Efficacy and safety of WP6 in patients with asthenospermia: An open clinical study

Wakkumbura H.P.¹, Weerasinghe W. A. R. P.¹, Deepthika S.H.K.²

Abstract

Subfertility is a common problem affecting one in six couples worldwide. The infertility level measured by total fertility rate (TFR) is estimated at 2.6 for the period between 1993 and 2010. An abnormality is present in the male partner among 30% of sub fertile couples. Semen quality is a measure of the ability of semen to accomplish fertilization. Decreased semen mortality is asthenospermia. There are compounds of Ayurvedic preparations that have been widely used in the management of asthenospermia. In this study, it is established that WP6 is effective in the management of asthenospermia. WP6 is a herbal preparation, administered to 35 healthy patients with asthenospermia who were selected by full clinical examination from infertility clinic at Gampaha Wickramarachchi Ayurveda Teaching Hospital. All patients (25 – 45 years) had been treated with water dissolved WP6, 5 g twice a day for a period of 4 months and examined for physical changes with one month interval. Seminal fluid was analyzed. Reports of all patients were taken before and after the treatment and the data were analyzed using SPSS16 software. After 4 months, the percent of rapid linear progressive sperm has increased significantly 13.68 ± 3.414 to the 29.19 ± 4.039 (p<0.001). Patients have shown significant improvement of reducing immotility sperm percentage after the treatment. Any adverse effect had not been reported during the period of treatment and follow up period. Therefore this study has shown that WP6 is effective in the management of asthenospermia.

Keywords: Subfertility, Fertility rates, Asthenospermia, Sperm motility, WP6

¹ Department of Rajunahaththiy and Sriy Roga, Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Yakkala, Sri Lanka
² Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Yakkala, Sri Lanka
Introduction

Sperm motility is described by the ability of sperm to move properly towards an egg. This can also be thought of as the quality of the sperm, which is a factor in successful pregnancies, as opposed to the quantity. Sperm motility also facilitates the passage of the sperm through the cumulus oophorus and zona pellucida, which are a series of layers that surround the ovulated egg-cell plasma membrane of an oocyt.e.

The sperm motility is activated by changes in intracellular ion concentration. The change in cell volume which alters intracellular ion concentration can also contribute to the activation of sperm motility. Without technological intervention, a non-motile or abnormally-motile sperm is not going to fertilize. Therefore assessing the fraction of a sperm population that is motile is perhaps the most widely-used measure of semen quality making sperm motility an important factor of it. Insufficient sperm motility is a common cause of sub fertility or infertility. According to WHO grading, there are four types of sperm motility; grade A (fast progressive sperm swim forward and in a straight line), grade B (slow progressive sperm swim forward but either in a curved or crooked line), grade C (non progressive sperm move their tails but do not move forward), grade D (immotile sperm, do not move at all). The motility is usually estimated by direct microscopic examination of the semen to determine the percent of the sperms that are swimming. As per the WHO guidelines, a report with 25% or more with grade A or 60% or more with grade A+B within one hour collection is asthenospermia, which is considered as a cause of male sub - fertility.

In the past, the study of sub - fertility cases concentrated mainly on the female factor when pregnancy failed to occur. However, according to the recent studies, sterility in the husband is believed to be singularly responsible for 40% of sub - fertility cases, while in 20% of these cases, a combination of both male and female factors is associated, leading to sub - fertility.

There are many factors that influence the sperm quality. Exposure to any of the temporary factors can cause up to a three month delay before sperm quality returns to normal, due to spermatogenesis. The genetic quality of sperm, as well as its volume and motility, typically decrease with age. In other words, older sperm are less likely to result in a successful pregnancy. Sperm samples obtained via sexual intercourse contain 70-120% more sperm, with sperm having a slightly higher motility and slightly more normal morphology, compared with sperm samples obtained via masturbation. Sexual intercourse also generates a 25-45% increase in ejaculate volume, mainly by increased prostate secretion.

Sperm are heat-sensitive, and cannot endure high temperatures. The body has compensatory mechanisms, like the cremaster muscle relaxing and letting the testicle hang further
away from the warm body, sweating and a countercurrent exchange of blood cooling inflowing blood. Physical trauma can close or crush the capillaries that supply the sperm producing tissue, resulting in permanent or temporary partial or total inability to produce sperm in the affected testicle. There is suspicion that many toxic substances like, polychlorinated biphenyls (PCBs), DDT, and hexachlorobenzene, phthalates, including several types of medication like, depo-provera, adjudin, gossypol, THC present in marijuana, selective serotonin reuptake inhibitors (SSRIs), penicillin and tetracycline, and hormones like, anabolic steroids and also components of the diet like, coffee, alcohol, cola, soy products and zinc deficiency can influence sperm quality. Other factors, depend on sperm quality, outside the human body are semen pH and temperature, the environment in the uterus and fallopian tubes. In behavioral factors like, smoking, tobacco, marijuana, long-term stress, lack of exercise as well as excessive exercise, long-term mobile phone usage decrease sperm quality. Longer duration of sexual stimulation before ejaculation increases sperm quality. Different therapies, nutritional therapy and multifaceted therapies have been used in the treatment of male asthenospermia.

The WP6 is a polyherbal formulation comprising of Withania somnifera, Asteracantha longifolia, Macuna pruriens, Argyreia speciosa, Tribulus terrestris, and Asparagus asperatus. The present study was conducted to evaluate the effectiveness and safety of WP6 in the management of asthenospermia.

**Material and Methods**

**Study design**

Patients initially chosen on a random basis were thoroughly apprised of the treatment pattern and the follow up schedule. The study was an open clinical trial A written informed consent was obtained from all the patients.

**Study population**

Thirty two male patients in the age group of 25 – 45 years with asthenospermia who attended the sub fertility clinic of Gampaha Wickramarachchi Ayurveda Teaching Hospital, Yakkala, between January 1, 2012 and May 31, 2012, were enrolled in the study. All patients had been treated with water dissolved WP6, 5 g twice a day for a period of 4 months and examined for physical changes with one month interval.

**Inclusion criteria**

Male patients in the age group of 25 – 45 years with primary sub fertility were included in the study. Patients who have healthy clinical status other than the asthenospermia, were selected by complete physical and systemic examination and seminal fluid analyze reports.

**Exclusion criteria**

The patients with undescending testicles, diabetes, heavy smoking, chronic alcoholism, coital difficulty, ejaculatory dysfunctions,
psychological disorders, immunological disorders, high blood pressure and patients with secondary male infertility due to surgical causes like congenital absence of testes and other systemic diseases requiring specific therapies were excluded from the study.

Methodology
A thorough clinical examination of all cases was carried out every two weeks for the period of four months. The semen was collected by masturbation in a clean sterile petridish in the GWAI laboratory, Gampaha Wickramaratne, Ayurveda Institute, Yakkala, observing all the aseptic precautions. Sperm motility parameters were observed by the seminal fluid analyze reports of all patients, taken before the initiation of treatment and after the completion of 4 months of medication.

Follow-up and assessment
The patients were followed up every two weeks for one month after medication by complete clinical evaluation.

Primary outcome measures
Effectiveness was assessed by an increase in percent of rapid motility and decrease in percent of immotile sperm at the end of four months. Safety was assessed by incidence of adverse effects and clinical evaluation carried out through and after the medications.

Statistical analysis
The changes in parameters from pre treatment and after the completion of 4 months of medication were evaluated by paired t-test. The minimum level of significance was fixed at 95% confidence limit and a 2- side p-value of <0.05 was considered significant.

Results

Table 1: Descriptive statistics of mean percent of rapid linear progressive sperm before and after the treatment

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Minimum statistic</th>
<th>Maximum statistic</th>
<th>Mean statistic</th>
<th>Std.Error</th>
<th>Std.Deviation statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre treatment</td>
<td>32</td>
<td>0</td>
<td>55</td>
<td>13.68</td>
<td>3.414</td>
<td>19.006</td>
</tr>
<tr>
<td>Post treatment</td>
<td>32</td>
<td>0</td>
<td>86</td>
<td>29.19</td>
<td>4.039</td>
<td>22.486</td>
</tr>
<tr>
<td>Valid N</td>
<td>32</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
95% confidence interval for population means percent of rapid linear progressive sperm before the treatment. Pre treatment (6.71, 20.65)

We are 95% confidence that the population mean percentage of rapid linear progressive sperm before the treatment is in between 6.71 and 20.65

Post treatment (20.94, 37.44)

We are 95% confidence that the population mean percentage of rapid linear progressive sperm after the treatment is in between 20.94 and 37.44

**Hypothesis to be tested:**

$\mu_{\text{before}}$ - Population mean percent of rapid linear progressive sperm before the treatment

$\mu_{\text{after}}$ - Population mean percent of rapid linear progressive sperm after the treatment

H0: $\mu_{\text{before}} \geq \mu_{\text{after}}$ Vs H1: $\mu_{\text{before}} < \mu_{\text{after}}$

By using paired t-test, value of the test statistic = -4.096, P value = 0.000

Since p-value < significance level (0.05) we reject H0

We can conclude mean percentage of rapid linear progressive sperm after the treatment is greater than the mean percentage of rapid linear progressive sperm before the treatment at the 0.05 level of significance.

![Figure 1: Mean percentage of Rapid linear progressive sperm.](image-url)
Table 2: Descriptive statistics of mean percentage of immotile sperm before and after the treatment.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre treatment</td>
<td>32</td>
<td>15</td>
<td>109</td>
<td>57.02</td>
<td>4.325</td>
</tr>
<tr>
<td>Post treatment</td>
<td>32</td>
<td>5</td>
<td>70</td>
<td>33.95</td>
<td>3.296</td>
</tr>
<tr>
<td>Valid N</td>
<td>32</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

95% confidence interval for population mean percent of immotile sperm before the treatment, Pre treatment (48.21, 65.85)
We are 95% confidence that the population mean percentage of immotile sperm before the treatment is in between 48.21 and 65.85
Post treatment (27.23, 40.67)
We are 95% confidence that the population mean percentage of immotile sperm after the treatment is in between 27.23 and 40.67

Hypothesis to be tested

\[ \mu_{before} - \mu_{after} \]

\[ H_0: \mu_{before} \leq \mu_{after} \text{ Vs } H_1: \mu_{before} > \mu_{after} \]

By using paired t test, value of the test statistic = 5.483, P value < 0.0001
Since p-value < significance level (0.05) we reject H0
We can conclude mean percentage of immotile sperm after the treatment is less than the mean percentage of immotile sperm before the treatment at the 0.05 level of significance.

Figure 2: Mean percentage of immotile sperm.
Adverse drug reactions

One patient complained of headache for a few days after initiation of treatment, which subsided on its own in few days, without any treatment. No untoward side effects were reported during the trial in all the 32 patients.

Discussion

WP6 is a polyherbal formulation consisting of Withania somnifera, Asperacantha longifolia, Mucuna pruriens, Argyreia speciosa, Tribul using terrestres, and Asperagas ascycedens. Most of these herbs have been used in traditional medicine as aphrodisiacs. Withania somnifera is used as a restorative and a tonic aphrodisiac in conditions associated with weakness or reduced sexual activity and hypnotic properties by somniferine. It improves appetite and is useful in the treatment of spermatorrhoea. Mucuna pruriens is used in spermatorrhoea and to treat sexual debility. It is used as an aphrodisiac and a prophylactic agent in patients with asthenospermia to increase the sperm motility. It counter acts male sterility and acts as a nerve tonic. Argyreia speciosa is an aphrodisiac, diuretic, and is used to control gonorrhoeal infection. Tribul using terrestres is used to treat spermatorrhoea, diseases of the genitourinary system, impotence and sexual debility. All these evidences confirm the synergistic role of various herbs in WP6. In the above trial, WP6 increased the sperm motility, which could be attributed to the presence of Mucuna pruriens and its constituents. The herbs like Withania somnifera and Tribul using terrestres along with other herbs reduced the abnormalities of the sperm. The motility of the sperms increased due to the combined aphrodisiac and stimulant effect of the herbs.

It is also used as a factor to indicate effectiveness of the drug, that 100% immotile patients had improve to the grade B and C. Though there was a significant improvement in the quality of semen it may be further confirmed by enrolling larger number of patients in the trial. It should be carried out further studies to evaluate necessity of long term treatments for the management of asthenospermia.

Conclusion

The study has shown that WP6 is effective in the management of asthenospermia, as it increases the sperm motility. WP6 may also help to treat male infertility associated with asthenospermia.

References

