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Single-Level Degenerative Cervical Disc Disease and Driving Disability: Results from a Prospective, Randomized Trial

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Abstract

Study Design Post hoc analysis of prospective, randomized trial.

Objective To investigate the disability associated with driving and single-level degenerative, cervical disc disease and to investigate the effect of surgery on driving disability.

Methods Post hoc analysis of data obtained from three sites participating in a multicenter, randomized, controlled trial comparing cervical disc arthroplasty (TDA) with anterior cervical discectomy and fusion (ACDF). The driving subscale of the Neck Disability Index (NDI) was analyzed for all patients. A dichotomous severity score was created from the NDI. Statistical comparisons were made within and between groups.

Results Two-year follow-up was available for 118/135 (87%) patients. One half of the study population (49.6%) reported moderate or severe preoperative driving difficulty. This disability associated with driving was similar among the two groups (ACDF: 2.5 ± 1.1, TDA: 2.6 ± 1.0, $p = 0.646$). The majority of patients showed improvement, with no or little driving disability, at the sixth postoperative week (ACDF: 75%, TDA: 90%, $p = 0.073$). At no follow-up point did a difference exist between groups according to the severity index.

Conclusions Many patients suffering from radiculopathy or myelopathy from cervical disc disease are limited in their ability to operate an automobile. Following anterior cervical spine surgery, most patients are able to return to comfortable driving at 6 weeks.

Keywords
- cervical
- spondylosis
- fusion
- arthroplasty
- driving
- herniation
- randomized controlled trial

Introduction

Patients with cervical spine pathologies resulting in radiculopathy or myelopathy may be limited in many of their activities of daily living (ADL). At preoperative visits, patients will frequently ask when they may return to normal activities, including driving. Bible et al showed that the act of backing up a motor vehicle requires the greatest range of motion (ROM) in the cervical spine of 15 ADLs.[1] Although disability with driving is a subsection of the Neck Disability Index (NDI), a validated cervical spine outcomes questionnaire, no reports of the disability from cervical spine disease exist, nor studies reporting outcomes following anterior procedures of the cervical spine.[2]

The "gold standard" for management of single-level, symptomatic cervical degenerative disc disease (SCDD), causing radiculopathy or myelopathy, is anterior cervical discectomy and fusion (ACDF).[3] Two recent randomized, controlled trials

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have shown cervical total disc arthroplasty (TDA) is a viable alternative to ACDF.[4,5] The impetus behind the development of TDA is the hope to maintain motion at the treated level and to maintain near normal cervical spine kinematics.[6] The effects of these two procedures, and any differences therein, on disabilities associated with ADLs have not been reported.

The purpose of this study was to investigate the disability while driving associated with SCDD as reported by patients in the NDI. Secondary aims were to investigate the effect of anterior surgery on self-reported driving disability scores and to report the rate of return to normal driving in the two arms of the study.

Materials and Methods

One hundred thirty-five patients from three centers participating in a prospective, multicenter, randomized, U.S. Food and Drug Administration Investigational Device Exemption (IDE) trial comparing TDA to ACDF were the subjects for this post hoc analysis.[4] All patients completed an NDI questionnaire at their preoperative visit and at each follow-up visit (6 weeks, 3 months, 6 months, 1 year, 2 years). Included in the NDI instrument is a driving disability index, with the use of an ordinal scale (►**Table 1**). The driving disability score was converted to a dichotomous severity score, graded as "none or little" (score 0, 1, or 2), or "moderate or severe" (score 3, 4, or 5). The mean disability scores were calculated with the use of this scale across all time points. The location and quality of the pain was not recorded, nor was the driving situation (e.g., turning, prolonged driving). The purpose was to assess the effect of anterior surgery (ACDF or TDA) on driving disability and not to compare the results of the two procedures.

Patients suffering from single-level SCDD causing radiculopathy or myelopathy were randomized in a 1:1 fashion to ACDF or TDA. All patients failed a minimum of 6 weeks of nonoperative management, except those patients with acute myelopathic symptoms. The inclusion criteria were skeletally mature (at least 21 years of age) patients suffering from SCDD at a single level between the third and seventh cervical vertebrae. To be eligible for randomization, a NDI score of at least 30 points was required. Patients who had undergone prior surgical intervention at the level of ACDF or TDA were excluded, as were patients with significant spondylosis, facet arthrosis, or radiographic instability (defined as $>$ 3.5-mm translation or $>$ 11 degrees). The surgical techniques have been published previously.[7] Both groups followed similar postoperative courses and were allowed to return to gentle activities as tolerated. The use of a soft collar was not routine and left to the judgment of the surgeon and the patient.

Table 1 Driving subsection of Neck Disability Index questionnaire

Score	Driving[a]
0	I can drive my car without any neck pain
1	I can drive my car as long as I want with slight pain in my neck
2	I can drive my car as long as I want with moderate pain in my neck
3	I can't drive my car as long as I want because of moderate pain in my neck
4	I can hardly drive at all because of severe pain in my neck
5	I can't drive my car at all

[a]The severity of the disability was graded as none or little (grades 0, 1, 2) or severe (grades 3, 4, 5) disability.

Statistical Methods

Statistical comparisons of demographic variables between groups were performed using analysis of variance for continuous variables and Fisher exact test for categorical variables. Statistical comparisons between the ordinal, driving disability index variables were performed using the nonparametric Wilcoxon rank-sum test. Statistical significance was defined as $p < 0.05$.

Results

One hundred thirty-five patients were randomized to ACDF or TDA at three sites (ACDF = 69, TDA = 66). Twenty-four-month follow-up was available for 118 (87%) patients. The ACDF group consisted of 40 men and 29 women, and the TDA group consisted of 32 men and 34 women. The mean age in the ACDF group was 45.9 years of age and 43.0 years of age in the TDA group ($p = 0.025$). The groups were statistically similar in terms of level of education, tobacco use, alcohol use, and worker's compensation status (►**Table 2**).

The driving disability index score was similar between groups at the initial visit (ACDF: 2.5 $\pm$ 1.1, TDA: 2.6 $\pm$ 1.0, $p = 0.646$). Sixty-seven (49.6%) patients reported moderate or severe disability with driving at the initial visit. Significant index score improvements ($p < 0.001$) were present in both the ACDF and TDA groups at all follow-up points. Reported NDI driving disability index scores were statistically different between groups at 6 weeks (TDA: 0.9 $\pm$ 1.8, ACDF: 1.4 $\pm$ 2.8, $p = 0.044$) and 3 months (TDA: 0.6 $\pm$ 0.9, ACDF: 1.0 $\pm$ 1.1, $p = 0.023$). At no subsequent point did the mean index scores differ between groups. At 12 and 24 months the majority of patients reported no neck pain with driving (TDA = 33/66, ACDF = 36/69, $p = 0.858$) (►**Fig. 1**). When the NDI scores were converted to severity scores, no significant difference was found between groups at any point (►**Table 3**).

Discussion

The disability associated with driving and SCDD has not been well described. The purpose of this study was to determine the prevalence of driving disability in those patients with SCDD and to investigate the rate of return to pain-free driving after surgery. Importantly, the time to subjective improvement provides surgeons with data to offer their patients at the time of preoperative counseling.

In this post hoc analysis of data from a multicenter, randomized, controlled IDE trial, we found that nearly 50%

Table 2 Demographic information for study participants

Variable	ACDF ($n = 69$)	TDA ($n = 66$)	p value[a]
Age (mean ± SD)	45.9 ± 7.7	43.0 ± 7.2	0.025
BMI			
Gender, *n* (%)			
Male	40 (58.0)	32 (45.8)	0.303
Female	29 (42.0)	34 (51.5)	
Race, *n* (%)			
Caucasian	66 (95.7)	63 (95.5)	0.472
African American	0	0	
Hispanic	2 (2.9)	1 (1.5)	
Asian	1 (1.4)	0	
Other	0	2 (3.0)	
Education level, *n* (%)			
Less than high school	8 (11.6)	7 (10.6)	0.714
High school	21 (30.4)	16 (24.2)	
Beyond high school	40 (58.0)	43 (65.2)	
Worker's compensation case, *n* (%)			
Yes	1 (1.4)	2 (3.0)	0.614
No	68 (98.6)	64 (97.0)	
Tobacco used, *n* (%)			
Yes	10 (14.5)	12 (18.8)	0.641
No	59 (85.5)	52 (81.3)	
Alcohol used, *n* (%)			
Yes	4 (5.8)	2 (3.1)	0.682
No	65 (94.2)	62 (96.9)	

Abbreviations: ACDF, anterior cervical discectomy and fusion; BMI, body mass index; SD, standard deviation; TDA, total disc arthroplasty.
[a]Analysis of variance was used for continuous variables. Fischer exact test was used for categorical variables.

of preoperative patients with SCDD reported moderate or severe disability while driving. The majority of patients in each group reported improvements at all points, with 92% of patients reporting no disability, or mild disability, at the 24-month postoperative visit. More importantly, however, both groups showed significant improvements in their subjective complaints at the 6-week visit, with 80% of ACDF patients and 92% of TDA patients reporting none or little disability at their first postoperative visit. As postoperative immobilization was not standardized, the early improvement in the TDA group may not be a surprise. No significant difference was observed between the treatment arms at any subsequent point. When the NDI scores were divided into binary disability grades of none or little disability and moderate or severe disability, no significant difference between the treatment arms was observed at any point. This is the expected outcome, as a discectomy is performed with each procedure, removing the offending intervertebral disk.

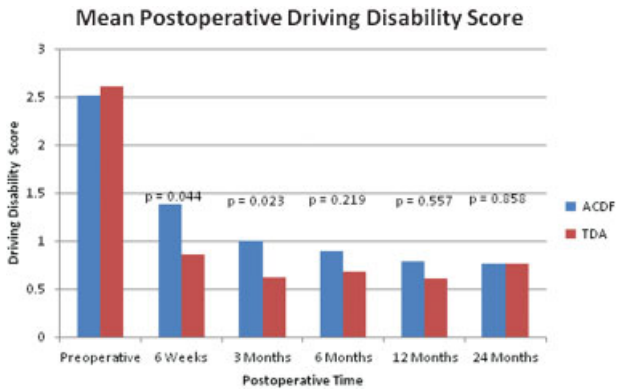

Fig. 1 Mean postoperative driving disability scores. Wilcoxon rank sum test used to compare values between groups. Abbreviations: ACDF, anterior cervical discectomy and fusion; TDA, total disc arthroplasty.

Although the NDI has been validated as an outcomes measure, the individual subsections have not. The minimum clinically important difference for the NDI is 10 points, though no minimum clinically important difference has been suggested for any of the individual components.[8] For this reason, we created a binary grading system, using the scoring system of the NDI. Those patients who reported no pain or no restriction in their ability to drive were defined as having

Table 3 Summary of driving function (question 8) of NDI questionnaire

Severity of disability	ACDF ($n = 69$)	TDA ($n = 66$)	p value[a]
Preoperative			
None or little	35 (51.5)	32 (48.5)	0.863
Moderate or severe	33 (48.5)	34 (51.5)	
6 wk			
None or little	52 (80.0)	60 (92.3)	0.073
Moderate or severe	13 (20.0)	5 (7.7)	
3 mo			
None or little	59 (80.0)	60 (93.8)	0.744
Moderate or severe	6 (9.2)	4 (6.3)	
6 mo			
None or little	54 (91.5)	55 (91.7)	0.999
Moderate or severe	5 (8.5)	5 (8.3)	
12 mo			
None or little	55 (90.2)	62 (95.4)	0.313
Moderate or severe	6 (9.8)	3 (4.6)	
24 mo			
None or little	52 (91.2)	56 (91.8)	0.999
Moderate or severe	5 (8.8)	5 (8.2)	

Abbreviations: ACDF, anterior cervical discectomy and fusion; NDI, Neck Disability Index; TDA, total disc arthroplasty.
Note: NDI question 8 graded as none or little (grades 0, 1, 2) or moderate or severe (grades 3, 4, 5).
[a]p values are from Fisher exact test.

"none or little" driving disability. Those patients that reported any restrictions in their ability to drive were graded as "moderate or severe" disability. For the purpose of this study, a grading system that presents the data to patients as "able" and "unable" was most clear and allows for simpler counseling of patients.

The NDI is a validated questionnaire that contains questions regarding the disability associated with seven ADLs.[9] Of the seven ADLs investigated, driving has been shown to be the ADL requiring the greatest ROM (in rotation).[1,10] The other ADLs queried were either too nonspecific (e.g., work, recreation) or do not involve similar ROM as driving an automobile (e.g., personal care). The ADL associated with maximum ROM in flexion and extension is tying one's shoes, and future questionnaires may incorporate this ADL, as the kinematics are different from driving.

As this is a post hoc analysis, we are limited in the conclusions. The IDE was not designed to study the effect of ACDF or TDA on driving disability. As noted, the use of a cervical collar was left to surgeon discretion. As a collar could certainly affect patient perceptions of driving ability and cervical collars are more likely after ACDF, this could account for the early differences between the ACDF and TDA groups. After 3 months, no differences between NDI driving scores existed, a point at which most cervical collars would have been discontinued. Neglected in this study, but important for surgeons counseling their patients, is the return of driving reaction time (DRT), and the time to daily living without the use of narcotics. The use of an automobile with the use of narcotics is strictly prohibited. Reaction times may be altered following some orthopedic procedures.[11,12] In other reconstructive areas of orthopedic surgery, DRTs have been shown to normalize 1 to 8 weeks after surgery.[13,14] Following lumbar fusion, patients have been shown to have safe DRT at the time of discharge.[11] Whether ACDF and TDA patients are more similar to a lumbar fusion patient or to a total hip arthroplasty patient is not known. Also, as patients were seen at intervals defined by the IDE, we were unable to report whether the improvements noted occurred any faster than available follow-up data allowed.

We have shown here, using data obtained from a prospective, randomized trial, that many patients suffering from SCDD are limited in their ability to operate an automobile. Following ACDF or TDA, most patients are able to return to unrestricted driving by 6 weeks. These improvements continue and are sustained at 2 years of follow-up. Surgeons counseling patients who plan to undergo one of these two procedures may use these data to reassure patients that a rapid return to this ADL may be reasonably expected.

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