Efficacy of Bidirectional Fiber-optic Phototherapy for Neonatal Hyperbilirubinemia

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ABSTRACT. ***Objective.*** **To evaluate the efficacy of fiber-optic phototherapy using the standard Ohmeda Biliblanket, a large version, double standard Biliblankets, and conventional phototherapy using daylight fluorescent lamps in full-term, healthy infants with nonhemolytic hyperbilirubinemia.**

Methods. **Full-term, healthy infants with nonhemolytic hyperbilirubinemia (bilirubin concentration, >255 μmol/L or 222 μmol/L at <48 hours of age) were allocated randomly to one of four modes of phototherapy: standard fiber-optic mat (Ohmeda Biliblanket), a large version, double standard Biliblankets, and conventional phototherapy. Bilirubin levels were monitored every 12 hours. Exposure was stopped when bilirubin levels were less than 185 μmol/L, the minimum duration being 24 hours.**

Results. **A total of 171 infants were studied; 42 were exposed to standard fiber-optic phototherapy, 43 to large fiber-optic phototherapy, 42 to double–fiber-optic phototherapy, and 44 to conventional phototherapy. Durations of exposure were 87.05 ± 6.09 (SEM), 82.57 ± 5.84, 64.85 ± 5.43, and 62.61 ± 3.74 hours, respectively; the 24-hour decline rates were 10.26% ± 1.84%, 14.50% ± 1.53%, 21.82% ± 1.71%, and 19.00% ± 1.65%, respectively; the overall decline rates over the whole exposure period were 0.47% ± 0.03%, 0.52% ± 0.04%, 0.71% ± 0.05%, and 0.75% ± 0.04% per hour, respectively. The efficacy of double–fiber-optic phototherapy and conventional phototherapy was similar and significantly better than that of the large fiber-optic mat and the standard fiber-optic mat in duration, 24-hour decline rate, and overall decline rate. The large mat was slightly better than the standard-size mat with regard to 24-hour decline rate and overall decline rate, but this difference was not significant. Failure of phototherapy occurred only in the large fiber-optic mat group (3 of 43) and the standard fiber-optic mat group (4 of 42); none occurred in the other two groups, but differences not statistically significant. The nursing personnel were more comfortable with single fiber-optic phototherapy, which caused no initial disturbance to the swaddled infants as did conventional phototherapy, but found double–fiber-optic phototherapy difficult to use.**

Conclusion. **For efficacy of fiber-optic phototherapy in full-term infants to be comparable to that of our conventional phototherapy, the light dose of the standard mats needs to be doubled.** ***Pediatrics*** **1997;99(5). URL: http://www.pediatrics.org/cgi/content/full/99/5/e13;** ***fiber-optic phototherapy, neonatal hyperbilirubinemia, efficacy.***

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Fiber-optic phototherapy delivered via a fiber-optic cable to a transparent flat device (mat) that can be placed directly in contact with the infant skin has been demonstrated to be effective for neonatal hyperbilirubinemia.[1–3] The fiber-optic Biliblanket device (Ohmeda Critical Care, Columbia, MD) was found to be more effective than the Wallaby phototherapy system (Fiberoptic Medical Products Inc, Allentown, PA).[4] However, in our experience the efficacy of the standard-size mat for full-term infants is distinctly less than that of conventional phototherapy using our own setup[5]; this was attributed to the relatively small size of the mat, resulting in exposure of the skin being limited to a small area. A bigger mat or two standard mats would improve the performance of fiber-optic phototherapy; the present report compares these two forms of phototherapy against that of a standard fiber-optic mat and conventional phototherapy in terms of efficacy and practicality.

METHODS

Full-term, healthy infants with nonhemolytic hyperbilirubinemia as previously defined[5] (no abnormality on a hemogram, no evidence of blood group isoimmunization, a negative result of the direct Coombs test, hemoglobin level greater than 140 g/L, and hematocrit level greater than 0.40 with exclusion of glucose-6-phosphate dehydrogenase deficiency [tested by a modification of the method of Bernstein by Tan and Boey[6]]) were exposed to phototherapy when their bilirubin concentrations were greater than 255 μmol/L (15 mg/dL) or greater than 222 μmol/L (13 mg/dL) in the first 48 hours of life (early onset jaundice). Bilirubin concentrations greater than 255 μmol/L cause significant prolongation of the central conduction time.[7] The infants were randomly allocated using the lottery method to four forms of phototherapy: (1) a standard-size fiber-optic Biliblanket, a device consisting of a halogen lamp with an attached fiber-optic cable containing 2400 optic fibers that end spread out in a flat mat; the light is transmitted via the fibers to the mat, which is placed in direct contact with the skin during phototherapy; (2) a single large fiber-optic mat, a stretched version of the standard mat with the same number of optic fibers; (3) double fiber-optic mats, two of the standard mats, one placed against the front and the other against the back of the infant; and (4) conventional phototherapy using seven overhead daylight fluorescent lamps (TLD18W/54; Philips Electronic Instruments, Mahwah, NJ) arranged in an arc 35 cm above the infant, a height that permitted clear observation of, as well as good accessibility to, the infants and at the same time provided adequate heat to maintain normothermia. In the first three groups it was possible to swaddle the infants with the mat(s) placed against the infants' skin; to ensure maximal efficacy, the fiber-optic mat was used without its sheath and set at maximal power. The size of the mat was 11 × 20 cm, and the illuminated part was 11 × 13 cm; those of the large mat were 11 × 24 and 11 × 16 cm, respectively. The increment in size of the illuminated part was about 23%. No eye pads were required. In the conventional phototherapy group, the infants were exposed completely unclothed, with their eyes covered.

The irradiance of the standard fiber-optic device (without the sheath and set at maximal power) measured at the center and the four corners averaged 19.01 $\mu W/cm^2$ per nanometer; that of the seven overhead lamps averaged 6.73 $\mu W/cm^2$ per nanometer; the irradiance of the larger fiber-optic mat was similar to that of the standard mat; because of its larger size, the light dose of the larger mat would be about 23% more than that of the standard fiber-optic mat. Because of the different spectra of the two types of light, the irradiance values of the Biliblanket were 867 $\mu W/cm^2$ in the 400- to 480-nm range, 437.0 $\mu W/cm^2$ in the 425- to 475-nm range, 342.0 $\mu W/cm^2$ in the 440- to 480-nm range, and 775.8 $\mu W/cm^2$ in the 440- to 500-nm range; the values of the seven overhead lamps were 403.2, 205, 106.6, and 201.6 $\mu W/cm^2$, respectively. In the double–fiber-optic setup the total irradiance would be twice that of the standard fiber-optic mat. The irradiance in the blue spectrum was relatively low, but that in green spectrum was substantial in fiber-optic phototherapy (hence the greater values in the spectrum involving the 500-nm band). The measurements were made using an International Light (Newburyport, MA) 400A radiometer/photometer. Fluid intake was increased during phototherapy to offset the increased fluid loss during exposure.

Capillary blood was sampled at start of exposure and every 12 hours thereafter to monitor the serum bilirubin response to exposure. The lights were switched off during sampling. The capillary samples were placed in labeled red drinking straws and kept in a light-proof box until the moment of determination under standard conditions using an American Optical bilirubinometer, which was calibrated regularly against known standards.

In infants with increasing bilirubin values exceeding the starting value on two consecutive determinations during exposure, direct-acting bilirubin was determined as previously described;[6] when this was minimal (<10 μmol/L [0.6 mg/dL]), phototherapy was deemed to have failed, and the infant was transferred to high-intensity phototherapy as previously described.[8] Direct-acting bilirubin was also estimated in random samples.

Phototherapy was terminated when bilirubin values had declined to less than 185 μmol/L (11 mg/dL) on two successive estimations, the minimal duration being 24 hours; the prolonged central conduction time was observed to improve with bilirubin decline during exposure, complete reversal occurring 24 hours after cessation of exposure.[7] Bilirubin levels were then monitored daily to determine the rebound, for at least 2 days; if rebound bilirubin concentrations increased beyond those of the prephototherapy values, additional phototherapy was performed following the same guidelines.

The nursing personnel caring for the infants were interviewed regarding convenience, ease of use, infant care, and acceptability of the fiber-optic device compared with conventional phototherapy. The parents were also interviewed regarding their reaction to the new device. Informed consent from the parent(s) and approval for this study from the director of medical affairs of the National University Hospital were obtained.

The data were statistically evaluated using analysis of variance, Student's t test, and the χ^2 test.

RESULTS

Altogether 171 full-term, healthy infants (Table 1) with nonhemolytic hyperbilirubinemia were studied. All remained well during and after the exposure; phototherapy was well tolerated, but initial restlessness was observed with conventional phototherapy before the infants settled down. Phototherapy was effective in decreasing bilirubin concentrations in all four groups. The response was the greatest in the double–fiber-optic and daylight groups, the former demonstrating slightly better efficacy initially, with the latter being better in overall efficacy (Fig 1). Statistical evaluation by analysis of variance demonstrated significant differences among the four groups in duration of exposure ($P < .003$), 24-hour decline ($P < .001$), and decline over the whole exposure duration ($P < .001$). Student's t test was then performed to evaluate the differences between individual groups. The large fiber-optic mat was slightly better than the standard-size fiber-optic mat, but the improvement was not significant; duration of exposure was about 5% shorter, 24-hour decline rate (expressed as percentage of starting bilirubin concentration) 40% better, and overall decline rate (decline during the whole period of exposure expressed as percentage of decline per hour) 10% faster. Both of these phototherapy modes were significantly less effective than double–fiber-optic and daylight phototherapy (Table 2). Failure occurred only with the standard and large fiber-optic mats; none occurred with the double–fiber-optic and conventional modes, but the difference was not significant. One infant each from the double phototherapy and conventional phototherapy groups needed second exposures compared with none in the other two groups. The response to the second exposure was as good as to the first.

The direct-acting bilirubin was minimal in all the samples tested; all the values obtained were less than 10 μmol/L.

The nurses caring for the full-term infants were unanimous in their approval of the fiber-optic mat, being more comfortable without the conventional overhead phototherapy frame; absence of glare was a positive factor, although this was thought to be a minor problem. Cleaning the soiled fiber-optic mats was the only disadvantage, but this was offset by little need to clean the cots, otherwise required during conventional phototherapy. The nurses thought

TABLE 1. Data of Infants Studied

Infant Characteristic	Daylight Phototherapy	Fiber-optic Phototherapy		
		Double Mat	Large Mat	Standard Mat
No. (M:F)	44 (27:17)	42 (20:22)	43 (26:17)	42 (23:19)
Birth weight, g*	3080.5 ± 77.1	3119.2 ± 64.5	3059.4 ± 57.7	3200.1 ± 49.8
Gestational age, wk*	38.2 ± 0.3	38.7 ± 0.2	38.8 ± 0.2	38.6 ± 0.2
Age, d*	4.1 ± 0.2	4.0 ± 0.2	4.1 ± 0.2	4.0 ± 0.2
Hemoglobin, g/L*				
Start	181.5 ± 3.4	184.2 ± 3.0	180.5 ± 2.9	185.0 ± 4.1
End	169.4 ± 3.1	164.2 ± 5.0	165.9 ± 2.8	167.3 ± 3.1
Hematocrit*				
Start	0.56 ± 0.01	0.56 ± 0.01	0.57 ± 0.03	0.56 ± 0.01
End	0.51 ± 0.01	0.51 ± 0.01	0.51 ± 0.01	0.51 ± 0.01
Bilirubin, μmol/L*				
Start	261.8 ± 2.7	259.8 ± 2.9	262.8 ± 2.5	260.9 ± 2.4
End	152.8 ± 2.6	153.8 ± 2.6	164.0 ± 2.2	165.0 ± 2.2

* Values expressed as mean ± SEM.

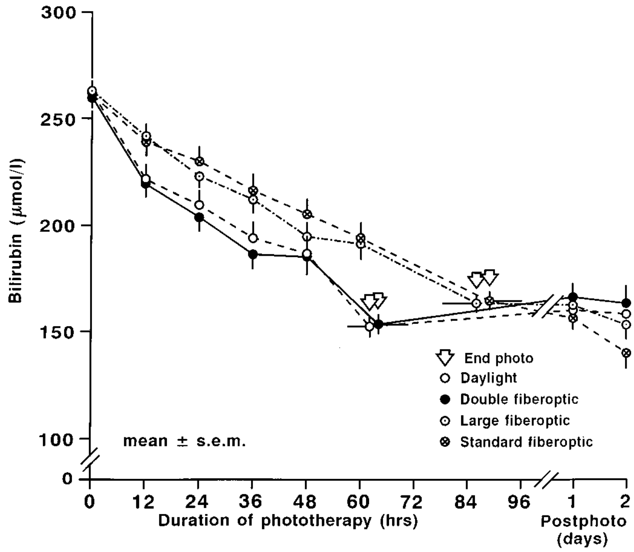

Fig 1. Bilirubin decline in response to type of phototherapy.

that the major drawback was the long duration of exposure imposed by the mats. The infants were immediately comfortable with the mats, manifesting none of the initial restlessness observed with conventional phototherapy. All the parents were reassured with the infants swaddled and without eye pads. However, the double–fiber-optic arrangement was found to be clumsy and difficult to apply neatly; nursing the infants was also inconvenient, and the cleaning of two mats for each case was deemed excessive and tedious. Feeding during exposure was also not convenient with two fiber-optic mats attached. However, the infants were not adversely affected.

TABLE 2. Decline of Bilirubin Concentration and Type of Phototherapy

Decline/Failure by Therapy Group	Response	*P*
Duration, h*		
Double fiber-optic	64.85 + 5.43†	
		<.05
Large fiber-optic	82.57 + 5.84†	
		1.0 ≫ .5
Standard fiber-optic	87.05 + 6.09†	
		<.001
Conventional	62.61 + 3.74†	
24-h decline, %*		
Double fiber-optic	21.82 + 1.71‡	
		<.01
Large fiber-optic	14.50 + 1.53§	
		.1 ≫ .05
Standard fiber-optic	10.26 + 1.84‡	
		<.001
Conventional	19.00 + 1.65§	
Overall decline rate, %/h*		
Double fiber-optic	0.71 + 0.05†	
		<.01
Large fiber-optic	0.52 + 0.04‡	
		.4 ≫ .3
Standard fiber-optic	0.47 + 0.03†	
		<.001
Conventional	0.75 + 0.04‡	
No. of failures		
Double fiber-optic	0 of 42	
		.3 ≫ .2
Large fiber-optic	3 of 43	
		1.0 ≫ .9
Standard fiber-optic	4 of 42	
		.2 ≫ .1
Conventional	0 of 44	

* Values presented as mean ± SEM.
† $P < .01$.
‡ $P < .001$.
§ $P < .05$.

DISCUSSION

The efficacy of the fiber-optic phototherapy was distinctly less than that of conventional phototherapy in the full-term infants despite the fiber-optic irradiance per unit area being greater than that of the conventional setup. This was probably attributable to the relatively small area exposed (with a reduced total light dose) and the emission spectrum being mainly in the green region, which was less effective than that of blue light,[9] the latter being relatively low. A recent report claimed that a blue-green light combination[10] presumably of equivalent irradiance in both spectra was highly effective; an even higher degree of efficacy was observed in our larger preterm infants exposed to special blue light.[11] The emissions in the blue and green regions in the daylight lamps used in this study were fairly comparable, although of a lesser irradiance, especially in the green wavelength, compared with that of the fiber-optic mat. Even a 23% increase in the size of the fiber-optic mat did not improve its performance significantly.

The best results were obtained by double–fiber-optic phototherapy and conventional phototherapy; because twice the surface area was exposed in this double arrangement, the light dose was significantly increased, being twice that of standard fiber-optic phototherapy. The same light dose can be achieved by increasing the irradiance twofold without increasing the surface area; the effect would be the same.[12] The rate of response, however, was less than twice that of the latter, which was not surprising, given the pattern of response of hyperbilirubinemia to increasing irradiance.[8] This type of phototherapy was more difficult and inconvenient to administer; nursing such infants was also relatively difficult. Cleaning two mats for each infant was an added inconvenience. With conventional phototherapy, probably about one third of the total skin surface area was exposed (about 730 cm^2) compared with much less surface area exposed to the fiber-optic mats (143 and 176 cm^2 for the standard and large mats, respectively); hence, with conventional phototherapy, the total light dose (area exposed × irradiance) would be much greater even though the irradiance per unit area would be less. Our conventional phototherapy setup[13] seemed more effective than the commercial sets currently on the market, despite being set 35 cm above the infant. Conventional phototherapy might therefore be preferable to double–fiber-optic phototherapy, although lack of glare in the latter would be an advantage. The interruptions for feeds during conventional phototherapy did not interfere with its efficacy; this is not unexpected, because short interruptions after about 3 hours of phototherapy[14] have no impact on efficacy. Should maximal efficacy be required, our own doublebank blue-light phototherapy[13] used at an optimal dose[11,13] should provide maximal efficacy in full-term infants with severe or rapidly increasing jaundice,[15] especially of a hemolytic nature.

This study demonstrated that fiber-optic phototherapy with the Ohmeda Biliblanket in full-term infants was adequate for routine use only with the double arrangement, sandwiching the infant in between two mats. This apparent inadequacy of the standard fiber-optic Biliblanket for full-term infants reinforces our earlier study,[5] in which exposure was too long, and failures occurred too often. Increasing the light dose and improving the spectral emission of the lamp used will enhance efficacy. If spectral emission were not improved, an increase in the light dose of 100% would be needed for performance comparable to that of conventional phototherapy; this would require an increase of light intensity, blanket size, or both. When the spectral emission of the light can also be improved, the overall light dose need not be increased to this degree to ensure the same result; a single enlarged mat with a more appropriate light spectrum might thus be comparable to conventional phototherapy in efficacy. When such a situation can be realized, then fiber-optic phototherapy, with its advantages of convenience, ease of use, freedom from obstruction, and easy accessibility, might then be able to achieve its full potential and be the preferred choice for treating neonatal hyperbilirubinemia. Until then, the present Ohmeda Biliblanket should mainly be used for small preterm infants who generally would respond adequately to such treatment.[5]

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