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Dandolu V[1], Alemi G[1], Sura S[1]
1. *University of Nevada School of Medicine*

SACRAL NEUROMODULATION- HOW COMMON IS REMOVAL OR REPLACEMENT OF DEVICE AFTER INSERTION?

Hypothesis / aims of study

To evaluate the rate of generator removal and replacement in subjects who had sacral neuromodulation.
The rates in the literature are variably reported, the studies involved small number of patients and loss to follow-up rates were high.(1-3)

Study design, materials and methods

This is a population based cross sectional study based on 2001-2010 US Thomson Reuters MarketScan Commercial Claims and Encounters data. The database composed of detailed information about clinical utilization, expenditures and enrollment across inpatient, outpatient, emergency room and prescription drug claims of several individuals enrolled in employer-sponsored and public health insurance plan.
Study cohort included patients 18 years of age and older who received direct sacral nerve stimulation procedure. All sacral nerve stimulation procedures performed were identified from inpatient admission, inpatient services, outpatient services and facility header files using CPT or ICD-9-CM procedure codes. Specifically, following procedure codes were used to identify sacral nerve procedures: PNE (CPT code - 64561 or ICD-9-CM code - 04.92); stage 1 (CPT code - 64581); stage 2 (CPT code - 64590 or ICD-9-CM code – 86.94); generator removal (CPT code – 64595), generator replacement (use of cpt 64590 in a patient that already had generator implantation at prior encounter. All statistical analyses were performed using SAS 9.3.

Results

There were a total of 9736 sacral neuromodulation generators implanted in 7779 individuals during the study period. 79.1% were in women and 20.9% in men. 639 subjects (8.21%) had two implants, 88 subjects (1.13%) had 3 implants, 17 (0.21%) had 4 implants and 126 (1.62%) had more than 4 implants.
There were 982 generator explants (12.62%) as identified by cpt code 64595.
The most common diagnoses associated with device explants were urinary incontinence, urgency, frequency (34.11%), urinary retention (5.28%), and mechanical or other complications related to the implant (29.84%).
Another 985 subjects (12.66%) had generators removed and replaced in the same encounter. An additional 128 subjects had generators removed at one encounter and replaced at a subsequent encounter resulting in a total 1145 replants (14.72%).
Among the generator replacements, 25.33% reported mechanical or other complications related to genitourinary device, implant, as the indication for generator replacement, while a significant number reported the underlying condition rather than an actual indication for replacement of device (eg 38.16% incontinence/frequency/ urgency and 7.16% urinary retention etc.)

Interpretation of results

The rate of surgical interventions including generator removal and generator replacement, were more common than reported in literature (1-3). Loss to follow-up, or seeking different provider for removal limit the accuracy of results from single surgeon experience. The claims data set overcomes these limitations as the results are available irrespective of who follows the patient. However claims that are submitted late or denied for whatever reason are not captured in this dataset. Therefore the rates from this study still are underestimates than true rates but represent the most unbiased numbers we can obtain.

Concluding message

It is of great concern that a high proportion of implants does not work or lose efficacy after implantation, as this is a very expensive procedure. Patients undergoing sacral neuromodulation need to be counselled regarding the high rate of removal and replacement of device. When explants or replants are reported, surgeons need to be more precise in reporting the indication for surgical intervention rather than noting the underlying diagnosis to have more meaningful data in the future.

References

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Disclosures

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