Section: Obstetrics and Gynecology

Original Research Article

ROLE OF MIFEPRISTONE AND ITS EFFICACY IN INDUCTION OF LABOUR AFTER TWENTY WEEKS IN PREVOIUS ONE AND TWO LOWER SEGMENT CAESAREAN SECTION WITH INTRAUTERINE FETAL DEMISE

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Abstract

Background: Induction of labour is a commonly performed procedure in obstetrics. Women with previous caesarean delivery have increased risk of uterine rupture particularly if labour is induced. Performing repeat caesarean in women with previous cesarean section with intrauterine fetal demise is not a good idea; effort should be made to deliver vaginally. But it is unclear that which inducing agent is preferred in previously scarred uterus. So with this background, current study was done to evaluate the efficacy of mifepristone for cervical ripening and induction of labour in previous 1 and 2 cesarean sections with intrauterine fetal demise after 20 weeks of gestation. **Materials and Methods:** This study is a prospective, observational or randomized controlled trial (RCT) planned for one year, with a sample size of 50 pregnant women. It will focus on women who have experienced intrauterine fetal demise (IUFD) after 20 weeks of gestation, have a history of one or two previous lower segment cesarean sections, and whose gestational age has been confirmed by ultrasound. Participants must consent to the study. **Result:** In the second trimester, Bishop Scores improved from 2.67±1.19 to 8.50±1.51 without statistical significance (P = 0.156). In the third trimester, scores also improved but with statistical significance (P = 0.021). Bishop scores improved significantly in the 11-20 hours group (P = 0.007), 21-30 hours group (P = 0.024), and 31-40 hours group (P = 0.017), whereas scores in the >40 hours group were not statistically significant (P = 0.144). Cases requiring mechanical dilatation showed significant improvement in Bishop scores over 48 hours (2.54±1.12 to 8.29±1.70, P = 0.037). **Conclusion:** Bishop Scores improved from the second to third trimester, with statistical significance observed in the third trimester (P = 0.021). Significant improvements were noted in the 11-20 hours (P = 0.007), 21-30 hours (P = 0.024), and 31-40 hours groups (P = 0.017), but not in the >40 hours group (P = 0.144). Mechanical dilatation cases also showed significant improvement in Bishop Scores over 48 hours (P = 0.037).

INTRODUCTION

Intrauterine fetal demise at any gestational is a mental trauma both for the patient and obstetrician. IUFD is defined as fetal death (FD) after 20weeks of gestation,[1,2] which can either early or late IUFD. If FD occurs <24 weeks, it is called early IUFD. If FD occurs >24 weeks, it is called late IUFD. According to the Indian census of 2006, the rate of IUFD is 6.4 per 1000 live births in India. The lowest rates of IUFD are seen in Finland and Singapore, where it is as low as 2 per 1000 births, while the highest rates are found in Pakistan, where it is 47 per 1000, and Nigeria, where it is 42.[3] In last one year, number of IUDs delivered at Government Doon Medical College was 158 which is 2.4% of total deliveries.

Induction of labour in previous cesarean section poses significant challenge for the obstetrician due to limited favourable available options.[4] There are also increased chances of uterine rupture after induction of labour in previously scarred uterus in comparison to unscarred uterus. Vaginal delivery is always better

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and is associated with fewer complications as compared to caesarean section. The probability of vaginal delivery depends upon the status of cervix. Condition of cervix best assessed by scoring called Bishop Score. Score of less than 6 require induction of labour. There are various pharmacological agents which are available and can be used for labour induction such as oxytocin, prostaglandins and antiprogesterone (mifepristone).

Nowadays Mifepristone is also being used for induction of labour. Mifepristone is a 19 nor-steroid derivative and it is progesterone antagonist hence increases sensitivity of the uterus to prostaglandins. Mifepristone is rapidly absorbed when given orally and attains maximum serum level in 2 hours and half-life is 25 hours.[5] So the inhibitory action of progesterone is withdrawn, also prostaglandin dehydrogenase action is inhibited and there is increased synthesis of prostaglandins.[6] Prevention of progestogenic effect by mifepristone promotes cervical ripening owing to the action of estrogens, such as increase in cervical collagenase and prostaglandin synthetize activity, enhance expression of the extracellular matrix degrading protease stromelysin-1 (MMP-3).[7] These properties of Mifepristone makes it a useful drug for cervical ripening and hence termination of pregnancy. We have performed this study to evaluate the role of mifepristone in previous one and two LSCS with intrauterine fetal demise.

MATERIALS AND METHODS

Study Design: Prospective, observational, or randomized controlled trial (RCT)

Duration: 1 year (From 01/01/2024 to 31/12/2024)

Study Place: Burdwan Medical College.

Sample Size: 50

Inclusion Criteria

- Pregnant women with IUFD after 20 weeks of gestation.
- History of one or two previous lower segment caesarean sections.
- Gestational age confirmed by ultrasound.
- Women who consent to participate in the study.

Exclusion Criteria

- History of more than two caesarean sections.
- Contraindications to mifepristone use, such as active liver disease or renal failure.
- Severe preeclampsia, HELLP syndrome, or other contraindications to labor induction.
- Women with multiple pregnancies or major fetal anomalies.

Statistical Analysis:

Data were entered into Excel and analyzed using SPSS and GraphPad Prism. Numerical variables were summarized using means and standard deviations, while categorical variables were described with counts and percentages. Two-sample t-tests were used to compare independent groups, while paired t-tests accounted for correlations in paired data. Chi-square tests (including Fisher's exact test for small sample sizes) were used for categorical data comparisons. P-values ≤ 0.05 were considered statistically significant.

RESULTS

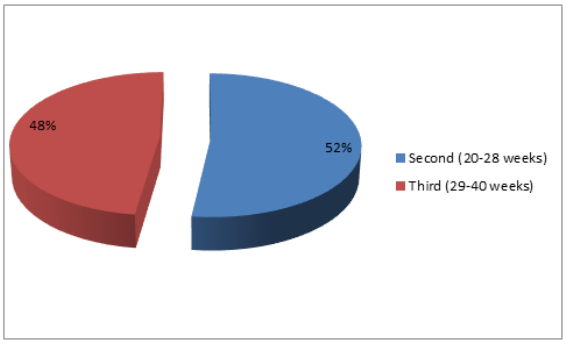

Figure 1: Distribution of Trimester

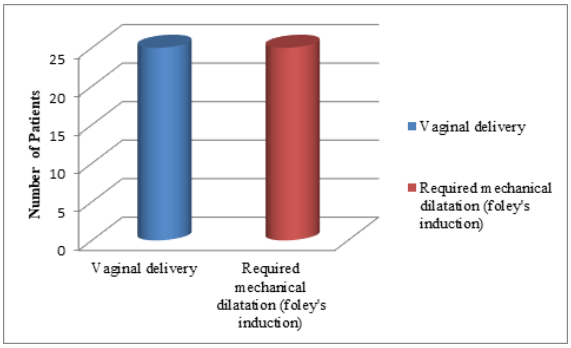

Figure 2: Distribution of Maternal outcome

The age distribution of individuals is categorized into three groups: those under 20 years, those aged 21-30 years, and those aged 31-40 years. The majority of individuals, 25 in total, fall under the age of 20. In contrast, only 5 individuals are in the 21-30 age group, making it the smallest category. The remaining 20 individuals belong to the 31-40 age group. This distribution highlights that the population is predominantly composed of younger individuals, with a notable decrease in numbers in the 21-30 age range and a subsequent rise in the 31-40 age group.

The data represents the distribution of numbers across two trimesters of pregnancy. In the second trimester (spanning 20-28 weeks), the recorded number is 26. Conversely, in the third trimester (spanning 29-40 weeks), the number slightly decreases to 24. This distribution indicates a relatively stable count across the two trimesters, with a slight decline as pregnancy progresses into the later stages.

The data outlines maternal outcomes related to delivery methods. Among the cases, 25 resulted in vaginal deliveries, indicating a natural progression of labor without additional mechanical interventions. Similarly, 25 cases required mechanical dilatation through Foley's induction, a common method to assist cervical ripening and initiate labor. This equal distribution highlights the varied approaches to

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managing labor and delivery based on individual clinical scenarios.

Women under 20 showed significant improvement in Bishop Scores over 48 hours (2.00±0.53 to 9.00±1.41, P = 0.012), while those aged 21-30 exhibited stable scores (P = 0.417). Women aged 31-40 also had notable improvement (P = 0.011). Women with one previous LSCS showed an improvement in Bishop Scores over 48 hours (2.73±1.25 to 7.86±2.03) but without statistical significance (P = 0.147). Similarly, those with two prior LSCS had improved scores (P = 0.239). In the second trimester, Bishop Scores improved from 2.67±1.19 to 8.50±1.51 without statistical significance (P = 0.156). In the third trimester, scores also improved but with statistical significance (P = 0.021). Bishop scores improved significantly in the 11-20 hours group (P = 0.007), 21-30 hours group (P = 0.024), and 31-40 hours group (P = 0.017), whereas scores in the >40 hours group were not statistically significant (P = 0.144). Cases requiring mechanical dilatation showed significant improvement in Bishop Scores over 48 hours (2.54±1.12 to 8.29±1.70, P = 0.037).

Table 1: Distribution of Age in years.

		Number	%
Age in years	< 20	25	50
	21-30	5	10
	31-40	20	40
	Total	50	100
Trimester	Second (20-28 weeks)	26	52
	Third (29-40 weeks)	24	48
	Total	50	100
Maternal outcome	Vaginal delivery	25	50
	Required mechanical dilatation (Foley's induction)	25	50
	Total	50	100

Table 2: Distribution of all demographic Parameter

Variables		Mean±SD			P value
		Bishop score (Pre)	Bishop score (At 24 Hour)	Bishop score (At 48 hour)	
Age in year	< 20	2.00±0.53	5.13±0.99	9.00±1.41	0.012
	21-30	3.20±1.32	6.38±2.46	6.33±2.31	0.417
	31-40	3.00±1.33	5.69±1.74	7.83±1.94	0.011
Previous LSCS	One	2.73±1.25	5.88±2.02	7.86±2.03	0.147
	Two	3.12±1.31	5.69±1.79	7.83±2.13	0.239
Trimester	Second	2.67±1.19	5.70±1.55	8.50±1.51	0.156
	Third	2.77±1.16	5.75±2.26	6.80±2.38	0.021
Mean induction delivery interval	11 to 20	3.10±1.28	5.71±1.38	9.00±1.00	0.007
	21-30	2.77±1.48	5.38±1.59	7.33±2.08	0.024
	31-40	2.80±1.22	6.33±2.59	8.50±2.12	0.017
	>40	2.84±1.28	5.77±1.96	7.20±2.49	0.144
Additional inducing agent	Required mechanical dilatation	2.54±1.12	5.55±1.75	8.29±1.70	0.037

DISCUSSION

The data presented provides a comprehensive analysis of the age distribution, trimester-wise data, maternal outcomes related to delivery methods, and the improvement in Bishop scores across various categories. This discussion aims to elaborate on these findings and their implications in the clinical context.

Age Distribution

The age distribution of individuals is segmented into three distinct groups: those under 20 years, individuals aged 21-30 years, and those aged 31-40 years. The majority of individuals, 25 in total, fall under the age of 20. This demographic dominance suggests a trend where a significant proportion of pregnancies occur in younger women, potentially reflecting societal norms, early marriages, or early childbearing practices in the study region. Conversely, the 21-30 age group, comprising only 5 individuals, represents the smallest category. This notable dip may indicate delayed pregnancies in this age group due to personal, educational, or career-related priorities. In contrast, the 31-40 age group includes 20 individuals, signifying a resurgence in pregnancy rates. This rise could be attributed to advancements in assisted reproductive technologies and a growing acceptance of later pregnancies. Overall, the age distribution underscores a predominantly younger reproductive population with a distinct bimodal trend.

Trimester-wise Distribution:

The data on trimester-wise distribution indicates a relatively stable count across the second and third trimesters. In the second trimester (20-28 weeks), the recorded number is 26, while in the third trimester (29-40 weeks), the count slightly decreases to 24. This marginal decline could be attributed to various factors, including pregnancy loss, medical terminations, or preterm deliveries occurring before the third trimester. The relatively stable numbers between the two trimesters suggest consistent care and monitoring of pregnancies as they progress.

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However, the slight decline in the later stages may warrant further investigation into potential complications or risk factors associated with advanced gestation.

Maternal Outcomes Related to Delivery Methods

The maternal outcomes reveal an equal distribution of cases between vaginal deliveries and those requiring mechanical dilatation through Foley's induction. Out of the cases studied, 25 resulted in vaginal deliveries, indicating a natural progression of labor without additional mechanical interventions. This outcome highlights the efficacy of spontaneous labor in achieving successful deliveries in suitable cases. On the other hand, 25 cases required mechanical dilatation through Foley's induction, a widely used method to assist cervical ripening and initiate labor. The equal distribution of these outcomes reflects the variability in labor and delivery management, emphasizing individualized clinical decision-making. Factors such as maternal age, Bishop Scores, previous obstetric history, and fetal conditions likely influenced the choice of delivery method. The findings underscore the importance of tailoring labor induction methods to optimize maternal and fetal outcomes.

Improvement in Bishop Scores

Age-wise Analysis

- **Women Under 20 Years:** Women under 20 showed significant improvement in Bishop scores over 48 hours, increasing from 2.00±0.53 to 9.00±1.41 (P = 0.012). This statistically significant change indicates that younger women respond favorably to labor induction methods. The physiological adaptability and favorable cervical conditions in this age group may contribute to their better response. These findings highlight the importance of leveraging their inherent biological advantage to achieve optimal outcomes.
- **Women Aged 21-30 Years:** In contrast, women aged 21-30 exhibited stable Bishop Scores, with no statistically significant change (P = 0.417). This stability could reflect intrinsic or extrinsic factors such as underlying cervical resistance or variations in obstetric care. The lack of significant improvement in this age group may necessitate closer monitoring and alternative induction strategies.
- **Women Aged 31-40 Years:** Women in the 31-40 age group demonstrated significant improvement in Bishop scores (P = 0.011), underscoring their positive response to induction methods. Despite being older, this age group showed adaptability, potentially aided by modern obstetric interventions and improved healthcare access. The findings emphasize that age alone should not deter clinicians from pursuing labor induction in older women.

Impact of Previous LSCS

- **One Previous LSCS:** Women with one previous lower segment cesarean section (LSCS) showed an improvement in Bishop scores over 48 hours, increasing from 2.73±1.25 to 7.86±2.03, although this change was not statistically significant (P = 0.147). The lack of statistical significance could stem from a limited sample size or variability in patient characteristics. Nonetheless, the observed improvement suggests a potential for successful labor induction in these cases with appropriate monitoring.
- **Two Previous LSCS:** Similarly, women with two prior LSCS experienced improved scores, though without statistical significance (P = 0.239). These findings highlight the challenges and limitations of labor induction in women with multiple cesarean deliveries, emphasizing the need for individualized risk assessments and judicious decision-making.

Trimester-specific Analysis

- **Second Trimester:** In the second trimester, Bishop scores improved from 2.67±1.19 to 8.50±1.51, albeit without statistical significance (P = 0.156). The improvement reflects the potential effectiveness of induction methods during this period, although the lack of statistical significance may necessitate larger sample sizes for more conclusive results.
- **Third Trimester:** In the third trimester, Bishop scores improved significantly (P = 0.021), indicating a robust response to labor induction in later stages of pregnancy. The findings reinforce the efficacy of induction methods in optimizing cervical conditions and facilitating successful deliveries in advanced gestation.

Time-wise Analysis

- **11-20 Hours Group:** Significant improvement in Bishop scores was observed in the 11-20 hours group (P = 0.007), demonstrating the efficacy of induction methods within a relatively short timeframe.
- **21-30 Hours Group:** The 21-30 hours group also showed significant improvement (P = 0.024), highlighting the sustained effectiveness of induction methods over an extended period.
- **31-40 Hours Group:** Significant improvement was noted in the 31-40 hours group (P = 0.017), emphasizing the potential for continued progress with prolonged induction durations.
- **>40 Hours Group:** In contrast, scores in the >40 hours group were not statistically significant (P = 0.144), suggesting diminishing returns with prolonged induction durations. These findings underscore the need for timely interventions to optimize outcomes and minimize risks.

Impact of Mechanical Dilatation

Cases requiring mechanical dilatation showed significant improvement in Bishop scores over 48 hours, increasing from 2.54±1.12 to 8.29±1.70 (P = 0.037). This significant change highlights the effectiveness of Foley's induction in achieving favorable cervical conditions. Mechanical dilatation remains a valuable tool in labor induction,

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particularly in cases with an unfavorable initial Bishop score.

Clinical Implications

The findings of this study have several clinical implications:

- **Tailored Care:** The varied responses to labor induction across different age groups, previous obstetric histories, and gestational stages underscore the importance of personalized care in obstetric practice.
- **Optimizing Induction Strategies:** The significant improvements in Bishop scores with mechanical dilatation and within specific timeframes highlight the need for timely and evidence-based induction methods.
- **Monitoring and Risk Assessment:** The lack of significant improvements in certain subgroups, such as women with multiple previous LSCS or prolonged induction durations, emphasizes the need for vigilant monitoring and comprehensive risk assessments to prevent adverse outcomes.

CONCLUSION

We conclude that, the data presents a diverse range of outcomes and characteristics across different groups. The age distribution reveals a predominantly younger population, with a notable dip in the 21-30 age group and a subsequent increase in the 31-40 group. The pregnancy trimesters show stable numbers, with a slight decline in the third trimester. Delivery methods highlight a balanced distribution between vaginal deliveries and those requiring mechanical dilatation. The Bishop score improvement is significant in several groups, including women under 20 and those in the 31-40 age range, demonstrating notable cervical ripening. Furthermore, the second and third trimesters show varying degrees of improvement, with statistical significance in the latter. Mechanical dilatation also resulted in significant improvement in Bishop scores, underscoring its effectiveness in labor preparation. Overall, the findings suggest that age, trimester, and intervention methods all play a role in influencing maternal outcomes, with certain factors showing a stronger impact on cervical readiness and labor progression.

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