Comparative evaluation of three different tobacco cessation interventions among the rural population of Modinagar, India - A randomized controlled trial

[1]Dr Anil Kumar, 3rd Year Student, Department of Oral and Maxillofacial Pathology

[2]Dr. Sanjeet Singh, Professor, Department of Oral and Maxillofacial Pathology

[3]Dr. Deepti Jawa, Professor, Department of Pediatrics & Preventive Dentistry

[4]Dr. Nishant Singh, Professor, Department of Oral and Maxillofacial Pathology

[5]Dr. Paramjit Singh, Professor, Department of Oral and Maxillofacial Pathology

[6]Dr. Kanika Sharma, Reader, Department of Oral and Maxillofacial Pathology

Corresponding Author: Dr Anil Kumar, 3rd Year Student, Department of Oral and Maxillofacial Pathology

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Introduction: Human health is one of the most important factors influencing economic development in any economy. Adverse habits like smoking, alcoholism etc. affect the overall health of human body and it has been that for the past few decades tobacco usage is dangerous in developed countries. Tobacco use is harmful to all human biological system; including the oral cavity.

Material and method: in the present study a randomized controlled trial was done among 150 subjects allocated in three groups. Counseling only, NRT using gum plus counseling and NRT using patch plus counseling and subjected to respective intervention for 3 months period. The reduction in frequency and amount of tobacco use, change in nicotine dependence score and difference in levels of exhaled carbon monoxide between baseline and follow up were used to evaluate the effectiveness of three interventions.

Results : There were more number of smokers who smoke daily at baseline but reduced at follow-up in all of the study groups but more number of reductions in smoking frequency has been reported in Group II (NRT using gum + counseling) and Group III (NRT using patch + counseling) than Group I (counseling) (p=0.001). Similarly more percentage reduction in nicotine dependence scores was seen in Group II and Group III than Group I.

Conclusion: NRT using Gum given with brief counseling was an effective routine smoking cessation intervention

Keywords: Tobacco, Cessation, Nicotine, Counseling, Patch, Gum.

Introduction

Nicotine dependence has been recognized as one of the major public health problems facing the human race, both in the developing and the developed countries. It kills one person prematurely every six smokers globally and one in two long-term smokers – largely in low- and middle-income countries. The total number of premature deaths caused by tobacco during the twentieth century has been estimated at about 100 million and, if current trends of tobacco use continue during the twenty-first century, the death toll is projected to go up to one billion. The World Health Organization (WHO), which

provides these estimates, also predicts that India will have the fastest rate of rise in deaths attributable to tobacco in the first two decades of the twenty-first century. Many of these deaths will occur in the productive years of adult life, as a consequence of an addiction acquired in youth.[1]. Tobacco use is harmful to all human biological system; including the oral cavity.[2]

This invivo study was done to comparatively evaluate three different tobacco cessation interventions (Counseling only, Nicotine replacement therapy using Gums with counseling and Nicotine Replacement Therapy using Transdermal Patch with counseling) among the rural population of Modinagar, India

Materials and Method

A randomized control trial was conducted at Department of oral pathology to evaluate the effectiveness of three different tobacco cessation interventions (Counseling only, Nicotine replacement therapy using Gums and Nicotine Replacement Therapy using Transdermal Patch) for the period of 3 months.

A specially prepared structured questionnaire was administered to the study participants to know the demographic variables, dietary habits, sugar exposure, and oral hygiene practices, history regarding the alcohol usage, duration, form and frequency of tobacco usage. Fagerstrom test of nicotine dependence questionnaire was also used to know the scores for nicotine dependence.

Clinical evaluation of smoking was done by measuring the exhaled carbon monoxide using carbon monoxide monitoring device i.e. Mini Carbon Monoxide Meter that fulfilled the eligibility criteria.(fig:1)

Total 150 subjects were included in the study that was smoking tobacco.

Counseling group (Group I)

The subject in the counseling group was given tobacco cessation advice for the initial period of 20 minutes along with the 11 written materials for reinforcement.

The Nicotine gum group (Group II)

Nicotine gums in the dosage of 4mg per day for those who smoke 25 or more cigarettes a day and 2 mg per day for those who smoke less than 25 cigarettes per day, was given to the NRT group for the entire intervention period and this was scheduled for 12 weeks as follows :-

Weeks 1-6: One piece of gum every 1-2 hours

Weeks 7-9: One piece of gum every 2-4 hours

Weeks 10-12: One piece of gum every 4-8 hours.

The NRT patch group (Group III)

Nicotine patches are applied directly to the skin. They are applied once a day, usually at the same time each day. Nicotine patches come in various strengths and may be used for various lengths of time**.** You should wear the patch continuously for 16 to 24 hours, depending on the specific directions inside your nicotine patch package. A switch to a lower strength patch may be considered after the first 2 weeks on the medication. A gradual reduction to lower strength patches is recommended to reduce nicotine withdrawal symptoms. Nicotine patches may be used from 6 to 12 weeks[3]

NICOTEX TRANSDERMAL PATCH-1 (21 mg delivered over 24 hours)

Weeks 1-4: one patch everyday

↓

NICOTEX TRANSDERMAL PATCH-2 (14 mg delivered over 24 hours)

Weeks 5-8: one patch everyday

↓

NICOTEX TRANSDERMAL PATCH-3 (7mg delivered over 24 hours)

Weeks 9-12: one patch everyday

Intragroup Comparison of Nicotine Dependence Scores

Groups	Baseline	3month	Paired T value	p value
GROUP I (Counselling)	4.20±0.75	2.80±0.75	16.333	0.001 (Sig)
GROUP II(NRT- GUM)	3.60±1.03	1.40±0.83	10.782	0.001 (Sig)
GROUP III (NRT-PATCH)	3.80±0.75	1.98±1.22	9.866	0.001 (Sig)

Results

From base line to follow-up change in Nicotine dependence scores was observed in all groups. In Group I (counseling) at baseline the mean score was 4.20±0.75 which has changed to 2.80±0.75 at follow-up. In Group II (counseling + NRT using Gum) the mean Nicotine dependence score at baseline was 3.60±1.03 which has changed to 1.40±0.83 at follow-up. In Group III (counseling + NRT using patch) the mean Nicotine dependence score at baseline was 3.80±0.75 which changed to 1.98±1.22 at follow-up. Above scores were found to be statically significant (Table 1).

There was significant change in level of carbon monoxide in Group II followed by Group III. Whereas least number of change was observed in Group I. In Group II change in CO levels was 81.36±5.07 % followed by Group III which was 78.13±4.92. And in Group I it was 19.62±9.35. The above scores were found to be statically significant (p=0.001).

Discussion

There are number of tobacco cessation interventions available for example- nicotine gums, nicotine patch, nasal spray etc. In this study Nicotine Gum and Patch therapy has been evaluated. The Nicotine gum therapy was found to be more efficient.

The reason for this is that nicotine gum helps by replacing some of the nicotine you would normally get from smoking and it can help to manage cravings.

Nicotine patch therapy can not only increase your addiction and tolerance to nicotine, but it also puts you at risk for nicotine toxicity.

Nasal spray causes burning sensation, throat irritation so cannot be used for Nicotine replacement therapy.

There was significant change in level of carbon monoxide and nicotine dependence score in Group II (nicotine gum + counseling) followed by Group III, whereas least number of changes was observed in Group I.

In past literature studies have been done with Nicotine replacement therapy to evaluate the effectiveness for example-

Fagerström K.O et al (1993)[4]. This study tested whether combining the two methods would relieve withdrawal more effectively compared to either treatment alone. The findings suggest: combining nicotine gum with transdermal nicotine may be superior to either treatment alone, but nicotine patch may cause toxicity, gum therapy manages craving of smoking without risk of toxicity. This is in accordance with my study.

Thorsteinn Blonda et al (1999)[5] evaluated the efficacy of using nicotine patch for 5 months with a nicotine nasal spray for 1 year. The low percentage of participants using the nasal spray at 1 year, and the few relapses during the second year, suggest that it is not cost effective to use a nasal spray and suggested that nicotine patch is the accepted criteria.

Hartmann-Boyce et al (2004)[6] To determine the effect of NRT compared to placebo in aiding smoking cessation, and to consider whether there is a difference in effect for the different forms of NRT (chewing gum, transdermal patches, nasal spray, inhalers and tablets/lozenges) in achieving abstinence from cigarettes. NRT with nicotine gum is better to prevent toxicity. The result of this study relates correctly with present study.

S.Erhan Deveci et al identified decrease in CO level of person who stopped smoking for more than 7 days and also showed varied data of regular smokers.. Our results show that exhaled CO levels may be used to distinguish smokers from non-smokers as same as the others.CO measures as blood carboxyhaemoglobin or in expired air gave sensitivity and specify of about 90% for distinguish smokers from non-smokers.[9] This is in accordance with my study.

Maria K. W. et al (2017) [10] The aim of this study is to compare the effectiveness of combined NRT with single NRT among HK Chinese. Single NRT group received counseling and nicotine patch. Primary outcome was abstinence rate measured as self-reported 7-day point prevalence with CO validated at 52 weeks. Here NRT is proven better that counseling alone. The result of this study relates correctly with the present study.

Conclusion

It was concluded that the Nicotine gum therapy proves to be more efficient in tobacco cessation intervention when compared with counseling alone and counseling + NRT using patch therapy.

References

1. Reddy KS et al , Gupta PC. Report on tobacco control in India. Ministry of Health & Family Welfare, Government of India. Report number. 2004;1:1–378

2. George et al Johny MK, Mulamoottil MV, Lonappan J. Tobacco- a deadly poison. Asian Pac. J. Health Sci. 2014;1(4S):6–13

3. T F Heatherton et al The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire British Journal of Addiction (1991) 86, 1119-1127

4. Fagerström, K.O et al Effectiveness of nicotine patch and nicotine gum as individual versus combined treatments for tobacco withdrawal symptoms1993

5. Thorsteinn Blonda et al Nicotine nasal spray with nicotine patch for smoking cessation: randomised trial with six year follow up 1999

6. Hartmann-Boyce et al Nicotine replacement therapy for smoking cessation n The Cochrane Library 2004, Issue 2

7. Mamta Parashar, et al Prevalence and correlates of nicotine dependence among construction site workers: A cross-sectional study in Delhi

8. Robert E. Rake et al Nicotine Addiction 2012, Pages 1105-1122

9. S.ErhanDeveci et al The measurement of exhaled carbon monoxide in healthy smokers and non-smokers

10. Maria K. W. Leung et al Combined nicotine patch with gum versus nicotine patch alone in smoking cessation in Hong Kong primary care clinics: a randomised controlled trial2017