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Original Research Article

Effectiveness of mifepristone versus balloon catheter in induction of labour in women with previous caesarean sections: a randomised comparative study

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ABSTRACT

Background: Termination of pregnancy is a stressful situation for the patient specially due to increasing trend of caesarean sections (CS) wherein due to risk of scar rupture a repeat caesarean is advocated by many practitioners. Especially in these cases vaginal delivery should be preferred over CS to avoid the added stress of a major surgery to the woman which increases the risk of scar rupture and adhesions in subsequent pregnancies. Hence the aim was to compare the safety and effectiveness of mifepristone versus balloon catheter in termination of pregnancy in women with previous CS.
Methods: Prospective randomized comparative study was done at obstetrics and gynaecology department of Teerthankar Mahaveer medical college and research centre, Moradabad UP from January 2020 to July 2021. 60 subjects were randomised into 2 groups by the envelope method.
Results: The mean bishops score at 36 hours was found to be 10.2±1.25 and 9.81±1.54 in groups M and B respectively. No statistically significant difference was found between the bishops score of the two groups at 24 and 36 hours. Patients induced with mifepristone had significantly longer induction delivery, Induction augmentation and Induction-labour intervals. However, these patients ultimately had more number favourable outcomes in terms of vaginal delivery, although not statistically significant.
Conclusions: Foleys insertion is an invasive and painful process and more uncomfortable for the patient. Mifepristone can safely be used in place of foleys catheter for induction of labour in patients with previous 1 CS.

Keywords: Bishops, Pregnancy, Caesarean, Mifepristone

INTRODUCTION

With advances in maternal care and quality of life, termination of pregnancy is frequently recommended in pregnant patients who have had earlier CS. Termination of pregnancy is a stressful situation for the patient especially due to increasing trend of CSs wherein due to risk of scar rupture a repeat caesarean is advocated by many practitioners. Indications of these 2nd and third trimester terminations could be varied ranging from antepartum heamorrhage, anomalous baby, Intra uterine death of baby, severe pre-eclampsia. Especially in these cases vaginal delivery should be preferred over CS to avoid the added stress of a major surgery to the woman which increases the risk of scar rupture and adhesions in subsequent pregnancies.

According to a WHO global survey done in nine Asian countries previous history of CS is the most common indication of repeat caesarean delivery.[1] These women significantly contribute to the increasing rates of CS as they land up in repeat caesarean in their next pregnancy. For the past 23 years, surge in cases of CS has been reported in India, with wide differences in rates across the country.

Labor induction is a medical procedure which is beneficial for both mother and the baby. The status of the cervix has a direct impact on the success of labour induction. Women who have an unfavourable cervix and have not gone through the cervical ripening phase prior to labour face the biggest difficulty when it comes to labour induction[2]. Medical, surgical, or mechanical procedures can be used to end a pregnancy (Oxytocin, Dinoprost, Mifepristone, Misoprostol) (Laminaria tent, balloon catheter).[2]

With recent advances in medical science, people even in the remote areas have easy access to CS. Due to lack of knowledge about antenatal care and contraception we see a lot of grand multipara females with IUD/ anomalous babies who require termination of pregnancy with previous history of CS.

Although many medical and mechanical methods for induction of labour are available, but in patients with scarred uterus, still the most effective method with least side effects is being searched for to decrease incidence of repeat CS and related morbidities.

Hence the purpose of this research was to identify a better way to induce labour in women who had previously had a CS for termination of pregnancy and to compare the safety and effectiveness of mifepristone versus balloon catheter in termination of pregnancy in women with previous CS.

METHODS

The present study was done at obstetrics and gynaecology department of Teerthankar Mahaveer medical college and research centre, Moradabad UP after getting clearance from central research committee and institutional ethics committee from January 2020 to July 2021.

It was prospective randomized comparative study in which all antenatal patients (>12 weeks gestational age) coming to our institute with history of previous 1 CS requiring termination of pregnancy for medical reasons were included.

Antenatal patients (>12 weeks POG) coming to TMMC for termination of pregnancy, women with previous LSCS, Singleton pregnancy, Bishop's score < 6 were included in the study and those with previous myomectomy, medical/ obstetrical complications that preclude vaginal delivery, placenta previa / undiagnosed vaginal bleeding, heart disease, PPROM with chorioamnionitis, short interconception period (<6 months) and cervicovaginal Infection were excluded from the study.

All study subjects were randomised into 2 groups by the envelope method. Once the patient was enrolled in the study, she was offered the allocated treatment care as generated by enclosed envelopes.

Group 'M': Patients receiving MIFEPRISTONE tablets orally and group 'B': Patients for Foley's bulb induction

Total sample size required 44 for both groups with min of 22 per group. After receiving written informed consent, individuals randomly enrolled in 2 different groups (M/B) using envelope method. All patients received thorough medical history, thorough physical examination and standard and relevant investigations.

Patients in M group received tab. mifepristone 200 mg orally as a single dose. Outcomes were recorded at 0, 12, 24, 36 hourly basis with monitoring of progress of labour and cervical ripening.

In B group, Foley's no 16 was inserted intracervically under all aseptic precautions in the labour room. Bulb was inflated with 30 ml of saline. Patients were monitored for progress of labour at 12 hours, 24 hours and 36 hours. If there is no progress at 12 h or it is not expelled spontaneously then bulb was further increased by 30 ml after 12 hours depending on Bishops score and uterine contractions. Patients in both groups were monitored for a total of 36 hours from point of intervention. After 36 hours, both groups were offered oxytocic in the form of oxytocin /misoprostol once their bishops score was more than 6. Operative intervention was done in case of maternal distress (worsening of maternal vitals), scar tenderness, impending rupture or fetal distress.

Statistical analysis

Collected data was run in SPSS software version 24 to formulate the results in the present study.

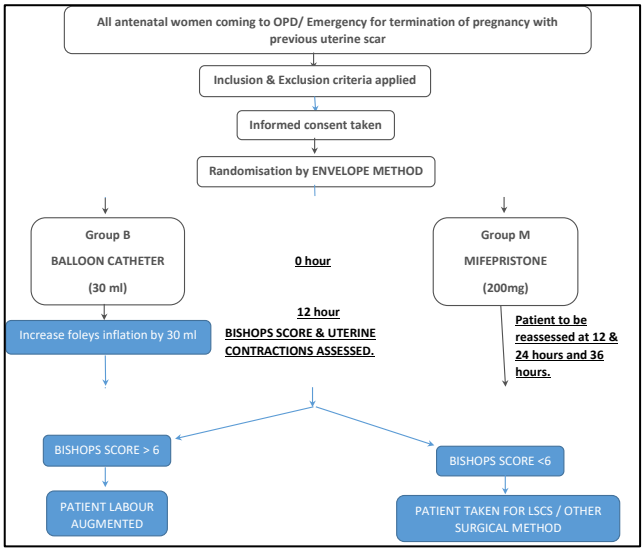

Figure 1: Schematic flow chart depicting methodology.

RESULTS

Most of the patients enrolled in present study between 26-30 years age. Mean age of patients in mifepristone and foleys bulb groups were 28.65±5.47 and 27.71±4.22 years respectively. Both groups comparable in terms of clinical history and examination findings. No statistically

significant difference found in terms of clinical history and examination findings as p>0.05 (Table 1).

Table 2 shows comparison of the Bishop's score at various intervals during induction in groups B and M respectively. The present study revealed that patients induced with foleys bulb group showed a faster increase in the bishops score with time as compared to patients induced with mifepristone. The bishops score of patients in group M at 12 hours was 3.27, while the bishops score in group B at 12 hours was 4.38. A statistically significant difference was found in bishops score at 12 hours between groups B and M (p<0.05). Although both groups showed similar increase in bishops score at the end of 36 hours. No statistically significant difference can be seen between bishops score at various intervals in both groups at 24 and 36 hours as p>0.05.

Table 3 show a tabular comparison of the mode of delivery in patients induced with mifepristone and foleys bulb respectively. The 24 out of 30 (80%) patients induced with mifepristone delivered vaginally, while only 18 out of 30 (60%) patients induced with foleys bulb delivered vaginally. Six out of 30 (20%) patients in group B had an operative vaginal delivery as compared to only 3 out 30 (10%) patients in group M. Six out 30 (20%) patients induced with foleys bulb catheter were taken up for LSC.S/ Hysterotomy as compared to only 3 out 30 patients (10%) induced with mifepristone. However, no statistically significant difference was found in terms of mode of delivery as p>0.05.

Table 4 shows a comparison of indications of CS/ hysterotomy in patients of group B and group M. 13.33% patients in group B were taken up for LSCS due to scar tenderness as compared to only 3.33% patients in group

M. 6.667% patients in group B were taken for CS in view of non progress of labour, while only 3.33% patients in group M were taken for LSC.S in view of non progress of labour. No statistically significant difference was found in terms on indication of LSCS as p>0.05.

Table 5 shows a comparison of induction to labour, induction-augmentation and induction delivery intervals among patients induced with foleys bulb and mifepristone. Mean induction to labour interval (in hrs), induction augmentation interval, induction to delivery interval (in hrs) was comparatively less in Foleys bulb group as compared to mifepristone group. When mean induction to labour interval (in hrs), induction augmentation interval, induction to delivery interval (in hrs) was compared statistically in Foleys bulb and mifepristone group using t test, it was found to be statistically significant as p<0.05.

Table 1: Comparison of clinical history and examination findings in mifepristone and foleys bulb groups.

Variables	Mifepristone, (n=30)		Foleys bulb, (n=30)		Chi square	P value
	N	%	N	%		
Leaking PV	8	26.67	8	26.67	0	1
Bleeding PV	7	23.33	10	33.33	0.81	0.54
Pain abdomen	11	36.67	16	53.33	5.01	0.13
GDM	3	10	0	0	2.09	0.15
PIH	6	20	4	13.33	1.26	0.26
Pallor	17	56.67	26	86.67	5.41	0.08
Gestational age	27±2.909		29.5±2			
BP, mean ± SD	114.80±12.43		117.51±11.08		0.93	0.41
Symphysio fundal height	25.85± 2.5		27.2 ±1.35		0.94	0.43
BISHOP score, mean ± SD	2.74±1.01		2.86±1.24		0.31	0.72

Table 2: Comparison of Bishops score with induction in mifepristone and Foleys catheter.

Time	Bishop's score							
	0 hour		12 hours		24 hours		36 hours	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Mifepristone	2.74	1.01	3.27	1.24	7.14	1.29	10.2	1.25
Foleys Bulb	2.86	1.24	4.38	2.09	6.91	1.38	9.81	1.54
T test	0.31		4.53		2.24		0.19	
P value	0.72		0.039		0.14		0.67	

Table 3: Mode of delivery.

Mode	Mifepristone, (n=30)		Foleys bulb, (n=30)		Chi square	P value
	N	%	N	%		
Vaginal	24	80	18	60		
Operative vaginal delivery	3	10	6	20	3.11	0.064
LSCS	3	10	6	20		

Table 4: Comparison of indications of LSCS/ hysterotomy in group B and group M.

Indication	Mifepristone, (n=30)		Foleys bulb, (n=30)		P value
	N	%	N	%	
Non-progress of labour	1	3.33	2	6.667	0.74
Scar tenderness	1	3.33	4	13.33	0.32
Fetal distress	1	3.33	0	0	0.81
Antepartum heamorrhage	0	0	0	0	1

Table 5: Comparison of induction to labour and delivery interval among the study groups.

Groups		Induction to labour interval (hrs)	Induction augmentation interval	Induction to delivery interval (hrs)
Foleys bulb	Mean	25.60	2.71	33.76
	SD	8.15	1.09	8.83
Mifepristone	Mean	32.47	3.56	40.82
	SD	5.64	1.44	5.891
T test		8.58	8.03	7.51
P value		0.006	0.003	0.01

Table 6: Outcome of induction in patients in both groups.

Parameters	Group M	Group B	P value
Number of patients	30	30	
Patients augmented	27	24	
Induction-labour interval	32.47±5.64 hours	25.60±8.15 hours	0.006
Induction augmentation interval	3.56±1.44 hours	2.71±1.09 hours	0.008
Induction-delivery interval	40.82±5.891 hours	33.76±8.83 hours	<0.01
Vaginal delivery	24	18	
Operative vaginal delivery	3	6	0.17
LSC.S	3	6	
Scar dehiscence	3.33%	13.33%	0.35
Atonic postpartum heamorrhage	3.33%	16.66%	0.19
Hospital stay	4.08±1.02 days	4.72±1.17 days	0.039

Table 6 shows comparison of outcome of induction on patients enrolled in groups M and B. As we can see from table, statistically significant difference found between 2 groups on terms of induction labour, induction augmentation and induction delivery intervals. Patients induced with mifepristone had longer intervals as compared to patients induced with Foleys bulb. However, found more number of patients induced with Mifepristone had a favourable outcome as compared to patients induced with Foleys bulb. Patients induced with Foleys bulb had higher need of surgical intervention as compared to patients induced with mifepristone. Patients induced with foleys bulb had higher incidence of postpartum heamorrhage, scar dehiscence and longer hospital stay as compared to patients who received mifepristone.

DISCUSSION

Induction of labour is the most common obstetric intervention. The stimulation of uterine contractions prior to the start of labour is referred to as "induction."

Due to increased medical litigation and the risk of scar dehiscence, uterine rupture, and an increased rate of foetal and maternal mortality and morbidity associated with induction in patients with a scarred uterus, many obstetricians do not prefer induction of labour in women with a scarred uterus.[3] The purpose of this study was to identify a better way to induce labour in women who had previously had a CS.

The bishops score of patients in group M at 12 hours was 3.27, while the bishops score in group B at 12 hours was 4.38. a statistically significant difference was found in bishops score at 12 hours between groups B and M ($p<0.05$). Although both groups showed similar increase in bishops score at the end of 36 hours. No statistically significant difference can be seen between bishops score at various intervals in both groups at 24 and 36 hours as $p>0.05$. According to Sharma et al rate of surgical intervention was statistically substantially higher in patients induced with foleys bulb than in those induced with mifepristone [group 1 vs. group 2; 3.51.7 (n=49) vs. 5.71.6 (n=50), respectively, p=0.000] for Bishop score after 24 hrs. However, there was no significant difference in Bishop score between the two groups after 48 hours. These findings are in line with what we found in our research.[4]

In the present study, 80% (24 out of 30) patients induced with Mifepristone delivered vaginally while CS was performed in 10% patients (3 out of 30). On the other hand, out of the 30 patients induced with foleys bulb, 60% patients (18 out of 30) delivered vaginally, 20% patients (6 out of 30) had a CS and 20% patients (6 out of 30) required instrumentation in the form of curettage. 3 out 30 (10%) patients in Group M required instrumentation. Although a statistically significant result could not be elicited in terms of mode of delivery in the present study, our study showed that more number of patients delivered vaginally after induction by mifepristone. We recommend more studies with larger sample sizes to elicit a statistically significant result.

In Dahiya et al study, 61.53% patients in Mifepristone group and 32.3% patients in Foleys bulb group had normal vaginal delivery, found significant results ($p<0.001$). This difference in the findings could be attributed to larger sample size in the study by Dahiya et al as compared to our study.[5]

Most common indication for emergency CS was scar tenderness which was observed in 13.33% patients induced with foleys bulb, as compared to 3.33% patients induced with mifepristone. 6.667% patients in group B developed Non progress of labour 3.33% patients in group M. The non- significant results found when group B developed scar tenderness as compared to Group M. $P>0.05$. In the study by Chanderdeep et al LSCS cause acute fetal distress observed in 18% patients induced with Foleys bulb and 8.7% patients induced with mifepristone.[4] Other indications for LSC.S in the study by Chanderdeep et al were prolonged labour, meconium stained liquor, non progress of labour and scar tenderness. The non significant results showing the Scar tenderness was reported in 8% foleys bulb group and 5.2% Mifepristone group. Scar discomfort was experienced in 1.53 percent of patients in the foleys Bulb group, but none in the Mifepristone group, according to Krishna Dahiya et al.[5] In the Mifepristone and Foleys Bulb groups, foetal distress was indicated as an indication for LSC.S in 21.5 percent and 26.5% of patients, respectively. These findings, however, were not statistically significant

In the present study patients induced with Foleys Bulb had shorter induction-labour interval, induction-augmentation interval and induction-delivery intervals as compared to patients induced with mifepristone. Patients induced with Foleys bulb went into labour in 25.6±8.15 hours of induction. They went into active labour after 2.71±1.09 hours at which point augmentation of labour was done using oxytocin. These patients delivered in 33.76±8.83 hours from induction. Patients induced with Mifepristone went into labour in 32.47±5.64 hours of induction. They went into active labour after 3.56±1.44 hours at which point augmentation of labour was done using oxytocin. These patients delivered in 40.82±5.891 hours from induction. When these intervals were compared statistically found significant in Foleys bulb and mifepristone group ($p<0.05$).

Our study is in accordance with Prager et al, who found that induction to delivery interval was significantly shorter in F.C group (12.9 hours) as compared to misoprostol (16.8 hours) and PGE2 (17.3 hours) respectively with a $p=0.00001$.[6]

In a similar study, Dahiya et al discovered that the mean induction to active phase of labour interval in the mifepristone group was 16.746.07 hours and 15.225.81 hours in the Foleys bulb group.[5] The mifepristone group had a 24.717.37-hour induction to delivery period, while the Foleys bulb group had a 25.569.75-hour induction to delivery interval, with statistically insignificant difference.

The median period from the commencement of induction to delivery in patients treated with mifepristone was 36 hours 23 minutes in a study by Stenlund et al.[7] These results are similar to those of the current investigation.

In the present study, 13.33% (4 out of 30) patients in foleys bulb group developed scar dehiscence as compared to 3.33% (1 out of 30) patients in the mifepristone, statistically non-significant with as $p>0.05$.

A study by Manish et al reported the statistically non-significant higher incidence of scar dehiscence in patients induced with foleys bulb using 80 ml saline (9.1%) as compared to patients induced with foleys bulb using 30ml saline (2.5%).[8]

The non-significant results with 16.66% patients induced with foleys bulb developed atonic postpartum heamorrhage as compared with 3.33% patients induced with mifepristone. Dahiya et al reported incidence of postpartum heamorrhage in mifepristone and foleys bulb group to be 12.3% and 15.3% respectively and these findings were not statistically significant.[5]

Blood transfusion was found in 13.63% and 27.27%of the subjects in mifepristone and Foleys bulb group respectively with statistically insignificant difference as $p>0.05$. However, this was required by the patients due to the heamoglobin status of the patients prior to induction and was not related to the induction process. Similar to Dahiya et al and Sharma et al.[4,5] Mean hospital stay (in days) was 4.08±1.02 and 4.72±1.17 in mifepristone and Foleys bulb group respectively, when compared found to be significant $p<0.05$. ICU admission, cervical tear, wound infection and urinary retention was not found in any of the subject irrespective of the group.

Limitations

Since the present study was conducted during the COVID-19 pandemic, less number of patients were recruited in both groups. Due to this a statistically significant result could not be elicited in terms of mode of delivery. Hence

the author suggests more and larger number of randomised trials on this topic to establish the efficacy and safety of the methods to induce labour in patients with a scarred uterus.

CONCLUSION

Foleys insertion is an invasive and painful process and more uncomfortable for the patient. Mifepristone can safely be used in place of foleys catheter for induction of labour in patients with previous CS. This study helps us identify safer, cheaper, more effective ways for induction of labour in patients with prior CS, thus reducing the burden of CS associated morbidity in the community.

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