Effectiveness of ManSure, a herbal reproductive health supplement, on semen quality (sperm count, sperm quality, sperm motility) in infertile men

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OBJECTIVE:
The study is conducted to assess and evaluate the impact of ManSure (reproductive health supplement for men) on semen profile in infertile men. The study investigated the potential of ManSure to improve reproductive performance of males.

INTRODUCTION:
It is estimated that male infertility contributes to about 50% of human infertility. The male infertility is explained by several cellular abnormalities and impairment manifested by sperm quality, sperm count and sperm motility. Ayurveda, the traditional system of medicine has been used since ancient time for the treatment of several diseases and male infertility is one of them. Some of the herbs and plant extracts are demonstrated as an effective remedy for male infertility and reproductive performance of man. The herbs which had enough evidence for proven role in semen profile improvement are Konch Beej (M.Pruniens), Safed Musli (C. borivilianum) and Ashwagandha (W. Somnifera). ManSure is an ideal combination of such potent proven herbs which are medically proven to increase sperm count, sperm quality and sperm motility. Konch Beejc ( M.Pruriens) improves male fertility and sperm quality by its action the hypothalamus-pituitary-gonadal axis¹. Amongst many, one of the study established that oral administration of M. pruriens to infertile men for 3 months not only resulted in general improvement in sperm count and motility but it also led to significant reduction in the level of psychological stress, as assessed by a questionnaire and serum cortisol levels². Safed Musli (C. borivilianum) is a potent and important herb in Ayurveda which is used to improve male sexual health. Water extract of Safed Musli (C. borivilianum) improves the quantity and quality of semen in a statistically significant manner in healthy male adults and improves serum testosterone level³. Ashwagandha (W. Somnifera) is a very popular and widely used herb for male impotency and reproductive health. Ashwagandha (W. Somnifera). The treatment with Ashwagandha (W. Somnifera) has the potential to increase sperm concentration, improves sperm quality and semen hormone levels⁴. ManSure is an ideal combination of the potent herbs Konch Beej (M.Pruriens), Safed Musli (C. borivilianum) and Ashwagandha (W. Somnifera) which can help in increasing the sperm count and in improving sperm quality and sperm motility.

STUDY DESIGN AND SETTING:
The randomized, double blind and placebo controlled study was conducted Shantah IVF and Surrogacy Center in Delhi.
Evaluation Criteria:
The subjects were assessed at baseline (day 1 visit) and the progress was evaluated in every 4 weeks till the end of the study for 12 weeks on below parameters:

- Serum Testosterone level
- Serum Hormonal Level
- Sperm Count
- Sperm Motility
- Semen Analysis
- Semen Volume

SUBJECTS AND METHODOLOGY:
The study was conducted amongst 50 healthy men in the age group of 30 – 42 years undergoing for infertility screening and treatment. The subjects were divided into two groups; Group A who were administered ManSure capsule with the dosage of 2 capsules (500mg) twice a day and the Group B subjects were given placebo. The subjects in both groups were dispensed ManSure as per defined dosage and placebo for 12 weeks.

All the subjects in the study had sperm count between 5-20 million/mL with sperm motility between 10%-30%. All the subjects were healthy and have been involved with regular sexual intercourse with their female partners for over a one year period.

The subjects of the study were randomized in the groups – Group A had the subjects who were administered ManSure capsule and the subjects in the Group B were dispensed matching placebo. The ManSure administered Group A had 27 subjects (n=27) and the placebo treated group has 23 subjects (n=23). The frequency of administering of ManSure and Placebo in both groups was same i.e 2 Capsules (500mg) twice daily for 12 weeks.

With the baseline results from the day 1 visit, the subjects were assessed in every 4 weeks during the 12 weeks’ study. The subjects were assessed and progress was registered in every 4 weeks. The final evaluation and assessment was performed after completion of 12 weeks. The effectiveness of ManSure was measured in the form of improvement in semen profile (sperm count, sperm quality, sperm motility) and semen hormonal level in third screening visit after 12 weeks. The progress and results were compared with the day 1 visit (baseline) and the progress of defined criteria and parameters was noted.

The baseline parameters of semen profile for both groups on Day 0 were as below:

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<thead>
<tr>
<th>Table-1; Semen profile on day 0 (baseline, n=50, Group A &amp; Group B)</th>
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<tbody>
<tr>
<td>Mean ±SD</td>
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<tr>
<td>Total Motile Sperm Count (X 10⁶/ml). Total Motile Sperm Count = ejaculate volume x sperm concentration X fraction of motile sperm</td>
</tr>
<tr>
<td>Semen Volume (mL)</td>
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<tr>
<td>Sperm Concentration (X 10⁶/ml)</td>
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<td>Sperm Motility (%ge)</td>
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Semen profile, serum testosterone level and serum hormonal level was categorized for both groups and was recorded the same post intervention at regular interval of 4 weeks. The probability value P<0.05 were considered significant.
The Group A who were administered ManSure showed significant improvement as the Total Motile Sperm Count increased significantly. As per the semen parameters after 12 weeks study, the Group A demonstrated increase in sperm concentration as compared to the Day 1, visit 0. The sperm concentration was increased by over 154% in the Group-A treated with ManSure. The semen volume was also increased from baseline 1.70 ml to 2.83 ml showing an increase of 66% which is considered as a good response.

The Group A showed immense improvement in all the parameters of semen profile in comparison to the Group-B treated with Placebo.

**CONCLUSION:**

Infertility is a major concern and it is said to be caused by several known and unknown factors. It is estimated that 15% of couples experiences of infertility problem and out of these total infertility problem, 50% of infertility issues is contributed by male. As per various scientific researches semen quality and sperm concentration is considered as one of the important factors causing infertility in men. The World Health Organization defines infertility as an inability to conceive after 12 months of unprotected sex with the same partner. And the male infertility is inability of man to cause pregnancy in a fertile female. Low sperm count and decreased sperm motility is one of the biggest reason behind male infertility. The ingredients as in ManSure have immense potential to increase sperm count, sperm concentration, and sperm quality and sperm motility. The ingredients in ManSure have been used in Ayurveda since the time unknown for helping men to improve their fertility condition. The present study established the efficacy of the same herbs and ingredients (Konch Beej - M.Pruriens, Safed Musli-C. borivilianum and Ashwagandha- W. Somnifera) which are used to formulate ManSure. The study highlighted that the treatment with ManSure can help in improving the reproductive performance of man. In this study, the treatment with ManSure resulted in increased level of testosterone and increase in serum levels of LH.

**RESULTS:**

Treatment with ManSure helps in increasing sperm concentration, sperm quality and sperm motility in all the infertile subjects of the study group. The patients with low sperm count recovered the sperm count and quality significantly with the continued use of ManSure, the reproductive health supplement for man. The semen profile of all the subjects who were administered ManSure was recovered and improved in the 12
week’s study. The improvement in seminal plasma, seminal fructose level and sperm count validates the role of ManSure in recovering reproductive function in infertile men.

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5. Clinical Evaluation of the Spermatogenic Activity of the Root Extract of Ashwagandha (Withania somnifera) in Oligospermic Males: A Pilot Study