

LODHRA AND PIPPALI IN THE MANAGEMENT OF GARBHA CHALANA W.S.R. TO PREMATURE UTERINE CONTRACTIONS

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ABSTRACT

Background: Preterm labour accounts for approximately one-third of preterm births, causing 40-75% of neonatal deaths. Although there are no definite measures till date to prevent preterm labour, tocolytics are extensively used these days in spite of its known adverse effects. In Ayurveda, *Garbha Chalana* (initial descent of the fetus towards expulsion) mentioned by Harita and Yogaratnakara can be interpreted as the very initial symptom of movement of *Garbha* (fetus) towards early expulsion. The concept of *Garbha Chalana Chikitsa* can be considered as an effective and safe alternative in preventing *Akala Prasava* (preterm labour). Since this research work is the very first study of its kind, only 8th month *Garbha Chalana Chikitsa* is taken for the study. **Aim:** To evaluate the tocolytic activity of *Lodhra* and *Pippali* in preterm uterine contractions. **Material and methods:** In the present randomized comparative clinical trial, 40 patients with premature contractions in 8th month of pregnancy were randomly assigned in 2 groups of 20 patients each. *Lodhra* (2.5 g) and *Pippali* (250 mg) with honey (Q.S.) and milk (50 ml) as adjuvant were administered in trial group (LP group) and Tablet Duvadilan 10 mg (Isoxsuprine Hydrochloride) was given in standard group (IH group). **Result:** Statistical analysis of LP group showed significant result in arresting the duration and frequency of uterine contractions where as IH group was beneficial in reducing the pain abdomen and intensity of contraction. **Conclusion:** Tocolytic action of *Lodhra* and *Pippali* are almost similar to the standard drug and hence it can be effectively used to prevent preterm labour without any untoward effects.

Keywords: Premature labour, Tocolytics, *Garbha Chalana*

INTRODUCTION

Preterm labour is defined as the one where the labour starts before the 37th completed week.¹ Preterm labour is a leading cause for maternal and perinatal mortality and morbidity. India contributes about 3.6 million preterm deliveries in the world, accounting 23.6% of the total deliveries. Many preterm babies end up in dreaded complications like respiratory distress syndrome, necrotizing enterocolitis, cerebral edema, mental retardation etc. as a result of lung immaturity.² In spite of meticulous care taken to prevent preterm labour, success rate of the treatment is not very encouraging and usually land up in preterm delivery. Premature contraction of uterus is the very first sign of premature labour, followed by progressive changes in cervix such as dilation and effacement. Tocolytics are most widely used in the management of preterm labour. Though these drugs are proved to produce adverse effects such as fluid overload, pulmonary edema, myocardial ischaemia, hyperglycaemia, hypocalcaemia etc.,³ there are no substitutions available for tocolytics till date to prevent preterm labour. Although delivery may be delayed long enough for administration of corticosteroids, this treatment does not result in improved perinatal outcome. Therefore there is a definite need for alternative, safe and effective treatment to arrest the preterm contractions right from the beginning.

Various Ayurvedic lexicons derive the term *Chalana* as the one which is moving from its original place or proceeded or moved or departed or trembling or shaking,⁴ collectively it can be taken as movement with the influence of external factors. Hence, *Garbha Chalana* may be interpreted as initiation of descent of fetus due to various factors. As it is explained from 1st month to 8th month, it can be also be inferred as untimely descent of the fetus leading to *Akala Prasava*. The concept of *Garbha Chalana*, which is one among the unexplored topics of Ayurveda, is explained in Yoga Ratnakara⁵ and Harita Samhita.⁶ *Garbha Chalana* probably denotes the very early manifestation of pregnancy loss. If *Garbha Chalana* is not tackled timely, it would progress to manifest in the form of *Garbha Srava* (abortion), *Garbha Pata* or *Akala Prasava*. In order to prevent the progression, *Garbha Chalana*

Chikitsa is mentioned to ensure safe continuation of pregnancy and prevention of its unwanted early terminations. Though some research works have been carried out on *Masanumasika Garbhini Paricharya* (month wise antenatal regime), the concept of *Garbha Chalana* remains obscure till now and its utility in the prevention of premature termination of pregnancy at any gestational age has not been studied yet. Critical analysis of *Garbha Chalana* is necessary in order to prevent *Akala Prasava*. In order to put some light in this regard, the current study is planned. As this study is first of its kind, the study is limited only to 8th month *Garbha Chalana Chikitsa*.

AIM & OBJECTIVES

To assess the efficacy of *Lodhra* and *Pippali* in preventing *Garbha Chalana* w.s.r. to preterm uterine contractions during 8th month of pregnancy., Clinical evaluation of tocolytic activity of *Lodhra* and *Pippali*.

MATERIALS AND METHODS:

Study Design: It is a randomised comparative clinical trial. Randomisation was done by coin flipping method.

Source of data: Total of 40 patients with premature contractions in the 8th month of pregnancy, fulfilling the inclusion criteria, was selected for the study. Informed consent was obtained from the patients. Ethical clearance was obtained from the Institutional ethical committee.

Source of the drug: The required amount of *Lodhra* and *Pippali* were procured and authenticated from the hospital Pharmacy.

Inclusion Criteria:

- Pregnant patients in the age group of 18-35 years.
- Both primi and multi gravida were included.
- Patients completing 7th month of pregnancy, presenting with painful premature uterine contractions with regular intervals.
- Cervical dilatation less than or equal to 2.5 cm.

Exclusion Criteria:

- Pregnant lady having complications like pre-eclampsia, antepartum haemorrhage, premature rupture of membranes, polyhydramnios, twins, grand multi parity, gestational hypertension, diabetes mellitus.

- If onset of labour is due to acute fever, acute pyelonephritis, diarrhoea, acute appendicitis, toxoplasmosis.
- Pregnant lady with uterine malformation, severe anaemia and low body mass index.
- Pregnant women suffering with urinary tract infection, bacterial vaginosis, chlamydial vaginitis, trichomoniasis, candidal infections.
- Pregnant women diagnosed with congenital malformations of the foetus, intra uterine death, intra uterine growth retardation, placenta previa or abruption.
- Patients with uterine contractions more than 6 per 20 minutes, interval of 2-3 minutes with duration lasting more than 45 seconds and progressing cervical dilatation are excluded in the study.

Withdrawal criteria of trial group:

- Increasing intensity of contraction without altering the frequency or duration of uterine contractions.
- Increasing pain abdomen with uterine contractions.
- Progressive dilatation of cervix.

Treatment protocol:

Total 40 pregnant patients fulfilling the inclusion criteria were randomly divided into two groups of 20 patients each. Trial group was administered *Lodhra* and *Pippali* and Standard group was given Tab. Duvadilan. Grouping and dosage of the drugs are tabulated in Table 1 and details of the trial drugs are mentioned in Table 2.

Table 1: Grouping and posology

| Group | Drug | Duration | Form | Route | Adjuvant |
|-----------------------|---|------------------------|-------------|-------|-----------------------------|
| Trial group (n=20) | <i>Lodhra</i> (2.5 g) <i>Pippali</i> (250 mg) | 4 th hourly | Fine powder | Oral | Honey (Q.S) Milk (50 ml) |
| Standard group (n=20) | Tab. Duvadilan (10 mg) (Isoxsuprine hydrochloride) | 8 th hourly | Tablet | Oral | Water |

Q.S: Quantity Sufficient

Table 2: Details of the trial drug

| Drug | Latin name | Family name | Part used |
|----------------|---------------------------------|---------------------|-----------|
| <i>Lodhra</i> | <i>Symplocos racemosa Roxb.</i> | <i>Symplocaceae</i> | Bark |
| <i>Pippali</i> | <i>Piper longum L.</i> | <i>Piperaceae</i> | Root |

Assessment criteria:

- Subsidence of pain abdomen.
- Subsidence of intermittent hardening of uterus.
- Decrease in contractions of uterus assessed manually and by tocometer.
- Arrest of further changes in cervix indicative of progression of labour, through vaginal examination.

Assessment of Uterine contraction:

Evaluation was done on the basis of frequency, duration & intensity of contractions. Readings were taken at 1st hour, 3rd hour, 5th hour, 24th hour and after 1 week of drug administration.

1) Frequency of uterine contraction per 20 minutes

| | | |
|-----------|----------|---|
| >4 times | Severe | 3 |
| 2-3 times | Moderate | 2 |
| 1 time | Mild | 1 |
| Nil | Improved | 0 |

2) Duration of uterine contraction per 20 minutes

| | | |
|-----------|----------|---|
| >30 sec | Severe | 3 |
| 10-30 sec | Moderate | 2 |
| <10 sec | Mild | 1 |

3) Intensity of uterine contraction per 20 minutes

| | | |
|-------|----------|---|
| >60 | Severe | 3 |
| 40-60 | Moderate | 2 |
| <40 | Mild | 1 |

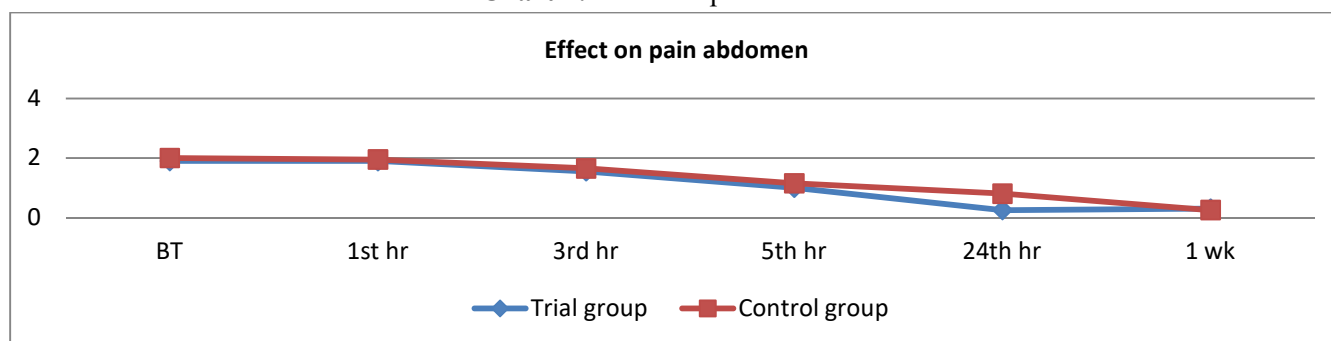
Statistical Analysis: The data obtained were subjected to statistical analysis. Paired and unpaired t-test were applied to compare the values within the group and between two groups respectively.

OBSERVATIONS & RESULT: Effect of the treatment, as observed on 1st, 3rd, 5th, 24th hour and on 1st week are shown in chart 1 to 4. Statistical evaluations of both the groups are tabulated in Table 3 and

the percentages of relief obtained are described in Table 4.

Effect on pain in abdomen: Both LP group ($p=0.000$) and IH group ($p=0.000$) showed statistically significant result in reduction of pain. Within 24 hours of observation, IH group showed 85% of improvement and LP group had 80% improvement. In both the groups, relief of pain was maintained at same level after 1 week also [chart 1].

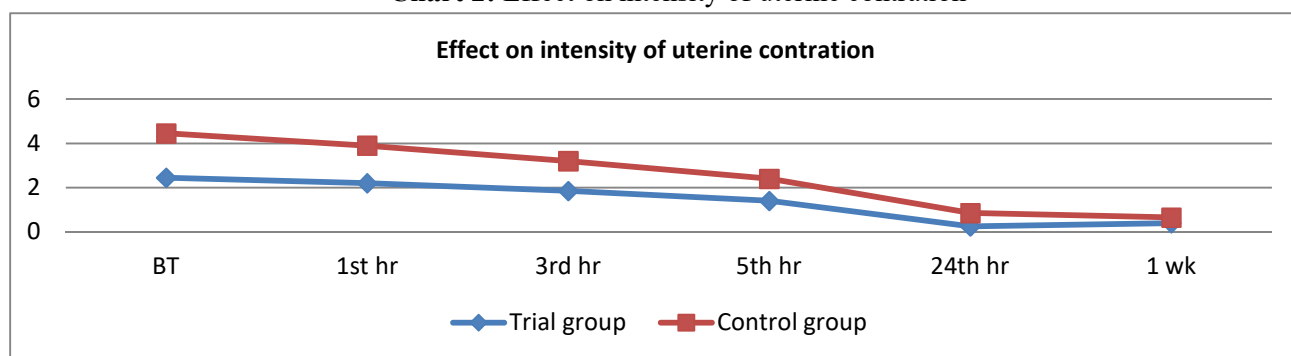
Chart 1: Effect on pain abdomen

**Effect on intensity of contraction:**

After 24 hours of observation LP group showed good effect on intensity of uterine contraction with 60% of reduction and 85% reduction in IH group. But after 1

week, the IH group ($p=0.000$) showed good result with improvement of 90% and LP group ($p=0.000$) with 70%. Both groups had significant results [chart 2].

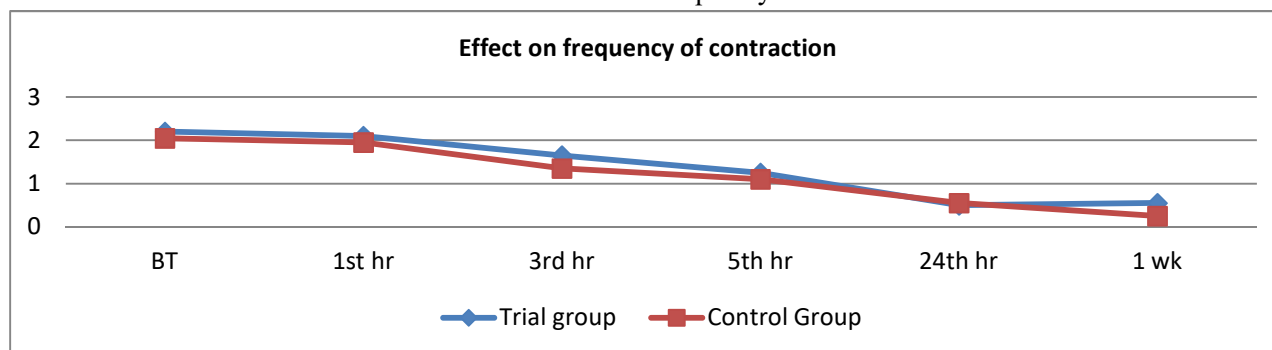
Chart 2: Effect on intensity of uterine contraction



Frequency of contraction:

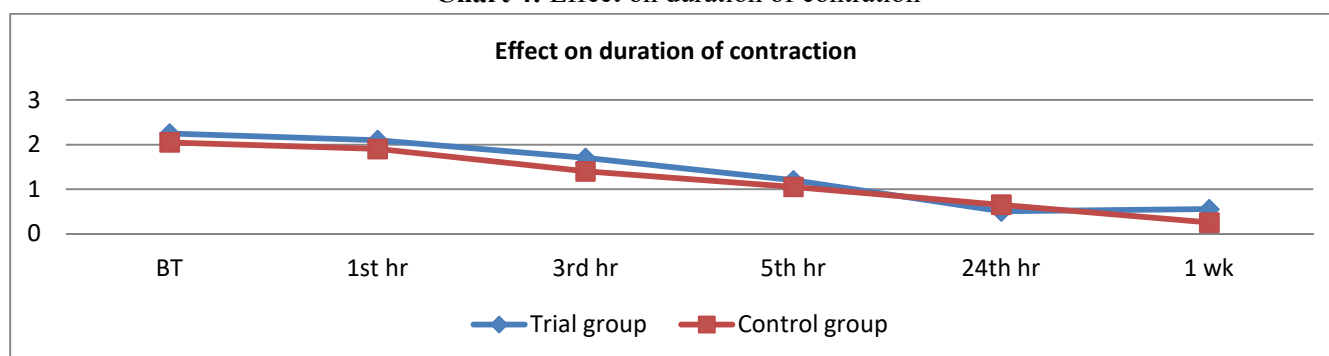
In the 24 hour observation, LP group had 75% relief whereas IH group had 55% relief. After 1 week, relief

in frequency of contraction in LP group ($p= 0.000$) was increased to 80% and 65% in IH group ($p= 0.000$) which were statistically significant [chart 3].

Chart 3: Effect on frequency of contraction**Effect on duration of contraction:**

LP group ($p= 0.000$) showed 50% and 55% reduction in duration of contraction after 24 hrs and 1 week re-

spectively whereas IH group ($p= 0.000$) showed 55% and 50% reduction after 24 hour and 1 week respectively. Both groups had significant results [chart 4].

Chart 4: Effect on duration of contraction

The results were statistically significant when compared within the groups. However when the efficacy of treatment was compared between the groups, the result did not show statistically significant difference.

Thus it can be derived that the tocolytic activity of LP group had similar efficacy with that of the modern standard drug of IH group.

Table 3: Effect of treatment on LP group and IH group

| Group | Mean of BT | Mean of AT | d | SD | SE | Within group | | Between group | | DF |
|-----------|------------|------------|--------|--------|--------|--------------|-------|---------------|-------|----|
| | | | | | | T | p | t | P | |
| Pain | | | | | | | | | | |
| LP | 1.900 | 0.300 | -1.600 | 0.7539 | 0.1686 | -9.491 | 0.000 | 0.447 | 0.657 | 19 |
| IH | 2.000 | 0.250 | -1.750 | 0.6387 | 0.1428 | -12.25 | 0.000 | 0.447 | 0.657 | 19 |
| Intensity | | | | | | | | | | |
| LP | 2.450 | 0.400 | -2.050 | 1.0990 | 0.2245 | -8.342 | 0.000 | -1.055 | 0.298 | 19 |
| IH | 2.000 | 0.250 | -1.750 | 0.6387 | 0.1428 | -12.25 | 0.000 | -1.055 | 0.299 | 19 |

| Frequency | | | | | | | | | | |
|-----------|-------|-------|--------|--------|--------|--------|-------|-------|-------|----|
| LP | 2.200 | 0.550 | -1.650 | 0.9881 | 0.2209 | -7.468 | 0.000 | 0.555 | 0.582 | 19 |
| IH | 2.050 | 0.250 | -1.800 | 0.6959 | 0.1556 | -11.56 | 0.000 | 0.555 | 0.582 | 19 |
| Duration | | | | | | | | | | |
| LP | 2.250 | 0.550 | -1.750 | 1.2183 | 0.2724 | -6.240 | 0.000 | 0.752 | 0.000 | 19 |
| IH | 2.050 | 0.250 | -1.800 | 0.6959 | 0.1556 | -11.56 | 0.000 | 0.752 | 0.000 | 19 |

LP- *Lodhra* and *Pippali* group; IH- Isoxsuprine Hydrochloride

BT- Before treatment; AT- After treatment

SD- Standard Deviation; SE- Standard error
t-student 't' test; d- difference

P- P value; DF- Degree of freedom

Table 4: Percentage of relief in LP group and IH group

| Duration | Pain | | Intensity of contraction | | Frequency of contraction | | Duration of Contraction | |
|---------------------|------|-----|--------------------------|-----|--------------------------|-----|-------------------------|-----|
| | LP | IH | LP | IH | LP | IH | LP | IH |
| 1 st hr | 45% | 60% | 30% | 60% | 50% | 40% | 25% | 35% |
| 3 rd hr | 55% | 65% | 45% | 65% | 55% | 45% | 35% | 45% |
| 5 th hr | 80% | 65% | 55% | 75% | 60% | 50% | 40% | 55% |
| 24 th hr | 80% | 85% | 60% | 85% | 75% | 55% | 50% | 55% |
| 1 wk | 80% | 85% | 70% | 90% | 80% | 65% | 55% | 50% |

hr- hour; wk-week

LP- *Lodhra* and *Pippali* group; IH- Isoxsuprine Hydrochloride

DISCUSSION

In Ayurveda, month wise diet regime has been explained for a healthy pregnant lady in *Masanumasika Garbhini Paricharya*. Similarly, the concept of *Garbha Chalana Chikitsa* is explained, wherein, month wise treatment is mentioned to prevent or manage pregnancies with the risk of early termination.

In Ayurveda classics, the line of management explained for *Garbha Srava*, *Garbha Pata*, *Prasramsamana Garbha*, *Garbhini Paricharya*, *Garbhini Shoola Hara Yogas*, *Garbha Rakshakara Yogas* almost resemble with line of management of *Garbha Chalana*. Therefore management of *Garbha Chalana* during 8th month of pregnancy may also be considered as the management to stop premature labour. Vitiating of *Apana Vata* is the causative factor for the initiation of premature contraction. The *Vata* which is necessary for the *Prakruta Gathi* may get hampered and represents itself in the form of *Garbha Chalana*. The majority of drugs mentioned in the management of *Garbha Chalana* possess *Sheeta Virya*, *Madhura Vipaka* with *Rakta Pitta Hara*, *Sthambhana* and *Vata Shamaka* in action. The drugs

also have anti inflammatory, anti spasmodic, analgesic properties.

*Lodhra*⁷ being *Sheeta Virya*, having *Laghu* and *Ruksha Guna* does the *Sthambhana Karma*. In many research works, *Lodhra* has been proved to have anti-inflammatory, anti-muscarinic, analgesic and anti-bacterial properties. Due to the anti-muscarinic property, it may probably block the excitation of post ganglionic para-sympathetic nerve endings and may help in inhibiting the smooth muscle. Being anti-inflammatory, it may act by inhibiting the cyclooxygenase pathway in the synthesis of prostaglandin thereby checking the production of prostaglandin thus preventing the preterm labour. *Lodhra* blocks the uterine contraction and spontaneous motility and also block the pitocin sensitive receptors. It also reduces the frequency and intensity of the contractions. *Pippali*⁸ being *Madhura Vipaka*, *Ushna Virya* enhances the bioavailability of the drug, helping in maximum absorption of the main drug. It also acts as *Rasayana* by its *Madhura Vipaka*. Being *Vedana Shamaka*, it alleviates *Vata*. In various research studies, *Pippali* is known to have anti-diarrheal, muscle relaxant, analgesic, anti-spasmodic activities which may relax the

smooth muscle by blocking the cyclo-oxygenase and relieves the pain. Thus the trial drug being *Sthambhaka* and *Vata Shamaka*, reduce the pain and premature contractions by its well established anti inflammatory, analgesic and anti spasmodic activity. Isoxsuprine Hydrochloride belongs to the category of adrenergic agonists especially beta receptor stimulants. It is an orally effective long acting selective beta receptor stimulant which has direct effect on smooth muscle relaxation. On uterine muscle it causes relaxation through beta receptors. Beta two adrenoceptor agonists will suspend the premature contraction by the action of myometrial relaxation. Through the property of cyclo oxygenase inhibition, it helps to inhibit the preterm labour. Smooth muscle relaxant property of drug isoxsuprine helped to suppress the uterine contractions and reduced the pain in standard group. Both trial and standard drug showed good effect on pain, intensity, frequency and duration of the contractions.

CONCLUSION

Lodhra & Pippali and Isoxsuprine Hydrochloride almost had similar efficacy in arresting the premature contractions associated with pain. In reducing the intensity of premature contractions, Isoxsuprine Hydrochloride group exhibited slight more effect. *Lodhra* and *Pippali* were beneficial in decreasing the frequency and duration of the contractions than the modern drug Isoxsuprine Hydrochloride. Present study showed that tocolytic activity of *Lodhra* and *Pippali* were almost analogous with that of Isoxsuprine Hydrochloride and can be used safely as preventive medicine for premature contractions or also can be given as maintenance therapy after the initial dose of modern tocolytics so as to minimize the burden and complications of using tocolytics and corticosteroids.

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