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Study Questions Need to Operate on Disk Injuries

By GINA KOLATA

People with ruptured disks in their lower backs usually recover whether or not they have surgery, researchers are reporting today. The study, a large trial, found that surgery appeared to relieve pain more quickly but that most people recovered eventually and that there was no harm in waiting.

And that, surgeons said, is likely to change medical practice.

The study, published in *The Journal of the American Medical Association*, is the only large and well-designed trial to compare surgery for sciatica with waiting.

The study was controversial from the start, with many surgeons saying they knew that the operation worked and that it would be unethical for their patients to participate in such a study.

In the end, though, neither waiting nor surgery was a clear winner, and most patients could safely decide what to do based on personal preference and level of pain. Although many patients did not stay with their assigned treatment, most fared well with whatever treatment they had.

Patients who had surgery often reported immediate relief. But by three to six months, patients in both groups reported marked improvement.

After two years, about 70 percent of the patients in the two groups said they had a "major improvement" in their symptoms. No one who waited had serious consequences, and no one who had surgery had a disastrous result.

Many surgeons had long feared that waiting would cause severe harm, but those fears were proved unfounded.

"I think this will have an impact," said Dr. Steven R. Garfin, chairman of the department of orthopedic surgery at the University of California, San Diego. "It says you don't have to rush in for surgery. Time is usually your ally, not your enemy," Dr. Garfin added.

As many as a million Americans suffer from sciatica, said Dr. James Weinstein, a professor of orthopedic surgery at Dartmouth who led the study. The condition is characterized by an often agonizing pain in the buttocks or leg or weakness in a leg.

It is caused when a ruptured disk impinges on the root of the sciatic nerve, which runs down the back of the leg. And an estimated 300,000 Americans a year have surgery to relieve the symptoms, Dr. Weinstein said.

Patients are often told that if they delay surgery they may risk permanent nerve damage, perhaps a weakened leg or even losing bowel or bladder control. But nothing like that occurred in the two-year study comparing surgery with waiting in nearly 2,000 patients.

The study did not include people who had just lower back pain, which can have a variety of causes. Nor did it include people with conditions that would require immediate surgery like losing bowel or bladder control.

Instead, they were typical of a vast majority of people with sciatica who are made miserable by searing pain. For such patients, fear that delaying an operation could be dangerous “was the 800-pound gorilla in the room,” said Dr. Eugene J. Carragee, professor of orthopedic surgery at Stanford.

Dr. Carragee said that he had never believed it himself, but that the concern was widespread among patients and doctors.

“The worry was not knowing,” he added. “If someone had a big herniated disk, can you just say, ‘Well, if it’s not bothering you that much, you can wait?’ It’s kind of like walking on eggshells. What if something terrible did happen?”

With the new results, it is clear that the risk of waiting “is, if not extraordinarily small, at least off the radar screen,” Dr. Carragee said.

The study involved 13 spine clinics in 11 states. All the participants had pain from herniated disks and leg pain. The patients were asked whether they would allow the researchers to decide their treatment at random. Those who did not have surgery generally received physical therapy, counseling and anti-inflammatory drugs.

In the end, the study could not provide definitive results on the best course of treatment because so many patients chose not to have the treatment that they had been randomly assigned.

About 40 percent of those assigned to surgery decided not to have it, often because their conditions improved while they awaited the operations. A third of patients assigned to wait decided to have operations, often because their pain was so bad that they could not endure it any longer.

Others asked not to be assigned at random and were followed to see what treatment they chose and how they fared.

The researchers are also conducting a separate analysis on the cost effectiveness of surgery compared with waiting. Although that analysis has not been published, Dr. Anna N. A. Tosteson of Dartmouth, an author of the study, said that Medicare paid a total of \$5,425 for the operation and that private insurers might pay three to four times that.

Although the results answered one question, about the safety of waiting, they were also, in a sense, disappointing, said Dr. David R. Flum, a contributing editor at The Journal of the American Medical Association and an associate professor of surgery at the University of Washington.

“Everyone was hoping the study would show which was better,” Dr. Flum said.

“And everyone was surprised by the tremendous number of crossovers in both directions,” he added, referring to the large number of participants who changed from surgery to waiting and vice versa.

That muddied the data.

Sciatica tends to run in families and occurs when the soft gel-like material inside a spinal disk protrudes through the outer lining of the disk like a bubble on a bicycle tire. That compresses and inflames a nerve root that forms the sciatic nerve.

The resulting pain can feel like a burning fork in the buttocks, Dr. Weinstein said. Or it can be a searing pain down the back of a leg. The pain can be so intense that some people cannot walk. Some cannot sit. Some, Dr. Weinstein said, “can barely crawl.”

The operation is quick and generally effective, Dr. Garfin said. It involves gently pushing the compressed nerve root away from the herniated disk. Then the surgeon makes an incision in the disk and deflates it. The nerve returns to its normal position, the inflammation goes away, and the pain often disappears.

The Journal of the American Medical Association published two papers on the study, one reporting on the randomized trial and the other on the patients who chose not to be randomized. It also published editorials by Dr. Carragee and Dr. Flum.

The reason for all the attention, Dr. Flum explained, was that the study was large and well designed, that its authors had no conflicts of interest, and, “We can learn a lot.”

The message, in the end, Dr. Weinstein said, was that no matter which treatment a patient received, “nobody got worse.”

He added, “We never knew that until we did the study.”