



The Effect of Chamomile Cream on Episiotomy Pain in Primiparous Women: A Randomized Clinical Trial

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ABSTRACT

Introduction: Episiotomy is a surgical incision made in the perineum to enlarge it. Perineal pain is the most common complaint of mothers after episiotomy. Chamomile extract has been proposed as a sedative in traditional medicine. This study was conducted to assess the effect of chamomile cream on the pain after episiotomy.

Methods: This triple blind clinical trial was performed on 114 eligible women at Ommolbanin Hospital in Mashhad, Iran in 2014. They were randomly assigned to two groups using random blocks. After delivery, mothers in the intervention group used 0.5 g of prescribed chamomile while the control group used placebo cream on the stitch twice a day lasting ten days. Episiotomy pain was evaluated before intervention and 12 hours after episiotomy repair and also on the first, seventh, tenth and fourteenth day after delivery by McGill pain questionnaire. Data was analyzed by SPSS ver.13.

Results: There was no significant difference between the two groups before the intervention, 12 hours and the first day after delivery. However, a significant difference was found on the seventh, tenth and fourteenth day after delivery. McGill mean (SD) score on the seventh, tenth and fourteenth in experimental group was 11.36 (5.04), 4.44 (3.43) and 7.16 (4.10) respectively. It was reported 14.88 (7.34), 7.41(4.92) and 9.96 (4.81) in placebo group, respectively.

Conclusion: Chamomile cream can be used to reduce episiotomy pain in Primiparous women.

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Introduction

Episiotomy is performed with a pudendal block¹ during second stage of labor to expand the opening of the vagina which improves maternal and neonatal outcomes.²⁻⁴ It is one of the most common medical procedures performed on women in Iran, which have been reported 88.3% at Ommolbanin hospital of Mashhad, in 2006.⁴ Also Khajavi et al., reported that the prevalence of episiotomy is 97.3% in primiparous women in Tehran, Iran which is higher than other countries.⁵

Although its routine use in childbirth has steadily declined in recent decades, it is still widely practiced in Asian countries. It could be explained because of the short perineal and

sturdy tissue of Asian women. Little research has been yet conducted on episiotomy.⁶ Khajavi et al., reported that Medio-lateral episiotomy is widely used in Iran despite its disadvantages.⁵

The most common complaint of episiotomy is perineal pain.⁵ Khajavi et al., showed that perineal pain in the first, tenth, fortieth and ninetieth day after birth was 96.4%, 63%, 25% and 12%, respectively.⁵ Episiotomy Pain is always difficult and stressful for primiparous women, which has several negative aspects such as negative effect on the first experience of motherhood, mothers' inability to care the infant,⁷ delay in mother-infant communication, insomnia, fatigue, confusion,

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anxiety, and ignoring health educations in relation to maternal- infant care.^{8,9}

Thus, we have to recover women more quickly after childbirth by removing their perineal pain and discomfort.¹⁰ Drug or non-drug methods are used to reduce the perineal pain.³ Non-drug methods include using hot and cold compression, and salt water or diluted Savlone in the bathroom.^{3,11,12} Drug methods such as acetaminophen, aspirin, and ibuprofen and diclofenac sodium.¹² Despite empirical evidence of drug treatments, some issues should be considered in selecting them such as: pain intensity, constipation property, digestive problems, risks and possible complications of baby through the breast milk.¹³ Drug treatments make high costs for consumer and the health care system as well as it has more side effects.¹⁴

World Health Organization (WHO) has a great emphasis on using herbal medicine because of complications of chemical drugs. Currently, finding the most effective method with minimal complications, availability and easily acceptance by women has always been considered by researchers.¹⁵

Chamomile is one of the plants that are currently used in Iranian traditional medicine as an analgesic, which contains 120 chemical compositions including α -bisabolol, bisabolol oxides, spiro-ethers, chamazulene and flavonoids.¹⁵ Episiotomy pain often caused by inflammation and edema.⁶ Due to the strong anti-inflammatory effect of chamomile which has been mentioned in several studies,^{15,16-22} it seems that chamomile could be used as a pain killer by reducing edema and inflammation in the first days after delivery.¹⁶ In addition to the mechanisms in inhibiting the prostaglandin synthesis in reducing pain, other painless mechanisms are also possible.²³

Based on the importance of reducing episiotomy pain, the complications of chemical drugs, the general trend towards herbal medicine, the researchers decided to conduct a study on the effect of chamomile cream on episiotomy pain and provide more favorable services by using its findings to ensure maternal health.

Materials and methods

This triple blind clinical trial was done on 114 eligible women admitted to Ommolbanin hospital in Mashhad, Iran. To determine the sample size based on a preliminary study, the mean and deviation of the 10th day were obtained in experimental group 0.87 (0.90) and in control group 0.56 (1.10).

After the approval of the ethics committee of Mashhad University of Medical Sciences, The study was registered in the Iranian registry center of clinical trials with IRCT2013051413336N1 code.

Dried chamomile flowers (*Matricaria Chamomile*) was purchased from Zardband Company of Tehran and its identity was confirmed by herbarium Lab of Mashhad Pharmacy School. For making Chamomile extract, 60 gr of crushed chamomile which made by mill was poured in to each thimble and extracted with 70% alcohol by Soxhlet extractor and then after removing the solvent by rotary evaporator, concentrated extract was prepared in the laboratory of Pharmacology, School of Medicine, Mashhad. Then concentrated extract was weighed and its efficiency was obtained and according to Charousaei and Dabirian,¹⁷ chamomile cream 1.3% was made of the combination of chamomile extract with cold cream and placebo cream containing simple foundation of cream (Cold Cream) by the pharmacist and were coded (code A and B). Tubes of chamomile and placebo creams were similar in appearance. Encoded process was done by the pharmacist. It should be mentioned that participants, statistical analysts, researcher and research assistant were unaware of codes until the end of the study.

The inclusion criteria of this study were as following: Primiparous women aged 18-35 years, vaginal delivery with episiotomy, living with her husband, body mass index in the range of 19.8-30, absence of disease impaired wound healing, not using drugs affecting wound healing, singleton pregnancy with cephalic presentation, lack of symptomatic infection of the vagina and vulva (infectious

discharge, itching, and irritant), no revealed abnormalities in the baby, no severe rectocele or cystocele (grade 2 or higher), no septum or mass in vagina, no obstetric problem history, not using sedative for 4 hours before delivery and no reconstructive surgery history of the vagina and the perineum.

The exclusion criteria were as following: the presence of disorder in the progress of labor, duration of second stage of labor for more than 2 hours, extension of the incision area and turning into grade 3 or 4 tear or rupture except episiotomy tear, abnormal vaginal bleeding, shoulder dystocia (when maneuvers used to relieve shoulder dystocia except Mac Robert maneuver), expulsion the placenta by hand, hematoma formation, having sexual intercourse until end of the study (15 days postpartum), curettage or resection within the first 24 hours after delivery, undesired events during the first 14 days after delivery, using cream regularly, having puerperal fever, infection of the episiotomy area, need to suturing again and complications arising from the use of chamomile cream.

In this study, data were gathered by questionnaires including base information and examination results (selection form of the subjects, forms of delivery stages and episiotomy, daily form of sedative, antibiotics consumption, health and nutrition care, etc.), constipation assessment scale in pregnancy and Short-form McGill Pain Questionnaire.

The validity of the base information and examination and the constipation assessment form was confirmed by content validity. The validity of Short-form McGill Pain Questionnaire was determined by criterion-related validity on 10 participants. Thus, the ability of the instrument to measure episiotomy pain compared to the pain visual tool (correlation coefficient $r=0.85$).

The reliability of the selection form and daily data entry form were confirmed. The reliability of labor stages forms and episiotomy information were confirmed with the assessor agreement ($r= 0.89$, $r=0.94$). The reliability of Short-form McGill Pain Questionnaire was approved by internal reliability (Cronbach's

alpha) ($r =0.91$). In addition, the reliability of Constipation Assessment Scale has been confirmed by Brusard and Brend (1998, $r =0.92$)²⁴ and Tabatabai Chehr (2001, $r =0.82$) in pregnant women.²⁵

The procedure were as following: after the approval of the ethics committee of Mashhad University of Medical Sciences (code 911324), the purposes of the study was explained to eligible women referred to Ommolbanin hospital. They were selected by simple sampling method and then they were randomly assigned into two groups A or B using random blocks after obtaining informed consent.

Delivery stages care, delivery, repair of episiotomy was done by the researcher assistant. After expulsion the placenta and repair of episiotomy in lithotomy position, information about the baby, episiotomy incision size, type of yarn used and the number of stitches were recorded. After repair of episiotomy, the researcher gave the necessary training about stitch and perineum care, personal hygiene, how to complete daily information form (such as sedative and antibiotics consumption, using cream for the stitches, hygiene, nutrition and physical activity) to the mothers. Also educational pamphlet was given to them. An encoded package cream was given to the mothers 2 hours after episiotomy recovery and they were taught how to use it. They had to rub 0.5gr of the cream (in the size of knuckle) on the stitches after washing their hands and perineum so that it completely covers the surface of the wound and repeat it twice a day (every 12 hours) to ten days. Pain in the perineal area were evaluated immediately before the intervention (2 hours after perineal repair), 12 hours after the complete repair of episiotomy and on 1st, 7th, 10th days after delivery and also 14th day (if there was any moderate to severe pain on tenth day after birth).

Mothers completed short-form McGill Pain Questionnaire to assess episiotomy pain. The questionnaire consisted of three parts: sensory-emotional-verbal descriptions (in the range of

painless to severe pain), Visual Pain Scale (0-10 scores) and pain intensity (in the range of painless to severe pain). The total score of pain is equal to the total score obtained in almost all categories in different aspects of pain, which is in the range of 0-60 scores. Omitting variables of the study were evaluated on 7th, 10th, and 14th days after delivery.

Data were analyzed using SPSS Ver. 13. The normality of data were determined by using the Kolmogorov-Smirnov test. To compare the two groups in terms of quantitative variables with normal distribution, independent t-test in with non-normal distribution Mann-Whitney test was used. To compare the groups in terms of qualitative- ordinal variables, the Kruskal-Wallis test was used and for qualitative-nominal variables, Chi-square test was applied. To compare the quantitative variables changes in the two groups, repeated measures were used. $P < 0.05$ was considered significant.

Results

During the study (May- November 2013), 16 patients were excluded due to the elimination

criteria (7 patients in the control group and 9 in the intervention group due to not using the cream regularly, not referring and access to the researcher, infection and the need for suturing again). Finally, 98 patients completed the study (Figure 1).

The analysis was conducted on the 48 patients in the control group and 50 patients in the intervention group (per protocol or on treatment analysis). The difference between two groups was not statistically significant in terms of characteristics such as age, education, socioeconomic status, characteristics of pregnancy, doing strengthening exercises, pelvic floor muscle and other intervening variables during labor such as fatigue and hunger in the second stage of labor, disturbance in progress of the first stage of labor, duration of second and third stage of labor, the number of vaginal examinations for first and second stage of labor, fetal head position at birth, the interval time between injection of lidocaine and episiotomy incision, information about the baby weight, sex and height, pain during urinating and defecating, having constipation, antibiotics consumption, hygiene care, nutrition, physical activity in

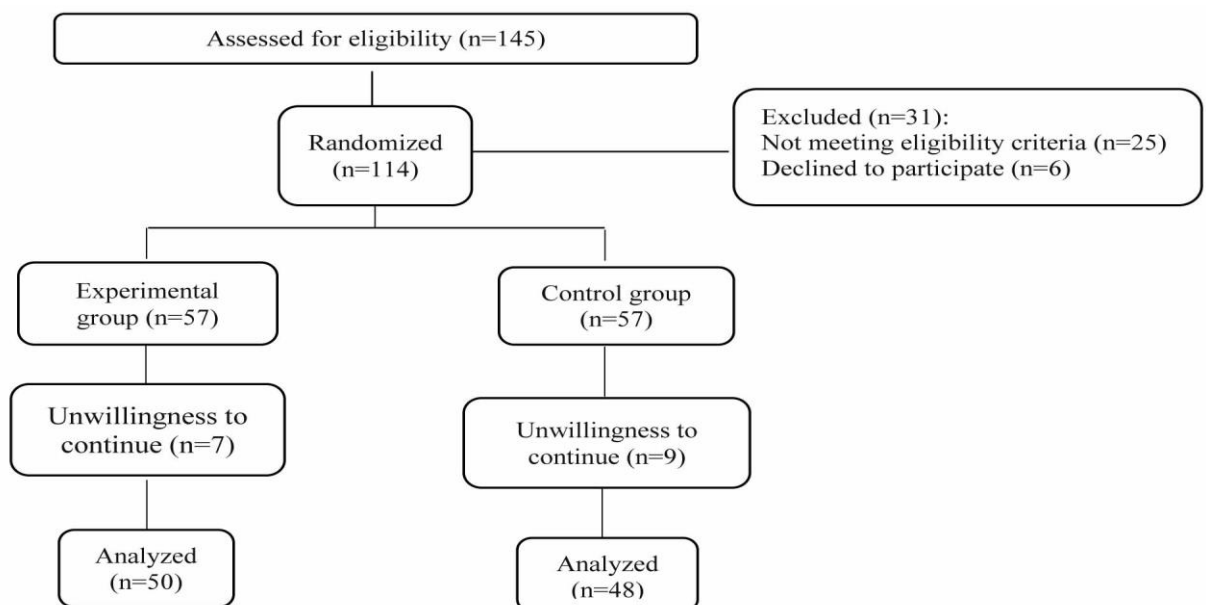


Figure 1. Flow chart of the study

the first and 10th days after delivery and other variables related to episiotomy ($P>0.05$) (Table 1).

Comparison of scores from 17 variables of McGill Pain Questionnaire before intervention ($P= 0.16$), 12 hours after episiotomy recovery ($P=0.38$) and the first day after delivery ($P=0.11$) using t-test showed that there was no significant difference between two groups, but episiotomy pain on the 7th day ($P=0.03$), the 10th day ($P=0.02$) and 14th days after delivery ($P=0.03$) were significant between two groups (Table 2). Comparison of mean scores of episiotomy pain between two groups using ANOVA with repeated measures indicated that the episiotomy pain intensity in patients treated with chamomile cream was decreased on the seventh day, tenth and fourteenth days after delivery compared to patients treated with placebo ($P=0.05$).

Mann-Whitney test showed that none of the sensory and affective components of pain before the intervention, 12 hours after episiotomy recovery, the first and fourteen days after delivery were significantly different in two groups ($P>0.05$), except irritant pain on the first day ($P=0.04$) and fourteenth day ($P=0.03$) and the sensitivity on the first day ($P=0.03$) and fourteenth day ($P=0.04$) had significant differences between the two groups.

Considering sensory components of episiotomy pain based on the Mann-Whitney test showed that irritant pain, being sensitive on the seventh and tenth day, heaviness feeling on seventh day and cramp pain on tenth day after delivery were significantly different in the two groups ($P<0.05$). Among emotional components, tormentor pain on the tenth day after delivery was significantly different between two groups ($P<0.05$).

In this study, the rate of using gelofen tablet, diclofenac, indomethacin and acetaminophen suppository was not significantly different between the two groups. But the amount of acetaminophen tablet was significantly lower in patients treated with chamomile cream than the placebo group ($P=0.001$). It appears that Chamomile cream decreases the need for sedative by reducing pain.

In present study, there was no report on side effects of using Chamomile cream and placebo cream among mothers in both experimental and control groups. Mothers satisfaction of using the cream on the seventh day after birth ($P=0.05$) was not significantly different between the two groups, however on the tenth day after the birth, mothers had more satisfaction about chamomile cream than placebo cream ($P=0.03$).

Table 1. Comparison of variables mean scores related to episiotomy in chamomile and placebo groups

Variable	Chamomile (n=50) Mean (SD)	Placebo (n=48) Mean (SD)	95% CI	P [€]
Length of skin incision(mm)	51.98 (6.40)	51.76(7.03)	2.45-2.89	0.87 [¥]
Length of vaginal incision(mm)	8.36(57.66)	55.94(9.64)	1.86-5.30	1.72 [¥]
Depth of episiotomy incision(mm)	17.40 (5.18)	17.28(5.95)	—	0.87
Duration of repairing episiotomy(min)	19.52 (6.28)	19.68(4.37)	1.98-2.30	0.88 [¥]
Number of stitches with yarn zero	10.66 (15.72)	7.66(2.58)	—	0.07
Number of stitches with yarn 2zero	11.34(2.23)	10.79(2.40)	—	0.71
Number of stitches of vagina	5.70(1.61)	5.84(1.34)	—	0.54
Number of stitches of muscle	1.92(1.35)	1.82(1.46)	0.45-0.65	0.72 [¥]
Number of sutures under the skin	5.16(1.05)	5.04(1.02)	—	0.35
Number of stitches on the skin	6.22 (0.58)	6.04(1.19)	—	0.10
Lidocaine dose used (ml)	4.46 (0.50)	4.30(0.46)	—	0.10

[€]Results of Mann-Whitney test, [¥]t- test was used

Table 2. Comparison of episiotomy pain scores between chamomile and placebo groups

Variable	Chamomile (n=50)	Placebo (n=48)	95% CI	P [†]
	Mean (SD)	Mean (SD)		
Pain before intervention	8.74 (5.96)	9.48(6.51)	0.73-4.21	0.16
Pain 12 hours after an episiotomy repair	11.9 (4.84)	12.46 (5.84)	1.37-2.89	0.38
Pain first day after birth	12.44 (5.27)	13.04(4.82)	0.40-3.60	0.11
Pain seventh day after birth	11.36 (5.04)	14.88 (7.34)	0.13-4.90	0.03
Pain tenth day after birth	7.10 (4.10)	9.96 (4.81)	0.42-6.16	0.02
Pain fourteen day after birth	4.44 (3.43)	7.41(4.92)	0.02-3.57	0.03

[†]t- test was used.

Discussion

The results of this study indicated that the using chamomile cream has not reduced pain 12 hours after episiotomy recovery ($P=0.38$) and also on the first day after birth. Qnais showed that chamomile extract at a dose of 100, 200 and 300 mg/kg has dose-dependent analgesic effect.²⁶ The prevalence and the rate of pain reported more in the first few days after birth. Khajavi et al., showed that perineal pain were 96.4%, 63%, 25% and 12% in the first, tenth and fortieth and ninetieth day after birth, respectively.⁵ Also, Macarthur et al., in the University of Toronto in Canada reported perineal pain 97% during 24 hours after delivery,¹⁰ which is similar to Khajavi et al.⁵ In the present study, 98% of patients complained perineal pain in the first 24 hours after delivery ranging from 5-49 by McGill pain questionnaire which is similar to the other studies.^{5,10} Thus, it seems that patients require more analgesic drugs within the first day after birth. Regarding to the dose-dependent analgesic effect of chamomile, it seems that the dose used in this study for analgesic in the first 12 hours and the first day after birth was less than the needed dose. The results of this study are coordinated with Pazandeh's et al., study these authors, reported that chamomile essence has not reduced episiotomy pain in the first 12 hours after delivery.¹⁶

The findings of this study showed that the use of chamomile cream was effective for pain relief on seventh ($P=0.03$), tenth ($P=0.02$) and fourteen days ($P=0.03$) after delivery. The mean pain score in seventh

and tenth days after delivery in the placebo group versus chamomile group was 1.3 (the pain score on the seventh day in chamomile group was 11.36 (5.04) versus 14.88 (7.34) in control group and on the tenth day after delivery in chamomile group was 7.10 (4.10) versus 9.96 (4.81). The mean pain score on the fourteen day in placebo group versus chamomile group was 1.7. In present study, chamomile may be effective through several mechanisms (opioidergic, serotonergic, anti-inflammatory) in analgesia. As a result, several studies have raised the possibility of analgesic effect of chamomile through opioidergic.^{23, 26-28}

In this regard, Mohebbali et al., showed that Chamomile in both phases of the Formalin test has analgesic effect on mice. In the first phase, its analgesic effect is caused by mechanisms in the central nervous system. The second phase of the formalin test is partly due to the inflammation process.²⁷ there are some evidences that shows extract effect is somewhat similar to receptor antagonists of serotonergic in reducing pain; of course, the extent of this effect and its similarity depends on the amount of Germacranolide and Parthenolide in the extract. Therefore, it is possible that part of the nociceptive is applied through serotonergic system.²³

The anti-inflammatory effect of Chamomile essence is due to inhibitory effect of Chamomile essences especially Bisabolol and Chamazulene on Cyclooxygenase and Lipooxygenase enzymes.²⁷

According to the reports, acquired lakton from Chamomile contains Epoxyartemurin and Partenolid which have preventing

effects on creating components resulting in Arachidonic Acid that is Thromboxane B2 and Leukotriene.¹⁵ Epigenin in the extract has analgesic effect and also has interference with the body's Histamine system and cause reversible inhibition and dose-dependent inflammation of the skin.²⁶

Pain, warmth, redness, swelling and loss of function are some local signs of inflammation.²⁹ In the present study, it seems that chamomile, because of its strong anti-inflammatory properties, has relieved episiotomy pain by reducing pain mediators in the inflammatory part and reducing inflammatory Prostaglandins and due to its anti-inflammatory property resulting from Azulene, Chamazulene, Alpha Bisabolol essence¹⁵ by reducing swelling and inflammation in the first days after birth. Modarres et al., showed that the severity of menstrual pain was significantly lower in the group taking Chamomile capsules than the group taking Mefenamic acid capsules two days after using drugs in the first month of treatment ($P < 0.001$) and the second month of treatment ($P < 0.001$).

These results confirmed that analgesic effect of chamomile is aligned.³⁰ In Charousaei's & Dabirian study stoma symptoms (pain, itching) was removed in group, which used Chamomile compresses twice a day, more than the group using Hydrocortisone 1% cream.¹⁷ Confirming the analgesic effect of aromatherapy with chamomile, Lim & Lee showed that inhalation aromatherapy for ten minutes after tonsillectomy, with a mixture of Lavender and Chamomile oil in the ratio 1:2, reduces the amount of perceived pain, systolic and diastolic blood pressure and the heart beating.³¹

Pazandeh et al., used Chamomile essence produced by steam distillation method to reduce episiotomy pain; participants poured 3 drops of Chamomile essence in two liters of warm water and used it 2 times a day for 20 minutes during 2 weeks as aromatherapy while sitting in bath. The result showed that Chamomile essence has

not lessened episiotomy pain in the first 12 hours after birth and in 7th and 14th days after birth,¹⁶ which is not consistent with the results of the present study. This difference could be related to the differences in the type, quality and quantity of the prescribed herbal medication.

McGill pain tools describe pain in 3 dimensions: sensory, emotional and evaluative. Based on our results, irritant pain and sensitivity 24 hours after labor and on the seventh, tenth and fourteenth days after delivery, feeling of heaviness on the seventh day and cramp pain on the tenth day was significantly lower in mothers using Chamomile cream than ones using the placebo cream. In the present study, Chamomile may lead to reduction in sensitivity and cramp pain and heaviness feeling through softening and moisturizing wound skin, as well as its anti-inflammatory effects resulting from α -bisabolol and chamazulene essence and its anti-spasmodic effect resulting from flavonoids and comarin.¹⁵ Sahba and Mohammadalipour found that Chamomile mouth wash reduces the needed time for controlling pain and irritant feeling,²² that is in line with the results of the present study.

In traditional books, consuming Chamomile products as external use has been also recommended for softening necrosis and granulated tissue (rigid tissue), swelling, inflammation, ulcer guard and skin rash.^{32,33} Chamomile is also a key ingredient in creams used to treat eczema²¹ and used as an emollient for hairs.³²

The limitations of this study were as follows: individual and genetic differences, impossibility of monitoring the use of creams and observing personal hygiene. Although it was attempted to control them by providing similar training and giving pamphlets to mothers.

It is recommended to evaluate the effect of Chamomile with more doses on reduction of episiotomy pain on the first day after delivery as well as the effect of Chamomile cream prepared by the soxhlet

method comparing to the Percolated method.

Conclusion

This study confirms analgesic and anti-inflammatory effect of this plant which has been reported in traditional medicine text books. Since Chamomile cream reduces episiotomy pain and no significant side effect has been reported by mothers, and also because in recent years the tendency of people to use herbal medicine has been increased, Chamomile cream could be used as a pain killer of episiotomy in primiparous women to improve the quality of obstetric services.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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