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Discussion Paper

# Intermediate-Dose Niacin and Natural Cholesterol Management

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The intake of niacin at intermediate dosage levels --- 100-1000mg/day---has been shown to significantly improve the levels of both HDLs and triglycerides. Coupled with other elements of natural cholesterol management, including those that lower LDL cholesterol, intermediate dosage levels of niacin in the form of supplements may provide a meaningful contribution in enhancing long term cardiovascular health.

## Intermediate-Dose Niacin and Natural Cholesterol Management

Niacin, also known as Vitamin $B_3$, is vital for good health. Niacin helps convert food into energy, build red blood cell counts, and synthesize hormones.

For basic good health, a relatively small amount of niacin, about 20mg/day, is needed. Americans typically obtain this level from a balanced, healthy diet. Our bodies also can manufacture niacin.

At *substantially* higher levels—1000-2500mg/day--- a specific type of niacin significantly improves cholesterol levels. Niacin as nicotinic acid can lower LDL cholesterol by up to 25%, raise HDL cholesterol by as much as 35%, and lower triglyceride levels by 20% to 50%.[i] The medical community[ii] generally defines these high dosages as a drug that should be taken under a physician's care. The primary concerns relate to potential liver complications. A doctor will monitor liver function as part of a routine blood test. As a practical matter, the very real and sometimes intense flushing side-effects associated with nicotinic acid at these levels may make a "buffered" prescription nicotinic acid the only viable option.

Nonetheless, nicotinic acid supplements are approved for sale by the Food and Drug Administration. Further, the intake of niacin at intermediate dosage levels --- 100-1000mg/day---has been shown to significantly improve the levels of both HDLs and triglycerides. Coupled with other elements of natural cholesterol management, intermediate dosage of niacin in the form of supplements may provide a meaningful contribution in long term cardiovascular health.

### Cholesterols Management: Beyond LDL Reduction

LDL cholesterol reduction has been the primary focus of the medical and pharmaceutical community. This focus is supported by the significant and extensive research confirming the positive health effects of lowered LDL, including reduced heart attacks, strokes and other cardiovascular diseases.

Increasingly, medical science recognizes that LDL reduction alone is only part of cholesterol management and cardiovascular health and wellness.

Researchers are assessing the composition of cholesterol and triglycerides in our blood. For instance, the NIHs' National Cholesterol Education Program (NCEP) reports that "strong epidemiological evidence links low levels of serum HDL cholesterol to increased CHD (coronary heart disease). High HDL-cholesterol conversely conveys reduced risk."[iii] The NCEP identifies having HDLs less than 40mg/dl as a risk factor for heart disease. Levels above 60mg/dl are associated with a reduced risk of heart disease.

Statins, the leading medication for LDL reduction, have been associated with some HDL increases. Yet, under the NCEP guidelines, statins are typically recommended only when LDL levels are elevated.

Low HDL levels *without* elevated LDL levels are nonetheless fairly common. Up to 50% of patients not typically candidates for LDL-lowering medications have low levels of HDLs. In patients with premature coronary artery disease, low HDL levels are the most common abnormality in blood lipids.[iv]

A number of recent studies indicate that small increases in HDLs can significantly reduce the incidence of cardiovascular-related death. A 1mg/dl increase in HDL has been associated with a 2%-3% reduction in coronary artery disease.[v] Another extensive study concluded that increasing HDLs by 6% in patients with low HDL cholesterol decreased heart-related deaths and non-fatal heart attacks by 22%.[vi]

Intermediate Daily Dosages of Niacin as Nicotinic Acid

Between the 20mg recommended for basic health and the 100x greater levels used to manage at-risk patients lies a potential role for niacin for promoting cardiovascular health. In one study, patients took 50mg of niacin as nicotinic acid twice per day for 3 months. The patients on the niacin experienced an average 5% increase in HDLs, or an average of 2.1mg/dl.[vii] In another study, 500mg/day of niacin as nicotinic acid raised HDLs by 10% (close to 5mg/dl) and lowered LDLs by 5% and Triglycerides by 5%.[viii] At 1000mg/day, improvements were 15%, 7% and 11% for HDL, LDL and triglycerides respectively.

| Niacin (as Nicotinic Acid): Daily Levels for Different Purposes | | | | |
|---|---|---|---|---|
| Dose Level | 16-20mg | 100 to 500mg/day | Up to 1000mg/day | 1000-2500mg/day |
| Purpose | General Health | Intermediate Dosages to Promote Healthier HDL, LDL & TG Levels | Intermediate Dosages to Promote Healthier HDL, LDL & TG Levels | High Dose Prescription Niacin for Risk Factor HDL, LDL & TG Levels |
| Soucre | Foods | Supplements | Supplement/Prescriptions | Prescriptions |
| otential Effects | | | | |
| HDLs | | up to 10% Increase | up to 15% Increase | up to 35% Increase |
| LDLs | | up to 5% Decrease | up to 10% Decrease | up to 25% Decrease |
| TG | | up to 5% Decrease | up to 10% Decrease | up to 50% Decrease |

The medical community has refrained from endorsing the use of nicotinic acid supplements at these dosage levels as part of a more natural, statin-free solution to blood lipid management. The medical community's reticence flows, in part, from doctors' distrust of nutritional supplements. Supplements are subject to fewer regulations than pharmaceuticals, but the industry also is not without regulatory requirements, and many high quality and reliable supplement manufacturers and retailers exist.

Another issue surrounding niacin relates to the potential for consumer confusion. There are three types of niacin available---nicotinic acid, niacinamide, inositol hexanicotinate. Only nicotinic acid has been shown to be effective for cholesterol management.

Further, there are three forms of nicotinic acid—immediate release, sustained release and extended release.

Immediate release nicotinic acid often causes a very uncomfortable flushing of the skin accompanied by an intense feeling of heat, tingling and itching---even at relatively low levels of niacin. The flushing can start a few minutes or a few hours after taking niacin. Flushing typically subsides within 30 minutes, often much sooner.

At the intermediate dosage levels, flushing can be managed by gradually increasing the levels of nicotinic acid. You can start by trying 50mg with lunch and dinner. As your body grows accustomed to these levels, you can try raising your niacin intake with these meals. You might also try taking nicotinic acid before bed.

For individuals who cannot overcome the flush or for those looking to move to higher a dosage level, nicotinic acid is sold as a supplement in a sustained release version. The sustained releases version reduces the intensity of flushing, but at higher levels, it has been associated with liver damage.

The third form of nicotinic acid, extended release niacin, is available as a prescription. This form has typically been used at high level and only to treat harmful cholesterol levels that cannot be remedied through nutrition, certain lifestyle changes and statins.

Integrating Niacin into Natural Cholesterol Management

Intermediate doses of niacin as nicotinic acid may be meaningful for raising HDL cholesterol for cardiovascular health promotion, since the corresponding 5-10% increase in HDLs can significantly lower the risk of heart attack. The impact at these dosage levels alone may fall short of achieving more optimal cholesterol and triglyceride levels. When coupled with other nutrients, however, these niacin dosages may enable an individual to achieve optimal targets. Substantial LDL reductions can be further achieved through the restricted intakes of saturated and trans fats, higher intakes of monounsaturated fats, and therapeutic levels of plant sterols and selected types of fibers (including soluble fiber from oats, barley, psyllium, beans and certain fruits) .[ix] While Omega-3s have not been proven to lower LDL cholesterol, they lower triglycerides and may positively alter other factors leading to the build-up of arterial plaque. Modest weight loss and increased physical activity can further raise HDLs.

With many Americans suffering from the side-effects of statins and others preferring to minimize a lifetime of prescription drugs, it seems appropriate for the medical community to take a greater interest in the role of intermediate dosages of niacin, particularly as a component of broader therapeutic nutrition efforts.

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[i] Anne Goldberg, M.D. et al, **Multiple-Dose Efficacy and Safety of an Extended-Release Form of Niacin in the Management of Hyperlipidemia.** *The American Journal of Cardiology, Vol. 85, pp 1100-1105 May 1, 2000.*

[ii] **Detection, Evaluation & Treatment of High Blood Cholesterol in Adults,** *Third Report of the National Cholesterol Education Program Expert Panel* National Institute of Heart, Lung and Blood Institute, National Institutes of Health, September 2002. www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf

[iii] Ibid "II Rational for Intervention".

[iv] Ibid.

[v] DJ Gordon et al., **High Density Lipoprotein Cholesterol and Disease: Four Prospective American Studies,** *Circulation* 1989

[vi] HB Robins et al., **Gemfibrozil for the Prevention of Coronary Heart Disease in Men with Low Levels of High-Density Lipoprotein Cholesterol,** *The New England Journal of Medicine* 1999.

[vii] Jennifer Wink, MD et al., **Effect of Very-Low-dose Niacin on High-Density Lipoprotein in Patients Undergoing Long-Term Statin Therapy,** *American Heart Journal,* Volume 143, Number 3, March 2002.

[viii] Goldberg Op Cite, p1102

[ix] Ibid