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THE USE OF LOCALLY FABRICATED COMPACT FLUORESCENT LAMPS (CFL) PHOTOTHERAPY DEVICES IN THE MANAGEMENT OF SIGNIFICANT NEONATAL HYPERBILIRUBINAEMIA

RUNNING TITLE: Neonatal Hyperbilirubinaemia in Nigeria

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ABSTRACT

One of the challenges of managing significant neonatal hyperbilirubinaemia in resource-poor settings is limited access to effective phototherapy devices hence the need to try appropriate technologies. The objective was to assess the effectiveness of Compact Fluorescent Lamps phototherapy devices in the management of significant neonatal hyperbilirubinaemia in a resource-poor setting. A cohort of babies with significant hyperbilirubinaemia managed with locally fabricated Compact Fluorescent Lamps (CFL) phototherapy devices (2014-2016) were compared with historical controls managed with conventional imported phototherapy devices (2007-2010) for severity of hyperbilirubinaemia and requirements for Exchange Blood Transfusion. A total of 96 babies in the subject group and 202 babies in the control group were studied. The proportion of babies with peak TSB >30mg/dl was significantly higher among the controls compared to the subjects ($p < 0.001$). The interval between the commencement of phototherapy and the peak TSB was greater than 1 day among 30.2% (29/96) subjects compared to 74.3% (150/202) babies in the control group ($p < 0.001$). The mean duration of phototherapy was significantly shorter for the subjects compared to the controls. EBT was performed for 38.5% of the subjects and 51.5% of the controls. Single sessions of EBT were required for 78.4% of the subjects compared to 45.2% of the controls ($p = 0.001$). In conclusion, the locally fabricated Compact Fluorescent Lamps phototherapy devices reduced EBT rate among babies with significant hyperbilirubinaemia.

Key words: Exchange Blood Transfusion, Hyperbilirubinaemia, Neonatal jaundice, Nigeria, Phototherapy.

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INTRODUCTION

Neonatal jaundice remains a leading reason for admission into neonatal units in most parts of the developing world (Owa and Osinaike, 1998). Excessive accumulation of lipid-soluble unconjugated bilirubin is fraught with the danger of neurotoxicity and brain damage (Gomella *et al,* 2009). Phototherapy is useful for preventing serum unconjugated bilirubin from reaching dangerous levels which constitute a risk for neurotoxicity by converting lipid-soluble bilirubin to water-soluble forms which are readily excreted without need for the hepatic conjugating mechanisms. When phototherapy fails in this function or when the rate of rise of serum bilirubin is rapid, Exchange Blood Transfusion (EBT) is used to rapidly reduce serum bilirubin (Ogunlesi *et al,* 2009). Unfortunately, EBT may be associated with multiple complications, some of which may cause severe morbidities and mortality, such as hypoglycaemia, hypocalcaemia, metabolic acidosis, cardiac arrhythmias, intestinal perforation, limb gangrene, necrotizing enterocolitis and transmission of severe infections (Gomella *et al,* 2009). In addition, EBT, despite its effectiveness in rapidly and significantly reducing serum bilirubin, is associated with challenges such as difficulty in sourcing fresh and safe blood and increased cost of care (Olusanya *et al,* 2014)(Mabogunje *et al,* 2016). Therefore EBT should be the last resort in the management of hyperbilirubinaemia.

Unfortunately, EBT remains a commonly performed clinical procedure in some specialized health facilities in resource-poor settings due to inefficient phototherapy, (Owa and Ogunlesi, 2009), and high rate of admission with severe hyperbilirubinaemia due to delay in seeking appropriate care (Ogunlesi and Ogunlesi, 2012). In addition, such facilities record high EBT rate and multiple EBTs for some babies, particularly for preterm infants, due to huge challenges in providing efficient phototherapy services as the conventional imported phototherapy devices frequently break down and repair or replacement are frequently difficult.

For term and late preterm infants with jaundice high enough to warrant inpatient care, the American Academy of Pediatrics (AAP) recommends "intensive phototherapy" which implies an irradiance in the blue to blue-green spectrum (430-490nm) of at least 30 mW/cm²/nm and delivered to as much of the infant's surface area as possible (American Academy of Pediatrics, 2004). In a developing country like Nigeria, this is difficult to achieve with the normal white fluorescent bulbs. The special bulbs recommended are usually very expensive or unavailable and easily damaged or rendered ineffective by frequently low electric voltages. A 2011 Nigerian study reported that, only 6% of the imported and locally fabricated phototherapy devices across many facilities produced an irradiance of 10 mW/cm²/nm (Owa *et al,* 2011).

The prime role of phototherapy in the management of significant neonatal hyperbilirubinaemia is widely acknowledged. Effective phototherapy is known to reduce the need for EBT. Therefore, early commencement of effective phototherapy forms the basis of most globally acceptable management guidelines and protocols (Atkinson *et al,* 2003) (Olusanya *et al,* 2015). This is known to have contributed to the drastic reduction in the incidence of severe or complicated neonatal hyperbilirubinaemia in the developed world. On the other hand, inability to adhere to these guidelines is a major reason for the resurgence of severe neonatal hyperbilirubinaemia in the developed world (Johnson *et al,* 2009).

Unfortunately, lack of efficient phototherapy devices is the bane of management of significant neonatal hyperbilirubinaemia in the developing world where studies have demonstrated poor spectral irradiance among phototherapy devices (Satrom *et al,* 2014)(Borden *et al,* 2018)(Diala *et al,* 2018). In some Nigerian studies, (Owa *et al,* 2011)(DIala *et al,* 2018)(Cline *et al,* 2013) the mean spectral irradiance of sampled phototherapy devices was remarkably low and none had up to 30μW/cm²/nm recommended for intensive phototherapy. Interestingly, both the few imported phototherapy devices and the locally fabricated devices recorded grossly sub-

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optimal spectral irradiances. In a particular study, [10] the imported devices using blue lights had relatively higher, though sub-optimal, spectral irradiance compared to the locally fabricated devices. This is challenging in settings where babies with indirect hyperbilirubinaemia tend to present late at the hospital with severe degree of hyperbilirubinaemia, (Ogunlesi and Ogunlesi, 2012) (Thielemans *et al,* 2018) and prompt institution of effective treatment measures are required to prevent bilirubin encephalopathy.

Unfortunately, the conventional phototherapy machines using blue fluorescent light tubes, which are frequently imported from Europe and parts of Asia into Nigeria are not always available for use or are difficult to maintain. This challenge led to the idea of locally fabricating phototherapy machines using compact fluorescent lamps (CFLs, also known as energy-saving bulbs) which deliver blue light for phototherapy. The CFLs are manufactured to be highly light efficient over a wide range of voltage input (170-240V), which also underpins their usability in resource-poor settings. These locally-fabricated devices (AVA-2014) (Figures 1), were first designed by one of the investigators (AVA) for use in the Neonatal Ward of Olabisi Onabanjo University Teaching Hospital, Sagamu in April 2013 and underwent modifications until April 2014 when they were incorporated into the routine services of the Newborn Unit.

It is important to assess the effectiveness of these locally fabricated phototherapy devices in the treatment of significant newborn hyperbilirubinaemia and this is best done, in ideal situations, with the aid of an irradiance meter. Unfortunately, the irradiance meter is expensive and not available in our unit as earlier reported in most Nigerian facilities (Owa *et al,* 2011). [10] Therefore, in the absence of irradiance meter, the EBT rate, the peak serum bilirubin level and the number of days required for phototherapy are used as proxies for assessing the efficiency of phototherapy services in the unit.

The objective of the study was to assess the effectiveness of Compact Fluorescent Lamps phototherapy devices in the management of significant hyperbilirubinaemia among late preterm and term babies.

METHODS

This study used a retrospective design to compare the management of significant neonatal hyperbilirubinaemia over the period between 2014 and 2016 versus the period between 2007 and 2010. These periods were characterized by the use of the locally fabricated phototherapy devices and the imported blue fluorescent light phototherapy devices respectively in the Newborn Unit of the Olabisi Onabanjo University Teaching Hospital, Sagamu, Nigeria . The facility offers specialized neonatal care services aside mechanical ventilation, blood gas analysis and total parenteral nutrition to babies delivered at the Maternity Unit of the hospital who require hospitalization and babies referred to the hospital from other public and private facilities within and outside Sagamu. The pattern of admissions into the neonatal unit had earlier been described with jaundice constituting up to 20% among inborn and out-born babies (Ayeni *et al,* 2012). Ethical approval for this study was granted by the Health and Research Ethics Committee of the Olabisi Onabanjo University Teaching Hospital, Sagamu, Nigeria with reference number OOUTH/HREC/022/2015. Informed consent was obtained from the care-givers of babies recruited into the prospective arm of the study.

The subjects included all the term and late preterm babies (Gestational age $\geq$35 weeks) who were hospitalized for significant hyperbilirubinaemia between April 2014 and December 2016. For the purpose of this study, significant hyperbilirubinaemia was defined as Total Serum Bilirubin (TSB) beyond the age-specific threshold values, (American Academy of Pediatrics, 2004) requiring intervention while severe hyperbilirubinaemia was defined as TSB >10mg/dl/kg. While under care in the hospital, TSB was measured daily using spectrophotometry in the laboratory. Babies with significant hyperbilirubinaemia who were previously managed with the conventional imported phototherapy machines were used as

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historical controls. The identities of the babies in both groups were extracted from the admissions register of the ward and the personal hospital records were retrieved from the hospital's Health Information Management Unit. Only babies whose hospital records were available and with complete data were included in the study. Babies with conjugated hyperbilirubinaemia (defined as serum conjugated bilirubin >20% of serum TSB) and those with prolonged neonatal jaundice (hyperbilirubinaemia persisting beyond 14 days of age) were excluded (Gomella *et al,* 2009).
The data captured included the age on admission (in hours), sex, body weight on admission, number of phototherapy days, interval between the commencement of phototherapy and the peak TSB, use of EBT, number of EBTs per baby, timing of EBTs and intervals between multiple EBTs, occurrence of Acute Bilirubin Encephalopathy (ABE), total duration of admission and immediate outcome of hospitalization (documented as either discharge, death or leaving against medical advice).

Description of the locally-fabricated Compact Fluorescent Lamps (CFL) Phototherapy Device (AVA-2014)

The standard locally fabricated phototherapy devices use six to eight white fluorescent tubes (each supplying 20 or 40 Watts) while the blue CFL bulbs use six to eight bulbs (each supplying 18/13 Watts) when placed close to the babies (Thukral and Deorari, 2018).

The intensity of blue light generated by 18W blue CFLs was compared to the output of 40 Watts blue CFLs and it was observed that the light intensity increased by about two times more. Furthermore, it was decided not to place the CFL bulbs very close to the babies to minimize but optimize exposure to ultraviolet light hence a distance of at most 30cm from the baby was adopted (Report on Health Canada Survey, 2009). It was also noted that the infra-red radiation (heat generation) with the 40 Watts blue CFLs was remarkably higher than that of the 18 Watts bulbs. Since it was safer to move the bulbs away from the baby, it was logical to use bulbs with greater illuminance (40 Watts instead of 18 Watts). Striking a balance between more intensity of light, ensuring less heat (infra-red radiation) and safe levels of UV radiation, we fixed the distance between the light sources (blue CFL bulbs) and the baby at 40-50cm. To achieve a closer distance to the baby, the recommendation was to use CFLs that have a double casing, as this would dampen the UV radiation, (Wendee, 2012) but such bulbs were not available in our locality.

The actual irradiance could not be measured because we did not have an irradiance meter, but at distances of 50cm to the baby, the illuminance was 16,000 lux (using 6 original bright blue CTORCH® CFLs – we found this brand to be the bulb with the highest illuminance around at the time the machine was fabricated). We did attempt using up to about twelve bulbs, but we had to abandon this because of the heat generated, hence the six bulbs device was adopted. Therefore, the idea of using CFL bulbs was conceived in the year 2013 and the design was completed in 2014. This locally designed phototherapy devise was named AVA-2014 (Figure 1).

The six 40 Watts bright blue CFLs (CTORCH®) were fitted into a wooden box with white wooden reflectors (Figure 1).

Figure 1: Locally-fabricated CFL bulb phototherapy device (AVA-2014)

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This box fits into a moveable stand (with adjustable height) with wheels and it is connected to the mains voltage through a fused plug.

The CFL bulbs were usually changed after three months of use or when the illuminance falls below 11000-12000 lux. The standard recommendation is to change the CFL bulbs when the irradiance falls to two thirds of its original value (Thukral and Deorari, 2018).

The safety measures we deployed included the full encasement in the bulb box to prevent breakages. There were no significant concerns about the mercury content of CFLs as a Canadian report stated that the level of mercury that can be emitted from a broken CFL, would normally not harm a child even after one week of exposure (Kiger, 2018).

Data Management

The data were managed with the SPSS 21.0 software. The data (interventions required, duration of treatment, outcome of hospitalization) of the infants in both groups were compared. The comparisons of mean values and standard deviations was done using Student's t-test while proportions were compared using Chi-Squared test or Fisher's Exact Test. Statistical significance was defined by p-values less than 0.05.

RESULTS

General Characteristics

A total of 96 babies in the subject group [comprising 52 (54.2%) males and 44 (45.8%) females] and 202 babies in the control group [comprising 70 (34.7%) females and 132 (65.3%) males] were studied. The sex distributions were similar in both groups (χ^2 = 3.44; p = 0.064). Overall, 85 (28.5%) babies were in-born while 213 (71.5%) were out-born; out-born babies comprised 65.8% (70/96) of the subjects and 70.8% (143/202) of the controls (χ^2 = 0.144; p = 0.704).

The mean ages of the subjects and the control group were comparable (94.3±46.4 hours Vs 111.4±97.5 hours; t = -1.635, p = 0.103). Majority of babies in both groups (99.0% of subjects and 90.6% of controls) presented within the first week of life The distribution of the babies according to the estimated gestational age (EGA) showed the subjects had 18 (18.7%) preterm and 78 (81.3%) term babies while 53 (26.2%) and 149 (73.8%) of the controls were preterm and term respectively (χ^2 = 2.02; p = 0.156).

The mean body weights of both groups were comparable; 2.7±0.7kg for the subjects and 2.82±0.6kg for the control group (t = -1.648; p = 0.10). Among the subjects, 26 (27.1%) and 70 (72.9%) babies weighed <2.5kg and ≥2.5kg respectively compared to 53 (26.2%) and 149 (73.8%) in the control group (χ^2 = 0.02; p = 0.87).

Pattern of jaundice and management modalities

The identified aetiologies of hyperbilirubinaemia among the entire population of babies included Glucose-6-Phosphate (48; 16.1%), ABO incompatibility (48; 16.1%), sepsis (24; 8.1%), prematurity (18; 6.0%), Rhesus incompatibility (8; 2.7%) and concealed haemorrhages (cephalohaematoma) (11; 3.6%). Several combinations of aetiologies occurred among 69 (23.2%) babies while no identifiable aetiology was recorded among 72 (24.2%) babies. The pattern of distribution of the various aetiologies between the subjects and the controls were significantly different as shown in Table I
(p < 0.001).

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Table I: Pattern of aetiological factors

Parameters		*Subjects (n = 96)*	*Controls (n = 202)*	*Statistics*
Aetiological factors	ABO incompatibility	16 (26.7)	32 (15.8)	χ^2 = 66.108
	Cephalohaematoma	2 (2.1)	9 (4.4)	df = 7
	G6PD deficiency	21 (21.9)	27 (13.4)	P < 0.001
	Prematurity	7 (7.3)	11 (5.4)	
	Rhesus isoimmunisation	5 (5.2)	3 (1.5)	
	Sepsis	21 (21.9)	3 (1.5)	
	Combined factors	3 (3.1)	66 (32.7)	
	Unknown factors	21 (21.9)	51 (25.2)	
Peak TSB (mg/dl)	12.0-20.0	66 (68.8)	82 (40.6)	χ^2 = 23.791
	20.1-25.0	13 (13.5)	56 (27.7)	df = 3
	25.1-30.0	11 (11.5)	24 (11.9)	P < 0.001
	>30.0	6 (6.2)	40 (19.8)	
Phototherapy -Peak TSB interval (day)*	1	67 (69.8)	52 (25.7)	χ^2 = 52.640
	> 1	29 (30.2)	150 (74.3)	P < 0.001
Duration of phototherapy (days)	<4	20 (20.8)	8 (4.0)	χ^2 = 60.354
	4-7	61 (63.5)	71 (31.5)	df = 2
	>7	15 (15.6)	123 (60.9)	P < 0.001

The mean Peak TSB for the subjects was significantly lower than the mean peak TSB for the controls; 19.3 ± 6.6mg/dl Vs 23.0 ± 8.8mg/dl; t = -3.632, p< 0.001. As shown in Table I,

the peak TSB was 12.0-20.0mg/dl among the majority of the babies in both groups but the proportion of babies with peak TSB >30mg/dl was significantly higher among the controls than the subjects (p < 0.001).

The interval between the commencement of phototherapy and the peak TSB was greater than 1 day among 30.2% (29/96) subjects compared to 74.3% (150/202) babies in the control group with statistically significant difference (p < 0.001) as shown in Table I.

The mean duration of phototherapy for the subjects was significantly shorter than the mean duration for the controls; 5.4 ±2.6 days Vs 8.5 ± 2.7 days (t = -9.192; p <0.001). The total duration of phototherapy was <4 days among 20.8% (20/96) of the subjects compared to 4.0% (8/202) among the controls whereas 60.9% (123/202) of the controls

had phototherapy for more than 7 days compared to 15.6% (15/96) of the subjects (p <0.001) as shown in Table I.

Overall, 141 (47.3%) of the 202 babies had EBT; these proportions comprised 38.5% (37/96) of the subjects and 51.5% (104/202) of the controls. Twenty-nine (78.4%) babies among the subjects and 47(45.2%) among the controls had a single session of EBT (χ^2 = 12.096; p = 0.001). As shown in Table 2,

Table 2: Pattern of Exchange Blood Transfusion among babies

Parameters		*Subjects (n = 96)*	*Controls (n = 202)*	*Statistics*
EBT	Yes	37 (38.5)	104 (51.5)	χ^2 = 4.373
	No	59 (61.5)	98 (48.5)	P = 0.037
Pattern of EBT	Single	29/37 (78.4)	47/104 (45.2)	χ^2 = 12.096
	Multiple	8/37 (21.6)	57/104 (54.8)	P = 0.001
Number of EBT	1	29/37 (78.4)	47/104 (45.2)	χ^2 = 20.354*
	2	8/37 (21.6)	34/104 (32.7)	df = 2
	3	0 (0.0)	23/104 (22.1)	P < 0.001
Timing of EBT	Only once on admission	21/37 (56.8)	26/104 (25.0)	χ^2 = 19.084
	Once on admission and once after	6/37 (16.2)	28/104 (26.9)	df = 4
	Once on admission and multiple after	0 (0.0)	26/104 (25.0)	P = 0.001
	Once only after admission	8/37 (21.6)	18/104 (17.3)	
	Multiple only after admission	2/37 (5.4)	6/104 (5.8)	

the remaining 8.3% (8/96) babies among the subjects only had two sessions of EBT while 32.7% (34/202) and 22.1% (23/202) babies in the control group had 2 and 3 sessions of EBT respectively. Among the 37 subjects who had EBT, 21 (56.8%) had only one session of EBT at presentation compared to 25.0% (26/104) among the controls. Table II also shows that 6 (16.2%) of the 37 subjects had EBT at presentation had repeat EBT compared to 54 (51.9%) of the 104 controls (p = 0.001).

Factors associated with EBT among subjects
Table III

Parameters		*EBT done (n = 37)*	*EBT not done (n = 59)*	*Statistics*
EGA	Preterm	7 (18.9)	11 (18.6)	χ^2 = 0.001
	Term	30 (81.1)	48 (81.4)	P = 0.973
Place of Birth	Inborn	1 (2.7)	25 (42.4)	χ^2 = 16.168*
	Outborn	36 (97.3)	34 (57.6)	P < 0.001
Age	Within 1 week	36 (97.3)	59 (100.0)	χ^2 = 1.61
	≥1 week	1 (2.7)	0 (0.0)	Exact P = 0.385
Weight (kg)	<2.5	7 (18.9)	19 (32.2)	χ^2 = 2.032
	≥2.5	30 (81.1)	40 (67.8)	P = 0.154
Peak TSB (mg/dl)	12.0-20.0	11 (29.7)	55 (93.2)	χ^2 = 16.168*
	20.1-25.0	10 (27.0)	4 (6.8)	df = 3
	25.1-30.0	11 (29.7)	0 (0.0)	P < 0.001
	>30.0	5 (13.5)	0 (0.0)	
	4-7	23 (62.2)	38 (64.4)	df = 2
	>7	11 (29.7)	4 (6.8)	P = 0.002
Phototherapy-Peak TSB Interval (days)	1	24 (64.9)	43 (72.9)	χ^2 = 0.693
	>1	13 (35.1)	16 (27.1)	P = 0.405

Table III shows that subjects who had EBT were characterized by outborn status, peak TSB above 25.1mg/dl, duration of phototherapy greater than 7 days and TSB/kg greater 10mg/dl/kg. The babies who had EBT and those who did not have EBT in the subjects group were comparable in terms of EGA, age on admission and body weight and interval between commencement of phototherapy and peak of TSB values. Similarly, babies who had EBT in the control group were characterized by prematurity, outborn status, body weight less than 2.5kg, peak TSB values greater than 25.0mg/dl, interval between the commencement of phototherapy and peak TSB and TSB/kg greater than 10mg/dl/kg as shown in Table IV.

Table IV: Factors associated with exchange blood transfusion among controls

Parameters		*EBT done (n = 104)*	*EBT not done (n = 98)*	*Statistics*
EGA	Preterm	37 (35.6)	16 (16.3)	χ^2 = 9.661
	Term	67 (64.4)	82 (83.7)	P = 0.002
Place of Birth	Inborn	4 (3.8)	55 (56.1)	χ^2 = 64.185
	Outborn	100 (96.2)	43 (43.9)	P < 0.001
Age	Within 1 week	96 (92.3)	87 (88.8)	χ^2 = 0.739
	≥1 week	8 (7.7)	11 (11.2)	P = 0.390
Weight (kg)	<2.5	37 (35.6)	16 (16.3)	χ^2 = 9.661
	≥2.5	67 (64.4)	82 (83.7)	P = 0.002
Peak TSB (mg/dl)	12.0-20.0	23 (22.1)	59 (60.2)	χ^2 = 59.865
	20.1-25.0	23 (22.1)	33 (33.6)	df = 3
	25.1-30.0	21 (20.2)	3 (3.1)	P < 0.001
	>30.0	37 (35.6)	3 (3.1)	
Duration of Phototherapy (days)	<4	7 (6.7)	1 (1.1)	χ^2 = 4.906
	4-7	35 (33.7)	36 (36.7)	P = 0.086
	>7	62 (59.6)	61 (62.2)	
Phototherapy-Peak TSB Interval (days)	1	52 (50.0)	0 (0.0)	χ^2 = 86.246
	>1	52 (50.0)	98 (100.0)	Exact P < 0.01

Among the babies in the control group, the age on admission and the duration of phototherapy had no association with the use of EBT.

Outcome

ABE was diagnosed among 113 (37.9%) babies; these comprised 20/96 (20.8%) among the subjects and 93/202 (46.0%) among the controls (χ^2 = 17.563, p < 0.001; OR = 3.24, CI = 1.84-5.70). All the subjects with ABE arrived at the hospital with the complication while 0.9% (2/202) of the controls developed ABE after hospitalization.
The duration of admission ranged between 1 and 46 days with the median of 7 days; 163 (54.7%) stayed ≤7 days while 135 (45.3%) stayed longer than 7 days. Two hundred and three [76/96 (79.2%) of the subjects and 127/202 (62.9%) of the controls] babies were discharged home while 53 [5/96 (5.2%) of the

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subjects and 48/202 (23.7%)] died. The remaining 42 babies were prematurely discharged voluntarily and the actual outcome outside the hospital was unknown. The prevalence of ABE in relation to outcome was as follows: discharge (53/203; 26.1%), death (51/53; 96.2%) and voluntary discharge (9/42; 21.4%).

DISCUSSION

The efficiency of phototherapy devices is measured by the prevention of EBT while on phototherapy, reduction of duration of phototherapy and prevention of acute bilirubin encephalopathy. Therefore, various modifications of conventional phototherapy have been tried in different parts of the world with varying degrees of success (Thielemans *et al,* 2018) (Jiao *et al,* 2018). One of this is the modification of the type of light source. Light-Emitting Diodes (LED) has been demonstrated to significantly reduce the incidence of severe neonatal hyperbilirubinaemia in a facility at Thai-Myanmar border (Thielemans *et al,* 2018). It was also shown to significantly reduce EBT rates in Myanmar by 33% among out-born babies and 69% among inborn babies (Arnolda *et al,* 2015).

Due to the challenges of replacing or repairing the imported phototherapy devices in our facility, difficulty in sourcing original blue light fluorescent tubes and frequent fluctuation of electric voltage outputs, it was observed that the phototherapy devices were inefficient. This was compounded by the lack of a monitoring device such as irradiance meter. The non-availability of conventional blue light devices or LED devices prompted the need for trial of other technologically-appropriate options such as the AVA-2014.

In this comparative study, the babies in both groups (subjects and controls) were comparable in terms of age at presentation, sex and estimated gestational age. Interestingly, close to three-quarters of the population studied were out-born in agreement with previous reports (Ogunlesi *et al,* 2007). This is one of the reasons why significant and severe neonatal hyperbilirubinaemia remains a leading cause of neonatal morbidity and mortality in the developing parts of the world where most deliveries take place outside the hospital and babies with hyperbilirubinaemia may not be detected until the illness gets severe (Olusanya *et al,* 2014) (Mabogunje *et al,* 2016).

In the current study, the peak TSB among the subjects was significantly lower than the peak TSB for the controls. Similarly, the interval between the commencement of phototherapy and peak TSB was greater than one day among a third of the subjects compared to three-quarters of the controls. On the average, 20% of the subjects had phototherapy for less than four days compared to 4% of the controls and the mean duration of phototherapy was significantly shorter among the subjects compared to the controls. These observations suggest plausible greater and faster clearance of bilirubin among the subjects using the locally fabricated devices. Although the study did not compare brand new imported devices with the locally fabricated devices, lack of original blue fluorescent tubes and the worn out state of the imported devices which could not be repaired or replaced as at when due, may be a reason for inefficient phototherapy. That situation was not peculiar to our facility as earlier reported, [10] basically due to the poor state of funding of the public health sector in Nigeria.

The overall EBT rate of 47.3% was higher than 27.9% earlier reported in another Nigerian facility (Onyearugha and George, 2014). However, the EBT rate was significantly lower among the subjects (38% versus 51%) just as the need for repeated EBTs was higher among the controls compared to the subjects (54.8% versus 21.6%). Indeed only one extra EBT session was required among some of the subjects who had repeated EBTs whereas more babies in the control group required up to three sessions of EBTs. These observations were clear indications that the locally fabricated devices prevented a lot more sessions of EBTs compared to the old, worn out imported devices.

Out-born status and high level of hyperbilirubinaemia (TSB >25mg/dl) were associated with the need for EBT in both groups.

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This implies that the two groups were comparable as far as the characteristics of the babies who required EBT were concerned. Despite the variations in the relative intra-group prevalence of the various aetiologies of hyperbilirubinaemia, the two leading aetiologies in both groups included Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency and ABO incompatibility. Therefore, the pattern of aetiologies may not distinctively explain the pattern of EBTs in both groups. Rather, the effectiveness of the phototherapy devices must have been responsible for the observed differences. Virtually all the babies with ABE arrived at the hospital with that complication. This reflected delay in seeking appropriate care for babies with jaundice which has been previously documented in Nigeria (Owa and Ogunlesi, 2009) (Ogunlesi and Ogunlesi, 2012). Therefore, the prevalence of ABE was not used as an outcome variable in this study.

An extensive search of the literature did not yield similarly designed studies, the findings of which could be compared with the present study. Therefore, it is attractive to postulate that the locally fabricated devices using blue CFL bulbs may be viable alternatives in such situations of dearth of optimally-functioning imported phototherapy devices. Since these devices were not compared with brand new imported devices, the primary aim of this comparison was not to demonstrate superiority of the locally fabricated CFL bulb devices but to show that the latter devices may also suffice in facilities where optimally-functioning imported devices are not available. Perhaps the efficiency could have been more objectively assessed if we had irradiance meters to determine the spectral irradiance from each devise. The lack of irradiance meter to measure spectral irradiance and the retrospective arm of the study are considered limitations to the study. These factors may limit the generalizability of the findings. However, this study has opened up an area of biomedical engineering which may be explored in the future given the peculiarities of resource-constrained parts of the world where jaundice remains one of the major determinants of good neonatal outcome and quality equipment are inadequate.

CONCLUSION

The use of locally fabricated CFL bulb phototherapy devices was associated with lower peak TSB, shorter duration of phototherapy, short interval between commencement of phototherapy and peak TSB, lower EBT rate and less need for repeat EBTs. For resource-limited settings, where optimally-functioning imported phototherapy devices are still lacking or available but difficult to maintain, the blue CFL bulbs may suffice for facility-based management of hyperbilirubinaemia and ultimately minimising EBT requirements. Advocacies for improved funding of the public health sector as well as more widespread use of health insurance schemes should be instituted to facilitate the procurement of more facilities and equipment required in the management of neonatal morbidities.

The efficacy of the CFL can be further studied using randomized controlled trials with the use of irradiance meter.

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