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ORIGINAL RESEARCH ARTICLE

Evaluation of phototherapy with reflectors: A randomized controlled trial

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Abstract *Background and objectives:* Neonatal jaundice is one of the most prevalent clinical conditions requiring evaluation and management within the first few days of life. Phototherapy is the single most common intervention used for the treatment of neonatal jaundice. The aim of our study was to evaluate the efficacy and tolerability of phototherapy with reflectors compared to conventional phototherapy in controlling neonatal hyperbilirubinaemia.
Patients and methods: In this randomized controlled study, we studied neonates for one year (from June 2010 to June 2011) who were full term and healthy with uncomplicated jaundice and who were admitted to the neonatal intensive care unit (NICU) of El-Nasr General Hospital, Port-Said, Egypt. The subjects were randomized in two groups: group A (n = 30) received phototherapy with reflectors and group B (n = 30) received conventional phototherapy. Serum bilirubin levels were measured on admission and every 12 h thereafter. With declining readings, bilirubin was measured once daily until hospital discharge.
Results: There was no significant difference in total serum bilirubin on admission between the two groups. On discharge, bilirubin levels significantly decreased in group A compared to group B. There was a reduction in the duration of the hospital stay in group A compared to group B. The only observed complication in the groups was hyperthermia, which was not significantly different between the two groups.
Conclusion: The present study examined the efficacy and tolerability of phototherapy with reflectors in comparison to conventional phototherapy and found that phototherapy with reflectors was significantly better at controlling bilirubin levels in neonates with indirect hyperbilirubinaemia and at shortening hospitalization time.

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1. Introduction

Neonatal jaundice is the leading cause of hospital admission and re-hospitalization in the first week of life worldwide [1—3]. Appropriate treatment with phototherapy and/or exchange transfusion is effective in controlling excessive bilirubin levels in affected infants [4,5]. Severe hyperbilirubinaemia may lead to acute bilirubin encephalopathy (ABE), kernicterus, and a significant risk of mortality in newborns [6—8]. Survivors may also acquire long-term neurodevelopmental sequelae, such as cerebral palsy, sensorineural hearing loss, intellectual difficulties or gross developmental delays [9—12].

Phototherapy is the single most common intervention used for the treatment of neonatal jaundice [13].

The greater the surface area exposed, the greater the effectiveness of phototherapy [14]. Light intensity and the area of light-exposed skin can also be increased through the use of reflecting surfaces [15—17].

The purpose of this study was to evaluate the efficacy of phototherapy with reflectors versus conventional phototherapy in controlling neonatal indirect non-haemolytic hyperbilirubinemia.

2. Patients and methods

This study was carried out in the neonatal intensive care unit (NICU) of El-Nasr General Hospital, Port-Said, Egypt. A randomized controlled trial was conducted after obtaining informed consent from one or both parents of the neonates in this study. The study duration was one year, from June 2010 to June 2011. This study was approved by the ethics scientific committee at Cairo University hospital in accordance with the University bylaws for human research.

Full term ($\geq$37 weeks gestation), healthy newborns were eligible for enrolment if they met the following criteria: postnatal age $>$24 hours (h) and $\leq$10 days and had non-haemolytic indirect hyperbilirubinemia in the first week of life. We excluded preterm babies, cases with haemolytic jaundice, including Rh haemolytic disease, evidence of haemolysis in a peripheral smear, a positive Coomb's test, or a glucose-6-phosphate dehydrogenase (G6PD) deficiency. We also excluded cases requiring intensive care unit admission, including neonates with major congenital anomalies, or neonates with clinical or laboratory evidence of sepsis. The decision to start phototherapy was based on the AAP guidelines for term and near-term babies [5].

All Participants were subjected to the following:

a) A detailed history and full physical examination on admission and on a daily basis afterwards. In addition, neonates had their temperature monitored and potential side effects recorded, including presence of loose stools and skin rashes.
b) Clinical investigations including the following: a complete blood count (CBC), and serum bilirubin on admission and every 12 h thereafter; with declining readings, bilirubin was measured once daily until hospital discharge. In addition, a reticulocyte count and maternal and neonatal blood group tests were collected, and Coombs test were conducted. The rate of bilirubin decline was calculated and compared in both groups.
c) Randomization process: All eligible neonates were randomized into one of two groups: Group A infants (n = 30) received phototherapy with reflectors, and Group B infants (n = 30) received phototherapy without reflectors (conventional phototherapy). Randomization was conducted using opaque sealed envelopes that were indistinguishable between groups so that the investigators were unable to influence group designations. Each envelope had the assignment of the infant (Group A or B) with 30 envelopes for each group.

The phototherapy with reflectors unit utilized in the study consisted of two parallel lamps with an equal length of fixed stainless steel slices behind each lamp. The fixed slices allowed for 2 lamps to be used instead of 4 to reduce the cost of the complete unit. In addition, the slices may also increase phototherapy efficiency by potentially enhancing the rate of bilirubin decline, thus reducing the risk of hyperbilirubinemia complications. The measurements of the phototherapy unit included the following: height (distance) of the phototherapy from the incubator was 12 cm; length of 71 cm; width of 25 cm; height from the ground of 160 cm, and lamp length of 59 cm (Fig. 1). The sling measurements include the following: a length of 59 cm, a distance from the lamp of 10 cm, and a width of 10 cm. The phototherapy was placed at a distance of 45 cm from the baby. All babies were naked and wore eye pads and diapers while receiving phototherapy. The lamps were changed after every 1000 h of work.

d) Statistical Analysis: Collected data were organized, tabulated and statistically analyzed using the statistical package for social sciences (SPSS), version 16 (SPSS Inc. USA), and ran on an IBM compatible computer using the Microsoft® Windows 7 operating system. For qualitative data analyses, the frequency and percent distributions were calculated; for comparisons between groups, the Chi square (X^2), Mann—Whitney or Wilcoxon tests were used. For quantitative data, the mean and standard deviations (SD) were calculated; for comparisons between two means, the student (t) test was used. For correlation analyses between two parameters, the bivariate Pearson's correlation coefficient was calculated; it was proportional if the sign was positive and inverse if the sign was negative. The correlation was considered mild ($r < 0.3$), moderate ($0.3 \leq r \leq 0.7$)

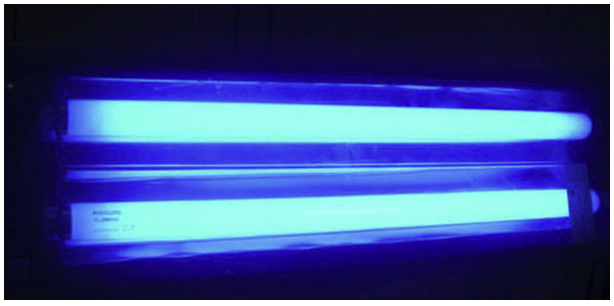

Figure 1 Phototherapy with reflectors.

or powerful ($r > 0.7$). For the interpretation of the results, a P value $\leq .05$ was considered statistically significant.

3. Results

The details of the flow of the participants are shown in Fig. 2.

The two groups were comparable with respect to gender, age, weight, and mode of delivery. The total serum bilirubin and haemoglobin concentrations at the start of phototherapy were also similar between groups (Table 1). All mothers and their neonates were Rh positive. Table 2 shows the outcome variables of the studied neonates with significant decreases in total serum bilirubin levels in both groups after discharge compared to their values on admission. A significant decline in serum bilirubin was observed after 12 h in group A compared to 24 h in group B (Fig. 3). The duration of the hospital stay was significantly lower in group A compared to group B (Fig. 4).

There was a statistically significant moderate, inverse correlation between the duration of hospitalization and total bilirubin decrease in group A. The correlation between the duration of hospitalization and total bilirubin decrease was mild and non-significant in group B (Table 3).

Hyperthermia was the only observed complication in the two groups. There was no significant difference in the presence of hyperthermia between the two groups (Table 4).

4. Discussion

The results of the current study suggest that the fixation of reflective stainless steel slings behind phototherapy lamps can accelerate the rate of total serum bilirubin decline and shorten the duration of hospitalization in neonates with non-haemolytic hyperbilirubinaemia without increasing phototherapy complications. A study performed by Djokomulijanto et al evaluated the use of white curtains around the beds of infants treated with phototherapy and reported a significantly greater rate of bilirubin decline and a dramatically shorter duration of phototherapy without an increase in complications in the study group compared to the control group [16]. Similarly, another study evaluated a simple and relatively inexpensive method using a fluid bed to provide high-intensity double-surface (HIDS) phototherapy which increased the irradiance of phototherapy

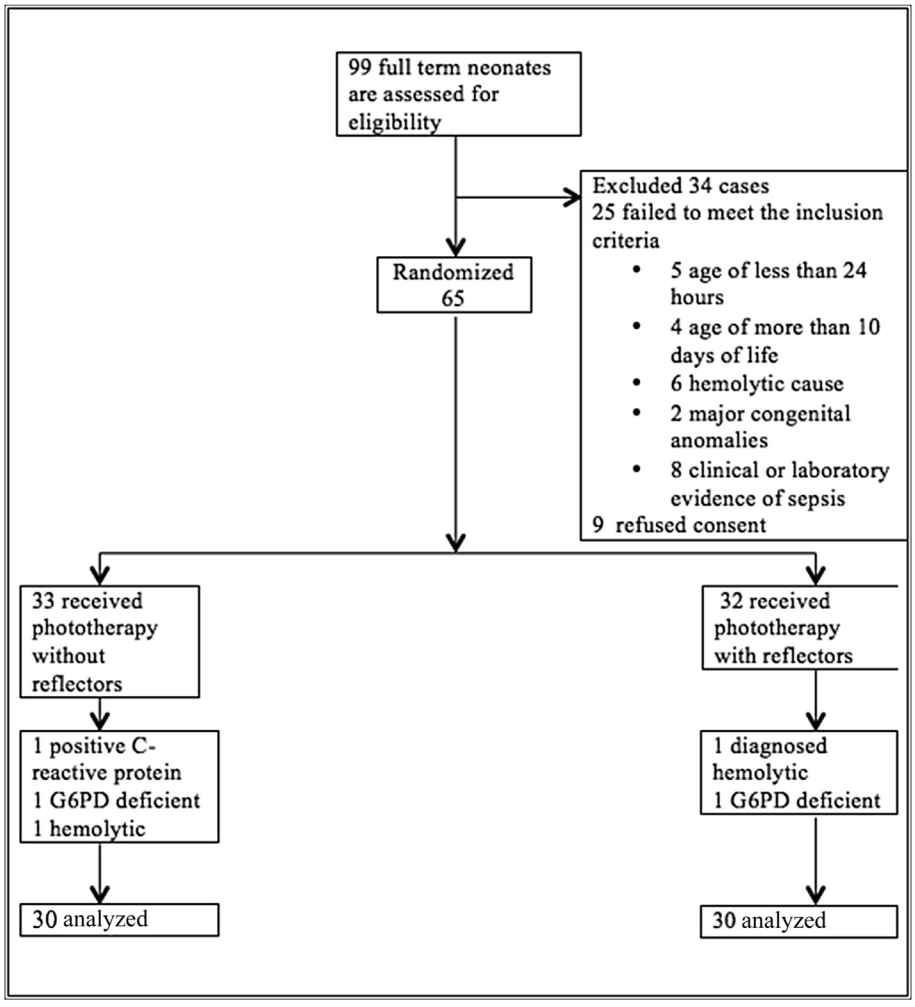

Figure 2 Study flow chart.

Table 1 Demographic data and variables at the start of phototherapy.

		Group A (phototherapy with reflectors) (n = 30)	Group B (phototherapy without reflectors) (n = 30)	Total	Significance
Gender	Males	15 (50.0%)	13 (43.3%)	28 (46.7%)	$P = .60$(NS)*
	Females	15 (50.0%)	17 (56.7%)	32 (53.3%)	
Mode of delivery	Normal vaginal delivery	13 (43.3%)	14 (46.7%)	27 (45.0%)	$P = .79$(NS)*
	Cesarean section	17 (56.7%)	16 (53.3%)	33 (55.0%)	
Weight		2.93 (0.42)	3.09 (0.35)	3.01 (0.39)	$P = .12$(NS)*
Age		3.46 (0.89)	3.83 (1.28)	3.65 (1.11)	$P = .20$(NS)*
TSB on admission		17.88 (2.99)	16.89 (2.71)	17.38 (2.87)	$P = .18$(NS)*
Haemoglobin concentration		14.76 (1.57)	14.44 (1.79)	14.60 (1.68)	$P = .46$(NS)*
WBCs count		9.98 (1.29)	9.12 (1.80)	9.55 (1.61)	$P = .037$(S)*
Platelet count		325.60 (58.92)	331.03 (61.13)	328.32 (59.59)	$P = .72$(NS)*
Reticulocyte percentage		1.15 (0.44)	1.52 (0.52)	1.33 (0.52)	$P = .005$(S)*
Maternal blood group					
Group A		7 (23.3%)	5 (16.7%)	12 (20.0%)	$Chi^2 = 1.22^{\#}$,
Group B		4 (13.3%)	6 (20.0%)	10 (16.7%)	$P = .74$ (NS)*
Group AB		5 (16.7%)	7 (23.3%)	12 (20.0%)	
Group O		14 (46.7%)	12 (40.0%)	26 (43.3%)	
Neonatal blood group					
Group A		8 (26.7%)	7 (23.3%)	15 (25.0%)	$Chi^2 = .39^{\#}$,
Group B		5 (16.7%)	6 (20.0%)	11 (18.3%)	$P = .94$ (NS)*
Group AB		2 (6.7%)	3 (10.0%)	5 (8.3%)	
Group O		15 (50.0%)	14 (46.7%)	29 (48.3%)	

All values, except *P* value*, and $Chi^{2\#}$ are expressed in number (%) or mean ± SD, S: significant, NS: non-significant.

and the area of the body exposed, proving to be significantly more effective in reducing bilirubin than conventional phototherapy [18].

In Hansen's study, using white pads around the infant's bed during phototherapy resulted in an irradiance increase and thus, shortened the duration of phototherapy [19]. More recently, Babaei et al studied the effect of a white plastic cover around the phototherapy unit on hyperbilirubinemia in full term neonates and observed that the total serum bilirubin in the covered group during the first 48 h of treatment declined significantly compared to the control group; in addition, the study group also had a decreased duration of hospitalization and no increase in phototherapy complications [20].

Additionally, a study conducted by Salehzadeh et al showed that the use of a mirror behind phototherapy lamps can enhance the effectiveness of phototherapy without increasing the risk of hyperthermia [17].

Sivandan et al studied the effect of a sling application on the efficacy of phototherapy in healthy full term neonates with non-haemolytic jaundice and found no dramatic difference in the phototherapy duration between the study and control groups [21]. Sivandan et al findings are the opposite of ours, which may be due to Sivandan's use of a cover with a low reflection coefficient. In our study, the neonates with haemolytic jaundice were excluded because they have rapidly rising serum bilirubin and a higher potential need for intensive phototherapy or exchange transfusion. The use of phototherapy with reflectors in such complex cases should be studied separately. Preterm babies were excluded from our study, as the guidelines for jaundice management are different from those for term babies. Preterm babies are also more susceptible to bilirubin encephalopathy due to the immaturity of their blood brain barrier and associated morbidities.

Our study has a few limitations: first, the sample size was limited, making it difficult to statistically determine important outcomes; second, we had no access to a photo radiometer to measure the average irradiance of our devices.

Table 2 Outcome variables of the two groups.

Outcome variable	Group A (phototherapy with reflectors) (n = 30)	Group B (phototherapy without reflectors) (n = 30)	*P* value
TSB			
At 12 h	14.95 (2.98)[a]	16.88 (2.51)	.009(S)
At 24 h	11.65 (2.92)[a]	14.25 (2.14)[b]	.001(S)
On second day	8.73 (2.06)[a]	11.36 (2.01)[b]	.001(S)
On discharge	7.26 (0.58)[a]	8.26 (1.46)[b]	.001(S)
Duration of hospital stay			
	3.50 (0.51)	4.43 (0.50)	.001(S)

S: significant.

[a] Statistically significant decrease of levels in group A in comparison to their basal values.

[b] Statistically significant decrease of levels in group B in comparison to their basal values.

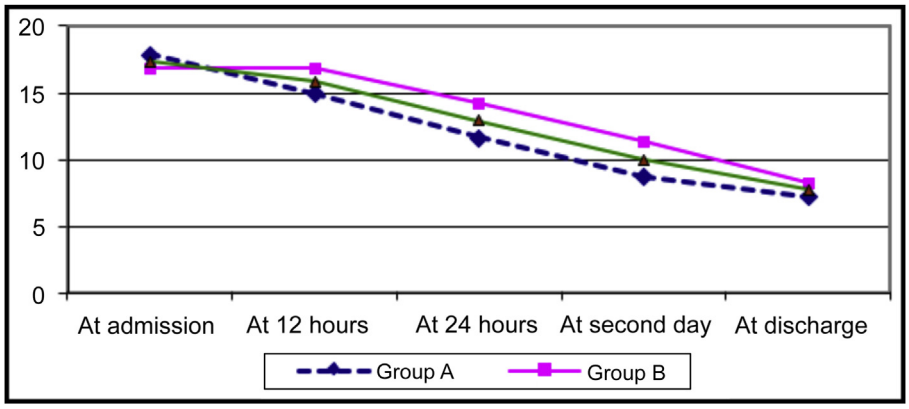

Figure 3 Total bilirubin concentration in the two groups at different time intervals.

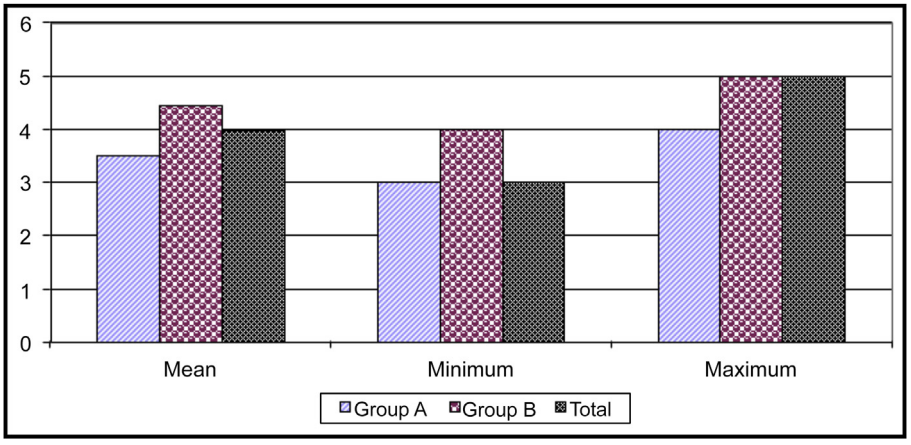

Figure 4 Comparison between group A and group B in regard to the duration of hospitalization.

Table 3 Correlation between duration of hospital stay and decrease in bilirubin (difference between the first and last days).

		Total serum bilirubin change in group A	Total serum bilirubin change in group B	Bilirubin change in all patients
Hospital stays	r	−0.585	−0.274	−0.038
	p	0.001(S)	0.143(NS)	0.772(NS)
	n.	30	30	60

5. Conclusion

The present study provided evidence for the efficacy and tolerability of phototherapy with reflectors in controlling serum bilirubin levels and shortening hospitalization time compared to conventional phototherapy.

Table 4 Incidence of complications in studied groups.

		Group A	Group B	Total
Complications	Fever	2 (6.7%)	4 (13.3%)	6 s (10.0%)
	No complications	28 (93.3%)	26 (86.7%)	54 (90.0%)
Statistics	$X^2 = 0.74$, $p = 0.38$			

Disclosure

The authors declare no conflicts of interest.

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None.

Authors' contributions

HA participated in the collection of data and drafting of the manuscript; EA participated in the analysis, interpretation of the data and manuscript drafting; RS participated in the study design and manuscript preparation; and MH participated in concept development, study design and critical review. All authors read and approved the final manuscript.

Prior presentation

None.

Ethical clearance

An informed consent has been taken from the parent of each participant in the study.

References

[1] Young Infants Clinical Signs Study Group. Clinical signs that predict severe illness in children under age 2 months: a multicentre study. Lancet 2008;371:135—42.

[2] Burke BL, Robbins JM, Bird TM, Hobbs CA, Nesmith C, Tilford JM. Trends in hospitalizations for neonatal jaundice and kernicterus in the United States, 1988—2005. Pediatrics 2009;123:524—32.

[3] Tomashek KM, Crouse CJ, Iyasu S, Johnson CH, Flowers LM. A comparison of morbidity rates attributable to conditions originating in the perinatal period among newborns discharged from United States hospitals, 1989—90 and 1999—2000. Paediatr Perinat Epidemiol 2006;20:24—34.

[4] National Institute for Health and Clinical Excellence (NICE). Neonatal jaundice. (Clinical guideline 98.). 2010. www.nice.org.uk/CG98.

[5] Management of hyperbilirubinaemia in the newborn infant 35 or more weeks of gestation. Pediatrics 2004;114:297—316.

[6] Slusher TM, Vreman HJ, McLaren DW, Lewison LJ, Brown AK, Stevenson DK. Glucose-6-phosphate dehydrogenase deficiency and carboxy-hemoglobin concentrations associated with bilirubin-related morbidity and death in Nigerian infants. J Pediatr 1995;126:102—8.

[7] English M, Ngama M, Musumba C, Wamola B, Bwika J, Mohammed S, et al. Causes and outcome of young infant admissions to a Kenyan district hospital. Arch Dis Child 2003;88:438—43.

[8] Hameed NN, Na' Ma AM, Vilms R, Bhutani VK. Severe neonatal hyperbilirubinemia and adverse short-term consequences in Baghdad, Iraq. Neonatology 2011;100:57—63.

[9] Mwaniki MK, Atieno M, Lawn JE, Newton CR. Long-term neurodevelopmental outcomes after intrauterine and neonatal insults: a systematic review. Lancet 2012;379:445—52.

[10] Gladstone M. A review of the incidence and prevalence, types and aetiology of childhood cerebral palsy in resource-poor settings. Ann Trop Paediatr 2010;30:181—96.

[11] Amin SB, Smith T, Wang H. Is neonatal jaundice associated with autism spectrum disorders: a systematic review. J Autism Dev Disord 2011;41:1455—63.

[12] Maulik PK, Darmstadt GL. Childhood disability in low- and middle-income countries: overview of screening, prevention, services, legislation. Epidemiol Pediatr 2007;120(Suppl. 1):S1—55.

[13] Vreman HJ, Wong RJ, Stevenson DK. Phototherapy: current methods and future directions. Semin Perinatol 2004;28:326—33.

[14] Hart G, Cameron R. The importance of irradiance and area in neonatal phototherapy. Arch Dis Child Fetal Neonatal Ed 2005;90(5):F437—40.

[15] Hansen TWR. Neonatal jaundice. eMedicine. 2002 [accessed 11.08.06], http://www.emedicine.com/ped/topic1061.htm.

[16] Djokomuljanto S, Quah BS, Surini Y. Efficacy of phototherapy for neonatal jaundice is increased by the use of low-cost white reflecting curtains. Arch Dis Child Fetal Neonatal Ed 2006;91:F439—42.

[17] Salehzadeh F, Mirza Rahimi M, Jahangiri S, Habibzadeh S, Sani NA, Samshirgara M, et al. Mirror covered tunnel phototherapy increases the efficacy of phototherapy for neonatal jaundice. Iran J Neonatol 2010;1:20—3.

[18] Garg AK, Prasad RS, Hifzi IA. A controlled trial of high-intensity double surface phototherapy on a fluid bed vs. conventional phototherapy in neonatal jaundice. Paediatrics 1995;95:914—6.

[19] Hansen TWR. Treatment of neonatal jaundice. Tidsskr Nor Laegeforen 2005;125(5):594—8.

[20] Babaei H, Alipur AA, Hemmati M, Ghaderi M, Rezaei M. Effect of white plastic cover around the phototherapy unit on hyperbilirubinemia in full term neonates. Iran J Pediatr 2013 Apr;23(2):143—8.

[21] Sivanandan S, Chawla D, Misra S, Agarwal R, Deorari AK. Effect of sling application on efficacy of phototherapy in healthy term neonates with non-hemolytic jaundice: a randomized controlled trial. Indian Pediatr 2009;46(1):23—8.