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Efficacy of combination of multinutrients in reduction of sperm DNA fragmentation

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***Abstract*---**High Sperm DNA fragmentation can cause decreased fertility & implantation rate or can cause Recurrent implantation failure and if fetus born then can lead to Genetic abnormality in the fetus such as Down Syndrome, Edward syndrome or Patau's syndrome. The objective of the study is to combine the peripheral data of the patients to evaluate the safety and efficacy of Combination tablet in reduction of Sperm DNA fragmentation index. The result shows that the factors affecting the DFI. The Institutional Ethics Committee approved the study procedure (Ref No: SRMC/RP/4505).

***Keywords*---**DNA fragmentation, Co-Q10 tablets, male in fertility.

Introduction

(Agarwal, A. *al.*, 2015) Infertility is a reproductive condition defined as the inability to generate a clinical pregnancy after at least 12 months of unprotected sexual activity. (Prangthip P. *al*, 2016) It could be due to female factors (35% to 40% of couples), male factors (20% to 40% of couples), both (20% to 30% of couples), or it could be unexplained.However, studies of the effects of CoQ10 intake on seminal plasma antioxidant levels are limited. Our findings are congruent with those of (Nadjarzadeh A. *al,* 2011) who showed that CoQ10 administration (200 mg/day for 3 months) increased SOD and CAT activity in the seminal plasma of infertile men. Furthermore, a positive correlation was found between seminal CoQ10 concentrations and semen parameters In contrast, in a study by (Eroglu M. *al.,* 2014) basal CoQ10 levels in seminal fluid did not appear to be associated with sperm quality parameters or TAC. Our study has certain limitations. (Natali, A. *al*, 2020) We did not investigate pregnancy or live birth rates post-therapy, as those were not the primary outcome measures of the study. (Langsjoen, P. H., *al.,* 2016) The present study is focused on combination of the peripheral data of the patients to evaluate the safety and efficacy of multi nutrient tablet in reduction of Sperm DNA fragmentation index. (Barkat A. *al.,* 2011)

Material and Method

Research Question Is there any impact to recombinant tablet on DFI and infertility of Male?

- **Setting –** Infertility treatment centre, Indira IVF centre Udaipur.
- **Duration –** January 2019 to April 2020
- **Type of Study -** A type of prospective cohort study in which health conditions are measured before and after a treatment.
- **Sample Size**–48
- **Sample size for each group using above formula:**
  - Before treatment: 6
  - After treatment: 6
- **Study Site**– Department of reproductive medicine, Indira IVF centre Udaipur.

Population
Participants

- Male Patients above the age of 21 years, in a monogamous, heterosexual marriage, trying
- to conceive but having difficulty with conception.
- Patients with Sperm DNA Fragmentation Index ≥15% at the time of screening.
- Patients with normal or clinically non-normal seminal parameters not limited to leucospermia.
- Patients with primary or secondary infertility.
- Patients who are willing to commit to study restrictions not limited to abstinence from Masturbation and sexual intercourse for specific periods.

Exclusion criteria

- Patients who have aspermia, azoospermia, cryptozoospermia.
- Patients who have history/diagnosis of cancer inclusive of Patients in remission.
- Patients with testicular atrophy and congenital abnormalities not limited to absence of vas deferens.
- Patients who are currently on or were on a antioxidant and/or vitamin supplements up to 3 months prior to screening.
- Patients with history of substance abuse.
- Patients with diagnosis of HIV, HCV, HBV and other sexually transmitted diseases.
- Patients with known history of clinically significant, gastrointestinal, cardiovascular, hematological, hepatic, immunological, renal, respiratory, neurological abnormalities or diseases.
- Patients who have undergone major surgical procedure 4 weeks prior to screening.
- Patients who are on steroids, hormone therapy, anti-depressants, anti-psychotics.
- Patients who mentally unable to comprehend the responsibilities and adhere to the stipulations of the protocol.
- Patients who mentally unable to comprehend the responsibilities and adhere to the stipulations of the protocol.
- Patients who in the opinion of the investigator are deemed unfit to participate in the study.

Data Collection

Due permission were taken from competent authorities for data collection from Department of reproductive medicine Indira IVF centre. Care seekers at Indira IVF reproductive medicine department for infertility treatment with >15% Sperm DNA Fragmentation and apparently healthy will be recruited after their informed written consent. Indian diabetes risk score will be calculated by using a validated questionnaire which comprised of family history, physical activity, age and waist circumference (in CMS) and then classified as low risk, moderate risk and high risk for having diabetes

Interventions

Combination of multinutrient tablet.

Objectives

To evaluate the safety and efficacy of multi nutrient tablet in reduction of Sperm DNA fragmentation index.

Implementation Process

- Patient with repeated IVF failure or poor sperm parameter were send for Sperm DNA fragmentation
- Simple random sampling was done during data collection; every third patient was counseled to participate in our study, if >15% DFI.
- Every week 1-3patientwas inducted for data collection, covering the required sample size in 10 months.
- Patients were recruited after obtaining a written informed consent.
- On the next visit after 3 month patient information is recorded, semen examination and sperm DFI was done to note any change.

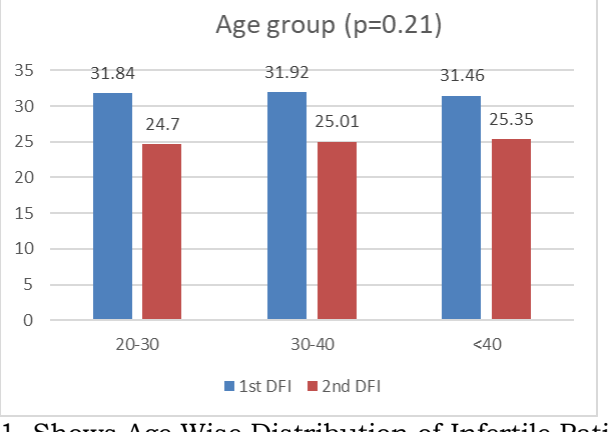
Result and Analysis

To assess efficacy of combination in male subject with raised sperm DNA fragmentation Index to improve the outcome of assisted reproductive technique.

Table 1
Shows Age Wise Distribution of Infertile Patients

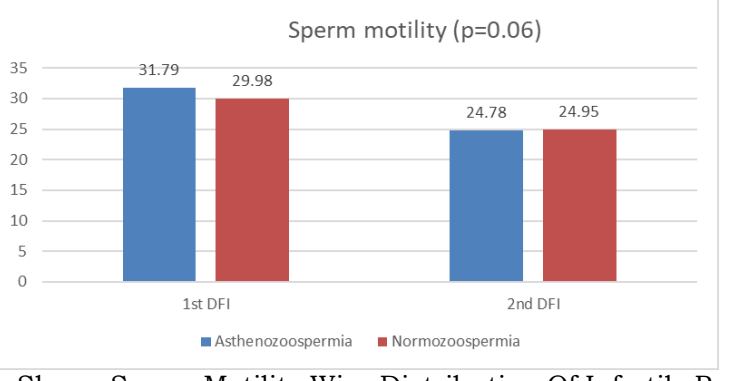
Sr. No.	Groups	Age Groups (In Years)	No. of Subjects	1st DFI Percentage (%)	2nd DFI Percentage (%)
1	Infertile Patients	20-30	5	31.84	24.7
		30-40	20	31.92	25.01
		<40	14	31.46	25.35

Table-1 Shows distribution of the infertile patients in different age group. The present study includes infertile patients from the age group 20-40 years. The percent wise distribution of infertile patients was31.84%, 31.92%, 31.46% from the age group 20-30, 30-40,<40respectively. The maximum numbers of patients were from the age group 30-40 and <40;hence control patients were selected from the same age group with percentage 25.01% and 25.35% respectively (Table-3)



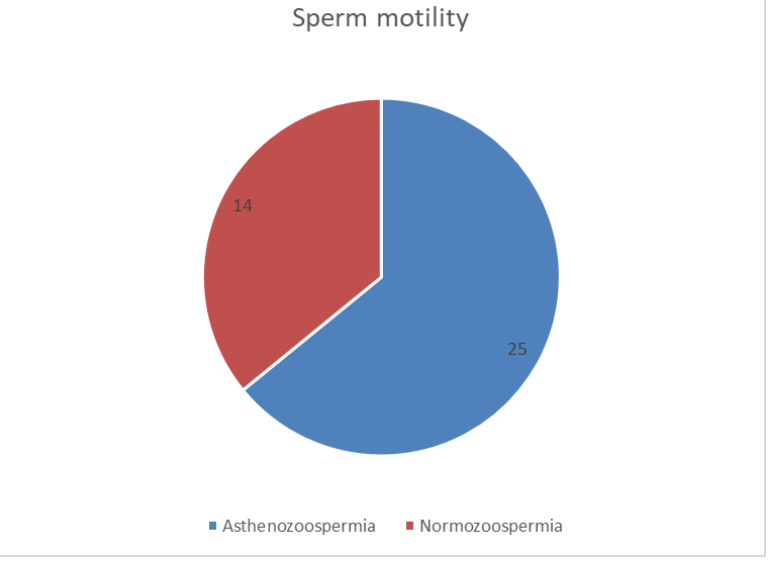
GRAPH NO. 1. Shows Age Wise Distribution of Infertile Patients

Shows that distribution of the infertile patients with different Sperm Motility age group.The present study includes infertile patients from the age group 20-40 years. Thepercent wise distribution of infertile patients with Asthenozoospermiawere 31.79%, 24.78%, from the age group 20-30, 30-40,<40respectively. Thepercent wise distribution of infertile patients with Normozoospermiawere 29.98%, 24.95%, from the age group 20-30, 30-40,<40respectively.



GRAPH NO. 2. Shows Sperm Motility Wise Distribution Of Infertile Patients

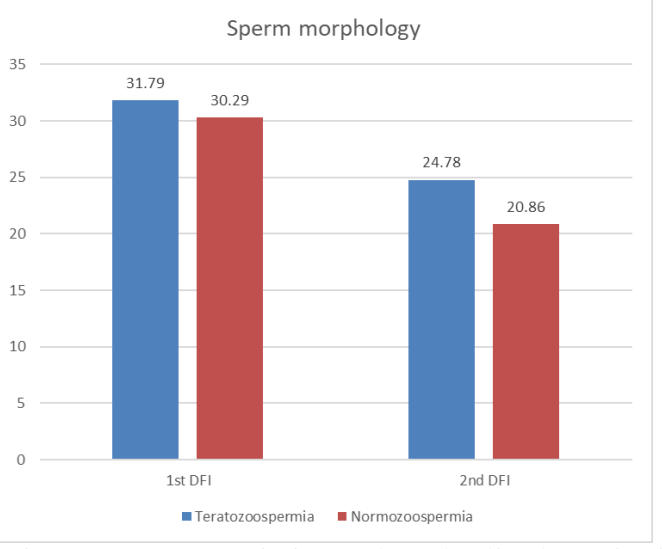
Result: p=0.061 which is found out to be significant



Conclusion: DFI values are found out to be decreased in both the groups.

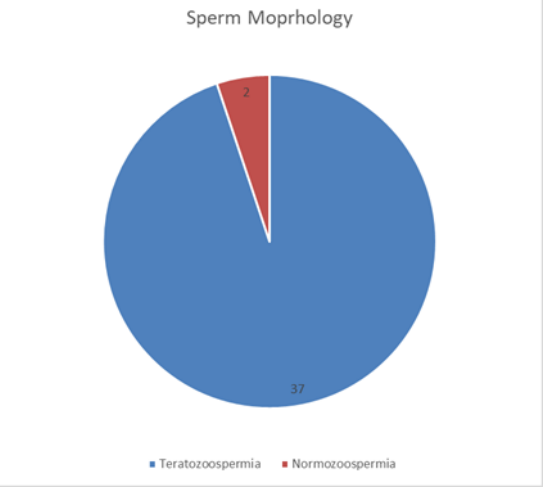
It shows distribution of the infertile patients with different Sperm Morphology age group.The present study includes infertile patients from the age group 20-40 years. Thepercent wise distribution of infertile patients with Teratozoospermiawere 31.79%, 24.78%, from the age group 20-30, 30-40,<40respectively. Thepercent wise distribution of infertile patients with

Normozoospermia were30.29%, 20.86%, from the age group 20-30, 30-40,<40respectively.



GRAPH NO. 3. Shows Sperm Morphology Wise Distribution Of Infertile Patients

Result: p=0.36 which is found out to be significant



Conclusion: DFI values found out to be decreased in both the groups.

This shows distribution of the infertile patients with different Sperm Count age group.The present study includes infertile patients from the age group 20-40 years. Thepercent wise distribution of infertile patients with Oligozoospermia were31.79%, 24.78%, from the age group 20-30, 30-40,<40respectively. Thepercent wise distribution of infertile patients with Normozoospermiawere 31.6%, 25.19%, from the age group 20-30, 30-40,<40respectively.

Conclusion

DNA fragmentation has been shown to be a robust indicator of fertility potential, more so than conventional semen parameters. Men with high levels of DNA fragmentation will have significantly lower odds of conceiving naturally or through procedures such as intrauterine insemination and IVF. Intracytoplasmic sperm injection (ICSI) may be much more successful in this group, and couples may be counselled to proceed directly to ICSI, avoiding costly procedures, recurrent failures or pregnancy losses. Oxidative stress is the major cause of DNA fragmentation in spermatozoa. Endogenous and exogenous factors that contribute to oxidative stress are discussed and in many cases are easily modifiable. Antioxidants play a protective role, although a delicate balance of reduction and oxidation is required for essential sperm function, including fertilization. Reducing oxidative stress may improve a couple's chances of conception either naturally or via assisted reproduction treatment. Sources of oxidative stress therefore should be thoroughly examined in men with high levels of DNA fragmentation and modified where possible.

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