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Research Article

A RANDOMISED CONTROLLED TRIAL COMPARING TRANSCERVICAL FOLEY CATHETER WITH AND WITHOUT EXTRA-AMNIOTIC SALINE INFUSION FOR INDUCTION OF LABOUR IN A PERIPHERAL MEDICAL COLLEGE

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Abstract

Purpose- To compare the efficacy and safety of trans-cervical Foley catheter alone to trans-cervical Foley catheter with extra-amniotic saline infusion for labour induction and cervical ripening in women with unfavourable cervix, comparing induction to delivery intervals in two groups, rate of cesarean delivery and Neonatal outcome in terms of APGAR score at 1 and 5 minutesMethods- This study was conducted during the period from 1st July 2012 to 30 th June 2013 in the Dept of G&O , Bankura Sammilani Medical College ,Bankura, WB. All mothers with term pregnancy admitted in antenatal ward and labour room of our department were included in this single blinded Randomised Controlled Trial study .Inclusion criteria included were women with term and and singleton pregnancy ,cephalic presentation with intact membrane and bishop's score of 6 or less. 100 pregnant women(study group 50,control group 50) were randomly assigned to treat with either trans-cervical Foley catheter with extra amniotic infusion (study group) or trans-cervical catheterization alone (control group).The parameters that were studied include to record cervical ripening by using Bishop's score, to record progress of labour, fetal heart rate ,time interval between induction of labour and delivery and APGAR scoring at 1 and 5 min of each baby delivered to know the fetal outcome. Results- Most patients coming to Obstetrics dept of our college for confinement, belong to 18-20 yrs of age group, the maximum no of patients in both groups belong to 39 weeks of gestational age. Most of the patients taken from study population were having Bishop's score =3or 4 before induction of labour. The mean values of Bishop's score after induction of labour in study and control group are 9.82 and 9.24 respectively and p value calculated is 0.04 which is statistically significant. It was observed that all the Foley catheters got removed simultaneously before 12 hrs and none of them were required to remove manually. Mean values were calculated by t test and their values are 4.49 hrs and 5.50 hrs for study and control group respectively. Since the p value is 0.029(<0.05), it is statistically significant . The mean values of induction delivery time interval in study and control group are (10.57+- 3.24)hrs and (12.43=+-3.24) hrs respectively. P value is 0.011, so there is significant difference between their induction delivery time intervals in two groups.Conclusions- Our conclusion is ,induction of labour by using Foley with EASI results in shorter induction to vaginal delivery time interval , than Foley alone. Ceserean rate was same with EASI group as in Foley alone group. Apgar score was similar in both groups. So both methods are suitable, effective and safe for induction of labour and can be practiced in rural based hospitals and low economic health set up.

Keywords- Extra amniotic saline infusion ,Foley catheter, induction of labour, Randomized controlled trial

Abbreviations- EASI-Extra amniotic saline infusion, LUCS- Lower uterine cesarean section, RCT- Randomized controlled trial, IOL- Induction of labour, SNCU-Sick Neonatal Care Unit

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INTRODUCTION

Induction of labour is one of the most common procedures in obstetrics and one of the fastest growing medical procedures in developed countries like United States, where its incidence has increased more than double from 9.5% in 1991 to 22.5% in 2006[1] .According to WHO data (year 2011), in developed countries upto 25 % of all deliveries at term involved induction of labour[2].In developing countries the rates are generally lower(in India approx 10%)[3], but in some settings they can be as high as those observed in developed countries.

It was seen in various studies that pharmacological methods like oxytocin, prostaglandins and corticosteroids stimulates myometrium and thus causing uterine hyper stimulation and fetal distress[4,5]. Mechanical methods of cervical ripening act primarily by dilating and stretching the lower uterine segment and cervix, and are usually not associated with uterine hyper stimulation. Several studies suggested that cervical ripening with an extra amniotic Foley catheter, which is a mechanical method of IOL, has advantages of simplicity , low cost, reversibility and lack of serious side effects[4,5,6].Various studies have been done in recent past establishing relationship between IOL by various methods and incidence of rising ceaserean section as a consequence of their failure[7].

The purpose of our study is to compare the efficacy and safety of usage of foley catheter with and without extraamniotic saline infusion for IOL and to evaluate the success or failure of induction, at a rural tertiary maternity care unit.

MATERIALS AND METHODS

This study was conducted during the period from 1st July 2012 to 30 th June 2013 in the Dept of G&O , Bankura Sammilani Medical College ,Bankura, WB. All mothers with term pregnancy admitted in antenatal ward and labour room of our department were included in this single blinded Randomised Controlled Trial study. Inclusion criteria included were women with term and singleton pregnancy ,cephalic presentation with intact membrane and bishop's score of 6 or less. The patients which were not included in the study were mothers with intrauterine fetal demise or anomalous fetus, post cs patients, placenta previa, non reassuring fetal heart rate pattern and patients having allergy to latex. 100 pregnant women(study group 50,control group 50) were randomly assigned to treat with either transcervical Foley catheter with extra amniotic infusion (study group) or transcervical catheterization alone (control group).The parameters that were studied include to record cervical ripening by using Bishop's score, to record progress of labour, fetal heart rate ,time interval between induction of labour and delivery and APGAR scoring at 1 and 5 min of each baby delivered to know the fetal outcome. In control group 16 F

Foley catheter with 30 ml balloon was introduced past the internal cervical os into the lower uterine segment, but outside the chorioamnion.The balloon was then inflated with normal saline ,pulled back against internal os until snug, and Foley was tapped to the inside of the maternal thigh under minimal tension. In addition ,in study group room temperature normal saline was infused through Foley catheter at a rate of 30 ml/hr. All women were receiving intravenous oxytocin , initially with low dose of 1mU/ml at the rate of 15 drops/min and then gradually incremented till satisfactory response was achieved which is considered 4-5 contractions /10 min without causing hyperstimulation. The Foley catheter would have to be removed if anyone of the following occurred (i) expulsion,(ii)non reassuring fetal heart rate mandating membrane rupture,(iii) spontaneous membrane rupture or (iv)12 hrs had elapsed since placement. If the Foley catheter was found still in place after elapsing 12 hrs,it had to be removed and oxytocin drip was to be continued. Induction of labour was to be said failed cervix fails to dilate>4cm even after 12 hrs of adequate contractions and membrane rupture. For prophylaxis against group B streptococcus causing endometritis or chorioamnitis, patients were kept under antibiotic coverage during the whole procedure.

RESULTS:

Most patients coming to Obstetrics dept of our college for confinement, belong to 18-20 yrs of age group. Elderly gravida are very few in number as inferred from table 1.The table 2 shows that the mean age of patients in study group is 21.44yrs and that in control group is 21.78 yrs with SD of 3.17 and 3.58 respectively. The p value calculated by t test is 0.616, so it statistically not significant and the age factor in both group is similar. Chi-square test done from the variable 'gravidity'(table 3) in two groups having values of 2.884 ,df=3 and p value is 0.4 which is>0.05 , so the two groups, study and control are similar on the basis of gravidity. From Table 4&5 it is clearly seen that the maximum no of patients in both groups belong to 39 weeks and since p value calculated by t test is 0.91 which is >0.05 , so it is statistically insignificant. From Table 6&7 it is our inference that most of the patients taken from study population were having Bishop's score =3or 4 before induction of labour and t test value is 0.48 and p value is 0.63 and thus statistically in significant. From Table 10 it can be seen that the mean values of Bishop's score after induction of labour in study and control group are 9.82 and 9.24 respectively. Comparision of two means was done by t test , t test value is 2.069; the p value calculated is 0.04 and thus there is significant difference between the scores after induction of labour in study and control group. From Table 11 it was observed all the Foley catheters got removed simultaneously before 12 hrs and none of them were required to remove manually. Mean values were calculated by t test and their values are 4.49 hrs and 5.50 hrs for study and control group respectively. Since the p value is 0.029(<0.05), it is statistically significant ; so there is significant difference between the time interval in two groups. From Table 12 it is seen the mean values of induction delivery time interval in study and control group are (10.57 hrs+- 3.24) and (12.43=+-3.24) respectively. P value is 0.011, so there is significant difference between their

induction delivery time intervals in two groups. From frequency table 13 it is seen that instrumental and cesarean delivery in control group is more than those in study group. APGAR scores in both 1 and 5 min of birth are similar in statistical calculation.

TABLE-1: DISTRIBUTION OF TOTAL PATIENTS ACCORDING TO AGE GROUP

Age(Year)	STUDY GROUP N=50	CONTROL GROUP N=50
18-20	23(46.0%)	25(50.0%)
21-23	16(32.0%)	12(24.0%)
24-26	07(14.0%)	08(16.0%)
27-29	03(6.0%)	03(6.0%)
30-32	01(2.0%)	02(4.0%)

TABLE-2: t-TEST-COMPARISON OF MEAN AGE IN TWO GROUPS (STUDY AND CONTROL)

	N	Mean	SD	SE	t-test	P value	df
Study Group	50	31.44	3.170	0.448	-0.503	0.616	98
Control group	50	21.78	3.582	0.507			

TABLE-3: DISTRIBUTION OF PATIENTS ACCORDING TO PARITY AND GRAVIDA

GRAVIDA	PARITY	STUDY	CONTROL
PRIMI	0+0	28(56%)	22(44%)
SECOND	0+1	5(10%)	7(14%)
	1+0	7(14%)	12(24%)
THIRD	0+2	2(4%)	1(2%)
	1+1	2(4%)	2(4%)
	2+0	5(10%)	4(8%)
FOURTH	1+2	1(2%)	1(2%)
	2+1	0(0%)	1(2%)

TABLE-4: GESTATIONAL AGE IN TWO GROUPS

GESTATIONAL AGE	STUDY GROUP N=50	CONTROL GROUP N=50
37 weeks to 37weeks 6 days	1(2%)	1(2%)
38 weeks to 38weeks 6 days	11(22%)	15(30%)
39 weeks to 39weeks 6 days	28(56%)	21(42%)
40 weeks to 40weeks 6 days	10(20%)	13(13%)

TABLE-5: t- TEST- COMPARISON OF MEAN GESTATIONAL AGE OF TWO GROUPS

Group	Mean GA(in weeks &days)	SD	t-test value	df	P-VALUE
Study	39.3	0.66	0.110	98	0.913
Control	39.2	0.80			

Table-6 BISHOP'S SCORE BEFORE INDUCTION

Bishop's score	Study(n=50)	Control(n=50)
1-2	14(28%)	18(36%)
3-4	32(64%)	29(58%)
5-6	4(8%)	3(6%)

TABLE-7: t-TEST-CONPARISON OF MEAN BISHOP'S SCORE BEFORE INDUCTIONIN TWO GROUPS

Group	Mean	SD	SE	T test Value	df	P value
Study N=50	2.98	1.059	0.180	0.480	98	0.632
Control N=50	2.88	1.023	0.145			

TABLE-8: INDICATION FOR INDUCTION OF LABOUR

Indication	Study (n=50)	Control(n=50)
PIH	12(24%)	8(16%)
Pre-eclampsia	5(10%)	6(12%)
Post dated	9(18%)	13(26%)
Oligohydramnios	8(16%)	10(20%)
IUGR	4(8%)	2(4%)
Diabetes	0(0%)	1(2%)
Elective	8(16%)	9(18%)
Others	4(8%)	1(2%)

TABLE-9 : BISHOP'S SCORE AFTER INDUCTION.

Score	Study (n=50)	Control (n=50)
6-7	4 (8%)	5 (10%)
8-9	14 (28%)	20 (40%)
10-11	28 (56%)	24 (48%)
12-13	4 (8%)	1 (2%)

TABLE-10 : t-TEST-COMPERISON OF MEAN BISHOP'S SCORE AFTER INDUCTION IN TWO GROUP.

	Median (range) in hour.	Mean (in hour)	SD	t test value	df	P value
Study (n=50)	10.07(5.45-17.45)	9.82	1.521	2.069	98	0.041
Control (n=50)	12.10 (6.55-18.45)	9.24	1.271			

TABLE-11 :TIME INTERVAL BETWEEN FOLEY CATHER INSERTION AND REMOVAL.

	Mean (in hour)	SD	t test value	df	P value
Study (n=50)	4.49	2.09	-2.216	98	0.029
Control (n=50)	5.50	2.28			

TABLE-12 : INDUCTION DELIVERY INTERVAL.

	Mean (in hour)	SD	SE mean	t test value	df	P value
Study(n=50)	10.57	3.24	0.28	-2.591	98	0.011
Control (n=50)	12.43	3.24	0.28			

TABLE-13 : MODE OF DELIVERY.

Mode	Study (n=50)	Control (n=50)	Chi-square test value	df	p value
CS	8 (16%)	13 (26%)			
Forceps	6 (12%)	9 (18%)			
Spontaneous	36 (72%)	28 (56%)	2.790	2	0.248

TABLE-14 APGAR SCORE.

		STUDY (n=50)	C0NTROL(n=50)	
APGAR SCORE IN 1 MINUTE	Mean	6.98	6.96	
	SD	1.857	2.128	
	SE mean	0.263	0.301	
	t test	0.050		
	df	98		
	p value	0.96		
	Median value		8(2-10)	8(3-10)
APGAR SCORE IN 5 MINUTE	Mean		9.06	8.84
	SD		0.998	1.167
	SE mean		0.141	0.165
	t test		1.013	
	df		98	
	p value		0.314	
	Median value		9(6-10)	9(6-10)

DISCUSSION

This study ,which is randomized controlled trial was restricted to Bankura Sammilani Medical College & Hospital , a rural based tertiary care unit.The results of this study were compared with the results of few other studies in which Foley catheter was used for induction of labour.Mean values of Gestational age calculated by LMP are39.3+-0.7 and 39.2+-0.8 weeks respectively in study and control group with p value of 0.913 which is statistically insignificant. In Monique's study[8], the mean values of of GA are 38.6+- 2.9 and 39.0+-4.5 weeks in study and control group respectively with p values of 0.43 which is comparable to our study.Regarding birth weight of babies in study and control group , p value calculation is 0.818,which is statistically insignificant. Bishop's score measured before induction of labour in study and control group is 2.98+-1.059 and 2.88+- 1.023 respectively and p value is 0.632; so their baseline character is also similar for statistical analysis.In the RCT of Monique et al [8], they had taken patients with Bishop's score 3.0 and 2.0 respectively in the study and control group before induction (p value=0.55).As already discussed in frequency table ,frequency induced hypertension, pre-eclampsia, post-dated pregnancy, oligohydramnios, IUGR ,diabetes and elective indications were the indications of induction of labour.p value calculated by chi-square test is 0.90.Other studies such as RCT by Monique et al [8], and Zafarghandi et al [9] had also mentioned the similar indications in their study published in AJOG,Nov-2010.

In study group the mean time for spontaneous removal of catheter was 4.49+- 2.09 hrs and in control group it was 5.50 +- 2.28 hrs,p value= 0.029 which is statistically significant i.e there is significant difference in the time interval between Foley catheter insertion and removal.Therefore from this value, it can be commented that Foley's balloons was expelled out earlier when when extra amniotic saline infusion was added to it. It may be due to the fact that EASI causes more mechanical stripping of membrane and hence more release of prostaglandins as compared to Foley catheter alone. In RCT by Zafarghandi et al [9] ,the mean interval for removal of Foley catheter with EASI was 4.9 hrs which is similar to to our value.Monique et al [8] has found similar result ; the mean time of Foley expulsion was shorter in EASI group (4.1+- 2.3 hrs) than in the Foley group(5.3+- 3.2 hrs);p value 0.005. Bishop's score after induction in study group was 9.82+- 1.521 and in control group was 9.24+-1.271.p value calculated by t test is 0.041 which is statistically significant.

In our study , induction delivery time interval is is 10.57 +- 3.24 hrs in study group and 12.43+- 2.24 hrs in control group. Median value in study and control group is 10.07 hrs and 12.10 hrs respectively. Since the p value is 0.011, there is significant difference in delivery induction interval in two groups . Karjane et al [10] has similar result as ours. The time from induction to delivery was 16.58 hrs in study and control group vs 21.47 hrs in control group,p value <0.01. But in their study the overall duration of labour was more than our study which may be due to the fact that they have not given oxytocin to all patients . Four other studies conducted by Monique et al[8] ,Lin et al [11], Gunn et al[12],and Zafarghandi et al[9] had different results from our study and their p values were not statistically significant. Regarding mode of delivery , 36(72%) mothers delivered spontaneously by vaginal route,6 (12%) by forceps delivery and 8(16%) by cesarean section. In control group, 28(56%) mothers delivered spontaneously, 9(18%)by forceps and 13 (26%) by cesarean section. The no of cesarean delivery in mothers who were induced by Foley catheter with EASI is less as compared to Foley only group, but statistically it is same in both groups; p value =0.248.All other four studies as conducted by Monique etal [8], Karjane et al [10]Lin et al [11], Guin et al[12] gave similar

results.In our study p value of mean APGAR score in 1 min and 5 min were 0.96 and 0.314 respectively.14% in study group and 24% in control group were meconium stained . p value calculated by Fisher's Exact Test is 0.308 which is statistically insignificant.18% in study group and 26% in control group were admitted in SNCU immediately after birth; Fisher's Exact p value being 0.47.

CONCLUSION

Our conclusion is ,induction of labour by using Foley with EASI results in shorter induction to vaginal delivery time interval , than Foley alone. Ceserean rate was same with EASI group as in Foley alone group. Apgar score was similar in both groups . Various studies have used various sizes of balloon catheters with usage of various amount of normal saline for inflating the balloons. Also ,the rate of extra amniotic saline infusion varies in the studies.These varying factors may affect the results. Both methods are safe as they cause less foetal distress, less maternal complication, and few admissions of early neonates in SNCU;also both of them are cost effective. So both methods are suitable, effective and safe for induction of labour and can be practiced in rural based hospitals and low economic health set ups.

Conflict of interest- None.

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