Anterior Cervical Fusion with Bone-Morphogenic Protein-7 (OP-1): A Prospective Study of its Effects on Postoperative Laryngeal Swelling

Jack Chen, MD, Orange, CA (n), Jeffrey Deckey, MD, Orange, CA (n), Jeffrey Fischgrund, MD, Orange, CA (n), Gregory Carlson, MD, Orange, CA (n)

INTRODUCTION: Recombinant human bone-morphogenic protein-7 (trademark OP-1, Stryker) has shown clinical efficacy in inducing posterolateral fusions in the lumbar spine. Its use in anterior cervical spine surgery, however, has not been described. The purpose of this study is to evaluate the safety of its use in terms of postoperative prevertebral soft-tissue swelling and complications related to airway and swallowing difficulty.

METHODS: 30 consecutive patients were treated with anterior cervical decompression and fusion. All patients were treated with allograft rings packed with OP-1 and stabilized with anterior instrumentation. Lateral radiographs of the cervical spine were taken preoperatively, on postoperative day 2, and on postoperative day 7. We recorded the day of when patients were able to tolerate regular diet. Adverse events related to soft-tissue swelling, including prolonged hospitalization (greater than 48 hours), hospital readmission, or prolonged dysphagia were also recorded.

RESULTS: Nine patients had a 1-level fusion, fourteen patients had 2-level fusions, and seven patients had 3-level fusions. The average preoperative prevertebral soft tissue swelling measured 3.9mm at C3 and 17.8mm at C6. On postoperative day 2, the average measurements were 12.9mm at C3 and 18.4mm at C6. This was compared to previously published control measurements of 12.7mm and 17.3mm. On postoperative day 7, the average swelling measured 10.8mm and 20.1mm, respectively, at C3 and C6. Reported historical controls are 9mm and 18mm.

Twenty-nine patients (97%) were discharged home within 48 hours. Twenty-nine patients (97%) tolerated soft diet on postoperative day one. There were no hospital readmissions. One patient required reintubation and evacuation of a postoperative hematoma. The hematoma was deemed to be due to an arterial bleed. One patient, who had undergone a three level procedure, complained of dysphagia at her four week follow-up. Her dysphagia resolved at her eight week follow-up.

CONCLUSIONS: Our series show that the incidence of soft-tissue swelling complications with the use of rhBMP-7 is low. Furthermore, our measurements of prevertebral swelling after surgery show trends comparable to those reported after anterior fusion with tricortical iliac crest autogenous graft and plate fixation.

If noted the author indicates something of value received. The codes are identified as a - research or institutional support; b - miscellaneous funding; c - royalties; d - stock options; e - consultant or employee; n - no conflicts disclosed and * disclosure not available at the time of printing. For full information, refer to inside cover.

♦ The FDA has not cleared this drug and / or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an “off label” use). For full information refer to the inside back cover.