Clinical Evaluation of Tentex Royal in Erectile Dysfunction

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ABSTRACT
A study was conducted to evaluate the clinical efficacy of Tentex Royal in patients with erectile dysfunction (ED). The study included 45 patients with a history of ED. Each patient was given Tentex Royal 2 capsules daily at night for 6 weeks. All patients had follow-up to evaluate the effect of the drug and to rule out any side effects after the second week and then every week for a further 4 weeks. Among the 45 patients included in the study, 40 patients completed the treatment. Thirty two patients (80%) showed significant clinical improvement; 18 patients (45%) were cured in 3 weeks and 14 patients (35%) showed improvement in 6 weeks. Thus, Tentex Royal is effective and safe in the treatment of patients with ED.

Keywords: Tentex Royal; erectile dysfunction; libido

INTRODUCTION
Erectile dysfunction (ED) is a potentially devastating ailment that affects not only men, but also their sexual partners. The Massachusetts Male Aging Study revealed that age is the single most important variable associated with erectile difficulty (Feldman et al., 1994). Currently, about 20-30 million American men are impotent, with projections of up to 47 million by the year 2020 (Gillenwater, 1997). This can be a rather difficult and embarrassing topic for most of these individuals to discuss. Moreover, most patients and healthcare professionals do not have an adequate understanding of the available treatment options. Hence, it has been estimated that only 5-10% of men with ED will seek medical intervention. Since this is one of the most under-treated conditions in the United States, the evaluation and management of impotence has become an emerging market, resulting in the expansion of numerous men’s impotence clinics (Overmyer, 1996).

Over the past few years, there has been an increased understanding of the physiology of erection and the pathophysiology of ED. We are beginning to understand the events leading to tumescence and detumescence at the cellular and molecular level. Combined with the advent of sophisticated diagnostic modalities, more and more of these patients are diagnosed with treatable organic causes of ED. Currently, there are a multitude of treatment options available, ranging from oral to injectable medications and various surgical treatments. A thorough understanding of penile physiology as well as current diagnostic and treatment modalities is necessary for proper evaluation and treatment of patients with ED.

Erectile dysfunction is a common problem in newly married couples. Impotence means that the penis is too limp to penetrate the vagina. More than 90% of patients have psychological problems, which lead to impotence. Usually patients who present with incomplete erection were involved in masturbation after puberty.
The objective of the clinical trial was to evaluate and establish the efficacy of Tentex Royal capsule (The Himalaya Drug Company, Bangalore) in ED.

MATERIAL AND METHODS
An open clinical trial was conducted at Heritage Hospitals, Varanasi including 45 patients with a history of ED. Personal histories that included sexual and chronic diseases were recorded. A written, informed consent was obtained from all the patients. Each patient was given 2 capsules daily at night for 6 weeks. All the patients had follow-up to evaluate the effect of the drug and to rule out any side effects after the second week and then every week for a further 4 weeks. Those patients with no erection or who did not respond within 6 weeks had continued treatment for 12 weeks and more.

The initial evaluation was done with a detailed history and physical examination including preliminary assessment to determine if psychological factors were involved in the causation of ED. With respect to the laboratory investigations, a complete blood count, blood chemistry and testosterone assay tests were done. Since a majority of the patients were in the psychological group for ED, no other organic investigations were carried out.

RESULTS
Out of 45 patients included in this study, 40 patients completed the treatment. 32 (80%) showed significant clinical improvement. They had erections good enough for intercourse.

Out of 40 patients who completed the study, 30 patients had psychological problem due to a history of masturbation, extra-marital affairs or post-marriage anxiety neurosis.

Patients with incomplete erection responded well to Tentex Royal capsules. Eighteen patients (45%) were cured in 3 weeks. Another 14 patients (35%) showed improvement in 6 weeks (Table 1). Seven patients who did not show any improvement during 6 weeks were requested to continue with the treatment for 12 weeks.

Twelve patients who had no erection and loss of libido were evaluated at 12 weeks and later (Table 2).

Serum testosterone level marginally increased in patients with incomplete erection after 6 weeks of treatment. Semen analysis also showed an increase in quantity and quality of sperm.

Table 1: Response to Tentex Royal capsule in incomplete erection

<table>
<thead>
<tr>
<th>Duration of treatment</th>
<th>Patients cured</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 weeks</td>
<td>18</td>
<td>45</td>
</tr>
<tr>
<td>6 weeks</td>
<td>14</td>
<td>35</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>80</td>
</tr>
</tbody>
</table>

Table 2: Response to Tentex Royal capsule in patients with no erection and loss of libido

<table>
<thead>
<tr>
<th>Duration of treatment</th>
<th>Patients showing temporary improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 weeks</td>
<td>4</td>
</tr>
<tr>
<td>Above 12 weeks</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
</tr>
</tbody>
</table>

DISCUSSION
Tentex Royal capsule contains an extract of *Tribulus terrestris* and powders of *Asteracantha longifolia*, *Prunus amygdalus*, *Blepharis edulis* and *Crocus sativus*. 
The herbs mentioned above have been conventionally used in the management of ED for centuries. *Tribulus terrestris* has been clinically proven to improve sexual desire and enhance erection (Adimoelja, 2000). The pharmacological properties of *Tribulus terrestris* extracts have been studied on the rabbit corpus cavernosum muscles. The extract showed increase in relaxation of cavernosum smooth muscles in a dose-dependent manner (Adaikan et al., 2000). *Prunus amygdalus* extract showed a significant increase in the sperm content and the motility in the epididymides and vas deferens. *Prunus amygdalus* has been used as an aphrodisiac in Arab Medicine (Qureshi et al., 1989). *Crocus sativus*, saffron is used in medicine as an aphrodisiac and antioxidant agent (Kazuho Abe and Hiroshi Saito, 2000).

Clinical trials in progress at various academic institutions in India, have shown encouraging results in patients with ED without producing any side-effects. This indicates the safety of Tentex Royal capsule on repeated and long-term administration. Moreover, Phase I study showed that Tentex Royal capsule are well-tolerated without producing any abnormality on hematological, biochemical and physiological functions.

This open clinical trial has shown that Tentex Royal capsule is effective in patients with incomplete erection as well as in patients with no erection and loss of libido.

**CONCLUSION**
Considering the results of the clinical trial, it can be concluded that Tentex Royal capsule is effective and safe in patients with incomplete erection. A total of 80% patients responded to Tentex Royal capsule within the stipulated period of treatment.

**REFERENCES**


