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Letters to the Editor

Classical Predictors Do Not Predict Success with Sacral Nerve Stimulation for Chronic Pelvic Pain; A Retrospective Review in a Single Center

Muhammad Kashif, MBBS, FCPS, FCAI, FFPMRCA,* Andreas Goebel, MD, PhD, FRCA, FFPMRCA,† Vanja Srbljak, MD, FCAI, EDRA,‡ Rajiv Chawla, MD, FRCA, FCARCSI, FFPMRCA,§ Mark Draper, BSc,‖ Alison Cox, BSc,¶ and Manohar Sharma, MBBS, MD, FRCA, FFPMRCA, MSc§

*Consultant in Anaesthesia and Pain Medicine, University Hospitals of Derby and Burton, UK; †Senior lecturer University of Liverpool and Consultant in Pain Medicine, Walton Centre of Neurosciences, UK; ‡Specialty Doctor in Anaesthesia, University Hospitals of North Midlands, UK; §Consultant Pain Medicine, Walton Centre of Neurosciences, UK; ‖Specialist physiotherapist, Pain and Neuromodulation, Walton Centre of Neurosciences, UK; ¶Clinical Nurse Specialist, Pain and Neuromodulation, Walton Centre of Neurosciences, UK

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Dear Editor,

We reviewed our experience of sacral nerve stimulation for chronic pelvic pain in order to find factors that could help with patient selection in the future.

Chronic pelvic pain (CPP) is a common condition that can have a significant impact on quality of life [1]. Despite availability of multiple treatment options, results are often mixed and symptoms persist for years [2]. Sacral nerve stimulation (SNS) is an emerging technology that involves application of barely perceptible electric current to the S3/S4 nerves through percutaneously inserted electrodes. SNS is recommended by the National Institute for Health and Care Excellence for the treatment of urinary urge incontinence and urgency/frequency. However, there is little evidence for use of SNS in the treatment of chronic pelvic pain. Although some patients get good pain relief from SNS, predictors for positive response are not well established.

We explored baseline characteristics associated with meaningful pain relief following SNS implant in chronic pelvic pain patients to ascertain parameters for a prospective predictor study.

In this review, we retrospectively analyzed results from routine clinical questionnaires for all the patients who were treated with SNS for chronic pelvic pain from 2009 to 2016 at our tertiary-level pain treatment center. We correlated pain intensity outcomes with the baseline characteristics of the patients.

After assessment by a consultant in Pain Medicine, patients deemed suitable for SNS had a two-week trial of sacral nerve stimulation, with success defined as 50% or greater reduction in their average pain scores. During the trial, the S3 or S4 nerve was stimulated. S4 nerve stimulation was used only when S3 stimulation failed to produce paresthesia. After a successful trial, patients received the SNS implant eight to 12 weeks later (Figures 1 and 2). Our trial-to-implant ratio was 50%. The range of parameters used for neuromodulation included an amplitude of 0.6–4.7 v, frequency of 14–50 Hz, and pulse width of 180–210 us. Patients were followed up by the neuromodulation team, and outcomes were recorded in the questionnaires and clinical notes.

Clinical baseline data included diagnosis and duration of pain, response to medical treatment and/or pudendal nerve block, pain scores including average and worst 24-hour numeric rating pain score (11-point numeric rating scale [NRS], 0–10), and various quality of life scores including the Hospital Anxiety and Depression Scale (HADS), Oswestry Disability Index (ODI), Euro Qol Descriptive (EQ-5D), and Brief Pain Inventory (BPI). Pain scores were also available at one-year follow-up.

All the patients were reviewed by physiotherapists and psychologists as part of multidisciplinary assessment and received suitable conservative therapies before being

Figure 1. Sacral nerve stimulator implant anteroposterior view

Figure 2. Sacral nerve stimulator implant lateral view

offered SNS. None of the patients had attended a pain management program before the SNS implant.

We identified 12 patients who had the SNS implant after successful trial. "Positive response" was defined as 30% or greater reduction in average pain scores at one-year follow-up after the SNS implant.

Seven patients (60%) reported 30% or greater reduction in their pain scores at one-year follow-up. Documentation

Table 1. Patient demographics, baseline and follow-up data

Patient No.	Age, y	Sex	BL/FU ANRS	BL/FU WNRS	Responder/ Nonresponder	Diagnosis/ Duration of Pain, y	Character of Pain	Area of Pain	Localization of Pain	Bladder or Bowel Dysfunction	Oral Morphine or Equivalent, mg	PNB/PNB Outcome
1	69	M	4/0	8/4	Responder	Pudendal neuralgia/6	Deep, hot, sharp	Perineum	Localized	No	40	Yes/1 failed 1 successful
2	34	F	6/0	10/8	Responder	BPS/10	Deep, dull	Pelvis, lower abdomen	Diffuse	No	20	No/NA
3	52	M	7/5	10/7	Responder	Idiopathic rectal pain/6	Tenesmus, constant ache	Pelvis, perineum, rectum	Diffuse	No	0	No/NA
4	54	F	8/5	10/6	Responder	Postsurgical/7	Stabbing	Rectum	Localized	Yes	0	No/NA
5	62	F	8/2	9/6	Responder	Postsurgical/5	Dull, aching	Vaginal, perineal, pelvis	Diffuse	Yes	20	Yes/failed
6	46	F	6/1	9/2	Responder	Post-traumatic/7	Sharp, piercing	Urethral	Localized	Yes	20	No/NA
7	43	M	9/6	10/7	Responder	Idiopathic testicular pain/9	Shooting, stabbing	Testis	Localized	No	40	No/NA
8	53	M	7/7	8/8	Nonresponder	BPS/5	Deep, dull ache	Lower abdomen, pelvis	Diffuse	Yes	20	No/NA
9	23	F	4/4	6/6	Nonresponder	BPS/10	Throbbing	Lower abdomen	Diffuse	Yes	0	No/NA
10	82	M	7/7	8/8	Nonresponder	Postsurgical/2	Stabbing, pricking	Scrotum, penis	Localized	No	0	Yes/failed
11	68	F	9/7	10/9	Nonresponder	Idiopathic rectal pain/8	Burning, deep	Rectum, perianal, pelvis	Diffuse	No	20	Yes/failed
12	66	F	5/5	10/10	Nonresponder	Postsurgical/10	Deep shooting	Rectum, pelvis	Diffuse	Yes	40	No/NA

BL ANRS = baseline average numeric rating score; BL WNRS = baseline worst numeric rating score; BPS = bladder pain syndrome; FU ANRS = follow-up average numeric rating score; FU WNRS = follow-up worst numeric rating score; NA = not applicable; PNB = pudendal nerve block.

Table 2. Summary data (median and range)

	Responders (Total No. 7)		Nonresponders (Total No. 5)	
	Range	Median	Range	Median
Age, y	34–69	52	23–82	59.5
Duration of pain, y	5–10	6.5	2–10	8
Baseline average NRS	4–9	7	4–9	7
Follow-up average NRS	0–6	2	4–7	7
Oral morphine equivalent, mg	0–40	20	0–40	20
Baseline HADS anxiety	6–19	13	9–18	10.5
Baseline HADS depression	6–15	10	9–13	9
Baseline ODI	18–70	53	30–60	46.5
Baseline BPI	3.75–8.42	8	5–7	7.57
Baseline EQ-5D	0.O51–0.316	0.122	0.264–0.584	0.484

BPI = Brief Pain Inventory; EQ-5D = Euro Qol Descriptive; HADS = Hospital Anxiety and Depression Score; NRS = numeric rating score; ODI = Oswestry Disability Index.

of the baseline psychometric and quality of life scores was found to be incomplete. EQ-5D was available for six patients, HADS and ODI for 11, and BPI for eight patients. The implant was removed at six months in two patients because of lack of any pain-relieving effect. One patient developed superficial infection that was treated with antibiotics, but the implant was left in situ.

The mean reduction in average NRS score was 65% in the seven responders, and only 4% in nonresponders.

In this review of our practice, we identified that although all patients had successful trials, only 60% had satisfactory pain relief after the implant.

We reviewed various baseline parameters to identify any difference between responders and nonresponders (Table 1 and Table 2). The only difference that we could identify was localization of pain, as four out of seven responders had localized pain, whereas four of five nonresponders had diffuse pain. However, localization of pain was deemed to be a subjective characteristic of pain as there were no predefined criteria for localization of pain. Also, the sample size was too small to recommend localization of pain as a predictor of success with sacral nerve stimulation.

Martellucci and colleagues also identified multiple localizations of pelvic pain as a negative factor for sacral neuromodulation [1]. Future prospective studies that are adequately powered and have predefined criteria for localization of pain are needed to confirm whether localized or diffuse pain can serve as a predictor.

At our center, we perform transforaminal sacral nerve stimulation at the S3 or S4 foramen. Pudendal nerve neuromodulation with neurophysiological guidance is another option that has been trialed in some centers [2].

The literature on sacral nerve stimulation as a treatment modality for chronic pelvic pain is very limited, and few studies have tried to identify predictors of success with SNS. Martelluci in his review of SNS treatment recommended age <60 years and duration of symptoms <24 months as predictors of success [3]. Govaert et al. [4] in their retrospective review reported good results with sacral nerve stimulation when positive SNS trial was used as a predictor of success. Gajewski and Al-Zahrani [5] identified the presence of urgency in bladder pain syndrome as a positive predictor for long-term success with SNS implant. In our review, we could not identify any of the above-mentioned factors as a predictor of positive response.

One of the reasons for failed SNS treatment, despite having a successful trial, could be the difference in the area of the electric field created by the trial and implant leads. Trials are usually done with a single monopolar percutaneous nerve evaluation lead, which creates a relatively larger electric field between the lead tip and ground pad. But implants are done with the tined lead, which involves two contacts on the same lead and creates a relatively smaller electrical field.

A limitation of our study is that we defined positive response as 30% or greater reduction in pain scores, which may not allow comparison with other studies using a 50% threshold. Of note, four out of seven responders had 50% or greater reduction, and the remaining three had 30–50% reduction in their pain scores.

We could not identify any difference in quality of life or psychometric scores; however, these scores were not consistently documented in all patients. In our future prospective study, we aim to record quality of life, pelvic pain impact, and psychometric questionnaires in all patients to identify any of these parameters as a predictor. Moreover, catastrophizing and self-efficacy questionnaires will be included in the future study as catastrophizing and self-efficacy can be important factors in determining success with invasive treatments like SNS.

Conclusion

We were unable to find any factor as predictor of success with SNS implant for chronic pelvic pain. Localized pain may serve as a predictor of success, but this needs to be

further confirmed by a prospective study, which we plan to conduct in the future.

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