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Targeted drug delivery

Feedback from patients

BY DAVID SCHULTZ, MD

Nura Pain Clinic manages approximately 650 Minnesota patients who have had a "pain pump" (Medtronic Synchromed II or Flowonix Prometra) implanted and/or re-implanted for Targeted Drug Delivery (TDD) at some time over the past 25 years. We have long believed that opioids targeted to the spinal cord are far preferable to systemic opioids targeted to the brain when treating complex chronic pain that has failed to respond to all other treatments. With the opioid crisis raging across the country, our preference for spinal over systemic opioids has only been reinforced.

A targeted approach

TDD with a programmable, continuous infusion pump and spinal catheter is a reversible, non-destructive method for controlling severe chronic pain that moves patients from the "fix it" path of more surgeries and more medical interventions to the "quality of life" path of reduced pain and improved function. Pump medications are targeted to the spinal cord and block pain at the spinal cord level, thus keeping the brain free from drug effects. A typical intrathecal pump infusion in our clinic consists of an opioid mixed with a local anesthetic. These drug admixtures are continuously infused at low dose into the spinal fluid with the catheter tip placed at the spinal level of maximal pain, blocking regional spinal pain receptors and avoiding brain drug effects of mental clouding, somnolence, and confusion.

Although physical dependence may develop with pump opioids and withdrawal may occur if the pump infusion is abruptly stopped, addiction potential is eliminated because there is no euphoria or "high" feeling associated with spinal opioid infusion. Furthermore, for those pump patients with severe physical pain and an addiction history, the physician controls the drugs within the pump and the opioid cannot be abused and/or diverted by the patient.

Interestingly, pain pumps can be effective even without opioid. We have long considered Bupivacaine to be the most important pump medication, and some of our patients have Bupivacaine as their only pump drug. Bupivacaine is a powerful spinal anesthetic with many years of safe experience in the operating room for surgical anesthesia and in the OB suite for labor epidural infusion. Low-dose spinal Bupivacaine blocks pain fibers while leaving the sensory motor nerves unaffected so that patients may function normally. Local anesthetic and opioid are synergistic in the spine, since Bupivacaine blocks nerve conduction whereas spinal opioids bind to spinal opioid receptors.

Feedback from patients

During an 18-month period from May 2018 to August 2019, we invited our pump patient population to take an anonymous, 18-question survey assessing satisfaction levels. We asked for feedback on TDD as a pain management option and overall satisfaction with the implanted pain pump using multiple-choice questions with an open-ended comments section for additional observations. The survey was voluntary and anonymous, and patients did not receive any compensation for survey completion. The primary outcomes of this survey were defined as patient satisfaction across three domains: relief of pain, improvement in quality of life, and improvement in physical function. Secondary outcomes evaluated opioid consumption, health care utilization, comfort of the implanted pump, and side effects.

Four hundred and forty-three patients (74% of the active pump population) completed the survey. The majority of patients reported improvement in pain, improvement of physical function, improvement in quality of life, and reduction in opioid use. Complete discontinuation of oral opioid intake was reported in approximately 40% of patients. We have recently published our survey results in the peer-reviewed journal Neuromodulation (available at https://tinyurl.com/mp-tdd-survey).

Survey respondents were 28 to 94 years old, and 60% were female. The most common indication for pump implant was low back pain with post-surgical spine syndrome (ICD-10 M96.1). Other common diagnoses included chronic abdominal pain, atypical facial pain, post-herpetic neuralgia, intractable neck pain, and cancer-associated pain. Many of our patients had substantial comorbidities, including obesity, hypertension, diabetes, and chronic obstructive pulmonary disease. Some patients had multiple comorbidities.

Improvements in pain, physical function, and quality of life

Overall, 96% of surveyed patients reported benefit from pump implantation (328/342), with 78% of patients reporting moderate to strong benefit

(265/342). Similarly, pain relief was evident, with 94% of patients reporting improved pain control following pump implantation (398/422) and 59% of patients stating their pump provides good to excellent pain relief (249/422). Only 6% (24/422) of patients reported worsened control of chronic pain following pump implantation.

Importantly, 78% (318/410) of patients stated they had improved physical functioning after TDD. Only 3% reported worse functioning after pump implant (14/410). Overall, 87% (357/413) of patients responded that pump implantation improved their quality of life compared to pre-implantation. Only 9/414 (2%) reported worsened quality of life following pump implantation.

Opioid consumption

With regard to continued oral and transdermal opioid intake, 89% of survey responders reported taking less oral opioid medication than before pump implantation. No pump patients were taking transdermal or long-acting oral opioids after implant. Nearly 40% of patients stated they had completely stopped all opioid intake and relied solely on TDD for pain control.

Opioids targeted to the spinal cord are far preferable to systemic opioids targeted to the brain.

Side effects

Patient-reported side effects were also diminished following pump implantation. Seventy-two percent of patients reported being more mentally alert. More than half of patients reported having no side effects (56%) from TDD and, overall, 94% reported no or manageable side effects. Of those patients with side effects, constipation was the most common. Ten years of Medtronic's Product Surveillance Registry (PSR) data shows that the most common adverse events were untoward drug reactions and that serious adverse events were rare and usually involved device-related infections. Rate of infection after pump implant at Nura is less than 0.5%.

Pump and catheter location

Our approach has always been to place the catheter tip at the site of maximal pain. Catheter tip locations ranged from spinal level C1 for head and face pain, down to T12 for pain in lower extremities. We have seen no increased incidence of side effects or complications related to placement of catheter tips at cervical spinal levels.

Pump discomfort and pocket-site pain were additional concerns we addressed. The pump was implanted in the upper buttock in 76% (314/411) of patients and in the abdomen in 15% (60/411), and a majority of patients had the larger 40cc pump size. Upper buttock pump implant allows for prone positioning and decreased surgery times with very low infection rates. The pump was reported as comfortable by 92% of respondents. Regardless of buttock or abdomen pump pocket, 91% of patients were happy with the location of their pump.

Health care utilization

In terms of health care utilization, the majority of patients selected for TDD trial had visited the emergency room or been admitted to the hospital for pain relief in the year prior to pump implant. After implant, 77% of survey respondents stated that they had not gone to the ER or hospital for pain since their pain pump was implanted, and another 15% reported going less often than before. Seven percent said they go to the ER/hospital about as often as before, and only 1% of respondents said they went to the ER/hospital more often after the pump implant than before.

Opioid consumption

Post-implant, 88% of survey responders reported taking less oral opioid medication and 39% of patients stated they had completely stopped oral and transdermal opioid intake. Other published studies have assessed decrease in oral opioid use by measurements of changes in dose consumed, percentage of patients non-reliant on oral opioids, and scoring scales of medication consumption. Throughout all these different measurements, decreases in oral opioid use were observed following TDD therapy, with one study showing a 92% rate of elimination of oral opioid use over a 5-year follow-up period (Caraway et. Al, Neuromodulation 2015). Another study following long-term effects of oral opioid use in patients with intrathecal TDD therapy showed a reduction in oral opioid use over the follow-up period (Herring et. Al. Pain Med 2019).

In their own words

As an interventional pain doctor for the past 30 years, I have often asked my patients what treatment has worked best for them. Patients are often grateful for pain-relieving procedures such as spinal injections and nerve ablations, but I have always been struck by comments from my pain pump patients who often tell me the pump was the best thing they ever did and that they could not imagine living without it. We do not often hear comments like that from pain patients in regard to any other therapy. At the end of our survey, we asked patients to tell us anything else about their pain pump that they thought was important and the intense emotional connection that many patients have to their implanted pump came across loud and clear. Although a few of our pump patients made negative comments, we were inundated with positive comments such as:

"This was my last resort to 10 years of going through everything possible to trying to control my pain. The pump saved my life, literally. It is my miracle in life. Thank you."

Conclusion

Targeted Drug Delivery with a pain pump is a drastic treatment, and we do not consider TDD as an option unless the patient has severe, intractable pain that has failed to respond to all other treatments, including medication management, spinal injections, surgeries (if indicated), and trials of neurostimulation. Nonetheless, I believe that TDD is the very best treatment we have to offer for those patients whose only recourse would be to live a life on high-dose oral or skin patch opioids.

David Schultz, MD, is the medical director and founder of Nura pain clinics. Dr. Schultz is a board-certified anesthesiologist with additional board certification in pain medicine from the American Board of Anesthesiology, the American Board of Interventional Pain Physicians, and the American Board of Pain Medicine. He has been a full-time interventional pain specialist since 1995.