Collective commentaries regarding two articles disputing value of cervical disc arthroplasty vs. Anterior cervical diskectomy and fusion

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There is an ongoing discussion of the pros and cons of cervical disc replacement (CDR) vs. anterior cervical diskectomy and fusion (ACDF). Qureshi et al.’s article focused on the analysis of cost-effectiveness, and compared single-level CDR and single-level ACDF. The authors utilized a Nationwide Inpatient Sample and evaluated quality adjusted life years (QALY). They studied IC-9 codes and determined the average cost of hospitalization, physician costs, and the mean medicare reimbursements. Their model presumed a 20-year viability of the CDR. Within this time frame, CDR had a higher average QALY with reduced cost ($3042) vs. ACDF ($8760). The authors, therefore, concluded that CDR and ACDF were both cost effective procedures, but the CDR “must remain functional for at least 14 years to establish greater cost effectiveness.” They concluded that future long-term studies of CDR were warranted to establish durability.

In contrast, Davis et al. wrote about cervical total disc replacement utilizing the Mobi-C cervical artificial disc vs. anterior discectomy and fusion (ACDF) for the treatment of 2-level symptomatic degenerative disc disease. Previously they claimed that CDR was safe and effective for one level disease, but few documented its adequacy for two level procedures. In this prospective, randomized, controlled multicenter (24 centers involved) US Food and Drug Administration (FDA) clinical trial utilizing investigational device exemption (IDE), they evaluated the Mobi-C CDR.

Of the 330 patients randomized in this study, patients were assigned either 2-level CDR (225 patients) vs. 2-level ACDF (105 patients using allograft bone/anterior plate) between the levels of C3-C7. At 24 postoperative months they concluded that the 2-level CDR was superior to the 2-level ACDF. Patients receiving the CDR achieved greater results on the outcome scales/scores (Visual Analog Scale (VAS), Neck Disability Index (NDI)) obtained 3, 6, 12, and 24 months postoperatively. Those undergoing ACDF required secondary operations 11.4% of the time vs. a lesser 3.1% for CDR. In short, they concluded that this study documented, utilizing Level I clinical evidence, that for two adjacent levels of cervical surgical pathology, the Mobi-C CDR resulted in better outcomes vs. 2-level ACDF.

REFERENCES

1. Davis RJ, Kim KD, Hisey MS, Hoffman GA, Bae HW, Gaede SE, et al. Cervical total disc replacement with the Mobi-C cervical artificial disc compared
with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: A prospective, randomized, controlled multicenter clinical trial. J Neurosurg Spine 2013 [In Press].

2. Qureshi SA, McAnany S, Gaz V, Kehler SM, Hecht AD. Cost-effectiveness analysis: Comparing single-level cervical disc replacement and single-level anterior cervical discectomy and fusion. J Neurosurg 2013 [In Press].

Nancy E. Epstein M.D.
Although both studies were well done, the major point made in the first study by Qureshi et al. was that the durability of these CDR devices remains in question. I would like to see a comparison made between single and/or 2-level CDR vs. single and/or two level ACDF but for the latter, utilizing allograft/plating as well as autograft/plating. This would be a better way to determine whether CDR are truly better constructs (as indicated in these studies) compared with ACDF particularly those still utilizing the gold standard, iliac autograft.

Ron Pawl M.D.
Now that I have given each article proper attention, they are like comparing diamonds and coal. Both are carbon-based, but the latter is good only for a short burst of heat and is then reduced to a cinder while the former is a thing of beauty that lasts. As near as I can tell, there are at least six different devices marketed for cervical disc replacement. The excellent article by Davis et al. describes two-level surgery using the Mobi-C artificial disc compared with two level fusions/plating. It is a well-thought-out, multiple institutional study. Alternatively, the article by Quereshi et al. discusses cost effectiveness but without reporting, which disc replacement devices were used or the numbers of patients with each device. As you know, I am not an expert on statistical analysis, but the article by Quereshi sounds like GIGO (Garbage In Garbage Out) to me.

Thomas Ducker MD
As a reviewer for the insurance carriers, the debate on CDR and ACDF comes up often. The age of the patient and the status of the plan X-rays are important and makes a big difference. Most of us are comfortable with CDR in the reasonable-aged patient with healthy appearing X-rays. With either CDR or ACDF procedures, further operations at 15 years postoperatively are sometimes needed. So, most of us appreciate the articles. And patients can be given a summary copy as part of their informed consent.

Donald Hilton MD
Both of these studies provide encouraging results regarding what is intuitive: That replacement decreases adjacent level disease and therefore would be expected to be advantageous both clinically and economically. Regarding the single level study, it would be useful for the authors to include posterior foraminotomy as a possible treatment for radiculopathy; this would likely compare very favorably with both fusion and replacement. Regarding the second study, the main point is that the reoperation rate at 2 years is much lower for replacement than for two-level fusion. The 11.4% reoperation rate in the fusion group at 2 years seems high, however. In our group of nine surgeons, we looked at patients operated from October 2010 to October 2011 undergoing two-level ACD surgery and examined the reoperation rate using October of 2013 as an end point (2- to 3-year follow-up). Our reoperation rate was 5.6% (11 reoperations out of 196 surgeries), which would compare favorably with the replacement group rate of 3.1%. It would be helpful to see a broader investigation utilizing surgeons with no financial ties to the single replacement product used in the two-level study, as was done in this instance.

Dr. Paul Arnold
Two recent articles published in Journal of Neurosurgery: Spine purportedly extol the virtues of CDR over straightforward ACDF. One article looked at cost effectiveness, and the other at standard outcome measures. In these two particular reports, the differences appeared pretty clear in favor of CDR.

However, when one looks with a bit more granularity, the advantages are not so obvious. CDR becomes superior to ACDF only in postoperative year 14 and beyond, a milestone that may or may not exist, since so few studies have this length of follow-up. In contrast, ACDF has a track record approaching 60 years. The second article, a randomized trial comparing the two procedures, is a bit more persuasive. Nevertheless, it was performed as an IDE in controlled circumstances, and better data will emerge as the device becomes more widely used. The take home message is that while CDR appears to be a safe, cost effective surgical procedure, its superiority over a standard spine procedure is not yet assured.

Dr. Fred Cohen
Actually I am very skeptical about the artificial disc vs. ACDF results for many reasons (even though on the surface it looks like the authors took great pains to avoid many criticisms). One of the more general criticisms relates to the lead article in “The Back Letter” from October 2013 (Vol 28, #10, front page), which makes it pretty clear to those of us who do not depend upon spine surgery for income or a living that, despite all of these continued “improvements” in technology and operative technique, the US spine care system continues to produce record numbers of chronic spine patients and most, if not all, of the published and validated back and spine care guidelines are violated and ignored in greater percentages than ever. The “system” in the US fosters all manner of unproven treatments and technologies (and at least to me this does/will include the 2-level artificial disk replacement).