Societies. **2019 ESC/EAS guidelines for the management of dyslipidaemias**: Lipid modification to reduce cardiovascular risk. Atherosclerosis. 2019;290:140–205

Low risk

The low-risk category applies to individuals with a SCORE < 1%

Moderate risk

Subjects are considered to be at moderate risk when their SCORE is ≥1 and < 5% at 10 years. Many middle-aged subjects belong to this category. This risk is further modulated by factors in other categories

High risk

Subjects with any of the following:

- **Markedly elevated single risk factors such as familial dyslipidaemias and severe hypertension.**
- **Diabetes mellitus (type 1 or type 2) but without CV risk factors or target organ damage.**
- **Moderate chronic kidney disease (GFR 30–59 mL/min/1.73 m2).**
- **A calculated SCORE of ≥5% and < 10%**

Very high risk

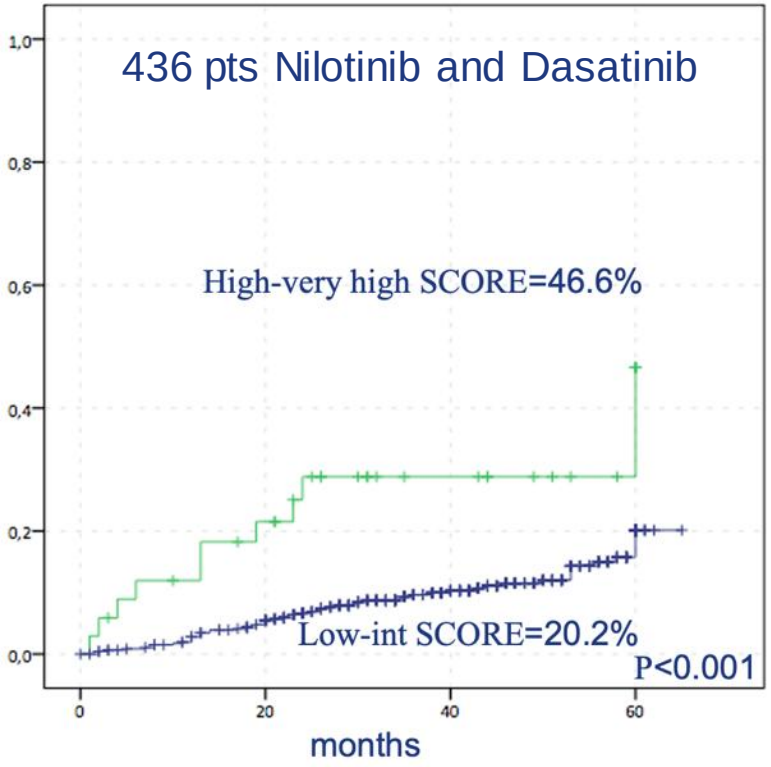
Subjects with any of the following:

- **Documented CVD by invasive or non-invasive testing (such as coronary angiography, nuclear imaging, stress echocardiography carotid plaque on ultrasound), previous myocardial infarction, ACS, coronary revascularization (PCI, CABG), and other arterial revascularization procedures, ischaemic stroke, peripheral artery disease (PAD).**
- **Diabetes mellitus (type 1 or type 2) with one or more CV risk factors and/or target organ damage (such as microalbuminuria: 30–300 mg/24 h).**
- **Severe chronic kidney disease (CKD) (GFR ,30 mL/min/1.73 m2).**
- **A calculated SCORE ≥10%.**

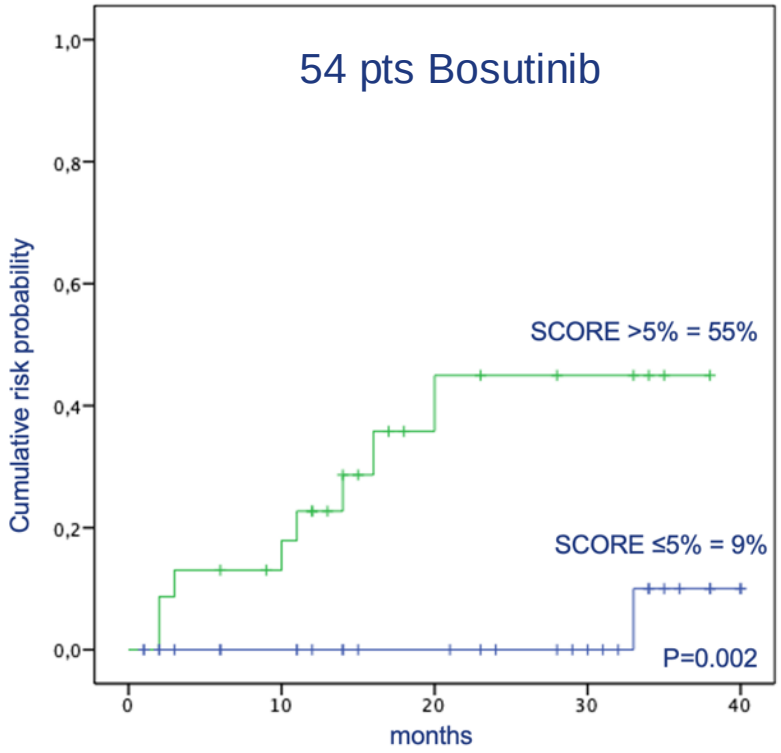
European Guidelines on cardiovascular disease prevention in clinical practice

European Heart Journal (2012) 33, 1635–1701

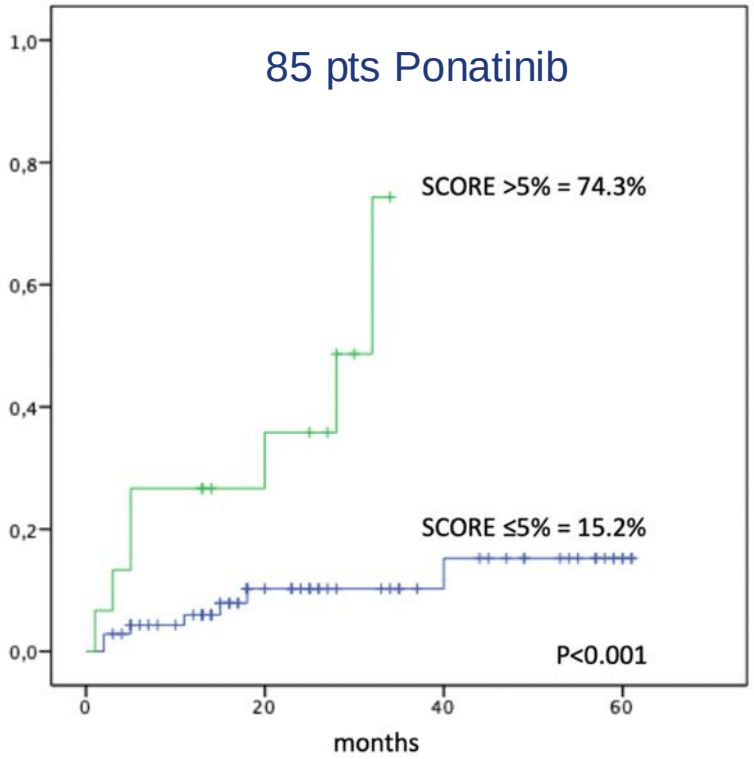
Cardiovascular adverse event cumulative incidence according to the SCORE risk in CML patients



Caocci et al. Am J Hematol. 2018 Jul;93(7):E159-E161



Caocci et al. Ann Hematol. 2019 Aug;98(8):1885-1890



Caocci et al. Hematol Oncol. 2019 Aug;37(3):296-302

ESC European Society of Cardiology
European Heart Journal (2021) **42**, 2439–2454
doi:10.1093/eurheartj/ehab309

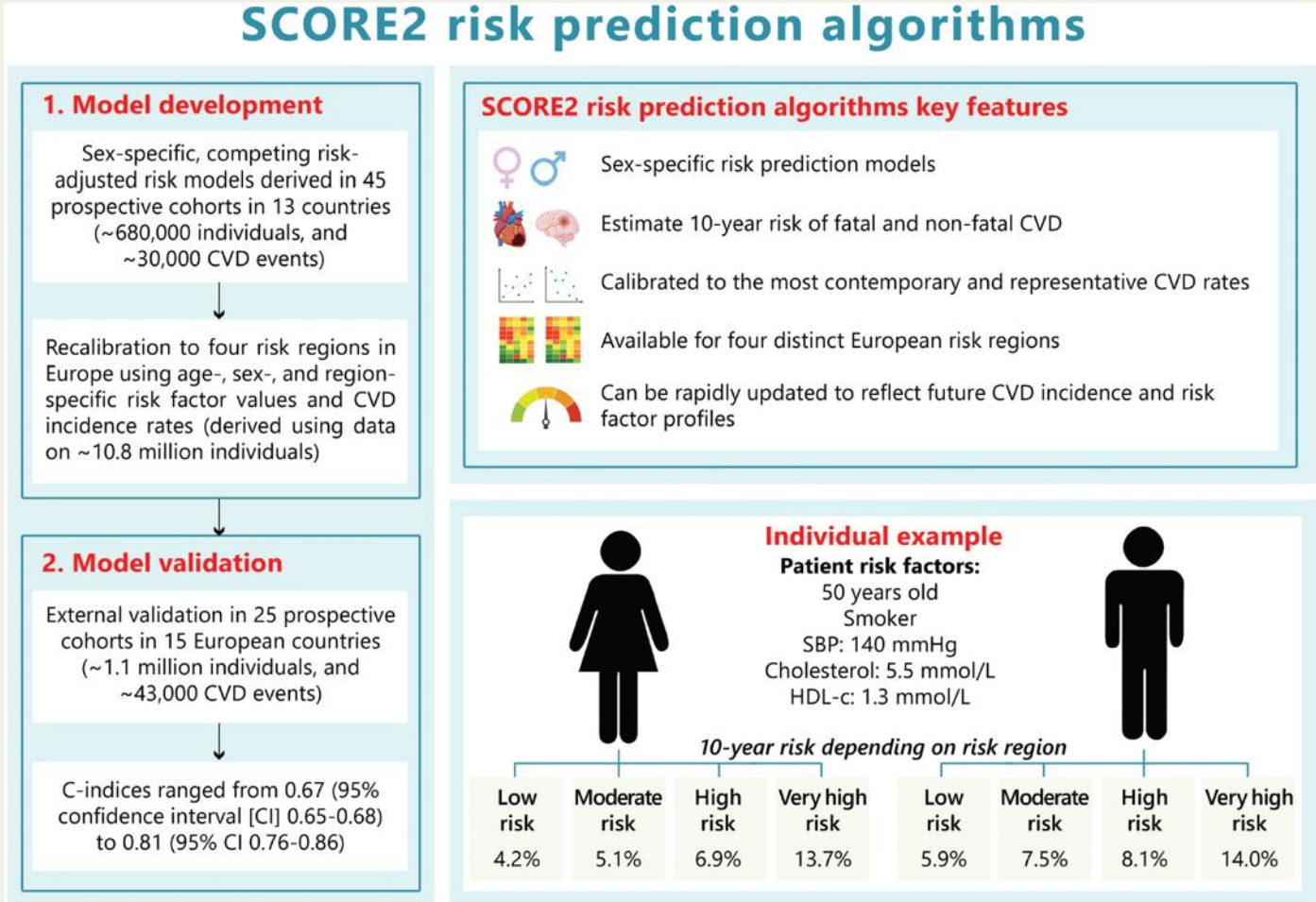
CLINICAL RESEARCH
Epidemiology and prevention

SCORE2 risk prediction algorithms: new models to estimate 10-year risk of cardiovascular disease in Europe

SCORE2 working group and ESC Cardiovascular risk collaboration

Received 25 January 2021; revised 8 March 2021; editorial decision 4 May 2021; accepted 5 May 2021; online publish-ahead-of-print 13 June 2021

See page 2468 for the editorial comment on this article (doi: 10.1093/eurheartj/ehab310)



Development process, key features and illustrative example of the SCORE2 risk prediction algorithms for European populations.

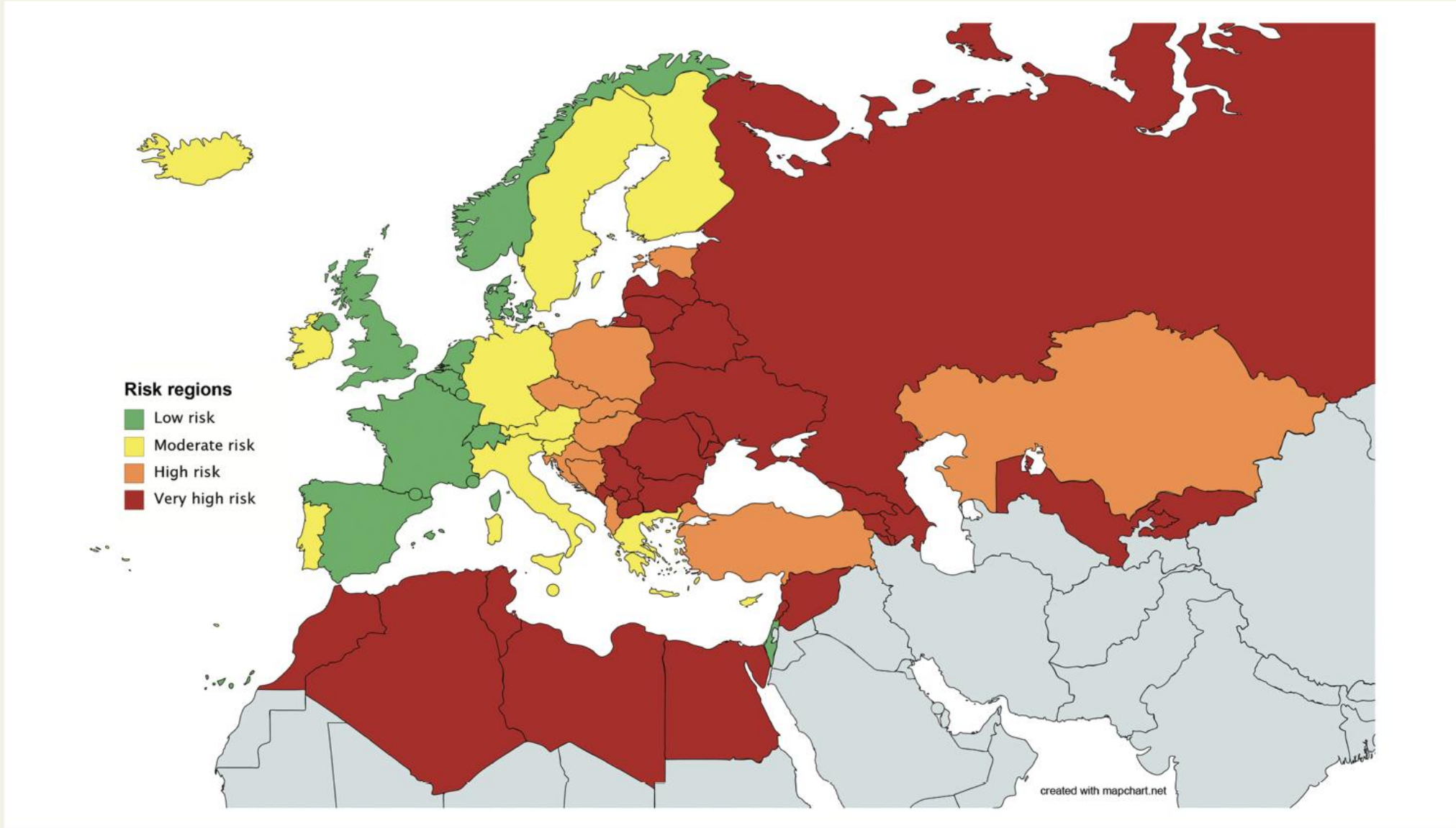


Figure 2 Risk regions based on standardised cardiovascular disease mortality rates. Countries were grouped into four risk regions according to their most recently reported WHO age- and sex-standardized overall CVD mortality rates per 100,000 population (ICD chapters 9, I00-I99). The four groupings were: low risk (<100 CVD deaths per 100,000), moderate risk (100 to <150 CVD deaths per 100,000), high risk (150 to <300 CVD deaths per 100,000), and very high risk (≥300 CVD deaths per 100,000).

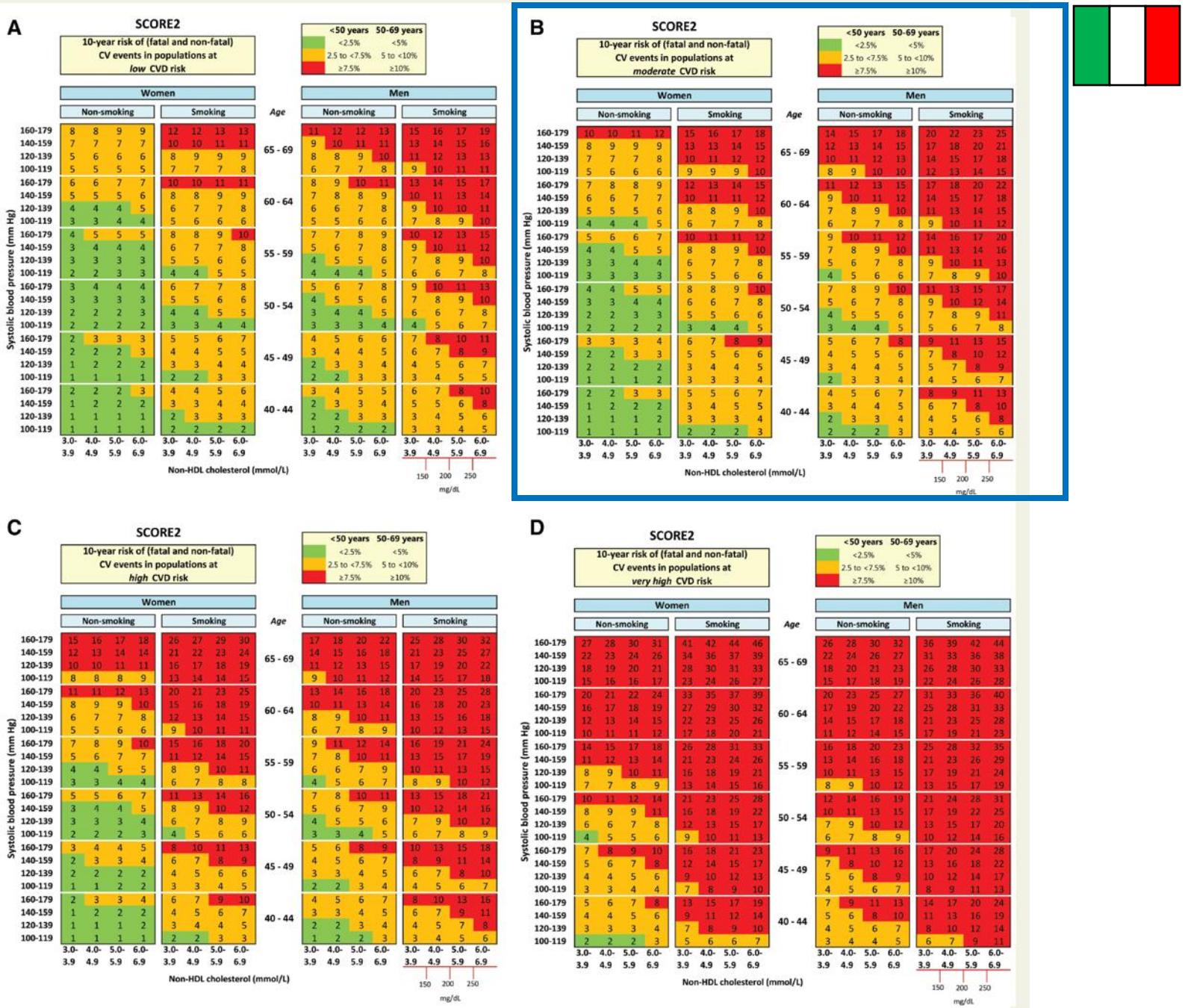


Figure 3 SCORE2 charts for estimation of CVD risk in four European risk regions.

ESC European Society of Cardiology
European Heart Journal (2021) **42**, 2455–2467
doi:10.1093/eurheartj/ehab312

CLINICAL RESEARCH
Epidemiology and prevention

SCORE2-OP risk prediction algorithms: estimating incident cardiovascular event risk in older persons in four geographical risk regions

SCORE2-OP working group and ESC Cardiovascular risk collaboration

Received 8 February 2021; revised 9 March 2021; editorial decision 22 April 2021; accepted 7 May 2021; online publish-ahead-of-print 13 June 2021

See page 2468 for the editorial comment on this article (doi:10.1093/eurheartj/ehab310)

SCORE2-OP: estimating incident cardiovascular event risk in older persons in four geographical risk regions

1. Model derivation

Competing risk-adjusted, sex-specific coefficients were derived in ~28,500 participants from the prospective CONOR study

2. Model recalibration

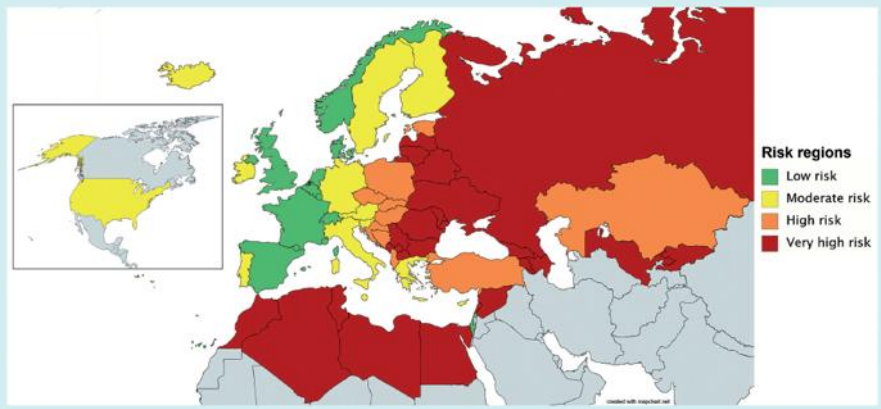
The model was recalibrated to four geographical risk regions using contemporary region-specific CVD event rates and risk factor levels

3. External validation

The model was exernally validated in ~340,000 individuals from different risk regions

4. Individualized predictions

An individual's risk factor levels can be applied to the two-dimensional SCORE2-OP charts or to an online calculator to estimate their 5- and 10-year CVD event risk according to their risk region of origin



Individual example

Patient risk factors
75 years old
Smoker
No diabetes
SBP: 140 mmHg
Cholesterol: 4.5 mmol/L
HDL-c: 1.4 mmol/L

10-year risk depending on risk region:

Low risk	Moderate risk	High risk	Very high risk	Low risk	Moderate risk	High risk	Very high risk
14%	18%	28%	44%	16%	21%	24%	37%

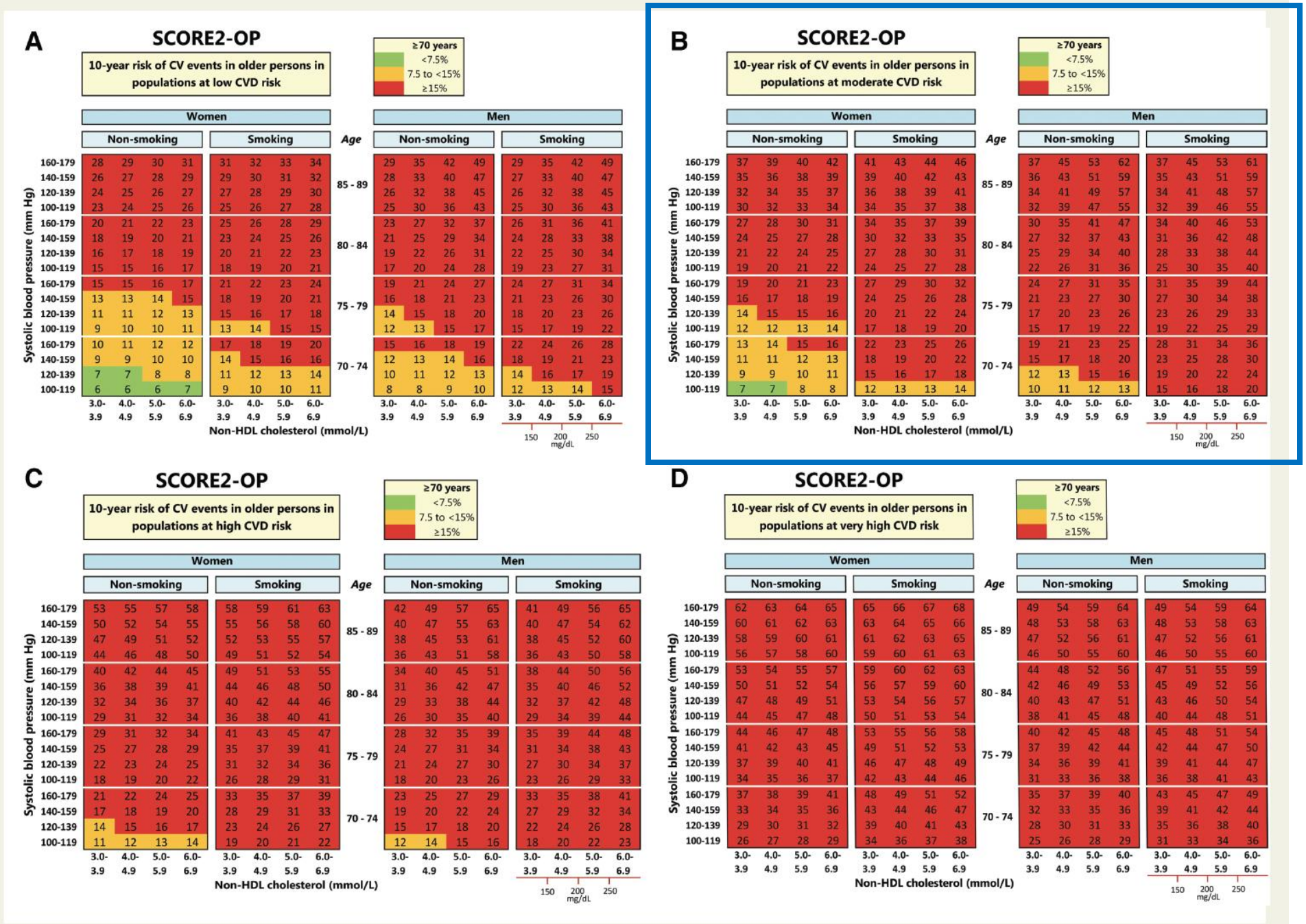


Figure 3 Regional risk charts of predicted 10-year cardiovascular disease risks.

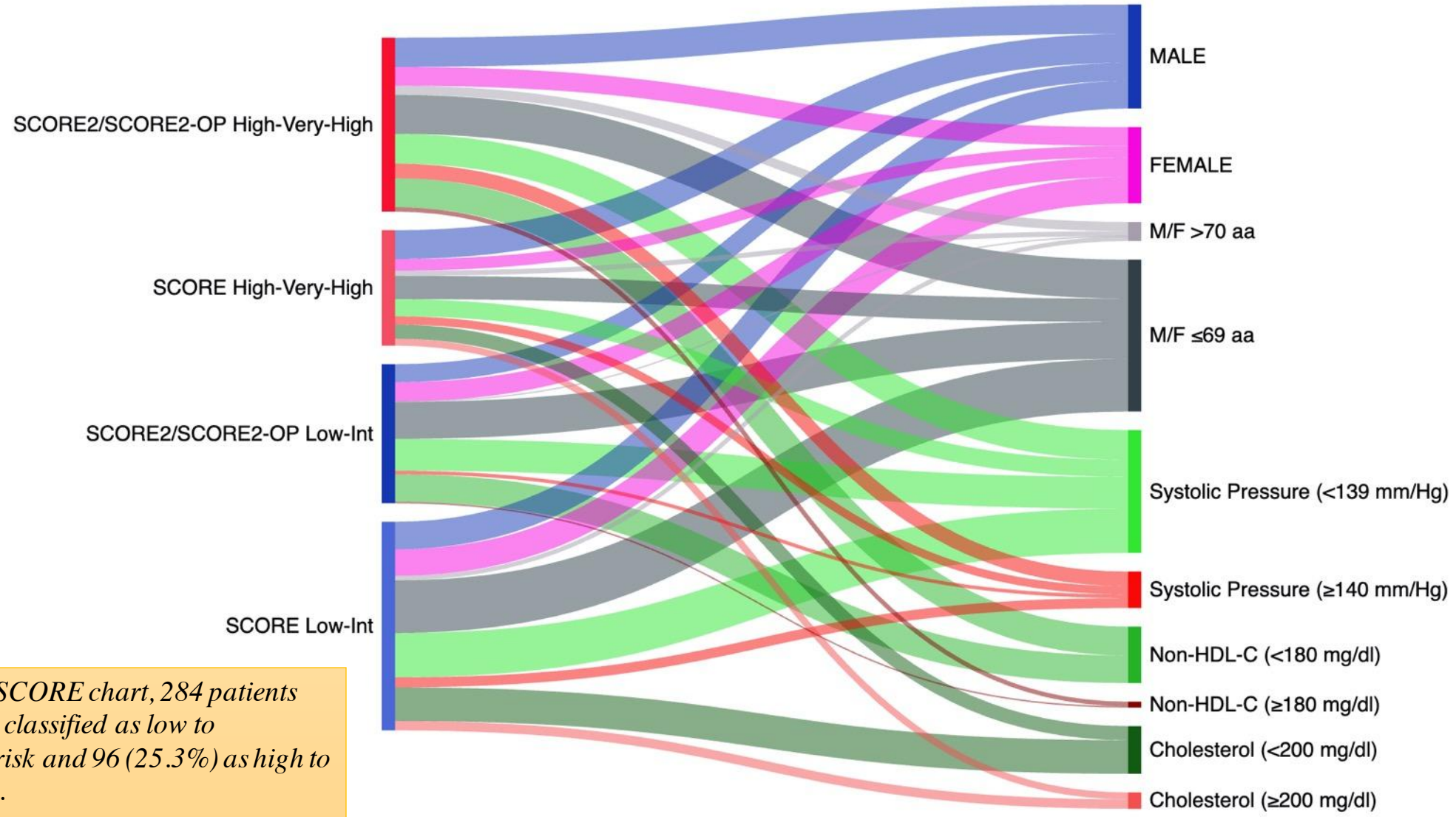
Annals of Hematology
https://doi.org/10.1007/s00277-023-05556-0

ORIGINAL ARTICLE

The new Systematic Coronary Risk Evaluation (SCORE2 and SCORE2-OP) estimates the risk of arterial occlusive events in chronic myeloid leukemia patients treated with nilotinib or ponatinib

Olga Mulas[1] · Elisabetta Abruzzese[2] · Luigiana Luciano[3] · Alessandra Iurlo[4] · Immacolata Attolico[5] · Fausto Castagnetti[6] · Sara Galimberti[7] · Massimiliano Bonifacio[8] · Mario Annunziata[9] · Antonella Gozzini[10] · Ester Maria Orlandi[11] · Fabio Stagno[12] · Gianni Binotto[13] · Patrizia Pregno[14] · Claudio Fozza[15] · Maurizio Loi[1] · Malgorzata Monika Trawinska[2] · Fiorenza De Gregorio[3] · Daniele Cattaneo[4] · Francesco Albano[16] · Miriam Iezza[6] · Claudia Baratè[7] · Luigi Scaffidi[8] · Chiara Elena[11] · Valentina Giai[14] · Emilia Scalzulli[17] · Massimo Breccia[17] · Giorgio La Nasa[1] · Giovanni Caocci[1,18]

Ann Hematol. 2024 Feb;103(2):427-436



Applying the SCORE chart, 284 patients (74.7%) were classified as low to intermediate risk and 96 (25.3%) as high to very high risk.

The SCORE2/SCORE2-OP algorithm translated more patients (191, 50.3%) to the high–very high cardiovascular risk category.

Sankey diagram showing the flow of 455 CML patients from the SCORE to the SCORE2/SCORE2-OP, following recalibration of the age- and sex-adjusted risk, based on the European area of cardiovascular risk, and considering the variable non-HDL-cholesterol instead of total cholesterol

Ann Hematol. 2024 Feb;103(2):427-436

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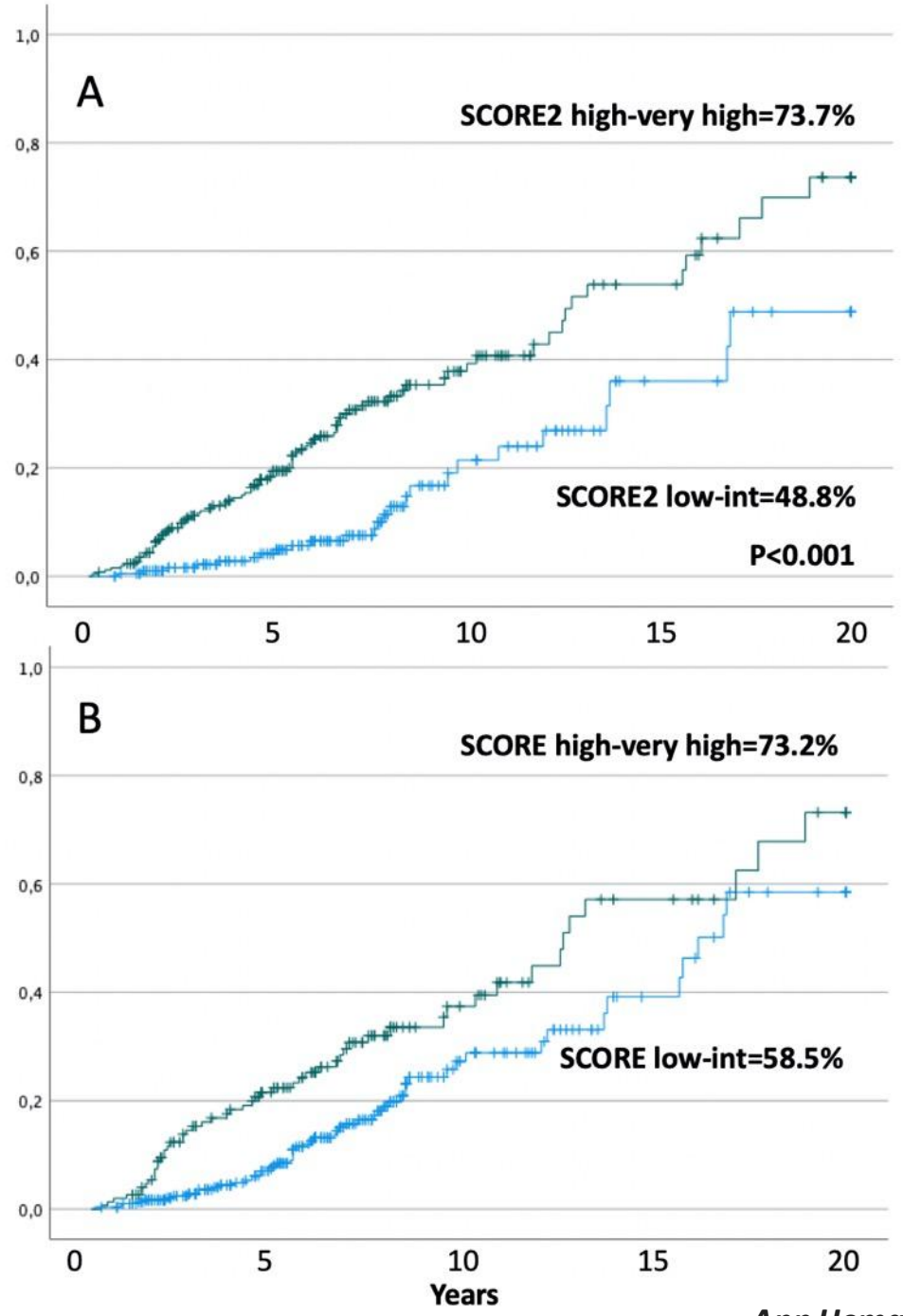
The SCORE2/SCORE2-OP algorithm translated more patients (191, 50.3%) to the high–very high cardiovascular risk category

the SCORE2 risk chart had significant predictive value for patients receiving nilotinib and ponatinib treatment

The SCORE2/SCORE2-OP showed a better specificity in predicting AOEs than the SCORE in patients at low risk



Ann Hematol. 2024 Feb;103(2):427-436

Table 4 Heart Failure Association–International Cardio-Oncology Society baseline cardiovascular toxicity risk stratification

Baseline CV toxicity risk factors	Anthracycline chemotherapy	HER2-targeted therapies	VEGF inhibitors	BCR-ABL inhibitors	Multiple myeloma therapies	RAF and MEK inhibitors
Previous CVD						
HF/cardiomyopathy/ CTRCD	VH	VH	VH	H	VH	VH
Severe VHD	H	H	–	–	–	H
MI or PCI or CABG	H	H	VH	–	–	H
Stable angina	H	H	VH	–	–	H
Arterial vascular disease	–	–	VH	VH	VH	–
Abnormal ankle-brachial pressure index	–	–	–	H	–	–
PH	–	–	–	H	–	–
Arterial thrombosis with TKI	–	–	–	VH	–	–
Venous thrombosis (DVT/PE)	–	–	H	M2	VH	–
Arrhythmia[a]	–	M2	M2	M2	M2	M1
QTc $\geq$ 480 ms	–	–	H	H	–	–
450 $\leq$ QTc $<$ 480 ms (men); 460 $\leq$ QTc $<$ 480 ms (women)	–	–	M2	M2	–	–
Prior PI CV toxicity	–	–	–	–	VH	–
Prior IMiD CV toxicity	–	–	–	–	H	–
Cardiac imaging						
LVEF $<$ 50%	H	H	H	H	H	H
LVEF 50–54%	M2	M2	M2	–	M2	M2
LV hypertrophy	–	–	–	–	M1	–
Cardiac amyloidosis	–	–	–	–	VH	–
Cardiac biomarkers						
Elevated baseline cTn[b]	M1	M2	M1	–	M2	M2
Elevated baseline NP[b]	M1	M2	M1	–	H	M2

ESC European Society of Cardiology
European Heart Journal (2022) **43**, 4229–4361
https://doi.org/10.1093/eurheartj/ehac244

Risk level:

Low risk
no risk factors OR one moderate1 risk factor;

Moderate risk (M)
moderate risk factors with a total of 2–4 points
(Moderate 1 [M1]=1 point; Moderate [M2]=2 points);

High risk (H)
moderate risk factors with a total of ≥5 points OR any high-risk factor;

Very-high risk (VH)
any very-high risk factor.

Age and CVRF						
Age ≥ 80 years	H	H	–	–	–	M1
Age 65–79 years	M2	M2	–	–	–	M1
Age ≥ 75 years	–	–	H	H	H	M1
Age 65–74 years	–	–	M1	M2	M1	M1
Age ≥ 60 years	–	–	–	M1	–	–
CVD 10-year risk score > 20%	–	–	–	H	–	–
Hypertension[c]	M1	M1	H	M2	M1	M2
Chronic kidney disease[d]	M1	M1	M1	M1	M1	M1
Proteinuria	–	–	M1	–	–	–
DM[e]	M1	M1	M1	M1	M1	M1
Hyperlipidaemia[f]	–	–	M1	M1	M1	–
Family history of thrombophilia	–	–	–	M1	M1	–
Current cancer treatment						
Dexamethasone > 160 mg/month	–	–	–	–	M1	–
Includes anthracycline before HER2-targeted therapy	–	M1[g]	–	–	–	–
Previous exposure to						
Anthracycline	H	M2[h]	H	–	H	H
Trastuzumab	–	VH	–	–	–	–
RT to left chest or mediastinum	H	M2	M1	–	M1	M2
Non-anthracycline chemotherapy	M1	–	–	–	–	–
Lifestyle risk factors						
Current smoker or significant smoking history	M1	M1	M1	H	M1	M1
Obesity (BMI > 30 kg/m^2)	M1	M1	M1	M1	M1	M1

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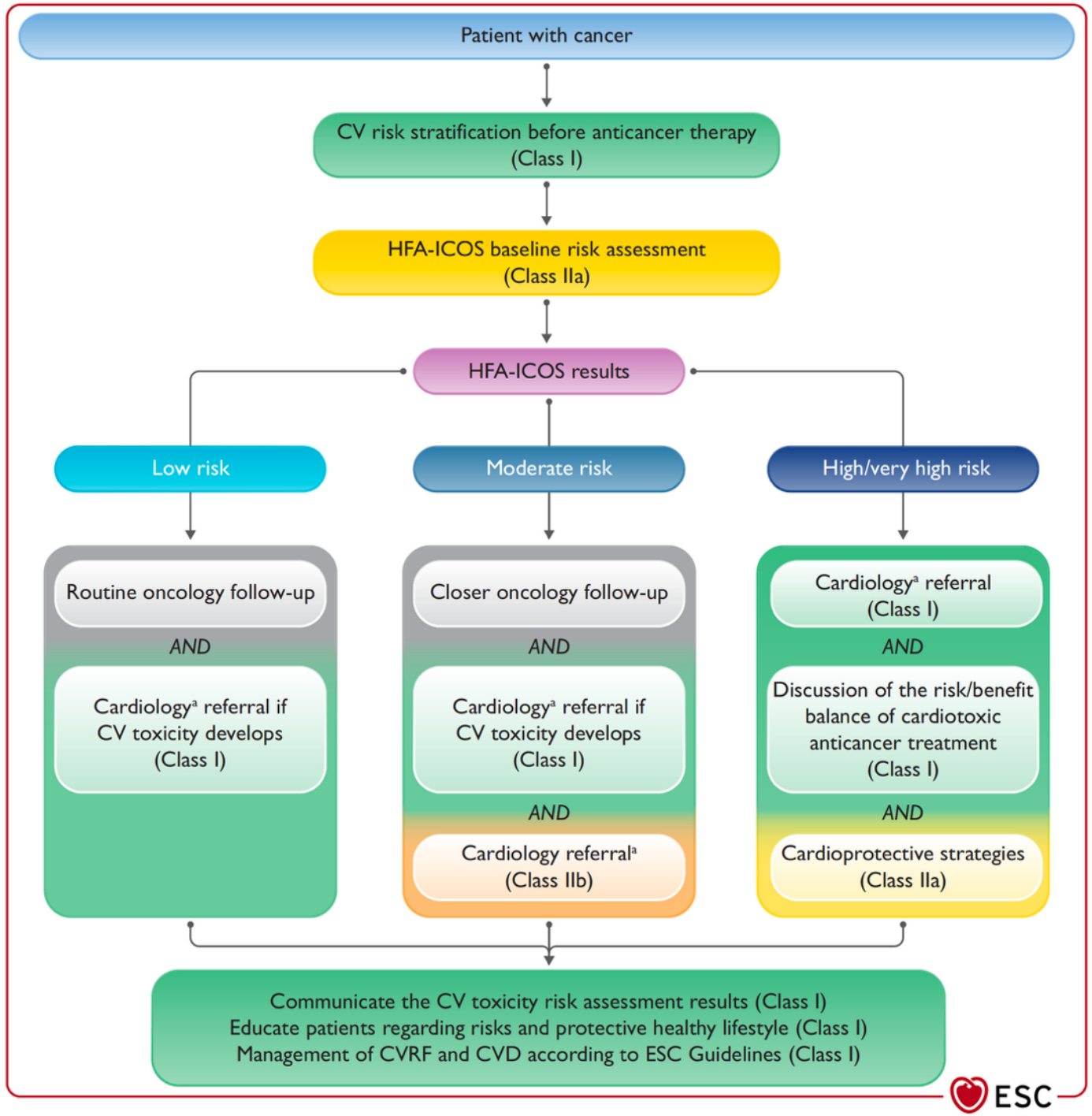
https://doi.org/10.1093/eurheartj/ehac244

Table 1 **Classes of recommendations**

Classes of recommendations	Definition	Wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended or 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



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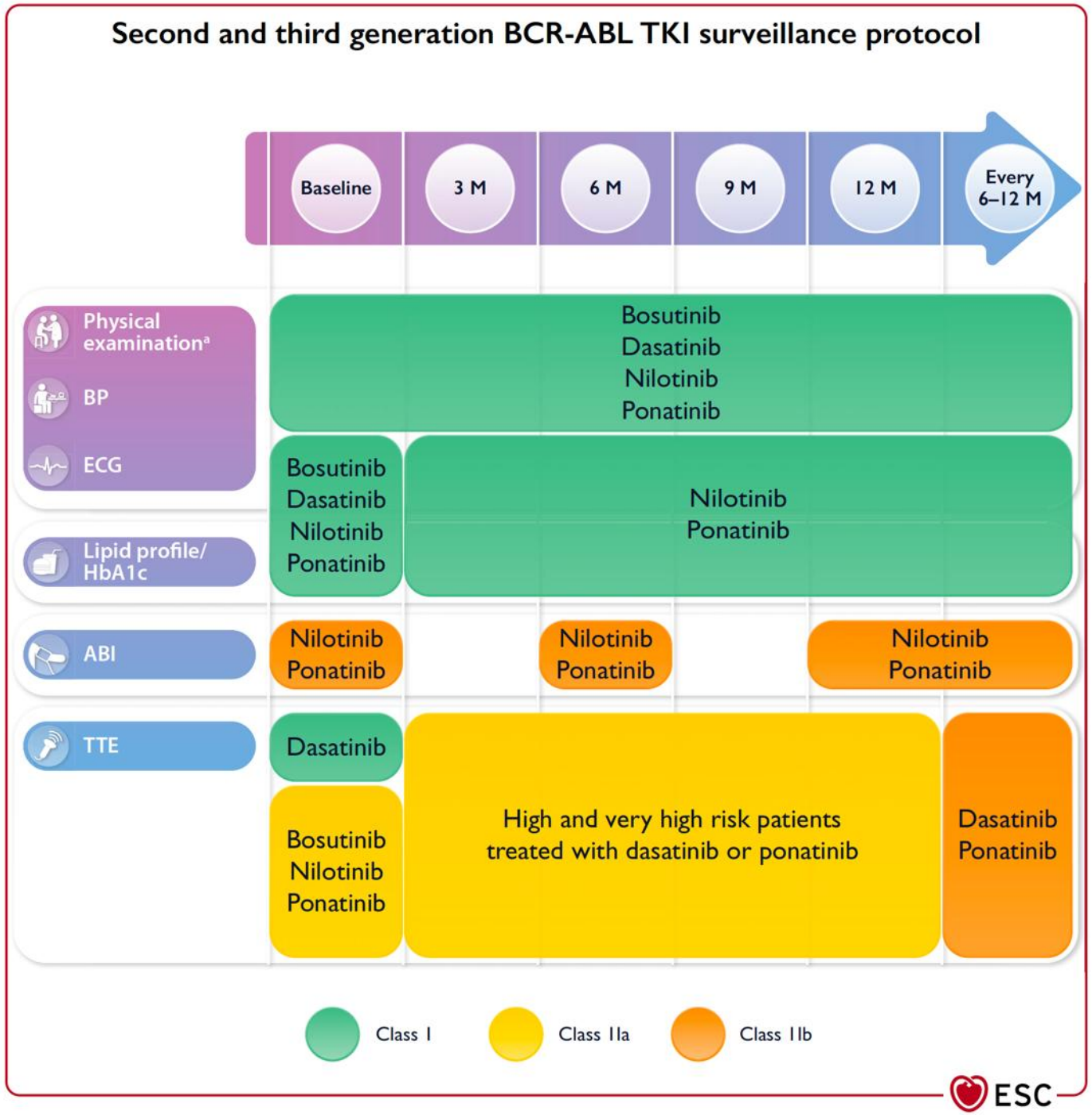
CML patients and cardiovascular risk:

1) Stress attention on CV patient history
2) Hard work on modifiable CV risk factors
3) Apply a CV risk score
4) Monitor as well as you can



Recommendation Table 11 — Recommendations for baseline risk assessment and monitoring during second- and third-generation breakpoint cluster region–Abelson oncogene locus tyrosine kinase inhibitors

Recommendations	Class[a]	Level[b]
Baseline CV risk assessment[c] is recommended in patients who require second- or third-generation BCR-ABL TKI.[256,261]	I	C
In patients treated with nilotinib or ponatinib, CV risk assessment[c] is recommended every 3 months during the first year and every 6–12 months thereafter.[256,261]	I	C
QTc[d] measurement should be considered at baseline, at 2 and 4 weeks after starting nilotinib, and 2 weeks after any dose increase.[259]	IIa	C
Baseline echocardiography should be considered in all patients before starting second- and third-generation BCR-ABL TKI.	IIa	C
Baseline echocardiography is recommended in patients scheduled to receive dasatinib.	I	C
Echocardiography should be considered every 3 months during the first year in high- and very high-risk patients receiving dasatinib or ponatinib.	IIa	C
Echocardiography may be considered every 6–12 months in patients who require long-term (>12 months) ponatinib or dasatinib.	IIb	C
Serial assessment of ankle brachial index may be considered to detect subclinical peripheral vascular disease.	IIb	C

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How I monitor for cardiovascular toxicity

Cardiovascular evaluation before starting Nilotinib or Ponatinib

	Baseline	3 months	6 months	12 months	Every 6 months	Every 12 months
Interview	x	x	x	x	x	
Heart lung vessel exam	x	x	x	x	x	
Blood pressure	x			Home BP monitoring		
Lipids Glycaemia HbA1c	x	x	x	x	x	
ECG	x		x	x	x	
Arterial Echo Doppler	x		x	x		x
Echocardiogram	x			As clinically indicated		
Exercise stress test or coronary CT	As clinically indicated			As clinically indicated		

BP, blood pressure; CT, computed tomography; ECG, electrocardiogram; HbA1c, glycated haemoglobin.

Presenter's personal opinion. Table adapted from Müller MC, et al. *Crit Rev Oncol Hematol.* 2017;120:52–9.

Courtesy of Paolo Spallarossa

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