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Helmets for positional skull deformities: A good idea, or not?

Probably not. Helmets appear to be no more effective than waiting for natural skull growth to correct the shape of an infant's head.

PRACTICE CHANGER

Do not recommend helmet therapy for positional skull deformity in infants and children. Wearing a helmet causes adverse effects but does not alter the natural course of head growth.¹

STRENGTH OF RECOMMENDATION

B: Based on a single-blind, randomized controlled trial (RCT).

van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, et al. Helmet therapy in infants with positional skull deformation: randomised controlled trial. *BMJ*. 2014;348:g2741.

ILLUSTRATIVE CASE

The parents of a 6-month-old girl with moderate plagiocephaly bring their daughter in for a well child visit. Previously, you had recommended that the parents increase "tummy time" when the baby is awake, change her position in bed, and monitor the progression of the condition. They do not feel these interventions have made a difference in the shape of their daughter's skull, and ask about using a helmet to help correct the deformity. How would you counsel them?

Positional skull deformity (PSD) is a common problem of infancy. Approximately 45% of infants ages 7 to 12 weeks are estimated to have PSD, although three-quarters of them have mild cases.² The incidence of PSD began to increase in 1992 after the American Academy

of Pediatrics (AAP) introduced its "Back to Sleep" campaign, which encouraged parents to place their infants on their back at bedtime to reduce sudden infant death syndrome.³

There are 2 common forms of PSD: plagiocephaly, and brachycephaly.¹ Plagiocephaly is unilateral occipital flattening, which may be accompanied by ipsilateral forehead prominence and asymmetrical ears. Brachycephaly is symmetric flattening of the back of the head, which can lead to prominence of the temporal areas, making the head appear wide. Children with severe plagiocephaly have a misshapen, asymmetric skull, while children with brachycephaly have a flattened skull. The cranial sutures remain open in both kinds of PSD.

Evaluating infants for PSD is part of the routine physical exam, and when the condition is noted, the exam should also differentiate PSD from other causes of skull deformity, such as craniosynostosis. Infants and preschool-aged children with PSD may score lower on developmental testing than children without skull deformity.⁴ However, these differences are small and inconsistent (2-3 points on a 100-point scale).⁴ Skull deformity persists into adolescence in only 1% to 2% of patients.⁵

Neither the AAP nor the American Academy of Family Physicians has a guideline or consensus statement on PSD. Helmets are intended to correct PSD by fitting closely to an infant's head but allowing room for the skull to

grow at the flattened area.¹ A 2011 clinical report by Laughlin et al⁶ recommended against using helmets for infants with mild to moderate deformities, but stated that there was little evidence of harm. Earlier studies have suggested that physical therapy might be effective for plagiocephaly caught early (7 and 8 weeks of age).^{7,8} Biggs⁹ suggested considering helmet therapy for infants whose cranial sutures remain open and who do not respond to 4 to 8 weeks of physical therapy for PSD. van Wijk et al¹ conducted an RCT to explore the risks and benefits of helmet therapy for children with PSD.

STUDY SUMMARY

Helmets for infants: No help and some harm

This single-blind RCT of 84 infants ages 5 or 6 months with moderate or severe PSD compared helmet therapy (n=42) to no intervention (allowing natural growth, n=42). Infants were excluded if they had very severe PSD or skull deformity from another cause, such as torticollis or craniosynostosis.

Infants in the helmet therapy group received a custom-made helmet that they wore 23 hours a day until they were a year old, with regular evaluation by an orthotist and modification of the helmet as necessary to allow skull growth. The control group had usual care and no helmet.

The primary outcome was improvement in skull shape at age 24 months as measured by the oblique diameter difference index (ODDI), a unitless measurement of plagiocephaly calculated by taking the ratio of measures of 2 dimensions of cranial diameter, and the cranioproportional index (CPI), a similar measurement of brachycephaly. Infants were considered fully recovered if they achieved an ODDI score of <104% and a CPI score of <90%. These scores indicate a normal head shape; higher scores indicate worse PSD.

At the end of the study, the reduction in ODDI and CPI scores was almost the same in both the helmet therapy and the control groups. Ten children in the helmet group (26%) and 9 in the control group (23%) experienced complete resolution of their PSD ($P=.74$).

Secondary outcomes included infant motor development, infant quality of life, parental satisfaction with the shape of their infant's head, and parental anxiety. Both groups were similar in infant motor development, infant quality of life, and parental satisfaction. Parental anxiety was assessed using the Spielberger State-Trait Anxiety Inventory (scores range from 20-80; a higher score indicates greater anxiety). There was less parental anxiety in the helmet therapy group: (-3.9; 95% confidence interval, -7.5 to -0.2; $P=.04$).

All parents of infants in the helmet therapy group reported at least one adverse effect from the intervention. These effects included skin irritation (96%), bad helmet odor (76%), pain associated with the helmet (33%), and feeling hindered from cuddling their child (77%).

WHAT'S NEW

RCT provides stronger evidence that helmets are not effective

This is the first RCT that assessed helmet therapy for PSD in children.¹ Before this, the evidence on helmets for PSD had been obtained mainly from observational or poorly designed studies with significant flaws.⁶ This study by van Wijk et al¹ included objective measurement of skull deformity, along with clinically meaningful outcomes of parental satisfaction, motor development, and parental anxiety. It also found that helmet therapy was significantly more expensive than care that focused on waiting for PSD to resolve on its own (\$1935 vs \$196, respectively).¹

CAVEATS

Results may not apply to all infants with skull deformity

These findings do not apply to infants with very severe cases of PSD or those with skull deformity due to secondary causes, such as craniosynostosis, who were excluded from this study.¹ In addition, this is the only RCT to date that has assessed helmet use in PSD, so it is possible that future studies will find helmets are effective.

CONTINUED



At the end of the study, improvement in skull shape was almost the same in the helmet therapy and control groups.

CHALLENGES TO IMPLEMENTATION

Parents may find this evidence hard to accept

To appropriately implement this recommendation, a family physician must be comfortable making the assessment of mild, moderate, severe, or very severe PSD. Referral to physical therapy might be appropriate for infants with very severe PSD.

If another physician or physical therapist recommends helmet therapy—or if a parent requests it—explaining the findings of this study may be challenging. We believe that the reduction in parental anxiety in the helmet group likely occurred because the parents believed that the helmet would accelerate the normal reshaping of the skull shape that occurs spontaneously in almost all infants with PSD. Since this study shows that helmets don't help correct skull deformities, parents can be assured that a helmet is unnecessary, costly, and causes adverse effects. **JFP**

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