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# Peripheral nerve stimulation on trial: A novel, cost-effective approach to determine patient candidacy prior to implantation

*Dear Editor,*

Peripheral nerve stimulation is an effective neuromodulation technique in the management of chronic pain. It is indicated in clinical conditions like mononeuropathy of peripheral nerves, chronic knee pain, chronic shoulder pain, occipital neuralgia, post amputation pain and complex regional pain syndrome. However, there is limited literature on trialing stimulation to determine permanent PNS implant candidacy [1]1.

Peripheral nerve stimulation (PNS) was first described in the 1960s as a neuromodulation technique for pain [3,4]. Early peripheral nerve stimulators required open nerve exposure to place cuff or paddle electrodes. Limitations of the techniques included obtaining nerve exposure, difficulty in maintaining lead positioning for paresthesia coverage and diminishing pain relief over time. Widespread use of peripheral nerve stimulation, has been limited by reimbursement challenges and paucity of research. Peripheral nerve stimulators have evolved with miniaturized leads and external pulse generators that require minimally invasive ultrasound guided techniques for placement. This has led to a significant interest in use of this modality. However, there is currently no consensus or established protocol on the optimal workflow for a PNS trial [4]. Some physicians implant a peripheral nerve stimulator after a diagnostic nerve block [5] and others based on clinical history and diagnosis alone. Recent literature reports suggest that nerve blocks alone have not been necessarily useful in predicting peripheral nerve stimulation outcomes [1]. In contrast, data and best practices recommend a spinal cord stimulator trial prior to implantation [2]. Additionally there are differences among device manufacturers with some using trial leads (Nalu Medical, Carlsbad, CA) and others do not (Bioventus Stim Router, Durham NC). In this report we propose a simple, cost effective, and efficient method to trial and determine candidacy for permanent peripheral nerve stimulator implantation. It can help identify the nerve target for implantation and aids the patient's understanding of stimulation and coverage of painful areas serves as a trial pre-implantation. Neuromodulation techniques are postulated to work based on the gate control theory of pain [3]. They reduce the perception of pain utilizing non-noxious stimuli to be preferentially transmitted [3]. For most patients, it is difficult to conceptualize this sensation without prior exposure. A trial of stimulation in addition to confirming nerve target also provides a preview of stimulation to the patient.

We hope that this technique will enable other practitioners to appropriately identify patients and minimize treatment failure.

A trial of peripheral nerve stimulation is performed prior to ultrasound guided injection of the target nerve. This approach requires the use of a Bioventus Stim Pod external device which mimics the waveform the EPG (external pulse generator) provides and is used by the company representatives during a permanent implantation procedure to confirm lead placement. This device is battery-operated, and reusable and has a universal 1-pin connector.

In this workflow, a patient experiences peripheral nerve stimulation delivered by Stim Pod (electrical stimulation delivered through a standard stimulating nerve block needle prior to injection of local anesthetic). We have found success when stimulation is obtained between 0.2 and 1.5 mA at a frequency of 100 HZ. Stimulation is applied for a duration between 5 and 10 minutes to allow the patient to experience the sensation and determine if coverage of the painful area is obtained. We typically use the longer duration of stimulation if a peripheral nerve stimulating catheter is used. After obtaining adequate coverage of stimulation, a mixture of local anesthetic with or without steroid is injected adjacent to the nerve. This combines two steps of the diagnostic and treatment algorithm. In this workflow, the trial has already been performed and the patient's experience of intra-procedural peripheral nerve stimulation can be used to determine their candidacy for permanent implantation. There may be concern, that there is a risk of false negatives [4] due to the brevity of the stimulation time in this type of trial to alleviate pain. However, when the gate theory of pain is considered, the main endpoint is simply to ensure the non-noxious stimulus overlaps the painful area and over time, pain relief is achieved [3]. With regards to contextual pain, (only perceived during certain activities or in certain positions), a slight modification is to place a perineural stimulating catheter instead of a rigid needle connected to the Stim Pod. The insertion site is covered with a sterile occlusive dressing and the patient is asked to perform the inciting movement while the stimulation is transmitting. Once the patient has had an opportunity to experience stimulation, coverage of painful area is assessed and if there is there is overlap the injectate is delivered through the stimulating catheter. This ensures all of the benefits of an efficient trialing workflow while avoiding the need for redundant steps of separate block and trial procedures. (Fig. 1 illustrates the work flow). We routinely perform this technique in our practice and have implanted PNS for chronic foot and ankle pain post-surgery, chronic post inguinal hernia pain and chronic knee pain after performing a trial as described above.

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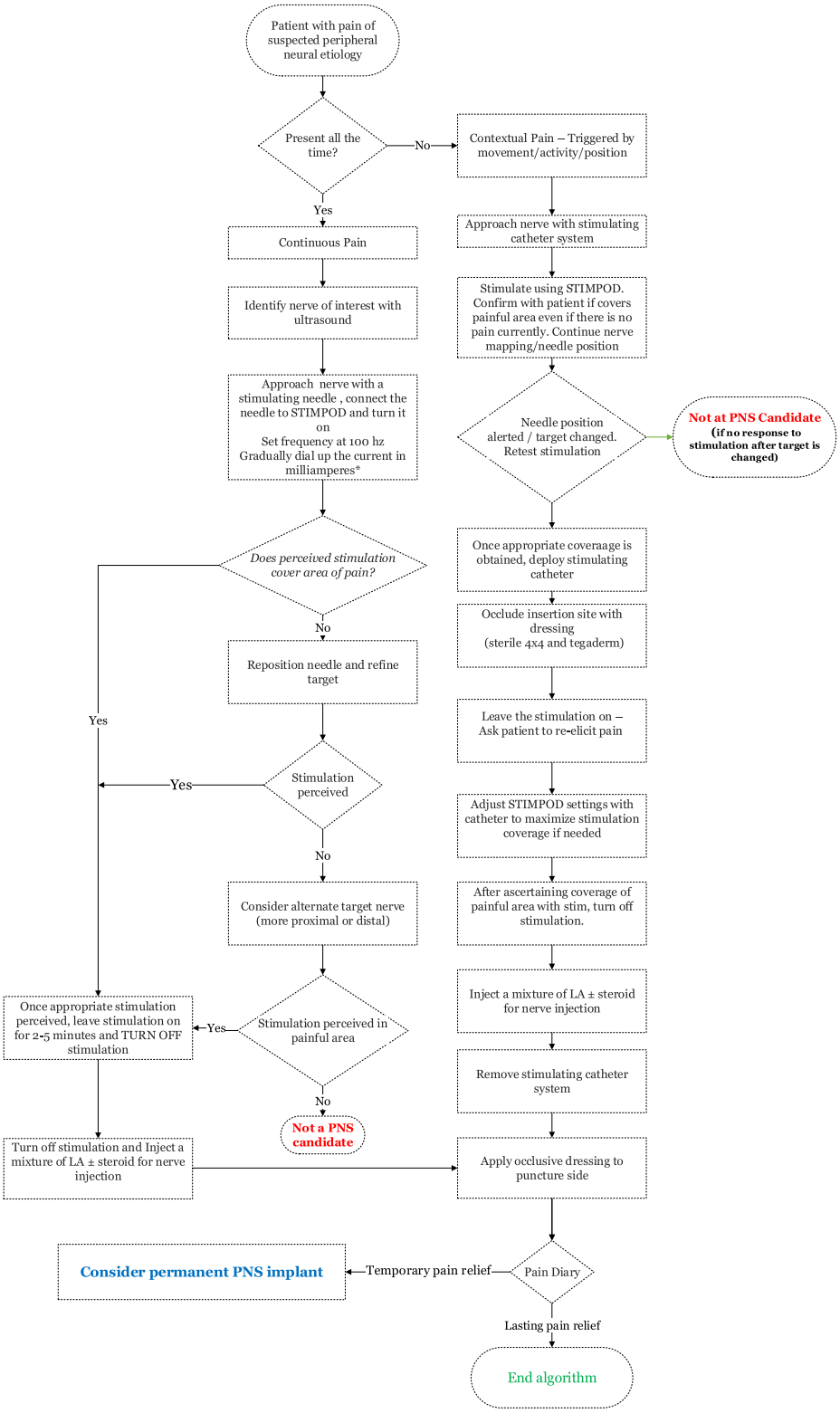


**Fig. 1.**

As peripheral nerve stimulation gains popularity, it is imperative to identify patients who are appropriate candidates in order to achieve good outcomes. Currently, physicians may perform a diagnostic nerve block prior to PNS implantation [5]. However recent evidence suggests that this is not correlated to improved outcomes [1]. Use of a stimulation trial has been emerging as a potential technique. But existing literature demonstrates that long trials are logistically challenging [6]. Additionally, not all manufacturers provide trialing systems. There is limited literature on screening patients for peripheral nerve stimulation, unlike other neuromodulation therapies like spinal cord stimulation and dorsal root ganglion stimulation. In the single report describing an in-office trial [6], the authors used trial stimulation for between 10 and 60 minutes with the primary end point being analgesia. In addition, in some cases a long trial of between 6 and 7 days was undertaken. These

long trial periods necessitate catheter insertion. The advantage of the technique we describe is the need for a shorter trial period. For the most patients without contextual pain, simply inserting a stimulating needle to achieve stimulation for several minutes, as Wall and Sweet [7] did for 2 min, is adequate to understand if a permanent implant can be helpful to leverage the inhibitory interneuron effect of the gate control theory of pain [3] over the long-term.

## Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Sam Nia, MD reports a relationship with Bioventus LLC that includes: consulting or advisory. Sam Nia, MD reports a relationship with Nalu Medical Inc that includes: consulting or advisory. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Bhavana Yalamuru*
*Department of Anesthesiology, Pain Division, University of Virginia, Charlottesville, VA, USA*

Sam Nia
*Pain Management and Palliative Care, Department of Neurosciences, Nassau University Medical Center, East Meadow NY, 11554, USA*
*E-mail address:* snia@numc.edu.

* Corresponding author.
*E-mail address:* By2g@uvahealth.org (B. Yalamuru).