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RESEARCH ARTICLE

A RANDOMISED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFECT OF SHATAPUTI ABHRAKA BHASMA IN KSHEENA RETAS VIS-A-VIS OLIGOSPERMIA

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Abstract

Background: Ksheena retas is a condition where Shukra is moderately decreased, especially in the middle age due to etiology undefined in this type, the body growth, pubertal development and level of Shukra may be normal initially until the etiological factors bring about a fall.Here the cause could be Aharajanya (Katu, Kashaya Rasa), Viharajanya (Abhighata), Vyadhikarshaaa etc. it leads to qualitative or quantitative decrease in the retas.In the present context ksheenaretas can be taken as quantitative decrease in the sperm count. Oligospermia is defined as a reduction in the sperm count below 20 million. it is a major cause of male infertility which is characterized by reduced level of sperm. In the literature, it is mentioned as alpamatrasnehapana (24ml) act as deepana and vrishya.Shataputi Abhraka Bhasma is mentiond as param vrushya and shukrala in the literature in the present study this ShataputiabhrakaBhasma is administerd as trial drug. so an attempt was made in the present study to evaluate the efficacy of shataputi Abhraka Bhasma in trial group B and shatavaryadigritha(indigenous formulation) in control group A.

Objective: To evaluate the effect of ShataputiAbhraka Bhasma in ksheenaretas vis-à-vis Oligospermia.

Method: It is a Randomised controlled clinical study with pre and post-test design. Shatavaryadighrita (indigenous formulation) prepared was administerdin group A for 30 days. AndShataputiabhraka Bhasmain group B for 30 days.

Results: Mean sperm count of 13.125mill/ml was increased in control group A and mean sperm count of 2.7143mill/ml was decreased in trial group B after the intervention.

Conclusion: it can be concluded from the result that control drug shatavaryadigritha is effective in the management of Ksheena retas and Shataputi Abhraka Bhasma proved insignificant.

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Introduction:-

Male is said to be Infertile if he is unable to impregnate his fertile partner even after one year of unprotected sexual intercourse [1].

Infertility is a worldwide problem and approximately 8-10% of couples within reproductive age group are infertile (fertile period). It is estimated that globally 60-80 million couples suffer from infertility every year, of which probably between 15-20 million are in India alone.[2]

Oligospermia is defined as a sperm count below 20million/ml[3] semen. in Ayurveda oligospermia is understood as Ksheena Retas. Ksheena Retas is defined as " Ksheena retasah karanaihi Svamanadalpibhoota Retasah'[4]. The condition in which due to various etiological factors there is reduction in the normal quantity of semen or sperm count usually seen in madhyavayas. In Ayurveda many vajikarana drugs/panchakarma therapies like virechana, vrishyabasti (Anuvasana and Niruha),Uttarabastiare proved to be effective in management of oligospermia but these modalities has limitations these are not feasible, time consuming, not cost effective and are not patient friendly. Rasaushadhis are known for smaller dosage they do not cause any nauseating sensation during consumption. These medicines provide quick results.[5]ShataputiAbraka Bhasma is also one Such drug said to be a paramavrushyashukrala.[6] It's Spermetogenic properties proved in Animal Experiments (after heat exposure in rats) [7] Hence this clinical trial was conducted using ShatapatiAbhraka Bhasma as a trial drug with control shatavaryadighrita(Indigenous formulation contains Ashwagandha, shatavari, kapikachu, yastimadhu, gokshura, bala, atibalaandvidarikanda these are shukralaand vajeekara.[8]

Objective of the Study:-

To evaluate the effect of ShataputiAbhraka Bhasma in ksheenaretas vis-à-vis Oligospermia.

Materials and Methods:-

Source of Drugs and Method of preparation:

Shatavaryadighrita

A specific indigenous formulation was prepared as per the classics for the study at the B.V. Pundits Sadvaidyashala private limited (A GMP certified unit), Nanjangudu-571301

ShataputiAbhraka Bhasma

This Bhasma is prepared as per the classics by shreedhoothpapeshwar private limited, and this drug was purchased from Ashwini ayurvedic medical store, Mysuru.

3) Madhu:Honey processed and marketed by Dabur India private limited.

Methods:-

Source of data:

Subjects were selected from the OPD and IPD of Government Ayurveda Medical College and Hospital, Mysuru and Hi – Tech Panchakarma Hospital, Mysuru.

Sample Size and Sampling Method:

The study was completed in 45 subjects reported to have Oligospermia.

In the present study a total of 47 subjects were registered. There were 2 dropouts in controlled Group A and no dropouts in trial group B. Study was completed in 45 subjects with 24 subjects in controlled group A and 21 subjects in trial group B.

Inclusion Criteria

1. Male subjects of age between 25 - 50 years were selected.
2. Subjects with Oligospermia i.e., sperm count less than 20 million/ml were selected.

Exclusion Criteria

1. Subjects with Azoospermia were excluded
2. Subjects with Congenital disorders related with reproductive system like bilateral absence of the vas deferens, cryptorchidismwere excluded.

3. Subjects with Post-traumatic oligospermia were excluded
4. Subjectshaving drug induced oligospermiawere excluded

Diagnostic Criteria:
Subjects with the total sperm count with less than 20 million/ml were selected for the study.

Assessment Criteria
Change in total Spermcount
1. Severe oligospermia (more than 0-up to 5mill/ml)
2. Moderate oligospermia (more than 5mill/ml- up to 10mill/ml)
3. Mild oligospermia (more than 10mill/ml- up to 20mill/ml)

Assessment Schedule:
1. Pre-test assessment -0^{th} day
2. Post-test assessment -after completion of shamanaoushadhi.ie on 31^{st} day.

Statistical Methods
1. Descriptive Statistics
2. Paired t test
3. Willcoxan signed rank test

All the statistical operations were made through SPSS for windows software.
Method of Semen investigation was carried out with the following steps -
A) Color
B) Volume
C) Liquefaction time
D) Viscosity
E) Total sperm count
F) Motility
G) Total normal and abnormal forms

Research Design
This is a controlled clinical study consisting of two groups. The intervention is as follows.

Intervention
Group A (control group)
Shatavaryadighrita (an indigenous formulation)

Dosage:
24ml in two equally divided dosages once in the morning and once in the evening just before food with lukewarm water as shamanangasnehapana for 30 days.

Group B (trial group)
A) Shataputiabhrakabhasma
Dosage: 125mg with honey twice a day morning and evening After food for 30 days.

Results:-

Sperm count:
Mean sperm count of 13.125mill/ml was increased in control group A and mean value of 2.7143mill/ml was decreased after the intervention in trial group B.

Statistically control group A is highly significant with p value of .000. And it is showing insignificant in group B with p value of .059.

Overall Assessment of Oligospermia:
Statistically group A is highly significant with p value of .000 group B is insignificant with p value of .059

Volume of semen
The difference of Increased mean volume of semen was 0.8709ml in group A and Mean volume 0.5 ml was decreased in group B.

Statistically control group A is significant with the p value 0.021. and insignificant in group B.

Liquefaction Of Semen
There is significant decrease with mean value of 1.0416minutes in control group A and mean value of 6.4285minutes was increased in trial group B.

Statistically control group A is significant with p value of .000 trial group B is insignificant.

Fast progressive motility
Mean value of 7.7083% of fast progressive motility in control group A was increased and 3.3334% was decreased in trial group B after intervention.

Statistically control group A is significant with p value of .000 and trial group B is Insignificant.

Slow progressive motility
Mean value of 5.2083% was increased in control group A and 5.7143% was decreased in trial group B after intervention.

Statistically group A is highly significant with p value of .000, in group A mean value 5.2083% slow progressive motility was increased.

Non -progressive motility
Mean value of 3.75% was non progressive in control group A and 0.2381% was increased in trial group B.

Statistically control group A is insignificant with p value of .122. and trial group B is also insignificant with p value of 0.080.

Immotile sperms
Mean value of 8.75 %was decreased in control group A, mean value of 7.8572% was increased in trial group B.

Statistically control group A is highly significant with p value of .000. and nonsignificant in trial group B with p value of 0.756.

Normal forms of sperms
Mean value of 7.0833% was increased in control group A, and mean value of 0.4762% was increased in trial group B.

Statistically control group a is highly significant with p value of .002. and trial group B is insignificant with p value of .715.

Abnormal forms of sperms
Mean value of 7.0833% was decreased in control group A, mean value of 0.4762% was increased in trial group B.

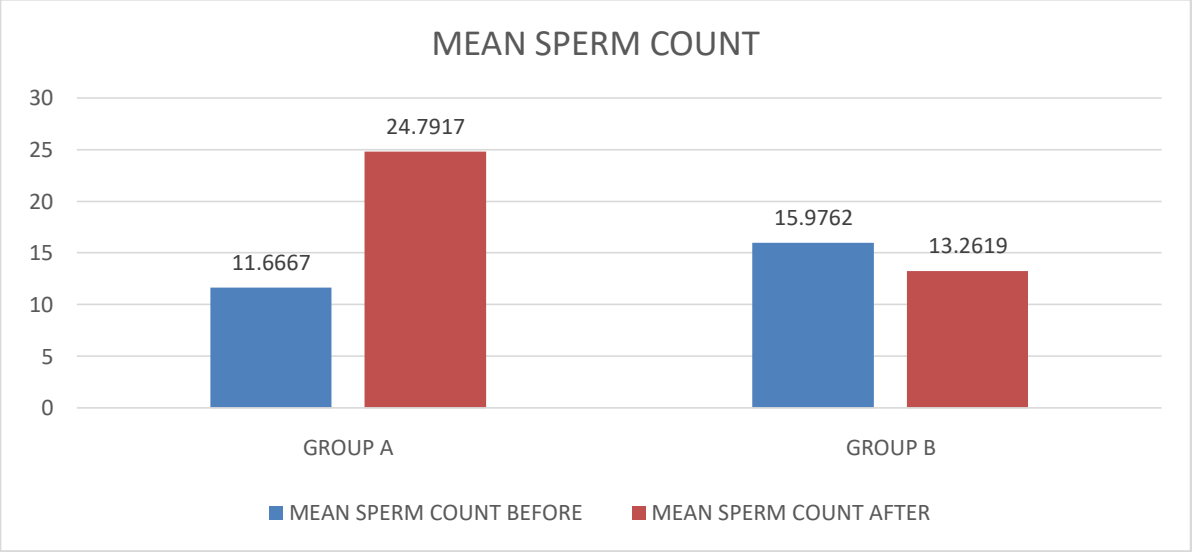
Statistically control group A is significant with p value of .004 and insignificant in group B.

Additional Observation
Testosterone total levels
Mean value of 25.16247ng/dl was decreased in control group A, and mean value of 131.9095ng/dl was increased in trial group B.

Statistically trial group B is highly significant with p value .000, it is insignificant in control group A.

Viscosity
Statistically control group A is nonsignificant with p value .157 and trial group B is nonsignificant with p value 1.000.

Illustration 1:- Distribution of Ksheena Retas subjects according to sperm count.



Disscussion:-

The word ksheena means diminished, wasted, expended, lost, destroyed, worn away, waning as the moon, weakened, injured, broken, torn, emaciated and feeble.

In the present context, meaning of the term ksheena can be taken as decreased.

Retas is defined as the substance which flows out of the body during copulation in the present contest the word Retas is limited to sperms.

Shukrameans bright, resplendent, clear, pure, light colored, white, the essence of anything, semen, virile, seed of animals and sperm. In Charaka samhita it is explained as shukra is that substance which is responsible for the origin of garbha.

In present context meaning of shukra can be taken as semen with special reference to sperm.

In the present study, the definition of ksheenashukra is limited to Oligospermia, i.e., decreased sperm count less than 20mill/ml.

Mean sperm count of 13.125mill/ml was increased in control group A and mean sperm count of 2.7143mill/ml was decreased in trial group B after the intervention.

Probable mode of action of shatavaryadigritha
The drugs which possess madhura, snigdha, jeevaniya, brimhana and guru are called vrishya. Bhavaprakasha explained vrishya as shukravridhikara.

Shukra vridhikara:
The dravya which facilitate and increase in production of shukra. Eg: Shatavari, ashwagandha and ghrita.

Shukra srutivridhikara:
The dravya which initiate the ejaculation of semen are termed as shukrasrutikara. The dravya which possess both vridhikara and shrutikara are known as shukrasrutivridhikara. Eg: Go ghrita and kapikachu.

In the present study shatavari, ashwagandha, kapikachu, yastimadhu, gokshura, bala, atibala and vidarikandha were used. These have shukralaand vajeekaraaction.

Shatavari:Shatavari may help in regeneration of seminiferous tubules. This in turn causes increase the process of spermatogenesis[9].

Lyophilized aqueous extracts of Asparagus racemosus showed better improvement in sperm count in Wistar strain male albino rats[10].

Ashwagandha:
Ashwagandha is an aphrodisiac drug which showed significant improvement in ksheenashukra subjects[11]. In another study it showed significant improvement in increasing the sperm count after 90 days of administration[12].

Kapikachu:
Kapikachu showed increase in serum testosterone and sperm count in infertile men[13].

It helps in regeneration of seminiferous tubules. This in turn causes increase in the process of spermatogenesis[14].

Yastimadhu:
Yastimadhuchurna is one of the vajeekaranadravya. It showed significant effect on ashakti maithuna, kamashakti and shukra visarga[15].

Gokshura:
This aphrodisiac drug supplement showed improvement sexual function in one study[16].

Bala:
It showed significant improvement in sperm parameters, it reduced sperm abnormalities and increased viability of sperms[17].

Atibala:
This dravyashowed significant increase in sperm count and mating performance[18].

Vidarikandha:
Pueraria tuberosa possess androgenic effect and it significantly increased the sexual behavior and hormone levels[19].

Hence observation regarding increase in sperm count was benefitted by the combined effect of these vajeekaranadravya by increasing the shukra dhatu in Ksheena shukra subjects.

Shataputiabhraka Bhasma is mentiond as param vrushya and shukrala in this study it is proved that it increases testosterone levels there by it decreases the sperm count by negative feedback mechanism. It is shukralainterms of sarvadaihikashukra(testosterone).

In the present study testosterone total mean value of 25.16247 ng/dl was decreased in controlled group A and mean value of 131.9095 ng/dl was increased in trial group B.

Statisticaly trial group is highly significant in increasing testosterone total levels with p value of .000.

Testosterone total levels can be taken as a part of sarvadaihikashukra by this we can conclude that the trial drug helps only in increasing sarvadaihikashukra and it is proved insignificant in increasing sperm count (Dravya bhoota /roopa Dravya shukra/retas).

Conclusion:-

On the basis of concepts, analysis and clinical observations made in this study, the following conclusions were drawn:

1. shatavaryadigritha is effective in increasing spermcount

2. Shataputiabhraka Bhasmais insignificant in increasing sperm count. Hence it should not be used in the treatment of oligospermia.
3. StatisticalyshataputiAbhraka Bhasma is highly significant in increasing testosterone total levels with p value of .000. hence it can be used in the treatment of low levels of testosterone, erectile dysfunction, premature ejaculation, low libido. It is insignificant in the management of oligospermia.

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