



EFFECTIVENESS OF TOCOLYTICS IN PRETERM LABOUR: A CLINICAL ANALYSIS OF CONTRIBUTING FACTORS

V SIREESHA^{*1}, N. CHAITANYA², MEGHANA. CH², K. MEGANA², C. VANI³ AND T.
RAMARAO⁴

1: Pharm D Department, CMR College of Pharmacy, Hyderabad, Telangana, India

2: Pharm D Department, CMR College of Pharmacy, Hyderabad, Telangana, India

3: Department of Pharmacy Practice, Pulla Reddy Institute Sciences, Annaram, Hyderabad
Telangana, India

4: Department of Pharmaceutical sciences, CMR College of Pharmacy, Hyderabad, Telangana, India

***Corresponding Author: Dr. V. Sireesha: E Mail: Sireeshaganesh59@gmail.com**

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ABSTRACT

Background: Preterm labor is one of the leading causes of perinatal morbidity and mortality. The aim of the study is to identify the associated risk factors, to evaluate the efficacy of tocolytics in preterm labor and also to assess the neonatal mortality and morbidity in preterm labor.

Methodology: A prospective observational study was conducted in the in-patient department of Gynaecology and obstetrics at Gandhi Hospital over a 6 months of study period i.e., July 2023 to December 2023 and as per the inclusion criteria 104 Preterm cases were enrolled in the study and analyzed.

Results and discussion: The Chi-Square test is a statistical procedure for determining the difference between observed and expected data. This test is used in our studies to correlate with our data. Chi-square analysis is done between tocolytics and APGAR score at 1min and 5min; steroids and APGAR score at 1min and 5min. The obtained p-value is <.001 with fisher exact test value of 47.467. It indicates that there is statistically significant association between use of tocolytics and APGAR Score at 1 min, suggesting that the administration of tocolytics might impact the Apgar scores of newborns taken at 1 min and 5min.

Conclusion:

This study suggests that Preterm births cannot be prevented completely but their incidence can be minimised by using tocolytics. Co-administration of Tocolytics and Corticosteroids will promote the fetal outcomes and decreases the neonatal morbidity and mortality. Prediction and prevention of Preterm labour is not possible despite of extensive research done on the subject.

Keywords: APGAR score, Cervical cerclage, Preterm labor, steroids, Tocolytics

INTRODUCTION

Preterm labor (PTL) is a leading cause of neonatal morbidity and mortality and poses significant challenges to both medical outcomes and healthcare systems [1]. It is defined as childbirth occurring between 22 and 37 weeks of gestation, with gestational age typically determined by the first day of the last menstrual cycle and early fetal ultrasound scans [2]. PTL is a critical contributor to infant survival rates and quality of life, with premature birth often leading to severe complications such as respiratory difficulties, cerebral palsy, and hearing impairments [9] [10]. The global prevalence of PTL is concerning, with an estimated 20 million premature births annually, and rates being higher in developing countries compared to developed nations [5]. The precise causes of PTL remain unclear, with 45–60% of preterm births being of unknown origin [4]. Other factors contributing to PTL include preterm premature rupture of membranes (PPROM) (20%), and medically necessary preterm deliveries (15–20%) [6]. Women who have previously experienced a preterm birth are at higher risk of recurrent preterm labor [3]. Various medical conditions

increase the likelihood of PTL, such as urinary tract infections (UTIs), sexually transmitted diseases (STDs), high blood pressure, gestational diabetes, multiple pregnancies, placental issues, and cervical abnormalities [7]. However, the predictive value and sensitivity of these risk factors vary widely [8]. In terms of diagnosis, PTL is often identified through symptoms such as irregular lower abdominal pain, lumbar discomfort, cervical dilation, uterine contractions, and premature amniotic fluid leakage [12]. Sonography is frequently used to detect asymptomatic cervical changes, and fetal fibronectin, a protein found in cervicovaginal secretions, may serve as a potential biomarker to predict preterm labor before membrane rupture [13].

Importance of Arresting Preterm Labor:

Preterm birth remains the serious problems in perinatal medicine and is related with a high threat of neonatal complications and long-term morbidity [14]. Preterm labor below thirty-four weeks needs to be arrested for at least forty eight hours with drugs such as Atosiban, Magnesium sulphate, Dipin tocolysis since it offers clear advantages for the fetus to achieve fetal

pulmonary maturity [15]. Prevention and treatment of preterm birth aim is to improve outcomes for the child and also to reduce illness and fatal rate.

1. Strategies for Prevention of Preterm Birth:

Cervical cerclage is one strategy used for prevention. [16]

2. Agents Suppressing Uterine Contractions:

Progestin compounds, Steroids, Antimicrobial therapy.

3. Tocolytics for Inhibiting Uterine Contraction [17]

Beta adrenergic agents.

Calcium channel blockers [18].

Oxytocin receptor antagonist [19]

Prostaglandin synthetases inhibitors

Magnesium sulfate [20].

Nitric oxide donors [21].

APGAR score:

APGAR is a quick test performed on a baby at one and five minutes after birth. The 5 signs of the APGAR score are HR, respiratory rate, reflex irritability, muscle tone and colour. Apgar score is categorized as low (0–3), intermediate (4–6), and normal (7– 10) [22]. Risk factors for low APGAR scores include abnormalities of gestational length and prenatal growth, congenital malformation. APGAR test is done by a health care provider. Each category is scored with 0,1 or 2 depending on the observed condition [22].

Apgar Scoring System				
Indicator		0 Points	1 Point	2 Points
A	Activity (muscle tone)	Absent	Flexed limbs	Active
P	Pulse	Absent	< 100 BPM	> 100 BPM
G	Grimace (reflex irritability)	Floppy	Minimal response to stimulation	Prompt response to stimulation
A	Appearance (skin color)	Blue Pale	Pink body Blue extremities	Pink
R	Respiration	Absent	Slow and irregular	Vigorous cry

Figure 1: APGAR Scoring

MATERIALS AND METHODS: It is a prospective study conducted in the inpatient department of Gynaecology and obstetrics of Gandhi Hospital over 6 months i.e., July 2023 to December 2023 104 Preterm cases were enrolled in the study, pregnant women

admitted with preterm labour pains excluding women with gestational age 37 weeks and above, women having no early ultrasound evidence or Whose LNMP was unclear and Pregnant females with chronic

medical ailments and the following results were obtained.

STATISTICAL ANALYSIS: The p-value is $<.001$. it indicates that there is statistically significant association between use of tocolytics and APGAR Score at 1 minute and 5 minutes. Suggesting that the administration of tocolytics might impact the Apgar scores of newborns at 1 minute and 5 minutes. SPSS software was used to perform all statistical analyses.

ETHICAL APPROVAL: The study was approved by the institutional ethics committee.

RESULTS:

104 preterm cases were observed during a study period of 180 days, no patient has left or absconded during the wards and they were identified, included and analysed for the final outcome of the study.

Following data was examined for the collected cases.

Table 1 indicates that out of 104 pregnant females, 80 (76.92%) patients are between 20-30 years of age, 22 (21.2%) patients are having age above 30 years and only two patients (1.92%) below 20 years.

Figure 2 shows that out of 104 patients 71 patients (68%) are having gestational age between 30-35weeks, 26 patients (25%) are above 35 weeks and 7 patients (7%) are of less than 30 weeks.

Table 2 indicates the multifactorial etiology associated with preterm labor, after

investigation of 104 cases, 21 patients were having anemia + oligohydromnios then followed by 18 patients are having PIH + Oligohydromnios, 12 patients are having anemia + PIH+ Oligohydromnios, 12 patients are having anemia + preeclampsia, 11 patients are having bleeding P/V+ preeclampsia.

As shown in the **Table 3**, after giving Tocolytics to 60 patients among them 38 patients received Dipin tocolysis (63.33%) and 22 patients received MgSo4 (36.7%) and neonatal morbidity was seen in 57 patients (95%) and mortality was seen in 3 patients (5%). while out of 44 patients who have not administered any Tocolytics 40 patients (90.9%) showed neonatal morbidity and 4 patients (9.1%) showed neonatal mortality.

As depicted in the **Table 4**, giving steroids to 95 patients a 94 patients (98.94%) showed neonatal morbidity and one patients (1.06%) showed neonatal mortality while out of 9 patients without any steroids 3 patients (33.33%) showed neonatal morbidity and 6 patients (66.66%) showed neonatal mortality.

As shown in the **Table 5**, out of 60 patients who received tocolytics 26 (43.3%) patients showed maximum delay in delivery i.e 1 day followed by more than 1 day in 19 patients (31.7%), then followed by 15 patients (25%) who showed delay for less than 1 day.

Table 6 describe the overall distribution of cases who had received Tocolytics and Steroids with APGAR Score to know the effectiveness of Tocolytics and Neonatal outcomes. Out of 104 Preterm labour cases 60 Pregnant women's were given tocolytics among them neonatal mortality is seen in 3 and the APGAR Score of 5-8 at 1 minute and 5 minutes was maximum in Newborns, minimum newborns showed APGAR Score of >8 at 1 minute and <5 at 5 minutes. Whereas 44 patients were not given with Tocolytics among them the neonatal mortality is seen in 4, Maximum newborns showed APGAR Score of <5 at 1 minute and 5 minutes and minimum newborns showed APGAR Score of >8 at 1 minute and 5 minutes.

Out of 104 Preterm cases 95 Pregnant women received Steroids among them

neonatal mortality is seen in 1 and maximum newborns showed APGAR Score of 5-8 at 1 minute and 5 minutes and minimum newborns showed APGAR Score of >8 at 1 minute, <5 at 5 minutes. Whereas 9 Pregnant women were not received any steroids among them the neonatal mortality is seen in 6.

The above **Table 7** shows the birth weight of babies, out of 83 cases maximum babies (72.295%) are having birth weight of 1.5-2.5kgs, followed by 14 babies (16.87%) weighing >2.5kgs then 9 babies (10.84%) are having birthweight <1.5kgs.

Due to the presence of cells with expected counts less than 5 in our contingency table, we employed Fisher's exact test

Table 1: Patient age wise distribution (n=104)

S. No.	Age of the patient [years]	Total number of cases [n=104]	Percentage [%]
1.	<20 Years	2	1.92%
2.	20 -30 Years	80	76.92%
3.	>30 Years	22	21.2%
	Total	104	100%

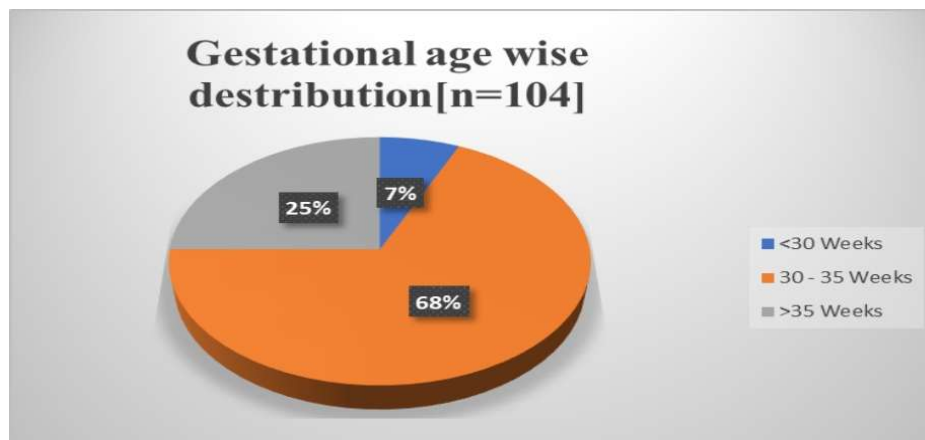


Figure 2: Gestational age wise distribution in collected cases

Table 2: Multifactorial Etiology

S. No.	Factors	Number of cases
1.	Anaemia + PIH + Oligohydromnios	12
2.	Oligohydromnios + Anaemia	21
3.	Pre-eclampsia + Anaemia	12
4.	PIH + Oligohydromnios	18
5.	Pre-eclampsia + Bleeding p/v	11

Table 3: Neonatal Mortality and Morbidity in patients who received Tocolytics and patients who did not received Tocolytics

S. No.	Category		Neonatal Morbidity [n=97]	Neonatal Mortality [n=7]
1.	Tocolytics covered group [n=60]	Dipin tocolysis	38 (63.33%)	57 (95%)
		MgSo ₄	22 (36.7%)	
2.	Tocolytics uncovered group [n=44]		40 (90.9%)	4 (9.1%)

Table 4: Neonatal Morbidity and Mortality in patients administered with steroids and patients without steroids

S. No.	Category	Neonatal Morbidity [n=97]	Neonatal Mortality [n=7]
1.	Steroids covered groups [n=95]	94(98.94%)	1(1.06%)
2.	Steroids uncovered groups [n=9]	3(33.33%)	6 (66.66%)

Table 5: No. of day's pregnancy prolonged after giving Tocolytics

S. No.	No. of days pregnancy prolonged	Total no.of cases (60)	Percentage (%)
1.	<1 day	15	25%
2.	1 day	26	43.3%
3.	>1 day	19	31.7%

Table 6: Distribution of cases according to the patients covered with Tocolytics, steroids & APGAR Score

	Tocolytics			Steroids		
	YES (60)	NO (44)	P value	YES (95)	NO (9)	P value
APGAR Score at 1 min :			<.001			<.001
<5	5	29		9	2	
5 -8	50	11		82	1	
>8	2	0		2	0	
APGAR Score at 5 min :			<.001			<.001
<5	1	27		1	2	
5 - 8	35	13		51	1	
>8	21	0		41	0	
	3 dead	4 dead		1 dead	6 dead	

Table 7: Birth weight of babies

S. No.	Birth weight	Total number of cases [n=97]	Percentage [%]
1.	<1.5 kgs	9	9.3%
2.	1.5 - 2.5 kgs	72	74.2%
3.	>2.5 kgs	16	16.5%

Effectiveness of Tocolytics with APGAR Score at 1 Min

	Value	df	Asymptomatic significance (2 sided)	Exact significance (2 sided)	Exact significance (1 sided)	Point probability
Pearsons Chi-Square	45.504 ^a	3	<.001	<.001		
Likelihood Ratio	49.802	3	<.001	<.001		
Fisher-freeman-Halton exact test	47.467			<.001		
Linear by Linear association	15.621 ^b	1	<.001	<.001	<.001	.000
N of valid cases	104					

Fisher's exact Chi-square (χ^2) test was performed for categorical variables such as use of tocolytics and APGAR Score at 1 min to test its association at 5% level of significance. The p-value is <.001 with fisher exact test value of 47.467. It indicates

that there is statistically significant association between use of tocolytics and APGAR Score at 1 min, suggesting that the administration of tocolytics might impact the Apgar scores of newborns taken at 1 min

Effectiveness of Tocolytics with APGAR Score at 1 Min

	Value	df	Asymptomatic significance (2 sided)	Exact significance (2 sided)	Exact significance (1 sided)	Point probability
Pearsons Chi-Square	58.141 ^a	3	<.001	<.001		
Likelihood Ratio	76.070	3	<.001	<.001		
Fisher-freeman-Halton exact test	68.702			<.001		
Linear by Linear association	.816 ^b	1	.366	.378	.215	.059
N of valid cases	104					

Fisher's exact Chi-square (χ^2) test was performed for categorical variables such as use of tocolytics and APGAR Score at 5 min to test its association at 5% level of significance. The p-value is <.001 with fisher exact test value of 68.702. It indicates that there is statistically significant association between use of tocolytics and APGAR Score at 5 min, suggesting that the administration of tocolytics might impact the Apgar scores of newborns taken at 5 min.

DISCUSSION

A prospective observational study was conducted to assess the effectiveness of tocolytics and risk factors associated with preterm labor. The ultimate aim of the study was to show that it can be beneficial to society by improving the morbidity and mortality of preterm babies.

A total of 104 preterm cases were identified, included and analyzed for the study from In-patients units of Department of obstetrics and gynecology as per the inclusion criteria, Gandhi Hospital, Secunderabad.

In our study the maximum cases of preterm labor were in an age group of 20-30 years (76.92%) was found to be more which is similar to the study reported by **Shannon F. Fernandes (2015) [23]**.

In our study the maximum preterm births are observed in the gestational age group of 30-35 weeks, which is contrary to the study reported by **Ahanthem SS (2015) [24]**.

In our analysis the Preterm births were higher among the mothers having oligohydramnios as risk factor (40.4%), followed by anemia (34.61%), preeclampsia (33.65%), bleeding p/v (24.03%), PIH (22.11%), PPROM (6.73%), polyhydromnios

(7.7%), IUGR (5.8%), Placenta previa (4.8%) which is contrary to the study conducted by **Dagnew Getnet Adugna (2022) [25]**.

In our study 41 patients were presented with primigravidas (39.42) while the 63 patients were multigravidas accounting for (60.58). The results were similar to the study conducted by the **Mohammed Atiya [26]**.

In our study among the multigravidas presenting in preterm labor, 39 patients (61.9%) were pregnant for second time, 18 patients (28.58%) were pregnant for third time, 4 patients (6.34%) were pregnant for fourth time and 2 patients (3.2%) were pregnant for fifth time. This is similar to the study conducted by **Samim S et al (2021) [27]**.

Our study shows that after giving steroids to 95 patients, 94 patients (98.94%) showed neonatal morbidity and 1 patient (1.06%) showed neonatal mortality while out of 7 patients who has not received any steroids 3 patients (33.33%) showed neonatal morbidity and 6 patients (66.66%) showed neonatal mortality.

Our study describes the overall distribution of cases who had received Tocolytics and Steroids with APGAR Score to know the effectiveness of Tocolytics and Neonatal outcomes. Out of 104 Preterm labour cases 60 Pregnant women were given with tocolytics among that 60 neonatal mortality is 3 and the APGAR Score of 5-8 at 1 minute

and 5 minutes was found to be maximum in Newborns, minimum newborns were showing APGAR Score of >8 at 1 minute and <5 at 5 minutes. Whereas 44 patients were not given with Tocolytics among them the neonatal mortality is 4. Maximum newborns are showing APGAR Score of <5 at 1 minute and 5 minutes and minimum newborns are showing APGAR Score of >8 at 1 minute and 5 minutes. Out of 104 Preterm cases 95 Pregnant women were received Steroids among 95 the neonatal mortality is 1 and among 95 patients, maximum newborns were showing APGAR Score of 5-8 at 1 minute and 5 minutes. Minimum newborns are showing APGAR Score of >8 at 1 minute, <5 at 5 minutes. Whereas 9 Pregnant women were not received any steroids among them the neonatal mortality is 6. The chi-square analysis was done between the Tocolytics and APGAR score and the P value was found to be <.001 which implies the strong statistical significant relationship. This statement is supported by the study performed by **J Williams (2022) [28]**. Thus, it reflects that Patients given with Tocolytics showed less neonatal mortality and average APGAR scoring when compared with the patients who didn't receive tocolytics.

In our study the maximum babies (74.2%) are having birth weight of 1.5-2.5kgs, followed by 16 babies (16.5%) weighing >2.5kgs, then 9 babies (9.3%) are having

birthweight <1.5kgs similar to the study conducted by **Bhanu pratap SG (2015) [29]**.

CONCLUSION

Preterm birth, one of the leading causes for neonatal death and illness. In order to limit the Preterm births, tocolytic are usually prescribed to prolong the pregnancy. Tocolytics are the class of drugs which delay the contractions and during that delay period corticosteroids can be administered to the patient to prevent the complications in preterm babies. The commonly used tocolytics are nifedipine and magnesium sulphate as they show less side-effects. Preterm births cannot be prevented completely but their incidence can be minimized by giving tocolytics.

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