

Clinical study to evaluate role of Ayurvedic *Virechana* (therapeutic purgation) and oral *Phala Ghrita* intake in the management of oligozoospermia

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Abstract

Background: Parenthood is one most desired goal of every couple, and failure to procreate causes great anguish. Infertility is a social stigma at many places in India dominated by illiteracy and lower socio-economic standards. It affects the psychological harmony, marital life and social functioning of those affected. Infertility is the inability of a sexually active, non-contracepting couple to achieve spontaneous pregnancy in 1 year. *Shodhana* (bio-purification) is recommended in such cases to enhance the effects of ayurvedic anti infertility therapy (*vajikarana*). *Virechana* (therapeutic purgation) is largely indicated for cases having a semen abnormality (*shukra dushti*). *Phala Ghrita* (PG) is a poly herbal formulation reported to be useful in improving fertility. **Aim:** This study aimed to evaluate efficacy of *Phala Ghrita* oral administration after performing a course of *virechana* in cases of oligozoospermia. **Materials and Methods:** 51 eligible male participants between the age of 21 and 40 years, with sperm count <15 million/ml, received *Phala Ghrita* for 8 weeks in the dose of 10g, after undergoing *virechana*. Percentage changes in the semen parameters and associated symptoms of oligozoospermia in comparison to baseline were the primary outcomes measured. **Results:** *Phala Ghrita* administered after *virechana* provided increase of 66.07 % in total sperm count, 45.19% increase in sperm motility, 15.73% increase in normal form of total sperm, 40.62% decrease in abnormal forms, and increase in semen volume by 43.12%. **Conclusion:** Administration of *Phala Ghrita* after performing *virechana* provided statistically highly significant improvement on various seminal parameters related to male infertility including oligozoospermia.

Keywords: *Ksheena Shukra*, Oligozoospermia, *Phala Ghrita*, *Virechana*, Male infertility

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Introduction

Male infertility is a significant problem affecting more than 80 million couples worldwide ^[1]. As couples are increasingly delaying parenthood, their advancing age, combined with environmental issues, daily stress, drugs, and genetics, independently affect male fertility shown by reduced sperm quality and their fertilizing capacity (both assisted and unassisted). Epidemiological data

suggests that these issues can also lead to increased adverse birth outcomes including congenital anomalies and repeated assisted reproductive failures, especially when the semen parameters are normal. Standard semen analysis fails to detect any abnormality, especially in cases of idiopathic infertility ^[2]. In spite of this, semen analysis has an important role in the routine diagnosis of male infertility and reproductive failure ^[3].

Several factors (environmental, therapeutic, genetic, occupational, etc.) are responsible for male reproductive

failure^[4]. It primarily affects the hypothalamic-pituitary-gonadal (HPG) axis, which results in hormonal imbalance and testicular damage causing reproductive failure and infertility. Many measures are available to treat infertility, but many these are expensive and time consuming. In Ayurveda, *Vata* and *Pitta* vitiation is proposed to cause qualitative and quantitative abnormalities of semen (*Shukra Dhatu*).^[5] As a result, *Shukravaha Srotasa* (conduits of semen) gets deranged, ending in infertility. *Vajikarana* (anti infertility) drugs are recommended here, after performing *Virechana* (bio-purification). *Phala Ghrita* is the one common drug used for this indication in Ayurveda. A pilot study was therefore planned to evaluate the efficacy of *Phala Ghrita* after performing *Virechana* in the cases of oligozoospermia.

Materials and Methods

For the clinical study, fifty-one 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 from the OPD of *Kayachikitsa* department of IPGT and RA Jamnagar. Before initiating this study, permission was obtained from the Institutional Ethics Committee of the institute; vide Ref-PGT/7/-A/ethics/2015-16/2675, dated: 11/12/2015, and the study was also registered in CTRI (vide CTRI/ / 20164/01/006559). Consent was obtained from all participants before including them in the study.

Inclusion criteria

Male patients with age group of 21 - 40 years having sperm count <15 million/ml^[6] with clinical presentation of oligozoospermia, i.e., *Daurbalya* (generalized debility), *Shukra Avisarga* (inability to discharge semen), and *Pandu* (anemia) were selected for the present study.

Exclusion criteria

Male patient age below 21 and above 40 years having Sperm count >15 million/ml, Patient of azoospermia and aspermia or suffering from varicocele, accessory sex gland infection, sexually transmitted diseases, severe systemic diseases etc. were excluded. Patients who had history of

previous medications and trauma leading to oligozoospermia, and patient not eligible for *Virechana* were also excluded from the trial.

Laboratory investigation

Semen analysis

In the present study to avoid such differences the collection time was fixed between 8.30 am to 9.30am throughout the study period. (Valsama 1988). Semen sample was taken 3 times before treatment as per the protocol of semen collection. After collection the semen samples were examined at room temperature for volume, motility, liquefaction time, morphology and total sperm count.

Semen analysis was carried out on registering the patients, which was taken as the baseline, and thereafter it was repeated after *Samsarjana Krama* (post *virechana* dietary regimen) 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 was 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, ultra-sonography was done to rule out hydrocele, varicocele, and other pathologies.

Methods

Detail of Trial Drug (*Phala Ghrita*)

For this clinical trial *Phala Ghrita* was used as trial drug. *Phala Ghrita* was prepared in the Pharmacy of Gujarat Ayurved University using the textual method of *ghrita kalpana*. Raw drugs of ingredients for the study were procured from Pharmacy and authenticated by pharmacognocny Laboratory of IPGT & RA, Jamnagar. (Table 1)

Final product was analyzed in pharmaceutical laboratory of IPGT & RA, GAU, Jamnagar. The drug was packed in airtight containers in required quantity and given to patients for this trial.

Method of preparation of *Haritakyadi Yoga*

For the preparation of *Haritakyadi Yoga*, 18gm (each in same amount) of fine powder of *Haritaki* (*Terminalia chebula*. Retz), *Saindhava* (Rock salt), *Amalaki* (*Embolia officinalis*. Gaertn), *Vacha* (*Acorus calamus* Linn.) , *Vidanga* (*Embelia ribes*. Burm.f), *Rajani* (*Curcuma longa* Linn.), *Pippali* (*Piper longum* Linn.) and *Shunthi* (*Zingiber officinale* Rosc.), were taken and mixed with 2gm of jaggery. About half glass of water was added to this and heated until it was luke warm. This preparation was given to patients on empty stomach for *virechana* purpose.

All ingredients of *Haritakyadi Yoga* were received from IPGT & RA, Gujarat Ayurved University, Jamnagar pharmacy and authenticated by its pharmacognocny laboratory. After authentication of ingredients, the preparation was made stored in airtight bag for the use.

Method of *Virechana Karma*

Before administration of *Phala Ghrita*, all the registered patients were given *virechana*. Patients were initially given 2gms of *Trikatu* powder twice a day for the first 3 days for the purpose of *ddeepana* (enhancing metabolic fire) and *pachana* (enhancing digestion) with lukewarm water after meal. On the 4th day, after assessing the status of the patients, pure ghee (*Accha Sneha*)^[7] in the dose of 40 ml was given in the early morning on empty stomach with lukewarm water. The patients were observed for symptoms of fat digestion and accordingly for the next 5–7 days, the dose of ghee was given in increasing order till the occurrence of proper *snehana* (therapeutic oleation) features. After completion of internal *snehana* for the next 3 days, whole body massage bala oil and steam fomentation.^[8] A normal non oily diet was recommended in this period. On the day of *virechana*, after massage and fomentation in the morning, *Haritakyadi Yoga* was given for the purpose. (Table-2).

According to the type of *shuddhi* (purification) observed at the end of *virechana* procedure, appropriate dietary regimen was advised which including *peya* (thin gruel of rice), *vilepi* (thick gruel of rice), *kkrita yusha* (non-

processed soup of vegetables and/or pulses), and *krita yusha* (processed soup of vegetables and/or pulses) in a sequential manner^[9].

After completion of *virechana*, *Phala Ghrita* was administered for 60 days, where patients were asked to report

fortnightly, and on every visit, the details regarding the status were recorded.

Criteria for assessment

The efficacy of the treatment was assessed on the basis of changes observed in concerned parameters. Subjective parameters were evaluated through an appropriate scoring system^[10] developed for symptoms like sexual desire, erection, rigidity, performance anxiety, ejaculation, orgasm, overall satisfaction, erectile function, and post act exhaustion. The changes observed after the completion of treatment are shown in Appendix 1.

Objective parameters

Changes in the semenogram in particular to total sperm count were observed. Changes in serum levels of FSH, LH, and testosterone were also observed compared with baseline values.

Statistical analysis

Descriptive statistics for demographic data was applied whereas paired *t*-test was applied for quantitative parametric paired data. Analysis was done 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 ($P < 0.001$), and insignificant ($P > 0.05$).

Observation

Total fifty-one male patients of oligozoospermia were registered for the study, of which 49 patients completed the full course of treatment and two patients left the treatment due to personal reasons. In the study, maximum number of the patients (60.78%) were in the age group of

21–30 years, belonged to the Hindu religion (92.15%), and had secondary education. Nearly 66.66% of the patients were from urban area and were belonging to poor socioeconomic class (66.66%) and 49.01% of them were laborer.

Around 41.17% of the patients were doing heavy physical work, 58.83% of the patients in the present trial were having *vishmagni* (irregular agni), 52.94 % of patients had irregular dietary habits, 72.54 % of the patients had the habit of taking hot water bath, and 90.32% of the patients were wearing tight undergarment. About 52.94% of the patients had the habit of chewing tobacco followed by 27.45 % having addiction of smoking tobacco, 56.86 % of the patients were having reduced and disturbed sleeping pattern, and 35.29 % of the patients were having psychological factor such as stress and worry.

Nearly 49.01% of the patients had *vata pitta prakruti* and were of *madhyama bala* (moderate strength). About 88.23% and 56.86% of the patients had *lavana* (salt) and *katu* (bitter) predominant diet respectively. Almost 61.89% of the patients had a history of consumption of hot food, 86.27% of the patients had primary infertility while 13.72% of the patients had secondary infertility, 80.39% of the patients complained of exertion during intercourse, followed by 96.07 % of patients with less motivation, 86.27% of patients with loss of sexual desire, 82.35 % of patients with general debility, 60.78 % of the patients complained of low semen volume, 27.45 % of patients each had joint pain and premature ejaculation, 25.49 % of patients had dryness of mouth, and the remaining 1.30% of patients had *pandu* (anemia).

Results

Effect on seminal parameters

Phala Ghrita provided increase of 66.07 % on total sperm count, 45.19% increase in sperm motility, 15.73% increase in normal form of total sperm, 40.62% decrease in abnormal forms, and increase in semen volume by 43.12% after completion of whole trial. Further analysis revealed when effect was assessed for the period of before treatment and after *samsarjan krama* (post therapy dietetic regimen

for revival) 66.07% increase in total sperm count was found and 51.84% increase in total sperm count was found when effect was assessed for the period between *samsarjana karma* and after the treatment.

In sperm motility before treatment and after *samsarjan krama* 39.58% increase was found. When assessed during after *samsarjana krama* and after completion of treatment in 55.08 % increase in sperm motility was found. Before treatment and after *samsarjan krama* assessment revealed that *Phala Ghrita* provided 12.60 % increase in normal sperm count. After *samsarjana krama* and after treatment *Phala Ghrita* provided 5.43 % increase in normal sperm count respectively.

Complete treatment of *virechana* followed by administration of *Phala Ghrita* provided 45.19 % statistical significant increase in sperm motility. Further when this effect was assessed for the period from initiation of *virechana* procedure till the completion of *samsarjana karma* 39.58 % statistical significant increase was found in sperm motility. When the result were analyzed for the period from after completion of *virechana* procedure to completion of 60 days administration of *Phala Ghrita* 55.08 % statistical significant improvement was found on these parameter.

Similarly the analyzing of the result showed that during before treatment and *samsarjan krama* decrease in abnormal form was 24.95%. After *samsarjana krama* and after completion of treatment that showed that there was a decrease in abnormal form of sperm of 24.85 was found. (Table 3)

Effect on hormones

Phala Ghrita provided 28.36% increase in serum FSH 17.12% increase in serum LH and 16.54 % increase in Serum testosterone value. These changes however were statistically insignificant. [Table 4].

Effect on hematological parameters

There were no statistically significant changes ($P > 0.05$) in any of the hematological parameters such as hemoglobin,

total red blood cell count, total leukocyte count, differential count, and biochemical parameters such as fasting blood sugar, serum cholesterol, serum triglyceride, serum creatinine, blood urea, and serum glutamic pyruvic transaminase. **effect of therapy on subjective criteria**

Phala Ghrita provided statistically highly significant ($P < 0.001$) result on generalized debility (80.95%), tiredness (80%), unable to do sexual act (73.46%), low semen volume (55.91%), sexual desire (76.90%), erectile dysfunction (70.92%), erectile rigidity (65.60%), orgasm function (72.72%), increase in overall satisfaction (81.74%), frequency of coitus (58.88%), and duration of coitus (48.48%) and ejaculatory function (79.06%) (Table 5).

Overall effect of therapy

The intervention has given excellent responses to 8 patients (16.32 %) shown by the impregnation of their partners. 32 patients (67.74%) showed marked positive response, 15 patients (29.41%) showed moderate positive response, and 2 patients (3.92%) had mild positive response in response to the intervention.

Discussion

Faulty eating habits (*vishamashana*) lead to improper formation of “*Rasa*” and subsequently irregular *dhatu* synthesis. Irregular and unhealthy dietary and life style routines play significantly with reproductive functions and cause infertility. On the other hand, complex carbohydrates such as whole grains and fresh fruit, improve fertility. These life style and diet irregularities may affect the metabolism and cause poor nutritional status and oligozoospermia^[11].

Lower socio economic status leading to un-affordability of quality nutrition is *vata* provocative. Malnutrition is found associated with hypogonadism leading to a decrease of Leydig cell function which in turn causes reduced stimulation of LH, ultimately resulting in decreased testosterone secretion causing oligozoospermia.

Environmental factors also result in disturbed reproductive functions. Testis is susceptible to heat, which causes

disrupted spermatogenesis after exposure. It was found that majority of men who were exposed to high temperature at their workplace - welders, dyers, blast furnace workers and those employed in cement and steel factories - were more prone to infertility^[12]. This is due to excess environmental temperature causing a negative effect on sperm production. Even 1° elevation in testicular temperature is found to cause 14% depression of spermatogenesis^[13]. 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^[14].

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^[15]. 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^[16]. 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^[17].

To procreate is natural instinct and if couple is not able to reproduce it gets socially and psychologically disturbed^[18]. Psychological factors such as stress and worry which were reported in the present clinical trial have been listed as the causes of poor digestion (*ajirna*) leading to poor nutrition and oligozoospermia. Experimental studies show that there is hypothalamic testicular suppression due to stress which results in deranged spermatogenesis leading to oligozoospermia^[19].

Causative factors primarily affect the hypothalamic-pituitary-gonadal (HPG) axis, which results in hormonal imbalance and testicular damage causing reproductive failure and infertility. Hence, it is important to maintain hormones its normal state. FSH and LH exert their effect by binding to plasma membrane receptors of the target

cells. LH mainly functions to stimulate testosterone secretion from the Leydig cells of the testicle, while FSH stimulates Sertoli cells to facilitate germ cell differentiation. Gonadotropin release is modulated by a variety of other signals, such as estradiol (a potent inhibitor of both LH and FSH release), and inhibin from the Sertoli cell, which causes a selective decrease in FSH release^[20]. Decrease amount of LH production fail to initiate spermatogenesis thus causing oligozoospermia due to secondary deficiency of testosterone.

Probable mode of action of *Virechana* and *Phala Ghrita*

Vajikarana drugs (fertility enhancers) should be administered after purifying the body, i.e., proper *shodhana* either by *vamana* or by *virechana*. Statistically highly significant increase in sperm count was found after the completion of *virechana* (66.07%) and hence, it is clear from the study that *virechana* enhances the level of *shukra* definitely. Previous study on oligozoospermia concluded that *virechana* should be performed before administration of *vajikarana* drugs and better and early changes in total sperm count can be achieved by *virechana* ^[21]. In this study, significant result in sperm count and reduction in abnormal form of sperm along with significant effect on Serum LH hormone level was found^[22]. Further, *virechana* possibly increases the bio-availability of drugs by opening channels and improves the nutritional assimilation of the trial drug.

Phala Ghrita^[23] is a combination of around 18 herbs processed with *Ghrita* and cow's milk. Ingredients of the *Phala Ghrita* are *Go- Ghrita*(Cow's ghee), *Satavari*, *Go-Dugdha* (Cow's milk), *Ashwagandha*, *Yashtimadhu*, *Payasya*, *Bala* having *madhura* (sweet), *snigdha* (unctuous) and *sheeta* (cold) quality. *Sharkara* is also homologous with the drugs on the basis of qualitative aspect. *Phala Ghrita* due to its *madhura*, *tikta Rasa*, *sheeta virya*, *snigdha guna* leads to *brihana*, *balya*, *Rasayana*, *vayah sthapana* and its *vata-Pitta shamaka* properties and helps in *Vata-Pitta* induced semen pathologies. It is said to have *vrishya*, *rasayana*, *pusamvatva* and aphrodisiac properties.

Due to properties like *madhura rasa*, *shita virya* and ,

snigdha guna of ingredients of *Phala Ghrita*, *vata*, and *pitta shamana* takes place which are the *dosha* involved in the pathogenesis of oligozoospermia. Drugs like *Haritaki*, *Ajmoda*, *Hingu* acts as *vatanulomaka*, hence *apana vayu* functions normally which ultimately helps increase in sperm count. Other drugs like *Triphala* possess *sarvadhātu poshaka* Property. *Ashwagandha*, *Shatavari*, *Vidarikanda*, *Godhrita*, *Go-dugdha* having *vrishya* property, thus it leads to increase in sperm count.

Aphrodisiac action of *Shatavari* is due to the presence of shatavarin that boosts the hormones increase in hormone production and also stimulates its effect. Roots of plant are considered to be appetizer and aphrodisiac. It is also considered as *Rasayana*, having effects like improved immunity, vitality, resistance against disease and stress and strength (*balya*)^[24]. Studies show that the testosterone and estrogen are present in cow's milk. Cow milk and ghee are found promoter of the sexual stamina and semen quantity^[25]. Study showed that association of dairy foods intake and semen quality parameters in a cohort of men attending a fertility clinic and found that low-fat dairy food intake was associated with higher sperm concentration and motility^[26]. Study on *Ashwagandha* experimental research has been carried out to address possible therapeutic modalities for the treatment of oligospermia showed that treatment with a high-concentration, full-spectrum root extract of *Ashwagandha* resulted in significantly improved semen parameters in concert with improved and regulated sexual hormone levels in oligospermic males. The analyses of the data indicated significantly increased sperm concentration and overall motility, which are regarded as the most important criteria for normal fertilizing ability of the spermatozoa. Study outcome showed significant improvement to increase the semen volume in the *Ashwagandha* treated infertile males^[27]. The extract might be acting through the stimulation of endogenous estrogens synthesis which contributes to male fertility. Increases in LH, FSH, and testosterone levels also indicate an effect on gonadotropin release hormone GnRH. GnRH agonist effect may be the mechanism involved in the androgenic and estrogenic activities evidenced in male rats^[28].

Conclusion

It can be concluded from the present clinical trial that *virechana* is an essential procedure needed to be performed before *vajikarana* drugs as it provides better and early changes in the total sperm count. A detailed analysis of the observations proposes that *Phala Ghrita* is effective in the management of Oligozoospermia (*ksheena shukra*)

when administered after *virechana* as it seen by statistical highly significant increase in total sperm count, sperm motility, normal form of sperm, volume of semen and significant decrease in abnormal form of sperm. Increase in S.Testosterone, S.FSH and S.LH indicates that the combined therapy of *virechana* followed by *Phala Ghrita* acts through hormonal pathway to improve seminal parameters.

Appendix –I: Scoring pattern adopted for sexual parameters

Symptoms	Grade	Score
Sexual Desire	No desire at all	3
	Lack of Desire	2
	Occasional desire only on demand of partner	1
	Self and partner normal desire	0
Erectile function	No erection or swelling without any methods	5
	Erection with artificial method	4
	Very slight swelling but unable to penetrate	3
	Some swelling, able to penetrate	2
	Erection with occasional failure	1
	Full swelling whenever desire	0
Ejaculatory function	On mere thoughts / slight or no ej. at all	4
	During foreplay before penetration	3
	During sexual intercourse < 30 sec / at least 1-5 pelvic thrusts	2
	During sexual intercourse < 60 sec / at least 5-10 pelvic thrusts	1
	During sexual intercourse >60 sec / at least >10 pelvic thrusts	0
Overall Satisfaction	No satisfaction after every act	4
	Satisfaction in 25% act	3
	Satisfaction in 50% act	2
	Satisfaction in 75% act	1
	Satisfaction after every act	0
Frequency of coitus	0/ week	3
	1 – 2 / week	2
	3 – 4 / week	1
	> 4 / week	0

Scoring for Associated symptoms:

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

The symptoms of *sroto dushti* were given score of 2, 1, 0 where 2 score was given to symptoms present before treatment. After the completion of treatment, if complete remission in that symptom was reported than 0 grade was given. If slight improvement in the symptoms found, then it was given the score of 1.

Table 1: Ingredients of *Phala Ghrita*^[30]:

No.	Drug.	Latin Name	Part Use
1.	<i>Manjishtha</i>	<i>Rubia cordifolia</i> Linn. (<i>Rubiaceae</i>)	Root
2.	<i>Tagar</i>	<i>Valeriana wallichii</i> DC(<i>Valerianaceae</i>)	Root
3	<i>Haritaki</i>	<i>Terminalia chebula</i> Retz. (<i>combretaceae</i>)	Fruit
4	<i>Amalaki</i>	<i>Embelica officinalis</i> Gaertn.(<i>Euphorbiaceae</i>)	Fruit
5	<i>Bibhitaki</i>	<i>Terminalia belirica</i> Roxb.(<i>combretaceae</i>)	Fruit
6	<i>Kushtha</i>	<i>Saussurea lappa</i> C.B.clarke (<i>compositae</i>)	Root
7	<i>Vacha</i>	<i>Acorus calamus</i> Linn. (<i>Araceae</i>)	Rhizome
8	<i>Haridra</i>	<i>Curcuma longa</i> Linn. (<i>Zingiberaceae</i>)	Rhizome
9	<i>Daru Haridra</i>	<i>Berberis aristata</i> DC (<i>Barberidaceae</i>)	Bark
10	<i>Madhuka</i>	<i>Glycyrrhiza glabra</i> Linn.(<i>Fabaceae</i>)	Bark
11	<i>Ajmoda</i>	<i>Apium graveolens</i> Linn. (<i>umbelliferae</i>)	Seed
12	<i>Katuki</i>	<i>Picrorhiza kurroa</i> Royleex Benth. (<i>Scrophularaceae</i>)	Root
13	<i>Payasya</i>	<i>Ipomea digitata</i> Linn. (<i>convolvulaceae</i>)	Bulb
14	<i>Hingu</i>	<i>Ferula foetida</i> Regal. (<i>umbelliferae</i>)	Gum resin
15	<i>Ashvagandha</i>	<i>Withania somnifera</i> Dunal. (<i>solanacea</i>)	Root
16	<i>Shatavari</i>	<i>Asparagus racemosus</i> willd (<i>lilliacea</i>)	Root
17	<i>Goghrita</i>	Cow milk	-

In the original reference, *Meda* and *Kakoli* are mentioned, but as these drugs are not available, instead of it two parts of *Shatavari* and *Ashvagandha* were used in the preparation of *Phala Ghrita*.

Table 2: Details of *Virechana Karma*

Procedure	Drug & dosage	Duration
<i>Deepana & Pachana</i>	<i>Trikatu Churna</i> (<i>Shunthi, Maricha, Pippali</i>)- 2gm /thrice a day with warm water after meal	3-4 days
<i>Snehapana</i>	<i>Shuddha Ghrita</i> (as per <i>Koshtha and Agni</i>) in increasing dose	3-7 days
<i>Abhyanga & Vashpa Svedana</i>	<i>Bala Taila</i> for <i>Abhyanga</i> , twice a day For <i>Vashpasveda</i> <i>Dashamoola Kvatha</i> was used.	3 days
<i>Virechana Karma</i> ^[29]	<i>Haritakyadi Yoga</i> - <i>Haritaki, Saindhava, Amalaki, Guda, Vacha, Vidanda, Rajani, Pippali, Shunthi</i> - in equal quantity- 18gm	In average dose
<i>Sansarjana Krama</i>	Regulatory diet regimen as per <i>Shuddhi</i>	3-7 days

Table 3 : Effect of therapies in on seminal parameters

Seminal parameters	Mean Value Million/ml		Diff.	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
Total sperm count	11.54	63.65	52.19	66.07%↑	26.03	3.72	14.01	<0.001	HS
	BT	AS							
	11.53	41.91	30.38	66.07↑	27.26	3.89	7.80	<0.001	HS
	AS	AT							
Sperm motility	41.98	61.65	21.74	51.84%↑	22.77	3.25	6.68	<0.001	HS
	BT	AT							
	40.59	87.86	47.26	↑45.19	114.88	16.41	2.80	0.006	HS
	BT	AS							
	40.59	56.63	16.04	↑39.58	16.14	2.31	6.96	0.001	HS
	AS	AT							
Abnormal form of sperm	56.63	87.85	31.22	↑55.08	114.47	16.35	1.901	0.050	NS
	BT	AT							
	21.30	15.08	6.22	↓40.62	15.51	2.21	2.80	0.007	HS
	BT	AS							
	17.14	15.08	2.06	24.95%↓	9.18	1.31	1.57	0.123	NS
	AS	AT							
	21.30	17.14	4.16	↓24.85	8.93	1.27	3.26	0.002	HS

BT= before treatment, AT- after treatment, AS: After *Samsarjana Krama* SD= Standard deviation, SE= Standard Error, HS= highly Significant, NS- Not significant, ↑ = increase

Table 4: Effect of therapies on S.FSH, LH and testosterone in patients of *Ksheena Shukra* (oligozoospermia)

Hormone	Mean Value (ng/ml)		Diff.	%	Paired 't' test (n=20))			Significance
	BT	AT			S.D. (±)	't'	P	
(n=20) FSH	9.62	24.44	13.81	28.36↑%	32.11	1.92	0.069	NS
(n=20) LH	5.25	6.08	0.81	17.12%↑	0.94	3.89	0.001	HS
S. Testosterone (n=20)	531.34	636.46	105.12	16.54↑	86.45	5.43	0.001	HS

BT= Before treatment, AT- After treatment, SD= Standard deviation, SE= Standard Error, HS= highly Significant, NS- Not significant, ↑ = increase

Table 5: Effect of therapy on subjective criteria

Criteria		BT	AT	Diff	%	Pair	P	Significance
sexual desire	Mean Score	2.18	0.55	1.63	76.19	49	<0.001	HS
	S.D(±)	0.44	0.54					
	S.E(±)	0.06	0.77					
erectile function	Mean Score	2.26	0.714	1.55	70.92	49	<0.001	HS
	S.D(±)	0.60	0.46					
	S.E(±)	0.08	0.06					
erectile rigidity	Mean Score	2.25	0.877	1.36	65.60	45	<0.001	HS
	S.D(±)	0.66	0.69					
	S.E(±)	0.09	0.09					
ejaculatory function	Mean Score	2.08	1.36	0.71	79.06	36	<0.001	HS
	S.D(±)	0.57	0.56					
	S.E(±)	0.08	0.08					
orgasm function	Mean Score	1.94	0.69	1.25	72.72	45	<0.001	HS
	S.D(±)	0.65	0.62					
	S.E(±)	0.09	0.08					
overall satisfaction	Mean Score	2.69	0.53	2.16	81.74	45	>0.05	NS
	S.D(±)	4.45	0.54					
	S.E(±)	0.63	0.07					
frequency of coitus	Mean Score	1.40	3.30	-1.89	58.88	45	<0.01	S
	S.D(±)	0.70	1.40					
	S.E(±)	0.10	0.20					
	S.D(±)	0.60	1.10					
	S.E(±)	0.20	0.30					
duration of coitus	Mean Score	6.40	12.82	6.41	48.48↑	46	<0.001	HS
	S.D(±)	1.95	9.11					
	S.D(±)	0.57	0.22					
	S.E(±)	0.09	0.36					

BT- Before treatment, AT- After treatment, S= significant. SD= Standard deviation, SE= Standard Error, HS= highly Significant, NS- Not significant, ↑ = increase

References

1. Boivin J, Bunting L, Collins JA, Nygren KG. International estimates of infertility prevalence and treatment-seeking: potential need and demand for infertility medical care. *Hum Reprod.* 2007; 22:1506–12
2. Nallella KP, Sharma RK, Aziz N, Agarwal A. Significance of sperm characteristics in the evaluation of male infertility. *Fertil Steril.* 2006;85:629–34
3. Omu AE. Sperm parameters: paradigmatic index of good health and longevity. *Med Princ Pract.* 2013;22(Suppl 1):30–42.
4. Phillips KP, Tanphaichitr N. Human exposure to endocrine disrupters and semen quality. *J Toxicol Environ Health B Crit Rev.* 2008;11:188–220.
5. Sushruta, Sushruta Samhita. Shareera Sthan, 2:4, edited by Vaidhya Jadavji Trikamji Acharya, Chaukhamba Sanskrit Sanshthan Varanasi, Reprint 2013;. page no.349.
6. WHO Criteria for normal semenogram 2010. Impact of the new WHO Guidelines on diagnosis and practice on male infertility, the open reproductive science journal, Vol-3, 2010, page 7-15.
7. Agnivesha, Charaka, Dridhabala. Charaka Samhita, Sutra sthana 13/61. In: Vaidya Jadavji Trikamji Acharya, editor. Reprint ed. Varanasi: Chaukhamba Surbharati Prakashan; 2008. p. 85.
8. Agnivesha, Charaka, Dridhabala. Charaka Samhita sidhhi sthana 1/10. In: Vaidya Jadavji Trikamji Acharya, editor. Reprint ed. Varanasi: Chaukhamba Surbharati Prakashan; 2008. p. 678
9. Agnivesha, Charaka, Dridhabala. Charaka Samhita Sidhhi sthana 1/11. In: Vaidya Jadavji Trikamji Acharya, editor. Reprint ed. Varanasi: Chaukhamba Surbharati Prakashan; 2008. p. 678.
10. Mehra BL. Studies on Klibya (Male Sexual Dysfunction) and its Management with Vajikarana. Jamnagar: Department of Kayachikitsa, I.P.G.T. & R.A., G.A.U.; 1996.
11. Wells JL, Dumbrell AC. Nutrition and aging: assessment and treatment of compromised nutritional status in frail elderly patients. *Clin Interv Aging.* 2006;1(1):67–79.
12. Kumar, Naina, and Amit Kant Singh. “Trends of Male Factor Infertility, an Important Cause of Infertility: A Review of Literature.” *Journal of Human Reproductive Sciences* 8.4 (2015): 191–196. PMC. Web. 22 Jan. 2019.
13. Kumar N, Singh AK. Trends of male factor infertility, an important cause of infertility: A review of literature. *J Hum Reprod Sci.* 2015 Oct-Dec;8(4):191-6. doi: 10.4103/0974-1208.170370. PMID: 26752853; PMCID: PMC4691969.
14. Durairajanayagam, Damayanthi & Sharma, Rakesh & Du Plessis, Stefan & Agarwal, Ashok. (2014). Testicular Heat Stress and Sperm Quality. 10.1007/978-1-4939-1040-38.
15. Aydos K, Guven MC, Can B, Ergun A. Nicotine toxicity to the ultrastructure of the testis in rats. *BJU Int* 2001;88:622–6.
16. Said TM, Ranga G, Agarwal A. Relationship between semen quality and tobacco chewing in men undergoing infertility evaluation. *Fertil Steril* 2005;84:649-53.
17. Sofikitis, N., Miyagawa, I., Dimitriadis, D., Zavos, P., Sikka, S., and Hellstrom, W. Effects of smoking on testicular function, semen quality and sperm fertilizing capacity. *J Urol.* 1995; 154: 1030–1034.
18. Gollenberg, A.L., Liu, F., Brazil, C., Drobnis, E.Z., Guzick, D., Overstreet, J.W. et al. Semen

- quality in fertile men in relation to psychosocial stress. *Fertil Steril*. 2010; 93: 1104–1111.
19. Schweiger, U., Deuschle, M., Weber, B., Korner, A., Lammers, C-H., Schmider, J. et al. Testosterone, gonadotropin, and cortisol secretion in male patients with major depression. *Psychosom Med*. 1999; 61: 292–296.
 20. Shaughnessy, Peter. (2014). Hormonal control of germ cell development and spermatogenesis. *Seminars in Cell & Developmental Biology*. 29. 10.1016/j.semedb.2014.02.010..
 21. Agnivesha , 'Charaka Samhita', revised by Charaka and Dridhabala with 'Ayurveda Deepika' commentary, by Chakrapanidatta, edited by Vd.Jadavaji Trikamaji Acharya, Chaukhambha Surabharati Publications, Varanasi -221 001, (India), reprint 2008, Chikitsa 2- 1:50, 51, page no. 392
 22. Varsakiya J, Goyal MR, Thakar AB, Donga SB, Kathad D. Role of Shodhana with Haritakyadi Yoga in Increasing Sperm Count in the Case of Oligozoospermia: An Open-labeled Clinical Trial. *J Res Ayurvedic Sci* 2018; 2 (4):233-239.
 23. Vagbhatas, Ashtang Hridaya, K. R Srikanta Murthy, Chaukhambha Krishnadas Academy, Varanasi. Reprinted 2009, Uttar Sthana-34/63-67. Page no- 326
 24. Available from <https://pdfs.semanticscholar.org/25fc/e2caf8d5164f7ea15e1b440dc79ff2e7f599.pdf> accessed date 2/1/19.9.00am.
 25. Hoffmann B, Rattenberger E. (1977). Testosterone concentrations in tissue from veal calves, bulls and heifers and in milk-samples. *J Anim Sci*, 45 (3): 635–641.
 26. Afeiche MC, Bridges ND, Williams PL, et al. Dairy intake and semen quality among men attending a fertility clinic. *Fertility and sterility*. 2014;101(5):1280-1287.e2. doi:10.1016/j.fertnstert.2014.02.003.
 27. Vijay R. Ambiye, Deepak Langade, Swati Dongre, Pradnya Aptikar, Madhura Kulkarni, and Atul Dongre, "Clinical Evaluation of the Spermatogenic Activity of the Root Extract of Ashwagandha (*Withania somnifera*) in Oligospermic Males: A Pilot Study," Evidence-Based Complementary and Alternative Medicine, vol. 2013, Article ID 571420, 6 pages, 2013. <https://doi.org/10.1155/2013/571420>.
 28. S. J. Winters and P. Troen, "Evidence for a role of endogenous estrogen in the hypothalamic control of gonadotropin secretion in men," *The Journal of Clinical Endocrinology and Metabolism*, Vol. 61, No. 5, pp. 842–845, 1985.
 29. Agnivesha , 'Charaka Samhita', revised by Charaka and Dridhabala with 'Ayurveda Deepika' commentary, by Chakrapanidatta, edited by Vd.Jadavaji Trikamaji Acharya, Chaukhambha Surabharati Publications, Varanasi -221 001, (India), reprint Chikitsa Sthana, Adhyaya-7/120, Page 456
 30. Vagbhata, Ashtang Hridaya, K. R Srikanta Murthy, Chaukhambha Krishnadas Academy, Varanasi. Reprinted 2009, Uttar Sthana-34/63-67. Page 326.

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