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Clinical Evaluation of Herbal Medicine for Oligospermia

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Abstract: Infertility is one of the most tragic of all marital problems. Despite recent advances in the treatment of male infertility, the problem has not been satisfactorily tackled. The infertility may be due to an inadequate number of spermatozoa in the semen, the failure of the spermatozoa to move with sufficient vigor towards their goal or that they are deficient in other respects. Aims of the study is to investigate the safety and efficacy of Xperm (Herbal Medicine) in test group in comparison with Sulfonylureas plus (Allopathic) in control group. A Causi experimental randomized controlled, two-arm parallel group clinical trial conducted at Shifa-ul-Mulk Memorial Hospital for Eastern Medicine, Hamdard University Karachi. Hundred patients in the age group of 20-50 years with idiopathic infertility with a total sperm count less than 20 million/ml. Comparison of data recorded by participants relating to these variables showed significant differences between test and control groups ($p<0.05$) despite the fact that no side effects were at all recorded in test group. Overall clinical success was observed in both treatment groups however the efficacy of the test treated medication (Xperm) was superior as $p = 0.03$. Xperm is more effective than the Sulfonylureas plus in the treatment of Oligospermia and male infertility.

Key words: Oligospermia, herbal treatment, Xperm, sulfonylureas plus

INTRODUCTION

Infertility primarily refers to the biological inability of a person to contribute to conception. Infertility may also refer to the state of a woman who is unable to carry a pregnancy to full term. There are many biological causes of infertility, some which may be bypassed with medical intervention. Reproductive endocrinologists consider a couple to be infertile if the couple has not conceived after 12 months of contraceptive-free intercourse if the female is under the age of 34. Twelve months is the lower reference limit for Time to Pregnancy (TTP) by the World Health Organization (Makar and Toth, 2002; Cooper *et al*., 2010).

Male infertility refers to the inability of a male to achieve a pregnancy in a fertile female. In humans it accounts for 40-50% of infertility. Male infertility is commonly due to deficiencies in the semen and semen quality is used as a surrogate measure of male fecundity. It is customary to define infertility clinically as the inability of a couple trying to conceive to do so within one year. This may make the usual definitions of prevalence and incidence somewhat confusing in this context (Brugh and Lipshultz, 2004; Hirsh, 2003).

More than 90% of male infertility cases are due to low sperm counts, poor sperm quality, or both. The remaining cases of male infertility can be caused by a number of factors including anatomical problems, hormonal imbalances and genetic defects. Male fertility, according to recent evidence, also appears to decline with age, due to decreased sperm function and accumulating genomic damage. Other risk factors for male reproductive dysfunction include gonadotoxins such as chemotherapeutic agents, radiation exposure and a variety of pharmaceutical agents that act either as direct spermatotoxins or through a steroidal pathway. Common drugs known to impair male fertility include cimetidine, sulfasalazine, nitrofurantoin, ethanol, cannabis and androgenic steroids. Whether nicotine results in impaired male fertility is controversial; however, because of its negative effect on erectile function, nicotine use is discouraged in men attempting to impregnate their partners. A male who does not have biological offspring and who presents for reproductive evaluation is labeled as having "primary infertility," whereas one who is unable to impregnate his partner but who already has biological children is referred to as having "secondary infertility" (Sallmen *et al*., 2005; MacLeod, 1951; Guzick *et al*., 2001; Greenberg *et al*., 1978).

A physical examination of the scrotum, including the testes, is essential for any male fertility work-up. It is useful for detecting large varicoceles, undescended testes and absence of vas deferens, cysts, or other physical abnormalities. Checking the size of the testicles is helpful. Smaller-sized and softer testicles along with tests that show low sperm count are strongly associated with problems in sperm formation. Normal testicles accompanied by a low sperm count, however, suggest possible obstruction.

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Semen analysis comprises a set of descriptive measurements of spermatozoa and seminal fluid parameters that help to estimate semen quality.

Conventional semen analysis includes measurement of particular aspects of spermatozoa such as concentration, motility and morphology and of seminal plasma. Quantification and identification of non-spermatozoidal cells and detection of antisperm antibodies are also part of basic semen analysis.

The treatment of male infertility includes therapies targeted to specific medical and surgical diagnoses, empiric pharmacological agents intended to improve spermatogenesis and artificial reproductive techniques employed to bypass reproductive barriers in the female genital tract. Often, two or all three types of therapy are implemented simultaneously. Male reproductive medicine and surgery remains one of the most actively evolving areas in urology, with a variety of therapeutic modalities under investigation (World Health Organization, 1997).

MATERIALS AND METHODS

Study design: The study was based on an experimental, randomized, clinical trial. The study have been conducted according to the principal of good clinical practice i.e., an informed consent was obtained from the patients before the enrollment, proper history and clinical examination were recorded on each follow up. The study was carried out from 1st April 2007 to 30th April 2009.

Patients: Clinical trial was conducted on 100 patients suffering from oligospermia from both groups (50 patient from control and 50 from experimental group) between ages of 20-50 years irrespective of socioeconomic status.

The case group was presented herbal formulation Xperm which comprises of different herbal medicinal plants components such as *Tribulus testeries*, *Wethania somnifera*, *Sida cardifolia*, *Aspragus recemosus*, *Orches latfolia* and *Mucuna pruriens*. The control groups are subjected to allopathic dosage form design Sulfonylureas plus dietary supplements.

Sample selection: The sample was selected from the out patient department registered and enrolled in Shifa ul Mulk Memorial Hospital and on the basis of semen analysis and inclusion and exclusion criteria the patient fulfilling the infertility criteria as candidates were selected. The study period include was from 2007 to 2009. Among this population all the patient suffering from infertility were interviewed and upon their consent to participate they were grouped as test and control groups.

Assessment: Primary analysis was based on a semen analysis. The data was adjusted based on the number of cases in the light of demographic factor using statistical methods like multinomial logistic regression. The data were composed in separate group. The groups were compared after random selection of subject in equal proportion using statistical analysis were performed using SPSS and excel software, the Chi Square test was determined. All differences were considered statistically significant by generating a 'p-value' from test statistics. The significant result with 'p-value' less than 0.05 was considered as statistically significant.

RESULTS

According to the statistical analysis a significant difference was observed between two treated groups ($p<0.05$) at the end of therapy. All differences that were equal to or more than the set cut-off values were considered clinically significant. The evaluation of treatment is significantly improved in the test group compared with control group at the end of therapy. So it can be concluded that the efficacy of the Xperm is significant and has long lasting effects.

DISCUSSION

This unicenter trial has been conducted, for comparing the efficacy and safety of two different treatment modalities showed the greater efficacy of coded herbal formulation Xperm as test drug and allopathic treatment Sulfonylureas plus dietary supplements as control drug for the treatment of oligospermia and infertility. 100 patients have been selected at baseline after the adjustment made out of 125 patients. The clinical assessment included semen quantity, semen quality, low sperm count, sperm concentration and sperm motility, as well as physician and patient's opinions on improvement. The data on clinical proforma was gathered and subjected to statistical analysis.

It has been previously reported that *Tribulus testeries*, *Wethania somnifera*, have good results in oligospermia and male infertility for the improvement of sperm quantity and quality. So by taking advantage the coded herbal formulation Xperm contains a total six ingredients in which *Tribulus testeries*, *Wethania somnifera*, *Sida cardifolia*, *Aspragus recemosus*, *Orches latfolia* and *Mucuna pruriens* for the treatment of semen abnormalities causing infertility in man (Bucci, 2000; Brown *et al*., 2000; Brown *et al*., 2001).

Treatment assignment and follow-up: One hundred patients consented to participate in the study. Pretreatment clinical and laboratory parameters for the treatment groups were noted. The two treatment groups were comparable in efficacy results and side effects of the medicine administered. All subjects were clinically studied and completed the assigned therapy.

Sperm counts: After having the complete follow-ups in test group out of 50 patients 46 patients were recorded

Table 1: Total counts in total patients at after treatment

		Treatment group			
After treatment		Test (Xperm)	Control (Sulfonylureas plus)	Total (n)	p-value
Total counts	<20 millions/ml	04	12	16	0.026
	> = 20 millions/ml	46	38	84	
	Total	50	50	100	

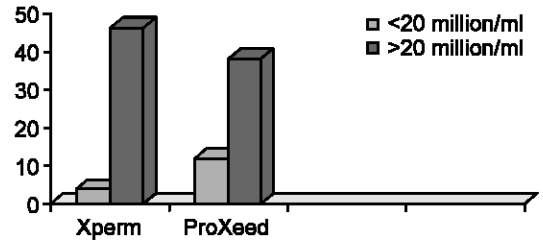

Fig. 1: Total counts in total patients at after treatment

> = 20 millions/ml and only 04 patients were recorded <20 millions/ml. Whereas in control group, out of 50 patients 38 patients were recorded > = 20 millions/ml and 12 patients were recorded <20 millions/ml. After applying the Chi-square test and Fisher's exact test the p-value were calculated 0.026 which is less than 0.05 that shows there is a significant difference between these two drugs as shown in Table 1.

Conclusion: The finding from this study demonstrated the following salient clinical assessment; there was statistically significant difference when comparing the effectiveness of herbal treatment Xperm to Sulfonylureas plus for the treatment of Male infertility. This is clearly evident that Xperm possesses a therapeutic value for the treatment of oligospermia leading to infertility.

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