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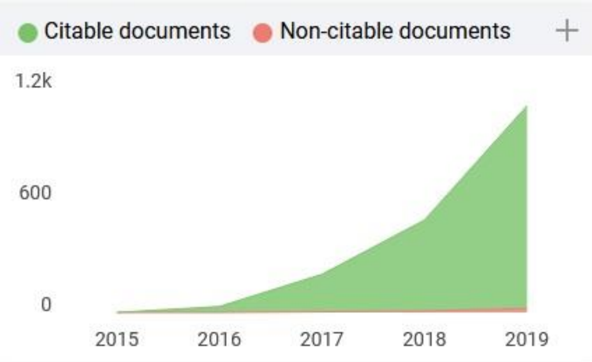

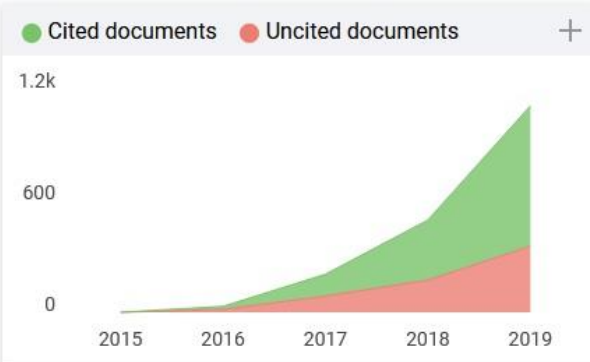

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Research article

An evaluation of phototherapy device performance in a tertiary health facility

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ABSTRACT

Introduction: A range of phototherapy devices are commercially available. The American Academy of Pediatrics (2004) recommends routine intensity measurement of phototherapy devices to ensure that babies affected by hyperbilirubinemia receive effective phototherapy.

Objective: The aims of this study were to calculate the irradiance decay velocity of phototherapy devices used in a tertiary care hospital to evaluate whether current maintenance procedures for phototherapy devices are effective, and to contribute to the improvement of a standardized maintenance procedure in daily practice, thus helping to ensure that all babies affected by hyperbilirubinemia receive prompt treatment.

Methods: This research represents a prospective observational study conducted at Dr. Soetomo Academic Teaching Hospital in Surabaya, Indonesia from February 2019–July 2019. The intensities of 11 phototherapy devices were measured at specific times using a Bili Blanket Meter II. We calculated the Δ irradiance differences in μW/cm^2/nm and calculated them as velocity μW/cm^2/nm/hour of use.

Results: Among the 11 phototherapy devices included in this study, nine were fluorescent and two were light-emitting diode (LED) machines. The mean (standard deviation) irradiance decay velocity of the fluorescent lamps was 0.02 (±0.03) μW/cm^2/nm/hour of use, while that of the LED lamps was 0.015 (±0.007) μW/cm^2/nm/hour of use. The fastest irradiance decay velocity was 0.08 μW/cm^2/nm/hour of use, while the slowest irradiance decay velocity was <0.01 μW/cm^2/nm/hour of use, both of which were from fluorescent-based devices. There was one fluorescent-based device that provided an intensity lower than the therapeutic level.

Conclusion: Irradiance decay occurred in all phototherapy device lamps. It is important to perform routinely intensity measurements, regardless of manufacturer recommendations, to avoid ineffective phototherapy resulting from intensities lower than the required therapeutic levels.

1. Introduction

Hyperbilirubinemia occurs in approximately 40%–60% of cases in the first seven days of the neonatal period and carries a risk of bilirubin neurotoxicity [1]. Phototherapy (PT) is a method used to decrease unconjugated bilirubin levels. Presently, there are various PT devices commercially available [2, 3]. The clinical response on PT depends on the effectivity of the particular device. Light intensity emitted during PT is identified as delivering pharmacotherapy to the point of having a measurable dose [4]. Studies in the Netherlands and the USA demonstrated high variability in the lower ranges of irradiance of PT devices [5, 6]. This led to uncertainties in effectiveness of PT in our hospital and setting. Current practice in Indonesia for maintaining PT lamps is based simply on the duration in hours a lamp is in use, using a so-called hour-meter. Technicians who are asked by nurses will change the lamp if it is dimmed or dies, or if its hour-meter exceeds the manufacturer's recommendation. Studies in developing countries such as Cameroon and Nigeria reported that inadequate light intensity is sometimes used for PT, thus not achieving adequate therapeutic levels [7, 8]. According to a study by Sampurna et al (2019), eight out of 17 hospitals studied in Indonesia also use PT devices which do not achieve therapeutic levels [9]. Therefore, suboptimal PT may still exist, which can translate into ineffective therapy that is unable to decrease bilirubin levels.

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Guidelines proposed by the American Academy of Pediatrics (AAP) (2004) specify the use of a light source that is capable of producing irradiation at a level greater than 30 μW/cm^2/nm, which highlights the importance of measuring irradiance [2]. However, the development of a radiometer for evaluating light sources is not progressing. Moreover, this evaluation has to be carried out considering various wavelengths of the light sources, as indicated by a fundamental understanding of bilirubin photochemical reactions [10]. In Indonesia, most hospitals change PT lamps based solely on the manufacturer's recommendations. A study at Massey Street Children's Hospital in Lagos, Nigeria, have reported that several PT devices will have a lower intensity of irradiance before being changed according to the manufacturers' recommendations [11]. It is therefore important to routinely check the intensity of PT devices, to ensure that babies with hyperbilirubinemia receive effective PT. It is also important to know the irradiance levels in the higher ranges. The results of a study conducted in Brazil highlighted the effectiveness of high-intensity PT to quickly reduce TSB levels and the need for exchange transfusions. Nevertheless, long-term observation is still required to evaluate outcomes following high intensity PT [12]. The AAP recommends to measure the intensity of spectral irradiance of each PT device, before its first use, and next periodically, to make sure that the infants receive therapeutic and effective irradiance levels [3]. Although the use of an irradiance-meter is recommended by the AAP, we presume that it is not applied well in Indonesia. We hypothesized that the performance of PT devices also was not always adequate in our own hospital, a tertiary University Hospital in Indonesia, where the maintenance was done if the lamp was dimmed or the PT device exceeded the hour-meter.

Therefore, we aimed to investigate the irradiance decay velocity of PT devices used at Dr. Soetomo Academic Teaching Hospital, to evaluate whether maintenance based solely on manufacturer recommendations are effective, or new standardized maintenance procedures should be implemented by using irradiance meters. This may help to ensure that all babies with hyperbilirubinemia receive prompt and effective treatment.

2. Material and methods

This was a prospective observational study conducted at Dr. Soetomo Academic Teaching Hospital, using a silhouette model (Figure 1) [5]. It was conducted from February 2019 to July 2019. Data sampling was done by the intensity measurements of all PT devices in the neonatal units in our hospital. We reviewed a total of 11 PT devices and used the

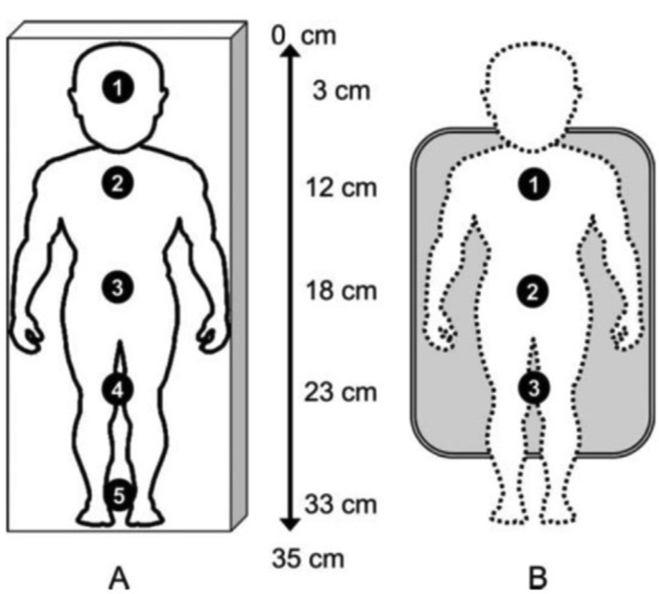

Figure 1. Silhouette model illustration. Used with the permission of Van Imhoff et al. (2013) [5].

Ohmeda Bili Blanket Meter II (Konica Minolta Inc., Tokyo, Japan) as an intensity measuring tool. This tool is designed to measure light intensity ranging from 400 to 520 nm with peak sensitivity at 450 nm [13]. Measured energy was divided with a 60 nm bandwidth as stated by the device manufacturer generated integrated radiation of 0.1–299.9 μW/cm^2/nm, similarly as reported by Van Imhoff et al [5]. Following the manual, the Bili Blanket Meter II was calibrated by the manufacturer before being used, with our measurements being performed within one year after calibration.

The PT devices in our unit had wavelengths ranging from 420–470 nm, while others ranged from 400–500 nm with a peak spectrum at 436 and 465 nm. The distance from the lamp to the silhouette model was 30 cm. Measurements were made from five equally distributed points, i.e., 3, 12, 18, 23, and 33 cm apart of the silhouette model representing the head, chest, abdomen, leg, and palm (Figure 1). Each measurement point was measured five times. Mean data and standard deviation (SD) were calculated and recorded as representative of the intensity of each PT device.

Data sampling was done three times starting in February 2019. The first measurement was considered the starting point and was later compared with the final measurement. Once all data sampling was finished, we calculated the Δ difference of irradiance in μW/cm^2/nm and compared the irradiance decay of each PT device. We also measured the irradiance decay velocity (μW/cm^2/nm/hour) of use. Data collected from each period of measurement were collected in Microsoft Excel.

3. Results

We included 11 PT devices. Nine out of 11 were fluorescent and the remaining two were light-emitting diode (LED) machines (PT device nos. 4 and 5). The mean (SD) irradiance decay velocity of the fluorescent lamps was 0.02 (±0.03) μW/cm^2/nm/hour of use and 0.015 (±0.007) μW/cm^2/nm/hour of use for the LED lamps. Only one PT device emitted an intensity lower than the therapeutic level. These characteristics and calculations are shown in Table 1 below.

The LED-based PT devices provided high-intensity irradiance more reliably in the study. With a decay velocity of 0.01–0.02 μW/cm^2/nm/hour of use they remained above 50 μW/cm^2/nm throughout the observation period. The fluorescent-based PT devices included in the study were able to provide intensive PT of >30 μW/cm^2/nm (4 PT devices) for the initial measurement, but only 2/4 could maintain this intensive irradiance.

PT device number 1 (XHZ-90) had the fastest irradiance decay velocity (0.08 μW/cm^2/nm/hour of use), while PT devices 9 and 10 had the slowest (<0.01 μW/cm^2/nm/hour of use); all three of these were fluorescent lamps. In the LED lamp group, the irradiance decay velocity for PT devices 4 and 5 were 0.01 μW/cm^2/nm/hour of use and 0.02 μW/cm^2/nm/hour of use, respectively. PT devices 6, 7, 8, 9, and 10 were the newest devices with an age lower than 48 h prior to the start of the study. PT device numbers 8, 9, 10, and 11 were used more than 500 h during the course of the study.

Almost all devices were measured every 30 days except for device 9 (52 days interval) and device 10 (59 days interval). However, unexpected findings were found to some devices. PT device number 1 had not been used between measurements 1 and 2 at all, yet the mean irradiance fell from 16.75 to 15.76 μW/cm^2/nm. For device 3, the irradiance increased from measurement 2 to 3, in spite of approximately 50 h of usage. For device 4, irradiance also increased between measurements 1 and 2 despite 75 h of use. For device 5, which had not been used between measurements 1 and 2, irradiance dropped from 59.2 to 55.64 μW/cm^2/nm. Similarly, device 7 had hardly been used at all between measurements 1 and 2, yet irradiance dropped from 25.69 to 21.7 μW/cm^2/nm. For device 9, which had 155 h of use between measurements 1 and 2, irradiance nevertheless increased from 30.62 to 31.73 μW/cm^2/nm. Finally, for device 10, irradiance increased from 30.82 to 31.62 μW/cm^2/

Table 1. The characteristics of PT devices: duration of use and irradiation levels (in μW/cm²/nm) and velocity of irradiation decay per hour of use (μW/cm²/nm/hour).

PT Devices	Brand	Type of PT Lamp	Hours of use			Irradiance measurement (Mean ± SD)			Delta Hours of use	Delta Irradiance	Irradiance Velocity Decay per hour of use
			Initial hour meter	2nd-hour meter	3rd-hour meter	1st Measurement	2nd Measurement	3rd Measurement			
1	XHZ-90	Fluorescent	5114.14	5114.22	5144.23	16.75 ± 1.6	15.76 ± 1.2	14.22 ± 5.3	30.09	2.53	0.08
2	XHZ-90	Fluorescent	4611.25	4671.32	4693.26	16.83 ± 1.4	16.66 ± 1.7	15.88 ± 2.0	82.01	0.94	0.01
3	My Life/MP71	Fluorescent	11643.98	11681.79	11729.82	9.072 ± 1.3	6.59 ± 0.7	7.14 ± 0.9	85.84	1.93	0.02
4	SEEFAR NICE 4000	LED	2688.00	2763.00	2906.00	51.63 ± 9.5	54.22 ± 8.2	50.39 ± 9.3	218.00	1.24	0.01
5	SEEFAR NICE 4000	LED	2223.00	2223.00	2446.00	59.20 ± 9.8	55.64 ± 11.2	53.77 ± 12.7	223.00	5.43	0.02
6	GEA	Fluorescent	7.53	48.27	242.31	27.55 ± 2.3	21.24 ± 2.6	16.61 ± 2.5	234.78	10.94	0.05
7	GEA	Fluorescent	46.46	46.50	252.56	25.69 ± 2.2	21.70 ± 2.7	22.50 ± 1.4	206.10	3.19	0.02
8	Nideal PT Unit 2000	Fluorescent	44	280.30	666.90	32.97 ± 1.5	29.23 ± 2.3	27.76 ± 2.8	622.90	5.21	0.01
9	Nideal PT Unit 2000	Fluorescent	0	155.20	534.80	30.62 ± 2.3	31.73 ± 2.7	30.48 ± 2.4	534.80	0.14	0.00
10	Nideal PT Unit 2000	Fluorescent	2.40	223.60	518.10	34.07 ± 2.1	30.82 ± 1.8	31.62 ± 2.0	515.70	2.45	0.00
11	Nideal PT Unit 2000	Fluorescent	71.80	321.10	627.50	32.35 ± 2.3	29.16 ± 1.6	25.98 ± 2.8	555.70	6.37	0.01

nm between measurements 2 and 3 despite of having been used for roughly 300 h.

4. Discussion

Both the fluorescent and LED-based PT devices showed a decay in intensity or their irradiance during use. Fluorescent-based PT devices showed the fastest rate of irradiance decay, despite two of these also showing the slowest decay velocities among all 11 lamps. When viewed based on the age of the lamps, the two fluorescent-based PT devices with the lowest irradiance decay velocity were the relatively new lamps compared with others. LED lamps tended to have the lowest irradiance decay velocity compared with other lamps. They could still provide high intensity PT up to the third measurement, while 50% of the fluorescent-based PT devices failed to maintain intensive irradiance up to the third measurement. The other 50% of the fluorescent-based PT devices provided standard-intensity irradiance during all three measurement. This may be relevant for health care workers in their choice of a PT device for infants in whom bilirubin levels should fall rapidly.

We noticed some inconsistencies in irradiance measurements. PT devices 1, 5, and 7 had not been used at all between measurements, yet their mean irradiance had decreased. Other PT devices (3, 4, 9, and 10), despite being used, showed increased irradiance levels. According to Subramanian et al. [14], other factors like operating voltage, manufacturing defects, exposure to voltage spikes, on-and-off cycling frequency, and ambient operating temperature may influence irradiation levels. These factors may have contributed to our findings.

In low–middle-income settings such as South Asia, fluorescent-based PT devices are dominant due to their affordability. This may, however, lead to overtreatment [15]. In addition, despite the greater number of features available when using LED PT, the use of this type of PT device is still uncommon, particularly in more rural settings [16]. This observation was also true in our study, as nine of the 11 PT devices included were fluorescent-based, and only two were LED-based. The use of LED-based PT devices has begun being adopted worldwide; however, our study supports the conclusions available in the literature, i.e., that fluorescent-based devices are still commonly used [11].

According to the findings of this study, the hourly intensity decay velocity among fluorescent-based devices had a wider range than LED-based devices. The fluorescent-based device irradiance decay velocity varied in the range of 0.00–0.08 per hour of use, while the LED range was between 0.01–0.02 per hour of use. This suggests greater stability of intensity provided by LED devices compared with fluorescent-based devices. Moreover, LED-based devices emit more stable irradiance without the need for regularly replacing lamps. Accordingly, they should be used in settings where no intensity-meter is available or where regular measurement is constrained [11, 17].

The current practice of maintenance for PT in Indonesia is to change the lamps based on hour-meters, or when the PT lamp has dimmed or died [9]. This study indicates that as PT devices are used, an unpredictable decrease occurs in the intensity of PT lamps, as measured by an intensity-meter. Guidelines put forth by the American Academy of Pediatrics (AAP) and the National Institute for Health and Care Excellence (NICE) recommend to measure irradiance intensity regularly [3, 18]. Research conducted by Olusanya et al noted that quite some time before the hour-meter indicates that the lamp should be replaced, its performance is already below the standard dose of PT [11]. More attention should be focused on fluorescent-based devices, as they showed more varied hourly intensity decay than LED-based devices. Although some reports suggest regularly changing fluorescent lamps (every 2000 h) and LED lamps (every 20000 h), it can be extremely difficult to schedule these changes and to predict the irradiance decay of PT devices, if no regular measurements of irradiance are conducted [4, 16, 19].

The LED-based devices in this study provided high intensity and maintained their irradiance throughout the study period above 50 μW/cm²/nm. The fluorescent-based PT devices indicated more varied irradiance and several could only provide standard PT, with only two among nine fluorescent-based PT devices being able to provide intensive PT. It is extremely important for healthcare personnel to know the strengths and weaknesses of their PT devices [9]. This underlines the importance of having intensity meters in neonatal units. A subsequent recommendation is for the medical devices industry to add intensity-meter features in all PT devices produced in the future. Having intensity meters in neonatal units will prevent under-treatment of jaundice among neonates due to the unobserved intensity deterioration in device efficiency [3, 4, 5, 11]. The use of LED-based PT devices can more rapidly decrease bilirubin, reduce trans-epidermal water loss, and reduce the risk of hyperthermia compared with conventional PT devices [16, 17]. The use of LED PT devices can also reduce exchange transfusion due to PT failure [20].

A limitation of this study was that not all of the observed devices underwent the same degree of use during the course of the study. The aim of this was to limit any negative impact on the quality of health service provided that may have been caused by this study. However, this limitation may have an advantage in that it mimics the typical daily patterns of these PT devices. Further studies might include more variety regarding the types of PT devices observed and measured. A larger number of observed devices will improve confidence in future findings and enable more accurate estimates of the range of irradiance decay of PT devices.

5. Conclusion

Irradiance decay occurred in all of the PT device lamps observed in this study. One notable finding was the observed inconsistencies in irradiance measurements which did not reflect the age and usage of the PT devices. This clearly underscores the need to ensure that the therapeutic efficacy of any PT device is objectively evaluated periodically by an irradiance meter regardless of the manufacturer's recommendations and the light source (LED or fluorescent) of the device. This prevents ineffective PT as a result of lamp intensity lower than the required therapeutic levels. As such, the irradiance of light sources and the instrument used to measure irradiance must be standardized and calibrated periodically. If a radiometer is not available, the light source should be observed prior to or at the validated date. Similar to medical drugs having a validated date, this should also be considered for PT devices. Hospitals should also notify equipment manufacturers in the event of a poor light source.

Declarations

Author contribution statement

Mahendra T.A. Sampurna, Arend F. Bos: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Risa Etika, Martono T. Utomo: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Siti A. D. Rani, Abyan Irzaldy, Zahra S. Irawan, Kinanti A. Ratnasari: Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

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Competing interest statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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