Original Articles

Randomized Controlled Trial of Compact Fluorescent Lamp Versus Standard Phototherapy for the Treatment of Neonatal Hyperbilirubinemia

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Background: *Special blue tube lights of standard length are used in most neonatal units to deliver phototherapy. Of late, special blue compact fluorescent lamp phototherapy equipments have been introduced in India, which are claimed to be better than standard tube lights.* ***Aim:*** *To compare special blue compact fluorescent lamp (CFL) phototherapy with special blue standard-length tube lights (STL).* ***Methods:*** *This randomized, controlled trial was conducted in a level III NICU. Neonates, otherwise healthy, of gestation >34 weeks with hyperbilirubinemia requiring phototherapy, were included. Rh iso-immunized babies, those who underwent prior exchange transfusion and whose parents declined to consent were excluded. By stratified block randomization, babies were allocated to receive phototherapy by CFL or STL. CFL and STL were both special blue lights with irradiance maintained above 15 μW/nm/cm^2. Total serum bilirubin (TSB) was measured 12 hourly till phototherapy was stopped or an exchange transfusion was done. Temperature and clinical and laboratory parameters of dehydration were recorded 12 hourly till 72 hrs. Nursing staff answered an objectivized proforma about the disadvantageous effects on nurses.* ***Results:*** *Fifty babies were enrolled in each group. Baseline characteristics, causes of jaundice, hemolysis, baseline TSB and irradiance were similar in both groups. Mean duration of phototherapy (P = 0.98) was similar in both groups. Kaplan-Meier analysis of phototherapy duration showed no difference in the survival curves of the 2 groups (P = 0.6). Axillary temperature was similar in both groups and no baby was dehydrated. Nursing staff reported no significant differences between CFL and STL vis-à-vis glare hurting the eyes, giddiness and headache.* ***Conclusions:*** *CFL phototherapy has no superiority over STL phototherapy in terms of efficacy and adverse effects on the neonate and effects on nursing staff.*

Keywords: *Jaundice, Neonate, Phototherapy.*

ABOUT 3% of all hospital-born babies in India develop significant jaundice, with Total Serum Bilirubin (TSB) levels more than 15 mg/dL(1). Phototherapy is a useful method for treating neonatal hyperbilirubinemia because it is easily available and devoid of all complications of double volume exchange transfusions. The efficacy of phototherapy depends on the dose and wavelength of light used and the surface area exposed(2). Phototherapy is associated with side-effects like dehydration and hyperthermia. Glaring,

giddiness and headache caused to nursing staff and difficulty in clinical monitoring are disadvantages associated with blue light phototherapy(3).

Over the last 2 decades, there has been a constant endeavour to develop ways to increase the efficacy of phototherapy and at the same time reduce the side-effects and disadvantages to nursing personnel. Recently, compact fluorescent special blue lamp phototherapy units have been introduced in the Indian market. The manufacturers of these units claim that they are more efficacious and more acceptable to nursing staff compared to conventional units. These advantages are said to be due to the smaller size, focused area, lower scatter and higher irradiance. A Medline search did not yield any information regarding the use of compact fluorescent lamps. To test the hypothesis that compact fluorescent lamps are superior to conventional phototherapy units, we performed a randomized, controlled trial.

Subjects and Methods

This study was conducted on inborn neonates with jaundice admitted to a level III neonatal unit in Northern India. The study protocol was approved by the Institute's Ethics Committee. Neonates with gestational age more than 34 completed weeks, with hyperbilirubinemia requiring phototherapy (as per Cockington's charts) and who were otherwise "healthy" were included in the study(4). For the purpose of the study, "healthy" was defined as "an active baby exclusively on oral feeds with normal physiological vital parameters". Those with Rh isoimmunization, those who had undergone a double volume exchange transfusion for any reason prior to enrollment and whose parents declined to give informed consent were excluded. Babies who satisfied the eligibility criteria were randomly allocated to the 2 intervention groups: Compact Fluorescent Lamp (CFL) and Standard-length Fluoresent Tube Light (STL) phototherapy. Stratified, block randomization procedure was used, with stratification for gestational age (<37 weeks and ≥37 weeks). The random numbers were computer generated, and slips bearing the allocated group were placed in serially numbered, opaque, sealed envelopes.

The CFL equipments (supplied by Phoenix India Ltd) comprised of 4 special blue CFL's and 2 white CFL's (Dulux®L 18W/71, Osram, Italy) mounted on metal frames with adjustable heights. The lamps were covered by a special transparent sheet that focuses and prevents scattering of light. The STL equipments were indigenously made, and comprised of 4 special blue tube light (TL 20 W/52BB®, Phillips India) and 2 white tube lights mounted on metal frames with adjustable heights. Before starting phototherapy on a subject, the irradiance was checked by a photoradiometer (Fluoro-lite 451®, Minolta/ Air Shields, USA). Our target was to maintain irradiance above 15 μW/nm/cm^2 at all times and lamps were replaced whenever necessary, to maintain this irradiance. Our unit policy is to place the baby as close as possible to the light source, provided it does not interfere with nursing care and does not cause temperature instability. Except for an eye pad, all areas are left uncovered. There is no specified protocol for position changes.

After enrolment, information was recorded regarding demographic data and causes of jaundice. Blood group, direct Coomb's test (DCT), Glucose-6-phosphate dehydrogenase (G6PD) levels, peripheral blood smear and reticulocyte counts were performed. Total Serum Bilirubin (TSB) was measured every 12 hours by direct spectrophotometry (Twin Beam Micro-bilimeter, Ginevri, Italy). The

rate of decline of phototherapy and the duration of phototherapy were calculated. The time for which the babies were taken out of phototherapy for feeding, nappy changes etc were also recorded to give an estimate of the actual number of hours under phototherapy. Phototherapy was discontinued after 2 consecutive TSB values below phototherapy zone were obtained. Exchange transfusions were done based on Cockington's charts. The urinary frequency, clinical signs of dehydration, weight, serum sodium and axillary temperature were recorded every 12 hours. Mothers were instructed to feed their babies every 2-3 hours.

To test the acceptability of the equipments by nursing staff, we randomly selected 50 nurses, of the 64 nurses working in the neonatal unit, and administered to them a questionnaire. They had to answer the following 3 questions: Does the light (*a*) cause a glare and hurt the eyes? (*b*) cause giddiness? (*c*) cause a headache? They selected answers from 4 options: 'no', 'minimally', 'moderately' and 'extremely'. Separate answers were given for CFL and STL.

The primary outcome was the total duration of phototherapy. Secondary outcomes were: rate of decline of TSB, need for exchange transfusion, temperature instability, evidence of dehydration and nurses' reports of 'moderate' or 'extreme' distress.

A convenience sample of 100 babies was recruited, since there were no prior data on this subject. Data of the 2 groups were analyzed by Chi square test for categorical variables, Student's *t* test for normally distributed numerical variables and Mann Whitney test for variables with skewed distributions. Babies who underwent a double volume exchange were not included in the analysis of the duration of phototherapy. For calculating the rate of decline of TSB, babies who underwent an exchange transfusion were included till the point of time when they underwent this procedure. Thereafter, they were excluded from analysis.

Results

Of 293 consecutive babies with gestation more than 34 weeks who received phototherapy, 100 babies, who satisfied the eligibility criteria were enrolled and randomized (*Fig. 1*). There were 50 babies in each group. Baseline demographic characteristics, causes of hyperbilirubinemia and incidence of hemolysis were balanced between the 2 groups (*Table I*). The mean TSB before starting phototherapy was comparable in both groups. There was no difference in the mean irradiance of the equipments at onset of phototherapy between the CFL and STL groups [Mean irradiance (± SD): 18.39 ± 2.38 vs 17.77 ± 1.81 respectively, $P > 0.05$].

The total number of hours of phototherapy prescribed were similar in both groups ($P = 0.98$) as was the time for which subjects were actually kept under phototherapy ($P = 0.96$) (*Table II*). The number of subjects who underwent a double volume exchange after treatment allocation was higher in the CFL group, but this did not achieve statistical significance.

The hour-specific TSB at 12 hourly intervals after starting phototherapy were compared. There were no differences in the percent change in each 12 hour interval, nor in the percent change in TSB from baseline.

Repeated measures ANOVA was performed to analyze the effect of the intervention on TSB. All subjects had at least 2 values of

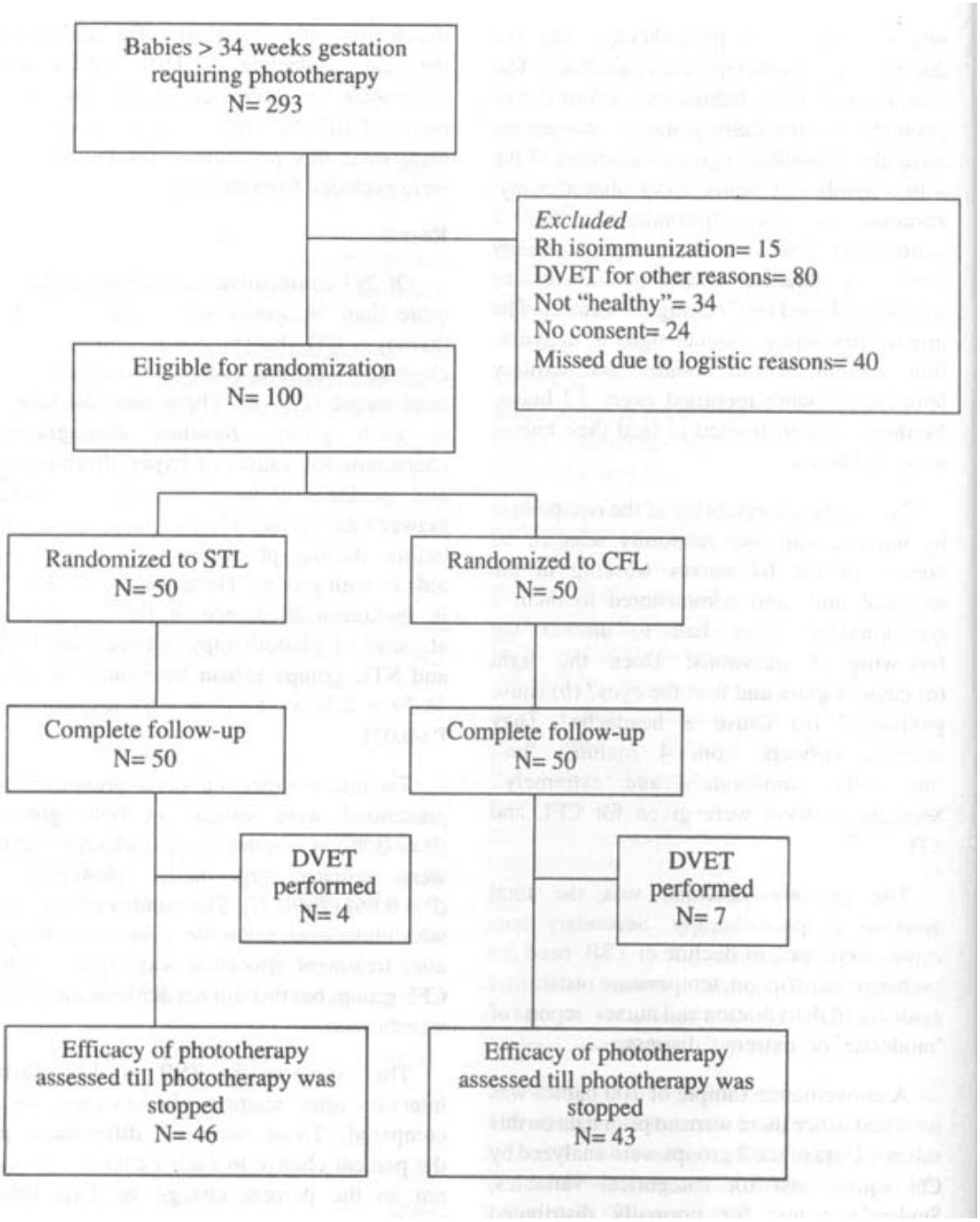

Fig. 1. The Study Flow Chart

TABLE I– *Baseline Information*

Parameters	CFL group (n = 50)	STL group (n = 50)
Preterm gestation	24 (48)	20 (40)
Males	27 (54)	28 (56)
Oxytocin use	16 (32)	17 (34)
ABO incompatibility	8 (16)	4 (8)
G6PD deficiency	6 (12)	5 (10)
Reticulocyte count % (mean ± SD)	1.03 ± 1.45	0.69 ± 1.02
Hemolysis on peripheral smear	0	0
Baseline irradiance in (μW/nm/cm^2 (mean ± SD)	18.39 ± 2.38	17.77 ± 1.81
Baseline TSB in mg/dL (mean ± SD)	16.25 ± 1.52	15.38 ± 1.95

All figures in parentheses are percentages

TSB, *i.e.*, baseline and 12 hours, but many did not have subsequent values because of stoppage of phototherapy. Therefore, only baseline and the 12-hr values were included in the repeated measures ANOVA because inclusion of subsequent values would make the analysis unbalanced. We observed an association between the 12-hr TSB level and the type of phototherapy source. The estimated marginal mean TSB in the CFL group was significantly higher than in STL group [15.53 (95% confidence interval: 15.01, 16.05) versus 14.55 (95% confidence interval: 14.03, 15.08) respectively; F value = 6.8; P = 0.01]. There was a decline in mean TSB between baseline and 12 hours [15.86 (95% confidence interval: 15.5, 16.2) versus 14.23 (95% confidence interval: 13.7, 14.8); F value = 42.4; P <0.001)].

Kaplan-Meier analysis of the duration of phototherapy in the 2 groups was performed (*Fig. 2*). The median duration in the CFL group [36.0 hrs (95% confidence interval: 29, 43)] was comparable to that in the STL group [42.0 hrs (95% confidence interval: 31.3, 52.7)], the difference being non-significant (P value of log rank test = 0.62).

Sub-group analyses were performed to compare the effects of CFL versus STL among various sub-groups: preterms, babies with ABO incompatibility and those with G6PD deficiency. No statistically significant differences were found.

Adverse effects were compared between the CFL and STL groups. The axillary temperatures were similar at 12, 24, 48 and 72 hours (all P values >0.05). There were no cases of hyperthermia or hypothermia in either group. There were no cases of dehydration among our subjects, and serum sodium, urine specific gravity and weight changes were similar till 72 hours (all P values >0.05).

The analysis of the reports of the nursing staff showed a slight trend towards more disadvantages associated with STL, but it did not reach statistical significance. Eyes feeling hurt by the glare of CFL and STL was reported to a 'moderate or extreme' degree by 38% and 48% respectively (P = 0.16). Giddiness was reported as 'moderate or extreme' by 14% and 20% respectively (P = 0.42) and headaches were reported as 'moderate or extreme' by 6% and 8% respectively (P = 1).

TABLE II–*Phototherapy and Exchange Transfusion*

Parameter	CFL group (n = 50)	STL group (n = 50)	P value
Hours of phototherapy from starting till stopping Mean ± SD [range]	40.66 ± 23.94 [12-120]	40.78 ± 21.83 [12-96]	0.98
Actual time under phototherapy* Mean ± SD [range]	29.86 ± 17.57 [8-96]	29.32 ± 16.00 [8-78]	0.96
Exchange transfusions	7 (14%)	4 (8%)	0.34

* Excludes the time for which babies were taken out of phototherapy for feeding, nappy change and other aspects of nursing care.

Discussion

The results of our randomized controlled trial showed that, overall, CFL has no advantage over STL phototherapy in reducing the duration of phototherapy, and both have no adverse effects on temperature maintenance and hydration. The need for exchange transfusions, in fact, showed a higher trend in the CFL group and on repeated measures ANOVA the mean TSB was higher in the CFL group. In these respects, CFL was an inferior modality.

We selected a group of relatively larger and healthy babies, so that the outcome would not be influenced by co-morbidity. Preterm and sick babies may have concomitant disturbances in fluid balance, hemolysis due to sepsis or disseminated intravascular coagulation, internal bleeds *etc.*, that may affect the outcome, hence this group was excluded. We excluded babies with Rh iso-immunization and those who have already received an exchange transfusion, because they are qualitatively different from other babies with hyperbilirubinemia: they have different rates of hemolysis and a higher likelihood of requiring multiple exchange transfusions.

The efficacy of phototherapy is altered by factors that affect bilirubin production, such as oxytocin use, G6PD deficiency and ABO incompatibility, all of which were balanced between the 2 groups. Since gestational age is a key determinant of the incidence and severity of hyperbilirubinemia, we had stratified our population as preterm and term. To compare the efficacy of 2 modes of phototherapy, it is essential that the baseline TSB values be comparable, because the rate of hourly decline of TSB is greater at high baseline TSB levels and *vice versa*(5). In our study, baseline TSB values were comparable. We had to exclude subjects who underwent an exchange transfusion from the analysis of duration of phototherapy, because an exchange transfusion produces a drastic reduction of TSB and this would interfere with any further estimation of phototherapy duration.

The efficacy of phototherapy depends on the wavelength and irradiance of the light source and the surface area of the infant exposed. These determinants of efficacy have been demonstrated in several controlled trials. Tan reported that the decline of TSB is most rapid with special blue lights and total duration of exposure is also less, when compared to green or fluorescent day-light lamps(6). High intensity blue light phototherapy have been found twice as effective as standard daylight phototherapy in non-hemolytic jaundice(7). Double surface phototherapy is more effective

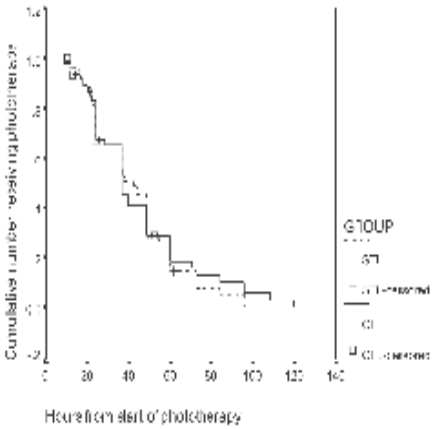

Fig.2. Kaplan-Meier analysis comparing duration of phototherapy in 2 groups. Subjects undergoing exchange transfusions were censored after the transfusion.

than single phototherapy, where it is delivered by combining overhead phototherapy with a bili-blanket or with a phototherapy bed(8). A more recent study concluded that when using low light irradiance, there was no statistically significant difference in the effectiveness of photo-therapy using blue-green LEDs, blue LEDs or conventional halogen-quartz bulbs(9). Light emitting diodes have been found to be as effective as conventional blue light phototherapy at comparable irradiance(10).

There is no previous study comparing CFL and STL phototherapy. The manufacturers of CFL equipments claim that it provides focused light with no scattering. This is supposed to increase efficacy and decrease the glare that hurts the eyes of the nursing personnel. However, we were unable to detect any significant difference in efficacy or acceptability of the CFL equipment. The reason for similar efficacy may be attributed to the similar irradiance in both groups, and maintained by us at more than 15 (μW/nm/cm^2. We did not test the wavelengths of the emission spectra of the 2 kinds of lamps. We assume there was also no difference in the emission wavelength of the two kinds of lamps, because both were special blue lamps. In our unit, double surface phototherapy was not practiced during the study period.

An *a priori* sample size calculation was not done because there was no existing data on which to base it. However, a post hoc power calculation showed that with a standard deviation of phototherapy duration equal to 24 hours (as observed in our study), to identify an effect size of difference in mean duration equal to 12 hours, our sample size had 70% power. For 80% power we would have required ~64 in each group.

A drawback of our study was that the intervention was unblinded. The sample size had insufficient power to detect a clinically meaningful difference in phototherapy duration (*i.e.*, 12 hours), although a comparison of the actual data shows that the durations were so similar in 2 groups, that even an appropriate sample size would have resulted in a negative study.

The initial cost of the CFL equipment and the recurring cost of the CFL lamps is higher than STL equipments. We did not record the useful life-span of each type of lamp, and hence we cannot comment on the per hour cost efficiency of CFL versus STL lamps.

We conclude that CFL phototherapy equipment is not superior to STL equipment, provided the irradiance is similar. There are also no significant differences in adverse effects and effects on nurses. On the basis of these parameters, there is nothing to choose between these 2 types of equipment, except for considerations of cost efficiency.

Contributions: MS collected the data. SD conceived the idea, planned the study, analyzed the data and wrote the manuscript. AN was involved in planning, supervising the study and corrected the manuscript.

Key Message

- Compact fluorescent lamp phototherapy has no advantage over the conventional standard length fluorescent tube lights.

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Competing interests: None.

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