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FUNDING SOURCE AND CLINICAL TRIAL OUTCOME

In the paper published in the December 2008 issue of *The American Journal of Orthopedics* “The Roles of Funding Source, Clinical Trial Outcome, and Quality of Reporting in Orthopedic Surgery Literature” (2008;37(12):E205-212), Khan and colleagues¹ analyzed 100 original randomized clinical trials reported in 5 journals (*Journal of Bone and Joint Surgery—American Volume [JBJS Am]*, *Spine*, *Journal of Arthroplasty*, *Journal of Orthopaedic Trauma*, and *American Journal of Sports Medicine*) over 2 years (2002-2004). A significant positive association between reported clinical trial outcome and funding source in the orthopedic surgery literature across subspecialties was observed. The authors stated that large, prospective, multicenter collaborative trials that involve hundreds of patients and critically evaluate treatments are ultimately the goal for orthopedic clinical research. They noted that these trials will redefine practice and change patient care—effects similar to those in the medical subspecialties.

We disagree that large, prospective, multicenter collaborative trials that involve hundreds of patients and critically evaluate treatments are a guarantee of valid results and instead find that such trials’ results certainly may leave room for questions. We do so in light of significant shortcomings that were found within several similarly organized studies published in leading orthopedic journals (including those journals that were included in the analysis of Khan and colleagues).

Moreover, we would like to draw attention to correspondence we have published in recent years in other journals (*Spine*, *JBJS Am*, *American Journal of Neuroradiology*) in regard to several large-scale studies on use of rhBMP-2 in spine procedures, wherein we raised questions of methodology and findings.²⁻⁶

We sincerely welcome the authors’ warnings about the impact that funding sources for clinical research in orthopedic surgery may have on clinical judgments and practice and also their suggestions on how to minimize the influence of the financial support in the future.

To conclude, we believe that large, prospective, multicenter collaborative trials are not a guarantee of valid results and instead find that such trials’ results may well be open to question.

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Tomislav Smoljanovic, MD, PhD
Igor Smigovec, MD
Ivan Bojanic, MD, PhD
Zagreb, Croatia

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AUTHORS’ REPLY

We read with great interest the comments by Smoljanovic and colleagues. We would like to thank them for their input and observations, but we are at a loss to understand the relevance of their concerns to the scientific content of our paper entitled “The Roles of Funding Source, Clinical Trial Outcome, and Quality of Reporting in Orthopedic Surgery Literature” (*Am J Orthop*.2008;37(12):E205-E212).

Furthermore, the issues that they have raised in their current letter were also presented by them in another forum¹ and were answered comprehensively. The contents of that prior letter and of the associated response also have no bearing on the conclusions drawn in our paper.

We would be eager to respond to Smoljanovic and colleagues for any concerns they have that are specific to the hypothesis, methods, results, and conclusions clearly stated within the confines of our paper and not on issues pertaining to some of the clinical trials that formed the study cohort in our paper. Again, we thank Smoljanovic and colleagues for their interest.

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Safdar N. Khan, MD, Sacramento, California
Harvinder S. Sandhu, MD, New York, New York

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(Continued on page 585)