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Efficacy of Varenicline in Nicotine Deaddiction

Tejvir Singh Walia[1], Poulomi Ghosh[2], Suprakash Chaudhury[3]

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Abstract

Background: Tobacco smoking is one of the major avoidable causes of disease and mortality among adult smokers globally. India has 200 million estimated smokers. Every year in our country, smoking causes the deaths of almost 600,000 males between the ages of 25 and 69. The most common reason for smoking is the physical nicotine dependence. Varenicline is a novel class of drugs for the cessation of smoking that reduces the rewarding effects of nicotine and also reduces cravings and withdrawal symptoms associated with quitting nicotine. The present study was undertaken to study the efficacy of Varenicline in nicotine de-addiction.

Materials and Methods: 50 healthy and well-motivated Security Forces Personnel, ages ranging from 20-58 years, who self-reported nicotine deaddiction constituted the sample for the present study and were administered the Fagerstrom Tolerance Questionnaire for Nicotine dependence.

Results: There was a significant difference existing between the pre and post-values on the Fagerstrom Tolerance Questionnaire after six months of review. Subjects who had responded well to deaddiction with Varenicline remained in remission even after six months.

Conclusion: Varenicline is a first-line smoking cessation therapy option, as a possible substitute for bupropion SR or NRT.

Keywords: Varenicline; Nicotine deaddiction; Relapse; Follow-up.

Author's Affiliation: [1]HOD, Department of Psychiatry, 167 Military Hospital, Pathankot 145001, Punjab, India, [2]Junior Resident, [3]Professor & HOD, Department of Psychiatry, Dr D.Y. Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune 411018, Maharashtra, India.

Correspondence Author: Suprakash Chaudhury, Professor & HOD, Department of Psychiatry, Dr D.Y. Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune 411018, Maharashtra, India.

Email: suprakashch@gmail.com

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INTRODUCTION

Tobacco smoking is one of the major avoidable causes of disease and mortality among adult smokers globally.[1] The 2019 Global Burden of Disease (GBD) Study states that over 8 million individuals die from smoking related causes annually.[2] India with 200 million estimated smokers has the same prevalence of smoking in rural as well as urban areas. Among Indians aged 15 and older, tobacco smoking comprised 16.6% of the general populace (29.3% men and 2.3% women). It is more common among young individuals in the

age group of 20-24 years. The impoverished and those with lower levels of education are more likely to smoke cigarettes. Every year in our country, smoking causes the deaths of almost 600,000 males between the ages of 25 and 69. The most common reason for smoking is the physical dependence on Nicotine.[3] Pharmacotherapy and behavioral strategies together are effective in helping smokers stop.[4] Effective tobacco cessation treatments range from straightforward counseling to comprehensive programs that combine cognitive behavioral therapy with medication, such as bupropion or nicotine replacement therapy (NRT).[8] The FDA in the United States authorized bupropion, an atypical antidepressant, as the first medication not containing nicotine for adult smokers who want to quit. Clinical investigations indicate that one in five smokers can successfully quit with bupropion.[9] In Indian research, the discontinuation rates at six and twelve weeks with bupropion alone were 26.3% and 28.9%, respectively, while with medication plus behavioral treatment, the rates were 47.3% and 54.1%, respectively.[10] Another study revealed that when compared to a placebo, the combination of nicotine receptor agonist and nicotine replacement therapy had a noticeable odd of 4.4, bupropion and nicotine receptor agonist 4.0, and bupropion and nicotine replacement therapy 3.8 for continued abstinence at six months. When comparing monotherapies to placebo, nicotine receptor agonists had a noticeable odd of 2.7, NRT 2.2, Bupropion 2.1, and Nortriptyline 2.0.

Nicotine addiction is facilitated by nicotine's activation of the central α4β2 nicotinic acetylcholine receptor (nAChR), which releases dopamine and eventually results in the rewarding outcomes of smoking.[5] Varenicline is a novel class of drugs for the cessation of smoking that binds this receptor with a stronger affinity than nicotine, reducing the rewarding effects of nicotine, and as a nAChR partial agonist, varenicline reduces cravings and withdrawal symptoms associated with quitting nicotine.[6] Clinical studies have indicated that varenicline is more effective than placebo and bupropion-SR at helping people quit smoking, and it also shows a considerable delay in the recurrence of smoking.[7] Few studies have been conducted in India to support the effectiveness of varenicline, despite several clinical practice recommendations strongly favoring it over nicotine patches and bupropion. The current study was doneto determine the effectiveness of nicotine deaddiction with Varenicline.

MATERIALS AND METHODS

The type of study was a prospective cohort study with a purposive sampling technique. The Institutional Ethics Committee gave its approval for the study before its commencement. Before the study, each participant provided written informed permission after being informed of the aim and objective of the research.

Sample

Fifty healthy and well-motivated Indian personnel in government service with ages ranging from 20 to 58, with a mean age of 40.45 years, who self-reported Nicotine deaddiction at psychiatry OPD, constituted a sample for the present study. Those who had already experienced mental illness weren't eligible to participate in the research and were excluded.

Tools

Sociodemographic Data sheet: This self-made proforma recorded demographic details and history of smoking.

Fagerstrom Tolerance Questionnaire for Nicotine Dependence (FTQN) - Fagerstrom developed FTQN to find out the tolerance level for Nicotine dependence. It was a 5-point rating scale administered to find out the degree of Nicotine dependency. FTQN consisted of 10 statements and the subject was asked to rate his smoking habit. It usually took ten minutes to complete the test. All the items were scored on a 5-point rating scale. The minimum score was 10 and the maximum was 50. A high level of nicotine dependency was indicated by a score of more than 10, which was linked to more severe withdrawal symptoms and more difficulty quitting.

Procedure:

After getting consent patients were clinically evaluated using the semi structured proforma and administrating the FTQN. Thereafter the subjects were administered tablets of Varenicline Tartrate (1 starter and 5 maintenance packs) during treatment. It was a 12-week course and the subjects were followed for 6 months for any relapse. In the end, the FTNQ was administered again.

Statistical Analysis: A standard scoring procedure was adopted and the results were

analyzed using a statistical software called "***Statistica***".

RESULTS

Out of the 50 subjects, 2 subjects dropped out of the study because of personal reasons. Hence, the final sample consisted of 48 subjects only. 11 subjects did not respond well to the Nicotine deaddiction therapy.

Table 1 shows the mean score of subjects on FTQN. Results indicate that the performance of subjects, who responded well to Nicotine deaddiction, was better than the subjects, who relapsed. Subjects, who had a low degree of nicotine dependency, responded well to the therapy as is evident by the scores of responders and non-responders when compared using the Mann-Whitney test. The difference was statistically significant ($p<0.01$).

Table 1: Mean raw score on Fagerstrom Tolerance Questionnaire for Nicotine Dependence

Subjects	Mean	SD	-
Subjects reported for Nicotine Deaddiction (n=48)	40.82	9.95	
Subjects responded well for Nicotine Deaddiction (n=37)	31.19	9.96	P value p<0.01
Subjects relapsed during the Nicotine Deaddiction (n=11)	39	2.05	

The subjects who were treated successfully for Nicotine addiction were followed for 6 months. During the follow-up, the subjects were administered FTQN to see the efficacy of Tablet Varenicline Tartrate in Nicotine deaddiction. Table 2 shows the mean pre and post-score of subjects on FTQN. It is evident from the table that the performance on follow-up was significantly better ($P<0.01$) than the pre-test score. Subjects showed a significant reduction in their nicotine tolerance levels and they were able to stay away from their nicotine habit.

Table 2: Mean pre and post raw scores on Fagerstrom Tolerance Questionnaire for Nicotine Dependence **(*n*=37)**

Subjects	Mean	SD	P value
Pre Test	31.19	9.96	p<0.01
Post Test	5.27	1.98	

DISCUSSION

All healthcare providers should prioritize helping smokers who wish to stop and motivating them to do so. Varenicline presents a novel therapeutic alternative for the treatment of nicotine addiction. The current study finding that 37 (77.08%) of 48 smokers responded well clearly indicated that tab Varenicline Tartrate is an effective medicine for Nicotine deaddiction and is in agreement with earlier studies. According to a Cochrane review of nine trials involving over 7,000 smokers, The chance of maintaining abstinence for at least six months is more than doubled (RR = 2.33 vs. placebo) by varenicline.[11] In addition, a meta-analysis of 18 studies revealed that a blend of medicine and counseling is more beneficial than either treatment alone. It also revealed a dose-response relationship between the degree of abstinence rates and the level of support for quitting smoking, with a 1-year abstinence rate of roughly 25% for substantial assistance and VAR.[12] Varenicline proved to be more effective than nicotine patches, gum, and other NRT, according to a comprehensive review encompassing 267 research.[13] Shish-Tzu Tasi *et al*[14] suggested that Varenicline was an effective therapy in the treatment of Taiwanese and Korean smokers, who were motivated to quit smoking. Previous studies have also proposed that the degree of nicotine dependency influences the effectiveness of VAR.[15]

Varenicline is also effective in helping people who have cardiovascular illness and/or chronic lung disease stop smoking. According to one study, preloading a progressive quitting strategy for patients who are unable or unwilling to give up cigarettes abruptly improves the effectiveness of varenicline. Long-term varenicline therapy is effective in preserving abstinence.[16] Following a thorough assessment and risk-benefit analysis, varenicline is generally safe and has no increased risk of adverse effects related to the heart or nervous system. In brief clinical studies, varenicline 1 mg BID was shown to be a more effective smoking cessation assistance than placebo when measured systematically by abstinence.[17] In a trial where the duration of therapy was prolonged to 24 weeks, varenicline was linked to greater rates of abstinence, a longer time to relapse, and a higher chance of long-term abstinence when compared to placebo.[18] However, varenicline and placebo showed a substantial difference in abstinence rates, with varenicline showing rates ranging from 22% to 23% and the placebo showing rates of 8% to 10%.[19] Therefore, varenicline is regarded as a first-

line therapy for nicotine dependence, much like bupropion. Our findings corroborate with other studies and hence is an important finding which if replicated by larger studies in the future may act as a milestone in eradicating Nicotine Dependence.

Limitations

The sample was modest and from one center only and consisted entirely of males, therefore results may not be generalized to the entire population.

CONCLUSION

Varenicline is a first line smoking cessation therapy option, as a possible substitute for bupropion SR or NRT. It was apparent from the follow-up that the scores on FTQN were considerably low, hence, subjects who had responded well to deaddiction with Varenicline remained in remission even after six months. Further research is necessary to evaluate the long-term effectiveness and safety of Varenicline.

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