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Effect of aluminum foil reflector on serum bilirubin and duration of phototherapy among term neonates undergoing phototherapy for hyperbilirubinemia: A randomized controlled trial

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Abstract

Background: Jaundice is a common clinical issue especially in the first week of life and one of the leading causes for readmission to the hospital. This study aimed to assess the effect of aluminium foil reflector on serum bilirubin level ,duration of phototherapy and duration of hospital stay.

Methods: A randomized controlled trial was carried among 50 term neonatesin neonatal intensive care unit(NICU) .Term neonates were randomly assigned in to experimental and control group by block randomization. Consecutive sampling technique was used to enroll the neonates who met the inclusion criteria. During photo therapy neonates in the control group received standard careand the neonatesin the experimental group received standard care along with aluminium foil reflector around all the four sides of neonatal cot. Data were analysed using chi square test, fisher exact test and independentt-test.

Results: After the intervention the serum bilirubin levels in the experimental and control groupswere13.20±3.35 and 14.07±3.12 respectively (P = 0.348),total duration of phototherapy in hours in experimental group and control groupswere 35.76±17.20 and 38.08±16.36 respectively(P = 0.627) and duration of hospital stay in days in experimental group and control group were 2.6±0.91 and 2.92±1.22 respectively (P = 0.299).

Conclusion: Aluminium foil reflector aids in decreasing bilirubin level, reduced the duration of phototherapy and duration of hospital stay among term neonates.

Keywords: Term neonates; Aluminium foil reflector; Serum bilirubin; Hyperbilirubinemia; Duration of Phototherapy

1. Introduction

Jaundice is the seventh most common significant contributor to neonatal mortality in the first seven days of life worldwide [1].Global incidence of severe neonatal jaundice (SNJ) per 10000 live births is 667.8 (95% CI 603.4 to 738.5) in the African region, 251.3 (132.0 to 473.2) in Southeast Asia, 165.7 (114.6 to 238.9) in the Eastern Mediterranean, 9.4 (0.1 to 755.9) in the Western Pacific, 4.4 (1.8 to 10.5) in America, and 3.7 (1.7 to 8.0) in Europe [2].

In newborn infants hyperbilirubinemia results from two simultaneous events. Fetal red blood cells have a limited lifespan of 45–90 days, which causes more bilirubin to be produced. Furthermore, during the first few days of life, the liver's ability to conjugate and excrete bilirubin is reduced, which leads to an accumulation of bilirubin in the body

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[3].Urinary tract infection, sepsis, biliaryatresia, thyroid abnormalities and galactosemia were some of the cause for elevated conjugated bilirubin [4].

It is clinically manifested as yellowish discoloration of the skin, sclera, and mucous membrane. When the bilirubin level rises, dermal icterus in newborns first manifests in the face before spreading to the body and then the extremities. Severe hyperbilirubinemia, which affects 8% to 9% of newborns during their first week of life, occurs when the total bilirubin is above the 95th percentile for age in hours. 5–10% of newborns who develop jaundice require management of hyperbilirubinemia with phototherapy or other treatments [5].

Phototherapy is a universally accepted method for managing neonatal hyperbilirubinemia. It is a safe and well-established, effective therapy due to its efficiency in reducing high serum-free bilirubin levels and limiting its neurotoxic effects. It causes adverse reactions sometimes like interference with mother-infant interaction, dehydration, hypoglycemia, rash, bonze baby syndrome, hemolysis and retinal injury [6].Comparison of the effect of intermittent phototherapy and continuous phototherapy on bilirubin level exhibited that continuous phototherapy was effective [7].Comparison of the effect of blue light phototherapy with white light photo therapyon bilirubin level showed that blue light phototherapy was effective [8].Comparison of light emitting diode (LED)phototherapy with conventional phototherapy on serum bilirubin level and urinary lumirubin level reported that LED phototherapy was effective [9]. Increasing body surface area exposure during phototherapy decreases the duration of phototherapy and length of stay in NICU [10].Utilization of reflective material around the phototherapy declines serum bilirubin level and duration of hospital stay [11].Placing white curtains around phototherapy unit improves the treatment effectiveness for treating neonatal jaundice [12].

Naturally the light emitted from the phototherapy unit fails to reach the baby's skin due to dispersion, and the most common causes of dispersion of the light from the phototherapy unit are the intensity of the light and wavelength of light and the distance between the infant and the phototherapy unit and at last the body surface area of the neonate exposed during phototherapy [13].Aluminium foil reflector can increase the irridance and shorten the duration of phototherapy [14].

Phototherapy side effects can be overcome by reducing the duration of phototherapy. Aluminium foil reflector is one of the methods through which duration of phototherapy and duration hospital stay can be reduced.

2. Materials and Methods

2.1. Design

A randomized controlled trial was adopted to identify the effect of aluminium foil reflector on bilirubin level and duration of phototherapy among term neonates.

2.2. Setting

The study was conducted in NICU of a tertiary care hospital during September 2022 to February 2023.

2.3. Sample size calculation

Based on mean difference in serum bilirubin level between the groups as2.5±2.45mg/dl at 90% power and 5% level of significance and considering 20% attrition rate 50 term neonates were enrolled in the study.

2.4. Mode of selection of subjects

Term neonates were randomly assigned to experimental and control group using block randomization .Allocation concealment was done by using serially numbered opaque envelops. Term neonates who met the inclusion criteria were selected though consecutive sampling technique.

2.5. Inclusion criteria

Term neonates with hyperbilirubinemia admitted in NICU receiving phototherapy were included in the study.

2.6. Exclusion criteria

Term neonates who had hyperbilirubinemia with major congenital anomalies, hemodynamically unstable neonates and neonates on ventilator were excluded from the study.

2.7. Data collection procedure

On first day of phototherapy for the term neonates informed consent was obtained from parents. Maternal and neonatal clinical characteristics were collected form medical records. Initially in both groups baseline bilirubin level was obtained. In control group neonates received routine care(eyes and genetalia were covered and remaining parts of the body were exposed to phototherapy light). In the experimental group the neonates received phototherapy using aluminium foil reflectors. Aluminium foil is silvery white sheet which is made up of aluminium. It is thin sheet which can be easy fold into any desired shape. Aluminium foil reflects all the light (92–98%) in direct manner. The reflecting surface of the aluminium foil was placed around all four sides of the neonatal cot which increase the irridance of the light towards the baby and shortening the duration of phototherapy. Until the end of phototherapy aluminium foil will be positioned all the time around the newborn's crib. After 24 hours in both groups serum bilirubin levels were monitored.Term neonates were monitored dailytill their discharge to identify the duration of phototherapy and duration of hospital stay.The study was registered under the Clinical Trial Registry,India,with registration number 2022/09/045362.

2.8. Data collection instruments

Data collection instrument had four sections. The first section included maternal and neonatalclinical characteristics. It comprised of gender, gestational age at birth and admission, weight at birth and at admission, mode of delivery and blood group of mother and neonate.

Second section dealt with serum bilirubin level assessment at baseline and 24 hours after the intervention.

Third section dealt with monitoring of duration of phototherapy which included date and time of initiation of phototherapy, date and time of cessation of phototherapy and total hours of phototherapy.

Fourth section consisted of monitoring of duration of hospital stay.

2.9. Data Analysis

Data were analyzed using SPSS version 23 (SPSS Inc., Chicago, 111. USA) .Both descriptive and inferential statistics were used for analysis of data. Descriptive stastics(frequency, percentage, mean, standard deviation)were used to describe the clinical variables of study participants. Independent t test was used to compare serum bilirubin level, duration of phototherapy and duration of hospital stay. Chi-square test was used to identify the association of level of serum bilirubin with clinical variables.

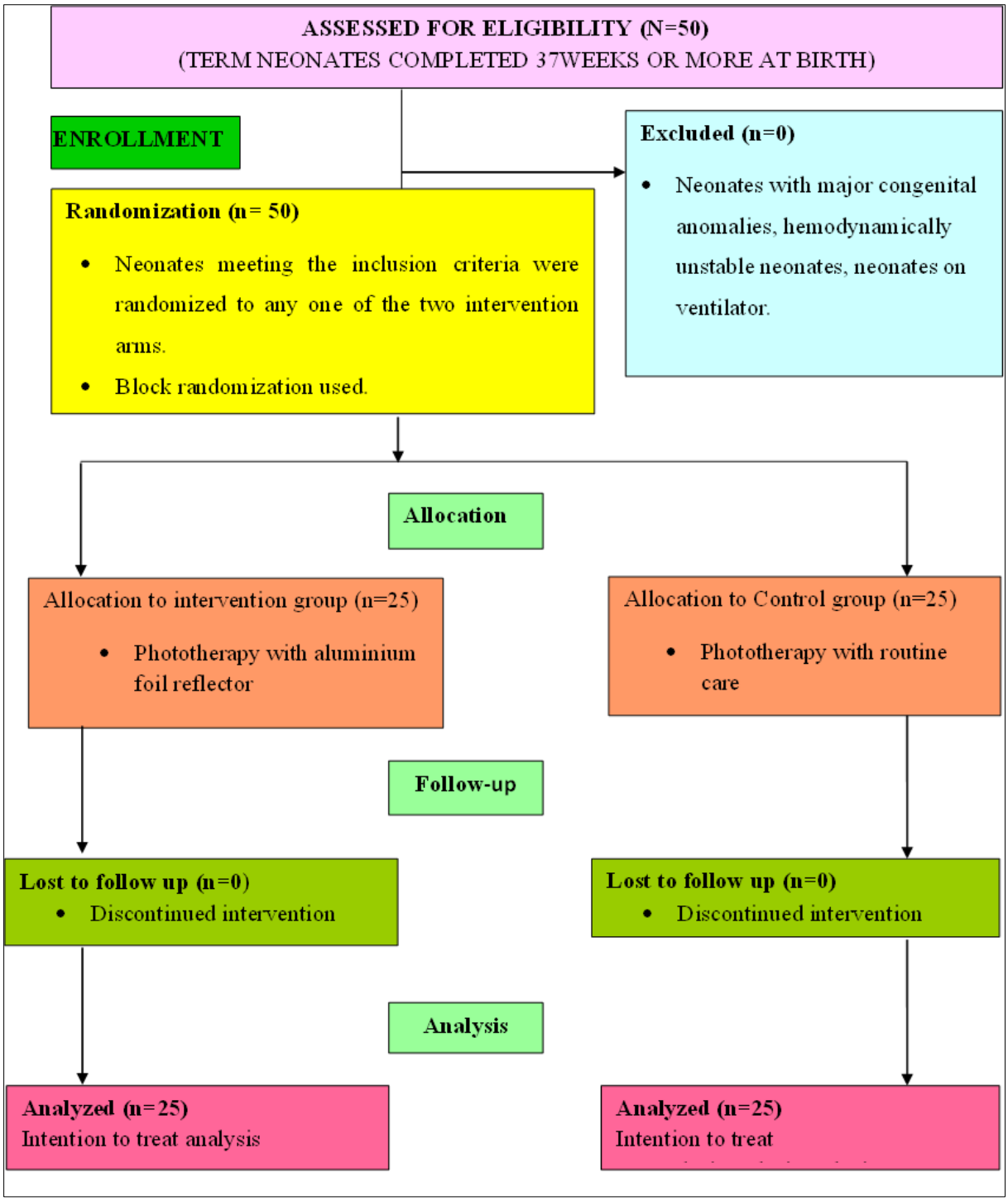

Figure 1 Consort diagram

3. Results

In both the groups most of the neonates were male and majority of them had B+ blood group. Mean gestational age of the neonates in experimental and control groups were 38.88+_1.23 and 38.88+_1.30 respectively.Mean weight of the neonates in experimental and control groups were 2710+_601.61 and 2847+_400.55 respectively Table 1.

Table 1 Demographic and clinical variables among neonates N=50

Variables	Experimental group (n=25)		Control group (n=25)		Chi Square X^2	P VALUE
	N	%	N	%		
[a]GENDER						
FEMALE	11	44	8	32	0.764	0.382
MALE	14	56	17	68		
[c]BLOOD GROUP						
A+VE	8	32	8	32	1.925	0.619
A-VE	0	0	0	0		
B+VE	10	40	6	24		
B-VE	0	0	0	0		
O+VE	4	16	6	24		
O-VE	0	0	0	0		
AB+VE	3	12	5	20		
AB-VE	0	0	0	0		
[b]GESTATIONAL AGE IN WEEKS AT BIRTH						
MEAN±SD	38.44±1.26		38.48±1.04		- 0.122	0.903
[b]GESTATIONAL AGE IN WEEKS AT ADMISSION						
MEAN±SD	38.88±1.23		38.88±1.30		0.000	1
[b]AGE OF NEONATES IN HOURS						
MEAN±SD	74.36±96.28		41.28±95.37		- 1.055	0.299
[b]WEIGHT OF THE BABY IN GRAMS AT BIRTH						
MEAN±SD	2821.2±579.76		2908.6±371.49		- 0.635	0.529
[b]WEIGHT OF THE BABY IN GRAMS AT ADMISSION						
MEAN±SD	2710.4±601.61		2847.2±400.55		- 0.946	0.349

[a] Chi-square test, [b]Independent student t test, [c]Fisher's exact test

Most of the mothers had spontaneous vaginal delivery and majority were with o+ blood group Table 2.

Table 2 Maternal clinical characteristics N=50

SLNO.	VARIABLE	EXPERIMENTALGROUP (N=25)		CONTROLGROUP (N=25)		*P VALUE
		N	%	N	%	
1.	MODE OF DELIVERY					
	Spontaneous vaginal delivery (SVD)	11	44	18	72	0.1
	Lower segment cesarean section (LSCS)	8	32	4	16	
	Forceps delivery	1	4	2	8	
	Vaccum delivery	5	20	1	4	

2.	BLOOD GROUP					
	A+VE	3	12	5	20	0.677
	A-VE	1	4	0	0	
	B+VE	8	32	5	20	
	B-VE	2	8	1	4	
	O+VE	11	44	12	48	
	O-VE	0	0	1	4	
	AB+VE	0	0	1	4	
	AB-VE	0	0	0	0	

*Fisher's Exact Test

Comparison of serum bilirubin level between the groups showed marked decrease in experimental group and it was not significant Table 3.

Table 3 Comparison of total serum bilirubin level between the groupsN=50

TOTAL SERUM BILIRUBIN LEVEL (mg/dl)	**EXPERIMENTALGROUP (N=25)**		**CONTROLGROUP (N=25)**		**[a]P VALUE**
	MEAN	**SD**	**MEAN**	**SD**	
INITIAL	16.57	4.82	16	3.93	0.646
AFTER 24 HOURS	13.20	3.35	14.07	3.12	0.348

[a]Independent student t test

Comparison of duration of phototherapy between the groups revealed marked decrease in experimental group and it was not significant Table 4.

Table 4 Comparison of duration of phototherapy between the groups N=50

VARIABLES	**EXPERIMENTALGROUP (N=25)**		**CONTROL GROUP (N=25)**		**[a]P VALUE**
	MEAN	**SD**	**MEAN**	**SD**	
Duration of phototherapy in hours	35.76	17.20	38.08	16.36	0.627

[a]Independent student t test

Comparison of duration of hospital stay between the groups revealed marked decrease in experimental group and it was not significant Table 5.

Table5 Comparison of duration of hospital stay between the groups N=50

VARIABLES	**EXPERIMENTALGROUP (N=25)**		**CONTROL GROUP (N=25)**		**[a]P VALUE**
	MEAN	**SD**	**MEAN**	**SD**	
Duration of hospital stay in days	2.6	0.91	2.92	1.22	0.299

[a]Independent student t test

There was no association between serum bilirubin level and neonatal clinical characteristics in experimental group Table 6 .

Table 6 Association between serum bilirubin level and neonatal clinical variables in experimental group N=25

Variables	**Total serum bilirubin**						**Chi Square X^2**	**df**	**P Value**
	5.5-10.5 mg/dl		**10.6-15.5 mg/dl**		**15.6-20.5 mg/dl**				
	N	**%**	**N**	**%**	**N**	**%**			
GENDER									
Male	3	21.4	8	57.2	3	21.4	0.108	2	0.947
Female	2	18.2	7	63.6	2	18.2			
BLOOD GROUP OF BABY									
A+VE	0	0	7	87.5	1	12.5	8.056	6	0.234
B+VE	3	30	4	40	3	30			
O+VE	2	50	2	50	0	0			
AB+VE	0	0	2	66.7	1	33.3			
MODE OF DELIVERY									
Spontaneous vaginal delivery (SVD)	1	9	9	82	1	9	7.848	6	0.249
Lower section Caesarean delivery (LSCS)	2	25	4	50	2	25			
Forceps delivery	0	0	0	0	1	100			
Vaccum delivery	2	40	2	40	1	20			
Blood group of mother									
A+VE	0	0	3	100	0	0	9.545	8	0.298
A-VE	0	0	1	100	0	0			
B+VE	2	25	6	75	0	0			
B-VE	1	50	0	0	1	50			
O+VE	2	18.2	5	45.5	4	36.3			
Birth weight in grams									
Very low birth weight (VLBW) (<1500 grams)	1	100	0	0	0	0	5	4	0.287
Low birth weight (LBW) (1500-2500 grams)	2	25	5	62.5	1	12.5			
Normal birth weight (>2500 grams)	2	12.5	10	62.5	4	25			
Admission weight in grams									
Very low birth weight (VLBW)(<1500 grams)	1	100	0	0	0	0	5	4	0.287
Low birth weight (LBW) (1500-2500 grams)	2	25	5	62.5	1	12.5			
Normal birth weight (>2500 grams)	2	12.5	10	62.5	4	25			
Gestational age at birth									
Early term (37-39 weeks)	3	17.64	10	58.82	4	23.52	0.490	2	0.783

Full term (39[1]-41 weeks)	2	25	5	62.5	1	12.5			
Gestational age at admission									
Early term (37-39 weeks)	3	17.64	10	58.82	4	23.52	0.490	2	0.783
Full term (39[1]-41 weeks)	2	25	5	62.5	1	12.5			

There was no association between serum bilirubin level and neonatal clinical characteristics in control group Table 7.

Table 7 Association between serum bilirubin level and neonatal clinical variables in control group N=25

Variables	**Total serum bilirubin**						**Chi Square X^2**	**Df**	**P Value**
	5.5-10.5 mg/dl		**10.6-15.5 mg/dl**		**15.6-20.5 mg/dl**				
	N	**%**	**N**	**%**	**N**	**%**			
GENDER									
Male	2	11.7	8	47.06	7	41.7	2.310	2	0.315
Female	3	37.5	3	37.5	2	25			
BLOOD GROUP OF BABY									
A+VE	0	0	6	75	2	25	6.471	6	0.373
B+VE	2	33.33	2	33.33	2	33.3			
O+VE	2	33.33	2	33.33	2	33.3			
AB+VE	1	20	1	20	3	60			
MODE OF DELIVERY									
Spontaneous vaginal delivery	3	16.7	7	38.9	8	44.4	8.1590	6	0.227
Lower section Caesarean delivery	2	50	2	50	0	0			
Forceps delivery	0	0	2	100	0	0			
Vaccum delivery	0	0	0	0	1	100			
Blood group of mother									
A+VE	0	0	2	40	3	69	11.320	10	0.333
B+VE	1	20	2	40	2	40			
B-VE	1	100	0	0	0	0			
O+VE	2	16.7	6	50	4	33.3			
O-VE	1	100	0	0	0	0			
AB+VE	0	0	1	100	0	0			
Birth weight in grams									
Low birth weight (LBW) (1500-2500 grams)	1	25	2	50	1	25	0.259	2	0.879
Normal birth weight (>2500 grams)	4	20	9	42.5	8	38.09			
Admission weight in grams									
Low birth weight (LBW)	1	20	3	60	1	20	0.808	2	0.668

(1500-2500 grams)									
Normal birth weight (>2500 grams)	4	20	8	40	8	40			
Gestational age at birth									
Early term (37-39 weeks)	4	20	9	45	7	35	0.51	2	0.975
Full term (39^1-41 weeks)	1	20	2	40	2	40			
Gestational age at admission									
Early term (37-39 weeks)	4	21.85	9	47.36	6	31.5	1.981	4	0.739
Full term (39^1-41 weeks)	1	20	2	40	2	40			
Late term (41^1-42 weeks)	0	0	0	0	1	100			

4. Discussion

This randomized controlled trial included 50 term neonates. Comparison o fserum bilirubin level between the groups revealed that though marked reduction in experimental group it was not significant.

Similarly a quasi experimental study conducted by Nagaty Abolemagd etal in Mina university hospital for obstetric and pediatrics in Minia general hospital in Egypt for 3 months in NICU among 70 neonates revealed that the serum bilirubinlevel in experimental group and control group at baseline were 15.5±1.6 and15.3±1.5 respectivelyand48 hoursafter the intervention it was 12±1.2 and 12.6±1.3respectively and there was no significant difference betweenthegroups(P= 0.068) [15].In consistent with this a randomized controlled trial conducted by Abdhamid et al in hospital sains ,Malaysia from May 2010 to April 2011among 160 neonates in NICUalso showed insignificance p=0.531[16].In addition to this a randomized controlled trial conducted by Sivanandan et al in postnatal ward of a tertiary care hospital from October 2015 to march 2017 among 84 term neonates reported that after 24 hours of intervention serum bilirubin levels in experimental and control groups were 12±1.8 and 12±1.6 and it was not significant p=0.37[17].

In contrast to this a clinical trial conducted by Dachlan et al during July 2013 to August 2013 at Dr. Hasan Sadikin hospital, Bandung, Indonesia reported that serum bilirubin levels in experimental group and control group at baseline were 18.5±3.1and18.1±3respectively and after24hoursof phototherapy it was 13.9±2.6 and 15.9±2.7respectively and it was significant P=0.003[18].In addition to this a study conducted by Philip et al in NICU of Krishna hospital, Karad, Maharashtra, India,for one month among 30 neonates exhibited that after 24 hours of phototherapy bilirubin levels in experimental and control groups were13.85+_12.15 and 14.4+_13.8 respectively and it was significant p<0.001[19].Furthermore a randomized controlled trial by Negi et al revealed that after 24 hours of intervention bilirubin levels in experimental and control groups were 9.1+_0.9 and 12.4+_1.8 were respectively and it was significant p<0.001[20]. In addition to this a randomized controlled trial done by Kurniashi et al among 60 neonates reported that 24 hours after the intervention bilirubin levels in experimental and control groups were 9.0+_2.4 and 13.9+_1.85 and it was significant p=0.001 [21].In addition to this a randomized controlled trial conducted by Hashim et a lin NICU of el-nasr general hospital, port-said, Egypt from June 2010 to June 2011 among 60 neonates showed that after 24 hours of intervention bilirubin levels in experimental and control group were 11.65+_2.92 and14.25+_2.14 respectively and it was significant p=0.001 [22].

Comparison of duration of phototherapy between the groups showed insignificance. Similarly a randomized control trial conducted by Abd Hamid IJ et al in NICU of Hospital Sains Malaysia in Kelantan, Malaysia from May 2010 to April 2011 revealed insignificance p=0.531 [16]. In consistent with this a randomized controlled trial conducted by Sivanandan et al in postnatal ward of a tertiary level neonatal unit showed that total duration of phototherapy in hours in experimental group and control group were 23.3±12.9 and 24.9±15.4 respectively and there was no significant difference(P = 0.6) [17].

The findings of the study was incompatible with a randomized controlled trial conducted by Divya R Nair et al in Puducherry among94 term neonates reported that after intervention the bilirubin levels were62.8±17.7 and 49.5±18.9 in control and experimental groups respectively and it was significant (P = 0.0007) [23].

Similarly an open clinical trial conducted by Dachlan et al reported that t he duration of phototherapy in aluminium foil reflector group was 72 hours and in routine care groupit was 96 hours and there was 24 hours duration difference between the groups and it was significanct P = 0.01 [18].In addition to this a single –center randomized controlled study done by Lahiri et al in a NICU of a tertiary care center from June 2011 to May 2012 among 102 term neonates exhibited that the mean duration of phototherapy in experimental and control groups were 28.87+_4.11 and 51.44+-18.62 hours respectively and it was significant p<0.01 [24].Furthermore a randomized controlled trial conducted by Babaei et al among 182 term neonates revealed that the duration of phototherapy in experimental and control groups were 36.6+-12.9 and 50.3+-23.8 respectively and it was significant p<0.0001 [25].In addition to this a randomized trial conducted by Devpura et al in Rajasthan from November 2011 to October 2012 among 100 term neonates reported that mean duration of phototherapy in experimental and control groups were 53.28+-21.02 and 62.88+-20.22 hours respectively and it was significant p=0.02 [26].

In current study comparison of the duration of hospital stay in between the groups showed insignificant.

In contrast to this a randomized control trial by Babaei et al showed that the mean duration of hospital stay in experimental and control groups were 43.1±13.3 and 85.2±23.8 hours respectively and it was significant P = 0.0001 [25].Similarly a randomized clinical trial conducted by Salehzadeh et al for 6 months in Imam Khomeini hospital of Ardabil medical sciences university among 60 neonates exhibited that the duration of hospital stay in experimental group and control groups were 2.63+-0.67 and 2.97+-0.66 respectively and it was significant p=0.027 [27].In accordance with this a randomized controlled trial by Hashim et al revealed that the duration of hospital stay in experimental and control groups were 3.50+-0.51 and 4.43+-0.50 respectively and it was significant p=0.001 [22].

In current study in experimental group and control groups there was no significant association of bilirubin level with gender of the neonate. Similarly a quasi experimental study conducted by Gunjan et al in Panipat, Haryana among 60 neonates also reported insignificant p>0.05.Gestational age had no association with bilirubin level in this study. In consistent with this Gunjan et al also revealed the same p>0.05 [28].

In present study birth weight had no association with bilirubin level . In contrast to this birth weight showed significance in Gunjan et al study p=0.007 [28].

5. Conclusion

The findings of this study showed that applying aluminium foil reflector around four sides of the neonatal crib helps in reducing serum bilirubin level in term neonates. This study adds one more piece of evidence that increasing the irradiance of phototherapy light by cost effective material will aids in faster reduction in serum bilirubin level.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

This study involved human subjects and followed ethical norms approved by Institutional Ethical Committee.

Statement of informed consent

Informed consent was obtained from mothers of all term neonates included in the study.

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