bili-hut™ vs. BiliBed for Home Phototherapy of Term, Breastfed Newborns

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INTRODUCTION

Neonatal jaundice is a common condition occurring in up to 80% of infants in the first week of life, with 5-10% requiring medical intervention with phototherapy to prevent neurotoxic sequelae of hyperbilirubinemia.[1-4] Numerous studies have demonstrated that home phototherapy for low-risk, jaundiced neonates is safe and effective using a variety of light configurations including a single fiberoptic pad device (GE Bilisoft)[5], a double fiberoptic pad device (NeoMedLight BiliCocoon)[6] or an undersurface fluorescent device (Medela BiliBed)[7].

Little Sparrows Technologies bili-hut™ is a next generation portable LED phototherapy application that delivers multidirectional illumination with a curved light array and is designed to treat more skin surface area than traditional undersurface light configurations. Our pilot study is the first to assess efficacy of bili-hut™, comparing it with the Medela BiliBed undersurface blue fluorescent phototherapy in home treatment of hyperbilirubinemia.

Hypothesis:

1) Multidirectional LED therapy with bili-hut™ is faster than traditional undersurface fluorescent technology with Medela BiliBed.

2) bili-hut phototherapy decreases nursing hours required without additional complications such as readmission.

bili-hut™

BiliBed

METHODS

Inclusion criteria

- Term gestation (37 – 42 weeks gestation)
- Exclusive breastfeeding
- Low medical / neurological risk (e.g., absence of risk factors for hemolysis, no fever or temperature instability, etc.)
- No prior treatment with phototherapy
- Pre-treatment total serum bilirubin (TSB) obtained within 8 hours of initiating phototherapy

Recruitment

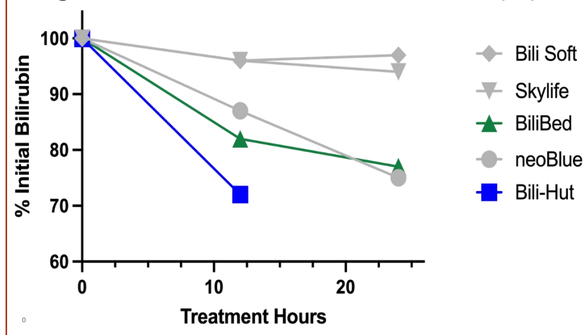
- All eligible infants referred for home phototherapy were offered participation in the study.
- Those who accepted and signed consent were randomized to treatment with bili-hut™ (Little Sparrows Technologies, Inc.) or Bilibed (Medela, Inc.) based on availability of the treatment modality at the time of initiation.

Procedure

- All equipment in this study was maintained and used in accordance with manufacturer's instructions.
- The initial (pre-treatment) total serum bilirubin level (TSB) was obtained by the primary care provider, prompting referral to the home phototherapy nurse service (Healthy Babies Happy Moms, Inc.).
- Upon receiving the referral, a nurse delivered and set up the phototherapy equipment in the home, instructed the parents on its use, weighed and clinically assessed the newborn and provided lactation support as needed.
- Parents were instructed to only remove the infant from phototherapy for breastfeeding and diaper changes.
- The following morning after initiation of therapy a nurse returned to the home to draw a follow up TSB and clinically assess the newborn.
- The nurse contacted the pediatrician with TSB result and clinical assessment. The pediatrician made the determination regarding stopping or continuing phototherapy.
- TSB levels were checked every 12--24 hours thereafter if phototherapy was continued.
- A final (rebound) level was drawn 8-12 hours after discontinuation of treatment if ordered by the primary care physician.

RESULTS

Fig 1. Percent Bilirubin Reduction vs. Time (hr)



To normalize data for purpose of comparison, initial average TSB for each study arm is defined as 100% with further reduction expressed as a percent relative to initial value. A second TSB was drawn on the following morning 6-14 hr after treatment initiation, with additional TSB values drawn at 12 to 24 hour intervals until the physician determined treatment could be stopped. Using the calculated bilirubin reduction rate and assuming linearity, these values were extrapolated to a projected value at 12 hours for graphic comparison. Treatment times were determined by recording the device timer reading at the start and completion of treatment and at time of blood sampling.

Preliminary results show TSB decreased more rapidly with bili-hut™ treatment, with a 28% decrease from initial pre-treatment compared to 18% with BiliBed, and also more rapidly than published historical declines with BiliSoft, Skylife, and neoBlue, as shown in gray. TSB Bilirubin reduction rate with bili-hut™ and BiliBed averaged 0.46 (+/- 0.04) mg/dL/hr and 0.27 (+/- 0.02) mg/dL/hr, respectively, with associated treatment times averaging 14.8 hours and 26.2 hours, respectively.

Fig 2. Patient Demographics

Treatment type	Gestational age	Weight	Age at initiation of treatment	Bili level at initiation
BILIHUT™ n=8	38.5 weeks (37 – 39 w)	3373 g (3118-3685g)	69.4 h (57-110 h)	18.5 (15.7-21.0) (mg/dL)
BILIBED n=6	38.7 weeks (37-40 w)	3670 g (3288-4054g)	96.6 h (69-145 h)	18.0 (15.6 – 21.3)

A total of 14 newborns of a have been recruited for this study to date. Recruitment will continue until 20 newborns (10 bili-hut and 10 BiliBed) have been treated. The average gestational age of infants was nearly identical, although infants treated with bili-hut phototherapy were chronologically younger (69.4 vs. 96.6 hours), smaller (3373g vs. 3670g), and had slightly higher pre-treatment bilirubin levels (18.5 mg/dL vs. 18.0 mg/dL (316.4 µmol/L vs. 307.8 µmol/L)).

DISCUSSION

Overall, the preliminary results of this pilot trial agree with prior studies [5-7] demonstrating that home phototherapy is a safe and effective alternative to hospital admission for management of neonatal jaundice. All infants in this study were successfully treated at home, avoiding hospital readmission.

When comparing bili-hut multidirectional LED phototherapy to Medela BiliBed undersurface fluorescent phototherapy, bili-hut phototherapy demonstrated a more than 50% faster decline in TSB (0.46 vs 0.27 mg/dL/hr) and shorter average treatment time (14.8 vs 26.2 hours). The practical outcome of this is fewer nursing contact hours and improved resource utilization.

CONCLUSIONS

- Preliminary data suggests that bili-hut™ is an effective means of providing home phototherapy to term breastfed neonates, with more than 50% faster rate of TSB decline and decreased total treatment time when directly compared to Bilibed, as well as faster than historical data from other phototherapy devices.
- More data are needed regarding the use of the bili-hut™ in term neonates. Bili-hut use should also be studied in late preterm neonates who are otherwise well and infants with hemolysis risk factors, as other investigators have done, to assess ability to avoid readmissions for phototherapy in populations who are at higher risk for significant jaundice.
- Cost analysis of bili-hut home phototherapy, given its rapid treatment times, avoidance of readmission and reduction in nursing contact hours, will provide additional insight to its financial impact in health systems.
- Limitations of this study include a small sample size limited to term breastfed neonates. Study recruitment is ongoing.

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