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BATTERY EXPLANTATION AFTER SACRAL NEUROMODULATION IN THE MEDICARE POPULATION

Hypothesis / aims of study

Sacral neuromodulation is increasing in popularity for the treatment of medically refractory bladder symptoms. The manufacturer lists the battery life for the original model as 7 years (5.5-9.2). It is unknown, however, how well these batteries perform outside of manufacturer trials in the general population and how many of these devices are removed prematurely. Removal can be performed for infection, damage to device, site pain, poor clinical response, need for MRI, and battery depletion (1,2). It is unknown who is at risk for premature removal, but studies suggest that more revisions are performed on devices implanted earlier in the learning curve of the device and in those who had percutaneous tests compared to tined (2). It is our aim to determine the real world battery life and determine who is at risk for early explantation.

Study design, materials and methods

A 5% sample of Medicare from 1997-2007 was used to identify patients who had a sacral neuromodulation battery implantation using CPT code 64590. Any patient who had their battery explanted within thirty days was excluded since this was likely infection or early device malfunction. Any patient who did not have a battery explantation (CPT code 64595) was considered to have a working implant. Multivariate analysis was carried out to determine those factors that increase the risk of battery removal including the patient variables of age, race, diagnosis, and gender as well as provider variables such a number of procedures performed and specialty. The ICD-9 diagnosis associated with the battery implantation was utilized to divide patients into five mutually exclusive groups.

Results

In total there were 561 battery implants with 81.5% of the population being female and 92.6% Caucasian. 3 implants were removed within 30 days (4.8 %) and were excluded from the analysis. At 60.5 months 89.7% of implants were still in place (Figure 1) and mean time to explantation could not be calculated given the small number of explants in the group. On multivariate analysis (including the variables of provider volume, provider specialty, patient age, diagnosis, gender and race) none reached statistical significance except interstitial cystitis as a diagnosis(Table 1). Fully 11 of 19 (57.9%) of batteries implanted for interstitial cystitis were removed and the odds of explantation was 10.5 (3.9-28.4 95% CI).

Interpretation of results

Long term results indicate good battery survival for individuals who received neuromodulation for a diagnosis of overactive bladder, urgency incontinence, and non obstructive retention in other trials (2) and our results have confirmed this observation. In other series IC patients have as high as a 50% explantation rate over 60 months (1) while some have reported no explantations (3). This review of a 5% Medicare sample had a 57.9% battery explantation rate, which on multivariate analysis was the only factor that increased the risk for battery removal. In a prior analysis of the success rate of battery implantation in this same population, the success in IC was not different than other diagnosis so an excess of implants does not explain the excess risk of removals.

There are several limitations to this analysis, we do not have the indication for the device removal, and there are more elderly in the Medicare population so these results may not be generalizable. Also, not all patients who lose effectiveness have their device removed, hence would be mislabelled as a success. There is also the possibility that an individual had their device removed under a different form of insurance so would not be captured as an explant.

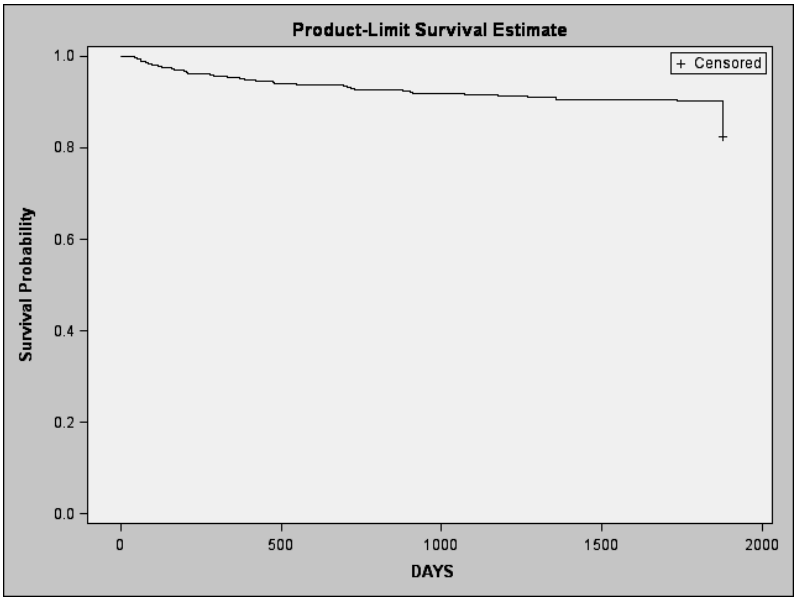
Concluding message

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

Table 1: Multivariate Analysis of Predictors of Battery Explantation

Effect	Explanted devices	Odds ratio of removal	95% confidence limit
High volume provider Low volume provider	29/256 (11.3%) 34/302 (11.3%)	1.10	0.63-1.93
Urologist Other surgeon	53/461 (11.5%) 10/97 (10.3%)	1.20	0.56-2.56
Caucasian Other races	58/517 (11.2%) 5/41 (12.2%)	0.81	0.29-2.27
Female Male	56/455 (12.3%) 7/103 (6.8%)	1.94	0.82-4.57
Age less than 75 Age over 75	46/369 (12.5%) 17/189 (9.0%)	1.19	0.64-2.21
Diagnosis vs. all others: Neurogenic bladder Interstitial cystitis Retention OAB wet OAB dry	 5/26 (19.2%) 11/19 (57.9%) 5/69 (7.3%) 32/294 (10.9%) 10/115 (8.7%)	 2.27 10.48 0.64 0.61 0.60	 0.78-6.65 3.86-28.5 0.24-1.73 0.29-1.29 0.22-1.11

Figure 1: Kapplan Meier Curve of Battery Survival



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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**It utilised a completely de-identified data set**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**