Role of *Virechana* and *Ashwatha Phala Churna* in the management of *Ksheena Shukra* (oligozoospermia): A pilot study

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Abstract

Background: Infertility is the inability of a sexually active, noncontracepting couple to achieve spontaneous pregnancy in 1 year. Low sperm count (oligozoospermia) is one of the main causes of male infertility and is correlated with *Ksheena Shukra* (oligozoospermia). *Shodhana* procedures are to be performed before the administration of *Vajikarana* drugs, especially *Virechana Karma* has been indicated in the cases of *Shukra Dushti*. The fruit of *Ashwatha* (*Ficus religiosa* Linn.) has been indicated in premature ejaculation and low sperm count. Aim: This study aimed to evaluate the effect of *Virechana* and *Ashwatha Phala Churna* in the management of *Ksheena Shukra* (oligozoospermia). Materials and Methods: Eligible male participants between the age of 21 and 50 years, with sperm count <15 million/ml, received *Ashwatha Phala Churna* for 60 days in the dose of 3 g, after undergoing *Virechana Karma*. The primary outcomes measured were percentage changes in the seminal parameters and associated symptoms of *Ksheena Shukra* in comparison to baseline. Results: The *Ashwatha Phala Churna* administered after *Virechana* provided 59.78% increase in sperm count, 36.81% increase in semen volume, and 16.18% decrease in abnormal form of sperm and 91.34% of increase was reported in total sperm count after *Virechana Karma* which was also statistically significant. Conclusion: Overall assessment of the therapy showed that administration of *Ashwatha Phala Churna* after performing *Virechana* provided statistically significant improvement on seminal parameters, especially total sperm count.

Keywords: Ashwatha Phala Churna, Ficus religiosa Linn., Ksheena Shukra, oligozoospermia, Virechana

Introduction

Infertility is empirically defined as the inability of a couple to conceive even after 1 year of coital activity without contraception. Recent studies have indicated that the prevalence of oligozoospermia is extremely high in the metropolis as well as in the smaller towns of India. [1] About 15% of couples do not achieve pregnancy within 1 year and seek medical treatment for infertility. Eventually, 5% remain unwillingly childless. In 50% of involuntarily childless couples, a male infertility-associated factor is found together with abnormal semen parameters. [2,3]

Historically, the concepts of infertility have changed over time, and also the problems. Increased mental stress, tobacco-alcohol addiction, pollution, faulty eating and clothing habits, change in culture, and so on have endangered the reproductive capacity of men, which may be attributed to the increased prevalence of oligozoospermia. Many measures are available to treat infertility, but most of the times, these approaches are expensive and time killing. In Ayurveda, it is advocated to use *Vajikarana* drugs, especially after performing *Virechana* for managing cases of *Ksheena Shukra*. Among many herbal drugs listed for *Ksheena Shukra*, *Ashwatha* is the one which is easily available and cost-effective. Hence, a pilot study was planned to evaluate the clinical efficacy of *Ashwatha Phala Churna* after performing *Virechana Karma* in the cases of *Ksheena Shukra* (oligozoospermia).

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Materials and Methods

For the clinical study, twenty male patients suffering from primary or secondary infertility for >1 year and having sperm count <15 million/ml and willing to participate in the clinical trial were selected irrespective of religion and caste from the OPD of Kayachikitsa or referred from Streeroga and Prasruti Tantra Department. The study was initiated after getting approval from the Institutional Ethics Committee of the institute; vide Ref-PGT/7/-A/2013-14/1767, dated: 10/9/2013, and the study was also registered in CTRI (vide CTRI/REF/2014/01/006207). Consent was obtained from all participants before including them in the present study.

Inclusion criteria

- Patients with clinical presentation of Ksheena Shukra (oligozoospermia), i.e., Daurbalya, Shukra Avisarga, and Pandu
- Sperm count <15 million/ml^[4]
- Male patients with age between 21 and 50 years.

Exclusion criteria

- Patients of azoospermia and aspermia
- Patients suffering from varicocele, accessory sex gland infection, sexually transmitted diseases, severe systemic diseases, etc.
- Patients suffering from genetic disorders such as Klinefelter's syndrome
- Patients undergoing treatment for major psychiatric illness
- Patients with a history of previous medications and trauma leading to oligozoospermia
- Patients not eligible for Virechana procedure.

Laboratory investigation Semen analysis

Semen analysis was carried out on registering the patients, which was taken as the baseline, and thereafter it was repeated after *Samsarjana Krama* and on the 60th day of the treatment. Serum follicle-stimulating hormone (FSH), serum luteinizing hormone (LH), and serum testosterone were taken as biomarkers and were done before and after the treatment in selected patients. Routine hematological and urine examination was carried out to assess the present status of the patients and to exclude other pathologies. In suspected cases, ultrasonography was done to rule out hydrocele, varicocele, and other pathologies.

Methods

Posology

Virechana Karma was performed, before administration of Ashwatha Phala Churna. The details of drugs used for Virechana Karma have been mentioned in Table 1. After Virechana, Ashwatha Phala Churna was given in the dose of 3 g twice a day orally after meal with a cup of warm milk for 60 days.

Table 1: Drugs used for Virechana Karma

Drug name	Latin name	Used part	
For Deepana & F	Pachana		
Pippali	Piper longum Linn	Fruit	
Maricha	Piper nigrum Linn	Fruit	
Sunthi	Zingiber officinale Rosc	Rhizome	
For Snehapana			
Ghrita	-	-	
For Virechana Yo	oga		
Haritaki	Terminalia chebula Retz	Fruit	
Amalaki	Emblica officinalis Gaertn	Fruit	
Bibhitaki	Terminalia bellirica (Gaertn.) Roxb	Fruit	
Trivritta	Operculina turpethum (L.) Silva Manso	Root	
Danti	Baliospermum montanum (Willd.) Muell Arg	Moola	

Method of Virechana Karma

Before administration of Ashwatha Phala Churna, all the registered patients were given Virechana. For this purpose, patients who met inclusion criteria and gave consent for the Virechana were administered Trikatu Churna for the first 3 days for *Deepana* and *Pachana* in the dose of 2 g twice in a day with lukewarm water after meal. On the 4th day, after assessing the status of the patients, plain ghee (Accha Sneha)[5] in the dose of 40 ml was given in the early morning on empty stomach with lukewarm water. The patients were observed for Sneha Jeerna Lakshana and accordingly for the next 5-7 days, the dose of ghee was given in increased pattern till the patients achieved proper Snehana features. After completion of internal Snehana, whole body massage and fomentation with Bala Taila and Vashpaswedana was done daily for the next 3 days. [6] During this period, patients were kept on a normal diet with precautions, to avoid excessive oil or heavy food items. On the day of Virechana, after massage and fomentation in the morning, Virechana Yoga of Triphaladi Kwatha was given.

Method of preparation of Triphaladi Kwatha

For the preparation of *Triphaladi Kwatha*, 50 g of coarse powder of *Triphala* and 25 g of *Trivritta* were taken. To this, four times water was added and boiled until it was reduced to one-fourth. To this prepared *Kwatha*, *Danti* powder was added in the amount 6 g, 8 g, and 10 g respectively for *Mridu Koshtha*, *Madhyam Koshtha* and *Krura Koshtha* patient after taking into consideration the status of *Koshtha* of the patients.

Thereafter, according to the type of *Shuddhi*, at the end of *Virechana* procedure, 3, 5, and 7 days of dietary regimen was advised which included *Peya*, *Vilepi*, *Akrita Yusha*, and *Krita Yusha* in a sequential pattern.^[7]

After completion of *Virechana, Ashwatha Phala Churna* was administered for 60 days, where patients were asked to report fortnightly, and on every visit, the details regarding the status was recorded

Criteria for assessment

The efficacy of the treatment was assessed on the basis of improvement in the subjective as well as objective parameters. For the subjective parameters, an appropriate scoring pattern^[8] was adopted for parameters such as sexual desire, erection, rigidity, performance anxiety, ejaculation, orgasm, overall satisfaction, erectile function, and postact exhaustion [Appendix 1].

Objective parameters

Improvement in the semenogram was observed, especially on the total sperm count. Changes in serum FSH, serum LH, and serum testosterone were also considered for assessment and they were assessed in comparison to the baseline score.

Statistical analysis

General data were subjected to suitable statistical analysis such as descriptive statistics for demographic data, Wilcoxon signed-rank test for nonparametric paired data, and paired *t*-test for quantitative parametric paired data.

After preparing the master chart of all the required data in Microsoft Excel worksheet, statistical calculations were made with the help of SigmaStat 3.5 software and InStat 3 software. The results were interpreted as significant (P < 0.05), highly significant (P < 0.01), very highly significant (P < 0.001), and insignificant (P > 0.05).

Observation

A total of twenty male patients of *Ksheena Shukra* (oligozoospermia) were registered for the present study, of which 19 patients completed the full course of treatment and one patient left the treatment due to personal reasons.

In the study, the maximum number of patients (62.5%) was in the age group of 21–30 years, belonged to the Hindu religion (92.5%), and had secondary education. 77.5% of the patients were from urban area and were belonging to poor socioeconomic class (67.5%) and 40% of them were labourer.

Around 67.5% of the patients were doing heavy physical exertion, 77.5% of the patients in the present trial were having *Vishamagni*, 87.5% of patients had irregular dietary habits, 67.5% of the patients had the habit of taking hot water bath, and 75% of the patients were wearing tight undergarment. About 62.5% of the patients had the habit of chewing tobacco followed by 27.5% having addiction of smoking tobacco, 62.5% of the patients were having reduced and disturbed sleeping pattern, and 75% of the patients were having psychological factor such as stress and worry.

The 67.5% of the patients had *Vata Pitta Prakruti* and were of *Madhyama Bala*. About 60% and 20% of the patients had *Lavana* and *Katu Rasa* predominant diet, respectively. Almost 63.89% of the patients had a history of consumption of *Ushna Ahara*, 90% of the patients had primary infertility while 10% of the patients had secondary infertility, 82% of the patients complained of *Shrama Maithuna* (exertion during intercourse), followed by 75% of patients with *Alpa Cheshtata* (less

motivation), 70% of patients with loss of sexual desire and 57.5% of patients with *Daurbalya* (general debility). 47.5% of the patients complained of *Alpa Shukra Pravriti* (low semen volume), 50% of patients each had *Sandhi Shula* and premature ejaculation, 30% of patients had *Shosha* (dryness of mouth), and the remaining 10% of patients had *Pandu* (anemia).

Discussion

The etiological factors such as urban lifestyle including irregular eating and sleeping habits, lack of exercise, consumption of fast food, cold drinks, and stress with fast life were reported in the present clinical trial, which may hamper the metabolism and become a cause of poor nutritional status and oligozoospermia.^[9]

People from low strata of the society are unaffordable to the current costly private diagnostic and medical facilities. Persons under the conditions of poverty eat less nutritious, cheaper food which are usually *Vata* provoking. It is also noted that malnutrition causes hypogonadism which leads to a decrease of Leydig cell function which in turn causes reduced stimulation of LH, ultimately resulting in decreased testosterone secretion causing oligozoospermia. This is supported by findings that very low caloric or protein deficiency causes hypogonadism and decreases the function of Leydig cell, which may result in hampered testosterone secretion and further leads to infertility.

Most of the workers who are working in hot temperature zone are more prone to testicular hyperthermic changes. Further, a decrease in sperm output in testicular hyperthermia has also been reported.^[10]

Vishamagni reported in the patients is probably because of comparative hyperactivity of Vata on Agni. It may lead to Vata and Agni vitiation causing Amottpati, ultimately improper formation of Dhatu causing Shukra Kshaya, which can also be correlated with vitiation of Apana Vata.

Faulty food habits (*Vishamashana*) lead to improper formation of *Rasa* and subsequently irregular *Dhatu* metamorphosis. The data are also suggestive of the current trend of lifestyle and food habits in the present-day lifestyle.

Addiction of smoking tobacco and excessive use of tobacco hamper the normal digestive pattern, resulting in malnourished state, ultimately resulting in oligozoospermia. A study of infertility evaluation of Indian men who were addicted to tobacco chewing has associated its use with decrease in sperm quality.^[11] The study showed that nicotine causes degenerative changes in the seminiferous tubules, which was revealed by altered general tubular architecture, decreased thickness of the spermatogenic cell masses, sertoli cell vacuolation, and thickened basal lamina. ^[12] Cigarette smoke has also effects on spermatogenesis which may be due to toxic substances in the cigarette or the histologic reactions due to hypoxemia induced by smoke.^[13]

Psychological factors such as stress and worry which were reported in the present clinical trial have been listed as the causes of *Ajirna* and hamper metabolism, ultimately causing

oligozoospermia. Experimental studies show that there is hypothalamic testicular suppression due to stress which results in deranged spermatogenesis leading to oligozoospermia.^[14]

Results

Effect on seminal parameters

Ashwatha Phala Churna provided statistically highly significant (P<0.001) result in increasing sperm count (59.78%), statistically significant result in abnormal form of sperm (16.18%), and statistically highly significant (P<0.001) result in increasing semen volume (36.81%). Analysis of the effect on sperm count after *Virechana Karma* (91.34%) showed that a positive improvement was obtained, which was statistically significant [Table 2].

Effect on hormones

Serum testosterone and serum FSH were decreased by 13.58% and 8.27%, respectively, whereas serum LH was increased by 6.57% after the treatment with *Ashwatha Phala Churna*. All these changes reported on hormones were statistically insignificant [Table 3].

Effect on hematological parameters

There were no statistically significant changes (P > 0.05) in the hematological parameters such as hemoglobin, total red blood cell count, total leukocyte count, differential count, and all biochemical parameters such as fasting blood sugar, serum cholesterol, serum triglyceride, serum creatinine, blood urea, and serum glutamic pyruvic transaminase. This proves that there was no adverse effect of the treatment.

Discussion on the effect of therapy on subjective criteria Ashwatha Phala Churna provided statistically highly significant (P < 0.001) result on Daurbalya (75%),

Sandhi Shula (81.81%), Shrama (64.29%), Maithune Ashakti (60%), Alpa Shukra Pravriti (72.22%), sexual desire (53%), erectile dysfunction (62.50%), erectile rigidity (60%), orgasm function (53%), increase in overall satisfaction (61%), frequency of coitus (26%), and duration of coitus (64.47%) and significant (P > 0.05) result in ejaculatory function (50%).

Overall effect of therapy

Assessment of overall effect of the therapy showed that *Ashwatha Phala Churna* administered after *Virechana Karma* provided marked positive response in 20% of the patients, moderate positive response in 60% of the patients, and mild positive response in 20% of the patients.

Probable mode of action of *Virechana Karma* and *Ashwatha Phala Churna*

Vajikarana drugs (aphrodisiac recipes) should be administered after purifying the body, i.e., proper *Shodhana* either by *Vamana* or by *Virechana*. Statistically significant increase in sperm count was found after the completion of *Virechana Karma* (91.34%) and hence, it is clear from the generated data that *Virechana* enhances the level of *Shukra* definitely. Further, *Virechana Karma* increases the bio-availability of drugs by opening channels and improves the nutritional assimilation of the trial drug.

Due to Madhura Rasa, Shita Virya, Snigdha Guna of Ashwatha Phala, Vata, and Pitta Shamana take place which are the Doshas involved in the pathogenesis of Ksheena Shukra. It leads to Shukra Gata Vata-Pitta Shamana. In addition, Ashwatha Phala Churna possesses Vrishya effect, [15] thus increasing the production of spermatozoa which ultimately causes increase in sperm count.

Table 2: Effect of therapy in 19 patients Ksheena Shukra (oligozoospermia) on seminal parameters									
	Mean Value Million/ml		Diff.	%	Paired 't' test				Significance
	ВТ	AT	_		S.D	S.E	't'	Р	
Sperm count	7.58	27.84	20.26	↑59.78%	19.18	4.40	4.60	< 0.001	HS
Sperm count AV	7.58	15.18	7.61	91.34	9.31	2.15	3.53	0.002	S
Sperm motility	46.58	48.95	2.37	↑4.97%	29.69	6.81	0.35	0.732	IS
Normal sperm	24.21	35.79	11.58	↑24.94	29.96	6.87	1.69	0.109	IS
Abnormal Sperm	40.84	29.63	11.21	↓16.18	21.87	5.02	2.23	0.038	S
Semen Volume	1.021	1.605	0.584	↑36.81%	0.68	0.16	3.74	< 0.001	HS

AV: After Virechana Karma, BT: Before treatment, AT: After treatment, S: Significant, HS: Highly significant, IS; Insignificant

Table 3: Effect of trial drugs on sex hormones in 10 patients of Ksheena Shukra (oligozoospermia)									
Hormones	Mean Va	lue (mg/dl)	Diff.	%	Paired 't' test				Significance
	ВТ	AT			S.D	S.E.	't'	P	
S.FSH	12.54	10.71	1.83	8.27%↓	3.74	1.18	1.55	0.157	IS
S.LH	5.02	5.25	0.23	6.57%↑	1.47	0.46	0.47	0.639	IS
S.testosterone	548.53	525.72	22.81	13.58↓	110.89	35.07	0.65	0.532	IS

BT: Before treatment, AT: After Treatment, IS: Insignificant

Conclusion

It can be concluded from the present clinical trial that *Virechana Karma* is a must procedure to be performed before the administration of *Vajikarana* drugs as it provides better and early changes in the total sperm count. After detailed analysis of observations made and results achieved, it can be concluded that *Ashwatha Phala Churna* is effective in the management of *Ksheena Shukra* when administered after *Virechana Karma*.

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Conflicts of interest

There are no conflicts of interest.

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Appendix 1: Scoring pattern adopted for sexual parameters

Symptoms	Grade	Score
Sexual Desire	No desire at all	3
	Lack of Desire	2
	Desire only in demand of partner	1
	Self and partner normal desire	0
Erectile	No erection or swelling without any	5
function	methods	4
	Erection with artificial method	3
	Very slight swelling but unable to	2
	penetrate	1
	Some swelling, able to penetrate	0
	Erection with occasional failure	
	Full swelling whenever desire	
Ejaculatory	On mere thoughts/slight or no ej. at all	4
function	During foreply Before penetration	3
	During sexual intercourse <30 sec/at least	2
	1-5 pelvic thrusts	1
	During sexual intercourse <60 sec/at least 5-10 pelvic thrusts	0
	During sexual intercourse >60 sec/at least >10 pelvic thrusts	
Overall	No satisfaction after every act	4
Satisfaction	Satisfaction in 25% act	3
	Satisfaction in 50% act	2
	Satisfaction in 75% act	1
	Satisfaction after every act	0
Frequency of	0/week	3
coitus	1-2/week	2
	3-4/week	1
	> 4/week	0
Scoring for Ass	ociated symptoms	
Daurbalya	Can't do any work	4
	Weakness and work affected	3
	Weakness but routine work not affected	2
	Slight weakness	1
	No weakness	0
Mukha shosha	Dryness not relieved by anything	2
	Dryness relieved by anything putting in	1
	mouth	0
	No dryness of mouth	

हिन्दी सारांश

क्षीण शुक्र (ऑलिगोस्पर्मिया) की चिकित्सा में विरेचन एवं अश्वत्थ फल चूर्ण की भूमिका का अध्ययन जितेंद्र नाथाभाई वारासिकया, मनदीप गोयल, अनूप ठाकर, भूपेश आर. पटेल

बंध्यत्व एक ऐसी अवस्था है जिसमें की दम्पति गर्भ निरोधक उपायों का उपयोग न करने पर भी गर्भावस्था की प्राप्ति नहीं कर पाता है। वाजीकरण औषधियों का प्रयोग शोधन मुख्यतः विरेचन कर्म के बाद प्रयुक्त करना अधिक लाभकारी है। अश्वत्थ फल चूर्ण का प्रयोग शीघ्र शुक्राणुपतन तथा शुक्राणु अल्पता में किया जाता है। अतः शुक्राणु अल्पता के प्रबंधन में विरेचन कर्म पश्चात प्रयुक्त अश्वत्थ फल चूर्ण के मूल्यांकन के लिए एक चिकित्सीय शोध किया गया। प्रस्तुत शोध कार्य के लिए वयस्क पुरुष (21-50 वर्ष) जिनकी शुक्राणु संख्या 15 मिलियन/मि.ली. से कम थी, उनको विरेचन कर्म करवाने के बाद अश्वत्थ फल चूर्ण दिन में दो बार दूध के साथ 60 दिनों तक दिया गया। शुक्राणुओं में वृद्धि की तुलना प्रारम्भिक शुक्राणु की संख्या के आधार पर की गई। प्रस्तुत चिकित्सा से कुल शुक्राणु की संख्या में 59.78 % की वृद्धि, वीर्य की मात्रा में 36.81 % वृद्धि तथा असामान्य शुक्राणुओं की 16.81 % कमी पायी गई। इसके उपरांत मात्र विरेचन कर्म के पश्चात ही 91.34 % वृद्धि कुल शुक्राणुओं की संख्या में प्राप्त हुई जो कि सांख्यिकीय दृष्टि से भी सार्थक थी। अतः इस अध्ययन से यह निष्कर्ष निकाला गया कि विरेचन कर्म करवाने के बाद उपयुक्त अश्वत्थ फल चूर्ण ने वीर्य के सभी मापदण्डों पर, विशेषतः कुल शुक्राणु संख्या वृद्धि की दृष्टि से उक्तम परिणाम दिये।