

Cervical spine surgery performed in ambulatory surgical centers: Are patients being put at increased risk?

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Abstract


Background: Spine surgeons are being increasingly encouraged to perform cervical operations in outpatient ambulatory surgical centers (ASC). However, some studies/data coming out of these centers are provided by spine surgeons who are part or full owners/shareholders. In Florida, for example, there was a 50% increase in ASC (5349) established between 2000–2007; physicians had a stake (invested) in 83%, and outright owned 43% of ASC. Data regarding “excessive” surgery by ASC surgeon-owners from Idaho followed shortly thereafter.

Methods: The risks/complications attributed to 3279 cervical spine operations performed in 6 ASC studies were reviewed. Several studies claimed 99% discharge rates the day of the surgery. They also claimed major complications were “picked up” within the average postoperative observation window (e.g., varying from 4–23 hours), allowing for appropriate treatment without further sequelae.

Results: Morbidity rates for outpatient cervical spine ASC studies (e.g. some with conflicts of interest) varied up to 0.8–6%, whereas morbidity rates for 3 inpatient cervical studies ranged up to 19.3%. For both groups, morbidity included postoperative dysphagia, epidural hematomas, neck swelling, vocal cord paralysis, and neurological deterioration.

Conclusions: Although we have no clear documentation as to their safety, “excessive” and progressively complex cervical surgical procedures are increasingly being performed in ASC. Furthermore, we cannot rely upon ASC-based data. At least some demonstrate an inherent conflict of interest and do not veridically report major morbidity/mortality rates for outpatient procedures. For now, cervical spine surgery performed in ASC would appear to be putting patients at increased risk for the benefit of their surgeon-owners.

Key Words: Ambulatory surgical center, cervical spine surgery, complications, increased risks, outpatient

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INTRODUCTION

Although there is no clear documentation as to their safety, spine surgeons are increasingly performing more and increasingly complex cervical spine operations in ambulatory surgical centers (ASC). Data from Florida (acquired from 2000–2007, but published in 2010) demonstrated that physicians were invested in 83% of

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ASCs, and outright owned 43% of these facilities.^[5] In a study from Idaho (also published in 2010), this resulted in surgeon-owners (many with a clear conflict of interest) performing “excessive” and increasingly extensive orthopedic procedures in their own ASC facilities compared with nonowners.^[9] For those performing cervical spine surgery in ASC, this would likely translate into more overall operations and more complex cervical spine procedures being performed in ASC without consideration for patient safety and the greater risk for major morbidity and/or mortality. Here, reviewed the literature regarding morbidity for cervical surgery performed in ASC vs. inpatient procedures, and asked, does outpatient cervical ASC surgery put patients at increased risk?

PHYSICIAN OWNERSHIP OF AMBULATORY SURGICAL CENTERS’ RESULTS IN THEIR PERFORMING “EXCESSIVE” OPERATIONS

Multiple studies on outpatient cervical spine surgery point to the “potential cost-savings” of utilizing ASCs (e.g., avoiding hospitalization and the higher hospital facility fee); but cost-savings for whom? The insurance companies pay lower facility fees to ASCs, but those who are part/full owners of ASCs, often spine surgeon themselves with a vested self-interest, are not “saving” anybody anything, but are, rather, financially benefitting. As surgeons’ incomes have decreased across multiple specialties, more have bought into or own ASCs where some now perform “excessive” operations when compared with their nonowner counterparts.^[5,9] From 2000 to 2007, utilizing Florida’s “Healthcare Cost and Utilization Project’s State Ambulatory Surgery Databases,” Hollingsworth *et al.* (in 2010) found “Medicare-certified surgicenters increased by nearly 50%... (total 5,349).” Notably, physicians “... had a stake in 83 percent of these facilities and owned 43 percent outright.”^[5] Mitchell *et al.* (2010) utilizing Idaho insurance data over a 5-year period further confirmed that financial incentives motivated physician owners of ASCs to perform “excessive” orthopedic procedures; carpal tunnel repair was 54–129% higher for surgeon owners vs. nonowners; 33–100% higher for rotator cuff tear for surgeon owners vs. nonowners; and 27–78% higher for arthroscopy for surgeon owners vs. nonowners.^[9] Solutions to such “conflicts of interest” for surgeon owners may require changing federal laws requiring full financial disclosure, reducing facility fees to owners, or looking at other safety constraints.

CERVICAL SPINE SURGERY IN AMBULATORY SURGICAL CENTER

Between 2007 and 2016, multiple authors concluded that ACDF could be safely performed in outpatient ASCs with

lower morbidity rates (e.g., 0.8–6% morbidity; some likely reported by surgeon-owners of ASCs) vs. those reported from inpatient studies (e.g., up to 19.3%, reported by authors without a conflict of interest) [Table 1].^[3-7,10-13] In 2007, Villavicencio *et al.* evaluated the safety/efficacy of 99 (96.1%) 1–2 level ACDF discharged from an ASC within <15 hours (median 8 hours), and 4 3-level ACDF (3.9%) discharged from an ASC after 23 hours [Table 1].^[13] The complication rate for outpatients was 3.8%; 1.9% major ($n = 2$, vertebral fracture and dehydration requiring readmission), and 1.9% minor ($n = 2$, allergic reactions (no hospitalization), and transient (< or = 3 months) neurologic deficits). (Notably, since when are neurological deficits considered minor?) The authors concluded these data were comparable to those obtained from a meta-analysis of the inpatient ACDF literature that documented a morbidity rate of 0.95% (e.g., 6 out of 633 patients; not a significant difference). Of interest, no other study in this review recommended utilizing ASCs to perform 3-level ACDF, and indeed, in this study, only 4 of the 103 patients covered 3 levels, all of whom required 23-hour postoperative observation. In 2010, Garringer and Sasso retrospectively analyzed the 48-hour postoperative complication rate following 645 consecutive outpatient (ASC) 1-level ACDF [Table 1].^[4] Utilizing a 4-hour post-procedure observation period, they identified 2 immediate postoperative hematomas, while an additional 6% of patients required unplanned admissions to the hospital (e.g., notably 80% were for nausea or pain). In 2011, Trahan *et al.* compared inpatient vs. ASC results of 68 1-level ACDF (30 inpatient; 38 or 56% ASC), and 49 2-level ACDF (28 inpatient; 21 or 43% outpatient) [Table 1].^[12] Morbidity included only 1 (1.4%) ASC patient who exhibited postoperative neck swelling requiring a 23-hour hospital stay. In 2012, Sheperd and Young studied 150 patients undergoing 1–2 level ACDF (with limited comorbidities) performed in a dedicated spine ASC [Table 1].^[10] The complication rate was 3.9%; 6 patients returned to the hospital. Reasons for hospital evaluation included; neck pain (2 patients), dysphagia (1 patient), vocal cord paralysis/dysphagia (1 patient), nausea (1 patient), and cervical swelling (1 patient); only 1 patient was readmitted, and none sustained long-term sequelae. They claimed a 100% satisfaction rate for postoperative patients, however, failed to emphasize that only 75 of the original 150 patients filled out the survey. In 2013, Lied *et al.* performed a prospective, consecutive analysis of 96 patients undergoing 1–2 level ACDF as outpatients in a private ASC [Table 1].^[7] They averaged 49.1 years of age, and underwent 1 (60 patients) or 2 (36 patients) level ACDF. On average, patients were observed for 350 min before discharge; 95 of 96 were discharged home or to a hotel on the day of the surgery. There were no mortalities, but a 5.2% surgical morbidity rate, with all

Table 1: Outpatient cervical spine surgery: Summary of 8 studies

Author Reference Year	Number of Patients	Levels of Surgery	Type of Surgery	Observations - Conclusions Complications	Complications
Baird ^[2] 2014	US ACS Database* Adults >20 years of age	Cervical Analysis CPT-4 ICD-9-CM**	ACDF 68% Posterior Decompression (PD) 21%	Younger, more ACDF Older, more PD (80,90's):	99% Discharged home; incomplete assessment of complications
Sheperd ^[10] 2012	ACDF 1-2 Levels 150 Patients 2007-2009	Limited Comorbidity	Ambulatory Spine Center (ACS) Dedicated to Spine Surgery	3.9% Complications 6 Return to hospital 2 Neck pain 1 dysphagia	6 Complications 1 vocal cord paralysis 1 nausea 1 swelling Survey 75 of 150 (100% satisfaction)
Lied ^[7] 2013	96 1-2 level ACDF Prospective Consecutive ACS	Average age 49.1 years 60 patients 1 level 36 patients 2 Levels	Discharge at 350 minutes postoperatively 95 of 96 sent home/hotel on Day 0	91% satisfied with surgery NASSQ	Mortality 0% Morbidity 5.2% 2 (2.1%) hematoma 2 (2.1%) dysphagia 1 (1.1%) neurologically worse
Trahan ^[12] 2011	117 ACDF 1-2 Levels 2005-2009 ACS	ACDF Allograft 58 (50%) Inpatient 59 (50%) outpatient	68 1 Level 38 (56%) Outpatient	49 2-Level 21 (43%) Outpatient	1 (1.4%) ACS complication; readmit neck swelling (23-hour stay)
Garringer ^[4] 2010	645 1-Level ACDF 1 Surgeon	4-hour postoperative observation	No deaths No retropharyngeal clots	6% unplanned readmissions 80% due to nausea or pain	48-hour complications: 2 (0.3%) epidural hematomas (before discharge)
Adamson ^[1] 2016	1000 consecutive 1-2 level ACDF (ASC)	Vs. In hospital 484 ACDF ASCs 629 1 level 365 2-level	Average age 49.5 484 males 516 females Postoperative observation ASC 4 Hours	30-day readmission rate 2.2% 90-day postoperative complications similar for both groups	Complications: 8 (0.8%) to hospital: 3 Pain control 2 Chest pain 1 CSF leak 1 Hematoma 1 1 Neurologically worse; Reoperation No deaths
Villavicencio ^[13] 2007	103 patients 20 hours to 4 days hospital stay Variance: medicolegal concerns	99 (96.1%) 1-2 level ACDF Four 3-level ACDF	99 1-2 level ACDF discharged <15 hours (average: 8) Four 3-level ACDF discharged <23 hours	Major 1.9% Morbidity: Vertebral fractures Readmission (dehydration) Minor 1.9% Morbidity: Allergy Transient deficit <3 mos.	3.8% Complications up to 6 months Complication rate meta-analysis 633 patients 0.95% (6 patients) No statistically significant difference ACS vs. Inpatient databases in complications
McGirt ^[8] 2015	NSQUIP 2005-2011 7288 Patients ACDF	Inpatient 6120 ASC 1168	Study included: CPT Codes 30-day morbidity and mortality rates	ACDF ACS: 58% lower odds of major morbidity 80% lower odds return to OR in 30 days	Major morbidity 0.94% outpatient vs. 4.5% inpatient Return to OR 0.3% outpatient vs. 0.2% in patient Both significantly lower ACS vs. inpatient

*US Database: "United States Healthcare Cost and Utilization Project's State Inpatient and Ambulatory Surgery Databases for California, New York, Florida, and Maryland (2005 to 2009)", ** Fourth revision (CPT-4) (Current Procedure Terminology-4) and International Classification of Diseases, ninth revision Clinical Modification (ICD-9-CM), ACDF: Anterior Cervical Decompression/Fusions; PD: Posterior Decompression; ASCs: Ambulatory Surgical Centers; NSQIP: National Surgical Quality Improvement Program; CSF: Cerebrospinal fluid

complications “picked up” within the postoperative observation period; 2 (2.1%) postoperative hematomas, 2 (2.1%) postoperative dysphagia, and 1 (1%) neurological worsening.

LARGE-SCALE EVALUATION OF CERVICAL SURGERY IN AMBULATORY SURGICAL CENTERS

Two large database analyses of cervical spine surgery performed in ambulatory surgical centers

In 2014, Baird *et al.* utilized the “United States Healthcare Cost and Utilization Project’s State Inpatient and Ambulatory Surgery Databases for California, New York, Florida, and Maryland (2005 to 2009),” combined with the Current Procedure Terminology fourth revision (CPT-4), and International Classification of Diseases ninth revision Clinical Modification (ICD-9-CM) codes to identify adults (e.g., over the age of 20) undergoing cervical spine procedures in ASCs [Table 1].^[2] They found that 68% of the procedures were ACDF typically performed in younger patients, whereas 21% were posterior decompressions (PD) performed in patients in their 80s or 90s. Notably, all patients were selected for limited major comorbid factors, allowing for 99% of the patients to be discharged on the day of the surgery. Here, however, the authors openly acknowledged the study’s limited ability to evaluate postoperative complications, and hence, patient safety. In 2015, McGirt *et al.* utilized the National Surgical Quality Improvement Program [NSQIP]) to assess the efficacy of ACDF performed in 7288 inpatients and outpatients (e.g., ASC) (2005–2011) facilities [Table 1].^[8] Utilizing the CPT codes, they examined 30-day postoperative morbidity/mortality rates for the 6120 inpatients vs. 1168 ACDF performed in ASCs. They observed significantly lower outpatient (ASC) vs. inpatient major morbidity (0.94% vs. 4.5%) and return to OR (operating room: 0.3% vs. 2.0%) rates within 30 postoperative days. They concluded “1- to 2-level ACDF can be safely performed in the outpatient ambulatory surgery setting in patients who are appropriate candidates.” However, their data do not likely accurately reflect differences in the two populations (e.g., more stringent selection of patients for ASC surgery without major comorbidities), plus other complications/morbidity not ascertained by the study design.

Large clinical series of cervical spine surgery performed in a surgeon-owned ambulatory surgical centers

In 2016, Adamson *et al.* retrospectively analyzed the safety/efficacy of 1000 consecutive 1 (629 cases; 62.9%) or 2-level (365 cases; 36.5%) ACDF performed in the “authors” ASC (2006 to 2013) vs. 484 comparable ACDF performed inpatient at the Vanderbilt University Hospital [Table 1].^[1] ASC patients were observed for 4 hours in the postoperative care unit, and all except

8 (0.8%) were discharged home; these 8 were transferred to the hospital for pain control ($n = 3$), chest pain/electrocardiogram changes ($n = 2$), cerebrospinal fluid (CSF) leak ($n = 1$), hematoma ($n = 1$), and a new neurological deficit/weakness requiring reoperation ($n = 1$). There were no deaths. The 30-day hospital readmission rate and the 90-day surgical morbidity rates were comparable for both the ASC and inpatient groups. Of interest, this was the only study in which the authors “clearly” openly acknowledged that data came from their “own ASC.” However, their different selection criteria (e.g. choosing ASC patients without significant comorbidities) for patients undergoing cervical surgery in ASC vs. inpatient surgery likely allowed them to markedly reflected the observed outcomes/morbidity that allowed them to mistakenly conclude “ACDF can be safely performed in the outpatient ambulatory surgery setting without compromising surgical safety.”

HOSPITAL-BASED INPATIENT CERVICAL SURGERY STUDIES REPORT HIGHER PERIOPERATIVE MORBIDITY AND MORTALITY

Articles on inpatient cervical spine surgery likely more accurately report perioperative morbidity/mortality as they do not have the “conflict of interest” (e.g., do not own the hospitals) noted for ASC (e.g. at least some of whom have surgeon owners). At least some of whom have surgeon-owners of ASC.^[1,3,6,11] In 2007, Fountas *et al.* reviewed the literature on complications of 1015 inpatient ACDF; patients were followed for an average of 26.4 postoperative months [Table 2].^[3] Cumulative complications included; 1 (0.1%) mortality (due to an esophageal perforation), and a 19.3% morbidity rate (196 of 1015 patients). Morbidities included; dysphagia (9.5%), hematomas (5.6% with 2.4% requiring surgery), recurrent laryngeal nerve palsy (3.1%), CSF leak (0.5%), and esophageal perforation (0.5%). The authors commented that, in the literature they reviewed, most complications were “generally underreported,” and often “entirely missing” from large clinical series. In 2014, following less than 4-level ACD performed in an inpatient setting, Starmer *et al.* evaluated the postoperative complication rates for 164,9871 patients identified from the Nationwide Inpatient Sample (NIS: 2010–2011) [Table 2].^[11] Dysphagia was reported in 32922 cases (2.0%), and highly correlated with age at/over 65 years, the presence of more severe comorbidities, reoperations, disc arthroplasty, vocal cord paralysis, tracheostomy, gastrostomy, and aspiration pneumonia (that correlated with a higher in-hospital mortality rate). In 2015, Lau *et al.* compared the perioperative, radiographic, and clinical outcomes for patients undergoing 2-level corpectomy (ACCF: 20 patients) vs. 3-level ACDF (35 patients) (surgery 2006–2012: 1-2 surgeons) [Table 2].^[6] Preoperative Nurick

Table 2: Summary of perioperative and postoperative complications of inpatient ACDF

Author Reference Year	Number of Patients	Levels of Surgery	Type of Surgery Complications	Observations- Conclusions Complications	Conclusions Complications
Starmer ^[11] 2014	ACD < 4 Vertebrae NIS 1,649,871	Dysphagia Dysphonia LOS Mortality Complications	Complications: Dysphagia Predictor of: Pneumonia Tracheostomy Gastrostomy Aspiration pneumonia	32922 (2%) dysphagia Correlated with: age > 65 years Advanced comorbidities Revisions	32922 (2%) dysphagia Disc replacement Vocal cord paralysis Conclusion: Dysphagia correlated with in-hospital mortality
Lau ^[6] 2015	3-Level ACDF 35 patients 2 Level Corpectomy (ACCF) (20 patients) 2016-12	CSM Cervical Spondylotic Myelopathy Preoperative Nurick Scores Higher ACCF	Same Results: Reoperations for ASD Pseudarthrosis Neck pain VAS Same Nurick Same EBL LOS	PSF (posterior fusion) 60% ACCF group 17.1% for 3-level ACDF Addition of PSF to ACCF increased LOS to 7.2 days vs. 4.9 for 3-level ACDF/PSF	2 level ACCF Higher EBL for anterior surgery vs. 3-level ACDF Without PSF results comparable both groups
Fountas ^[3] 2007	1015 ACDF for CSM	ACDF used Autograft Allograft With/without plate Smith-Robinson	Patients followed 26.4 months. Mortality 0.1% (1 death) esophageal perforation	Morbidity 19.3%: Dysphagia 9.5% Hematoma 5.6% (surgery 2.4%) Recurrent laryngeal palsy 3.1% Spinal fluid leak 0.5%	Morbidity 19.3% (196) Worse myelopathy 0.2% Horner's 0.1% Instrument backout 0.1% Superficial wound infection 0.1% Esophageal perforation 0.3%

NIS: Nationwide Inpatient Sample; LOS: Length of Stay; ACDF: Anterior Cervical Discectomy; CSM: Cervical Spondylotic Myelopathy; ACCF: Anterior Cervical Corpectomy Fusion; PSF: Posterior Surgical Fusion; EBL: Estimated Blood Loss

scores were higher for ACCF patients, 60% of whom also underwent additional posterior fusions (PF) while lower scores were observed for those undergoing 3-level ACDF (only 17.1% of whom had accompanying PF). This made sense as those with greater deficits/more severe pathology required more extensive surgery vs. those with lesser degrees of neurological compromise with less pathology. As would be anticipated, the addition of PF to ACCF increased the LOS to 7.2 days vs. 4.9 days for 3-level ACDF/PF. They also observed that, without PF, the two groups had comparable LOS. Of interest, no significant differences in ultimate outcomes were noted for the two groups (e.g., similar visual analog scale and Nurick scores), while frequencies of postoperative adjacent segment disease and pseudarthrosis were comparable.

CONCLUSION

Spine surgeons are performing more frequent and increasingly complex cervical spine operations in ASCs.^[1-4,6-8,10-13] By 2007, in Florida, physicians were invested in 83% of ASC and were outright owners of

43% of these facilities.^[5] Data from Idaho by 2010 showed surgeon-owners were performing “excessive” and overly extensive surgical procedures in their own ASC vs. nonowners.^[9] Here, it is likely that morbidity rates for cervical spine ASC surgery were “underreported” (3279 patients who were also carefully selected with fewer comorbidities; 0.8% to 6%) in some cases by surgeon-owners with conflicts of interest, while the data coming from comparable inpatient cervical procedures (up to 19.3%) were more veridically noted [Tables 1 and 2].^[1-4,6-8,10-13] In the future, fuller financial disclosures from physicians who own ASCs will likely be required along with reduced facility fees, greater ASC oversight (e.g., regarding morbidity/mortality), and constraints on the type/extent of surgery performed in ASC settings. For the moment, cervical spine surgery performed in ASC appears to be putting patients at increased risk for the benefit of surgeon-owners.

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