RESEARCH ARTICLE

Attempting Tobacco Cessation - An Oral Physician's Perspective

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Abstract

<u>Introduction:</u> Tobacco use is a global health care problem. Repetitive exposure to nicotine produces neuroadaptation resulting in nicotine dependence. Smoking is associated with a range of diseases, causing high levels of morbidity and mortality and is one of the leading causes of preventable deaths, with more than 4.6 million smokers worldwide dying each year from smoking related illnesses. Stopping smoking has major health benefits. Quitting at any age provides both short and long term benefits. <u>Materials and methods:</u> 45 patients attending the outpatient department at the Oxford Dental College, Bangalore, were randomly allocated to three groups of interventions namely placebo, counseling and nicotine replacement therapy (NRT). Initially each one was assessed for carbon monoxide levels using a breath analyser (pico smokerlyser bedfont UK). They were followed up for six months and the carbon monoxide levels were again assessed using the same instrument. The paired t test was used to compare the results before and after the intervention. <u>Results:</u> The scores before the initiation of intervention and after treatment were compared and all three interventions were found to be statistically significant after six months. It was noticed that patients with very low or low dependence followed by high dependence had good response in the placebo group (68% and 47.6% respectively), in the counseling group maximum response was seen in the medium followed by the very low group (61% and 59% respectively), and maximum response was seen in very high followed by the very low group with NRT (78.7% and 60.5% respectively). <u>Conclusion:</u> The inference that can be drawn from the present study is that non-invasive, non pharmacological methods like placebo and counseling are effective in low to medium groups, and NRT is effective with higher nicotine dependence.

Keywords: Tobacco cessation - smoke analyser - nicotine replacement therapy - nicoine dependence

Introduction

Smoking is one of the leading causes of preventable death (Coruz et al., 2007). Pleasure, craving, habit, stimulation, stress reduction, relaxation are the important reasons for smoking (Cahall et al., 2010). It is associated with many diseases resulting in high morbidity and mortality. More than 4.9 million smokers die annually from smoking related illness (Coruz et al., 2007). A reduction in an average lifespan upto 10 years is noted in people who consume tobacco (Cahall et al., 2010) both smoked or smokeless.

Both short term and long term benefits are associated with quitting of smoking (Coruz et al., 2007). A reduction in the associated risks have been observed in smokers who successfully quit and maintain abstinence (Rose et al., 2010). Though many effective interventions to quit smoking exist, very few receive these (Coruz et al., 2007) and most are unaware. For patients willing to quit, 3 areas of addiction have to be addressed namely psychologic, the habit and physical addiction. The first two are addressed through counseling or behavioral therapy and the last one by medication (Cahall et al., 2007).

Considering these areas for smoking de-addiction a comparative study was designed to assess smoking cessation using behavioral therapy, placebo and nicotine replacement therapy. The objectives of the study were to assess efficacy of smoking cessation using behavioral therapy, placebo and NRT and to compare the cessation levels with each therapy.

Materials and Methods

Source of data collection

75 patients with smoked tobacco habit attending the OPD at The Oxford dental college, Bangalore were randomly selected and enrolled in the study.

Inclusion criteria

Patients with a positive history of smoking tobacco habits.Healthy patients with no other systemic diseases.

Exclusion criteria

Patients with any systemic diseases. Patients with other addictive habits like alcohol and smokeless form of tobacco.

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Study Design

Each patient was questioned regarding the habit details and level of dependence was assessed using Fagerstrom test for nicotine dependence. A standardized proforma, was filled which included the frequency, duration and level of dependence. Based on the level of dependence patients were categorized as mild, moderate, high and very high levels of dependence. They were randomly allocated to behavioral therapy (counseling), nicotine replacement therapy or placebo irrespective of their level of dependence. Only 15 subjects in each group were available for recall and follow up out of the 75 smokers making the sample size 45.

The carbonmonoxide levels were assessed in each participant before the initiation of any intervention using a pico smokerlyser manufactured by Bedfont Company UK. Each participant was asked to take a deep breath and to hold it for 5-10 seconds and slowly blow into the mouthpiece of smokerlyser completely. The values of carbonmonoxide and corresponding carboxyhemoglobin levels were noted.

Group 1. The behavioral therapy included initiating assessment and intervention using the 5 **A**'s which comprised of **A**sking about the tobacco use, **A**dvising the patient to quit, **A**ssessing the patient's willingness to quit, **A**ssisting the patient to quit by counseling using a pictorial depiction of the various side effects and harm of smoking in the form of a booklet specifically designed for this study and **A**rranging follow up contacts for relapse prevention by psychological support. The sessions lasted from 45-60 minutes. Some participants had 2-3 sessions.

Group 2. The nicotine replacement therapy (NRT) included delivery of 2 mg NRT gums for a period of 8-12 weeks. They were asked to chew the gum until they perceived a peppery or tingling sensation, thereafter they were instructed to keep in their cheek region and slowly chew it again. Each gum was asked to retain for a minimum period of 45 minutes. Any citrus fruits/juices, or any other beverages, soft drinks were avoided 1 hour before NRT. The smokers were asked to decide a quit date and quit smoking completely and NRT to be used thereafter to assist withdrawal symptoms. Any side effects with the use of NRT were noted.

Group 3. The placebo included delivery of placebo gums for a period of 8-12 weeks. This was described as a newer effective intervention for smoking cessation.

All the patients in the above groups were followed up periodically to assess the progress of cessation using the smokerlyser. A final assessment of carbonmonoxide levels were made after 6 months of intervention using a paired t test.

Results

The age range of 45 patients who participated in the study was categorized into 4 groups (Figure 1). The younger age subjects (25-32y) were more in the placebo group (n=6) and the elderly (40+) were predominant in the counseling (n=6) and NRT groups (n=7).

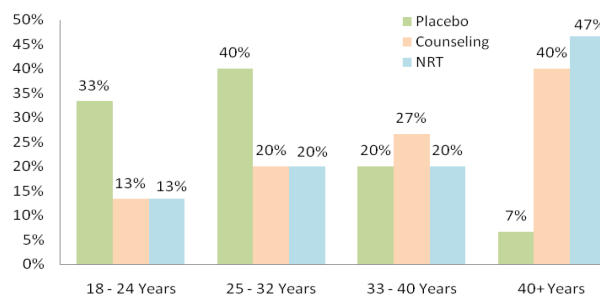It was observed that 47% of respondents were treated by NRT and they are in the age group of 40+ years,

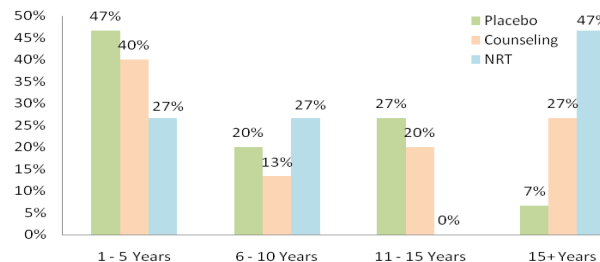**Figure 1. Patients by Age Category**

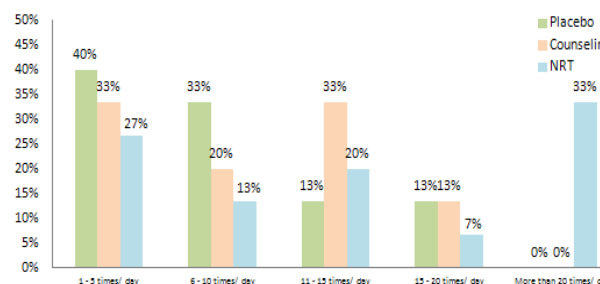**Figure 2. Patients by Duration of Smoking Habit (in years)**

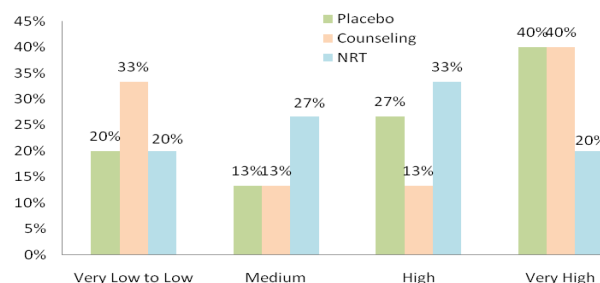**Figure 3. Frequency of Smoking per Day**

Figure 4. Patients by Nicotine Dependence Score

followed by 40% of the respondents were treated by counseling. In the age group of 25-32 years 40% of the respondents were treated with placebo. The least no of respondents, 7%, were in the bracket of 40 and above years in Placebo treated patients. Thus it was evident that majority of the respondents who were treated with NRT and Counseling were in the age group of 40+ years.

Out of 45 subjects 28 smoked cigarettes and 17 smoked beedis. Smokers were categorized based on the duration into 4 groups (Figure 2). People who smoked for 1-5 years were maximum in the placebo group (47%), and people who smoked for more than 15 years were maximum in the NRT group (47%).

Based on the frequency 4 groups were made (Figure 3) 40% smoked 1-5 (cigarettes or beedis) per day in placebo group, 33% smoked 1-5 per day and 11-15 times per day, and 33% smoked more than 20 times per day in the NRT

Table 1. Patients Treatment Type by PPM Scores

Paired t-test	Mean Score (Month)	N	Mean	SD	t-test (value)	df	p-value	Decision
Placebo:	Before	15	14.8	7.2	7.612	14	0.0002	S
	After 6	15	6.7	4.4				
Counseling:								
	Before	15	17.9	7.9	5.838	14	0.0015	S
	After 6	15	9.5	7.8				
NRT:	Before	15	19.9	7.9	8.362	14	0.0001	S
	After 6	15	9.0	5.2				

Table 2. Patients Treatment Type by Nicotine Type

Treatment Type	Nicotine Level	PPM Score Before	PPM Score After 6 month	Enhancement %
Placebo:	Very Low to Low	14.7	4.7	68.2%
	Medium	20.0	12.0	40.0%
	High	17.0	8.9	47.6%
	Very High	11.7	6.3	45.7%
Counseling:	Very Low to Low	14.2	5.8	59.2%
	Medium	9.0	3.5	61.1%
	High	24.0	15.0	37.5%
	Very High	22.0	12.7	42.4%
NRT:	Very Low to Low	14.3	5.7	60.5%
	Medium	21.5	9.0	58.1%
	High	17.8	8.2	53.9%
	Very High	26.7	5.7	78.7%

Table 3. Smoking Level by Outcome Across 3 Different Treatment Groups (shift %)

Treatment Type	Frequency of Smoking/Day (times/day)	Outcome Reduced 0-1	2-5	6-10	>10	Total
Placebo	1-5 n (%)	5 (83)	1 (17)	0 (0)	0 (0)	6 (100)
	6-10 n (%)	3 (60)	2 (40)	0 (0)	0 (0)	5 (100)
	11-15 n (%)	0 (0)	2 (100)	0 (0)	0 (0)	2 (100)
	15-20 n (%)	0 (0)	0 (0)	2 (100)	0 (0)	2 (100)
Counseling						
	1-5 n (%)	3 (60)	2 (40)	0 (0)	0 (0)	5 (100)
	6-10 n (%)	1 (33)	1 (33)	1 (33)	0 (0)	3 (100)
	11-15 n (%)	1 (20)	3 (60)	1 (20)	0 (0)	5 (100)
	15-20 n (%)	0 (0)	0 (0)	1 (50)	1 (50)	2 (100)
NRT	1-5 n (%)	1 (25)	3 (75)	0 (0)	0 (0)	4 (100)
	6-10 n (%)	0 (0)	1 (50)	1 (50)	0 (0)	2 (100)
	11-15 n (%)	0 (0)	0 (0)	3 (100)	0 (0)	3 (100)
	15-20 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)
	>20 n (%)	0 (0)	1 (20)	1 (20)	3 (60)	5 (100)

Table 4. PPM Levels by Treatment Groups

Treatment Type	N	Mean	Std. Deviation	95% Confidence Interval for Mean Lower	Upper
PPM Score Before					
Placebo	15	14.8	7.2	10.8	18.8
Counseling	15	17.9	7.9	13.6	22.3
NRT	15	19.9	7.9	15.5	24.3
Total	45	17.5	7.8	15.2	19.9
PPM Score After 6month					
Placebo	15	6.7	4.4	4.2	9.1
Counseling	15	9.5	7.8	5.2	13.8
NRT	15	9.0	5.2	6.1	11.9
Total	45	8.4	6.0	6.6	10.2

group.

Table 1 shows that difference between the before and after 6 months levels of PPM score (as per smoker analyser) by Placebo, Counselling and NRT treatment groups. We accepted the alternative hypothesis as p-value is <0.05. This indicates that there is a significant difference in PPM score of before and after in all the three treatment groups at 95%CI.

Based on Fagerstorm's questionnaire the subjects were categorised into four groups. The PPM scores before and after 6 months were compared. The placebo group showed 68% improvement (enhancement) in the very Low to low category, counseling group 61.1% improvement in the medium category and NRT showed maximum improvement in the very high category.

Table 3 showed the reduction in the number of cigarettes/beedis in all the three groups after 6 months. This study showed that treatment group NRT is more effective in helping people to stop smoking cigarettes/beedis (who smoked more than 10 per day).

Discussion

Oral physicians are the first to note any changes that can occur due to addictive habits such as tobacco in the oral mucosa.

Attempting tobacco cessation by oral physicians have not been published extensively in literature and limited publications were reviewed by the Cochrane database review (Carr et al., 2009)

The present study compared three modes (counselling, placebo and NRT) of treatment for smoking cessation. A similar study was done by Etter et al. (2002). They assigned the subjects into placebo, NRT or no treatment (Dar et al., 2005). All subjects were assessed using the Fagerstorm's scale as this quantifies the degree of nicotine dependence with reliability and validity in this study. Cahall et al. (2004) divided into four group (Figure 4) for assessment of the level of dependence only and not for categorization under any treatment group.

Further each patient was analysed through a breath analyser (pico smokerlyser Bedfont UK). Carbon monoxide (CO) is a combustion product of many fossil fuels (including cigarettes, beedis). It has 240 times more affinity to haemoglobin than oxygen (Cunnington et al., 2002). CO from the inhaled tobacco smoke enters the lungs and then the blood stream to combine with haemoglobin to remain for the next 24 hours. This CO re enters the alveoli vowing to the concentration gradient. Hence the CO level in exhaled air seems to be a reliable indicator of Carboxyhemoglobin in blood (Kumar et al., 2010).These devises are economical, instant, portable and non invasive (Cunnington et al., 2002; MacLaren et al., 2010). 0-6 PPM was considered normal, 7-10 PPM as light smokers and above 10 PPM as a regular smoker as per the specifications of the smokerlyser.

Placebo was defined as 'the effect of expecting drug in the absence of pharmacological actions of the drug' according to Perkins et al. 2003. A normal sugar free gum was bottled and given to the patients as a newer, more effective gum with better taste and lesser side effects,

following the design by Reuven et al. 2005 (Dar et al., 2005).

A brief advice offered by a doctor can result in smoking abstinence ranging from 5-10% (Cornuz et al., 2007). Verbal instructions to modify the health related issues, employed commonly for smoking cessation is termed behavioural intervention. These are more efficacious when used in combination of pharmacological interventions (Mottillo et al., 2009). Out of the four behavioural interventions (brief advice, intensive interventions like individual counselling, group counselling and telephonic counselling) (Mottillo et al., 2009). intensive counselling like the individual counselling has been very effective (Lancaster et al., 2008). We employed the individual counselling using pictorial representation of the various hazards of smoking including cancer. A similar representation was used by Walsh et al. 1999. The 5 A's (ask about the habit, advice to quit, assess willingness to quit, assist to quit, arrange follow up) were used. The 5R's (relevance to quit, risks of habit, rewards of quitting, road blocks in quitting, repetition of motivation) were also employed in each group (Cornuz et al., 2007). Schneider et al demonstrated that higher quit rates were noted in placebo and counselling than NRT alone without counselling (Cahall et al., 2004).

Nicotine replacement therapy (NRT) is the most commonly used intervention for smoking cessation introduced almost 20 years back designed to replace blood nicotine levels, minimising withdrawal symptoms like depression, anxiety, weight gain, insomnia, irritability etc (Cahall et al., 2004; Cepeda-Benito et al., 2004). It is considered safe as its devoid of all the carcinogens and harmful chemicals contained in a cigarette or beedi (Cepeda-Benito et al., 2004). They have shown to double the success rate when compared to placebo and minimise the withdrawal symptoms (Cahall et al., 2004; Cornuz et al., 2007; Silagy et al., 2007). Common side effects include nausea, hiccoughs, indigestion (Cornuz et al., 2007). Out of 15 NRT patients, 3 patients reported bad taste and nausea, and 1 reported hiccoughs.

Although 75 patients were enrolled initially into the study only 45 continued till the end completing the protocol, underlining the high attrition rate, which was due to the difficulty in quitting the addiction. The high attrition may be attributed to the difficulty in understanding the health hazards secondary to smoking vowing to the high illiteracy levels and lower socioeconomic groups in the general population. On the contrary even the educated class are addicted to this habit. However due to increase in the awareness they find it relatively easier to quit the habit.

15 patients in each group were followed up for a period of 6 months from the onset of treatment. The age range of the 45 patients was between 19-53 years, for convenience the participants were categorized into 4 groups (Table 1). The 25-32 years group were more in the placebo group (n=6) and the elder age group (40+) were predominant in the counseling (n=6) and NRT group (n=7). Only males participated in the study. 28 subjects smoked cigarettes and 17 smoked beedis. Maximum beedi smokers were seen under the counseling group and minimum under NRT group. Only cigarettes and beedis were included, as

they are the commonly smoked tobacco forms practiced in India. A beedi is a crude form of smoked tobacco which is 4-8 cm in length containing 0.25-0.50 g of coarse ground tobacco, rolled into a cone in a dried piece of temburni leaf (Sujatha et al., 2012).

Based on the duration of smoking four categories were made (Table 3). Patients who smoked since 1-5 years were maximum in the placebo group and people who smoked for more than 15 years were maximum in the NRT group. the subjects were grouped into 4 groups based on frequency (Figure 3) with least frequency (1-5 years) being maximum in placebo, and those with the frequency of more than 20 being maximum in the NRT group. The PPM scores before the initiation of intervention and after treatment were compared (Table 1) and all three interventions were found to be statistically significant after six months. It was noticed that patients with very low or low dependence followed by high dependence had good response by placebo (68% and 47.6% respectively), in the counseling group maximum response was seen in the medium followed by very low group (61% and 59% respectively), and maximum response was seen in very high followed by very low group in NRT (78.7% and 60.5% respectively). In a review of 14 randomized control trials (RCT) significantly higher rates were seen in NRT (23%) than placebo (13%) at the end of 6 months (Cornuz et al., 2007).

Placebo group had maximum reduction of 0-1 cigarette/beedi per day (46.7%), counseling group had maximum reduction of 2-5 cigarette/beedi per day (33.3%) and maximum reduction more than 10 cigarettes/beedis per day was seen in the NRT group, thus making NRT more effective in high smokers. In a Cochrane review of 35,600 participants it was found that NRT was more effective than placebo or no treatment given (Kumar et al., 2010). Etter et al reported that NRT was only slightly more effective than placebo even in heavy smokers (Dar et al., 2005).

In conclusion, the goal of any intervention must be complete long term abstinence from the habit as the true objective is to decrease or eliminate smoking induced morbidity and mortality. Very few studies are available comparing three arms of intervention (behavioral therapy, placebo and NRT). these interventions much reach public more easily. A through awareness is the key to make people realize the related health hazards and to increase the willingness to quit the habit.

The inference that can be drawn by the above study is that non invasive, non pharmacological methods like placebo and counseling were effective in low to medium groups, and NRT was effective in higher dependence group. Although complete abstinence was seen in very few subjects, most of them reduced the frequency. Hence a little quality time from the oral physician can make a remarkable difference in smokers, improving their quality of life.

Acknowledgements

compiled the statistical data.

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