Original Research Article

A study of the outcome of Nicotine use disorder treatment devised as per an evidence-based treatment protocol

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ABSTRACT

Introduction: Tobacco is the most common form of nicotine. It is smoked most commonly in cigarettes, then, in descending order, cigars, snuff, chewing tobacco, and in pipes. Effective treatments have now been identified and should be used with every current and former smoker. Guidelines that are available might not be specific and tailor made for patient population we come across. Hence, we reviewed and critically appraised available guidelines, systemic reviews, meta-analysis, review articles etc and we designed our evidence-based treatment protocols accordingly and this study will test the treatment effectiveness in nicotine use disorder.
Material & Methods: It was a prospective observational study. Individuals aged above 18 years with nicotine use disorder were enrolled into the study. The participants were assessed using structured Performa including demographic data, quit attempts and severity of Nicotine dependence using the Fagerström Nicotine Dependence Scale. Group A includes participants who were given Bupropion and Group B were given varenicline. Follow up was done at 1 and 3 month and patients assessed for relapse.
Results: Out of 90 participants 40 patients dropped out and 50 patients who completed the study, at 1 month of follow up there was no significant difference in relapse between two groups but at 3 months follow up compared to Group B (Varenicline), in group A (Bupropion) number of relapse is significantly higher (p value = 0.044).
Conclusion: At the end of the 3 months, significant difference was found between the medications in terms of the success of smoking cessation. Patients taking Bupropion had significantly higher relapse rate as compare to varenicline.

Keywords: nicotine dependence, Bupropion, Varenicline.

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INTRODUCTION

Tobacco dependence is a chronic disease that deserves treatment. The World Health Organization (WHO) estimates there are 1.1 billion smokers worldwide in 2015, and they smoke 6 trillion cigarettes a year. The WHO also estimates that tobacco kills more than 5 million persons each year. Worldwide mortality from tobacco use is expected to double to 10 million deaths per year in the next few decades in the absence of effective action. Cigarette smokers who are between the ages of 30 and 69 have 2 to 3 times the rate of mortality when compared with similar people who have never smoked [1-2]. Smoking cessation is effective in reducing mortality from coronary heart disease, cerebrovascular disease, COPD, and tobacco-caused cancers; as well as improving health outcomes for surgical, diabetic, and mental health patients[1, 3-6].

Smoking is addictive in nature because of the psychoactive nicotine substance contained in tobacco. The risk of dependence in smoking is similar to that in heroin and alcohol use [7]. Pharmacological support is an important component of smoking cessation and should be recommended to those want to quit [8-10]. In this context, guidelines that are available might not be specific and tailor made for specific patient population. Hence, we reviewed and critically appraised available guidelines, systemic reviews, meta-analysis, review articles and we designed our evidence-based treatment protocols accordingly and this study will test the treatment effectiveness in nicotine use disorder.

METHODOLOGY

The study was carried out on patients presenting to the opd/ipd of department of psychiatry, Dhiraj hospital diagnosed with nicotine use disorder as per DSM-V and treated according to departmental evidence-based protocol devised for the treatment of nicotine use disorder. The study design was prospective observational design. A total of 90 individuals aged above 18 years were enrolled into the study with prior written consent. Patients presently or previously diagnosed for other psychiatric disorder, those with intellectual disability and suffering from serious debilitating medical illness were excluded from the study. After smoking cessation, the participants were assessed using structured Performa including demographic data, quit attempts and severity of Nicotine dependence using the Fagerström Nicotine Dependence Scale. Follow up was done at 1 month and 3 months wherein patients assessed for relapse.
Patients were given one of the two medications (varenicline or bupropion). Nicotine replacement therapy, motivational interview, stress reduction counseling and physical activity were included in the program for all patients. The decision for selecting particular drug was clinical. Of the total 90 participants, 60 were given bupropion and 30 varenicline in 2:1 ratio.
Fagerstrom Test for Nicotine Dependence (FTND) is a widely used scale in the determination of nicotine dependence. FTND consists of 6 questions scored between 1 and 10 points with a score of > 4 indicating the possibility of dependence. Based on the total score obtained from a comprehensive evaluation of this test; nicotine dependence is graded in 2 categories as smokers (<5), heavy smokers (≥ 5) [11].
The study was approved by the institutional ethics committee of the hospital.

STATISTICAL ANALYSIS

Statistical analysis of the data was performed utilizing the SPSS v20.0 Statistical Software. Definitive statistics were expressed as mean rank and difference for continuously measured variables and as frequency and percentage for nominal variables. Relationships between variables were evaluated using correlation analysis. The Chi-square test was used for categorical variables, while variables specified with measurement were evaluated through the Independent Samples t-test. A value of $p < 0.05$ was considered statistically significant.

RESULTS

In present study we have recruited total 90 patients which were further divided into two groups by 2:1 ratio i.e. Group A (given Bupropion) and Group B (given Varenicline). Whereas at 1st month follow up in Group A (Bupropion) there were 9 dropouts and in group B (Varenicline) there were 7 dropouts. By the end of 3rd month total number of dropouts in group A (Bupropion) raised to 22 and that of group B (Varenicline) was 18. At the end of the study total 50 out of 90 enrolled patients had completed the study. Analyzing these 50 patients, Table 1 shows, Demographical variables of both the group and we have found that there was homogeneous distribution in both the groups except in Occupation and gender, as of total 50 participants, 94% (n = 47) were male and 6% (n = 3) female i.e. most of the participants were male and all 3 females were in group A. Also, in occupation majority were unskilled workers i.e. 62% (n=31) and all 3 unemployed participants were in group A.
In table 2, Participants were divided into two groups i.e. Heavy Smokers (FTND Score ≥ 5) and Smokers (FTND Score < 5) by using Fagerstrom Test for Nicotine Dependence and we have found that 35 (70.00%) were heavy smokers (FTND Score ≥ 5) whereas 15 (30.00%) were smokers (FTND Score < 5).

In both the groups, patients were divided homogenously. Also, most participants had more than 5 previous quit attempts i.e. 24 out of 50 (48.00 %). There was no significant variation in distribution among the two groups for number of previous quit attempts.

Table 1: Demographic Parameters of both groups

Age Group	Group A (Bupropion) (n=38)	%	Group B (Varenicline) (N=12)	%	Total	%
18-29	13	34.21	4	33.33	17	34.00
30-39	9	23.68	3	25.00	12	24.00
40-49	4	10.53	1	8.33	5	10.00
50-59	5	13.16	2	16.67	7	14.00
60-69	4	10.53	2	16.67	6	12.00
70+	3	7.89	0	0.00	3	6.00
Marital Status						
Married	24	63.16	8	66.67	32	64.00
Single	12	31.58	3	25.00	15	30.00
Widower	2	5.26	0	0.00	2	4.00
Divorced	0	0.00	1	8.33	1	2.00
Gender						
Female	3	7.89	0	0.00	3	6.00
Male	35	92.11	12	100.00	47	94.00
Education						
Uneducated	7	18.42	2	16.67	9	18.00
Attended primary school	6	15.79	2	16.67	8	16.00
Not completed high school	7	18.42	2	16.67	9	18.00
Completed high school	11	28.95	3	25.00	14	28.00
Under graduated	4	10.53	2	16.67	6	12.00
Post graduated	3	7.89	1	8.33	4	8.00
Occupation						
Skilled Worker	5	13.16	1	8.33	6	12.00
Unskilled Worker	23	60.53	8	66.67	31	62.00
Business	2	5.26	1	8.33	3	6.00
Unemployed	3	7.89	0	0.00	3	6.00
Student	4	10.53	2	16.67	6	12.00
Housewife	1	2.63	0	0.00	1	2.00

In table 3, At 1 month of follow up there was no significant difference in relapse between two groups but at 3 months follow up compare to Group (Varenicline) B, in group A (Bupropion) number of relapse were significantly higher (p value = 0.044). In table 4, comparing number of quit attempts to number of relapse in each group, it was observed that at higher number of quit attempts (>5), number of relapse in Group B (varenicline) were lesser at both 1 month and 3 months i.e. at 1 month 20.00% (1 out 5) patients relapsed in group B (varenicline) as compared to 37.84% (7 out of 19) in group A (bupropion), Similarly, at 3 months 20.00% (1 out of 5) patients relapsed in group B (varenicline) as compared to 47.37% (9 out of 19)

patients in group A (bupropion). Also, number of relapse in heavy smokers are lesser in group B, at 1 month 11.11% (1 out of 9) and at 3 months no patient (0 out of 9) relapsed as compare to Group A, at 1 month 26.92% (7 out of 26) and at 3 months 38.46% (10 out 26) relapsed.

Table 2: Clinical Parameters in both groups

Smoker	Group A (Bupropion)	%	Group B (Varenicline)	%	Total	%
Heavy Smoker	26	68.42	9	75.00	35	70.00
Smoker	12	31.58	3	25.00	15	30.00
Quit Attempts						
> 5	19	50.00	5	41.67	24	48.00
3 – 5	11	28.95	4	33.33	15	30.00
< 3	8	21.05	3	25.00	11	22.00

Table 3: Relapse at Follow up visits in both groups

No of relapse	Group A (Bupropion) Out of 38	%	Group B (Varenicline) out of 12	%	p value
At 1 month	11	28.95%	2	16.67%	0.349
At 3 months	15	39.47%	1	8.33%	0.044

Table 4: Quit Attempts and Relapse

	Group A (Bupropion) (no. of patients)	Group A (Bupropion) (no. of Relapse)	%	Group B (Varenicline) (no. of patients)	Group B (Varenicline) (no. of Relapse)	%
Previous Quit Attempts						
At 1 month						
> 5	19	7	36.84	5	1	20.00%
3 – 5	11	3	27.27	4	1	25.00%
< 3	8	1	12.50	3	0	0.00%
At 3 months						
> 5	19	9	47.37	5	1	20.00
3 – 5	11	4	36.36	4	0	0.00
< 3	8	2	25.00	3	0	0.00
Severity of Smoking						
At 1 month						
Heavy Smoker	26	7	26.92	9	1	11.11
Smoker	12	4	33.33	3	1	33.33
At 3 months						
Heavy Smoker	26	10	38.46	9	0	0.00
Smoker	12	5	41.67	3	1	33.33

DISCUSSION

In this study it has been observed that relapse rate in significantly higher with bupropion as compare to varenicline (p=0.044) at the end of 3 months but the number of drop outs were higher with varenicline in patients of nicotine use disorder. In meta-analyses by Hughes and others [12] results from four trials comparing bupropion to varenicline, more patients quit smoking when given varenicline as compare to bupropion (N = 1810, RR 0.68, 95% CI 0.56 to 0.83). In another systematic review which examined 10 studies, findings suggested that varenicline groups achieved higher rates of abstinence compared to both NRT and placebo, bupropion and NRT were of similar effectiveness, and bupropion and varenicline both had higher abstinence rates compared to placebo [13]. The results of the current study are consistent with literature in this respect.

Clinical variable also show difference in 2 groups as bupropion is having higher relapse in patients who are heavy smokers, and have more number of previous quit attempts as compare to varenicline and this difference is not statically significant.

CONCLUSION

At the end of the 3 months, significant difference was found between the medications in terms of the success of smoking cessation. Patients taking Bupropion had significantly higher relapse rate as compare to Varenicline. The rate of success of both the medications was in consistent with the literature. Variables like heaviness of smoking and previous quit attempts also show difference with patients on Varenicline having lesser relapse rates.

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