

UK EXPERIENCE OF 2-STAGE SACRAL NEUROMODULATION FOR WOMEN WITH URINARY RETENTION

Hypothesis / aims of study

Patients with the primary disorder of sphincter relaxation have a chronic lifelong condition. The typical patient is female in her mid-twenties who presents with an inability to void, resulting in chronic painless complete or partial urinary retention. On investigation they have an elevated urethral pressure profile (UPP), an enlarged sphincter volume (SV) on ultrasound assessment, and a pathognomic electromyography (EMG) abnormality. Most patients manage their symptoms using clean intermittent self catheterisation (CISC), though characteristically they have problems with removal of the catheter following easy insertion. CISC can therefore be painful, difficult and intolerable resulting in some patients having a permanent indwelling suprapubic catheter. A common complication in managing this condition is recurrent urinary tract infections, which can seriously affect the quality of life of the individual. Sacral neuromodulation is an effective treatment for this condition (1), as it restores the sensation of fullness and allows the initiation of voiding. Previously long term outcome data has been published on the single stage neuromodulation for women with retention (2).

The aim of this study was to report our initial outcome data for the newer 2 stage minimally invasive percutaneous technique, from a referral centre offering the procedure only for urinary retention. We also compare the efficacy and safety of this newer neuromodulation technique to the traditional open single stage procedure

Study design, materials and methods

Ethical approval was not required for audit of our current surgical practice. All patients gave signed informed consent for the procedure. The case records were reviewed for all women with urinary retention who had a sacral nerve stimulator implanted between 2004-6 (2-stage) and compare with our existing published data on women who were implanted between 1996-2002 (single stage).

Patients all underwent detailed sphincter studies (UPP, SV & EMG) as part of their clinical assessment. The first stage of the 2 stage procedure involves implantation of the tined lead into the S3 foramen and connection to a temporary external battery box. Position of the tined electrode was confirmed by motor and sensory responses and fluoroscopy. A urinary diary was issued for 7 days: if voiding was restored, patients were eligible to have a permanent implantable pulse generator (IPG) (InterStim, Medtronic).

The length of follow-up, number and types of revision procedures, adverse events and explanation were noted.

Results

	Single stage technique	2-stage technique
Implanted Dates	1996-2002	2004-2006
Number of women	26	30
Mean Age	35	36
Retention (Complete/Partial)	22/4	22/8
Mean Follow up	37 months	10.3 months
Successfully Spontaneous Voiding at follow-up	77% (20/26)	80% (24/30)
Surgical Revision rate	(14) 54%	(4) 13%
Loss of efficacy	7 (0.5 – 12 months)	2 (all within 1 month)
Complications	24	8

All patients undergoing the classic single stage procedure had a positive EMG, whereas only 18/30 patients undergoing the 2 stage procedure had this test. EMG was positive in 15/18 patients from the 2 stage group.

28 out of 30 women underwent a Peripheral Nerve Evaluation test prior to the procedure, with 21/28 (75%) having successful voiding without a significant residual (<200ml).

All women, except for two, were implanted under general anaesthesia, with a mean time between 1st and 2nd stage of 32 days. (Average post-operative stay after 1st stage was 2.27 days and after 2nd stage was 1.9 days).

Out of 30 patients who underwent the two stage technique, 23 women had relied on CISC and 6 had a suprapubic catheter. At 3 months following completion of the 2 stage procedure, 6 patients still required intermittent CISC and one patient had a suprapubic catheter. Three women did not proceed to the 2nd stage and had their electrodes removed due to lack of response.

There were 4 women (13%) who had surgical revisions: loss of response (2), infection (1), Box Pain + Haematoma (1). Complications included Sciatica (3), Wound Infection (2), Haematoma (1), Box Site pain (1), SNS induced Migraine (1). All complications resolved or were controlled with medication.

Interpretation of results

The minimally invasive two staged SNS technique offers comparable efficacy with the traditional procedure but there has been a reduction in the number of surgical revisions and adverse complications with the two stage technique.

PNE may become unnecessary as the first stage allows a longer temporary stimulator trial period to assess efficacy. The technique is percutaneous and minimally invasive allowing patients to be discharged home quickly. It is hoped the tined lead will reduce revision procedures required due to lead migration.

Although our follow-up was over a shorter period, need for revision surgery for loss of efficacy manifests usually in the first 12 months after the procedure (2).

Concluding message

Our experience with sacral neuromodulation shows that the 2 stage technique appears to be a significant improvement in terms of reduction of adverse events. This treatment is currently the only effective means of restoring voiding.

References:

- (1) Eur Urol. 2000 Oct; 38(4):439-43.
- (2) BJU International 94, 335-337

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DISCLOSURES: NONE

HUMAN SUBJECTS: This study did not need ethical approval because Audit of current surgical practice but followed the Declaration of Helsinki Informed consent was obtained from the patients.