EVALUATION OF SHUNT FLOW THROUGH A HYDROCEPHALIC SHUNT: A CONTROLLED MODEL FOR EVALUATION OF THE PERFORMANCE USING SHUNTCHECK

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Abstract:

ShuntCheck is a device that can non-invasively detect the presence of CSF flow in hydrocephalus patients with indwelling ventricular drainage shunts using thermal dilution with transcutaneous temperature detection technology. A Next Generation version of ShuntCheck (v2.2) has been developed and is currently under FDA review.

ShuntCheck v2.2's ability to detect no, low, or normal shunt flow was tested in an animal model. Test results showed that under conditions of no or very low flow (0 to 5 ml/hour) ShuntCheck was able to detect "flow not confirmed" 100% of the time. As flow rate increased to clinically average levels (>6 ml/hr), ShuntCheck showed "flow confirmed" with increasing diagnostic accuracy, reaching 92% accuracy at a flow rate of 10 ml/hour.

ShuntCheck v2.2's very high sensitivity and high specificity give it a very high negative predictive value compared to current shunt test procedures, CT Scan, Shunt Tap and Shunt Series, which are only useful at a late stage of clinical symptoms. Growing concern about radiation build up due to frequent CT scans and the lack of a strong rule-out test for shunt failure, suggest that ShuntCheck may be clinically useful in assessing shunt function in hydrocephalus patients, especially in the presence of symptoms of shunt failure

Introduction:

Determining the presence of flow in an indwelling ventricular drainage shunt in patients with hydrocephalus is a major clinical problem at this time. The most frequently used method is CT Scan, but this method is static and is useful late in clinical course. In addition, frequent CT Scans can result in radiation build up in the patient, which, in the long term, can have clinically significant adverse effects.[1] Based on need for a non-invasive, non-harmful and easily repeatable method for diagnosing shunt flow, a new concept in measuring shunt flow in real time has been developed. This device, called ShuntCheck, uses thermal dilution to evaluate shunt flow. Simple and elegant in concept, the device uses methods to cool the underlying shunt by applying ice on the skin over the shunt cephalad in the neck. Caudal to the cooling event, thermosensors placed in an area where the shunt can be easily palpated at the clavicle detect the flow of cooled fluid to ascertain the flow of cooled CSF. ShuntCheck v2.2 reports the results as "Flow Confirmed" in readings which show a characteristic drop in skin temperature, and "Flow Not Confirmed" in readings which fail to show this temperature drop in the absence of fluid flow.

The functionality of this device was tested in an in-vivo animal system, which provides an accurate and controlled experimental condition where the flow or lack of flow can be

controlled with the use of a positive pressure pump programmed to deliver precise flow or no-flow status to the thermosensors.

Methods:

An animal model was developed to detect fluid flow through a subcutaneous shunt tube inserted just under the flank skin of newborn piglet. A CSF shunt attached to a continuous infusion pump on one side was then passed subcutaneously through the flank of a piglet. Piglets were chosen as the model for these studies since they have skin thickness and physiological temperature responsiveness—ability to re-warm after a cooling event and thermal conduction properties—similar to human skin. [2,3] Artificial CSF, at 37°C, was infused at specific rates through the shunt using the infusion pump. The ShuntCheck test was conducted on the skin of the pig in a manner that would be identical to testing conducted in shunted humans and reported result of "flow confirmed" or "flow not confirmed" was recorded.

Two separate experiments were carried out.

In the first set of experiments, neurosurgeons (n = 3) and non-neurosurgeon nurse practitioners (n = 8), who were blinded, were asked to place ShuntCheck v2.2 over the implanted shunt and their results were compared to those obtained by the Product Developer (a PhD scientist) who conducted tests under similar conditions, and served as a "control" operator. A technician operated the infusion pump, running randomly pre-selected flow rates of 0 ml/hr or 10 ml/hr (an estimate of physiological CSF fluid flow rate through a shunt).

In the second set of experiments, a single, blinded research operator evaluated the device under conditions of varying flow rates from 0, 5, 7.5, 10 and 20 ml/hr infused in a random fashion. A technician operated the infusion pump, running randomly pre-selected flow rates of 0, 5, 7.5, 10, 15 or 20 ml/hr. The technician recorded the ShuntCheck v2.2 result ("flow" or "flow not confirmed") at the conclusion of each test.

Results:

User Variability and Detection of Flow vs No Flow at Physiological Flow Rate

User variability in placing the shunt at no flow and normal flow rates were evaluated in the first study. The data from this study is shown in the table below:

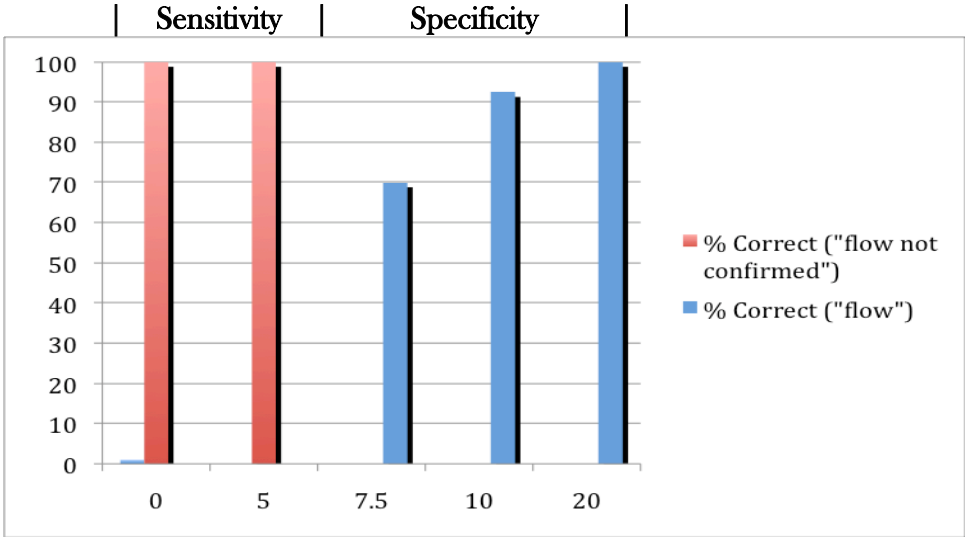
	Sensitivity (Detecting No Flow)		Specificity (Detecting Flow)	
	% Correct	Tests Run	% Correct	Tests Run
Total Tests	100	80	92	80
NeuroSurgeons	100	15	100	15
Nurses	100	40	90	40
Product Developer	100	25	92	25

Both neurosurgeons and non-neurosurgeon operators were able to operate ShuntCheck to 100% accuracy in the absence of flow—ShuntCheck detected lack of flow in all instances

when there was no flow. In the presence of flow, neurosurgeons placed the thermosensor accurately to detect flow 100% of the time, while other operators reached the low 90% range. With further experience, it is believed that these operators will also obtain results close to neurosurgeons.

Sensitivity & Specificity at Various Flow Rates

In the second experiment, the specificity and sensitivity of ShuntCheck v2.2 was determined at a range of different CSF flow rates. The results show that ShuntCheck was able to detect lack of flow at flow rates at 0 and 5 ml/hour with 100% accuracy (100% Sensitivity). At clinically normal levels (> 6ml/hr), [4,5] ShuntCheck showed increasing accuracy in detecting flow –Specificity at 7.5ml/hr was 70%, at 10ml/hr was 92% and at 20ml/hr was 100%.



Discussion:

The functionality of ShuntCheck v2.2, a new diagnostic method to evaluate shunt flow, was studied under control conditions where fluid flow could be regulated in an animal model. Such a study could not be conducted in a clinical situation since flow rates cannot be regulated in a similar fashion.

ShuntCheck v2.2 was shown to be 100% accurate in generating a "Flow Not Confirmed" in cases of no or very low CSF flow (0 and 5ml/hr), translating to 100% Sensitivity – a sensitivity level difficult to achieve with other diagnostic tests. The reason for this accuracy is based on the design of ShuntCheck, which uses both active and control thermosensors and a software program which was precisely defined to evaluate the fall in temperature in the presence of a flow (and lack of temperature fall when there is no flow). ShuntCheck could be very useful as an aid to diagnosis when a child presents in the ER or to the neurosurgeon's office complaining of symptoms related to shunt blockage.

ShuntCheck v2.2 results are compared to published results for current shunt diagnostic procedures in the table below:

Procedures	Sensitivity	Specificity
CT Scan 1[6] (Pitteti, 2007)	68%	90%
Shunt Tap 2[7] (Sood 2000)	79%	56%
Radio Isotope 3[6] (Pitetti 2007)	80%	53%
Xray Series 4[8] (Hidaka, 2001)	27%	99%
ShuntCheck (ShuntCheck Internal Studies)	100%	70 to 100%

Pitetti 2007 (N = 410) Sood 2000 (N = 33) Hikada 2001 (N = 231)

ShuntCheck v2.2's 100% Sensitivity and 70 to 100% Specificity yields a very high Negative Predictive Value, making ShuntCheck a valuable rule-out test for shunt failure. Given the concerns about current tests – radiation build up for CT Scans, infection risk with Shunt Taps, very low sensitivity of Shunt Series – the non-invasive, quick, and accurate qualities of ShuntCheck make it a valuable addition to the diagnostic procedures used in evaluating shunt function.

Because the procedure is completely non-invasive and only requires the application of ice to the skin, it now becomes feasible to evaluate shunt flow in symptomatic and asymptomatic patients in a rapid, accurate and non-invasive way which can be repeated if necessary, as often as needed.

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