

A CLINICAL STUDY ON SPERMATOGENIC EFFECT OF *Kshiravidari* (*Ipomea digitata* Linn) IN OLIGOZOOSPERMIA

GIRISH K J¹, ANUP B THAKAR² AND M S BAGHEL³

Department of Kayachikitsa¹, S D M College of Ayurveda, Hassan, Karnataka – 573201 (India)
Department of Panchakarma², I P G T & R A³, Gujarat Ayurved University, Jamnagar (India)

Abstract : In the present clinical study, total 65 patients of oligozoospermia (< 40 mil/ml – three successive weekly semen analyses) were managed in two groups viz. study (*Kshiravidari*) group (n=35) and placebo group (n=30). In *Kshiravidari* group, *Kshiravidari* (*Ipomea digitata* Linn.) tuber was administered in the tablet form (each 500 mg) in a dose of 6 gm per day in divided doses, and in placebo group, *Bhrista Godhuma Churna* (fried wheat powder) in capsule form [4 capsules / day (each 500 mg)] was administered, in both therapy with milk as *Anupana*. In both the groups, therapy was given for one and half month (45 days), further 45 days of follow-up. Semen examination was carried out after completion of therapy i.e. on 45th day. During follow up period semen examination was done 15 days after completion of therapy i.e. on 60th day, and second examination was done 45 days after completion of treatment i.e. on 90th day. Clinical study has shown that *Kshiravidari* (*Ipomea digitata* Linn.) increases the sperm count (mil/ml) (mild to moderate degree) and also total sperm count (mil) in patients of oligozoospermia. This proves *Vrishya* property of *Kshiravidari* as potent spermatogenic agent. However, due to the increase in the viscosity and liquefaction time, the drug decreases the RLP (Rapid Linear Progressive) and SLP (Slow Linear Progressive) motility (%), and simultaneously increases the NP (Non-Progressive) and IMM (Immotile) motility (%) of sperm. Three patients of oligozoospermia were able to impregnate their partners within total of 60 days of duration of follow-up period, which also shows the fertility enhancing effect of *Kshiravidari*.

Keywords: Male infertility, Oligozoospermia, *Kshiravidari*, *Ipomea digitata* Linn.

Introduction

The inability to procreate i.e. infertility is seldom, if ever a physical debilitating disease. But, it may, however, severely affect the couples psychological harmony, sexual life and social function. Infertility, defined as the inability to conceive after at least one year of unprotected intercourse, affects about 15-20% of couples and in 40 % of these cases male factor is identified as main cause of infertility⁽¹⁾.

Oligozoospermia is the seminal disorder in which sperm count is below 40 mil/ml^(2,3,4). Sperm count in healthy male ranges widely between 5 million to 170 million sperm cells / ml, but datas from 15 publications in men with proven fertility showed a mean value of sperm concentration of 76 ±18.6 and mean normal range of 40-140 mil/ml is confirmed⁽⁵⁾. So, this author has also accepted the lower limit of normal sperm count as 40 million /ml, below which it would be considered as oligozoospermia.

¹Lecturer, ²Sr.Lecturer ³Director, I.P.G.T.&R. and Professor of Kayachikitsa

Oligozoospermia (*Kshinashukra*) is a *Doshabalapravritta*, *Krichhrasadhya* disease of *Shukravaha Srotas*⁽⁶⁾, which is manifested clinically as

“*Na cha Garbham Jayate*” (infertility)⁽⁷⁾.

Samprapti of *Kshinashukra* (oligozoospermia) is not mentioned in classics separately. But it is mentioned that vitiation of *Vata* and *Pitta Dosa* are responsible for manifestation⁽⁶⁾.

After review of literature regarding management of oligozoospermia with single drug (herb), *Kshiravidari* (*Ipomea digitata*, Linn.) has been selected. It is stated in *Ayurveda* classical texts that “*Shukrakarikriya*”⁽⁸⁾ and “*Upachaya*”⁽⁹⁾ method of management has to be carried out in case of subnormal quality of *Shukra* (semen) (oligozoospermia) i.e. *Shukravardhaka* measures (enhancement of spermatogenesis) with drugs having *Madhura Rasa*, *Guru-Snigdha Guna*, *Vrishya*, *Shukravardhaka*, *Balya* and *Rasayana* properties⁽¹⁰⁾. *Kshiravidari* fulfills the criteria and hence the drug was chosen for the study.

Kshiravidari (*Ipomea digitata*, Linn.) has already undergone both pharmacological and clinical study with special reference to its *Vajikarana* effect by **Acharya RN(1996)**⁽¹¹⁾; which was conducted on a small sample (n=7) with positive outcome on seminal parameters in infertile males. So, this drug was taken up to ascertain its spermatogenesis property with controlled study in a large sample of oligozoospermia patients.

Aims and Objectives

The present clinical trial was carried with following aims and objectives:

To evaluate the effect of *Kshiravidari* (*Ipomea digitata* Linn.) on various seminal parameters with special reference to the management of oligozoospermia.

Patients and Methods

Study Design

Present study was single blind, controlled, clinical research at OPD level with appropriate sample. The patients included in the clinical trial were randomly divided into two groups namely-

A. Study Group (*Kshiravidari* Group)

B. Placebo Control Group (P C Group)

Established cases of oligozoospermia from *Vajikarana* unit of Kayachikitsa department, Institute for Post Graduate Teaching and Research in Ayurveda (I P G T & R A), Gujarat Ayurved University, Jamnagar as well as cases referred by other physicians of other departments were included in this study. Such oligozoospermia patients selected were randomly assigned either into study or placebo control group.

Inclusion criteria of patients to Study group and Placebo Control Group:

1. Infertile male patients whose sperm concentration was below 40 mil / ml in average of three successive weekly semen analyses were included in present study^(2,3,4). Apparently healthy male patients between age group of 21 to 50 years were selected irrespective of race, caste, religion etc.

Exclusion criteria of Study group and Placebo Control group:

1. Accessory sex gland infection, testicular maldescent, previous reproductive organ surgery, STD were excluded
2. Patients categorized under azoospermia were excluded
3. Past history of mumps, orchitis, trauma, addictions, acute febrile illness were taken into account
4. Diabetes, thyroid disorders, tuberculosis, vascular diseases, any longstanding infection was taken into consideration.

Laboratory Investigations

All patients conforming to above said criteria were included in the study and subjected to thorough physical and genital examination. In all the groups i.e. study, placebo control group patients were subjected for hematological such as Hb%, TC, DC, PCV, ESR; urine routine examination such as albumin, sugar, microscopic examination; examination of biochemical parameters such as FBS, serum cholesterol, serum urea, serum creatinine, serum total protein, serum albumin, serum globulin and A/G ratio and other investigations (if and when required) were carried out to rule out major pathological conditions.

History and relevant data was recorded in a detailed research / clinical proforma which was specially prepared for this study by incorporating the all aspects of the present disease on Ayurvedic and modern parlance.

Interventions

Drug, Dosage, Duration, Diet

(A) Study group (*Kshiravidari* group)

In this group, 35 patients of oligozoospermia were administered tablets (each 500 mg) of *Kshiravidari* (*I. digitata* Linn.)

tuber (authenticated at Department of Dravyaguna, I P G T & R A, G A U, Jamnagar) which was prepared in Pharmacy of Gujarat Ayurved University, Jamnagar, in a dose of 6 gm / day in divided doses with milk⁽¹²⁾ as *Anupana* for a period of 45 days.

(B) Placebo Control group

In this group, 30 patients of oligozoospermia were administered placebo capsule of *Bhrishta Godhuma Churna* (fried wheat powder) 4 capsules / day with milk⁽¹²⁾ as *Anupana* for a period of 45 days.

All the patients registered in the study were advised to follow normal routine diet.

Criteria of assessment of effect of therapy

Assessment of effect of therapy on oligozoospermia patients was done on the basis of seminal parameters

Assessment of Seminal Parameters

Assessment of effect of therapy was done on the basis of seminal parameters observed before and after completion of therapy. Patients of study group were subjected to semen analysis after completion of drug administration and was repeated on 60th (i.e. 15 days after the drug withdrawal) day and 90th day of therapy (*viz.* 45 days after withdrawal of drug).

Semen analysis

Semen analysis of patients was carried out by the scholar himself as per the recommended standards of semen examination by WHO (1993)⁽¹³⁾ for diagnosis and assessment of effect of therapy, in *Vajikarana* laboratory in the Department of Kayachikitsa, I P G T & R A, Gujarat Ayurved University, Jamnagar.

Examination of following parameters of semen sample was carried as per the guidelines of **WHO (1993)**⁽¹³⁾.

1. Appearance
2. Liquefaction time
3. Volume
4. Viscosity
5. pH
6. Sperm count
7. Sperm motility
8. Sperm morphology
9. Sperm viability

Follow-up of Treatment

1. In study group, patients were put on placebo capsules for next 45 days for further follow-up, after withdrawal of the drug.

2. Semen analysis during follow-up period: Semen analysis of the study group was carried out at regular interval (60th and 90th day of therapy) during follow up period.

Assessment of Overall Effect of Therapy

After assessing seminal parameters before and after the treatment, patients have been graded into five groups to assess the overall efficacy of the therapy as shown below:

- **Conceived** - Oligozoospermia patients who after treatment whose wives conceived.
- **Complete remission** - Improvement in percentage of sperm count >100% .
- **Markedly improvement** - Improvement in percentage of sperm count between 51-100%.
- **Improved** - Improvement in percentage of sperm count between 25-50%.
- **Unchanged** - Improvement in percentage of sperm count <25%.

Statistical Analysis

The obtained clinical and seminal data were analyzed using SigmaStat® statistical software. The values were expressed as mean \pm SEM (standard error of mean). The data were analyzed by paired 't' test. A level of $p < 0.05$ was considered as statistically significant. Level of significance was noted and interpreted accordingly.

Observations

80 infertile males with oligozoospermia were registered in the study, out of which 65 patients completed the whole course of study, in which 35 patients were belonging to study group while 30 were in placebo control group; and 15 patients of oligozoospermia enrolled in this study left the therapy in between.

Analysis of data obtained in the clinical study showed that most of patients of oligozoospermia groups (*Kshiravidari* and placebo group) were between the age of 21-40 years (90%); belonging to Hindu religion (86.25%); middle class (38.75%); secondary level education (62.50%); labourers (47.5%); exposed to occupational heat (32.5%); cases of primary infertility (81.25%); *Prakriti* was *Vatapitta* (41%); had *Madhyama Sara* (67.5%); had *Rajasa Manasika Prakriti* (70%); were mentally tense (45%); mentally depressed (5%).

In oligozoospermia groups, maximum patients were using cotton undergarments (85%); which was tight (50 %); had habit of warm water bath (37.5%); were addicted to tobacco items (56.25%); had history of unprotected sex life with duration of 1 to 5 years (52.5 %); were unaware of fertility period (55%); were sexually unhappy (23.75%); 15%

patients complained of *Klaibya* and 23.75% had coital difficulties.

Genital Examination Findings

Among oligozoospermic patients, in majority, testicular size was between 4-16 ml in 66.25% and 60.25% patients on right and left side respectively; testicular consistency was soft on both sides in 11.25%; varicocele was present on both sides in 3.75% patients; in 15% patients varicocele was detected on left side.

Results

The effect of both therapies on various semen parameters are as follows :

Effect on Sperm Count (mil/ml) and Total Sperm Count (mil)

The sperm count (mil/ml) was increased by 66.59 % after one and half month ($p < 0.05$) in *Kshiravidari* group ($n = 30$), while it was decreased by 6.08 % in placebo group ($n=30$). During follow-up period, in *Kshiravidari* group, sperm count was further increased by 91.79% ($p > 0.05$) and 31.47% ($p > 0.05$) at the end of second month ($n=18$) and third month ($n = 18$) respectively in patients of oligozoospermia.

Total sperm count per ejaculate (million) was increased by 476% with *Kshiravidari* therapy ($p < 0.001$) ($n=30$); whereas with placebo therapy ($n=30$), it was decreased by 3.15% after 45 days of therapy. During follow-up study, total sperm count at the end of second month was further increased by 32.34% ($p > 0.05$) ($n=18$), which was further increased by 20.36 % at the end of third month ($p > 0.05$) ($n=18$) in *Kshiravidari* group.

On the basis of the above data, it may be stated that *Kshiravidari* therapy provided

better and statistically significant ($p < 0.05$) improvement in sperm count and total sperm count ($p > 0.001$) in comparison to placebo therapy in patients of oligozoospermia (after 45 days of therapy).

Effect on Motility (%)

In *Kshiravidari* group, at end of one and half month of therapy, RLP motility was decreased by 18.62% ($p > 0.05$) ($n = 33$); where as in placebo group it increased by 0.95% ($p > 0.05$). It was further decreased by 41.68% and 35.67 % at end of second month ($n = 18$) and third month ($n = 18$) respectively during follow-up ($p < 0.002$) in study group.

At end of one and half month ($n=33$), SLP motility was decreased by 33.09% in *Kshiravidari* group and 11.57% in placebo group. The decrease in SLP motility in both therapies was statistically insignificant. At end of second month ($n=18$) and third month ($n=18$) SLP motility was decreased by 46.04% and by 49.94% ($p > 0.05$) in study group.

It is evident that *Kshiravidari* decreased the RLP and SLP motility in comparison to placebo therapy. At end of one and half month, NP motility was decreased by 4.38% in *Kshiravidari* group ($n=33$) and same was increased by 14.32% in placebo group ($n=27$). During follow up period, in *Kshiravidari* group, at the end of second month ($n=18$) and third month ($n=18$), it was decreased by 6.80% ($p > 0.05$) and 73.22% respectively ($p < 0.05$).

At end of one and half month, IMM spermatozoa was increased by 13.57% with *Kshiravidari* treatment ($n=33$) ($p < 0.05$) and by 7.6% with placebo therapy ($n=27$). In *Kshiravidari* group, it was further increased by 19.34% and 16.43% ($p > 0.05$) at the end of

second (n=18) and third month (n=18) during follow-up period.

With the above description it can be concluded that *Kshiravidari* therapy decreased and increased the NP and IMM motility of spermatozoa respectively in comparison to placebo therapy.

Effect on Total Abnormal Count of Sperm (%), Liquefaction Time (min.), Viscosity (grade), Volume (ml) of Semen and Sperm Vitality (%)

At the end of one and half month, there was an increase in total abnormal forms of sperm by 13.15% with *Kshiravidari* treatment (n=29) ($p < 0.05$), whereas in placebo group (n=26) the same was minimally increased by 0.74%. During the follow-up study, at end of second month (n=15) and third month (n=17), it was increased by 10.65% and 21.19% ($p < 0.001$) respectively in study group.

At the end of one and half month, *Kshiravidari* (n=34) increased the liquefaction time by 11.73%, while in placebo group (n=30) it was decreased by 8.32%. During follow-up study, at the end of second month (n=18) and third month (n=18), it was further increased by 14.59% ($p > 0.05$) and 28.29% ($p > 0.05$) respectively in *Kshiravidari* group.

At the end of one and half month, *Kshiravidari* (n=34) increased viscosity of semen by 29.03% ($p > 0.05$) and decrease of 5.56% in placebo group (n=30) was recorded. In follow-up period, at the end of second (n=18) and third month (n=18), it was increased by 210.66% and 75.95% ($p < 0.002$, $p < 0.01$) respectively in study group.

After completion of therapy, it was observed that volume of semen was increased by 12.07% in *Kshiravidari* group ($p > 0.05$) (n=34) and 12.34% in placebo therapy (n=30). During follow-up study, on 60th day (n=18), it was increased by 8.36% and which was decreased by 13.06% by the end of third month (n=18) ($p > 0.05$) in study group.

After completion of course of drug administration, viability of sperm was increased by 15.09% with *Kshiravidari* therapy (n=34) ($p < 0.05$) and was decreased by 9.20% in placebo group (n=25). During follow-up period, on 60th day (n=14) and 90th day (n=17), it was further increased by 14.50% and 2.12% ($p > 0.05$) respectively in *Kshiravidari* group.

In short, *Kshiravidari* therapy increased total abnormal forms, liquefaction time, viscosity, volume of semen and viability of sperm in comparison to placebo therapy after 45 days.

Effect on Body Weight and certain laboratory parameters

Even bodyweight was increased significantly in patients of oligozoospermia by the end of 45 days therapy with *Kshiravidari* and end of follow-up period i.e. 90 days. *Kshiravidari* insignificantly increased the serum total protein and serum globulin with 45 days of therapy in oligozoospermia patients.

Overall Effect of Therapies

As all the patients enrolled in the study were oligozoospermic, overall effect of therapies was assessed on the basis of change in sperm count and conception by the female partners of the patients.

In *Kshiravidari* group, 8.57% conception was reported, while in placebo group no conception was reported. Complete

remission i.e. improvement in sperm count by >100%, was observed in 17.14 % patients in study group; whereas 3.33 % in placebo group. Markedly improvement i.e. improvement in sperm count between 51-100% was recorded in 11.42% patients in *Kshiravidari* group and 36.66% in placebo group. Improvement i.e. improvement in percentage of sperm count was between 25-50%, in 25.71% in study group and 30% in placebo therapy. Unchanged i.e. improvement in percentage of sperm count <25%, was found in 40% in *Kshiravidari* group and 30% in placebo therapy.

In this way, *Kshiravidari* provided better improvement in conception and sperm count in comparison to placebo therapy.

Discussion

Probable mode of action of *Kshiravidari* (*Ipomea digitata* Linn.) on results obtained in various semen parameters are as follows :

Kshiravidari possesses *Madhura Rasa* (*Pradhana Rasa – Madhuro Rasah Shukrabhivardhanah*⁽¹⁴⁾), *Guru* and *Snigdha Guna*, *Madhura Vipaka* and *Sita Virya* (*Shukralaha*⁽¹⁵⁾)⁽¹⁰⁾. It has *Viryavardhaka* and *Vrishya* properties⁽¹⁶⁾. All these factors might have synergistically acted and have brought improvement in sperm count and total sperm count in patients of oligozoospermia. In oligozoospermia/*Kshinashukra*, *Vata-Pitta Dosa* are the main culprits⁽⁶⁾. The drug might have helped in *Vighatana* of *Samprapti* of the disease. Previous study carried out by **Acharya RN (1996)**⁽¹¹⁾ has also shown significant improvement in sperm count in patients of *Shukradusti* (male infertility). This proves the spermatogenic effect of *Kshiravidari*

(*Ipomea digitata* Linn.) in patients of oligozoospermia/*Kshinashukra*.

Kshiravidari increased the viscosity of semen insignificantly at the end of one and half month. Moreover, *Kshiravidari* increased the viscosity of semen remarkably during follow-up period also (at the end of second and third month). *Piccilatva* (viscosity) is the quality of *Kapha Dosa*⁽¹⁷⁾. *Kshiravidari* possesses all the qualities which enhance the *Kapha Dosa* also. Because of *Madhura Rasa*, *Guru* and *Snigdha Guna*, *Kaphavridhikara* properties and high starch content⁽¹⁸⁾ of *Kshiravidari* might have increased the mucous content of semen, because of which semen became viscous⁽¹⁹⁾.

In patients of oligozoospermia, *Kshiravidari* has gradually reduced the RLP and SLP motility during therapy. *Kshiravidari* therapy has not shown positive effect in improving the RLP and SLP motility. This effect can be explained due to simultaneous increase of the viscosity and liquefaction time of semen. It has been proved that hyperviscosity of semen bears negative impact on motility of the spermatozoa⁽²⁰⁾. Even on NP and IMM motility also *Kshiravidari* did not show any positive effect. Because, *Kshiravidari* decreased the RLP and SLP motility; on the other way, it has increased the NP and IMM motility. Negative effect of *Kshiravidari* on motility of sperm can be attributed to the *Guru* and *Snigdha Guna* and *Shita Virya* of *Kshiravidari*. This shows the motility inhibiting property of *Kshiravidari* (*Ipomea digitata* Linn.).

However, *in-vitro* study with 50% ethanol extract of *Kshiravidari* (*Ipomea digitata* Linn.) did not show any spermatozoa motility enhancing property

when studied in the concentration of 0.1 to 0.4 mg per ml of semen. Fresh juice of *Kshiravidari* enhanced motility of spermatozoa when added to *in-vitro* in the concentration of five mg per ml of semen⁽²¹⁾.

Even *Kshiravidari* increased the total abnormal count through out the period of study, which was not desirable, as morphology of sperm is one of important qualities of semen which determines the overall fertility potential of semen.

The prostatic and epididymal contributions to the semen usually do not exceed 1ml. Semen volume is main functional activity of seminal vesicles⁽²²⁾. The drug *Kshiravidari* might have hampered the function of seminal vesicle, there by moderate reduction in seminal volume was observed. *Kshiravidari* possesses *Kaphakara* and *Viryavardhaka* properties which help in increasing the quantity of semen, however this increase doesn't seem to be long lasting as is evident from the decrease of semen volume during follow-up.

Kshiravidari has increased the vitality of sperm. It shows that it has increased the number of live sperm cells, which may be correlated and attributed to the *Rasayana*⁽²³⁾ property of *Kshiravidari*. This fact is supported by the *in-vitro* study by **Jageti and Baliga (2004)**⁽²⁴⁾ showed that *Ipomea digitata* extracts demonstrated direct scavenging of NO and exhibited significant activity. This shows that *Kshiravidari* possesses antioxidant property which may decrease the level of "stress" on testis and there by increasing the vitality of sperm.

Conclusion

Kshiravidari increases the sperm count and total sperm count (mild to moderate degree) in patients of oligozoospermia. It increases the viscosity and liquefaction time, resulting in decrease in RLP and SLP motility and simultaneously increase the NP and IMM motility of sperm. Three patients were able to impregnate their partners within total of 45 days of duration of follow-up period.

Moreover, the drug *Kshiravidari* has not manifested any physiological or psychological untoward effects in the patients studied. Thus *Kshiravidari* a herbal drug may be very useful in treatment of oligozoospermia, so also is a good *Vajikara* drug. However, further experimental studies are recommended to find out the exact mode of action of this drug.

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Address for correspondence : Dr. Girish K.J., Ph.D.(Ayu.), Lecturer, Department of Kayachikitsa, S.D.M College of Ayurveda, Thannerhalla, Hassan, Karnataka – 573201 (India) E-mail: girideepa@yahoo.co.in