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Letter to the Editor

Study on helmet therapy suffers from several weaknesses

A Health Brief in the August issue of *AAP News* highlighted a recent study from the Netherlands on helmet vs. “natural” therapy for positional plagiocephaly and brachycephaly (<http://aapnews.aapublications.org/content/35/8/2.1.full.pdf+html>). This study by R.M. van Wijk, et al. in the *British Medical Journal* (2014;348:g2741) reports on data collected from 29 pediatric physical therapy practices and finds no difference in head shape outcomes at 24 months among those assigned to helmet therapy vs. those assigned to no treatment at all.

Although timely and intriguing given the prevalence of positional head shape deformity in the wake of the Back to Sleep campaign (renamed the Safe to Sleep campaign), the study suffers from important and critical weaknesses that must be understood by our general pediatric providers.

First, subject numbers were particularly small (with 42 patients per group), and infants with “severe” deformities were excluded. Also excluded were infants with torticollis and other developmental neuromuscular delays, making overall conclusions non-generalizable given the estimated 40%-50% prevalence of these associated conditions in infants with positional cranial deformities.

Second, analysis in this study relied on manual calculations with a non-standard technique (40 degree diagonals rather than 30 degrees), and no such measurements were made during the actual conduct of the study to determine clinical endpoints for helmet wear.

Third, 100% of patients in the helmet group were noted to have side effects of wear, including 96% with skin irritation, 76% with unpleasant

odor and 33% with pain. Moreover, 73% admittedly had problems with helmet fit, resulting in shifting or rotating of the orthotic.

Fourth, “full recovery,” or full normalization of head shape, was seen in only 26% and 23% of helmet and natural course patients, respectively. Such results suggest overall inadequate treatment of the presenting problem and should be considered unacceptable.

In summary, we find significant weaknesses in the methodology employed by van Wijk, et al. that necessarily call into question any conclusions about the lack of effectiveness of helmets. Numerous studies have shown excellent results with cranial orthoses that have been fit properly and appropriately monitored by orthotic specialists. While some infants may benefit from “conservative” measures alone (i.e., repositioning therapy and/or physical therapy specifically to address torticollis and core muscular development), we continue to believe that cranial orthoses serve a useful function in regulating growth of the asymmetric infant skull.

We urge parents with questions and pediatricians to consult with craniofacial plastic surgeons regarding the appropriate mode and timing of treatment for positional plagiocephaly and/or brachycephaly.

— *AAP Section on Plastic Surgery Executive Committee*
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