Variation in the Phototherapy Practices and Irradiance of Devices in a Major Metropolitan Area

Amy R. Borden^a Katie M. Satrom^b Paul Wratkowski^b Thomas N. George^b
Constance A. Adkisson^c Hendrik J. Vreman^e Austin P. Johnson^d
Kent J. Nichols^d Tina M. Slusher^{b, c}

^aChildren's Minnesota, Saint Paul, MN, ^bDepartment of Pediatrics, University of Minnesota, ^cHennepin County Medical Center, and ^dUniversity of Minnesota Medical School, Minneapolis, MN, and ^eDepartment of Pediatrics, Stanford University School of Medicine, Stanford, CA, USA

Keywords

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Abstract

Background: Phototherapy (PT) is widely used to prevent and treat severe hyperbilirubinemia and its associated risks for both acute and chronic bilirubin encephalopathy. Intensive PT, recommended for inpatient treatment of hyperbilirubinemia in term and near-term infants, is defined as having a spectral irradiance of $\geq 30 \mu\text{W}/\text{cm}^2/\text{nm}$. **Objectives:** We aimed to assess local PT practices by measuring the irradiance of PT devices in local neonatal intensive care units and newborn nurseries. **Methods:** The irradiance footprint, including maximum irradiance at the center of the footprint, of 39 PT devices in 7 area hospitals was measured according to current practice in these facilities. **Results:** The mean $\pm$ SD (range) footprint irradiance was 20.7 ± 5.8 (8.8–29.4) $\mu\text{W}/\text{cm}^2/\text{nm}$. The mean $\pm$ SD maximum irradiance at the footprint center for all devices at a mean clinically used treatment distance of 33.1 ± 9.3 (25.5–60.0) cm was 27.8 ± 7.0

(14.7–42.0) $\mu\text{W}/\text{cm}^2/\text{nm}$. Sixty-two percent of the devices did not meet the minimum recommended spectral irradiance for intensive PT. For the sites without irradiance-based protocols, the maximum irradiance of the devices ($n = 33$) at the treatment distances was $25.8 \pm 6.1 \mu\text{W}/\text{cm}^2/\text{nm}$. **Conclusions:** Despite established PT guidelines, local protocols and practices vary. Based on an assessment of 7 local hospitals, intensive PT was suboptimal for 62% of devices. Straightforward changes, such as decreasing the distance between an infant and the light source and establishing a consistent irradiance-based protocol, could substantially improve the quality of the intervention.

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Introduction

Neonatal hyperbilirubinemia is common worldwide, affecting at least 60% of term and near-term neonates [1]. Globally, severe hyperbilirubinemia has been estimated to affect at least 481,000 neonates annually. Of these infants, >63,000 survive with moderate to severe long-term

disability [2], including hearing loss, choreoathetoid cerebral palsy, developmental delay, and other neurological impairments [3]. A divide remains between the incidence of severe hyperbilirubinemia in high- versus low- and middle-income countries [4]; in high-income countries, it is reported to be 31.6/100,000 live births [4–8]. The incidence of bilirubin encephalopathy in the USA is approximately 1/27,000–55,000 live births [9]. Severe hyperbilirubinemia has been gaining recognition among the world's leaders in health policy research as an important clinical and public health issue that needs further attention [10], as there has been concern about a possible reemergence of bilirubin encephalopathy in the USA as well as other regions of the world [10].

Phototherapy (PT) is the standard treatment for neonatal hyperbilirubinemia. Since its advent 60 years ago, PT has reduced the need for exchange transfusions and improved the neurodevelopmental outcomes of infants with jaundice caused by hyperbilirubinemia [11]. The efficacy of PT is quantified, in part, by the intensity or irradiance that the light source can deliver, the dimensions of the irradiance footprint relative to the patient's body surface area (BSA), and the duration of treatment. Irradiance is measured with a spectroradiometer and is usually expressed in terms of microwatts per square centimeter per nanometer over a given wavelength range, usually 400–520 nm. Irradiance is not only determined by the intensity delivered by the light source, but also the distance between the light source and the skin to be treated [1]. Also important is the area that can be treated by a given light source or the size of the light footprint. Furthermore, irradiance is highest in the center of the light footprint and decreases towards the periphery [12]. The current recommendations of the American Academy of Pediatrics (AAP) for PT state that a conventional PT device should deliver a spectral irradiance of 8–10 $\mu\text{W}/\text{cm}^2/\text{nm}$ in the bandwidth of 430–490 nm, and intensive PT should have a spectral irradiance of at least 30 $\mu\text{W}/\text{cm}^2/\text{nm}$ over the same bandwidth, delivered to as much of the infant's BSA as possible [13].

Over the past 20 years, several studies have evaluated the irradiance of local PT devices. A number of these have demonstrated that devices in resource-limited countries deliver subtherapeutic PT [14–16]. In addition, van Imhoff et al. [17] found that a startling 50% of PT devices in The Netherlands failed to meet even the minimum recommended irradiance levels. In light of these prior studies, the objective of our study was to determine the effectiveness of PT devices in the hospitals of a major US city, by measuring the maximum and mean footprint irradiances using a handheld irradiance meter.

Fig. 1. Phototherapy device measurement set-up that involves a 3.8×3.8 cm grid, measuring 34.2×45.6 cm, to model the anterior surface area of a typical term infant. Irradiance was measured at the center of each square in the grid using an Ohmeda Medical BiliBlanket[®] Meter II (GE Healthcare, Maple Grove, MN, USA).

Methods

The irradiance of 39 overhead PT devices at 7 area hospitals, including 2 academic centers and 5 community hospitals, was measured according to the current practice guidelines at each facility. Both neonatal intensive care units (NICUs) and newborn nurseries were included. As no human subjects were directly participating, IRB waivers were obtained from all governing bodies. At each site, a nurse manager or charge nurse demonstrated the typical PT set-up based on the general practices, policies, and/or protocols at each institution. The distance from the light source to the infant, the use of an isolette versus a crib, and the existence of a PT protocol varied. Clinically used treatment practices at each site were replicated for measurements at that specific site.

Irradiance was measured using the Ohmeda Medical BiliBlanket[®] Meter II (GE Healthcare, Maple Grove, MN, USA). This meter measures a spectral range of 400–520 nm with a center wavelength of 450 nm and a bandwidth of 60 nm. The measuring range of its spectral irradiance is 0.1–299.9 $\mu\text{W}/\text{cm}^2/\text{nm}$. According to the manufacturer's instructions (GE Healthcare, 2012), the device can be used to measure irradiance from LED, fluorescent, halogen, and fiberoptic PT devices.

The irradiance was measured using a footprint, a 3.8×3.8 cm grid with a maximum 34.2-cm width and 45.6-cm length, with a total of 90 squares, in order to model the exposed anterior surface area of a typical term infant, adapted from Vreman et al. [14]. Each of the 90 squares/footprint was measured once. Two measurements were calculated for every PT device: the mean irradiance of all of the footprint's individual irradiance measurements (90 measurements/grid) and the single maximum irradiance as measured at the very center of the grid. The depth of a term neonate's trunk is approximately 10 cm [18], which was accounted for by the combined depth of a 7-cm-high square box and the 3-cm-high irradiance meter.

Table 1. Summary of site protocols including number of devices measured, type of device at each site, type of light source, presence of a phototherapy protocol, the use of isolette versus crib, and typical treatment distance from light source based on local practice guidelines

Site	Number of devices measured	Type of device	Light source ^a	Protocol	Isolette vs. crib	Mean $\pm$ SD (range) time device was in use, h	Treatment distance
1	15	Dräger 4000	blue + white	no	isolette	5,127 $\pm$ 2,199 (497–10,311)	30 cm
2	13	Dräger 4000	blue + white	no	both	14,907 $\pm$ 12,289 (1,355–36,215)	31 cm
		Natus neoBlue	LED	no	both	3,836 $\pm$ 978 (2,747–4,638)	31 cm
		Dräger 8004	white	no	both	not recorded	60 cm ^b
3	3	Natus neoBlue	LED	no	both	not recorded	30 cm
4	2	Natus neoBlue	LED	no	both	8,195 $\pm$ 722 (7,685–8,706)	none, i.e., as close to baby as possible
5	1	Natus neoBlue	LED	yes	both	2,620	none (based on measured irradiance)
6	2	Dräger 4000	blue + white	yes	both	470 $\pm$ 477 (133–807)	none (based on measured irradiance)
7	3	Dräger 4000	blue + white	yes	both	1,198 $\pm$ 147 (1,034–1,319)	none (based on measured irradiance)

^a Blue, blue-fluorescent lamp; white, white halogen lamp.

^b The site used 3 types of phototherapy devices, 2 with an isolette or crib at a distance of 30 cm from the light source; a third device was only used with a crib at a distance of 60 cm from the light source.

The light source was centered directly over the grid at a set distance above the irradiance meter, according to the clinically used distance at each site (Fig. 1). An isolette or crib was used for these measurements based on the standard practices at each hospital. All sites that utilized isolettes placed the light source as close to the top of the isolette as possible without touching the Plexiglass. This distance was initially measured at 2 cm, and then replicated throughout the study, when appropriate. Additional measurements were then taken at distances of 20 and 15 cm from the infant to the light source, to demonstrate how irradiance changes with distance.

In addition to the above measurements, information was collected for each PT device, including the brand, model No., type of lamp, number of lamps, and any nonworking devices or lamps. Information was also obtained from equipment management personnel about the maintenance of the devices and how often the lamps are checked and replaced.

Results

Treatment practices and the presence of a PT protocol were found to vary widely between sites, even for those belonging to the same healthcare affiliate. Three of the 7 sites adjusted the PT device based on height; only 1 of

these 3 measured a standardized distance, and height was estimated at the other 2. At 2 sites, the height was based on the fixed distance of the adjunct equipment being used.

Three additional sites had established protocols that determined the distance from the light source, based on a target irradiance of $\geq 30 \mu\text{W}/\text{cm}^2/\text{nm}$. At these sites, irradiance was measured in the center of the light footprint and the infant was placed at a height needed to achieve the target irradiance. Irradiance was remeasured at a set time throughout a 24-h period (i.e., every 8 h). The final site had no set standard for height or irradiance.

All sites, except for one, had a single type of PT device. Six sites recorded the number of hours the lights had been in use (Table 1). All of the units with blue and/or white lights had functioning lamps. Each location inspected the devices on an annual basis.

The mean $\pm$ SD (range) clinically used treatment distance from lamp to infant for all sites was 33.1 ± 9.3 (25.5–60) cm. The mean of all maximum irradiances at the footprint center for all devices at this distance, as measured, was 27.8 ± 7.0 (14.7–42.0) $\mu\text{W}/\text{cm}^2/\text{nm}$. Twenty-four

Table 2. Maximum and mean irradiance at the clinically used treatment distance and maximum irradiance at 20 and 15 cm

	At site 1 (<i>n</i> = 15)	At site 2 (<i>n</i> = 13)	At site 3 (<i>n</i> = 3)	At site 4 (<i>n</i> = 2)	At site 5 (<i>n</i> = 1)	At site 6 (<i>n</i> = 2)	At site 7 (<i>n</i> = 3)
Irradiance at the treatment distance, $\mu\text{W}/\text{cm}^2/\text{nm}$							
Maximum	24.9 (4.7)	24.1 (6.9)	35 (0.9)	36.4 (0.2)	54.6	30.7 (2.3)	40.9 (1.0)
Mean	19.6 (3.3)	16.8 (5.1)	25.0 (0.8)	23.6 (0.1)	37.2	23.5 (2.0)	29.2 (0.5)
Maximum irradiance, $\mu\text{W}/\text{cm}^2/\text{nm}$							
At 20 cm	42.8 (6.9)	36.1 (7.9)	46.1 (2.4)	42.5 (0.1)			
At 15 cm	60.6 (9.9)	43.7 (11.7)	51.4 (3.9)	46.4 (0.0)			

Values are expressed as mean (SD). *n*, number of phototherapy devices per site. Sites 5–7 had irradiance-based protocols and the distance was therefore not changed.

(62%) of the devices did not meet the minimum recommended spectral irradiance for intensive PT of $\geq 30 \mu\text{W}/\text{cm}^2/\text{nm}$. The mean footprint irradiance based on all data points along the grid of each device was 20.7 ± 5.8 (8.8–29.4) $\mu\text{W}/\text{cm}^2/\text{nm}$.

For the sites without irradiance-based protocols (*n* = 33), the maximum irradiance at the footprint center of all devices at the treatment distance was $25.8 \pm 6.1 \mu\text{W}/\text{cm}^2/\text{nm}$. For 73% of the devices, it was $<30 \mu\text{W}/\text{cm}^2/\text{nm}$. When the distance from infant to device was decreased to 20 cm from the light source, the maximum irradiance at the footprint center was $40.9 \pm 7.4 \mu\text{W}/\text{cm}^2/\text{nm}$. At 15 cm, the maximum irradiance was $53.1 \pm 12.4 \mu\text{W}/\text{cm}^2/\text{nm}$ and it was $\geq 30 \mu\text{W}/\text{cm}^2/\text{nm}$ for 85% of the devices (Table 2).

Discussion

Our results demonstrate that clinical practice does not always deliver intensive PT, as measured by the irradiance level delivered by the PT device. This conclusion is consistent with data worldwide that reveal a shortcoming in our ability to consistently and optimally treat infants with neonatal hyperbilirubinemia [15, 17–20].

To assess the irradiance of PT devices in local hospitals, maximum and mean footprint irradiance levels were measured under current standardized conditions. Although appropriate standards for mean footprint irradiances have not yet been formalized, none of the units had a footprint irradiance of $\geq 30 \mu\text{W}/\text{cm}^2/\text{nm}$. Notably, mean footprint irradiance has been shown to be a more accurate approximation of the overall dose the neonate receives [14], especially for devices that have footprints smaller than the patient's BSA. While the mean footprint

irradiance is an important parameter, it is not practical to measure it in a busy nursery. However, it is important for the characterization and development of new devices, and it could be measured during routine scheduled yearly maintenance checks by the biomedical engineering department. In contrast, the maximum irradiance is the parameter described in the 2004 AAP guideline; this is an important measurement to make at the center of the light footprint at the beginning of treatment with PT and each time the device height is changed.

Common barriers to achieving appropriate irradiance levels differ between the resource-limited and resource-sufficient areas of the world. In contrast to previous studies from low-to-middle-income countries [15], our study found no significant deficits in the equipment being used. All PT devices were in good working condition, with no lamps broken or missing, and all were serviced annually. Our data illuminate other variables that impact irradiance, however, including the distance of the infant from the light source, the skin surface area exposed, the infant's position relative to the center of the light footprint, the type of light source used, and whether there was a protocol in place to standardize correct PT practices.

Our results for the type of light source used were similar to previous in vitro studies, revealing that blue-fluorescent and LED devices produce higher irradiance than white-light halogen lamps [14, 16]. Four of the 7 hospitals were still using some devices with a mix of blue and white lights, in order to allow for an examination light source when the blue lights are turned off during patient care. According to the AAP, it is possible to bring fluorescent lamps within 10 cm of the infant when using a bassinet [13]. However, we found that about half of the hospitals in our study were placing infants at a distance much fur-

ther than this, regardless of the type of device used. Lastly, in most of the hospitals, the PT protocol was nonexistent, outdated, incomplete, or infrequently followed.

Compared to many of the other interventions and treatments for the care of ill infants, PT seems simple and straightforward, but it is important that caregivers learn, remember, and apply the basic principles required to achieve targeted irradiance levels. The results of our study have served as the basis for quality improvement initiatives to increase the use of PT devices and practice guidelines that achieve the minimum irradiance for intensive PT.

The staff of the hospitals involved in this study were both surprised by the data revealing subtherapeutic irradiance levels and motivated to make the changes required for improvement. As a result of these efforts, our hospitals are improving irradiance by instituting measures such as discontinuing the use of white-fluorescent lamps and also any equipment that does not allow for adjustment of distance between the infant and the lamp. They are placing more emphasis on the correct positioning of the infant in the center of the light footprint and at a minimum distance from the device, and also rewriting protocols and reeducating staff about these changes.

Similar reactions to local irradiance data have been noted in other locations as well. Hulzebos et al. [21] noted that, in a follow-up of their 2013 study [17], while irradiance of Dutch PT devices still varied, it had improved markedly from the previously reported results. Furthermore, nurseries throughout Nigeria are working to improve their PT, as highlighted in a recent article [22] and in unpublished data (Proceedings of PANConf 2017, Zaira, abstract 107 [Abdulkadir et al.: Phototherapy: how efficient are devices fabricated in Nigeria?]).

Ideally, nurseries will move to irradiance-based protocols which factor in the gestational age of the neonate, the rate of rise in total serum bilirubin (TSB), the nearness to exchange transfusion, and the presence of acute bilirubin encephalopathy. It is also important to note that the optimal distance from the infant varies based on the intensity (irradiance) of the light source, the configuration of the light bulb, and the heat produced by the lamp. Some PT devices should never be placed closer than the manufacturer's recommended distance (i.e., halogen bulbs) which can potentially burn an infant's skin [17].

The strength of this study is that it included a variety of hospital types, including academic, county/public, and private community sites. We demonstrated the wide variation in practices within a single metropolitan area, including different types of devices used and protocols

practiced. However, a limitation was the small sample size, in that only 7 sites were studied with a total of 39 devices being evaluated. Our study also did not take into consideration the complications involved with delivering PT to critically ill neonates, involving the presence of supportive equipment including ventilators, CPAP devices, etc., that may limit the amount of exposed skin. With critically ill neonates, active nursing care and position changes may also affect the PT dose delivered, but our data can still be helpful by recommending keeping the infant as close to the center of the light footprint as possible. Lastly, our study only addressed the irradiance delivered to the infant, but did not directly measure the efficacy of the PT by its ability to significantly decrease TSB levels in a timely manner. Here, we recommend referring to previous works [23, 24] that report improved TSB measurements with an increased irradiance.

Conclusion

Neonatal hyperbilirubinemia is common and PT has become the mainstay of treatment for affected term and preterm neonates. Although PT has virtually eliminated the need for exchange transfusions and improved neurodevelopmental outcomes for infants with hyperbilirubinemia [11], our results demonstrate that it continues to be used at subtherapeutic irradiance levels, even in resource-adequate settings. This study highlights that even with a long-standing and widely used therapy, it is easy to become complacent about practice guidelines. However, straightforward and inexpensive changes can help to provide high-quality PT to infants with hyperbilirubinemia. We encourage other clinical centers to evaluate the quality of their PT practices and make the necessary quality improvement changes so as to optimize this important intervention that significantly decreases both mortality and life-long morbidity.

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Disclosure Statement

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