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After Surgery: Treating Pain at Home

Insurers Question the Use Of Popular Pumps to Deliver Drugs Directly to Wound Site

By LAURA LANDRO

IN THE QUEST to better treat pain after surgery, one of the most promising developments has been home infusion pumps that continuously bathe surgical wounds in anesthetic via a tiny catheter inserted into the skin.

The home pumps, which use local anesthetics such as lidocaine, provide an alternative to narcotic drugs that can carry serious side effects and the risk of addiction. With studies showing nearly half of the 70 million patients who have surgery each year don't get adequate treatment for postsurgical pain, doctors have been eager to try new strategies.

But while the home pumps are growing in popularity, especially at outpatient surgery centers, there is conflicting evidence on the risks and benefits. Three of the largest health insurers, Aetna, United Healthcare and Cigna, say they won't cover the devices—which cost up to \$400—because there haven't been any well-designed, large clinical trials in peer-reviewed medical journals.

More than 50 studies published in the five years since the pumps were introduced, covering a total of about 3,000 patients, show that the devices reduce the need for narcotics, help patients get back on their feet sooner, recover their range of motion and physical activity, and reduce the likelihood of developing chronic pain from their surgeries. But most of the studies looked at 25 to 90 patients, a relatively small sample. In a review last month, Aetna picked apart the studies as inconsequential and poorly designed and called the pumps "experimental." It also raised questions about an increased risk of infection and leakage of fluid from the catheters.

Pump makers and doctors who have conducted the studies say that some newer techniques are reducing the risk of surgical-site infections, including using



External infusion pumps like this I-Flow device deliver anesthetic to a wound site to help control pain after surgery.

silver-coated catheter tubes and methods that tunnel the devices to the nerves close to the wound, but not directly into it.

They also note that other managed-care companies and insurers, including some of the Blue Cross Blue Shield companies, do pick up the tab for the devices. **I-Flow Corp.** of Lake Forest, Calif., which makes the On-Q PainBuster model, says it has contracts with plans covering a total of 30 million patients to provide reimbursement for the pumps in outpatient surgery centers nationwide. For patients whose insurance refuses to pay, **I-Flow** will charge a reduced fee of about 10% of the cost, and then battle the insurer itself to get reimbursement, says Chief Executive Don Earhart, but will drop its claim if it can't collect.

Kathryn Merchant, who runs a local community foundation in Cincinnati, says a pain pump placed close to her incision helped her recover quickly from a total knee replacement. Though she took five of the narcotic painkillers prescribed in the first few days, she stopped using any after that. "I walked around with this round ball of liquid that was my new best friend," she says. "The whole process wasn't any fun, but I had no knee pain when those stitches came out on day 10."

The idea of using a local anesthetic for pain relief has been around for decades, but only recently have devices been developed for patients at home. Interest

has been driven in part by pressure to prescribe fewer narcotics amid the growing illegal trade in painkillers like OxyContin. Unlike patient-controlled narcotic pumps, which allow patients to administer their own painkillers, these anesthetic pumps are automatically controlled. The pumps use a balloon filled with liquid anesthetic, and can be worn either inside or outside clothes. In many cases, patients can remove the devices

themselves when the infusion is complete, after as many as five days.

Who Is a Candidate

Patients may be candidates for pumps if they are having surgery in an area that is fed by nerves directly and is large enough for a catheter; this includes Caesarean sections and orthopedic, heart and cosmetic surgeries.

Though firm numbers are hard to come by, more than one million devices have been implanted in patients in the U.S., from manufacturers including **I-Flow**, Stryker Corp., DonJoy and McKinley Medical. There were 34 "adverse events"—medical problems reported to the Food and Drug Administration—as of 2004, including infections and the death of tissue around the surgical site, known as necrosis.

Michael Schurr, professor of surgery at University of Wisconsin Hospital, Madison, published a study in 2004 reporting only modest improvements in pain relief in patients undergoing hernia surgery; the catheters leaked and were hard to manage. "We had a very high concern about the risk of infection," Dr. Schurr says.

But a number of physicians say their patients do well with the devices. Frank Deterbeck, a professor at Yale-New Haven Hospital who specializes in cardio-

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thoracic surgery, says the pumps have been especially effective in reducing the need for heavy narcotics for some of his patients who underwent major surgeries. Dr. Detterbeck, who has received compensation for lectures and a video on I-Flow devices, recently implanted one in a patient who had a portion of her lung removed to excise a baseball-sized fungus. He sent her home with an anesthetic pump draped over her shoulder under her clothes. The patient, Vera Shanov, a teacher and consultant, says she felt the need for only a small dose of the narcotic prescription she went home with, used some extra-strength Tylenol and was back at her spinning class in six weeks.

Alternative Method

Some surgeons are starting to use a

method called “continuous peripheral nerve blocks” that use anesthetic to block the flow of pain signals to nerves near the wound site but not directly in it. The block is used during surgery, then the patient is sent home with a home infusion system to continue the block for the next 72 hours. Because the catheters are inserted and managed by anesthesiologists, they have been covered by Medicare and other insurers. Duke University for example, has sent hundreds of patients home with such devices. Susan M. Steele, head of the department of ambulatory anesthesia, says she believes the technique is far superior to directly bathing a wound with anesthetic, and carries fewer risks.

But the method is complicated, requiring special training by the anesthesiologist, and it isn’t appropriate for all

surgeries. I-Flow, which makes equipment for both uses, says the PainBuster direct-to-wound pumps, which are inserted by surgeons, can be used in 10 times as many surgeries.

Timothy Kremcheck, a sports-medicine specialist at Beacon Orthopaedics and Sports Medicine in Cincinnati and who was Ms. Merchant’s doctor, says there is always a risk for infection with a catheter inserted in a joint after surgery. But Dr. Kremcheck, who has received compensation for lectures on I-Flow products, says he has had good results. His patients were able to get off narcotics quickly and start physical therapy sooner. “If you can diminish the amount of pain so people can become functional,” says Dr. Kremcheck, “you’ve won the battle.”



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