

Assessment Efficacy and Complication of the Distance between Phototherapy Lamps and Neonate's Body Level on Serum Bilirubin Decrease and Phototherapy Complications in Neonatal Hyperbilirubinemia

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ABSTRACT

Background: Jaundice is one of the most leading causes of neonate hospitalization (51.8%) during the first four weeks of life, and phototherapy is one of the most common and safest methods for the treatment of jaundice. Different results have been obtained from the studies conducted on the investigation of factors affecting increased phototherapy effect on the reduction of neonatal jaundice. However, there still exist many questions concerning the methods that maximize the effect of phototherapy.

The current research aimed to determine the effect of the distance between phototherapy lamps and neonate's body on the reduction of serum bilirubin and phototherapy complications in the neonates with physiologic jaundice.

Methods: The study was carried out on 60 newborns with jaundice. The neonates in the intervention group were put under phototherapy within a distance of 20 cm, and the ones in the control group underwent phototherapy within a distance of 40 cm. Daily bilirubin was measured at times 0, 12, and 24, and the neonates were examined in terms of serum bilirubin reduction and phototherapy complications.

Results: The obtained results revealed that phototherapy within the distance of 20 cm causes more reduction in the total bilirubin 12 and 24 hours after phototherapy. However, there was no significant difference between bilirubin 48 hours after phototherapy and phototherapy duration and the complications between the two groups.

Conclusion: Based on the results, the method of phototherapy distance reduction could be used as a safe and effective way for the quicker reduction of serum bilirubin level, prevention of hyperbilirubinemia complications and complications of blood transfusion in neonates with physiologic jaundice.

Keywords: Jaundice, Neonate, Phototherapy distance

Introduction

Jaundice is one of the leading causes of newborn hospitalization which can lead to permanent neurological damage or even death if neonate jaundice is not treated immediately (1-3). Phototherapy is the most common and safe method for the treatment of jaundice and is typically used as double, standard, or special (4). Standard phototherapy involves 4 lamps and produces irradiance up to 12 $\mu\text{w}/\text{cm}^2/\text{nm}$. The irradiance level rises with the increased number

of phototherapy lamps and employment of the multiple phototherapies, as well as the reduction in the distance between phototherapy and neonate's body surface. An extensive review of the relevant literature is indicative of the bulk of studies conducted to investigate the factors affecting the efficacy of phototherapy in reducing neonatal jaundice, including increasing skin contact with light, increasing the number of phototherapy lamps, using light with different

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wavelengths, which can increase the irradiance level (14-17). No study has yet investigated the effect of the distance between the phototherapy and neonate's body surface on the reduction of blood bilirubin. Review of related literature did not provide explicit and comprehensive information concerning the effect of the distance between phototherapy lamps and neonate's body and controversial opinions surround this issue. Some studies demonstrated that the distance between the neonate's body surface and phototherapy lamps is 45 cm (3,4). According to Nelson, the distance between special phototherapy and the newborn should be 15 to 20 cm. The present study aimed to investigate the effect of reducing the phototherapy distance on the reduction of blood bilirubin taking into account the different perspectives on the distance between an neonate's body surface and the phototherapy lamps, as well as the prevalence of neonatal jaundice and the lack of both special phototherapy devices and a 8-lamp phototherapy device in all treatment centers. If the distance between a neonate's body surface and the phototherapy lamps is effective in the reduction of blood bilirubin, an 8-lamp phototherapy device can be replaced with a 4-lamp phototherapy device in order to reduce the. Moreover, it can be applied as a standard, safe, and cost-effective method for the immediate treatment of neonatal jaundice which can reduce both hospital and patients' treatment costs.

Methods

This randomized clinical trial was performed on 60 term neonates with inclusion criteria who were diagnosed with physiological jaundice admitted to the neonatal intensive care unit of Imam Reza Hospital from 31/05/2017 to 11/03/2018. According to similar studies, 30 subjects were allocated to each group with 95% confidence interval, 95% test power, and 1.3 common variance.

Sampling was initially purpose-based and the newborns who met inclusion criteria were randomly assigned into two groups of intervention and control.

The random allocation rule which is the simplest method of limited randomization represents a large block for the entire sample size which means that the balance in the number of individuals assigned to each group will be achieved at the end of the study. In the current study, the applied box contained 60 cards (30 to A and 30 to B). For each neonate with inclusion criteria, a card was taken out of the box. If it was

A, the neonate was assigned to the intervention group, and if it was B, he was allocated to the intervention group. The neonates in group A received phototherapy with 20 cm distance, and neonates in group B received phototherapy within a 40cm distance of neonate's body. The current study was conducted following the approval of the Ethics Committee of Sabzavar University of Medical Sciences with the ethical code of IR.MEDSAB.REC.1396 and the clinical trial code RCT20170922036321N1, as well as coordination with authorities in neonatal ICU of Imam Reza Hospital. The neonates who met inclusion criteria entered the study upon obtaining informed consent from their parents.

Inclusion criteria entailed: 1) uterus age > 32 weeks, 2) the weight > 2500 g, 3) age > 24 hours, 4) absence of anomaly and congenital infection, 5) normal sucking reflex, 6) no evidence of Rh incompatibility, 7) presence of urine and stool within the first 24 hours.

Baby bilirubin level

Two days (10-15 mg/ dl), three days (13-17 mg/ dl), four days (14-18 mg/ dl), five to seven days (15-18 mg/ dl), seven days and more (18-208 mg/ dl)

- Laboratory values of direct bilirubin less than 1.5 mg/ dl

Exclusion criteria

1) history of infection, 2) jaundice resulting from G6PD deficiency and hypothyroidism, 3) need for blood transfusion and 4) need for medication, including intravenous immunoglobulin during treatment.

Thereafter, the neonates were randomly assigned into control and intervention groups. Phototherapy treatment was performed within 40 cm distance in the control group, and in the intervention group, phototherapy was carried out within a 20 cm distance of the neonate's body. Phototherapy devices were all of the same type made in Iran with the Tosan brand, model 23 with 4 bulbs and 220 volt 50Hz with a code of 02300478 and a useful life of 2000 hours. The devices were equipped with a timer for measuring the lifetime of a lamp and a fan to cool electrical parts.

At the beginning of phototherapy, naked neonates with covered eyes and genital area were placed into the incubator with a phototherapy device. The status of newborns during this study is supine. The temperature of the baby was controlled every 6 hours at the baseline and

during phototherapy. They were checked for dehydration and weighed on a daily basis. The number of stool secretions in terms of looseness, sucking power, incidence of skin rash, and volume of received liquids (milk and serum) were monitored every 6 hours and recorded in the daily information form. The phototherapy was stopped every two hours for 20 minutes for breastfeeding and changing diapers. The blood serum bilirubin in the neonates was measured 12 and 24 hours after the initiation of phototherapy. In addition, in order to investigate the duration of phototherapy, serum bilirubin was measured every 24 hours after the second day. To measure serum bilirubin levels, blood samples were extracted from the back of the arm (1 cc) and sent immediately to the lab. The tester did not know whether the blood sample was extracted from the intervention or control groups. Thereafter, bilirubin level and phototherapy complications in both groups were determined and compared based on the research objectives; subsequently, the obtained data were analyzed in SPSS software (version 16).

Results

Based on the results, 70% of neonates were boys and neonates in both case and control groups were not significantly different in terms of weight, age, hematocrit, and bilirubin at the time of

hospitalization, delivery type, and gestational age (Table 1).

Moreover, bilirubin reduction was higher in the intervention group 12 and 24 hours after phototherapy, compared to the control group ($P = 0.001$). In addition, no significant difference ($P = 0.050$) was observed in bilirubin reduction 48 hours after phototherapy in the neonates in both groups (Table 2).

The average and standard deviation of phototherapy duration in the neonates under study within a 20 cm distance of the lamps was obtained as 0.6 ± 2.1 and it was measured at 0.6 ± 2.2 in the 40 cm distance. Mann-Whitney test did not show this difference as significant ($P = 0.396$).

In addition, the mean and standard deviation of the temperature of the newborns was estimated at 37.0 ± 0.3 in the 20.4 cm distance group, and it was measured at 37.1 ± 0.2 in the group with a 40 cm distance. The statistical tests did not show this difference as significant ($P = 0.077$). No neonate in the research population was reported to have loose stool.

In the intervention group, where phototherapy was carried out at a 20 cm distance, 4 neonates, and in the control group with phototherapy within 40 cm distance, 2 neonates showed skin rash that the difference was not significant between the two groups.

Table 1. Descriptive Statistics

variable	Group		p
	20 cm (n = 30) Mean±SD or N (%)	40 cm (n = 30) Mean±SD or N (%)	
Age (week)	2.9±1.1	3.1±2.02	.715†
Sex			.260††
Male	23 (76.7)	19 (63.3)	
Female	7 (23.03)	11 (36.7)	
Bilirubin at the time	14.1±2.5	13.8±2.2	.663†
Gestational age	35.6±2.2	36.2±2.6	.446†
Hematocrit	45.8±2.1	45.0±3.0	.258‡
Delivery type			1.000††
Vaginal	6 (20.0)	6 (20.0)	
CS	24 (80.0)	24 (80.0)	

†: Mann-Whitney U test, ††: Chi-squared test, ‡: Student's T-Test

Table 2. Statistics on the reduction of bilirubin and weight

Variable	Group		P (between-group)
	20 cm (n = 30) Mean±SD	40 cm (n = 30) Mean±SD	
bilirubin reduction			
After 12 hours	2.3±0.9	1.6±0.6	<.001†
After 24 hours	4.0±1.5	3.2±1.1	.024†
After 48 hours	5.8±2.0	4.9±1.4	.050†
P (within-group)	<.001‡	<.001‡	
Weight reduction			
After 24 hours	15.5±8.0	15.7±11.5	.884††
After 48 hours	24.7±9.6	23.8±16.8	.892††
P (within-group)	<.001‡‡	<.001‡‡	

†: Student's T-Test, ††: Mann-Whitney U test, ‡: Repeated measures analysis of variance (rANOVA), ‡‡: Wilcoxon signed-rank test

The mean and standard deviation of weight loss after 48 hours were obtained as 24.7 ± 9.6 in the 20 cm group and 23.8 ± 16.8 in the group with a 40 cm distance. The statistical test did not show this difference as significant ($P=0.892$; Table 2).

Discussion

Since no study has been conducted on the effect of the distance between phototherapy lamps and neonate's body on the reduction of bilirubin and its complications in the neonates with jaundice, the results of the present study were compared with the findings of the studies in which increasing number of lamps and the reduction of phototherapy lamp distance to the neonate's body were used or with the studies conducted for increasing efficiency of phototherapy.

Results of the current study indicated that bilirubin reduction after 12 and 24 hours in case and control group was significant, which is consistent with the findings of the study conducted by Eghbalian et al. (2009) on comparing effect and complications of phototherapy in double-level phototherapy (cylindrical) and unit-level (binary) on non-conjunctival neonatal jaundice. In the mentioned study, the mean total bilirubin in the one-level and double-level groups 12 hours after the treatment was obtained as 00.15 ± 38.1 and 75.16 ± 34.2 mg/dl, respectively, indicating a significant reduction in bilirubin levels in both groups. This finding is in line with the obtained results of the present study.

The mean bilirubin 24 hours after treatment in the one-level group was measured at 15.12 ± 70.1 and in the double-level group was obtained as 81.12 ± 83.22 mg/dl which was statistically significant between the two groups. In addition, there was no significant difference in total bilirubin reduction in both groups at discharge time and hospitalization time. This finding is also in accordance with the finding of the current study. One reason is increased phototherapy energy by the higher number of lamps in the study performed by Eghbalian and enhanced phototherapy energy by the reduction of distance between phototherapy lamps and neonate's body in the current study (8). Eghbalian put the distance of phototherapy lamps from neonate body level at a fixed number of 20 cm but changed the neonate's body surface area under phototherapy. In neonatal two-level phototherapy with 4 lamps from the upper surface and 4 lamps from the lower surface and in the single-level (two-group) neonates with two 4-

lamp devices from the upper surface underwent phototherapy. concluded that increasing neonate body surface area results in a faster decrease in blood bilirubin levels at 12 and 24 hours after phototherapy. In the present study, neonate body surface area was fixed in both groups and the distance between phototherapy lamps and neonate body level changed and the results revealed that the reduction in distance between phototherapy lamps and neonate body level resulted in a faster decrease in blood bilirubin level 12 and 24 hours after phototherapy. This can be attributed to increased phototherapy effect by increasing the level of skin contact with light in the study performed by Eghbalian and increased optical energy by reducing the phototherapy distance in the present study. However, in both studies there was no significant difference in total bilirubin reduction between the two groups at discharge and hospital stay. Accordingly, it can be concluded that decreasing the phototherapy distance and increasing the neonate's body surface area in phototherapy when serum bilirubin is higher than normal is more effective in reducing bilirubin. Therefore, when bilirubin is close to normal, shortening the phototherapy distance and increasing the baby's body surface has no effect on the faster reduction of serum bilirubin.

Findings of the study conducted by Paion et al. (2008) suggested that double-level phototherapy causes quicker reduction of serum bilirubin concentration, compared to double-level phototherapy, so that average bilirubin was obtained as 1.7 ± 3.5 and 2.3 ± 6.5 mg/dl 24 and 48 hours after phototherapy in neonates under one-level phototherapy. Whereas, it was reported to be 2.1 ± 8.4 and 0.2 ± 5.4 mg/dl in neonates under double-level phototherapy with 30 cm distance. These findings showed a statistically significant difference and were not consistent with the current study. In the present study, reduction of average serum bilirubin 24 hours after phototherapy in two phototherapy groups showed significant differences; however, a contrasting result was obtained 48 hours after phototherapy, as compared to the study performed by Paion. It can be due to different types of intervention so that in the study carried out by Eghbalian, apart from increasing number of lamps, increasing body surface of the neonates was also effective in the reduction of neonatal serum bilirubin (10). In the pioneer study, the distance of phototherapy lamps from neonate body level was obtained as 30 cm in both groups. Nonetheless, the number of lamps

and the surface of the neonate's body increased. Therefore, it can be inferred that both methods have been shown to decrease neonatal bilirubin more rapidly (12).

Djokomuljanto (2005) indicated that the effect of reflecting mirrors on the reduction of neonatal jaundice can reduce bilirubin 10 and 24 hours after phototherapy, which is in accordance with the current study. It can be attributed to higher effect of light radiation in increasing the light energy, leading to serum bilirubin reduction (11). In the abovementioned method, by using mirrors and light reflection, the number of photons emitted to the baby's skin and the surface of the skin's exposure to light are increased. Moreover, the efficacy of phototherapy in the treatment of jaundice increased since the distance from the surface of the lamp also affects the amount of light energy. In the present study, reducing the phototherapy distance between phototherapy lamps and neonate body level also increases the light energy and is effective in the reduction of neonatal blood bilirubin.

Findings of the study conducted by Salehzadeh et al. (2015) on the effect of phototherapy with mirror coating in jaundice treatment indicated that bilirubin level 24 and 48 hours after initiation of treatment was much lower in the intervention group, as compared to the control group ($P=0.036$) and ($P=0.005$). It is consistent with the results of the current study due to bilirubin reduction 24 hours after phototherapy. However, it is inconsistent with bilirubin reduction 48 hours after phototherapy which can be probably owing to a different type of intervention. In the study carried out by Salehzadeh, hospitalization stay in the intervention group was much lower, compared to control group (0.027), which is not in harmony with the current study. It can be due to higher effect of increasing light radiation and increasing light energy on bilirubin reduction (12).

The study performed by Naderi et al. (2008) implied that the effect of triple phototherapy with double phototherapy in neonates with indirect hyperbilirubinemia on the reduction of jaundice in 8, 16, and 24 hours after treatment and at the time of discharge had no significant difference. The results of this study are in contrast with the findings of the current study, and it can be attributed to the absence of adequate space for placement and effectiveness of the third phototherapy device so that the skin contact surface with light in triple group was not different from the double group. Therefore, the number of devices at the same level had no effect on

increasing phototherapy power. The mean and standard deviation of duration period in the first and second groups was obtained as 37.68 ± 14.95 and 31.4 ± 13.24 , respectively. The minimum and maximum hospitalization period in both groups were 16 and 60 hours, without any significant difference between two groups which is in line with the current study (13).

A review of the related literature revealed that phototherapy is a method with low complications in treatment of jaundice (10-12, 14-16). In the current study, complications of phototherapy in neonates, such as weight loss, hypothermia and hyperthermia, skin rash, loose stool were investigated in both case and control groups and the results revealed no statistically significant difference between the two groups.

The results of various studies that have used phototherapy in different ways for treating neonatal jaundice have not reported any phototherapy complications (1, 4-7). These results are consistent with the result of our study, but some studies, including Eghbalian et al. (2009), concluded that the skin rash in the neonatal group under double phototherapy was more common ($P<0.05$). This result contradicts the present study. This can probably be attributed to the increased light exposure to the baby's surface leading to more skin rashes. Another study performed by Behjati et al. (2005) examined the effects of phototherapy on 200 neonates with jaundice in three phototherapy modes. The results of the mentioned study indicated that 179 neonates had a normal stool and 21 neonates had loose stool after phototherapy. In preterm neonates, the loose stool was significantly higher ($P < 0.05$) which was consistent with the current study. In the current study, term and close to term neonates were investigated and loose stool was not observed (17). Therefore, the current study consistent with other studies in this regard supports the effectiveness of phototherapy in the reduction of neonatal serum bilirubin level. In addition, the data demonstrated that the reduction of distance between phototherapy lamps with neonate's body enhances this effectiveness.

Conclusion

The obtained results indicated that the method of phototherapy distance reduction could be used as a safe and effective way for the quicker reduction of serum bilirubin level, prevention of hyperbilirubinemia complications and complications of blood transfusion in

neonates with physiologic jaundice.

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Conflicts of interests

The authors declared that there is no conflict of interest.

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