

Ommaya Reservoir with Lumbar Intrathecal Catheter: A Technical Description of an Alternative to Frequent Lumbar Puncture for Tofersen Delivery in SOD1+ Amyotrophic Lateral Sclerosis

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Abstract

Background: Tofersen is an antisense oligonucleotide (ASO) approved by the FDA in 2023 for intrathecal delivery and requires lumbar puncture, which was associated with adverse events in 83.7% of patients in the VALOR clinical trials. Currently, there is no standard alternative delivery method to lumbar puncture in this population.

Case and Technical Description: A 38-year-old female with SOD1-associated ALS presented with increasing intense anxiety and severe pain due to her monthly lumbar punctures for intrathecal Tofersen infusion. She underwent placement of an Ommaya reservoir in her left flank, attached to a lumbar intrathecal catheter that will be used to administer Tofersen as an alternative to lumbar puncture. Fluoroscopy was used intraoperatively to plan both the lumbar and flank incisions over the location that will house the reservoir. Following exposure, a Touhy needle was used to assist in catheterizing the intrathecal space at L3-L4, and the catheter was advanced to the T12 level, where it was secured, with confirmation of adequate CSF flow. Subsequently, a tunneling device was used to thread the catheter through the fascia between the lumbar and flank incisions, where it was secured to the Ommaya reservoir. Following closure, the valve was aspirated to ensure proper function of the intrathecal reservoir system.

Conclusion: This report presents the first reported implantation of an Ommaya reservoir with a lumbar intrathecal catheter for the delivery of Tofersen in patients with SOD1-associated ALS. Similar implanted lumbar reservoir systems have been used successfully for SMA patients and may reduce the procedural burden experienced by SOD1 ALS patients as a result of lumbar puncture-associated adverse events. However, further study is needed to demonstrate efficacy by evaluating this approach's impact on key clinical benchmarks and biomarkers from the VALOR trials.