LETTER
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Effects of oral Shilajit tablets on sexual function and sexual quality of life among reproductive-aged women: a triple-blind randomized clinical trial

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Abstract

Background: Shilajit is mentioned in the "Kama Sutra" as a potent enhancer of sexual desire. This study aimed to investigate the effects of oral Shilajit tablets on sexual function and sexual quality of life among women of reproductive age. **Methods:** Forty-eight reproductive-aged women participated in a placebo-controlled triple-blind clinical trial. The intervention group took oral Shilajit tablets (200 mg) twice daily for 60 days and the control group took the placebo. Data collection tools were Sexual Quality of Life-Female and Female Sexual Function Index. Data were collected before the intervention, 30, 60, and 90 days after the start of the study. **Results:** Forty-three women completed the study. The mean score of total sexual function in the intervention group was significantly higher than before the intervention ($P < 0.001$). The mean score of sexual function was 28.93 after 90 days in the intervention group while it was 22.09 in the control group. This finding was observed in most domains of the sexual function index. The mean score of sexual quality of life increased after 60 days of intervention in both groups; however, the difference was not statistically significant ($P = 0.094$). **Conclusion**: The study indicated that Shilajit, as a complementary therapy, may improve sexual function and most of its domains; while there was no effect on improving the quality of sexual life.

Keywords: sexual quality of life; sexual function; Shilajit; mumie; complementary medicine

Author contributions

Sadiqa Mosavi, data collection, preparing the first draft; Malihe Tabarrai, data collection, revising the draft; Shadab Shahali, conception or design of the work (supervisor), revising the draft; Mojgan Tansaz, interpretation of data, revising the draft; Hamid Salehinia, analysis and interpretation of data; Susanne Grylka-Baeschlin, interpretation of data, revising the draft; Azam Rahmani, conception or design of the work (supervisor), revising the draft, final approval the revisions. All the listed authors have read and approved the submitted manuscript.

Competing interests

The authors declare no conflicts of interest.

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Peer review information

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Abbreviations

ANOVA, analysis of variance; FSFI, Female Sexual Function Index.

Citation

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Highlights

1. Although Shilajit is considered a potent enhancer of sexual desire in the "Kama Sutra", there were no evidence-based documents in this regard.
2. Shilajit could improve sexual function and most of its domains in a 3-month follow-up.
3. Shilajit did not have a statistical effect on sexual quality of life.
4. Participants reported no severe and considerable side effects for Shilajit.

Medical history of objective

The ancient Indian texts, such as the *Rigveda* and the *Ayurveda*, contain information about the medicinal properties and benefits of Shilajit, a natural substance with potent healing properties. The texts describe how it can strengthen the immune system, increase endurance, and improve overall health. Shilajit was used by ancient physicians to treat various ailments, including digestive issues, arthritis, diabetes, and sexual dysfunction. According to the ancient texts, Shilajit is formed from rocks and plant residues in the mountains, and it takes hundreds of years of pressure and temperature to form. People would search for Shilajit deposits in the mountains and process it into medicinal forms. Shilajit was highly valued in ancient times for its many medicinal benefits and was widely used in medicine and healthcare. The ancient records offer insights into the pharmacology and clinical applications of Shilajit, and modern scientists can conduct further research into its potential uses.

Background

Based on the principles of sexual and mental health, all aspects of women's health, especially physical, mental, and social health, could be affected by sexual function [1]. Sexual dysfunction is a common problem in women [2]; it could cause personal anxiety and destroy self-esteem [3]. It also may have a negative effect on interpersonal relationships, reduce the quality of marital life, and provoke conflict and divorce [4, 5]. A systematic review estimated the prevalence of sexual dysfunction among reproductive-aged women at 50% worldwide by 2020 [6].

Various treatments including hormone therapy, phosphodiesterase inhibitors type 5, psychotherapy, homeopathy, carbon dioxide laser, diet modification, hypnosis, yoga, and acupuncture have been used to improve female sexual dysfunction [7–9]. Many synthetic drugs are expensive or have serious side effects. Some side effects included increased weight gain, acne, hair loss, hirsutism, suppressed sexual desire, somnolence, hypotension, and syncope [8, 10–12]. Therefore, effective natural treatments are still in demand and traditional therapies could be a treatment option [13].

In recent years, researchers have considerably focused on the role of herbal supplements on women's sexual function [14]. Some herbal medicine and natural products that have been used for improving sexual function include ginseng, fennel, fenugreek, bindii, red clover, schisandra, hop, black cohosh, soy, ginkgo biloba, nigella sativa, neroli oil, maca, date pollen, aphrodite and combination of St John's wort and vitex [15].

One of the medicines used in traditional medicine is Shilajit, which is mentioned in Kamasutra as a powerful enhancer of sexual desire and has been used as an aphrodisiac [16, 17]. Shilajit is a natural and mineral product that is created from remains of dead plants and animals and is discharged like tar in caves, breaks [18]. Some of the features of Shilajit include improving the flowing of blood to the reproductive organs [19], increasing testosterone [20], reducing mental and physical stress [21], and adapting skeletal muscle by upregulation of extra cellular matrix (ECM)-associated genes controlling muscle mechanotransduction, elasticity, healing, and regeneration properties [22].

Interventions to promote sexual function and sexual quality of life have been extensively addressed in the published literature [23–26]. Since no research has addressed the effects of Shilajit on sexual function and sexual quality of life, this study was planned to determine the effects of oral Shilajit tablets on sexual function and sexual quality of life among reproductive-aged women.

Materials and methods

Study design

This was a randomized, triple-blind, placebo-controlled clinical trial. This study was approved by the Ethics Committee of Tarbiat Modares University (IR.MODARES.REC.1399.106) and registered at the Iranian Registry of Clinical Trials (IRCT20200617047808 N1-2020-11-26). We calculated the study sample size based on the preliminary results of a pilot study with 15 people in each group with a 95% confidence interval and 80% power of the test. The average score of the total sexual function was chosen as the primary outcome to determine the sample size. Considering the mean scores of one month after the intervention in the primary group, the mean was 24.65 for the control group and 26.93 for the intervention group; including the standard deviation of 1.79, the sample size was calculated as 20 people for each group. The following formula was used and each group was considered 24 participants, allowing for an attrition rate of 20%.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (S_1^2 + S_2^2)}{(\mu_1 - \mu_2)^2}$$

Enrollment, randomization, and blinding

This study was carried out on women referred to Khark Traditional Medicine Health Center affiliated with the Tehran University of Medical Sciences (Tehran, Iran). The sampling was carried out from January 20 to Jun 21, 2021. The participants were selected through convenience sampling. At the health center, the aims of the study were clarified to the participants by the researchers. Informed written consent was obtained from the participants and they were assured of data anonymity and confidentiality. They were also notified of their right to withdraw from the study at any time during the research. Eligibility criteria were assessed for 120 women (Figure 1). Using block randomization with four blocks and an allocation ratio of 1:1, we allocated the participants to the intervention or control groups. Opaque, coded, and sealed envelopes were used to conceal the allocation. The person in charge of the allocation was not aware of the contents of the envelopes.

To ensure blinding in this study, the patient, researcher, and data analyzer were blind to the Shilajit tablets and placebo groups. The tablets were made by another person outside the study in groups A and B and the same packaging was considered for them.

Study participants

To eliminate the effect of confounding factors, the following inclusion criteria were applied: women 18–45 years old, Iranian and living in Tehran, literacy in Persian, living with husband during the study, and being sexually active during the last two months. The exclusion criteria were known underlying disease (such as hypertension, diabetes, asthma, thyroid, heart disease, pelvic visceral prolapse, hyperlipidemia, tumor, hemosiderosis, hemochromatosis, thalassemia, hyperuricemia, and sickle cell anemia), any mental diseases, being addicted to drugs or taking drugs that affect sexual function (e.g. hydrochlorothiazide, propranolol, phenothiazine, diazepam, clonazepam, imipramine, and clomipramine), a history of a stressful event in the past month, any disorders in their reproductive organs (such as cervicitis, vaginitis, genitourinary infection, pelvic genital pain disorders, active sores or genital lesions interfering with intercourse), a history of rape, infertility, and pelvic surgery, and being pregnant or breastfeeding during the time of the study. Withdrawal criteria included being reluctant to continue participating in the study, not taking the Shilajit tablets regularly (use less than 80% of cases), and having an allergy to Shilajit tablets or side effects during the study. All of these criteria were based on the statements of the participants or laboratory tests.

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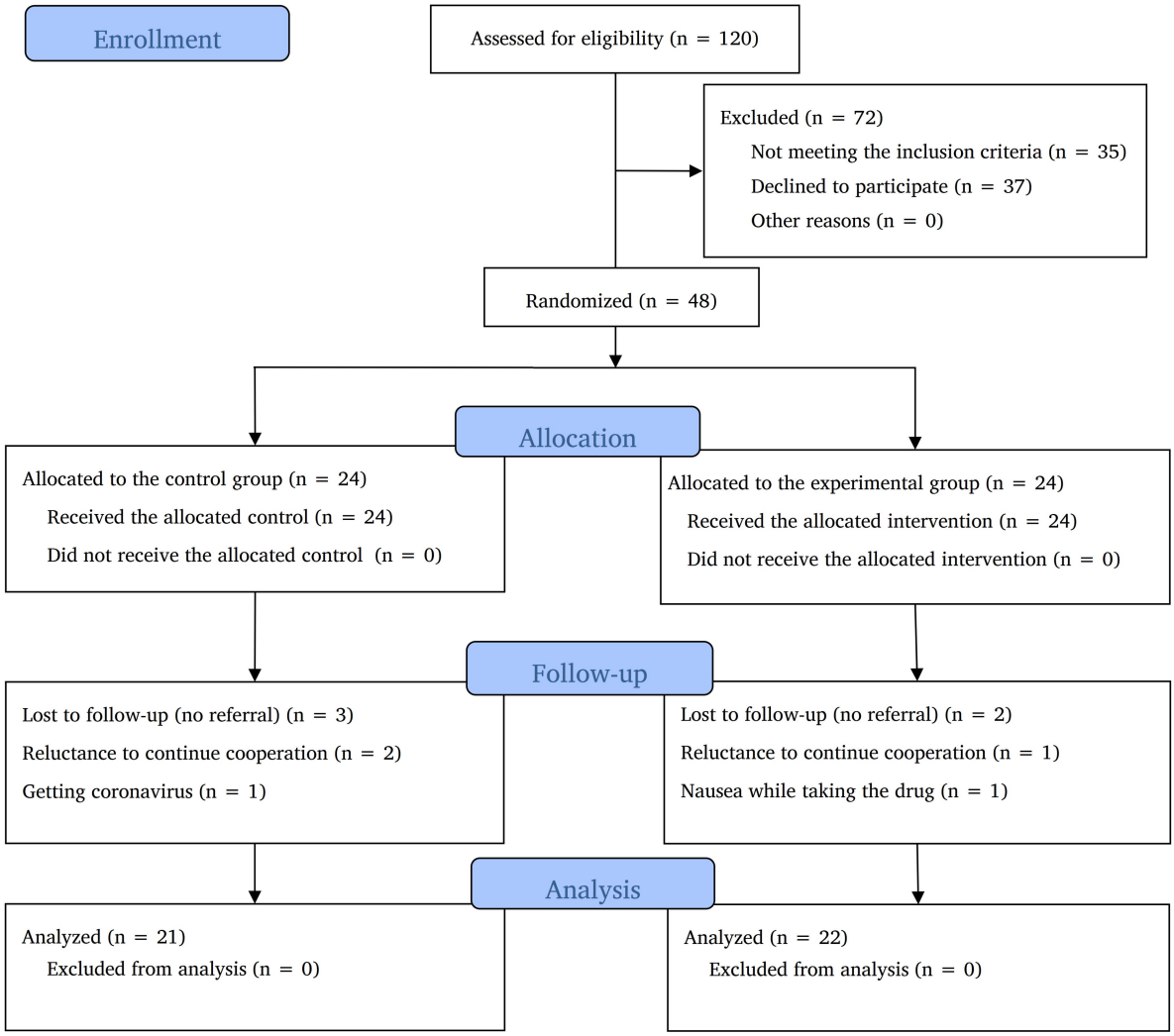

Figure 1 CONSORT flow diagram

Intervention

After the interview and checking inclusion and exclusion criteria and randomization, we collected data. The data collected were age, occupation, level of education of participants and their husbands, economic status, duration of their marriage, number of children, number of abortions, number of pregnancies, type of delivery, and number of deliveries. Afterward, the participants were explained how to use drugs correctly and how to fill in the daily consumption plan sheet. The intervention group received 200 mg Shilajit twice daily for 60 days. These tablets were produced by Talaye Sabze Tooba Herbal Pharmaceutical Company (Tehran, Iran). Placebo tablets that had the same guidelines as the intervention group were given to the control group. The placebo tablets were produced by Shahid Beheshti Traditional Medicine Research Center (Tehran, Iran) with exactly the same color, weight, shape, and size as Shilajit. These tablets contained lactose and avicel (trade name for microcrystalline cellulose partially hydrolyzed with acid and condensed to a fine powder).

Shilajit and placebo preparation

Shilajit (200 mg) is available in Iranian pharmaceutical companies and is used in traditional Iranian medicine for fractures, dislocation and bruises, various kinds of inflammation, ulcers and bowel problems, circulatory and cardiovascular activity, poisoning, alcohol withdrawal and detoxification, and skin condition such as stretches, redness, and sensitivity.

To prepare the placebo, firstly, we mixed the required lactose and avicel in a blender, and then the colors were added to the mixture; they were mixed well in a mixer for two minutes. The mixed powder was then transferred to a hopper and pressed with a double convex round mandrel.

Outcomes, measurements, and follow up

The primary and secondary outcome of the study was improving the score of sexual function and the sexual quality of life score, respectively. The data collection tools included the data entry forms: a form for including/excluding participants according to the pre-defined criteria, a form for collecting socio-demographic characteristics, the Female Sexual Function Index (FSFI), the Sexual Quality of Life Questionnaire, and a checklist for assessing side effects.

The FSFI has 19 items in six areas [desire (two items), arousal (four items), lubrication (four items), orgasm (three items), pain (three items), and satisfaction (three items)]. Each item is recorded from zero (or one) to five, higher scores indicate greater sexual function. The total score ranges from 2 to 36). Rosen et al. (2000) and also Mohammadi et al. (2008) in Iran have approved the reliability and validity of this scale [27, 28].

Another scale used in this study was the Persian version of the Sexual Quality of Life-Female. Symonds et al. developed the first version of the questionnaire in 2005. This questionnaire contains 18 items with a rating on a 6-point Likert-type scale. Items 1, 5, 9, 13 and

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18 should be graded in reverse. The minimum and maximum scores obtained in this tool are 18 and 108, respectively. This questionnaire has six domains, including "readiness based on sexual arousal and privacy", "sexual relationship based on interaction", "outputs of sexual relationship", "framework of cohabitation", "cultural and religious norms", and "passive sexual socialization". The higher overall score indicates the desired and better quality of sexual life. Based on the range of answers, the classification would be as follow: up to 36: poor, 37–72: average, and 73–108: good. Translation and validation of the scale have been assessed by Maasoumi et al. (2013); the reliability (Cronbach's alpha) of the scale has been reported as 0.77 [23]. Participants responded to the questionnaires before the intervention and 30, 60, and 90 days after the intervention.

Protocol deviation

The following measures were taken to address deviations from the protocol. (1) A questionnaire was designed to investigate the reasons for not completing the follow-ups; the reasons for non-referrals were assessed by telephone. (2) Participants were asked to notify the researcher of any problems, complications or side effects, including drug sensitivity. (3) The analysis included per-protocol analysis.

Data analysis

After data collection, we analyzed the data using SPSS software version 19. Using the Kolmogorov-Smironov test, we assessed the normality of the data. Analyzing descriptive data was conducted by absolute and relative frequency distributions, mean, and standard deviation. To compare before and after data in quantitative variables, repeated measure analysis of variance (ANOVA) was used and for parametric bread variables, $\chi 2$ (chi-squared test) and Fisher exact test were used. We used independent t-test and Mann-Whitney U to compare the two groups. The significant level for the *P*-value was considered less than 0.05.

Results

During the study, 120 women were evaluated for assessing eligibility criteria. Of these, 35 women did not meet the inclusion criteria and 37 women did not consent to participate in the study. Leaving 48 women eligible for the study, 48 women were dedicated to experimental and control groups. Two women were excluded from the experimental group due to unwillingness to continue the study and nausea. The severity of nausea was mild but the patient was reluctant to continue the study. Three women were excluded from the control group due to their unwillingness to continue the study and getting the coronavirus. Finally, the data of 43 women in two groups were analyzed (Figure 1).

The mean age of women and husbands was 35.4 (± 6.31) and 40.28 (± 6.69), respectively. The mean duration of marriage was 12.36 (± 7.61) years. In terms of education, 67,4% of women and 55.8% of husbands had a university education. In terms of socioeconomic status, more than eighty-three percent (83.3%) of participants were middle class. In terms of occupation, 93.0% of women were housewives and 51.0% of husbands were self-employed. The mean number of pregnancies, children, abortions, and deliveries were 1.70 (± 1.20), 1.37 (± 1.00), 0.37 (± 0.75), and 1.35 (± 0.99), respectively. There were no remarkable differences between the two groups in terms of demographic and fertility factors and the two groups were homogeneous (Table 1).

Table 1 The demographic characteristic of the participants

Variables		Experimental group (n = 22)	Control group (n = 21)	*P*-value
Age (year) (mean ± SD)		35.50 ± 5.27	35.20 ± 7.37	0.93*
Spouse's age (year) (mean ± SD)		40.41 ± 6.56	40.14 ± 6.99	0.89*
Duration of marriage (year) (mean ± SD)		11.43 ± 7.15	13.33 ± 8.13	0.42*
Gravid (mean ± SD)		1.64 ± 1.21	1.81 ± 1.40	0.67*
Parity (mean ± SD)		1.36 ± 0.90	1.33 ± 1.11	0.92*
Number of children (mean ± SD)		1.41 ± 0.90	1.33 ± 1.11	0.81**
Abortion (mean ± SD)		0.27 ± 0.55	0.48 ± 0.92	0.38**
Educational level N (%)	Primary school and Secondary school	1 (4.5)	1 (4.8)	0.46***
	High school diploma	6 (27.3)	6 (28.0)	
	University education	15 (68.2)	14 (66.0)	
Spouse's educational level N (%)	Primary and secondary school	1 (4.5)	3 (9.3)	0.23***
	High school diploma	8 (36.4)	7 (34.9)	
	University education	13 (59.1)	11 (55.8)	
Occupation N (%)	Housewife	20 (90.9)	20 (95.2)	0.58****
	Employed	2 (9.1)	1 (4.8)	
Spouse's occupation N (%)	Retired	1 (4.5)	1 (4.8)	0.98****
	Employed	10 (45.5)	9 (42.9)	
	Self-employed	11 (50.0)	11 (52.4)	
Economic situation N (%)	Weak	1 (4.5)	0 (0)	0.48***
	Moderate	18 (81.8)	18 (85.7)	
	Good	3 (13.6)	3 (14.3)	
Delivery type N (%)	Vaginal	7 (31.8)	6 (28.6)	0.33***
	Cesarean section	10 (45.5)	9 (42.9)	
	Both	1 (4.5)	0 (0)	
	None	4 (18.2)	6 (28.6)	

*, independent t test; **, Mann-Whitney U; ***, Fisher exact test; ****, chi-squared test. N, number; SD, standard deviation.

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There was a significant difference in the FSFI ($P < 0.001$) and most of its domains such as desire ($P = 0.011$), arousal ($P < 0.001$), lubrication ($P < 0.001$), and sexual satisfaction ($P = 0.005$). However, there was no difference in orgasm ($P = 0.108$) and pain ($P = 0.103$) (Table 2).

There were some inconsistencies between the results following 30 and 60 days of treatment, as well as by the end of the 90-day follow-up. For example, the difference in arousal was not statistically significant on day 30 ($P = 0.09$) while it was significant on 60 ($P = 0.01$) and 90 ($P = 0.007$) days of follow-up. In addition, lubrication on day 60 ($P = 0.02$) was significant but it was not significant on day 30 ($P = 0.25$) and 90 ($P = 0.11$). Similarly, the results of orgasm on day 60 ($P = 0.03$) were significant; although it was not significant on days 30 ($P = 0.05$) and 90 ($P = 0.09$) (Table 2).

The mean score of sexual quality of life increased after 90 days of intervention in both groups. Although this increase was higher in the intervention group (6.2 points), the difference was not statistically significant ($P = 0.094$) (Table 3).

Table 2 The mean total score of FSFI and the mean scores of its dimensions in the Shilajit/placebo groups

Variable	Shilajit mean (SD)	Placebo mean (SD)	*P*-value*	*P*-value***
Desire (1–5)				
Baseline	2.78 (0.89)	3.22 (0.87)	0.790	0.011
30 days	4.09 (0.57)	3.11 (0.88)	0.100	
60 days	4.17 (0.77)	3.11 (1.14)	0.130	
90 days	4.17 (0.77)	3.11 (1.23)	0.070	
P-value**	< 0.001	0.821		
Arousal (0–5)				
Baseline	3.30 (0.95)	3.12 (1.00)	0.570	< 0.001
30 days	4.55 (0.89)	3.14 (1.15)	0.090	
60 days	4.67 (0.75)	3.04 (1.17)	0.010	
90 days	4.74 (0.069)	3.07 (1.21)	0.007	
P-value**	< 0.001	0.912		
Lubrication (0–5)				
Baseline	4.20 (0.88)	3.98 (0.67)	0.450	< 0.001
30 days	4.75 (0.65)	3.91 (0.85)	0.250	
60 days	4.88 (0.61)	3.84 (0.99)	0.020	
90 days	4.90 (0.61)	3.72 (0.90)	0.110	
P-value**	< 0.001	0.310		
Orgasm (0–5)				
Baseline	3.81 (1.37)	3.86 (1.30)	0.650	0.108
30 days	4.58 (1.04)	3.88 (1.48)	0.050	
60 days	4.61 (1.02)	3.81 (1.46)	0.030	
90 days	4.67 (1.00)	3.34 (0.09)	0.090	
P-value**	< 0.001	0.970		
Satisfaction (0–5)				
Baseline	4.06 (1.07)	3.80 (1.42)	0.040	0.005
30 days	4.87 (0.85)	3.72 (1.04)	0.002	
60 days	4.78 (0.87)	3.50 (1.56)	0.003	
90 days	5.01 (0.93)	3.57 (1.57)	0.010	
P-value**	< 0.001	0.471		
Pain (0–5)				
Baseline	4.87 (1.06)	4.89 (1.05)	0.770	0.103
30 days	5.39 (0.73)	4.83 (1.15)	0.010	
60 days	5.37 (0.76)	4.77 (1.11)	0.110	
90 days	5.40 (0.77)	4.79 (1.11)	0.100	
P-value**	<0.001	0.922		
Total FSFI score (2–36)				
Baseline	23.02 (4.03)	22.90 (4.84)	0.920	< 0.001
30 days	28.25 (2.55)	22.62 (5.54)	< 0.001	
60 days	28.50 (2.69)	22.08 (6.53)	< 0.001	
90 days	28.92 (2.69)	22.09 (6.10)	< 0.001	
P-value**	< 0.001	0.596		

*, independent t test (between group analysis); **, repeated measure ANOVA (within group analysis); ***, repeated measure ANOVA (interaction between time and group). ANOVA, analysis of variance; FSFI, Female Sexual Function Index; SD, standard deviation.

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Table 3 The mean total score of sexual quality of life and the mean scores of its dimensions in the Shilajit/placebo groups

Variable	Shilajit	Placebo	*P*-value*	*P*-value***
Sexual quality of life				
Baseline	81.32 (19.62)	74.05 (20.86)	0.240	0.094
30 days	85.41 (22.47)	76.48 (21.68)	0.190	
60 days	86.59 (17.15)	74.81 (23.32)	0.060	
90 days	87.64 (16.42)	75.38 (23.10)	0.510	
P-value**	0.019	0.724		

*, independent t test (between group analysis); **, repeated measure ANOVA (within group analysis); ***, repeated measure ANOVA (interaction between time and group). ANOVA, analysis of variance.

Discussion

We assessed the effects of oral Shilajit tablets on sexual function and sexual quality of life among married women of reproductive age. The score of sexual function 30, 60, and 90 days after intervention in the intervention group showed a significant increase compared to before the intervention. Significant improvement was found in most domains of sexual function including desire, arousal, lubrication, and sexual satisfaction; but there was no significant difference in the domains of orgasm and pain. The mean score of sexual quality of life in both groups was not significant.

The literature review revealed that several animal studies have shown the effects of Shilajit on sexual function and sexual desire [29–31] but no human studies have been performed specifically on women. Mishra et al. conducted a randomized laboratory intervention study to investigate the effect of Shilajit on the sexual function and fertility of male cadmium-infertile mice. The index of libido was better in the group that received the highest amount of Shilajit [29]; Similarly, Saeed et al. evaluated the effect of asphaltum (Shilajit) on libido, serum testosterone, hematology, and biochemical metabolites in Lohi rams. They found that the mean score of sexual desire and serum testosterone increased significantly [30]. The results of these studies are consistent with the results of the present study. In 2006, Park et al. conducted a study to assess the effect of long-term administration of Shilajit on mouse spermatogenesis and oogenesis. It was found that Shilajit in adult mice increases testosterone in addition to spermatogenesis and oogenesis [16]. In another study, rams were kept under the same conditions for a period of 9 weeks; after 7 weeks of treatment with Shilajit, the mean score of libido and serum testosterone levels increased significantly compared to the control group [30]. Although this research has not been conducted on humans, it seems that the findings of these studies are in line with the results of the present study.

Improved libido following the use of Shilajit may be due to stimulation of the central nervous system [32]. An interventional study was conducted with the aim of investigating the parasympathomimetic effects of Shilajit on the relaxation of rat corpus cavernosum. This study hypothesized that the parasympathetic effect of Shilajit on the relaxation of the corpus cavernosum in mice may be one of the instruments that explains Shilajit's traditional role as an aphrodisiac. This study assessed the acute peripheral effects of standard acetylcholine, Shilajit, and their combination in rat corpus cavernosum in two forms; in vivo and in vitro. In vitro results showed that 400 and 800 μg/mL of Shilajit could increase the relaxation of cavernous strips as well as acetylcholine-mediated relaxation. The peripheral parasympathomimetic activity of Shilajit was established by atropine-blocking Shilajit-induced relaxations (in vitro) and Shilajit-induced decreases in mean arterial blood pressure and heart rate (in vivo). Furthermore, the results of this study confirmed the parasympathomimetic effect and the beneficial effects of Shilajit on sexual behavior for the treatment of male sexual dysfunction [30]. Although the above study was performed on male mice, the corpus cavernosum homolog is also present in the female clitoris [33]. Activation of the parasympathetic nerves relaxes the blood vessels and smooth muscles of the corpus cavernosum, which directs blood to the genitals, thereby improving the orgasm and sexual satisfaction of women.

Numerous clinical trials show that testosterone is effective in treating sexual dysfunction in women [34–36]. Several studies have shown that Shilajit increases dehydroepiandrosterone sulfate (DHEAS), a precursor of testosterone [16, 20, 30, 37, 38]. It seems the raise of dehydroepiandrosterone sulfate leads to an increase the testosterone level and therefore results in improving sexual function.

Increased blood flow in the genital area can arouse and improve sexual dysfunction in women [36]. In a study by Das et al., Shilajit was shown to induce genes associated with endothelial cell migration and blood vessel growth [39]. In another study, the angiogenic effects of Shilajit were reported to be due to magnesium ions and copper ions in Shilajit [18]. The reason for the improvement of lubrication and arousal in our study can also be related to this feature.

Other mechanisms for the effects of Shilajit on women's sexual function could be related to a decrease in anxiety and strengthening of the pelvic floor and skeletal cell transcripts. Genital blood flow and sexual pleasure significantly decrease in the state of anxiety [40]. Shilajit is able to reduce mental and physical stress and boost self-confidence to cope with stress by improving memory [21, 41]. Numerous studies have shown that a strong pelvic floor is associated with sexual activity and can improve sexual function [42]. A study aimed to determine the effect of Shilajit on skeletal cell transcripts showed that by using Shilajit, skeletal adaptation will happen by rearranging genes that regulate mechanical properties, elasticity, repair, and control [22].

The results of female sexual function were not significant in terms of orgasm and pain. Although some domains of female sexual function respond appropriately to drugs, some domains seem non-drug-sensitive. Orgasm, for example, is a skill that has to be obtained over time and it needs practice [43]; therefore, orgasm may not be affected by drugs; although different factors could affect women's orgasm, it is mostly affected by psychological factors and women's orgasmic capacity [44]. In addition, psychological factors, such as childhood sexual abuse, marital dissatisfaction, and vaginal atrophy, play a more important role than physical factors in sex-related pain complaints [45]. In fact, for improving some psychological factors of pain, it is necessary that besides using drugs, psychotherapy is applied. Similarly, for vaginal atrophy, some lubricant drugs should be used; therefore, based on the reason of the sexual pain, other kinds of therapies and drugs may be needed. It is suggested that future research focus on the effect of Shilajit on sexual pain specifically, with and without other psychotherapies and drugs.

According to the results of this study, there were some inconsistencies between the results following 30 and 60 days of treatment, as well as by the end of the 90 days follow-up. For example, the difference in arousal was not significant on day 30 while it was significant on 60 and 90 days of follow-up. Several animal studies regarding the effect of Shilajit on sexual arousal demonstrated that this drug could be effective when the length of drug use is rather long (more than 6–7 weeks) [29–31]. In addition, some supplements have short-term and long-term effects. For example, in the short-term, ginseng improves concentration and stress resistance, and in the long-term, it improves well-being [46]. Perhaps the mechanism of

Shilajit's effect is the same, and for this reason, it has had a long-term effect on some domains and a short-term effect on other domains.

The results of this study showed that sexual quality of life increased after 60 days of intervention in both groups. Although this increase was higher in the intervention group (6.2 points), the difference was not significant. The results of a study showed that sexual dysfunction can lead to a decrease in the quality of sexual life. The finding of this study was not consistent with the results of the present study in the field of sexual quality of life. An explanation could be that sexual function mostly refers to the physical dimension and short-term factors while the quality of sexual life is a completely mental (subjective) concept. Quality of sexual life refers to the sensation of sexual attraction, interest, contribution in sexual behaviors, and the insight of sexual function [47, 48]. However, healthy sexual function results from the interaction of all physical, psychological, social, and emotional factors. The scope of most existing questionnaires and assessment scales related to sexual function (including the FSFI questionnaire) focuses on the objective, not subjective, dimensions of sexual life.

The present investigation was the first to assess the effect of oral Shilajit tablets on sexual function and sexual quality of life among married women of reproductive age. One of the limitations of this study was the small sample size due to the time limitation and also high price of each Shilajit tablets in Iran. Another limitation was that we did not measure sex hormone levels in our study.

Conclusion

The results of this study indicated the effect of Shilajit on improving sexual function and most of its domains; while there was no effect on improving the quality of sexual life. Shilajit could be considered as an effective drug to improve female sexual function. Studies with large sample sizes is necessary to confirm the effects of Shilajit on sexual function. In addition, research on the combination of Shilajit with other empowering sexual supplements is suggested.

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