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Clinical study to Evaluate the Role of Kakolyadi Taila Uttar Basti & Shalmalimula Granules in Shukra-Dusti

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Abstract:
This case study explores to "Evaluate the Role of Kakolyadi Taila Uttar Basti & Shalmalimula Granules in Shukra-Dusti". We report here total 30 cases, 18 to 50 age group who's diagnosed for Shukra-dusti, initially presented with the symptom of fatigue, Lytharginess and general weakness etc. Before trial drugs started basic screening investigation done i.e. CBC, BT, CT, RBS, ESR, HIV, HbsAg etc. and confirmation of disease, semen analysis was done. Then administration of trial drugs Kakolyadi Taila Uttar Basti & Shalmalimula Granules with milk, total duration of therapy is 2 months, After Post-treatment it is observed that both drugs were found to be effective and statistically highly significant in correcting the subjective parameters like Daurbalya (78.64%), Mukhashosha (50%), Sexual Desire (91.1%), Erection (88.61%), Ejaculation (85.27%), Self – Satisfaction (80.27%), Performance Anxiety (71.83%), Post Act Exhaustion (69.5%), Partner Satisfaction (90.55%).
In objective parameters both trial drugs had shown statistically also highly significant result in Sperm Count (40%) and Motility of Sperm (87.22%).
Average percentage improvement in subjective parameters is 78.41% and objective parameters were 63.61%. It was found that average percentage of improvement of therapy was 71.01 %.
Based on above results it is prove that Kakolyadi Taila Uttar Basti & Shalmalimula Granules is effect treatment in the management of Shukra-Dusti.

Keyword: Shukra-dusti, Kakolyadi Taila, Uttar Basti, Shalmalimula Granules, subjective, objective.

Introduction:

Every man desires to become a father, for this, it is necessary for him to remain healthy.
Ayurveda is a well-established theories and wealth of ancient lineage to achieving a holistic, physical, mental and social well-being. To know about the Ayurvedic state of health and well-being, an individual must delve into the study of Dosha, Dhatu, and Mala. According to Ayurveda there are seven Dhatus with Shukra being the seventh Dhatu, these are *Rasa* (plasma), *Rakta* (formed blood cells), *Mamsa* (muscle tissues), *Meda* (fatty tissues), A*sthi* (bone tissue), *Majja* (bone marrow and nervous tissues) and *Shukra* (reproductive tissues). *Shukra* is the seventh *Dhatu*, which is considered as essence of

all *Dhatus* providing the body with power and vitality.[i] In its *Prakrut Awastha* (equilibrium form), *Shukra Dhatu* provides nourishment to the body & helps in reproduction, while in its *Dushta Awastha* (imbalance form), it can lead to various health issues related to fertility and sexual health[ii].

Sukra Dusti refers to the vitiation or abnormality of the male reproductive tissue and semen, which can lead to male infertility. Today era sukra-dusti is one of the burning issues in reproductive health system in India incidences of this issue expands day by day because of the disturbing lifestyle pattern, food habit, abnormal sexual life (ex.-time, age) bad habits like - smoking, excessive alcohol intake), obesity, increase in environmental pollution, industrial and occupational hazards (exposure to heat, chemical and radiation etc.)[iii] all these contributed to the increased incidence of Sukra-dusti.

sukra dusti manifests as poor sperm quality or quantity (such as *Oligozoospermia*, *Asthenozoospermia*, or *Teratozoospermia*), it maps directly to standard ICD diagnostic codes for male infertility and semen abnormalities.[iv]

Common corresponding ICD codes include:

- **N46.1:** Oligospermia (Low sperm count)
- **N46.0:** Azoospermia (Absence of sperm)
- **N46.8:** Other male infertility (Includes reduced motility or morphological defects)
- **N46.9:** Male infertility, unspecified.

All type of male infertility most common identifiable anomaly is asthenozoospermia[v] (Reduced Motility Of Sperm). Some other terminology related to *Sukra-kshya* such as –Oligozoospermia - Low Sperm Count.

Teratozoospermia - Abnormal Morphology of Sperm. Necrozoospermia - Dead Sperm.

According to acharya charak there are 8 main cause of Sukra-kshya[vi].

जरया चिन्तया शुक्रं व्याधिभिः कर्मकर्मणात् । क्षयं गच्छत्यनशनात् स्त्रीणां चातिनिषेवणात् ॥

(च. सू. २-४/४३).

Prevalence of Disease:

While the WHO does not publish a single global incidence rate for "semen abnormalities," they report that infertility affects approximately **1% of the male population** and contributes to about 50% of global infertility cases (which impact 1 in 6 people worldwide). Clinical studies utilizing **WHO Laboratory Manual** guidelines typically find that **40% to 80%** of men seeking fertility treatments present with at least one abnormal semen parameter.

MATERIAL & METHODS

A non-randomized, single arm, masking (none) open label, 30 patients, interventional (clinical trial) was conducted. Total 32 patients were registered in the present trial, out of them, 30 patients completed the treatment and 02 were dropped out.

- **Inclusion Criteria:**
  - Male patients aged between 20-50 years.
  - Male patients suffering from *Shukra- Dusti*.
  - Patients with clinical presentation of *Shukra- Dusti* were selected.
  - Patients fit for *Basti Karma*.
- **Exclusion criteria:**
  - Patients suffering from genetic disorders such as Klinefelter's syndrome.
  - Patients undergoing treatment for major psychiatric illness.

- Patients suffering from varicocele, accessory sex gland infection.
- Patients of pyospermia and necrospermia.
- Sexually transmitted disease.
- Severe systemic disease etc.
- Any history of previous trauma leading to Male genital organ.
- Patients having history of Diabetes mellitus.

Criteria for Diagnosis:

All the patients confirming the above said inclusion criteria particularly related to Shukra Dusti are selected on the basis of their clinical presentation, Semen Analysis and ultrasonography (USG Scrotum if needed) finding.

Laboratory Investigations:

A. Before treatment: -

- CBC, ESR, BT, CT, RBS
- Urine Analysis - Routine & Microscopic.
- Serological tests for HIV & HBsAg.
- Serum Creatinine.
- USG Scrotum (if needed).
- Semen analysis.

B. After treatment: Only Semen Analysis.

Drug Administration (Posology of Drugs)

Name of Drug	***Kakolyadi Taila Uttar Basti –***	***Shalmali-mula Granules***
Dose	20 ml/ day for 3 consecutive days followed by gap of 3 days (2 Sitting in a month)	8 to 10 gm Two-time in a day.
Duration	2 months	2 months
Route	Urethral	Orally
Anupan	No	Milk
No. of Patient	30 Patients	
Type of study	Open	
Duration of drug trial	60 days	

Duration: Total duration of the intervention will be 2 months.

Follow up: Patients were first assessed on the day of enrollment and next assessment is done on the day of completion of treatment.

Patients were followed up to 2 month on every 15th day.

OBSERVATION

The main observations in the clinical study are summarized below:

1. Demographic Profile

The majority of patients i.e., 56.66 % belonged to age group of 26-35 years, maximum 96.66% patients were Hindu and maximum 56.66% patient belonged to urban area.

Maximum patients i.e., 60 % were Graduate, maximum 36.66% patients were Serviceman and maximum 66.66% patients were from middle class.

2. Personal History-

The maximum number of patients in the present study were having vegetarian diet i.e., 73.33% and rest 26.67% were having mixed type of diet.

3. Chronicity of Disease -

Among 30 patients, 80% patients were having primary infertility (They have no any children) and 20% patients had secondary infertility (have 1 or 2 children). Maximum numbers of patients i.e. 13 (43.33%) patients had 1-2 years chronicity of Shukra-dusti.

RESULT

The information obtained is subjected to analysis. The effects of treatment were analysed statistically by Mean, SD, SE,' for subjective parameters which are non-parametric "Wilcoxon Signed rank test" and 'paired student t-test' for objective and laboratory parameters which are parametric.

The Subjective parameter wise effect of both drugs as presented in **Table 1.**

Table No. 1 - Showing Subjective Parameters of 30 patients of Shukra-dusti by using "Wilcoxon Signed rank test"

Sr. No.	Lab. Investigation (Semen Analysis)	Mean Score		MD	S.D±	S.E±	% Relief	Correlation coefficient (r)	P value	Results
		B.T.	A.T.							
1.	Sperm Count	1.0333	0.4	0.6333	0.7184	0.1312	40	0.8054	0.0001	Sig. (****)
2	Motility	1.73	0.33	1.4	0.4982	0.0909	87.22	0.6227	0.0001	Sig. (****)

From the clinical study, it is observed that both drugs were found to be effective and statistically highly significant in correcting the subjective parameters like Daurbalya (78.64%), Mukhashosha (50%), Sexual Desire (91.1%), Erection (88.61%), Ejaculation (85.27%), Self – Satisfaction (80.27%), Performance Anxiety (71.83%), Post Act Exhaustion (69.5%), Partner Satisfaction (90.55%).

Sr. No.	Chief Complaints	Mean Score		MD	S.D±	S.E	% Relief	Sum of signed ranks (W)	P value	Results
		B.T.	A.T.							
1.	Daurbalya	2.3333	0.5666	1.7666	0.7279	0.1329	78.64	-435	0.0001	Sig. (****)
2	Mukhashosha	0.5333	0.000	0.5333	0.5713	0.1043	50	-120	0.0001	Sig. (****)
3	Sexual Desire	1.933	0.27	1.6667	0.5467	0.0998	91.1	-435	0.0001	Sig. (****)
4	Erection	2	0.27	1.7333	0.8277	0.1511	88.61	-435	0.0001	Sig. (****)
5	Ejaculation	2.167	0.43	1.7333	0.5208	0.0950	85.27	-435	0.0001	Sig. (****)
6	Self - Satisfaction	2.366	0.633	1.733	0.5208	0.0950	80.27	-435	0.0001	Sig. (****)
7	Performance Anxiety	2.8	0.933	1.8666	0.6288	0.1148	71.83	-435	0.0001	Sig. (****)
8	Post Act Exhaustion	2.9	1.03	1.8666	0.6288	0.1148	69.5	-435	0.0001	Sig. (****)
9	Partner Satisfaction	2.266	0.3	1.9666	0.6686	0.1220	90.55	-435	0.0001	Sig. (****)

Table no. - 2: Showing Objective Parameters of 30 patients of Shukra-dusti by using Paired student t-test'

In objective parameters both trial drugs had shown statistically also highly significant result in Sperm Count (40%) and Motility of Sperm (87.22%).

Overall effect of the therapy-

Average percentage improvement in subjective parameters is 78.41% and objective parameters were 63.61%. It was found that average percentage of improvement of therapy was 71.01 %. It shows that effect of therapy was a little more in Subjective parameter comparatively.

Adverse Drug Reaction: No any adverse effect of both trial drugs found in the present study.

Probable modes of action of Kakolyadi Tail:

Kakolyadi tail have 4 main incrident Kakoli, Ksheerkakoli, Mudagaparni, Satavari having Madhur rasa, guru snigdha guna (only mudagaparni lagu guna) , Sheeta veerya and Vata- pitta samak (mudagaparni tridoshar) properties. Acharya Charaka a indicated in Jeevaniya, Brihniya, Shukrajanana, Snehopaga, Prajasthapana, Vatanulomana, etc. It is also having Balya, Angamarda-prasaman and Snehopaga properties and thus it might help in quality and quantity of sperm. The drug has properties like Antioxidant, Anti-inflammatory, Neutralize free radicals and fight oxidative stress, cellular-protection, support hormonal balance, increase stamina, reduce fatigue, support tissue-building and muscle strength. Contains Vitamins & Minerals (calcium, magnesium, potassium, zinc, and selenium) which help normalize the production of Spermatozoa in testicles.

Probable modes of actions Shalmali Granules:

Shalmali Granules have 2 main incrident Sarkara & Shalmali ; Shalmali have Kasaya- madhur rasa, Laghu-Snigdha-Picchila guna, Sheeta veerya, Vipak madhur and Vata-Kapha samak ; Sarkara have madhur rasa, Snigdha guna, Sheeta veerya, Vata-pitta samak properties; Shalmali guna mentioned in different Ayurveda-Nighatuu i.e. Rajnigatuu, keyadevnigatuu etc. According to Bhaisajyaratnawali Vridha-shalmali moola ras taken with sarkara it increase semen with in 7 days. The drug has properties like antibacterial and pain-relieving effects, High levels of tannins precipitate proteins, helps restore damaged epithelial mucosa and anabolic phytosterols works to improve sperm quality and quantity.

Probable mode of action of Uttar Basti

The Uttar Basti procedure involves administering Tail in intraurethral, utilizing its subtle and oily properties to pacify Vata Dosha and stimulate the Shukravaha Srotosha (channels). This stimulation aids in awakening production of sperm in testicle, at the level of normal function of testicular cells, eliminating Srotorodha (obstructions), and promoting spermatozoa development. The balanced Vata-pitta & kapha Dosha, then facilitates controlled defect sperm production, and inhence the good quality of sperm. These processes collectively contribute to the proper maturation of Spermatozoa in quality and quantity.

Picture – Showing the Procedure of Uttar-Basti, in 32 years of patient.

Conclusion:

- From the clinical study, it is observed that both drugs were found to be effective and statistically highly significant in correcting the subjective parameters like Daurbalya (78.64%), Mukhashosha (50%), Sexual Desire (91.1%), Erection (88.61%), Ejaculation (85.27%), Self – Satisfaction (80.27%), Performance Anxiety (71.83%), Post Act Exhaustion (69.5%), Partner Satisfaction (90.55%).
- In objective parameters both trial drugs had shown statistically also highly significant result in Sperm Count (40%) and Motility of Sperm (87.22%).
- Average percentage improvement in subjective parameters is 78.41% and objective parameters were 63.61%. It was found that average percentage of improvement of therapy was 71.01 %. It shows that effect of therapy was a little more in Subjective parameter comparatively.
- Thus, based on above results it is clear, that *Kakolyadi Taila Uttar Basti* and *Shalmalimula Granules* orally is effective in the management of Shukra-Dusti.

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