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RESEARCH ARTICLE

COMPARISON OF COMPACT FLUORESCENT LAMP (CFL) VERSUS STANDARD LENGTH TUBE LIGHT (STL) PHOTOTHERAPY UNITS IN MANAGEMENT OF NEONATAL HYPERBILIRUBINEMIA

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ABSTRACT

Objective: To compare efficacy of special blue compact fluorescent lamp (CFL) phototherapy with special blue standard-length tube lights (STL) phototherapy in terms of rate of fall of serum bilirubin levels, required duration of phototherapy and to compare the incidences of clinically observable side effects between both groups.
Study design: Randomized prospective Observational Study.
Setting: Tertiary level of neonatal intensive care unit. Study was conducted from December 2011 to September 2012.
Participants: Stable neonates of gestation >34 weeks with hyperbilirubinemia requiring phototherapy, were included. Sick babies, Rh iso-immunized babies, those who required and underwent exchange transfusion and whose parents refused for consent were excluded.
Intervention: Babies were enrolled on consecutive basis and after randomization were allocated to receive phototherapy by CFL or STL. CFL and STL were both special blue lights with irradiance maintained above 15 µW/nm/cm2. Total serum bilirubin (TSB) was measured 24 hourly till phototherapy was stopped or an exchange transfusion was done. Vital parameters and clinically observable side effect were recorded 12 hourly till phototherapy was stopped.
Results: 100 babies were enrolled in each group. Baseline characteristics, causes of jaundice, baseline haemoglobin and TSB were similar in both groups. Base line irradiance was more in CFL group compare to STL group {P=0.000, highly significant (HS)}. Rate of fall of serum bilirubin {P< 0.001(HS)} was more in CFL group. Mean required duration of phototherapy {P=0.002(HS)} was less in CFL group. Side effects were comparable in two groups (P > 0.05).
Conclusions: CFL phototherapy is superior to STL phototherapy in terms of efficacy with comparable side effects.

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INTRODUCTION

Jaundice is the most common abnormal physiological finding in infants during first week of life. Among hospital born neonates in India, 3% develop total serum bilirubin (TSB) levels more than 15 mg/dL (National Neonatology Forum of India, 2004). Phototherapy is now the most preferred and standard method of treatment for neonatal hyperbilirubinemia by virtue of its non-invasive nature and its safety. The efficacy of phototherapy depends on the spectrum of light emitted, spectral irradiance delivered to surface of infant and the surface area exposed (American Academy of Pediatrics, 2004).

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Fever, loose stools, rashes, dehydration are common clinically observable side effect of phototherapy (Drew *et al*., 1976). Over the last 2 decades, there has been a constant efforts to develop ways to increase the efficacy of phototherapy and at the same time reduce the side-effects. Since long special blue standard length tube lights (STL) phototherapy are used in most neonatal units for management of neonatal hyperbilirubinemia. In last couple of years, special blue compact fluorescent lamp (CFL) phototherapy equipments have been introduced in India, which are claimed to be better than standard tube lights. The manufacturers of these units claim that they are more efficacious and are having lesser side effect compared to conventional units. These advantages are said to be due to the smaller size, focused area, lower scatter and higher irradiance. There are very less studies available comparing CFL and STL phototherapy (Sarin *et al*., 2006). We

performed a prospective observation study to test the hypothesis that compact fluorescent lamps are superior to conventional phototherapy units.

MATERIALS AND METHODS

The study was conducted in tertiary neonatal units under S.M.S medical college, Jaipur in newborn admitted for neonatal hyperbilirubinemia in phototherapy range as per AAP charts 2004. A total 200 'stable' neonates of gestation age more than 34 weeks with hyperbilirubinemia requiring phototherapy (as per AAP guidelines) were enrolled for the study after taking written consent from parents/legal guardians. For the purpose of study, "stable neonate" was defined as "an active baby exclusively on oral feeds with normal vital parameters". Sick babies, Rh iso-immunized babies, those who requiring and already had undergone exchange transfusion and whose parents refused for consent were excluded. These neonates were enrolled on consecutive basis and divided randomly in two treatment groups A&B. Group A included 100 neonates (>34 week), were managed with special blue compact fluorescent lamp (CFL) phototherapy unit. Group B included 100 neonates (>34 week), were managed with special blue standard length tube light (STL) phototherapy unit. Babies who underwent exchange transfusion were replaced by new baby in same group.

Special blue compact fluorescent lamp (CFL) phototherapy units used in our neonatal unit were supplied by BIRD MEDITECH Mumbai, India comprised of 4 special blue CFL's (PHILIPS PL-L 18w/52/4p, made in Poland) and 2 white CFL's (OSRAM DULUX L 18W/865 FPL 18E D, made in Korea) mounted on metal frame with adjustable heights. The lamps were covered by special transparent sheet that focuses and prevent scattering of light. Special blue standard length tube light (STL) phototherapy units used in our neonatal unit were supplied by MEDITRIN INSTRUMENT, Mumbai comprise of 4 special blue tube light (PHILIPS TL 20W/52 made in Holland) & 2 white tube light (PHILIPS TL 20W/54-650 CT 21, made in India).

After inclusion, information was collected and recorded with respect to demographic characteristics and causes of jaundice. Serum bilirubin concentration was measured just before the commencement of phototherapy (0 hours) and then every 24 hours. Before starting phototherapy on each subject, the spectral irradiance was checked for both type of phototherapy unit by photo radiometer. Our target was to maintain irradiance above 15µW/cm2/nm at all times and tubes/lamps were replaced whenever necessary, to maintain this irradiance. Both type of phototherapy units were adjusted at same height (30 cm). All infants were kept unclothed under phototherapy but genitalia and eyes were covered. All the newborn in study were managed with single surface continuous phototherapy and removed from under the light only for feeding, changing and blood sampling. All babies were examined thoroughly daily and monitored every 12 hourly for vitals, weight, urine output, temperature, clinical jaundice, development of rashes, number of stools and sign of dehydration. Phototherapy was discontinued after falling total serum bilirubin level less than photo range (as per AAP charts).

Statistical analysis

All data collected were entered in excel sheet to prepare master chart. Qualitative data were summarized as percentage and quantitive data were summarized as mean(s) and standard deviation(s). Chi-square ($\times^2$) test was used to find out the significance of difference between proportions & percentages. While unpaired 't' test was used to find out significance of difference between two means. 'P' value less than 0.05 (<0.05) was taken as significant difference.

RESULTS

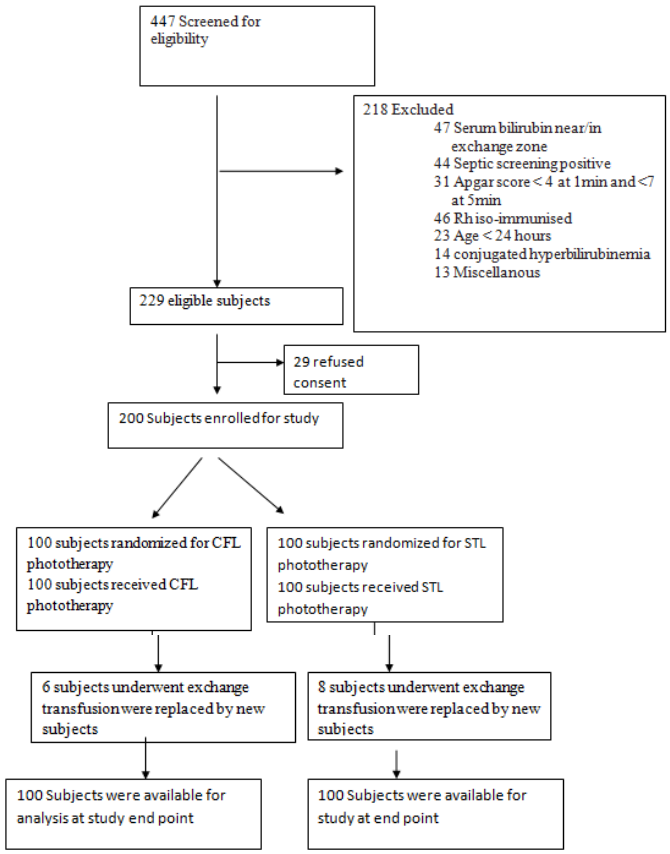

Fig. 1 Trial flow

Of 447 babies with gestation more than 34 weeks who received photo-therapy, 200 babies, who satisfied the eligibility criteria after excluding those whose parents refused for consent were included in study on consecutive basis after randomization. Base lines variables like sex, preterm babies, gestation age, birth weight, age of onset of jaundice, mode of feeding, mode of delivery, oxytocin used during delivery, cephalohematoma, ABO incompatibility and base line hemoglobin were comparable in both groups (p > .05).

Base line serum bilirubin level were comparable but there was statistically significant difference between two groups (p=0.04) and base line irradiance were significantly more in CFL group compare to STL group {P=0.000(HS)} (Table 1).

Table 1. Baseline information

Parameters	(N-100)	(N-100)	P value
Males	66 (66)	54 (54)	] 0.112
Females	34(34)	46(46)	
Mean gestation age(weeks)	37.61	37.55	0.846
Preterm babies	39	40	1.000
Mean birth weight (kg)	2.48	2.43	0.468
Mean age of onset of jaundice(days)	3.72	3.39	0.052
Normal vaginal delivery	59(59)	65(65)	] 0.466
LSCS	31 (31)	35(35)	
Breast feed	86(86)	84(84)	] 0.843
Top feed	14(14)	16(16)	
Cephalohematoma	6(6)	6(6)	] 1.000
Oxytocin	23 (23)	25 (25)	
Cephalohematoma+ Oxytocin	1	1	
ABO incompatibility	38 (38)	40 (40)	0.885
Hemolysis on peripheral smear	0	0	
Baseline irradiance in (µW/nm/cm2 (mean ± SD)	37.30 ±1.42	22.46 ± 3.43	0.000
Baseline TSB in mg/dL (mean ± SD)	17.42.± 2.67	16.24 ± 2.99	0.004
Base line hemoglobin in g/dl (mean ± SD)	15.65±1.65	15.94±1.75	0.228

Table 2. Outcome variables

Parametrs	CFL group (N-100)	STL group (N-100)	P value
Mean serum bilirubin fall in 1st 24 hours in mg/day (mean±SD)	3.53±1.75	1.95±2.53	0.000
Mean per hour fall in serum bilirubin in mg/dl/hr (mean±SD)	0.1574±0.06354	0.09436±0.06733	<0.001
Duration of phototherapy in hours (mean±SD)	34.32±14.97	41±17.93	0.002

Outcome variable like fall of serum bilirubin in 1st 24 hours (p=0.000), per hour rate of fall of serum bilirubin (p<0.001) were significantly more in CFL group compared to STL group and required duration phototherapy (p=0.002) was significantly less in CFL group (Table 2).

We compare fall in serum bilirubin in 1st 24 hours only because of number babies available in subsequent analysis reduced significantly, this would make analysis unbalanced.

Side effect likes rashes, fever, loose motion, dehydration were more frequent in CFL group but they did not achieve statistical significance as p value were >0.05 and were mild and benign in nature (Table 3).

Table 3. Side effects

Complication	CFL (N=100)	STL (N=100)	Total	CHI-SQUARE	'P' VALUE
Dehydration	5	4	9	0.000	1.000
Fever	14	9	23	0.350	0.554
Loose Motion	17	12	29	0.277	0.599
Rashes	22	15	37	0.490	0.484

DISCUSSION

In our study we included stable and healthy neonates of more than 34 completed weeks of gestation age, suffering from neonatal hyperbilirubinemia, requiring phototherapy who developed jaundice between 2nd- 7th day, so that the outcome would not be influenced by co-morbidity. Preterm (<34weeks) 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, so 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 neonates 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, cephalohematoma, ABO incompatibility, baseline hemoglobin all of which were balanced between the 2 groups. Since numbers of preterm babies were comparable between two groups so gestational age did not affect outcome, as incidence and severity of hyperbilirubinemia and toxicity on brain depend upon gestation age. 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 (Rubaltelli *et al*., 1978). In our study, baseline TSB values were almost comparable with only marginal difference that would not affect outcome significantly. Base line irradiance were significantly more in CFL group compare to STL group (P=0.000).

In our study mean fall serum bilirubin in 1st 24 hours and mean per hour rate of fall of serum bilirubin was significantly more in CFL group compare to STL group and required duration phototherapy (p=0.002) was significantly less in CFL group. In only one similar study available till date comparing CFL & STL phototherapy units in management of neonatal jaundice by Sarin *et al*. (2006), mean rate of fall of serum bilirubin, mean required duration of phototherapy were almost same in two groups. Thus this major difference in fall of serum bilirubin after onset of phototherapy in our study and study by Sarin *et al.* (2006) seems probably due to observed high photo irradiance in CFL group compare to STL group in our study [Mean irradiance ± SD: 37.300±1.4427 vs 22.455± 3.4265 µW/cm^2/nm in CFL and STL group respectively, P >0.000], but Sarin *et al.* reported almost equal photo irradiance in CFL& STL groups [Mean irradiance (± SD): 18.39 ± 2.38 vs 17.77 ± 1.81 respectively, P >0.05] at onset of phototherapy.

This difference in observed photo irradiance in CFL & STL group in our study and study by Sarin M, Dutta S *et al* was probably because we kept two units at same distance of 30 cm from baby skin surface but in their study distance was variable.

We id not test the wavelengths 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, we used only single surface phototherapy in both type phototherapy units during the study period. The efficacy of phototherapy depends on irradiance of light source, wavelength of light source and surface area of infant exposed under phototherapy. These determinants of efficacy have been demonstrated in several control trials. High intensity blue light phototherapies have been found to be twice as effective as standard daylight phototherapy in non-hemolytic jaundice (Tan *et al*., 1992). Martins *et al*. (2007) in their study adjusted the devices to obtain a similar exposed surface area, but high irradiance in LED group resulted in better efficacy with LED units in management of neonatal jaundice (Martins *et al*., 2007). Seidmans *et al*. (2003) and Maisels *et al*. (2007) reported the same efficacy in form of decline in serum bilirubin in response to different type of phototherapy units using strategy of "similar photo irradiance" (Seidman *et al*., 2003; Maisel *et al*., 2007). The initial cost of the CFL equipment and the recurring cost of the CFL lamps were 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.

Conclusion

We concluded that CFL phototherapy units are better than STL phototherapy units in efficacy in term of rate of fall of serum bilirubin and required duration of phototherapy without significant increase in side effect.

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