COMPARISON OF 30 ML AND 60 ML FOLEY CATHETER FOR CERVICAL RIPENING

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Abstract

Object: This study is to compare the efficacy of 60ml with 30ml of intracervical balloon (Foley) catheter for pre induction cervical ripening.

Material and methods: This is a study of 88 multigravida mothers with the confirmed period of gestation of 40 weeks and 2 days. The period of study was from 1.11.2008 to 1.5.2010 at the Colombo south teaching hospital and Castle street hospital for women in Colombo Sri Lanka

A total of 88 mothers participated in the study. The mother were equally distributed to the two groups. (44 mothers in 60 ml group and 44 mothers in 30 ml group)

Results: Higher proportion of cervical favorability was achieved in 60 ml Foley catheter group compared to 30ml group. This difference was statistically significant ($p<0.001$).

There was no significant difference between the 30ml volume and 60ml volume group in relation to maternal age. ($p=0.23$) Higher proportion of Vaginal delivery was achieved in 60ml Foley balloon group compared to 30ml Foley balloon group. This proportion was statistically significant. ($p=.0.01$) Cervical ripening using Foley balloon inflated with 60ml was more likely to achieve delivery within 30 hours compared with 30ml group ($p<0.001$).Duration of labour was significantly short in 60ml group($p=0.001$).

Keywords: Cervical ripening, induction of labour, Foley catheter, mechanical methods of induction, post-term pregnancy and Bishop score

Introduction

Induction of Labour

If the continuation of pregnancy is a threat to the life of the foetus, mother or both, the labour is induced to deliver the fetus. There has been a substantial increase in the

incidence of induction of labour during the past few decades. The .induction rate is around 10-20% in many centres and 10% of the inductions are for pregnancies beyond 41 weeks of gestation

Induction of labour to prevent post-term pregnancy

Postdate pregnancy complications increase as the pregnancy advances even before reaching 42 weeks of gestation[52].Therefore, all women with uncomplicated pregnancies should usually be offered induction of labour between 41-42 weeks. The exact timing should be taken into account with woman's preference and local circumstances according to NICE guideline[53].

Induction of Cervical Ripening

If the Bishop's score is less than 5, the cervix needs further ripening for induction. Pharmacological and mechanical methods are available for cervical ripening.

Prostaglandin E2 (PGE 2) is one of the commonest pharmacological agent used in Sri Lanka. Mechanical method of cervical ripening includes hydroscopic dilatation, membrane sweeping, and use of Foley catheter . Routine use of membrane sweeping might be beneficial in woman with gestational age of 40 weeks according to a recent Cochrane review.[54]

Use of Foley catheter has been popular for last 2 decades in Sri Lanka since it is simple, cheap, effective and well tolerated by the patient. There is a slightly increased infection rate which is peculiar to some of the other mechanical methods as well.

Intacervical Balloon Foley Catheter

The use of Foley catheter to ripe the unfavorable cervix was first introduced by Ezimokhai and Nuuabineli in 1980.

Foley catheter is a popular mechanical device for cervical ripening in patients with unfavorable cervix. The use of an extra-amniotic catheter balloon has the advantage of reversibility and lack of systemic or serious side effects on mother and the foetus compared to the use of medical methods of cervical ripening.

One of the major advantage of the Foley induction is that it ripens the cervix without effective uterine contraction. Therefore the uterine hyperstimulation is very minimal compared to prostaglandin induction. If the induction process goes beyond 48 hours, the

[52] Barrillceux PS, Bofill JA, Terrone DA, Mogourn FF, May WL, Morrison JC. Cervical ripening and induction of labour with Misoprostol, Dinoprostone gel and a Foley catheter: A randomized trial of 3 techniques. Am J. Obstet. Gynecol 2002; 186:1124-1129.

[53] National Institute for Clinical Excellence (2008) Induction of labour;NICE Guideline 70. Available from www.nice.org/CG070.Accessed June 24 2009.

[54] Boulvein M, Ster C, Jrion O. Membrane sweeping for induction of labour. Cochrane Data base Syst. Rev. 2005 Jan (25);(1):CD000451 Review.

neonatal infection rate is slightly high. Foley induction may increase Caesarean section rate compared to spontaneous onset of labour and delivery[55]

Contraindications for Cervical Ripening.

Contraindications for induction of labour and vaginal delivery include :

- Foetal malpresentation
- Active herpes genitalis infection
- Non assuring fetal well being monitoring
- History of previous difficult or traumatic vaginal delivery
- Unexplained vaginal bleeding
- Placenta previa or vasa previa

Maternal pyrexia

History of previous caesarean section or major uterine surgery

Objectives

General Objective

This study is to compare the efficacy of 30ml of intracervical balloon catheter with 60ml of intracervical balloon catheter for pre induction cervical ripening in low risk multiparaous mothers with singleton pregnancy, vertex presentation, intact membranes and Bishop score of 5 on less than 5 at the period of gestation 40weeks and 2 days. The dating was confirmed by first trimester ultrasound scan

Specific Objectives

(a**)**To ascertain the success rate of induction of cervical ripening by using different volume of Foley balloon catheter.

(b)To compare the obstetric outcomes between 30ml and 60 ml Foley balloon catheter ©To compare the maternal and foetal complication during the period of cervical ripening, during labour and immediate post partum period.

Materials and methods

Study design.

This is a randomized clinical study to compare the efficacy of Foley balloon catheter inflated with 30ml and 60ml of distilled water. Mothers were allocated to each two groups by using computer generated random number table . By stratified block randomization, mothers with different parities were equally distributed among two groups.

[55] Lyrdrup J, Nicholson C, Weber T, Molint Z E, Guldberk J. Induction of labour by balloon catheter: A randomized comparison with PGE2 vaginal pessaries. Eur J Obstet Gynecol Reprod 1994; 47:189-192.

Study setting and duration

The study was conducted in ward 17, Colombo South university Teaching Hospital Sri Lanka(CSTH) and ward 01 of the Castle Street Hospital for Women Colombo Sri Lanka(CSHW) . The period of study was from 01st of November 2008 to 01st May 2010.

Study Population

Multiparaous mother presented to ward 17 at CSTH and ward 01 at CSHW, with 40weeks and 2 days of period of gestation.

Inclusion Criteria

Multiparaous mothers with 40weeks and 2 days of period of gestation whose dates were confirmed by early ultrasound examination and singleton pregnancy, vertex presentation, intact membranes and Bishop's score of less than 5.

Exclusion criteria

Complications like pregnancy induced hypertension, gestational diabetes mellitus ,heart disease complicating pregnancy, parity 5 and above, past Caesarean sections, lower lying placenta (<3cm to internal os), recent history of any bleeding and any contraindication for vaginal delivery.

Sample size is calculated using following formula.

$N=(u+v)^2 [p1(1-p1)+p2(1-P2)] / (p1-p2)^2$

u- power- 90% = 1.28

v-confident interval 95% = 1.96

p1-expecting success rate of group 1 – 95%

p2 success rate of group 2 –70%

N = 41, therefore minimum 44 mothers (N+4%) should be allocated to each two group. According to previous study p2 was taken as 70% for favorability of cervix after Foley catheter induction in primipara and 95% success rate was expected for p1.[56]

Data Collection

Data was collected by interviewing patients and from hospital notes using data collection instrument.

All mothers assigned to this study were adequately counseled regarding procedure and importance of this study. And they were assured that all information obtained from them was used only for study, they were not revealed what so ever.

[56] Adenij O A,Glodukon A. Pre induction cervical ripening: Trans cervical Foley catheter versus intra vaginal Misoprostol.J Obstet Gynecol 2005;25(2):134-149

Intervention

Ethical clearance was taken from the Ethical Review Committee of both hospitals. Informed written consent was taken from all mothers . 60ml inflation catheter was used for 1st group and 30ml used for 2nd group.

Cervical assessment was done under aseptic condition by Registrar or senior medical officer at 40 weeks and 2 days and Bishop's score was recorded. Bishop's score of 5 or less were considered for Foley induction.

Procedure of insertion of intracervical Foley catheter

No.18 Foley for 30mL group and No.22 Foley for 60mL group were used. Catheter tip was introduced into the space between the amniotic membrane and the lower segment of the uterus gently with the long artery forceps under direct vision. Catheter bulb was inflated with 60mL for the 1st group and 30mL for 2nd group with distilled water. Gentle traction was applied and kept it with plaster to medial aspect of the thigh. Mother s were requested to inform the staff if the catheter was fallen before 24 hours and asked the staff to mention the time of fall. If the balloon did not fall spontaneously, bulb was deflated and removed after 24hours. The Bishop's Score was recorded at the same time by registrar or senior medical officer.

If cervix was favorable (≥ 8), patient was sent to the labour room for induction of labour. If not favorable, waited for another 24hours to decided the mode of delivery. After 24hours of catheter introduction, cervix was assessed by senior medical officer. When Bishop's score was 8 or more, mother was sent for induction of labour..Foetal wellbeing was assessed during labour with intermittent CTG monitoring and colour of liquor.

If any complication occurs due to Foley catheter, it was documented and the mother was treated accordingly. When the mothers complained mild to moderate pain, they were treated with paracetamol. If the pain was severe or associated with bleeding the catheter was removed.

Using data collection sheet the relevant information regarding following aspects was documented.

- Bishop's score at the time of induction of cervical ripening.
- Bishop's score 24 hours after induction of cervical ripening.
- Maternal complications during cervical ripening; pain (mild/moderate/sever), bleeding and maternal pyrexia.
- Complication during labour: maternal pyrexia, meconium stained liquor and CTG abnormality

- Post partum complications; maternal pyrexia(temperature 38 C or above in two occasions), neonatal pyrexia

Primary outcome Measures

Changing the Bishop's score 24 hours after Foley catheter induction: Whether cervix was favorable or not. Bishop' score was 8 or more, considered as favorable for induction.

Secondary outcome measures

- Interval between inductions of cervical ripening to delivery.
- Spontaneous catheter expulsion rate
- Mode of onset of labour
- Duration of labour.
- Vaginal delivery rate
- Caesarian delivery rate.
- Failed induction rate.
- Lack of progress rate.
- Pain and bleeding rate during induction of cervical ripening.
- Meconium stained liquor and CTG abnormality during labour.
- Maternal pyrexia during labour
- Maternal and neonatal pyrexia rate during immediate (within 1st 3 days) post partum period.

Data Processing and analysis

Statistical Method

Data were entered and analyzed by using Statistical Package for Social Sciences (SPSS, USA) computer program (version 17.0). Descriptive statistics were used to calculate means, frequencies and standard deviation. The continuous data are expressed as average with standard deviation and qualitative deta as an absolute and relative frequency are presented as relative risks (RR) with a 95% confident interval(CI). Standard Error Difference between percentages for two proportions (z-test) was applied when appropriate. The results were analyzed using the Student *t* test for quantitative variables and for the association between qualitative variables, chi-square test was used.

The level of statistical significance was set at p=0.05.

Results

When Foley catheter was expelled spontaneously before 24 hours it was considered as a favorable out come. Cervical favourablity was achieved in 97.7% of the mothers in the 60 ml group and 56.8% of the mothers in the 30 ml group. This was statistically significant (P<0.001)

Vaginal delivery occurred in 93.2% of the 60 ml group and 72.7% in the 30 ml group. Time interval between the insertion of Foley catheter to delivery was significantly shorter in 60 ml group compared to 30 ml group.

Demographic characteristic of two study group.

Table 1: Distribution of Maternal age

Age in years	Study group				Significance (df=1)	
	60_{mL} volume		30_{mL} volume			
	n	%	n	%	χ^2	p-value
23 – 25	5	11.4	2	4.5	1.47	0.23
26 – 28	9	20.5	7	15.9		
29 – 31	8	18.2	11	25.0		
32 – 34	9	20.5	11	25.0		
≥35	13	29.5	13	29.5		
Total	**44**	**100.0**	**44**	**100.0**		
Mean±SD	31.3±4.6		32.1±4.3			t=0.88,p=0.38

n=number of subjects ,df=degree of freedom

Maternal ages of mothers were ranging from 23 to 40 in years, with a mean age of 31.7 ± 4.4. The age of group 30ml group was ranging from 24 to 40 ages with a mean of 32.1 ± 4.3 ages; the ages of 60ml group is ranging from 23 to 38 ages with a mean of 31.3 ± 4.7 ages (Table 1).

There was no significant difference between the 30ml volume and 60ml volume group in relation to maternal age. (p=0.23)

Table 2: Distribution of parity

Parity	Study group				Significance	
	60_{mL} volume		30_{mL} volume			
	n	%	n	%	χ^2	p-value
2	26	59.1	26	59.1	0.06	0.96,NS
3	11	25.0	11	25.0		(df=2)
4	7	15.9	7	15.9		
Total	**44**	**100.0**	**44**	**100.0**		

NS=Not Significant, n=number of subjects

With regard to parity, equal number of mothers from each category was allocated to each group by stratified sampling method to nullify the confounding errors.

Primary out come measures

KEY: Bishop score — Label of Bishop score
≥8 - Favorable
<8 - Not favorable

Table 3: Comparison of cervical favorability after Foley catheter induction.

Bishop score status	Study group				Significance (df=1)	
	60_{mL} volume		30_{mL} volume			
	n	%	n	%	RR(95%CI)	p-value
Favorable	43	97.7	25	56.8	12.65(1.86-86.17)	<0.001, S
Not favorable	1	2.3	19	43.2		
Total	**44**	**100.0**	**44**	**100.0**		

n=number of subjects, S= Significant, NS=Not Significant,df=degree of freedom,RR=Relative Rick, CI=Confident Interval.

Higher proportion of cervical favorability was achieved in 60 ml Foley catheter group than 30ml group. This difference is statistically significant (p<0.001).

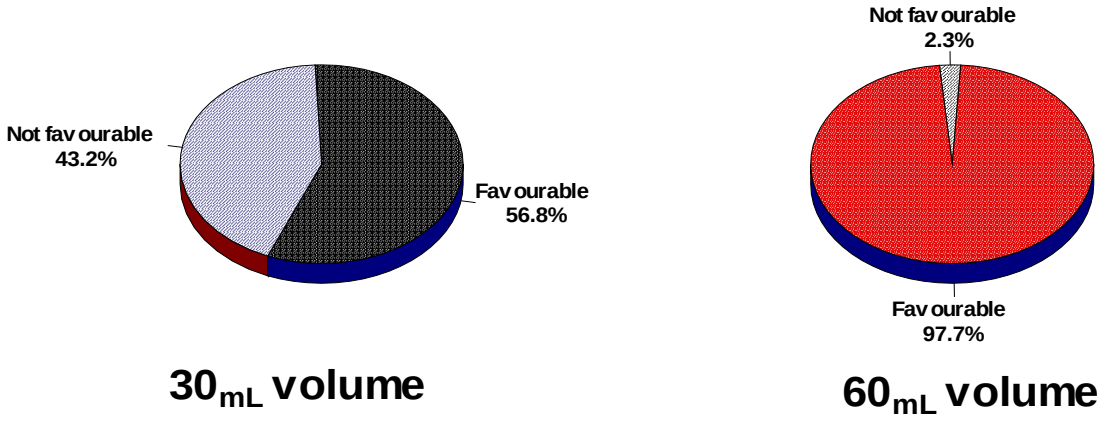

Figure 5.1 Comparison of cervical favorability after Foley catheter induction

Secondary outcome measures

Table 4: Mean and Standard Deviation of Bishop score before and after Foley catheter induction.

	Study group				Significance	
	60_{mL} volume		30_{mL} volume			
	Mean	SD	Mean	SD	t-value	p-value
Before Foley's catheter	4.3	0.5	4.3	0.6	0.18	0.86,NS
After Foley's catheter	8.1	0.5	7.0	1.3	4.96	<0.001,S
Difference (mean change)	3.8	0.6	2.8	1.3	4.85	<0.001,S

n=number of subjects ,S= Significant ,NS=Not Significant ,SD=Standard Deviation

Mean change in Bishop score after Foley catheter induction was more in 60ml group. This difference of means was statistically significant (p< 0.001).

Table. 5. Comparison of mode of delivery.

Mode of delivery	Study group				Significance (df=1)	
	60_{mL} volume		30_{mL} volume			
	n	%	n	%	RR,(95%CI)	p-value
Vaginal delivery*	41	93.2	32	72.7	2.81(1.00-7.86)	0.01,S
Caesarean section	3	6.8	12	27.3	0.36(0.13-1.00)	
Total	**44**	**100.0**	**44**	**100.0**		

n=number of subjects, Vaginal delivery (Normal vaginal delivery Vacuum delivery Forceps Delivery)*
S= Significant df=degree of freedom, RR=Relative Rick, CI=Confident Interval.

Vaginal delivery was achieved in higher proportion in 60ml Foley balloon group compared with 30mL Foley balloon group. This proportion was statistically significant. (p=.0.01).Caesarean section rate is significantly low in 60ml group.

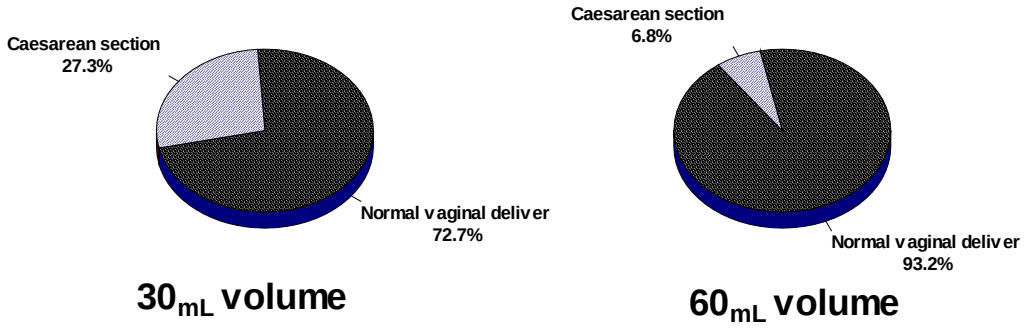

Figure 5.2 Comparison of Mode of delivery

Table 6: Comparison of different mode of vaginal delivery and Caesarean section rate.

Mode of delivery	Study group				Significance
	60_{mL} volume		30_{mL} volume		
	n	%	n	%	
Normal vaginal delivery	31	70.5	25	56.8	p=0.16
Vacuum delivery	8	18.2	5	11.4	p=0.26
Forceps Delivery	2	4.5	2	4.5	
Caesarean section	3	6.8	12	27.3	p=0.01
Total	**44**	**100.0**	**44**	**100.0**	

n=number of subjects

When normal delivery was considered there was no significant different between two group (p=0.16). But in 60ml group there is more trend towards vacuum delivery. In case of forceps delivery both group was having equal proportion.

Table 7: Complications during Foley catheter induction

Variables	Study group				Significance (df=1)	
	60_{mL} volume		30_{mL} volume			
	n	%	n	%	RR(95%CI)	p-value
Complication status						
Yes	34	77.3	13	29.5	2.98(1.68-5.23)	<0.001
No	10	22.7	31	70.5		
Total	**44**	**100.0**	**44**	**100.0**		
Pain						
No	10	22.7	31	70.5		<0.001
Mild	19	43.2	11	25.0	2.69(1.42-4.75)	
Moderate	15	34.1	2	4.5	3.62(2.05-6.37)	<0.001
Severe	0	0.0	0	0.0		
Total	**44**	**100.0**	**44**	**100.0**		
Bleeding						
Yes	10	22.7	1	2.3	2.06(1.51-2.82)	0.003
No	34	77.3	43	97.7		
Total	**44**	**100.0**	**44**	**100.0**		
Pyrexia						
Yes	1	2.3	0	0.0		*
No	43	97.7	44	100.0		
Removable Foley's catheter						
Removed	3	6.8	0	0.0		*
Not removed	41	93.2	44	100.0		
Total	**44**	**100.0**	**44**	**100.0**		

n= number of subjects, df=degree of freedom. RR=Relative Rick, CI=Confident Interval. , Significant test can't be applied due to zero cell numbers.*

The complications during cervical ripening was more among 60ml group (p=0.001) . Pain and bleeding were the common complications. Power of the sample was not enough to compare effect on pyrexia and removal of catheter due to complications.

Table 8. Comparison of spontaneous expulsion of catheter and onset of labour.

Variables	Study group				Significance (df=1)	
	60_{mL} volume		30_{mL} volume			
	n	%	n	%	RR(95%CI)	p-value
Spontaneous expulsion of catheter						
Yes	20	45.5	5	11.4	2.10(1.46-3.04)	<0.001
No	24	54.5	39	88.6		
Total	**44**	**100.0**	**44**	**100.0**		
Onset of labour						
SOL	10	22.7	4	9.1	1.69(1.09-2.62)	p=0.08
IOL	27	61.4	37	84.1	0.59(0.38-1.92)	p=0.01
SOL with augmentation	7	15.9	3	6.8	1,02(0.60-1.72)	p=0.16
Total	**44**	**100.0**	**44**	**100.0**		

n=number of subjects ,SOL=spontaneous onset of labor,IOL=induction of labour. RR=Relative Rick, CI=Confident Interval.

Foley catheter expelled spontaneously in significant number of mothers of the 60ml group,. More spontaneous labour onset occurred in 60ml group (p<0.001). Mother of 30ml group required more induction of labour than 60ml group (p=0.01). These findings were statistically significant.

Table 9. Intrapartum Complications.

Variables	Study group				Significance (df=1)	
	60_{mL} volume		30_{mL} volume			
	n	%	n	%	RR(95%CI)	p-value
Complications during labour						
Yes	20	45.5	13	29.5	1.39(0.92-2.09)	0.12
No	24	54.5	31	70.5	0.72(0.48-1.08)	
Total	**44**	**100.0**	**44**	**100.0**		
Pyrexia -2 (after delivery)						
Yes	8	18.2	4	9.1	1.41(0.88-1.28)	0.21
No	36	81.8	40	90.9	0.71(0.45-1.13)	
Total	**44**	**100.0**	**44**	**100.0**		
Meconium stained liquor						
Yes	16	36.4	9	20.5	1.44(0.96-2.16)	0.09
No	28	63.6	35	79.5	0.69(0.46-1.04)	
Total	**44**	**100.0**	**44**	**100.0**		
CTG abnormality during labour						
Yes	10	22.7	6	13.6	1.32(0.84-2.08)	0.27
No	34	77.3	38	86.4	0.76(0.84-1.19)	
Total	**44**	**100.0**	**44**	**100.0**		

n=number of subjects, df=degree of freedom ,CTG=cardiotocography. . RR=Relative Rick, CI=Confident Interval.

Table 10: Indication for Caesarean section in two study group.

Indication for Caesarean section	**Study group**				**Significance**
	60_{mL} volume		**30_{mL} volume**		
	n	%	n	%	p-value
Lack of progress	0	0.0	7	58.3	*
Fetal distress	2	66.7	0	0.0	*
Delayed second stage	0	0.0	1	8.3	*
Lack of progress with Fetal distress	1	33.3	2	16.7	*
Failed Induction	0	0.0	1	8.3	
Fetal distress and Maternal distress	0	0.0	1	8.3	*
Total	**3**	**100.0**	**12**	**100.0**	

n=number of subjects, Significant test can't be applied due to zero cell numbers.*

In 60ml group fetal distress was the common indication for Caesarean section. However lack of progress was the common of indication in the 30 ml group.. The sample size was not adequate enough to compared two groups whether there was significant different or not.

Table 11. Time duration from Foley catheter induction to delivery and duration of labour.

Variables	Study group				Significance	
	60_{mL} volume		30_{mL} volume			
	Mean	SD	Mean	SD	t-value	p-value
Duration of Labour (hours)	5.8	1.8	7.9	3.2	3.98	<0.001,S
Time duration from Foley induction to delivery	34.2	17.6	45.6	14.1	3.34	0.001,S

S= Significant ,NS=Not Significant,SD=Slandered Deviation

Cervical ripening using Foley balloon inflated with 60ml was more likely to achieve delivery within 30 hours compared to the 30ml group (p<0.001).

Duration of labour was significantly shorter in 60ml group(p=0.001).

Table 12: Post partum complications

Post partum complications	**Study group**				**Significance (df=1)**	
	60_{mL} volume		**30_{mL} volume**			
	n	%	n	%	RR(95%CI)	p-value
No complications	32	72.7	35	79.5	1.29(0.77-1.87)	0.39
Maternal pyrexia	7	15.9	5	11.4	1.22(0.71-2.10)	0.33
Neonatal pyrexia	2	4.5	2	4.5	1.05(0.38-2.28)	0.66*
Maternal and neonatal pyrexia	3	6.8	2	4.5	1.26(0.59-2.68)	0.47*
Total	**44**	**100.0**	**44**	**100.0**		

df=degree of freedom, *n=number of subjects. ,*Fisher's exact probability test was applied due to small (<5) cell numbers.*

There were nither statistically significant nor clinically significant differences exsisted with regard to postpartum complications.

Discussion

The Caesarean section rate is continued to escalate over the past few decades. Caesarean section is associated with increased blood loss, increased days of hospital stay, scar in the uterus and limited obstetric outcome in the future pregnancies. Therefore the aim is to achieve vaginal delivery if possible. One of the main determinants of the successful vaginal delivery is cervical favorability.

The induction rate is about 18-20% in many centres. The success of induction mainly depends on parity and cervical favourability.[57]

In this randomized trial, equal proportion of mothers with regard to parity was equally distributed among two study group to reduce the confounding errors. But stratified sampling was much difficult in clinical setting as needs arises different situation and different times round the clock.

In 60ml Foley catheter group, majority of mothers achieved high cervical score within 24 hours after cervical induction, than in 30ml group. This difference was statistically significant. One study compared the different preparation of prostaglandins for cervical ripening. It was found that success rate of cervical favorability with Misoprostoal was 98%. Therefore 60ml Foley catheter group in respect of cervical favorability was more or less equal to Misoprostol. Mothers among 60ml group mean change in Bishop score was statistically significant when compared to 30ml group . High intracervical balloon volume therefore changes the Bishop score more effectively and efficiently. When higher volume was being used, probable main effect on cervix was mechanical effect and some form of inflammation due to foreign body causing local prostaglandin production. Our ultimate goal was successful vaginal delivery, majority of mothers in 60ml volume group culminated in successful vaginal delivery than 30ml group. Higher Caesarian section rate was found 30ml group (27%). But higher volume group it was smaller as 6.8%. One previous study shows that Foley catheter induction in primipara, achievement of successful vaginal delivery was 70%[58]. But that study failed to define intra cervical balloon volume.

Substantal number of mothers among 60ml group went in to spontaneous labour. In 30ml group higher proportion of mothers needed induction of labour. Therefore the possibility of primary Caesarean section was higher in low volume group. 60ml group needed significant occasions of augmentation with syntocinon during labour. Therefore

[57] Arulkumaran S,Martan S.The foetus risk in labour-identification and management. In contribution to Obstetrics and Gynaecology 1991; 1:179-199.

[58] Cromi A, Ghozzi F, Tomere S, Ucelle S, Lisclietti B, Bolis P. Cervical ripening with Foley catheter. In.J.Gynecol Obstet 2007; 97(2):105-109.

higher volume group which was having more favorable cervix went into spontaneous onsets of labour and low volume group was needed more induction due to low cervical score.

Nine mothers out of 44 in 60ml group needed assisted vaginal delivery due to fetal distress and second stage delay. But in 30 ml group it was 7 out of 44.

When considering indication of Caesarean section, in 30ml group, 9 section done for failure to progress (58%), one for failed induction and one section for delayed second stage in labour. In 60ml group main indication was fetal distress. Therefore these indications might correlate with cervical dystocia and cervical score. But sample size of this study was not adequate enough to comment on clinical significance of these issues. Further studies with large sample size will be needed to evaluate any relationship with Foley catheter balloon volume and fetal distress.

Previous study shows that induction of labour using for Foley catheter result in short induction to vaginal delivery interval[59] and another reason in vivo study suggested that cervical small muscle activity contributed to the duration of latent phase of labour (10). In this study 60ml group duration of labour was significantly shorter than 30ml group . For multipara accepted duration of labour is 08 hours. Therefore 60ml group achieved same duration of labour as with its physiological counter part. The time duration from induction to delivery was short in 60ml group. Therefore shortening the duration of cervical ripening time, burden of fetal monitoring, bed occupancy and average hospital stay can be cut down by certain extent.

In 60ml group, duration of labour was shorter than 30ml group. Therefore detrimental fetal outcomes and maternal outcomes due to prolonged can be minimized by using larger intracervical balloon catheter.

Before generalization of favorable features to clinical practice, side effects profile should be considered as same extent.

During cervical ripening procedure, 55.9% of mothers in 60ml group experienced mild to moderate pain which could be amenable with paracitamol. Only 3 out of 44 mothers in 60ml groups had to remove the catheter due to bleeding. There was a trend of minor complication during cervical ripening in 60ml group. But this study failed to address the issue of maternal acceptability and satisfaction and it should have been highlighted in this study.

[59] Nicole W, Welsh S W.Induction of labour using Foley balloon with or without extra amniotic saline infusion. J Obst and Gynaecol2006; 107:234-239.

Conclusion

60ml Foley catheter pre induction cervical ripening method has the following advantages over 30 ml volume.

1. Great success rate of cervical ripening.
2 Significant change in Bishop score.
3 Greater reduction in cervical ripening to delivery interval.
4 Short duration of labour.
5 High success rate of vaginal delivery.

This study was not able to establish significant complication during labour and immediate post partum period. Clinically and statistically significant mild complication during cervical ripening was established.

Limitations

1. As a unit policy for use of Foley catheter only for multipara, external validity of this trial with regard to primipara is questionable.
2. In clinical ward setup sometimes it was not practical to assess the cervix by same person as it is somewhat subjective assessment with inters observer variance.
3. Size of the study was seldom enough to evaluate the less common side effects of two methods.
4. The study did not address the maternal satisfaction and acceptability and of two method.
5. Blinding of study was not done because sometimes author himself had to insert the catheter due to practical reason. There might be a possibility of bias when cervix being assessed.

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