Enhanced Oral Bioavailability of Ultrasome™-CoQ10 Compared to generic CoQ10 Among Elderly Hospitalized Patients in a Randomized Double-Blind Controlled Study

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Purpose

The objective of this study was to compare the oral bioavailability of Coenzyme Q10 among geriatric patients after administration of generic CoQ10 or Ultrasome™-CoQ10 - a formulation based on a new patented technology, that aims to improve the absorption of food supplements and biopharmaceuticals.

Methods

The selected population was hospitalized, geriatric patients undergoing continuous treatment with various medications. Patients were randomly assigned into two groups. Each subject received a single dose of 90mg CoQ10 in either hard gelatin capsules of Ultrasome™-CoQ10, or generic CoQ10 (control group). Blood samples were drawn from patients at time 0 (prior to receiving the capsule), 1, 2, 4, and 8 hours post-administration. Plasma levels of CoQ10 were determined by a validated HPLC assay (expressed as μg/ml). The inter-subject base line variability was minimized by selection of individuals to those with prestudy endogenous CoQ10 plasma level of 0.30μg/ml. Ten to twelve participants in each group fulfilling this criteria were enrolled in the study and compared for the effect of supplemented CoQ10 formulations on mean CoQ10 plasma levels. All patients involved in this study were under close medical supervision prior to the outset and during the course of the study.
The population study include 30 patients (14 males & 16 females) aged between 64-93, with an average age of 80.97±7.47. According to the inclusion criteria, 22 patients enrolled (10 males & 12 females), aged between 64-93, with an average 80.59±8.53. The generic CoQ10 group consisted of 12 patients (5 males & 7 females), average age 81.83±8.43 and the Ultrasome™-CoQ10 group involved 10 patients (5 males & 5 females), average age 79.1±8.85.

Results

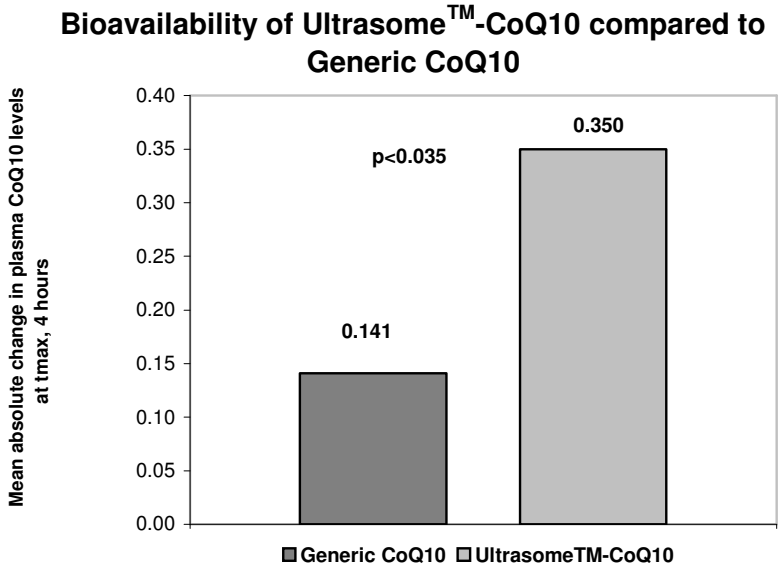
The study group showed good tolerability and no side effects were observed. After a single-dose administration of 90mg CoQ10, peaks of plasma CoQ10 levels (Cmax) appeared at 4 hrs post-capsule intake (tmax). At tmax, the average plasma level of CoQ10 among the patients who received Ultrasome™-CoQ10 was 1.061μg/ml, whereas among the control group (those who received the generic product) it was 0.698μg/ml (Table 1). A significant higher net plasma increase was found in the group receiving Ultrasome™-CoQ10 compared to generic CoQ10. The mean absolute change (from baseline to post-supplementation value) in plasma CoQ10 values was greater in Ultrasome™-CoQ10 group (0.350μg/ml) than in the control group (0.142μg/ml) (Figure 1). Analysis of variance (ANOVA) showed a statistically significant difference ($p<0.035$) between the two formulations. This result demonstrates a 2.5-fold increase in absolute change in CoQ10 plasma concentration from baseline in patients supplemented with Ultrasome™-CoQ10 as compared to those who received generic CoQ10.

Table 1.

	generic CoQ10	Ultrasome-CoQ10
Mean baseline CoQ10 plasma level (μg/ml ±SE)	**0.557 ± 0.061**	**0.711 ± 0.082**
Mean CoQ10 plasma level at tmax (4hrs) (μg/ml ±SE)	**0.698 ± 0.085**	**1.061 ± 0.112**
Mean absolute change in plasma CoQ10 level at (t4-t0) (μg/ml)	**0.141***	**0.350***

***Difference between mean absolute change in Ultrasome-CoQ10 and generic product statistically significant (ANOVA p=0.035)**

Figure 1.



Discussion

The study was conducted on elderly patients (average age 80.59±8.53) suffering from a variety of diseases (including conditions that reduce endogenous CoQ10). In previous studies only healthy subjects (age range: 25-40) were examined. Notably, the improved oral bioavailability of Ultrasome™-CoQ10 was effective despite the debilitating health conditions of the population treated. The importance of this study is not only on the bioavailability and kinetics of the study, but also on the clinical facts of outstanding, good absorption of Ultrasome™-CoQ10 in elderly hospitalized patients.

Conclusions

The results of this study demonstrate the effectiveness of Ultrasome™-CoQ10 with significant enhanced oral bioavailability of CoQ10 in comparison to a generic CoQ10 given to geriatric patients suffering from several chronic diseases. Increased plasma response to supplemental treatment with Ultrasome™-CoQ10, is of clinical and statistical significance. CoQ10 deficiency has been found in patients with diabetes mellitus, severe ischemic heart disease and in patients treated with cholesterol lowering "statins drugs". Supplementary CoQ10 therapy has been shown to be beneficial in treating congestive heart failure, dyslipidemia, complications of diabetes and Parkinson's disease. Improved oral absorption of Ultrasome™-CoQ10 is particularly important in elderly patients diagnosed with chronic and debilitating conditions known to have poor gastrointestinal absorption.

Acknowledgments

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