Clinical Trial on Efficacy of Amalakyadi Yoga on Oligoasthenoteratozoospermia (Kshina Shukra)

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Abstract
To create a healthy progeny is one of the foremost Dharmas of an individual, so fertility is an existential necessity since the time immemorial. Impaired sperm parameters especially decreased sperm count, motility and abnormal morphology leads to male infertility. Hence the current study was conducted with aim to evaluate the efficacy and safety of oral administration of Amalakyadi Yoga (AY) on oligoasthenoteratozoospermia. The results of the study showed that trial drug significantly improved the sperm count and motility moderately and total abnormal sperms reduced by 10.62%. Hence it is concluded that Amalakyadi Yoga can be of great help in managing the sperm abnormalities in infertile males.

Keywords: Male infertility, oligoasthenoteratozoospermia, sperm count, sperm motility, sperm morphology, Amalakyadi Yoga

Introduction:
Infertility seldom causes any physical debility, but its severity affects the couple’s psychological harmony, sexual life and social function. A couple may be considered infertile if, after two years of regular sexual intercourse, without contraception, the woman has not become pregnant (and there is no other reason, such as breast feeding or postpartum amenorrhea).1 Gradual increase of infertility by an alarming 16.71% is estimated (W.H.O., 1993). Nearly 30 million couples in the country suffer from infertility and making the incidence rate of 10-20%.2 The Indian reports, both from the Institute for Research in reproduction, Mumbai and from Mehta et al, Bangalore reveal decline trend of semen quality.3

Male infertility can be defined as an inability to induce conception due to defect in spermatogonic functions. The male partner carrying pathological semen reports include low sperm count, motility, abnormal forms and sperm functional tests and whose female partners have been ruled out for the possible etiological factors of infertility. As per the Ayurvedic classics reproduction is the work of Shukra Dhatu. Out of eight types of semen disorders (Shukra dushti) mentioned in the classics, Kshina Shukra is one which occurs due to involvement of Vata and Pitta4 and characterized by decrease in quality and quantity of Shukra. It incapacitates the patient from conceiving his life partner, ending in infertility. As a seed does not grow when impaired by unseasonal implantation and when afflicted by water, microbes, insects and fire, similarly polluted semen in human beings does not help in procreation of an offspring.5 In contemporary science the conditions associated with Kshina Shukra can be well matched with Oligoastheno teratozoospermia. In this condition the sperm count comes below 40 million/ml, motility of sperms comes below 50% (RLP+SLP) and morphologically healthy sperms less than 25%. In Ayurveda, the treatment of Kshina Shukra has been highlighted as Upachaya of Shukra. It can be done with the help of Shukra itself, or the drugs having Shukra like qualities or functions. Kshina Shukra has mentioned under the description of Dhatu Kshaya Lakshana in Sutra Sthana6 and its treatment in Shareera Sthana.7 Different Nidana for Shukra Kshaya has been indicated in Vajikarana Adhyaya.8 Eight types of Retodoshas are mentioned in Sutra Sthana and again re-mentioned in Chikitsa Sthana under the title of Shukradushti.9 Kshina Shukra condition is one of them and its treatment with Upachaya is mentioned.10

The branch of Ayurveda deals with this specialty is known as Vajikarana or Vrshya Tantra. It provides progeny to infertile couple, at the same time excellency of progeny with suitable therapeutic measures. Drugs having Madhura Rasa, Guru-Snigdha Guna, Vrshya, Shukra Vardhaka, Balya and Rasayana properties11 has to be used for the treatment of Kshina-Shukra. Amalakyadi yoga (AY), test drug, consists of Ámalaki, Guduchi and Gokshura having Vrshya and Rasayana properties. AY is prepared in the form of tablet by giving Bavana (fortification) with the decoction (Kashaya) of same drugs and it was
administered in a dose of 3 tablets thrice a day for 45 days in 26 patients. Seminal parameters were compared before and after treatment and statistically analysed with SPSS 16.

**Aims and Objectives:**
To evaluate efficacy of Amalakyadi yoga on seminal and clinical parameters in the management of Kshina Shukra (Oligoasthenoteratozoospermia).

**Materials and Methods:**
Ethical clearance number: SDM/IEC/32/2010-11
Established cases of Oligoasthenoteratozoospermia from Vajikarana unit of Kayachikitsa department, SDM College of Ayurveda, Hassan as well as cases referred by other physicians were included in the study.

**Method of Preparation of Amalakyadi yoga:**
One part of powder each of Gokshura, Guduchi, Amalaki was taken and was given Bhavana with its Kashaya and made into tablets each of 700 mg.

**Diagnostic Criteria:**
The sperm count < 40 mill/ml\(^{12, 13}\) motility< 50% SLP + RLP\(^{18}\) and morphologically healthy sperms <25% were considered as Oligo-asthenoteratozoospermia.

**Inclusion Criteria:**
Male infertility patients aged between 25- 50 yrs

**Exclusion Criteria:**
Varicocele, accessory sex gland infection, testicular maldescent, previous reproductive organ surgery, and sexually transmitted diseases were excluded. Patients categorized under Azoospermia were excluded
Past history of mumps, orchitis, trauma, addictions, and acute febrile illness were taken into account
Diabetes, thyroid disorders, tuberculosis, vascular diseases, and any long-standing infection were also being taken into consideration.

**Drug, Dosage and Anupana:** The cases of oligoasthenoteratozoospermia were administered with Tablet Amalakyadi Yoga in a dose of 3 tablets each of 700 mg three times a day with lukewarm water for 45 days.

**Diet:** All the patients registered in the study were advised to follow their normal routine diet.

**Criteria of Assessment of Effect of Therapy:**
Effect of therapy on oligoasthenoteratozoospermia patients was assessed on the basis of seminal parameters observed before and after treatment.

**Semen Analysis:** Semen analysis of patients was carried out by the scholar himself as per the recommended standards of semen examination by WHO for diagnosis and assessment of effect of therapy, in specially setup Vajikarana laboratory in the OPD of Vajikarana, SDM College of Ayurveda and Hospital, Hassan. Following investigations of semen sample were carried as per the guidelines of WHO (1993)\(^15\).

Appearance, liquefaction time, volume, viscosity, pH, sperm count, sperm motility and sperm morphology of the sperms.

**Statistical Methods**
The present study was an outpatient based clinical trial with pre and post test design. The data collected during clinical study were tabulated and statistically analyzed using SPSS-16 software. Data obtained were assessed by Student’‘t’ test. The changes observed with P<0.05 were considered as significant and with P<0.001 was considered as highly significant.

**Observations**
**Status of patients:** In the present study more than 50 patients were screened with complaints of no issues since a year of unprotected sexual intercourse and among them 26 patients of Oligoasthenoteratozoospermia were registered in the present study, amongst them 20 completed the full course of study and 6 (23%) patients left against medical advice (LAMA) for unknown reasons and were considered as drop outs.

### Table-1

<table>
<thead>
<tr>
<th>Semen investigation</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>% of Change</th>
<th>S.D (±)</th>
<th>S.E (±)</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sperm count in millions/ml</td>
<td>9.95</td>
<td>23.57</td>
<td>↑136.88</td>
<td>15.80</td>
<td>3.53</td>
<td>3.86</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Rapid linear progressive %</td>
<td>21.21</td>
<td>26.68</td>
<td>↑25.79</td>
<td>13.99</td>
<td>3.21</td>
<td>1.71</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Slow linear progressive in %</td>
<td>28.11</td>
<td>34.74</td>
<td>↑23.59</td>
<td>7.21</td>
<td>1.65</td>
<td>4.01</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non Progressive in %</td>
<td>11.32</td>
<td>12.37</td>
<td>↑9.28</td>
<td>8.15</td>
<td>1.87</td>
<td>.563</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Immotile in %</td>
<td>39.58</td>
<td>26.84</td>
<td>↓32.19</td>
<td>19.19</td>
<td>4.40</td>
<td>2.89</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>RLP + SLP in %</td>
<td>49.32</td>
<td>61.42</td>
<td>↑24.53</td>
<td>16.30</td>
<td>3.74</td>
<td>3.23</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Total sperm count ejaculate</td>
<td>32.33</td>
<td>86.50</td>
<td>↑167.55</td>
<td>48.50</td>
<td>11.13</td>
<td>4.52</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total abnormal sperms in %</td>
<td>83.21</td>
<td>74.37</td>
<td>↓10.62</td>
<td>9.10</td>
<td>2.09</td>
<td>4.24</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Seminal volume in ml</td>
<td>3.25</td>
<td>3.67</td>
<td>↑12.92</td>
<td>0.90</td>
<td>0.20</td>
<td>2.07</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Liquification time in minutes</td>
<td>20.5</td>
<td>20.75</td>
<td>↑1.21</td>
<td>4.72</td>
<td>1.06</td>
<td>0.24</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>pH</td>
<td>7.65</td>
<td>7.48</td>
<td>↓2.22</td>
<td>0.44</td>
<td>.098</td>
<td>1.79</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>
Age: All the patients included in the study were adult males aged between 25 and 50 years. Among them maximum i.e. 38.4% belonged to 36-40 years age group and 30.6 % were patients between 25-30 years.

Working Pattern: From the current study it was found that 42.31 % of patients were doing jobs with mental work whereas 30.77 % were doing job that involves both physical energy and mental stress and 26.92% of patients were doing works only with physical exertion.

Results
The effects of AY on the various semen parameters along with statistical analysis are shown in Table-1. The drug significantly increased sperm count, slow linear progressive, RLP+ SLP in % and non progressive. It significantly decreased immotile sperms and Total abnormal sperms in %

Discussion
Amalaki, Gokshura and Guduchi of Amalakyadi Yoga are well known single drugs for their Virshya and Rasayana properties 7,16,17,18. These drugs have Madhura Vipaka and Shukra vardhaka action. More over Bavana was done with the same kVatha for 7 times which further enhances the potency of the drug. It has been mentioned that “Samskarohi Gunantaradhanam”. Recent studies also prove the spermaticogen properties of the above mentioned drug.

All the ingredients of AY possess Madhura Vipaka, Guru and Snigdha Guna and Shita Virya19. It has Vryavardhaka and Vrshya properties20. All these factors might have synergistically acted and have brought improvement in sperm count, motility and morphology in patients of Oligoasthenoteratozoospermia. Statistically insignificant changes noted in volume (↑), pH (↓) and liquefaction time (↑) (within normal). It shows that the drug does not have any adverse action and helps to maintain normal physiological parameters of semen. Mild (insignificant) improvement in seminal volume points towards shukravruddhi property of drugs.

Effect on the Sperm Count: The drug significantly increased the total sperm count in millons/ml by 136.88% and total sperm count/ ejaculate by 167.55%. This suggests spermaticogen maturation and capacitance activity of sperms. This finding also supports the Shukravrudhikara property of the drugs.

The Guru and Snigdha properties of Guduchi and Gokshura might have contributed to increase the viscosity of the semen may be because of that there was a mild increase in the liquefaction time.

Effect on the Motility: The motility (RLP + SLP) was significantly improved that may be because of the Rasayana effect of the drug used. Rasayana will do the Dhatu Pushthi thereby Ojas may also get nourished. Ojas is directly related to the Bala and the Bala of Shukra Dhatus may helped in the motility of the sperms.

Effect on the Morphology: There was a significant improvement in the morphology, after the treatment, this may be due to the Rasayana effect of the drug. Change in morphology may also be due to anti-oxidant activity of Amalaki. Studies show supplementation in vitro with the antioxidants ascorbate, urate and alpha tocopherol separately has beneficial effects for sperm DNA integrity (C M Hughes, S E Lewis, et al.1998).

The above results showed that Amalakyadi Yoga is potent Vrsya, Balya and Vritya-vardhaka drug so it can be used effectively in the management of Oligoasthenoteratozoospermia (Kshina Shukra).

Conclusions
Amalakyadi yoga significantly increased the sperm count/ml and total sperm count/ ejaculate in patients of Kshinashukra (Oligoasthenoteratozoospermia). Amalakyadi yoga significantly improved the rapid and slow linear progressive motility of sperms in patients of Kshinashukra (Oligoasthenoteratozoospermia). Amalakyadi yoga decreased the total abnormal forms of sperms in patients of Kshinashukra (Oligoasthenoteratozoospermia).

As impaired sperm parameters especially decreased sperm count, motility and abnormal morphology lead to male infertility and Amalakyadi yoga has shown beneficial effects on all these parameters hence Amalakyadi yoga may be recommended for treating the patients of Oligoasthenoteratozoospermia (Kshina Shukra).

References


5. Acharya JT. Charaka Samhita with Ayurveda Dipika commentary of Chakrapani Datta. Reprint
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