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A Clinical Study on Oligozoospermia & its Management with a Unani Formulation

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ABSTRACT

Infertility represents an increasing medical problem affecting 15% of couples, and its treatment is stressful, invasive, and costly. The male factor accounts for almost 50% of infertility cases. Besides clearly defined causes of male infertility (genetic disorders, ductal obstruction, etc.), there are several possible causes where the exact mechanism of sperm dysfunction is not known yet. Infertility has emerged to become a very big problem today; couples remain stressed due to this.

With this preview a randomised, double blind, placebo controlled study was conducted on 60 eligible subjects fulfilling the inclusion criteria to evaluate the different aspects of oligozoospermia and to evaluate the safety and efficacy of Cap Oligo-s in the treatment of Idiopathic oligozoospermia. Cap Oligo-s is a compound Unani formulation having 13 distinct renowned Unani drugs and is indicated for the treatment of oligozoospermia. After informed consent Cap Oligo-s was given to test group in dosage of 2 cap (500mg each) in the morning and 2 cap in the evening with plain water. No extra specific diet was recommended during the therapy. Placebo which was prepared with millet flour filled in the capsule shells as identical to the test drug in all manner was administered orally in same dosage to placebo group. Blinding was achieved at the source where the drug was prepared by labeling two different codes. Assessment was done by volume of semen, sperm count and pH of semen. It was found that the test drug was found statistically extremely significant in increasing volume of semen ($p < 0.0001$), sperm count ($P > .0005$), and improving pH of semen ($P > .0005$) respectively.

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References: 19

Keywords: Oligozoospermia, infertility, Unani medicines.

INTRODUCTION

Oligozoospermia, also oligospermia, refers to semen with a low concentration of sperm and is a common finding in male infertility. According to WHO, 60-80 millions infertile couples are found worldwide. In India 10-15% of couples in the reproductive age group are estimated to be infertile. In those 25% cases are of male infertility'. Data accumulated over the past four decades reveals that in approximately 33% of all couples evaluated for

infertility, significant pathology is found only in male partners. In another 20% both male and female partners are found to be abnormal. Thus in approximately 50% of infertile couples, male factor is at least partly responsible for the failure to conceive¹.

In the classical Unani literature the semen deformities are mentioned under the caption "Qillat e mani and Riqqat e mani". the term Qillat means deficiency, Mani means Semen and Riqqat means

Fluidity^{34,35} According to ancient Unani Physicians including Hippocrates and Avicenna, semen is obtained as a result of Hazam e chaharrum. The words used in urdu translation of Avicenna's Canon of Medicine is "Mani Hazam e Udhwi se Peda hoi hai". The great Arab physician Razi state in kitab ul Murshid that Mani is one of the waste products in our body, excessive and restricted storage may cause harmful effects on body. Therefore optimal excretion is very needful for health of genitals and body.

According to Unani concepts, Hippocrates the Father of Medicine stated in the book of "Sadidi" and other authentic books by ancient physicians asbab of Qillat e Huwain e Manvia are excessive coitus, Masturbation, stress and strain, surrounding environment, malnutrition, excessive consumption of narcotics like opium, charas, brown sugar, Zof e Aam, Zof e Aza e Raisa, Isterkha e Qazaib wa Mulhiq Aaza, Zof e Balghami, cease on coitus, exposure or excessive sitting or bathing in highly cold or hot water, psycogenic effects & shyness³⁶.

Many oligospermic men are obsessed about their low sperm count and this seems to become the very important concern in their lives. We know that a low sperm count is not related to physique, general state of health, diet, sexual appetite or frequency. While not knowing the cause can be very frustrating, medicine still has a lot to study and understand about male infertility, which is a relatively neglected field today.

As the major cause of male infertility usually is a sperm problem. However, do remember that this is no reflection on your libido or sexual prowess. Sometimes men with testicular failure find this difficult to understand (but doctor, I have sex twice a day! How can my sperm count be zero?). The reason for this is that the testis has two compartments. One compartment, the seminiferous tubules, produces sperms. The other compartment, the "interstitium" or the tissue in between the tubules (where the Leydig cells are) produces the male sex hormone, testosterone, which causes the male sexual drive. Now while the tubules can be easily damaged, the Leydig cells are much more resistant to damage, and will continue functioning normally in most patients with testicular failure³⁷.

Keeping in view the above facts, an attempt has been made in this study to find out the effective, economical and easily available drug which should be free from side effects. The main objective of this study was to evaluate the different aspects of oligozoospermia and to evaluate the safety and efficacy of Cap Oligo-s in the treatment of idiopathic oligozoospermia.

MATERIALS & METHODS

A randomized, double blind, placebo controlled clinical trial conducted in the department of Moalijat, A & U Tibbia College & Hospital, Karol Bagh. Sixty males between the age group of 21-60 fulfilling the inclusion criteria and after written informed consent were randomly divided into test and placebo group by simple random technique. The duration of study was 90 days follow up was done every 30 days. The test group was given Oligo-S a compound Unani formulation manufactured by Dehvi Naturals. The Placebo was prepared with millet flour filled in the capsule shells as identical to the test drug in all manner and administered orally in the dose of 2 cap BD. Blinding was achieved at the source where the drug was prepared by labeling two different codes.

INCLUSION CRITERIA

- Oligospermic patients aged between 21-60 years.
- Sperm count with range of 5-19 million sperm/ml.
- Semen per ejaculate < 2.0 ml.
- Not currently receiving any other treatment.
- Patients willing to give written informed consent for participation in the study.

EXCLUSION CRITERIA

- Patients with obstructive pathology in the course of ejaculation where the surgical intervention is required.
- Known cases of genetic abnormalities excluded by careful family history.
- Patients associated with metabolic and/or systemic disorders like Diabetes, Hypertension, Tuberculosis, CRE, Hypothyroidism STDs and HIV.
- Patients diagnosed as Post traumatic Oligozoospermia, severe oligozoospermia,

azoospermia, necrozoospermia (necrozoospermia) and teratozoospermia (teratozoospermia).

- Patients with history of mumps, Chain Smokers and chronic Alcoholics.
- Hernia, Hydrocele, Varicocele, Testicular Atrophy, Undescended Testes excluded by clinical examination.
- Patients with Urinary Tract Infections and Enlarged Prostate were also excluded.

Collection of semen for Analysis

Abstinence: Before collection of the ejaculate minimum of 3 days and maximum of 5 days abstinence was followed. Masturbation method was taken as the preferred method for sample collection.

Grading of Sperm count

- a) Normal (20 million/ml or more) - 0
- b) Mild (>15 - <20 million/ml) - 1
- c) Moderate (>10 - <15 million/ml) - 2
- d) Severe (5 - <10 million/ml) - 3

The following examinations were performed for the exclusion of any concomitant acute and chronic diseases before the commencement of protocol therapy.

- Complete Blood Count, Blood Sugar Random, Mantoux Test, VDRL, HIV 1 & 2, S.TSH, LFT, KFT, Urine routine and microscopic examination.

PARAMETERS FOR ASSESSMENT OF SAFETY

The safety was assessed by monitoring adverse events either volunteered by the patients or elicited by the investigator by monitoring CBC, LFT, KFT at baseline, after one week and at the termination of the study.

These parameters indicate the renal and hepatotoxicity of the test substances with specificity and systemic toxicity in general.

CRITERIA FOR THE ASSESSMENT OF RESULT

Grading of Response in terms of increase in sperm count

Type of response	Increase in the sperm count over the initial count per cc
1. No response	Count unaltered
2. Slight improvement	3-4 million from original
3. Moderate improvement	5-6 million from original
4. Good response	10 million and more than original

CONCOMITANT MEDICATION

Other drugs must not be used concomitantly during the period of the study and the patients must not participate concurrently in any another study were ensured

ADVERSE EVENT

Adverse events were carefully sought during the entire study. Any sequel originating during the study period was duly followed up and recorded. Adverse event form is a part of the CRF.

STATISTICAL DATA ANALYSIS

The Data collected through study was statistically analyzed by using Paired T-test for Pre and Post study outcome in both groups.

OBSERVATION & RESULTS

A randomized, double blind, placebo controlled clinical trial conducted in the department of Moalijat, A & U Tibbia College & Hospital, Karol Bagh. Sixty males between the age group of 21-60 fulfilling the inclusion criteria and after written informed consent were randomly divided into test and placebo group by simple random technique. The main results of the study are as under:

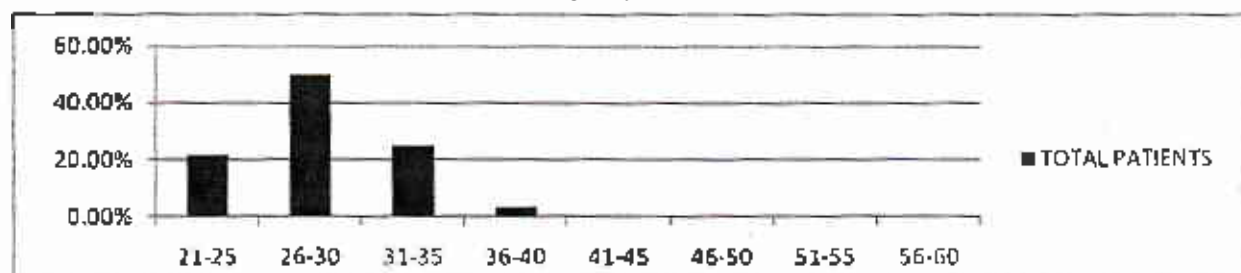
In Present Clinical Study the incidence of oligozoospermia was observed higher in the age group of 26-30 years(50%) followed by age group of 31-35(25%), 21-25(21.66), 36-40(3.33%) (Figure 1). Majority of the patients were Muslims (55%) followed by Hindus (45%). (Figure 2). Majority of the

patients were non-vegetarians (65%) (Figure 3). More than half of the patients were from Medium socioeconomic group (53.33%) (Figure 4). Seventy percent patients were from damvi and safravi group (Figure 5). Maximum number of Patients came with 1 to 4 years of illness (81.66%) followed by 5 to 8 years of illness (36.66%), and 9 to 12 years (1.66%) (Figure 6). Effect of trial drug on seminal volume was observed in both groups (test as well as placebo). The mean value of seminal volume in placebo group

at 0 day was 1.28 ± 0.37 , at 90 day after treatment was $1.520.53$. Mean percent change was 18.75% increase. After statistical analysis no significant improvement was observed in placebo group ($p > 0.05$). On the other hand mean value of seminal volume at baseline in test group was $1.220.38$, at 90 day after treatment was $3.41.23$. Mean percent change was 170.68% increase. After statistical analysis extremely significant improvement was observed in test group ($p < 0.0001$) (Table 1).

Fig. 1: Distribution of Patients according to age group

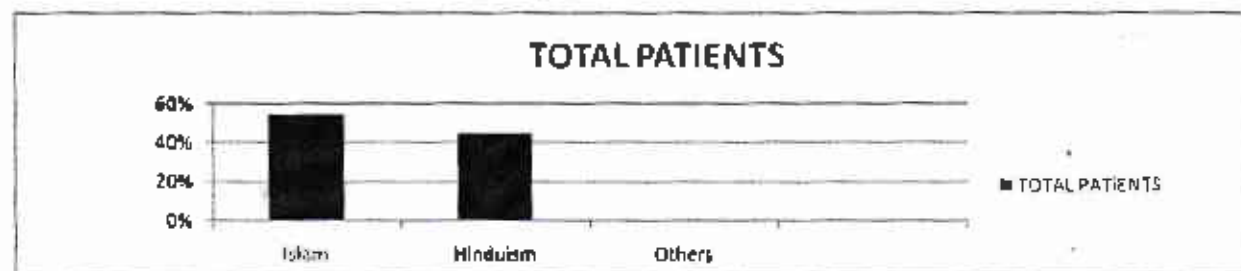
N=60



In Present Clinical Study the higher incidence of oligozoospermia was observed in the age group of 26-30 years (50%) followed by age group of 31-35 (25%), 21-25 (21.66%), 36-40 (3.33%).

Fig. 2: Distribution of Patients according to Religion.

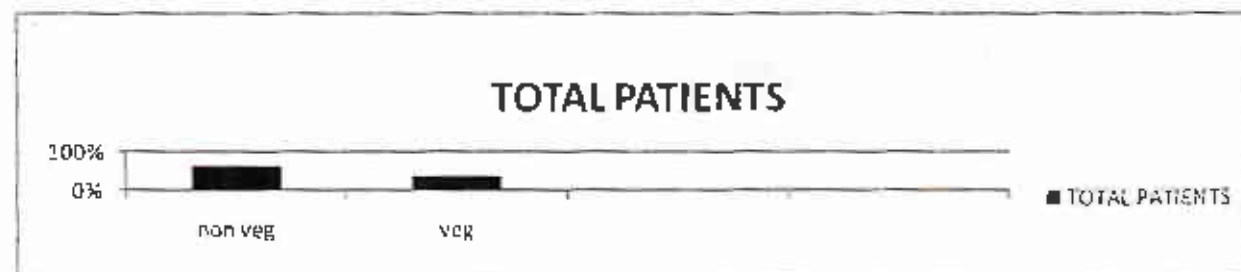
N=60



In present study more patients were from Islam group (55%) than Hinduism (45%).

Fig. 3: Distribution of Patients according to Dietary Pattern.

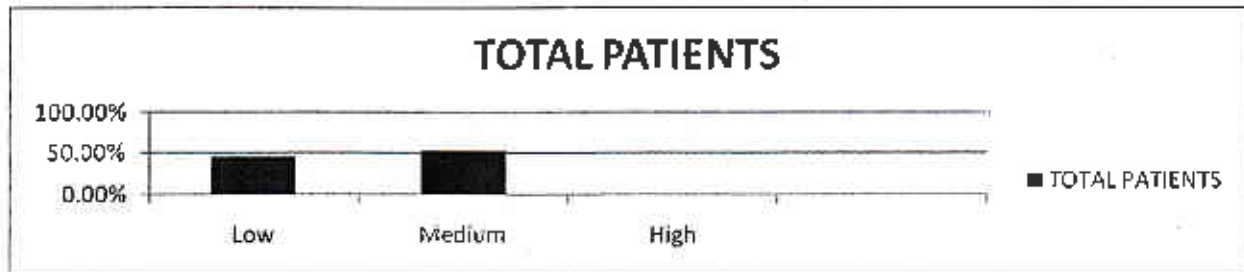
N=60



In present clinical study 65% patients were from non veg group and 35% Patients were from veg group.

Fig. 4: Distribution of patients according to socioeconomic status.

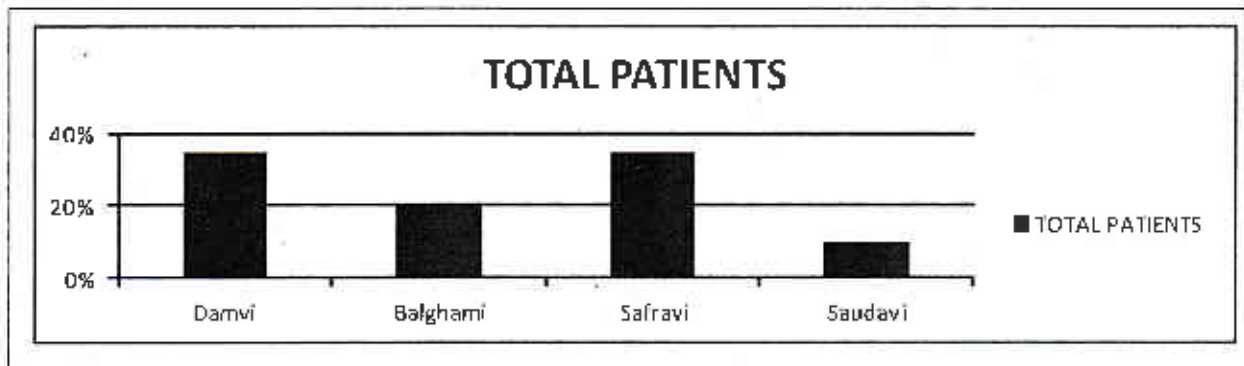
N=60



In present study higher incidence of patients were from Medium socioeconomic group (53.33%) followed by Low socioeconomic group (46.66%). There was no patient recruited from high socioeconomic group.

Fig. 5: Distribution of Patients according to Mizaj.

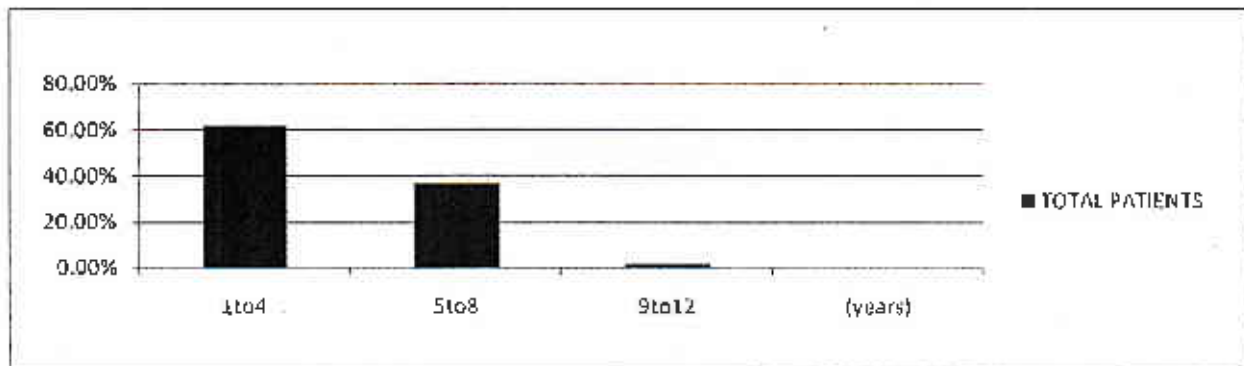
N=60



In present study there is higher incidence of Patients from Damvi and Safravi group (35% each) collectively we can say 70% patients were from damvi and safravi group. There were total of 20% patient from Balghami group, and out of total only 10% patients were from Saudavi group.

Fig. 6: Distribution of Patients according to Duration of illness.

N=60



In present study duration of illness ranged from 1 to 12 years. Maximum no of Patients came with 1 to 4 years of illness (61.66%) followed by 5 to 8 years of illness (36.66%), and 9 to 12 years (1.66%).

Effect of trial drug on seminal volume was observed in both groups (test as well as placebo). The mean value of sperm count in semen of placebo group at baseline (0 day) was 11.534.54, at 90th day after

treatment was 11.704.92. Mean percent change was 1.47% increase. After statistical analysis no significant improvement was observed in placebo group ($p > 0.05$). On the other hand mean value of

sperm count in semen of test group at baseline (0 day) was 10.633.82, and at 90th day (after treatment) was 31.215.33. Mean percent change was 193.50% increase. After statistical analysis extremely significant improvement was observed in test group ($p < 0.00000$) (Table 2).

On the other hand mean value of pH of semen in test group at 0 day (baseline) was 9.221.03, at 90th day after taking trial drug 8.550.85. Mean percent reduction was 7.26%. After statistical analysis very significant improvement was observed in test group

($p < 0.005$). The mean value of pH of semen in placebo group at 0 day (baseline) was 8.83 at 90th day after taking trial drug was 8.82. Mean percent change was 0.11% decrease. After statistical analysis no significant improvement was observed in placebo group ($p > 0.05$) (Table 3).

Assessment for safety parameters was done for test as well as placebo at 0, 6th and 90th day. All parameters of safety remained within normal limit (Table 4,5).

Table 1: Effect on Seminal Volume in Both Groups.

	Placebo group	Test group
Volume(in ml) at 0 DAY	1.28	1.22 0.38
Volume(in ml) at 90th DAY	1.52 0.53	3.4
% Change	18.75% increase	170.68% increase
T value	-1.959619	-8.750001
P value	0.059	0.000
Statistical Result	Not significant	Extremely Significant

Table 2: Effect On Sperm Count In Both Groups.

	Placebo group	Test group
Volume(in ml) at 0 DAY	1.28	1.22 0.38
Sperm count(mill/ml) at 0 DAY	11.53	10.63
Sperm count(mill/ml) at 90th DAY	11.7	31.2
%Change	1.47% increase	193.50% increase
T value	-0.299084	-8.049587
P value	0.767009	0.00000
Statistical Result	Not significant	Extremely Significant

Table 3: Effect on Ph of Semen in Both Groups.

	Placebo group	Test group
pH at 0 DAY	8.83	9.22
pH at 90th DAY	8.82	8.55
% Change	0.11% decrease	7.26% decrease
T value	0.043753	2.944880
P value	0.965401	0.006
Statistical Result	Not significant	Very Significant

Table 4: Table Safety Profile Test Group.

	0 Day	8th Day	90th Day
Hb	14.2	14.1	14.2
TLC	6440	7223	7090
DLC			
POLY	60.93	62.9	62.9
LYMPH	3.7	32.1	31.8
MONO	1.8	1.63	1.9
EOSINO	72.4	3	3.07
BASO	0.9	0.9	0.8
ESR	12	10	7.7
S. Bilirubin	0.7	0.7	0.7
S.G.O.T	25	26	25
S. G.P.T	28	27	25
S. Alk.Phos	176	179	170
S. Urea	28	27	27
S. Creatinine	0.8	0.8	0.8

Table 5: Table Safety Profile Test Group.

0 Day	8th Day	90th Day	
Hb 13.9	14.1	13.9	
TLC	6597	7123	6503
DLC			
POLY	62.3	63.76	65.13
LYM	34.2	32.5	29.8
MONO	32.1	2	2.2
EOS	61.0	2.7	2.86
BASO	60.6	0.76	0.63
ESR	12.26	11.5	9.7
S. Bilirubin	0.7	0.69	0.73
S.G.O.T	24.6	25.8	27.43
S.G.P.T	28.23	26.16	29.03
S. Alk. Phos	168.26	160.5	170.4
S. urea	28.4	25.0	26.6
S. Creatinine	0.96	0.64	0.80

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