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Published by Indonesian Pediatric Society

E-ISSN 2338-476X | P-ISSN 0030-9311

Editorial Board

Vol. 65 No. 3 (2025): May 2025

DOI: https://doi.org/10.14238/pi65.3.2025

Published: 2025-06-30

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

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DOI: https://doi.org/10.14238/pi65.3.2025.245-52

PDF

Published
2025-06-20

How to Cite

Fadilah TF, Adisasmita AC, Ascobat P, Siswanto JE, Koestoer RA, Susianti Y, Irwan H, Gunarsih

artikel pediatrica

by Tubagus Ferdi Fadilah FK

Submission date: 10-Oct-2024 11:52AM (UTC+0700)
Submission ID: 2480871319
File name: Artikel_Penelitian_Pendahuluan_BLUI_Blanket_PI_English.docx (198.38K)
Word count: 4410
Character count: 26837

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. This study evaluates the efficacy of the BLUI (Blue Light Universitas Indonesia) LED phototherapy blanket in reducing bilirubin levels in infants with physiological jaundice.

Methods: Conducted from December 2022 to February 2023, this preliminary study involved 14 infants with physiological jaundice at Hermina Hospital Ciputat, Sariasih Hospital Ciputat, and the General Hospital of South Tangerang. The study employed strict inclusion criteria, focusing on infants with gestational age ≥35 weeks and birth weight ≥2000 grams. The primary variable was the reduction in total serum bilirubin levels, assessed using spectrophotometers and chemistry analyzers across the participating hospitals. A paired sample t-test was used to compare bilirubin levels before and after the intervention.

Results: The study included 14 infants, with an average age of 6.86 days and a mean gestational age of 37.71 weeks. The BLUI Blanket demonstrated a mean bilirubin reduction of 3.11 mg/dL over 24 hours, with a 19.02% decrease. The intervention was well-tolerated, with minimal adverse effects, such as 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.

Keywords: Neonatal jaundice, bilirubin reduction, phototherapy, BLUI Blanket, LED therapy, preliminary study.

INTRODUCTION

Neonatal jaundice, or neonatal 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.

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, this method 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.[8]

As an alternative, the present study focuses on the development and assessment of the effectiveness and safety of the BLUI (Blue Light Universitas Indonesia) LED phototherapy blanket prototype. This technology employs an array of LEDs to form 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. This study will evaluate the efficacy of this prototype in reducing total bilirubin levels in infants with physiological jaundice and ensure the safety and functionality of the device as a basis for further experimental studies.

METHODS AND MATERIALS

This research aims to evaluate the safety and efficacy of the intervention, providing insights into the safety of the treatment and operational functionality of the device used. The primary focus of this study is to assess the efficacy of the BLUI (Blue Light Universitas Indonesia) LED phototherapy blanket in reducing total bilirubin levels in infants with physiological jaundice. This phase serves as a preliminary study before proceeding to the subsequent experimental phase.

The study was conducted in the newborn unit and perinatology ward at Hermina Hospital Ciputat, Sariasih Hospital Ciputat, and the General Hospital of South Tangerang. The research was conducted from December 2022 to February 2023 as a preparatory stage for subsequent studies in this research series.

The target population for this preliminary study consisted of infants with physiological jaundice. The selected sample comprised patients with physiological jaundice undergoing inpatient care in the perinatology units of the three participating hospitals. Strict inclusion criteria were applied in selecting samples to ensure the relevance and accuracy of the research findings.

Inclusion Criteria

- Gestational age ≥ 35 weeks and birth weight ≥ 2000 grams (p25).
- Postnatal age > 24 hours – 28 days.
- No history of birth trauma/cephalohematoma/bleeding.

- Total serum bilirubin levels ≥ 10 and ≤ 19 mg/dl (medium-risk thresholds for infants with gestational age 35–36 6/7 weeks and well), and total serum bilirubin levels ≥ 12 and < 22 mg/dl (lower risk thresholds for infants ≥ 38 weeks and well).
- Asian race.[10]
- Absence of circulatory disorders, no respiratory distress, saturation above 90%.
- Consent from patient's parents/guardians to participate in the study and sign the informed consent.

Exclusion Criteria

- Infection (clinically fever/hypothermia; laboratory examinations showing increased leukocyte count and peripheral blood smear).
- Direct bilirubin levels exceeding 2mg/dl or 20% of total serum bilirubin levels.

Sample Size Estimation

Considering practical aspects and limitations in the number of devices and human resources, a minimum sample size of 10 subjects is deemed adequate for this preliminary study.

Identification of Research Variables

The research focuses on several key variables to assess the effectiveness of the intervention. The primary dependent variable is the reduction in total serum bilirubin levels, which serves as the main indicator of the intervention's success. The independent variable is the BLUI Blanket, a novel phototherapy device being evaluated for its efficacy. Additionally, the study considers various neonatal factors, including gender, gestational age, temperature, birth weight, and age, which may influence the outcomes. Covariate factors such as the feeding method, frequency, volume of fluid intake, and therapy interval are also examined to account for their potential impact on the bilirubin reduction process.

Data Collection Tools and Materials

Serum Bilirubin Spectrophotometer

At Hermina Hospital Ciputat, quantitative measurement of total bilirubin in serum or plasma is performed using an ELITechGroup Auto Chemistry Analyzer, Selectra Pro S model. At Sariasih Hospital Ciputat, the analysis employs a DIRUI Industrial Co., Ltd. spectrophotometer, model DIRUI BM 240S, serial number 220T240CS0231. Meanwhile, at the General Hospital of

South Tangerang, the examination uses a Horiba Medical Clinical Chemistry Analyzer, Pentra C400 model, serial number 211C4-1420.

BLUI Blanket Phototherapy

This phototherapy blanket prototype utilizes LED lamps, specifically the HI-LED Ilker FSHI 5050.B020.6012 model (Turkey), operating at a wavelength of 460 – 470 nm. This device is designed to deliver effective phototherapy, ensuring optimal blue light exposure at the appropriate spectrum for treating neonatal jaundice.[9]

Preliminary Study Subject Recruitment Flowchart

The Preliminary Study Subject Recruitment Flowchart can be seen in Appendix Figure 1.

Preliminary Data Analysis

To obtain valid and reliable results, data analysis in this study is conducted through two primary stages, data processing and analysis. The data processing phase involves several key stages to ensure data accuracy and reliability. It begins with data checking (editing) to correct errors, followed by code assignment (coding) to organize data into categories. The data is then processed using statistical methods, and finally, data cleaning is performed to remove anomalies, ensuring a robust dataset for analysis. Univariate Analysis involves calculating measures of central tendency (mean, median) and variation (variance, range, and standard deviation) for numerical and categorical data. Numerical and categorical data include total bilirubin, duration of therapy, body temperature, gestational age, birth weight, age, and feeding frequency. Categorical data comprise 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 statistical analysis method Paired Sample T-Test used to compare two sets of paired data. It is used to determine if there is a statistically significant difference between the means of BLUI Blanket intervention by comparing results before and after within the same group.

Research Ethics

This study was conducted with Ethical Approval from the Ethics Committee of the Faculty of Medicine, Trisakti University, official consent from the management of Hermina Hospital Ciputat, Sari Asih Hospital Ciputat, and the General Hospital of South Tangerang, the responsible attending physician, as well as consent from the parents of the patients.

RESULTS

This study was conducted over a three-month period, from December 2022 to February 2023. Prior to commencement, the research proposal and protocol underwent submission and received ethical approval from the Research Ethics Committee of the Faculty of Medicine, Trisakti University, with Ethical Clearance Number: 053/KER/FK/I/2023, indicating compliance with ethical standards in research. Furthermore, the research protocol also obtained approval from the Medical Services Department of Hermina Hospital Group (PT. Medikaloka). This approval was supported by the Director of Hermina Hospital Ciputat, the Director of Sariasih Hospital Ciputat, and the Director of South Tangerang General Hospital, all of whom expressed their agreement and support for the research implementation.

The successful acquisition of these various approvals indicates that the research met stringent regulatory and ethical criteria and received strong institutional support, which is crucial for conducting quality and responsible research. This comprehensive approval process also ensures that the research is conducted with consideration for the well-being of subjects, scientific integrity, and compliance with applicable ethical norms.

Basic Characteristics of Subjects and Conditions During Phototherapy

In this study, a total of 14 subjects diagnosed with neonatal jaundice, who met the inclusion criteria, were recruited. 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 Appendix Table 1.

Regarding infant characteristics, 42.9% were male and 57.1% were female. The average age of the infants was 6.86 days with a standard deviation of 2.25 days, and the age range was between 4 and 11 days. The average gestational age was 37.71 weeks with a standard deviation of 1.38 weeks, and the gestational age ranged from 34 to 49 weeks. The average birth weight was 2998.21 grams with a standard deviation of 451.88 grams, with the birth weight ranging from 2540 to 3824 grams. In terms of maternal characteristics, 64.3% of the infants were bottle-fed, while 35.7% were fed using a combination of bottle and other methods. All infants (100%) were fed more than 8 times per day. The bottle feeding volume was deemed adequate in 57.1% of the infants and inadequate in 42.9% of the infants.

During phototherapy over 24 hours, the average therapy interval was 30.71 minutes with a standard deviation of 38.22 minutes, and the interval ranged from 5 to 145 minutes. The average room temperature was 24.8°C with a standard deviation of 0.74°C, and the temperature range was from 22.5 to 25.5°C.

For secondary outcomes within 24 hours, 92.9% of the infants did not develop skin rashes, while 7.1% did. Normal body temperature was observed in 78.5% of infants, while 21.4% exhibited subfebrile body temperatures (ranging from 37.5 to 38°C). The average body temperature was 37.23°C with a standard deviation of 0.31°C, and the body temperature range was from 36.92 to 37.92°C. None of the infants experienced dehydration. Stool consistency varied, with 7.1% of infants having hard/solid stools, 35.7% having formed soft paste-like stools, and 57.1% having spreading soft stools. None of the infants had mucous/fibrous or watery stools.

Changes in Serum Bilirubin Levels 24 Hours Following Phototherapy

The results of bilirubin level examinations before and after the 24-hour intervention are presented in Appendix Table 2.

Prior to the commencement of phototherapy, the average serum bilirubin level in the infants studied was 16.35 mg/dL with a standard deviation of 1.42 mg/dL. The observed range of bilirubin levels before therapy spanned from 13.80 to 18.30 mg/dL, with a 95% confidence interval between 15.53 and 17.17 mg/dL. Following 24 hours of phototherapy, the average serum bilirubin level decreased to 13.23 mg/dL with a standard deviation of 1.67 mg/dL. The observed range of bilirubin levels post-therapy was between 10.50 and 16.80 mg/dL, with a 95% confidence interval between 12.27 and 14.19 mg/dL. The computations illustrate an average reduction in serum bilirubin levels of 3.11 mg/dL with a standard deviation of 1.62 mg/dL, representing a 19.02% decrease from baseline levels. The range of bilirubin reduction was between 0.70 and 6.00 mg/dL, with a 95% confidence interval from 2.18 to 4.05 mg/dL. The Paired Samples T-Test results evidenced that the reduction in serum bilirubin following phototherapy was statistically significant, with a p-value of 0.000. This p-value indicates a substantial difference between pre- and post-phototherapy bilirubin levels, underscoring the efficacy of phototherapy in reducing bilirubin levels in the studied infants. These findings provide compelling evidence for healthcare practitioners to employ phototherapy as a part of the management strategy for hyperbilirubinemia in infants.

DISCUSSION

The study involved 14 infants undergoing phototherapy, with comprehensive baseline characteristics and conditions outlined. In terms of gender distribution, there were 6 male infants (42.9%) and 8 female infants (57.1%). The average age of the infants was 6.86 days, with a standard deviation of 2.25 days, and an age range from 4 to 11 days, indicating that the intervention was implemented at a relatively early neonatal age. The average gestational age was 37.71 weeks with a standard deviation of 1.38 weeks, and the range of gestational age was 34 to 49 weeks, signifying that the study predominantly involved full-term infants. The average birth weight was 2998.21 grams with a standard deviation of 451.88 grams, and the birth weight ranged from 2540 to 3824 grams.

Regarding maternal characteristics, the feeding method utilized involved bottle feeding in 9 infants (64.3%) and a combination of bottle and direct breastfeeding in 5 infants (35.7%). All infants were fed more than 8 times a day. The volume of bottle feeding received by infants varied, with 6 infants (42.9%) receiving an insufficient volume and 8 infants (57.1%) receiving a sufficient volume.

During phototherapy, the average interval for clinical activities such as blood sampling or feeding, as well as non-clinical activities like bathing, was 30.71 minutes, with a standard deviation of 38.22 minutes, and the interval ranged from 5 to 145 minutes. This variability indicates a wide range of time adjustments for individual subjects during the intervention. The room temperature during phototherapy was relatively constant, averaging 24.8°C with a standard deviation of 0.74°C, and the temperature range was from 22.5 to 25.5°C. This stable room temperature condition is crucial to ensuring that changes in neonatal body temperature during the intervention are attributable to the device and not environmental fluctuations.

Secondary outcomes over 24 hours showed that most infants did not develop skin rashes, with only 1 infant (7.1%) experiencing a rash. The majority of infants had normal body temperatures, with 11 infants (78.5%) having normal body temperature and 3 infants (21.4%) exhibiting subfebrile temperatures. The average body temperature of the infants was 37.23°C, with a standard deviation of 0.31°C, and the range of body temperature was from 36.92 to 37.92°C. This data confirms that the body temperature of the neonates was mostly normal, facilitating easy monitoring of temperature changes during the intervention. None of the infants experienced dehydration during phototherapy. The consistency of infant stools varied, with 1 infant (7.1%) showing hard/solid stools, 5 infants

(35.7%) having formed soft paste-like stools, and 8 infants (57.1%) having spreading soft stools. None had mucous/fibrous or watery stools.

Overall, the study results indicate that the majority of infants undergoing phototherapy maintained stable conditions with normal body temperatures and did not experience dehydration. The high frequency of feeding (more than 8 times per day) may have contributed to the stability of the infants' conditions. The variation in therapy intervals demonstrates flexibility in phototherapy administration but remains within a safe range. The relatively constant room temperature also supported the infants' comfort during therapy. The conclusions drawn from this study suggest that the intervention with the BLUI Blanket was conducted on neonates with consistent demographic, physical, and jaundice conditions. With high bilirubin levels and controlled environmental temperatures, the intervention showed significant changes in bilirubin levels and neonatal physiological conditions.

Changes in Serum Bilirubin Levels 24 Hours After Phototherapy

Before the intervention with the BLUI Blanket, the average measured serum bilirubin level in subjects was 16.35 mg/dL, with a standard deviation of 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 24 hours of phototherapy using the BLUI Blanket, results revealed a reduction in average serum bilirubin levels to 13.11 mg/dL (standard deviation 1.67), representing a 19.02% decrease from baseline levels. This clinically significant reduction illustrates the intervention's efficacy in lowering bilirubin levels. Research by Bhutani et al. (2011) demonstrated that phototherapy effectively reduces the risk of kernicterus in infants with hyperbilirubinemia.[11] In Indonesia, research by Suryawan et al. (2019) found that phototherapy significantly reduced serum bilirubin levels and mitigated the risk of neurological complications in infants with neonatal jaundice. This study aligns with global findings that highlight the efficacy of phototherapy in managing neonatal jaundice.[3]

The bilirubin reduction observed in this study falls 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 µW/cm²/nm.[12]

Comparison of the Efficacy of BLUI Blanket Phototherapy with Similar Methods in Reducing Bilirubin Levels

The author's comparisons of this study's findings with several prior studies offer broader context and understanding of this research's position within the field. This study established that the use of the BLUI Blanket reduced serum bilirubin levels by 3.11 mg/dL within 24 hours, equating to a 19.02% reduction. The results indicate that the BLUI Blanket is an effective method for addressing hyperbilirubinemia in infants. To provide a broader perspective, comparisons were made with several previous studies using similar phototherapy methods. Appendix Table 3 summarizes findings from several relevant studies.

From the comparison table, it is evident that the Double–Fiber-Optic Phototherapy method reported in Tan's 1997 study 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%.[13] In 2019, Ambarita's study utilizing the Biliblanket reported a bilirubin reduction of 1.547 mg/dL, approximately 11.32%. Meanwhile, Kusuma's 2017 study employing the Fiberoptic Biliblanket achieved a bilirubin reduction of 2.72 mg/dL or 17.90%.[7,14] The current study using the BLUI Blanket demonstrated a reduction of 19.02%, comparable to conventional methods and approaching the results of Double-Fiber-Optic Phototherapy.

These findings indicate that the BLUI Blanket is a highly effective phototherapy method, with reductions comparable to or exceeding some other methods such as the Biliblanket and Standard Fiber-Optic Mat. Based on these comparisons, the Double–Fiber-Optic Phototherapy method from Tan's 1997 study remains the most effective in terms of bilirubin reduction percentage at 21.82%. However, the BLUI Blanket used in the current study also yielded excellent results with a reduction of 19.02%, nearing the outcomes of the more advanced Double-Fiber-Optic Phototherapy, and surpassing several other methods previously used in research. This method not only provides significant reductions but also offers practicality and safety in its use. Therefore, the use of the BLUI Blanket can be recommended as a primary option in administering phototherapy for infant hyperbilirubinemia, given the effectiveness demonstrated in this study.

The outcomes of this study hold significant implications for clinical practice, particularly in selecting effective phototherapy methods for managing infant hyperbilirubinemia. However, the study presents limitations, including a limited sample size and a short observation period.

Thus, the findings of this study support the use of the BLUI Blanket as an effective intervention for managing neonatal jaundice, potentially reducing the risk of severe complications associated with hyperbilirubinemia in newborns. The benefits of the BLUI Blanket in this study can be emphasized in several aspects. The efficiency and uniformity of lighting, with the use of LED technology, provide a more even and efficient light distribution, which is crucial in phototherapy to ensure consistent exposure across the affected area. Its design makes the BLUI Blanket safer and more comfortable, allowing infants to rest under more natural and calm conditions during therapy, which may contribute to the therapy's effectiveness. The controlled body and room temperature during the study indicated that the BLUI Blanket could be used in various environmental conditions without compromising the therapy's efficacy or patient comfort.

CONCLUSIONS

Preliminary research demonstrated that using the BLUI Blanket reduced serum 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.

Conflict of Interest Statement

Conflict of Interest: none declared.

Acknowledgements

The authors would like to express their gratitude to all individuals and organizations that contributed to this research. Special thanks are extended to Hermina Hospital Ciputat, Sariasih Hospital Ciputat, and the General Hospital of South Tangerang for their invaluable support and guidance throughout the study. Their collaboration and assistance were crucial in facilitating the research process and ensuring its successful completion.

Funding Acknowledgment

This research was supported by funding from the Indonesia Endowment Fund for Education (Lembaga Pengelola Dana Pendidikan, LPDP). The authors are grateful for the financial assistance provided, which was instrumental in the successful completion of this study.

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APPENDICES

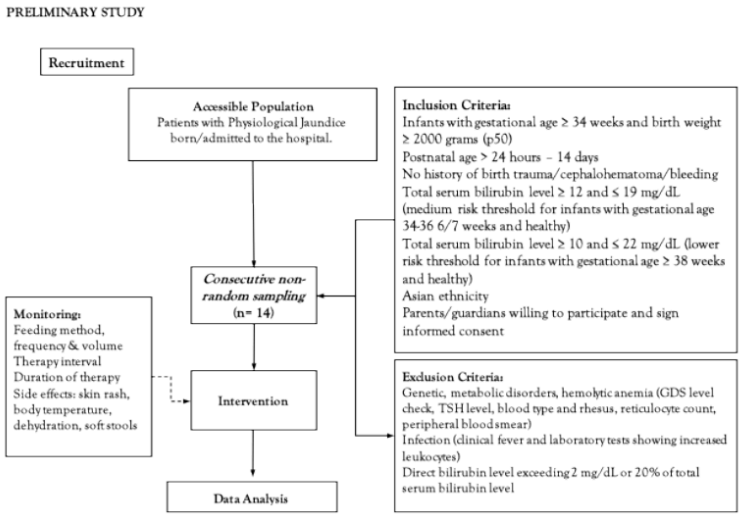

Figure 1. Preliminary Study Subject Recruitment Flowchart

Table 1. Basic Characteristics of Conditions During Phototherapy from the Study Population

Variable	Number of Respondents n=14 (%)
Infant Characteristics	
Gender	
Male	6 (42.9%)
Female	8 (57.1%)
Age (days)	
Mean	6.86
Standard Deviation	2.25
(Min – Max)	(4 – 11)
CI (95%)	(5.56 – 8.16)
Gestational Age (weeks)	
Mean	37.71
Standard Deviation	1.38
(Min – Max)	(34 – 49)
CI (95%)	(36.92 – 38.52)
Birth Weight (grams)	
Mean	2998.21
Standard Deviation	451,88
(Min – Max)	(2540 – 3824)
CI (95%)	(2737.31 – 3259.12)
Maternal Characteristics	
Feeding Method	
Bottle	9 (64.3%)
Both	5 (35.7%)
Feeding Frequency (Category)	
< 8 kali	0 (0.0%)
≥ 8 kali	14 (100.0%)
Bottle Feeding Volume (Category)	
Insufficient	6 (42.9%)
Sufficient	8 (57.1%)
Conditions During Phototherapy (within 24 hours)	
Therapy Interval (minutes)	
Mean	30.71
Standard Deviation	38,22
(Min – Max)	(5 - 145)
CI (95%)	(8.65 – 52.78)
Room Temperature (°C)	
Mean	24.8
Standard Deviation	0.74
(Min – Max)	(22.5 – 25.5)
CI (95%)	(24.39 – 25.24)
Secondary Outcome (within 24 hours)	
Skin Rash (Category)	
No skin rash	13 (92.9%)
Skin rash present	1 (7.1%)
Body Temperature (Category)	
Not Normal	3 (21.4%)
Normal	11 (78.5%)
Body Temperature (°C)	
Mean	37.23
Standard Deviation	0.31

(Min – Max)	(36.92 – 37.92)
CI (95%)	(37.05 – 37.41)
Dehydration (Category)	
Tidak dehidrasi	14 (100%)
Dehidrasi	0 (0%)
Stool Consistency (Category)	
Hard/solid	1 (7.1%)
Soft-formed paste	5 (35.7%)
Soft-spread	8 (57.1%)
Mucous/fibrous	0(0.0%)
Watery/liquid	0 (0.0%)

Table 2. Changes in Serum Bilirubin Levels After 24 Hours of Phototherapy

Variable	Number of Respondents n=14	*p-value*
Bilirubin Before Therapy		
Mean	16.35	
Standard Deviation	1,42	
(Min – Max)	(13.80 – 18.30)	
CI (95%)	(15.53 – 17.17)	
Bilirubin Total Serum (mg/dL)		
Mean	13.23	
Standard Deviation	1,67	0.000*
(Min – Max)	(10.50 – 16.80)	
CI (95%)	(12.27 – 14.19)	
Difference in Bilirubin Reduction (mg/dL)		
Mean	3.11	
Standard Deviation	1.62	
(Min – Max)	(0.70 – 6.00)	
CI (95%)	(2.18 – 4.05)	

** Paired Sampel T-Test*

Table 3. Comparison of Bilirubin Reduction

Study	Phototherapy Method	Bilirubin Reduction (mg/dL) in 24 hours	Percentage Reduction (%)
Tan (1994)	*Ohmeda Biliblanket fiberoptic*		9.2
Tan (1997)	*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 (2019)	*Biliblanket*	1.547 mg/dL	11.32
Kusuma (2017)	*Fiberoptic Biliblanket*	2.72 mg/dL	17.90
This study	***BLUI Blanket***	**3.11 mg/dL**	**19.02**

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