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## A clinical study on the effectiveness of individualized homoeopathic medicines in reducing the dependence in tobacco use disorder

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### Abstract

**Objective:** To evaluate the effectiveness of individualised homoeopathic medicine in nicotine dependence and to assess improvement in their quality of life following homoeopathic treatment.

**Materials and Methods:** The prospective clinical study was conducted in the Outpatient and Inpatient department of the National Homoeopathy Research Institute in Mental Health, Kottayam. Out of 130 cases screened, 33 diagnosed cases with satisfying DSM-5 Diagnostic criteria were taken for the study. Each case was systematically analyzed and individualized homoeopathic medicines were administered to patients as per the homoeopathic principle. The duration of the study was six months. Each case assessed at baseline and every month with Fagerstrom Test for Nicotine Dependence (FTND). Quality of life of the patient assessed with WHOQOL-BREF at every 3-month interval. The outcome of the treatment was measured by analyzing the symptom score obtained in with Fagerstrom Test for Nicotine Dependence (FTND) and WHOQOL-BREF. The final evaluation of the data was done with the Wilcoxon signed rank test.

**Results:** Out of 33 cases, there was a significant improvement in all the cases with a corresponding reduction in total score obtained in the rating scales. Sulphur was the most frequently indicated remedy in this study. There was a pronounced reduction of the overall score with Fagerstrom Test for Nicotine Dependence (FTND) after treatment, with a statistical significance of  $p < 0.001$ . Quality of life also improved markedly with a statistical significance of  $p < 0.001$ . Almost all the subjects could lead a fruitful social, vocational and family life after the intervention.

**Conclusion:** The study shows that homoeopathic medicines are effective in the management of Tobacco Use Disorder. Quality of life also improved markedly in the entire domain. The study would have been more productive if the duration of the study was much longer.

**Keywords:** Tobacco use disorder; homoeopathy; fagerstrom test for nicotine dependence

### Introduction

Tobacco use disorder (TUD) is the most prevalent, deadly, and costly of SUDs (Substance Use Disorders) <sup>[1]</sup>. The prevalence of addiction to nicotine, the primary psychoactive substance in tobacco, surpasses all other SUDs <sup>[2]</sup>.

It is also one of the most ignored, particularly by psychiatrists, because despite recent research that shows commonalities between tobacco dependence and other substance use disorders, tobacco dependence differs from other substance dependencies in unique ways <sup>[3]</sup>. Tobacco does not cause behavioral problems, hence few tobacco-dependent persons seek or are referred for psychiatric treatment <sup>[4]</sup>. Tobacco is a legal drug and most persons who stop tobacco use have done so without treatment <sup>[1]</sup>.

The WHO Global Action Plan for the Prevention and Control of Non communicable Diseases 2013– 2020 includes a target for reducing the global prevalence of tobacco use (smoked and smokeless tobacco) by 30% by the year 2025 relative to 2010 <sup>[8, 9]</sup>. Although the target for reducing tobacco use was set as a global target, each country is at liberty to set its own target <sup>[10]</sup>. This report reveals whether tobacco use in each country is likely to achieve a 30% reduction by 2025, or, if not, whether the trend is upwards, flat or downwards <sup>[11]</sup>. As per the report released by World Health Organization tobacco is the only legal drug which causes death of many of its users when used exactly as intended by manufacturers <sup>[12]</sup>. It causes death of over six million worldwide and most of them are premature <sup>[13]</sup>. According to WHO it is expected an increase of 10 million deaths a year in the world from tobacco smoking by 2030. It not only causes death of active smokers but about 6, 00,000 deaths from

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second hand smoke. It is associated with many non-communicable chronic diseases and predispose to many communicable diseases too <sup>[14]</sup>.

A double blind placebo controlled study was to done by Nicolette Liesel hellberg at Technikon Natal Homoeopathic Day Clinic in Durban, South Africa on 2001 to evaluate the efficacy of a homoeopathic complex, Avena sativa 03, Ignatia amara 04, Daphne indica 06, Nux vomica 06, Caladium seguinum 060, Nicotinum 060 and Nicotiana tabacum 060 in helping people to stop smoking in terms of the number of cigarettes smoked per day <sup>[15]</sup>. Dr. Abdul Lethif, former principal and controlling officer Govt. homoeopathic medical college Trivandrum conducted a study on efficacy of homoeopathic and biochemic medicines for removing the habit of tobacco smoking and alcoholism. Study was conducted on 652 patients. The cases have treated with constitutional and symptomatic treatment along with Sterculia tincture and Quercus tincture. 334 patients took medicines for tobacco smoking. A success rate of 62.8% in two weeks. The commonly used medicines were Staphisagria, Calcarea phos, Nuxvomica, Natrium. mur and Lachesis. The ultimate aim of the research is to check the effectiveness of caladium seguinum 30 C and 200 C in tobacco de-addiction and rehabilitation with facile management of withdrawal symptoms <sup>[6]</sup>. Prospective study was conducted in randomly selected 30 patients attending the outpatient, inpatient of Bakson Homeopathic Medical College and Hospital. Adults of age group 15–60 who showed tobacco dependence were included in the study. In this study cases were reviewed in every 2 weeks. Outcome of study were measured by Fagerstrom test score changes. These results confirm the age old observations of homoeopathic stalwarts regarding the use of Plantago Major in reducing craving for tobacco especially in the present scenario when large number of tobacco users were planning or thinking of quitting tobacco use <sup>[7]</sup>.

Therefore, a study is needed to analyze the effectiveness of individualized homoeopathic medicines in tobacco use disorder. Thus, an interventional, non- comparative study is planned to evaluate the efficacy of individualized homoeopathic medicines in tobacco use disorder.

### Primary objective

To find out the efficacy of Individualized Homoeopathic medicines in reduction of dependence for tobacco smoking in tobacco use disorder.

### Secondary objectives

1. To arrive at a group of medicines effective in reducing the dependence in tobacco use.
2. To study the changes in quality of life in patients with dependence for tobacco smoking.

### Materials and Methods

#### Study Design

The type of research study is a prospective clinical study and it is quantitative research. In the case of quantitative research, the data collected has been converted into numerical form so that statistical calculations can be made and conclusions can be drawn. The statistical analysis of the collected data helps the researchers to find out if there are changes in the primary and secondary outcome variables exist. Since the data collected was not found to be normally distributed, non-parametric test, Wilcoxon Signed Rank test

was used for the statistical evaluation of the data to check whether the study is significant or not.

### Sample selection and sampling technique

**Sample size:** A sample of 33 cases diagnosed with Tobacco use disorder in the age group of 18-60 years were selected including cases from outpatient department of National Homoeopathy Research Institute in Mental Health, Kurichy, Kottayam, from March 2021 to September 2021. Cases were under 6 months follow up for analysis.

The sample was selected by purposive sampling and cases were selected based on clinical symptoms of nicotine dependence and based on DSM-5 Diagnostic criteria <sup>[15]</sup>.

### Inclusion criteria

Cases fulfilling the diagnostic criteria of DSM-5 for tobacco dependence. Cases in the age group of 18 to 60 years.

### Exclusion criteria

Cases with life threatening conditions. Cases with co morbid major psychiatric conditions. Other substance dependence.

### Methods of study

After obtaining approval from Institutional Ethical Committee, the study was registered under CTRI and started on 9<sup>th</sup> February 2021. Cases were selected from Outpatient department of National Homoeopathy Research Institute in Mental Health, Kottayam. Out of 130 cases screened, 33 cases were selected and enrolled for the study. Patients who presented with craving for nicotine in the last one year were screened by using a verbal questionnaire and detailed screening done with the help of DSM-5 diagnostic criteria. After screening, the consultant psychiatrist has done the assessment for diagnostic confirmation of the cases. A written informed consent was obtained from each subject, who qualified the inclusion criteria were enrolled.

Detailed homoeopathic case taking was done on the standardized case recording format. Appropriate laboratory investigations were done to rule out other systemic illnesses. Cases were assessed at baseline with Fagerstrom Test for Nicotine Dependence (FTND). The quality of life of the patient was assessed with WHOQOL-BREF. Individual totality is erected on the basis of analysis and evaluation of the case. Repertorisation was done with synthesis repertory by using RADAR OPUS software and the final selection of remedy was done after comparison with standard Materia Medica. Indicated homoeopathic remedy prescribed ranging from 30C to 1M potency. Dose and Repetition of medicine done based on homoeopathic principles. Each case was reviewed at every 4-week interval. No medicines were repeated still improvement ceases, in such cases administered with placebo. Remedy repeated with the same potency in cases which improvement stops, and higher potency of the same remedy was given in cases with no further improvement. The case was retaken and a new similimum was prescribed in cases with no improvement at all. The severity of dependency assessed with FTND every month. Assessment was done with WHOQOL-BREF at every 3 months. The outcome of the treatment was assessed according to symptomatic improvement and changes in the scoring on rating scales. The Data was statistically analyzed using IBM SPSS Version 16. Normality of the data was checked using Shapiro Wilks test. Since the variables showed significant deviation from Normality, Wilcoxon

signed rank test was used to compare the FTND total scores and WHO QOL domains before and after the intervention. The TUD dependence categories before and after the intervention were compared using Marginal Homogeneity Test.

Due to the restrictions during the lockdown period due to COVID 19 pandemic crisis, those who met difficulties to reach hospital OPD, were directed to collect medicine from a homoeopathic dispensary near to their location after proper communication with the medical officer in charge and the assessment was done telephonically by using FTND and WHOQOL-BREF rating scales. At the end 6 months follow up, data were statistically analysed with the Wilcoxon signed rank test

### Assessment Criteria

The changes in the intensity of symptoms in Fagerstrom Test for Nicotine Dependence were assessed at baseline and every month up to six months. Quality of life of patient was assessed based on WHO-QOL BREF scoring at baseline, 3<sup>rd</sup> and 6<sup>th</sup> month.

### Intervention

#### Case taking and analysis

All the details were recorded according to homoeopathic way of case taking in a standardised case recording Proforma. Analysis and evaluation of all the cases were done for finding the totality of symptoms. Predominant miasm was found out in each case by miasmatic cleavage. Each case were repertorised using Synthesis repertory. Individualized homoeopathic medicines are prescribed based on homoeopathic principle of single remedy and minimum dose. No medicine was repeated until improvement ceases. The potency was selected based on the symptom severity and susceptibility of the patient. In between the periods of medication all the patients were kept under placebo. Placebos used were Sugar of milk and Blank tablets. All the patients were followed for a period of 6 months.

#### Remedy, Potency and repetition of the dose

The individualized Homoeopathic medicine selected as per the law of similars and prescribed singly at one occasion in the sugar of milk along with blank tablets. Indicated homoeopathic remedy prescribed ranging from 30C to 1M potency. Dose and Repetition of medicine done based on homoeopathic principles.

#### Review and follow up

Periodical analysis and evaluation of patients were done at monthly interval with FTND to assess changes in intensity of nicotine dependency. WHOQOL-BREF was used to assess quality of life at every 3 month interval. Patients were asked to report at the earliest if there is an aggravation of symptoms in between the visits. The change in the intensity and frequency of symptoms were noted during each visit. Repetition was done in necessary cases depending on the improvement or else placebo was given. Remedy was changed in cases with no improvement by retaking the case. At the end of 6 months, analysis of the outcome was done.

#### Statistical tests

As the sampling technique used in this study was purposive sampling, non-parametric test is used. The results of the

study are tabulated for getting a valid conclusion. The statistical analyses were conducted based on symptom score using Wilcoxon Signed Rank Test.

FTND score were analysed at the baseline and end of the study and quality of life of patients were analysed with the help of WHOQOL-BREF at every 3 months interval. The test helps to establish whether the changes observed after treatment were significant or not. Data presentation includes tables, chart and figures.

### Results

Description of the data collected from 33 patients who have attended National Homoeopathy Research Institute in Mental Health, Kottayam with the features of tobacco use disorder and qualified the predefined inclusion criteria are given under this section. Cases were selected between the age group 18-60. It can be observed that the maximum number of patients with Tobacco use disorder came under the age group 41-60 (Middle adulthood), which was about 60.60% of the total study population. Out of 33 cases, 33 were males (40%) and there were females. It shows Maximum incidence was reported among males. Out of 33 cases, 21 were Hindu (63.63%), 2 were Muslims (6.06%) and 10 were Christian (30.30%). Out of 33 cases, 24 were married 9 were unmarried. This study shows incidence of depression higher among married males. This study shows 27 patients (81.81%) were from rural areas and 6 patients (19.35%) were from urban areas indicates a predominance of depression among rural population. A higher incidence was noted among housewives comprising 30.30% of the total group. In this study group 5 patients were from the upper class (15.15%), 19 were from the middle class (57.57%) and 9 patients were from the lower class (27.27%). Out of 30 cases, 4 participants (12.12%) were illiterate, 15 participants (45.45%) up to matriculation, 3 participants (0.09%) were completed higher secondary, 11 participants (33.33%) were graduates and none were postgraduate. 10 different medicines were prescribed during the entire course of study, among these, 5 (50%) medicines were belonged to the mineral kingdom and 5 (50%) medicines from the vegetable kingdom. Out of 30 cases 30<sup>th</sup> potency given to 3 cases (10%), 200<sup>th</sup> potency to 21 cases (70%) and 1M to 6 cases (20%) at baseline. The Qualities Of Life of the cases were assessed at baseline, 3<sup>rd</sup> month and 6<sup>th</sup> month using WHO QOL. There was a statistically significant improvement in all the 4 domains. Friedman test was used to assess the changes

#### Statistical Analysis

To study the effectiveness of individualized homoeopathic medicine in the management of nicotine dependency, the symptom score based on the observations on FTND were assessed at baseline and end of the study and WHOQOL-BREF at baseline, 3<sup>rd</sup> month and 6<sup>th</sup> month. (Table 7, 8). The data was statistically analyzed using software's STATCRAFT (Version 2.0.3) and IBM SPSS (Version 16). Normality of the data was checked using Shapiro Wilks test. Since the variables showed significant deviation from Normality, Wilcoxon signed rank test was used to compare the TUND total scores and WHO QOL domains before and after the intervention. The TUD dependence categories before and after the intervention were compared using Marginal Homogeneity Test.



## Discussion

In order to reach a valid conclusion from the result obtained from the study of 33 cases for 6 months, here is a discussion from a few findings that have been evolved out of this study. Maximum number of patients came under the age group of 41-60 (middle adulthood), constituting 60.60% of the whole. In this study, nicotine dependence was more common among middle adulthood. The next significant age group was 22-40, 36.36% of patients were included in these groups. Only 3.03% of patients were included in the age group of 18-21. So from this study, it is observed that a steady increasing trend in nicotine dependence with age. The male sex constituted a major section of the study forming 100% of the total. Out of 33 patients, all were males. Studies related to nicotine dependence showed that severe and very severe grades of nicotine dependence were higher among males. The observation holds good with literature data as the maximum prevalence is seen among males. In this study, 21 were Hindu (63.6%), 2 were Muslims (6.1%) and 7 were Christian (30.30%).

The rural population showed up a larger part of the patients i.e., about 83.33%. Various studies also showed that nicotine dependence is more prevalent in rural areas. In this study prevalence of nicotine dependence was more among middle-class people, constituting 57.57% of the total study subjects. 15.15% were in the upper class and 27.27% were in the lower class. It was seen from the baseline profile that 27.3% of the participants ( $n = 9$ ) were those who completed SSLC, 39.39 ( $n=13$ ) were completed graduation. 12.1% ( $n=4$ ) completed higher secondary education and 12.1% ( $n=4$ ) participants were illiterates. So from this current study we can conclude that nicotine dependence is seen more among literates, i.e. more common among those who completed SSLC and graduation 36.36% of the cases under study had a positive family history of nicotine dependence. This supports the fact of the genetic predisposition for nicotine dependence. 24.2% of the cases had a family history of alcohol dependence and 2% each of the cases had a family history of cannabis and hash dependence respectively. By the degree of severity of nicotine dependence, based on clinical features presented by the patients, moderate dependency was found among 45.45% ( $n=$ ) of the total cases. 24.21% cases ( $n=$ ) had severe dependency, 15.15% ( $n=5$ ) each cases had mild and mild to moderate dependency respectively. (Table 1)

During the course of the study, individualized homoeopathic remedies were prescribed based on the symptom similarity of the patient. The most frequently prescribed homoeopathic similimum were Sulphur ( $n=8$ ), Nux vomica ( $n=5$ ), Calcarea carb ( $n=3$ ), Arsenicum album ( $n=3$ ), Natrium muriaticum ( $n=3$ ), Staphysagria ( $n=2$ ), Ignatia ( $n=2$ ), Caladium ( $n=2$ ) and Phosphorus ( $n=1$ ). During the study, these 10 individualized constitutional medicines were prescribed at the baseline. Among this 5 medicines belonged to the mineral kingdom and 5 medicines belonged to the vegetable kingdom there were studies supporting that Sulphur was the most indicated remedy for nicotine dependence. Similarly another study implicated Arsenicum album, Calcarea carbonica, Lycopodium, Phosphorus, Caladium, Natrum muriaticum and Staphysagria as useful medicines for the treatment of nicotine dependency.<sup>16-21</sup> The most frequently used potencies at baseline was 200<sup>th</sup> potency, used in 21 cases (63.3%), 1 M in 6 cases (18.1%) and 30 C in 3 cases (9.0%) based on homoeopathic principles.

The study shows marked improvement in all cases (96.66%)

Before treatment, there were 8 patients (24.24%) had severe dependency and 15 patients (45.4%) had moderate dependency, five patients (15.1%) had low to moderate dependence and five had (15.1%) low dependence. At the end of 6 months of treatment, the number of patients in the moderate severity group was only 1 (3.33%), in the low to moderate severity it was 2 (6.0%), in the low severity it was 7 (21.2) and all other came to normal. There was a considerable symptomatic improvement in the nicotine dependency after treatment, which was correlated by a marked reduction in total symptom score on Fagerstrom Test for Nicotine Dependence rating scale with statistical significance of  $p$  value  $<0.001$  establishing the effectiveness of individualized homoeopathic treatment.

No adverse events were reported in any cases during the study period. Treatment was strictly based on homoeopathic principles, individualization and repertorisation of each case for the management of different intensities of depressive disorders. The highest Fagerstrom Test for Nicotine Dependence (FTND) score before treatment was 10. 5 patients had nicotine dependence of mild severity, 5 had nicotine dependence of low to moderate-severity, 15 had nicotine dependence of moderate severity and 8 patients had nicotine dependency of severe intensity as per the FTND scores at the baseline. The outcome assessment based on the FTND scores indicated that all patients had significant improvement in their nicotine dependence. The median FTND score analyzed at baseline of the study was 6.0(4.0, 7.5) the median score at the end of the study was 0.0(0.0, 1.0). The difference in the median scores at baseline and at the end was found to be statistically significant ( $p<0.001$ ). (Table 4). The quality of life of the patient also improved markedly with  $p<0.001$  in all four domains as per WHOQOL. i.e. physical health, psychological health, social relationship, and environmental health. For domain 1, median transformed score (0- 100) at baseline was 56.0(50.0, 63.0) and 56.0 (56.0, 63.0) at the end of study (6<sup>th</sup> month) with  $p$ -value  $<0.001$ . For domain 2, median transformed score (0-100) at baseline was 38.0(31.0, 44.0) 63.0(56.0, 69.0) at the end of study with  $p$ -value  $<0.001$ . For domain 3, the median transformed score (0-100) at baseline was 50.0(44.0, 56.0) and 75.0(75.0, 75.0) at the end of the study with  $p$ -value  $<0.001$ . For domain 4, the median transformed score (0-100) at the baseline was 56.0(50.0, 63.0) and 81.0(75.0, 88.0) at the end of the study with  $p$  value  $<0.001$ . (Table 3). From the baseline FTND scores, it was found that with homoeopathic treatment, out of the 33 patients who had nicotine dependence, all the patients had significant improvement in their overall condition and the FTND scores fell below 5 at the end of the study with few exceptions. In this study, the majority of cases were clinically observed about the general improvement. From the analysis of the above results obtained, it was obvious that the individualized Homoeopathic medicines are very effective in the management of nicotine dependency with improvement in their quality of life.

## Limitations

There was no control group to compare the result of the study. Number of samples used in this study was small, it is not sufficient to make valid generalization of the outcome. Duration of this study was 6 months, this time period is not enough to assess occurrence of relapses. The age group studied was 18-60 years, which excluded two major segments like adolescent (12-18yrs) and old age (above 60yrs) having a prevalence of nicotine dependence. This

seriously limits the scope of study. The regular monthly follow up of patients were disrupted during the time of lock down due to COVID 19 pandemic. In such cases we advised them to collect medicine from their nearby government homoeopathic dispensaries, after our proper telephonic communication with the concerned medical officers.

**Table 1:** Distribution of data according to severity of nicotine dependence

Severity	No. of patients	Percentage
Low	5	15.15%
Low to moderate	5	15.15%
Moderate	15	45.45%
Severe	8	24.24%

**Table 2:** Distribution of data according to the prescription at the baseline

Remedy given	No. of cases	Percentage
Sulphur	8	24.24%
Nux vomica	5	15.15%
Lycopodium	4	12.12%
Calc carb	3	9.09%
Arsenicum album	3	9.09%
Natrum mur	3	9.09%
Ignatia	2	6.06%
Staphysagria	2	6.06%
Caladium	2	6.06%
Phosphorus	1	3.03%

**Table 3:** Pre-post comparison of FTND total score and domains of WHO QOL BREF

Variable	Baseline	End	Test statistic	P value
FTND Total score	6.0(4.0,7.5)	0.0(0.0,1.0)	-5.029	<.001
<b>WHO QOL</b>				
<b>Domain 1</b>				
Row score	22.0(21.0,24.0)	23.0(23.0,24)	-3.729	<.001
Transformed Score(4-20)	13.0(12.0,14.0)	13.0(13.0,14.0)	-3.729	<.001
Transformed Score(0-100)	56.0(50.0,63.0)	56.0(56.0,63.0)	-3.273	.001
<b>Domain 2</b>				
Row score	15.0(14.0,17.0)	21.0(20.0,22.0)	-5.030	<.001
Transformed score(4-20)	10.0(9.0,11.0)	14.0(13.0,15.0)	-5.039	<.001
Transformed Score(0-100)	38.0(31.0,44.0)	63.0(56.0,69.0)	-5.024	<.001
<b>Domain 3</b>				
Row score	9.0(8.0,10.0)	12.0(12.0,12.0)	-4.992	<.001
Transformed score(4-20)	12.0(11.0,13.0)	16.0(16.0,16.0)	-4.988	<.001
Transformed Score(0-100)	50.0(44.0,56.0)	75.0(75.0,75.0)	-4.988	<.001
<b>Domain 4</b>				
Row score	26.0(24.5,27.0)	33.0(32.0,35.0)	-5.020	<.001
Transformed score(4-20)	13.0(12.5,14.0)	17.0(16.0,18.0)	-5.038	<.001
Transformed Score(0-100)	56.0(50.0,63.0)	81.0(75.0,88.0)	-5.033	<.001

**Table 4:** Pre- post comparison of TUD dependence based on FTND total score

Dependence at end of the study						MH Statistic	P value
		Nil	Low	Low to Moder ate	Moder ate	Total	
Dependence at baseline	Low	5	0	0	0	5	92.000
	Low to Modera te	5	0	0	0	5	
	Modera te	13	2	0	0	15	
	High	0	5	2	1	8	
Total		23	7	2	1	33	

## Conclusion

From this study it can be concluded that individualized homoeopathic medicines are effective in the management of nicotine dependence syndrome. The Fagerstrom Test for Nicotine Dependence and WHOQOL-BREF score before and after treatment were found to be significant by the Wilcoxon signed rank test ( $p < 0.001$ ). This study shows that homoeopathic medicines have a promising role in the management of nicotine dependence

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## Conflict of Interest

Not available

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Not available

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