



Research Article

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A RANDOMIZED CLINICAL STUDY TO EVALUATE THE EFFECT OF SUKHPRASAVKAR LEPA, MATRA VASTI AND YONI PICHU ON AMELIORATING THE PROCESS OF LABOUR

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ABSTRACT

In today's era safe and healthy motherhood is a challenge and forming a major area of concern, finds special emphasis in Ayurveda as antenatal care (Garbhini Paricharya). World Health Organization (WHO) has been warning about the rising rate of C-section in the world and recommends that countries should maintain a rate of 10-15%. Pregnancy is challenging time for a woman as it changes the woman both physically as well as psychologically, so the study is aimed to provide natural, cost effective procedure, to bring down the rate of mortality and morbidity and to ease the delivery by simple measures. Total 60 pregnant women were randomly selected for the clinical trial. The efficacy of oil enema and vaginal tampon on cervical status and progress of labour along with comparative study of two medicated pastes were evaluated for their effect on progress, duration of stages of labour and pattern of uterine contractions for augmentation of labour. Maximum number i.e. 96.55% women of group I and 84% of group II delivered vaginally with small episiotomy. Therapy had good effect on cervical ripening and shortens the duration of stages of labour with favorable Bishop's score showing significant results ($p < .001$). The therapeutic intervention shortened the duration of three stages of labour and had highly significant results as compared to standard data. It reduces intensity of pain felt by pregnant women during the course of labour.

Keywords: Pregnancy, Oil enema, Vagina tampon, Herbal paste, Cervix dilatation, Labour

INTRODUCTION

Woman is an epitome of love, sacrifice and care and the most distinct quality she possess, is the ability to nurture life. She has a vital role in completing the circle of life. Pregnancy is a gift from God and it is an unparalleled privilege. It is a magnificent experience every woman can ever have. Going into pregnancy is a really challenging time for a woman because it is forever changing both physically as well as psychologically. The beautiful experience of pregnancy is journey of physical, psychological and social changes. Everyone aspires that end of this journey should be very smooth and comfortable with minimum pain, discomfort and interventions. Expenditure of C-section is increasing in many countries around the world. Caesarean rate is rising in Brazil and Taiwan and it is reported to be more than 60% in some countries. World Health Organization (WHO) has been warning about the rising rate of C-section in the world and recommends that countries should maintain a rate of 10-15% ¹. In today's era safe and healthy motherhood is a challenge and forming a major area of concern finds special emphasis in Ayurveda as antenatal care (Garbhini Paricharya). By adopting the Ayurvedic monthly antenatal care regime (Masanumasik Garbhini Paricharya) of food (Ahar), life style (Vihar) and medicine (Aushad) described in Ayurvedic text, we can fulfill dual goal of easy parturition and healthy progeny. Childbirth is a natural, life altering event but in modern era, future mother is more conscious about her pregnancy, health and well-being of the coming child and the first pregnancy is always full of scare and fear for the inexperienced mother regarding her own

health status during pregnancy, labour and status of the growing baby in the uterus as well as final outcome of pregnancy. Every women and her family aspires an easy, natural and safe delivery without any complication and the same is termed in Ayurveda classical text as Sukh Prasav (less painful delivery) but in present scenario with drastically increasing rate of cesarean section, more number of instrumental deliveries, routine use of episiotomy as well as poor pain tolerance, sedentary life style, poor bearing down efforts, demand for elective cesarean section has raised to reduce the discomfort to absolute nil. Consumer organizations,² guidelines³ and textbooks⁴⁻⁵ has different and contradictory information about risk related to cesarean, which can lead to confusion over normal and cesarean section delivery, particularly given a desire to support normal birth in the face of increasing cesarean rates. Cesarean section has multiple risks to mother and baby, which includes maternal death,⁶ infection and postnatal depression ⁷⁻⁸. In a study, Torkan et al.⁹ examined the quality of life of 100 women within intervals of 8, 12, and 14 weeks (during the postnatal period). The results indicated that natural childbirth was associated with higher quality of life as compared to C-section during the postnatal period. The subject's physical health improved during this period. Ayurveda has abundant knowledge to give to human kind, so that they can lead a healthy life as designed by nature and has described many drugs to speed up the birth process for the sake of natural vaginal delivery with minimum aids. By following this Ayurveda antenatal care regimen (Garbhini Paricharya), we can fulfill the desire of having natural and safe delivery with healthy progeny. So, efforts have been made since time immemorial to ease the pain and to make

this event happy and comfortable. Our Acharyas have described antenatal care (Garbhini Paricharya) for nine months of pregnancy and has mentioned the use of enema (Anuvasan Basti) and vaginal tampon (Yoni Pichu) of medicated oil prepared with drugs mentioned in Madhur Sakandh¹⁰ (group of drugs) during ninth month along with application of herbal paste (Sukhprasavkar Lepas) at the onset of labour for easy and safe delivery.

AIM AND OBJECTIVES

Pregnancy is challenging time for a woman as it changes the woman both physically as well as psychologically, so the study is aimed to provide natural, cost effective procedure, to bring down the rate of mortality and morbidity and to ease the delivery by simple measures. The study was designed to evaluate the effect of oil enema (Anuvasan Basti) and vaginal tampon (Yoni Pichu) on cervical status and progress of labour along with comparative study of two medicated pastes applied on and around umbilicus named as Sukhprasavkar Lepa I and II for evaluating their effect on progress, duration of stages of labour and pattern of uterine contractions for augmentation of labour.

MATERIAL AND METHODS

Selection of drug

Trial drugs were selected according to textual description by Acharya Charaka, while describing antenatal care (Garbhini Paricharya) in 9thmonth Acharya has mentioned use of enema (Anuvasana Basti) and tampon (Yoni Pichu) with medicated oil prepared with the drugs mentioned in Madhura skandha¹⁰. So from a number of drugs of Madhura Skandha only four drugs were selected for the present study and named as Balyam Tail¹⁰. The study was carried out as per the International Conference Harmonization – Good Clinical Practices Guidelines. (Table 1)

For most of the woman labor is a time of fear, apprehension and agony. Therefore, to counter this pain and to lessen the duration of labour there is wide range of chemical products in contemporary science but with a lot off adverse effects. Many Acharayas have described number of labour easing medicaments (Sukhprasavkar yogas) for easy natural termination of pregnancy without side effects. So, two naval pastes (Sukhprasavkar Lepa)^{11, 12} were prepared to apply on and around the umbilicus during labour. (Table 2,3)

Selection of Pregnant women

Total 60 pregnant women fulfilling the inclusion criteria were randomly selected from O.P.D and I.P.D. Dept. of Prasuti Tantra avum Stree Roga of R. G. G. P. G. Ayurvedic Hospital Paprola, Distt. Kangra (H.P.).

Inclusion criteria

- Pregnant women willing for the trial.
- Both primi and multi gravida preferably primigravida.
- Pregnant women between 32-36 weeks of pregnancy with age group between 20-30 years.
- Pregnant women having gynaecoid or border line pelvis and cephalic presentation.

Exclusion criteria

- Pregnant women not willing for trial
- Age group < 20 years and >30 years.
- Pregnant women having cephalopelvic disproportion, absolute contracted pelvis, cervical dystocia, history of APH, history of precipitate labour, history of absolute indication of CS or bad obstetric history.
- Pregnant women having systemic diseases like diabetes mellitus, hypertension, tuberculosis, jaundice, heart disease, epilepsy, ascites, generalized oedema.
- Diseases related to pregnancy like eclampsia, preeclampsia, polyhydramnios, oligohydramnios etc.
- Benign and malignant tumours and cysts of genital tract.

Laboratory investigations

Routine Haematological examination - Hb%, TLC, DLC, ESR, BT, CT, Blood group + Rh factor.
Biochemical tests - S. Creatinine, B. Urea, Serum Uric acid, FBS, LFT, GTT.
Screening tests - HIV, VDRL, HBs Ag.
Urine Examination tests - Routine, Microscopic.

Method of study

IEC & Consent: - Approval from the Institutional Ethical Committee (IEC) was taken prior to begin with this study vide IEC/125/2011 dated 11.04.2011. Written & informed consent of the pregnant women was taken before their registration for the study.

Pregnant women fulfilling the inclusion criteria will be randomly divided into two groups.

Trial Group I - 30 gravida of this group will be given enema (Matra Anuvasan Basti) fortnightly and tampon (Yoni Pichu) daily between 32-36 weeks and application of medicated naval paste (Sukh Prasvakar Lepa-I) during active 1st stage of labour.

Trial Group II - 30 gravida of this group will be given enema (Matra Anuvasan Basti) fortnightly and tampon (Yoni Pichu) daily between 32-36 weeks and application of medicated naval paste (Sukh Prasvakar Lepa-II) during active 1st stage of labour.

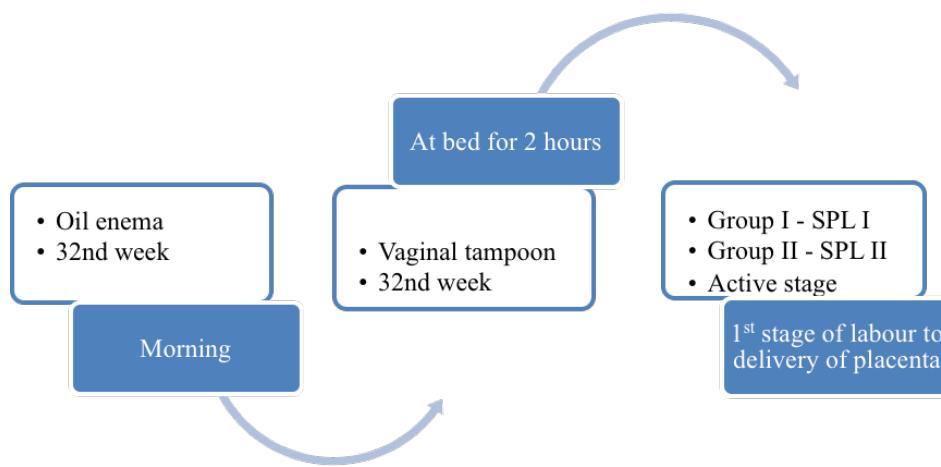
Criteria of Assessment

The clinical results were accessed by observing whether the pregnant woman had low pain intensity and non complicated labour or not and for that the following parameters were adopted.

Subjective Criteria - Pain intensity Gradation was done to evaluate pain felt by the gravida after naval paste application.

Objective Criteria - Pain Intensity by Visual Analogue Scale, Onset of labor, Modified Bishops Score, Contractions (Frequency of contractions, Duration of contractions, Intensity of contractions, Uterine Resting Tone, Rate of cervical dilatation, Pattern of FHR, Partograph, Duration of Labor (Duration of active phase, Duration of second stage, Duration of third stage, Mode of delivery, Post-Partum Hemorrhage).

Clinical intervention



Administration of Enema (Matra basti) - Enema was administered just after the breakfast. Pregnant woman was asked to lie down in left lateral position on the table with her left leg in out stretched posture, while the right leg flexed at the knee and the head was slightly flexed. 60 ml syringe along with rubber catheter was used for the administration of oil enema. Administration of medicated oil (Balyam taila) was done slowly without shaking the hand within 30-40 seconds, leaving behind a little quantity of oil in the syringe. During the administration of oil enema, the patient was instructed to take deep breath. After the administration of enema, the syringe was removed, and the gravida was advised to breathe normally. Immediately after the drug administration, the patient was asked to lie with hands and legs freely spread over the table for half an hour and was asked to retain the oil as long as possible.

Administration of vaginal tampon (Yoni pichu) – Tampon was prepared by wrapping sterilized gauze piece over cotton ball. It was soaked in oil (Balyam Taila) and inserted into the vagina. Tail of tampon was kept outside vagina for its easy removal. Patient was instructed to insert the tampon herself daily at bed time after micturition and to retain it at least for 2 hours and to remove it before micturition or in the morning if she didn't pass urine at night.

Preparation of Naval Paste (SPL I and SPL II) - 40 gm of dry powder of SPL taken and kept in a bowl. A small amount of hot water and about 10 ml of *Ricinus communis* oil (Erand Sneha) is mixed well with the powders. Mix it well and the paste becomes soft and is ready for application.

Application of Naval Paste (SPL I and SPL II) – The pregnant woman is made to lie on her back with arms by her sides on a firm mattress, the head and neck should be supported by pillow to make her comfortable. Paste was applied externally around umbilicus on abdomen in about $\frac{1}{4}$ part of finger (i.e. 5mm thickness) during active phase of labour in each group respectively. Prepared paste was applied starting gently from umbilicus and around the umbilicus on abdomen up to a radius of approximately 5cm with the help of fingers or steel spatula. After applying the paste, it should be leveled equally. The paste was covered with butter paper, so that it should not spill with the movement of patient. Patient is kept under observation in the same position for 15 minutes and then allowed to move. It is to be repeated after drying of first application of paste. Duration of

paste application was from 1st stage of labour till delivery of placenta.

OBSERVATIONS AND RESULTS

Total 61 pregnant women were registered in the clinical trial. Out of 61, 7 pregnant women dropped out after taking enema (Matra Basti) and vaginal tampon (Yoni Pichu) and remaining 54 pregnant women had undergone labour in R.G.G.P.G.A.C. and Hospital. Out of these 54 women who entered into labour, one pregnant woman of group I and three pregnant women of group II underwent caesarean section due to fetal distress during latent phase of labour i.e. before application of herbal paste (Sukhprasavkara Lepa). So, further clinical study was conducted only on remaining 50 pregnant women.

The age of maximum number 78.68% of pregnant women were from 20-25 years age group and 21.32% pregnant women were from 26-30 years age group. 90.16% of pregnant women were primigravida and 9.84% were second gravid. (Figure 1) 98.36% of pregnant women were nulliparous and 1.64% was primipare (Figure 2). The vaginal passage is rigid in primigravida the duration of stages of labour are long and primigravida are more anxious about the labour pains and outcome of pregnancy so, nullipare women were selected for the study. In case of ROM (Rupture of membrane) (Figure 3), it was elucidated that 86.20% of pregnant women in group I and 80% in group II had ROM in active phase and only 13.79% of group I and 16% of group II had ROM before active phase and only 4% pregnant women of group II had pre-labour ROM. As the ROM itself can initiate and enhance the labour pains and shorten the duration of labour, but in present study most of the gravida had ROM in late active phase i.e. after application of naval paste, so the results cannot be attributed to as effect of ROM. Measurement of FHR (Figure 4), elucidated that 96.55% gravida of group I had normal pattern of FHR during the whole course of labour followed by 3.45% who had fetal bradycardia before active phase of labour while in group II 88% had normal FHR pattern followed by 8% who had fetal bradycardia and 4% had fetal tachycardia. As fetal heart rate abnormal pattern was observed before active phase i.e. before application of naval paste so, it cannot be attributed to effect of therapy.

Effect of therapy on type of delivery - In group I maximum number of gravida (96.55%) had NVD with small episiotomy,

and 3.44% of the gravida underwent L.S.C.S due to fetal distress i.e. because of the short cord. Whereas in group II 84% of the gravida had NVD with small episiotomy, 4% had forceps delivery due to fetal distress and outlet contraction and 12% pregnant women underwent caesarian delivery. (Figure 5)

Effect of therapy on Modified Bishop's score - Bishop's score was favorable in all the pregnant women of both the groups. (Figure 6)

Effect of therapy on intensity of pain felt by gravida - After the application of naval paste maximum number (92.85%) of gravida in group I and 95.45% gravida of group II experienced moderate (but tolerable) pain during labour followed by 7.15% gravida of group I and 4.54% gravida of group II who experienced severe pain. In normal phenomenon of labour the intensity of pain increases as the labour progress and the pregnant women feels more severe pain. But the present data show that, maximum gravida experienced same pattern of pain throughout the process of labour. (Figure 7)

Effect of Therapy on Pattern of Uterine Contractions - In maximum number of gravida i.e. in 85.71% of group I and 54.55% of group II, the pattern of uterine contractions was 3-5 contractions/10min. with mean duration of 40-45 sec with moderate intensity in active phase of labour and same pattern was maintained throughout active phase. Ideally 3-5 contractions/10min. with duration of 45 sec has been defined as adequate for normal labour and is noticed in 95% gravida with spontaneous labour. In this study it has been observed that frequency and duration of contractions was not increasing but duration of stages of labour was significantly decreased in group I But in group II the effect of therapy on pattern of uterine contractions has not shown significant results. (Figure 8, Figure 9)

Effect of therapy on rate of cervical dilatation - The study unveiled that in group I, maximum no of gravida i.e. 92.85% had cervical dilatation rate more than standard mean rate followed by 7.14% having cervical dilatation rate equal to standard mean rate whereas in group II only 68.18% gravida had cervical dilatation rate more than standard mean rate followed by 22.72% having equal rate and 22.72% having cervical dilatation rate less than standard mean rate. On intergroup comparison of mean cervical dilatation rates, group I showed highly significant results. (Figure 10, Table 4)

Effect of Therapy on Duration of Stages of Labour - Study shows that on comparison of duration of stages of labour with standard data it was found that the mean duration of first stage of labour in group I was 7hrs. whereas in group II it was 10hours.24minute which was less than standard mean duration of 13hrs 18 minute so, highly significant results were obtained.

On comparison of active phase of labour with standard mean duration, the mean duration of active phase of labour in group I was 3hours 54 minutes which was less than standard mean duration of 5 hours 48 minute so highly significant results were obtained whereas in group II mean duration was 5hrs 24 minute

which was slightly less than standard mean duration of 5hrs 48 minute so statistically insignificant results were obtained.

On comparison of second stage of labour with standard mean duration, the mean duration of second stage in group I was 22minute 28 seconds whereas in group II it was 28 minute 21 seconds which was less than standard mean duration of 57 minutes so, showing highly significant results.

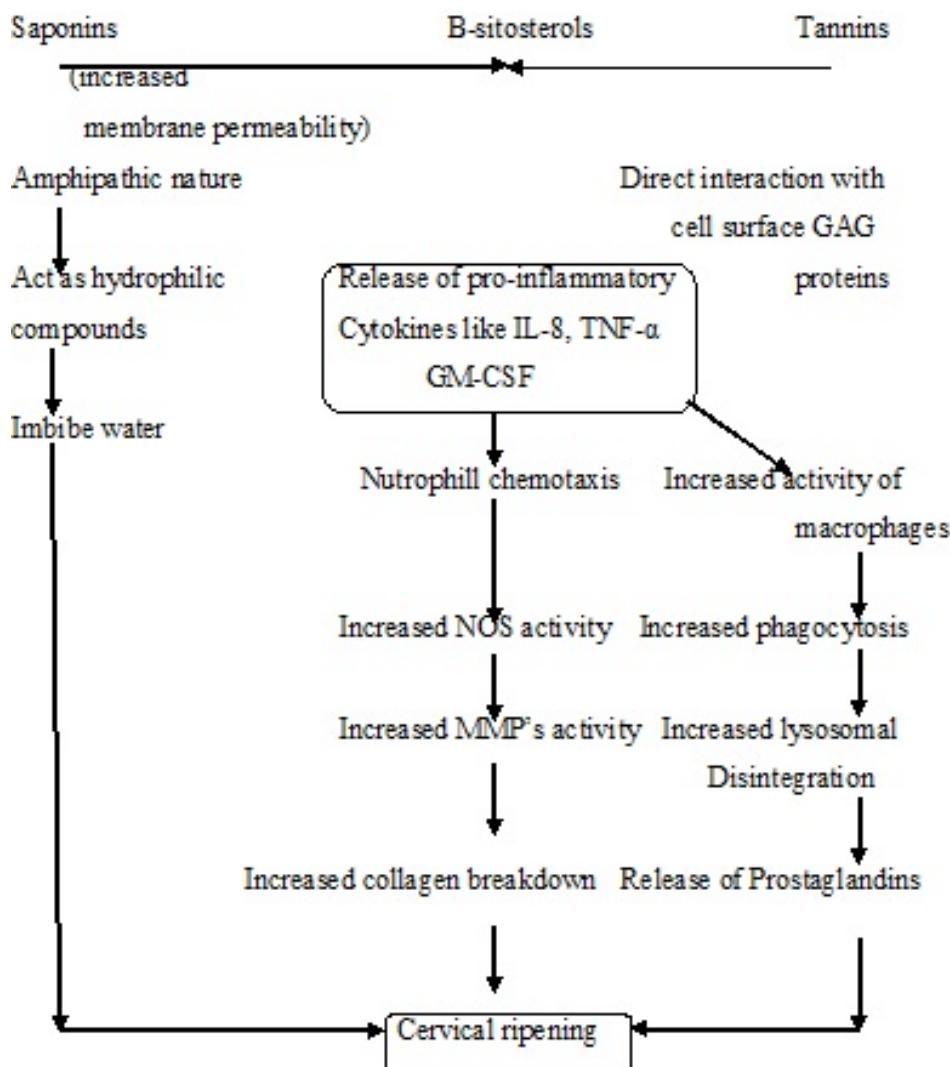
On comparison of third stage of labour with standard mean duration, the mean duration of third stage in group I was 6 minute 04 seconds whereas in group II, It was 4 minute 21seconds which was less than standard mean duration of 15 minutes so, highly significant results were obtained. (Table 5-7)

Inter Group comparative study of duration of all the stages of labour revealed that although the mean duration of all the stages of labour in both the groups except active phase of labour in group II was less than standard mean duration and was statistically significant and duration of active phase was statistically insignificant in Group-II as according to 'p' value but on intergroup comparison of all the stages of labour it was found statistically insignificant

Thus therapy protocol of Group-I was more effective than that given in Group-II. The therapy shortened the duration of all the stages of labour and this effect was attributed to cervical ripening properties of medicated oil used as enema and tampon (Balyam Taila Basti and Pichu) as well as to naval herbal paste (Sukhprasavkar lepa I and II) in maintaining the effective uterine contractions for progression of labour (Table 8).

DISCUSSION

The present study was completed to evaluate the efficacy of medicated oil enema (Anuvasan Basti) vaginal tampon (Yoni Pichu) and herbal naval paste (Shukhprasav Lepa I and II) on easing the painful and time taking process of normal vaginal delivery. The medicated oil (Balyam Taila) found effective in cervical ripening as it contains high percentage of polyunsaturated fatty acids like linoleic, stearic, palmitic, oleic acids and their role in cervical ripening and parturition has been established¹³. These fatty acids are precursors of arachidonic acid from which prostaglandins are synthesized which ultimately cause cervical ripening¹⁴. As a whole, all the constituents of Balyam Taila contain Glycosides specially saponins which interact with membrane cholesterol to form pores in cell membrane, thus making it permeable for influx of neutrophils, calcium ions causing collagenolysis through increased activity of MMP's (Matrix Metalloproteinases) and ultimately cervical ripening takes place¹⁵. Saponins are amphipathic in nature, so act as hydrophilic compounds therefore imbibes water and cause cervical softening¹⁵. All the constituents of oil have potent anti-inflammatory properties,¹⁶ so causes release of pro-inflammatory cytokines like IL-8, TNF- α , GM-CSF which causes neutrophil chemotaxis, activation of macrophages leading to increased NOS activity and lysosomal activity therefore increased MMP's activity ultimately leading to cervical ripening¹⁷. Oil acts as lubricant so, makes the vaginal passage and cervix soft.



Picture 1: Probable mode of action of Ingredients of Balyam Taila

The mechanism of action of medicated oil enema (Basti) can be postulated in two ways first is absorption and second is stimulation of ENS. The drug absorbed rectally is carried into the systemic circulation which facilitates absorption and systemic exposure of drugs, the portion absorbed from upper rectal mucosa is carried by the superior haemorrhoidal vein into the portal circulation whereas the drug absorbed from lower rectum enter directly into the systemic circulation via middle and inferior haemorrhoidal veins. So, the oil drugs (Basti dravyas) absorbed from trans-rectal route can shw the effect all over the body. ENS also contains support cells which are similar to astroglia of the brain forming a diffusion barrier around the capillaries surrounding ganglia which is similar to blood brain barrier and allows systemic absorption of the drug thereby producing systemic effects. Gut is a sensory organ consisting neural immune and sensory detectors and cells provide direct input to local regulatory system and then passes it to CNS. ENS is a collection of neurons in the gastrointestinal tract that constitutes Brain of Gut. It also influences the Autonomic nervous system thereby producing systemic effects. ENS makes use of more than 30 neurotransmitters, most of which are identical to ones found in CNS such as acetylcholine, dopamine and about 50% of the dopamine lies in gut. It also contains sensory, motor and interneurons which respond to mechanical, thermal, osmotic and chemical stimuli. These neurons secrete an intimidating array of

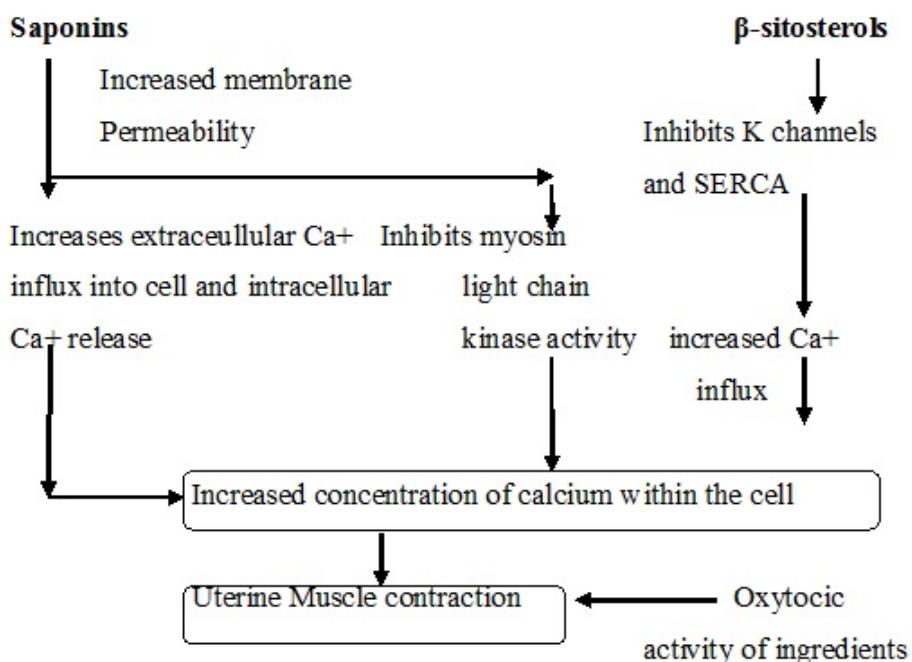
neurotransmitters and exert their excitatory and inhibitory functions. So, medicated oil enema (Matra Basti) can stimulate the ENS and thus, it shows its systemic effects by stimulation of CNS¹⁸.

Vaginal tampon (Yoni Pichu) application is a type of local oleation therapy. Efficacy of local application of drug lies in the fact that, it helps in decreases the symptoms and is easy to administer. The topical application of drug has advantage of producing high drug concentration near the tissue and a high influx through the membrane is thus achieved. It lubricates the whole vaginal canal due to its unctuousness and thus prevents unnecessary friction. Daily insertion of vaginal tampon in the ninth month of pregnancy causes irritation of cervix, which leads to slow production of prostaglandins resulting in enhance gap junction formation and thereby initiates labour. Repeated vaginal examination during tampon application can cause slow rise in maternal plasma oxytocin level. The Ferguson Reflex i.e. mechanical irritation of cervix due to daily tampon application initiates paracervical ganglion to carry the afferent impulses to the inferior mesenteric ganglion which synapses in the dorsal horn before ascending to brain in the anterolateral column. Then, via median forebrain bundle, the efferent reaches the paraventricular nuclei and supraoptic nuclei of hypothalamus which

stimulates posterior pituitary to release oxytocin for further initiation of labour¹⁹.

Probable Mode of Action of Ingredients of herbal naval paste (Sukhprasavkara Lepa I and II) can be explained as the synergistic effect of all the ingredients in the formulation rather than the action of individual drug that plays a vital role in therapeutics. The main constituent of herbal naval paste (Sukhprasavkar Lepas) contains Saponins and β -Sitosterol, alkaloids etc. Saponins increase membrane permeability by interaction with membrane cholesterol thus enhances extracellular calcium influx

into the cell and also release of calcium within the cell thereby, increasing the concentration of intracellular calcium which is a key factor for muscle contraction²⁰. Saponins, also inhibits Myosin light chain kinase activity. Beta-Sitosterol increase amplitude and frequency of phasic contractions due to nonestrogenic effects acting to inhibit K channels and inhibit SERCA (Sarcoplasmic reticulum calcium ATPase) thereby increasing calcium entry on L-type Ca-channels²¹. In some clinical studies, it was proved that some of the alkaloids of these drugs contain oxytocic activity and are described in Table 9.



Picture 2: Probable mode of action of Herbal paste (Sukhprasavkar Lepas)

Table 1: Ingredients of Balyam taila

S.no.	Name of ingredient	Botanical name	Part used	Quantity
1.	Erand	<i>Ricinus communis</i>	Rt.	1 part
2.	Guduchi	<i>Tinospora cordifolia</i>	St.	1 part
3.	Ashwagandha	<i>Withania somnifera</i>	Rt.	1 part
4.	Sariva	<i>Hemidesmus indicus</i>	Rt.	1 part
5.	Murchitt Tila Taila	<i>Sesamum indicum</i>	Sd.	16 parts

Table 2: Ingredients of paste SPL – I¹¹

S.no.	Name of Ingredient	Botanical Name	Part used	Quantity
1.	Pipalimoola	<i>Piper longum</i>	Rt.	1 part
2.	Vachamoola	<i>Acorus calamus</i>	Rt.	1 part
3.	ErandTaila	<i>Ricinus communis</i>	Sd.	Q.S.

Table 3: Ingredients of paste SPL - II¹²

S.no.	Name of Ingredient	Botanical Name	Part used	Quantity
1.	Patha	<i>Cissampelos pareira</i>	Rt.	1 part
2.	Langli	<i>Gloriosa superb</i>	Rt.	1 part
3.	Vasa moola	<i>Adhatoda vasica</i>	Rt.	1 part
4.	Apamarg moola	<i>Achyranthes aspera</i>	Rt.	1 part
5.	Erand Taila	<i>Ricinus communis</i>	Sd.	Q.S.

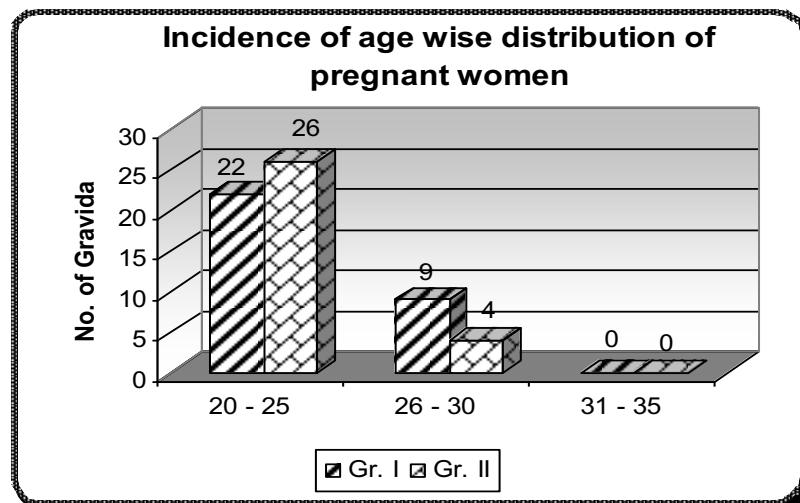


Figure 1: Incidence of age wise distribution of pregnant women

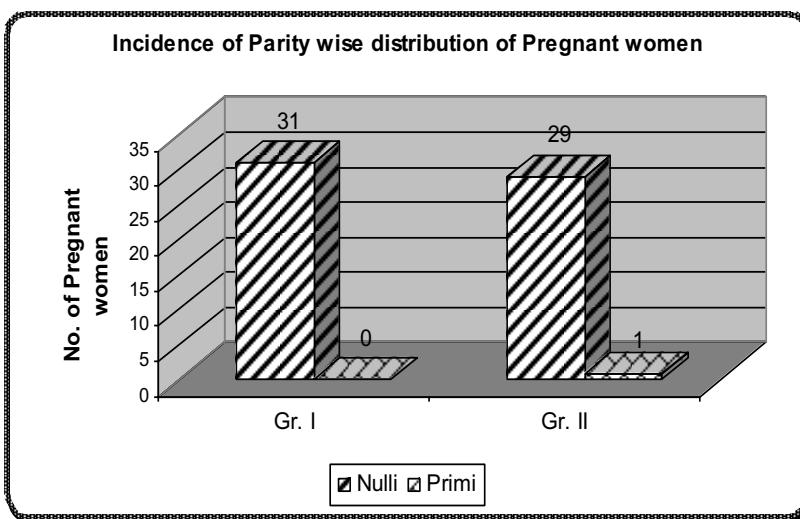


Figure 2: Incidence of parity wise distribution of pregnant women

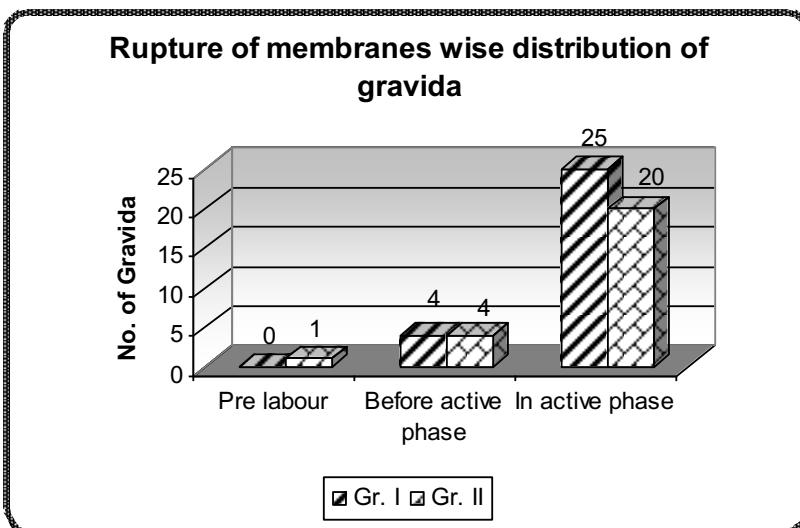


Figure 3: Rupture of membranes wise distribution

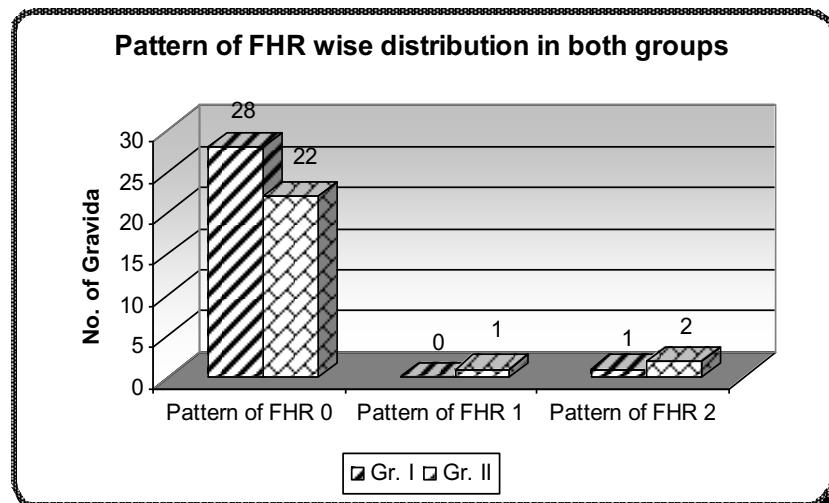


Figure 4: Pattern of FHR wise distribution in both groups

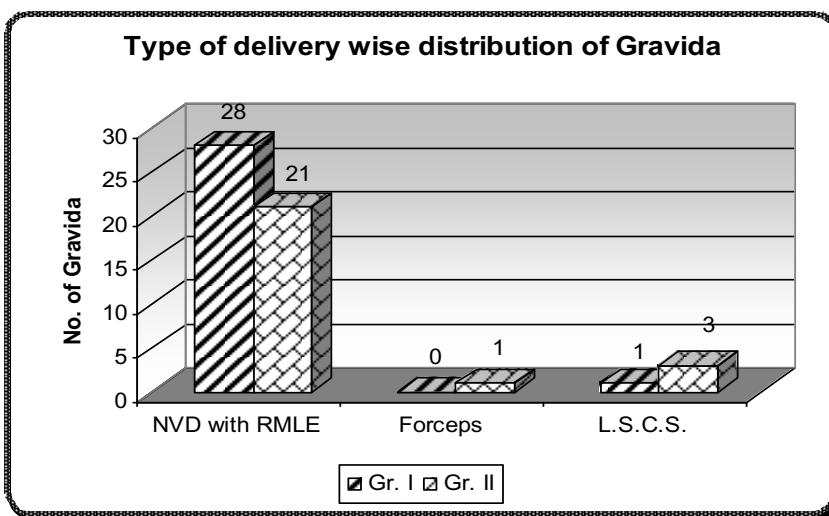


Figure 5: Type of delivery wise distribution

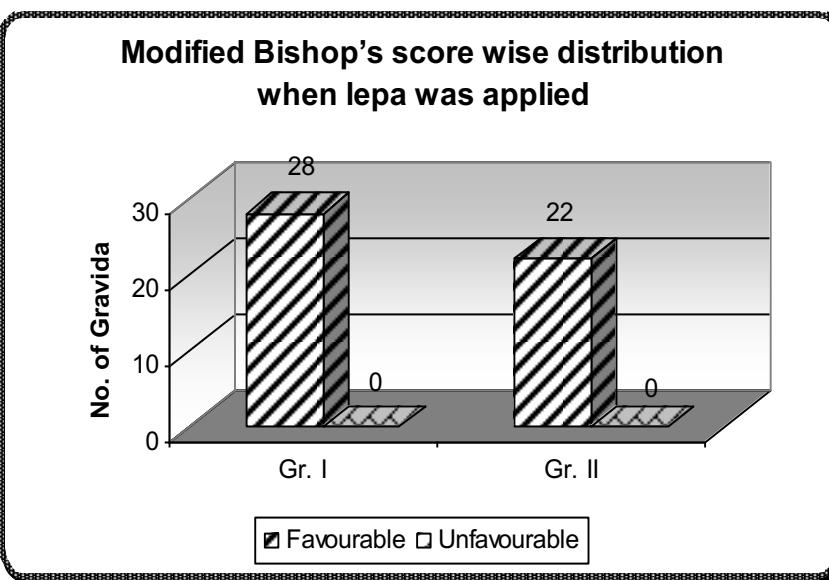


Figure 6: Modified Bishop's score wise distribution when herbal paste was applied

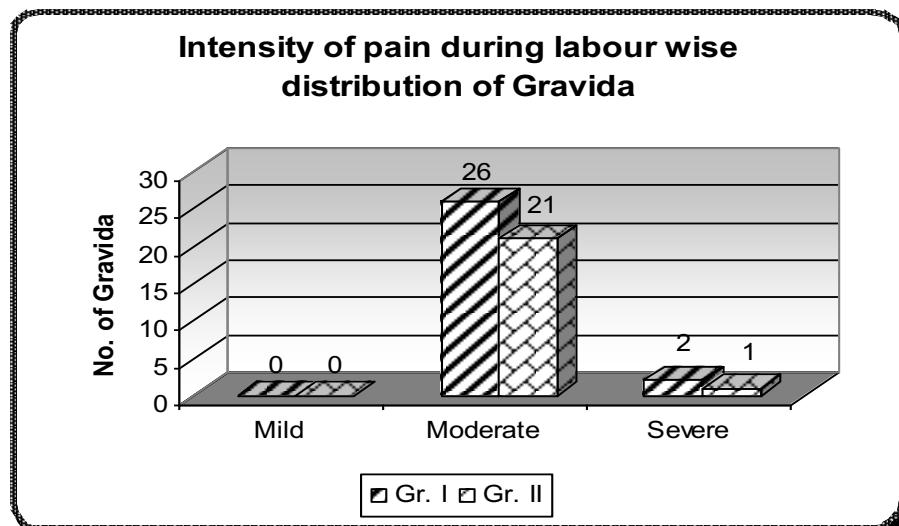


Figure 7: Intensity of pain during labour wise distribution

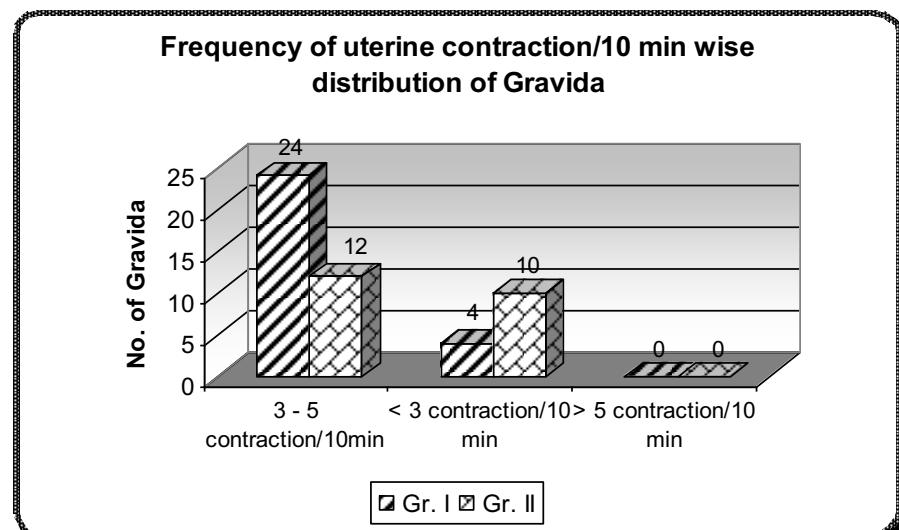


Figure 8: Effect of therapy on uterine contractions

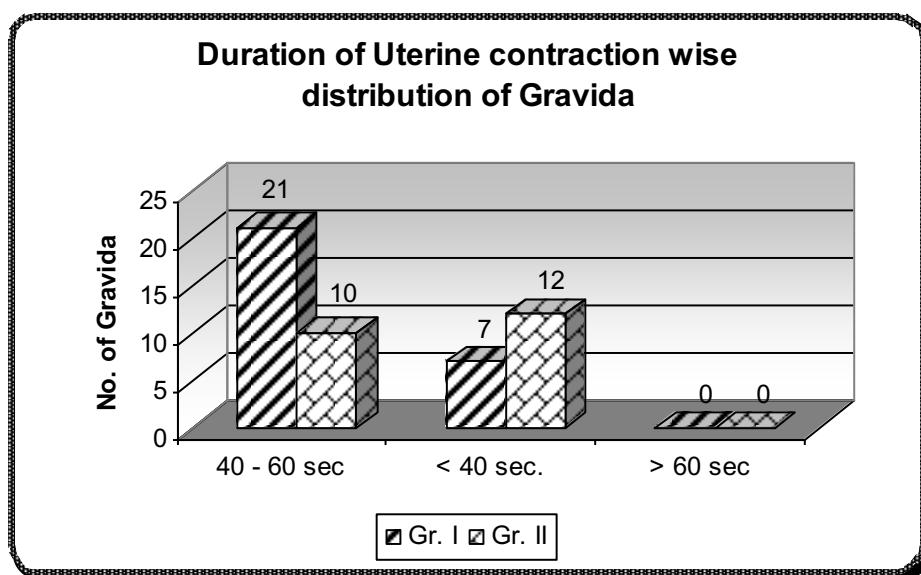


Figure 9: Duration of uterine contractions wise distribution

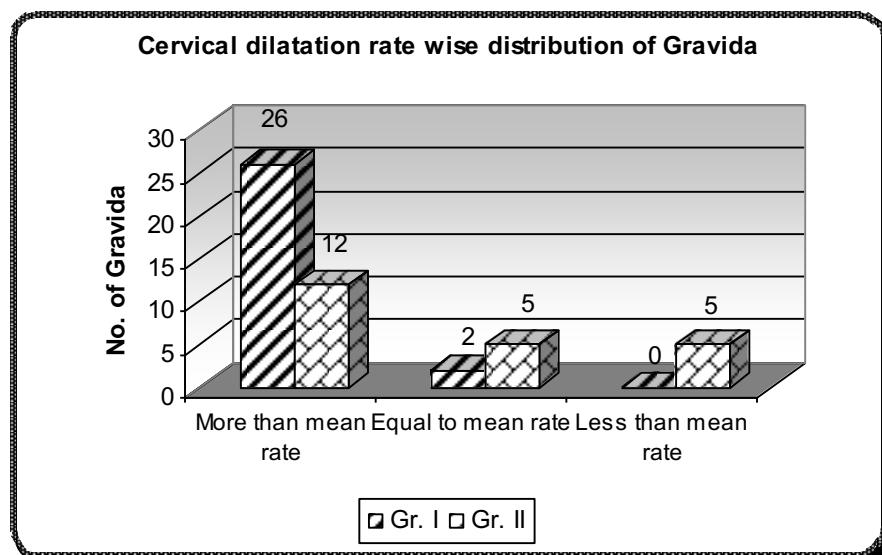


Figure 10: Cervical dilatation rate wise distribution

Table 4: Comparison of rate of cervical dilatation with standard mean rate of cervical dilatation in both groups

Sr. No.	Groups	Standard mean cervical dilatation rate	Mean rate of dilatation	SD	SE	't'	'p'
1.	Gr. I	1.2 cm/hour	1.95	0.56	0.11	7.06	<0.001
2.	Gr. II	1.2 cm/hour	1.27	0.35	0.075	0.94	>0.05

Table 5: Comparison of duration of stages of labour with standard mean duration in 28 pregnant women of group I

Sr. No.	Stages of Labour	Standard mean duration	Mean duration	S.D.	S.E.	't'	'p'
1.	Stage I	13.3 (13 Hour 18 min)	7.0 (7 Hours)	70.23	13.27	28.47	<0.001
2.	Stage II	0.95 (57 min)	0.37 (22 Min 28 sec)	3.48	0.65	52.72	<0.001
3.	Stage III	0.25 (15 min)	0.094 (6 min 04 sec)	6.75	1.27	7.33	<0.001

Table 6: Comparison of duration of stages of labour with standard mean duration in 22 pregnant women of group II

Sr. No.	Stages of Labour	Standard mean duration	Mean duration	S.D.	S.E.	't'	'p'
1.	Stage I	13.3 (13 Hour 18 min)	10.4 (10 hour 24 min)	69.24	14.76	11.84	<0.001
2.	Stage II	0.95 (57 min)	0.46 (28 min 21 sec)	6.46	1.37	21.17	<0.001
3.	Stage III	0.25 (15 min)	0.07 (5 min 35 sec)	0.89	0.19	52.43	<0.001

Table 7: Comparison of duration of active phase of labour with standard means duration in both groups

Sr.No.	Groups	Standard mean duration	Mean duration	SD	SE	't'	'p'
1.	Gr. I	5.8 (5 hours 48 min)	3.91 (3 hours 54 min)	57.36	10.04	10.55	<0.001
2.	Gr. II	5.8 (5 hours 48 min)	5.43 (5 hours 24 min)	55.00	11.72	1.88	>0.05

Table 8: Overall result of therapy in gravida of both groups

Sr. No.	Result	Gr. I		Gr. II	
		No. of Gravida	Percentage	No. of Gravida	Percentage
1.	Grade I	28	96.55	18	72
2.	Grade II	0	0	4	13.79
3.	Grade III	1	3.55	3	10.34

Table 9: Pharmaceutical component and activity of various drugs used in this study

Drugs	Property	Action	Main chemical
Vacha ²²	Oxytocin like property	Contracts uterus	Asarone
Pippali ²³	Uterine Contractile activity counter irritant	Contracts uterus, Analgesic	Hexane fraction of crude extract
Castor oil ²⁴	Prostaglandin like activity	Contracts uterus	Ricinoleic acid
Patha ²⁵	Oxytocin like property	Increased myometrial activity	Methanolic extract
Langali ²⁶	Oxytocin like property	Contracts uterus	Colchicine
Vasa ²⁷	Oxytocin like property	Contracts uterus	Vasicine
Apamarg ²⁸	Prostaglandin like activity	Increased myometrial activity	Polyphenols, saponins

CONCLUSION

Observation of all the available facts, data and discussion with probable reasoning, shows fruitful results. The study was done on 61 pregnant women and 54 completed the trial. The effect of Therapy was accessed on duration of stages of labour and according to nature of delivery. Maximum number i.e. 96.55% women of group I and 84% of group II delivered vaginally with small episiotomy. Thus, therapy (Balyam Taila Matra Basti and Pichu) lubricates the vaginal passage and perineal muscles thereby increasing its elasticity as shown by decreased rate of instrumental deliveries and decreased mean duration of stages of labour. The therapy shortened the duration of three stages of labour and had highly significant results as compared to standard data. So it can be concluded that therapy has good effect on cervical ripening as well as due to its oxytocin like effect, therapy is effective in maintaining the pattern of uterine contractions required for progression of labour. Therapy reduced the intensity of pain felt by pregnant women during the course of labour and this effect might be due to counter irritant effect of certain ingredients of herbal paste as well as due to antispasmodic activity of ingredients which causes good relaxation of uterus in between the contractions. So, it decreases the pain and agony of labour and makes it comfortable. Inter Group comparative study of results in both the groups showed that although the mean duration of all the stages of labour was less as compared to standard data but on intergroup comparison statistically it was insignificant but time duration of labour in group I was less than that given in group II pregnant women.

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