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Recovery Success Through Combined Use of Vivitrol and Counseling versus Pharmacological
Treatment Alone in Opiate-Addicted Patients

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Abstract

The growing incidence of opiate addiction in the United States has been declared a public health emergency (Hargan, 2017). Vivitrol, a monthly injectable extended-release naltrexone, helps to block the cravings of opiates so patients can focus on changing their behavior and lifestyle.

Counseling has been suggested as an effective adjunctive therapy when used concurrently with Vivitrol. This study is a retrospective chart review and aims to compare the outcomes between two groups of patients; one that receives the monthly Vivitrol injection plus attend regular counseling and one group, equal in size, that receives Vivitrol alone.

Keywords: Vivitrol, opiate-addiction, recovery success, counseling, self-efficacy, research

Recovery Success Through Combined Use of Vivitrol and Counseling versus Pharmacological Treatment Alone in Opiate-Addicted Patients

The growing incidence of opiate addiction in the United States has been declared a public health emergency (Hargan, 2017). Opiate addicts come from every socioeconomic class and walk of life. This project seeks to compare the outcomes in recovery success for persons receiving naltrexone as a medication assisted treatment (MAT) and persons receiving both naltrexone and counseling concurrently.

Background

Drug and alcohol abuse are a growing concern worldwide and have many negative consequences on the health and well-being of those affected (Bashirian, Hidarnia, Allahverdipour, & Hajuzadeh, 2012). Tennessee ranks higher than the national average for opioid-overdose deaths at 19.3 per 100,000 persons compared to 14.6 per 100,000 persons, according to 2017 data (National Institute on Drug Abuse, 2019). Tennessee ranked third nationally for highest number of opioid prescriptions, with 94.4 prescriptions for every 100 persons. The Tennessee Department of Health requires that all Neonatal Abstinence Syndrome (NAS) cases be reported within 30 days of birth and in 2017 there were over 1,000 cases, representing 1.35% of all live births. Of the NAS cases reported, nearly 1 in 3 were as a result of diverted opioid medications (National Institute on Drug Abuse, 2019). Addiction is defined as, “an inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response” (ASAM, 2011). The problem of addiction has been studied by numerous investigators in efforts to determine factors contributing to recovery success.

Problem Statement

Opioid dependence has been linked with increased rates of morbidity and mortality, increased healthcare costs, and psychological suffering for the addict and their family. Substances used in opioid dependence can be illicit, like heroin, or illicitly acquired or misused prescription medications, such as morphine, hydrocodone, oxycodone, and buprenorphine (Kjome & Moeller, 2011). The Food and Drug Administration (FDA) approved extended-release naltrexone (Vivitrol) for treatment of alcohol dependence in 2006 and to prevent opioid relapse in 2010. Vivitrol is an intramuscular injectable opioid antagonist released over 28 days used to block the cravings of opiates (Alanis-Hirsch, et al., 2015). The FDA approval of this medication allowed providers to have an alternative treatment to agonist therapy, such as methadone and buprenorphine, which carry the risk of diversion and abuse. Naltrexone does not cause the development of dependence or tolerance over time, and dosing cessation does not result in withdrawal (Kjome & Moeller, 2011).

It has been advised to combine medications with counseling for better recovery success outcomes but there is limited data available in the literature of studies on Vivitrol and counseling. Many of the studies focus on the effects of Buprenorphine as the primary medication assisted treatment (MAT). In a systematic review by Dugosh et al. of the current treatment options available for addiction, a significant gap was noted and a suggested a need for future research. Due to the enormity of the nation's current opioid epidemic, it is critical that health care providers learn the most effective ways to treat addiction (Dugosh, et al., 2016). This study aims to determine if psychosocial interventions are an essential part of addiction treatment, when combined with the medication Vivitrol.

Clinical Question

Opioid abuse can be a lifelong battle that requires substantial resources and therapeutic efforts by the patient, families, and health care providers (Taylor, Raffa, & Pergolizzi, 2011). The purpose of this project is to compare outcomes between recovery success variables for persons receiving Vivitrol and persons receiving Vivitrol and counseling concurrently. The population of interest in this project is patients suffering from opiate addiction. The interventions being compared are Vivitrol alone versus Vivitrol plus counseling. Counseling will be defined as a monthly counseling session (either group or individual therapy) by a licensed addiction counselor or social worker. The goal of this project is to determine if combined therapy of Vivitrol and counseling is superior to Vivitrol alone in this sample population. This comparison study will determine if there is evidence of a greater likelihood of recovery success within the sample population that can support the efficacy of Vivitrol alone or Vivitrol in addition to counseling.

Significance

The rate of both illicit and prescription drug abuse has steadily risen throughout the United States. Meanwhile, the efforts by health care providers to offer better treatments for pain have consequently caused a rise in misuse, abuse, addiction, and diversion of many prescription opioids (Taylor, Raffa, & Pergolizzi, 2011). Some have even called the current epidemic the worst in the history of the United States, with an estimated 92 million American adults reporting the abuse or misuse of prescription opioids in 2015. From a financial standpoint, it has been estimated that the opioid epidemic costs the United States approximately \$78 billion annually (Stuart, et al., 2018). According to the World Health Organization (WHO), investing in evidence-based treatment for substance abuse decreases negative health outcomes and social

effects such as crime, economic burden, and Hepatitis C and HIV infections. For every dollar spent on addiction treatment, seven dollars are return in cost-savings (World Health Organization, 2019).

Opioid addiction is difficult to treat because it is a chronic, relapsing condition that requires substantial effort in treatment plan development using a collaborative approach for best success (Stuart, et al., 2018). Evaluating the recovery success for these treatments will assist in building evidence-based recommendations in the treatment of persons with opiate addiction. This project will add to the existing body of nursing knowledge in opiate-addiction treatment.

Review of Literature

Vivitrol Success

In a 24-week randomized controlled trial comparing Vivitrol to placebo in individuals with current opioid dependence, subjects completed a 30-day detoxification and received either the 380mg Vivitrol injection or placebo injection every 4 weeks. Data was collected based on urine drug screens and self-report of relapse and craving control. Opioid-free weeks were significantly different between treatment groups with a median of 90% of opioid-free urine screens in the Vivitrol group and only 35% in the placebo group. Subjects in the Vivitrol group reported a 50% mean reduction in subjective craving compared with no change in craving for subjects receiving placebo. Retention rates in the 24-week program were significantly longer in the subjects receiving Vivitrol compared to the placebo group (Kjome & Moeller, 2011).

Combination of Drug and Psychosocial Support

Dunn et al. (2013) examined psychosocial interventions delivered in conjunction with Vivitrol to treat opiate addiction. Subjects were divided into two groups: individuals receiving therapeutic counseling in addition to Vivitrol and individuals receiving therapeutic counseling

alone. Findings indicated that the participants receiving both counseling and Vivitrol as opposed to counseling alone had a higher percentage of subjects who completed the entire 6 months of injectable naltrexone. However, there were no differences in relapse into opiate use, verified by urine drug screens, between the two groups (Dugosh, et al., 2016).

Another study evaluated the subjects receiving psychosocial plus maintenance pharmacological treatment (Vivitrol) and standard maintenance treatment alone. Neither group reported any difference in depression or psychiatric symptoms, but the subjects in the combined Vivitrol and therapy group showed a higher rate of abstinence at the end of the program. In addition, the combined medication plus therapy was shown to be more likely to produce positive effects in retention of maintaining abstinence (Taylor, Raffa, & Pergolizzi, 2011).

Theoretical Framework.

The theoretical model that guides this project is the Transtheoretical Model of Behavioral Change. This model describes how long-term behavior changes such as remaining abstinent, surrounding oneself with positive influences, and leading a productive lifestyle, involve multiple actions and adaptations over time. The stages of change include precontemplation (no recognition of need for change), contemplation (thinking about change), preparation (planning for change), action (adopting new habits), and maintenance (ongoing practice of new behavior or healthier lifestyle) (Butts & Rich, 2018).

This model helps explain how co-morbid conditions can affect an individual's thought processes. Individuals with comorbid conditions, such as mental or substance-abuse disorders, rely on different processes as they learn new behaviors and may need different interventions than those without a mental health or substance-abuse problem (Butts & Rich, 2018). Patients suffering from addiction, especially, may not always move through stages in a linear pattern and

often repeat certain stages. For example, one can admit they have a problem with addiction and desire to change. They may change their phone number, move out of the environment they were living in, and remain abstinent for several months. Depending on their personal level of motivation and self-efficacy, it is easy for them to relapse and return to the earlier stages of change. Awareness of this model will inform and guide the investigators in data analysis.

Project Design

This project is a descriptive design utilizing a retrospective chart review comparing recovery success for persons receiving Vivitrol plus counseling versus Vivitrol alone.

Inclusion and Exclusion Factors

Inclusion criteria for this study include patient's aged 18 and older, current opiate addiction, and consent to treat and receive Vivitrol injection. Exclusion criteria for this study include patients under the age of 18, a reported allergy to the Vivitrol injection, or refusal of consent to treat and receive the injection.

Operational Definitions

Successful recovery is defined as maintaining abstinence through report of appropriate urine drug screen and patient's self-report of denial of opiate relapse. Relapse is defined as an inappropriate or failed urine drug screen or patient's self-report of opiate-relapse. Counseling is recommended on a monthly basis, but not required. Those patients who attend counseling are compared to those that choose not to attend.

Setting

Westbrook Medical Center is a family medicine office located in a mid-size city in the Appalachian region of the Southeastern United States. The office offers primary care and addiction treatment to patients of all ages. They have a successful Vivitrol program that is

recommended to last 12-18 months and is designed to incorporate both the monthly injection and counseling sessions with the onsite counselor.

Method

This comparison study was conducted through a retrospective chart review of the patients at Westbrook Medical Center.

Data Collection

Data collection occurred over three months: May 15, 2019 to July 15, 2019. The total time abstinent for each patient varied since data was collected during a random point in the program, rather than start to finish. Some of the patients may have been in their first month of abstinence with only one Vivitrol injection thus far and some may have been 9-10 months free of opiate relapse. The following variables were abstracted from the patient's medical record: gender, age, insurance type (socioeconomic status), current opiate-addiction, number of months receiving Vivitrol, number of months abstinent of opiates, attendance of counseling, urine drug screen results, and patient self-report of cravings. Westbrook uses an electronic medical record and all charts are password protected, ensuring secured data storage. The data was collected on a Microsoft Excel spreadsheet without patient identifiers. The study is considered IRB exempt category 4 since it is conducted with existing data, documents, records, pathological specimens, and/or diagnostic specimens, and the information is recorded by the investigator so that the subjects cannot be identified.

Counseling Attendance

Counseling has been suggested as a critical intervention as adjunctive therapy with Vivitrol. Because counseling is recommended but not required in Westbrook's program, it is an ideal location for a retrospective chart review to compare the group of patients that attend

counseling on a regular basis with the patients that do not attend counseling. The attendance of counseling is documented in every patient's chart at each visit. This study aims to evaluate if counseling makes a difference in the outcome of recovery success.

Sample Size

The sample size was determined by matching the selected number of persons receiving Vivitrol and counseling to those receiving Vivitrol alone. During the planning and data collection period, it was decided that 25 patients in each group be evaluated, with a total of 50 patient charts for this project.

Results

Analysis

The data was entered into a Microsoft Excel spreadsheet for analysis. The spreadsheets are secured by the investigator on a password-protected laptop to which only the investigator has access. All data collected will be deleted from the laptop in December 2019 upon completion of this project and this program.

Statistician Consult

A statistician was consulted to conduct the appropriate statistical tests to determine the difference between the two groups in the sample. Dr. Eric Heidel, a University of Tennessee statistician, conducted these tests and corresponded via email. The statistical test tables can be found at the end of this paper.

Statistical Findings

In the sample of 50 patient-charts reviewed, there were 25 subjects in the Vivitrol plus counseling group and 25 subjects in the Vivitrol alone group. There were 11 male and 39 female subjects overall. The Vivitrol alone group had 9 male and 16 female and the Vivitrol plus

counseling group had 2 male and 23 female subjects. 86% of these patients had either government insurance or were non-insured. The remaining 14% had commercial insurance. Statistical tests were computed based on the variables mentioned previously, such as age, number of months receiving Vivitrol, and number of months abstinent of opiates.

As presented in the Appendix, these variables are used to compare the difference between the two groups in Table 1. In the Vivitrol alone group, the mean age was 33, mean number of months receiving Vivitrol was 5.2, and mean number of months abstinent of opiates was 6.2. In the Vivitrol plus counseling group, the mean age was 34, mean number of months receiving Vivitrol was 9.2 and mean number of months abstinent of opiates was 10.1. There is a significant difference between the groups for number of months receiving Vivitrol and remaining abstinent of opiates. This indicates a greater likelihood of remaining abstinent of opiates the longer a patient is receiving the Vivitrol injection.

Table 2, also located in the Appendix, presents the frequency and percentage statistics for Chi-Square. Gender, insurance, self-reported cravings, and UDS results were compared between the Vivitrol only and Vivitrol plus counseling groups in the sample size. There is a significant difference in positive drug screens between the two groups. Those receiving both Vivitrol and counseling had 21 subjects with negative (clean) UDS and 4 positive (failed) UDS. They were 85.8% less likely to have a positive (failed) drug screen than the Vivitrol alone group that had 14 negative (clean) and 11 positive (failed) screens. There was also a significant difference between the treatment groups for gender. Women had 6.47 times higher odds of having both Vivitrol and counseling, representing 92% of that group. There was a non-significant difference between the groups for insurance type or self-report of cravings.

Discussion

Summary of Findings

The goal for the study was to discover if combined therapy of Vivitrol plus counseling is superior to Vivitrol alone in recovery success. The hypothesis was that combined therapy would prove to be superior to medication therapy alone. This hypothesis was tested during this project. It has been advised to combine MAT with counseling for better recovery success outcomes but there is limited data available in the literature of studies on Vivitrol and counseling. After reviewing the findings of the statistical methods used, it is well supported by these results that Vivitrol combined with counseling is far better than pharmacological treatment alone. In this sample population, the patients with combined Vivitrol and counseling were 85.8% less likely to have a positive urine drug screen. This means that these patients remained abstinent while on the combined therapy. In contrast, the patients who received Vivitrol alone without counseling were only about 15% likely to have a negative (clean) urine drug screen.

Implications for Future Nursing Practice

It is also noted in the findings that women were about 6 times more likely to choose the Vivitrol plus counseling option. This means that out of the selected sample size, men were about 6 times less likely to attend counseling while receiving Vivitrol. That is a very relevant finding. Differences in gender pertaining to addiction treatment was not one of the original research questions but could absolutely be a topic for future nursing research.

Contrary to the findings in this study from a selected sample size, recent studies have indicated that men have actually been shown to be more likely to seek therapy than women (Becker, McClellan, & Reed, 2017). Due to the stigma associated with mental health issues in society, therapy can be a shameful experience to patients suffering from addiction. Individuals

dealing with issues in need of therapy may feel that they will be viewed as weak, flawed, or unable to handle everyday stressors if they seek help. Women are more shame prone than men due to social norms and are therefore less likely to seek psychosocial help (Miller-Prieve, 2016). Additionally, men experience less stigma than women pertaining to seeking help for addiction. When combined with less social support, that means an increased likelihood of isolation and greater risk of relapse for women than men (Becker, McClellan, & Reed, 2017).

This study can be added to the existent body of nursing knowledge as evidence that combined therapy is significantly more effective in maintaining recovery success. During the literature review, many studies also indicated a greater likelihood of recovery success through combined use of MAT and psychosocial intervention, but few studies have been published on Vivitrol combined with counseling (Dugosh, et al., 2016). This study will aid in education for patients on the reason behind the recommendation to attend counseling and receive their monthly Vivitrol injection.

Strengths and Limitations of the Study

One of the strengths of this project is the ability to collect data from existing patients from Westbrook Medical Center. There are enough patients in the sample size to have equal groups of patients receiving Vivitrol plus counseling as well as those receiving Vivitrol alone. As mentioned earlier, the study was performed at a random point in the program with patient's total time receiving Vivitrol, counseling, and/or remaining abstinent varying and no prompting was given prior to the data collection. The retrospective review format of this project improves the strength and accuracy of the study.

A weakness noted only after reviewing the results of the study would be the limited number of clinical questions for this project. If more questions were asked prior to data

collection and analysis, the results could have presented a broader picture of addiction treatment instead of only focusing on treatment method. Questions that could have been asked include: Does gender play a role in counseling attendance? Does age or socioeconomic status play a role in the notion of readiness to change and compliance in the Vivitrol program? Since counseling was recommended but not required in Westbrook's program, does this indicate an increased level of motivation or self-efficacy in those individuals who chose to attend regular counseling sessions? These questions would have greatly extended the amount of research needed to complete the project but would have added to the impact.

Conclusion

The purpose of this project was to evaluate if Vivitrol combined with counseling was superior to Vivitrol alone in recovery success. The study was completed using a retrospective chart review at a clinic with an existing patient base who were attending monthly appointments. As a result of the significant findings in this project, research clearly supports that Vivitrol and counseling combined is far more likely to achieve recovery success as opposed to the medication alone. Knowledge of this information should serve as a call to action to providers on the importance of combination therapy for addiction treatment in their patients.

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Appendix

Table 1.

Descriptive Statistics for Independent Samples t-tests

| Variable | Vivitrol only | Vivitrol and Counseling | <i>p</i> -value |
|--------------------------------------|---------------|-------------------------|-----------------|
| Age | 33.8 (9.3) | 34.4 (8.5) | 0.80 |
| Number of months receiving Vivitrol | 5.2 (6.6) | 9.2 (7.1) | 0.045 |
| Number of months abstinent of opiate | 6.2 (8.4) | 10.1 (7.7) | 0.09 |

Note: Values are mean (standard deviation)

Table 2.

Frequency and Percentage Statistics for Chi-square

| Outcome | Level | Vivitrol | Vivitrol and Counseling | <i>p</i> -value |
|------------------------|----------|------------|-------------------------|-----------------|
| Gender | Male | 9 (36.0%) | 2 (8.0%) | 0.017 |
| | Female | 16 (64.0%) | 23 (92.0%) | |
| Insurance | BCBS | 3 (12.0%) | 4 (16.0%) | 0.20 |
| | Medicaid | 19 (76.0%) | 21 (84.0%) | |
| | None | 3 (12.0%) | 0 (0.0%) | |
| Self-reported cravings | No | 20 (80.0%) | 22 (88.0%) | 0.44 |
| | Yes | 5 (20.0%) | 3 (12.0%) | |
| UDS results | Negative | 14 (56.0%) | 21 (84.0%) | 0.03 |
| | Positive | 11 (44.0%) | 4 (16.0%) | |

Note: Values are Frequency (percentage)