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ORIGINAL RESEARCH ARTICLE

Evaluation of phototherapy with reflectors: A randomized controlled trial

Mohammed ElSayed Hashim [a], **Reem Nabil Said** [a], **Enas Abdallah Ali Abdallah** [a,*], **Heba F. Abd Elghafar** [b]

[a] *Department of Pediatrics, Faculty of Medicine, Cairo University, Kasr Al Ainy St., Cairo 11562, Egypt*
[b] *Port Said General Hospital, Kesm AlArab, Port Said, Egypt*

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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.

* Corresponding author. Department of Pediatrics, Faculty of Medicine, Cairo University, Cairo, Egypt. Tel.: +20 1001012307.
E-mail address: dr_enasabdallah@yahoo.com (E.A.A. Abdallah).
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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 ($0.3 \leq r \leq 0.7$)

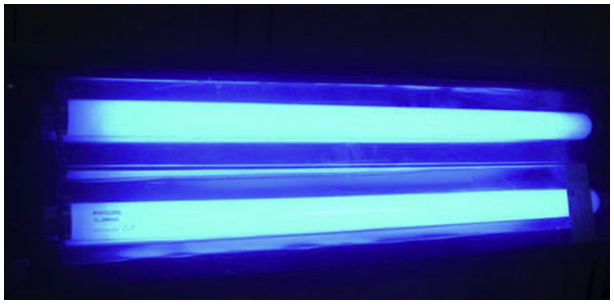

Figure 1 Phototherapy with reflectors.