

The Effect of Alcea Angulata in Combination with Honey for Cervical Ripening in Nulliparous Women: A Randomized Controlled Trial

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ABSTRACT

Background & Objective: Oral consumption of Alcea Angulata species, which contains tannins, calcium, and carbohydrates, can induce contractions and facilitate childbirth during uncomplicated pregnancies. The present study was conducted with aim to assess the effect of Alcea Angulata in combination with honey for cervical ripening in nulliparous women.

Materials & Methods: This randomized controlled trial study was conducted on 80 nulliparous women at 39 weeks of gestation who were divided into two groups: the intervention group received Alcea Angulata powder and honey (n=40), and the control group received no intervention (n=40). Outcomes were measured from the start of the intervention to delivery, including the interval from intervention to delivery, Bishop score, mode of delivery, delivery complications, Apgar scores at 1st and 5th minutes, need for neonatal resuscitation, and presence of meconium-stained amniotic fluid. Bishop score and stripping score were also monitored weekly until 40th week of pregnancy and on days 2, 4, and 6 post-due date if no delivery occurred.

Results: The mean scores of the interval between first intervention and delivery time were 131.3 ± 77.8 and 132.1 ± 107.3 h in the intervention and control groups, respectively ($P=0.633$). Moreover, the two groups did not significantly differ regarding 1-minute Apgar score ($P=0.197$), 5-minute Apgar score ($P=0.429$), need for neonatal resuscitation ($P=0.099$), and meconium-stained amniotic fluid ($P=0.099$).

Conclusion: The use of Alcea Angulata with honey did not significantly affect the time between intervention and delivery. It also showed no significant negative neonatal outcomes, suggesting the safety of the intervention.

Keywords: Alcea angulata, Honey, Cervical ripening, Persian medicine, Randomized controlled trial



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1. Introduction

In vaginal delivery, the neonate is born through the vagina by uterine contractions. These contractions during the 40-37 weeks of pregnancy help the cervix to dilate and facilitate the process of giving birth (1). However, since the cervix plays an essential role in labor induction, more than 20% of pregnant women require induction, and more than 50% need intervention to reach the cervix (2). Cervical preparation methods have recently reduced cesarean section rates; oxytocin has been the most frequently used medication for labor induction (3).

Pharmacological and non-pharmacological methods have been used to prepare the cervix and induce labor (4), with oxytocin being the most common factor and prostaglandins being another drug currently used for cervix and labor induction (5). Nevertheless, these medicines can cause diarrhea, nausea, vomiting, headaches, and other side effects; moreover, prostaglandins are expensive and rare products that are not easily available (6).

The complementary medicine methods have been used in the management of easy delivery for many years. Among these therapies, medicinal plants have played a significant role in the health of women during pregnancy and childbirth (7). Complementary and alternative medicine has little side effects and pregnant women may consider them the best treatment for pregnancy-related problems (8). Complimentary and alternative medicine is also used by individuals who want to take control of their own health, who are dissatisfied with conventional treatment and are concerned about the side effects of chemical drugs. A combination of conventional medicine, complementary medicine, and herbal products appears to be more effective than the mere use of conventional medicine for pregnancy-related issues (9).

Alcea Angulata is a member of the Malvaceae family believed to have originated in Asia and Europe. It has been used therapeutically since ancient times as herbal medicine in the Middle East. *Alcea Angulata* relieves skin irritations, inflammation, severe coughs, angina, bronchitis, inflammatory diseases, kidney stones, constipation, and colic (10). *Alcea Angulata* which can be consumed as food, contains polyphenols, polysaccharides, mucins, anthocyanins, fibers, and polysaccharides, which act as antioxidants and scavengers of free radicals. Also, it contains tannins, calcium, and carbohydrates that can cause contractions and facilitate childbirth (11). Research has been conducted on the application of *Alcea Angulata* in the treatment of vaginal atrophy among postmenopausal women and the findings indicated a notable enhancement in the symptoms of vaginal atrophy (12). Jean et al., employed Marshmallow (*Alcea*) as a therapeutic strategy to alleviate the symptoms of vaginal atrophy (13).

All over the world, honey is used for its unique biotherapeutic properties, including anti-inflammatory, antioxidant, and anticancer properties, restorative functions, as well as substantial benefits to the cardiovascular system, nervous system, and reproductive system. Honey includes more than 200 nutrients and medicinal compounds, such as carbohydrates, proteins, vitamins, enzymes, and phenolic compounds (14). Some studies reported that honey, as a rich source of glucose, was found to be beneficial to the progress of labor (15,16). According to Persian traditional medicine texts, such as the Book of Exir-e Azam, *Alcea rosea* and honey are effective in facilitating childbirth (17).

Honey has been shown to facilitate childbirth. Also, honey syrup, date honey syrup and honey saffron syrup have been proven to have no complications (18-20). They also concluded that the oral consumption of honey syrup during labor increases labor progress. Uterine muscle contractions during childbirth require a rich source of glucose, which can be an effective source of carbohydrates and a substitute for glucose (18). *Alcea Angulata* contain a chain of oligosaccharides

connected to amino acids and a combination of colloidal polysaccharides, which have softening and anti-inflammatory properties, and as a result, cause ripening of the cervix and keep the uterine mucosa moist. The Medicinal Plant Research Center introduced the oral consumption of *Alcea Angulata* species, such as *Alcea* and *Altaya*, during uncomplicated pregnancies (21). However, no research has been conducted on the effect of the marshmallow plant in facilitating childbirth. Considering that childbirth facilitation methods can reduce the burden of unnecessary cesarean sections and improve women's health, the methods presented in Iranian traditional medicine books are simple and accessible. They likely do not have the side effects of common pharmaceutical treatments. This study was conducted with aim to investigate the effectiveness of *Alcea Angulata* in combination with honey in facilitating childbirth in primiparous women.

2. Materials and Methods

This randomized controlled trial study included 80 nulliparous women selected via the simple sampling method from those who were referred to Ghaem and Ommolbanin Hospitals in Mashhad, Iran, from 22 November 2018 to 14 May 2019. The sample size was determined according to a similar study (22) and based on the opinion of a gynecologist, a minimum difference of three points in the Bishop score. Using the formula for a two-mean test in two independent communities with an alpha of 0.05 and a beta of 2.0, the minimum number of participants needed in each group was determined to be 35. However, taking into account a 10% attrition rate, this number was increased to 40 participants per group.

The study was initially explained to patients, and they signed an informed consent form. The participants were then assigned to two groups: control and intervention. The control group received routine stripping protocol, while the intervention group received a combination of *Alcea Angulata* powder and honey, along with routine stripping protocol.

Nulliparous women aged 18-40 with a singleton pregnancy at 39 weeks gestational age (based on ultrasound in the first trimester) were screened at the time of enrollment in the delivery program. The inclusion criteria were: healthy fetus, cephalic appearance, normal amniotic fluid volume, absence of maternal medical and underlying chronic diseases, as well as obstetric problems, bishop score less than six on vaginal examination, closed amniotic sac, non-reactive Nonstress Test (NST), no uterine contractions, no history of smoking, not using any other herbal medicine by the mother, and non-use of alcohol or drug. Complications, such as nausea, forgetting to take the drug three times, as well as indications for emergency vaginal and cesarean deliveries, were regarded as the exclusion criteria.

Alcea Angulata was standardized based on the phenolic compounds in Alcea Angulata extract. It was powdered and soaked in 70% ethanol (100 mL) for three days at 40°C with occasional shaking and was centrifuged in order to remove sediment particles from the extract. Supernatants were collected and dried at 40°C. As a standard, a 20 µL of 10 mg/mL solution of dried extract or 20 µL of 50-500 mg/L solutions of gallic acid was mixed with 100 µL of Folin-Ciocalteu reagent and 300 µL of sodium carbonate solution (1 mol/L). The volume of the mixture was adjusted to 2 mL by the addition of deionized water. A spectrometer was used to measure the absorbance at 765 nm after 2 h. A standard curve was drawn for gallic acid, and the phenolic content was expressed as milligrams of gallic acid equivalents (10). Considering that no clinical trial has been conducted to facilitate childbirth, the selected dose of the drug was used in rabbits (400-800 mg of extract per kilogram of body weight) (23). According to the fact that 10 gr was mentioned as safe and there were no complications in rabbits (24), we chose a dose of 4 grams of the plant. It was possible to prescribe 25-50 gr per day, but due to pregnancy, the minimum possible dose was tested for several patients in the office, and no complications were reported; However, The consumption of 5 gr is mentioned without hindrance, but since the study group was pregnant women, we considered a lower dose of 4 gr.

A total of 40 participants were enrolled in each group by assuming a Bishop Cervix score, more than 4 or less than 7 or more with a significance level of 5% and a power of 80%.

The intervention group received 2 gr of Alcea Angulata powder and 12 gr of honey orally, dissolved in 100 cc of water at 60 degrees Celsius. This was divided into two doses per day, along with routine pregnancy stripping, for a week until the onset of labor pains. Only routine pregnancy stripping was administered to the control group. In the first visit, the score of cervical Bishop (Dilation, Effacement, Station, Cervical Consistency, Position of Cervix) was estimated for all participants. In the intervention group, membrane stripping was performed during a vaginal examination. Stripping was performed on a weekly basis until the 40th week of pregnancy and then at 40 weeks and 2 days, then 40 weeks and 4 days, and finally at 40 weeks and 6 days, however if no delivery was performed in both groups. Vaginal examinations were performed in each center by an experienced midwife.

Based on the data on the related participants, interventions to deliver interval (days) were regarded as the primary outcome. Moreover, maternal outcomes (Bishop score, mode of delivery, complications of delivery, interventions during delivery, and time variables related to the delivery process) were considered as the secondary outcomes. In addition, Apgar scores in the 1st and 5th minutes, the need for neonatal resuscitation, meconium-stained amniotic

fluid, and the quality of life were deemed as the secondary outcomes. The Bishop score and the stripping score were determined weekly until the 40th week of pregnancy, as well as 2, 4, and 6 days after that in case of no delivery in both groups. The side effects of the drug were recorded.

The data were analyzed using SPSS software (version 16.0) (SPSS, Inc. Chicago, IL, USA). The descriptive data were summarized as mean±SD and percentage. Data normality was checked prior to data analysis using the One-Sample Kolmogorov-Smirnov Test. The student's t-test, Mann-Whitney U test, and chi-square were employed to analyze the data. The outcome was compared using Friedman or repeated measures ANOVA. $P < 0.05$ was considered statistically significant.

3. Results

Out of 100 participants included in this study, 83 women were randomly assigned to two groups based on inclusion criteria. In addition, three patients were excluded from the intervention group and finally, 80 patients were analyzed (Figure 1).

The mean age of pregnant mothers were 21.5 ± 3.5 and 24.6 ± 5.2 years in the intervention and control groups, respectively, signifying that the women in the intervention group were younger than the control group ($P = 0.01$). The mean gestational age based on first-trimester ultrasound, Bishop score, mother's educational level, history of hypertension, frequency of membrane stripping, and history of diabetes had no statistically significant difference between the two study groups ($P > 0.05$).

The causes for hospitalization of pregnant mothers (contraction, bleeding, premature rupture of membranes, age more than 41 weeks of pregnancy, decreased fetal movements, disturbed Biophysical Profile (BPP), and non-reactive NST) showed no statistically significant difference between the two groups ($P < 0.05$). The results of Fisher's exact test revealed no statistically significant difference between the two groups in terms of the type of interventions performed during the delivery process and the rate of cesarean section ($P = 0.934$). Table 1 presents the demographic and clinical profiles of the study groups.

Table 2 illustrates the mean time between the first visit of the mothers and the time of delivery in both groups. The mean scores of the time interval between the first intervention and delivery time of mothers were obtained at 131.3 ± 77.8 and 132.1 ± 107.3 h for intervention and control groups, respectively. This time interval was longer in the control group; nonetheless, the difference was not statistically significant ($P = 0.633$). The time interval between hospitalization and delivery in the intervention group was significantly less than that in the control group ($P = 0.012$). However, based on the analysis of covariance (ANCOVA), by controlling age and removing the confounding effect of

this variable, the interval between hospitalization and the start of the delivery was not significantly different between the two groups ($P=0.053$).

The results of the Mann-Whitney test indicated no statistically significant difference between the two

groups in terms of 1-minute Apgar score, 5-minute Apgar score, the need for neonatal resuscitation, and meconium-stained amniotic fluid. The neonates born to women in both groups did not suffer from neonatal infections, such as sepsis ([Table 3](#)).

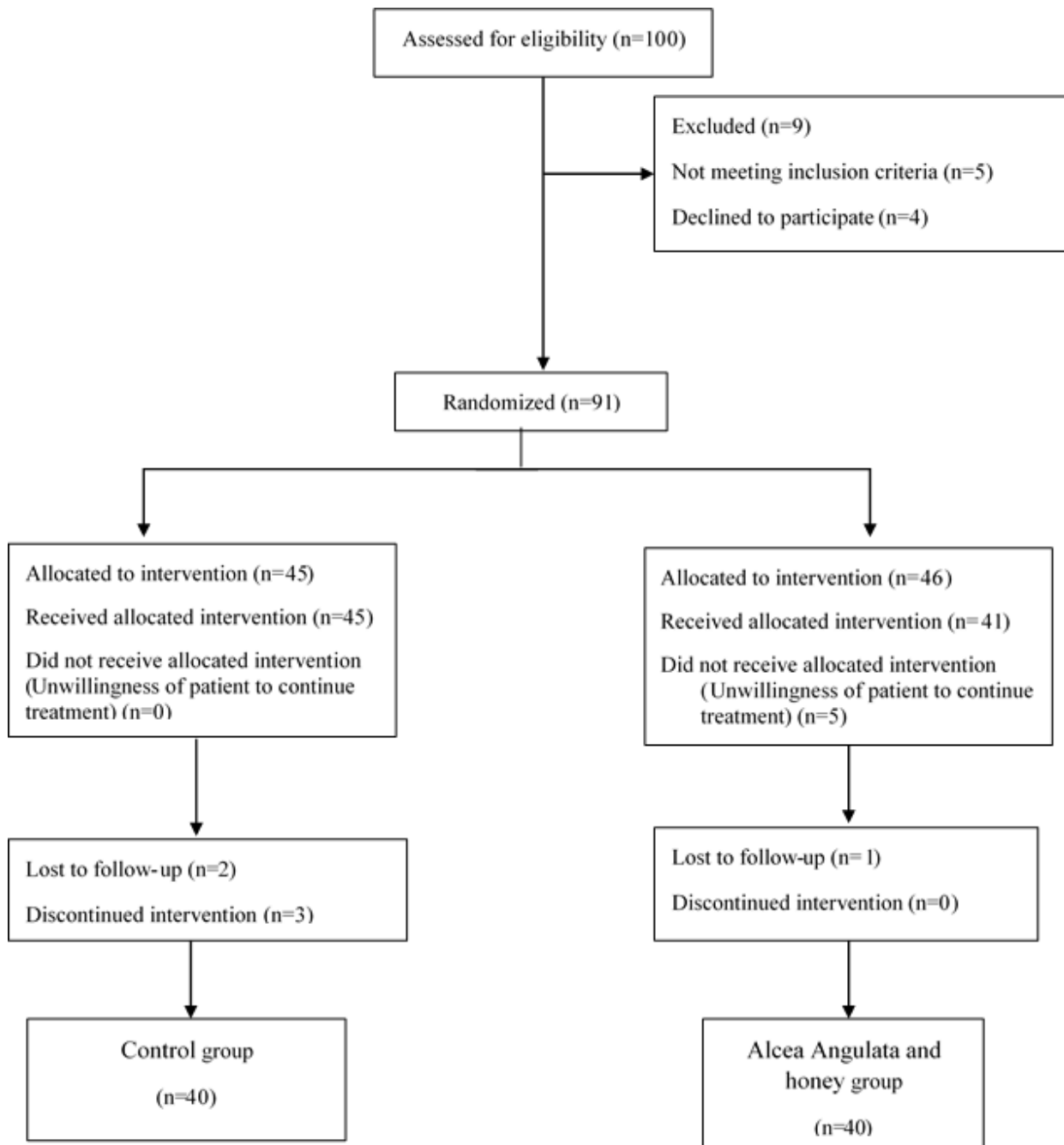


Figure 1. Flow Diagram of the Patients

Table 1. Distribution of demographic and clinical profiles of pregnant women studied in two intervention and control groups

Variables	Intervention group	Control group	P-value*
Age of mother (years) (mean±SD)	21.5±3.5	24.6±5.2	0.01
Gestational age based on first-trimester ultrasound (mean±SD)	39.1±0.7	39.2±0.7	0.367
Bishop's score (mean±SD)	1.5±0.7	2.3±1.9	0.257
Educational level			
<High school n (%)	19(63.3)	17(42.5)	0.132
High school and Bachelor's degree n (%)	11(36.7)	21(52.5)	
≥ Master's degree n (%)	0(0)	2(5.0)	
History of underlying disease			
Diabetes n (%)	0(0)	1(2.5)	0.668
Hypertension n (%)	1(3.4)	0	
Frequency of membrane sweeping (during intervention) (mean±SD)	1.6±0.7	2.2±1.2	
No n (%)	28(96.6)	39(97.5)	0.696
Gestational age based on LMP (mean±SD)	39.0±0.6	39.0±0.5	0.898
Interventions during childbirth			
Extra dose of Misoprostol (n; %)	4(8.9)	3(6.7)	0.934
Oxytocin n (%)	8(17.8)	5(6.7)	
No n (%)	33(73.3)	26(11.1)	
Final delivery method			
Cesarean section n (%)	11(24.4)	6(8.9)	0.421
Vaginal n (%)	34(75.5)	31(75.5)	

Table 2. Time interval variables related to the delivery process in the two groups

Variables	Intervention group	Control group	P-value*
Interval between the first visit and delivery (hours) (mean±SD)	131.3±77.8	132.1±107.3	0.633
Interval between hospitalization and delivery (hours) (mean±SD)	3.0±3.2	4.4±2.3	0.012
Duration of stage 2 (hours) (mean±SD)	0.8±0.6	0.9±0.6	0.321

* Mann-Whitney test was used to compare the two groups.

Table 3. Outcomes of neonates born in two intervention and control groups

Variables	Intervention group	Control group	P-value*
1-minute Apgar score (mean±SD)	8.5±1.4	9.0±0.2	0.197
5-minute Apgar score (mean±SD)	9.9±0.6	9.9±0.2	0.429
Need for neonatal resuscitation			
Yes n(%)	1(3.3)	0	0.99
No n(%)	29(96.7)	37(100)	
Meconial amniotic fluid			
Yes n(%)	1(6.7)	2(5.4)	0.99
No n(%)	29(93.3)	35(94.6)	

4. Discussion

The preparation of the cervix and pelvis for vaginal delivery before the development of labor symptoms increases the chance of successful vaginal delivery. Moreover, it encourages expectant mothers to undergo this mode of delivery, decreasing the rates of cesarean

sections. The purpose of the present study was to evaluate the effectiveness of Alcea Angulata in conjunction with honey in facilitating delivery in nulliparous women. The results pointed out that in comparison with the control group, the time interval between the intervention and delivery of the intervention group did not show a statistically

significant difference. However, the intervention group demonstrated a shorter duration in hours at the beginning of the full cervical dilatation stage.

As a predictor of vaginal delivery, the Bishop score can predict the time interval between induction and delivery in the breech position. Herbal compounds are one of the methods available to achieve a suitable cervix for childbirth and induction without the use of drugs (25). The Bishop coefficient is more heavily affected by cervix dilatation (degree of opening). As a result, labor induction with a low bishop coefficient increases the likelihood of success compared to one with a higher bishop coefficient but a lower dilatation (14). The present study found no significant difference in gestational age or Bishop score among the young mothers (aged 21-24 years) before the intervention. Karimi et al., in their meta-analysis reported that eating date fruit significantly reduces the duration of the active phase, improves the bishop score, and may decrease cesarean sections (26). Several herbal medicines, including evening primrose, castor oil, red raspberry leaf, pecan, *Sisymbrium*-seeds, chamomile, and saffron, have been found to be effective in preparing the cervix and facilitating childbirth (27-34). Furthermore, Ghaderi et al., reported that saffron honey syrup reduced labor duration in nulliparous women (35). In the last weeks of pregnancy, *Alcea Angulata* and honey can cause labor induction and stimulation since honey provides the glucose required for uterine muscle contractions, reducing labor duration (26).

Nevertheless, since some mothers need uterotonic drugs during the labor process to strengthen labor pains (36), in the current study, most mothers in the two groups went through the normal course of labor with the same natural contractions without the need for labor-strengthening drugs, such as oxytocin. Although there were no significant statistical differences between the two groups in this regard, the frequency of misoprostol and oxytocin drug use was reported to be higher in the control group compared to the intervention group. Medicinal plants facilitate the start of labor (37). Nevertheless, the efficacy of herbal medicine should be challenged in the context of extensive studies due to the distribution of different plant species throughout the globe.

The results of this study pointed out that the mode of delivery did not differ statistically significantly between the two groups. However, cesarean deliveries were more common in the control group than in the intervention group. According to Saberi et al., the intervention group which used castor oil did not differ significantly from the control group in terms of cesarean rates (38). Mohammadinia et al., on the other hand, pointed to a statistically significant decrease in cesarean sections after treatment with khakshir syrup (32).

Uterine muscle contractions need a wealthy source of glucose during labor, and uterine muscles become inert in the absence of glucose (39). Since honey

contains 75-80% carbohydrates, it can be an effective source of carbohydrates and a substitute for glucose (37). Kordi et al., Also indicated that the consumption of honey date syrup, which contains 100 gr of carbohydrates, during labor significantly reduces the duration of the active phase of labor compared to placebo and usual care groups (18).

Lack of preparation of the cervix and induction of labor can enhance the rate of cesarean section and postpartum hemorrhage (40). Nevertheless, an increase in the bishop score and preparation of the cervix can improve the rate of normal vaginal labor and decrease the rate of cesarean section (26). The most current causes of cesarean section are an abnormal progression of labor and non-effective contractions of the uterine (41,42). Inadequate consumption of energy-booster foods during labor leads to the enhancement of non-effective uterine contractions and the rate of cesarean section (43).

The short supply reserves of body fluids and glycogen in pregnant women with limited consumption of liquids and food during labor can result in inadequate uterine perfusion and nutrition, followed by abnormal labor progression, extended labor, and the enhancement of cesarean section rate (44). *Alcea Angulata* is a plant containing a chain of oligosaccharides attached to amino acids, as well as a combination of colloidal polysaccharides that contain many sugars, flavonoids, proteins, alkaloids, and minerals. Based on old texts of Persian medicine, these compounds have softening and anti-inflammatory properties, causing the body's mucus to be moistened as a result of a prepared cervix and uterus (45).

The results of this study indicated that both groups had referred to the maternity hospital due to the onset of labor pains. Although there was no significant difference in terms of the reasons for hospitalization, the rupture of the amniotic sac had a higher frequency in *Alcea Angulata* and honey group, while the control group had visited the maternity hospital more frequently due to uterine contractions and bleeding. According to the reasons for mothers' referral to hospitals, it seems that *Alcea Angulata*, similar to Khakshir syrup, was effective on the delivery process in the form of preparing the cervix (32). Khakshir had a gradual effect on the onset of labor due to the higher frequency of the opening of the water sac (fetal membranes) in the intervention group (32). Based on the results of the present study, there were no adverse perinatal outcomes, such as bleeding, fetal distress, and delay in the onset of labor that would lead to hospitalization for delivery. In general, women believed that the use of herbal medicines is effective as a pleasant and healthy method in preparing for the onset of labor pains. It assumes critical importance in childbirth, which is a stressful experience for many women, leading to major maternal consequences (46).

In the present research, there were no statistically significant differences between the two groups in terms

of adverse neonatal outcomes, including Apgar scores, need for resuscitation, meconium-stained amniotic fluid, and neonatal sepsis. These results point to the harmless effect of the intervention. Mohammadinia et al., demonstrated that the sisymbrium seeds caused no significant difference between the two groups in the first-and fifth-minute Apgar score and meconium of newborns (32). Some other studies investigated the effect of castor oil on cervical preparation and reported no significant difference between the first- and fifth-minute Apgar scores and meconium excretion of neonates in the two groups (47,48).

In this study, components such as improvement of the second phase of labor with shortening of the duration and reduction of cesarean section were reported, and this intervention was not associated with adverse maternal and fetal complications. Kianitalaei et al., showed the improvement of sexual performance of postmenopausal women in all areas of sexual performance with *Althaea Officinalis* plant by softening and moisturizing the vaginal mucosa. Although in this study the difference in the cervical Bishop score was not statistically significant, the shortening of the second stage of the labor phase could somehow show an improvement in the intervention group. The present study is a new type of study that should be investigated in more extensive studies with larger sample sizes on the effect of marshmallow plants in facilitating childbirth.

Other similar studies on the effect of saffron capsule (45), saffron syrup (35), date syrup (19) and saffron and date syrup (49) have shown the effectiveness of medicinal plants in facilitating the onset of labor (cervix softness and readiness) and continuing the course of labor phases (strengthening uterine contractions and shortening the duration of labor). In this study, a new plant species that is widely used in Iranian traditional medicine was identified, which is one of the strengths of this study. One of the limitations of this study is the sample size, the dose, the number of times, and the duration of consumption of *Alcea Angulata* plants by mothers, which should be investigated in future studies. Therefore, health care systems with healthy and low-risk medicinal plants will be available. This study is the first which examined the effects of *Alcea Angulata* and honey on the onset of labor pain. The lack of a tocometric device for the accurate measurement of the onset time and intensity of uterine contractions was one of the limitations of this study.

5. Conclusion

The results of this study demonstrated that the time interval between intervention and delivery in the intervention group did not show statistically significant difference when *Alcea Angulata* was used with honey. At the beginning of full cervical dilatation, the intervention group displayed a shorter duration. In addition, there was no significant difference between the two groups when it came to negative neonatal outcomes, including Apgar scores, resuscitation needs, meconium-stained amniotic fluid, and neonatal sepsis, pointing to the safety of the intervention. Since *Alcea Angulata* and honey are not considered for the onset of labor pains in term births, it is recommended to conduct similar studies with larger sample size.

6. Declarations

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Ethical Considerations

The study was approved by the Ethics Committee of Mashhad University of Medical Sciences (ethical code: IR. MUMS. REC. 1397.193). It was also registered at the Iranian Registry Clinical Trials (IRCT20181106041578N1).

Authors' Contributions

Fatemeh Rahmani Ivary and Mahdi Yousefi contributed to designing and performing the study. Hassan Mehrad-Majd conducted pathology analysis. Masoumeh Mirteimouri, Sedigheh Ayati, and Soodabeh Bioos helped to collect data. Roshanak Salari and Atiyeh Vatanchi supervised the study process.

Conflict of Interest

The authors declared no conflict of interest.

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