Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

Original Research Article

To determine the optimal Foley‘s catheter balloon Volume (30 ml vs 60 ml) to improve vaginal delivery rate within 24 hours of the induction of labour in women with intrauterine fetal demises with unfavourable cervix

Dr. Divyanshi Jain[1] (Senior Resident), Dr. Renu Jain[2] (Prof.) & Dr. Pragya Priyadarshini[3] (Senior Resident)

Dept. of OBGY, Kamla Raja Hospital and J.A. Group of Hospitals, Gwalior (M.P.)[1,2&3]
Corresponding Author: Dr. Pragya Priyadarshini

Abstract

Background & Methods: The aim of the study is to determine the optimal Foley‘s catheter balloon Volume (30 ml vs 60 ml) to improve vaginal delivery rate within 24 hours of the induction of labour in women with intrauterine fetal demises with unfavourable cervix

Results: There is a significant increase in bishop’s score of group B (7.54+-2.41) as compared to group A (5.02 +-2.06) at the time of expulsion or removal. The time interval between transcervical foleys insertion and expulsion/removal was significantly low in group B (10.39+-4.95) as compared to group A (14.74+-5.72).1 patient in group B, Transcervical Foleys was removed within 6-12 hour due to abruptio placentae and 4 patients in group A and 1 patient in group B, Transcervical Foleys were removed due to failed induction (>24 hours).

The requirement of oxytocin was significantly higher in group A (78%) as compared to group B (36%). Maximum patient delivered vaginally in both group Out of 50 patients in group A, 4 patients had LSCS in view of failed induction and in group B, 3 patients out of 50 had LSCS in view of abruptio placentae, second stage arrest, severe preeclampsia (mild convert into severe)respectively.

Pain reported by patients during insertion was comparable in both groups but during cervical ripening it was more in group B than in group A. There was no case of ruptured uterus in both groups. In both groups these were the cases of adherent placenta in which PPH occurred. 4 patients had puerperal pyrexia in group A and 3 patients had puerperal pyrexia in group B coming out to be most common complication.

Conclusion: In pregnant women with intrauterine fetal demise in third trimester and with an unfavourable cervix, induction of labour with a transcervical foley‘s catheter inflated by saline is a safe and effective method for cervical ripening without increase risk of maternal morbidity. Foley's catheter balloon inflated by 60 ml saline is more effective in achieving successful cervical ripening,decreasing need for augmentation by oxytocin,less induction to delivery interval as compared to foley's catheter balloon inflated by 30ml balloon. Satisfaction rate in both groups was same although pain reported by patients in group B was more as compared to patients in group A.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

Keywords: Foley‘s catheter, balloon, vaginal, intrauterine, fetal & unfavourable cervix.
Study Design: Prospective Observational Study.

1. INTRODUCTION

The current definition of fetal death adopted by the Centers for Disease Control and Prevention National Center for Health Statistics is based on a definition recommended by the World Health Organization (MacDorman, 2015). It states that ―Fetal death means death prior to complete expulsion or extraction from the mother of a product of human conception irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.‖[(1)]
The perinatal mortality surveillance report (CEMACH3) defined stillbirth as a baby delivered with no signs of life known to have died after 24 completed weeks of pregnancy.[(2)]
Incidence of intrauterine fetal death (IUFD) in western countries ranges from 4.7% to 12.0%[(3)] and in India ranges from 24.4 to 41.9%.(4)(5) More than 85% of women with intrauterine fetal death (IUFD) labored spontaneously within 4 weeks of the diagnosis.[(4)]
When a baby dies in utero, the options are either to wait for the labor to start spontaneously or to induce it. But when the fetal death occurs after 24 weeks of gestation, spontaneous expulsion may take several weeks. Such retention of the fetus can be associated with emotional distress, intrauterine infection and time related risk of consumptive coagulopathy[(5)].
Timely induction thus reduces the maternal and perinatal morbidity and mortality. Induction of labour has become one of the most important tools in an obstetrician's armamentarium.
Induction implies stimulation of contractions before the spontaneous onset of labor, with or without ruptured membranes. When the cervix is closed and uneffaced, labor induction will often commence with cervical ripening, a process that generally employs prostaglandins to act and open the cervix. Augmentation refers to enhancement of spontaneous contractions that are considered inadequate because of failed cervical dilation and fetal descent—inertia uteri—as described by Williams (1903).[(6)]

2. MATERIAL AND METHODS

TYPE OF STUDY: Prospective comparative study.
PLACE OF STUDY: Department of Obstetrics and Gynaecology, Kamla Raja Hospital and J.A. Group of Hospitals, Gwalior (M.P.) PERIOD OF STUDY: October 2019 - July2021
SAMPLE SIZE: Minimum 100 cases were taken.

- Group A-50 cases were induced with transcervical Foley's catheter balloon inflated to 30 ml.
- Group B-50 cases were induced with transcervical Foley's catheter balloon inflated to 60 ml.

INCLUSION CRITERIA
Pregnant women admitted with intrauterine fetal demise diagnosed by real time ultrasonography with :

- Gestational age > 28 weeks

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

- Maternal age > 18 years
- Singleton pregnancy
- Longitudinal lie
- Not in labor.
- Intact membrane
- Bishop‘s score < 5

EXCLUSION CRITERIA

- Refusal of consent for inclusion in study.
- Gestational age < 28 weeks
- Transverse lie.
- Multiple Pregnancy.
- Patients with rupture of membrane.
- Patients in labour.
- Cephalopelvic disproportion
- Placenta previa
- Abruptio placenta
- History of previous 2 LSCS and other uterine surgery (like myomectomy).
- Presence of active infection of lower genital tract.
- Severe Preeclampsia and Eclampsia.

3. RESULT

Table 1: BASELINE CHARACTERISTICS

S. No.	Characteristics	GroupA (n=50)	GroupB (n=50)	p-value
1	Maternal age (years;mean±SD)	23.46±3.16	23.84±3.07	0.356
2	Parity n(%)			0.964
	0	38(78%)	40(80%)	
	1	6(12%)	7(14%)	
	2	4(8%)	2(4%)	

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

	3	2(4%)	1(2%)	
3	Gestational age (weeks;mean±SD)	33.55±3.27	34.04±3.52	0.467
4	Initial bishop's score (mean±SD)	2.20±0.81	2.28±0.81	0.847

The baseline characteristics were similar among two groups.there were no statistically significant differences in maternal age, parity, gestational age and initial bishop's score.

Table 2: OUTCOMES OF PATIENTS

S.NO	OUTCOMES	GROUP A (n=50)	GROUP B (n=50)	P VALUE
1	Bishop Score at the time if expulsion/removal (meanSD)	5.02±2.26	7.54±2.41	<0.001
2	Time Inteval between transcervical foley's insertion & expulsion/removal	14.74±5.72	10.39±4.95	<0.001
3	Augmentation with oxytocin n(%)	39(78%)	18(36%)	<0.001
4	Mode of delivery			1.000
	Vaginal	46(92%)	47(94%)	

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

	LSCS	4(8%)	3(6%)	

As the table shows, there is a significant increase in bishop's score of group B (7.54+-2.41) as compared to group A (5.02 +-2.06) at the time of expulsion or removal. The time interval between transcervical foleys insertion and expulsion/removal was significantly low in group B (10.39+-4.95) as compared to group A (14.74+-5.72).1 patient in group B, Transcervical Foleys was removed within 6-12 hour due to abruptio placentae and 4 patients in group A and 1 patient in group B, Transcervical Foleys were removed due to failed induction (>24 hours). The requirement of oxytocin was significantly higher in group A (78%) as compared to group B (36%). Maximum patient delivered vaginally in both group Out of 50 patients in group A, 4 patients had LSCS in view of failed induction and in group B, 3 patients out of 50 had LSCS in view of abruptio placentae, second stage arrest, severe preeclampsia (mild convert into severe)respectively.

Table 3: LABOUR DYNAMICS

S. No.	**Labour Dynamics**	**Group A (N=50)**	**Group B (N=50)**	**P-Value**
1	Duration of First Stage of Labour (mean±SD)	16.37±7.45	13.29±5.17	<0.005
2	Duration of Second Stage Of labour (mean±SD)	39.26±13.02	38.35±12.18	0.913
3	Duration of third stage of labour (mean±SD)	11.92±5.37	10.96±6.79	0.558
4	Duration of induction to delivery (mean±SD)	18.52±5.99	14.03±5.53	<0.001

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

	Within 24 hours	29(58%)	41(82%)	
	>24 hours	17(34%)	6(12%)	

There was a statistically significant difference between both groups with respect to duration of first stage of labor.in group A (16.37+-7.45) as compared to groupB (13.29+-5.17). Duration of second and third stage of labour comparable in both group. Duration of induction to delivery significantly low in group B (14.03+-5.53) as compared to group A (18.52+-5.99

Table 4: PAIN ANALYSIS (VAS SCORE)

S. No.	**Pain Analysis**	**Group A { n =50}**	**Group B {n=50}**	**P Value**
1	Pain during insertion	5.90±2.40	6.84±1.92	0.429
2	Pain during cervical ripening	5.80±1.75	7.54±1.51	<0.001

Pain reported by patients during insertion was comparable in both groups but during cervical ripening it was more in group B than in group A.

Table 5: MATERNAL COMPLICATIONS

Maternal Complications	**Group A(30ml) n-50 (%)**	**Group B (60ml) n-50 (%)**
Hyperstimulation	0 (0%)	1 (2%)
Chorioamnionitis	0 (0%)	1 (2%)
Rupture Uterus	0 (0%)	0 (0%)

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

PPH	1 (2%)	3 (6%)
Puerperal Pyrexia	4 (8%)	3 (6%)
Total	5 (10%)	8 (16%)

There was no case of ruptured uterus in both groups. In both groups these were the cases of adherent placenta in which PPH occurred. 4 patients had puerperal pyrexia in group A and 3 patients had puerperal pyrexia in group B coming out to be most common complication

4. DISCUSSION

The present study was conducted in the department of Obstetrics Gynaecology, Kamla Raja Hospital G.R.M.C, Gwalior. The above study was ―A prospective study of cervical ripening with a transcervical foley balloon catheter inflated by 30ml normal saline compared with 60ml normal saline in intrauterine fetal death in 3rd trimester."

The study was carried out in 100 patients who fulfilled the inclusion criteria were divided into two groups(A and B). Participants were alternatively allocated to either procedure till we reached our target number of 50 in each group over the study period.

In the present study, the majority of patients in group A (76%) and in group B (60%) were of the age group 20-25 years.we did not investigate the cause of IUFD in young patients. To identify the cause of IUFD in young patients we recommend further study on identification of the cause of IUFD.

Mohammed T et al, Davalagi V et al study showed the maximum number of patients belonged to 20-25year of age group which was comparable to our study.[7][8]Another study by Ning Gu et al showed that maximum number of patients belonged to 20-30 year of age (28.0+-3.4).[8]

Majority of patients in both groups were illiterate, belonged to rural areas and were the referred cases and unbooked by booking status during ANC period.

In both groups, the majority of patients belonged to rural areas. In rural populations,access to health care facilities is low because of low level of education(health care awareness) among them, these women do not get proper antenatal care,this might be the reason for the high proportion of these women in our study.

M. jozwiak et al, Ning gu et al and Davalagi V et al also reported similar results in their studies.[9],[7],[8]

In the present study, the majority of patients were primiparous in both groups, (76%) in group A and (80%) in group B. In our study we did not investigate the cause of IUFD so to know the reason for the high proportion of primiparous with IUFD found in our study, we recommend further study on identification of cause of IUFD[10].

The majority 46% of patients were between 28-32wk of gestational age. In group B, the majority 42% of patients were between 33-36wk of gestational age. The mean and standard deviation of gestational age was 33.55±3.27 in group A and 34.04±3.52 in group B.

Out of 100 patients included in our study, 41 patients were admitted at gestational age between 28-32wk. Because the majority of patients were unbooked, uninvestigated so the

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE8, 2023

cause of IUFD in this gestational age was not identified, we recommend it for further study to identify the cause of IUFD at this gestational age[11].

5. CONCLUSION

In pregnant women with intrauterine fetal demise in third trimester and with an unfavourable cervix, induction of labour with a transcervical foley‘s catheter inflated by saline is a safe and effective method for cervical ripening without increase risk of maternal morbidity. Foley's catheter balloon inflated by 60 ml saline is more effective in achieving successful cervical ripening,decreasing need for augmentation by oxytocin,less induction to delivery interval as compared to foley's catheter balloon inflated by 30ml balloon. Satisfaction rate in both groups was same although pain reported by patients in group B was more as compared to patients in group A.

6. REFERENCES

1. Williams Obstetrics, textbook of obstetrics 2018;Stillbirth ;25rd edi McGraw Hill education UK ; 644-650.
2. Confidential Enquiry into Maternal and Child Health (CEMACH). Perinatal Mortality 2007: United Kingdom. CEMACH: London; 2009.
3. Fretts RC, Boyd ME, Usher RH, et al. The changing pattern of fetal death. 1961-1988. Obstet Gynecol. 1992;79(1):35–39.
4. Malati AJ, Lalana GC. Perinatal mortality in vellore Part I: A study of 21,585 infants. Indian J Pediatrics. 1986;53(3):347–352.
5. Kumari R, Mengi V, Kumar O. Maternal Risk Factors and Pregnancy Wastage in a Rural Population of Jammu District. JK Science. 2013;15:82–85.
6. Williams obstetrics, textbook of obstetrics 2018;Induction and augmentation of labor 25rd edi McGraw Hill education UK; 503-515.
7. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O, Boulvain M. Mechanical methods for induction of labour. Cochrane Database Syst Rev. 2012;3: CD001233.
8. Ning Gu, Tong Ru, Zhigun Wang, Yimin Dai et al. Foley Catheter for induction of labour at term : An Open Label randomized controlled Trial., PloS one: 2015; 10(8) ; e0136856. 3. Hu Yali, et al. RCT study foley catheter for induction of Labour at term : a Multi – Centre Randomized Controlled Trial : 2013 ; 11(2): 11745.
9. Indira I, Latha G, Lakshmi Narayanamma V. Comparative study of induction of labour with Foley's catheter inflated to 30 mL versus 60 mL. *J Clin Sci Res*. 2016; 5: 153– 9.
10. Sandberg EM, Schepers EM, Sitter RL, Huisman CM, Wijngaarden WJ. Foley catheter for induction of labour filled with 30 mL or 60 mL: a randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2017; 211: 150– 5.
11. Davalagi V et al. Int J Reprod Contracept Obstet Gynecol. 2019 Apr;8(4):1341-1346.