Bilihut Phototherapy Unit

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Device

Phototherapy is one of the first line treatments for neonatal hyperbilirubinemia, also known as neonatal jaundice.[1,2,3] Hyperbilirubinemia in neonates is caused by elevated total serum bilirubin and appears as yellow discoloration of skin, mucous membranes, and/or sclera.[2] If left untreated, it can result in encephalopathy (acute symptoms of neurotoxicity) and/or kernictus (permanent disabling manifestations of neurotoxicity).[1,4] According the American Academy of Pediatrics (AAP), units and lamps used to deliver phototherapy vary widely with no standardized method for delivering.[1] Per the manufacturer, Bilihut is differentiated from other phototherapy units with a flexible curved canopy design that delivers light to "50% more of the infant's skin" while shielding mother's and baby's eyes from the lights, and features a partially enclosed design that "reduces heat loss," which may reduce the need for incubation in some infants.[5] The unit can fit most standard bassinets/cribs and includes the canopy with reflective interior, a disposable "nest" (including disposable mattress), an environment high temperature warning indicator with automatic shut off, and "high intensity" lights that meet AAP guidelines.[5,6,7]

Actions for Consideration

Partner: Identify pediatricians, nurses, and the appropriate clinical and non-clinical value analysis team members, and partner with them to understand product use and population specific need. Reimbursement specialists and case management may be particularly helpful if outpatient utilization/home care is considered.

Connect: Collecting and reviewing data including usage frequency, cost, patient (caregiver) satisfaction, and outcomes may help inform management of these products. Reimbursement information as well as cost of necessary disposables should be included in the analysis.

Communicate: Share product utilization and educate the team, emphasizing safe use. Discuss pricing, reimbursement, satisfaction, and clinical outcomes. Robust data sharing will not only enhance discussions, but may lead to actionable conversations between peers.

HealthTrust Resources: Access the Clinical Knowledge Insights Library to find other relevant documents and toolkits with actionable information. Examples for this product include resources on product conversion, value analysis, and clinical trials.[8] Network on HealthTrust Huddle, our member community that shares ideas and seeks guidance from colleagues.[9]

Professional Society Statements and Clinical Practice Guidelines

AAP *Clinical Practice Guideline Revision: Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation,* includes recommendations for goals of phototherapy, levels of irradiance, monitoring of patients during treatment, and discontinuation parameters. Found here.[1]

FDA Approval

Bilihut obtained FDA 510K approval (K190899) with indications for use as "…provides phototherapy for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the clinical or home setting." Found here.[10]

Clinical Evidence

There are no studies found directly utilizing Bilihut. There are numerous studies on phototherapy in the treatment of neonatal jaundice. A sample is included below:

- A 2020 systematic review by Van Rostenberghe et al. aimed to assess the effects of utilizing reflective materials with phototherapy versus phototherapy alone. Twelve studies (1288 infants) were included which used reflective curtains on 3-4 sides of the cot. They concluded that very low-certainty evidence suggests the duration of phototherapy may be reduced with the use of reflective materials, and moderate-certainty evidence suggests reduction of hospitalization, potentially resulting in a greater decline in serum bilirubin. Limitations included "substantial heterogeneity" between studies, potential exclusion of applicable studies, post hoc addition of an outcome, potential inconsistencies in what was considered reflective material, and two authors being involved in studies included in the review.[11]
- A 2022 retrospective multicenter cohort study by Zhang et al. compared the effectiveness and complications of intensive phototherapy (IPT) versus exchange transfusion (ET) in the treatment of "extreme" hyperbilirubinemia. A total of 1164 patients over a three-year period were included. Outcomes included duration of hospitalization, ocular motility disorders, development of encephalopathy, athetosis, and motor and language development. They concluded that IPT is safe and effective in treating extreme hyperbilirubinemia and that the indication for ET could be "stricter"; however, a plan should be in place for emergent ET as necessary "especially for infants with risk factors." Limitations included sample size in the high-risk group, the exclusion of patients less than 35 weeks, and inclusion of only one race in the study.[12]
- A 2021 randomized controlled multicenter trial by Pettersson et al. assessed whether home phototherapy was "feasible and safe" in term neonates who fulfilled criteria for in-hospital phototherapy but were otherwise healthy. The study included 250 newborns over a three-year period. Outcomes included effect on bilirubin levels, number of hospital admissions after failed home treatment, and duration of phototherapy. They concluded that home therapy "could be" a safe alternative to inpatient with daily check ups and 24-hour, seven day a week, phone support. Limitations included sample size, the majority of participants coming from single center, potential differences in type of phototherapy used in the control group, and the amount of phototherapy documentation without direct clinical supervision in the home group.[13]

Healthtrust Huddle Insight

Members within our HealthTrust Member Network offered the following insight (via survey within Healthtrust Huddle) with regard to Bilihut[14]:

- Appears to offer a controlled and comfortable environment for treatment.
- Sits right next to the mother's bed, in the hospital or at home, for convenience.
- Potential ability to affect more body surface.
- Smaller neonates would still need incubators which this is not compatible with.
- Potential concern that patient not in direct visibility at all times.
- More information is needed on home use and how patient would be monitored.
- Appears to reduce bright light in mom's and baby's eyes.
- Potential to reduce cost as may prevent incubator use in some patients.

Summary

There are numerous options available, with varying methods of delivery, for the treatment of neonatal jaundice with phototherapy. Careful review and understanding of interest, specific population needs, cost (including disposables), caregiver feedback, and product attributes will help determine direction and potential opportunity. Where there is limited evidence with direct utilization of a product, a trial of the product(s) is a potential consideration. Share data to engage clinicians. When considering a change of product ensure physicians are included in the discussion, that evidence and pricing are shared, and appropriate support is provided from the supplier.

References

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