



Study Report

18 March, 2021

Title: Comparison of commonly used (Neo i Care) versus newly developed (Giggles) eye covering devices during phototherapy.

Investigators: Dr. Shilpa U. Kalane and Dr. Uday P. Devaskar

Location: Neonatal Intensive Care Unit (NICU), Deenanath Mangeshkar Hospital (DMH), Pune, Maharashtra, India.

Introduction:

Mr. Jaydeep Deshpande (CEO, Vitalis Technologies, Pune, India) approached us, Dr. Kalane and Dr. Devaskar. They had developed a new eye covering device (ECD) named Giggles which is presumably better than existing devices used during phototherapy (PT). Mr. Deshpande provided data that Giggles had undergone extensive testing regarding its efficacy and safety. Important attractive features of giggles included: Dome rather than a patch like structure allowing the baby to freely open and close eyelids, made out of silicone rather than some kind of a fabric material, easily washable and therefore reusable, and esthetically pleasing. Therefore, we decided to honor Mr. Deshpande's request to conduct this study in the NICU of DMH.

Study design: Open label Randomized Control Trial (RCT)

Sample size: Sixty neonates (30 in each group)

Materials and Methods:

Institutional Review Board of DMH approved the study protocol (IHR-2020-Aug-SK-380). All neonates >36 weeks of gestation at birth admitted to the NICU needing phototherapy were eligible. Babies with a skin disease, conjunctivitis, nasolacrimal duct obstruction, abnormal neurologically findings, suspected or proven sepsis, moderate to severe respiratory distress and circulatory shock were excluded.

Neonates were randomly assigned to control or the study group using randomization by block random sequence using sequence generator software by a Neonatologist not involved in the study. Sequentially numbered, sealed envelopes were kept with the NICU study nurse coordinator who was not involved in the patient care. None of the ECD were reused between



patients. All the neonates received standard NICU treatment. Initiation and the cessation of PT were at the discretion of the attending physician.

The study was conducted over a period of about six months. Statistical analysis was performed using unpaired t test and chi square test. P value of <0.05 was considered statistically significant.

Outcome Measures: These included: Number of spontaneous dislodgements and need for reapplication, incidence of eye discharge, level of baby's discomfort or irritability, number of apneic episodes, conjunctival redness, periorbital skin rash, user friendliness and the esthetics. In addition, opinion of every NICU nurse taking care of these babies undergoing PT regarding the use of these ECD was evaluated personally and in the form of a written survey

Results:

Baseline demographic characteristics: Gestational age (weeks) (38.1 ± 1.4 vs 38.5 ± 1.5), birthweight (kg) (2.7 ± 0.5 vs 2.7 ± 0.5), gender distribution, age (h) at the initiation (92 ± 67 vs 101 ± 97) and discontinuation (129 ± 66 vs 144 ± 94) of PT, total serum bilirubin (mg/dl) at the beginning (15.6 ± 4.6 vs 15.3 ± 5.1) and stoppage (9.3 ± 2.3 vs 9.1 ± 2.5) of PT and the duration (h) (43.4 ± 32.4 vs 45.4 ± 32.2) of PT were comparable in both groups.

Outcome Measures: 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 comparable in both groups. Thus, giggles was found to be non-inferior ECD to the Neo i Care. However, there were more incidences of collection of moisture in the study group (0.6 ± 1.8 vs 1.8 ± 2.4 %)

Evaluation by the NICU Nurses:

In general, 75 % of nurses preferred Giggles while 25 % preferred Neo i Care. Similarly, Giggles was esthetically a preferred ECD (74 vs 26 %). There was no preference while applying (51 vs 49 %) or removing (47 vs 53 %) either of the ECD. Babies in the study group did better while breast (21 vs 79 %) or the cup feeding (24 vs 76 %). During the entire course of PT, babies in the study group were more comfortable (32 vs 68 %) and easy to take care of. ECD in the control group became dirty more often needing frequent cleaning (44 vs 8 %).

There was no difference in the incidence of vomiting, abdominal distension, apnea or skin abrasions. There was a higher incidence of eye discharge in the study group (23 vs 10 %).



Almost all the nurses were comfortable in allowing the parent to take giggles ECD home as a souvenir if they chose to do so.

All parents and the attending Pediatricians preferred Giggles though this was not studied systematically.

In conclusion, newly developed Giggles seems to be a better alternative to existing ECD used during Phototherapy.

Acknowledgment:

We are grateful to the parents of all the neonates enrolled in the study. We extend our special thanks to the entire NICU nursing staff for helping us to carry out this project to fruition and for their insightful input.

Respectfully submitted,

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