EDITORIAL

EBM based risk management of spine surgery

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One of the major scientific triumphs of the twentieth century was the adoption of Evidence-based Medicine (EBM) concepts for medical research. Indeed, for scientists and physicians of our generation, systematic reviews, meta-analyses, and clinical guidelines are all part of our scientific landscape, it's hard to believe that prior to the passage of the United States' Kefauver-Harris Amendment in 1962, human clinical trials for new drugs and medical devices were not even a legal requirement for obtaining FDA approval (FDA). However, unlike some of the classic studies in medical specialties that have resulted in significant improvements, the history of clinical trials in surgical specialties has been considerably less spectacular, owing to the inherent difficulties in randomizing and blinding surgical patients. This is especially true in the case of spine surgery.

Although there are a variety of approaches to reconciling the seemingly contradicting outcomes of these two trials in terms of the clinical effectiveness of lumbar fusion, a few points should be made. The Swedish research did not take pre-operative flexion–extension x-rays to assess segmental instability, which is a substantial departure from the great majority of spine surgeons' conventional practice. Although 90 percent of the fusion surgeries were instrumented posterior-lateral fusions, only six instances were subjected to inter-body fusion, according to the study's supplementary appendix. It's worth noting that, at least in North America, an inter-body cage is used in a large percentage of instrumented lumbar fusion surgeries, which has been linked to higher fusion rates and better foraminal height and segmental lordosis restoration.

Furthermore, when compared to open procedures, a significant portion of these procedures are performed using a minimally invasive approach, which has been linked to lower perioperative blood loss and hospital stay, less tissue damage to the paraspinal muscles, and possibly better long-term functional outcomes, particularly in the case of back pain. As a result, it could be reasonably argued that the Swedish study only demonstrated that if patients with lumbar stenosis are selected for fusion without a standard protocol for investigating spinal instability and are operated on with old techniques that do not include inter-body fusion or minimally invasive strategies, the outcomes of such inadequately specified fusions are no distinct than either decompression by itself.

In contrast, the North American study found that, even when patients with documented instability are excluded and only patients with stable grade 1 spondylolisthesis are considered, instrumented fusion combined with decompression appears to be associated with lower rates of re-operation and slightly better long-term quality of life outcomes. Despite the limits imposed by its brevity, the current study offers some valuable insights into the search for empirical evidence in spine surgery. Prospective randomised clinical trials in spine surgery are complex not just in terms of design and execution, but also in terms of interpretation. The issue of how to interpret low-quality information in illnesses linked with high morbidity rates, as demonstrated by STASCIS, appears to be even more difficult. Although we have high-quality scientific data in a few key areas of spine surgery, particularly when contemplating novel spinal devices, we are definitely in the early phases of our search for high-quality scientific evidence for the majority of our everyday procedures. May we never forget that the quality of the process by which we make daily judgments while the data is still lacking is just as vital as, if not more important than, our eventual goals in such a praiseworthy scientific endeavour.

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