The development and clinical testing of new devices and technology can be an exciting experience. The mere possibility that we may be able to influence or radically change the ways in which treatments and outcomes might influence a patient’s life is exhilarating. Could a new device or technology change a decades-old approach to a clinical problem? The clinical, financial and social impact of such change and development is staggering. Therefore, the importance of responsible and unbiased reporting is ever so critical when introducing a new medical device or technology.

Unfortunately, the authors of this study appear to have been overwhelmed by their enthusiasm of using recombinant human bone morphogenetic protein type 2 (rhBMP-2) and a cylindrical cage through a posterior lumbar interbody fusion (PLIF) approach. There are lengthy discussions of various trends throughout this study, which imply the superiority of rhBMP over autograft. However, one fact remains: in every clinical measure examined in this study, there were no statistically superior outcomes in the rhBMP group except one, and the clinical significance of this one statistically significant finding is unclear. The authors claimed statistical significance in the measure of back pain using a visual analog scale. However, within the time-honored Oswestry scales there was no statistical difference in postoperative back pain between the two groups. If the visual analog findings are truly of statistical importance, why was there no consistency between the two measures?

This was designed to be a large multicenter study, but when the investigators began to see bone growing into the spinal canal, “Out of abundant caution, investigators suspended enrollment.” The authors fail to mention any role the US Food and Drug Administration may have had in suspending enrollment in the study. In fact, the only other statistically superior outcomes in the rhBMP group except one, and the clinical significance of this one statistically significant finding is unclear. The authors claimed statistical significance in the measure of back pain using a visual analog scale. However, within the time-honored Oswestry scales there was no statistical difference in postoperative back pain between the two groups. If the visual analog findings are truly of statistical importance, why was there no consistency between the two measures?


COMMENTARY

Neil Kahanovitz, MD, Philadelphia, PA

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this statistically significant variable present in the majority of their patients.

The authors discuss the degree and extent of postoperative graft site pain extensively. However, when asked if they would undergo surgery again, 69% of the investigational group responded positively compared with 83% of the control patients; the very same group of patients undergoing iliac crest bone graft harvest. Much like the rest of the data, these percentages showed no statistical significance, and the clarity of their conclusions based on these trends obviously needs to be tempered.

It is easy to get caught up in the exciting possibilities of new technology and devices. But let us all beware that solid scientific data must prevail. Solid science does not reside in trends. It is dependent on statistically significant data.


RESPONSE TO COMMENTARY
Charles L. Branch, Jr., MD

As a coauthor of this paper and a deputy editor of The Spine Journal, I am pleased to have the opportunity to respond to my colleague’s commentary. This manuscript underwent a very critical review, and this process enhanced the quality of the final manuscript. This process also reminds all of us that the interpretation of sets of data may and will be affected by the individual bias of the interpreter. As physician scientists, we are obligated to collect and report data scientifically and accurately. We are also obliged to vigorously debate the interpretation of data in order to derive the greatest good for our patients and the advancement of medicine.

This report documents one of but a few prospective, randomized, controlled clinical trials of a spinal fusion technique. In the field of evidence-based medicine, this would be recognized as Class 1 data or evidence, of which there is a paucity in the spine fusion literature. These data were collected scientifically and accurately in a Food and Drug Administration–monitored clinical investigation supported by the device manufacturer. We believe that these are quality data that must be published and subjected to interpretation and vigorous debate.

This manuscript includes interpretation of the data by the authors. Certainly the possibility of having a substance that precludes the use of harvested iliac crest autograft and that enhances the fusion process is desirable and unquestionably biases our interpretation of the data. The fact that this substance has limited commercial availability would unquestionably stimulate interpretive bias from a competitive perspective. The analysis and debate that follows is very healthy and important.

We believe that our discussion does reflect the reality of the data. Stand-alone threaded cylindrical posterior interbody fusion cages have been recognized to have significant limitations, and this awareness in the surgeon investigator group led to the cessation of enrollment in this study. Harvesting iliac crest for graft material from a posterior approach is associated with increased pain and morbidity. The bone formation in the spinal canal in the recombinant human bone morphogenetic protein type 2 (rhBMP-2) group was statistically significant when compared with the control group, yet this appeared to have little or no impact on clinical outcome. In fact, the rhBMP-2 group had superior clinical outcome by some measures. Perhaps most important is our belief that this small series should be considered as a pilot study the encouraging but not conclusive results of which should prompt, not discourage, further studies investigating the role of rhBMP-2 in a posterior interbody fusion technique.