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Impact of Bladder Management Strategies on Autonomic Dysreflexia Severity in People With Spinal Cord Injuries

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ABSTRACT

Purpose: We investigated whether severity of autonomic dysreflexia (AD) was associated with more patient-reported bladder and bowel symptoms and compared AD severity by bladder management strategy in people with spinal cord injury (SCI).

Methods: The Neurogenic Bladder Research Group SCI Registry is a prospective study which evaluated quality of life after SCI. Bladder and bowel symptoms were assessed through Neurogenic Bladder Symptom Score and Neurogenic Bowel Dysfunction score, respectively. AD severity was assessed with the Autonomic Dysreflexia Following Spinal Cord Injury (ADFSCI) instrument. Bladder management was classified as volitional voiding, clean intermittent catheterization (CIC), indwelling catheter (IDC), and surgery (augmentation and diversion).

Results: AD scores were identified for 1473 people. The mean age was 45. Bladder management was CIC in 754 (51%), IDC in 271 (18%), surgery in 195 (13%) and voiding in 259 (18%). On univariate analysis, higher ADFSCI scores occurred with complete injuries (3.1 vs 3.4, $p = 0.03$), cervical/thoracic injuries (3.8 vs 1.5, $p < 0.0001$), and chronic pain (3.9 vs 2.9, $p = 0.0004$). IDC (5.2) and surgery (4.5) had higher ADFSCI scores than CIC (3.0) and volitional voiding (2.8) ($p < 0.0001$). Sub-analysis showed bladder augmentation had significantly higher ADSCI scores than diversion (4.7 vs 3.7, $p = 0.03$). On multivariate analysis, level of injury, bladder management, and bowel and bladder symptoms remained associated with worse AD.

Conclusion: Level of injury, age, worse bowel and bladder symptoms and bladder management type were associated with higher AD scores. Bladder management with surgery, particularly bladder augment, and IDC had associated greater AD symptoms compared to CIC or voiding.

Trial Registration: clinicaltrials.gov NTC06216081 and HSRP20153564, U.S. National Library of Medicine, wwwcf.nlm.nih.gov.

1 | Introduction

Almost 300,000 people in the United States live with a spinal cord injury (SCI) [1]. The majority of patients (74%–80%) with SCI report urologic dysfunction [2]. Common urinary symptoms associated with neurogenic lower urinary tract dysfunction (NLUTD) include urinary incontinence, frequency, urgency, and retention, in addition to increased risk of urinary tract infections (UTIs) [3]. These symptoms can cause unexpected hospitalizations, social isolation, and significant

economic burdens while also having a profound impact on quality of life (QoL) [3]. In fact, some individuals with SCI (both tetraplegic and paraplegic) both assign greater importance to improving bladder and bowel function than mobility [4].

One SCI-related condition is autonomic dysreflexia (AD), a condition characterized by episodic, uncontrolled elevation of systolic blood pressure (SBP), with or without baroreflex-mediated bradycardia [5]. AD occurs with injuries above the T6 level, and the risk for developing AD increases with higher levels of SCI, with up to 90% of patients with cervical or thoracic spinal cord injury being at risk [5]. AD symptoms can occur up to 40 times per day and include debilitating headaches, sweating, flushing of the skin, piloerection, stuffy nose, blurred vision, and anxiety [5]. The severity of these episodes ranges from silent to life-threatening and can result in myocardial infarction, cerebral hemorrhage, or death [6]. Common triggers of AD are caused most frequently by bladder or rectal distension [5].

Most patients with SCI require both bladder and bowel management emptying strategies as they are often unable to void on their own [7]. Management options for NLUTD include reflexive voiding, clean intermittent catheterization (CIC), indwelling catheterization (IDC; urethral or suprapubic), or surgery, such as bladder augmentation (with or without a catheterizable channel), urinary diversion, or continent pouch [7]. Of these management types, CIC has traditionally been the first-line treatment given its association with fewer urologic complications [7]. However, recent prospective data from the Neurogenic Bladder Research Group Spinal Cord Injury Registry (NBRG-SCI) showed that those using IDC and surgery reported improved urinary-specific QoL scores compared to CIC [8]. This suggests that many factors may impact how a SCI person perceives urinary-specific QoL.

Currently, most literature classifies AD severity by the frequency of episodes rather than symptom severity; there is a need to assess the patient-perceived impact of AD and understand how this correlates with other patient factors. Another knowledge gap is what individual-specific variables impact the severity of AD, such as bladder management strategies. Our primary objective was to determine if there was an association between AD severity and SCI patient-reported demographics and QoL measures to better develop a phenotype of individuals with SCI at risk for worse AD symptoms. Specifically, we focused on associations between patient-reported bladder, bowel, and pain symptoms and AD severity. Our secondary objective was to investigate the relationship between AD symptom severity and bladder management type.

2 | Methods

2.1 | Participants

The NBRG-SCI registry is a multicenter, prospective observational cohort evaluating self-reported bladder-related outcomes from patients with SCI, collected between 1/1/2016 – 6/30/2017 (ClinicalTrials.gov NTC06216081 and HSRP20153564). The registry consists of consentable, English-proficient individuals above the age of 18 willing to answer 5 sets of questionnaires over 1 year. Exclusion criteria included congenital SCI, such as cerebral palsy or spina bifida, and progressive SCI. The study methodology has been previously published [9]. This study was approved by institutional internal review board (15-PAF06991).

Upon enrollment, participants were interviewed and reported demographics and baseline data. Baseline data included co-morbidities and relevant past medical and surgical history (urologic and non-urologic), background for SCI, medications, past and current bladder and bowel management, and associated complications or hospitalizations. Four bladder management strategies were assessed: (1) surgical reconstruction, (2) IDC, (3) CIC, or (4) reflexive voiding.

After the enrollment interview, patients completed electronic questionnaires including Neurogenic Bowel Dysfunction (NBD) for bowel-specific difficulties, Neurogenic Bladder Symptom Score (NBSS) for bladder-specific outcomes, modified SCI SF-12 for QoL and psychosocial measures, and chronic pain reported as a dichotomous yes or no variable [10–12]. All electronic questionnaires were administered via the secure and Health Insurance Portability and Accountability Act (HIPAA)-compliant Assessment Center Platform (www.asessmentcenter.net).

2.2 | AD Assessment

The severity of AD was assessed using the AD Following SCI Instrument (ADFSCI), which was created to assess individual symptoms of BP instability or impaired autonomic functions [13]. The ADFSCI significantly correlates with hypertensive episodes during 24 h ambulatory blood pressure monitoring with a very high test-retest reliability (ICC 0.98) [13]. The ADFSCI has 6 domains, each scored with a Likert scale of 0 to 4, 0 as never and 4 as very often for the frequency and severity of AD symptoms [13]. AD is classified in the following domains: exercise, bladder emptying, bowel function, sexual activity, provoked activities, and unprovoked activities [13]. Total AD score ranges from 0 to 24, with higher scores indicating worse AD [13].

2.3 | Data Analysis

SAS 9.4 was used for statistical analyses. The Wilcoxon-Ranked sum test, Kruskal-Wallis test, and both a univariate and multivariate regression model were used to determine associations between variables and ADFSCI score.

3 | Results

The registry consisted of 1473 people with AD scores, of which 889 (60%) were men and the mean age was 45 years (Table 1). 904 participants (62%) were paraplegic, and 563 (38%) had complete injury. The mean time since injury was 14.5 years ± 11.8. Bladder management was defined as CIC in 750 (51%), IDC in 269 (18%), surgery in 195 (13%), and voiding in 259 (18%). Regarding SCI injury level, 627 were cervical (43%), 677 thoracic (46%), and 126 (9%) sacral or lumbar. There were 43

TABLE 1 | Baseline demographics for cohort with mean AD score and corresponding *p*-value with univariate analysis.

Sex		N (N%)	Mean AD Score (SD)	*p* $p = 0.1918$
	Male	584 (39.7%)	3.94 (5.15)	
	Female	889 (60.3%)	3.34 (4.35)	
SCI Level				$p < 0.0001$
	C	627 (43.9%)	5.16 (4.92)	
	T	677 (47.3%)	2.59 (4.28)	
	L and S	126 (8.8%)	1.53 (3.48)	
Complete Injury				$p = 0.0296$
	No	904 (61.6%)	3.37 (4.53)	
	Yes	563 (38.4%)	3.91 (4.94)	
Para- vs Quadriplegia				$p < 0.0001$
	Para	840 (57.0%)	2.40 (4.16)	
	Tetra	633 (43.0%)	5.14 (4.91)	
Pain				$p = 0.0004$
	No	453 (30.8%)	2.86 (4.06)	
	Yes	1018 (69.2%)	3.89 (4.92)	
Bladder Management				$p < 0.0001$
	CIC	750 (50.9%)	3.00 (4.39)	
	IDC	269 (18.3%)	5.25 (4.90)	
	Surgery	195 (13.2%)	4.48 (5.28)	
	Voiding	259 (17.6%)	2.85 (4.35)	
Number of UTIs				$p < 0.0001$
	0	388 (26.4%)	2.66 (4.28)	
	1–3	674 (45.8%)	3.62 (4.62)	
	4+	410 (27.8%)	4.39 (5.04)	

Abbreviations: AD, autonomic dysreflexia; C, cervical; CIC, clean intermittent catheterization; IDC, indwelling catheterization; L, Lumbar; S, Sacral; SCI, spinal cord injury; SD, standard deviation; T, thoracic; UTI, urinary tract infection.

participants who did not report level of injury. The mean AD score among all participants in the study was 3.58 ± 4.70. The mean AD score for each level of SCI was 5.16 ± 4.92 in cervical, 2.59 ± 4.28 thoracic, and 1.53 ± 3.48 for sacral and lumbar patients ($p < 0.001$, Figure 1). The mean NBSS was 24.14 ± 10.77, while the mean NBD was 12.49 ± 6.48 (Table 2).

On univariate analysis, higher AD scores were reported among people with complete injuries (3.91 vs 3.37, $p = 0.03$) and multiple UTI's (4.39 vs 2.66, $p < 0.0001$) (Table 1). As expected, higher AD scores were also reported for individuals with cervical/thoracic (CT) injuries versus lumbar/sacral (LS) injuries (3.83 CT vs 1.53 LS, $p < 0.0001$). Higher AD score correlated positively with higher (worse) NBD ($r = 0.243$, $p < 0.0001$), more years since injury ($r = 0.056$, $p = 0.03$), and negatively with age ($r = -0.189$, $p < 0.0001$). Participants who reported that they had chronic pain also scored significantly higher than participants who did not (3.89 vs 2.86, $p = 0.0004$). Both mental ($r = -0.173$) and physical ($r = 0.107$) portions of the SF 12 were also negatively correlated with AD scores ($p < 0.0001$), indicating those with worse AD endorsed worse QoL. There was no significant correlation between participant sex ($p = 0.19$) and AD scores or the NBSS and AD scores ($r = 0.041$, $p = 0.11$) (Table 2).

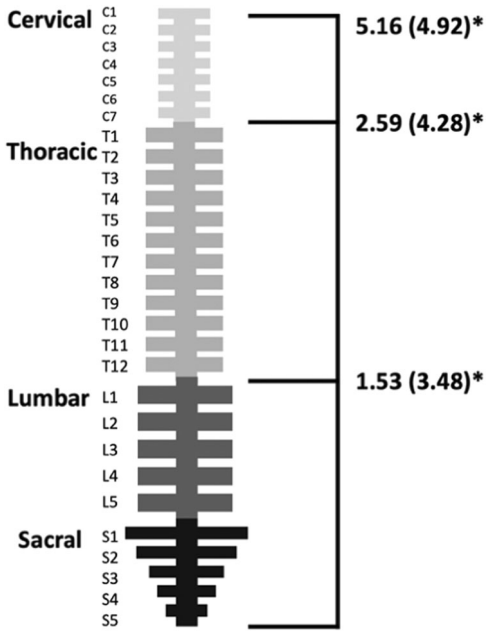

FIGURE 1 | Stratification of mean AD score (SD) reported by participants by injury level. *$p < 0.0001$.

Different strategies of bladder management also were associated with AD score (Figure 2A). Compared to CIC (AD score 3.00 ± 4.39), patients with IDC (5.25 ± 4.90, $p < 0.0001$) and surgery (4.48 ± 5.28, $p < 0.0001$) had significantly higher AD-FSCI scores. Patients who used voiding as their primary bladder management reported the lowest AD scores (2.85 ± 4.35, $p < 0.0001$). Among those with surgical interventions, patients with bladder augmentation ($N = 127$, 4.70 ± 5.50) had higher associated AD scores compared to patients with diversions ($N = 43$, 3.74 ± 4.09) ($p = 0.03$; Figure 2B).

Multivariate regression analysis showed that level of injury, bowel dysfunction, and bladder management type remained significantly associated with higher AD score ($p < 0.001$) (Table 3). For every 10-point increase in NBD score, there was a 1-point increase in AD score. Compared to CIC, patients with surgical reconstruction (augment or diversion) had 1 point higher AD scores on average, whereas patients with IDC had 2 points higher AD scores. Patients who voided ad lib had lower AD scores, with patients scoring 0.23 points lower than CIC. Worse bladder dysfunction ($p = 0.02$), younger age ($p < 0.001$), and increased time from injury (< 0.0001) were also significantly associated with worse AD. The SF-12 mental ($p < 0.0001$) and physical ($p < 0.0001$) portions remained significantly associated with more severe AD in the adjusted model. Chronic pain, completeness of injury, and number of UTIs were not associated with AD score in the multivariate analysis.

TABLE 2 | Correlations between age, years since injury, and measured standardized scales and AD score with univariate analysis.

	N/Mean Value of Respective Parameter (SD)	r, *p*
Age	1473/44.83 (13.13)	r = −0.189, $p < 0.0001$
Years since injury	1473/14.58 (11.75)	r = 0.056, $p = 0.0304$
SF 12 Physical	1449/40.21 (11.14)	r = −0.107, $p < 0.0001$
SF 12 Mental	1449/48.20 (11.31)	r = −0.173, $p < 0.0001$
NBD total	1371/12.49 (6.48)	r = 0.243, $p < 0.0001$
NBSS total	1473/24.14 (10.77)	R = 0.041, $p = 0.1115$

NBD = Neurogenic Bowel Dysfunction; NBSS = Neurogenic Bladder Symptom Score

4 | Discussion

This study demonstrates a phenotype for at-risk patients for worse AD in addition to establishing an independent relationship between AD symptoms, more severe bladder and bowel symptoms, and long-term bladder management strategy. In an unadjusted assessment of the phenotype of individuals at risk for AD, the greatest risk factors were younger age, greater time from injury, those with chronic pain, more UTIs, higher injury levels, worse bowel symptoms, quadriplegia, completeness of injury and worse QoL symptom scores for both mental and physical portions. We found no association between sex and AD. These results align with similar studies demonstrating AD to be gender-independent and more common among younger patients [14].

TABLE 3 | Correlations between participant characteristics and measured standardized scales and AD score with multivariate analysis.

	F Value	*p*
Age	76.99	< 0.0001
Years since injury	31.24	< 0.0001
SCI Level	25.29	< 0.0001
Pain	2.03	0.1546
Complete Injury	0.26	0.6082
Sex	0.00	0.9524
Bladder Management	11.33	< 0.0001
Number of UTIs	1.60	0.2014
SF 12 Physical	25.30	< 0.0001
SF 12 Mental	23.96	< 0.0001
NBD Total	30.59	< 0.0001
NBSS Total	5.13	0.0237

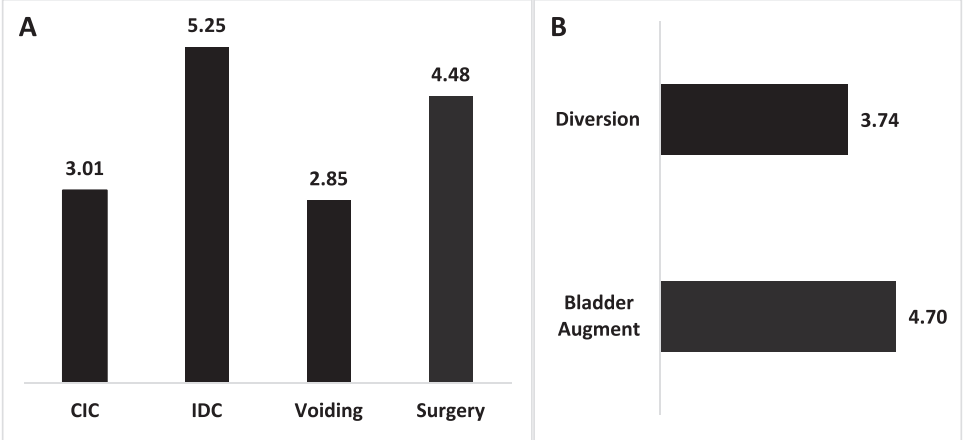

FIGURE 2 | A Mean AD score by bladder management type, $p < 0.0001$. B Mean AD score by surgical management type, $p < 0.05$.

In the univariate model, NBSS score was not associated with AD severity; however, we found that worse urinary and bowel symptoms independently correlate with higher AD severity with the multivariate model. One explanation for this disparity may be that in the univariate model, worsening bladder symptoms are not stratified by injury level or bladder management type. Our data show a robust relationship between bladder management, urinary symptoms, and AD severity independently, so injury level and bladder management may have confounded the relationship between AD and urinary symptom severity. Overall, these findings build on previously reported relationships between AD severity and worse bladder and bowel symptoms in patients with SCI [15].

There is little previously reported information associating long-term bladder management strategy with AD symptom severity. We demonstrate that those using voiding reported the least AD symptoms, followed by CIC, surgery, and IDC, which reported the most symptoms. This aligns with a study that demonstrates the highest incidence of AD with IDC, CIC, then voiding with no CIC [14]. One possibility for the higher incidence of AD noted in patients who use IDC in our cohort may be the AD may worse without the indwelling catheter and this management technique was selected to minimize over AD impact. This data is not available in a cross-sectional data set. This theory would support the high urinary QOL reported with IDC in previous NBRG publications [8]. Conversely, it is also possible that the catheter itself can inflammation, which may trigger AD, however, this is less likely given the high QOL noted previously [14, 16].

Lower AD and NBSS scores in the CIC population may also reflect a different bladder physiology compared to those managed with IDC. The NBSS-QoL is based on three domains of incontinence, physical factors (voiding and urine storage), and social factors [10]. Patients use CIC to empty in timed intervals may minimize bladder distension, which may explain why their AD is better managed. However, their urinary-QoL scores are likely worse because of frequency of which the bladder needs to be emptied and the mechanical difficulty of performing CIC. Furthermore, the QoL differences observed in our previous report may also have reflected perceived improvement in other domains impacting QoL, such as time burden and independence, which is not always possible with CIC. At minimum, however, these findings add to the shared decision-making discussion regarding potential impact of bladder management strategy on AD symptoms.

People with reconstructive bladder surgery also had more associated AD symptoms compared to CIC, and bladder augmentation was associated with worse AD symptoms than urinary diversion. This may be related to several possible reasons. First, patients with a bladder augment still have native bladder that can trigger AD symptoms when distended, whereas those with a conduit or orthotopic diversion do not. Second, bladder augment surgeries could potentially negatively impact bowel function, compared to a urinary diversion since a bladder augment requires more bowel (30–50 cm) than an ileal or colon loop diversion (8–12 cm). Supportive evidence for this is seen in a previous publication showing neurogenic bowel symptoms in those who had undergone previous urologic reconstructive surgery [17]. A third possibility is that patients undergoing augmentation have worse AD symptoms at baseline, which was one of many factors pushing them toward surgical management.

It is interesting to note that chronic pain was not independently associated with high AD scores in this cohort given the relationship between these parallel networks. Neuropathic pain is prevalent among patients with SCI due to sensitization of at-level and below-level spinal networks of the pain and sympathetic neurologic pathways [18]. One explanation could be that bladder and bowel symptoms were specifically differentiated from pain in our cohort. The NBSS has three domains, as discussed above, while the NBD has domains of anal incontinence, constipation, obstructed defecation, and impact on QOL [10, 11]. In contrast, chronic pain in this study was a self-reported categorical variable. This may have led to perceived overlap between generalized pain and specific urinary and bowel symptoms. This would support the findings that an unadjusted analysis showed a relationship between pain and AD scores, but an adjusted analysis did not. A more detailed assessment of pain may have allowed better differentiation of this variable.

This study is not without limitations. Although the study represents a diverse cohort of SCI people of different injury levels, time from injury, and geographic distribution, the cross-sectional design of this study limits our findings to correlational rather than causal relationships. Additionally, medical records were unavailable to researchers, making technical details of urologic surgeries, including length of bowel used unavailable. People participating in study also needed to have access to the online questionnaires, which may have created an unintended selection bias among the cohort. The interpretation of the clinical impact of the observed changes in the AD scores is not known.

However, we suggest that results from this study can help guide the risk-benefit assessment of different bladder management strategies in patients with SCI by involving AD in discussions about expectations. Additionally, comparing different surgical management types to one another using technical details from surgeries is necessary to elucidate specific mechanisms that worsen AD in surgical patients.

5 | Conclusion

High AD scores are noted not only in SCI people with cervical injuries but also among those with worse bladder and bowel symptoms. Patients using CIC for bladder management reported less AD symptoms than those using IDC and surgical reconstruction. Bladder augment was associated with higher AD score compared to urinary diversion.

Author Contributions

Jeremy B. Myers, Sara M. Lenherr, Blayne Welk, and John T. Stoffel contributed to the design and statistical analysis of the research. Rita Palanjian, Blayne Welk, Jeremy B. Myers, Sean P. Elliott, John T. Stoffel contributed to writing the manuscript. Data were collected and quality was overseen by Jeremy B. Myers, Sean P. Elliott, and John T. Stoffel. Jeremy B. Myers and Sara M. Lenherr conceived and supervised the project.

Ethics statement

Institutional Review Board number 15-PAF06991. Participants provided written informed consent before initiating in the study protocol.

Consent

Written informed consent for publication of clinical details and/or images was obtained from the patient (or patient's legal guardian) before data collection, ensuring all identifiable information was removed or anonymized to protect patient privacy. A copy of the consent form is available for review upon request.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Investigators will publish results. The datasets generated and/or analyzed during the current study are not publicly available because they are identifiable. Results are available from corresponding author by reasonable request.

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