Battery Explantation After Sacral Neuromodulation in the Medicare Population

Anne P. Cameron,[1]* Jennifer T. Anger,[2] Rodger Madison,[3] Christopher S. Saigal,[4] J. Quentin Clemens[1]
and the Urologic Diseases in America Project
[1]Department of Urology, University of Michigan, Ann Arbor, Michigan
[2]Cedars-Sinai Medical Center, Los Angeles, California
[3]RAND Corporation, Los Angeles, California
[4]Department of Urology, University of California in Los Angeles, Los Angeles, California

Aims: To determine sacral neuromodulation battery life and the patient and provider risk factors for early explantation in a population-based sample. **Methods:** A 5% sample of Medicare beneficiaries from 1997 to 2007 served as the data source. All patients who had a sacral neuromodulation device implanted in that time period were included. Variables included in a multivariate analysis of risk factors for removal included gender, age, race, diagnosis, type of test phase, provider specialty, and volume. The number of device reprogramming events was also recorded in this time period. **Results:** Mean follow-up was 60.5 months. Patients on average had 2.15 reprogramming episodes in their first year, with that number decreasing over subsequent years. Out of the 558 batteries implanted 63 (11.3%) were explanted. Of the 19 implanted individuals who carried the diagnosis of interstitial cystitis (IC), 11 (57.9%) had the battery removed. This was the only variable that predicted early removal, with an odds ratio of explantation of 10.5 (95% CI: 3.9–28.4). **Conclusion:** Very few sacral neuromodulation batteries, once implanted, are removed prematurely. Patients with IC, however, are at very high risk of requiring premature battery removal. *Neurourol. Urodynam. 32:238–241, 2013.* © 2012 Wiley Periodicals, Inc.

Key words: interstitial cystitis; Medicare; outcome assessment; overactive urinary bladder; sacral neuromodulation

INTRODUCTION

Sacral neuromodulation is increasing in popularity for the treatment of medically refractory bladder symptoms, with over 100,000[1] devices implanted worldwide since FDA approval in 1997. The manufacturer lists the battery life for the original model as 7 years (5.5–9.2) and the newer smaller model at 4.4 years (2.5–5.4).[1]

It is unknown, however, how well these batteries perform outside of manufacturer trials and how many of these devices are removed prematurely. In small trials actual battery longevity has been similar to those listed by the manufacturer,[2] but removal can be performed for infection, damage to device, site pain, poor clinical response, need for MRI, and battery depletion.[3–5] It is unknown which individuals are at higher risk for the need for removal, but studies suggest that more revisions are performed on devices implanted earlier in the learning curve of the device,[4] and in those who had percutaneous tests compared to staged testing with the tined lead,[5] but these results are not universal.[2] Certain urological diagnoses may increase one's risk of device explantation. Interstitial cystitis (IC) patients over the long-term had a 50% explantation rate in one study, but in another study of exclusively IC patients there were no explantations reported.[2,6] It is also unknown how frequently patients require device reprogramming and if this has any impact on device survival.

Our goal in this analysis was to identify the explantation and device reprogramming rate over the long-term and to identify patient and provider risk factors for early explantation.

MATERIALS AND METHODS

A 5% sample of Medicare beneficiaries from 1997 to 2007 was the data source utilized. All patients in the sample who had a sacral neuromodulation battery implantation identified using CPT code 64590 (insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver) and had a urological diagnosis associated with this procedure were included in the analysis. Any patient who had their battery explanted within 90 days was excluded since this was likely due to infection or early device malfunction (n = 3, 4.8%). For analysis purposes, patients were divided into five mutually exclusive diagnosis groups based on the first two ICD-9 diagnostic codes linked to the battery implantation. Any patient with a neurogenic bladder diagnosis (NGB) was placed in the neurogenic category; those with IC were placed in the IC group unless they had a diagnosis of NGB. Those with incomplete bladder emptying or non-obstructive urinary retention were placed in the retention group unless they had IC or NGB. Those with urgency incontinence or other forms of incontinence except stress incontinence were placed in the "wet" overactive bladder (OAB) group unless they had one of the preceding diagnoses. The remaining persons with urgency, frequency, and nocturia were placed in the "dry" OAB group since they did not have a diagnosis of incontinence. All other urologic diagnosis associated with a procedure that did not fit into one of the above-mentioned categories were grouped into

the "other" category. Any person who had no urologic diagnosis whatsoever associated with their procedure was excluded since these were likely other types of neuromodulating devices.

Medicare demographic data were also utilized to determine patient age and race/ethnicity. The specialty of the provider who performed the implant was taken from the CMS claim line item for the procedure. Physicians were tracked by their unique physician identification number (UPIN) and the surgeon volume was determined for each provider and divided into high and low volume based on the number of implants performed in the entire period (1997–2007). Those surgeons in the 75th percentile and above of surgical procedures were deemed to be "high volume." The implant was considered to be preceded by a percutaneous test if the patient underwent a percutaneous test (64561) followed by a simultaneous permanent lead and battery implant (64581 + 64590). Patients who had a permanent lead placed (64581) followed by a device implant at a later date (64590) were considered to be a two-staged procedure. Any patient who did not have a battery explantation identified by code 64595 (revision or removal of peripheral or gastric neurostimulator pulse generator or receiver) at any point during follow up was considered to have a working implant.

Reprogramming events of the device (95972) were recorded at yearly intervals following implant. For those patients who had a device removed, the number of reprogramming events was recorded in the 12 months before explantation. The reprograming event numbers were compared between patient groups using an unpaired t-test.

Initial data on the success of test stimulation in this population has previously been reported.[7] A multivariate logistic regression was carried out to determine those patient or provider factors that increase the risk of battery removal. Kaplan–Meier curve was created to determine battery survival over time with a battery explantation deemed as battery failure with patient mortality accounted for in calculations.

RESULTS

In total there were 561 battery implants from 1997 to 2007. 81.5% of the population was female and 92.6% Caucasian. Three implants were removed within 90 days (4.8%) and were excluded leaving 558 implants evaluable. At the end of follow-up (mean 60.5 months) 89.7% of implants were still in place (Fig. 1) with a total of 63 explantations. Mean time to explantation could not be calculated given the small number of explants in the group. These results did not change even after accounting for patient mortality (n = 27) during the follow-up period.

Of the 63 devices explanted seven (11.1%) had a new battery implanted on the same day as explant. Out of these six had urgency incontinence and only one had IC.

Reprogramming occurred on average 2.15 times the first year after implant, 0.70 times year 2, 0.65 time year 3, 0.48 times year 4, and 0.36 times year 5. There were no differences in the number of reprogramming events based on age or type of test phase. However, compared to the reference diagnosis of IC, individuals who were implanted with a diagnosis of NGB or OAB both wet and dry were reprogrammed more frequently. In the year before device explant patients had their device reprogrammed a mean of 0.35 times with no difference in the number of reprogramming events among any of the groups except IC who had zero reprogrammings (Table I).

On multivariate analysis (including the variables of provider volume, provider specialty, type of test phase, patient age, diagnosis, gender, and race), none reached statistical significance except IC as a diagnosis. Eleven of 19 (57.9%) batteries implanted for IC were removed and the odds of explantation for IC was 10.5 (95% CI: 3.9–28.4; Table II).

DISCUSSION

These findings suggest that sacral neuromodulation implantable devices are infrequently removed, with only 10.3% of batteries removed in the 60.5 months timeframe among a 5% sample of the Medicare dataset. Devices were reprogrammed most frequently in the year following implant, but surprisingly patients only had their device reprogrammed 0.35 on average in the year prior to explantation.

Ninety days was chosen as the cutoff for explantation due to infection. All three of these very early device removals were
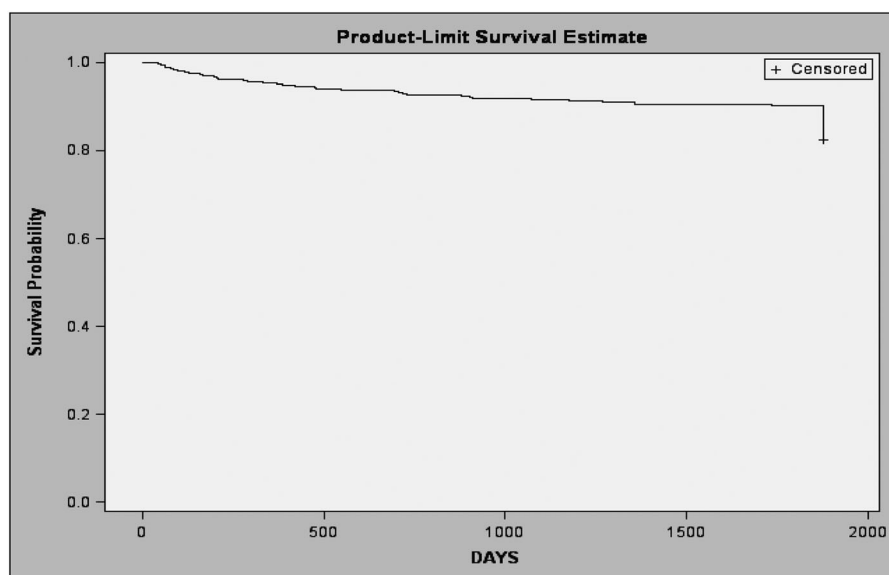

Fig. 1. Kaplan–Meier estimator for battery explantation.

TABLE I. Sacral Neuromodulation Device Reprogramming Events After Implantation and 12 Months Before Explantation

Effect	First year (n = 558)	P-value[a]	Second year	Third year	Fourth year	Fifth year	In year prior to explant[b] (n = 63)	P-value
Total	2.15	—	0.70	0.65	0.48	0.36	0.35	—
Percutaneous test	2.04	Ref.	0.69	0.56	0.31	0.00	0.35	Ref.
Two-stage test	2.20	0.34	0.71	0.71	0.60	0.60	0.36	0.49
Interstitial cystitis	1.49	Ref.	0.27	0.69	0.78	0.87	0.00	—
Neurogenic bladder	2.37	0.011	0.72	0.34	0.97	1.13	0.73	0.22
Retention	2.07	0.053	0.65	0.54	0.30	0.11	0.22	0.54
Overactive bladder wet	2.14	0.038	0.74	0.77	0.54	0.24	0.26	Ref.
Overactive bladder dry	2.26	0.019	0.72	0.55	0.33	0.50	0.95	0.15

[a]Includes only first year, insufficient data to compare second through fifth year.
[b]Includes only patients who were explanted.

within the first 30 days of implant. These results are comparable to other large series where infections occurred in 3.5% at a mean of 16.5 days after device implant.[8]

Seven patients who had their device removed (11.1%) had a new device implanted on the same day. Clinically, this would be performed in cases of battery depletion or device breakage or malfunction and not in cases of inefficacy or pain from the device. Only one of these seven patients carried the diagnosis of IC. Other studies have shown similar results with low explantation rates of 9.8–14.1% for urgency incontinence, urgency/frequency syndrome, and non-obstructive urinary retention.[3–5,9,10] In these studies the majority of explantations were performed for loss of efficacy or device infection. In three long-term studies of device complications,[2–4] the reported rate of infection was 4–17%, loss of efficacy 0–28%, device damage 2–4%, lead migration 3–8%, and hematoma/seroma 10%. Pain at the site of the device was reported between 15% and 53% and new onset pain 0–43%. Unfortunately we were not able to determine the reason for battery explantation in our series.

Patients in this study with a diagnosis of IC fared poorly with a 57.9% explantation rate. In this analysis, IC was the only identifiable risk factor for early battery removal. Assuming that these individuals do not have a greater risk of infection than others, one would have to presume that the majority of these explants were for lack of efficacy or new pain at the device site, and since only one of these patients had a new device implanted when the device was removed this assumption is likely. Others have evaluated the long-term results of sacral neuromodulation devices in patients with IC. In a study of 17 individuals with IC implanted with a neurostimulator, none required revision or explantation over an average of 14 months.[6] In a group of 46 individuals with

painful bladder syndrome/IC, 28% were explanted mostly for poor efficacy and 50% required revisions over 61.5 months.[11] In another study of exclusively IC patients followed an average of 60 months, 11 of the 22 patients required explantation for battery depletion (4), ineffectiveness (3), infection (1), and other reasons (3).[2] The authors felt that, despite the high explantation rate, the long-term effectiveness of the device was good with no decrease in benefits for 86% of patients at 59.9 months.

Perhaps patients with IC in this series fared so poorly long-term because the S3 nerve root stimulation is not the ideal route for neuromodulation and they are better treated with stimulation of another nerve. In a prospective trial with 17 IC patients with an implanted battery stimulated with either a standard sacral lead or a pudendal nerve lead, Peters et al.[12] found more improvements in urgency and frequency at 6 months with the pudendal stimulation but no difference in pain. Zabihi et al.[13] had a 42% success rate in treating both pain and voiding symptoms in a group of 23 individuals with chronic pelvic pain or IC who had already failed traditional S3 sacral neuromodulation with bilateral S2–S4 neuromodulation.

In this series patient who had a two-staged test did not have better device survival than patients who had a percutaneous tests and did not require more reprogramming events. This is in contrast to the findings of a retrospective series of 104 patients with an equal number of two-staged tests and percutaneous tests where lack of efficacy was reported three times higher in patients who had the percutaneous test.[5] These patients, however, all were implanted with the older non-tined lead which may be the contributing factor, not the type of test. A more recent series did not report a difference in device revisions between the two test types.[2]

TABLE II. Patient and Provider Variable's Impact on Sacral Neuromodulation Device Explantation

Effect	Explanted devices	Odds ratio of removal	95% Confidence limit
High volume provider versus low volume provider	29/256 (11.3%) 34/302 (11.3%)	1.10	0.63–1.93
Urologist versus other surgeon	53/461 (11.5%) 10/97 (10.3%)	1.20	0.56–2.56
Percutaneous test versus two-stage test	45/365 (12.3%) 18/193 (9.3%)	0.69	0.38–1.27
Caucasian versus other races	58/517 (11.2%) 5/41 (12.2%)	0.81	0.29–2.27
Female versus male	56/455 (12.3%) 7/103 (6.8%)	1.94	0.82–4.57
Age ≤75 versus >75	46/369 (12.5%) 17/189 (9.0%)	1.19	0.64–2.21
Diagnosis versus all others			
Neurogenic bladder	5/26 (19.2%)	2.27	0.78–6.65
Interstitial cystitis	11/19 (57.9%)	10.48	3.86–28.5
Retention	5/69 (7.3%)	0.64	0.24–1.73
Overactive bladder wet	32/294 (10.9%)	0.61	0.29–1.29
Overactive bladder dry	10/115 (8.7%)	0.60	0.22–1.11

The finding of reprograming episodes occurring most frequently in the first year after implant is not surprising since this is a new device for the patient that can often be optimized soon after implant with device reprogrammings. The lack of reprogramming episodes in the year prior to explant, however, is surprising since lack of efficacy is often initially treated with a change in device settings to improve the clinical situation.[1,14]

It is possible that patients had exhausted all reprogramming options prior to device removal; however, waiting 12 months after reprogramming to have an ineffective device removed seems unlikely. Perhaps those patients who had devices explanted were not offered reprogramming as an option or had the device explanted for pain, which is not typically treated with reprogramming. Given that the majority of explants were for IC which is a chronic pain condition and that this patient population had the fewest reprogramming episodes in the year prior to explant, the latter is certainly likely.

There are several limitations to this analysis. There are inherent problems with utilizing billing data to determine patient outcomes. Coding of diagnosis and procedures is not always accurate, but given that there is only one possible CPT code for battery implantation (64590) and one for removal (64595), and that accurate coding is essential for reimbursement, it is unlikely that procedure coding would be erroneous. There is however the possibility that an individual could have their battery removed under a different type of insurance, and would not be captured in this dataset. However, this is also likely to be uncommon.

Medicare patients as a whole are a more elderly population, hence these results may not be generalizable to the general population, but the explantation rate is comparable to other series with mixed age populations. Therefore, there is no reason to believe that the elderly have a greater rate of explantation. The major limitation of this analysis is the assumption that a device is still functional if it has not been explanted. Many individuals lose efficacy, but may elect not to have the device explanted since it is causing no symptoms and this would require another surgery. With no clinical information about bladder symptoms we cannot estimate this number. Also, for those individuals who did have their device explanted, we do not know the clinical reasons for the failure. We assume that the device was indeed removed for a failure, but the need for an MRI or spontaneous resolution of their symptoms is not a device failure per se, but may have been coded as such in this analysis.

CONCLUSIONS

Very few sacral neuromodulation batteries once implanted are removed prematurely. Patients with IC, however, are at very high risk of requiring a battery removal likely due to pain or device non-efficacy.

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