ORIGINAL ARTICLE

Mustard Seed Pillow for Prevention of Deformational Plagiocephaly in ≤ 32 Weeks' Gestational Age Infants: An Open Label Randomized Controlled Trial

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ABSTRACT

Objectives: To assess the effectiveness of using mustard seed filled pillows in preventing deformational plagiocephaly (DP) in premature infants.

Method: A prospective open label randomized trial was conducted in a tertiary care hospital in South India. Eligible preterm infants born at ≤32 weeks and <1500 g admitted in the neonatal intensive care unit (NICU) were randomly allocated to the intervention and control groups. In addition to standard nesting, the intervention group was positioned using a mustard pillow, while the control group was positioned using nesting alone. Plagiocephaly was assessed using the Cranial Index (CI), Cranial Vault Asymmetry Index (CVAI) and Argenta classification within the first week and at 4 weeks postnatal age.

Results: Twenty-eight infants, each in the control and intervention groups, were included for analysis. At 4 weeks postnatal age, the intervention group had lower mean (SD) CVAI scores when compared to the control group [3.16 (1.89 vs 7.85 (2.63)] with adjusted odds ratio, aOR (95% CI) of 28.2 (3.8, 210.01), *P* < 0.01. More number of infants in the control group had plagiocephaly measured using Argenta classification [aOR (95% CI) 25.70 (2.80, 235.67), *P* < 0.01]. There were no differences in the Cranial Index scores in the intervention and control groups [aOR (95% CI) 0.41 (0.11, 1.52), *P* = 0.184].

Conclusion: A mustard seed pillow is an easily available and a cost-effective intervention for preventing plagiocephaly in hospitalized preterm infants.

Keywords: *Head shape deformity, Neonatal Intensive Care Unit, Premature infants*

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INTRODUCTION

Deformational plagiocephaly (DP) is a cranial bone deformity, resulting from the application of unequal external pressure to the cranium after birth [1]. Preterm infants may develop scaphocephaly characterized by bilateral head flattening and/or plagiocephaly characterized by asymmetrical flattening of one side of the skull [2].Thirty eight percent of preterm infants have DP at term equivalent age [3]. A systematic review found positive associations between DP and developmental delay [4].

Early prevention of DP by frequently changing the position of the infant's head, positioning devices, and bedding pillows has been recommended [5]. Commercial devices such as cranial cups or memory foam pillows have been found to be effective in preventing and treating DP. Unfortunately, these are unavailable or expensive to procure in most developing countries [6,7].

Mustard seed pillows are easily available, cost effective, and traditionally used to position infants. Mustard seed pillows can mould to the shape of the infants' head and shoulder, equalizing pressure on the cranium and allowing symmetric positioning without restricting movement [8]. Their use in head and face shaping has been described in Nepal and Rajasthan, India [9,10].

This study aimed at comparing the effectiveness of a combination of mustard seed pillow with standard nesting with isolated standard nesting in the prevention of deformational plagiocephaly in hospitalized preterm infants: by measuring Cranial Index (CI), Cranial Vault Asymmetry Index (CVAI), and Visual Assessment

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(Argenta Classification), assessing motor development using Test of Infant Motor Performance (TIMP), and, comparing body alignment and symmetry with the Infant Positioning Assessment Tool (IPAT).

METHODS

This study was an open-label randomized controlled trial approved by the Institutional Review Board and Ethics Committee and registered with the Clinical Trial Registry India.

It was conducted in a tertiary care neonatal intensive care unit. The period of recruitment was between Jan, 2019 to Sep, 2019. Informed written consent was obtained from parents.

Inclusion criteria were preterm infants of gestational age ≤ 32 weeks and birth weight of less than 1500 g. Neonates with major congenital deformities or infants undergoing interventions that were contradictory to supine positioning were excluded. Once infants were off any invasive respiratory support (mechanical ventilation or continuous positive airway pressure), they were randomly allocated into intervention and control groups. Randomization was done by computer-generated sequences using SAS software and sealed in serially numbered opaque envelopes by the primary investigator (CFS).

A rectangular pillow filled with mustard seeds was used in the intervention group. There were two sizes (based on a pilot study with 15 infants): 11.5 × 9.25 inches filled with 850 grams of mustard seeds, and 9.5 × 8 inches with 450 grams of mustard seeds. The pillows were placed at the mid-scapular level of the infant inferiorly and surrounded by the nesting blankets superiorly and laterally as per standard protocol. The same procedure of standard nesting was used in the control group. The position of the infants was changed every two hours in both groups.

Cranial Index (CI) and Cranial Vault Asymmetry Index (CVAI) were measured in all infants. Both are determined by 3 variables: cranial length, cranial width, and transcranial diagonals measured using a craniometer. CI was calculated by obtaining a ratio of cranial width and cranial length multiplied by 100. Increased values of CI imply worsening of brachycephaly and combined head deformities. It has reported intra-rater reliability Intraclass Correlation Coefficient (ICC) of 0.96 to 0.99 and inter-rater reliability ICC of 0.98 [11,12]. CVAI is obtained by measuring the cranial diagonals of the unaffected side (A) and the affected side (B), where (A > B). CVAI is the difference between the cranial diagonal diameters (A-B) divided by long cranial diagonal diameter (A) multiplied by 100. Severity of DP is classified into 5 levels with higher levels implying worse plagiocephaly. Test-retest reliability (ICC = 0.958) and inter-rater reliability (ICC = 0.874) are reported to be good [11,12].

Argenta Classification is a visual assessment scale used to classify DP into five categories of increasing severity with Type 1 being the least severe and Type 5 being the most severe. Type 1 is restricted to flattening of the back of the skull, Type 2 adds the malposition of the ear, Type 3 adds deformity of the forehead, Type 4 adds a facial deformity and Type 5 adds abnormal vertical growth of the face [13,14]. CI, CVAI and Visual assessment (Argenta Classification) was assessed on two time points, i.e., within week 1 and week 4 (28 -35 days of life).

The infant positioning assessment tool (IPAT) was done once a day. IPAT is a 6-item checklist of infant positioning and symmetry. Scores range from 0 to 12, with optimal scores above 10, and scores < 8 indicating the need to reposition [17]. The Test of Infant Motor Performance (TIMP) is designed to assess functional motor performances of infants from 32 weeks post-conceptional age to 16 weeks after term age. The TIMP has the strongest psychometric properties among neonatal assessments for preterm infants and strong predictive values for later neurodevelopment with the highest predictive accuracy when infants are assessed at 3 months of age [18,19]. The Test of Infant Motor Performance (TIMP) was done at discharge. All outcome assessments were evaluated by a single neonatal therapist (HJ).

The sample size was estimated considering the Cranial Index, as a reference [6]. Using the formula for differences in proportion, the assumed proportion of infants with abnormal CI in the control group being 46% and in the intervention group as 13%; 80% power and alpha error 5%, the calculated study sample was 29 in each group.

Statistical analysis: Descriptive statistics was used. Chisquare and Fisher's exact test were used to determine the association between demographic and other characteristics. Student's t-test was used to compare the difference between the two groups in case of normally distributed data. Logistic regression analysis was done for CI, CVAI, Argenta classification and TIMP for the second assess-ment, adjusting for variables of the study group, gestatio-nal age, birth weight, days on oxygen, perinatal asphyxia, chronic lung disease, and major brain lesion. The line plot was given with descriptive statistics to compare the positioning scores of both groups. Since IPAT scores were performed more than 30 time-points continuously in days the functional t-test methodology under the Functional Data Analysis (FDA) framework was used to assess significant differences in the scores between groups. All tests were two-sided at $\alpha = 0.05$ level of significance. Statistical Package for Social Sciences (SPSS) software Version 21.0 (IBM Corp) was used for analysis.

RESULTS

Fig. 1 depicts the flow of participants in the study and the intervention strategies used. **Table I** presents the baseline characteristics of participants in both groups. There were no significant differences in demographic characteristics, or neonatal complications. However, the control group received significantly longer duration of ventilation and more days of oxygen ($P = 0.02$).

Table II presents the details of various assessments at the two time points of assessment (week 1 and 4). The first assessment showed significantly higher mean scores of CVAI implying higher levels of plagiocephaly in the intervention compared to the controls. At four weeks postnatal age, the intervention group had significantly lower mean CVAI scores when compared to the control group. More infants in the control group had plagiocephaly by Argenta classification. There were no differences in the CI scores or motor performance. Mean positioning scores using IPAT were significantly better in the intervention group compared to the control group. There were no adverse events reported with the use of mustard seed pillows.

When logistic regression analysis adjusting for variables like gestational age, birth weight, days on oxygen, perinatal asphyxia, chronic lung disease, and major brain lesion was done, the intervention group had greater chances of lower CVAI scores compared to the control group at 4 weeks postnatal age, adjusted odds ratio (aOR), 95% confidence interval (CI) of 28.2 (3.8, 210.01), $P < 0.01$. More number of infants in the control group had plagiocephaly measured using Argenta classification [aOR (95% CI) 25.70 (2.80, 235.67), $P < 0.01$]. There were no differences in the Cranial Index scores in the intervention and control groups [aOR (95% CI) 0.41 (0.11, 1.52), $P = 0.184$].

DISCUSSION

Progressive flattening of the skull in premature infants has been attributed to malleability of cranial bones, head turn preference, and inability to spontaneously reposition their head due to a relatively large head mass and poor neck muscle tone [18,19]. Conservative methods such as active repositioning, rotating the head during feedings and sleep, and providing supervised prone time may be used to

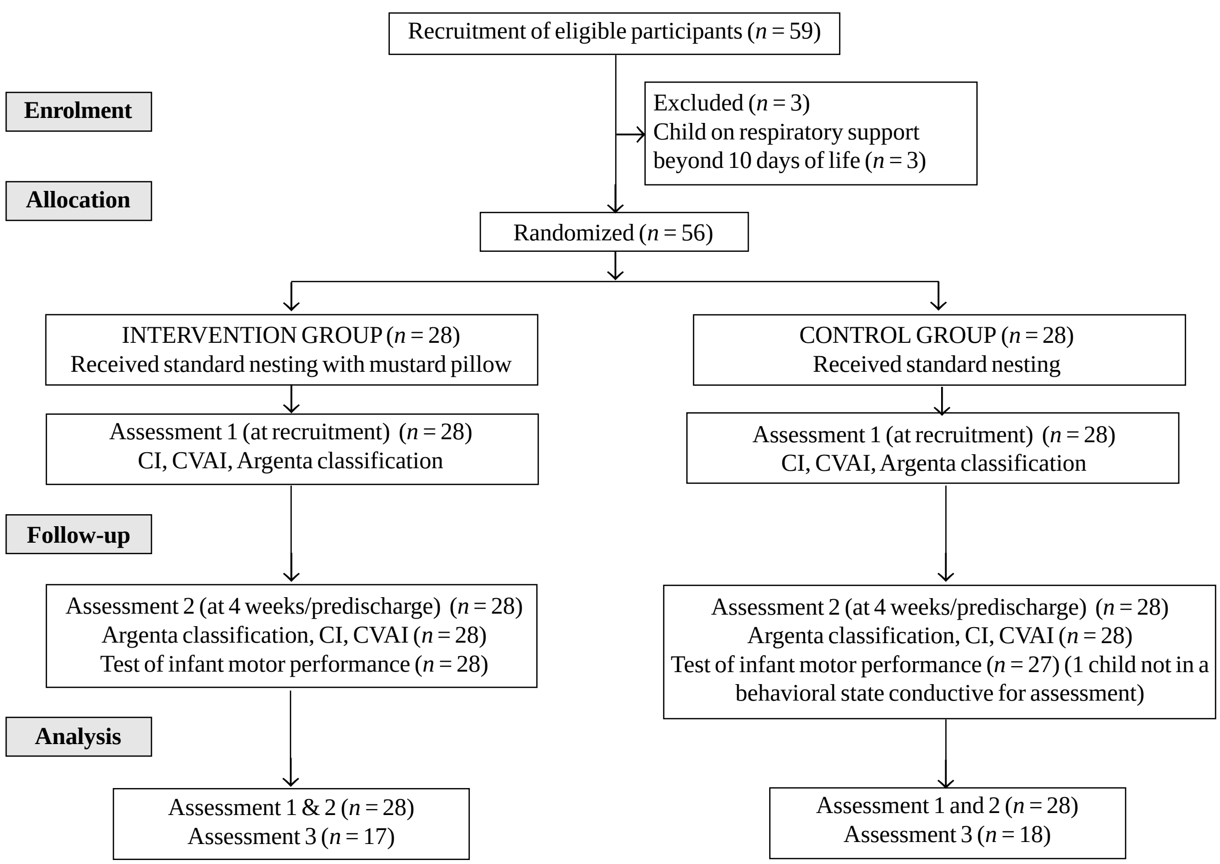

Fig. 1 Flow of participants from enrollment to analysis

Table I Clinical Characteristics of Infants in Control and Intervention Group

Characteristics	*Control group (n = 28)*	*Intervention group (n = 28)*
Gestational age at birth (week)[a]	29.50 (1.6)	29.71 (1.5)
Birth weight (g)[a]	1175.7 (232.3)	1146.2 (223.3)
Length at birth (cm)[a]	35.75 (3.0)	36.61 (2.7)
Head circumference (cm)[a]	26.50 (1.4)	26.73 (1.6)
Length of hospital stay (days)[a]	48.50 (21.0)	46.93 (19.1)
Male gender	17 (60)	18 (64)
Twin gestation	7 (25)	7 (25)
Type of delivery		
Normal vaginal delivery	1 (4)	5 (18)
Lower segment cesarean section	25 (89)	23 (82)
Breech extraction/ Instrumental	2 (8)	0
Perinatal asphyxia	6 (21.4)	4 (14.3)
Ventilated	25 (89.3)	23 (82.1)
Hours of ventilation[a]	15.02 (18.7)	3.15 (6.3)
Continuous positive airway pressure (CPAP)	25 (44.6)	21 (37.5)
Hours on CPAP[a]	42.10 (43.0)	29.71 (29.8)
Apneic episodes	15 (53.6)	11 (39.3)
Days on oxygen[a]	18.17 (34.9)	3.75 (9.6)
Hyaline membrane disease	9 (32.1)	7 (25.0)
Bronchopulmonary dysplasia	2 (7.1)	2 (7.1)
Hypoglycemia	5 (17.9)	3 (10.7)
Septicemia	6 (21.4)	2 (7.1)
Major brain lesion on cranial ultrasound	0	4 (14.3)

Values expressed as n (%) or mean (SD)[a]. P > 0.05 for all variables except hours of ventilation and days on oxygen where P = 0.02 and P = 0.04, respectively.

prevent DP, but are not always successful or feasible in hospitals with high staff patient ratios [6,20]. Pillows were found superior and easier to use than stretching exercises in correcting positional head deformities in infants in one study [5]. Pressure relief positioners (air mattresses, waterbeds, water pillows, therapeutic mattresses, and gel pillows) have been used previously with some success in preventing DP [21]. However, these devices are expensive and may not correct all types of plagiocephaly [22]. Donut-shaped gel pillows effectively disperse pressure away from the occiput, but transfer it to a narrow region of scalp tissue, increasing the risk of pressure injuries [23].

Our study showed that fewer hospitalized preterm infants, when positioned on a mustard seed pillow with additional nesting, showed DP at 4 weeks postnatal age compared to infants using isolated nesting by CVAI index and Argenta classification.

There was no significant difference in the Cranial index scores of interventional and control groups at the second assessment. This may imply that mustard seed pillows cannot prevent brachycephaly. Infants in our study were predominantly placed in the supine position, which predisposes to brachycephaly per se. Other studies report similar findings while evaluating positioning pillows for correcting DP; there was no decrease in brachycephaly, but significantly lower CVAI scores in the pillow groups [5,7].

Our study found no differences in the motor performance of infants between groups measured at 4 weeks. Several studies have found associations with a mutually predictive ability between DP and asymmetric motor performance of premature infants at term equivalent age, 3 months and 6 months [7,24]. A possible reason why this association was not found in the present study may be since TIMP was administered at around 36 weeks corrected age. This may be too early to detect a difference in motor development. Also, this study was not adequately powered to assess motor outcomes. We recommend that future studies evaluate neuro developmental outcomes after a more prolonged duration.

The results of the IPAT indicate that the intervention group was consistently more optimally positioned than the control group. The mustard pillow supports the head, neck, and shoulders, thus facilitating flexion and midline positioning and contributing to optimal positioning. Standard recommendations for positioning infants in the NICU include placing the head near the midline, with support under the shoulder and humerus to facilitate shoulder protraction, allowing hands to touch the chest or mouth [18]. During the study, nurses reported the need to frequently reposition the infants who were placed on the pillow when head end elevation was indicated.

This study was the first to look at the effectiveness of mustard pillows in preventing DP in preterm infants in the NICU. There are however, a few limitations. The outcome assessor was not blinded to group allocation since it was not feasible in our setting. Since there was a single assessor, inter-observer variability could not be measured. Baseline neurological status and associations of neonatal complications such as osteopenia and other cranial pathologies were not evaluated. The study was conducted in a tertiary care intensive care unit, and therefore generalizability of the results to primary and secondary care settings is not known. We conclude that Mustard seed pillow is an easily available and cost-effective intervention for preventing plagiocephaly in hospitalized preterm infants.

Table II Comparison of CVAI, CI, Argenta Classification and TIMP in the Intervention and Control Groups

	Intervention group (n = 28)	*Control group (n = 28)*	*P value*	*Intervention group (n = 28)*	*Control group (n = 28)*	*P value*
	At recruitment			*4 weeks postnatal age*		
Head circumference (cm)[a]	26.72 (1.56)	26.50 (1.39)	0.56	29.22 (1.85)	29.61 (1.12)	0.34
Cranial vault asymmetry index (CVAI)[a]	4.45 (2.02)	2.54 (1.24)	< 0.01	3.16 (1.89)	7.85 (2.63)	< 0.01
CVAI *classification*[b]						
Level 1	11 (39)	22 (79)		18 (64)	2 (7)	
Level 2	15 (54)	6 (21)		9 (32)	6 (21)	
Level 3	0	0	< 0.01	0	8 (29)	< 0.01
Level 4	2 (7)	0		1 (4)	9 (32)	
Level 5	0	0		0	3 (11)	
Cranial Index (CI)[b]						
Normocephaly	11(39)	7 (25)		12 (42)	14 (50)	
Dolicocephaly	3 (10)	7 (25)	0.33	8 (28)	10 (35)	0.45
Brachycephaly	14 (50)	14 (50)		8 (28)	4 (14)	
Argenta classification[b]						
No plagiocephaly	19 (68)	24 (86)		20 (71)	2 (7)	
Type 1	9 (32)	4 (14)		6 (21)	11 (39)	
Type 2	-	-		1 (4)	10 (36)	< 0.01
Type 3	-	-	0.20	1 (4)	3 (11)	
Type 4	-	-		0	0	
Type 5	-	-		0	2 (7)	
TIMP (n = 27/28)						
Raw score[a]				33 (8.7)	34.7 (8.6)	0.45
Classification[b]						
Average				4 (14)	3 (11)	
Low average				3 (10)	5 (18)	0.86
Below average				17 (60)	15 (56)	
Far below average				4 (14)	4 (15)	
Infant positioning assessment tool						
Number of days scored[a]; (range)				20.9 (8.0) (9-42)	19.64 (8.3) (8-36)	0.55
Score[a]				9.12 (1.39)	7.41 (1.69)	< 0.01

Values in mean (SD)[a], n (%)[b], TIMP: Test of infant motor performance

Ethical Clearance: Institutional Review Board and Ethics Committee of Christian Medical College, Vellore (IRB number 11649)

Trial Registry: Clinical Trial Registry of India (CTRI/2019/03/017910).

Contributors: CFS: Conceptualized and designed the study, data collection, analysis and interpretation, drafted and revised the manuscript. HJ: Study design, supervised data acquisition and analysis, interpretation of data, revised the manuscript. RJS: Study design, supervised data collection, interpretation of data, and revised the manuscript. RK: Data analysis and interpretation, revised the manuscript. MK: Study design, data acquisition and interpretation, revised the manuscript.

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WHAT THIS STUDY ADDS?

- Mustard seed pillows can be used in hospitalized preterm infants.
- The use of mustard seed pillow in addition to standard nesting is effective in preventing deformational plagiocephaly during hospital stay.

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