Antenatal Corticosteroid Therapy: A Comparative Study of Dexamethasone and Betamethasone Effects on Fetal Doppler Indices

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Abstract:

Background: Preterm delivery, defined as delivery before 37 weeks of pregnancy, is the leading global reason for neonatal mortality and morbidity. Preterm neonates have serious problems such as respiratory distress syndrome, bronchopulmonary dysplasia, retinopathy, intraventricular hemorrhage and patent ductus arteriosus, one of the most challenging issues of modern perinatology is the prevention of these serious morbidities in infants**. Aim of the work** The aim of this study was to compare the effects of antenatal administration of corticosteroids in the form of dexamethasone or betamethasone for Enhancement of Fetal Lung Maturity on Doppler Indices (UA, MCA). **Patients and Methods:** A prospective randomized comparative study was conducted at the Obstetrics and Gynecology Department, Benha University Hospital, Benha – Egypt through the period from October 2018 to June 2019 and was subjected to approval by the Local Ethics Committee of the Department. The study included 84 cases of high risk pregnant women admitted to the department and candidates for corticosteroids therapy for possible preterm birth, Doppler study of the pulsatility index (PI) of the umbilical artery (UA)& the middle cerebral artery (MCA): 24 hrs. (day one) and 72 hrs (day three) after the first dose of dexamethasone or betamethasone**, Results:** the results of study revealed that that there was significant decrease in umbilical artery PI after treatment in both groups from before treatment to after and there were significant decrease Middle cerebral artery PI after. Dexamethasone, **Conclusion** In our study there is no significant difference between dexamethasone and betamethasone used for fetal lung maturity.

Keywords: Preterm, prospective, corticosteroids, Lung Maturity.

Introduction

Preterm delivery, defined as delivery before 37 weeks of pregnancy, is the leading global reason for neonatal mortality and morbidity. Preterm neonates have serious problems such as respiratory distress syndrome, bronchopulmonary dysplasia, retinopathy, intraventricular hemorrhage, periventricular leukomalacia, necrotizing enterocolitis, and patent ductus arteriosus, one of the most challenging issues of modern perinatology is the prevention of these serious morbidities in infants ***(1).***

Maternal administration of synthetic corticosteroids (betamethasone or dexamethasone) has been used for long time to improve fetal lung surfactant production and hasten the fetal lung maturity in women at risk for preterm birth ***(2).***

Corticosteroids also reduce the occurrence of Respiratory Distress Syndrome (RDS), intraventricular hemorrhage, necrotizing enterocolitis also reduce the neonatal mortality in preterm infants ***(3).***

Serious side effects on the neonate have not been described when prenatal treatment has been administered during the second half of pregnancy ***(4).*** However, a transient reduction of fetal heat rate variation and fetal body movements following maternal betamethasone movements and breathing administration was recently reported by Monitoring of biophysical activities is a powerful tool for the assessment of fetal wellbeing ***(5).***

Doppler ultrasound has been used to measure the blood flow velocity in vessels during the cardiac cycle in the fetoplacental, uteroplacental circulation and has been focused on arteries for the evaluation of downstream distribution of cardiac output ***(6).***

Evaluation of fetal well-being with Doppler waveform studies after maternal corticosteroid administration is therefore important knowledge of fetal haemodynamic effects after exogenous corticosteroids is limited ***(7)***

Patients and Methods

A prospective randomized comparative study was conducted at the Obstetrics and Gynecology Department, Benha University Hospital, Benha – Egypt through the period from October 2018 to June 2019 and gained the approval by the Local Ethics Committee of the Benha faculty of Medicine. Informed consent after explaining the study purpose and methods to the subjects, were collected. The study included 84 cases of high risk pregnant

women admitted to the department or attended antenatal clinic and candidates for corticosteroids therapy for possible preterm birth

Inclusion criteria:

- Pregnant women with gestational age from 28 to 34 weeks with singleton pregnancies.
- Pregnant women at risk of preterm labor.

Exclusion criteria:

- Pregnancies with infants with major fetal structural malformations.
- Women on corticosteroids treatment for another disease.
- Any associated medical problem with pregnancy (gestational diabetes, renal disorders, cardiac problems, RH isoimmunization, bronchial asthma, hepatic disease).
- Women who had any contraindication of corticosteroids administration had also been excluded.
- Women with a condition requiring immediate delivery such as active labor, placental abruption, severe preeclampsia, eclampsia, chrioamnionitis.

Sample size:

84 cases were randomized to 2 groups.

Randomization table (1):

1	1	22	1	43	2	64	B
2	1	23	1	44	1	65	A
3	2	24	2	45	2	66	A
4	1	25	1	46	2	67	B
5	2	26	1	47	1	68	B
6	1	27	2	48	2	69	A
7	1	28	1	49	1	70	B
8	2	29	2	50	2	71	B
9	1	30	2	51	1	72	B
10	2	31	2	52	2	73	A
11	1	32	1	53	1	74	B
12	2	33	1	54	2	75	B
13	1	34	2	55	2	76	A
14	2	35	2	56	2	77	B
15	1	36	2	57	2	78	A

16	2	37	2	58	1	79	A
17	1	38	2	59	2	80	B
18	1	39	1	60	1	81	A
19	1	40	1	61	1	82	A
20	1	41	1	62	1	83	B
21	2	42	1	63	2	84	B

Allocation and concealment:

Opaque envelopes were numbered serially and in each envelope the corresponding letter which denotes the allocated group was put according to randomization table .The all envelopes were closed and put in one box .When the first patient arrives, the first envelop was opened and the patients was allocated according to the letter inside

Study procedures:

The participants were randomized using a computer-generated random list. The statistician generated the random allocation sequence, and the investigators enrolled the participants.

All patients were subjected to the following:

- **Initial evaluation (day 0):**

1) Personal history, detailed obstetric history, past history and family history.

2) Estimation of gestational age: calculated according to the date of the last normal menstrual period and confirmed by first trimester ultrasound. If there is a discrepancy (more than five days), early ultrasound was used to determine gestational age.

3) General and obstetric abdominal examination.

4) Routine obstetric ultrasound scanning: trans-abdominal ultrasound for gestational age, fetal biometry, presentation, amniotic fluid volume, placental location and exclusion of fetal anomalies (using 2-5 MHz probe – Voluson 730 PRO, GE Healthcare, USA).

5) Doppler study of the pulsatility index (PI) and **resistance index (RI)** of the umbilical artery (UA)and the pulsatility index (PI) and **resistance index (RI) of** the middle cerebral artery (MCA) before treatment .

6) Maternal blood sample was taken for Routine laboratory investigations in the form of (CBC, ABO, Rh Random blood

sugar, liver function, kidney function, coagulation profile).

Participants were divided into 2 groups **Group A:** patients receive dexamethasone (four intramuscular injections of 6 mg dexamethasone were given 12 h apart). **Group B:** received betamethasone were given 24 h apart, accordingly to National Institutes of Health (NIH) recommendations) **(8).**

Subsequent evaluation (day 1 and 3):

1) Doppler study of the pulsatility index (PI) of the umbilical artery (UA), the middle cerebral artery (MCA): 24 hrs (day one) and 72 hrs (day three) after the first dose of dexamethasone or betamethasone

2) Doppler study of the resistant index (RI) of the umbilical artery (UA), the middle cerebral artery (MCA): 24 hrs (day one) and 72 hrs (day three) after the first dose of dexamethasone or betamethasone.

Method of Doppler examination:

Doppler ultrasound assessment of umbilical artery (UA) and middle cerebral artery (MCA) waveforms were analyzed:

-Umbilical Artery Doppler:

The patients placed in a semi-recumbent position with a left lateral tilt, and then the uterine contents are quickly scanned by the real time ultrasound in order to select an area of amniotic cavity with several loops of umbilical cord. Ideally these cord loops should not be close to the cord insertion. Using a Pulsed Wave Doppler, the characteristic sound and shape of the umbilical artery wave form was demonstrated and identified.

A minimum of 3 separate readings were averaged before the final values obtained, with 3 waveforms for each reading. Because of the potential effect of foetal breathing movements on waveform variability, recording were performed during periods of foetal apnoea. Both the resistance index (RI) and PI were calculated.

Middle Cerebral Artery Doppler:

The standard plane for measuring the biparietal diameter is visualized. This plane includes the thalamus and the cavum septum pellucidum, the colour and flow mapping function was then superimposed and the middle cerebral artery can be seen pulsating at the level of the insula. The middle cerebral artery can be seen running from the internal carotid artery in a lateral direction into the Sylvian tissue.

Three readings were averaged; with the average of 3 waveforms calculated for each reading. Both the RI and PI were calculated.

Daily Fetal Movement count:

The Sadovsky method was employed, as it spans the whole day. Three times per day, after a meal, the participant would lay in left lateral, or semi-sitting position, for 1 hour, and count fetal movements.

Once reached 4 movements, a woman would stop counting, and record the value. If less than 4 in 1 hour, a second hour entails until the 4th count is achieved. If after 2 hours the 4 counts were not reached, the value is recorded.

Participants were instructed to write down their findings, and a sheet designed for this purpose could be given to them if they desired.

Statistical analysis

Data was subjected to computer assisted statistical analysis using SPSS package (version19) . Nominal data was described as frequency and percentage and compared using Chi Square tests. Numerical data was described as mean and standard deviation and compared using t test. P value less than 0.05 was considered significant.

Results:

This study was conducted on 84 cases divided into two groups: Group (A) received dexamethasone and group (B) betamethasone, p-values less than 0.05 were considered statistically significant.

Table (2): Comparison between the two studied groups (dexamethasone group and betamethasone group) according to demographic data.

	Group A (n = 42)	**Group B (n = 42)**	**t**	**p**
Age (years)				
Min. – Max.	23.0 – 40.0	23.0 – 40.0		
Mean ± SD.	32.67 ± 4.21	32.55 ± 4.23	0.129	0.897
Median	33.0	33.0		
BMI (kg/m^2)				
Min. – Max.	19.0 – 32.0	19.0 – 32.0		
Mean ± SD.	26.79 ± 2.54	26.74 ± 2.58	0.085	0.932
Median	27.0	27.0		

This table shows that there were insignificant differences between two groups regarding demographics data

Table (3): Comparison between the two studied groups (dexamethasone group and betamethasone group) according to (GA, Parity and Fetal weight (kg)

	Group A (n = 42)	Group B (n = 42)	Test of Sig.	p
GA				
Min. – Max.	28.0 – 34.0	28.0 – 34.0		
Mean ± SD.	32.48 ± 1.58	32.48 ± 1.57	**t=0.0**	**1.000**
Median	33.0	33.0		
Parity				
Min. – Max.	0.0 – 3.0	0.0 – 3.0		
Mean ± SD.	1.26 ± 1.21	1.31 ± 1.20	**U= 861.5**	**0.848**
Median	1.0	1.0		
Fetal weight (kg)				
Min. – Max.	1.16 – 2.60	1.16 – 2.60		
Mean ± SD.	2.02 ± 0.28	2.0 ± 0.29	**t=0.343**	**0.732**
Median	2.0	2.0		

This table shows that there were insignificant differences between two groups regarding GA, Parity and Fetal weight p-value 1.000, 0.848 and 0.732 respectively

Table (4): Comparison between the different studied periods (before, after 24 hrs. and after 72 hrs.) according to umbilical resistance index(RI).

Umbilical RI	Before	After 24 hr	After 72 hr	F	p
Group A					
Min. – Max.	0.55 – 0.65	0.56 – 0.65	0.55 – 0.70		
Mean ± SD.	0.62 ± 0.03	0.62 ± 0.02	0.65 ± 0.03	**32.210***	**<0.001***
Median	0.62	0.63	0.66		
	p_1=0.660,p_2<0.001*,p_3<0.001*				
Group B					
Min. – Max.	0.55 – 0.65	0.56 – 0.65	0.60 – 0.75		
Mean ± SD.	0.62 ± 0.03	0.62 ± 0.02	0.67 ± 0.03	**84.248***	**<0.001***
Median	0.62	0.63	0.66		
	p_1=0.193,p_2<0.001*,p_3<0.001*				

F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using **Post Hoc Test** (**Bonferroni)**
p: p value for comparing between the studied periods, $\mathbf{p_1}$: p value for comparing between before and after 24 h, $\mathbf{p_2}$: p value for comparing between before and after 72 hr, $\mathbf{p_3}$: p value for comparing between after 24 hr and after 72 hr

*: Statistically significant at $p \leq 0.05$

Table (5): Comparison between the different studied periods (before, after 24 hrs. and after 72 hrs.) according to umbilical pulsatile index (PI).

Umbilical PI	Before	After 24 hrs	After 72 hrs	Fr	p
Group A					
Min. – Max.	**0.99 – 1.50**	**0.96 – 1.09**	**0.95 – 1.05**		
Mean ± SD.	**1.09 ± 0.12**	**0.97 ± 0.02**	**0.97 ± 0.02**	**64.443***	**<0.001***
Median	**1.07**	**0.97**	**0.97**		
	p_1=0.913,p_2<0.001*,p_3<0.001*				
Group B					
Min. – Max.	**0.99 – 2.10**	**0.96 – 1.09**	**0.95 – 1.05**		
Mean ± SD.	**1.15 ± 0.19**	**0.97 ± 0.02**	**0.97 ± 0.02**	**71.047***	**<0.001***
Median	**1.14**	**0.97**	**0.97**		
	p_1=0.913,p_2<0.001*,p_3<0.001*				

Fr: **Friedman test**, Sig. between periods was done using **Post Hoc Test** (**Dunn's)**

p: p value for comparing between the studied periods, **p_1**: p value for comparing between before and after 24 hrs, **p_2**: p value for comparing between before and after 72 hrs, **p_3**: p value for comparing between after 24 hrs and after 72 hrs

*: Statistically significant at $p \leq 0.05$

Table (6): Comparison between the different studied periods (before, after 24 hrs and after 72 hrs) according to middle cerebral artery pulsatile index (PI).

Middle cerebral artery PI	Before	After 24 hrs	After 72 hrs	F	p
Group A					
Min. – Max.	**1.90 – 2.02**	**1.55 – 2.60**	**1.50 – 1.80**		
Mean ± SD.	**1.96 ± 0.03**	**1.74 ± 0.16**	**1.66 ± 0.10**	**27.164***	**<0.001***
Median	**1.96**	**1.75**	**1.70**		
	p_1=0.060,p_2<0.001*,p_3<0.001*				
Group B					
Min. – Max.	**1.90 – 2.02**	**1.90 – 2.02**	**1.50 – 1.80**		
Mean ± SD.	**1.96 ± 0.03**	**1.96 ± 0.03**	**1.66 ± 0.10**	**0.051**	**0.950**
Median	**1.96**	**1.96**	**1.70**		

F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using **Post Hoc Test** (**Bonferroni)**

p: p value for comparing between the studied periods, p_1: p value for comparing between before and after 24 hr, p_2: p value for comparing between before and after 72 hr, p_3: p value for comparing between after 24 hr and after 72 hr *: Statistically significant at $p \leq 0.05$

Table (7): Comparison between the different studied periods (before, after 24 hrs and after 72 hrs) according to middle cerebral artery resistance index(RI).

Middle cerebral artery RI	Before	After 24 hr	After 72 hr	Fr	p
Group A					
Min. – Max.	0.75 – 0.90	0.75 – 0.90	0.73 – 0.89		
Mean ± SD.	0.82 ± 0.05	0.83 ± 0.05	0.81 ± 0.05	**81.012***	**<0.001***
Median	0.80	0.80	0.79		
	p_1<0.001*,p_2<0.001*,p_3<0.001*				
Group B					
Min. – Max.	0.75 – 0.90	0.75 – 0.90	0.74 – 0.90		
Mean ± SD.	0.82 ± 0.05	0.83 ± 0.05	0.82 ± 0.06	**7.760***	**0.021***
Median	0.83	0.80	0.82		
	p_1=0.445,p_2=0.300,p_3=0.785				

Fr: **Friedman test**, Sig. bet. periods was done using **Post Hoc Test** (**Dunn's**

p: p value for comparing between the studied periods, $\mathbf{p_1}$: p value for comparing between before and after 24 hrs, $\mathbf{p_2}$: p value for comparing between before and after 72 hrs, $\mathbf{p_3}$: p value for comparing between after 24 hrs and after 72 hrs

*: Statistically significant at $p \leq 0.05$

Table (8): Comparison between the two studied groups (dexamethasone group and betamethasone group) according to fetal movements.

Fetal movements	Group A (n = 42)	Group B (n = 42)	t	p
Before				
Min. – Max.	**10.0 – 14.0**	**10.0 – 14.0**		
Mean ± SD.	**11.52 ± 1.21**	**11.50 ± 1.31**	**0.086**	**0.931**
Median	**11.0**	**11.0**		
After				
Min. – Max.	**4.0 – 8.0**	**4.0 – 8.0**		
Mean ± SD.	**6.64 ± 1.10**	**6.50 ± 1.06**	**0.605**	**0.547**
Median	**7.0**	**6.0**		
p between before and after	**<0.001***	**<0.001***		

t: Student t-test

p: p value for comparing between the studied groups p_1: p value for **Paired t-test** for comparing between before and after *: Statistically significant at $p \leq 0.05$

Discussion

Preterm delivery is a leading cause of perinatal morbidity and mortality world-wide and remains a significant problem in modern obstetrics. .Preterm infants are at risk for specific diseases such as respiratory distress syndrome, intraventricular hemorrhage, broncho-pulmonary dysplasia, patent ductus arteriosus, necrotizing enterocolitis, sepsis, apnea and retinopathy ***(9).***

Synthetic corticosteroids have been successfully employed for more than 20 years to enhance fetal lung maturity where preterm delivery is anticipated .Maternal administration of synthetic corticosteroids (betamethasone or dexamethasone), for accelerating the maturity of the fetal lung, reduces neonatal mortality, respiratory distress syndrome, intraventricular hemorrhage and necrotizing enterocolitis in preterm infants ***(9).***

In the current study we aimed to compare the effects of antenatal administration of corticosteroids in the form of dexamethasone or betamethasone for enhancement of Fetal Lung Maturity on Doppler Indices, study conducted on 84 cases divided into two groups group A received dexamethasone and group B received betamethasone.

In the current study we found that there were insignificant differences between two groups regarding demographics data and there were insignificant differences between two groups regarding GA, Parity and Fetal weight, this agree with the study done previously ***(10)*** with p-value 1.000, 0.848 and 0.732 respectively and they found that there were no significant differences between the groups with regard to baseline characteristics**.**

In a study done in 2011 **(8)** there were 67 patients assigned to receive either dexamethasone (n = 34) or betamethasone (n = 33). Mean gestational age at dexamethasone and betamethasone administration was 31.5 0.3 weeks. Mean maternal age was 29.7 1.1 years. There were no statistically significant differences between numbers of nulliparous (12 versus 10) and multiparous (22 versus 23) in both groups**.**

In a study which included 33 pregnancies treated with betamethasone with mean maternal age 31 years, the mean gestational age at examination was 26 weeks **(11).**

In the current study umbilical artery PI decreased after treatment but with insignificant differences in umbilical artery PI before and after 24 and 72 hours of treatment in both groups, but there were

significant decrease in umbilical artery PI in each group from before treatment to after.

A reduction in the umbilical artery and ductus venosus PI within 24 h following antenatal corticosteroid therapy was noted. The changes were maintained for up to 48 h, Moreover on evaluated pregnancies with severe placental insufficiency, where the mothers received betamethasone for fetal lung maturation showed a reduction in UA PI within the first 24 hours after steroid administration was observed in 29 (90.6%) cases, with return of positive diastolic flow in 22/32 (68.7%) cases with absent end diastolic flow (AEDF) at D1 **(12)**.

Significant changes in UA PI were observed along the evaluations (p<0.001), with this difference being significant between D0 and D1 (p<0.001), between D0 and D2 (p0.017) and between D1 and D2 (p0.016), regarding MCA PI, analysis of variance for repeated measures showed no significant differences along the evaluations (p0.581) **(12)**.

The literature was reviewed and six of 17 studies reported an improvement in umbilical artery blood flow waveforms after corticosteroid treatment (13)**.**

The effects of maternal corticosteroid administration on fetal and utero-placental circulation in pregnancies at risk of preterm delivery were evaluated. Significant changes in PI and RI of both umbilical artery and fetal middle cerebral artery within 24h following corticosteroid therapy and maintained for up to 48h. But after 7 days of treatment the doppler results returned to the values before treatment (11)**.**

This significance may be explained by the overall increase in placental size and associated increase in number of chorionic villi throughout pregnancy which result in an expansion of the distal vascular pool of the umbilical artery, characterized with a decreasing values of vascular resistance ***(6).***

In the current study it was found that there were insignificant differences in Middle cerebral artery PI before treatment in both groups but after 24, 72 hours group A showing significant decrease than B, there was significant decrease in Middle cerebral artery PI in group A from before treatment to after but in group B there were insignificant difference .

In the current study there were insignificant differences in middle cerebral artery RI before and treatment in both groups but there were significant decrease in Middle cerebral artery PI in both groups from before treatment to after.

In a previous study carried out by ***(14)***, corticosteroids had no effect on doppler indices obtained from fetal middle cerebral artery, placental arteries or fetal pulmonary trunk. These findings have been subsequently confirmed by ***(15).***

In disagreement with our result, it was found that after administration of corticosteroid on 18 patients at risk for preterm delivery populations there was no change in *UA-PI, MCA-PI* and *UA-PI/MCA-PI ratio* (16)**.**

It was found also that after administration of corticosteroid on 31 patients at risk for preterm delivery populations there was no change in *UA-PI, MCA-PI* and *UA-PI/MCA-PI ratio* (17).

In a study done before the researchers disagree with our result as they found that pulsatility indices of umbilical and middle cerebral arteries remained unchanged at 48 h and 96 h in comparison to baseline (*p*-NS) **(17).**

The lack of change in the flow characteristics of the middle cerebral artery suggests that no major redistribution of blood flow in the fetal compartment occurred during the study period. However, fetal hypoxia cannot be ruled out on this basis, since acute hypoxia, in contrast to chronic hypoxia, is generally not associated with significant redistribution of fetal blood flow ***(18).***

No significant changes were observed in the fetal middle cerebral artery and in maternal uterine arteries .Two days after treatment, in fetuses with absent or reversed end-diastolic (ARED) flow, the flow velocity waveform in the umbilical artery changed from reversed to absent, from reversed to positive or from absent to positive diastolic flow in 12 of 15 cases **(*11).***

Decrease in MCA PI may be caused by a direct effect of corticosteroids on the fetal brain. Cerebral areas where corticosteroid receptors are present, in particular a number of brainstem nuclei, are part of the presumptive sleep center in the pons, and are thought to control motor activity of the fetus in the third trimester ***(19).***

In the current study we found that fetal movement decreased in both groups but difference was insignificant between two groups regarding fetal movements before and after treatment

It was showed that the administration of dexamethasone decreases fetal movement and breathing and as a result the biophysical profile scores may be decreased ***(20).***

Conclusion

In our study both dexamethasone and betamethasone cause significant transient decrease umbilical artery PI after treatment and there were significant transient decrease middle cerebral artery PI after dexamethasone, In our study They is no significant difference between dexamethasone and betamethasone used for fetal lung maturity.

Trials comparing the commonly used corticosteroids are needed.

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