Evaluating Decision Regret in Patients Who Have Undergone Sacral Neuromodulation

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OBJECTIVE To quantify decision regret in individuals who had undergone sacral neuromodulation (SNM). Secondary objectives evaluated for correlation of subjects' regret score with symptom relief, complications, device explant status, or military deployment status.

METHODS Each subject's decision regret was assessed via a telephone survey utilizing a validated decision regret tool, and regret scores were calculated. A score of 50 was utilized a cutoff, below which patients were deemed to have minimal regret while those scores above 50 were associated with significant decision regret. Comparative statistics were used to identify correlation between regret scores and patient outcomes and military deployment status.

RESULTS Out of 170 identified subjects, 96 completed the full survey. The mean age of study participants was 49.8 ± 14.5 years, and 58.3% of the participants were female. The average time from implant to survey was 64 months. The mean regret score for patients reporting symptom improvement with the device was 5.4 ± 9.2 (vs 44.1 ± 27.6 for those who did not report symptom improvement, $P < .001$). Regret scores for patients who had device complications were significantly higher than those who did not. At the time of the survey, 82.3% of subjects had the implant in place. Those subjects who underwent device explant had higher regret scores than those who retained their device.

CONCLUSION Decision regret related to SNM appeared low. SNM adverse outcome variables (poor symptom improvement, device complications, and explanted device) were associated with significantly higher decision regret scores than those with more ideal outcomes, but overall decision regret was still low. Military deployment had no correlation with SNM regret. UROLOGY 197: 63–68, 2025. Published by Elsevier Inc.

Overactive bladder (OAB) is a problem affecting approximately 16.5% of the U.S. population.[1] OAB affects many areas of a person's health: recent studies have shown that there are great psychological effects from having OAB (most commonly depression and anxiety, but also adverse effects to self-esteem, sexuality, and relationships).[2] There are many treatment options for OAB—ranging from patient education and behavior modification to pharmacological intervention to surgical intervention. Included within the American Urological Association Guidelines for minimally invasive surgical interventions for OAB is sacral neuromodulation (SNM).[3,4] Siegel et al reported on the therapeutic success rate of SNM and found that the therapeutic success at 5-years, defined as a response of 50% or greater improvement in average leaks or voids per day, was 67%.[5] Some have questioned the reported success rates of SNM, so Dobberfulh et al evaluated the success rates of staged SNM in California during a 6-year period. They reported that the success of progression from the first to the second stage implant, and thus therapy success, was 69%.[6] Though progression to a second stage implant may indicate success, patient reported success is also key to determining the overall success of SNM. A study of 198 women who underwent SNM evaluated both progression to the second stage implant and patient reported success at the first post-operative visit and 6 months later. They found that progression to a second stage implant was 92.4%, patient reported success at the first post-operative visit was 83.3%, and 70.3% at 6 months post-operative.[7] Many studies have looked at patients' quality of life and

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Patient Demographics / Diagnosis / Implant duration to survey		
Age, years, SD (n=96)	49.8	14.5
Female, %, fraction	58.3%	(56/96)
Stated race/ethnicity, %, fraction (n=96)		
White (non-latino)	60.4%	(58/96)
Latino	1.0%	(1/96)
African American	12.5%	(12/96)
Asian	3.1%	(3/96)
Pacific Islander	1.0%	(1/96)
Other	19.8%	(19/96)
Diagnosis (n=96)		
OAB	64	66.7%
urge incontinence	14	14.6%
urinary retention	6	6.3%
neurogenic bladder	4	4.2%
fecal incontinence	3	3.1%
interstitial cystitis	3	3.1%
none	1	1.0%
nocturnal enuresis	1	1.0%
Implant still in place at time of attempted survey, %, fraction (n=96)	82.3%	(79/96)
Time from implant to survey, months, SD (n=96)	64.0	30.0
Reason for device explant, if explanted (n=17)		
Not working	29.4%	(5/17)
Needed MRI	17.6%	(3/17)
Both (not working and needed MRI)	11.8%	(2/17)
Other	35.3%	(6/17)

Figure 1. Patient demographics.

treatment successes after undergoing SNM, but studies evaluating decision regret are lacking.[8-10] To our knowledge, there is only one other published study evaluating decision regret in patients undergoing SNM. They found that SNM was associated with low regret and high satisfaction at three month follow-up.[11] Patient reported success is clearly an important marker of overall success of a therapeutic modality, but as healthcare becomes more patient driven, decision regret is another marker of success that should be evaluated. There is a scarcity of data on decision regret in SNM, but it is widely reported on in the bariatric surgery literature.[12,13] Our study aimed to calculate overall decision regret scores and evaluated for the correlation of decision regret scores with surgical outcomes. We hypothesized that in general, SNM would be associated with low decision regret, and, secondarily, adverse procedural outcomes would be associated with higher decision regret. Decision regret for undergoing SNM procedures and military deployment status was an exploratory outcome.

MATERIALS AND METHODS

Following Local Institutional Review Board Approval (NMCSD2019.0020), we identified all patients who had undergone SNM device implantation at tertiary level military medical center between 2012 and 2022. These patients included active duty members, non-active duty dependents, and retired military members. Patients unwilling or unable to consent were excluded. Using the electronic medical record, each patient's record was queried to obtain basic characteristics: age, gender, ethnicity, date of implant, pre-surgical diagnosis, and a phone number. Each patient with a valid phone number was contacted by a resident physician, and an 8-question phone survey administered. Each subject's decision regret was assessed with the Breuhat regret scale, and regret scores were calculated by reverse coding questions 2 and 4 and converting to a 0-100 scale.[14] In prior studies utilizing this decision regret tool, a value of 50 was used as a cutoff for regret.[12,15] Regret scores less than 50 were

deemed to be without decision regret and scores above 50 were associated with some degree of decision regret. Novel questions regarding device functionality, patient perceived complications, explant status and reason for explant, and military duty status were also asked. Supplementary Figure 1 depicts the survey that was administered over the phone to each participant. Descriptive and comparative statistical analyses were completed utilizing the SPSSv29 package (International Business Machines, Armonk, NY).

RESULTS

Out of the 170 identified subjects, 118 had active telephone numbers listed in their medical record. Three patients were deceased at the time of phone survey administration, and 21 patients were unable to be reached after three attempts at contact. Of the 97 patients we were able to reach by telephone and ask for consent to participate, 96 patients were willing to participate (98.9%). The one patient who declined to participate in the study did so because they did not remember that a SNM device had been implanted.

As shown in Figure 1, the median age of study participants was 49.8 ± 14.5 years, and 58.3% of the participants were female. Most of our study participants were Caucasian (60.4%), and 66.7% had OAB as their primary diagnosis. Over 80% of our participants still had a sacral neuromodulator device in place at the time of the survey (82.3%), and their devices had been in place for a mean duration of 64 ± 30 months. Of the 17 patients who had a device explanted and never replaced, five patients had the device removed because it was not working, three patients had it removed to obtain an magnetic resonance imaging, and two patients had it removed both because it was not functional and because they needed an magnetic resonance imaging. The

Patient survey responses regarding neuromodulation implant		(n=96)
"It was the right decision"		
strongly agree	57	59.4%
agree	19	19.8%
neither agree nor disagree	9	9.4%
disagree	7	7.3%
strongly disagree	4	4.2%
"I regret the choice that was made"		
strongly agree	4	4.2%
agree	6	6.3%
neither agree nor disagree	12	12.5%
disagree	21	21.9%
strongly disagree	53	55.2%
"I would go for the same choice if I had to do it over again"		
strongly agree	53	55.2%
agree	16	16.7%
neither agree nor disagree	4	4.2%
disagree	13	13.5%
strongly disagree	10	10.4%
"The choice did me a lot of harm"		
strongly agree	4	4.2%
agree	2	2.1%
neither agree nor disagree	3	3.1%
disagree	27	28.1%
strongly disagree	60	62.5%
"The decision was a wise one"		
strongly agree	54	56.3%
agree	20	20.8%
neither agree nor disagree	7	7.3%
disagree	10	10.4%
strongly disagree	5	5.2%

Figure 2. Decision regret scale responses.

remaining six patients who underwent explant did not specify why they had their device removed.

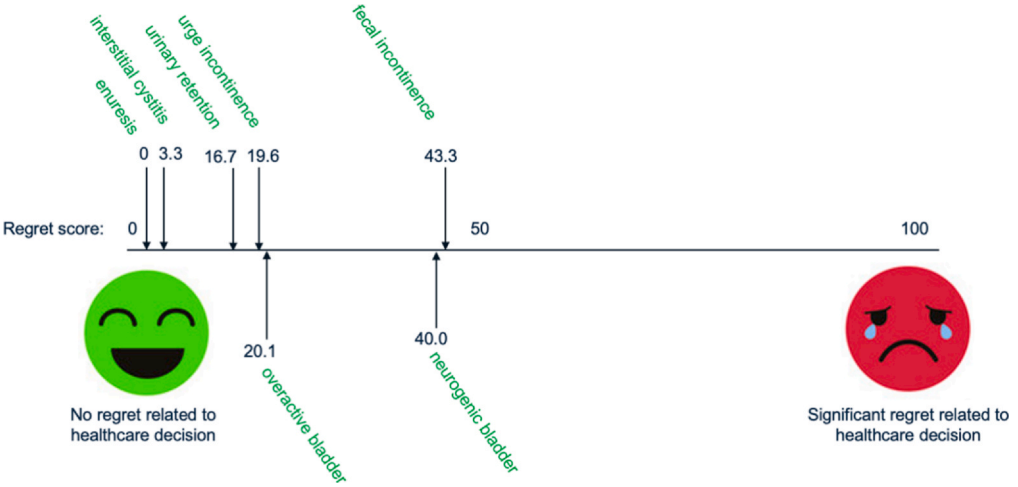
Overall, there was no significant difference in regret scores amongst different diagnoses ($P = .39$). Notably, all calculated overall regret scores fell below the pre-determined cutoff of "significant regret" set at a score of 50—Figures 2 and 3 depict survey responses and regret scores, respectively.

The median regret score for patients reporting > 50% symptom improvement with the device was significantly lower than those who did not report > 50% symptom improvement (5.4 ± 9.2 vs 44.1 ± 27.6, $P < .001$). Regret scores for patients who had device complications were significantly higher than those who did not (29.4 ± 32.4 vs 17.3 ± 23.3, $P = .04$). At the time of the survey, 82.3% of subjects had the SNM implant in place. Those subjects who underwent device explant had higher regret scores than those who retained their device (48.2 ± 31.4 vs 14.5 ± 21.1, $P < .001$). Of the subjects who underwent a military deployment with the device in place, there was no significant difference in decision regret scores (12.5 ± 19.2 vs 21.6 ± 27.2, $P = .34$). See summary of regret scores by implant status in Figure 4. Also, notably, all regret scores fell below the cutoff of 50 (Fig. 4).

DISCUSSION

Though many studies have established success rates for SNM, this study explored an aspect of a patient's medical experience that is less reported on in the literature. Evaluating decision regret for a surgical procedure with reported success rates around 67% is important when counseling patients if this can be framed within an understanding of low regret. In treating a condition that is associated largely with quality of life, objective success measurements might not correlate with patient reported success, and evaluating decision regret can provide insight into this difference. Procedures that are associated with less objective symptom improvement might be accompanied by high patient satisfaction and low regret because of the patient's perception in significant quality of life improvement. Our results support that overall decision regret after pursuing SNM is low.

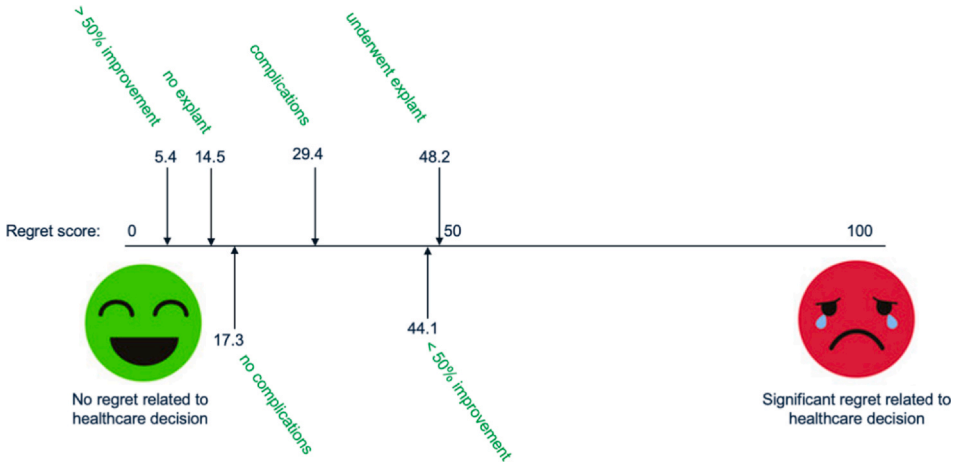
Perhaps more important than identifying low regret scores for those with successful SNM outcomes is evaluating the regret scores of patients who did not have the ideal post-SNM outcomes. We found that decision regret scores for those with non-ideal/adverse outcomes, although higher their respective counterparts, were on average still below the regret threshold of 50. In other words, having a device complication, device explant, or



Decision Regret Scores by Diagnosis (Median +/- SD) n=95^			
overactive bladder (n=64)	20.1	+/- 26.3	p=0.39*
interstitial cystitis (n=3)	3.3	+/- 5.8	
neurogenic bladder (n=4)	40.0	+/- 34.2	
urinary retention (n=6)	16.7	+/- 19.7	
urge urinary incontinence (n=14)	19.6	+/- 27.5	
enuresis (n=1)	0.0	n/a	
fecal incontinence (n=3)	43.3	+/- 37.5	

^diagnosis not listed for one patient
*one way ANOVA *F(6,87)=1.07*

Figure 3. Decision regret scores by diagnosis.



Decision Regret by Implant Outcomes		median regret score	SD	p-value*
underwent explant				
	yes (n=17)	48.2	31.4	**<0.001**
	no (n=79)	14.5	21.1	
50% symptom improvement				
	yes (n=58)	5.4	9.2	**<0.001**
	no (n=38)	44.1	27.6	
device complications				
	yes (n=26)	29.4	32.4	**0.04**
	no (n=70)	17.3	23.3	
deployed with device				
	yes (n=10)	12.5	19.2	0.34
	no (n=86)	21.6	27.2	

*Mann-Whitney U test

Figure 4. Decision regret scores by implant outcome.

poor symptom improvement did not appear to result in significant regret for undergoing SNM. A treatment modality that is associated with low decision regret is preferable, especially for a patient population who has likely experienced many previous unsuccessful therapies.

To our knowledge, this study reports decision regret with the longest follow up time, with a median time to follow up of 64 months.[11] The long duration from surgery to survey in our study provides a more durable response from patients. Our study also had very high response rate for patients who were reached via telephone; 96/97 patients were willing to participate in the study (although we cannot rule out a degree of selection bias from patients who may have refused to answer the phone calls). We also calculated regret scores using a validated tool that had previously been utilized in evaluating decision regret in bariatric surgery.

Our study was limited by a single surgeon at a single institution. Our average participant age was lower than that of the other study, likely related to the large active duty military population in our study. Specific to our military population, military deployment status had no impact on patients' regret. This warrants further investigation, both for those involved in military operations but also those with similar non-military jobs (first responders, overseas contractors, etc). Some of the diagnoses were also low in number, resulting in an underpowered analysis for fecal incontinence, interstitial cystitis, and nocturnal enuresis. We did not differentiate between the different versions of the SNM device. However, as now some devices on the market have a rechargeable battery (and others longer lasting batteries), regret related to battery exchanges is mitigated by advances in technology. Future studies looking at the different variations of the SNM devices (different battery lifespans versus rechargeable batteries) could clarify more about decision regret in patients who underwent SNM. Qualitative research examining patient stories about their experiences with SNM could also provide insight into decision regret with SNM. We should also acknowledge that although the Breuhat regret scale was validated for internal consistency, it has not been validated specifically for interventions for urinary complaints.

CONCLUSION

In our study population of active duty military, military family members, and military retirees, decision regret related to SNM appeared low. SNM adverse outcome variables (poor symptom improvement, device complications, and explanted device) were associated with significantly higher decision regret than those with more ideal outcomes, though still overall low regret when utilizing predetermined "regret" cutoff scores. Military deployment appears to have no correlation with SNM regret.

Ethical Declaration

Naval Medical Center San Diego Institutional Review Board Approval #NMCSD2019.0020.

Disclosures

None.

Data Availability

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.urology.2024.10.067.

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