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New cholesterol guidelines and primary prevention in women

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ABSTRACT

Cardiovascular disease (CVD) remains the leading cause of death for women in the United States. The role of primary prevention of CVD is a necessary focus of healthcare, given the overall prevalence of CVD and its risk factors in women. In 2013, the American College of Cardiology and the American Heart Association released new guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk (ASCVD) in adults that were based on results of randomized controlled trials. These guidelines apply to both men and women. Achievement of a target cholesterol level is no longer part of the guidelines. Rather, the guidelines recommend an appropriate and fixed intensity of a statin based on calculation of an individual's risk of ASCVD or in diabetics or those with severely elevated LDL-C for primary prevention. The new guidelines emphasize statin therapy over other lipid-lowering therapy. The new guidelines are evidence-based, coming from randomized control trials that have clearly demonstrated improved outcomes using statin therapy in those with ASCVD and those at high risk of ASCVD, not based on LDL targets but rather LDL lowering. This evidence-based approach to ASCVD prevention should be used in women. There were no specific sex differences in the new guidelines, and the focus of this article is to provide the evidence to support the use of these guidelines in women.

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Cardiovascular disease (CVD) remains the leading cause of death for women in the United States, with an estimated 400,332 women dying of cardiovascular disease in 2010 [1]. Although there have been noted reductions in mortality from CVD in women owing to better treatment of CVD, this has resulted in more women living with CVD and its potential

consequences. Such an approach that focuses on treating CVD is expensive and will result in an increase in risk factor burden on the population and may threaten the current favorable trends in CVD. In addition, studies continue to show an increased risk of in-hospital mortality in young women presenting with an acute myocardial infarction,

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Table 1 – Women in primary prevention randomized control trials of statins.

Study	Number of women enrolled	Total enrolled studied	Percent women (%)	Mean age (years)	Drug name
ACAPS	445	919	48	61	Lovastatin
AFCAPS/ TexCAPS	997	6605	15	62	Lovastatin
HPS	1816	5963	30	NA	Simvastatin
ALLHAT	5051	10,355	49	NA	Pravastatin
ASCOT	1942	10,305	30	NA	Atorvastatin
MEGA	5356	7832	69	60	Pravastatin
PROSPER	1894	3239	58	75	Pravastatin
JUPITER	6801	17,802	38	68	Rosuvastatin

compared with men of the same age [2]. For these reasons, a focus of primary prevention of CVD is necessary to not only reduce mortality from CVD but also to reduce the overall impact of CVD on the overall health of the nation and its economic burden on the USA healthcare system.

Identifying and treating CVD risk factors has become a focus of the American Heart Association in order to reduce the burden of CVD in the United States [3]. There is significant evidence showing that controlling CVD risk factors is far from optimal. Based on the NHANES III study, <7.5% of the population met six of the seven key CVD health metrics (including not smoking, eating a healthy diet, being physically active, and having a normal weight, blood pressure, glucose level, and cholesterol level) [4]. In addition, a large analysis of 18 studies from the United States showed that in 257,384 participants, only 3% of persons had their key CVD risk factors optimally managed [5]. By focusing on identification and treatment of CVD risk factors, the impact on CVD will be greater because of the ability to prevent (rather than treat) CVD.

In 2013, a joint task force from the American College of Cardiology (ACC) and the American Heart Association (AHA) released new guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk (ASCVD) in adults [6]. The biggest change in these guidelines that applies to both men and women is the removal of a target cholesterol level. Instead, the guidelines recommend fixed intensity of a statin based on whether they are in a statin benefit group. In primary prevention, these include, high-risk groups such as those with elevated levels of LDL-C on a primary basis or those with diabetes, aged 40–75 years, and LDL-C level 70–189 mg/dl. Those in a lower risk primary prevention group having a 10-year estimated ASCVD risk ≥ 7.5 are also shown to benefit, but membership in this group does not equate with statin treatment. This occurs only after a clinician–patient risk/benefit discussion that

addresses other risk factors and optimal lifestyle, the potential for benefit vs the potential for adverse effects, or drug–drug interactions with statin therapy and includes an informed patient preference. The new guidelines emphasize statin therapy over other lipid-lowering treatments and have eliminated past recommendations to treat to a specific low-density lipoprotein (LDL) or non-high-density lipoprotein (non-HDL) goal. There were no specific sex differences in the guidelines released. Nonetheless, the data on which these guidelines were made were influenced by trials that had relatively fewer women and did not often report sex-specific results. More recent trials have included more women, and these results have impacted the recommendation of the newest lipid guidelines (Tables 1 and 2).

Does the ASCVD risk assessment overestimate risk in women?

Critics of the new guidelines on cholesterol management have suggested that the risk score calculator recommended in the guidelines overestimates risk. Nonetheless, the ASCVD risk calculator was based on more than one population and is a pooled cohort equation that was developed and validated on Caucasian and African American men and women [7]. The pooled cohorts included participants from several large NHLBI-sponsored cohort studies that were both geographically and racially diverse, such as the Atherosclerosis Risk in Communities (ARIC) Study [8], the Cardiovascular Health Study [9], the Coronary Artery Risk Development in Young Adults (CARDIA) Study [10], the Framingham [11], and the Framingham Offspring Study [12]. Subsequent reports have validated the accuracy of the ASCVD risk calculator, including women [13,14]. Nevertheless, given the populations on which these were developed, these may overestimate risks in Hispanic-Americans and East

Table 2 – Women in secondary prevention randomized control trials of statins.

Study	Number of women	Total enrolledstudied	Percent women (%)	Mean age (years)	Drug name
4S	827	4444	19	61	Simvastatin
PLACII	22	151	15	62	Pravastatin
CARE	576	4159	14	61	Pravastatin
LIPID	1516	9014	17	62	Pravastatin
HPS	3266	14,573	22	NA	Simvastatin
PROSPER	1106	2565	43	76	Pravastatin
SPARCL	1908	4731	40	64	Atorvastatin

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