

Original Research Article

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## Comparison of effectiveness of light emitting diode phototherapy with conventional phototherapy and combination phototherapy of conventional with fiberoptic biliblanket, and light emitting diode phototherapy with fiber optic biliblanket for treatment of neonatal hyperbilirubinemia

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### ABSTRACT

**Background:** Hyperbilirubinemia is a common problem in neonates with an incidence of 70-80%. Phototherapy is the preferred method of treatment for neonatal hyperbilirubinemia by virtue of its noninvasive nature and its safety. LED phototherapy, conventional phototherapy and fiber optic phototherapy are the modalities used in management of nonhemolytic hyperbilirubinemia in the first week of life in healthy near term and term neonates. The present study was conducted with the objective to compare effectiveness of double surface light emitting diode phototherapy with conventional double surface phototherapy and combination phototherapy of conventional and fiberoptic biliblanket, and light emitting diode phototherapy with fiber optic biliblanket for treatment of neonatal hyperbilirubinemia.

**Methods:** Total of 236 neonates with hyperbilirubinemia were prospectively randomized to four groups to receive single surface conventional and fiber optic biliblanket combination phototherapy (n=60; Group-1), double surface LED phototherapy (n=59; Group-2), fiber optic biliblanket and single surface LED phototherapy groups (n=62; Group-3) and double surface conventional phototherapy group (n=55; Group-4). Bilirubin levels were measured at different time intervals and adverse effects were noted if any.

**Results:** The rate of percentage and overall decrease of bilirubin was best in Group-2 (48.27%; 8.6 mg%) followed by Group-4 (45.49%; 8.1 mg%), Group-3 (41.26%; 7.27 mg%) and Group-1 (39.37%; 6.9 mg%). None of the babies presented side effects in Group-1 and Group-3. Neonates in Group-4 had shown loose stools (n=1), skin rash (n=3) and hyperthermia (n=2). Hyperthermia and skin rash was found in each case in Group-2.

**Conclusions:** Rate of decrease of bilirubin was best in double surface LED phototherapy followed by double surface conventional phototherapy, fiber optic biliblanket with single surface LED combination phototherapy and fiber optic biliblanket and single surface conventional phototherapy.

**Keywords:** Fiber optic biliblanket, Light emitting diode phototherapy, Phototherapy, Neonatal hyperbilirubinemia

## INTRODUCTION

Neonatal hyperbilirubinemia is the most clinical problem encountered in about 60% of the infants during their first weeks of life.<sup>1</sup>

This condition was characterized by yellowing of babies' skin and tissues and can also be referred to as neonatal jaundice.

Elevated levels of unconjugated bilirubin were fatally responsible for this condition.<sup>2</sup> However, high levels of bilirubin was toxic and may affect the development of central nervous system leading to neurotoxicity or kernicterus in newborn infants.<sup>3-5</sup>

As per the recommendations of Maisels, phototherapy is like a percutaneous drug and was preferred choice of treatment for treating neonatal jaundice.<sup>6,7</sup>

Phototherapy converts lipid soluble forms of bilirubin to non-toxic and easily excretable forms by configurational and structural isomerization and photo-oxidation.<sup>2</sup> The efficacy of phototherapy depends on the exposed surface area.

Of different types, double surfaced phototherapy was more effective than other forms.<sup>8</sup> Conventional or fiberoptic phototherapy gives good results in cases of nonhemolytic jaundice.

Intensive phototherapy by placing the baby in biliblanket and using additional overhead phototherapy are the significant remedies for treating hemolytic jaundice.<sup>9</sup>

We did not find other studies comparing the effectiveness of double surface Light Emitting Diode phototherapy with conventional double surface phototherapies and the combination of them with fiberoptic biliblanket.

Hence, the present study was undertaken to compare the effectiveness of double surface light emitting diode phototherapy with conventional double surface phototherapy and combination phototherapy of conventional and fiberoptic biliblanket, and light emitting diode phototherapy with fiber optic biliblanket for treatment of neonatal hyperbilirubinemia in terms rate of fall of bilirubin and incidence of side-effects.

## METHODS

This was an open labeled randomized trial conducted at Department of Pediatrics, zonal Hospital (7 Air Force hospital) Kanpur during the period from March 2013 to March 2015.

A total of 240 neonates who were born at a gestation of  $\geq 35$  weeks and developed jaundice requiring phototherapy within first week of life as per American

Academy of Pediatrics practice parameter guidelines were included in the study.

Babies with hydrops fetalis, major congenital malformations, sepsis (symptomatic screen positive/culture positive), Rh iso immunization, who developed jaundice requiring phototherapy for the second time and with first bilirubin value  $>20$  mg/dl were excluded from the study.

All neonates born at  $>35$  weeks of gestation were monitored for appearance of jaundice by physical examination by the pediatrician in charge of the baby -12 hrly.

Jaundice was assessed by blanching the skin with thumb pressure, revealing the underlying color of the skin and subcutaneous tissue performed in a well-lit room or, preferably, in daylight at a window. Jaundice was assessed based on Kramer's scale.

After getting informed consent from the parents and approval from institutional ethics committee, the neonates were randomly distributed into 4 groups based on the type of phototherapy allocated. Of the total 240 neonates, 4 of them could not complete study as parents requested discharge due to domestic commitments.

### **Study procedure**

Of 236 babies 60 were randomized to Group 1: single surface conventional and fiber optic Biliblanket combination phototherapy, 59 to double surface LED phototherapy (group 2), 62 to fiber optic biliblanket and single surface LED phototherapy groups (group 3) and 55 to double surface conventional phototherapy group (group 4).

Base line foetal and maternal characteristics were noted as per predesigned proforma. All babies were exclusively breast fed in all four groups.

The phototherapy unit was positioned at 35 cm from the baby in case of Conventional Phototherapy.

Phototherapy was given in the ward at the mother's bed side. Irradiance was measured by Joey Dosimeter at the center of unit at the level of the baby in Conventional phototherapy.

The baby was placed on the illuminating portion of the fiberoptic system directly and irradiance was measured by dosimeter at the centre of illuminating surface.

Neonates in the four groups were subjected to total serum bilirubin (TSB) analysis of capillary blood obtained by heel stick every 12-24 hours.

The lights were switched off during sampling. Serum bilirubin was estimated by Diazo method with the help of

fully Automated Biochemistry Analyser ERBA EM 360 (Transasia Biomedical Ltd).

#### **Care of the baby under phototherapy**

Neonates under Conventional phototherapy remained naked except for an eye pad and a nappy. Mothers were instructed to note the time duration for which the lights were switched off for activities like feeding, nappy change, for sampling etc. A chart was provided to the mother to note the above events.

#### **Monitoring of babies under phototherapy**

Baby's temperature was monitored every eight-hourly using digital thermometers by the nursing staff. If babies become hypothermic hot air blowers were used.

Loose stools, feed intolerance, skin rashes and other side effects, if any were recorded.

#### **Stopping of phototherapy**

Phototherapy was stopped if 2 values of TSB taken 12 hrs. apart were below the cut off for phototherapy as per AAP charts.

#### **Statistical analysis**

Data was compiled and analyzed using SPSS 18.0 statistical software. Post-hoc tables were used for group comparison P values less than 0.001 can be considered as significant statistically.

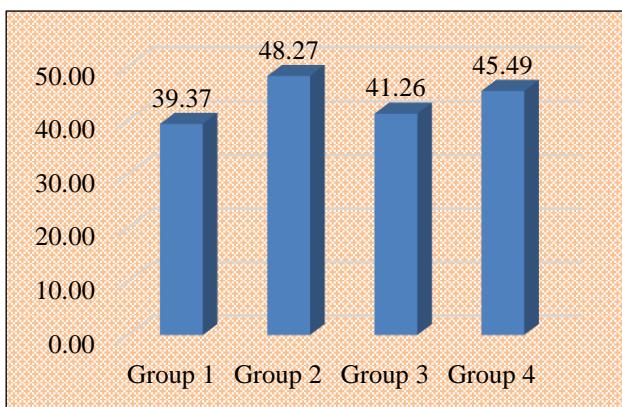
## **RESULTS**

A total of 236 neonates were included in the study and they were randomly divided into 4 groups.

Table 1 provides their base line neonatal and maternal characteristics.

**Table 1: Comparison of baseline characteristics in study groups.**

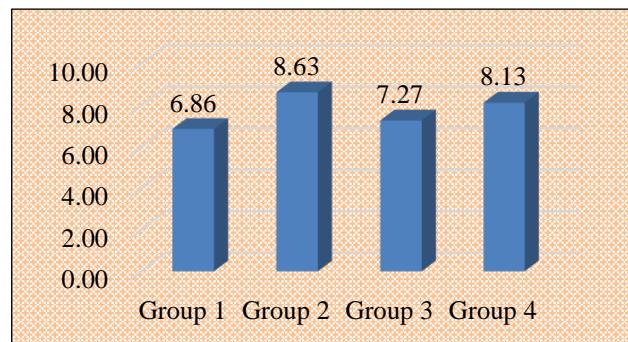
Characteristics	Group-1 (N=60)	Group-2 (N=59)	Group-3 (N=62)	Group-4 (N=55)	P value
<b>Neonatal</b>					
Gestational age (weeks)	37.0±1.64	37.6±1.51	37.8±1.49	37.2±1.47	0.012
Gestational weight (kgs)	2.65±0.50	2.85±0.55	2.90±0.50	2.75±0.50	0.046
<b>Maternal</b>					
a) Primi	32 (53%)	28 (47%)	32 (52%)	28 (50%)	
<b>b) Mode of delivery</b>					
Vaginal	32 (54%)	30 (50%)	32 (52%)	28 (50%)	
Vacuum	6 (10%)	9 (16%)	5 (7.4%)	6 (10.7%)	0.985
Forceps	0	0	0	0	
LSCS	22 (36%)	20 (34%)	25 (40.4%)	21 (39.3%)	



**Figure 1: Rate of percentage decrease of bilirubin in study groups.**

The values are similar in all the groups. The mean gestation age at which the babies were born in Group-1, Group-2, Group-3 and Group-4 was 37.0, 37.6, 37.8, and 37.4 weeks respectively.

The mean body weight of Group-1, Group-2, Group-3 and Group-4 neonates was 2.65, 2.85, 2.90 and 2.75 Kgs respectively. Children born to primi mothers in Group-1, Group-2, Group-3 and Group-4 was 32 (53%), 28 (47%), 32 (52%) and 28 (50%) respectively. No forceps delivery was seen in all the 4 groups.



**Figure 2: Overall decrease in bilirubin in study groups.**

Most of them were born through vaginal delivery followed by LSCS and vacuum. There was no statistically significant difference in baseline characteristics of all four groups.

Table 2 presents the group wise comparison of bilirubin at different points of study (before to after 60 hours of phototherapy).

**Table 2: Group wise comparison of bilirubin at different points of study.**

Bilirubin estimation at different time intervals	N	Mean	Std. deviation	F value	P value	
Initial_Bil	Group 1	60	17.00	1.94	3.032	0.03
	Group 2	59	17.79	1.38		
	Group 3	62	17.41	1.53		
	Group 4	55	17.77	1.61		
	Total	236	17.48	1.65		
Bil_6 hrs	Group 1	60	16.53	1.91	0.733	0.533
	Group 2	59	17.04	1.20		
	Group 3	62	16.78	1.34		
	Group 4	55	16.73	2.79		
	Total	236	16.77	1.89		
Bil_12 hrs	Group 1	60	15.58	1.40	1.063	0.365
	Group 2	59	15.77	1.07		
	Group 3	62	15.94	1.59		
	Group 4	55	15.34	3.07		
	Total	236	15.67	1.91		
Bil_24 hrs	Group 1	60	14.08	1.53	3.811	0.011
	Group 2	59	13.80	1.20		
	Group 3	62	14.38	1.56		
	Group 4	55	13.45	1.89		
	Total	236	13.94	1.59		
Bil_36 hrs	Group 1	60	13.43	1.90	8.215	<0.001
	Group 2	59	11.95	1.43		
	Group 3	62	13.08	2.06		
	Group 4	55	12.34	1.81		
	Total	236	12.71	1.90		
Bil_48 hrs	Group 1	60	12.60	1.66	21.595	<0.001
	Group 2	59	10.65	1.27		
	Group 3	62	12.36	1.70		
	Group 4	55	11.11	1.61		
	Total	236	11.70	1.77		
Bil_60 hrs	Group 1	60	10.14	1.10	10.964	<0.001
	Group 2	59	9.16	0.91		
	Group 3	62	10.14	1.15		
	Group 4	55	9.64	1.21		
	Total	236	9.78	1.17		

The findings revealed significant ( $p<0.001$ ) gradual decrease in bilirubin in all four groups from 36-60 hours.

As shown in Figure 1 and 2, the rate of percentage and overall decrease of bilirubin was best in Group-2 (48.27%; 8.6 mg%) followed by Group-4 (45.49%; 8.1 mg%), Group-3 (41.26%; 7.27 mg%) and Group-1 (39.37%; 6.9 mg%).

No major or minor side effects were noted among babies who received either of the units for phototherapy (Table 3).

Only one baby developed loose stool in conventional phototherapy group and had hypothermia with the lowest temperature recorded was 36.00C.

**Table 3: Side effects noticed among the study groups.**

Adverse effects	Group 1 (N=60)	Group 2 (N=59)	Group 3 (N=62)	Group 4 (N=55)
Hypothermia $\leq 36^{\circ}\text{C}$	0	0	0	0
Hyperthermia $\geq 38^{\circ}\text{C}$	0	1 (1.6%)	0	2 (3.6%)
Skin rash	0	1 (1.6%)	0	3 (5.5%)
Burn/ dehydration	0	0	0	0
Loose stool	0	0	0	1 (1.8%)

Skin rashes were seen in 3 (5.5%) neonates and hyperthermia was noted in 2 (3.6%) neonates. Hyperthermia and skin rash was seen in each neonate in Group 2.

## DISCUSSION

Light emitting diode (LED) phototherapy units are coming in a big way in the field of phototherapy. The inherent advantage of LED fiber optic phototherapy units over conventional phototherapy units with fluorescent tube lights in terms of keeping baby and mother together so as to improving bonding, continue breastfeeding even when phototherapy is going on makes them an attractive option for their use in the management of neonatal jaundice. Hence, we undertook a prospective randomized trial comparing double surfaced LED phototherapy and conventional phototherapy, fiber optic phototherapy in combination with single surfaced LED and conventional phototherapy in management of neonatal jaundice.

In the present study, the rate of percentage and overall decrease in bilirubin in neonates was more in Group-2, followed by Group-4, Group-3 and Group-1. This was in agreement with the findings noticed by Tan.<sup>10</sup> He determined that rate of decrease in bilirubin was proportional to light intensity, signifying that phototherapy of higher intensity would increase its effectiveness.

The present study results were also supported by the findings of Silva et al.<sup>11</sup> His findings suggest that at higher levels of bilirubin double surface phototherapy group was more effective when compared to the single surface phototherapy. Some studies have compared conventional phototherapy unit with fiber optic units. On contrary to the present study findings, Gale et al found no difference in the decrease in bilirubin levels between conventional and fiber optic phototherapy.<sup>12</sup>

In another prospective, randomized study done by Al-Alaiyan et al, the effectiveness of fiber optic, conventional and a combination phototherapy in decreasing bilirubin concentrations in neonatal nonhemolytic hyperbilirubinemia were compared. The groups were similar in clinical characteristics at study

entry in terms of birth weight, age and bilirubin concentration. An analysis of present study also demonstrated similar trends.<sup>13</sup> In previous studies, few side effects were reported with conventional therapy which includes imbalance of thermal environment and water loss, bronze baby syndrome, electrolyte disturbance, retinal damage, skin rashes, impairment of immune system and circadian rhythm disorder. In the present study, neonates exposed to conventional therapy were affected with few side effects such as skin rash (3; 5.5%), hyperthermia (2; 3.6%) and loose stools (1; 1.8%).<sup>14-17</sup>

## CONCLUSION

The study concludes that rate of fall of bilirubin is faster with double surface LED phototherapy. In observation of less frequent side effects, less energy consumption, longer life span, and lower costs, LED phototherapy seems to be the better option than current conventional phototherapy and combination phototherapies. More studies are warranted for evaluating the efficacy of LED phototherapy in infants with incidence of pathologic jaundice (e.g., hemolytic) and severe hyperbilirubinemia.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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