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Original Article

The effect of the BLUI blanket on the reduction of bilirubin levels in neonatal jaundice: a preliminary clinical study

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Abstract

Background Neonatal jaundice is a prevalent condition in newborns, characterized by elevated bilirubin levels. Conventional phototherapy treatments for neonatal jaundice typically require hospital admission, separation from mothers, and may interfere with breastfeeding and bonding. The Blue Light Universitas Indonesia (BLUI) LED phototherapy blanket was developed to address these limitations by providing a portable, home-based alternative that maintains mother-infant contact while delivering effective therapy.

Objective To evaluate the efficacy of the BLUI LED phototherapy blanket in reducing bilirubin levels in infants with physiological jaundice.

Methods A preliminary study was conducted from December 2022 to February 2023, involved 14 infants with physiological jaundice at Hermina Hospital Ciputat, Sariasih Hospital Ciputat, and the General Hospital of South Tangerang. The inclusion criteria were infants with physiological jaundice, gestational age ≥35 weeks, and birth weight ≥2,000 grams. The dependent variable was the reduction in total serum bilirubin levels, assessed by spectrophotometry. Paired sample T-test was used to compare bilirubin levels before and 24 hours after intervention with the BLUI Blanket. Results The study included 14 infants, with a mean age of 6.86 days and mean gestational age of 37.71 weeks. The BLUI Blanket demonstrated a mean bilirubin reduction of 3.11 mg/dL after 24 hours of continuous treatment, with a 19.02% decrease. The intervention was well-tolerated, with minimal adverse effects, such as maculopapular skin rash occurring in only one infant. Conclusion The BLUI Blanket is an effective and safe phototherapy device for reducing bilirubin levels in infants with physiological jaundice. This preliminary study supports further research to confirm these findings in larger populations. [Paediatr

Keywords: neonatal jaundice; bilirubin reduction; phototherapy; BLUI blanket; LED therapy; preliminary study

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eonatal jaundice is a common condition in newborns, resulting from increased bilirubin levels in the blood. This condition can be categorized into physiological and pathological jaundice, with a still relatively high prevalence. Globally, approximately 60% of full-term infants develop clinical jaundice during the first week of life, while in Indonesia, prevalence ranges from 13.2% to 58%. ¹⁻⁷ Currently, fluorescent phototherapy using devices such as fluorescent tube lamps and LED projector lamps remains the primary method employed in various healthcare facilities.

Physiological jaundice typically appears on the second or third day after birth and is a normal process due to the immature liver's inability to effectively conjugate bilirubin and the intensified breakdown of

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red blood cells. It is characterized by a gradual increase in bilirubin levels that doesn't exceed certain thresholds (usually below 12-13 mg/dL in full-term infants) and resolves within the first week of life without causing harm. In contrast, pathological jaundice appears within the first 24 hours after birth or persists beyond the first week, with bilirubin levels rising rapidly (>0.5 mg/dL/hour) or exceeding normal physiological thresholds. It may be associated with conditions such as hemolysis, sepsis, congenital infections (including syphilis, CMV, rubella, and toxoplasmosis), hidden bleeding, erythroblastosis fetalis, or genetic disorders like Crigler-Najjar syndrome.⁸

Despite its effectiveness, the use of fluorescent phototherapy presents several challenges. A major issue is the separation of mother and infant during the treatment period, potentially impeding the bonding process between mother and child and limiting exclusive breastfeeding. Additionally, fluorescent lamp phototherapy increases costs associated with inpatient room use and lacks portability. These limitations highlight the necessity for developing and adopting more efficient and user-friendly therapeutic technologies for both patients and healthcare practitioners.⁹

As an alternative, we developed and assessed the effectiveness and safety of the *Blue Light Universitas Indonesia* (BLUI) LED phototherapy blanket prototype. This technology employs an array of LEDs in the form of a therapeutic blanket that aims to overcome the limitations of fluorescent methods.9 The BLUI LED phototherapy blanket is expected to have lower production costs, be easy to use and transport, be lightweight, provide more uniform radiation, and offer flexibility in placement near the infant. We did a preliminary study to evaluate the safety and efficacy of the BLUI blanket in reducing total bilirubin levels in infants with physiological jaundice as well as assess the safety and functionality of the device as a basis for further experimental studies.

Methods

This preliminary study was conducted in the Newborn Unit and Perinatology Ward at Hermina Hospital Ciputat, Sariasih Hospital Ciputat, and the General Hospital of South Tangerang from December 2022 to February 2023. The selected sample comprised patients with physiological jaundice undergoing inpatient care in the perinatology units of the three participating hospitals.

Inclusion criteria were: gestational age \geq 35 weeks and birth weight \geq 2,000 grams (at or above the 25th percentile for gestational age), postnatal age >24 hours to 28 days, no history of birth trauma/ cephalohematoma/bleeding, total serum bilirubin levels \geq 10 and \leq 19 mg/dL (medium-risk thresholds for infants with gestational age 35-36 weeks plus 6 days who are clinically stable), and total serum bilirubin levels ≥12 and <22 mg/dL (lower risk thresholds for infants ≥ 38 weeks who are clinically stable), Asian ethnicity, absence of circulatory disorders, no respiratory distress, oxygen saturation above 90%, and written informed consent from patient's parents/ guardians. Exclusion criteria were infection (fever/ hypothermia; laboratory examinations showing increased leukocyte count and suggestive peripheral blood smear), direct bilirubin levels exceeding 2 mg/dL, or 20% of total serum bilirubin levels.

Before initiating BLUI phototherapy, all infants underwent a comprehensive assessment including complete blood count, direct and indirect bilirubin measurements, blood type determination, and Coombs test. Blood samples for bilirubin measurement were collected at two specific timepoints: immediately before initiating the first BLUI therapy session (0 hours, pre-therapy) and exactly 24 hours after the start of treatment (24 hours, post-therapy), regardless of whether the infant was receiving therapy at that exact moment. This standardized timing for blood collection ensured consistent measurement intervals across all study participants. At Hermina Hospital Ciputat, quantitative measurement of total serum or plasma bilirubin was performed using an ELITechGroup Auto Chemistry Analyzer (Selectra Pro S model). At Sariasih Hospital Ciputat, the analysis employed a DIRUI Industrial Co., Ltd. Spectrophotometer (model DIRUI BM 240S; serial number 220T240CS0231). At the General Hospital of South Tangerang, a Horiba Medical Clinical Chemistry Analyzer (Pentra C400 model; serial number 211C4-1420) was used. To address potential variability from using different analyzers, the researchers implemented several validation measures. All devices underwent regular calibration and maintenance according to national

clinical laboratory standards. Measurements were conducted by trained laboratory technicians following standardized protocols. Despite brand differences, all analyzers utilized the same spectrophotometric method for total bilirubin measurement.

The duration of therapy with the BLUI blanket is a minimum of 24 hours from the time hyperbilirubinemia was identified. The therapy continued until bilirubin levels reached the discharge criteria: ≤10 mg/dL for late preterm infants (35-36 weeks plus 6 days gestational age) and ≤12 mg/dL for term infants (≥37 weeks gestational age), and based on the attending physician's assessment. Treatment was off (the BLUI blanket was temporarily removed) for feeding, diaper changes, and maternal bonding time. We defined it as therapy interval. Body temperature was monitored throughout the therapy to ensure patient safety, while room temperature was maintained at an average of 25.8 (SD 0.69)°C for the BLUI Blanket group to ensure optimal device

performance and patient comfort.

Four prototype BLUI Blanket devices were used for the 14 subjects. It utilizes LED lamps (HI-LED Ilker FSHI 5050.B020.6012 model, Turkey), operating at a wavelength of 460-470 nm. These prototypes were specifically developed at Universitas Indonesia and it was designed to deliver effective phototherapy, ensuring optimal blue light exposure at the appropriate spectrum for treating neonatal jaundice 10, as an alternative to conventional phototherapy. As shown in Figure 1, the BLUI Blanket is a wearable phototherapy device that allows the infant to remain in close proximity to the mother while receiving treatment. The image clearly illustrates how the blanket is positioned on the infant, demonstrating its nonintrusive design that facilitates continued maternalinfant bonding during therapy while providing the necessary therapeutic light exposure.

Univariate analysis involved calculating measures of central tendency (mean, median) and



Figure 1. Physical characteristics of BLUI Blanket and its practical application in a clinical setting

variation (variance, range, and standard deviation) for numerical and categorical data, including total bilirubin, duration of therapy, body temperature, gestational age, birth weight, age, and feeding frequency. Categorical data comprised skin rash, dehydration, stool consistency, gender, feeding method, and fluid intake volume. Results are presented in frequency distribution tables (f) and percentages (%) for each group. Bivariate analysis with paired sample T-test was used to compare total serum bilirubin levels pre- and post-intervention with the BLUI blanket within the same group.

This study was approved by the Ethics Committee of the Faculty of Medicine, Trisakti University, the management of Hermina Hospital Ciputat, Sari Asih Hospital Ciputat, and the General Hospital of South Tangerang. Each participating hospital had a designated attending physician responsible for supervising the research implementation at their respective site, ensuring protocol adherence and patient safety throughout the study period.

Results

A total of 14 infants who met the inclusion and exclusion criteria were enrolled in our study. These participants subsequently underwent phototherapy treatment using the BLUI Blanket. The basic characteristics of the conditions during phototherapy for the study population are presented in **Table 1**.

Of all subjects, 6/14 subjects were male and 8/14 subjects were female. The mean age of the infants at the initiation of therapy was 6.9 (SD 2.3) days. The median gestational age was 38 (range 34-39) weeks. The mean birth weight was 2,998.2 (SD 451.9) grams.

In terms of feeding, 9/14 infants were bottle-fed, while 5/14 subjects were fed using a combination of bottle and direct breastfeeding methods, as detailed in the Methods section. All infants were fed more than 8 times per day. The bottle feeding volume was deemed adequate in 8/14 infants and inadequate in 6/14 infants.

The BLUI blanket phototherapy protocol consisted of intermittent treatment sessions over a 24-hour observation period. The total cumulative phototherapy exposure for each infant during the 24-hour observation period was approximately 18

hours, with 6 hours of accumulated rest intervals. The median room temperature during therapy was 25.0 (range 22.5-25.5)°C.

For secondary outcomes assessed during the initial 24-hour observation period, 13 out of 14 infants did not develop skin rashes. Normal body temperature was observed in 11 out of 14 infants, while 3/14 infants exhibited subfebrile. The median body temperature was 37.1 (range 36.9-37.9) °C. Most of subjects had spreading soft stools. None of the infants had mucous/fibrous or watery stools.

The results of bilirubin level examinations before and after the 24-hour observation period are presented in Table 2. Prior to the commencement of phototherapy, subjects' mean total serum bilirubin level was 16.35 (SD 1.42) mg/dL (95%CI 15.53 to 17.17). After the 24-hour observation period with intermittent BLUI blanket phototherapy sessions (total therapy exposure of approximately 18 hours with mean rest intervals of 30.71 minutes between sessions), the mean total serum bilirubin level decreased to 13.23 (SD 1.67) mg/dL (95%CI 12.27 to 14.19). Hence, mean total serum bilirubin level decreased by 3.11 (SD 1.62) mg/dL, a 19.02% decrease from baseline level (95%CI 2.18 to 4.05). The paired samples t-test revealed a significant reduction in serum bilirubin following phototherapy (P=0.000). These findings provide compelling evidence for healthcare practitioners to employ phototherapy as a part of the management strategy for hyperbilirubinemia in infants.

Discussion

Our finding provide compelling evidence for healthcare practitioners to employ phototherapy as a part of the management strategy for hyperbilirubinemia in infants. The majority of infants undergoing phototherapy maintained stable conditions with normal body temperatures and none experienced dehydration. The high frequency of feeding (more than 8 times per day) and relatively constant room temperature may have contributed to the stability of the infants' conditions. The variation in median therapy intervals [15 (range 5-145) minutes] demonstrates that the BLUI Blanket protocol allows for individualized adjustments based on each infant's feeding schedule, maternal bonding

Table 1 . Basic characteristics of subjects

Variables	(N=14)	95%CI
Infant characteristics before phototherapy		
Gender, n		
Male	6	
Female	8	
Mean age (SD), days	6.9 (2.3)	5.56 to 8.16
Median gestational age (range), weeks	38 (34–39)	36.92 to 38.52
Mean birth weight (SD), grams	2,998.2 (451.9)	2,737.31 to 3,259.12
Feeding characteristics during phototherap	ру	
Feeding methods, n		
Bottle only	9	
Both bottle and other methods	5	
Feeding frequency (category), n		
<8 times/day	0	
≥8 times/day	14	
Bottle feeding volume (category), n		
Inadequate	6	
Adequate	8	
Conditions during phototherapy		
Median therapy interval (range), minutes	15 (5-145)	8.65 to 52.78
Median room temperature (range), 0C	25.0 (22.5–25.5)	24.39 to 25.24
Secondary outcomes (within 24 hours)		
Skin rash, n (%)		
Absent	13	
Present	1	
Body temperature (category), n (%)		
Not normal	3	
Normal	11	
Median body temperature (range), °C	37.1 (36.9-37.9)	37.05 to 37.41
Dehydration, n (%)		
Absent	14	
Present	0	
Stool consistency, n (%)		
Hard/solid	1	
Soft-formed paste	5	
Soft-spread	8	
Mucous/fibrous	0	
Watery/liquid	0	

needs, and clinical assessment, while still maintaining effective treatment parameters. The safety of this interval is supported by clinical guidelines that recommend brief, planned interruptions during phototherapy to facilitate essential care activities without compromising treatment efficacy or infant safety.

Before the intervention with the BLUI Blanket, the mean serum total bilirubin level in subjects was 16.35 (SD 1.42) mg/dL. The elevated serum bilirubin

levels observed in these neonates indicated jaundice necessitating immediate intervention to prevent brain damage and other complications. Following the 24-hour observation period with intermittent BLUI Blanket phototherapy sessions, there was 19.02% decrease of bilirubin level from the baseline. This clinically significant reduction illustrates the intervention's efficacy in lowering bilirubin levels. A study demonstrated that phototherapy effectively reduced the risk of kernicterus in infants with

Table 2. Changes in serum bilirubin levels after 24 hours of phototherapy (N=14)

Variables		95%CI	P value
Mean total serum bilirubin pre-therapy (SD), mg/dL	16.35 (1.42)	15.53 to 17.17	
Mean total serum bilirubin post-therapy (SD), mg/dL	13.23 (1.67)	12.27 to 14.19	0.000*
Mean difference in bilirubin reduction (SD), mg/dL	3.11 (1.62)	2.18 to 4.05	

^{*}Paired sample T-test

hyperbilirubinemia.¹¹ In Indonesia, research by Suryawan et al. found that phototherapy significantly reduced serum bilirubin levels and mitigated the risk of neurological complications in infants with neonatal jaundice.³

The bilirubin reduction observed in our subjects was within the expected range based on existing literature, which indicates that phototherapy can lower bilirubin levels by 1-2 mg/dL per day. The average 19.02% reduction approaches the 20% target recommended by the American Academy of Pediatrics (AAP), given the phototherapy radiation intensity emitted by the BLUI Blanket, measured at $6.6-8.8 \, \mu \text{W/cm}^2/\text{nm}.^{12}$

To provide a broader perspective, comparisons were made to several previous studies using similar phototherapy methods. **Table 3** summarizes findings from several relevant studies.

The Double-Fiber-Optic Phototherapy method reported by Tan demonstrated the highest bilirubin reduction, achieving 21.82%. The conventional (fluorescent) phototherapy method in the same study also showed excellent results with a reduction of 19.00%. In 2019, a study utilized the Biliblanket and reported a bilirubin reduction of 1.547 mg/dL, approximately 11.32%. In addition, another study employed the Fiberoptic Biliblanket and achieved a bilirubin reduction of 2.72 mg/dL or 17.90%. In The BLUI Blanket demonstrated a reduction of 19.02%, comparable to conventional methods and approaching

the results of Double-Fiber-Optic Phototherapy.

The outcomes of this study have implications for clinical practice, particularly in selecting effective phototherapy methods for managing infant hyperbilirubinemia. Clinicians may consider using the BLUI Blanket as an alternative to conventional hospital-based phototherapy methods, especially due to advantages such as ease of use, portability, and its ability to support mother-infant interaction during therapy. The BLUI Blanket also has potential for home-based care in mild to moderate hyperbilirubinemia cases, potentially reducing hospitalization requirements and healthcare costs, although this aspect requires further research for confirmation.

After the 24-hour observation period in this study, most infants required continued therapy with the BLUI Blanket until bilirubin levels reached safe levels (typically below 12 mg/dL). The total duration of therapy varied based on individual bilirubin reduction rates, with most infants requiring an additional 24-48 hours of intermittent therapy following the initial observation period.

In conclusion, our preliminary study demonstrated that using the BLUI Blanket reduced serum total bilirubin levels by 3.11 mg/dL within 24 hours, equivalent to a 19.02% reduction. This result suggests that the BLUI Blanket phototherapy is highly effective for managing infant hyperbilirubinemia. However, our study had several limitations, including a small sample size and a short observation period.

Table 3. Comparison of bilirubin reductions among studies using various phototherapy methods

Study	Phototherapy methods	Bilirubin reduction in 24 hours, mg/dL	Percentage reduction (%)
Tan ¹³	Standard Fiber-Optic Mat (Ohmeda Biliblanket)	-	10.26
	Large Fiber-Optic Phototherapy	-	14.50
	Double-Fiber-Optic Phototherapy	-	21.82
	Conventional Phototherapy	-	19.00
Ambarita, et al.7	Biliblanket	1.547 mg/dL	11.32
Kusuma ¹⁴	Fiberoptic Biliblanket	2.72 mg/dL	17.90
Our study	BLUI Blanket	3.11 mg/dL	19.02

Additionally, we did not include a control group of subjects who received either no therapy or alternative phototherapy methods, which would have provided more robust comparative data on the BLUI Blanket's effectiveness. No standardized therapy interval in our study, which was noted as a limitation requiring more structured protocols in subsequent research phases. This will be addressed in future research as this was intended as a preliminary investigation.

While we describe benefits of the BLUI Blanket including the efficiency and uniformity of lighting with LED technology providing more even and efficient light distribution, these specific technical advantages were based on manufacturer specifications rather than direct measurements in our study. Similarly, our assertion that the BLUI Blanket design is safer and more comfortable, allowing infants to rest under more natural and calm conditions during therapy, is based on observational assessment rather than comparative data against other phototherapy methods. Future studies should include direct comparisons with conventional phototherapy methods to quantitatively assess these potential advantages.

Conflict of interest

None declared.

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