A Comparative Study between Intrauterine Foley's Catheter Versus Foley's with 100 ml of Extra-Amniotic Saline Infusion for Induction of Labour in Nulliparous with Unfavorable Cervix

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KEYWORDS
Extra amniotic saline infusion, foley's mechanical induction, induction of labour, unfavourable cervix

ABSTRACT

Objective: This study was performed to compare efficacy, mean time interval between induction and delivery and side effects like differences in caesarean rates, maternal and foetal morbidities like chorioamnionitis, uterine hyperstimulation, foetal and neonatal distress in intrauterine foley's catheter versus foley's with 100 ml of extra amniotic saline infusion used for induction of labour in nulliparous women with unfavourable cervix.

Material and Method: This comparative study was conducted on selected 100 women admitted in the Department of Obstetrics & Gynaecology, in a tertiary care hospital with term pregnancy divided into two groups, i.e., foley's catheter alone group i.e., group A and foley's catheter with extra amniotic saline infusion group i.e., group B consisting of 50 patients each.

Results: The mean duration from induction to active phase of labour for group A was 607.34 ± 200.60 min and for group B was 447.82 ± 130.70 min which was statistically significant. However, the mean duration between induction of labour to delivery in group A was 918.06 ± 301.76 minutes and group B was 820.86 ± 337.06 minutes which was statistically not significant. There was statistically significant rate of side effects including increased caesarean section rates in group B (84%) as compared to group A (60%).

Conclusion: While the use of extra amniotic saline infusion with a Foley 's catheter results in more rapid cervical ripening and a shorter duration from induction to the active phase of labor compared to the Foley's catheter alone, it cannot be deemed superior. This is due to the lack of a significant difference in the mean induction-to-delivery interval, as well as a notable increase in side effects, including higher rates of cesarean deliveries.

Introduction

Induction of labour is defined as artificial termination of pregnancy any time after age of viability by a method that aims to secure delivery either because of any maternal or foetal indications, or involving both irrespective of the outcome of delivery. Success rate of labour induction depends on the state of cervix at the time of labour induction and women with unfavorable cervix are at an increased risk of prolonged labour and caesarean section. [1] There are various methods of cervical ripening before induction of labor, including prostaglandins, foley's catheter, extra amniotic saline infusion and oxytocin. [2] However, each method has its own complications and contraindications. Hence, no single method can be considered superior to other. Prostaglandins though easily available and cost effective can cause foetal distress, uterine hyperstimulation, rupture uterus and are contraindicated in bronchial asthma. Foley's catheter, with or without saline infusion has been associated with

rapid improvement in bishop score and shorter labour with relatively less complications in comparison to other methods of induction. [3] Extra amniotic Saline Infusion (EASI) may be a suitable, simple and reversible alternative to prostaglandins for cervical ripening especially where prostaglandins are contraindicated or uterine hyperstimulation should be avoided but it is associated with higher rate of caesarean section and fetal distress.[4]

Aim & Objective

- To determine whether EASI improves the efficacy of foley's catheter in nulliparous women with unfavourable cervix undergoing cervical ripening and induction of labour.
- To determine the mean time interval between induction and delivery in both groups.
- To find out secondary outcomes in both the groups which include differences in the caesarean rates, rate of selected maternal and neonatal morbidities like chorioamnionitis, hyperstimulation and foetal distress.

Materials and Methods

This comparative study has been conducted in Department of Obstetrics & Gynaecology in our tertiary care hospital from June 2022 to June 2023. In the study 103 nulliparous cases requiring termination of pregnancy with unfavourable Bishop score were selected out of which 3 were excluded as two of them did not give consent and another one had a history of MTP by medical methods. Written informed consent was taken from the remaining 100 patients. Height, weight, BMI and socio-economic status was ascertained by B J Prasad scale. Randomization was done by envelope method. 50 cases were selected for foley's catheter induction (i.e Group A) and another 50 cases selected for EASI with foley's catheter induction (i.e GroupB). All women received concurrent dilute oxytocin infusion for augmentation as per protocol. Changes in the Bishop score was noted. Interval from induction to active phase of labour and from active phase to vaginal delivery assessed by partogragh plotting. Caesarean rate, outcome of labour, hyperstimulation, meconium stained liquor, fetal distress during labour by CTG monitoring and APGAR Scores of babies at 1 minute and 5 minutes after delivery were assessed.

Inclusion criteria:

- Nulliparous
- Singleton pregnancy
- Intact membranes
- Vertex presentation
- Bishop score less than 6
- Gestational age 37 completed weeks to 42 weeks

Exclusion criteria:

- Multiple pregnancy
- Ruptured membrane
- Vaginal Cervical infection or bleeding
- women with spontaneous labour (contraction ≥ 3 in 10 minutes).
- Patients with any contraindications for vaginal delivery

Observations & Results

In this study it was observed that maximum number of cases belong to 20-25 years age group with a minimum age of 18 years to maximum age of 38 years. Mean age in EASI with foley's group (24.30 years) and foley's catheter group (23.84 years) was comparable. Overall Mean

age of study participants was 24.07 ± 3.41 years. Similarly, the mean height (159.68 ± 5.76 cm) for EASI with foley's versus (158.56 ± 3.84 cm) for foley's group, Mean weight(60.66 ± 6.21 kg) for EASI versus (59.14 ± 3.98) for foley's group and BMI (23.82 ± 2.50 kg/m^2)for EASI versus (23.52 ± 1.41 kg/m^2)for foley's group were almost comparable in both groups and the difference was not statistically significant (Figure 1a.1b).

In current study most of the subjects belong to lower socio-economic status in both EASI with foley's (80%) and foley's catheter (82%) (Figure 1c). The mean gestational age in EASI with foley's group was 271.04 ± 8.93 days compared to 276.02 ± 7.94 days in foley's catheter group and the difference between both the groups was not statistically significant (P value =0.243) (Figure 2). Pre-induction bishop score in EASI with foley's (2.68 ± 1.07) and in foley's catheter group (3.04 ± 1.14) was noted. (Figure 3)

In our study various indication for induction of labour were found, out of which Crossed Expected Delivery Date (CEDD) was the most common cause of induction of labour in both groups followed by pregnancy induced hypertension. In EASI with foley's group CEDD (48%), followed by pregnancy induced hypertension (PIH) (24%), antepartum eclampsia (12%) and IUGR (16%). Similarly in foley's group crossed EDD (38%), antepartum eclampsia (20%), IUGR (20%), PIH (16%) and border line oligohydramnios (6%). Hence patients in both groups were comparable with respect to indication for induction and the difference between both groups was not statistically significant with P value 0.231 (Figure 4).

Hence from above discussion it is observed that in our study both groups were similar with respect to potential confounders such as age, height, weight, BMI, socio economic status, gestational age, preinduction Bishop score and indication for induction. The mean duration from induction to active stage of labour in EASI with foley's group was 447.82 ± 130.70 minutes as compared to 607.34 ± 200.60 minutes in foley's catheter group (Table A). The mean interval from induction of labour to active stage of labour in EASI with foley's group was significantly lower compared to foley's catheter group and the difference between both groups was statistically significant with P value of <0.001. The mean induction to delivery interval in the present study in EASI with foley's group was 820.86 ± 337.06 minutes and in foley's group 918.06 ± 301.76 minutes, which was lower compared to foley's catheter group but the difference between both groups was not statistically significant with P value =0.132. (Table B)

In our study failure to progress to labour in EASI with foley's group was 36% and in foley's group was 40%, the difference was not statistically significant (P value 0.680) (Table C). The caesarean section rates were significantly higher in EASI with foley's group i.e. 84% as compared to foleys group i.e. 60% and the difference between both groups was statistically significant with P value 0.008. Most common cause of lower segment cesarean section (LSCS) in current study is fetal heart rate (FHR) abnormalities (57.1%) in EASI with foley's group and non-progress of labour (43.3%) in foley's catheter group. Other causes were obstructed labour seen in 11.9% in EASI with foley's group and 23.3% cases in foley's catheter group (Figure 6).

In present study incidence of fetal distress and meconium-stained liquor was significantly higher in EASI group compared to foley's group. The incidence of fetal distress by CTG was observed in 48% of cases and meconium stained liquor in 36% of cases in the EASI group, compared to 20% and 16%, respectively, in the foley's catheter group (Figure 7).

In our study there was no significant intrapartum, postpartum complication between the two groups however neonates delivered by EASI with foley's method had low APGAR score as compared to neonates delivered by foley's catheter method (P value at 1 min 0.001 & P value at 5 mins 0.044). (Table D)

Discussion

In present study the mean duration from induction to active stage of labour in EASI with foley's group was 447.82 ± 130.70 minutes as compared to 607.34 ± 200.60 minutes in foley's catheter group. The mean interval from induction of labour to active stage of labour in EASI with foley's group was significantly lower compared to foley's catheter group and the difference between both groups was statistically significant with P value of ≤0.001. Similar results were also seen in a study by Mansour ghanaie et al, where mean duration from induction to active phase for EASI with foley's group was 357 ± 135 minutes and for foley's catheter group 457 ± 178 minutes and for PGE2 group 609 ± 238 minutes and difference was statistically significant with P value 0.04. [5] In a study conducted by Nicole W Karjane, time from induction to vaginal delivery was 16.58 ± 7.55 hours in the EASI with foley's group compared with 21.47 ± 9.95 hours in the foley's group (P <0.01) whereas in our study the mean induction to delivery interval in EASI with foley's group was 820.86 ± 337.06 minutes and in foley's group 918.06 ± 301.76 minutes, which was lower compared to foley's catheter group but the difference between both groups was not statistically significant with (P value =0.132). [6] In a study conducted by Monique G Lin et al the proportion of women delivered by 24 hours was comparable between groups (delivery 24 hours, EASI 89.7% and foley's 87.9%, P =0.70), as was the rate of caesarean delivery (foley's 18.7%, EASI 27.8%, P= 0.14). In contrast to our study where caesarean section rates were significantly higher in EASI with foley's group i.e. 84% as compared to foleys group i.e. 60% and the difference between both groups was statistically significant with P value 0.008.[7] In our study there was no significant intrapartum, postpartum complication between the two groups however neonates delivered by EASI method had low APGAR score as compared to neonates delivered by foley's catheter method with statistical significant P value at 1 min 0.001 and P value at 5 mins 0.044, whereas In a study by Swapan Das et al, Apgar score at 1 min and 5 min were similar in both group with a mean Apgar score at 1 min of 6.98 ± 1.86 in EASI with foley's group and 6.96 ± 2.128 in foley's alone group, (P= 0.96) and mean Apgar score at 5 min was 9.06 ± 0.998 and 8.84 ± 1.167 respectively (P= 0.314) and 14% in EASI with foley's group and 24% in foleys group were meconium stained (P= 0.308) which was not statistically significant and neonatal admission in special newborn care unit (SNCU) was 18% in EASI with foley's and 26% in foley's group (P = 0.47). [8] In a similar study by Debra A Guinn, there were no differences between the groups for time to delivery (foley's 17.7 ± 10.5 hours vs EASI 17.4 ± 11.7 hours, P= 0.9), the proportion of women delivered before 24 hours (foley's 41/49 [84%] vs EASI 39/51 [77%], P= 0.37) or caesarean rates (foley's 9/49 [17.7%] vs EASI 9/51 [18.4%], P= 0.92). There were also no differences in complications, including chorioamnionitis, endometritis and neonatal morbidity [9].

Conclusion

In this study, we conclude that while EASI with a Foley's catheter results in more rapid cervical ripening and a shorter duration from induction to the active phase of labor compared to the Foley's catheter alone, it is not a superior method. This is due to the lack of a significant difference in the mean induction-to-delivery interval. Additionally, the rates of cesarean deliveries, fetal heart rate abnormalities, meconium-stained liquor, and low APGAR scores at birth were significantly higher in the EASI with foley's group compared to the foley's catheter group.

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Conflict of interest: All the seven authors declare that they have no conflict of interest and

there is no violation of human rights.

Ethical Approval: This study was approved by the Institutional ethics committee. The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

Informed consent: Written informed consent was obtained from all study participants.

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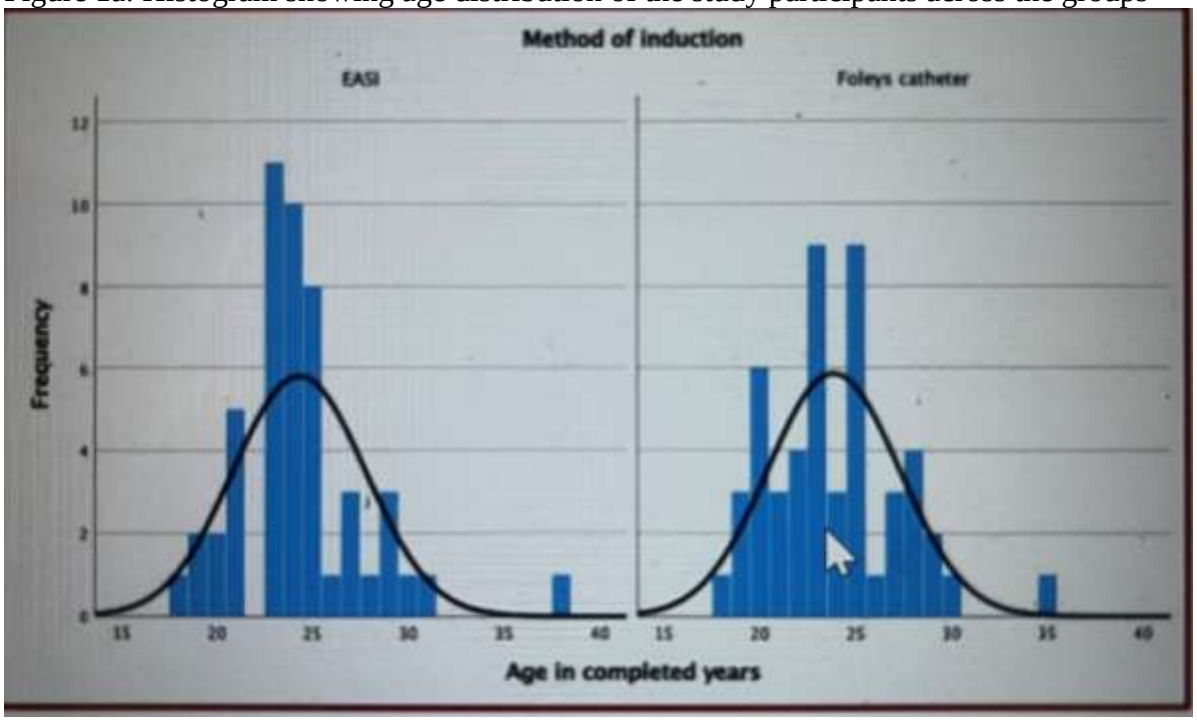
Figure 1a: Histogram showing age distribution of the study participants across the groups



FIGURES

Figure 1b: Bar graph showing comparison of height and weight between the groups

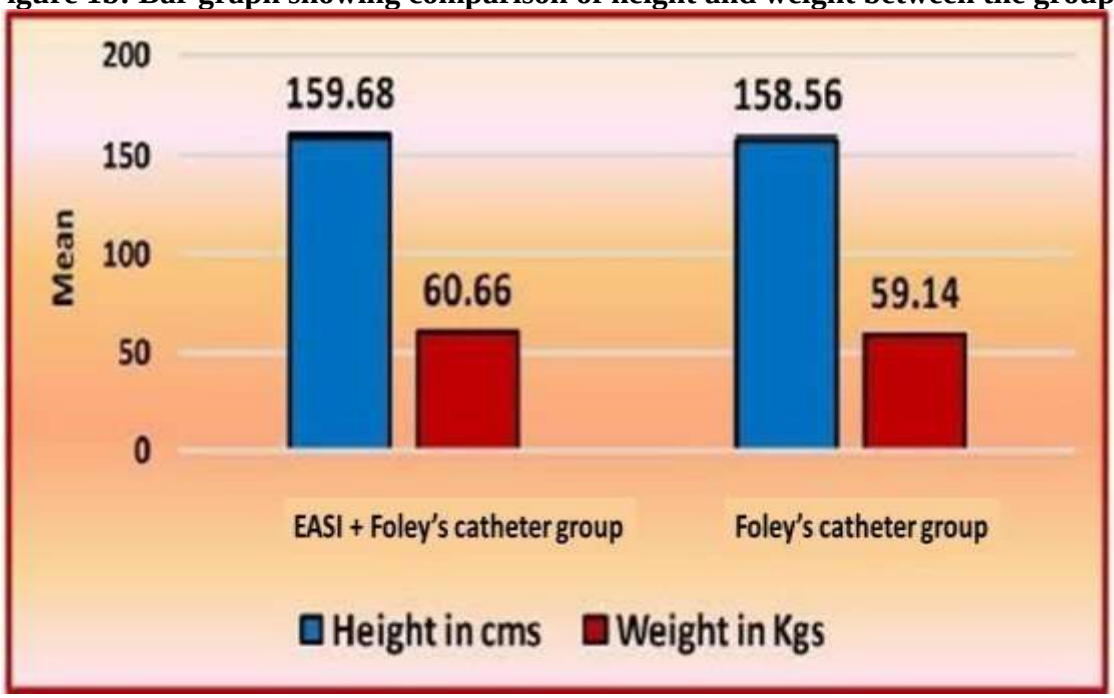


Figure1c: bar graph showing sociodemographic distribution between two groups

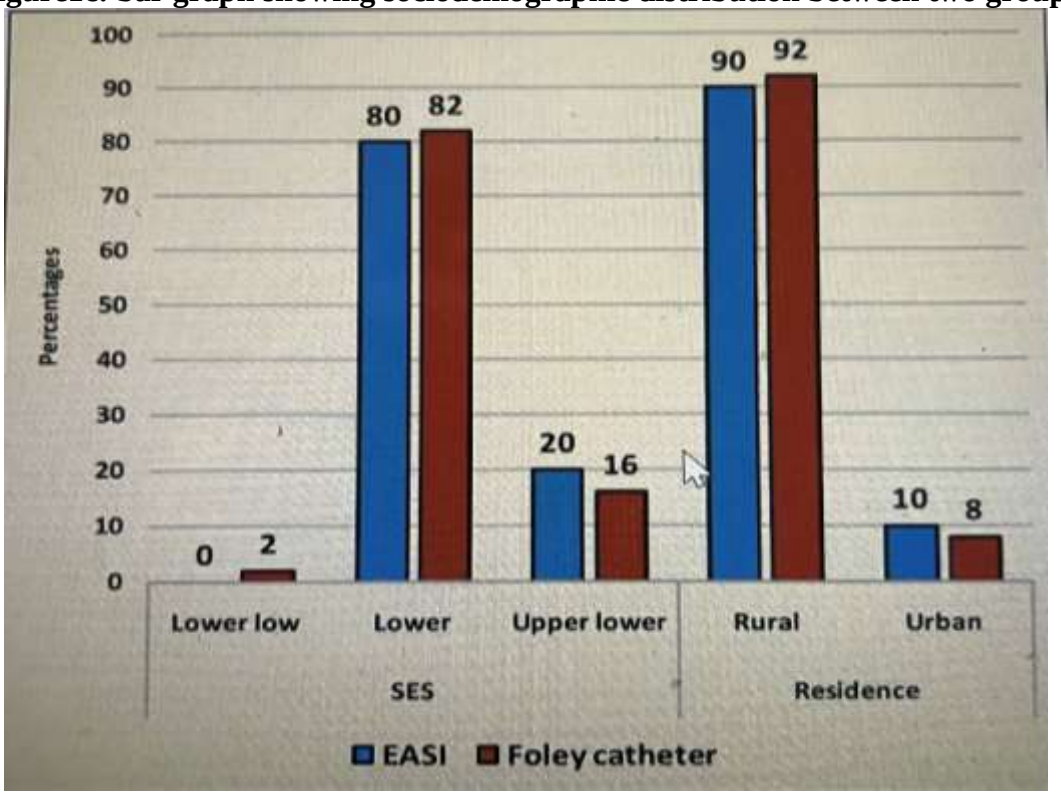


Figure 2: Box plot showing comparison of gestational age between the groups

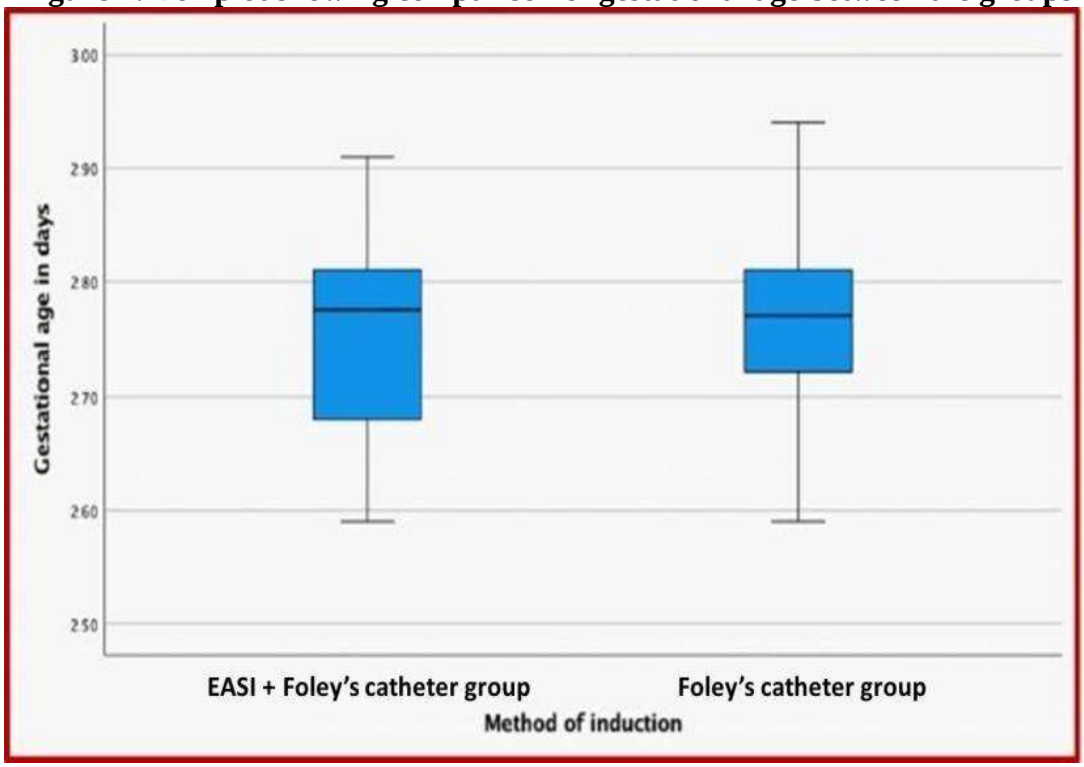


Figure 3: bar graph showing pre induction bishop score between two groups

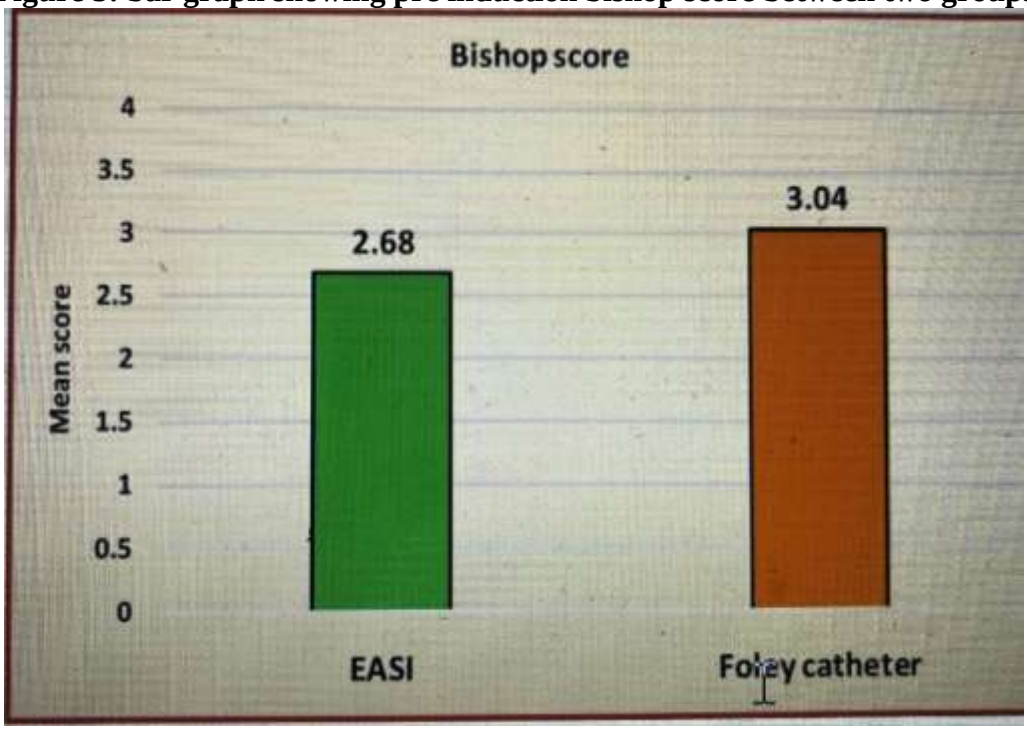


Figure 4: Comparison of indication for induction of labour across the groups

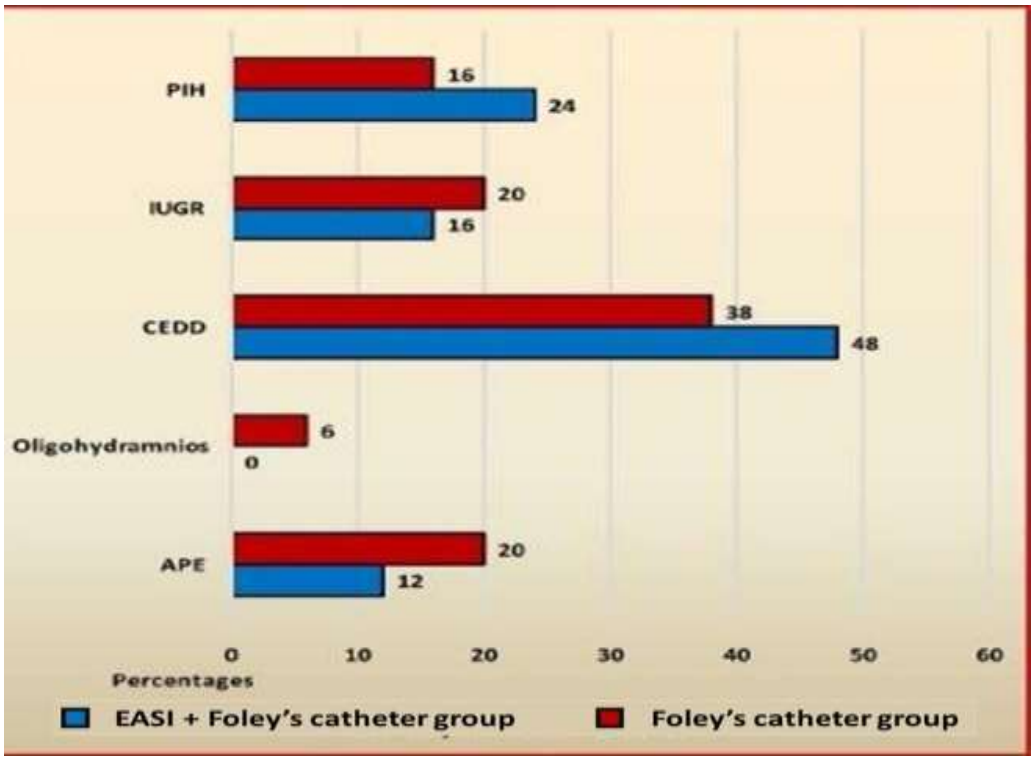


Figure 5: comparision showing the mode of delivery between the two groups

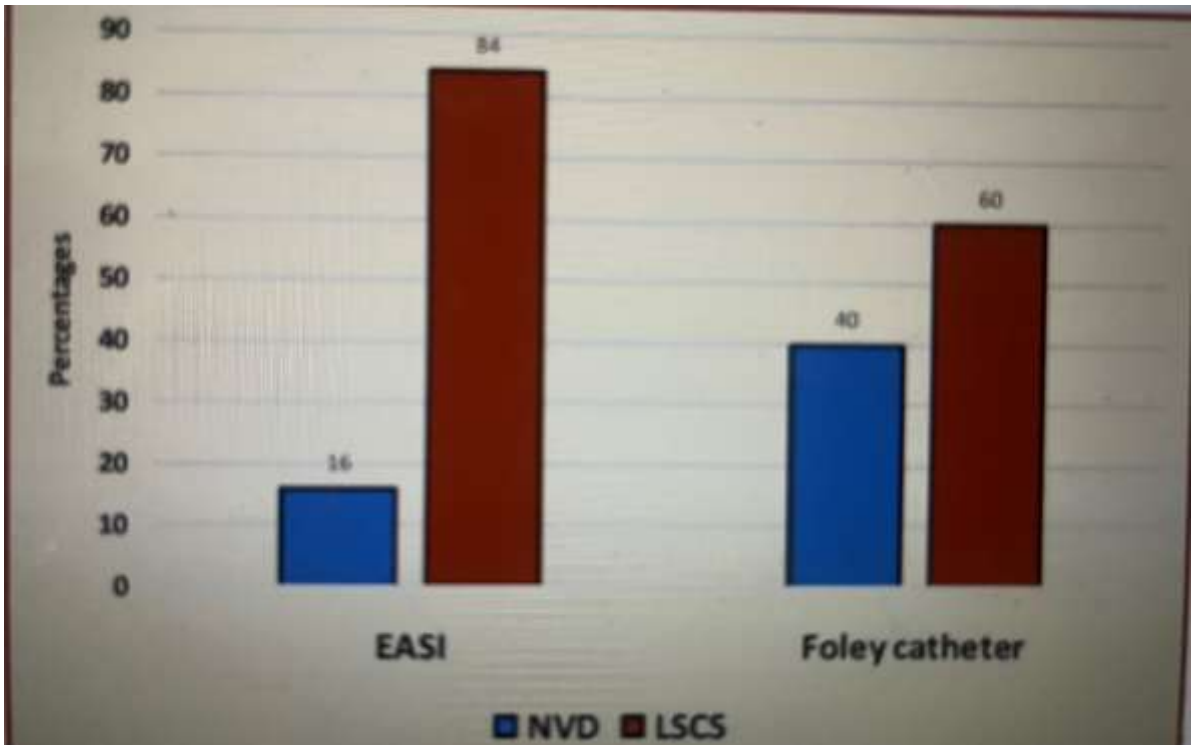


Figure 6: Bar graph showing Comparison of indication for LSCS between the groups

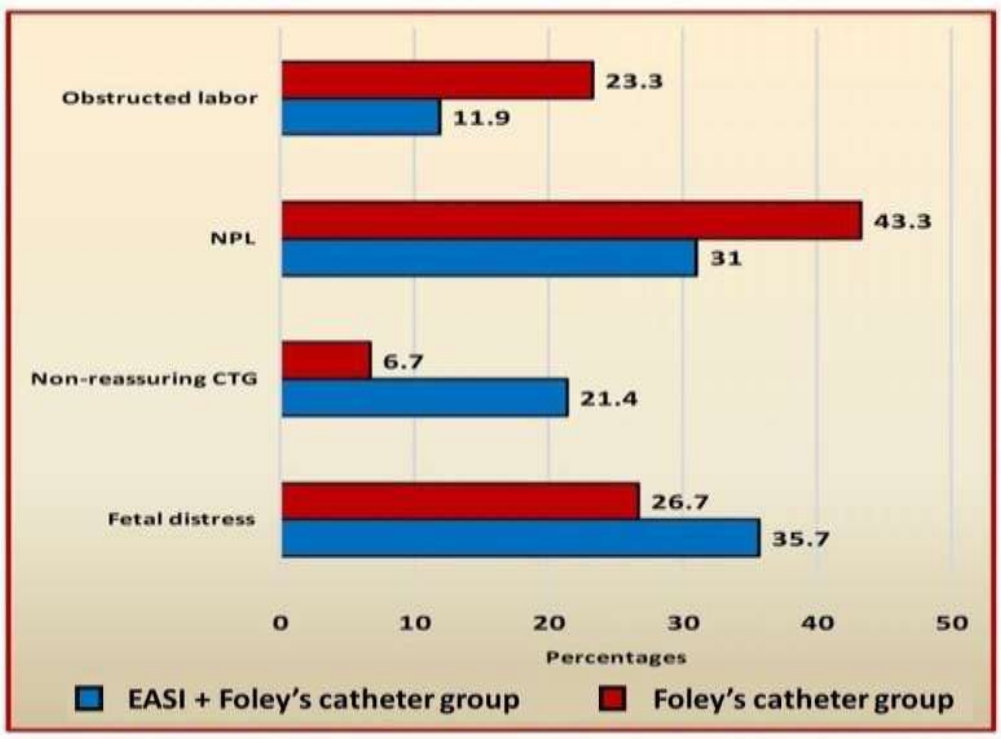
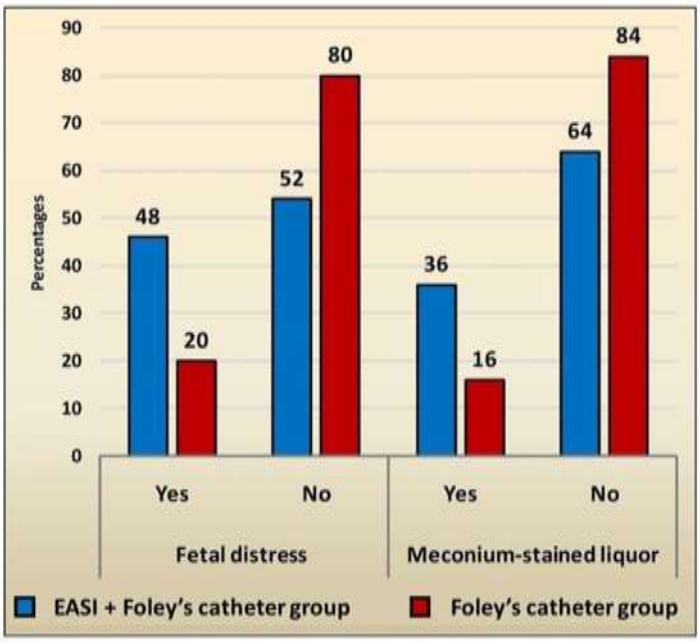


Figure 7: comparision of adverse events between two groups



Tables

Table A: Comparison of duration between inductions to active phase of labour across the groups

Method of induction	Mean	SD	t-value	P value
EASI + Foley's Catheter group	447.82	130.7	-4.711	<0.001
Foley's Catheter	607.34	200.6		

Table B: Comparison of duration between inductions to delivery between the groups

Method of induction	Mean	SD	t-value	P value
EASI	820.86	337.06	-1.519	0.132
Foley's Catheter	918.06	301.76		

Table C:: Comparison of Non progress of labour between the groups

VARIABLE		EASI + Foley's Catheter group (N%)	Foley's Catheter (N%)	x^2 Value	P VALUE
FAILURE TO PROGRESS	YES	18(36.0)	20(40.0)	0.164	0.680
	NO	32(64.0)	30(60.0)		

Table D: Comparison of APGAR scores between the two groups

APGAR score	EASI	Fouley;s group	T - value	P - value
At 1min	**7.48 ±0.97**	**8.40 ± 0.88**	**-4.954**	**0.001**
At 5 mins	**9.02 ±0.82**	**9.34 ± 0.74**	**-2.041**	**0.044**