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TITLE: ShuntCheck versus Neuroimaging for Diagnosing Ventricular Shunt Malfunction in the Emergency Department

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TITLE: ShuntCheck versus Neuroimaging for Diagnosing Ventricular Shunt Malfunction in the Emergency Department

Background: Diagnostic alternatives to computed tomography (CT) or magnetic resonance (MR) neuroimaging for children with suspected ventricular shunt malfunction are limited. ShuntCheck (NeuroDx Development LLC) is a novel, non-invasive device that uses a thermal gradient applied to the skin to assess cerebrospinal fluid (CSF) flow in a ventricular shunt.

Objective: As part of a planned secondary outcome for the ShuntCheck Multi-Center Pediatric Outcomes Trial (ClinicalTrials.gov ID NCT01881711), we compared test performance of ShuntCheck to neuroimaging in children assessed clinically as low risk for malfunction.

Design/Methods: We performed a prospective multi-center, operator-blinded trial of emergency department (ED) patients with shunted hydrocephalus ≤ 29 years of age with suspected shunt malfunction. Prior to neuroimaging, ED physicians classified children as “low risk” if judged clinically as unlikely to require neurosurgery within 48 hours. ShuntCheck results were classified as “flow detected” (negative test) or “flow not detected” (positive test). We defined shunt malfunction as neurosurgical revision performed for mechanical shunt obstruction within 7 days. We compared test characteristics and tested non-inferiority of the negative predictive value (NPV) of ShuntCheck versus neuroimaging for diagnosing shunt malfunction (*a priori* non-inferiority margin -2.5%).

Results: We included 406 encounters. The median patient age was 12 years (IQR 7-16). ED clinicians completed pre-imaging questionnaires to stratify malfunction risk in 366 (90%) eligible encounters. Of these, 235 (64%) were classified as “low risk”. Shunt malfunction occurred less frequently in “low risk” versus “not low risk” children [17/235 (7.2%) vs 49/128 (38%), p <0.001]. ShuntCheck and neuroimaging were both performed in 125 “low risk” encounters. Diagnostic test performance is reported in the table. The NPV of ShuntCheck was not inferior to neuroimaging for diagnosing shunt malfunction (ShuntCheck 100% vs neuroimaging 97.3%; risk difference 2.7%, 95% confidence interval -1.2% to 6.5%).

Conclusion(s): ShuntCheck was not inferior to neuroimaging for diagnosing shunt malfunction in children assessed clinically as low risk for requiring neurosurgical revision. ShuntCheck may obviate neuroimaging and spare unnecessary radiation exposure for many of these children.

TABLE:

Test Characteristics.		
Test Characteristic	ShuntCheck n/N (%) [95% CI]	CT/MR n/N (%) [95% CI]
Sensitivity	9/9 (100%) [66.4, 100%]	6/9 (66.7%) [30.0, 92.5%]
Specificity	69/116 (59.5%) [50.0, 68.5%]	109/116 (94.0%) [88.0, 97.5%]
Negative Predictive Value	69/69 (100%) [93.4, 100%]	109/112 (97.3%) [92.4, 99.1%]
Positive Predictive Value	9/56 (16.1%) [13.3, 19.3%]	7/13 (46.2%) [19.2, 74.9%]

(No Image Selected)

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