

EDITORIAL

Evidence for Including Lutein and Zeaxanthin in Oral Supplements for Age-Related Macular Degeneration

David C. Musch, PhD, MPH

In a National Eye Institute press release¹ issued on May 5, 2013, with simultaneous online publication in JAMA,² the results from the second phase of the Age-Related Eye Disease Study 2 (AREDS2) were announced.



Related article page 142

This press release was titled "NIH study provides clarity on supplements for protection against blinding eye disease," and indeed in its first paragraph, the primary outcome was clearly stated: "The plant-derived antioxidants lutein and zeaxanthin also had no overall effect on [age-related macular degeneration (AMD)] when added to the combination; however, they were safer than the related antioxidant beta-carotene." This study provided us with a striking example of a major clinical trial in which the primary outcome was negative, but yet its broader findings preempted substantial changes in the formulation of so-called eye vitamins that constitute a major market presence and are likely recommended by most eye care practitioners for a patient they determine to be at risk for developing neovascular AMD. The ability of companies to market their eye vitamins as providing an exact match to the AREDS2 formula is evidently important because we encounter such statements in venues ranging from our professional journals to television commercials. While some might say that the train has long since left the station, the purpose of this editorial is to critically evaluate the evidence underlying formulation changes that are under way or have already taken place.

In this issue's article,³ the AREDS2 investigators provided us with a detailed look at additional analyses that led them to support adding lutein and zeaxanthin to, and deleting beta carotene from, the previously recommended oral formulation for eye health, termed the AREDS formula. Like the analyses presented in their initial report, some of these analyses were termed *exploratory* in nature and relied on results from inspecting subgroups that were not prespecified and thus were *post hoc* in nature. Subgroup analyses have been viewed as a 2-edged sword by Wittes,⁴ who wrote: "If reporting on subgroups is tempting but treacherous, failing to report on them seems unscientific and incurious." As Fleming and Warelet⁵ pointed out, the results of such analyses should usually be viewed as hypothesis generating rather than definitive in nature. They advised that definitive conclusions from such analyses occur only in rare situations: when very strong associations are found that are biologically plausible and supported by results from other sources. Even so, claims of treatment efficacy that result from such findings are not uncommon. The subgroup analysis finding from the Steroids for Corneal Ul-

cers Trial that corticosteroids may be beneficial for treatment of bacterial keratitis when baseline visual acuity is count fingers or worse, or when the ulcer was completely centrally located, was advised to be viewed with caution in a letter to the editor.⁶ In their reply, the trial's investigators fully agreed that their findings, while based on prespecified subgroup analyses, should be subject to further confirmation.⁷ When pivotal phase 3 trials of proposed treatments yield negative or equivocal results, a commonly encountered directive from the sponsor is to revisit the data in an attempt to identify subgroups that show efficacy; thus the derogatory term *data dredging* and the humorous, but sometimes real, claim that if you torture your data long enough, they will confess.

A critical look at the evidence from AREDS2 for an efficacious effect of lutein/zeaxanthin supplementation starts with the authors' JAMA article,³ in which a prespecified comparison of those receiving lutein/zeaxanthin vs those who did not receive lutein/zeaxanthin revealed a 10% reduction in the risk for progression to late AMD. A second prespecified analysis showed that those in the lowest quintile of dietary intake of lutein/zeaxanthin who received lutein/zeaxanthin along with the original AREDS formulation had a 26% reduced risk for progression to late AMD relative to participants receiving the original AREDS formulation without lutein/zeaxanthin. Finally, an exploratory look at the group given lutein/zeaxanthin in its supplement showed an 11% reduced risk for developing neovascular AMD vs those who received only beta carotene in their supplement.

The further analyses presented herein include an exploratory analysis of the 1114 participants who received lutein/zeaxanthin added to an AREDS formulation without beta carotene vs the 1117 participants who received only beta carotene in the AREDS formulation. This revealed that those receiving lutein/zeaxanthin without beta carotene supplement had an 18% reduction in the risk for late AMD and a 22% reduction in the risk for neovascular AMD (both which met the $P < .05$ criterion), as well as a 6% reduction in the risk for geographic AMD (which yielded a P value of .67). A prespecified analysis of progression on the AREDS severity scale for AMD⁸ did not reveal a beneficial effect of lutein/zeaxanthin supplementation (with or without beta carotene) on reducing the risk for a 2 or more step progression. However, in an exploratory look at the subset who only received lutein/zeaxanthin (without beta carotene) vs the subset who received only beta carotene, lutein/zeaxanthin supplementation reduced the risk for a 2 or more step progression by 13%. The results were compelling for the subset of 1748 subjects who had bilateral large drusen and were evaluated for progression to neovascular AMD, which developed in 11.5% (99

Age-related Macular Degeneration And Lutein Absorption The Evidence

JA Banks



Age-related Macular Degeneration And Lutein: The Evidence:

Age-related Macular Degeneration (AMD) and Lutein S. Pratt, 2002-05 **Age-related macular degeneration (ARMD)** Sics Editore, 2014-10-01 Age related macular degeneration is the most important cause of visual impairment in the elderly The non exudative or dry form progresses slowly the exudative or wet form rapidly within weeks or months Refer a patient with suspected exudative form of the disease without delay for investigations and treatment Also consider the significance of the disease in the patients daily life **Carotenoids and Retinal Disease** John T. Landrum, John Nolan, 2013-10-18 The macular carotenoids play key roles in eye health and retinal disease Age related macular degeneration AMD the most common cause of acquired blindness in much of the world is associated with low levels of macular pigment Macular pigment is also essential for enhancing visual performance by reducing glare disability and improving photostress recovery Carotenoids and Retinal Disease presents an up to date thorough volume devoted to the chemistry pathobiology visual science and medical and public health significance of the macular carotenoids With contributions from an international group of leading experts this book covers a range of topics from macular anatomy to clinical trials It begins with a chapter tracing the discovery of macular pigment through the more recent functional recognition of carotenoids The text covers AMD risk factors epidemiology pathogenesis and classifications It reviews evidence from epidemiological studies of relationships between AMD and the carotenoids lutein zeaxanthin and meso zeaxanthin as well as evidence from clinical trials on the effects of macular carotenoid supplementation in subjects with AMD and normal subjects The book explores the use of molecular genetics in studying macular pigment and AMD pathogenesis bioavailability of macular pigment functions of lutein zeaxanthin and meso zeaxanthin and the identification of macular carotenoid binding proteins involved in pigment uptake and transport It also covers xanthophyll membrane interactions and the macular carotenoids in human serum and their capacity to protect against AMD Further the implications of light distribution on the retina for AMD are discussed Advancing our understanding of how the macular carotenoids enhance vision and prevent vision loss this book provides a valuable reference for researchers and clinicians involved in the treatment and prevention of retinal disease *Age-related Macular Degeneration Diagnosis and Treatment* Allen C. Ho, Carl D. Regillo, 2011-08-09 Age Related Macular Degeneration Diagnosis and Treatment is written by two leading experts from Wills Eye Hospital Covering the latest therapies and treatments developed in the last few years this is a concise yet highly illustrated and practical text that guides the clinician through diagnosis and treatment of the leading cause of blindness in older Americans **The Effects of Egg Lutein on Age-related Macular Degeneration and Cardiovascular Disease Risk Factors** Shymaa Mohsen Hussein Ata, 2013 **Bilberry & Lutein** Beth M. Ley, 2001 **An Investigation of the Effects of Lutein and Zeaxanthin Supplementation on Inflammatory Markers, Oxidative Stress and Age-related Macular Degeneration Risk** Ryan Alexander Graydon, 2007 Macular Degeneration (EasyRead Edition) , **Relationships of Body Fat, Retinal Levels of Lutein**

and Zeaxanthin, and Age-related Maculopathy in the Carotenoids in Age-related Eye Disease Study Tara Lea LaRowe, 2005 *Nutritional Supplements for Age-related Macular Degeneration*, 2012 Age related macular degeneration AMD is the leading cause of irreversible vision loss in the developed world In 2004 AMD affected 1 75 million persons in the United States a number that is expected to rise to nearly 3 million by 2020 due to the aging of the population The severity of macular degeneration ranges from Category 1 least severe to Category 4 most severe and advanced AMD is defined as having geographic atrophy involving the center of the macula or features of choroidal neovascularization Observational studies suggest that people with dietary intakes higher in various carotenoids antioxidants and omega 3 fatty acids have a lower risk of developing AMD This has led to several supplementation trials designed to examine the ability of nutritional supplement with carotenoids antioxidants or omega 3 fatty acids to prevent the progression of AMD Our report focuses on the evidence documenting the potential benefits and harms of certain dietary supplements in patients with AMD We conducted a systematic review of published literature to address the following key questions In patients with age related macular degeneration do nutritional supplements containing carotenoids antioxidants or omega 3 fatty acids alone or in combination prevent functional visual loss In adult populations what are the harms of carotenoid antioxidant and omega 3 fatty acid supplementation *Nutritional Supplements for Age-Related Macular Degeneration: a Systematic Review* U. S. Department of Veterans Affairs, Health Services Research & Development Service, 2013-06-05 Age related macular degeneration AMD is the leading cause of irreversible vision loss in the developed world In 2004 AMD affected 1 75 million persons in the United States a number which is expected to rise to nearly 3 million by 2020 due to the aging of the population AMD is characterized by the appearance of involutinal changes e g drusen in the structure of the central retinal pigment epithelium RPE leading to the loss of normal central macular vision AMD can be categorized as dry non exudative or wet exudative Dry AMD represents the great majority of AMD patients 90% and may lead to slow visual loss over many decades with the most severe cases developing geographic atrophy and profound loss of central vision Dry AMD can progress to wet AMD with the development of neovascularization beneath the diseased RPE leading to hemorrhage scarring and the devastating loss of macular vision over a period of months By convention there are four categories which describe the severity of macular degeneration Category 1 are those patients essentially free of age related macular abnormalities with a total drusen area less than five small drusen 63 m and visual acuity of 20 32 or better in both eyes Category 2 patients have mild or borderline age related macular features multiple small drusen single or nonextensive intermediate drusen 63 124 m pigment abnormalities or any combination of these in one or both eyes and visual acuity of 20 32 or better in both eyes Category 3 patients require the absence of advanced AMD in both eyes and at least one eye with visual acuity of 20 32 or better with at least one large drusen 125 m extensive as measured by drusen area intermediate drusen or geographic atrophy GA that does not involve the center of the macula or any combination of these Category 4 patients have visual acuity

of 20/32 or better and no advanced AMD in one eye with the fellow eye having either lesions of advanced AMD or visual acuity less than 20/32 with AMD abnormalities sufficient to explain reduced visual acuity as determined by examination of photographs. Advanced AMD is defined as having GA involving the center of the macula or features of choroidal neovascularization. Observational studies suggest that people with dietary intakes higher in various carotenoids, antioxidants, and omega-3 fatty acids have a lower risk of developing AMD. This has led to several supplementation trials designed to examine the ability of nutritional supplement with carotenoids, antioxidants, or omega-3 fatty acids to prevent the progression of AMD. Our report focuses on the evidence documenting the potential benefits and harms of certain dietary supplements in patients with AMD. Recommendations to the Department of Veterans Affairs with regard to these supplements will have important implications to that patient population as well as to older U.S. adults. We conducted a systematic review of published literature to address the following key questions:

1. In patients with age-related macular degeneration, do nutritional supplements containing carotenoids, antioxidants, or omega-3 fatty acids alone or in combination prevent functional visual loss?
2. In adult populations, what are the harms of carotenoid, antioxidant, and omega-3 fatty acid supplementation?

Age-related Macular Degeneration Frank G. Holz, Daniel Pauleikhoff, Richard F. Spaide, Alan C. Bird, 2012-08-31. Age-related macular degeneration is the most common cause for the loss of central vision beyond the age of 50 in industrial nations. Tripling of the number of affected patients is expected over the next 25 years. Especially over the last years, the standard of knowledge regarding etiology, risk factors, diagnostics, and therapy of this retina illness has substantially grown; this will be covered in this up-to-date multi-authored work. Apart from epidemiologically and genetically identified risk factors, both the various pathophysiological aspects, including the role of the complement system, and clinical manifestations, including OCT and angiographic characteristics, are clearly represented. Furthermore, the different therapeutic approaches are presented and discussed, including proven procedures such as intravitreal anti-VEGF therapy and seeing aid systems, in addition to the latest and upcoming methods in the area of pharmacology. The volume is well illustrated, and tables and summaries complete the presentation.

Age-related Macular Degeneration National Eye Institute, 1999. Age-Related Macular Degeneration Jennifer I. Lim, 2012-11-15. The value of Age-Related Macular Degeneration has stood the test of time, but progress in both basic and clinical ophthalmology has been relentless, mandating the need for an updated book. This second edition focuses on the pathophysiology and the epidemiology of age-related macular degeneration (AMD), the clinical features, and management of dry eye.

Recent Advances and New Perspectives in Managing Macular Degeneration Pinakin Gunvant Davey, 2022-09-28. Macular degeneration is a blinding disease with huge socioeconomic costs. This book presents a comprehensive overview of macular degeneration, including age-related macular degeneration (AMD). Chapters address such topics as the disease state of macular degeneration, diagnosis, and management of AMD, treatment considerations, and vision rehabilitation. It is a useful resource for both novice readers and experts in the field.

100 Questions & Answers About

Macular Degeneration Jeffrey Heier, 2009-12-04 Whether you are a newly diagnosed patient or a friend or relative of someone suffering with Macular Degeneration this book offers help 100 Questions Answers About Macular Degeneration provides authoritative practical answers to common questions about this condition to help patients and families achieve a greater understanding of all aspects of dealing with Macular Degeneration including treatment options sources of support and much more This book is an invaluable resource for anyone coping with the physical and emotional turmoil of this disease

Macular Degeneration Michael A. Samuel, 2008 Written by renowned ophthalmologist Michael Samuel a retinal specialist this text casts the spotlight on macular degeneration and dispels the myths surrounding this disease Macular Degeneration Michael Samuel, 2009-04-02 In easy to understand language ophthalmologist Michael Samuel M D a renowned retinal specialist casts the spotlight on this disease and offers a wealth of insights into what macular degeneration is what causes it and the array of contemporary treatment options Page 4 of cover *Macular Degeneration (EasyRead Super Large 20pt Edition)* , **Lutein and the Aging Eye** Shen Nian, 2018 Lutein is a carotenoid highly concentrated in the macula of the retina Lutein cannot be synthesized and must be supplied in the diet for example dark green leafy vegetable and egg yolk Lutein is believed to absorb blue light leading to the protection of retina from light related damage It can also protect the retina against oxidative stress and inflammation In fact dietary and supplementary lutein have been shown to be associated with possible reduced risk of age related macular degeneration a leading cause of elderly blindness attributed largely to lutein s antioxidant properties Lutein is also beneficial as a nutritional supplement in preventing diabetic retinopathy Moreover lutein is very safe and widely used In this chapter we will discuss the basic chemistry of lutein its uptake transport distribution and functions in the normal eye Lastly the effects of lutein in age related eye diseases will be summarized

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