

Papas K, Kalbfleisch J, and Mohon R. **Bioavailability of a novel water-soluble vitamin E formulation in malabsorbing patients.** Digestive Diseases and Sciences 2007 52:347-352.

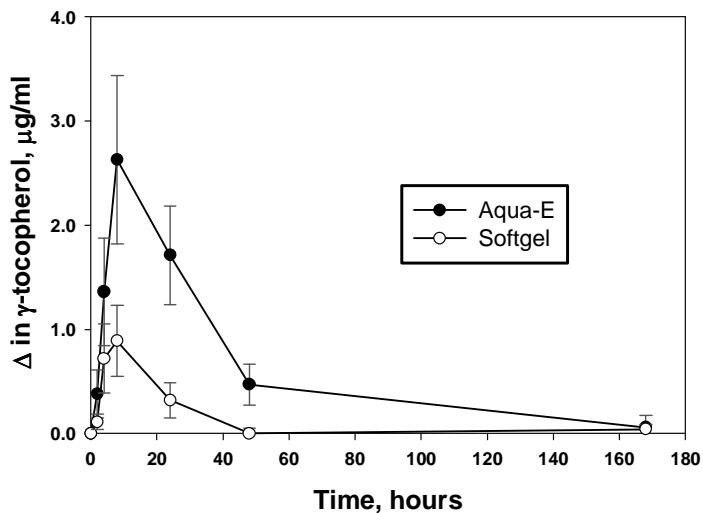
Background: In cystic fibrosis (CF), pancreatic insufficiency and a diminished bile acid pool cause malabsorption of important nutrients and dietary components leading to deficiency, poor nutritional status and oxidative stress. Of particular significance is the malabsorption of fat-soluble nutrients and antioxidants, which are important for normal immune and neurological function. CF patients are often deficient in these compounds despite supplementation with the current standard of care therapy.

Objective: Compare the pharmacokinetic profile of this water-soluble vitamin E formulation (Aqua-E) with an oil-based softgel formulation in a malabsorbing patient population.

Design: Patients with CF who had documented malabsorption were recruited for participation in this pharmacokinetic study. Patients that met inclusion and exclusion criteria discontinued vitamin E supplementation, except for that in a multivitamin, for 7 to 21 days prior to the day of dosing. Patients were randomized to a single dose of 20 ml of Aqua-E or 3 oil-based softgels which contained equivalent amounts of tocopherols. Blood was drawn from patients at time 0, 2, 4, 8, 24, 48 and 168 hours and analyzed for tocopherols.

Results: Eight patients were enrolled in the study and randomized to Aqua-E or softgels. The primary outcome, the absorption of γ -tocopherol in Aqua-E (AUC=115 $\mu\text{g/ml}\cdot\text{hrs}$), was significantly greater than that of oil-based softgels (AUC=27 $\mu\text{g/ml}\cdot\text{hrs}$, $p = 0.015$). Total-tocopherols ($\alpha + \gamma + \delta$) in Aqua-E (AUC=294 $\mu\text{g/ml}\cdot\text{hrs}$) showed a strong trend toward increased absorption compared to that of oil-based softgels (AUC=117 $\mu\text{g/ml}\cdot\text{hrs}$, $p = 0.069$).

Figure 1. Changes in γ -tocopherol plasma levels above baseline over time in patients receiving a single dose of Aqua-E or oil-based softgel



Conclusion: This novel water-soluble formulation showed a marked and statistically significant increase in absorption of γ -tocopherol in malabsorbing CF patients as compared to an oil-based formulation.