

Editorial

Abdominal binders

JOHN R. W. KESTLE, M.D.

Department of Pediatric Neurosurgery, University of Utah, Salt Lake City, Utah

Sklar and colleagues² describe their experience managing “over-shunting headaches” with an abdominal binder. Seventy children with over-shunting headaches complied with application of a binder for about 1 month. In 61 patients (87%), the headaches “greatly improved or went away.” This headache relief persisted even after use of the binder was discontinued. Among the 61 patients with relief, 36 (59%) eventually had recurrent headaches, but the recurrence was delayed (mean 1.5 years). Twenty-nine of these tried the binder again and among the 19 with follow-up, the binder was again effective in 15.

These are interesting results. Children with chronic headaches and small ventricles can be very difficult to treat, often undergo repeated surgical interventions, and may have a poor quality of life. Anything that might help them is welcome, especially a simple noninvasive intervention.

On the other hand, proving the efficacy of a treatment requires adherence to clinical research methods that are designed to eliminate bias and objectively assess outcome. A list of 6 simple criteria from Sackett et al.¹ helps us evaluate clinical papers on therapy. I have applied them below.

Was the study design appropriate? No. This was a retrospective chart review, a study design often used as the first step to evaluate a new idea (and sometimes the only step, especially in surgery). There was no control group. The outcome was assessed by the treating (that is, unblinded) surgeon. Despite best intentions, the potential for observer bias and patient reporting bias is real. There was no objective measurement of headache, and observer bias occurs at the time the observations are recorded. Looking at the charts twice does not alter that. Compliance with binder use was not measured. Unfortunately, the study design limits the strength of the conclusions.

Were the patients recognizably similar to yours? The clinical diagnosis of over-shunting was described reasonably well, but headache frequency was only reported in 39 of 70 patients. The binder was used in patients with

headaches who did not have typical over-shunting. It is unclear whether these patients were included in the data. There were 14 children whose headaches were mild who were not treated with the binder.

Is the therapy feasible in your practice? Yes. The binder and its technique of application were described and illustrated and are likely available to any pediatric neurosurgeon.

Were all clinically relevant outcomes reported? No. The paper does not discuss complications related to the binder, except to say that 19 patients were noncompliant with its use.

Were clinical importance and statistical significance considered? The reported results seem clinically important. Headache relief was common. Recurrent headache was discussed. Without a control group, there is no basis for comparison and therefore no evaluation of statistical significance.

Were all the patients accounted for at the end? Nineteen of the 89 patients did not undergo follow-up (7 were noncompliant, 9 were lost to follow-up, and 3 were admitted to the hospital but the reason for admission is not given). There are additional missing patients in the data on recurrent headache and repeat use of the binder. The authors suggest that “...it is likely that some of the ... patients lost to follow-up ... had favorable responses...” Perhaps, but the opposite is also possible.

So, is this a model study for the evaluation of treatment efficacy? No. This is a large experience with a novel low-risk treatment that may help chronic headache sufferers who are often subjected to repeat surgery and its complications. I will keep it in the back of my mind when I encounter these children whose care can be challenging. (<http://thejns.org/doi/abs/10.3171/2012.1.PEDS11523>)

Disclosure

The author reports no conflict of interest.

References

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2. Sklar FH, Nagy L, Robertson BD: The use of abdominal binders to treat over-shunting headaches. Clinical article. **J Neurosurg Pediatr** 9:615–620, 2012

Response

FREDERICK H. SKLAR, M.D.

Department of Pediatric Neurosurgery, Children's Medical Center Dallas, Texas

We appreciate the comments of Dr. Kestle and the opportunity to respond. We do not wish to inflate the scientific worth of this retrospective study. Indeed, it is only a retrospective study. As such, we evaluated information recorded in medical records over an 18-year period. These records were contemporaneously compiled and were not designed to examine or study a specific neurosurgical question. Dr. Kestle is correct to emphasize that there was no control group and that no effort was made to eliminate observer bias. Headache scales were inconsistently notated, and we took no steps to address the possibility of a placebo effect. Accordingly, these are some of the reasons why retrospective studies are less than ideal. We agree with Dr. Kestle on these issues, but we cannot upgrade the design of this study, which comprises patient observations gathered over nearly 2 decades. Although these results cannot be subjected to statistical analysis, it is suggested that this retrospective study reports an apparently effective alternative to surgery in the treatment of patients with over-shunting headache and is therefore important.

I first started using abdominal binders to treat over-shunting headaches more than 30 years ago. In my clinical practice, these patients more often than not appeared to improve dramatically after wearing an abdominal binder for 4–6 weeks. Headache relief was frequently long lasting. Over the years, the other pediatric neurosurgeons in my group practice have made similar observations on the effectiveness of the binder. Based on these clinical observations, the binder appears to be a nonsurgical alternative treatment of over-shunting headaches, at least in Dallas, Texas.

To estimate the efficacy of this treatment, there needed to be a study. Ours was a retrospective approach, which is less than ideal, as pointed out by Dr. Kestle. However, even with all the problems of retrospective studies, an 87% success rate with the use of an abdominal binder certainly is suggestive that there is substance to these observations. Dr. Kestle states, "Looking at the charts twice does not alter" the facts that the study lacks objective measures of headache and may have observer

bias. However, the second look was done specifically to determine in how many instances there was complete relief of headache, a question that was not considered in our first review. Indeed, the second look indicated that 69% of binder responders had complete relief of headache! Headache scales represent attempts to quantify pain severity and its impact on behavior, and these methods are obviously subjective at best. In contrast, complete relief of headache is essentially an all or none condition that is not as sensitive to patient subjectivity and observer bias. We suggest that the second look strengthened the worth of these data and results considerably.

For the record, there were no complications related to binder usage. Noncompliance was an issue, however, and we attempted to exclude data from patients who were identified by the medical record to have been non-compliant.

Dr. Kestle writes, "this is a large experience with a novel low-risk treatment that may help chronic headache sufferers who are often subjected to repeat surgery and its complications." This is why we encourage pediatric and adult neurosurgeons to try the abdominal binder early in the treatment of patients with probable over-shunting headaches. The risk of complications is very low in our clinical experience. Surgery can always be considered if the binder fails. Most of our pediatric patients presented with a long history of headache. Parents and older patients will likely opt for a nonsurgical approach if they are given the choice. We hope that clinicians will not relegate this nonsurgical treatment approach to the backs of their minds, as has been suggested, because they may discover that it actually works!

We do think this noninvasive treatment requires rigorous scientific evaluation and corroboration with a prospective study designed to minimize symptom subjectivity, observer bias, and the effect of placebo. With some positive firsthand clinical experience using the binder to treat over-shunting headaches (and headaches from other causes of intracranial hypotension), some neurosurgeons may be motivated to perform a prospective investigation. If our observations hold true, the focus of study should then be shifted to clarify the mechanism of action, since this may provide some insight into the pathophysiology of hydrocephalus and the CSF compartment.

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