Abdominal Versus Standard Placement of the Sacral Nerve Stimulator Implantable Pulse Generator

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OBJECTIVES To determine patient factors prompting anterior abdominal wall placement of the sacral nerve stimulator implantable pulse generator and investigate revision and infection rates for buttock (standard) and abdominal placement.

METHODS We retrospectively reviewed records of consecutive sacral nerve stimulation procedures by a single surgeon from 2012 to 2017 at a single institution.

RESULTS 75 patients underwent sacral nerve stimulation——60 with standard and 15 with abdominally placed implantable pulse generators. The mean age and body mass index of the standard group was higher than that of the abdominal group and the majority was female. A greater proportion of patients in the abdominal group had a neurological diagnosis and was wheelchair-dependent. Overall, a total of 20 patients underwent 38 revision surgeries. The indications for revision surgery were pain, loss of efficacy, or lead migration. The standard group accounted for more revisions than the abdominal group (34 vs 4 cases, $P = .048$), with no revisions due to pain in the abdominal group. The infection rate (2% vs 13%, $P = .10$), average time from implantation to revision, and operative duration were not statistically different between groups.

CONCLUSION In a subset of patients who were wheelchair-dependent or lacked gluteal fat, placement of the implantable pulse generator in the anterior abdominal wall resulted in no revisions due to pain. Operative duration and infection rates were similar between abdominal and standard placement. Abdominal placement with extended length leads could be considered as a primary or revision option in these select patients. UROLOGY 127: 49—52, 2019. © 2019 Elsevier Inc.

Sacral nerve stimulation (SNS; InterStim, Medtronic, Minneapolis, MN) is effective treatment modality for refractory voiding dysfunction, specifically frequency, urgency, urge incontinence, and nonobstructive urinary retention.[1-3] In the 1990s, the implantable pulse generator (IPG) was placed in the lower part of the anterior abdominal wall. However, a 2001 study of 39 patients undergoing buttock implantation demonstrated shorter operative times, fewer incisions, and lower complication and reoperation rates.[4] Buttock implantation has shown promise in subsequent years[5,6] and its indications expanded to include fecal incontinence and constipation,[7] but revision rates approach 30% for a variety of reasons including lead migration and pain at the implant site.[8] In wheelchair-dependent patients or those lacking gluteal fat, primary abdominal wall placement of the IPG or revision to the abdominal wall may prevent the pressure-relate pain associated with the IPG. The purpose of this study was to determine the patient factors prompting abdominal placement at our institution, describe this technique, and examine outcomes of both buttock (standard) and abdominal placement.

METHODS

We identified 75 consecutive patients who underwent standard or abdominal placement of the SNS IPG by a single surgeon at our institution from 2012 to 2017. The electronic medical record was retrospectively reviewed for patient demographics, IPG location, operative details, and revision and infection rates. The operative time to complete each stage included repositioning the patient during abdominal placements when stage I and II were performed on the same day. Continuous variables were assessed using paired t test. Categorical variables were assessed

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with Fisher's exact test or Chi-squared analysis. A P value of $< .05$ was considered to be significant. All statistical analyses were performed with SAS 9.4 (SAS Inc., Cary, NC). The institutional review board at our institution approved this study.

Abdominal Placement Technique

All patients received preoperative vancomycin and gentamicin, which were fully infused prior to incision. Patients undergoing stage I placement were positioned in the prone position on the operating table. The S3 foramen was fluoroscopically identified, finder needles placed, and responses evaluated. The lead was introduced and electrodes were tested. The lead was tunneled to a pocket laterally and cephalad, to allow subsequent tunneling to avoid the anterior iliac crest. Depending on body habitus, a 45 cm lead may be placed and the redundant lead coiled. On stage II implantation, the patient was placed in modified lateral decubitus position, with the side of abdominal implantation facing up. The external wire was removed in its entirety. A 10 cm or 25 cm extender was utilized to connect to the Interstim I device. The position for the stimulator was chosen in the anterior lower abdominal wall, roughly at the level of the anterior superior iliac spine and 3 cm medial to it. The extender or 45 cm lead was tunneled from the connection site to a pocket created in the anterior abdominal wall. If stage I and II were performed on the same day, the lead was placed prone and an Ioban (3M, St. Paul, MN) placed over the lateral incision to keep the field sterile when repositioning the patient. The Ioban was removed and the abdominal and lateral sites were prepped with Chloraprep (BD, Franklin Lakes, NJ). All patients were sent home with 7 days of dicloxacillin postoperatively or Bactrim if penicillin-allergic.

RESULTS

Overall, 75 patients were identified. Of these, 60 patients underwent standard and 15 underwent abdominal placement of the IPGs. They were followed for a mean of 35 months and 24 months, respectively. Patient demographics are listed in Table 1. The average age of patients undergoing standard placement was higher than that in the abdominal group (63 years vs 54 years, $P = .047$), as was body mass index (BMI) (32 kg/m^2 vs 26.8 kg/m^2, $P = .007$). Females comprised the majority of both groups ($P = .66$). A greater proportion of patients in the abdominal group had a neurological diagnosis (7% vs 80%, $P = .001$) and was wheelchair-dependent (2% vs 73%, $P < .0001$). The neurological diagnoses leading to voiding dysfunction are listed in Table 2.

Table 2. Neurological etiologies of voiding dysfunction

	Standard Placement (n = 60)	Abdominal Placement (n = 15)
Neurological diagnosis	4 (7%)	12 (80%)
Multiple sclerosis	2 (3%)	5 (33%)
Cerebral palsy	2 (3%)	2 (13%)
Incomplete spinal cord injury	0	2 (13%)
Stroke	0	1 (7%)
Myotonic dystrophy	0	1 (7%)
Primary lateral sclerosis	0	1 (7%)

Twelve patients had the IPG placed in the anterior abdominal wall on initial implantation. Nearly all of these were due to being wheelchair-dependent while one patient had a BMI of 16 kg/m^2 and a lack of gluteal fat. Three patients had the IPG revised from the standard location to the abdomen. Of these, 2 patients had refractory pain at the IPG site which resolved with resiting and one had significant weight loss causing discomfort after initial standard placement. Fourteen IPGs implanted abdominally were Interstim I and were performed with the 25 cm extender. One IPG was the Interstim II with a 45 cm lead utilized to reach the abdominal site.

Similar proportions of patients underwent 2-stage SNS testing in the operating room (40% standard vs 53% abdominal, $P = .35$) (Table 3). The time to complete each stage was similar (first stage 62 minutes vs 70 minutes, $P = .07$; second stage 32 minutes vs 47 minutes, $P = .09$) but there was a trend toward increased operative time for the abdominal placements.

A total of 20 patients underwent 38 revision surgeries (Table 4). The standard group accounted for more of these revision surgeries than the abdominal group (34 vs 4 cases, $P = .048$). Revision surgeries were due to pain (29% standard group vs 0% abdominal group, $P = .56$), loss of efficacy (53% vs 75%, $P = .61$), or lead migration (18% vs 25%, $P > .99$). The infection rate was not significantly different (2% [1/60 patients] vs 13% [2/15 patients], $P = .10$). The average time from implantation to need for revision was shorter in the abdominal group, although not statistically significant (31 months vs 11 months, $P = .24$).

COMMENTS

In our analysis, abdominal placement of the IPG was linked to a low revision rate, specifically due to pain, in a subset of patients who were wheelchair-dependent or lacked gluteal fat. There was no significant difference in

Table 1. Demographics of patients undergoing standard and abdominal placement of the sacral nerve stimulator implantable pulse generator

	Standard Placement (n = 60)	Abdominal Placement (n = 15)	P value
Mean age (years, range)	63.4 (28-92)	54.5 (21-88)	0.047
Female sex (n, %)	54 (90%)	13 (87%)	0.66
Mean BMI (kg/m^2, range)	32 (18.9-60.6)	26.8 (16.4-35.7)	0.007
Hypertension (n, %)	30 (50%)	4 (27%)	0.10
Diabetes (n, %)	11 (18%)	1 (7%)	0.44
Neurological diagnosis (n, %)	4 (7%)	12 (80%)	0.0001
Wheelchair-dependent (n, %)	1 (2%)	11 (73%)	<0.0001
Mean follow-up (months)	35	24	0.02

BMI, body mass index.

Table 3. Operative details for patients undergoing standard and abdominal placement of the sacral nerve stimulator implantable pulse generator

	Standard Placement (n = 60)	Abdominal Placement (n = 15)	*P* value
2 stage SNS testing in OR (n, %)	24 (40%)	8 (53%)	0.35
Mean 1st stage time (minutes, range)	62 (34-124)	70 (39-121)	0.07
Mean 2nd stage time (minutes, range)	32 (18-56)	47 (28-92)	0.09

OR, operating room; SNR, sacral nerve stimulator. ()

Table 4. Revision and infection rates for patients undergoing standard and abdominal placement of the sacral nerve stimulator implantable pulse generator

	Total (N = 75)	Standard Placement (n = 60)	Abdominal Placement (n = 15)	*P* value
Patients undergoing revision surgery (n, %)	20 (27%)	17 (28%)	3 (20%)	>0.99
Total revision cases	38	34	4	0.048
Pain	10 (26%)	10 (29%)	0 (0%)	0.56
Loss of efficacy	21 (55%)	18 (53%)	3 (75%)	0.61
Lead migration	7 (18%)	6 (18%)	1 (25%)	>0.99
Infections (n, %)	3 (4%)	1 (2%)	2 (13%)	0.1
Time to revision (months) ($N = 22$, $n_1 = 18$, $n_2 = 4$)	27	31	11	0.24

operative duration or infection rate between standard and abdominal placement.

Despite its efficacy, SNS implantation is associated with a high revision rate that has undergone minimal improvement over time. In a 2000 study of 51 SNS patients, 33.3% had a revision surgery and 15.3% reported pain at the IPG site.[9] White et al published a prospective study of 221 patients in 2009 in which 30.3% experienced an adverse event requiring lead or IPG revision,[10] with nearly 3% having IPG site pain as the reason for their revision. In the InSite trial of 272 SNS subjects published in 2017, 32% had surgical revisions related to the neurostimulator or lead, with implant site pain accounting for 13% of all patients.[11] We performed up front abdominal placement or revised previously placed IPGs to the abdomen in select patients who were wheelchair-dependent or had minimal gluteal fat and none of these patients underwent revision due to pain in 24 months of follow-up. Additionally, White et al found on multivariate analysis that a change in BMI class was a significant predictor of adverse events, such as pain at the implant site and lead migration. One patient in our study with initial standard placement experienced significant weight loss causing discomfort, and revision of the IPG to the abdomen resolved this issue. Initial abdominal placement was performed in another patient with minimal gluteal fat as previously mentioned, and pain was not a problem for this patient.

In a prospective, multicenter study of 152 patients with SNS, nearly 80% of SNS were placed abdominally. The revision rate due to pain at the IPG site decreased with standard placement, but this did not reach statistical significance due to the small number of patients with standard placement.[6] This contrasts with our study in which we found no revisions due to pain with abdominal placement. This is likely due to the fact that a significant proportion of patients undergoing abdominal placement in our study had a neurological diagnosis and were wheelchair-dependent. The generalizability of our data is likely limited to this population but the results also shed light on a way to decrease the morbidity from an SNS in this group.

Our abdominal cohort contained four revisions, of which 3 were caused by loss of efficacy and one a result of lead migration. This may be attributed to increased tension on the lead with abdominal placement causing loss of efficacy or lead migration. Interestingly, the time from initial implantation to revision surgery was shorter in the abdominal group than the standard group, although not statistically significant. We hypothesize that this is due to decreased mobility and increased use of wheelchairs and transfer boards, which may also lead to increased tension on the lead and predispose to a quicker need for revision.

A retrospective analysis of 290 patients found a 3.8% infection rate with standard placement of the IPG. BMI and immunosuppression were found to be significant predictors of infection.[12] In our cohort of patients with standard placement of the IPG, there was a 2% infection rate. Patients were given vancomycin and gentamicin for preoperative antibiotics and dicloxacillin for postoperative coverage, with Bactrim given for penicillin-allergic patients. However, as detailed in the recent International Continence Society best practice statement for sacral neuromodulation, there is no agreed upon perioperative or postoperative protocol for antibiotic therapy.[13] Rather, the local antibiogram, patient's allergy profile, and surgeon discretion must be taken into account.

There are no contemporary studies evaluating infection rates with abdominal placement. There was a 13% infection rate in our abdominal placement group. Operative duration may be a risk factor for infection after SNS[14] and there was a trend toward higher operative time for the abdominal group for both stages of our study, although not statistically significant. Additionally, the majority of

patients in our abdominal group was wheelchair-dependent and had chronic neurological processes. Our cohort may have been an at-risk population at baseline and at greater risk for postoperative infections.

There were several limitations to this study. First, we had a small sample size in our abdominal group but this was due to careful patient selection based on who was deemed to benefit from abdominal placement. Second, it was a retrospective study and we did not collect data on symptom improvement or patient satisfaction. However, a randomized controlled trial between standard and abdominal placement would not be possible given that abdominal placement is not appropriate for all patients. Furthermore, as mentioned previously, our 2 cohorts varied in baseline demographics and this limited comparisons between the two. Our aim, though, was to show the lack of revisions due to pain with abdominal IPG placement in select patients. Finally, the Interstim I device with an option for the 25 cm extender has been phased out. When the battery expires it may be necessary to revise abdominally placed IPGs to the standard location if the 45 cm lead with the Interstim II device does not have adequate length to reach the abdomen, tension-free in all patients. While the Interstim I does have a longer battery life, the possibility of needing to move the IPG elsewhere was discussed with patients. We hope that issues with sitting or lying on the device may be less of a problem with the use of smaller devices in the future. Nonetheless, data from studies such as ours may be necessary to show device companies that providing extenders in the future can be beneficial in select patients.

CONCLUSION

We found abdominal placement of the SNS IPG to result in no revisions due to pain in a subset of patients who were wheelchair-dependent or lacked gluteal fat. There was no significant difference in infection rate or operative duration between abdominal and standard placement. Abdominal IPG placement with extended length leads could be considered a primary or revision option in wheelchair-dependent patients or those lacking gluteal fat in whom pain at the IPG site would otherwise require additional revision surgeries.

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