Cardiovascular risk profile evolution over 15 years: comparison between CV-PREVITAL Trial and Moli-sani Study participants

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ABSTRACT

Fifteen years elapsed between two surveys of cardiovascular (CV) risk factors in the same Italian region. Modifiable CV risk profiles were compared among 2,199 individuals enrolled in the CV-PREVITAL trial (2022-2024) at IRCCS Neuromed with those of 16,656 participants from the Moli-sani Study (2005-2010), matched for age and absence of prior CV disease. The Moli-sani Risk Score is a validated algorithm incorporating nine common modifiable risk factors measured overall risk. Most individual risk factors were more favorable in CV-PREVITAL compared with Moli-sani participants, besides hypertension in men and glucose levels in women. Relative fat mass was similar in both cohorts. Men in CV-PREVITAL had a mean Moli-sani Risk Score 4.8 points lower than Moli-sani men; women showed a 4.5-point reduction. These findings suggest a meaningful decline in modifiable CV risk over a 15-year interval, potentially reflecting enhanced prevention awareness, improved therapeutic efficacy, and cumulative effects of long-term public health communication.

Key words: cardiovascular risk; epidemiology; cohort study.

Introduction

Cardiovascular (CV) disease remains the leading cause of death in developed countries, yet the condition is largely preventable.[1] More than 90% of CV events can be ascribed to modifiable risk factors, including smoking, diet, physical activity, obesity, lipid profile, blood pressure, and glycemic control.[2] Prevention strategies targeting these factors have the potential to substantially reduce disease burden, but effectiveness depends on sustained population-level behavior change and improved medical management.[3]

The Moli-sani Study, conducted between 2005 and 2010 in the Molise region of south-central Italy, enrolled over 24,000 participants and established a comprehensive profile of cardiovascular risk in an Italian population.[4] From this cohort, a weighted risk algorithm was developed, the Moli-sani Risk Score, which quantifies the combined impact of nine modifiable risk factors on the probability of fatal or nonfatal cardiovascular events.[5]

Fifteen years later, the CV-PREVITAL trial began enrolling participants in the same geographic region.[6] The trial represents a new opportunity to assess whether CV risk profiles have shifted during this interval. By comparing risk factor distribution in the newer CV-PREVITAL Neuromed cohort with a matched subset of the original Moli-sani participants, we can detect temporal trends in modifiable risk while controlling for measurement procedures, population characteristics, and regional context. Such comparisons are valuable for understanding whether public health communication, improved medications, or behavioral shifts have produced detectable changes in population risk.[7]

Methods

Study populations

The Moli-sani Study is a population-based cohort enrolled in 2005-2010 in the Molise region, Italy. Extensive information on the Moli-sani Study has been reported elsewhere.[4,5] From the original 24,325 participants, we selected 16,656 individuals aged 45 years or older without prior CV disease for the derivation of the Moli-sani Risk Score. To enhance comparability with the CV-PREVITAL cohort recruited from the same region, we identified a subset of Moli-sani participants in the same age range and, as in CV-PREVITAL, without prior cardiovascular disease, yielding 7,872 men and 8,784 women for comparison.

The CV-PREVITAL Study is a multicenter, prospective, randomized controlled trial sponsored by the Italian Ministry of Health and designed to evaluate the effectiveness of mobile health intervention in primary CV prevention.[6] At the IRCCS Neuromed recruitment center in Pozzilli (Isernia) 2,268 individuals aged 45 years or older, apparently free of CV disease, were enrolled between October 2022 and February 2024. For the present analysis, we retained 2,199 participants with complete baseline data.

Risk factor assessment

Both studies measured the same core variables using standardized procedures. Smoking was assessed by questionnaire and expressed as number of cigarettes daily. Mediterranean diet adherence was evaluated using validated food frequency questionnaires adapted to the Italian context.[8] Lipid fractions (LDL, HDL, triglycerides) and glucose were measured in fasting blood samples. Blood pressure was recorded using calibrated devices,

and mean arterial pressure was calculated.[9] Relative fat mass was computed from height, waist circumference, and sex using a validated formula.[10]

The primary outcome measure was the Moli-sani Risk Score, a validated weighted algorithm incorporating nine modifiable CV risk factors: smoking, Mediterranean diet adherence, LDL cholesterol, HDL cholesterol, triglycerides, mean arterial pressure, glucose, leisure-time physical activity, and relative fat mass. The score was standardized so that a one-point change in the score corresponds to the CV risk equivalent of one year of age at baseline.[5]

Statistics

Baseline characteristics are presented separately by sex, with means and standard errors adjusted for age. Comparisons between Moli-sani and CV-PREVITAL Neuromed cohorts used age-adjusted analysis of covariance for continuous variables and logistic regression for categorical outcomes. All analyses were conducted using SAS 9.4.

Results

Men

Among men, the CV-PREVITAL cohort (n=987) was comparable in age with the Moli-sani subset (n=7,872), with mean ages of 58.6 and 59.5 years, respectively (Table 1). Smoking prevalence was notably lower in CV-PREVITAL: 16.8% *vs* 24.5% in Moli-sani, with smokers in the recent cohort reporting fewer cigarettes (14.7 *vs* 16.8 daily). Mediterranean diet adherence improved from 4.6 to 5.2 points. Lipid profiles shifted favorably: LDL cholesterol decreased from 130 to 118 mg/dL, and

Table 1. Characteristics of individuals in Moli-sani or in CV-PREVITAL (Neuromed center of recruitment) cohorts.

	Men				Women			
	Moli-sani (n=7,872)		CV-PREVITAL Neuromed (n=987)		Moli-sani (n=8,784)		CV-PREVITAL Neuromed (n=1,212)	
	Mean or number	SEM or %	Mean or number	SEM or %	Mean or number	SEM or %	Mean or number	SEM or %
Years of recruitment	2005-2010		2022-2024		2005-2010		2022-2024	
Age (years)	59.5	0.1	58.6	0.3	59.1	0.1	57.5	0.2
Diabetes	1123	14.3%	56	5.7%	657	7.5%	58	4.8%
Hypertension*	2352	29.9%	375	38.0%	2893	32.9%	326	26.9%
Components of the Moli-sani Risk Score								
Smokers	1931	24.5%	166	16.8%	1676	19.1%	181	14.9%
No. of cigarettes in smokers	16.8	0.2	14.7	0.7	10.9	0.2	12.2	0.5
Mediterranean Diet adherence (points)	4.6	0.1	5.2	0.1	4.3	0.1	5.8	0.1
LDL cholesterol (mg/dL)	130	0.4	118	1	136	0.4	121	1
HDL cholesterol (mg/dL)	52.3	0.1	53.5	0.4	62.7	0.2	64.0	0.4
Triglycerides (mg/dL)	150	1	122	2	119	0.7	105	2
Mean arterial pressure (mmHg)	105.3	0.1	97.2	0.3	102.0	0.1	92.3	0.3
Glucose (mg/dL)	107	0.3	103	1	98	0.2	104	1
Relative fat mass (%)	29.4	0.1	29.4	0.1	42.4	0.1	41.9	0.1
Moli-sani Risk Score (points)	-2.3	0.1	-7.1	0.2	-2.9	0.1	-7.4	0.2

*Pharmacologically treated for hypertension. Means are adjusted for age (continuous) within each cohort and sex.

triglycerides dropped from 150 to 122 mg/dL, while HDL cholesterol remained essentially stable. Additionally, mean arterial pressure declined substantially, from 105 to 97 mmHg and blood glucose fell from 107 to 103 mg/dL. Relative fat mass showed no meaningful change (29.4% in both groups).

The mean Moli-sani Risk Score decreased from -2.3 in Moli-sani to -7.1 points in CV-PREVITAL, a difference of 4.8 (95%CI: 4.4 to 5.2) points (Table 1).

Women

Among women, the CV-PREVITAL cohort (n=1,212) and the Moli-sani subset (n=8,784) had mean ages of 57.5 and 59.1 years, smoking prevalence fell from 19.1% to 14.9% and Mediterranean diet adherence improved from 4.3 to 5.8 points (Table 1). LDL cholesterol decreased from 136 to 121 mg/dL, HDL cholesterol rose modestly from 63 to 64 mg/dL and triglycerides fell from 119 to 105 mg/dL. Mean arterial pressure declined from 102 to 92 mmHg. Contrary to the trend in men, blood glucose increased in women: from 98 in Moli-sani to 104 mg/dL in CV-PREVITAL. Relative fat mass remained stable.

The Moli-sani Risk Score decreased from -2.9 in Moli-sani to -7.4 points in CV-PREVITAL, indicating a 4.5-point reduction (95%CI: 4.1 to 4.9).

When comparing the cohorts within the same five 10-year age strata, the Moli-sani Risk Score remained consistently lower in CV-PREVITAL by roughly 4-6 points in both men and women, with no clear age-related differences (*data not shown*).

Discussion

This comparison reveals a substantial and broad-based improvement in modifiable CV risk profiles across a 15-years interval. The consistency of improvement in both men and women, across age strata, and for most individual risk factors and the aggregate Moli-sani Risk Score, suggests genuine population-level shifts rather than random variation.

The most striking findings are the reductions in smoking prevalence, blood pressure, and LDL cholesterol. These align with documented secular trends in many developed countries and likely reflect multiple overlapping factors.[11] Enhanced public awareness of smoking-related CV risk, combined with tobacco control policies and greater availability of cessation aids, has contributed to declining smoking rates.[12] Antihypertensive medications have become more effective, their use and prescription has notably improved in the last years, and there is growing awareness of target blood pressure goals.[13] Statin therapy has become standard for many individuals,[14] contributing to lower LDL cholesterol population-wide.[15]

The improvement in Mediterranean diet adherence is noteworthy and was more pronounced in women. This may reflect increased media emphasis on Mediterranean-style eating, greater availability of traditional foods, and public health campaigns specifically promoting Mediterranean diet patterns.[16] Body weight remained stable across both cohorts despite the marked improvement in Mediterranean diet adherence, especially among women. This is striking because better diet quality did not translate into weight loss.[17] The likely explanation involves counteracting dietary trends, particularly the growing consumption of ultra-processed foods. These foods, high in calories but low in nutritional value, can offset the benefits of Mediterranean diet adoption when it comes to weight control.[18] This suggests that the CV improvements that we observed came mainly from pharmacological interventions, better blood pressure control, and improved diet quality itself, rather than from weight reduction.

An unexpected finding was the rise in glucose levels among women. This may reflect differences between cohorts in fasting state, timing of glucose measurement (fasting glucose in Moli-sani *vs* glycated hemoglobin converted to mean glucose in CV-PREVITAL), or true population-level increases in glycemic burden.

Most remarkably, the reduction in Moli-sani Risk Score of approximately 4.8 points in men and 4 to 5 points in women provides a synthetic measure of this progress. Since one point of the Moli-sani Risk Score is calibrated to the cardiovascular risk equivalent of one year of age, this 4.5-point decrease means that individuals in the CV-PREVITAL cohort present a modifiable risk profile roughly 4 to 5 years younger than their age-matched counterparts from 15 years prior. This slower aging of the modifiable risk profile likely reflects accumulated benefits of prevention efforts, improved therapeutics, and heightened awareness of cardiovascular risk factor management.

These findings deserve careful interpretation. The two cohorts were recruited from different geographic areas within the same region (the Campobasso province for Moli-sani; the Isernia province for CV-PREVITAL) and at different times. While both are drawn from similar populations with comparable recruitment methods and measurement standardization, unmeasured differences in population composition or socioeconomic factors could have contributed to observed differences.

The long-term Moli-sani Study itself may have had indirect effects on the regional prevention culture, promoting a better health and prevention awareness among citizens, which was achieved along the years through several public health dissemination events in the region. In fact, during and after recruitment, the research team conducted extensive community engagement activities, including the *'Campanili della Salute'* initiative (public meetings held in various municipalities to discuss cardiovascular prevention), meetings with senior citizen associations, and school-based educational programs (https://www.moli-sani.org). Participation in this large CV prevention study, combined with these outreach efforts, may have heightened awareness and motivated engagement with preventive behaviors in the broader community. Such effects are difficult to quantify but plausible, particularly in a relatively small region like Molise where multiple recruitment waves have occurred.

In conclusion, CV risk profiles in Southern Italy have improved substantially over 15 years, particularly for blood pressure, smoking, and lipid management. The broader context of improved prevention awareness, more effective therapeutic options, and possibly the legacy of major epidemiological studies appears to have produced meaningful population-level benefits.

Conference presentation

This work was preliminary presented at the XXVIII Congress of the Italian Society for the Study of Hemostasis and Thrombosis, SISET, Rome, November 2024.[17]

Acknowledgments

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Appendix

Moli-sani Study Investigators

The enrolment phase of the Moli-sani Study was conducted at the Research Laboratories of the Catholic University in Campobasso (Italy), the follow up of the Moli-sani cohort is being conducted at the Research Unit of Epidemiology and Prevention of the IRCCS Neuromed, Pozzilli, Italy.

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