Original Article

COMPARISON OF LED PHOTO-THERAPY WITH CONVENTIONAL PHOTO-THERAPY IN THE TREATMENT OF HYPERBILIRUBINEMIA IN NEONATES IN TERMS OF SAFETY AND EFFECTIVENESS

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ABSTRACT:

BACKGROUND: neonatal jaundice is a commonly occurring cause of severe brain damage if not effectively treated and diagnosed**.**

OBJECTIVE: To compare the effects of LED phototherapy with conventional phototherapy in treatment of unconjugated neonatal jaundice in terms of mean duration of phototherapy, drop in total serum bilirubin levels and side effects observed by the treatment modalities.

METHODS: A randomized control trial was conducted in the department of Pediatrics, D.H.Q Hospital, Faisalabad. 140 neonates, aged between 2-28 days of both genders having unconjugated jaundice were included in the study. All the children were divided into two groups. Patients received LED phototherapy in group A and conventional phototherapy in group B. Data was subjected to percentages, chi square tests, frequency for qualitative and independent t tests for non-qualitative variables on the statistical package for social sciences (SPSS) software, version 22.

RESULTS: Out of 140 patients, mean age of the patients in gestational weeks was 35.44±7.36. 77(55%) patients were male while 63(45%) patients were female. Mean duration of phototherapy in group A and B were 48.1±24.1 hours and 96.3±33.2 hours respectively (p-value=0.0001). The rates of fall of TSB were 0.45[SE = 0.03] and 0.10 [SE = 0.01] mg/dL/hour in the LED and fluorescent groups, respectively (*P* = 0.472)2(2.9%) patients had hyperthermia in group A while 10(14.3%) patients had hyperthermia in group B (p-value=0.016).

CONCLUSION: LED phototherapy is more advantageous over the conventional method for the treatment of unconjugated neonatal jaundice, in terms of duration, safety profile and also it results in lesser degree of hyperthermia.

KEY WORDS: unconjugated hyperbilirubinemia, jaundice, LED, photoherapy, hyperthermia

INTRODUCTION:

Neonatal jaundice is one of the commonest causes of hospitalization, as during the first seven days of life eighty percent of new born children who are pre-term and sixty percent of

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babies delivered full term and 80% of preterm neonates are affected in the first week of life.[1]If poorly managed, severe neonatal jaundice may result in neurological issues such as hearing loss, behavioral changes, intellectual deficitsand even death[2].

Mainstay of treatment is either phototherapy or exchange transfusion.[3] Usually we carry out phototherapy in these instances[4]. This can reduce bilirubin in all neonates irrespective of age of gestation, pigmentation of skin or absence/presence of hemolysis[1].

Effectiveness of phototherapy can be affected by different things included amount of exposed body surface area, wavelength and irradiance of the light source[5]. Usually as sources of light, halogen and fluorescent tubes are used. These have limitations like over production of heat which will be unsafe for the neonates. This issue is minimized by using fiber optics blankets with the light source but this is not very effective due to a limited exposure area.[6]

Owing to these issues, light-emitting diodes (LEDs) have recently been investigated as a replacement to these conventional light sources. They generate less heat, have longer duration of life and much lower energy consumption , which makes them more efficient and cost effective than other light sources. Some of these lights are having wavelengths nearer to the absorption spectrum of bilirubin.[7]

In Pakistan most of our hospitals are using conventional fluorescent phototherapy for treatment of indirect hyperbilirubinemia, In one study duration of phototherapy with LED was 2.7±1.5 days and with conventional phototherapy it was 4.2±1.4 days (p<0.001).[8] Hyperthermia was present in 0% neonates treated with LED phototherapy while with conventional phototherapy it was 12% (p = 0.03).[9] In another study it was concluded that both the LED phototherapy and conventional phototherapy is equally effective. Duration of phototherapy with LED was 25h (22-36h) and with conventional phototherapy it was 26h (22-36h) with p = 0.44. Hyperthermia with LED was 2.8% and with conventional phototherapy it was 4.6% (p = 0.43).[10]

LED phototherapy is a relatively new modified modality of phototherapy here. Though it has been practiced for some time in other parts of the world but due to dearth of evidence in our population and controversies in literature, the results of this study will be helpful in selecting a proper treatment modality as a first line of treatment for neonatal jaundice to reduce the morbidity particularly in the Pakistani setup.

MATERIALS AND METHODS:

A randomized control trial was conducted in the Neonatology Unit of the department of Pediatrics of D.H.Q Hospital Faisalabad from 29th June 2015 to 28th December ,2015.

The sample size of the patients was calculated using WHO sample -size calculator for 2 proportions,

P_1 = 12%[9]

P_2 = 0%[9]

Power of study = 80%,

Level of significance = 5%

Sample size = 140 (70 in each group).

The Inclusion criteria for sample selection comprised of both male and female neonates between age ranges 35.5-38 gestational weeks (chronological age 2-28 days)and neonates having unconjugated jaundice Neonates presented with yellow coloration of skin and eyes with measured Total Serum Bilirubin level ≥ 8mg/d, as per guidelines of American Association of pediatrics for neonates of gestational age > 35 weeks.

Neonates with respiratory distress syndrome, ABO incompatibility, perinatal asphyxia (Apgar score <4 at 1 minute or <7 at 5 minutes), septic patients, congenital malformations, those requiring blood exchange or having a direct-reacting component of bilirubin >2 mg/dL (conjugated hyperbilirubinemia) were excluded from our study.

The phototherapy amount was as per recommendation of consultant neonatologist.

After taking approval from hospital ethical committee, patients admitted in the neonatology unit of the hospital who fulfilled the inclusion criteria were enrolled and informed consent was taken from their parents. Patients were randomly allocated by computer generated random number table in two equal groups of 70 each. Before initiation of therapy blood samples of both mother and infant were obtained and complete blood count was done for evidence of any infection and to test for G6PD deficiency.

70 patients in group A received LED phototherapy (Bilitron 3006 super-LED phototherapy system, Tavern Medical Inc. Sao Paolo, Brazil), while70 patients in group B received Fluorescent tube (Philips TL52/20W) phototherapy. In both the groups, infants were at equal distance from the light source that is about twenty-five cm. During phototherapy, all infants remained in open cradles at room temperature. The patients were not clothed except for patches for eye protection and diapers, they were maintained on enteral nutrition. Total serum bilirubin level was measured by venous sampling at the initiation of phototherapy and then 12 hourly. Body temperature via axilla was taking 6 hourly during treatment. Hyperthermia was assessed as per operational definition(body temperature > 37.5ºC). All the information was collected on a specially designed performa.

STATISTICS:

The data was entered and analyzed in SPSS version 22. Descriptive statistics including mean and standard deviation of numerical values like age, birth weight and duration of phototherapy were evaluated. Frequency and percentage was calculated for qualitative variable like gender and hyperthermia. Duration of phototherapy was compared by using independent sample t-test between both groups. Chi-square test was applied to compare hyperthermia between two groups. Effect modifiers like age, gender and birth weight were controlled by stratification. Post stratification independent sample t-test and chi-square test were applied. p-value less than or equal to 0.05 was considered significant.

Table I. Descriptive Statistics Of Quantitative Variables In Both Groups

Group		n	Minimum	Maximum	Mean	Std. Deviation
LED phototherapy	Age in days	70	2	28	14.64	7.512
	Birth weight in g	70	1567	3697	2688.74	585.771
Conventional phototherapy	Age in days	70	3	27	16.24	7.170
	Birth weight in g	70	1560	3697	2636.63	531.881

Distribution of patients with hyperthermia in both groups was as shown in Table #2.There was significant difference between two groups with p-value = 0.016.
In group A, mean duration of phototherapy was 2.31±1.27 days and in group B, it was 4.6±1.23 days. There was a statistically significant difference between two groups with p-value p= 0.0001.

Table II:Distribution Of Hyperthermia

		Group		
		LED phototherapy	Conventional phototherapy	Total
Hyperthermia	Yes	2	10	12
		2.9%	14.3%	8.6%
	No	68	60	128
		97.1%	85.7%	91.4%
	Total	70	70	140

Chi-square value = 5.833 p-value = 0.016* (significant ≤0.05)
Table# 3 and Table 4 show hyperthermia and phototherapy (respectively) according to stratification of age, gender and birth weight in both groups..

Table III: Comparison Of Hyperthermia Between Two Groups In Relation To Age (Days), Gender And Body Weight (G).

Age distribution	Hyperthermia	Group			p-value
		LED phototherapy	Conventional phototherapy	Total	
= 15 days	Yes	2 5.6%	5 17.2%	7 10.8%	0.131
	No	34 94.4%	24 82.8%	58 89.2%	
> 15 days	Yes	0 .0%	5 12.2%	5 6.7%	0.035*
	No	34 100.0%	36 87.8%	70 93.3%	
Gender Male	Yes	1 2.5%	1 2.7%	2 2.6%	0.955
	No	39 97.5%	36 97.3%	75 97.4%	
Female	Yes	1 3.3%	9 27.3%	10 15.9%	0.009*
	No	29 96.7%	24 72.7%	53 84.1%	
Birth weight (g) = 2500 g	Yes	2 6.5%	7 20.6%	9 13.8%	0.099
	No	29 93.5%	27 79.4%	56 86.2%	
> 2500 g	Yes	0 .0%	3 8.3%	3 4.0%	0.066
	No	39 100.0%	33 91.7%	72 96.0%	

Table IV:Comparison Of Duration Of Phototherapy Between Two Groupsin Relation To Age (Days), Gender And Body Weight (G)

Age distribution		Group	n	Mean	Std. Deviation	p-value
= 15 days	Duration of phototherapy in days	LED phototherapy	36	2.11	1.116	0.0001*
		Conventional phototherapy	29	4.86	1.026	
> 15 days		LED phototherapy	34	2.53	1.398	0.0001*
		Conventional phototherapy	41	4.41	1.341	
Gender	Duration of phototherapy in days	LED phototherapy	40	2.10	1.194	0.0001*
Male		Conventional phototherapy	37	4.68	1.292	
Female		LED phototherapy	30	2.60	1.329	0.0001*
		Conventional phototherapy	33	4.52	1.176	
Birth weight (g)	Duration of phototherapy in days	LED phototherapy	31	2.42	1.259	0.0001*
=2500g		Conventional phototherapy	34	4.53	1.285	
=2500g		LED phototherapy	39	2.23	1.287	0.0001*
		Conventional phototherapy	36	4.67	1.195	

(*p-value significant ≤0.05)

RESULTS:

140 neonates with unconjugated jaundice (mean age 35.44±7.36 gestational weeks and mean birth weight 2662.69±558.07 g) were included in the study. Randomly 70 children underwent LED phototherapy (Group A) and other 70 children underwent conventional phototherapy (Group B).

Descriptive statistics of quantitative variables (age and weight) are given in Table #1 .

DISCUSSION:

Neonatal hyperbilirubinemia and jaundice occur in almost all babies and may be harmless if its conversion to extreme hyperbilirubinemia (EHB; total bilirubin (TB) >428 µmol/l in full-term babies) is recognized, monitored, and prevented or managed in a timely manner.[11]

Major risk factors for development of extreme hyperbilirubemiainclude diseases causing hemolysis in newborns such as Rh-incompatibilty, glucose 6 phosphate dehydrogenase deficiency etc. Additionally, dehydration and sub-optimal breast feed are also contributing factors.

Currently, the only intervention for hyperbilirubinemic brain damage is exchange transfusion hence it becomes essential to use preventive methods.[12]

In preventive methods, we use conventional phototherapy to cause a drop in the bilirubin by photochemically reducing it. However even this method causes skin rashes and has other disadvantages such as a lack of mother-infant interaction and no visual sensory inputs.[13]

In quickly rising bilirubin levels and severe cases, ntensity of the phototherapy is increased so a faster fall of bilirubin levels may be achieved, this is done via multiple phototherapy units. Intensity of the light and area of exposed surface to the light can be made to increase by multidirectional devices, hence causing greater reduction in serum bilirubin levels.

Our study aimed to compare LEDs with fluorescent phototherapy units in the treatment of neonatal jaundice and the results showed significant drop in the duration of phototherapy as well as drop in rate of total bilirubin. This was consistent with other studies.

LED units showed a hyperthermia of 5.6% but this was considerably less as compared to the fluorescent light group that showed hyperthermia of 17.2%.[14]

In group A, mean duration of phototherapy was 2.31±1.269 days and in group B, it was 4.6±1.232 days (p-value = 0.0001). In group A, hyperthermia was present in 2.9% patients and in group B, it was 14.3% (p-value = 0.016).

In a study carried out by Edris *et al*[8], LED phototherapy showed a shorter duration as compared to its conventional couterpart(p <0.001). They concluded that LED phototherapy is effective in reducing needs for exchange transfusion and duration of phototherapy than the conventional phototherapy which favors the results of this study.

In consistence with our work, Sherbiny*et al*[9] did an experiment. According to their results, hyperthermia was present in 12% neonates in conventional phototherapy group and it was 0% in LED phototherapy group (p = 0.03). They concluded that LED phototherapy is a safe rescue treatment for neonatal hyperbilirubinaemia, and its implementation may reduce the need for exchange transfusion.

Mohammadizadeh*et al*[6]concluded in their work that th treatment duration was 37.5 ± 26.8 and 45.3 ± 32.1 hours in the LED and conventional phototherapy groups, respectively (*P* = 0.292). Hyperthermia was markedly significant in group receiving conventional phtotherapy as compared to LED (*P* = 0.006). They concluded LED light source is as effective as fluorescent tubes for phototherapy of preterm infants with indirect hyperbilirubinemia. Considering less frequent side effects, less energy consumption, longer life span, and lower costs, LED phototherapy seems to be a better option than current conventional phototherapy.

Takci*et al*[14] conducted a study to compare intensive light-emitting diode and intensive compact fluorescent phototherapy in non-hemolytic jaundice.Hyperthermia was present in 8.69% patients in LED phototherapy and in 15% patients in conventional phototherapy.

Although most of the above mentioned studies reported rare and comparable side effects in both the non LED and LED groups, we found an increase in hyperthermia with the fluorescent light group although it was not permanent in nature but transient.

LIMITATIONS:

The limitations of our study that may have influenced the results included a small sample size, restricted to one single hospital unit. Also, results would have been much more accurate if a controlled temperature environment would

have been available to eliminate other sources of heat losses and hyperthermia.

CONCLUSIONS:

Our study shows that LED phototherapy is more efficient and effective than conventional phototherapy for neonatal hyperbilirubinemia as it results in less degree of hyperthermia and is more time efficient (as it takes less time than the conventional bulbs to achieve lower levels of bilirubin), having a higher safety profile. However, more studies are required especially in preterm and pathological jaundice to establish a final verdict.

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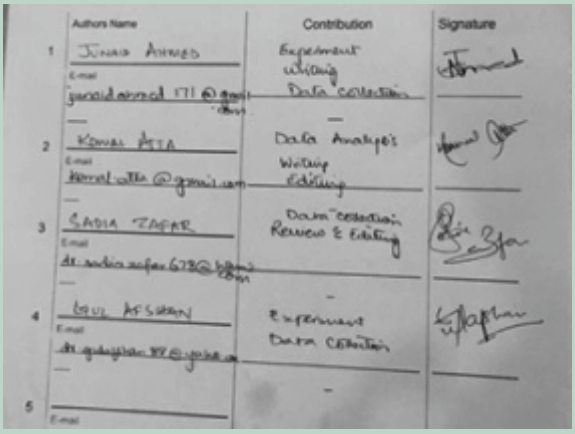

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