Intrathecal Baclofen Therapy
椎管巴氯芬治療

Introduction

Intrathecal baclofen therapy (ITB) is one of the management for severe spasticity by using an implantable infusion system to deliver an adjustable and precise amount of baclofen directly to the intrathecal space. Baclofen is a muscle relaxant and antispastic. ITB therapy cannot cure spasticity. But it can relieve the symptoms of spasticity by improving muscle tone, improve the motor function, decrease pain associated with spasticity and quality of life. It allows physician to adjust the dosage to be delivered with reference to patient's clinical response and individual needs. As a modulatory therapy, there is no nervous tissue destruction and the therapy is reversible. Since medicine goes directly into the spinal fluid, effective concentrations of the drug can be achieved at a fraction of a typical oral dose. Therefore, despite ITB may still have undesirable side effects, its side effects may be less pronounced as the oral baclofen.

This therapy is indicated for use in the management of severe spasticity due to brain insult and of spinal cord in origin. For patients with traumatic brain injury, they should wait for at least one year after the injury before consideration of ITB. For spasticity of spinal cord origin, ITB is reserved for patients unresponsive to oral baclofen or those who experience intolerable central nerve system side effects.

The procedure

Before the procedure, patient has to be assessed for the severity of spasticity, fitness for surgery, response to current treatment and how spasticity affects the quality of life. After that, a standard screening test is required to determine whether ITB Therapy may be suitable as a treatment option. In the test, patient receives a bolus dose of baclofen injection through a lumbar puncture, and the patient's responses as well as the side effects are evaluated. Patient with suboptimal response may require a trial with a higher dose. Usually patient has to stay overnight to complete the screening test.

Patient who has good response and tolerable side effects in screening test will be eligible for ITB. The procedure will be undergone under general anesthesia. An incision will be made on the lower back with a catheter inserted into the thecal space surrounding the spinal cord. The catheter is connected to a programmable pump that

will be placed in a subcutaneous pocket in the abdomen. After that, the incisions will be sutured up and the procedure is complete with the patient recovered from anesthesia. The procedure usually takes 1-2 hours.

After recovery from the operation, the physician will turn on the pump and start the ITB. But it may take weeks or even months to adjust the pump to deliver the optimal dose of baclofen. During this period, the physician may also adjust the current oral medications. Patient and the care givers have to recognize the symptoms of underdose and overdose of baclofen and report to the physician during clinical visits so that appropriate adjustment can be made.

Risk

Common risks related to the device and procedure: Catheter dislodgement/break, pump migration, skin erosion, implant site infection including central nervous system infection like meningitis, leakage of cerebrospinal fluid, pain at implant site, bruising, spinal cord and/or spinal nerves damage causing paralysis, headache, pump malfunction, mortality if severe complication occurs.

Common risks related to the baclofen: hypotonia (34.7%), somnolence (20.9%), headache (10.7%), convulsion (10.0%), dizziness (8.0%), urinary retention (8.0%), nausea (7.3%), and paresthesia (6.7%).

Serious consequences:

- Overdose of baclofen can cause respiratory depression, flaccidity, seizure, cardiac arrhythmia, coma, mortality.
- Abrupt withdrawal of baclofen can cause agitation, rigidity, seizure, hyperthermia, myoclonus, rhabdomyolysis, multi-organ failure, coma, mortality.

Preparation before the procedure

Patient should stop antiplatelet agent and anticoagulants before the procedure. There should be no systemic and local infection at implant site.

Care after the procedure

It is recommended to limit activity for 6-8 weeks after the procedure. After that, patients can gradually resume physical therapy or other forms of rehabilitation.

Patients and their caretakers have to aware of the symptoms of underdose and overdose of baclofen that may signify problems of the ITB. They should contact their physician-in-charge or visit the Emergency Department promptly if symptoms developed.

In addition, patients should have regular follow up to check the function of the pump, the battery status, the baclofen status, effects and adverse actions to ITB.

Depends on the usage, the pump has to be refilled for baclofen every 3-6 months. Patients should follow the refill schedule or the pump will run out of baclofen resulting in baclofen withdrawal symptoms like rigidity, seizure, hyperthermia, myoclonus, rhabdomyolysis, multi-organ failure, coma and even mortality. The battery of the pump typically lasts for 4-7 years and so the pump needs to be replaced that usually carried out under general anesthesia. On the other hand, the catheter may last longer and may not need to be replaced at the same time.

Follow up

Patient should follow the refill schedule and has regular follow up to monitor clinical response as well as the pump status. Any cause that result in abrupt cessation of ITB can be dangerous and potentially life threatening.

Remarks

Patients and their care givers should contact their physician-in-charge or visit the Emergency Department promptly if they suspect device malformation, observe symptoms of under/overdose of baclofen.

This is general information only and the list of complications is not exhaustive. Other unforeseen complications may occasionally occur. In special patient groups, the actual risk may be different. For further information please contact your doctor.