



Efficacy of “Bala- tail Utterbasti” in Oligospermia -A Clinicopathological Study.

More Sunil S¹. More Manjusha S²

1. Professor & Head, Department of Streerog & Prasutitantra, S. S. Ayurved College, Panchavati, Nashik, M.S.-422003, Email Id: sunilmore68@rediffmail.com
2. Associate Professor & Head, Department of Panchakarma, S.S.Ayurved College, Panchavati, Nashik.M.S. Email Id: manjushasunilmore@gmail.com

Introduction:

10 % of the world population suffer from sterility. 80 % of the couples achieve conception if they then desire, within one year of having regular intercourse with adequate frequency. Infertility is a failure to conceive within one or more years of regular unprotected coitus. Infertility is the social stigma in our country, particularly in urban areas, which affects the couples psychological harmony, sexual life and social functioning. Male infertility has got less attention, even though it is widely described. According to a population study, in 30% of the infertile couples problem lies for males. The most common reason for infertility in male is the inability to produce adequate number of healthy sperms leading to oligospermia. Ksheenashukra is one of the major variety of shukradosha, explained in ayurveda. In ksheenashukra there is diminished level of shukra both quantitatively and qualitatively which ultimately leads to childless couples. In ayurvedic text, many herbal preparations mentioned in management of ksheenashukra. Bala-tail Utterbasti said to be vrushya, hence can be considered as ideal treatment for shukradosha. This present study is intended, to clinical evaluation of action Bala-tail Utterbasti in oligospermia. Currently several modern medical therapies along with surgeries are available to overcome this disorder causing mental and social discomfort. The case study included Oligospermia; the objective of present study was to evaluate the efficacy and safety of the Bala-tail Utterbasti (i.e. insertion of oil-based medicine through urethra into the bladder cavity). Uttar basti has an ancient medical reference of renowned ayurvedic surgeon ‘Sushruta’ in his text Sushrut Samhita Sharirstan2/10. In reference with this context, a clinical study using Bala-tail Utterbasti was performed to evaluate its efficacy in infertility disorders

OBJECTIVES:

- Preparation of Balatail.
- To evaluate effect of Balatail Utterbasti on Ksheenashukra (Oligospermia)

MATERIALS & METHODS

- Type of study-It was a *open Randomised study*

Drug used : Bala-tail.

Dose-20ml

Route of administration of drug-Through urethra into the bladder

Instrument use-Infant feeding tube(no.7), Disposable syringe(5ml)

Time-Daily once for 3days in a month

Duration-For 3 consecutive months

Procedure-20ml Bala-tail was administered under all aseptic precautions through urethra into the bladder in a operation theater as prescribed quantity.

Follow-up of patients-On 0,30th day,90th day have been taken.

- Method of preparation of study drug: Bala-tail used for utterbasti was prepared by 'Snehapakvidhi' mentioned in Bharatbhaishajya- Ratnakar 4681, at SSAM&H Nasik.

Source of data: In present clinical study 30 male patients were selected, irrespective of their religion.

All patients were selected from OPD & IPD section Srirog-prasuti department of S.S.A.M&H, Nasik

Sampling: 30 cases of ksheenashukra were selected incidentally. Patients were registered and studied with the help of CRF(case record form) prepared for the study. Informed consent was obtained before study.

Inclusion criteria

- Diagnosed case of Oligospermia
- Married couples without any evidence of conception.
- Known case of primary infertility, secondary infertility or unknown infertility with or without sexual dysfunction.

Exclusion criteria

- Azospermia
- Congenital testicular disorders, Genetic disorders,Endocrinal disorders.
- With other systemic disorders like IHD, Hypertension, Nephrotic conditions, Tuberculosis.
- Traumatic or surgical conditions of genitor- urinary tract.
- Orchitis.

Diagnostic criteria

Diagnosis was entirely based on the sperm count as per World Health Organization criteria for normal semenogram (W.H.O., 1992) (i.e. sperm count less than 20 million cells / ml of semen), with or without abnormality in the volume and motility.

Laboratory Investigations

- Semen analysis –1.Sperm count.
2. Semen volume.
3. Sperm motility.

Sampling method and Research design

Total 30 patients diagnosed as ksheenashukra were selected from the OPD &IPD of Srirog-prasuti department of S.S.A.M&H, Nasik.

Study Design: Present study was a single blind study of pre and post test design. Study was conducted after ethical clearance.

Intervention

- Amapachana – Amapachak vati 500mg two times daily with ushnodaka before food till nirama-lakshana appears.

- Kostashuddhi - Gandharvaharitakyadi yoga-2to6gm dose according to kosta, in stat dose for one night.
- Bala-tail Utterbasti- 20ml once in a day for 3days in a month for 3consecutive months.

Drug review:

Chemical Constituent

1. Bala

Chemical constituent contains-Ephedrine like alkaloid.

2. Tila

Chemical constituent: Vitamins-thiamine, niacin, riboflavin, nicotinic acid, folic and ascorbic acid, pyridoxin, vit.A, -tocopherol.

Drug Action:

Bala-tail as a whole has a

Balya,snehana,sandhanias, vranashodhan, varanaropana, Medhya, Shulaprashamana, Vagikara, Mutrasangrahaniya, Hri dya, Shukrala, Prajasthapana, Jwaraghna, Ojavardhaka,

Assessment

Assessment of the treatment was entirely based on the seminal parameters. Semen analysis was done before starting the treatment and after completion of whole treatment. Following criteria were observed.

- 1.Improvement in sperm count.
- 2.Improvement in motility of sperm.
- 3.Improvement in the volume of semen.

The data obtained from study i.e before and after the treatment are analyzed statistically using student's t-test (paired).

Sperm Count

- No improvement - no increase or decrease in sperm count
- Mild improvement - 1-10 million / ml increase
- Moderate improvement - 11-20 million / ml increase
- Marked improvement - 20 million / ml and above

Motility

- No improvement - no increase or decrease in motility
- Mild improvement - 1-15% increase in motility
- Moderate improvement - 16-30% increase in motility
- Marked improvement - 30% and above increase in motility

Volume

- No improvement - no increase or decrease in volume of ejaculate

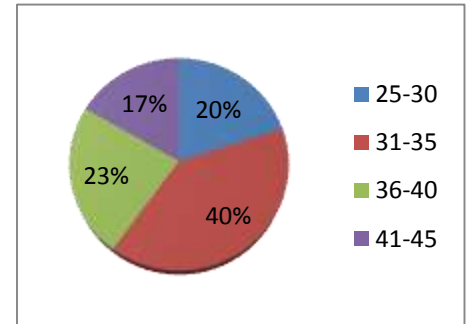
- Mild improvement - 0-1ml increase in volume of ejaculate
- Moderate improvement - 1-2ml increase in volume of ejaculate
- Marked improvement - above 2ml increase in volume of ejaculate

The complete results of the treatment were observed and ascertained:

I Demographic data:

Table No.1 Showing distribution of 30 patients of Oligospermia according to age:

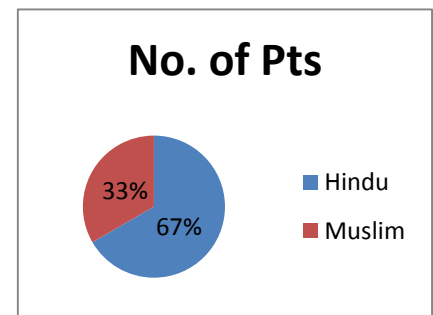
Age (Years)	No.of Patients	Percentage
25-30	6	20%
31-35	12	40%
36-40	7	23.33%
41-45	5	16.67%



The maximum number of patients were observed in age group between 31-35 years (40%).

Table No.2 Showing distribution of 30 patients of Oligospermia according to religion:

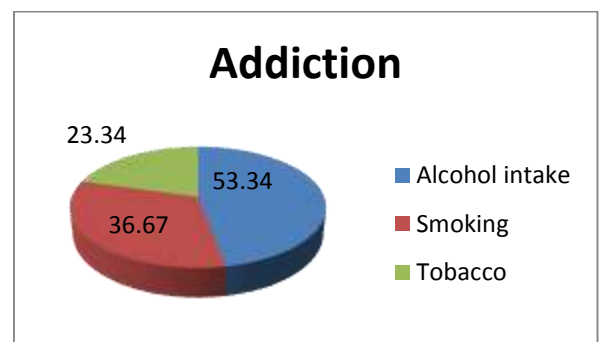
Religion	No.of Patients	Percentage
Hindu	20	66.67%
Muslim	10	33.33%



The maximum number of patients were observed in Hindu (66.67%) religion.

Table No.3 Showing distribution of 30 patients of Oligospermia according to addiction:

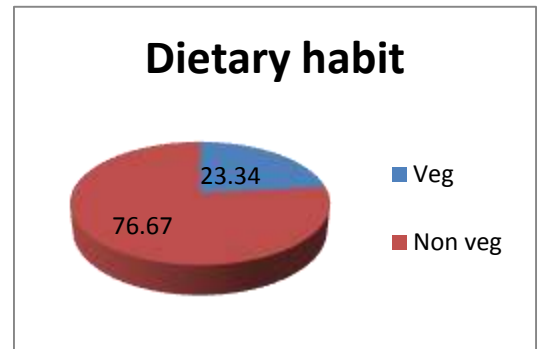
Addiction	No.of Patients	Percentage
Alcohol intake	16	53.34%
Smoking	11	36.67%
Tubacco chewing	7	23.34%



The maximum number of patients were observed under addicted to alcohol intake (53.34).

Table No.4 Showing distribution of 30 patients of Oligospermia according to dietary habit:

Diet	No.of Patients	Percentage
Veg	7	23.34%
Non veg	23	76.67%



The maximum numbers of patients were observed in Non-veg diet group (76.67%).

RESULTS

Table 1: Showing sperm count before and after treatment

Sperm Count Improvement(million/ml)	Sperm count in Millions before treatment	Sperm count in Millions after treatment
Marked (20mil/ml&above)	00	05
Moderate(11-20)	16	02
Mild (1-10)	12	20
No (increase or decrease)	2	3

$\sum d$	286.8	SE d	9.56
SD (d)	11.1250	SE (d)	2.0311
T	4.706	p value	p<0.001

Remarks: Highly significant

Table 2: Showing sperm motility before and after treatment

Motility Improvement	Sperm Motility before treatment	Sperm Motility after treatment
ked30%and above	04	04
Moderate-16-30%	20	02
Mild-1-15%	05	20
No(increase&decrease)	1	03

$\sum d$	267	d	8.9
SD (d)	10.3934	SE (d)	1.8975

T	4.690	p value	p<0.001
---	-------	---------	---------

Remarks: Highly significant

Table 3: Showing semen quantity before and after treatment.

Volume Improvement	Semen quantity before treatment	Semen quantity after treatment
Marked(above 2ml)	18	03
Moderate(1-2ml)	12	09
Mild(0-1ml)	00	18
No(increase or decrease)	00	00

D	0.7067	SE d	0.1096
SD (d)	0.6005	P value	P<0.001
T	6.4479		

Remarks: Highly significant

The objective parameters like sperm count in million/ml (Table No 1), sperm motility in percent (Table No 2), and semen volume in ml (Table No 3) were studied before and after treatment. These were subjected to statistical analysis by student's t-test (paired). The results are as listed in the tables.

Balatail Utterbasti showed p value <0.001, proving highly significant in increasing the count of sperm.

Bala-tail Utterbasti was also highly significant with p value < 0.001 in increasing the motility of sperm and volume of semen.

Out of 30 patients, 18 showed normal value of sperm count i.e above 20 million after treatment. Hence the effect of Bala-tail Utterbasti was on 60% of patients.

DISCUSSION

The hypothesis on the action of Bala-tail Utterbasti and ksheenshukra was verified by this study. So far only minimum number of work has been carried out in this regard. The result shows that it has significant positive result in improving seminal parameters.

DISCUSSION AND OBSERVATIONS

Data was collected in the Case Record form designed for the purpose and analysed after the completion of the study.

Age:

Out of total 30 patients in whom study was completed belonged to age group between 25 to 45 years.

Maximum of 12 patients which belonged to age group of 31 to 35 years and 6 patients 25 to 30 years respectively. This is because in India this the age when males get married. And when they don't conceive

pregnancy, they think of treatment, due to increased awareness about infertility. Further, increasing incidence of oligospermia is seen in very young subjects, but very specific reasoning cannot be given as sample size is small.

7 patients are between the age group of 36-40 years and 5 patients are between 41 to 45 years, this is probably because of the awareness that on advancing age fertility decreases. Hence may this age group have restricted to try further?

Religion:

Maximum 20 patients were Hindus and only 10 were Muslims, no specific reasons can be given but probably this is due to more proportion of Hindus inhabiting the population area of study.

Food Habits:

Maximum 23 patients were non-vegetarians consuming mixed diet which usually is comprised of more of katu-amla-lavana, ushna gunas which are the nidanas for ksheenashukra as mentioned in classics.

Addiction:

16 patients were addicted to Alcohol intake which acts as leydig cell toxin which damages the normal morphology of sperms and reduces normal sperm count.

Tobacco is said to reduce volume and sperm count and 11 patients belong this group.

Anya streesanga may lead to sexually transmitted disease (STD). But STD was not seen in patients reported for study.

Sperm Count:

- After the treatment and before treatment semen analysis for sperm count compared, it was found that sperm count had been increased after treatment.
- After the treatment, in 5 patients there was marked improvement, 20 patients showed mild improvement and 2 patients moderate improvement. In 3 patient sperm count remained same before and after treatment.

Sperm Motility:

- Although abnormality in motility was not the criteria for study but the assessment was made. Majority of 4 patients showed marked improvement in motility of sperm. No improvement was seen in 4 patients. Mild improvement was seen in 21 patients and moderate improvement seen in 1 patient.
- Simultaneously the number of motile sperms was increased & number of sluggishly motile and non-motile sperms were decreased.

Sperm Volume:

- Volume of the semen depends on the secretion of accessory sex glands. In the present study abnormality in the volume was not observed in majority of the patients. The increase in volume suggests that Bala-tail Utterbasti acted on the accessory sex organs and increased their secretions.

- Liquification time is said to be normal within 40 minutes. Liquification time may be a delayed due to the increased viscosity of the seminal fluid, which may be taken for increased picchilata of kapha. Improvement in the liquification time may have been achieved by the drugs in the Bala-tail which may have acted by decreasing the viscosity of the seminal fluid, i.e. by decreasing the picchilaguna of kapha.
- The highest increase in the volume was noticed i.e. by 2 ml in three patients. Moderate increase in 9 patients & mild increase in 8 patients.
- Among the signs and symptoms attributed to ksheenashukra only dourbalya, mukhashosha and delayed ejaculation was noticed in majority of the patients. All the above symptoms were found to be reduced in both the
- These results can be attributed to vrushya effect Bala-tail Utterbasti for the study. The ultimate aim of treating Oligospermia or may be any case of infertility is to get conception. Though the duration of the treatment was less in the study, it was very pleasing to hear that 16 couples achieved conception after the treatment in variable period of time.
- Infertility is the problem of the couple, so the history taking and treatment also should be evaluated for both partners. Although in the study the male factor was corrected in majority of the patients, various other factors also contributed to infertility which were not considered in the present study.

CONCLUSION

- Ksheenashukra is a disease which can be confidently compared to oligospermia.
- All the lakshanas mentioned for ksheenashukra such as sada, bhrama etc. were not found in the patients. So a lab investigation like semen analysis plays a vital role in diagnosis and assessment of prognosis.
- Semen analysis can be interpreted on the basis of shukradosha mentioned by acharya Charaka.
- Period of sexual abstinence is important before semen analysis which ranges from 3 to 7 days.
- In this study improvement was seen in the seminal parameters.
- Statistically significant result obtained in this present study. Good result in terms of sperm count, sperm-motility, and semen volume was observed.
- Based on the study it can be concluded that Bala-tail Utterbasti is beneficial in conditions where sperm count is less, semen volume reduced and sperm motility is reduced.
- Bala-tail Utterbasti is beneficial in treatment of ksheenashukra with special reference to oligospermia.

References:

1. Acharya Priyavrata Sharma, editors. *Charaka Samhita of Agnivesa*. Vol.2, 6th Edition 2000. Chaukhamba Sanskrit Sanstan Varanasi, Page.no.769to771, Vonivyapad Chiksadhya-30.
2. Prof.J.K.Ojha, editor, *A Hand Book of Dravyaguna*. 1st.ed.Sanskrit Pratishthan. vanaspatika Dravya Varanasi, Chaukhamba 2004 page no.45and346
3. Premavati Tivari, editor. *Ayurvediya Prasutitantra Evam Striroga*. 2nd ed. Chaukhamba Orientalia, Varanasi, 2nd part- page478-496.
- 4 T.N. A.Jeffcoate, editor. *Principles of Gynaecology*. 3rd. London. Butterworth & co. Ltd Publication, 1967, Page no. 749-751.

5. Sushrut Samhita Sarirasthanam by Bhaskar Govind Ghanekar, Published by Meharchand LachhmandasPublication, reprint-March2006 New Delhi. Page no.23, 2/10.
6. Stri.Nagindas Chhaganlal Shah Sangrahit Bharatbhaishajya Ratnakar, 3rd part-Page no.585 (4681).Reprint2005Prakashak B.Jain Publication (Pvt.Ltd) New Delhi.