STUDY ON OUTCOME OF SMOKING CESSATION ATTEMPT AT QUIT SMOKING CLINIC IN A HEALTH CLINIC

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ABSTRACT

Background: Smoking is the leading preventable cause of non-communicable disease worldwide. Therefore effort for effective measure in smoking cessation will be beneficial. However, relapse is the central problem in the treatment of nicotine addiction. Understanding the relapse phenomena in smoking cessation program will promote better informed intervention and ultimately to achieve lifelong abstinence among the smokers. Due to the paucity of studies regarding the time to smoking relapse in this country, the objective of this study is to determine the time and survival curve of smoking cessation among the smokers attending a quit smoking clinic in one of health clinic at Kuala Lumpur. This study also aims to describe the characteristics of smokers and to determine factors that are associated with smoking cessation and relapse.

Methodology: A retrospective cohort study will be conducted using raw secondary data from a quit smoking clinic in a health clinic at Kuala Lumpur. About 770 smokers attending the clinic to participate in the program between 2008 and 2014 using simple random sampling method were identified. Medical records were reviewed to determine their characteristics and their outcome until December 2015. A standard proforma will be used to collect the data from the medical records.

Data Analysis: Both descriptive and inferential statistics will be used. Kaplan meier estimate will be used to describe the survival curve of the quit attempt. Multivariate analysis using Cox proportional hazards model to determine significant factors associated with cessation and relapse, and to obtain its hazards ratio.

Expected Outcome: The median time of smoker to the first relapse is expected to be different compared to existing local data given the heterogeneity of the sample populations. However, the median time to the successful smoking cessation is expected to be no different since the approach is to set a target quit date a priori compared to flexible quit date approach.

Keywords: Survival Analysis, Smoking, Cessation, Relapse, Kuala Lumpur
1.0 Introduction

Tobacco smoking is the leading preventable cause of non-communicable disease (NCD) death based on Global Burden of Disease 2010 (Naghavi et al., 2015). Tobacco smoking accounted for 6.3 million deaths every year worldwide (Institute for Public Health [IPH], 2011). It is predicted to increase to about 8 million deaths per year by 2030 based on current trend (IPH, 2011). Tobacco smoking including second hand smoke is associated with multiple diseases such as cancer, cardiovascular disease, respiratory disease and stroke (US Department of Health and Human Services, 2014). According to Zheng et al. (2014), Asian smoker particularly are at 1.5 fold elevated risk of death from any cause. Numerous studies have explored the risk of tobacco smoking and second hand smoke. It is still a major public health problem that needs effective intervention. The prevalence of smoking especially among young smoker and female smoker are on the rise (Hitchman & Fong, 2011). Based on the latest National Health and Morbidity Survey (NHMS) 2015, the prevalence of smoking was 22.8%, and more common among males 43% compared to women 14% (Institute for Public Health, 2015). Despite that, only 9.5% had quit from smoking (successfully abstinence for 12 months). However, the attempt for quit cessation is high with almost half 48.6% of adult smokers had tried for smoking cessation for the past 12 months and almost 80% of those attempt for quit smoking are without any assistance (IPH, 2010). In NHMS 2015 the prevalence of quit attempt was 52.3% (Institute for Public Health, 2015).

In Malaysia, the prevalence of smokers aged 15 years and above is 23.1% almost 4.75 million in 2010 and 22.8% in 2015. The rate of smokers is significantly higher among men (43.9%) compared to women (1%). The highest prevalence is in the 25 to 44 aged groups which are the productive aged group (IPH, 2015). Over the last 20 years the prevalence of smoking in Malaysia has been around 20 to 25%, and the consumption around 12 to 13 sticks per day but showing a decreasing trend (IPH, 2011). However, the mean age of smoking initiation was decreasing from 19.9 to 18.6 years. As the current cohort start to smoke earlier, the trend of smoking related disease and mortality will be expected to be accumulating in coming years.

WHO Framework Convention on Tobacco Control (FCTC) requires ever parties involved to take effective measures to promote tobacco cessation and adequate treatment for tobacco dependence (Yach, 2003). Malaysia became one of the parties in FCTC in 2005. The treatment for tobacco dependence includes the provision of behavioral support or medications or both (WHO, 2010). Malaysia has produced the clinical practice guideline for the treatment of tobacco dependence in 2003 that includes counselling, nicotine replacement therapy and medication (Mahayiddin et al, 2003). The quit smoking clinics (QSC) was initiated and funded by Health Promotion Division, Ministry of Health. The first quit smoking clinic in Malaysia was established at Hospital Ipoh, Perak in 1996 following the initiation Tobacco Cessation Clinic (TCC) by WHO (Ezat et al., 2008). The quit smoking clinic was then expanded to every hospital and health clinics. At present there were more than 300 QSCs nationwide. Apart from that, there are also other agencies that provide QSC exclusively for their staff such as Dewan Bandaraya Kuala Lumpur (DBKL) and public universities such as Universiti Malaya. The practice of QSC was based on the Malaysian Clinical Practice Guideline on treatment of tobacco use and dependence 2003 and were managed by certified healthcare professional based on Certified Smoking Cessation Provider (CSCSP) implementation.

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Relapse period after abstinence is a major problem in addiction treatment. Therefore, prevention of relapse particularly smoking relapse is the main problem in quit smoking program. A systematic review on unaided smoker found that most of the relapse occurs in the first week after quit date, around 49% to 76% (Hughes et al, 2004). At 3 months the relapse rate increased up to around 80 to 90%. However study from clinical trial on nicotine replacement therapy (NRT) found that 50% of lapse occur on first 32 days and of this relapse 90% have a second relapse 1 day after relapse (Shiffman et al, 2006). This might indicate that relapse is a major problem either in unaided smoker or with intervention. Recent review on relapse survival curve found that maximum risk of relapse was within 70 days after continuous abstinence. The risk than reduced to nearly zero after 100 days. It was suggested that 100 days of uninterrupted abstinence might be an important marker for prolonged abstinence (Kirshenbaum et al., 2009). However the pattern might be seen differently in Asian culture. A study in Japan found that the median time to relapse was 105 days (Igarashi et al, 2014). Within the first 7 days only 25% of subjects relapsed. In Malaysia, there are limited studies looking into the survival time from abstinence to relapse. A study among university staff in Malaysia found out that the survival rate reduced to 40% in the first 14 days after the quit date. The rate then reaches 25% between 2nd weeks to 2nd month. The curve than become plateau at the end of 2nd month to 6th month (Yasin et al, 2012). One might conclude that the first 60 days can be an important marker for a prolonged abstinence.

This research intends to look into the natural history of quit smoking and focusing to the time to relapse. By understanding factors that related to successful cessation and factors that contribute to relapse, modification and suggestion to the local quit smoking program can be made to help smokers achieve lifelong smoking abstinence. In addition to that, the result of this study can contribute to the body of knowledge regarding the predictors for successful quit smoking and risk factor for relapse. This can help health care providers in quit smoking clinics to detect possible relapse and also focusing on potential successful smoking cessation. A tailored intervention can be made by specifically to particular time and particular smoker group to help them quit smoking and prevent relapse.

2.0 Models of Smoking Cessation and Relapse

There are several models that explain the smoking behaviour particularly on the process of cessation and relapse. One of the models that gain popularity is Transtheoretical Model (TTM) by Proschaska and Di Clemente in 1983. The theory posit that the process of smoking cessation involve 5 stages; the pre-contemplation stage, the contemplation stage, the preparation stage, the action stage and the maintenance stage. Smoker’s progressions from stages are in sequence. At the pre contemplation stage, smoker does not have any intention yet to stop smoking. At contemplation stage, they are started to considering of changing the behavior within the next 6 months. According to the National Health and Morbidity Survey, majority of current adult smokers are in this stage. When smoker have more control over their behaviour, they will plan to change and make an attempt to quit. At this preparation stage, smoker plan to quit within 1 month, in which the risk of lapse is high. In action stage, there are specific changes to their behaviour particularly their lifestyles. Within this stage, the risk has of relapse is reduced and last about 6 month. Finally, maintenance stage is when action modification has attained stability of 6 months and they will maintain the behaviour.
Apart from TTM, there are other few other models that notably relevant in explaining smoking behaviour such as Theory of Reasoned Action (TRA) by Ajzen & Fishbein and Relapse Prevention Theory. Compared to the TTA, TRA posit that people are rational and they will use information available to them. Consequently, people will consider the implication of their action before deciding on that behaviour. However, TRA cannot be applied when behavior are not under the control of individual. Relapse prevention theory by Marlatt and Gordon (1985) initially develop to model the process of relapse in addictive behaviour. The theory proposed that effective coping in high risk situation such as smoking and alcoholism reduce the risk of relapse. Nonetheless, theories are useful in applying various strategies to help smoker at various stages.

3.0 Conceptual Framework

![Conceptual framework diagram]

Legend:
- Variables under study
- Potential confounder
- Association

Figure 1: Conceptual framework.
4.0 Materials and Methods

4.1 Study Location

Kuala Lumpur is the capital of Malaysia covering an area of 243 square kilometer. The estimated population of Kuala Lumpur in 2014 is 1.67 million. The study will be conducted at a quit smoking clinic in a health clinic at Kuala Lumpur. It is located within the Lembah Pantai Health District covering 362,700 population. Lembah Pantai Health District is under the Health Department Of Federal Territory Kuala Lumpur and Putrajaya.

4.2 Study Design

Retrospective cohort study design

4.3 Study Period

1st January 2008 until 31st December 2015

4.4 Sampling

4.4.1 Study Population

All smokers attending a quit smoking clinic in Kuala Lumpur.

4.4.2 Sampling Population

Inclusion criterias;
i.Malaysian citizen
Exclusion criteria;
i.Those who only come at baseline without any follow up.

4.4.3 Sample Size

The sample size estimation was based on Sample Size Determination in Health Studies by Lemeshow and Lwanga (1990). Two population proportions formula was used due to it being analytical in nature and comparing 2 groups for hypothesis testing. The study was designed to measure associations between age of started smoking and relapse. Using the formula by Lemeshow and Lwanga (1990):

\[
N = \left( \frac{Z_{\alpha/2} \sqrt{2p(1-p)} + Z_{1-\beta} \sqrt{p_1(1-p_1)p_2(1-p_2)}}{(p_1 - p_2)^2} \right)^2
\]

Figure 2: Hypothesis testing for two population proportion formula (Lemeshow et al, 1990)

Where
\(N\) = Sample size estimate
\(Z_{\alpha/2}\) = standard error associated with 95% confidence interval = 1.96
\(Z_{1-\beta}\) = standard error associated with 80% power = 0.842


\[ P_1 = \text{population proportion 1} \]
\[ P_2 = \text{population proportion 2} \]
\[ P = \frac{(P_1 + P_2)}{2} \]

The chosen sample size estimation was based on age of started smoking and relapse. The calculation below was based on relapse study in Malaysia (Su et al, 2012):

\[ P_1 = 0.63 \text{ (proportion of relapse in smoker started smoking at teenage)} \]
\[ P_2 = 0.55 \text{ (proportion of relapse in smoker started smoking in adulthood)} \]
\[ P = \frac{P_1 + P_2}{2} = \frac{(0.63 + 0.55)}{2} = 0.59 \]
\[ N = \left( \frac{1.96 \sqrt{2(0.59)(1-0.59)} + 0.842 \sqrt{0.63(1-0.63)0.55(1-0.55)}}{(0.63-0.55)^2} \right)^2 \]
\[ = 383 \]
Taking into account adjustment for comparison between two groups = 383 x 2 = 765
= 770 final sample size estimate.

### 4.4.4 Sampling Technique

A simple random sampling technique was used. A lists of all smokers attending the quit smoking clinic from 1st of January 2008 until 31st December 2014 will be acquired. The sampling unit will be the smoker’s research id number. The estimated number of smoker attending the clinic for the period is around 1000. The sample size required is 770. Using table of random numbers, the required random numbers will be selected.

### 4.5 Instrument

Data will be recorded on a standardised proforma based on the patient medical records. The proforma will be consisting of 3 parts. The first part consists of the demographic data such as the age, gender, ethnicity, marital status, occupation, educational level and income. The second part of the pro-forma consists of the nicotine dependent test using the Fagerstrom test. The third part is the smoking related data will consist all the patient smoking history data such as age of smoking initiation, smoking history, type of tobacco consumption, history of previous quit attempt, number of visits, duration of follow up, types of intervention given , reason for quit attempt, reason for relapse and other information.

### 4.6 Validity and Reliability

Face validity will be determined through feedback from enumerators. Enumerators will be independently reviewed the patient medical record and trained how to use the proforma. To ensure reliability, data will be double entered and any discrepancies will be resolved. To further determine inter-rater reliability, Kappa agreement and intra-class correlation coefficient will also be obtained.

### 4.7 Method of Data Collection

The source of data is raw secondary data that has not been analyzed. The data will be retrieved from the quit smoking clinics at the Klinik Kesihatan. Approval from the State’s Director of Health (Jabatan Kesihatan Wilayah Persekutuan) and the National Medical Research Register (NMRR) has been acquired for conducting research at the Ministry of
Health’s facility. The data will be verified in the patient folder record and enter into the standardized proforma by the enumerator.

5.0 Data Analysis

Data will be analyzed using IBM SPSS version 22.0. All categorical data will be described as percentage (%) while continuous data either mean and standard deviation or median and interquartile range. Statistical test will be used to accordingly.

Univariate (crude) analysis of variable using chi-square test and independent t test. Significant level was taken at 0.05. Kaplan Meier estimate will be used to describe the survival curve of quit attempt with the primary endpoint is the relapse and successful quit attempt. Multivariate analysis using Cox proportional hazards model will be used to determine the predictor for smoking cessation and relapse. The Cox model also will be used to estimate their hazard ratio and its associated 95% confidence interval.

6.0 Expected Outcome

The median time of smoker to the first relapse is expected to be different compared to existing local data given the heterogeneity of the sample populations. However, the median time to the successful smoking cessation is expected to be no different since the approach is to set a target quit date a priori compared to flexible quit date approach.

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Declaration

No conflict of interest is declared.
Authors Contribution

Author 1: Literature Review, Preparing Research Proposal and research activities.
Author 2: Contributing in methodological aspects, planning research activities and data analysis.
Author 3: Contributing in methodological aspects and planning research activities.

References


