# CLINICAL CASE SERIES

**Spine** 

# **OPEN** Predictors of Treatment Outcomes in Geriatric Patients With Odontoid Fractures

*AOSpine North America Multi-Centre Prospective GOF Study* 

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**Study Design.** Multicenter prospective cohort study.

**Objective.** To identify patient and treatment characteristics associated with treatment success or failure in the management of odontoid fractures.

Summary of Background Data. Odontoid fractures are the most common cervical spine fractures in the elderly and represent a significant management challenge with widely divergent views regarding operative *versus* nonoperative management.

**Methods.** A total of 159 patients 65 years and older with radiographically confirmed type II odontoid fractures were enrolled at 10 sites in the United States and 1 site in Canada between January 2006 and May 2009. Subjects were followed at 6 and 12 months post–initial treatment with Neck Disability Index and SF-36v2 scores. Final treatment outcome was classified as failure or success. Treatment failure was defined as death by any cause, decline in Neck Disability Index by more than 9.5 absolute points, or occurrence of a major treatment-related complication. Baseline characteristics between the groups were compared using *t* test for the continuous variables and  $\chi^2$  test for the categorical variables.

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Baseline characteristics associated with treatment outcomes were identified by multiple logistic stepwise regression analysis.

**Results.** A total of 101 (63.5%) patients were treated surgically and 58 (36.5%) conservatively. Forty-four (27.7%) patients had a successful outcome and 86 (54.1%) had a treatment failure; for 29 patients (18.2%), treatment status could not be determined (3 withdrew; 26 were lost to follow-up). Twenty-nine (18.2%) patients expired before the 12-month follow-up. Follow-up information was available for 103 of 127 surviving (81.1%) patients. Twelve-month SF-36v2 scores were worse in the failure group. The characteristics associated with treatment failure were older age (odds ratio  $[OR] = 1.08$  for each year of age); initial nonsurgical treatment  $(OR = 3.09)$ ; male sex  $(OR = 4.33)$ , and baseline neurological system comorbidity ( $OR = 4.13$ ).

**Conclusion.** Older age, initial nonsurgical treatment, and male sex are associated with failure of treatment in patients with geriatric odontoid fractures.

Key words: odontoid fracture, type II, geriatric, treatment outcomes, predictors, surgical treatment, conservative treatment. Spine 2013;38:881-886

**OD** dontoid fractures comprise 11% of all traumatic cervical spine injuries, with type II odontoid fractures.<sup>1-3</sup><br>accounting for 40% to 60% of these fractures.<sup>1-3</sup> vical spine injuries, with type II odontoid fractures Within the geriatric population, type II odontoid fractures are the most common cervical spine injury and commonly occur because of low-energy falls to the same level.<sup>4,5</sup> With the geriatric population representing the fastest growing demographic segment in North America, the number of geriatric odontoid fractures is increasing.<sup>6,7</sup> Although geriatric patients generally sustain this injury without neurological damage, these patients often have significant medical comorbidities that increase mortality.<sup>4,7,8</sup> Elderly patients are more likely to experience significant complications as a result of treatment, including nonunion, morbidity, and mortality.<sup>6,9</sup>

Despite type II odontoid fractures being the most common spinal fracture in older adults, there is no consensus on treatment. Previous literature consists primarily of small and uncontrolled cohort studies with varying inclusion criteria that do not allow for direct comparison of surgical and conservative treatment.<sup>7,10</sup> Furthermore, there is a paucity of

information regarding clinical outcomes. Although rates of nonunion have been found to be higher in patients treated conservatively, it is unknown whether a lack of fusion correlates to decreased function and quality of life.<sup>11</sup> There are presently no studies in the literature investigating the factors that cause failure of treatment and result in a poor outcome in elderly patients with type II odontoid fractures.

### **MATERIALS AND METHODS**

A multicenter cohort study was conducted to compare the outcomes after conservative and surgical treatment in patients 65 years and older. Between January 2006 and May 2009, a total of 10 sites in the United States and 1 in Canada prospectively enrolled 159 patients with radiographically confirmed type II odontoid fractures. The key inclusion criteria were type II odontoid fracture; age 65 years and older; stable and unstable fracture patterns; and a cooperative, mentally competent patient without previous odontoid fractures. Patients with pathological fractures and any form of mental incapacity or substance abuse were excluded.

The decision for operative or nonoperative treatment was made by the treating surgeons in each of the centers on the basis of surgeons' and patients' personal preferences. Nonoperative options ranged from skeletal traction, followed by hard or soft collar immobilization, to primary immobilization in a soft or hard collar, to halo immobilization. Operative techniques used were anterior odontoid screw fixation, anterior C1–C2 facet screw fixation, posterior C1 lateral mass and C2 isthmus or pedicle screw fixation, posterior C2–C1 transarticular screw fixation, C1 sublaminar and C2 spinous process wiring (Gallie technique), and Brooks fusion (C1–C2 sublaminar wire placement). Each participant consented for the trial at the time of treatment.

The patient demographics recorded were age, sex, marital status, race, ethnicity, preinjury occupation, preinjury living situation, socioeconomic status, litigation, and workers' compensation. The injury factors recorded were date and type of fracture, stability, presence of subluxation or dislocation, Frankel grade, ASIA (American Spinal Injury Association) score, Injury Severity Score, and presence of associated injuries. General health demographics assessed were medical history for significant comorbid conditions, need for supplemental oxygen, pacemaker, body mass index, bone density, presence of hoarseness or dysphagia, smoking status, medication history, and ASA (American Society of Anesthesiologists) physical status classification.

Subjects were followed prospectively in clinic at 6 and 12 months post–initial treatment with the Neck Disability Index  $(NDI)^{12}$  and SF-36v2,<sup>13</sup> as well as for adverse events. Pretreatment NDI and SF-36v2 scores were based on subjects' recollection of their status prior to injury. The SF-36v2 Physical Component Summary and Mental Component Summary scores were calculated using the 1998 US norms and the orthogonal approach to transformation. Adverse events were adjudicated for the relationship to the treatment. The study was externally monitored to ensure that the data were accurate, reliable, and complete.

#### **Data Analysis**

Subjects were classified in success and failure groups, based on treatment outcomes. Treatment failure was defined as death by any cause; decline in NDI by more than 9.5 absolute points (a literature-based clinically significant difference), or occurrence of a major treatment-related complication. The NDI threshold of 9.5 was based on a literature-reported significant clinical difference for NDI.<sup>12</sup>

The study endpoints were the absolute changes between the preinjury and 6 and 12 month post-treatment scores in the NDI, 8 SF-36v2 health dimensions, and 2 SF-36v2 composite scores (Physical Component Summary and Mental Component Summary). Missing scores for subjects who failed to attend their follow-up visit at 12 months were imputed using the last-value carryforward approach if a 6-month score was available.

The main analysis of differences between the failure and success groups was performed using repeated-measures analysis of variance. To adjust for potential differences between the groups, the following approach was adopted. The selection of baseline characteristics to be used in the adjustment was performed in 2 steps, separately for each of the 11 outcomes. First, screening for potential adjustment variables was performed by calculating the Pearson correlation coefficient between the candidate variable and the target change in the outcome score. The variables that were included as candidate predictors were demographics, comorbidities, presence of associated injuries, and Injury Severity Score. Second, candidate predictors with a *P* value of 0.2 or less were carried into a stepwise forward elimination multiple regression model with a threshold probability to stay in the model of 0.1 or less. The variables that stayed in the multiple regression models were used as adjustment variables in the repeated-measures analysis of variance.

The analysis of predictors of treatment failure was performed by multivariate logistic regression. The predictor variables were age, sex, race, treatment type, smoking status, comorbidities, baseline SF-36v2 scores, and Injury Severity Score, and Abbreviated Injury Scale scores. The forward stepwise model was used with the probability for a variable to enter the model of 0.15 and probability for a variable to stay in the model of 0.10.

#### **RESULTS**

Of the 159 subjects in the study, 101 (63.5%) were treated surgically and 58 (36.5%) nonsurgically. Nonunions occurred in 12 (20.7%) patients who were treated nonsurgically compared with 5 (5%) patients who received surgical treatment (Fisher exact  $P = 0.0030$ ). Thirteen  $(22.8\%)$ patients in the nonoperative arm failed nonoperative treatment and received subsequent surgical treatment. Altogether, 29 (18.2%) patients died, and 3 (1.9%) patients withdrew before the 12-month follow-up. Patient outcomes information was available for 103 of 127 surviving (81.1%) patients.

Of the 159 patients enrolled in the study, 44 (27.7%) had a successful outcome, 86 (54.1%) had a treatment failure, and the status for 29 (18.2%) could not be determined (3 patients

**882** www.spinejournal.com May 2013

withdrew and 26 were lost to follow-up). Patients in the failure group were older (average age 81.7 and 77.9 years in the failure and success groups, respectively,  $P < 0.05$ ). Also, patients in the failure group were more likely to be treated nonoperatively (47.7% and 18.2% in the failure and success groups, respectively,  $P < 0.05$ ). There were no differences in race, marital status, baseline comorbidities, and baseline injury scores between the 2 groups (Table 1). The average scores for SF-36v2 and NDI at the baseline in the failure and success groups are shown in Table 2. Patients in the failure group had higher SF-36v2 Bodily Pain scores than those in the success group (49.7 and 45.6, respectively,  $P < 0.05$ ). There were no differences between the groups in other SF-36v2 dimensions and NDI.

In the surviving patients, 12-month SF-36v2 scores were worse in the failure group compared with those in the success group (Table 3). The NDI improved an average of 6.5 points in the success group but declined an average of 20.6 points in the failure group ( $P < 0.05$ ). SF-36v2 Bodily Pain scores improved in the success group and declined in the failure group (3.4 and  $-5.4$ , respectively,  $P < 0.05$ ). The SF-36v2 Global Health improved slightly in the success group and declined in the failure group (0.5 and −4.8, respectively, *P* < 0.05). SF-36v2 Mental Health improved in the success group but declined in the failure group  $(2.6 \text{ and } -5.3, \text{respec-}$ tively,  $P < 0.05$ ). The average change in Role Limitation Physical was −0.6 and −7.6 in the success and failure groups, respectively  $(P < 0.01)$ . Social Functioning improved in the success group but declined in the failure group  $(4.2 \text{ and } -7.1)$ , respectively, *P* < 0.01). Energy/Fatigue declined for −0.4 and  $-8.3$  in the success and failure groups, respectively ( $P < 0.05$ ). Physical Component Summary score was almost unchanged in the success group (0.1), but declined in the failure group ( −4.8) ( *P* < 0.05). Finally, Mental Component Summary score increased in the success group but declined in the failure group (1.2 and  $-8.4$ , respectively,  $P < 0.05$ ).

Odds ratios (ORs) of baseline characteristics associated with treatment are shown in Table 4. Factors that were associated with an increased risk of treatment failure were nonoperative treatment (OR =  $3.09$ ;  $95\%$  confidence interval [CI], 1.19–8.00;  $P = 0.0203$ ), male sex (OR = 4.33; 95%) CI, 1.62–11.57;  $P = 0.0034$ ), age in years (OR = 1.08; 95% CI, 1.02–1.15; *P* = 0.0121), and SF-36v2 Bodily Pain (OR = 1.06; 95% CI, 1.01–1.11; *P* = 0.0262). The better baseline physical function was associated with a reduced risk of treatment failure (OR = 0.97; 95% CI, 0.930–1.006;  $P = 0.0971$ .

## **DISCUSSION**

This large, multicenter, prospective study reports novel data demonstrating that nonoperative treatment, older age, and male sex are associated with failure of treatment in patients with geriatric odontoid fractures. Better baseline SF-36v2 Physical Function is associated with treatment success.

Both operative and nonoperative treatment options for type II odontoid fractures in the geriatric population carry a high risk of treatment failure and poor outcomes.<sup>6,14,15</sup> Surgical



*AIS indicates Abbreviated Injury Scale; ISS, Injury Severity Score.* 





management is complicated in this population because of high levels of medical comorbidities, poor bone quality, and impaired physiological reserves.<sup>7</sup> A literature review revealed that the in-hospital mortality rate after surgery for type II odontoid fractures in the geriatric population was 6.2%. 16 The mortality rate at 1 year in other studies averaged 21%, 29%, and 45% for patients with type II odontoid fractures aged 65 to 74 years, 75 to 84 years, and 85 years and older, respectively. 17 Comparatively, the results from this trial indicate a mortality rate at 1 year of 13.9 per 100 in patients older than 65 years who were treated surgically. Studies have shown that anterior approaches have a greater effect on patient morbidity as a result of complications related to implant fixation.<sup>16,18</sup> Other factors that can affect surgical outcomes, such as age or medical comorbidities, have not been analyzed to the same extent. 16 A retrospective study designed to compare the outcomes between subaxial and atlantoaxial injuries in older adults showed identical mortality rates in both groups. 19 Studies have also shown that the mortality rate in operatively treated patients with subaxial injury was significantly higher than in the nonoperatively treated patients.<sup>19</sup> The 1-year mortality rate in elderly patients after hip fractures, for example, ranges between  $27\%$  and  $33\%$ . <sup>20,21</sup> Early surgical treatment has shown significant improvements in this mortality rate.  $22,23$ 

Nonsurgical management techniques (varying from traction, followed by halo, halo alone, or collar alone) also have accompanying risks. Compliance in wearing a halo or rigid cervical orthosis in this age group is poor and may contribute to high rates of nonunion.<sup>24,25</sup> Outcomes vary in conservatively treated patients, with reported mortality rates of patients treated with halo vests ranging from 6% to 40%. 26 This lower rate could be attributed to meticulous treatment of



minor complications associated with halo vests, treatment in a spinal cord injuries center (as opposed to a general trauma center), and the patient group including both traumatic and nontraumatic cases. Studies have shown that older age is the greatest risk factor for failure of halo vest immobilization.<sup>26,27</sup> Previous studies have reported that irrespective of the type of orthosis used, patients achieved fracture stability, although only 35% to 50% achieved radiographical osseous union.<sup>28</sup> Paradoxically, clinical results do not seem to correlate with radiological findings.<sup>29</sup> Hence, for the purposes of our trial, it was determined that defining results in terms of functional outcome was more relevant.

Smith *et al<sup>6</sup>* concluded that the rate of in-hospital complications was high in octogenarians with type II odontoid fractures irrespective of the type of treatment. The acute inhospital mortality rate was 12.5% in the surgical group and 15% in the nonsurgical group ( $P > 0.05$ ). However, these data were collected retrospectively. Some of the previous studies comment on matching the patients' physical demographics in the surgical and nonsurgical groups, $7,10,16$  but none of the studies discuss the functional status of the patients before injury. This may lead to selection bias in patients who are more fit being treated surgically and patients who are less fit being treated nonsurgically. In our trial, the surgical and nonsurgical groups were matched for all domains of SF-36v2 and NDI (Table 1). This was further reinforced by making statistical adjustments to remove the confounding effects of variables, including baseline comorbidities. Data collected from



our trial indicated that initial conservative treatment had a 2.92 times higher risk of failure than that with early surgical treatment. On the basis of these results, early operative treatment of type II odontoid fractures in the geriatric population is associated with a better outcome than that with nonsurgical treatment.

The incidence of neurological compromise after type II odontoid fractures is approximately 13%, and this rate does not seem to show any predisposition to age.<sup>15</sup> The main cause for acute neurological deficit after these fractures is due to posterior displacement of the odontoid. A recent study found that the mortality risk associated with a type II odontoid fracture and accompanying neurological deficit was 6 times higher than that without neurological deficit.<sup>30</sup> These patients also had an 11-fold higher increased threat of respiratory distress.

Few studies have looked at the functional outcome after surgical or nonsurgical treatment of these fractures. The outcome tool used to determine success or failure of treatment in most studies is the presence either of osseous union of the fracture or of a stable fibrous union. Platzer *et al*<sup>18</sup> showed that 83% of patients with type II odontoid fracture returned to preinjury level within 1 year. However, most of the patients were young and the outcomes in the geriatric age group were not presented. 18 In our study, failure of initial treatment was defined as death, major complications, or failure to improve clinically in 1 year with respect to NDI scores. Because radiological findings do not clinically correlate with functional outcome in odontoid fractures, the presence of osseous union was not considered a measure of successful treatment.<sup>28</sup> In our study, the group with poor outcome had significantly lower scores for all components of NDI and SF-36v2. There seemed to be a greater risk for poor functional outcome with advancing age in our cohort of patients. This risk was found to increase by 1.05 times for every year beyond the age of 65.

This study has several important limitations, primarily the absence of randomization and determination of treatment in concordance with the personal preference of the surgeon. The study is thus prone to selection bias, because it is possible that surgeons tended to operate on healthier patients and opted for nonsurgical measures in the more frail patients. To overcome this possible bias, our results were adjusted by a series of confounding variables including baseline comorbidity. Furthermore, our site-specific data show that the choice of treatment is primarily surgeon preference and not the patient status. However, unadjusted confounding represents a possible source of limitation. A second limitation of our study is the relatively short follow-up period of 1 year. This time frame was chosen to account for the patients' advanced age and hence their high mortality rate as seen in previous studies.

Our study suggests that older age, male sex, and initial nonsurgical treatment were associated with failure of treatment in patients with geriatric odontoid fractures.

# ➢ **Key Points**

- $\Box$  Type II odontoid fractures are the most common spinal fracture in the geriatric population and represent a significant management challenge; however, there is no consensus on treatment.
- $\Box$  Both surgical and nonsurgical treatment options of type II odontoid fractures in the geriatric population carry a high risk of treatment failure and poor outcomes. Surgical management in this population is complicated because of high levels of medical comorbidities, poor bone quality, and impaired physiological reserves.
- $\square$  There are currently no published studies investigating the factors associated with treatment failure and poor outcomes in elderly patients with type II odontoid fractures.
- $\square$  Data collected from our trial indicated that initial conservative treatment had a 2.92 times higher risk of failure than that with early surgical treatment. On the basis of these results, early operative treatment of type II odontoid fractures in the geriatric population is associated with a better outcome than that with nonsurgical treatment.
- $\Box$  This large, multicenter, prospective study identified the factors associated with failure of treatment in geriatric patients with type II odontoid fractures as nonsurgical treatment, older age, male sex, and neurological impairment.

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