



RESEARCH ARTICLE

Role of *Shodhana* with *Haritakyadi Yoga* in Increasing Sperm Count in the Case of Oligozoospermia: An Open-labeled Clinical Trial

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ABSTRACT

Aim and objectives: Infertility is often defined as the inability to conceive after 12 months of regular sexual intercourse without the use of birth control. Around 10% of women aged 25–44 years are estimated to have difficulty conceiving or staying pregnant. Worldwide, 8–12% of couples experience fertility problems. Between 45% and 50% of cases are thought to stem from factors that affect men. Oligozoospermia refers to semen with a low concentration of sperm and is a common finding in male infertility. Hence, the present clinical trial was planned to assess the role of *Shodhana* (biocleansing) performed by *Haritakyadi Yoga* in increasing the sperm count in the case of oligozoospermia. *Vajikarana* therapy improves the nourishment and function of the reproductive organs and vitalizes tissues of the reproductive organs, increasing semen potency specially administered after *Shodhana* (biocleansing). *Haritakyadi Yoga* is mentioned in the *Rasayana* chapter of *Charaka Samhita* for the purpose of *Shodhana* (biocleansing) before administration of *Rasayana* and *Vajikarana* (aphrodisiac) drugs.

Materials and methods: For the clinical study, 93 male patients 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 and caste. The effect of the therapy was assessed by the status of seminal parameters before and after the *Shodhana* procedure.

Results and discussion: Performing *Shodhana* (biocleansing) with *Haritakyadi Yoga* induced *Vamana* (emesis) and *Virechana* (purgation) with a moderate type of *Shuddhi* in a maximum number of treated patients. It also provided a statistically significant increase in the total sperm count (71.24%), sperm motility (16.82%), semen volume (47.14 mL), serum luteinizing

hormone (LH) (19.84%), serum follicle stimulating hormone (FSH) (33.09%), and serum testosterone (20.56%).

Conclusion: Results of the present clinical trial indicates that performing *Shodhana* (biocleansing) with the *Haritakyadi Yoga* procedure is effective in the case of oligozoospermia.

Keywords: Ayurveda, *Haritakyadi yoga*, Oligozoospermia, *Shodhana*, Total sperm count, *Vajikarana*.

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INTRODUCTION

Today, man has achieved tremendous progress in every aspect. Society has become broad-minded, and yet there is no change in the approach toward couples without a child. Infertility is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.¹ Worldwide, 8–12% of couples experience fertility problems. Between 45% and 50% of cases are thought to stem from factors that affect men.² Out of these, in about 30–40%, the cause is unexplained and in the rest of the cases, critical illness, malnutrition, genetic abnormalities, pollution, and also side effects of some medicines, hormones, and chemicals are responsible. In recent years, progress in medical technology has offered hope to many infertile couples, especially in the developed world. However, the progress that has been made has raised new medical, ethical, and social issues that require attention not only from health professionals, but also from the society as a whole.³ Further, *Haritaki* itself is a *Rasayana Ausadha*, and administration of this yoga is described as a preprocedure to *Kutipraveshika* and as such because of its ability to produce *Srotosodhana* and *Agni Deepana*, which will render the body suitable for *Rasayana* or *Vajeekarana Ausadha*. So, curiosity arises to seek the reason behind advising the consumption of this

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specific preparation (*Haritakyadi Yoga*) only before *Rasayana* and *Vajikarana*. Otherwise, as a part of prior detoxification, i.e., *Shodhana Karma*, any *Anulomaka Kalpa* could have been used. Hence, the present study was planned to evaluate the effect of *Shodhana* (biocleansing) performed with *Haritakyadi Yoga* in the case of oligozoospermia.

Shodhana (cleansing procedures/biopurification) is one of the unique concepts of Ayurveda, which deals mainly with elimination of the aggravated *Doshas* from the body. These *Doshas* (toxins and waste material) should be eliminated from natural as well as the nearest root of the body.

It has been mentioned in Ayurveda that for a permanent and prolonged effect of drugs, proper *Shodhana* is must especially in the case of *Rasayana* (rejuvenate) and *Vajikarana* (aphrodisiac) treatment. Hence, all the classics of Ayurveda advocates the use of *Shodhana* (cleansing procedures) prior to *Shamana* therapy especially *Rasayana* (rejuvenate) and *Vajikarana* (aphrodisiac) therapies. *Shodhana* (cleansing procedures) therapy not only increases the bioavailability of the drug, but also cures the ailments. *Shodhana* (biocleansing) procedures open the occluded channels in the body and may enhance the therapeutic efficacy of the drug.⁴ *Shodhana* (biocleansing) prepares the body in such a way that maximum assimilation and utilization of the *Rasayana* drugs may occur. Further, *Haritakyadi Yoga* is specially advised for *Shodhana* (biocleansing) to be performed prior to the administration of *Vajikarana* drugs. A previous study on oligozoospermia concluded that *Virechana Karma* should be performed before administration of *Vajikarana* drugs, and better and early changes in the total sperm count can be achieved by *Virechana Karma*. In this study, significant results in sperm count and reduction in the abnormal form of sperm along with a significant effect on the serum LH hormone level were found.⁵

AIMS AND OBJECTIVES

To evaluate the effect of *Shodhana Karma* with *Haritakyadi Yoga* on seminal parameters in the case of oligozoospermia.

MATERIALS AND METHODS

Selection of Subjects

The present study was an open-labeled clinical trial with efficacy as the end point. For the clinical study, 93 male patients having sperm count less than 15 million/mL were registered after taking their consent and were subjected to routine hematological, biochemical, and urine examination to rule out any major illness, and if fulfilling criteria of inclusion for the present clinical trial were registered from the outdoor patients (OPD) of Kayachikitsa Department or referred from Prasruti Tantra and Stree

Roga (PTSR) Department of Institute for Post Graduate Teaching & Research in Ayurveda (IPGT & RA) hospital, Jamnagar, and then were subjected to semen analysis. Detailed semenogram along with biomarkers serum FSH, serum LH, and serum testosterone (in selected cases) was done in pathology and biochemical laboratory of IPGT & RA Hospital, Jamnagar. A detailed clinical research proforma was filled incorporating all the points of history taking, physical examination, and assessment of the treatment. Before recruitment of subjects in the present clinical trial, approval from the Institutional Ethics Committee was taken. Ethical clearance was obtained from the Institutional Ethics Committee of the Institute for Postgraduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar-361008; vide letter No. PGT/7/-A/ethics/2015-16/2625, dated:11/12/2015. The study has also been registered in Clinical Trial Registry, India (CTRI; www.ctri.nic.in) vide CTRI/2016/01/006559.

Diagnostic Criteria⁶

Patients having sperm count less than 15 million/mL were selected for the present clinical trial (WHO recommended standard for normal semenogram 2010^{7,8}).

Inclusion and Exclusion Criteria

For this study, male patients of age between 20 years and 40 years having sperm count <15 million/mL (according to WHO-2010) were included, and patients not having symptoms, i.e., *Muktanal* (complete prolapse of rectum), *Kshatagud* (fissure of anal), *Adhog Raktapitta*, *Kamagi Vyagra* (excessive desire of intercourse), *Ajirna* (indigestion), *Nav Jwara*, *Adhmana* (raised tension in the abdomen), *Ati Snigdha* (excessive oiliness), *Ati Sthoola* (obese), *Ati Krishna*, *Chinta Prasakta* (stressed), and *Ati Sara* (diarrhea)⁹ were eligible for *Shodhana*.

Known cases of azoospermia and aspermia, suffering from varicocele, accessory sex gland infection, sexually transmitted diseases, severe systemic diseases, etc., genetic disorders like Klinefelter's syndrome, taking treatment for major psychiatric illness, history of previous medications, and trauma, leading to oligozoospermia, were excluded from the study. Also, patients not eligible for *Shodhana* were not included in the study.

Laboratory Investigation

Serum FSH, LH, and serum testosterone were used as biomarkers before and after the treatment in selected patients. These tests were performed only in 40 patients due to financial restrictions. Routine hematological and urine examination was carried out to assess the status of the patient and to exclude other pathologies. These

investigations were done before and after the treatment. In suspected cases, ultrasonography of the scrotum was done to rule out hydrocele, varicocele, and other pathologies.

Collection of Semen Samples

Sexual abstinence of 3–5 days was strictly followed in collection of samples in the study to avoid natural fluctuation in semen parameters with duration.

Semen analysis was done on registering the patient, which was taken as baseline, thereafter it was repeated 15 days after completion of the *Shodhana* procedure.

Method of Shodhana

For the purpose of *Shodhana*, after the patient qualified for inclusion criteria and has given consent, for the first 3 days, for *Deepana* and *Pachana*, 2 g of *Trikatu* powder was administered twice in a day with lukewarm water after meal. On the 3rd day, after assessing the status of the patient, ghee in a dose of 40 mL was given¹⁰ early morning on empty stomach with lukewarm water, and the patient's response to it was observed, and accordingly for the next 5–7 days, an increased dose of ghee was given (double dosage than the previous day) till the patient achieved proper *Snehana* (internal oleation) features. After completion of *Snehana*, for the next 3 days, whole body massage and fomentation were done twice daily.¹¹ During all this period, the patient was kept on normal diet with precautions, to avoid excessive oil or heavy food items. On the day of *Shodhana*, after massage and fomentation early morning, *Haritakyadi Yoga* was given for the purpose of *Shodhana* (Table 1).

Method of preparation of Haritakyadi Yoga

For the preparation of *Haritakyadi Yoga*, 18 g (each in the same amount) of fine powder of *Haritaki* (*Terminalia chebula* Retz.), *Saindhava* (rock salt), *Amalaki* (*Emblica officinalis* Gaertn), *Vacha* (*Acorus calamus* Linn.), *Vidanga* (*Embelia ribes* Burm. f), *Rajani* (*Curcuma longa* Linn.), *Pippali* (*Piper longum* Linn.), and *Shunthi* (*Zingiber officinale* Rosc.)

was taken. To it, 2 g of *Guda* was added. To this, half glass of water was added and heated until it became lukewarm. About 18 g of *Haritakyadi Yoga* was given to patients early morning on empty stomach.

Thereafter, according to the type of *Shuddhi* at the end of *Shodhana*, 3, 5, and 7 days of dietary regimen was given, which included *Manda* (rice water), *Peya* (thin gruel), *Vilepi* (thick gruel), and *Yusha* (seasoned pulse soup) in a sequential pattern.¹²

Assessment Criteria¹⁴

For the purpose of the effect on semen parameters, the semen status at baseline was compared with semen reports collected and analyzed after the completion of *Samsarjana Krama*. Similarly, serum FSH, serum LH, and serum testosterone were analyzed with baseline and endpoint status.

Data Presentation and Statistical Analysis

General data were subjected to suitable statistical analysis, such as the paired *t* test for quantitative 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. The results were interpreted as significant $p < 0.05$, highly significant $p < 0.01$, very highly significant $p < 0.001$, and insignificant $p > 0.05$.

Effect of Shodhana

In 93 registered patients of the present clinical trial, *Shodhana* was performed. These data show that maximum, i.e. 49 (52.69%), patients required 5 days for *Snehapana* (internal oleation), followed by 7 (7.52%) patients who required 7 days for *Snehana*, and 27 (29.03%) patients who required 6 days for achieving *Snehana*. Data observed during trial reveal that *Snehodvega* (aversion of *Sneha*) was reported in 84 (90.33%) patients, followed by *Twaka Snigdha* (moistening of skin) and *Adhastad Sneha Darshana* (passing of fat in stool) in 28 (30.96%) and 66 (70.76%) patients, respectively, during *Snehapana*. Among

Table 1: Details of the *Shodhana* procedure

Procedure	Drug and dosage	Duration
<i>Deepana</i> and <i>Pachana</i>	<i>Trikatu Churna</i> (<i>Shunthi</i> , <i>Maricha</i> , <i>Pippali</i>)—2 g thrice a day with warm water after meal	3–4 days
<i>Snehapana</i>	Ghee (as per <i>Koshtha</i> and <i>Agni</i>) in increasing dose	3–7 days
<i>Abhyanga</i> and <i>Bashpa Svedana</i>	<i>Bala Taila</i> for massage and <i>Vashpa Sveda</i>	3 days
<i>Shodhana Yoga</i> ¹³	<i>Haritakyadi Yoga</i> which contains <i>Haritaki</i> , <i>Saindhava</i> , <i>Amalaki</i> , <i>Guda</i> , <i>Vacha</i> , <i>Vidanga</i> , <i>Rajani</i> , <i>Pippali</i> , <i>Shunthi</i> —in equal quantity—18 g	In average dose
<i>Samsarjana Krama</i>	Regulatory diet regimen as per <i>Shuddhi</i>	3–7 days

Table 2: Shodhana overview of 93 patients of oligozoospermia

Average for <i>Sneha</i> (ghee)	240 mL
Average for days taken for <i>Snehapana</i> (ghee)	5 days
Average time taken for the beginning of first <i>Vega</i>	46 minutes
Average number of <i>Virechana Vega</i> (purgation)	17.18
Average number of <i>Vamana Vega</i> (emesis)	6
Average total time taken for <i>Shodhana</i> (complete cleansing procedure)	8 hours and 8 minutes
Average days for <i>Samsarjana Krama</i> (controlled diet regimen)	5.38 days

the patients registered for the present study, 92.47% achieved *Madhyama Shuddhi* (moderate cleaning), 5.37% of patients achieved *Pravara Shuddhi* (excellent cleaning), and the remaining 2.15% patients achieved *Avara Shuddhi* (least cleaning). Among the 93 patients, 89.24% patients had *Agnidipti* (increased appetite), followed by *Laghuta* (lightness) in 76.44% and *Indriya Prasada* (cheerfulness) in 94.62% patients. *Vatanulomana* (proper flatus and bowel movement) was observed in 93.54% of the patients after the completion of the *Shodhana* procedure. The overall review of the data collected on 93 patients showed that 240 g of average *Sneha* (ghee) was administered in patients. After administration of *Shodhana* preparation, an average time of 46 minutes was taken to initiate the first bout of *Vamana*. As maximum patients had moderate type of cleaning, an average of 17.18 *Vega* was reported for *Virechana Karma* and an average of 6 *Vega* was reported for *Vamana* with *Haritakyadi Yoga*. On average, 8 hours and 8 minutes were taken to complete *Shodhana*. On average, 5.38 days were taken for *Samsarjana Krama* (controlled diet regimen) completion (Table 2).

RESULTS AND DISCUSSION

Analysis of the effect of the *Shodhana* procedure on semen parameters showed that the mean total sperm count before performing *Shodhana* was 11.59 million/mL, which was increased to 40.30 million/mL after the completion of the *Shodhana* procedure. Further, abnormal sperm form was also reduced by 52.12%, which is also highly

statistically significant. The 47.14% increase in semen volume and 16.82% in sperm motility after were also statistically significant (Table 3). Similarly, 19.84% increase was found in serum LH levels, 33.09% increase in the serum FSH level, and 20.56% increase was found in the serum testosterone level. The findings were statistically significant (Table 4).

DISCUSSION

To produce progeny, four things are necessary, i.e., *Ritu* (proper period), *Kshetra* (uterus), *Ambu* (nourishment), and *Beeja* (sperm/ovum), and defect in any of these factors may lead to infertility; among these, *Beeja Dushti* (defective sperm/ovum) is the prime cause of infertility. Oligozoospermia is one of the most prevalent reasons for male infertility in clinical practice. In most of the cases, functional deformity in spermatogenesis is the major reason for oligozoospermia, which involves either a defective mechanism of testosterone or excess production of a reactive oxygen specimen or both.¹⁵ *Acharya Charaka* has mentioned the fruitfulness of *Shodhana Karma* as, by the administration of these therapies, the disease is cured and normal health is restored; mind becomes clear,¹⁶ and helps achieve fertility and virility. *Shodhana* therapies (Fig. 1) play an important role in the management of *Shukra Dosha*.¹⁷ In the treatment of *Klaibya* (impotency), *Acharya Charaka* has stated *Sneha Virechana*, which supports the opinion of *Acharya Kashyapa* that by the use

Table 3: Effect of *Shodhana* on seminal parameters of 93 patients of oligozoospermia

Seminal parameters	Mean value million/mL		Diff.	%	Paired t test				Significance
	BT	AS			SD (±)	SE (±)	t	p	
Sperm count (million/mL)	11.59	40.30	-28.71	71.24↑	11.07	1.15	8.40	<0.001	HS
Sperm motility (%)	44.29	51.75	7.45	16.82↑	21.01	2.19	2.35	<0.01	S
Normal sperm form (%)	45.03	84.73	39.70	88.12↑	14.31	1.49	23.98	<0.001	HS
Abnormal form of sperm (%)	36.70	1.57	19.13	52.12↓	14.78	1.54	10.21	<0.001	HS
Semen volume (mL)	1.47	2.80	-1.32	47.14↑	0.069	0.072	11.35	<0.01	S

BT—before treatment, AS—after *Shodhana*, SD = standard deviation, SE = standard error, HS = highly significant, and ↑ = increase

Table 4: Effect of *Shodhana* on hormones of 40 patients of oligozoospermia

Hormone	Mean value (ng/mL)		Diff.	%	Paired t test				Significance
	BT	AT			SD (±)	SE (±)	t	p	
Serum FSH (n = 40)	8.43	12.60	4.17	33.09↑%	5.91	0.93	-2.25	0.02	S
Serum LH (n = 40)	5.11	6.40	1.27	19.84%↑	2.14	0.34	-2.43	0.01	S
Serum testosterone (n = 40)	526.79	663.17	136.38	20.56↑	198.64	31.40	2.99	0.001	HS

n = 40. S = significant and HS = highly significant



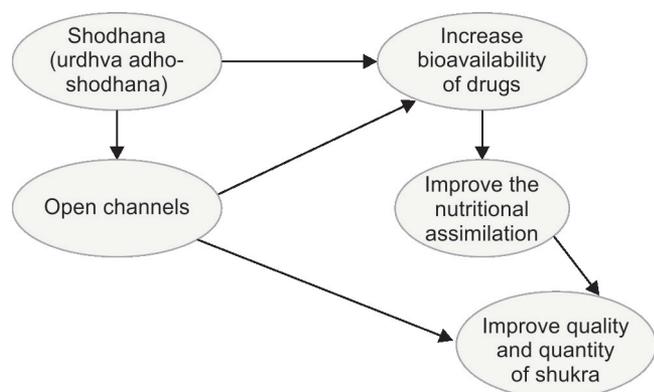


Fig. 1: Mode of action of Shodhana therapy

of Virechana/Shodhana, Shukra gets the ability to perform proper functioning.

The Shodhana process helps in removing the free radicals (oxidants) present in the microcirculatory channels of Shukravaha Srotasa (a system related to reproduction), which interferes with the function of Shukra and, by doing so, increases the activity¹⁸ of Shukra (motility). Vajikarana drugs (aphrodisiac recipes) should be administered after purifying the body,¹⁴ i.e., proper Shodhana either by Vamana or Virechana. No adverse effect raised in any patient during therapy.

For the present clinical trial, Haritakyadi Yoga¹⁹ was selected, which has been mentioned by Charaka for the purpose of Shodhana (biocleansing) to be performed before administration of Rasayana drugs. From the observations of the present study, it can be said that administration of 18 g of Haritakyadi Yoga after proper Snehapana, Abhyanga, and Svedana induces Madhyama type of Shuddhi. As Haritakyadi Yoga contains Vacha, an average of 4 to 6 Vega of Vamana was reported in the initial stage of administration of this Yoga, which was followed by 18 to 20 Virechana Vega in all patients.

Haritaki (*Terminalia chebula*) has been found to be effective in breaking the chain reaction and also proved to have the best hydroxyl radical scavenging activity among all. Thus, "Karshana Guna" (scavenging property) of Haritaki²⁰ is proved and is helpful in cleansing the channels or vessels, and elimination of Dosha corrects the derangement of Apana Vayu, which is responsible for ejaculatory function of sperm. Amalaki (*Embellica officinalis*) is the richest source of ascorbic acid and is needed for the smooth functioning of glutathione. An increase in the concentration of vitamin C increases the concentration of glutathione. Vitamin C increases the cellular content of glutathione and ameliorates apoptosis. Thus, vitamin C acts an antiaging agent and immune-booster. Also, vitamin C helps improve the status of male reproductive hormones. Polyphenols in Vidanga (*Embellica ribes*) have shown a positive neuroprotective function and increase the glutathione (GSH) levels of brain, and thus relieve the

oxidative stress and maintain an endogenous hormone level, which is helpful to achieve progeny to couple. Shunthi (*Zingiber officinale*) possesses antioxidant activity, which is attributed to its high phenolic contents, and also has aphrodisiac action. Pippali²¹ (*Piper longum*) mainly acts on catalase enzyme. Piper longum possesses aphrodisiac property and has a good carminative property, which is helpful in digesting food in a proper way and leads to better nourishment of Rasa to Shukra Dhatu (all tissue contents), resulting in improvement in Shukra Dhatu.²² Owing to all these properties, Shodhana performed specially with Haritakyadi Yoga may have provided additional benefits to the status of oligozoospermia.

CONCLUSION

It can be concluded that administration of Haritakyadi Yoga induces simultaneous Vamana and Virechana and can be used as a choice of drug for Shodhana (biocleansing) before administration of aphrodisiacs. Findings of the present clinical trial have given a clue that Shodhana alone can provide statistically significant improvement in the seminal parameters. Thus, it can be concluded from the present clinical trial that the Shodhana (biocleansing) procedure specifically with Haritakyadi Yoga can be performed before administration of Vajikarana drugs and better early changes in total sperm count can be achieved. A significant result in sperm count and reduction in the abnormal form of sperm along with a significant effect on the serum LH hormone level prove the efficacy of Shodhana (biocleansing) as a part of treatment for patients of oligozoospermia.

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हिंदी सारांश

हरितक्यादि योग के साथ शोधन की ओलिगोस्पर्मिया में उपयोगिता - एक चिकित्सीय परीक्षण

जीतेंद्र वरसाकिया, मनदीप आर गोयल, अनुप बी ठाकर, शिल्पा बी दोंगा, दिव्यारानी काथड

सार: जन्म नियंत्रण साधन के उपयोग के बिना नियमित संभोग के 12 महीनों के बाद गर्भ धारण करने में अक्षमता को वन्ध्यत्व के रूप में परिभाषित किया जाता है। 25 से 44 वर्ष की आयु की लगभग 10 प्रतिशत महिलाओं को गर्भ धारण करने में कठिनाई होने का अनुमान है। दुनिया भर में 8 से 12 प्रतिशत जोड़े प्रजनन क्षमता की समस्याओं का अनुभव करते हैं। उनमें से 45 से 50 प्रतिशत मामलों में पुरुष को प्रभावित करने वाले कारणों से के लिए सोचा जाता है। ओलिगोस्पर्मिया शुक्राणु की अल्पसंख्यता के साथ वीर्य को संदर्भित करता है और पुरुष वन्ध्यत्व एक कारण है। इसलिए वर्तमान नैदानिक परीक्षण की योजना बनाई गई थी कि ओलिगोस्पर्मिया के मामलों में शुक्राणुओं की संख्या बढ़ाने में हरितक्यादि योग द्वारा किए गए शोधन की भूमिका का आकलन किया जाए। वाजीकरण थैरेपी प्रजनन अंगों के पोषण और कार्य में सुधार करती है और प्रजनन अंगों के ऊतकों को महत्वपूर्ण बनाती है, जो वीर्य पोटेंसी को बढ़ाते हैं, विशेष रूप से शोधन के बाद। हरितक्यादि योग का उल्लेख चरक संहिता के रसायण अध्याय में रसायण और वाजीकरण योग के देना से पहले शोधन का उद्देश्य किया गया है।

सामग्री और विधि: नैदानिक अध्ययन के लिए, प्राथमिक या द्वितीयक वन्ध्यत्व से पीड़ित 93 पुरुष रोगियों में एक वर्ष से अधिक और 15 मिलियन/एमएल से कम शुक्राणुओं की संख्या होने को चिकित्सीय परीक्षण के लिये चुना गया। चिकित्सा के प्रभाव का आकलन शोधन प्रक्रिया से पहले और बाद में सेमिनल मापदंडों की स्थिति से किया गया।

परिणाम: हरितक्यादि योग प्रेरित विरेचन (शुद्धिकरण) के साथ अधिक से अधिक उपचारित रोगियों में मध्यम प्रकार की शुद्धि के साथ शोधन का परिणाम मिले। इसमें कुल शुक्राणुओं की संख्या (71.24%), शुक्राणु गतिशीलता (16.82%), वीर्य की मात्रा (47.14), सीरम LH (19.84%), सीरम FSH (33.8%) और सीरम टेस्टोस्टेरोन (20.56%) में सांख्यिकीय महत्वपूर्ण वृद्धि प्रदान की।

निष्कर्ष: वर्तमान नैदानिक परीक्षण के परिणाम इंगित करते हैं कि ओलिगोस्पर्मिया के मामले में (हरितक्यादि योग) प्रक्रिया के साथ शोधन प्रभावी है।

शब्द कुँजी: आयुर्वेद, हरितक्यादि योग, ओलिगोस्पर्मिया, शोधन, कुल शुक्राणु गिनती।