

Methods of Trials for Consideration of Intrathecal Drug Delivery Systems (IDDS)

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There are two basic methods for trialing intrathecal drug delivery systems:

- Bolus injection
- Continuous infusion.

The decision on the type of trial to use depends on many factors, including patient's clinical status and diagnoses, reason for the trial, type of medication used for trial, and physician preference/facility capabilities. In either case, physicians engaged in intrathecal therapy should have thorough knowledge of pharmacology and pharmacokinetics of intrathecally administered agents.^[1]

There are various advantages and disadvantages with the different trialing modalities.

- A single bolus injection with a needle allows potentially for a quicker trial. However, patients may need to have repeat injections, and sometimes this has been accomplished with insertion of an intrathecal catheter and injecting bolus doses on separate days.
 - Single bolus intrathecal injections, titrated to effect on separate days, have been used in trialing morphine^[2], ziconotide^[3], and baclofen.^[4]
 - With single bolus intrathecal trials that are performed in the outpatient setting, potential side effects should be clearly communicated to the patient and family members.
- A continuous catheter trial allows for dose titration, targeting a particular dermatome, and direct observation of patients, who are typically admitted.
 - Continuous catheter trials have been accomplished using an epidural or intrathecal route. Compared to the epidural approach, the intrathecal route has been shown to have less adverse events and result in superior in pain relief—when used for longer periods than typical trials.^[5] It also may mimic better what would occur at implant.
 - Nonetheless, most external pumps used for continuous infusion deliver medication 20 times faster than implanted IDDS.

- Although two models of external pumps are capable of delivering low rates of infusion similar to implanted IDDS, adoption has been limited because of logistic and safety concerns such as keeping an externalized intrathecal catheter for prolonged periods while slowly titrating the intrathecal infusion.
- A catheter with an internal stylet may be needed for positioning in higher spinal dermatomal areas when needle entry occurs at the lumbar level.
- Continuous catheter infusion allows for combination intrathecal medication trials.
- In some cases, such as in anticoagulated patients and in patients admitted with cancer pain, a staged intrathecal trial may be desired. The process involves placing a potentially permanent intrathecal catheter, securing it to the fascia, and tunneling an externalized extension catheter for a short-duration, inpatient trial with an external pump. Upon trial completion, the patient would proceed to implanting the pump, in case of successful trial, or explanting the catheter if the trial was unsuccessful. The physician should have a secure operating room slot at the conclusion of the trial.

References

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