

The Use of Transcutaneous Thermal Convection Analysis to Assess Shunt Function in the Pediatric Population

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BACKGROUND: The diagnosis of shunt malfunction is largely made by subjective clinical history and assessment in association with neurodiagnostic imaging.

OBJECTIVE: To evaluate the use of a transcutaneous thermal convection device for the diagnosis of shunt malfunction.

METHODS: We present the results of a trial of a commercially available device under an Institutional Review Board–approved protocol. All patients had neurodiagnostic studies that defined their shunt function at the time of transcutaneous thermal convection measurement. Thirty-seven shunts were studied in 35 patients. To be included, patients had to be between 0 to 18 years of age, had to be due within a 3-month period for routine follow-up evaluations, and had to have neurodiagnostic imaging (computed tomography or magnetic resonance imaging) as part of this visit and a shunt series. All patients were seen in routine follow-up, and none had clinical symptoms of shunt malfunction.

RESULTS: Three patients had fractured shunts. The remaining 32 patients had functioning shunts as determined by clinical criteria, computed tomography or magnetic resonance imaging scans, and, when appropriate, a shunt series. In these remaining patients, flow was initially confirmed in only 40%. After some filtering of the data, this was increased to 51%. Although these results are disappointing, they outline the current issues with the technique and the state of its utility and point to the need for further refinement.

CONCLUSION: Our current research suggests that cerebrospinal fluid flow as detected by thermoconvection analysis is not a reliable indicator of shunt function in the pediatric population.

KEY WORDS: Hydrocephalus, Shunt, Shunt fracture, Shunt malfunction, Transcutaneous thermal convection

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Cerebrospinal fluid (CSF) shunts are the mainstay procedure in the management of hydrocephalus. The effectiveness of this treatment is directly dependent on the patency of the shunt. The diagnosis of shunt malfunction is largely made by subjective clinical history and assessment in association with neurodiagnostic imaging (ultrasound, computed tomography, or magnetic resonance imaging). Occasionally, invasive confirmatory procedures such as accessing the device and performing contrast shunt studies are used. With a documented failure rate of > 80% at 12 years, an accessible, user-friendly, objective, noninvasive device to ascertain shunt flow with certainty and consistency would be a significant advancement in the

management of shunted patients.¹ Transcutaneous thermal convection analysis has potential in this regard.² Theoretically, this device could be used in an outpatient setting, in the emergency room, or even by parents at home as a primary screen, reducing emergency room visits, hospital admissions, and public health costs.³⁻⁷

The concept of thermosensitivity of CSF shunt patency was first published in 1968.⁸ The first device to assess thermosensitivity was described in 1980 by Chiba and Yuda.⁷ It is based on the concept that if a column of moving fluid is cooled in 1 spot, a drop in temperature can be recorded in the direction of movement distal to the area cooled. This simple yet elegant theory has been verified in the laboratory. The clinical

application of such a device is very appealing as a noninvasive technique to assess shunt function and to screen shunted individuals with common neurological complaints such as headaches. In fact, in the initial report by Chiba and Yuda, the device was 100% accurate. Ishiwata et al⁶ had the same success with testing lumboperitoneal shunts. We present our contradictory results with a commercially available Food and Drug Administration–approved (K040021) device.

PATIENTS AND METHODS

The ShuntCheck device, supplied by NeuroDx Development, has a thermosensor array patch incorporating 3 thermosensors arranged over the distal shunt catheter and a handheld hardware component comprising a circuit board for collecting thermosensor data plus a processor for integrating temperature and time data.

Under an Institutional Review Board–approved protocol, 37 shunts in 35 patients were studied. To be included, patients had to be between the ages of 0 and 18 years, had to be due within a 3-month period for routine follow-up evaluations, and had to have neurodiagnostic imaging (computed tomography or magnetic resonance imaging) as part of this visit and a shunt series. All patients were seen in routine follow-up, and none had clinical symptoms of shunt malfunction. Patients were excluded if they did not have neurodiagnostic imaging and a shunt series as part of this visit.

The study group included children from 0 to 18 years of age with a mean age of 10 years 8 months and a median age of 13 years 6 months. There were 18 male and 17 female patients. Two patients had bilateral shunts. At least 7 different types of shunt valves were identified with 12 unknown types of valves in this patient population. Two patients had known fractured shunt tubing, and 1 patient was diagnosed with a newly discovered fractured shunt tube. The newly discovered fracture shunt tube was electively revised.

The test was done in the sitting position and then repeated in the supine position. No patient was unable to lie supine with the head elevated $\leq 30^\circ$ or was unable or unwilling to endure the test. The thermosensor array patch was placed over the palpated CSF shunt at the level of the clavicle. In infants, if this was not possible, it was placed over a rib. A base temperature reading was taken for 30 seconds. A standardized cube of ice was then placed on the skin over the shunt in the “ice window” integrated into the thermosensor array patch. Temperature readings were collected for 60 seconds, after which the ice was removed and temperature readings were collected for another 6 minutes. The test could be repeated after 4 minutes. The commercially available ShuntCheck Device reports the results as “flow confirmed” or “flow not confirmed.” The device also displays the data in a graphic form, which can be filtered and interpreted by the examiner.

RESULTS

Thirty-seven shunts in 35 patients were tested. By clinical criteria, no patient had signs or symptoms of shunt malfunction or increased intracranial pressure. On neurodiagnostic imaging, 97% of patients had stable or improved (decreased) ventricular size. One patient (3%) had a questionable increase in ventricular size. The ShuntCheck Device indicated that 38% had CSF flow confirmed by original data. When these data were filtered (noise removed and examiner

interpreted), this number increased to 49%. Flow was confirmed in 50% in the sitting test and in 50% in the supine test. Thus, there was a significant number of false negatives, ie, flow not confirmed while clinically present. Sixty-two percent had false negatives using original data; this was reduced to 52% with the use of filtered data. Again, half of these tests were in the sitting position and half in the supine position.

In the 3 patients with broken shunts, 2 had no flow confirmed and 1 had good flow. This last patient in the supine position had one of the best flow graphs obtained in the study group. All patients were followed up clinically and radiographically in 3 months to 1 year, depending on age. None required a shunt revision.

Several technical problems were encountered in the use of the device. It was difficult to use in both obese patients and infants because of difficulty in palpating the exact course of the shunt tubing. One patient had improper ice application, resulting in the need to repeat the test. Nineteen tests were difficult to interpret because of noise caused by movement during the test; this occurred in 11 patients and 12 shunts.

In this study, ventricular size determined by neurodiagnostic tests did not correlate with flow determined by the ShuntCheck device; ie, there was no correlation with the size of the ventricles and flow detection by the device. Ten patients had slitlike ventricles, 14 had small ventricles, 5 had normal-sized ventricles, 3 had moderate dilatation, 2 had large dilatation, and 1 had very large dilatation.

DISCUSSION

The evaluation of shunt patency in shunt-dependent patients has historically relied on parental or patient history, clinical examinations, imaging studies, and, when required, invasive testing of the shunt such as tapping and shuntograms. A direct measure of CSF flow status such as that offered by thermoconvection analysis strives to obviate the need for consolidation of multiple subjective measures and focuses on providing the clinician with an objective data end point to assess shunt flow in a binary fashion. This technology has been validated and has demonstrated efficacy in vitro and in clinical studies testing ventriculoperitoneal, ventriculoatrial, and lumboperitoneal shunts in the adult population.

Our research and data set reflect the application of this innovative measurement tool in the pediatric population, with drastically different efficacy compared with the published literature in the adult trials. In trying to rationalize these results, we have considered many factors. Pediatric hydrocephalus has a wide variety of causes. Hydrocephalus in children could be and probably is a different entity than hydrocephalus in adults. However, the results are most likely related to this group of functioning shunts. Shunts are designed in general and theoretically not to function continually (excluding the Orbis Sigma, a shunt designed to have a continuous flow). Patients in this study had various shunts, but no patient had an Orbis Sigma shunt.

Shunt type was not a factor in our results. In fact, there may be times when no flow is present in a functioning shunt or flow may be below the level of detection ($< 5 \text{ cm}^3/\text{h}$) at the time of the study. Our most dramatic flow determination on the graphic display was in a child with smaller-than-normal ventricles and fractured tubing below the clavicle.

The K040021 ShuntCheck device tested in this trial used a thermosensor array with a predetermined threshold for CSF flow detection $> 5 \text{ cm}^3/\text{h}$, with flow confirmed if this threshold of flow was detected by the device in the 8- or 16-minute window of data collection. Although this standardized threshold allows easy binary clinical interpretation of data, it may not allow for the variability in types of shunt flow possible in the tested population. For example, if a particular patient's shunt functions naturally in a pressure-spike-driven intermittent pattern or achieves clinical treatment of hydrocephalus by draining CSF at a rate of flow $< 5 \text{ cm}^3/\text{h}$, the ShuntCheck device would read "flow not confirmed" when adequate shunt patency and flow are present for that patient. In essence, a lack of flow confirmation does not imply no flow but rather a lack of continuous flow $> 5 \text{ cm}^3/\text{h}$.

The ShuntCheck device in its current configuration is not a clinical tool that detects the presence or absence of CSF flow but rather gauges the speed of a fluid column that provides inference of shunt function or failure when the flow rate is subthreshold or the flow pattern is intermittent. Further research in a similar patient population conducted with a reduced threshold may circumvent the issue of subthreshold flow rate. However, that would not eliminate false negatives resulting from the variability of flow pattern. If a reduced threshold cannot be accomplished, perhaps it is possible to enhance flow so that patency rather than flow would be assessed.

It is imperative that the reliability of this device is confirmed in patients with clinically functional shunts before application and data interpretation in a population base of functional and nonfunctional shunts as would be encountered in clinical practice to avoid revising functional shunt systems or delaying shunt revision in the dependent patient with a failed mode of CSF diversion. Another study should be done in the presence of shunt malfunction. In confirmed shunt malfunction, if the device always reported "no flow," it could be useful as a confirmation of the diagnosis, preventing unnecessary explorations. On a theoretical basis, this device should work. Further investigation is needed to assess why it did not accurately predict shunt patency in this population.

CONCLUSION

Our current research suggests that CSF flow as detected by thermoconvection analysis is not a reliable indicator of shunt function in the pediatric population. The promise of this technology is readily apparent, but further research is indicated and warranted to guide the technical modifications necessary before this device can be dependably used in a pediatric population.

Disclosure

The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENT

This study evaluates the value of a commercially available device to assess shunt function by thermal convection. The study population consisted of children presenting for well-shunt checkups, none of whom had symptoms of shunt failure. Three had fractured shunts. No independent measure of flow such as a nuclear medicine shuntogram was performed.

This study confirms our experience, and that of others, that this technique, although elegant in theory, is worthless in clinical practice. The study is flawed. Without an independent measure of cerebrospinal fluid flow, the results are questionable. Patients could have been shunt independent, and some patients with fractured shunts can still have flow through the fibrous tract.

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