103

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UNILATERAL VERSUS BILATERAL STAGE I NEUROMODULATOR LEAD PLACEMENT FOR THE TREATMENT OF REFRACTORY VOIDING DYSFUNCTION

Hypothesis / aims of study

We sought to determine if bilateral third sacral (S3) nerve lead insertion during the stage I trial period improves the "success" rate for advancing to stage II (permanent) sacral neuromodulator placement.

Study design, materials and methods

Medical records of all patients undergoing stage I sacral neurostimulator (InterStim®, Medtronic, Minneapolis, Minnesota) implantation for the treatment of refractory voiding dysfunction from October 2001 to June 2007 were retrospectively reviewed. Prior to surgery each patient underwent thorough urological history, physical examination, urine analysis and urodynamic testing. Patients were divided into two cohorts based on unilateral versus bilateral stage I lead placement in the S3 foramina. The decision to perform unilateral or bilateral placement was determined by surgeon discretion. Patients in the bilateral cohort had each lead tested separately during the trial period to determine which, if any, worked better. Patients that underwent successful unilateral or bilateral stage I lead placement proceeded to unilateral stage II implantation. The S3 lead that was not utilized was removed at the time of stage II implantation. Progression from stage I to stage II was performed for all patients that exhibited greater than 50% improvement in urinary symptoms during a 2 week trial period, based on subjective (symptom scores) and objective (diaries and pad weight tests) measures. Patients that did not report a 50% improvement in symptomatology following stage I implantation underwent removal of all components. Information abstracted from medical records included indications for neuromodulation trial, lead location(s), progression from stage I to II and complications. Any patient with who developed lead infection had the components explanted and was not considered "successful". The primary outcome measure for this study was progression to stage II. Statistical significance was determined using Fisher's exact test.

Results

One-hundred and twenty-four (104 female and 20 male) patients underwent stage I sacral neuromodulator implantation. Fifty-five (44%) received unilateral and 69 (56%) bilateral S3 leads. Mean age of the unilateral group was 51.8 years while those receiving bilateral leads averaged 49.9 years (p = 0.53). Indications for implantation are listed in table I. Pre-existing chronic co-morbidities were statistically similar for each group. Successful stage I trials were reported in 32/55 (58%) and 53/69 (76%) of unilateral and bilateral cohorts, respectively (p = 0.03). When examined based on indications for neuromodulation, patients undergoing bilateral lead placement for urinary urgency/frequency demonstrated a significantly higher success rate than the unilateral group (p = 0.04). Subjects receiving bilateral implants for urinary retention or pelvic pain did not demonstrate a significantly improved outcome when compared to the unilateral cohort (table II). Five wound infections were reported - 2 (3.6%) following unilateral and 3 (4.3%) after bilateral stage I lead placement. No other complications were encountered.

Table I: Indications for sacral neurostimulator trial

	Unilateral S3 lead placement (%)	Bilateral S3 lead placement (%)	P value
Urinary urgency/frequency	40 (73)	55 (80)	0.40
Non-obstructive urinary retention	14 (25)	13 (19)	0.39
Pelvic pain	1 (2)	1 (2)	0.94
Total	55	69	

Table II: Outcomes following stage I implantation

		Successful unilateral trial (%)	Successful bilateral trial (%)	P value
Overall		32/55 (58)	53/69 (77)	0.03
	Urgency/frequency	24/40 (60)	44/55 (80)	0.04
	Non-obstructive urinary retention	8/14 (57)	8/13 (62)	0.92
	Pelvic pain	0/1 (0)	1/1 (100)	

Interpretation of results

Sacral nerve stimulation is an efficacious treatment for patients with refractory voiding dysfunction, namely urgency/frequency or non-obstructive urinary retention. Previously published reports indicate successful staged implantation rates ranging from 40 to 80% depending on indication. In our study, successful unilateral trial stimulation was reported in 58% of patients. Success rates improved to 77% in the bilateral group (p = 0.03). Our results do suggest that when bilateral leads are implanted and tested separately, there is a greater likelihood of symptomatic improvement with resultant progression to stage II pulse generator implantation. This was particularly true for our urgency/frequency patients but not for those undergoing the procedure for urinary retention or pelvic pain. However, the population of patients in the latter two groups may be too small to determine statistical meaning.

Limitations of bilateral stage I lead placement include increased cost and operative time. The additional hardware cost of bilateral lead insertion is approximately $1500 (US dollars) when compared to placement of a single lead. While operative times can vary, in our experience the bilateral stage I procedure takes approximately 20-30 additional minutes when compared to conventional, unilateral lead placement. Furthermore, with the added hardware being implanted, one could hypothesize a higher risk for device infection. Device infection after sacral modulator implantation has been reported in up to 12% of patients. Based on the current study, however, it does not appear that bilateral lead placement increases the risk for wound infection or complication. Individual surgeons should decide if the increased operative time and cost balances improved patient outcomes.

Concluding message

Sacral neuromodulation is a successful treatment modality for refractory urinary urgency/frequency and non-obstructive urinary retention. Based on our retrospective review, patients receiving bilateral stage I S3 leads demonstrated significantly improved outcomes when compared to those receiving unilaterally placed leads. Therefore, surgeons may consider bilateral percutaneous lead placement when performing stage I neuromodulation for refractory voiding dysfunction. Randomized, prospective clinical trials may be warranted to fully determine the benefit of bilateral stage I lead placement.

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Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**