Clinical Study on Efficacy of Vrishya Granules (Kalpita Yoga) and Shatapushpadi Vrishya Basti in the Management of Ksheenashukrata with Special Reference to Oligozoospermia

JOSHI RAM KISHOR, BUDDHI PUNDEL

ABSTRACT

The Clinical study on safety and efficacy of Vrishya granules (Kalpita yoga) and Shatapushpadi Vrishya Basti in the management of Ksheenashukrata with special reference to Oligozoospermia is a Single centred, open label, randomized (simple), Interventional type clinical study. Thirty men with poor semen quality i.e. Oligozoospermia (case subjects) were selected from Outpatient department of National Institute of Ayurveda Hospital, Jaipur. Screening on the basis of inclusion and exclusion criteria was done and Informed consent was taken. For Subjective symptoms Ayurveda Parameters and International Index of Erectile Function Questionnaire were assessed in each individual. Semen quality was assessed by measuring PH, volume, count and motility. Hormone level i.e. serum testosterone was also analyzed. Safety parameters such as Random Blood Sugar, kidney function tests, liver function tests, urine routine analysis were also carried out.

The statistical value is highly significant with Vrishya granules (Kalpita yoga) and Shatapushpadi Vrishya Basti in the management of Oligozoospermia. Use of Vrishya Granules & Shatapushpadi Vrishya Basti found safe and effective in poor sperm quality i.e. Oligozoospermia.

Key Words: Ksheenashukrata, Oligozoospermia, Vrishya Granules, Shatapushpadi Vrishya Basti, Infertility

Introduction

Primary Male Infertility in a man is defined as his failure to father a child after 12 month of unprotected intercourse with his partner. Secondary Male Infertility is a condition when a man has achieved pregnancy with his partner at least once. More than 6 million couples in the U.S.A. and more than 25 million world-wide experience infertility each year. Approximately 15-20 percent of all cohabiting couples are infertile. Of these, in up to 50 percent of cases it is the male factor or the husband who is responsible for the infertility. This means that nearly 7.5 to 10 percent of all men in the reproductive age group are infertile i.e. incapable of fathering children due to problem related to Sperm. Data available over the past twenty years reveal that in approximately 30% of cases pathology is found in the man alone and in another 20% both the man and woman are abnormal. Therefore the male factor is at least partly responsible in about 50% of infertile couple.

Out of around 250 million individuals in India estimated to be attempting parenthood at any given time, 13 to 19 million couples are likely to be infertile. The national census reports of the past three decades viz. 2001, 1991 and 1981 showed that infertility has risen by 50 percent. Now a day, infertility is no longer recognized as only a female problem. It actually refers to a range of disorders some of which affect male and some female and contribute to childlessness. Study reports suggest that male infertility is almost as high as female. Every fifth healthy young Indian man between age group 18 to 25 suffers from abnormal sperm count.

In 100 couples, 40% male and 50% percent female suffer from infertility. The remaining 10% are common. Changing lifestyle and food habits, stressful life, environmental pollution, urbanization, use of chemical fertilizer and pesticides, estrogren factor available in , gradually increasing incidences of obesity, diabetes mellitus, hypertension; use of medicines, addictions like tobacco, alcohol, smoking, Gudkha chewing, multiple sexual partners, sexually transmitted
Any abnormality in Shukra Dhatu ultimately results in failure of conception. As per modern medical science, the most common abnormalities of sperm are Oligozoospermia (low sperm number), asthenozoospermia (reduced motility of sperm) & tetrazoospermia (abnormal morphology of sperm) among which Oligozoospermia is one of the leading causes of infertility in males. It is defined as the less sperm in ejaculated semen (less than 20 million per millilitre of semen). In Ayurveda literature Kshinashukrata has been described as one of the most important cause of infertility in men.

Ayurveda fundamentals describe that the drugs with similar properties of any Dhatu nourishes that very Dhatu. Vrishya drugs directly convert into Shukra Dhatu after their digestion & assimilation. So in current clinical trial, the drug Vrishya Granules was planned. It contains 10 herbal drugs with Snigdha Guna, Sheeta Vipaka as that of Shukra Dhatu. As per Samanya Vishesha theory of Ayurveda it will be beneficial in the treatment of Kshinashukrata. Ayurveda texts have described Basti as the best treatment of Vata vitiated Dhatu. Therefore the treatment of Kshinashukrata (Oligozoospermia); Vrishya Granules and Shatapushpadi Vrishya Basti were selected for this Clinical trial.

**Aim and Objectives**
- Conceptual & clinical study on Ksheenashukrata (Oligozoospermia)
- To evaluate the efficacy of Vrishya Granules and Shatapushpadi Vrishya Basti in the management of Oligozoospermia.
- Complete analytical & scientific review of classical and modern literature available in reference to Ksheenashukrata (Oligozoospermia).
- Documentation of immediate, intermediate and remote adverse effects associated with present therapy.

**Materials and Methods**

The present study was Single centred; Open label, simple Randomized, Interventional type, phase III clinical trial using pre and post-test design. Patients were randomly divided into two groups: Group A (Vrishya Granules) and Group B (Vrishya Granules and Shatapushpadi Basti). Randomization was done using lottery method. The patients were recruited from the outpatient and inpatient department of National Institute of Ayurveda Hospital after obtaining informed consent from patients.

**Inclusive criteria:**
- Male aged between 25-50 years.
- Known case of Oligozoospermia (sperm count less than 20 million/ml).
- Patient willing to sign consent form

**Exclusive criteria:**
- Disorder of sexual organ e.g. Hypospadias, Vericocele
- Patient below 25 years & above 50 years
- Male with primary & secondary azoospermia
- Patient with chronic diseases like hypertension, COPD, DM, CAD.
- Renal failure & hepatic dysfunction.
- Male having any sexually transmitted disease.
- Erectile dysfunction due to nerve damage e.g. trauma, surgery
• Known case of infertility due to mumps orchitis.
• Patient having Chemotherapy & radiotherapy.
• Patients undergone bladder neck surgery.
• Patient with HIV/AIDS

**Intervention and Duration**

Before starting the trial medicine and procedure Panchakol Choorna 2 grams twice daily with lukewarm water after meal was given for 3 days.

**Group A** (Vrishya Granules: Kalpita Yoga)

- **Dose:** 6 grams per oral twice a day
- **Anupana:** 200ml of cow whole milk
- **Duration:** 30 days

**Group B** – (Vrishya Granules + Shatapushpadi Vrishya Basti)

- **Vrishya Granules:**
  - **Dose:** 6 grams per oral twice a day
  - **Anupana:** 200ml of cow whole milk. **Duration:** 30 days
- **Shatapushpadi Vrishya Basti**
  - **Dose:** 50 ml daily in the form of Matra Basti. **Duration:** 30 days

**Criteria for Assessment**

**Assessment of Efficacy**

1) **Subjective Parameters:**
   A) IIEF 15
   B) Ayurveda Symptoms

2) **Objective Parameters:** semen analysis, Serum testosterone

**Observation of Adverse Drug Reaction**

To assess adverse drug reaction the reporting ADR form for ASU Drugs was adopted. The trial subjects were counseled to report primary emergency care unit of NIA Hospital if any adverse reaction occurs. The subjects were provided with mobile number of research fellow to ease the reporting at an earliest. The ADR form was filled thoroughly in every follow up.

**Objective Assessment**

All the laboratory examination was done at the central laboratory of National Institute of Ayurveda Hospital, Jaipur.

**Biochemical Laboratory Investigations**

1) Random Blood Sugar
2) Liver Function Test: Serum Bilirubin, SGOT, SGPT
3) RFT: Blood urea, Serum Creatinine
3) Urine Analysis

**Data Collection and Statistical Analysis**

Both group subjects were pre-tested with clinical examination, haematological and biochemical investigation and semen analysis.. The clinical examinations were done on day ‘zero’, day 15 and day 30 of trial. The haematological, biochemical and semen analysis data was collected on day ‘zero’, and day 30 of trial.

**Observation and Results**

Total 30 registered patients of Ksheenashukrata presented with 17 different symptoms as chief complaint before treatment. Out of total of 30 patients, significant improvement was absorbed in all symptoms.

In both groups Semen pH, Semen Volume, Total sperm Count, Rapid Linear Progression (RLP) found increased and SLP, NP and IM found reduced thus showing statistically highly significant results. More better results were observed in Group A than in Group B. For parametric data, paired t-test for statistical calculation and unpaired t-test for intergroup comparision has been carried out.

**Safety Parameters:**

On safety analysis no change was observed in Random blood sugar, Renal Function Tests and Liver Function Test parameters, Vital Signs. For non parametric data, the Wilcoxon’s matched-pairs signed-ranks tests for statistical calculation and Mann-Whitney Test Inter Group Comparison has been carried out.

**Discussion**

Astavidha and Dashavidha Ayurveda Parikshya were performed. The symptoms observed in patients were Daurbalya, Bhrama, Aharshana, Lingashaithilya, Panduta, Klaiyya, Shighrashukra Skhalana, Timir Darshana, Memory loss, Burning micturation, Medhra Vedana, Suicidal tendency and Dhat syndrome.

After completion of trial the numbers of patients with respective symptoms have been decreased. For analysis of data Paired t test was applied for parametric data.

For non parametric data Wilcoxon matched-pairs signed-ranks test was applied for intergroup comparison of effect of treatment and Mann-Whitney Test for intergroup comparison. Statistically highly significant result was observed both group in sperm count, Rapid Linear Progression, non progressive and immotile sperm and significant result was found Sluggish Linear Progression. Statistically highly significant result was observed both groups in Total Serum Testosterone. The result in liver function test, kidney function test and urine analysis, vital signs were in significant. The result of non parametric data i. e. IIEF – 15 was highly significant both group in intergroup comparison. The inter group comparison showed highly significant result in orgasmic function, significant in erectile function and insignificant in sexual desire, intercourse satisfaction and overall satisfaction. The drugs used in this trial are Guru, Snigdha, Madhura and Sheeta. Panchakol is Deepan and Pachana so it was given to enhance Agni and Aama.
Table no. 1. Rasa Panchaka of Vrishya Granules (Rasa, Guna, Virya, Vipaka)

<table>
<thead>
<tr>
<th>S.No</th>
<th>Local name</th>
<th>Rasa</th>
<th>Guna</th>
<th>Virya</th>
<th>Vipaka</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Ashwagandha</td>
<td>Tikta, Katu, Madhura</td>
<td>Laghu Snigdha</td>
<td>Usna</td>
<td>Madhura</td>
</tr>
<tr>
<td>2.</td>
<td>Amalaki</td>
<td>Pancharasas (no salt) Amla dominant</td>
<td>Guru, Rukshya</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>3.</td>
<td>Bidari kanda</td>
<td>Madhura</td>
<td>Guru Snigdha</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>4.</td>
<td>Gokshur</td>
<td>Madhura</td>
<td>Guru Snigdha</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>5.</td>
<td>Kapikachhu</td>
<td>Madhura, Tikta</td>
<td>Guru Snigdha</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>6.</td>
<td>Shatawari</td>
<td>Madhura, Tikta</td>
<td>Guru Snigdha</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>7.</td>
<td>Sharkara</td>
<td>Madhura</td>
<td>Guru Snigdha</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>8.</td>
<td>Sweta Mushali</td>
<td>Madhura</td>
<td>Guru Snigdha</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>9.</td>
<td>Yestimadhu</td>
<td>Madhura</td>
<td>Guru Snigdha</td>
<td>Sheeta</td>
<td>Madhura</td>
</tr>
<tr>
<td>10.</td>
<td>Sunthi</td>
<td>Katu</td>
<td>Laghu Snigdha</td>
<td>Usna</td>
<td>Madhura</td>
</tr>
</tbody>
</table>

Pachana. Before administration of Vajikaran medicines Srotas Suddhi is a must to get better result of the therapy. Snehana and Svedana are the Purvakarma adopted before administration of Vrishya Basti. Snehana nourishes Dhatu, Jatharagni, immunity and subsequently body as a whole. These procedures are helpful to increase the bioavailability of the medicine. Medicines having Madhura rasa and Vipaka; Guru Snigdha Guna and Sheeta Vira were selected to prepare granules named Vrishya Granules. The drug acted on Shukra Dhatu according to Samanya Vishesha theory of Ayurveda. - Table no. 1.

**Probable Mode of Action**

All the ingredients contain Madhura Vipaka, 70% of drugs contain Sheeta Vira, 70% have Guru Snigdha Guna and 80% have Madhura Rasa. According to Samanya Vishesha theory of Ayurveda these drugs are effective in increasing the quality and quantity of Shukra. Milk was selected as Anupana. Milk is best in Jeevaniya Dravya. Regular use of milk and ghee is best in Rasayana therapy (Rejuvination). Milk has all the qualities that Ojas possesses. It is Madhura, Snigdha, Sheeta, Prinana, Brimhana, Vrishya, Balya, Manaskara and Jeevaniya. It is useful in Shukra Dosh. Regular use of Kshira shows best Rasayana effects. Milk is the Best Jiviniya Dravya. So it is useful in Ksheenashuktta. All the ingredients have Vrishya properties. Many researches proved that these drugs have antioxidant property. It is also proved from researches that antioxidant drugs and diet improve the quality of semen.

**Mode of Action of Basti**

The gastro-intestinal system has its own nervous system. It is known as enteric nervous system (ENS) or intrinsic nervous system. The ENS is popularly known as Brain of the Gut. This lies entirely in the wall of the gut from oesophagus to anus.

ENS controls GI movements and secretions. ENS secretes various neurotransmitters named Acetylcholine, nor epinephrine, serotonin, dopamine cholocystokinine etc. These neurotransmitters control various types of gastrointestinal activities. ENS may be activated by: Tactile simulation, Chemical stimulation and Distension of gut wall. Basti have some role in stimulating in intestinal secretions. Practically, enhancement of Agni is reported after completion of Basti therapy.

**Conclusion**

Pathology for Oligozoospermia is Defective transportation of sperm and Defective Spermagenesis. Oligospermia can be correlated with Vataja Shukra Kshya. Vata- Pitta Prakriti persons are more prone to Oligozoospermia. Vitiated Vata and Pitta cause Oligozoospermia. Both Vrishya granules and Shatapushpadi Vrishya Basti are safe and effective in the management of Oligozoospermia.

**REFERENCES**

12. Harrison’s, Principle of Internal Medicine, Volume one Dan L. Longo et al MC Graw Hill 18th edition, - 2012(1)