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Maternal and fetal outcome by inducing labour using dilapan-s: A cervical osmotic dilator

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Abstract
Introduction: Induction of labour is a widely used practice in obstetrics. It is the process of artificially stimulating the uterus to start labour and expulsion of fetus prior. The commonly used methods for induction of labour are mechanical methods such as osmotic dilators, balloon catheters, amniotomy and pharmacological methods such as oxytocin infusion and prostaglandins. Among mechanical methods, Dilapan-S is the second generation osmotic hygroscopic dilator. It is a synthetic gel rod acting by absorbing fluid from the cells of the cervical canal, resulting in reversible cell wall dehydration and softening. By its mechanical stretch, it increases the volume of the rod(s) initiating the endogenous prostaglandin release causing collagen degradation and ripening of the cervix.
Objectives of the study:
1. To determine the efficacy and safety of Dilapan-S, an osmotic cervical dilator in induction of labour.
2. To assess the maternal and perinatal outcome following induction with Dilapan-S.

Results: This study was performed on 55 pregnant. Syntocin augmentation was required in 42(72.4%) total, among which 13(61.9%) were primigravida and 29(85%) were multigravida. There was statistical significant difference in the requirement of syntocin augmentation distribution with respect to parity. In almost all vaginal deliveries and vaccum assisted vaginal delivery there was 100% need of syntocin augmentation showing significant difference in need of syntocin augmentation distribution with respect to mode of delivery. Out of 55 cases who underwent induction, 60% had vaginal delivery of which 8 were primigravida and 25 were multigravida, 38.2% had LSCS of 12 primigravida and 9 multigravida and 1.8% (one primigravida) had vaccum assisted vaginal delivery? There was a significant difference in mode of delivery distribution with respect to Parity.
Conclusion: Dilapan-S was effective method of induction of labour in terms of improving cervical ripening and vaginal delivery rate (60%) and was safe with no uterine hyper stimulation or maternal infections or mortality associated. There was need of syntocin augmentation for most of the patients (76.4%). Dilapan S was safe with good fetal outcome, reassuring type of CTG and with reduced need of NICU admission.

Keywords: Induction, bishop score, CTG, APGAR score

Introduction
Induction of labour is a widely used practice in obstetrics [1]. It is the process of artificially stimulating the uterus to start labour and expulsion of fetus prior.
It is done in those who are either at or after term to improve the outcome of the mother and baby minimizing maternal and fetal or neonatal morbidity and mortality by a timely intervention for termination of pregnancy.
Globally, in healthcare facilities, about 10% of all the deliveries involved induction of labour. Historically induction was done only in the events of life threatening maternal diseases. But, with the advent of safer and improved methods the threshold for intervention for induction of labour has been reduced. The commonly used methods for induction of labour are mechanical methods such as osmotic dilators, balloon catheters, amniotomy and pharmacological methods such as oxytocin infusion and prostaglandins [2]. The method of choice may be influenced by several factors such as parity, patient preference, cervical and membranes status [3].
Among mechanical methods, Dilapan-S is the second generation osmotic hygroscopic dilator made from patented hydrogel aquacryl**.** It is a synthetic gel rod acting by absorbing fluid from the cells of the cervical canal, resulting in reversible cell wall dehydration and softening [4].
By its mechanical stretch, it increases the volume of the rod(s) initiating the endogenous prostaglandin release causing collagen degradation and ripening of the cervix [5].

A marker string is tied securely to the handle of the DILAPAN-S which indicates its location. It will be supplied sterile and for only single use.

Dilapan-S is commonly inserted into the cervical canal or the extra- amniotic space and works by dilating the cervical canal and/or release of prostaglandins and oxytocin [6].

This study can be used to know the efficacy of Dilapan-S for labour induction in SDUAHER.

This study will be helpful for cervical ripening with hygroscopic dilators and shortening the duration of labour in patients undergoing induction and to reduce the operative deliveries.

Dilapan-S, increases the cervical ripening, and is associated with less risk of uterine hyper stimulation and impact on the fetal heart rate and has no drug related side effects. As Dilapan-S, has not gain and much popularity in recent days, this study will be helpful to reintroduce it for induction of labour by evaluating its efficacy.

Hence in this study, for induction of labour with dilapan-S which is an osmotic dilator and the maternal and perinatal outcome of the same are documented.

Objectives of the study

1. To determine the efficacy and safety of Dilapan-S, an osmotic cervical dilator in induction of labour.
2. To assess the maternal and perinatal outcome following induction with Dilapan-S.

Materials and methods

- The study will include 55 term pregnant women (37 weeks to 42 weeks of gestation) with cephalic presentation admitted to labour room at SDUAHER, after obtaining written informed consent and performing routine investigations.
- Source: The study will include 55 term pregnant women with cephalic presentation admitted to labour room at SDUAHER, after obtaining written informed consent and performing routine investigations.
- Study design: A clinical prospective interventional study.
- Study period: January 2019 to June 2020.
- Method of collection of data: A prospective interventional study will be conducted in the Department of Obstetrics and Gynaecology at Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar from January 2019 to JUNE2020.
- Inclusion Criteria
- -Singleton pregnancy with cephalic presentation.
- -Gestational age of 37 completed weeks or more
- -Pregnant women where pharmacological methods are contraindicated, conditions like cardiac disorders (PDA)
- Exclusion Criteria
- -Grandmultiparity
- Malpresentation
- -Severe hydrocephalus of the fetus
- -Abnormally implanted placentas(including placenta previa)
- -Clinical signs of uterine, vaginal and vulvar infection. Study population and Sample size: n=55
- Sample size is estimated by the proportion of deliveries with absolute error of 12%, confidence interval of 95% and prevalence of 29.2, required sample size is 55.
- $n = Z\alpha^2 PQ / d^2$
- n is the sample size,
- Zα is 1.96 at 95% confidence interval
- P is the prevalence, that is29.2
- Q is(1-P)
- d is the absolute precision, that is12%
- α is null hypothesis

Methodology

- Pregnant women fulfilling inclusion criteria are registered for the study.
- Detailed history regarding age, parity, gestational age, menstrual history, obstetric history and any complications in the present pregnancy was taken.
- General clinical examination, complete obstetric examination and necessary investigations were done.
- A written consent was taken.
- Vagina, cervix, perineum were prepared with an antiseptic solution.
- DILAPAN-S was removed from the sealed package using a sterile technique, moistened with sterile water or saline to lubricate the surface prior to insertion.
- It was introduced into the cervical canal with the assistance of speculum gradually so that it traverses the internal and external os, without undue force applied.
- The border of the collar should rest at external os and should not be inserted past the handle.
- -The amount of dilatation achieved depends on the amount of time insitu. One 4mm dilator rod can increase upto 10 to 12.5 mm in 24 hours. So the dilators were progressively placed until the endocervix is full.
- On an average 1 to 5 dilators are used. A sterile guaze pad should be placed in the vagina to maintain the position of the dilators.
- Patients were monitored for signs of progress of labour by partogram and fetal heart rate.
- Serial records of cardiotocography, modified BISHOP score, partograph are recorded along with monitoring contractions and performing vaginal examinations to assess the changes of the cervix. The dilapan is left for 24 hours (maximum of 36hours).
- The dilator were removed by holding the handle with the forceps and pull down in longitudinal axis of the dilator and cervix.
- Post induction Bishop score was assesed and if favourable (6 to 10) and if contractions were not adequate, augmentation of labour was done with IV oxytocin drip of5mU/min in primigravida and 2.5mU/min in multigravida which was started at the rate of 4 drops/min and the drip was increased by 4 drops every 20 minutes till effective contractions are produced for delivery.
- Assessment of objectives were based on preinduction and post induction Bishop score, number of Dilapan S rods used, need of augmentation with IV oxytocin drip, induction delivery time interval, mode of delivery, APGAR score and need of NICU admission and maternal complications such as PPH, hyper stimulation and fever.

Results

This study was performed on 55 cases who fulfilled the above mentioned inclusion and exclusion criteria.

Table 1: Age distribution

		Number of cases with Dilapan-S	%
Age	<20 years	2	3.6%
	21 to 25 years	28	50.9%
	>25 years	25	45.5%
	Total	55	100.0%

Total number of patients in the study were 55. Maximum number of patients (50.5%) were aged between 21-25 years.

Table 2: Age distribution with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of primigravida with Dilapan-S	%	Number of multigravida with Dilapan-S	%	Number of total cases with Dilapan-S	%
Age	<20 years	1	4.8%	1	2.9%	2	3.6%
	21 to 25 years	13	61.9%	15	44.1%	28	50.9%
	>25 years	7	33.3%	18	52.9%	25	45.5%

In Primigravida, 4.8% were < 20 years, 61.9% were 21 – 25 years and 33.3% were > 25years.
In Multigravida, 2.9% were < 20 years, 44.1% were 21 – 25 years and 52.9% were > 25years. There was no significant difference in Age distribution with respect to parity

Table 3: Parity distribution

		Number of cases with Dilapan-S	%
Parity	Primigravida	21	38.2%
	Gravida 2	20	36.4%
	Gravida 3	11	20.0%
	Gravida 4	3	5.5%
	Total	55	100.0%

Maximum number (38.2%) of patients were primigravida.

There was no significant difference in age distribution with respect to parity ($\chi 2 = 2.023$, df = 2, p =0.364).

Table 4: Period of Gestation Comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of primigravida with Dilapan-S	%	Number of multigravida with Dilapan-S	%	Number of total cases with Dilapan-S	%
Period of gestation	37 TO 38+6 weeks	2	9.5%	3	8.8%	5	9.1%
	39 to 39+6 weeks	5	23.8%	11	32.4%	16	29.1%
	40 to 41+6 weeks	14	66.7%	20	58.8%	34	61.8%

$\chi 2 = 0.462$, DF = 2, p = 0.794

In Primigravida, 9.5% had 37 TO 38+6 weeks period of gestation, 23.8% had 39 to 39+6 weeks and66.7% had 40 to 41+6 weeks period of gestation.
In Multigravida, 8.8% had 37 TO 38+6 weeks period of gestation, 32.4% had 39 to 39+6 weeks and 58.8% had 40 to 41+6 week period of gestation.
There was no significant difference in period of gestation distribution with respect to parity.

Table 5: Bishop Score (Pre induction) comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Pre induction Bishop Score	2	3	14.3%	5	14.7%	8	14.5%
	3	13	61.9%	20	58.8%	33	60.0%
	4	5	23.8%	9	26.5%	14	25.5%

In Primigravida, 14.3% had Bishop Score of 2, 61.9% had 3 and 23.8% had 4.
In Multigravida, 14.7% had 2, 58.8% had 3 and 26.5% had 4.
There was no significant difference in Bishop Score distribution with respect to parity.

Table 6: Post induction Bishop Score comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Post induction Bishop score	<4	3	14.3%	2	5.9%	5	9.1%
	>4	18	85.7%	32	94.1%	50	90.9%

In Primigravida, 14.3% had less than 4 and 85.7% had more than 4postinduction Bishop score. In Multigravida, 5.9% had less than 4 and 94.1% had more than 4postinduction Bishop score.
There was no significant difference in Post Induction Bishop distribution with respect to parity.

Table 7: Indication for Induction of labour comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Indication for Induction	Post dated	13	61.9%	20	58.8%	33	60.0%
	Oligohydramnios	5	23.8%	11	32.4%	16	29.1%
	PROM	3	14.3%	3	8.8%	6	10.9%

In primigravida, 61.9% had postdated, 23.8% had oligohydramnios and 14.3% had premature rupture of membranes as indication for induction of labour.
In multigravida, 58.8% had postdated, 32.4% had oligohydramnios and 8.8% had premature rupture of membranes as indication for induction of labour.
There was no significant difference in induction for induction of labour distribution with respect to parity.

Table 8: Number of Dilapan-S Rods induced comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Dilapan-S Rods Number	1	1	4.8%	0	0.0%	1	1.8%
	2	12	57.1%	15	44.1%	27	49.1%
	3	7	33.3%	15	44.1%	22	40.0%
	4	1	4.8%	4	11.8%	5	9.1%

In primigravida, total 1 case(4.8%) required 1 Dilapan-S rod, 12 cases (57.1%) required 2 Dilapan-S rods, 7 cases (33.3%) required 3 Dilapan-S rods, 1 case(4.8%) required 4 Dilapan-S rod.
In multigravida, 15 cases(44.1%) required 2 Dilapan-S rods, 15 cases (44.1%) required 3 Dilapan-S rods, 4 cases (11.8%) required 4 Dilapan-S rods.
There was no significant difference in the number of Dilapan-S rods distribution with respect to parity.

Table 9: Latent Labour Time interval comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Latent Labour Time interval	<12 hours	3	14.3%	6	17.6%	9	16.4%
	>12 hours	18	85.7%	28	82.4%	46	83.6%

85.7% and 82.4% primigravida and multigravida respectively took more than 12 hours' time interval in latent stage of labour.
There was no significant difference in Latent Time distribution with respect to parity.

Table 10: Induction delivery time interval comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Count	%	Count	%	Count	%
Induction delivery time interval	<12 hours	0	0.0%	8	23.5%	8	14.5%
	>12 hours	12	57.1%	14	41.2%	26	47.3%
	24 hrs	9	42.9%	12	35.3%	21	38.2%

57.1% and 41.2% primigravida and multigravida respectively took more than 12 hours induction delivery time interval.
There was no significant difference in induction to delivery time interval distribution with respect to parity.

Table 11: Syntocin Augmentation comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Syntocin Augmentation required	Required	13	61.9%	29	85.3%	42	76.4%
	Not required	8	38.1%	5	14.7%	13	23.6%

Syntocin augmentation was required in 42(72.4%) total, among which 13(61.9%) were primigravida and 29(85%) were multigravida.
There was a significant difference in the requirement of syntocin augmentation distribution with respect to parity.

Table 12: Vaginal delivery and LSCS Syntocin Augmentation required comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Vaginal delivery syntocin augmentation required	Required	8	100.0%	22	88.0%	30	90.9%
	Not equired	0	0.0%	3	12.0%	3	9.1%
LSCS syntocin augmentation required	Required	8	61.5%	6	66.7%	14	63.6%
	Not required	5	38.5%	3	33.3%	8	36.4%

Among primigravida, 8 cases (100%) requiring syntocin agumentation had vaginal delivery and 8 cases (61.5%) underwent lower section cesarean section.

Among multigravida, 22 cases (88%) requiring syntocin augmentation had vaginal delivery and 6 Cases (66.7%) underwent LSCS.

Table 13: Syntocin Augmentation required comparison with respect to modes of delivery

		MOD							
		Vaginal		LSCS		Vacuum		Forceps	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Syntocin Augmentation required	Required	33	100.0%	8	38.1%	1	100.0%	0	0.0%
	Not required	0	0.0%	13	61.9%	0	0.0%	0	0.0%

In almost all vaginal deliveries and vaccum assisted vaginal delivery there was 100% need of Syntocin Augmentation.

There was a significant difference in need of Syntocin Augmentation distribution with respect to Mode of delivery.

Table 14: Mode of delivery comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Mode of delivery	Vaginal	8	38.1%	25	73.5%	33	60.0%
	LSCS	12	57.1%	9	26.5%	21	38.2%
	Vaccum	1	4.8%	0	0.0%	1	1.8%
	Forceps	0	0.0%	0	0.0%	0	0.0%

Out of 55 pregnant women who underwent induction, 60% had vaginal delivery of which 8 were primigravida and 25 were multigravida, 38.2% had LSCS of 12 primigravida and 9 multigravida and 1.8% (one primigravida) had vaccum assisted vaginal delivery?

There was a significant difference in Mode of Delivery distribution with respect to Parity.

Table 15: LSCS indication comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
LSCS Indication	Fetal Distress	11	84.6%	5	62.5%	16	76.2%
	Maternal Desire	1	7.7%	2	25.0%	3	14.3%
	Cephalopelvic disproportion	1	7.7%	1	12.5%	2	9.5%
	Deep transverse arrest	0	0.0%	0	0.0%	0	0.0%

Primigravida and multigravida who underwent LSCS had fetal distress as an indication among 84.6% and 62.5% respectively.

$\chi 2 = 1.477$, df = 2, p = 0.478

There was no significant difference in LSCS indication comparison with respect to Parity.

Table 16: Colour of Liquor comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
Liquor	Clear	16	76.2%	30	88.2%	46	83.6%
	Meconium	5	23.8%	4	11.8%	9	16.4%

Liquor was clear in 76.2% primigravida and 88.2% multigravida.

There was no significant difference in Liquor comparison with respect to Parity

Table 17: Apgar score comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
APGAR AT 1MINUTE	<7	0	0.0%	1	2.9%	1	1.8%
	>7	21	100.0%	33	97.1%	54	98.2%
APGAR AT 5MINUTES	<9	0	0.0%	1	2.9%	1	1.8%
	>9	21	100.0%	33	97.1%	54	98.2%

APGAR score at 1st minute was more than 7 in all the cases of primigravida and 97.1% in multigravida. APGAR score at 5 minutes was more than 9 in all the cases of primigravida and 97.1% in multigravida.

There was no significant difference in Apgar comparison with respect to Parity.

Table 18: Cardio TOCO graphy (CTG) comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
CTG	Reassuring	11	52.4%	27	79.4%	38	69.1%
	Non Reassuring	10	47.6%	7	20.6%	17	30.9%
	Abnormal	0	0.0%	0	0.0%	0	0.0%

Among primigravida, CTG was reassuring in 52.4% and non-reassuring in 47.6% cases. Among multigravida, CTG was reassuring in 79.4% and non-reassuring in 20.6% cases.

There was no significant difference in CTG comparison with respect to Parity

Table 19: NICU admission comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%	Number of cases with Dilapan-S	%
NICU	Admitted	6	28.6%	3	8.8%	9	16.4%
	Not	15	71.4%	31	91.2%	46	83.6%

6 neonates among primigravida and 3 neonates among multigravida mothers needed NICU admission.

There was no significant difference in NICU Admission comparison with respect to Parity.

Table 20: Cause for NICU admission comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Count	%	Count	%	Count	%
Cause of NICU admission	Fetal distress	6	100.0%	2	100.0%	8	100.0%
	Asphyxia	0	0.0%	0	0.0%	0	0.0%

Fetal distress was the cause of NICU admission in all the cases.

Table 21: Maternal complication comparison with respect to Parity

		Parity					
		Primigravida		Multigravida		Total	
		Count	%	Count	%	Count	%
	Fever	0	0.0%	0	0.0%	0	0.0%
	PPH Atonic	0	0.0%	0	0.0%	0	0.0%
	Traumatic PPH	0	0.0%	0	0.0%	0	0.0%
	Hyper stimulation	0	0.0%	0	0.0%	0	0.0%
Maternal complication	Precipitate Labour	0	0.0%	0	0.0%	0	0.0%
	Uterine Rupture	0	0.0%	0	0.0%	0	0.0%
	Cord Prolapse	0	0.0%	0	0.0%	0	0.0%
	No	0	0.0%	0	0.0%	0	0.0%

There were no maternal complications seen.

Discussion

This was a prospective interventional study to determine the safety and efficacy of Dilapan-S for induction of labour and to compare the maternal and perinatal outcome.

In our study, the pre-induction Bishop's Score with less than 4 was seen in 76.2 % primigravida and 73.5% multigravida, with p value of 0.971. Post induction Bishop's score was more than 4 in 85.7% and 94.1%among primigravida and multigravida respectively with p valve of 0.292.

According to the study of Vlk R *et al.*, successful pre induction Bishop Score was achieved in about 86.5% of women. In a study conducted by Oleg R *et al.*, the mean initial BISHOP score was3.6 and in another study conducted by Antonio F *et al.*, the mean initial BISHOP score was 3 seen in 193 patients.

The most common indication for induction of labour was post-dated pregnancy (60%) in our study. Similarly in a study by Oleg. R *et al.* also, the commonest indication of labour was also postdated pregnancy.

Number of dilapan s rods inserted

In the present study, for most of the women (total 49.1%, 57.1%in primigravida and 44.1% in multigravida) average number of Dilapan-S rods needed was 2. Similarly in the study conducted by David. A *et al.* also mean number of dilators used were 2.

Induction delivery time interval

The mean induction to delivery interval time in our study was more than 12 hours but less than 24 hours with significant value of 0.37.

David A *et al.* concluded that the mean induction to delivery interval was more than 24 hours with standard deviation of 14.6 in his study.

Oxytocin augmentation

In the present study, percentage of cases requiring oxytocin augmentation was 76.4% which was statistically significant with a value of 0.047.

	Requirement of syntocin augmentation	P value
Oleg. R *et al.*	11	0.047
David. A *et al.*	17	1

Mode of delivery: In the present study, the rate of achieving vaginal delivery was 60%, LSCS 38.2% and vacuum assisted vaginal delivery 1.8%. The route of delivery was statistically significant with p value of 0.23.

Various studies	Mode of delivery	Percentage
R.Vlk *et al.*	Vaginal delivery caesarean section	71.6%, 28.4%
Oleg R *et al.*	Vaginal delivery caesarean section	60.3%, 39.7%
David A *et al.*	Vaginal delivery caesarean section Instrumental delivery	34.7%, 26.9% 38.4%

The CTG in our present study was statistically significant with p value of 0.035, in which 69.15% showed reassuring type of CTG with no abnormal CTG. According to the studies conducted by Oleg. R *et al.* and Antonio. F, abnormal fetal heart rate patterns were seen in 2 cases with p value of 0.35.and 13 cases with p value of 0.55 respectively.

Conclusion

Dilapan-S was effective method of induction of labour in terms of improving cervical ripening and vaginal delivery rate (60%) and was safe with no uterine hyper stimulation or maternal infections or mortality associated.

There was need of syntocin augmentation for most of the patients (76.4%).

Dilapan S was safe with good fetal outcome, reassuring type of CTG and with reduced need of NICU admission.

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