Investigating the effect of Primrose Capsule (Primula Flower Oil) on cervix preparation and commencement of child delivery pains

Investigación del efecto de Primrose Capsule (Primula Flower Oil) en la preparación del cérvix y el comienzo de los dolores de parto infantil

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Abstract

Introduction: Oenothera biennis (primrose) oil is one of the most common herbal medicines used for preparing cervix but its effectiveness is yet to be proved. There are limited articles on the effectiveness of this medicine in inducing delivery. The present study was designed and conducted with the objective of investigating the effectiveness of vaginal administering of evening primrose in inducing delivery.

Study Method: the present study is a triple blind case-evidence clinical trial. Out of the individuals featuring the required qualifications for entering the study, 160 were randomly selected and assigned into two equal groups. Following the acquisition of the consent letter, the participants were subjected to clinical examinations. Their preliminary information was recorded. Then, two soft primrose capsules were placed in the posterior choledosac of the intervention group participants. Placebo capsules were used in control group. Next, the patients were asked to leave a contact number for the future required follow-ups in terms of the delivery pain commencement and labor duration and delivery time. In the end, the collected information was analyzed using SPSS.

Result: based on the analyses, the two groups were not found significantly different in terms of the demographic data. Moreover, no significant difference was observed in terms of the interval between the primrose administration and delivery pain initiation (T1) and the interval between primrose use till delivery (T2) as compared to the control group (P>0.05).

Discussion: it seems that the vaginal application of primrose capsule is not effective in cervix preparation. However, there is a need for further research in this area. The current studies on the effectiveness of the evening primrose is limited to two researchers that have also found results consistent with what has been found here and two other studies with results not in accordance with the current paper's findings. More comparative studies seem to be useful in this regard.

Keywords: cervix preparation, primrose (primula), delivery induction.

Resumen

Introducción: El aceite de Oenothera biennis (onagra) es una de las hierbas medicinales más comunes que se utilizan para preparar el cuello uterino, pero su efectividad aún no se ha demostrado. Hay artículos limitados sobre la efectividad de este medicamento para inducir el parto. El presente estudio fue diseñado y realizado con el objetivo de investigar la efectividad de la administración vaginal de onagra para inducir el parto.

Método de estudio: el presente estudio es un ensayo clínico de prueba de casos triple ciego. De los individuos con las calificaciones requeridas para ingresar al estudio, 160 fueron seleccionados al azar y asignados en dos grupos iguales. Tras la adquisición de la carta de consentimiento, los participantes fueron sometidos a exámenes clínicos. Su información preliminar fue registrada. Luego, se colocaron dos cápsulas de prímula suave en el coledosac posterior de los participantes del grupo de intervención. Se utilizaron cápsulas de placebo en el grupo control. A continuación, se les pidió a los pacientes que dejaran un número de contacto para las futuras actividades de seguimiento requeridas en cuanto al comienzo del parto, la duración del parto y el tiempo de parto. Al final, la información recolectada fue analizada utilizando SPSS.

Resultado: según los análisis, los dos grupos no se encontraron significativamente diferentes en cuanto a los datos demográficos. Además, no se observó una diferencia significativa en términos del intervalo entre la administración de onagra y el inicio del dolor en el parto (T1) y el

intervalo entre el uso de la primavera hasta el parto (T2) en comparación con el grupo de control (P> 0,05).

Discusión: parece que la aplicación vaginal de la cápsula de onagra no es efectiva en la preparación del cuello uterino. Sin embargo, hay una necesidad de investigación adicional en esta área. Los estudios actuales sobre la efectividad de la onagra se limitan a dos investigadores que también encontraron resultados consistentes con lo que se ha encontrado aquí y otros dos estudios con resultados que no están de acuerdo con los hallazgos del presente documento. Más estudios comparativos parecen ser útiles en este sentido.

Palabras clave: Preparación del cuello uterino, prímula, inducción del parto.

Introduction

Delivery induction is one of the common clinical cases with a prevalence rate between 10% and 30%. Cervix readiness is one of the important conditions before delivery induction in such a way that it is estimated that normal delivery does not occur in the absence of ready cervix [1]. The most common method for cervix preparation is Bishop's scoring system (Bishop Score). The time to vaginal delivery is in an inverse relationship with Bishop's score. This scoring system includes five items, namely dilation, effacement, fetus head's position, cervix's consistency and state. Scores above six indicate the vaginal delivery likelihood and scores below six are reflective of the reduction in the natural delivery success[1].

Various methods have been suggested for cervix preparation. Amongst the nonmedicinal methods, the sexual intercourse, stimulation of nipples, nervous stimulation of the skin, hot water bath, enema, acupuncture, herbal medicines, castor oil, mechanical methods and surgery can be pointed out. There are different drugs for preparing cervix. Amongst the available drugs, as well, prostaglandins, including misoprostol, can be pointed out[1]. The use of natural processes during pregnancy is one of the notable issues should be researched further[3].The prevalence of using plant byproducts in pregnancy has been estimated up to 55% and this amount depends on the geographical region and ethnic cultures[4]. Based on the estimations in the US, between 45% and 95% of the obstetricians recommend plant-based and natural products during pregnancy. In between, evening primrose, castor oil, black cohosh and blue cohosh are more frequently prescribed[5].

Evening primrose is one of the most common herbal medicines prescribed for cervix preparation but its effectiveness has not yet been proved. It seems that the use of evening primrose during pregnancy has not been prohibited. In some studies, this oil has been used as a supplement[6], and it has been stated that it might ease the delivery process for the mothers.

Evening primrose is a biennial and wild plant with yellow flowers that grows in the north and south of the US and Europe. The plant is used for treating systemic diseases caused by inflammation (like atopic dermatitis and rheumatoid arthritis, breast pain, menopausal symptoms and pre-menopausal signs[7]. The oil of this plant is one of the most common herbal medicines used for cervix preparation but its effectiveness is yet to be proved[8]. Primrose capsule contains the oil of evening primrose[9]. And it is made from the seeds of this plant and linoleic acid accounts for the greatest quotient of its ingredients (60-65%).

In the end, according to the studies performed up to now, there is a scarcity of research about the effectiveness of evening primrose oil in delivery induction and, additionally, its vaginal use has not been so far examined. Besides reducing the systemic effects, the vaginal out-patient administering of this drug can induce delivery as a noninvasive, cheap and available method with few side effects. According to the aforementioned materials, the present study deals with the investigation of vaginal administering of this product in cervix preparation in pregnancy termination candidates in their week 37 of gestation.

Materials and methods

The present study was carried out on pregnant women in their week 37 of gestation (based on LMP or sonography of the first trimester of pregnancy). These women were pregnancy termination candidates and had referred to the emergency unit of Karaj's Kamali educational-treatment center during 2019. Sampling was conducted based on convenience method. The study sample volume was computed based on the (formula 1) for comparing two means F:

$$n = \frac{2(2_{1-\frac{\alpha}{2}}+2_{1-\beta})^2\ \delta^2}{d^2} \qquad (1)$$

With α=0.05 (type I error), β=0.2 (type II error, variance=9 and d=4 based on a review of the related texts. According to this, 80 pregnant women were randomly selected as the case group (group A) and 80 women were randomly selected as control group (group B) by picking previously coded packets and allowed to enter the study after offering a written consent.

The study inclusion criteria were as follows: the generally good status of the mother, absence of any hospitalization indicator except pregnancy termination, Bishop Score below 4 during examination, no need for emergency delivery, mother's ability of quick presence in the treatment center and the individuals with the foresaid conditions

who did not want to participate in the study for any reason were put aside.

After acquiring the mood self-reports, vaginal palpation was carried out and the demographic forms were completed. Sampling was conducted by two obstetricians who had found identical examination results during vaginal palpation. Following the examinations, two soft evening primrose capsules (1000 mg) were placed inside the posterior choledosac of the case group participants and two soft placebo capsules (similar in shape and size to primrose capsules) were placed in the posterior choledosac of the control group participants by the obstetricians and the participants were asked to leave a contact number for future follow-ups in regard of the commencement of the delivery pains and delivery time. The collected information was analyzed using Chi-square and t-tests in SPSS. To render the study blond, the obstetricians and the patients as well as the statistical analysts were kept unware of the placebo or drug application on the participants.

Results: Based on the performed studies, the two groups were found not significantly different in terms of mother's age (P\0.589), number of pregnancies (P=0.905), number of deliveries (P=0.898), infant's weight (P=0.989) and Bishop Score 9P=0.996), gestation age (P=0.332), education level (P=0.744), first minute Apgar (P=0.941), infant's gender (P=0.800) and background diseases (P=0.440). These findings can be seen in (Table 1).

The study findings are indicative of the idea that the participants did not significantly differ in terms of T1 (the interval between primrose use and delivery pain commencement) and T2 (the interval between primrose use till delivery). Furthermore, 79 individuals from the case group and 80 individuals in the evidence group were found with no background diseases. Also, no significant difference was documented between the groups' participants in terms of background diseases in Fisher's test (P=0.440).

Table 1: demographic information of the two groups

Mother's age	72	26.4722
	80	26.9625
Bishop Score	79	0.9747
	82	0.9756
Fetus weight	75	2.8893
	78	2.8897
Gestation age	78	275.81
	82	274.79
Number of pregnancies	78	1.8333
	82	1.8537
Number of deliveries	77	0.6753
	82	0.6585

The mean time spans between capsule use till pain initiation (T1) are 19.06 and 13.4 hours in the case evidence groups, respectively, and the mean time intervals between the capsule use till delivery (T2) are 73.83 and 60.68 hours, respectively (table 2). Based on Fisher's exact test, there was found no significant difference between T1 in the case group and T2 in the control group (P=0.168). In addition, no significant difference was evidenced between the case and control groups' participants in terms of T2 (P=0.150).

Table 2: Comparison between onset of contractions and delivery in two groups

Group	Number	Mean	Std. deviation	Std. error
A T1	80	19.06	34.245	3.829
A T1	82	13.41	13.459	1.496
B T2	80	73.83	65.657	7.341
B T2	82	60.68	45.624	5.038

Discussion

The present study is a clinical case-evidence double blind research conducted on 162 individuals qualified for entering the study (80 individuals in intervention group and 82 individuals in the control group). The study goal was investigating the effectiveness of evening primrose capsule in cervix preparation and initiation of delivery pains. In the present study, the two groups were rendered identical in terms of the fetal variables, mother's age, and the mother's BMI, fetus weight, number of pregnancies and number of deliveries as well as education level, score, Bishop Score and fetal gender and the influential background diseases.

Behrashi his colleague showed that numerous factors such as fetus weight at birth and optimality of cervix status influence labor induction[10]. In the study by Dove et al and Jahdi and others, as well, the basic information was similar to the present study's data and the homogenization was conducted for the purpose of increasing the generalization power[12]. In various studies, paradoxical results have been reported for the use of medicinal herbs and induction success. In the study by Gholami et al, the initiation time of the delivery signs in the group that had received capsules containing chamomile was significantly lower than the group treated with drugs; additionally, delivery signs were recorded in a larger number of the case group's participants within a week following the initiation of chamomile capsule use[13].

In the study by Mohammadini et al, no significant difference was observed between the group treated with hedge-mustard seeds and the control group in terms of the spontaneous commencement of the delivery pains[14]. Moreover, in the study by Turk Zahrani, receiving wild rue smoke twice a day significantly increased cervix preparation and the results were found indicating a significant difference in terms of the delivery initiation time and the duration of the first and the second stages of delivery between the intervention and control groups[15]. There is a

scarcity of research on the present study's goal and none of the studies have dealt with the vaginal use of this oil for softening the cervix for advancing the labor[16]. In another study, Bishop Score's variations were found significantly larger in the intervention group treated with evening primrose oil than the control group[17].

Evening primrose oil features prostaglandin effects[11]. The most important components of the oil are linoleic acid and gamma-linoleic acid that is a natural precursor of prostaglandins[18].

Various studies showed that the use of evening primrose causes significant increase in gamma linoleic acid in the blood[19].

Due to prostaglandin properties of evening primrose oil that is used in line with preparing cervix and initiation of delivery pain, the study that was conducted for investigating the effect of oral use of western primula on Bishop Score and cervix length in Filipino women, a significant relationship was found between the intervention and control groups' participants in terms of the changes in Bishop Score and cervix length[20].

Furthermore, in the study by Vahdat et al who investigated the effect of western primula flower's oil on the softening of cervix in hysteroscopy candidates with no past record of normal delivery[21], the total time of the cervix dilation duration was shorter[22]. The aforesaid studies' results are consistent with the present research's findings.

In the study by Jahdi et al, the difference in Bishop Score was not significant between the intervention and control groups[23]. In the study by Bazrafcan et al who examined the effect of the oral use of primula flower oil on the pregnancy duration and gestation outcomes, no significant difference was observed between the intervention and control groups' participants. The results of the two foresaid studies are consistent with the present research's findings[9].

Conclusions

The reason for the paradoxical results in various studies might be the differences in the intervention type, study method and sampling styles. In the current research paper, no side effect of using evening primrose ointment was evidenced. In the study by Esmaeilzadeh et al, as well, the use of evening primrose was found accompanied by such side effects as extreme increase in uterus contractions and the subsequent increase in the risk of the membrane rupture. The reason for this problem could be the use of higher dosages for longer periods of time. So, according to the study constraints regarding the amount and the duration of ointment use as well as considering the scarcity of the studies conducted in this regard and also bearing witness to the paradoxical results of the various studies, doing further research including comparative examinations using various plants and herbs is recommended.

Acknowledgement: Researcher apperciated clinical research development center of Kamali hospital in Alborz University of medical science.

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