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ORIGINAL RESEARCH

Comparison of Medical Treatment and Acupuncture in Treatment of Psychogenic Erectile Dysfunction: a Prospective, Randomized, Placebo-Controlled Study

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Abstract
Objective: Erectile dysfunction (ED) is the persistent inability to achieve or maintain an erection that is sufficient for satisfactory sexual performance. The aim of this study was to assess the impact of acupuncture in psychogenic ED patients, in comparison with the medical treatment.
Material-Method: A total of 60 male patients, with psychogenic ED were randomized into 4 groups as electro-acupuncture only, electro-acupuncture and oral sildenafil 25 mg, a placebo sham acupuncture and oral sildenafil 50 mg only. The treatment lasted for six weeks in all groups, and patients were evaluated with the International Index of Erectile Function (IIEF-5 scores).
Results: After the treatment, all groups except the placebo group showed a significant increase in IIEF-5 scores, without significant differences among them.
Conclusion: Acupuncture can be used in the complementary treatment of psychogenic ED patients.

Keywords: Psychogenic Erectile Dysfunction, Acupuncture, Complementary Medicine

INTRODUCTION

Erectile dysfunction (ED) is the persistent inability to achieve or maintain an erection that is sufficient for satisfactory sexual performance.[1] It is known as the most common sexual problem in men in general practice and urology.[2,3] ED incidence increases with age and seen in one out of every three men in their lifetime.[2,4]

Sexual potency is an important indicator of physical and mental well-being.[5] ED is a frequently encountered problem in primary healthcare, and it is usually a challenge requiring interdisciplinary collaboration in urology, cardiology, endocrinology, or psychiatry. ED can be connected to an organic or a psychological disorder, or both.[5]

The currently available therapies for the treatment of ED include the followings: oral phosphodiesterase type 5 [PDE5] inhibitors, intra-urethral alprostadil, intracavernous vasoactive drug injection, vacuum constriction devices and penile prosthesis implantation.[6] Also, there is growing evidence about using low-intensity extracorporeal shock wave therapy (ESWT) for ED.[6] Complementary medicine is increasingly used to treat ED.[7] Research suggests that acupuncture can influence the central nervous system activation and neurotransmitter modulation, and thus may have an impact on different health issues.[8] Therefore, in this study we aimed to evaluate the effect of acupuncture on psychogenic ED.

MATERIALS AND METHODS

This prospective, randomized, placebo-controlled study evaluated patients that were treated for ED at the urology clinic in Umraniye Education and Research Hospital, in Istanbul, Turkey, between January 2009 to June 2010. ED patients aged between 20 to 55 years, who were diagnosed with psychogenic ED – having a stable relationship with a female partner for ≥ 1 year, the International Index of Erectile Function (IIEF-5) score <21 for 3 times,[9,10] normal blood pressure, blood

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glucose, creatinine, lipids, follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin (PRL), total T (tT), bioavailable T (bT), albumin, sex hormone-binding globulin (SHBG), total prostate specific antigen (PSA) levels were all normal, Rigiscan (Osbon Medical Systems; Augusta, GA, USA) testing erection frequency >3 times, rigidity of >70% for ≥10 minutes, expansion >2cm, Peak Systolic Velocity of the cavernosal arteries >35cms^{-1} after intracavernosal injection of Alprostadil 10µg during Penile Doppler Ultrasonography- were included in the study. Men who have any comorbidities (diabetes mellitus, hypertension, dislipidemia, hyperprolactinemia or low levels of total testosterone, etc) or medications, uncontrolled pyschiatric disorder, penile anatomic defects or spinal cord injury, history of smoking, alcohol or drug abusing, any surgery which can cause ED (radical prostatectomy or radical pelvic surgery etc) were excluded from the study. Patients were randomized into four groups of 15 patients each. The patients in Group 1 were given two sessions of electro-acupuncture per week over 6 weeks. The patients in Group 2 were given two sessions of electro-acupuncture per week with combination of sildenafil 25 mg on the same days over 6 weeks. The patients in Group 3 represent the placebo group and received two sessions of sham acupuncture per week over 6 weeks. The patients in Group 4 were given sildenafil 50 mg twice a week only over 6 weeks. All patients were given specific standardized instructions for taking the medication. Patients in the acupuncture groups were treated by the same acupuncture specialist at corresponding points for electro-acupuncture twice a week, a total of 12 sessions. Each patient was assessed by the IIEF-5 score, immediately before the treatment and at the end of the 6-week treatment. The acupuncture specialist had 16 years of experience and has gained his license from corresponding authorities of Ministry of Health in Turkey. To carry out this study, written permission was obtained from the institutions where this study was conducted, ethical approval was obtained from the Ethics Committee of the Umraniye Education and Research Hospital for the thesis of specialization in medicine which was registered at the archive of the Databases of National Thesis Center of the Council of Higher Education (No: 681667) and informed consents of the patients were obtained. The participants were informed that their names will not be specified in the survey and will be kept confidential. Trial development and reporting was guided by the Consolidated Standards of Reporting Trials (CONSORT) and The Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) statements.[8,9]

Acupuncture technique

Group 1 was acupuncture group and Group 2 was acupuncture + medical treatment group, therefore both were treated by acupuncture. Each treatment session consisted of puncture of the acupoints known to be effective for ED.[4] Electro-acupuncture was used for the following acupuncture points of the respected meridians: Bladder (BL 23, 27, 34 and 47), Kidney (K 1, 3), Conception Vessel (CV 4, 6), Stomach (St 36). In scientific studies that test the efficacy of acupuncture in the treatment of a disorder, "sham acupuncture" is used as a control and Group 3 was identified as the control group. Therefore, in the placebo group (Group 3), the needles were inserted into different points than the classical acupuncture points, and then electrical stimulation was applied. Subjects did not know whether they were getting true or sham acupuncture. The acupuncture needle (Hua Long, 0.25x25 mm Sterile Steal Acupuncture Needles, China) was inserted into certain acupoints bilaterally at the depth of 3-5 mm and then stimulated using electrodes at 2 Hz for low-frequency electro-acupuncture treatment (AGISTIM Duo, 4 channelx4 mA. max./0.1- 9.9 Hz. Lyon, France). The correct placement of the needle was performed by an experienced acupuncturist and confirmed by the characteristic but subjective needle sensation *'de qi'*. After 45 min., the electrical stimulation was terminated, and all needles were removed.

Statistical analysis

Information received from the patient was entered into an excel program of the computer (Microsoft Excel, 2007). The Statistical Package for Social Sciences (SPSS 17.0) program was used in the evaluation of findings in statistical analysis. Data were analyzed using descriptive statistical methods (mean, standard deviation, frequency). In addition, a chi-square test was used for comparison of the qualitative data. Results were evaluated with the 95% confidence interval and statistical significance was attained when a p-value is less than 0.05($p<0.05$).

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RESULTS

Sixty patients with psychogenic ED were were evaluated prospectively. The mean age was 39.6 ± 8.5 years. The distribution of age and pre-treatment IIEF-5 scores were observed homogeneous (p = 0.717; p = 0.04, respectively) between the groups evaluated. The average IIEF-5 scores before and after the treatment were shown in Table 1.

Table 1. Pretreatment and postreatment IIEF-5 scores.

	pretreatment IIEF-5 score	***postreatment IIEF-5 score***	***p value***
Group 1	13.33	20.17	0.003
Group 2	15.43	22.29	0.0018
Group 3	15.33	17.50	0.06
Group 4	15.13	22.38	0.012

IIEF: International Index of Erectile Functions.

All groups except Group 3 showed a significant increase in IIEF-5 scores. The increase was observed less in Group 3 in comparison to the other groups; between the Group 1 and Group 3: p = 0.005; between the Group 2 and Group 3: p = 0.009; between the Group 4 and Group 3: p =0.002 (Table 2). No significant differences were detected between Group 1, Group 2 and Group 4.

Table 2. Comparison of increase in IIEF scores in the groups and group 3 (placebo).

Group comparison	***p value***
Group 1 and Placebo (Group 3)	0.005
Group 2 and Placebo (Group 3)	0.009
Group 4 and Placebo (Group 3)	0.002

IIEF: International Index of Erectile Functions.

In our study, no significant side effects of sildenafil or adverse events of acupuncture therapy were observed.

DISCUSSION

With advancing age, the prevalence of organic ED is increasing; therefore, diagnosis of pure psychogenic ED is not easy in elders.[2] Vascular, neurological and psychological factors are mixed together in the elderly ED patients.[2] Therefore, in our study, patients over 55 years of age were excluded from the assessment, and the average age of the patients included was 39.6 years.

Hypertension, hyperlipidemia, diabetes mellitus and depression are prevalent in patients with ED.[11] The majority of our patients seen in the andrology clinic in our hospital were diagnosed with comorbitidies and thus were excluded from our study. Depression can cause ED and ED can cause depression.[5] Over 40 percent of male with severe depression have problems with sexual functions and almost half of the people using antidepressant medications due to a decline in sexual satisfaction.[12,13] One study even found that 82 percent of men with ED also reported symptoms of depression.[14] In our study, only psychogenic ED patients without comorbidities and hormonal imbalance were included.

In all kinds of ED patient subgroups, sildenafil was found to be most effective. The difference between any dose of sildenafil and placebo for the outcome “able to have intercourse” ranged from 36% to 76%. In eight studies, for the erectile function domain of IIEF-5, the difference from placebo ranged from 3.7 to 11. For the intercourse satisfaction domain of IIEF-5, the range between sildenafil and placebo was 1.4 to 4 in seven studies involving 1607 patients.[6] For the sildenafil patients, 55% to 89% of the patients "able to have intercourse". The erectile function domain scores of IIEF-5 was between 14 to 27.1 while the intercourse satisfaction domain scores were between 7 to 11. Baseline IIEF-5 erectile function domain scores were between 9.3 to 17.8. For the intercourse satisfaction domain, baseline scores were between 4.9 to 7.4.[6] In our study, sildenafil was used twice a week independently from the sexual intercourse. But, on demand usage of sildenafil could contribute the functions and change the results.

Since ancient times, acupuncture has been a treatment option and raised again in this context recently. In urology, acupuncture has been succesfully applied for overactive bladder, lower urinary tract symptoms, dysuria syndrome, nocturnal enuresis and renal colic.[15–20] Acupuncture has also been used in the treatment of premature ejaculation, impotence and increased or decreased libido.[21,22] According to a recent systematic review, the available evidence supporting that the efficacy of acupuncture for the treatment of ED was insufficient and the available studies failed to show the specific therapeutic effect of acupuncture.[23]

Future well-designed and rigorous randomised controlled trials with a large sample size are required**.** In a previous pilot study, the use of acupuncture as a mono-therapeutic modality, did not influence the profile of the stress and sex hormones, but did improve the quality of erection and restored the sexual activity with an overall effect of 39%.[24] Aydın et al. compared hypnosis, acupuncture, placebo and oral placebo treatments in a study done with 29 patients. The success rate for the acupuncture group was 60%, 70% for the hypnosis, 43% and 47% in the placebo groups.[25] Engelhardt et al. reported favorable results also.[4] Both studies had methodological problems, such as an unclear randomization and allocation concealment process, small sample sizes, and a lack of assessor blinding, although they adopted a sham control as placebo. Although acupuncture was not significantly superior to sham acupuncture, the 60% and 68.4% improvement reported by Aydin et al. and Engelhardt et al., respectively, might suggest that acupuncture could be a complementary treatment for psychological ED.[4,25] It is possible that the acupuncture treatment could act as a strong placebo, and it might also be meaningful for the treatment of psychological ED.[23]

Jiang et al. revealed that combining the acupuncture with psychotherapy better than psychotherapy alone, although the study had a small size and unclear risk of bias.[26] In our study, all groups showed increase in the IIEF-5 scores. However, less increase was observed in the placebo group in comparison to other groups.

The major limitation of the current study is that the number of patients in the groups is quite small. To investigate the dose-dependent efficacy of sildenafil, two different doses were used as 25 mg/day and 50 mg/day. However, the lack of a "sildenafil 25 mg only group, without sham" is another limitation. Therefore, further studies with a longer follow up data are needed.

CONCLUSION

Treatment and follow-up of ED in clinical practice requires a holistic and interdisciplinary approach as sufferers may be skeptical of pharmacological remedies. It seems that acupuncture and sildenafil together may improve psychogenic ED. Hence, for patients with psychogenic ED, acupuncture treatment can be considered as a complementary treatment. Further extensive, long-term follow-up studies are needed.

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Conflict of interest

The authors declare that they have no conflict of interest.

Disclosure of statement

No competing financial interests exist.

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