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(REVIEW ARTICLE)

The Sinclair method: The need for integrated and holistic approaches in alcohol treatment and recovery

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Abstract

The world's consumption of alcohol per capita in 2016 among male and female drinkers worldwide was on average 19.4 litres of pure alcohol for males and 7.0 litres for females, and three million deaths worldwide are attributable to alcohol each year. The pathology of alcoholism and addiction has been a source of medical and psychological interest for nearly two centuries. This article provides a summary of genetic and neurobiological research, along with a comparison of a variety of treatment methods employed including the 12-step abstinence program, holistic approaches, and modern advances of pharmacotherapy interventions, such as the Sinclair Method.

Keywords: Alcohol Addiction; Alcohol Treatment; Alcohol Use Disorder; Alcoholism; Sinclair Method; Naltrexone

1. Introduction

Global consumption of alcohol per capita in 2016 was on average 19.4 litres for males and 7.0 litres for females, contributing to three million deaths annually [1][3]. In the UK, the annual consumption rate is over 10 litres [2]. Considered a social and physical "global burden", alcohol consumption is related to multiple diseases, suicides, vehicle deaths, disability, and psychological disorders like depression and stress [4] [5].

1.1. History of the disease and treatment

The pathology of alcoholism has been a source of interest even before Norman Kerr, founder of Society for the Study of Inebriates in 1884, declared drunkenness was a disease, "a natural product of a depraved, debilities or defective nervous organization." It was not until 1909 when Oscar Jennings wrote "The Re-education of Self Control in the Treatment of the Morphia Habit" that addicts were viewed as sick individuals rather than willing victims [2].

Shortly after the United States ended prohibition in 1933, two men from Ohio founded Alcoholics Anonymous (AA), a 12-step program of character development for individuals to 'admit powerlessness over their addiction and commit to sobriety.' Abstention was considered the only effective method of treatment. Twenty years later, the Minnesota Model of inpatient addiction treatment by the Hazelden Foundation, asserted that alcoholism was a disease and should be treated as a primary disorder rather than a symptom [6]. During this same time, British physicians delineated Alcohol Dependence Syndrome as a disease distinct from other forms of drinking, through seven elements including behaviour, biology, and cravings [2]. However, with abstention came symptoms of seizures and delirium. In 1960, Jellinek, an American biostatistician and physiologist, wrote "The Disease Concept of Alcoholism", explaining withdrawal symptoms based on the modern disease concept of alcoholism. It was this model that emphasized the need for medical treatment as with other illnesses [7].

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Since the founding of AA, the 12-Step approach has been seen as the gold standard treatment for Alcohol Use Disorder (AUD). Due to the nature of AA being "anonymous", there is little reliable statistical data. Various reports from non-clinical membership surveys performed by AA, addiction specialists claim sobriety success rates from 8% to 24% at 1-5 years [8][9].

In addition to attempts at social temperance and support treatment options, the medical models of treatment for AUD have included pharmacological and behavioural treatment options. Even governmental policies have been created to reduce the purchase of alcohol, including taxation and regulation of publicity [10].

1.2. The holistic approach

The holistic approach is derived from the philosophy of humanism and mutual understanding of a patient's physical, emotional, psychological, and spiritual dimensions. It entails a close relationship between patient and provider to ensure the whole person is considered in their individualized treatment plan [11]. Florence Nightingale, considered the 'Mother of Nursing', wrote about the human potential and connection of body, mind, and spirit of the sick, stressing how a well-managed environment is key to treatment. [12]. Today, there is exists several hybrid methods of addiction treatment that also integrate creative therapy, spiritual and cultural awareness, and physical exercise [13].

1.3. Genetic and neurobiological research

Since the era of Jellinek's studies, there has been much research into a genetic predisposition for alcoholism. Several genetic factors and variants have been identified that suggest a risk for addiction traits. Nonetheless, alcohol dependence is considered a complex disease where inheritance is only one part of the aetiology, and both environmental and social factors seem to weigh on the outcome [14].

Genes *ADH1B* and *ALDH2* have been found to affect the methods of alcohol metabolism and show the largest risk for dependency. Catalysed primarily by ADH, ethanol metabolism begins with oxidation to acetaldehyde and once accumulated, the results are dizziness, nausea, and tachycardia. Individuals that carry a single copy of the ALDH2*504K gene have this reaction to the extreme with small amounts of alcohol, acting as a deterrent to drink excessively [14].

Continued studies on the genetics of alcohol dependence link low central serotonin turnover rates as markers of early-onset disease, with neurobiological alterations. Neurobiological research leans toward the stimulation of inhibitory GABAergic neurotransmission, the cause of seizures and autonomic dysregulation displayed during abstinence. Alcohol craving has been explained by the dopaminergic reward system and opioidergic stimulation due to positively-reinforcing effects of consumption. This can lead to 'addiction memory', when the stimulus-dependent dopamine release develops stronger responses upon re-exposure after a period of abstinence [7].

1.4. Modern advances with pharmacotherapy

Considering AUD as a disease and not only a behavioural issue, researchers have examined enhanced treatment with pharmacological interventions. Six medications have received approval for preventing relapse or reducing consumption: disulfiram (inhibitor of acetaldehyde dehydrogenase), naltrexone and nalmefene (opioid receptor antagonists), acamprosate (presumed modulation of the glutamatergic system), gamma-hydroxybutyrate (modulation of GABA and GHB receptors), and baclofen (GABA-B receptor agonist). Their effects are categorized as small to medium [15].

Volpicelli and O'Malley determined that naltrexone, an opioid antagonist that had demonstrated safety and tolerability in previous studies, reduced consumption and relapse. Naltrexone received US FDA approval in 1994 to treat alcohol use disorder (AUD). Additional studies performed in the UK, USA, Sweden, Finland, and Australia indicated similar positive results, and in 1996 WHO concluded that Naltrexone was a 'safe and effective treatment for alcohol dependence.' [16-18].

Naltrexone works to block endogenous opioids, released through alcohol consumption. When taken just prior to drinking, the antagonist prevents alcohol from producing its effects like euphoria and conviviality, reducing and eventually eliminating the craving (see Figure 1). The Sinclair Method, as proposed by John David Sinclair in 2001, instructs that Naltrexone be given while the subject is drinking alcohol to impede these effects, so the body does not relate alcohol to pleasure. The method, considered 'pharmacological extinction', has shown to be effective in allowing the patient regain control over their consumption.[19] [20]. Recommended treatment with naltrexone varies from weeks to months depending on the patient and involves ongoing medical management and concomitant supportive counselling [21].

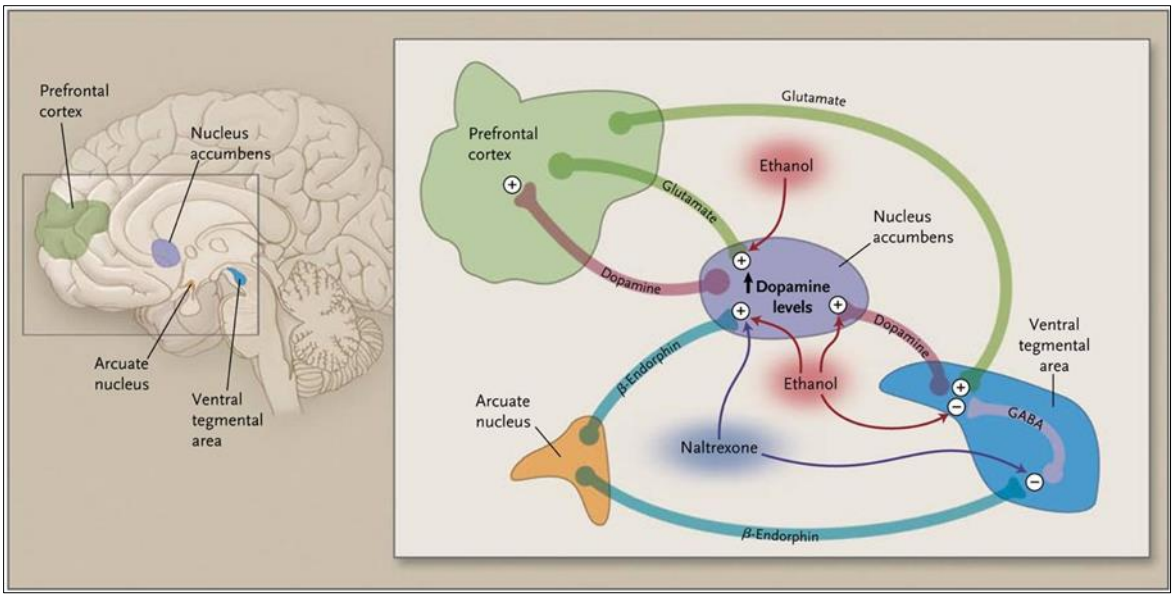

Figure 1 Neurochemical circuits involved in alcohol dependence and craving

When an alcohol-dependent person consumes alcohol, dopamine is elevated in the nucleus accumbens. One mechanism of this elevation is the release of β-endorphin, which stimulates dopamine release either directly (in the nucleus accumbens) or indirectly (in the ventral tegmental area) by inhibiting the activity of γ-aminobutyric acid (GABA) neurons, thereby alleviating the blockade on dopamine cells. Naltrexone reverses both of these actions. [21].

The Sinclair Method approach begins with the first seven to ten days acclimatising the patient to medication and side effects. Along with coaching and cognitive behavioural therapy (CBT) techniques, the aim is to help the individual change their relationship with alcohol.

In the case of contraindication, other pharmaceutical options include acamprosate, a structural analogue of gamma-aminobutyric acid (GABA) as a first-line treatment. Other lesser used drugs include disulfiram, baclofen and topiramate [22] [23].

1.5. Patient experiences

Individuals that have used naltrexone have reported positive benefits, despite difficulty in getting prescriptions. One patient, also a doctor, explained that, while aware he was an ideal candidate according to guidelines, he went to several providers over the course of a few years, but none would prescribe. He described his illness as "a dirty secret."

I was full of self-loathing. Why could I not control this 'monster'. How come I was so self-disciplined in all other aspects of my life? I ran 3 miles every morning, hit the gym a few times a week, ate healthy, yet I needed the reward of alcohol at the end of the day.

Finally, after several years of battling with doctors, he found an addiction psychiatrist to prescribe naltrexone, and his results were immediate.

The effect was instant, and I struggled to even be able to drink a glass of wine, and frequently tipped the second glass down the sink and had a cup of tea…. I can still drink if I choose, but I will only drink with protection of a pill.

Additionally, another patient expressed their benefits of treatment:

Over the last 3 years to say that my life has changed doesn't really do it justice for what has actually happened. I believe I might have drunk roughly 12/13 times since August 2020, NEVER having the desire to overdo it and NEVER needing a drink the following day! These days If I decide to have a drink something strange happens, my brain suddenly out of nowhere goes "that's enough alcohol for me."

The results of naltrexone treatment can vary and depend upon the individual's desire to reduce consumption, social habits, and other variables, including collaboration with behavioural or psychosocial programs. Figure 2. shows data from five patients during their treatment with naltrexone. While 3 of the 5 patients, A, B and E, achieved null consumption by an average of 25.7 weeks, patients C and D achieved null consumption at an average of 82 weeks or 19 months.

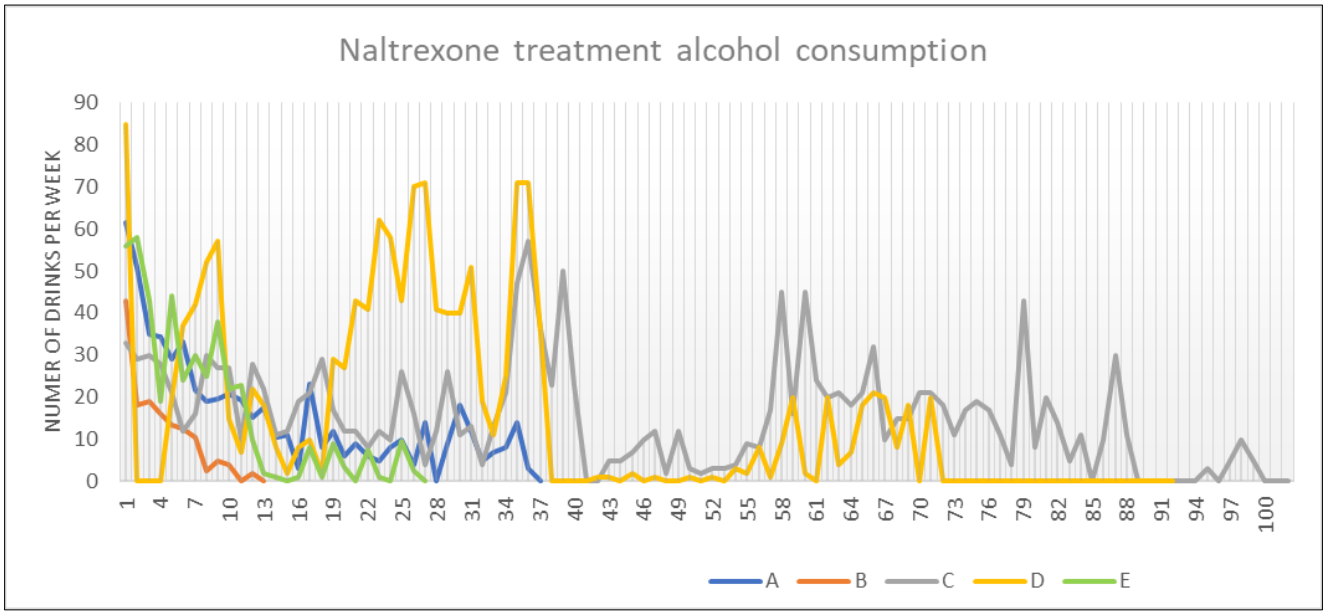

Figure 2 Alcohol consumption during naltrexone treatment

Data provided by The Sinclair Method UK.

1.6. COMBINE Treatment

From 2001 to 2004, after a previously inconclusive US governmental study, independent research was conducted at eleven US academic sites. The Combined Pharmacotherapies and Behavioural Interventions (COMBINE) study placed 1383 volunteers in nine groups during a randomized controlled study to compare outcomes based on treatment with naltrexone, acamprosate, both, or placebo and with or without combined behavioural intervention (CBI) and CBI alone. Whilst there was not a great significance between the highest four groups, the treatment with naltrexone, or the combination of naltrexone and acamprosate, along with medical management, had the highest outcomes of days abstinent over a year. In the one year follow up period the global clinical outcome, participants treated with naltrexone, with and without CBI, had a lower percentage incidence of return to heavy drinking (78.7 and 78.6 respectively) than the higher rates of placebo with no CBI (84.3) or CBI only (86.6) [24] [25]

1.7. Coordinated treatment with positive psychology

Previously, clinical psychology was more focused on researching the disease model, finding treatment for what was wrong with the patient so as to achieve an "absence of disease." In recent years, there have been changes in the study of illnesses, not just the complexity of human development, but also to understand the change processes between the mind and its surroundings, enabling an understanding of potential positive outcomes [26] [27]. This is an advancement beyond the pathology aspect and towards how to achieve overall positive well-being and optimal functioning [28].

The field of positive psychology focuses on the science of positive emotion and character strengths. Positive intervention exercises are designed to promote self-awareness, optimism and mindfulness, enabling the patient to be more aware and have better decision-making skills [29].

Unfortunately, medication non-compliance rates for individuals with serious chronic illnesses are about 50% [30]. A systematic review related to medication compliance concluded that *positive affect*, subjective feelings of pleasurable environmental engagement, improves medication adherence for those with chronic illnesses [31][32]. Thus, a positive state of mind and perceived happiness helps an individual to *want to feel better* and comply with taking medication.

2. Discussion

There is significant evidence that the Sinclair Method has notable benefits for use in AUD and should be considered a viable option for many patients that seek recovery, in contrast to lagging success rates of abstinence-based talk therapy [8]. The discrepancy between success and failure rates of these approaches, and the health risks related to current consumption rates, prompts us to consider whether the concerned stakeholders (e.g. policymakers, payors, providers and patients) should focus better appropriation of education, funding, and regulation for more optimal outcomes.

Whilst there is no shortage of data and testimonials praising this "miracle drug", there is less research regarding those who fail on The Sinclair Method, nor the reasons why. Some psychologists reject the premise of pharmacological extinction and continue to advocate more traditional psychotherapeutic approaches, such as abstinence-oriented Cognitive Behaviour Therapy (CBT). Although many therapists may include an element of CBT, the current discussion seems rather polarised (Pharmacological approach vs Psychotherapeutic approach).

3. Conclusion

We propose a closer examination between these treatment models to shed light on rates of successful outcomes, non-compliance or relapse and the aetiology of causes. Further research may also reveal opportunities to modernise synthesis between approaches. This will broaden our understanding of the benefits and limitations of each approach, indicating that resources could be better appropriated to deliver improved economic and public health outcomes.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors have no conflicts of interest to report.

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