TITLE: Vitalux for the Prevention and Treatment of Age-related Macular Degeneration: Clinical Effectiveness

DATE: 12 January 2011

RESEARCH QUESTION

What is the clinical effectiveness of Vitalux for prevention and treatment of age-related macular degeneration?

KEY MESSAGE

Evidence from systematic reviews and one randomized trial suggests that Vitalux is not effective for prevention but may be effective for slowing progression of age-related macular degeneration.

METHODS

A limited literature search was conducted on key health technology assessment resources, including PubMed, the Cochrane Library (Issue 12, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between January 1, 2000 and December 21, 2010. Retrieval was limited to the human population. Filters were applied to limit the retrieval by health technology assessments, systematic reviews, meta-analyses, and randomized controlled trials. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.
RESULTS

Rapid response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials.

Five systematic reviews and one randomized controlled study were identified pertaining to the use of the Vitalux multivitamin/multimineral formulation for the prevention and treatment of age-related macular degeneration. No relevant health technology assessment reports were identified. The majority of the systematic review evidence is based on the results of the included randomized trial. Additional information that may be of interest, including randomized trials of similar vitamin/mineral supplements, has been included in the appendix.

OVERALL SUMMARY OF FINDINGS

Overall, evidence from systematic reviews and one randomized trial suggests that Vitalux or Vitalux-like multivitamin/multimineral supplements are not effective in the prevention but may be effective in slowing the progression of age-related macular degeneration. As most of the evidence regarding Vitalux comes from a single trial, authors of one included systematic review concluded that it is unclear as to whether this data is generalizable to other populations. Significant harms identified and further details regarding the selected studies are included in Table 1.

<table>
<thead>
<tr>
<th>Author, Study Type</th>
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<td>Evans, SR¹</td>
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To determine if antioxidant vitamin or mineral supplements prevent or slow the progression of age-related macular degeneration (AMD).

Randomized controlled trials (RCTs) comparing antioxidant vitamin and/or mineral supplements with control were identified and analyzed.

No evidence suggested that antioxidant vitamin (beta-carotene, vitamin C, vitamin E, and zinc slowed the progression to advanced AMD and slowed visual acuity loss in individuals with signs of the disease may benefit from the type of supplementation used in the AREDS trial (which was the primary source of data for the review).*

Authors concluded that while current evidence does not support supplementation for the prevention of AMD, those with AMD or signs of disease may benefit from the type of supplementation used in the AREDS trial. Harms identified: Increased risk of lung cancer in smokers taking high-dose beta-carotene; increased risk of heart failure in participants with vascular
## Table 1: Details of Included Studies

<table>
<thead>
<tr>
<th>Author, Study Type</th>
<th>Objective</th>
<th>Methods</th>
<th>Results</th>
<th>Conclusions</th>
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<tr>
<td><strong>Evans &amp; Henshaw, SR²</strong></td>
<td>To determine if vitamin and mineral supplements prevent AMD.</td>
<td>RCTs comparing antioxidant vitamin and/or mineral supplementation versus control lasting a least 1 year were included.</td>
<td>3 RCTs were identified</td>
<td>No evidence was found that suggested that apha-tocopherol and beta-carotene supplements prevented or delayed the onset of AMD.</td>
<td>Authors concluded that there was no evidence that the general population should supplement with antioxidant and/or minerals to prevent or delay AMD.</td>
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<td><strong>Arnold &amp; Heriot, SR³</strong></td>
<td>To determine the effect of interventions to prevent the progression of early or late stage AMD.</td>
<td>SRs, RCTs, observational studies, and harms data were included.</td>
<td>No results are presented in the abstract.</td>
<td>No conclusions are presented in the abstract but it indicates that the full text presents information regarding the effects of antioxidant vitamins (plus zinc).</td>
<td>GRADE evaluations on the evidence were performed by authors.</td>
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<tr>
<td><strong>Chong et al., SR⁴</strong></td>
<td>To evaluate the effectiveness of dietary antioxidants in the primary prevention of AMD.</td>
<td>RCTs and prospective cohort studies were included.</td>
<td>Vitamins A, C, and E; zinc; leutein; zeaxanthin; alpha- and beta-carotene; beta cryptoxanthin;</td>
<td>Authors concluded that there was insufficient evidence to support the use of antioxidant</td>
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*Vitalux for the Prevention and Treatment of Age-Related Macular Degeneration*
Table 1: Details of Included Studies

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<tr>
<td>Evans, SR5</td>
<td>To assess the effects of antioxidant vitamin and/or mineral supplementation on the progression of AMD.</td>
<td>RCTs comparing antioxidant vitamin and/or mineral supplementation versus control in patients with AMD were included.</td>
<td>Beta-carotene, vitamin C, vitamin E, and zinc were found to have a beneficial effect on progression to advanced AMD and people taking supplements were less likely to lose 15 or more letters of visual acuity.</td>
<td>Authors concluded that as most of the data included in the review came from the AREDs trial, the results may not be generalizable to the general population.</td>
<td>Harms: beta-carotene was found to increase the risk of lung cancer in smokers; vitamin E was found to increase the risk of heart disease in people with diabetes or vascular disease.</td>
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<tr>
<td>Age-Related Eye Disease Study Research Group (AREDS), RCT6</td>
<td>To determine the effect of high-dose vitamin C, vitamin E, beta-carotene, and zinc supplementation on the progression of AMD and on visual acuity.*</td>
<td>Patients randomly assigned to receive daily oral tablet containing vitamin C, 500 mg; vitamin E, 400 IU; and beta carotene, 15 mg; zinc (80 mg of zinc as zinc oxide) and copper (2 mg of copper as cupric oxide); antioxidants plus zinc; or placebo.</td>
<td>3,640 participants aged 55-80 years enrolled Average follow-up: 6.3 years</td>
<td>Compared to placebo, antioxidants plus zinc resulted in a statistically significant odds reduction in progression to more advanced AMD.</td>
<td>Authors concluded that those with early AMD or early signs of AMD and without significant contraindications (such as smoking) should consider taking a supplement similar to that used in the study.</td>
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AMD = age-related macular degeneration; AREDS = Age-Related Eye Disease Study; GRADE = Grading of Recommendations Assessment, Development and Evaluation; mg = milligrams; RCT = randomized controlled trial; SR = systematic review

*Vitalux was used in the AREDS trial
REFERENCES SUMMARIZED

Health technology assessments
No literature identified.

Systematic reviews and meta-analyses


   Full-text available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2943806

   Full-text available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2018774


Randomized controlled trials

   Full-text available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1462955

PREPARED BY:
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APPENDIX – FURTHER INFORMATION:

Randomized controlled trials- similar vitamin formulation or formulation details unknown


Cost information


Review articles


Additional references

