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Giggles: Development of a New Eye Covering Device Used During Neonatal Phototherapy

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ABSTRACT

About 10 % of all neonates worldwide develop jaundice needing phototherapy (PT) during which an eye covering device (ECD) is used. The existing ECDs made of fabric are tight bands preventing the baby from opening his eye lids, are a source of discomfort and are not aesthetic. The major emphasis of new ECD named Giggles was to use a dome like design allowing free eye lid movements. It was also important to ensure complete light blockage, a good fit to prevent dislodgement, easy to clean, non-fabric material, reusable while maintaining good hygiene, soft, not causing skin irritation, mouldable, light, medically acceptable, durable, affordable and aesthetic. An open label randomized control trial was conducted to compare the efficacy of giggles vs the existing ECD. All neonates needing PT who were >35 weeks G.A. and B.W. >2.0 kg were eligible for the study. Babies in the control group (n-30) were treated with the standard ECD while those in the study group (n-30) were treated with Giggles. Primary outcomes were baby's comfort level and irritability, the number of spontaneous dislodgements needing reapplication and the aesthetics. Babies in the study group did better during breast or the cup feeding. Babies in the study group were more comfortable and easier to take care of. Episodes of dislodgement needing reapplication were similar. Care givers and the parents alike loved the aesthetics of giggles.

Keywords

Hyperbilirubinemia, Phototherapy, Eye Covering Device.

Abbreviations

AAP: American Academy of Pediatrics, BW: Birth Weight, DMH: Deenanath Mangeshkar Hospital, ECD: Eye Covering Device, GA: Gestational Age, HB: Hyperbilirubinemia, NICU: Neonatal Intensive Care Unit, PT: Phototherapy, VI: Vitalis Investigators, UV: Ultra Violet.

Introduction

Hyperbilirubinemia (HB), an increase in serum bilirubin level or jaundice, is a common condition in the immediate newborn period. HB is not only frequent in premature or full-term babies admitted to the neonatal intensive care unit (NICU), but also among the healthy full-term neonates [1,2]. Visible jaundice develops in 50-75% of all full-term babies [1]. Annually severe HB (i.e. serum bilirubin >20 mg/dl) needing phototherapy (PT) occurs in ~1.1 million full-term babies worldwide [3,4]. Severe HB increases the risk of bilirubin-induced encephalopathy called kernicterus [1,2,5,6]. PT light of specific wavelength (430-490 nm) and concentration degrades bilirubin in the skin by photo-oxidation [1,2,5,6]. Therefore, to reduce serum bilirubin level, PT has been commonly used for > six decades [1,2,5,6]. PT is not only effective but also safe in reducing serum bilirubin concentration. However, because of a potential for damaging the retina, it is a universal practice to use an eye covering device (ECD) during the entire course of PT which can last from one to five days [1,2,5-7].

The existing ECDs include bandages, blindfolds or strips of gauze. All ECDs are tight bands, which prevent the neonate from opening his eyelids (Figure 1). The tight eye closure is a source of irritation and discomfort. Tight ECD can also lead to eye infections like conjunctivitis or keratitis. Unintentional displacement of ECD is also common needing frequent reapplications. Displacement can obstruct both the nostrils leading to life threatening event. Majority of ECDs are made of some kind of a fabric like material and therefore not easy to clean making it non-reusable. Finally, these ECDs are not aesthetic (Figure 1). Here we describe development of a new ECD named Giggles. Preliminary observations have been reported [8].

Figure 1: Commonly used ECD with tight eye closure band.

Materials and Methods

After a discussion among all investigators, it was decided to develop a new ECD with primary emphasis on a dome like structure allowing free movement of baby's both the eye lids. Vitalis Investigators (VI) agreed to design, develop and test the new ECD. Neonatologists (Deenanath Mangeshkar Hospital, DMH) agreed to provide needed guidance and conduct a clinical trial after the final prototype was ready.

Before designing the new ECD named Giggles, VI studied current PT practices and nature of existing ECD. Research indicated that all existing ECDs used in several countries were made out of fabric, woven or non-woven, except one made out of foam (Figure 1). Application of all ECD lead to forced eyelid closure restricting a baby from free eye lids movements (Figure 1). Many ECD were ill-fitting leading to frequent dislodgement needing reapplication and the possibility of life-threatening event due to nostril coverage. Frequent dislodgement of the ECD could potentially lead to accidental exposure of the retina to PT light. All ECD were not easy to clean and therefore not reusable even in the same baby. Generally, PT is used for 1 to 5 days and ECD is applied continuously except during feeding breaks.

Design objectives

We needed to develop an ECD that would: Allow free and comfortable eyelid closing and opening while ensuring complete PT light blockage, have good fit to prevent frequent dislodgements, easy to clean, mostly non-fabric material that can be reused while maintaining good hygiene, soft, and baby friendly not causing skin irritation or allergic reaction and pleasing to the eye. In addition, the material needed to be mouldable, light, medically acceptable, and opaque to the PT light for at least five days, durable and affordable.

Material

Different materials including various types of polyurethane, polycarbonate and silicon were examined. Several prototypes using these materials were manufactured and tested for irritation and opacity. Finally, VI decided to use silicone with embedded black dye to maintain opacity. Both are FDA approved. Silicone, being non-reactive, is commonly used for other medical devices. It is soft, flexible, affordable and easy to wash or sterilize and therefore suitable for multiple use.

Size

In addition to the available information, we examined 35 babies to determine the optimum size. (Figure 2). These dimensions (cm, max-min) are: End to end eye: 5.5-10.2, Eye horizontal: 2.5-3.0, Eye vertical: 1-2.8, Vertical resting: 2.4-3, Nose between eyes: 2-2.5, Eye to ear: 4-6.5, Ear horizontal: 2-3, Ear to ear (back): 10.5-15, Head circumference: 31-40. After taking these measurements, we decided on the following two sizes: **Large**: head Circumference 31-40 cm, front piece: length-14 cm, width-3.4 cm (without stretch), headband: length- 29.7 cm. width-1.5 cm (without stretch). **Small:** head circumference 22-31 cm, front piece: length-10.5 cm. width-2.55 cm (without stretch). Headband: length-19.7 cm. width: 1.5 cm (without stretch). Before making a final decision, for precision, these prototypes were tried on many babies.

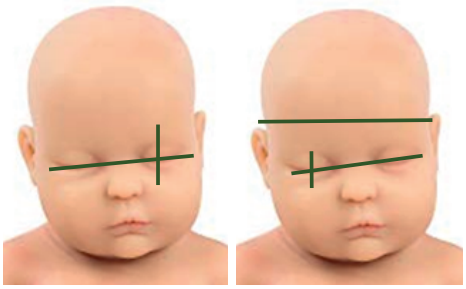

Figure 2: Various measurements.

Designing Giggles

After considerable discussion, the ECD was divided in two parts: The front piece to cover the eyes, referred to as giggles, and the holding piece that circles the head to hold giggles in place. While we started with a round shape, prototypes with different shapes were also attempted. Circular or square design did not match with the baby's eye contour. These shapes would have needed bigger size to cover both the eyes. Therefore, a shape that fitted both the eyes was attempted. It covered both the eyes optimally without a need to increase the size. This shape was then altered to ensure that nose does not get pinched between the eye covers. The shape of the ECD was changed from a well like structure for depth to a

bubble design with two hollow domes covering both the eyes. The nasal bridge size was also adjusted to ensure flexibility without compromising a good fit. Final dome like design is shown in Figure 3A.

Figure 3A: Dome like structure.

Designing the holding piece

Initially, we envisioned ECD as a goggle, with a design similar to a pair of shades: eye covering dome in the front and temples resting on the ear pinna. The idea was to design an ECD easy to apply and wear. Several prototypes with different designs were developed for the holding piece with the band with ear pinna being the support. However, baby's pinna being small and delicate, could not support anything that was heavy or firm. A circular design going around the ear with a small push button for size adjustment was also tried. Similarly, a band like design with a pillow like support at the back was attempted. However, none of the above designs would allow easy size adjustments according to the shape of the baby's head and circumference. Finally, a straight band around the head, with horizontal slits for size and shape adjustment was discovered to be the best option (Figure 3B).

Figure 3B: Front strap.

Connecting Goggles and the headband

Just like the front piece and the band, the connection between them also needed to be soft, while keeping the ECD firmly in place without hurting the baby while allowing adjustment for the size. Small plastic buttons were embedded into the front piece and the band allowing for size adjustment. Since the plastic buttons were not soft, this idea was discarded. Slits were introduced into the front piece to have an elastic band fitting with Velcro. However, this design would not allow easy cleaning and repeated use. We were keen to use silicone for everything for softness and ease of cleaning. A silicone loop functioning as the band was also tried. However, multiple such loops would be required to accommodate head circumference size ranging from 22 to 40 cm. A solution was found by reversing the position of the slit by putting on the headband. The eyepiece was provided with two mushrooms like buttons on either end for proper fit. (Figure 3C-F). Final prototype of giggles is shown in Figure 4.

Figure 3C: Head Band.

Figure 3D: Dome with buttons.

Figure 3E: Band with slits.

Figure 3F: Mushroom buttons.

Figure 4: Final prototype of Giggles.

The slits were made horizontal and reinforced with greater thickness to ensure they do not tear. However, the headband was kept thin to ensure comfort for the baby. This button fits firmly into the slits provided on the head band.

Test for skin irritation and sensitization

Giggles, made out of FDA approved silicone rubber embedded with black dye, underwent evaluation for skin irritation and sensitization testing by the GLR Laboratories (Chennai, Tamil Nadu, India). These studies were performed using male New Zealand White rabbits (n=6) and male guinea pigs (n=26, species: Cavia Parcellus, Strain: Dunkin-Hartley). These studies were performed in strict compliance with the methodologies well-established by the OECD Principles of Good Laboratory Practice [9-15]. After these experiments, it was concluded that application of giggles for more than five days does not lead to skin irritation or sensitization in the rabbit or the guinea pig. Details of these experiments and the entire report are beyond the scope of this manuscript but available on request.

Test for Opacity

Several options for achieving opacity were considered. These included attaching a ultra-violet (UV) film and a combination of UV film and aluminium between layers of PU/silicone. Many dyes of different colours and strengths were also tested. FDA approved black dye met the desired opacity. It was then embedded in silicone used for making giggles. Subsequently, spectroscopic examinations were conducted to ensure giggles was opaque to the blue light in the range of 430-490 nm. Spectroscopic examination was performed at the Venture Centre (Pune, India) using Perkin Elmer Lambda 356 device. The standard testing wavelength is 380 to 800 nm. The blue light range used during PT is from 430 to 490 nm. First test was performed on new giggles which was not sterilised or exposed to the blue-light (n=3). The second test was performed after giggles was exposed to the blue-light for 5 days and washed with soap and water twice a day every day. The transmission of light was zero in all tests. The details of these experiments and the report are beyond the scope of this manuscript. They are available on request. As quality control, we periodically perform spectroscopic examination.

Registration

After the final prototype was developed, it was registered with the Central Drugs Standard Control Organisation (CDSCO, NO: Vitali-Pune-MH/ M/ MD/004145). CDSCO is India's national regulatory body for cosmetics, medical devices and pharmaceuticals. It serves a similar function to the FDA of the USA or Medicines and Healthcare products Regulatory Agency of the United Kingdom. The clinical study protocol was registered under CTRI (CTRI/2021/03/031780).

Patent

Vitalis Technologies holds the patent no 29/2021 from the Official journal of the patent office, India.

Clinical Trial

After the final prototype was ready, an open label randomized control trial was conducted in the NICU of Deenanath Mangeshkar Hospital (DMH) to compare the efficacy of giggles vs the existing ECD. Institutional Review Board approved the study (IHR-2020-Aug-SK-380). Inclusion criteria were all neonates needing PT as per the American Academy of Pediatrics (AAP) guideline who are >35 weeks G.A. and B.W. >2.0 kg [2]. Exclusion criteria: All neonates with skin disease, eye infection or critical illness needing mechanical ventilation. A sample size of 60, 30 in each group by performing a block randomization with randomly selected block sizes of six was selected. Randomization was done using computer generated numbers by the Neonatologist not involved in the study. Sequentially numbered, sealed envelopes were kept with the designated study nurse coordinator who was not involved in the patient care. All neonates received standard NICU treatment. Initiation and cessation of PT was according to the AAP guidelines [2]. In-group 1 (control), Neo i Care (Alliance Hospital Products India Pvt Ltd) and in-group 2 (study) giggles were used. All ECDs were removed during feedings and changed when dirty. The serum bilirubin concentrations were determined as clinically indicated. During PT all infants were examined regularly for complications like eye discharge or periorbital skin changes. The NICU nurse recorded every episode of accidental displacement needing readjustment. A questionnaire regarding their experience with both the ECDs was sent to 60 NICU nurses after enrolling first 30 patients and at the end of the study. Primary outcomes were baby's comfort level, irritability, and the number of spontaneous dislodgements needing reapplication. Secondary outcomes included incidence of eye discharge, number of apneic events, conjunctival redness, periorbital skin rash, user friendliness and the esthetics.

Statistical analysis was performed using unpaired t test and chi square test. P value of <0.05 was considered statistically significant.

Table 1: Neonatal demography in control and study (Giggles) groups. (All data Mean ± S.D.).

Characteristics	Neo-i-Care N=30	Giggles (N=30)	P value
G. A. at birth (weeks)	38.1 ± 1.44	38.5 ± 1.5	0.226
B. W. (kg)	2.72 ± 0.5	2.68 ± 0.53	0.757
Gender (M / F)	12 / 18	16 / 14	0.301
Age (h) PT started	91.7 ± 66.7	101.4 ± 96.6	0.656
Total serum bilirubin when PT started (mg/dl)	15.6 ± 4.6	15. 3 ± 5.1	0.795
Duration of PT (h)	43.4 ± 32.4	45.5 ± 32.2	0.806
Total serum bilirubin when PT stopped (mg/dl)	9.3 ± 2.3	9.1 ± 2.5	0.818
Age when PT stopped (h)	129.3 ± 66.5	144.9 ± 93.7	0.459

Results

Sixty patients were enrolled (30 each group) during 6 months. Demographic characteristics were comparable in both groups (Table 1). Babies in the giggle group did better during breast (79 vs 21%) or the cup feeding (76 vs 24%). During the course of PT, babies in the study group were more comfortable (68 vs 32%) and were easier to take care of. Episodes of dislodgement needing reapplication (12.6 ± 6.9 vs 11.3 ± 7.3 %), need for changing the ECD, slippage on the nose (2.3 ± 3.8 vs 2.7 ± 2.6 %), eye discharge (87 ± 90 %), periorbital skin irritation (90 ± 93 %) were similar in both the groups. There was higher incidence of water like eye discharge in the study group (23 vs 10% and 0.6 ± 1.8 vs 1.8 ± 2.4 %). There was no preference while applying (51 vs 49 %) or removing (47 vs 53 %) either of the ECD. Giggles became dirty less often than the control ECD (8 vs 44%) needing less frequent cleaning. About 75% of nurses preferred giggles, while 25 % preferred Neo i Care. Giggles was esthetically preferred (74 vs 26 %). The incidence of vomiting, abdominal distension, and apnea or skin abrasions was similar in both the groups (data not shown).

Discussion

While not every birth is recorded, ~ 67, 000 (UNICEF) and 385, 000 (United Nations) babies are born daily in India and worldwide [16,17]. About 10 % of all full-term babies develop severe HB (serum bilirubin > 20 mg/dl) needing PT [3,4]. Thus, ~ 6700 and 38,500 full-term babies with severe HB will need daily treatment with PT in India and globally respectively. The AAP recommends treating HB with PT when serum bilirubin level exceeds 15 mg/dl [2]. Incidence of HB needing PT is even higher in very sick full-term or preterm babies [1,2,5,6]. Thus, burden of using PT in all neonates worldwide is enormous. Since this is the first study using giggles, we chose to enroll only close to full-term babies admitted to the NICU who were not very ill. Use of ECD during PT is an integral part of the treatment of a baby with HB [6]. Therefore, it is imperative that a better ECD is made available. Here we describe the genesis of giggles, a better ECD for use during neonatal PT.

Giggles was devised with great precision and efforts using modern technology. There were many challenges, which VI were able to overcome during its development. Silicon used in developing giggles is hypoallergenic and skin friendly, not associated with increased local side effects like erythema or itching compared to the other ECD. In addition, it is more comfortable, fits better, is safe and hygienic, easy to apply and needs cleaning less often, reusable and aesthetic. Currently available ECDs are eye patches made of fabric. Giggle's bubble-like design allows the baby to have freedom of eyelids movements.

Displacement of ECDs needing frequent reapplication is common. To prevent accidental eye exposure to UV light, the ECD needs to fit well. The strap of giggles is designed to do so. However, in the present study, accidental displacement of the ECD was similar in both the groups. There was higher incidence of water collection in the giggles group. Nonetheless, it did not seem to pose any problem. It is likely collected water is baby's tears since silicone compared to fabric is non-absorbent.

Over whelming majority of NICU nurses preferred giggle over the other ECD because it was easier to take care of babies treated with giggles since they were more comfortable and cried less. In addition, giggles was aesthetically more appealing. However, the survey may not be very accurate since the study was Unblinded and it may be subject to recollection bias. While not studied systematically, most parents and other physicians loved the rock star look of a baby wearing giggles.

In summary, we have developed a new ECD for use during neonatal PT. We believe giggles will be an improvement in the existing ECD. Genesis of giggles is a good example of clinicians and biomedical engineers working together. More such collaborations are needed with a common goal of improving the health of neonates worldwide.

Acknowledgement

We thank the Government of India, Department of Science and Technology, under the 'Nidhi Prayas' scheme, for a grant to develop giggles. We are grateful to parents of all babies enrolled in the study. Our sincere gratitude to the entire NICU nursing staff at DMH for their help and encouragement. Giggles received the best innovation award at the NEOCON, 2021 conference held in Bengaluru, India.

Author Contribution

While the need to develop a better ECD was conceived by Dr Devaskar and Dr Kalane, the team of VI were responsible for initiating and finishing the entire project of developing and testing the efficacy and safety of giggles. VI were successful in obtaining a grant from the Government of India. Dr Kalane obtained the IRB approval and was the PI for conducting the clinical trial. Mrs Thorat was the clinical research nurse coordinator. While Dr Devaskar wrote the initial draft of the manuscript, all other investigators contributed in making it final.

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