



Neonatal Phototherapy: Monitoring the Optimal Dose

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Received: October 13; 2022
Accepted: November 27, 2022
Posted: December 15, 2022
Editor: Dr. Francisco Xavier Jijón Letort.

Bibliographic letterhead:

Vélez P, Villarreal J. Neonatal phototherapy: Monitoring the optimal dose. Ecuadorian Journal of Pediatrics 2022;23(3):17482 DOI: <https://doi.org/10.52011/169>

e-ISSN: 2737-6494

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Summary

Introduction: Phototherapy is the treatment for neonatal jaundice, but it must ensure a sufficient "dose" of irradiated light in the correct spectral band and over a sufficiently large skin surface. Several types of phototherapy equipment have been developed to meet this technical requirement; even currently on the market, there is high light intensity equipment that allows intensive phototherapy to be applied.

Purpose of the review: This review aims to answer the following questions: How do we determine if phototherapy equipment emits sufficient light intensity to ensure the treatment dose? Regarding equipment maintenance, the leading guideline used in most neonatology units is the number of hours of use, but is it the proper parameter?

Recent findings: With this review, we invite health professionals in neonatology units to speak regarding irradiance, understood as the measure to determine the ideal time for maintenance and replacement of the lights of the phototherapy equipment and thus ensure an effective treatment in neonates.

Conclusion: Devices with LED technology must be verified with irradiance emissions $> 10 \mu\text{W}/\text{cm}^2/\text{nm}$ to guarantee bilirubin degradation.

Keywords:

MESH: phototherapy, neonatal jaundice, ultraviolet rays.

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Introduction

One of the leading causes of admission to neonatology services is jaundice; approximately 50% of full-term infants and 80% of preterm infants develop jaundice, usually between 2 and 4 days of life [1].

In Ecuador, this pathology of the newborn ranks second among the ten leading causes of morbidity in children under one year of age, with a rate of 220 affected children per 10,000. In ninth place is hemolytic disease of the newborn, an essential 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 most cases also presents jaundice [2].

The deposit of bilirubin in the skin causes jaundice. Unconjugated bilirubin can cause neurotoxicity, with acute or chronic encephalopathy, manifesting clinically as developmental delay, deafness, and seizures, with phototherapy being the treatment of choice to reduce the severity of neonatal hyperbilirubinemia [3].

Phototherapy for the treatment of jaundice in neonatal patients has been used for more than 30 years. Phototherapy reduces bilirubin levels by transforming them into water-soluble isomers that bypass the liver and can more easily eliminate them [4].

There are different methods of providing phototherapy for the treatment of jaundice. Fluorescent tubes and 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 energy efficient, has a longer life, has low heat output and is as effective as other light sources in decreasing hyperbilirubinemia [5].

However, after the care of preterm infants, the costs of providing intensive or special care for newborns with jaundice may be restrictive in low-income countries or low-resource hospital settings, as are most public health institutions in Ecuador [6].

When the parameters for monitoring the operation of medical equipment have not been standardized or are based on recommendations with little scientific support, they often produce therapeutic failures that delay the recovery of the health of patients, which is why the health personnel who work in the neonatol-

ogy units must know the parameters to take into account in the maintenance of their equipment and thus guarantee that the treatment provided is adequate.

Phototherapy lamps

Phototherapy is the first step in the treatment of hyperbilirubinemia in newborns. It is a safe and convenient method to reduce serum bilirubin levels, avoid neurotoxicity, and use invasive treatments such as "exchange transfusion" [7].

The mechanism of action of phototherapy is produced by structural changes in the bilirubin molecule due to the effect of light absorption and its consequent transformation to more soluble molecules for its subsequent elimination. These reactions occur in the extravascular space of the skin and are related to the dose of phototherapy [8].

To initiate the light reaction for the treatment of jaundice, the bilirubin molecule must absorb a photon of light; however, not all photons have the same possibility of being absorbed, and this possibility is given by the wavelength of the photon light, which to be effective must be in the range close to 460 nm, the range in which blue light is found [9].

Phototherapy, as a treatment for neonatal hyperbilirubinemia, depends on how far the skin is from the light source and how light penetrates the skin barrier to allow the conversion of bilirubin molecules; in vivo activity is influenced by several factors, such as the ability of the light ray to penetrate the skin and the deviation of the wavelength curve due to the presence of fatty acids bound to albumin [10].

Different phototherapy equipment is used throughout the world to manage neonatal jaundice. Currently, two types of phototherapy devices are available: conventional phototherapy light and fiber optic phototherapy devices. Conventional light sources include broad-spectrum fluorescent or tungsten halogen lamps and narrow-spectrum LED lights [11].

Halogen lamp systems are characterized by having broadband radiation sources, but their emission spectrum only partially overlaps the bilirubin absorption spectrum. Quartz halogen bulbs emit white light and tend to heat up quickly, and filtration may be required prior to phototherapy [12].

Fluorescent tubes were the most widely used type of light source. The first fluorescent lamps used for phototherapy emitted light spectra in the violet (419 ± 33 nm) and blue (447 ± 51 nm) regions [8]. Unique blue fluorescent lamps with light spectra of 450 ± 50 nm were manufactured some years ago for phototherapy to treat hyperbilirubinemia [1]. They had the advantage of being inexpensive, but their light intensity and irradiance decreased over time and needed to be changed after 1000–1500 hours [1].

On the other hand, LED light systems are the most recent lamps. They have the advantage of allowing the intensity of irradiation to be attenuated or increased using a single piece of equipment. An LED is a type of semiconductor diode that emits light when connected to an electrical circuit [4].

LEDs are characterized because they generate less heat loss than conventional lamps. They have a longer useful life than halogen lamps (10,000 hours) and can also be adapted to the user's needs. LEDs have helpful features such as being lightweight and compact; they are more resistant due to the absence of glass parts and the ability to focus with a lens or by spatial orientation, in addition to offering low power consumption [8].

When regulated, the light color remains almost constant; the point light source allows directing the light with complete accuracy thanks to the encapsulation of the diode with synthetic material that fulfills the functions of protection and lens [5].

The useful life of LED phototherapy equipment

In neonatology rooms, the usual procedure for maintaining phototherapy equipment in service and monitoring the level of light emission necessary for treatment is to record the hours of use and replace the lamps upon arrival at the established maximum. With this replacement, it is trusted that the equipment will be in condition to carry out the treatment.

However, these maximum hours of use vary from equipment to equipment, from 800 to 10,000 hours. There is no standardized level for this range of hours of use or precise rules on issues as necessary as, for example, the type of lamp, the wavelength of the radiation used (blue, white, or green), manufacturer's

standards, the influence of continuous versus intermittent use, the number of on/off cycles, the supply voltage and the quality of the electrical supply, the temperature of the room, and others of equal importance.

Currently, there is no standard for calculating the useful life of LEDs, but a very long life is assumed (more than 10,000 hours). The LED rarely has a total failure, although it suffers a slow loss process in a performance called light degradation. Generally, a slight level of light reduction in a short time is moderately essential as long as it does not reach a set percentage (80% mostly) of its initial value [6].

LEDs are characterized by the fact that they do not fail abruptly; their luminous power decreases over time. Its useful life is based on the light maintenance factor of the lamp, which is the amount of light emitted by the source at a specific time in the future. The useful life is known as L_{xx} , where "xx" is the percentage of light remaining after a certain number of hours of use. For example, if a lamp has a record of L_{80} at 10,000 hours, it means that after 10,000 hours of use, the LED will emit 80% of the light that it was initially capable of emitting [15].

With the advent of LED lighting, different standards and terminologies have been established to define the useful life of conventional lamps; the most used are those recommended by the "Illuminating Engineering Society of North America." This organization designed a series of standards, including the LM-80 standard, that is used to measure the depreciation of the luminous flux (lumen) of LED light sources based on a test period of between 6,000 and 10,000 hours (Figure 1) [17]. All this summarizes that the useful life of LEDs is not measured only in hours but in the percentage of luminous flux emitted, and this is the basis to take into account for scheduled maintenance and change of luminaires in phototherapy equipment.

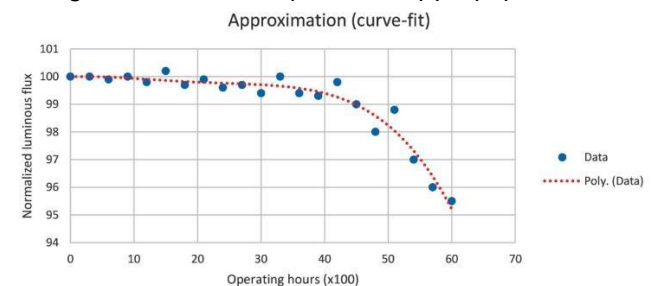


Figure 1. LM-80 standard application.

Irradiance or phototherapy dose

The American Academy of Pediatrics (AAP) has established that the characteristics that phototherapy equipment must meet to provide adequate treatment include the emission of a spectrum of light between blue and green (460–490 nm range) that allows the degradation of bilirubin [1], positioning the emission peak between 460 ± 10 nm and finally, the uniformity in the intensity of the irradiance delivered and the time of use of the light source [8]. In summary, the AAP presents the "dose" of phototherapy required to achieve the treatment objective: to reduce hyperbilirubinemia, thus introducing the term irradiance.

Irradiance refers to the number of photons received per square centimeter of the exposed body surface and is quantified as $\mu\text{W}/\text{cm}^2$. When measured within a specific wavelength range (effective for treatment), it is known as "spectral irradiance" and is expressed as $\mu\text{W}/\text{cm}^2/\text{nm}$. On the other hand, "deliverable spectral irradiance" is different for each type of light source. It depends on its geometric design and the distance between the light source and the patient in an inverse relationship, where the irradiance will increase as the light source increases. The light source moves closer to the patient [9].

The spectral irradiance, as well as the amount of a drug, determines the efficacy of the treatment, and therefore, a higher dose would be associated with greater efficacy [5]. Thus, a study carried out in Denmark on LED-type phototherapies showed that when the irradiance increased from 20 to 55 $\mu\text{W}/\text{cm}^2/\text{nm}$, the rate of bilirubin reduction also increased approximately from 30% to 50%, and no tendency was shown to decrease. Stabilization occurs as irradiance increases, with no evidence of a saturation point [10].

On the other hand, the effective dose of phototherapy depends on the amount of exposed body surface area in the newborn. The larger the exposed area, the greater the rate of bilirubin decline [4]. In clinical practice, exposure is usually flat: ventral with overhead light sources and dorsal with illuminated mattresses, and approximately 35% of the total body surface area (ventral or dorsal) is exposed with either method [22].

It should also be considered that some areas of the body, such as those between the fingers and the buttocks, are generally not effectively accessible by

light; the use of eye shields, diapers, and other possible body coverings can significantly interfere with the delivery of therapeutic light to the body [3]. Currently, the limited exposure of the newborn area by all light sources is the most significant impediment to more effective phototherapy [19].

Eliminating subjectivity

One of the ways to assess the effectiveness of phototherapy is to monitor the irradiance level, an unusual practice in neonatology units because, although it is not necessary to measure the irradiance spectrum before each phototherapy session, periodic checks are essential to determine if the proper irradiance is being used [22].

However, these measurements must be standardized so that the studies are comparative. To overcome this drawback and quantify irradiance distribution patterns, a standardized "fingerprint" method was designed. This footprint was based on average data for the surface area of an infant's skin, which can range from 1281 cm^2 at 28 weeks to 2200 cm^2 at 38 weeks [23, 24], which, depending on the irradiance pattern, can be reduced to 430 cm^2 and 710 cm^2 for premature and full-term infants, respectively (Figure 2) [25].

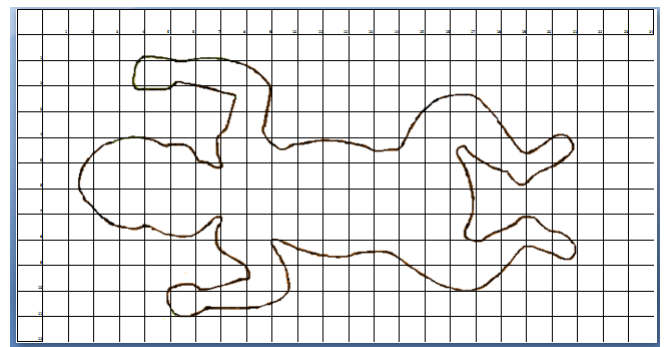


Figure 2. Neonate silhouette for standardized footprint

Once the footprint is established, the minimum, maximum, and mean irradiance values are determined within the entire footprint illuminated at different heights between the bed and the phototherapy panel: 60 centimeters for fluorescent tube lamps (minimum distance between the patient and the lamp) and at distances of 40 and 20 centimeters for LED lamps, taking into account that one of the direct determinants of

irradiance is the distance between the patient and the lamp [19, 23].

With this, the values obtained from each piece of equipment are compared with the standards established by the AAP: irradiance for conventional phototherapy must be equal to or greater than $10 \mu\text{W}/\text{cm}^2/\text{nm}$ and for intensive phototherapy, equal to or greater than $30 \mu\text{W}/\text{cm}^2/\text{nm}$ [22].

According to each type of light source, it has been determined that the emitted irradiance is not uniform throughout the footprint. The irradiance is highest in the center of the footprint and decreases toward the periphery [26]. Only one-third of the exposed area is estimated to be irradiated by a source extended over the newborn. All light reaching the baby from the source is assumed to be in a single plane, which is true of most phototherapy lamps today (Figure 3) [21].

Borden et al. developed a study to determine the effectiveness of phototherapy devices in some US hospitals, measuring maximum and mean footprint irradiances using a handheld irradiance meter. They demonstrated that despite established phototherapy guidelines, protocols and practices vary locally, and most impressively, 62% of phototherapy devices registered suboptimal levels for intensive phototherapy ($25.8 \pm 6.1 \mu\text{W}/\text{cm}^2/\text{nm}$), registering the highest levels in the center of the light footprint, as expected [21].

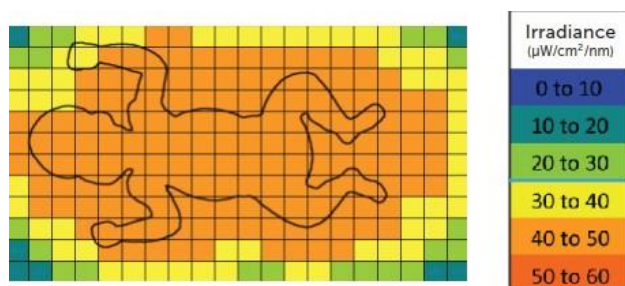


Figure 3. Irradiance distribution by standardized footprint.

Importance of measuring irradiance

Routine irradiance measurement is unusual in neonatology units, and when done, it is only sometimes done correctly. As a result, these practices can result in clinically unreliable and inaccurate phototherapy dose assessments, resulting in ineffective phototherapy and consequent prolongation of treatment duration, over-treatment due to a low meter reading, or delayed or expedited replacement of bulbs or spare parts [9].

In 2011, the Committee on the Fetus and Newborn of the American Academy of Pediatrics emphasized the importance of monitoring the intensities and spectral results of phototherapy devices to predict the effectiveness of phototherapy for neonatal hyperbilirubinemia [22].

In 2014, a study was conducted in Nigeria to measure irradiance variation over time in devices with LED technology and fluorescent tubes. Irradiance levels were measured weekly over 19 weeks. The LED fixtures showed stable irradiance levels and did not require lamp changes. The fluorescent tube-based devices showed a rapid decrease in irradiance (up to 65% of initial), and all required three complete lamp changes approximately every 5–6 weeks. This study was conducted in the context of the lack of routine monitoring of irradiance levels of phototherapy devices in most clinical settings, as well as several reports finding that the use of suboptimal irradiance phototherapy devices is widespread [27].

In India, Pejaver and Vishwanath audited irradiance levels based on the age of the devices and the type of light. A total of 58 devices were examined at 24 centers providing neonatal care. Of these, only 18 devices (31%) provided an acceptable level of irradiance, and only 5 of the devices (8.6%) had the recommended unique blue lights [8].

In Brazil, a total of 36 phototherapy devices were studied in 6 maternity hospitals, and it was found that 28% of the devices emitted irradiances lower than $4 \mu\text{W}/\text{cm}^2/\text{nm}$; it was verified that the devices with LED technology showed irradiance above $10 \mu\text{W}/\text{cm}^2/\text{nm}$, establishing a rapid and effective therapy in terms of emitted irradiation. Notably, 50% of the maternity hospitals did not have radiometers to monitor this irradiance. This lack of monitoring equipment demonstrates the interest of the neonatology unit in the preventive maintenance of phototherapy equipment [9].

In Nigeria, Owa and others studied 63 phototherapy devices, but only 6% provided an irradiance level of $10 \mu\text{W}/\text{cm}^2/\text{nm}$ or more and 75% less than $5 \mu\text{W}/\text{cm}^2/\text{nm}$ [30].

As seen in these studies and more, routine irradiance measurement should be considered one of the standards in maintaining phototherapy equipment so that effective treatment is guaranteed.

In a study in Egypt that evaluated the irradiance levels delivered by phototherapy devices, it was shown that the irradiance levels were variable, with LED devices producing a double level than fluorescent lamps. Regarding fluorescent lamps, approximately 30% of the devices presented levels unsuitable for intensive phototherapy, and the uniformity in the irradiance distribution was much lower [26].

More recently, in Indonesia in 2019, it was shown that the irradiance levels were too low ($\leq 10 \mu\text{W}/\text{cm}^2/\text{nm}$), and in other devices, intensive phototherapy levels were not reached: $30 \mu\text{W}/\text{cm}^2/\text{nm}$. Only three hospitals provided very high irradiation levels: $> 50 \mu\text{W}/\text{cm}^2/\text{nm}$. A notably influential factor was that half of the distances between the device and the bed were more significant than what was recommended by the manufacturers. The distance was inversely correlated with irradiance levels [8].

It has been shown that if factors directly influencing irradiance are taken into account, the performance of phototherapy is remarkably improved. For example, 76 phototherapy devices from 16 hospitals in Nigeria were evaluated before and after adjustments, such as reducing the distance between the device and the bed, changing bulbs, and removing obstacles between the patient and the device. The mean irradiance of all phototherapy devices was $7.6 \pm 5.9 \mu\text{W}/\text{cm}^2/\text{nm}$, and 38% of the devices were below the minimum irradiance ($5 \mu\text{W}/\text{cm}^2/\text{nm}$). When the adjustments above were made, the mean spectral irradiance of the devices was significantly improved from $9.0 \pm 6.6 \mu\text{W}/\text{cm}^2/\text{nm}$ to $27.3 \pm 5.2 \mu\text{W}/\text{cm}^2/\text{nm}$ ($P < 0.001$). Thus, it was shown that simple adjustments to the devices make a large difference in the emitted phototherapy dose [32].

In a comparative study by Hulzebos et al. in the Netherlands in 2008 and 2013, significant improvements in the irradiance level of phototherapy devices in Dutch NICUs were demonstrated since 2008 with simple and practical recommendations such as irradiance measurement before and during the use of phototherapy devices, regular maintenance of the devices, and limiting the distance between the device and the neonate, according to the manufacturer's recommendations. In 2008, only 40% of phototherapy devices reached irradiance levels greater than $10 \mu\text{W}/\text{cm}^2/\text{nm}$. However, in 2013, 80% of the devices

reached an irradiance more significant than this value, demonstrating the importance of measurement of irradiance to provide an effective dose [4, 33].

The convenience of carrying out spectral measurements of neonatal phototherapy light sources has already been described. A wide range of spectrometer and radiometer systems can provide such measurement capability in the visible spectrum; however, such instruments are not routinely used by maintenance personnel and must meet certain specifications, such as the ability to measure a specific light spectrum in terms of neonatal phototherapy.

Conclusions

The maintenance of phototherapy equipment has particularities. Currently, there are no spare parts with adequate characteristics for fluorescent tubes (they do not comply with the recommended light spectrum); the cost of spare parts for LED light plates is high for public hospitals, which is why neonatology units must consider the measurement of irradiance as part of the preventive maintenance of phototherapy equipment and thus guarantee the quality of neonatal jaundice treatment. Devices with LED technology must be verified with irradiance emissions $> 10 \mu\text{W}/\text{cm}^2/\text{nm}$ to guarantee bilirubin degradation.

Abbreviations

LED: light-emitting diode.

Supplementary information

No supplementary materials are declared.

Acknowledgments

Does not apply.

Author contributions

Paola Vélez Pinos: Conceptualization, Data conservation, Acquisition of funds, Research, Resources, Software, Writing original draft.
Jorge Villarreal Altamirano: Conceptualization, Data conservation, Supervision, Acquisition of funds, Research, Resources, Writing: review and editing.
All authors read and approved the final version of the manuscript.

Financing

The authors financed the expenses incurred in the production of this research.

Availability of data and materials

The data sets generated and analyzed during the current study are not publicly available due to participant confidentiality but are available through the corresponding author upon reasonable scholarly request.

Statements

Ethics committee approval and consent to participate

It was not required for a narrative review.

Publication Consent

This does not apply to studies that do not publish MRI/CT/Rx images or physical examination photographs.

Conflicts of interest

The authors declare they have no conflicts of interest.

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PMid:28252660

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