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Single-surface Intensive Phototherapy or Double-Surface Intensive Phototherapy in Neonatal Non-Hemolytic Hyperbilirubinemia: A Comparison of Effectiveness and Complications

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Abstract

Background: Severe indirect hyperbilirubinemia causes neurotoxicity, leading to potential permanent injuries to the neonatal nervous system. The present study intended to compare the effectiveness and complications of Single-Surface Intensive Phototherapy (SSIP) and Double-Surface Intensive Phototherapy (DSIP) in treating non-hemolytic hyperbilirubinemia in the neonatal ward of the Besat Hospital, Hamadan, Iran.

Methods: In this prospective randomized clinical trial, 150 healthy full-term neonates born between 37-42 weeks gestation with ages <14 days old and birth weights ≥2500 gr who were affected by non-hemolytic hyperbilirubinemia with total serum bilirubin of 15-20 mg/dL were randomly allocated to two groups. Each group (n=75) underwent either SSIP or DSIP. Demographics, bilirubin level alterations, weight, platelet count, number of defecation per day, and body temperature of the patients were monitored and recorded in a specific questionnaire. Data analysis was performed using SPSS version 26.0 software, with the Chi-square and independent t-test.

Results: The pre-intervention levels of indirect bilirubin were 17.07±1.46 mg/dL in the SSIP group and 17.10±1.54 mg/dL in the DSIP group (P-value = 0.853). After 24 and 48 hours of treatment, the mean indirect bilirubin level of the SSIP group reduced to 13.12±1.71 mg/dL and 9.69±1.68 mg/dL, respectively. In the DSIP group, the levels were 11.85±2.17 mg/dL and 8.43±1.56 mg/dL after 24 and 48 hours of treatment, respectively. The absolute reductions of indirect bilirubin were 7.76±3.28 mg/dL for the SSIP group and 8.96±4.49 mg/dL for the DSIP group (P-value = 0.458). Therefore, the indirect bilirubin levels were significantly different between the groups after 24 and 48 hours of treatment and at the time of discharge (P<0.05). There were no significant inter-group differences in weight, platelet count, and incidence of skin rash, while the number of defecation and body temperature were higher in the DSIP group (P <0.05). However, body temperature alterations had no clinical relevance.

Conclusion: Compared to the SSIP, the DSIP showed faster effectiveness and led to a shorter hospital stay, while it did not entail higher levels of complications.

Keywords: Neonates, Non-hemolytic Hyperbilirubinemia, Single-Surface Intensive Phototherapy, Double-Surface Intensive Phototherapy

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Introduction

Neonatal jaundice is a common illness usually requiring medical intervention. Unconjugated hyperbilirubinemia is

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↑What is "already known" in this topic:
Phototherapy is the treatment of choice for neonatal hyperbilirubinemia. Some studies have shown a significant reduction in bilirubin levels with double phototherapy compared to single phototherapy, but the phototherapy irradiance was less than 30 µW/cm2/nm as recommended by AAP.

→What this article adds:
The results of this study show that DSIP reduced bilirubin levels more rapidly than SSIP and leads to a shorter hospital stay, while it does not cause more complications. Therefore, it is recommended to consider the routine use of the DSIP for the treatment of neonatal jaundice.

a transient, normal phenomenon in most neonates;

however, in some neonates, the plasma levels of unconjugated bilirubin are extremely increased, which is worrisome because indirect bilirubin can cross the blood-brain barrier, resulting in cerebral injury. During the first weeks of life, neurotoxic effects of bilirubin are known as acute bilirubin encephalopathy, while the long-term or permanent cerebral injury is called kernicterus (1, 2).

Phototherapy is the standard therapeutic modality for neonatal hyperbilirubinemia. It is the method of choice for neonatal jaundice treatment due to its safety and unique effectiveness in reducing high levels of serum-free bilirubin and limiting the related neurotoxicity. Moreover, this method can decrease the need for exchange transfusion (3).

The effectiveness of the method depends on the light wavelength and intensity as well as the area of the neonate's body exposed to phototherapy. These factors can be particularly critical if the serum bilirubin levels are extremely high or increasing rapidly or the neonate shows the signs and symptoms of acute bilirubin encephalopathy. In case of these situations, there is an urgent need to reduce the bilirubin levels as soon as possible (4).

Since 2004, the American Academy of Pediatrics (AAP) has been recommending intensive phototherapy with an irradiance of ≥30 μW/cm^2.nm and a wavelength of 430-490 nm to treat neonatal hyperbilirubinemia. These wavelengths convert indirect bilirubin into water-soluble isomers, which are less toxic and are easily excreted in the bile and urine (5).

Since the introduction of phototherapy for neonatal jaundice treatment about 50 years ago, several studies have compared various techniques and modes of phototherapy, such as single-surface, double-surface, and triple-surface phototherapies as well as phototherapy devices from different brands. Some of these studies have reported the superiority of double-surface phototherapy over the single-surface method. However, some studies have not shown that the effectiveness of intensive phototherapy can be increased by increasing the irradiance (light intensity × body area) (6, 7). Therefore, there is a need for further studies to reach a standard protocol. The present study intended to compare the Single-Surface Intensive Phototherapy (SSIP) and Double-Surface Intensive Phototherapy (DSIP) in terms of effectiveness in indirect bilirubin reduction and side effects in the neonates with non-hemolytic hyperbilirubinemia who were admitted to the neonatal ward of the Besat Hospital, Hamadan, Iran.

Methods

The present study was a prospective randomized clinical trial performed at the neonatal ward of the Besat Hospital, Hamadan, Iran, from June 2019 to November 2020. The study population included neonates presenting to the mentioned hospital with jaundice who met the eligibility criteria.

Inclusion criteria were healthy, full-term neonates (born between 37-42 weeks gestation) with age <14 days and birth weights ≥2500 gr who were exclusively breastfed and affected by non-hemolytic hyperbilirubinemia with a total serum bilirubin concentration of 15-20 mg/dL. The eligible neonates had no evidence of ABO or RH incompatibility. Also, they had a negative direct Coombs test, normal reticulocyte count, and normal G6PD levels. Exclusion criteria included any history of asphyxia, prematurity, intrauterine growth restriction, acute bilirubin encephalopathy, and sepsis.

The following equation was used to calculate the sample size needed to compare the effectiveness of SSIP and DSIP:

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left(\sigma_1^2 + \sigma_2^2\right)}{(\mu_1 - \mu_2)^2}$$

For effectiveness comparison, the confidence interval was considered at 95% ($1-\alpha=0.95$), while the statistical power was 80%. According to the study by Eqbalian et al. (8), a common variance of 2.25 among the groups, a minimum significant inter-group difference of 1.2, and a potential drop-out rate of 10% were considered. Finally, the needed sample size was calculated at least 30 in each group, which increased to 35 (70 in total) for higher statistical power.

Also, the following equation was used to calculate the sample size needed to compare the complications of DSIP and SSIP:

$$n_1 = n_2 = \frac{(p_1(1-p_1) + p_2(1-p_2))(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{(p_1 - p_2)^2}$$

For complication comparison, the confidence interval was considered at 95% ($1-\alpha=0.95$), while the statistical power was 80%. According to the study by Eqbalian et al. (8), a complication incidence rate of 15% and 35% in the two groups and a potential drop-out rate of 10% were considered. Finally, the needed sample size was calculated at least 75 in each group.

Therefore, a total of 150 neonates were selected and randomly allocated to two groups of SSIP and DSIP using the following randomization method: The questionnaires for data collection were coded from 1 to 150 (1-75 for SSIP and 76-150 for DSIP). When entered into the study, each neonate was given a questionnaire with a specific number by drawing lots. Then, the questionnaire was completed during the intervention. Furthermore, this study was non-Blinded, due to the obvious and distinct entity of the intervention (i.e., SSIP vs. DSIP),

Before the treatment initiation, the neonates underwent diagnostic tests to diagnose the cause of hyperbilirubinemia. Total and indirect bilirubin were measured at baseline and every 24 hours until discharge. Moreover, age, gender, time of jaundice onset, weight, platelet count, number of defecation per day before the visit, presence of skin rash, and body temperature were recorded. Platelet count, number of defecation per day, and incidence of skin rash were also recorded daily until discharge, while the body temperature was monitored

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every 6 hours.

The mothers were instructed on how to care for their neonates. The neonates had appropriate eye covers during the therapy and were continuously monitored by the nurses. Also, breastfeeding support was provided by experienced nurses. Other routine nursing care were performed for the neonates as well.

We used a Tosan 024 phototherapy device for intensive phototherapy. For SSIP, six lamps of the total 12 lamps of the device were used. The lamps were located on the upper part of the device 20-30 cm above the neonate and covered the angles of 0-180 degrees. For DSIP, all 12 lamps on the upper and lower parts of the device were used. The lamps were above and also under the neonate and covered the angles of 0-360 degrees. Data analysis was performed using the SPSS software version 26.0.in, the independent t-test, and the chi-square test.

Ethical Considerations

The present study was approved by the Ethics Committee for Research of the Hamadan University of Medical Sciences with the ethics code of IR.UMSHA.REC.1398.167. Moreover, it was registered in the Iranian Registry of Clinical Trials with the code IRCT20191203045595N1. Also, the neonates' parents were provided with the necessary explanations and gave written consent in case of willingness to participate in the study.

Results

The present study included 150 neonates in two groups.Kolmogorov–Smirnov test was implemented to evaluate the distribution of descriptive data (P>0.05). Also,there was no significant inter-group difference in gender, time of jaundice onset, and age, weight, and total bilirubin level at the time of admission, indicating the appropriate randomization. Therefore, the comparison of the intervention results was feasible (Table 1).

The pre-intervention levels of indirect bilirubin were 17.07±1.46 mg/dL and 17.10±1.54 mg/dL in the SSIP and DSIP groups, respectively (P=0.853). After 24 and 48 hours of treatment, the mean indirect bilirubin levels reduced to 13.12±1.71 mg/dL and 9.69±1.68 mg/dL in the SSIP group, respectively. In the DSIP group, the levels were 11.85±2.17 mg/dL and 8.43±1.56 mg/dL after 24 and 48 hours of treatment, respectively. The absolute reductions of indirect bilirubin were 7.76±3.28 mg/dL for the SSIP group and 8.96±4.49 mg/dL for the DSIP group (P<0.001). The results of inter-group comparisons and the significance of differences are presented in Table 2.

Phototherapy complications, including weight alteration, were not different between the groups. However, the rate of increased body temperature and defecation per day was higher in the DSIP group after 24 hours of phototherapy (P values of 0.002 and 0.005, respectively) (Table 3).

Discussion

In general, the present study showed that the DSIP was more effective than the SSIP in reducing bilirubin in neonates with non-hemolytic hyperbilirubinemia with baseline bilirubin levels of <20 mg/dL. This modality also led to a shorter hospital stay compared to SSIP without increasing the rate of phototherapy-related complications.

In the present study, after 24 hours of treatment, the indirect bilirubin levels were reduced to 13.12±1.71 mg/dL and 11.85±2.17 mg/dL in the SSIP and DSIP groups, respectively. Moreover, after 48 hours of treatment, the levels further reduced to 9.69±1.68 mg/dL and 8.43±1.56 mg/dL in the SSIP and DSIP groups, respectively. Therefore, the bilirubin reductions were significantly higher in the DSIP group than in the SSIP group. Moreover, the patients in the DSIP group needed a significantly shorter duration of therapy. However, no case of lack of response to phototherapy was observed in both groups. These findings were compatible with those of Eqbalian et al. (8), Niza et al. (9), and Milyana et al. (10). However, Naderi et al. (11) did not report any significant difference in bilirubin reduction between the groups. As mentioned, we found that DSIP could lower the indirect bilirubin levels back to a desirable level faster because there was an increased area of neonates' bodies exposed to

Table 1. Descriptive data by group

Variable	Single surface phototherapy Group N=75	Double surface phototherapy Group N=75	P-value
Neonatal age (day)	8.53±2.38	8.60±2.49	0.874
Sex			0.300
Male	45	37	
Female	30	38	
Admission weight (g)	3197.7±157.1	3160.3±148.9	0.160
Time of jaundice onset (day)	5.89±2.52	5.84±2.46	0.903
Total serum bilirubin level at the time of admission (mg/dl)	17.43±1.47	17.48±1.55	0.909

Table 2. Mean and standard deviation of indirect bilirubin in each group

Variable	Single surface phototherapy Group N=75	Double surface phototherapy Group N=75	P-value
Initial bilirubin (mg/dl)	17.43±1.47	17.48±1.55	0.909
Bilirubin at 24 h after phototherapy (mg/dl)	13.12±1.71	11.85±2.17	0.001
Bilirubin at 48 h after phototherapy (mg/dl)	9.69±1.68	8.43±1.56	0.001
Bilirubin decline (mg/dl/day)	3.81±0.49	5.16±1.06	0.001
Duration of hospital stay (days)	2.3±0.50	1.8±0.64	0.001

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Table 3. Mean and standard deviation of phototherapy complications in each group

Variable	Single surface phototherapy Group N=75	Double surface phototherapy Group N=75	P-value
Body weight (g)			
Starting phototherapy	3197.7±157.1	3160.3±148.9	0.160
48 h after phototherapy	3163.2±154.8	3129.2±150.9	0.202
Absolute weight loss	35.7±12.8	33.4±13.7	0.293
Weight loss rate (g /day)	15.7±5.4	18.8±6.1	0.001
Platelet count ($\times 10^3$ / mm^3)			
Starting phototherapy	294.9±69.5	287.8±74.6	0.558
48 h after phototherapy	248.7±65.8	237.0±67.5	0.283
Absolute platelet count reduction	46.3±21.46	50.8±20.49	0.205
Platelet reduction rate ($\times 10^3$ / mm^3/ day)	20.1±8.9	30.2±15.0	0.001
Defecation (number/day)			
Starting phototherapy	5.7±1.4	5.6±1.2	0.426
48 h after phototherapy	7.5±1.4	8.1±1.3	0.002
Increased defecation rate	0.7±0.6	1.5±1.0	0.001
Temperature (^{0}C)			
Starting phototherapy	36.73±0.14	36.74±0.15	0.581
48 h after phototherapy	36.80±0.17	36.87±0.19	0.005
Increased temperature rate (^{0}C/day)	0.03±0.006	0.07±0.003	0.001

intensive light, leading to faster bilirubin degradation (5, 9, 12). Therefore, this modality can decrease the phototherapy equipment use duration, hospitalization costs, and hospital stay, especially in case of higher admissions to the neonatal ward and shortage of medical staff.

The length of hospital stay was 1.8±0.64 days in the DSIP and 2.3±0.50 days in the SSIP group, which was significantly different between the groups, indicating sooner discharge of the neonate in the DSIP group. According to Arnolda et al. (13), the hospital stay of the neonates undergoing DSIP was 13.8 hours less than those undergoing SSIP on average. Moreover, Ruthwan et al. (14) reported shorter hospital stay in the DSIP group than in the SSIP group. However, Silva (15) reported no difference in hospital stay between the groups. It seems that faster bilirubin degradation is the cause of shorter hospital stays in the DSIP.

Also, phototherapy complications were compared between the groups. There was no significant inter-group difference in weight at the time of admission and discharge and absolute weight loss. However, the weight reduction was significantly faster in the DSIP group ($P<0.05$). The findings were compatible with similar studies (10, 12, 16) in the insignificance of difference in weight loss between the groups. This finding can mainly be attributed to sweating and increased bowel movements of the neonates.

In terms of platelet count reduction, the absolute platelet count reduction was 46.3±21.46 thousand per mm^3 in the SSIP group and 50.8±20.49 thousand per mm^3 in the DSIP group, indicating a daily rate of platelet reduction of 20.1±8.9 thousand per mm^3 and 30.2±15.0 thousand per mm^3 in the SSIP and DSIP groups, respectively. Although there was no significant inter-group difference in platelet count at the times of admission and discharge, the therapeutic intervention led to a significant reduction in platelet count in both groups. This decrease was faster in the DSIP group. However, the absolute reduction was not significantly different between the groups, which was compatible with the studies by Parzadeh et al. (17) and Sajid et al. (18). This reduction, which did not increase the chance of bleeding, can be attributed to platelet degradation due to phototherapy. However, there have been studies showing increased platelet count with phototherapy, which can be attributed to increased platelet release from bone marrow (19, 20).

In terms of defecation frequency, there were significant inter-group differences and also significant differences between the baseline and post-intervention values. The bowel movement changes were significantly faster in the DSIP group than in the SSIP group. Increased defecation per day during phototherapy is somehow common and expected (21, 22). Yurdakok et al. (23) attributed this phenomenon to increased intestinal secretions and changes in trans-epithelial voltage. They noted that water, sodium, and potassium absorption might be impaired in neonates receiving phototherapy; however, this is transient and resolves after treatment cessation.

In terms of skin rash, one patient in the SSIP group and no patient in the DSIP group had skin rash pre-intervention. However, at the time of discharge, 3 and 4 patients in the SSIP and DSIP groups had skin rashes, respectively. These changes were not significant. It should be noted that, in general, the prevalence of this complication is less than other common complications of phototherapy (21, 22). Our findings regarding skin rash were compatible with the study by Silva et al. (15), while the study by Eqbalian (8) reported a significant increase in skin rashes with phototherapy.

In terms of body temperature changes, the increase in body temperature of the neonates was not so high to be considered a fever, but it was significant. This complication is a common complication of phototherapy (21) with controversial results in different studies. Some researchers even did not collect the related data for insignificance (12), while others reported no significant changes (8, 10), and some reported an increased body temperature (16). Body temperature rise is not important as long as it does not lead to fever and can be prevented by increased fluid consumption (24).

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Nowadays, it has been suggested to use LED lamps in phototherapy devices instead of conventional fluorescent lamps. Some studies have shown the higher effectiveness and much fewer side effects of these LED lamps compared to fluorescent lamps (25, 26). The slight amount of heat produced by LED lamps helps to apply higher light intensity, thereby increasing the effectiveness.

Conclusion

According to our results, we concluded that the DSIP showed faster effectiveness compared to the SSIP and led to a shorter hospital stay, while it did not entail higher levels of complications. Therefore, it is recommended to consider the routine use of the DSIP for neonatal phototherapy.

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Conflict of Interests

The authors declare that they have no competing interests.

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