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“COMPARATIVE CLINICAL TRIAL OF EFFICACY OF GOKSHUR SIDDHA TAILA PICHU DHARAN WITH TILA TAILA PICHU DHARAN IN NINETH MONTH OF PREGNANCY IN PRIMI GRAVIDA PATIENTS FOR SUKHAPRASAVA.”

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ABSTRACT:

Background: Acharya Charak has mentioned Garbhini as the most delicate individual and to be handled with utmost attention like a vessel full of liquid. Prasav or delivery a very complex phenomenon of the female body. **Objectives:** To compare the efficacy of gokshur siddha taila pichu dharan with tila taila pichu dharan in ninth month of pregnancy in primi gravida patients for sukhaprasava. To evaluate whether Gokshur taila pichu is safe to administer per vaginally and has any side effect or allergy in primi patients for sukhaprasava. **Methods:** Patients who are willing to participate in study and Primigravida in age group of 18 to 30 years having Gestational age from 36 to 38 weeks were taken into the study. Study was conducted on for gokshur siddha taila pichu dharan with tila taila pichu dharan in 9th month of pregnancy in primi gravida patients for sukhaprasava. **Discussion & Result:** It was observed that both the group intervention shown significant improvement in bishop's score. Thus, Gokshur Siddha taila and Tila Taila both Yonipichu are equally effective in improving Bishop's score., in Primi Gravida Patients for Sukhaprasava.

KEYWORDS: *taila pichu dharan, gokshur, til tail, yonipichu.*

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INTRODUCTION:

Motherhood is considered as worship of God since many ages. Since, the origin of universe is from Prakriti, as like Prakriti Stree also have been also defined as beejadharmini and prasav dharmini. Menstruation, Conception & Motherhood are the creative aspects of procreation. A pregnant woman is very delicate individual and hence to be handled with care and love. Acharya Charak has mentioned Garbhini as the most delicate individual and to be handled with utmost attention like a vessel full of liquid. Prasav or delivery a very complex phenomenon of the female body. The process of prasav is controlled and regulated by Vayu, mainly Apana vayu. Considering today's lifestyle, changing dietary habitats, rising stress levels and sedentary lifestyle vatadushti is common amongst all individuals and due to vatadushti the rate of normal labour is decreasing considerably day by day. This vatadushti leads to Apanavataprtiloman, Thus, function of Apanavayu i.e., garbhanihishkramana gets hampered resulting in obstruction in the progress of normal labour. Complications of labour and their effects on parturient are many times very severe. To avoid these complications Acharya Charak has given the regimen of Garbhini Paricharya during antepartum period. Garbhini paricharya deals with maintaining health of the mother in antepartum and postpartum period, to support healthy progeny and facilitate sukhaprasava. There is possibly injury to perineum, vagina, cervix, bladder and anal canal in spite of surgically planned episiotomy which can lead to various complications like dyspareunia, incontinence, fistula etc. Also, an obstructed labour leads to raised chances of foetal morbidity due to prolonged hypoxia. A study of Gokshur siddha taila yoni pichu dharan in comparison with tila taila yoni pichu dharan

has been carried out in primi patients to study the efficacy of drug in Sukhaprasava.

AIM- To compare the efficacy of gokshur siddha taila pichu dharan with tila taila pichu dharan in nineth month of pregnancy in primi gravida patients for sukhaprasava.

Objectives:

1. To compare the efficacy of Gokshur siddha taila pichu dharan with tila taila pichu dharan in nineth month of pregnancy in primi patients for sukhaprasava.
2. To evaluate whether Gokshur taila pichu is safe to administer per vaginally and has any side effect or allergy in primi patients for sukhaprasava.

Materials and Methods-

a) DRUG STANDARDIZATION- Gokshur Mool Bharad and Tila Taila purchased from local market, authentication and standardization done.

b) METHOD OF PREPARATION. (S.O.P.): 1. Taila was prepared as per standard GMP norms. Gokshur Taila was prepared according to standard method of sneha kalpana in Sharangdhar Samhitas. Essential component for the preparation of Gokshur Taila were collected from genuine resources and taken as follows-

2) Pichu- Pichu is described as Beejahinkarpas which is kept in gauze piece (protamvatram) and tied with cotton thread.

PICHU SOP-

Definition: yoni pichu is insertion of tampons soaked in medicinal oil or liquid.

Preparation of pichu-

- 1) Pichu is made of cotton swab 2×3 cm (1 inch) is wrapped with gauze piece and tied with a long thread.
- 2) It is dipped in medicated oil/liquid.
- 3) Oils are the most preferred media because of its retention ability.

Types -

1. Elongated - 1 finger breadth and 4 finger long

2. Circular - 1 inch length and breadth.

Site - Prathamaavarta (vagina)- Elongated Pichu

Pichu Time of retention of Pichu- 5 to 6 hours up to next sense of micturition.

Pre procedure:

1. Patients were screened according to the inclusion and exclusion criteria.

2. Written informed consent is taken.

3. All procedure explained to the patient orally.

Group A - Trial group**Group B - Control group**

4. Sample size 88 was decided.

5. Detailed case taking with history taking of each patient was done.

6. Thorough obstetric examination was done, with routine haematological and urine laboratory investigations. Pelvic assessment was done and conformed with senior personals when the patients came in labour.

Procedure of Pichu Dharana-

- Pichu (Tampon) was autoclaved.
- Patient advised to void urine before pichu insertion.
- Patient lied down in supine position with flexed knees. i.e., Lithotomy position.
- Pichu was soaked in lukewarm Bala siddha taila and was inserted deep inside the vaginal cavity. It was administered twice a week and volunteer was asked to administer herself with all the aseptic precautions required.
- This helped easy removal of pichu after 5 to 6 hours. Patients were asked to remove the pichu if any complication observed.
- Patients were keenly observed throughout the ANC period.
- Partogram was assessed during labour.

Karmukatva of Pichu- The advantage of this procedure is that the lady can carry this

procedure by herself at her home. Yoni pichu helps in improving musculature of vaginal canal. Pichu can act as wound healing or antibacterial depending upon the drug used.

Duration-

- Gestational age 36-38 wks.
- Once in a day.
- Daily.
- At morning.
- For 5-6 hours or until patient feels for micturition even before 4 hours.

ELIGIBILITY CRITERIA:**INCLUSION CRITERIA-**

1. Patients who are willing to participate in study.
2. Primigravida in age group of 18 to 30 years.
3. Gestational age from 36 to 38 weeks.

EXCLUSION CRITERIA-

1. Pregnant women below 18 years and above 35 years.
2. Gestational age below 34 weeks and above 37 weeks.
3. Multipara.
4. Patients with bad obstetric history (BOH)
5. Malpresentation.
6. Pelvic deformity.
7. Previous uterine or vaginal surgery.
8. Placental abnormalities.

OBSERVATIONS:

Out of 88 patients 33 patients were in 18-21 age group. Out of which 20 were given trial drug while 13 were given control drug. From the age group 18-21 yrs 10 patients had LSCS (4 from trial group and 6 from control group) and 22 patients delivered normally. Similarly, 34 patients from 22-25 age group were included in the study of ou which 16 were given trial drug while 18 were given control drug. From which 24 delivered normally while 10 patients had LSCS.

Table no.1 Distribution According to Nature of Onset of Labour-

Onset of labour	Trial	Control
Spontaneous	32 (72%)	30 (68%)
Induced	12 (28%)	14 (31%)

According to the data collected, around 72% patients had spontaneous onset of labour in the trial group whereas 68% patients in control group had spontaneous onset of labour. In the trial group, 12 patients were given induction out of which 4 patients needed LSCS. In control group 14 were given induction out of which 7 needed LSCS.

Distribution According to Criteria of Bishop's Score-**Table no.2 A. Distribution according to dilatation of cervix at onset of labour-**

Dilatation of Cervix	Trial	Control
>3 cm	29 (65%)	24 (54%)
<3 cm	15 (35%)	20 (46%)

29 patients had cervical dilatation >3cm at the onset of labour and 15 patients had <3cm dilated in the trial group. In the control group, 24 patients had cervical dilatation >3cm and in 20 patient's dilatation of cervix was up to <3cm at the onset of labour.

Table no.3 B. Distribution according of effacement of cervix at onset of labour-

Effacement of cervix in %	Trial	Control
>50%	8 (18%)	5 (11%)
<50%	36 (82%)	39 (89%)

In the trial group, 8 patients had effacement >50% and in the control group, 5 patients had cervical effacement >50%. 36 patients from trial and 39 patients from control group had cervical effacement <50%.

DISTRIBUTION ACCORDING TO CRITERIA OF BISHOP'S SCORE-**Table no.4 A). Distribution according to dilatation of cervix at onset of labour- Between Control and Trial Group-**

P value and statistical significance		
Test	Chi-square	
Chi-square, df	1.2, 1	
Z	1.1	
P value	0.2761	
One- or two-sided	Two-sided	
Statistically significant (P < 0.05)?	No	
Effect size	Value	95% CI
Relative Risk	1.3	0.83 to 2.1
Reciprocal of relative risk	0.78	0.48 to 1.2

According to Chi square test, the value of P is 0.2761 which is >0.05. Hence, it is not statistically Significant. Thus, the dilatation of cervix at the onset of labour was almost observed same in control and trial group.

Table no.5 Dilatation of Cervix in Trial group before and after treatment-

Column B vs Column A	After Pichu vs Before pichu
Paired t test	
P value	<0.0001
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=17.85, df=43
Number of pairs	44
R squared (partial eta squared)	0.8811

Table no.6 Dilatation of Cervix in Control group before and after treatment-

Column B vs Column A	After Pichu vs Before pichu
Paired t test	
P value	<0.0001
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=7.949, df=43
Number of pairs	44
R squared (partial eta squared)	0.5950

According to the data analysed by paired t test, dilatation of cervix before and after treatment was equally significant before and after treatment in both groups. While Dilatation of cervix at the onset of labour in comparison of trial and control group was not significant. This implies that there is equal effect of both drugs on dilatation of cervix.

Table no.7 Distribution according of effacement of cervix at onset of labour-

Test	Chi-square	
Chi-square, df	0.81, 1	
Z	0.90	
P value	0.3674	
One- or two-sided	Two-sided	
Statistically significant (P < 0.05)?	No	
Effect size	Value	95% CI
Relative Risk	1.3	0.71 to 1.9
Reciprocal of relative risk	0.78	0.52 to 1.4

According to Chi square test, the value of P is 0.3674 which is >0.05. Hence, it is not statistically significant. Thus, the effacement of cervix at the onset of labour was almost observed same in control and trial group.

Table no.8 Trial Group-

Column B vs Column A	After Pichu vs Before pichu
Paired t test	
P value	<0.0001
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=8.646, df=43
P value (one tailed)	0.0104
Was the pairing significantly effective?	Yes

Table no. 9 Control group-

Column B vs Column A	After Pichu vs Before pichu
P value	<0.0001
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=5.914, df=43
P value (one tailed)	0.0326
Was the pairing significantly effective?	Yes

According to the data analysed by paired t test, effacement of cervix before and after treatment was equally significant before and after treatment in both groups. While effacement of cervix at the onset of labour in comparison of trial and control group was not significant. This implies that there is almost equal effect of both drugs on effacement of cervix.

Table no.10 Distribution according to cervical consistency-between control and trial group-

Test	Chi-square	
Chi-square, df	0.35, 1	
Z	0.59	
P value	0.5569	
One- or two-sided	Two-sided	
Statistically significant (P < 0.05)?	No	
Effect size	Value	95% CI
Relative Risk	1.5	0.60 to 8.3
Reciprocal of relative risk	0.66	0.12 to 1.7

According to Chi square test, the value of P is 0.5569 which is >0.05. Hence, it is not statistically significant. Thus, the consistency of cervix at the onset of labour was almost observed same in control and trial group.

Table no.11 Distribution according to cervical position-

According to Chi square test, the value of P is 0.3932 which is >0.05. Hence, it is not statistically significant. Thus, the position of cervix at the onset of labour was almost observed same in control and trial group.

Test	Chi-square
Chi-square, df	1.9, 2
P value	0.3932
Statistically significant (P < 0.05)?	No

Table no.12 Distribution According to Bishop's score -

Column B vs Column A	Control group vs Trial group
Paired t test	
P value	0.2154
P value summary	Ns
Significantly different (P < 0.05)?	No
One- or two-tailed P value?	Two-tailed
t, df	t=1.257, df=43
Number of pairs	44
Mean of differences (B - A)	-0.4886
SD of differences	2.578

P value (one tailed)	0.0072
Was the pairing significantly effective?	Yes

According to paired t test, the p value is 0.2154 hence bishops score is not significant compared to both groups. But if we consider before and after results of both groups, they show significant improvement in bishop's score. Thus, Gokshur Siddha taila and Tila Taila both Yonipichu are equally effective in improving Bishop's score.

DISCUSSION:

Results & discussion:

1) Age wise distribution -

According to Ayurveda the reproductive age of a female is between 16-25 years of age. In modern science, woman delivering her 1st baby after the age of 30 is said to be elderly primi. Elderly primi patients have higher risk of complications like PIH, IUGR, post maturity and labour related complications like premature labour, prolonged labour, uterine inertia due to malposition, inelasticity of soft tissues of birth canal, maternal and foetal distress. According to statistics, there is no significant difference in success rate of Yonipichu of trial and control group according to age.

2) Onset of Labour-

Data from the WHO Global Survey on Maternal and Perinatal Health, which included 373 health-care facilities in 24 countries and nearly 300 000 deliveries, showed that 9.6% of the deliveries involved labour induction. According to a study conducted at AFMC, 36% patients in India are induced due to post-dated pregnancy. In the trial group, 12 patients were given induction out of which 4 patients needed LSCS. In control group 14 were given induction out of which 7 needed LSCS. However, after comparing both groups, drug effect is not significant for induction of labour.

3) Cervical Dilatation-

Gokshur is a drug with Madhur rasa, Madhur Vipak and Sheeta virya Also It has mansagamitva. It enhances cervical dilatation thus It reduces chances of prolong labour thereby reducing chances of foetal

distress. Cervical dilatation before and after use of pichu in both groups was significant but there is no statistical significance of dilatation at the onset of labour between the trial and control groups. This implies that both groups have equal effect on dilatation and ripening of cervix up to the onset of labour. But if we consider dilatation of cervix per hour after onset of active labour. Trial group i.e., Gokshur pichu shows significant effect. Thus, properties of active constituents of Gokshur helps in dilatation of cervix in active phase of labour thereby causing smooth progress of labour.

4) Cervical Effacement-

Effect of Pichu on effacement at the onset of labour is found almost equal in both trial and control groups. However, there is marked improvement in effacement before and after pichu in both groups. Thus, Both Gokshur pichu and tila taila pichu are almost equally effective in improving effacement of cervix in prelabour stage, However, if we consider duration of labour and cervical dilatation per hour it is much more significant in Gokshur pichu. This concludes that Gokshur has significant action on cervical effacement in active stage of labour since Gokshur siddha taila pichu causes cervical ripening and softening.

5) Position of cervix-

Gokshur siddha taila pichu is helpful in cervical ripening and softening which helps in cervical positioning. However, If we compare both groups both Gokshur and tila taila siddha Yonipichu show almost equal effect. Thus, Pichu can be effective in improving cervical position also.

6) Bishop's score-

Cervical ripening is a series of complex biochemical changes taking place in the cervix mediated by the hormones. Alteration of cervical collagen and ground substances, ultimately results in soft and pliable cervix. These changes are catalysed by *pichu* treatment. *Taila* cause *mardavavour* and *kledana* locally, thus enhancing the ripening action. Both groups show favourable Bishop's score at the time of onset of labour. If we compare both trial and control groups, Both *Gokshur* and *tila taila siddha pichu* are almost equally effective in Cervical ripening before labour which causes favourable Bishops Score.

7) Duration of 1st stage of labour-

The average span of 1st stage of labour is 12 hrs in primi patients. The shorter duration of 1st stage of labour (6-7hrs) was found in the patients of trial group compared to control group. Thus, *Gokshur siddha taila Yonipichu dharan* was effective in reducing duration of first stage of labour, effectively without causing precipitate labour. Precipitate labour can cause foetal distress and maternal and foetal complications.

8) Duration of 2nd stage of labour-

The 2nd stage of labour starts from full dilatation of cervix upto expulsion of foetus. Its average duration is 2 hrs in primigravida. *Gokshur siddha taila pichu* improves muscle flexibility of *apatyapatha* and *snehan* causing good descend of foetus thus, shortening the duration of 2nd stage of labour. Hence, the application of *pichu* facilitates easy gliding movement of the head of foetus, prevents cervical dystocia and increases flexibility of perineum, thus reducing complications like prolonged labour, obstructed labour, etc. *Gokshur siddha taila pichu* is observed effective in reducing 2nd stage of labour as compared to *tila taila pichu*.

9) Partogram curve-

Both trial and control groups show evidences of normal curve which reduces chances of prolong labour. Thus, *pichu* treatment cut short 2nd stage of labour and aid in Normal Vaginal Delivery. Both groups show normal partogram curves, Thus, when compared to patients who have not given any effective in good outcome of labour process.

10) Perineal tear-

Pichu increases elasticity of perineum and stretching capacity, thus application of *pichu* has markedly reduced the possibility risks of perineal tear comprising of cervical tear and vaginal lacerations. Thus, *pichu* application in pre labour phase reduces the after complications of labour and thus helps in early recovery of mother after labour and reduces chances of further complications.

11) Parity-

This study included administration of *Yonipichu* in primi gravida patients only to avoid bias related to parity. Similar *pichu* was given to some second and third gravida patients in same institute. It has been observed clinically that multigravida had a smooth labour progress and minimal after delivery complications.

CONCLUSION:

The clinical study was done to compare the efficacy of *gokshur siddha taila pichu dharan* with *tila taila pichu dharan* in ninth month of pregnancy in primi gravida patients for *sukhaprasava*. Both *Gokshur* and *tila taila siddha Yonipichu* do not have any significant effect on onset of labour. Progress of labour depends on rate of dilatation of cervix per hour. *Gokshur taila pichu* enhances cervical dilatation and thus progress of labour. Bishop's score was highly favourable at the onset of labour in both groups, as application of *pichu* caused cervical changes favouring dilatation and effacement. Thus, favourable Bishop's score is an indicator towards

maximum possibility of normal labour. Duration of 1st stage of labour was reduced by Gokshur siddha taila pichu, thus reducing the total duration of labour. Effectiveness of Gokshur pichu application is seen in the 2nd stage of labour due to its local action leading to cervical changes favouring early ripening of cervix. Normal partogram is seen due to reduction in duration of labour, as partogram usually reflects the progress of labour in both groups. Due to early ripening of cervix, prevention of cervical dystocia and maintenance of elasticity of perineum, minimal invasion during intra-partum stage was seen. Therefore, there was marked reduction in the use of ventouse delivery. Chances of normal labour has increased. Maternal complications after normal labour like cervical tear and vaginal wall lacerations has been significantly reduced due to application of Yonipichu. Pichu application is cost effective, time required is negligible, no need of any assistance, safe to administer, and is free of infections, if done with proper aseptic precautions. Thus, from the above points, it can be concluded that Gokshur siddha taila yoni pichu administration in the 9th month of pregnancy is highly effective in easy facilitation of labour process. It helps in duration of 2nd stage and also minimises maternal and foetal complications.

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