Bioavailability of antioxidant vitamins from an innovative and fun to eat complementary balanced diet

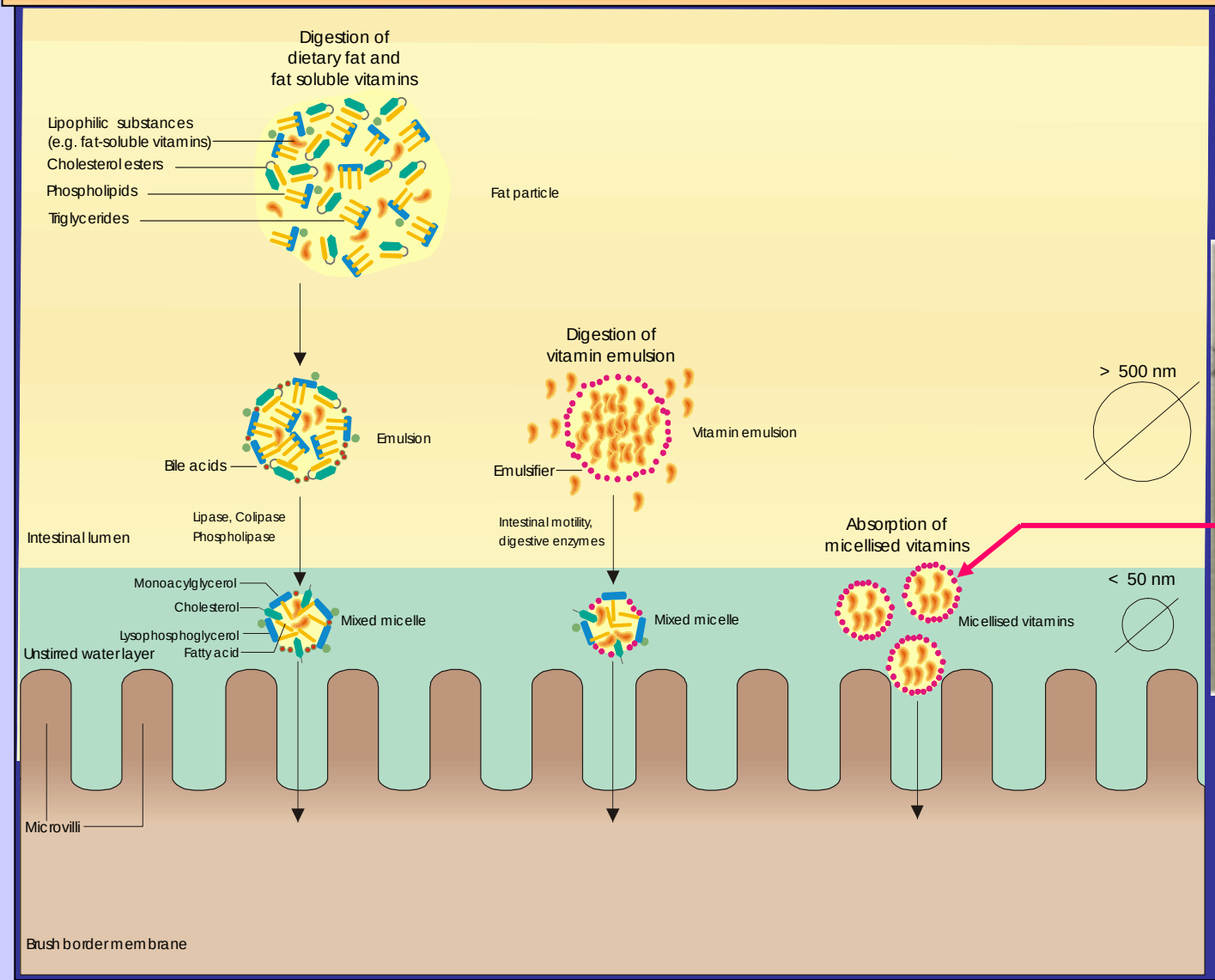
Evelyn Back, Research Nutritionist

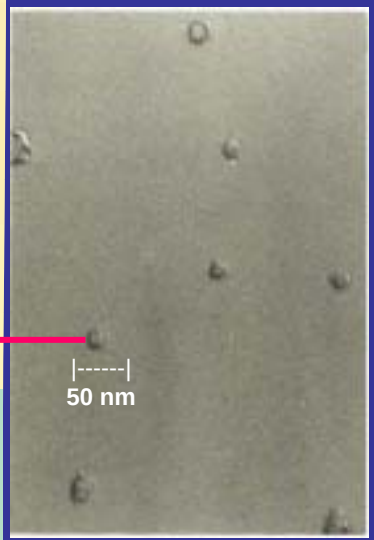
University of Hohenheim, Stuttgart/Germany

Background

- Cystic fibrosis patients often suffer from fat soluble vitamin deficits due to fat maldigestion and malabsorption
- Bioavailability: high dose supplementation with fat soluble vitamins corrects deficits in some, but not all patients (trials)
- Compliance: is a problem in every day life, particularly in children and adolescents

Digestion and absorption of fat soluble vitamins





Micelles in AQUANOVA® vitamin E solubilisate

Complementary balanced diet with improved bioavailability

Jelly babies containing

- 100 IU d-α-tocopherol as d-α-tocopheryl acetate from AQUANOVA® vitamin E solubilisate
- 2 mg β-carotene from AQUANOVA® β-carotene solubilisate
- 400 mg Vitamin C (crystalline)

Study setup

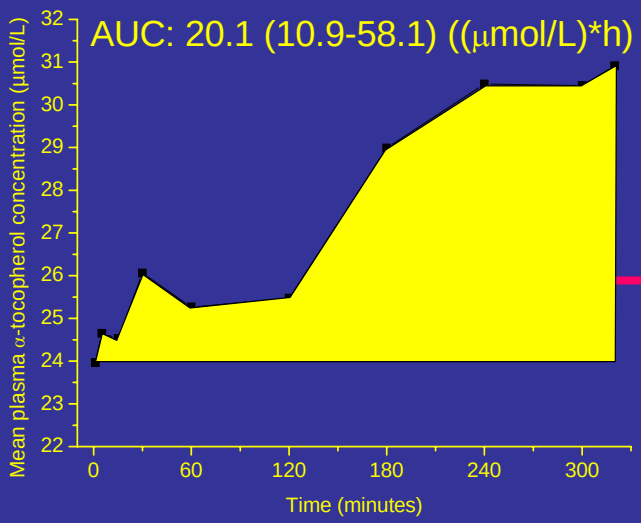
- 3 study days
  - Day 0: 1 Jelly baby sucked
  - Day 10: 1 Jelly baby swallowed
  - Day 20: reference products swallowed
    - 100 IU d-α-tocopheryl acetate in soft gelatine capsules
    - 2 mg β-carotene in dragée
    - 400 mg vitamin C (crystalline)
- Venous blood samples taken at 0, 1, 5, 15, 30, 60,180, 240, 300 and 320 minutes
- Standardized breakfast after 60 minutes
- Statistics: Wilcoxon signed rank test

Baseline data

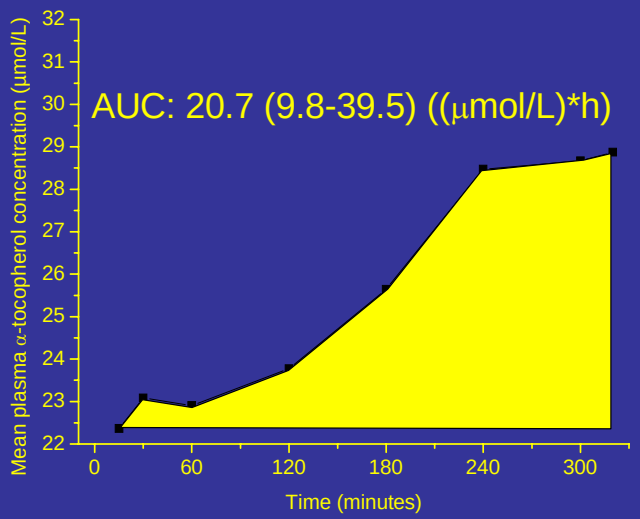
- 14 healthy adult volunteers
  - 6 males, 8 females
  - aged 25.3 (22.7–35.3) years
  - BMI 24.3 ± 3.7 kg/m^2
- Baseline vitamin and cholesterol plasma concentrations similar on all study days
- Vitamin intake from standardized breakfast 0-5% of supplemented vitamins

$AUC_{0\text{-}320min}$ for α-tocopherol

Jelly babies sucked

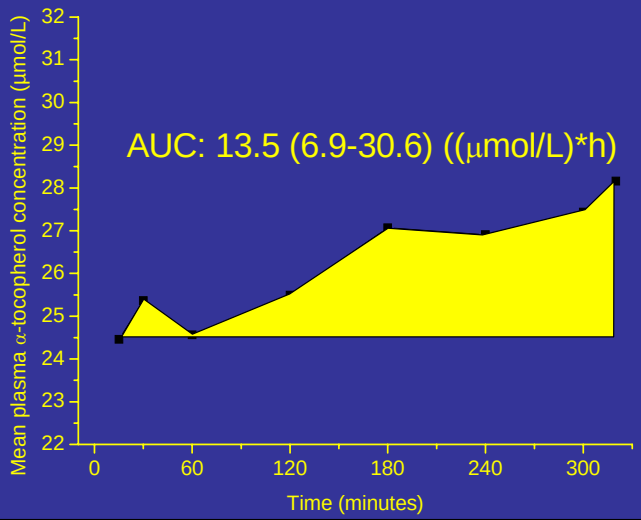


Jelly babies swallowed



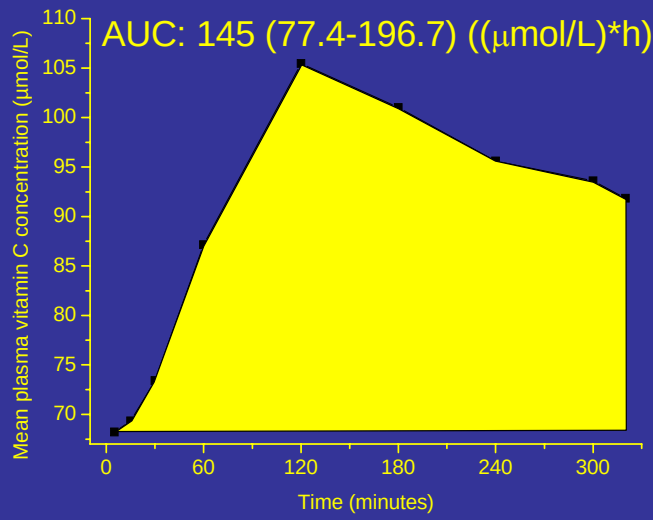
p = 0.016

Vitamin E soft gelatine capsules swallowed

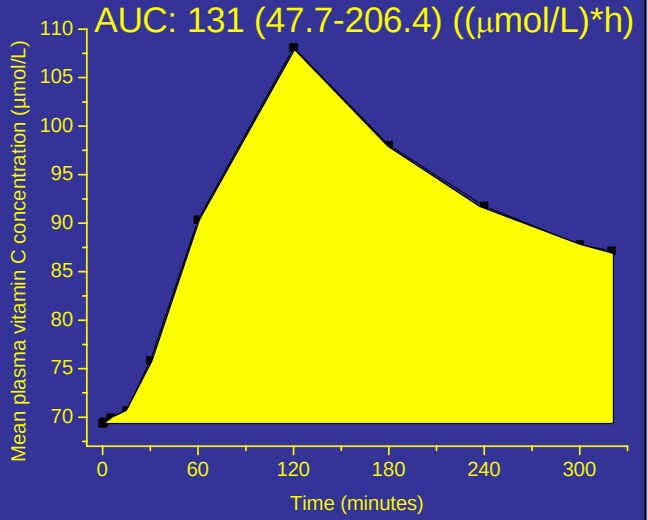


$AUC_{0\text{-}320min}$ for vitamin C

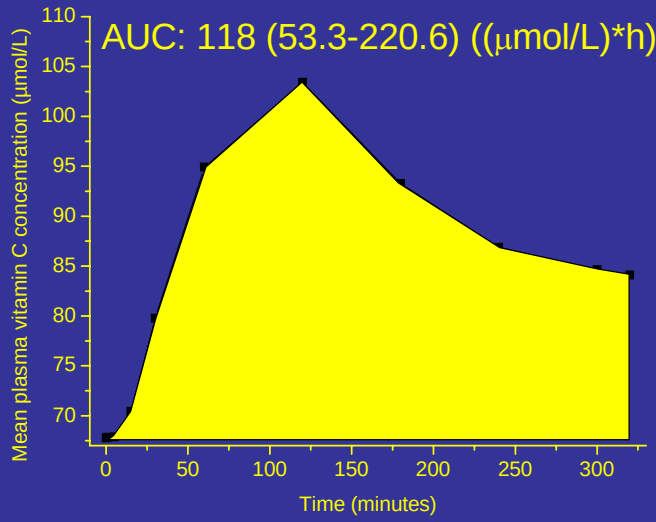
Jelly babies sucked



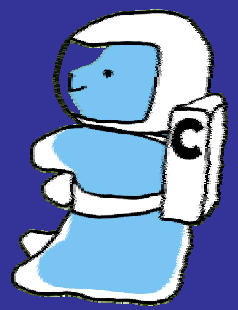
Jelly babies swallowed



Crystalline vitamin C swallowed



No significant differences between study days



Summary of own results

- Short time bioavailability of micellised α-tocopheryl acetate from jelly babies significantly better than from fat soluble preparation when jelly babies are sucked
- β-carotene:
  - applied dose = maximum allowed by German food law
  - Changes in plasma concentrations relatively low
  - Differences in AUC btw. day 0 and 20 significant, but interpret with caution
- Vitamin C: similar AUC for all study days as always administered in crystalline form

Evidence from the literature I

Studies ranking water miscible and fat soluble preparations as comparably effective

- Soltani-Frisk et al, Acta Paediatr 2001;90(10)
  - 10 mg/kg body weight of water miscible (E-vimin®) vs. fat soluble all-rac-α-tocopheryl-acetate
  - Emulsifiers: polysorbate, polyethylene glycol
  - Result: similar AUCs for either preparation
- Winklhofer-Roob et al, Am J Clin Nutr 1996:63(5)
  - 400 IU/d of water miscible (E-vimin®) or fat soluble all-rac-α-tocopheryl-acetate
  - Emulsifiers: polysorbate, polyethylene glycol
  - Result: similar plasma concentrations after 3 months

Evidence from the literature II

Studies ranking water miscible preparations superior over fat soluble preparations

- Nasr et al, J Pediatr 1993;122(5 Pt 1):
  - 200 IU/d water miscible all-rac-α-tocopheryl-acetate (Aquasol® E) or 800IU/d d-α-tocopheryl-acetate
  - Emulsifiers: polysorbate 80, propylene glycol
  - Result: 200 IU/d of water miscible preparation had similar effect on plasma concentrations as 800IU/d of fat soluble preparation
- Harries et al, Arch Dis Child 1971;46(247)
  - 10 IU/kg body weight water miscible or fat soluble all-rac-α-tocopheryl-acetate
  - Emulsifiers: cremophor® EL
  - Result: significantly higher plasma concentrations after 4 weeks with water miscible preparation

Next step: Intervention trial

- 60 patients receive
  - either jelly babies with solubilisates + crystalline vit. C
  - or jelly babies with fat soluble forms of the fat soluble vitamins + crystalline vitamin C
  - for 6 months
- Primary outcome variable: change in vitamin E plasma concentration
- Secondary outcome variables:
  - Change in other vitamin plasma concentrations
  - Change in tissue vitamin concentrations
  - Change in sputum vitamin concentrations
  - Clinical status (sick days, antibiotic use, lung function)
  - Changes in oxidative stress

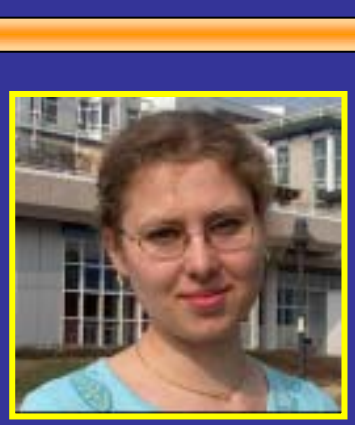
Acknowledgement

Prof. Biesalski, PhD

MD

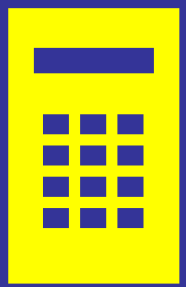
Prof. Stern, MD

and team



Mrs. Ocenášková, MD

Mr. Nohr,



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(TA)

Mrs. Riedle

(TA)

Additional Data

Comparison of AUCs

	AUC day 0	AUC day 10	AUC day 20	p
α-tocopherol [(µmol/L)*h)]	20.1 (10.9–58.1)	20.7 (9.8–39.5)	13.5 (6.9–30.6)	d 0 vs. d 20: p = 0.016
β-carotene [(µmol/L)*min)]	20.5 (4.2–86.7)	11.6 (2.7–32.0)	4.4 (0.38–25.0)	d 0 vs. d 20: p = 0.016
Vitamin C [(µmol/L)*h)]	145.0 (77.4–196.7)	131.2 (47.7–206.4)	118.0 (53.3–220.6)	NS

Maximum increase in plasma concentrations

	Δconc. day 0	Δconc. day 10	Δconc. day 20	p
α-tocopherol (µmol/L)	9.55 (4.53-19.93)	8.62 (4.37-15.16)	6.13 (2.05-10.17)	d 0 vs. d 20: p = 0.023 d 10 vs. d 20: p = 0.002
β-carotene (µmol/L)	0.225 (0.07-0.95)	0.146 (0.03-0.85)	0.139 (0.07-0.46)	d 0 vs. d 20: p = 0.023
Vitamin C (µmol/L)	41.4 (18.4-53.3)	40.1 (20.5-59.5)	36.1 (27.6-52.6)	NS