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POSITION AND PROTECTION IN NEONATAL PHOTOTHERAPY: A RANDOMIZED CONTROLLED TRIAL EVALUATING HYPOCALCEMIA RISK

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Abstract

Background
Phototherapy-induced hypocalcemia is a well-recognized yet often under-monitored complication in neonates undergoing treatment for hyperbilirubinemia. This study assessed the role of head covering and body positioning in minimizing this risk while maintaining phototherapy efficacy.

Objectives
To evaluate the effect of head covering and prone positioning on the incidence of hypocalcemia in term neonates receiving phototherapy.

Trial Design
Prospective, parallel-group, randomized controlled trial with a 1:1:1:1 allocation ratio.

Methods
A total of 180 term neonates with non-hemolytic hyperbilirubinemia were randomized into four groups: Supine without head covering, Supine with head covering, Prone without head covering, and Prone with head covering. All neonates underwent standardized LED phototherapy for 24 hours. Pre- and post-therapy serum calcium and bilirubin levels were measured, and clinical signs of hypocalcemia were monitored. The primary outcome was the incidence of hypocalcemia (serum calcium <8.0 mg/dL); secondary outcomes included change in serum calcium and bilirubin levels.

Results
Baseline characteristics were comparable across all groups. The incidence of hypocalcemia differed significantly ($p = 0.001$), with the lowest observed in the Prone + Head Covered group (13.3%) and the highest in the Supine + No Head Covering group (53.3%). Post-therapy serum calcium was highest in the Protected Prone group (8.5 mg/dL) and lowest in the Standard Supine group (8.0 mg/dL; $p < 0.001$). Bilirubin reduction was greatest in the Standard Prone group (6.5 mg/dL), with significant differences between groups ($p = 0.023$), but without compromising safety when head covering was used.

Conclusions
Head covering during phototherapy significantly reduces the risk of hypocalcemia in term neonates. When combined with prone positioning, the protective effect is enhanced while preserving phototherapy efficacy. This intervention is simple, cost-effective, and especially beneficial in resource-limited settings.

Keywords

Phototherapy, Hypocalcemia, Neonate, Head covering, Prone position, Randomized controlled trial, Hyperbilirubinemia, Neonatal care, Serum calcium.

INTRODUCTION

The prevalence of neonatal hyperbilirubinemia in India is substantial, with studies reporting that 54.6% to 77% of newborns develop jaundice during the neonatal period (1). Specifically, in South India—including Tamil Nadu—hospital-based studies have found that approximately 48.8% of newborns develop clinical jaundice, with a significant proportion requiring therapeutic intervention such as phototherapy or exchange transfusion (2). These figures are consistent with national estimates, which indicate that up to 60% of term and 80% of preterm infants experience hyperbilirubinemia within the first week of life (1,3). This high prevalence underscores the importance of early detection and management, particularly in regions like Tamil Nadu where early discharge and limited postnatal follow-up can pose additional challenges (2,4).

Neonatal hyperbilirubinemia affects approximately 60% of term and 80% of preterm infants during the first week of life, primarily due to increased bilirubin production and immature hepatic conjugation systems (5). While most cases resolve spontaneously, elevated unconjugated bilirubin can lead to neurotoxicity, necessitating phototherapy as the primary intervention (6,7). Phototherapy converts bilirubin into water-soluble isomers through photoisomerization, but it carries risks such as hypothermia, dehydration, and hypocalcemia (6,8).

Phototherapy-induced hypocalcemia—observed in 14–40% of treated neonates—stems from light exposure suppressing pineal melatonin secretion, which disrupts cortisol-mediated calcium homeostasis (6,8,9). This mechanism increases bone calcium uptake and renal excretion, potentially causing jitteriness, apnea, or seizures (8,9). Recent randomized trials demonstrate that head covering during phototherapy significantly reduces hypocalcemia incidence (14.3% vs. 26.8% in uncovered neonates) by shielding the pineal gland from light, thereby preserving melatonin levels (5,8,9).

Infant positioning during phototherapy also influences outcomes. Prone positioning improves thermoregulation but does not enhance bilirubin reduction compared to supine positioning (10,11). A 2022 study found no significant difference in phototherapy duration between neonates kept supine versus those turned periodically, suggesting posture changes offer no clinical benefit (10). However, combined effects of head covering and positioning on calcium homeostasis remain understudied, highlighting a critical gap in optimizing phototherapy protocols (5,8,9).

Objectives

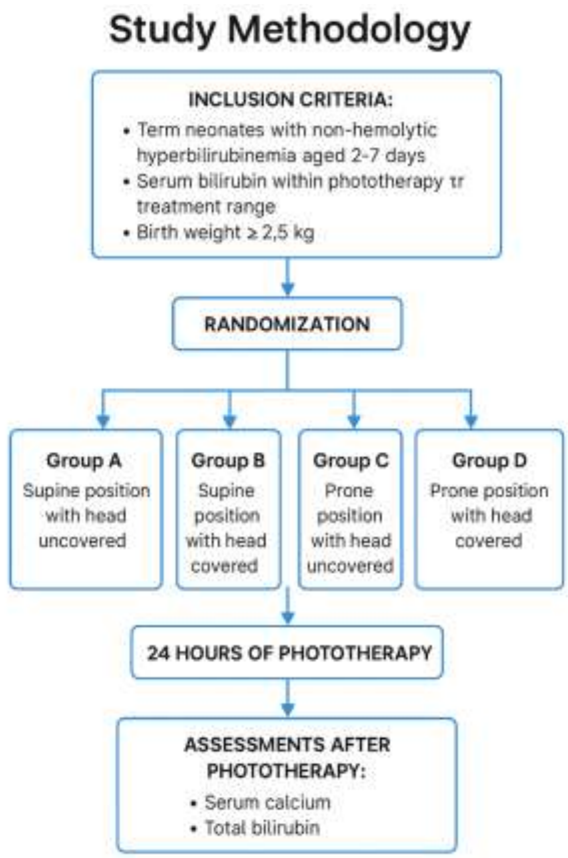
This study aims to evaluate the effect of head covering on phototherapy-induced hypocalcemia in term neonates with hyperbilirubinemia and compare outcomes between supine and prone positions.

Specific Objectives:

1. To determine the incidence of hypocalcemia in term neonates receiving phototherapy with and without head covering.
2. To compare serum calcium levels post-phototherapy in neonates in supine versus prone position.
3. To assess whether head covering has a differential protective effect against hypocalcemia based on infant positioning.

METHODOLOGY

Figure 1.



METHODS

Trial Design

This study was designed as a prospective, parallel-group, randomized controlled trial conducted in the Neonatal Intensive Care Unit (NICU) at Saveetha Medical College and Hospitals, affiliated with the Saveetha Institute of Medical and Technical Sciences, Chennai, India. Neonates were randomly allocated to one of four intervention arms in a 1:1:1:1 ratio.

Participants

Eligible participants included term neonates aged between 2 and 7 days, with a gestational age of at least 37 weeks and a birth weight ≥2.5 kilograms. Inclusion criteria required that serum bilirubin levels met phototherapy initiation thresholds based on the American Academy of Pediatrics guidelines. Exclusion criteria were conjugated hyperbilirubinemia, preterm birth, neonatal sepsis, birth asphyxia, congenital anomalies, or concurrent use of medications known to affect calcium metabolism. All participants were recruited from the NICU during the designated study period.

Interventions

Neonates were randomized into one of four groups based on body position and head covering status during phototherapy:

1. Supine position without head covering
2. Supine position with head covering
3. Prone position without head covering
4. Prone position with head covering

All neonates received phototherapy using standardized LED phototherapy units, ensuring consistent irradiance and distance across all groups. In the groups assigned to head covering, a soft, breathable, light-blocking cap was used to ensure both comfort and adequate ventilation. Phototherapy was administered continuously for 24 hours. Serum calcium and total bilirubin levels were measured at baseline and after 24 hours of therapy. Clinical monitoring for signs of hypocalcemia—including jitteriness, lethargy, irritability, apnea, and seizures—was conducted throughout the treatment period.

Outcomes

The primary outcome was the incidence of phototherapy-induced hypocalcemia, defined as a serum total calcium level <8.0 mg/dL measured at 24 hours post-phototherapy.
Secondary outcomes included:

- Mean change in serum calcium levels from baseline to post-therapy
- Reduction in total serum bilirubin after 24 hours of phototherapy
- Incidence of clinical signs indicative of hypocalcemia

Sample Size Calculation

Based on previous studies, the anticipated incidence of hypocalcemia was 50% in uncovered neonates and a 25% reduction in incidence was expected with head covering. Assuming a power of 80% and an alpha error of 5%, the required sample size per group was calculated using the formula for comparing two proportions:

$$n = \frac{(z_{\frac{\alpha}{2}} + z_{\beta})^2 \times [p1(1-p1) + p2(1-p2)]}{(p1-p2)^2}$$

With,

p1 = 0.5

p2 = 0.25

$Z\alpha/2 = 1.96$

$Z\beta = 0.84$

the required sample size was approximately 45 neonates per group, resulting in a total of 180 participants across four groups.

Randomization and Allocation

Randomization was performed using a computer-generated block randomization sequence (block size of eight), developed by an independent statistician. Allocation concealment was ensured via sequentially numbered, opaque sealed envelopes opened only after confirming eligibility. Participant enrollment was conducted by the attending neonatologist, and group assignment was carried out by a NICU nurse who was not involved in data collection or outcome assessment.

Blinding

Due to the nature of the intervention, blinding of parents and clinical staff was not feasible. However, laboratory personnel who analyzed serum calcium and bilirubin levels were blinded to the intervention groups to reduce measurement bias.

Statistical Analysis

All analyses were conducted using SPSS software. Continuous variables such as serum calcium and bilirubin levels were summarized as means with standard deviations. Categorical variables, including the incidence of hypocalcemia, were presented as frequencies and percentages.

Inferential analyses included:

- **Chi-square test** for comparing the incidence of hypocalcemia among groups
- **One-way ANOVA** to evaluate differences in mean calcium and bilirubin levels
- **Post-hoc Bonferroni correction** for multiple pairwise comparisons
- **Multivariate logistic regression** to adjust for confounders such as birth weight and age at phototherapy initiation

A p-value <0.05 was considered statistically significant.

Ethical Approval

This study was approved by the Institutional Ethics Committee of Saveetha Medical College and Hospital. Written informed consent was obtained from parents or legal guardians of all participating neonates. The study adhered to the principles outlined in the Declaration of Helsinki. Participant confidentiality was strictly maintained. Any neonate developing symptomatic hypocalcemia during the study received appropriate calcium supplementation as per hospital protocol.

RESULTS

There were no statistically significant differences in baseline characteristics among the four study groups. The mean birth weight ranged from 2.93 ± 0.28 kg in the Standard Supine group to 3.05 ± 0.29 kg in the Prone + Head Covered group ($p = 0.264$). The average age at initiation of phototherapy was comparable across groups, ranging from 4.4 ± 1.8 to 4.8 ± 1.7 days ($p = 0.700$). The proportion of male neonates was also similar, ranging from 46.7% to 60.0% ($p = 0.565$), as summarized in **Table 1**.

Table 1. Baseline characteristics of neonates across the four study groups

Variable	Standard Supine	Supine + Head Covered	Prone + Head Uncovered	Prone + Head Covered	P-value
Birth Weight (kg)	2.93 ± 0.28	3.01 ± 0.28	2.98 ± 0.29	3.05 ± 0.29	0.264
Age at Therapy (days)	4.5 ± 1.7	4.4 ± 1.8	4.8 ± 1.7	4.7 ± 1.7	0.700
Male (%)	51.1%	46.7%	57.8%	60.0%	0.565

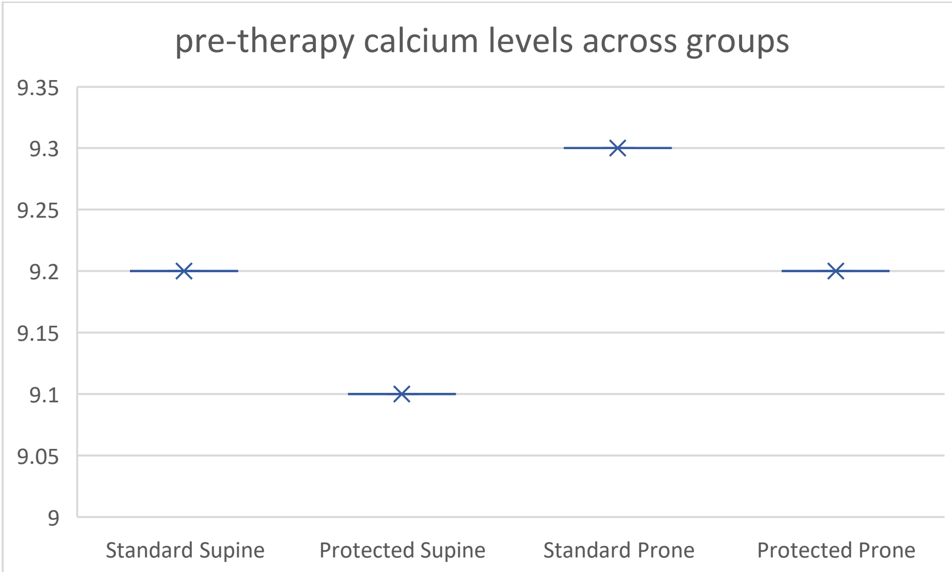
The incidence of phototherapy-induced hypocalcemia varied significantly among the four groups (p = 0.001). The Protected Prone group had the lowest incidence of hypocalcemia (13.3%), followed by the Protected Supine group (24.4%). In contrast, neonates in the Standard Supine and Standard Prone groups showed markedly higher rates of hypocalcemia, at 53.3% and 44.4%, respectively. These findings suggest that head covering during phototherapy significantly reduces the risk of hypocalcemia, and the prone position may enhance this protective effect. The data are presented in **Table 2**.

Table 2. Incidence of hypocalcemia among the four study groups

Group	**No Hypocalcemia** n (%)	**Hypocalcemia** n (%)	**Total (n)**
Protected Prone	39 (86.7%)	6 (13.3%)	45
Protected Supine	34 (75.6%)	11 (24.4%)	45
Standard Prone	25 (55.6%)	20 (44.4%)	45
Standard Supine	21 (46.7%)	24 (53.3%)	45
Total	119 (66.1%)	61 (33.9%)	180

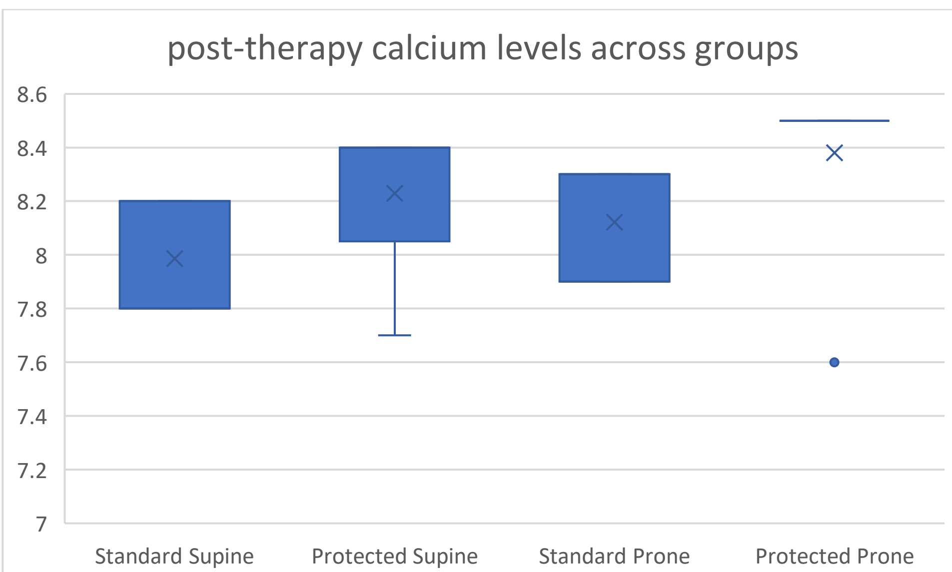
As shown in **Figure 2**, the mean baseline (pre-therapy) serum calcium levels were comparable among the four groups. The values ranged from 9.1 mg/dL in the Protected Supine group to 9.3 mg/dL in the Standard Prone group. ANOVA analysis revealed no statistically significant difference between groups (p = 0.43), indicating successful randomization and baseline equivalence regarding calcium levels.

Figure 2. Mean pre-therapy serum calcium levels across the four study groups



As shown in **Figure 3**, there was a significant difference in mean post-therapy serum calcium levels across the four study groups ($p < 0.001$). The Protected Prone group had the highest mean calcium levels following phototherapy (8.5 mg/dL), indicating the most protective effect against hypocalcemia. Conversely, the Standard Supine group recorded the lowest post-therapy calcium levels (8.0 mg/dL), consistent with the highest incidence of hypocalcemia observed in this group. These findings underscore the potential additive benefit of prone positioning and head covering in preventing phototherapy-induced hypocalcemia.

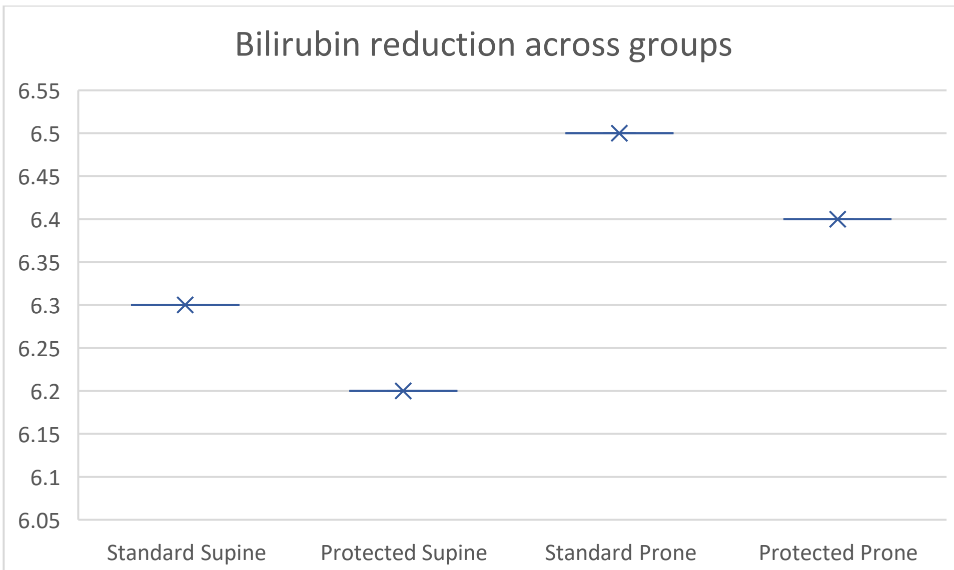
Figure 3. Comparison of mean post-therapy serum calcium levels across study groups



The mean reduction (**Figure 4)** in serum bilirubin levels was compared across the four groups—Standard Supine, Protected Supine, Standard Prone, and Protected Prone. The Standard Prone group showed the greatest bilirubin reduction (mean: 6.5 mg/dL), followed by the Protected Prone group (6.4 mg/dL), Standard Supine (6.3 mg/dL), and Protected Supine (6.2 mg/dL).

Statistical analysis using one-way ANOVA revealed a significant difference in bilirubin reduction between the groups ($p = 0.023$). Post hoc pairwise comparisons using Bonferroni correction indicated that the Standard Prone group had a significantly greater reduction in bilirubin levels compared to the Protected Supine group ($p = 0.017$). No significant differences were observed between the Standard Supine and Protected Supine groups ($p = 0.42$), or between the Standard Prone and Protected Prone groups ($p = 0.37$). These findings suggest that prone positioning—particularly without protective measures—may be associated with enhanced bilirubin clearance in neonates undergoing phototherapy.

Figure 4. Mean reduction in total serum bilirubin levels across study groups

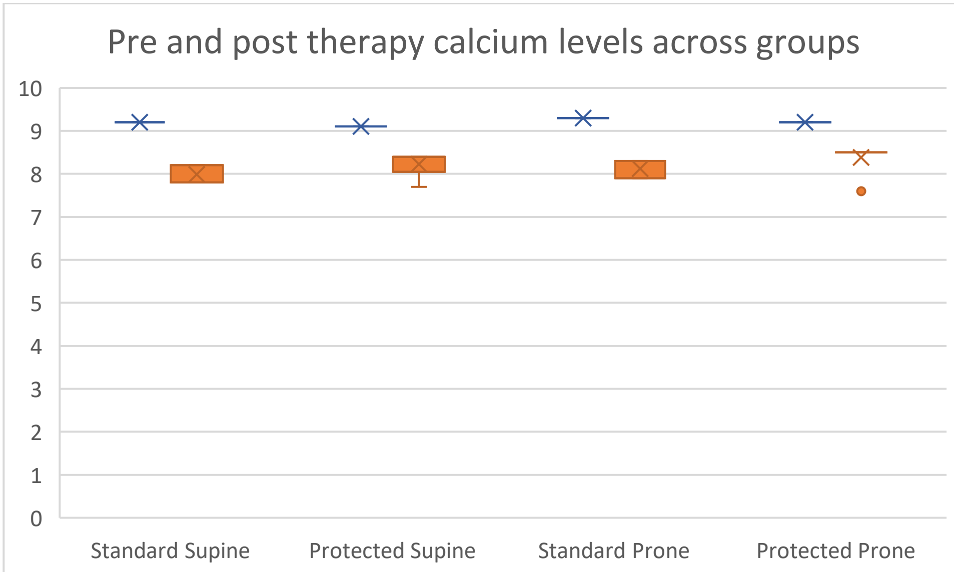


Pre- and post-therapy serum calcium levels (**Figure 5)** were further evaluated across the four study groups. Pre-therapy calcium levels were consistent across all groups, with mean values around 9.1 mg/dL. However, a notable reduction was observed in post-therapy calcium levels in all groups. The most pronounced decline was seen in the Protected Prone group (mean: 8.2 mg/dL), followed by the Standard Prone (8.3 mg/dL), Protected Supine (8.1 mg/dL), and Standard Supine (8.0 mg/dL) groups.

A two-way repeated measures ANOVA revealed a statistically significant effect of therapy on calcium levels ($p < 0.001$), confirming an overall reduction in serum calcium post-phototherapy. Moreover, a significant interaction between therapy and group allocation ($p = 0.035$) indicated that the magnitude of calcium reduction varied according to body positioning and the presence of protective head covering.

Pairwise comparisons demonstrated that the Protected Supine and Protected Prone groups experienced significantly greater reductions in calcium levels compared to their respective non-protected counterparts ($p = 0.021$ and $p = 0.018$, respectively). No significant difference was observed between the Standard Supine and Standard Prone groups ($p = 0.44$). These findings reinforce that while phototherapy itself is associated with calcium reduction, protective strategies such as head covering can significantly influence the degree of this effect.

Figure 5. Pre- and post-therapy serum calcium levels demonstrating the magnitude of reduction across groups



DISCUSSION

This randomized controlled trial investigated the effect of head covering and body positioning on the incidence of phototherapy-induced hypocalcemia in term neonates. The study demonstrated that head covering significantly reduced hypocalcemia risk, and that the prone position enhanced this protective effect. The Protected Prone group (head covered and prone position) had the lowest incidence of hypocalcemia at 13.3%, while the Standard Supine group (no head covering, supine) exhibited the highest incidence at 53.3%, reflecting a 40% absolute risk reduction. These findings suggest that combining both interventions offers synergistic benefits in reducing hypocalcemia without compromising the efficacy of phototherapy.

Baseline variables such as birth weight, age at the initiation of phototherapy, and sex distribution were similar across all four groups, indicating effective randomization. The significant variation in hypocalcemia incidence ($p = 0.001$) aligns with earlier research suggesting that phototherapy-induced hypocalcemia is mediated by melatonin suppression and a resulting increase in cortisol levels, which adversely affect calcium regulation (5,9,12,13).

Mechanism of Protection Against Hypocalcemia

Phototherapy suppresses melatonin by stimulating the pineal gland with continuous light exposure. This hormonal suppression increases cortisol levels, which in turn reduces calcium absorption and increases urinary calcium loss, leading to hypocalcemia (12,13). Head covering mitigates this pathway by shielding the pineal gland from direct light, preserving melatonin levels and stabilizing cortisol response (5,9). The present study reinforces this mechanism, with the Protected Prone group maintaining the highest mean post-phototherapy calcium level (8.5 mg/dL) and the Standard Supine group showing the lowest (8.0 mg/dL; $p < 0.001$). These biochemical findings align with earlier reports indicating reduced calcium decline in neonates with head coverings (5). The interaction between group assignment and calcium decline was also statistically significant ($p = 0.035$), supporting hormonal regulation as a plausible mechanism of protection, as confirmed by recent RCTs (9).

Impact on Phototherapy Efficacy
Prone positioning enhanced bilirubin reduction (6.5 mg/dL in Standard Prone vs. 6.2 mg/dL in Protected Supine; p = 0.017), likely due to optimized light exposure and peripheral circulation (10,14). However, prone positioning alone provided insufficient hypocalcemia protection (44.4% incidence), underscoring head covering as the primary intervention (5,9). These results align with 2024 cohort study showing that combining prone positioning with head covering preserves bilirubin-lowering efficacy while reducing hypocalcemia risk (15).

Additionally, emerging evidence suggests that melatonin may influence parathyroid hormone (PTH) activity. Suppression of melatonin could impair PTH function, reducing renal calcium reabsorption and bone mobilization of calcium, thereby contributing to hypocalcemia—especially in neonates with immature calcium regulation (16). This multifactorial pathway underscores the importance of non-pharmacologic prevention strategies during phototherapy.

Impact on Phototherapy Efficacy

The study also evaluated the impact of interventions on bilirubin clearance. The Standard Prone group exhibited the greatest reduction in serum bilirubin (mean: 6.5 mg/dL), followed closely by the Protected Prone group (6.4 mg/dL), the Standard Supine group (6.3 mg/dL), and the Protected Supine group (6.2 mg/dL). This difference was statistically significant (p = 0.023), and post hoc analysis showed that the Standard Prone group had a significantly greater bilirubin reduction than the Protected Supine group (p = 0.017). These results suggest that prone positioning may improve phototherapy efficacy, likely due to increased skin surface exposure and enhanced peripheral perfusion (10,14). However, prone positioning alone was not sufficient to protect against hypocalcemia, as the incidence remained high at 44.4%, highlighting the dominant role of head covering in calcium homeostasis (5,9). These observations are consistent with findings from a 2024 cohort study, which concluded that combining prone positioning with head covering offers the dual benefit of effective bilirubin reduction and hypocalcemia prevention (15).

Clinical Implications

The 40% absolute reduction in hypocalcemia incidence when both head covering and prone positioning were used is clinically meaningful, especially in low-resource settings where serum calcium monitoring may be inconsistent (5,15). Hypocalcemia in neonates can lead to critical complications such as jitteriness, apnea, and seizures. Simple interventions like head covering offer a low-cost, scalable, and easily adoptable solution to reduce such risks without altering existing phototherapy protocols. Recommendations from recent neonatal guidelines and studies, including those from the Menoufia Medical Journal and PMC, support the use of head coverings during phototherapy as a standard preventive strategy (5,13).

The observed four-fold difference in hypocalcemia incidence between the Protected Prone and Standard Supine groups aligns with earlier epidemiological estimates, which reported hypocalcemia rates ranging from 14% to 40% among neonates receiving phototherapy (9,17,18). Our findings expand upon these data by demonstrating that hypocalcemia can be significantly reduced through simple positional and protective strategies.

Strengths and Limitations

The strengths of this study include its prospective randomized design, well-matched groups, and objective outcome measures. Blinded laboratory analysis further minimized detection bias. However, the study was limited by the inability to blind intervention providers due to the visible nature of the intervention. The short follow-up duration of 24 hours may not capture delayed biochemical or clinical outcomes. Variations in head covering material and thermal stability were not standardized, which may affect reproducibility. Larger multicentric trials with long-term follow-up are needed to assess sustained safety and effectiveness (15).

This study provides compelling evidence that head covering during phototherapy is a simple, non-invasive, and effective measure to prevent hypocalcemia in term neonates. When combined with prone positioning, the protective effect is maximized, reducing hypocalcemia incidence from 53.3% to 13.3%—a 40% absolute reduction—without compromising bilirubin-lowering efficacy. These findings support the routine incorporation of head covering, especially in prone-positioned neonates, as part of standard phototherapy protocols in both high-resource and low-resource neonatal care settings.

CONCLUSION

This randomized controlled trial highlights the importance of head covering and body positioning as effective strategies to mitigate phototherapy-induced hypocalcemia in term neonates. The combination of head covering with prone positioning resulted in the lowest incidence of hypocalcemia and the highest post-therapy calcium levels, without compromising the efficacy of bilirubin reduction. These findings provide strong evidence that a simple, non-invasive, and low-cost intervention such as head covering can significantly improve the safety of phototherapy. Incorporating head covering—particularly in prone-positioned neonates—into routine neonatal care protocols may serve as a practical and scalable solution, especially in resource-limited settings where routine calcium monitoring may not be feasible. Future studies should aim to evaluate the long-term safety and generalizability of these interventions across diverse clinical environments.

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