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Clinical Lipidology Roundtable Discussion

JCL Roundtable: Lipid-lowering drugs in those older than 75 years of age



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Emory University School of Medicine, 3208 Habersham Rd., NW, Atlanta, GA 30305, USA (Dr. Brown); University of Alabama at Birmingham, 701 19th St. S., LHRB 310, Birmingham, AL 35294, USA (Dr. Bittner); National Clinical Research, 2809 Emerywood Pky. #140, Richmond, VA 23294, USA (Dr. McKenney); and Florida Lipid Institute, 2828 Casa Aloma Way, Ste. 600, Winter Park, FL 32792, USA (Dr. Ziajka)

KEYWORDS:

Elderly population; Blood cholesterol; Lipid drugs; Vascular disease; Atherosclerosis **Abstract:** Using drugs in the elderly requires some special considerations; however, there is no question that our older patients benefit tremendously from the use of agents that prevent and/or control many of the risk factors for vascular disease that are most prevalent in the latter years of life. Recently, the American College of Cardiology and the American Heart Association issued guidelines for the management of blood cholesterol elevations. For the first time, little specific guidance was given for the age group older than 75 years of age. The rationale given for this approach was primarily that the data from randomized trials comparing drug therapy to treatment with placebos were inadequate for such recommendations. There was also concern regarding safety in this group. This Roundtable will consider this lack of recommendations in a broader context than statin trials. © 2014 National Lipid Association. All rights reserved.

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Dr. Brown: As stated in the American College of Cardiology and the American Heart Association guidelines: "Fewer people >75 years of age were included in the statin RCTs (randomized clinical trials) reviewed by the Expert Panel. RCT evidence does support the continuation of statins beyond 75 years of age in persons who are already



Dr. Brown

taking and tolerating these drugs. A larger amount of data supports the use of moderate-intensity statin therapy for *secondary prevention* in individuals with clinical ASCVD [atherosclerotic cardiovascular disease] >75 years of age. However, few data were available for initiation of high-intensity statin therapy used for secondary prevention.

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The ACC/AHA guidelines state that few data were available to indicate an ASCVD risk reduction benefit in primary prevention among individuals >75 years of age. Therefore initiation of statins for primary prevention in individuals >75 years of age requires consideration of additional factors, including increasing comorbidities, safety considerations, and priorities of care."

Unfortunately, this cautious stance has the potential to be misinterpreted to mean that one should only rarely consider statins in those at 75 years of age or older. Furthermore, it suggests that higher doses of statins may be particularly hazardous in this group. In view of the strong evidence that rates of morbidity disease and mortality from vascular in this age group is much higher than in those younger, this lack of guidance may inhibit the application of truly beneficial therapy. Atherosclerosis is the cause of myocardial infarction, stroke, and ruptured aortic aneurysms. It also contributes to congestive heart failure, claudication, and dementia. Therefore, it seems appropriate to reexamine this stance on therapy with colleagues who have had many years of experience in treating older patients, and who have participated in years of clinical research involving lipid management in this age group. I have asked Dr. Vera Bittner (University of Alabama at Birmingham), Dr. James McKenney (Virginia Commonwealth University and president and chief executive officer of the National Clinical Research in Richmond, VA), and Dr. Paul Ziajka (founder and director of Florida Lipid Institute, Winter Park, FL) to join me to discuss this important issue. This discussion was recorded as we attended the Scientific Sessions of the National Lipid Association in Orlando, FL, on May 2, 2014.

Dr. Brown: I would like to hear your opinions on the position that a specific age should be considered as a reason to begin or withhold statin therapy or any other lipidlowering medication. Perhaps Dr. McKenney would like to comment first.



Dr. McKenney: As we manage patients, we are all keenly aware of the patient's cholesterol level and use this number, among other things, to determine our treatment approaches. As we construct or use our treatment guidelines, the cholesterol level is an important consideration. But I submit that time is another important factor. The longer

Dr. McKenney

we live with any cholesterol level, the greater the chance that significant atherosclerosis has developed and the greater the chance that serious events will occur. This concept of cumulative lifetime exposure to a cholesterol level is important as we consider the elderly patient because it suggests that risk is increasing. There is no threshold age at which atherogenesis and events cease to be a problem. In fact, the opposite is true. Risk continues to escalate with time or age. If I could, I'd like to cite some statistics that support this notion.

Dr. Brown: Please do.

Dr. McKenney: Last year, the Multi-ethnic Study of Atherosclerosis reported on the prevalence of coronary calcium scores in about 6500 black, Chinese, Hispanic, and white men and women aged 45 to 84 years on enrollment. The prevalence of a coronary artery calcium score higher than 300, a level I believe everyone would agree is high, was reported to increase with age. In 55-year-old men, 7% had levels of 300 or greater; in 65 year olds, 17% met or exceeded this level; in 75 year olds, 33%; and in 85 year olds, 50%. The prevalence in women was lower but advanced significantly with age. I believe this speaks to the progressive nature of atherosclerosis, a process that should not be ignored simply because the patient is older than age of 75 and no randomized clinical trials are available to address the benefit and risk of treatment in this age group.

Another statistic that caught my eye comes from the American Heart Association's 2014 Heart Disease and Stroke Statistics report. Here, the prevalence of cardiovascular (CV) disease including coronary heart disease, heart failure, stroke, and hypertension in the US population is reported. The report indicates that 37% of those between 40 and 60 years of age have CV disease; 71% of those in the 60- to 79-year-old group have CV disease; and a whopping 85% of those who were 80 years or older have CV disease. Another important finding is that 80% of all coronary deaths in this country occur in people older than age 65. These data indicate that CV disease is rampant and escalating in our aging population and that most of the burden of major CV events is realized in the elderly population, which to me calls for prevention efforts.

Finally, I would like to cite data from the meta-analyses conducted by the Cholesterol Treatment Trialists' Collaboration of 27 statin outcome studies involving about 175,000 patients, including both people with and without vascular disease. Considering only the patients who received placebo, which included 22 studies or low-dose statins, which included 5 of the 27 studies, the annual event rate of major vascular events was 3.5% of individuals younger than 60 years of age, 4.1% of those 60 to 70 years old, and 5.1% of those older than 70 years of age. These data again show evidence of a prevalent and progressing disease.

Dr. Brown: From the data you have quoted, one might simply assume that in developed nations, people older than 75 should be considered as candidates for secondary prevention. They are highly likely to have disease, evident or occult. You hardly need to do a test to place them in a category of high risk and recommendations would be to treat with low-density lipoprotein cholesterol (LDL-C) lowering medications if the patient's level is higher than 70 mg/dL. Another interpretation could be that it is too late to treat with hope of benefit.

Dr. Bittner: No, I do not think it is too late to treat. To my knowledge, nobody has shown that the pathophysiology of atherosclerosis changes at age 75 or that the mechanism of coronary events (ie, plaque rupture and plaque erosion with superim-



posed thrombosis) changes. Statins should Dr. Vera Bittner

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