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SHAPE Task Force Recommends Noninvasive Cardiac Screening for Asymptomatic Adults

Laurie Barclay, MD

July 13, 2006 — Asymptomatic adults should be screened with noninvasive tests for heart disease, according to a report by the Screening for Heart Attack Prevention and Education (SHAPE) Task Force, published in a Pfizer-sponsored supplement of the July 17 issue of the *American Journal of Cardiology*.

"The SHAPE guideline is seeking to reduce the burden of unpredicted cardiovascular events (acute coronary syndromes and sudden cardiac death) in the apparently healthy population," SHAPE Task Force chairman Morteza Naghavi, MD, told Medscape. He is founder and president of the Association for Eradication of Heart Attack (AEHA) in Houston, Texas. "An important and unique aspect of the SHAPE guideline is identification and aggressive treatment of the vulnerable patients, those with the most burden of atherosclerotic plaque who bear the highest risk of a near-term event."

But critics of SHAPE note that current official guidelines, such as those of the American Heart Association (AHA) and the American College of Cardiology (ACC), do not support this approach. Furthermore, they cite the lack of evidence that the proposed screening would improve outcomes.

"The cardiology community must recognize the major difference between the guidelines process of the AHA, ACC, [the United States Preventive Services Task Force] USPSTF, and National Heart, Lung and Blood Institute (NHLBI) in comparison to that of this free-standing group [SHAPE]," Philip Greenland, MD, the Harry W. Dingman professor of preventive medicine and medicine and executive associate dean for clinical and translational research at the Feinberg School of Medicine, Northwestern University in Chicago, Illinois, told Medscape. "This report should be repudiated both for its lack of scientifically supportive evidence but also for the serious risk that it could subvert the legitimate guidelines efforts that it apparently wishes to ignore."

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SHAPE Recommends Widespread Cardiovascular Imaging Screening

The AHEA, funded by Pfizer and other pharmaceutical industry groups (see Disclosures below), convened the SHAPE Task Force, an international panel of prominent cardiologists. The report recommends noninvasive atherosclerosis screening of all asymptomatic men aged 45 to 75 years and asymptomatic women aged 55 to 75 years, except for those defined as very low risk because of the absence of known risk factors (cholesterol >200 mg/dL, blood pressure >120/80 mm Hg, diabetes, smoking, family history, or metabolic syndrome). The SHAPE Task Force urges all hospitals and healthcare policies to consider their proposal, and AEHA plans to proliferate SHAPE-accredited clinics throughout the United States.

"The SHAPE guideline is presenting a new paradigm for individualized risk assessment of atherosclerotic cardiovascular disease," said SHAPE Task Force Editorial Chair Prediman K. Shah, MD. He is the Shapell and Webb chair and director of cardiology and the Atherosclerosis Research Center at Cedars-Sinai Medical Center in Los Angeles, California. "Identification of subclinical atherosclerosis by imaging helps motivate individuals to take preventive measures. We believe the existing guidelines, such as [National Cholesterol Education Program] NCEP, which are primarily therapeutic guidelines, poorly perform in risk assessment, and that SHAPE Guidelines can complement the existing therapeutic guidelines."

The SHAPE Task Force cites a retrospective review by Akosah and colleagues, published in the May 7, 2003, issue of the Journal of the American College of Cardiology, which suggests that the NCEP III guidelines underestimate risk of myocardial infarction in the young adult. In the review, of 222 young adults (aged 55 years or younger for men and 65 years or younger for women) hospitalized for acute myocardial infarction during a 3-year period, only 25% overall, and only 18% of women, met NCEP III criteria to qualify for pharmacotherapy.

"Use of risk factors alone, such as the Framingham risk score, is grossly inaccurate in identifying risk, especially in the intermediate score range," SHAPE Writing Group coordinator Erling Falk, MD, professor and director of cardiovascular pathology at Aarhus University Hospital in Denmark, told Medscape. "By identifying atherosclerosis of coronary and/or carotid arteries, the SHAPE paradigm gets at the disease itself rather than its predictive risk factors. This has 2 potential advantages: those with no evidence of atherosclerosis can be reassured, spared the expense and potential side effects of aggressive drug therapy, whereas those with atherosclerosis can be selectively targeted to prevent a near-term event," Dr. Falk said.

On the basis of predictive value, availability, reproducibility, "complementary value with respect to the concept of the vulnerable patient, and/or cost-effectiveness relative to the status quo," the SHAPE panel chose as screening tests coronary artery calcification determined by computed tomography (CT) scan (CACS), and carotid artery intima-media thickness (CIMT) and plaque determined by ultrasonography.

"The body of evidence on the need for individual risk assessment based on the presence and the severity of atherosclerosis is colossal," SHAPE author Pamela Douglas, MD, the Ursula Geller professor of research in cardiovascular diseases and chief of cardiovascular medicine at Duke University Medical Center in Durham, North Carolina, told Medscape. "The evidence on the efficacy of coronary calcium score and CIMT has grown rapidly in the past 5 years."

Algorithms Identify Those at High Risk

The SHAPE Task Force recommends "careful and responsible implementation of these tests as part of a comprehensive risk assessment and reduction approach." The group provides algorithms to identify those patients most likely to have a cardiovascular event, and to start appropriate treatment. These algorithms mandate that the aggressiveness of the treatment should be proportional to the level of risk.

"There is good evidence that both coronary calcium and CIMT measures identify persons at high risk for cardiovascular disease, and there is good evidence that lowering [low-density lipoprotein] LDL [cholesterol] reduces risk in persons with high LDL or coronary disease," Diane Bild, MD, MPH, deputy director, Division of Epidemiology and Clinical Applications at the NHLBI, told Medscape. "However, the SHAPE recommendations 'connect these dots' without empiric evidence supporting the specific proposed screening and treatment strategy.... The benefits of wide

implementation of these guidelines is unclear, and the downside is costs of screening and treatment, as well as 'labeling' people as having disease for which the proposed treatment has not been documented to be beneficial," she added.

For individuals of moderately high risk and above (CACs > 0 or CIMT > 50th percentile), the SHAPE algorithms include specific LDL cholesterol targets. The authors state that a high percentage of patients at risk are missed by Framingham risk scores, and they estimate that using their proposed strategy would result in ~25 million men and ~20 million women being treated with statins based on evidence of high-risk subclinical atherosclerosis, resulting in a 50% to 65% increase in the statin-eligible population. For individuals at very high risk (CACs >100 and CIMT > 90th percentile or a CACS of 400 or higher, or carotid plaque causing 50% or more stenosis), the task force also recommends considering angiography.

"If SHAPE is adopted, we anticipate a significant reduction in out-of-hospital sudden cardiovascular death that has remained steadily high in the past several decades," Dr. Douglas said. "With careful implementation of SHAPE (screening and follow-up to achieve targeted therapeutic goals), we anticipate over 90,000 [fewer] sudden cardiovascular deaths and \$21 billion to be saved each year."

The cost-effectiveness committee of the SHAPE Task Force extensively reviewed existing data and created multiple analytical models based on a range of assumptions. These decision models estimate that screening the approximately 50 million asymptomatic men and women meeting the above criteria could potentially greatly improve outcomes. The SHAPE guideline claims that the benefits of comprehensive screening would include preventing more than 90,000 sudden cardiovascular deaths annually; reducing the population with a history of myocardial infarction, currently estimated at 13.2 million, by up to 25%; and saving approximately \$21.5 billion annually by saving individuals at highest risk, most of whom are now unaware of their risk status.

"Currently, the data do not support that there is an advantage to adding these tests to the measurement of modifiable risk factors, which are direct targets for intervention — lowering blood pressure, lowering LDL cholesterol, and smoking cessation," Dr. Bild said. "The SHAPE authors claim that these tests may serve to motivate patients to comply with therapy, but that is arguable and, as a strategy, should be further reviewed in the scientific community."

Current Guidelines Do Not Support SHAPE Recommendations

The ACC, the AHA, the NHLBI, the US Centers for Disease Control and Prevention (CDC), and the USPSTF have made a significant effort over many years to address the issue of detecting the asymptomatic patient at risk for cardiovascular events, according to Dr. Greenland. These previous efforts involving hundreds of experts reviewing the evidence for and against early detection have been "well-informed, well-intentioned, and highly serious," and have resulted in a series of highly evidence-based guidelines. According to Dr. Greenland, who says he is "greatly disturbed" by the SHAPE proposal, the above-mentioned professional societies and governmental agencies are now close to completing updated revisions of some of the evidence-based guidelines.

"In contrast, this SHAPE report, from a group that apparently has no oversight or outside input or review, which also offers no framework for its recommendations, and which also provides almost no scientific support for its recommendations, is an apparent effort to subvert the long-standing evidence-based guidelines approaches of the groups named above," Dr. Greenland said. "Not only is this paper scientifically extremely questionable, given its remarkable lack of evidence offered in support of its recommendations, but it makes light of the legitimate efforts of the groups that have had longstanding roles and minimally biased approaches to addressing these same problems."

The SHAPE writing group is also heavily weighted toward imaging specialists and is short on epidemiology experts, according to AHA spokesperson Robert O. Bonow, MD, chief of cardiology at Northwestern University Medical School and Northwestern Memorial Hospital in Chicago, Illinois. He notes that cardiovascular imaging has increased by about 20% in Massachusetts and some other states, and that Medicare and other payors are now scrutinizing this increase and requesting pre-authorization for imaging procedures.

"There are a number of issues with the [SHAPE] 'guidelines,'" Dr. Bonow told Medscape. "The AHA does not recommend routine screening with imaging techniques. There are no data indicating how this would impact patient behavior, whether it provides incremental benefit over current primary

prevention guidelines, and whether it would have a positive effect on cardiovascular outcomes."

The cost of imaging 50 million people, to the tune of hundreds or thousands of dollars each, is staggering on its own, not including additional costs generated by the imaging, such as stress testing and angiography. Another issue addressed by Dr. Bonow is radiation exposure from multidetector CT scanners and noninvasive angiography, which he says is associated with more radiation exposure than a cardiac catheterization.

"You can justify that for someone that's sick, but to recommend this as the screening procedure creates some concern about the radiation exposure," Dr. Bonow pointed out. "There's no evidence that stress testing or angiograms improves outcome. If you have a positive imaging test, only 10% of people are actually going to have an event, so it's the same kind of issue you have with a lot of higher risk people that all need to be treated. It's just going at it from the high-tech approach, where we don't have any real evidence if that's the right thing to do."

Patients often fail to comply with existing guidelines for primary prevention, according to Dr. Bonow. Even physicians may not optimally treat modifiable risk factors such as blood pressure, cholesterol, blood sugar, and smoking.

"The problem is that we're not doing as good a job at that as we can do," Dr. Bonow said. "Yet that's where we have lots of evidence, decades worth of evidence, that treating those things substantially reduces heart attacks and strokes.... There's no data with imaging that it actually improves outcome; it doesn't even improve behavior."

He cited a randomized trial by O'Malley and colleagues, published in the May 7, 2003, issue of *JAMA*, of 450 subjects showing that using coronary calcification screening to motivate patients to make evidence-based changes in risk factors was not associated with improvement in modifiable cardiovascular risk at 1 year.

Dr. Bonow noted that the scientific evidence underlying the SHAPE proposal is "still in development and not yet ready for prime time. It is a hypothesis worth testing, but it needs to be tested before it can be made into guidelines."

Need for Additional Research

"The principle of identifying and treating asymptomatic persons who are at high risk for cardiovascular disease events is a laudable and major goal for preventive cardiology, and the SHAPE proposers are trying to push clinical practice towards this goal," Dr. Bild of the NHLBI said. "The fact that these testing methods are available and are already being used — without guidelines — creates the current situation. However, the precise screening approach recommended by SHAPE has not been proven to reduce morbidity and mortality through randomized controlled clinical trials — the type of evidence that is generally needed before making public health recommendations. "

Experts independent of SHAPE whom Medscape interviewed agreed on the need for large-scale, prospective, randomized trials to determine which screening and treatment strategies yield the best outcomes in reducing morbidity and mortality. The cost-effectiveness of the strategy would also need to be examined before making recommendations for clinical guidelines, they said.

"While we certainly agree with the need for further validation studies, especially in a few subgroups, [this] notion must be viewed in light of distasteful facts," Dr. Naghavi, of the SHAPE Task Force, said. "Such a trial (1) would be very expensive and has failed to find industry sponsors (the National Institutes of Health has also rejected the proposal for such a study due to cost); (2) in a subgroup of such a trial (the vulnerable patients, which is the focus of the SHAPE guideline), the amount of evidence is so overwhelming that many believe it is unethical to randomize such individuals to a placebo or anything less than the most aggressive treatment. Nevertheless, the SHAPE Task Force has planned to take advantage of this wave of awareness and will be promoting advocacy and lobbying efforts in Congress to allocate the budget for a 'mega trial' conducted by NHLBI."

"Even if you can argue that you're going to save some lives this way, and therefore you're going to decrease expenses in the long run, that's yet to be proven," Dr. Bonow, of the AHA, concluded. "I don't want to sound too negative because obviously the imaging techniques are very exciting —

they do what they're supposed to do: they identify diseased arteries. But until you can prove that it actually changes things you can't make that a guideline. It's a hypothesis worth testing, but the science is still in evolution here, and it needs to be tested before you make it a guideline."

Disclosures: The AEHA has received funding from the following companies in the past 5 years: Pfizer, Merck, Astra-Zeneca, GlaxoSmithKline (GSK), CV Therapeutics, diaDexus, Amersham, General Electric (GE), Boston Scientific, and Guidant funded the Vulnerable Plaque/Vulnerable Patient symposia; Pfizer and Merck supported the AEHA Web site; Pfizer, diaDexus, and GSK supported the SHAPE Task Force meeting; and Pfizer supported the SHAPE Task Force report publication (Dr. Naghavi reported that the AEHA invited all statin-producing drug companies to participate but only succeeded with Pfizer).

Dr. Naghavi is the AEHA founder and president; he has served as a scientific advisor to Pfizer Inc and diaDexus Inc; he serves as a consultant to Endothelix Inc and Volcano Corporation; he has received research/grant support from Pfizer Inc; and he is a shareholder in Endothelix Inc and Volcano Corporation. Dr. Douglas serves as a consultant to GE Healthcare and Northpoint Domain; she receives research/grant support from Medtronic; and she is a shareholder in CardioDX, GE Healthcare, Genentech, Millennium, Momenta Pharmaceuticals, and Northpoint Domain. Dr. Falk serves as a consultant to Endothelix Inc. Dr. Shah has no financial arrangement or affiliation with a corporate organization or a manufacturer of a product discussed in the American Journal of Cardiology supplement.

Dr. Bild and Dr. Greenland report no financial relationships relevant to a conflict of interest on this topic. Dr. Bonow is a consultant for BMS Medical Imaging regarding isotopes used in nuclear cardiology, and he is a nonpaid consultant for King Pharmaceuticals regarding development of pharmacologic stress testing.

Am J Cardiol. 2006;98[suppl]:2H-15H

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