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Comparison of Gallium nitride derived light-emitting diodes (LED) and compact fluorescent lamp (CFL) phototherapy units in management of neonatal hyperbilirubinemia at tertiary neonatal centre

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Abstract

Background: Light emitting diode (LED) devices have been shown to be as effective as any other phototherapy device by in vitro and few in vivo studies, but the clinical data comparing LEDs with compact fluorescent lamp (CFL) phototherapy units are limited. Objectives: To compare the effectiveness of Gallium nitride derived LED versus CFL phototherapy units. **Methods:** Hemodynamically stable neonates of >34 weeks of gestation age, suffering from neonatal hyperbilirubinemia and requiring phototherapy were included in the study. Rh and ABO incompatible babies were also included. Jaundiced newborn who were requiring or already received exchange transfusion, sick newborns (e.g. birth asphyxia, acidosis, hypoglycaemia, respiratory distress, septicaemia etc.), newborns with conjugated hyperbilirubinemia and babies who developed any significant complication during the course of phototherapy were excluded. **Results:** The mean baseline photo irradiation in CFL group was 40.63±8.03 µW/cm2/nm, compared to 48.91±9.24 µW/cm2/nm in LED group (p value - 0.0006) and mean fall rate of serum bilirubin was significantly more in LED group (0.18±0.059 mg/dl/hr) as compared to CFL group (0.16±0.050 mg/dl/hr) (p value - 0.022), and mean duration of phototherapy in CFL group was 38.35±14.96 hours compared to 33.83±12.82 hours in LED group (p value - 0.02). **Conclusion:** Results of our study shows that LED phototherapy unit is better than CFL phototherapy unit for management of neonatal jaundice in terms of rate of fall of serum bilirubin, shorter duration of phototherapy and power saving device with minimal adverse effects.

Key words: Gallium nitride derived light-emitting diodes (LED) phototherapy, Compact fluorescent lamp (CFL) phototherapy, Neonatal Hyperbilirubinemia, Exchange transfusion.

INTRODUCTION

Pathological or uncontrolled physiological neonatal jaundice can result in varying degree of neurological deficit or even death in extreme cases.[1] Therefore, to prevent the long term crippling devastating encephalopathy and death, it needs extra caution, vigilance and early intervention. Various modalities have been developed for the management of neonatal hyperbilirubinemia including phototherapy, exchange transfusion and drug therapy.[2] Phototherapy is relatively safe, non-invasive, and preferred modality for the management of neonatal jaundice with minimal side effects. Various types of phototherapy devices were evolved over the period of time, and efficacy of these depends on the spectrum of light emitted, spectral irradiance, the surface area exposed, and distance from light and initial serum bilirubin level.[2]

Recently, the blue Gallium nitride derived light-emitting diodes (LEDs) have been utilized as light source in phototherapy units which emit a high intensity narrow band of blue light overlapping the peak spectrum of bilirubin breakdown. LEDs have several advantages which conventional devices are lacking such as light weight, compact size, high energy efficiency, low voltage battery and extreme long life (20,000 hours).[3,4] These unique characteristics of LEDs make them an attractive light source for the optimal phototherapy unit.

Although, LED devices have been shown to be more effective than any other phototherapy device by in vitro and few in vivo studies, but the clinical data comparing LEDs with compact fluorescent lamp (CFL) and conventional phototherapy units are limited.[5,6] Therefore, we planned the present study to compare the efficacy of LED device with respect to bilirubin photo-degradation with commercially used conventional fluorescent tubes phototherapy device.

MATERIAL AND METHODS

The present study was carried out on newborns presenting with jaundice at a neonatal unit in the Department of Paediatrics of a tertiary care centre of Jaipur between November 2011 and October 2012. Hemdynamically stable neonates of more than 34 weeks of gestation, suffering from neonatal hyperbilirubinemia and requiring phototherapy (as per AAP charts),[7] were included in the study. Rh and ABO incompatible babies were also included in the study. Jaundiced newborn who were requiring or already received exchange transfusion, sick newborns (e.g. birth asphyxia, acidosis, hypoglycaemia, respiratory distress, septicaemia etc.), newborns with conjugated hyperbilirubinemia and babies who developed any significant complication during the course of phototherapy were excluded.

All the neonates were clinically screened for jaundice. Those suspected to have clinically significant jaundice were investigated for blood serum bilirubin level for confirmation. Neonates who met inclusion criteria were enrolled for the study after taking informed written consent from mother/father/legal guardian. These neonates were enrolled on consecutive basis and recruited alternatively in two treatment groups, A and B. Neonates

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of group A were managed with blue LED phototherapy unit at a height of 25 cm while neonates of group B were managed with special blue CFL phototherapy unit at a height of 40 cm according to manufacturer's guidelines.

Serum bilirubin concentration was measured just before starting phototherapy (0 hours) and then at 6 hour and then every 24 hours as per AAP guideline.[7] New light sources were used initially in both types of phototherapy units for management of neonatal hyperbilirubinemia. 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 the times and light sources were replaced whenever necessary, to maintain this irradiance. All Infants were kept unclothed under phototherapy but genitalia and eye were covered. All the newborn in study were managed with single surface continuous phototherapy and removed from phototherapy 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, and development of rashes, number of stools and sign of dehydration. Mother and care taker were advised for frequent feeding of baby. Time and date of starting and discontinuing phototherapy was noted exactly.

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. The LED phototherapy units (BIRD MEDITECH, Mumbai) comprise of 9 special blue gallium nitride LED bulb (12w, operational voltage100-250Ac,50Hz), emit blue light in 450-470nm (peak absorb wave 458nm) with irradiance of >25µw/cm²/nm. It has wide effective area, long life (20,000 hour), do not emit infrared radiation. Photo radiometer (FLUXMETER, Model-FLM) to measure irradiance was made and supplied by MEDITRIN INSTRUMENTS, Mumbai-400095, India.

Phototherapy was discontinued when total serum bilirubin level fell below the phototherapy range (as per AAP charts). Outcome variables were mean fall in serum bilirubin level per hour, total duration of phototherapy, clinically observable adverse effects, and failure of phototherapy. Failure of phototherapy was considered when bilirubin level rises despite of phototherapy or does not decreased at 24 hour or reached to values 20% lower than those that would indicate a need for exchange transfusion.[8]

All collected data were entered in excel sheet to prepare master chart. Qualitative data were summarised as percentage and quantitative data were summarised as means and standard deviation. Chi-square test was used to find out the significance of difference between proportions and 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

In this study, a total 200 patients were recruited and divided into 2 groups, group A & B, each consisting of 100 babies. Babies in group A were given phototherapy with gallium nitride LED and group B were given phototherapy with special blue CFL phototherapy unit. A total of 22 cases were excluded from the study due to various reasons including refusal to consent (4 patients), requiring or already received an exchange transfusion or double surface phototherapy (3 patients), sick newborns (6 patients), newborns with conjugated hyperbilirubinemia (9 patients).

Various demographic variables were comparable in both groups (Table 1). There were no statistical difference in terms of birth weight, gestational age, gender, and route of delivery, age at admission to the neonatal unit, blood group incompatibility and serum bilirubin level at the initiation of therapy. Use of oxytocin was found to be the most common risk factor for neonatal jaundice in newborn (15%) followed by cephalohematoma (12.5%). Distribution of above risk factors were comparable in both groups with no statistically significance difference (p value >0.05).

There were significant differences in the absolute change in serum bilirubin level per hour and change in serum bilirubin level in first 24 (p value - 0.009) and 48 hours (p value - 0.006) after initiation of therapy but was not significant in between 48 to 72 hours (p value - 0.739) (Table 2). Duration of phototherapy was shorter in the LED phototherapy group and this was statistically significant (p value-<0.05).

Commonest adverse effect was fever in 25 (12.5%) cases followed by rash in 21 (10.5%) cases and the least common was dehydration in 10 (5%) cases. In CFL group, maximum number of cases (24%) developed fever while hypothermia was the least common side effect (1%). On the contrary, hypothermia (10%) was the most common side effect in LED group. Other side effects were very less in number (Table 3). So, LED group had significantly lesser side effects as compared to CFL group (p value <0.05) except hypothermia which was more in LED group.

Table 1: Demographic profile of study population

	CFL Group	LED Group	P value
Gender (M/F)	47/53	44/56	0.607
Birth weight (in kg) (Mean±SD)	2.54 ± 0.40	2.56 ± 0.38	0.834
Gestational Age (week) (Mean±SD)	38.42 ± 1.65	38.48 ± 1.47	0.846
Admission Age (days) (Mean±SD)	3.30 ± 0.91	3.36 ± 1.04	>0.05
Vaginal/ Caesarean section	45/55	49/51	0.471
TSB at admission(gm/dl) (Mean±SD)	16.78± 2.24	16.79± 1.97	0.9772
ABO incompatibility	38	39	0.884
Rh incompatibility	15	14	0.842
Feeding (breast feeding/ top feeding)	81/19	83/17	0.743

Table 2: Comparison of study outcomes

Study Outcome	CFL Group	LED Group	P value
Serum bilirubin fall in 0-24 hours (Mean±SD)	2.45±1.65 mg/dl/day	3.07±1.82 mg/dl/day	0.0095
Serum bilirubin fall in 24-48 hours (Mean±SD)	2.55±1.08 mg/dl/day	3.26±1.26 mg/dl/day	0.0066
Serum bilirubin fall in 48-72 hours (Mean±SD)	2.82±1.53 mg/dl/day	2.65±0.49 mg/dl/day	0.739
Total fall in serum bilirubin	0.164 mg/dl/hr	0.182 mg/dl/hr	0.022
Duration of phototherapy (hrs)	38.35	33.83	0.023
Photo irradiation (µw/cm^2/nm)	40.63±8.03	49.91±9.24	0.0006

Table 3: Distribution of clinically observable side effects in both groups

Adverse effects	CFL (N=100)		LED (N=100)		Total (N=200)		Chi-Square	'P' Value
	No.	%	No.	%	No.	%		
Dehydration	8	8	2	2	10	5	2.63	0.1048
Fever	24	24	1	1	25	12.5	22.12	0.0000
Loose Motion	14	14	4	4	18	9	4.94	0.0262
Rashes	17	17	4	4	21	10.5	7.66	0.0056
Hypothermia	1	1	10	10	11	5.5	8.53	0.0035

Among 200 cases, failure of phototherapy was found in total 5 (2.5%) neonates and these required double surface phototherapy, among these two were in LED and 3 were in CFL group.

DISCUSSION

Recently, LED phototherapy had been used as an upcoming modality in the management of neonatal hyperbilirubinemia with variable effects as compared to conventional phototherapy.[5-10] In our study, mean baseline photo irradiation was significantly higher in LED group as compared to CFL group which is in collaboration with previous study done by Kumar et al.[5] In this study, LED phototherapy was found to be more effective than conventional fluorescent phototherapy with respect to bilirubin photodegradation. LED phototherapy reduced TSB level in the first 48 hour of phototherapy significantly and these were comparable with previous studies by Karagol et al and Chang et al,[6,9] that reported a significant higher efficacy of LEDs in bilirubin photodegradation than conventional phototherapy both in vitro and in vivo. However, in our study there was no significant difference between two treatment modalities after 48 hours, which could due to be a major fall in first 48 hours. More effective reduction in serum bilirubin by LED phototherapy units may be because of higher photo-irradiance and more concise peak wavelength (458nm) as compared to CFL units.[11] However, some of the other previous studies, efficacy of CFL and LED phototherapy units in terms of reduction rate of bilirubin were equal.[5,12] The probable cause of this may be that Maisel et al,[12] used the strategy of similar photo-irradiance by adjusting the distance while second study,[5] was conducted 3 year back when LED phototherapy was just introduced in Indian market for the management of neonatal jaundice. LED phototherapy device used in our study was probably more advanced & improvised and we kept the LED light source at relatively closer distance (20-25cm) from body surface of neonate compared to them (25-30cm). It would be possible that babies in their study exposed to lesser photo-irradiance as compared to our study, as we observed that on reducing distance of phototherapy irradiance was increased.

In our study, duration of phototherapy in the patients receiving LEDs was significantly shorter than those in CFL group. In a study by Karagol et al,[6] the duration of phototherapy in LED was apparently less than the conventional unit but was not significant that might be because of smaller number of cases in their study. Incidence of failure of phototherapy in our study was 5 (2.5%) and among these 3 (3%) cases were in CFL group and 2% were in LED group that required double volume exchange transfusion and were non-significant similar to a previous study.[5]

In present study, the most common observed adverse effects in CFL group were fever (25%) followed by rashes (17%) while in LED group, it was hypothermia (10%) followed by diarrhoea (4%). In our study, side effects were significantly less in LED group in comparison to CFL group that were contradictory with the study by Kumar et al.[5]

Our study does have few limitations like we have not calculated the exact sample size, and smaller no of cases. Evaluation of the effect of various determinants like body surface area, distance and photo wavelength, which can affect the efficacy of phototherapy devices, was not done. We also have not studied the difference in the rate of fall of bilirubin level in relation to the underlying causes of hyperbilirubinemia, inborn vs. outborn patients and neonates already admitted in the hospital vs. who came directly from home. Therefore, before laying down any recommendation for universal use of LED phototherapy in neonatal jaundice, further studies are required to prove its superior efficacy. These studies should be undertaken to compare not only

the LED devices with different types of phototherapy units but also to study the effects of other determinants of efficacy like distance, spectral irradiance, body surface area and photo wavelength in more scientific manner with a larger sample size.

CONCLUSION

Results of our study showed that LED phototherapy units are better than CFL phototherapy units for the management of neonatal jaundice in terms of rate of fall of serum bilirubin, shorter duration of phototherapy and power saving device with minimal adverse effects. However, further studies are required to prove its efficacy and recommending its universal use in neonatal jaundice..

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