Evaluation of the benefits and efficacy of light emitting diode (LED) device with respect to conventional fluorescent tube phototherapy device in neonatal hyper bilurubenimia in near term and full term neonates

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Abstract

Introduction: Neonatal jaundice is a common, in most cases a benign problem in neonates. About 60% of term and 80% of preterm babies develop jaundice during the first week of life. About 5-10% of all newborns need phototherapy for this commonest morbidity in neonatal life. The commonly used light sources are special blue fluorescent tubes, compact fluorescent tubes and halogen spotlights. In recent years a new type of light source light emitting diodes (LED) has been incorporated into phototherapy. **Methodology:** Hospital based prospective and observational study. The study was done over a period of two years in SNCU, NICU and Newborn ward, department of paediatrics, S.C.B. Medical College, Cuttack from September 2014 to August 2016. Investigation were done in the department of pathology, biochemistry and central laboratory. **Results:** The duration of phototherapy was shorter in patients who received LED phototherapy than those treated with conventional phototherapy. The children receiving LED phototherapy in children with conventional phototherapy. Rebound hyperbilirubenimia was more in children treated with LED phototherapy. About 12% babies developed rebound hyperbilirubenimia in those treated with LED Phototherapy as compared to 8% of conventional phototherapy. Side effects are more in conventional phototherapy. **Conclusion:** LED is safe rescue treatment for severe neonatal hyperbilirubenimia and its implementation reduce the failure of phototherapy and need for exchange transfusion.

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Keywords: Phototherapy, Kernicterus, Hyperbilirubinemia

Introduction

Hyperbilirubenimia is defined as the increase in serum bilirubin level in circulation. Jaundice attributable to physiological immaturity of neonates to handle increased bilirubin production is termed as physiological jaundice. Visible jaundice usually appears between 24 to 72 hours of life. TSB (Total Serum Bilirubin) levels usually rises in term infants to a peak level of 12 to 15 mg/dl by 3 Days of life and than fall. In preterm babies, the peak level occurs on the 3to 7 days of age and TSB can rise over 15mg/dl.Pathological jaundice is said to be present when TSB concentrations are not in physiological jaundice range, which is

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defined arbitrarily and loosely as more than 5mg/dl on first day, 10mg/dl on second day and 12-13 mg/dl thereafter in term neonates. Any bilirubin value of 17mg/dl or more should be evaluated for the cause and possible intervention, such as phototherapy [7,8]. About 60% of term and 80% of preterm babies develop jaundice during the first week of life [1,2]. About 5-10% of all newborns need phototherapy for this commonest morbidity in neonatal life [3]. Premature babies have much higher incidence of neonatal jaundice requiring therapeutic intervention more commonly than the term newborns [4]. Although the outcome for the majority is benign, infaints with untreated, severe hyper bilirubenimia (defined bilirubin as serum level>20mg/dl) can develop signs of Acute billirubin

encephalopathy (ABE). Management of hyperbillirubenimia includes detection of at risk neonates, investigating the cause of pathological hyperbillirubenimia, deciding the thresholds for starting and stopping treatment and follow-up of neonates with severe hyperbillirubinemia [5].

Common risk factors for pathological unconjugated jaundice include blood group incompatibility, glucose-6-phosphate dehydrogenase enzyme deficiency, prematurity, instrumental delivery and non-optimal breastfeeding. A direct relationship between severe unconjugated hyperbilirubenimia and neurological damage has been demonstrated. Acute bilirubin encephalopathy is caused by the toxic effects of unconjugated bilirubin on the central nervous system.

A morbidity which if untreated, may progress rapidly to advanced manifestations such as opisthotonous and seizures. Intervention such as exchange blood transfusion and phototherapy aim at reducing the serum bilirubin in order to prevent bilirubin brain toxicity [9].Understanding the dose response effect and other factor that influence the way light works to lower the bilirubin levels has led to the effective use of phototherapy and has eliminated the need of exchange transfusion in all most all jaundiced infaints [11]. The efficacy of phototherapy depends upon wavelength irradiance, exposed body surface area, distance of photo therapy and duration of exposure. Intensive phototherapy is provided by use of high levels of irradiance in the 430to 490 nm band (usually 30 µW/cm sq/nm or higher) delivered to as much of infant's body surface area as possible [14].

The commonly used light sources are special blue fluorescent tubes, compact fluorescent tubes and halogen spotlights [13,14]. In recent years a new type of light source light emitting diodes (LED) has been incorporated into phototherapy. LEDs are power efficient, portable device with low heat production so that it can be placed very close to the skin of the baby without any apparent untoward effects. They are durable light sources with average life span of 20,000 hours [17]. Blue LEDs have a narrow spectral band of high intensity monochromatic light that overlaps the absorption spectrum of bilirubin [17]. The unique characteristics of LEDs make them attractive light source for an optimal phototherapy unit.

The present study is to evaluate efficacy of LED phototherapy in comparison with conventional phototherapy in the management of neonatal hyperbillirubinemia and to compare its side effects and ability to prevent exchange transfusion, to compare the comfort level of staff during photo therapy.

Aim-To evaluate the benefits and efficacy of light emitting diode (LED) with respect to conventional fluorescent tubes phototherapy device in management of neonatal hyperbilirubinemia in term and near term newborns.

Objectives- To evaluate the benefits of LED phototherapy as compared to conventional photo therapy in decreasing serum total bilirubin level and duration of treatment with unconjugated hyperbilirubinemia during the first 28 days of life.

Sample Size- 200 Newborn babies

Selection of Babies- All the newborn babies who were admitted in the neonatal wards of paediatrics department at S C B Medical College& SVPPGIP, Cuttack, full filling the inclusion criteria were examined & investigated in detail and necessary data was noted in a pre-designed Performa.

Inclusion criteria

- 1. Gestational age >35 weeks
- 2. Birth weight >2kg
- 3. Post natal age less than/equal to 28 days

Exclusion criteria

- 1. Gestational age <35 weeks
- 2. Birth weight <2kg
- 3.Newborns with ABO or Rh incompatibility (Pathological jaundice)
- 4. Neonates without sepsis & birth asphyxia
- 5. Babies more than 28 days of life

Materials and Methods

This study is Hospital based prospective and observational study. The study was done over a period of two years in SNCU, NICU andNewborn wardof department of paediatrics, S.C.B. Medical College, Cuttack from September 2014 to August 2016. Investigation were done in the department of pathology, biochemistry and central laboratory.

All the babies were appropriate for gestational age (AGA) and with normal finding on physical examination. Babies with normal blood count and peripheral smear, no evidence of blood group isoimmunisation, negative direct coomb test (DCT), normal reticulocyte count and normal enzyme activities are taken for study.

Out of two hundred newborns, 100 newborns are treated with conventional phototherapy (Group 1). were taken by assessing the values with hour specific Bhutani's nomogram. Visible icterus was evaluated by using Kramer's rule. The skin colour of baby was elicited by using Felix Von Luschan skin colour scale. All the neonates were followed till the baby was present in the hospital i.e. recovery or discharged otherwise (LAMA/DAMA/DEATH)

The newborns are placed in open cribs undressed except for diaper and had eyes covered, interrupted only for feeding, cleaning and blood test. In both groups distance of baby from phototherapy unit was matched. Conventional phototherapy was utilised in group 1 at a distance of 40cm. LED device was also kept at distance of 40cm. The conventional fluorescent phototherapy unit we used is NEOTECH, MEDITRIX phototherapy unit. The LED system is BRILLIANCE LED SYSTEM, D REV PHOENIX Obelis s a, Boulevard General wahs 53,1030 brussels.

The irradiance of phototherapy units at surface are measured at the level of face, xiphoid and knees by photoradiometer.(THOR MULTIESTER MOD3620FANEM BRASIL). Laboratory examinations included total and direct serum bilirubin at the time of enrolment, blood groups of the newborn and the mother, blood test for hemolysis, unusually shaped red cell, or evidence of infection and test for G6PD deficiency.

Venous sampling for serum bilirubin is done at 8, 24 and 48 hours. The values are compared with transcutaneous bilirubin level which is taken using a DRAGER-JM103 transcutaneous bilirubinometer over the covered area. Axillary body temperature was measured every 4 hours.

The present study is an attempt to evaluate the efficacy of LED Phototherapy with respect to conventional phototherapy and the benifits like preventing exchange transfusion, decreasing side effects and its role in management of neonatal hyperbilirubenimia.

Observation

Gestational age	Boy baby	Girl baby	Total
Late pre term	12	20	32
Term	108	60	168
Total	120	80	200

Table-1: Gestatinal age and sex distribution in our study (n =200).

Out of two hundred newborn 168(84%) were term and remaining were late preterm as shown in table 1. Boy baby were 120(60%) and girl baby were 80(40%) with a boy to girl ratio 1.5:1

Table-2: Postnatal age of presentation to hospital and day of onset of jaundice.

Day of life	Admission (no of babies)	Onset of jaundice(no of babies)
Less than 24 hours	Nil	nil
24-48 hours	68 (34%)	50(25%)
More than 48 hours	132 (66%)	150 (75%)

The mean age of presentation to hospital 51.89+/-4.5 hours with a majority 132~(66%) babies brought to the hospital after 48 hrs of post natal life followed by 68 (43%) babies admitted between 24-48 hours as shown in table 2. Most of the babies developed jaundice after 48 hours, 150 cases (75%), 50 cases (25%) developed jaundice between 24-48 hours. There is no case with jaundice developed less than 24 hours.

Table -3: Kramer's grading at the time of admission.

Kramer's stage	number of babies
III	14
Iv	102
v	84
Total	200

At presentation 102 (51%) babies had Kramer stage IV for jaundice followed by 84(42%) with stage V jaundice and remaining 14 (7%) have stage III jaundice.

Table-4: Demographical, clinical and laboratory characteristics.

Parameter	Conventional group	LED Group
Mean gestational age in week	38.76 +/-1.13	38.38+/-1.14
Gestational age range in week	35-41	35-41
Mean weight at initiation of phototherapy in grams	2772+/-227	2719+/-282
Mean weight at stoppage f phototherapy in grams	2610+/-197	2576+/-276
Mean weight loss in grams	161+/-110	142+/-41
Mean post natal age at admission in hours	52.22+/-4.8	51.56+/-4.2
Mean postnatal age at development of jaundice in hours	52.58+/-5.10	52.84+/-3.74
Mean time of initiation of phototherapy in hours	52.58+/-5.10	52.84+/-3.74
Mean initial bilirubin in mg /dl	17.38+/-1.17	18.88+/-1.04
Mean biliribin at 8 hour in mg/dl	16.80+/-1.44	15.06+/-1.73
Mean biliribin at 24 hour in mg/dl	16+/-2.17	14.62+/-1.73
Mean biliribin at 48 hour in mg/dl	14.88+/-3.99	12.48+/-2.80
Mean biliribin at stoppage in mg/dl	12.92+/-3.6	12.26+/-2.84
Mean duration	60.68+/-16.9	50+/-2.58
Fall of bilirubin in mg dl/hr	0.058+/-0.03	0.137+/-0.04
Relative change in bilirubin at 8hour (%/hr)	0.41+/-0.2	1.2+/-0.5
Relative change in bilirubin at 48hour (%/hr)	0.29+/-0.3	0.7+/-0.3
Rebound jaundice in number	8	12
Relative change in bilirubin at 8hour (%/hr)	20	6
Mean irradiance (µW/cm square /nm)	18.04+/-1.40	36.34+/-1.13
Side effect in number	20	12
Comfort Likerts scale	20 %	80%

As shown the table LED over score conventional florescent phototherapy in each and every respect.

Table-5: Gestational age of study group.

Gestational	TYPE	Ν	MEAN	Std.	Std. Error	t and p value
age in weeks			(week)	deviation	mean	
	LED	100	38.38	1.14	0.101	t=1.67
						df=97.99
						p=0.098
	Conventional	100	38.76	1.135	0.101	

In this study we allotted 100 newborn babies to LED group with an average gestational age of 38.38+/- 1.14 weeks and 100 to conventional group with average gestational age of 38.76+/-1.135 weeks. Gestational age is compared by dividing the babies into two groups LED and conventional and independent t test was applied to find out the statistical difference. The test shows gestational age did not have any statistical difference in child with LED and conventional phototheray.

postnatal	Туре	Ν	Mean	Std. deviation	Std. Error	t and p value
			hours		mean	
Age	LED	100	51.56	4.200	0.594	t=0.726
In hours	Conventional	100	52.22	4.871	0.689	df=95.93
						p=0.470

Table -6: Post natal age of admission.

We allotted 100 newborn babies each into LED and Conventional phototherapy group with LED group having mean post natal age of admission 51.56 +/-4.20 hours and conventional group having mean postnatal age of 52.22+/-4.87 hours. Postnatal age was compared in both the groups and the statistical difference was measured by independent t test. It shows that the postnatal age had no statistical difference in both the age group.

Table-7: Time of initiation, stoppage and duration of phototherapy.

Time	LED	Conventional	difference	t and p value
Time of initiation	52.84	52.58	0.260	t=0.290
in hours				df =89.95
				p=0.772
Time of stoppage in	102.84	113.26	10.420	t=4.091
hours				df =54.076
				p=0.002
Duration of	50	60.68	10.680	t=4.413
phototherapy in				df =51.291
hours				p=0.001

There is no statistical difference in the time of phototherapy (t=0.290, p=0.772) but there is significant statistical difference in the time of stoppage (t=4.091, p=0.001) and duration (t=4.313, p=0.001) of phototherapy in both the groups.

Table-8: Fall of bilirubin during phototherapy.

Hrs of phototherapy	Туре	Ν	Mean	Std. deviation	Std. Error mean	t and p value
Bilirubin at initiation	LED	100	18.8	1.043	0.147	t=6.748
(mg/dl)	Conventional	100	17.9	1.176	0.166	df=96.614
						p=0.081
Bilirubin at 8hrs (mg/dl)	LED	100	15.06	1.038	0.147	t=1.034
	Conventional	100	16.80	1.443	0.204	df=89.01
						p=0.03
Bilirubin at 48hrs	LED	100	12.48	2.808	0.397	t=3.485
(mg/dl)	Conventional	100	14.88	3.978	0.563	df=88.129
						p=0.001
Bilirubin at stoppage	LED	100	12.26	2.841	0.402	t=4.088
(mg/dl)	Conventional	100	12.92	3.619	0.512	df =92.779
						p=0.1
Fall of bilirubin	LED	100	0.137160	0.045698	0.006462	t=9.713
(mg/dl/hr)	Conventional	100	0.058122	0.034963	0.004944	df=91.725
						P=0.002

The mean bilirubin at initiation of phototherapy is 18.8+/- 1.04 mg/dl in LED group and 17.9+/-1.17 mg/dl in conventional group and bilirubin level at 8 hours is 15.06+/-1.04mg/dl in LED group and 16.80+/-1.44mg /dl in conventional group, while the bilirubin at 48 hours is 12.48+/-2.80mg/dl in LED group and 14.88+/-3.97 mg/dl in conventional group. The bilirubin at stoppage is 12.26+/-2.841mg/dl and 12.92+/-3.619mg/dl in both groups. The fall of bilirubin is 0.1371+/-0.0456mg/dl/hour in LED group and 0.0581+/-0.004mg/dl/hr in conventional group. There is no significance difference in the case of bilirubin at initiation and bilirubin at stoppage since the p value is more than 0.05 as seen in the bilirubin at 8, 48 hours; and the fall of bilirubin shows a definite statistical difference between LED and conventional group (p value<0.05).

Table-9: Irradiance of phototherapy.

Irradiance in	Туре	N	Mean	Std. deviation	Std. Error	T and p
µW/cm square					mean	value
/nm	LED	100	36.3460	1.13573	0.1606	t=71.695
	CONVENTIONAL	100	18.0400	1.40349	0.1984	df=93.914
						p=0.001

The mean iradiance of LED phototherapy unit is 36.35+/-1.13 where as in conventional fluorescent phototherapy unit is by using THOR 3620 Flux meter. Comparing the irradiance of LED phototherapy unit and conventional fluorescence tube phototherapy unit there is a significant statistical difference (t=71.69, p=0.0001)

Table-10: Weight loss during phototherapy.

	Туре	Ν	Mean	Std.	Std. Error	t and p
				deviation	mean	value
Weight at initiation in	LED	100	2719	282.642	39.972	t=1.033
grams	Conventional	100	2772	227.713	32.203	df=93.75
						p=0.304
Weight at stoppage in	LED	100	2576	276.642	39.123	t=0.750
grams	Conventional	100	2611	197.370	27.912	df=92.618
						p=0.478
Weight loss in grams	LED	100	142	41.699	5.897	t=1.069
	Conventional	100	161	110.583	15.639	df=90.658
						p= 0.06

The weight at initiation in LED group and conventional group is 2719+/-282.64 and 2772+/-227.71g respectively. The weight at stoppage is 2576+/-276.64g and 2611+/-197.37g in both groups. Hence the mean weight loss is 141+/-1.699g and 161+/-110.583g in both group respectively. There is no significant difference regarding the weight of the babies during initiation and stoppage of phototherapy groups (t = 1.033 and p= 0.304, t=0.750 and p=0.06). Even the weight loss is more during conventional phototherapy, there is no definite statistical difference.

Table-11: Rebound hyperbilirubinemia.

Туре	Ν	Rebound	p and t values
LED	100	12	t=0.887
Conventional	100	8	df=94.30
			p=0.38

Out of 100 babies treated with LED Phototherapy 12 babies have rebound hyperbilirubinimia as compared to 8 in conventional phototherapy. There is significant between both group since the p value is 0.38.

Table-12: Failure of Phototherapy.

ТҮРЕ	Ν	Failure		p and t value
LED	100	Exchange transfusion	0	t= 2.107
		DSPT	6	df=79.729
Conventional	100	Exchange transfusion	4	p=.003
		DSPT	16	

There is total number of 20 failure in conventional phototherapy, sixteen of them going for DSPT and four out of them going for exchange transfusion. In LED group there is only six failures all going for DSPT. There is a significant difference in failure of phototherapy between both group.

 Table-13: Side effect & Staff and parental comfort during phototherapy.

Туре	N	Side effect	t and p value	N=200 Staff and parental comfort	t and p value
LED	100	Hyperthermia 0 Hypothermia 2 Burns and rash 4 Dehydration 0 Irritability & crying 6	t= 1.488 df=88.136 p=0.140	160	t= 2.578 df= 76.658 p=0.012
Conventional	100	Hyperthermia 4 Hypothermia 0 Burns and rash 5 Dehydration 1 Irritability & crying 10		40	

The LED group total of about twelve babies developed some side effect while in conventional group about twenty babies developed side effects showing p value 0.140. so there is no significant statistical difference. In LED group there is no case of hyperthermia, while 2 babies developed hypothermia (2%). There are no case of dehydration, while four babies developed rash (4%). In conventional group they developed four cases of hyperthermia (4%), five cases of rashes (5%) and one case of dehydration (1%), irritability and excessive crying is more in conventional (10%) than LED (6%).

Out of total 200 staff (nursingstaff and doctors) 160 favoured LED phototherapy. Here we got the p value 0.012 and is statistically significant.

Discussion

Out of 200 newborns included in our study, 68(84%) babies were term and remaining 32(16%) babies were late preterm with baby boy being 120 (60 %) and girl baby 80(40%) and M:F ratio 1.5:1 as shown in table 1. This might not be true as study includes only term and late pre term babies. Recent review by Cochrane includes both term and preterm babies, which is different from our study. The study conducted by Majid

Mohammadizadeh [21]in Iran in 2012 includes only preterm neonate. The average age of gestation in babies treated with LED phototherapy is 38.38+/-1.14 weeks and conventional group is 38.76+/-1.13 weeks. Similar results were observed by other authors [28,29]. Table 2 shows the mean age of presentation to the hospital 51.89+/-4.5 hours with majority 132(66%) babies brought to hospital after48 hours of post natal life

followed by 68(38%) babies between 24-48 hours[10,]. The average post natal age of presentation in LED group is 51.56+/-4.871 hours, a study by Martin 2007 have similar results [19,20]. There is significant difference in time of stoppage (t=4.091,p=0.002) and duration of photo therapy (t =4.431,p=0.001) while comparing LED with conventional group as shown in table -10. The study shows duration of phototherapy with LED is much lower. Similar results were observed by other authors [19,21,22,26].

The mean bilirubin at the time of initiation and stoppage was almost similar in two groups, there by indicating that uniform guidelines was followed for starting and stopping of phototherapy. This is in accordance with Kumar et al [28]. LED phototherapy might be useful in treating severe hyperbilirubenimia and there by preventing its complications [19,20,23,24]. The average irradiance of LED in our study is $36.34+/-1.35\mu$ W/cm square /nm which was below reported level according to Tan et al [27].

The rebound hyperbilirubinemia is more in LED as compared to conventional, this is against Belma et al[23], Seidman 2003[23]. The weight loss during phototherapy is more in conventional group (161+/-110gms) than LED group (142+/-41.699gms), this is comparable with Kumar et al 2009[28], uras et al 2009[29]. The study shows that LED phototherapy re more efficient in preventing failure of phototherapy and exchange transfusion, which is same as study done by kumar et al 2010[19] and martins 2007[21]. Uras et al 2009 studied that there were no failure of phototherapy in both LED and conventional group [29]. In our study, in LED group 12 percent children developed any type of side effect against a 20 percent of side effects in babies treated with conventional phototherapy, it is similar to study conducted by Kumar 2010[19] and Martins [21]. In our study which is Likert scale study, out of 200 newborn babies treated with phototherapy about 80% show more comfort with LED phototherapy while only 20% opts for conventional phototherapy. It shows a definite statistical difference since more opting for LED phototherapy [p=0.012]. The study is similar with study done by Seidman et al [23,24].

Conclusion

Jaundice usually becomes clinically apparent to parents by zone IV and hence need immediate treatment to prevent kernicterus. This can be achieved by institution of proper proper phototherapy more device. LED

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phototherapy is more efficacious in bringing down the serum bilirubin level. The rate of fall of bilirubin is more with LED phototherapy unit than conventional fluorescent tube phototherapy unit. The maximum fall of billirubin is during initial phase of phototherapy. LED Phototherapy unit have twice the irradiance of conventional phototherapy unit. LED is safe rescue treatment for severe neonatal hyperbilirubenimia and its implementation reduce the failure of phototherapy and need of exchange transfusion.

LED phototherapy device has caused less frequent side effects and there was no acute severe side effects. It produces less heat and dehydration so can be placed very close to the newborn. Moreover LED phototherapy unit provide more nursing comfort as compared to the conventional phototherapy unit. Only draw back with of LED with our study it causes rebound jaundice. Hence LED could be a resourceful technique in view of its efficacy and least side effects and cost effectiveness.

Abbreviations

ABE: Acute bilirubin encephalopathy, NIND: Neurological induced neurological dysfunction, C F T: Compact fluorescent tube, **DSPT**: Double surface phototherapy, g/dl: gram per deci liter, i.e.: that is, LED: light emitting Diode, Kg: kilogram, LAMA: Left against medical advice, N: Number of cases/observation, NNHB: Neonatal hyper bilirubinemia, S: Serum, T S B: Total serum bilirubin, %: percentage, &: and, µmol/L: Micro mol per litre, **µW/cm square /nm:** micro watt per centimetre square per nanometer.

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