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A CLINICAL STUDY ON THE EFFECT OF IKSHURADI LEHYA IN THE MANAGEMENT OF SHUKRA KSHAYA W.S.R TO OLIGOSPERMIA

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ABSTRACT

Infertility is the global problem in field of reproductive health. In India, infertility is a social stigma, particularly in rural areas, which affects the couples psychological harmony, sexual life and social functioning. Infertility may cause heavy shadow on the physiological and social adequacy of female, and diminish social standards of male partner. The recent incidence shows that male factor is at least partly responsible in about 50% of infertile couples. Considering this the present study was carried out.

Selected patients were treated with oral administration of *Ikshuradi Lehya*, in the dose of 48 grams before food in the morning for 60 days and follow up done after 30 days of the treatment. 200 ml milk is advised as *Anupana* along with *Ikshuradi Lehya*. The response following the intervention was assessed every month by adapting the Sexual Parameters and Semen Analysis. Further the change observed by the completion of the treatment was subjected to paired t test to know the statistical significance. Sexual parameters and seminal parameters showed marked improvement with the statistical significance. Result shows better improvement in the seminal parameters and sexual parameters after 90[th] day than of the 60[th] day

Conclusion: Semen parameters and sexual parameters showed marked improvement following medication with *Ikshuradi Lehya* and was proved to be statistically significant.

Key words: *Shukra Kshaya, Ikshuradi Lehya*, Oligospermia.

INTRODUCTION

Reproduction is the singular important phenomenon that is the sole determinant of the continuation of species. Since the beginning of recorded history, the human race has placed a great emphasis on fertility. Therefore, the capacity of reproduction may be an essential ingredient of the sense of wellbeing, mediated by gender in equalities and sexual differences[1]. Male infertility has received less attention, even though it is widely reported. In 1992 it was first reported in the study of decrease in semen quality in last 50 years. It showed a significant decrease in mean sperm count from 113 million/ml to 66 million/ml and in seminal volume from 3.4 ml to 2.75 ml (1940 to 1990). The Indian reports, both from the Institute for research in reproduction, Mumbai and from Mehta et al, Bangalore seem to agree with

this decline trend of semen quality over the years. The incidence of infertility varies in different regions .Almost 15% of couple worldwide are infertile. In that approximately 45% cases of pathology is found in man alone and in another 20% both man and women. Therefore male factor is at least partly responsible in about 50% of infertile couples[2]. New infertility prevalence calculation as per WHO is one in every four couples in developing countries has been found to be affected by infertility. According to survey done in 2010, 48.5 million couples are affected by infertility[3]. Vajeekarana, one among the Ashtanga Ayurveda deals with the fertility, potency and healthy progeny. There is the detailed description of Ashtavidha Shukra Dusti and its management by different types of Vajikarana Yoga[4]. Shukrakshaya is the type of Shukradusti resulting in infertility in which Oligospermia is one of the presentations. Oligospermia is the condition where the sperm density less than 20 million/ml. Different sorts of Vajikarana yoga are explained in the management of the same. Hence a sincere effort has been made to evaluate the effect of Ikshuradi Lehya in the patients suffering from Shukra Kshaya. The present study "A clinical study on the effect of Ikshuradi Lehya[5] in the management of Shukra Kshaya w.s.r. to Oligospermia" was carried out with an aim to explore the therapeutic effect of Ikshuradi Lehya on the activity of the disease in patients suffering from Shukra Kshaya/ Oligospermia.

OBJECTIVES

1) To study the Ksheena Shukra with possible correlation to Oligospermia
2) To evaluate the clinical efficacy of Ikshuradi Lehya on seminal parameters in patients suffering from Ksheena Shukra / Oligospermia.

MATERIALS AND METHODS

STUDY DESIGN: It was an open labelled clinical study with pre-test and post-test design.

SOURCE OF DATA: 20 male patients diagnosed as Ksheena Shukra/ Oligospermia were selected from IPD/OPD of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi.

Drug - *Ikshuradi Lehya* prepared from Shri Dharmasthala Manjunatheshwara Pharmacy, Udupi.

METHOD OF COLLECTON OF DATA

- 20 patients diagnosed as Ksheena Shukra/ Oligospermia were selected from IPD/OPD of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi.
- A special proforma was prepared with details of history taking, symptoms as mentioned in our classics and allied sciences. Patients were analysed and selected accordingly.

DIAGNOSTIC CRITERIA

- A male patient complaining of infertility with minimum of 1yr of married life.
- Seminogram with sperm count less than 20 million/ml.

INCLUSION CRITERIA

1) Male patients between age group of 22 years to 45 years
2) Patients with sperm count less than 20 million/ml

EXCLUSION CRITERIA

1) Male patients below 22 years and above 45 years
2) Patients with Absolute Azoospermia.
3) Patients with major systemic disorders like Tuberculosis, AIDS and STD

etc. which interfere in course of treatment will be excluded.

DURATION OF CLINICAL TRIAL

60 days of intervention and followed by 30 days of follow up after treatment.

PLAN OF STUDY: 20 male patients (2 dropped out) complaining of primary or secondary infertility visiting OPD and IPD of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi were subjected to semen analysis and those diagnosed as Ksheena Shukra/ Oligospermia were selected. These patients were treated by oral medication with Ikshuradi Lehya in the dose of 1 Pala (48 grams) once daily before breakfast with milk. All the selected patients were administered orally with Haritaki Churna 12gms for 3 days for Koshta Shuddhi to fulfil the minimum pre-requisition for Vajikarana therapy.

ASSESSMENT CRITERIA

1) Semen Analysis
2) Sexual parameters to assess the total effect of the drug.

Investigations

1) Semen Analysis: It will be carried out to diagnosis and to assess the effect of therapy.

2) If required any other investigations.

Subjective Parameters

Sexual functional parameters-

Sexual desire

No desire at all - 0
Lack of the desire - 1
Desire but no activity - 2
Desire only on demand of partner - 3
Normal desire - 4
Excess desire - 5

Orgasm

No enjoyment - 0
Lack of enjoyment - 1
Enjoyment in 25% of sexual intima- 2
Enjoyment in 50% of sexual intima- 3
Enjoyment in 75% of sexual intima- 4
Enjoyment in every act - 5

Rigidity

Unable to maintain erection or continue sexual act - 0
Some loss in erection but able to continue sexual act - 1
Able to maintain erection and continue sexual act - 2

Erection

No erection by any method - 0
Erection by artificial methods- 1
Erection but unable to penetrate- 2
Initially difficult but able to penetrate-3
Erection with occasional failure- 4
Erection whenever desire - 5

Ejaculation

No ejaculation at all - 0
Delayed ejaculation without orgasm- 1
Ejaculation before penetration - 2
Ejaculation with penetration - 3
Ejaculation with own satisfaction - 4
Ejaculation with own and partners satisfaction-5

Shukra Vega (Time taken for Ejaculation)

Ejaculation within/before pelvic thrusting - 0
Ejaculation between 1-5 pelvic thrusting - 1
Ejaculation between 5-10 pelvic thrusting - 2
Ejaculation above 10 pelvic thrusting - 3

Post act Exhaustion:

No exhaustion at all – 0
Slight exhaustion occasionally – 1
Exhaustion in 25% of occasions – 2
Exhaustion in 50% of occasions – 3
Exhaustion in 75% of occasions– 4
Exhaustion after every encounter – 5

OBSERVATIONS

It is observed that 50% of the patients belonged to the age group of 31-40

years. This is followed by 33.30% of the patients in the age group of 21-30 years. Maximum number of patients was drivers, business, and agriculture profession and each group is having 16.70% of patients. It's followed by labour, service, engineer profession and each group is having 11.10% of patients. It's followed by salesman, fisherman, carpenter profession and each group's having 5.50% of patients. 55.60% were from the rural area and the remaining 44.40% were urban dwellers. 33.30% were alcoholic, 22.20% were smokers, 11.10% of patients were addicted to Coffee. 22.20% didn't have any habits.

A majority of patients i.e. 55.55% belonged to Pittakapha Prakruti. 27.78% of patients belonged to Vatapitta Prakruti. 16.67% of patients belonged to Kaphavata Prakruti.

In the study 38.90% of patients reported about practicing masturbation only in adolescence, 27.80% of patients practicing masturbation occasionally and 5.50% of patients gave a history of regular masturbation. 27.80% of patients never practiced masturbation. 61.10% of patients were having BMI between the range of 18-25 which is the normal range followed by 38.90% of patients were having BMI more than 25 kg/m2 which indicates over weight/ obesity. all came with history of no issues with minimum of one year marital life span with regular unprotected intra vaginal coitus which indicates the primary infertility. in 27.80% of the cases, both male and female factors were responsible for infertility. In 72.20% of the cases only male factor was responsible for infertility. It was observed that 100% of the patients were found to have non-tender, palpable epididymis. Spermatic cord findings show that 88.90% of patients had normal non-tender Spermatic cord. 11.10% of patients had tenderness of spermatic cord.

RESULTS

EFFECT OF THERAPY ON SEMINAL PARAMETERS

Sperm Count: Administration of Ikshuradi Lehya was found to be effective in increasing the Sperm Count. **After 60th day,** the mean score for total Sperm Count prior to the treatment was 8.094 million/ml which increased to 9.700 million/ml after the treatment with mean difference of 1.606. It was reported 19.84% increase in sperm count which was found statistical significance at the level of P= 0.016.

After 90th day, the mean score for total Sperm Count prior to the treatment was 8.094 million/ml which increased to 15.846 million/ml after the treatment with mean difference of 7.752. It was reported 95.77% increase in sperm count with the statistical significance of the improvement as P <0.001.

Sperm Active Motility: Administration of *Ikshuradi Lehya* was found to be effective in increasing the Sperm Active Motility. **After 60th day,** the mean score for total Sperm Active Motility prior to the treatment was 30.833% which increased to 33.056% after the treatment with mean difference of 2.222. It was reported 7.20% increase in sperm active motility which was found statistical significance at the level of P=0.036.

After 90th day, the mean score for total Sperm Active Motility prior to the treatment was 30.833% which increased to 35.941% after the treatment with mean difference of 5.412. It was reported 17.55% increase in sperm active motility with the statistical significance of the

improvement as P=0.019. Properties of medicine like

Sperm Sluggish Motility

After 60th day, the effect of Ikshuradi Lehya on Sluggish motility has mean score of 20.611% before and 23.444% after treatments, with the mean difference of 2.833. It was reported 13.74% increase in sperm active motility which was found statistical insignificant at the level of P= 0.056.

After 90th day, the effect of Ikshuradi Lehya on Sluggish motility has mean score of 20.611% before and 25.056% after treatments, with the mean difference of 4.444. It was reported 21.56% increase in sperm sluggish motility which was found to be statistical insignificant at the level of P = 0.072. In any sample the sum of active, sluggish and non-active sperm motility is always 100%. Any alter in the individual value is by increase/ decrease value of other. Here it can be inferred that as there is increase in active motility, sperms might be moved to active motility phase. As there is decrease in non-motility it may due to betterment in motility to next phase. That's why there is makeable improvement in percentage without statistical significance.

Sperm Non Motility

After 60th day, the effect of Ikshuradi Lehya on non- motility has mean score of 48.556% before and 43.500% after treatments, with the mean difference of 5.056. It was reported 10.41% decrease in sperm non active motility which was found statistical significant at the level of P= 0.002.

After 90th day, the effect of Ikshuradi Lehya on Non motility has mean score of 48.556% before and 37.667% after treatments, with the mean difference of 10.889. It was reported 22.42% decrease in sperm non motility which was found to be statistical significant at the level of P = 0.012.

Semen Volume

After 60th day, the effect of Ikshuradi Lehya on Semen Volume has been increased to mean score of 2.247 ml before and 2.303 ml after treatments, with the mean difference of 0.0556. It was reported 2.47% increase in sperm volume which was found statistical insignificant at the level of P= 0.172.

After 90th day, the effect of Ikshuradi Lehya on Semen Volume has been increased to mean score of 2.247 ml before and 2.425 ml after treatments, with the mean difference of 0.178. It was reported 7.92% increase in sperm volume which was found to be statistical significant at the level of P =0.014.

Liquefaction Time

After 60th day, the effect of Ikshuradi Lehya on Liquefaction Time has mean score of 19.167 before and 20.000 after treatments, with the mean difference of 0.833. It was reported 4.34% increase in liquefaction time which was found statistical insignificant at the level of P =0.187.

After 90th day, the effect of Ikshuradi Lehya on Liquefaction Time has mean score of 19.167 before and 21.389 after treatments, with the mean difference of 2.222. It was reported 11.59% increase in liquefaction time which was found to be statistical significant at the level of P =0.042. Mild change was found in liquefaction time in the present study. The liquefaction time was within the normal limit.

EFFECT OF THERAPY ON SEXUALL PARAMETERS

Sexual Desire

After 60th day, the effect of Ikshuradi Lehya on Sexual Desire has mean score of 3.722 before and 4.611 after treatments, with the mean difference of .889. It was improved with 23.88% which was found statistically highly significant (P <0.001).

After 90th day, the effect of Ikshuradi Lehya on Sexual Desire has mean score of 3.722 before and 4.722 after treatments, with the mean difference of 1.000. It was improved with 26.86% which was found statistically highly significant (P <0.001).

Orgasm: The ejaculation along with other motor activities including rapid heart rate and increase in blood pressure, respiration and pleasurable, sensations are referred as orgasm. **After 60th day,** the effect of Ikshuradi Lehya on Orgasm has mean score of 3.333 before and 4.000 after treatments, improvement of 20.01% was found, with the mean difference of 0.667. It was statistically highly significant (P <0.001). **After 90th day,** the effect of Ikshuradi Lehya on Orgasm has mean score of 3.333 before and 4.278 after treatments, improvement of 28.32% was found, with the mean difference of 0.944. It was statistically highly significant (P <0.001).

Rigidity: Effect of Ikshuradi Lehya on Rigidity has mean score of 2.00 before and 2.00 after treatments, improvement of 00% was found, with the mean difference of 00 with a statistical insignificance of the improvement as P 1.000. It's same **after 60th** and **after 90th day**.

Erection: In the present study, **after 60th day,** the effect of Ikshuradi Lehya on Erection has mean score of 3.833 before and 4.222 after treatments, improvement of 10.14% was found, with the mean difference of 0.389. It was statistically significant (P =0.015). **After 90th day,** the effect of Ikshuradi Lehya on Erection has mean score of 3.833 before and 4.444 after treatments, improvement of 15.94% was found, with the mean difference of 0.611. It's statistically highly significant (P<0.001).

Ejaculation: In the Present study, **after 60th day,** the effect of Ikshuradi Lehya on Ejaculation has mean score of 3.833 before and 4.222 after treatments, improvement of 10.14% was found, with the mean difference of 0.389. It's statistically significant (P =0.015). **After 90th day,** the effect of Ikshuradi Lehya on Ejaculation has mean score of 3.833 before and 4.556 after treatments, improvement of 18.83% was found, with the mean difference of 0.722. It's statistically significant (P =0.002).

Shukra Vega (Time taken for Ejaculation): In the Present study, **after 60th day,** the effect of Ikshuradi Lehya on Shukra Vega has mean score of 1.889 before and 2.833 after treatments, improvement of 49.97% was found, with the mean difference of 0.944. It's statistically highly significant (P<0.001). **After 90th day,** the effect of Ikshuradi Lehya on Shukra Vega has mean score of 1.889 before and 2.889 after treatments, improvement of 52.65% was found, with the mean difference of 1.000. It's statistically highly significant (P<0.001).

Post Act Exhaustion: After 60th day, the effect of Ikshuradi Lehya on Post Act Exhaustion has mean score of 2.500 before and 1.556 after treatments, improvement of 37.76% was found, with the mean difference of 0.944. The analysis by applying the paired't' test proved the statistical significance of the improvement as P <0.001. **After 90th day,** the effect of Ikshuradi Lehya on Post Act

Exhaustion has mean score of 2.500 before and 1.222 after treatments, improvement of 51.12% was found, with the mean difference of 1.278. The analysis by applying the paired't' test proved the statistical significance of the improvement as P <0.001.

EFFECT ON SPERM COUNT

1) Severe Oligospermia (Sperm count between 0 to 5million/ml): In the study after 60th day, 4 (22.20%) patients had sperm count between 0 to 5 million/ml. After 90th day, 2 (11.10%) patients had sperm count between 0 to 5 million/ml.

2) Moderate Oligospermia (Sperm count 5 to 10 million/ml): In the study after the 60th day, 7 (38.90%) patients had sperm count between 5 to 10 million/ml. After the 90th day, 1 (5.60%) patient had sperm count between 5 to 10 million/ml.

3) Mild Oligospermia (Sperm count 10 to 20 million/ml): In the study after 60th day, 7 (38.90%) patients had sperm count between 10 to 20 million/ml. After 90th day, 11 (61.10%) patients had sperm count between 10 to 20 million/ml.

4) Normal Sperm Count (sperm count ≥20 million/ml): In the study after 60th day, 0 (00%) patients had sperm count ≥20 million/ml. After 90th day, 4 (22.20%) patients had sperm count ≥20 million/ml.

OVERALL EFFECT OF THERAPY

After 60th day, 11.10% of patients of the group had no improvement. Mild improvement is seen in 50% of the patients. Marked improvement was observed in 38.90% of the patients. In none complete remission was seen.

After 90th day, complete remission was found in 22.20% of patients. Marked improvement was seen in 61.10% of patients. Mild improvement was found in 5.60% of patients. 11.10% patients of the group were unchanged at the end.

DISCUSSION [6,7,8,9,10,11,12]

Ikshuradi Lehya is mentioned as Vajikara, which is indicated in Shukra Kshaya. Ikshuradi Lehya contains Kokilaksha, Gokshura, Kapikachcu, Shatavari, Shweta Musali, Masha and Tila; the above drugs are having the qualities like Madhura Rasa, Snigda-Guru Guna, Sheeta Veerya, Madhura Vipaka, Vatapittashamaka; these qualities are attribute to that of Shukra and tend to cause Shukravruddhi. Shukrala, Balya, Rasayana, Vrushya are the qualities that are by virtue of Prabhava does Shukravruddhi. Kokilaksha does Shukra Shodana. Gokshura and Kapikacchu are having action of improving sexual vigour and the research proving that the drugs like Shweta Mushali, Kapikacchu Kokilaksha, Masha and Tila are spermatogenetic effect; so this particular formulation has enough medication to improve the semen quality and sexual parameters.

CONCLUSION

The formulation Ikshuradi Lehya contains Kokilaksha, Gokshura, Kapikacchu, Shatavari, Swetamushali, Masha and Tila. The studies had proved that, the drug like Kokilaksha, Gokshura, Kapikacchu, Shatavari and Swetamushali are effective in improving libido and enhancing spermatogenesis.

Semen parameters showed marked improvement following medication with Ikshuradi Lehya and was proved to be statistically significant.

After 60th day, there is notable enhancement in sperm count with 19.84% improvement with statistical significance (P= 0.016).

After 90th day, 95.77% of enrichment in sperm count with highly significant p value (P <0.001).

Sexual parameters including Sexual Desire, Orgasm, Erection, Ejaculation, Shukra Vega (Time taken for Ejaculation) showed marked improvement to the tune of 10-50% following medication except Rigidity. In Post act Exhaustion marked reduction found.

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