Commentary: Utilization Trends of Cervical Disk Replacement in the United States

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Cervical disc replacement (CDR) devices have been introduced into the spinal market as a safe and viable alternative to anterior cervical discectomy and fusion that allow for complete segmental stabilization following complete intervertebral disc excision, while preserving natural biomechanical and kinematic properties.^{1,2} Although there are no official guidelines outlining indications for CDR exist, a manuscript from a plenary session of the 2011 Congress of Neurological Surgeons meeting (prior to FDA approval for contiguous 2-level disease) recommends that the following be present when replacing the cervical intervertebral disc (CDR)³: (1) single level disease with signs of radiculopathy, (2) cord compression due to anterior or disc related pathology, (3) preserved segmental motion, (4) preserved disc space height, and (5) no significant facet arthropathy. Currently, their use in an emergent setting or in combination with anterior or posterior fusion (hybrid surgery) and multi-level use (>2 levels) are not approved by the FDA and have only been published in case reports.⁴⁻⁸ Herein, we investigate the trends of CDR utilization, particularly off-label, since its introduction into the market using a nationwide administrative database.⁹⁻¹¹

METHODS

Data Source and Patient Cohort

We queried the National Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project database between January 1, 2004 and December 31, 2013 for adult patients undergoing CDR using the International Classification of Diseases Ninth Revision, Clinical Modification (ICD-9 CM) procedure codes (84.61, 84.62, and 84.66, effective by Center for Medicare and Medicaid Services in October 2004).

ABBREVIATIONS: CDR, cervical disc replacement; ICD-9 CM, International Classification of Diseases Ninth Revision, Clinical Modification; NIS, National Inpatient Sample

We also documented the implementation of anterior cervical fusion (ICD-9 CM: 81.01, 81.02, 81.31, 81.32) and posterior cervical fusion (ICD-9 CM: 81.03, 81.33). Beginning with 2012, the database contains a 20% stratified sample of all discharges from approximately 1000 US community hospitals, excluding rehabilitation and long-term acute care hospitals. As the data contained in NIS are de-identified, this study was exempt from Institutional Review Board approval.

Primary Outcome

Off-label utilization of CDR comprised the primary outcome of interest. The criteria we used for its definition are presented in Table 1. We also investigated the use of the procedure in the presence of a FDA-labeled contraindication (Table 2), based on the original pre-market approval documents for each device from the FDA database.^{12,13}

Statistical Analysis

Using a well-established sampling weight methodology, we calculated population-level estimates of utilization trends.¹⁴ Separate analyses were conducted for elective and for emergent cases. Numbers for the associated diagnoses represent unweighted frequencies. Statistical analysis was performed using SAS version 9.3 (SAS Institute Inc, Cary, North Carolina).

RESULTS

An estimated total of 22 282 CDR procedures (weighted frequency) were performed in the United States from 2004 through 2013. Among these, 89.8% (n = 20 002) were elective cases, while 10.2% (n = 2280) were emergent.

Elective Setting

Among the elective cases, an estimated 14 146 CDRs were performed stand-alone (Figure 1). Between 2004 and 2009, there was a 7-fold increase of frequency of use of CDR from 348 cases in 2004-2005 to 2427 cases in 2009. The highest number of inpatient, elective CDRs was performed in the year 2009. The rates trended down until

TABLE 1. Criteria Used in This Study to Define Off-label Cervical Disc Replacement

- Utilization in emergent setting
- Hybrid surgery (concurrent with anterior or posterior cervical fusion or both)
- By indication (diagnoses other than degenerative disc disease)
 - For example, cervical spine fractures, dislocation, traumatic spondylopathy, etc.

TABLE 2. FDA Labeled Contraindications to the Utilization of Cervical Disc Replacement

- Isolated axial neck pain
- Ankylosing spondylitis
- Rheumatoid arthritis
- Diffuse idiopathic skeletal hyperostosis
- Severe spondylosis with bridging osteophytes
- Ossification of the posterior longitudinal ligament
- Significant kyphotic deformity or significant reversal of lordosis
- Disc height loss >50%
- Spinal infection
- Metal allergy to components of the prosthesis
- Severe osteoporosis/osteopenia
- Segmental instability
- 3 or more levels requiring treatment
- Absence of motion <2°
- Insulin dependent diabetes mellitus
- Morbid obesity
- Severe facet joint arthropathy
- HIV, Hepatitis B, Hepatitis C infection
- Paget's disease, osteomalacia or other metabolic bone disease
- Neuromuscular disorders such as muscular dystrophy, spinal muscular atrophy, amyotrophic lateral sclerosis

2012, reaching a nadir at 1500 cases before an uptick in 2013 to 1765 cases. During the same period, the frequency of hybrid cases paralleled the rising CDR trends and increased nearly 4-fold from 298 cases in 2004-2005 to 1076 cases in 2009. Among a total of 5856 hybrid cases from 2004 to 2013, only 2.3% (n = 135) were posterior fusion while 95.6% (n = 5596) were anterior, and 2.1% combined anterior/posterior (n = 125).

Emergent Setting

An estimated total of 1484 emergent stand-alone cases were performed between 2004 and 2013. The frequency increased more than 4-fold from 56 cases in 2004/2005 to 241 cases in 2009, followed by a decrease from 238 in 2010 to 116 in 2011 followed by an upward trend through 2013 (Figure 2). With regard to hybrid procedures, we found 796 cases from

2004 through 2013. The frequency increased 3-fold from 43 cases in 2005 to 120 cases in 2011. Similar to elective fusions, the overwhelming majority (n = 662, 83.2%) were accompanied by anterior fusion, while the remaining (n = 43, 5.4%) were done with posterior fusion, and (n = 91, 11.4%) a combined anterior/posterior approach. Finally, a summary of off-label diagnoses and contraindications for elective and emergent cases is presented in Table 3.

DISCUSSION

Leveraging data from the NIS we found that CDR utilization has increased nearly 32-fold since the first device was introduced, both in elective and emergent setting. Interestingly, rates reached a peak in 2009 followed by a sudden drop and then a plateau, which might be attributed to less enthusiastic adoption of the technology from spinal surgeons or increased utilization in the outpatient setting. A significant proportion of patients underwent a hybrid procedure, most likely with the aim of allowing compensatory hyperkinesia adjacent to the fused segment and preventing the long-term development of adjacent segment disease.¹⁵ Interestingly, we also found a fair prevalence of CDR in the setting of these trauma, including fractures and dislocations.^{16,17} We also found the procedure being performed in the presence of several other contraindications like morbid obesity, OPLL, rheumatoid arthritis, and ankylosing spondylitis.

Limitations

Our study has the following limitations: (1) we were unable to capture cases performed in the ambulatory surgical care setting, (2) we could not specify number of operative levels, (3) we could not search for all contraindications, given the lack of relevant ICD-9 codes, and (4) a proportion of the observed trends might be attributed to statistical noise while calculating population-level estimates. Despite these limitations, NIS, as an administrative database, is a highly effective tool for evaluating nationwide patterns and trends of novel surgical technologies.¹⁸⁻²⁰

CONCLUSION

This study revealed that the prevalence of CDR has increased over time. A significant number of CDRs were performed with anterior or posterior cervical fusion, both in the elective and the emergent setting reflecting the use of the technique in an off-label manner. Further studies are needed to provide insight into safety and efficacy outcomes following device implantation in such patients.

TABLE 3. Frequency of Off-Label Use and Use in the Presence of Known Contraindications

Diagnosis	ICD-9 CM code	Frequency		
		Elective	Emergent	Total
Contraindications				
Ankylosing spondylitis	720.0	2	1	3
Rheumatoid arthritis	714.0	32	3	35
Diffuse idiopathic skeletal hyperostosis	721.6	0	0	0
Ossification of posterior longitudinal ligament	723.7	6	2	8
Pregnancy	V22.0,V22.1	0	0	0
HIV	V08, 042	12	1	13
Hepatitis B infection	070.2, 070.3	6	0	6
Hepatitis C infection	070.41, 070.44, 070.51, 070.54, 070.7	29	10	39
Osteoporosis	733.00,733.01,733.02	38	7	45
Insulin-dependent diabetes mellitus	V58.67, 250.01, 250.1, 250.63, 250.83	38	7	45
Morbid obesity	278.01	65	9	74
Vertebral osteomyelitis	730.28	0	5	5
Cervical spine fracture	805.0, 805.1, 806.0, 806.1	8	40	48
Traumatic spondylopathy	721.7	14	2	16
Off-label use				
Cervical spine dislocation	839.0, 839.1	46	33	79
Cervical spinal cord tumor	192.2, 225.3	0	0	0
Postlaminectomy syndrome, cervical region	722.81	22	2	24

Disclosures

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REFERENCES

- Dmitriev AE, Cunningham BW, Hu N, Sell G, Vigna F, McAfee PC. Adjacent level intradiscal pressure and segmental kinematics following a cervical total disc arthroplasty. *Spine*. 2005;30(10):1165-1172.
- Lee JH, Kim JS, Lee JH, Chung ER, Shim CS, Lee S-H. Comparison of cervical kinematics between patients with cervical artificial disc replacement and anterior cervical discectomy and fusion for cervical disc herniation. *Spine J*. 2014;14(7):1199-1204.
- Ding D, Shaffrey ME. Cervical disk arthroplasty. *Neurosurgery*. 2012;59:91-97.
- Chang P-Y, Chang H-K, Wu J-C, et al. Is cervical disc arthroplasty good for congenital cervical stenosis? *J Neurosurg Spine*. 2017;26(5):577-585.
- Chang H-K, Huang W-C, Wu J-C, et al. Cervical Arthroplasty for traumatic disc herniation: An age- and sex-matched comparison with anterior cervical discectomy and fusion. *BMC Musculoskelet Disord*. 2015;16(1):228.
- Wu T-K, Wang B-Y, Cheng D, et al. Clinical and radiographic features of hybrid surgery for the treatment of skip-level cervical degenerative disc disease: a minimum 24-month follow-up. *J Clin Neurosci*. 2017;40:102-108.
- Li Y, Fogel GR, Liao Z, Tyagi R, Liu W. Prosthesis and hybrid strategy consideration for Treating 2-level cervical disc degeneration in hybrid surgery. *Spine* 2017. doi:10.1097/BRS.0000000000002316
- Ji GY, Oh CH, Shin DA, et al. Artificial disk replacement combined with fusion versus 2-Level fusion in cervical 2-level disk disease with a 5-year follow-up. *Clin Spine Surg*. 2017;30(5):E620-E627.
- Qureshi SA, Koehler SM, Lu Y, Cho S, Hecht AC. Utilization trends of cervical artificial disc replacement during the FDA investigational device exemption clinical trials compared to anterior cervical fusion. *J Clin Neurosci*. 2013;20(12):1723-1726.
- Nandyala SV, Marquez-Lara A, Fineberg SJ, Singh K. Comparison between cervical total disc replacement and anterior cervical discectomy and fusion of 1 to 2 levels from 2002 to 2009. *Spine* 2014;39(1):53-57.
- Nesterenko SO, Riley LH 3rd, Skolasky RL. Anterior cervical discectomy and fusion versus cervical disc arthroplasty. *Spine* 2012;37(17):1470-1474.
- Moatz B, Tortolani PJ. Cervical disc arthroplasty: pros and cons. *Surg Neurol Int*. 2012;3(Suppl 3):S216-S224.
- Devices CF, Health R. *Search for FDA Guidance Documents - Guidance for Industry and FDA Staff: Preparation and Review of Investigational Device Exemption Applications (IDEs) for Total Artificial Discs*. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm071154.htm>. Accessed September 6, 2017.
- NIS Trend Weights. Available at: <https://www.hcup-us.ahrq.gov/db/nation/nis/trendwghts.jsp>. Accessed August 27, 2017.
- Zang L, Ma M, Hu J, Qiu H, Huang B, Chu T. Comparison of hybrid surgery incorporating anterior cervical discectomy and fusion and artificial arthroplasty versus multilevel fusion for multilevel cervical spondylosis: a meta-analysis. *Med Sci Monit*. 2015;21:4057-4067.
- [PDF]summary of safety and effectiveness data (ssed) - FDA. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf11/p110002b.pdf. Accessed January 10, 2018.
- Food US, Administration D, Others. *Summary of Safety and Effectiveness: Prestige LP Cervical Disc*. PMA Number P090029/S003. 2016. 2016.
- Anderson JE, Chang DC, Parsons JK, Talamini MA. The first national examination of outcomes and trends in robotic surgery in the United States. *J Am Coll Surg*. 2012;215(1):107-114.
- Halabi WJ, Kang CY, Jafari MD, et al. Robotic-assisted colorectal surgery in the United States: a nationwide analysis of trends and outcomes. *World J Surg*. 2013;37(12):2782-2790.
- Monn MF, Cary KC, Kaimakiotis HZ, Flack CK, Koch MO. National trends in the utilization of robotic-assisted radical cystectomy: an analysis using the Nationwide Inpatient Sample. *Urol Oncol*. 2014;32(6):785-790.