Hela Abroug,1 Aymen El Hraiech,2 Ons Mehrez,3 Manel Ben Fredj,1 Imen Zemni,1 Arwa Ben Salah,2 Mohamed Ali Azaiez,
2 Walid Jomaa,
2 Faouzi Maatouk 2 and Asma Sriha Belguith 1

1Department of Epidemiology and Preventive Medicine, University Hospital of Monastir, Tunisia. 2Department of Cardiology, Fattouma Bourguiba Hospital, Monastir, Tunisia. 3Department of Family Medicine Faculty of Medicine, University Hospital of Monastir, Tunisia. (Correspondence to: Asma Sriha Belguith: belguith_asma@yahoo.fr).

Abstract

Background: Few randomized controlled trials have examined the efficacy time of smoking cessation in hospitalized patients with acute coronary syndrome (ACS, either during the hospitalization or after hospital discharge.

Aims: We aimed at assessing smoking cessation rates at 24 weeks among patients with acute ACS, in two groups; the first had begun nicotine replacement therapy (NRT) during hospitalization, and the second after hospital discharge. We also determined factors predicting success.

Methods: We conducted a randomized controlled trial in the cardiology department and in the smoking cessation service at University Hospital of Monastir, Tunisia. Participants were randomly assigned to group “A” or to control group “B”. The endpoint assessment was smoking abstinence at 24 weeks, defined as self-reported abstinence in the past week, confirmed by a measured exhaled carbon monoxide ≤ 8 ppm. We analyzed data by intention to treat. We used binary logistic regression model to determine factors predicting abstinence.
Results: All participants were male and the mean age was 55 ± 11 years. At 24 weeks there were no significant difference in smoking cessation rate between initiating smoking cessation during hospitalization or after hospital discharge: 54.5% (95% CI: 44.7–64.3) in group “A” and 45.5% (95% CI: 35.7–55.3) in control group (P = 0.81). Having a high level of nicotine dependence (OR: 0.72; 95% IC, OR: 0.54–0.96) and a good compliance in follow up (OR: 6.56; 95% CI, OR: 2.07–20.78) were predicting abstinence factors.

Conclusion: Smoking cessation rate after ACS was high regardless of the start date. The good compliance in follow-up was the key predicting factor of success.

Keywords: Smoking cessation, acute coronary syndrome, predicting factors, clinical trial, Tunisia

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Introduction

Smoking is the main preventable cause worldwide of morbidity and premature death (1) and is a major and independent risk factor for coronary heart disease (CHD) (2). More than two-thirds of sudden cardiac death resulting from acute thrombus occurs in smokers (3). Compared to non-smokers the odds ratio (OR) for myocardial infarction is approximately 2.5, and for cardiovascular diseases overall the OR is approximately 2 (2,4). Smoking cessation in persons with known CHD reduce the risk of recurrent myocardial infarctions or cardiovascular death from 30% to 50% (5) during the subsequent 3 to 7 years (6). Nevertheless, although smoking cessation is potentially the most effective CHD prevention strategy, quitting smoking is difficult
and two-thirds of patients will return to smoking within one year of their ACS (7,8). Therefore, being hospitalized for a major cardiac condition, such as ACS, can be an opportunity to prompt many individuals to stop smoking.

Exploiting this “teachable moment” immediately after an ACS, it may be possible to increase smoking abstinence in this high-risk population (8). Cessation rates among smokers hospitalized for ACS range from 31% without intervention to 60% with sustained intervention post-hospitalization, at one year follow-up (9). Nicotine replacement therapy (NRT), Bupropion, and Varenicline have demonstrated efficacy for smoking cessation compared to placebo, yet majority of smokers considered smoking as voluntary behaviour and declined to be treated. Currently, smoking cessation remains a secondary concern in cardiology departments and there are few strategies offered to smoker patients with established CHD.

Nicotine replacement therapy improved cessation rates with an OR of 1.84 (95% CI: 1.71–1.99) without major adverse events (1), with equal cessation rates in the general population despite benefits of clinical outcomes among CHD patients (10). Many studies have examined the benefits of smoking cessation after ACS and the efficacy of smoking cessation pharmacotherapy in hospitalized patients with ACS, but few randomized controlled trials have examined the efficacy time of smoking cessation in hospitalized patients with ACS either during the hospitalization or after hospital discharge. We aimed at comparing among patients with ACS the smoking cessation rates with NRT when begun in-hospital, as well as that that begun post-hospital discharge.

**Methods**  
**Design and study population**

A randomized controlled trial was conducted simultaneously in the smoking cessation service and the department of cardiology at the University Hospital of Monastir, Tunisia. This study was performed from January 2015 to June 2016 with a mean of 24 weeks of run-up and 24 weeks of follow-up. Patients aged more than 18 years were included, as well as hospitalized with an ACS actively smoking at the time of inclusion, motivated to quit smoking, able to provide informed consent, and willing to participate in a clinical study including a follow-up examination every 2 weeks after hospital discharge. Active smoking was defined as smoking one cigarette or more (or water pipe) per day during the month preceding the hospital stay. Non-inclusion criteria were the refusal of assistance for smoking cessation, inability to follow-up clinical visit (professional, regional or physical hindrance), diagnosis of depression or of serious health condition at admission (ventilated patient, cardiogenic shock, etc).

**Sampling**
We hypothesized that NRT after ACS during hospitalization would improve the rate of smoking cessation rate compared to that post-hospital discharge. Previous studies reported a rate of 51% among smokers who received the NRT in-hospital smoking cessation intervention (11) and 32.7% among patients receiving treatments after hospital discharge (12). Expected sample size of 68 participants was calculated with a power of 0.80 and a two-sided P < 0.05. The proportion of patients who dropped out or withdrew was expected to be 30%. Hence a minimum sample size of 89 was necessary, and final sample was 99 consecutive patients.

Randomization was performed after consent was obtained. Participants randomized to group A received counseling and NRT during in-hospital stay one day after SCA. Those in group B benefited from counseling during in-hospital stay, while the NRT was offered on a mean of 14 days after SCA at the first clinical visit post-hospital discharge. All patients received regular follow-up visits in smoking cessation center every 2 weeks. Of the 99 patients enrolled in the study, 44 (81.4%) and 30 (66.6%) patients had respectively completed the follow-up smoking cessation in group A and group B. Loss to follow-up was equal in both groups (P = 0.931) (Figure 1).

Study protocol and data collection

During hospitalization

All patients in the sample received an individual therapeutic education including a motivational interview. Patients were asked about their sociodemographic status, history of tobacco use, level of nicotine dependence (Fagerstrom test for Nicotine Dependence: FTNDs) (13), psychological state (using Hospital Anxiety and Depression Scale (HADS) [14], co-addiction (alcohol, drugs, cannabis) and the level of motivation to quit smoking (QMAT scale). Participants in group A started NRT patches and gum. The first appointment was scheduled at 1 week post-hospital discharge.

Post-hospital discharge

Participants in group B arm started NRT patches and gum. At the first clinic visit, 2 weeks after SCA event, side effects, symptoms of withdrawal, medication adherence and smoking status were assessed during follow-up. Smoking status was assessed by self-reporting of smoking in the preceding 7 days and confirmed by Exhaled Carbon monoxide (ECO). The threshold of exhaled carbon monoxide was a value under 8 ppm. Follow-up involved clinic visits every 2
weeks and telephone calls those patients missing their meeting, for whom a new consultation was organized as soon as possible.

A reduction of NRT dose by a third was required every 28 days and NRT dosage adjustment was done according to signs of under or overdose. During the processing time period, a close collaboration with a team comprising psychiatrist, addictologist and a clinical psychologist to manage more complicated cases such as dual addiction, depression and type A personalities.

Follow-up assessment

The primary endpoint was 7-day smoking abstinence at 24 weeks following randomization, defined as self-reported abstinence in the past week before the 24 week clinic visit, confirmed by a measured ECO ≤ 8 ppm. Participants with self-reported abstinence who had ECO values > 8 ppm, or who reported any smoking in the last week and ECO ≤ 8 ppm, were classified as current smokers. Secondary endpoints included measures by a face-to-face survey, compliance to medication, occurrence of side effects of NRT patches (allergic skin reaction) (15), withdrawal symptoms (nervousness, headache, lack of concentration, insomnia, and craving) and the benefits of smoking cessation (improvement of respiratory signs, increased appetite, sleep quality, enhancement of physical activity). Compliance with treatment was defined as good if the wearing of nicotine patches was on a regular basis.

Endpoint assessment

Smoking cessation status was assessed during visits at 24 weeks. A telephone survey was performed for patients who had missed appointments.

Conflict of interest

No conflict of interest with a pharmaceutical company was reported during the realization of this study. The major concern during the follow-up was treatment availability.
Ethical considerations

Written and informed consent from all study participants was obtained. Participants were given the opportunity to ask questions and decide whether to participate. This trial is registered with Clinical Trials.gov, number: NCT03209622.

Statistical analysis

Statistical analyses were performed using the SPSS 19.0 statistical software. The primary data analysis examined point prevalence smoking abstinence at 24 weeks. All analyses were intention-to-treat adjusted on ACS type (STEMI or NSTEMI). Binary logistic regression was used to determine the factors that were independent predictors of success smoking cessation. Variables leveled ≤ 20% in the univariate analysis were included in the multivariate analysis. A P value of 5% was considered statistically significant.

Results

Patient characteristics at baseline

The 99 participants included were male. Mean age was 55 years (SD: 11). At baseline, 93 patients (94%) used cigarettes with a mean of 32±14 cigarettes per day. A high nicotine dependence was found among 55% of patients. Two-thirds of patients had two or more major cardiovascular risk factors other than smoking. Half of patients (49.5%) had non-ST segment elevation myocardial infarction. The sample included 54 patients in group A and 45 in group B (P = 0.366). The participant characteristics in the 2 groups are summarized in Table 1. Despite randomization, the Non-ST segment-elevation myocardial infarction was found in 37.5% and 62.5% in group A and group B, respectively (P = 0.002). Length of stay in cardiac intensive care unit was longer in group B (P = 0.007).

Smoking abstinence at 24 weeks

The success rates of smoking cessation, with intention-to-treat analysis, were respectively 57.1% (95% CI: 39.6–74.6) in group A and 42.9% (95% CI: 20.8–64.9) in group B. OR adjusted by length of stay in cardiac intensive care unit and SCA type was 0.824 (0.334–2.032) (P = 0.674) (Table 2).

Predictors of smoking cessation success
Factors associated for successful smoking cessation are shown in Table 3. The likelihood of success was associated with good follow-up compliance, good motivation to quit, having a history of diabetes, type of ACS (non ST segment-elevation myocardial infarction) and living in a tobacco-free family environment. Smokers having a high dependence had less chance of success (OR: 0.7, 0.54–0.96; P = 0.028).

Discussion

This study was designed to compare two protocols of smoking cessation immediately after ACS. There was no significant difference between the initiation of smoking cessation by NRT during hospitalization or post-hospital discharge. To our knowledge, there have been no previous trials on smoking cessation performed in a patients having ACS in Tunisia.

Particularities of the study population

Patients included in our study were all male. The average age of our coronary population was close to that found in literature reviews studying smoking cessation in the same population (16–20). Majority of patients were heavy smokers with a high number of cigarettes smoked per day. These results were similar to those described by studies studying smoking cessation after ACS (21). These results are encouraging for the promotion of effective awareness-raising actions for heavy smokers. During the study period, no women developed ACS related to smoking. In fact, in Tunisia female smoking is considered a social taboo, thus limiting tobacco use in women.

Special features of smoking cessation after ACS

Smoker psychology and ability to change his behaviour were described in the Prochaska and Di Clemente model (22). After a cardiac event, the successive stages of the Prochaska cycle are ‘short circuited’ (22) and the patient is often highly motivated to quit smoking (8). Indeed, in the current study the majority of patients were already highly motivated to quit smoking and hospitalization in the cardiology department could be a good opportunity to initiate smoking cessation (23). Also, having a coronary revascularization such as angioplasty or coronary artery bypass surgery was an alarming event for a patient hospitalized for ACS and increased intention to quit (24,25). Previously, the safety and the effectiveness of the use of NRT for patients immediately after ACS were unclear because of potential haemodynamic effects of nicotine (26). Recently, safety and efficacy of NRT in patients with recent SCA were documented (1,2,16,27) and the use of NRT to quit smoking roughly doubles the success rate in long-term abstinence by reducing withdrawal symptoms (16).

Rates of smoking cessation in the study population compared to the literature

Smoking abstinence rates at 24 weeks were 54.5% in group A and 45.5% in group B. Our result...
was equivalent to those reported in the literature, particularly in randomized controlled trials with rates ranging from 30.4 to 62% (7,9,10,17–20,24). This result could be explained by the effectiveness of a multidisciplinary managing team and the intensive intervention adopted in this protocol. This finding was supported by the literature, which showed that intensive intervention was more effective (28). Difference in smoking abstinence rates from the literature could be explained by the pharmacotherapy used: NRT, Varenicline or Bupropion, with NRT being the only available treatment for smoking cessation in Tunisia. Cardiologists have to be more effective on promoting quitting motivation (29); offering brief advice and encouragement to patients is insufficient (27,28) and they must start NRT as soon as possible.

Predictors of smoking cessation success

According to our findings and regardless of treatment groups, patients with a ST segment-elevation myocardial infarction and having no other household smokers were significantly associated with smoking cessation. Likewise, smoking cessation rate was related to a good compliance to treatment (10–11,30–31). These results suggested that such a programme should be applied as a main part of the post-ACS routine following the recommendations of the European Society of Cardiology (32). Having diabetes multiplied the chances of smoking cessation in our study population; this was consistent with results by Kim H-E et al. (33). However, in the literature the presence of other diseases such as stroke (30), previous cardiac events (5), disease related to smoking, depression (30,34) and a history of anxiolytic use (34) were significantly associated with smoking cessation failure. Concomitant with other studies, a high level of nicotine dependence was significantly associated with smoking cessation failure (30). Finally, a high motivation score to quit was a significant predictive factor for smoking cessation (35), showing that the period of hospitalization is an opportunity to help these patients.

Limitations

Primary limitation was sample size. However, the study continued to determine long-term effect of early NRT after ACS.

Conclusions

At 24 weeks there were no significant differences in smoking cessation rates between initiating smoking cessation during hospitalization or post-hospital discharge. Having diabetes, a non-ST segment-elevation myocardial infarction, a good motivation for smoking cessation, a good treatment compliance and living in a tobacco-free family environment were predicting factors of success for quitting. High nicotine dependence decreased this chance.

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References


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