Journal of Substance Use

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ijsu20

Percutaneous electrical nerve field stimulation to reduce clincial opiate withdrawal: a case series

Frank D. Buono, Rosemary Pickering, Rebecca Berlepsch & Shelley Halligan

To cite this article: Frank D. Buono, Rosemary Pickering, Rebecca Berlepsch & Shelley Halligan (2021): Percutaneous electrical nerve field stimulation to reduce clincial opiate withdrawal: a case series, Journal of Substance Use, DOI: 10.1080/14659891.2021.1961894

To link to this article: https://doi.org/10.1080/14659891.2021.1961894

Published online: 10 Aug 2021.

JOURNAL OF SUBSTANCE USE
https://doi.org/10.1080/14659891.2021.1961894

Taylor & Francis
Taylor & Francis Group

Percutaneous electrical nerve field stimulation to reduce clincial opiate withdrawal: a case series

Frank D. Buono [a,b], Rosemary Pickering[b], Rebecca Berlepsch[b], and Shelley Halligan[b]

[a]Department of Psychiatry, Yale School of Medicine, New Haven, Connecticut, USA; [b]Aware Recovery Care, Wallingford, Connecticut, USA

ABSTRACT

Background: Medication-assisted treatment can reduce mortality and withdrawal symptoms, yet treatments can have side effects and are cost ineffective. Research has supported alternative approaches to withdrawal symptoms, specifically percutaneous nerve field stimulator (PNFS); yet, to date, there is a lack of understanding of the initial acceptability within treatment programs.

Methods: A retrospective case series evaluated PNFS to reduce opioid withdrawal symptoms for five adult patients participating in an in-home withdrawal management program. The device was worn for five consecutive days, in which a licensed practical nurses monitored their care. Evaluation included the clinical opiate withdrawal scale (COWS) and clinical reviews based on self-report and clinician interview.

Results: Significant reductions were noted for all five participants, with the average COWS score for Day 1 at 19.1 reducing to 2.6 at Day 5. In addition, 2-day post-COWS scores demonstrated a continual reduction to 1.4. Qualitative feedback from the patients was recorded, and generalized themes were recorded and addressed.

Conclusions: Future controlled, prospective studies should investigate the possibility that PNFS can significantly reduce negative symptoms of opiate withdrawal symptoms, along with providing alternatives to medication-assisted treatments for those who are suffering from opiate use disorder.

ARTICLE HISTORY
Received 19 May 2021
Accepted 25 July 2021

KEYWORDS
Percutaneous nerve field stimulator (PNFS); opiate use disorder; withdrawal; case series

Introduction

Opioid use disorder (OUD) continues to be a detrimental issue, with over 7 million Americans misusing opiates over the last year (2018), and over 50,000 fatalities (SAMHSA, 2019). Typically, medication-assisted treatment (i.e., buprenorphine) in combination with behavioral treatments, has been demonstrated to have the highest efficacy in long-term success (Kennedy et al., 2021; Ronquest et al., 2018; Timko et al., 2016). Yet the transition period, also called induction phase, is a critical point of time in the detoxification of substance use. During this phase, withdrawal from treatment, side effects from detoxification, and lack of engagement are common barriers due to the intense process (Bart, 2012; Marsch, 1998), leading to potential disengagement. However, non-pharmacologic implementation to assist in the transition phase could provide alternative methods to reduce the withdrawal effects.

Percutaneous nerve field stimulation (PNFS) has shown moderate-to-high level of evidence and utility for the implementation of alternative methods to facilitate within chronic pain management (Deer et al., 2020). As opposed to pharmacological interventions, research has shown PNFS to have milder symptoms (i.e., nausea, cramping, and fevers) than standard approaches within pain samples (Gilmore et al., 2020; Roberts et al., 2016). None-the-less, within the induction period of detoxification from OUD, few articles have examined the effectiveness of the PNFS device (Miranda & Taca, 2018; Ward et al., 2020). Moreover, to the knowledge of the authors, research has not evaluated the impact of standardized assessments for clinical opiate withdrawal over the course of the device's treatment. Given this, the current retrospective case series focused on five patients who were administered a PNFS over the course of 5 days while obtaining clinical withdrawal data through patient's interviews.

Methods

Procedure

Clinical data were extracted through a retrospective medical chart review of five patients admitted to an in-home withdrawal management (IHWM) program between May 2019 and February 2021. The chart review was exempt approved by the human subject's research program (HRPO) at the first author's institution. All patients were treated by the senior author (SH) during and after their in-home care, with daily check-ins from (RP & RB). All patients were admitted with OUD and self-reported past illicit substance use and had a secondary or tertiary diagnosis of a substance use disorder. The female patients were not pregnant. Demographic and illness characteristics, diagnoses (APA, 2013), clinical opiate withdraws scores (Wesson & Ling, 2003), and family history were recorded and independently confirmed by the second author (FB), who managed the data on a password-protected Microsoft Access database created specifically for this study. Protected health information from the original charts was de-identified, and individuals were assigned an arbitrary research number and entered into the database. The

CONTACT Frank D. Buono frank.buono@yale.edu Department of Psychiatry, Yale School of Medicine, 300 George Street, New Haven, CT 06510, USA

COWS is used to help clinicians determine the stage or severity of opiate withdrawal and assess the level of physical dependence on opioids and completed by two licensed practical nurses (RP and RB). All individuals consented after being informed of the minimal risks to utilizing the S.T. Genesis, along with other treatments. At discharge, all patients were interviewed with an informal qualitative interview.

S.T. Genesis is a FDA cleared PNFS developed by Speranza Therapeutics (Boca Raton, FL). Neurostimulation treatment is applied through electrodes applied to specific cranial nerve branches: V, VII, IX, and X. Stimulation is performed by sending subtle electrical pulses through the electrodes. These nerve areas located on the external ear could potentially gain access to brain areas involved in fear, pain, and nociception. The device can provide stimulation for five consecutive days before needing to be removed by a medical professional.

Location

Aware Recovery Care (Wallingford, CT) provides an IHWM as an alternative to inpatient stays. The delivery of these services is overseen by a licensed professional specialized visiting addiction team. Patients admitted to any level of withdrawal management must meet the diagnostic criteria for substance withdrawal disorder of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Aware is equipped to offer clients IHWM if they fall between levels 1 and 2 within the ASAM criterion.

Results

As seen on Table 1, COWS, blood pressure, and heart rate were recorded across interval recording (Day 1, 2, 3, 5, and 2-day post-device) for all clients. Aggregate values across all patients can be seen as well.

Client 1

A 39-year-old man with OUD reported first opiate use at age 33. First opiate use at age 33 was prescription pills for 6 months due to a torn ACL, which then progressed to heroin use (unknown route). The client reported using two bags of heroin from age 33 to age 39. The patient reported significant traumatic experiences (physical and emotional) at adolescence and the death of family members later in life. Prior to putting the device on, the patient's COWS was 18, and by day 2, the individual's COWS dropped to 4. The patient reported on Day 3 to the nurse, "This has been the most comfortable detox I have ever experienced. I didn't want to quit again because I knew I was going to be sick, but this made it very easy." By the completion of Day 5, the patient remained a COWS of 4. It should be noted the patient successfully completed the withdrawal management program.

Client 2

A 30-year-old woman with a history of OUD had previous treatment for stimulant use and sedative use in 2017. The client reported using two bags of heroin intranasally a day prior to admission. The client has a psychiatric history of PTSD, Anxiety disorder, and major depressive disorder. The client identified a past trauma as a marriage at 16 years old and the divorce from that person. The client is currently unemployed and previously worked in the mental health field. The patient on day 2 reported to the nursethat the unit made it very easy compared to the many previous detox admissions. "I would do the Speranza again if needed in the future before going back to inpatient detox. I feel much better", and after the device was removed reported that "she felt much better." The patient successfully completed the withdrawal management program.

Client 3

A 52-year-old man with a history of OUD reported use of 3 to 10 tablets of Percocet 30 mg daily within 24 h for approximately 5 years. The client reported first use of opiates at age 20. This escalated to daily use in his 40s. The client is currently employed as a full-time firefighter who reports trauma in his experiences as a first responder. The client self-reported significant substance use across multi-generational family members. The client was in an inpatient setting prior to treatment with IHAT for 2 weeks. The client denies history of in-patient SUD treatment; however, he reports an outpatient level of care with a suboxone provider. The client reported he had a total period of 2 weeks of abstinence while undergoing his treatment with the outpatient suboxone provider. The client also reported previous experience with 12 step programs with poor results in the past. The IHAT team assessed for IHWM using the S.T. Genesis device, in which he was accepted. By day 4, the patient reported improved sleeping and feeling better. The client went on to successfully complete the 52-week program, and the patient tested negative for opioids at urine tox screen at discharge of the program.

Client 4

A 39-year-old man was unemployed due to lay-off during COVID-19. Diagnosis at intake was OUD-Severe. At time of

Table 1. Evaluation of clinical opiate withdrawal scores across patients.

	Day 1			Day 2			Day 3			Day 5			Two Day Post		
	COWS	BP	HR	COWS	BP	HR	COWS	BP	HR	COWS	BP	HR	COWS	BP	HR
Patient 1	18	148/94	94	4	143/93	83	4	128/83	96	4	132/87	96	3	152/100	88
Patient 2	19	130/84	110	4	99/54	83	6	105/75	86	1	111/76	80	1	122/74	84
Patient 3	21	146/93	96	4	122/80	100	5	96/69	90	5	110/67	83	1	129/84	78
Patient 4	19	152/101	106	3	154/78	74	1	122/74	78	2	124/82	72	1	154/70	74
Patient 5	20	127/84	75	6	126/71	70	0	112/77	70	1	127/84	63	1	94/67	66
Average	19.4		96.2	4.2		82	3.2		84	2.6		78.8	1.4		78

COWS = clinical opiate withdrawal scores; BP = blood pressure; HR = heart rate.

intake, the client reported illicit drug use of 1 bag of heroin per day and historical use of 10 bags per day. Additionally, he reported treatment for anxiety, hypertension, bilateral knee pain, and OUD. The client reported a knee injury 10 years ago while lifting heavy cases at work that resulted in surgery and need for pain medication. The client reports that chronic knee pain is the catalyst triggering OUD. The client completed a portion of the aware treatment before dropping out at Week 26 due to noncompliance.

Client 5

A 34-year-old woman admitted for OUD-Moderate who reported use of oxycodone and Tylenol with codeine, xanax, and valium. She reported not being able to stop using the opiates. "I would use anything I could get my hands on not to feel pain." The client had multiple traumatic experiences (mental, physical, and sexual), leading to prolonged prison sentence, due to substance use behavior. Patient was diagnosed with General Anxiety Disorder; Major Depressive Disorder, Moderate Recurrent; Obsessive Compulsive Disorder at admission. The IHAT team assessed for IHWM using the S.T. Genesis device, in which she was accepted. Patient reported on Day 1 after the device was attached, "I don't know what voodoo you did but I feel like an entirely new person. I don't have pain and cramps and the sweating has stopped." The patient did successfully complete the 52-week program after utilizing the Speranza unit.

Discussion

The current case series attempted to understand the impact of the Speranza device on withdrawal for individuals suffering from OUD. In all the above cases, the utilizations of the PNFS appeared to reduce COWS over time. All patients total scores were considered moderate (values between 13 and 24) at Day 1. At Day 2, all client's scores were considered mild, and after 2 days, all clients were under the benchmark score for mild (>5). It should be noted that four out of five patients completed the 52-week program treatment, and the significant reduction in their withdrawal provided them an opportunity to fully address their OUD. The current pilot study adds to the current literature on PNFS for detoxification (Ward et al., 2020) and extends the findings by providing an empirically valid and reliable psychometric evaluation across multiple recording time periods.

It should be noted that no patients reported moderate or severe reactions to the use of the Speranza device, which is considered extremely common within detoxification using other approaches (Miranda & Taca, 2018; Roberts et al., 2016). Only one patient reported mild reactions (nausea); however, this was alleviated through an over-the-counter supplement. Moreover, several of the individuals described their withdrawal as easier than previous attempts, allowing the patients to focus on their recovery. In discharge, qualitative interviews highlighted thematic content indicating ease of use, less pain from previous detox, and overall positive reactions. As briefly outlined in the results, patients seem not to understand how a device connected to their ear could help their detox so much. Indications across these five patients were consistent; however, future research needs to complete a more thorough thematic review to determine saturation of material.

This case study evidence indicates that noninvasive device-generated auricular neural stimulation of certain cranial nerves, primarily vagus nerve, provides a cutting-edge approach to alleviate opioid withdrawal symptoms (Koob & Volkow, 2010). This approach may specifically help expedite the recovery phase during acute detoxification from opioids. This alternative approach can ultimately reduce the need of supportive medications and can facilitate smooth transition from detoxification to commencing medication-assisted treatment in opioid dependent patients along with other behavior modalities, such as IHAT. The S.T. Genesis shows significant reduction in COWS, as well as its ability to be appropriate for the majority of patient presenting with a withdrawal management. In summary, the S.T. Genesis is associated with a reduction in opioid withdrawal scores and allows for patients suffering from OUD withdrawal to safely and effectively complete OUD detox without the use of medications. While this noninvasive modality appears to be an exciting new opportunity in alleviating the current opioid epidemic, more studies are clearly needed to further validate the potential of this intervention and support its use with the hope of helping patients and their families.

The current study is not without limitations. First, the current methodology is a retrospective study, and no individuals were prospectively randomly assigned to a study condition. However, the preliminary case study adds to the growing literature using alternative methods for detoxication and can set precedent for future randomized controlled trials. Second, the implications of the current study should be taken in context. The current results do not provide rationale for generalization, given the low sample size. Third, while all individuals individually consented and were medically cleared to use the device, the current device may not be appropriate for all individuals. It is recommended to contact your medical expert before using this device. Fourth, the current study did not assess the impact of the reduction in COWS on motivation for the treatment or depressive and/or anxiety symptoms. Future research needs to assess if there is a positive relationship between these covariates.

Conclusion

In summary, the case series demonstrates impressive clinical and functional findings for five individuals who were treated with the Speranza device to facilitate reducing withdrawal symptoms during detoxification. As stated, the findings provide a precursor to larger ended research studies evaluating the impact of such devices for patients with OUD, along with another approach to treat individuals with when going through detoxification.

Acknowledgments

We would like to thank Tracie Samuelson for her assistance throughout this project.

Disclosure statement

There are no relevant financial or non-financial competing interests to report across any of the authors.

ORCID

Frank D. Buono http://orcid.org/0000-0003-1324-7857

References

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA.

Bart, G. (2012). Maintenance medication for opiate addiction: The foundation of recovery. *Journal of Addictive Diseases*, *31*(3), 207–225. https://doi.org/10.1080/10550887.2012.694598

Deer, T. R., Esposito, M. F., McRoberts, W. P., Grider, J. S., Sayed, D., Verrills, P., Lamer, T. J., Hunter, C. W., Slavin, K. V., Shah, J. M., Hagedorn, J. M., Simopoulos, T., Gonzalez, D. A., Amirdelfan, K., Jain, S., Yang, A., Aiyer, R., Antony, A., Azeem, N., Levy, R. M., & Mekhail, N. (2020). A systematic literature review of peripheral nerve stimulation therapies for the treatment of pain. *Pain Medicine*, *21*(8), 1590–1603. https://doi.org/10.1093/pm/pnaa030

Gilmore, C. A., Patel, J., Esebua, L. G., & Burchell, M. (2020). A review of peripheral nerve stimulation techniques targeting the medial branches of the lumbar dorsal rami in the treatment of chronic low back pain. *Pain Medicine*, *21*(Suppl 1), S41–S46. https://doi.org/10.1093/pm/pnaa084

Kennedy, A. J., Wessel, C. B., Levine, R., Downer, K., Raymond, M., Osakue, D., … Liebschutz, J. M. (2021). Factors associated with long-term retention in buprenorphine-based addiction treatment programs: A systematic review. *Journal of General Internal Medicine*. Advance online publication. https://doi.org/10.1007/s11606-020-06448-z

Koob, G. F., & Volkow, N. D. (2010). Neurocircuitry of addiction. *Neuropsychopharmacology*, *35*(1), 217–238. https://doi.org/10.1038/npp.2009.110

Marsch, L. A. (1998). The efficacy of methadone maintenance interventions in reducing illicit opiate use, HIV risk behavior and criminality: A meta-analysis. *Addiction*, *93*(4), 515–532. https://doi.org/10.1046/j.1360-0443.1998.9345157.x

Miranda, A., & Taca, A. (2018). Neuromodulation with percutaneous electrical nerve field stimulation is associated with reduction in signs and symptoms of opioid withdrawal: A multisite, retrospective assessment. *The American Journal of Drug and Alcohol Abuse*, *44*(1), 56–63. https://doi.org/10.1080/00952990.2017.1295459

Roberts, A., Sithole, A., Sedghi, M., Walker, C. A., & Quinn, T. M. (2016). Minimal adverse effects profile following implantation of periauricular percutaneous electrical nerve field stimulators: A retrospective cohort study. *Medical Devices (Auckl)*, *9*, 389–393. https://doi.org/10.2147/MDER.S107426

Ronquest, N. A., Willson, T. M., Montejano, L. B., Nadipelli, V. R., & Wollschlaeger, B. A. (2018). Relationship between buprenorphine adherence and relapse, health care utilization and costs in privately and publicly insured patients with opioid use disorder. *Substance Abuse and Rehabilitation*, *9*, 59–78. https://doi.org/10.2147/SAR.S150253

SAMHSA, S. A. A. M. H. S. A. (2019). *Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health*. https://www.samhsa.gov/data/

Timko, C., Schultz, N. R., Cucciare, M. A., Vittorio, L., & Garrison-Diehn, C. (2016). Retention in medication-assisted treatment for opiate dependence: A systematic review. *Journal of Addictive Diseases*, *35*(1), 22–35. https://doi.org/10.1080/10550887.2016.1100960

Ward, H. B., Mosquera, M. J., Suzuki, J., & Mariano, T. Y. (2020). A systematic review of noninvasive brain stimulation for opioid use disorder. *Neuromodulation: Technology at the Neural Interface*, *23*(3), 301–311. https://doi.org/10.1111/ner.13108

Wesson, D. R., & Ling, W. (2003). The clinical opiate withdrawal scale (COWS). *Journal of Psychoactive Drugs*, *35*(2), 253–259. https://doi.org/10.1080/02791072.2003.10400007