

Comparison between intermittent phototherapy and continuous phototherapy in neonates more than 34 weeks of gestation with jaundice

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Abstract

Background: Phototherapy is the standard treatment for neonatal hyperbilirubinemia. Continuous phototherapy (CPT) has traditionally been preferred for rapid bilirubin reduction, but prolonged uninterrupted light exposure may interfere with breastfeeding, maternal–infant bonding, and thermoregulation, and has been associated with skin rash and other adverse effects. Intermittent phototherapy (IPT), which alternates cycles of light exposure with scheduled rest periods, has been proposed as an equally effective alternative with fewer drawbacks. This study compared the rate of fall of serum bilirubin, along with secondary clinical outcomes, between IPT and CPT in neonates more than 34 weeks of gestation.

Methods: This randomized controlled trial was conducted in the Neonatal Intensive Care Unit of the Department of Pediatrics, SGRDIMSRI, Sri Amritsar, between August 2023 and February 2025. Neonates of more than 34 weeks of gestation with non-hemolytic hyperbilirubinemia and total serum bilirubin (TSB) <18 mg/dL, meeting phototherapy criteria as per the American Academy of Pediatrics (AAP) 2004 guidelines, were randomized by computer-generated variable block randomization into a CPT group or an IPT group (12 hours on, 12 hours off), with allocation concealed using sequentially numbered opaque sealed envelopes. The primary outcome was the rate of fall of serum bilirubin (mg/dL/hour). Secondary outcomes

included duration of phototherapy, phototherapy-related rash, breastfeeding establishment, and duration of hospitalization.

Results: Eighty neonates were studied, 40 in each group. Baseline demographic, anthropometric, and biochemical parameters, including TSB at presentation (16.08 ± 1.58 vs. 15.67 ± 1.33 mg/dL, $p = 0.21$), were comparable between groups. The mean rate of fall of serum bilirubin was significantly higher in the IPT group than in the CPT group (0.28 ± 0.10 vs. 0.19 ± 0.04 mg/dL/hour, $p < 0.0001$). The mean duration of phototherapy was significantly shorter with IPT (21.90 ± 6.01 hours) than with CPT (33.90 ± 6.59 hours, $p < 0.0001$). Phototherapy-induced rash occurred less frequently with IPT (27.5%) than with CPT (60.0%, $p = 0.003$). Breastfeeding establishment was numerically higher with IPT (85.0% vs. 70.0%, $p = 0.10$), and duration of hospitalization did not differ significantly between groups ($p = 0.90$).

Conclusion: In neonates more than 34 weeks of gestation with non-hemolytic hyperbilirubinemia, intermittent phototherapy with 12-hour on/12-hour off cycles achieved a significantly faster rate of fall of serum bilirubin and shorter treatment duration than continuous phototherapy, with fewer skin reactions and no compromise in overall clinical outcome. Intermittent phototherapy may be considered a safe, effective, and family-friendly alternative to continuous phototherapy in this population.

Keywords: Phototherapy, Hyperbilirubinemia, Intermittent Phototherapy, Continuous Phototherapy.

Introduction

Neonatal hyperbilirubinemia is one of the most common problems encountered in the first week of life, affecting more than 60% of term and up to 80% of preterm

infants, with approximately 5–10% of affected neonates requiring treatment.^{1,2} If unrecognized or inadequately treated, severe unconjugated hyperbilirubinemia can cross the blood–brain barrier and cause acute or chronic bilirubin encephalopathy, with lifelong consequences including cerebral palsy, sensorineural hearing loss, and cognitive impairment.³ Phototherapy remains the cornerstone of management, converting toxic unconjugated bilirubin into water-soluble photoisomers and lumirubin that can be excreted without hepatic conjugation, and it has substantially reduced the need for exchange transfusion since its introduction.^{4,5}

Two broad approaches to delivering phototherapy have evolved: continuous phototherapy (CPT), in which light exposure is uninterrupted except for brief breaks for feeding and routine care, and intermittent phototherapy (IPT), in which scheduled periods of light exposure alternate with periods of rest. The rationale for IPT rests on the two-step model of bilirubin photodegradation: an initial, near-instantaneous photochemical reaction occurs at the skin surface, after which unbound bilirubin migrates from the deeper blood pool into the skin over roughly one to three hours to replenish the substrate available for further photo-conversion.⁶ If this migration step is genuinely rate-limiting, continuous illumination beyond this window may add little additional benefit while still exposing the neonate to the drawbacks of prolonged light exposure, including thermal instability, insensible water loss, skin rash, and interruption of breastfeeding and maternal–infant bonding.^{7,8}

Clinical trials comparing CPT and IPT have produced inconsistent findings. Several studies, including the trial by Sachdeva et al. in late preterm and term neonates using a 12-hour on/12-hour off IPT schedule, found IPT to be at least as effective as CPT, with a significantly

greater rate of fall of bilirubin in the intermittent arm.⁹ A 2023 Cochrane systematic review pooling 12 randomized trials and 1,600 infants concluded that there was little or no difference between the two modalities in the rate of decline of bilirubin, though the certainty of evidence was rated low, and safety outcomes remained inadequately addressed.¹⁰ Other trials using shorter on/off cycles (for example, one or two hours on alternating with shorter rest periods) have similarly reported comparable bilirubin decline between arms, while a few have favored continuous exposure for a faster initial decline.^{11,12}

Much of the existing literature has used variable on/off cycle lengths, heterogeneous phototherapy devices, and mixed populations that include preterm and hemolytic cases, limiting direct comparability. Neonates beyond 34 weeks of gestation with non-hemolytic jaundice represent a physiologically more stable group in whom the trade-off between treatment intensity and family-centered care is particularly relevant, since brief interruptions for feeding and bonding are unlikely to carry the same risk as in a sicker or more preterm infant. We therefore undertook this randomized controlled trial to compare a 12-hour on/12-hour off intermittent phototherapy schedule against continuous phototherapy in this population, with the rate of fall of serum bilirubin as the primary outcome, alongside duration of phototherapy, phototherapy-related rash, breastfeeding establishment, and duration of hospitalization as secondary outcomes.

Materials and Methods

Study design and setting

This randomized controlled trial was conducted in the Neonatal Intensive Care Unit (NICU) of the Department of Paediatrics, Sri Guru Ram Das Institute of Medical

Sciences and Research (SGRDIMSR), Sri Amritsar, from 1 August 2023 to 28 February 2025, after approval from the Institutional Ethics Committee. Written informed consent was obtained from a parent or legal guardian of every enrolled neonate, using participant information sheets and consent forms available in English, Hindi, and Punjabi.

Inclusion Criteria

Neonates of more than 34 weeks of gestation admitted to the NICU with hyperbilirubinemia, having a total serum bilirubin (TSB) <18 mg/dL and falling within the phototherapy range according to the American Academy of Pediatrics (AAP) 2004 guidelines, were eligible.

Exclusion Criteria

Neonates were excluded if they had major congenital malformations; an APGAR score <3 at 5 minutes; onset of jaundice within the first 24 hours of life; TSB >18 mg/dL at admission or TSB in the exchange transfusion range; or evidence of hemolytic jaundice, defined as a positive direct Coombs' test, hemolysis on peripheral smear, or a reticulocyte count >6%.

Methods

Eligible neonates were randomized in a 1:1 ratio into a continuous phototherapy (CPT) group or an intermittent phototherapy (IPT) group using computer-generated variable block randomization, with block sizes in multiples of two. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes, opened only after a neonate had been confirmed eligible and enrolled. Given the nature of the intervention, blinding of was not done.

Data from our unit from neonates receiving phototherapy showed a mean rate of fall of serum bilirubin of 0.15 ± 0.07 mg/dL/hour with continuous phototherapy. Assuming intermittent phototherapy

would produce a 0.05 mg/dL/hour greater reduction, a sample size of 80 neonates (40 per group) was calculated to provide 90% power with a two-sided alpha of 0.05, allowing for 10% attrition.

All neonates received phototherapy using the same LED phototherapy device (Lullaby™ LED Phototherapy System), with the light source maintained at a distance of 25–30 cm from the neonate, and eye and genital shields in place throughout treatment. Neonates in the CPT group received continuous phototherapy, interrupted only for feeding and diaper changes, until the discontinuation criteria were met or phototherapy failed. Neonates in the IPT group received phototherapy in cycles of 12 hours on and 12 hours off, continued until the discontinuation criteria were met or phototherapy failed. Phototherapy was discontinued once the neonate was out of range for treatment as per institutional practice. Failure of phototherapy was defined as a TSB >18 mg/dL or bilirubin reaching the exchange transfusion range as per AAP 2004 guidelines; neonates with a rise in bilirubin >0.5 mg/dL/hour was planned to be withdrawn from the trial.

Serial TSB samples were drawn by venepuncture every 12 hours and analyzed in the institute's central laboratory using the bilirubin/conjugated bilirubin (BuBc) assay based on dual-wavelength direct spectrophotometry on the VITROS 5600™ Integrated System.

Outcomes

The primary outcome was the rate of fall of TSB, calculated as the difference between the maximum serum bilirubin after enrolment and the bilirubin level at the end of phototherapy, divided by the actual duration of phototherapy in hours, expressed as mg/dL/hour. Secondary outcomes were duration of phototherapy

(actual hours under treatment), failure of phototherapy, phototherapy-related side effects (including skin rash), percentage of neonates exclusively breastfed at discharge, and duration of hospitalization.

Statistical analysis

Continuous data with a normal distribution were expressed as mean ± standard deviation and compared using Student's t-test. Categorical variables were expressed as number (percentage) and compared using the chi-square test or Fisher's exact test, as appropriate. A p-value <0.05 was considered statistically significant. Analysis was performed on an intention-to-treat basis.

Results

A total of 115 neonates were screened for eligibility. Ten were excluded because consent could not be obtained, 18 had bilirubin in the exchange transfusion range, 3 had a positive direct Coombs' test, and 4 had TSB >18 mg/dL at admission. Eighty neonates met the eligibility criteria and were randomized, 40 to the CPT group and 40 to the IPT group (Figure 1).

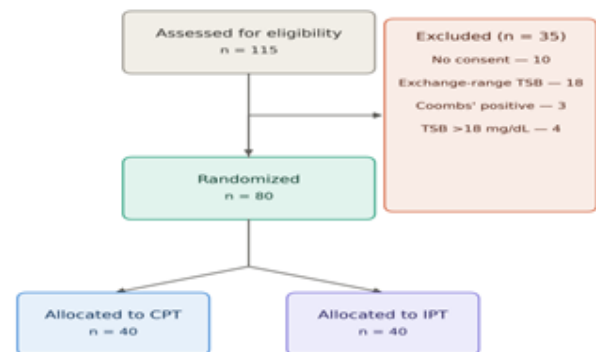


Figure 1: Consort flow diagram showing screening, exclusions, randomization and allocation of participants to continuous (CPT) and intermittent (IPT) phototherapy.

Baseline characteristics

The two groups were comparable with respect to age at enrolment (81.32 ± 26.40 hours in CPT vs. 84.40 ± 31.58 hours in IPT, $p = 0.63$), gender distribution (60.0% vs. 62.5% male, $p = 0.81$), gestational age distribution ($p = 0.47$), mode of delivery (67.5% vs. 62.5% by lower segment caesarean section, $p = 0.63$), and birth weight (2869.75 ± 477.79 g vs. 2873.75 ± 406.52 g, $p = 0.96$). Anthropometric measurements at enrolment (current weight, length, head circumference), maternal obstetric risk factors, feeding practices, percentage weight loss from birth weight, and stool and urine frequency were

also similar between groups (all $p > 0.05$). Baseline haematological parameters (haemoglobin, total leukocyte count, platelet count, reticulocyte count) and thyroid profile did not differ significantly between groups, apart from a borderline difference in free T3 (3.40 ± 0.98 vs. 3.88 ± 1.17 , $p = 0.05$). Mean TSB at presentation was comparable between the CPT and IPT groups (16.08 ± 1.58 vs. 15.67 ± 1.33 mg/dL, $p = 0.21$), confirming that both groups entered treatment with a similar degree of hyperbilirubinemia.

Table 1: Baseline characteristics of the CPT and IPT groups.

Parameter	CPT group (n = 40)	IPT group (n = 40)	p-value
Mean age at admission (hours), mean $\pm$ SD	81.32 ± 26.40	84.40 ± 31.58	0.63
Delivery mode, n (%)			0.63
LSCS	27 (67.5)	25 (62.5)	
NVD	13 (32.5)	15 (37.5)	
Birth weight (g), mean $\pm$ SD	2869.75 ± 477.79	2873.75 ± 406.52	0.96
Weight loss from birth weight (%), mean $\pm$ SD	10.27 ± 5.41	9.88 ± 6.22	0.76
Feeding practices, n (%)			0.19
Formula	21 (52.5)	13 (32.5)	
Exclusive breastfeeding	15 (37.5)	22 (55.0)	
Mixed feeding	4 (10.0)	5 (12.5)	
Haemoglobin (g/dL), mean $\pm$ SD	17.63 ± 2.40	17.33 ± 2.32	0.57
Reticulocyte count (%), mean $\pm$ SD	2.54 ± 1.40	2.12 ± 1.06	0.13
TSB at admission (mg/dL), mean $\pm$ SD	16.08 ± 1.58	15.67 ± 1.33	0.21

LSCS, lower segment caesarean section; NVD, normal vaginal delivery; TSB, total serum bilirubin. Gender distribution, gestational age, anthropometric measurements, maternal obstetric risk factors, stool/urine frequency, remaining haematological parameters, and thyroid profile were also comparable between groups (all $p > 0.05$, data not shown).

Primary outcome: rate of fall of serum bilirubin

The mean rate of fall of serum bilirubin was significantly higher in the IPT group than in the CPT group (0.28 ± 0.10 mg/dL/hour vs. 0.19 ± 0.04 mg/dL/hour; $p < 0.0001$) (Table 2).

Table 2: Comparison of serum bilirubin, phototherapy duration, and hospitalization between the CPT and IPT groups.

Parameter	CPT group (n = 40) Mean $\pm$ SD	IPT group (n = 40) Mean $\pm$ SD	p-value
TSB at presentation (mg/dL)	16.08 ± 1.58	15.67 ± 1.33	0.21
Rate of fall of serum bilirubin (mg/dL/hour)	0.19 ± 0.04	0.28 ± 0.10	<0.0001
Duration of hospitalization (hours)	47.70 ± 6.18	47.60 ± 10.34	0.90

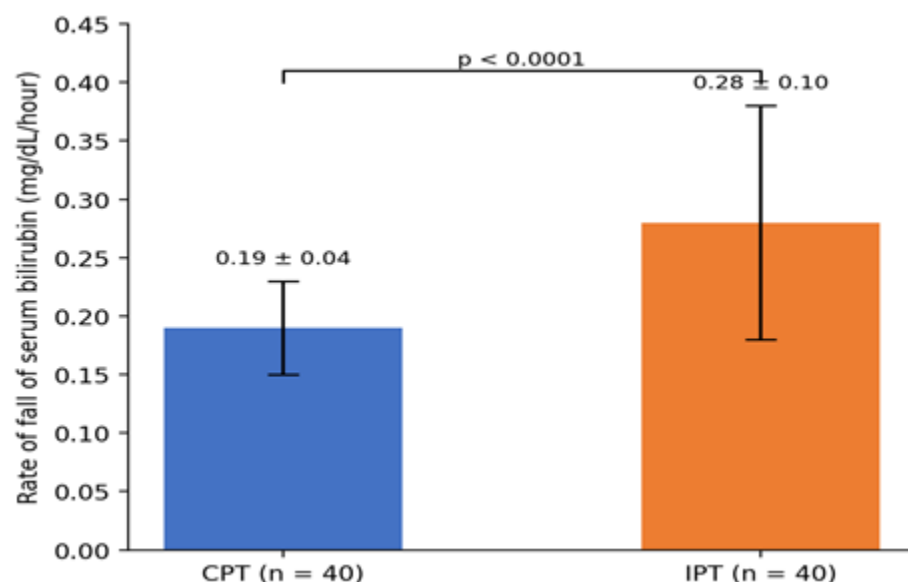


Figure 2: Comparison of the mean rate of fall of serum bilirubin (mg/dL/hour) between the CPT and IPT groups. Error bars represent standard deviation.

Secondary outcomes

The duration of phototherapy required was significantly shorter in the IPT group (mean 21.90 ± 6.01 hours) than in the CPT group (mean 33.90 ± 6.59 hours; $p < 0.0001$). In the CPT group, 67.5% of neonates required 36 hours

of phototherapy, 25.0% required 24 hours, and 7.5% required 48 hours, with none completing treatment within 12 hours. In the IPT group, 72.5% completed treatment within 24 hours, 22.5% within 12 hours, and

only 5.0% required 36 hours, with none requiring 48 hours.

Phototherapy-induced skin rash occurred significantly more often in the CPT group (24/40, 60.0%) than in the IPT group (11/40, 27.5%; $p = 0.003$) (Table 3). Breastfeeding was successfully established in 34/40 (85.0%) neonates in the IPT group compared with 28/40 (70.0%) in the CPT group, a difference that did not reach

Table 3: Comparison of phototherapy-related rash and breastfeeding establishment between the CPT and IPT groups.

Outcome	CPT group n (%)	IPT group n (%)	p-value
Phototherapy-induced rash	24 (60.0)	11 (27.5)	0.003
Breastfeeding established at discharge	28 (70.0)	34 (85.0)	0.10

Discussion

In this randomized controlled trial of 80 neonates more than 34 weeks of gestation with non-hemolytic hyperbilirubinemia, intermittent phototherapy delivered in 12-hour on/12-hour off cycles achieved a significantly faster rate of fall of serum bilirubin than continuous phototherapy, along with a significantly shorter overall duration of phototherapy and a lower incidence of phototherapy-related skin rash. Breastfeeding establishment was numerically higher with IPT, and the duration of hospitalization was virtually identical between the two groups.

These findings are consistent with the two-step model of bilirubin photodegradation, in which the rapid photochemical isomerization occurring at the skin surface is followed by a slower, rate-limiting migration of unbound bilirubin from the blood pool into the skin over one to three hours.⁶ If replenishment of the substrate at the skin is genuinely the limiting step, scheduled rest periods should not compromise, and may even optimize, the efficiency of subsequent light

statistical significance ($p = 0.10$). Duration of hospitalization was almost identical between the two groups (47.70 ± 6.18 hours in CPT vs. 47.60 ± 10.34 hours in IPT; $p = 0.90$). No neonate in either group required intravenous fluids or exchange transfusion, and no neonate developed phototherapy failure as defined by protocol.

exposure, which is consistent with the faster rate of fall observed in our IPT arm.

Our results closely mirror those of Sachdeva et al., who compared the same 12-hour on/12-hour off intermittent schedule with continuous phototherapy in 75 late preterm and term neonates with non-hemolytic moderate hyperbilirubinemia and similarly found a significantly higher rate of fall of bilirubin with IPT (0.18 vs. 0.13 mg/dL/hour IQR, $p = 0.002$), along with a significantly shorter duration of phototherapy[9].The consistency of this finding across two independently conducted trials using an identical on/off schedule, a decade apart and in different LED-based phototherapy systems, strengthens the case that a 12-hour cycle length is long enough to allow adequate bilirubin re-equilibration in the skin without sacrificing overall efficacy.

Other trials using shorter cycle lengths have generally reported comparable, rather than superior, bilirubin decline with IPT. Taheritafti and Taheritafti compared 18 hours on/8 hours off IPT with 24-hour CPT in 60 term neonates and found no significant difference in the rate of bilirubin decline, duration of hospital stay, or

duration of phototherapy between arms, while also noting no clinically important difference in serum melatonin levels.^[13] Similarly, the 2023 Cochrane systematic review by Gottimukkala et al., pooling 12 randomized trials involving 1,600 term and preterm neonates, found little or no difference between IPT and CPT in the rate of decline of bilirubin overall, although continuous phototherapy appeared more effective specifically in preterm infants; the review also highlighted that intermittent regimens consistently reduced the total number of hours of phototherapy exposure, and that safety outcomes were inadequately addressed across the included trials, with the overall certainty of evidence rated low.¹⁰ A separate single-centre randomized trial by Gottimukkala et al. in neonates of 35 weeks' gestation or more likewise reported comparable rates of bilirubin fall between IPT and CPT, with fewer side effects and better parental acceptance in the intermittent group.¹⁴ Taken together with our results, this body of evidence suggests that IPT is, at minimum, non-inferior to CPT for bilirubin reduction in late preterm and term neonates, and that shorter total phototherapy exposure and fewer adverse effects can be achieved without sacrificing efficacy; the specific superiority we observed may in part reflect the particular 12-hour cycle length and the moderate, non-hemolytic severity range of our study population.

The significantly shorter duration of phototherapy in our IPT group has direct practical relevance. A shorter treatment course reduces cumulative light exposure and the associated risks of thermal instability, insensible fluid loss, and interference with the neonate's normal sleep-wake and circadian cues, while also potentially shortening hospital stay and reducing costs and parental anxiety.^{7,18} In our cohort, however, overall duration of

hospitalization did not differ between groups, suggesting that discharge in this setting was determined by factors beyond the rate of bilirubin decline alone, such as feeding establishment and routine postnatal observation; this mirrors the findings of Sachdeva et al. and Taheritafti et al., both of whom also reported no significant difference in hospital stay despite differences in phototherapy duration.^{9,13}

The markedly lower incidence of phototherapy-induced rash in the IPT group (27.5% versus 60.0% with CPT) is a clinically meaningful safety finding. Continuous, uninterrupted light exposure has previously been linked to transient erythematous and petechial skin reactions, and scheduled rest periods in the IPT arm likely reduced cumulative light and heat exposure to the skin.¹⁵ While some trials, such as that of Gottimukkala et al. and Asharab et al., have reported a low and similar incidence of rash in both arms, the direction of effect in our study — favoring IPT — is consistent with the broader literature suggesting that intermittent regimens are, if anything, associated with fewer cutaneous adverse effects than continuous exposure.^{10,14}

Breastfeeding establishment, though not statistically significant in our cohort, was numerically higher in the IPT group (85.0% vs. 70.0%), consistent with the theoretical rationale that scheduled interruptions in phototherapy facilitate more frequent direct breastfeeding and skin-to-skin contact between mother and infant. Several authors have highlighted that IPT allows for improved maternal-infant bonding and reduced parental anxiety compared with continuous exposure, which may translate into modest improvements in breastfeeding outcomes even where our sample size was not powered to detect a statistically significant difference in this secondary outcome.^{7,8}

Our study has several strengths, including a robust randomization and allocation concealment procedure, a pre-specified sample size calculation, restriction to a well-defined, clinically relevant, non-hemolytic and late-preterm-to-term population, and the use of a single, standardized LED phototherapy device across both arms, which minimizes device-related confounding that has affected comparisons across some earlier trials using different light sources.¹⁶ Nonetheless, several limitations should be acknowledged. The trial was conducted at a single tertiary care centre, which may limit generalizability. The relatively modest sample size, while adequately powered for the primary outcome, limits the precision of estimates for secondary outcomes such as breastfeeding establishment. Blinding of the intervention was not feasible given its nature, which could theoretically have influenced ancillary aspects of care such as feeding support, although the primary outcome (rate of fall of bilirubin) is an objective laboratory measure unlikely to be influenced by observer expectation. Longer-term outcomes such as rebound hyperbilirubinemia after discharge, neurodevelopmental follow-up, and formal parental satisfaction and cost-effectiveness analyses were not assessed and merit evaluation in future multicentric trials.

Conclusion

In neonates more than 34 weeks of gestation with non-hemolytic hyperbilirubinemia, intermittent phototherapy delivered in 12-hour on/12-hour off cycles produced a significantly faster rate of fall of serum bilirubin and a significantly shorter duration of phototherapy than continuous phototherapy, together with a lower incidence of phototherapy-related skin rash and no compromise in duration of hospitalization. These findings support intermittent phototherapy as a safe,

effective, and family-centered alternative to continuous phototherapy in this population, with the additional practical advantages of reduced cumulative light exposure and greater opportunity for breastfeeding and maternal–infant bonding. Larger, multicentric randomized trials with longer follow-up are recommended to confirm these findings, standardize optimal cycle length, and evaluate long-term neurodevelopmental and cost-effectiveness outcomes.

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