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MEDICAL TREATMENT: WHAT WORKS AND WHAT DOESN'T

TAKING OUR PULSE

If you have been following the media, both mass media and medical sources, you have probably noticed an onslaught of research and articles casting doubt on the effectiveness of many medical interventions. Some of these studies have been highlighted in this very newsletter. Many “standard” and highly-regarded medications, procedures and surgeries have been cast into doubt, generating concern on the part of both patients and physicians. Why is this happening and how should we react to it?

JUST WHAT THE DOCTOR ORDERED

Research methodologies and the tools of statistical analysis have advanced significantly over the last few decades. Emerging treatments are now subject to careful evaluations through sophisticated randomized, blinded, controlled trials. But many older interventions were never rigorously studied in this way. Skeptical scientists are now “catching up” by applying the same evidence-based approach to a variety of traditional therapies. In this process, we are seeing challenges to the conventional wisdom, as the following examples will reveal.

- A. Epidural steroid injections, facet blocks and other injections into the spine are frequently performed to relieve back pain, but...

Spinal Injection Therapy for Low Back Pain

“Among the internationally available multidisciplinary guidelines on low back pain, only one guideline, from Belgium, recommends injection therapy. Guidelines from the United States, Europe, Italy, and the United Kingdom do not recommend injection therapy for chronic low back pain. Instead, they recommend brief education about low back pain back schools (ie, school-based education and skills programs, including exercises, supervised by a paramedical therapist or medical specialist), NSAIDs, opioid analgesics, back exercises, spinal manipulative therapy, multidisciplinary rehabilitation, and behavioral therapy.

Based on available literature, injection therapy for low back pain and sciatica can be regarded as having limited clinical benefit. The reported guidelines indicate that clinicians currently have other more evidence-based and noninvasive treatment options at their disposal, such as NSAIDs in the acute phase and supervised exercise therapy and multidisciplinary rehabilitation in the chronic phase. Patients with low back pain differ in their clinical presentation and any respond differently to treatments. Injection therapy of any kind may be beneficial in individual cases or subgroups. Nevertheless, given the weak scientific evidence base and the availability of noninvasive and more effective alternatives, physicians and policy makers should not recommend the use of injection therapy for patients with low back pain and sciatica.”¹

- B.** Spine surgery, and particularly spinal fusion, has increased dramatically in recent years, but research has not always confirmed the value of these extensive procedures.

Surgery Versus Nonsurgical Treatment of Lumbar Spinal Stenosis

“Background: Primary care management decisions for patients with symptomatic lumbar spinal stenosis (LSS) are challenging, and nonsurgical guidance is limited by lack of evidence.

Objective: To compare surgical decompression with physical therapy (PT) for LSS and evaluate sex differences.

Design: Multisite randomized, controlled trial.

Conclusion: Surgical decompression yielded similar effects to a PT regimen among patients with LSS who were surgical candidates. Patients and health care providers should engage in shared decision-making conversations that include full disclosure of evidence involving surgical and nonsurgical treatments for LSS.”²

Long-term Outcomes of Lumbar Fusion Among Workers’ Compensation Subjects, A Historical Cohort Study

“Conclusion: Lumbar fusion for the diagnoses of disc degeneration, disc herniation, and/or radiculopathy in a WC setting is associated with significant increase in disability, opiate use, prolonged work loss, and poor RTW status.”³

Fusion for Lumbar Spinal Stenosis – Safeguard or Superfluous Surgical Implant?

“Both trials show clearly that for most patients, stenosis surgery should be limited to decompression when no overt instability is present. Evidence from the suggests that fusion for the treatment of stenosis is no longer the best practice and that its use should be restricted to patients who have proven spinal instability, as confirmed on flexion-extension radiographs; vertebral destruction caused by trauma, tumors, infections, or spinal deformities, such as congenital spondylolisthesis or adult scoliosis, or neuroforamen stenosis with compressed exiting nerves caused by postsurgical disk collapse. Fusion might even be debatable for neuroforamen stenosis caused by disk

collapse after failed initial surgery, because evidence to support fusion for this indication is lacking.

The goal of surgery in lumbar spinal stenosis is to improve walking distance and to relieve pain by decompression of nerve roots. The addition of instrumented fusion – ‘just to be sure’ – for the treatment of the most frequent forms of lumbar spinal stenosis does not create any added value for patients and might be regarded as an overcautious and unnecessary treatment.”⁴

- C. Knee conditions, which may be acute or chronic, are being treated with various modalities:
- viscosupplementation (injections of hyaluronic acid [Synvisc, Hyalgan] to lubricate the joint)
 - meniscectomy for meniscal tears
 - arthroscopic debridement and lavage for arthritis.

Viscosupplementation for Osteoarthritis of the Knee, A Systematic Review of the Evidence

“Background: The purpose of this analysis was to determine the clinical significance of injectable hyaluronic acid (HA) in the treatment of knee osteoarthritis, and to assess which trial-level factors influence the overall treatment effect of HA on pain.

Conclusions: Meta-analysis of only the double-blinded, sham-controlled trials with at least sixty patients did not show clinically important differences of HA treatment over placebo. When all literature was added to the analysis, the overall effect was greater but was biased toward stronger treatment effects because of the influence of nonblinded or improperly blinded trials.”⁵

Exercise therapy versus arthroscopic partial meniscectomy for degenerative meniscal tear in middle aged patients: randomized controlled trial with two year follow up

“Conclusion: The observed difference in treatment effect was minute after two years of follow-up, and the trial’s inferential uncertainty was sufficiently small to exclude clinically relevant differences. Exercise therapy showed positive effects over surgery in improving thigh muscle strength, at least in the short term. Our results should encourage clinicians and middle aged patients with degenerative meniscal tear and no definitive radiographic evidence of osteoarthritis to consider supervised exercise therapy as a treatment option.”⁶

We cannot recommend performing arthroscopy with lavage and/or debridement in patients with a primary diagnosis of symptomatic osteoarthritis of the knee

“Collectively all three included studies did not demonstrate clinical benefit of arthroscopic debridement or lavage. The work group also considered the potential risks to patients (anesthesia intolerance, infection, and venous thrombosis) associated with surgical intervention.

It was agreed that the lacking evidence for treatment benefit and increased risks from surgery were sufficient reasons to recommend against arthroscopic debridement and/or lavage in patients with a primary diagnosis of osteoarthritis of the knee.”⁷

In summary, these studies, and others, reflect the evolution in scientific scrutiny of many well-established procedures that we may choose to discard as they are found to be ineffective in all cases (or in specific circumstances).

This may be objectionable to some physicians (and patients) whose anecdotal experience leads them to question the research. It may also be a source of conflict in litigated cases. However, as specialty societies, such as the American Academy of Orthopaedic Surgeons, publish consensus guidelines dealing with these topics, the weight of expert, clinical, peer-reviewed evidence should prevail.

Broadspire’s Utilization Review and Physician Review Services (PRS) departments are available to review requests for surgery and other interventions, and to conduct peer-to-peer discussions with treating physicians concerning these issues.

CIRCULATING IN THE PRESS

Why “Useless” Surgery is Still Popular

“The expectation is that medical practice will change if an operation turns out not to help.

If only.

It looks as if the onus is on patients to ask what evidence, if any, shows that surgery is better than other options.

Take what happened with spinal fusion, an operation that welds together adjacent vertebrae to relieve back pain from worn-out discs. Unlike most operations, it actually was tested in four clinical trials. The conclusion: Surgery was no better than alternative nonsurgical treatments, like supervised exercise and therapy to help patients deal with their fear of back pain. In both groups, the pain usually diminished or went away.

The studies were completed by the early 2000s and should have been enough to greatly limit or stop the surgery, says Dr. Richard Deyo, professor of evidence-based medicine at the Oregon Health and Sciences University. But that did not happen, according to a recent report. Instead, spinal fusion rates increased – the clinical trials had little effect.

In 2009, the prestigious New England Journal of Medicine published results of separate clinical trials on a popular back operation, vertebroplasty, comparing it to a sham procedure. They found that there was no benefit – pain relief was the same in both groups. Yet it and a similar operation, kyphoplasty, in which doctors inject a sort of cement into the spine to shore it up, continue to be performed.

Dr. David Kallmes of the Mayo Clinic, an author of the vertebroplasty paper, said he thought doctors continued to do the operations because insurers pay and because doctors remember their own patients who seemed better afterward.

The latest controversy – and the operations that arguably has been studied the most in randomized clinical trials – is surgery for a torn meniscus, a sliver of cartilage that acts as a shock absorber in the knee. It's a condition that often afflicts middle-aged and older people, simply as a consequence of degeneration that can occur with age and often accompanying osteoarthritis. The result can be a painful, swollen knee. Sometimes the knee can feel as if it catches or locks. So why not do an operation to trim or repair the torn tissue?

About 400,000 middle-aged and older Americans a year have meniscus surgery. And here is where it gets interesting. Orthopedists wondered if the operation made sense because they realized there was not even a clear relationship between knee pain and meniscus tears. When they did MRI scans on knees of middle-aged people, they often saw meniscus tears in people who had no pain. And those who said their knee hurt tended to have osteoarthritis, which could be the real reason for their pain.

Added to that complication, said Dr. Jeffrey N. Katz, a professor of medicine and orthopedic surgery at Harvard Medical School, is the fact that not everyone improves after the surgery. "It is not regarded as a slam-dunk," he said. As a result, he said, many doctors have been genuinely uncertain about which is better – exercise and physical therapy or surgery. That, in fact, was what led Dr. Katz and his colleagues to conduct a clinical trial comparing surgery with physical therapy in middle-aged people with a torn meniscus and knee pain.

The result: The surgery offered little to most who had it. Other studies came to the same conclusion, and so did a meta-analysis published last year of nine clinical trials testing the surgery. Patients tended to report less pain – but patients reported less pain no matter what the treatment, even fake surgery."⁸

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