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OLIGOSPERMIA WITH SPECIAL REFERENCE TO UTTARAVASTHI - AN OPEN LABEL UNCONTROLLED CLINICAL STUDY

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ABSTRACT

Subfertility is one of the conditions that strike deep into the psyche of the couples that experience it. It is estimated that one sixth of all the couples have difficulty in conceiving the number of children they wants, when they want them.[1] It is not always a disease but the consequence of some pathogenic process, resulting in lifelong consequences. Even though the medical science have many an inventions and artificial reproductive techniques, the management of subfertility is not upto the mark. It is also not cost effective as far as the common man is considered[2]. Ayurveda has been on the route of specialisation right from its evolution in the universe. Of the eight specialities developed, vajeekarana is aimed at the management of the problems of genitourinary system and subfertility is considered as one among the utilities of this speciality[3]. Biological factors as well as the socio cultural factors are also being discussed under the aetiological factors. Ayurvedic parlance is really a treasure of several therapeutic combinations as well as procedures advisable in conditions like subfertility including oligo asthenospermia. Of these, the most important procedure mentioned is about a technique called Uttaravasthi ie. the method of introducing selected medicaments through the genitourinary route[4]. Prior to this procedure, one has to perform snehana, sodhana and nirooha. It seems ideal that, a management protocol is a need for the management of conditions like subfertility where the ultimate dhatu, the sukradhatu has been affected[5].

In this particular study, the subjects selected were those with two years of continuous marital life and those presenting with oligo asthenospermia and failed to beget a child by these.

Those with a normal female partner clinically, were only included. They were managed with the selected management protocol. The protocol was designed from the observations of the previous studies held in our department. The assessment was done before treatment and after completion of 3 months of treatment. RESULT- It was observed that the selected management protocol has significant effect in the improving the seminal parameters on assessment.

Key words- Oligospermia, Uttaravasthi, Sukrakshaya, Vajeekarana.

INTRODUCTION

Many a disorders in the human may not be considered as ultimate, but may lead to much ill health and mental agony in due course. Subfertility is one among them, which undoubtedly makes a man unhappy and diseased. The individual undergoes a lot of distress, agony and grief leading to lack of sexual desire and is treated as a disaster by many[6].

The overall values of the seminal parameters are on the decline as per studies[7]. Likewise the fertility problems are on the rise, even though a lot of advancements happened in the medical community. The drop on seminal parameters is expected due to the change in life style, alteration in nutrient supplementation, smoking, alcohol, stress, strain, injudicious use of drugs, use of chemical fertilizers and also industrialisation[7].

If a couple is not successful in having children, after a year of trying to conceive, the infertility evaluation has to be thought about. Medical world is in search for the evolution of new as well as effective drugs, to be proven clinically in this regard. The Ayurvedic parlance is seriously approaching the problems with fertility. A strict protocol has been mentioned as per the condition after strict clinical examination and diagnosis. Snehana, sodhana, followed by vasthi and vrishya drug is the commonly accepted protocol[8]. The vrishya drugs are classified on their mode of action by Acharya Sarnghdhara – sukrajanaka, sukrapravarthaka and both janaka and pravarthaka[9]. This is an indication of the specificity of drug selection in the Ayurvedic management of fertility problems. Besides while mentioning the group of drugs as per the therapeutic action named as ganas, Acharya Cahraka is mentioning sukrajanaka, sukrasodhaka and sukrarechaka ganas. The ideal drug on use varies for the production, purification and excretion processes according to the Ayurvedic experts. Many a studies had been conducted all over with the Ayurvedic treatment modalities, with promising results.

Uttaravasthi is a unique treatment modality mentioned in Ayurveda for the conditions affecting the genitourinary system, including subfertility[10]. Many are practising the procedure in both male and female, but statistical evaluation is still on the primary stage. Many a studies had not been reported yet, with the inclusion of Uttaravasthi, in the modalities for male subfertility. This study is aimed at assessing the efficacy of Uttaravasthi in the management of oligospermia, when administered after sufficient preparatory procedures.

Any couple coming for an evaluation of fertility does so with a little fear and reluctance. Psychological support is also an obligation from the part of physician in this regard. This study was proposed to evaluate the efficacy of the selected Ayurvedic modality in oligospermia at the clinical level.

AIM

To assess the efficacy of selected treatment modalities in the management of oligospermia

OBJECTIVES

1) To study oligospermia from the Ayurvedic point of view
2) To study the practise of Uttaravasthi in detail
3) To assess the efficacy of Uttaravasthi in oligospermia when administered along with the selected modalities.

MATERIALS

1. Concerned Modern and Ayurvedic literature
2. Participants 10 in number
3. The selected drugs for the trial
4. Patient Consent Form
5. Case Record Form

CLINICAL STUDY

Study Design

Open label Uncontrolled Clinical Trial

Settings

Kayachikitsa OPD & IPD - VPSV Ayurveda College Hospital, Kottakkal

Duration of Treatment

1 month’s intervention and 2 months follow up

Sample size: 10

Diagnostic criteria:

- Satisfying the WHO criteria for oligoasthenospermia [11].

Inclusion criteria

- Married individuals of the age group 25 – 40 yrs
- Sexual relationship for more than 1 year
- Primary subfertility with oligospermia (sperm density below 20 million /ml or active motile < 50% on semen analysis)
- Married individuals with the partner having no known fertility problems
- Those who are fit for snehana, swedana, virechana, vasthi and uttaravasthi

Exclusion Criteria

- Subjects with systemic diseases
- Those with endocrine anomalies
- Those with developmental anomalies of the genitourinary system
- Subjects with azoospermia
- Those with testicular trauma and with other obstructive causes
- Those who are not willing to give a written consent

Assessment Criteria

- WHO's criteria for seminal parameters

The assessments were done before treatment and after three months of the treatment

DRUG STUDY

The drugs were prepared from a GMP certified company as per the requirement of the study.

Table 1 - Management protocol

Purpose	drug	Dose	Time	duration
Rookshana	Vaiswanara choorna[12]	5 gm twice daily with hot water	Before food	3 days
Snehana	Kalyanaka gritha[13]	As per the agni (50 ml – 300 ml)	6 AM	Max. 7 days
Swedana	Ooshmasweda	-	3 PM	3 days
Virechana	Avipathy choorna[14]	25gm with warm water		1 day
Yapana vasthi	Hapushadi yapana vasthi [15]	600 ml	10 AM	7 days
Uttaravasthi	Ksheerabala taila[16]	30 ml	10 AM	3 days

Peyadi karma was done after virechana for 3 days before performing yapana vasthi.

Table 2 - Ingredients of yapanavasthi

Drug	Amount
Makshika	100 ml
Saindhava	15 gms
Sukumara gritha	100 ml
Ksheerabala taila	100 ml
Hapusha (kalka)	30 gms
Ksheera	200 ml

Uttaravasthi – procedure

The procedure was performed after sodhana and the yapanavasthi. A perfect counselling and hence consent was obtained from the subject. Strict aseptic measures were followed as the procedure was done at the surgical theatre. The catheter and the holding instruments were sterilized.

The patient was laid in the supine position. The genital parts were rinsed with diluted antiseptic solution. The penis was lifted and the glans and the meatus cleaned. Xylocaine jelly was applied at the tip of the catheter (rubber catheter 5 or 6). The tip of the catheter was introduced directly to the urethra and slightly pushed forward. This was continued till the tip of the catheter reaches the bladder and the urine was drained. The syringe filled with 30 ml of the drug was attached to the catheter and the medicine, gently inserted inside. The catheter was gently removed. The patient was advised to lie on bed, changing their position to left and right sides, on intervals. The drug was seemed to expel with the next reflux of voiding. The procedure was repeated for three days. The patient was advised to go on with a light diet.

The subjects were discharged after 2 days of observation and rest after the Uttaravasthi. The assessment was done after 60 days of discharge.

Data Collection

The selected subjects were examined in detail and the data was collected as per the prepared Case Record Form. Repeated semen analysis was conducted three times, with three days abstinence [17].Assessment was done before treatment, after 60 days of the treatment.

Data Analysis

The Outcome data was measured and statistically analysed by the 'student paired t *test'*. [18]

OBSERVATION AND ANALYSIS

A) Data related to clinical picture

The study recorded a predominance of patients in the age group 36 – 40 (50%). Hard work or unlimited exertion and the related stress seem to be affecting fertility as 50 % of the patients from that group. 30% of the individuals were addicted to smoking and alcohol. 80% of the subjects preferred the mixed diet with non vegetarian dominance. In the sample, 80% of the patients were not having any detectable cause, which indicates the high incidence of the idiopathic cause of oligospermia. 60 % were not having anything supportive from the families of both the partners in subfertility.

50 % of the patients were of Vatha pitta prakrithi, 30% were of Kaphapitta prakrithi and 20% of Vathakapha prakrithi. On the analysis of manodoshas, in 54%, tamas was predominant and rajas in 46% of the subjects. 25% of the patients were having excess stress, 10 % were having strain, 25% were having excess fear, 30% were anxious.

50 % of the patients were having their sexual life not satisfactory, as expected. Premature ejaculation was there in 40% of the individuals. Of the sukravaha dushti laxanas, 40% of the patients were having klaibya and 25% were having apraharsha[19].50% were having previous investigations and treatment. 50 % of the patients were having mild oligospermia (density above 10 mill/ ml). Regarding motility, 50% were of the group, severe defect in active motility (less than 20%).

B) Table -3, Data related to clinical study

Parameter	BT ± SD	AT ± SD	t value	P value
Volume	1.85 ± 3.33	2.68 ± 0.64	7.43	< 0.001
Density	27.46 ± 29.57	40.7 ± 33.59	3.32	< 0.01
Pus cells	6.45 ± 2.74	2.4 ± 0.87	4.74	< 0.01
Active motile	21.3 ± 14.68	39.5 ± 19.54	2.92	< 0.05
Sluggish motile	20.11± 2.11	18.3 ± 8.81	0.99	> 0.1
Non motile	50.6 ± 25.88	43.2 ±23.76	0.99	> 0.1
Morphology	40.6 ± 16.3	59.34 ± 12.2	2.4	< 0.05

(BT – before treatment; AT – after treatment; SD – standard deviation)

There was improvement in seminal parameters following the treatment in the subjects. It was effective in significantly improving the sperm density at 1 % level. The sperm motility improved statistically significant at 5% level. The management also was success in reducing the pus cells in semen by 1% level. In the area of morphology also, the trial package was statistically effective at 5% level. But it was not effective in reducing the sluggishly motile sperms, statistically. The general health as well as the performance of sexual act was enhanced in the subjects. Premature ejaculation which was seen in 50% of the subjects improved in almost all the patients after the treatment.

DISCUSSION

Dhatus are the functional units of the body as explained by the Ayurvedic science. Sukradhatu is the ultimate dhatu and the abnormal affection of the dhatu lead to sexual as well as fertility problems both in male as well as female. Eight sukradoshas easily explains the commonest clinical conditions in relation with genitourinary system of male and the specific treatments are also explained along with as per the condition.[20]. Within this spectrum, many of the fertility associated problems can be explained as well as approached.

The three doshas are involved in the process of sukradushti all over. Sukra dushti is caused by alteration of functions of vyanavatha and apana vatha[21]. The qualities of vatha like rooksha, laghu etc. if exceeded may alter the functioning of sukra, which is opposite in qualities to it.

Vitiated pitta due to its ushna and teekshna guna alters the guna of sukra. It may even affect the spermatogenesis. Eventhough Kapha seems similar in qualities to sukradosha, the excessive guru and pichila gunas affects the physical qualities of semen and affects the liquification process as well as the motility of the spermatozoa. That is why, the eight sukradoshas are mentioned as due to the combination of the three doshas.

The status of agni is also having unavoidable role in the normal dhatu metabolism and hence the normalisation of the sukradhatu. Hence the management starts with the equilibrium of agni, any dosha being suspected in the aetiopathogenesis.

Causative factors

The changes in lifestyle are creating depletion in the seminal parameters all over the world as mentioned above. The factors' causing the sukradushti has been elaborately explained by

Acharyas[22]. Of the dietary factors, asatmya ahara, rooksha, tikta, kashaya, lavana rasa diet may contribute to sukrakshaya. The asatmya ahara ie. the non compatible food also includes alcohol, smoking, tobacco etc. Anasana or subproper diet may lead to dhatukshaya and also a decline in shukra dhatu.

Viharas like ativyavaya, ativyayama, ati ayasa are also contributory to the shukra dushti. Manasika hetus like stress, anxiety, intolerance, sorrow etc. also are leading to shukradushti as per studies[23]. The resultant endorphin release by the brain may affect the normal release of GnRH which helps the spermatogenesis.

Management

The management protocol mentioned for the sukradosha is snehana, swedana, sodhana, Nirooha as well as Anuvasana followed by Uttaravasthi as per Acharya Susrutha [24]. Vasthi is the utmost treatment for sukradosha as per Acharya Vaghbata and Uttaravasthi is one of the classification of Vasthis mentioned. Hence this study is an attempt with a selected protocol with Vasthi and Uttaravasthi after sneha sweda and sodhana. Susrutha advises vajeekarana drugs for sukradosha.[25].

The snehasweda and sodhana procedures may create an atmosphere for the procedures like yapana vasthi and uttaravasthi to work with. The Yapanavasthis are the ideal combinations which can be used effective in sukrakshaya and other associative conditions, especially explained by Acharya Charaka[26]. Several studies have reported the relationship between the immune system alteration and fertility problems and the term immunologic infertility is on the merge. The concept of antisperm antibody is one among such discussions. The Sodhana procedure adopted in the management of Sukradosha, not only purifies the body from the altered doshas, but also helps in immune enhancement.

Uttaravasthi

The transurethral route of drug administration is specifically working in the disorders of genitourinary system including subfertility issues. The procedure seems to stimulate the swadishtana chakra which is attributed as the sacral plexus, resulting in a neural activation overall[27]. It also normalises the deranged apana, which is the key factor component of vatha dosha behind the sukra janana and pravritti [28]. Slight absorption of the drug also is to be expected from the trigone of the bladder[29]. The flushing out effect from the bladder is also to be considered as well. The trial drug Ksheerabala taila is itself vatha pitta samana, rasayana,

indriya prasadana and sukrasodhana as well[30]. This drug is ideal for performing Uttaravasthi in sukrakshaya and seems to be effective as well.

Psychological aspects

Infertility affects several aspects of life. The longer the duration of the management goes on, the more the severity, of the psychological issues. Ignoring the emotional issues may create a vicious cycle, delays the response to specific therapy and add on to the distress[31]. How badly the fertility problem affects the couple depends on the social support system, their personality and the strength of their marital relationship. The couples should be taught ways to decrease the stress and to cope with the situation. The codes of conducts as mentioned along with the rasayanas as Achara rasayana by acharya Charaka, is to be employed in this regard[32]. Eliciting the relaxation response is also possible with techniques as yogasana and pranayama in the subfertile couples, so as to improve their psychological reflexes.

CONCLUSION

From this study, we can conclude that the selected Ayurvedic treatment modality including Uttaravasti, is effective in the management of oligospermia significantly. The management improves the general health of the individuals including sexual performance as well as the haemoglobin level. Eventhough the reproductive medicine has expanded beyond our imaginations, it is still to challenge the time tested traditional knowledge and its wide spread as well as safe applications.. The global deterioration of seminal parameters is an issue of vital importance, as it threatens the existence and continuation of human species. The dietary and codes of conducts mentioned by the Ayurvedic Scholars has to be followed strictly so as to avoid such circumstances. The vast and abundant Ayurvedic literature seems be able to answer several questions regarding subfertility from the modern medical world.

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