Five-Year Results of Cervical TDR vs ACDF

Written by Mary Beth Nierengarten

Although anterior cervical discectomy and fusion (ACDF) has traditionally been the standard surgical treatment for symptomatic cervical degenerative disc disease (DDD), the literature suggests that the efficacy is decreased and the complication rates increased when ACDF is used at 2 contiguous levels vs 1 level. Few data currently exist that compare the effectiveness of 1-level total disc replacement (TDR) with 2-level TDR.

Hyun W. Bae, MD, Cedars-Sinai Spine Center, Los Angeles, California, USA, presented the 60-month follow-up results from the pivotal LDR Spine USA Mobi-C® Cervical Disc Prosthesis IDE clinical trial [NCT00389597] that compared patient outcomes between 1- and 2-level ACDF and between 1- and 2-level TDR.

The single-blind, prospective, randomized, multicenter trial compared ACDF to TDR in patients who were diagnosed with symptomatic cervical DDD at 1 or 2 levels of the cervical spine with no previous cervical fusions. A Food and Drug Administration (FDA) Investigational Device Exemption was obtained to conduct the study.

The trial was conducted at 24 sites in the United States, with all sites performing both 1- and 2-level procedures and both TDR and ACDF procedures. In the phase 3 trial, the patients were randomized in a 2:1 fashion in the 1-level arm (TDR = 164; ACDF = 81) and in the 2-level arm (TDR = 225; ACDF = 105).

The outcomes measured included the neck disability index (NDI), neck and arm pain as measured with the visual analog scale (VAS), patient satisfaction, patient recommendation to others for this surgery, SF-12 Mental and Physical Health Composite Scores, adverse events representing major complications, subsequent surgery rates, and overall success rate. Outcome measurements were collected prior to surgery and after surgery at week 6, and months 3, 6, 12, 18, 24, 36, 48, and 60. The follow-up rate at 60 months was 88.5% in the TDR group and 83.1% in the ACDF group.

The NDI scores were nearly equivalent for 1-level and 2-level TDR and 1-level ACDF. However, for 2-level ACDF, at about 24 months the scores became worse and this became significant at months 36, 48, and 60 ($P < .05$). The VAS scores were also higher at months 36, 48, and 60 with 2-level ACDF. Although patient satisfaction was high (> 90%) for all groups at all time points, it was somewhat lower for 2-level ACDF, as was the likelihood the patient would recommend the operation.

There was no difference in the rate of complications with TDR in the patients who had it performed at 1 or 2 levels. The overall success rate was higher with TDR than with ACDF performed at 1 or 2 levels at months 24, 36, 48, and 60, while the success rate with ACDF declined when it was performed at 2 levels vs 1 ($P < .05$).

In this trial, there was no significant reduction in efficacy with TDR as the number of levels treated with Mobi-C increased from 1 to 2 levels. However, in patients treated with ACDF, there was a reduction in treatment effect when the number of levels increased from 1 to 2. The long-term results of this trial continue to demonstrate the Mobi-C is safe and effective, concluded Dr Bae.

RISCIS: Phase 3 Trial on Off-Label Use of Riluzole for SCI

Written by Mary Beth Nierengarten

Acute spinal cord injury (SCI) is a devastating injury that can be the result of varying traumatic mechanisms. While early surgical decompression and different pharmacological agents have been advocated over the years, it is still unclear how effective these treatments are in improving neurological outcomes. Thus, there is a continued need for further work in this area.

Michael G. Fehlings, MD, University of Toronto, Toronto, Ontario, Canada, described the rationale and design of the ongoing Riluzole in Spinal Cord Injury Study [RISCIS; NCT01597518], a phase 3, multicenter, double-blind, randomized controlled trial to evaluate the efficacy and safety of off-label use of riluzole to treat patients with acute SCI. The trial was initiated based on the preliminary data from the phase 1/2a trial [NCT00876889] showing the safety and efficacy of riluzole in this setting. This established the feasibility of a multicenter trial to evaluate riluzole for traumatic SCI.

The phase 1/2a trial compared 36 patients with traumatic SCI treated with riluzole and 36 control patients in a registry cohort but did not find a significant difference in complications between the groups (Table 1).

In addition, the study found no between-group difference in the percent conversion of the American Spinal Injury Association Impairment Scale grade (Figure 1).

Based on these preliminary results, the ongoing phase 3 trial [NCT01597518] will evaluate the safety and efficacy of riluzole in the treatment of traumatic SCI. The primary outcome of the study is the change in the International Standards for Neurological Classification of SCI (ISNCSCI) total motor score from baseline to 180 days. Secondary outcomes are measures of ISNCSCI grade, ISNCSCI sensory scores, spinal cord independence measure, Short Form-36 Health Survey version 2.0, EuroQol health outcomes measure, pain numeric rating scale, and graded and redefined assessment of strength, sensibility, and prehension.

Table 1. Complications in the Riluzole Registry Groups

	Riluzole (n = 36)		Registry (n = 36)		
	Patients, no.	Incidence, %	Patients, no.	Incidence, %	*P* Value
Infection	14	0.389	13	0.361	.81
Pulmonary	11	0.306	16	0.444	.22
Neuropsychiatric	10	0.278	10	0.278	1.00
Hematological	7	0.194	9	0.250	.57
Cardiovascular	5	0.139	11	0.306	.09
Gastrointestinal/genitourinary	5	0.139	9	0.250	.19
Skin	4	0.111	3	0.083	.69

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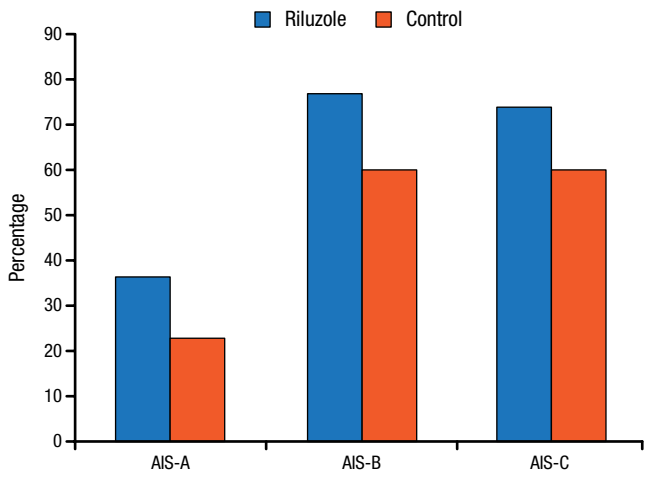
Figure 1. Percent Conversion of AIS Grade



AIS, American Spinal Injury Association Impairment Scale.
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Enrollment into the phase 3 trial began in January 2014. Patients with acute traumatic SCI (n = 351) from 35 international sites will be randomized in a 1:1 fashion to riluzole 100 mg BID for 24 hours, followed by riluzole 50 mg BID for 13 days after the injury or to the same dosing regimen of placebo.

Patients included in the study must be able to receive the study drug within 12 hours of injury, have an ISNCSCI impairment scale grade of A, B, or C, and have a neurological level of injury C4 to C8 based on the first ISNCSCI assessment after arrival to the hospital.

Patients excluded from the study are those with an injury arising from a penetrating mechanism and those with significant concomitant head injury.

According to Dr Fehlings, the study will use an adaptive sequential design to allow sample size changes during the interim analysis. To date, the study has enrolled 11 patients. Dr Fehlings hopes to come up with a neuroprotective strategy that could influence clinical practice in treatment of SCI.

Pseudarthrosis Increased After Unilateral-Instrumented TLIF for Lumbar Spondylosis

Written by Mary Beth Nierengarten

Although the use of either unilateral or bilateral segmental pedicular instrumentation with transforaminal lumbar interbody fusion (TLIF) is effective in the treatment of lumbar spondylosis, patients who underwent TLIF buttressed by unilateral instrumentation were 7 times more likely to suffer pseudarthrosis and were more likely to require a reoperation.

Jeremy Steinberger, MD, Icahn School of Medicine at Mount Sinai, New York, New York, USA, presented the results of a prospective cohort study that looked at the incidence of complications in patients with lumbar spondylosis who underwent TLIF with either unilateral or bilateral instrumentation.

The study included 80 consecutive patients (40 men and 40 women), with a mean age of 44.2 years (range, 24–68 years). Patients were excluded from the study if they had an infection, tumor, spondylolisthesis, or fracture. All patients underwent 1- or 2-level TLIF between October 2007 and November 2009 for either degenerative disc disease or lumbar spondylosis. All surgeries were performed by the same 2 surgeons.