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ORIGINAL ARTICLE

Randomized controlled trial of two cigarette quit programmes in coronary care patients after acute myocardial infarction

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Abstract

Background: Tobacco cessation after acute myocardial infarction (AMI) substantially improves outcome but how effective individual programmes are needs to be established. To date, few studies have examined this factor.

Aims: To assess the outcome of two smoking cessation programmes after AMI.

Methods: One hundred and ninety-eight current smokers admitted to coronary care with an AMI participated in a randomized controlled study comparing two outpatient tobacco interventions, the Stanford Heart Attack Staying Free (SF) programme and a Usual Care (UC) programme.

Results: Log–rank analyses revealed that patients in the SF programme were retained longer ($P < 0.001$) and had higher cotinine validated abstinence rates ($P < 0.001$) compared with patients in the UC programme. Twelve months after intervention, 39% of the SF programme compared with 2% of the UC programme demonstrated cotinine validated tobacco cessation, representing a significant reduced relapse rate in the SF programme (χ^2, $P < 0.001$).

Conclusions: The SF smoking cessation programme initiated in hospital can significantly reduce smoking rates at 12 months after myocardial infarction. Although superior to the UC quit programme, Australian outcomes were lower than the American programme originators' published outcomes. (Intern Med J 2001; 31: 470–475)

Key words: acute myocardial infarction, randomized trial, smoking cessation, treatment programme.

INTRODUCTION

After cancer, ischaemic heart disease is the second most frequent cause of death (22.5% of all deaths) in Australia.[1] The decline in smoking prevalence seen in previous Australian surveys has plateaued, confirming the need for a sustained commitment to anti-smoking programmes.[2] Currently, approximately 26% of Australians smoke tobacco.[2,3] An episode of hospitalization has often been identified as presenting a valuable opportunity for patients to stop smoking.[4,5] However, the reality remains that while many hospital inpatients consider quitting smoking, few feel encouraged to do so or seek support.[6] During the last 5 years, comprehensive guidelines and reviews of smoking cessation have been published.[4,5,7] These have had widespread professional endorsement. However, the limitations of the published studies on which they are based curtail their usefulness. Considerable heterogeneity of effect among trials of tobacco cessation is well recognized.[8] There has been difficulty in achieving similar outcomes when programmes are applied to other health-care settings and patient populations, reflecting the distinction between efficacy and effectiveness. As few studies have directly compared the available treatments, it is difficult to recommend one approach over another.[7] There is little evidence about the relative effectiveness of different psychological approaches.[7] Not all professional groups achieve

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similar outcomes even when applying an identical programme.[9]

While the benefits of smoking cessation are well known (≥ 50% reduction in the risk of recurrent myocardial infarction or cardiovascular death with successful quitting), there is currently no generally accepted or widely applied programmes for cardiac patients while in hospital.[10]

The current study evaluated and compared two hospital tobacco interventions after acute myocardial infarction (AMI) and in addition to self-report, used urinary cotinine estimates as a validation measure. The Usual Care (UC) programme was locally developed and didactic. The Stanford Heart Attack Staying Free (SF) programme originated in the USA and incorporated many of the more recent techniques found useful in achieving behavioural change.[11]

METHODS

Subjects

One hundred and ninety-eight patients sequentially admitted to the coronary care unit (CCU) were identified by nursing staff as current cigarette smokers (tobacco use in the week before hospitalization). All had suffered AMI, documented by two or more of the following: elevated serum creatine phosphokinase, history of prolonged ischaemic chest pain and the appearance of new Q waves or evolving ST segment change on an electrocardiogram.

Patients were offered a tobacco quit programme. Recruitment occurred while in CCU. Participants were randomly assigned to receive one of two nurse-managed programmes, either the SF or the UC programme.[11] A random list of odd and even numbers was generated and a sequence of 200 sealed envelopes created. With patient consent an envelope was opened and they were assigned to either programme.

Ethics approval

Ethics approval for the present project was obtained from the Princess Alexandra Hospital Research Ethics Committee. The procedures followed in the present study were in accordance with the ethical standards of the Helsinki Declaration of 1975, as revised in 1993.

Treatment programmes

All patients were advised to stop smoking by a staff cardiologist involved in their care. Nicotine replacement is not on the Queensland hospital standard drug list and unavailable through the hospital pharmacy. Although not offered as part of either programme both groups were informed of its availability outside hospital. All patients were asked to notify the clinic if nicotine replacement treatment was used. Alcohol and drug assessment (ADAU) clinic appointments were at 3-, 6- and 12-month intervals. While both treatments aimed for smoking abstinence as their primary goal, they differed in terms of content and delivery.

Usual care

The UC programme included verbal and printed advice about tobacco cessation. It was primarily didactic. Patients watched an educational video during their CCU stay and were reviewed by the ADAU nurse. Outpatient ADAU supportive counselling and follow up was offered at 3-, 6-, 12-month intervals. All patients were advised by the attending cardiologist to stop smoking.

Stanford Heart Attack Staying Free programme

The nurse managing the SF programme began on transfer from the CCU. Before transfer the attending cardiologist advised all patients to stop smoking.[11] In addition, all SF patients were interviewed by the ADAU physician and medical implications of tobacco cessation and aims of the programme were discussed. The programme included a number of behavioural components. Patients were given the programme manual 'Staying Free', designed to identify high-risk situations for relapse. It contained simple exercises to develop a plan to manage these situations. After manual review, patients completed a 28-item questionnaire assessing confidence to maintain cessation.

If patients reported less than 70% confidence to resist identified, high-risk, relapse situations they were counselled on specific coping strategies. Two audiotapes for home use reviewed the programme's principal points and included exercises for progressive muscle relaxation. The manual was worked through by the patient during a 2-week period (both as inpatient and outpatient), targeting the early stages of recovery.

On hospital discharge the ADAU nurse initiated telephone contact weekly for 4 weeks and at 2, 3, 6 and 12 months. These included inquiries about relapse and confidence to remain abstinent. Additional support and advice were given if considered necessary.

Data collection instruments

Patient tobacco use

Cigarette nicotine content (low ≤ 0.4 mg, medium ≥ 0.4–1.2 mg, high ≥ 1.2 mg) and reported daily usage.

Nicotine dependence

The level of nicotine dependence was measured by the Fagerstrom tolerance questionnaire (FTQ).[12] Ratings range from 0 to 2 (very low dependence) and ≥ 8 (very high dependence), with a maximum score of 10.

Self-efficacy to resist smoking

All patients completed the SF programme self-efficacy measure to record patient confidence to resist urges to smoke in 28 identified high-risk situations (e.g. when you are feeling stress, when you see others smoke, when you are drinking an alcoholic beverage). Ratings ranged from 0% (no confidence to quit) to 100% (absolute confidence).

Smoking cessation

Smoking cessation status was recorded on direct questioning at follow-up ADAU outpatient clinics. Biochemical validation involved a urinary cotinine (relatively long-lived metabolite of nicotine) estimate upon each visit to ADAU.[13] A level above 400 ng/mL was used to indicate a probable return to smoking. No patient reported nicotine supplement use.

Data analysis

To examine potential biases between group randomization on key subject demographics, independent *t*-tests were employed with interval (i.e. FTQ and self-efficacy ratings) and χ^2 analyses with nominal data (i.e. gender, cigarette strength/use). Log–rank analyses were carried out to compare attrition and relapse across treatment groups during the programme. All analyses were carried out using the SPSS statistical package for Windows, version 9.

RESULTS

Patient characteristics

Of 198 cigarette smokers, 145 (64%) were male and 53 (36%) female. There were 73 males and 23 females in the SF treatment and 72 males and 30 females in the UC treatment, representing relatively equal gender proportions across treatment groups (χ^2 (1, 200) = 0.7, P = 0.24 NS). Despite randomization, an administrative error resulted in 96 patients in the SF programme and 102 patients in the UC programme and two omissions. The mean age of the subjects was 53.9 ± 11 and did not differ significantly between treatment programmes (t (1, 198) = – 1.44, P = 0.15 NS). Patients in both programmes reported similar cigarette brand strength (χ^2 (2, 176) = 0.37, P = 0.82 NS), daily smoking frequency (χ^2 (3, 171) = 1.10, P = 0.78 NS) and levels of nicotine dependence (FTQ) (t (1, 133) = 0.68, P = 0.68 NS). Self-efficacy quit estimates did not differ between treatment groups (t (1, 154) = 0.63, P = 0.53 NS). These data are reported in Table 1.

Attendance by treatment group

Programme attendance

Of 198 patients discharged from the CCU, 141 (71%) attended the tobacco outpatient clinic at 1 month, 118 (60%) at 3 months and 68 (34%) at 12 months. During the period of the study, nine patients died. These included four deaths in the SF programme and five in the UC programme.

Attendance across programme duration by treatment group

A log–rank survival analysis was used to examine the differences between observed and expected events (in this case attrition from treatment programmes) during the 12-month study period. There was a difference between treatment groups across programme duration (log–rank (1, 198) = 17.99, $P < 0.001$), indicating significantly higher retention in the SF treatment group over 12 months. The attendance figures are summarized in Fig. 1.

Urinary cotinine status by treatment group

Only two patients (one from each programme) reported abstinence conflicting with elevated urinary cotinine levels. For study purposes they were recorded as continuing to smoke tobacco.

Relapse across study duration

A log–rank analysis examined smoking relapse of patients during the 12-month study period. The results indicated that patients in the UC group relapsed earlier and more frequently that those in the SF group (log–rank (1, 198) = 21.18, $P < 0.001$). Figure 1 summarizes the urinary cotinine status by treatment group across programme duration.

Table 1 Age, gender, cigarette strength, daily usage, Fagerstrom score and quitting self-efficacy by group

Measure	Total sample (n = 198)	SF group (n = 96)	Standard CCU group (n = 102)	P
Subject age				
Mean years (SD)	53.9 (10.95)	52.89 (10.39)	55.13 (11.51)	0.15
Gender				
Male	145 (64%)	73 (76%)	72 (70%)	
Female	53 (36%)	23 (24%)	30 (29%)	0.24
Cigarette strength				
Low	63 (32%)	35 (37%)	28 (28%)	0.83
Medium	55 (27%)	29 (30%)	26 (27%)	
High	58 (30%)	29 (30%)	29 (28%)	
Missing	22 (11%)	3 (3%)	19 (19%)	
Daily cigarette usage				
≤10	68 (34%)	33 (34%)	35 (33%)	0.78
11–20	49 (25%)	27 (28%)	22 (22%)	
21–30	53 (27%)	31 (33%)	22 (22%)	
≥31	2 (1%)	1 (1%)	1 (1%)	
Missing	26 (13%)	4 (4%)	22 (22%)	
Self-reported measures				
Mean Fagerstrom (SD)	4.62 (1.78)	4.61 (1.82)	4.8 (1.81)	0.68
Mean self-efficacy (SD)	66 (22.5)	65.03 (22.44)	67.35 (23)	0.52

SF, Stanford Heart Attack Staying Free; CCU, coronary care unit; SD, standard deviation.

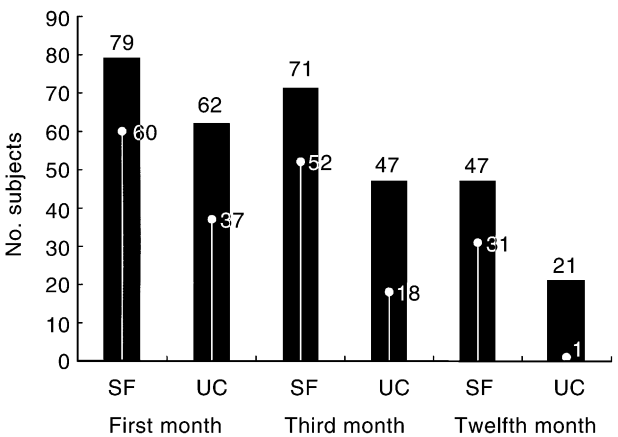

Figure 1 Tobacco programme (■) attendance and (○) abstinence by group after acute myocardial infarction. SF, Staying Free; UC, Usual Care.

Abstinence at 12 months

Of the 68 patients remaining in the study after 12 months, 47% (32/68) recorded negative urinary cotinine estimations across the 1-, 3- and 12-month sessions. In terms of treatment group differences, 39% (31/79) of the SF group and 2% (1/62) of the UC group who commenced the programmes remained abstinent across the duration of the study period (χ^2 (1, 68) = 28.03, $P < 0.001$).

DISCUSSION

The present randomized study compared two different smoking cessation programmes after AMI. The patients were long-established, older smokers with a mean age of 54 years. They had been unable to quit tobacco independently. Patients in both treatment groups were comparable across a number of indices. An addiction medicine physician, in addition to the attending cardiologist, individually reviewed all the SF patients. Both programmes were delivered by the same nurse.

A problem inherent in smoking intervention research is accurately classifying smoking status, particularly among patients who fail to attend. Like the programme (SF) on which our study was based, abstinence rates were calculated by categorizing study participants who were lost to follow up as having relapsed to smoking. Programme attendance and urinary cotinine estimations were used as outcome measures of programme compliance. However, a clear weakness in our study is the absence of follow-up data on almost 66% of participants who had dropped out after 12 months. This was more pronounced in the UC programme because of the higher drop-out rate (UC 79% *vs* SF 51%).

Our findings confirm that the SF group had consistently better programme attendance. After 12 months,

SF patients were more than twice as likely to attend outpatient programme sessions. Urinary cotinine levels in this group were consistent with self-reported abstinence. Quit rates for both groups may have been considerably higher but the present paper only reports the verifiable patient outcomes. This structured quit smoking programme managed by health professionals has the demonstrated benefit of retaining smokers who have had AMI. In the treatment of a chronic, relapsing condition such as nicotine dependence, improved retention in treatment programmes offers a greater opportunity to intervene effectively.

Approaches to assist these patients quit tobacco have changed during the last decade. The design of the SF programme used here distinguishes between the process of stopping smoking and maintaining abstinence. It recognizes many of the psychological components of nicotine dependence and applies cognitive and behavioural (CBT) techniques. Treatment is directed at modifying maladaptive behaviour, engendering a sense of personal control and problem solving by developing responses to deal with 'high' risk relapse situations. To minimize relapse, more contact in the form of telephone support is included. This significantly improves treatment outcome.[7,11,14] The developers of the SF programme replicated their findings 4 years later in a broader case-management system for coronary risk factor modification after AMI.[14] These SF programme outcomes are in marked contrast with the estimated 21% overall smoking intervention efficacy (biochemically unvalidated), reported in the 1980s from four earlier trials among men at high risk of ischaemic heart disease.[8]

Using an identical SF programme we achieved a 32% verified quit rate, 12 months after AMI. This represents an encouraging outcome and is the first reported Australian study that employed this intervention. However, our results are significantly below the SF group's 71% reported quit rate[11], or the 70% reported in the follow-up study incorporating broader risk-factor modification.[14] The magnitude of the outcome differences is difficult to explain. Education, occupation and negative attitudes towards smoking are factors that have been identified as important in tobacco quitting among cardiac patients.[15] The American relationship between employment, health insurance and hospital access may identify patients more responsive to CBT-based programmes. Health-care system resourcing and patient demographic differences may also be important factors. The financial reward to attend outpatient follow up in the original SF study may have had some effect. The heterogeneity of effect among trials of tobacco cessation is again demonstrated here.

There is evidence that hospital-based smoking interventions are best delivered by professionals who are primarily responsible for the intervention and readily identified with the outcome.[9] Here, one health-care professional, a clinical nurse, delivered both programmes, thereby minimizing therapist effects between programmes. Hospital-based interventions for non-cardiac populations have produced substantially inferior results. A self-report quit rate of 17%, reduced to 8% based on cotinine verification, was reported by Rigotti[16] with Stevens' published self-report outcomes being 20%.[9] Interestingly, again, the SF programme biochemically verified that cessation rates at 12 months were higher at 27% in non-cardiac patients.[17]

When we began the SF/UC trial, nicotine replacements were not widely used in patients with cardiac disease and study patients elected not to purchase them. Now the evidence for improved outcome and safety with nicotine-replacement therapy mandates that all patients should consider using these agents to complement programmes.[18,19] Bupropion, an atypical antidepressant, can further improve outcomes.[20]

The potential for reducing the community burden of AMI through secondary prevention is considerable and tobacco cessation remains one important element of this. Efforts directed towards secondary prevention are modest, poorly funded in comparison with the care of the acute ischaemic episode and generally inadequately evaluated. Health administrators may believe that successful overseas-originated programmes translate effectively to Australia and overseas outcomes can be applied as benchmarks here. The present report demonstrates how misleading that belief can be and highlights the importance of having available Australian benchmarks. There is a need for further validated Australian outcome data in this area.

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