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Original Research Article

Efficacy, tolerability and compliance of nicotine patches among Qatari population: a retrospective study

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ABSTRACT

Background: Tobacco use is a primary global health concern with significant adverse effects on public health and life expectancy. This study evaluated the safety, efficacy, and compliance of nicotine replacement therapy (NRT) among smokers in the Qatar population.
Methods: A retrospective analysis was conducted on 400 individuals enrolled in a smoking cessation program in an outpatient department. The participants were randomized into a NRT group (300 participants) and a control group (100 participants).
Results: No significant differences were found in adverse effects between the NRT and control groups, including palpitations, chest pains, nausea, vomiting, gastrointestinal complaints, and insomnia. Skin allergy or itching was rare in the NRT group. There was no statistically significant increase in anxiety or depressive symptoms associated with NRT use. Additionally, there was no significant difference in both groups' primary outcomes or efficacy.
Conclusion: These findings suggest that NRT is a safe and effective smoking cessation method for smokers in the Qatar population. The use of NRT should be considered alongside counseling and medical monitoring to improve smoking cessation rates.

Keywords: NRT, Transdermal nicotine patch, Efficacy, Adverse effects of patch, Cigarette smoking, Qatar

INTRODUCTION

Tobacco consumption across the globe is an issue of monumental concern for health. A staggering 70% of deaths related to smoking are reported in individuals aged over 60, dramatically curtailing life expectancy by approximately 15 years.[1] In Qatar, a country in the Middle East, recent statistics have shown that the rate of tobacco use among adults, encompassing both Qatari nationals and expatriates, stands at 25.2%.[2] The Clinical Practice Guideline for smoking cessation issued by the US Public Health Service, along with recommendations made by various countries, fervently encourage the utilization of smoking cessation pharmacotherapy for all individuals embarking on the journey to quit smoking.[3]

A plethora of studies and literature on smoking cessation services for adults are available, and the wealth of knowledge on this subject has been exhaustively examined through various Cochrane reviews.[4,5]

Nicotine replacement therapy (NRT) is an umbrella term for pharmaceutical interventions that exist in a diverse range of forms, such as skin patches, chewing gum, nasal and oral sprays, inhalers, lozenges, electronic cigarettes, and tablets, all ingeniously designed to deliver nicotine to the brain.[6-8,10,11-17] NRT works by attenuating the cravings for smoking, alleviating withdrawal symptoms, and ultimately bolstering the chances of successfully abstaining from smoking.[4,12] It accomplishes this by substituting the nicotine that would otherwise be sourced from cigarettes, thereby diminishing the compulsion to smoke and aiding in the cessation process.[6] NRT, backed by a robust safety and efficacy profile, has been embraced globally as a cornerstone pharmacotherapy in the battle against tobacco addiction.[4-23]

Within the NRT spectrum, the transdermal nicotine patch (TNP) emerges as a particularly productive method. TNP, a widely favored choice among smokers seeking to quit, has earned the approval of the FDA as a treatment for nicotine dependence and can be procured either over the counter or through a prescription.[8,13] These patches are engineered to achieve plasma nicotine concentrations within the lower range typically observed after smoking a single cigarette, around 10-20 ng/ml.[10] Setting themselves apart from other nicotine delivery systems, these patches gradually and passively administer nicotine by being affixed to the skin and releasing a steady dose of nicotine through dermal absorption.[4] TNP systems are available in varying formulations; certain brands are designed to be worn for 24 hours (offering 7, 14, and 21 mg dosages), while others are tailored for 16 hours of daily use (with dosages of 5, 10, and 15 mg).[4,6] TNP aims to methodically wean individuals off nicotine by delivering it in a controlled manner, thereby eradicating physical dependence on the substance.[14]

METHODS

In this retrospective study, we scrutinized data from 400 individuals who participated in a smoking cessation program in our outpatient department of the Tobacco Control Center, Hamad Medical Corporation, Doha, Qatar, where the study was held from March 2021 up to November 2023. The primary objectives of this study were to evaluate the efficacy of NRT, to monitor the incidence of any adverse effects, and to assess the adherence of participants to the prescribed treatment regimen.

Selection criteria

Patients were eligible for inclusion if they were active smokers enrolled in the smoking cessation program at the Tobacco Control Center, Hamad Medical Corporation, Doha, Qatar, between March 2021 and November 2023, had baseline demographic and smoking-history data available, and had documented follow-up for outcome and adverse-event assessment. Patients allocated to the NRT group received nicotine patch therapy as part of the cessation plan, while patients allocated to the control group received standard counseling and behavioral support without nicotine patch therapy. Exclusion criteria included incomplete medical records for primary outcome or adverse-event assessment, absence of follow-up data, non-active smoking status at presentation, or use of another pharmacologic smoking-cessation therapy during the study period (Figure 1).

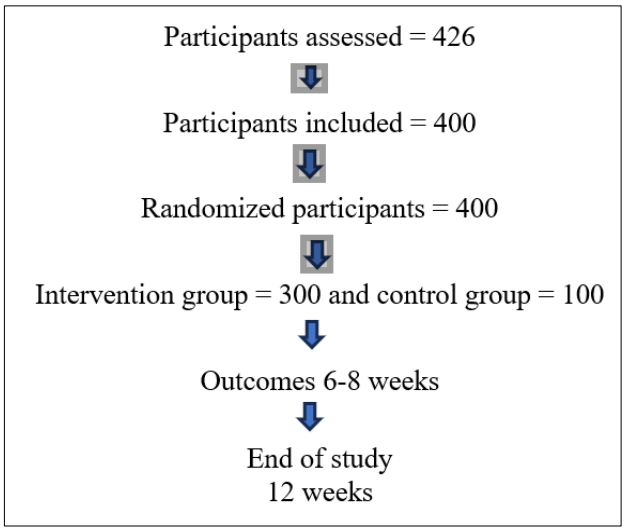

Figure 1: Selection criteria.

Categorical data were summarized and expressed as frequency (percentage). Quantitative data were summarized and expressed as mean±standard deviation if normally distributed or median [inter-quartile range (IQR)] if not. Descriptive statistics were used to summarize the patients' demographic, laboratory, coexisting conditions, and other related features. Associations between two or more qualitative variables were examined and assessed using Pearson's Chi-square and Fisher's exact tests as appropriate. Pictorial presentations of the key results were made using appropriate statistical graphs. A two-sided p value <0.05 was considered to be statistically significant.

RESULTS

We enrolled 400 patients. The number of adverse events was comparable between groups (NRT: 4, control: 6, p=0.2). At week 6, average quitters were comparable between the two groups: NRT=116 versus the control group=31 (Figure 2).

Four hundred active smokers were identified in our outpatient department, and 300 randomized participants were enrolled in the NRT group, whereas 100 were enrolled in the control group to study the safety and efficacy of NRT amongst smokers in the Qatar population. No significant differences were found between the NRT

and control group patients concerning adverse effects (Figure 3).

Palpitations and chest pains (NRT=10, control group p<0.3); nausea and vomiting (NRT=12, control group=5, p<0.1); insomnia (NRT=112, control group=56, p<0.2). Evidence specific to skin allergy/itching was present in very few participants in the NRT group=1 versus the control group=0. There was no statistically significant increase in anxiety or depressive symptoms associated with NRT use.

There was no significant difference in primary outcomes/efficacy between the groups NRT and control groups (Tables 1 and 2).

Table 1: Patient characteristics for both groups.

Characteristics	Smokers n=300	Control group n=100
Demographics		
Age in years		30-55
Gender	Nationality	
Co-morbidities		DM, HTN, CAD
Smoking history		
Type of smoking		
Cigarette	265	85
Shisha	35	15
Smoking duration (years)		10-20
Consumptions per day (no. of cigarettes per day)		10-30
Previous smoking cessation attempt	No	No
Nicotine patch		
Any other alternative used for cessation/behavioral modification/exercise/meditation		
Using nicotine patch		Yes
Nicotine patch dose (mg)	14-21	-
Number of patches used	20-30	-
Frequency of patch usage	Daily	-
Regular follow up at cessation clinic	Yes	Yes
Was patch usage successful in cessation?		Yes
Was behavioral modify-cation successful in cessation?	Yes	Yes
Date of cessation/weeks	3-4	4-6
Withdrawal symptoms of smoking		Yes
Nicotine toxicity (i.e., smoking with the use of patch)		No
Any adverse effects of patch		Yes
Allergy to patch	Yes	NA

Table 2: Duration and dosage of nicotine patch.

Daily smoking/ weight	Weeks (patches/day)		
	Week 1-2	Week 3-4	Week 5-8
>20/< 70 kg	2	1	0.5
>20/<70 kg	2	1	0.5
<20/<70 kg	1	0.5	0.5

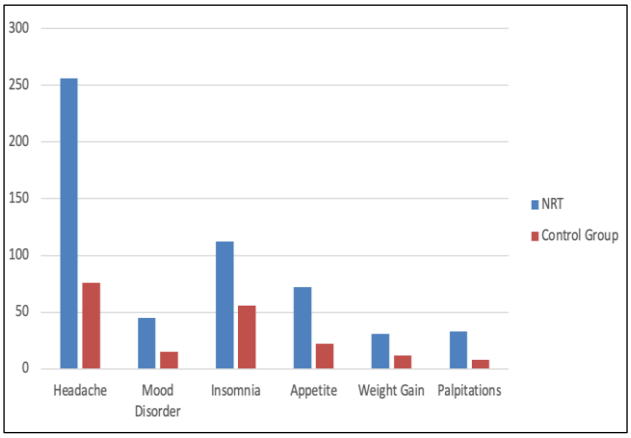

Figure 2: Summary estimates of adverse events reported in several patients.

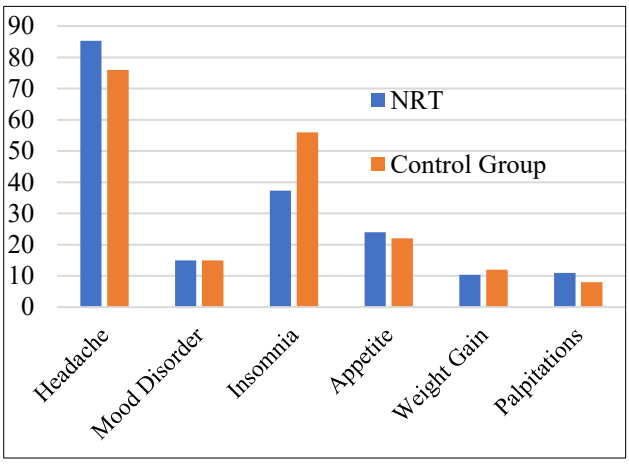

Figure 3: Summary estimates of adverse events reported as a percentage.

DISCUSSION

According to a sizable population-based cross-sectional survey in Qatar, the prevalence of current tobacco uses among individuals 18 and older, both Qataris and non-Qataris, is roughly 25.2%.[2] Here, we discuss the findings of a study conducted in our outpatient department involving 400 active smokers. The participants were divided into two groups: 300 were enrolled in the NRT group, while 100 were assigned to the control group. The study aimed to assess the safety and efficacy of NRT among smokers in the Qatar population.

The American Heart Association and the United States Department of Health and Human Services encourage using NRT to assist smokers in quitting.[23] In general, the use of NRT, including the TNP, is well tolerated in both adolescents and adults, and TNP has emerged as one of the most popular and effective smoking cessation methods for adult smokers attempting to quit.[8] TNP releases nicotine gradually and is simple to apply. They are available in dosages of 5, 10, and 15 mg per patch, which can be worn for up to 16 hours; however, doses of 7, 14, and 21 mg per patch can be worn for up to 24 hours.

Nicotine absorbs through the skin quickly and effectively, with a relatively high F of 68–82%.[15] The effectiveness of nicotine patches was examined in a trial, and regular use of the drugs for 3-weeks increased quitting rates at the 6-week checkpoint compared to non-regular users.[22] The two studies that used this procedure exhibited longer-term cessation rates comparable to those mentioned in the adult literature.[19-21]

Additionally, data indicate that TNP therapy may be beneficial when used with psychotherapy for at least ten weeks and at a dose based on daily cigarette consumption.[16] An alternative source of nicotine is offered by NRT. Nicotine receptor stimulation reduces cravings and withdrawal symptoms. Peak withdrawal symptoms include nicotine cravings, irritability, anxiety, restlessness, disturbed sleep, and a slowed heart rate. These symptoms peak within the first 72 hours following quitting.[23]

The clinical practice guidelines for treating tobacco use and dependence stated that smokers using TNP were roughly twice as likely to be smoke-free after six months compared to smokers who received a placebo.[8] A recent Cochrane review discovered that smokers using TNP were 64% more likely to be smoke-free across 43 clinical trials compared to smokers in control or placebo groups.[4-6] All the information points to TNP as a medication that helps smokers quit more successfully.[8]

Limitations

This study has limitations inherent to its retrospective, single-center design, including reliance on the accuracy and completeness of medical records, possible selection bias, unequal group sizes, lack of blinding, and a relatively short follow-up period. Potential confounding factors, including baseline nicotine dependence, previous quit attempts, adherence to patch use, counseling intensity, and concurrent behavioral modification, could not be fully controlled. These limitations may affect the generalizability of the findings and the ability to detect small differences in efficacy or adverse events.

CONCLUSION

The use of NRT is not associated with significant adverse effects. In addition to counselling and medical monitoring, clinicians should inform patients of minimal potential side effects associated with the use of NRT for the treatment of tobacco dependence. However, no statistical difference in efficacy was noted in our study. NRT did not affect the number of adverse events compared with placebo. Time to quit smoking/tobacco at week 6 in NRT patients was longer but not statistically significant than in control patients. An adequately powered randomized controlled trial to further study the safety and efficacy of NRT in the population seems feasible and is warranted.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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