Evaluation of an Affordable LED Phototherapy Device for Resource-Limited Settings

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Background

Surveys of phototherapy devices in resource-limited settings have shown that suboptimal phototherapy is often delivered due to limitations in the design and/or maintenance of devices (Fig. 1). Brilliance, a LED-based overhead phototherapy device (Table 1) developed by D-Rev: Design for the Other 90%, USA, and manufactured by Phoenix Medical Systems, India, has low maintenance requirements (its LEDs last 30,000 hours, compared to 3,000 hours for typical fluorescent lamps), is robust to the variable electrical power common to resource-limited settings, and has a low projected production cost (less than $135 per device).

Objectives

To evaluate in vitro the potential efficacy and performance of Brilliance for preterm and term infants.

Materials and Methods

The in vitro efficacy of Brilliance (prototype) was assessed according to the standardized bench method outlined in Vreman et al.1 Evaluation parameters include light potency (emissions wavelength range and peak in nm), intensity (irradiance in µW/cm²/nm), treatable body surface area (BSA) comparable to term infants and in vitro photodegradation rate of bilirubin in aqueous human serum albumin solution at 37°C (τ1/2 in min). The latter is considered to be an index of in vitro efficacy for phototherapy devices. The amortized cost of treatment per newborn for all devices was calculated based on a 48-hour treatment time standard.

Results

Table 1. Technical specifications of Brilliance. Irradiance was measured with the Brilliance Light Meter II (Olympus/GE Healthcare). *measured of homogeneity of irradiance distribution to meet IEC 60601-2-50 requirements.

Device Design and Specifications

Table 2. Characteristics of evaluated phototherapy devices. Irradiance was measured with the Brilliance Light Meter II (Olympus/GE Healthcare). Normalized 3-D efficacy was determined with the photodegradation rate of unconjugated bilirubin in human serum albumin (τ1/2)1 adjusted for 3-D BSA.

Table 3. Cost assessment of affordability. Illumination source lifespan and a 48-hour treatment time standard were factored into the retail value of each device to approximate cost.

Conclusions

• This study demonstrates that Brilliance meets the 2004 AAP guideline for effective phototherapy2.
• Brilliance yielded superior and lower normalized τ1/2 values than leading commercial phototherapy devices for the BSA of term infants (Table 2).
• Brilliance also has the lowest cost of treatment per newborn over a 48-hour period—$0.75 per treatment (Table 3). Cost-of-care and variations in treatment time due to degenerative performance of fluorescent and halogen phototherapy devices were not factored into the comparison.
• Its low cost and ease of maintenance suggest Brilliance is a potentially appropriate device for treating neonatal hyperbilirubinemia in low-resource settings.
• Clinical trials are planned to define its effectiveness at resource-limited hospitals.

References


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