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Original Article

The Role of Vitamin E in Enhancing the Efficacy of Tamoxifen on Sperm Parameters in Male Infertility: A Clinical Experimental Study

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Abstract

Objective: To compare the outcome of tamoxifen versus tamoxifen plus vitamin E on the semen quality of infertile males with abnormal semen parameters.

Methodology: This clinical experimental study was done in the Department of Obstetrics and Gynecology, Sharif Medical City, Lahore for 6 months after approval from the hospital's ethical review board from January 15, 2024 till July 15, 2024. A total of 110 infertile males provided written consent and underwent semen analysis. Infertile married males aged 20 to 40 years and diagnosed with abnormal semen parameters were included in this study. Patients having leukocytospermia, diminished testicular volume, severe oligospermia were excluded from the study. Demographics and baseline data were recorded and participants were divided into group A which received oral Tamoxifen 10mg twice daily for three months, while Group B received Tamoxifen 10mg plus capsule vitamin E 400mg once a day orally. After three months, semen analysis was repeated to assess changes in sperm parameters. Data collection adhered to a pre-designed proforma.

Results: The mean age in both the groups was 29.40+3.89 years; sperm count in Group A increased from 6.13+0.92 to 16.31+1.33 and in Group B 6.16+0.90 to 19.83+1.58 (p=0.000), and motility increased from 13.98+1.00 to 30.58+2.13 in Group A and 14.05+1.04 to 34.69+1.90 in Group B, (p=0.001)

Conclusion: Our study findings strongly support the synergistic effect of combining tamoxifen with vitamin E in enhancing sperm motility, providing valuable insights for potential therapeutic interventions in male infertility.

Keywords: Male infertility, tamoxifen, semen analysis, oligospermia, vitamin E, sperm motility.

Introduction

Infertili ty is defined as the failure of a couple to conceive after one year of regular and unprotected coitus.[1] Within the couple, both partners are equally responsible for this delay in conception and the dictum must change in Pakistan that males are not responsible and it is only women who should be treated.[2] There is a recent rise in male factor identification in the workup of infertile couples, possibly more because of increased awareness and increased participation of men in the investigations and not due to an increase in male infertility.[3] The medical management of reduced sperm count is very contentious, with many hormonal and non-hormonal remedies available. Several studies have shown benefits with different treatWment protocols using single or multiple drugs such as L-carnitine, tamoxifen, pentoxifylline, coenzyme Q10, follicle-stimulating hormone, and kallikein.[4] Endocrine and systemic disorders, including hypogonadotropic hypogonadism, account for approximately 5–15% of male infertility cases.[5] Primary testicular defects in spermatogenesis are the most common cause, responsible for 70–80% of cases.[6] Sperm transport disorders contribute to 2–5% of cases, while idiopathic male infertility accounts for 10–20%.[7] Certain medications, cancer and hypothalamic-pituitary disorders can cause male factor infertility.[8,9]

For male factor infertility semen analysis is one of the simple test. Single semen analysis report is not relied upon, there should be a gap of at least one week between two samples with 3 days of abstinence.[10] Collection of semen is done by masturbation or by the use of non toxic condoms.[9] The success of male factor infertility is dependent on results of semen anlysis and female fertility status.[10] The semen is evaluated for volume, pH, leukocytes, immature germ cells, and liquefaction, while the sperm is assessed for count, concentration, vitality, motility, progression, debris, and morphology.[7] The Semen Analysis adapted from WHO 2 includes ejaculate volume of 1.5 mL (1.5 – 5 ml), pH > 7.2, Sperm concentration 15 million per ml, Total sperm count of 39 million per ejaculate (33 – 46 million), Sperm Morphology (normal) forms > 4%, Motility 40% (38 – 42%, Vitality of 58% with progressive motility of 32% and total motility of > 40%.

Tamoxifen (TX) is the selective anti-estrogen receptor modulators (SERM) drug category. It has been used in the treatment

of infertile men with idiopathic infertility, oligospermia, and nonobstructive azoospermia.[4] Daily use of 20 mg TX in men with sexual dysfunction for six consecutive months increased the sperm count in the ejaculate.[5] Several studies have reported improved total sperm count, sperm morphology, and increases in pregnancy rates after treatment with tamoxifen.[8,9] Various antioxidants have been claimed in literature which improve semen parameters like vitamin C, Co enzyme Q 10 and L- carnitine and vitamin E. We chose vitamin E (α-tocopherol) 400mg as prescribing drug as it improves sperm motility and morphology by reducing reactive oxygen species, which are commonly elevated in cases of male infertility. Increasing doses of vitamin E are claimed to have harmful effect by increasing the reductive stress which is as detrimental as oxidative stress. This dosage is both efficacious and safe for prolonged use and has been documented in similar studies assessing its impact on male fertility.[10] Vitamin E is widely available, cost-effective, and has an established safety profile, making it a practical choice in clinical settings, especially in low-resource environments like Pakistan.[11]

Male infertility is increasingly recognized as a major contributor to infertility among couples in Pakistan. Despite its growing prevalence, local data on male infertility and the effectiveness of available treatment options remain scarce. Infertility affects approximately 21.9% of couples in Pakistan, with male factors contributing to nearly 40% of these cases. Tamoxifen is commonly prescribed for idiopathic oligospermia due to its affordability and accessibility; however, emerging evidence suggests that its efficacy may be enhanced when combined with Vitamin E as adjunct therapy.[12] Given the mixed findings in existing literature, this study was conducted to generate reliable local evidence that could guide the selection of more effective treatment regimens for improving male fertility outcomes in clinical practice.

Methodology

This clinical experimental study was done in the Department of Obstetrics and Gynecology, Sharif Medical City, Lahore, for a duration of 6 months, from January 15, 2024 to July 15, 2024. It included a 3-month intervention phase followed by a 3-month follow-up to assess sustained effects and monitor any delayed responses or side effects. We lost 3 patients from follow-up. The sample size was 110 with a non-probability consecutive sampling technique. The sample was divided into 2 groups with 55 in each group calculated with a 95% confidence level, 80% power of the study, and mean sperm count i.e. 19.3+2.04 with tamoxifen plus Capsule vitamin E per oral once a day and 17.77+3.56 with tamoxifen alone.[10]

We excluded the infertile married male of age 20 to 40 years diagnosed with abnormal semen parameters, patients having leukocytospermia, diminished testicular volume (< 12 cm^3 as depicted by ultrasonography), severe oligospermia (sperm count <5 million per ml), history of epididymo-orchitis, prostatitis, genital trauma, testicular torsion, inguinal or genital surgery, urinary tract infection or previous hormonal therapy, cryptorchidism or varicocele, occupational and environmental exposure to potential reproductive toxins, history of use of cancer chemotherapy, testosterone, antiandrogens, and tobacco.

After approval from the hospital's ethical review board with letter number SMDC/SMRC/141-20, a total of 110 infertile males were included after written informed consent. Demographics like name, age, BMI, and duration of infertility were noted. A semen sample was obtained for semen analysis. The sample was collected in a private room, wide-mouth container kept at body temperature, after abstaining from any sexual activity for 3 to 7 days. The sample was collected by masturbation with avoidance of any lubricants. The sample was then incubated at 37°C until complete liquefaction occurred. All samples were sent to the laboratory for measurement of sperm parameters. Randomization was done by lottery method to divide the patients into two groups. Group A received Tamoxifen 10 mg twice daily for three months, while Group B was given Tamoxifen 10 mg along with Vitamin E 400 mg daily for the same duration. After 3 months, the semen sample was taken again and semen analysis was done to determine changes in semen parameters, including sperm count, and motility (as per operational definition). All the research data was taken on a pre-developed proforma.

Data analysis was done using SPSS 20. Quantitative variables such as age, BMI, duration of infertility, pre- and post-treatment sperm count, and motility, were analyzed as mean and standard deviation was calculated. Categorical variables like smoking, socioeconomic status, and occupation were analyzed as frequency and percentage. Independent sample t-test was used to compare changes in semen parameters in both groups. P-value < 0.05 was taken as significant. Data was stratified for age, BMI, duration of infertility, smoking, socioeconomic status, and occupation. Post-stratification, an independent sample test was used to compare the change in semen parameters in both groups in each stratum. P-value <0.05 was taken as significant.

Result

A total of 110 (55 in each group) cases fulfilling the selection criteria were enrolled to compare the outcome of tamoxifen versus tamoxifen plus vitamin E on the semen quality of infertile males with abnormal semen parameters. Descriptive statistics of age, BMI, duration of infertility, occupation, and smoking are shown in Table 1. Comparison of the outcome (sperm count) of tamoxifen versus tamoxifen plus vitamin E on semen quality of infertile males with abnormal semen parameters shows that at baseline sperm count was 6.13+0.92 in Group A and 6.16+0.90 in Group B, P-value was 0.835 whereas after 3 months it improved as 16.31+1.33 in Group A and 19.83+1.58 in Group B, p-value=0.001 (Table 6). Comparison of the outcome (motility) of tamoxifen versus tamoxifen plus Vitamin E on semen quality of infertile males with abnormal semen parameters shows that motility at baseline in Group A was 13.98+1.00 and in Group B 14.05+1.04, P value=0.711 whereas after 3 months it improved as 30.58+2.13 in Group A and 34.69+1.90 in Group B, P-value=0.001 (Table 3). The data was stratified for age, BMI, duration of infertility, smoking, socioeconomic status, and occupation. Post-stratification, an independent sample test was used to compare the change in semen parameters in both groups in each stratum. P-value <0.05 was taken as significant.

Table 1. Comparison of Baseline Demographic Characteristics Between Group A and B

Demographic variables		Group A (n=55)	Group B (n=55)
Age (Years)		29.40± 3.89	29.03±3.82
BMI (Kg/m^2)		27.44±3.47	27.82±3.39
Duration of infertility（Years)		2.64±0.70	2.65±0.71
Occupation	Office Job	37 (67.3%)	37 (67.3%)
	Labourer	18 (32.7|%)	18 (32.7|%)
Smoking	Yes	12 (21.8%)	10 (18.2%)
	No	43 (78.2%)	45 (81.8%)

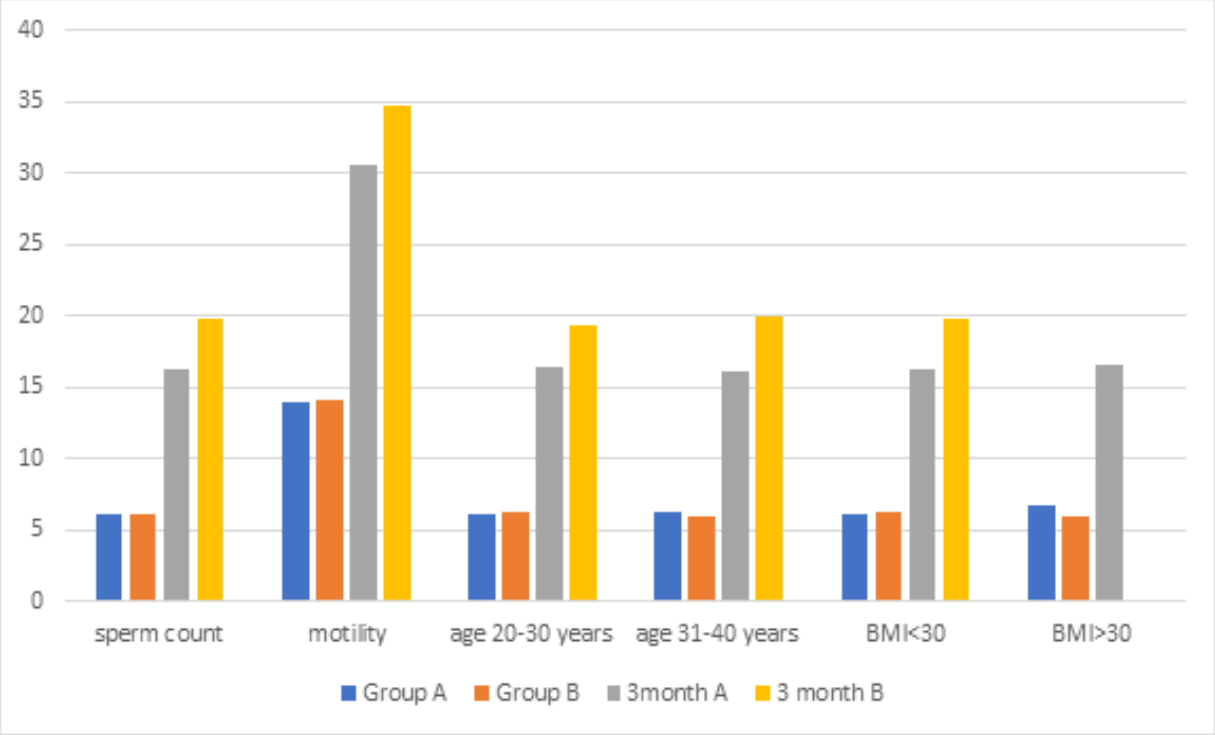

Figure 1: Trends in Semen Quality Parameters Over 3 Months in Groups A and B

Table 2. Statistical Comparison of Groups A and B at Baseline and After 3 Months of Treatment

		Group A (n=55)	Group B (n=55)	P-value
Sperm count	Baseline	6.13±0.92	6.16±0.90	0.835
	After 3 months	16.31±1.33	19.83±1.58	0.000
Motility	Baseline	13.98±1.00	14.05±1.04	0.711
	After 3 months	30.58±2.13	34.69± 1.90	0.00
Age				

20-30 years	Baseline	6.06±0.85 (n=34)	6.28±0.88 (n=36)	0.295
	3 months	16.44±19.78 (n=34)	1.39±1.64 (n=36)	0.00
31-40 years	Baseline	6.24±1.04 (n=21)	5.95±0.91 (n=19)	0.886
	3 months	16.10±1.22 (n=21)	19.95±1.51 (n=19)	0.00
BMI				
<30	Baseline	6.04±0.88 (n=47)	6.21±0.90 (n=42)	0.366
	After 3 months	16.26±1.34 (n=47)	19.79± 1.46	0.00
>30	Baseline	6.63±1.06 (n=8)	6.00±0.91 (n=13)	0.168
	After 3 months	16.63±1.30 (n=47)	20.00±2.00 (n=42)	0.00

Table 3. Comparison of the duration of infertility, occupation, smoking status, and socioeconomic status as a baseline and 3 months following treatment in groups A and B on semen quality of infertile males with abnormal semen parameters.

Variables		**Group A Mean (SD)**	**Group B Mean (SD)**	**P-value**
Duration of Infertility				
3 years	Baseline	6.02±0.91	6.27±0.89	0.178
	After 3 months	16.31±1.36	19.69±1.43	0.00
> 3 years	Baseline	6.86±0.69	5.43±0.53	0.001
	After 3 months	16.29±1.25	20.86±2.27	0.001
Occupation				
Office job	Baseline	6.11±0.91	6.14±0.92	0.899
	After 3 months	16.49±1.30	19.84±1.71	0.00
Laborer	Baseline	6.17±0.99	6.22±0.88	0.859
	After 3 months	15.94±1.35	19.83±1.34	0.000
Smoking status				
Smoker	baseline	6.58±0.73	6.00±0.67	0.080
	After 3 months	16.50±1.38	20.00±1.05	0.00
Nonsmoke**r**	baseline	6.00±0.93	6.20±0.94	0.319
	After 3 months	16.26±1.33	19.80±1.69	0.000
Socioeconomic Status				
Low	baseline	6.16±1.00	6.17±0.78	0.960
	After 3 months	16.31±1.34	20.13±1.63	0.000

Middle	baseline	6.16±0.90 (n=19)	6.24±0.99 (n=21)	0.79
	After 3 months	16.47±1.35(n=19)	19.24±1.30(n=21)	0.000
High	baseline	5.80±0.45 (n=5)	6.00±1.0(n=11)	0.679
	After 3 months	16.80±1.30(n=5)	20.36±1.75(n=11)	0.000

Discussion

The study aimed to examine the effects of a therapy regimen that includes vitamin E and tamoxifen on improving semen parameters in men with oligospermia.[13] The main objective is to find out whether this combination treatment method can significantly enhance sperm characteristics. It is believed that the use of tamoxifen in conjunction with vitamin E would improve sperm parameters, which in turn will increase the likelihood of conception and the likelihood of a successful pregnancy.[14] The baseline descriptive statistics of our study provide a snapshot of the study population, emphasizing the demographic characteristics of participants in both Group A and Group B. The mean age in group A and B was 29.40±3.89 and 29.03±3.82 as shown in table 1. BMI, duration of infertility, occupation a smoking status in group A and B was comparable, these finding align with the previous work done in other studies.[14] The comparison of baseline sperm counts and motility between Group A (tamoxifen alone) and Group B (tamoxifen plus vitamin E) reveals a P-value of 0.000 which is statistically significant (Table 2) . These findings are supported by the Shen Cheun Khaw by comparing L- carnitine with placebo in their study with marked improvement on sperm concentration in L-carnitine group.[15]

The subsequent three-month analysis demonstrates a noteworthy improvement in sperm count and motility in both groups. However, the more pronounced increase in Group B suggests that the addition of vitamin E enhances the effects of tamoxifen (Table 2). This aligns with findings of Kun Peng Li where use of antioxidant led to improvement in semen parameter as compared to the placebo.[5,16] where tamoxifen alone led to a significant rise in sperm concentration. The comparison of age and BMI in different groups showed marked improvement after 3 months of treatment with a P-value of 0.00 (Table 2). Duration of infertility, occupation, smoking status and socioeconomic status in both groups has P-value of 0.00-0.001 which is significant (Table 3). these finding align with finding by other authors.[16,17]

The tamoxifen did not adversely affect traditional semen parameters, it increased the percentage of sperm cells with abnormal morphology and abnormal chromatin as supported by study done in Taiwan by Yao-cheng Wu.[17] This underscores the importance of considering not only conventional semen parameters but also aspects of sperm quality that directly impact fertility. The combination of tamoxifen with vitamin E in our study might address or mitigate these concerns, given vitamin E protective effects on sperm DNA integrity. The finding of our study show a positive impact of tamoxifen and vitamin E on total sperm count, sperm concentration, and motility as shown in Table 1, was also supported by Pallav et al in a study done in India.[18] The observed improvements are attributed to the alleviation of oxidative stress and enhanced sperm mitochondrial functionality. This aligns with the rationale behind combining tamoxifen with vitamin E in our study, suggesting a potential synergistic effect that contributes to the overall improvement in semen quality.[19] The increase in mean sperm count and motility in the combination group compared to tamoxifen alone across different studies strengthens the argument for the synergistic effects of this combination. The detailed analysis underscores the promising potential of tamoxifen, particularly when combined with vitamin E, as a therapeutic option for male infertility with abnormal semen parameters.[20]The combined treatment approach appears to yield superior results in terms of sperm count and motility compared to tamoxifen alone. While acknowledging these positive outcomes, the potential impact on sperm morphology and chromatin integrity warrants careful consideration.[20,21]

Insights from the comparison with previous literature highlight the multifaceted benefits of tamoxifen, which extend beyond traditional semen parameters to include enhancements in oxidative stress reduction and mitochondrial function. This holistic perspective strengthens the case for tamoxifen as a potential intervention for male infertility. However, it's crucial to approach these findings with a nuanced understanding, considering potential side effects and long-term implications. Future research should delve into optimal dosages, long-term effects, and the broader applicability of this treatment approach.[22] Moreover, a careful evaluation of the trade-offs, including potential adverse effects on sperm morphology and chromatin integrity, should guide the development of clinical recommendations.[23] In summary, our study contributes meaningfully to the evolving landscape of male infertility treatment, aligning with existing evidence and paving the way for further exploration of tamoxifen-based interventions with vitamin E supplementation.[24-26] This detailed analysis provides a comprehensive view, laying the groundwork for future investigations and potential advancements in the field.

Limitations

The sample size of the study was small which may limit the generalization of the results and it was a single-centered study. There was a short follow up period of 3 months only which is also one of the major limitations. Future studies with a large sample size and long-term follow-up are required.

Conclusion

Our study findings strongly support the synergistic effect of combining tamoxifen with antioxidants in enhancing sperm motility, providing valuable insights for potential therapeutic interventions in male infertility

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ST: Final write-up and proofreading; AF: Final proofreading.

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