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A Focused Review

The Diagnosis of Intrathecal Infusion Pump System Failure

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Ongoing informed clinical management and rational application of various tests assist in the diagnosis of intrathecal infusion pump system failure. The goal is to rapidly identify the cause of the failure with the least risk to the patient at a reasonable cost-to-benefit ratio. We offer a review of our approach to the patient with suspected intrathecal pump failure and a brief description of the most often used diagnostic tests.

Keywords: Intrathecal infusion pump, intrathecal catheter failure, pump malfunction, complications, drug withdrawal, Indium 111, Baclofen

The use of implanted pumps for the continuous infusion of intrathecal medications is a proven therapy for the management of spasticity and/or pain (1-2). Most often, the systems are reliable and only occasionally fail. Despite incidence of system failure, patients are generally satisfied with their therapy (2-5). Sudden total failure can lead to life-threatening withdrawal, with profound immediate clinical deterioration (6-8). Gradual or intermittent failures often produce a puzzling clinical picture requiring experienced clinical decisions along with diagnostic interventions (9-10).

Correctly diagnosing changes in a patient's clinical status may require time. Patient symptoms and history most often dictate the initial approach. Ongoing pump refills and maintenance visits are important and help reduce the time required to raise a suspicion of system failure. Refill visits require significant ongoing informed clinical judgment and represent a critical opportunity to make patient care changes. New pathology, disease progression, medication changes, infectious processes, or metabolic diseases can result in altered drug response. As time and clinical conditions permit, these causes are addressed before the patient is placed at risk from diagnostic testing of the pump system. After addressing these concerns, attention is turned to the pump system, including the drug mix, reservoir volume, pump programming, the catheter and connector integrity, and catheter tip location.

Accurate, safe, timely and cost-effective (11) diagnosis is desirable. The severity of symptoms often dictates how quickly a diagnosis is needed. To avoid overdose, drug presence in the catheter must be considered when diagnostic studies are performed. Although drug withdrawal is often the presenting symptom, drug withdrawal and drug overdose may result from the diagnostic workup. Liberal titration of oral medications is often sufficient to comfort and stabilize the patient in withdrawal. Rarely, intermittent bolus or continuous infusion of medications by intrathecal puncture and/or temporary intrathecal catheter is required to mitigate an acute withdrawal syndrome until surgical correction of the failure can take place.

Review of Literature

Complications with intrathecal infusion therapies arise from human error, medication, or mechanical system failure. Complication rates vary across studies and time and are dependent upon the medication, indication for use, and clinician experience. Regardless of cause, severe complications have decreased over the past 10 years largely due to improvements in equipment (catheter, pump, and programming software) as well as surgical implant and pump maintenance techniques (12-13).

Human error during programming or refilling the pump, medicine preparation, implanting, or manipulating the device during a procedure can all lead to complications with the therapy (14) which could result in health complication or life-threatening situations. System interruptions such as an inflammatory mass at the catheter tip also contribute to drug delivery failure and complicate the clinical picture (15-19). These causes of loss of benefit or implanted system malfunction must be considered.

Complications arise with the mechanical implanted system that includes the pump and a one- or two-piece catheter. From 1984-1992 Gianino (20) reported system complication rate of 19.9% during baclofen clinical trials, and 18.8% in a retrospective survey of patients receiving intrathecal drugs for pain. Stempien (12) reported a 10% re-operation rate using data compiled from 40 centers.

Pump malfunction is rare and has declined with successive pump model generations. Causes of pump failure are listed in Table 1. Unexpected battery depletion, component or motor failure, and catheter access port failure are considered pump malfunctions. These failures can result in cessation of therapy or a change in flow performance; they require surgical replacement of the pump. One group of pumps implanted between July 1996 and October 1999 exhibited a rare increased risk of sudden stall from gear 5 shaft wear. Registered implanting and follow-up physicians were notified (21). On aver-

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age these failures occurred 25 months after implant and have thus been explanted, or have safely reached the expected end of battery life.

A change in performance or failure of the catheter is the most common long-term mechanical system dysfunction and had been reported to occur in 40% of implants (22-23). Penn (24) later reported survival analysis with a steady rate of catheter malfunction out to 80 months, with the mean time to first failure recorded at 20 months. A more recent prospective work by Follett (25) reviewed 209 patients from 22 centers with 1,764 cumulative patient months of catheter experience. He reported 49 catheter complications in 37 patients – seven related to the catheter, and 42 to the implant procedure. Even more recently, Follett (26) summarized the relationship between implant techniques and complication rates.

There are many possible causes for a change in a catheter's performance including micro fracture, kinking, disconnection, breakage, dislodgement, migration to the epidural space or out of spine completely, complete or partial occlusion from tip fibrosis, hygroma, or inflammatory mass. According to Le Breton (27), catheter kinking and perforation represent 50% of the causes of catheter malfunction. These events may result in under infusion of the drug, causing a clinical deterioration that ranges from a return of mild underlying disease symptoms to life-threatening withdrawal. Delivery of the drug into the pocket or subcutaneous tissue might also result; mostly this results in substantially less drug effect, as the most potent delivery site of these drugs is intrathecal. Additionally, if the catheter fails, resulting cerebral spinal fluid (CSF) leakage may lead to spinal headache, CSF subcutaneous collection or, rarely, central nervous system (CNS) pressure-related problems. A catheter break at the spinal entry site may lead to a free-floating catheter fragment in the thecal sac. Most often, implanting a new catheter and connecting to the existing pump catheter segment is required. Seldom is retrieval of a thecal sac catheter fragment indicated.

Table 1. *Causes of pump failure*

- Change in performance, or failure of the catheter
  - Micro-fracture,
  - Pinhole leak,
  - Disconnection
  - Breakage
  - Migration
  - Partial occlusion
  - Tip fibrosis / granuloma
  - Inflammatory mass
- Unexpected battery depletion
- Component or motor failure
- Catheter access port failure

Table 2. *Diagnostic approaches*

- Initial evaluation, including patient history will often identify the source of the problem
- Verification of pump contents, volume, and pump settings is the critical initial step
- Plain X-Ray (*PA* and *LAT* to visualize the entire catheter)
- Serial x-ray or fluoroscopy to confirm that the pump roller is moving at the expected rate
- Magnetic Resonance Imaging (MRI) Study
- Catheter Access Port Aspiration
- Nuclear Medicine Scan
- Fluid Collection Assay

Although the frequency of complications with implanted intrathecal pump systems may be decreasing, such complications continue to develop, are not always obvious, and may manifest with subtle symptoms. A number of diagnostic procedures are useful in determining the cause of failure. Clinicians need to be proficient when performing these procedures, especially since system manipulation during testing can cause severe drug overdose or withdrawal.

System Mechanics

Intrathecal infusion pumps are extremely low volume by comparison to most other drug infusion systems. Volumes as low as 0.05 ml per day can be programmed using the Medtronic SynchroMed pump. Generally, volumes of 0.1-0.2 ml per day are used. The pump is low pressure so an occlusion by catheter kinking or by fibrin clot at the catheter tip will interfere with fluid flow, resulting in loss of benefit (LOB). Lower than expected infusion rates will result in a greater than expected reservoir volume at time of refill. This fact is the reason that careful tracking of pump residual volume at refill visits can be an early indication or confirmation of failure.

On occasion, catheters do not completely break, but instead develop a hole. The catheter material is flexible and pliable, but it does not withstand puncture or cutting forces. Sutures applied directly to or around the catheter may, in time, cause a hole to develop. Splices or connections with titanium pins may puncture the catheter at the time of implant or may wear a hole in the catheter. Puncture of the catheter by a suture needle or during the installation of a local anesthetic solution may also occur. Mechanical stress by continued twisting or bending of the catheter can lead to catheter failure. Any hole in the catheter, other than within the intrathecal space, will generally result in LOB. Medication will leak out the hole instead of being delivered into the CSF. If a hole exists outside the intrathecal space and the catheter is intact up to that point, CSF leakage through the hole nearly always occurs. Spinal fluid pressure is transmitted down the catheter to the hole. The low daily infusion volume of medication is lost through the defect along with the CSF. Determining the location of these small holes may be difficult, but is important for guiding surgical correction (26, 28).

Diagnostic Approaches

The most expeditious way to diagnose and correct pump malfunction is to have a systematic approach. The history is the appropriate place to start. This will often lead to identification of several potential causes that can be further investigated. Diagnostic approaches to pump failure are listed in Table 2.

Initial Evaluation

A thorough history will often explain LOB and provide evidence for the need of testing. Informed consideration of the disease process, current symptoms onset, physical exam findings, comorbidities, diagnostics or therapeutics risking trauma to the system, recent prescription or over-the-counter medications or "alternative therapy" changes are used to make decisions regarding therapy benefit and system function. Refill and intrathecal therapy history should be reviewed, including past reservoir volumes as compared to expected volumes (29). Interrogation of the pump to verify alarm date, expected reservoir volume, and battery life is followed by a refill to verify expected reservoir volume. Syringe accuracy must be considered when comparing actual to expect-

ed volumes. Many syringes have 20% accuracy and when a pump is filled with one syringe and the residual volume is checked using a different syringe, considerable discrepancies may occur due to these syringe errors.

As in many situations, patient history will most often point to the problem and tests are used to confirm the clinical impression. As mentioned previously, when the failure is sudden and complete, time may not be available to perform the necessary testing and quick decisions must be made to correct the problem. Often this results in the implementation of supportive measures and emergent surgical intervention. It may seem obvious, but the critical initial step is verification of the pump contents and volume as well as correct pump settings. If the situation is such that time is available and the clinical situation allows, programming an appropriate medication bolus may help determine if the clinical change is the result of system failure or some change in the patient's clinical state.

Our protocol includes programming a bolus dose equal to approximately three hours of regular rate infused over five minutes. The basal infusion rate is continued in addition to the bolus. Depending on drug or drug mixture in the pump, an effect from the bolus will take up to three hours before a clinical change is noticed. Minimal, or no response, to the bolus may indicate system malfunction and usually indicates need for further diagnostic studies. A positive effect, however, usually supports patient-related change, such as an infectious process or disease progression, and may indicate a need for continued dose titration. Tachyphylaxis, or drug tolerance, is not well understood and varies with different drugs and patient populations. Consideration of drug tolerance may be important in some management situations (30-31).

Diagnostic Studies

There are multiple tests and diagnostic studies that can be employed when determining the cause of failure. The rational application of these studies in a systematic manner by knowledgeable clinicians will most often lead to the proper diagnosis. Clinical conditions, patient history, facility resources and clinician experience will play varying roles in the selection of which tests will be implemented, and in what order (32).

Plain X-ray Study

If the catheter is fractured, dislodged, or disconnected at the pump site, this generally will show up on a plain x-ray or fluoroscopic study. Often this is all that is needed to discover gross catheter failures. Catheter sections at high risk of positional kinking or fracture may also be visualized. Fractures of catheters most often occur where the catheter pierces the intraspinal ligaments. This is where sheer stresses on the catheter are the greatest. When fractures occur at this location, often a segment of catheter will migrate into the intrathecal space. In this situation, the distal catheter segment will often be visible below the insertion site with the patient x-rayed in an upright position. These fragments are most often left alone and attempts are not made to retrieve them unless they are felt to be causing some neurological problem. The second most common place for catheters to fracture is within the pump pocket. This often results when a pump is not secured and twists within the pocket, allowing the catheter to eventually fail due to the twisting. Disconnects from the pump may occur due to dense scar formations around the connector, and then due to external mechanical stress such as that from a wheelchair harness.

Although the catheter is somewhat radio-opaque, "overexposure" may be needed to visualize the entire catheter. Anterior-posterior and lateral views of the abdomen and thoracic/cervical spine are done to view the tip of catheter. Physicians often request an abdominal x-ray at the expected level of the catheter tip. The catheter portion coiled behind the pump is difficult to visualize with complete certainty. When the x-ray is directed along the length of a segment, it will often appear to have a kink and in our experience, it is very difficult to discern catheter kinks on plain x-ray.

Roller Study

Based on the pump's calibration constant, one can calculate how long it should take the pump's roller to turn 90 degrees. Serial x-ray or fluoroscopy is used to confirm that the pump roller is moving at the expected rate. One can then assume that the pump is at least trying to infuse the medication and is not stalled. If the catheter is occluded, the roller will still turn but no drug will be infused. Some pumps have been shown to be susceptible to roller stall, however, this issue has mostly been resolved and very rarely occurs (33).

Magnetic Resonance Imaging (MRI) Study

Standard MRI (1.5 Tesla or less with 20 minute pulse sequence) is considered safe for patients implanted with the SynchroMed pump and is the study of choice to detect catheter tip masses, epidural hematoma, abscess, or to verify the location of the intraspinal catheter segment. However, the magnetic field temporarily stops the roller of the pump motor from turning and prevents drug infusion for the length of the MRI magnet exposure. Therefore, precautions may need to be taken to prevent drug deprivation effects during exposure for those patients receiving high intrathecal drug doses. These precautions include a drug bolus before the procedure which also enhances comfort and minimizes movement during the procedure. Interrogation of the pump after the study verifies pump settings. Programmable pumps have, on rare occasion, been reset due to exposure to the MRI magnet. Although this magnetic force and torque on the pump is less than gravity, the magnetic field of 2.0 T or greater may cause a sensation of tugging at the pump implant site, risk of tissue heating, and greater image distortion (34-35).

Catheter Access Port Aspiration

Pumps with a catheter access port (CAP) allow for aspiration and flush of the catheter. This provides information about intrathecal position and basic catheter integrity and is useful as a first line assessment. CAP aspiration provides useful information if the catheter appears grossly intact from x-ray and/or the patient has no response to a drug bolus. The CAP port should not be injected unless the solution has first been aspirated. Injecting without first aspirating can result in a significant drug overdose. For example, a pump and catheter containing baclofen 2000µg per ml would have 2000 µg/ml x 0.18 ml catheter volume or 360 µg baclofen from port to catheter tip. This is enough for a significant overdose in most patients.

Following a careful surgical preparation, a Huber type none-coring needle is used to access the port. A special "catheter access kit" is available for the procedure from the manufacturer. Read the manufacturers' instructions to perform the test for a specific pump. Aspirate at least 1.5ml

to ensure the medication is out of the catheter. If 2-3 ml of CSF can be easily aspirated with a steady flow, there is general support that the catheter tip is in the CSF and the catheter is not obstructed. If the catheter is partially occluded from a kink or fibrin clot, then it is generally more difficult to aspirate. If a small hole is present, CSF will still be easily aspirated through the otherwise intact catheter. A larger catheter defect will allow CSF to be aspirated, but may not be a steady flow. If a catheter is fractured or develops a defect within a space such as the pump pocket, then CSF often will leak from the catheter and fill this space. Also, seroma fluid may be present within the pocket or at the catheter spinal insertion site. This fluid may be aspirated through a catheter defect via the catheter access port and may be thought to demonstrate an intact catheter. This "false" aspiration may lead to the improper assumption of a grossly intact catheter. If x-ray is available, once the catheter has been cleared of medication, infusion of 2-4 ml of contrast suitable for intrathecal administration using fluoroscopy may be useful to verify the catheter tip location in the intrathecal space. The contrast injection will not help in detecting small holes in the catheter as the contrast will preferentially flow through the catheter and not out the defect. A completely fractured catheter may not allow for aspiration of any significant fluid. In this instance, injection of contrast into the catheter access port is not recommended.

Nuclear Medicine Scan

The most useful test of catheter integrity is a nuclear medicine evaluation using the radioisotope Induim 111 DTPA with a half-life of several days. This tool should be considered if the patient is stable, that is, not expected to develop unmanageable withdrawal over the next 24-48 hours. The length of the evaluation depends on the current pump infusion rate and availability of Indium which requires preparation in a cyclotron and is not available at all centers. Our method is similar to methods described by others (36-37).

Interrogate the pump to verify the pump model, expected reservoir volume, drug concentration and dose. Refer to the implant record to determine the catheter length and volume as well as manufacturer references for expected internal pump catheter volume. Calculate volume flow rate to determine time interval for the tracer to infuse to catheter tip. Using aseptic technique, infuse 0.5 to 1.0 millicurie of Indium 111 DTPA into the pump reservoir. The Indium solution depends on the volume of current infusing medicine already in the reservoir. After injecting the Indium, flush the needle with some previously withdrawn pump contents so that a tract of Indium is not left in the skin. Ideally, infusion of 0.5-0.75 millicurie of radioisotope in 1 ml of preservative-free sterile normal saline into a 10 ml reservoir volume to infuse over 48 hours provides adequate dilution. Slower infusion rates or greater reservoir volumes may require higher Indium doses. The addition of this volume to the pump reservoir will somewhat lessen the drug concentration. If this is of concern, to account for this concentration change, calculate and program a slight increase in the infusion rate with a bridge bolus. It is important to maintain the current infusion dose to avoid overdose or withdrawal symptoms and to allow current flow to evaluate actual expected flow of the infusing drug. Sequential schographic analysis over the appropriate time frame allows evaluation of the Indium's course out of the pump, into the catheter and, if functioning properly, into the CSF. A large field-of-view gamma camera fitted with a medium energy collimeter with a 20% window for three minutes is used. A pump-sized lead shield is used to cover the pump to increase the sensitivity to the background and achieve an accurate count of Indium outside of the pump reservoir. Anterior, posterior, and oblique views may be needed. Outlining the patient's anatomical features with a spot marker allows for quick identification of flow out of the catheter, into the CSF and ventricle. Evidence of radioisotope in the kidneys or bladder prior to visualization of radioisotope in the spinal anatomy is highly suggestive of a catheter defect. However, if some radioisotope contamination occurred during pump filling, then this can lead to uptake and early kidney and bladder counts. This false finding will generally be verified by continuation of the study to a point where either there is continued bladder and kidney activity without evidence of migration of the radioisotope out the catheter, or the bladder and kidney counts subside and the radioisotope is seen coursing out the catheter. Collection of isotope at any site without continuation of counts further within the catheter indicates a catheter failure at that location. The most common site for this to occur is the spinal canal entry site. With a two piece catheter this location is generally where the splice to the pump catheter segment resides, the catheter is anchored, and the spinal ligament shear stress is greatest.

Fluid Collection Assay

Seroma formation is common following surgical trauma and forms around most implanted foreign bodies. The amount and duration of the seroma are variable, but may require analysis when there is concern over system malfunction or infection. Some seroma fluid collection is expected during the first two to three months following implant and generally decreases to some small, but often perceptible, amount. This is normal, and attempts to drain by repeated aspiration are generally avoided. Needle puncture into the capsule increases the infection risk and often the seroma will re-accumulate within a short time. In rare situations, the amount of seroma may be so large that concerns of wound healing compromise are raised. Reducing the pressure within the pocket by needle aspirations may improve the outcome. Surgical suction drains are avoided in the initial surgical implant, but may be employed when pocket revisions are required due to wound dehiscence or other non-infection related pocket complications. When a catheter fractures, CSF will usually leak into the surrounding tissue. Differentiating between seroma and CSF may be difficult with simple chemistry and microscopic studies. Analyzing for beta-transferrins can be used as a marker for CSF (38). If beta-transferrins are present in the aspirated fluid, then one may assume that at least a portion of the fluid is CSF in origin and therefore a catheter leak exists.

Conclusion

Management of the patient with an intrathecal infusion pump requires continued assessment of the patient's clinical state and response to the therapy with vigilance toward possible refill errors and mechanical system failures. When a patient's condition changes, skilled evaluation and assessment of multiple factors needs to be accomplished in a timely manner to avoid overlooking causes of change that may not be pump related. For instance,

in a person with chronic illness, infection is more common than is failure of a baclofen pump system. With mounting data suggesting catheter tip masses may be more common than once thought, special vigilance is necessary regarding their formation and early diagnosis when patients complain of new pain or new neurologic findings. Ascribing multiple patient problems to the intrathecal pump is common. Having the clinical experience and confidence to correctly identify a change as being related to the pump, or not, is expected of those who implant intrathecal infusion pumps and manage the often complex care of these patients.

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