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I hope you will find *Practical Pointers* interesting and helpful.

Richard T. James Jr. M.D.

Editor/Publisher.

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“May Have A Major Effect On Clinical Practice”

1-1 A PRAGMATIC VIEW OF THE NEW CHOLESTEROL TREATMENT GUIDELINES.

The updated guideline from ACC/AHA on prevention of atherosclerotic cardiovascular disease (ASCVD) by use of statin drugs was released in November 2013.¹

The new guidelines have been the subject of controversy.

Nevertheless, the recommendations may have a major effect on clinical practice. This commentary provides a brief practical summary of the new guidelines, including points that are in dispute.

The new guidelines represent a substantial departure from previous recommendations. They rely on randomized, controlled trials that largely involved fixed doses of statin drugs in populations at risk of ASCVD; non-fatal myocardial infarction [MI]; death due to coronary heart disease [CHD]; or fatal or non-fatal stroke).

Statin therapy is suggested for 4 groups of patients:

Using the new approach, the expert panel identified 4 groups of patients for whom the benefit of statins clearly outweighs the risk:

- 1) Clinically evident atherosclerotic cardiovascular disease. High intensity statin. (Secondary prevention)
- 2) Type 1 or 2 diabetes, age 40-75, and LDL-c 70-189. If calculated 10-year risk is less than 7.5%, moderate dose statins; if 7.5% and over, higher intensity. (Primary prevention)
- 3) LDL-c 190 and above, High intensity statin, (Primary prevention)

(Note: Although LDL-c is not included in the risk calculator, the guidelines require determination of LDL-c levels. Ed.)

- 4) No diabetes, age 40-75, and LDL-c 70-189 and calculated 10-year risk of 7.5% and above. High intensity statin. (Primary prevention)

(Note: Many more patients will be taking high dose statins. Ed.)

The risk calculator: <http://cvriskcalculator.com/>

The calculator asks 9 questions: Age, gender, race (African American or other), total cholesterol, HDL-cholesterol, systolic BP, treatment for BP, diabetes, smoking. (Note; LDL-cholesterol is not included, although the guideline assumes it is determined. Ed.)

In these groups, high-intensity statin therapy (designed to reduce LDL-c by 50% or more) is generally recommended.

Moderate-intensity statin therapy (aimed at reduction of 30% to 50%) is for patients who cannot tolerate high doses, or patients with diabetes and a 10-year risk of ASCVD less than 7.5%.

Concerns have been raised about the new risk calculator, which is based on data derived from several large cohort studies. The calculator itself had not been prospectively tested for accuracy in predicting risk. It may overestimate observed risks.

High intensity statins:

Atorvastatin 40-80 mg; rosuvastatin 20 to 40 mg

Moderate intensity statin:

Atorvastatin 10-20 mg,; rosuvastatin 5-10 mg; simvastatin 20-40 mg; pravastatin 40-80 mg; lovastatin 40 mg and others.

Patients receiving statins should be monitored for muscle and liver injury and new-onset diabetes.

Patients for whom statins are not advised:

The new guidelines also identify patients for whom available data do not support statin therapy and for whom no recommendation is made:

- 1) Age over 75 years, unless clinical ASCVD is present.
- 2) A need for hemodialysis.
- 3) New York Heart Association class II, III, or IV heart failure.

The panel found no evidence to support use of non-statin cholesterol-lowering drugs.

Key implication for clinicians:

- 1) Avoidance of statin in certain patient groups.
- 2) Elimination of routine re-assessments of LDL-c levels in patients receiving statins. Target levels are no longer emphasized.
- 3) Avoidance of non- statin drugs in statin-tolerant patients.
- 4) More conservative use of statins in patients older than age 75 who have no clinical ASCVD.
- 5) Diminished use of surrogate markers such as C-reactive protein.
- 6) Use of the new risk calculator that is certain to target large numbers of patients for statin

treatment.

Overall, the new recommendations will move treatment toward statins and deemphasize other agents for a broader range of patients.

There is likely to be considerable interest in prospectively testing the new calculator in multiple groups of various ethnic backgrounds

NEJM January 16, 2014;370:275-79 Commentary. first author John R Keaney Jr. University of Massachusetts Medical School, Worcester.

<http://cvriskcalculator.com/>

1 ACC/AHA PUBLISHES NEW GUIDELINES FOR MANAGEMENT OF BLOOD CHOLESTEROL November 12, 2013 by AHA

<http://newsroom.heart.org/news/acc-aha-publish-new-guideline-for-management-of-blood-cholesterol>

NEW AMERICAN GUIDELINES FOR PREVENTION OF CARDIOVASCULAR DISEASE: Review and Critique Abstract in Practical Pointers November 2013

Case examples of application of 2013 cholesterol guidelines:

1) High-intensity statin recommended:

Black man with low HDL-cholesterol

Age 62, male, total-c 140, HDL-c 35, systolic BP 130, no antihypertension drugs, not diabetic, non-smoker,

(Calculated 10-year risk = 9.1%, High dose statin recommended despite low cholesterol because age 60 and low HDL-c)

(Note: This patient would likely not receive statins based on the LDL-c guidelines. Ed.)

2) Moderate intensity statin recommended:

White woman with diabetes

Age 48, female, white, total-c 180, HDL-c 55, systolic

BP 130, not taking antihypertensive meds, diabetic, non-smoker. .

Calculated 10-year risk = 1.8%

(Qualifies because she has diabetes, but has a 10-year risk of < 7.5%.)

3) Statin not recommended:

White man with high cholesterol

Age 57, male, white, total-c 265, HDL-c 45, systolic

BP 110, not taking antihypertensive meds, non-diabetic, non-smoker,.

Calculated 10-year risk = 7.2%,

(Total-c is high, but he has no other risk factors.)

(Note based on cholesterol levels alone, this patient would likely receive statins. Ed.

This is a work in progress. Changes are likely as time progresses. There has been no prospective study measuring the effectiveness of the new calculator. This is essential before this new guideline will be generally accepted.

For patients with established ASCVD, no calculation is needed. Statin prescription is advised.

Patients with diabetes should receive statins, either low dose or high dose, depending on risk score.

The risk calculator will be used in the majority of patients, adding complexity to decision-making. But the need for continuing cholesterol determinations is avoided.

1-2. NEW OBESITY GUIDELINES: Promise and Potential of Obesity-2 (OB-2)

More than one in 3 US adults are obese—a public health challenge.

The goal of the new guidelines is to help primary care clinicians manage obesity more effectively.

OB-2, published as “2013 ACCF/AHA/TOS2 Guidelines for Management of Overweight and Obesity in Adults”. has been long awaited. The expert panel for OB-2 was first convened in 2008 by the NHLBI and tasked with updating OB-1 (1998). In 2013, the NHLBI elected to partner with the American Heart Association and the American College of Cardiology to promote and publish the guidelines.

From 23 critical questions suggested, 5 risks of overweight and obesity and the benefits of weight loss were chosen, along with an evaluation of 3 treatment strategies—diet, behavioral therapies, and surgery.

Recommendation 1: Identifying patients who need to lose weight.

OB-2 endorses body mass index (BMI) as a first step, not the sole criterion to judge potential health risks.

Waist circumference (WC) is treated as a risk factor.

This recommendation emphasizes that the greater the BMI and WC the greater the risk of CVD, type-2 diabetes, and all-cause mortality.

The commonly used cut points were endorsed.

An algorithm provides additional information on measurement frequency and defines criteria for instituting a weight loss effort—obese or overweight adults with 1 or more indications of increased disease risk or obesity-associated co-morbidities (hypertension, glucose intolerance, dyslipidemia and type-2 diabetes, sleep apnea, or non-alcoholic fatty liver disease).

Recommendation 2: Counseling about benefits of weight loss.

Primary care clinicians should counsel patients who need to lose weight that lifestyle changes that produce modest sustained weight loss produce meaningful health benefits, and that greater weight loss produces greater benefits. Sustained weight loss of as little as 3% to 5% is likely to result in clinically meaningful reductions in levels of triglycerides, blood glucose, HbA_{1c}, and risk of developing type-2 diabetes.

Greater loss will reduce BP, improve levels of cholesterol, and reduce the need for medications.

OB-2 suggests that weight loss can provide benefits for those with only 1 risk factor. It considers increased waist circumference a risk factor.

Recommendation 3: Dietary therapy for weight loss.

There is no ideal diet for weight loss—no evidence of superiority of any of the myriad diets reviewed.

Prescribe a diet to achieve reduced calorie intake as part of a comprehensive lifestyle intervention.

The content of the diet should be determined on the basis of the patient's preferences and health status.

Successful weight loss can be achieved with a variety of dietary approaches.

Recommendation 4: Lifestyle interventions and counseling.

This component of OB-2 will, if implemented, have the most far-reaching effects. There is a strong endorsement that obese or overweight patients enrolled in comprehensive lifestyle interventions for weight loss should attend programs delivered for 6 months or longer. The gold standard of therapy is on-site, high-intensity (ie, 14 or more sessions in 6 months) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist. Further therapy should continue for a year or more. The expert panel hopes that payers will recognize the value of well-run programs that use this approach. Lesser-intensity approaches (delivered electronically, including by telephone) are secondary approaches because the amount of weight loss, and the health benefits are less.

Recommendation 5: Bariatric surgery.

OB 2 guides primary care practitioners to advise their adult patients who meet criteria (BMI > 40, or 35 and over with obesity-related comorbid conditions) that bariatric surgery may be an appropriate option to improve health, and advises clinicians to refer these patients to experienced bariatric surgeons.

The evidence statements address efficacy, safety, and predictors of success for several different surgical procedures. There should be a high follow-up rate for at least 2 years, and prospective collection of data on complications.

Gaps in the report:

The largest gap is the lack of a question addressing pharmacotherapy. Orlistat is still approved. Sibutramine has been removed from the market.

The algorithm of OB-2 provides guidance based on expert opinion about when and how to consider medications for chronic weight management.

Conclusion:

OB-2 indicates that good treatments are available for patients needing to lose weight. However, for patients to achieve health benefits from weight loss, they must have knowledgeable primary care clinicians (PCC) and access to these treatments. But a major educational gap exists. OB-2 may help clinicians engage patients in managing weight. PCC need to know the success rate of a comprehensive lifestyle and surgery with which they interact. They should also be reimbursed for providing high quality obesity care.

JAMA January 1, 2014; 311:23-24 First author Michael D Jensen, Mayo Clinic, Rochester, Minn
2013 ACCF/AHA/TOS2 Guidelines for Management of Overweight and Obesity in Adults
1 BMI 20-25 normal; 25-30 overweight; 30 and above obese Waist circumference in men < 102 cm;
in women < 88 cm

If an obese patient manages to lose 3% to 5% of weight, they may be encouraged to continued weight loss.

The comments about ineffectiveness of various weight-loss diets are welcome. In the past, Practical Pointers has included articles promoting specific diets for weight loss. None are consistently effective. The type of dietary changes depend on the tastes and habits of the individual patient.

Drug therapy is still an open question. JAMA January 1, 2013 lists 3 FDA approved drugs for long-term use: Orlistat (blocks fat absorption); Lorcaserin (appetite suppression); and Phentermine plus topiramate (appetite suppression).

The recommendations for lifestyle interventions and counseling are interesting, but, I believe, are rarely applicable for primary care patients. High-intensity sessions for a year or more would be costly and require considerable dedication. Few obese primary care patients would be able to comply.

1-3 DIETARY FIBER INTAKE AND RISK OF CARDIOVASCULAR DISEASE: Systematic review and meta-analysis

Numerous observational studies have reported that greater fiber intake is associated with lower risk of CVD. Other studies report no association.

This study explores potential dose-response associations and attempts to quantify the potential sources of heterogeneity between studies.

A widespread literature search (1990-2013) included articles (N = 19) reporting intake of total fiber, soluble fiber, and insoluble fiber from foods in relation to coronary heart disease of CHD and CVD. All were prospective observational studies with at least 3 years of follow-up. All studies accounted for influences of appropriate potential confounders.

Primary outcome = fatal, non-fatal, or total primary (first occurrence) of CHD or CVD.

RESULTS

Risk of CVD and fiber intake

Outcome and exposure	No. of studies	Risk ratio
Total fiber (per 7 grams /day)	10	0.91
Soluble fiber (per 4 g / day)	4	0.88
Insoluble fiber (per 7 g /day)	3	0.82
Cereal fiber (per 7 g /day)	5	0.92
Fruit fiber (per 4 g / day)	4	0.96
Vegetable fiber (per 4 grams /day)	4	0.92

Risks for CHD were similar.

Greater intake of total fiber, insoluble fiber, and fiber from cereals and vegetables was associated with lower risk of CVD and CHD. With each increase of 7 grams per day intake of total fiber, relative risks were 0.91 for CVD and 0.91 for CHD, a reduction of 9%.

BIAS, CONFOUNDING AND OTHER REASONS FOR CAUTION:

Fiber intake could be a surrogate marker for another healthy lifestyle of dietary behavior. However, there are plausible mechanisms and evidence for the action of fiber on key risk factors for development of CVD and CHD.

Dietary associations are notoriously challenging

CONCLUSION:

For each 7 grams per day of intake of fiber, risks for CVD and CHD were each 9% lower.

BMJ January 18, 2013;32:11 Research: First author Diane E Threapleton University of Leeds, UK
BMJ2013347:f6879 doi:10.1136/bmj.f6879

1-4 EAT MORE FIBRE : Editorial comments on the preceding study

Dozens of studies have investigated the association between dietary fiber and chronic disease. The preceding article is an important addition.

The investigators performed a state of the art meta-analysis of 22 cohort studies relating intake of dietary fiber with CVD and CHD. There was a consistent inverse relationship between fiber and the first CHD and CVD event. For both outcomes, every 7 grams per day of intake of total fiber was associated with a significant 9% lower relative risk of a first event.

The study also generated a dose response curve, rather than comparing the highest with the lowest intake groups.

The authors acknowledged that their careful analysis is limited by the quality of the included studies. Most of the data on intake was obtained from food frequency questionnaires, which are better at describing dietary patterns than individual nutrient intake. Even more important is the potential for confounding owing to the association between high fiber intake and other healthy nutritional factors and healthy behaviors. Ultimately, randomized trials will be needed to confirm the relationship.

Nevertheless, clinicians should enthusiastically recommend that patients consume more fiber.

There are indications that increased dietary fiber also reduces lipids and blood glucose, lessens constipation and diverticular disease, and increases satiety. Some studies showed a reduction in mortality with increased intake. Nutritional guidelines recommend consumption of 30 to 38 grams a day for men and 21-28 grams for women. The average intakes in Western countries is about half that.

Dietary recommendations should include a mix of soluble and insoluble fiber from multiple food sources. Good sources include whole grains, grains, vegetables, legumes, and seeds. Soluble fiber is found in oats, nuts, seeds, legumes, and most fruit. Insoluble fiber in whole wheat, wheat bran, brown rice, other whole grains, and most vegetables.

Seven grams additional fiber can easily be provided by one portion of whole grains, one portion of legumes, or two to four servings of fruits and vegetables.

Recommendations to eat more fiber are consistent with other nutritional recommendations: less sucrose and high fructose corn syrup, fewer refined carbohydrates, less trans fat and saturated fat, and less meat. Clinical experience suggests that many patients will respond better to dietary counseling that recommends eating more of certain foods, rather than constant focus of eating less.

Persuading patients to eat more whole grains is challenging. whole grains include barley, brown rice, rye, oats, and whole wheat. One strategy is to identify food products with whole grains listed as the first ingredient. Another strategy is to determine the ratio of grams of carbohydrates to grams of fiber. Breads with a ratio of 10:1 and cereals with a ratio of 1:5 are consistent with a high fiber product.

Patients should eat whole fruits, rather than drinking juice.

Conclusion: The evidence for recommending high fiber intake comes from several lines of imperfect evidence, mostly observational studies and expert opinion. The increases in fiber needed to achieve benefit are modest. A dose response can be estimated. Given the alignment with other nutritional recommendations, it makes sense to counsel patients to increase fiber intake.

“The recommendation to consume diets with adequate amounts of dietary fiber may turn out to be the most important nutritional recommendation of all.”

BMJ January 18, 2014; 348: 7 Editorial by Robert B Baron University of California, San Francisco
BMJ2013:347:f7401

The Mediterranean diet contains a good supply of fiber.

It may be difficult to separate the effects of fiber from the benefits of other food nutrients.

What is the mechanism? The authors made little comment. Low fiber foods are “healthy “ foods. Foods that promote benefits beyond the benefits of fiber.

“Could This Current Problem Have Occurred Due To AF?”

1-5 ATRIAL FIBRILLATION BEGETS MYOCARDIAL INFARCTION: Editorial and Meta-analysis

For decades, stroke has been the principally recognized and most clinically relevant sequela of AF. Recent analysis demonstrated that AF may also lead to worsening renal function, a particularly important observation given that chronic renal disease has been primarily considered a risk factor for development of AF.

AF itself may also lead to increased risk of incident MI.

There is a growing recognition of important bidirectional relationships between AF and other cardiovascular comorbidities (kidney disease, heart failure, and now MI).

A study in this issue of JAMA Internal Medicine¹ analyzed data from the Reasons for Geographic and Racial Differences in Stroke Study. Almost 24 000 participants without baseline coronary disease were observed for almost 7 years. About 7% had AF. Participants with AF had nearly a 2-fold risk of incident MI compared with those without AF.

This was a large population-based sample. The primary outcome of the study (MI) was rigorously adjusted for potential confounders.

It may be that emboli passing from the left atrium to the coronary circulation are more common than conventionally thought.

Both women and African Americans with AF were at increased risk of MI, mirroring the increased risk of stroke in these groups. If the increased risk of MI is due to emboli arising from the left atrial appendage, one would expect anticoagulation to be preventive.

These editorialists performed a meta-analysis of randomized controlled trials in patients with AF comparing anticoagulation vs anti-platelet agents or placebo on incident MI. They found that warfarin reduced risk of MI by 25%. Analyses restricted to antiplatelet therapy showed similar trends, but without statistical significance.

The addition of aspirin to systemic anticoagulation results in increased bleeding without any clear benefit.

Although the results of the study are informative, they do not suggest change in AF treatment strategies. `

AF begets many problems. There is clearly a complex bidirectional relationship between AF and multiple conditions. Our regular clinical practice must extend beyond the question “Why does the patient have AF?” to “Could this current problem have occurred due to AF?”

JAMA Internal Medicine January 2014; 174:5-6 First author Jonathan W Dukes, University of California, San Francisco.

1 Atrial Fibrillation and the Risk of Myocardial Infarction. JAMA Internal Medicine January 2013;174:1071-13 First author Elsayed Z Soliman, Wake Forest School of Medicine, Winston-Salem, NC

doi:10.1001/jamainternmed.2013.11392

doi:10.1001/jamainternmed.2013.11912

Growing Evidence That Some Chronic Inflammatory Diseases (Rheumatoid Arthritis, Systemic Lupus Erythematosus, And Some Forms Of Vasculitis) Are Associated With Increased Rates Of CVD.

1-6 RISK OF CARDIOVASCULAR DISEASE EARLY AND LATE AFTER A DIAGNOSIS OF GIANT-CELL ARTERITIS: Observational cohort study

GCA has a predilection for large and medium-sized arteries. It can result in ischemic blindness. The mainstay of treatment is high doses of corticosteroids for substantial periods.

Imaging studies have described a high prevalence of large-artery stenosis and aneurysms in these patients.

Information on risk factors for cardiovascular disease (CVD) is important when the association of GCA with CVD is explored.

This study determined the association between GCA and incident CVD (myocardial infarction [MI], cerebrovascular accidents [CVA], or peripheral vascular disease [PVD]).

STUDY

1. Obtained data from The Health Improvement Network (THIN), a database derived from general practices in the UK that included approximately 7.3 million patients.
2. For each case of GCA selected up to 5 individual without GCA at the time of diagnosis, matched by age, sex, and time of entry into the database. None of the matched individuals had MI, CVS or PVD.
3. All GCA patients used corticosteroids.
4. Obtained information about risk factors for CVD (smoking, hypertension, cholesterol, diabetes, body mass index).
5. Collected data from 1999 to 2011.

RESULTS

1. Included 3408 patients with incident GCA and 17 027 reference participants. At baseline, mean age was 72, 73% female.
2. Median follow-up was 3.9 years among those with GCA and 4.2 years for reference participants.

3. Association of GCA with incident CVD per 1000 person-years:

	GCA	Reference	Hazard ratio	HR*
MI	10.0	4.9	2.06	11.9
Stroke	8.0	6.3	1.28	3.9
PVD	4.2	2.0	2.13	3.9
Combined	22.2	13.2	1.68	4.92

*Hazard ratios were more pronounced during the first month after diagnosis.

4. Adjustment for CVD risk factors did not attenuate the association between GCA and study outcomes.

DISCUSSION

1. This large population study shows elevated risks for CVD among patients with GCA.
2. There is a suggestion that risk of CVD events may be higher in the period immediately after diagnosis of GCA. High doses of corticosteroids have pro-thrombotic effects.
3. These results are consistent with growing evidence that some chronic inflammatory diseases (rheumatoid arthritis, systemic lupus erythematosus, and some forms of vasculitis) are associated with increased rates of CVD.
4. These findings imply that a diagnosis of GCA (immediately after diagnosis and long-term) should alert clinicians to be mindful of possible CVD events. Treatment of GCA with aspirin is already routine practice.

CONCLUSION

GCA is associated with increased risks for MI, CVD, and PVD.

Annals Internal Medicine January 21, 2014;160:73-80 First author Gunnar Tomasson, University of Iceland, Reykjavik

Primary funding source: National Institute of Arthritis and Musculoskeletal and Skin Diseases

GCA is not a rare disease. It frequently affects the temporal and ophthalmic arteries, Temporal artery biopsy is diagnostic.

Corticosteroids do not reduce risk of CVD.

Infarcts leading to MI, stroke, and PVD were more likely due to arterial damage from the GCA than from atherosclerotic disease. Never the less, I believe anti-atherosclerotic measures should be instituted at diagnosis along with anti-platelets.

The article did not mention GCA's first cousin, "polymyalgia rheumatica" (PR), which is also due to arteritis.

PR may be caused by inflammation of blood vessels similar to temporal arteritis in patients with GCA. The two may co-exist.

Symptoms of PR include: pain and stiffening of the neck, shoulders, and hips, especially in morning; fatigue and lack of appetite; anemia; low grade fever; fatigue, and weight loss.

The sedimentation rate is markedly increased

About 15% of people with PM also have temporal arteritis; about 50% of people with temporal arteritis have PM.

The average age is about 70, especially women. (Source: Wikipedia)

