High first puncture success rate attained with a novel bioimpedance spinal needle in pediatric hemato-oncologic lumbar punctures

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Background. Lumbar puncture is a key clinical procedure in children with acute lymphoblastic leukemia (ALL), first for diagnostic purposes and then for administration of several intrathecal chemotherapy injections according to scheduled treatment protocol. Repeated puncture attempts may increase the incidence of post-procedural complications and traumatic taps. In ALL patients, traumatic taps with blasts at diagnosis are associated with poorer event-free survival. Therefore, success of the puncture at the first attempt is of paramount importance.

Objectives. This study aimed to evaluate the first puncture success rate of a novel bioimpedance spinal needle system in lumbar punctures of pediatric ALL patients and post-procedural complications, including post-dural puncture headache (PDPH) and incidence of traumatic taps.

Methods. Fifty ALL patients aged from 1.8 to 16.0 years participated in the study (ClinicalTrials ID NCT04070144). The study material comprised a total of 152 lumbar puncture procedures (1 – 4 procedures/patient), which were conducted by 25 physicians in pediatric hemato-oncologic departments of three university hospitals. These procedures belonged to patients' normal treatment protocol, but instead of using conventional 22G needles the punctures were performed using a novel bioimpedance spinal needle (Injeq IQ-Tip® system, Injeq Oy, Tampere, Finland, www.injeq.com). The IQ- Tip® system employs a conventional spinal needle configured as a bioimpedance electrode, which continuously measures bioimpedance at the needle tip and detects in real time when the tip reaches the cerebrospinal fluid (CSF) in the subarachnoid space. The first puncture success was defined as: an eligible CSF sample was obtained and/or intrathecal treatment was delivered with one needle insertion and skin penetration. Patients' complications were monitored with one-week diary and one-month follow-up of hospital registers. Red blood cell (RBC) content was determined using standard cytometric methods. Ethical approval was obtained from Regional Ethics Committee of the Expert Responsibility area of Tampere University Hospital (ETL-code R19050).

Results. The first puncture success rate was 79.5% (95% confidence interval from 72.1 to 85.6%). During the week after the procedure, the incidence of PDPH was 6%, nausea 15%, headache 14%, backache 14% and fever 7%. During the subsequent follow-up, the most common complication was fever with incidence of 13%. Using the stringent threshold of 10 RBCs/µL, the incidence of traumatic taps was 17%.

Conclusion. Our results demonstrated that the novel method achieves a high first puncture success rate among pediatric ALL patients in real-world clinical settings. Incidences of complications were expected and in line with those reported in the literature. Noteworthy, the incidence of traumatic taps was quite low compared to findings in the literature. All the present findings speak for the apparent clinical utility of the novel bioimpedance spinal needle system in pediatric hemato-oncologic punctures.