Statin therapy in the primary prevention of atherosclerotic cardiovascular disease

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ABSTRACT: It's unsure whether using a cardiovascular Genetic Risk Score (cGRS) to target statin initiation in the primary prevention of atherosclerotic cardiovascular disease enhances clinical decision making or health outcomes Atherosclerotic Cardiovascular Disease (ASCVD). Our goal was to calculate the cost-effectiveness of cGRS testing in guiding therapeutic decisions about statin commencement in people with a low-to-intermediate (2.5%-7.5%) 10-years ASCVD risk. For low- to intermediate-risk patients, testin for a

27-single-nucleotide polymorphism cardiovascular genetic risk score is often not a cost-effective technique for focusing statin medication in the primary prevention of atherosclerotic cardiovascular disease. The cost-effectiveness of cardiovascular genetic risk score testing is influenced by assumptions regarding statin disutility and cost, as well as age, gender, 10-years atherosclerotic cardiovascular disease risk, and willingness-to-pay threshold.

Key Words: : Cardiovascular genetic risk score; Atherosclerotic Cardiovascular Disease; Coronary Heart disease; Coronary artery calcium

INTRODUCTION

Every year, almost 1.2 million people in the United States have their first Cardiovascular Disease (ASCVD) event (Myocardial Infarction (MI), coronary heart disease mortality, or stroke) [1]. Statins, a class of highly effective lipid-lowering drugs, reduce the risk of MI, stroke, and death from Coronary Heart Disease (CHD) and are recommended as preventive therapy in nondiabetic, ASCVD-free individuals with a 10-years predicted ASCVD risk of less than 7.5% (calculated using the pooled cohort equations). Given the substantial diversity in individual-level risk estimates and variation in patient preferences for daily drug use, the pooled cohort equations alone may not be appropriate for guiding statin treatment decisions in patients close to the 7.5% treatment threshold [2]. Furthermore, rather than proof from cost-effectiveness assessments, the 7.5% criterion is relied on expert opinion.

Besides the from the 7.5% threshold, the 2013 American College of Cardiology/American Heart Association guidelines on ASCVD risk reduction recommend testing for non-traditional risk factors such as Coronary Artery Calcium (CAC), ankle-brachial index, and high-sensitivity C-reactive protein to provide information about other aspects of risk not covered by traditional risk factors, such as atherosclerotic burden or vessel reactivity, and to aid clinicians and patients [3]. While there is no consensus on which non-traditional risk factors are the most clinically useful or how to interpret risk factor test results in the context of existing ASCVD-predicted risk estimates, decision modelling can be used to help determine the clinical utility of testing for new non-traditional risk factors like CAC [4].

Cardiac genetic risk testing allows doctors to more precisely identify those who are at high risk of developing ASCVD and who could benefit from statin medication [5]. The cardiovascular Genetic Risk Score (cGRS) of a person may indicate a genetic predisposition to accelerated atherosclerosis due to mistakes in cholesterol metabolism, thrombosis, and other endothelium-related variables [6]. After controlling for established ASCVD risk variables, a substantial, independent link between a 27-Single-Nucleotide Polymorphism (SNP) cGRS and cardiovascular disease outcomes. However, it's unclear if its effect on projected risk leads to significant variations in clinical decision-making about statin beginning or, in the end, improves cardiovascular outcomes. Clinical decision analysis and cost-effectiveness or cost-utility modelling can be used to explicitly compare alternative clinical options regarding their relative downstream risks, benefits, and costs in the absence of large, generalizable randomised controlled trials comparing clinical management with and without additional testing for novel risk factors [7]. The clinical value and cost-effectiveness of cGRS testing for targeting statin medication in the primary prevention of ASCVD were assessed using modelling in this study.

DISCUSSION

Obtaining a cGRS test to target statin medication for primary prevention of ASCVD was not a cost-effective method at a WTP of \$50,000 per QALY gained in a set of clinical scenarios of persons with 10-years estimated ASCVD risk ranging from 2.5% to 7.5%. Instead, we discovered that treating all patients with statins is the optimal option under base case assumptions of low-cost statins and low statin disutility [8]. cGRS testing, on the other hand, can be cost-effective if a small set of assumptions about statin cost and disutility are met, which are based on sex, age, 10-years ASCVD risk, and WTP threshold. Under base case assumptions, the best option for a 45-yearsold woman with a 10-years ASCVD risk of 2.5% is to treat everyone without testing. Despite the fact that this 10-year ASCVD risk is much lower than current statin therapy thresholds, our findings are consistent with findings, which show that 10-year ASCVD risk thresholds of 5% for recommending statin therapy can be cost-effective. We chose to focus our research on people with a 10-year ASCVD risk of less than 7.5% because, at greater levels of risk, treating everyone is the best option, even if assumptions regarding statin disutility and cost vary widely [9].

Furthermore, the sensitivity of our findings to statin cost and statin disutility is consistent with previous research on the cost-effectiveness of statin therapy in intermediate-risk patients. A recent study found that the prevalence of statin disutility >0.01 (trading away 5 weeks of perfect health to avoid 10 years on statins) was 7.4%, with 87% of people unwilling to trade any length of time to avoid statin therapy [10]. We can't do anything about a patient's disutility for taking daily preventive drugs if we don't know about it. We can presume that the conditions under which cGRS testing is the preferred technique are uncommon during ordinary clinical practise because we don't know about an individual patient's disutility for taking daily preventive drugs.

We found no combinations of statin disutility and statin cost that led to a cGRS testing technique being favoured in the 2-way sensitivity analysis for the 65-years-old lady with a 7.5% of 10-years ASCVD risk [11]. For several combinations of statin disutility and statin cost, cGRS testing was recommended for a 45-years-old woman with a 7.5% of 10-years ASCVD risk. These data highlight the relevance of underlying clinical risk variables, particularly age, in determining 10-years ASCVD risk. When a lifetime horizon is simulated, the treated 45-years-old has more years to accrue benefits from cGRS testing than a 65-years-old. In contrast to the 65-years-old, the untreated 45-years-old has more years to avoid treatment

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inefficiency [12]. As a result, being able to make risk-based and preferencebased judgments concerning cGRS testing is critical. Future research should focus on determining the most effective strategy to operationalize in clinical practise.

Despite the fact that the 27-SNP cGRS test is an independent predictor of ASCVD outcomes, the association is weak. Other approaches to statin therapy targeting, such as selective imaging (CAC scanning), are far more effective at improving discrimination and reclassification in intermediate-risk patients [13]. CAC scanning has been proven to be cost-effective only under a limited set of assumptions regarding statin disutility and cost, despite the fact that it increases risk prediction. Other versions of cGRS tests may need to focus on gene variants related to cardiovascular risk pathways that don't overlap with traditional risk factors like inflammation and thrombosis in the future [14]. Decision modelling and cost-effectiveness studies are approaches for comparing alternative clinical alternatives in terms of their relative risks, benefits, and costs in the long run. The National Academy of Science and Medicine published a framework for genetic test estimation in March 2017, endorsing the use of clinical decision analysis to evaluate both clinical utility and cost-effectiveness of new genetic tests [15]. The research described here is an example of the type of analysis that might assist identifies circumstances in which genetic risk testing may (or may not) be a cost-effective technique for modifying decisions about preventative therapy beginning for individual patients.

Decision analysis can also be used to determine whether to invest in largescale, expensive clinical studies to definitively assess the clinical utility of cGRS testing or to pursue commercialization. The 27-SNP cGRS test used in this study, for example, is not currently marketed, and commercialization would necessitate investment in the equipment and processes required to ensure analytic validity. The test developer would also need to charge a high enough price for the test to ensure a return on investment for research and development [16]. Our findings show, however, that the cost of cGRS testing and the severity of the connection between the cGRS and CHD outcomes play only a minor impact in deciding the overall clinical value of cGRS testing for CHD.

CONCLUSION

Our findings show that using cGRS testing to target statin medication in the primary prevention of ASCVD in patients with a 10-year ASCVD risk of less than 2.5% is not cost-effective. Although there are a few scenarios in which cGRS testing procedures might be preferable, these are unlikely to be encountered in ordinary primary care.

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