

## Effect of low-cost white reflecting sling application on efficacy of phototherapy in healthy term neonates with non-hemolytic jaundice: A randomized controlled trial

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### ABSTRACT

**Objective:** The objective of this study was 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 h and 14 days of age were randomly assigned to receive single surface phototherapy with (n=50) or without slings (n=50). **Outcome Measure:** Primary outcome was rate of reduction of serum bilirubin levels and secondary outcome was duration of phototherapy (hour) required. **Results:** Birth weight (2780±360 vs. 2790±260 g), gestation (38.22±1.0 vs. 38.08±0.90 week), and initial serum total bilirubin (17.36±1.06 vs. 16.96±1.20 mg/dL) were comparable between the two groups. There was a significant difference in the duration of phototherapy (mean ± standard deviation [SD]) between the sling (53.28±21.02 h) and no sling (62.88±20.22 h) groups (p=0.02). The irradiance of phototherapy equipment ( $\mu\text{W}/\text{cm}^2/\text{nm}$ , mean±SD) was higher in sling group compared to no sling group (24.17±0.13 vs. 22.11±0.21). **Conclusion:** Hanging of white reflective sling on sides of CFL phototherapy equipment resulted in marginal increase in irradiance and reduction in the duration of phototherapy.

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

Neonatal jaundice is very common clinical condition worldwide which is encountered frequently by caregivers in pediatric and obstetrical hospital and it consumes lot of hospital resources. Phototherapy is appropriate and relatively safe measure for the treatment of indirect hyperbilirubinemia in the neonates. This is now a standard and preferred method of treatment for neonatal hyperbilirubinemia by virtue of its non-invasive nature and its safety [1,2]. This is the single most common intervention used for the treatment of neonatal jaundice and its efficacy is well established by several control trials [1,3,4]. Efficacy of phototherapy depends on the spectrum of light emitted, special irradiance delivered to the surface of the baby, and surface area exposed [5]. The various modes of phototherapy are single surface (conventional) phototherapy (SSPT), double surface phototherapy, high-intensity phototherapy, fiberoptic blanket, halogen phototherapy, compact fluorescent lamp (CFL), and light-emitting diode phototherapy [6-9].

A sling made of reflective material, hung on the sides of a phototherapy unit, may increase the exposed body surface area by reflecting light and therefore can increase the efficacy of the phototherapy [10-12]. In developing nations such as India, where the burden of neonatal jaundice is high in comparison

to the available resources, this approach can be used to obtain the maximum possible utilization of each phototherapy unit. Although use of white reflective material has been recommended to achieve the faster decline of serum bilirubin [6], use of low-cost white reflecting 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.

### MATERIALS AND METHODS

This randomized controlled trial was conducted in a tertiary care institution of Rajasthan. The study was approved by the Institutional Ethics Committee and written informed consent was obtained from one or both parents before the recruitment. All term ( $\geq 37$  weeks) neonates born in the hospital between November 2011 and October 2012 were eligible for enrollment if they satisfied the following criteria: Age more than 24 h and  $\leq 14$  days, apgar score at 5 min  $> 6$ , and serum total bilirubin (STB)  $< 21$  mg/dl. Exclusion criteria were hyperbilirubinemia requiring exchange transfusion, evidence of hemolysis in peripheral

smear, Rh hemolytic disease, positive direct Coombs test (DCT), glucose-6-phosphate dehydrogenase (G6PD) deficiency, major congenital malformations, culture positive sepsis, and need of intensive care and conjugated hyperbilirubinemia. Neonates with ABO incompatibility but negative DCT and having no evidence of hemolysis on peripheral blood smear were included in the study.

### Intervention and Randomization

All term neonates born during study period were clinically monitored for the development of jaundice. Serum bilirubin was done as per judgment of treating team. The decision to start and stop phototherapy was based on American Academy of Pediatrics (AAP) guidelines for term neonates [6]. The babies included in the study were randomized to receive single SSPT either with slings or without slings using paper chit method. CFL phototherapy units (MODEL - Bird Meditech, Mumbai, India) having 4 special blue CFL (Philips 18w/52/4p, Poland) and two white CFL mounted on metal frame with adjustable heights were used. 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 linen bed sheets. 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 at the level of abdomen of the neonate before initiating phototherapy using photometer (flux meter, model, M/S Meditrin Instruments, Mumbai, India) and then every 12 hourly.

### Outcome Measurement

During phototherapy, STB was measured every 12 h. Serum bilirubin estimation was done by semiautomatic analyzer based on method of Jendrassik and Grof using peripheral venous blood. Starting and stopping of phototherapy were done as per AAP guideline (2004) for neonates  $\geq 35$  weeks gestation. Rebound of jaundice was clinically evaluated 8 h after stopping phototherapy. A single unit phototherapy was said to have "failed" if at any time during phototherapy, a STB  $>20$  mg% was documented. Such a baby was treated with intense phototherapy with 2 conventional units or a conventional unit and a fiberoptic 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. All babies were examined thoroughly daily and monitored every 12 hourly for vitals, weight, urine output, temperature, clinical jaundice, and development of rashes, number of stools, and sign of dehydration. Neonate's temperature was monitored every 6 h. Side effects such

as loose stools, feed intolerance, and skin rashes were recorded. Duration of phototherapy was calculated from the inbuilt hour counter.

### Sample Size and Statistical Analysis

Sample size was calculated at 80% study power and alpha error of 0.05% assuming standard deviation of 15.4 h in duration of phototherapy in no sling group based on study of Sivanandan et al. [13]. For minimum mean detectable difference of 10 h in duration of phototherapy, 38 patients in each group were required as sample size which was enhanced and rounded off to 50 patients in each group as final sample size for our study, expecting 20% drop out or attrition. Data were entered and analyzed using MedcalC version 14.2.1.0 software. Qualitative data were summarized as percentage and quantitative data were summarized as means and standard deviation. Chi-square ( $\chi^2$ ) test was used to find out the significance of difference between proportions and percentages. Unpaired t-test was used to find out significance of difference between two means.  $p < 0.05$  was taken as statistically significant.

## RESULTS

Fig. 1 details the flow of participants in the trial. Two babies in the sling group and four in the no sling group were detected to have G6PD deficiency after enrolment. Another neonate enrolled in the sling group was found to have hemolysis of uncertain etiology. Infants with G6PD deficiency and hemolysis were not included in analysis. Both the groups were comparable with respect to birth weight, gestational age, gender, and other maternal and neonatal variables (Table 1). Age at the onset of phototherapy, initial STB, and hemoglobin were also similar in two groups. Phototherapy units in sling group had a significantly higher flux (Table 2).

Outcome variables for the two groups are compared in Table 3. None of the neonates in either group required exchange transfusion. There was no significant difference in STB at the start of phototherapy, postnatal age at the start of phototherapy, ABO incompatibility setting, and G6PD deficiency. None of the participants developed hyperthermia, feed intolerance, vomiting, and decreased urine output. The duration of phototherapy was significantly lower in sling group ( $53.28 \pm 21.02$  h) than in no sling group ( $62.88 \pm 20.22$  h), ( $p = 0.022$ ).

## DISCUSSION

In our study, we investigated the use of slings in increasing the efficacy of single surface CFL phototherapy. We observed that phototherapy unit covered with sling increases the photo irradiance and reduces the mean duration of phototherapy as compared to phototherapy unit without slings. The rate of fall of STB in first 12-24 h showed a trend toward being higher in the study group. To the best of our knowledge, only one such Indian study was published by Sivanandan et al. [13] and they found that white reflective sling resulted in marginal increase in irradiance; however, it did not decrease the duration of phototherapy.

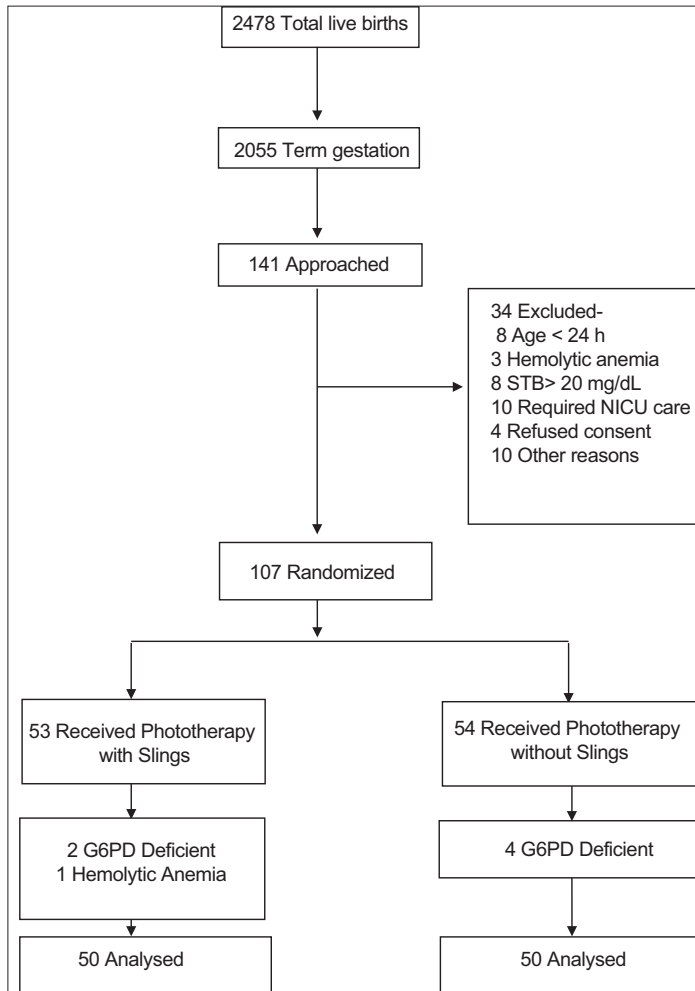


Figure 1: Study flow chart

Other two studies [11-12] have reported a significant increase in irradiance and shortening in the duration of phototherapy on using slings. First one [11] used white bed sheets around cots and second one [12] used locally produced underpads (used to protect the sheets of the cots against fecal or urinary soiling) as slings. 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 cutoffs are used in experimental and control groups.

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. We monitored babies for adverse effects which were mild in nature and not significant. The slings did not interfere with the monitoring and nursing the babies as the sling was covered on three sides of the phototherapy unit and one side was kept open for observation of the baby. Photo irradiance and hence efficacy could have been improved if phototherapy unit was covered on all the four sides; though constant observation of the baby would have been compromised.

Table 1: Demographic variables of sling and no sling groups

Parameters	n=50 (%)		p value
	Sling	No sling	
Males	26 (52)	30 (60)	0.42
Gestation age (weeks)	38.22±1.00	38.08±0.90	0.462
Birth weight (kg)	2.78±0.36	2.79±0.26	0.911
Caesarean delivery	14 (28)	19 (38)	0.395
Vaginal delivery	36 (72)	31 (62)	0.395
Oxytocin to mother	10 (20)	12 (40)	0.695
ABO incompatibility	27 (54)	24 (48)	0.689
Exclusive breastfeeding	43 (86)	40 (80)	0.424
5 min Apgar score	7-9	7-9	NA

Values are expressed in number (%) or mean±SD, p>0.05. SD: Standard deviation

Table 2: Baseline variables at start of phototherapy

Parameters	n=50		p value
	Sling	No sling	
Age (days)	2.84±0.53	2.96±0.70	1.00
Serum bilirubin (mg/dl)	17.36±1.06	16.96±1.20	0.08
Hemoglobin (gm/dl)	17.93±1.25	17.69±1.13	0.317
Flux (µw/cm <sup>2</sup> /nm)	24.17±0.13	22.11±0.21	0.00

Values are expressed in mean±SD. SD: Standard deviation

Table 3: Outcome variables of two groups

Parameters	n=50		p value
	Sling	No sling	
Duration of phototherapy (h)	53.28±21.02	62.88±20.22	0.022
Fall of TSB at the end of 12 h (mg/dl)	1.15±0.92	0.60±0.90	0.003
Rate of fall of STB in first 12 h (mg/dl/h)	0.09±0.08	0.05±0.07	0.009
Fall of TSB at the end of 24 h (mg/dl)	0.99±1.54	0.70±1.06	0.0275
Rate of fall of STB between 12 and 24 h (mg/dl/h)	0.08±0.13	0.06±0.09	0.0373

All value are expressed in mean±SD, p>0.05. STB: Serum total bilirubin, TSB: Total serum bilirubin, SD: Standard deviation

In the present study, we used white linen bed sheets as slings for phototherapy units which are easily available but further studies can be done using better reflecting material which may also increase the irradiance and decrease the duration of phototherapy and hospital stay. Using slings in phototherapy units, we can reduce hospital stay of patient, economic burden on patient, and patient load on hospitals. Hence, we can make better use of the limited resources in hospitals, especially in developing nations in a cost-effective manner.

### CONCLUSIONS

Low white reflective slings in CFL phototherapy units as used in our study resulted in a marginal increase in irradiance and a trend toward a greater rate of fall in total serum bilirubin along with decrease in total duration of phototherapy in term neonates with non-hemolytic settings.

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