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RESEARCH ARTICLE

EFFICACY OF NEW HIGH INTENSITY BLUE LIGHT EMITTING DIODE PHOTOTHERAPY COMPARED TO CONVENTIONAL COMPACT FLUORESCENT TUBES PHOTOTHERAPY FOR UNCONJUGATED HYPERBILIRUBINEMIA IN NEONATES- A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Objectives: To compare LED phototherapy with the standard compact fluorescent lamp (CFL) phototherapy in the management of healthy term and late pre- term neonates with non-hemolytic jaundice and to see whether it is as effective as or more effective than the compact fluorescent lamp (CFL) phototherapy

Methods: The protocol and study design were submitted & was approved by the institution research committee & ethics committee. New born infants born at 35 or more completed weeks of gestation who developed hyper bilirubinemia needing phototherapy within the first 7 days of life and willing for the study were enrolled after getting informed consent.

Results: Out of 120 newborn babies in the study group, 60 babies were in LED group and 60 babies were in CFL group. Sexual ratio in LED (M:F) is 31:29 &CFL group is 34:26 .The mean birth weight in LED was 2.9kg and in CFL group was 3.1 kg. The mean age in hours at onset of phototherapy was 67.4hrs in LED & 70.1in CFL group and time of detection of hyperbilirubinemia was also comparable in both groups. Mean STB at beginning of phototherapy was 17.4 in LED & 17.8 in CFL and STB after 6hours were 14.7 & 15.1 in LED & CFL groups respectively. At the ends of phototherapy the STB values was 11.8 in LED and 13.4 in CFL groups and mean age of newborn at the end of phototherapy was 83 hrs and 86.1 hrs in LED & CFL groups and mean duration of phototherapy was 15hrs and 16 hrs in LED & CFL groups respectively. The failure rate of phototherapy in LED group was 3.3% while CFL group was 1.7%, which is not significant. The rate of decrease in STB at 6hrs and end of phototherapy in both groups were not statistically significant.

Conclusion: Both CFL and LED phototherapy are equally effective in reducing serum total bilirubin although their properties like light intensity irradiance, zero decay of light intensity, area of body surface irradiated, which are determinants of effective phototherapy, are significantly different.

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INTRODUCTION

Hyperbilirubinemia in term or late preterm newborns continues to carry the potential for acute bilirubin encephalopathy and chronic sequelae (American Academy of Pediatrics, 2004). Phototherapy and exchange transfusion are the main modalities of treatment. In phototherapy insoiuable bilirubin is converted into soluble isomers that can be excreted in urine and feces. In the past years flurescent lamps were used to emit light. Now adays Light emitting diode (LED) lamps are used instead of flurescent lamps. The conventional phototherapy units with flurescent lamps have limited capacity to produce high irradiance and also generate considerable heat (Vinod and Bhutani, 2011). Although LED devices have been shown to be effective, the clinical data comparing LEDs with conventional units are limited. Some studies shows that LED device was much more effective than conventional phototherapy in reducing serum bilirubin level, while other studies says that it is as effective as conventional phototherapy and suggests further studies. Hence, we decided to conduct this study to know whether LED phototherapy is as or more efficacious as the standard compact fluorescent tube (CFT) phototherapy in the management of hyperbilirubinemia in neonates.

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Review of Literature

Hyperbilirubinemia is very common and usually benign in the new born. Commonest cause of jaundice in newborn is physiological jaundice. Physiological jaundice is the jaundice which usually appears between 24-72 hours of age. Total Serum Bilirubin (TSB) level usually rises in full-term infants to a peak by 4 days of age and then falls. A rise to 12mg/dL is in the physiologic range. In premature infants, the peak may be 10 to 12 mg/dL on the fifth day of life, possibly rising over 15 mg/dL without any specific abnormality of bilirubin metabolism. Physiological jaundice is mainly due to immaturity of liver to handle the bilirubin load. It is mainly a diagnosis of exclusion of pathological conditions. Pathological jaundice is suspected when TSB concentration is exceeding 5 mg/dl on first day of life in neonate, 10 mg/dL on second day, or 12-13 thereafter. Any TSB elevation exceeding 17 mg/dL should be presumed pathologic and warrants investigation for a cause and possible intervention, such as phototherapy. Bilirubin toxicity depends on the serum level, age of the child and integrity of blood brain barrier. Only unconjugated bilirubin will cross the bloodbrain barrier to cause encephalopathy. Factors that disrupt the blood-brain barrier include hyperosmolarity, anoxia, and hypercarbia, and the barrier may be more permeable in premature infants. The management of hyper bilirubinemia include adequate hydration, breast feeding, phototherapy and exchange transfusion (Maiscls and Kring, 2007). Phototherapy in Clinical trials have proved the efficacy of phototherapy in reducing excessive unconjugated hyperbilirubinemia and its implementation has drastically curtailed the use of exchange transfusions. The initiation and duration of phototherapy is defined by a specific range of total bilirubin values based on an infant's postnatal age and the potential risk for bilirubin neurotoxicity (American Academy of Pediatrics, 2004). Clinical response to phototherapy depends on the efficacy of the phototherapy device as well as the balance between an infant's rates of bilirubin production and elimination. The active agent in phototherapy is light delivered in measurable doses, which makes phototherapy conceptually similar to pharmacotherapy

Standards for phototherapy devices

Factors which determine efficacy of phototherapy devces are (1) emission range of the light source, (2) the light intensity (irradiance), (3) the exposed ("treatable") body surface area illuminated, and (4) the decrease in total bilirubin concentration. Devices with maximum emission within the 460- to 490-nm (blue-green) region of the visible spectrum are the most effective for treating hyperbilirubinemia (Vinod and Bhutani, 2011; Maisels and McDonagh, 2008). Lights with broader emission also will work, although not as effectively. Special blue (BB) fluorescent lights are effective but should not use white lights painted blue or covered with blue plastic sheaths. Devices that contain high intensity gallium nitride LEDs with emission within the 460- to 490-nm regions are also effective and have a longer lifetime (20 000 hours), lower heat output, low infrared emission, and no ultraviolet emission.

Irradiance measurement

For routine measurements, irradiance meters supplied or recommended by the manufacturer are used. Visual estimations of brightness and use of ordinary photometric or colorimetric light meters are inappropriate. By bringing the light source close to the infant irradiance can be increased; however, this should not be done with halogen or tungsten lights, because the heat generated can cause a burn. Furthermore, proximity may reduce the exposed body fixtures, increasing the surface area. Irradiance distribution in the illuminated area (footprint) is not uniform; measurements at the center of the footprint may be more than those at the periphery and are different among phototherapy devices (American Academy of Pediatrics, 2004). Exposed skin surface area may be reduced by physical obstruction of light by equipment, head covers, large diapers, eye masks that enclose large areas of the scalp, tape, electrode patches, and insulating plastic covers (Johnson *et al*., 2009). Combining several devices, such as fluorescent tubes with fiber-optic pads or LED mattresses placed below the infant or bassinet, will increase the surface area exposed. If the infant is in an incubator, the light rays should be perpendicular to the surface of the incubator to minimize reflectance and loss of efficacy. The clinical effect of phototherapy will be evident within 4 to 6 hours of initiation with an anticipated decrease of more than 2 mg/dL (34_mol/L) in serum bilirubin concentration (American Academy of Pediatrics, 2004). The clinical response depends on the rates of bilirubin production, enterohepatic circulation, and bilirubin elimination; the degree of tissue bilirubin deposition and the rates of the photochemical reactions of bilirubin. Aggressive implementation of phototherapy for excessive hyperbilirubinemi referred to as the "crash-cart" approach has been reported to reduce the need for exchange transfusion.

Aim

To compare LED phototherapy with the standard compact fluorescent lamp (CFL) phototherapy in the management of healthy term and late pre- term neonates with hemolytic jaundice and to see whether it is as effective as or more effective than the compact fluorescent lamp (CFL) phototherapy

Study setting

Study type: Randomized Controlled Trial

Study Period: February 2012 to December 2012

Intervention*:* Single-surface LED or CFT phototherapy

Primary outcome variable: Duration of phototherapy

MATERIALS AND METHODS

Inclusion criteria-Newborn infants born at 35 or more completed weeks of gestation at TDMCH, Alappuzha who developed hyperbilirubinemia needing phototherapy after 24 hrs. and within the first 7 days of life were included in the study

Exclusion criteria

1) Infants with perinatal asphyxia (Apgar score <4 at 1 minute or <7 at 5minute)
2) Onset of jaundice within 24 h of age,
3) Culture-positive or clinical sepsis 5) Major congenital malformations

METHODOLOGY

The protocol and study design were submitted & was approved by the institution research committee & ethics committee. New born infants born at 35 or more completed weeks of gestation who developed hyperbilirubinemia needing phototherapy within first 7 days of life and willing for the Study were enrolled after getting informed consent. The decision to start phototherapy was made by bedside physicians on the basis of the age of the baby in hours and serum total bilirubin (STB) levels, as per American Academy of Paediatrics guidelines. Phototherapy was stopped when two consecutive STB levels, measured 6 hours apart were less than 15 mg/dL.

Intervention: Enrolled newborns were randomised using computer generated random numbers to receive single surface Light Emitting Diode (LED) or Compact Fluorescent Lamps (CFL) phototherapy. A distance of 25-30 cm was maintained between the baby and the bulb/lamp surface for both type of units. Additional therapy for hyperbilirubinemia like fluid/feed supplementation and phenobarbitone and Radiant warmers were used as and when required.

Outcome variables: The duration of phototherapy is the primary outcome measured. It is calculated by subtracting age at start of phototherapy from age at end of phototherapy in hours. Brief periods of discontinuation of phototherapy for feeding the baby or changing nappy were not excluded while calculating total duration of phototherapy. The secondary outcomes were failure of phototherapy, rate of fall of STB and serum bilirubin at 6 hours of phototherapy. 'Failure of phototherapy' was defined as STB rising or becoming more than 20 mg/dL during phototherapy. 'Rate of fall of STB' is calculated by dividing the difference between STB at start and end of phototherapy with duration of phototherapy

Data collection: STB measured every 6 h in our biochemistry lab. Data collected using the Proforma.

Statistical analysis: data were analysed SPSS version 16 with the help of a statistician. Data were analysed using student –t test and chi-square test. A *P* value of <0.05 was taken as significant

OBSERVATION AND RESULTS

Birth weight comparison

Birth weight groups (in Kg)	Type of phototherapy				Total	
	LED		CFL			
	N	%	N	%	N	%
<2.5	8	13.3	2	3.3	10	8.3
2.5-3.5	47	78.3	46	76.7	93	77.5
>3.5	5	8.3	12	20.0	17	14.2
Total	60	100.0	60	100.0	120	100.0

Comparison of Age in hours at onset of Phototherapy

Age in hours at detection of hyperbilirubinaemia		Type of phototherapy				Total	
		LED		CFL			
		N	%	N	%	N	%
Age in hours	24-48	8	13.3	4	6.7	12	10.0
	48-96	51	85.0	54	90.0	105	87.5
	>96 hrs	1	1.7	2	3.3	3	2.5
Total		60	100.0	60	100.0	120	100.0

Sexual ratio in phototherapy –male to female ratio in both group were comparable

Sex ratio		Type of phototherapy				Total	
		LED		CFL			
		N	%	N	%	N	%
Sex	Male	31	51.7	34	56.7	65	54.2
	Female	29	48.3	26	43.3	55	45.8
Total		60	100.0	60	100.0	120	100.0

STB at beginning of phototherapy

Type of phototherapy	N	mean	SD	t	p
LED	60	17.4	1.2	-1.798	.075
CFL	60	17.8	1.1		

STB at 6 hours of phototherapy

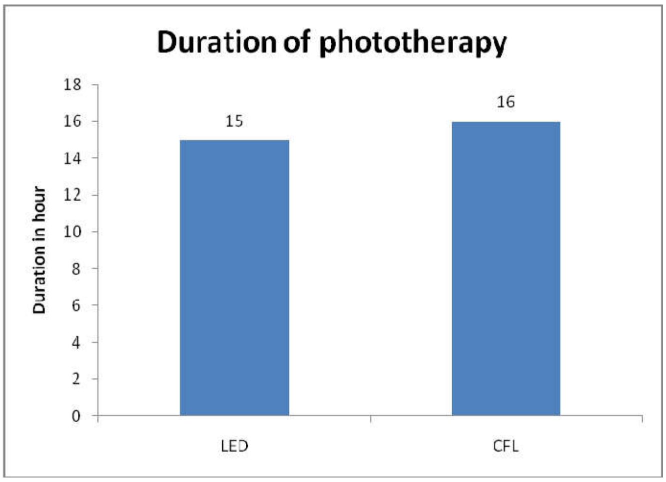
Type of phototherapy	N	mean	SD	t	p
LED	60	14.7	1.5	-1.362	.176
CFL	60	15.1	1.4		

STB at end of phototherapy

Type of phototherapy	N	mean	SD	t	p
LED	58	11.8	1.0	-.926	.356
CFL	59	13.4	1.26		

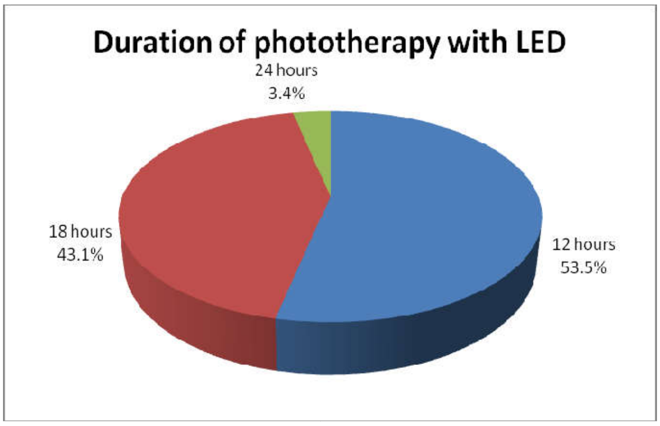
Duration of Phototherapy

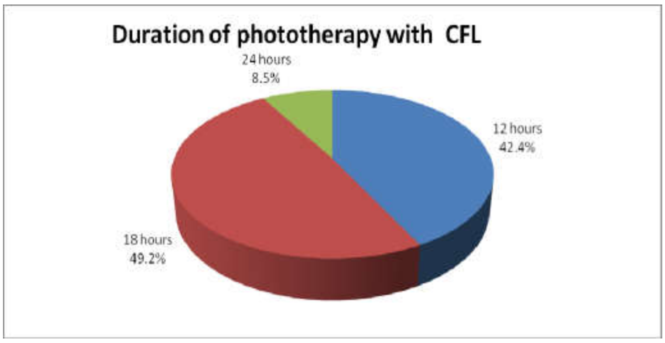
Type of phototherapy	N	mean	SD	t	p
LED	58	15.0	3.4	-1.446	.151
CFL	59	16.0	3.8		



Duration of Phototherapy

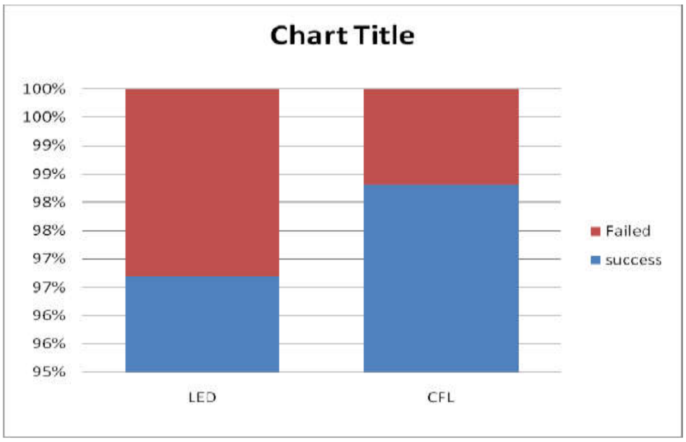
Duration of Phototherapy in hours	Type of phototherapy				Total	
	LED		CFL			
	N	%	N	%	N	%
12	31	53.4	25	42.4	56	47.9
18	25	43.1	29	49.2	54	46.2
24	2	3.4	5	8.5	7	6.0
Total	58	100.0	59	100.0	117	100.0





Outcome of therapy

Outcome		Type of phototherapy				Total	
		LED		CFL			
		N	%	N	%	N	%
	Success	58	96.7	59	98.3	117	97.5
	Failed	2	3.3	1	1.7	3	2.5
Total		60	100.0	60	100.0	120	100.0



Rate of decrease of serum bilirubin

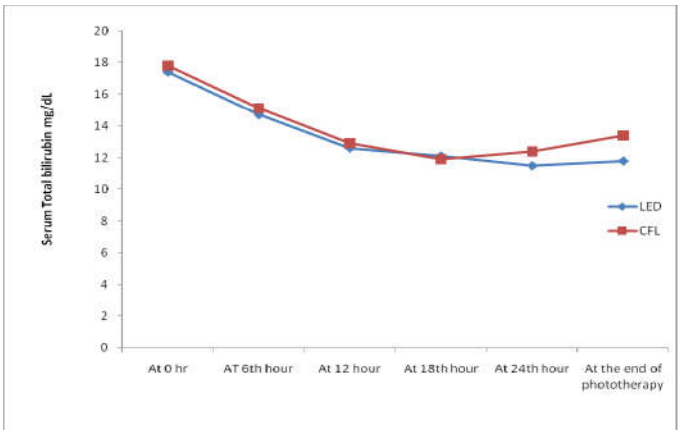
Type of phototherapy	N	mean	SD	t	p
LED	58	.39	.13	.929	.355
CFL	59	.27	1.04		

Decrease of bilirubin at 6 hrs. of phototherapy

Type of phototherapy	N	mean	SD	t	p
LED	60	2.7	1.4	-.058	.954
CFL	60	2.7	1.4		

Decrease of bilirubin at end of phototherapy

Type of phototherapy	N	mean	SD	t	p
LED	58	5.6	1.4	.712	.478
CFL	59	4.4	1.26		



DISCUSSION

This study is done to compare the effectiveness of LED phototherapy unit (Billiton Fanem Inc, Brazil) and the CFL phototherapy unit (OSRAM Blue lamp 18w) in lowering the STB in neonates with non-hemolytic jaundice. The effectiveness of phototherapy depends on the unit characteristics such as (1) emission range of the light source, (2) the light intensity (irradiance), (3) the exposed ("treatable") body surface area illuminated (American Academy of Pediatrics, 2004; Vinod and Bhutani, 2011; Kumar *et al*., 2010). The primary outcome variable i.e., the duration of phototherapy and other outcome variables such as rate of decline of serum total bilirubin, serum bilirubin at 6 hrs of phototherapy, failure of phototherapy, all were comparable between the LED and CFL group. No statistically significant difference observed in any of the outcome variable studied. Phenobarbitone not used in both groups. The use of IV fluids were comparable in both groups. The result of our study is similar to the observation made in previous studies conducted in India and abroad, i.e., both are equally effectiveness (Kumar *et al*., 2010; Daniel S Seidman *et al*., 2003). Some studies showed increased effectiveness for LED (Yun Sil Chang, 2005; Bianca M. R. Martins, 2007). The irradiance was low for CFL phototherapy at the footprint area (<30μ/cm/nm) as the conventional phototherapy units have limited capacity to produce high irradiance. The light intensity decay was more for CFL, the irradiance difference was more than 7 at the end of the study. For LED, The irradiance was >30μ/cm/nm which is the level recommended by the AAP 2011 guidelines and the light intensity decay was nil during the study period as per the irradiance measured by the flux meter supplied with LED unit. But area irradiated was low for LED phototherapy unit because of the device design

Conclusion

Both CFL and LED phototherapy are equally effective in reducing serum total bilirubin although their properties like light intensity, irradiance, decay of light intensity, area of body surface irradiated, which are determinants of effective phototherapy, are significantly different.

Suggestions

The effectiveness of LED phototherapy can be improved by modification in device design so that more of skin surface area can be irradiated. The effectiveness of CFL phototherapy can be improved by using lamps with high irradiance if available and periodically checking the irradiance using the flux meter available and change the lamp when the irradiance fall below 30μ/cm/nm.

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