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Dr. Jayashree V
Associate Professor, Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College, Annamalai University, Chidambaram, Tamil Nadu, India

Dr. Latha K
Professor, Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College, Annamalai University, Chidambaram, Tamil Nadu, India

Dr. Kousalya Devi A
Final Year Post Graduate, Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College, Annamalai University, Chidambaram, Tamil Nadu, India

Correspondence
Dr. Jayashree V
Associate Professor, Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College, Annamalai University, Chidambaram, Tamil Nadu, India

Study of maternal and fetal outcome with usage of transdermal niyroglycerine patch in pre-term labour

Dr. Jayashree V, Dr. Latha K and Dr. Kousalya Devi A

Abstract
Preterm labour is onset of labour with intact membranes after 28 weeks but before 37 weeks of gestation. Majority of preterm labour complication occur before 33 weeks. Aim of study is to find out the effect of transdermal nitroglycerine patch on maternal and fetal outcome.
Method: The study was done in department of obstetetrics and gynaecology, in Rajah muthiah medical college and hospital, Chidambaram from November 2016 to October 2018. A prospective randomized study of 80 women of preterm labour was selected after getting consent.
Results: Results of our study with transdermal nitroglycerine patch are equally good with other tocolytic drugs. Maternal and fetal outcome is favourable in patients of preterm labour. Side effect profile was less with transdermal nitroglycerine patch.

Keywords: Transdermal nitroglycerine (NTG patch)

Introduction
Preterm labour is defined as onset of labour prior to completion of 37 weeks of gestation, very extreme preterm birth is <28 weeks of gestation, extreme preterm birth (28-31weeks), moderate/ late preterm (32-37 weeks). Resuscitation of extremely preterm infants may present an ethical, moral and financial dilemma [1]. The mortality rates among these infants are high and surviving infants may have a high rate of complications such as bronchopulmonary dysplasia, necrotizing enterocolitis, intraventricular haemorrhage and sepsis. Neonatologist attempt resuscitation of infants born at less than 24 weeks of gestation only in few countries worldwide due to reduced chances of survival below this age [5].
Preterm labour is defined by the presence of uterine contractions of atleast 4 in 20 minutes or 8 in 60 minutes with cervical changes having effacement of 80% or more and cervical dilatation of more than one cm [4]. Risk factors for preterm labour includes multiple births [3], age <18 years and >35 years, bacterial vaginosis, trichomonas vaginalis, infection by Chlamydia trachomatic etc. Conditions such as asymptomatic bacteriuria [12], pyelonephritis, pneumaturia, acute appendicitis etc. may also be responsible for intra amniotic inflammatory response [6].
Nitroglycerine a nitric oxide donor is effective as a tocolytic agent due to its high efficacy, lesser side effects and better patient compliance. It is a vasodilator, this is essential for maintanence of normal smooth muscle tone of uterus [15]. The pharmacological action of nitroglycerine is relaxation of vascular smooth muscle and dilatation of peripheral arteries and veins. Pregnancy is prolonged by its direct effect on uterine blood flow [2].

Materials and method
Our study was conducted in labour ward of Rajah Muthiah Medical College and Hospital, Chidambaram. From November 2016 to October 2018. A total of 80 pregnant women with preterm labour were selected randomly after explaining the procedure and getting consent.

Inclusion Criteria
1) Patient having preterm labour age 18 and above giving valid consent.
2) Gestational age between 28 to 34 weeks as determined by menstrual age, clinical examination and ultrasound scan.
3) 2 uterine contractions in 10 minute period each lasting 20 seconds
4) Progressive cervical effacement upto 75%
5) Cervix dilatation upto 3cm.
6) Patient with intact membranes.

Exclusion Criteria

1. High risk pregnancy including multiple gestation, cardiac disease, PIH, previous caeserian section, renal disease and pulmonary disease.
2. Foetus with fetal distress, IUGR, congenital anomalies.
3. Oligohydramnios and polyhydramnios.
4. Age < 18 years.

Successful tocolysis was described as continuation of pregnancy for atleast 48 hours after tocolysis therapy and allowing time for steroid administration to accelerate fetal lung maturity. Whereas failed tocolysis was described as delivery occurring within 48 hours or discontinuation of therapy due to development of side effects.

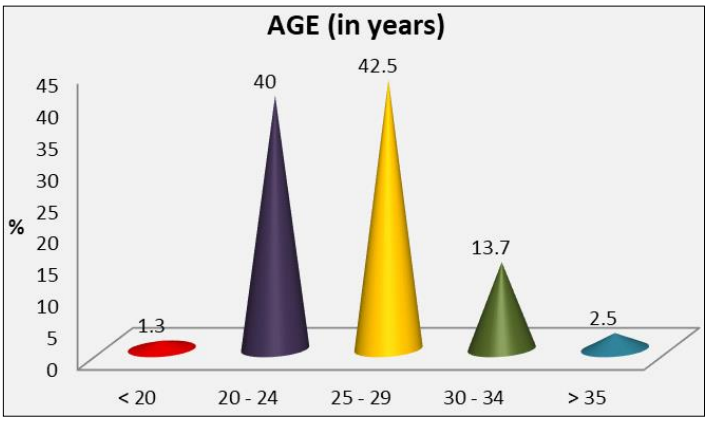
Patients with preterm labor was admitted in labor ward and monitored for every 15 minutes during first two hours followed by hourly monitoring. After per vaginal examination patient was placed in lateral recumbent position and monitored for contraction and fetal heart rate. Intra venous bolus of 500ml of normal saline was infused as a protective measure of hypotensive effect of nitroglycerine. Diminishing contraction of an irritable uterus helps to differentiate from preterm labor. Once the diagnosis was confirmed tocolytic therapy was initiated with the application of 10mg of NTG patch over patient's abdomen. If after one hour no reduction in contraction, an additional 10mg NTG patch was applied and the same number of patches replaced after 24 hours. The primary aim was to delay the delivery for atleast 48 hours till the time of steroid action.

Observation

Our study included 80 women with preterm labor out of which the gestational age at presentation from 30 to 34 weeks was 65% and gestational age at presentation from 30 to 32 weeks was 26.2% and only 8.8% belongs to gestational age was 28 to 30 weeks.

Table 1: Age Distribution

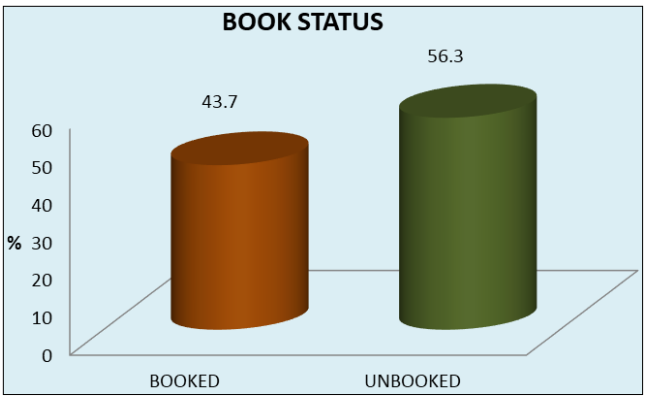
Age (in years)	Number	Percentage	Mean	S.D
< 20	1	1.3	25.8	3.8
20-24	32	40.0		
25-29	34	42.5		
30-34	11	13.7		
>35	2	2.5		
Total	80	100		



Age distribution shows that the common age was 25-29 years in which 42.5% was observed. The next common age was 20 to 24 years in which 40% was observed. The Mean age was 25.8±3.8 years.

Table 2: Booked Status

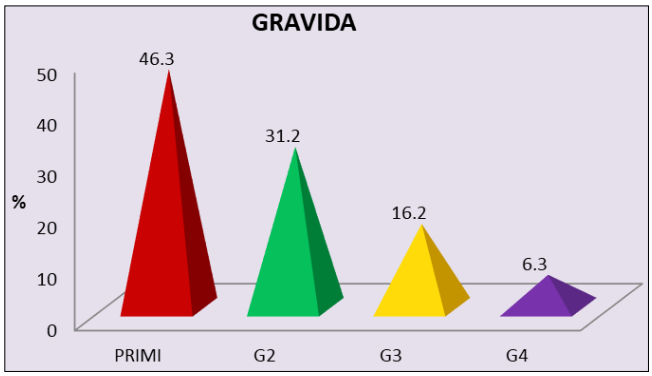
Book Status	Number	Percentage
Booked	35	43.7
Un Booked	45	56.3
Total	80	100



The majority of the study women were unbooked (56.3%). Therefore, preterm labour was more common for them Amoung bound women, the preterm labour was 43.7%.

Table 3: Gravida

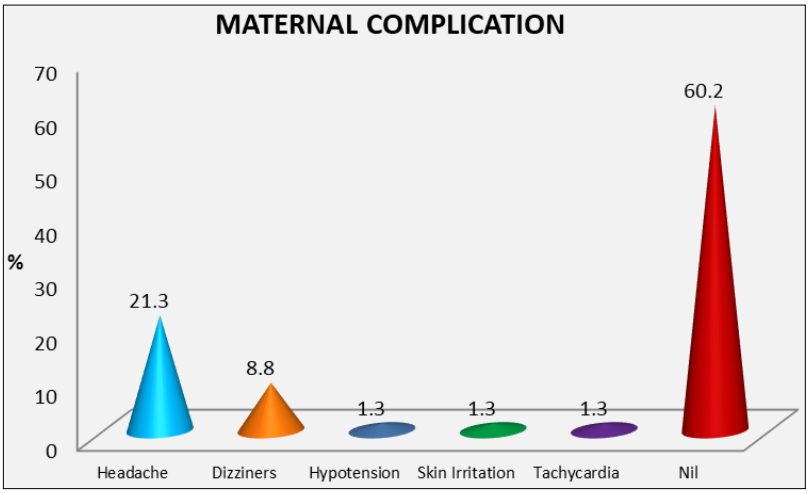
Gravida	Number	Percentage
Primi	37	46.3
G2	25	31.2
G3	13	16.2
G4	5	6.3
Total	80	100



Prime gravida was common (46.3%) followed by gravida status of 2 (31.2%). 16.2% of the women had gravida 3 and 6.3% had gravida 4.

Table 4: Maternal Complication

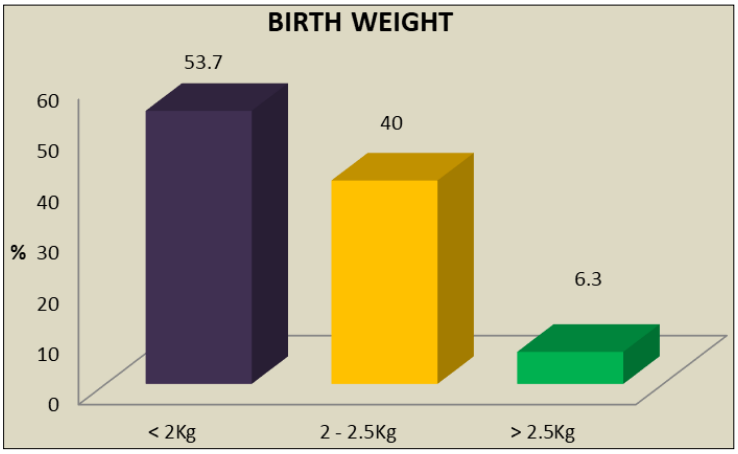
Maternal Complication	Number	Percentage
Headache	17	21.3
Dizziness	7	8.8
Hypotension	1	1.3
Skin Irritation	1	1.3
Tachycardia	1	1.3
Nil	53	60.2
Total	80	100



Headache was the common maternal complication (N = 17, 21.3) followed by dizziness (N = 7, 8.8%) Majority of the study women had no maternal complications (N = 53, 60.2%).

Table 5: Birth weight of baby

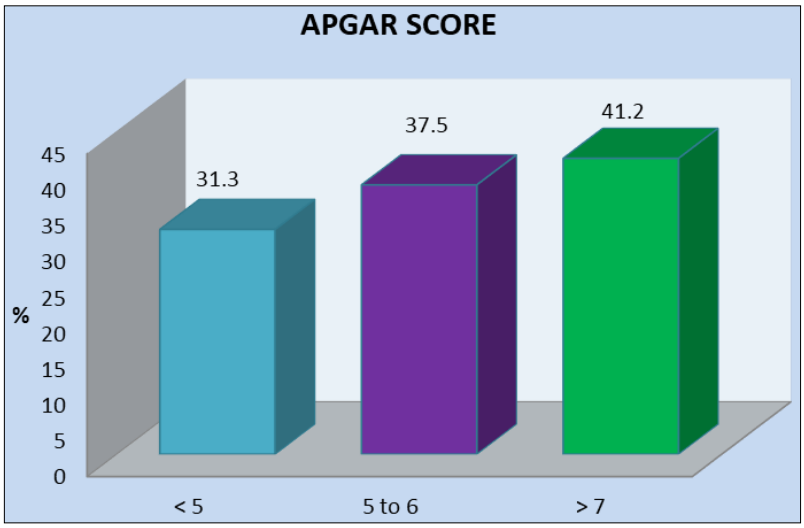
Birth Weight (kg)	Number	Percentage	Mean	S.D
<2	43	53.7	1.8	.38
2 – 2.5	32	40.0		
>2.5	5	6.3		
Total	80	100		



Birth weight of less than 2 was observed in 53.7% (N = 43) and between 2 to 2.5 was observed in 40% (N = 32) Normal birth weight was reported for only 6.3% (N = 5)

Table 6: Apgar score

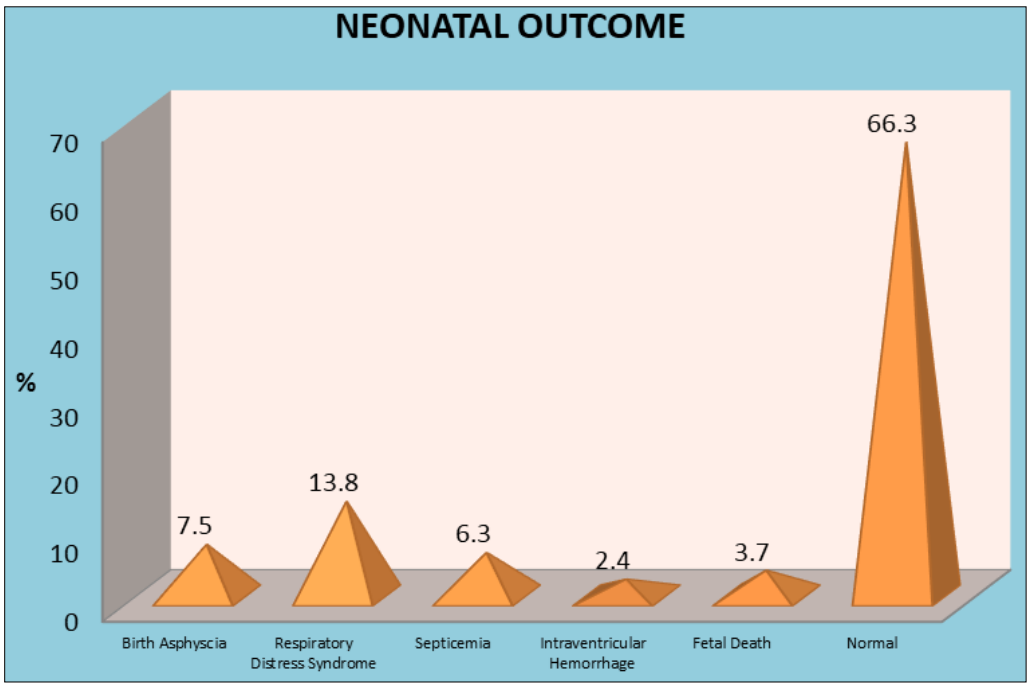
Apgar Score	Number	Percentage
<5	25	31.3
5 – 6	22	27.5
>7	33	41.2
Total	80	100



Apgar score of less than 5 was reported in 31.3% (N = 25). The score of 5 – 6 was reported in 27.5% (N = 22). The score of 7 or more was observed in 41.2% (N = 33).

Table 7: Out Come

Neonatal Outcome	Number	Percentage
Birth Asphyxia	6	7.5
Respiratory Distress syndrome	11	13.8
Septicemia	5	6.3
Intraventricular Hemorrhage	2	2.4
Fetal Death	3	3.7
Normal	53	66.3
Total	80	100



Neonatal outcome was good in 66.3% (N = 53). Among poor outcome, respiratory distress syndrome was common (N = 11, 13.8) followed by birth asphyxia (N = 6, 7.5%) and seplicemia (N = 5, 6.3%). Fetal mortality was 3.7% (N = 3).

Table 8: Comparison of gestational age at presentation vs tocolysis

GA	Tocolysis		Success		Total	Chi-square	Test
	N	%	N	%		Value	'P'
28 – 30	5	71.4	2	28.6	7	6.49	.03
30 – 32	4	19.0	17	81.0	21		
32 – 34	18	34.6	34	65.4	52		
Total	27	33.7	53	66.3	80		

Success rate was very low at the GA of 28 – 30 weeks (28.6%) success rate was 81% at 30 to 32 weeks and 65.4% at 32 to 34 weeks. The chi-square test of association is statistically significant (X^2 = 6.49, P = 0.03). Hence, the success rate is significantly influenced by the GA at presentation that is the success rate is more for higher gestational age.

Table 9: Neonatal Outcome Vs Tocolysis

Neonatal Outcome	Tocolysis		Success		Total
	N	%	N	%	
Birth Asphyxia	3	50	3	50	6
Respiratory Distress syndrome	4	36.4	7	63.6	11
Septicemia	3	60	2	40	5
Intraventricular Hemorrhage	2	100	-	-	2
Fetal Death	3	100	-	-	3
Nil	12	22.6	41	77.4	53
Total	27	33.7	53	66.3	80
Chi-Square Test	Value		'P'		
	15.02		0.010		

All intraventricular hemorrhage outcome (N = 2, 100%) has failed tocolysis. The majority of the septicemia outcome (N = 3, 60%) was found in failed tocolysis. Fetal mortality was 100% (N = 3) for failed tocolysis. The most of the normal outcome (N = 41, 77.4%) was achiued in success tocolysis. The chi-square test of association is statistically significant (X^2 = 15.02, P = .010). Hence, the neonatal outcomes are significantly better.

Table 10: Associations of Tocolysis with Apgar score

Apgar score	Tocolysis		Success		Test	Chi-square	Test
	N	%	N	%		Value	'P'
<5	17	68	8	32	25	24.49	.001
5 – 6	8	36.4	14	63.6	22		
≥7	2	6.1	31	93.9	33		
Total	27	33.7	53	66.3	80		

In Apgar score of ≥7, the success tocolysis was 93.9% (N = 31). In Apgar of 5 – 6, the success tocolysis was 63.6% (N = 14) and in Apgar of <5, the success rate was only 32% (N = 8). The chi-square test of association is statistically significant (X^2 = 24.49, P = .001). Therefore, apgar score is significantly higher for success tocolysis.

Conclusion

Obstetricians are facing difficulty in every day practice in managing preterm labour with fewer drugs with proven or equivocal efficacy which differ in uterine specificity, maternal and fetal side effects [11]. Usage of tocolytis has two benefits: prolonging the pregnancy for atleast 48 hours and reducing the perinatal mortality and morbidity associated with premature babies [7].

Majority of women in our study belons to 25 to 29 years of age.

The majority of women in our study with preterm labor was unbooked (56.3%) [9].

In our study women with preterm labor, 46.3% was primigravida, 31.2% was second gravida.

Majority of women have no side effects. 21.3% suffered from mild headache and 8.8% had dizziness [12].

Among the babies born 53.7% belongs to birth weight less than 2kg, 40% belong to birth weight 2 to 2.5kg and 6.3% belongs to birth weight above 2.5kg.

APGAR score [14] of less than 5 was reported in 31.3% (N=25), the score of 5 to 6 reported in 27.5% (N=22), The score of 7 and more was observed in 41.2% (N=33).

Success rate was very low with gestational age 28 to 30 weeks (28.6%), 81% at 30 to 32 weeks and 65% at 32 to 34 weeks.

The majority of adverse outcome[8] like Intraventricular haemorrhage and septicaemia was ound in failed tocolysis, favourable outcome was observed in successful tocolysis (77.4%, N=41).

Thus Nitroglycerine patch appear to be safe in stopping the progress of uterine contractions in preterm labor, especially in developing countries where advanced facilities are not available [10].

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