Comparing the Effects of Nicotine Replacement Therapy and Nursing Counseling on Smoking Cessation among the Candidates for Coronary Artery Bypass Graft Surgery: A Clinical Trial

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Background: There is limited data about the effects of smoking cessation (SC) strategies among the candidates for coronary artery bypass graft (CABG) surgery. Objectives: This study aimed to compare the effects of nicotine replacement therapy (NRT) and nursing counseling (NC) on SC among the candidates for CABG. Methods: This randomized controlled trial was made in the heart center of Afshar hospital, Yazd, Iran. Sixty candidates for elective bypass graft were recruited and were randomly allocated either to a NC or a NRT group. Study interventions were implemented from 3 weeks before to 3 weeks after the surgery. Before and after hospitalization for the surgery, patients in the counseling group received telephone counseling while during their 1-week hospital stay, they received face-to-face counseling. Patients in the NRT group received nicotine gum before and after hospitalization and were treated with nicotine patches during their 1-week hospital stay. Data were collected through three questionnaires. The Chi-square and the independent-sample t tests were run to analyze the data. Results: SC rate in the counseling group was significantly higher than the NRT group (63.3% vs. 33.3%; P = 0.038). Moreover, cessation rate among the participants with lower nicotine dependency was significantly greater than those with moderate-to-severe dependency (P = 0.01). Conclusion: NC is more effective than NRT in improving SC rate among the candidates for CABG.

Keywords: Coronary artery bypass graft, Counseling, Nicotine replacement therapy, Nurse, Smoking cessation

INTRODUCTION

Coronary artery disease (CAD) is a leading cause of death among people aged 75 or more. It is estimated that more than eighty million Americans suffer from CAD.[1] The rates of death from cardiovascular disease among male and female Iranians were reported to be 33 and 201 cases per 100,000 persons, respectively.[2]

The most common treatment modalities for CAD are medical management, percutaneous intervention, and coronary artery bypass graft (CABG) surgery.[3,4] Beside appropriate treatments, modification of CAD risk factors is also necessary for maximizing recovery and survival rates.[3] The most important modifiable CAD risk factors include smoking, dyslipidemia, diabetes mellitus, and a body mass index of >30.[5] Smoking cessation (SC) is among the main modalities for CAD management.[6] It has numerous positive effects on the recovery and the survival of patients with CAD.[7–9] Preoperative period, also known as the “teachable moment,” enhances patients’ teachability and encourages them to stop their unhealthy behaviors such as smoking.[10]

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One of the most effective SC strategies is pharmacological modalities such as nicotine replacement therapy (NRT).[11] Many studies reported the effectiveness of NRT in improving SC rate[11-13] while some other studies showed the insignificant effects of NRT on SC.[14] Besides, pharmacological therapies for SC are usually associated with different complications such as nausea, vomiting, gastrointestinal problems, and sleeplessness.[15] Another shortcoming of these therapies is patients’ poor adherence to them.[16] The pitfalls and side effects of pharmacological therapies highlight the necessity to use nonpharmacological therapies.[13]

Behavioral approaches such as counseling are among the nonpharmacological therapies for SC.[12] According to the United States Department of Health and Human Services, the best counseling approach for SC is the “5As” approach which includes five strategies, namely, Ask, Advise, Assess, Assist, and Arrange.[17]

As the largest group of health-care providers, nurses have a significant role in implementing behavioral SC programs and improving SC rate.[18,19] Nonetheless, the most previous studies used a wide range of nursing interventions for SC in combination with pharmacological therapies or other counseling approaches and thus, the pure effects of nursing counseling (NC) on SC have still remained unknown.[19,20] Besides, beliefs about the negative effects of SC before elective CABG[21] resulted in the reduction of SC programs for CABG candidates.[15]

**Objectives**

This study aimed to compare the effects of NRT and NC on SC among the candidates for CABG.

**Methods**

As a nonblind randomized clinical trial, this study was made on the candidates for elective CABG who referred to the heart center of Afshar hospital, Yazd, Iran, from May to December 2014. Patients were approached if they were active cigarette smokers (i.e. used to smoke two or more cigarettes per day during the last year before the study), aged >18, were candidates for elective CABG, had easy access to telephone, were not alcohol or drug abusers and did not suffer from serious mental disorders, acute respiratory diseases, or orodental disorders.

Sample size was calculated through the Pocock’s formula and using the findings of Sadr Azodi et al.,[9] who reported a successful SC rate of 30%. Thus, with a power of 0.80, a type II error of 5%, and an effect size of 35%, thirty patients were deemed necessary for each study group.

Patients were allocated to either NRT or NC group in the ratio of 1:1 using opaque, sealed envelopes in blocks of ten. Block randomization was performed by the second author at the day of CABG. Patients in the NC group received face-to-face and telephone counseling about SC while patients in the NRT group were treated with nicotine gums and patches.

**The procedure**

NRT or NC were implemented from 3 weeks before to 3 weeks after CABG. Participants were initially provided with a pamphlet containing materials on the physical and mental problems caused by SC and how to deal with them. Before hospitalization, patients in the NC group received NC over the telephone for 3 weeks while during their hospital stay, they received face-to-face counseling. The “5As” approach was used for counseling. The five steps of this approach were as follows: Ask about cigarette smoking; Advise SC; Assess SC desire; Assist SC through counseling services, and Arrange follow-up services.[17] The first three steps were taken at the time of recruiting patients to the study. Assistive counseling included educations about the benefits of SC, self-efficacy reinforcement, and behavioral modification strategies. Finally, we arranged and performed follow-up assessments through making independent telephone contacts with both patients and their family members. The contacts were made twice a week for 6 consecutive weeks during the course of the study intervention. Patients in the NRT group and their families were initially provided with instructions about how to use nicotine gums and patches and how to prevent their side effects. Then, 530 gum packs of nicotine gums (produced by Kimia Afarin Alborz, Iran) were given to each patient. They were asked to use 2–3 gums per day during the 3-week prehospitalization and the 2-week postdischarge periods. Moreover, during the 1-week course of their hospitalization, they were treated with nicotine patches. Each patch was used for 24 h. SC assessments in the NRT group were performed in the same way as the NC group. All patients were provided with a phone number to report any sensitivity to nicotine (in the NRT group) or their reluctance to stay in the study. They were hospitalized 1 day before CABG and stayed in hospital for 6 days after CABG.

Data were collected through a demographic questionnaire, a data sheet for patients’ clinical and cigarette smoking profiles (included items such as current cigarette smoking status and history of SC), and the Fagerström Tolerance Questionnaire (FTQ). For the purpose of validity assessment, the first and the second instruments were amended based on the suggestions provided by 10 faculty members affiliated to Tehran Faculty of Nursing and Midwifery Faculty, Tehran, Iran. FTQ has six questions which assess nicotine dependence. The 0–10 score of FTQ is used to predict SC rate.
FTQ scores are interpreted as follows: 8–10: severe dependency; 4–7: moderate dependency; and 0–3: low dependency. The validity and reliability of the Persian FTQ were assessed and upheld by Ziaadini et al. They reported the Cronbach’s alpha of the questionnaire as 0.835.[23] Moreover, the specificity and sensitivity of FTQ were reported to be 67.5% and 76.2%, respectively.[23]

Cigarette smoking status was assessed twice a week for 6 consecutive days through making independent telephone contacts with both patients and their families. Successful SC was achieved and documented only when all SC assessments during the 6-week period of the study confirmed it.

Ethical considerations
This study approved by Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran (Ref. No. 130.486.193) and was registered in the Iranian Registry of Clinical Trials (IRCT2014071518499N1). The aims of the study were explained to the participants. They were free to withdraw from the study at any time without suffering any negative consequence. Moreover, they were ensured that their data would be handled confidentially. All of them signed the informed consent form of the study.

Data analysis
The SPSS software (SPSS INC., Chicago, IL, USA) was used to analyze the data. Participants’ demographic characteristics were described using measures of descriptive statistics while the study groups were compared with each respecting SC rate, FTQ score, and nicotine dependency through the independent-sample $t$ and the Chi-square tests. $P < 0.05$ were considered statistically significant.

RESULTS
In total, sixty CABG candidates participated in this study [Figure 1]. Table 1 shows participants’ demographic characteristics and clinical and smoking profiles. Although we did not impose any inclusion criteria respecting the participants’ gender and marital status, all participants were male and married. There were no significant differences between the groups concerning participants’ demographic characteristics and clinical and smoking profiles ($P > 0.05$).

At the end of the study, SC rates in the NC and the NRT groups were 63.3% and 33.3%, respectively [$P = 0.038$; Table 2]. Moreover, the Chi-square test revealed significantly higher SC rate among participants with lower baseline nicotine dependency [$P = 0.01$; Table 3].

DISCUSSION
The findings indicated significantly higher SC rate among patients who received NC compared with patients who were treated with NRT. Similarly, Park et al. found NC more effective than pharmacological therapies in SC.[24]

The present study evaluated the pure effects of NC and NRT on SC. However, most previous studies combined

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**Figure 1:** The study flow diagram
for all smokers. The higher effectiveness of NC strategy might be attributed to the nature of human interactions that were made in nurse–patient interactions during the counseling sessions, especially during the face-to-face counseling sessions. This interpretation is also consistent with Park et al. conclusion that for successful SC, patients need frequent, brief contacts, and social support.\textsuperscript{[24]}

Study findings also revealed that at the end of the interventions, i.e., 3 weeks after CABG, SC rate in the NC group was as high as 63.3%. This rate is similar to the rate reported in an earlier study\textsuperscript{[26]} and higher than the rates reported in some previous clinical trials.\textsuperscript{[24,25,27]}

Such difference can be attributed to the differences among the studies regarding their sample sizes, methods, follow-up periods, and participants’ characteristics.

We also found that baseline nicotine dependency significantly contributed to SC so that patients with lower dependency were more willing and successful to quit smoking compared with those with moderate-to-severe dependency. Etter and Stapleton\textsuperscript{[28]} and Cropsey et al.\textsuperscript{[29]} also reported that the severity of nicotine dependency needs to be taken into account when developing and implementing SC interventions to improve long-term SC rate. Unfortunately, we did not consider the importance of this factor in designing the present study. Perhaps, more intensive follow-up interventions should be designed for patients with severe nicotine dependency.

In the present study, smoking status was assessed just based on a self-report basis and further investigations

### Table 2: Comparison of smoking cessation after interventions between the study groups\textsuperscript{a}

| Smoking cessation\textsuperscript{b} | Nursing consult | Nicotine replacement therapy | P\textsuperscript{c} |
|-----------------------------------|-----------------|------------------------------|-------------------|
| Yes                               | 19 (63.3)       | 10 (33.3)                    | 0.038             |
| No                                | 11 (36.7)       | 20 (66.7)                    |                   |

\textsuperscript{a}Data are presented as n (%), \textsuperscript{b}Smoking cessation defined here by no smoking during study time interval (3 weeks before surgery until 3 weeks after surgery), \textsuperscript{c}Chi-square test

### Table 3: Comparison of smoking cessation rate after interventions based on nicotine dependency\textsuperscript{a}

| Nicotine dependency | Smoking cessation status\textsuperscript{d} | P\textsuperscript{e} |
|---------------------|---------------------------------------------|-------------------|
| Low (0-3)           | 12 (92.3)                                   | 1 (7.7)           | 0.01          |
| Moderate (4-7)      | 15 (44.1)                                   | 19 (55.9)         |               |
| Severe (8-10)       | 2 (15.4)                                    | 11 (84.6)         |               |

\textsuperscript{a}Data are presented as n (%), \textsuperscript{d}Smoking cessation defined here by no smoking during study time interval (3 weeks before surgery until 3 weeks after surgery), \textsuperscript{e}Chi-square test

NC with other pharmacological therapies. For instance, Sadr Azodi et al.\textsuperscript{[9]} and Heale et al.\textsuperscript{[25]} encouraged patients in their NC group to use NRT as well and reported the significant effect of this intervention on SC. A meta-analysis study also reported the wide diversity of SC-related nursing interventions as a limitation in the previous studies.\textsuperscript{[19]} All these findings highlight the importance of our findings which showed the stronger preference of NC over NRT and indicated that there is no need for pharmacological therapy

### Table 1: Comparison the demographic and clinical characteristics of two groups\textsuperscript{a} (n=30)

| Variables                        | Group: Nursing consult | Group: Nicotine replacement therapy | P    |
|----------------------------------|------------------------|-------------------------------------|------|
| Age (years)                      | 52.0 ± 7.23            | 52.64 ± 9.62                        | 0.81\textsuperscript{b} |
| Education level                  |                        |                                     |      |
| Illiterate                       | 4 (13.3)               | 5 (16.7)                            | 0.30\textsuperscript{c} |
| Primary education                | 9 (30)                 | 11 (36.7)                           |      |
| Secondary education              | 12 (40)                | 7 (23.3)                            |      |
| Diploma and academic degree      | 5 (16.7)               | 7 (23.3)                            |      |
| Comorbidities                    |                        |                                     |      |
| Diabetes                         | 6 (20)                 | 3 (10)                              | 0.62\textsuperscript{d} |
| Hypertension                     | 3 (10)                 | 6 (20)                              |      |
| Hypercholesterolemia             | 5 (16.7)               | 3 (10)                              |      |
| Chronic heart disease            | 12 (40)                | 14 (46.7)                           |      |
| No comorbidity                   | 4 (13.3)               | 4 (13.3)                            |      |
| Years of smoking (years)         | 27.2 ± 17.25           | 29.3 ± 16.42                        | 0.73\textsuperscript{b} |
| Cessation history                |                        |                                     |      |
| Yes                              | 16 (53.3)              | 19 (63.4)                           | 0.30\textsuperscript{c} |
| No                               | 14 (46.7)              | 11 (36.6)                           |      |
| Family smoking history           |                        |                                     |      |
| Yes                              | 18 (60)                | 16 (53)                             | 0.39\textsuperscript{c} |
| No                               | 12 (40)                | 14 (47)                             |      |

\textsuperscript{a}Data are presented as n (%) or mean±SD, \textsuperscript{b}Independent-samples t-test, \textsuperscript{c}Chi-square test, \textsuperscript{d}Fisher’s exact test. SD: Standard deviation
such as expiratory carbon monoxide measurement were not performed. Moreover, most participants referred to the study setting from different cities located around Yazd, Iran, and thus, they might have differed from each other respecting their personal, psychological, and cultural characteristics. Besides, most of them were reluctant to participate in the study and SC follow-up assessments and hence, follow-up assessments were performed only at the end of the intervention. Further studies are needed to evaluate the pure effects of NC in more homogenous communities, larger samples, and longer follow-up periods.

**Conclusion**

NC is more effective than NRT in improving SC rate among cigarette smokers who are candidates for CABG. This intervention can be used in different areas and situations (such as smart homes) to facilitate SC. The use of NC to facilitate SC among the candidates for elective CABG can prevent postoperative restenosis of coronary arteries and improve patients’ survival rate.

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**Conflicts of interest**

There are no conflicts of interest.

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