Title page

**Title: Trend of cardiovascular risk factors in elder Iranian population:
2002-2014**

Short running title: CVD risk factors trends in elderly; TLGS

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Abstract and key words

Aim: Current study aims to investigate the sex-stratified secular trend of CVD risk factors among an elderly population in Iran during a median follow-up of 8.76 years.

Methods: A total of 1490 participants (733 women) aged ≥ 60 years were evaluated in four study phases of 2002-2005, 2005-2008, 2008-2011, and 2011-2014. The trends of CVD risk factors for each gender were estimated using generalized estimating equations.

Results: The age-adjusted prevalence of diabetes, hypertension, central obesity, and chronic kidney disease at the baseline was 24%, 43%, 55%, and 32% in men and 31%, 57%, 60% and 53% in women, respectively, and had noticeable upward trend during the study period to reach 35%, 56%, 61%, and 51% in men and 42%, 71%, 74%, and 67% in women, respectively. However, lipid profile parameters showed favorable trends. Despite increasing trend in drug consumption, approximately 27% of diabetic women and 37% of diabetic men did not use anti-diabetic medication, respectively; the results were 23% and 35% for hypertensive women and men, respectively. Among men, there was a decreasing trend towards low physical activity, from 40% at baseline to 26% at the most recent follow-up. The prevalence of smoking remained steady throughout follow-up.

Conclusions: Despite the benefits of lipid lowering, the status of other risk factor profiles are often sub-optimal in both genders. There remains much room for improvement in risk factors management, particularly for hypertension, smoking and adiposity status and a need for an intervention.

Keywords: Cardiovascular diseases; Geriatric medicine; Cohort study; Risk factors,
Secular trend.

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Text

Introduction

The world's elderly population has been increasing rapidly ¹. In addition, population age structures are expected to change dramatically over the forthcoming decades with elderly populations projected to constitute 21.1% of the total global population by 2050 ¹. Similarly, the Middle-East is going through an important health transition. Aging and population growth as well as improvements in life expectancy and other health indicators, will have a major influence on the region's health and resources, particularly among low- and middle-income countries such as Iran ². It is worth noting the high prevalence, morbidity and mortality of cardiovascular diseases (CVD) in general and elderly populations in Iran and the Middle-East ³⁻⁶.

Many studies have shown trends in CVD risk factors in general populations in most regions of the world, but there are few studies in elderly populations ⁷. It is therefore difficult to generalize the efficacy of preventive programs to this group. Thus, the objective of the present study was to investigate sex-stratified secular trends of traditional CVD risk factors (i.e. general and central adiposity, hypertension, diabetes, chronic kidney disease, hyperlipidemia, low physical activity, and smoking) among an elderly population in a large community-based longitudinal study of a Middle-East population, the Tehran Lipid and Glucose Study (TLGS).

Methods

Study Subjects

Detailed descriptions of TLGS and data collection methods have been reported elsewhere⁸. Briefly, TLGS is a community-based prospective cohort study conducted on a representative sample of Tehran, the capital city of Iran. A multi-stage stratified cluster random sampling technique was used to select more than 15000 people aged over three years from urban district #13 of Tehran. The sampling frame was chosen from the urban district #13 of Tehran for two important reasons 1) the stability of the population residing in that district is high 2) the age distribution of the population of district #13 is representative of the overall population of Tehran. Data collection was started in 1999-2001 (phase 1) and is ongoing on a triennial basis, designed to continue for at least 20 years. In the current study, data of participants who participated in phase 2 (2002-2005) were used. From total of 1754 individuals aged ≥ 60 years at the examination date of phase 2, 264 participants without any follow-up were excluded. The remaining 1490 participants with at least 1 follow-up were included in the analyses. Hence, 84.9% of eligible baseline participants (1490/1754) were included in the current study. All subjects filled a written consent after being informed about the general aspects of the work and the study was approved by the Ethical Committee of Research Institute for Endocrine Sciences. A summary of clinical and laboratory measurements (i.e. general information, medical history, physical activity, anthropometrics, blood pressure, biomarkers) has been reported

in Supplementary File 1. Moreover, the definitions of terms were summarized in Table 1 as well as Supplementary File 1.

Statistical Analyses

The baseline characteristics of participants were reported as mean (standard deviation (SD)) for numerical variables and frequency (%) for categorical measures. Comparison of baseline characteristics between men and women were performed by Chi-square test for categorical variables and Student's t-test for continuous variables. As triglyceride (TG) levels had a log-normal distribution, the mean (SD) of natural logarithm of TG level at baseline examination was summarized and compared by Student's t-test.

To assess the secular longitudinal trends of continuous variables that are fasting plasma glucose (FPG), high-density lipoproteins (HDL-C), TG, total cholesterol (TC), non-HDL-C, low-density lipoproteins (LDL-C), waist circumference (WC), waist-hip ratio (WHR), systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI) and estimated glomerular filtration rate (eGFR) and dichotomous variables that are diabetes, low HDL-C, hypertriglyceridemia, high non-HDL-C, high LDL-C, hypertension, general and central obesity, current smoking, chronic kidney disease (CKD), low physical activity, and medication consumption, linear and logistic generalized estimating equation (GEE) models with an exchangeable working correlation matrix and robust standard errors were fitted, respectively. The trends for glucose lowering and anti-hypertensive medications were assessed in diabetic and hypertensive sub-samples, respectively, while the secular

trends for lipid lowering medications was reported in whole sample size. Models for assessment of time trend were fitted separately for men and women and age-adjusted marginal means and p-values for trend were reported. The effect modification of gender on the trend of risk factors was tested by fitting a model including gender, the risk factor, and their cross-product in a pooled model including both genders. P-values for interaction were calculated using the Wald test.

All analyses were performed using Stata statistical software (version 12 SE). P-values < 0.05 were considered significant.

Results

A total of 757 men and 733 women, aged 68.3 (SD: 5.7) and 66.3 (5.0) years at baseline (2002-2005), respectively, were followed-up until 2011-2014. The median period of follow-up was 8.76 years (inter-quartile range: 7.46-9.70 years). Baseline characteristics of participants are shown in Table 2 by gender. Women had higher FPG, HDL-C, TG, TC, non-HDL-C, LDL-C, WC, BMI, SBP and DBP level at baseline examination; however, they were younger and had lower smoking rates. The baseline characteristics of the respondents and non-respondents are compared in Supplementary Table 1. Generally, there was no clinically major difference between respondents and non-respondents.

Figure 1 shows age-adjusted trends of anthropometrics, blood pressure measures as well as lipid and glucose profiles of participants by gender. The population average serum level of FPG, HDL-C, WC, WHR, DBP and BMI increased significantly in both genders.

On the other hand, participants' TG, TC, non-HDL-C, LDL-C, eGFR decreased significantly at the same period. The SBP remained almost steady in both genders along the study period.

Figure 2 shows the secular trends in age-adjusted prevalence of CVD risk factors (dichotomous risk factors) in both genders. The age-adjusted prevalence of diabetes, hypertension, central obesity, and CKD had noticeable upward trend during the study period in both genders. The increasing trend for obesity was more prominent in women (p-value: 0.001). On the other hand, lipid disorders in both genders and low physical activity in men showed a downward trend. The age-adjusted prevalence of low HDL-C, hypertriglyceridemia, high non-HDL-C, and high LDL-C had decreasing trends in both genders. The decreasing trends in high non-HDL-C and high LDL-C were more prominent in women. While the age-adjusted prevalence of low physical activity decreased from 40% to 26% in men, it remained almost steady in women with the prevalence of almost 50% during the study period.

Table 3 shows the crude and age-adjusted secular trend of drug consumption. In hypertensive and diabetic patients, there were increasing trends in anti-hypertensive and glucose lowering drugs' consumption during the study. The increasing trend in anti-hypertensive drug consumption was more prominent in men. The lipid lowering drugs consumption showed more prominent increasing trends from 4% in men and 10% in women at baseline to 26% and 41% at the latest follow-up.

For sensitivity analysis, we repeated the GEE analyses in the CVD-free participants (N=1023). The results were similar after exclusion of those with prevalent/incident CVD cases.

Discussion

Our study provides valuable evidence regarding the secular trends of cardiovascular diseases risk factors over the last decade in the elderly in a high risk and under-studied Middle-Eastern population. Our results showed that not only did the elderly population have very high levels of CVD risk factors at baseline, but also, over the period of a decade, dramatic increasing trends of CVD risk factors including general and central adiposity, hypertension, diabetes and CKD were observed in both genders. Conversely, a favorable trend was shown for lipid profile parameters in both genders and low physical activity in men. The prevalence of smoking among the study population remained steady throughout follow-up. During the same period, the rate of medication consumption increased significantly in both genders. This increase was more prominent for lipid lowering medications.

Regarding obesity status, significant increases in the rate of general and central adiposity were observed in both genders. In fact, in 2014 (phase 5) more than 70% of women and 60% of men showed a central adiposity phenotype. Importantly, the rate of central adiposity was more prominent among women than men. A meta-analysis conducted among 209166 Iranian individuals showed the trend of obesity was similar in both genders;

however, women had almost a constantly higher risk of obesity than men during the recent two decades ⁹. Obesity among this elderly population was generally associated with higher mortality and morbidity and poorer quality of life ¹⁰. In our recent study, we showed that in the elderly population, the central adiposity measures confer a significant risk for CVD events ¹¹. Hence, as acknowledged by the American Society for Nutrition, weight-loss therapy should be advised among the older members of the Iranian population who are obese and have functional impairments or metabolic complications, with the aim of minimizing muscle and bone losses ¹⁰.

Our results revealed increasing trends in prevalence of diabetes in both genders in the elderly. These results are in line with global diabetes trends, which have increased steadily in developing and developed countries since the 1950s ¹². The prevalence of type 2 diabetes is estimated to increase by 55% worldwide at an alarming pace in developing countries by 2035 ¹². The obesity and aging were suggested as the main drivers of the rising trend of type 2 diabetes ¹². Despite the emphasis of international guidelines for commencement of metformin at the same time as lifestyle management at the time of the diagnosis of type 2 diabetes ¹³, about 27% of diabetic women and 37% of diabetic men did not use any anti-diabetic medication at the end of follow-up in this population.

Our finding of high and increasing prevalence of hypertension in this elderly population is in line with previous studies in Iran and National data ^{14, 15}. In our recent study, hypertension was found to be the most powerful mediator of central obesity for CVD

events in the elderly population, accounting for 30–45% of the excess risk¹¹. In eight trials including 15693 elderly patients with isolated systolic hypertension, active treatment reduced total mortality by 13%, cardiovascular mortality by 18%, all cardiovascular complications by 26%, stroke by 30%, and coronary events by 23%¹⁶. There is ample amount of evidence that dietary salt intake is the main driver of hypertension and that a decrease in salt intake leads to a decrease in the blood pressure and, in turn, the CVD risk¹⁷. According to world health organization (WHO) technical report, daily salt intake should be less than 5 g (equivalent to about two grams of sodium); however, based on the per capita amount of salt production in the country, experts believe that the average amount of salt consumed in the country is about 10-15g per day¹⁷. Moreover, unfortunately, 23% and 35% of hypertensive women and men, respectively, were not receiving any anti-hypertensive medication at the end of the study.

Similar to the general Iranian population, a favorable trend for lipid profiles was shown among Tehranian elderly population¹⁸ that might be attributable to a significant increase in rate of lipid lowering medication consumption. Given the dyslipidemia is prevalent in the Iranian population¹⁹, diagnosis and treatment of the dyslipidemia has been one of the main goals of healthcare system in Iran. Moreover, results from last decade studies showed that Iranians consumed high level of fat, most of which was trans-fatty acids¹⁹. Therefore, government started extended national plans for replacement of trans-fatty acids with unsaturated fats. Our results might be the results of those national plans. In the current

study we used the traditionally recommended cutoff value of serum LDL-C to classify our population ²⁰. However, the American Heart Association and American Stroke Association (ACC/AHA) recommendation on statins for primary prevention for patients between 40 and 75 years does not recommend any target for lipid profile value ²¹. Furthermore, there is no recommendation for elderly adults aged ≥ 75 years due to the few clinical trials for this age group ²¹.

Despite the efforts to ban smoking in public places, smoking did not decrease over the study period in our elderly population. This finding is in contrast with declining trend of smoking globally ²². Recent meta-analysis of 25 cohort study consisted of 503905 participants over 60 years showed that not only smoking is a major independent risk factor of cardiovascular events and increases CVD mortality, but also smoking cessation in elderly is beneficial in reducing the excess risk ²³.

Regarding CKD, our data analysis confirmed a rising and similar trends in both genders, importantly in 2014 about 67% and 51% of our women and men, respectively, suffered from CKD. The prevalence of CKD increased with age globally. A sex difference in the prevalence of CKD with aging was reported ²⁴. A systematic-analysis of world-wide population-based data on the global burden of chronic kidney disease from 2010 showed that, in low- and middle-income countries, CKD was more prevalent among women than men (13.1% vs.9.7%) in the 60-69 year age group ²⁴. In a collaborative meta-analysis,

Matsushita et al. showed hazardous risk of lower eGFR was a predictor for total and CVD mortality among population aged less or more than 65 years²⁵.

The effect of physical activity on CVD outcome in the elderly is not consistent. Some data suggested that physical activity in this age group has a hazardous effect and declared that physical activity may trigger sudden death especially in people who do not exercise regularly²⁶; in contrast among Japanese elderly physical activity was shown to have a protective effect on CVD mortality in both healthy and those with preexisting disease²⁷. In our data analysis, we showed a favorable trend in the level of physical activity only among elder men that might potentially translate to a better outcome. According to the Iran's national surveys conducted on 2007 and 2011, Iranian population, particularly women, have become less active. Furthermore, work-related activity was dramatically decreased in women²⁸.

Our results regarding the prevalence and trend of CVD risk factors were considerably different between two genders. Difference in the prevalence and the trend of the CVD risk factors between men and women was also shown in our previous studies in the same population^{18, 29}. Such differences should be interpreted considering both physiological and health-related behaviors differences between genders. It has been suggested that the health-related behaviors of a population are heavily influenced by the historical context of communities and cultural norms³⁰. In a study in INTERHEART global case-control study

including 27098 participants from 52 countries by Anand et. al.³⁰, it was found that the differences between genders in age of first myocardial infarction is largely explained by the higher risk factor levels at younger ages rather than sex-related physiological differences.

Our study does however have some limitations; first, the actual burden of measured risk factors in the community might be underestimated since inclusion of subjects in a cohort study can increase the level of attention they pay to controlling their health risks (cohort effect). Second, our study design is prone to the survival bias as the subjects with very high levels of risk factors could be lost in subsequent phases due to death from CVD events or non-CVD causes. However, our results remained essentially unchanged, when we excluded prevalent/incident cases of CVD. Finally, our results cannot be directly extrapolated to other populations because it was conducted among ethnically homogenous, elderly Iranian population.

In conclusion, this study shows that among an elderly Iranian population, along almost a decade of follow-up, lipid parameters including high LDL-C, high TG and low HDL-C had most decreasing trend; while, the trend of diabetes, CKD, hypertension, general and central obesity were increasing and no improvement was shown for smoking cessation. The level of physical activity was improved only among men. Despite increasing trends in drug consumption, still about 27% of diabetic women and 37% of diabetic men did not use anti-

diabetic medication; the results were 23% and 35% for hypertensive women and men, respectively. Hence, despite the benefits of lipid lowering, the status of other risk factor profiles are often sub-optimal. There remains much room for improvement in risk factor management particularly for hypertension, smoking and central adiposity status and a need for an intervention.

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Disclosure statement

The authors declare no conflict of interest.

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Figure legends

Figure 1 title: The secular trends of anthropometrics, blood pressure measures and lipid and glucose profiles by gender; Tehran Lipid and Glucose Study (2002-2014)

Figure 1 Legend:

Models for assessment of time trend were fitted separately for men and women and age-adjusted marginal means and p-values for trend were reported. The effect modification of gender on the trend of risk factors was tested by fitting a model including gender, the risk factor, and their cross-product in a pooled model including both genders. P-values for interaction were calculated using the Wald test.

FPG, fasting plasma glucose; HDL-C, high-density lipoprotein cholesterol; TC, total cholesterol; non-HDL-C, non-high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; WC, waist circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; BMI, body mass index; WHR, Weight to hip circumference; eGFR, estimated glomerular filtration rate.

Formula for calculating LDL-C values as follows: $\text{LDL-C (mg/dl)} = \text{non-HDL-C} \times 90\% - \text{TG} \times 10\%$

Figure 2 title: The secular trends of CVD risk factors by gender; Tehran Lipid and Glucose Study (2002-2014)

Figure 2 Legend: Models for assessment of time trend were fitted separately for men and women and age-adjusted marginal means and p-values for trend were reported. The effect modification of gender on the trend of risk factors was tested by fitting a model including gender, the risk factor, and their cross-product in a pooled model including both genders. P-values for interaction were calculated using the Wald test.

Hypertension was defined as ,SBP $\geq$ 140 mmHg or DBP $\geq$ 90 mmHg or using anti-hypertensive medication; diabetes as FPG $\geq$ 7 mmol/L, or 2h-PCPG $\geq$ 11.1 mmol/L or taking anti-diabetic medication, high LDL-C as $\geq$ 3.37 mmol/L, high non-HDL-C as $\geq$ 4.14 mmol/L ,low HDL-C as $\leq$ 1.04 mmol/L for men and $\leq$ 1.29 mmol/L for women, high triglycerides as $\geq$ 1.69 mmol/L; central obesity as waist circumference $\geq$ 95 cm; general obesity as BMI $\geq$ 30 kg/m², physical inactivity <600 metabolic equivalent task-minutes per week, Chronic kidney disease as eGFR<60 mL/min/1.73m².

SBP, systolic blood pressure; DBP, diastolic blood pressure; FPG, fasting plasma glucose; 2h-PCPG, 2-hour post challenge plasma glucose; LDL-C, low-density lipoprotein cholesterol; non-HDL-C, non-high-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; BMI, body mass index; eGFR, estimated glomerular filtration rate.

Supplementary File legends

Supplementary File 1

Supplementary File 1 title: clinical/laboratory measurements and definitions of terms.

Supplementary Table 1

Supplementary Table 1 title: Baseline characteristics of respondents and non-respondents.

Table 1. Definition of terms

Definitions	
Diabetes	fasting plasma glucose ≥ 7 mmol/L (126 mg/dl), or 2-hour post-challenge plasma glucose ≥ 11.1 mmol/L (200mg/dl) or taking anti-diabetic medication
Hypertension	Systolic blood pressure ≥ 140 mmHg or diastolic blood pressure of ≥ 90 mmHg or any use of antihypertensive medication
Low HDL-C	HDL-C serum value < 1.03 mmol/L (40mg/dL) and < 1.29 mmol/L (50mg/dL) for men and women, respectively
Hypertriglyceridemia	Triglycerides ≥ 1.69 mmol/L (150mg/dL)
High Non-HDL-C	The Non-HDL-C serum value ≥ 4.14 mmol/L (160 mg/dL).
High LDL-C	The LDL-C serum value ≥ 3.37 mmol/L (130mg/dL).
Chronic kidney disease	Estimated glomerular filtration rate (eGFR) was estimated according to the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. CKD was defined estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73m ²
General obesity	Body mass index ≥ 30 kg/m ²
Central obesity	Waist circumference ≥ 95 cm
Current smoking	'Current smoker' is someone who has smoked in the last 28 days
Physically inactive	Not achieving a minimum of 600 MET (metabolic equivalent task) per week
Cardiovascular Diseases	Compound measure of coronary heart disease (CHD) (i.e. definite myocardial infarction, unstable angina pectoris, probable myocardial infarction, angiography proven CHD among those with acute coronary syndrome and CHD death) events, stroke, or cerebrovascular death based on the outcome committee decision.

HDL-C, High-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol

Table 2. Baseline characteristics for participants by gender[†]

Characteristics	Men (n=757)	Women (n=733)	P value	Total (n=1490)
Age (year)	68.34(5.65)	66.32(4.97)	<0.001	67.35(5.43)
FPG (mmol/L)	5.98(2.05)	6.33(2.42)	0.003	6.16(2.25)
HDL-C (mmol/L)	0.95 (0.24)	1.09(0.26)	<0.001	1.02(0.26)
Natural logarithm of TG	0.61 (0.55)	0.74 (0.50)	<0.001	0.68 (0.53)
TC (mmol/L)	5.11(0.93)	5.79(1.10)	<0.001	5.45(1.08)
Non-HDL-C (mmol/L)	4.16(0.91)	4.69(1.10)	<0.001	4.43(1.04)
LDL-C (mmol/L) [‡]	3.32(0.76)	3.73(0.90)	<0.001	3.52(0.85)
WC (cm)	95.99(10.42)	97.76(10.47)	0.001	96.85(10.48)
SBP (mmHg)	132.51(20.41)	134.11(21.33)	0.142	133.30(20.88)
DBP (mmHg)	76.81(11.73)	77.87(10.57)	0.071	77.33(11.19)
BMI (kg/m ²)	26.33(3.96)	29.43(4.44)	<0.001	27.84(4.48)
Smoking, No. (%)	126(16.87)	34(4.68)	<0.001	160(10.85)

[†] values are presented as mean (SD) unless otherwise indicated.

[‡] formula for calculating LDL-C values as follows: LDL-C (mg/dl) = Non-HDL-C* 90% - TG *10%

FPG, fasting plasma glucose; HDL-C, high-density lipoprotein cholesterol; TG, triglycerides; TC, total cholesterol; Non-HDL-C, non-high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; WC, waist circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; BMI, body mass index

Table 3. The crude and age-adjusted secular trend of drug consumption by gender

Type of medication		Phase 2 (2002-2005)	Phase 3 (2005-2008)	Phase 4 (2008-2011)	Phase 5 (2011-2014)	P for trend	P for interaction
<i>Absolute prevalence</i>							
Glucose-lowering [†]	Men	83/173	90/165	98/181	99/170		
	Women	118/203	126/198	153/217	140/192		
Anti-hypertensive [†]	Men	120/310	66/289	182/332	210/315		
	Women	251/390	124/295	304/410	301/387		
Lipid-lowering [‡]	Men	35/757	51/676	93/627	119/544		
	Women	86/733	121/677	192/632	202/539		
<i>Adjusted prevalence</i>							
Glucose-lowering [†]	Men	32.89	42.19	48.69	62.94	<0.001	0.263
	Women	46.74	54.66	66.55	72.88	<0.001	
Anti-hypertensive [†]	Men	35.90	21.43	51.86	65.23	<0.001	0.028
	Women	60.05	39.88	72.67	77.38	<0.001	
Lipid-lowering [‡]	Men	4.18	7.52	16.18	26.35	<0.001	0.214
	Women	10.00	16.52	30.82	41.01	<0.001	

† The trends for glucose lowering and anti-hypertensive medications were reported in only diabetic and hypertensive sub-samples, respectively

‡ The trend for lipid lowering medication was reported in whole sample size.

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