An Open label Uncontrolled Clinical Study of Apathyakara gritha in Oligoasthenospermia

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Abstract:
Despite of all the medical advancements, Subfertility is one of the burning issues in the society. It is estimated that one sixth of all the couples have difficulty in conceiving the number of children they want, when they want them. Of all the affected ones, the male factors contribute to nearly 1/3rd. Even though the medical science have many an inventions and artificial reproductive techniques, the management of subfertility is not upto the mark or as expected. It is also not cost effective, as far as the common man is concerned.

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. Subfertility and its management is considered as one among the utilities, of this speciality. Biological factors as well as the socio cultural factors are also being discussed, under the aetiological factors of the problems in relation with fertility. Ayurvedic parlance is really a treasure of several therapeutic combinations as well as procedures, advisable in conditions like subfertility, including oligo asthenospermia.

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 when needed. Those with a normal female partner clinically, were only included to rule out the mixed or combined effects. They were managed with the selected medicine, as per the protocol. Simple counselling was done together in all. The assessment was done before treatment and after completion of 2 months of treatment.

Aim: To assess the efficacy of Apatyakara gritha in oligospermia, when administered internally

Method: Open label uncontrolled clinical trial with sample size 20

RESULT- Assessments were done according to WHO criteria for seminal parameters. It was observed that the selected drug has significant effect in the improving the seminal parameters in the present scenario

Key Words: Oligospermia,, Sukrakshaya, Vajeekarana, Apatyakara gritha.

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

The overall values of the seminal parameters are on the decline, as per studies. Likewise the fertility problems are on the rise, even though a lot of advancements happened in the medical community, in the recent days. 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 drastic industrialisation.
If a couple is not successful in having children, after a year of trying to conceive, the evaluation of infertility has to be contemplated. Medical world is in search for the evolution of new, secure, economic as well as effective drugs, to be proven clinically in this regard. The Ayurvedic parlance is seriously approaching the problems with fertility, right from its period of evolution⁴. A strict protocol has been mentioned as per the condition after strict clinical examination and diagnosis. Snehana, sodhana, followed by vasthi, uttaravasthi and vrishya drug is the commonly accepted protocol by almost all the scholars⁵.

It is quit ideal about the depth of thinking of the therapeutic action of the drugs acting on the genitourinary system by the ancient Ayurvedic scholars. The vrishya drugs are classified on their expected mode of action by Acharya Sarngdhara – sukrajanaka, sukrapravartaka and both janaka and pravarthaka⁶. This is an example 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 Charaka is mentioning sukrajanaka, sukrasodhana and sukrapechaka gana7. The ideal drug on use varies for the production, purification and excretion processes of the seminal fluid and its contents according the Ayurvedic experts. Many a studies had been conducted all over, with the Ayurvedic treatment modalities, with promising results. It seems ideal that, a management protocol is a need, rather than a single drug, for the management of conditions like subfertility, where the ultimate dhatu, the sukradhatu has been affected⁸.

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 regard⁹. Hence a simple counselling method was also included with the supervision of a clinical psychologist from our psychotherapy department, in all those included.

This study was aimed at assessing the efficacy of Apatyakara gritha in the management of oligospermia, when administered internally, in those who satisfied the inclusion criteria.

AIM: To assess the efficacy of Ayurvedic treatment modalities in the management of oligospermia

OBJECTIVES
1) To study oligospermia from the Ayurvedic point of view
2) To study the efficacy of apatyakara gritha when administered orally, in oligospermia

Materials
1. Concerned Modern and Ayurvedic literature
2. Participants 15 in number
3. The selected drug for the trial ie. Apatyakara gritha ¹⁰
4. Patient Consent Form
5. Case Record Form

CLINICAL STUDY:

Study Design: Open label Uncontrolled Clinical Trial
Settings: Kayachikitsa OPD & IPD - VPSV Ayurveda Medical College Hospital, Kottakkal
Intervention: 25ml of warm gritha at 7 AM. Breakfast after 4 hours
Duration of Treatment: 1 month’s intervention and 1 month follow up
Diagnostic criteria: Those satisfying the WHO criteria for oligoaesthenospermia ¹¹
Sample size: 15

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 administering gritha

Exclusion Criteria:
• Subjects with systemic diseases or on medications for the same
• 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 two months of the treatment

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

Table 1 – Ingredients of Apatyakara gritha 12

<table>
<thead>
<tr>
<th>Drug</th>
<th>Rasa</th>
<th>Guna</th>
<th>Veerya</th>
<th>Vipaka</th>
<th>Doshakarma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shatavari</td>
<td>Madhura, tikta</td>
<td>Guru, snigdha</td>
<td>Seeta</td>
<td>Madhura</td>
<td>Tridoshagna, vayasthapana</td>
</tr>
<tr>
<td>Asparagus racemosus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vidari</td>
<td>Madhura, tikta</td>
<td>Guru, snigdha</td>
<td>Seeta</td>
<td>Madhura</td>
<td>Rasayana, vrishya, Vatha pitta samana</td>
</tr>
<tr>
<td>Pueraria tuberosa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Masha</td>
<td>Madhura, tikta</td>
<td>Laghu, snigdha</td>
<td>Seeta</td>
<td>Madhura</td>
<td>Vathapitta samana, jeevaneeya</td>
</tr>
<tr>
<td>Vigna radiata</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gokshura</td>
<td>Madhura, tikta</td>
<td>Laghu, snigdha</td>
<td>Ushna</td>
<td>Madhura</td>
<td>Vrishya, vata kaphahara</td>
</tr>
<tr>
<td>Tribulus terrestris</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atmagupta</td>
<td>Madhura, tikta</td>
<td>Guru, snigdha, pichila</td>
<td>Ushna</td>
<td>Madhura</td>
<td>Vajeekara, balya</td>
</tr>
<tr>
<td>Mucuna pruriens</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dugdha (Milk)</td>
<td>Madhura</td>
<td>Snigdha, guru</td>
<td>Seeta</td>
<td>Madhura</td>
<td>Vathapitta samana</td>
</tr>
<tr>
<td>Gritha (ghee)</td>
<td>Madhura</td>
<td>Snigdha</td>
<td>Seeta</td>
<td>Madhura</td>
<td>Vathapitta samana</td>
</tr>
</tbody>
</table>

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. 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’.14

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 were 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. Stress in relation with the job was affecting the performance at home, in 60% of the subjects. Premature ejaculation was complained in 40% of the individuals. 50% of the individuals seem highly anxious about their sexual performance. 25% were not able to perform the act, when expected from them.

Of the dushti laxanas of the sukravaha srotus, 40% of the patients were having klaibya and 25% were having apraharsha.50% were having previous investigations and history of treatment elsewhere. 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

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

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

There was improvement in seminal parameters following the intervention in the subjects. It was effective in significantly improving the sperm density at 1 % level. The sperm motility improved and it was also statistically significant at 5% level. The management also was a success in reducing the pus cells in semen, by 1% level. In the area of morphology also, the trial drug 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. There was also an improvement in the hemoglobin level, in all the patients at 5% level.
C) Table 4, Data related to the symptoms of Sukrakshaya

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>SD</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpasukrata</td>
<td>1.6</td>
<td>0</td>
<td>0.54</td>
<td>18.55</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Chirat sukra praseka</td>
<td>0.45</td>
<td>0.2</td>
<td>0.54</td>
<td>2.912</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Dourbalya</td>
<td>1.35</td>
<td>0.55</td>
<td>0.51</td>
<td>9.798</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Klaibya</td>
<td>1.65</td>
<td>0.27</td>
<td>0.42</td>
<td>16.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maithuna asakthi</td>
<td>1.22</td>
<td>0.22</td>
<td>0.50</td>
<td>12.49</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Medra vedana</td>
<td>0.9</td>
<td>0.15</td>
<td>0.43</td>
<td>10.82</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mukha soshana</td>
<td>0.75</td>
<td>0.27</td>
<td>0.50</td>
<td>5.94</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sadana</td>
<td>0.4</td>
<td>0.02</td>
<td>0.49</td>
<td>4.83</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Shrama</td>
<td>1.12</td>
<td>0.35</td>
<td>0.65</td>
<td>7.52</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Discussion

The structural units, the dhatus are explained in Ayurveda so as to explain the functional units, the doshas and their role in bodily functions. 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 explain the commonest clinical conditions in relation with genitourinary system of male and the specific treatments are also explained, along with each and every condition. Within this spectrum, many of the fertility associated problems can be explained as well as approached.

In the side of management also, in any disease, the affection of the ultimate dhatus make the prognosis worse. Sukra is the ultimate dhatu and is. Why the disorders associated with sukra is to be dealt with utmost seriousness and care. Hence a detailed protocol with snehana, sweda, sodhana, nirooha, uttaravasthi followed by the vrishya drug is the ultimate solution. The gravity of the protocol is opted by the physician, considering all the parameters of assessment.

All the three doshas, Vatha, Pitta and Kapha are involved in the process of sukradushti in one or other condition. Sukra dushti is chiefly caused by alteration of functions of the fractions of Vatha dosha, Vyana and Apana vatha. Vyana vatha is the controlling by the higher centre while Apana is in charge of local functioning of the genital system. The qualities of vatha like rooksha, laghu etc. if exceeded may alter the functioning of sukra, which are opposite in qualities to it.

Vitiated pitta, due to its ushna and teeksha guna, alters the qualities of sukra. It may even affect the spermatogenesis and its stages. Eventhough Kapha seems similar in qualities to sukradosha, the excessive guru and pichila gunas, affect the physical qualities of semen and affects the liquification process as well as the motility of the spermatozoa. These steps are very much critical, in the stage of fertilization. This is the logic behind the mentioning of the eight sukradoshas, as per the combination of the three doshas.

The status of agni is also having unavoidable role in the normal dhatu metabolism and hence the normalization of the sukradhatu. Likewise is the contribution of aama, in the various stages of reproduction. Hence the management starts with the equilibrium of agni and the removal of aama dosha, whether Vatha, Pitta or Kapha being suspected as the culprit, in the aetiopathogenesis of subfertility.

Causative factors

The changes in lifestyle are creating depletion in the seminal parameters all over the world, as mentioned above. The factors causing the vitiation of shukra dhatu has been elaborately explained by the Acharyas. Of the dietary factors, asatmya ahara, rooksha, tikta, kashaya, lavana rasa diet contributes to sukrakshaya. The asatmya ahara ie. the non compatible food also includes alcohol, smoking, tobacco etc. The relation between the aforesaid things and their role in subfertility, has been well authenticated. Anasana or subproper diet may lead to dhatukshaya and also a decline in shukra dhatu.
Viharas like excessive intercourse, non controlled exercises, severe stress and strain, sleep dysfunctions are also contributory to the shukra dushti. Manasika hetus like stress, anxiety, intolerance, sorrow etc. also are leading to shukradushti as per studies. The resultant endorphin release by the brain is said to affect the normal release of GnRH which helps the spermatogenesis and hence the quality of semen.

Management

The management protocol mentioned for sukradosha is snehana, swedana, sodhana, Nirooha followed by Uttaravasthi and vajeekarana drugs, as per Acharya Susrutha. A lot of samana drugs or internal medications are mentioned to be used for this condition.

Prior to going for the detailed sodhana chikitsa, many drugs mentioned in all the available samhithas can be used. Samana chikitsa is having its own role in the management of any disease, including subfertility. It is the preliminary approach that is to be done at the OPD level. Many a drugs have to be selected and administered with proper assessment protocols. Apatyakara gritha is one such drug by acharya Charaka in this context. The evaluation of such drugs is very much essential to make them acceptable to the whole medical community.

Psychological aspect

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. 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. A Psychologist has to cope hands with an urologist in attaining the ultimate aim, in the evaluation as well as management of a subfertile couple. The codes of conducts as mentioned along with the rasayanas as Achara rasayana by acharya Charaka, is to be employed effectively in this regard. 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

Subfertility is one of the conditions that strikes deep into the psyche of the couples that experience it. It is not always a disease but the consequence of some pathogenic process, resulting in lifelong consequences. If not properly solved in time, it may affect the familial relationships.

From this study, we can conclude that the selected Ayurvedic drug, Apatyakara gritha is effective in the management of oligoasthenospermia, significantly. The management improves the general health of the individuals including sexual performance, as well as the psychological status. Even though 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 concern, 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 in our life, so as to avoid such circumstances. The vast and abundant Ayurvedic literature seems be able to answer several questions regarding subfertility, in the present era. Apatyakara gritha is only a humble representative of the abundant Ayurvedic vocabulary of Ayurveda. It is hard time to explore many such combinations and point out the efficacy of the medical world, so as to increase the acceptance and utility of Ayurveda.

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