Clinical evaluation of Tentex forte and Himcolin cream in the treatment of functional erectile dysfunction

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ABSTRACT
The term “erectile dysfunction” can mean the mobility to achieve erection, an inconsistent ability to do so, or the ability to achieve only brief erections. In this study, the efficacy of Tentex forte and Himcolin cream in the treatment of functional erectile dysfunction has been evaluated. Tentex forte and Himcolin cream could improve the frequency, quality and sustainability of erection. There was increased sexual desire in men and readiness to initiate sexual intercourse.

INTRODUCTION
Erectile dysfunction (ED), one of the most prominent complaints concerning sexual activity has been reported to affect as many as 152 million men worldwide.1-3 Most common in young and healthy men is Functional Erectile Dysfunction, caused due to psychogenic factors, such as fear of performance and failure of expectation. Although psychological elements play a part in the genesis and development of Erectile Dysfunction in a large number of patients, mainly older men predominant are somatic causes like erectile failure with vascular pathology, and neurological, hormonal and drug-related factors.

Treatment programs for ED usually involve the following:
- The Psychotherapeutic approach focuses on reconstruction of cognitive bias, change of dysfunctional values and behavioral patterns and improvement in communication between sexual partners.
- Pharmacotherapy involves locally acting vasoactive drugs (such as Papaverin and Alprostadil), central stimulants (like apomorphine) and herbal drugs with aphrodisiac activity.
- Surgical interventions like insertion of penile prostheses.

In 1964, the Department of Sexology of the Bulgarian Medical Academy in Sofia accepted an integrative approach to treat erectile dysfunction, using pharmacotherapy with psychotherapy. In 1999, holistic tradition was continued to treat of ED, taking into consideration specific economical and cultural conditions in a contemporary manner.
Due to social and economic crisis in the last 13 years, there were a lot of Bulgarian men who experienced constant stress concerning lack of work, fear of unemployment, financial hardship, increasing crime rate, insufficient medical care and malnutrition. In this situation, functional ED is very common. Sexual problems increase the risk of other psychosomatic disorders, disturb relationships in families and contribute to a deteriorating quality of life for Bulgarians. Drugs like Sildenafil citrate and Apomorphine are unaffordable for an average Bulgarian due to their high costs.

In our Institute, effective treatment of ED fulfils the following requirements:
- To support the psychotherapeutic approach to improve interpersonal and sexual communication and recover spontaneity between sexual partners.
- To increase sexual desire and improve erection.
- To use economical products that can be afforded for more than two – three weeks, for sustainable therapeutic results.
- To have no side effects
- To engage both partners.

Preliminary information has shown that Tentex forte and Himcolin cream covered all the above-mentioned criteria. Hence, the therapeutic efficacy and safety was evaluated.

MATERIALS AND METHODS
This open clinical trial was conducted at the Sexology Institute in Sofia, to determine the efficacy of Tentex forte and Himcolin cream, used concurrently in men with Functional Erectile Dysfunction. The different aspects of erection and sexual functioning were evaluated before treatment and after 2 and 4 weeks of treatment.

Patients were administered Tentex forte at a dose of 2 tablets, twice daily, combined with local application of Himcolin cream on the penis and pubic area before sexual intercourse.

Inclusion Criteria
Eligible patients were men 18 years or older experiencing functional ED, which was defined as the inability to achieve or maintain erection for satisfactory sexual intercourse for more than 3 months duration. All patients experienced a 50% or greater failure rate to maintain an erection on at least 4 separate attempts over the 4-week treatment-free baseline period. The decision for “functional” character of ED was taken based on the following:
- Good nocturnal erection prior to 2 weeks
- One event of sexual intercourse prior to 2 weeks
- Good erection during masturbation or visual sex stimulation
- Absence of other information, like organic causes of erectile failure.

Exclusion Criteria
Conditions that precluded study entry included anatomical abnormalities of the penis, radical prostatectomy, spinal cord injury, unstable angina pectoris and myocardial infarction. Patients were also excluded if they had hypertension or poorly controlled diabetes mellitus with complications. Patients receiving hormonal treatment, treatment with antidepressants,
antipsychotic or other psychoactive drugs, or those with serene psychiatric symptoms were also excluded.

Participants of the trial
Fifty men aged between 19-59 years (50% married, 32% single, 16% divorced, 2% widowers) were included in the trial.

Baseline clinical and laboratory investigations
Each patient included in this study completed a sexological interview to clarify problems, sexual symptoms and other somatic complaints. The patients were asked about onset of ED, development of dysfunction, quality of relationships with partner/s, social environment and other important subjects, concerning sexual life. All the patients were also subjected for general, physical and psychological examinations. Hemogram, urine examination, systemic biochemistry and semen examination were also undertaken.

EVALUATION OF SEXUAL FUNCTIONING
For comparison between baseline levels of sexual functioning and change after 2 to 4 weeks of treatment with Tentex forte and Himcolin, an “International Index of Erectile Functioning” (IIEF) was utilized. The IIEF, consisting of the following subscales was used:

Total evaluation of erection / sexual functioning questionnaire:
- Ability to penetrate
- Maintenance of erection after penetration

Erectile function:
- Frequency of erection during sexual activity
- Quality of erection during sexual activity
- Maintenance of erection till the end of intercourse
- Confidence in getting and keeping erection

Satisfaction from sexual activity:
- Attempts for intercourse
- Satisfaction from intercourse
- Enjoyment from intercourse

Orgasmic function:
- Frequency of ejaculation during sexual stimulation
- Frequency of orgasm during sexual stimulation

Sexual desire:
- Frequency of sexual desire
- Rating of sexual desire

Overall satisfaction:
- Overall sex-life satisfaction
- Sexual partnership satisfaction.

**Global efficacy question**
The patient’s answers on each question was rated in a standard six stage scale in which 0 – stood for no activity, 1 – minimal activity / satisfaction, and 5 – maximal activity / satisfaction.

During the initial sexological interview, each patient in the trial, filled a written questionnaire. The same was repeated in the second therapeutic meeting – 2 weeks later and during the final control meeting, after four weeks of treatment with Tentex forte and Himcolin cream. The average score on each question and on each subscale was compared twice. Initial analysis was between baseline data and data after 2 weeks of treatment. Second analysis was between baseline data and data received after 4 weeks of treatment. Statistical analyses were used to calculate index “p”.

**RESULTS AND DISCUSSION**

**Therapeutic efficacy concerning ability to penetrate and maintain erection during intercourse**

There was a rapid improvement in both parameters of erectile function after 2 weeks of treatment with Tentex forte and Himcolin cream. The results were statistically significant after the fourth week of therapy ($p<0.001$) (Figure 1).

The total score on this subscale, ranging between 0 and 10, is presented on Figure 1a. There was a statistically significant improvement in quality of erection after 4 weeks of treatment.

An analysis was done on the following:

- Frequency of erection during sexual activity
- Quality of erection during sexual activity
- Maintenance of erection till the end of intercourse
- Confidence in getting and keeping erection.

![Figure 1: Evaluation of Total Erectile Functioning](image)

![Figure 1a: Evaluation “Sexual Functioning Questionnaire”](image)
Tentex forte, when used with Himcolin cream, proved effective in improving the four different dimensions of erection. Data were presented in Figure 2.

The total score on this subscale (minimum 0 and maximum 20) is presented in Figure 2a. The difference in data before treatment and on the second and fourth weeks of treatment is obvious.

**Figure 2: Specific improvements in different characteristics of erection**

**Figure 2a: Satisfaction from erectile function**

**Therapeutic efficacy concerning general satisfaction from sexual activity**
Clinical trials indicate that therapy with Tentex forte and Himcolin cream improves general satisfaction from intercourse in patients of functional ED. Administration of both, increased the willingness to initiate sexual intercourse with partner, as well as satisfaction from quality of intercourse. In all these dimensions, therapeutic effects after 2 and 4 weeks of treatment were statistically significant ($p<0.001$). Data were shown in Figure 3. The cumulative score on this subscale (minimum 0 and maximum 15) in 3 different months of evaluation is presented in Figure 3a.

**Figure 3: Satisfaction from sexual activity**

**Figure 3a: Evaluation of intercourse satisfaction**

**Therapeutic improvements in orgasmic function**
The clinical trial tested therapeutic effects after 2 and 4 weeks’ treatment with Tentex forte and Himcolin cream not only for the excitement phase of the copulative cycle, but also for the orgasmic phase. Improved erection increased the frequency of orgasms and ejaculations
responses during sexual activity. There was a clear improvement even after 2 weeks of treatment and especially after the 4th week of Tentex forte and Himcolin cream application. Data on the therapeutic changes are shown in Figure 4. The cumulative score on this subscale is in Figure 4a.

**Figure 4: Improvement in culmination phase**

**Figure 4a: Evaluation of orgasmic function**

**Therapeutic change in sexual desire**

Tentex forte and Himcolin cream improves not only the quality of erection in men with ED but also increases the level of their sexual desire after 2-4 weeks of application. The data shown in Figure 5 presents statistically significant changes after 2 and especially after 4 weeks of treatment.

Total score on this subscale (minimum 0 and maximum 10) is presented in Figure 5a. Thus, Tentex forte and Himcolin cream increased level of sexual desire significantly after the 4th week of treatment.

**Figure 5: Improvement in sexual desire**

**Figure 5a: Evaluation of sexual desire**

**Overall satisfaction from sexual life and relationship with sexual partner**

The system-integrative approach to erectile dysfunction in patients aims not only to overcome erectile failure but results in overall improvement of interpersonal communication and relationship between sexual partners. During the initial interview and the next 2 clinical meetings with the patients, we focused on replacing a dysfunctional performance pattern of
sexual activity with a more spontaneous, interpersonal style of sexual communication. This psychotherapeutic change was strongly supported by Tentex forte and Himcolin cream. On the other hand, improved interpersonal relationships and communication reinforced stability of sexual functioning. It was an excellent opportunity to refocus attention of the couple from performance anxiety to mutual pleasure. Himcolin cream, used as a tool for sexual massage not only improved erection but created a more spontaneous pleasurable atmosphere during sexual interaction. Data reflecting therapeutic changes in sexual life and relationships with sexual partner are shown in Figure 6. The cumulative score on this subscale (minimum 0 and maximum 10) is presented in Figure 6a.

Overall satisfaction from therapy
The clearest information about the efficacy of 2 and 4 weeks’ treatment of ED with Tentex forte and Himcolin cream were received from answers to the question – “Has the treatment improved your erections?” Statistical significance of data showing excellent result here are most prominent. After the 2nd week of treatment, 32 of 50 patients (74%) reported that they were satisfied with the therapeutic effect of Tentex forte and Himcolin cream. The number of satisfied patients increased to 42 (84%) at the end of the 4th week of treatment. Data is shown in Figure 7.

CONCLUSIONS
The clinical trial of Tentex forte and Himcolin cream in 50 patients with functional erectile dysfunction at the Sexology Institute “Interact” in Sofia, Bulgaria, clearly brought out the following:

1. Tentex forte and Himcolin cream are excellent therapeutic tools in the treatment of functional ED to improve the frequency, quality and sustainability of erection.
2. Therapy with Tentex forte and Himcolin cream increases sexual desire in men and readiness to initiate sexual intercourse.
3. Tentex forte and Himcolin cream improves orgasmic response and increases overall satisfaction.
4. A combination of Tentex forte and Himcolin cream supported the W. Masters and V. Johnson - psychotherapeutic approach that focuses on improvement of sexual communication between partners and recovery of spontaneity during sexual activity. This contributes to sustainability of therapeutic results and general improvement of interpersonal relationships.
5. Tentex forte and Himcolin cream is economical and easy to use therapy, can be recommended as the therapy of choice for individuals and couples suffering from ED.

REFERENCES