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Irradiance levels of phototherapy devices fabricated in Nigeria

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Abstract: *Background:* Phototherapy (PT) remains difficult to deliver in many resource-constrained countries, including Nigeria due to the unavailability of devices that can deliver intensive PT (irradiance ≥30 μW/cm^2/nm) needed to treat the more severe cases of hyperbilirubinaemia. The basic equipment is expensive and replacement parts are often not available.
Objective: To compare the blue light irradiance of four locally designed and fabricated PT devices with a proprietary device.
Materials and Methods: Four types of intensive PT devices were locally fabricated. Irradiance was measured using an Olympic Medical Bili-Meter. The mean irradiance of triplicate measurements at three positions in the light footprint of each device was determine that distances of 10, 20, 30, 40, 50, 60cm from light source to meter sensor.
Results: The irradiance of the fabricated devices (F1-4) and commercial device (C) measured at the most common clinically-used distance of 30 cm for intensive PT were 29.5 ±6.3, 30.3 ±5.3, 25.8 ±5.0,49.0 ±10.5 and 39.2 ± 13.6μW/cm^2/nm respectively with corresponding maximum central irradiance of 36.4, 32.1, 31.2,59.5 and 54.5 μW/cm^2/nm. At a distance of 25cm, all devices delivered irradiance ≥ 30μW/cm^2/nm. The cost of each local device was less than 12% of the commercial one.
Conclusions: Locally fabricated devices cost much less and were suitable for delivery of intensive phototherapy (≥30 μW/cm^2/nm) at a distance of 25cm.

Keywords: Affordable, phototherapy, devices, irradiance, neonatal jaundice.

Introduction

Neonatal hyperbilirubinaemia (HB) and its visual manifestation as jaundice occur world wide in up to 60% of term newborns and in about 80% of preterm babies[1]. Severe HB >20 to30 mg/dL total bilirubin poses a risk of acute bilirubin encephalopathy (ABE) and kernicterus in Nigeria.[2-4]

Phototherapy (PT), the principal treatment of HB,[5] remains inaccessible to many newborn clinical facilities in low-income countries.[2-6] This is due to a number of factors, including the prohibitively high cost of PT devices relative to the local economy, lack of spare parts, especially lamps, and erratic electrical power delivery.[2-6] The devices presently used to provide PT can be classified into those providing conventional and intensive PT on the basis of delivering irradiances of >8 to 10 and ≥ 30μW/cm^2/nm, respectively.[7-10]
In Nigeria, PT devices are quite expensive with conventional and intensive irradiance delivering devices being sold for approximately between 100,000 to 200,000 and 1,500,000 to 2,000,000 Naira each respectively at an exchange rate of 315 naira/ USD. The much higher cost of intensive PT devices leaves most clinical services no other option but procuring the far less expensive, but inferior, conventional devices, without adequate irradiance if they have any resources at all.[3] Thus, most newborn clinical services are unable to treat severe HB quickly and effectively enough to prevent the serious sequelae of this condition.

In an effort to prevent such scenarios from happening in the future, we endeavored to determine if we could design, and locally fabricate, affordable PT devices that could deliver irradiances high enough to qualify for the delivery of intensive PT, as defined by the AAP guidelines.[5]

We thus, designed and built four types of PT devices, loosely patterned after locally used devices. We subsequently evaluated their efficacy and that of a commercially- obtained device by measuring the irradiance at varying distances between light source and meter at three different positions in the light foot print.

Materials and Methods

The four devices were produced by a Nigerian engineering team which also ensured that all electrical work conformed to mechanical and electrical safety requirements. All devices were attached to a horizontal arm of a 4-wheeled dolly for ease of mobility. After proper training, all devices were tested by the clinical staff of the neonatal ward as described under irradiance measurement Protocol, below.

Devices

1. Fluorescent Tube Device (Figure 1, F-1) consists of a wood panel with fenestrations for air circulation. It has the following dimensions: 70 x 40 x 6 cm (L xW x H). Two sets of five opposing lamp holders were mounted 4 cm apart, along the short sides of the panel. The holders were fitted with five blue light fluorescent tube lamps (TL-52, T8, 60x2.5cm, 20 Watt, Philips, Eindhoven, The Netherlands). Mechanical ballasts (Philips) were mounted to supply the lamps with the necessary regulated power. The lamps emit blue light with a spectral range of 400-626 nm, a bandwidth of 403-472 nm, and a peak wavelength of 437 nm.[11] The panel also contained a power connector, fuse and switch. The lamps cost 8000 Naira each. The total cost of all materials was 120,000 Naira.

2. Compact Fluorescent Lamp Device (Figure 1, F-2): The lamp fixture has the following dimensions: 55 x 29.5 x 15.5cm (L x W x H).It contains six compact fluorescent U-tubes (DELUX, 18Watt/71, Blue 2G11,Osram, Muenich, Germany) spaced as seen in the Figure. The lamps deliver blue light with a spectral wavelength of 400 to 500 nm and peak of 460nm.The fixture with lamps weighs 5.9kg. The lamps, which have a life span of 1000 hours, cost 8,000 Naira each. The cost of all materials was 180,000 Naira.

3. Light-emitting diode (LED) Tube Device with three tubes (Figure 1, F-3), is based on domestication of the design developed by HJV using 1.5x1.5x1/16 inch (2.54cm/inch) aluminum angle frame, which is readily available and affordable in Nigeria. The dimensions are 64 x34 x 5cm(L x W x H). Inside the fixture, two sets of five lamp holders were mounted, 6.0 cm apart, along the opposite short edges of the frame, as seen in the Figure. The fixture also contained a fused power inlet unit with detachable power cord, and a power switch. The fixture was fitted with three T8 custom-developed led Tubes (Grandol Industry Ltd., ShenZhen, China) equally spaced as seen in the Figure. Each 60cmx2.5cm diameter aluminum tube had nine 3-Watt LEDs mounted, 5.5 cm apart on a central circuit board. The power supply (driver) is mounted within the aluminum tube space under the circuit board. Each tube is powered by 100-265 V AC and consumes up to 20 Watt of power. The LEDs of the tube emit light at a 90° angle with a spectral wavelength range of 400 to 530 nm, a bandwidth of 455 to 479 nm, and peak wavelength of 467 nm. Each LED has an estimated lifetime of ~30,000hr.The fixture was painted white, inside and out. With three tubes, it weighs 1.4kg. The tubes, which were special ordered from the supplier, each costs 8,000 Naira or US $20. The total cost of all parts was 134,000 Naira.

4. LED Tube Device with five tubes(Figure 1, F-4),is essentially the same as device F-3, but it is fitted with five instead of three LED tubes in order to deliver maximum intensive PT irradiance for treatment of severe HB. The weight of this device was1.8kg and the total cost of all parts was 150,000 Naira.

5. Commercial Intensive PT Device © This is a commercially-obtained intensive PT device (Phototherapy 4000 Dräger Medical GmbH, Lübeck, Germany) which delivers irradiation in a central area (EBi) of 1.6 ±0.3 mW/cm^2 with four blue and two white lamps and EBi of 2.3 ±0.4 mW/cm^{2}with six blue fluorescent lights at 40 cm distance. The lamps (Draeger Fluorescent light “blue” 2M 21 010) deliver blue light with a spectral wavelength of 400 to 550 and a peak of450nm.The fixture has the following dimensions: 54 x 28.5 x 13.5 cm (L x W x H) and weighs 7.2 kg It was obtained at a cost of $4000(1,600,000Naira).

Irradiance Measurement Protocol

The efficacy of the fabricated and commercial devices was determined through irradiance measurements in the light footprint of each device, with a handheld clinical irradiance meter (Bili-Meter, Model 22, Olympic Medical- now Natus Medical, San Carlos, CA, USA) which has a band width and peak sensitivity of 425-475 and 450 nm, respectively. It measures irradiance in terms of µW/cm^2/nm. Specifically, triplicate measurements of irradiance were made at three different sites in the light footprint (center and two peripheral positions, 5 cm from each of the short edges) at 10, 20, 30, 40, 50, and 60 cm distance from the light emission surface of the device to the upper surface of the irradiance sensor. For each distance, the irradiance was determined through calculating the mean of the triplicate measurements at each of the three footprint sites, thus a total of 9 measurements.

Results

The mean irradiances of the locally- fabricated devices (F1-4) and the commercial device (C) are documented in Table 1. The maximum central irradiance measure for the devices F1- 4 and the commercial device at 30 cm distance were 36.4, 32.1, 31.2, 59.5 and 54.5µW/cm^2/ nm respectively (Table 1). Figure 2, graphically displays the distances at which the different PT devices begin to deliver mean irradiance for intensive phototherapy indicated by the red line on the graph; devices F-1 and F-2 provided irradiance of 30µW/cm²/nm at a distance of 30cm, while devices C and F-4 provided irradiance of 30 µW/cm²/nm at distances of 39 and 49 cm respectively. F-3 could only provide an irradiance of 30 µW/cm²/nm at a distance of 26 cm. The locally– fabricated devices cost between 120,000 – 180,000 naira in materials. The cost of labour was not determined, as this is strongly influenced by the size of a production run. Overall none of the fabricated devices cost up to 12% of the commercial device.

Table 1: Mean (SD) irradiance and Maximum Central Irradiance at various device distances from irradiance meter

Device	Distances (cm) between phototherapy device and irradiance meter						
	10	20	30	40	50	60	Cost (Naira)
F-1	80.3(17.9) {101}	43.3(11.9) {56.1}	29.5(6.3) {36.4}	21.0(5.8) {25}	14.7(2.3) {17.4}	10.9(2.0) {13.2}	120,000
F-2	83.8(14.1) {99.9}	45.3(7.5) {53.5}	30.3(5.3) {32.1}	18.3(3.8) {22.1}	13.1(1.5) {14.6}	9.0(0.7) {9.8}	180,000
F-3	40.1(9.7) {51.2}	33.8(7.1) {41.4}	25.8(5.0) {31,2}	19.4(4.8) {23.7}	16.2(3.4) {19.4}	13.1(1.1) {15.0}	134,000
F-4	99.9(7.6) {106.7}	66.5(10.2) {76.4}	49.0(10.5) {59.5}	38.3(7.6) {47.0}	26.1(4.6) {33.2}	20.1(4.2) {25.1}	150,000
C	69.6(69.6) {150}	49.3(86.5) {91.4}	39.2(13.6) {54.5}	23.2(4.0) {27.8}	15.3(1.7) {17.2}	10.7(1.1) {11.7}	1,600,000

Values are given as mean ±SD of triplicate measurements at each of three light foot print sites (n=9 measurements total).
Figures in round brackets are standard deviations
Figures in squiggle brackets are Maximum Central Irradiance readings
One Nigerian Naira = 0.04USD

Fig 2: Irradiance (µW/cm²/nm) delivered by the five PT devices as a function of distance (cm) between the device light emission surface and detector. (Red line indicates 30 µW/cm²/nm)

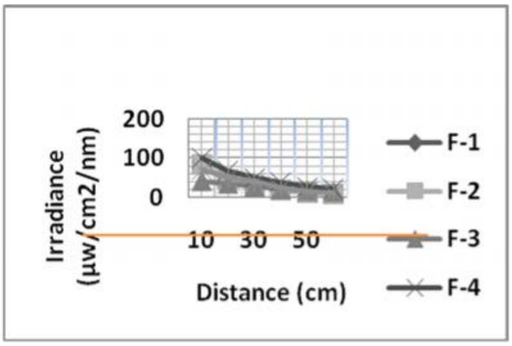

Fig 1

Fig 2

Fig 3

Fig 4

Fig C

Fig 1; Locally fabricated (F) phototherapy devices F 1- 4 and a commercially-obtained (C) device. F1, 2, and C use fluorescent lamps, while F3 and 4 use led-tubes as light sources.

Discussion

The efficacy of a PT device is in large part a function of the deliverable irradiance to the skin of a jaundiced patient.[12] For the efficacy to be optimal, it has to be delivered to the largest possible body surface area (BSA).[12,13]

Thus, it is important that the light footprint of a device is sufficiently large to cover the entire BSA. Hence, we have built devices that all have a light emission surface area and a corresponding light footprint measuring at least approximately 30 x 60 cm, large enough to treat the bodies of even the largest term newborns.

Traditionally, the irradiance is measured at a distance from emission surface to the top of the meter sensor unit, the latter which should represent the level of the patient's skin. Because the irradiance, delivered by a point source of light, is inversely related to the square of the distance (Inverse Square Law), decreasing the distance significantly increases a device's irradiance, even if the light does not strictly originate from a point light source, like the TL-52 lamp. This concept is demonstrated in Table 1, and even more so, by its graphical presentation in Figure 2. These results show that four of the five devices deliver intensive PT at the most generally recommended distance of 30 cm.

There is no compelling reason why the distance to the skin cannot be reduced however, care needs to be taken that lamps which run hot (often the halogen type) are kept far enough from an infant to prevent the skin from overheating. When PT is delivered at 25cm (Figure 2), all devices will deliver intensive PT at irradiances of ≥ 30μW/cm^2/nm. The literature reports the use of distances as short as 10 cm.[9, 14] If this distance was to be used with the presently studied devices, the deliverable near maximal irradiance would range from 40-100 μW/cm^2/nm. It is noteworthy, that the LED tube-based device with three (3) tubes (F-3), designed for treatment of moderate HB(15 < 20 mg/dL), delivers the most modest levels of irradiance at any distance. Use of this device conserves LED tubes and prevents overtreatment of newborns, especially the vulnerable preterm neonate.

The irradiances of devices F-1, 2 and 3 clustered relatively together while LED tube device F-4, was clearly capable of delivering the highest irradiance at any distance. The commercial device (C) at shorter distances had very high standard deviation because the difference in irradiance between the central and peripheral area was quite high due to the use of white light generating bulbs at the extreme ends of the device. These white light generating bulbs are allegedly used exclusively for the convenience of nursing personnel who have difficulty tolerating the intense blue light by attenuating it with the white light and are ideally not meant to be used for PT but contrariwise usually the case in many LMICs. An infant undergoing PT under this device should be positioned as close to the center of the device as possible or alternatively replace the white light tubes with blue light tubes to optimize PT.

The optimum irradiance level towards reducing plasma/serum total bilirubin levels per hour of therapy has not been satisfactorily established.[7, 18-20] For many years, a level of 35μW/cm^2/nm has been considered optimal, however, more recent works indicate that an irradiance of even above 55 μW/cm^2/nm[18]and as high as 70 did not reach an efficacy plateau.[11]

In infants with total bilirubin levels at or near exchange blood transfusion (EBT) levels(> 20 mg/dL) or in infants with signs of acute bilirubin encephalopathy (ABE), urgently bringing down bilirubin levels is a necessary strategy towards preventing the complications and sequelae of both the treatment (EBT) and the disease (ABE).[5,18] The use of intensive PT is a primary reason for fewer EBT's in high income countries as compared to Nigeria.[2,3] The availability of these locally fabricated PT devices avails clinicians in neonatal practice the opportunity to improve the management outcome of newborns with jaundice in Nigeria and as well possibly reduce EBT rates in the country.

There have been concerns about the use of high irradiance in the extremely low birth weight infants and concerns are emerging even for term infants.[15-17] These concerns support the need for measuring irradiance levels and ultimately developing protocols, which would prescribe the level of irradiance needed, based on the maturity of the infant, the risk of ABE and the need for EBT. While these refinements are outside the scope of the present study, the present data provide the basis for determining the irradiance we supply with our devices through adjustments of the distance between light-emitting surface and the skin of the patient.

None of the fabricated devices cost up to 12% of the commercial device. Though the cost of labour was not imputed, this suggest that such devices could provide cheaper options for achieving capacity to provide cost efficient intensive phototherapy in our facilities.
This study did not evaluate the rate of decay of the PT lamps. Different light sources decay at different rates.[8] The PT lamp decay is usually specified by the manufacturer in usage- or lifetime hours, but this parameter is sometimes greatly affected by a number of factors, including wide fluctuations in electrical power, ambient- and PT lamp temperatures, and types of ballast used for fluorescent tubes etc. Life span of PT lamps significantly affects the total cost of a device over time. For instance, LED lamps last far longer than fluorescent tubes (50,000 versus 10,000 hrs. and warrantees or 5- versus 2 yrs.).A follow-up study, to determine the decay of the light sources we have tested, is planned which is a needed next step to complement this study. The frame design for the PT F- 1 is being reviewed to incorporate the use of aluminum as opposed to the wood panel to improve safety and make it fire proof.

Conclusions

Locally fabricated PT devices are less expensive. Where protocols and guidelines dictate the need for intensive PT, our locally fabricated devices proved to be efficient and cost effective. They are suitable for use to provide intensive PT at an average distance of 25 cm in our hospitals. The authors will be happy to share construction details with interested parties.

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