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Effectiveness and tolerability of a novel blend of CoQ10, L-carnitine, zinc, lycopene, and astaxanthin in males with infertility: Findings from a UNESCO study

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Abstract
Introduction: Oxidative stress (OS) and mitochondrial dysfunction play a crucial role in the etiology of male infertility. Coenzyme Q10 (CoQ10) is a potent antioxidant and mitochondrial bio-energizer that improves semen parameters in infertile men. The use of CoQ10 with various other antioxidants has also shown a beneficial effect in enhancing sperm parameters.
Objective: To investigate the effectiveness and tolerability of a unique combination of ubiquinol, L-carnitine, zinc, lycopene, and astaxanthin in male patients with infertility.
Methods: It was a multicenter, prospective, observational, real-world evidence study involving 79 doctors who enrolled 648 male patients with infertility. Patients received a study product once daily for three months. Semen analysis was done at baseline and the end of the treatment. A change from baseline in semen volume, sperm concentration, sperm motility, and sperm morphology were analyzed.
Results: The treatment with our study product for a mean duration of 2.90 months showed a significant improvement in semen volume (17.85%; p= 0.003), sperm concentration (42%; $p<0.0001$), sperm motility (43.62%; p= 0.0014) and sperm morphology (20.34%; $p<0.0001$) as compared to baseline.
Conclusion: A novel blend of ubiquinol, L-carnitine, zinc, lycopene, and astaxanthin for three months demonstrated a significant improvement in sperm parameters and should be considered as a treatment option for the management of male patients with infertility.

Keywords: Male infertility, Coenzyme Q10, Ubiquinol, L-carnitine and Antioxidants

Introduction
Infertility refers to the inability of a sexually active, non-contracepting couple to achieve a pregnancy within one year. In India, the prevalence of infertility ranges from 3.9% to 16.8% and shows variations among different states castes, and tribes within the same region [1]. Studies have reported that 40% of infertility cases are attributed to men, 40% to women, and 20% to both sexes. Sperm abnormalities such as low sperm concentration (oligospermia), poor sperm motility (asthenospermia), and abnormal sperm structure and shape (teratozoospermia) are significant factors in male infertility [2].
Reactive oxygen species (ROS) induced damage to sperm is a significant contributor to male infertility, accounting for 30-80% of cases [3]. Mitochondria are a primary source of ROS in sperm cells. The generation of ROS is regulated by the mitochondrial electron transport chain (ETC) as part of signaling pathways. Optimal mitochondrial function and ROS are crucial in regulating various physiological aspects of reproductive function, ranging from spermatogenesis to fertilization. They are essential for sperm motility, hyperactivation, capacitation, acrosome reaction, and DNA integrity, all of which are vital for human sperm function and semen quality [4, 5]. However, an excessive production of ROS coupled with a decline in antioxidant defense mechanisms can lead to oxidative damage. Elevated ROS production within mitochondria may damage mitochondrial DNA and cause subsequent dysfunction. Diminished mitochondrial activity escalates oxidative stress damage, thereby exacerbating mitochondrial impairment. As a result, oxidative stress and mitochondrial dysfunction can either cause each other or be interconnected [4, 6]. Further, oxidative stress and mitochondrial dysfunction result in lipid

peroxidation, loss of membrane integrity accompanied by increased permeability, structural DNA damage, and apoptosis. These factors have a negative impact on semen quality, sperm motility, sperm concentration, sperm morphology, sperm DNA fragmentation, and overall fertility. Therefore, employing antioxidants to mitigate excessive oxidative stress and protect mitochondrial function presents a potential treatment option for male infertility [4, 5, 7, 8].

Coenzyme Q10 (CoQ10) is an antioxidant molecule and a component of the mitochondrial respiratory chain. In 1978, British biochemist Peter Mitchell was awarded the Nobel Prize in Chemistry for discovering the critical role coenzyme Q10 plays in the electron transport chain in mitochondrial membranes, which generates cellular energy in the form of ATP [9]. It is also involved in water production in mitochondria [10]. The antioxidant and mitochondrial bio-energizer properties of CoQ10 help in maintaining the efficient energy system of spermatozoa and protecting them against damage caused by ROS. Inadequate levels of CoQ10 have been associated with sperm DNA damage, decreased sperm motility, and lower sperm count [11, 12]. The biosynthesis of Coenzyme Q10 in the body requires at least 15 genes highlighting the complex and intricate process by which this compound is synthesized within the body. Further, CQ10 affects the expression of 694 genes and therefore acts as a potent gene regulator [13, 14]. At the molecular level, CoQ10 exists in both oxidized form (ubiquinone) and reduced form (ubiquinol), and these two redox forms undergo continual inter-conversion within cells as part of CoQ10 normal function. CoQ10 is transported as ubiquinol in the bloodstream, regardless of its initial dietary form (ubiquinone or ubiquinol). Based on this rationale, it has been suggested that the reduced form of CoQ10, ubiquinol, is more readily absorbed from the gastrointestinal tract [15]. In a study conducted by Zhang Y *et al*., it was observed that ubiquinol appeared to be a more effective supplemental form for enhancing CoQ10 levels than ubiquinone [16].

Furthermore, CoQ10 is a commonly used and well-documented antioxidant in treating idiopathic male infertility [17]. Additionally, supplementation with other antioxidants like L-carnitine, zinc, lycopene, and astaxanthin has shown beneficial effects on sperm parameters [7].

While there are several micronutrient supplementation products available in the market that claim to improve the spermiogram [18] this real-world evidence aims to assess the effectiveness and tolerability of a novel blend of ubiquinol (a more bioavailable form of CoQ10) with L-carnitine, zinc, lycopene, and astaxanthin on sperm parameters in male infertility patients in India.

Methods

Study Design

The UNESCO (**U**niversal **N**utriSciences **E**valuation of **S**emen parameters with **Co**Q LC) study was designed as a multicenter, prospective, observational, real-world evidence study involving male infertility patients**.** Suraksha Institutional Ethics Committee approved the study protocol and related materials in compliance with ICMR (Indian Council of Medical Research), New Drugs and Clinical Trials Rules, 2019, ICH GCP, and the declaration of Helsinki. Before the start of the study, written consent was obtained from all participants.

Setting and participants

648 patients aged between 20 to 50 years with a history of infertility of at least 12 months despite regular unprotected intercourse were included in this study. The study was conducted by 79 doctors across India. Patients with severe Oligozoospermia/Azoospermia, genital tract infection, medical or surgical conditions that can result in infertility, and drug/substance abuse were excluded from the study.

Study intervention

During the study, the enrolled subjects were instructed to orally take a tablet containing ubiquinol 50 mg, L-carnitine 1000 mg, astaxanthin 8 mg, lycopene 2.5 mg, and Zinc 10 mg once daily for three months. Universal NutriScience Pvt Ltd, Mumbai, marketed the formulation. The record of concomitant medication was maintained during the study.

Outcome measures

The change from baseline to end of treatment in semen volume, sperm concentration, sperm motility, and sperm morphology were evaluated. Semen samples were obtained after 3 to 5 days of sexual abstinence.

Statistical Analysis

A primary database was created in validated Microsoft Excel spreadsheets while processing case record forms received from the study sites. The data were analyzed using an unpaired student t-test. P-values < 0.05 were considered statistically significant.

Results

Patient demographics

A total of 648 males were enrolled during the study based on inclusion and exclusion criteria. The subjects' mean age (SE) was 33.97 (0.206) years. 511 patients received the treatment for three months, 14, 82, 34, and 7 patients received the treatment for 1, 2, 4, and 5 months, respectively. The treatment's mean duration (SE) was 2.90 (0.022) months. Intake of concomitant medication was observed in only 48 patients (7.4%).

Semen volume

There was a significant improvement (P= 0.003) in the semen volume at the end of treatment (2.64 mL) when compared to baseline (2.24 mL), with a mean difference of 0.4 and a percent improvement of 17.85% as depicted in Figure 1 and Table 1. The average ejaculate volume should be 1.5 to 6 mL, while higher and lower volumes indicate hyperspermia and hypospermia, respectively [19].

Sperm concentration

The sperm concentration improved significantly ($p<0.0001$) after the three months of treatment as compared to the baseline. The mean sperm concentration at baseline was 27.39 million/mL, which improved significantly to 38.90 million/mL, with a mean difference of 11.51 and a percent improvement of 42.02%, as depicted in Figure 2 and Table 1.

Sperm motility

The sperm motility improved significantly ($p< 0.0001$) after the three months of treatment as compared to baseline. The mean sperm motility at baseline was 28.63%, which significantly enhanced to 41.12%, with a mean difference of 12.49 and a percent improvement of 43.62%, as depicted in Figure 3 and Table 1.

Sperm morphology

There was a significant improvement (P= 0.0014) in the sperm

morphology at the end of treatment (25.64%) when compared to baseline (20.34%), with a mean difference (MD) of 5.3 and percent improvement of 26.05% as depicted in Figure 4 and Table 1.

Table 1: Semen parameters at baseline and end of treatment

Semen parameters	Baseline (Mean ± SE)	End of treatment (Mean ± SE)	Mean difference (95% CI; P value)
Semen volume (mL)	2.24±0.059	2.64±0.080	0.4 (0.15 to 0.71; 0.003)
Sperm concentration (million/mL)	27.39±1.02	38.90±1.18	11.51 (8.72 to 14.81; <0.0001)
Sperm motility (%)	28.63±0.83	41.12±0.88	12.49 (2.15 to 8.93; 0.0014)
Sperm morphology (%)	20.34±1.15	25.64±1.28	5.3 (10.49 to 15.19; <0.0001)

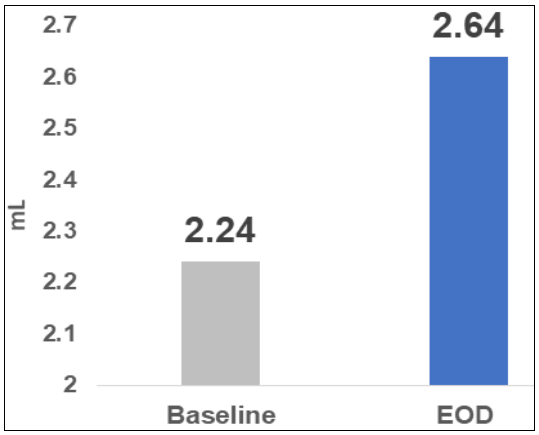

Fig 1: Mean change in semen volume from baseline to EOD with study product

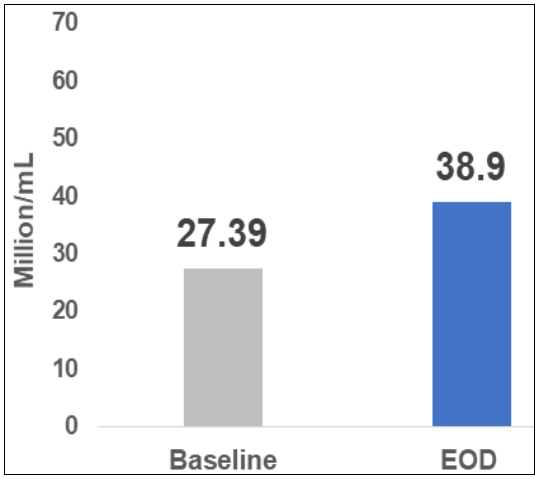

Fig 2: Mean change in sperm concentration from baseline to EOD with study product

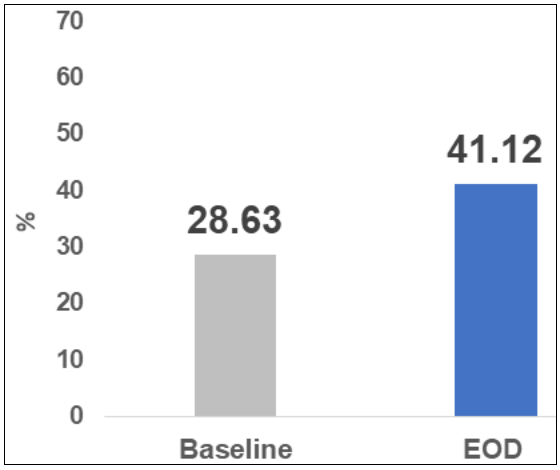

Fig 3: Mean change in sperm motility from baseline to EOD with study product

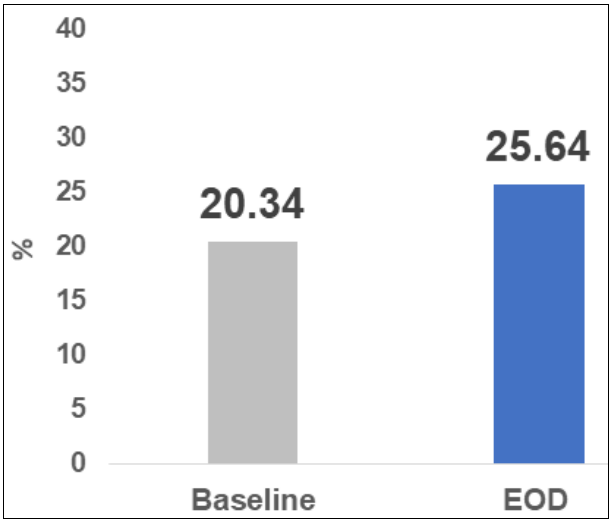

Fig 4: Mean change in sperm morphology from baseline to EOD with study product

Adverse effects

No adverse events were reported during the trial.

Discussion

In recent years, a decline in semen quality among men has been witnessed globally [20]. Researchers have extensively studied oxidative stress and mitochondrial dysfunction as a key factor in male infertility [4, 12]. CoQ10, an important antioxidant found in various body tissues, including sperm mitochondria, plays a crucial role in cellular respiration and energy production. It also acts as a protective agent against sperm damage caused by ROS [12]. Additionally, several other antioxidants have been investigated to lower the excessive OS in the treatment of infertility [21]. In this context, this is the first real-world evidence study aimed to investigate the impact of a novel blend of ubiquinol, L-carnitine, zinc, lycopene, and astaxanthin on enhancing sperm parameters in 648 male infertility patients across India. This unique combination has shown a significant improvement of 17.85%, 42%, 43.62%, and 20.34% in semen volume, sperm concentration, sperm motility, and sperm morphology, respectively.

A supplementation with ubiquinol 200 mg for six months in patients with male subfertility has demonstrated a significantly less improvement in sperm concentration and morphology [MD for sperm concentration: 3.9; MD for sperm morphology: 0.5] [22]. Another study with CoQ10, at a dose of 200 mg/day for three months, significantly showed an improvement in semen volume [% improvement- 6.32%], sperm concentration [% improvement- 18.75%], sperm motility [% improvement- 22.43%] and sperm morphology [% improvement- 5.5%] [12].

Moreover, various forms of carnitine, such as LC (L-carnitine), L-acetyl carnitine (LAC), or a combination of both (LAC and LC), have been shown to enhance sperm motility. Additionally, a recent network meta-analysis study found that zinc as an

antioxidant in supplementation improves sperm quality parameters in infertile men [23].

One prospective open-label study demonstrated two times greater effects with a combination of carnitines, L-arginine, zinc, tocopherol, glutathione, selenium, and coenzyme Q10 vs carnitines alone. Thus, a combination of antioxidants demonstrates a better result in the management of male infertility [24]. In this study, ubiquinol, combined with other antioxidants, has also demonstrated a significant increment in sperm parameters. It is worth mentioning that comparing our results with previous studies is challenging due to variability in study design, patient groups, and therapeutic protocols. Moreover, several studies conducted to date lack agreement on standardized antioxidant regimens [20]. The novel blend of ubiquinol with L-carnitine, zinc, lycopene, and astaxanthin was well tolerated, as no adverse events were reported during treatment.

One of the limitations of the study is that it was a single-arm study, which means we didn't have a comparison group to evaluate the treatment outcomes. The first real-world investigation involving 648 male infertile patients enrolled by 79 doctors across India is the key strength of this study.

Conclusion

The present study showed that a novel blend of Ubiquinol with L-carnitine, zinc, lycopene, and astaxanthin improved semen volume, sperm concentration, sperm motility, and sperm morphology in male patients with infertility. These findings suggest that CoQ10, in combination with other antioxidants, improves sperm parameters by reducing OS and OS-induced sperm damage. The improvement in sperm parameters also means that CoQ10 has played a role in maintaining the efficient energy system in spermatozoa. Therefore, this unique combination of ubiquinol with other antioxidants should be considered a treatment option for managing infertile male patients.

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Conflict of interest: The authors declare no conflict of interest.

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Appendix: UNESCO study investigators

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