SynchroMed II

The Medtronic SynchroMed® II programmable infusion system consists of an implanted infusion pump that can be noninvasively programmed, an intraspinal catheter, and an external programmer.

It permits dosage adjustments by increasing or decreasing the flow rate and/or by altering the mode of administration (continuous mode, scheduled boluses, and/or step-function dosing), as required by an individual patient.

The classic site for placement of the pump is in the abdominal wall. In some patients, there are confounding factors that make placement of an abdominal pump impractical.

Four patients, aged 13 to 33 years, underwent infraclavicular placement of a Synchromed II infusion pump. In one patient, severe scoliosis and hip joint contractures precluded placement of the pump in the traditional position. Another patient had several ostomies on the abdominal wall, leaving no place for the pump. In a third, a combination of scoliosis and ostomy rendered the abdomen inappropriate for pump placement.

In 3 patients, a 20-mL pump was placed in the infraclavicular fossa. In the fourth, a 40-mL pump was placed in the left infraclavicular fossa. All patients tolerated the operation well. There were no postoperative reports of local pain or discomfort. One patient died from unrelated respiratory compromise several months after pump placement. At last follow-up (average of 11 months), the pumps were functioning well, and there were no wound-related complications.

The infraclavicular fossa is a viable alternative to the abdomen as the site for placement of a drug infusion pump [1)].

Complications

Infusion systems must deliver accurate and steady dosing, or patients will experience adverse effects related to overdosing or underdosing. In some cases, the effects can be fatal or life-threatening [2)].

They can fail to resume normal functioning after MRI, potentially causing complications. The magnetic field of an MRI will temporarily stop the rotor of the pump motor and suspend drug delivery for the duration of the MRI exposure. The pump should resume normal operation when removed from the MRI magnetic field, but there is a potential for a delay in the return of proper drug infusion and a delay in the logging of motor stall events after an MRI in the SynchroMed II pumps.

A 57-year-old man who underwent multiple MRIs with an implanted IDDS experienced 2 separate memory failures leading to multiple complications. After the first pump malfunction, the patient developed withdrawal symptoms and was treated in the emergency department. The first time, a memory reset resolved the problem. The second time, 29 months later, the patient was admitted to the hospital to manage withdrawal symptoms and the pump had to be exchanged with a new device. Post-MRI pump interrogation should be performed on all patients with IDDS to ensure proper functioning of the pump. Special attention should be paid to patients receiving baclofen, as acute withdrawal can be very serious, even deadly [3)].

Medtronic has issued a number of advisories, most recently in June 2013, regarding the safety of the Medtronic SynchroMed II intrathecal pumps.

The decision to replace the pump should take the following factors into consideration: history of pump volumes, magnitude of the volume discrepancy, presence/severity of overdose symptoms, and the individual patient situation. Information specific to this new risk with the SynchroMed II Infusion System can be found with product advisories at http://professional.medtronic.com/pt/neuro/idd/ind/product-advisories.

Ten percent of subjects experienced catheter complications. The manufacturer has subsequently introduced a new catheter designed to prevent common catheter complications and posts product performance reports annually at http://professional.medtronic.com/ppr/intrathecal-drug-delivery-systems/index.htm [4].

2015

A case report illustrates an overdose of baclofen in a 10-year-old boy due to a likely malfunction of a SynchroMed II pump. This ultimately necessitated a pump replacement. One-year follow-up showed no further incidents of baclofen overdose, with multiple pump refills [5].

2014

2 cases of intrathecal pump malfunction, which most likely led to overinfusion of fentanyl intrathecally. To reduce the risk of this complication, particular attention should be paid to drug reservoir volume discrepancies and overdose symptoms reported by patients [6].

Sixty-four months post insertion of a SynchroMed II, model 8637; a patient was reviewed as a matter of urgency , as he was complaining of worsening spasticity and pain. The device was interrogated and this indicated a motor stall at the time of interrogation. The interrogation also revealed that this was the third period of motor stall in the preceding three days. According to the patient, and consistent with the interrogation, the device had been alarming intermittently for the previous three days.

He was commenced on oral baclofen overnight, which gave some improvement to his symptoms. A replacement intrathecal pump was inserted the following day. This provided the patient with his usual level of relief. The product Engineering Department at Medtronic reviewed the original pump.

The patient's new intrathecal pump has been functioning uneventfully since its replacement and he continues to receive good symptom relief from his new pump. Internal inspection of the pump by the Engineering Department at Medtronic revealed corrosion of the motor gearbox [7].

2010

A 12-year-old girl suffering from spastic diplegia was implanted with a Medtronic SynchroMed II pump (Medtronic Inc., Minneapolis, Minn., USA). During a refill at 3 months 19 ml of baclofen were still in the pump. It was assumed that there was a lumbar catheter obstruction and a revision was performed. At 11 months she was receiving 180 microg/day. When she presented for refill, there were again 19 ml of baclofen in the reservoir. The pump was refilled, stopped and restarted at a lower dose. Ten minutes after restart the patient was complaining that she could not move her legs. Within the next

50 min she lapsed into coma, from a presumed baclofen overdose. She was intubated and ventilated. The reservoir was emptied of baclofen and the pump stopped. Seventeen hours after the baclofen overdose, the patient woke up gradually with no new neurological deficits. The pump was removed a week later. Medtronic laboratories examined the pump and reported no technical fault.

The implanted Medtronic SynchroMed II pump suffered an unusual malfunction. It is postulated that the pump had suffered a motor stall, and when it was restarted, it gave an unusually high, potentially lethal, dose to the patient [8].

1)
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