



Effect of Bastibaj, a Traditional Persian Formula, on Premature Ejaculation: Observation of a Traditional Treatment

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Abstract

Premature ejaculation (PE) is one of the main sexual problems among the male population. There is a folk treatment for this ailment in a small town near Kashan, Iran. The treatment contains hydro-alcoholic extracts of *Tribulus terrestris* L., *Rosa × damascena* Herrm, *Zingiber officinale* Roscoe, and *Crocus sativus* L. in honey. The aim of this preliminary study was to evaluate the effect of the syrup on premature ejaculation. The study population was 17 outpatients visited by a traditional healer. Each patient was diagnosed clinically based on the Premature Ejaculation Diagnostic Tool (PEDT). Inclusion criteria included male participants between 20 to 60 years old, PE more than 6 months, PEDT score more than 11, IELT more than 1 minute, no severe organic disease. Exclusion criteria included taking any chemical drug during the intervention, and sexual contacts less than twice in 3 weeks. 17 male patients aged between 26-65 years old were eligible for the study according to the inclusion criteria. The patients enrolled in the study, filled out the written consent form and conditions of the research were explained. The medication (Bastibaj syrup) was administered for the patients 5 milliliters 3 times daily for 3 sequential weeks. The intravaginal ejaculatory latency time was recorded in all coitus. After the course of the intervention, the mean of IELTs before and after the intervention was compared via paired T-test. Results show that the mean IELT before the intervention (33.2 seconds) in comparison to after it (129.3 seconds) has been improved significantly ($P < 0.01$). According to the results, the study revealed that the traditional remedy prescribed in this study, i.e. Bastibaj, can be effective in patients with premature ejaculation, and can prolong the IELT significantly.

Keywords: Premature ejaculation; Traditional Persian Medicine; Herbal medicine; Bastibaj

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Introduction

Premature ejaculation (PE) is the most prevalent sexual dysfunction in men which globally affects 20 to 40% of men's population [1,2]. High levels of distress, interpersonal difficulty related to ejaculation, low sexual self-confidence, low satisfaction with intercourse, and lower overall quality of life are considered as the consequences of PE [1,3,4].

Recently, several oral or topical treatments have been studied for PE. Selective serotonin reuptake inhibitors (SSRIs), mu opioid receptor i.e. tramadol, phosphodiesterase type 5 inhibitors (PDE5i) e.g. sildenafil and its analogs as oral pharmaceuticals; and lidocaine and prilocaine as topical anesthetics have been the topics of several investigations [1,5,6]. However, because of the limitations of these studies such as small sample size, absence of a correct placebo control arm, the unclear procedure of randomization and so on, none of the various medications commercially presented for PE, except dapoxetine, have yet approved for this indication [5].

On the other hand, folk medicine is one of the considerable sources of inspiration for drug discovery. Folk medicine is a part of people's culture. In traditional societies, any information about a disease is shared by others and passed through the generations [7]. Despite the development of modern medicine, rural areas of Iran have still conserved this kind of traditional information and traditional healers have still pre-

served their place.

The countryside of Mashhad Ardehal town is one of the culturally intact areas of Iran. In this rural area, a hand-made syrup consisted of *Tribulus terrestris*, *Rosa damascena*, *Zingiber officinale*, *Crocus sativus*, and honey is traditionally prescribed for PE. The aim of this study was observation and scientifically evaluation of the efficacy of the medicament.

Methods

Study Design

In this analytical observation, we evaluated the effectiveness of traditionally used syrup on premature ejaculation. The syrup -Bastibaj- is administered by a traditional healer in one of the rural areas of Mashhad Ardehal, a small town near Kashan, Iran. To determine the effect of the syrup, we observed the patients visited by the healer and accomplished an assessment during the process of treatment. This observation was carried out on such an intervention which can be considered as a non-randomized before-after uncontrolled trial. In spite of that, the researchers didn't interfere in the process of treatment, and it was all done by the folk medicine healer during a routine practice. Therefore, the active role of the researchers in the field was to assess the process of treatment and the effectiveness of the medicament via standard valid tools. This study was conducted in the stage from August 2018 to January 2019. The study

population was the patients complaining PE referring to the traditional healer in the above-mentioned region. Once the terms and conditions of the survey were explained and the consent form was filled out, the Premature Ejaculation Diagnostic Tool (PEDT) was completed by all patients. Patients who met the inclusion and exclusion criteria were enrolled in the study.

Inclusion and exclusion criteria

Inclusion criteria were male participants between 20 to 60 years old with a permanent sexual contact with the partner for more than 6 months, PE more than 6 months (IELT less than 1 minute), PEDT score more than 11, ability to make and maintain erection, having coitus at least once a week, lack of diabetes mellitus and no severe cardiac, renal or genitourinary disease, no psychological or psychiatric disorder, no anatomic genital anomaly, lack of any surgery on genitourinary tract, no drug or substance abuse or allergy to drug ingredients, and no usage of any chemical drug effective on sexual function, such as phosphodiesterase inhibitors, selective serotonin reuptake inhibitors (SSRIs), and opioids. Exclusion criteria comprised taking any chemical drug during the intervention, sexual contacts less than twice in 3 weeks and any kind of drug reaction during the study.

Intervention

We observed the treatment period from the beginning to 3 sequential weeks for each patient. At the pre-trial visit, the patient's history was taken and the physical examination was performed by a physician.

Then, the PEDT questionnaire was filled out by all patients.

PEDT is a standard tool derived from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-4-TR) for evaluation of PE. It is a 5-item questionnaire including ejaculation control, frequency of PE, ejaculation with minimal sexual stimulation, interpersonal difficulty, and distress. According to the previous studies, a total score equal to or more than 11 is considered as the definite PE [8].

Moreover, each patient was rendered a standard chronometer (CATIGA CG-512, China) to record the important times. The patient's partner was trained to take the time from vaginal penetration to the moment of ejaculation (IELT) and to write down in a table. So, by the first coitus, the data related to the baseline evaluation was collected and recorded.

Thereafter, all patients started a 21-day trial concomitant with the usual management of the traditional healer. Bastibaj was administered 5 milliliters 3 times daily. After each week the patients were visited to check for the probable side effects and to receive the sufficient drug for the next week. In all intercourses, IELTs were measured and recorded by the patients. At the fourth (final) visit the second time assessment of PEDT was accomplished.

Primary and secondary outcomes

The primary outcome was the assessment of IELT and the severity of PE which was evaluated by the PEDT questionnaire. The secondary outcomes were set as herbal drug side effects recorded based on a diary during

the trial period.

Statistical Analysis

Data were collected and stored in an Excel sheet (Microsoft Office Excel, 2010). Statistical analysis was performed using the Statistical Package for the Social Sciences software (SPSS, Inc., USA, version 16). Paired t-test was used to compare before-after situation and $P < 0.05$ was considered statistically significant.

Results

This study consisted of 17 male participants aged 26 to 48 (mean=43.4). The most frequent innate temperament was hot and wet (8 persons), followed by cold and wet (4 persons), and equable (2 persons). One person

was also in each of hot and equable, cold and equable, and hot and dry temperament (table 1). The results showed that the mean intra-vaginal ejaculatory latency time before the intervention was 32.9 seconds. This factor has been significantly improved to 119.5 seconds after the intervention ($P=0.01$) (table 2).

Discussion

Folk medicine comprises medical aspects of traditional knowledge that developed over generations within various societies before the era of modern medicine [9]. This field of disease management which is a part of complementary and alternative medicine is taken into consideration as a new way for the introduction of novel remedies from ancient times to the modern era

Table 1. Demographic data, temperaments, and past medical history of the cases consumed Bastibaj.

Case No.	Age (year)	Innate temperament	Past medical history
1	48	Cold and wet	
2	47	Hot and wet	
3	54	Hot and wet	Primary hypertension
4	65	Cold and wet	
5	39	Hot and wet	Dermatitis, painful ejaculation, Gastrointestinal problems
6	58	Equable	Diabetes
7	53	Hot and wet	Erection problem
8	26	Hot and wet	
9	33	Cold and wet	
10	47	Equable	Depression- under treatment of opioid addiction
11	30	Cold and equable	
12	31	Hot and wet	Gastrointestinal upset
13	58	Hot and equable	
14	30	Cold and wet	Varicocelelectomy
15	34	Hot and dry	
16	42	Hot and wet	
17	43	Hot and wet	Micropenis

Table 2. IELTs before and after the intervention, treatment results, and side effects observed in patients.

Case No.	Intravaginal ejaculation latency time (Sec)			Treatment Result	Adverse reactions
	Before	After	Δ		
1					
2	40	103	63	Patient satisfaction	
3	35	92	57	Patient satisfaction	
4	29	90	61	Patient satisfaction	
5	50	223	173	Patient satisfaction	
6	18	29	11	Treatment failure	Heartburn
7	37	341	304	Patient satisfaction	
8	45	336	291	Patient satisfaction	
9	20	20	0	Patient satisfaction	
10	23	34	11	Treatment failure*	
11	40	57	17	Treatment failure	
12	23	65	42	Patient satisfaction	
13	31	46	15	Treatment failure	
14	26	83	57	Patient satisfaction	
15	33	68	35	Patient satisfaction	
16	45	78	33	Patient satisfaction	
17	35	35	0	Treatment failure	

* Treatment failure in premature ejaculation but improvement in penile erection

[10]. Therefore, folk medicine can potentially be noted as a pool of pristine ideas for maintaining human health and disease management [11].

This study was designed as an analytical observation of a clinical intervention on PE by a traditional healer in the rural suburbs of Mashhad Ardehal, Kashan, Iran. In this study, we reported the before-after evaluation of IELTs in 17 patients suffering from PE. The syrup administered in this survey is composed of hydro-alcoholic extracts of *Tribulus terrestris* L., *Rosa damascena* Herm, *Zingiber officinale* Roscoe, and *Crocus sativus* L. in honey. Our results

showed that Bastibaj syrup can significantly improve PE.

Taking a glance at the studies performed on the ingredients of Bastibaj shows that there are several surveys proving their effects on sexual function. There are several animal experiments and few human studies indicating the effect of *Tribulus terrestris* on sexual function, desire, and behavior [12,13,14]. Also, some studies detected hormonal changes due to the effect of *Tribulus terrestris* [15]. Nevertheless, animal or human studies on the effect of this herb on PE are not a lot. In the study of Sansalone et al., the researchers revealed that combi-

nation therapy including *Tribulus terrestris* can improve IELT significantly [16].

Rosa damascena Herrm has also been studied as an effective medicinal herb on sexual activity. It is demonstrated that the damask rose can enhance sexual function [17,18]. A clinical study on patients with major depressive disorder consuming selective serotonin-reuptake inhibitors (SSRIs) showed that *Rosa damascena* can ameliorate SSRI-induced sexual dysfunction [19]. In spite of that, there is a lack of evidence verifying the damask rose effect on PE.

Crocus sativus L. is considered as a medicinal plant acting as an aphrodisiac [20]. In some clinical study, it has been claimed that saffron can be effective in erectile dysfunction [21]. Moreover, Kashani L. et al. showed that women with SSRI-induced sexual problems can be improved by concomitant consumption of saffron with fluoxetine in some processes including arousal, lubrication, and pain [22,23]. It also has some local enhancing effects [24]. Nonetheless, to our knowledge, the effect of saffron on PE suffers from lack of evidence. *Zingiber officinale* has active compounds such as gingerol, shogaols, and gingerdione. It is medically used for its anti-tumorigenic, immunomodulatory, anti-inflammatory and antioxidant properties [25]. Also, it is associated with a beneficial effect on male reproductive function in rats, confirmed by increased sperm count, sperm motility, testosterone level, and decreased malondialdehyde level [26,27,28,29,30]. Moreover, the result of a double-blind randomized clinical trial on the effect of ginger on human sperm quality and DNA fragmentation

showed its efficacy in decreasing sperm DNA fragmentation in infertile men [31]. To the best of our knowledge, there are no published controlled trials on the effect of ginger on premature ejaculation. However, there are animal studies in the effect of this medicinal herb on erectile dysfunction. For instance, Khanavi M. et al. demonstrated that the extract of *Z. officinale* root can improve erectile dysfunction in studied samples through specifying human platelet cyclic adenosine monophosphate (cAMP) and cyclic guanosine monophosphate (cGMP) phosphodiesterase inhibitory activity [32].

According to the aforementioned studies, recent investigations support the effectiveness of Bastibaj syrup on other aspects of sexual dysfunctions, except PE. It seems that this study reports the effectiveness of above-mentioned herbs on PE for the first time. Although this survey was a preliminary study with small sample size, it raises the possibility of the effect of such a combination on PE. Therefore, it should be considered as a cue for more investigations on this herbal formulation. Future studies should be carried out as a double-blind controlled clinical trial to eliminate placebo effects and to approve the safety of the medicine.

Conflicts of Interest

None.

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None.

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