Scholars Journal of Applied Medical Sciences (SJAMS) **ISSN 2320-6691 (Online)**
Sch. J. App. Med. Sci., 2016; 4(8B):2830-2833 **ISSN 2347-954X (Print)**

(An International Publisher for Academic and Scientific Resources)
www.saspublishers.com DOI: 10.36347/sjams.2016.v04i08.021

Original Research Article

Comparison of Effectiveness of Light Emitting Diode (LED) versus Compact Fluorescent Light (CFL) Phototherapy in Neonatal Hyperbilirubinemia

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Abstract: About 60% of term and 80% of preterm newborns develop physiological jaundice. Jaundice is regarded as pathological if it appears in first 24 -36 hrs of life, serum bilirubin rising at a rate of more than 5 mg/dl/day, jaundice persisting after 10 -14 days of life and direct bilirubin fraction > 2 mg/dl. Most dreaded complication of neonatal jaundice is kernicterus which is due to deposition of bilirubin in the brain leading to bilirubin encephalopathy and subsequently kernicterus with devastating permanent neurodevelopmental handicaps. The primary treatment of neonatal hyperbilirubinemia is phototherapy and in some cases exchange transfusion. Compact Fluoroscent Light (CFL) light was the mainstay in use so far, but in recent years Light Emitting Diode (LED) has emerged as better light source for phototherapy purpose. Lot of studies have been done all over the world comparing the efficacy of both the light sources, but only few studies are available in India; hence the present study was designed to compare the efficacy. 109 healthy near term and term neonates with physiological hyperbilirubinemia were randomized to two groups i.e. LED (n=55) and CFL (n=54); the study revealed that LED lights are more efficacious than CFL lights in the management of neonatal hyperbilirubinemia.
Keywords: Neonatal hyperbilirubinemia, Phototherapy, CFL versus LED

INTRODUCTION

In the first week of life, approximately 60% term and 80% of preterm babies develop physiological jaundice and about 10% of breastfed babies still have jaundice at 1 month of age [1]. Among hospital born neonates in India, 3% babies develop serum total bilirubin levels more than 15 mg/dl [2]. Bilirubin is considered as an important antioxidant agent and is believed to protect the neonate against the toxic effects of free oxygen radicals.

Jaundice is considered pathological if it appears in the first 24 -36 hr of life, serum bilirubin rising at a rate of more than 5 mg/dl/day, jaundice persisting after 10 -14 days of life, direct bilirubin fraction > 2 mg/dl.[3] Other factors suggesting a pathological cause of jaundice are family history of hemolytic disease, hepatomegaly, splenomegaly, failure of phototherapy, vomiting, lethargy, poor feeding, excessive weight loss, bradycardia, abnormal vital signs, light colored stools, dark urine positive for bilirubin and signs of kernicterus [3-5].

Most dreaded complication of neonatal jaundice is kernicterus which is due to deposition of bilirubin in the brain leading to bilirubin encephalopathy and subsequently kernicterus with devastating permanent neuro developmental handicaps [6]. Exact level of bilrubin that is likely to cause neurotoxicity in any baby varies and it depends on multiple factors like acidosis, gestational age, postnatal age, rate of rise of serum bilirubin, serum albumin concentration and associated illness [3, 4].

Bilirubin which is produced by catabolism of haemoglobin is conjugated in liver and further excreted into the intestines. Immaturity of the hepatic glucoronyl transferase and inadequate milk intake delays clearance of bilirubin within RE system. Heme is broken down into biliverdin and CO. Biliverdin is reduced to bilirubin by biliverdin reductase. Catabolism of 1 mol of hemoglobin produces 1 mol each of CO and bilirubin. This unconjugated bilirubin (UCB) is nonpolar, insoluble in water, and is transported to liver cells bound to albumin. In liver, it is conjugated by glucuronosyl transferase to bilirubin diglucoronide,

which is water soluble and easily excreted by liver and biliary tract. In the intestine, some conjugated bilirubin may be converted back to its unconjugated form and reabsorbed by the intestine. UCB being non-polar has high affinity for lipid rich basal ganglia. Increased UCB crosses blood brain barrier, affects basal ganglia and can cause kernicterus [3, 4].

Main mode of treatment of neonatal jaundice is either phototherapy or exchange transfusion. Exchange transfusion rapidly lowers serum bilirubin to safe levels, but it has potential serious complications like metabolic acidosis, electrolyte abnormalities, hypoglycemia, hypocalcemia and volume overload [4].

Phototherapy being non-invasive, cheap, safe with fewer side effects has become the treatment of choice for management of neonatal jaundice worldwide [5]. Most commonly used light sources which are used now are conventional Compact Fluorescent Light (CFL) units followed by newly developed Light Emitting Diode (LED) phototherapy units. Problems with CFL units are emission of broad wavelengths, need for frequent assessment of irradiance and timely change of light units [7, 8]. LED phototherapy provides higher irradiance, narrow spectrum wavelength and extended life span (Duration of change of bulbs nearly 20,000 hrs compared to 2000 hrs in CFL). In theory LED lights are superior to CFL units [9].

After LED development, lot of studies were done all over the world comparing the efficacy of LED units with CFL units in the management of neonatal jaundice, but few published studies are available in India comparing CFL with LED units. Hence we conducted the study "to compare the efficacy of CFL with LED units in the management of neonatal hyperbilirubinemia"

METHODS

This is a single center randomized control trial conducted in neonatal intensive care unit of Kalinga Institute of Medical Science (KIMS), Bhubaneswar from July 2015 to Jun 2016. The study protocol was approved by ethics committee of the institution.

Sample size

There is limited data of Indian studies regarding the comparison between LED and CFL units in the management of neonatal hyperbilirubinemia. Hence a proper sample size could not be calculated using standard statistical method. Total 109 babies were taken for the study and divided into 2 groups.

Inclusion criteria:

- Newborn babies up to 7th day of life, born after 35 weeks of gestation who required phototherapy for hyperbilirubinemia are included in the study.
- A level of serum bilirubin (SB) at which phototherapy was started was based on American Academy of Pediatrics (AAP) guidelines.
- Phototherapy was stopped when serum total bilirubin levels were < 12 mg/dl as per AAP guidelines[10] and institutional protocol.

Exclusion criteria:

- Babies requiring exchange transfusion or intensive phototherapy
- Conjugated hyperbilirubinemia (Conjugated SB > 2 mg/dl)
- Glucose -6 phosphatase deficiency
- Rh hemolytic disease
- Culture positive or proven sepsis
- DCT positive or any evidence of hemolysis
- Perinatal asphyxia (Apgar score <4 at 1 min, <7 at 5 min)
- RDS
- Major congenital anomalies
- Age > 7 days
- Gestation < 35 weeks
- Infant of diabetic mother
- Congenital hypothyroidism
- Already received phototherapy before admission
- Refusal to give written consent for study enrollment

Intervention

Enrolled newborns (Total-109) were randomized into 2 groups to receive single surface LED or CFL phototherapy by using web based random number generated. Demographic and clinical variables were recorded. Gestational age is calculated according to mother's last menstrual period. Commercially available phoenix CFL units consisting of 6 special blue CFL bulbs and Lullaby LED units were used for the study. New bulbs were installed in all the units which were used for the study. Irradiance was measured at the start of study and then every 6 months till completion of the study.

All the babies were exposed to light completely unclothed with protection over the eyes and diaper region. Distance of 35 cm was maintained between the baby and lamp surface. Period during which phototherapy was stopped due to various reasons like feeding, nappy change and blood samplings were noted and absolute phototherapy duration and rate of fall of serum bilirubin were calculated.

Outcome variables

Primary outcome was the rate of fall of serum bilirubin and duration of phototherapy required and secondary outcome consisted of failure of phototherapy, hypothermia, dehydration and appearance of rash. Failure of phototherapy was defined as total serum bilrubin rising to more than 20 mg/dl during phototherapy which required either use of double surface phototherapy or exchange transfusion.

Monitoring

Side effects of phototherapy like dehydration and appearance of rash was monitored. Axillary temperature was measured every 4 hours to detect hypothermia or hyperthermia. Serum bilirubin level was measured at the start of phototherapy, after 6 hours, at the end of treatment and after 24 hours of stoppage of phototherapy (to assess rebound rise).

Statistical Analysis

Data entry and analysis were done using Windostart Version 9.2 software. Continuous data with normal distribution was analysed by student t-test. A p-value of <0.05 was taken as statistically significant.

RESULTS:

Total 112 healthy near term and term neonates were included in the study out of which 3 cases were discharged against medical advice. Rest 109 neonates were randomized to two groups i.e. LED (n=55) and CFL (n=54). Demographic and baseline characteristics of study population are furnished in Table-1 and final result/analysis are furnished in Table-2. Age at the start of phototherapy, sex, gestation, wt of the baby and other demographic variables were similar in both groups.

Table 1: Demographic and baseline characteristics of study population

Characteristics	LED (n=55)	CFL(n=54)	P value
Hours of Life	96.73 ± 18.95	99.87 ± 19.68	P = 0.398
Gestation in Wks	37.56 ± 1.15	37.24 ± 1.31	P=0.175
Birth wt (Gm)	2738.91 ± 321.14	2746.85 ± 304.24	P=0.895
Wt at admission (Gm)	2569.27 ± 310.11	2577.39 ± 294.05	P=0.889
PCV at admission	53.77 ± 6.62	52.46 ± 7.57	P=0.341

No significant difference between 2 groups i.e. CFL & LED groups

Table 2: Final result, outcome and analysis

Characteristics	LED (n=55)	CFL(n=54)	P value
SB at start	19.64 ± 1.96	20.1 ± 2.35	P=0.270
SB at 6 hr	17.36 ± 1.84	18.15 ± 2.57	P=0.071
SB at discharge	10.07 ± 1.039	10.22+ 0.911	P = 0.415
Rebound SB	11.354+ 0.994	11.237 + 0.874	P = 0.514
ROF at 6 hr	0.375 ± 0.076	0.307±0.053	P = 0.000
ROF(Total)	0.309 ± 0.058	0.276 ± 0.053	P= 0.003
Phototherapy duration in hours	31.98 ± 7.46	36.67 ± 11.62	P=0.014

SB- Serum Bilirubin, ROF –Rate of Fall of SB in mg/dL/hr. ROF at 6 hr, ROF total and Phototherapy duration is significantly different between LED and CFL group.

Mean serum bilirubin level of 55 neonates in LED group was 19.64 ± 1.96 mg/dl (at start), 17.36 ± 1.84 (after 6 hrs) and 10.07 ± 1.039 mg/dl (at discharge). Rate of fall of serum bilirubin in LED group at 6 hrs was 0.375 ± 0.076 mg/dl/hr and total rate of fall was 0.309 ±0.058 mg/dl/hr. Total phototherapy duration in LED group was 31.98 ± 7.46 hour.

Mean serum bilirubin level of 54 neonates in CFL group was 20.1 ± 2.35 mg/dl at start, 18.15 ± 2.57 mg/dl at 6 hr and 10.22 ± 0.911 mg/dl at the time of discharge. Rate of fall of serum bilirubin during first 6 hrs was 0.307 ± 0.053 mg/dl/hr and total rate of fall was 0.276 ± 0.053 mg/dl/hr. Total phototherapy duration was 36.67 ± 11.62 hour.

There was no significant difference in initial serum bilirubin levels, at 6 hour of phototherapy and at the time of discharge in both groups. However rate of fall of serum bilirubin after first 6 hrs was higher in LED (0.375mg/dl/hr) than CFL (0.307mg/dl/hr) and was statistically significant (p=0.000).

Similarly total rate of fall of serum bilirubin at the time of discharge was higher in LED group (0.309 mg/dl/hr) than CFL group (0.276 mg/dl/hr) and was statistically significant (p=0.003)

Total phototherapy duration in LED group is lower (31.98 hr) as compared to CFL group (36.67 hr) and was statistically significant (p=0.014).

The rebound rise of SB after 24 hours of stoppage of phototherapy is 11.354 mg/dL in LED group and 11.237 mg/dL in CFL group, which is statistically insignificant (p=0.514)

Side effects were rare and comparable in both groups. In LED groups two babies had hypothermia and rash noticed in two babies. In CFL group two babies had hyperthermia, one baby had mild dehydration and rash was noticed in three babies. None of the babies in our study had failure of phototherapy. After discharge, none of the babies required phototherapy for rebound rise in serum bilirubin level. Otoacoustic Emission (OAE) tests were normal in all babies.

DISCUSSION

Neonatal jaundice is a benign condition, but causes irreversible brain damage if high levels of UCB persist for longer period and it crosses immature blood brain barrier to cause bilirubin encephalopathy.

Phototherapy being non-invasive method has been used for the management of neonatal hyperbilirubinemia for decades, but there is no standard recommended phototherapy device with highest efficacy and little side effects.

Present study compares efficacy of LED and CFL light in reducing SB to safe level. It showed that with LED phototherapy rate of fall of serum bilirubin is more compared to CFL light i.e. 0.375 mg/dl/hr versus 0.307mg/dl/hr in first 6 hour and 0.309 mg/dl/hr versus 0.276 mg/dl/hr towards the end of the treatment. Similarly total duration of phototherapy to achieve safe bilirubin level is more with CFL units (36.67 hrs) as compared with LED units (31.98 hrs). But in comparison, multicentric trial by Kumar *et al.;* [11, 12] and randomized trial by Meisel *et al.;* [7] showed both LED and CFL units were equally efficacious and median duration of phototherapy were comparable in both groups. Cochrane review [13] concluded both CFL and LED units were equally efficacious i.e. comparable in both duration of phototherapy and rate of decline in serum bilirubin. But Reddy TR *et al.;* [14] showed that LED group showed higher efficacy than CFL group.

Side effects like hypothermia, rash, dehydration, significant rebound rise in SB after stoppage of phototherapy and failure of phototherapy were rare and comparable in both groups like previous studies by Kumar *et al.;* [12].

CONCLUSION:

Result of this study showed that LED lights are more efficacious than CFL lights in the management of neonatal hyperbilirubinemia without producing any significant side effects.

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