

Infusion Pump Surgery: Achievements and Limitation

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Abstract

- Background** Infusion pump is a special pump machine, with two different types, programmable and fixed flow pumps. These pumps used for administration of drugs through lumbar intrathecal route.
- Objectives** To evaluate the infusion pump surgery as a new surgical technique in Iraq used for treatment of pain and spasticity and to discuss the limitations and achievements regarding surgical techniques, the cases that to be selected for surgery and general conditions of selected cases pre and post surgery .
- Methods** Five patients were collected from Al-Kadhimiya Teaching Hospital complaining of either spastic lower limb due to dorsal spinal tumor, radiculopathy due to bullet injury not relieved by other techniques, or generalized pain due to tumors with different locations and liver metastases. Surgery done for all patients using (Isomed/Medtronic) fixed flow infusion pump.
- Results** Four patients have pain relief with different percentage when using morphine and one patient with spasticity showed mild improvement after baclofen pump injection.
- Conclusion** Infusion pump surgery is a new technique in Iraq, which is effective in the management of intractable pain and spasticity not relieved by medications.
- Keyword** Morphine, baclofen pumps, spasticity, isomed.

Introduction

Infusion pump is a drug infusion system includes a drug reservoir and a pump/controller assembly. The drug reservoir consists of a drug chamber and a propellant gas chamber. The pump/controller includes a bacterial filter, a controller circuit board, a battery in programmable types, and a micropump⁽¹⁾.

Implantation of an intrathecal drug delivery system is indicated for:

1. Chronic, intractable pain of malignant and/or benign origin that responds to opioids.
2. Long-term infusion of baclofen for severe spasticity of spinal or cerebral origin that responds to baclofen.

3. Long-term intravascular infusion of antibiotics or drugs for chemotherapy⁽²⁾.

Pain management:

Approximately 10% of end-stage cancer patients undergo unavoidable pain in spite of medical treatment on WHO's advice. The intrathecal drug infusion pump is for pain control of the end-stage cancer patients by intrathecal analgesic infusion. The drug delivery efficiency is approximately 300 times as high as conventional oral administration and can be obtained with significantly less systemic side effect⁽¹⁾. With the improvements in implantable materials and the miniaturization of computing systems, it has become a realistic possibility to implant devices for the continuous or intermittent injection of drugs into the cerebrospinal fluid (CSF)⁽³⁾.

Neuraxial drug infusion has become a popular interventional treatment for intractable pain, especially for pain with a significant nociceptive component. Thus, the use of intrathecal analgesics for the treatment of cancer pain is well accepted. In contrast, the use of this therapy for chronic nonmalignant pain has been controversial reflecting concern that neuropathic pain (common in chronic nonmalignant pain syndromes) does not respond adequately to opioids and that the efficacy and cost effectiveness of neuraxial drug infusion for neuropathic pain have not been determined in controlled trials. Despite these concerns, intrathecal analgesic therapy has been used to treat neuropathic pain conditions with favorable results and the most common indication for intrathecal analgesic administration is failed back surgery syndrome, which typically includes components of nociceptive (low back) and neuropathic (extremity) pain⁽⁴⁾.

Once the pump has been implanted, a catheter attached to the pump is guided to the lumbar spinal canal. The pump delivers pain relieving medication directly to the spinal canal. Any number of pain medications can be used with the pump. The advantages of the pump are to reduce the side effects of medications used for pain, enhance the quality of life, and reduce the overall cost of treatment. The clinical application range is targeted to the chronic pain patients (chronic pancreatitis, failed back surgery syndrome, reflex sympathetic dystrophy syndrome..etc.) and others who need continuous medication. The implantable intrathecal drug infusion system is known to have broad application range, excellent effect, and minimum side effect⁽¹⁾.

Spasticity affects about 500,000 people in the USA and more than 12 million people worldwide⁽⁵⁾ is defined as hypertonia in which one or both of the following signs are present (a) resistance to externally imposed movement that increases with increasing speed of stretch and varies with the direction of joint movement, and/or (b) resistance to externally imposed movement rises

rapidly above a threshold speed or joint angle. It is a sensorimotor phenomenon related to the integration of the nervous system motor responses to sensory inputs.

Although most commonly considered as a velocity-dependent increase to tonic stretch, it is related to hypersensitivity of the reflex arc and changes that occur within the central nervous system (CNS), most notably, the spinal cord. Injury to CNS results in loss of descending inhibition, allowing for the clinical manifestation of abnormal impulses. Muscle activity becomes overactive. This is mediated at several areas of the stretch reflex pathway. Although spasticity is part of the upper motor neuron syndrome, it is frequently tied to the other presentations of the said syndrome.

Contracture, hypertonia, weakness, and movement disorders can all coexist as a result of the upper motor neuron syndrome. Spasticity is a common phenomenon in patients with a wide variety of neurological disorders like cerebral palsy, multiple sclerosis, cardiovascular accidents, strokes, traumatic brain, and spinal cord injury. These patients not only suffer from severe contractures and deformities but also severe pain that incapacitates them⁽⁶⁾. Baclofen stimulates the presynaptic gamma-aminobutyric-acid B (GABA_B) receptor, which inhibits sensory input to spinal neurons, but may also act post-synaptically⁽⁷⁾.

Intrathecal baclofen (ITB) systems have been effectively used since the mid-1980s for treating patients with severe spasticity. The therapeutic advantage of ITB systems has especially been seen in cases with medically refractory spasticity. Common indications for ITB therapy include cerebral palsy, traumatic brain injury, spinal cord injury, diffuse anoxic brain injury, hereditary diseases such as Rett syndrome, and other etiologies leading to severe and unmanageable spasticity. Several studies have supported the use of ITB systems for the treatment of dystonia too. Although some patients may not regain complete functionality or remission of pain, ITB therapy has shown to positively affect the quality of life and ease

patient daily treatment by their caregivers. While ITB is an effective treatment option, there are still significant complications associated with the intricate surgical technique and prolonged duration of treatment⁽⁸⁾.

Intrathecal administration of baclofen offers the benefit of delivering the medication directly into the central nervous system (CNS) without systemic side effects. Chronic intrathecal baclofen infusion (CIBI) with a surgically implanted pump device (Infusion System, Medtronic, Inc., Minneapolis, MN) has been shown to reduce spasticity and improve function, and its use has been indicated in nonambulatory or minimally ambulatory patients with spastic quadriplegia. The potential adverse effects with CIBI are significant and include infection, pump malfunction, and life-threatening withdrawal or overdose⁽⁹⁾. ITB is also used particularly if the oral form is poorly tolerated or ineffective^(6,10).

ITB improves both spasticity and spasms. As a result of reduced spasticity and spasms, patients will be able to sleep better, become more independent with mobility, and their ability to do self-care helps improve urinary function. A decrease in muscle pain and fatigue that accompany spasm may also be seen. Thus, effective Baclofen therapy can be delivered using ITB pump, where effects of baclofen are maximized, while its side effects are minimized⁽⁶⁾. ITB pump implantation was routinely preceded by an ITB trial, and only patients responding favorably to the trial were offered a permanent pump⁽⁸⁾.

ITB is a technique in which a very low dose of baclofen is delivered into the intrathecal space by way of a catheter attached to an implantable pump. The dose is less than 1% of that delivered orally because of the direct delivery system to the central nervous system; such delivery reduces the principal side effect of sedation⁽¹¹⁾.

After implantation of the pump, ITB doses are titrated over the first few months, regardless of the movement disorder being treated. When treating spasticity, infusions often begin at 100 µg/ day and are increased by 10% to 20% daily

until spasticity is perceptibly reduced to the patient and physician; doses are then adjusted at less frequent intervals on an outpatient basis⁽¹²⁾.

Complications:

1. Infections occur in 5% to 10% of patients and are caused most frequently by *Staphylococcus aureus*.
2. CSF leaks occur after baclofen catheter insertion in 5% to 15% of patients with CP (most of whom are children), in contrast to the 3% leak rate reported in adults
3. As catheter technology has improved, the frequency of catheter malfunctions has decreased from 25% to about 5% to 10%.
4. Although several small series reported previously that ITB caused more rapid progression of scoliosis than was observed before pump implantation, those series had no controls.
5. The effect of ITB on seizures has also been clarified. Authors of small series had reported either increased seizure frequency or no change in frequency.
6. Most ITB overdoses are iatrogenic and related to programming errors, which can occur when initially filling the baclofen catheter or when changing baclofen concentrations. Mild overdoses cause only listlessness and do not need to be treated. Moderate overdoses cause lethargy and hypotonia and are treated by monitoring pulse oximetry while waiting for the baclofen to metabolize. Some authors have recommended intravenous injection of 1 to 2 mg of physostigmine to treat overdoses, but the effects of such injections are minimal and brief. Severe overdoses cause bradypnea and coma and are treated by assisted ventilation^(6,12).

Contraindications to implantation of an intrathecal drug delivery system were:

1. Systemic infection
2. Pump cannot be implanted less than 2.5 cm from the surface of the skin
3. Known allergies to the materials or medications
4. Drug abuse⁽²⁾.

Method

Prospective case series study included five patients suffering from pain and spasticity of different pathology attending Al-Kadhimiya Teaching Hospital; one patient has spastic lower limbs due to dorsal spinal tumor, 1 patient has radiculopathy due to bullet injury not relieved by laminectomy and bullet extraction or sympathectomy, and 3 patients had generalized pain due to tumors with different locations and with liver metastases. Baclofen and morphine injected to the pump with different concentrations. Isomed fixed flow pump from medtronics used in all cases. Intrathecal Baclofen used for spasticity, and morphine sulphate for pain. Daily drug flow is 0.5 ml/day, Pump chamber=35 ml.

Surgical procedure:

For all patients same procedure done, under general anesthesia, patient positioned in full lateral position with flexion of both knees to abdomen to enhance better flexion of the back, midline incision at level of third and fourth lumbar spine depending on surface landmarks (anterior superior iliac spine), then after skin and subcutaneous incision, Touhae needle directed at that level (L3-L4) toward intrathecal route (Fig. 1), when CSF drops out then a special catheter with stylet directed intrathecally through Touhae needle reaching the level D12-L1, by inserting about 28 cm from the catheter, fluoroscopic guidance was not a routine job.



Fig. 1. Intradural insertion of lumbar catheter

After fixation of catheter to prevent slipping or kinking, subcutaneous tunneling from the back to the anterior abdominal wall (right hypochondrial region) was made and a para median incision to the anterior abdominal wall, either longitudinal or horizontal to make a pocket for the pump just above the rectus abdominis (Fig. 2).



Fig. 2. Anterior abdominal pocket for the pump

Checking the action of pump before insertion to the abdomen about 5-10 ml of fluid aspirated from the chamber, then the chamber filled with drug using special draining system with filter (Fig. 3).



Fig. 3. Filling the pump using special system

The chamber can be filled with 35 ml of the drug. Isomed/medtronics, constant flow pump was used is that pumps 0.5 ml /day (Fig. 4).

Patient # 1

Forty six years lady with bilateral lower limb spastic weakness following spinal dorsal tumor operated upon, infusion pump done for her using baclofen to decrease spasticity of lower limbs and improving the functional status of the limbs. Baclofen ampoule (10mg/20ml) injected to the pump.



Fig. 4. Isomed/medtronic infusion pump

Patient # 2

Sixty years old man referred for morphine pump insertion due to severe backpain associated with epigastric pain, the patient is a known case of end stage pancreatic tumor, 5ml of morphine (10mg/ml) diluted with 25 ml of normal saline 0.9% injected to the pump (0.8mg of morphine intrathecal/day).

Patient # 3

Forty three middle aged man with liver and cervical metastatic tumor and complaining of severe epigastric pain associated with bilateral upper limb pain and spasticity, 4ml of morphine (10mg/ml) diluted with 26ml normal saline 0.9% injected to the pump (0.7mg of morphine intrathecal/day).

Patient # 4

Seventy years old man with pancreatic adenocarcinoma associated with liver metastases leading to severe backpain and epigastric pain, the patient addict on 70mg /day of morphine i.v preoperatively. 5ml of morphine (10mg/ml) diluted with 25 ml of normal saline 0.9% injected to the pump (0.8mg of morphine intrathecal/day).

Patient # 5

Twenty five years young aged man with bullet injury to the back leading to root injury, laminectomy at level of trauma to decompress the root but pain still present then sympathectomy done and pain still present. Morphine pump decided and inserted to him, 0.3 mg/day intrathecal morphine calculated to keep the patient under low comfortable dose.

Results

The mean age was 47.5yr (range from 25-70yr) and male to female ratio was 4:1. Pathology that indicate surgery, 40 % (2 cases) spinal cord tumor, 40% (2 cases) pancreatic tumor, (1 case) 20% root injury and liver metastases in 2 cases (40%) Baclofen used for 1 patient (20%), and morphine for 4 patients (80%).

The first patient with spastic painful weakness due to previous spinal dorsal tumor, baclofen used, as it's the first surgery for pump implantation there is some technical difficulties during operation that consisting of difficult removal of stylet from intrathecal catheter leading to small perforation in the catheter managed by using connector and bypass the perforation. There was mild improvement in spasticity and pain after surgery, but during the following refilling sessions every 2months, the patient felt no difference in spasticity as before surgery.

The second, and fourth patients, complained from end stage pancreatic tumors with liver metastasis in the fourth patient, morphine used in different doses depending on the severity of pain, there is dramatic response and pain diminished just after surgery, the fourth patient complained from morphine addiction equal to 70 mg /day, reduced to 0.8 mg /day intrathecally, with comfortable effect. The third and fourth patients, complained from liver metastases.

The fifth patient complained from root injury due to bullet injury to the back, decompressive laminectomy for pain management followed by sympathectomy without diminished pain sensation,

Low intrathecal dose of morphine decided to keep the patient under minimal comfortable

dose, slightly increasing depending on patient condition (Table 1).

Table1. Characteristics of patients' data

Patient	Age (yr)	Sex	Pathology	Complaint	Type of drug
# 1	46	F	Spinal cord tumor	Spastic pain	Baclofen
# 2	60	M	Pancreatic tumor	Epigastric pain+backpain	Spastic morphine
# 3	43	M	Cervical secondary with liver metastasis	painful limbs +epigastric pain	morphine
# 4	70	M	Pancreatic tumor+liver metastasis	Backpain+ epigastric pain	morphine
# 5	25	M	Root injury	radiculopathy	morphine

Discussion

Intrathecal therapy has been proven to be very effective in the treatment of chronic therapy-resistant pain and spasticity resulting from damage of central nervous system of various etiologies⁽¹³⁻¹⁵⁾. Regarding the first patient, there was mild improvement in spasticity and pain after surgery but unfortunately presurgical complain returned back after 3rd refilling session and this is due to constant flow of baclofen without ability to increase the dose/day that meet the patient need after third session. The pumps, which was available, an Isomed type that flow 0.5 ml/day, while in other study a programmable synchomed pump used⁽⁷⁾ that the dose can be increased or even stopped according to the patient need and general condition.

For treatment of intractable pain in patients with end stage secondary metastases, morphine used in different doses depending on patient condition, as in other studies that^(1,2,4). The drug delivery efficiency of approximately 300 times as high as conventional oral administration can be obtained with significantly less systemic side effect⁽¹⁾ as in our study, the daily comfortable dose after surgery for the fourth patient was 0.8mg/day, which was 70 mg/day i.m before surgery.

In conclusion, infusion pump surgery is a new minimal invasive surgical procedure in Iraq for treatment of spasticity and pain in different pathologies, with comfortable results. Programmable type of pump is better when baclofen decided while in cases that need

morphine there is no difference in using constant flow or programmable pump due to the ability of changing morphine concentration.

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