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A Clinical Study in Evaluating the Efficacy of Eranda Taila for Augmentation of Labor

Abstract

Background and Objectives: The journey of pregnancy and delivery of a baby is a memorable event in every woman's life. Labor is an intricate process relying on many factors like passage – the pelvis; passenger – the fetus and power – uterine contractility and maternal expulsive effort for its successful outcome. The time taken for normal labor in primi is 12–14 hours and latent phase of labor is expected not to exceed more than 8 hours, thus any intervention that augments and eases labor is well accepted, providing comfort to mother and fetus. Garbha niskramana kriya being one of the important functions of apanavata, its normalcy is necessary for normal labor. Our ancient acharyas have explained anuvasana basti in the ninth month paricharya of garbhini, where basti tends for vatanulomana, particularly apanavata and for garbhamarga snehanarth. Eranda taila having vatanulomana, yonivishodhana and adhobhaga doshahara property is used since ages and by folklore people in labor, selected for the study.

Method: A single blind comparative study, conducted on 45 primi and primipara gravida term pregnancy patients from IPD and OPD of S.D.M. Ayurveda Hospital, Kuthpady, Udupi. Selected 45 patients were randomly assigned in three groups of 15 patients each. Intervened with Eranda taila orally 30 mL, Matra Basti 30 mL and 2.5 IU of oxytocin in 1 pint of RL fluid administered as per the protocol of induction to the respective groups. The outcome measures, which were assessed, were progress in labor using the standard parameters of Bishop's score and partogram and compared within groups.

Results: Eranda taila matra basti showed fast progress on all the parameters for delivery with statistical significance in time taken for first stage of labor with p value <0.05. Eranda taila paana showed slow and gradual progress and the control group had almost nearer action as eranda taila matra basti.

Conclusion: Eranda taila matra basti group showed good results than the other study groups by augmenting the labor and reducing duration of first stage of labor.

Keywords: Prasava, Labor, Eranda taila, Bishop's score, Cervical dilation.

Introduction

Labor and delivery are the focus and climax of the reproductive process. Once the woman is in labor, management should focus on the goal of delivering baby with minimal discomfort and pain to mother as well as fetus. The trendy generation of this era with sedentary life style, unhealthy food and environment have less capacity of pain tolerance and sustenance thereby increasing the rates of Cesarean section. With an idea to augment labor and prevent maternal morbidity and perinatal complications, the active management during labor is introduced in recent practice of obstetrics.

Ayurveda, the science of life, has explained prasava in detail. The whole process of labor is governed by the prasuti maruta. As garbha nishkramana is the function of apana vata, it is referred as prasutimaruta. Vyana vata along with apana vata is

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responsible in producing good uterine contractions. Thus, vata anulomana is necessary for normal and fast progression of labor and any abnormality in it will lead to complications in mother as well as fetus and distort the labor.

The drug eranda taila is madhura, tikta, katu rasa, madhura vipaka and ushna virya⁸ having vatahara, vatanulomana, yonivishodhana and adhobhaga doshahara qualities. It is proved that the castor oil metabolite ricinoleic acid activates intestinal and uterine smooth-muscle cells via EP(3) prostanoid receptors.⁹

An experimental study carried out by Mamatha suggested that the drug eranda taila has got the oxytocic effect by which it helps in initiating uterine contractions. ¹⁰

The present study is taken up for the purpose of evaluation of the efficacy of eranda taila when given orally, or matra basti and to compare it with control group.

Materials and Methods

This is a single blind comparative study, conducted on 45 primi and primipara gravida patients in true labor pain with bishop's score between 5 and 8 from IPD & OPD of S.D.M. Ayurveda Hospital, Kuthpady, Udupi.

Intervention

The selected patients were assigned into three groups, group of minimum 15 patients each at random.

- Group I: 30 mL eranda taila (SDM Pharmacy) given orally once with hot water.
- Group II: 30 mL eranda taila (SDM Pharmacy) matra basti administered once.
- Group III: Induction with 2.5 IU of oxytocin in 1 pint of RL fluid administered as per the protocol of induction.

Administration of drug and/or observations is continued till the progress of labor is satisfactory as indicated by the partograph. In the present study, intervention is done only when the graph in the partograph crossed the action line if maternal and fetal conditions are stable. In case of fetal distress with or without meconium staining, further plan is opted according to the need.

Administration of Oxytocin or Epidosin is considered in case of delay in progress as assessed with partograph. When the pain of labor is severe or patient is becoming

restless with pain, injection Tramadol 100 mg I/V is given.

Record of administration of any drug other than in the protocol was recorded and considered in the final results. Application of forceps or vacuum is done, whenever found necessary.

LSCS was done wherever the case turned to be an indication.

Inclusion Criteria

- Pregnant women in age group of 18 to 35 years
- Patients of primi and primi para
- Patients with true labor pains having Bishop score 5 to 8

Exclusion Criteria

- Patients with systemic disorders like diabetes mellitus, hypertensive disorders, renal disorders, cardiac disorders, severe anemia, eclampsia, bleeding hemorrhoids
- Cephalo-pelvic disproportion in patients with mal presentation, mal position, cord prolapsed, previous cesarean section. Fetal distress, meconium stained liquor at admission. Ante partum hemorrhage. Preterm labor

Investigations

Blood Investigation

Blood group, Rh type, Hb%, TC, DC, ESR, RBS, platelet count, bleeding time, clotting time, HIV, HbsAg, VDRL

Urine Investigation

Abdominal USG

Assessment

Duration, intensity and frequency of uterine contraction assessed at standard intervals using tocometer

Progress of labor assessed on standard parameters of Bishop's scores and partograph

Time taken in different stages of labor assessed

Final Assessment

Outcome of the different stages of labor was observed, assessed and compared within the trial and control group.

Observations and Results

was considered to be statistically significant.

The data were collected and analyzed demographically and results evaluated statistically using one-way ANNOVA test, unpaired t-test. A p-value of 0.05 or less

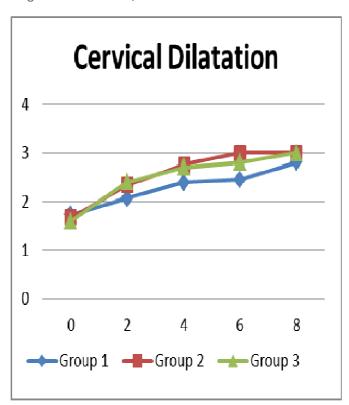
The following observations were made during the course of clinical study:

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Age	48.89% 24–29 years	26.67% 18–24 years	24.44% 30–35 years
Religion	66.67% Hindus	28.89% Muslims	4.44% Christians
Socio-economic status 60% lower middle class		40% upper middle class	
Education 77.78% high school		11.11% primary	11.11% graduation
Occupation	88.89% housewives	11.11% working	
Diet	Diet 82.22% mixed		
Menstrual history	Menstrual history 93.33% regular cycles		
Gravidity 55.56% primi		44.44% primipara	
Pakriti	42.22% vata-pitta	28.89% pitta-vata	13.33% pitta-kapha

Comparison of Therapeutic Effect in Different Groups on Cervical Dilatation

Intervals of Assessing in hrs [n]		Cervical Dilatation	
	Eranda Taila Paana Mean	Eranda Taila MB Mean	Control Group Mean
0	1.733	1.667	1.600
2	2.067	2.333	2.400
4	2.385	2.750	2.700
6	2.444	3.000	2.800
8	2.800	3.000	3.000

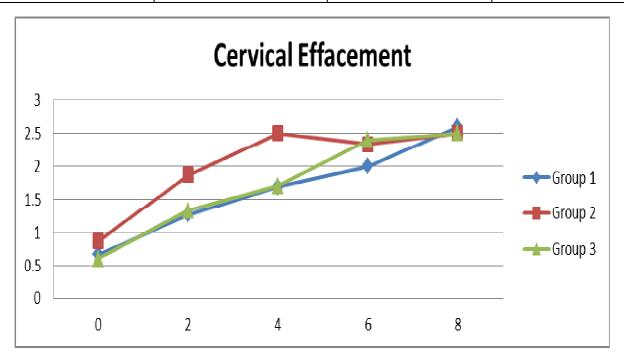
Cervical Dilatation scoring was given as 1=1-2 cm, 2=3-4 cm and 3=>5 cm



Graph showed the sustained action of all three groups remained nearly same, with eranda taila matra basti group (Group II) and control group (Group III) having

almost similar action while eranda taila paana group (Group I) being little slow in progress.

Intervals of Assessing in	Cervical Effacement					
hours [n]	Eranda Taila Paana Mean	Eranda Taila MB Mean	Control Group Mean			
0	0.6667	0.8667	0.6000			
2	1.267	1.867	1.333			
4	1.692	2.500	1.700			
6	2.000	2.333	2.400			
8	2.600	2.500	2.500			



Graph showing, eranda taila matra basti group (Group II) had fast progress on first four hours then slowed down at 6th hour while eranda taila paana group (Group

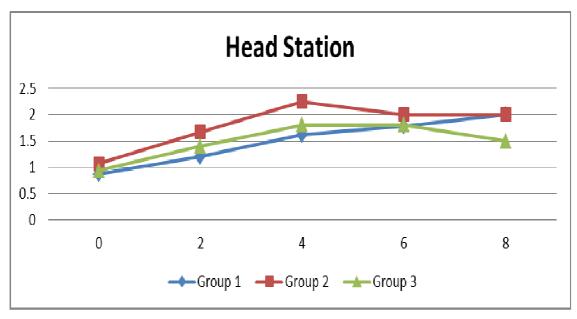
I) and control group (Group III) was having almost similar action.

Comparison of Therapeutic Effect on Station of Head in Different Groups

Intervals of assessing in	Station of Head					
hours [n]	Eranda Taila Paana Mean	Eranda Taila MB Mean	Control Group Mean			
0	0.8667	1.067	0.9333			
2	1.200	1.667	1.400			
4	1.615	2.250	1.800			
6	1.778	2.000	1.800			
8	2.000	2.000	1.500			

Scoring given was 0=-3, 1=-2, 2=-1,0, 3=+1, +2

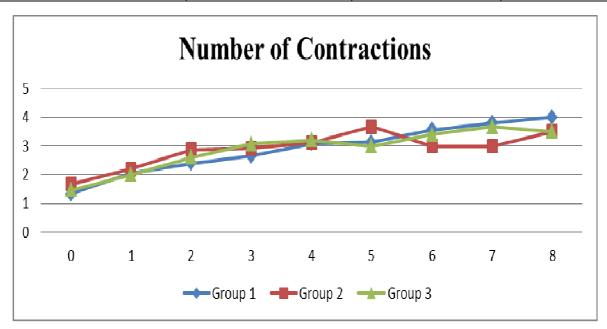
Eranda taila paana Group I and control Group III had almost similar action while eranda taila matra basti Group III had fast progress on first



four hours and then eranda taila paana Group I showed effect nearer to eranda taila matra basti Group II at the eighth hour, control group being the last.

Comparison of Therapeutic Effect between Different Groups on Number of Contractions

Intervals of Assessing in hours [n]	N	umber of Contractions		
	Eranda Taila Paana Mean	Eranda Taila MB Mean	Control Group Mean	
0	1.333	1.667	1.467	
1	2.067	2.200	2.000	
2	2.400	2.867	2.600	
3	2.643	2.917	3.071	
4	3.083	3.111	3.200	
5	3.125	3.667	3.000	
6	3.571	3.000	3.400	
7	3.800	3.000	3.667	
8	4.000	3.500	3.500	

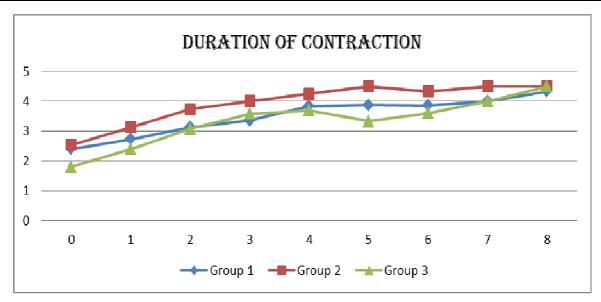


Gradual increase in number of contractions seen in eranda taila paana (Group 1) and control group (Group 3). Eranda matra basti (Group 2) going in the fast rate till 5th hour declined.

Comparison of Therapeutic Effect between Different Groups on Duration of Contractions

Scoring given as 1=10-20 sec, 2=20-30 sec, 3=30-40 sec, 4=40-50 sec, 5=50-60 sec

Intervals of Assessing in hours [n]	Di	uration of Contractions			
	Eranda Taila Paana Mean	Eranda Taila MB Mean	Control Group Mean		
0	2.400	2.533	1.800		
1	2.733	3.133	2.400		
2	3.133	3.733	3.067		
3	3.357	4.000	3.571		
4	3.833	4.250	3.700		
5	3.875	4.500	3.333		
6	3.857	4.333	3.600		
7	4.000	4.500	4.000		
8	4.333	4.500	4.500		

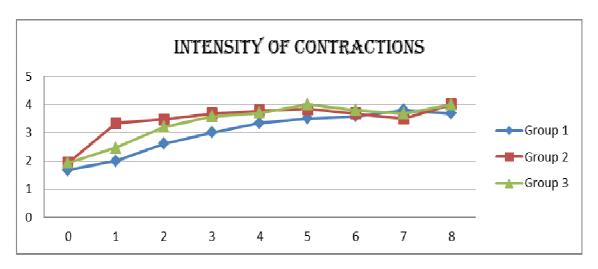


The superiority of the eranda taila matra basti Group II in bringing about the contractions of good duration was seen. Eranda paana Group I and control Group III had almost similar action. At the end of eighth hour, all three groups had similar duration.

Comparison of Therapeutic Effect between Different Groups on Intensity of Contractions

Scoring Given 1=80-85, 2=86-90, 3=91-95, 4=96-100

Intervals of Assessing in	Intensity of Contractions					
hours [n]	Eranda Taila Paana Mean	Eranda Taila MB Mean	Control Group Mean			
0	1.667	1.933	1.933			
1	2.000	3.333	2.467			
2	2.600	3.467	3.200			
3	3.000	3.667	3.571			
4	4 3.333	3.778	3.700			
5	3.500	3.833	4.000			
6	3.571	3.667	3.800			
7	3.800	3.500	3.667			
8	3.667	4.000	4.000			



The superiority of the eranda taila matra basti (Group II) in bringing about the contractions of good intensity was observed; eranda paana Group I had less intensity

compared to other two groups. Control Group III was going in parallel from third hour with almost same intensity as eranda taila matra basti group.

Comparison of Bishop Score in Different Treatment Groups

Intervals of Assessing		Bishop Score	
Bishop Score [n]	Eranda Taila Paana	Eranda Taila MB	Control Group
0	1.93	2.53	1.733
2	3.6	4.8	4.26
4	4.92	6.75	5.5
6	6	7	7
8	6.8	7.5	6.5

Improvement in the Bishop score in the eranda taila matra basti Group II was faster than in the other groups.

Comparison of Time Taken for Stages of Labor

Time taken for first stage of labor

Groups	Mean Score in Min		One-Way ANOVA					
		SD	SE	DF	SS	MS	F	Р
Eranda paana [15]	452.67	126.74	32.725	44	672974	62582	3.570	0.0370
Eranda MB [15]	341.67	130.57	33.713					
Control [15]	420.33	89.292	23.055					

The differences in the mean values among the treatment groups are significantly greater than expected by chance. The P value is 0.0370, considered significant. (Hours were converted into minutes; mean value of eranda taila paana group is 7.53 hours with maximum being 12 hours and minimum being 5.16

hours; mean value of eranda matra basti group is 5.69 hours with maximum being 10 hours and minimum being 3.5 hours and mean value of control group is 7.00 hours with maximum being 10 hours and minimum being 4.5 hours.)

Time Taken for Second Stage of Labor

Groups	Mean Score in Min	One-Way ANOVA						
		SD	SE	DF	SS	MS	F	Р
Eranda paana [15]	23.800	16.925	4.370	44	6498.8	229.84	0.5224	0.5969
Eranda MB [15]	22.933	9.468	2.445					
Control [15]	19.467	8.766	2.263					

The differences in the mean values among the treatment groups are not significantly greater than expected by chance. The P value is 0.5969, considered not significant.

Time Taken for Third Stage of Labor

Groups	Mean Score in Min	One-Way ANOVA						
		SD	SE	DF	SS	MS	F	Р
Eranda paana [15]	5.467	2.416	0.6239	44	446.58	44.68	4.004	0.0256
Eranda MB [15]	8.467	3.114	0.8040					
Control [15]	7.600	3.355	0.8663					

The differences in the mean values among the treatment groups are significantly greater than expected by chance. The P value is 0.025, considered significant.

Incidence of Requirement of Other Drugs

Group	Oxytocin	Tramadol	Epidosin	Methergin
Eranda Paana [15]	9(60%)/8.951U	2(13.3%)	4(26.67%)	6(40%)
Eranda MB [15]	5(33.33%)/6IU	5(33.3%)	2(13.33%)	12(80%)
Control [15]	15(100%)/26.75IU	4(26.7%)	9(60%)	12(80%)

Mean of Systolic and Diastolic Blood pressure

	Mean of Systolic Blood Pressue		Mean of Diastolic Blood Pressure	
Group	ВТ	AT	BT	AT
Eranda Taila Paana [15]	1.6667	2.1333	1.6667	2.1333
Eranda Taila Matra Basti [15]	1.6000	2.1333	1.6000	2.0000
Contro I[15]	1.4667	1.8000	1.4000	1.8000

Scoring Given 1=100-120 mmHg, 2=120-140 mmHg, 3=140-160 mmHg

On analysing the data of subsequent recordings of systolic and diastolic blood pressure at the time of admission and after drug administration there was not much difference found. Minimal increase in blood pressure was to be physiological during labor.

Discussion

The recent trend of obstetric practice is looked upon with the view of active management during labor, with the advantages it offers in expedite delivery within 12 hours, without increasing maternal morbidity and perinatal complications like prevention of prolonged labor and with its attendant complications of infections, ketosis, dehydration, exhaustion and disillusionment in the mother as well as fetus.

It becomes a necessity to be equipped essentially with the safe and effective drugs to induce, enhance or augment and to shorten the labor whenever necessary. In Ayurvedic classics, references for a number of drugs are available at various instances like sukhaprasava, vilambita prasava, garbasanga, aparasanga and moodagarbha. There is a need to explore and establish an oxytocic drug from the indigenous system of medicine for active management of labor. Thus the above study is planned with the selection of drug eranda to see its action in augmenting labor.

On observations of the mean values of cervical dilatation, cervical effacement, head station, number, duration and Intensity of contractions in groups, there is overall good progress in Group II, i.e., eranda taila matra basti group compared to other two groups.

It was seen that in Group II the progress being good till 5 hours decreases at 6th hour, the reason for which may be explained as:

- Its action might have declined due to its reducing active principle concentration in the body after 5 hours.
- Majority of the patients, i.e., 80% delivered by 6 hours with good progress leaving behind the patients with slow progress.
- Similar observations were seen in the study done by Mamatha on a comparative study on role of vasa swarasa and eranda taila in sukha prasava where it

was said that the concentration of the drug eranda decreased after 4–6 hours of administration. ¹⁰

In Group I eranda taila paana group, there was gradual and slow progress observed throughout the process of labor. The efficacy was not good enough in comparison to Group II. The number, duration and Intensity of contractions were not that strong due to which 53.33% patients required induction in late first stage and second stage of labor.

Group III control group and Group II eranda taila matra basti almost had nearer action on cervical dilatation and at 6 hours on cervical effacement. It also had a good number of contractions and intensity almost similar to Group II. The duration of contraction was similar to eranda taila paana Group I and had slow progress on descent of head compared to other two groups may be due to its gradual and rhythmic progress on labor.

Bishop Score

- The present study gives an opinion that eranda is beneficial in improving the Bishop's score than control group with induction of oxytocin.
- Eranda taila when given through matra basti, its
 action was fast compared to eranda taila paana
 Group I, might be because of the fast absorption
 through rectal mucosa and as the oral drug has to
 surpass the liver metabolism to show its action.
- These findings suggest that the drug is beneficial in improving the Bishop's score and thereby affecting successful labor progression. If the score is high, chances of early and successful delivery are more.

Time Taken for Different Stages of Labor

The mean time taken for full cervical dilatation in different groups was 7.53, 6.09, 7.00 hours respectively in eranda taila paana Group II, eranda taila matra basti Group II and control Group III, with fast completion in Group II with statistical significance of p value 0.0370. Time taken for second stage of labor in different groups was 23.800, 22.933 and 19.467 minutes respectively in Group I, Group II and Group III. Group III being infused with continuous oxytocin, with its sustained action resulted in good bearing down and swift delivery. Though there is difference in the mean values, it is statistically insignificant. Time taken for third stage of labor was 5.467, 8.467 and 7.600 minutes which is statistically significant with P value 0.0256.

Discussion on Incidence of Mode of Delivery

In eranda taila paana group out of 15 patients, 4 (26.67%) patients because of insufficient pain and 1

(6.7%) patient due to fetal distress, required induction in late first stage of labor, 3 (20%) patients required induction in second stage of labor because of poor bearing down efforts. Total 14 (93.33%) patients delivered with episiotomy and 1 (6.67%) patient without episiotomy.

In eranda taila matra basti group, out of 15 patients, 1 (6.7%) patient required induction in late first stage of labor because of insufficient pain, 2 (13.4%) patients had fetal distress because of poor bearing down efforts the fetus being at perineum for long time landed in distress which required induction in second stage of labor, Thus the fetal distress may not be due to drug effect. In other 2 (13.4%) patients also due poor bearing down efforts required induction in second stage of labor. Total 11 (73.33%) patients delivered with episiotomy, 1 (6.7%) with vacuum-assisted episiotomy delivery and 3 (20%) without episiotomy.

In control group out of 15 patients, 13 (86.67%) patients delivered with episiotomy and 2 (13.4%) patients without episiotomy.

Requirement of Other Drugs

Oxytocin

Out of the three groups, control Group III, all patients were infused with Oxytocin, patients required total 26.75 IU. In eranda taila paana group 60% of patients required total 8.95 IU of Oxytocin due to its slow progress and insufficient pain. In eranda taila matra basti group 33.33% patient in total needed 6 IU Oxytocin mostly in second stage of labor due to poor bearing down efforts which was statistically not significant.

Inj. Tramadol Hydrochloride was used as analgesic, antispasmodic and mild sedative. In eranda taila paana group only 13.3% patients required Inj. Tramazac. In eranda taila matra basti group 33.33% patients required Tramazac. This shows that contractions in eranda matra basti were strong enough to cause discomfort and pain and in control group 26.5% of patients required inj. Tramazac, which is statistically insignificant.

Inj. Valethmate Bromide: Used mainly for effacement and dilatation of cervix. In eranda taila paana group 26.67% patients and only 13.33% patients in eranda taila matra basti group required Epidosin; by this we can say that eranda along with increasing uterine contraction also enhances cervical dilatation. In control group highest 60% patients needed Epidosin which was statistically significant with P value 0.021.

Action of Basti

Basti is one of the principal treatments for vata. Acharya vagbhata explained that virya of drug is transferred successively from apana to other vata and maintain normalcy similarly, the eranda taila by its ushna virya and tikshna guna reaches to all the minute channels there by does vatanulomana and maintains normalcy of vata.

Guda being moola of siras, the active principle of eranda taila gets absorbed and augments the avi. This can be understood as viscera's in body are supplied by autonomous nervous system and when basti is administered there may be stimulation of autonomic nervous system - stimulates hypothalamus to secrete oxytocin and increases uterine contractions.

Matra basti can stimulate the ENS (enteric nervous system) and thus it can influence the central nervous system and all bodily organs. Apart from its influence on GIT, ENS also influences the autonomic nervous system thereby producing systemic effects. As it is explained by Goyal and Hiram (1996) it is involved in immune and inflammatory process, so we can say that basti shows their local and systemic effect and help in uterine contractions.

Conclusion

In the present study, eranda taila matra basti group showed best results than the other study groups by augmenting the labor and reducing duration of first stage of labor.

On observations done in the study, its gives further scope of using eranda taila matra basti in increased doses or another administration of basti with ensuring the safety is advisable after 5 hours of first dose in patients who have slow progress of labor. In eranda taila paana, whether another dose can be given has to be thought as it may produce excess purgation leading to dehydration and its associated complications.

Conflict of Interest: None

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