Frequency and Acceptability of Adverse Events After Anterior Cervical Discectomy and Fusion

A Survey Study From the Cervical Spine Research Society

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Purpose: Anterior cervical discectomy and fusion has a low but well-established profile of adverse events. The goal of this study was to gauge surgeon opinion regarding the frequency and acceptability of these events.

Methods: A 2-page survey was distributed to attendees at the 2015 Cervical Spine Research Society (CSRS) meeting. Respondents were asked to categorize 18 anterior cervical discectomy and fusion–related adverse events as either: "common and acceptable," "uncommon and acceptable," "uncommon and sometimes acceptable," or "uncommon and unacceptable." Results were compiled to generate the relative frequency of these responses for each complication. Responses for each complication event were also compared between respondents based on practice location (US vs. non-US), primary specialty (orthopedics vs. neurosurgery) and years in practice.

Results: Of 150 surveys distributed, 115 responses were received (76.7% response rate), with the majority of respondents found to be US-based (71.3%) orthopedic surgeons (82.6%). Wrong level surgery, esophageal injury, retained drain, and spinal cord injury were considered by most to be unacceptable and uncommon complications. Dysphagia and adjacent segment disease occurred most often, but were deemed acceptable complications. Although surgeon experience and primary specialty had little impact on responses, practice location was found to significantly influence responses for 12 of 18

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complications, with non-US surgeons found to categorize events more toward the uncommon and unacceptable end of the spectrum as compared with US surgeons.

Conclusions: These results serve to aid communication and transparency within the field of spine surgery, and will help to inform future quality improvement and best practice initiatives.

Key Words: anterior cervical discectomy and fusion, adverse events, survey, complications, cervical spine

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Anterior cervical discectomy and fusion (ACDF) remains one of the most widely accepted and effective procedures performed by spine surgeons internationally.[1,2] While technical aspects of the procedure may have evolved slightly over the years, ACDF often results in good or excellent clinical outcomes, with numerous clinical studies supporting its efficacy.[3–9] A 2007 meta-analysis reported the overall fusion rates of ACDF since the year 1990 to be 89.5%, with fusion rates declining as the number of levels treated increased.[10,11] From a safety perspective, ACDF-related complications have shown a steady decline over the years; between 1990 and 2007, the overall procedure-related complication rates for ACDF decreased from 4.6% to 3.0%.[2]

Although ACDF is typically safe and effective, adverse events still exist, ranging from mildly problematic to catastrophic. A vast array of complications has been demonstrated in the literature. These complications can occur in the immediate perioperative or postoperative period, or can occur months to years after the index procedure. Examples of immediate adverse events include postoperative dysphagia, recurrent laryngeal nerve palsy, esophageal injury, thoracic duct injury, carotid or vertebral artery injury, epidural or neck hematoma, wound infection, durotomy/cerebrospinal fluid (CSF) leak, and spinal cord/nerve root injury. Examples of delayed (>3 mo) adverse events include hardware malfunction or breakage, graft extrusion, pseudarthrosis, adjacent segment degeneration and/or recurrent symptoms in the setting of either adequate or inadequate decompression.[12–25] It is evident that these complications encompass a vast array of possibilities and degrees of severity. However, what is lacking from the literature is a comprehensive agreement as to which complications are acceptable or to be expected over a large sample of surgeries, versus complications that are less acceptable which may be the result of flawed technique or, more commonly, exceptional patient/disease circumstances.

In order to develop a better understanding of the frequency and acceptability of ACDF-related complications, a survey study involving an international group of spine surgeons was performed.

METHODS

Survey Design and Administration

To gauge surgical opinion regarding adverse events pertaining to ACDF, a 2-page anonymous survey was distributed at the 43rd Annual Cervical Spine Research Society (CSRS) meeting (December 2015, San Diego, CA). The survey questions were designed to assess spine surgeons' opinions concerning specific ACDF-related adverse events ranked on a spectrum ranging from common and acceptable, to uncommon and unacceptable. The survey was issued during a general meeting session; respondents included orthopedic and neurological surgeons, who deposited their responses in a sealed box upon exiting the meeting room.

The survey consisted of 2 components. In the first component, respondents' demographic and practice related data were gathered including information related to: surgeon's age, CSRS membership status, country of practice, years in practice, number of cervical spine surgeries performed annually and their primary specialty (orthopedic vs. neurosurgery). In the second component of the survey, respondents were asked to categorize 18 ACDF-related adverse events as: (1) common and acceptable; (2) uncommon but acceptable; (3) uncommon and sometimes acceptable, and; (4) uncommon and unacceptable. The specific events addressed in the survey included: wrong level surgery, esophageal injury, recurrent laryngeal nerve injury, vertebral artery injury, CSF leak with and without ossification of the posterior longitudinal ligament (OPLL), intraoperative spinal cord injury and nerve root injury, retained drain, epidural hematoma with airway compromise or neurological deficit, C5 palsy, dysphagia, wound infection, persistent symptoms with inadequate decompression, persistent symptoms despite adequate decompression, graft migration or hardware failure, pseudarthrosis, and adjacent segment disease.

Statistical Analysis

Data collected from the distributed paper surveys were collated in an electronic database. Frequency of responses for each question were tallied and expressed as percentages. Univariate statistics, χ^2 and Fisher exact test, were used to compare the frequency of specific responses between surgeons depending on demographic and practice pattern characteristics including: years in practice (<15 vs. ≥ 15 y, which was median value among respondents), location of practice (US vs. all other countries) and specialty (neurosurgery vs. orthopedics). A P-value of <0.05 was used to define significance. All analyses were performed using SAS version 9.4 (SAS Inst., Cary, NC).

RESULTS

Population Demographics and Overview of Responses

In total, 115 survey responses were collected from 150 questionnaires administered, corresponding to a 76.7% response rate. The demographic data for the survey's sample population are shown in Figure 1. With respect to the demographical information obtained, 64 (55.7%) of respondents confirmed CSRS membership, with the remaining 51 (43.4%) being nonmembers. As regards age, 23 respondents (20.5%) were between the ages of 30 and 40 years, 32 (27.8%) were between 40 and 50 years, 39

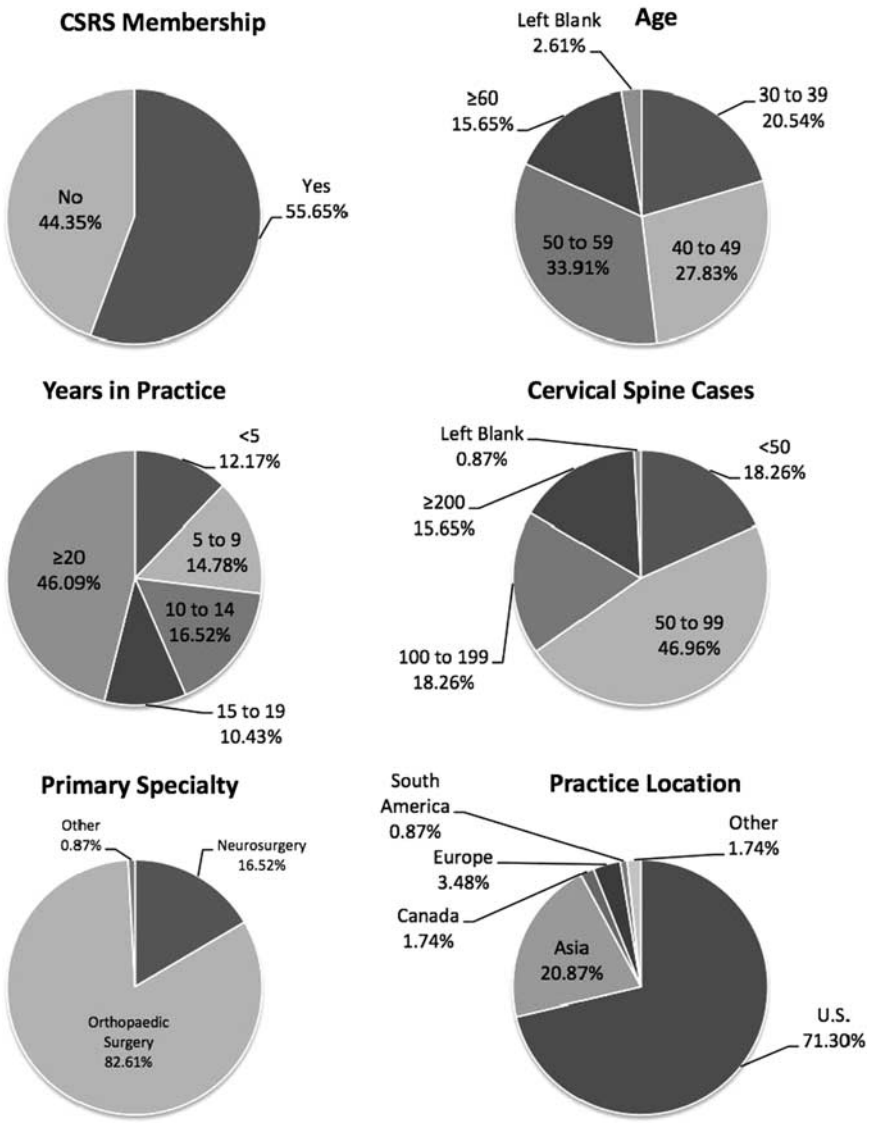

FIGURE 1. Population demographic data from the survey administered at the 43rd Annual "Cervical Spine Research Society" (CSRS) Meeting (December 2015, San Diego, CA).

(33.9%) were between 50 and 60 years, 18 (15.7%) older than the age of 60 years, and 3 (2.6%) left the age response field blank. In terms of practice location, 82 respondents (71.3%) were based in the United States, 24 (20.9%) in Asia, 2 (1.7%) in Canada, 4 (3.5%) in Europe, 1 (0.9%) in Mexico, and 2 (1.7%) in another location not listed in the survey. Fourteen respondents (12.2%) were in practice <5 years, 17 (14.8%) between 5 and 9 years, 19 (16.5%) between 10 and 14 years, 12 (10.4%) between 15 and 19 years, and 53 (46.1%) with 20 or more years in practice. Neurosurgery as a primary specialty made up 16.5% (19 respondents) of the sample population, orthopedic surgery comprising 82.6% (95 respondents), and 0.87% (1 respondent) in other primary specialties not mentioned in the questionnaire. In addition, 21 respondents (18.3%) reported involvement in <50 cervical spine cases annually, 54 (47.0%) with 50–99 cases, 21 (18.3%) with 100–199 cases, 18 (15.7%) with 200 or more cases, and 1 (0.9%) left the question field blank.

Respondents' categorization of adverse events is displayed in Table 1. The survey responses indicate that adverse events found to be the most acceptable are dysphagia, adjacent segment disease, CSF leak with OPLL, whereas the least acceptable are wrong level surgery, retained drain, and esophageal injury.

There was no complication that was deemed to be entirely (100%) unacceptable (Table 2). The only complications that were deemed unacceptable by >50% of respondents were wrong level surgery (87%), esophageal injury (59%), retained drain (58%), and spinal cord injury (50%). The only complications that were deemed to be somewhat acceptable were recurrent laryngeal nerve injury

TABLE 1. Overview of the Frequency/Acceptability Categorization by Respondents for all 18 Complications Surveyed

	Rank [n (%)]				
Complications	**Common and Acceptable**	**Uncommon but Acceptable**	**Uncommon and Sometimes Acceptable**	**Uncommon and Unacceptable**	**Left Blank**
Wrong level surgery	0 (0.00)	4 (3.48)	11 (9.57)	97 (84.35)	3 (2.61)
Esophageal injury	0 (0.00)	20 (17.39)	38 (33.04)	55 (47.83)	2 (1.74)
Recurrent laryngeal nerve	6 (5.22)	48 (41.74)	48 (41.74)	12 (10.44)	1 (0.87)
Vertebral artery injury	0 (0.00)	24 (20.87)	47 (40.87)	42 (36.53)	2 (1.74)
CSF leak w/o OPLL	5 (4.35)	45 (39.13)	46 (40.00)	18 (15.65)	1 (0.87)
CSF leak w/ OPLL	43 (37.39)	46 (40.00)	19 (16.52)	6 (5.22)	1 (0.87)
Intraoperative spinal cord	1 (0.87)	14 (12.17)	42 (36.52)	57 (49.56)	1 (0.87)
Intraoperative nerve root	1 (0.87)	17 (14.78)	60 (52.17)	36 (31.31)	1 (0.87)
Retained drain	2 (1.74)	14 (12.17)	31 (26.96)	65 (56.52)	3 (2.61)
Epidural hematoma w/ airway compromise or neurological deficit	0 (0.00)	38 (33.04)	41 (35.65)	34 (29.57)	2 (1.74)
C5 palsy	21 (18.26)	63 (54.78)	24 (20.87)	6 (5.22)	1 (0.87)
Dysphagia	79 (68.70)	23 (20.00)	10 (8.70)	2 (1.74)	1 (0.87)
Wound infection	11 (9.57)	65 (56.52)	28 (24.35)	10 (8.70)	1 (0.87)
Persistent symptoms w/ inadequate decompression	4 (3.48)	21 (18.26)	62 (53.91)	26 (22.61)	2 (1.74)
Persistent symptoms despite adequate decompression	28 (24.35)	60 (52.17)	22 (19.13)	4 (3.48)	1 (0.87)
Graft migration or hardware failure	6 (5.22)	42 (36.52)	47 (40.87)	18 (15.65)	2 (1.74)
Pseudarthrosis	35 (30.43)	49 (42.61)	25 (21.74)	5 (4.35)	1 (0.87)
Adjacent segment disease	68 (59.13)	36 (31.30)	10 (8.70)	0 (0.00)	1 (0.87)

CSF indicates cerebrospinal fluid; OPLL, ossification of the posterior longitudinal ligament.

(57%), persistent symptoms with inadequate decompression (55%), and nerve root injury (53%). The most acceptable complications were deemed to be adjacent segment disease (91%), dysphagia (89%), CSF leak with OPLL (78%), persistent symptoms with adequate decompression (77%), pseudarthrosis (74%), C5 palsy (74%), and wound infection (67%).

There were some complications that were deemed by all respondents to be uncommon: wrong level surgery (100%), esophageal injury (100%), vertebral artery injury (100%), epidural hematoma (100%) (Table 2). Other complications that were deemed uncommon by $>50\%$ of respondents include: spinal cord injury (99%), nerve root injury (99%), retained drain (98%), persistent symptoms with inadequate decompression (96%), CSF leak (96%), graft migration (95%), recurrent laryngeal injury (93%), wound infection (90%), C5 palsy (82%), persistent symptoms with adequate decompression (75%), pseudarthrosis (69%), and CSF leak with OPLL (62%). The most common complications were dysphagia (69%) and adjacent segment disease (60%).

In analyzing the association between survey responses and respondent characteristics, years in practice (dichotomized at 15 y) seemed to have little impact, with

TABLE 2. Summary of Responses Surrounding Acceptability (Unshaded) and Frequency (Shaded) of Individual Complications

Complications	**Unacceptable (%)**	**Somewhat Acceptable (%)**	**Acceptable (%)**	**Common (%)**	**Uncommon (%)**
Dysphagia	2	9	89	69	31
Adjacent segment disease	0	9	91	60	40
CSF leak w/ OPLL	5	17	78	38	62
Pseudarthrosis	4	22	74	31	69
Persistent symptoms w/ adequate decompression	4	19	77	25	75
C5 palsy	5	21	74	18	82
Wound infect	9	25	67	10	90
Recurrent laryngeal nerve injury	14	57	29	7	93
Graft migration	16	42	42	5	95
CSF leak	16	40	44	4	96
Persist symptom w/ inadequate decompression	23	55	22	4	96
Retained drain	58	28	14	2	98
Nerve root injury	32	53	16	1	99
Spinal cord injury	50	37	13	1	99
Epidural hematoma	30	36	34	0	100
Vertebral artery injury	37	42	21	0	100
Esophageal injury	59	27	14	0	100
Wrong level	87	10	4	0	100

CSF indicates cerebrospinal fluid; OPLL, ossification of the posterior longitudinal ligament.

the one exception that 6 of 49 (12.2%) respondents among the less experienced surgeon group considered persistent symptoms with adequate decompression to be common and acceptable as compared with 22 of 65 (33.9%) respondents in the more experienced group ($P < 0.05$). Surgeon specialty, neurosurgery versus orthopedics, was found to impact responses in 2 situations. For wrong level surgery, 12 of 19 (63.2%) neurosurgeons felt this event to be uncommon and unacceptable, whereas 84 of 92 (91.3%) orthopedic surgeons had the same response ($P < 0.05$). There was also a significant difference in the manner in which the specialties considered persistent symptoms in the setting of adequate decompression with 7 (36.8%) neurosurgeons and 21 (22.3%) orthopedic surgeons considering this common and acceptable, 7 (36.8%) neurosurgeons and 52 (55.3%) orthopedic surgeons considering this uncommon and acceptable, 2 (10.5%) neurosurgeons and 20 (21.3%) orthopedic surgeons considering this uncommon and sometimes acceptable, and 3 (15.8%) neurosurgeons and 1 (1.1%) orthopedic surgeon consider this uncommon and unacceptable ($P < 0.05$). As regards location, there were significant differences noted in the responses between US and non-US practicing respondents for 12 of 18 (66.7%) adverse events surveyed. In those questions where responses differed, non-US respondents tended to categorize adverse events more harshly (ie, toward the uncommon and unacceptable end of the spectrum) as compared with US respondents (Table 3).

DISCUSSION

For many years, the ACDF has represented the main "work horse" of spine surgeons when treating degenerative cervical radiculopathy and myelopathy. A well-known profile of adverse events is associated with ACDF, with individual events ranging in severity from frequent and mild to rare and life threatening. Events on the mild end of the spectrum may be interpreted as inevitable occurrences, experienced often by surgeons performing ACDF, with little in the way of long-term untoward effects experienced by the patient. On the opposite end of the spectrum, catastrophic complications may be interpreted as unacceptable, owing either to surgeon error or exceptional patient or situational circumstances. The goal of this survey study was to gauge surgical opinion among an international group of neurosurgical and orthopedic spine surgeons regarding where these individual events rank on this spectrum.

Among adverse events considered, wrong level surgery and retained drain were considered the most uncommon and unacceptable. This likely reflects a sentiment among respondents that these events reflect a technical surgical error. Also, a large proportion (but less than half of respondents) considered both esophageal and vertebral artery injuries to be uncommon and unacceptable, commensurate with the fact that while rare, these are potentially the most catastrophic adverse events related to ACDF. On the opposite end of the spectrum, dysphagia and adjacent segment disease were both considered to be common and acceptable by the majority of respondents; in other words, these events are to a certain extent "a cost of doing business" and are to be expected in a certain proportion of patients regardless of surgical technique.

With respect to differences in responses depending on surgeon characteristics, specialty (neurosurgery vs. orthopedic surgery) and years in practice (dichotomized at 15) seemed to have little impact. However, geographical location of practice was noted to impact responses for two-thirds of complications surveyed. Interestingly, for every adverse event in which a difference existed, non-US respondents categorized the complication event more toward the "uncommon and unacceptable" end of the spectrum, with US respondents categorizing events more toward the "common and acceptable" end of the spectrum. The explanation for this finding is not altogether intuitive. It is possible that cultural differences and surgical training environments led surgeons in certain countries to interpret complications as more severe and unacceptable. Although, this phenomenon has been relatively uninvestigated in the realm of spine surgery, recent evidence from internal medicine literature suggests a difference in treatment approach and patient outcomes depending on the country of physicians' medical training.[26] It is also possible, that for non-US respondents, difficulties surrounding English language comprehension may have influenced responses. An alternate explanation may be that, given the relatively harsh medico-legal environment in the United States, surgeons from this country, either through conscious or subconscious mechanisms, tend to down play the severity or frequency of complication events.

The results generated here, while not altogether surprising, provide a foundation for further dialogue and discussion focused on developing standards for quality and improvement in spine surgery. Although the term "acceptable" appears to carry a quality implication, the authors do not imply that "unacceptable" complications occur through medico-legal negligence or breach of a standard of care. Furthermore, complications can be unacceptable or intolerable due to their morbidity (such as paralysis in the case of spinal cord injury) without reference to the mechanism of occurrence. This survey was not intended to assess standard of care and, indeed, that term was not used in the survey. Furthermore, standard of care may vary according to patient factors (eg, obesity, smoking, and history of previous surgery), geographic region, and setting (urban vs. rural, academic, etc.). For instance, esophageal injury may be "unacceptable," but it can occur without negligence in the setting of a patient who has a history of extensive scar tissue or radiation to the anterior neck. This study creates a framework for profiling the acceptability and frequency of complications associated with a specific procedure allows for development of consensus among surgeons to create systems of education and patient safety to address complications that are preventable and unacceptable. Such a consensus can be used for benchmarking surgical performance, to ensure that the highest quality of care is delivered to patients on a consistent basis. Such data can also be invaluable for

TABLE 3. Comparison of Responses Between US-based and Non–US-based Respondents

	n (%)				
Complications	**Common and Acceptable**	**Uncommon but Acceptable**	**Uncommon and Sometimes Acceptable**	**Uncommon and Unacceptable**	***P***
Wrong level					1.0
US	—	3 (3.8)	8 (10.1)	68 (86.1)	
Non-US	—	1 (3.0)	3 (9.1)	29 (87.9)	
Esophageal injury					< 0.01
US	—	18 (22.2)	33 (40.7)	30 (37.0)	
Non-US	—	2 (6.3)	5 (15.6)	55 (78.1)	
Recur laryngeal nerve injury					0.04
US	5 (6.2)	9 (48.2)	32 (39.5)	5 (6.2)	
Non-US	1 (3.0)	9 (27.3)	16 (48.5)	7 (21.2)	
Vertebral artery injury					0.03
US	—	21 (26.3)	35 (43.8)	24 (30.0)	
Non-US	—	3 (9.1)	12 (36.4)	18 (54.6)	
CSF leak					< 0.01
US	4 (4.9)	39 (48.2)	32 (39.5)	6 (7.4)	
Non-US	1 (3.0)	6 (18.2)	14 (42.4)	12 (36.4)	
CSF leak w/ OPLL					< 0.01
US	39 (48.2)	35 (43.2)	5 (6.2)	2 (2.5)	
Non-US	4 (12.1)	11 (33.3)	14 (42.4)	4 (12.1)	
Spinal cord injury					0.02
US	0	13 (16.1)	33 (40.7)	35 (43.2)	
Non-US	1 (3.0)	1 (3.0)	9 (27.3)	22 (66.7)	
Nerve root injury					0.01
US	0	16 (19.8)	44 (54.3)	21 (25.9)	
Non-US	1 (3.0)	1 (3.0)	16 (48.5)	15 (45.5)	
Retained drain					0.13
US	0	12 (14.8)	22 (27.2)	47 (58.0)	
Non-US	2 (6.5)	2 (6.5)	9 (29.0)	18 (58.1)	
Epidural hematoma					0.55
US	—	29 (35.8)	30 (37.0)	22 (27.2)	
Non-US	—	9 (28.1)	11 (34.4)	12 (37.5)	
C5 palsy					0.11
US	18 (22.2)	46 (56.8)	13 (16.1)	4 (4.9)	
Non-US	3 (9.1)	17 (51.5)	11 (33.3)	2 (6.1)	
Dysphagia					< 0.01
US	63 (77.8)	14 (17.3)	3 (3.7)	1 (1.2)	
Non-US	16 (48.5)	9 (27.3)	7 (21.2)	1 (3.0)	
Wound infection					0.08
US	9 (11.1)	50 (61.7)	18 (22.2)	4 (4.9)	
Non-US	2 (6.1)	15 (45.5)	10 (30.3)	6 (18.2)	
Persistent symptom w/ inadequate decompression					0.16
US	3 (3.8)	17 (21.3)	46 (57.5)	14 (17.5)	
Non-US	1 (3.0)	4 (12.1)	16 (48.5)	12 (36.4)	
Persistent symptom w/ adequate decompression					< 0.01
US	20 (24.7)	48 (59.3)	13 (16.1)	0	
Non-US	8 (24.2)	12 (36.4)	9 (27.3)	4 (12.1)	
Graft migration					0.01
US	4 (5.0)	34 (42.5)	35 (43.8)	7 (8.8)	
Non-US	2 (6.1)	8 (24.2)	12 (36.4)	11 (33.3)	
Pseudarthrosis					< 0.01
US	33 (40.7)	33 (40.7)	13 (16.1)	2 (2.5)	
Non-US	2 (6.1)	16 (48.5)	12 (36.4)	3 (9.1)	
Adjacent segment disease					< 0.01
US	58 (71.6)	19 (23.5)	4 (4.9)	—	
Non-US	10 (30.3)	17 (51.5)	6 (18.2)	—	

CSF indicates cerebrospinal fluid; OPLL, ossification of the posterior longitudinal ligament.

educating patients during the informed consent process. Other studies have similarly reported avoidable and unavoidable complications for the purposes of education and training.[27]

It is important to note, that while surgeons' opinion surrounding the acceptability of adverse events is of importance, understanding the patient perspective is also vital to this discussion. A previous study, comparing responses

between spine surgeons and patients who underwent one of several spine procedures found that patients were more critical than surgeons in evaluating the severity of postoperative complications.[28] Future work is needed to illuminate the patient perspective surrounding the acceptability and relative severity of adverse events within the context of ACDF.

Generalizability and Limitations

With respect to generalizability of these findings, the fact that this survey was conducted at a highly regarded academic spine meeting, attended by both orthopedic and neurosurgeons at various stages of practice from several different countries, helps to ensure the external validity of survey results. The academy society that conducts the meeting is one of the smallest societies and consists entirely of surgeons. It is notable, however, that the vast majority of respondents in this study were primarily US based; this was likely due to the fact that the meeting was held at a US location. On the basis of the findings of significant differences noted between the responses of US-based and non–US-based surgeons, it is possible that inclusion of a higher proportion of non-US respondents would have altered study findings. In addition, while it is acknowledged that orthopedic surgeons do comprise the majority of spine surgeons internationally compared with neurosurgeons, orthopedic surgeons are likely over-represented in this survey. However, given that there was little difference in responses noted between the specialties, it is unclear whether this imbalance significantly impacts the findings of this study.

Finally, it is acknowledged that a number of patient-related and disease-related factors contribute to the level of complexity of an ACDF and hence the potential for adverse events; these factors were not specified for respondents when they were asked to opine on the acceptability and frequency of adverse events in this survey. Further, different surgeons will likely have different perspectives on the occurrence and acceptability of adverse events depending on the complexity of cases they treat. Future work is needed to determine how the details surgeons' practices, specifically surrounding the complexity of cases treated, influence their perception surrounding adverse events.

CONCLUSIONS

While ACDF is a safe and effective procedure for the treatment of cervical radiculopathy and myelopathy, its performance is associated with a well-known profile of adverse events, with individual complication events ranging from rare and severe to common and minimally problematic. The current survey study provides an overview of current surgical opinion on the relative frequency and acceptability of these complication events after ACDF. While surgeon experience and primary specialty had little impact on the perception of complication frequency and acceptability, non–US-based surgeons had a tendency to view complication events as less frequent and more unacceptable as compared with US-based surgeons. These results will aid in improving communication and transparency within the spine surgery community in future discussions regarding complications after ACDF procedures.

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