



Cervical fusion for adult patients with atlantoaxial rotatory subluxation

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Background: Atlantoaxial rotatory subluxation (AARS) is a rare injury of the C1/C2 junction. It is often associated with trauma in adults. Treatment may depend on the duration of symptoms and clinical presentation, but there is no consensus regarding the ideal management of these injuries. Our objective is to ascertain the prevalence of neurological deficit, complications, and outcomes of patients diagnosed with AARS undergoing cervical fusion (CF) versus those treated without CF.

Methods: The 2016–2019 National Inpatient Sample (NIS) was queried using International Classification of Diseases, 10th revision (ICD-10) for adult patients with C1/C2 subluxation. Patients undergoing CF were defined through ICD-10 procedure codes. Baseline health and acute illness severity was calculated using the 11-point modified frailty index (mFI-11). Presenting characteristics, treatment complications, and outcomes were evaluated of CF *vs.* non-CF patients.

Results: Of 990 adult patients with AARS, 720 were treated without CF and 270 were treated with CF. CF patients were more often myelopathic. Patients that had undergone CF treatment were negatively associated with having had extensive trauma. Patients undergoing CF experienced significantly longer length of stay (LOS), increased healthcare resource utilization, and decreased inpatient mortality. Sepsis had a negative association with patients that underwent CF treatment while pneumonia had a positive association.

Conclusions: Adult patients undergoing CF for AARS demonstrated an increase in healthcare resource utilization but also a significant decrease in mortality. Extent of acute injury appears to have a strong influence on decision making for CF. Further study of decision making for treatment of this rare injury in adults is warranted.

Keywords: Acute atlantoaxial rotatory subluxation (AARS); spinal fusion; outcome assessment; spine surgery; healthcare resource utilization

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Introduction

Acute atlantoaxial rotatory subluxation (AARS) is an injury to the C1/C2 junction involving disruption of the alar ligaments, the transverse ligament, or the facet joints (1). AARS is more common in children in whom there is some ligamentous laxity, underdeveloped neck muscles, a more horizontal configuration of the C1/2 joint, and a relatively greater head size in proportion to the torso; but adults are at higher risk of neurovascular injury (1-8). Traumatic adult AARS is most commonly diagnosed by computerized tomography (CT) imaging presenting with neck pain following sports- or motor vehicle-related trauma (9). From the literature available, adult traumatic AARS appears to have a predominance in females over males by a ratio of approximately 3:1 and in patients under 30 years old versus patients over 30 by more than 2:1 (10).

Current management options for adult traumatic AARS include closed reduction with a trial of hard cervical orthosis, open surgical fixation, or both. The first reported case in the literature, Fielding advocated for conservative management using closed reduction and hard cervical orthosis (11). While this method demonstrated some moderate success, residual joint instability has led to treatment failures, which subsequently required fusion surgery (10,12). Closed reduction and immobilization in a hard cervical orthosis is considered for patients who are neurologically intact and do not have any associated spinal stenosis or subaxial injuries (1). Open surgical fixation of AARS, however, is associated with favorable outcomes and is considered the preferred treatment by many other authors (13-15). Given that late spinal cord injury from high cervical spinal instability may be associated with severe morbidity or mortality, identification of the optimal treatment and risk factors for poor treatment outcomes is important.

The National Inpatient Sample (NIS) database of the Healthcare Cost and Utilization Project (HCUP) comprises 20% of inpatient hospital discharges in the United States (16). Compared to other national inpatient databases, such as the National Surgical Quality Improvement Program (NSQIP), the NIS is a claims-based database sampled nationwide and offers a larger study population. Additionally, while the NSQIP samples tend to derive from academic centers, the NIS includes all US hospital discharge data (17). The NIS has been used to describe changes in the rates of primary atlantoaxial spinal fusions and their direct association with decreased inpatient mortality over a 22-year period (18). In this study, we

analyzed characteristics, complications, and outcomes of adult AARS patients treated with either cervical fusion (CF) or non-CF approaches. We present the following article in accordance with the STROBE reporting checklist (available at <https://jss.amegroups.com/article/view/10.21037/jss-22-19/rc>).

Methods

Data source

Data was acquired from the National Inpatient Sample (NIS) database, developed for The Healthcare Cost and Utilization Project by the Agency of Healthcare Research and Quality. As a stratified discharge database representing 20% of all inpatient admissions, the NIS is the largest all-payer health care database in the United States and is derived from 4,550 hospitals in 48 states (19). This database is sampled from the State Inpatient Databases (SID), which include inpatient data of the hospital stay, such as clinical and resource use information made available from discharge abstracts. With this information, various resource utilization and outcome trends can be identified (20).

Patient selection

The 2016-2019 NIS was queried using the International Classification of Diseases (ICD) 10 diagnosis codes for adult patients with subluxation of C1/C2 cervical vertebrae (S13.120). From this group, patients undergoing CF were defined using ICD 10 procedure codes (0RG0, 0RG1, 0RG2, 0RG4). All diagnosis and procedure codes used for selection can be found in [Table S1](#). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Data characteristics and outcome measures

Baseline demographics and clinical characteristics analyzed included patient age, gender, ethnicity, comorbidities, and risk factors. To evaluate characteristics of patients presenting with AARS, presence of plegia, myelopathy, or bowel-bladder dysfunction were analyzed. Complications of treatment were also assessed, including deep vein thrombosis (DVT), acute kidney injury (AKI), acute respiratory distress syndrome (ARDS), aspiration pneumonitis, osteomyelitis, sepsis, complications following use of a device not otherwise specified during treatment,

complications following procedure, and complications following use of a device for grafts. Prolonged length of stay (LOS) was defined as inpatient hospitalization greater than 10 days. Primary outcomes measured included discharge disposition, prolonged LOS, and inpatient death. All diagnosis codes used to define these variables are available in [Table S2](#).

Severity of injury and illness

Patient baseline illness and injury severity were assessed using two different scoring systems. For baseline illness, the 11-point modified frailty (mFI-11) index was used, with patients having greater than 2 points considered frail. The variables used to define the mFI-11 included a prior history of diabetes mellitus, chronic obstructive pulmonary disease or pneumonia, congestive heart failure, myocardial infarction, percutaneous coronary intervention, stenting, or angina, hypertension requiring medication, peripheral vascular disease or ischemic rest pain, impaired sensorium, transient ischemic attack or cerebrovascular accident, cerebrovascular accident with neurological deficit, and non-independent functional status. Severity of injury was defined by diagnosis related groups (DRG), a three tier system defining the extent of trauma either without comorbidity or complication (CC), with CC, or with major comorbidity or complication (MCC). Extensive trauma was defined as DRG codes with either CC or MCC. Variables used to define severity of illness and injury can be found in [Table S3](#).

Mechanism of injury

Documentation of the mechanism of the injury was extracted by using ICD 10 diagnosis codes. Patients with fall, motor vehicle collision (MVC), motorcycle, and pedestrian struck as mechanisms of actions were identified ([Table S4](#)).

Statistical analysis

Categorical variables were compared using Pearson's chi-squared test. Normality of continuous variables was tested for by using the Shapiro-Wilk test. The Student's T with Levene's Equality of Variance test and Mann-Whitney U test were used to compare normally distributed and non-normally distributed variables, respectively. Multivariate logistic and linear regression as performed to evaluate for categorical and continuous outcome variables, respectively. Statistical analysis was conducted using SPSS Statistical

Software (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp.).

Results

Baseline characteristics

A total of 990 patients with adult AARS were identified from the NIS databases of 2016–2019. Of these patients, 270 (27.3%) underwent a cervical fusion procedure. Those who underwent CF were less likely to be older than 65 years (OR 0.514, 95% CI: 0.384–0.689, $P<0.001$) and less likely to identify as female (OR 0.633, 95% CI: 0.476–0.84, $P=0.001$) in comparison to non-CF patients. There were no significant differences across the CF and non-CF populations for the parameters of race.

There were some pertinent differences in comorbidities between the CF and non-CF groups. AARS patients who underwent CF were more likely to be obese (OR 5.875, 95% CI: 3.108–11.107, $P<0.001$). They were less likely to carry a diagnosis of hyperlipidemia (OR 0.42, 95% CI: 0.277–0.638, $P<0.001$). AARS CF patients were more likely to be diagnosed with psychological conditions such as bipolar disorder (OR 3.571, 95% CI: 1.949–6.545, $P<0.001$) and anxiety (OR 1.791, 95% CI: 1.238–2.591, $P=0.002$). AARS CF patients were much more likely to be considered frail (OR 2.059, 95% CI: 1.038–4.083, $P=0.035$), while they were less likely to have suffered extensive traumatic injury (OR 0.522, 95% CI: 0.358–0.76, $P<0.001$) than the non-CF cohort ([Table 1](#)).

Complications

Of the patients with AARS, treatment complications such as pneumonia, osteomyelitis, sepsis, DVT, acute kidney injury, aspiration pneumonitis, and ARDS were analyzed for differences between the CF and non-CF groups. CF AARS patients were more likely to experience pneumonia (OR 3.76, 95% CI: 1.896–7.458, $P<0.001$) and less likely to experience sepsis ($P=0.017$) than non-CF AARS patients. No significant differences in DVT, AKI, aspiration pneumonitis, or ARDS were identified ([Table 2](#)).

Mechanism of extent of injury

The most reported mechanism of traumatic injury was fall, seen in 405 (40.9%) of patients. Extensive trauma and inpatient death were positively associated with motorcycle

Table 1 Demographics and comorbidities

Variables	All, n=990	Non-fusion, n=720 (72.7%)	Fusion, n=270 (27.3%)	OR (95% CI)	P value
Demographics					
Age greater than 65, years	445	355 (49.3)	90 (33.3)	0.514 (0.384–0.689)	<0.001
Female	485	375 (52.1)	110 (40.7)	0.633 (0.476–0.84)	0.001
White race	540	390 (54.2)	150 (55.6)	1.058 (0.798–1.401)	0.696
Medicaid insurance	125	90 (12.5)	35 (13)	1.043 (0.686–1.584)	0.845
Comorbidities					
Obesity	45	15 (2.1)	30 (11.1)	5.875 (3.108–11.107)	<0.001
Hyperlipidemia	195	165 (22.9)	30 (11.1)	0.42 (0.277–0.638)	<0.001
Depression	95	75 (10.4)	20 (7.4)	0.688 (0.411–1.151)	0.152
Bipolar disorder	45	20 (2.8)	25 (9.3)	3.571 (1.949–6.545)	<0.001
Anxiety	145	90 (12.5)	55 (20.4)	1.791 (1.238–2.591)	0.002
Smoker	170	125 (17.4)	45 (16.7)	0.952 (0.655–1.383)	0.796
Alcohol abuse	75	50 (6.9)	25 (9.3)	1.367 (0.828–2.259)	0.22
Frail	35	20 (2.8)	15 (5.6)	2.059 (1.038–4.083)	0.035
Extensive trauma	220	180 (25.0)	40 (14.8)	0.522 (0.358–0.76)	<0.001

OR, odds ratio; CI, confidence interval.

Table 2 Complications of hospital stay

Complications	All, n=990	Non-fusion, n=720 (72.7%)	Fusion, n=270 (27.3%)	OR (95% CI)	P value
Pneumonia	35	15 (2.1)	20 (7.4)	3.76 (1.896–7.458)	<0.001
Sepsis	15	15 (2.1)	0 (0)	0.979 (0.969–0.99)	0.017
DVT	10	5 (0.7)	5 (1.9)	2.698 (0.775–9.395)	0.105
AKI	65	50 (6.9)	15 (5.6)	0.788 (0.435–1.429)	0.475
Aspiration pneumonitis	25	20 (2.8)	5 (1.9)	0.66 (0.245–1.777)	0.408
ARDS	5	5 (0.7)	0 (0)	0.993 (0.987–0.999)	0.17

OR, odds ratio; CI, confidence interval; DVT, deep vein thrombosis; AKI, acute kidney injury; ARDS, acute respiratory distress syndrome.

collisions and pedestrian struck mechanisms of trauma ($P<0.001$ for all). Patients undergoing CF were less likely to have associated extensive trauma ($P<0.001$). Concurrently presenting neurologic deficits among the AARS population were analyzed for associations between CF and non-CF groups. Myelopathy, plegia, and bowel-bladder dysfunction were assessed. CF AARS patients were more likely to experience myelopathy (OR 1.019, 95% CI: 1.002–1.036, $P<0.001$), while plegia and bowel bladder dysfunction did not demonstrate any significant association with fusion status for AARS patients (Table 3).

Outcomes

Patients undergoing CF were significantly more likely to have a prolonged LOS greater than 10 days (OR 4.455, 95% CI: 3.204–6.194, $P<0.001$). The CF patient group was significantly less likely to have routine discharge (OR 0.604, 95% CI: 0.445–0.82, $P=0.001$) as well as inpatient death (OR 0.924, 95% CI: 0.904–0.943, $P<0.001$) (Table 4).

Extensive trauma significantly predicted inpatient death ($P<0.001$). Female gender and white race negatively predicted for inpatient death ($P=0.003$ and $P=0.002$,

Table 3 Neurologic dysfunction

Signs and symptoms	All, n=990	Non-fusion, n=720 (72.7%)	Fusion, n=270 (27.3%)	OR (95% CI)	P value
Myelopathy	5	0 (0)	5 (1.9)	1.019 (1.002–1.036)	<0.001
Plegia	25	15 (2.1)	10 (3.7)	1.808 (0.802–4.074)	0.148
Bowel bladder dysfunction	10	5 (0.7)	5 (1.9)	2.698 (0.775–9.395)	0.105

OR, odds ratio; CI, confidence interval.

Table 4 Outcomes of hospital stay

Outcomes	All, n=990	Non-fusion, n=720 (72.7%)	Fusion, n=270 (27.3%)	OR (95% CI)	P value
Prolonged LOS >10 days	195	90 (12.5)	105 (38.9)	4.455 (3.204–6.194)	<0.001
Routine discharge	355	280 (38.9)	75 (27.8)	0.604 (0.445–0.82)	0.001
Inpatient death	55	55 (7.6)	0 (0)	0.924 (0.904–0.943)	<0.001

OR, odds ratio; LOS, length of stay; CI, confidence interval.

Table 5 Logistic regressions: inpatient death and routine discharge

Variables	Inpatient death		Routine discharge	
	Slope (95% CI)	P value	Slope (95% CI)	P value
Cervical fusion	0 (0)	0.988	0.349 (0.240–0.508)	<0.001
Age greater than 65	2.95 (0.926–9.399)	0.067	0.088 (0.059–0.131)	<0.001
Female	0.259 (0.106–0.633)	0.003	0.937 (0.679–1.293)	0.691
White race	0.163 (0.053–0.501)	0.002	1.033 (0.747–1.428)	0.846
Obesity	107,163,736.832 (0)	0.989	0.906 (0.367–1.766)	0.589
Hyperlipidemia	0 (0)	0.99	1.148 (0.726–1.816)	0.554
Depression	0 (0)	0.995	1.195 (1.069–3.589)	0.029
Bipolar disorder	0 (0)	0.997	1.104 (0.476–2.559)	0.818
Anxiety	0 (0)	0.995	1.568 (0.927–2.654)	0.094
Smoker	0.627 (0.18–2.181)	0.463	1.928 (1.269–2.929)	0.002
Alcohol abuse	0 (0)	0.995	1.219 (0.66–2.252)	0.527
Medicaid insurance	4.741 (0.991–22.683)	0.051	0.422 (0.269–0.661)	<0.001
Frail	0.875 (0.146–5.252)	0.884	0 (0)	0.997
Extensive trauma	102.843 (28.281–373.983)	<0.001	0.483 (0.327–0.713)	<0.001

CI, confidence interval.

respectively). No other significant associations were observed to predict inpatient mortality.

Depression ($P=0.029$) and extensive smoker status ($P=0.002$) positively predicted routine discharge. Negative predictors for routine discharge included age greater than 65, cervical fusion ($P<0.001$), Medicaid insurance status ($P<0.001$), and extensive

trauma ($P<0.001$). No other significant associations were observed to correlate with routine discharge status (*Table 5*).

Healthcare resource utilization

Significant positive predictors of increased length of stay

Table 6 Regressions: healthcare resource utilization

Variables	LOS		Total charges	
	Slope (95% CI)	P value	Slope (95% CI)	P value
Cervical fusion	3.534 (2.488 to 4.58)	<0.001	142,672.207 (119,078.263 to 166,266.152)	<0.001
Age greater than 65, years	1.094 (0.049 to 2.139)	0.04	7,413.014 (-16,099.48 to 30,925.507)	0.536
Female	-1.311 (-2.221 to -0.401)	0.005	-18,327.55 (-38,803.477 to 2,148.376)	0.079
White race	0.69 (-0.228 to 1.608)	0.14	13,803.368 (-6,823.814 to 34,430.551)	0.189
Obesity	1.961 (-0.195 to 4.117)	0.075	7,909.861 (-40,423.932 to 56,243.654)	0.748
Hyperlipidemia	-1.231 (-2.416 to -0.047)	0.042	-42,779.765 (-69,320.908 to -16,238.623)	0.002
Depression	0.901 (-0.833 to 2.635)	0.308	5,915.486 (-32,927.251 to 44,758.223)	0.765
Bipolar disorder	3.047 (0.778 to 5.317)	0.009	8,000.006 (-42,834.012 to 58,834.024)	0.758
Anxiety	1.203 (-0.318 to 2.724)	0.121	-44,262.614 (-78,356.614 to -10,168.615)	0.011
Smoker	-2.175 (-3.405 to -0.945)	<0.001	-34,007.755 (-61,608.648 to -6,406.862)	0.016
Alcohol abuse	1.878 (0.176 to 3.579)	0.031	-30,918.235 (-69,045.177 to 7,208.706)	0.112
Medicaid insurance	3.601 (2.191 to 5.01)	<0.001	26,191.886 (-5,444.666 to 57,828.438)	0.105
Frail	6.547 (4.134 to 8.959)	<0.001	57,892.251 (3,844.72 to 111,939.781)	0.036
Extensive trauma	0.554 (-0.519 to 1.627)	0.311	51,959.402 (27,887.856 to 76,030.947)	<0.001

LOS, length of stay; CI, confidence interval.

in patients with AARS were cervical fusion ($P<0.001$), age greater than 65 ($P=0.04$), bipolar disorder ($P=0.009$), alcohol abuse ($P=0.031$), Medicaid insurance ($P<0.001$), and frailty ($P<0.001$). Length of stay was significantly decreased by female gender ($P=0.005$), hyperlipidemia ($P=0.042$), and smoking ($P<0.001$) in patients with AARS.

Cervical fusion was a significant predictor of increased total hospital charges ($P<0.001$). Other predictors were frailty ($P=0.036$) and extensive trauma ($P<0.001$). Predictors of decreased hospital charges were HLD ($P=0.002$), anxiety ($P=0.011$), and smoking ($P=0.016$) (*Table 6*).

Discussion

While patients undergoing CF for AARS demonstrated increased healthcare resource utilization (HRU), a significantly lower rate of mortality was also seen. A previous NIS study of atlantoaxial fusion procedures by Hendow *et al.* demonstrated a marked 62% decrease in mortality rate (5.3% to 2.2%) from 1993 to 2014, suggesting a trend in increasing safety for these procedures. In the NIS years 2016 to 2019, our analysis of fusion procedures for AARS similarly corroborates these results, with zero

reported patient inpatient deaths for this cohort (18). The majority of AARS cases are due to trauma, such as falls and motor vehicle collisions, with potential for severe injury (13,21,22). In this study, fall was the most reported mechanism and was negatively associated with inpatient death. Furthermore, patients that underwent CF had lower reported evidence of extensive trauma. Lower association of spinal operative management with greater severity of trauma has been reported extensively in the literature (23-26). It is also commonly reported in the trauma literature that patients with less severe injuries have decreased mortality (27-30). The finding of decreased inpatient death likely represents selection bias towards less severe injury, and with operative management of spinal trauma, increased LOS and HRU may be an expected finding (31). This pattern of withholding aggressive treatment in severely injured patients has been reported in various fields and is a known clinical pattern (32). Although there is an increased investment in the healthcare in CF patients, improvement of associated outcomes, led by better prognostication from less severe injuries, may justify the expenses.

With few exceptions, patients who underwent CF for AARS demonstrated a similar risk of complications

compared to the non-CF group. Given the critical prognosis of sepsis (33), decreased incidence of this complication in the CF group further demonstrates the tendency for non-operative management with increasing severity of injury. Although the rate of DVT and pneumonia were increased in the CF group, their occurrence is within the range reported in the literature following spinal surgeries (34,35). However, when DVTs occur they can prolong the LOS by 3–5 days (36). PNA following spine surgery has also been associated with an increased LOS of 5–9 days (37). Thus, prolonged LOS seen in the CF cases could also be attributable to additional complications beyond the surgery alone. Our study reports an average LOS for patients who underwent fusion of C1/C2 for AARS of 15.2 days. This is significantly greater than what is reported in the literature for either an anterior or posterior approach to cervical spine surgery with an average LOS of one to five days, an expected finding of increased HRU in multi-trauma patients likely representing a large proportion of our study cohort (38–40). The complications we studied therefore suggest reasons for a more prolonged post-operative LOS.

The overall low rate of neurological deficits did not differ significantly between CF and non-CF patients, although the fusion group had higher rates of myelopathy. This finding is consistent with other reports of low incidence of neurologic deficits in patients with AARS (1,3,10,41–44). Given the nature of biomechanical injury causing rotatory subluxation of C1 on C2, neurological presentations are usually rare, except for cases with significant compression of the upper cervical spinal cord associated with cervical myelopathy (4,45,46). As quoted in the literature, physiologic rotation of C1 on C2 normally permits 25 to 53 degrees of motion (3,47). Importantly, rotation and the subsequent swinging movement of the ipsilateral mass out and into the spinal canal leads to physiologic narrowing of the spinal cord at the level of C1–C2 (46). This narrowing, however, is not usually associated with injury to the spinal cord in AARS. These injuries most commonly present with minimal ligamentous disruption and posterior or anterior displacement, thus significantly reducing the potential for increased displacement and harm to the spinal cord (3,48).

The presence of significant gender skew towards male patients in our overall study population is notable. Although this is unexpected given the predominance of female AARS cases reported in the literature (10), this is consistent with literature describing a majority of traumatic injuries as a whole in males and may likely contribute to the demographic difference we see with a

larger sample in our study (49–51). Despite the deterrence from surgical management that is often associated with medical comorbidities, more patients with obesity, bipolar disorder, and anxiety underwent CF. Taken with the age and demographic difference, the findings indicate that older patients with hyperlipidemia and more severe trauma were treated with non-fusion management for AARS. Causative conclusions cannot be made in this retrospective analysis; however, the study cohort suggests that although serious systemic comorbidities influence surgical decision-making, their importance may not be as great as severity of injury in deciding whether an AARS patient undergoes CF. Interestingly, while increasing age was associated with less CF, frail patients were significantly more likely to undergo operative management for AARS. Given the extensive literature describing worse outcomes of surgical fusion in frail patients (52–56), this is an unexpected finding.

This study provides insight into complications and outcomes of AARS. However, it is not without limitations. The main limitations of this study are due to its design as a non-randomized retrospective investigation that utilized the NIS database. When using such a database, there is an inherent risk of incorrect coding, which may lead to over or under estimation of outcomes. Due to these limitations in coding, data acquisition was unreliable for non-operative AARS treatment modalities such as cervical orthosis. By focusing on the years 2016–2019, we sought to avoid any errors due to the shift from ICD-9 to ICD-10 codes. Additionally, although we analyzed outcomes such as LOS, discharge disposition, and inpatient mortality, we were unable to assess patient outcomes after discharge. For example, the NIS does not include any metrics regarding functional status, quality of life post-discharge, reports of imaging, severity of dislocation, mobility, osseous status of the C1/2 joint, and detailed clinical exam or lab values. Thus, this precluded possible comparisons of the long-term impacts of fusion versus non-fusion approach.

Conclusions

CF for AARS compared with nonoperative care was associated with increased LOS, HRU, and decreased mortality. Association of non-CF management of AARS was seen with increased injury severity and more damaging mechanisms of injury. In this population of patients with AARS, the severity of the trauma seems to be a determining factor in decision making for CF. Further investigation of long-term patient outcomes may further characterize

if clinical benefits of CF for AARS outweigh concerns regarding health care resource utilization.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://jss.amegroups.com/article/view/10.21037/jss-22-19/rc>

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://jss.amegroups.com/article/view/10.21037/jss-22-19/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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