

Accurate detection of cerebrospinal fluid from the tip of the IQ-Needle during pediatric lumbar puncture – preliminary results of clinical study

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Background & Aim

A lumbar puncture (LP) for cerebrospinal fluid (CSF) sample is essential for diagnoses. The procedure is challenging, especially in neonates, and high number of the punctures fail or are traumatic. Injeq IQ-Needle™ (IQ-Needle) is developed to provide immediate alert when the needle tip enters CSF. Earlier study in adults showed successful results and now the method is tested in pediatric LPs. Aim is to test feasibility and performance of the device to detect CSF during pediatric and neonatal LP.



Equipment: Bioimpedance from the tip & Real-time tissue analysis

Materials and methods

IQ-Needle consists of a 22G-40 spinal needle and a customized stylet, which enables real-time bioimpedance measurement during the LP. The needle is connected to the analyzer with tissue classification algorithm. When the needle tip is in contact with the CSF, analyzer alerts the physician with a sound.

The IQ-Needle was investigated in patients younger than 18 months whose care required diagnostic LP. In this first phase of the study (ten patients, ages 2-490 days) the classifier was fine-tuned. The LP procedure was conventional but performed with the IQ-Needle. Physician was instructed to guide the needle with normal haptic perception, not with the device information.

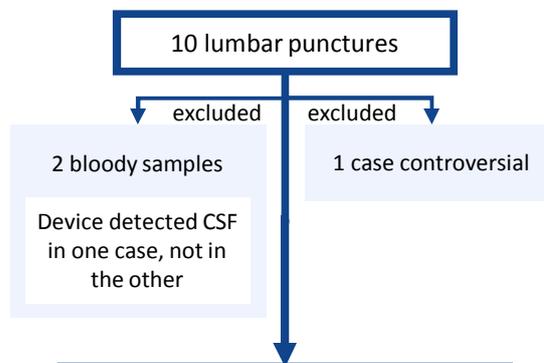
Results

Device CSF alerts were verified by checking CSF flow and the device performance was assessed by the physician.

The device correctly detected CSF in all seven cases with successful CSF sample (7 true positive, 7 true negative).

Blood changes CSF bioimpedance and this most likely explains the case without CSF detection. The initial classifier was tuned to more sensitive in order to detect even bloody CSF contacts. The study continues using the tuned classifier with 30 patients and statistical analyses will be performed on the future results and data.

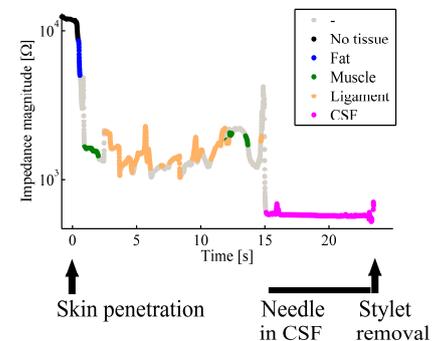
Flow chart of preliminary phase of the study



7 successful CSF samples

Device performance table evaluated using CSF flow test by physician

N=7		Physician	
		CSF flow	No flow
Device	CSF alert	7	0
	No alert	0	7



Example lumbar puncture. When needle tip gets in contact with CSF, device alerts physician. Single frequency data plotted.

Conclusions

IQ-Needle has a high value adding potential in pediatric lumbar punctures. When the CSF contact is immediately detected, unrecognized subarachnoid space enters are prevented. This can make the procedure easier, prevent complications and reduce patient discomfort.