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Original Article

Efficacy and Safety of White Cotton Cover Around Phototherapy Unit in Term Jaundiced Neonate at a Tertiary Care Teaching Institute: An Open Label Randomised Controlled Trial

RM ***Meshram***, P ***Sachdev***

Abstract ***Background:*** Phototherapy is a promising treatment modality for neonatal jaundice; however, its utility is limited in low- and middle-income nations with a high burden of the disease. ***Objectives:*** To compare the efficacy and safety of a single-surface phototherapy unit covered with a white cotton curtain against a conventional single-surface phototherapy unit. ***Methods:*** An open-label, randomised controlled trial was conducted on 200 full-term neonates with significant hyperbilirubinemia at the Neonatal Intensive Care Unit of a tertiary care teaching institute in central India over a period of one year. A computer-generated randomisation technique was used to allocate 100 neonates each to the experimental and control groups. Experimental group neonates were exposed to a single-surface phototherapy unit covered by a white cotton curtain, whereas control group neonates were treated using a conventional single-surface phototherapy unit. Demographic, maternal, and neonatal data were collected. Total serum bilirubin (TSB) was assessed at the initiation of phototherapy, at 6, 12, and 24 hours, and 24 hours post-discontinuation of phototherapy. The rate of bilirubin decline, duration of phototherapy, and adverse side effects were observed. The independent 't'-test, Mann-Whitney U test, Chi-square test, and Fisher's exact test were used for intergroup comparisons. ***Results:*** Maternal/neonatal demographics, gestational age, birth weight, Apgar scores, and baseline TSB levels were comparable between the groups. The mean TSB in the experimental group at 6, 12, and 24 hours, as well as 24 hours post-discontinuation, was statistically significantly lower than that of the control group ($p<0.0001$). The mean duration of phototherapy was significantly shorter in the experimental group (13.69±5.35 hours) than in the control group (16.26±6.89 hours; $p=0.003$). The rate of bilirubin decline was significantly higher in the experimental group at all evaluated time points ($p<0.001$). No major adverse events were noted, except for mild hyperthermia in three neonates within the experimental group. ***Conclusion:*** Utilising a white cotton curtain around a phototherapy unit significantly increases its therapeutic efficacy among full-term neonates with hyperbilirubinaemia.

Key words Curtains; Full term neonates; Hyperbilirubinaemia; Jaundice; Phototherapy

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Introduction

In the first week of life, more than 80% neonates exhibit some degree of jaundice, making it the most common clinical condition requiring hospital admission and re-admission.[1] Approximately 80% of preterm and 60% of term infants develop jaundice.[2,3] Physiologically, bilirubin is generally harmless and acts as an antioxidant,

yet it requires careful clinical monitoring. However, when total serum bilirubin exceeds the >95th percentile for age during the first week of life, it can become highly neurotoxic. The physiological impact of bilirubin on a neonate depends on various compounding factors, including gestational age, chronological age at onset, and associated comorbidities such as sepsis, birth asphyxia, or acidosis, which can disrupt the blood-brain barrier.[4-7]

A recent systematic review reported that the prevalence of significant jaundice ranges from 0.73% to 3.34% across the WHO region in hospitalised neonates, with jaundice-related mortality ranging from 0% to 1.49%, peaking in the African and Eastern Mediterranean regions.[8] In India, the incidence of significant jaundice requiring intervention varies widely by clinical setting; however, a recent cohort study reported that 22.2% of neonates in the Indian subcontinent experienced severe hyperbilirubinaemia compared to only 4.8% in Europe.[9] In a subset of infants, untreated significant hyperbilirubinaemia allows unconjugated bilirubin to cross the blood-brain barrier and deposit in basal ganglia neurons. This induces acute bilirubin encephalopathy, which can lead to permanent neurological damage, kernicterus, or death.[7,10,11] Therefore, early detection and efficient management are crucial to intercepting this pathological cascade before permanent injury occurs.

Earlier in this century, Indian traditional practitioners frequently placed naked, jaundiced infants in direct sunlight. Later, R.H. Dobbs and his resident Richard Cremer (1958) scientifically demonstrated that both sunlight and artificial blue light significantly decrease bilirubin levels in newborns.[2,12] The primary photochemical mechanisms of phototherapy include photoisomerisation, structural isomerisation (to lumirubin), and photooxidation, which collectively convert toxic bilirubin into water-soluble structural isomers that can be excreted in bile and urine without hepatic conjugation.[13]

The clinical effectiveness of phototherapy depends on the wavelength of light, irradiance spectral intensity, duration of exposure, and total exposed body surface area. The dose-response relationship dictates that higher spectral irradiance (30-40 μw/cm²/nm), optimal blue-green spectrum (430-490 nm), continuous exposure, and maximised skin surface exposure yield faster bilirubin clearance.[14-16] Although universally recognised as the gold-standard treatment for neonatal jaundice, phototherapy can elicit serious short- and long-term adverse effects. These include dehydration, diarrhoea, thermal instability, haemodynamic alterations, skin irritation, retinal damage, bronze baby syndrome, and theoretical concerns regarding DNA damage or long-term oncogenic risks.[16-19]

While phototherapy is an established and promising treatment modality globally, its regular accessibility is constrained in low- and middle-income countries due to an overwhelming disease burden. Cost-effective, high-efficiency modifications are required to minimise treatment duration and hospital turnaround times. Various modifications, such as light-emitting diodes, compact fluorescent tubes (CFLs), and reflecting curtains, have been evaluated.[20,21] Hanging a simple white cotton curtain around a conventional phototherapy unit represents an affordable, easily implemented, and highly accessible modification. This adjustment could optimise care in resource-limited facilities at primary or secondary healthcare levels.[22-24] Therefore, this study was designed to evaluate the therapeutic efficacy and safety of a single-surface phototherapy unit modified with surrounding white cotton curtains compared to a conventional single-surface phototherapy setup.

Methods

Study Design, Setting and Duration

This academic, open-label randomised controlled trial was conducted in the Neonatal Intensive Care Unit (NICU) of a tertiary care teaching institute in central India over a 12-month period (February 2024 to January 2025).

Study Population, Randomisation and Blinding

Full-term neonates presenting with significant hyperbilirubinaemia – defined according to the guidelines of the American Academy of Pediatrics (AAP)[25] – were screened. Eligible participants were enrolled and allocated using a computer-generated randomisation sequence. Due to the nature of the physical intervention, blinding was not feasible.

Inclusion Criteria

- Neonates of either sex with gestational age ≥37 weeks and a birth weight >2.5 kg
- Chorological age between > 48 hours and <10 days
- Apgar score >6 at 5 minutes
- Significant hyperbilirubinaemia meeting AAP phototherapy thresholds

Exclusion Criteria

- Neonates with Rh or ABO haemolytic diseases
- Neonates presenting with critical hyperbilirubinaemia requiring exchange transfusion.
- Evidence of active haemolysis on peripheral blood smear, positive Direct Coomb's test (DCT), or G6PD deficiency.
- Conjugated hyperbilirubinaemia (direct bilirubin >20% of total serum bilirubin)
- Neonates with systemic sepsis, birth asphyxia or major congenital anomalies.
- Prior or concurrent administration of phenobarbital or traditional herbal medications.

Sample Size

The minimum sample size of 192 was estimated based on the prevalence of hyperbilirubinaemia reported in literature using following assumptions and formula.

$$n = \frac{\left\{ Z_{(1-\alpha/2)} \sqrt{2\bar{P}(1-\bar{P})} + Z_{(1-\beta)} \sqrt{P_1(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

- Where, $\bar{P} = (P_1 + P_2) / 2$
- $P_1 = 0.60$ (proportion of outcome in unexposed group)
- $P_2 = 0.80$ (proportion of outcome in exposed group)
- Ratio of unexposed to exposed = 1.3, expected odds ratio = 2.6
- Significance level (1-α) = 5% (Z1α/2) = 1.96)
- Statistical power (1-beta) = 80% (Z1-beta = 0.84)

To account for potential dropouts, a final sample size of 200 neonates (100 in the experimental group and 100 in the control group) was targeted.

Data Collection

Eligible neonates were randomised immediately following screening. Baseline maternal, neonatal, demographic data, and feeding histories were detailed. Every neonate underwent a thorough clinical examination within a thermoneutral environment under optimal illumination to rule out underlying sepsis, malformations, or red-flag clinical signs.

A 3 ml of venous blood sample was drawn from each participant for primary haematological and biochemical workups. Serum bilirubin quantification was performed using a timed end-point Diazo method at the central biochemistry laboratory at baseline, and at 6, 12, 24, and 48 hours following the initiation of phototherapy, as well as 24 hours post-discontinuation.

During the intervention, both groups were monitored for clinical adverse events (hyperthermia, skin rashes, dehydration) by the on-duty paediatric resident and researcher every 6 hours. Axillary temperature was recorded using a digital thermometer. Clinical dehydration was defined by the presence of oliguria (urine output <1 ml/kg/h), a capillary refill time >3 seconds, or a sunken anterior fontanelle. Standard supportive neonatal care, including demand breastfeeding, was maintained uniformly across both cohorts.

Interventions

- **Experimental Group:** Neonates were treated under a single-surface phototherapy unit enclosed by a white cotton curtain (150 GSM - 200 cm X 100 cm) draped around the frame.
- **Control Group:** Neonates were treated under an identical conventional single-surface phototherapy unit without any surrounding drapes.

Both phototherapy configurations were manufactured by NEOCARE (India) and operated under identical technical specifications: an irradiance of 35 μw/cm^2/nm (validated via a Nice 4020 Radiometer) and an operational voltage of 100-250 V AC, 50 Hz. The light source was consistently positioned at a standardised distance of 40 cm above the neonate. Maximum body surface exposure was maintained, with the eyes and genitalia shielded using standard protective blocks. Criteria for phototherapy discontinuation followed the standardised AAP curve thresholds. Any neonate developing severe haemolytic escalation or requiring an exchange transfusion was excluded from the analytical cohort and escalated to advanced critical protocols. Mothers received comprehensive discharge counselling regarding optimised feeding, recognising danger signs, and immunisation schedules.

Ethical Consideration

The study protocol received formal clearance from the Institutional Ethics Committee (Letter No: 2160/IEC/GMC/NGP dated 11/01/2024). Written informed consent was obtained from parents or legal guardians using an approved consent pro-forma available in the local language. Strict data confidentiality was maintained, and guardians retained the right to withdraw their infants from the trial at any stage without compromising standard care. The trial conformed to the Declaration of Helsinki and Good Clinical Practice guidelines.

Statistical Analysis

Data were coded, cleaned, and compiled in Microsoft Excel before analysis using STATA version 14.0 [StataCorp LLC, College Station, Texas, USA]. Categorical variables are expressed as frequencies and percentages. Continuous variables are presented as mean±standard deviations. The independent Student's 't'-test, Mann-Whitney U test, Chi-square test, and Fisher's exact test and ANOVA test were used to compare outcomes between the groups, with statistical significance defined at $p<0.05$.

Results

A total of 200 neonates completed the trial (100 in the experimental group, 100 in the control group). Male neonates predominated in both groups. Mean birth weight and admission weight were comparable between the groups. Over half of the neonates in the experimental group were fed within 1 to 2 hours of birth compared to 42% in the control group; most infants across both groups were exclusively breastfed (Table 1).

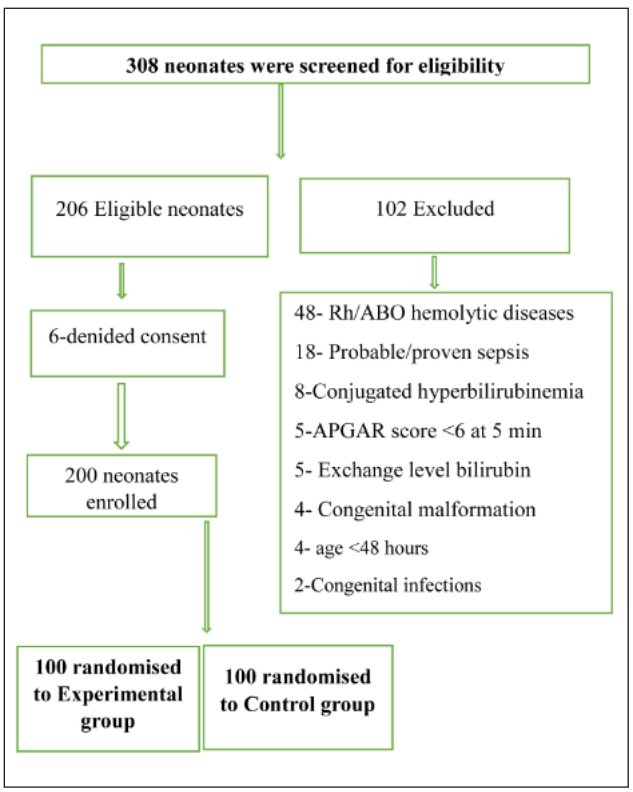

Figure 1 Participant flow (CONSORT Diagram summary).

Baseline clinical characteristics, vital signs, maternal demographics, and baseline laboratory profiles (including parental-fetal blood groups, hemoglobin, haematocrit, platelets, and inflammatory markers) demonstrated no statistically significant differences between the two study groups, ensuring excellent post-randomisation comparability (Table 2).

The baseline mean total serum bilirubin (TSB) levels in the experimental and control groups were 21.07±1.74 mg/dL and 21.45±1.23 mg/dL respectively, showing no statistically significant baseline difference ($p=0.07$). However, the mean TSB levels in the experimental group at 6, 12, and 24 hours, as well as 24 hours post-discontinuation, were statistically significantly lower than those observed in the control group ($p<0.0001$) (Table 3).

The mean duration of phototherapy was significantly shorter in the experimental group (13.69±5.35 hours) than in the control group (16.26±6.89 hours; $p=0.003$) (Table 4). The rate of bilirubin decline was significantly higher in the experimental group at 6 hours ($p<0.0001$), 12 hours ($p<0.0001$), and 24 hours ($p=0.005$). This higher rate of total serum bilirubin clearance in the experimental group remained significant post-discontinuation ($p<0.001$) (Figure 2).

No serious adverse events were recorded in the control group. In the experimental group, three neonates developed transient hyperthermia, which resolved with standard environmental and fluid adjustments. Other side effects, such as loose stools or dehydration rashes, were not observed in either group.

Discussion

This randomised controlled trial assessed whether hanging a simple white cotton curtain around a single-surface phototherapy unit could optimise its efficacy and safety compared to standard open setups. While baseline serum bilirubin concentrations were identical between both groups, the intervention group demonstrated significantly lower TSB levels at 6, 12, and 24 hours. Crucially, the experimental group achieved a more rapid rate of bilirubin clearance, which translated to a significantly shorter duration of phototherapy and a shorter hospital stay, with minimal adverse events.

Exposed skin surface area and light intensity are the main determinants of phototherapy performance. Although phototherapy is an effective treatment for neonatal hyperbilirubinaemia, its availability is often constrained in

low-resource settings by high patient volumes and a shortage of equipment. While direct sunlight exposure can reduce bilirubin levels, it is not clinically recommended due to risks of ultraviolet radiation, sunburn, and hyperthermia.[25] Consequently, focus has shifted toward low-cost modifications designed to optimise artificial light delivery.

In this study, white cotton curtains were used to bounce reflected light back onto the infant's skin, maximising the effective surface area exposed to therapeutic wavelengths. This setup achieved significantly lower mean TSB values throughout the treatment window ($p<0.0001$). These findings align with those of Philip et al[26] and Nair et al,[27] who reported that hanging low-cost white cotton cloth

Table 1 Demographic, maternal and neonatal characteristics of study participants

Characteristics	Experimental group (n=100, %)	Control group (n=100, %)	P-value	Statistics value
Gender (Male)	55 (55)	59 (59)	0.56	X^2=0.3248
Gestational age (weeks)				
Mean±SD	38.95±0.7	38.87±0.59	0.38	t=0.874
Birth weight (gms) (Mean±SD)	2866.3±266.2	2874.26±267	0.83	t=0.211
Weight on admission (gms) (Mean±SD)	2764±255.9	2748.37±255.83	0.66	t=-0.432
Mode of delivery				
Vaginal	46 (46)	51 (51)	0.48	X^2=0.49
Caesarean	54 (54)	49 (49)		
Apgar score at				
1 minute (Mean±SD)	7.56±0.56	7.45±0.51	0.14	t=-1.452
5 minutes (Mean±SD)	9.1±1.4	9.35±1.3	0.19	t=1.309
Initiation of feeding				
Within an hour	22 (22)	25 (25)	0.43	X^2=1.6625
1-2 hours	51 (51)	42 (42)		
>2 hours	27 (27)	33 (33)		
Type of feeding				
Exclusive breastfeed	44 (44)	43 (43)	0.69	X^2=0.7358
Top-feeding	26 (26)	31 (31)		
Mixed feeding	30 (30)	26 (26)		
Maternal age (years) (Mean±SD)	26.66±4.07	26.37±3.71	0.59	t=-0.527
Parity				
Primipara	36 (36)	34(34)	0.76	X^2=0.0875
Multipara	64 (64)	66 (66)		
Residence				
Rural	42 (42)	48 (48)	0.39	X^2=0.7336
Urban	58 (58)	52 (52)		
Baseline Vital Parameters				
Heart rate/min (Mean±SD)	130.28±7.75	129.43±14.07	0.59	t=-0.529
RR/min (Mean±SD)	37.05±5.15	37.37±4.3	0.63	t=0.477
Oxygen saturation (%) (Mean±SD)	98.18±0.8	98.11±0.66	0.50	t=-0.675
Capillary Refill time (≤3 seconds)	100 (100)	100 (100)	1	
Temperature (°C) (Mean±SD)	36.95±0.14	36.93±0.13	0.29	t=-1.047
Extent of jaundice (Kramer Scale) (Mean±SD)	4.66±0.47	4.72±0.45	0.35	t=0.922

SD: Standard deviation; RR: Respiratory rate; t: Independent 't' test; X^2: Chi-square test; °C: Degree Celsius

Table 2 Laboratory parameters of study participants

Laboratory parameters	Experimental group (n=100)	Control group (n=100)	P-value	Statistics value
Haemoglobin (g/dL) (Mean±SD)	14.77±1.05	14.64±0.96	0.36	t=-0.914
Haematocrit (%) (Mean±SD)	46.55±3.4	46.44±3.36	0.81	t=-0.230
Leucocyte count /cumm (Mean±SD)	7012±794.71	6910±776.74	0.35	t=-0.918
Platelet (10^5x/cumm) (Mean±SD)	2.42±3.2	2.37±3.1	0.91	t=-0.112
CRP (mg%) (Mean±SD)	0.97±0.69	0.97±0.58	1	t=0.000
Blood sugar (mg/dL) (Mean±SD)	120.48±8.35	120.5±7.75	0.98	t=0.018
Serum Calcium (mg/dL) (Mean±SD)	9.11±0.22	9.1±0.24	0.75	t=-0.307
Serum Albumin (gm/dL) (Mean±SD)	3.23±0.2	3.22±0.19	0.71	t=-0.362
Neonatal blood group				
'A' positive	39 (39)	41 (41)	0.99	X^2=0.11
'AB' positive	1 (1)	1 (1)		
'B' positive	26 (26)	26 (26)		
'O' positive	34 (34)	32 (32)		
Maternal blood group				
'A' positive	29 (29)	31 (31)	0.95	X^2=0.33
'AB' positive	16 (16)	15 (15)		
'B' positive	31 (31)	28 (28)		
'O' positive	24 (24)	26 (26)		
Paternal blood group				
'A' positive	35 (35)	37 (37)	0.49	X^2=2.3731
'AB' positive	4 (4)	2 (2)		
'B' positive	22 (22)	29 (29)		
'O' positive	39 (39)	32 (32)		

SD: Standard deviation; CRP: 'C' Reactive Protein; g: gm; dl: deciliter; t: Independent 't' test; X^2: Chi-square test)

Table 3 Comparison of mean total serum bilirubin (TSB) level between groups across time points

Group	Baseline	At 6 hours	At 12 hours	At 24 hours	24 hours after discontinuation	F-value	P-value
Experimental (Mean±SD)	21.07±1.74	19.77±1.84	18.49±1.92	18.15±2.14	16.97±2.05	163.53	<0.001
Control (Mean±SD)	21.45±1.23	20.78±1.25	19.76±1.17	19.36±1.06	18.09±1.12	899.25	<0.001
P-value	0.07	<0.0001	<0.0001	<0.0001	<0.0001		

Table 4 Duration of phototherapy in hours between the two groups

Duration of phototherapy in hours	Experimental	Control	P-value	't' test
Mean±SD	13.69±5.35	16.26±6.89	0.003	2.946

around phototherapy units enhanced efficacy and significantly shortened treatment duration. Similar positive outcomes have been reported by other researchers evaluating reflective hanging designs.[28,29]

Similarly, Sabry et al[23] and Hashim et al[24] in Egypt used low-cost reflective sheets around phototherapy units for full-term neonates with unconjugated hyperbilirubinaemia. They reported a significant reduction in overall phototherapy duration and hospitalisation costs without any added clinical complications. Other investigators have evaluated white curtains, reflective slings, or foil mirrors against single-surface, double-surface, or older CFL systems, consistently demonstrating improved light distribution and shorter hospital stays.[30-35] A systematic review by Lee et al[22] confirmed that utilising reflective materials around phototherapy systems effectively speeds up bilirubin reduction in developing countries.

Similarly, a randomised controlled trial by Babaei et al[36] in Iran evaluated plastic reflecting covers around phototherapy frames, reporting a more rapid decline in TSB during the first 48 hours and a shorter duration of jaundice. Other studies utilising aluminium foil reflectors also demonstrated shorter treatment windows than conventional setups.[20,37]

Phototherapy is generally safe, but it can cause minor side effects, including loose stools, temperature fluctuations, dehydration, skin rashes, or disrupted maternal-infant bonding.[13,17,18] In this study, transient hyperthermia occurred in three neonates in the experimental group, whereas none occurred in the control group. This was likely due to heat retention within the curtain enclosure. No instances of severe dehydration or significant skin rashes were observed, which may be due to the temperature-controlled NICU environment, close vital sign monitoring every 6 hours, and support for frequent on-demand breastfeeding. In comparison, Babaei et al reported minor hyperthermia and transient rashes in both their covered and uncovered groups without significant intergroup differences. Similarly, Kurniasih et al and Hashim et al noted mild temperature variations across arms, while Sabry et al observed minor skin rashes and transient diarroea.

Limitations

A limitation of this study is that efficacy was evaluated using total serum bilirubin rather than direct measurements of lumirubin (the structural photoisomer), which serves as a more direct marker of photoisomerisation. Additionally, continuous daily radiometer monitoring of spectral irradiance and automated internal calibrations were not performed throughout the study period.

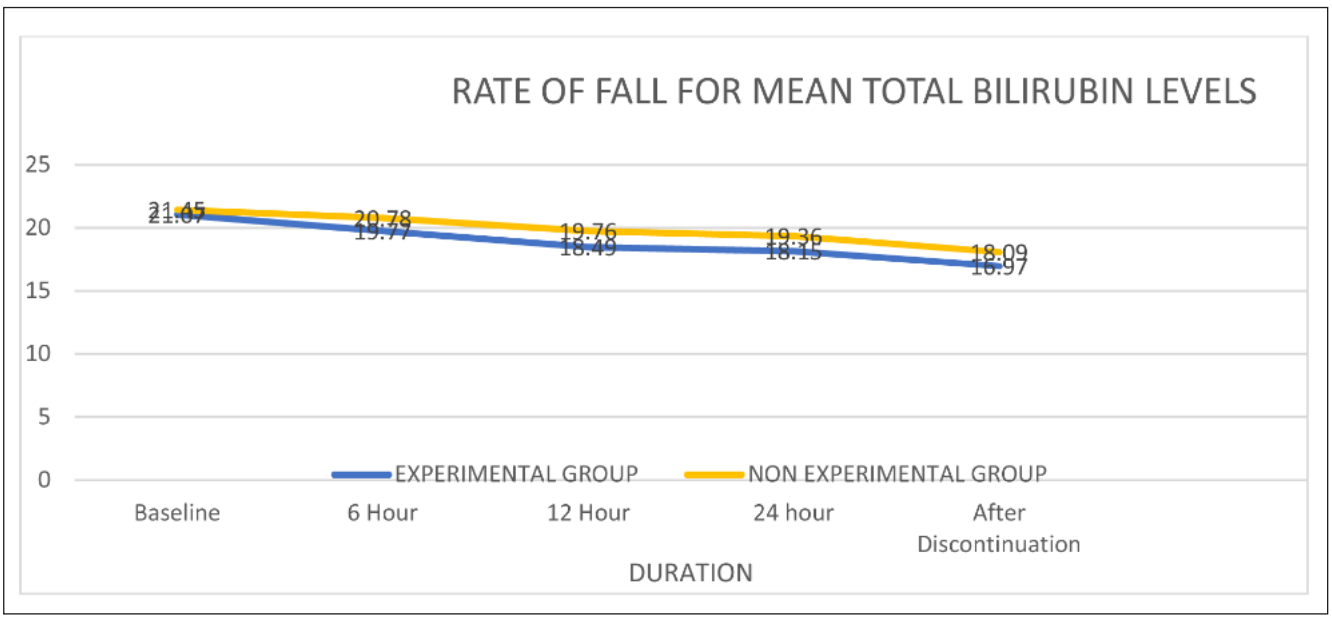

Figure 2 Rate of fall of mean bilirubin concentration.

Conclusion

Surrounding a phototherapy unit with a white cotton curtain is a simple, safe, and inexpensive modification that significantly increases the clearance rate of total serum bilirubin and reduces overall treatment duration in full-term neonates. This modification offers a practical solution for resource-limited healthcare centres managing a high burden of neonatal jaundice. Further multi-centre trials across different clinical settings are recommended to confirm these safety and efficacy findings.

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Conflict of Interest

None

Ethical Consideration

Written informed consent/assent were obtained from parents and children. The study was approved by Institutional Ethics Committee.

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