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Clinical Research

Clinical study of *Tribulus terrestris* Linn. in Oligozoospermia: A double blind study

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Abstract

Infertility is a problem of global proportions, affecting on an average 8-12% of couples worldwide. Low sperm count (Oligozoospermia) is one of the main causes of male infertility and it is correlated with *Kshina Shukra*. The fruits of *Gokshura (Tribulus terrestris)* Linn are considered to act as a diuretic and aphrodisiac; they used for urolithiasis, sexual dysfunctions, and infertility. Hence, it was planned to study the effect of *Gokshura* in the management of *Kshina Shukra* (Oligozoospermia), and to evade the preconception, a double-blind, randomized, placebo-controlled study was designed. In this study, eligible subjects between the age of 21 and 50 years, with a complaint of *Kshina Shukra* (Oligozoospermia), were randomized to receive either *Gokshura* granules or placebo granules for 60 days. The primary outcome measures were percentage changes in the *Pratyatmaka Lakshanas* (cardinal symptoms) of *Kshina Shukra*, *Agni bala*, *Deha bala*, *Satva bala*, the semenogram, and in the Quality of the Sexual Health Questionnaire. The placebo granules showed 70.95% improvement, whereas, the *Gokshura* granules showed 78.11% improvement in *Rogi bala (Agni bala, Deha bala, Satva Bala, and the Quality of Sexual Health)* and *Rogabala (Semen Analysis and Pratyatmaka Lakshanas)*. The *Gokshura* granules have shown superior results in the management of *Kshina Shukra*, as compared to the placebo granules.

Key words: *Gokshura, Kshina Shukra, Oligozoospermia, Tribulus terrestris*

Introduction

Infertility is a problem of global proportions, affecting on an average 8-12% of couples worldwide.^[1] Based on the National Women's Health Information Center (NWHIC), the annual incidence of male infertility is at least two million cases. Recent studies have indicated that the prevalence of Oligozoospermia is extremely high in the metropolis as well as in the smaller towns of India.^[2]

Infertility is defined as the inability to achieve pregnancy after one year of unprotected coitus.^[3] Male infertility is considerably to be less complicated than female infertility, but can account for 30-40% of infertility.^[4] Except for some physical defects, low sperm count (Oligozoospermia) and poor sperm quality are responsible for male infertility in more than 90% of the cases. Out of these, in about 30 to 40% the cause is unexplained, and

in the rest of the cases critical illness, malnutrition, genetic abnormalities, pollution, side effects of some medicines, hormones, and chemicals play a major role.^[5]

More than 190 studies on *Vajikarana* (Aphrodisiac therapy)^[6] have been carried out in various Ayurvedic Academic Institutes in India, at the PG and PhD level, wherein, researchers have considered various aspects of the problem, like its etiology, pathogenesis, and complications of the diseases related to the reproductive system, in both Ayurvedic and Modern parlance. Out of 190 studies more than 50 studies have been carried out on Oligozoospermia. The term Oligozoospermia is correlated in the research studies with *Kshina Shukra* (23 studies); *Alpa Shukra* (1 study); *Shukra Dosh*a (3 studies); *Shukra Dushti* (13 studies); *Shukra Kshaya* (11 studies); *Shukralpata* (3 studies); *Kshina Retas* (1 study); *Bijopaghata* (1 study), and *Shukradhatu Vikara* (3 studies). Acharya Susruta has included *Kshina Shukra* under *Shukra Dushti*. Here, *Vata dosha* along with *Pitta* undergo vitiation and create a disturbance in the normal qualities and quantity of the *Shukra Dhatu*.^[7] Oligozoospermia is a seminal disorder in which the sperm count is below 20 million/ml.^[8]

However, it is evident that several studies were conducted

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on this subject, but only few studies have been carried out to recognize the clinical efficacy of single herbs, in this subject. *Gokshura* (*Tribulus terrestris*) is mentioned as a *Vrishya* (Aphrodisiac)^[9] and also used in almost all prescriptions, along with other drugs, to treat the malady *Kshina Shukra*. Studies have suggested that *Gokshura* can enhance the hormone levels to within a normal range. It can increase the testosterone by increasing the luteinizing hormone and the gonadotropin-releasing hormone.^[10] This hormone is effective in building muscles as well as improving fertility and libido, and it has also been proved to be active in stimulating spermatogenesis and sertoli cell activity in rats.^[11] However, to generate an evidence based on this, this clinical study has been carried out on *Gokshura* for the role of *Vrishya* (Aphrodisiac).^[12]

Aim of Study

The aim of this study is to find out the effect of *Gokshura* in the management of *Kshina Shukra* (Oligozoospermia).

Hypothesis

Gokshura is not effective in the management of *Kshina Shukra* as a Null Hypothesis. However, it is effective in the management of *Kshina Shukra* as an Alternate Hypothesis.

Materials and Methods

The methodology used for this study is explained as per the Consolidated Standards of Reporting Trials (CONSORT) Statement, 2010.^[13]

A total of 72 patients with *Kshina Shukra* were selected from the Outpatient Department of the Institute for Postgraduate Teaching and Research Hospital, Gujarat Ayurved University, Jamnagar. The patients were divided into two groups, by following the Computer-Generated Randomization Plan. Out of them, 63 patients completed the treatment and they were divided into two groups — Group A – 31 patients and Group B – 32 patients — taking into consideration the inclusion and exclusion criteria.

Inclusion criteria

- Age group between 21 to 50 years
- Sperm count < 20 million/ml
- Patients presenting with *Pratyatmaka Lakshana* (Cardinal Symptoms) of *Kshina Shukra*, with semen samples suggestive of Oligozoospermia, were selected.

Exclusion criteria

- Age below 21 or above 50 years
- Sperm count > 20 million/ml
- Patients with azoospermia and aspermia
- Genetic defects like Klinefelter's syndrome
- Patients with diseases like varicocele, accessory sex gland infection, sexually transmitted diseases, systemic diseases like diabetes mellitus (DM), and so on, were excluded from this study.

Laboratory investigations

Routine hematological, biochemical, and urine examination, semen analysis, and Serum follicle-stimulating hormone (FSH), Serum luteinizing hormone (LH), and Serum Testosterone were carried out before and after the treatment, and a semenogram was carried out before treatment, on the thirtieth, sixtieth, and ninetieth, days of the study.

Ethical clearance

Ethical clearance was obtained from the Institutional Ethics Committee of IPGT and RA Jamnagar; Vide Ref-PGT/7/Ethics/2009–2010/3494/15 Dated: 8 February, 2010, before starting the study, and this study was registered in the Clinical Trial Registry of India, vide CTRI/2011/07/001907.^[14]

Blinding

The prepared drugs were blinded and labeled as Group A and Group B by the Department of *Rasa Shastra* as the study was designed as a Double-blind Randomized Placebo-controlled study.

Method of allocation concealment

Both drugs in granule form were given, 6 g twice daily, before food, in the morning and night, with warm water, for 60 days.

Before dispensing the medicine, *Koshtha Shuddhi* (bowel cleansing therapy) was carried out with 20 ml of *Eranda Taila* (oil of *Ricinus communis*), in both the groups. After *Koshtha Shuddhi* (bowel cleansing therapy), a light diet was advised on the same day. The following day onwards the patients were given medicine and also allowed to take a normal diet.

Follow-up

The patients were advised to visit the hospital every fortnight during the treatment and for one month after the treatment for follow-up.

Criteria for assessment

The improvement in the patients was assessed mainly on the basis of relief in the signs and symptoms of *Kshina Shukra* (Oligozoospermia), improvement in the semenogram, especially in the total sperm count, and also in the serum FSH, LH, and testosterone level, improvement in *Deha Bala*, *Chetasa Bala* and *Agni Bala*, and improvement in the Quality of Sexual Life Questionnaire.^[15]

Arbitration of criteria considered for assessment in the interpretation of results was as follows;

- *Roga Bala*: 70% – Semen Analysis – 50%; *Lakshanas* – 20%
- *Rogi Bala*: 30% – *Agni Bala* – 5%; *Deha Bala* – 5%; *Chetsa Bala* – 5%; Sexual Quality of Life (QoL) – 15%

A. *Roga Bala*: *Roga Bala* was used to assess the signs and symptoms of *Kshina Shukra*. The details of the scoring pattern adopted for the assessment of the clinical signs and symptoms are given in Table 1.

B. *Rogi bala*: *Rogi bala*, was assessed for any improvement in the Sexual QoL and in the symptoms of *Agni Bala*, *Deha Bala*, as well as *Chetasa Bala*, and the scoring patterns adopted are given in Table 2.

Statistical analysis

The data generated in the clinical study was analyzed by applying

Table 1: Scoring pattern of Roga Bala

Roga bala	Grade	Score
<i>Aharshanam</i> (Lack of Sexual Desire)	No desire at all	0
	Lack of Desire	1
	Desire only in demand of partner	2
	Self and partner normal desire	3
	Excess desire	4
<i>Dhvajanucchraya</i> (Lack of Penile Erection)	No erection or swelling without any methods	0
	Erection with artificial method	1
	Very slight swelling, but unable to penetrate	2
	Some swelling, able to penetrate	3
	Erection with occasional failure	4
<i>Linga Shaitilya</i> (Lack of Penile Rigidity)	Full swelling whenever there is desire	5
	No rigidity at all	0
	Some stiffness, but unable to penetrate	1
	Loss of stiffness, can penetrate, but unable to maintain till the end	2
	Some loss of stiffness, able to maintain till the end	3
<i>Kshipram Munchatti</i> (Premature ejaculation)	Fully rigid to maintain erection to continue the sexual intercourse till last	4
	On mere thoughts/slight or not at all	0
	During foreplay	1
	Before penetration	2
	During sexual intercourse<30 seconds with at least 1-5 pelvic thrusts	3
<i>Apraharsha</i> (Lack of orgasm)	During sexual intercourse<60 seconds with at least 5-10 pelvic thrusts	4
	During sexual intercourse>60 seconds with at least>10 pelvic thrusts	5
	No orgasm at all	0
	Lack of enjoyment in most of the occasions	1
	Enjoyment in 25% intercourse by ejaculation inside the vagina	2
Performance anxiety	Enjoyment in 50% intercourse by ejaculation inside the vagina	3
	Enjoyment in 75% intercourse by ejaculation inside the vagina	4
	Enjoyment in every intercourse by ejaculation inside the vagina	5
	Anxiety that hampers in almost all the encounters	0
	Anxiety that hampers 75% of the encounters	1
<i>Maithunottara Shrama</i> (Post act exhaustion)	Anxiety that hampers 50% of the encounters	2
	Anxiety that hamper in 25% of the encounters	3
	Slight anxiety, does not hamper sexual act	4
	No anxiety at all	5
	After every sexual act	0
<i>Maithunaavrutti</i> (Frequency of coitus)	In 75% of the encounters	1
	In 50% of the encounters	2
	In 25% of the encounters	3
	Slight exhaustion occasionally	4
	No exhaustion at all	5
	0/week	0
	1-2/week	1
	3-4/week	2
	>4/week	3

Table 2: Scoring pattern of Rogi Bala

	Grade	Score
Agni Bala		
<i>Abhyavaharana Shakti</i> (Improvement in Hunger)	Having food in good quantity twice/thrice	1
	Having food in normal quantity twice a day	2
	Having food in moderate quantity twice a day	3
	Having food in less quantity twice a day	4
	Having food in less quantity once in a day	5
	Not having food at all	6
<i>Jarana Shakti</i> (Improvement in digestion process)	Presence of five symptoms	1
	Presence of any four symptoms	2
	Presence of any three symptoms	3
	Presence of any two symptoms	4
	Presence of one symptom	5
	Absence of any symptom	6
<i>Ruchi Aharakale</i> (Taste and appetite)	Equally willing to have all the <i>Bhojya Padartha</i>	1
	Willing to have some specific <i>Ahara/Rasa Vishesha</i>	2
	Willing to have only one among <i>Katu/Amla/Madhura</i> foodstuffs	3
	Willing to have only foods most liked and not others	4
	Unwilling to have food, but can take the meal	5
	Totally unwilling to have meals	6
<i>Vata Mutra Purisha Retasam Mukti</i> (Proper excretion of flatus, urine, feces and semen)	Occurs easily during the normal routine	1
	Difficulty in defecation, but daily, with discomfort in abdomen	2
	Cannot pass stool daily and feeling heaviness in abdomen	3
	Passes stool after 2-3 days, having gaseous distention	4
	Passes stool after 3-4 days with <i>Grathitha, Sakashta Malapravritti</i> , and having gaseous distention with <i>Udgarapravritti</i>	5
Deha Bala		
<i>Balavridhhi</i> (Increase in body strength)	No weakness	1
	Slight weakness	2
	Feeling weakness but ability to work unaffected	3
	Ability to work affected	4
	Cannot do any type of work	5
<i>Svara Varna Yoga</i> (Texture luster and voice)	Patient looks cheerful	1
	Lethargic and tired	2
	Looks gloomy	3
<i>Sharira Upachaya</i> (Increase in body weight)	Increase in weight by more than 2 kg	1
	Increase in weight by 2 kg	2
	No change	3
Satva/Chetasa Bala		
<i>Nidra labho yathakalam</i> (Sleep in proper time)	Sound sleep	1
	Sleep gets disturbed in early morning	2
	Sleeps with disturbed intervals and remains unsatisfied	3
	Disturbed sleep at night and tries to compensate during the day	4
	No sleep in the day or night	5
<i>Sukhena cha pratibodhanam</i> (Feeling of well-being)	Total relief and feeling of well-being at the physical and mental level	1
	Improved in physical comfort level	2
	Improved in physical and mental level	3
	Not feeling well and not interested in any work	4
<i>Vaikarikanam cha swapnanam adarshanam</i> (No pathological dreams)	Absent	1
	Occasionally	2
	Daily	3
<i>Mano Buddhi Indriya Avyapatti</i> (Proper and unaltered functioning of mind, intellect, and sensories)	Enthusiastic, vigorous, having concentration and interest in routine work	1
	Less enthusiastic and not concentrating but interested in routine work	2
	Less enthusiastic and not interested in routine work	3
	Loss of enthusiasm, concentration and vigor	4

the student's 't' test^[16] in the subjective and objective criteria of a single group, and to compare the effect of the therapy on the two groups. The obtained results were interpreted as:

- Not significant (NS) : $P > 0.05$
- Significant (S) : $P < 0.05$ or $P < 0.01$
- Highly significant (HS) : $P \leq 0.001$

Observations

The following flowchart depicts the figures of the clinical study. One hundred and fifty-two patients were screened during this study. Among them 80 patients were excluded, as they did not fulfill the eligibility criteria. Seventy-two patients fulfilling the eligibility criteria were randomly allocated by, using the Computerized Randomization Plan, into two groups, Group A with 37 patients and Group B with 35 patients, and were given intervention.

In Group A, out of 37 patients, six discontinued and in Group B, three patients discontinued out of 35; due to various reasons. Finally, the statistical analysis was completed on 63 patients, of which 31 patients belonged to Group A and 32 patients belonged to Group B.

In this study, the maximum number of patients belonged to the 21-30 years age group (46.25%), belonging to the Hindu religion (93.05%). They belonged to the lower middle class (45.83%), had primary level education (27.7%), were laborers (43.06%), and were exposed to occupational heat (59.72%). The maximum number of patients had *Mandagni* (43.05%) and *Kapha Vata Prakruti* (54.17%). All the patients of this study were found with a well-developed secondary character and they had a good relationship with their respective partners (94.44%).

The maximum number of patients were habituated to tobacco (58.33%) and most of the patients wore cotton undergarments (80.77%), tight underwear (67.31%), had a habit of warm water bath (37.5%), were mentally depressed (30.56%), were unaware of the fertility period (38.89%); and practiced *Vegadharana* (Suppression of urges) (83.33%).

It was observed that the maximum number of patients had primary infertility (66.67%) with severe oligozoospermic conditions (26.39%) for one to three years of chronicity (43.75%). With respect to symptoms of *Kshina Shukra* reported by the patients, they were *Daurbalya* (weakness), 52.78% *Mukha Soshha* (Dryness of Mouth), 47.22% *Linga Shaithilya* (Loss of Penile rigidity), and 45.83% *Klaibya* (Erectile dysfunction).

Results

Effect of therapy on symptoms

Group A: The granules provided a highly and statistically significant ($P < 0.001$) result in the case of *Daurbalya* (weakness) (48.14%), and significant ($P < 0.05$) results in cases of loss of penile erection (6.03%), loss of penile rigidity (9.41%), premature ejaculation (6.12%), lack of orgasm (9.76%), and performance anxiety (8.69%). The results were insignificant ($P > 0.05$) in the case of post-act exhaustion (1.33%), frequency of coitus (2.08%), *Mukha soshha* (dryness of mouth) (6.66%), and depression (22.22%). However, Group B granules provided a highly and statistically

significant ($P < 0.001$) result in *Daurbalya* (weakness) (78.26%), loss of penile erection (9.44%), loss of penile rigidity (17.02%), premature ejaculation (10.68%), lack of orgasm (13.54%), and post-act exhaustion (13.33%). Significant ($P < 0.05$) results were observed in frequency of coitus (18.36%) and performance anxiety (10.81%) and insignificant ($P > 0.05$) results in *Mukha soshha* (Dryness of mouth) (18.75%) and depression (15.38%).

Effect of therapy in Agni bala, Deha bala, and Satva bala

Group A granules provided a highly statistically significant ($P < 0.001$) result giving *Abhyavaharana Shakti* (20.45%), *Jarana Shakti* (21.92%), *Ruchi Hi Aharakale* (12.05%), *Balavridhhi* (15.38%), *Svaravarna Yōga* (19.18%), a significant ($P < 0.05$) result in *Sukhena Cha Pratibodhanam* (8.57%), and *Mano Buddhi Indriya Avyapatti* (8.82%); and an insignificant ($P > 0.05$) result in *Vata Mutra Purisha Retasam Mukti* (7.5%), *Sharira Upachaya* (1.09%), and *Nidra Labho yathakalam* (5.56%). However, Group B Granules provided a highly statistically ($P < 0.001$) significant result giving *Abhyavaharana Shakti* (32.29%), *Jarana Shakti* (20.51%), *Ruchi Hi Aharakale* (19.04%), *Balavridhhi* (25.67%), *Svaravarna Yōga* (22.53%), a significant ($P < 0.05$) result in *Vata Mutra Purisha Retasam Mukti* (13.63%), *Sukhena cha Pratibodhanam* (7.57%), and *Mano Buddhi Indriya Avyapatti* (8.82%); and an insignificant ($P > 0.05$) result in *Sharira Upachaya* (1.11%) and *Nidra Labho Yathakalam* (7.84%).

Effect of therapy in hematological and biochemical parameters

There were no statistically significant changes ($P > 0.05$) in all hematological parameters like Hemoglobin, total red blood cell (RBC) count, total leukocyte count, and in the differential count in both the granules, as well as, in the biochemical parameters like fasting blood sugar (FBS), S. Cholesterol, S. Triglycerides, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), Total Protein, and so on. However, there was a change from the pre-test to post-test mean values of the above parameters, which was within the physiological limits. There was a statistically insignificant difference found in all of these parameters ($P > 0.05$). The difference found between the two groups was statistically insignificant. This proves that there was no adverse effect of the treatment.

Effect of therapy in hormones

S. Testosterone and S. FSH had decreased from 555.613 to 530.457 (4.53%↓), and 8.401 to 6.937 (17.42%↓), respectively, and S. LH had increased from 5.554 to 6.314 (13.7%↑) after treatment, in the Group A granules. However, the Group B granules had increased S. Testosterone from 515.69 to 599.81 (16.3%↑) and decreased S. FSH and S.LH from 10.812 to 6.998 (35.3%↓) and 6.673 to 4.444 (33.4%↓), respectively. There was a statistically insignificant difference found in all of these parameters ($P > 0.05$). On comparing the two groups on the effect of therapy on the hormones, it showed that it was statistically insignificant ($P > 0.05$) [Figure 1].

Effect of therapy in seminal parameter

The percentage of relief in Seminal Parameters like Sperm total

count was 104.2%, and 25.42% in abnormal forms. Although Motility, RLP (Rapid Linear progressive), SLP (Slow Linear progressive), and NP (Non-progressive) had decreased, they were 12.05, 14.83, 16.55, and 18.45%, respectively. When subjected to statistical analysis, The total sperm count was found to be statistically significant, that is, $P < 0.01$. The remaining parameters were statistically insignificant in the Group A granules, whereas, in the Group B granules, percentage of relief in Seminal Parameters like Liquefaction time, volume, sperm total count, motility, RLP, SLP, NP, and abnormal forms was 3.32, 12.9, 86.31, 7.89, 20.1, 3.33, 7.53, and 12.25%, respectively. After subjecting the data to statistical analysis, the total sperm count and abnormal forms were found to be statistically highly significant ($P \leq 0.001$). RLP was observed to be statistically significant, that is, $P < 0.05$ [Figure 2].

In both groups, the total sperm count was recorded before treatment, at the end of the first, second, and third month, it was analyzed by the Kruskal-Wallis One Way Analysis of Variance on the Ranks test and it was observed that there was a statistically significant difference in both the groups, i.e. ($P < 0.01$). Even though, both the drugs increased the total sperm count on comparing the effect of therapy between the two groups, there was no statistically significant difference found ($P > 0.05$).

Effect of therapy on quality of sexual health

Group A granules provided 27.80% improvement and in Group B granules, 49.38% improvement was observed, which was highly significant ($P \leq 0.001$). On comparing, there was a statistically significant difference found ($P < 0.05$) between both groups in the domain of sexual life, psychosexual, and Global index [Figure 3].

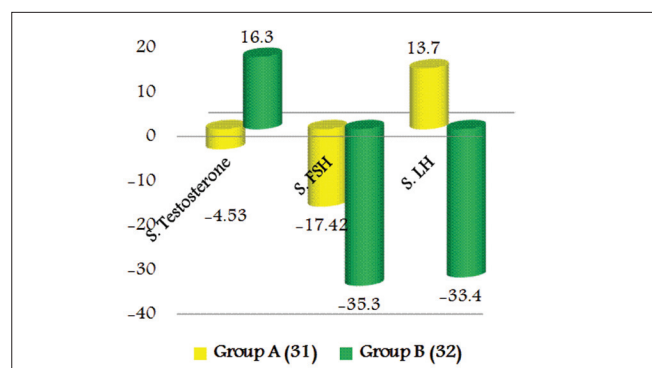


Figure 1: Effect of therapy on hormone

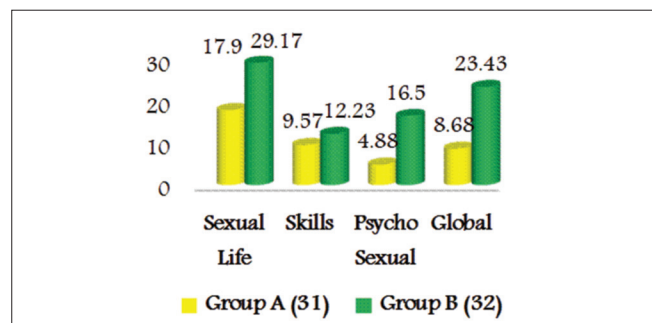


Figure 3: Effect of therapy on quality of sexual life

Overall effect of the therapy

Group A granules, showed 70.95% improvement and Group B Granules showed 78.11% improvement in *Rogi bala* (*Agni bala*, *Deha bala*, *Satva Bala*, and Sexual QoL) and *Rogabala* (Semen Analysis and *Lakshanas*). One patient having Group A granules and two patients having Group B granules were able to impregnate their partners in the second month of treatment [Figure 4].

Discussion

The etiological factors classified under various headings such as chromosomal anomalies (*Bijadosha*) have been postulated to be one of the principal genetic factors in male infertility. These disorders occur due to the vitiation of the *Bijabhaga* of parents, which is responsible for the formation of *Bija* in the fetus.^[17] Several somatic chromosomal abnormalities are associated with male infertility. A specific defect in the male sex (Y) chromosome can cause the common form of male infertility, that is, oligozoospermia.^[18] Certain genetic disorders that cause oligozoospermia are Klinefelter's Syndrome, Kallmann's syndrome, Reifenstein's Syndrome, Testicular Malposition (Cryptorchidism), and so on.

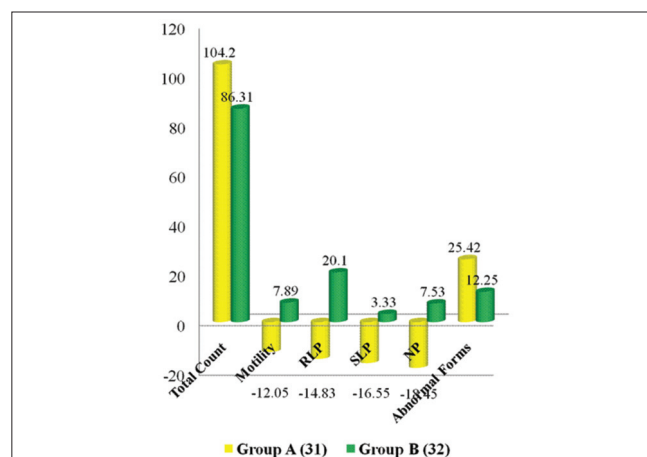


Figure 2: Effect of therapy on seminal parameters

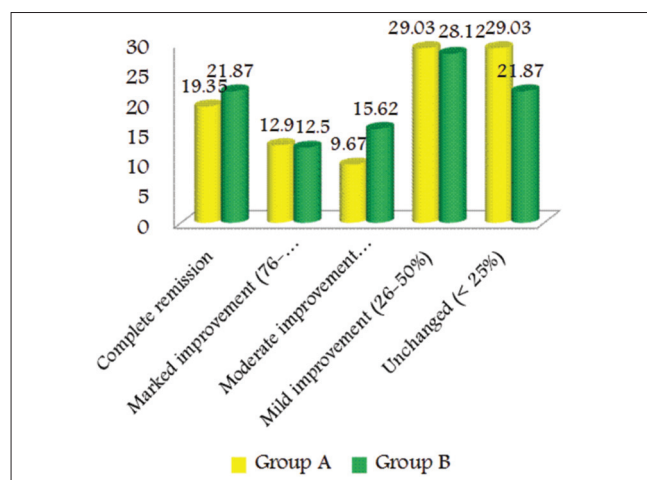


Figure 4: Overall effect of therapy

Dietetic factors are described as *Shukravaha Srotodushtikara Nidanas*, particularly *Anasana* (Fasting),^[19] *Alpa-Pramitaasana* (Inadequate diet),^[20] and *Visamaasana* (Irregular diet),^[21] which can impede the *agni* and may produce *Shukradushti*, which ultimately leads to impaired fertility. Deprived sustenance may alter the metabolism, which may result in *dhatu kshaya*. *Shukra* is the essence of all the former *dhatu*s. Thus, any disturbances in the digestive process may lead to defective formation of *Shukra*, that is, *Majjakshaya* leads to *Alpa Shukra*.^[22] Very low caloric or protein deficiency causes hypogonadism and decreases the function of the Leydig cell and further leads to infertility.^[23] *Kshara* (Alkali), *lavana* (Salt), and *Amla* (Sour)^[24] may cover the drugs of chemicals/pesticides described in modern medicine. The factors can be listed as *Khavaigunyakara* for *Shukravaha srotas*.

Viharaja Nidanas like excessive coitus (*Ati maithuna*), untimely coitus (*Akala maithuna*), coitus in other than vagina (*Ayuvana maithuna*), abstinence, intercourse with unaroused partner, coitus in old age (*Jaraya Gamana*), excessive exercise (*Ati Vyayama*), excessive exposure to heat (*Ati-Ushna sevana*),^[25] and suppression of ejaculation (*Shukravega Nigrahaha*) are said to be responsible for the *Shukravaha sroto dushti*, which leads to *Kshina Shukra*.

The psychological causative factors are *Chinta* (worry), *Bhaya* (fear),^[20] *Krodha* (anger), *Shoka* (depression), and so on, and unhealthy sexual/coital practices. Iatrogenic causative factors include improper *Kshara* (Alkali),^[26] *Agni* (cauterization), and *Sastra Karma* (surgical procedures), anti-psychotic drugs such as^[27] Cyproterone, Ketoconazole, and the like, disease-Induced factors include — diseases such as Hemorrhoids, Varicocele and so on, and other factors like smoking^[28] and caffeine are also known causative factors of oligozoospermia.

The pathogenesis of *Kshina Shukra* is not mentioned in the classics, but it is stated that the vitiation of *Vata* and *Pitta Dosha*, is responsible for the manifestation of *Shukrakshaya*.^[29] *Mithyahara Vihara Sevana* leads to *Agnimandya* as well as *Amotpatti*, hence, leading to an improper formation of *Ahara Rasa*; which further leads to *Rasa Kshaya* due to the fault of *Jatharagni*, resulting in the depletion of the successive *Dhatu*s and ending in *Shukrakshaya*. It has been said that the etiological factor affecting the *Dhatu* may also disturb the *Doshas*. This may also happen vice-versa. The *Nidanas* lead to *Doshadushti*, *Khavaigunya*, *Dushya-daurbalya*, and *Dhatvagnimandya*. This may happen simultaneously or gradually. In this case of *Kshina shukra*, the provocation of *Vata* and *Pitta* damages the *Shukradhatu* also, causing *Shukradhatu Daurbalya* and *Shukravaha Srotodushti*.

Acharya Sushruta has indicated that *Lakshanas* of *Shukrakshaya* should be considered as that of *Kshina Shukra*.^[7] It must also be noted that *Dalhana* has described *Kshina Shukra* as *Swa-Maanat Alpihuta Shukra*, which means the *Shukra* is of sub-normal parameters and this may be in terms of *Dravyataha* (by substance), *Gunataha* (by property), or *Karmataha* (by action). Hence, it is clear that many other symptoms of *Shukrakshaya* or *Kshina Shukra* may not be available in the patients, due to the selective *Kshaya* of sperm count. Hence, it is clear that except for a decrease in sperm count; the symptoms of *Kshina Shukra* may not be well-appreciated in patients. The sperms are nowhere related to the sexual and physical parameters.

Nidana Parivarjana (cessation of causative factors)^[30] and *Panchakarma*^[31] are recommended for treating the malady *Kshina Shukra*, before administering the *Vajikarana* therapy. The main line of treatment in *Kshina Shukra* has been suggested to be '*Kshine Shukrakari Kriya*,^[32] and *Upachaya*^[33] is the primary line of treatment. It can also be managed by a line of treatment advocated for *Shukravaha Srotodushti* and *Dushtashukra Rogas*. *Doshapratyanika Chikitsa* can be adopted, that is, *Vataja* and *Pittaja Shukradushti* for the better management of *Kshina Shukra*. The drugs that have *Madhura Rasa* (Sweet), *Snigdha*, *Guru Guna* (unctuous and heavy quality), *Jivana* (promotes quality of life), and *Brimhana* (nourishing property) are highly recommended for the management of *Kshina Shukra*.

Opening of the blinding

The Blinding Committee of the Department, in the presence of Scholar and guide, opened the sealed cover containing the information on blinding after the statistical analysis of the collected data was completed. On unmasking it, it was found that Group A consisted of Placebo granules and Group B had *Gokshura Granules*.

Probable mode of action of *Gokshura* granules

Gokshura has *Madhura rasa* (sweet), *Guru* and *Snigdha guna* (unctuous and heavy quality), *Sheeta Virya* (Cold in Potency), *Vrishya* (Aphrodisiac), *Rasayana* (Rejuvenator), *Brimhana* (Nourishing therapy), and *Vatapittahara* properties.^[34] *Vatapittahara Karma* does the *Samprapti Vighatana* in the *Kshina Shukra*, as it is a *Vata*- and *Pitta*-predominant disease. However, *Madhura Rasa*, *Snigdha*, and *Guru Guna* increase the *Shukra Dhatu* qualitatively and quantitatively. *Gokshura* is known for its utility in *Mutravaha Srotas*,^[9] by correction of the *Apana Vata*, it exerts action on the *Shukra* also, along the lines similar to how *Shukra Visarga* is governed by *Apana Vata*.

Tribulus terrestris contains three groups of active phytochemicals. They are Dioscin, protodioscin, and diosgenin. Protodioscin is a potent natural precursor of the testosterone enhancer.^[35] It also increases the production of Testosterone in another natural way. *Tribulus* leads to the production of the luteinizing hormone (LH). When the LH levels are increased, the natural production of testosterone also increases. LH is a hormone that also deals with sex drive. LH has been used to increase fertility and helps to relieve impotence.^[35]

Probable mode of action of placebo

In present study barley powder was selected as the Placebo. The knowledge imparted regarding sexuality and fertility may be the reason behind the action of placebo, as psychological counseling has profound benefits on *Shukra*. The placebo effects presumably have different mediators depending on the specific learned association and whether it is referring to acquisition of the association or the placebo response. The central nervous system (CNS) is the primary location and mediator of the physiological basis of the placebo effect, through its role in learning and memory and its outputs on the sensory, motor, and autonomic pathways, as well as the immune and endocrine systems. People have individual traits that predispose them to be more or less responsive to certain stimuli; the interaction between the learned associations of the clinical situation

and the person's particular biology produces a response. The response could be a basic physiological process, such as the modulation of sensory processing, release of neurotransmitters, or alterations in the hypothalamic-pituitary-adrenal axis or immune system activity. The placebo response could also be a slightly more complex physiological process, including change in mood, change in motivation/effort, or cognitive set-shifting.^[36] Jon-Kar Zubieta published findings that the nucleus accumbens is central to the machinery of the placebo effect. His group has confirmed that specific neural circuits and neurotransmitter systems respond to the expectation of benefit during placebo administration, and that these expectations induce measurable physiological changes.^[37]

Koshtha Shuddhi with *Eranda Taila* was carried out prior to administration of the granules. The *Vatanulomana* exerted by *Eranda Taila* corrects the gastrointestinal functioning by its properties of *Deepana* (Appetizer) and *Pachana* (Carminative).^[38] *Eranda Taila* is widely prescribed as a *Vatahara*. *Koshtha Shodhana* increases the digestion and absorption of food and nutrients. Better bioavailability of food causes better nutrition to the *Dhatu*s. *Vatanulomana*, especially correction of *Apana Vata* has its own benefits in *Kshina Shukra*. These are the possible mechanisms behind the placebo effect in the present study.

Conclusion

After detailed discussion on observations made and results achieved, this present study shows significant remission in the signs and symptoms of *Kshina Shukra*, vis-à-vis oligozoospermia, corroborated with definite improvement in the total sperm count. *In toto*, from this study it can be concluded that the Alternate Hypothesis of this study is accepted, that is, *Gokshura* is effective in the management of *Kshina Shukra*, with lifestyle modification. *Gokshura* Granules have shown superior results in the management of *Kshina Shukra*, as compared to placebo granules.

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हिन्दी सारांश

क्षीण शुक्रता में गोक्षुर का चिकित्सकीय अध्ययन

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वंध्यत्व एक जागतिक समस्या है, जो कि औसतन ८ से १२ प्रतिशत युगलों में पायी जाती है। निम्न शुक्रता पुरुष वंध्यत्व का मुख्य कारण है, जिसका क्षीण शुक्र के साथ संबंध जोड़ा जा सकता है। गोक्षुर के फलों में मूत्रल एवम् वाजीकर प्रभाव है, तथा मूत्राशमरी, यौनरोग एवम् वंध्यत्व में यह कार्यकारी है। इस कारण क्षीण शुक्रता की चिकित्सा में गोक्षुर के फलों की कार्मुकता का अध्ययन किया गया। प्रस्तुत अध्ययन में यादृच्छिक और कूटभेषज (प्लासिबो) नियंत्रित अध्ययन की रचना की गयी। इस अध्ययन में क्षीण शुक्रता के २१ से ५० वर्ष आयु वाले चिकित्सा योग्य रूग्णों को यादृच्छिक पद्धति से गोक्षुर ग्रॅन्युल्स ६ ग्राम दिन में दो बार तथा प्लासिबो ग्रॅन्युल्स ६ ग्राम दिन में दो बार का ६० दिनों तक सेवन कराया गया। प्राथमिक परिणामों में क्षीण शुक्रता के प्रत्यात्मिक लक्षण, अग्नि बल, देह बल, सत्व बल, सीमेनोग्राम एवम् यौन स्वास्थ्य प्रश्न सूचिका में लाभप्रद परिवर्तन पाये गये। रोगी बल (अग्नि बल, देह बल, सत्व बल एवम् यौन स्वास्थ्य प्रश्न सूचिका) और रोग बल (वीर्य विश्लेषण व प्रत्यात्मिक लक्षण) में प्लासिबो ग्रॅन्युल्स से ७०.९५% तथा गोक्षुर ग्रॅन्युल्स से ७८.११% सुधार पाया गया। क्षीणशुक्रता की चिकित्सा में प्लासिबो ग्रॅन्युल्स की तुलना में गोक्षुर ग्रॅन्युल्स द्वारा बेहतर लाभ पाया गया।