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A CLINICAL STUDY TO EVALUATE THE EFFECT OF AN AYURVEDIC PREPARATION ON THE PHENOMENON OF LABOR

[1]Dr Priyanka [2]Dr Chawla Kumar Satbir

[1]Lecturer, Prasutitantra & Striroga Department, Chaudhary DeviLal College of Ayurveda, Yamuna Nagar, Haryana.[2]Lecturer, Agadtantra Department, Glocal College of Ayurvedic Medical Sciences and Research centre, Saharanpur, Uttar Pradesh-India.

ABSTRACT

Ayurveda is serving the humanity till from the beginning of life on this earth. Even today every field of our life is touched by *ayurveda* directly or indirectly. The present study is an example of contribution of *Ayurveda* in day-to-day life. This study helps in reducing the pain felt by every woman during labour. The aim is to reduce the intensity and duration of the labour pain and also the incidence of caesarean and forceps application during delivery. Present study includes the use of *Anuvaasana basti* and *picchu* of *taila* medicated with *dravyas* of *madhuragana* in the 9th month of pregnancy for *Sukh-Prasava*as mentioned in *Ayurveda.* The trial drug was prepared by the *murchita taila* named *Balyam-1 (Kalpita yoga).*The 30 registered patients *(*Primigravida) were selected randomly, which were given *Anuvaasana basti* fortnightly and *Picchu* applied daily from the beginning of 32 week till delivery with *Balayam-1*. Laboratory investigations Hb%, Blood group with Rh factor, TLC, DLC, ESR, BT, CT, HIV, VDRL, HBsAg, FBS, Lipid profile, LFT, Blood urea, Serum Creatinine, Urine (Routine and Microscopic), Ultrasonography were also assessed. The trial drug showed highly significant results ($p<0.001$) by effectively reducing the standard mean duration in all the three stages of labour. Hence the trial drug *Balayam-1* can be effectively used to reduce the intensity and duration of labour pain.

Keywords: *Picchu*, *AnuvasanaBasti*, *BalyamTaila*, Labour

INTRODUCTION

Pregnancy and birth are the most crucial passages in a woman's life. Pregnant women undergo emotional and physical changes during pregnancy and it usually start from the moment they are conceiving or when fertility occurs. The symptoms of pregnancy and the level of difficulty experienced are different for every woman. In *Ayurveda acharya Charaka* described *Garbhini Paricharya* which describes *Ahara* (diet), *vihara* (life style) and *vichara* (thought process) to be followed by pregnant woman during pregnancy[1]and she will be able to deliver a child with good health with ease. But generally labor is a complex synchronized process and an obstruction at any stage during the mechanism of labor can be fatal to both mother and the child. *Acharya Sushruta* says that as a ripened fruit naturally detaches from its stalk at its own course of time, similarly *Garbha* in its appropriate time also detaches from its *Nadinibandha* and proceeds for *prasava*[2]. *Acharya Charaka* has

mentioned the use of *Anuvaasana Basti* and *Pichu* of oil medicated with *Madhuragana dravyas*[3] for example *shalparni, vidari, bala*etc.[4] having the combination of *jala* and *prithvi mahabhoota* and due to their *adhogami, guruta* and *vata-shamaka* properties they facilitate easy expulsion of the fetus without any obstruction and also provides strength to the muscles and boost the immunity[5] i.e. *sukha* and *nirupdrava prasava*a it helps lubrication of garbhasthana (uterus but here cervix) and garbhamarga (vaginal canal and perineum). In *Ayurveda*, the duration of *Prasava* is not clearly mentioned though the deleterious effects and methods of treatment of *vilambita prasava* available[6]. As per the Ayurvedic concepts any obstruction at any stage of mechanism of labor can attributed to *vatavaigunya* which may hamper the normal *nishkramana kriya* of *garbha* which is *karma* of *apanavayu*. In order to normalise the function of *vata* the use of *sneha* are done. *Taila* is considered as the best *shamanaaushadha* of *vata*. The use of oil medicated with *madhura drvyas* as *Anuvaasana Basti* and *Pichu* from the beginning of 9th month (32 weeks) of pregnancy keeps the *vatadosha* in *samayaavastha* which is aggravated during labor pains[7] and it ultimately results in reducing the intensity of labor pain and decreases the time of stages of labor. The present clinical study has been conducted keeping in view, to reduce the pain and problems felt by every pregnant women during the time of labor and delivery. The trial medicine helps in providing the effective, economical and complication free modality of treatment. Hence the present study has been undertaken to normalise the complicated procedure of mechanism of labor before its starting through simple means of treatment for the purpose of *Nirupadrava prasava*.

AIMS AND OBJECTIVES

- To study the effect of trial drug *(Balyam-1)* on labor regarding its stage wise duration with incidence of caesarean section, forceps application and requirement of episiotomy.
- Psychological preparation of the patient for comfortable labor.
- Monitoring of the patient for any complication arising after treatment.

MATERIALS AND METHODS

Selection of drug

Acharya Charaka has advised use of *Auvaasana basti* and *Pichu* with oil prepared with the drugs of *Madhura Gana* (groups) in the 9th month[3].

Preparation of drug

The trial drug was prepared in *Charaka* pharmacy of R.G.G.P.G. Ayurvedic College Paprola, under supervision of *RasShashtra* Department of the college. Initially the *murchhana* of *TilaTaila* was carried out as mentioned in *Bhaishajya Ratnavali*[8]. Then *Balyam taila-1* was prepared with *Taila pakavidhi*[9]

Table 1: Dravyas forMurchhana

S.no.	Drug	Botanical Name	Quantity
1.	*TilaTaila*	*Sesamum indicum*	4 liters
2.	*Manjistha*	*Rubia cordifolia*	250 grams

3.	*Amalaki*	*Emblica officinalis*	60 grams
4.	*Vibhitaki*	*Terminalia bellirica*	60 grams
5.	*Haritaki*	*Terminalia chebula*	60 grams
6.	*Tvaka*	*Cinnamomum cassia*	60 grams
7.	*Ketaki*	*Pandanus fascicularis*	60 grams
8.	*Musta*	*Cyperus rotundus*	60 grams
9.	*Lodhra*	*Symplocosracemosa*	60 grams
10.	*Vata*	*Ficus bengalensis*	60 grms
11.	*Haridra*	*Curcuma longa*	60 grams
12.	Hribera	*Juniperus communis*	60 grams

Table 2: KwathaDravyas

S.no.	Drug	Botanical Name	Quantity
1.	*Bala*	*Sida cordifolia*	1 part
2.	*Shalaparni*	*Desmodium ganneticum*	1 part
3.	*Vidari*	*Pueraria tuberosa*	1 part
4.	*MurchhitaTilaTaila*	*Sesamum indicum*	12 part

Selection of patient

For the present study, 30 registered patients, fulfilling the inclusion criteria and after their consent, were randomly selected from the OPD and IPD of P.G. Dept. of Prasuti Tantra evum Streeroga of R.G.G.P.G.Ayu. College and Hospital, Paprola, (H.P.)

Inclusion criteria

- Pregnant women who were willing for trial and primigravida between 32-36 weeks of pregnancy were randomly selected for the trial with age group between 20-35 years.
- Patients having adequate pelvis, border line pelvis and cephalic presentation.

Exclusion criteria

- Patient not willing for trial.
- Age group < 20 years and >35 years.
- Patients having cephalopelvic disproportion, absolute contracted pelvis, history of APH and Malpresentation.
- Patients having systemic disease like diabetes mellitus, hypertension, tuberculosis, jaundice, heart disease, epilepsy, and ascites.
- Disease related to pregnancy like eclampsia, pre-eclampsia, poly-hydramnios etc.
- Malignancy of genital tracts.

Plan of study

A detailed research performa (case history sheet) was prepared to note down all the details of the patients and disease. The selected 30 patients were given *Anuvaasana basti* (*matrabasti*) and *Yoni Pichu* daily with *balyamtaila 1*.

Duration - *Anuvaasana Basti* fortnightly and *Yoni pichu* daily till delivery

Anuvaasanabasti - 60 ml

Pichu - Soaked with *Balyam taila1*

Parameter of evaluation

Clinical result was assessed by observing whether the patient had *Sukha* and *Nirupadrava Prasava* or not. For that, following criteria of scoring and criteria for assessment of therapy were adopted:-

Table 3: Gradation Index

S.no.	Criteria	Grade
1.	**Onset of Nature of labor**	
	Spontaneous	0
	Induced	1
2.	**Duration of Stages of Labor**	
	Duration of 1st stage	
	Less than mean duration	0
	Equal to mean duration	1
	More than mean duration	2
	Duration of 2nd stage	
	Less than mean duration	0
	Equal to mean duration	1
	More than mean duration	2
	Duration of 3rd stage	
	Less than mean duration	0
	Equal to mean duration	1
	More than mean duration	2
3.	**Mode of Delivery**	
	Normal vaginal delivery without episiotomy	0
	Normal vaginal delivery with episiotomy	1
	Forceps delivery	2
	Lower Segment Caesarean Section	3

Table 4: On the basis of assessment criteria patients were given following Grades

Criteria	Grade I	Grade II	Grade III	Grade IV
Onset of labor	0	0	0 or 1	0 or 1
Duration of stages	0	0	1	2
Mode of delivery	0	1	2	3

GRADE I (score not >0**):** Patients having Spontaneous Normal vaginal delivery with spontaneous onset of labor and duration of stages less than standard mean duration.

GRADE II (score not>1**):** Patients having Normal vaginal delivery with episiotomy, spontaneous onset of labor and duration of stages less than standard mean duration.

GRADE III (score not>9**):** Patients havingvaginal delivery assisted with forceps, onset of labor either spontaneous or induced and duration of stages equal to standard mean duration or more.

GRADE IV (score not>15**):** Patients having delivery by Lower Segment Caesarean Section, onset of labor either spontaneous or

induced and duration of stages greater than standard mean duration.

Criteria for assessment of overall effect of therapy according to grading

Grade I	-	Marked
Grade II	-	Moderate
Grade III	-	Mild
Grade IV	-	No effect

Laboratory Investigations

- Haematological examination - Hb%, Blood group with Rh factor, TLC, DLC, ESR, BT, CT, HIV, VDRL, HBsAg, FBS, Lipid profile, LFT, Blood urea, S.Creatinine.
- Urine – Routine and Microscopic examination.
- Ultrasonography

Statistical analysis

The information regarding demographic data is shown in percentage. Analysis of criteria of assessment was done statistically in form of mean score and its comparison with the standard values using unpaired't' test. Results were considered significant or insignificant depending upon the value of 'p'.

Highly significant	$p<0.001$
Significant	$p<0.01$; $p < 0.05$
Insignificant	$p>0.05$

OBSERVATIONS AND RESULTS

Present study was conducted on 30 patients, out of which 3 patients discontinue before delivery. So, among 27 patients included in the study, maximum 83.33% patients belong to age group 20- 25 yrs. 100% patients belong to Hindu community. Maximum 76.66% patients had education up to higher secondary. 90% were housewives, 66% patients belongs to middle class.Maximum 40%patients had constipation. Maximum 73.33% patients had normal psychological status. 86.66%patients were having sound sleep.Maximum 60% patients were of *Vata-kapha Prakriti*. Maximum number of patients i.e. 76.66% was of *Madhayama Samhanana*. Maximum 70% of patients were of *Madhyama Satva.* Maximum 90% of patients had regular past menstrual cycle. Maximum 53.33% of patients were registered at 32-33 weeks of gestational period. Maximum 70% of patients had *Basti Pratyagamana Kala* of 2 to 4 hours.

RESULTS

Table 5: Effect of therapy onset of nature of labor in 27 Patients

Sr. No.	Nature of labor	No. of Patients	Percentage
1.	Spontaneous	27	100
2.	Induction	0	0

Table 6: Effect of therapy on Mode of Delivery in 27 patients

Sr. No.	Mode of Delivery	No. of Patients	%age
1.	Normal	12	44.44
2.	Episiotomy	14	51.85
3.	Forceps	1	3.70
4.	L.S.C.S.	0	0

Table 7: Comparison of duration of stages of labor with standard mean duration in 27 patients

Sr. no	Stages of labor	Standard mean duration	Mean duration	S.D.	S.E.	t	p
1.	Stage (I)	13.3 (13hr. 8min)	8.92 (8hrs 54min)	2.77	.533	8.198	<.001
2.	Stage (II)	0.95 (57min)	0.51 (30min 24sec.)	10.43	2.12	2.48	<.001
3.	Stage (III)	0.25 (15 min)	0.07 (4min 20sec.)	1.45	.29	36.79	<.001

The standard mean duration of all the three stages of labor in all the 27 patients was reduced.

Table 8: Overall Result of therapy

Sr. no.	Result	Effect of therapy	No. of patients	Percentage
1.	Grade-I	Marked	12	44.44
2.	Grade-II	Moderate	13	48.15
3.	Grade-III	Mild	2	7.41
4.	Grade-IV	No	0	0

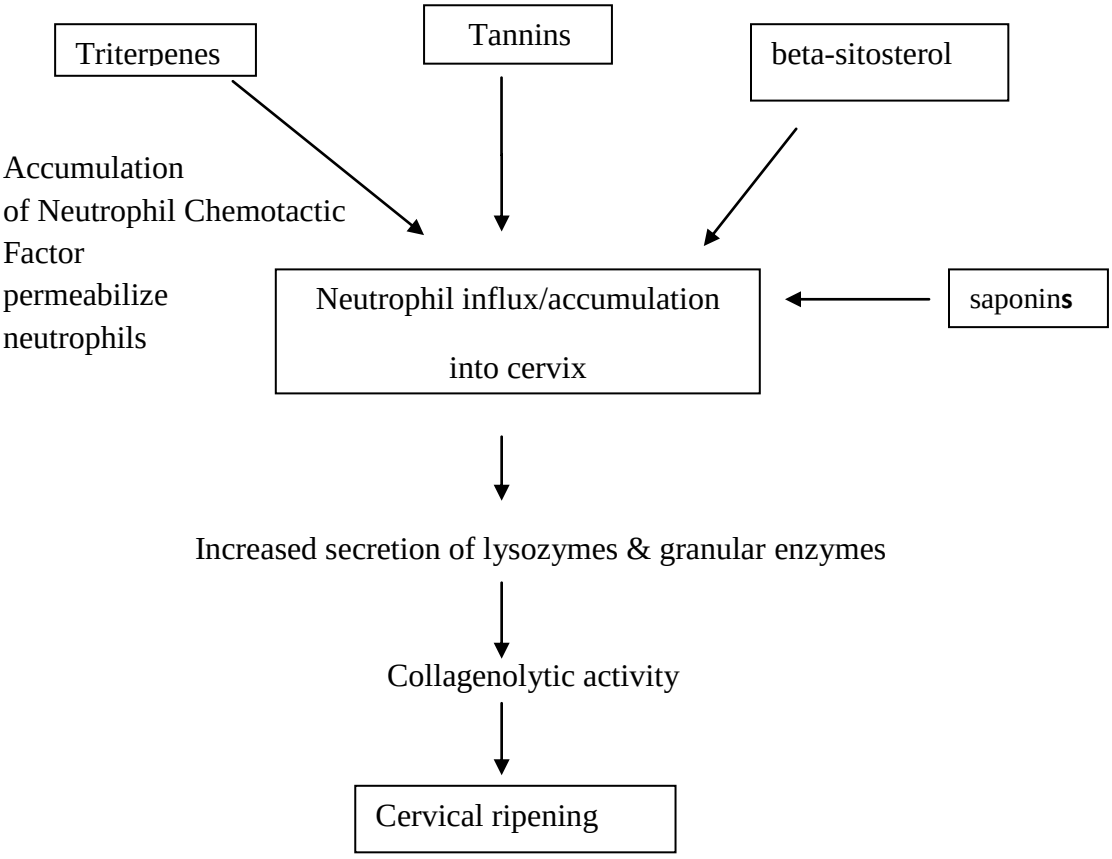
Out of 27 patients 44.44% achieved Grade-I (score not >0) hence showed marked effect of therapy and 48.15% patients achieved Grade-II (score not >1) and showed moderate effect of therapy. Followed by 7.41% achieved Grade III (score not >9) showed mild effect of therapy. None of the patient achieved Grade IV.

DISCUSSION

At normal term pregnancy birth is accomplished by a coordinated ripening and dilatation of cervix, accompanied by uterine contractions and descent of presenting part. In the present clinical trial *tilataila* medicated with *madhuragana darvyas* is used for *Anuvaasana basti* and *yoni pichu*. *Tilataila* has high percentage of poly-unsaturated fatty acid (omega– 6 fatty acid)[10] which may be assumed as the cause of slow cervical ripening. Further local application of *Balyam taila-1* in form of *yoni pichu* restores moisture of genital tract andripening phase occurs over the final weeks of pregnancy, leading to cervical dilatation as labor approaches. The *yoni pichu* also exert the mild and continuous stretching pressure on the cervix and vaginal wall there may be possibility that this pressure may cause the ferguson reflex in the mild form and hence help in cervical ripening. *Anuvaasana* and *matrabasti* have got a property to regulate sympathetic activity by regulating adrenaline and noradrenaline secretions and helps in the balance of Autonomic Nervous System[7]. Thus use of *basti* may also affect theAutonomic Nervous System governing myometrium and thus helps in regulating their function during labor[11]. Total 27 patients completes the trial with *Balyam taila-1* which showed highly significant ($p<0.001$) results after statistical analysis of assessment criteria but no significant was observed in the laboratory investigations. It is the effect of the trial drug that all the patients had spontaneous nature of labour, maximum with normal and episiotomy mode of delivery and it highly reduces the

standard mean duration of all the three stages of labour which helps in reducing the pain and discomfort during delivery.

Figure 1: Probable Mode of Action constituents of Balyam taila-1



CONCLUSION

The present clinical trial concludes that *Anuvaasana basti* and *yoni pichu* of *Balyam taial-1* if used from the beginning of 9th month (32 weeks) of pregnancy till delivery it effectively reduces the time of three stages of labor. This ultimately reduces the intensity and time of pain felt by every mother during delivery. So, the trial drug is an effective medicine to ease down the phenomenon of labor.

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CORRESPONDING AUTHOR

Dr Priyanka,
Lecturer, Department of Prasutitantra & Stree Roga, Chaudhary Devi Lal College of Ayurveda, Yamuna Nagar, Haryana-India
E-mail:vana_sat@rediffmail.com.

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