RESEARCH PAPER

Effect of Sling Application on Efficacy of Phototherapy in Healthy Term Neonates with Non-hemolytic Jaundice: *A Randomized Conrolled Trial*

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Objective: To evaluate the efficacy of white reflecting material (slings) hung from the sides of compact fluorescent lamp (CFL) phototherapy equipment in reducing the duration of phototherapy in healthy term neonates with non-hemolytic jaundice.

Design: Randomized controlled trial.

Setting: Postnatal ward of a tertiary level neonatal unit.

Participants and intervention: Healthy term neonates with non-hemolytic jaundice between 24 hours and 10 days of age were randomly assigned to receive single surface phototherapy with (*n*=42) or without slings (*n*=42).

Outcome measure: Duration of phototherapy in hours (h) and the requirement of exchange transfusion.

Results: Birthweight (2790±352 vs. 2923±330 g), gestation (38±1.3 vs. 37±1.0 wk) and initial serum total bilirubin (STB) (16.6±2.4 vs. 16.1±2.2 mg/dL) were comparable between the two groups. There was no significant difference in the duration of phototherapy (mean±SD) between the Sling (23.3±12.9 h) and No sling (24.9±15.4h) groups (P=0.6). The irradiance of phototherapy equipment (microwatt/cm^2, mean±SD) was higher in Sling group compared to No sling group (195.8± 24.2 versus 179.7±27.7, P=0.01). There was a trend towards a higher rate of fall of serum total bilirubin (mg/dL, mean±SD) in the Sling group (0.23±0.49) compared to No sling group (0.03±0.47) (P=0.06).

Conclusion: Though hanging of white reflective sling on sides of CFL phototherapy equipment resulted in marginal increase in irradiance, it did not decrease the duration of phototherapy.

Key words: *Hyperbilirubinemia, Neonate, Phototherapy, Slings.*

Phototherapy is the single most common intervention used for treatment of neonatal jaundice(1). The therapeutic efficacy of phototherapy can be enhanced by use of special blue light and by employing "Double-surface" phototherapy units(2-5). A sling made of reflective material, hung on the sides of a phototherapy unit may also increase the exposed body surface area by reflecting light and therefore, can increase the efficacy of phototherapy(6-8). Although use of white reflective material has been recommended to achieve faster decline of serum bilirubin(2), use of slings for this purpose has not been investigated adequately.The objective of our study was to evaluate whether, the use of white reflecting material hung on sides of a phototherapy unit increases the efficacy of phototherapy in term neonates with non-hemolytic jaundice.

METHODS

Subjects: All term (≥37 wk) neonates born in the hospital between October 2005 and March 2007 were eligible for enrollment if they satisfied the following criteria: age >24 hour (h) and ≤10 days,

Apgar at 5 min greater than 6 and serum total bilirubin (STB) less than 21 mg/dL. Exclusion criteria were hyper-bilirubinemia requiring exchange transfusion, Rh hemolytic disease, evidence of hemolysis in peripheral smear, positive direct Coomb's test (DCT), glucose-6-phosphate dehydrogenase (G6PD) deficiency, major congenital malformation, culture-positive sepsis and need of intensive care .

Intervention and randomization: All term neonates born during the study period were clinically monitored for the development of jaundice. STB was measured as per judgment of treating team. The decision to start phototherapy was based on AAP guidelines for term and near-term babies(2). The eligible infants were randomized by sealed, serially numbered, opaque envelopes to single compact fluorescent light (CFL) phototherapy unit either with or without slings. The phototherapy units (Model CFL 100, M/s Phoenix Medical System Private Limited, India) were fitted with six light sources (Osram Dulux L 18W/71), four blue CFLs and two white CFLs. Two such phototherapy units were designated to be used exclusively for the study and the white-reflecting material could be hung to any of these units by Velcro strips. This method ensured that the same phototherapy unit could be used with or without slings. The slings were made up of white plastic sheets with reflecting inner surface. The slings covered three sides of the unit. The one side was left open for uninterrupted observation of the neonate. The phototherapy was administered in the postnatal wards on the mothers' cots. The distance between the lamps and the surface of baby was kept constant at 45 cm. The irradiance of the phototherapy unit was measured every 8 h at level of skin of abdomen of the neonate using a standard flux meter (Ginevri, Rome, Italy) sensitive to wavelengths of 425-475 nm.

Outcome measurement: During phototherapy, STB was measured every 8-12 h. Venous blood samples were obtained in pre-heparinized capillaries, spun and analyzed with a twin-beam spectrophotometer (Ginevri, Rome, Italy). Mother's and neonates' blood group and Rh type, peripheral smear for hemolysis, reticulocyte count, direct Coomb's Test and G6PD status were determined. If phototherapy was started after 72 h of age, it was discontinued if two consecutive STB levels measured 8-12 h apart, were less than 15 mg/dL. If phototherapy was started before 72 h of age, it was discontinued when two consecutive STB values measured 8-12 h apart, were less than the age-specific threshold for initiating phototherapy. Rebound of jaundice was clinically evaluated 8 hours after stopping phototherapy. A single unit phototherapy was said to have 'failed' if at any time during phototherapy a STB of >20 mg% was documented. Such a baby was treated with intense phototherapy with 2 conventional units or a conventional unit and a fibreoptic bed phototherapy, based on the availability. All neonates wore eye pads and diapers while under phototherapy. Rooming-in and exclusive breast feeding were encouraged. Mother was allowed to switch-off the lights during nursing and diaper change. Neonate's temperature was monitored every 6 h. Side effects like loose stools, feed intolerance, skin rashes were recorded. Duration of phototherapy was calculated from the inbuilt hour counter.

Sample size and statistical analysis: Based on a previous study(9), average duration of phototherapy required in term neonates with non-hemolytic jaundice using a single unit phototherapy is 39.0±14.7 h. For detecting 20% difference in duration of phototherapy with two-sided alpha of 0.05 and 90% power, 75 subjects were needed to be enrolled in each group. Data were entered and analyzed using Epi Info™ Version 3.3.2 (CDC, Atlanta, US). Chi square and two-sample *t*-test were used for discrete and continuous variables respectively. Analysis was based on intention-to-treat.

The study was approved by the Institutional Ethics Committee and written informed consent was obtained from one or both parents prior to enrollment.

RESULTS

***Fig.*1** details the flow of participants in the trial. One baby in the Sling group and three in the No sling group were detected to have G6PD deficiency after enrollment. Another neonate enrolled in the Sling group was found to have hemolysis of uncertain

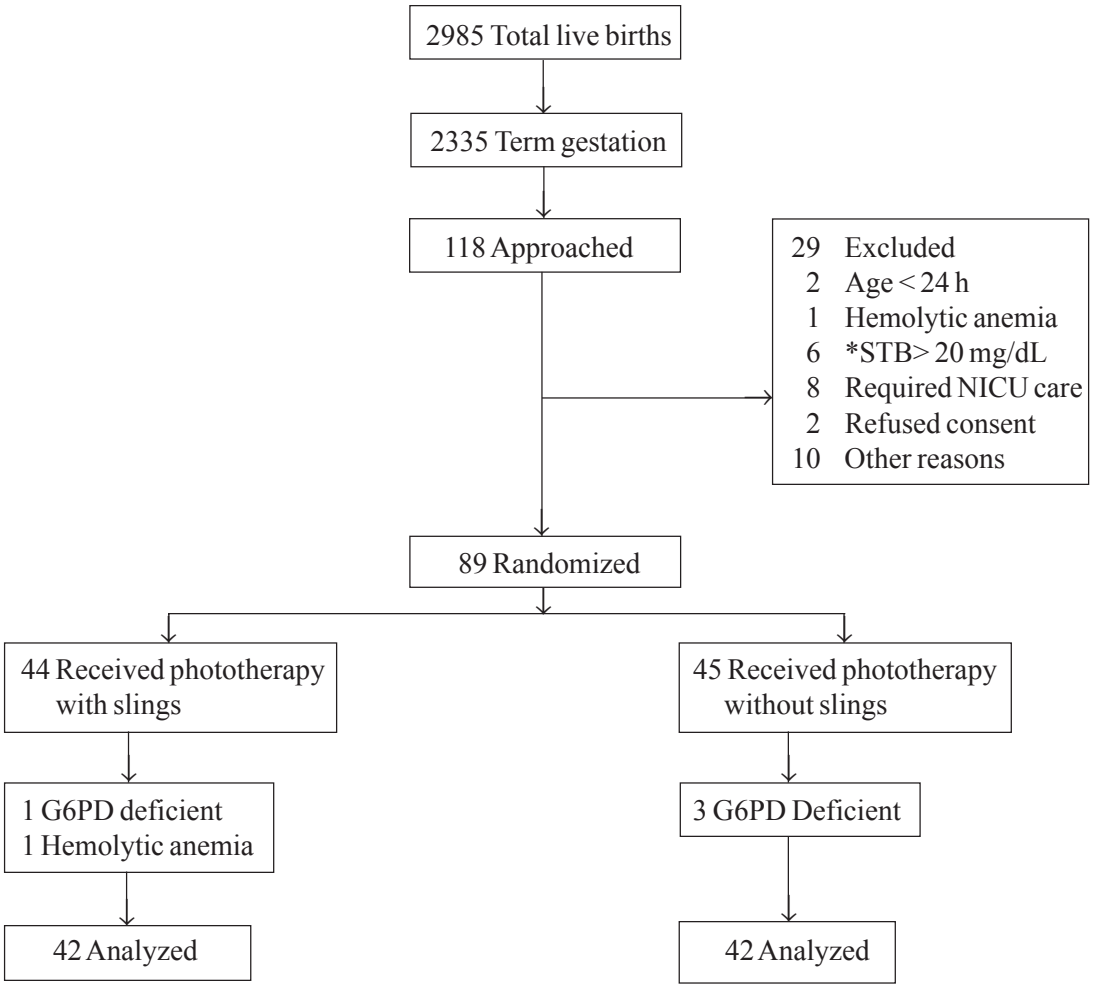

FIG.1 *Study flow chart.*

** Serum total bilirubin*

etiology. Infants with G6PD deficiency and hemolysis were not included in analysis.

The Sling and No sling groups were comparable with respect to birth weight, gestational age, gender and other maternal and neonatal variables (***Table* I**). However, diabetes mellitus was more frequent in the mothers of babies in the No sling group. Age at onset of phototherapy, initial STB and packed cell volume (PCV) were also similar in two groups. Phototherapy units in Sling group had a significantly higher flux (***Table* I**).

Outcome variables for the two groups are compared in ***Table* II**. None of neonates in either group required exchange transfusion. There was no significant difference in STB at start of phototherapy, postnatal age at start of phototherapy, ABO incompatibility setting, G6PD deficiency and minor internal bleed in the neonates who failed single-surface phototherapy and those who did not. None of the participants developed hyperthermia, feed intolerance, vomiting, decreased urine output, and skin rashes.

DISCUSSION

Our study investigated the use of slings made of white reflective material in increasing efficacy of a single-surface CFL phototherapy. We did not observe any significant difference in mean duration of phototherapy on addition of slings to

Table I Demographic and baseline variables

Demographic data	Sling group (*n*=42)	No Sling (*n*=42)
Males	25 (60%)	22 (52%)
Gestational age (wks)	38 ±1.3	37±1.0
Birth weight (g)	2790±351	2923±330
Vaginal delivery	29(69%)	24 (57%)
Caesarean section	5(12%)	9(21%)
Forceps delivery	6(14%)	1(3%)
Vacuum	2(5%)	8(19%)
Oxytocin to mother	32(72%)	27(64%)
Diabetes mellitus	10(24%)	3(7%)
Hypertension	6(14%)	4(9.5%)
Hypothyroid	3(7%)	1(2.4%)
Small-for-gestation	1(2)	0
Large-for-gestation	1(2)	3(7)
Minor internal bleed	0	1(2.3%)
5 min Apgar (range)*	8-9	8-9
ABO incompatibility setting	13(32%)	12(29%)
Rh Negative neonates	0 /21 (0%)	3/23 (13%)
Rh Negative mothers	2/41(4.9%)	2/41(4.9%)
Variables at start of phototherapy		
*Age (h)	65 ±24.9	73±44
*Total serum bilirubin (mg/dL)	16.6±2.4	16.1±2.2
*Packed cell volume (%)	52±5.7	51±5.6
#Flux (microwatt/cm^2)	194.1±26	179.7±27.7

*All values except * expressed in number (%) or mean ±SD*
* P>0.05; # *P*= 0.01

phototherapy units, although the irradiance of phototherapy unit in Sling group was marginally higher. The rate of fall of STB in first eight hours showed a trend towards being higher in the study group.

Djokomuljanto, *et al.*(7) and Hansen, *et al.*(8) have reported significant increase in irradiance and shortening in the duration of phototherapy on using slings. Djokomuljanto, *et al.*(7) used locally produced underpads (used to protect the sheets of the cots against faecal or urinary soiling) as slings and Hansen, *et al*.(8) used white bed sheets around cots. Although, previous investigators have employed different thresholds for initiation or discontinuation of phototherapy, use of different guidelines should not interfere with the comparison of various studies if same cut-offs are used in experimental and control groups.

With standard phototherapy systems, a decrease of 6% to 20% of the initial bilirubin level can be expected in the first 24 hours(10) and we documented a comparable 19.5+23.0% (mean+SD) decline in the Sling and 13.5+10.9% decline in the No sling group. Our inability to find any significant difference in duration of phototherapy may be due to lower reflective index of the sling material, lower initial STB, varying level of production of bilirubin or other unknown factors. The fourth side of the phototherapy unit was without any sling in the Sling group. This could have lessened the potential efficacy of sling application.

Table II PRIMARY AND SECONDARY OUTCOMES

Outcome	Sling group (*n*=42)	No sling group (*n*=42)	*P* value
Duration of phototherapy (h)	23.3±12.9	24.9±15.4	0.6
Mean difference (95% CI)	–1.67 (–8.00 to 4.66)		
#Failure of single surface phototherapy* (*n*, %)	4 (9.5%)	5(12%)	0.5
#TSB at the end of 8 h (mg/dL)	15±3.3	16±2.9	0.19
#TSB at cessation of phototherapy (mg/dL)	12±1.8	12±1.6	0.37
+Rate of fall of TSB in first 8 h (mg/dL/h)	0.23±0.49	0.03±0.47	0.06
#Absolute fall of TSB in first 24 h (mg/dL)	2.3±3.3	2±3.7	0.65
#Percent fall of TSB in first 24 h (%)	19.5+23.0	13.5±10.9	0.57

*All values except * in mean ±SD; #P>0.05; +P=0.01; h=hours, TSB = Total serum bilirubin.*

WHAT IS ALREADY KNOWN?

- Efficacy of phototherapy can be increased by increasing surface area of exposure and by increasing the irradiance.

WHAT THIS STUDY ADDS?

- Addition of white reflective slings increased the irradiance of compact fluorescent light phototherapy.

Neonates with hemolytic jaundice were excluded from our study, because they have more rapidly rising and higher initial STB and are more likely to need intensive phototherapy or exchange transfusion. Therefore, use of 'sling-enhanced' phototherapy in them needs to be investigated separately. Our study included only term babies, because the guidelines for preterm babies are different and the premature babies are more susceptible to bilirubin-induced neurotoxicity because of the immaturity of the blood brain barrier and other co-morbid conditions.

We monitored babies for hyperthermia, hypothermia, feed intolerance, skin rashes and did not find any in either group. The slings did not interfere with the monitoring and nursing the babies. They may have affected the mother – infant bonding and caused eyestrain to health care workers. These side effects were not monitored. The feeding patterns and postnatal weight loss of babies were also not monitored.

The present study has few limitations. We estimated the total bilirubin for monitoring the response to phototherapy. The predominant process of bilirubin elimination by phototherapy, and probably the rate-limiting mechanism, is the irreversible photo-alteration of bilirubin to a structural isomer called lumirubin, which is not separately measured by spectrophotometers. Chromatographic methods to measure lumirubin levels although not routinely available would have been a better indicator of efficacy of sling phototherapy. Since the retrospectively calculated power of the study is only 18%, the study may be underpowered to find a difference in duration of phototherapy between the two groups. The strengths of the present study are its design, minimal trial deviates and accurate measurement of duration of phototherapy.

In conclusion, reflective slings in CFL phototherapy units as used in our study resulted in a marginal increase in irradiance and a trend towards a greater rate of fall in total serum bilirubin in term neonates with non-hemolytic settings. However, there was no reduction in duration of phototherapy with use of this intervention.

Contributors: SS participated in acquisition of data and manuscript preparation, DC participated in analysis, interpretation of data and manuscript preparation, SM participated in acquisition of data, RM participated in study design and manuscript preparation, AKD participated in concept, design and critical review.

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REFERENCES

1. Vreman HJ, Wong RJ, Stevenson DK. Phototherapy: current methods and future directions. Semin Perinatol 2004 ; 28: 326-333.
2. American Academy of Pediatrics, Subcommittee on Hyperbilirubinemia. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. Pediatrics 2004; 114: 297-316.
3. Dicken P, Grant LJ, Jones S. An evaluation of the characteristics and performance of neonatal phototherapy equipment. Physiol Meas 2000; 21: 493-503.
4. Maisels J M. Why use homeopathic doses of phototherapy? Pediatrics 1996; 98: 283-287.
5. Tan KL. Efficacy of bidirectional fiber-optic phototherapy for neonatal hyperbilirubinemia. Pediatrics 1997; 99: e13.
6. De Carvalho M, De Carvalho D, Trzmielina S, Lopes JMA, Hansen TWR. Intensified phototherapy using daylight fluorescent lamps. Acta Pediatr; 88: 768-771.
7. Meslo MTL, Hansen TWR. Effektivisering av

lysbehandling med enkle midler. Jordmorbladet 2000; 7: 18-21.

8. Djokomuljanto S , Qua BS, Surini Y, Noraida R , Ismail NZN, Hansen TWR, *et al.* 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; F439-442.
9. Sarici SU, Alpay F, Unay B, Ozcan O, Gokcay E. Double versus single phototherapy in term newborns with significant hyperbilirubinemia. J Trop Pediatr 2000; 46: 36-39.
10. Tan KL. Comparison of the efficacy of fibreoptic and conventional phototherapy for neonatal hyperbilirubinemia. J Pediatr1994; 125: 607-612.
11. Fiberoptic phototherapy systems. Health Devices 1995; 24: 132-153.
12. Sarici SU, Alpay F, Dundaroz MR, Ozcan O, Gokcay E. Fibreoptic phototherapy versus conventional daylight phototherapy for hyperbilirubinemia of term newborns. Turk J Pediatr 2001; 43: 280-285.
13. Garg AK, Prasad RS, Hifzi IA. A controlled trial of high-intensity double-surface phototherapy on a fluid bed versus conventional phototherapy in neonatal jaundice. Pediatrics 1995; 95: 914-916.