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Epidurals Linked to Paralysis Seen With \$300 Billion Pain Market

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By David Armstrong

Dec. 28 (Bloomberg) -- Valinda Parrish talks to her 60-year-old husband like a doting mother speaks to a child. "I am going to go outside for a little bit," she tells him. "Use your horn if you need me."

Rollie Parrish, nearly blind and in a wheelchair, toots the air horn he keeps on his lap if he wants something to eat or has to go to the bathroom. Four years ago, the Vietnam veteran had just spent a weekend deer hunting when he went to a hospital near his home in Nederland, Texas, for a shot of steroids to his neck to ease chronic pain. He suffered a stroke during the procedure, according to a lawsuit that was settled out of court. "He knows what happened to him, and he is angry," his wife of 29 years said in an interview.

A surge in steroid injections to alleviate back and neck pain in the U.S. is bringing with it an increase in severe and unexpected complications, including paralysis and death. Reports of the side effects have prompted the U.S. Food and Drug Administration to review the safety of steroid injections into the epidural space near the spinal cord, in consultation with an advisory group, the agency confirmed. Some 8.9 million Americans received the shots last year.

"We used to say this is so safe," said James Rathmell, chief of pain medicine at Massachusetts General Hospital in Boston and a member of the advisory group, who alerted the FDA to cases of such shots causing harsh complications. "It is a very rare event, but it is not zero, and it's devastating."

Booming Pain Market

The review comes during a boom in epidural shots, which take minutes to administer and bring doctors profitable reimbursements from Medicare and private insurers.

Steroid shots have become the most popular way physicians in the U.S. treat neck and back pain, according to research studies. One by Laxmaiah Manchikanti, chairman of the American Society of Interventional Pain Physicians, found the number of such injections to Medicare patients increased 159 percent between 2000 and 2010.

That growth reflects a rise in spending on all treatments for all kinds of pain, a market estimated to be as much as \$300 billion a year. Epidurals are one of the interventional procedures -- including implants of spinal cord stimulators and shots of pain killers -- on which Americans spent \$23 billion this year, 231 percent more than in 2002, according to Marketdata Enterprises Inc., a Tampa, Florida-based company that has tracked the market since 1992. These are distinct from more invasive approaches, such as spinal fusion and disc surgery.

Critical Arteries

The rise in the injections, according to doctors, is being driven by two events: an aging population prone to back and neck pain and generous reimbursements for treatments.

“The problem with interventional pain is the majority of treatment is medical management,” Rathmell said. “If you pay people to do stuff, they will do more stuff.”

For a typical epidural steroid shot, Medicare pays about \$200 if given in a doctor’s office, about \$400 if done at a surgery center and about \$600 if performed at a hospital.

Some private insurers reimburse more, as much as 150 percent of Medicare rates, according to companies that provide billing services to physicians. The cost of the equipment, supplies and staffing needed for a typical shot can be as low as \$120, according to Edgewater, Maryland-based Mowles Medical Practice Management LLC.

Known technically as corticosteroids, the drugs used in the injections have anti-inflammatory powers that make them popular for easing pain in hips, knees, shoulders and other parts of the body, in addition to the back and neck. The FDA review of the epidural shots is being conducted by the agency’s Safe Use Initiative, a unit formed in 2009 to reduce “preventable harm” from medications, said Sandy Walsh, an FDA spokeswoman. She said it was too early to know what action might be taken.

Slow to Dissolve

Walsh said the agency is focusing on steroid injections made with the so-called transforaminal approach, which brings a needle within millimeters of critical arteries feeding the spinal cord. It was the method used on Parrish, the suit said.

About half of the 8.9 million epidural steroid shots in the U.S. last year were administered that way, Manchikanti said.

Another area of concern, according to Rathmell and other physicians advising the FDA, is the use of particulate steroids, a form of the drug that is slow to dissolve and that they said may create blockages that trigger strokes if accidentally shot into arteries.

Particulate steroids include Kenalog from Bristol-Myers Squibb Co. and Depo-Medrol from Pfizer Inc., as well as generic versions of the two.

The labels for both formulations of Kenalog “clearly state they are not indicated for epidural use,” said Ken Dominski, a spokesman for Bristol-Myers, in an e-mail. The Kenalog label says that “reports of serious medical events, including death” have been associated with such shots. Parrish was injected with a mixture that included Kenalog, according to the lawsuit.

Reporting Harmful Results

A spokeswoman for Pfizer, Joan Campion, said in an e-mail that Depo-Medrol “has over 50 years of clinical use with a well-established safety profile when administered properly.”

There is no comprehensive system to track complications related to steroid injections, or any other drugs. While the FDA requires manufacturers to report harmful results they learn of, healthcare professionals are under no such obligation.

Until about a decade ago, the kinds of injuries Parrish suffered weren’t thought to be a possible effect of epidural steroid injections, according to doctors who specialize in pain treatment. They said the most common consequences they saw were relatively minor, such as headaches.

Then researchers and malpractice insurance companies began learning of cases of people becoming paralyzed and even dying after receiving the shots, recounting the phenomenon in alerts to doctors and in medical publications.

'Devastating' Complications

A survey of physicians reported in the journal *Spine* in 2007 uncovered 78 cases where patients who got shots in the neck, known as the cervical area of the upper spine, suffered serious injuries; there were 13 deaths.

"When you look at cervical complications, these are devastating," said Richard Rosenquist, chairman of the pain management department at the Cleveland Clinic in Ohio and head of the panel that wrote the pain-practice guidelines for the American Society of Anesthesiologists.

Earlier this year, an analysis of malpractice claims between 2005 and 2008 identified 31 cases in which patients who received the shots in the neck reported spinal cord injuries, and eight who suffered strokes. In the analysis, Rathmell and colleagues in Boston and at the University of Washington in Seattle called the cases "alarming" and said there is an "extreme dearth of evidence" about the safety of the shots.

Temporary Respite

The anti-inflammatory effect of the steroids, which are usually mixed with a local anesthetic, is short-term. Doctors typically caution patients that the treatment provides only a temporary respite, if any at all.

For Rollie Parrish, who worked as a painter for the city of Beaumont, Texas, the goal was getting relief from neck and shoulder pain so he could enjoy Christmas in 2007, according to his wife. His doctor referred him to anesthesiologist Ravi Halaswamy, who specializes in treating pain.

On Dec. 13 at Christus St. Elizabeth Hospital in Beaumont, Parrish received a shot of two steroids -- dexamethasone and Kenalog -- in the middle of his neck. Halaswamy inserted the needle into an area where nerve roots exit the spinal canal, the lawsuit against Halaswamy said.

Within seconds, the suit said, the upper left part of Parrish's body began contracting in signs of a stroke. A breathing tube was inserted, and critical care experts decided Parrish should undergo surgery to relieve swelling in his brain, the suit said. It said he was left with what hospital records described as "terminal and irreversible" symptoms.

Confidential Settlement

Three weeks later, he was diagnosed as being in a so-called locked-in state that the suit described as similar to being buried alive. While Parrish was able to hear and see, he couldn't respond because his muscles were paralyzed.

Intense physical, psychological and speech therapy have allowed him to speak again, Valinda Parrish said. The lawsuit claimed he wasn't warned brain injury was a possible consequence and said that if he had been, he probably would have declined to undergo the procedure.

The case against Halaswamy was settled with an agreement that the terms not be disclosed, according to Parrish's lawyer, Collin Cobb. An attorney for Halaswamy, Matthew Hughes, said the doctor had denied the allegations in court documents, and declined to be interviewed for this story.

'No Role'

The transforaminal approach is favored by some doctors as it delivers the solution closer to the nerves causing pain than other techniques. Because it sends the needle so near to arteries, other doctors said they believe the dangers of that approach are too high.

Cervical injections using the transforaminal approach have “no role” considering the risks, said Manchikanti, who is a professor at the University of Louisville in Kentucky. He said the pain society he heads has stopped teaching the technique.

While injections to the neck are considered riskier because the epidural space is narrower, researchers said shots to other areas can result in complications.

Luciano Rolando was 82 when he received a shot of Kenalog in the lower back. A former automobile industry executive who retired to Naples, Florida, he had suffered back pain for years before being referred to Stephen L. Friedman of the Comprehensive Pain Center of Naples.

Severe Weakness

Within hours of the injection in June 2009, Rolando was experiencing pain in his legs and losing sensation when urinating, according to a lawsuit he filed in state court. Eventually, Rolando became incontinent and suffered severe leg weakness, his complaint says. Today, he uses a wheelchair and wears adult diapers, according to his lawyer, Gary Wilkins.

Wilkins said an expert he hired said air entered Rolando’s spinal cord during the injection, and that the procedure was inherently risky because of his age and the fact he was taking blood thinning medication at the time of the procedure.

Ilisa Hoffman, an attorney representing Friedman, said her client denies he was negligent.

“The steroid injection was indicated and necessary and was preformed correctly,” she said. “Dr. Friedman is an extremely qualified pain management specialist and performed the injection absolutely appropriately.”

Physicians who do epidurals in hospitals typically undergo a review by a credentialing committee and, if approved, are assigned a monitor who reviews their work. In other settings, doctors may not be required to have any special training.

‘Unsuspecting Public’

The Cleveland Clinic’s Rosenquist said there are dangers in the fact that most any doctor can give someone a spinal injection. “The unsuspecting public has no idea someone might have gone to a weekend course and on Monday morning is testing out their brand new skill on you,” he says. “It’s horrible.”

Medicare patients receive transforaminal epidurals in a doctor’s office more than any other setting, according to a 2010 audit by the inspector general for the U.S. Department of Health and Human Services. It found a third of the shots didn’t meet Medicare requirements, 13 percent because they weren’t medically necessary and the rest when providers submitted bills that lacked documentation showing why the shot was needed or when the procedure was improperly coded. In some cases, according to the audit, multiple shots were given in close intervals with no evidence they were relieving pain.

“Unfortunately, universally accepted guidelines regarding the number of spinal interventions deemed excessive do not currently exist,” researchers at the University of Colorado said in a study published this month in the Spine Journal.

Limiting Shots

The North American Spine Society this year suggested a maximum of four injections within six months for cervical epidurals, adding that setting “an absolute limit” on the number “would seem inappropriate and may overly restrict some patients from receiving necessary and reasonable care.”

The guidelines for pain management from the American Society of Anesthesiologists make no mention of how many shots are appropriate. The Mayo Clinic in Rochester, Minnesota, tells patients shots are usually restricted to a few annually because steroids can weaken spinal bones and nearby muscles and upset the natural hormone balance, leading to potentially serious medical conditions. The risk of side effects may increase with the number of steroid injections, the clinic warns on its website.

The study by the Colorado researchers, who mined a database of insurance payments to more than 12 million people, found one patient who was billed for 51 epidural injections in a year. A New Jersey man who received 13 of the shots in a five-month period after injuring his spine in a car accident said they caused him to suffer kidney failure, according to a lawsuit filed in state court last year.

--Editors: Anne Reifenberg, Gary Putka

To contact the reporter responsible for this story: David Armstrong in Boston at darmstrong16@bloomberg.net

To contact the editor responsible for this story: Gary Putka at gputka@bloomberg.net