A PROSPECTIVE DOUBLE BLIND PLACEBO CONTROLLED CROSS OVER TRIAL OF CARNITINE THERAPY IN SELECTED CASES OF MALE INFERTILITY

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Objective: Carnitine has been demonstrated in several uncontrolled clinical trials over the past decade to have beneficial effects on semen quality in patients with idiopathic male-factor etiologies. The goal of our study was to determine the efficacy of L-carnitine therapy on semen quality in selected cases of male infertility.

Design: Subjects were randomized to therapy or placebo in a double blind crossover trial in a University based tertiary referral center.

Materials/Methods: One hundred patients were randomized with male infertility using the following criteria: age (range: 20-40yr), infertility duration >2 yr., and 3 baseline semen analysis, each demonstrating the following characteristics: concentration 10 - 20 X10^6/mL; percent motility 10 - 30%; forward progression <15%; abnormal morphological forms (WHO, 1999) <70%; curvilinear velocity 10 - 30µ/sec (normal >50µ/sec); and, linearity <4 (normal >5). Patients were submitted to a therapy of L-carnitine 2g/day or placebo. All subjects had an initial 2 months run-in period and then randomized to 2 months of carnitine or placebo. Next, both groups had 2 months washout and then crossed over to either placebo or carnitine for 2 months with 2 additional months of follow-up.

Results: Eighty-six patients completed the trial. A statistically significant improvement in semen quality, compared to the placebo, was seen after the L-carnitine therapy in sperm concentration (P = 0.01), percentage motility (P = 0.04), and forward sperm progression (P = 0.05). The increase in forward sperm progression was more significant in patients with severe oligo-asthenospermia, <5 X 10^6 forward motile sperm/ejaculate or <2 X 10^6 forward motile sperm/mL (P = 0.03, and 0.02, respectively).

Conclusions: This is the first report of a double-blind placebo-controlled study using L-carnitine in the therapy of patients with male infertility. We demonstrated that L-carnitine supplementation significantly improves two of the most important sperm parameters: concentration and motility. In addition, it also improves these parameters in patients with severe oligo-asthenospermia. Future trials will evaluate its efficacy on pregnancy outcome.

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