

Color Blind, or Just Plain Blind?

Are you an African-American? Are you over 45? If you are, data suggests you are almost twice as likely as a white American to have heart failure and more than twice as likely to die from it. In the November 11, 2004, issue of the *New England Journal of Medicine*, Taylor et al published the results of an experimental therapy that was deemed such a success the independent scientists monitoring the study recommended it be brought to an early end so placebo users could switch to the active treatment. The active treatment had demonstrated a 43-percent lower incidence of dying during a year's treatment. The "miracle" results were well publicized by the media during the November 2004 meeting in New Orleans of the American Heart Association (AHA). Although there have been ethical debates in the media recently concerning "drugs aimed at specific races or ethnic backgrounds," I shall leave that debate to others and merely review the science of the so-called miracle results.

The NEJM study was conducted using the drug BiDil, currently awaiting approval from the U.S. Food and Drug Administration (FDA). Rejected by the FDA a decade ago, in its new iteration and backed by the Association of Black Cardiologists (ABC), BiDil, a combination of isosorbide dinitrate and hydralazine, has risen from the ashes and promises to further the cardiovascular benefits of nitric oxide, the basis for the 1998 Nobel Prize in Medicine. Running a Pub Med search comprised of BiDil's two ingredients, plus the search term "nitric oxide," produces the following meager results: isosorbide nitrate – 95 hits; hydralazine – 126 hits; and BiDil – 9 hits. Considering the two drugs that make up BiDil have been around for over a decade and nitric oxide really hit the charts in 1998, that's not too many journal articles out there.

I contacted the ABC's chairman of the board, explaining that an alternative to BiDil already exists – the amino acid arginine. As I informed him of 27,000+ references in Pub Med for "arginine" and "nitric oxide," I could hardly contain my excitement as I described recent PET (positron emission tomography) scans that demonstrate dramatically increased blood flow to the heart muscle when utilizing a state-of-the-art, time-released arginine formulation. My assertion that arginine deserves consideration for a major clinical study was met with, in my opinion, the level of interest usually found in those assigned the job of watching fingernail polish dry. The "you can send me some data and I will bring it up for review at the next board meeting" response certainly did not espouse what I expected from a leader in cardiovascular medicine.

Let's review the respective scorecards.

For BiDil:

1. Will be an expensive pharmaceutical –
2. Increases nitric oxide to tissues, which can dramatically lower the risk of heart failure –
3. May be available in a year or so –
4. Side effects that have been reported for BiDil and/or its two component ingredients include: *allergic reaction, blood in urine or stools, numbness, tingling, pain or weakness of arms or legs, irregular or very fast heartbeat, new or worsening chest pain, fainting, dizziness, dry mouth, low blood pressure, skin rash, sweating, feeling of extreme pressure in the head, headache, nausea, vomiting, water retention, diarrhea, decreased appetite, and bluish discoloration of the lips, fingernails, or palms* –
5. Was touted as a significant new therapy by the AHA at the aforementioned New Orleans meeting.

For time-release arginine:

1. Is an inexpensive dietary supplement –
2. Increases nitric oxide to tissues, which can dramatically lower risk of heart failure –
3. Is available now, without prescription –
4. Has virtually no documented side effects: *may increase herpes flare-ups for those with active herpes; lysine supplementation is recommended* –
5. After submitting significant evidence to the AHA of the cardiovascular benefits of time-release arginine, attempts to exhibit the evidence and inform cardiologists at the aforementioned AHA conference in New Orleans were denied.

These results beg the question: What will it take to draw attention to the fact that pharmaceutically-oriented organizations such as the AHA and ABC are not color blind when it comes to seeing the color green, but are completely blind when it comes to seeing beyond the drug model, especially when more effective, infinitely less harmful alternatives are available. *All* persons – not just African-Americans over the age of 45 – should insist on immediate studies, with the mandated cooperation of such organizations as the AHA and ABC, of *every* alternative to the drugs so casually prescribed on a daily basis. If the AHA experiences its own Vioxx debacle with its own Pandora's box, many people will have died unnecessarily.

Al Czap,
Publisher