

TITLE: Evaluate the effect of *Yapana basti* on biological markers of reproduction-A Case Series on Oligozoospermia.

ABSTRACT :

Background: Definition of Infertility is a couple inability to conceive baby after one year of regular unprotect sexual intercourse. In present era of urbanization and industrialization, there has been a drastic change in our lifestyle, dietary habits, and sexual health. According to the World health organisation(WHO), the overall incidence of infertility as 16.7% globally and The male partner is responsible for around 30 to 40 % directly. The main cause of male infertility is Oligozoospermia(Shukra kshaya).

Purpose: To determine the Effect of *Yapana basti* on biological markers(Serum FSH, Serum LH, Serum Testosterone) of Reproduction in Population of Delhi -NCR. **Design:** Case series.**Methods:** *Mustadi Yapana Basti* was given to each participant for 15 consecutive days. The Oligozoospermia (*Shukra Kshaya*) Assessment through Questionnaire and Objective assessment (sperm count and serum biomarkers) was used to evaluate the prognosis as well as to find the therapeutic effect. Data were collected two times before and one month after therapy. **Results:** Five study participants with a sperm count of less than 15 million/ml with a mean age of 29 years (range 25--40) were enrolled in the study. All five participants showed marked improvement at the end of treatment. Results were assessed by serum biomarkers of male reproductive health and semen analysis. *Basti* treatment gives a significant improvement in all the symptoms of *Shukra Kshaya* and semen parameters as well as on biomarkers in this case series. **Conclusion:** *Yapana Basti* shows a

beneficial effect on serum biomarkers of spermatogenesis, and improved sperm count.

परिचय: नियमित असुरक्षित संभोग के एक वर्ष के बाद भी गर्भ धारण करने में असमर्थता को बांझपन के रूप में परिभाषित किया गया है। शहरीकरण और औद्योगीकरण के वर्तमान युग में, हमारी जीवन शैली, आहार संबंधी आदतों और यौन स्वास्थ्य में भारी बदलाव आया है। विश्व स्वास्थ्य संगठन (डब्ल्यूएचओ) के अनुसार, वैश्विक स्तर पर बांझपन की कुल घटनाएं 16.7% हैं और पुरुष साथी सीधे तौर पर लगभग 30 से 40% के लिए जिम्मेदार है। पुरुष बांझपन का मुख्य कारण ओलिगोजोस्पर्मिया (शुक्रक्षय) है। **उद्देश्य:** दिल्ली-एनसीआर की जनसंख्या में प्रजनन के जैविक मार्करों (सीरम एफएसएच, सीरम एलएच, सीरम टेस्टोस्टेरोन) पर यापन बस्ती के प्रभाव को निर्धारित करने के लिए। डिजाइन: केस श्रृंखला। विधियाँ: मुस्तादि यापना बस्ती प्रत्येक प्रतिभागी को दी गई थी लगातार 15 दिनों तक। प्रश्नावली और वस्तुनिष्ठ मूल्यांकन (शुक्राणु संख्या और सीरम बायोमार्कर) के माध्यम से ओलिगोजोस्पर्मिया (शुक्र क्षय) की गंभीरता का मूल्यांकन एवं चिकित्सा की प्रतिक्रिया को निर्धारित किया गया था। बेसलाइन पर और चिकित्सा के एक महीने बाद डेटा एकत्र किया गया था। **परिणाम:** २९ वर्ष (२५-४० की सीमा) की औसत आयु वाले १५ मिलियन/मिली से कम शुक्राणुओं वाले पांच अध्ययन प्रतिभागियों को अध्ययन में नामांकित किया गया था। सभी पांच प्रतिभागियों ने उपचार के अंत में सुधार का अनुभव किया। परिणामों का मूल्यांकन पुरुष प्रजनन स्वास्थ्य और वीर्य विश्लेषण के सीरम बायोमार्कर द्वारा किया गया था। बस्ती उपचार शुक्राक्षय के सभी लक्षणों और वीर्य मापदंडों के साथ-साथ इस मामले की श्रृंखला में बायोमार्कर पर एक महत्वपूर्ण सुधार देता है। **निष्कर्ष:** यापना बस्ती शुक्राणुजनन के सीरम बायोमार्कर और शुक्राणुओं की संख्या पर लाभकारी प्रभाव दिखाती है।

Keywords: Biomarkers, infertility, *Shukra*, Oligozoospermia, *Yapana Basti*.

INTRODUCTION:

Background:

The clinical definition of infertility as per WHO Glossary is that it is the reproductive system disease or disorder classified by the failure to achieve

a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse". [1, 2]. As fertility can be influenced by a variety of factors, one possible explanation for the declining trend is that there are environmental and/or occupational factors along with modified lifestyle practices that contribute to infertility.[3-6] The key factors that are associated with infertility such as addiction of smoking, alcohol and illicit drugs, Metabolic diseases such as diabetes and obesity, psychological stress, the advanced age of marriage, changing dietary practices, and excessive coffee consumption. Other factors such as testicular heat exposure, intense cycling exercise, lack of sleep, and exposure to electromagnetic radiation from mobile phone use. A high-fat diet and obesity, resulting from an unhealthy lifestyle, affect fertility, but also the development of offspring and their health in later stages of life.[7] Due to all these factors, along with postponing parenthood, infertility is increasing day by day. Infertility obscures the most intimate relationship.

The male partner is responsible for around 30 to 40 % of total cases, the female is about 40 -50% and both for 10 % of cases. In about half of the cases, the Male factor is involved. [8, 9] Causes of male infertility include abnormal sperm production or function, impaired delivery of sperms, general health and lifestyle issues, and exposure to environmental factors.

[10-12]

The method of evaluation of male infertility starts with a semen analysis, which evaluates sperm count, motility, and sperm morphology especially.[12] It is an essential investigation for the assessment of male infertility and its interpretation helps a vital role in the treatment of male infertility. Low sperm

count (Oligozoospermia) and poor sperm quality are responsible for approximately 90% of male infertility cases.^[9] Oligozoospermia is one of the main factors responsible for male infertility. Oligozoospermia, a pathological term describing a sperm density below the fifth centile infertile men,^[13] recently reduced sperm count from 20 to 15 million/ml.^[14] Decrease sperm count leads to a decrease in the chance of conception and hampers fertility.

Oligozoospermia resembles with *shukra-kshaya*. In *Ayurveda*. *Shukra-kshaya* is a condition in which there is the qualitative and quantitative reduction in *shukra dhatu* but in oligozoospermia, there is a quantitative reduction of sperms. *Shukra kshaya* is diagnosed with the help of subjective parameters described in classical *ayurvedic* texts.

Ayurveda has described several drugs and special therapeutic procedures to treat the problem of Infertility. *Acharya Charaka* also specially mentioned *Basti Karma* for the enhancement of *Shukra dhatu* as well as for the management of *Śhukra-doṣha*. According to the Classics, It is indicated that properly administered *Basti* enhances the low level of *Shukra* and improves the virility, vigor, and life span of an individual.^[15]

Yapana Basti: *Basti karma* is a widely practiced *panchakarma* treatment in India. *Basti* is the principal treatment of *Vatika* disorders and *Vata Dosha* is mainly involved in the condition of *Shukra Kshaya*. *Basti* is considered as half treatment and According to some Acharyas, it is the complete treatment; no medicine can be compared with *Basti chikitsa*.^[16] One of the prime causes of *Shukra Kshaya* is *ativyavaya*(excessive indulgence in sex) and in disease due to *maithuna*(sex), *Yapana Basti* is indicated. Moreover, the *Yapana Basti* are having *Rasayana as well as vatahara* effect and can

be administered for a longer duration without any adverse effects. It has properties of both *Sneha Basti* and *niruha Basti* and promotes semen, muscular tissue as well as helps sterile women and men to get children. The dose of *yapana Basti* is 600 ml for the present case series.

The aim and objectives behind this case series was to determine the response and therapeutic effect of *Yapana Basti karma* in oligozoospermia using standardized outcome measures especially serum biomarkers for Reproduction.

MATERIALS AND METHODS

Sample Recruitment

Case series was designed as prospective. Five diagnosed cases of oligozoospermia who visited Ayurvedic and Unani Tibbia College and hospital, Govt. of NCT of Delhi for treatment were enrolled between December 2019 and February 2020. Participants having ages from 20 to 40 years irrespective of, irrespective of religion, occupation, and socioeconomic status that were willing to give the informed consent form were included. It was decided to exclude people with history of diseases such as uncontrolled diabetes, mental illness and severe hypertension that require medication. Participants who were unwilling to follow with the study SOPs were considered unsuitable for this study. The study was approved by an institutional ethical committee, then study was registered in **Clinical Trial Registry India** at vide (CTRI) number- **CTRI/2019/08/020538** on 05/08/2019.

Study Intervention:

In this study, *Mustadi yapana Basti* mentioned in *Sushruta Samhita* is selected.^[17] *Acharya Charaka* mentioned *Mustadi Yapanaa Basti* for “*Shukra-mansa-bala-janana*”(Enhance the semen, muscles and gives strength) and “*Sadyobalajanaorasayanchet*” (gives strength quickly and having rejuvenating effects) in *Sidhi Sthana*.^[18] *Acharya Sushruta* mentions it as *Rajabasti* and it is superior to all *Yapanaa Basti* and mentions its qualities as “ *balya-sjivvano-vrishaya*”(Prolonging life, gives strength and enhance sperm or semen).^[19] The raw drugs for the preparation of *Mustadi Yapana Basti* were purchased from the market of Khari Bawli, New Delhi. Physical verification of the drugs was done and certified from Dravya Guna Dept. of Ayurvedic and Unani Tibbia College and Hospital. Parameters of the finished product of *Basti dravya* were got analyzed from “Sophisticated Industrial Materials Analytic Labs. Pvt. Ltd.”(Govt. Approved).Each participant was treated for 15 consecutive days. During each treatment, 600 mL of *basti dravya* was used for each participant. Fresh *basti dravya* was prepared daily and administered through the anal route. Subjects were advised to lie down in the left lateral position with their left leg stretched out, while the right leg flexed at the knee and held near abdomen during administration. It is believed that administered *Basti dravya* passed out the anal route within One *Muhurta* (48 min).^[20]

Outcome Measure

The *Shukra Kshaya* assessment questionnaire, Semen analysis, and serum biomarkers of reproduction(Sr.FSH, Sr.LH, Sr. Testosterone, Sr.

Inhibin-B) were used to evaluate the nature and severity of oligozoospermia as well as response to the *Yapana basti*. The *Shukra kshaya* assessment questionnaire is a ten-item questionnaire assessing the different dimensions of *Shukra Kashya* including *klaibya* (erectile dysfunction). *Klaibya* was assessed by the international index of erectile dysfunction. Each question is rated on a scale from 0 to 4 with a total score of 36; more the score towards the higher side, more severe the disease (*shukra kshaya*). Additionally, the adverse events were recorded in form if occurred during the study for safety purposes. Collection of data were done two times, firstly at the time of enrollment and secondly when the treatment was over. Participants also were asked to give their feedback or perspective about the overall effect of therapy at the end.

Data Analysis

For analysis of demographic profiling and ayurvedic parameters descriptive statistics were used. Total (mean) scores and the percentage of improvement were calculated to find out the differences in outcomes. Paired *t*-tests were used to compare means before and after the intervention.

RESULTS

All the five study participants completed the study. The mean age of 29 years (range 25 y-40 y; SD \pm 6.2) was observed. As the sample size is small, data of individual participants were examined. Comparing baseline to after treatment data, all five participants experienced improvement. For two

participants, the percentage of improvement ranged from 78.9% to 84.6%. In other three participants, the overall improvement was within a range of 54.1% to 72.2%. (Table 1, Figure 1).

Table 2 and Figure 2 reported the mean scores of *Shukra Kashya* and *klaibya*. At baseline, the mean score of *Shukra Kshaya* was 21.6, which decreased at the end which showed improvement, and at the end of the study, the corresponding score was 6.2. The mean score of *klaibya* at the baseline was 13.8, which was increased over time- indicative of improvement, and at the end of the study, the corresponding score was 21.

Table 3 and Figure 3 reported the mean scores of Serum biomarkers of reproduction. The mean score of *Serum FSH* was 6.15 before the intervention, which increased at the end to corresponding score of 7.71 indicative of improvement. The mean score of *Serum LH* at the baseline was 4.93, which was decreased over time- showed no improvement and at the end of the study, the corresponding score was 4.73. The mean score of Serum testosterone was 96.92, which increased to 453.81 indicative of significant improvement and the mean score of serum inhibin-B at the baseline was 86.01, which increased to 138.19 overtime showed improvement.

Table 4 and Figure 4 report the mean scores of Semen Parameters. At baseline, the mean score of *Sperm count* was 10.4, which increased over time—indicative of improvement, and at the end of the study, the corresponding score was 55. The mean score of *Normal Sperm* at the baseline was 20.4, which was increased over time- showed improvement

and at the end of the study, the corresponding score was 50.4. The mean score of Total motility was 45.4, which increased to 62 indicative of significant improvement. Other parameters also showed improvement as shown in Table 4.

To find out the statistically significant changes in pre and post test, the Comparison of means was also done. A paired sample t-test was used for comparing the means of *Shukra Kshaya*, Serum Biomarkers, and Semen Parameters at baseline and at the end. For the baseline and post-treatment, there was an overall improvement in *Shukra Kshaya* and *Klaibya* (significant at $P < .005$) Table 5.

On Objective parameters of assessment especially on serum biomarkers, there was an overall improvement in Serum Testosterone (significant at $P < .001$) Table 6 and for comparison in Serum FSH, Serum LH, and Serum Inhibin-B, the improvement was not significant ($P > 0.05$) (Table 6).

For the comparison of means in semen parameters, there was an overall improvement in all parameters (significant at $P < .05$) especially the sperm count, sperm active motility, and semen volume (Table 7).

DISCUSSION:

Since the old days, the emphasis on getting a child is considered as the highest duty. To produce an offspring is a dream of every married couple since time immemorial mankind put a lot of emphasis on producing an offspring. The infertile person is said to be *Nindya* according to *Acharya Charaka*. The person without a child is compared to be a tree without branches.^[21] The grief of a man who faced the infertility problem is not less

in Modern society. Infertility affects the psychological harmony, reproductive life, and social function of the couple. Infertility has a direct relationship with impairment in the semen i.e. *Shukra Kshaya*. *Sodhana* therapies play a very important role in the management of *Shukra Kshaya*. *Basti* by expelling out *Vit, Shleshma, Pitta, Anil, Mutra* offers firmness of the body and enriches *Shukra*.^[16]

Mustadi Yapana Basti is a type of *Yapana Basti* used to increase *Bala, Mamsa, and Shukra*. *Yapana Basti* is *Mridu* in action, they promote *Dhatu*. It is promotive of *Shukra, Mamsa*, and strength when given to the person involved in excessive sexual indulgence. It is curative of all diseases and suitable in all seasons. It induces fertility in sterile women and men.^[22] All the actions which are necessary for the longevity of life can be attributed to *Mustadi Yapana Basti*.

Mustadi Yapana Basti contains *Bala mula, Gokshura, Purnanava, and Madan phala*, etc. The *Kalka* contains drugs like *Priyangu, Sauf* and *Yaṣṭimadhu*, etc. The other conventional drugs are *Kṣhira, Madhu, Go-Ghrit, and Mansa Rasa*. This *Basti* is especially indicated for *Shukra Kshaya*. Due to ingredients like *milk, cow ghee, Sida cordifolia, Pluchea lanceolata, Tribulus terrestris, Glycyrrhiza glabra* which have properties of *balya, snigdha, jivaniya, guru, and madhur rasa, madhur vipak and sheet virya; mustadi yapana basti* reduces *dourbalya* as well as others symptoms due to vitiated *vata*.

Maximum ingredients present in *Mustadi Yapana Basti* have antioxidant properties and beneficial effects on semen analysis and sperm count. The

aqueous rhizome extract of *Cyperus rotundus* (ARECR) showed an increase in sperm count, sperm motility, testosterone, and restoration of antioxidants. This indicates the beneficial effect in preventing the dysfunction of testicular cells.^[23] *Tinospora cordifolia* is useful in enhancing male sexual activity and treating various sexual disorders like an erectile failure, premature ejaculation, lack of sexual desire, and ejaculatory incompetence.^[24] *Sida cordifolia* serves as a tonic to restore sexual strength, promote spermatogenesis, and enhance male fertility.^[25] *Boerhavia diffusa* rejuvenates liver, male reproductive system, and other organ systems, aphrodisiac, increases libido, erection, and quality and quantity of semen.^[26,27] *Vetiveria zizanioidis* is useful as sperm purifying and improving sperm quality herb.^[28] The herb *Tribulus terrestris* possesses androgen, testosterone, dihydrotestosterone (DHT), and dehydroepiandrosterone (DHEA) increasing property.^[29] Studies showed that aqueous extract of *Solanum nigrum* bears pro fertility properties like an increase in sperm counts, percentage of motility, morphology, and percentage of live sperm, the blood level of follicle-stimulating hormone, Luteinizing hormone and testosterone, hematological parameters, testis, epididymal and general body weights.^[30] So overall *Mustadi Yapana Basti* has ingredients that have a beneficial effect on sperm quality, quantity as well as on biomarkers of spermatogenesis.

The results suggest that there was a marked improvement in *Shukra Kshaya*, semen parameters (sperm count) along with serum biomarkers of reproduction (specially Sr. Testosterone) with *Yapana Basti* at the end of the study in most patients. These results are similar to other studies in terms of

effect in semen parameters but novel in the case of serum biomarkers. No adverse events or side effects were reported during the entire study period. The overall feedback of the participants that were collected at the end also supported the improvements noticed in the sperm count, *Shukra Kshaya*. The following quotes indicate some of the impressions of participants in this study:

I was very happy that I was capable to perform better during sexual intercourse.

I was felt a marked improvement in my confidence and desire now.

During the treatment, I felt very relaxed and felt improvement in weakness.

I was able to maintain my erection longer than before.

So the aim of our study “to determine the usefulness of *Yapana Basti* on serum biomarkers of spermatogenesis” was fulfilled because we believe that this is novel approach in case of infertility treatment.

LIMITATION:

The small size of study resulted in lack of generalizability and the lack of a control group also limits the outcome validation of the study, and the biases due to single group study cannot be ignored.

CONCLUSION:

Yapana basti may be beneficial for oligozoospermia(*shukra kshaya*). *Yapana Basti* shows a beneficial effect on serum biomarkers of spermatogenesis especially serum testosterone and improved sperm count. The results and the impressions of the participants encourage the researchers to pursue further rigorous research on this modality using a larger sample and adding a comparison group.

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Subject	Baseline	At the end of the study	Percentage Improvement Baseline vs End of study
1	24	11	54.2
2	19	4	78.9
3	18	5	72.2
4	21	7	66.7
5	26	4	84.6

Table 1: *Shukra kshaya* total scores of participants and percentage improvement.

Subjective parameter	Baseline	At the end of the study
<i>Shukra Kshaya</i> Score	21.6(3.36)	6.2(2.9)
<i>Klaibya</i> Score	13.8(2.39)	21(0.7)

Table 2: *Shukra Kshaya* and *Klaibya* Mean Values (SD).(N = 5)

Serum Biomarkers	Baseline	At the end of the study
Serum FSH	6.13(4.5)	7.75(3.7)
Serum LH	4.93(4.02)	4.73(2.28)
Serum Testosterone	96.92(93.08)	453.81(93.49)
Serum Inhibin-B	86.01(13.25)	138.19(55.57)

Table 3: Serum biomarkers of spermatogenesis Mean Values (SD).(N = 5)

Semen Parameters	Baseline	At the end of the study
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Sperm Count	10.4(1.67)	55(23.49)
Semen Volume	1.26(0.67)	2.1(0.65)
Normal Sperm%	20.4(15.2)	50.4(14.52)
Total Motility	45.4(13.54)	62(11.51)
Active motility	17(10.34)	38(13.04)

Table 4: Semen Parameters Mean Values (SD).(N = 5)

O u t c o m e measures	Timepoints	Mean(SD)	95% Confidence interval	P-value
S h u k r a kshaya	Baseline vs End of study	15.40(3.78)	10.70 to 20.10	0.0008
Klaihya	Baseline vs End of study	7.2(2.28)	10.03 to 4.37	0.0021

Table 5: Mean comparison of subjective parameters.

O u t c o m e measures	Timepoints	Mean(SD)	95% Confidence interval	P-value
Sr.FSH	Baseline vs End of	1.6080	4.3692 to 1.1532	0.1812
Sr.LH	study	0.1980	5.1155 to 5.5115	0.9226
Sr. Testosterone	Baseline vs End of	356.8960	458.7858 to 255.0062	0.0006
Sr. Inhibin-B	study	52.1800	106.7534 to 2.3934	0.0567

Table 6: : Mean Comparison of Serum biomarkers.

O u t c o m e measures	Time points	Mean(SD)	9 5 % Confidence interval	P-value
Sperm count	Baseline vs End of	44.60(22.89)	7 3 . 0 2 t o	0.0121
Semen Volume	study	0.840(0.54)	16.18	0.0256
Normal Sperm%	Baseline vs End of	30.0(6.4)	1 . 5 1 2 t o	0.0005
Total Motility	study	16.60 (11.2)	0.168	0.0295
Active motility	Baseline vs End of	21(11.9)	3 8 . 0 5 t o	0.0171

Table 7 : Mean Comparison of Semen parameters.