Poor Analytical Skills Leads To Dangerous Misinformation

There has been a recent spate of inappropriate news headlines regarding niacin. Some of them are listed here:

"ACC: HPS2-THRIVE may signal the end for niacin" -*Medpage Today*

"Niacin causes serious unexpected side-effects, but no worthwhile benefits, for patients who are at increased risk of heart attacks and strokes"- *Sacramento Bee*

"Niacin therapy unhelpful, occasionally harmful" - *Naharnet*

"Niacin doesn't help heart may cause harm, study says"- *USA Today*

The conclusions reached by these news organizations is unjustified. The truth is that when these studies are analyzed, we can easily conclude: laropiprant, not the niacin, is bad.

The study compared statin alone (Group A; the pharmaceutical marketer's favorite) to (Group B; niacin + laropiprant [tredaptive] + statin).[1] Group B had a bad outcome. Which should we blame, niacin or laropiprant? Well, niacin has been used for over 60 years without any serious side effects and has been shown to reduce mortalities due to cardiovascular disease even 10 years after patients stop taking it.[2-4] Laropiprant has hardly been used at all. It is a relatively new drug that interferes with prostaglandin D1 (PGD1) pathways, which in this case is used to prevent the flushing side effect so that more patients can take it. It is not used for any apparent clinical benefit for cardiovascular disease reduction other than reducing the unpleasantness of too much niacin for some. PGD1 is known to work favorably through peroxisome proliferator-activated receptors to correct dyslipidemia. Niacin is in over 7,000 publications as indexed in Pubmed (over 35,000 as nicotinic acid,), while laropiprant is in less than 100, the first coming out in 2006.

It's essential to clarify what form of niacin is being used. When Medpage Today reports, "may signal the end of niacin" they really must be referring to extended-release niacin (ERN). The patent for ER niacin is expiring soon. Generics are now entering the market. The clinical data to date indicates that the immediate-release niacin (IRN) still works better and has fewer complications than the ERN.

The truth of the matter is that IRN outperformed all other forms of niacin in clinical studies that were completed. A recent review of the clinical trials data for all niacin studies indicates that IR niacin has the greatest positive impact on reducing mortality from cardiovascular disease than any other form of niacin.[5] The Coronary Drug project study reported reductions in cardiac mortality of 11%, 15 years after stopping niacin intake, in a study involving over 8000 patients.[2] The Ischaemic Heart Disease study had a follow up of five years and reported over 25% reduction in total mortality for over 500 patients taking a combination of niacin with clofibrate.[6] By comparison every clinical trial that has been completed since these trials has failed to achieve such favorable results and they all involved the patented ERN. These are truly amazing unparalleled high quality data that support IRN as the best treatment for correcting cardiovascular disease risk factors. IRN is available almost anywhere. One hundred tablets of IRN can be purchased for approximately 10 USD. It is important that the flush warning is on the bottle. The flush response is easily managed with a baby aspirin or by introducing niacin at lower doses initially.

The authors of these news stories are doing an injustice to their readers. Heart disease is the number one killer in the U.S.A. The clinical data indicate that niacin is one of the most clearly beneficial therapeutic approaches to treating cardiovascular disease. In *The New 8-Week Cholesterol Cure: The Ultimate Program for Preventing Heart Disease,* Kowalski describes his personal story as a heart attack about to happen.[7] In chapter 8

he gives niacin more credit than anything else for correcting all of his risk factors. IRN, like human physiology, has not changed recently. These news articles represent misinformation that negatively impacts human health!

–W. Todd Penberthy, PhD.
Department of Molecular Biology & Microbiology
Burnett School of Biomedical Science
University of Central Florida College of Medicine,
email: wtpenber@mac.com

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Editor's Reply

In my clinical experience, there are very few patients that find immediate realease niacin (IRN) intolerable and thus discontinue treatment once they are properly educated. I have included some clarification as well as additional information so that our readers will continue to prescribe IRN and spare their patients the misery of cardiovascular disease.

In the Coronary Drug Project,[1] patients who were administered niacin had reductions in myocardial infarction (24%), strokes (26%), cardiovascular surgery (46%), and deaths (11%; adding a mean of 1.63 years of life to men 30 to 65 years old with one or more preceding myocardial infarctions). Follow-up results showed that there was a decrease in nonfatal recurrent myocardial infarction and a reduction in mortality from all causes nine years after termination of the same trial.[2] In a subsequent publication by Canner et al,[3] he mentioned the following information: Of the five drug regimens, only niacin significantly decreased definite recurrent nonfatal MI at sixyears and total mortality at 15-year follow-up. In this publication, Canner at al introduced a new post hoc analysis of niacin pertaining to its therapeutic effects upon metabolic syndrome (MS). For example, patients taking niacin with MS were compared to MS patients not on niacin, and the 15-year mortality rates were 60% and 64% respectively. The mortality rates were 50% for the non-MS niacin group and 57% for the non-MS placebo group. The authors noted that there was homogeneity of the treatment effect across groups, and that these results support the use of niacin in post-infarction patients with and without MS.

Niacin should be highly considered as an agent for the secondary prevention of coronary events, including reducing all-cause mortality. It has a very important mechanism of action that makes it an excellent therapy, especially among patients that do not want to be on statin medications. Niacin significantly modifies the entire cholesterol profiles (i.e., reduces total cholesterol, reduces low-density lipoprotein cholesterol, increases high-density lipoprotein cholesterol, and reduces triglycerides), and also modifies additional risk factors like fibrinogen[4] and C-reactive protein.[5] Recent information has emerged about niacin's ability to lower blood pressure when administered over a long period of time;[6] an effect that would also help in secondary coronary prevention.

–Jonathan E. Prousky, MSc, ND
Chief Naturopathic Medical Officer,
Professor
Canadian College of Naturopathic
Medicine
email: jprousky@ccnm.edu
Editor, Journal of Orthomolecular
Medicine, email: editor@orthomed.org

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