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Original Research Article

A study on the effectiveness of nicotine and counselling in tobacco smoking cessation

Neetu Bala¹, Rekha Bansal², Parveen K. Sharma¹, Dinesh Kansal^{1*}, Himani Prajapati¹

¹Department of Pharmacology, ²Department of Pulmonary Medicine, Dr. RPGMC Kangra, Tanda, Himachal Pradesh, India

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***Correspondence:**

Dr. Dinesh Kansal,

Email: dinesh.kansal56@gmail.com

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ABSTRACT

Background: Effectiveness of pharmacotherapy and counselling has been suggested by various research workers in smoking cessation, but studies show variable results with pharmacotherapy. Also efficacy of counselling and pharmacological intervention differs from centre to centre. So we conducted this study, to observe the role of counselling and nicotine gums in our setup.

Methods: 86 smokers willing to quit smoking were enrolled. Baseline counselling was provided at the time of enrolment, then at 1 week, 1 month, 3 months and at 6 months. Telephonic counselling was given to those who did not come for face to face counselling. Nicotine gums were prescribed for 3 months duration. At the end of 12 months, follow up outcome was measured.

Results: At 1 week 24% smokers, at 1 month 23%, at 3 months 12% and at 6 months 33% smokers attended face to face counselling session. At 1 week 66%, at 1 month 57%, at 3 months 63% and at 6 months 59% smokers received telephonic counselling. Nicotine gums were used by only 76% smokers. Out of those who used nicotine gums, only 3% used gums for 3 months duration and 97% stopped prematurely. Among those who used gums, 29% experienced side effects. Total 22 (26%) smokers stopped smoking at 12 months.

Conclusions: Less number of smokers coming for follow up counselling visits, suggest lack of motivation. Alternative counselling, like telephonic counselling, was much more accepted and was found to be helpful. Acceptance of nicotine gums was very less which also shows the lack of motivation. Abstinence rate of 26% shows that counselling and nicotine gums help in quitting smoking.

Keywords: Counselling, Nicotine gums, Smoking cessation

INTRODUCTION

Smoking is the inhalation of the smoke of burning tobacco, encased in cigarettes, pipes and cigars.¹ Tobacco is an addictive plant containing nicotine and Nicotine is the drug in tobacco that causes addiction. Nicotine acts on the central nervous system by binding to nicotinic cholinergic receptors, predominantly alpha-4, beta-2 present in the pre synaptic region. This triggers the

release of transmitters such as acetylcholine, dopamine, nor adrenaline, serotonin, and beta-endorphin, among others. Nicotine which acts on the transmission of dopamine and nor-adrenaline, mediates their gratifying effects. Signs and symptoms of withdrawal develop in relation to adaptive responses in these neurological systems after repeated nicotine doses.² An average cigarette delivers between 1 to 3 mg of nicotine, while a bidi contains three to five times the amount of nicotine as regular cigarette.³ Tobacco dependence itself is a disease

and as a chronic disease, often involving relapses. Nicotine dependence is both physical and psychological and requires proper treatment.

Role of counselling in smoking cessation

Behavioural therapy for tobacco dependence and withdrawal helps in smoking cessation. Counselling helps in improving self-confidence, increasing motivation, and overcoming withdrawal symptoms.⁴

Role of nicotine replacement therapy in smoking cessation

Nicotine-containing medications make it easier to abstain from tobacco by replacing the nicotine formerly obtained from tobacco and thereby providing nicotine mediated neuropharmacological effects, such as increased expression and reduced turnover of nicotine receptors in the brain and other parts of the body and activation of dopaminergic reinforcement systems in the brain.⁴ The nicotine replacement medications reduce the withdrawal symptoms and may provide at least some effects for which the patient previously relied on smoking, like sustaining desirable mood and attention spans, making it easier to handle stressful or boring situations.⁴ Unlike smoking, nicotine medications deliver nicotine slowly, and the risk of abuse is low.⁵ Quitting tobacco is uncommon in India.^{6,7} Information on long term quit rates is also limited in India.⁸⁻¹⁰ So we planned to conduct this study, to observe the role of counselling and nicotine gums in our setup as the studies suggest that majority of smokers are bidi smokers in our area.

Interventions for smoking cessation

Simple advice; the cochrane review found that brief advice from doctors increased the quit rate (odds ratio 1.69, 95% confidence interval 1.45 to 1.98).¹¹ Simple advice from the physicians not to smoke can effectively motivate them and can lead to quit rate of 2-10%.⁴ More intensive advice was slightly more effective. Nurses providing individual counselling were also effective.¹¹

Behavioural and psychological Intervention/ counselling

Motivated smokers may seek help from smoking cessation counsellors or clinics, either one to one or in a group. Both individual counselling and group therapy increase the chances of quitting. Three types of counselling and behavioural therapies have been shown to produce higher abstinence rates: providing smokers with problem-solving/skill training (e.g. avoiding situations where other people are smoking, identifying triggers to smoking). Providing social support as a part of treatment. Helping smokers to obtain social support outside of treatment.¹¹

The Cochrane review of nine studies found that the individual counselling was better than the brief advice or usual care (1.55, 1.27 to 1.90). Individual behavioural counselling for smoking cessation can lead to cessation rate of approximately 11% to 20%.⁴

Pharmacological interventions for smoking cessation

Nicotine replacement products like Nicotine patch, gum, lozenge, inhaler, nasal spray and non-nicotine medications like bupropion SR, Varenicline are found to be effective in quitting smoking.¹²

Nicotine gums

It is available in 2-mg and 4-mg dosage forms, each of which typically deliver approximately 50% of their nicotine over a 15-30 minute period of oral use.¹³ Whereas 90% of the Nicotine present in inhaled smoke is absorbed over a period of 1-2 minute after smoking a cigarette.¹⁴ Smokers who use fewer pieces of gum achieve much lower concentrations of nicotine, which may reduce the efficacy of the treatment. Due to the importance of replacing nicotine in adequate quantities, success with nicotine gum treatment depends in part on how many pieces of gum the smoker chews per day. Smokers, who are more dependent have been shown to improve their chances of achieving abstinence with the 4-mg than the 2-mg gum.¹⁵ After a few weeks or months, the number of doses per day is reduced gradually, until it is no longer required. Nicotine gum also provides substitute oral activity during tobacco abstinence. The Cochrane review of over 90 trials found that nicotine replacement helps people to stop smoking. Overall, it increased the chances of quitting about one and a half to two times (1.71, 1.60 to 1.83), whatever the level of additional support and encouragement. However, observational population-based studies in US have shown mixed results. Some of the studies have shown that pharmacotherapy increases smoking cessation rates.¹⁶⁻¹⁸ Yet, some of the population based studies have shown no difference in cessation rates between those who use and those who did not use pharmacotherapy.^{19,20}

Combined therapy

Quit rates are high with combined therapy.²¹ The continuous validated abstinence rates for nicotine replacement therapy plus counselling, relative to counselling alone or usual care were 11%, 4% and 8% respectively (p=0.25), and for validated point abstinence 17%, 6% and 8% (p=0.03). The relative risk for continuous validated abstinence for NRT plus counselling versus the other two groups combined was 1.83 (95% CI 0.76 to 4.12, p=0.15), and for validated point abstinence the RR was 2.51 (95% CI 1.25 to 5.03, p=0.009).²¹ Abstinence rates were highest for the NRT plus counselling group. Based on the 40 studies (15,021 participants) there was good evidence for a benefit of combination pharmacotherapy and behavioural treatment

compared to usual care or brief advice or less intensive behavioural support (RR 1.82, 95% CI 1.66 to 2.00) with moderate statistical heterogeneity ($I^2 = 40\%$).²²

METHODS

This study was conducted over a period of one year and six months at Dr. Rajendra Prasad government medical College, Kangra at Tanda, Himachal Pradesh. Smokers with all grades of nicotine dependence willing to quit smoking, attending the outpatient clinic in the department of pulmonary medicine from April 2015 to October 2015 were enrolled after informed written consent. Exclusion criteria were terminally ill patients and smokers with history of hypersensitivity to nicotine. Detailed history of smoking, other substance abuse and other health related issues was elicited. At the time of enrolment, first session of counselling was given for a minimum of 20 minutes duration. Then counselling was provided at 1 week, 1 month, 3 months and at 6 months of follow up visit. Telephonic counselling was given to those who did not come for face to face counselling.

Elements of counselling

Counselling elements were to explain the risks associated with smoking, to explain the benefits of quitting smoking, avoiding triggers (Identify events, internal states, or activities) that increase the risk of smoking or relapse, asking help from the God (to explain powerlessness to provide intra treatment social support and to help patient to obtain extra-treatment social support.

Nicotine gum schedule

Smokers were prescribed nicotine gums for 12 weeks duration. Nicotine gums were prescribed for first six weeks, 1-2 hourly or S.O.S, next three weeks, 2-4 hourly or S.O.S and last three weeks, every 6 hourly or S.O.S. 4 mg gums were prescribed for smokers smoking >25 cigarettes/bidis and 2 mg for those who smoke <25 cigarettes/bidis or S.O.S. Light smokers or minimally dependent smokers were prescribed nicotine gums as per the physician's advice. Patients were encouraged to keep in touch with other patients in the study.

Outcome criteria

Follow up was done at 1 week, 1 month, 3 months and 6 months, and at the end of 12 months, outcome was measured. Self-reported reduction in cigarette, bidi consumption or total abstinence after 1 year is considered as end point, based on self-reporting by the smokers, confirmed by close relatives (witnessed) and exhaled carbon monoxide (CO) levels <10 ppm. Exhaled carbon monoxide levels were measured using piCO Smokelyzer. The primary endpoint was continuous abstinence from smoking and secondary endpoint was point prevalent abstinence. Continuous abstinence refers to sustained

abstinence between the point of intervention and a follow-up point. Point prevalent abstinence refers to abstinence during a time window immediately before the follow-up point (7 days).

RESULTS

Total 86 smokers willing to quit smoking were enrolled over a period of 6 months and were followed for the period of one year. The data obtained was compiled & analysed for the following parameters.

Nicotine gum usage

Nicotine gums were prescribed to all the smokers. Out of that only 65 (76%) used nicotine gums. 21 (24%) did not use the gums. Among those who used nicotine gums only 2 (3%) completed 3 month duration treatment. Rest 63 Patients (97%) used gums for an average 15.7 days then stopped using gums on their own, prematurely.

Reasons for premature discontinuation of nicotine gums

65 smokers used nicotine gums, out of those 63 stopped gums prematurely. Various reasons given for premature discontinuation were: smoking continued while usage of gums or relapsed back to smoking in 20 (32%). Side effects in 19 (29%). Stopped smoking within few days of using gums, therefore gums were no longer needed in 12 (19%). Bad taste of nicotine gums in 7 (11%). High cost of gums in 6 (10%). Stressful situations in life or family problems in 3 (5%) (Figure 1).

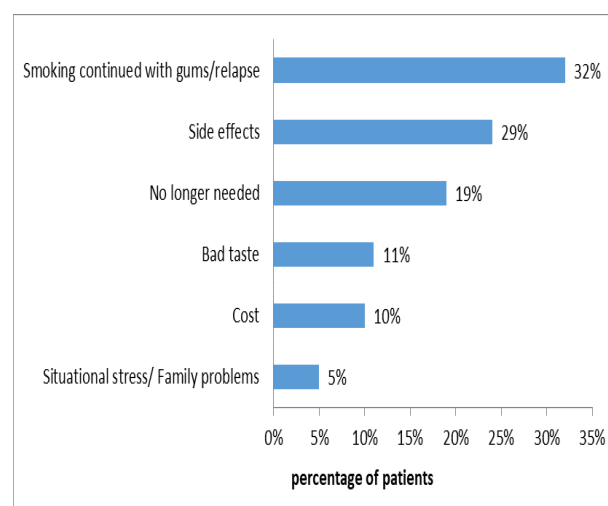


Figure 1: Reasons for premature discontinuation of nicotine gums (N=63).

Side effects associated with nicotine gums

Total 19 (29%) smokers experienced side effect like nausea in 6 (9%), sore throat in 6 (9%), hiccups 4 (6%), dizziness in 3 (5%) and vomiting in 3 (5%) (Figure 2).

Number of smokers who attended face to face counselling sessions at every follow up visit

Base line counselling was attended by all 86 smokers at the time of enrolment. Then the participants were called for the subsequent counselling sessions, but at 1 week only 21 (24%), at 1 month 20 (23%), at 3 months 10 (12%) and at 6 months 28 (33%) smokers came for face to face counselling sessions (Figure 3).

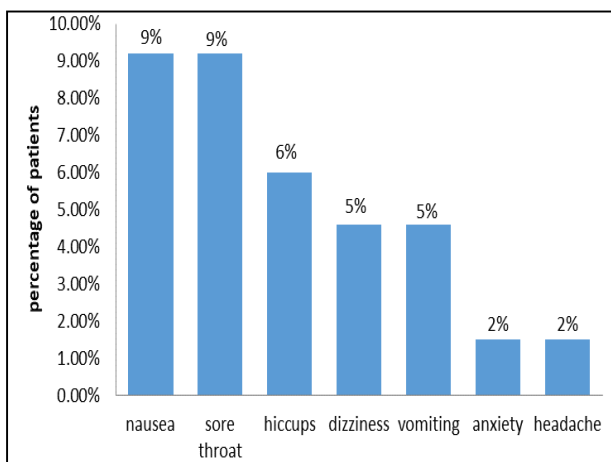


Figure 2: Side effects associated with Nicotine gums (N=19).

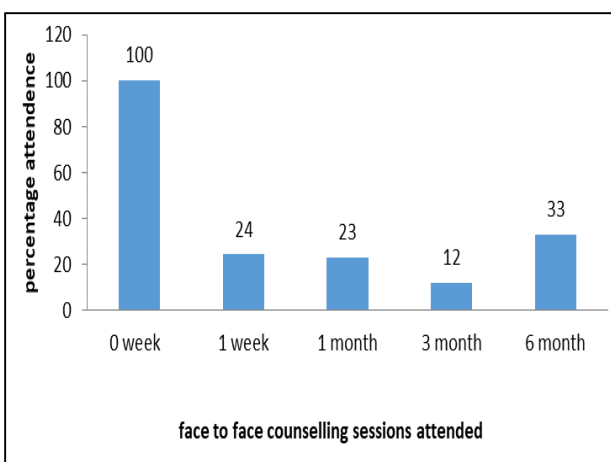


Figure 3: face to face counselling sessions attended by smokers.

Number of smokers who received telephonic counselling at every follow up visit

Those smokers who did not come for the counselling sessions were contacted telephonically to reinforce quitting smoking or remain abstinent. If they had already stopped smoking, their smoking cessation outcome was confirmed by their family members and was counselled to continue their abstinence. At 1 week 57 (66.3%) smokers, at 1 month 49 (57%), at 3 months 54 (63%) and at 6 month 48 (59%) smokers were given telephonic counselling (Figure 4).

Total number of face to face counselling sessions attended by smokers

If we take cumulative attendance then two sessions was attended by 48.8%, three by 24.8%, four by 10.4% and five was attended by 7% of the participants (Figure 5).

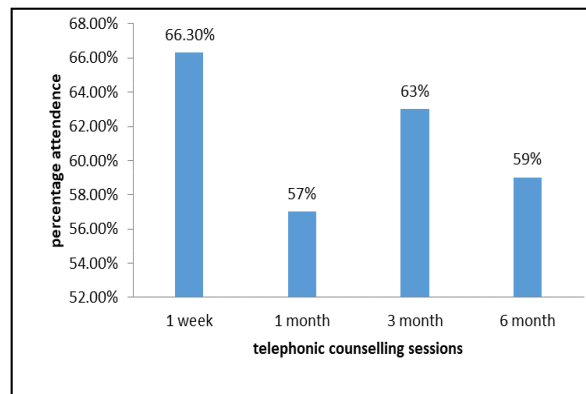


Figure 4: Telephonic counselling sessions attended by smokers.

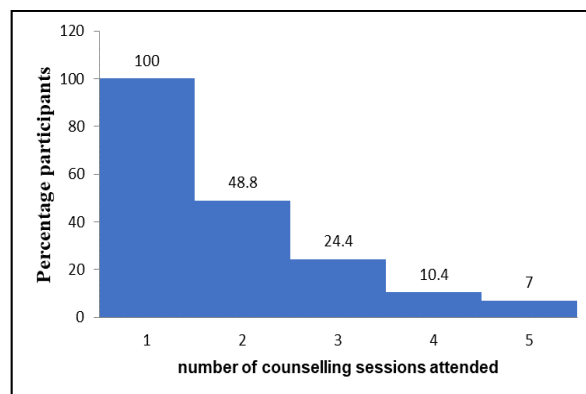


Figure 5: Total number of face to face counselling sessions attended by smokers.

Overall counselling sessions received at every follow up date

At 1 week 91% received counselling, 80% at 1 month, 74% at 3 months and 88% at 6 months (Figure 6).

Number of smokers who had not received any of the counselling sessions at follow up visits

Those who had not received any counselling (could not be contacted by any means) were 8 (9%) at 1 week, 17 (20%) at 1 month, 22 (26%) at 3 months, 10 (12%) at 6 months and 13(15%) at 1 year (Figure 7).

Outcome at 1 year

Number of smokers who stopped smoking at 1 year: Total 22 (26%) smokers stopped smoking at the end of one year. 4 were proven cases confirmed by exhaled air

carbon mono-oxide levels, 15 were confirmed by the witnesses (spouses and children) and 3 were self-proclaimed abstinent cases. Out of 22, 12 were continuously abstinent since the beginning and 10 were point prevalent abstinent before the follow up.

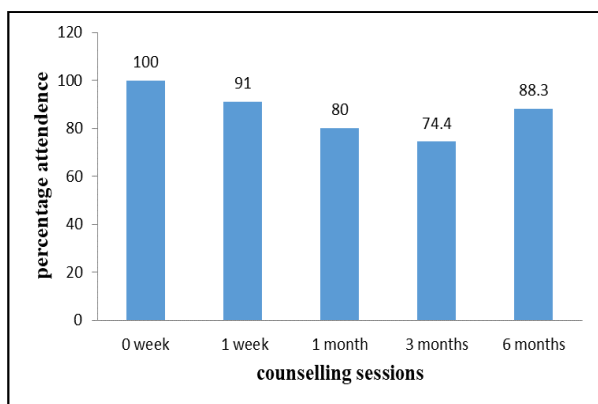


Figure 6: Overall counseling sessions received.

Number of smokers who reduced smoking to 50% at 1 year: Total 19 (22%) smokers reduced smoking at the end of one year. 8 were proven cases of smoking reduction confirmed by exhaled air carbon mono-oxide levels, 4 were confirmed by witnesses and 7 were self-proclaimed smoking reduction cases.

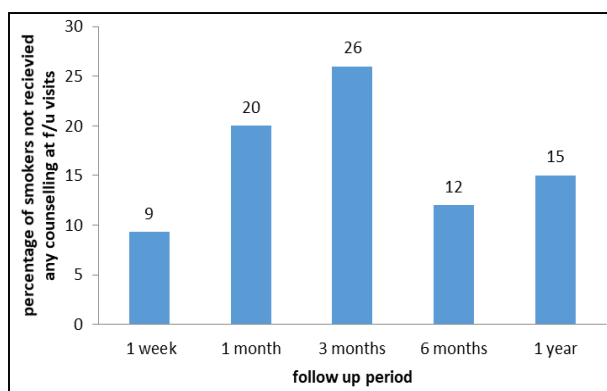


Figure 7: Smokers not received any counseling at follow up visits.

Number of smokers who continued smoking at 1 year: Total 32 (37%) smokers continued smoking at the end of one year. Number of smokers who were lost to follow up: Total loss to follow up was 13 (15%) at 1 year. Lost to follow up, were those smokers, who could not be contacted at 1 year follow up.

DISCUSSION

Smoking is widely prevalent. Smokers keep trying to quit because of various social and medical factors. Pharmacological and behavioural rehabilitation has been suggested by various research workers active in this field, but studies show variable results with pharmacotherapy.

This could be because various local factors may be having effect on the outcome. So we conducted the interventional study to find out the effect of counselling and pharmacotherapy in our setup as very less information is available on quit rates in India and also quitting is considered difficult here. Many factors affect cessation rates. Interventions may help in quitting smoking.

In the present study, total 86 smokers willing to quit were enrolled. Smokers coming for scheduled counselling session were very less; at 1 week only 21 (24%), at 1 month 20 (23%), at 3 months 10 (12%) and at 6 months 28 (33%) smokers came for face to face counselling. This shows that smokers don't come for the scheduled counselling sessions for smoking cessation. This could be explained by lack of motivation among smokers for quitting smoking. Telephonic counselling is much more acceptable than face to face counselling; at 1 week 57 (66.3%) smokers, at 1 month 49 (57%), at 3 months 54 (63%) and at 6 month 48 (59%) smokers were given telephonic counselling. This could be due to cost effective delivery, time saving, easy to use and easy availability regardless of location. This format appeals to those who are reluctant to get help face-to-face. More importantly it allows the counsellor to proactively follow up the smokers, thus addressing the problem of high attrition rates.²³

Acceptance of the nicotine gums was very less; only 65 (76%) smokers used nicotine gums. Among those who used nicotine gums none of the smokers followed prescribed dosing schedule. It is consistent with some of the studies which say that smokers do not use medication for the recommended duration.^{24,25} Smoking continued with gums or found ineffective, was the main reason for premature discontinuation of gums. This could be because smokers were using insufficient doses of the gums or they were having unrealistic expectations from the medication to work immediately and completely curb the cravings. Stopping gums due to bad taste in 19% shows that smokers lack motivation for quitting. Stress was not the direct reason for stopping gums, but due to stress smokers reverted back to smoking and then stopped medication. Side effects noted with the gums in 19 (29%) were mild and predictable and disappeared once medication was stopped.²⁶ The number of smokers, who were abstinent, kept on decreasing at every follow up. This has shown that long term quit rates were less among smokers. Quit rate was of 26% is very significant. In various similar studies, where face to face counselling was combined with telephonic counselling sessions, smoking cessation rates have been increased significantly in comparison to individual counselling alone.²⁷⁻²⁹ A meta-analysis has shown that proactive telephone counselling has odds ratio of 1.2 and estimated abstinence rate of 13.1%. Individual counselling has odds ratio of 1.7 and estimated abstinence rate of 16.8%. Group counselling has odds ratio of 1.3 and estimated abstinence rate of 13.9%.²²

CONCLUSION

Quitting smoking is a difficult process. In the present study, 26% smokers stopped smoking at one year follow up. Counselling was found to be of great help in remaining abstinent and reducing bidi/cigarette consumption. But compliance with scheduled counselling sessions was not much in the present study. At 1 week only 24%, at 1 month 23%, at 3 months 12% and at 6 months 33% smokers came for face to face counselling sessions. Alternative counselling like telephonic counselling was found to be helpful. At 1 week 66%, at 1 month 57%, at 3 months 63% and at 6 month 59% smokers were provided telephonic counselling. Present study shows that the acceptance of nicotine gums among smokers was very less. Further population based studies should be conducted on large number of smokers to the check effectiveness of nicotine gums and counselling.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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