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Dr. Gajulapalli Rajachandra
Associate Professor, Department of Medicine, Father Muller Homoeopathic Medical College, Mangalore, Karnataka, India

Pearly Sharon
Final BHMS Student, Father Muller Homoeopathic Medical College, Mangalore, Karnataka, India

Dr. Deepthi Gilla
Research Officer (H)/Assistant Professor, Department of Psychiatry, National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala, India

Corresponding Author:
Dr. Gajulapalli Rajachandra
Associate Professor, Department of Medicine, Father Muller Homoeopathic Medical College, Mangalore, Karnataka, India

Effectiveness of dynamic homoeopathic preparation of *Nux vomica* in reducing the craving for alcohol in dependent subjects

Dr. Gajulapalli Rajachandra, Pearly Sharon and Dr. Deepthi Gilla

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Abstract
Background: Alcohol is one of the main contributors to diseases world-wide which leads to a potentially preventable death. Alcohol use disorders are the most prevalent of all substance use disorders. Alcohol dependence poses physical, psychological, economic and social issues to the individual, families and community.
Objectives: To assess the effectiveness of *Nux Vomica* 1M in reducing the craving for alcohol in dependent subjects.
Materials and Methods: Cases presenting with Alcohol dependence are assessed with Penn Alcohol Craving Scale (PACS) and Severity of Alcohol Dependence Questionnaire (SADQ) for craving and dependence respectively. *Nux vomica 1M* was given orally twice a day for 8 weeks. The data obtained from the pre and post treatment was statistically analyzed.
Results: Paired sample t test showed that there is a statistically significant difference between the before and after PACS scores (t=9.55, df=29, $p< 0.001$) with a mean difference of 7.77±0.81(95%CI: 6.10to 9.43). The before and after scores of SADQ were significantly different (t=8.94, df=29, $p< 0.001$) with a mean difference of 11.67±1.31 (95%CI: 8.99 to 14.34).
Conclusion: The study corroborates the evidence that *Nux Vomica* 1M is effective in treatment of Alcohol Dependence Syndrome by reducing the craving for Alcohol. Studies with longer duration and rigorous study design are warranted.

Keywords: Alcohol dependence syndrome (ADS), homoeopathy, *Strychnos nux vomica*, Penn alcohol craving scale (PACS), severity of alcohol dependence questionnaire (SADQ)

Introduction
Alcohol dependence is a chronic, relapsing bio-behavioural disease [1]. Alcohol dependence syndrome poses major health, social, and economic problems for both the drinker and the community. Among all psychiatric disorders, alcohol use disorder is commonest affecting adults in the United States and one-third experience alcohol use disorder at some point of time and stands first among all substance use disorders [2].
In India, men (27.3%) statistically dominate compared to women(1.6%) when it comes to alcohol consumption. 14.6% of the Indian population aged between 10 and 75 years uses alcohol [3]. Alcohol misuse furthers both acute and chronic illnesses that leads to potentially preventable death. In the United States, alcohol use is the third leading cause of preventable death [4].
According to ICD-10, Dependence Syndrome (F-10) is a collective phenomenon comprising physiological, behavioural, and cognitive attributes where usage of certain substances is given supremacy by an individual than for other earlier valued behaviours. A strong desire for psycho-active drugs, alcohol or tobacco is a characteristic feature and return to substance after abstaining for a period leads to a swifter reappearance of other symptoms of the syndrome when compared with nondependent individuals [5]. Alcohol abuse and alcohol dependence disorders are specified as alcohol use disorder in DSM-5. It is subclassified as mild, moderate and severe [6].
Though various persevering studies have been done on alcoholism with regard to the nature, cause and pathophysiological mechanisms, individual characteristics such as psychology, biology and genetics coupled with socio-cultural environment provide obscure details currently [7]. Yet, more researches are vital to understand the psycho-neuro-biological and genetics and the factors such as social and environment critical in the contribution to etiology and treatment [8].

The combination of impairment of function in reward circuitry and recruitment of brain stress system circuitry drives a person to consume alcohol. A strong neuro-chemical basis on the background is responsible for this behaviour [9] Neuro-adaptive changes in occasional drinkers to make them dependent are due to the down-regulation of the dopamine and GABA systems, permanent up-regulation in the glutamate system and dysfunctional stress systems of the brain [10].

Withdrawal syndrome ensues when one stops or reduces drinking abruptly. Symptoms include signs of autonomic hyperactivity such as tachycardia, elevated blood pressure, diaphoresis, and tremors; Hyperexcitable CNS may culminate in motor seizures; Hallucinations and delirium tremens [11].

Alcohol dependence manifests along with a variety of psychiatric disorders, particularly disorders that involve substance use and individuals who exhibit violent or aggressive behaviour [12]. Sleep-related complaints are common among alcohol abusers [13].

Current pharmaceutical and behavioral treatments can help patients reduce alcohol consumption or facilitate alcohol abstinence [8]. Conventionally, psycho-social intervention is anchored to the treatment of alcohol dependence. Recommendations on simultaneous pharmacotherapy is insisted along with conventional treatment [14]. Diagnostic evaluation with subsequent personalized treatment work-up based on the severity is needed in routine medical practice [10]. Patients are to be motivated to give up alcohol altogether or atleast convince them to agree on a reduction in consumption as a treatment goal. 85% of patients will relapse when no treatment succeeds after initial detoxification [15].

Few studies have shown effectiveness of individualized homoeopathic remedies when treating alcohol dependence syndrome [16]. But the selection of the right homoeopathic similimum is a tedious process and requires access to skilled homoeopathic physician. A specific medicine, if found effective can be useful in large scale.

Nux Vomica is great Anti-Alcoholic Remedy. It is a remedy to be given while the patient is still under the influence of any of the stages of alcoholism [17]. In the book, Homeopathic drug pictures Dr M.L Tyler tells that "Nux Vomica is a great medicine for drunkards." [18] The active principle in Nux Vomica is Strychnine, which acts through the blockage of glycine and acetylcholine receptors. [19] *Nux Vomica* was useful in 25% of patients of a randomized controlled trial where both Homoeopathic and Standard Allopathic treatment was conducted by Central Council for Research in Homoeopathy [16]. Therefore, this study is taken up to study the effectiveness of *Strychnos nux vomica* in reducing craving for alcohol.

Materials and Methods

A prospective, clinical observational study was conducted on 30 subjects who were alcohol dependent. The patients who reported to the Father Muller Homoeopathic Medical College Hospital, Deralakatte, Mangaluru and peripheral centres associated with it between December 2019 and March 2020 were screened with CAGE Questionnaire and referred to Medicine OPD. If the unit physician had prescribed Nux Vomica 1M potency, orally twice daily, Penn Alcohol Craving Scale (PACS), Severity of Alcohol Dependence Questionnaire (SADQ) scales were administered to assess baseline severity of craving for alcohol as well as severity of dependence. Cases that qualified the selection criteria viz. ages 18-60 were asked to give written informed consent and willing patients were enrolled for the study. ADS Subjects with systemic illness or other chronic disease and subjects with history of severe withdrawal symptoms were excluded from the study. The investigational agent i.e *Nux vomica 1M* was procured from Father Muller Homoeopathic Pharmaceutical Division, Mangaluru (GMP certified), which was prepared as per the Homoeopathic Pharmacopoeia of India. The intervention period was 2 months. The SADQ and PACS scales of each subject were assessed on the first visit and on every follow up.

Results

Demographic data: most of the subjects (58%) in the current study are in the age group 18-20 years. The age-wise distribution of cases has been presented in Figure no.1. The gender-wise distribution of the cases is represented in figure no.2

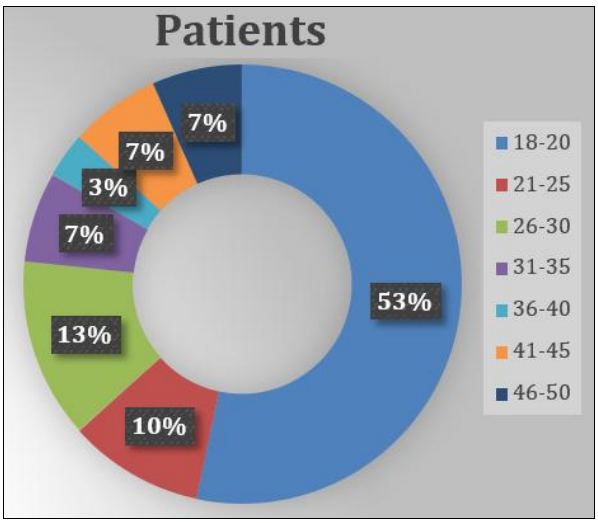

Fig 1: Distribution of Patients according to age

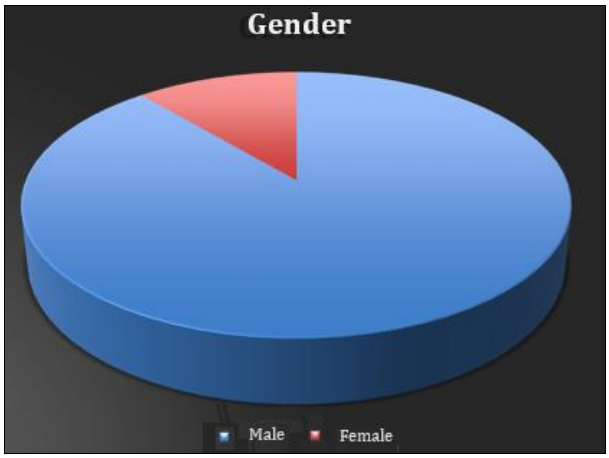

Fig 2: Distribution of Patients according to sex

The quantitative data obtained from the pre and post treatment was statistically analyzed using Paired sample t test. Paired sample t test showed that there is a statistically significant difference between the before and after PACS ($t=9.55$, $df=29$, $p< 0.001$) scores with a mean difference of 7.77±0.81 (95%CI: 6.10to 9.43). The before and after scores

of SADQ were significantly different (t=8.94, df=29, $p<$ 0.001) with a mean difference of 11.67±1.31 (95%CI: 8.99 to 14.34). The changes in PACS and SADQ are shown in Figure 3 and Figure 4 respectively.

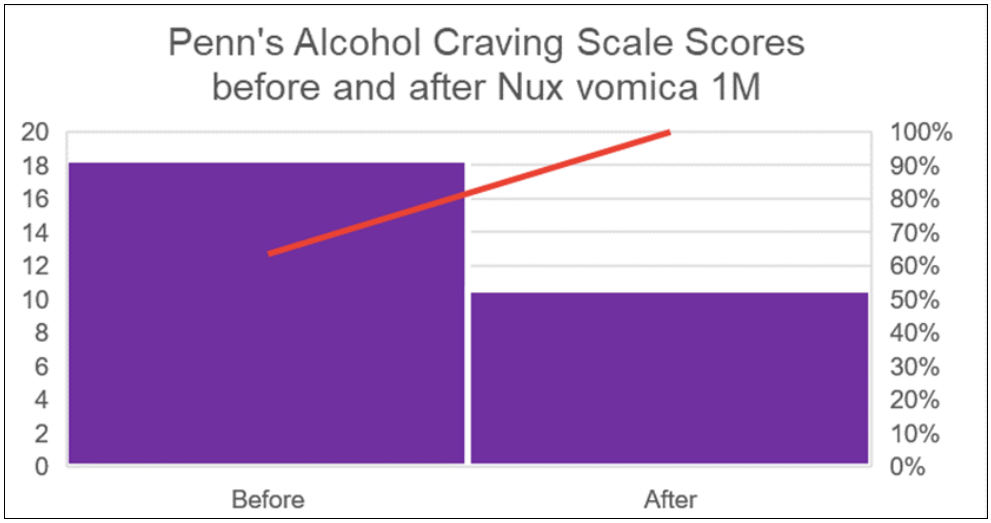

Fig 3: PACS scores before and after treatment

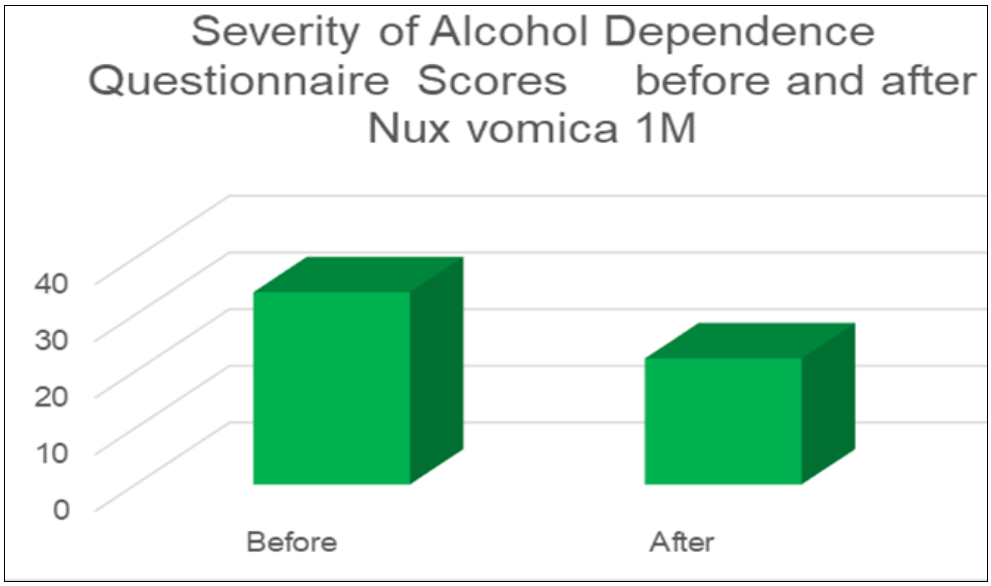

Fig 4: SADQ scores before and after treatment

Discussion

According to the 2009 NSDUH, 6.9 million youth in which 18.1% were between 12 and 20 years of age were binge drinking and 2.1 million youth where 5.4% were between 12 and 20 years of age were reported of heavy drinking. Youth and young adults of college attendees are observed to have increased alcohol intake rates [21]. The age distribution in the study is in consonance with the available literature. So, measures should be taken to create awareness among high school and college students regarding harmful effects of alcohol.

There was a general improvement along with reduction in craving for alcohol in most of the ADS subjects during the study. There were no drop-outs or lost to follow-up during the study as there is general improvement and also as the study duration was short.

In a randomized comparative trial between Individualized Homoeopathy standard Allopathic Treatment, the mean changes in the SADQ score over 12 months in alcohol dependence patients favoured Homoeopathic treatment than Standard Allopathic care from baseline at the exit of treatment period [16]. The results are in consonance with our study with significant reduction in SADQ scores compared from baseline to post treatment.

Also, another research for treating sleep disorder in alcohol-dependent patients concluded with a favourable outcome by homoeopathy to break the cycle of dependence on alcohol [22].

An observational pilot suggests Homoeopathy as treatment to be thought for acute alcohol withdrawal. *Nux vomica* is one of the medicines indicated in the study [21]. In the current study few patients presented mild withdrawal symptoms like nausea, vomiting, tremors of upper limbs, perspiration etc., which were also well managed with *Nux vomica* itself. This validates the finding that *nux vomica* is a useful remedy in reducing alcohol dependence as well as the withdrawal symptoms.

A pilot Study on effectiveness of Homoeopathic Treatment in the Management of Alcoholism Conducted at Atmtha kendram, Changanacherry, Kottayam District, Kerala concludes Nux Vomica 1M is very effective [23]. The current study corroborates the evidence that Nux Vomica 1M is

very effective in reducing craving for alcohol in ADS patients. There were no adverse events reported during the study, which makes *Nux Vomica* a safe and effective treatment regimen for management of Alcohol dependence. The limitation of the study is lack of control group and short study duration, which must be rectified in future studies.

Conclusion

Dynamic homoeopathic preparation of *Nux Vomica 1M* is effective in the management of Alcohol Dependence Syndrome by significantly reducing the craving for Alcohol. Controlled studies with longer duration and rigorous study design must be conducted in the future to corroborate the evidence, study the long term effects of *Nux Vomica* and relapses if any after administration of the medicine.

Conflict of interest

The authors do not have any conflicts of interest to declare.

Ethical Considerations

Written informed consent was received from all the participants before enrolling for the study. Ethical clearance was obtained from the Father Muller Institution Ethics Committee, Kankanady.

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