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EFFICACY AND TRENDS IN USAGE OF SACRAL NERVE NEUROMODULATION IN A HEALTH MAINTENANCE ORGANIZATION SETTING - KAISER PERMANENTE SOUTHERN CALIFORNIA.

Hypothesis / aims of study

Sacral nerve neuromodulation (SNM) has been gaining popularity in treatment of various disease processes including nonobstructive urinary retention, overactive bladder, interstitial cystitis, and fecal incontinence. It is a 2 staged procedure requiring percutaneous lead placement followed by a trial period. If clinically effective, implantation of a permanent battery device ensues. Although SNM has been utilized for some 14 years, there have been few studies focusing on its trend of usage and utilization efficacy.

With this study, we aim to characterize the usage trend of SNM and define its overall success rate in the Southern California Kaiser Permanente patient population. Our success rate will be determined by rate of conversion from stage 1 to stage 2 and the long-term usage of stage 2 sacral neuromodulation. We will also determine the longevity of the sacral nerve stimulator. Lastly, we attempt to identify positive and negative predictors of stage 2 implantation.

Study design, materials and methods

After Institutional Review Board approval was obtained, a retrospective review of patients who underwent stage 1 and stage 2 sacral neuromodulation between August 1998 to August 2011 was performed. Subjects were identified by using current procedure terminology codes of sacral stimulator stage 1 placement, stage 2 placement, removal, and revision. All subjects are members of Southern California Kaiser Permanente Health Plan. Subjects all underwent urodynamic evaluation and had diagnosis of neurogenic bladder, interstitial cystitis, idiopathic nonobstructive urinary retention, and overactive bladder. Patients younger than 18 years of age and with diagnosis of fecal incontinence were excluded.

Success rate is defined by rate of stage 2 procedure completion and clinical confirmation of device functionality. Removal of percutaneous lead, whether due to lack of clinical efficacy or patient preference, is considered as failure. Longevity of device is the duration of neuromodulator maintenance without need of revision or removal. Relevant complications including wound infection, device failure, and persistent pain due to device position were noted. All data were recorded in a standard database. Descriptive statistics and chi-square test were performed with Graphpad Prism.

Results

Patient Characteristics					
		Stage 1	**Stage 2**	**Total**	**P value**
Number of Subjects		**42 (23%)**	**146 (77%)**	**188**	
Mean Age (Range)		62 (17 - 85)	61 (16 - 84)		0.29
BMI (kg/m^2)		29 (20 - 50)	30 (18 - 59)		0.21
Gender					0.72
	Male	18 (43%)	57 (39%)	75 (40%)	
	Female	24 (57%)	89 (61%)	113 (60%)	
Race					0.43
	Asian	6 (14%)	8 (5%)		
	Caucasian and African American	24 (57%)	105 (72%)		
	Hispanic	11 (26%)	32 (22%)		
	Other	1 (3%)	1 (1%)		
Diagnosis					0.56
	Wet Overactive Bladder	13 (31%)	66 (45%)	79 (42%)	
	Dry Overactive Bladder	18 (43%)	48 (33%)	66 (35%)	
	Urinary Retention	4 (9%)	10 (7%)	14 (7.5%)	
	Neurogenic Bladder	3 (8%)	9 (6%)	12 (6.5%)	
	Interstitial Cystitis	4 (9%)	13 (9%)	17 (9%)	

Interpretation of results

A total of 202 subjects were identified and 14 were excluded. 188 subjects were enrolled. 146 (77%) subjects underwent successful stage 2 procedure after a mean trial period of 8 days. 42 (23%) subjects had only percutaneous lead trial after a mean trial period of 7 days. There was no statistically significant difference between age, race, gender, BMI, and diagnosis between those who failed percutaneous trial and those who proceeded to stage 2. Of those who underwent stage 2 procedure, 9 subjects (6%) underwent revision after a mean usage time of 27 months and 7 subjects (5%) underwent removal after a usage time of 17 months). Mean follow up time for was 13.8 months (3 to 110).

Concluding message

Our data reports similar conversion rates as reported in available literature, suggesting similar pattern of SNM usage in a HMO setting. Long term follow up and accrual of data is necessary to confirm above finding.

References

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