Response to letter to editor regarding 'Anatomical characterization of the inferior petrosal sinus and adjacent cerebellopontine angle cistern for development of an endovascular transdural cerebrospinal fluid shunt'

We thank the authors for their interest in our study[1] and would like to address the points that they raise in their letter to the editor.[2]

Based on preclinical and clinical testing of the endovascular shunt implant, we have determined that antiplatelet drugs are not required before the deployment of the device in the inferior petrosal sinus (IPS). As in other neurointerventional procedures, navigation of a modern low-profile catheter can be readily performed while on intravenous anticoagulation with reversal at the time of dural puncture. The described endovascular shunting device bears a proprietary heparin-based coating and is not intended to occlude or thrombose the IPS itself. Rather, the IPS is utilized as the path towards the cistern. Once connection between the IPS and the cerebellopontine angle (CPA) cistern is established, the device allows flow of cerebrospinal fluid (CSF) via a low-profile tubular valved shunt directly to the internal jugular vein, without needing to rely on IPS patency.

Piercing of the dura overlying the IPS is not expected to automatically cause bleeding at the puncture point, just as piercing the thecal sac during a lumbar puncture or when placing a lumbar drain or performing a cervical spinal puncture does not automatically cause bleeding and result in a hematoma. This lack of bleeding into the subarachnoid space has been demonstrated in animal studies and now in initial human experience. As we know, the local CSF pressure is higher than local venous pressure, and it is not expected that venous blood will reflux into the cistern. We have performed a number of transdural sinus punctures with the endovascular shunt device into the adjacent CPA cistern without encountering hemorrhage.

Regarding the thickness of the dura mater in the region of interest, during development of the endovascular shunt system we performed repeated cadaveric experiments with a prototype device which revealed controllable transdural traversal with subsequent dural self-sealing after removal of the access needle in a reproducible fashion. As stated above, this process can be performed without the use of either antiplatelet or anticoagulation at the time of access. Part of the safety and effective reach to the subarachnoid space of this approach resides in the angle of penetration. We do agree that many coils can be placed in the IPS if needed without rupture complication, and this adds to the safety of our proposed approach. The ability to place coils in the IPS if needed constitutes one of the safety mechanisms of using the IPS as an access route for an endovascularly deployed valved shunt connecting the cistern to the internal jugular vein. Regarding the presence of a vein adjacent to the IPS, the proposed procedure entails intraprocedural high-resolution cone-beam computed tomography (CT) venography and analysis which would highlight any venous anatomical variability that would be concerning before attempting transdural access at a potential target site.

The proposed procedure relies on careful preprocedural imaging with pre-planning and utilization of three-dimensional roadmapping technique to ensure that vascular structures including arteries and veins are clear from the intended targeted site of transdural shunt placement. High-resolution imaging enables avoidance of inappropriate target sites such as when a vertebral artery, posterior inferior cerebellar artery (PICA) loop, or prominent vein is adjacent to a putative site of puncture. This is not dissimilar to planning not to puncture tentorial dura overlying a cortical vein. The proposed procedure is not intended to be performed in a blind fashion, but rather to leverage the highest resolution preoperative magnetic resonance imaging and intraprocedural cone-beam CT, both of which are now widespread and ubiquitous in neuroscience centers of excellence.

In summary, we have made significant progress in device and catheter delivery design since this first feasibility report. We are in the process of sharing our initial human results with the scientific community that describe a reproducible and safe patient-specific preoperative imaging analysis to insure safe and effective access and delivery of a miniature shunt device as well as effective reduction in intracranial pressure immediately following device deployment.

Care and training will be part of the expected skillset for the neuroendovascular operators performing this procedure, no different from those needed for safe intracranial thrombectomy, flow diverter placement, or coiling of a small intracranial aneurysm.

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Competing interests AMM and CBH are co-inventors of the CereVasc eShunt and are consultants for, and shareholders and investors in, CereVasc Inc.

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2 Arslan S, Ozveren MF. Letter regarding the endovascular transdural cerebrospinal fluid shunt device. *J Neurointerv Surg* 2021:e24.

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