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A RANDOMISED CONTROLLED CLINICAL TRAIL ON THE EFFECT OF *VASA APAMARGA VARTI* IN *SUKHAPRASAVA*

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ABSTRACT

The WHO defines "normal birth" as spontaneous in onset, low risk at the start of labour and remaining so throughout labour and delivery. The process of normal childbirth is categorized in three stages of labor: the shortening and dilatation of cervix, descent and birth of the infant and the expulsion of the placenta. *Ayurvedic* texts have described that at the onset of labour the head of the fetus gets turned and comes forward due to action of *prasutimaruta* and is expelled through the vaginal passage. This is *sukhaprasav*, other situations are abnormal. The present study was carried out to evaluate the role of *Vasa apamarga varti* in the management of *sukhaprasava*. 30 female patients with 9 months ammenorrhea were registered for the present research work and were divided into 2 equal groups. 15 patients were treated with Trial group drug i.e. *Vasa Apamarga varti* and 15 patients were treated with Control group drug i.e. *Shatavari Varti*. After conducting clinical trial on 30 patients, observation and results were obtained. Statistical analysis shows that both trial and control drug were significantly effective to conduct normal delivery. The comparison between groups A to group B for the assessment parameters shows highly significant ($p < 0.001$). Normal labor with vaginal delivery in Group A patients is 80% at third follow up, whereas improvement (with operative delivery) is seen in 20 % cases. In Group B, improvement (with operative delivery) is seen in 13% cases, whereas 86.6% cases shown no improvement.

Keywords: Normal labour, *Sukhaprasav, Vasa, Apamarga, Shatavari,Varti.*

INTRODUCTION

Womanliness means only motherhood. Motherhood provides one of the most intimate bonds that can exist between two human beings. To become mother is an earnest desire and a great honor to a woman. Labour & delivery are the focus and climax of the reproductive process. They are both a physical and emotional challenge for the mother and hazardous journey for the fetus. Labour can be defined as the process by which regular painful contractions bring about effacement & dilatation of the cervix & descent of the presenting part, ultimately leading to expulsion of the fetus and placen-

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ta from the mother. Though labour is a physiological process of the female, sometimes it may lead to abnormality which hampers the life of mother and fetus. A normal labour can become abnormal at any stage. Uterine inertia or uterine dysfunction, fetal distress, postpartum haemorrhage etc are the abnormal conditions of labour. *'Prasava'* or *Garbhanishkramana*[1] is the function of *'Apanavayu'*. Along with *Apanavayu, vyanavayu* also takes part in induction of labour or *Aavi* (uterine contractions). If function of both these *vayus* alters then *'Aavi'* becomes exaggerated or diminished or irregular causing *vilambitaprasava*. So any cause which vitiates *apanavayu* is cause for abnormal uterine function. The labour is said to be prolonged when the combined duration of first and second stage is more than the arbitrary time limit of 18 hours. In day today practice of obstetrics many patients are observed undergoing *vilambita prasava*[2] and main cause is *Vilambita Aavi*. At present drugs with good oxytocic activity like oxytocin, prostaglandins etc are used for the management of hypotonic inertia. *Ayurvedic* practitioner has some limitations to use the modern drug. So, a classical remedy to avoid all such adverse effects is necessary. Our *acharyas* told some drugs for *Sukhprasava*, with the help of these drugs labour can be completed without any complication. *Vasa & Apamarga* was told by both *Chakradatta*[3]*& Vangasen*[4]for *sukhprasava*. These drugs were administered in the form of *yoni varti*. In this present study a possible effect of *Vasa Apamarga Varti* was evaluated.

AIMS AND OBJECTIVES

1. To achieve normal vaginal delivery within normal duration & without any complications
2. To evaluate efficacy of *Vasa Apamarga Varti* in *sukhaprasava.*

MATERIALS AND METHODS

30 patients were admitted with true labour pains in IPD of *Prasooti tantra and Striroga* department of Major S. D. Singh P. G. Ayurvedic Medical College & Hospital, Farrukhabad, diagnosed as true labour pains were registered for the study. The complete details of the patients were recorded as per a detailed proforma consisting of all the relevant data.

Treatment Protocol

A single blind clinical study on *Vasa Apamarga Varti* was done to see its effect on labour. In study, total 30 patients were selected and assigned into 2 groups. In each group 15 patients are taken.

Group A – Trial group: *Vasa Apamarga-Varti* was kept in posterior fornix at the interval of 2 hour according to response of patient. Recording of Pulse, B.P., F.H.S., and Partography was done after application of *varti.*

Group B – Control Group: *Shatavari Varti* in posterior fornix at the interval of 2 hour according to response of patient. Recording of Pulse, B.P., F.H.S., and Partography was done after application of *varti.*

Selection Criteria:

a) Inclusive Criteria:

1. Patient willing to take part in this study
2. Age group 20 to 30 yrs
3. Primigravida with vertex presentation.
4. Patients who gave written informed consent.

b) Exclusive Criteria:

1. CPD
2. Multiparous women
3. Malpresentation
4. Placenta previa
5. APH

6. High risk pregnancies including jaundice, pre eclampsia, anemia ,twins , PIH etc.
7. Elderly primigravida
8. Pre-existing diseases like DM, Heart disease etc .

Diagnosis and clinical observation:

The diagnosis of true labour pains was done on the basis of detailed clinical study and with the help of per vaginal examination. In history taking following points are emphasized like age, occupation, socioeconomic status, past history (medical/ surgical) of illness, family history, history of present illness, chief complaints, associated complaints, investigations, previous menstrual history, contraceptive history, *ashtavidhapariksha*, , general examination, systemic examination, *garbhinipariksha*, abdominal examination, vaginal examination, partogram.

All investigations were done which includes haemogram, blood group, urine routine, HIV, VDRL, Hbs Ag, third trimester USG.

Parameters of assessment:

The main criteria for assessment of therapeutic trials were based on.

1. Maintaining partograph, duration of first and second stages of labour in hours.
2. No. of contraction/10 minutes before treatment and after treatment at 3 hrs, 6 hrs, 9 hrs.
3. Duration of each contraction in seconds before treatment and after treatment at 3 hrs, 6 hrs, 9 hrs.
4. Station of head in relation to ischial spine before treatment and after treatment, recorded in figures (-3,-2,-1,0,+1,+2,+3) at 3 hrs, 6 hrs, 9 hrs.
5. Cervical dilatation in cms before treatment & after treatment at 3 hrs, 6 hrs, 9 hrs.
6. Cervical effacement in % before treatment & after treatment at 3 hrs, 6 hrs, 9 hrs.
7. Total duration of labour including three stages in hour.
8. Apgar score of delivered baby at 1st min. and 5th min. in figures (0-10)
9. Bishops score at the time of admission.
10. **Score for Assessment:**
11. **I. Descent of Head:**
12. 3 → Zero Station
13. 2 → +1 Station
14. 1 → +2 Station
15. 0 → +3 Station
16. **II. No. of contractions:**
17. 3 → 1/10 Minutes
18. 2 → 2/10 Minutes
19. 1 → 3/10 Minutes
20. 0 → 4/10 Minutes
21. **III. Duration of contraction:**
22. 3 → 30 – 45 Seconds
23. 2 → 45 – 60 Seconds
24. 1 → 60 – 75 Seconds
25. 0 → 75 – 90 Seconds
26. **IV. cervical dilatation :**
27. 3 → 0 to 2 cm
28. 2 → 2 to 4 cm
29. 1 → 5 to 7 cm
30. 0 → 8 to 10 cm
31. **V. cervical effacement:**
32. 3 → 0 to 20 %
33. 2 → 20 to 40 %
34. 1 → 50 to 70 %
35. 0 → 80 to 100 %

Results: The result of whole study is graded as follows

(67-100%) - Normal labour with vaginal delivery

(34-66%) - Improved (with operative delivery)

(0-33%) - No improvement

Using the partograph:[5]

A partogram provides a composite record of all the important features of labour on a single sheet. Delay in labour can be detected early by the use of a partogram and

timely correction of dysfunctional labour is possible. Many variations of the original partogram are now in use, modified to suit the local circumstances. The WHO partograph has been modified to make it simpler and easier to use. The latent phase has been removed and plotting on the partograph begins in the active phase when the cervix is 4cm dilated.

Record the following on the partograph:

Patient information: Fill out name, gravida, para, hospital number date and time of admission and time of ruptured membranes.

Fetal heart rate: Recorded every half hourly.

Cervical dilatation: Assessed at every vaginal examination and marked with a cross (X). Begin plotting on the partograph at 4 cm.

Alert line: A line starts at 4 cm of cervical dilatation to the point of expected full dilatation at the rate of 1 cm per hour.

Action line: Parallel and 4 hours to the right of the alert line.

Apgar score:

It is used to assess neonatal oxygenation status at birth; calculated at 1st and 5th minutes after birth of baby. One minute score indicates need for immediate resuscitation of new born, while 5 minute score correlates well with long term neurological sequelae. It is based on degree of cardio respiratory and neurological depression present. It is introduced by Virginia Apgar (in 1953).

BISHOPS SCORE[6]:

Bishop's score, is a pre-labour scoring system to assist in predicting whether induction of labor will be required.

Components

The total score is achieved by assessing the following five components on vaginal examination: The Bishop score grades patients who would be most likely to achieve a successful induction. The duration of labor is inversely correlated with the Bishop score; a score that exceeds 8 describes the patient most likely to achieve a successful vaginal birth. Bishop scores of less than 6 usually require that a cervical ripening method be used before other methods.

Scoring

Each component is given a score of 0-2 or 0-3. The highest possible score is 13.

Scoring is done with following values and observations.

Table.no.1

Score/ Parameter	0	1	2	3
Position	Posterior	Intermediate	Anterior	-
Consistency	Firm	Intermediate	Soft	-
Effacement	0-30%	31-50%	51-80%	>80%
Dilation	0 cm	1-2 cm	3-4 cm	>5 cm
Fetal station	-3	-2	-1, 0	+1, +2

Interpretation

A score of 5 or less suggests that labour is unlikely to start without induction. A score of 9 or more indicates that labour will most likely commence spontaneously. A low Bishop's score often indicates that induction is unlikely to be successful. Some sources indicate that only a score of 8 or greater is reliably predictive of a successful induction.

Drug Review:

Properties of *Vasa (Adhatoda vasica)* [7]

Rasa – Tikta, kashaya

Guna – Laghu, Ruksha
Virya – Sheeta
Vipaka – katu
Doshakarma – kaphapittaghna ,hrudya ,swarya.

Chemical Analysis of *Vasa* (*Adhatoda vasica*)[8]

1. Uterotonic activity of vasicine in different species of animals in vitro was similar to oxytocin & methylergometrin. (IJMR,1977,66,865)
2. Vasicine showed abortificient effect in guinea pigs depending on stage of pregnancy. (INDIAN J.EXP.Biology, 1978, 16,1075)
3. Vasicine produced marked potentiation of contractile response of isolated uterus to oxytocin .It potentiated oxytocin response in isolated mammary strips of rat .(Gautam & Sharma , 1982)
4. Vasicine causes contraction & rhythmic contractile movements of uterus which is causes abortificient activity in laboratory animals without undesirable effects. At the dose of 60 mg & above it proved effective to terminate the pregnancy & negligible blood loss. It acts through release of endogenous prostaglandins & hence may be used as a ideal abortificient (C.K. Atal RRL Jammu)

2. ***Apamarga*** *(Achyranthes aspera)*[9]

Properties:-

- *Rasa – katu , tikta ,*
- *Vipaka – katu*
- *Veerya- ushna*
- *Gunas – laghu ,ruksha , teekshna , sara.*
- *Doshghnata – kaphavataghna.*

Pharmacological Actions:-

Anti fertility activity: It is extensively used as an anti fertility, contraceptive, abortificient in folk medicine.[10]

Method of preparation of *Varti*[11]

Usually the *varti* is prepared by two methods. 1) Medicinal drug were made in to fine powder form. Then these contents are mixed uniformly in syrup made of jaggery and molded into required size and shape of *varti.* 2) *Varti* is also made up by grinding the fine powder of the drugs with the fluids specified in the formulae to form a soft paste. Then this is made into *varti* form according to required size and shape. For making the *gudavarti* the *guda* [jaggery] is used as a base. In certain condition the *guda* should be equal to the quantity of the *dravyachurna*. First of all *guda* and appropriate quantity of water is mixed and *guda* is dissolved in water. Then this liquid is filtered with cloth. Then the obtained liquid is allowed to make *paka* by heating. When proper *paka* is attained, during that time the vessel is taken from the fire and respective *dravyachurna* is mixed little by little uniformly. ***Varti*:** *"Vartateanyateetivarti'* is one among the *sthanikachikitsa* having *shodhana* properties and stay for longer duration in site is selected for this study. A *varti* basically comes under *kalka kalpana*.

Various varieties are explained in our classics. They differ in shape and size, are elongated with tapering end and slightly broader in the middle, they help in expelling the collected *mala, mutra, puya, rakta, kapha etc doshas.* Depending upon the site and action, *varti* is classified in to different types in that *yoni varti* is one among them. In this study *Apamarga (500mg) & Vasa (500mg) varti* was prepared for *sukhprasava.* From this 1 gm *varti* is prepared. The *varti* is administered at onset of true labour pains & repeated at 2 hourly according to progress of labour.

OBSERVATIONS AND RESULTS

Table no.2 : Showing overall effect of therapy

	Trial group						Control group					
	AT1		AT2		AT3		AT1		AT2		AT3	
	No. of pts	%	No. of pts	%	No. of pts	%	No. of pts	%	No. of pts	%	No. of pts	%
Normal labour with vaginal delivery (67-100%)	0	0	3	20	12	80	0	0	0	0	0	0
Improved (with operative delivery)(34-66%)	9	60	9	60	3	20.	1	6.67	1	6.67	2	13.33
No Improvement (0-33%)	6	40.	3	20.	0	0	14	93.33	14	93.33	13	86.6

This table shows standard error and mean of assessment parameters and percent of improvement of both groups at first, second, third follow up. The comparison between group A to group B for the assessment parameters shows highly significant ($p< 0.001$). Normal labor with vaginal delivery in Group A patients is 80% at third follow up, whereas improvement (with operative delivery) is seen in 20 % cases. In Group B, improvement (with operative delivery) is seen in 13% cases, whereas 86.6% cases shown no improvement.

DISCUSSION

When all three stages of labor occurs without any complications & in normal time period, then we can say it as *Sukhaprasava.* During labor *ApanaVayu* plays a great role. Detailed description about process of labor & its management is given in Ayurvedic & modern classics. Present study was carried out on *Varti* prepared by *Vasa & Apamarga* which is placed in posterior fornix during onset of true labor pains. Animal study has shown oxytocic activity of *vasa apamarga* without any major side effects and complications. Vital parameters related to normal labour like change in station of head, cervical dilatation & effacement, number of contractions in 10 minutes, duration of contractions were analyzed after insertion of *'varti'* at 2 hourly interval and observations are noted at 3 hrs, 6 hrs, and 9 hrs duration. Two groups were made for study. Group A consists 15 patients in whom *Vasa Apamarga-Varti* is kept and Group B consists 15 patients in whom *Shatavari Varti* (placebo) is kept. In each group, all patients were 18 to 30 years age and primigravida. To assess effect of *Vasa ApamargaVarti* the drug has been tried on primigravida patients only to nullify the effect of laxity of muscles on labour and to avoid precipitate labour if at all, as generally occurs in multigravida. For

progress assessment Partograph was prepared for all patients.

At first follow up, in Group A there was highly significant effect on cervical dilatation, effacement, descent of head & duration of contraction as p value is < 0.001 and has shown significant effect on number of contractions as the p value is <0.01. At second follow up also in Group A there was highly significant effect on cervical dilatation, effacement, descent of head & duration of contraction as p value is < 0.001 and has shown significant effect on number of contractions as the p value is <0.01. In third follow up, group A patients has shown highly significant results on all the parameters.

It was observed that in Group B patients there was no any remarkable change noted after insertion of *ShatavariVarti*. Out of 15 patients two were having good contractions with effacement at the time of admission & timely dilatation of cervix , has delivered normally. Other remaining patient did not show significant improvement in the assessment parameters.The difference of observations of both groups were statistically proved to be highly significant (p< 0.001)

Total duration of all three stages taken by patients in Group A was between 8 – 10 hrs & that of Group B patients was between 10 – 14 hrs. In group A twelve patients delivered vaginally with normal labour without any complication and good neonatal apgar score. In group A, out of remaining three patients one delivered vaginally with cervical tear & mild PPH, one was assisted delivery with ventouse and third one underwent caesarian section for fetal distress in which it was found to have cord around neck twice and baby weight 3.5 kg.

Probable mode of action of drug

1. *Vasa* and *Apamarga* is having oxytocic property and uterine stimulant activity due to its *guna, karma* and *prabhava.*
2. It regulates the function of *Apanavayu.*
3. *Vasa* and *Apamarga* acts on uterine myometrium and causes contraction.
4. The active principles of drugs get absorbed through mucosal layer of vagina.
5. It doesn't cause any adverse effects on fetus.
6. No local and systemic adverse effects seen on mother.

CONCLUSION

In third follow up, group A patients has shown highly significant results on all the parameters. In group A twelve patients delivered vaginally with normal labour without any complication and good neonatal apgar score. It is economic, easily available and easy to administer. It doesn't cause any adverse effects on fetus. No local and systemic adverse effects seen on mother.It can be taken into consideration for routine practice for active management of labour. A further research is required for using *Vasa* and *Apamarga* drugs for induction of labour.

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