ROLE OF ASHVATHA PHALA CHURNA AND SHVETA PALANDU SVARASA BHAVITA YAVANI IN THE MANAGEMENT OF KSHEENA SHUKRA (OLIGOZOOSPERMIA) AFTER SHODhana THERAPY - CLINICAL STUDY.

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Introduction: Almost 30% of cases of infertility will have a male factor attached to it, though in the society there are many misconceptions and wrong ideas regarding the cause and occurrence of infertility in men. A low sperm count is in no way related to weakness or one being abnormal, hence the semen count needs to be assessed and the cause for it being low should be determined as timely treatment can not only prevent it from falling further but counts may improve.

Aims & Objectives: To compare the clinical efficacy of Ashvatha Phala Churna and Shveta Palandu Svarasa Bhavita Yavani Vati after performing Virechana Karma on Ksheena Shukra (Oligozoospermia).

Materials and methods: For the clinical study, 40 male patients complaining of symptoms and features of oligozoospermia or 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, caste. Before administering of Shveta Palandu Svarasa Bhavita Yavani Vati and Ashvatha Phala Churna, Virechana procedure was carried out.

Result and discussion: Analysis of generated data showed that in Group A 19 patients were treated with Ashvatha Phala Churna 3gm twice a day with warm milk and Shankara for 60 days after performing Virechana Karma provided increase in Sperm count of 59.78 %, 16.18% decrease in Abnormal forms, and increase in Semen volume by 36.81%. In Group B 19 patients were treated with Shveta Palandu Svarasa Bhavita Yavani Vati - 4 Vati twice a day with Goghrita for 60 days, provided increase in sperm count (65%), and abnormal form of sperm (20.74%) decrease.

Conclusion: Both the trial drugs Ashwattha Phala Churna and Shveta Palandu Svarasa Bhavita Yavani Vati have definite role in the management of Ksheena Shukra when administered after Virechana Karma, But Shveta Palandu Svarasa Bhavita Yavani Vati is comparatively better than Ashwattha Phala Churna.
Introduction:--
Since Vedic period, to have healthy children has been praised and desired. Love, strength, happiness, professional excellence, wide spread influence, fame, pleasure are reliant upon children. Nature has gifted living being with the unique quality to procreate; these are the key of existence and survival of their own generation. Every human has always been instrument of this rule of nature to become a parent. Parenting is always an important aspect of social life. On the other hand, infertility has been considered as a cursed condition and is looked as a medico-social problem, as it is said that a person without a child is like a tree just with one branch devoid of fruits and shadow with an unwanted smell[1].

Many aspects of male infertility are poorly understood, and many cases of male infertility are diagnosed as idiopathic [2] except some physical defects, low sperm count and poor sperm quality are responsible for the male infertility more than 90% of cases.

Male factor is present in one half of infertile couples [3]. Some of the known responsible factor for male infertility are poor semen quality, endocrine inter relationship, testicular function and genetical factors etc [4].

Infertility is defined as the inability of a couple after 1 year of coital activity without contraception (Mosher and Pratt 1991). In today’s era, increased mental stress, tobacco –alcohol addiction, pollution, faulty eating & clothing habit, change in culture etc. have endangered reproductive capacity of men, leading to oligozoospermia(Ksheena Shukra) and ultimately ending up with infertility. Ksheena Shukra is one of the eight types of Shukradushti mentioned in the classics and is a Vata Pittaja Vyadhi [2] being more prevalence in Madhyama Vaya, a disease from Apana Vata province, which incapacitates man from conceiving his life partner, ending in Infertility.

Current treatment of this disease is hormone therapy, other placebo therapies and surgical approaches. In the past pharmacological treatment has been used empirically for infertile patients, when surgical treatment had failed or was unavailable. Hence, there is a search for alternative treatment modalities in other system of medicine, which is safe and cost effective.

Number of Vajikarana drugs has been mentioned in the Ayurvedic classics. Ashvatha Phala Churna and Shveta Planadu Svarasa Bhavita Yavani Vati are two among those. Further Samshodhana is one of the important therapies 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 [6].

The role of Shodhana procedures as preoperative regimens before the administration of medicine is adequately substantiated by Acharya Charaka, as mentioned that with these therapies only, the occluded channels in the body can cleared off to enhance the therapeutic efficacy of the drug [7]. It is clear from the available references that Virechana enhances the quality level of Shukra [8]. Therefore, Virechana Karma was also selected for the present study.

Aims & Objectives:-
To evaluate and compare the clinical efficacy of Ashvatha Phala Churna and Shveta Palandu Svarasa Bhavita Yavani Vati after performing Virechana Karma on Ksheena Shukra (Oligozoospermia).

Material and method:-
For the clinical study, 40 male patients complaining of symptoms of Ksheena Shukra or suffering from primary or secondary infertility from more than one year and having sperm count less than 15 million/ml and willing to participate for the clinical trial were selected irrespective of religion, caste from the O.P.D of Kayachikitsa Department or referred from SRPT Department Ethical clearance was obtained from Institutional Ethics Committee of Institute; Vide Ref- PGT/7/-A/2013-14/1767, Dated:10/9/2013. The study has also been registered in CTRI (Clinical Trials Registry- India) (CTRI: www.ctri.nic.in) vide CTRI /2014/01/006207. Informed consent was also taken from all the study subjects before including them in the present study.
Inclusion criteria:
Male patient with age between 20-50 years with clinical presentation of Ksheenashukra (Oligozoospermia). i.e. Daurbalya, Shukra Avisarga, Pandu etc. and having Sperm count <15 million/ml[9]

Exclusion criteria:
Male patient age below 21 and above 50 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 genetic disorders like Klinfelter’s syndrome or taking treatment for major psychiatric illness, history of previous medications and trauma leading to oligozoospermia, and patient Ayogya for Virechana were also excluded from the present clinical trial.

Laboratory Investigation:
Semen analysis: It was done on registering the patient which was taken as baseline, thereafter it was repeated after Samsarjana Krama and 60th day of the treatment. S. Follical stimulating hormone (FSH), S. Luteinizing hormone (LH), S. Testosterone was done as a biomarkers before and after the treatment in selected patients. Routine haematological and urine examination was carried out to assess the present status of the patient and to exclude other pathologies. In suspected cases USG was done to rule out hydrocele, vericocele and other pathologies.

Method of semen analysis:
Collection of semen sample: Sexual abstinence of 3—5 days was strictly followed in collection of sample in the study to avoid natural fluctuation in semen parameters with duration.

Method of Collection:
Preferably masturbation was recommended for the collection of semen sample because there are fewer chances for contamination and it provides the complete collection of ejaculate. Before collection to avoid contamination all the patients were instructed to clean the hands and glans penis thoroughly with tap water. Collection was done adjacent to the Laboratory. If the patient fails to masturbate, penile vibrator was used to induce the ejaculation. In case of failure of both of above said methods, collection by coitus interrupts method was advised. The different timings of the day is having effect on the quality of semen (Valsama 1988). In the present study to avoid such differences the collection time was fixed between 8.30 am to 9.30 am throughout the study period.

Precleaned, warmed and labeled wide mouth containers i.e. 50ml glass beakers were used for semen collection. After collection the semen samples were examined at room temperature for Volume, percentage of motility, Liquefaction time, Morphology, Total sperm count, and presence of White blood cell.

Methods:
The present clinical trial was an open labeled randomize study with efficacy as a end point.

Method of Virechana Karma:
Before administration of Ashwaththa Phala Churna or Shveta Plandu Svarasa Bhavita Yavani Vati, all the registered patients were given Virechana. For this purpose after the patient qualified for inclusion criteria and gave consent for the Virechana, for the initial 3 days, for Deepana and Pachana, 2gm of Trikatu Churna was administered twice in a day with luke warm water after meal. on 3rd day, after assessing the status of the patient, plain ghee in the dose of 40ml was given, early morning on empty stomach with luke warm water and was observed for Sneha Jeerna Lakhshana and accordingly for next 5 to 7 days, the dose of ghee was given in increased dose pattern till the patient achieved proper Snehana features. After completion of internal Snehannapana, for the next 3 days whole body massage with Bala Taila and Vashpaswedana was done twice daily. During all this period, patient was kept on normal diet with precautions, to avoid excessive oil or heavy food items. On the day of Virechana after massage and fomentation in the morning, Virechana Yoga of Triphaladi Kvatha was given which was prepared. For by 50gm of coarse powder of Triphala and 25gm of Trivritta. To this 4 times water was added and boiled until it was reduced to one fourth. To this prepared Kvatha, 2-10 gms of Danti powder was added taking into consideration Koshtha of the patient.
Thereafter according to the type of Shuddhi at end of Virechana, 3, 5, 7 days of dietary regimen was followed which included of Manda, Peya, Vilepi, Yusha in a sequential pattern.

After completion of the therapy, follow up was done for 1 month, to assess the status of patient, where patient were asked to report fortnightly.

Criteria for assessment:

Objective:
Improvement in the semenogram was observed especially in total sperm count. Change in S.FSH, S.LH, S.Testosterone was also considered for the assessment.

Statistical Analysis:
General data was subjected to suitable statistical analysis such as descriptive statistics for demographic data, Wilcoxon Signed Rank test for non-parametric paired data, paired t-test for quantitative parametric paired data, un-paired t-test for quantitative unpaired data.

After preparing the master chart of all the required data in Microsoft excel work sheet, statistical calculations were made 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, insignificant p>0.05.

Posology:

Group-A:
Ashvatha Phala Churna:

For the preparation of Ashvatha Phala Churna, (Ficus religiosa.Linn) fruits of Ashvatha were dried under indirect sunlight and thereafter fine powder was done.

After completion of Samsarjana Krama, Ashvatha Phala Churna[10] was given in the dose of 3gm twice a day orally Before food in Morning and evening a cup of warm milk with 5gm of Sharkara for 60 days,

Group-B:
Shveta Pandalu Bhavita Yavani Vati:

For the preparation of Shveta Pandalu Bhavita Yavani Vati fine powder of Yavani fruit (Tachyspermum ammi .Linn.) was made and then six Bhavana of Shveta Pandalu Svarasa (Allium cepa .Linn.)was given. For each Bhavana, sufficient amount of Shveta Pandalu Svarasa was added to the powder of Yavani and was triturated for 6-8 hrs daily till the Bhavana given to the powder was completely absorbed. On the 6th day, Vati was prepared by this powder in the pill machine.

In this group, after performing of Virechana Karma as per the procedure mentioned in group-A, Shveta Pandalu Svarasa Bhavir Yavani Vati was administered after the completion of Samsarjana Krama given orally in dose of 4 vati (500mg each ) twice a day before food in Morning and evening with 5 gm of Ghrita for the 60 days of period.

Effect of therapy:

Considering the relief in major symptoms and improvement in the quantity and quality of semen, the subjects were divided into the following groups to assess the total efficacy of each therapy. 0% - No change, < 25 % - mild positive response, 26-50 % - moderate positive response, 51- 75% - marked positive response, 75% -100%-Excellent response

Results and Discussion:

In this clinical trial, total 40 male patients were registered out of which 38 patients completed the course of therapy. In group A, 19 patients and in group B 19 patients completed the trail. Only 2 patients left the treatment, among them 1 left the course of treatment due to job transfer to other city while another did not report for the treatment due to family issue.
Effect of therapies on objective criteria:--
For the Present clinical trial, semen analysis done before treatment, after completion of Samsarjana Krama and after two months of treatment with the trial drugs. The data thus generated on the semen parameters has been presented in the sequence of effect on semen analysis before treatment and after Samsarjana Krama, then after Samsarjana Krama and after two months of treatment.

Analysis of 38 patients effect on sperm count showed that positive improvement was obtained in both the groups i.e. in Group A 59.78% increase and Group B 65% increase was reported. When subjected to statistical analysis, these finding were statistically highly significant (p<0.001). On applying Un-paired t Test, the difference of increase in Sperm count in A group and B group was statistically significant. That shows group B is better than Group A for increase in Sperm count. Analysis of effect on sperm count after Virechana Karma showed that positive improvement was obtained in both the groups i.e. Group A 91.74% increase and Group B 74.50% increase was reported which was statistically highly significant (p<0.001). (Table No-1) (Table No-2)

In 38 patients of oligozoospermia analysis of effect on sperm motility showed that Group A provided 4.97 % increase and Group B – 10.99 % increase in sperm motility. However, this change in motility of sperm was statistically insignificant. (Table No.3). On Analysis of effect on increase in normal sperm showed that both the groups i.e. Group A (24.94 %) and Group B (9.04 %) provided increase in normal sperm count respectively. When subjected to statistical analysis, increase in the groups was statistically insignificant (p<0.1). (Table No.4). Analysis of effect on Abnormal Sperm form in 38 patients showed that there were decrease in abnormal form by 16.18% in group A and 20.74% in group B. When subjected to statistical analysis, it was found that these results statistically significant in both the groups (p<0.01). (Table No.5). On applying Un-paired t Test, the difference of decrease in abnormal form of Sperm in A group and B group was statistically insignificant. (Table No.6)

The 36.81% increase in semen volume was found after the completion of treatment in group A which was statistically highly significant. In group B 22.67% increase in semen volume was found, but this increase was statistically insignificant (Table No.7). A group provided 8.27% decrease and group B provided 17.38% increase in serum FSH value. However these changes reported in Serum FSH was statistically insignificant in both the groups. Group A provided 6.57% increase and Group B provided 24.08% increase in serum LH. The effect provided on serum LH in group A was statistically insignificant. Whereas 24.08% increase provided by group B was statistically significant. Group A provided 13.58% decrease and Group B provided 6.55% increase in serum testosterone, but these changes provided in serum testosterone was statistically insignificant in both the group (Table no.8).

In both the group heamatological and biochemical parameters remained within normal limits before and after the treatment.

Overall Effect of Therapy:--
The overall effect of therapies showed that 4 patients (20%) each had mild positive response in group A and group B. 12 patients (60%) showed moderate positive response in Group A and 14 patients (70%) in group B. Whereas 4 (20%) and 2 (10%) patients in group A and Group B showed marked positive response respectively (Table No-9).

Probable mode of action of Virechana Karma:--
Vajikarana drugs (Aphrodisiac recipes) should be administered after purifying the body i.e proper Shodhana either by Vamana or Virechana. In both the groups, statistically significant increase in sperm count was found after the completion of Virechana Karma and hence. It is clear from the generated data that Virechana enhance the level of Shukra definitely. Further, Virechana Karma increases bio-availability of drugs by opening channels and improves the nutritional assimilation which may lead to increase S.LH level.

Probable mode of action of Ashwaththa Phala Churna:--
Due to Madhura Rasa, Shita Virya, Snigdha Guna of Ashwaththa Phala, Vata and Pitta Shamana take place which are the Dosha involved in the pathogenesis of Ksheena Shukra. It leads to Shukra Gata Vata-Pitta Shamana. Additionally Ashwaththa Phala Churna possess Vrishya effect and hence increases the production of spermatozoa which ultimately causes increase in sperm count.

Probable mode of action of Shveta Palandu Svarasa Bhavita Yavani Vati :-
Due to Deepana, Pachana and Vatanulomana action, Yavani, it corrects Jatharagni and Apanavayu thus resulting into the proper formation of Rasadi Dhatu and Shukra Dhatu. Further Shveta Palandu possess Vrishya and Rasayana properties thus help to form best of Rasa formation and Shukra by Uttarottar Dhatu Poshana. Allium cepa(Palandu) contains variety of phytochemical and micro constituents such as trace elements, vitamins like vit. C. and flavonoids and sulphur compounds which helps in increasing the spermatozoa formation.

Combined effect of Shveta Palandu Svarasa Bhavita Yavani Vati increase the Vrishya effect of each other & remove demerits of Palandu i.e Adhmana, ultimately increase sperm count.

**Conclusion:-**

Ashwattha Phala Churna group provided statistically highly significant improvement on sperm count and significant decrease in abnormal form of Sperm, whereas Shveta Palandu Svarasa Bhavita Yavani Vati group provided statistically highly significant improvement on sperm count, abnormal form of sperm and statistically significant increase in Serum LH.

Hence it can be concluded from present clinical trial that Virechana Karma is must procedure to be performed before administration of Vajikarana drugs and better and early changes in total sperm count can be achieved by Virechana Karma. Both the trial drugs Ashwattha Phala Churna and Shveta Palandu Svarasa Bhavita Yavani Vati have definite role in the management of Ksheena Shukra, but Shveta Palandu Svarasa Bhavita Yavani Vati is comparatively better than Ashwattha Phala Churna.

**Table No.1:** Effect of trial drugs on Sperm count of 38 patient of Ksheena Shukra (Oligozoospermia):

| Gr. | Mean Value | Diff. | Paired ‘t’ test | Significance |
|-----|------------|------|----------------|--------------|
|     | Million/ml |      | S.D. (±) | S.E. (±) | ‘t’ | P   |
| BT  | AT         |      |          |          |    |     |
| A   | 7.58       | 27.84| 20.26    | 59.78%↑  | 19.18   | 4.40  | 4.60 | <0.001 | HS |
| B   | 8.68       | 35.47| 26.79    | 65%↑     | 20.14   | 4.62  | 5.78 | <0.001 | HS |

BT- Before treatment, AT- After treatment, Gr.-Group

**Table No. 2:** Comparison of effect of therapy on Sperm count.

| Group | n | Difference in means | Unpaired ‘t’ test | Significance |
|-------|---|---------------------|------------------|--------------|
|       |   |                     | S.D. (±) | S.E. (±) | ‘t’ | ‘p’ |     |
| A     | 19 | 9.18                | 7.81     | 1.79    | -2.027  | 0.03  | S   |
| B     | 19 | 17.84               | 15.20    | 3.49    |          |       |     |

**Table No.3:** Effect of trial drugs on Sperm motility of 38 patients of Ksheena Shukra (Oligozoospermia):

| Gr. | Mean Value | Diff. | Paired ‘t’ test | Significance |
|-----|------------|------|----------------|--------------|
|     | %          |      | S.D. (±) | S.E. (±) | ‘t’ | ‘p’ |     |
| BT  | AT         |      |          |          |    |    |     |
| A   | 46.58      | 48.95| 2.37     | 4.97%↑   | 29.69  | 6.81 | 0.35  | 0.732 | IS |
| B   | 40.79      | 46.84| 6.05     | 10.99%↑  | 28.12  | 6.45 | 0.94  | 0.360 | IS |

n=19 in A group, n=19 in B group. IS= Insignificant
### Table No.4: Effect of trial drugs on Normal Sperm of 38 patient of Ksheena Shukra (oligozoospermia).

| Gr. | Mean Value | Diff. | Paired ‘t’ test | Significance |
|-----|------------|-------|-----------------|--------------|
|     |            |       |                 |              |
| BT | AT         |       | S.D. (±)        | S.E. (±)     | ‘t’ | p  |
| A  | 24.21      | 35.79 | 11.58           | 24.94↑       | 29.96 | 6.87 | 1.69  | 0.109 | IS  |
| B  | 22.79      | 34.47 | 11.68           | 9.04%↑       | 24.74  | 5.68  | 2.06  | 0.054 | IS  |

n=19 in A group, n=19 in B group. IS= Insignificant, ↑ increase;

### Table No.5: Effect of trial drugs on Abnormal Sperm form of 38 patients of Ksheena Shukra (oligozoospermia):

| Gr. | Mean Value | Diff. | Paired ‘t’ test | Significance |
|-----|------------|-------|-----------------|--------------|
|     |            |       |                 |              |
| BT | AT         |       | S.D. (±)        | S.E. (±)     | ‘t’ | p  |
| A  | 40.84      | 29.63 | 11.21           | 16.18        | 21.87 | 5.02  | 2.23  | 0.038 | S   |
| B  | 34.42      | 20.32 | 14.11           | 20.74        | 23.19  | 5.32  | 2.65  | 0.016 | S   |

n=19 in A group, n=19 in B group. S= Significant,

### Table No.6: Comparison of effect of therapy on abnormal form

| Group | N | Difference in means | Unpaired ‘t’ test | Significance |
|-------|---|---------------------|------------------|--------------|
|       |   |                     | S.D. (±)         | S.E. (±)     | ‘t’ | p  |      |              |
| A     | 19| 23.58               | 21.44            | 4.91         | 0.532 | 0.603 | NS  |              |
| B     | 19| 27.05               | 19.97            | 4.58         |       |      |     |              |

### Table No.7: Effect of trial drugs on volume of Semen of 38 patients of Ksheena Shukra (oligozoospermia):

| Gr. | Mean Value | Diff. | Paired ‘t’ test | Significance |
|-----|------------|-------|-----------------|--------------|
|     |            |       |                 |              |
| BT | AT         |       | S.D. (±)        | S.E. (±)     | ‘t’ | p  |      |              |
| A  | 1.021      | 1.605 | 0.584           | 36.81%↓      | 3.74  | 1.18 | 1.55 | 0.157 | IS  |
| B  | 0.90       | 1.16  | 0.263           | 22.67%↑      | 0.75  | 0.17 | 1.53 | 0.145 | IS  |

n=19 in A group, n=19 in B group. HS= Highly Significant, IS= Insignificant, increase, ↓ decrease

### Table No.8: Effect of trial drugs on Hormone in 38 patients of Ksheena Shukra (oligozoospermia):

| Hormone       | Gr. | Mean Value (ng/ml) | Diff. | Paired ‘t’ test | Significance |
|---------------|-----|--------------------|-------|-----------------|--------------|
|               |     |                    |       |                 |              |
| S.FSH (mg/dl) | A   | 12.54              | 10.71 | 1.83            | 8.27%↓       | 3.74  | 1.18 | 1.55 | 0.157 | IS  |
| B             |     | 6.98               | 10.00 | 3.022           | 17.38↑       | 7.12  | 2.37 | 1.27 | 0.239 | IS  |
| S.LH (mg/dl)  | A   | 5.02               | 5.25  | 0.23            | 6.57%↑       | 1.47  | 0.46 | 0.47 | 0.639 | IS  |
| B             |     | 4.16               | 5.57  | 1.41            | 24.08↑       | 1.04  | 0.35 | 4.09 | 0.004 | S   |
| S.Testosterone (ng/dl) | A | 548.53 | 525.72 | 22.81 | 13.58↑ | 110.89 | 35.07 | 0.65 | 0.532 | IS  |
| B | 574.98 | 630.00 | 55.02 | 6.55↑             | 128.38 | 42.79 | 1.29 | 0.234 | IS  |

n=10 in A group, n=10 in B group. IS= Insignificant, S= Significant, increase, ↓ decrease

### Table No.9: Overall effect of therapies in 38 patients of Ksheena Shukra (Oligozoospermia):

| Groups | No response | Mild Positive response | Moderately Positive response | Marked Positive response | Excellent response |
|--------|-------------|------------------------|------------------------------|--------------------------|-------------------|
| Group A – Ashvatha Phala Churna | 0 | 20% | 60% | 20% | 0 |
| Group B – Shveta Palandu Svarasa Bhivita Yavani Vati | 0 | 20% | 70% | 10% | 0 |
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