

Maternal and perinatal effects with the use of floral therapy in childbirth: randomized clinical trial

*Efeitos maternos e perinatais com utilização de floral no
trabalho de parto: ensaio clínico randomizado*

*Efectos maternos y perinatales del uso de floral em
el parto: ensayo clínico aleatorizado*

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ABSTRACT

Objective: To evaluate the clinical, obstetric, maternal and perinatal effects of the use of flower essences in labor, against factors that enhance it.

Method: Clinical trial, randomized, controlled, in 164 parturients divided into two groups, flower essences and placebo, respectively, evaluated before and after the intervention. Carried out in a vaginal delivery center, in the city of São Paulo, from May to October 2018. Data were analyzed using descriptive statistics, Student's t test, bilateral hypothesis, negative and positive observed critical t, Pearson's chi-square, exact test. Fisher.

Results: It was observed in the Experimental Group, moderate increase in systolic blood pressure ($p=0.046$), frequency ($p=0.055$) and intensity of contractions ($p=0.031$), as well as a reduction in time to birth (194 minutes), higher number of vaginal deliveries ($p=0.038$) and better pattern of fetal vitality.

Conclusion: There was evidence of a positive action of the Floral Essence on the potentiating factors of labor, being effective in maternal clinical and obstetrical repercussions, as well as perinatal ones.

Keywords: Labor, obstetric. Complementary therapies. Flower essences. Clinical trial.

RESUMO

Objetivo: Avaliar os efeitos clínicos, obstétricos maternos e perinatais com o uso de essências florais no trabalho de parto, frente a fatores que o potencializam.

Método: Ensaio clínico, randomizado, controlado, em 164 parturientes divididas em dois grupos, essências florais e placebo, respectivamente, avaliadas pré e pós intervenção. Realizado em centro de parto normal, na cidade de São Paulo, de maio a outubro de 2018. Os dados foram analisados por estatística descritiva, teste t de Student hipótese bilateral, t crítico observado negativo e positivo, Qui-quadrado de Pearson, Exato de Fisher.

Resultados: Observou-se no Grupo Experimental, moderada elevação da pressão arterial sistólica ($p=0,046$) da frequência ($p=0,055$) e intensidade das contrações ($p=0,031$), assim como, redução do tempo ao nascimento (194 minutos), maior número de partos vaginais ($p=0,038$) e melhor padrão de vitalidade fetal.

Conclusão: Evidenciou-se ação positiva da Essência Floral perante os fatores potencializadores do trabalho de parto, sendo efetiva nas repercussões clínicas e obstétricas maternas, bem como perinatais.

Palavras-chave: Trabalho de parto. Terapias complementares. Essências florais. Ensaio clínico.

RESUMEN

Objetivo: Evaluar los efectos clínicos, obstétricos, maternos y perinatales del uso de esencias florales en el parto, frente a factores que lo potencian.

Método: Ensayo clínico, aleatorizado, controlado, en 164 parturientas divididas en dos grupos, esencias florales y placebo, respectivamente, evaluadas antes y después de la intervención. Realizado en un centro de parto vaginal, en la ciudad de São Paulo, de mayo a octubre de 2018. Los datos fueron analizados mediante estadística descriptiva, prueba t de Student, hipótesis bilateral, t crítica observada negativa y positiva, chi-cuadrado de Pearson, prueba exacta. Pescador.

Resultados: Se observó en el Grupo Experimental, aumento moderado de la presión arterial sistólica ($p = 0,046$), frecuencia ($p = 0,055$) e intensidad de las contracciones ($p = 0,031$), así como una reducción del tiempo hasta el nacimiento (194 minutos), mayor número de partos vaginales ($p = 0,038$) y mejor patrón de vitalidad fetal.

Conclusión: Se evidenció una acción positiva de la Esencia Floral sobre los factores potenciadores del parto, siendo efectiva en las repercusiones clínicas y obstétricas maternas, así como perinatales.

Palabras clave: Trabajo de parto. Terapias complementarias. Esencias florales. Ensayo clínico.

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■ INTRODUCTION

Pregnancy is a period of intense changes in the maternal organism, which must adapt to these changes caused by the continuous growth and development of the fetus. The final stage of pregnancy, when labor begins, is a critical moment for the mother-child binomial, due to the occurrence of a series of physiological mechanisms aimed at physiological mechanisms aimed at expulsion of the fetus and other products of conception^(1,2). Scientific evidence demonstrates that pregnant women have been subjected to a model of childbirth care and birth that lead to a disturbing experience, and pain during labor is the greatest fear⁽²⁾.

In view of these negative experiences of women in labor, the use of integrative and complementary practices (PICs), which are non-pharmacological methods for the prevention of diseases and the promotion, maintenance and recovery of health is recommended. These practices are based on a humanized care model focused centered on a holistic approach of the individual, integrality of care and non-invasive methods^(3,4).

Flower essences, which are considered PICs, are extracts of wild flowers and plants that have been specially selected and contain energy properties of plant origin, to act on emotional, spiritual and mental states. They are used as a therapeutic work tool and intend to be an expression of thinking, feeling and acting in life in general^(5,6).

Of the numerous goals of this therapy, one concerns the balance of the individual's emotions, seeking to reduce or eliminate feelings such as stress, panic, aggressiveness, anxiety, among others^(6,7,8).

Bach's rescue remedy combination, the Five Flower essences, seeks to "regain emotional balance", due to its effectiveness in situations of stress crises, experienced by parturients in the active phase of labor. It consists of five flowers, namely: *rock rose* – used in cases of great fear and panic, desperate situation; *impatiens* – indicated for severe pain, impatience, anxiety; *cherry plum* – to help the mind stay rational and in control in difficult times; *star of Bethlehem* – to help recover from shocks and physical or emotional traumas, and *clematis* – for use in situations of tiredness, to maintain awareness^(4,5).

During the evolution of labor, pain gradually increases and is directly associated with the intensity of uterine contractions. In the latency stage, the pressure exerted by the uterus between contractions is approximately 20 mmHg; in the active stage of expulsion, this pressure reaches 50mmHg. It should be noted that the normal tone of the uterine muscle is 10 mmHg, and when this value is higher, it is felt by the woman. However, the painful sensation is triggered from

20 mmHg on. However, the sensation of pain is triggered from 20 mmHg onwards, and the measurements of the intensity of uterine contractions, resulting from their sum in a 10-minute period, are characterized as uterine activity (UA). Uterine activity is measured in Montevideo Units (MU)^(9,10).

The relationship between pain, anxiety and stress has been increasingly recognized by scholars and health professionals, and this set can trigger maternal clinical changes such as increased blood pressure (BP), which impacts heart rate (HR) and the respiratory rate (RR), increasing ventilation. This leads to an increase in the partial pressure of carbon dioxide (pCO₂), destabilizing the maternal respiratory system, which then triggers metabolic changes in the body.

The fetus is totally dependent on maternal conditions, and its well-being and vitality are significantly dependent on a metabolically stable maternal system^(4,10,11).

Therefore, it is important to relieve pain and anxiety and consequently the maternal stress pattern to prevent the fetal organism from being affected by disorders in uteroplacental blood flow that may occur in case of changes in the pregnant woman's breathing pattern^(4,7).

Despite scientific evidence showing the benefits of floral therapy, its use as a non-pharmacological method for the relief of symptoms in labor is not described in the literature. One of the reasons is the lack of professionals who provide assistance in childbirth and with experience in this type of complementary therapy.

Therefore, the present study can contribute to filling this gap, and its results can improve knowledge about the use of an effective integrative practice in the parturition process.

Considering the aspects presented here, the following hypothesis was presented: is there an association between the use of flower essences as non-pharmacological therapy during labor on maternal and perinatal clinical and obstetric parameters? In this regard, the present study aimed to evaluate the clinical, maternal and perinatal obstetric effects with the use of flower essences in labor, in view of the factors that maximize these effects.

■ METHODS

Experimental, randomized, controlled and triple-blind clinical trial, between researcher, statistician and participants, in which a pre- and post-intervention design was used with repeated measures between two groups. However, to overcome possible sample losses, sample size was increased by 10%, totaling 164 parturients, subdivided into two groups of 82, called odd and even.

Due to the lack of research that could support the sample of this study, for the sample size calculation, a pilot study

was carried out with 30 parturients allocated in two random groups and treatment with two paired measures (flower and placebo). Sample size was determined with the use of the statistical software Power Analysis and Sample Size Systems 14 (PASS14). Maternal HR was used as a dimensioning variable. Paired Student's *t* test was used to detect differences in means between groups of variations between the two evaluation moments, before and after, with a significance level of 5% ($p \leq 0.05$). In this context, the necessary sample calculated was 74 parturients per group, totaling 148 women. However, because of probable losses, the sample size calculation was increased by 10%, totaling 164 parturients, subdivided into two groups.

A total of 170 parturients were eligible, six were excluded due to refusal and 164 were randomized, 82 for each group. In both control and experimental groups, there were losses in the follow-up period. Thus, 75 parturients made up the Control Group (CG) and 78 the Experimental Group (EG), as shown in the flowchart of the study participants, according to CONSORT⁽¹²⁾ (Figure 1).

The study participants were parturients with low obstetric risk, who met the following inclusion criteria aged 18 years or older, full-term pregnancy: gestational age (GA) of 37 to 42 completed weeks calculated by the date of the last menstrual period (LMP) and/ or by the result of the early ultrasound (USG), performed up to the 20th week^(1,10), with a single fetus, alive, in flexed cephalic presentation, free from any clinical and/or obstetric pathology, being in labor, that is, with cervical dilation of at least 4 centimeters (cm) and maximum of 8 cm. Parturients who were smokers, who had smoked less than 2 hours ago and those who reported having ingested caffeine in the last 10 hours were excluded, as nicotine and caffeine influence the secretion of catecholamines; who had mental disorders, documented in the medical record, and users of psychoactive substances, as such substances could influence their decision and autonomy⁽¹³⁾.

The study was carried out in an intra-hospital normal birth center, in the southern zone of the city of São Paulo, Brazil, where care was provided by obstetric nurses, with the support of medical staff, obstetricians and neonatologists. The institution is attached to the Unified Health System (SUS).

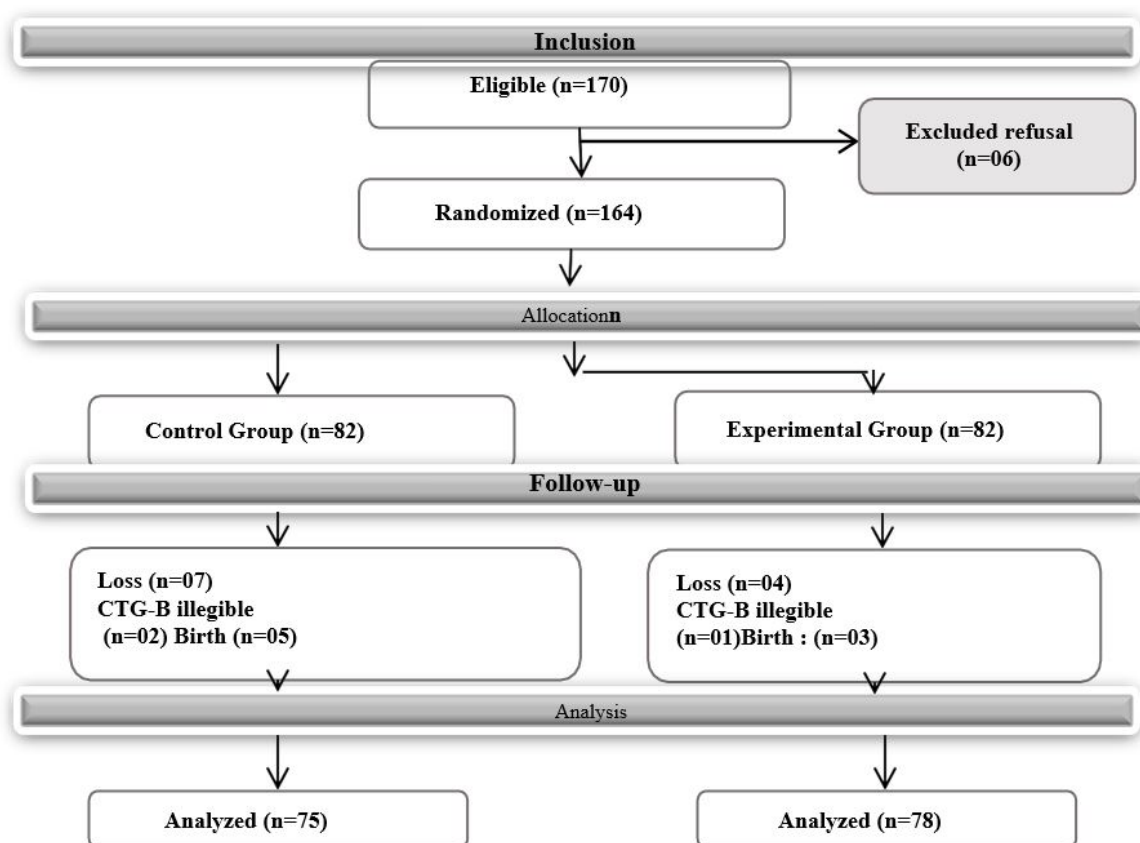


Figure 1 – Flowchart of recruitment and allocation of study participants. São Paulo, São Paulo, Brazil.

Source: The author.

Data were collected from May to October 2018, from Monday to Sunday for about ten hours a day by the researcher and an obstetric nurse specially trained for this purpose.

The women were approached individually. Those who voluntarily agreed to participate were informed on the study's objectives and procedures. Those who met all of the inclusion criteria, none of the exclusion criteria and showed good adherence to the interventions provided for by the protocol were included in the study. At that time, they were asked to sign the Free and Informed Consent Term (FICT) and were told of their right to have their confidentiality and anonymity protected and to withdraw at any time, without prejudice to pre-existing entitlements.

Interventions were identified on randomly distributed cards numbered from 1 to 164. For allocation into one of the groups – even or odd number – in a raffle, each parturient picked a card contained in a brown envelope, whose number corresponded to the therapy received. Even numbers indicated the receipt of 4 drops diluted in 20 milliliters (ml) of water every 15 minutes for one hour, from the bottle previously handled, registered and identified by the importer as even. In turn, odd numbers indicated the administration of 4 drops diluted in 20ml of water every 15 minutes for one hour from the bottle previously handled, registered and identified by the importer as odd. The numbers drawn were picked from the pile until the formation of each study group was completed, that is, the completion of the two intervention groups. It should be noted that the essences were packaged in equal dropper bottles containing 30ml, labeled with even or odd denomination by the importer Healing Essências Florais®. The odd bottle contained stock essence, Five-Flower Formula™, and the even bottle contained mineral water. The entire process of preparation and handling of the vials was photographed and only revealed after statistical analysis.

Data were collected in a printed instrument, especially designed for the study, and organized according to the coding of the variables, in digital spreadsheet, constituting the database in the Excel® software, version 2016. Data were analyzed using descriptive statistics, absolute and relative frequency, mean, median, standard deviation, Student's t test, bilateral Student's t test, two-tailed t-test, with positive and negative hypotheses, Pearson's chi-square test, Fisher's exact test, and received inferential statistical treatment, using the Project for Statistical Computing R software, at a significance level of 5%, considering 95.0% confidence interval, and p value ≤0.05.

An instrument (scale) to determine the indexes that maximize labor was developed, and the statistical results of

the study variables were interpreted based on the groups, according to the treatment, and through comparative analysis between these indices. There were three scores per treatment group pre and post-intervention, represented as follows: score 1 – presence of one maximizing factor (established labor); score 2 – presence of two maximizing factors (established labor and rupture of membranes or use of a labor inducer) and score 3 – presence of three maximizing factors (established labor, ruptured membranes and use of a labor inducer).

Among the predictive variables, regarding primary outcome, in the Experimental Group (EG), the variable was classified in the case in which the essence, stock, Five-Flower Formula™ was used. The secondary outcome variables were constituted by the analysis of maternal clinical factors: systolic and diastolic blood pressure measured in the right upper limb, measured in millimeters of mercury; pulse measured in beats per minute assessed in radial artery, and respiratory rate assessed in breaths per minute; obstetric factors: cervical dilation: in centimeters, state of amniotic membranes: ruptured or intact, gestational age: at term, parity: number of previous deliveries and type of previous delivery, use and type of labor inducer: absent or present, when present which one was used, type of delivery: vaginal or C-section, duration of intervention after birth: in minutes, contractile frequency: number of contractions in ten minutes, contraction intensity: average contractions in millimeters of mercury, uterine activity: contractile average during a ten-minute period in Montevideo units, presence of incoordination 1st and 2nd degree uterine: presence or absence, fetal factors such as; variability, decelerations and cardiotocographic categorization: classified according to the fetal cardiotocograph traces recommended by the International Federation of Gynecology and Obstetrics (FIGO)⁽⁹⁾ and perinatal factors; Apgar score: 1st and 5th minutes after birth and newborn weight: in grams.

The study was approved by the Research Ethics Committees of the institution to which it is attached, under No.2,632,972, CAAE No. 83553317.5.000.5505, and of Secretaria Municipal de Saúde de São Paulo, under no 1.344.993, CAAE nº50134315.2.3001.0086. It was also registered in the database of the Brazilian Registry of Clinical Trials (REBEC), with identifier RBR-5tt55v.

■ RESULTS

There was no difference between the study groups regarding the distribution of means and percentages between the sociodemographic variables analyzed, Table 1.

Table 1 – Sociodemographic characteristics of parturients according to the intervention group. São Paulo, São Paulo, Brazil, 2018

Variables	Total N= 153	Experimental Group N=78	Control N=75	P
<u>Age (years)</u>				0.196
Mean ± SD	25.1 ± 5.6	25.6 ± 6	24.5 ± 5.1	
Median				
(min. – max.)	24 (18 – 42)	24 (18 – 42)	23 (18 – 38)	
<u>Color, n(%)</u>				0.370 ^a
White	41/153 (26.8)	17/78 (21.8)	24/75 (32.0)	
Black	15/153 (9.8)	7/78 (9.0)	8/75 (10.7)	
Yellow	7/153 (4.6)	5/78 (6.4)	2/75 (2.7)	
Brown	90/153 (58.8)	49/78 (62.8)	41/75 (54.7)	
<u>Education, n(%)</u>				0.837 ^a
1 – 3 years	1/153 (0.7)	1/78 (1.3)	0/75 (0.0)	
4 -7 years	16/153 (10.5)	7/78 (9.0)	9/75 (12.0)	
8 -11 years	116/153 (75.8)	59/78 (75.6)	57/75 (76.0)	
12 years or more	20/153 (13.1)	11/78 (14.1)	9/75 (12.0)	
<u>Marital Status, n (%)</u>⁽¹⁾				0.161 ^b
Single	50/94 (53.2)	28/47 (59.6)	22/47 (48.9)	
Married	39/94 (41.5)	16/47 (34.0)	23/47 (46.8)	
Stable relationship	5/94 (5.3)	3/47 (6.4)	2/47 (4.3)	
<u>Family income, n(%)</u>⁽²⁾				0.584 ^a
1 minimum wage	49/112 (43.8)	26/62 (41.9)	23/50 (46.0)	
2 minimum wages	43/112 (38.4)	24/62 (38.7)	19/50 (38.0)	
3 minimum wages	14/112 (12.5)	7/62 (11.3)	7/50 (14.0)	
4 minimum wages	6/112 (5.4)	5/62 (8.1)	1/50 (2.0)	

Source: The author.

Note: p – Descriptive level of Student-t test, Fisher's Exact test ^(a) or Chi-Square test ^(b).(1) (n= 59) cases without information of marital status and ⁽²⁾ (n=41) cases without information about family income, respectively.

Regarding age, the mean obtained was 25 years old, and 58.8% declared themselves brown. Regarding schooling, 75.8% had completed 8 to 11 years of education. In both groups, about 53.2% were single and 43.8% earned up to one minimum wage monthly, as shown in Table 1.

Given the obstetric characteristics, cervical dilation was very similar in both groups of post-intervention evolution, in the 3 levels of scores, Table 2.

In the CG, in view of the contractile pattern, there was a decrease in frequency in score 2 and a significant increase in uterine intensity and activity in score 3, post-intervention, corroborating the evolutionary patterns of improvement regardless of 1st and 2nd degree incoordination in the EG (Table 2).

Labor duration was reduced in the EG, especially in scores 2 and 3, resulting in more vaginal deliveries (VD). Such data is shown in Table 2.

Table 2 – Summary measure of the behavior of maternal obstetric variables, according to evaluation moments, according to the labor maximizing indices between the Experimental and Control Groups. São Paulo, São Paulo, Brazil, 2018

Total Sample (n=153)				
Variables	GE*(n=78)	P	GC*(n=75)	P
<u>Cervical dilation-(cm)</u>	Pre/Post		Pre/Post	
Score 1	4,7/5,7	0,001	5,2/6,3	0,001
Score 2	4,0/5,1	0,001	4,0/5,3	0,021
Score 3	4,8/6,2	0,001	4,7/6,0	0,051
<u>Frequency of contractions - (amount)</u>	Pre/Post		Pre/Post	
Score 1	3,1/3,2	0,381	3,0/3,1	0,330
Score 2	2,5/3,2	0,116	3,2/2,8	0,055
Score 3	4,0/3,4	0,902	3,0/3,0	0,500
<u>Intensity of contractions (mmHg)</u>	Pre/Post		Pre/Post	
Score 1	34/39	0,106	43/42	0,568
Score 2	32/34	0,367	36/39	0,404
Score 3	38/45	0,143	36/52	0,031
<u>Contractile Uterine Activity -(UM)</u>	Pre/Post		Pre/Post	
Score 1	106/128	0,135	132/131	0,523
Score 2	86/118	0,185	112/110	0,523
Score 3	156/160	0,463	128/177	0,258
<u>1st and 2nd degree incoordination – (%)</u>				

Table 2 – Cont.

Total Sample (n=153)				
<u>Score 1</u>	Pre/Post		Pre/Post	
MN*	16(55,0%)	0,100 ^a	24(63,0%)	0,100 ^a
EM*	6(21,0%)		7(18,0%)	
MA*	2(7,0%)	0,202 ^a	1(3,0%)	0,202 ^a
EP*	5(17,0%)		6(16,0%)	
<u>Score 2</u>	Pre/Post		Pre/Post	
MN*	22(61,0%)	0,100 ^a	17(55,0%)	0,100 ^a
EM*	6(17,0%)		5(16,0%)	
MA*	3(8,0%)	0,703 ^a	4(13,0%)	0,703 ^a
EP*	5(14,0%)		5(16,0%)	
<u>Score 3</u>	Pre/Post		Pre/Post	
MN*	9(69,0%)	0,202 ^a	3(50,0%)	0,202 ^a
EM*	3(23,0%)		1(17,0%)	
MA*	1(8,0%)	0,403 ^a	0(0,0%)	0,403 ^a
EP*	0(0,0%)		2(33,0%)	
<u>Duration of intervention after birth – (min)</u>	min.		min.	
Score 1	407,1	0,103	422,0	0,103
Score 2	369,8	0,459	479,8	0,459
Score 3	396,4	0,166	591,0	0,166
<u>Type of delivery -VD*(%)</u>	PV		PV	
Score 1	83,0%	0,349	79,0%	0,349
Score 2	86,0%	0,018	71,0%	0,018
Score 3	100,0%	0,182	83,0%	0,182
<u>Type of delivery -VD*(%)</u>				
Between EG* and CG*	90,0%	0,038	78,0%	0,038

Source: The author.

Note: Analysis by Student-t test, ^a Fischer exact test.

*VD: Vaginal delivery; *EG: Experimental group; *CG: control group; *MN: maintenance of normality; *EM: Improved evolution; *MA maintenance of abnormality; *EP: evolution expected to worsen; p≤0,05.

The results of maternal clinical characteristics for the pre- and post-intervention study groups did not vary among the clinical variables, respiration, pulse and diastolic blood pressure (DBP) regarding labor maximizing indices.

There was a reduction in systolic blood pressure (SBP) in the CG, scores 1 and 2, being significant in the score 2. In the EG, there was a moderate increase in both scores. In score

3, SBP was high in the CG, while it was reduced, post-intervention, in the EG. Data presented in Table 3.

In the analysis of fetal variables variability, deceleration and physiological pattern categorization, the best results were observed in the EG compared to the CG, post-intervention, in relation to the maximizing factors of labor, as shown in Table 4.

Table 3 – Summary measure of the behavior of the maternal clinical variables, according to the evaluation moments, according to the maximizing indices of labor between the Experimental and Control Groups. São Paulo, São Paulo, Brazil, 2018

Total Sample (n=153)				
Variables	GE*(n=78)	P	GC*(n=75)	P
<u>Respiratory rate-(mpm)</u>	Pre/Post		Pre/Post	
Score 1	20/19	0,902	20/19	0,890
Score 2	20/18	0,959	23/18	0,980
Score 3	18/20	0,146	17/19	0,206
<u>Pulse-(bpm)</u>	Pre/Post		Pre/Post	
Score 1	76/75	0,691	80/78	0,833
Score 2	76/75	0,583	78/76	0,617
Score 3	86/86	0,523	84/83	0,517
<u>*SBP-(mmHg)</u>	Pre/Post		Pre/Post	
Score 1	123/126	0,046	123/121	0,736
Score 2	125/127	0,370	132/122	0,026
Score 3	122/122	0,459	124/129	0,310
<u>*DBP-(mmHg)</u>	Pre/Post		Pre/Post	
Score 1	73/75	0,221	73/71	0,699
Score 2	74/76	0,318	72/74	0,375
Score 3	73/72	0,590	76/75	0,546

Source: The author.

Note: Analysis by Student-t test.

* SBP: systolic blood pressure; * DBP: diastolic blood pressure; *EG: Experimental group *CG: control group; p≤0.05.

Table 4 – Summary measure of the behavior of fetal and perinatal variables, post-intervention, according to labor maximizing indices between Experimental and Control Groups. São Paulo, São Paulo, Brazil, 2018

Total Sample (n=153)				
Variables	EG*(n=78)	P	CG*(n=75)	P
<u>Fetal Variability-- (amount /%)</u>				
<u>Score 1</u>	Post		Post	
MN*	23(80,0%)	0,100 ^a	30(79,0%)	0,100 ^a
EM*	2(7,0%)		2(5,0%)	
MA*	1(3,0%)	0,202 ^a	3(8,0%)	0,202 ^a
EP*	3(10,0%)		3(8,0%)	
<u>Score 2</u>	Post		Post	
MN*	22(61,0%)	0,543 ^a	21(68,0%)	0,543 ^a
EM*	3(8,0%)		2(6,0%)	
MA*	6(17,0%)	0,865 ^a	4(13,0%)	0,865 ^a
EP*	5(14,0%)		4(13,0%)	
<u>Score 3</u>	Post		Post	
MN*	8(62,0%)	0,202 ^a	4(66,0%)	0,202 ^a
EM*	3(23,0%)		1(17,0%)	
MA*	0(0,0%)	0,365 ^a	0(0,0%)	0,365 ^a
EP*	2(15,0%)		1(17,0%)	
<u>Fetal Deceleration – (amount /%)</u>				
<u>Score 1</u>	Post		Post	
MN*	26(90,0%)	0,843 ^a	33(86,9%)	0,843 ^a
EM*	1(3,0%)		0(0,0%)	
MA*	0(0,0%)	0,900 ^a	2(5,2%)	0,900 ^a
EP*	2(7,0%)		3(7,9%)	

Table 4 – Cont.

Total Sample (n=153)				
<u>Score 2</u>	Post		Post	
MN*	25(69,0%)	0,478 ^a	24(77,4%)	0,478 ^a
EM*	4(11,0%)		0(0,0%)	
MA*	2(6,0%)	0,202 ^a	5(16,1%)	0,202 ^a
EP*	5(14,0%)		2(6,5%)	
<u>Score 3</u>	Post		Post	
MN*	7(53,8%)	0,202 ^a	5(83,3%)	0,202 ^a
EM*	2(15,4%)		1(16,7%)	
MA*	2(15,4%)	0,753 ^a	0(0,0%)	0,753 ^a
EP*	2(15,4%)		0(0,0%)	
<u>CTG*-(amount /%)</u>				
<u>Score 1</u>	Post		Post	
MN*	21(72,4%)	0,423 ^a	28(73,8%)	0,423 ^a
EM*	3(10,3%)		1(2,6%)	
MA*	1(3,4%)	0,202 ^a	4(10,5%)	0,202 ^a
EP*	4(13,9%)		5(13,1%)	
<u>Score 2</u>	Post		Post	
MN*	19(53,0%)	0,907 ^a	17(54,9%)	0,907 ^a
EM*	3(8,0%)		3(9,6%)	
MA*	8(22,0%)	0,897 ^a	3(9,6%)	0,897 ^a
EP*	6(17,0%)		7(22,6%)	
<u>Score 3</u>	Post		Post	
MN*	5(38,5%)	0,202 ^a	4(66,6%)	0,202 ^a
EM*	2(15,4%)		1(16,7%)	
MA*	2(15,4%)	0,202 ^a	0(0,0%)	0,202 ^a

Table 4 – Cont.

Total Sample (n=153)				
EP*	4(30,7%)		1(16,7%)	
Fetal weight-(grams)	3.264	0,297	3.332	0,297
Apgar score at 1 st minute – $\geq 8(\%)$	93,60%	0,271 ^a	88,00%	0,271 ^a
Apgar score at 5 st minute – $\geq 8(\%)$	100,00%	0,239	97,30%	0,239

Source: The author.

Note: ^a Analysis by Fisher exact test, Student-t test.*EG: experimental group; *CG: control group; *MN: maintenance of normality; *EM: improved evolution; *MA: maintenance of abnormality; *EP: Worse evolution; *FCT fetal cardiotocography; $p \leq 0.05$.

DISCUSSION

Analysis of obstetric characteristics showed homogeneity between the study groups. Participants had, on average, a gestational age of 39 weeks, 2 pregnancies, primiparity, cervical dilation of 5 cm, most with frequency of contractions of 3/10 minutes, and no induction of labor, meconium and uterine incoordination. In most women, fetal membranes were intact, and oxytocin was used when labor was induced.

As for cervical dilation, an average evolution of 1 cm ($p \leq 0.05$) was observed in scores 1, 2 and 3 in both study groups, considering the progression of labor among women in both intervention groups.

As for the frequency of contractions, there was a significant outcome in score 2 ($p=0.055$) of the CG. Artificial rupture of membranes is a common intervention. However, when this rupture is performed early, it can be associated with potential complications, such as fetal cardiac deceleration and infection^(4,9,10).

Randomized clinical study (RCT) carried out in the United States with nulliparous women ($n=705$), performed a meta-analysis and found that there was no difference in the time of the first and second periods of delivery, when routine early rupture of the membranes (amniotomy) was used compared to conservative management⁽¹⁴⁾.

As for the active phase of labor with the use of an inducer, a Cochrane systematic review analyzed three clinical studies that included 486 women with a moderate level of evidence and a statistical result ($p=0.05$), stating that continuous use of intravenous (IV) oxytocin can lead to combined uterine tachysystole and abnormal fetal heartbeat. Discontinuation in the use of oxytocin in parturients revealed occurrences (3/240) in comparison with its continued use (23/246). Another systematic review carried out by Cochrane in four clinical

studies with 728 women showed that discontinuation of IV oxytocin reduced the risk of uterine tachysystole, while its continuous use increased that risk⁽¹⁴⁾.

This result corroborated the analysis that found that despite progression of labor, with the presence of an inducer or ruptured fetal membrane, CG had a reduction in the frequency of contractions, while this frequency increased in the EG.

The variable intensity of contractions is rarely addressed or even absent in the literature when it comes to external tocography. However, in the literature, as well as in clinical practice, there are many studies on this variable when the measurement is performed by an internal method. The values of the intensity of uterine contraction, performed and analyzed by means of external tocography, are unknown by many professionals and even by researchers. However, in practice, we can see its importance, need and significance regarding the assistance provided to the mother/fetus binomial.

In the present study, the variable intensity of contractions, measured by external tocography, showed statistical significance in score 3 of the CG ($p=0.031$). This variable is directly related to intrauterine, intraamniotic, intramyometrial and uterine arterial pressure with myometrial contractility increasing pre-existing pressures, promoting circulatory stasis, hypercapnia, hypoxemia and transient acidosis. When contractions cease, proper uteroplacental exchanges can occur again^(4,10,11).

A prospective, descriptive temporal study for clinical validation of diagnosis with 55 parturients, carried out in the city of Ribeirão Preto, assessed the intensity of uterine contractions with a tocodynamometer, according to an external method, in which evidence of pain was observed, with verbal reports were and based on six pre-established characteristics. As data on the intrauterine pressure amplitude

triggered by contractions were recorded by the tocograph, an increase in its pressure, diaphoresis and pain defense/protection behavior were observed ($p=0.001$); anti-pain position and distracting behavior ($p<0.0001$); facial expression of pain ($p=0.035$) and focus on oneself ($p=0.002$) were found. The pre-established characteristics were vomiting, nausea, inappetence, increased appetite, narrowed focus and sleep disturbance, the latter being statistically significant ($p=0.044$)⁽¹⁵⁾.

The marked increase in intensity in the CG, characterizing a hypersystole, as it reached 52 mmHg, with the use of a labor inducer, ruptured fetal membranes and the active phase of labor, denotes a greater sensation of pain, favoring the triggering of tension for the parturient and more impact on fetal vitality.

Regarding the time of intervention after birth, it was 15 minutes shorter in the score 1 in the EG; in scores 2 and 3 the times were shorter, respectively 110 minutes (1:50h) and 195 minutes (3:15h). A study carried out in Germany ($n=932$)⁽²⁾ found that the average duration of labor for primiparous women was at least 8 hours, hardly reaching 18 hours, and for multiparous women, at least 5 hours, hardly reaching 12 hours^(2,4). The results obtained demonstrate that the Flower Essence Five Flower facilitated the physiological process of childbirth, activating the mechanisms of coping with pain and stress, resulting in emotional balance and contributing to reduce the time of labor⁽³⁾.

These findings allow us to state that in the EG the time of labor was reduced in the three scores, compared to the CG, since the pattern of contractions in the EG showed evolution regarding the parameters of frequency, intensity and uterine activity, in a physiological way, keeping within their reference values, whereas in the GC this happened in an unstable way, with different reference values.

Regarding the types of delivery, the results showed a greater number of vaginal deliveries in the EG ($p=0.038$) and a greater number of Cesarean sections in the CG related to score 2. These results are consistent with the RCTs reviewed by Cochrane, in which findings related to induction with oxytocin and the presence of ruptured fetal membranes were obtained as causal factors in the increase in the surgical procedure⁽¹⁴⁾.

Increase in SBP in the EG in scores 1 and 2 occurred in a balanced way, which is justified by the increase in the frequency of contractions in score 2, as well as the excessive elevation, in scores 1 and 2, of uterine activity. In the CG, the increase in SBP was caused by a greater imbalance in the intensity of contractions and uterine activity, in score 3, characterizing a higher level of pain or stress. Hyperalgesia releases inflammatory neuromediators, triggering an inflammatory reaction that activates nerve fiber nociceptors, facilitating pain transmission, promoting vasodilation and

vascular resistance. Peripheral neuromediators facilitate the depolarization of the neuronal membrane, modify the physiology of the central nervous system (CNS) and the peripheral nervous system (PNS), modulators of SBP, through cardiac sympathetic activity and blood vessels. Thus, the reason for the increase in SBP is understood⁽¹⁶⁾. Regarding the fetus, there was no significant difference in the pattern of variability in the results of scores 1, 2 and 3 in both study groups. However, the maintenance of normality and evolution of improvement was more prevalent in the EG. On the other hand, maintenance of abnormality and evolution of worsening was proportional in the two groups.

As for deceleration, maintenance of normality and the evolution of improvement, as well as lower occurrences of maintenance of abnormality were more significant in fetuses of women in the EG. However, worsening evolution was lower in the CG.

A study carried out in Amsterdam with 1,433 parturients found that the exacerbated increase in uterine activity during labor caused more compressed variability, the presence of decelerations and, consequently, led to cardiotocographic categorizations outside the physiological pattern, in addition to being directly linked to the increase in fetal acidemia rates⁽¹⁷⁾.

Thus, due to the higher concentration of abnormality in variability and the presence of decelerations in the CG, the prevalence of suspicious categorization and the number of cardiotocographies in physiological pattern were higher in the EG. It is known that the fetus needs a biologically and emotionally stable mother to maintain intrauterine balance^(4,11).

A study showed that the use of flower therapy is recommended in situations of emotional and mental imbalance experienced by the individuals, which can be caused by internal conflicts, intrusive thoughts, negative feelings and emotions, with physical repercussions^(18,19,20).

In this context, flower essence promotes the self-development of the human being, allowing release and relaxation, understanding of internal changes, providing the release of excess dysfunctional energy, generating different perceptions in each individual and sensations perceived by the body as changes in breathing pattern, triggering peace and calm. Thus, the flower compound Five Flower was able to recover the emotional balance of pregnant women who were facing an emergency situation in the active phase of labor. The therapy promoted relaxation, minimizing stress, enabling the balance of emotions, in a process that facilitates coping, providing a sensation of release and relaxation of dysfunctional energies, enabling physical as well as emotional stability^(3,4,8,20).

The newborns' birth conditions were assessed using the Apgar score, whose mean values for scores 1, 2 and 3 in both groups were 8 at the 1st minute and 10 at the 5th minute. The mean weight of newborns in scores 1, 2 and 3 (3,257g) and (3,365g) was verified in the EG and CG, respectively, without significant differences.

One limitation of this study is the lack of clinical research with the use of Floral Therapy in the obstetric area, as well as the scarcity of studies focused on tocography by external means, which makes it difficult to provide a more in-depth analysis and interpretation of the results.

■ CONCLUSION

The use of the Five Flower Floral Essence provided balance to the parturients, allowing gradual constancy in the frequency and intensity of contractions, permeating the uterine activity during the phases of labor, with proportionality, regardless of the maximizing factors, enabling its natural outcome. The constancy of the factors responsible for uterine contractility allowed more vaginal deliveries and a significant reduction in the time of intervention at birth. In view of the clinical variables, the floral therapy was used and maintained the control of systolic blood pressure.

Perinatal results showed lower occurrence of compressed variability and cases of deceleration, which maintained fetal vitality and favorable birth conditions. Thus, the Five Flower Floral Essence was effective in clinical, maternal and perinatal obstetric repercussions, confirming the hypothesis of the study.

The present study demonstrates the importance of the care provided by obstetric nurses by addressing the use of another essential practice of these professionals. In view of the results obtained, this study expects to support the development of care protocols, in order to improve obstetric care and professional qualification. It also intends to become a reference for further research, with the purpose of making more in-depth analyzes, increasing nurses' autonomy in the use of PICs, as well as supporting a greater involvement between health professionals and patients.

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