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Commentary on the effect of steroid use in anterior cervical discectomy and fusion surgery; a randomized controlled trial by Shiveindra B. *et al*. Journal of Neurosurgery Spine 2015;23:137-43

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Abstract

Background: Steroids are often used in patients undergoing anterior cervical discectomy and fusion (ACDF) surgery to limit postoperative dysphagia. However, a major concern remains steroids' impact is on fusion.

Methods: In this prospective, randomized, double-blinded controlled study, the authors assessed the impact of steroids on swallowing/airway and fusion rates in 112 patients undergoing multilevel ACDF. The patients were randomly assigned to saline or dexamethasone groups prior to surgery; multiple other variables including different outcome analyses were also utilized over a 2-year postoperative period. The patients were followed for 1, 3, 6, 12, and 24 months postoperatively, and computed tomography (CT) studies were performed at 6, 12, and 24 postoperative months to establish fusion.

Results: The authors found no significant 2-year differences in the clinical parameters or surgical outcomes for patients undergoing ACDF with or without steroids. Steroids reduced dysphagia in the 1st postoperative month, produced a "trend" for reducing postoperative airway complications (e.g., intubation), and length of stay. Notably, CT-fusion rates with steroids were reduced at the 6th postoperative month but equalized by the 1st postoperative year.

Conclusions: The authors concluded that dexamethasone administered at the time of ACDF surgery improved swallowing within the 1st postoperative month, reduced perioperative airway complications, reduced the length of stay, and reduced 6 month but not 12 month fusion rates. Although the findings regarding postoperative dysphagia are helpful, the performance of multiple 3D-CT scans postoperatively to document fusion would appear to subject these patients to excessive radiation exposure without sufficient clinical indications.

Key Words: Anterior cervical discectomy/fusion, complications, dysphagia, outcomes, pseudarthrosis rates, steroid use

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COMMENTARY

Summary of study

This commentary focuses on the study entitled "Effect of steroid use in anterior cervical discectomy and fusion (ACDF); a randomized controlled trial" by Shiveindra B. *et al*. This prospective, randomized, double-blinded controlled study looked at the impact of steroids (dexamethasone) versus saline alone on postoperative swallowing, airway complications, length of

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stay, and fusion rates in 112 patients undergoing multilevel ACDF. Over a 2-year postoperative period, multiple clinical and outcome variables were studied: Clinical data, Japanese Orthopedic Associations (JOA) scores, neck disability index, 12 item Short Form (SF) Health Survey, visual analog scale (VAS), swallowing scale scores, fusion status, complications, and reoperations were evaluated. The patients were followed for the 1st, 3rd, 6th, 12th, and 24th months postoperatively, and computed tomography (CT) studies were completed at the 6th, 12th, and 24th postoperative months to establish fusion. Although the authors found no significant differences in the long-term clinical parameters or surgical outcomes between the two groups undergoing ACDF with or without steroids, there were several notable factors. First, there was a significant reduction in the incidence of dysphagia for those receiving steroids versus saline within the 1st postoperative month, and a "trend" toward reducing airway related complications and length of stay were noted. More critically, despite CT-documented steroid-related reduced fusion rates at 6 postoperative months, fusion rates between the two groups were eqiualized at 1 postoperative year. The authors concluded that utilizing dexamethasone at the time of ACDF surgery improved postoperative swallowing within the 1st postoperative month, was responsible for a "trend" toward reducing related complications and length of stay, and only transiently reduced the fusion rates (e.g., reduced at the 6th postoperative month but this equalized for both steroids/no steroids by the 1st postoperative year).

QUESTION: BENEFITS OF POSTERIOR CERVICAL APPROACHES OVER ACDF

Laminoforaminotomy

Certainly, if one looks at patients undergoing cervical laminoforaminotomy for a lateral/foraminal disc, the perioperative morbidity is much reduced; e.g., there is no postoperative dysphagia, there are no carotid or esophageal injuries, and there is no concern regarding fusion, as these procedures do not involve a fusion. However, utilizing these operations for lateral/foraminal disc excisions is rapidly becoming a "lost art" as fewer and fewer of these procedures are being performed in favor of ACDF. Is it just that more spine surgeons are not being adequately trained as to how to perform these procedures? Are their "role models" themselves not familiar with the attributes of these approaches? Or in some cases, are reimbursement strategies unfavorable for performing these less lucrative operations?

Laminectomy with/without fusion

The arguments favoring posterior decompressive procedures/laminectomies with/without fusion are also notable. Indeed, multiple levels may be readily accessed, without the risks of multilevel ACDF as quoted in the first paragraph of this article: "Dysphagia, airway compromise, vocal cord paresis/paralysis, and vascular injury." Of interest, the remainder of the sentence states "its benefits over posterior approaches are numerous"; however, these benefits are not clearly apparent.

DYSPHASIA WITH ANTERIOR CERVICAL DISCECTOMY AND FUSION

In this article, utilizing ACDF, the authors go on to discuss the risks of dysphagia which "some continue to struggle... with for years postoperatively." They additionally cite the potentially life-threatening airway complications (6%) that include reintubation (2%). Here, the authors note that although dexamethasone/steroids help control the edema associated with retraction utilized to perform ACDF, they may reduce the incidence of fusion (e.g., as has been documented for spine fusions in other locals).

CRITIQUE OF STUDY DESIGN/METHODS

The authors performed a meticulously designed study in which patients with 2 or more level ACDF were chosen in a prospective, randomized, double-blind controlled fashion. Patients received either steroids (Decadron 0.2 mg/kg) vs. saline intraoperatively and also received 4 postoperative doses of steroids vs. saline every 6 h for 24 h. However, those developing severe dysphagia and/or warranting intubation received continued steroid treatment. The patients were followed postoperatively at 3, 6, 12, and 24 postoperative months using multiple outcomes analyses: JOA, VAS, SF-23, and other scores. Fusion was determined utilizing CT scans performed at 6, 12, and 24 months postoperatively. CT criteria for fusion included bridging osseous trabeculae at each level without lucency. Notably, performing 3 postoperative CT scans would expose patients to a rather high dose of radiation that many would deem unnecessary.

SMITH-ROBINSON ANTERIOR CERVICAL DISCECTOMY AND FUSION APPROACH UTILIZING INTERBODY CARBON FIBER CAGE, HYDROXYAPATITE, TYPE I COLLAGEN, AND AUTOLOGOUS ILIAC CREST BONE MARROW ASPIRATE

Although the Smith-Robinson approach is indeed one of the "gold standards" for performing ACDF, this cannot be said for the fusion construct used. Although iliac crest autograft would still be considered by many to be the "gold standard" for ACDF fusions, the authors' choice of carbon fiber cages with hydroxyapatite, type I collagen, and iliac crest bone marrow aspirate fall far short of this designation. Here, it also becomes clear that they over-radiated their patients, performing three CT studies 6,

12, and 24 months postoperatively, looking for eventual fusion versus pseudarthrosis.

BRACING FOR ANTERIOR CERVICAL DISCECTOMY AND FUSION

The authors cite the use of a hard collar for 4–6 postoperative weeks after which the collar was "weaned." My question here is why not use the CT scan to document that the patient has fused prior to removing the collar? That would make the CT a clinically useful tool. Here, they are performing the first CT 4.5–5 months after they have removed the orthosis. Using a collar for such a short duration does not allow adequate time for a 2 or more level fusion to occur, and subjects the patients to the increased risks of graft-related complications.

TOO MANY LEVELS FOR ANTERIOR CERVICAL DISCECTOMY AND FUSION FUSIONS: NOT INDICATED

The authors performed too many multilevel ACDF: 2 levels (28 patients), 3 levels (40 patients), 4 levels (42 patients), and 5 levels (2 patients). Although one can readily understand the necessity for 2-level fusions, performing so many 3–4 level fusions, much less two 5 level ACDF would just seem unjustified. Where are the magnetic resonance (MR), computed tomographic (CT), and clinical findings that document such extensive anterior disease, and where is the correlation with neurological findings? When so many levels are included in ACDF, choosing an alternative posterior approach would seem wise. Furthermore, how are the authors dealing with the "real" pseudarthrosis rate of up to 5–10% per fused level? Where are the reoperations for the failed fusions?

FOLLOW-UP DATA: NOT WHAT IT SEEMS

All patients were not really uniformly followed for 6, 12, and 24 postoperative months as we are initially led to believe. We were told at the beginning of this study that patients were randomly assigned to the steroid group (56 patients) vs. the saline group (56 patients) for multilevel ACDF. Notably, in the results section, page 140 (first paragraph on the left) we are informed that in the steroid group only 41 of 56 patients were followed for up to 3 months, 41 of 56 patients were followed up to 6 months, and 35 of 56 patients were followed up to 12 months. A similar problem with follow-up was also noted for those in the placebo saline group: 47 of 56 patients were followed at 3 postoperative months, 47 of 56 patinets were followed at 6 postoperative months, and 41 of 56 patients were followed at 123 months. Notably, there is also a lengthy and rather disorganized description as to how longer-term CT studies were read/interpreted.

SUMMARY

There are several basic problems with this study. First and foremost, is the mistaken assumption that ACDF approaches, here involving up to even 5 levels, are preferable and "safer" than posterior procedures. With adequate correlation of neurological examinations and preoperative MR and CT findings, ACDF of over 2 levels should be rare. Furthermore, the authors state that ACDFs have numerous benefits over posterior approaches; nevertheless, they fail to adequately document this, and further, clearly state the myriad of complications associated with multilevel ACDF procedures. In addition, although they adopt a prospective, randomized study design, the 56 patients in the steroid versus 56 patients in the saline groups were no longer present at any of the postopertive phases. The numbers already drop off at 3 months, and are further reduced at 12 months. It remains unclear who is still being studied at 24 postoperative months particularly with the claimed CT studies. In short, the authors' notation that steroid use for multilevel ACDF reduced dysphagia within the 1st postoperative month is of interest versus those receiving only saline, the value of their study stopped there. Although they noted that at 6 postoperative months fusion rates for ACDF for those receiving steroids versus saline was reduced, it then equalized at 12 postoperative months. Additionally one cannot even ascertain how many patients in fact had CT studies at 24 months.

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Conflicts of interest
There are no conflicts of interest.

COMMENTS FROM SNI: SPINE BOARD MEMBERS

Dr. Epstein has carefully and methodically dissected this paper, exposing what we thought had been reported, and what was reported. An example is the true length of follow-up of some of the patients. Moreover, that issue is one of the significant messages in the study. However, this paper also contains some smaller messages which are creeping into clinical scientific papers, especially papers on spine surgery. I refer to the increasing numbers of patient

assessment scales and indices that are being used in patient assessment. They are presented as objective measurements of clinical phenomena, because they consist of numbers which can yield averages, means, standard deviations, and ultimately statements of statistical significance. They are often used in a way which provides direct patient input into the determination of outcome. Perhaps, one of the earliest of these indices to be used is the VAS. The main one in this study was the FOSS. Others include the Oswestry Disability Index, the SF-12, and the modified JOA. One I met recently, but not included here, is the patient report outcome. I have no concern that these tools are used to simplify the gathering and reporting of clinical information. What concerns me is that they are often presented as having been "statistically validated," or "scientifically valid" without proper references of authority. In this paper, the authors address the results of the FOSS several times. They state it has been shown to be valid and reliable, without a citation, and then proceed to declare its use as a limitation of the study. It would not surprise me to see in the near future, a paper stating the outcome swallowing scale (FOSS) score was reliable, with a reference to this paper. It seems when this subject is addressed, proponents justify the use of these patient input oriented parameters as including in the final conclusions and measurements of quality of life. Give to the surgeon the science, and let her through her physician/patient relationships that address the quality of life questions.

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I generally agree. I too was trained in both techniques and thus had a more variable lot of treatments from which to choose. Furthermore, I cannot understand the need for 4 or 5 levels ACDF outside of a major spinal disruption disorder, which has not been noted to be the case in this report. Applying ACDF to simple disc herniations in all instances means the surgeon is not adequately trained, especially in view of the "minimally" invasive posterior type of procedures currently available. In my own practice, steroids were never routinely used. Frankly, I'm not sure this reviewed paper should have been published in the first place.

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To me, this is the highlight of the extension of the ridiculous. First of all, the operation is over used; thousands have been performed successfully without these secondary aids. Second, it can be done far more simply as Dr. Epstein has written. Third, it emphasizes the complications of an operation, that is, poorly designed, putting at risk the carotid artery, esophagus, and trachea – all with complications that one would not see posteriorly. Yes, there are indications for ACDF, but not in 100% cases.

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