Cholesterol guidelines: Epic fail

I've weighed in on this subject before: "You should get a second opinion on statin use—and here's why". I argue: "When it comes to cholesterol, it's not how low you go—*it's how you get there!* Natural ways always outperform drugs."

Although cholesterol-lowering drugs are more popular than ever, a recent review in ***BMJ Evidence Based Medicine*** should give us pause about their indiscriminate use.

It's by UK celebrity cardiologist Aseem Malhotra and co-authors. Malhotra is the controversial author of the ***Pioppi Diet***, a best-seller in England, that calls for adoption of a high-fat, low-carb modified Mediterranean diet for cardiovascular prevention. He's incurred the wrath of the medical establishment by decrying our excessive emphasis on saturated fat avoidance and statin drugs.

And I mean *wrath*. He and other critics of cholesterol-lowering drugs have been accused of "statin denialism", a form of medical heresy which endangers people's lives.

For example, James Stein of the University of Wisconsin issues this rebuke: *"Many lives have been lost or impaired because of statin non-compliance. There is a special place in hell for people who use fear tactics and misinformation to promote books and natural health aids, including crazy diets, at the expense of proven medical therapies . . ."*

But Malhotra is no wild-eyed radical. In a detailed, methodologically-sound review entitled, "Hit or miss: the new cholesterol targets", he challenges the rationale

for prescribing meds to optimize lipid profiles. He concludes:

"The negative results of numerous cholesterol lowering randomized controlled trials call into question the validity of using low density lipoprotein cholesterol as a surrogate target for the prevention of cardiovascular disease."

I'm a case in point. Just for fun, I plugged my personal data into a popular cardiovascular risk calculator put out by the American College of Cardiology.

It asked for my age, sex, and race, as well as smoking history (I smoked in college), and whether I had diabetes or hypertension (no). I dutifully entered my cholesterol (210) HDL (65) and LDL (135).

I was feeling pretty good about it, although nowhere did it allow me to refine the results by asking about my height and weight (normal at 5'10 and 165), my optimal lipoprotein(a) and homocysteine, or the pattern of my LDL particles (large, buoyant = low risk).

Nor did it credit my exercise routine of miles of running, biking, swimming and walking per week.

Not to mention the low-carb diet I follow, with time-restricted feeding. Or the cardioprotective nutrients I take (but the American College of Cardiology surely doesn't believe in them).

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Slavishly, the algorithm boiled it down to this: I'm just another old white male with an LDL cholesterol above the arbitrary, acceptable threshold of 130. My 10-year risk of heart disease or stroke was estimated to be 11.9%, which is well above the cutoff of 7.5% signifying "moderate risk"—for which it's strongly recommended I take "a moderate intensity statin" like Lipitor, Pravachol or Crestor.

I'd hasten to point out that a recent EBT heart scan revealed my coronary calcium score to be zero—which equates to a negligible risk of cardiovascular disease for decades hence, if ever. But the risk calculator didn't ask.

To that point, Malhotra cites the fact that fully 44% of individuals who, like me, were classified as statin candidates based on their estimated risk scores, were found to have zero plaque in the Multi-Ethnic Study of Atherosclerosis (MESA). Thus, the new cholesterol targets are truly "hit or miss".

Malhotra undertakes a detailed review of 35 studies that evaluated the benefits of three classes of drugs, mostly statins, but also Zetia, and the new PCSK9 inhibitors. The latter can slash cholesterol dramatically by as much as 70-100 points. They're injectable and can cost thousands of dollars per year. They've been widely billed as "game changers in our war against cholesterol".

Interestingly, Malhotra's analysis reveals, many of the 35 studies showed negligible benefits of these drugs. Thirteen of the clinical trials met the LDL cholesterol reduction target, but only one reported a positive impact on risk of death; five reported a reduction in the risk of "events".

A "successful" trial of Zetia, for example, demonstrated it reduced cardiovascular events. But Malhotra calculates that 56 patients would have to take it for six years for one patient to enjoy protection—55 would take it needlessly, with attendant side

effects.

Leyla Weighs In: The dangers of very low cholesterol

The kicker is that, while some of these drugs reduce heart attacks and strokes for select populations of at-risk individuals, virtually none of them reduced mortality. The all-important goal of prolonging life was almost never achieved through these drug interventions—even for the vaunted, expensive PCSK9 inhibitors.

And while we're playing "cholesterol limbo" (how low can you go), it would stand to reason that the more drastic LDL reduction achieved, the greater the protection conferred. But among the 35 studies there was much inconsistency; some studies showed benefits of minimal cholesterol reduction with low doses of statins, while others revealed only marginal upsides of more drastic LDL lowering. This very heterogeneity calls into question the aggressive targeting of LDL as a sure path to circulatory salvation.

Cholesterol-lowering drugs are now taken by tens of millions world-wide. But Malhotra points out that they're not curtailing the global epidemic of cardiovascular disease. In the US, for example, statin prescribing has skyrocketed, and cholesterol levels are falling, yet cardiovascular deaths appear to be on the rise. He marshalls evidence that in Sweden, widespread use has not correlated with any significant decline in heart attacks, while in Belgium, a modest decline in cardiovascular events was reported between 1999 and 2005, but mostly in elderly individuals not taking statins.

Malhotra's review concludes: *"In most fields of science the existence of contradictory evidence usually leads to a paradigm shift or modification of the theory in question, but in this case the contradictory evidence has been largely ignored, simply because it doesn't fit the prevailing paradigm."*

BOTTOM LINE: I'm not inalterably opposed to cholesterol-lowering drugs. But I agree with Malhotra that they should be used very sparingly, only for individuals with the highest risk, and not for mere prevention. And natural interventions, with diet, exercise and cardiovascular-protective nutrients like fish oil should take precedence over the prescription pad. Cholesterol-lowering drugs may even backfire, offering perverse incentives for at-risk individuals to eschew healthy lifestyle measures because they wrongly consider themselves "bullet-proof" (as in "I'll just take some more Lipitor after tonight's chow-down").

More at "Doubt cast on wisdom of targeting 'bad' cholesterol to curb heart disease risk".