WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 11, Issue 13, 1181-1190. Research Article ISSN 2277– 7105

A RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF TRIPHALADI KASHAYA IN PRASAVA

***[1]Dr. Adrija P., [2]Dr. Ramadevi G. and [3]Dr. Arpana Jain**

[1]3rd Year PG Scholar, [2]Guide, Professor & HOD, [3]Co-Guide & Assistant Professor
Dept. of Prasuti Tantra and Stree Roga, S.D.M. College of Ayurveda, Kuthpady, Udupi.

Article Received on
01 August 2022,
Revised on 22 August 2022,
Accepted on 11 Sept. 2022
DOI: 10. 20959/wjpr202213-25500

***Corresponding Author**
Dr. Adrija P.
3rd Year PG Scholar, Dept. of Prasuti Tantra and Stree Roga, S.D.M. College of Ayurveda, Kuthpady, Udupi.

ABSTRACT

Introduction: The Perinatal mortality rate in countries of Indian subcontinent are much higher than in developed countries. It was observed that the incidence of cesarean section increased more than from the earlier & increased perinatal death from birth asphyxia and septicemia. This calls for the caution and second thought on it. Caesarean sections can cause significant and sometimes permanent complications, disability or death particularly in settings that lack the facilities and/or capacity to properly conduct safe surgery and treat surgical complications. *Triphaladi Kashaya* is specially indicated for *Prasava.* This study is the one that lights the dept of classics in *Prasava* for further study. **Objectives:** To compare the effect of *Triphaladi Kashaya* with control group in *prasava.* **Materials & method:** -30 pregnant women from 38 weeks of gestation fulfilling the inclusion criteria were selected from IPD &OPD of SDM Ayurveda Hospital, Udupi. They were divided into two groups having 15 in each. Group I -was administered with *Triphaladi kashaya* in a dose of 50ml twice daily with 5ml of *Goghritha* from 38 weeks till labour starts. Group II - was administrated with 2.5 IU Pitocin in 500ml of RL. **Observations and Results:** According to statistics, *Triphaladi Kashaya* group found highly significant in total duration of labour. Control group was showing slow and steady progress in Bishop's score. Both groups were not significant in intensity of pain felt during labour. **Conclusion:** As per the observation and results, *Triphaladi kashaya* group have significant result than the control group in reducing the total duration of the labour and resulting in normal vaginal delivery. Both groups are not having any effect on labour pain.

KEYWORDS: *Triphaladi Kashaya*, Labour, Bishop's score, Duration of labour, *Prasava.*

INTRODUCTION

"Giving birth should be your greatest achievement, not your greatest fear."—Jane Weideman

Motherhood is a divine experience in every woman's life. It's an account of an additional responsibility of receiving, carrying, growing and transforming the genetic material from the male and reproducing it in the form of a well-developed baby & extracting it through parturition which needs proper strength and care which make labour as a vital part in women's life.

Last few hours of pregnancy are characterized by painful uterine contractions which leads to cervical dilatation & cause the fetus to descend through the birth canal which constitutes the normal labour. Its onset represents a series of biochemical changes in the uterus and cervix results from endocrine & paracrine signals emanating from both mother and fetus. Their relative contributions vary between species & these differences complicate elucidation of the exact factors that regulates the parturition.

The Perinatal mortality rate in countries of Indian subcontinent are much higher than in developed countries. Factors responsible are poverty, ignorance, malnutrition, illiteracy, cultural tradition, impaired fertility and gender discrimination etc. Maternal mortality is a result of complex interaction between medical, cultural, logistic and socio-economic factors which prevailing health care infrastructure in the community.

Induction implies stimulation of contractions before the spontaneous onset of labour with or without ruptured membranes. Its normally given to all gravidas according to their condition. The increased cesarean delivery risk associated with the induction is likely also strongly influenced by the induction attempt duration.

It was observed that the incidence of cesarean section increased more than the earlier & increased perinatal death from birth asphyxia and septicemia.[1] This calls for caution and second thought on it. Cesarean sections can cause significant and sometimes permanent complications, disability or death particularly in settings that lack the facilities and/or capacity to properly conduct safe surgery and treat surgical complications.

According to *Tridosha Sidhanta* in *Ayurveda*, labour is the process involved with *Tridoshas* where the *vata*[2] dominates the rest and leads to them till the completion of the labour. The

proper functioning of *Apanavayu* is highly essential for the *Prasava.*[3] For achieving this, various formulations are described in our classics.

Triphaladi Kashaya[4] is specially indicated for *Prasava.* It prevents that process from complications and maintains the hemostasis of both the mother and the newborn by properly functioning *Apana Vata.*

This study results shows lights on depth of classics in *Prasava* for further study. By this clinical study old concepts may be fortified or may be new concepts will be supplemented.

AIMS AND OBJECTIVES

- To compare the effect of *Triphaladi Kashaya* with control group in *prasava.*

MATERIALS AND METHODS

Clinical trials on human subjects have confirmed a comparative study of *Triphaladi Kashaya* in *Prasava* with the control group 30 Primigravida from 38weeks of gestation fulfilling the inclusion criteria attending the OPD and IPD of SDM Ayurveda Hospital, Udupi were taken for the study.

Study Design

A randomized open-label comparative clinical study to evaluate the effect of *Triphaladi kashaya* in *Prasava.*

Method of collection

- A special proforma was prepared with all points of history taking, physical signs, and investigations.
- The signs and symptoms were assessed on the basis of the standard method of statistical analysis.
- 30 pregnant women from 38 weeks of gestation fulfilling the inclusion criteria were selected.
- They were divided into two groups having 15 in each. Group 1 was administered with *Triphaladi kashaya* with *Goghritha* & *G*roup 2 was the control group administrated with oxytocin by following the normal standardized protocol of induction.

Intervention

- Group I -was administered with *Triphaladi kashaya* in a dose of 50ml twice daily with 5ml of *Goghritha* from 38 weeks till labour starts.
- Group II - was administrated with 2.5 IU Pitocin in 500ml of RL.

Inclusion criteria

- Primigravida from the gestation of 38 weeks.
- Age group- 18-35yrs.

Exclusion criteria

- Age group- below18 above 35yrs
- Pregnancy with complications
- Pregnancy with a history of threatened abortion
- Bad obstetric history
- Malpresentations and malposition
- Systemic illness

Criteria for assessment

Subjective parameter

- Intensity of pain felt

Grading was done with the Rating Scale of Pain Expression during Childbirth[5] (ESVADOPA Scale) which is specially designed for pain expression during labour. To fill in the scale, interrupting or interviewing the woman in labour is not necessary. There are 6 components in the scale; they are facial muscles, body response, verbal response, restlessness, ability to relax, and vegetative symptoms. Each of these items is scored from 0 to 3, with 0 meaning absence of pain expression and 3 meaning maximum pain expression. After the evaluation, a score is obtained that is categorized as follows: <1: Does not express pain; 1–6: Expresses mild pain; 7-12: Expresses moderate pain; and 13–18: Expresses intense pain.

Objective parameters

- Bishop's score[6]
- Partograph[7]
- Changes in the duration of each stage of labour

Final assessment: The outcome of the labour was observed and assessed & compared with the control group. During labour-Importance is given to the maternal & fetal well-being throughout the treatment course. Maternal BP, PR & Fetal heart rate was monitored every hourly. Labour is assessed in following headings - Time taken for the completion of 1st stage of labour is noted. 1st stage - noting the number, intensity & duration of uterine contraction. Cervical findings- softening, dilatation, effacement, bishop score and station of the head were noted. 2nd stage - Time taken from full dilatation to complete expulsion of fetus. 3rd stage - From the complete expulsion of fetus till the expulsion of placenta- duration was noted. Total time taken for the labour is compared with the control group.

OBSERVATIONS AND RESULTS

- **Mode of delivery**

In this study among 30 patients 70%of the patients underwent normal vaginal delivery and 30% of the patients underwent LSCS. In Group I (*Triphaladi Kashaya Group*), 86.7 percent of the patients underwent normal vaginal delivery & 13.3 percent of the patients underwent c-sections. In Group II, 53.3 percent of the patients underwent normal vaginal delivery and 46.7 percent of patients underwent c-sections.

Table no. 1: shows distribution based on Mode of delivery

Mode of delivery	Group 1		Group 2		Total	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
Normal vaginal delivery	13	86.7	8	53.3	21	70
LSCS	2	13.3	7	46.7	9	30

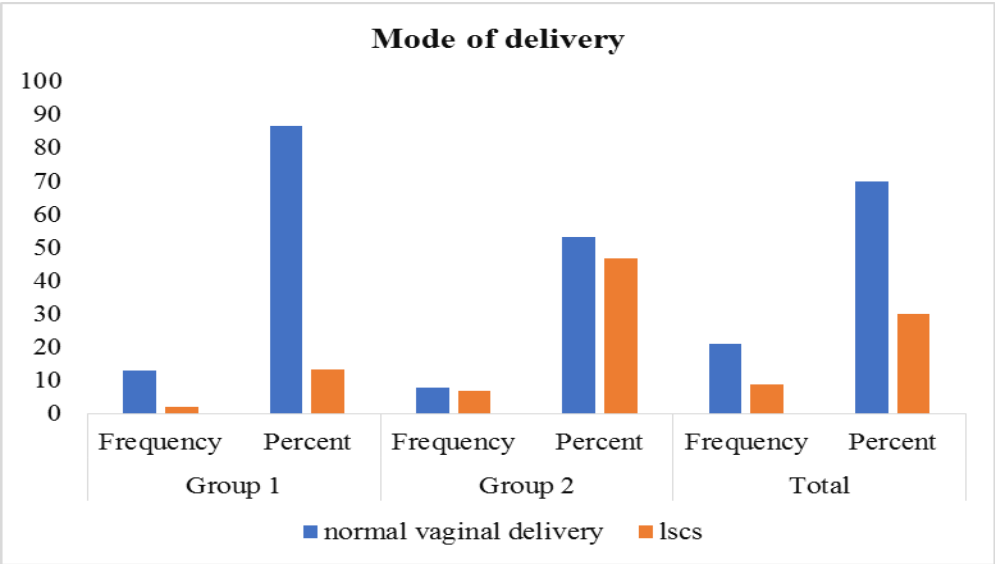

Figure no.1: showing distribution based on Mode of delivery.

- **Change in Duration of labour**

The total duration of the labour influences the fetal and maternal life after the delivery. When the labour is prolonged, it will lead to inadequate oxygen intake of the fetus resulting in hypoxia, asphyxia, acidosis, and hypoxic- ischemic encephalopathy (HIE) etc. In this study, The mean duration of 1st stage of labour in *Triphaladi Kashaya* group is 389.33 minutes and in control group its 515.33 minutes. In the 2nd stage of labour, 46.7% of patients took 10min in *Triphaladi Kashaya* group and 13.3% of patients took 10min in control group. The remaining 40% of patients in each group took 20 min and the rest of the patients underwent c-sections. In Group 1, 86.7% of patients took 10 min for the third stage of labour and the remaining patients underwent c-sections. In the control group, 33.3% of patients took 10min & 20% of patients took 20 min for the third stage of labour.

Table no. 2: shows the result of the duration of labor between the groups.

Independent Samples Test					
Duration of delivery	**t-test for Equality of Means**				
	F	**Sig.**	**t**	**df**	**P-value & interpretation**
The total duration of delivery	.000	.987	-6.039	28	.000 - HS
			-6.039	27.832	.000- HS
Duration of 1st stage of labor	.433	.516	-6.762	28	.000- HS
			-6.762	27.154	.000- HS

According to the above given statistical test, the resulted P value in the comparison of total duration of the labor & Duration of the 1st stage of labor in Group 1 and Group 2 is .000 which indicates highly significant in between the group.

- **PAIN**

Women have experienced severe pain during childbirth over the years and various attempts have been made to effectively manage labour pain. The intensity of the pain is associated with the uterine contractions which results in cervical dilatation. It is difficult to assess the labour pain through usual methods so that need lead to the development of ESVADOPA scale the Rating Scale of Pain Expression during Childbirth. As per the observations marked in the scale, the mean of total score on admission shows moderate pain in both groups. At the 2nd hour onwards till the delivery of the fetus the mean of total score was above 12 in *Triphaladi Kashaya* group as well as in control group, which represents intense pain expression as per the scale. According to the statistical analysis, all the P-values obtained are

not significant. So as per the observations the *Triphaladi Kashaya* have no effect on the intensity of pain.

DISCUSSION

The recent trend of obstetric practice is looked upon with the view of active management of labour, with the benefits it offers in expediting delivery among twelve hours, without maternal morbidity and perinatal complications like prolonged labour and with its attendant complications of infections, ketosis, dehydration, etc. also exhaustion and disenchantment within the mother. It becomes a necessity to be equipped basically with the safe and effective medication to induce, enhance or augment and shorten the labour whenever necessary.

Owing to the lack of clinical studies on ayurvedic drugs for labour, there is a need to explore and establish an oxytocic drug from the indigenous system of medicine for active management of labour.

As per *Ayurveda Prasava* takes place under the influence of *Avi*[8] which is considered uterine contractions. According to Modern, uterine contractions are activated by prostaglandin receptors and stimulated by estrogen and progesterone withdrawal. The intake of estrogenic compounds at term will initiate the activation of prostaglandin receptors, followed by the onset of labour.

The drug *Triphaladi Kashaya* consists of *Hareethaki*[9], *Vibheetaki*[10], *Amalaki*[11] & *Yashtimadhu*[12] with the *Anupama* of *Goghritha*[13] in which all the drugs are *Rasayana.*[14] Though it is referred from *Sahasrayoga* it was very commonly used in previous decades. Because it is very easily available, cost-effective and administrable. Hence this study is taken up to evaluate and compare its effect in labour with the control group. *Triphaladi Kashaya* prepared with *Hareetaki, Amalaki, Vibeetaki,* and *Yashtimadhu* with an equal quantity of each drug. The decoction was made as per the *Samanya vidhi* of *Kashaya* preparation and was administered along with *Goghritha anupana* as per told in its yoga.

All the drugs in *Triphaladi Kashaya* are having *Madhura vipaka,* which were more suitable for pregnant women. *Madhura* is formed by the combination of *Prithvi mahabhootha and Jala mahabhootha* which does the *Adhogaamitva* action of the *Dravya* with this *Vatanulomana* action of *Triphaladi Kashaya* can be explained.[15] *Anupana* of an Aushadha helps in spreading its action in the body like, how a drop of oil spreads on the water.

Likewise, *Goghritha* enhances spreads the action of the *Triphaladi Kashaya*, with its *Yogavahi guna. Goghritha is the Shrestha dravya* among all *Madhura rasa dravyas*, which implies its part in *Vatanulomana*, where the *Apana Vata* gets activated and triggers for *Garbha nishkramana kriya* in *Garbhini.*[16]

Amalaki & Vibheethaki contains gallic acid, ethyl gallate compounds and *Yashtimadhu* contains Liquiretigenin (LTG) which made the yoga rich in phyto-estrogenic compounds, stimulates the contraction associated proteins including connexin -43, prompts for the onset of labour.

The *yoga* contains Phyto-estrogenic compounds like Liquiretigenin[17] (LTG) does the activation of contraction-associated proteins[18] (cAP) which signals for the production of Prostaglandins[19], resulting in the ripening of the cervix, followed by initiation of the contractions. The contractions are maintained through the fatty acids, glycogens, etc. which provide energy for the muscle fibers and make them sustained till the end of the labour.[20] By the good contractions, cervical dilatation & effacement does the progression in Bishops score as well as in labour. The chain of reactions starting from the Phyto-estrogenic compounds does the maintenance of good contractions which helped in finishing the labour in a maximum of 7hrs in the *Triphaladi Kashaya* group. Its action on *Apana Vata* sustains the action of *avi* and makes the descent of the fetus.

Though Pitocin maintains the level of oxytocin[21] & promotes contractions, it may result into hypertonicity of the uterus lead to further complications like fetal distress then end up with emergency c- sections.[22] In this study normal duration of labour in primigravida is fulfilled by the oxytocin group but there is no significant decrease in it while compared to *Triphaladi Kashaya* group. Both groups failed to reduce the intensity of pain during labour.

CONCLUSION

Pregnancy is a journey with immense happiness of becoming a mother and labour is the most spectacular step for it. From ancient time onwards many drugs are used to augment and shorten this painful process of labour. All of them are differ in their mechanism of action from one drug to other. Although many researches done with different drugs, all are aimed at augmenting the labour, reducing its intensity of pain and delivering a healthy baby with normal vaginal delivery. *Triphaladi Kashaya* showed good acceleration on all the factors for delivery other than pain, by which it shortened the time taken for completion first stage of

labour with in a mean time of 6.9hrs compared to the control group and was statistically highly significant. Control group showed good results due to its sustained action of oxytocin. But according to this study the mean time for the first stage of labour as well as the total time taken for the labour was more compared to the *Triphaladi Kashaya* group. Thus by comparing all parameters of the study, *Triphaladi Kashaya* group showed good results in reducing the time duration of the labour and resulting in normal vaginal delivery.

Labour can be termed as rebirth of a woman herself, which literally means the difficulty of the procedure. so it's our responsibility to make it more comfortable for both mother and baby and this study shows that Ayurveda can beautifully handle it.

REFERENCE

1. Nauman Kiyani A, Khushdil A, Ehsan A. Perinatal Factors Leading to Birth Asphyxia among Term Newborns in a Tertiary Care Hospital. Iran J Pediatr, 2014; 24(5): 637-642.
2. Sumantran VN, Nair PP. Can the vagus nerve serve as biomarker for vata dosha activity? J Ayurveda Integr Med, 2019 Apr-Jun; 10(2): 146-151. doi: 10. 1016/j. jaim. 2019. 04. 003. Epub 2019 May 25. PMID: 31138487; PMCID: PMC6599167.
3. Acharya Yadavji Trikamji. Agnivesha. Charaka Samhita. Ayurveda Dipika commentary. Sha. Chapter no 2. 5th edition. Varanasi. :Chaukhamba Sanskrit Samsthana, 2001; P302.
4. K. V. Krishnan. editor. Sahasrayoga. Kashayaprakarana. 29th edition. Alappuzha: Mullakkal Publishers, 2010; P104.
5. Navarro-Prado S, Sánchez-Ojeda MA, Martín-Salvador A, Luque-Vara T, Fernández-Gómez E, Caro-Morán E. Development and Validation of a Rating Scale of Pain Expression during Childbirth (ESVADOPA). Int J Environ Res Public Health, 2020 Aug 12; 17(16): 5826. doi: 10. 3390/ijerph17165826. PMID: 32806536; PMCID: PMC7459959.
6. Dutta D. C. Konar H editor. D. C. Dutta's Textbook of Obstetrics. 6th edition. New Delhi: jaypee the health sciences publisher (p) Ltd, 2004; Ch12, P666: 522.
7. Dutta D. C. Konar H editor. D. C. Dutta's Textbook of Obstetrics. 6th edition. New Delhi: jaypee the health sciences publisher (p) Ltd, 2004; Ch12, P666: 529.
8. Tiwari P V editor. Kashyapa, Kashyapa Samhita. Shareerasthana. 5th chapter. Verse 30-31. Varanasi: Chaukhamba Sanskrit Samsthana. 2nd edition, 2000; P144.
9. A. Harini. Hedge Prakash. L. N. Textbook of Dravyagunavinjyana. Part2. New Delhi: Chaukambha Publications, 2018; P354.

10. A. Harini. HedgePrakash. L. N. Textbook of Dravyagunavinjyana. Part2. New Delhi: Chaukambha Publications, 2018; P169.
11. A. Harini. Hedge Prakash. L. N. Textbook of Dravyagunavinjyana. Part2. New Delhi: Chaukambha Publications, 2018; P31.
12. A. Harini. Hedge Prakash. L. N. Textbook of Dravyagunavinjyana. Part2. New Delhi: Chaukambha Publications, 2018; P903.
13. A. Harini. HedgePrakash. L. N. TextbookofDravyagunavinjyana. Part1. New Delhi: Chaukambha Publications, 2018; P303.
14. Madupu, Paramkusha. (2015). AYURVEDA RASAYANA DRUGS – A REVIEW ON CURRENT RESEARCH. World Journal of Pharmaceutical Research, 4: 843-858.
15. Madupu, Paramkusha. (2016). "RASA CHINTANA" (The Pharmaco-therapeutic Concept of Taste in Ayurveda)
16. Acharya Yadavji Trikamji. editor. Agnivesha, Charaka Samhita, Shareerasthana chapter 6, 5th Edition., Varanasi: Chaukhamba Sanskrit Samsthan, 2001; P335.
17. Gaur R, Yadav KS, Verma RK, Yadav NP, Bhkuni RS. In vivo anti-diabetic activity of derivatives of isoliquiritigenin and liquiritigenin. Phytomedicine, 2013 Nov; 18. pii: S0944-7113(13)00424-8. doi:10.1016/j.phymed.2013.10.015.
18. Cunningham F. Gary editor. Williams Obstetrics ebook. 25th edition. U. S. A: McGrawHill Education, 2018; P4/26.
19. Cunningham F. Gary editor. Williams Obstetrics ebook. 25th edition. U. S. A: McGrawHill Education, 2018; P12/26.
20. Dutta D. C. Konar H editor. D. C. Dutta's Textbook of Obstetrics. 9th edition. New Delhi: jaypee the health sciences publisher (p) Ltd, 2018; Ch13, P110.
21. Dutta D. C. Konar H editor. D. C. Dutta's Textbook of Obstetrics. 9th edition. New Delhi: jaypee the health sciences publisher (p) Ltd, 2018; Ch13, P465.
22. Dutta D. C. Konar H editor. D. C. Dutta's Textbook of Obstetrics. 9th edition. New Delhi: jaypee the health sciences publisher (p) Ltd, 2018; Ch13, P484.