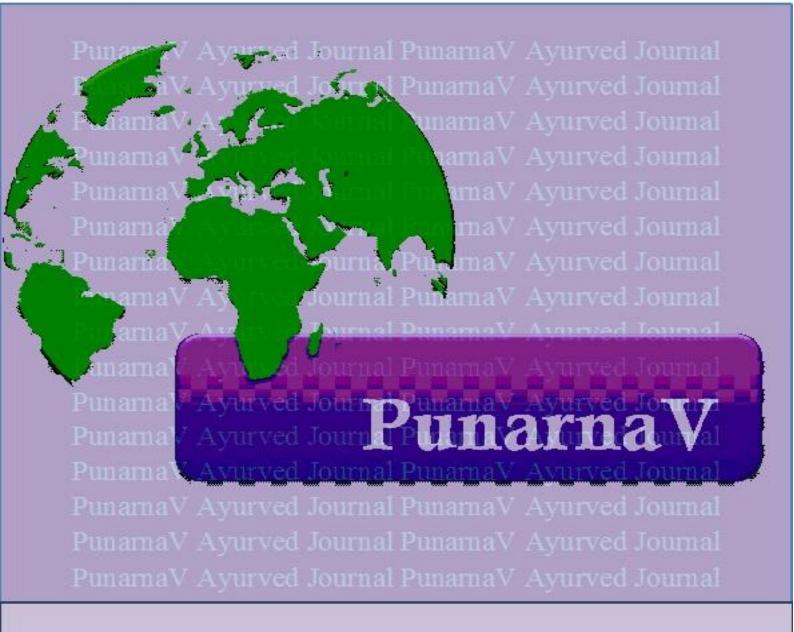
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A CLINICAL STUDY ON SHVETA PALANDU SWARASA BHAVITA YAVANI IN THE MANAGEMENT OF OLIGOZOOSPERMIA

JITENDRA VARSAKIYA¹, MANDIP GOYAL²

¹P.G. scholars, ² Assistant Professor,

Dept. of Kayachikitsa, I.P.G.T & RA, Gujarat Ayurved University, Jamnagar, India

ABSTRACT:

Infertility has been considered as a cursed condition and is looked as a medico-social problem. Today increased mental stress, tobacco—alcohol addiction, pollution, faulty eating & clothing habit, change in culture etc. have endangered reproductive capacity of men, leading to oligozoospermia, ultimately to infertility. Various modern therapeutic measures and associated reproductive technologies like artificial insemination, test tube baby etc. are expensive and common men cannot afford for it. This is reason why; today to explore fertility agents from herbal source is of top priority in the field of research in Andrology. As per Ayurveda, Vajikarana drugs if administered after proper Shodhana provide better effect. Shveta Palandu Swarasa Bhavita Yavani, a herbal preparation has been mentioned in classics as Shukravardhaka.

Aims and objectives: To evaluate role of Virechana Karma and Shveta Palandu Swarasa Bhavita Yavani Vati on Oligozoospermia.

Materials and methods: For the clinical study, 19 male patients complaining of symptoms and features of oligozoospermia or suffering from primary or secondary infertility for more than one year and having sperm count less than 15 million/ml were selected irrespective of religion, caste. Before administrating of Shveta Palandu Swarasa Bhavita Yavani Vati in the dose of 4 Vati (500mg each) twice a day morning and evening with Anupana of 5 gm of Ghrita, Virechana procedure was carried out.

Results and Conclusion: Statistical analysis of the obtained data revealed that administration of Shveta Palandu Swarasa Bhavita Yavani Vati after performing of Virechana provided statistically significant increase in sperm count as well as S.LH level and reduction in abnormal sperm form.

Key word: Ksheena Shukra, Oligozoospermia, Shveta Palandu Swarasa Bhavita Yavani Vati, Virechana.

INTRODUCTION

Infertility is empirically defined as the inability of a couple to conceive even after 1 year of coital activity without contraception (Mosher and Pratt 1991).

Correspondent:
Dr. Jitendra Varsakiya
P.G. Scholar
Department of Kayachikitsa,
I.P.G.T & RA,
Gujarat Ayurved University,
Jamnagar.

Historically, the concepts of infertility have changed over time, and also the problems. During ancient times, the main sufferer of the problems was supposed to be the female but with the advent of diagnostic pathology, it was realized that males were also responsible for infertility. Data available over past years reveal that in approximately one third of cases, significant pathology was found in male alone. Oligozoospermia is one of the major causes of infertility in male. Oligozoospermia is defined as low sperm count i.e 15 million/ml of semen. As the decreases, there sperm count corresponding decrease in likelihood of conception also.

Though Modern medical treatment has reached to its peak in MART (Medically Assisted Reproductive Technology), artificial insemination, in vitro-fertilization, and intracytoplasmic

sperm injection, but not accepted widely in India where poverty is rampant. So, it is unable to provide benefit to all class of people in society, also the treatment is found to be having low success rate.

On the other hand number of herbal preparation can be traced in classics under the headings of Vajikara/ Vrishya drugs, which can be effective as well as in reach of common men. Herbal combination i.e. Shveta Palandu Swarasa Bhavita Yavani had been mentioned in Sidhhabhaishjya Manimala as a Vrishya Yoga, which contains Shveta Palandu which Vrishya² and has been reported to have Aphrodisiac, anti bacterial, tonic. carminative, properties. Yavani is good carminative, improves the digestion and helps in Vatanulomana.

The efficacy of these drugs can further be achieved earlier, if it is administered after performing proper *Shodhana* especially *Virechana* which has said to enhance the potency of *Shukra*. Keeping these facts, a Clinical trial was planned with following aims & objectives.

AIMS AND OBJECTIVES

To evaluate role of *Virechana Karma* and *Shveta Palandu Swarasa Bhavita Yavani Vati* on Oligozoospermia.

MATERIAL

For the clinical study, 19 male patients complaining of symptoms oligozoospermia or suffering from primary or secondary infertility more than one year and having sperm count less than 15 million/ml and willing to participate for the clinical trial were selected irrespective of religion, caste. These patients were subjected to routine hematological and urine examination to rule out major illness. Then semenogram which included Total sperm count, motility, active motile, non motile along with biomarkers S.FSH S. S.Testosterone was done. The LH, and, study was initiated only after getting approval from ethics committee Vide Ref-PGT/7/-A/2013-14/1767, 10/9/2013. An informed written consent was taken from all subjects included in the present study.

INCLUSION CRITERIA:

- Age- 20-50 years of male
- Sperm count <15 million/ml (according to WHO-2010) and known case of infertility from more than year.
- Patient with clinical presentation of
 Ksheenashukra Oligozoospermia
 i.e. Daurbalya, Klaibya, Shukra
 Avisarga, Pandu etc .
- Patient indicated/eligible for Virechana.

EXCLUSION CRITERIA

- Age below 20 and above 50 years.
- Sperm count >15 million/ml
- Patient of azoospermia and aspermia
- Patients of various diseases like varicocele, accessory sex gland infection, sexually transmitted diseases, severe systemic diseases etc.
- Genetic disorders like Klinfelter's syndrome.
- Taking treatment for major psychiatric problem
- History of previous medications
 and trauma leading to
 oligozoospermia.
- Patient *not el*igible for Virechana.

PLAN OF CLINICAL STUDY:

Open label, randomized clinical trial containing 19 patients.

POSOLOGY³:

The details of drugs under trial for present study i.e. *Shveta Palandu Swarasa Bhavita Yavani Vati*, have been mentioned in Table No.1:

Table No.1: Ingredients of ShvetaPalanduBhavitaYavaniVati

No.	Drug.	Latin Name	Part Use
1.	Yavani	Tachyspermumammi .Linn.(Apeacea)	Fruit
2.	Palandu	Allium cepa .Linn.(Liliacea)	Bulb

Method:

Before administration of Shveta Palandu Swarasa Bhavita Yavani Vati, all the registered patients were given Virechana. For this purpose after the patient qualified for inclusion criteria and gave consent for the Virechana, for the first 3 days, for Deepana and Pachana, 2gm of Trikatu Churna was administered twice in a day with luke warm water after meal. On 3rd day, after assessing the status of the patient, plain Ghee in the dose of 40ml was given, early morning on empty stomach with Luke warm water and was observed for Sneha Jeerna Lakhshana and according to it next for 5 to 7 days, the dose of Ghee was increased till the patient achieved proper Snehana features. After completion of Snehana for the next 3 days, whole body massage with Bala Taila and Vaspaswedana was done. During all this period, patient was kept on normal diet with precautions to avoid heavy and fried food articles. On the day of Virechana in the morning after massage and Svedana then, Virechana Yoga Triphaladi Kwatha which composed of Triphala Yavakuta

50gms, *Trivrita Yavakuta* 25gms, *Dantimula Churna* 2-10gms was given.

Method of preparation of *Triphaladi Kwatha*:

For the preparation of *Triphaladi Kwatha*, 50gm of coarse powder of *Triphala* and 25gm of *Trivritta* was taken. To this 4 times water was added and boiled until it was reduced to one fourth. To this prepared *Kwatha*, 2-10 gms of *Danti* powder was added taking into considered status of *Koshtha* of the patient.

In 19 registered patients of the present clinical trial, advocated who were *Virechana Karma*, the overall review of the collected data showed that, after administration of Virechana Yoga, average time of 46 minutes was taken to initiate the first Vega of Virechana. As maximum patients had Madhyama type of Shuddhi, average of number of Virechana Vega in patients 15.90 was reported. On average, 7 hours and 38 minutes were taken to Virechana complete the Karma. According to type of Shuddhi at end of Virechana 3, 5, or 7 days of dietary

regimen was followed which included Manda, Peya, Vilepi, Yusha.

After the completion of Samsarjana Krama Shveta Palandu Swarasa Bhavita Yavani Vati 2 gm(4 Vati) twice a day orally before food in Morning and Night with Ghrita (5ml) for 60 days was given. All the patient were advised to follow certain diet and life style intervention like:

Do's and Dont's:

Use more fruits, green vegetable and pulses in diet, garlic, onion, carrot, soya been, rice, corn, almond, milk and milk products. In addition smoking, day sleep, use of cotton seed oil, exposure to direct heat, excessive salty diet, bakery items like bread, junk food like pizza, puff, cheese etc were asked to be avoided. After completion of therapy, follow up was done for one month, to assess the status of patient, where patient were asked to report fortnightly.

Criteria for assessment:

The efficacy of the treatment was assessed on the basis of improvement in the subjective as well as objective parameters.

Subjective:

Appropriate Scoring pattern was adopted for subjective sexual parameters like, Sexual desire, Erection, Rigidity, Performance anxiety, Ejaculation, Orgasm, overall satisfaction, erectile function, and post act exhaustion. Similarly associated complaints and symptoms of *srotasa* were graded and appropriate score was given. The effect assessed before and after the completion of treatment.

Assessment of subjective parameters:

The scoring pattern prepared by Mehra and Singh, 1995 have been adopted with slight modifications for the assessment of the effect of therapies on sexual parameters (Appendix-1). The symptoms of Sroto Dushti were given score of 2, 1, 0 where 2 score was given to symptoms present before treatment. After completion of treatment, if complete remission in that symptom was reported than 0 gra<mark>de w</mark>as given. If slight improvement in the symptoms found, then it was given the score of 1.

Data presentation

General data was subjected to suitable statistical analysis such as descriptive statistics for demographic data, wilcoxon Signed Rank test for non parametric paired data, paired t-test for quantitative parametric paired data, un-paired t-test for quantitative unpaired data.

After preparing the master chart of all the required data in Microsoft excel work sheet, statistical calculations were made with the help of Sigma stat 3.5 software and In stat 3 software. The results were interpreted as significant p < 0.05, highly

significant p < 0.01, very highly Significant p < 0.001, insignificant p>0.05.

Total effect of therapy:

Considering the relief in major symptoms and improvement in the quantity and quality of semen, the subjects were divided into the following groups to assess the total efficacy of each therapy.

- 0% No change
- < 25 % mild positive response
- 26 -50 % moderate positive response
- 51- 75% marked positive response
- 75% -100% Excellent response

RESULTS AND DISCUSSION

Analysis of the data obtained after completion of therapy showed that 67.28% increase in sperm count was found after completion of Virechan Karma including Samsarjana Krama which was statistically highly significant. After completion of Virechana Karma, when Shveta Palandu Swar<mark>asa Bh</mark>avita Yavani Vati was given to these patients for two months, it further provided 25.20% increase in sperm count which was also overall statistically significant. When effect of therapy was considered, it provided statistically highly significant 77.44 % increase in sperm count (p<0.001).(**Table No.2**). Analysis of effect on abnormal Sperm form showed that there was a decrease in abnormal form

by 20.74% which was statistically significant (p<0.01)(Table No.3). Similarly, 24.08% increase in serum LH value was also found which also statistically significant (**Table No.3**). The trial drug also provided 10.99% increase in motility of sperms, however this was statistically insignificant.

On analyzing the effect of therapy on subjective criteria, it was found that it provided statistically highly significant in all the parameters which included sexual desire 69% (p<0.0001), erectile rigidity 41% (p<0.0001), ejaculatory function 70% (p<0.0001), overall satisfaction 72% (p<0.0001), frequency of coitus 60 (p<0.0001), and duration of coitus 48.15% (p<0.0001). (**Table No.4**)

Table No.2: Effect on sperm count of *Shveta Palandu Swarasa Bhavita Yavani Vati* of 19 patient of oligozoospermia:

Mean Value Million/ml		Diff.	%		Si.				
GI.	ВТ	AT	Dill.	70	S.D. (±)	S.E. (±)	't'	P	Sig
After Virechana	8.68	26.53	17.84	67.28	15.22	3.49	5.109	< 0.001	HS

Sperm count									
After administered trial drug Sperm count	26.53	35.47	8.94	25.20	16.35	3.75	-2.38	<0.02	S
Whole therapy Sperm count	8.68	35.47	26.79	77.44	20.14	4.62	5.78	<0.001	HS

Table No. 3: Effect of *Shveta Palandu Swarasa Bhavita Yavani Vati* of 19 patient of oligozoospermia:

Gr.	Mean Value Million/ml		Diff.	%		Sig			
GI.	ВТ	AT	Dill.	70	S.D. (±)	S.E. (±)	't'	P	big
Abnormal form of sperm	34.42	20.32	14.11	↓20.74	23.19	5.32	2.65	< 0.016	S
S. LH	4.16	5.57	1.41	24.08↑	1.04	0.35	4.09	< 0.004	S

Table No.4: Effect on subjective criteria of *Shveta Palandu Swarasa Bhavita Yavani Vati*of 19 patient of oligozoospermia:

						THE P. P.	200	100			
		вт	AT	Diff	%	W	T+	T-	No. of Pairs	P	Sig.
Sexual Desire	Mean Score	2.47	0.84	1.63	69	190	100	0	4.0	<	HS
Desire	$S.D(\pm)$	0.70	0.69			190	190	U	19	0.0001	пэ
	S.E (±)	0.16	0.16								
Erectile Function	Mean Score	1.53	0.95	0.58	41			0	19	<	HS
Pulletion	$S.D(\pm)$	0.61	0.70	0.56	41	66	66	U	19	0.001	113
	S.E (±)	0.14	0.16								
Erectile Rigidity	Mean Score	1.32	0.58	0.74	88	78	78	0	12	0.0005	HS
Rigidity	S.D (±)	0.58	0.69	0.74							113
	S.E (±)	0.13	0.16								
Ejaculatory	Mean Score	2.0	0.84	1.16	70	105	105	0	14	0.0001	HS
Function	S.D (±)	0.82	0.50								
	S.E (±)	0.19	0.12								
Overall	Mean Score	1.74	0.63	1.11	72	136	136	0	16	<0.0001	HS
Satisfaction	$S.D(\pm)$	0.45	0.49								пъ
	$S.E(\pm)$	0.10	0.11								
Frequency	Mean Score	2.42	3.42		60	120	120	0	15	0.0004	EC
of Coitus	S.D (±)	0.69	0.61	-1	60	-120	-120			0.0001	ES
	S.E (±)	0.16	0.14								
Duration of Coitus	Mean Score	5.42	9.66								
	S.D (±)	4.04	6.75	-4.23	48.15↑	-171	-171	0	18	0.0001	-4.23
	S.E(±)	0.92	0.15								

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Probable mode of action of Shveta Palandu Swarasa Bhavita Yavani Vati

Due to *Deepana*, *Pachana* and *Vatanulomana* action *,Yavani* corrects *Jatharagni* and *Apanavayu* thus resulting into the proper formation of *Rasadi Dhatu* and *Shukra Dhatu*. Further *Shveta Palandu* possess *Vrishya* and *Rasayana* properties thus help to form best of *Rasa* formation and *Shukra* by *Uttarottar Dhatu Poshana*.

Shveta Palandu contains variety phytochemical and micro constituents such as trace elements, vitamins like vit. C. and flavonoids and sulphur compounds which helps in increasing the spermatozoa formation.Combine effect of Shweta Palandu Swarasa Bhavita Yavani Vati increase the Vrishya effect of each other & remove demerits of *Palandu* i.e *Adhmana*, ultimately increase sperm count.

CONCLUSION

Hence it can concluded from the clinical trial that performing of virechana followed by administration of *Shveta Palandu Swarasa Bhavita Yavani Vati* is a promising therapy for the patients of oligozoospermia. On further analysis it can

be concluded *Shveta Palandu Swarasa Bhavita Yvani Vati* is choice of drug when oligozoospermia is due to low S. LH level or increased abnormal form of sperm.

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Appendix-1: Scoring pattern adopted for sexual parameters

Symptoms	Grade	Score
Sexual Desire	No desire at all Lack of Desire Desire only in demand of partner Self and partner normal desire	3 2 1 0

Erectile function	No erection or swelling without any methods Erection with artificial method Very slight swelling but unable to penetrate Some swelling, able to penetrate Erection with occasional failure Full swelling whenever desire	5 4 3 2 1 0
Ejaculatory function	On mere thoughts / slight or no ej. at all During foreply Before penetration During sexual intercourse < 30 sec / at least 1-5 pelvic thrusts During sexual intercourse < 60 sec / at least 5-10 pelvic thrusts During sexual intercourse > 60 sec / at least > 10 pelvic thrusts	4 3 2 1 0
Overall Satisfaction	No satisfaction after every act Satisfaction in 25% act Satisfaction in 50% act Satisfaction in 75% act Satisfaction after every act	4 3 2 1 0
Frequency of coitus	0/ week 1 - 2 / week 3 - 4 / week > 4 / week	3 2 1 0

SCORING FOR ASSOCIATED SYMPTOMS

Daurbalya	Can't do any work	4
	Weakness and work affected	3
	Weakness but routine work not affected Slight	2
	weakness	1
	No weakness	0
	Daymaga not rolling d by anything	2
Multha abaaha	Dryness not relieved by anything	2
Mukha shosha	Dryness relieved by anything putting in mouth	1
	No dryness of mouth	0