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ABSTRACT

Background: Considering the high prevalence of lipid disorders in Iran and the confirmed relationship of this risk factor with cardiovascular diseases, the classification of people based on this risk factor has found a special place in preventing cardiovascular events. This study was designed to investigate the prevalence of dyslipidemia according to ESC2019 in the Shiraz Cohort Heart Study (SCHS).

Methods: Data of this cross-sectional study is extracted from the SCHS which is a 10 year long, cardiovascular-oriented, prospective cohort study that was conducted on 7,260 participants aged 40-70 to investigate cardiovascular risk factors in the metropolis of Shiraz. The outcome measured in this study is the LDL-C level based on the ESC2019 target guidelines.

Results: Men were more common in the moderate-risk and very high-risk group (1459 (68.9%) and 669 (59.6%), respectively). Results in the uncontrolled and controlled LDL-C groups were differentiated according to gender. Different risk groups and subgroups that had LDL-C higher than the normal limit showed the most significant findings in the high-risk groups with differences that were significant (P-value= 0.001). Although there were differences in the low-risk, moderate-risk, and very high-risk group but they were not significant (p=0.229, p=0.376 and p=0.540, respectively).

Conclusion: This study found that in the high-risk group, women had a significantly higher risk of dyslipidemia than men. However, in the very high-risk group, the results were seen in reverse. Therefore, results clearly showed gender difference in each risk group related to the type of risk.

Keywords: Dyslipidemia; LDL-C; ESC2019 guidelines; Iran

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INTRODUCTION

Coronary heart disease (CHD) is one of the major causes of death in most countries including Iran [1]. According to the reports of the World Health Organization, it is estimated that by 2030, about 22.2 million deaths will occur due to cardiovascular diseases (CVD), which has increased by about 19 million people compared to 2019 [2]. One of the risk factors of this disease is dyslipidemia, and it has been proven that the increase of certain types of plasma lipids leads to atherosclerosis of the coronary arteries [3]. Several risk factors for blood lipid disorders have been identified. These risk factors are increasing in today's developing societies [4].

One of the more important risk factors clearly defined as a risk for CVD is a disorder of the blood lipid profile known as dyslipidemia. Dyslipidemia is defined as an increase in total cholesterol (TC), low density lipoprotein cholesterol (LDL-C) and a decrease in high density lipoprotein cholesterol (HDL-C) [5].

Hypercholesterolemia is the most usual form of dyslipidemia and is associated with an increased risk of CVDs. An increase in the level of plasma LDL-C was the 15th leading risk factor for death in 1990, which reached the 11th rank in 2007 and the 8th rank in 2019 [6].

The prevalence of lipid disorders varies in different countries. The rate was 31.3% in Spain [7], 59% in America [8], 62.1% in China [9], 67.1% in Romania [10], and in India was 79% [11]. Research found that in Iran, this rate was 85.6% in the south [12], and 80.5% in the northwest of the country [13].

Considering the high prevalence of dyslipidemia in different societies and its confirmed risk for CVDs, determining the level of risk is particularly important for patient management. For this purpose, there are several guidelines for the classification of confirmed risk. One of these guidelines is the ESC2019 that provides different goals for LDL-C and non-HDL-C according to what risk factors are present in an individual [14].

In accordance with this guideline, in persons with a very high risk of CVD, the recommendation is to keep the LDL-C goal at less than 55mg/dl. People with a high CVD risk are recommended to have an LDL-C goal at less than 70 mg/dl and people with a moderate CVD risk, the recommended goal is to keep LDL-C levels less than 100 mg/dl. Finally, for those people who have a low risk for CVDs, an LDL-C goal at less than 116 mg/dL is recommended [15].

According to ESC2019 guidelines for LDL-C, Iran is not in the group of classified countries, and the classification of high-risk groups is based on other neighboring Middle East countries. Considering the high prevalence of lipid disorder in Iran and the confirmed relationship of these risk factors with CVDs, the classification of study subjects based upon the ESC2019 guideline is extremely important to reduce the risk of CVDs in Iran. Therefore, the aim of the study was designed and implemented to determine the prevalence of dyslipidemia, utilizing the ESC2019 guidelines for LDL-C, in the Shiraz population that participated in the SCHS study to identify specific risk factors contributing to the elevated levels of cardiovascular disease.

MATERIALS & METHODS

Study Population

This is a cross-sectional study utilizing the data collected on 7,260 participants in the Shiraz Cohort Heart Study (SCHS). The SCHS is a 10 year long, cardiovascular-oriented, prospective cohort study that is being conducted to investigate cardiovascular risk factors and incidence of cardiovascular events, mainly coronary heart disease, in the metropolis of Shiraz, Iran. The SCHS protocol, including the method of random selection of participants, as well as inclusion and exclusion criteria have been previously published [16].

Sample Size

The sample of this study is based on the information obtained from the SCHS. After monitoring and processing the data in the SCHS cohort study, all the subjects who met the inclusion criteria were used in this cross-sectional study. For this purpose, all the study participants whose laboratory tests were not available for any reason were excluded from the study population.

After screening and excluding participants according to the SCHS study protocols, all people under age 40 and above age 70 were excluded from the study population. At this stage, 7,260 subjects who met the inclusion criteria who were aged 40-70 years old remained in this cross-sectional study of the SCHS. These criteria included residency in the urban areas of Shiraz for at least the last year, and no intention to migrate to a place other than the Shiraz metropolis in the next few years. When participating in the study, they must declare their written consent along with their ink fingerprint and signature and their thorough readiness to complete all the contents of the questionnaire and perform all the tests and participate in the study.

The exclusion criteria were if participants refused to perform the required tests, lived far from the research center (to discourage dropouts), those with mental and physical disabilities who cannot answer questions or attend the research center. If people answered the questionnaire or interview that they had high blood pressure, diabetes or were taking medications for these disorders, they may be considered for the study.

Moreover, all subjects who were under 40 years old and older than 70 with underlying disease were excluded from the study population leaving 7,260 participants in this study.

Baseline Measurement

Initially, total serum cholesterol was measured after a 12 hour fast utilizing automated enzymatic methods standardized from the WHO Lipid Reference Center in Prague, Czech Republic. Blood pressure, weight and smoking status were recorded and used for analysis. Age was measured, using the difference between the year of examination and the year

of birth, accepting an average error of ± 6months. Relative body mass index (BMI) was calculated as a percent deviation of actual weight to standard weight based on mean of body weight distributions by height [16].

Classification of people at risk

In this study, based on the ESC2019 guidelines, patients were divided into the following categories:

Low-risk: subjects who are not included in other groups and their *Systematic Coronary Risk Evaluation* (SCORE) is <1 (equal to zero).

Moderate-risk: people with type-1 diabetes mellitus, type-2 diabetes mellitus (T1DM <35, T2DM <50) that lasted less than 10 years (including all subjects who have diabetes and are not in higher-risk groups), people whose SCORE is ≤5% and >1%.

High-risk: subjects with a total cholesterol >310 *mg/dl* and LDL >190 *mg/dl* or BP ≥180/110 *mm/Hg*, diabetic people without organ damage and diabetes for more than 10 years or with another risk factor (the risk factor includes one of the following: high blood pressure, blood fat (total cholesterol >200 *mg/dl*), tobacco use, moderate kidney damage (GFR 30-59 *ml/min*) and SCORE between 5-10%.

Very high-risk: subjects with prior CVDs such as cardiovascular and peripheral vessels, previous acute coronary syndrome (*ACS*), transient ischemic attack (*TIA*), stable angina, coronary artery bypass grafting (*CABG*), Percutaneous Coronary Intervention (*PCI*), arterial revascularization, stroke). In addition, diabetes with organ damage defined as follows: estimated Glomerular Filtration rate (eGFR) <60). Furthermore, a history of diabetic foot ulcer or diabetes with at least three major risk factors such as high blood pressure, blood fat (total cholesterol >200mg/dl), tobacco use, type-1 diabetes for more than 20 years, severe kidney failure with eGFR <30 and SCORE ≥10%

Statistical analysis

The baseline characteristics were presented as frequencies, mean ± SD, Chi-Square (χ^2) test was used to analyze with SPSS software-24. The level of significance in all tests was considered 0.05.

RESULTS

Table 1 shows the frequency distribution of demographic variables and disease history in the study participants. Among them, 47.7% were men and 52.3% were women. In terms of disease distribution, 0.2% had type-1 diabetes, 15.3% had type-2 diabetes. Moreover, 22.5% had high blood pressure, 28.7% had a history of high blood lipids, and 19.6% of all participants in the study were smokers. In addition, 5.9% had cardiovascular diseases.

Table 2 shows age, total cholesterol, LDL, HDL, and eGFR results in the study participants. Based on the findings, the mean and standard deviation of age was 51.82 ± 8.28 years. In addition, the mean and standard deviation of total cholesterol, LDL, HDL, eGFR variables were 190.28 ± 40.47, 108.62 ± 28.34, 47.05 ±10.58, and 66.82 ± 12.55, respectively.

Table 3 shows the distribution of the frequency of study subjects in different risk groups by gender, based on ESC2019 guidelines in SHCS study. In terms of risk groups according to gender, results identified that in the low-risk group, out of a total of 1,947 subjects, 23.7% (462) were men, and 76.3% (1,485) were women. In the moderate risk group, out of a total of 2,119 subjects, 68.9% (1,459) were men, and 31.1% (660) were women. In the high-risk group, out of a total of 2,072 subjects, 42.2% (874) were men and 57.8% (1,198) were women. In the very high-risk group, out of a total of 1,122 study subjects, 59.6% (669) were men, and 40.4% (453) were women.

Consequently, more women (3.2 times) compared to men were in the low-risk group. In the moderate-risk group there

Table 1: The Frequency of variables in different risk factors of study participants in Shiraz Cohort Heart Study

Cumulative Percent	Valid Percent	Percent	Number	Description	Variables
47.7	47.7	47.7	3464	Men	**Gender**
52.3	52.3	52.3	3796	Women	
0.2 0	0.2 0	0.2 0	15	Yes	**Type-1 Diabetes**
99.8	99.8	99.8	7245	No	
15.3	15.3	15.3	1113	Yes	**Type-2 Diabetes**
84.7	84.7	84.7	6147	No	
22.5	22.5	22.5	1630	Yes	**High Blood Pressure**
77.5	77.5	77.5	5630	No	
28.7	28.7	28.7	2086	Yes	**Lipid disorders**
71.3	71.3	71.3	5174	No	
19.6	19.6	19.6	1422	Yes	**Smoking**
80.4	80.4	80.4	5838	No	
5.9	5.9	5.9	427	Yes	**Cardiovascular Events**
94.1	94.1	94.1	6833	No	

Table 2: The mean and standard deviation of age, total cholesterol, HDL, LDL, and eGFR of study participants in Shiraz Cohort Heart Study

Standard deviation	Mean	Highest	Lowest	Total	
8.28	51.82	70.0	40.0	7260	**Age**
40.47	190.28	394.0	61.0	7260	**Total Cholesterol**
28.34	108.62	283.20	29.00	7260	**LDL**
10.58	47.05	122.0	18.0	7260	**HDL**
12.55	66.82	117.22	5.71	7260	**eGFR**
28.7	28.7	28.7	2086	Yes	**Lipid disorders**
71.3	71.3	71.3	5174	No	

Table 3: Different risk groups based on the ESC 2019 guideline by gender in the Shiraz Heart Cohort Study

Cumulative Percent	Valid Percent	Percent	Frequency	Gender	
23.7	23.7	23.7	462	Men	**Low risk**
76.3	76.3	76.3	1485	Women	
100.0	100.0	100.0	1947	Total	**(1947 subjects)**
68.9	68.9	68.9	1459	Men	**Moderate risk**
31.1	31.1	31.1	660	Women	
100.0	100.0	100.0	2119	Total	**(2119 subjects)**
42.2	42.2	42.2	874	Men	**High risk**
57.8	57.8	57.8	1198	Women	
100.0	100.0	100.0	2072	Total	**(2072 subjects)**
59.6	59.6	59.6	669	Men	**Very high risk**
40.4	40.4	40.4	453	Women	
100.0	100.0	100.0	1122	Total	**(1122 subjects)**

Table 4: Differentiation percentage and frequency of study subjects based on uncontrolled or controlled LDL-C by gender in low risk, moderate risk, high risk and very high-risk groups and total regardless of gender in Shiraz Cohort Heart Study

P-value	Total regardless of gender	Women	Men	LDL-C uncontrolled/controlled	Evaluation	Risk groups
0.229	100.0%	74.6%	25.4%	Based on the uncontrolled LDL-C	**Uncontrolled**	**Low risk (1947 Subjects)**
	32.8%	32.1%	35.1%	Based on gender		
	638	476	162	*Total* (Men & Women)		
	100.0%	77.1%	22.9%	Based on controlled LDL-C	**Controlled**	
	67.2%	67.9%	64.9%	Based on gender		
	1309	1009	300	*Total* (Men & Women)		
0.376	100.0%	31.9%	68.1%	Based on uncontrolled LDL-C	**Uncontrolled**	**Moderate risk (2119 subjects)**
	60.9%	62.3%	60.2%	Based on gender		
	1290	411	879	*Total* (Men & Women)		
	100.0%	30.0%	70.0%	Based on controlled LDL-C	**Controlled**	
	39.1%	37.7%	39.8%	Based on gender		
	829	659	170	*Total* (Men & Women)		
0.001	100.0%	58.8%	41.2%	Based on the uncontrolled LDL-C	**Uncontrolled**	**High risk (2072 subjects)**
	93.4%	95%	91.3%	Based on gender		
	1936	1138	798	*Total* (Men & Women)		
	100.0%	44.1%	55.9%	Based on controlled LDL-C	**Controlled**	
	6.6%	5.0%	8.7%	Based on gender		
	136	60	76	*Total* (Men & Women)		
0.540	100.0%	40.5%	59.5%	Based on the uncontrolled LDL-C	**Uncontrolled**	**Very high risk (1122 subjects)**
	97.0%	97.4%	96.7%	Based on gender		
	1088	441	647	*Total* (Men & Women)		
	100.0%	35.3%	64.7%	Based on controlled LDL-C	**Controlled**	
	3.0%	2.6%	3.3%	Based on gender		
	34	12	22	*Total* (Men & Women)		

were more men than women (2.2 times). In the high-risk group, there were more women than men (1.2 times). In the group of very high-risk individuals, the majority were men compared to women (1.5 times).

Table 4 shows more in-depth analysis of the uncontrolled and controlled LDL-C levels based on gender and different risk groups. From the low-risk groups 35.1% of men and 32.1% of women had LDL-C higher than the normal limit defined by ESC2019 guidelines. Regardless of gender the low-risk groups had a 32.8% higher LDL-C cholesterol higher than normal. However, differences of controlled LDL-C in this group related to gender was not significant (P-value=0.229).

From the moderate-risk groups 60.2% of men and 62.3% of women had LDL-C higher than the normal limit defined by ESC2019 guidelines. Regardless of gender, the moderate-risk groups had a 60.9% higher LDL-C cholesterol higher than normal. However, differences of controlled LDL-C in this group related to gender were not significant (P-value=0.376).

Significantly, in the high-risk groups 91.3% of men and 95.0% of women had LDL-C higher than the normal limit defined by ESC2019 guidelines. Based on gender the high-risk groups had a 93.4% higher LDL-C cholesterol higher than normal. Differences of the controlled LDL-C in this group related to gender were highly significant (P-value=0.001).

Finally, from the very high-risk groups 96.7% of men and 97.4% of women had LDL-C higher than the normal limit defined by ESC2019 guidelines. Regardless of gender, the low-risk groups had a 97% higher LDL-C cholesterol higher than normal. However, differences of controlled LDL-C in this group related to gender were not significant (P-value=0.540).

DISCUSSION

Dyslipidemia was found to be a major health problem in participants of the SCHS in the metropolis of Shiraz, Iran. The current study was designed and implemented with the aim of determining the prevalence of dyslipidemia according to the target set for the LDL-C level based on the ESC2019 guidelines findings of gender differences in the study results.

Moreover, in this study, even at different risk levels of LDL-C that were higher than the normal limit defined by the ESC2019 guidelines, there were some hazards for low risk, moderate risk, and very high-risk participants, but these were not significant. However, there was a highly significant gender difference for participants in the high-risk group, more women than men, for elevated levels of LDL-C according to the ESC2019 guidelines. Therefore, in general this analysis expressed study subjects that do not have control on their dyslipidemia in all these risk groups.

The findings of this study were compared to the results of studies such as Kim et al. [17], in which LDL-C in the very high and high-risk groups was poorly controlled in which a higher proportion of women (52.8%) were LDL-C goal non-achievers. Yang et al. [18], studied LDL-C goal attainment rates in high-risk patients and found that less 50% achieved their LDL-C goals and no gender differences in LDL-C control. Therefore, it should be noted that due to the differences in each risk group in terms of gender, at some point it is not possible to comment on which group is more at risk for dyslipidemia. However, in this regard all genders in the different risk groups had dyslipidemia. Thus, it is necessary to consider both groups with dyslipidemia as a health priority with some differences in risk. Consequently, the magnitude of LDL-C exposure, as well as the long-term exposure to persistently elevated LDL-C is recognized as a key contributor to a subject's atherosclerotic CVD risk.

In a 2020, cross-sectional study based on a baseline investigation of a population-based randomized controlled trial study by Minmin Wang et al. [19], involving 26,378 permanent residents of rural China age 45–69 years found that women exhibited a higher prevalence of dyslipidemia compared to men in several lipid parameters: Total cholesterol (TC) levels above 200 mg/dL; Triglycerides (TG) levels above 150 mg/dL; LDL-C levels above 130 mg/dL. However, women have a lower prevalence of low high-density lipoprotein cholesterol (HDL-C) (<40 mg/dL) compared to men. In LDL-C levels across age groups men tended to have higher median LDL-C values than women in their younger years (ages 20 to 59). Nevertheless, after midlife (age 60), women consistently exhibit higher LDL-C values compared to men.

However, in this study men had better control over their lipid profile than women in most cases. Only in the low-risk group, the control rate of women was better than that of men.

Considering the importance of the prevalence of dyslipidemia among studied subjects and the lack of control over the lipid profile, these results identified an alarming trend for the metropolis of Shiraz for the threat of CVD and the Iranian population in general. Therefore, due to the lack of previous solid data in the Shiraz metropolis for estimating LDL-C reduction rates, the findings of this study provide substantial scientific information to target these risk groups in a larger national cohort study in the future.

Consequently, focusing on screening, medication management, optimizing nutrition, increased physical activity, and positive lifestyle adjustments in patients with dyslipidemia are essential for primary prevention of CVD in the Shiraz population. In addition, sociocultural components of different genders may have an impact on atherosclerotic CVD risk.

Moreover, after comparing men to women in this study women need to do better at addressing improvements in their own healthcare needs. This is particularly true for those with more traditional roles, who may prioritize family, household, and caregiver responsibilities over their own health. On the other hand, men tend to have high degrees of work-related stress and tend to ignore their health needs until a significant health event occurs. Also, there is a suggestion that psychosocial stress may contribute to poor health outcomes and may be a reflection on a higher prevalence of low education, depression, and anxiety that contribute to CVD risk.

Moreover, the impact of possible lifestyle-related risk factors is disproportionately higher in women than in men. Additionally, adverse changes in weight, lipids, blood pressure, and glucose metabolism with menopause transition highlight potential accelerating cardiovascular risk. Women-specific risk factors, such as pregnancy-associated with dyslipidemia, should be considered to promote earlier ASCVD risk factor assessment.

It should also be noted that the control of lipid disorders in the population of Shiraz largely depends on the type of dominant culture. In the studied society, the traditional nutrition culture is based on fat and meat consumption which can be one of the possible reasons for the lack of control of lipid disorders in the SCHS population.

As a result, gender differences were identified related to risk factor patterns of LDL-dyslipidemia prevalence in persons aged 40-70 years old in SCHS study subjects. These differences should be taken into consideration in population-based lipid management projects such as the SCHS prospective longitudinal cohort study.

CONCLUSION

This study indicates that Shiraz metropolis men and women in the age group of 40-70 years old are at risk of developing dyslipidemia based on the ESC2019 guidelines. Although these risks were different in the study groups, in advance we need to anticipate this age group in the study population.

Considering the high prevalence of dyslipidemia in the studied community, especially in people with a higher risk of CVD, the development of training and retraining programs for these groups related to health and public health as well as group treatment is necessary. Developing programs based on the ESC2019 guidelines at the national and provincial levels can be helpful to benefit people related to public health and treatment in line with recent changes in terms of new goals to control the lipid profile.

Therefore, regarding the change in people's lifestyle due to the advancement of technology, it is appropriate to rely on the general education program of people in terms of risk factors related to CVD in society and importance of the issue of dyslipidemia. Regarding the evermore increasing progress of technology, it is better to pursue the public education of people through the creation of reliable scientific and educational resources in social networks, health-related applications and to try to modify the lifestyle and diet, as well as to continue treatment through electronic resources.

STUDY STRENGTHS AND LIMITATIONS

Study data was collected based upon strict quality assurance (QA) quality control (QC), testing [20], which ensures a good representation of the study population due to the accuracy, validity, and reliability of data. Another strength of this study is the accuracy of outcome measured for the LDL-C level, based on ESC2019 guidelines.

Moreover, strengths of the current study can be attributed to the low bias, valid and reliable data recording with highly accurate data with QA-QC and testing [20], considering that the information was first filled in the standard questionnaire form by the study population. Then, the electronic files were entered into by well-trained experts, using a standard guideline that reduces any bias in the study.

Another strength of this study was the use of the Shiraz Cohort Heart Study (SCHS) data that has a geographically normal distribution based on application of the inclusion criteria's study.

Most (with limited dropout) roughly correspond to the ESC2019 guideline recommendation of testing the LDL-C levels related to the data analysis to validate the estimated LDL-C levels for future implications of LDL-C reduction in individual study subjects.

However, the study may have limitations in that the inclusion criteria only enrolled persons aged 40-70 years old with cut points ranges, regardless of prevalence of dyslipidemia in younger or older indicated age ranges of the study participants.

Although the age and gender distributions of participants in this study are comparable with those in the entire population of in Shiraz metropolis, possible potential selection bias cannot be ruled out.

In addition, SCHS participants randomly accounted for about a sample of all eligible residents in the target population in the greater Shiraz metropolis**.** Although the age and gender distributions of participants in this study were comparable with those in the entire free-dwelling population of Shiraz, possible potential selection bias cannot be ruled out.

This study may have some unknown limitations due to the nature of the cohort study method. Therefore, careful interpretation with consideration that subjects were selected based on the availability of LDL-C measurements, which may be a weakness related to the generalizability of the results in a general population.

Thus, this study was conducted based on a population-based randomized controlled method with strict QA-QC and testing, which ensures a good representation of the study population, and the reliability of data collected.

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