Effectiveness Of Fiberoptic Phototherapy Compared To Conventional Phototherapy In Treating Hyperbilirubinemia Amongst Term Neonates: A Randomized Controlled Trial

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Abstract

Background: Neonatal jaundice is one of the most common problems in newborns. Effective treatment of jaundice requires therapeutic intervention with phototherapy. Over recent years, several studies reported fiberoptic phototherapy to be less effective than conventional phototherapy in term neonates. Our study aimed to compare the effectiveness of fiberoptic phototherapy with a larger illuminated area and higher irradiance to conventional phototherapy methods.

Methods: This was a randomized controlled trial conducted at Kilimanjaro Christian Medical Centre (KCMC). A total of 41 term neonates, less than 7 days of age with unconjugated hyperbilirubinemia were randomized. Thirteen (13) newborns were allocated to receive fiberoptic phototherapy, 13 to blue light conventional phototherapy and 15 to white light conventional phototherapy. Effectiveness was assessed by comparing the duration of phototherapy, bilirubin reduction rate and side effects of treatment. The data was analyzed with the independent t-test.

Results: The mean overall bilirubin reduction rate was comparable in the fiberoptic phototherapy group (0.74%/h) and the blue light conventional phototherapy group (0.84%/h), with no statistically significant difference (*p*-value 0.124). However, white light conventional phototherapy had a significantly lower mean overall bilirubin reduction rate (0.29%/h) as compared to fiberoptic phototherapy (*p*-value <0.001). The mean treatment duration of phototherapy was 69 h, 68 h and 90 h in the fiberoptic, blue light conventional and white light conventional phototherapy groups respectively. Side effects such as loose stool and skin rash were noted in some participants who received conventional phototherapy. No side effects of treatment were noted in the fiberoptic phototherapy group.

Conclusion: The effectiveness of fiberoptic PT and blue light conventional PT were comparable in terms of bilirubin reduction rate and treatment duration, whereas fiberoptic phototherapy was more effective than white light conventional PT, with a significantly lower bilirubin reduction rate and treatment duration. Fiberoptic phototherapy may mitigate side effects caused by conventional phototherapy.

Trial registration: The Pan African Clinical Trial Registry, PACTR202004723570110. Registered 22nd April 2020- Retrospectively registered, http://www.pactr.org/

Background

Globally an estimated 50% of term newborns develop hyperbilirubinemia (which may manifest as jaundice), typically 2-4 days after birth. About 25% of these babies will require phototherapy (PT) to avoid the effect of high serum unconjugated bilirubin, which can lead to bilirubin-induced neurologic dysfunction (BIND). BIND occurs when bilirubin crosses the blood-brain barrier and binds to brain tissue, resulting in brain injury if not treated appropriately in a timely fashion (1–3). Unconjugated hyperbilirubinemia in the newborn is typically caused by the normal physiological inability of the newborn infant to process bilirubin adequately due to the combined effects of increased red blood cell turnover and a transient deficit in bilirubin conjugation in the liver (3,4). However, it can occur from underlying

pathological conditions which result in increased bilirubin production and/or decreased bilirubin excretion (5). Etiologies of unconjugated hyperbilirubinemia in newborns are provided in table 1 (6).

Table 1 : Causes of unconjugated hyperbilirubinemia in newborns

Increased Bilirubin Production	Decreased Bilirubin excretion
Hemolytic disease • Immune mediated (Rh, alloimmunization, ABO incompatibility) • Heritable (spherocytosis, G6PD deficiency, pyruvate kinase deficiency)	Prematurity
Polycythemia	Increased enterohepatic circulation • Breastfeeding Jaundice • Pyloric stenosis • Small or large bowel obstruction
Extravasation of blood (cephalohematoma, intraventricular hemorrhage)	Inborn errors of metabolism (Gilbert syndrome, Crigler-Najjar syndrome)
Sepsis with disseminated intravascular coagulation (DIC)	Metabolic disorders (hypothyroidism, hypopituitarism)

Two interventions, phototherapy and exchange transfusion, are used to reduce total serum bilirubin (TSB) levels for infants with or at risk of developing hyperbilirubinemia. Phototherapy is now the preferred method of treatment for neonatal hyperbilirubinemia by virtue of its non-invasive nature and its safety (7–9). The use of high-quality phototherapy is paramount to decrease the likelihood of exchange blood transfusion.

Phototherapy refers to the use of light of specific wavelengths and doses to convert lipophilic bilirubin molecules in the body into water soluble isomers that can be excreted by the body to reduce TSB. Currently, there are several forms of phototherapy: conventional, fiberoptic and LED used in the treatment of hyperbilirubinemia (10).

The efficacy of phototherapy units varies widely because of differences in light source and configuration. The following characteristics of a device contribute to its effectiveness (Fig 1) (4):

1. Emission of light in the blue-to-green range that overlaps the in vivo plasma bilirubin absorption spectrum (~460-490 nm).
2. Irradiance: standard PT ± 10 μW/cm^2/nm versus intensive PT 30 μW/cm^2/nm.
3. Illumination of maximal body surface.
4. Distance: maximize irradiance by minimizing patient to light source distance.

Conventional and fiberoptic phototherapy have been proven to be equally effective in the treatment of hyperbilirubinemia among preterm neonates (11,12). However, a Cochrane review reported the efficacy of

fiberoptic phototherapy in a number of different clinical situations and patient populations, and found that fiberoptic phototherapy was less effective than conventional phototherapy at lowering serum bilirubin in term neonates (12). These findings were attributed to the low irradiance and/or small surface area illuminated by the mat of the fiberoptic phototherapy units used in previous studies (3,11,13).

Our study aimed to compare a fiberoptic phototherapy unit with both a larger illuminated area and high irradiance to conventional phototherapy with regard to bilirubin reduction rate, side effects and duration of treatment among term neonates with unconjugated hyperbilirubinemia.

Methods

Study design, duration and study area

A parallel randomized controlled trial to test three treatment groups was conducted in the neonatal care unit (NICU) at the Kilimanjaro Christian Medical Centre (KCMC) in Northern Tanzania from January 2019 to May 2019. The NICU has a bed capacity of 62 babies, with an average nurse to patient ratio of 1:10 per shift. The babies are nursed in locally made cots which are heated by incandescent bulbs. In our neonatal care unit, conventional phototherapy has been the only treatment modality used for unconjugated hyperbilirubinemia.

Eligibility criteria

Sixty-five term neonates (>37 weeks of gestation), less than 7 days of age, admitted with jaundice, were identified by clinicians working in the neonatal unit and screened for eligibility. We included those with both hemolytic and non-hemolytic unconjugated hyperbilirubinemia with a total serum bilirubin level that has reached phototherapy threshold values as per the American Academy of Pediatrics (AAP) nomogram which is a validated tool used for making decision regarding phototherapy in infants with unconjugated hyperbilirubinemia. Excluded from the study were: neonates receiving phenobarbitone, neonates with bilirubin levels that have reached exchange transfusion levels on the AAP nomogram, neonates with conjugated hyperbilirubinemia, neonates who have already received phototherapy prior to enrollment, and those whose parents refused to consent.

Sample size estimation

In order to obtain our sample size, we estimated a 34μmol/L effect size in the three arms, with a level of significance of 5%, power of 85% and an estimated SD of 24μmol/L for the level of serum bilirubin after 24 hours. The minimal expected sample size in addition to non-response rate of 20% was 39. We included in our final analysis a total of 41 term neonates who met the inclusion criteria.

Study variables and data collection method

Written consent was obtained from parents of eligible participants. A questionnaire was used to collect demographic data such as sex, gestational age at birth (determined according to the maternal history and

Ballard's scoring system), mode of delivery, birth weight in kilograms, age at enrollment in days, and mode of feeding.

Simple randomization was performed by drawing a paper from a container containing 45 folded papers: 15 marked 'FB' (Fiberoptic BiliBlanket), 15 marked 'B' (Bluelight PT) and 15 marked 'W' (White light PT). Participants were then allocated to intervention groups by the research assistants. This was an open label trial whereby both the parent of the participants and the researchers knew which intervention the neonate was receiving.

Before phototherapy initiation, a clinical assessment was done on the neonate, and vitals were recorded. Laboratory characteristics such as total serum bilirubin and direct serum bilirubin were recorded. Phototherapy was employed as per our standard nursery protocol and equipment. The neonate was nursed in an open cot wearing only a diaper which was folded to allow maximum skin exposure to phototherapy, and was turned every two hours from prone to supine positions.

The white light PT unit "Atom model PIT- 220 TL" (Atom Medical), consists of six white fluorescent bulbs (PHILIPS, TL-D 18W/64-765) and was placed 35 cm above the neonate with an illuminated cabinet of 66.5cm x34.5cm and a mean irradiance of 8 μW/cm2/nm. The blue light PT unit "Olympic Bili-Lite model 66" (Olympic Medical), consisted of four Olympic blue fluorescent bulbs placed 20cm above the neonate with an illuminated cabinet of 66cm x 27.9cm and a mean irradiance of 27 μW/cm2/nm. Eye pads were used for neonate on conventional phototherapy to prevent damage to the retina. The BiliBlu LED fiberoptic phototherapy unit (Martand Medical Services) with a body surface area of 25cm x 40cm was wrapped around the neonate with a mean setting of 34 $mW/cm^2/nm$ light irradiance. Irradiance of the phototherapy units was measured using the GE Healthcare BiliBlanket Light Meter II. Irradiance in all phototherapy units was measured from the skin surface of the neonate, 3 measurements were taken: one measurement centrally and two measurements at the two most extreme peripheries exposed to the PT light, subsequently an average irradiance was calculated for each participant. Phototherapy was administered continuously except during minor procedures such as feeding, diapering, physical examination and capillary blood sampling.

Serum bilirubin reduction rate was assessed as the decline in the TSB levels for the duration of exposure to phototherapy, expressed as a percentage of decline per hour. This was monitored through daily total serum bilirubin levels. Treatment failure was defined as the need for additional phototherapy units ('double phototherapy ') determined by serial serum bilirubin response while on phototherapy; a rise in serum bilirubin level more than 9μmol /L per hour after phototherapy initiation was an indicator for double phototherapy. Phototherapy was stopped when serum bilirubin levels were 50mmol/l below the phototherapy threshold value on the AAP nomogram. Treatment duration was then assessed as the duration of time of exposure to phototherapy in hours.

Blood samples were analyzed at the KCMC clinical laboratory. The Cobas Integra 400 Plus (Roche Company) was used to analyze the serum bilirubin levels. The sample reached the laboratory within

15min of collection. A minimum of 1ml of blood was required. Care was taken to prevent exposure to light by placing the samples in a dark blood transportation box.

Neonates were closely monitored for side effects of the treatments which included: loose, greenish stools; hydration status: assessed as the difference in daily body weight after starting PT (5% body weight loss was considered as mild dehydration, 5-10% body weight loss was considered as moderate dehydration and more than 10% body weight loss was considered as severe dehydration); skin rashes and brownish discoloration of skin as assessed by a dermatologist. Participant's vital signs including temperature, respiratory rate, heart rate were monitored every 4 hours throughout phototherapy. Weight was checked daily.

Feeds were calculated based on the daily kilocalories requirement for age. At enrollment, mothers were asked to express breast milk to quantify the milk production. When necessary, neonates were supplemented with infant formula milk to maintain the total daily feeds requirement. Neonates were fed every 3 hours in all PT groups. Those who were not maintaining adequate oral intake were supplemented with IV fluids to maintain the total daily fluid requirement, considering the postnatal age, and clinical and laboratory findings.

Research assistants recruited for the study were registered nurses working in the NICU. Research assistants enrolled the participants for the study. They were trained on how to randomize and assign participants to intervention. They were familiarized with the study protocol for PT, how to correctly place the PT unit, when to interrupt PT with clear documentation of duration of PT interruption, and measurement of the body weight & vital signs (axillary temperature, heart rate, respiratory rate). A pilot study was conducted to assess the feasibility of the fiberoptic PT unit and to familiarize the research assistants with the study.

Data analysis

Data analysis was done using Statistical Package for Social Sciences (SPSS) version 23. The data was analyzed with the independent t-test to compare means of bilirubin reduction rate (%/hr) and treatment duration between the three treatment groups. A *p*-value of $\leqq 0.05$ was regarded as statistically significant.

Result

Participant flow

A total of 65 term neonates, less than 7 days of age were admitted with jaundice between January 2019 to May 2019 and were assessed for eligibility. Of these, 24 participants were excluded: 21 had bilirubin levels below the phototherapy threshold and 3 had bilirubin levels at the exchange transfusion threshold. 41 participants were randomized and allocated to the three intervention groups. Thirteen 13 (31.7%) were allocated to blue light conventional phototherapy, 15 (36.6%) were allocated to white light conventional phototherapy and 13 (31.7%) were allocated to fiberoptic phototherapy. All participants received the

assigned intervention and were followed until phototherapy was stopped. Final analysis was performed on 41 participants as per allocation to intervention; no participants discontinued the study (Figure 2).

Baseline Characteristics

The majority of participants were male (61.0%); 87.8% of the participants were delivered through spontaneous vertex delivery. Exclusive breastfeeding was the most common mode of feeding (85.4%). The majority of the participants were aged 3 to 4 days at the time of enrollment (65.9%). The mean age of mothers was 27 years (Table 2).

Table 2: Baseline Characteristics (N=41)

Characteristics	%
Age at enrolment (days)	
≤2	9.8
3 to 4	65.9
>4	24.4
[Median; IQR]*	***[4.3;4.5]***
Sex	
Male	61
Female	39
Types of phototherapy	
Bili blanket	31.7
Blue Light	31.7
White Light	36.6
Mode of delivery	
SVD	87.8
CS	12.2
Type of Feeding	
Exclusive Breastfeeding	85.4
Infant formula milk	4.9
Infant formula milk and breastfeeding	4.9
Nil per oral (NPO)	2.4
Expressed breast milk	2.4
[Mean age of the mother; SD]*	***[27; 5.9]***

* Median and IQR
** Mean and standard deviation

Total serum bilirubin reduction rate

Total Serum bilirubin reduction rate per 24 hours as a %/hour

The total serum bilirubin reduction rate (as %/hour) in the blue light conventional phototherapy was 0.56, 0.73, 0.89 and 1.21 for each subsequent 24 hours. Whereas, the fiberoptic phototherapy total serum bilirubin reduction rate (as %/hour) was 0.59, 0.61, 0.76 and 0.99 for each subsequent 24 hours. The white light phototherapy had the lowest total serum bilirubin reduction rate (as %/hour) which was 0.14, 0.22, 0.31, 0.45, and 0.30 on each subsequent day. There was no statistically significant difference of the total serum bilirubin reduction rate per 24 hours between blue light conventional and fiberoptic PT, however there was statistically significant difference between fiberoptic and white light conventional PT (Table 3).

Overall Total serum bilirubin reduction rate as %/hr

On average, blue light conventional PT reduced bilirubin levels at a rate of 0.84% per hour, which was the highest overall reduction rate, followed by fiberoptic phototherapy at 0.74% per hour and the lowest overall bilirubin reduction rate was in the white light conventional PT group at 0.29% per hour. There was statistically significant difference in the overall bilirubin reduction rate between the fiberoptic and white light conventional PT group (p-value <0.001). However, there was no statistically significant difference when we compared the overall bilirubin reduction rate between blue light conventional and fiberoptic PT (p-value 0.124) (Table 3).

Table 3: Total serum bilirubin reduction rate per 24 hour (as a %/hour), Overall bilirubin reduction rate (as a %/hour) and Mean treatment duration in hours

	0-24h Mean±SD	24-48h Mean±SD	48-72h Mean±SD	72-96h Mean±SD	96-120h Mean±SD	Overall bilirubin decline rate %/hour	Mean treatment duration in hours
Fiberoptic	0.59±0.18	0.61±0.23	0.76±0.23	0.99*		0.74 ± 0.19	69.46 ± 7.55
Blue Light	0.56±0.13	0.73±0.17	0.89±0.15	1.21*		0.84 ± 0.40	68.77 ± 11.61
White Light	0.14±0.07	0.22±0.06	0.31±0.12	0.45±0.17	0.30*	0.28 ± 0.12	90.33 ± 19.91
Mean difference (Fiberoptic vs Blue Light)	0.03±0.06	0.12±0.08	0.13±0.08	0.78	-	0.10±3.28	0.69±3.84
(P-value)	(0.727)	(0.065)	(0.053)	-		(0.125)	(0.858)
Mean difference (Fiberoptic vs White Light)	0.45±0.05	0.39±0.06	0.45±0.07	0.54±0.18	-	0.46±2.70	20.87±5.19
(P-value)	(<0.001**)	(0.006**)	(0.034**)	-	-	(0.008**)	(<0.001**)

- no value computed, *Remained with few participants hence SD could not be estimated
** Significant p-values

Treatment duration

Mean treatment duration

The mean treatment duration in hours was similar in the blue light PT group and fiberoptic PT group (68 vs. 69 hours, p = 0.858). However, the mean treatment duration was longer in the white light conventional PT group (90 hours) than in the fiberoptic PT group (p = 0.002) (Table 3).

Side effects of treatment

Side effects such as loose stool during conventional PT (blue light PT group: 38%, white light PT group: 20%) and transient maculopapular rashes (Blue light PT group: 15%) were noted. No side effects were noted in the fiberoptic PT group (Table 4).

Table 4: Side effects of treatment (N=41)

Characteristics	Fiberoptic PT %	Blue Light PT %	White Light PT %
Hydration status at during phototherapy			
No dehydration	100	100	100
Some Dehydration	0	0	0
Severely dehydrated	0	0	0
Loose stool during phototherapy			
Yes	0	38	20
No	100	62	80
Rashes during phototherapy			
Yes	0	15	0
No	100	85	100
Brown discoloration of skin during phototherapy			
Yes	0	0	0
No	100	100	100

Discussion

In our study, phototherapy was effective in decreasing bilirubin levels in all three groups. The response was greater in the blue light conventional phototherapy (0.84%/h), followed by fiberoptic phototherapy (0.74%/h), whereas the white light conventional phototherapy (0.29%/h) had the lowest response in lowering serum bilirubin levels. The effectiveness of fiberoptic PT and blue light conventional PT were comparable in terms of bilirubin reduction rate and treatment duration, whereas fiberoptic phototherapy was more effective than white light conventional PT, with a significantly faster bilirubin reduction rate and shorter treatment duration. No side effects were reported in the fiberoptic PT group, while both conventional PT groups had some patients with loose stool. A transient erythematous skin rash was noted in a few patients receiving blue light conventional PT.

The effectiveness of a phototherapy unit is determined by several factors which includes distance of the light source from patient, surface area covered, wavelength and the irradiance of the phototherapy unit (14). In this study, the effectiveness of fiberoptic PT and blue light conventional PT were comparable in terms of bilirubin reduction rate, whereas white light conventional PT had a significantly lower bilirubin reduction rate as compared to fiberoptic PT. Schuman et al compared continuous fiberoptic PT to conventional PT comprised of both blue and white bulbs in the home setting(15). They found no statistically significant difference in the mean bilirubin reduction rate. The mixture of blue and white light in the conventional PT unit used in Schuman et al study might have affected the wavelength in their conventional PT unit. One of the advantages of fiberoptic phototherapy is no interruption of exposure, which impedes separation of mother and baby, encourages breastfeeding with long duration of phototherapy and obviates the need for eye patches We therefore postulate that continuous PT could further improve the effectiveness of the fiberoptic PT unit as noted in the study by Schuman et al.

Though not assessed in our study, we hypothesize that patients with physiologic jaundice, who are otherwise healthy, could receive PT at home, which would assist to reduce hospitalized neonates, positively affecting the workload in the NICU and economic burdens to families and the hospital.

Our data attests that fiberoptic phototherapy was more effective than white light conventional PT, with a significantly higher bilirubin reduction rate. A study by Tan increased the irradiance of the fiberoptic PT unit with the aim of improving the efficacy of the fiberoptic PT unit, however maintained a small illuminated surface area in their fiberoptic PT unit (16). This was compared to conventional PT using white light, and combined phototherapy which consisted of fiberoptic PT and white light conventional PT. Contrary to our findings, the efficacy of fiberoptic phototherapy was distinctly less, with an overall mean decline rate of 0.49%/h, as compared to 0.70%/h in the conventional phototherapy. The best result was obtained by combination exposure (0.97%/h). These findings could be influenced by the surface area covered, improved wavelength spectrum and a higher spectral irradiance in this arrangement, being equal to the sum of the two forms of phototherapy. These findings suggest that combined phototherapy might be the best way to lower serum bilirubin levels in term neonates receiving white light PT.

Our findings demonstrate that the effectiveness of fiberoptic PT and blue light conventional PT were comparable in terms of bilirubin reduction rate. This was in contrast to Sarici's findings, who compared the efficacy of fiberoptic PT to conventional PT using blue light in healthy term neonates with non-hemolytic unconjugated hyperbilirubinemia (17). In their study, they increased the illuminated area of their fiberoptic PT unit with the aim of improving its efficacy. The lower bilirubin reduction rate of the fiberoptic phototherapy in their study may be due to its lower spectral irradiance. We deduce that the improved effectiveness noted in the fiberoptic PT group in our study could be explained by the joint effects of a larger illuminated area, higher irradiance and the LED lights in the blue wavelength spectrum, identical to the maximum bilirubin absorption spectrum. A phototherapeutic effect is seen only when the wavelength can penetrate tissue and absorb bilirubin (14). It is noteworthy in Sarici's study, that the participants in the fiberoptic PT group were slightly older in age as compared to those in the conventional PT group; as such skin maturity could have influenced their findings.

Tan and Sarici found a shorter treatment duration with conventional PT units as compared to a fiberoptic PT unit (16,17). This could be explained by the wavelength, surface area exposed and irradiance in the two different treatment modalities. Their findings were different from our study, as the treatment duration was comparable in the fiberoptic PT group and blue light PT group, and was significantly longer in the white light PT group in our study. We therefore recommend fiberoptic phototherapy and blue light conventional PT as the treatment of choice, over white light conventional PT which has 1.3 times longer treatment duration. The longer treatment duration might increase the risk of acquiring nosocomial infection and increase the length of hospital stay, which has financial implications to both the hospital and family and also increases workload in the NCU.

Holtrop, Tan and Al-Alaiyan reported no side effects of treatment in the fiberoptic phototherapy group (10,16,18). This was consistent with our findings. Studies by Sarici, Rouf et al and Gutta et al observed a

significantly higher incidence of skin rashes and loose stools in the conventional phototherapy group which was similar to our findings (17,19,20). In our study, participants in the blue light conventional PT group had the highest incidence of side effects. Based on these findings, the fiberoptic PT could be considered the treatment of choice to avoid side effects (18).

The AAP noted that the most significant bilirubin decline is considered in the first 24 hours. The AAP further states that with the standard phototherapy units, a decrease of 6% to 20% of the initial bilirubin level can be expected in the first 24 hours, which our fiberoptic phototherapy achieved with the highest bilirubin reduction rate of 0.59%/hour (equivalent to 14%) in the first 24 hour (14).

Effective treatment to decrease bilirubin levels in neonates with severe jaundice includes phototherapy and exchange transfusion. In our NICU, conventional phototherapy has been the only treatment modality used. Our study was an effectiveness study; the intent was to compare fiberoptic PT to white and blue light conventional PT as we typically use it in our neonatal unit, and hence we included neonates with both physiologic and pathologic jaundice. Previous studies were efficacy studies, which required substantial deviations from clinical practice. The studies by Holtrop and Tan excluded neonates with hemolytic jaundice, whereas Sarici excluded neonates with hemolytic jaundice, infections, congenital malformations and enclosed hematoma (16–18). The major limitations of our study could be the use of suboptimal conventional phototherapy in the white light conventional phototherapy group as well as a relatively small sample size which could make generalization of results difficult.

Conclusions

Increasing both irradiance and the illumination area of the fiberoptic PT unit improved effectiveness of phototherapy in term neonates. Fiberoptic PT was comparable to blue light conventional PT, however, showed superiority to white light conventional PT in terms of serum bilirubin reduction rate & treatment duration. No side effects were observed in the fiberoptic phototherapy group, whereas blue light conventional PT group had the highest incidence of side effects. We therefore conclude that phototherapy delivered by the fiberoptic phototherapy unit is safe and the effectiveness is comparable to that of blue light conventional phototherapy, providing a convenient alternative phototherapy application strategy that obviates the need for eye patches and reduces side effects of treatment. It would likely also have favorable implications on patient costs and NCU workload if successfully adopted.

We recommend further studies to compare combined phototherapy with the fiberoptic PT as this might be the best way to lower serum bilirubin levels in term neonates. Further studies to explore the feasibility of home phototherapy in our setting should be considered.

List Of Abbreviations

AAP American Academy of Pediatrics

BIND Bilirubin Induced Neurologic Dysfunction

KCMC	Kilimanjaro Christian Medical Centre
LED	Light Emitting Diode
NICU	Neonatal Care Unit
PT	Phototherapy
SVD	Spontaneous Vertex Delivery
TSB	Total Serum Bilirubin

Declarations

Ethics approval and consent to participate

Ethical clearance certificate was obtained from Tumaini University College Research Ethical Committee with the research number 2330. Permission to conduct research was also obtained from the head of department of pediatrics and child health department at KCMC. Formal written consent was obtained from the parent or guardians of the study participant and we observed confidentiality of the names of the study participants by using code numbers. Those who did not consent received equal right of medical care.

Consent for publication

Not Applicable

Availability of data and material

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare no competing interest.

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Author's contributions

HNJ: conception and design of the study, analysis and interpretation of data, drafting the paper and revising it. LM: conception and design of the study, analysis and interpretation of data, drafting the paper and revising it. RMM: conception and design of the study, analysis and interpretation of data, drafting the

paper and revising it. DNM: drafting the paper and revising it. RNP: drafting the paper and revising it. All authors have read and approved the manuscript.

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Consort Statement

The study adheres to CONSORT guidelines. Included is a completed CONSORT checklist as an additional file

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Figures

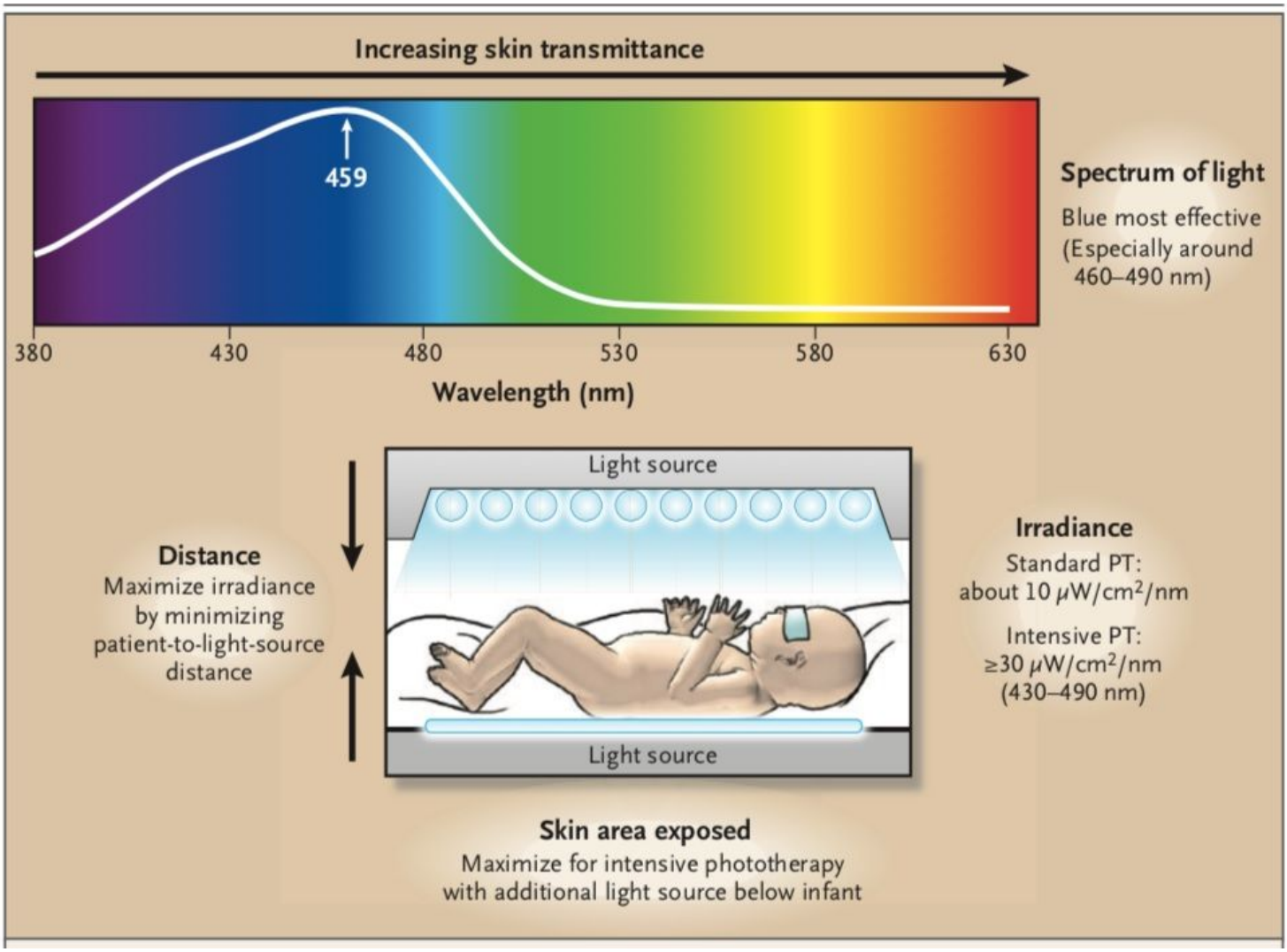

Figure 1

Diagram illustrating requirements for effective phototherapy

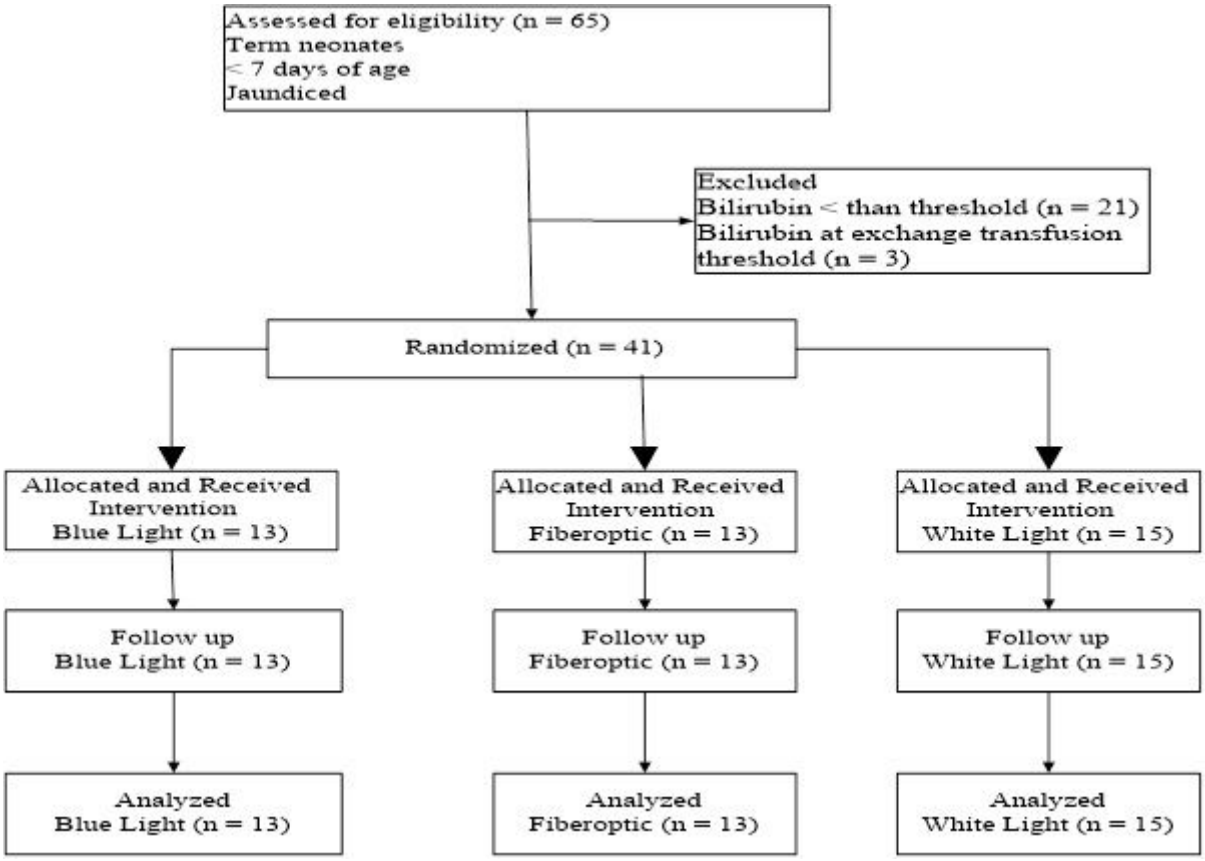

Figure 2

Participant flow chart. Flow chart showing the progress through the phases of a parallel randomized controlled trial of three groups: blue light conventional phototherapy, white light conventional phototherapy and fiberoptic phototherapy.

Supplementary Files

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- CONSORT2010ChecklistBMC.pdf