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UTILITY OF HEAD CAP ON PHOTOTHERAPY- INDUCED HYPOCALCEMIA IN TERM NEONATES WITH HYPERBILIRUBINEMIA- AN OBSERVATIONAL STUDY

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ABSTRACT

Background: Phototherapy is widely used to treat hyperbilirubinemia in term neonates but can lead to hypocalcemia, a potentially serious side effect. There is a growing interest in simple interventions like the use of head caps during phototherapy to reduce the risk of hypocalcemia.

Aim: To determine the effectiveness of head caps in decreasing phototherapy-induced hypocalcemia in term neonates with hyperbilirubinemia.

Methods: The study was conducted at Shri Sathya Sai Medical College and Research Institute between November 2022 and April 2024, focusing on 120 term neonates requiring phototherapy for hyperbilirubinemia, after excluding 26 based on predefined criteria. Inclusion criteria included term neonates with hyperbilirubinemia, while exclusions applied to neonates under 24 hours old, those with gestation periods less than 37 weeks, and neonates with conditions such as congenital anomalies, hypoxic-ischemic encephalopathy, or born to mothers with specific conditions like diabetes mellitus. Data collection covered baseline characteristics (birth weight, gender, gestational age), phototherapy details (age at initiation, baseline total serum bilirubin, duration), and biochemical parameters (ionized calcium, sodium, potassium) before and after 48 hours of phototherapy. Data were analyzed using Microsoft Excel and SPSS 21.

Results: In the study, Group A had 37 males and 23 females, and Group B had 34 males and 26 females, with no statistically significant gender difference ($p=0.631$). The mean gestational age was comparable between groups (Group A: 37.18 ± 0.49 weeks, Group B: 37.23 ± 0.72 weeks; $p=0.424$). Hypocalcemia incidence was significantly lower in Group B (with head cap) at 6.67% compared to 26.67% in Group A (without head cap) ($p=0.0021$). Serum sodium and potassium levels remained stable before and after phototherapy in both groups.

Conclusion: The study concluded that using a head cap during phototherapy significantly reduces the risk of hypocalcemia in term neonates. Covering the head is a simple, safe, and effective method to prevent phototherapy-induced hypocalcemia, emphasizing the need to monitor calcium levels during treatment.

Keywords: phototherapy, hypocalcemia, hyperbilirubinemia, term neonates, head cap, neonatal care.

INTRODUCTION

Hyperbilirubinemia is a common condition in neonates, particularly in term newborns, often necessitating phototherapy as the treatment of choice. Phototherapy effectively reduces bilirubin levels by converting unconjugated bilirubin into water-soluble isomers that can be excreted without the need for hepatic conjugation [1][2]. Despite its efficacy, phototherapy is not without side effects, with hypocalcemia being one of the significant concerns, potentially leading to complications such as seizures, apnea, and irritability [3][4].

Hypocalcemia during phototherapy is believed to result from light exposure inhibiting the pineal gland's secretion of melatonin, which in turn reduces parathyroid hormone (PTH) secretion, leading to decreased calcium levels [5][6]. The incidence of phototherapy-induced hypocalcemia varies, with studies reporting rates ranging from 10% to 40% in treated neonates [7][8]. Given the potential risks associated with hypocalcemia, it is critical to explore strategies that can mitigate this side effect while maintaining the efficacy of phototherapy.

One such strategy involves the use of head caps during phototherapy. The rationale behind this intervention is that covering the head may protect the pineal gland from light exposure, thereby preventing the suppression of melatonin and subsequent hypocalcemia [9]. This approach is supported by previous studies that have shown a reduction in hypocalcemia incidence when the head is shielded during phototherapy [8][10].

Despite the growing interest in this area, there remains a paucity of large-scale observational studies that evaluate the utility of head caps in preventing phototherapy-induced hypocalcemia in term neonates. This study aims to bridge this gap by assessing the effectiveness of head caps in decreasing the incidence of hypocalcemia among term neonates with hyperbilirubinemia undergoing phototherapy in a tertiary care setting. The findings of this study could have important implications for clinical practice, potentially leading to improved outcomes in neonatal care [11, 12, 13].

This study aims to evaluate the effectiveness of head caps in preventing phototherapy-induced hypocalcemia in term neonates with hyperbilirubinemia. By assessing the incidence of hypocalcemia and comparing it between neonates who received phototherapy with and without head caps, this study seeks to provide evidence for a simple and practical intervention that could be easily implemented in clinical settings.

MATERIALS AND METHODS

Study Design : An observational study
Study Area : NICU, Department of Pediatrics, SSSMCRI
Study Population: 120 ICTERIC neonates were allotted into two groups of 60 neonates. Group A underwent phototherapy without head cap and group B with the
head cap.
Study Duration : 18 months

Sample Size : Sample size calculation based on the previous study (I. Asghar et al.) Induced hypocalcemia in term neonates with hyperbilirubinemia) the mean and standard deviation of both group is 0.57 ± 0.37 and 0.34 ± 0.24 with 80% power and 5% level of significance including 10% non response error is 60 in each group.
Study Tools : Head cap, Phototherapy unit.
Inclusion criteria: Neonates with gestational age>37 weeks (TERM) admitted in
SSSMCRI with hyper-bilirubinemia receiving phototherapy.

Exclusion criteria:

- Neonates with age <24 hrs
- Gestation <37 weeks, (PRETERM)
- Congenital hypothyroidism
- Respiratory distress syndrome or hyaline membrane disease
- Clinical sepsis
- Congenital anomalies
- Hypoxic ischemic encephalopathy
- Serum bilirubin in exchange range
- Newborns with mothers having diabetes mellitus or hyperparathyroidism or on anticonvulsants

Methodology:
This observational study was conducted at Shri Sathya Sai Medical College and Hospital, a tertiary care center in Ammapettai, Tamil Nadu, over 18 months from November 2022 to April 2024. A total of 120 neonates were enrolled after obtaining approval from the Institutional Ethics Committee and written consent from the parents. Neonates younger than 24 hours, those with gestation periods less than 37 weeks, congenital hypothyroidism, respiratory distress syndrome, clinical sepsis, congenital anomalies, hypoxic-ischemic encephalopathy, serum bilirubin in the exchange range, or born to mothers with diabetes mellitus, hyperparathyroidism, or on anticonvulsants were excluded from the study.

The enrolled neonates were divided into two groups: Group A (controls) received phototherapy without a head cap, and Group B (cases) received phototherapy with a head cap covering the entire head, including the occipital area. Baseline characteristics such as birth weight, gestational age, and gender were recorded. Additionally, the age at the start of phototherapy, baseline total serum bilirubin (TSB) levels, and the mean duration of phototherapy were noted. Serum bilirubin levels were reassessed after

24 and 48 hours of phototherapy. Serum ionized calcium, sodium, and potassium levels were measured at the start and after 48 hours of phototherapy.

RESULTS

The study aimed to evaluate the effectiveness of head caps in preventing phototherapy-induced hypocalcemia in term neonates. Conducted between November 2022 and April 2024, the last patient was enrolled on April 24, 2024. Out of 146 newborns approached, 26 were excluded due to study criteria or lack of consent, leaving a final study population of 120 neonates.

A. Baseline characteristics

Gender distribution

The gender distribution of the study and control group is tabulated in

Table 1 Gender distribution of the neonates

GENDER	GROUP A	PERCENTAGE (%)	GROUP B	PERCENTAGE (%)
MALE	37	61.67	34	56.67
FEMALE	23	38.33	26	43.33
P VALUE	0.631			

In group A, 37 male babies and 23 female babies were observed. In group B, 34 male babies and 26 female babies were observed. The male: female ratio overall was 1.4:1. In the study group , the ratio was 1.6 :1 and in the control group ratio was 1. 3:1. This difference however was not statically significant (p=0.631).

B. Age at initiation of phototherapy

The comparison of age in hours among the group was determined and is tabulated in Table2 .

Table 2 Comparison of mean age in hours

Age (Hours)	Group A	Group B
Mean	85.88	87
SD	4.74	4.74
P Value	0.168	

The mean age at initiation of phototherapy in group A was 85.88±4 .74 hours and in group B was 87±4.74 hours. the difference was found to be statistically insignificant (p=0.168).

C. Duration of phototherapy

The mean duration of phototherapy administered is depicted inTable 3.

Table 3 Comparison of mean duration of phototherapy

Duration Of Phototherapy	Group A	Group B
Mean	44.91	45.45
SD	1.91	3.05
P Value	0.191	

In group A, the mean duration of phototherapy is 44.91±1.91 hours and in group B, the mean duration of phototherapy was 45.45±3. 05 hours . Although group B required phototherapy for longer duration, the difference was not significant (p=0. 191).

D. Serum bilirubin values

i. Before starting phototherapy

The mean bilirubin value before phototherapy was determined andtabulated in Table 4 .

Table 4 Comparison of mean bilirubin before phototherapy

Bilirubin Before Phototherapy	Group A	Group B

Mean	20.74	21.05
SD	1.33	1.67
P Value	0.197	

In group A, the mean bilirubin before phototherapy was 20.74±1 .33 mg/dL. In group B, the mean bilirubin before phototherapy was 21. 05± 1.67 mg/ dL. The p-value of mean bilirubin value before phototherapy was 0. 197 which is statistically not significant.

ii At 24 and 48 hours of phototherapy

The comparison of serum bilirubin between before phototherapy and 24 hours and 48 hours is represented in Table 5.

Table 5 Comparison of serum bilirubin at initiation, after 24 hours and48 hours of phototherapy.

Group	Serum Bilirubin			P Value
	Before Pt	24 Hours	48 Hours	
Group A	20.74	12.74	4.74	0.00001
Group B	21.05	13.05	4.94	0.00001

In group A, the mean serum bilirubin before phototherapy was 20.74 mg/ dL, after 24 hours 12. 74 mg/dL and after 48 hours 4. 74 mg/ dL. In group B, the mean serum bilirubin before phototherapy, after 24 and 48 hours of phototherapy was 21. 05 mg/d L, 13.05 mg/d L and 4. 94 mg/d L respectively. The fall in serum bilirubin value after 48 hours of phototherapy was found to be significant (p=0.00001).

E. Serum ionised calcium levels

The serum ical before and after phototherapy were calculated and tabulated in Table6

Table 6 Comparison of serum ical before and after phototherapy

Group	Serum iCal		P Value
	Before Pt	After Pt	
Group A	4.68	4.28	0.0001
Group B	4.72	4.52	0.00012

In group A, the serum ical before phototherapy was 4.68 mg/ dL and the serum ical after phototherapy was 4.28 mg/ dL. In group B, the serum calcium before phototherapy was 4.72 mg/dL and the serum calcium after phototherapy was 4. 52 mg/dL. The p-value of serum calcium before and after phototherapy is < 0.05 statistically significant were observed.

F. Incidence of hypocalcemia

The incidence of hypocalcemia in the two groups is tabulated in table7

Table 7 Incidence of hypocalcemia among groups

GROUP	HYPOCALCEMIA			
	YES	%	NO	%
GROUP A	16	26.67	44	73.33
GROUP B	4	6.67	56	93.33
X2 VALUE	9.411			
P VALUE	0.0021			

16 out of 60 patients in control group (26.67%) and 4 out of 60 patients in the study group. (6.67 %) developed hypocalcemia as shownin fig 1.

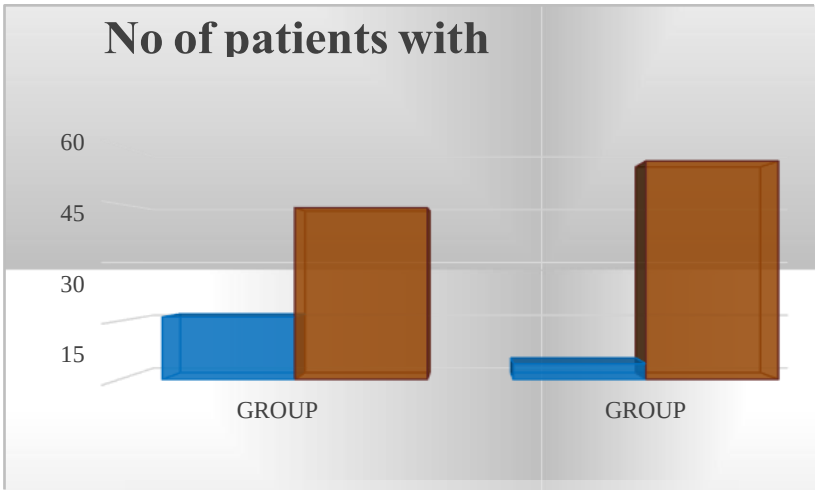

Figure 1 Incidence of hypocalcemia among group

DISCUSSION

Phototherapy is a widely used treatment for neonatal hyperbilirubinemia, a condition commonly encountered in both full-term and preterm infants. While effective in reducing bilirubin levels, phototherapy can lead to significant side effects, including hypocalcemia. Hypocalcemia, if left unaddressed, can result in serious complications such as seizures and cardiac dysfunction. Despite the established risk of hypocalcemia associated with phototherapy, the potential protective role of interventions like head caps remains underexplored. This study seeks to fill this gap by evaluating whether the use of head caps during phototherapy can effectively reduce the incidence of hypocalcemia and its impact on serum electrolyte levels.

Phototherapy has been shown to cause hypocalcemia in both full-term and preterm infants, with a well-established association between the two. However, evidence on the effectiveness of using head caps to prevent hypocalcemia during phototherapy is limited and inconclusive. This study aimed to assess the impact of head caps in reducing phototherapy-induced hypocalcemia and their effect on serum sodium and potassium levels.

The study included 120 newborns, with a gender distribution of 71 males (59.1%) and 49 females (40.8%). This gender ratio aligns with most literature, where more males are enrolled than females, as seen in studies by Raji et al. (1.2:1), Ezzeldi et al. (1.2:1)[14], and Asghar et al. (1.3:1)[15] . However, Karger et al. [16]reported a higher enrollment of female neonates (44.4% male to 55.6% female).

In our study, the mean TSB at the start of phototherapy was 20.74 mg/dL for Group A and 21.05 mg/dL for Group B. These values are consistent with those reported by Asghar et al., [17]where the mean TSB was 20.30 mg/dL in the control group and 20.34 mg/dL in the study group. In contrast, a study by Raja et al. [18] in India found slightly lower mean TSB values of 16.53 ± 1.95 mg/dL in controls and 16.4 ± 1.97 mg/dL in cases, likely due to earlier detection of jaundice as the study included only NICU admissions.

In a study by Ehsanipour F et al. (2008), a significant difference in hypocalcemia prevalence was observed between full-term neonates undergoing phototherapy without a cap (77.77%) and those with a cap (22.22%) [19]. Similar findings were reported by Nouh et al. (2013) in Egypt, where 29% of uncovered and 15.6% of covered neonates developed hypocalcemia [20]. Kargar M et al. (2014) in Iran also found a notable difference, with 38.8% of the control group and 13.8% of the case group developing hypocalcemia after phototherapy [21]. Ezzeldin Z et al. (2015) in Cairo reported a 9.7% incidence of hypocalcemia in the capped group versus 24.2% in the uncapped group, a statistically significant difference [14]. Similarly, Samane et al. (2016) found a significantly lower frequency of hypocalcemia in preterm infants receiving phototherapy with caps compared to those receiving conventional phototherapy [20].

Similar results were found by Barekatain et al. (2016) in Isfahan, Iran [22]. In a randomized controlled study in Assiut, Egypt, Bayomy AM et al. (2017) reported hypocalcemia in 48.6% of neonates without a

head cap and 20% with a head cap, showing a significant difference between the groups [23]. Elsayed et al. (2017) also found a statistically significant difference in Egypt, with hypocalcemia occurring in 24% of uncovered neonates and 12% of those with hats [24]. In India, Siddiqui et al. (2018) reported hypocalcemia in 27.6% of neonates without a cap and 10.5% with a cap, confirming significant differences [25]. Raji et al. (2018) also found a significant difference, with 45.3% of controls and 20% of cases developing hypocalcemia in another Indian study [26].

Our study also assessed whether using a head cap reduces the incidence of hyponatremia or hypokalemia. Although evidence exists linking phototherapy to hyponatremia, there is no established association with hypokalemia. Our findings did not show any significant impact of head cap use on serum sodium or potassium levels during phototherapy.

CONCLUSION

Neonates receiving phototherapy without a head covering had a significantly lower blood calcium level than those receiving one, although the risk of hypocalcemia was not statistically significant. For icterus neonates, covering one's head during phototherapy is a suitable and secure way to avoid phototherapy-induced hypocalcemia. Since wearing a helmet helps avoid hypocalcemia, it's critical to keep an eye on calcium levels when receiving phototherapy.

Ethical Clearance :
Ethical Clearance Certificate was obtained from the Institutional Ethics Committee(IEC) prior to commencement of study

Conflict of Interest : Nil - No conflict of interest
Source of funding : Self

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