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CUORE project: implementation of the 10-year risk score

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Abstract

Purpose: The Italian national prevention plan 2005–2008 included 10-year cardiovascular risk (10-CR) assessment of the general population aged 35–69 years using the CUORE project risk score. General practitioners (GPs) were encouraged to collect data on risk factors and 10-CR and to contribute to the Cardiovascular Risk Observatory (CRO). The aim is to demonstrate feasibility and effectiveness of 10-CR assessment as a first step to implement primary preventive actions at the individual level.

Methods: Data were collected using CUORE.EXE software, easily and freely downloadable by GPs from the CUORE project website (www.cuore.iss.it). CRO provides a web platform to analyse and compare data on 10-CR and risk factors at regional and national levels with the aim of supporting health policy decision processes.

Results: From January 2007 to May 2010, 2,858 GPs downloaded CUORE.EXE; 139,269 CR assessments on 117,345 persons were sent to CRO. CR mean was 3.0% in women, 8.3% in men; 30% of men and 65% of women were at lower risk (CR $< 3\%$), 9.2% of men and 0.4% of women were at high risk (CR $\geq 20\%$). Among those with at least two risk assessments ($n = 5{,}948$), 8% (95% CI 7–9%) shifted to a lower risk class after 1 year. Systolic blood pressure mean levels decreased by 1.6 mmHg (95% CI 1.2–2.1 mmHg), diastolic blood pressure by 0.9 mmHg (95% CI 0.5–1.3 mmHg), total cholesterol by 5.6 mg/dl (95% CI 4.3–6.8 mg/dl), and smokers prevalence by 3.5% (95% CI 2.5–4.6%); high-density lipoprotein cholesterol increased in women by 1 mg/dl (95% CI 0.5–1.4 mg/dl).

Conclusions: Data demonstrate that 10-CR assessment can be the first step to implement preventive actions in primary care.

Keywords

Cardiovascular risk assessment, cardiovascular prevention, general practitioners, surveillance

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Introduction

According to the European guidelines on cardiovascular disease (CVD) prevention, the 10-year global absolute cardiovascular risk assessment (10-CR score) is a first step for the implementation of preventive actions in clinical practice.[1] In Italy, the 10-CR score was developed using data from the Italian longitudinal studies of the Progetto CUORE; it predicts 10-year risk of fatal and non-fatal CVD events on the basis of age, sex, systolic blood pressure, antihypertensive treatment, total and high-density lipoprotein (HDL)-cholesterol, smoking, and diabetes.[2–4] Considering only the prediction of fatal events, the CUORE score in the adult population was very similar to the cardiovascular risk assessment of the SCORE project for low-risk European countries.[5]

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The introduction of 10-CR score in clinical practice prompted the Ministry of Health to launch the National Training Program for General Practitioners (GPs) on the use and application of cardiovascular risk charts, offered for free to regions/associations.[6] It includes five sequential packages linked to educational credits. A handbook for the residential training course (packages 1–2) was published and distributed.[7–9]

The Cardiovascular Risk Observatory (CRO) was developed to monitor the use of 10-CR score in clinical practice. It is a web-accessible tool (http://cuore-iss.cineca.it/) that provides stakeholders (Ministry of Health, Istituto Superiore di Sanità-ISS, Agenzia Italiana del Farmaco and Regions) with a platform to analyse GPs collected data (risk factors and 10-CR), improve quality through self-audit and compare 10-CR assessment at regional and national level

The aim of this analysis is to present some results from GPs and demonstrate feasibility of a surveillance system involving GPs.

Materials and methods

The National Training Program for GPs on the use and application of cardiovascular risk charts includes five sequential packages linked to educational credits: packages 1 and 2 are residential and aim at (i) facilitating the adoption of standardized methodologies for the assessment of cardiovascular risk; (ii) promoting the use and application of risk assessment in clinical practice through electronic tool (CUORE.EXE software, freely downloadable from the www.cuore.iss.it website); (iii) identifying persons eligible for counselling and/or treatment; and (iv) promoting the adoption of shared recommendations and a common language for cardiovascular risk prevention. The self-training package 3 is dedicated to the use and application of 10-CR score in clinical practice and to data collection. The last two packages 4 and 5 are dedicated to evaluate and discuss collected data and spread results.[7]

Risk factors and 10-CR score were collected through the CUORE.EXE software; that allows users to work off-line and to:

- assess the likelihood for men and women separately, aged 35–69 years and free of previous cardiovascular diseases of experiencing a major cardiovascular event (myocardial infarction or stroke) over the next 10 years on the basis of eight risk factors: age, sex, diabetes, smoking, systolic blood pressure, total cholesterol, HDL-cholesterol, antihypertensive treatment. The antihypertensive treatment was explicitly used to avoid underestimation of risk among treated subjects; the function takes into account the difference in risk between those who have a 'natural' level of systolic blood pressure and those who need treatment to reach the same level of blood pressure;
- elaborate the absolute risk of a person with the same age and sex of the examined one but all modifiable risk factors at 'favourable' level: non-smoker, non-diabetic, not undergoing antihypertensive treatment, systolic blood pressure $\leq$120 mmHg, and cholesterol $<$200 mg/dl;
- estimate, for motivational purposes, how much the risk of a smoker would be reduced at 1 year after cessation and how much the risk would be reduced if all modifiable factors (serum cholesterol and blood pressure) decreased by 10%;
- print out the patient's risk score, including lifestyle recommendations (nutrition, physical activity, smoking cessation);
- set up a data archive to monitor patient's cardiovascular risk trend over time;
- register prescribed therapies and lifestyle recommendations;
- collect obesity and overweight data;
- record any cardiovascular event occurring during follow-up;
- elaborate statistics on stored data;
- send collected data, kept anonymous, to the ISS.

Delivery of anonymous data, collected during package 3, to the CRO was approved by the Ethics Committee of the ISS on 27 April 2006.

On the basis of 10-CR score and AIFA indications,[10,11] persons are classified as high-risk (risk $\geq$ 20%), moderate risk, to be kept under control through healthy lifestyle (risk $>$ 3% and $<$20%), or low-risk (risk $\leq$ 3%). High-risk persons are recommended to assess their risk every 6 months, persons at moderate risk every year, the others every 5 years.

Mean level, median level, and 25th and 75th percentiles of 10-CR score were calculated by sex and 5-year age groups. In the subgroup of persons examined at least twice in 1 year, variations in continuous risk factors mean levels and categorical risk factors prevalences between baseline and follow-up and 95% confidence intervals were calculated using methods for paired case samples. Results are presented by sex at national level.

Results

From January 2007 to May 2010, 1,032 GPs (about 2.2% of 47,000 GPs in Italy) sent 139,269 risk assessments on 117,345 patients to the CRO (114 patients per GP, from a minimum of 15 to a maximum of around 624). Of all patients, 104,918 had complete data on risk factors, 10-CR score, treatment, and life style counselling (45,560 men and 56,358 women).

Table 1. Distribution of mean cardiovascular disease (CVD) risk in patients whose cardiovascular risk was assessed by general practitioners through the CUORE.EXE software

	Men					Women				
Age (years)	*n*	Mean CVD risk	25° Percentile	Median	75° Percentile	*n*	Mean CVD risk	25% percentile	Median	75% percentile
35–39	5,003	1.5	0.9	1.3	1.8	5,567	0.4	0.2	0.3	0.5
40–44	7,193	2.4	1.4	2.0	2.9	7,781	0.7	0.4	0.5	0.8
45–49	7,363	4.0	2.3	3.2	4.8	8,105	1.2	0.6	0.8	1.5
50–54	7,579	6.4	3.6	5.2	7.9	8,683	2.0	1.0	1.5	2.5
55–59	7,832	9.7	5.5	8.1	12.0	9,196	3.3	1.6	2.6	4.1
60–64	7,247	14.0	8.1	11.9	17.5	9,016	5.0	2.6	4.2	6.3
65–69	6,343	19.6	12.2	17.3	24.5	8,010	7.5	4.3	6.6	9.4
Total	48,560	8.3	2.5	5.5	11.3	56,358	3.0	0.7	1.8	4.1

Table 1 shows the distribution by 5-year age group and sex of the mean level, median level, and 25th and 75th percentiles of 10-CR score in those who received at least one risk assessment. Overall, risk was equally assessed in all age groups, though the majority of risk assessments were performed in the age range 55–59 years; mean 10-CR score was 3.1% in women and 8.4% in men; it steeply increases by age in both men and women: in the oldest men 10-CR score is 13 times higher than in the youngest, 19 times in women.

Following the classification of the population suggested in the Italian Prevention Plan 2005–2009, risk was found lower in 30% of men, to be kept under control through lifestyle in 61% of men and higher in 9% of men; corresponding values in women were 65%, 34%, and 0.4%. For counselling, 51% of men and 47% of women were counselled on dietary habit modification to reduce risk factor levels; 53% of men and 50% of women received counselling to increase their physical activity; 69% of smoking men and 94% of smoking women received counselling to stop smoking or were referred to specialized centres (data not shown). At present, 15% of men and 13% of women are under antihypertensive treatment; 8% of men and 5% of women are under hypercholesterolaemia therapy (data not shown).

A total of 5,948 patients were examined twice (10% of those to be reassessed) and had complete data to detect variation in risk: at first assessment, 478 men (15%) were found at low risk, 2,280 (72%) at moderate risk and 427 (13%) at high risk. At the second assessment, the great majority of men remained in the same category: 381 (80%) in low-risk category, 2,022 (89%) in moderate-risk category, and 253 (59%) in high-risk category. 305 men (10%) improved their risk factors, thus shifting from high or moderate-risk category to the low-risk category (data not shown).

Among women, 1,192 (43%) were found at low risk, 1,558 (56%) at moderate risk and 13 (1%) at high risk; at the second assessment, 90% of women at low and moderate risk remained in the same category: 1,074 in low-risk category and 1,395 in the moderate one; only 38% of high-risk women remained in the same category. 162 women (6%) improved their risk factors, thus shifting from high or moderate risk to the low-risk category (data not shown). Mean level of risk factors, prevalence of risk factors categories, difference between first and second examinations and related 95% confidence intervals are reported in Table 2. Despite age increases, total cholesterol, systolic, and diastolic blood pressure decreased significantly in both men and women; also smoking dropped substantially; HDL-cholesterol increased significantly in women. Prevalence of lower levels of systolic and diastolic blood pressure (<120 and <80 mmHg separately and in combination) increased in men but not in women; in both genders prevalence of hypertensive persons (including treated) increased significantly, also due to greater drug treatment use. In both genders, prevalence of 'Not adequately treated' and 'Not treated hypertension' decreased, while prevalence of 'Well treated' increased: these results may suggest an improved control of hypertension (Table 2). As regards total cholesterol, a statistically significant increase of low cholesterol prevalence in both genders and a significant reduction of high cholesterol group prevalence is evident. In women, prevalence of the lowest level of HDL-cholesterol decreases significantly, while prevalence of the highest level of HDL-cholesterol increases consistently (more than 3%) (Table 2).

Discussion

The National Training Program for GPs on the use and application of risk score/charts, collection and delivery

Table 2. Differences of mean and prevalence of risk factors at baseline (BL) and follow-up (FU) on the basis of cardiovascular disease (CVD) risk assessed by general practitioners through the CUORE.EXE software (May 2010)

	Men								Women							
Risk factors	*n*		Mean CVD risk BL		Mean CVD risk FU	Diff	95%	CI	*n*		Mean CVD risk BL		Mean CVD risk FU	Diff	95%	CI
Age, years	3185		55.1		56.1	1.0	0.9	1.0	2764		56.6		57.5	0.9	0.9	1.0
SBP, mmHg	3185		133.4		131.7	−1.7	−2.1	−1.3	2764		133.4		131.9	−1.5	−2.0	−1.0
DBP, mmHg	3123		82.0		80.9	−1.1	−1.5	−0.6	2709		80.8		80.1	−0.7	−0.9	−0.4
TC, mg/dl	3185		216.3		209.7	−6.6	−7.9	−5.4	2764		222.0		217.7	−4.3	−5.6	−3.1
HDL-C, mg/dl	3185		48.3		48.2	−0.1	−0.5	0.2	2764		55.7		56.7	1.0	0.5	1.4
	n	*n* BL	% BL	*n* FU	% FU	Diff	95%	CI	*n*	*n* BL	% BL	*n* FU	% FU	Diff	95%	CI
Current Smokers	3185	1159	36.4	983	30.9	−5.5	−6.7	−4.4	2764	452	16.4	417	15.1	−1.3	−2.3	−0.3
Diabetes[a]	3185	575	18.1	606	19.0	0.9	0.2	1.7	2764	483	17.5	502	18.2	0.7	0.0	1.4
Hypertension treatment	3185	1306	41.0	1401	44.0	3.0	1.9	4.0	2764	1432	51.8	1485	53.7	1.9	0.8	3.0
SBP, mmHg	3185								2764							
<= 120		493	15.5	500	15.7	0.2	−1.0	1.5		497	18.0	493	17.8	−0.2	−1.5	1.2
121–139		1008	31.6	1037	32.6	1.0	−0.8	2.6		615	22.3	621	22.5	0.2	−1.4	1.8
140–159		354	11.1	233	7.3	−3.8	−5.0	−2.6		195	7.1	157	5.7	−1.4	−2.5	−0.3
>= 160 or treated		1330	41.8	1415	44.4	2.6	1.6	3.7		1457	52.7	1493	54.0	1.3	0.2	2.4
DBP, mmHg	3155			3178					2740			2758				
<= 80		1147	36.4	1223	38.5	2.1	0.4	3.6		969	35.4	977	35.4	0.0	−1.6	1.5
81–89		522	16.5	413	13.0	−3.5	−5.1	−2.1		260	9.5	230	8.3	−1.2	−0.3	0.1
90–99		158	5.0	122	3.8	−1.2	−2.0	−0.3		67	2.4	60	2.2	−0.2	−1.0	0.4

>=100 or treated		1328	42.1	1420	44.7	2.6	1.7	3.9		1444	52.7	1491	54.1	1.4	0.5	2.7
BP, mmHg[b]	3185								2764							
Normal		438	13.8	446	14.0	0.2	−1.0	1.5		464	16.8	461	16.7	−0.1	−1.5	1.2
Prehypertension		996	31.3	1037	32.6	1.3	−0.4	3.0		630	22.8	636	23.0	0.2	−1.4	1.9
Hypertension I stage		406	12.7	271	8.5	−4.2	−5.5	−3.0		205	7.4	170	6.2	−1.2	−2.4	−0.1
Hypertension II stage		1345	42.2	1431	44.9	2.7	1.6	3.8		1465	53.0	1497	54.2	1.2	0.0	2.3
BP treatment condition[c]	3185								2764							
Not Hypertension		1434	45.0	1483	46.6	1.6	0.1	2.9		1094	39.6	1097	39.7	0.1	−1.2	1.4
Well treated		557	17.5	783	24.6	7.1	5.7	8.5		619	22.4	812	29.4	7.0	5.3	8.7
Not adequately treated		749	23.5	618	19.4	−4.1	−5.5	−2.7		813	29.4	673	24.3	−5.1	−6.7	−3.4
Not treated hypertension		445	14.0	301	9.5	−4.5	−5.8	−3.2		238	8.6	182	6.6	−2.0	−3.2	−0.9
TC, mg/dl[d]	3185								2764							
Normal cholesterol		1122	35.2	1229	38.6	3.4	1.6	5.1		804	29.1	925	33.5	4.4	2.7	6.1
Over cholesterol		1167	36.6	1305	41.0	4.4	2.3	6.4		1057	38.2	1063	38.5	0.3	−2.0	2.4
Hypercholesterolaemia		896	28.1	651	20.4	−7.7	−9.3	−6.1		903	32.7	776	28.1	−4.6	−6.4	−2.8
HDL-C, mg/dl	3185								2764							
<40		657	20.6	653	20.5	−0.1	−1.7	1.4		230	8.3	193	7.0	−1.3	−2.4	−0.2
40–59		2037	64.0	2078	65.2	1.2	−0.7	3.2		1618	58.5	1567	56.7	−1.8	−3.9	0.2
>=60		491	15.4	454	14.3	−1.1	−2.5	0.1		916	33.1	1004	36.3	3.2	1.4	4.9

[a]Serum Glycemia >=126 mg/dl or Treated. [b]Normal: systolic blood pressure (SBP)<=120 mmHg & diastolic blood pressure (DBP)<=80 mmHg. Prehypertension: SBP 121–139 mmHg or DBP 81–89 mmHg. Hypertension I stage: SBP 140–159 mmHg or DBP 90–99 mmHg. Hypertension II stage: SBP>=160 mmHg or DBP>=100 mmHg or Treated. [c]Not Hypertension: SBP<140 mmHg AND DBP<90 mmHg AND Not Treated. Well Treated: SBP<140 mmHg AND DBP<90 mmHg; Not Adequately Treated: SBP>=140 mmHg or DBP>=90 mmHg; Not Treated Hypertension: SBP>=140 mmHg or DBP>=90 mmHg AND Not Treated. [d]Normal cholesterol: TC<200 mg/dl. Over cholesterol: TC 200–239 mg/dl. Hypercholesterolemia: TC>=240 mg/dl. BP, blood pressure; DBP, diastolic blood pressure; HDL-C, high-density lipoprotein cholesterol; SBP, systolic blood pressure; TC, total cholesterol.

of data through the CUORE.EXE programme and development of the CRO is part of the Progetto CUORE.

Preliminary results presented here underline the importance of 10-CR assessment in clinical practice and demonstrate the feasibility to implement a risk factors surveillance system involving GPs' after an appropriate training programme.

Although data are derived from a non-representative sample of 1,032 GPs, it appears evident that risk can be reduced and maintained low despite age increase and counselling advices may be well received. Despite the number of followed-up persons is quite low (5,948 patients), they are well distributed throughout the country. Among men and women followed-up by GPs, statistically significant reductions of systolic and diastolic blood pressure, total cholesterol, and prevalence of smokers have been registered; moreover, results suggest an improvement in hypertension and hypercholesterolaemia control.

Study limitations

Among all GPs who downloaded the CUORE.EXE software from the www.cuore.iss.it website (2,858 GPs) and participated in the national training plan (3,517 GPs), those who sent their data represent only a small group (1,032).

One of the main difficulties expressed by GPs is the use of two different softwares (CUORE.EXE and the one routinely used in clinical practice) as this implies double recording of information and waste of precious time, that may be dedicated to lifestyle counselling. To obviate such a problem, personal data and laboratory measurements values recorded in archives were automatically linked to data collected during risk assessment through the CUORE.EXE software. In this way, according to indications of the Ethics Committee of the ISS, completeness and integrity of collected information were guaranteed. Variability of blood test results, due to different laboratories and the tendency of health operators to round down the last digit of blood pressure reading to zero, are well-known limitations of the study.

It is worth noting that the high prevalence of the moderate-risk category, to be kept under control through the adoption of healthy lifestyle, is due to its wideness. A subdivision of this category into further subcategories will help GPs pay more attention to stratification of risk.

The risk assessment tool should be carefully used when reassessing people undergoing lifestyle or risk factor interventions. Lowering blood pressure with antihypertensive medication or quitting smoking do not automatically reduce the risk to the level of a person with a normal blood pressure or to a never smoker. Cardiovascular risk remains higher in those who need antihypertensive treatment to reach a normal level of blood pressure compared to those who do not need treatment, as a result of the duration of exposure to hypertension before treatment, despite the level of all other risk factors is the same. Quitting smoking reduces the risk of cardiovascular diseases exactly to the same level of a never smoker after about 5 years (10 years for cancer); in the CUORE score a person who never smoked or is at least 1 year smoke-free is defined 'non-smoker'.

Some studies demonstrate how a physician-implemented cardiovascular risk evaluation/communication programme improves patients' modifiable risk factor profile and lowers predicted risk compared with usual care, and they give evidence for the efficacy of an intervention addressing multiple risk factors for primary prevention at 1 year using risk scores and counselling or treatment interventions.[12–15] On the other side, some puzzlements rise on the use of cardiovascular risk scores for primary prevention; doubts are more related to accuracy of tools in predicting CVD risk than to efficacy in using risk assessment and consequently in therapeutic and lifestyle interventions.[16] Some findings suggest that true cardiovascular risk in low-risk populations is likely to be overestimated, perhaps leading to unnecessary treatment of many patients. Conversely, in high-risk populations, true cardiovascular risk is likely to be underestimated, potentially resulting in high-risk people not reaching a treatment threshold and being denied appropriate drug treatment.[16]

Other studies involving GPs in primary prevention of CVD include cardiovascular risk assessment and achievement of risk factors targets in limited population. In a study conducted in Cyprus,[17] about 1,011 diabetic men and women were identified by the SCORE model at high-risk and studied following European guidelines on the use of treatment and goal attainment for blood pressure and lipids in primary care. Even though study populations are different (the Cyprus population is less numerous and at higher risk (about 40% at high risk) than the CRO study), both studies show suboptimal control and under-treatment of patients with cardiovascular risk factors in primary care: about 38% of men and women result as 'Not adequately treated' or 'Not treated hypertension' in the Italian study vs. about 44% with blood pressure off target in the Cyprus study.

The scarce participation of GPs in the surveillance system is coherent with some results deriving from the EUROPREV network.[18] In this study, 2,082 GPs were enrolled in 11 European countries to explore knowledge and attitudes of European GPs in implementing

evidence-based health promotion and disease prevention recommendations in primary care. Although GPs believe in prevention and health promotion activities, about 56% of them find such activities difficult to carry out, mainly for heavy workload/lack of time and no reimbursement.

Presently, the cardiovascular risk assessment is scarcely known and used, despite recommendations from the Ministry of Health to assess cardiovascular risk for statins reimbursement in primary prevention when there are no indication for family history as laid down in AIFA Note 13;[10,11] according to the Italian PASSI study,[19] only 7% of eligible persons aged 40–69 years underwent risk assessment. This may be due to the fact that little time has passed since cardiovascular risk assessment was introduced into clinical practice and GPs agreed to participate in a surveillance system for cardiovascular risk assessment included in a national training plan.

In addition, new collected data on cardiovascular risk factors and cardiovascular risk may be relevant for the contribution of the Italian cohorts of the Progetto CUORE.[2–4] As demonstrated in a comparison study between CUORE and SCORE mortality risk charts, the SCORE charts reflect quite well the Italian cardiovascular mortality, and, correspondingly, Italian cohorts of the CUORE project are quite representative of European countries at low risk for cardiovascular mortality.[5,20]

The last module of the national training plan on the use and application of cardiovascular risk chart[7] foresees discussion of CRO results with health operators at regional, sanitary district, and/or GPs' association levels. The discussion of the collected data, already started in some regions, may play a major role in the identification of strengths and weaknesses of preventive action and represents the first step to improve good clinical practice standards.

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Conflict of interest

None.

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