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Is cranial molding preventable in preterm infants?
A systematic literature review of the effectiveness of interventions

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Abstract

Aims*:* A systematic review of published studies was conducted to study the evidence supporting interventions to prevent or reduce cranial molding of the preterm infant in Neonatal Intensive Care Units.

Background: Incidence of cranial molding has increased over recent decades. Cranial molding is identified as a contributor for negative physical and psychosocial developmental effects.

Design and Method*:* A systematic literature review and critical appraisal according to the Cochrane Collaboration Center assessment criteria was performed.

Results*:* Eight intervention studies meeting the inclusion criteria were identified. Most studies used the anterior-posterior: bi-parietal ratio as measurement of cranial molding. One multi-center quasi-experimental intervention study showed that infants who received regular repositioning had a statistically significant reduction of bilateral head flattening compared to infants who did not receive this intervention. Other studies had either methodological weaknesses or showed no effect for the intervention studied.

Conclusion: Evidence is poor and restricted to one intervention; regular body repositioning. More well-designed randomized studies are needed to confirm the effect of regular head and body positioning.

Keywords*:* cranial molding, plagiocephaly, preterm infant, prevention, NICU.

Introduction

The increasing incidence of premature infants presenting with cranial molding has been linked to recommendations regarding sleep positions (side lying and supine position) to prevent Sudden Infant Death Syndrome as well as to the increased number of very low birth weight infants admitted to the Neonatal Intensive Care Unit (NICU)[1]. Supine positioning of newborn infants for longer periods of time seems to increase the prevalence of cranial molding. Cranial molding is measured by the ratio between the anterior-posterior and the bi-parietal distance (AP:BP ratio) also called the cranial index (CI). (Figure 1) Larger bilateral head flattening is indicated by larger CI's. Healthy infants are born with an AP:BP ratio of 1:3. A ratio of 1:4 or more is considered to be cranial molding[2].

The incidence of cranial molding in newborn infants varies from 16.0% to 22.0% at the age of 6 or 7 weeks and 19.7% at the age of 4 months and decreases to 3.3% at 2 years[3,4]. Research also showed that healthy newborn infants with a positional preference for one side, have higher risk to develop an a-symmetric head, compared to newborn infants without a positional preference (OR 7.1, 95%CI 3.90-12.78)[5].

Another group of infants with a higher risk of cranial molding are preterm infants (born < 37 weeks gestational age [GA])[2,6]. In this group cranial molding is caused by a combination of fast growing brain matter and the soft skull parts with low levels of calcium of these premature infants and being nursed for prolonged periods on hard surfaces.

Certain conditions, which are common in preterm infants, such as the relative large head of the preterm infant and the reduction of the muscle tone to be able to spontaneously change the head position, promote the effect of external compression. This results in prolonged time periods in the same positions which lead to either parietal or occipital flattening of the infant's head[7].

The degree of cranial molding depends on the frequency of positional changes and gestational age. The lower the gestational age, the lower the serum calcium levels. An adequate calcium level is necessary for bone building and consequently hardening of the skull parts. Because calcium is better absorbed from the blood through the umbilical cord and placenta than from par(enteral) feeding the hardening of the skull occurs much faster in the intra-uterine environment compared to the extra-uterine environment after preterm birth[2].

Cranial molding in preterm infants can have a number of negative consequences. Infants can become restricted in their possibilities of rotating the head when lying on their back. Consequently the intracranial pressure increases, resulting in psychomotor as well as cognitive developmental delays[8]. In addition, cranial molding is associated with auditory dysfunction and visual pursuit (coordination between eye movements and head rotation), with consequences on eye-hand grip coordination[9,10]. A study with magnetic resonance imaging (MRI) shows shifting of brain areas as a result of cranial molding[7]. Cranial molding is also identified as a contributor for the negative physical and psychosocial effects of a dissociated bonding process and lack of attachment between parents and their newborn infant[2,5,6,11,12].

Treatment of serious cranial molding may include correction of the skull by helmet therapy or by surgical intervention[13].

In the NICU's changing body and head positioning is used as an intervention to prevent cranial molding, but consensus on the procedure is lacking. The current guidelines are not evidence based.

Aim and objective

To conduct a systematic review of published studies of interventions aimed at prevention or limiting the cranial molding (AP:BP ratio) of preterm infants. Effectiveness of interventions and feasibility and applicability will be evaluated.

Methods

A systematic literature search was conducted using the method of the Evidence Based Medicine Group from Oxford[14], and using the PICO system: Patient, Intervention, Control intervention and Outcome[15].

The research question was: Which preventive interventions limit cranial molding in preterm infants admitted to the NICU?

The PICO was formulated as:

P: Preterm infant (24 to 36 weeks GA) admitted to the NICU

I: Preventive interventions

C:No intervention

O:Cranial molding measured by AP:BP ratio

Search strategy

The systematic literature search was independently conducted by 4 of the 10 members of the National Innovation and Research Study group from the 10 Dutch NICU's in the Netherlands.

Papers published between January 1982 until July 2010 were included. Databases searched were PubMed, CINAHL, Embase, British Nursing Index and Archive, Maternity and Infant Care and the Cochrane Library. The following keywords were used: 'cranial molding', 'plagiocephaly' ,'infant', 'preterm' and 'prevention' and were searched in the title and abstract. The boolean 'AND' was used to combine the used keywords and boolean 'OR' was used to combine keywords in the sense of either (cranial molding 'OR' plagiocephaly). The same strategy was performed but without 'prevention' to make the search less sensitive. In addition, the reference lists of included studies were reviewed for other potential studies that met the formulated PICO.

Selection criteria

Articles with an English or Dutch abstract were included. Exclusion criteria were studies concerning 'inborn skull deformation', 'healthy term infants' and 'diagnosis or treatment'.

In a second round the distinction was made in research articles describing the results of a scientific study and descriptive articles not describing scientific study results. Research articles were included, other articles were used as background information.

Critical appraisal

The included studies were independently critically appraised to establish the quality of the study and the effect of the interventions studied, by four researchers. The checklists of the Cochrane Center were used for this purpose[16]. All articles were appraised for validity and reliability with the appropriate checklist for the design used. The results of the individually critical appraisal were compared and in case of an inconsistent interpretation between the researchers a meeting was planned to reach consensus.

Results

The search strategy using the terms 'cranial molding or plagiocephaly', 'infant' and 'preterm' combined with the term 'prevention' resulted in seven articles of which only two met the inclusion criteria seemed relevant. A less sensitive search was performed; the keyword 'prevention' was deleted and this generated 72 articles. Abstracts of these 72 articles were assessed for their relevancy. Twelve articles were selected for their potential relevancy. Twelve other articles did not include an abstract or could not be judged for their relevancy based on the abstract provided. The other 48 articles were excluded because they appeared to be no research article or because the study described the effectiveness of an intervention to treat instead of to prevent cranial molding. From the initial selected 24 (12 and 12) articles we were unable to retrieve only one article[17]. Eventually eight articles emerged to answer our research question and were consequently critical appraised (see Figure 2).

Three studies used a randomized clinical trial (RCT) design[19-21]. Two studies had a quasi experimental design, one was a cohort study with a pretest - posttest design, one study had a patient-control design and one a case study design[2,18,22- 24]. Five of the studies compared different interventions, a pressure relief mattress, an air mattress, waterbed, water pillow or gel pillow with the standard practice of a so called hard mattress[18-22]. Two studies compared the effectiveness of (re)positioning with standard care[2, 23]. One study describes the use of a therapeutic mattress combined with a developmental care program[24].

Six of the included studies used the anterior-posterior bi-parietal (AP:BP) ratio as primary outcome for cranial molding. This ratio was measured at time points ranging from 3 till 13 weeks (Table 1). One study used the CI index as outcome for cranial molding.

Pressure relief mattresses

Four studies described the effect of pressure relieving mattresses[19-21,24].

The study of Cartlidge & Rutter had several limitations, such as a small sample size (17 infants in each group), and did not report a power analysis[19]. The preterm infants in this study were cared for on an air mattress or on a conventional mattress of 12 millimetre thickness (brand and type not mentioned). Randomization was performed by sequence of admittance; one infant in the control group followed by one infant in the experimental group. Measurement of the skull was not blinded; the assessor was acquainted with the infants' group. All measurements were performed by the same assessor. The follow-up was short until three weeks post delivery. The result of the AP:BP ratio control group vs. intervention group was1.48 vs. 1.40 respectively. Analysis showed effect of the intervention, but considering the methodology issues, results need to be interpreted with caution. The feasibility and applicability of this intervention are also doubtful since the used air mattress (Apnoea alarm Mark 3 Vickers Medical, Hampshire, UK) is no longer available.

Hemingway & Oliver performed a well designed blinded RCT. The sample size estimation was 100 infants to be included but only 84 infants were actually included[20]. A block randomisation was used; the researcher had no influence in the group assignment. The effect assessor was blinded for the intervention. The brand and type of the mattress used as well as the waterbed were not mentioned. Patient characteristics between groups were comparable. During interim analysis the effect of the intervention appeared to be unsatisfactory and as a consequence the study stopped.

At follow-up, 11 weeks after birth, only five infants were assessed, the other 79 infants were already transferred to other units, discharged home, transferred to a cot or deceased. The outcome AP:BP ratio was control vs. intervention 1.51 vs. 1.49. The results showed no effect in favour of the waterbed and the evidence was not conclusive and consequently the waterbed was not implemented in daily practice.

Chan et al. did not report a power analysis for their study[21]. The sample size was 144 infants. Intervention infants were cared for on a pressure relief mattress (Geo-Matt, Span America, Greenville USA), control infants on a standard mattress (no mention of brand and type). Randomization procedure was clear. Follow up was performed until 7 weeks after birth. The pressure relief mattress did, compared to the standard mattress, not reduce the cranial molding (AP:BP ratio 1.49 vs. 1.51 respectively). The study results however were not supportive for the use of this intervention and for that not applicable.

McManus & Capistran performed a case study and used a visco-elastic mattress and a twice-weekly developmental care program for an extremely low birth weight infant (24 4/7 weeks GA and 730 grams)[24]. Cranial molding was measured using the CI; the patient was admitted with a CI of 72 percent. By week 2, CI measurements approached normal limits (CI = 75 percent). When placed on continuous positive airway pressure, the CI became 66.7 percent. Following position changes to midline, CI measurements continued to improve and remained within normal limits until discharge. This dual-element program was feasible but this study does not reveal enough evidence due to the fact that N=1.

Water and gel pillows
Marsden studied the effect of a water pillow with a twin of 30 weeks gestational age in a patient-control study[18]. One of the twins received standard care (not specified) and a standard mattress (brand and type not mentioned) while the other twin was placed on a water pillow (Travenol Laboratories, Deerfield, USA). Before discharge, after 36 days in hospital, the AP:BP ratio was measured. The skull of the infant receiving standard care was more molded compared to the infant on a water pillow (AP:BP ratio 1.49 vs. 1.39 respectively).

Conditions and results of the intervention as well as the control infant were poorly described. There is very limited evidence for a positive intervention effect. Results as well as applicability are judged doubtful.

The study of Schultz et al. evaluated the effectiveness of gel pillows in preterm infants[22]. Power analysis was not performed. Sample size was underpowered with 81 infants of ≤ 34 weeks, weighing ≤1500 grams. Infants were randomly assigned at birth to usual care on a standard mattress (n = 40) or to placement on a gel pillow (n = 41). It was mentioned that nurses were not very helpful during the study. Beforehand nurses were convinced of the effect of gel pillows and supplied the control infants with liquid filled IV bags. Measurements (not blinded) were performed upon entry and weekly thereafter, until infants had been transferred, discharged or reached 2000 grams. Analysis revealed no statistically significant differences between subjects in the control group versus intervention group upon entry or at 10 weeks post intervention, AP:BP ratio 1.47 vs. 1.39 respectively. There is no evidence for a positive intervention effect and this intervention is for that reason not applicable.

(Re)Positioning
Hemingway & Oliver performed a multi-centre study with a quasi experimental design[2]. They studied the effects of (re)positioning on cranial molding. One hundred and forty six preterm infants were included in two comparing groups. The randomization procedure was described clearly. One group was cared for in supine- or side lying and the head was alternated between left and right side according to a standardized protocol. The other group was cared for according to a repositioning guideline including changing posture every 3 hours (range 2 to 4 hours) into one of the six prescribed positions; left side, right side, head in midline, supine position with head to the right, head in midline in anti-Trendelenburg and supine position with head to the left. Each position is applied equally over 24 hours. Different types of mattresses were used, the Geomatt (Span America, Greenville USA), a standard mattress, water- and gel pillows (brand and type not mentioned). Follow up of the preterm infant was until at least two weeks after birth and at most 13 weeks after birth. The AP:BP ratio was measured, the effect assessors were blinded for the intervention.

Until nine weeks after birth no differences appeared between both groups. From week nine forward a statistical significant difference between both groups occurred. The group repositioned according to the new guideline had a more round skull compared to those in the standard protocol group, AP:BP ratio 1.35 vs. 1.55 respectively (p=0.05). No specific explanation was given for this. The effect of the positioning guideline was well-founded and the study results are valid and applicable.

Vaivre-Douret and Golse studied the effects of two different lying-position body supports for physiologic and functional positioning[23]. Twenty-seven preterm infants were without randomization included. A first sample experimented with a “Home-Cocoon” support made by nurses with rolled sheets, and a second sample provided a “Coconou” support, made with a specifically designed rolled pad. Assessments were administered pretest (on admission without support) and posttest (at discharge) by a blinded single assessor. Cranial shape was measured subjectively as normal if without deformation or abnormal if there was at least cranial flattening. The follow-up lasted until 20 days after admittance. The “Coconou” group performed significantly better than the “Home-Cocoon” group, with fewer cranial deformities, Home-Cocoon vs. Coconou 43% normal vs. 85% normal ($P < .05$).

The study had some methodological shortcomings, the results are doubtful valid and not yet applicable.

Discussion

This systematic literature review resulted in one intervention with statistically significant effect on prevention of cranial molding, and studied according to the methodological standards. All other studies concerned non effective interventions for prevention of cranial molding. Moreover these studies revealed unsatisfactory methodological quality. Some of the interventions described in the studies are outdated since the material used is no longer available (e.g. mattresses of Geo-Matt). The interventions studied were limited and dated while modern materials as gel mattresses are not yet studied.

The only intervention shown to be effective is the repositioning guideline of Hemingway & Oliver[2]. This guideline is not applicable under all circumstances. The suggested postures are difficult if not impossible in case of drainage of pneumothorax, therapeutic hypothermia, severe illness or instability of the preterm infant.

Nurses, at least in the Dutch NICU's provide repositioning without having a standardized protocol and without evidence of the effect of the care provided on preventing cranial molding. As long as other interventions are not proven to be effective it is recommended to use the Hemingway & Oliver guideline[2]. One should realize the fact that posture to prevent cranial molding can also affect other functions of the body, like respiration and motor development of the preterm infant. Alternate postures could as a consequence of drainage prevent atelectases. Supporting a flexed body position during all postures could positively effect motor development and reduce stress. These effects are not studied in the studies included in this review.

Conclusion

In conclusion more well designed research is necessary to establish the possible positive effects or side effects of other interventions to prevent cranial molding, like gel mattresses or individualized developmental care. The repositioning guideline of Hemingway & Oliver has to be studied more extensively for long term outcome en side effects on respiration and motor development[2].

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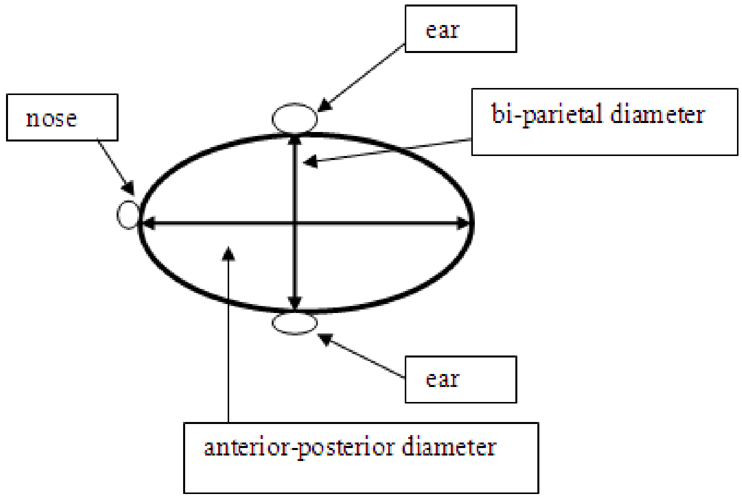
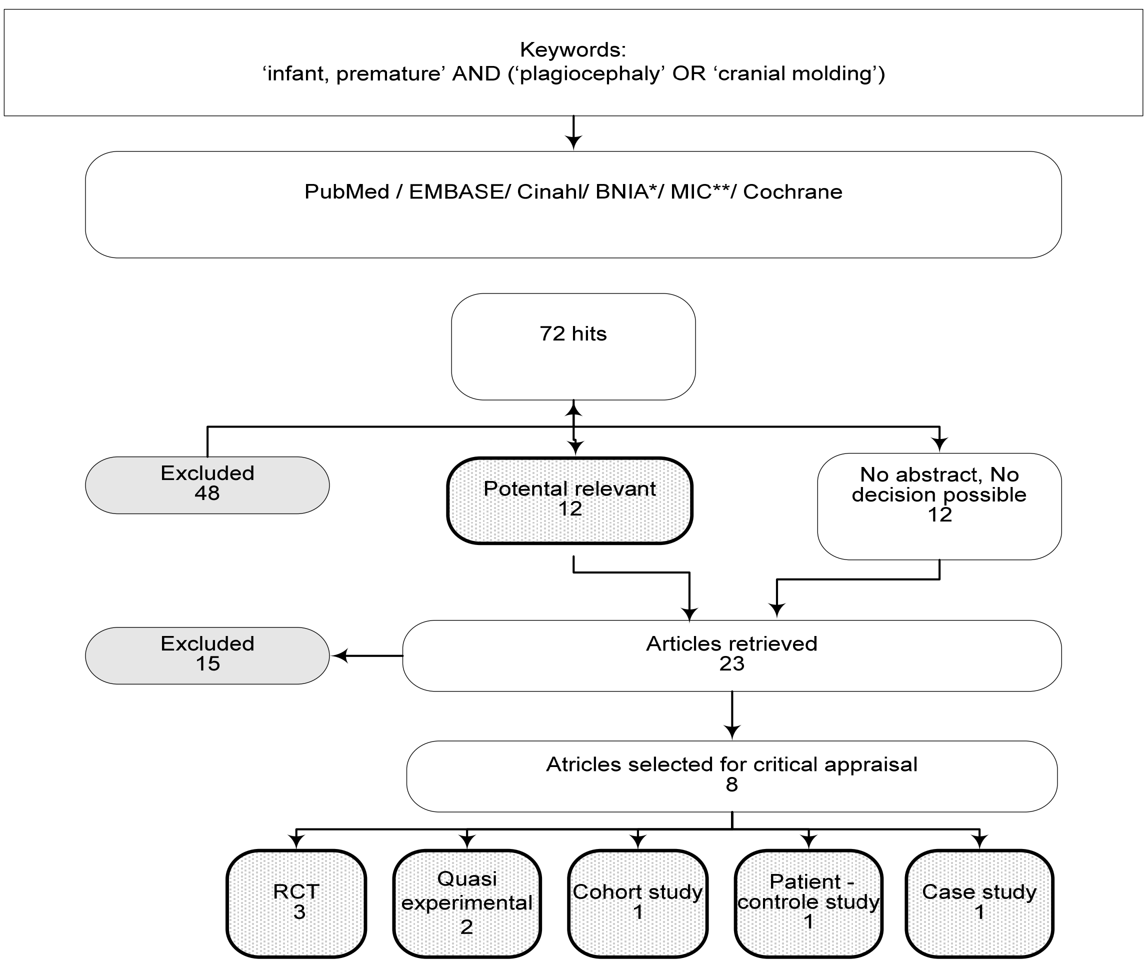


Figure 1. Measurement of the anterior-posterior diameter and bi-parietal diameter



BNIA*, British Nursing Index and archive; MIC**, Maternity and Infant Care

Figure 2. Flowchart search strategy and selection

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Table 1. Included studies on preventive interventions to decrease cranial molding

Authors	Design	Population	(Co-) Intervention	Primary outcome	Results control vs. intervention	Conclusion
Marsden, 1980[19]	Patient control	N=2, twins, GA[†]30 weeks without complications	Standard mattress vs. water pillow	AP:BP[‡] ratio follow-up at 36 days post partum	1.49 vs. 1.39	No baseline measurements and effectiveness not evaluated
Cartlidge & Rutter,1988 [20]	RCT*	N=34, preterm infants >26 and <31 weeks GA	Standard mattress vs. air mattress	AP:BP ratio follow-up day 21	1.48 vs. 1.40	Small group, short follow- up, no evidence for effect of air mattress, availability mattress doubtful
Hemingway & Oliver,1991[21]	RCT	N=47, preterm infants with GA <32 weeks	Customary firm mattresses vs. waterbed	AP:BP ratio follow-up till 11 weeks (or at discharge)	1.39 vs. 1.38	Adequate design, acceptable groups size, no evidence for the use of a waterbed
Chan, Kelley & Khan,1993[22]	RCT	N=144 preterm infants > 24 and < 36 weeks GA	Standard mattress vs. pressure relief mattress	AP:BP ratio follow-up till 7 weeks	1.51 vs. 1.49	Acceptable groups size, short study period, pressure relief mattress does not decrease cranial molding
Hemingway & Oliver, 2000[2]	Quasi experimental	N=146, preterm infants >22 and <32 weeks GA	Standard protocol vs. repositioning regimen	AP:BP ratio follow-up till 13 weeks	1.55 vs. 1.35[§]	Adequate groups size, long period of follow- up, repositioning schedules effective
Vaivre-Douret & Golse, 2007[24]	Pre-test/post-test study	N= 27 preterm infants > 28 and <35 weeks GA	Positioning and Home-Cocoon support vs. positioning and Coconou support	Normal abnormal head form during admission	57% vs. 15%[§] abnormal cranial shape	Small groups, subjective measurement of outcome, positioning in combination with Coconou effective
Schultz et al., 2008[23]	Quasi experimental	N=81 preterm infants ≤34 weeks GA and ≤1500gr	Standard mattress vs. gel pillow	AP:BP ratio Follow up at 5 and 10 weeks	1.47 : 1.39	Adequate design, underpowered, no evidence for the use of a gel pillow
McManus & Capistran, 2008[25]	Case study	N=1 preterm infant 24 4/7 GA and 730 g.	Therapeutic mattress and developmental care program	AP:BP ratio Follow up till 7 weeks	NA[‖]	Describes and not evaluates the possibilities of the two part intervention

*RCT = randomized clinical trial, [†]GA = gestational age, [‡]AP:BP = Anterior-Posterior diameter: Bi–Parietal diameter, [§] $P < 0.05$,
[‖]NA: Not applicable