Performance Evaluation for Hyperbilirubinemia Phototherapy Equipment

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Abstract: Phototherapy with blue light is regarded as a drug to manage Hyperbilirubinemia in neonates, with an appropriate dose and duration. However till now there is no standardized method for reporting phototherapy dosages in the clinical practice. According to the requirement of Egyptian standard: 5807/ 2007 and British standard BS EN 601601-2-50:2009 + A11:2011, present work provides a radiometric technique to evaluate the performance of phototherapy unit by measuring the irradiance levels and their distributions over the effective area in W/cm² under the phototherapy unit (luminaire). Accurate evaluation gives the opportunity to choose the best and the appropriate device for the treatment, as it allows gaining the maximum benefit from light sources used. Also, this work shows a brief comparison between light sources used in the phototherapy units, clarifying that fluorescent lamp provide homogenous irradiance with short lifespan while LEDs providing less uniformity with Longer lifespan.

Key words: Hyperbilirubinemia treatment, phototherapy, device performance, irradiance.

INTRODUCTION

The ‘dose’ of phototherapy would depend upon the device characteristics such as emission spectral data, maximum irradiance, mean irradiance, treatable percentage of body surface area (BSA), age of the light source, and possibly the amount of formation of photo isomers from bilirubin. (Sreeram et al., 2011). Currently, no guidelines are available for measuring the efficacy of different phototherapy devices. Effective phototherapy implies its use as a “drug” at specific blue light wavelengths (peak, 460 nm) and emission spectrum (range, 400 to 520 nm), preferably in a precise (narrow) bandwidth, that is delivered at an irradiance (dosage) of 30-35 μW/cm² nm to 80% of an infant’s body surface area (BSA). Radiation with visible light above about 500 nm is considered useless. (Vinod K Bhutani, 2009).

Misdistribution of light is a potential cause of phototherapy failure in the neonate (Malcolm I Levene, 1980). The light intensity of phototherapy units was recorded in various positions over an incubator phototherapy effective area. The effective area was divided into 9 equal rectangles each measuring 21 x 12 cm (Malcolm I Levene, 1980). The intensity was recorded in [μW/cm², Or μW/cm² /nm]. The peak sensitivity of the radiometer was at wavelength 450 nm. (Sreeram et al., 2011, Vinod K Bhutani, 2009, Malcolm I Levene, 1980).

N Modi and A J Keay, management of neonatal jaundice using irradiance range from 0.4 mW/cm² to 1.08 mW/cm² at the range of wavelengths from 420 to 480 nm. (N Modi And A J Keay, 1983).

Many studies had done to manage the neonatal jaundice using irradiance of wavelengths from 420 to 500 nm. (Sreeram et al., 2011, Novos Ltd., 2008, Danial et al. 2000).

Measurements Technique:

Preparation for Measurement:
A. Constructed a 4 X 8 matrix on a sheet -dimensional 60cm X 30cm or as noted by the manufacturer. (Figure 1)
B. Brake the phototherapy unit upon the sheet at distance of 50cm.
C. Align the center of the sheet with the center of the phototherapy unit (luminaire), using alignment laser.
D. Fix the sheet at the irradiated level.
E. Check the battery level of the measuring instrument (phototherapy Radiometer).
F. For each of the testing sets check the information regarding gain settings, and enclosure temperature.
G. Use a pre-prepared table to record the readings.

System Alignment:
The phototherapy unit and the sheet must be prepared in a specific format so that the center of the effective surface area (sheet) and the centre of the phototherapy unit lay on one vertical line, parallel and the distance between them is 50 cm or as specified by the manufacturer.

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Fig. 1: Set of 7.5 X 7.5 cm squares constructed on a sheet forming a matrix of 4 x 8 and total dimension of 30 X 60 cm as required by Egyptian standard: 5807/2007.

Measurements Procedure:
A. Align the system as described at 2.1 a figure 2.
B. Fix the sheet.
C. Warm up the phototherapy unit for 30 min.
D. Record the irradiance levels at each central point of the matrix on the sheet.
E. Repeat step D for 5 times.
F. Record the environmental conditions.

Fig. 2: Measurement set up.

RESULTS AND DISCUSSION

Tables 1 and 2 show some results from two kinds of phototherapy units. Table -1 shows the results from phototherapy lamps and table-2 represents the irradiance level using LEDs.

<table>
<thead>
<tr>
<th>Table 1: Irradiance levels at therapeutic level irradiated by lamps.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean spectral irradiance readings in µW/cm²</td>
</tr>
<tr>
<td>Position</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
</tbody>
</table>
Table 2: Irradiance levels at therapeutic level irradiated by LEDs.

<table>
<thead>
<tr>
<th>Position</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>241.5</td>
<td>855.2</td>
<td>1916.2</td>
<td>3539</td>
<td>2936.2</td>
<td>1519.2</td>
<td>680.4</td>
<td>272.1</td>
</tr>
<tr>
<td>2</td>
<td>427.7</td>
<td>1592.8</td>
<td>4511</td>
<td>5785.8</td>
<td>3972.8</td>
<td>2449.8</td>
<td>1168.8</td>
<td>364.7</td>
</tr>
<tr>
<td>3</td>
<td>427.3</td>
<td>1303.2</td>
<td>4541.4</td>
<td>4861.2</td>
<td>4297.6</td>
<td>3561.2</td>
<td>1496.2</td>
<td>369.1</td>
</tr>
<tr>
<td>4</td>
<td>349.8</td>
<td>719.5</td>
<td>2159</td>
<td>3183.4</td>
<td>3090.6</td>
<td>2446.6</td>
<td>958.4</td>
<td>279.6</td>
</tr>
</tbody>
</table>

According to Egyptian standard: 5807/2007 and BS EN 601601-2-50:2009 + A11:2011, It is noticed from evaluation of different phototherapy units using florescent lamp and LEDs, that the lamps produce better irradiance uniformity than that obtained from LEDs. Taking into account that LEDs providing higher irradiance levels.

**Uncertainty Budget:**

The equations used in calculating uncertainty U are:

- Irradiance Uniformity \( G = \frac{E_{bi \text{ min}}}{E_{bi \text{ max}}} \)
- Ambient light = \( \frac{\text{irradiance level when the phototherapy unit is OFF}}{\text{irradiance level when phototherapy unit ON}} \)
- Source instability (repeatable) = \( \frac{\text{STDEV}}{\sqrt{n}} \)
- Combined uncertainty \( U_c = \sqrt{\sum U^2} \)
- Expanded uncertainty \( (k=2) = 2 U_c \)

**Conclusions:**

Performance evaluation of phototherapy devices depending on accurate measurements of the irradiance levels and its distribution over the irradiated surface using calibrated phototherapeutic radiometer.

Select the ideal device to perform the required medical service basically depends on good evaluation of the available phototherapy devices.

Although, performance evaluation leads to improve the quality of treatment, it can provide accurate doses. Periodical measurements the irradiance levels give serious information of the phototherapy performance and its possibility to serve its continuity in the provision of medical service required.

Also, evaluation Follow-up leads to know the right time to replace the light sources. keeping in mind that complete evaluation at each replacement is must in order to maintain quality of the service, and also raise the economic value of the phototherapeutic unit.

**REFERENCES**


Multidirectional Intensive Phototherapy, Bilisphere, 360, Novos Ltd., 2008.

