Research Article

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EVALUATION OF THE EFFECTIVENESS OF FREE NICOTINE PATCH THERAPY IN A CHARITY CLINIC FOR SMOKING CESSATION

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ABSTRACT

The purpose of this study was to evaluate the efficacy of a free nicotine- patch therapy for smoking cessation in Saudi smokers. A single centered prospective study was carried out in a charity clinic for smoking cessation in Riyadh, Saudi Arabia. A total of 31 subjects who attended the smoking cessation clinic from June 2014 to August 2014 were studied. All participants were male and their mean age was 31.1±6.4 years. The duration of history of smoking was 12.9±6.8 years. The nicotine- patch therapy outcomes were measured at baseline and at 6 weeks after using nicotine- patch therapy. At base line the number of cigarettes per day was 27±10 and carbon monoxide (CO) level was 20.2±8.3. The analyzed statistics revealed that there were significant decreased in the number of cigarette per day (p=0.001) and Carbon Monoxide (CO) level (p=0.001) over 6 weeks of nicotine- patch therapy. After 6 weeks of therapy, abstinence rate was 58 % (verified by CO level) and no serious adverse reactions were documented. The most common side effects were nausea, headache and local irritation sings. In addition, our finding revealed that smokers were likely to suffer from withdrawal symptoms following trying to quit. These withdrawal symptoms include sleep disturbance, loss of concentration and weight gain as well as irritability. Results of this study show that free nicotine-patch therapy is an effective measure for smoking cessation in Saudi population.

Keywords: nicotine patch therapy, smoking cessation clinic, side effects

INTRODUCTION

Smoking is major public health problem and a condition that leads to increase morbidity and mortality (Fiore *et al.,* 2008). The World Health Organization (WHO) statistics showed more than 5 million of people killed per year due to tobacco use (WHO, 2014). It has been postulated that the number of tobacco- related deaths worldwide in the year 2020 could increase to 8.4 million (Al-Rifi, 2004). Complications related to smoking are cancer, heart disease, stroke, and chronic obstructive pulmonary disease (Preechawong *et al.,* 2011).

Smoking in Saudi Arabia influenced by cultural and environment; the country has history of smoking more than 50 years (Al-Rifi, 2004). Patterns of smoking in Saudi population include cigarette and other smoking paste-mixture such as Jurake and mehassel (Al-Arifi *et al.,* 2006). Consequently, smoking is major public health issue in Saudi Arabia, as it has been estimated that 2.4 -52.4% of Saudi Arabia are smoker (Bassiony, 2009). Among adolescents, the prevalence of current smoking ranges from 15%-30%.(Jarallah *et al.,* 1996; Lam *et al.,* 2005). In addition, smoking is not only dangerous to people but contributing to be social cost. Saudi Arabia spends around $315 million for purchasing tobacco every year (Bassiony, 2009).

The most effective intervention of reducing serious complications in smokers is to quit smoking (Lam *et al.,* 2005). Nicotine- patch therapy is an effective pharmacological assist for smokers attempting to quit, and it has been evidenced as first line treatment for smoking cessation (Xiao *et al.,* 2014). However, limited smoking cessation studies established in Asian populations have been established in China, and Taiwan (Lam *et al.,* 2005; Hsueh *et al.,* 2010,

Xiao *et al.,* 2014). In addition, there is little data from the Middle East namely Kingdom of Saudi Arabia focusing on ethnic differences in tobacco dependence, smoking cessation and behavioral aspects of quitting smoking.

Free nicotine patch program has shown significant impact in helping certain ethnicity to quit smoking achieving an abstinence rate of 26.7% in 4 months follow-up period among Asian American population in the United States (Shelley *et al.,* 2010). Several charity and free smoking cessation programs and clinics are available in Saudi Arabia; however, to best of our knowledge, no study was conducted to evaluate the efficacy, safety and tolerability of nicotine- patch therapy programs. Therefore, this study was done to investigate the effectiveness of a free nicotine- patch therapy for smoking cessation in Saudi Arabia.

MATERIAL AND METHODS

The current study was a single centered prospective study to evaluate the efficacy of a free nicotine-patch therapy in Saudi smokers through the period from June 2014 to August 2014. In addition to the efficacy, the safety of nicotine patch was assessed. The subjects were enrolled from a charity clinic for smoking cessation in Riyadh, Saudi Arabia. Any Saudi smoker who ages 18 years or older and smokes at least 10 cigarettes per day was included in the study. Subjects were excluded if subjects: (1) were using tobacco-containing products other than cigarettes;(2) were pregnant women; (3) had cardiovascular diseases; (4) used nicotine NRT within 6 months; (5) had a level of carbon monoxide less than 10 parts per million (ppm); (5) were diagnosed with psychiatric condition. Data collected included: socio-demographic data, physical examination, medical history and vital signs assessed by the clinic physicians, and analysis of an expired carbon monoxide (CO) sample. All these date were taken from patient's profile.

Intervention

The smoking cessation program was a 6-week program of free nicotine-patch therapy. Every subject received 21mg per day during the first and second week, 14 mg per day during the third and fourth week and 7mg per day during the fifth and sixth week. Proper application and usage of nicotine patch were delivered to all our study's subjects. The ethical approval was obtained from King Saud University College of Pharmacy. All participants were informed and briefed on the study. Then, they signed a written consent and scheduled for a medical screening examination.

Measures

Subjects attended the clinic weekly. Evaluations were done at baseline before the intervention of nicotine -patch therapy and at the sixth week visit after completing the treatment regimen. At baseline, data on number of cigarettes per day, CO levels, smoking history and patients' demographic data were obtained. The data collections were repeated after 6 weeks of receiving nicotine- patch therapy. The outcome of the nicotine-patch therapy was measured as changes in the number of cigarettes per day, the CO level, and abstinence rates. In addition, the adverse events were assessed by interviewing the participants.

Safety

The adverse events were assessed by interviewing the participants during their weekly visits. The researchers also reviewed the patient records to determine any adverse events

Efficacy

Abstinence rates: Smoking abstinence was determined by self-reported cigarette use and verified with a CO level lower than 10 ppm. The assessment of quit smoking included point-prevalence abstinence. The point-prevalence rate of abstinence measured at the 6th-week right after the treatment. Point-prevalence abstinence refers to the percentage of individuals who were not smoking during the previous 7 days (Chen *et al*., 2002).

CO levels: The CO levels were assessed by having subjects take a deep breath and hold it for 15 seconds before exhaling into a CO monitor (Bedfont Micro Smokerlyzer). Levels lower than 10 ppm was indicator of abstinence.

Statistical analysis

All the data were transferred to the spreadsheet of SPSS version 21 for analysis. Descriptive data were presented as numbers, frequencies, percentages, means and standard

Table I. The characteristics of participants (n = 31)

Variables	Mean (SD)	n (%)
Age in years	31.1(6.4)	
Gender		
Male		31(100)
Education level		
High school		14(45.2)
University		17(54.8)
The duration of history of smoking in eyras	12.9(6.8)	
The number of cigarettes per day	27(10)	
Carbon monoxide (CO) level	20.2(8.3)	

deviations. Wilcoxon test was used to analyse the significance of variations before and after intervention.

RESULTS AND DISCUSSION

Baseline characteristics

A total of 31 smokers who fulfilled the inclusion criteria were included in the study. The characteristics of participants are shown in Table I. All participants were male. The mean age of participants was 31.1±6.4 years. The duration of history of smoking was 12.9±6.8 years. The number of cigarettes per day was 27±10. The CO level was 20.2±8.3.

The outcomes of nicotine patch

The number of cigarettes per day

Reduction of the amount of cigarette smoking per day over the 6 weeks period summarized (Table II). The mean number of cigarette at baseline was 27 cigarette per day (SD=10) and at 6 weeks was 12.3(SD=16.3). There was significant reduction in the number of cigarette per day at base line and 6 weeks (p=0.001) from the intervention.

CO level

The CO level is an important measure of the efficacy of nicotine-patch therapy. The mean scores of the CO level pre-intervention and after the intervention was 20.2(SD=8.3), 11.1(SD=12.6) respectively (Table II). There was significant reduction in CO level after inter-vention of nicotine-patch therapy (p=0.001).

Abstinence rates

The point-prevalence rates of abstinence from smoking, as verified by CO levels showed that subjects were abstinent at 58 % at 6 weeks (18 of 31 subjects).

Adverse reactions

The majority of adverse reactions reported during the period of study were headache (19.3%), followed by itching (16.1) and redness (12.9). Table 3 shows others adverse reactions were reported. In addition only one participant of non quit smokers had adverse reaction namely headache.

Withdrawal symptoms

Withdrawal symptoms of smoking were sleep disturbance (35.4 %) , irritability (35.4 %) and loss of concentration (48.4%) (Table IV).

The present study evaluated the effectiveness and safety of nicotine-patch therapy in a population of Saudi Arabia. To our knowledge this was first smoking cessation carried out in Saudi Arabia smokers. The finding of this study revealed that nicotine-patch therapy for smoking cessation appeared to be safe and effective. These findings were consistent with a study evaluated the efficacy a free nicotine-patch program among Chinese American smokers living in New York City (Shelley *et al.*, 2010). A total of 375 subjects from two community-based organizations were enrolled to receive free nicotine patch therapy. Baseline and 4-months follow-up survey were used to determine the abstinence rate. The abstinence rate at 4 months was 26.7%. One of the main outcomes of smoking cessation is

Table II. The outcomes of nicotine patch therapy (n = 31)

Smoking status	Variables	Pre intervention Mean (SD)	Post intervention Mean (SD)	P* value
Quit smoking	CO level	16.3 (3.8)	2.8 (2.1)	P=0.001
	Number of cigarette	22 (4)	0.0	P=0.001
Continue smoking	CO level	25.6 (10.1)	22.8 (11.9)	P=0.067
	Number of cigarette	33 (12)	29 (13)	P=0.017
Total	CO level	20.2 (8.3)	11.1 (12.6)	P=0.001
	Number of cigarette	27 (10)	12 (16)	P=0.001

* Wilcoxon

Table III. Numbers of participants reporting adverse reaction events

Adverse events	n (%)
Redness	4 (12.9)
Itching	5 (16.1)
Headache	6 (19.3)
Nausea	4 (12.9)
Others	2 (6.4)

Table IV. Numbers of participants reporting withdrawal symptoms of smoking

Withdrawal symptoms	n %
Sleep disturbance	11(35.4)
Weight gain	8(25.8)
Irritability	11(35.4)
Loss of concentration	15(48.4)
Others	2(6.4)

abstinence rate. The abstinence rate of this study was 58% at 6 weeks. The abstinence rate had a high effect in smoking cessation through 6 weeks period of nicotine- patch therapy. Our higher abstinence rate was consistent with other studies (Chou *et al*., 2004; Paoletti *et al*., 1996), suggesting that the nicotine patch approach promoted smoking cessation in Saudi pupation.

This study found positive reduction in the number of cigarettes over 6 weeks. This demonstrated that nicotine patch therapy significantly reduce the daily cigarettes smoking. In addition, the significant reduction in CO level supported the reduction in daily cigarette smoking. The result supports the outcomes of previous studies that nicotine - patch therapy was effective in smoking reduction verified by reduction in CO level s and number of cigarette smoking per day (Joseph *et al*., 1996; Chou *et al*., 2004; Batra *et al*., 2005; Xiao *et al*., 2014).

This study confirmed the safety of nicotine –patch therapy amongst the Saudi smokers as reflected from the low prevalence of mild symptoms tolerated by Saudi smokers. This study reported 32.2% of side effect including systemic events (headache, nausea) and dermatitis disorders. However, our finding are much lower than those reported (50%) in USA (Transdermal Nicotine Study Group, 1991). Moreover, a similar study was carried out in china aimed to assess safety of nicotine patch in Chinese smokers reported that 26.3 % of subjects had gastrointestinal side effects (Xiao *et al*., 2014). This study showed that the most common withdrawal symptoms were sleep disturbance, loss of concentration, weight gain and irritability. All these withdrawal symptoms are consistent with several previous

studies (Dorothy *et al*.,1984; Hajek *et al*.,1989; Zhang *et al*., 2006; Tomson *et al*., 2006).

Although the findings of study are promising, the efficacy and safety of nicotine patch therapy in Saudi population, it has some limitations. One of the limitations is the participation was restricted to male smokers and limited by small size who attended the Naqa Charity Clinic. Therefore, the results of this study could only represent the situation in Riyadh city. Another limitation is the short-term follow-up of the smoking cessation and reducing rates. Thus, an extended time follow-up may be needed to demonstrate longitudinal benefits from the nicotine-patch therapy.

CONCLUSION

This study reported initial data on the safety and efficacy of nicotine patch therapy in Saudi population. The main contribution of this study showed that nicotine patch therapy can be an important adjunct to smoking cessation in Saudi smokers. Six –week abstinence rate showed higher effect after the use of nicotine-patch therapy.

REFERENCES

Al-Doghether MH., 2001. Do we need national guidelines for smoking cessation? *Ann Saudi Med*. 21: 3-4.

Al-Rifi M N., 2004. Prevalence of smoking and attitude toward smoking cessation among community pharmacists, Saudi Arabia. *J Pharm Tecnol*. 20:329-333.

Al-Arifi MN., Alkarfy, K . M., Al-Suwayeh, S . A, Aleissa , K . A., Shabana, E . I., Al-Dhuwaili, A . A., Al-Hassan, M . I., 2006. Levels of ^{210}Po in blood, urine and hair of some Saudi smokers. *J Radional Nucl Ch* 269:115-118.

Bassiony M M., 2009 . Smoking in Saudi Arabia. *Saudi Med J* . 30: 876-887.

Batra A., Klingler K., Landfeldt B., Friederich HM., Westin A., Danielsson T., 2005. Smoking reduction treatment with 4-mg nicotine gum: a double-blind, randomized, placebo-controlled study. *Clin Pharmacol Ther* 78: 689–696.

Chen R., Ku CH., Lu RB., Chou KR., 2002. The impact of smoking cessation programs on smoking-related health belief and rate of quit-smoking among schizophrenic patients. *J Med Sci* 22: 215–220.

Chou KR., Chen R., Lee JF., Ku CH, Lu R., 2004. The effectiveness of nicotine-patch therapy for smoking cessation in patients with schizophrenia. *Int J Nurs Stud* 41:321-330.

Dorothy K., Hatsukami Dk., Hughes JR., Pickens RW., Svikis D., 1984. Tobacco withdrawal symptoms: An experimental analysis. *Psychopharmacology* 84:231 - 236.

Fiore MC., Jaén CR., Baker TB., *et al*., 2008. Guideline Panel. Treating Tobacco Use and Dependence. 2008 Update. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service, 2008.

Hajek P., Jarvis M J., Belcher M. , Sutherland, G. , Feyerabend ,C., 1989. Effect of smoke-free cigarettes on 24 h cigarette withdrawal: A double-blind placebo-controlled study . *Psychopharmacology* 97*:* 99 – 102 .

Hsueh KC, Chen CY, Yang YH, Huang CL. Smoking cessation program in outpatient clinics of Family Medicine Department in Taiwan: a longitudinal evaluation. Eval Health Prof . 2010; 33(1): 12–25.

Jarallah J., Bamgboye E., Al-Ansary L., Kalantan K., 1996. Predictors of smoking among male junior secondary school students in Riyadh, Saudi Arabia. *Tob Control* ;5:26-9.

Joseph AM., Norman SM., Ferry LH., Prochazka AV., Westman EC., Steele BG., Sherman SE., Cleveland M.,

Antonnucio DO., Hartman N., McGovern PG., 1996. The safety of transdermal nicotine as an aid to smoking cessation in patients with cardiac disease. *N Engl J Med* 35:1792–1798.

Lam TH., Abdullah ASM., Chan SS., Hedley AJ .2005. Hong Kong Council on Smoking and Health Smoking Cessation Health Centre (SCHC) Steering Group. Adherence to nicotine replacement therapy versus quitting smoking among Chinese smokers: a preliminary investigation. *Psychopharmacology* 177: 400–408.

Paoletti P., Fornai E., Maggiorelli F., Puntoni R., Viegi G., Carrozzi L., *et al.*1996. Importance of baseline cotinine plasma values in smoking cessation results from a double blind study with nicotine patch. *Eur Respir* 9, 643–651.

Preechawong S., Vathesathogkit K., Suwanratsamee S., 2011, Effects of Tobacco Cessation Counseling Training on Thai Professional Nurses' Self-efficacy and Cessation Counseling Practices. *Pacific Rim Int J Nurs Res* 15: 3-12.

Shelley D, Nguyen N, Peng C-H, Chin M, Chang M, Fahs M. Increasing access to evidence-based smoking cessation treatment: effectiveness of a free nicotine patch program among Chinese immigrants. *J Immigr Minor Health*. 2010;12(2):198-205.

Tomson Toftgård M. , Gilljam H1., Helgason R S., 2006. Symptoms in smokers trying to quit. *Tob Indu Dis* 3:44-51.

Transdermal Nicotine Study Group 1991. Transdermal nicotine for smoking cessation. Six-month results from two multicenter controlled clinical trials. *JAMA* 266;3133–3138.

World Health Organization 2014. Why tobacco is a public health priority. (Updated 2014; Accessed 2014 November). Available from URL: http://www.who.int/tobacco/health_priority/en/index.html

Xiao D., Zhong N., Bai C., Xiu Q., Xie C.D., Hu D., Mao Y., PerfekR H., Kruse E., Li Q., Liu JJ., Wang C.,2014. Nicotine gum or patch treatment for smoking cessation and smoking reduction: a multi-centre study in Chinese physicians. *Front Med* 8:84-90.

Zhang L., Samet J., Caffo B., Punjab NM., 2006. Cigarette Smoking and Nocturnal Sleep. *Am J Epidemiol* 164: 529-537.