ORIGINAL RESEARCH

Role of adjuvants (zoafrag) in male infertility

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ABSTRACT

Objectives: Oxidative stress is the primary cause of sperm DNA damage and infertility, leading to potential risks such as pre- and post-implantation losses, congenital defects, and childhood cancer. Understanding oxidative stress origins and maintaining free radical levels is crucial for preventing these issues and improving male reproductive health. **Materials and methods:** The study conducted at Muzaffarnagar Medical College and Hospital focused on infertility treatment. It included a hospital-based observational study, outpatient department (OPD), inpatient department (IPD), and IVF center of the department of obstetrics and gynecology. The study lasted for 1 year and had a sample size of 50, based on the average size achieved in the previous five years. The participants were individuals attending the OPD for infertility treatment at Muzaffarnagar Medical College. The inclusion criteria were males with abnormal semen analysis without any other infertility factor in couples seeking infertility treatment, while female infertility patients were excluded from the study. Semen analysis and DNA fragmentation was performed to compare the results before and after the therapy. **Results:** Following the completion of the 90-day therapy period, a notable enhancement in the percentage of actively motile sperms was detected. On day 90, the active motility percentage was measured at 42.7%, accompanied by a standard deviation of 13.32. Throughout this duration, the observed values ranged from a minimum of 13% to a maximum of 61%. The calculated p-value for the active motility percentage was determined to be less than .00001 ($p<0.05$ significant). There was even significant decrease in DNA fragmentation index after 90 days therapy from 27.5% to 11.5%. **Conclusion:** Tablet zoafrag (protodioscin, Astaxanthin, Lycopene, L-carnitine, Coenzyme Q10 and selenomethionine) boosts ICSI, IVF, and IUI procedures by stimulating Sertoli and Leydig cells, increasing sperm production and converting testosterone to DHT. It improves acrosomal activity, allowing sperm to fuse with the oocyte membrane. It protects sperm PUFA, enhances sperm motility, and improves infertility. It also enhances sperm concentration and motility whereas decrease DNA fragmentation index after 90 days of therapy.

Key Words: Zoafrag, Coenzyme Q10, Protodioscin, Astaxanthin, infertility.

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INTRODUCTION

Infertility is a psychological, economic, and physiological condition that causes pain and stress, particularly in a culture that values child-bearing.Infertility, according to the World Health Organization's International Committee for Monitoring Assisted Reproductive Technology, is a reproductive system illness characterized by the failure to generate clinical pregnancy following a period of 12 months or more of regular unprotected sexual intercourse.[1] It is also defined as a couple's failure to conceive after 12 months of regular intercourse without the use of contraception in women 35 and after 6 months of regular intercourse without the use of contraception in women 35.[2] Male infertility is defined as a male spouse's inability to conceive with a fertile female companion.[3] Male factor infertility may result from abnormalities in seminal fluid or sperm, with sperm concentrations below 39 million per ejaculate in seminal fluid indicating infertility.

Different causes of male infertility abnormal sperm production, varicocele, infections, hormonal imbalances, and lifestyle factors like smoking, drug use, and alcohol consumption. A complete reproductive and medical history, a physical examination, and two semen tests acquired at least four weeks apart are used to evaluate the male partner.[4]

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Males with sperm parameters below WHO normal values are considered male factor infertility, characterized by low sperm concentration, poor motility, and abnormal morphology, with 90% of problems related to sperm count, with abnormal semen parameters positively correlated with sperm count. These issues stem from a disarray in control mechanisms, with semen analysis being the most fundamental investigation.

The WHO has updated the minimum standards for sperm analysis. The new reference ranges are as follows: ejaculate volume should be greater than 1.4 mL, total sperm count should be greater than 39 million per ejaculate, motility should be greater than 42%, normal morphology (using Kruger Strict criteria) should be greater than 4%, and pH should be greater than 7.2. [5]

Reactive oxygen species (ROS) significantly contribute to sperm failure in infertile males, causing fatty acid changes and DNA damage.[6,7,8] Astaxanthin, a carotenoid from Hematococcuspluvialis algae, is more effective than vitamin E in quenching reactive oxygen species.[9]

Zoafrag active ingredients are Protodioscin, Astaxanthin, Lycopene, L-carnitine, Coenzyme Q10 and Selenomethionine. Protodioscin the principal phytochemical agent of the Tribulus genus, operates on sertoli cells, germ cell proliferation, and seminiferous tubule growth. This component is known to convert testosterone into dihydrotestosterone, which is vital in masculine characteristics.

Coenzyme Q10, an essential antioxidant, is crucial for spermatozoa's energy system and membrane protection. Low CoQ10 levels are linked to reproductive disorders like varicocele and oligozoospermia. L-carnitine and LAC preserve sperm membranes.[10]

The purpose of this study is to explore male infertility patterns in tertiary care centre couples and to assess the influence of Zoafrag on male fertility, with an emphasis on sperm sample analysis owing to seminal fluid anomalies.

MATERIAL AND METHODS

A hospital-based observational study, outpatient department (OPD), inpatient department (IPD), and IVF centre of the department of obstetrics and gynaecology all patients seeking infertility treatment in Muzaffarnagar- Medical College and Hospital. The duration of the study was 3 months. The sample size was 50 based on the average size achieved during the previous five years. Each and every person attending OPD for infertility treatment at Muzaffarnagar Medical College. The inclusion criteria would be Males partner with abnormal semen analysis without any other infertility factor in couples seeking infertility treatment. Female infertility patients were excluded from the study. Semen analysis and DNA fragmentation was done to compare the results before and after the therapy. Follow up was done after every month for significant benefit and with no adverse effects was continued till 90 days. The Institutional Ethics Committee of Muzaffarnagar Medical College, Muzaffarnagar, accepted the study protocol for both the pre-test and the implementation phase. Following the presentation of oral and written information about the study's goal, all participants were given written informed consent.

RESULTS

The initial population consisted of 50 patients, with each individual's age varying. The average age of the patients was determined to be 35.4 years, with a standard deviation of
5.6.

To assess the effectiveness of the therapy, the sperm count of each patient was measured before commencing the treatment and again after a duration of 90 days. At the start of the study, the mean sperm count was found to be 22.3 million sperms per milliliter, with a standard deviation of 11.93. The lowest recorded value was 8 million sperms per milliliter, while the highest recorded value was 35 million sperms per milliliter.

After the 90-day therapy period, a significant increase in sperm count was observed. The mean sperm count at this point was 50.48 million sperms per milliliter, with a standard deviation of 12.43. The lowest recorded value was 42 million sperms per milliliter, while the highest recorded value was 76 million sperms per milliliter. These findings are summarized in Table 1, highlighting the substantial improvement in sperm count achieved through the administration of Tablet Zoafrag. Furthermore, the statistical analysis revealed a p-value of less than .00001 for the sperm count, indicating a significant difference.

On day 0, the active motility percentage was determined to be 26.82%, with a standard deviation of 11.81. The range of values observed ranged from a minimum of 12% to a maximum of 39%. However, after the 90-day therapy period, a significant improvement in the active motility percentage of sperms was observed. The active motility percentage on day 90 was found to be 55.7%, with a standard deviation of 9.32. The range of values recorded during this period ranged from a minimum of 44% to a maximum of 69%.The statistical analysis revealed a significant difference in the active motility percentage before and after the therapy. The calculated p-value for the active motility percentage was found to be less than .00001 ($p<0.05$ significant), indicating a statistically significant improvement as mentioned in Table 2.

The DNA fragmentation index on day 0, was determined to be 37.5% with a standard deviation of 10.24 with a range from 26% to 51%. Whereas on day 90, it was found to be 11.8% with a standard deviation of 11.95 with a range from 9% to 15%.

These results provide strong evidence to support the efficacy of Tablet ZOAFRAG in increasing sperm

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count and motility percentage of sperms whereas decrease the DNA fragmentation index.

Table 1: Descriptive values of semen parameters, according to day of evaluation

Variable	Day	n	Average	SD	Minimum	Maximum
Sperm Count (in Million)	0	50	22.3	11.93	8	35
	90	50	50.48	12.43	42	76
Active Motile %	0	50	26.82	11.81	12	39
	90	50	55.7	9.32	44	69
DNA Fragmentation index %	0	50	37.5	10.24	26	51
	90	50	11.8	11.95	9	15

Table 2: p value of semen parameters

Variable	t value	p value	
Sperm Count (in million sperms per milliliter)	28.64	< .00001	significant
Active Motile %	29.43	< .00001	significant
DNA fragmentation index %	28.54	< .00001	significant

The result is significant at $p < 0.05$.

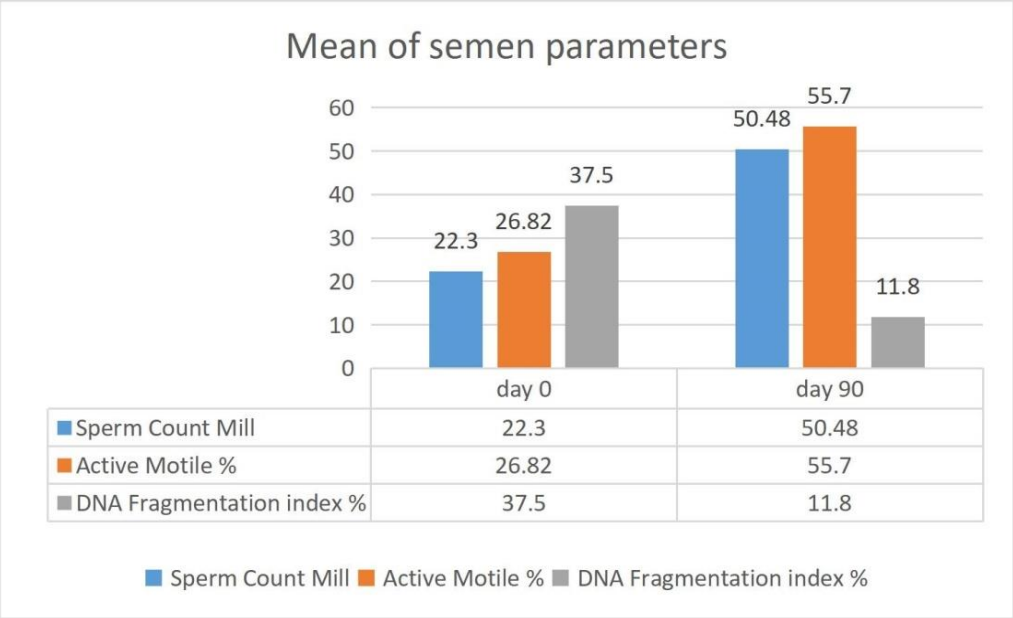

Figure 1: Mean of Semen Parameters

DISCUSSION

The findings of this study demonstrate that therapy with Zoafrag can increase sperm count and motility in men in a clinical ART program who have poor sperm quality. These findings lend support to the investigation of Zoafrag as a potential intervention in male factor infertility and provide a foundation for future case-controlled studies to assess the effect of Zoafrag supplementation on both sperm parameters and pregnancy rates after either ART or natural conception. There was significant increase in the sperm concentration (p<.00001) ,sperm motility (p<.00001) and decrease DNA fragmentation index between days (p<.00001).

Salgado et al. Between days 0 and 84, there were substantial increases in liquefaction time (p =.01), sperm concentration (p =.007), and sperm motility (p =.001). [11] In our study, there was a significant increase in the sperm concentration (p <.00001) and sperm motility (p <.00001) after 90 days of therapy.

Dinesh et al. how the levels of free radicals be maintained at physiological levels when they are beneficial for normal function. It is also important to develop techniques to identity cases with high free

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radical levels and also adopt certain life style measures which can minimise oxidative stress and improve male reproductive health. [12]

The statistical analysis demonstrated a substantial variation in the proportion of active motility before and after the treatment. The computed p-value for the active motility % was less than.00001 ($p < 0.05$ significant), suggesting a statistically significant improvement. These findings give significant evidence to demonstrate the efficacy of Tablet ZOAFRAG in boosting sperm count and motility % in a period of 90 days. Follow up was done after every month for significant benefit and no adverse effects were found on infertility treatment.

CONCLUSION

Zoafrag has been shown to enhance the success rates of Intracytoplasmic Sperm Injection(ICSI), Invitrofertilisation (IVF) and Intrauterine Insemination (IUI) procedures by stimulating Sertoli and Leydig cells, which leads to an increase in sperm production. Additionally, it aids in the conversion of testosterone to DHT, which can improve sexual function. Furthermore, it significantly improves acrosomal activity, allowing the sperm to penetrate the zonapellucida and fuse with the oocyte membrane. Zoafrag is particularly helpful for those experiencing primary infertility or metabolic syndrome-related infertility. It also protects the PUFA of the sperm and has antioxidant properties, which increases sperm viability. Moreover, it enhances sperm motility, provides anti-inflammatory and antioxidant action, and improves infertility. It offers a significant improvement in concentration and motility in the seminal plasma and decrease DNA fragmentation index. No adverse effects were found on infertility treatment during the study period. Glutathione peroxidase protects the sperm in the epididymis, while superoxide dismutase protects the sperm in the semen.

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