

Single surface phototherapy with reflecting curtains versus double surface phototherapy in unconjugated neonatal hyperbilirubinemia in a tertiary care NICU

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ABSTRACT



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BACKGROUND

Neonatal hyperbilirubinemia is treated with different modalities like single, double surface phototherapy and biliblankets. Reflecting curtains with single surface phototherapy is a cheaper and easy modality. So, this study was designed to compare the efficacy of single surface phototherapy with reflecting curtains [SSPRC] versus double surface phototherapy [DSP].

METHODS

A prospective comparative study in 120 term neonates with unconjugated hyperbilirubinemia was conducted from July 2021 – Jan 2022 in Neonatal intensive care unit of College of Medical Sciences, Bharatpur. The study population was randomized to either SSPRC or DSP. The primary outcome was mean decrease and rate of decrease of bilirubin in subsequent 6 and 12 hours. Secondary outcome were duration of phototherapy and complications. The analysis was done using SPSS version 18.0.

RESULTS

Mean bilirubin level at 6 hours after starting phototherapy was 16.27 mg/dL vs 16.71 mg/dL, $p=0.542$ and at 12 hours 14.61 mg/dL vs 14.70 mg/dL, $p=0.428$. Mean rate of decrease in SSPRC vs DSP was 1.63 mg/dL vs 1.81 mg/dL, $p=0.154$ at 6 hours, 3.29 mg/dL vs 3.82 mg/dL, $p=0.39$ at 12 hours. Mean duration of phototherapy was significantly lower in SSPRC 3.8 Vs 4.2 days, $p=0.031$. Complications were skin rashes 11.7% vs 16.7%, $p=0.432$ and change in frequency of stool 10.0% vs 8.3%, $p=0.752$.

CONCLUSION

Single surface phototherapy with reflecting curtain as double surface phototherapy is equally effective, reliable and successful in decreasing bilirubin in less duration with minimum complications. Therefore this technique can be of help where DSP is unavailable or unaffordable.

KEYWORDS

Single surface phototherapy; reflecting curtains; double surface phototherapy; unconjugated neonatal hyperbilirubinemia

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INTRODUCTION

Neonatal unconjugated hyperbilirubinemia is one of the commonest problems we encounter in NICU. When the total serum bilirubin (TSB) rises above the 95th percentile for age it is considered hyperbilirubinemia.^{1,2} About 50%-60% of newborns have this problem and is effectively managed by phototherapy.^{1,3} Many times in low resource settings, treatment is often sub-optimal or no treatment. This may lead to need for exchange transfusion and complications specially can be toxic for central nervous system and may cause behavioral and neurological impairment (Neurotoxicity or Kernicterus) even in term newborns.^{4,5} When jaundice is extensive it is managed by double surface phototherapy [DSP] which is costly and also uncomfortable for baby to lie over the glass surface for prolong time. Hence other modality which is cheaper, easier and more comfortable and beneficial maybe single surface phototherapy with reflecting curtain [SSPRC]. This study is designed to see whether a low cost SSPRC is as equally effective as DSP.

METHODS

A prospective comparative study carried out in neonates with unconjugated hyperbilirubinemia admitted in NICU of college of medical sciences, Bharatpur from July 2021 to January 2022. The study was approved by Institutional Review Board (IRB) of the institute and written informed consent was obtained from parents or guardians prior to study entry.

The study population were term newborns more than 24 hours to 14 days of life presenting with unconjugated hyperbilirubinemia. Serum bilirubin between 15mg/dl - 21mg/dl was the inclusion criteria. The exclusion criteria was Preterm newborns, Jaundice in first 24 hours and > 14 days of life, hemolytic jaundice, Serum bilirubin < 15mg/dl and > 21mg/dl, those requiring exchange transfusion, major congenital malformations, severe sepsis in shock and neonatal cholestasis with direct bilirubin level more than 20% of total bilirubin.

Following formula was used for sample size calculation:

$$\text{Sample size} = \frac{r+1}{r} \frac{SD^2 [Z\beta + Z\alpha/2]^2}{d^2} = 54$$

Where,

SD – Standard deviation [± 2.75 mg/dl]

d- expected mean difference between case and control [Based on previous studies, taken as 1.5mg/dl]

r=1

Z β = 0.84, considering power = 80%

Z $\alpha/2$ =1.96, considering 5% Type 1 error

The required sample size was fifty four in each group, but we included sixty babies in each group considering for the dropouts.

Total 120 cases of unconjugated neonatal hyperbilirubinemia was enrolled who fulfilled the inclusion criteria. For all babies detail history was taken and physical examinations done and duly filled in the performa. They were randomized into two groups using Randomization.com, as per chronology of admission, which is reproducible using seed number being 10371. The randomization plan was as:

According to randomization, the intervention group [SSPRC] had 60 babies receiving single surface phototherapy with reflecting curtains and a control group [DSP] had 60 babies receiving double surface phototherapy. The setup for both groups are shown in Figure 1 and Figure 2. In both groups the bilirubin level before starting phototherapy was between 15-21mg/dl.

Figure 1. The intervention SSPRC group



Figure 2. The control DSP group



Serum bilirubin were measured at baseline (before phototherapy), after 6 hours and 12 hours of phototherapy. Phototherapy was continued until the serum bilirubin decreased to ≤ 12 mg/dl and Serum bilirubin was also measured in the end of phototherapy. Duration of phototherapy, complications was noted.

The phototherapy units used in this study was new Dräger Phototherapy-4000, manufactured by Dräger Medical GmbH Lübeck, Germany. They consisted of six fluorescent tubes special blue light. The distance between phototherapy unit and the babies was 45 cm. The curtains for intervention group was designed using silver-colored reflecting cloth purchased at the local fabric store and sewn by a local tailor. The curtain was hanged from the side of the phototherapy unit and was approximately 57 cm long. The curtain covered the whole cot except the foot end part to allow observation of the baby during treatment. For all babies receiving phototherapy eyes were covered and dressed with only nappies. Each baby received continuous phototherapy, except during feeding, physical examination and blood sampling. The efficacy of phototherapy was assessed by mean decrease and rate of decrease in serum bilirubin level after 6, 12 hours and the end of phototherapy.

Sterile autoclaved dressing set containing forceps and gauze was used to clean area before drawing blood. One ml blood was taken at the start of phototherapy then subsequently repeated at 6, 12 hours and if babies were on phototherapy for longer period daily blood sampling continued until cessation of phototherapy. Phototherapy was stopped when the serum bilirubin dropped to ≤ 12 mg/dl. The serum bilirubin was measured using Colometric Jendrassik Grof method in Biochemical Lab. All babies were closely monitored for possible side effects of phototherapy like skin rash, hypo or hyperthermia, dehydration and changes in stool frequency. Duration of phototherapy for each patient was noted. Data was collected and entered to an excel sheet then again entered and analyzed using SPSS version 18.0 software and a p-value < 0.05 was considered statistically significant in all statistical analysis. Categorical variables were compared using chi-square test while independent sample t-test was used to compare continuous variable between the two groups.

REASULT

A total of 120 cases were analyzed 60 in SSPRC group and 60 in DSP group. Basic demographic characteristics of both the groups were similar. Mean gestation age of study population was 38.30 ± 1.15 weeks in SSPRC and 38.11 ± 0.99 weeks in DSP. The mean age at presentation of hyperbilirubinemia was 4.35 ± 2.26 days in SSPRC and 5.36 ± 3.23 days in DSP [Table 1]. Male predominance in both groups was noted with M:F 2.15:1 in SSPRC and 1.14:1 in DSP. Other basic demographic characteristics were similar between both groups. [Table1]

Table 1. Comparison of baseline characteristics between two groups

Groups	SSPRC	DSP	P-value
Gestation age in weeks [mean ±SD]	38.3±1.15	38.1±0.99	0.109
Age in days at presentation of rbilirubinemia [mean ±SD]	4.35±2.26	5.37±3.23	0.001
Weight in Kg [mean ±SD]	2.8542±0.48984	2.9573±0.47274	0.496
Maternal age [mean ±SD]	24.6±4.8	24.5±4.9	0.958
Sex : Female	19	28	0.092
Male	41	32	
Parity : Primi	31	34	0.853
Multi	29	26	
PROM : Yes	2	4	0.402
No	58	56	
ABO setting :Yes	15	15	1.000
No	45	45	
Liquor : Clear	52	56	0.224
Meconium	8	4	
Mode of delivery :			0.420
Normal	32		
LSCS	27	39	
Instrumental	1	20	

Mean bilirubin before starting phototherapy in SSPRC was 17.90 ± 2.24 and in DSP 18.52 ± 2.50 [$p < 0.431$]. Mean bilirubin level at 6 hours after starting phototherapy in SSPRC was 16.27 ± 2.02 and in DSP 16.71 ± 1.89 [$p < 0.542$]. Mean bilirubin level at 12 hours after starting phototherapy in SSPRC was 14.61 ± 2.19 and in DSP 14.70 ± 2.80 [$p < 0.428$]. Mean bilirubin level at end of phototherapy in SSPRC was 9.85 ± 1.49 and in DSP 10.01 ± 1.14 [$p < 0.101$] [Table 2].

Table 2. Comparison of unconjugated bilirubin levels at 0, 6 and 12 hours of phototherapy

Unconjugated bilirubin	Groups	Mean	Std. Deviation	P-value
0 hour (before starting phototherapy)	SSPRC	17.9050	2.24774	0.431
	DSP	18.5267	2.50307	
6 hours after phototherapy	SSPRC	16.2733	2.02090	0.542
	DSP	16.7150	1.89395	
12 hours after phototherapy	SSPRC	14.6183	2.19371	0.428
	DSP	14.7067	2.80821	
End of stopping phototherapy	SSPRC	9.8567	1.49965	0.101
	DSP	10.0150	1.14074	

The total decrease in bilirubin level at end of phototherapy was 8.04 ± 2.36 in SSPRC and 8.51 ± 2.58 in DSP [$p < 0.865$].

The mean rate of decrease of bilirubin level after 6 hours was 0.27 mg/dl/hr Vs 0.30 mg/dl/hr and after 12 hours 0.27 mg/dl/hr Vs 0.31 mg/dl/hr in SSPRC and DSP respectively and statistically insignificant. Rate of reduction of bilirubin at end of phototherapy was 2.11 mg/dl in SSPRC and 2.02 mg/dl in DSP. (Table 3).

Table 3. Rate of decrease of bilirubin in subsequent hours 0-6 hours, 0-12 hours, 0-end of phototherapy

Decrease in unconjugated bilirubin in different time intervals		Rate of decrease in unconjugated bilirubin (mg/dl/hr)	Mean	Std. Deviation	P Value
0 hrs – 6 hours	SSPRC	0.27	1.6317	1.80869	0.154
	DSP	0.30	1.8117	2.56198	
0 hrs – 12 hours	SSPRC	0.27	3.2867	2.15387	0.039
	DSP	0.31	3.8200	3.60197	
0 hrs – end of phototherapy	SSPRC	2.11	8.0483	2.36897	0.865
	DSP	2.02	8.5117	2.58202	

Duration of phototherapy in SSPRC was 3.80 ± 1.27 and in DSP 4.2 ± 1.8 with p value 0.031. Two complications were noted skin rashes 7 Vs 10 cases [$p < 0.432$] and change in stool frequency 6 Vs 5 with $p < 0.752$ in SSPRC and DSP respectively. (Table 4).

Table 4 Secondary outcome in two groups

Groups	SSRC	DSP	P Value
Mean Duration of phototherapy in days	3.8+ 1.27	4.2+1.8	0.031
Skin rash :Yes	7	10	0.432
No	53	50	
Change in Stool frequency : Yes	6	5	0.752
No	54	55	

DISCUSSION

Phototherapy is the use of visible light for the treatment of unconjugated hyperbilirubinemia in newborns. This therapy lowers serum bilirubin levels by transforming bilirubin into water soluble isomers that can be eliminated without conjugation in the liver. The dose of phototherapy determines how quickly this process can occur. The dose is determined by the wavelength of light, the intensity of the light (irradiance), the distance between the light and the infant, exposed body surface area and duration of exposure.⁶⁻⁸ Studies have shown that increasing light intensity will increase efficacy of phototherapy.⁹ The concept of using reflecting curtains with a single unit phototherapy has been described by various authors.^{10,11} It can increase the irradiance and shorten the duration of phototherapy.¹¹ The reason is most likely that the reflecting curtains reflect light, and increase intensity of light on the body of the infant leading to increased bilirubin decomposition.⁶ A dose-response relationship exists between the amount of irradiation and reduction in serum bilirubin, up to an irradiation level of 30-40 $\mu\text{W}/\text{cm}^2/\text{nm}$ and the use of reflecting curtains may deliver light energy up to 40 $\mu\text{W}/\text{cm}^2/\text{nm}$, suggested to be the saturation level.¹²

With this background, we have compared single surface phototherapy with reflecting curtain versus double surface phototherapy and the results showed that both the methods are equally effective in decreasing serum bilirubin in neonatal hyperbilirubinemia. The additional benefits with SSPRC in this study was shorter duration of phototherapy. A study done by Ari Kurniasih et.al also showed that White, reflecting curtains in phototherapy units was significantly more effective than phototherapy without curtains for treatment of neonatal jaundice.¹³

In this study the mean reduction in serum bilirubin levels during the first 6 hours and 12 hours of phototherapy was similar in both groups with $p < 0.542$ and $p < 0.428$ respectively. No statistical difference between SSPRC and DSP was also observed at 4 hours and 10 hours with p value 0.813 and 0.678 respectively in a study by Djokomuljanto

et al.¹⁰ The mean reduction of bilirubin at stopping of phototherapy in this study was also similar in both groups 9.85 ± 1.49 in SSPRC versus 10.01 ± 1.14 in DSP group with p value 0.101 which strengthens efficacy of SSPRC.

The reduction of bilirubin levels at 6 hours was 1.63 mg/dl in SSPRC and 1.81 mg/dl in DSP with $p < 0.154$ and at 12 hours this was 3.28 mg/dl in SSPRC and 3.82 mg/dl in DSP with $P < 0.039$ and at end of phototherapy it was 8.05 mg/dl in SSPRC and 8.51 mg/dl in DSP with $p < 0.865$. A similar study by Djokomuljanto et al with and without white reflecting curtains showed that the reduction of bilirubin after 4 hours of single phototherapy with curtains and without curtains was 1.62 mg/dL vs 0.23 mg/dL respectively.¹⁰ Yet in another study by Ari Kurniasih et.al the reduction of serum bilirubin after 12 hours of single phototherapy with curtains and without curtains was 3.8 mg/dL vs 0.1 mg/dL respectively.¹³

The rate of reduction of bilirubin after 6 hours was 0.27 mg/dl/hr in SSPRC and was 0.30 mg/dl/hr in DSP in this study. This rate of reduction after 4 hours was 0.4 mg/dL/h Vs 0.06 mg/dl/hr in a study by Djokomuljanto et al.¹⁰ After 12 hours the rate of reduction of bilirubin in our study was 0.27 mg/dl/hr in SSPRC and 0.31 mg/dl/hr in DSP. The rate of reduction after 12 hours in a study by Ari Kurniasih et.al noted this to be 0.3 mg/dL/h Vs 0.008 mg/dl/hr.¹⁴ Both studies had used single surface phototherapy without curtains but we used double surface phototherapy without curtains so this must be the reason the rate of reduction was seen slightly more in DSP than SSPRC in our study. However total reduction of bilirubin at end of phototherapy was 2.11 mg/dl in SSPRC and 2.02 mg/dl in DSP which is slightly more reduction in SSPRC group but statistically not significant indicating both are of equal efficacy. This further strengthens the suggestion that the efficacy of both treatment modalities may be quite similar and that the intensities of the light provided with the curtains were very similar to those provided by double phototherapy units.

Duration of phototherapy was significantly less [$p < 0.031$] in SSPRC group with mean days 3.80 ± 1.27 in SSPRC Vs 4.2 ± 1.8 in DSP. In meta-analysis of four studies reported that the duration of phototherapy was shorter when reflecting curtains were used which supports our findings.⁹

In meta-analysis of 15 studies none reported any important adverse events, such as hypothermia, hyperthermia, hypoglycemia or any acute life-threatening events due to curtains obscuring the baby.⁹ Changes in skin such as rashes, darker skin color and burns may occur if neonates are over-exposed to fluorescent light.¹⁴ We also observed skin rashes in 7 Vs 10 cases in SSPRC and DSP respectively with no statistical significance [$p < 0.432$]. Another complication noted was change in stool frequency in both groups. Based on results of this study it means that overall reflective curtains might provide more beneficial

effect.

Limitations: Small study population due to single centred study are the limitations of the present study. Larger scale and multi-centred studies are required for better results.

CONCLUSION

The results of this study suggest that SSPRC is as equally effective as DSP in treating neonatal unconjugated hyperbilirubinemia. It also showed shorter duration of treatment which means more newborns can be treated with fewer phototherapy units, also will be cost saving. These advantages makes SSPRC an easy, cost effective and more beneficial method of management. Moreover, the use of reflective curtains can be particularly useful for neonatal units in developing nations where there may be a lack of number and quality of phototherapy units.

LIST ABBREVIATIONS

SSPRC: Single surface phototherapy with reflecting curtains

DSP: Double surface phototherapy

TSB : total serum bilirubin

NICU : Neonatal intensive care unit

Vs: versus:

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