A PRELIMINARY HUMAN STUDY TO DETERMINE THE BIOAVAILABILITY OF THE RIGHT C® AND ANOTHER VITAMIN C IN A BLINDED CROSS-OVER STUDY

This study was conducted at Kilden Helse in Oslo, Norway under the direction of Dr. Roald Strand. The protocol was designed by Dr. Anthony J. Verlangieri, Professor of Pharmacology and Toxicology.

PURPOSE: To determine the rate of oral absorption of The Right C® (TRC) and Another Vitamin C (AVC) by analysis of Total Vitamin C (ascorbic acid, AA) delivered to plasma at 90 minutes post-ingestion.

STUDY DESIGN: 10 healthy male subjects were randomized into two groups as described below. They were to refrain from taking any vitamin supplements for at least 7 days prior to the start of the study. They were to avoid intake of fruits and vegetables prior to and during the study period.

The study grouping consisted of two groups: Subjects were designated, in The Right C® group, TRC1-TRC5; in AVC group, AVC1-AVC5. After the cross-over, the group designations were reversed.

The study required that all subjects fast prior to beginning the study.

The AVC subjects received 1000 mgs of AVC orally. Just prior to ingestion, a blood sample was collected in a heparin vacutainer tube.

Plasma was obtained and preserved with meta-phosphoric acid and frozen for analysis. This time period served to establish baseline levels of plasma AA mg/L for each subject. After ingestion of the test product, subjects were bled at 30 min., 60 min., and 90 minutes.

The TRC subjects were treated in similar fashion except that they received 1000 mgs of The Right C® orally. Blood samples were handled in the same way.

The subjects from both groups were washed out and the groups crossed-over and the procedures repeated. The phase before the cross-over was required to determine the inherent absorption characteristics unique to each subject independent of test material, and to establish plasma AA baselines to be used in calculating the rate of absorption or uptake for each test material after cross-over.

ASCORBATE ANALYSIS: Plasma AA was analyzed by High Pressure Liquid Chromatography. All results are expressed as mgs Total AA per liter of plasma at each time period (mg AA/L).

RESULTS: Cross-over data indicates that increased AA plasma levels observed in The Right C® subjects at 90 minutes was due to increased rate of absorption of TRC and not due to individual subject effects. The increased plasma level of AA in the TRC group, as compared to the AVC group, was due to The Right C® formulation (see Table 1).

TABLE 1

Average increase, above baseline, in Total Plasma AA (mg AA/L) at 90 min. post-ingestion of Test Material

Test Material	mg AA/L	SE Mean	Range
TRC	11.61*	0.88	10 – 13
AVC	6.22	1.20	5 – 8

p ≤ 0.05

Absorption rate or uptake rate was calculated and is graphically shown in Figure 1 (below). Initial uptake rate for TRC at 30 minutes was 30% faster, as compared to AVC. This absorption rate increased to 196% at 90 minutes. This means that the absorption, or uptake, of TRC was 196% greater than the rate of uptake of AVC. The increased rate of uptake for TRC is the mechanism by which TRC makes AA more rapidly absorbed and raises AA plasma levels more rapidly and higher than AVC.

The rate (R) of uptake for TRC is 0.132 mg/L/min; for AVC, it is 0.067 mg/L/minute. Extrapolation to 4 hours indicates that TRC would deliver 32 mg AA/L plasma, while AVC only 16 mg AA/L plasma. At 4 hours, The Right C® AUC (area under the curve) is approximated to be 205% greater than the AUC for AVC.

RESULTS AND DISCUSSION: The data indicate that The Right C® formulation is absorbed more rapidly than AVC by 196%, and raises plasma AA levels more rapidly and higher than AVC. Higher plasma levels promote more rapid increases in intracellular AA. Higher AA levels enable the cell to utilize AA at a higher rate in cell metabolism and provide superior anti-oxidant action in the plasma as well as the cell. On a whole blood basis, TRC increases a liter of whole blood by 34.9 mg AA in 4 hours, while AVC only increases this parameter by 7.7 mg per liter.

FIGURE 1

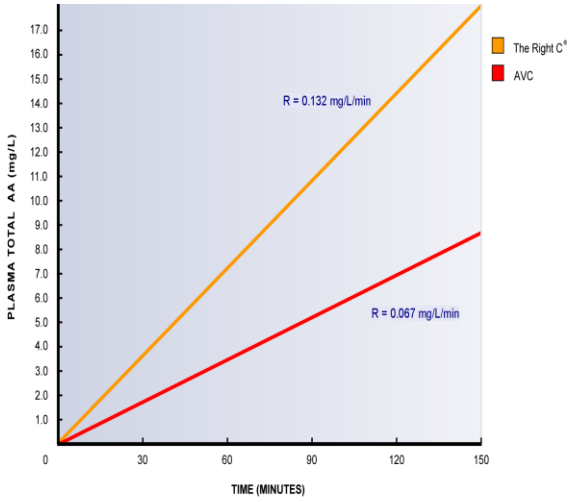


Figure 1
RATE OF ABSORPTION (R) UPTAKE

ORAL ABSORPTION STUDY OF VITAMIN C SUPPLEMENTS IN GUINEA PIGS

(A Preliminary Report)

PURPOSE: To determine the plasma total ascorbate levels in guinea pigs after oral gavage with Ascorbic Acid (AA), Another Vitamin C (AVC) or The Right C® (TRC), at a dose of 8 mgs/kg body weight as equivalent ascorbate activity (human dose equivalent of 560 mgs.)

PROCEDURES: Thirty albino guinea pigs housed for seven days on a 12 hour light/dark cycle and fed Purina Rabbit Chow diet. This depleted body ascorbic acid prior to administering the test material. The guinea pigs were then randomly assigned to 3 test groups (9 per group) and a control or plasma basal ascorbate group (3). The test materials were then administered at equal ascorbate activity by gavage. The basal group received vehicle only (distilled water). Blood samples were obtained at 0 minutes (basal group) and the test material groups at 30, 60 and 90 minutes.

Blood was collected into tubes containing EDTA and centrifuged at 2000 rpm for 3 minutes. The plasma was then transferred to a second tube and frozen prior to analysis.

HPLC was used to analyze the plasma samples for total ascorbate activity. Standards (ascorbic acid, Sigma) were run during analysis to check the calibration of the instrument. The recovery of ascorbate from the plasma was 99.2% and the relative standard deviation was 4.3%.

RESULTS: Mean Total Ascorbate Plasma (micrograms AA/ml)

Test Material	0	30	60	90 minutes
AA	----	0.31	0.64	0.46
AVC	----	1.02	0.49	0.25
TRC	**----**	**1.40**	**0.87**	**0.64**
Control	0.17			

The data are graphically presented in Figure 1 (over).

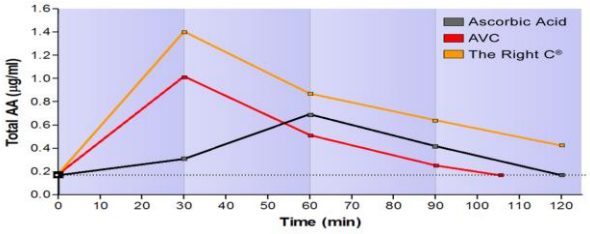
DISCUSSION OF RESULTS: The data shows, at equal ascorbate activity, administered as AA, AVC or TRC, that TRC attained the highest Plasma AA level at 30 minutes post-dose. Compared to AVC, TRC attained 41% higher plasma levels at 30 minutes. TRC plasma levels were 414% higher than AA at 30 minutes, while AVC was only 260% higher. At 60 minutes, TRC was 71%, and at 90 minutes, 160% higher, than the corresponding plasma levels attained with AVC. At 60 and 90 minutes, the plasma ascorbate concentrations from AVC fell below both TRC and AA.

The fourth point on each respective curve represents the result of regression analysis. Plasma levels of AVC return to baseline (control) levels at approximately 105 minutes post-dose. Extrapolation predicts that AA plasma levels return to baseline at 120 minutes, and TRC at approximately 180 minutes post-dose.

The AUC (area under the curve) for TRC is in the range of 175% greater than AVC, and 200% greater than AA plasma levels. The AUC is a measure of Total Ascorbate activity delivered and thereby absorbed over the test period.

CONCLUSIONS: At equal ascorbate activity doses, The Right C® attains higher ascorbate plasma levels than AVC or AA. These higher levels are maintained for the entire test period. The Right C® delivers 175% more ascorbate activity than delivered by an equal ascorbate activity dose of AVC. The maintenance of plasma levels by TRC is due to a more rapid and sustained oral uptake than AVC or AA. This is based on the fact that the downslopes of the plasma levels maintain the same rate until return to baseline.

FIGURE 1



THE RESEARCH

THE C GROUP, INC.

THE RIGHT C®

Enhanced Vitamin C Powder

An EnterCell™ / MultiPath® technology Product

RESEARCH & CLINICAL STUDIES

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