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ORIGINAL ARTICLE

IMPORTANT ROLE OF 17α HYDROXY PROGESTERONE CAPROATE (17OHPC) FOR THE PREVENTION OF PRETERM LABOUR

Manisha M. Laddad[1], N. S. Khirsagar[2], Sanjaykumar Patil[3], Rajashree Bhosale[4], Digvijay Kadam[5]

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ABSTRACT: OBJECTIVE: This is a prospective randomized case control study to evaluate the role of 17 α hydroxyprogesterone caproate (17OHPC) in the prevention of preterm labor in high risk asymptomatic patients with a history of preterm delivery. **METHODS**: The study included 100 patients with a singleton pregnancy and having a prior preterm birth. They were divided in 2 groups, group I (treatment group) included 50 asymptomatic patients who were given 17OHPC injections starting from 18-24 weeks till 36 weeks and group II (control group) included 50 patients who did not receive any treatment. **RESULTS:** The incidence of preterm delivery was found to be 6.6%. The median gestational age at delivery was 36 weeks in group I and 34W5D in controls. 50% cases in group I and 80% of controls delivered prematurely in the group with a prior preterm birth between 20-28 weeks. Conclusion In patients who had a prior history of a preterm delivery the recurrence of a preterm birth was less in the treated group as compared to controls. The median gestational age at delivery was significantly higher in 17OHPC treated patients with history of earliest prior preterm delivery at 20-28 weeks.

KEYWORDS: 17 α hydroxyprogesterone caproate, Preterm labor.

INTRODUCTION: Preterm birth is spontaneous onset of labor and delivery after 28wk and before 37wks.It is very essential to Reduce incidence of preterm birth, a major cause of morbidity and mortality, by timely intervention. Which can reduce the emotional trauma to the mother and the financial burden on the cost of health care services. The WHO (1969) recommended that preterm infants are those delivered at a gestational age <37 completed weeks, irrespective of birth weight. The incidence of preterm birth remains high i.e. 5-10%. [1, 2]

Although many risk scoring systems have been devised, predicting a preterm birth is difficult. Prior preterm birth is a strong predictor of preterm delivery. [2] Although the pathogenesis of preterm labor is not well understood, progesterone withdrawal is theorized to play a part. [3]

A multicentric randomized control trial conducted by the National institute of child health, Maternal fetal medicine units network demonstrated a significant (31%) reduction in preterm birth with weekly injections of 17OHPC among women with a history of prior spontaneous preterm birth. Responding to the above findings, ACOG issued a committee opinion in Nov. 2003[3, 4] on the use of progesterone to reduce preterm birth in support of the use 17OHPC among women with a history of prior spontaneous preterm birth. The present study evaluates the role of 17OHPC in the prevention of preterm labor in high-risk patients.

METHODS: This is a prospective case control study carried out on 100patients from Aug 2012 to Dec 2013 in K.I.M.S.D.U., Karad in obstetrics and gynae department.

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GA (weeks)	Indicated	Spontaneous	PPROM
32-36	113	167	50
27-31	84	36	25
20-26	20	7	14
Total 516	216 (41%)	210 (40%)	90 (19%)

Table 1: Incidence of PPROM, indicated, and spontaneous births

GA (weeks)	Cases (N = 50)		Control (N = 50)	
	N	%	N	%
20-28	16	33.7	10	20
28-35	26	52.1	33	66
35-37	8	14.04	7	14
Mean ± SD	29.6± 4.4		30.5 ± 3.8	

Table 2: Gestational age in prior preterm delivery

GA at earliest prior delivery (weeks)	Group	N	GA at delivery in current pregnancy	P value
20-28	Case	16	36 weeks 3 days	<0.05 Significant
	Control	10	33 weeks 1 days	
28-34	Case	26	33 weeks	>0.05 NS
	Control	33	35 weeks	
34-37	Case	8	37 weeks 5 days	>0.05 NS
	Control	7	35 weeks 5 days	

Table 3: Median gestational age at delivery in the current pregnancy

After approval from the ethical committee. The eligibility criteria included women with a singleton pregnancy between 16 and 24 weeks of gestational age and having a history of previous spontaneous preterm birth. Exclusion criteria were patients with fetal or uterine anomalies, twins, and patients with complications like PIH, APH, diabetics, PROM, etc. The patients were divided into two groups.

The treatment group (cases) included 50 asymptomatic patients with a prior preterm birth. They were given weekly IM injections of 17OHPC (250 mg) starting from 18 to 24 week of pregnancy till 36 weeks. The control group included 50 high-risk patients with a prior preterm birth who had not received any medication. These patients were those who presented with preterm labor or came in late gestational age. All patients had advised strict bed rest in head low position. The outcome of pregnancy and the neonatal outcomes were studied.

RESULTS: The incidence of preterm deliveries in our institution was found to be 8.8 % with 516 patients out of 5, 850 patients.

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GA at earliest prior delivery (weeks)	Group	N	% of PTD	P value
20-28	Case	16	50(8)	NS(r= 1.1)
	Control	10	80 (8)	
28-34	Case	26	35.3 (8)	NS (t= 1.1)
	Control	33	51(8)	
34-37	Case	8	36.3 (2)	NS (t = 0.85)
	Control	7	68.6 (4)	

Table 4: Relationship of gestational age in previous preterm birth and risk of preterm birth in current pregnancy

Delivering preterm. Table 1 shows that among all preterm births, 41% were indicated preterm births, 40% were spontaneous preterm births, and 19% were due to PPROM. Table 2 compares the gestational age in prior preterm delivery in the treatment and control groups. It shows that the mean gestational age of prior preterm delivery was 29.6±4.4 weeks in the treatment group (cases) and 30.5±3.8 weeks in the control, which was statistically similar.

Table 3 shows the median gestational age at delivery in the current pregnancy according to the treatment and the gestational age at the earliest prior preterm birth.

It was observed that the median gestational age. At delivery was 36 weeks 3 days in the cases and 33 weeks 1day in the controls with an earlier spontaneous preterm birth at 20-28 weeks. The cases in this were found to deliver at a significantly higher gestational age than the controls.

Table 4 shows that 50% of the cases and 80% of the controls delivered prematurely in the group with a prior preterm birth at 20-28 weeks. In the group with a prior preterm birth at 28-34 weeks, 35.3% of the cases and 51% controls delivered preterm. Although a numerically higher percentage of preterm delivery was observed in the controls, preterm delivery was not found to be statistically different between the cases and controls.

The adverse effects of the drug in the cases were pain (45.4%), swelling at the site of injection (15%), urticaria (3.34%), and injection site nodule (3.34%).The percentage of infants weighing <2.5 kg was 31.4% in the treatment group versus 45% in the controls. There was no statistical difference in the Apgar scores, neonatal morbidity, and mortality in the two groups.

DISCUSSION: The incidence of preterm delivery in our hospital was 8.8% as opposed to the 5-10% reported by Chabra and Patil.[1, 3, and 4]

Bloom and Yost[5] have identified previous preterm births as the risk factor with the highest predictive value for recurrence. In our study, it was found that the median gestational age was significantly prolonged in the cases as compared to the controls with the earliest prior delivery at 20-28 weeks. Spong et al.[6]

In their study showed that there was a significant increase in the median gestational age at delivery in the treated group with the earliest prior spontaneous preterm births at 20-27.9 weeks and 28-33.9 weeks. Meis and Klebanoff[7] reported that the incidence of preterm delivery (<37 weeks) was 36.3% in the progesterone-treated group as compared to 54.9% in the placebo group (P <0.001). Meis et al. also reported that the most common side effect was soreness (34.2%), swelling (14%), itching (11.3%), and bruising (6.7%).

All most same results about outcome observed in Nigar study[8] the reported rate of congenital anomalies in the treated group was also found to be consistent with that in the general population.

A recent publication of two randomized control trials[9] shows that current evidence supports the use of 17OHPC treatment begun early in the second trimester and continued weekly till 36 weeks for women with a previous history of preterm labor. At present, no evidence exists in using 17OHPC in women with multiple gestations, a short cervix, or other risk factors.

CONCLUSION: From the present study, it can be concluded that in patients who had a prior history of preterm delivery, the recurrence of a preterm birth was less in the treated group as compared to the controls. The median gestational age at delivery was significantly higher in 17OHPC-treated patients with a history of the earliest prior preterm delivery at 20-28 weeks. The limit of our study is the small sample size; so, large trials of this kind are required before conclusions can be drawn about a clinical advantage.

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AUTHORS:

1. Manisha M. Laddad
2. N. S. Khirsagar
3. Sanjaykumar Patil
4. Rajashree Bhosale
5. Digvijay Kadam

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Obstetrics and Gynaecology, Krishna Institute Medical Sciences, Karad.
2. Professor, Department of Obstetrics and Gynaecology, Krishna Institute Medical Sciences, Karad.
3. Associate Professor, Department of Obstetrics and Gynaecology, Krishna Institute Medical Sciences, Karad.
4. Resident, Department of Obstetrics and Gynaecology, Krishna Institute Medical Sciences, Karad.
5. Resident, Department of Obstetrics and Gynaecology, Krishna Institute Medical Sciences, Karad.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Manisha M. Laddad,
75/A Block, Vithal Housing Society,
Malkapur-415110, Karad District, Satara,
Maharashtra.
Email: drmanishald@gmail.com

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