

TOPICAL APPLICATION OF *KALIHARI* GEL AND THE OUTCOME OF LABOUR BY IMPROVISING CERVICAL RIPENING

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ABSTRACT

Objective: To determine the efficacy of *Kalihari* Gel on the Cervical Ripening and thereby the outcome on Labour at Term. **Methods:** Total 140 pregnant women with gestational age of 37-42 weeks were randomly divided into two control and treated groups having the 70 subjects in each group. The treated group was received the *Kalihari* aqueous extract in gel form locally. The primary outcome was the change in Bishop's score and the secondary outcome was the time and mode of delivery and lastly the tertiary outcome was the neonatal and maternal outcomes. The chi-square or Fisher exact test and Student's t-test were used for analysis of the data. **Result:** The Bishop score was significantly improved. The duration of labour time was reduced in trial groups and most of the deliveries were of spontaneous vaginal ones. The cesarean delivery rate was significantly lower in the trial groups There was no significant change was observed either in maternal or neonatal outcome. **Conclusion:** Local application of *Kalihari* Gel is an effective agent not only for cervical priming but also for induction of labour.

Keywords: cervical ripening, *Kalihari*, labour outcome

INTRODUCTION

Through the process of labor the fetus moves from the intrauterine to the extrauterine environment. It is a clinical diagnosis defined as the initiation and perpetuation of uterine contractions with the goal of producing progressive cervical effacement and dilation. Certain causes have made the induction of labor a common practice in obstetrics. In the absence of a ripe or favorable cervix, a successful vaginal birth is less likely¹. According to the most current studies, the rate varies from 9.5 to 33.7 percent of all pregnancies annually.

Therefore, cervical ripening or preparedness for induction should be assessed before the induction of labour. Assessment is accomplished by calculating a Bishop score. When the Bishop score is less than 6, it is recommended that a cervical ripening agent be used before labor induction. Nonpharmacologic approaches to cervical ripening and labor induction have included herbal compounds, castor oil, hot baths, enemas, sexual intercourse, breast stimulation, acupuncture, acupressure, transcutaneous nerve stimulation, and

mechanical and surgical modalities. Of these nonpharmacologic methods, only the mechanical and surgical methods have proven efficacy for cervical ripening or induction of labor. Pharmacologic agents available for cervical ripening and labor induction, in western system, include prostaglandins, misoprostol, mifepristone, and relaxin^{1b,c}. Whereas in alternative systems various herbal agents have been claimed and reported to have cervical ripening activity/. Among the most widely practiced herbal agents the Karpas, Kebuk and *Kalihari* are some reported to have efficacy for cervical ripening. In the present study to further substantiate the earlier claims and recent reports, the herbal drug *Kalihari* has been selected to study its efficacy on priming of cervix and also in initiation of labour.

MATERIAL AND METHODS

The selected drug was procured from local market, extracted the aqueous soluble portion and prepared the drug in gel form using modern chemical bases in aseptic atmosphere. The patients at or near term with unfavourable cervixes were registered from the antenatal clinic of Dept. of Prasuti & Stree Roga, S.S. Hospital, BHU, Varanasi after taking the informed written consent. A total number of 140 cases registered were randomly grouped into two group-1 Control, group-2 *Kalihari*, with 70 patients in each group.

Inclusion Criteria

1. Patients at or nearing term 35-38 weeks based on gestational age with unfavourable cervixes.
2. Women with > 7gms% haemoglobin

3. Hypertensive cases

4. Toxaemias of pregnancy

Exclusion Criteria

1. Indication for elective LSCS

2. Non reassuring FHR

3. Vaginal delivery contraindicated

4. Placenta previa

5. Previous uterine scar

6. CPD and

7. Diabetes, cardiac ailments and other systemic diseases

Drug & Dose

The *Kalihari* was extracted with water and evaporated to dryness. The dried extract was subjected to autoclave and the gel was got prepared in a local pharmacy using 10% w/w of the powdered dried material using modern pharmaceutical agents in aseptic atmosphere. The finished product was aseptically packed and advised to apply in the dose of 5g locally before going to bed from the time of registration to the time of onset of labour. The patients were asked to report after 15 days for follow up.

Assessment criteria

1. Vaginal rigidity assessed on the basis of laxity of vaginal muscles and graded as mild, moderate and severe

2. Cervical status- consistency, position and dilatation and graded as firm medium and soft. Apart from these findings the time of labour, mode of delivery. effect of drug on fetus and on mother etc were also assessed.

The chi-square, Z-test and Student's t-test were used for analysis of the data.

OBSERVATIONS & RESULTS

Table 1: Showing the Age Distribution of the Registered Subjects (n-70 in each group)

S.No	Age Range	Control	Treated
1.	18-20 year	17(24.3%)	20(28.6%)
2.	20-25 years	34(48.6%)	34(48.6%)
3.	25-30 years	15(21.4%)	13(18.6%)
4.	30-35 years	4(05.7%)	3(04.2%)

χ^2 1.430 DF =9, NS

"t" test

1.064 NS

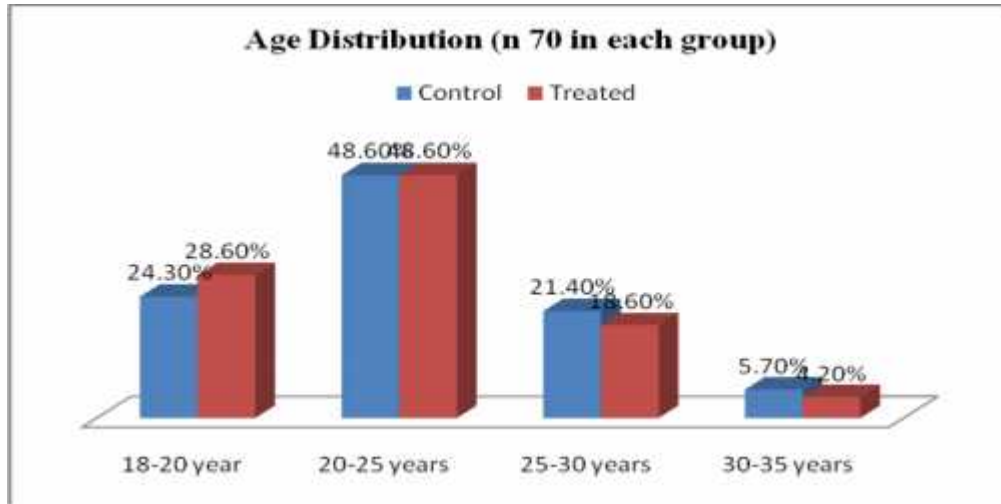


Table 2: Showing the Occupational distribution of the Registered Subjects (n-70 in each group)

S.No	Occupation	Control	Treated
1.	House Wife	58 (82.8%)	45(64.3%)
2.	Student	06(08.6%)	13(18.6%)
3.	Service	03(04.3%)	07(10.0%)
4.	Buisness	03(04.3%)	05(07.1%)

χ^2 17.72 DF=9 NS

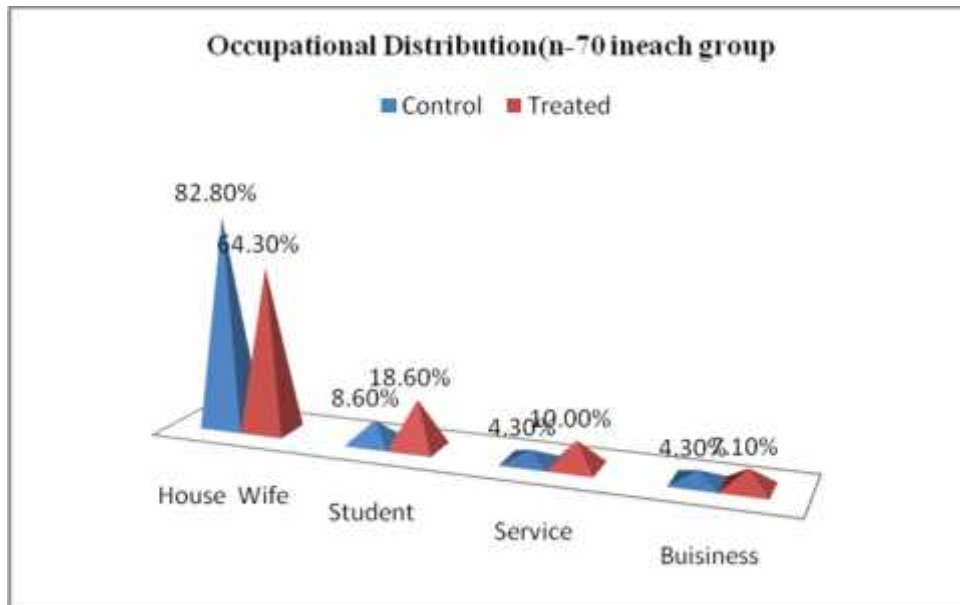


Table 3: Showing the Socioeconomic Status of the registered Subjects (n-70in each group)

S. No	Socioeconomic Status	Control	Treated
1.	LIG	25(35.7%)	22(31.4%)
2.	MIG	41(58.6%)	43(61.4%)
3.	HIG	4(5.7%)	5(7.2%)

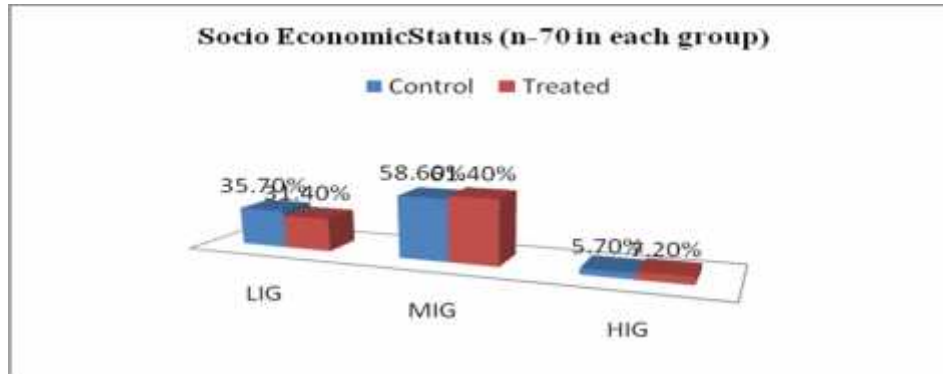


Table 4: Showing the Gravid position of the registered Subjects (n-70in each group)

S. No	Gravid	Control	Treated
1.	Primi	35(50%)	32(45.7%)
2.	Multi	35(50%)	38(54.3%)

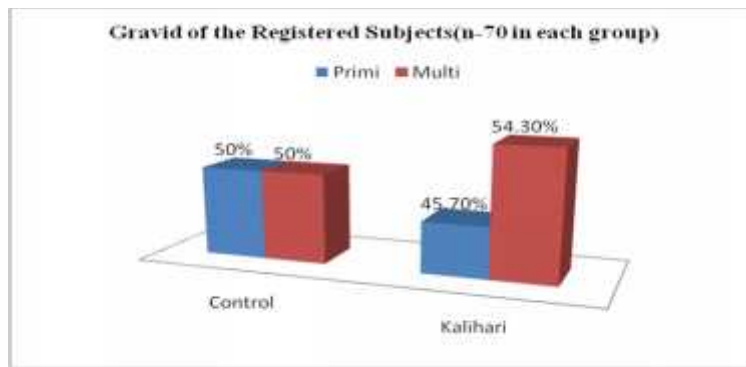


Table 5: Showing the Position of Cervix of the registered Subjects (n-70in each group)

S. No	Position of Cervix	Control Group		Treated Group	
		Before Tt.	After Tt.	Before Tt.	After Tt.
1.	Anterior	3(4.3%)	1(1.4%)	1(1.4%)	0(0.0%)
2.	Mid	59(84.3%)	63(90.0%)	68(97.2%)	70(100.0%)
3.	Posterior	8(11.4%)	6(8.6%)	1(1.4%)	0(0.0%)

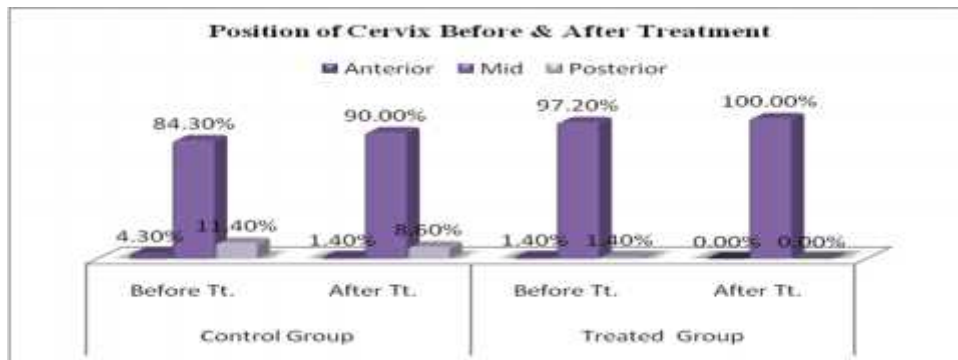


Table 6: Showing the Vaginal Rigidity (n-70in each group)

S.No	Grade	Control		Treated	
		Before	After	Before	After
1.	Mild Z value(self) After Tt. Z value(Con vs Tt)	9(12.6%)	28(40.0%) 3.80<0.001	8(11.4%)	63(90.0%) 15.19<0.001 7.25 <0.001
2.	Moderate Z value(self) After Tt. Z value(Con vs Tt)	40(57.2%)	31(44.3%) 1.55 NS	40(57.2%)	7(10.0%) 8.12<0.001 4.93<0.001
3.	Severe Z value(self) After Tt. Z value(Con vs Tt)	21(30.0%)	11(15.7%) 2.00<0.05	22(31.4%)	0(00.0%) 5.71<0.001 3.64<0.001

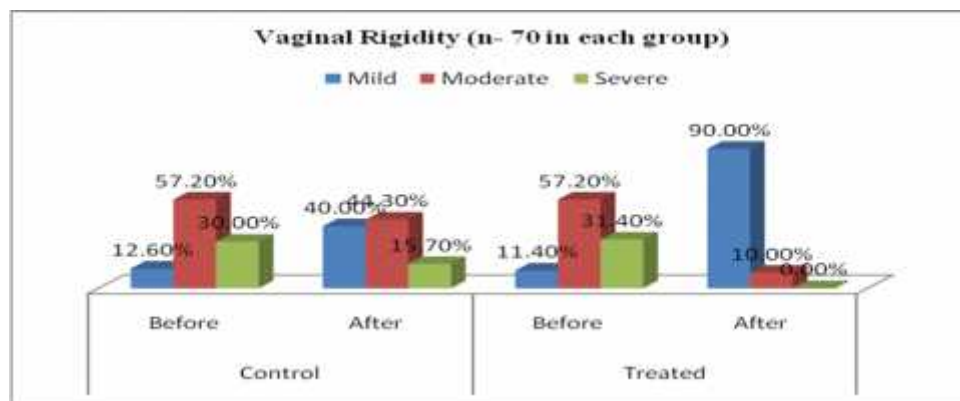


Table 7: Showing the Cervical Consistency (n-70in each group)

S.No	Grade	Control		Treated	
		Before	After	Before	After
1.	Firm Z value(self) After Tt. Z value(Con vs Tt)	40(57.1%)	18(25.7%) 3.92<0.001	41(60.0%)	1(1.4%) 9.83<0.001 4.63<0.001
2.	Medium Z value(self) After Tt. Z value(Con vs Tt)	30(42.9%)	20(28.6%) 1.75 NS	29(41.4%)	1(1.4%) 6.61<0.001 4.67<0.001
3.	Soft Z value(self) After Tt. Z value(Con vs Tt)	0(0.0%)	32(45.7%) 7.67<0.001	0 (0.0%)	68(97.2%) 48.5<0.001 8.10<0.001



Table 8: Showing the Cervical Ripening (n-70in each group)

S.No	Cervical Ripening	Control	Treated
1.	Ripen Z- Value	32(45.7%)	68(97.1%) 8.09 <0.001
2..	Un ripen Z Value	38(54.3%)	2(2.9%) 8.09 <0.001

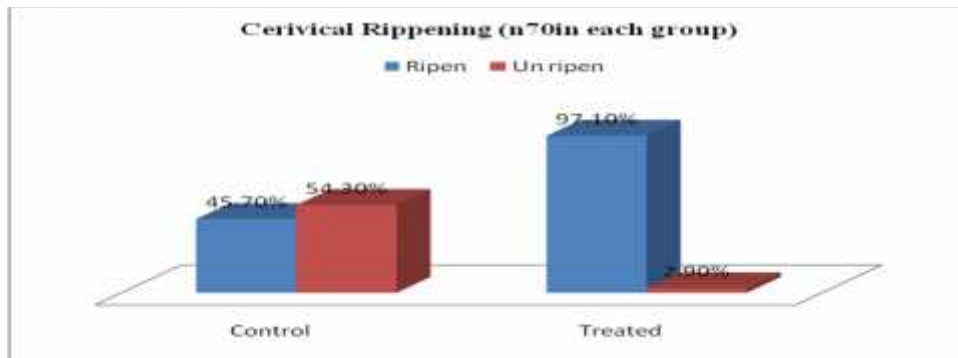


Table 9: Showing the Restlessness during Labour (n-70in each group)

S.No	Restlessness	Control	Treated
1.	Present Z- Value	10(14.3%)	0(0.0%) 3.5 <0.001
2..	Absent Z Value	60(85.7%)	70(100.0%) 3.5 <0.001

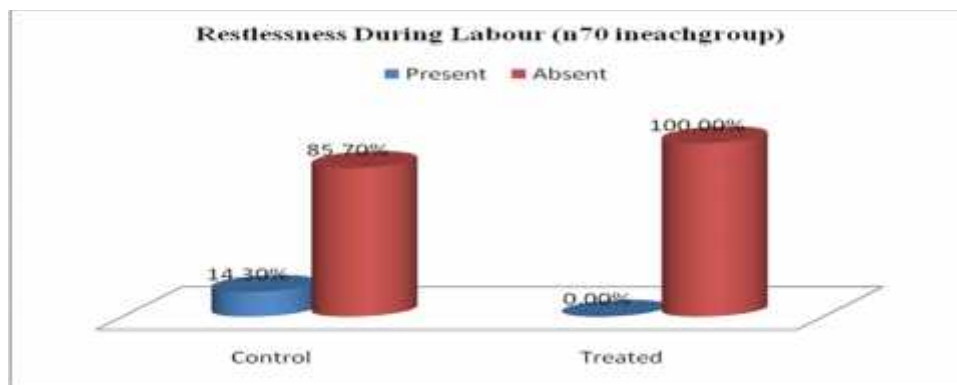
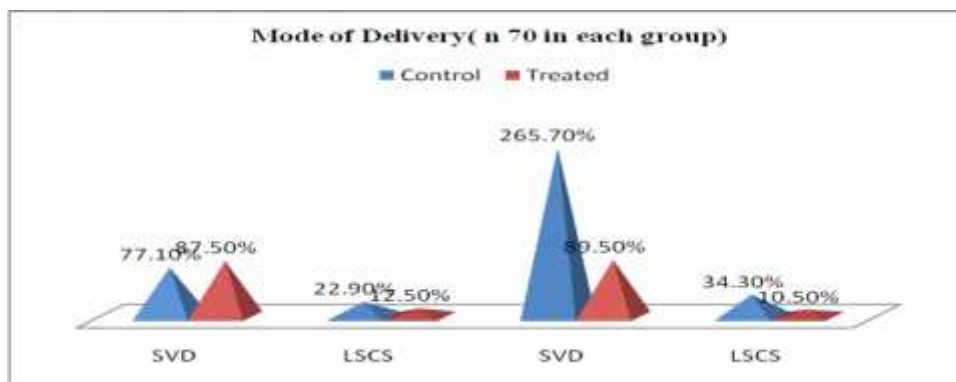


Table 10: Showing the Mode of Delivery (n=70 in each group)

Parity	Mode of Delivery	Control	Treated
Primi	SVD Z Value	27(77.1%)	28(87.5%) 1.21 NS
	LSCS Z Value	8(22.9%)	4(12.5%) 3.5 <0.001
Multi	SVD Z Value	23(65.7%)	34(89.5%)
	LSCS Z Value	12(34.3%)	4(10.5%) 2.58<0.01



DISCUSSION

Studies have demonstrated that if the total Bishop score is greater than 8, the rate of vaginal delivery after induction is similar to that of spontaneous labor. Low Bishop scores are associated with high rates of failed induction, leading to increased maternal-fetal morbidity and mortality and increased rates of cesarean section. ACOG recommends that the Bishop score be 6 or greater before proceeding with labor induction³ Ayurveda too has identified several factors responsible for Sukha Prasava (Spontaneous Vaginal delivery) Viz: Shukra, Asrik, Atma, Asaya and Kala⁴.

'kqdzkl' xkRek'k;dky lain
;L;ksipkj'p fgrS LrFkk UuS%A
xHkZ'pdkysp lq[kh lq[kap
latk;rs l ifjiw.kZnsg%AA p- 'kk
2@6

Among them the asaya factor and its management holds the key segment in

producing normal delivery The Asaya represents the uterus consists the corpus and cervix. Though they are differed in their structure and function but their synchronized actions have the important role during parturition and lack of coordination in between these two segments will lead to dystocia.

The uterine cervix will protect the foetus during the development by remaining firmly closed and also by providing resistance to pressure from above due to upright maternal position. However days before the onset of labour some biochemical changes will take place gradually under the influence of Hormones.

The favorable combination of position, consistency, station, dilatation and effacement of cervix is termed as cervical ripening. The clinical features of uterine contractions viz frequency, intensity and duration etc can't be relied upon as measures of progression of labour nor as

indices of normality. It is only the cervical ripening that is useful in assessing the progression of labour.⁵

It is *Kasyap* who laid emphasis on the clinical sign “*Yonioudarya*”⁶, during *Aasanna prasav*, can be compared with dilatation /ripening of cervix. *Bhavamishra* too while explaining the causes of delayed labour and post maturity mentioned in clear terms the *Vata* rendering the constriction / unfavourable passage⁷.

To overcome this condition the *Ayurved* has advised *Vasti* and *Pichu* from the start of 8th month in order to prepare the *garbhasaya* and *Garbhasaya marga*⁸. *Kashyap* has advised vaginal douches in cases of rigid /unyielding cervix. The *Ayurvedic* classics have advised measures like manual dilatation to use of various natural agents which can make the cervix favorable for spontaneous vaginal delivery. Among these agents *Kalihari*, *Kebuk* and *Kapas* etc are some and the *Kalihari*⁹ has been acclaimed widely in classics as well as reported, after scientific research, to have many fold actions on uterus. The drug has been prepared in gel form so that it will remain in situ for several hours and exert its pharmacological action, like that of *Pichu*¹⁰.

The subjects for the study have been selected from SS hospital, Varanasi after obtaining written consent to participate in the study. Among the age most of the subjects are in between 20-25 years of age range. In India it is the age for marriage and also it indicates the active reproductive age. Among the Occupancy of the registered subjects it is clear that the majority of the subjects were housewives followed by students. The reason was the patients from nearby villages are more accustomed to visit the SS hospital as it is only the biggest

hospital in vicinity. In rural areas most of the women were housewives. The hospital is in Institutional area hence the student community quite but naturally attended the OPD. The socioeconomic status reveals that the maximum subjects are from middle income group followed by low income group. As a routine practice the high income group patients doesn't prefer to attend public sector hospitals. Hence the middle and low income group subjects were more in registered subjects. The gravidal position of the registered subjects doesn't showed much variation might be because the floating population of Varanasi were more over the standing population, because of which the registration of primi gravida cases were equal to multi gravida. The position of the cervix is one of the parameter in assessing the Bishop's score and after treatment there was a shift in the cervical position to mid (central) from the initial(at the time of registration) position in *Kalihari* treated group which was a good sign for ripening of cervix. In control group there was no such shift is seen in the posterior position of cervix instead the change of anterior position to central position indicates the bad sign of unripenness of cervix. In minimizing the vaginal rigidity the drug *Kalihari* has showed a statistically highly significant (<0.001) improvement by providing laxity. In cervical consistency too the treated group has showed statistically highly significant (<0.001) results. The cervix showed the ripening in 50% of cases only in control group whereas in treated group 97% of cases have showed cervical ripening. The feeling of restlessness during labour was not seen in patients of treated group. Similarly all most all patients were cooperated at will during labour by treated group patients. This

might become possible because of the ripening of cervix. Cesarean section was necessitated in majority of cases irrespective of gravidity (Primi 22% and multi34%) in control group patients whereas in treated group very less number of cases was required cesarean section (primi12% and multi 10%). Thus the majority of deliveries in treated group have resulted in spontaneous vaginal mode. This was possible because of the ripening of cervix. The drug neither showed any sort of infection nor any sort of adverse reaction either to the mother or to the foetus in apgar score. Sushruta andchakrapani have advocatedit in the form of paste to promote delivery. The alkaloid colchicine which is present as an active constituent in the roots might has helped in ripening of the cervix and there by promoting the vaginal means of delivery. The reports also suggested that the rhizome is oxytotic and the aqueous extract has showed oytotic effect on isolated uterus of the various species studied. The fresh juice is uterine stimulant. Thus the study has once again substantiated not only the textual claimsbut also supports the earlier researches.

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