Objective: The objective of this review is to evaluate the efficacy and safety of sacral neuromodulation in treating chronic pelvic pain related to Painful bladder syndrome/Interstitial-cystitis.

Design: The databases searched were MEDLINE and EMBASE [1950- Nov 2011]. Additional searches were performed on the Cochrane Database of Systematic reviews (CDSR), Scopus, CINAHL, BIOSIS, The Cochrane controlled trials register, the science citation index, TRIP DATABASE.

Results: Overall 70.8% or 170/244 patients were successful at the trial stage. The only randomized controlled trial reported a decrease in Visual analogue pain scores of 49% (7.9 to 4.0) for sacral nerve stimulation [SNS] and 29%(4.5 to 3.2) for pudendal nerve stimulation [PNS] at 6 months follow up. Nine observational studies reported a decrease in pain scores/decrease in pain medications at long term follow up following permanent sacral neuromodulation. One study showed an 80% improvement in Global response assessment score.

Conclusion: The results from the randomised controlled trial and case series/case reports demonstrate a reduction of pain symptoms of Painful bladder syndrome following sacral neuromodulation

Key words: Pain, chronic, neuromodulation, sacral, pelvic pain, painful bladder syndrome, interstitial cystitis
Methodology

Search strategy
A comprehensive search was undertaken to systematically identify literature concerning clinical effectiveness of SNM in adults for chronic pain related to PBS/IC. The databases searched were MEDLINE and EMBASE spanning from 1950 to 2011. Additional searches were performed on the Cochrane Database of Systematic reviews (CDSR), Scopus, CINAHL, BIOSIS, The Cochrane controlled trials register, the science citation index, TRIP DATABASE, and the NHS Centre for Reviews and Dissemination database (DARE). Other sources such as Google scholar, National Research Register (NRR), the Current Controlled Trials register, and the MRC Clinical Trials Register, and the table of contents of key journals were searched online.

SNM for PBS/IC pain is a recent therapy for pain and there is a paucity of literature on this special topic. Initially, critical review of literature was restricted to literature published within the last 5 years, but it was found to be too strict and restrictive. Thereafter, for the purposes of this literature review, research articles published in the last 10 years (2001–2011) were selected.

The reference list of the relevant journal articles identified was hand-searched for trials relating to SNM in pain related to PBS/IC. Back chaining of reference lists was undertaken.

The keywords searched were: Sacral neuromodulation, sacral nerve stimulation, neuromodulation and chronic pelvic pain, urogenital pain, painful bladder syndrome, and interstitial cystitis. The search was limited to humans and literature in the English language.

Selection criteria
Type of studies
A single reviewer selected the studies after perusing the abstracts. For the purposes of this review, studies which have investigated the use of SNM in patients with PBS/IC were selected. Studies that included the use of SNM in chronic pelvic pain without PBS/IC were excluded. Studies that reported use of SNM in conditions like vulvodynia, endometriosis, clitoral pain, and anal pain were also excluded.

Type of participants
All adults with PBS/IC with inadequate response to medical and surgical treatments and who had undergone SNM were included.

Type of intervention
Studies with sacral nerve stimulation (SNS) by transforaminal, caudal and pudendal nerve stimulation (PNS) were included.

Clinical parameters for the selection of patients for SNM are still not very well defined and no predictive factors have been delineated. The present method of assessing and predicting success of a permanent implant is by means of a temporary trial of sacral stimulation.

SNM trial testing could be a temporary percutaneous nerve evaluation (PNE) or a two-staged procedure. PNE trial involves inserting a percutaneous electrode in the S3 sacral foramen and attaching to an external pulse generator. The trial usually lasts for 1 week and the outcomes of interest (urgency, frequency, and pain) are assessed. The two-staged lead procedure provides greater lead stability during the testing period. In this procedure, a quadripolar lead is inserted sacrally (S3) and tunneled subcutaneously to the anterior abdominal wall or buttock where it is attached to an external pulse generator. If the trial is successful, then the lead remains in place and a permanent implantable pulse generator (IPG) is implanted in the abdominal wall/buttock.

Transcutaneous electrical nerve stimulation (TENS) and tibial nerve stimulation were not considered in this review.

Type of outcomes
The following outcome measures were considered for the assessment of efficacy in treating pain:
1. Pain outcomes/pain medications usage
2. Quality of life measurements
3. Urological outcomes (along with pain outcomes)
   • Frequency of voiding
   • Bladder capacity
   • Number of leakage episodes per day

Additional exclusion criteria
Studies that involved stimulation of other parts of the nervous system spinal cord, deep brain, peripheral subcutaneous field stimulation, transcranial magnetic stimulation were excluded. The following were also excluded:
• Use of SNM in urological indications other than chronic pelvic pain
• Pregnant women and children
• Publications in languages other than English

Quality assessment of the studies
Quality assessment of the studies was done utilizing the checklist provided by the STROBE website Strengthening the Reporting of Observational studies in Epidemiology. This was done as most of the studies in this review fall under the category of observational studies. The lone [RCT] was quality assessed using the checklist for RCTs from the STROBE website mentioned above and checklist from the Oxford Centre for Evidence based Medicine.
A data extraction form was prepared using the recommendations of the IMMPACT group Initiative on Methods, Measurement and Pain Assessment in Clinical Trials available online at http://www.immpact.org/ and the STROBE checklists mentioned above.

Results

The flow diagram of the study selection process is shown in Figure 1.

The search strategy revealed 11 studies reporting the effectiveness of SNM for chronic pelvic pain related to PBS/IC. There was one RCT, five prospective case series studies, four retrospective studies, and one case report [Table 1]. Majority of the studies evaluated pain outcomes as a secondary measure.

The methodological quality of all 11 studies was assessed. Ten studies were graded as Level 4 evidence, whereas the study by Peters and Konstandt[6] could be graded as Level 3 evidence.

Seven of these studies were conducted in the United States of America, three in Europe, and one in Canada. Four of these studies[8,10,16] were either supported by Medtronic or the authors had a financial interest in Medtronic Inc., which manufactures the SNS kit (Inter Stim) used in these studies. The number of participants ranged from a solitary case report[7] to 209 participants in the Swiss registry study.[10] The average age of the participants ranged from 41 to 60 years in the included studies. Two of the studies[7,9] included only female patients, whereas all the other studies had a mixed male/female patient population.

There were 10 studies where the SNM technique used was transforaminal S3 nerve root stimulation, with one study[15] using caudal sacral root stimulation and another RCT comparing transforaminal sacral stimulation with PNS.[12] Seven studies used PNE for trial evaluation and the rest used staged lead testing. The methods of trial testing for SNM have been discussed earlier. The inclusion criteria used by the studies are shown in Table 2.

Overview of efficacy findings

There are two steps in evaluating the efficacy of SNM. In the first step, patients undergo trial testing. If the trial testing is positive, then the patients proceed to permanent implantation. The efficacy is considered under two heads: (a) success at trial stimulation and (b) success at long-term follow-up following permanent implantation.

Success at trial stimulation

Table 3 shows the success rate of trial stimulation. The success rate varied from 11.7 to 100%. Nine studies utilized improvement in baseline pain as the criterion for success during trial. Eight studies utilized greater than 50% pain relief as the criterion for proceeding to permanent implantation, whereas Siegel[8] used greater than 40% pain relief criterion.

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Table 1: Studies reporting efficacy of SNM for pain related to PBS/IC

| Author           | Year | Type of study                  | Total number of participants |
|------------------|------|--------------------------------|-----------------------------|
| Zermann et al.[7]| 2000 | Case report                    | 1                           |
| Siegel[8]*       | 2001 | Prospective observational case series | 10                          |
| Whitmore et al.[9]| 2003 | Prospective observational case series | 33                          |
| Peter and Konstandt[6] | 2003 | Retrospective observational case series | 21                          |
| Kessler et al.[10]| 2007 | Prospective observational case series | 209                         |
| Lavano et al.[11]*| 2007 | Prospective observational case series | 7                           |
| Peters[12]       | 2007 | Randomized control trial       | 22                          |
| Zabihi and Mourzinog[13]| 2008 | Prospective observational case series | 30                          |
| Marinkovic et al.[14]| 2010 | Retrospective case control    | 30                          |
| Gajewski et al.[2] | 2010 | Retrospective case series     | 78                          |
| Powell and Kreder[15]| 2010 | Retrospective                 | 39                          |

*Studies that evaluated pain outcomes as a primary measure
for proceeding to implantation. Three studies\textsuperscript{[2,10,12]} used both improvement in pain and urological variables as the criteria for success during the trial.

**Efficacy of SNS permanent implant**

A RCT by Peters et al.\textsuperscript{[12]} reported a decrease in visual analog pain scores of 49% (from 7.9 to 4.0) for SNS and 29% (from 4.5 to 3.2) for PNS at 6 months follow-up [Table 4]. The decrease in pain of nearly 50% is a clinically significant decrease with the use of SNM, but was not commented upon for statistical significance.

**Urological outcomes**

Frequently, the urological issues associated with pain include increase in number of bladder voids per day, decrease in voided volume, and incontinence. These variables improved with SNM.

At 6 months, the number of voids decreased by 33% for the SNS group and by 41% for those on PNS. Mean voided volume increased by 95% and 17% for PNS and SNS, respectively. Incontinence decreased by 92% and 17%, respectively, for PNS and SNS.

The O’Leary/Sant IC symptom and problem index (ICSPI) and Pain Urgency and Frequency questionnaire (PUF) scales are commonly used by urologists to identify and monitor PBS/IC patients. The ICSPI improved by 44% and 38% for PNS and SNS, respectively. PUF improved by 35% and 29% for PNS and SNS, respectively.

**Global outcome**

100% of those with SNS said “yes” when asked if they would undergo implantation again as opposed to 90% of those with PNS.

**Efficacy of case series/retrospective studies/case report**

**Pain outcomes**

The long-term pain outcomes of the 10 studies that were non-randomized trials are shown in Table 5. These outcomes reflect the patients who underwent permanent implantation. Eight studies showed a decrease in pain scores at long-term follow-up following permanent SNM. One study showed a significant decrease in narcotic consumption following SNM (Peter and Konstandt).\textsuperscript{[6]}

Four studies reported pain scores using the visual analogue scale. Siegel\textsuperscript{[8]} and Whitmore et al.\textsuperscript{[9]} utilized non-standard 4/5-point pain scales as an outcome measure. The decrease in narcotic consumption was statistically significant in the study by Peter and Konstandt.\textsuperscript{[6]}

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**Table 2: Inclusion criteria for patients in the studies**

| Author                        | Year | Inclusion criteria                                                                 |
|-------------------------------|------|--------------------------------------------------------------------------------------|
| Zerman et al.                 | 2000 | Clinical, cystoscopic                                                              |
| Siegel                        | 2001 | Clinical, cystoscopic; refractory to conventional Rx                               |
| Whitmore et al.               | 2003 | NIDDK                                                                                |
| Peter and Konstandt           | 2003 | Clinical, cystoscopic with six previous failed treatments                           |
| Kessler et al.                | 2007 | Refractory chronic pelvic pain and IC (clinical, cystoscopy)                        |
| Lavano et al.                 | 2007 | Clinical, cystoscopic; refractory to conventional Rx                               |
| Peters                        | 2007 | Clinical, cystoscopic; refractory to conventional Rx                               |
| Zabihi and Mouritzinos        | 2008 | Refractory chronic pelvic pain and IC (clinical, cystoscopy)                        |
| Marinkovic et al.             | 2010 | Clinical, cystoscopic; refractory to conventional Rx                               |
| Gajewski and Al-Zahrani       | 2010 | ESSIC criteria                                                                       |
| Powell and Kreder             | 2010 | Clinical, cystoscopic; refractory to conventional Rx                               |

**Table 3: Percentage success of trial stimulation**

| Author                        | Year | Percentage permanent implantation after trial testing |
|-------------------------------|------|-------------------------------------------------------|
| Zermann et al.                | 2000 | 100                                                   |
| Siegel                        | 2001 | 100                                                   |
| Whitmore et al.               | 2003 | 51.51                                                 |
| Peter and Konstandt           | 2003 | -                                                     |
| Kessler et al.                | 2007 | (11.7 for pain); overall 43.54                       |
| Lavano et al.                 | 2007 | 100                                                   |
| Peters                        | 2007 | 59                                                    |
| Zabihi and Mouritzinos        | 2008 | 77                                                    |
| Marinkovic et al.             | 2010 | 88.23                                                 |
| Gajewski and Al-Zahrani       | 2010 | 59                                                    |
| Powell and Kreder             | 2010 | 50                                                    |

**Table 4: Pain outcomes at 6 months follow-up for sacral nerve stimulation versus pudendal nerve stimulation**

| Author                        | Year | Pain outcome SNS     | Pain outcome PNS     |
|-------------------------------|------|----------------------|----------------------|
| Peters et al.                 | 2007 | VAS decrease from 7.9| VAS decrease from 4.5|
|                               |      | to 4.0 49% decrease  | to 3.2 29% decrease  |

**Urological outcomes**

**Global outcome measure**

GRA scale: The study by Gajewski et al.,\textsuperscript{[2]} reported an 80% decrease in global response assessment scale (GRA) for those who underwent SNM.

SF36 scale: Siegel\textsuperscript{[8]} reported 8/10 patients showed improvement in all 4 physical domains and 3/4 mental domains on the SF36 scale. Lavano et al.,\textsuperscript{[11]} reported a significant difference in all domains.

BDI: Siegel\textsuperscript{[8]} reported 6/10 patients had an improved BDI score following SNM.
Overview of safety findings

Adverse events related to the studies are shown in Table 6. One of the long-term problems is loss of efficacy/infection/pain that leads to removal of the device (termed explantation). Explantation rates were reported in eight studies. Four of these studies reported explantation/revision rates between 20 and 30%, whereas Kessler et al.,[10] reported only 2/209 IPG that developed a malfunction. Powell and Kreder[15] reported a 50% explantation rate. IPG site pain was reported in five studies. The incidence varied from 3.29% of IPG to 40%.

Revisions of lead/other lead issues were reported in four studies [Table 6]. The common issues reported were lead migration, broken leads, and lead fracture. The incidence of lead complications ranged from 3.29 to 28.57%.

Table 5: Pain outcomes for case series/retrospective studies/case reports

| Author                  | Year | Study type          | Number | Pain outcome                                      |
|-------------------------|------|---------------------|--------|--------------------------------------------------|
| Zermann et al.          | 2000 | Case report         | 1      | VAS score decreased to 0 from 6.7                |
| Siegel                  | 2001 | Prospective observational case series | 10 | 5-point pain scale. Worst pain decreased to 2.2 from 4.7; least pain decreased to 1.2 from 2.4; average numbers of hours of least pain decreased to 6.9 from 13 h |
| Whitmore et al.         | 2003 | Prospective observational case series | 33 | 4-point pain scale. 0.7 decreased to 1.6 (0.8); statistically significant |
| Peter and Konstandt    | 2003 | Retrospective observational case series | 21 | Intake of narcotics. Statistically significant decrease from 81.6 to 52 mg/day (36%; P = 0.015); 20/21 patients reported marked decrease in pain |
| Kessler et al.          | 2007 | Prospective observational case series | 209 | VAS statistically significant decrease from 8 to 2 median |
| Lavano et al.           | 2007 | Prospective observational case series | 7 | Pain decreased in 5/7 patients |
| Zabihi and Mourtzinos   | 2008 | Prospective observational case series | 30 | VAS improved by 40% (P = 0.04) |
| Marinkovic et al.       | 2010 | Retrospective case control        | 30 | VAS decreased from 6.5 to 2.4 (P < 0.01) |
| Gajewski, and Al-Zahrani| 2010 | Retrospective case series         | 78 | GRA 80% improvement; no pain outcome mentioned |
| Powell and Kreder       | 2010 | Retrospective         | 39 | Dysuria or pelvic pain 64.7 (11/17) cured; 35.3% same |

Table 6: Overview of adverse events in all studies

| Study                   | Year | Explantation/implantation issues/revision | Implant site pain | Revision of lead/lead issues | Infection at implant site | Others                                                                 |
|-------------------------|------|-------------------------------------------|-------------------|-----------------------------|--------------------------|------------------------------------------------------------------------|
| Zermann et al.          | 2000 | 0                                          | 4/10 (40%)        | 2/10 (20%)                  | 1/10 (10%)               | Severe pain at PNE; unpleasant tapping                                 |
| Siegel                  | 2001 | 2/10 (20%)                                 |                   | 2/10 (20%)                  |                          |                                                                        |
| Whitmore et al.         | 2003 |                                            |                   |                             |                          |                                                                        |
| Peter and Konstandt    | 2003 |                                            |                   |                             |                          |                                                                        |
| Kessler et al.          | 2007 | 1 = Implant migration; 1 = malfunction after MRI | 3/91 (3.29%) | 3/91 (3.29%); 2 migration/1 broken |                          | 1/91                                                                   |
| Lavano et al.           | 2007 | 1/7 (14.37%)                               |                   | 2/7 (28.57%); 1 lead fracture; 1 displaced |                          |                                                                        |
| Peters                  | 2007 |                                            |                   |                             |                          |                                                                        |
| Zabihi and Mourtzinos   | 2008 | 5/23 (22%); 1 revision                     |                   |                             |                          | 4/23 (17%)                                                             |
| Marinkovic et al.       | 2010 | 3/30 (27% reimplantation due to erosion)   | 3/30 erosions     |                             |                          |                                                                        |
| Gajewski and Al-Zahrani | 2010 | 28% explantation; 9 poor outcome; 4 painful stimulation; revision 50% - loss of efficacy, 12/46; pain in area of implant; 115 painful stimulation | 25% |                             |                          |                                                                        |
| Powell and Kreder       | 2010 | 11/22 (50%); 4/11 depleted batteries; 3/11 loss of efficacy |                   |                             |                          |                                                                        |
Three studies specifically reported infection at the IPG site. The other studies did not mention IPG site infection, but the rates of explantation/revision may be a clue to the infection rates. The rates of reported IPG site infection ranged from 8 to 17% [Table 6].

Powell and Kreder[13] reported an interesting problem with these IPGs. The sacral neuromodulator IPG malfunctioned after a shoplifting alarm went off, and in another case, the IPG was destroyed by DC cardioversion.

**Discussion**

Chronic pelvic pain can arise from other pelvic organs (prostate, endometrium, anal canal) and from the pelvic floor apart from the urinary bladder.[8] However, majority of the efficacy studies of SNM available in literature have been done for chronic pain related to PBS/IC. This efficacy study was restricted to patients presenting with chronic pain related to PBS/IC.

Painful bladder syndrome/Interstitial cystitis is still a poorly defined condition. The definitions used in this literature review include the National Institute of Diabetes and Digestive and Kidney diseases (NIDDK) criteria,[16] clinical and cystoscopic diagnosis and the ESSIC criteria.[17] Common to all these definitions is the exclusion of urinary tract infection/cancer and pain attributable to any other pelvic organ such as prostate or endometriosis. As of present, no single case definition has high sensitivity and specificity to identify PBS/IC.[18] Some studies like Kessler’s[10] also included urinary retention and other chronic pelvic pain patients, thus affecting the generalization of the results relating the efficacy of SNM for PBS/IC specifically.

The etiology of PBS/IC is still unknown. Postulated causes include inflammation of the bladder wall,[19] mast cell activation in the bladder,[20] urothelial dysfunction,[21] urothelial glycosaminoglycan (GAG) defect,[22] autoimmune,[23] and neurogenic inflammation.[24] Elbadawi and Light[24] studied microscopic specimen from the bladder wall and reported the changes did not support a primary role for mast cells or deficient GAG layer in the pathogenesis of PBS/IC. The changes in nerves showed degenerative and regenerative features, with some showing plasticity. The electron microscopic changes suggested a neurogenic inflammation that resulted in a leaky epithelium and mast cell activation. This hypothesis is very important, as neuromodulation therapy has been shown to be successful for neuropathic pain.

SNS is the application of electrical impulses to the sacral nerves. The sacral nerve may be stimulated by commonly placing the electrode next to the sacral nerve via the sacral foramen or by placing the electrode next to the pudendal nerve which has sacral origins [Figures 2 and 3]. The electrical impulse improves the bladder activity and pain by possibly modulating sacral afferent nerve activity. A trial testing, usually for a week, is carried out to test the efficacy by attaching the lead to a pulse generator externally. If the trial is positive, then a pouch is usually created surgically in the buttock/abdomen and the pulse generator is implanted permanently.

Historically, SNM was first described for treating voiding dysfunction after experiments in paraplegic dogs (Tanagho and Schmidt).[25] Electrical stimulation via a sacral electrode resulted in good bladder voiding with minimal sphincter response. Tanagho reported the first human trials in the late 1980s,[26] followed by a larger case series of 35 patients suffering from voiding difficulties resulting from spinal cord lesions.[27]

The United States Food and Drug Administration (FDA)
approved SNM in 1997 for urge incontinence, for urgency-frequency, and for non-obstructive urinary retention in 1999. The National Institute of Clinical Excellence (NICE) in the United Kingdom reviewed SNM for urinary urge incontinence and urgency-frequency and found that evidence from RCTs showed that 70% of patients achieved continence or exhibited an improvement of more than 50% showed improvement in their main incontinence symptoms after SNS. The technical evaluations by these bodies (especially NICE) have allowed an expansion of SNM services for urological conditions in the United Kingdom. The use of SNM for pain relief, specifically in PBS/IC, was prompted by the observation that the use of SNM also afforded pain relief to patients with urological symptoms. Shaker and Haussouna, while studying the efficacy of SNM for 20 patients with idiopathic non-obstructive urinary retention, reported a substantial decrease in their pelvic pain scores along with improvement in the urinary parameters.

At present, SNM is recommended for treatment of chronic pain related to PBS/IC only after all conservative measures have been exhausted. However, there was great variability in the number and type of treatment the patients had received prior to being considered for SNM treatment. Most of the studies included patients who had failed conventional medications, pain management program, and had undergone hydrodistention. None of the studies included patients who had undergone surgery such as cystectomy or urinary diversions prior to entering the study.

The average age of the participants ranged from 41 to 60 years in the included studies. It is thus not known whether these results are applicable in older patients or in patients younger than 40 years. The majority of studies included both sexes, with two studies including only women. Even in the mixed population, majority of the included patients were females. This reflects a female preponderance of PBS/IC.

The best evidence for the efficacy of SNM for pain related to PBS/IC comes from the RCT by Peters et al. However, this trial was a subset of a larger study whose primary objective was to evaluate urological outcomes, thus raising doubts that this RCT may not have been adequately powered for a pain outcome. The baseline characteristics of the SNS and PNS groups were not available, thus raising doubts about whether confounding variables had been eliminated prior to the intervention. This was a single-blind trial that does not eliminate observer bias. This study reports decrease of pain within each group (pre- and post-IPG), but there was no comparison of pain relief differences between the groups (SNS and PNS).

The rest of the evidence for SNM efficacy comes from case series/case reports and retrospective studies that are more prone to bias than RCTs. In general, case reports and case series are prone to biased selection of subjects, and hence the conclusions are difficult to generalize. This introduces selection bias with regard to age, sex, duration of symptoms, and the referral pathway (whether patients are referred to the pain clinic by Urologist or Uro-gynecologists). The case series in this review had no control group, and hence it is difficult to determine the size of efficacy effect as compared to conventional treatment or placebo. The outcome measures for pain were mainly VAS scores, with one study reporting decrease in narcotic requirements and another evaluating efficacy by means of [GRA] scale. An interesting fact was that in all the studies, improvement in urinary variables mirrored improvement in pain that points to a possible common pathophysiological dysfunction for both pain and urinary dysfunction in patients with PBS/IC. However, the case series reported similar outcomes to the RCT in that SNM was efficacious in providing pain relief to patients with PBS/IC.

Patient’s quality of life was studied in only three studies. One study utilized GRA scale to evaluate efficacy. All these studies showed improvement in patient’s perception of improvement at long-term follow-up.

The more recent studies reported adverse events. The explantation/revision rates ranged between 20 and 30% in most studies, which is consistent with long-term use of SNM for urological conditions where the experience has been longer. The most common reported complications were IPG site pain, revision of lead, and infection at IPG site. The clinical experience of the clinician or the troubleshooting algorithm for these complications was not mentioned.

The prediction of successful SNM long term in all studies depended on a success at trial stimulation. The majority of studies utilized >50% pain improvement/urinary variables at the trial stage to proceed to the permanent implantation stage. The success rate varied from 11.7 to 100%. The lower rates of success have been skewed mainly by the Swiss study Kessler et al., which had an 11.7% success rate for pain patients but 43.54% overall for both pain and urological patients. This could be attributed to using SNM for conditions other than PBS/IC, like chronic pelvic pain which is a conglomerate of ill-defined conditions under one roof and SNM may not be efficacious in all of them. If we exclude this study, then the success rate of trial stimulations has been upward of 50%. Apart from trial stimulation, no other feature predicted long-term success.

As SNM has evolved, the later trials have mainly used tined leads for trial testing and permanent implants because of their greater stability. Placement of permanent tined lead during the testing phase is the method of choice at present. The tined
lead is a lead with much improved anchoring properties.

The issue of bilateral versus unilateral stimulation for predicting long-term efficacy remains unanswered, and though buttock implantation of IPG has become the norm, there is insufficient evidence to recommend one over the other.

Conclusions

The use of SNM for pain related to PBS/IC has generally been done for patients with pain related to painful bladder syndromes that have failed multiple previous treatments.

alone provides evidence of some benefit from SNM in terms of reduced pain scores along with improvements in frequency and bladder volume in patients with pain related to PBS/IC. The case series/case reports also report broadly similar findings to the RCT. Benefits of SNM for pain were reported at follow-up to 7 years after implantation. The impact of SNM on quality of life in the long term could not be established.

The explantation/revision rates ranged between 20 and 30% in most studies. The most common reported complications were IPG site pain, revision of lead, and infection at IPG site.

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