

A Survey of Patient Perceptions of Non-invasive Vagus Nerve Stimulation (nVNS) Therapy for Acute Migraine Attacks

Introduction

Unmet Needs in Patients With Migraine

- Despite the wide range of available medications for the acute treatment of migraine attacks (ie, triptans, ergotamines, opioids, barbiturates), several unmet needs exist among the migraine population¹
 - Findings from the American Migraine Prevalence and Prevention (AMPP) study showed^{1,2}
 - 37% of patients were dissatisfied with their therapy regimen
 - 32% of patients excessively used or were dependent on opioids and barbiturates
 - 26% of patients had a history of cardiovascular events, which limits their treatment options because of contraindications for triptans and ergotamines
 - Primary reasons for treatment discontinuation among triptan and opioid users were lack of efficacy and concern about side effects⁴
- Medication nonadherence (ie, taking above or below the prescribed dose) increases the risk for medication overuse and migraine progression^{3,5}

Neuromodulation for Migraine Attacks: Vagus Nerve Stimulation

- The vagus nerve has been identified as a potential target in pain modulation (Table 1),⁶⁻⁸ unmet needs in migraine therapy have prompted exploration of vagus nerve stimulation as a nonpharmacologic treatment option

Table 1. Proposed Vagal Mechanisms in Pain Pathways⁶⁻⁸

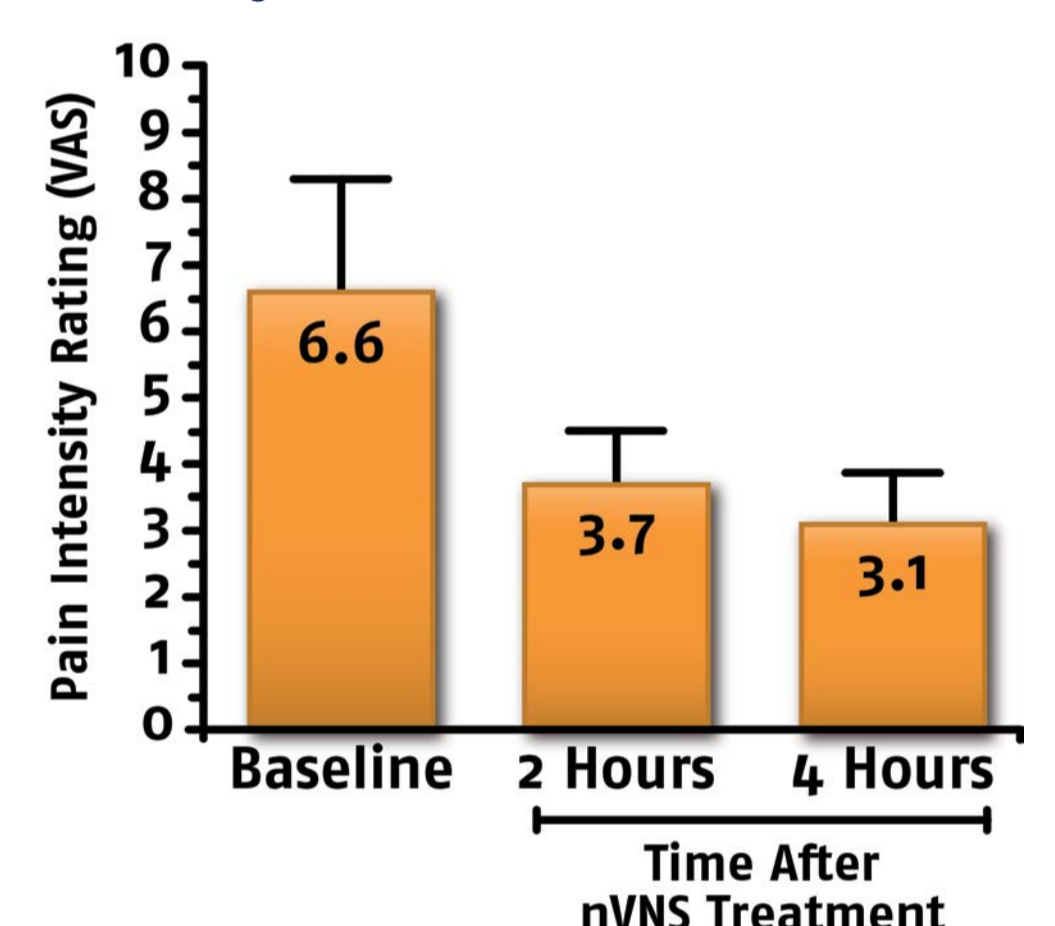
• Activation of anti-inflammatory pathways
• Inhibition of sympathetic activity and oxidative stress
• Alteration of activity in pain matrix regions of the brain
• Mediation of the antinociceptive effects of opioids
• Modulation of inhibitory neurotransmitter release leading to decreased glutamate levels in the trigeminal nucleus caudalis

- A non-invasive vagus nerve stimulation (nVNS) device (gammaCore[®]) has been developed and is CE-marked for the treatment of primary headache disorders
 - A recent study showed that 47% of patients with migraine experienced pain relief and 21% were pain-free at 2 hours after treatment with nVNS⁹
 - In a study of CH, 47% of attacks were aborted in an average of 11 minutes after nVNS treatment¹⁰

Study Rationale

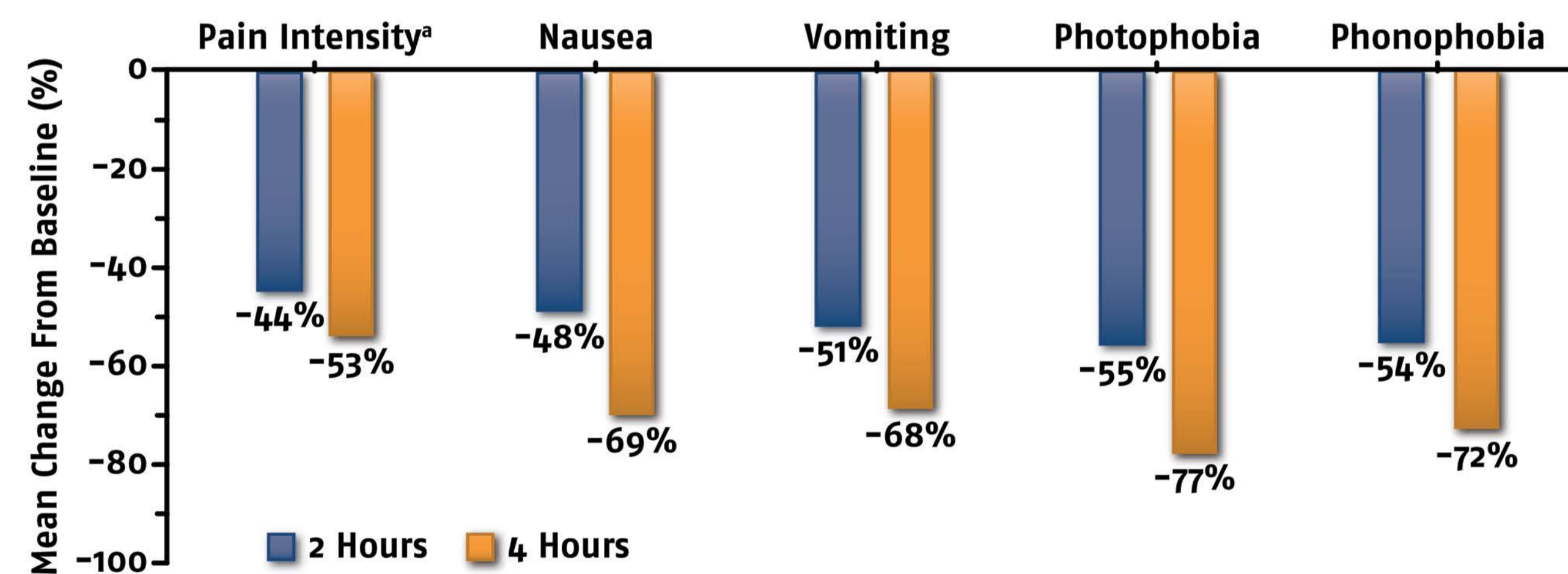
- Previously, we demonstrated that acute nVNS treatment of 79 migraine attacks in 22 patients reduced pain intensity and migraine-associated symptoms (Figures 1 and 2) with no serious side effects¹¹
- Because treatment adherence and persistence are key determinants of the long-term efficacy of migraine therapy, we conducted a survey to identify factors that influenced
 - Patients' initiation of nVNS
 - Patients' adherence to and persistence with nVNS

Figure 1. Improvement in Migraine Pain Intensity After Treatment With nVNS¹¹



Abbreviation: VAS, visual analog scale. Error bars represent standard deviation. Data are reported for 79 migraine attacks that occurred in 22 patients.

Figure 2. Percentage Reductions in Pain Intensity and Migraine-Associated Symptoms After Treatment With nVNS¹¹



Data are reported for 79 migraine attacks that occurred in 22 patients.
^a Pain intensity was measured using a VAS.

Methods

Patient Survey

- Surveys were mailed to 60 patients from our center who were currently receiving or who had previously received nVNS for the acute treatment of migraine attacks (Figure 3)
- The survey consisted of the following questions
 - What convinced you to use the vagus nerve stimulator instead of drugs?
 - What convinced you to continue using the vagus nerve stimulator?

Acute Treatment of Migraine Attacks With nVNS

- The nVNS device (Figure 3A) generates a low-voltage electrical signal that delivers a maximum voltage of 24 V and a maximum output current of 60 mA; the stimulation amplitude is adjusted by the user
- Patients administered 2 consecutive 120-second stimulations within 30 minutes of migraine onset (Figure 3B); additional stimulations were administered if treatment effect was insufficient

Figure 3. Non-invasive Vagus Nerve Stimulation
A. nVNS Device B. Application of nVNS



Images provided courtesy of electroCore, LLC.

Results

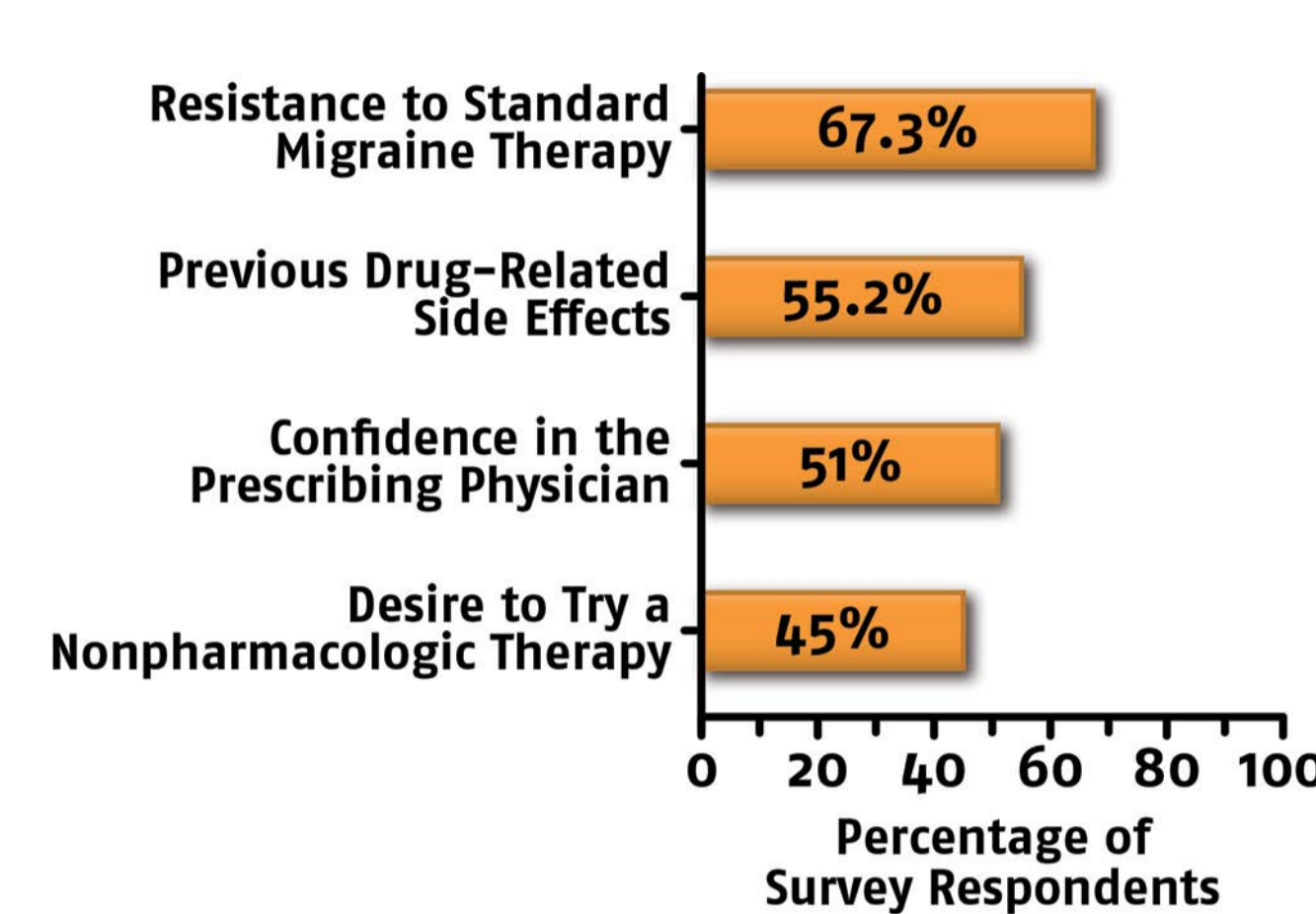
Survey Respondents

- Of the 60 patients who received survey questionnaires, 49 responded
 - The majority were female (73.5%; [36 of 49]), and the mean (SD) age was 40.3 (10.5) years (range, 21–60 years)

Survey Findings

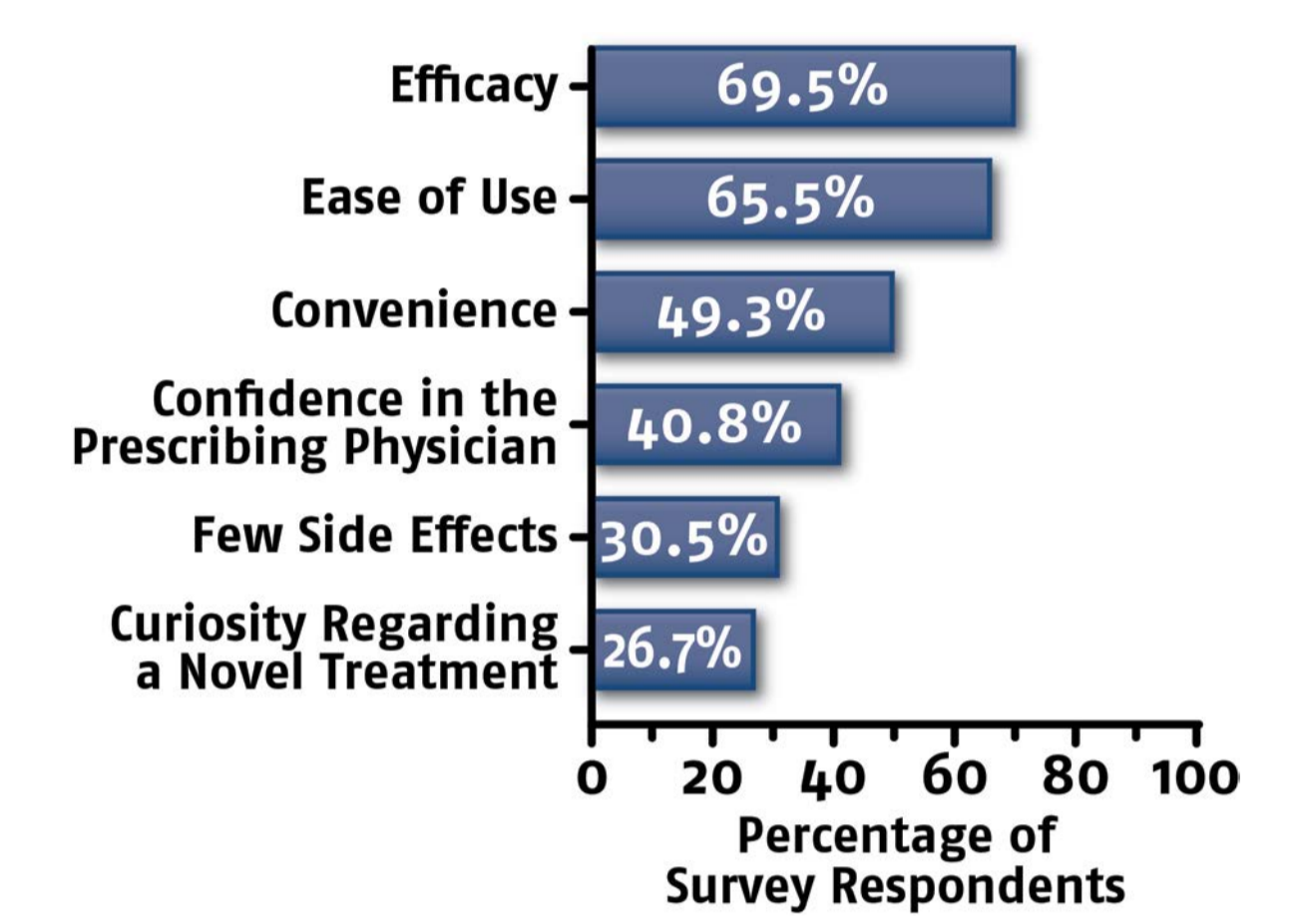
- The most common reasons for initiation of nVNS therapy were resistance to standard migraine therapy and previous drug-related side effects (Figure 4)
- The most common reasons for continued treatment with nVNS were efficacy and ease of use (Figure 5)

Figure 4. Reasons for Initiation of nVNS Therapy Among Survey Respondents (N=49)^a



^a Respondents were able to cite more than one reason.

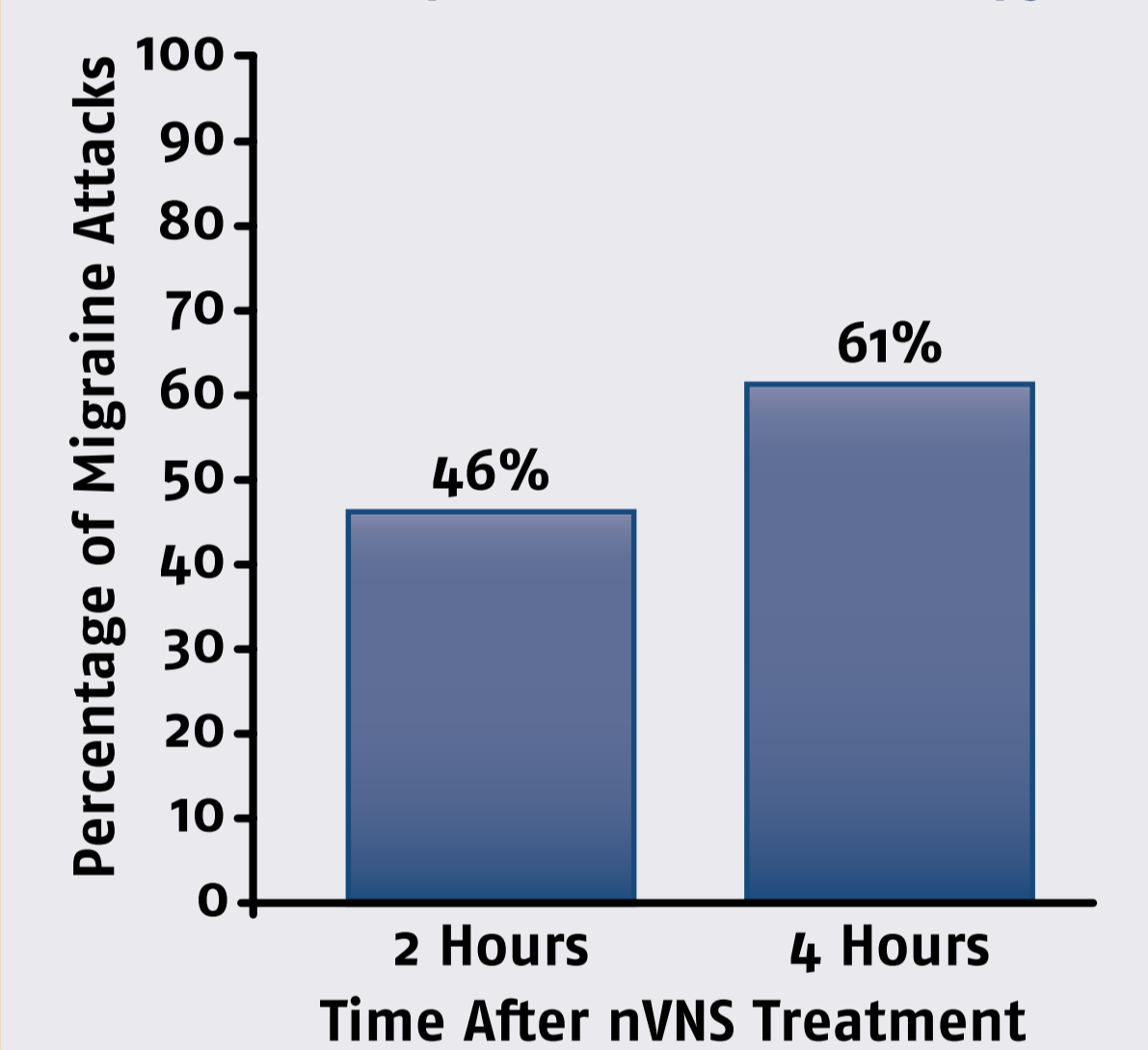
Figure 5. Reasons for Continuation of nVNS Therapy Among Survey Respondents (N=49)^a



Conclusions

- Despite the availability of multiple medications for the acute treatment of migraine attacks, patients are dissatisfied with standard pharmacologic therapy and express interest in nonpharmacologic treatments such as nVNS
- Resistance to standard pharmacologic therapy and medication side effects were key drivers of nVNS therapy initiation
- The clinical benefit and ease of use of nVNS led to treatment persistence
- Efficacy and ease of use of nVNS suggests patient satisfaction with therapy and extends previously reported findings (Figure 6)^{11,12}
- The efficacy of nVNS reported by patients surveyed may lessen their reliance on pharmacologic therapy, as was reported in a recent study of chronic CH¹³
- As an effective nonpharmacologic treatment alternative for migraine, nVNS may lower the risks of medication overuse and drug-related side effects

Figure 6. Proportion of Migraine Attacks That Were Responsive to nVNS Therapy¹¹



Data are reported for 79 migraine attacks that occurred in 22 patients.

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