URINARY INCONTINENCE AND PELVIC ORGAN PROLAPSE (KL NOBLETT, SECTION EDITOR)

# The Role of Sacral Nerve Stimulation in Female Pelvic Floor Disorders

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**Abstract** Female pelvic floor disorders, such as urge incontinence, nonobstructive urinary retention, painful bladder syndrome, fecal incontinence, chronic constipation, and sexual dysfunction, represent multiple challenges to the treating physicians. Sacral nerve modulation (SNM) gives a promising alternative and a minimally invasive treatment option for chronic pelvic floor disorders resistant to conventional treatment. This review covers the mechanism of action and surgical procedure of the SNM as well as the current and expanding indications for SNM in female pelvic floor disorders.

**Keywords** Sacral nerve modulation · Percutaneous nerve evaluation · Urgency-frequency · Urge incontinence · Urinary retention · Fecal incontinence · Urinary incontinence

# Introduction

The female lower urinary tract (LUT) and pelvis are innervated by three nervous systems: parasympathetic, sympathetic, and somatic. The parasympathetic system via the pelvic nerve (S2 to S4) activates the detrusor muscle of the bladder as well as inhibits the urethral sphincteric mechanism, favoring voiding. The sympathetic contributions originate from T12

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M. M. Hassouna (🖂) Toronto Western Hospital, University Health Network, Toronto, ON M5G 2C4, Canada e-mail: magdy.hassouna@uhn.on.ca to L1 and inhibit the bladder while activating the urethra, thus favoring storage. The somatic innervation, through the pudendal nerve (S2 to S4) regulates the urethra and pelvic floor muscles.

The first (SNM) procedure was performed in 1982 by Tanagho and Schmidt at the University of California in San Francisco [1]. The U.S. Food and Drug Administration (FDA) approved SNM for three chronic voiding dysfunction conditions: intractable urge incontinence in 1997, urgency- frequency, and nonobstructive urinary retention in 1999 [2]. Patients who have failed to respond or could not tolerate conservative treatments [3] are offered SNM therapy. In 2011, the FDA approved SNM for chronic fecal incontinence in patients who have failed or could not tolerate conservative treatment. The efficacy of SNM for the treatment of chronic constipation, interstitial cystitis/painful bladder syndrome, pelvic floor muscle dysfunctions, sexual dysfunctions, and vulvar disorders have been explored since the FDA approval.

# **Mechanism of Action**

The exact working mechanism of SNM is not yet fully understood. SNM probably has an impact one or more neuronal reflexes [4–7]: by inhibiting the spinal tract neurons involved in the micturition reflex as well as the neurons involved in spinal segmental reflexes, namely through stimulation of the afferent component of the same spinal segment. There is evidence of direct inhibition of postganglionic neurons and primary afferent pathways in one study on the pudendal nerve [5].

In fecal incontinence, Vitton et al. [8] described evidence of a somatosympathetic reflex pathway, which could explain the reasons why fecal incontinence treatment using SNM, leading to reduced colonic activity and increased tonus of the anal sphincter complex, may be successful [9].

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# Surgical Techniques for SNM Implantation

The following is a summary of the surgical technique  $[10\bullet]$ . A complete clinical evaluation should be undertaken, including history, physical examination, a voiding diary for minimum of 3 days at baseline, and possibly urodynamic assessment. Associated symptoms, such as pelvic pain and bowel symptoms, also should be assessed with the help of visual analogue scale and number of episodes of FI per week. The voiding parameters in the diary will be compared before and after the evaluation test to assess the objective response. Patients are counseled for the sacral nerve stimulation procedure risks and benefits. One should ensure that there are no contraindications for SNM (Table 1) [9].

The first crucial step in determining if the patient is a good candidate for definite implant is a test stimulation trial. Test stimulation can be either percutaneous nerve evaluation (PNE) or staged implant.

# PNE

In the 1990s, Schmidt et al. devised a simple outpatient diagnostic test that involved percutaneous placement of a wire to stimulate the S3 nerve root and evaluate motor and sensory responses.

 Table 1
 Relative contraindications for sacral nerve stimulation (adapted from [9])
 Provide the sacral nerve stim [9])
 Prove stimulation (adapted fr

Urologic	Lower urinary tract obstruction	
	• Urinary tract infection explaining symptoms	
	Stress urinary incontinence	
	Bladder calculi or tumors	
	Carcinoma in situ	
	• Ureteral calculi	
Gynecologic	Malignancies or infections	
	Prolapse that might explain symptoms	
	Pregnancy	
Gastroenterologic	Malignancies	
	<ul> <li>Infections that might explain symptoms</li> </ul>	
Neurologic	• Any undiagnosed or not yet managed neuropathy	
	Convulsive disorders	
	Cognitive impairment	
Orthopedic	• Bony abnormalities of the sacrum, spina bifida	
	Difficult or impossible transforaminal access	
Job-related	Heavy-duty jobs	
	Working within electrical or magnetic fields	
Sports	• Parachute jumpers, fight sports, most professional sports	
	• Diving (safe down to 20 m; deformation seen from 40 m)	

PNE is an office-based technique: an insulated thin temporary monopolar lead is placed into the third sacral nerve S3 foramen under local anesthesia with the patient in the prone position. In our center, we utilize 1 % plain lidocaine as a local anesthesia. The S3 foramen can be found 2-3 cm off the midline at the level of the sciatic notch. Placement of bilateral S3 foramen needles can be accomplished either using bony landmarks and/or fluoroscopy. Once the foramen needles are placed (either 3<sup>1</sup>/<sub>2</sub> or 5 inch), they are stimulated using an external pulse generator, and the side giving better response is chosen for the subchronic test. Responses signaling correct placement include bellows contraction of the pelvic floor and plantar flexion of the great toe (Table 2). With the PNE test, the patient will be able to confirm correct placement by the tingling sensation in rectum, vagina, scrotum, and/or perineum. Once the appropriate side and position selected, the temporary unipolar lead is connected to an external pulse generator and taped to the skin surface for the test period. Often, bilateral PNE leads are placed during the testing phase.

Pre- and post-PNE test voiding diaries are completed to assess symptoms response. Patients who demonstrate a minimum of a 50 % symptom improvement from baseline are considered candidates for placement of the permanent quadripolar lead and implantable pulse generator. The temporary leads of the PNE test are easily removed in the office once the test phase is complete, typically in 3 to 7 days [11•]. The duration of this test is limited to a maximum of 2 weeks due to increase risk of lead contamination and infection [12]; however, no prophylactic antibiotic is required during the PNE trial. During the test period, the patient is advised to restricted physical activities

Limitations of the PNE include mainly lead migration. Short-term test stimulation period as well as and this probably explains the relatively low success rate of PNE, estimated at approximately 50 % [13, 14]. Everaert et al. recorded false-positive PNE in 33 % of cases in home patients who have beneficial test stimulation with a temporary lead and did not continue to have a successful outcome after the permanent lead implantation [15].

Table 2 Sacral roots, motor and sensory response [55]

Nerve root	Motor response	Sensory response
S2	Anal sphincter contraction (A-P pinching of perineum/coccyx), leg/ heel rotation, planter flexion of foot, calf contraction	Sensory alteration of the base of penis or vagina
S3	Bellows reflex (inwards contractions), plantar flexion of great toe	Rectal sensation, extending into scrotum or labia
S4	Bellows reflex	Rectal sensation only

# A Quadripolar tinned lead



**Fig. 1** A Quadripolar tinned lead, the electrodes are shown. **B** Sacral foramen needle is inserted and guided to the desired location. **C** Location is verified by electrical stimulation to the needle, and the fluoroscopy is used to confirm the position of the needle in the S3 foramen. **D** The metal

dilator is removed and the plastic dilator is positioned. **E** The quadripolar lead is introduced through the dilator plastic sheath into position which is confirmed by stimulation, the plastic dilator sheath in withdrawn carefully under fluoroscopic guidance. Pictures adapted from Metronic Inc, 2003

# Staged Implant

Janknegt first described the staged implant approach where an implanted chronic lead, rather than the temporary lead, was placed for initial testing [16]. This approach is indicated for the patients who are not a candidate for officebased PNE test stimulation (e.g., obese, difficult anatomy, previous sacral surgery, or unable to tolerate the procedure Fig. 2 A Fluoroscopic view of the sacral foramens. **B** Permanent electrode leads position. **C** A-P view of the electrode position. **D** IPG position. Pictures adapted from Medtronic Inc, 2003

# A Fluoroscopic images of sacral foramens and Permanent electrode leads



under local anesthesia) or did not respond to the PNE test. The stimulation test is performed in the operating room as a first stage of two-stage implant. In patients with doubtful PNEs test result, a two-stage implant is suggested to increase the yield of screening patients to 70 % for a permanent implant [17].

In case of general anesthesia, the anesthetist is reminded to avoid any long-acting muscle relaxants, which may impair sacral nerve stimulation or visualization of motor response. Fluoroscopy imaging is used to help in placement confirmation of the quadripolar permanent lead (Figs. 1 and 2). A test period of 14 days is used to determine which patient meets the criteria to have the permanent implant if he is a good candidate for the therapy based on the response in the voiding diary.

# Chronic Implant

The implantation of the implantable pulse generator (IPG) can be performed under local or general anesthesia. Once the quadripolar permanent lead is inserted into S3 foramen the lead is then tunneled deeply through the subcutaneous fat typically to the ipsilateral upper buttock. However, depending on the patients' dominant hand side, she may have a preference for the location the chronic implantable pulse generator (IPG). The advantages and disadvantages for one stage versus two-stage procedure summarized in Table 3.

# **Current Indications for SNM**

# Intractable Urge Incontinence

Overactive bladder (OAB) is defined as urinary urgency, frequency, and nocturia, with or without urinary incontinence, and with no proven infection or other obvious disorder. Of those patients with OAB, up to 37.2 % have urge urinary incontinence.

Schmidt et al. [18] reported on Sacral neuromodulation therapy in 76 patients with refractory urge incontinence from 16 centers worldwide during the 6-month study period. Of the 34 patients receiving active SNM therapy compared with the delayed group, 16 (47 %) were completely dry and an additional 10 (29 %) demonstrated a more than 50 % reduction of incontinence episodes.

In a 5-year, prospective, multicenter trial, Van Kerrebroeck et al. evaluated the long-term efficacy and safety of SNM in patients with urge incontinence. The mean leaking episodes per day decreased from  $9.6\pm6.0$  to  $3.9\pm4.0$  with 68 % successful outcome at 5 years [19•]. Other randomized trials

 Table 3
 Comparison between the advantages and disadvantages of one-versus two-stage implant procedures [56]

	PNE (one-stage)	Tined lead (two-stage)
Advantages	• Office procedure, under local anesthesia	• Less risk of lead migration during the test trial
	Greater patient acceptance	Greater comfort due to level of sedation for anxious or pain focused patients
	• Office removal of the leads	<ul> <li>Quadripolar lead configuration allows for more precise placement and programming</li> </ul>
	• Accurate patient sensation feedback during insertion	• Symptoms improvement remains unchanged when converted to chronic implant
	• Less costly, more favorable reimbursement	• Longer trial period to assess for symptoms improvement
	• Less risk of infection because permanent lead and IPG will be placed in one sitting after successful PNE	Higher rate of true positives
Disadvantages	Higher rate of false negatives, must do staged implant if equivocal	• Requires two surgeries even if trial is unsuccessful
	• Potential to place permanent lead in less favorable location, thus requiring reoperation	• Greater potential for infection due to increased length of trial and potential contamination of permanent lead
		• More expensive if the trial is unsuccessful

showed evidence of a clear beneficial effect of the immediate implant at 6 months particularly in the number of total micturition and leakage episodes, the number of pads used, the rating of urgency, the maximum bladder capacity, and volume at first detrusor contraction, as well as on quality of life [20, 21•].

#### Urgency-Frequency

Urinary frequency–urgency syndrome is used to identify a patient group who suffer from urinary frequency and urgency at the same time with or without a pain component.

Hassouna et al. [22] in 2000 reported the outcomes of SNM on refractory urgency–frequency conditions in 51 patients from 12 centers during an initial 6-month period extended to 2 years. Outcomes at 6 months in the active SNM group showed improvement in the number of daily voids  $(16.9\pm9.7 \text{ to } 9.3\pm5.1)$ , volume voided  $(118\pm74 \text{ mL/s to } 226\pm124 \text{ mL/s})$  degree of urgency (rank score,  $2.2\pm0.6$  to  $1.6\pm0.9$ ), and Short-Form 36 (SF-36) quality-of-life measure.

Patients with urgency frequency syndrome had 56 % successful outcome 5 years after the SNM. The mean voids per day decreased from  $19.3\pm7.0$  to  $14.8\pm7.6$ , and mean volume voided per void increased from  $92.3\pm52.8$  to  $165.2\pm147.7$  mL [19•].

#### Nonobstructive Urinary Retention

Stimulation of the S3 has been shown to be effective in stimulating the urethral sphincter [23]. A large, multicenter (Medtronic MDT-103; USA, Canada, and Europe), prospective, randomized, clinical trial looked at the efficacy and safety of chronic neuromodulation to the S3 nerve. Results of this study led to approval by the FDA in October 1997.

Van Kerrebroeck et al. evaluated 152 patients 5 years after SNM implantation: 20.4 % patients with retention. The mean volume per catheterization decreased from  $379.9\pm183.8$  to  $109.2\pm184.3$  mL, and the mean number of catheterizations decreased from  $5.3\pm2.8$  to  $1.9\pm2.8$  with 71 % patients with retention had successful outcomes [19•].

Shaker and Hassouna reported 20 patients with urinary retention who showed significant improvement (postvoid residual decreased from 78 % to 10 % of total urinary output), with a mean follow-up of 15 months [2]. Denzinger et al. reviewed 20 patients, of whom 80 % were female, who suffered from idiopathic or neurogenic urinary retention for a median 60 months before SNM; 90 % of the stimulated patients showed significant success with implantation of IPG within a median of 43 days. Postvoid residual (PVR) urine was reduced significantly from a median of 350 mL to 135 mL [24•].

# Fecal Incontinence

Fecal incontinence (FI) is defined as uncontrollable loss of feces from the bowel and affects 0.4–18 % of the adult population. It can be due to anatomical or neurologic damage of the anal sphincter mechanism, idiopathic degeneration of the anal sphincters, or secondary to nonsphincter causes (i.e., dementia, diarrhea).

Wexner et al. evaluated a total of 133 patients with a mean duration of fecal incontinence of 6.8 years. Of these, 119 patients (90 %) had a successful test stimulation  $\geq$ 50 % and received a permanent implant. At 12 months, 83 % of subjects achieved therapeutic success and 41 % achieved 100 % fecal continence. Therapeutic success was 85 % at 24 months. Incontinent episodes decreased from a mean of 9.4 per week at baseline to 1.9 at 12 months and 2.9 at 2 years [25]. At 3 years follow-up, 86 % of patients reported  $\geq$ 50 % reduction in the number of FI episodes per week compared with baseline and the number of FI per week decreased from a mean of 9.4 at baseline to 1.7. Perfect continence was achieved in 40 % of subjects [26].

Uludağ et al. reported the long-term outcome and quality of life in 50 patients with FI who had permanent SNM implant. Initial improvement in continence with SNM was sustained with success rate of 80 % at 7 years  $[27^{\bullet}]$ .

Clinical outcome and cost-effectiveness were analyzed in a prospective, multicenter, cohort study that included 369 consecutive patients with urge urinary and/or FI over duration of 24 months. The SNM significantly improved the continence status and quality of life of patients with urge urinary and/or FI compared with alternative treatments [28•].

#### **Expanding Indications for SNM**

Painful Bladder Syndrome and Chronic Pelvic Pain

Painful bladder syndrome (PBS) or interstitial cystitis (IC) is characterized by urinary frequency, urgency, and pelvic pain often localized to the bladder or urethra. The disease is poorly defined and study outcomes often are difficult to compare due to differences in definition. The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) formulated criteria for a diagnosis of IC in 1987 and 1988 [29].

The International Continence Society (ICS) came with the term "painful bladder syndrome" (PBS) as "the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms, such as increased daytime and night-time frequency, in the absence of proven urinary infection or other obvious pathology" [30].

The term IC is reserved for PBS with typical cystoscopic and histologic features. IC should include some form of inflammation in the deeper layers of the bladder wall [31]. Standard pharmacotherapies often are ineffective and associated with significant side effects. Cystoscopic hydrodistention often provides only temporary relief, and cystectomy and urinary diversion have an unacceptably high failure rate for pain control [32], in addition to being a very invasive option.

Maher et al. evaluated 15 women with refractory IC/PBS who were treated with SNM. Of the 15 women, 73 % reported improvement in pelvic pain, daytime frequency, nocturia, and urgency; 87 % reported a 50 % decrease in bladder pain; and 47 % had a 50 % decrease in 24-h voiding frequency [33].

A recent review evaluated the efficacy and safety of SNM in treating chronic pelvic pain related to IC/PBS [34•]. The average age of the participants ranged from 41 to 60 years in the included studies. The majority were females. Overall, 70.8 % were successful at the trial stage. One study showed an 80 % improvement in Global response assessment score [34•].

Marinkovic et al. reported significant improvement in pelvic pain and urgency with 80 % satisfaction rate. They concluded that SNM provides adequate improvement in IC/ PBS patients with a minimum of 6 years of follow-up [35•].

A total of 78 patients fulfilled the clinical criteria for IC/BPS and showed cystoscopic evidence of glomerulation and/or ulcers. All patients failed conservative management before considering SNM. Permanent SNM, showed at least 50 % improvement in their symptoms with a temporary PNE test. Median follow-up was 61.5 months (SD  $\pm 27.7$ ). Good longterm success of the SNM was seen in 72 % of the patients [36•].

Martellucci et al. evaluated 17 consecutive patients suffering from chronic pelvic pain after pelvic surgeries with SNM; 47 % of patients fulfilled the criteria for permanent implantation and were followed for a mean of 39 months. Using a visual analog pain score, pain levels decreased from 8.2 preoperatively to 1.9, 2.1, 2.0, and 1.8 at 6, 12, 24 and 36 months, respectively [37•].

Chronic Constipation and Irritable Bowel Syndrome

Chronic constipation is another disabling bowel dysfunction that can be associated with bloating, abdominal pain, sensation of incomplete emptying, and pelvic organ prolapse in chronic severe cases. In one study of 19 patients suffering from severe rectal outlet obstruction, 42 % reported a significant improvement after SNM in the Wexner constipation scores and quality of life scores compared with the preoperative baseline level [38].

Prospective, multicenter study of 45 female patients who received SNM treatment for chronic constipation, 87 % achieved treatment success after a median 28 months followup [39•]. The defecation frequency increased from 2.3 to 6.6 evacuations times per week and from 2.3 to 4.8 days per week. Also, a decrease in time spent toileting, straining, perception of incomplete evacuation, and decrease in subjective rating of abdominal pain and bloating [39•].

Of 45 patients with irritable bowel syndrome, 35 patients improved symptomatically and 34 had enhanced quality of life related to bowel symptoms; 53 % of patients reported an improvement in irritable bowel syndrome-related symptoms after SNM [40].

# Female Sexual Dysfunction

High-tone pelvic floor dysfunction is an important cause of female sexual dysfunctions (FSDs) and is seen in many patients with various pelvic pain and hyperactive pelvic floor disorders, including IC/PBS, vulvodynia, urgency frequency syndrome, urinary retention, dyspareunia, and obstructed defecation syndrome.

Lombardi et al. evaluated the sexual function in females treated with SNM for LUTS by the Female Sexual Function Index (FSFI) and the Female Sexual Distress Score (FSDS). Concluded, The positive effects regarding improvement in sexual function index of arousal and lubrication in voiding dysfunction female group [41].

Between May 2003 and December 2008, a prospective study evaluated 30 consecutive female patients (median age 53 years) with OAB underwent SNM on Female Sexual Function index (FSFI). Comparison between preoperative, median midterm follow-up 22.5 months, and median last follow-up 36.3 months visits were performed. Regarding sexuality, the mean improvement was around 30 % at midterm and last follow-up [42•].

Caremel et al. found that SNM improves the quality of sexual activity in 45 % patients. The number of urinary and fecal episodes of incontinence decreased respectively for 50 % and 15 % patients during sexual activity. The quality of sexual life and orgasm score are significantly increased in the group of patients improved on the double incontinence [43•].

Another prospective study of 36 consecutive female patients with pain and LUT symptoms, who underwent SNM, showed that the FSFI scores improved by 52 % at 6-month follow-up [44]. The improvements were better in patients who underwent the treatment for LUT symptoms as compared with those who had pain as their primary complaint.

In a recent case report, SNM showed a beneficial affects in patients with severe vulvar vestibulitis who failed conservative therapy [45]. Another report reveled that SNM resulted in improvements of both LUT symptoms and clitoral pain in a patient [46•].

These studies demonstrated an evidence of potential benefit of SNM for female sexual disorders, mainly in the presence of urinary and/or bowel disorders [47•]. However, large and good quality studies are needed to demonstrate the full effect of SNM on FSDs.

#### **Complications of SNM**

The SNM study group has published several reports on the efficacy and safety of the procedure for individual indications [48]. A total of 581 patients were recruited and 219 underwent implantation for SNM. The complications were divided into both PNE-related and postimplant-related problems. Of the 914 test stimulation procedures done on the 581 patients, 181 adverse events occurred in 166 of these procedures: 11.8 % related to lead migration; technical problems and pain represented 2.6 % and 2.1 %, respectively. For the 219 patients who underwent implantation for the SNM, pain at the neurostimulator site was reported in 15.3 % at 12 months (Table 4). Surgical revisions performed in 33.3 % of cases include relocation of the neurostimulator and revision of the lead for suspected migration. Explantation of the system was performed in 10.5 % for lack of efficacy [48].

Hijaz et al. reported the complications in a review of 214 patients who underwent SNM; 161 underwent IPG

 Table 4 Reported complications with sacral neuromodulation therapy

 from the neuromodulation study group [49]

Complications	Probability of occurrence (Siegel series)
Pain at the neurostimulation site	15.3 %
New pain	9 %
Suspected lead migration	8.4 %
Infection	6.1 %
Transient electric shock	5.5 %
Pain at lead site	5.4 %
Adverse change in bowel function	3 %
Technical problems	1.7 %
Suspected device problems	1.6 %
Change in menstrual cycle	1 %
Adverse change in voiding function	0.6 %
Persistent skin irritation	0.5 %
Suspected nerve injury	0.5 %
Device rejection	0.5 %

implantation and were monitored for a mean follow-up of 16 months. The explantation and revision rate was 10.5 % and 16.1 %, respectively. Revisions were performed for decreases in response (17/26), IPG site discomfort (4/26), draining sinus at the IPG site (4/26), and lead migration (1/26) [49].

In a study by Spinelli et al. [50], the total infection rate in the whole series was 18/180 (10 %), which was slightly higher than that reported by the sacral neuromodulation study group (6.1 %) [49].

In a recent study, Pettit et al. reviewed their experience at the Mayo Clinic. The main surgical complication remains to be surgical site infection. They reviewed evidence-based suggestions and procedure-specific techniques and found that the infection rate dropped to less than 2 % [51].

# **SNM and Pregnancy**

The use of SNM has increased in females of childbearing age with various voiding dysfunctions. Medtronic product technical manual indicates that safety and effectiveness have not been established for pregnancy, the unborn fetus, and delivery. Due to the unknown teratogenic potential of electrical stimulation, it has been considered contraindicated in pregnant women with various voiding dysfunctions.

Wang and Hassouna were first to examine the effect of electrical stimulation on pregnant rats and fetuses. Rats in the stimulation group were stimulated 7 hours every day from Day 4 to Day 20 of gestation. The results showed that no abortions were observed and no significant difference between the stimulation group  $(2.27\pm0.51 \text{ g})$  and the sham group  $(2.13\pm0.51 \text{ g}; p=0.91)$  in terms of fetal body weight [52]. Thus, it was concluded that termination of pregnancy is not advised for prospective mothers when electrical stimulation has been performed unknowingly in early pregnancy.

Khunda et al. published a retrospective study about pregnancy in patients with chronic urinary retention syndrome who underwent a two-stage SNM implantation. A total of 10 patients with 13 pregnancies were reviewed. The SNM was switched off in 10 of the 13 pregnancies, with CUR recurring in 9 of the 10 pregnancies and recurrent urinary tract infections (UTI) occurring in 4 of these pregnancies (more than 3 UTI during the pregnancy). Those in whom the device was left on continued to void normally. One woman had a firsttrimester miscarriage, eight pregnancies went to term, and four deliveries were premature. Cesarean section was performed in eight pregnancies for obstetric reasons. Four pregnancies resulted in a vaginal delivery. There were no congenital anomalies reported. Following delivery, four of nine women experienced dysfunction of their SNM device when it was switched back on. They suggested the option of keeping the SNM on during pregnancy to be considered, and cesarean section should only be performed for obstetric reasons [53•].

Wiseman et al. obtained data on six pregnant women with SNM. In five patients, the stimulator was deactivated between weeks 3 and 9 of gestation, after which two with a history of urinary retention had urinary tract infection. In another case, stimulation was discontinued 2 weeks before conception. The only noted complication developed in a pregnancy in which birth was premature at 34 weeks. Three patients underwent normal vaginal delivery, including one in whom subsequent implant reactivation did not resolve voiding dysfunction. In three cases, elective cesarean section was performed. One with urinary retention had to have the device switched back on at 19/40 weeks due to difficult catheterization without any complications during pregnancy. All neonates in the series were healthy [54].

Women with electrical stimulation devices for pelvic health conditions who become pregnant may simply turn off their devices when considering and during pregnancy due to deficiency of the clinical evidence in pregnancy.

# Conclusions

SNM is a promising solution to many complicated and chronic female pelvic dysfunction. SNM is effective for intractable urge incontinence, urgency-frequency, nonobstructive urinary retention, and fecal incontinensace and should be consider as a second-line treatment before irreversible major surgery. Future indications for SNM may include IC/PBS, chronic pelvic pain, chronic constipation, and female sexual dysfunction.

There are too few studies regarding SNM in pregnancy to guide best practices. However, the pregnant subject with SNM should consult with her physician and may want to consider having active stimulation of her SNM therapy only if the benefits of the therapy outweigh the risks.

# **Compliance with Ethics Guidelines**

**Conflict of Interest** Baydaa Al-Sannan, Mai Banakhar, and Magdy M. Hassouna declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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