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DEVELOPING AN EFFECTIVE LOW COST BLUE-GREEN LED PHOTOTHERAPY METHOD FOR NEONATAL JAUNDICE TREATMENT

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Abstract - **Jaundice is an unusual situation in neonatal toddlers and is a scientific signal of excess conjugated or unconjugated hyperbilirubinemia. Phototherapy is the maximum broadly used treatment, and it has proved safe and powerful for over recent years. Compact fluorescent tubes, halogen bulbs, fiber optic blankets, and LEDs are commonly used light sources for phototherapy with varying efficiencies. In recent years, there are several studies reported blue-green LED phototherapy to be effective than conventional phototherapy in term neonates. This research aimed to develop the effectiveness of blue-green LED phototherapy with a larger illuminated area and higher irradiance to conventional phototherapy methods. This lamp device was built with a blue-green LED light source composed of a matrix of 15 x 25 LEDs that generates 460 nm. This device is characterized by being a very compact source with an effective low cost, long life and low energy consumption phototherapy method. The results obtained were comparable with industrially synthetic devices, but being self-made, it grew to become out to be less highly-priced, consequently greater efficient in terms of fitness costs. In this research work conclude that high intensity blue-green LED device was much more effective than conventional phototherapy methods for jaundice photo degradation. Further studies will be necessary to prove its clinical efficiency.**

Keywords - **Neonatal Jaundice, Hyperbilirubinemia, Blue-Green LED phototherapy Treatment**

I. INTRODUCTION

Neonatal Jaundice is the yellow coloration of the skin and mucous membranes produced by the deposit of bilirubin in the skin. About 50% of term newborns and 80% of premature infants develop jaundice, which usually appears between 2 and 4 days of life. When bilirubin levels are very high, they can cause neurotoxicity, with acute or chronic encephalopathy, manifesting clinically as developmental delay, deafness, and seizures [1].

Phototherapy is the treatment of choice to reduce the severity of neonatal hyperbilirubinemia, regardless of its etiology [2]. Phototherapy reduces bilirubin levels by transforming bilirubin into water-soluble isomers that can be eliminated unconjugated in the liver [3]. Like any treatment, the implementation of phototherapy is based on existing evidence-based guidelines that promote its safer and more effective use.

The optimal use of phototherapy has been defined by specific ranges of total serum bilirubin thresholds adjusted for the age of the newborn (in hours) and the potential risk of bilirubin neurotoxicity [2]. Thus, the efficacy of phototherapy in the treatment of hyperbilirubinemia is influenced by the wavelength of light used, the intensity of the light source, the total light dose received (phototherapy time, percentage of exposed skin) [3].

Effective phototherapy involves its use in specific blue light wavelengths (maximum emission, 450 ± 20nm) and emission spectrum (range, 400-520nm), preferably in a narrow bandwidth administered at ≥30μW irradiation. / cm2 / nm up to 45% of the child's body surface [2]. However, this is often not feasible in resource-limited clinical settings where self-made phototherapies are generally used to provide this treatment, but must meet established standards to achieve the ultimate goal: avoiding neurotoxicity [4].

The costs of providing intensive or special care for newborns with jaundice could be prohibitive, after the care of premature infants in low-resource countries [5]. The World Health Organization maintains a valuable compendium of innovative and low-cost technologies, including recommended phototherapy devices for middle-income countries, however, whatever the light source, the effectiveness of phototherapy devices can be seen and compromised by erratic energy supply, inadequate skin exposure from overcrowding with multiple infants placed under a single device, suboptimal irradiation levels, and poor equipment maintenance [6].

For these reasons, the development of affordable and inexpensive phototherapy devices, as well as simple measures such as monitoring light intensity, changing bulbs and cells regularly, and reducing the distance between the child and lamps, can improve the effectiveness of phototherapy [7]. Fluorescent tubes or halogen lamps have been used as light sources for phototherapy for many years. A light-emitting diode (LED) is a newer type of light source that is efficient in energy consumption, has a longer life and is portable with low heat production and is as effective as other light sources in diminishing hyperbilirubinemia, but they have special advantages in some countries. [8].

In several studies conducted on the efficacy of blue-green LED phototherapy compared to conventional (non-LED) phototherapy, blue-green LED phototherapy has been found to be effective in reducing serum total bilirubin levels, at rates similar to light source phototherapy conventional light sources [9]. In a prospective study in term neonates comparing the effectiveness of conventional versus blue-green LED phototherapy, it was shown that the mean duration of phototherapy in the blue-green LED group was significantly shorter than in the conventional phototherapy group (10 hours). Similarly, the rate of decline in serum bilirubin levels at 6, 12, and 18 hours was significantly higher in the blue-green LED group than in the conventional group [10].

In a study carried out in preterm children from 33 to 36 weeks of gestation, it was shown that blue-green LED light devices are more effective than phototherapy with fluorescent tubes in preterm children to reduce indirect hyperbilirubinemia, it is also considered the lower frequency of adverse events, less energy consumption and lower cost of therapy [11]. In summary, phototherapy with blue-green LED technology is more effective than conventional phototherapy by reducing the number of hours of treatment required in term and preterm newborns, therefore reducing the time of hospital stay and with it health costs. The dose of phototherapy, called irradiance, determines its effectiveness. The measurement is carried out in microwatts (μW) / cm² of the body surface of the exposed area / nanometers (nm) of the wavelength. Irradiance depends on the type of light used, the distance between the light and the patient, and the area of exposed skin [12].

To guarantee the effectiveness of phototherapy, it is necessary to monitor the level of irradiance emitted by the equipment, however this is an unusual practice in neonatology units. In a study carried out in 2016, irradiance levels (μW / cm2 / nm) were measured weekly with the BiliBlanket® II Meter device in fluorescent tube phototherapies and blue-green LED phototherapies over a period of 19 weeks. The LED devices showed stable irradiance levels that did not require changing any of the lamps, but the conventional devices did decline their irradiance and required a complete change of lamps at 5 to 6 weeks [13].

In neonatal jaundice ranks second in the top 10 causes of morbidity in children under 1 year of age, with a rate of 220 affected children per 10,000 children under 1 year of age; in ninth place is the hemolytic disease of the newborn, an important cause of jaundice, with a rate of 78 per 10,000, preceded in fifth place by prematurity (rate of 133 per 10,000), which in many cases also present jaundice [14]. Neonatology unit that has 12 beds for admission of children from 0 to 28 days, with an average annual admissions of about 600 patients, of which 50% are admitted for hyperbilirubinemia and require phototherapy. At the moment the Neonatology Unit has two phototherapy lamps with fluorescent tubes and two phototherapy devices with industrial commercialization blue-green LED technology.

For all the above it can be inferred that by optimizing the equipment to provide phototherapy, it is possible to improve the days of stay and therefore the health costs associated with jaundice. Thus, it is necessary to implement new technologies applied to the field of health, take advantage of the availability of technological resources to develop own devices that meet the recommended quality levels and at a lower cost. In this work, it was proposed to develop a proprietary blue-green LED phototherapy device that meets the technical specifications necessary for the treatment of neonatal jaundice and that is comparable in terms of efficacy with other industrially manufactured devices.

II. EXPERIMENTAL METHODS

In the different neonatology units, phototherapy lamps with blue fluorescent tubes are still used, whose spare parts are not easily found on the market and some of them do not have the necessary technical characteristics [15]. The possibility of designing a phototherapy system with blue-green LED technology that allows the treatment of hyperbilirubinemia and whose results based on the effectiveness in the patient are comparable with commercialized blue-green LED phototherapies in the market. This phototherapy device was developed and the follow-up of the evolution of neonatal hyperbilirubinemia was carried out by a specialist in Pediatrics. For the design of the lamp, the technical specifications necessary to comply with the effectiveness of the treatment of jaundice were taken into account (see Table 1) [16].

REQUIREMENT	ESTABLISHED VALUE
Wavelength	450-500nm
Irradiance	30μW / cm2 / nm
Illuminated Area	about 700cm2

Table 1: *Technical Specifications for Phototherapy Equipment for Neonatal Jaundice*

As a light source, a plate with high-power blue-green LEDs, which emit a spectrum of light between 440 and 500nm of wavelength necessary for the objective of treating jaundice (to degrade the bilirubin molecule), as shown see in Fig.1.

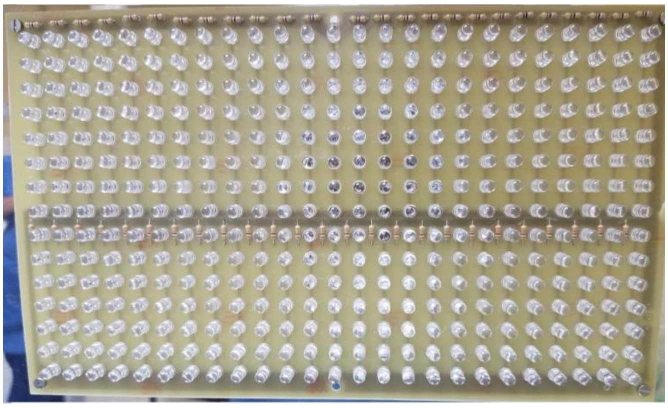

Fig.1: *Phototherapy plate with LED lamps prepared by the authors.*

The number of LEDs needed to generate the parameters required to deliver phototherapy was calculated. The equation that describes the illumination generated by the light source (each LED radiates a certain area) and obtain an approximate calculation to achieve minimum equipment specifications is the following [16]:

$$E = \frac{I\cos(\theta)}{R^2} \qquad (1)$$

Where E is the illumination in lux, I is the light intensity (cd), cos (θ) is the angle generated between the light source and the irradiated area and R is the radius between the light source and the irradiated area. In Fig.2, a computer generated model of the illuminance generated by the LED with apertures from 0 to 180 degrees is presented; With the application of the equation described above and after reviewing the characteristics of different types of LEDs, it was determined that the use of high-power LEDs covers a range of 140°, guaranteeing the correct light distribution necessary to apply effective phototherapy [16].

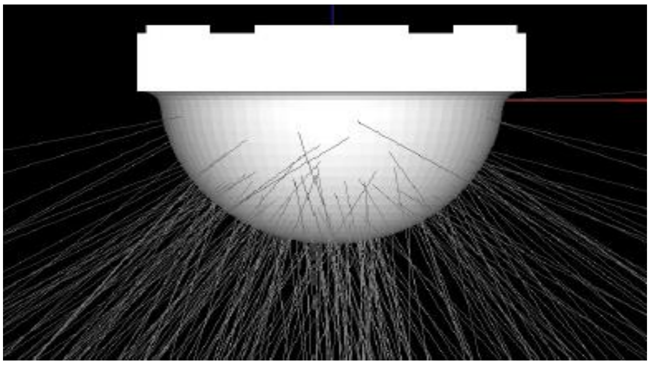

Fig.2: *Tracing the LED rays by light distribution in space according to the calculation provided with an angle of 140 degrees.*

In order to have a correct distribution of the luminous flux and with the calculations made by (1) it was determined that the board requires 375 LEDs. These LEDs were distributed in a 13 × 15 matrix for blue LED and 12 × 15 matrix for green LED, and this in turn divided into 5 sub-matrices of 5 × 15 for the correct control of the excitation of each of the blue-green LEDs are placed in between of each, which is schematically represented in Fig.3.

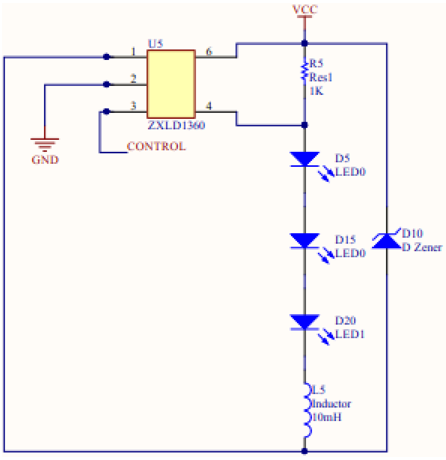

Fig.3: *Phototherapy plate with* blue-green *LED lamps*

The control part of this lamp is controlled by the 16F628 microcontroller and at each of its outputs it feeds each sub-matrix of blue-green LEDs made up of groups of controllers of the ZXLD1360 type. The control system linked and calibrated with the five sub-matrices delivered 460nm which was measured with an optical spectrum analyzer. One of the key parts for the development of the lamp is the correct distribution of irradiation on the exposed skin surface of the newborn, which must be greater than 45% (standard established by the American Academy of Pediatrics) [15]. This device was located on top of a regular crib, whose standard measurements for their beds are 60cm × 30cm, the lamp focuses all this area where the newborn will be located with eye protection.

To corroborate the irradiance (watts of power that affect the bed), a luminous power meter (radiometer) was used, for a specific wavelength (450-500nm) and it was verified at different heights between the bed and the panel. phototherapy from 20cm to 60cm distance, taking into account that one of the direct determinants of irradiance is the distance between the patient and the lamp. To measure clinical efficacy, the time that patients required phototherapy to lower their bilirubin levels to values that did not cause a risk of neurotoxicity was compared, based on the recommendations of the American Academy of Pediatrics that establish predictive normograms of bilirubinemia based on the hours of newborn life and gestational age [15]. These normograms classify newborns as high, intermediate, and low risk for developing hyperbilirubinemia (see Table 2).

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Risk according to patient	Hours of Life							
	12h	**24h**	**36h**	**48h**	**60h**	**72h**	**96h**	**≥120h**
Low	9	12	14	15	17	18	20	21
Intermediate	8	10	12	13	15	16	17	18
Height	6	8	9	11	12	13	14	15

Table 2: *Bilirubin Levels Requiring Phototherapy Treatment*

Distance between light source and patient (cm)	Spectral Irradiance (μW / cm² / nm)
20	95
30	74
40	55
50	40
60	33

Table 3: *Irradiance Levels Delivered*

Lamps with fluorescent tubes (Olidef brand), commercialized lamps with blue-green LED technology (Medix brand MediLed lamp) and the lamp made in this study were compared. For the sample calculation, the average annual admission of children to the Neonatology unit was taken into account, considering that 10% of full-term newborns, without concomitant pathology, develop clinically significant jaundice, with a margin of error of 5% and with a confidence level of 90%, the total number of patients to participate in the study was 84, so it was adjusted to 90, distributing 30 patients to each group, randomly, in order of admission to the unit : Group 1: Phototherapy with commercialized blue-green LED technology, Group 2: Self-made phototherapy and Group 3: Phototherapy of fluorescent tubes; They were placed in a nursery and the lamp at a distance of 50 centimeters from the bed. All lamps had 0 hours of prior use.

The average days of stay under phototherapy, the average rate of reduction of bilirubins in plasma at 24 and 48 hours after admission were calculated. Premature, underweight patients or those with any concomitant pathology that conditions elevated bilirubins were excluded. The study data were entered and analyzed in the IBM SPSS statistical system. A variety analysis was performed using frequency and percentage distributions; To determine differences in clinical efficacy between the teams, the odds ratio was used, with 95% confidence intervals, and p values less than 0.05 were taken as tests of statistical significance.

III. RESULT AND DISCUSSION

Once the blue-green LED phototherapy plate was made, it underwent the respective technical and clinical measurements. First, the irradiance emitted by the equipment was measured using a radiometer. Considering that the irradiance is influenced by the light spectrum (in this case 460nm), exposed body surface (45% of the newborn) and the distance between the phototherapy device and the newborn's bed, the irradiance was measured spectral at different distances between the light source and the patient bed, the results are shown in Table 3. At different distances, our lamp emits optimal levels of irradiance (≥30μW / cm2 / nm) necessary for the reduction of bilirubin levels, so it complies with the standards established by the American Academy of Pediatrics: conventional phototherapy whose irradiance varies from 6 at 12μW / cm2 / nm, and intensive phototherapy reaching 30μW / cm2 / nm [15].

Regarding the results of the clinical application of this self-made blue-green LED lamp, Table 4 summarizes the clinical characteristics of the participants. In all groups, the average weight was between 3000 and 3200 grams, with a gestational age of 39 weeks. Hours of life upon admission to phototherapy ranged from 60 to 70 hours. The average days of stay were around 2 days in the 3 groups. The phototherapy values with which the patients entered the three groups are summarized in Fig.4. It shows that in the group of commercialized blue-green LED Phototherapy the values are in the range of 22 to 7mg / dl, in our Self-made phototherapy from 22 to 10mg / dl and in fluorescent tube lamps from 21 to 10mg / dl.

Parameters	Fluorescent Tubes	Commercialized LED Lamp	Own LED Lamp
Average Weight	3050 grams	3200 grams	3034 grams
Average gestational age	39 weeks	39 weeks	39 weeks
Average age phototherapy	69.8 hours of life	63.2 hours of life	60 hours of life
Average days spent	1.83 days	2 days	2.1 days

Table 4: *Characteristics of the Studies*

After 24 hours of phototherapy, the control values obtained for the commercialized blue-green LED phototherapy were in the range of 20 to 6mg / dl for the phototherapy equipment of own elaboration between 19 and 7mg / dl and in the fluorescent tubes between 18 and 10mg / dl, taking into account that each of the admitted patients had different values of bilirubin that determined their treatment with phototherapy showing a reduction in each one of them.

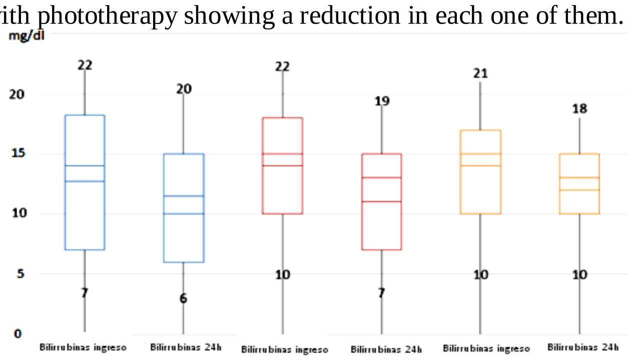

Fig. 4: *Bilirubin values at admission and 24 hours in the 3 phototherapy devices*

The performance of the device was measured by comparing the reduction of bilirubin levels in the 3 groups at 24 and 48 hours after admission. The bilirubin values with which the patients entered phototherapy in the three groups, on average, were 15mg / dl. At 24 hours of treatment it was evidenced that in the 3 groups the average reduction of bilirubin was 2 points (2.25-2.4mg / dl) from 15 to 13mg / dl. When measuring plasma levels at 48 hours in the three groups, the reduction was established between 1.86 and 2.17mg / dl and the values were reduced from 13 to 11mg / dl.

Statistical significance was sought in the reduction of serum bilirubin levels by comparing the reductions recorded by the self-made blue-green LED phototherapy device and fluorescent tubes by calculating odds radius, and a p value of 0.6 was found, likewise the self-made blue-green LED phototherapy device and the commercialized LED lamp were compared and the calculation of p was 1. Thus, in neither of the two cases was a statistically significant difference (value of $p \leq 0.05$) found between applying one or other phototherapy device (see Table 5).

Parameters	**Fluorescent Tubes**	**Commercialized LED Lamp**	**Own LED Lamp**
Average bilirubin at admission	15.8 mg / dl	14.93 mg / dl	15.62 mg / dl
Average bilirubin at 24 hours of phototherapy	13.4 mg / dl (2.4) (p = 0.6)	12.53 mg / dl (2.4) (p = 1)	13.37 mg / dl (2.25)
Average bilirubin at 48 hours of phototherapy	11.3 mg / dl (2.1) (p = 0.62)	10.67 mg / dl (1.86) (p = 1)	11.2 mg / dl (2.17)

Table 5: *Difference of Bilirubin Values for the 3 Devices*

The use of phototherapy for the treatment of jaundice in neonatal patients is the treatment used for more than 30 years, being a safe method to reduce bilirubin indices, and its rate of reduction proportional to light, demonstrating that the greater intensity of irradiation of phototherapy would increase its effectiveness. Phototherapy works by producing structural changes in the bilirubin molecule, due to the effect of light absorption and its subsequent transformation to more soluble molecules for subsequent excretion in urine and bile.

The efficacy of phototherapy depends on the absorption of photons of light by the bilirubin molecules. However, only light of certain colors or wavelengths can be absorbed by bilirubin to achieve this transformation. These reactions occur on the skin and are related to the phototherapy dose measured in irradiance levels [17]. The phototherapy lamp with blue-green LED technology developed in this study demonstrated optimal levels of spectral irradiance that comply with international guidelines and recommendations for the effective treatment of neonatal hyperbilirubinemia, so it can be used effectively for these patients.

The dose of phototherapy, in large part, determines the rate of regression of bilirubin to normal values. With an irradiation standard considered effective, a decrease in bilirubin from 6 to 20% can be obtained in the first 24 hours. Therefore, the higher the irradiation of the phototherapy device, the better and faster its success will be. When intensive phototherapy is used, a drop of 0.5 mg to 1 mg / dl per hour can be expected during the first 4 to 8 hours of therapy [5]. This treatment depends on the type of technology and quality of light source used in phototherapy. Among the most used devices are traditional phototherapy lamps with fluorescent tubes that do not emit a high degree of irradiation (between 6 and 12μW / cm2 / nm) and have a short useful life (1000 hours of use) which implies changes frequent in the tubes to guarantee an effective irradiance thus increasing the costs in the maintenance of the equipment [16].

On the other hand, phototherapy lamps with blue-green LED technology are more effective than phototherapy devices with fluorescent tubes to reduce hyperbilirubinemia, since they emit a greater irradiance (30μW / cm2 / nm or higher), they are easier to place close to the baby (due to lower heat production) and age slower than fluorescent lamps with a longer lifespan (up to 10,000 hours of use), thus maintaining the original irradiance for longer and reducing the need for blue-green LED replacements and hence the maintenance costs [13].

In this study, 3 phototherapy devices were compared (fluorescent tubes, commercialized blue-green LED lamp and the self-made device), and it was shown that the irradiance of the self-made device was superior to the phototherapy of fluorescent tubes and similar to the blue-green LED lamp of commercialization (above 30μW / cm2 / nm) and despite the fact that no statistically significant differences were found in the rate of reduction of bilirubin at 24 and 48 hours, the elaborated device can be used safely and effectively in the treatment of jaundice, in addition to ensuring lower health costs as it was prepared by the hospital staff and did not require replacements in the materials used throughout the study (see Fig. 5).

Fig. 5: *Self-made phototherapy implemented in the treatment of a newborn with jaundice*

IV. CONCLUSION

The blue-green LED phototherapy method was more effective than other conventional phototherapy methods, with a significantly higher bilirubin reduction rate and shorter treatment duration. The phototherapy lamp developed by research work proves to be effective for the phototherapy treatment of Neonatal Jaundice, complying with the required technical specifications, therefore it constitutes a valid alternative for use in neonatal units, and also promotes the development of proprietary technologies as a safe, effective and above all less expensive option compared to industrial manufacturing equipment's.

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