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Low-cost Home-use Light-emitting-diode Phototherapy as an alternative to Conventional Methods

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ABSTRACT

Background: The aim of our study was to evaluate whether a portable, light-weight, light-emitting-diode phototherapy unit designed for home use is as effective as conventional blue-light fluorescent phototherapy (CFP) for treating hyperbilirubinemia in neonates. Methods: A total of 50 patients were recruited sequentially for treatment using CFP ($n = 25$) and the home-type phototherapy unit ($n = 25$). Results: The average rate of decrease in bilirubin levels was 0.17 ± 0.02 and 0.20 ± 0.01 mg/dL/hours at the end of 24 hours in the groups receiving phototherapy by CFP and home-type phototherapy units, respectively. There was no statistically significant difference in the rate of the decrease in bilirubin levels between the groups ($p = 0.104$). Conclusions: It has been shown that the home-type phototherapy unit is as effective as CFP units in the treatment of neonatal hyperbilirubinemia and has the potential to become a standard of care for treatment of jaundiced neonates.

KEYWORDS: phototherapy, newborn, treatment, home type.

INTRODUCTION

The clinical manifestation of hyperbilirubinemia occurs in 60% of normal newborns and nearly all preterm infants (1). Since severe hyperbilirubinemia can cause kernicterus, it is important to detect unphysiological serum bilirubin levels in newborn babies to prevent permanent neurological damage. Phototherapy has been accepted as the standard therapy of indirect hyperbilirubinemia for years (2). Safety of phototherapy is considered more superior than other treatment modalities like exchange transfusion. Side effects of phototherapy are very rare and include bronze baby syndrome, purpuric eruptions in patients with cholestatic hyperbilirubinemia and mild dehydration (3).

Phototherapy can be delivered using several types of irradiation sources, including daylight, white or blue fluorescent bulbs (3). The spectral output of blue fluorescent bulbs is well matched to the absorption spectrum of bilirubin, and these bulbs are recommended by the American Academy of Pediatrics (AAP) for intensive phototherapy. Worldwide fluorescence blue-light phototherapy units use uniform irradiation to photoisomerize bilirubin into products that can be excreted in urine or bile. The light dosage for conventional blue-light fluorescent phototherapy (CFP) is typically 8–10 $\mu Wcm^{-2} nm^{-1}$ in the 430–490 nm band (3).

Recently, a number of phototherapy devices based on blue-light-emitting diodes (LED) have been reported (4, 5). These devices offer several advantages, including long bulb life (>10 000 h), low heat production and potential low cost. Although their number is limited, most studies have suggested that LED phototherapy is as effective as CFP (6, 7).

Although neonatal jaundice is a well-known cause of morbidity (8), phototherapy lights are often not available in the developing world because the estimated cost of phototherapy systems which are most commonly donated to hospitals is between US$3000 and $5000 and replacement of a set of fluorescent bulbs typically costs several hundred dollars (7). Since home phototherapy services are not commonly available, jaundiced neonates must be transferred to major hospitals most of the time. Hospitalization of newborn for phototherapy may cause additional disadvantages.

The objective of this study was to develop a low-cost, easily transportable, light-weight phototherapy system named 'home-type phototherapy system' and test its efficiency in reducing serum bilirubin concentration by comparing it with CFP systems in a prospective controlled multi-center clinical trial.

PATIENTS AND METHODS

Home-type phototherapy unit

The home-type low-cost LED phototherapy unit consists of a plastic tunnel and flexible LED light strips, which emit light within the range of 450–500 nm with a maximum intensity at 470 nm. A total of 6 m LED light strips are placed along the long axes of the tube as seen in Fig. 1. The length of the tunnel is 50 cm, width is 34 cm and height is 36 cm, with a total illuminated area of 1700 cm^2. The distribution of the irradiance in the tunnel is obtained by measuring the light intensity at 20 different locations from one end to the middle of the tunnel. The intensity was highest at the center and lowest at the end of the tunnel. Irradiance of the home-type phototherapy was in the range of

Fig. 1. Illustration of the home-type phototherapy unit. LEDs are placed along the plastic tunnel. The unit can be separated into two parts at the hinges located on the top of the unit and can fit in a 50 cm × 17 cm × 36 cm box for transportation.

16–20 $\mu Wcm^{-2} nm^{-1}$. The difference in the irradiance distribution of light in the tunnel is less than 20%. The unit can be packaged with dimensions of 50 cm × 17 cm × 36 cm and with a weight of less than 2 kg. Therefore, transportation of the home-type phototherapy unit is easy. The unit is a new design and total cost of the unit is expected to be less than $90 in the production stage.

Irradiance of the conventional fluorescence blue-light phototherapy units (Pedilight phototherapy unit GB 918, GE) was measured at different locations and found to be changing at a range of 7–12 $W/cm^2 nm^{-1}$ at a distance of 25 cm from the newborn. During the study, irradiance of the CFP systems were measured before and after the each treatment to be sure that irradiance is the same.

Patient's selection

The study was approved by the Akdeniz University institutional ethics committee. Clinical trials were performed at the hospitals of Akdeniz University and Antalya Research and Training Hospital. Patients with the following characteristics were included: gestational age ≥37 weeks; birth weight ≥2500 g; older than postnatal 4 days; non-hemolytic jaundice; or non-cholestatic jaundice (defined as direct bilirubin <20% of total serum bilirubin levels). Fifty term neonates with neonatal hyperbilirubinemia and indication for phototherapy according to AAP criteria were recruited to participate (2). Neonates with a serum indirect bilirubin (IB) level higher than 20 mg/dL were not recruited to reduce possible risk of kernicterus. Gestational age (weeks), postnatal age (hours), weight, baseline bilirubin level, blood type, direct Coomb's test, glucose-6 phosphatase enzyme activity, thyroid stimulant hormone, free T4 and other medical conditions were recorded. The patients were placed in a baby bed in supine position with a diaper and an eye patch. Patients were sequentially enrolled to receive phototherapy on the home-type unit or a CFP unit consisting of six special blue compact fluorescent bulbs (18W, OSRAM special blue lamp). Four phototherapy units of each type were designated as 'study machines' at each center and were available for the study. At the beginning of the enrollment, new lamps were installed in all CFP units. The LEDs were not changed during the study period. In both groups, each enrolled neonate received phototherapy using a single overhead phototherapy unit. The CFP units were placed at a distance of nearly 25 cm away from the infant. Clinical monitoring was done for side effects of phototherapy like dehydration and skin rash; and a 4 hourly axillary temperature measurement was done to detect episodes of hypothermia or hyperthermia.

Both the systems were planned to be used for 24 hours to measure the efficiency in reducing the bilirubin level. Serum bilirubin levels were obtained after 6 and 24 hours of the therapy, using peripheral venipuncture. Brief periods of discontinuation of phototherapy for feeding the baby or changing nappy were not excluded while calculating total duration of phototherapy.

The rate of decrease of bilirubin (mg $dL^{-1}h^{-1}$) was calculated using the following formula:

$$\text{Rate of decrease} = [(\text{initial bilirubin concentration} - \text{final bilirubin concentration}) / \text{total treatment time}].$$

SPSS for Windows (Statistical Package for the Social Sciences, version 19.0, SPSS Inc., Ill., USA) software was used for statistical evaluation. Distribution of normality was tested with the Shapiro–Wilk test. To compare each variable between groups, Student *t*-tests, including Levene tests for comparison of variances, and Mann–Whitney U tests were used where appropriate. All tests were two-sided, and $p < 0.05$ was considered to be significant.

RESULTS

Out of the 50 neonates, 25 were treated with the home-type phototherapy unit and 25 were treated with the CFP unit. No complications of phototherapy were observed in either group. As seen in Table 1, there was no statistically significant difference ($p > 0.05$) in the cohorts with regard to average value of gestational age, body weight, admission age and average initial bilirubin levels.

Figure 2 shows the average IB concentration for the two groups at the start off, after 6 hours and after 24 hours of phototherapy. For the first 6 hours of the treatment, the average IB level of the patients was lower in the CFP unit as compared to the home-type unit; at the end of 24 hours of the phototherapy, vice versa. The differences among the mean values for both treatment systems were not statistically significant, as seen in Table 2.

Average rate of decrease of IB concentration per hour for the patients treated with the CFP unit and the home-type phototherapy unit are shown in Fig. 3. For the first 6 hours of the phototherapy, the rate of IB level decrease is higher for the CFP unit than the home-type phototherapy unit. At the end of the 24 hours, the average rate of the decrease for the home-type phototherapy unit is higher than the CFP unit as seen in Fig. 3. However, as seen in Table 2, the difference between the average rate of the decrease for first 6 and 24 hours is not statistically significant. As seen in Table 2, there is no statistically significant difference between the data of CFP and home-type phototherapy units.

DISCUSSION

In the presented study, a LED phototherapy unit was specifically designed to be used at home in the treatment of jaundiced neonates. Efficacies of two different phototherapy units, CFP and home-type, have been assessed in reducing the average rate of IB level. In this pilot study, home-type phototherapy using low-cost LED lights was found to be as effective as CFP.

Table 1. Patient characteristics at the beginning of study in both groups

Patient characteristics	Conventional (n: 25)	Home-type (n: 25)	*p*
Gestational age (week)	38.30 ± 0.23	38.18 ± 0.22	0.786
Admission age (hour)	138.3 ± 6.4	133.7 ± 4.7	0.566
Body weight (g)	3206.9 ± 103.5	3234 ± 91.9	0.841
Baseline TSB (mg/dL)	18.07 ± 0.31	18.31 ± 0.31	0.782

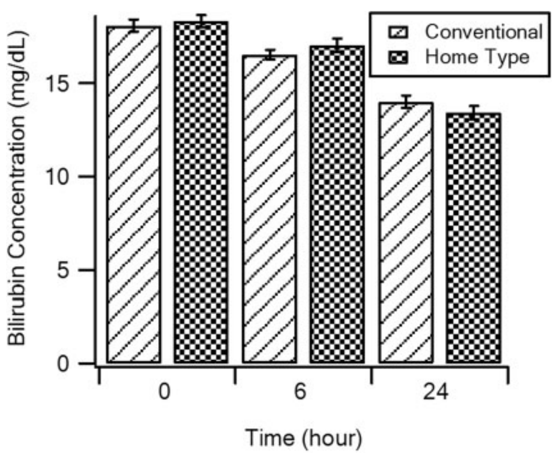

Fig. 2. Average IB levels of the patients before phototherapy, 6 hours and 24 hours after phototherapy using the two units: conventional fluorescence and home-type units.

Although CFP is relatively safe, it still has some side effects like bronze baby syndrome, purpuric eruptions in patients with cholestatic hyperbilirubinemia and mild dehydration. Since LEDs produce a low level of heat, less dehydration could be expected during LED phototherapy compared to CFP (5).

Since home phototherapy is not common, jaundiced neonates must be transferred to hospitals, where relatively expensive blue-light-emitting phototherapy devices are used commonly worldwide. A limited number of studies in literature suggest that LED phototherapy is as effective as conventional phototherapy where LED phototherapy devices were used in hospitals (6, 7). There are several drawbacks of the phototherapy in hospitals such as nosocomial infection risk, additional hospital expenses and separation anxiety of mother and baby. Therefore, effectiveness of phototherapy in home for the treatment of neonatal jaundice has been investigated in several studies by delivering CFP or fiber optic phototherapy systems to home. It has been shown that phototherapy in home is feasible, safe and effective alternative to phototherapy in hospital (9–11). CFP or fiber optic phototherapy systems used at home were actually designed to be used in hospital; therefore, delivering and using them at home needs professional assistant and increased expenses.

The home-type LED phototherapy unit has several advantages over CFP units: first, the home-type unit provides more homogenous irradiation due to its geometric design. Variation of the irradiance in the home-type phototherapy unit is less than 20%, which is much smaller than the standard 40%, accepted for CFP units. The home-type unit is light weight, can be transported easily and there is no need for professional assistant to set up and run it in home.

Irradiance of the light source is one of the most important parameters in the treatment of jaundice. In the assessment of the effectiveness of the light sources used in the treatment should be compared for the same level of irradiance. Irradiance of the CFP unit and the home-type phototherapy unit were in the range of 7–12 $\mu Wcm^{-2} nm^{-1}$ and 16–20 $\mu Wcm^{-2} nm^{-1}$, respectively. Spectra of the CFP unit and home-type phototherapy unit are different from each other as seen in Fig. 4, where the wavelength range of the fluorescence light is broader than the wavelength range of the LED light.

Kumar *et al.* evaluated whether LED phototherapy is as efficacious as compact fluorescent phototherapy for the treatment of jaundice (5). They found that the average rate of the decrease in bilirubin level is 0.19 mg/dL/hours for the irradiance of $>15\ \mu Wcm^{-2} nm^{-1}$. This is close to the result of the home-type phototherapy unit obtained as 0.203 ± 0.026 mg/dL/hour. Colindres *et al.* developed a LED box for treatment of jaundice (12) with a peak irradiation of 21 $\mu Wcm^{-2} nm^{-1}$ from 25 cm and found that the average rate of the decrease in bilirubin level is 0.057 ± 0.045 mg/dL/

Table 2. P-values between the data of conventional and home-type phototherapy units

Total serum bilirubin (TSB) levels and rate of decreases	Conventional (n: 25)	Home-type (n: 25)	*p*
Baseline TSB (mg/dL)	18.07 ± 0.31	18.31 ± 0.31	0.782
TSB level at 6 hours (mg/dL)	16.49 ± 0.25	17.00 ± 0.35	0.250
TSB level at 24 hours (mg/dL)	14.00 ± 0.34	13.40 ± 0.37	0.252
Rate of decrease in 6 hours (mg/dL/hours)	0.25 ± 0.04	0.22 ± 0.02	0.748
Rate of decrease in 24 hours (mg/dL/hours)	0.17 ± 0.02	0.20 ± 0.01	0.104

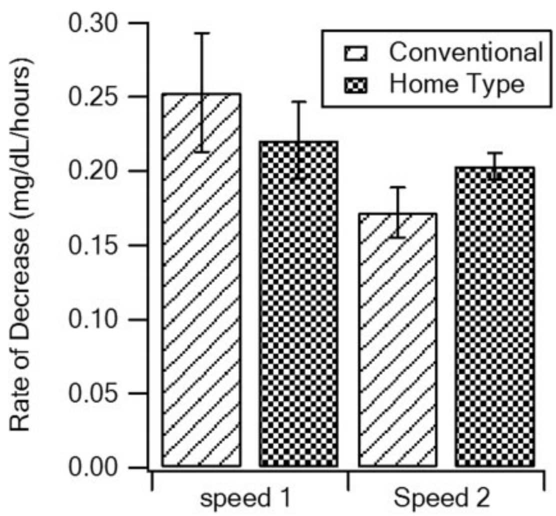

Fig. 3. Average speed in decrease rate of IB levels for the conventional and home-type phototherapy units within 6 and 24 hours.

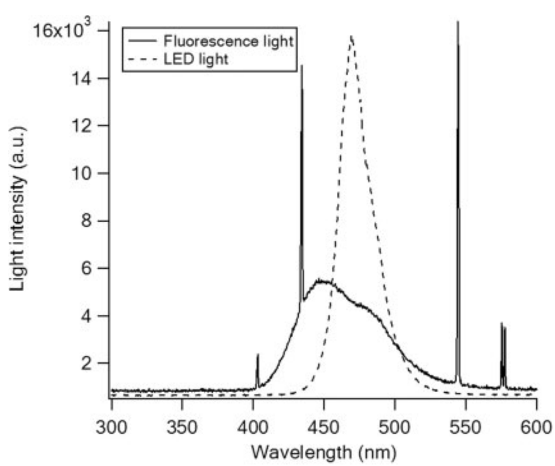

Fig. 4. Emission spectra of the fluorescence light sources and LED used for photodynamic therapy of jaundice.

hours. Karagöl *et al.* used a higher irradiance of LED, 35 μWcm^{-2} nm^{-1}, and found that the average rate of the decrease in bilirubin level is 1.06 ± 0.3 mg/dL/hours, significantly better than the decrease in conventional phototherapy (13).

The home-type LED phototherapy unit should be used at home after clinical evaluation of a newborn by a pediatrician in a hospital. The newborn bilirubin level should be measured in the standard procedure during the treatment by taking the newborn to a clinic. The unit may be rented by a hospital or a medical device distributor to the parents based on approval of a pediatrician. Setup of the device is easy to use at home; user just needs to bring two pieces of the device together and fix them as seen in Fig. 1. In urban area, the device may be preferred to be used at home to overcome infection problem that occurs in hospitals. The device has potential to be used in rural and low-income regions due to low price (expected market price of the device is around $200), light weight and ease of use.

CONCLUSION

The proposed home-type phototherapy unit is as effective as conventional fluorescence phototherapy in the treatment of jaundiced neonates and has the potential to become a standard of care for all jaundiced infants requiring phototherapy with a serum IB level below 20 mg/dL.

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