Clinical: Prosthesis

40

Meta-analysis of Lumbar Total Disc Replacement FDA-regulated Trials: A Missed Opportunity

Z. Hyder¹, D.D. Ohnmeiss¹, R.D. Guyer², S.L. Blumenthal², J.E. Zigler²

¹Texas Back Institute Research Foundation, Plano, TX, United States, ²Texas Back Institute, Plano, TX, United States

Introduction: In this new era of healthcare with increasing demands for evidence-based medicine and comparative effectiveness, the need for meta-analyses of level I trials is great. It would seem that one source of data for such analyses would be the large-scale United States Food and Drug Administration (FDA) regulated trials for new spinal implants. Our goal was to apply meta-analysis techniques to data from such trials. However, although on the surface the studies seemed very similar, when evaluating the details, such an analysis was not really valid. The purpose of this study was to describe problems encountered when trying to work with data from seemingly similar studies, but with very different details.

Methods: Three lumbar total disc replacement (TDR) studies were evaluated, using data gathered from their FDA Investigational Device Exemption trials in an attempt to perform a meta-analysis. These include the ProDisc-L (Synthes Spine; Westchester, PA), Charite Artificial Disc (DePuy Spine; Raynham, MA), and Kineflex-L Artificial Disc (Spinal Motion; Mountain View, CA). Details from the Maverick study were not available at the time this abstract was prepared.

Results: Patient selection criteria were similar for the studies and all were designed to be Level I prospective, randomized, multicenter trials. The control groups varied significantly. All three studies reported Oswestry Disability Index (ODI), visual analog scales (VAS) to assess pain intensity, satisfaction, and a multi-component definition for successful outcome. However, two studies used version 1 of the ODI, another used the chiropractic version which has been found to have distinctly different psychometric characteristics. Comparing the VASs used, two had scales from 0 to 100 and the other from 0 to 10. While these can be adjusted, the greater problem is that one study evaluated back and leg pain separately in two questions, while the others combined these symptoms into one question. Also problematic is that in those two studies, the time period over which patients were asked to indicate their average pain intensity was different. While all three studies evaluated patient satisfaction, a different method was used in each. The details in how adverse events and re-operations also varied in the studies. The number and details of the components used to define a successful outcome for an individual patient varied across the three trials as well.

Conclusions: An attempt was made to use meta-analysis techniques to evaluate data from FDA-regulated trials for three lumbar TDR devices versus fusion. However, this could not be accomplished and represents a great missed opportunity to learn much from these large prospective, randomized trials. Although on the surface it appeared all studies used ODI, VAS, and satisfaction as outcome measures, there were differences in the actual instruments used as well as definitions applied to success and other measures. It is hoped that increasing awareness of the problems of using non-validated or altered versions of questionnaires will result in a greater effort to use standardized instruments to allow data pooling and comparisons across multiple studies in order to facilitate addressing the increasing demand for evidence and comparative effectiveness in spine surgery.