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The authors respond

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The letter raises some important issues regarding the interpretation of the results of the SPORT study. As the writer points out, there were no statistically significant differences in the Intention-to-Treat (ITT) analyses for the primary outcomes between the groups randomized to surgery and to non-operative treatment. As pointed out in the article¹ the interpretation of this result is complicated by the high rates of cross-over which resulted in only small differences in treatment received between the two randomly assigned groups; therefore it is not surprising that there were not statistically significant differences in outcomes between the ITT groups. Interestingly, ITT analyses showed statistically significant advantages for the secondary outcomes of sciatica bothersomeness, satisfaction with symptoms, and self-rated improvement were seen out to 8 years despite these high levels of treatment crossover.

Given the limitations of the intention-to-treat analyses, adjusted as-treated analyses were performed in which patients were analyzed according to the treatment actually received. As also pointed out in the article, these analyses are no longer of randomly assigned groups, therefore the strong protection against confounding is no longer present – in other words the observed treatment groups are not balanced on baseline factors and the outcomes in these groups may represent a combination of baseline differences between the groups and the effects of treatment. The adjusted as-treated analyses used sophisticated statistical models to try to control for baseline differences affecting the treatment received, including age, baseline score, treatment center, gender, race, marital status, worker's compensation, smoking status, herniation location, working status, stomach comorbidity, depression, diabetes, self-rated health trend, duration of most recent episode, pre-randomization treatment preference, and other comorbidities (this category included any of the following patient self-reported comorbidities: stroke, osteoporosis, cancer, fibromyalgia, chronic fatigue, PTSD, alcohol, drug dependency, heart, lung, liver, kidney, blood vessel, nervous system, hypertension, migraine, anxiety, and bowel problems).

Thus, the specific differences in baseline scores pointed out in the letter were adjusted for in these analyses. In any non-randomized comparison there remains the possibility of residual confounding by unmeasured factors that might differ between the groups and the results of the adjusted as-treated analyses must be interpreted accordingly. However, given the high rates of cross-over, ITT and other possible randomized methods of comparison² were too

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biased or imprecise to provide useful estimates, and we believe that the adjusted analyses represent the best available evidence for the treatments studied in SPORT

In terms of predictors of better relative response to surgery compared to non-operative treatment, a separate analysis looking specifically at that question found statistically significant greater advantage to surgery at 8 years among patients with IDH who had sequestered fragments on MRI, higher levels of baseline back pain accompanying radiculopathy, a longer duration of symptoms, and those who were neither working nor disabled at baseline.³ These were, however, subgroup analyses and therefore must also be interpreted cautiously.

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