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Original article:

Incidence of hypocalcemia in term neonates receiving phototherapy with head covering.

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ABSTRACT

Background and objectives: Neonatal hyperbillirubenemia is the most common cause of admission seen in neonatal period. Hence it is important to understand create awareness regarding the complications associated with the treatment. The primary objective of this study is To evaluate incidence of hypocalcemia in neonates under phototherapy by intervention of head covering, secondary objective of this study is To compare hypocalcemia at baseline to 24 hours and 48 hours.

Methods:This study was done at BGS Institute of Medical Science Bangalore, a tertiary care hospital . An open label, randomised control study among 80 neonates were enrolled in study having met the inclusion/ exclusion criteria, with intervention of head covering. In view of clinical icterus total bilirubin and direct bilirubin sent and started phototherapy as per cut off values on AAP nomogram and serum calcium, ionised calcium sent in the same sample. Phototherapy was discontinued based on bilirubin values as per AAP nomogram cut off values. At the time of discontinuation of phototherapy serum calcium/ ionised calcium checked in the same sample.

Results :Based on the age-wise distribution of the neonates in study has shown physiological peak incidence of jaundice in term is on 4th day. The most common blood group in neonates was B positive, most common cause of jaundice was exaggerated physiological jaundice. A statistically significant reduction in serum calcium and Ionised calcium between pre phototherapy and post phototherapy. However no hypocalcemia was proven. Statistical significant difference was seen in head covering vs no head covering term neonates was seen.

Conclusion:This study highlights the role of head covering along with routine covering of eyes and genitals. The fall in serum calcium and ionised calcium seen in the course of this study.

Introduction

Neonatal hyperbilirubinemia (NNH) is the most common cause of Neonatal Intensive Care Unit (NICU) admissions worldwide. The incidence of neonatal hyperbilirubinemia is 55.2% world wide with incidence of 45% in India [1Unconjugated hyperbilirubinemia in the human,regardless of age, is defined as an indirect reacting bilirubin concentration of 2.0 mg/dL/day or greater, depending on the standard used in calibration of the reaction. Nearly all adults and older children normally have indirect-reacting bilirubin concentrations in circulation of less than 0.8 mg/dL (14 µmol/L) and δ-bilirubin of 0.2-0.3 mg/dL (3-5 µmol/L). Conjugated hyperbilirubinemia is defined as an elevation of the direct-reacting fraction in the van den Bergh diazo reaction of greater than 1.5 mg/ dL provided it comprises more than 10% of the TB concentration. In term babies

jaundice starts appearing between 36-72 hours of life, peaks around 96 hours of life, does not exceed 15mg/dl and disappears by day 10 of life.

Hypocalcemia is the known side effect of phototherapy 90% of preterm and 75% of full-term neonates develop hypocalcemia in the wake being subjected to phototherapy. Neonates undergo a physiological nadir in serum calcium levels usually by 24-48 hours of age, termed as early onset hypocalcemia and requires treatment with calcium supplementation for the first 72 hours. In contrast to late onset hypocalcemia usually presents after 7 days and requires long term therapy Hypocalcemia can cause jitteriness, irritability, convulsions, tetany, apnea with few long-term implications including

physical disability, mental retardation and cognitive impairment thus important to prevent hypocalcemia by using a simple method by head covering.There are several theories to explain the effect of phototherapy on calcium metabolism. Phototherapy leads to the inhibition of pineal gland via transcranial illumination, resulting in the decline of melatonin levels which stimulates secretion of corticosterone and reduces calcium absorption by bones, as a result hypocalcaemia develops . Since hypocalcaemia is accompanied by decrease in serum melatonin concentration this effect can be prevented by shielding the occiput with head cap.

Objectives:

PRIMARY OBJECTIVE:To evaluate incidence of hypocalcemia in neonates under phototherapy by intervention of head covering.

SECONDARY OBJECTIVE:To compare hypocalcemia at baseline to 24 hours and 48 hours.

Methodology:

The present study is conducted in the Department of Pediatrics, BGS Global Institute of Medical Sciences Hospital, Bangalore.

Study design: Randomized Control Trial; Open label; Parallel Study period: 18 months

Place of study: newborns receiving phototherapy at BGS Global Institute of Medical Sciences, Bangalore.

Sampling Method:Purposive sampling method

Randomization Allocation Method:Simple Random Allocation

For Intervention Group: Sl. No's of neonates-28, 10, 24, 77, 13, 22, 20, 41, 74, 17, 66, 19, 6, 76, 16, 36, 61, 1, 35, 7, 80, 27, 32, 5,62, 71, 26, 40, 69,25, 75, 9, 63, 79, 44, 33, 65, 48, 55, 2

Plan for Statistical Analysis:All the data collected compiled and entered into a Microsoft Excel worksheet. Descriptive statistics like Mean, SD and Percentages will be calculated Statistical test t-test, paired-t test, Mann Whitney U-test, Wilxcon test, ANOVA and Friedman will be used based on the suitability of data.

The data will be analyzed using Statistical software's Python, R Programming, SPSS.

Inclusion criteria**:** All neonates with neonatal jaundice as per AAP nomogram under phototherapy including full-term, preterm

Exclusion criteria:Neonatal sepsis,Perinatal asphyxia,Infant of diabetic mother (IDM),Newborn with congenital anomalies,IUGR neonates,Neonates in NICU for causes other than neonatal jaundice and those need exchange transfusion,Neonates whose parents did not give consent.

In view of clinical icterus total bilirubin and direct bilirubin sent and started phototherapy as per cut off values on AAP nomogram and serum calcium, ionised calcium sent in the same sample. Discontinuation of Phototherapy based on bilirubin values as per AAP nomogram cut off values. At the time of discontinuation of phototherapy serum calcium/ ionised calcium checked in the same sample.Sample collected by drawing 2ml of

blood from peripheral vein allowing the sample for centrifugation to obtain serum and then calcium levels measured.Clinical assessment of neonates for features of hypocalcemia that is irritability/excitability, jitteriness, lethargy and convulsions and also for other complications like rash loose stools, fever and dehydration. Evaluation of other causes of these symptoms and treated accordingly.

Phototherapy was given in all neonates (with intervention and without intervention) consisting high intensity light emitting diodes (LED) in the wavelength range of 460-490nm at an ambient room temperature 25-28º c with an eye patch and diaper placing the neonate disrobed under the lights in a cot or bassinet if the weight is >2kg or a radiant warmer if the baby is <2kg. Keeping the distance between baby and light 30-45cm (as per manufacturer recommendation).

In the test group a white color cap (hat)was used to cover the entire head including occipital area, ears, neck to prevent passage of light. Cap (hat) was used from the time of administration of phototherapy and for 48 hours of treatment. No head covering in control group.

Results:

Table 1: Comparison of Parameters Before and after Phototherapy (N=80)

Mean (SD)	Before Phototherapy	After Phototherapy	P Value
Total Bilirubin	14.96 (0.58)	9.48 (0.74)	<0.001*
Direct Bilirubin	0.172 (0.063)	0.147 (0.061)	0.005*
Serum Calcium	9.54 (0.92)	8.26 (0.70)	<0.001*
Ionised Calcium	5.20 (0.44)	4.75 (0.42)	<0.001*

In present study mean value of total bilirubin is 14.96mg/dl, direct bilirubin 0.17mg/dl, serum calcium 9.54mg/dl, ionised calcium 5.20mg/dl before stating phototherapy, with reduction in total bilirubin levels to 9.48mg/dl, direct bilirubin to 0.14mg/dl, serum calcium 8.26mg/dl, ionised calcium 4.75mg/dl.

Table 2: Association between Hypocalcemia and Duration phototherapy (N=80)

	24 hrs Mean (SD)	**48 hrs Mean (SD)**	**P Value**
Serum Calcium (Before)	9.09 (0.46)	9.68 (0.97)	0.016*
Ionised Calcium (Before)	5.07 (0.41)	5.24 (0.44)	0.167
Serum Calcium (After)	8.01 (0.67)	8.33 (0.70)	0.090
Ionised Calcium (After)	4.65 (0.47)	4.77 (0.41)	0.264
Difference Calcium	1.07 (0.48)	0.42 (0.30)	0.130
Difference Ionised	1.34 (0.68)	0.46 (0.28)	0.649

In present study at the end of 24 hours difference in serum calcium levels is 1.07, ionised calcium 1.34, statistically insignificant. At the end of 48 hours difference in serum calcium level is 0.13, ionised calcium 0.6, statistically insignificant.

	Cap Mean (SD)	**No Cap Mean (SD)**	**P Value**
Serum Calcium (Before)	9.62 (0.92)	9.47 (0.91)	0.447
Ionised Calcium (Before)	5.25 (0.44)	5.15 (0.44)	0.315
Serum Calcium (After)	8.34 (0.80)	8.18 (0.60)	0.324
Ionised Calcium (After)	4.80 (0.48)	4.70 (0.36)	0.301
Difference Calcium	1.28 (0.63)	1.28 (0.67)	1.000
Difference Ionised	0.45 (0.27)	0.45 (0.29)	1.000

Table 3: Association between Hypocalcemia and Intervention (N=80)

In present study mean value in subjects with cap serum calcium 9.62mg/dl, ionised calcium 5.25mg/dl before stating phototherapy, with out cap serum calcium levels 9.47mg/dl, ionised calcium 5.15mg/dl. After receiving phototherapy in subjects with cap mean value of calcium is 8.34mg/dl, ionised calcium 4.80, without cap serum calcium level is 8.18, ionised calcium is 4.70, statistically insignificant.

Table 4:Association between Hypocalcemia and Duration phototherapy among Cap Neonates (N=80)

	24 hrs Mean (SD)	**48 hrs Mean (SD)**	**P Value**
Serum Calcium (Before)	9.05 (0.52)	9.79 (0.95)	0.034*
Ionised Calcium (Before)	5.08 (0.34)	5.30 (0.45)	0.204
Serum Calcium (After)	8.07 (0.83)	8.42 (0.79)	0.262
Ionised Calcium (After)	4.65 (0.58)	4.84 (0.45)	0.316
Difference Calcium	0.97 (0.44)	1.37 (0.66)	0.105
Difference Ionised	0.43 (0.27)	0.46 (0.28)	0.795

In present study at the end of 24 hours of phototherapy in subjects with cap mean value of serum calcium 8.07mg/dl, ionised calcium 4.65mg/dl. At the end of 48 hours of phototherapy mean value is serum calcium 8.42mg/dl, ionised calcium 4.84mg/dl, statistically not significant.

Table 5: Association between Hypocalcemia and Duration Phototherapy among No Cap Neonates (N=80)

	24 hrs Mean (SD)	**48 hrs Mean (SD)**	**P Value**
Serum Calcium (Before)	9.13 (0.42)	9.56 (1.00)	0.215
Ionised Calcium (Before)	5.06 (0.49)	5.18 (0.43)	0.504
Serum Calcium (After)	7.95 (0.52)	8.25 (0.61)	0.193

Ionised Calcium (After)	4.64 (0.37)	4.71 (0.36)	0.611
Difference Calcium	1.17 (0.52)	1.31 (0.71)	0.601
Difference Ionised	0.42 (0.33)	0.46 (0.28)	0.710

In present study at the end of 24 hours of phototherapy in subjects without cap mean value of serum calcium 7.95mg/dl, ionised calcium 4.64mg/dl. At the end of 48 hours of phototherapy mean value is serum calcium 8.25mg/dl, ionised calcium 4.71mg/dl, statistically not significant.

Table 6: Association between Hypocalcemia and Duration among Term Neonates (N=80)

	24 hrs Mean (SD)	**48 hrs Mean (SD)**	**P Value**
Serum Calcium (Before)	9.58 (0.46)	10.35 (0.82)	0.033*
Ionised Calcium (Before)	5.60 (0.21)	5.59 (0.25)	0.938
Serum Calcium (After)	8.83 (0.38)	8.92 (0.27)	0.464
Ionised Calcium (After)	5.23 (0.23)	5.10 (0.19)	0.162
Difference Calcium	0.75 (0.48)	1.42 (0.85)	0.069
Difference Ionised	0.36 (0.36)	0.48 (0.30)	0.407

In present study among 40 term at the end of 24 hours of phototherapy mean difference values of serum and ionised calcium is 0.7mg/dl and 0.36mg/dl respectively, at the end of 48 hours mean difference of serum calcium and ionised calcium 1.42mg/dl and 0.48mg/dl respectively.

Table 7: Association between Hypocalcemia and Intervention among Term

	Cap Mean (SD)	**No Cap Mean (SD)**	**P Value**
Serum Calcium (Before)	10.30 (0.76)	10.15 (0.89)	0.568
Ionised Calcium (Before)	5.62 (0.25)	5.55 (0.24)	0.345
Serum Calcium (After)	9.06 (0.20)	8.74 (0.28)	<0.001*
Ionised Calcium (After)	5.21 (0.18)	5.02 (0.16)	0.001*
Difference Calcium	1.24 (0.77)	1.41 (0.92)	0.535
Difference Ionised	0.40 (0.32)	0.52 (0.29)	0.239

In present study among term neonates mean levels of serum calcium in subjects with head covering and without head covering P value is <0.001, statistically significant, mean levels of ionised calcium in subjects with head covering and without head covering P value is 0.001, statistically significant.

Discussion:

This study aimed to evaluate the incidence of hypocalcemia in neonates under phototherapy by intervention of head covering. To compare hypocalcemia at baseline to 24 hours and 48 hours.

The study included 80 neonates Department of Pediatrics, BGS Global Institute of Medical Sciences Hospital, out of which 40 neonates were term, Considering the age-wise distribution of the neonates in study has shown physiological peak incidence of jaundice in term is on 4th day and preterm is on 5th day. Other previous studies have shown physiological peak of serum bilirubin in term neonates on 4th day and preterm in 5th day. This can be attributed to the policy of routine screening for neonatal jaundice at 72 hours of life which was first recommended by Bhutani et al. in 2010.

In present study out of 80 subjects who had neonatal jaundice most common blood group is B positive 43 (53.8%), this can be explained by the most common blood group that is seen universal is B positive.

Among 80 neonates the most common cause of jaundice was physiological exaggerate jaundice 48 (60%), this can be explained by feeding issues and was present in 59 (73.8%) of neonates, followed by OB setting 15 (18.8%), which can be explained by the most common blood group seen in universal, followed by OA setting 11 (13.9%), cephalhaematoma 5 (6.3%) explained by birth injuries being less common in LSCS . The least common cause of jaundice being Rh incompatibility 1 (1.3%) due the prophylactic use of Anti-D immunoglobulin.

A statistically significant reduction in TSB noted in post phototherapy in the study population (p <0.001). This finding is not surprising and is line with existing literature as phototherapy is the gold-standard treatment of NNH.

A statistically significant reduction in serum calcium with mean 9.54mg/dl pre phototherapy, 8.25mg/dl post phototherapy, with p value <0.001. Ionised calcium 5.20 mg/dl pre phototherapy, 4.75mg/dl post phototherapy, with P value <0.001.

However no hypocalcemia was proven, this can be explained by maternal supplementation of calcium from 2nd to 3rd trimester and continuation in postnatal period.

Mean difference in serum calcium and ionised calcium in term vs preterm before starting phototherapy is statistically significant with p value <0.001 which can be explained by maximum transfer of calcium from mother to foetus occurs in last trimester.

In our study there is significant reduction in serum calcium and ionised calcium values in neonates with and without head covering with p value <0.001 in term neonates.

Conclusion

Exaggerated physiological jaundice is the most common cause of jaundice in present study.Not covering of the head showed a statistical significant fall in serum calcium and ionised calcium in term neonates. There was no statistical significance in head covering vs no head covering during phototherapy, but some extent there was reduction of serum calcium and ionised calcium.

The study also highlights the role of head covering along with covering of eyes and genitals during phototherapy as a routine practice.Although none of the study subjects showed clinical/ lab proven hypocalcemia study is

suggestive of need for evaluation of neonates receiving phototherapy for duration longer than 48 hours or on multiple occasions.

There is also need to further evaluate the role of calcium supplementation in conjunction with not covering head during phototherapy.The study shows need to sensitise staff towards possible fall in serum calcium and ionised calcium during phototherapy which becomes more significant in a resource limited setting which is not equipped to identify, evaluate and treat hypocalcemia such as in rural areas.

There is also need to evaluate the role of head covering resulting in prolongation of duration of phototherapy.In conclusion, the fall in serum calcium and ionised calcium seen in the course of this study highlights the need of health personnel to be cautious towards the possibility of hypocalcemia in neonates.

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