



RANDOMISED CLINICAL STUDY OF SHALMALI KWATH (DECOCTION OF SHALMALI MALBARICA) IN THE MANAGEMENT OF (SHUKRAKSHAYA) OLIGOSPERMIA

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ABSTRACT

The oligospermia refers to semen with a low concentration of sperm. The incidence of male infertility varies from 30-40 per cent to 30 per cent of male infertility due to factors like oligospermia, Asthenospermia, Azoospermia. According to the WHO guideline on semen analysis oligospermia is the condition where the sperm concentration is less than 20 ml. *Shukrasampat* is an important factor among the malefactors responsible for the formation of *Garbha* (formation of the foetus) which will be affected in a male who is suffering from *Shukra Kshaya* (oligospermia). The quantity and quality of *shukra* (male sperm) are decreasing day by day which may be due to altered lifestyle. rapid industrialization use of the drug or medication illness, stress, smoking, environmental toxins, obesity and dietary etc. *Shukra Kshaya* (oligospermia) is described under *Shukradushti*, in which *Vatadosha* along with

pitta undergo vitiation, the channels which carry *shukra* undergoes *dusti*. These studies were conducted on 30 patients of oligospermia, Patients having a total sperm count <20 million with clinical presentation of *shukrashya* (oligospermia) explained in Ayurveda text, were selected for the study. Decoction of *Shalmali* (40 ml) was given after meal mixed with sugar for 7 days. After 7 days of follow up again, sperm counts were taken. **Conclusion-** As per the overall result of the study carried out for seven days, it is found that *Shalmali kwath yoga* has good effects in oligospermia and relieves the symptoms of *sukra kshaya* like weakness, giddiness, dryness of mouth and the result could have been again best if it will give for a long duration of the period.

Keywords: *Sukra kshaya, Shalmali kwath, Oligospermia, vatadosha.*

INTRODUCTION

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] Acharya Charaka explained an infertile person is compared with a tree without branches^[2] The need to have children is of great priority in families hence treatment of infertility has become a global concern. The couple is not able to reproduce, and disappointment increases oxidative stress levels thereby worsening the condition. *Rutu (ovulatory period), Kshetra (Uterus), Ambu (amniotic fluid) and Bija (ovum and sperm)* are the four things that are necessary for a normal pregnancy. *Bija* means both male and female fertility factors i.e., *Sukra (sperm)* and *Artava (ovum)* respectively. In Ayurvedic classics, eight^[4] types of *Shukra dosha* are enumerated. This classification is based upon two methods, first one is based upon physical characters of *shukra is Tanu, Alpa (little quantity), Ruksh, Phenil* etc. and the next is based upon the involvement of Doshas in *shukra* e.g., *Vataj, Pittaj, shleshmaja, shukradusti* etc. *Vataj Kshiṇa shukra* is a disease of *shukra* in which both quality and quantity. *Shuddha Shukra* is one of the most necessary factors for healthy progeny.^[5] According to *Samhitas* after causative factor such as vata pitta aggravating food, vata pitta doshas get vitiated. The vitiated doshas do *agnidushti*, will produce *Aama*. *Aama* causes *rasadhatu dushti*. Due to *rasa dhatu Dushti* which hampers further body tissues production and *shukrashya (dimension of sperm)* will occur. *Shukrashya (dimension of sperm)* shows the following symptoms such as weakness, *klaibya* (impotency), *mukha shosha* (dryness of the mouth) *Alpa- rakta shukra darshana*

(ejaculation less in quantity or mixed with blood), *medhra- Vrushana vedana* (pain in penis and testes) Sexual maturation is sensitive to the action of the toxic chemical since they hurt the production and transport of gametes, spermatogenic cycle, sexual behaviour as well as fertility.^[5] The use of some of the established toxicants such as polybrominated diphenyl ethers has been restricted or even banned in foreign countries because of their adverse effect on fertility. In the past two decades, it was reported that increasing exposure to the toxic substance has been proposed as the mechanism for impairing the reproductive competence of the individual since many harmful chemicals may harm the male reproductive system and further exposure to a certain agent can lead to deleterious changes in the organ, thus lowering down the average sperm count. Disturbance of estrogen or androgen-mediated processes further aids to worsen reproductive health. Tetracycline antibiotics are bacteriostatic agents with a broad spectrum of antimicrobial activity. Tetracycline has also been linked to hypertriglyceridemia and Hypercholesterolemia. Long-term administration of tetracycline decrease serum and plasma level of testosterone hormone. Prolonged stress activates the hypothalamic-pituitary-adrenal axis and depresses the hypothalamic-pituitary-testicular axis. This in turn releases gonadotropin which insensate the Leading cell for luteinizing hormone (LH) action. Thus, the level of testosterone hormone is reduced. This alteration in function is reflected by impairment of both endocrine and spermatogenic functions of the testis.^[6,7] Just like a flower bud that does not emit its fragrance, *sukra* (male sperm) is not visible in a body because of its

underdevelopment when the flower bud matures and blossoms completely fragrance is also exhibited. Similarly, when a body grows to an adult man it is manifested out due to the maturity of all the dhatus. [8] Various traditional plants have also been widely used for infertility management. The present study focuses on the beneficial effect of traditional ayurvedic formulation on male infertility.

Aim - To determine the efficacy of *Shalmali kwath* (Decoction of Shalmali Malabarica) in oligospermia

Objectives: -

1. To study management of *shukra khaya* (Oligospermia)
2. To study the efficacy of *Shalmali kwath* (Decoction of Shalmali Malabarica).

Methodology: -

Sample Size -30, Study design- Randomised Clinical Study, Total no of patient =30patients, Trial Group- *Shalmali kwatha* (Decoction of Shalmali Malabarica), Dose-40ml, Kale (time)-After the meal, Route-oral, Anupan-sugar

Assessment Criteria: -

Subjective Criteria: -

Symptoms	Grade 0	Grade 1	Grade 2	Grade 3
Weakness	No weakness	Before contact	Weakness during contact	Weakness s Before and after contact.
Mukhash Osha (dryness of the mouth)	Nil	Absent	Present	Present
Bhrama (giddiness)	Nil	Absent	Present	Present

Objective Criteria

Gradation	Mild	Moderate	Severe
Sperm count	15-20	10-15	Less than 10

Observations and Results

1. Age-wise distribution of patients:

Duration -7 days

Follow up after 7 days

Patients from this group were given *Shalmali mool kwath* with *Sharkara* (sugar)orally twice a day before meal. Duration of treatment will be for 7 days and then follow up once after a weak.

Investigations: semen analysis

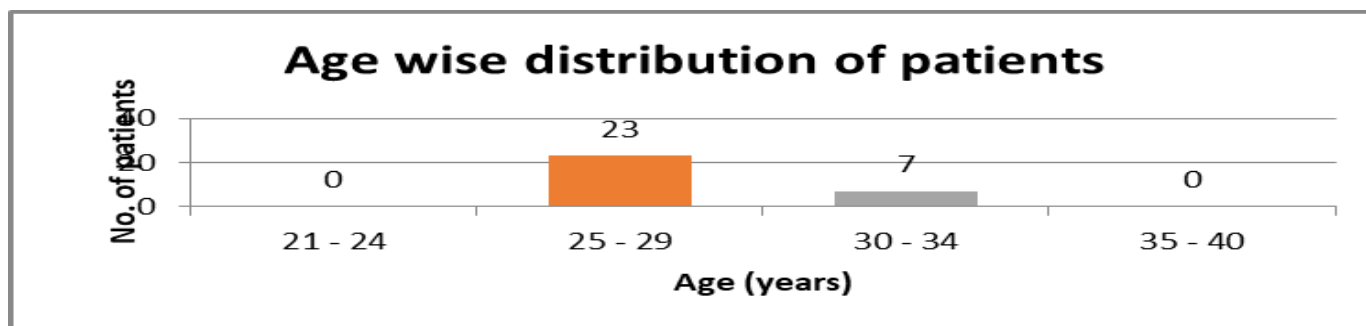
Inclusion Criteria:

1. Age above 21 years and below 40 years.
2. Patient having total sperm count <20 million
3. Patient with clinical presentation of *shukrashya*.

Exclusion Criteria:

1. Congenital anomalies of the genital organ.
2. Patient various diseases like varicocele in the scrotum with the sexually transmitted disease, systemic disease.
3. Surgical and traumatically injured condition of the genital organ.
4. Patient with azoospermia and aspermia

Out of 30 patients, 23 patients (77%) were from the age group 25 – 29 years while 7 patients (23%) belonged to the age group 30 – 34 years.



2. Distribution of patients according to Occupation:

Out of 30 patients, 19 patients (63%) were doing the job, 9 patients (30%) were labour while 2 patients (7%) were student

3. Distribution of patients according to Economic status:

Out of 30 patients, 5 patients (17%) were from the poor class, 11 patients (37%) belonged to the middle class and 14 patients (47%) were from the upper class.

4. Distribution of patients according to Appetite:

Out of 60 patients, 7 patients (23%) were with a good appetite, 14 patients (47%) were with moderate appetite while 9 patients (30%) were with poor appetite.

5. Distribution of patients according to Diet:

Out of 60 patients, 15 patients (50%) were taking a mixed diet 4 patients (13%) were non-vegetarian while 11 patients (37%) were vegetarian.

5. Sleep wise distribution of patients: Out of 60 patients, 9 patients (30%) were having normal sleep while 21 patients (70%) were with disturbed sleep.

6. Distribution of patients according to Sexual desire:

Out of 60 patients studied, 7 patients (23%) were with sexual desire while 23 patients (77%) were not experiencing sexual desire.

8. Distribution of patients according to Erection problem:

All 30 patients (100%) were experiencing erection problems.

9. Distribution of patients according to use of lubrication:

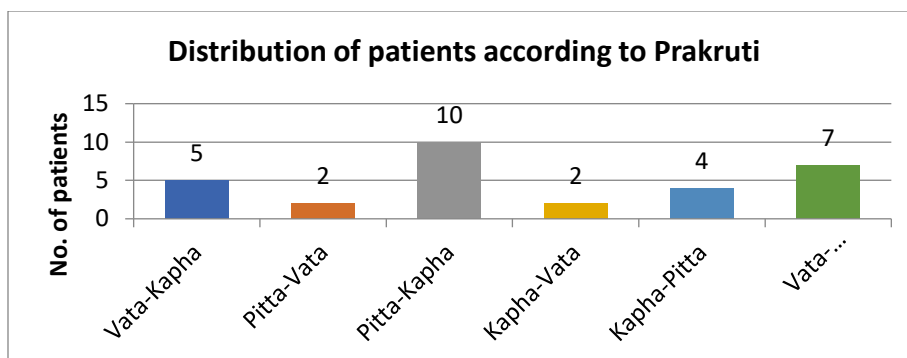
Out of 30 patients, 10 patients (33%) were using lubrication while 20 patients (67%) were not using lubrication.

10. Distribution of patients according to use of contraceptive:

Out of 30 patients, 11 patients (37%) were not using any contraceptive, 11 patients (37%) were using a condom and 8 patients (27%) were using pills.

11. Distribution of patients according to Prakruti:

Out of 30 patients, 5 patients (17%) were of Vata-Kapha Prakruti, 2 patients (7%) were of Pitta-Vata Prakruti, 10 patients (33%) were of Pitta-Kapha Prakruti, 2 patients (7%) were having Kapha-Pitta Prakruti, 4 patients (13%) were seen with Kapha-Pitta Prakruti while 7 patients (23%) were seen with Vata-Pitta-kapha Prakruti.



12. Statistical analysis of different parameters:

Daurbalya (Weakness)

Daurbalya	Mean score	Median score	Median difference	n	Wilcoxon signed-rank test (T ⁺)	P-Value
Before treatment	1.14	1.00	1.00	22	190.00	< 0.001
After treatment	0.27	0.00				

Over the study period, the mean reduction in Weakness score is 0.87 while the median reduction in the score is 2. Using Wilcoxon signed-rank test, the reduction in Daurbalya (Weakness) after treatment is observed to be significant (P-value < 0.001) at a 5% level of significance. I.e., it can be said that the treatment is efficacious in reducing Daurbalya (Weakness).

Mukhasosha (dryness of Mouth)

Mukhasosha (dryness of Mouth)	Mean score	Median score	Median difference	n	Wilcoxon signed-rank test (T ⁺)	P-Value
Before treatment	1.00	1.00	1.00	3	6.00	0.074
After treatment	0.00	0.00				

Over the study period, the mean reduction in Mukhasosha (dryness of Mouth) score is 1 while the median reduction in the score is 1. Using Wilcoxon signed-rank test, the reduction in Mukhasosha (dryness of Mouth) after treatment is observed to be insignificant (P-value = 0.074) at a 5% level of significance. I.e., the treatment cannot be claimed as efficacious in reducing Mukhasosha (dryness of Mouth).

Bhrama (Giddiness)

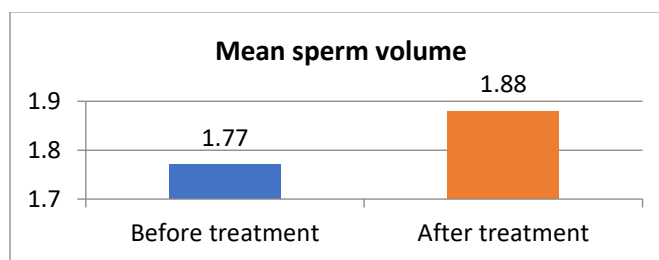
Bhrama	Mean score	Median score	Median difference	n	Wilcoxon signed-rank test (T ⁺)	P-Value
Before treatment	1.00	1.00	1.00	3	6.00	0.074
After treatment	0.00	0.00				

Over the study period, the mean reduction in *bhrama* (Giddiness) score is 1 while the median reduction in the score is 1. Using Wilcoxon signed-rank test, the reduction in *Bhrama* (Giddiness) after treatment is observed to be insignificant (P-value = 0.074) at a 5% level of significance. i.e., the treatment cannot be claimed as efficacious in reducing Bhrama.

Sperm volume

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
1.77	1.88	0.11	0.12	30	5.19	< 0.001

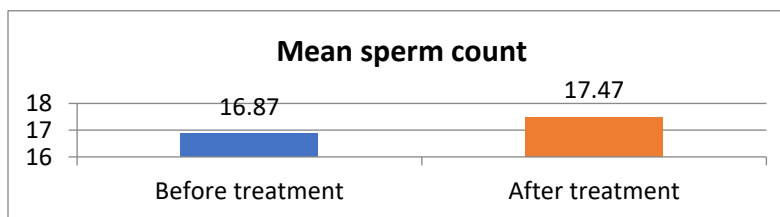
The mean increase in the above mean sperm volume over the study period was 0.11 with an S.D. of 0.12. This increase was significant (P-value < 0.001) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing sperm volume.



Sperm count

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
16.87	17.47	0.60	0.56	30	5.83	< 0.001

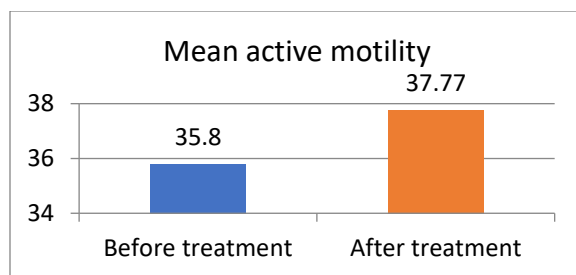
The mean increase in the above mean sperm count over the study period was 0.60 with an S.D. of 0.56. This increase was significant (P-value < 0.001) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing sperm count.



Active motility

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
35.80	37.77	1.97	4.75	30	2.27	0.016

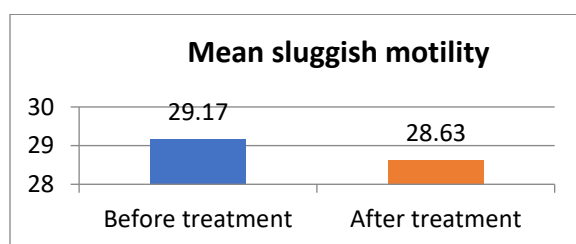
The mean increase in the above mean active motility over the study period was 1.97 with an S.D. of 4.75. This increase was significant (P-value = 0.016) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing active motility.



Sluggish motility

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
29.17	28.63	0.53	1.70	30	1.72	0.048

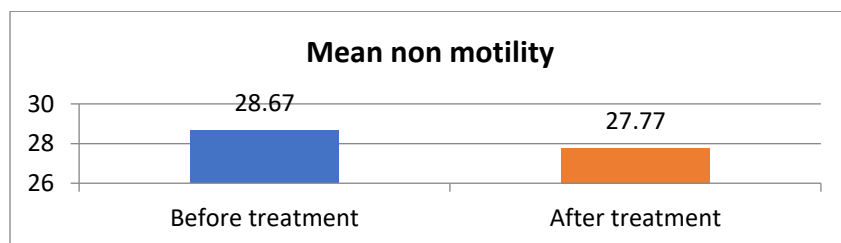
The mean decreases in the above mean sluggish motility over the study period was 0.53 with an S.D. of 1.70. This decrease was significant (P-value = 0.048) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in decreasing sluggish motility.



Non-motility

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
28.67	27.77	0.90	1.32	30	3.73	< 0.001

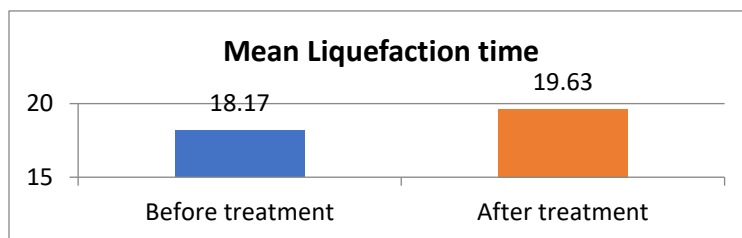
The mean decreases in the above mean non-motility over the study period was 0.90 with an S.D. of 1.32. This decrease was significant (P-value < 0.001) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in decreasing non-motility.



Liquefaction time

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
18.17	19.63	1.47	0.94	30	8.37	< 0.001

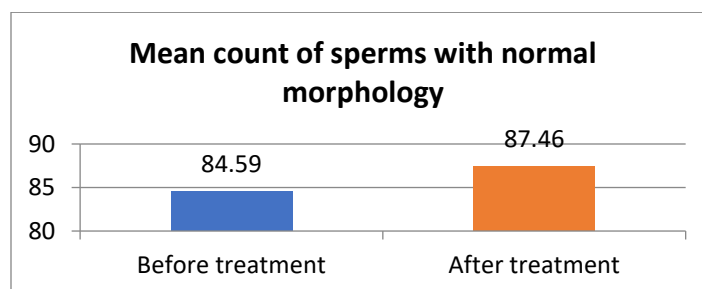
The mean increase in the above mean liquefaction time over the study period was 1.47 with an S.D. of 0.94. This increase was significant (P-value < 0.001) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing liquefaction time.



Sperms with normal morphology

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
84.59	87.46	2.87	12.71	30	1.24	0.113

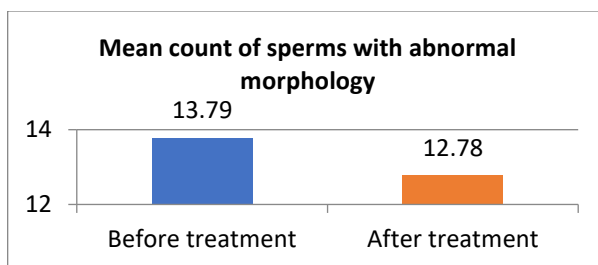
The mean increase in above mean sperms with normal morphology over the study period was 2.87 with an S.D. of 12.71. This increase was insignificant (P-value = 0.113) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered ineffective in increasing sperms with normal morphology.



Sperms with abnormal morphology

Mean		Mean diff	S.D. of diff.	sample size	Paired t statistic	P-value
B.T.	A.T.					
13.79	12.78	1.02	7.05	30	2.42	0.011

The mean decrease in the above mean sperms with abnormal morphology over the study period was 13.79 with an S.D. of 1.02. This decrease was significant (P-value = 0.011) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in decreasing sperms with abnormal morphology.

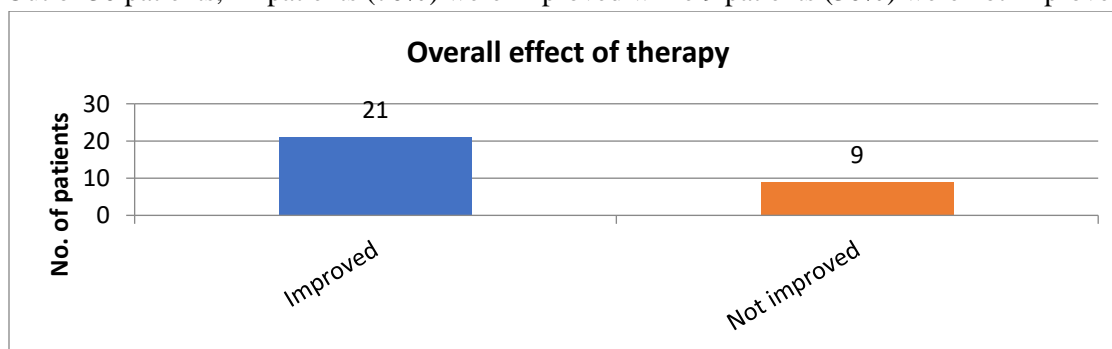


Mean per cent improvement in various Assessment parameters: -

Parameters	Mean % Improvement	Remark
Daurbalya(weakness)	84.09%	Significant
Mukhasosha (dryness of the mouth)	100.00%	Insignificant
Bhrama(giddiness)	100.00%	Insignificant
Sperm volume	7.33%	Significant
Sperm count	3.71%	Significant
Active motility	5.90%	Significant
Sluggish motility	1.69%	Significant
Non-motility	3.40%	Significant
Liquefaction time	8.23%	Significant
Sperm count with normal morphology	12.36%	Insignificant
Sperm count with abnormal morphology	10.92%	Significant
Average Mean % improvement	30.69%	

Distribution of patients according to relief:

Out of 30 patients, 21 patients (70%) were improved while 9 patients (30%) were not improved.



DISCUSSION

Oligospermia (*shukra Kshaya*) is a disorder in which depletion of *shukra* is observed both qualitatively and quantitatively, and which is the major cause for infertility. To understand the pathogenesis of *shukrashya* it is important to know about the formation of *Rasa dhatu* (lymph-body tissue) the decrease of *rasa dhatu* finally leads to diminution of *shukra* (sperm count). Formation of *rasa dhatu*(lymph) is affected when there are *jatharagni mandya* along with the vitiation of

apana, vyana vayu (types of *Vata dosha*). *Agnidushti* affects *shukra janana* (formation of sperm) indirectly. Psychological factors such as anger, grief, stress, anxiety etc. affected *Shukradushti* (the process of formation of sperm). Overall, the major side effect of the *Shukradushti* is infertility. If the sperm count is less than 20 million per millilitre then it is known as oligospermia.

Discussion on the plan of study: The present study was conducted on 30 randomly selected patients

having *shukrashya* (oligospermia). Patients were selected as per inclusion and exclusion criteria, which completed the prescribed treatment in a given time. Treatment is given to each patient for 7day, a dose of the drug *Shalmali mool kwath* 40ml twice a day after meal with sugar, findings were recorded on the 8th day.

The action of root –

The root of *bombax malabaricum* is stimulant, tonic, and aphrodisiac, slightly diuretic and demulcent. A review of *vajikarana yogas* (aphrodisiac therapy) mentioned in Ayurveda reveals the *Shalmali* in most of the combinations either as a chief constituent or as a *bhavana dravya*. This aphrodisiac property is present mainly in the roots of *Shalmali*. *Shalmali* are used traditionally in the Indian subcontinent as an aphrodisiac. Its juice is considered a nutritive, restorative, and sexual stimulant. The lyophilized aqueous extract of root on sexual behaviour, spermatogenesis and anabolic effects in males. Seminal fructose content and epididymal sperm counts were also significantly improved. *Shalmali* root is having sweet, light in nature, unctuous, cold in nature, it pacifies Vata and pitta dosha.

Discussion of General observation

- 1. Age:** Out of 30 patients, the majority of patients (77%) were from the age group 25 – 29 years.
- 2. Occupation:** Out of 30 patients, the majority of patients 19 patients (63%) were doing the job.
- 3. Economic status:** Out of 30 patients, the majority of patients 14 patients (47%) were from the upper class.
- 4. Appetite:** Out of 60 patients, 7 patients (23%) were with a good appetite, 14 patients (47%) were with moderate appetite while 9 patients (30%) were with poor appetite.
- 5. Diet:** Out of 60 patients, 15 patients (50%) were taking mixed diet 4 patients (13%) were non-vegetarian while 11 patients (37%) were vegetarian.
- 6. Sleep:** Out of 60 patients, 9 patients (30%) were having normal sleep while 21 patients (70%) were with disturbed sleep.
- 7. Prakriti:** Out of 30 patients, 33% were of Pitta-Kapha Prakriti.

Statistical analysis of different parameters

Daurbalya: Using Wilcoxon signed-rank test, the reduction in *Daurbalya* (weakness) after treatment is observed to be significant (P-value < 0.001) at a 5% level of significance.

Mukhasosha: Using Wilcoxon signed-rank test, the reduction in *Mukhasosha* (dryness of the mouth) after treatment is observed to be insignificant (P-value = 0.074) at a 5% level of significance.

Bhrama: Using Wilcoxon signed-rank test, the reduction in *Bhrama* (giddiness) after treatment is observed to be insignificant (P-value = 0.074) at a 5% level of significance.

Sperm volume:

The mean increase in the above mean sperm volume over the study period was 0.11 with an S.D. of 0.12. This increase was significant (P-value < 0.001) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing sperm volume.

Sperm count:

The mean increase in the above mean sperm count over the study period was 0.60 with an S.D. of 0.56. This increase was significant (P-value < 0.001) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing sperm count.

Active motility: The mean increase in above mean active motility over the study period was 1.97 with an S.D. of 4.75. This increase was significant (P-value = 0.016) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing active motility.

Sluggish motility: The mean decrease in above mean sluggish motility over the study period was 0.53 with an S.D. of 1.70. This decrease was significant (P-value = 0.048) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in decreasing sluggish motility.

Non-motility: The mean decrease in the above mean non-motility over the study period was 25.96 with an S.D. of 7.05. This decrease was significant (P-value < 0.001) as observed using paired t-test at a 5% level of

significance. Hence, treatment is considered effective in decreasing non-motility.

Liquefaction time: The mean increase in the above mean liquefaction time over the study period was 1.47 with an S.D. of 0.94. This increase was significant (P-value < 0.001) as observed using paired t-test at a 5% level of significance. Hence, treatment is considered effective in increasing liquefaction time.

CONCLUSION

In this study, Randomised Clinical Study of *Shalmali Kwath* in The Management of Oligospermia total of 30 patients with oligospermia was taken. It is noted that, out of 30 patients, 21 patients (70%) were improved while 9 patients (30%) were not improved. Since the clinical study was conducted on a limited number of patients it may not be claimed as final. A more detailed study may be needed in this regard to establish the effect of *Shalmali kwath* in oligospermia. As per the overall result of the study carried out for seven days, it is found that *Shalmali kwath* yoga has mild effects in oligospermia, the result could have appeared mild due to the short duration of the time. The current study shows as such an increase in semen volume, fructose, motility, count, so to ensure the efficacy of *Shalmali kwath* in oligospermia, time duration could be increased, or the dose of decoction needs to be varied and further research could be carried out.

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