

The impact of Date Palm Pollen Capsule on Vaginal Lubrication and Dyspareunia in Menopausal Woman

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ARTICLE INFO

Article type:
Original article

Article History:
Received: 23-Apr-2017
Accepted: 05-Aug-2017

Key words:
Date palm pollen
Dyspareunia
Vaginal lubrication
Menopause

ABSTRACT

Background & aim: Estrogen and androgen deficiency in menopause leads to poor vulvovaginal blood flow, vaginal dryness, and dyspareunia which can reduce the quality of life among the women. In this regard, this study investigated the impact of date palm pollen capsules on vaginal lubrication and dyspareunia in postmenopausal women.

Methods: The present triple-blinded, placebo-controlled clinical trial was conducted on 60 menopausal women aged 40-65 years, who referred to the health centers affiliated to the Mashhad University of Medical Sciences, Mashhad, Iran, in 2015. The subjects were randomly assigned to two groups of intervention and placebo (n=30), receiving date palm pollen and placebo capsules (350 mg, daily), respectively, for 35 days. The data were collected at two stages (at the baseline and after treatment) using the Female Sexual Function Index, a part of which evaluated vaginal lubrication and dyspareunia. Data analysis was performed in SPSS (version 16) using the independent t-test, Mann-Whitney U test, and ANCOVA.

Results: There was a significant difference between the two groups after the intervention in terms of vaginal lubrication (P<0.001) and dyspareunia (P=0.048). The results of the ANCOVA revealed a significant difference between the intervention and placebo groups regarding the two investigated domains of sexual function by controlling the effect of the confounding factors.

Conclusion: As the findings indicated, the administration of date palm pollen could improve vaginal lubrication and reduce dyspareunia in the postmenopausal women.

► Please cite this paper as:

Yosefzadeh S, Sadeghi S, Rakhshandeh H, Dadghar D, Mazloum SR. The impact of Date Palm Pollen Capsule on Vaginal Lubrication and Dyspareunia In Menopausal Woman. Journal of Midwifery and Reproductive Health. 2018; 6(4): 1409-1418. DOI: 10.22038/jmrh.2018.23071.1246

Introduction

The global trend of aging populations, along with the consequent increase in the number of postmenopausal women, has made a major health issue for the females who are at the age of menopause (1, 2). Vaginal atrophy is a frequently overlooked menopausal symptom, which is one of the

most important factors affecting sexual function and genitourinary health. It is estimated that 90% of the women are influenced by symptoms, such as dryness, itching, dysuria, and dyspareunia (3). The physiological reduction of estrogen and androgen during menopause leads to poor

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vulvovaginal blood flow and vaginal dryness, decreasing genital sensory thresholds and dyspareunia (4).

According to different studies, the incidence rates of vaginal dryness and dyspareunia vary within 27-55% and 32-41%, respectively, in the postmenopausal women (5-7), 75% of whom are untreated. Some women consider the symptoms of menopause as part of the aging process. Accordingly, due to the unawareness of therapeutic options, many of these women usually adapt lifestyle modifications, such as stopping sexual activity due to dyspareunia caused by vaginal dryness. This can have major impacts on sexual quality, satisfaction, and function, and thereby exacerbate atrophic symptoms (8, 9).

Hormone replacement therapy (HRT) has been traditionally used as the first-line treatment for the improvement of the menopausal symptoms (10). However, the women often seek for alternative therapies due to the side effects and risks of the HRT (11). In this regard, the complementary and alternative medicine (CAM) has recently gained an unprecedented popularity for the management of the menopausal symptoms. Accordingly, women are among the largest consumers of complementary medicine (12). The World Health Organization has recommended that CAM can be effective in the improvement of the menopausal symptoms (13).

Complementary herbal medicine is the most common form of treatment, which is widely used in the world and commonly among menopausal women for the elimination of the menopausal symptoms (16-14). The palm tree, *Phoenix dactylifera*, is a plant of Palmaceae family, different parts of which have therapeutic applications (17). The date palm pollen has been anciently consumed in Greece and China for the treatment of infertility and improvement of sexuality in women (18). The authentic books of traditional medicine, such as *Makhzan-Ol-Advieh*, *Tohfath-Ol-Momenin*, and *Riaz-Ol-Advieh*, have pointed to the numerous medicinal properties of date palm pollen, including strengthening male sexuality and female lust (19-21).

Scientists have been able to extract gonadotropin and estrone hormones from the date palm pollen (22, 23). Today, the discovery of gonadotropin hormones in the date palm pollen has confirmed the applicability of this plant in the treatment of infertility by primitive Arabs. Sex hormones are also found in the date palm pollen. All parts of this plant contain carbohydrates, alkaloids, steroids, flavonoids, vitamins, and tannins (24).

Abedi (2013) prescribed the date palm pollen to male rats and observed their improved sexual function (25). Likewise, Moshtaghi (2010) reported the enhancement of estrogen and progesterone hormones in adult female rats following the administration of date palm pollen (26). Furthermore, in the studies conducted by Bahmanpour (2006) and Mehraban (2014), the date palm pollen had positive effects on spermatogenesis and increased sex hormones in adult male rats (27, 28).

To the best of our knowledge, there are no human studies investigating the effect of date palm pollen on sexual function. However, this plant has been reported to elevate the level of sex hormones and improve sexual behavior in animal experiments. Therefore, regarding the high prevalence of sexual problems and their respective adverse effects on the quality of life among the menopausal women and considering their desire to use alternative therapies and complementary medicine, this study aimed to investigate the effect of date palm pollen on vaginal lubrication and dyspareunia among the postmenopausal women.

Materials and Methods

This triple-blinded, placebo-controlled clinical trial was conducted on 60 menopausal women aged 40-65 years who referred to the health centers affiliated to the Mashhad University of Medical Sciences, Mashhad, Iran, in 2015. The study population was selected using convenience sampling method. The participants were randomly assigned into two groups of intervention and placebo,

receiving date palm pollen and placebo capsules, respectively, using the tables of random number.

The sample size was determined to be 28 cases in each group, based on a pilot study conducted on 10 subjects of both groups for vaginal lubrication and dyspareunia indices and using the formula of comparing two population means (mean vaginal lubrication values of 44.4 ± 19.1 and 29.3 ± 20.5 with and without intervention, respectively) considering 95% confidence interval and 80% test power. Regarding the attrition, 65 subjects (32 in the control group and 33 in the intervention group) were evaluated.

However, two controls were excluded due to hypertension and unwillingness of the spouse; in addition, three cases were removed from the intervention group for taking other drugs (n=2) and the absence of the spouse (n=1). Therefore, the final analysis was performed on 60 people (30 cases in each group) (Figure 1).

The inclusion criteria were: 1) informed consent, 2) minimum education level of primary school, 3) age range of 40-65 years, 4) normal menopause, 5) absence of menstruation for at least one year without any surgical or pathological intervention, 6)

minimum of one sexual activity in the last month, 7) no history of sexual dysfunction before menopause according to the research unit, 8) Female Sexual Function Index (FSFI) score of < 28 , 9) absence of diagnosed psychological or systemic disease affecting sexual function, 10) no history of taking drugs affecting sexual function, 11) no history of HRT within the last six months, 12) no history of pelvic surgery (e.g., colporrhaphy and restoration), 13) absence of sexual dysfunction in the sexual partner, 14) lack of allergy to the pollen of plants and herbs, 15) non-use of complementary medicine or a specific herbal medicine during the last month to improve menopausal symptoms, 16) no history of chemotherapy or pelvic or whole body radiotherapy, and 17) no history of consuming tobacco, alcohol, or drugs.

On the other hand, the exclusion criteria included: 1) unwillingness to continue participating in the study, 2) drug hypersensitivity, 3) consumption of any other drugs during the study, 4) experience of unexpected events during the research period, and 5) no drug intake for two consecutive days or five intermittent days.

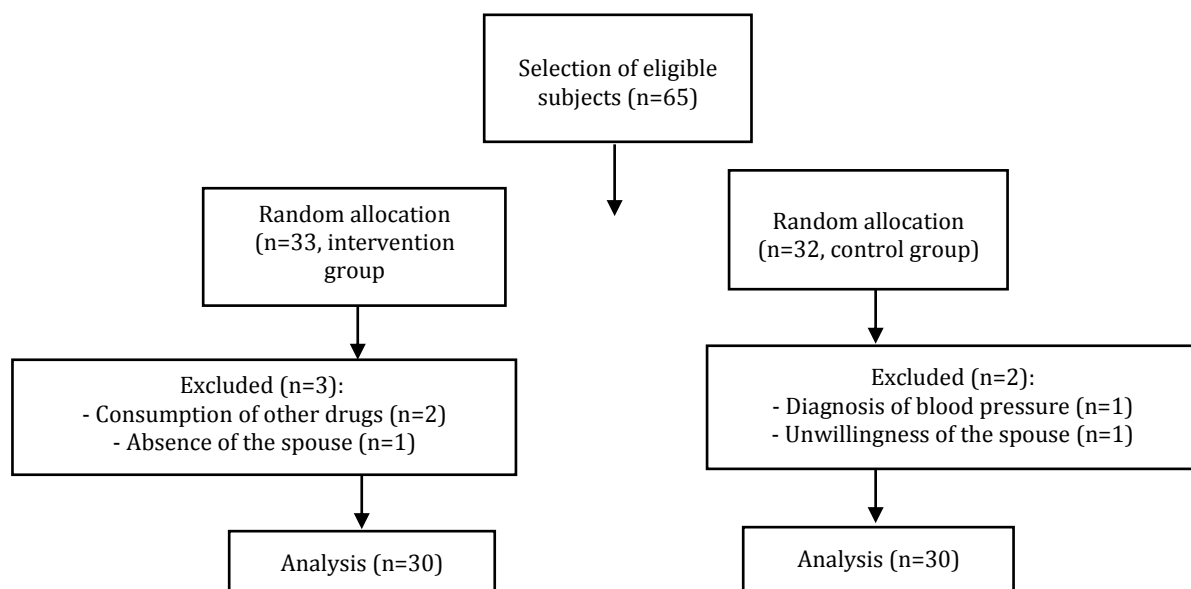


Figure 1. Flowchart of sample selection process

The sampling process was started after obtaining approval from the Ethics Committee of Mashhad University of Medical Sciences and in coordination with the authorities of the health centers. The researcher explained the study objectives and methodology to those meeting the inclusion criteria according to the items of the questionnaire. Subsequently, the participants completed the informed consent forms. The researcher dealt with the samples in a completely private atmosphere, and assured them about the confidentiality and anonymity of their data. Furthermore, they were ensured of the possibility of study withdrawal at any time without affecting the healthcare process.

Date palm pollen was purchased from the palm lands of Hormozgan Province, Iran. It was used after verification by the experts of Agriculture Jihad Organization of Hajjabad County in Hormozgan Province (herbarium code: 373846). Starch powder was applied to prepare the placebo capsules. The date palm pollen and placebo capsules were prepared in a pharmacy laboratory of the Faculty of Pharmacy, Mashhad University of Medical Sciences, Mashhad, Iran, by a pharmacist consultant with a completely similar appearance. The capsules were placed in bottles that were identical with the A and B codes. Each date palm pollen capsule contained 300 mg of date palm pollen and each placebo capsule contained 300 mg of starch.

The participants daily consumed one capsule for 35 days. Studies on laboratory animals were referenced to determine the dosage of the drug (300 mg) and the duration of the intervention (35 days) due to the absence of a similar study (27, 28). Since the current research was three-blinded, only the pharmacist was aware of the contents of the bottles, and the researcher and the statistical analyst were unaware of their contents until the end of the statistical analysis.

The data were collected using the demographic characteristic form and FSFI, a part of which evaluated vaginal lubrication and

dyspareunia at baseline and after treatment, filled out by the research samples. The required guidance was provided if further explanations were needed. To obtain a score, each of the domains was multiplied by a certain numerical coefficient (vaginal lubrication by 0.3 and dyspareunia by 0.4). The FSFI was completed at the baseline and after the intervention (i.e., 35 days' post-intervention).

The validity of the researcher-made form was determined by the content validity method. Therefore, after searching the books and scientific publications on the subject of interest, these forms were provided under the guidance of supervisors and advisors. After applying the corrective opinions of 10 faculty members and final confirmation, the main forms were completed and used for data collection.

The validity and reliability of the items focusing on vaginal lubrication and dyspareunia have been confirmed by Mohammadi et al. in 2008 (29) rendering the specificity and sensitivity values of 0.65/0.66 and 0.74/0.66, respectively. In the present study, the Cronbach's alpha coefficients were 0.83 and 0.87 for vaginal lubrication and dyspareunia, respectively.

During the capsule administration, the samples received a checklist for controlling the use of the drug and provided with required training for its completion. They were also requested to avoid taking herbs and phytoestrogens during the intervention. At the end of the second week, follow-up phone call was made to know the possible complications and concerns, emphasize on taking capsules, and respond to possible questions.

In the last week, the referral date was reminded to the research units after the completion of the intervention through phone calls. The questionnaire of side effects and satisfaction with treatment was completed at the end of the intervention. Finally, the data were analyzed in SPSS software (version 16) using Mann-Whitney U test, independent t-test, and analysis of covariance. P-value less than 0.05 was considered statistically significant.

Results

Tables 1 and 2 show the individual and social characteristics of the intervention and control groups. According to the results, there was no

significant difference between the two groups in terms of sociodemographic characteristics ($P \geq 0.05$).

Table 1. Quantitative analysis of demographic variables in the intervention and control groups

Demographic variables	Intervention group (n=30), Mean±SD	Control group (n=30), Mean±SD	Test results
Age	52.3±5.6	54.4±1.8	df=58, t=1.5, P=0.149, Independent t-test
Spouse's age	56.4±6.6	56.4±4.4	P=0.744, U=428.0, Mann-Whitney U test
Gravidity	5.2±2.9	5.2±6.8	P=0.447, U=399.0, Mann-Whitney U test
Body mass index (kg/m ²)	25.2±4.9	26.2±8.5	P=0.113, U=308.5, Mann-Whitney U test
Number of vaginal childbirth	3.8±2.4	4.2±2.6	df=57, t=-0.6, P=0.573, Independent t-test
Number of cesarean section delivery	0.6±1.0	0.5±0.9	P=0.848, U=439.0, Mann-Whitney U test
Number of children	4.1±2.0	4.1±2.0	P=0.934, U=444.5, Mann-Whitney U test
Age of marriage (years)	29.5±9.5	32.9±9.4	df=58, t=1.4, P=0.164, Independent t-test
Duration of menstruation cessation (month)	53.43±5.7	66.59±0.4	P=0.514, U=406.0, Mann-Whitney U test
Number of sex per week	1.0±1.6	1.0±2.6	P=0.416, U=404.0, Mann-Whitney U test

Table 2. Qualitative analysis of demographic variables in the intervention and control groups

Demographic variables	Intervention group frequency (%)	Control group frequency (%)	Test results
Education level			U=386.0
Primary school	19 (62.1)	19 (62.1)	P=0.531
Secondary school	2 (6.9)	6 (20.7)	Mann-Whitney U test
High school	6 (20.7)	2 (6.9)	
Associate degree and higher	3 (10.3)	3 (10.3)	
Spouse's education level			U=532.0
Primary school	17 (56.7)	19 (63.3)	P=0.763
Secondary school	6 (20.0)	3 (10.0)	Mann-Whitney U test
High school	4 (13.3)	5 (16.7)	
Associate degree and higher	3 (10.0)	3 (10.0)	
Occupation			t=2.9
Housewife	26 (86.7)	28 (93.3)	df=2
Employee	4 (13.3)	1 (3.3)	P=0.355
Retiree	0 (0.0)	1 (3.3)	Chi-square exact test
Spouse's Occupation			t=2.8
Employee	4 (13.3)	5 (16.7)	df=4
Laborer	1 (3.3)	4 (13.3)	P=0.644
Self-employed	15 (50.0)	11 (36.7)	
Retiree	8 (26.7)	7 (23.3)	
Unemployed	2 (6.7)	3 (10.0)	Chi-square exact test
Socioeconomic level			U=418.0
Very low	0 (0.0)	1 (3.3)	P=0.591
Low	11 (36.7)	7 (23.3)	Mann-Whitney U test
Average	16 (53.3)	19 (63.3)	
High above	1 (3.3)	3 (10.0)	
Very high	2 (6.7)	0 (0.0)	

There was no significant difference in the mean scores of dyspareunia before and after the intervention in both intervention and control groups (P=0.175, P=0.373, respectively).

Table 3. Mean score of dyspareunia in date palm pollen and placebo groups before and after the intervention

Dyspareunia	Date palm pollen group	Placebo group	Intergroup test results
Before intervention	3.1±9.1	4.0±4.8	U=360.5 P=0.175 Mann-Whitney U test
After intervention	4.0±2.9	4.0±0.9	U=391.0 P=0.373 Mann-Whitney U test
Difference between pre- and post-intervention stages	0.1±3.3	-0.1±4.0	U=317.5 P=0.048 Mann-Whitney U test
Intragroup test results	Z= -1.0 Wilcoxon test P=0.298	Z= -1.9 Wilcoxon test P=0.056	
After intervention by eliminating the effect of pre-intervention stage	4.3±0.1	3.0±9.2	df=2, f=3.4, P=0.003 Analysis of covariance test

However, the mean score changes in dyspareunia before and after the intervention was significantly higher in the intervention group, compared to those in the control group (P=0.048). The intragroup comparison showed no significant difference between the intervention and control groups regarding the mean score of dyspareunia after the intervention (P=0.298, P=0.056, respectively).

In addition, the analysis of covariance for the post-intervention dyspareunia was compared with the elimination of dyspareunia effect at the pre intervention stage in the two groups, and the results indicated a significant difference (df=2, f=3.4, P=0.003). The modified mean dyspareunia levels were 4.3±0.1 and 3.9±0.2 in the intervention and control groups after the intervention, respectively (Table 3).

Regarding the mean score of vaginal lubrication, there was no significant difference between the intervention and control groups before the intervention (P=0.353). However, after the intervention, the intervention group had a significantly higher mean score of vaginal lubrication than the control group (P=0.045). Accordingly, the mean score changes in the vaginal lubrication before and after the intervention were significantly higher in the intervention group, compared to those in the

control group (P<0.001).

Based on the intragroup comparison in the intervention group, the mean score of vaginal lubrication was significantly higher at the post-intervention stage as compared to that in the pre-intervention phase (P<0.001). Nonetheless, in the control group, the mean score of vaginal lubrication showed no significant before and after the intervention (P=0.181).

According to the analysis of covariance, there was a significant difference in the vaginal lubrication values after the intervention by eliminating the effect of vaginal lubrication before the intervention in the two groups (df=2, f=21.9, P<0.001). The modified mean scores of vaginal lubrication were 4.7±0.1 and 4.0±0.3 in the intervention and control groups, respectively, at the post-intervention stage (Table 4). No complications were observed due to the use of date palm pollen and placebo.

Discussion

In a study conducted by Abedi and Parviz (2013) entitled "Effects of aqueous of phoenix dactylifera pollen grain on sexual behavior of male rates", the intervention group showed an improvement in sexual behavior and increased serum levels of testosterone and estradiol, compared to the control group (25). In another study performed by Moshtaghi et al. (2007), entitled "Effect of Phoenix dactylifera

on serum concentrations of estrogen, progesterone and gonadotropins in adult female rats", date palm pollen increased the

concentration of estrogen and progesterone hormones (26).

Table 4. Mean score of vaginal lubrication in both date palm pollen and placebo groups before and after the intervention

Dyspareunia	Date palm pollen group	Placebo group	Intergroup test results
Before intervention	3.1±5.2	3.1±9.0	U=388.0, P=0.353 Mann-Whitney U test
After intervention	4.0±6.6	4.1±1.1	df=46, t=2.1, P=0.045 Independent t-test
Difference between pre- and post-intervention stages	1.0±1.9	0.0±2.9	U=214.0, P<0.001 Mann-Whitney U test
Intragroup test results	t = -6.9, df=29, P<0.001 Paired t-test	Z= -1.3, P=0.181 Wilcoxon test	
After intervention by eliminating the effect of pre-intervention stage	4.7±0.1	4.0±0.3	df=2, f=21.9, P<0.001 Analysis of covariance test

In the studies carried out by Mehraban (2013) and Bahmanpour (2006), the groups receiving the date palm pollen extract showed an increase in the level of sex hormones (27, 28). One of the functions of estrogen is the improvement of pelvic connective tissue resilience for comfortable intercourse. When the estrogen is not produced sufficiently before the menopause, vaginal dryness might occur (30).

In the postmenopausal women, the mucous membrane of the vagina is weakened, and the rugae is lost. These females have a pale and diaphanous appearance due to the reduction of the vesicularity. The loss of subcutaneous fat and elastic tissue makes labia minora and labia majora appear wrinkled. In addition, estrogen deficiency occurring after menopause causes atrophic changes and can be associated with symptoms, such as dyspareunia, itching, vaginal irritation, dryness, and vaginismus (31, 32).

Studies have shown that the reduction of sexual arousal and vaginal lubrication is associated with a decrease in the level of endogenous or administered androgens (33). During the menopause, the physiological reduction of estrogen and androgen leads to poor vulvovaginal blood flow, and thereby reduced sexual arousal. Moreover, vaginal dryness decreases genital sensory thresholds, dyspareunia, and sexual desire (4).

In line with the findings of the mentioned studies, the results of this study demonstrated

that the date palm pollen increased vaginal lubrication and decreased dyspareunia. This could be due to the effect of date palm pollen on the elevation of sex hormones, such as estradiol, progesterone, and testosterone. According to phytochemical studies, date palm pollen contains such compounds as natural antioxidants (e.g., flavonoids and glycosides), saponin, estrone, vitamins A and E, abundant minerals (e.g., bromine, zinc, cadmium, manganese, and copper), and fatty acids (e.g., palmitic acid, stearic acid, and linoleic acid) (23, 34-36).

According to various studies, such compounds as linoleic acid, palmitic acid, and zinc could inhibit the production of nitric oxide (steroid production inhibitors). Therefore, the date palm pollen may also increase the synthesis of steroid in the sex cells by inhibiting the synthesis of nitric oxide, and consequently enhance the concentration of hormones (37). The compounds, such as stearic acid and palmitic acid, have an inhibitory effect on the 5 α -reductase enzyme activity. The inhibition of this enzyme reduces the conversion of testosterone to dihydro-testosterone in the tissues, and ultimately increases testosterone concentrations (38).

Studies have shown that the present compounds, such as zinc and cadmium, enhance the production of testosterone

through the biosynthesis of 17β -Hydroxysteroid dehydrogenases, thereby increasing the metabolism of steroids (37). The vitamins are essential for the health of the uterus and vagina; in this regard, if the organs are not lubricated by vitamins, they will become dry and wrinkled (39).

Some vitamins, such as vitamins A and E, are used to treat menopausal disorders and vaginal atrophy (40, 41). Among vitamins, vitamin E is the best vitamin playing a key role in the stability of estrogen levels, which can improve menopausal symptoms, such as vaginal dryness (39). The saponin affects the release of nitric acid, improves blood flow to the female's reproductive system, and thereby attenuates the physical problems of the women (42). Accordingly, the date palm pollen can also improve vaginal lubrication and reduce dyspareunia because of having antioxidant compounds and active ingredients affecting sex hormones.

To the best of our knowledge, there are no studies evaluating the effect of date palm pollen on human sexual function for comparing their results with those of the present study. One of the limitations of the present study was the impossibility of controlling the effective factors, including psychological conditions and individual characteristics of the samples, which was largely resolved by random assignment.

Furthermore, due to the lack of similar human studies, pharmacist consultation and the studies investigating laboratory animals were used to determine the effective and uncomplicated amount of drug and the duration of the intervention with the shortest possible time to observe the drug effect (27, 28). During the study, the adverse effects were followed up using a checklist; nevertheless, no complication was reported. The triple blindness and using the control group in the research are the strengths of the present study. Further studies are recommended to examine the impact of date palm pollen on other dimensions of female sexual function and the administration of high-dose drugs.

Conclusion

As the findings indicated, the administration of date palm pollen capsule for 35 days could

reduce dyspareunia and improve vaginal lubrication in the menopausal women without any side effects.

Acknowledgements

The present study was derived from the MD thesis in midwifery approved by Mashhad University of Medical Sciences (No. 941140) and registered in the Iranian Registry of Clinical Trials (IRCT2016070928853N1). The authors would like to express their gratitude to the Research Council and the Ethics Committee of Mashhad University of Medical Sciences, the Nursing and Midwifery Faculty, as well as the research units who cooperated in this study.

Conflicts of interest

The authors declare no conflicts of interest.

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