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Research Article

TO FIND OUT VARIOUS CLINICAL FEATURES ASSOCIATED WITH APNEA IN PRETERM INFANTS

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A R T I C L E I N F O

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A B S T R A C T

Introduction: Apnea is defined as the cessation of breathing for more than 20 seconds or any duration if associated with bradycardia and/or change in skin color (pallor or cyanosis). Apnea in preterm infants is usually related to immaturity of the central nervous system and is called apnea of prematurity (AOP). Caffeine is now used as a standard pharmacotherapy for AOP. However, the optimal dosing regimen of caffeine citrate for treatment of apnea is not well studied. We aimed to compare the efficacy and safety of high versus conventional dose caffeine on AOP.

Aims and objectives: Study to evaluate and compare therapeutic effect of high dose versus low dose caffeine citrate for treatment of apnea in preterm infants and associated clinical features and biochemical derangements.

Material and methods: A total of 54 preterm infants <35 weeks gestation, presented with AOP within the first 14 days of life were enrolled and randomized into two groups 28 in high dose group (loading 40 mg/kg/day and maintenance of 20 mg/kg/day) and 26 in conventional dose group (loading 20 mg/kg/day and maintenance of 10 mg/kg/day).

Results: Most of the neonates in our study were of 30 weeks gestational age and 1-1.2kg birth weight and exhibited apnea between 3rd-5th day of life. High-dose caffeine was associated with a significant reduction in recurrence of apnea, duration of oxygen therapy, duration of caffeine therapy and duration of NICU stay, requirement for mechanical ventilation as compared to conventional dose group. High-dose caffeine was associated with significant increase in episodes of tachycardia but this was clinically nonsignificant.

Conclusion: The use of higher, than current standard, dose of caffeine may decrease recurrence of apnea in preterm infants without significant side effects.

INTRODUCTION

The infant mortality rate (IMR) is one of the indicators used to monitor achievements towards the Millennium Development Goals[1]. IMR is the number of deaths of children less than one year of age per 1000 live births. The leading causes of infant mortality are birth asphyxia, pneumonia, preterm birth complications, diarrhoea, malaria, measles and malnutrition.[2]

We hypothesized that a high-dose regimen of caffeine, as an initial therapy for apnea in premature infants, might gain more efficacy than the standard-dose regimen without increasing occurrence of adverse effects. Till date, in our country no study has been performed which compare the effect of high versus low dose of caffeine for apnea in preterm infants. Hence present study has been planned to evaluate comparative efficacy and safety of high versus conventional dose of caffeine citrate for treatment of apnea in premature infants admitted in NICU of JLN Medical College & Hospital, Ajmer. Caffeine is available free of cost to the patients under JSSY scheme.

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MATERIALS AND METHODS

Source of Data

Present Study was conducted in neonatal intensive care units (NICUs) of Rajkiya Mahilla Chikitsalaya (intramural) as well as J.L.N. Hospital (extramural), attached to JLN Medical College, Ajmer. Study period extended from July 2015 onwards for 1 year. The study protocol was approved by the Institutional Ethics Committee of J.L.N. Medical College. The written informed consent was obtained from a parent of each infant.

Design of the Study

This is a parallel randomized controlled, pilot, prospective study, comparing two different dose regimens of caffeine citrate in preterm infants.

Sample Size

Total 54 inborn patients of apnea of prematurity (intramural 42 and extramural 12) fulfilling the case inclusion criteria were enrolled for the present study.

Inclusion Criteria

1. Preterm Infants born less than 35 weeks Gestational age.
2. Preterm Infants within first 14 days of life.
3. Apnea definition - cessation of breathing for longer than 20 sec or for any duration if accompanied by central cyanosis and bradycardia (heart rate <100).

Exclusion Criteria

1. Preterm Infants born more than 35 weeks Gestational age.
2. Preterm Infants after 14 days of life.
3. Cessation of breathing for less than 20 seconds and not accompanied by cyanosis and bradycardia.
4. Signed informed consent not given by parents.
5. Major congenital malformation.

RESULTS AND OBSERVATION

Table 1 Characteristics of the study population

Characteristics	High-dose caffeine	Conventional-dose caffeine	p-value
Gestational age (weeks) (Mean)	30.71±1.28	32.15±0.957	0.05
Birth weight (Kgs) (Mean)	1.33±0.277	1.40±0.148	0.05
	Gender		
Male (Percentage)	14(50.0%)	12(46.2%)	0.689
Female (Percentage)	14(50.0%)	14(53.8%)	
	APGAR score		
1 min (median)	5 (2 – 5)	5 (6 – 7)	0.22
5 min (median)	6 (4 – 6)	6 (7 – 8)	0.25
	Mode of delivery		
NVD (Percentage)	20 (71.40%)	19 (73.1%)	0.84
LSCS (Percentage)	8 (28.60%)	7 (26.9%)	
Postnatal age at caffeine therapy (days) (Mean)	4.00±1.572	4.307±1.213	0.26

In current study in High dose group, total 28 preterm infants (50% male & 50% female) and in Conventional dose group, 26 preterm infants (46.2 % male & 53.8 % female) were enrolled. Both groups were comparable on following parameters- Gestational age, Birth weight, APGAR score at 1 min and 5 min, Mode of delivery, Postnatal age at caffeine therapy. There was no statistically significant difference.

Table 2 Variation in Heart rate during apneic spell

Heart Rate			
Group	High dose	Conventional Dose	Total
Bradycardia(<80/min)	14 26.00%	10 18.50%	24 44.50%
Tachycardia(>160/min)	6 11.10%	7 13.90%	13 25.00%
Normal(110-160)	8 14.80%	9 15.70%	17 30.50%
Total	28 51.90%	26 48.10%	54 10.00%
Chi-Square=1.55		P=0.460	

In most of the infants 44.50% apneic spell was associated with bradycardia, followed by normal heart rate and tachycardia in 30.5% and 25% respectively.

Table 3 Change in colour during apneic spell

Color	High Dose	Conventional Dose	Total
Cyanosis	13 24.08%	8 14.81%	21 38.89%
Pallor	7 12.96%	6 11.11%	13 24.07%
No Change	8 14.82%	12 22.22%	20 37.04%
Total	28 51.86%	26 48.14%	54 100.00%
Chi-Square=1.996		P=0.396	

Apnea was associated with cyanosis in 38.89% infants and with pallor in 24.07% infants.

DISCUSSION

The current study entitled "A clinico-biochemical study of apnea in preterm infants with special emphasis on comparative efficacy of its treatment with high versus conventional dose caffeine" was carried out in Department of Pediatrics, Jawaharlal Nehru Medical College, Ajmer from July 2015 to June 2016.

Caffeine is one of the most commonly used drugs in the neonatal intensive care units.

Caffeine is considered the preferred drug to treat AOP. However, the optimal dosing regimen of caffeine for treatment of apnea is not well studied. Our study was designed to evaluate the efficacy, safety, overall hospital course and neonatal outcome of two different dosing regimens of caffeine citrate for apnea in preterm infants. For this purpose total 54 preterm infants <35 weeks gestation were enrolled in study; 28 in high dose group and 26 in conventional dose group. Data were recorded in pre structured Performa and they were analyzed using statistical software.

Baseline characteristics of study population

Baseline characteristics were statistically comparable between the two groups. In high dose group, male and female ratio was 1:1, whereas male and female ratio in conventional dose group was 46.2% and 53.8% respectively.

CONCLUSION

The use of higher, than current standard, dose of caffeine may decrease recurrence of apnea in preterm infants without significant side effects.

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