

Effectiveness of Tactile and Kinaesthetic Stimulation on Hyperbilirubinemia: A Feasibility Study

SAUMYA KOTHIYAL¹, SUBHASISH CHATTERJEE²

ABSTRACT

Introduction: Neonatal hyperbilirubinemia is common among newborns, often necessitating hospitalisation and posing a risk of neural complications. Phototherapy, commonly used to treat hyperbilirubinemia, also has side effects, including eye and genital harm, dehydration, diarrhoea, and bronze baby syndrome. Therefore, there is a need to find alternatives or reduce treatment duration.

Aim: To investigate the efficacy of tactile and kinaesthetic stimulation as adjunctive therapies with phototherapy for reducing bilirubin levels in preterm neonates with hyperbilirubinemia.

Materials and Methods: A randomised controlled feasibility study, including 12 preterm neonates with hyperbilirubinemia, was conducted in the Neonatal Intensive Care Unit (NICU) of a Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Mullana, Ambala, India. The experimental

group (n=6) received three sessions of tactile and kinaesthetic stimulation for 15 minutes per session alongside phototherapy, compared to a control group (n=6) receiving phototherapy alone for three days.

Results: While no significant differences ($p>0.05$) in demographics of neonates were observed, both groups experienced significant reductions ($p<0.001$) in Total Serum Bilirubin (TSB) and Transcutaneous Bilirubin (TCB) levels, with change scores of 7.88 ± 2.29 (TSB experimental), 7.84 ± 2.85 (TSB control), 6.63 ± 2.77 (TCB experimental), and 6.27 ± 1.92 (TCB control). However, the change in mean levels of TSB and TCB was not significantly different when compared between the two groups ($p>0.05$).

Conclusion: There were significant reductions in TSB and TCB levels from Day 1 to Day 3 within each group. Both interventions were equally effective in reducing the bilirubin levels in the neonates.

Keywords: Bilirubin, Neonatal intensive care unit, Newborn, Phototherapy

INTRODUCTION

Neonatal hyperbilirubinemia is a prevalent condition among newborns, often necessitating hospital readmission. It is a highly prevalent condition globally, affecting as many as 60% of full-term newborns and up to 80% of preterm infants within the first week of their lives [1]. Elevated bilirubin levels can result in neural complications in neonates, such as bilirubin encephalopathy [2]. Early diagnosis and treatment are crucial to prevent these issues. Phototherapy is the primary treatment modality administered to neonates experiencing hyperbilirubinemia [3]. Furthermore, an extended duration of phototherapy can adversely impact the immune system, potentially resulting in Bronze Baby Syndrome [4]. The recognition of existing limitations catalyses exploring novel techniques that could potentially augment ability to address the complexities associated with neonatal hyperbilirubinemia.

Tactile and kinaesthetic stimulation, involving the application of touch and movement, respectively, present promising avenues for investigation due to their potential impact on neonatal growth and development. In existing literature, massage therapy given to neonates has proved to be a technique used widely in promoting neonatal growth by improving weight, bone strength, and height and has also proved to efficiently reduce hyperbilirubinemia in neonates [5,6]. While previous research has explored the impact of phototherapy and massage individually, there appears to be a gap in the literature regarding the combined effect of tactile and kinaesthetic stimulation with phototherapy specifically for neonates with hyperbilirubinemia.

The present study, therefore, aimed to bridge the existing knowledge gap by investigating the efficacy of tactile and kinaesthetic stimulation in conjunction with phototherapy for reducing bilirubin levels in neonates with hyperbilirubinemia. By adopting a multifaceted approach, authors aspire to not only contribute valuable insights to

the current understanding of neonatal care but also to potentially redefine and optimise therapeutic strategies for this vulnerable population. The objectives of present study encompass assessing the impact of tactile and kinaesthetic stimulation on bilirubin levels, evaluating the safety and feasibility of these interventions, and, ultimately, enhancing our capacity to provide holistic and effective care to neonates with hyperbilirubinemia.

MATERIALS AND METHODS

A randomised controlled feasibility study was conducted in the NICU of a tertiary hospital from June 2023 to September 2023. The present study received approval from the research advisory committee and obtained ethical clearance from an Institutional Ethical Committee with reference number IEC 2155. The study protocol was registered in the ClinicalTrials.gov Protocol Results System (PRS) under ID NCT05077787 on October 14, 2021. The study adhered to the Helsinki Declaration revised in 2013 and the National Ethical Guidelines for Biomedical Research involving Human Participants in 2017 [7].

Inclusion and Exclusion criteria: The study included twelve preterm neonates (Gestational Age (GA) less than 37 weeks) with neonatal hyperbilirubinemia >10 mg/dL and birth weight between 1000 g- 3500 g admitted to the NICU. The exclusion criteria were neonates with congenital deformities, gastrointestinal obstruction and biliary atresia, sepsis, or neonates on ventilatory support [8].

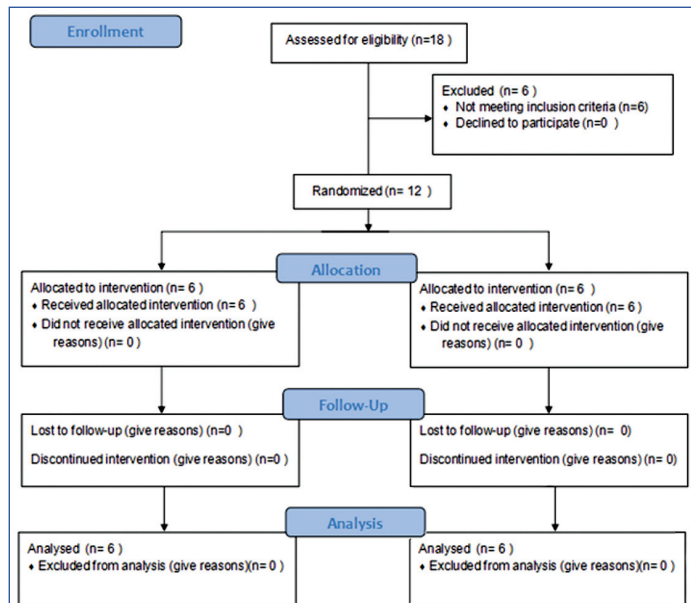
Study Procedure

Interventions: Neonates meeting the specified inclusion criteria were enrolled in the study, and their parents were subsequently requested to provide written informed consent following a comprehensive explanation of the procedure. Pertinent birth parameters, including neonatal gender, GA, age of the neonate,

occipitofrontal circumference, Appearance, Pulse, Grimace, Activity and Respiration (APGAR) score, and birth weight, were extracted from the neonate's medical records maintained in the hospital file.

Randomisation

The neonates were randomly assigned to either of the two groups using block randomisation and allocation method. Block randomisation with 3x4 blocks was used for recruiting the neonates, and they were recruited into experimental and control groups in a 1:1 ratio using Sequentially Numbered, Opaque, Sealed, and Stapled Envelopes (SNOSE) [9,10] The CONSORT flowchart of the present study has been presented in [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow chart.

Experimental group: In the experimental group, six neonates were recruited, and they received phototherapy and tactile and kinaesthetic stimulation in three phases for 15 minutes on three consecutive days. In the first phase, massage therapy was given for five minutes; in the second phase, kinaesthetic stimulation was given for five minutes, and in the third phase, massage therapy techniques were repeated, just after an hour of feeding the neonate twice daily. Massage therapy included in supine lying positions, facial techniques such as stroking, kneading, tapping, and effleurage, with defined parameters for duration and repetitions. The chest and abdomen procedures involve stroking, kneading, rolling, tapping, and vibration, each applied systematically to enhance neonatal growth and address hyperbilirubinemia concerns. In prone lying positions for the back, techniques encompass stroking, kneading, rolling, tapping, vibration, and effleurage, with specific movements from proximal to distal directions [11]. Kinaesthetic stimulation is given to the neonate in a supine lying position, and it includes six repetitions of each of the following movements: a) arm flexion/extension, with flexion lasting five seconds and extension lasting five seconds; leg flexion/extension, with five seconds of flexion and five seconds of extension for six repetitions; and c) simultaneous flexion/extension of the legs, with five seconds of flexion and five seconds of extension [12].

Control group: In the control group, six neonates were recruited, and they received phototherapy in addition to conventional NICU treatment.

Phototherapy: In both groups, newborns received double surface phototherapy using blue light in supine laying nude in an incubator only with eyes and genitals covered, in addition to standard NICU care [13]. The distance between the surface on which the neonate is lying and the light source, which emits light with an intensity of 10 to 15 watts per square centimeter per nanometer, was maintained

at a range of 20 to 30 centimeters, following the guidelines provided by the American Association of Paediatrics (AAP) [14-16].

Outcome measures:

Total Serum Bilirubin (TSB): TSB was collected by nursing personnel from the newborn's heel prick.

Transcutaneous bilirubin: The Bili check Transcutaneous Bilirubinometer was used to measure transcutaneous bilirubin, and the readings were obtained from unexposed sites such as the glabellar region of the forehead (just above the internal area, covered by an eye mask), the chest at the level of the manubrium sterni, and a point over the anterior superior iliac spine by keeping the transcutaneous bilirubinometer vertical in contact with the neonate's skin [17]. The average of these three readings was determined and considered as the transcutaneous bilirubin for the particular day [Table/Fig-2].



[Table/Fig-2]: Transcutaneous bilirubinometer.

The outcome measures were assessed at baseline and day 3 after the intervention.

STATISTICAL ANALYSIS

The data was analysed using IBM's Statistical Package for the Social Sciences (SPSS) software version 20.0 The significance cut-off point was set at 0.05. To assess normality, the Shapiro-wilk test was conducted, confirming that the data followed a normal distribution. Accordingly, the paired t-test and student's t-test were utilised for within-group and between-group analyses, respectively. Descriptive statistics were reported in terms of the mean and Standard Deviation.

RESULTS

The results of the study revealed significant trends in the impact of tactile and kinaesthetic stimulation in conjunction with phototherapy on bilirubin levels in neonates with hyperbilirubinemia. [Table/Fig-3] presents a comparison between an experimental group (n=6) and a control group (n=6) across various variables. In this context, none of the p-values are below the conventional threshold of 0.05, suggesting that there were no statistically significant differences between both the groups for age, body weight, APGAR Score, occipital circumference, and GA (p>0.05).

Group/group variables	Experimental group (n=6) Mean±SD	Control group (n=6) Mean±SD	p-value
Gender	Male=50%	Male=50%	1
	Female=50%	Female=50%	
Age (days)	3.33±1.21	3.50±1.22	0.82
Body weight (gm)	2350±296.6	2378±448.0	0.33
APGAR score	8.5±0.54	8.66±0.51	0.59
Occipital circumference	32.5±0.83	32.1±0.98	0.54
Gestational age (weeks)	35.2±1.04	35.2±0.77	0.85

[Table/Fig-3]: Demographic data of preterm neonates.

*test of significance- Independent- t-test

TSB levels significantly reduced after three days in both experimental and control groups ($p < 0.001$, $p = 0.001$, respectively) [Table/Fig-4]. However, the change in mean levels of TSB and TCB was not significantly different when compared between the two groups ($p > 0.05$) [Table/Fig-5].

Parameters	Time	Experimental group	p-value	Control group	p-value
		Mean±SD		Mean±SD	
TSB	Baseline	15.4±1.71	<0.001	16.16±1.59	0.001
	Day 3	7.58±1.17		8.32±2.20	
TCB	Baseline	16.00±3.32	0.002	16.83±1.31	<0.001
	Day 3	9.36±1.56		10.56±2.34	

[Table/Fig-4]: Within group analysis of Total Serum Bilirubin (TSB) and transcutaneous bilirubin levels in preterm neonates at baseline and after intervention.

Parameters	Experimental group		Control group		p-value
	Change score	SEM	Change score	SEM	
TSB Baseline - Day 3	7.88	2.29	7.84	2.85	0.98
TCB Baseline - Day 3	6.63	2.77	6.27	1.92	0.78

[Table/Fig-5]: Between group analysis of Total Serum Bilirubin (TSB) and transcutaneous bilirubin levels in preterm neonates after intervention.

[Table/Fig-6] presents results from a three-day study comparing the control and experimental groups. Effect size for both outcome measures was found to be excellent, i.e., greater than 0.80.

Baseline to Day 3	Variables	Control group		Experimental group	
		Effect size (Cohen's d)	Power (1-β)	Effect size (Cohen's d)	Power (1-β)
Between group analysis	TSB D1-D3	4.1	1.0	5.33	1.0
	TCB D1-D3	3.32	0.99	2.58	0.99

[Table/Fig-6]: Effect size and power analysis.

D1-D3: Day 1-Day 3

DISCUSSION

The present study aimed to evaluate the impact of tactile and kinaesthetic stimulation on preterm neonates to reduce both the duration and adverse effects associated with phototherapy. No statistically significant differences were observed between the control and experimental groups at baseline. The study's results did not provide sufficient evidence to reject the null hypothesis, leading to the acceptance of the null hypothesis instead of the alternative hypothesis.

The within-group analysis underscores the efficacy of the interventions in both the experimental and control groups. Notably, there were significant reductions in TSB and TCB levels from day 1 to day 3 within each group. These findings highlight the inherent effectiveness of the interventions in lowering bilirubin levels over the specified period. Our findings are consistent with existing literature suggesting that combining massage therapy with phototherapy holds promise as a potential intervention for mitigating elevated bilirubin levels in neonates [18,19]. Dalila H et al., reported analogous results in their pilot study, observing that the group receiving combined massage and phototherapy

demonstrated markedly lower bilirubin levels compared to the control group in present investigation [20]. Similarly, a study conducted by Chen J et al., in full-term neonates with hyperbilirubinemia revealed that massage therapy increased stool frequency, thereby promptly reducing bilirubin levels and facilitating the early discharge of neonates from the hospital [5].

Furthermore, Basiri-Moghadam M et al., demonstrated in their study that stable premature newborns who received massage exhibited a significantly lower increase in bilirubin levels compared to their counterparts who did not undergo such treatment [8]. The notable reduction in bilirubin levels observed in the massage group compared to the control group can be attributed to several factors. By encouraging a more regular and effective elimination of stools, massage plays a pivotal role in reducing bilirubin levels. The increased frequency of stool passage induced by massage contributes to a quicker resolution of jaundice [21]. By encouraging a more regular and effective elimination of stools, massage plays an important role in reducing bilirubin levels [22].

The between-group analysis revealed intriguing results. While both groups experienced significant reductions in bilirubin levels within each group, the mean differences between the experimental and control groups were not statistically significant on Day 3. Basiri-Moghadam M et al., conducted a study on preterm neonates showing a significant statistical difference in bilirubin levels between both groups on the 3rd and 4th day post-intervention, with the mean bilirubin level in the preterm neonatal sample group notably lower than that in the preterm neonatal control group [8]. Similarly, another study by Karbandi S et al., found no significant difference in the amount of bilirubin between the control group and the group receiving both massage and phototherapy [23].

The effect size and power analysis provided crucial insights into the strength and reliability of present study's findings. The experimental group displayed a slightly higher effect size of 5.33 with a power of 1.0, indicating a very reliable result. Importantly, both groups surpassed the conventionally accepted power threshold of 0.80, reinforcing the reliability of present study results.

The effect size was found to be excellent for both groups for both outcome measures, but it was observed that the effect size was higher for TSB in the experimental group compared to the control group, while it was lower for TCB when both groups were compared, signifying a more substantial reduction in bilirubin levels from Day 1 to Day 3. It is crucial to acknowledge that interpreting TSB levels involves considering various factors, including the neonate's age, GA, birth weight, and clinical status. These factors should be carefully weighed when interpreting TSB levels and making clinical decisions.

Despite the lack of statistical significance in the between-group analysis, the within-group analysis underscores the efficacy of the interventions within both the experimental and control groups. These high effect sizes and power values underscore the validity of the observed changes, despite the lack of statistical significance in the between-group analysis.

The present study appears to have important implications for clinical practice and future research in this area. The significant reductions in bilirubin levels over the specified time period highlight the practical impact of the interventions. The lack of statistical significance in the between-group analysis may prompt further exploration into individual responses to the interventions, considering factors such as GA, birth weight, and clinical condition.

Limitation(s)

The sample size of the present feasibility study is relatively small, as it is a feasibility study, which may limit the generalisability of the findings.

CONCLUSION(S)

In conclusion, significant reductions in TSB and TCB were observed within both the experimental and control groups. However, no significant difference was noted between the groups for the mean change in the levels of TSB and TCB. The within-group changes, effect sizes, and power values collectively suggest that the applied interventions, including tactile and kinaesthetic stimulation, had a notable impact on bilirubin metabolism in preterm neonates. These findings indicate a potential early impact of the experimental intervention on bilirubin levels in preterm neonates, warranting further investigation and monitoring.

Massage therapy and TKS appear to have potential as adjunctive therapies for preterm neonates with hyperbilirubinemia, but further research is necessary to fully understand their benefits and limitations. Further research is warranted to comprehensively understand the benefits and limitations of massage therapy and tactile and kinaesthetic stimulation as adjunctive therapies for preterm neonates with hyperbilirubinemia and to explore the specific characteristics of neonates that may influence the responsiveness to these interventions and to refine protocols for optimal efficacy.

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PARTICULARS OF CONTRIBUTORS:

1. Ph.D. Scholar, Department of Musculoskeletal Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation/MM (DU), Mullana, Ambala, India.
2. Associate Professor, Department of Neurological Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation/MM (DU), Mullana, Ambala, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Subhasish Chatterjee,
Associate Professor, Department of Neurological Physiotherapy,
Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation,
Maharishi Markandeshwar University (Deemed to be University), Mullana,
Ambala-133203, Haryana, India.
E-mail: subhasishphysio@gmail.com

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