Effectiveness of Double-Surface Intensive Phototherapy versus Single-Surface Intensive Phototherapy for Neonatal Hyperbilirubinemia

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Objective: *To compare the efficacy and adverse effects of double-surface intensive phototherapy (DsIPT) and single-surface intensive phototherapy (SsIPT) in term newborn infants with hyperbilirubinemia.*
Design: *Prospective randomized controlled trial.*
Material and Method: *Healthy full-term infants with nonhemolytic hyperbilirubinemia (total serum bilirubin between 13.0 to 19.9 mg/dl) were allocated randomly to two modes of phototherapy. Group 1 infants received single-surface intensive phototherapy. Group 2 infants received double-surface intensive phototherapy. Serum bilirubin, body weight, body temperature and number of defecation were measured at 24 and 48 hours after phototherapy.*
Results: *Sixty infants were studied, 30 in each group. Baseline characteristics were similar in both groups. The initial mean serum bilirubin had no statistically significant difference between SsIPT and the DsIPT groups. After 24 and 48 hours of phototherapy, mean serum bilirubin in the group receiving SsIPT declined 3.5 $\pm$ 1.7 and 6.5 $\pm$ 2.3 mg/dl, while in the DsIPT group, the mean serum bilirubin declined 5.4 $\pm$ 2.0 and 8.4 $\pm$ 2.1 mg/dl respectively. The mean body temperature after 24 hours of phototherapy in the DsIPT group was higher than SsIPT group significantly. The number of defecation in the SsIPT group increased significantly after 24 and 48 hours of phototherapy, but the body weight change in both groups was not statistically significant.*
Conclusion: *DsIPT was significantly more effective in reducing serum bilirubin than SsIPT in the term jaundiced infants after 24 and 48 hours of treatment. The adverse effect of DsIPT found in the present study was the increased of body temperature after 24 hours of phototherapy.*

Keyword: *Non-hemolytic unconjugated hyperbilirubinemia, Double - surface intensive phototherapy (DsIPT), Single-surface intensive phototherapy (SsIPT)*

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The incidence of jaundice is about 60% of the newborn infants[1]; East Asian infants have higher bilirubin levels at birth than other races[2-6]. Phototherapy is the mainstay of treatment of hyperbilirubinemia. The efficacy of phototherapy depended on the light spectrum (wavelength), flux of light, and surface area of the infant exposed to phototherapy[7-14]. Many studies have demonstrated significant reduction of bilirubin level by using double phototherapy compared with single phototherapy, but the irradiance of phototherapy is lower than recommendation of AAP, and some trials studied in low birth weight infants[12,13]. Since 2004, AAP recommended intensive phototherapy in which the irradiance was more than 30 μw/cm^2/nm for treatment of hyperbilirubinemia infants[15]. The purpose of the present study was to evaluate the efficacy of increased surface area of phototherapy (double-surface intensive phototherapy) compared with single-surface intensive phototherapy in reduction of bilirubin and adverse effects of phototherapy in nonhemolytic hyperbilirubinemia term infants.

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Material and Method

A prospective randomized controlled trial was conducted in the nursery of Bangkok Metropolitan Administration Medical College and Vajira Hospital from October 2006 to January 2007. The present study protocol was approved by the ethics committee for researches involving human subjects, the Bangkok Metropolitan Administration. Criteria for inclusion in the present study were as follows: (1) full-term, healthy infants gestational age 37-42 weeks, (2) birth weight equal or more than 2,500 g, (3) 1 and 5 minute Apgar scores more than 6, (4) nonhemolytic hyperbilirubinemia (no evidence of blood group isoimmunization, negative result of direct Coombs test, reticulocytes were in normal limit, normal G6PD level), (5) total serum bilirubin concentration between 13.0-19-.9 mg/dl, and (6) exclusive breastfed infants. The infants were randomized into two groups: single-surface intensive phototherapy (SsIPT) group and double-surface intensive phototherapy (DsIPT) group. The SsIPT consisting of four deep blue (Toshiba Lighting FL18W/T8/DB) and two daylight (Toshiba Lighting FL18W/T8/D) fluorescent lamps, and was placed at least 30 cm above the infant. The mean irradiance of this system, measured at the level of the skin of the abdomen of the newborn center of the phototherapy unit with a standard photometer (Joey Dosimeter, The Wallaby® Phototherapy System, PA).

Infants in the DsIPT group received a standard double phototherapy unit (Neonatal jaundice phototherapy apparatus/XHZ, Ningbo David Medical Device, P.R.C.). The standard double phototherapy comprised of two phototherapy units, above and beneath the infant. The upper phototherapy unit consisting of four deep blue (Toshiba Lighting FL18W/T8/DB) and two daylight (Toshiba Lighting FL18W/T8/D) fluorescent lamps, and was placed 30 cm above the infant. The lower phototherapy unit was placed 25 cm beneath the bassinet and consisting of four deep blue (Toshiba Lighting FL18W/T8/DB) fluorescent lamps. The bassinet made from acrylic plastic and lined on top with silicone sheet to allow the light to pass through. There was a fan placed below the bassinet to ventilate and prevent overheating to the infant. The mean irradiance of the lower phototherapy unit was measured at the center of the bassinet on the silicone sheet.

The infants wore eye patches and were diapered with cotton diapers as usual. Phototherapy was started when the infant's total serum bilirubin was 13.0 mg/dl or more, and terminated if duration of phototherapy was more than 48 hours and serum bilirubin less than 13.0 mg/dl. Total serum bilirubin was measured before starting the phototherapy and then every 24 hours until phototherapy was terminated.

Blood examinations for G6PD level, direct Coombs test, maternal and infant blood group, reticulocyte count, spherocyte count, and complete blood count were performed after entry to the present study. Total serum bilirubin was measured by direct spectrophotometry (Bilirubin meter BR-40, Optima Inc, Japan), which was calibrated regularly. The infants had recorded their body weights, body temperatures and number of defecation until discharge from ward. The mother was informed on how to care for her child during phototherapy to achieve the highest result and was supervised by the nurses. Routine nursing cares were similarly applied to all infants. Breast-feeding was stressed and supported by the experienced nurses. The results were analyzed using the SPSS version 13.0 software and are reported as a mean $\pm$ the standard deviation (SD). Unpaired t-test was used to test the different between mean $\pm$ SD. The p-value < 0.05 was defined as statistically significant.

Results

Sixty infants were enrolled in the present study, 30 in the SsIPT group and 30 in the DsIPT group. There were no significant differences in clinical or laboratory characteristics between the two groups (Table 1).

The mean initial serum bilirubin in the SsIPT group was less than the DsIPT group, but was not statistically significant (14.8 $\pm$ 1.7 vs. 15.7 $\pm$ 1.7 mg/dl, $p = 0.05$). The irradiance of phototherapy unit in the IPT group and upper unit of the DsIPT group were not statistically significant (32.7 $\pm$ 2.6 vs. 33.7 $\pm$ 1.6 $\mu w/cm^2/nm$, $p = 0.08$). After 24 hours of phototherapy, the mean serum bilirubin in the SsIPT group was 11.3 $\pm$ 2.1mg/dl, while in the DsIPT group it was 10.3 $\pm$ 1.9mg/dL, the difference was not statistically significant ($p = 0.05$).

The declined bilirubin in the SsIPT group was less than in the DsIPT group (3.5 $\pm$ 1.7 vs. 5.4 $\pm$ 2.0 mg/dl). The difference between the two groups was statistically significant ($p < 0.001$), and 48 hours after phototherapy the decline of serum bilirubin was also observed. However, differing from the first 24 hours of phototherapy, in the second 24 hours means serum bilirubin declined less than the former. Mean serum bilirubins in the second 24 hours after phototherapy declined 3.0 $\pm$ 1.8 mg/dl in the SsIPT group and 3.1 $\pm$ 1.7 mg/dl in the DsIPT group. The cumulative reductions

Table1. Baseline Data (mean ± SD)

Clinical and baseline laboratory characteristics	SsIPT group (n = 30)	DsIPT group (n = 30)	p-value
No. (M: F)	30 (18:12)	30 (14 :16)	
Birth weight (gm)	3105.0 ± 293.6	3156.0 ± 330.0	0.53
1 min Apgar score	9.2 ± 0.7	9.1 ± 0.5	0.41
5 min Apgar score	10.0 ± 0.0	10.0 ± 0.0	
Gestational age (wk)	38.7 ± 1.3	38.5 ± 1.0	0.67
Hematocrit (%)	52.4 ± 5.5	54.5 ± 5.8	0.16
Reticulocyte (%)	3.8 ± 1.7	4.1 ± 2.1	0.48

Table2. Serum bilirubin after phototherapy (mean ± SD)

Laboratory characteristics	SsIPT group (n = 30)	DsIPT group (n = 30)	p-value
Phototherapy irradiance (μw/cm^2/nm)			
Upper unit	32.7 ± 2.6	33.7 ± 1.6	0.08
Lower unit	-	32.6 ± 1.7	
Initial bilirubin (mg/dl)	14.8 ± 1.7	15.7 ± 1.7	0.05
Bilirubin at 24 h after phototherapy (mg/dl)	11.3 ± 2.1	10.3 ± 1.9	0.05
Absolute 24 h decline (mg/dl)	3.5 ± 1.7	5.4 ± 2.0	<0.001
Percent 24 h decline (%)	23.4 ± 10.7	34.1 ± 11.1	<0.001
Bilirubin at 48 h after phototherapy (mg/dl)	8.4 ± 1.7	7.3 ± 1.5	0.01
24-48 hours bilirubin decline	3.0 ± 1.8	3.1 ± 1.7	0.90
Cumulative 48 h decline (mg/dl)	6.5 ± 2.3	8.4 ± 2.1	0.001
Cumulative percent 48 h decline (%)	43.1 ± 12.4	53.3 ± 10.4	0.001
Bilirubin ≥ 13mg/dl after 24 h photherapy	6/30	2/30	
Bilirubin ≥ 13mg/dl after 48 h photherapy	0/30	0/30	
Exchange transfusion	0/30	0/30	

after 48 hours of phototherapy in both groups were different (6.5 ± 2.3 mg/dl in the SsIPT group vs. 8.4 ± 2.1 mg/dl in the DsIPT group, p = 0.001) (Table 2).

The adverse effects of phototherapy such as dehydration (weight loss) were not statistically different in both groups, the increasing body temperature was more frequently found in the DsIPT group after 24 hours of phototherapy, but the number of defecations in the SIPT group was higher than in the DsIPT group (Table 3).

Discussion

In general, if the infants became significantly jaundiced, they were treated with single-surface phototherapy and if the infants did not respond, the further treatments were increasing phototherapy unit beside or beneath the infant or exchange transfusion. Double-surface phototherapy have been reported many times, but all studies has been done before the recommendation of AAP in 2004.

The present study, followed that recommendation by using the high irradiance of light (30 μw/cm^2/nm or more) phototherapy unit called intensive phototherapy, and increased the area exposed to phototherapy by using phototherapy units above and beneath the infant simultaneously called double-surface intensive phototherapy. The objective of the present study was assessment of the efficacy and adverse effects of double-surface intensive phototherapy compared with single-surface intensive phototherapy. The subjects of the present study were healthy and all breastfed infants, so the efficacy of phototherapy system between the two groups could be demonstrated clearly and did not interfere with different types of feeding[22].

The reduction of bilirubin after 24 hours of phototherapy in the DsIPT group was clearly greater

Table 3. Adverse effects of phototherapy (mean ± SD)

Physical effects	SsIPT group (n = 30)	DsIPT group (n = 30)	p-value
Starting phototherapy			
Temperature (°C)	36.8 ± 0.3	36.9 ± 0.3	0.27
Body weight (gm)	2928.3 ± 283.4	2993.3 ± 302.5	0.39
Defecation (number/day)	3.5 ± 2.0	3.7 ± 2.2	0.76
24 h after phototherapy			
Temperature (°C)	36.9 ± 0.2	37.1 ± 0.2	0.003
Body weight (gm)	2971.7 ± 290.9	3021.7 ± 303.3	0.52
Percent body weight change from start of phototherapy (%)	1.5 ± 2.6	1.0 ± 2.6	0.46
Defecation (number/day)	5.0 ± 3.0	3.5 ± 2.2	0.04
48 h after phototherapy			
Temperature (°C)	36.9 ± 0.2	36.9 ± 0.2	0.13
Body weight (gm)	3010.7 ± 305.6	3043.3 ± 326.6	0.69
Percent body weight change from start of phototherapy (%)	2.3 ± 3.4	1.7 ± 3.3	0.44
Defecation (numbers/day)	7.2 ± 3.4	4.3 ± 3.0	0.001

than in the SsIPT group and approximately 1.5 times that was observed in the SsIPT group, the reason for this finding was most likely due to the increasing surface area exposed to phototherapy with high irradiance of light leading to increased bilirubin decomposition. The result of the present study was consistent with previous studies using double phototherapy compared with single phototherapy, but different in bilirubin reduction. Holtrop PC et al[13] found bilirubin reduction after 18 hours of double phototherapy was 2.9 ± 1.1 mg/dl (31 ± 11%) vs. 1.6 ± 1.4 mg/dl (16 ± 15%) from single phototherapy. The reduction rate of Holtrop's study was approximately 0.16 mg/dl/h, whereas the reduction rate of the present study was 0.23 mg/dl/h. Sarici Umit S et al[19] demonstrated the efficacy of double phototherapy using standard phototherapy unit consisted of five special blue lamps combined with fiberoptic phototherapy pad beneath the infant's body and the reduction rate of bilirubin was 1.29 ± 0.38%/h more than that in single phototherapy (1.02 ± 0.22%/h, but less than the present study (34.1 ± 11.1%/d = 1.42%/h) probably due to the higher irradiance of the authors' phototherapy units. Thaithumyanon P and Visutiratmanee C[20] reported the treatment jaundiced term infants with hemolysis using double phototherapy that consisted of a conventional phototherapy (eight white fluorescent lamps) plus an extra blue light commercial phototherapy bed, the reduction of bilirubin in the first 24 hours was 3.4 ± 2.0 mg/dl more than that was in single conventional phototherapy, but also less than the present study in which the bilirubin reduction in the first 24 hours was 5.4 ± 2.0 mg/dl probably due to the different underlying causes of jaundice and the higher light intensity and the effective blue spectrum of lights, which was the most effective wavelength to decompose bilirubin[7-10]. However, Nuntnarumit P and Naka C[21] reported the reduction of bilirubin 0.22 mg/dl/h result from using adapted-double phototherapy and almost the same rate of reduction of the present study (0.23 mg/dl/h). The differences of bilirubin reduction in the present study from the previous studies were probably due to the difference of the irradiance of the light, type of light sources, the instruments measuring the irradiance and bilirubin concentration and the type of feeding.

At 48 hours after phototherapy, the cumulative effects of phototherapy in both groups showed more decline in bilirubin level, but the declines of bilirubin in the second 24 hours were less than the first 24 hours. The pattern of bilirubin decline in the present study was similar to the previous studies, which demonstrated the rapid bilirubin decline in the first 24 hours[11,17-21].

The volume of fluid intake during phototherapy was not altered or supplemented by the medical personnel, the number of breastfed infants depended on the requirement of the infants, but supported by the experienced nurses. The infant weight of both groups was not decreased after 24 and 48 hours of phototherapy, which means that SsIPT and DsIPT did not affect significant fluid loss and the infants could compensate themselves with breast feedings.

The mean body temperature at 24 hours after phototherapy in the DsIPT group was higher than that in the SsIPT group and was statistically significant, probably due to the greater number of lamps and the heat radiation. However, the difference of body temperature between the two groups seemed to be meaningless in clinical outcome because the difference was only 0.2°C and 37.1°C was not clinically significant.

The last adverse effect which concerned the authors was the frequent defecation, the authors knew that phototherapy may increase the number of defecations, in the present study the number of defecations in the DsIPT group was less than in the SsIPT group, so the present study shows that the increasing surface area exposed to phototherapy (one fold of SsIPT) did not increase the number of defecations. However, the increasing number of defecations in the SsIPT group was not clinically significant when compared with the percentage of body weight change at 24 and 48 hours after phototherapy.

Conclusion

The present study demonstrated that double-surface intensive phototherapy was more effective than single-surface intensive phototherapy in reducing bilirubin in the treatment of breastfed term infants with nonhemolytic hyperbilirubinemia, especially in the first 24 hours. The phototherapy unit (Neonatal jaundice phototherapy apparatus/XHZ, Ningbo David Medical Device, P.R.C.) provided two sides of high irradiance of lights simultaneously with minimal adverse effects compared with single intensive phototherapy. The authors believe that double-surface intensive phototherapy is also effective in the treatment of hemolytic hyperbilirubinemia.

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ประสิทธิผลของการส่องแสงแบบเข้ม 2 ด้านพร้อมกันเทียบกับการส่องแสงแบบเข้มด้านเดียวในทารกแรกเกิดตัวเหลือง

พยนต์ บุญญฤทธิพงษ์, วราวุฒิ เกรียงบูรพา, กรรณิการ์ บูรณวนิช

วัตถุประสงค์: *เพื่อศึกษาประสิทธิผลและผลกระทบที่สำคัญของการส่องแสงแบบเข้มในทารกแรกเกิดตัวเหลือง*
วิธีการศึกษา: *ทำการศึกษาในทารกแรกเกิดครบกำหนด ที่มีภาวะตัวเหลืองที่ไม่ได้มีสาเหตุจากการแตกทำลายของเม็ดเลือดแดงและระดับสารบิลิรูบินในเลือดมีค่าระหว่าง 13 -19.9 มก./ดล. แบ่งทารกที่อยู่ในเกณฑ์การศึกษาเป็น 2 กลุ่ม กลุ่มที่ 1 ได้รับการส่องแสงแบบเข้มด้านเดียว กลุ่มที่ 2 ได้รับการส่องแสงแบบเข้ม 2 ด้านพร้อมกัน เปรียบเทียบผลการรักษาและผลกระทบที่สำคัญโดยดูจากระดับบิลิรูบิน น้ำหนักที่เปลี่ยนแปลงอุณหภูมิร่างกายและจำนวนครั้งของการถ่ายอุจจาระที่ 24 และ48 ชั่วโมงหลังการส่องแสง*
ผลการศึกษา: *มีทารกแรกเกิดตัวเหลืองที่ทำการศึกษาทั้งสิ้น 60 ราย แบ่งเป็นกลุ่มละ 30 ราย ปัจจัยพื้นฐานก่อนการรักษาไม่แตกต่างกันทางสถิติหลังการรักษา 24 และ 48 ชั่วโมง ระดับสารบิลิรูบินในกลุ่มที่1 ลดลง 3.5 $\pm$ 1.7 และ 6.5 $\pm$ 2.3 มก./ดล. ส่วนกลุ่มที่ 2 ลดลง 5.4 $\pm$ 2.0 และ 8.4 $\pm$ 2.1 มก./ดล. แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ผลกระทบที่สำคัญจากการส่องแสงรักษา พบอุณหภูมิร่างกายในกลุ่มที่ 2 สูงกว่ากลุ่มที่ 1 หลังได้รับการส่องแสงรักษา 24 ชั่วโมงอย่างมีนัยสำคัญทางสถิติ จำนวนครั้งของการถ่ายอุจจาระในกลุ่มที่ 1 มากกว่ากลุ่มที่ 2 หลังได้รับการส่องแสงรักษา 24 และ 48 ชั่วโมง อย่างมีนัยสำคัญทางสถิติ แต่ความแตกต่างของน้ำหนักตัวที่เปลี่ยนแปลง ไม่มีนัยสำคัญทางสถิติ*
สรุป: *การส่องแสงแบบเข้ม 2 ด้านพร้อมกัน รักษาทารกแรกเกิดตัวเหลืองที่ไม่ได้มีสาเหตุจากการแตกทำลายของเม็ดเลือดแดง มีประสิทธิผลในการลดระดับสารบิลิรูบินในเลือด หลังการรักษา 24 และ 48 ชั่วโมง ได้ดีกว่าการส่องแสงแบบเข้มด้านเดียว อย่างมีนัยสำคัญทางสถิติ ผลกระทบที่สำคัญที่พบจากการส่องแสงแบบเข้ม 2 ด้านพร้อมกัน คือ อุณหภูมิร่างกายเพิ่มขึ้นหลังการรักษา 24 ชั่วโมง มากกว่ากลุ่มที่ได้รับการส่องแสงแบบเข้มด้านเดียว อย่างมีนัยสำคัญทางสถิติ*