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CHEST

Original Research

SMOKING CESSATION

Intensive Smoking Cessation Intervention Reduces Mortality in High-Risk Smokers With Cardiovascular Disease*

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Purpose: **To compare an intensive smoking cessation intervention against usual care in hospitalized high-risk smokers with acute cardiovascular disease.**

Methods: **A total of 209 hospitalized smokers were randomized to the intensive intervention (n = 109) or to usual care (n = 100). Usual care consisted only of counseling and printed educational material provided prior to hospital discharge. Intensive treatment consisted of a minimum of 12 weeks of behavior modification counseling and individualized pharmacotherapy provided at no cost to the participant. Smoking status in all subjects was confirmed biochemically (*ie*, by measuring expired carbon monoxide) at 3, 6, 12, and 24 months after randomization. Outcomes included point prevalence and continuous abstinence smoking cessation rates, hospitalizations, and all-cause mortality.**

Results: **At each follow-up interval, point prevalence and continuous abstinence smoking cessation rates were significantly greater in the intensive-treatment group compared to the usual-care group. At 24 months, continuous abstinence smoking cessation rates were 33% in the intensive-treatment group and 9% in the usual-care group ($p < 0.0001$). Over the 2-year follow-up period, 41 patients in the usual-care group were hospitalized compared to 25 patients in the intensive-treatment group (relative risk reduction [RRR], 44%; 95% confidence interval [CI], 16 to 63%; $p = 0.007$). The all-cause mortality rate was 2.8% in the intensive-treatment group and 12.0% in the usual-care group (RRR, 77%; 95% CI, 27 to 93%; $p = 0.014$). The absolute risk reduction in mortality was 9.2% with a number needed to treat of 11.**

Conclusion: **Hospitalized smokers, especially those with cardiovascular disease, should undergo treatment with a structured intensive cessation intervention. The duration of the initial treatment should be 3 months.** ***(CHEST 2007; 131:446–452)***

Key words: coronary artery disease; myocardial infarction; smoking

Abbreviations: ARR = absolute risk reduction; CI = confidence interval; RRR = relative risk reduction

Epidemiologic evidence clearly links smoking with adverse outcomes in patients with manifest coronary heart disease.[1,2] Patients who continue to smoke after experiencing a myocardial infarction have a 50% higher risk of recurrent coronary events compared to nonsmokers.[1] In patients who stop smoking after a myocardial infarction, the risk of coronary events declines over time so that their risk is equal to that of nonsmokers by 3 years after smoking cessation.[1]

A number of different types of smoking cessation

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interventions have been evaluated in hospitalized smokers. The efficacy of these interventions varied widely with the intensity (*ie*, frequency and duration) of patient contact being the strongest predictor of success.[3–18] Interventions delivered during hospitalization with only brief follow-up have not been effective in increasing smoking cessation rates.[3,5,6,13,14,18] Interventions that included patient contact after hospital discharge for ≥ 3 months were associated with higher cessation rates compared with usual care.[4,7–12,15–17]

Despite the success of the higher intensity interventions in achieving smoking cessation, no structured cessation intervention has been shown to reduce morbidity or mortality. The present study was a randomized comparison of an intensive smoking cessation intervention against usual care in smokers hospitalized with acute cardiovascular disease designed to assess the impact of the intervention on morbidity and mortality.

Materials and Methods

Patients

Patients aged 30 to 75 years who were admitted to the coronary care unit at our university-affiliated teaching hospital with a diagnosis of acute coronary syndrome or decompensated heart failure were considered for participation in the study. Daily smokers who had smoked for a minimum of 5 years with a Fagerstrom score of > 7 were eligible to participate.[19] Smokers were excluded if they did not speak and read the English language. Patients with current alcohol or illicit substance addiction were excluded. The institutional review board of our university approved the study, and participants gave oral and written informed consent.

Protocol

Prior to hospital discharge, all participants received counseling (for approximately 30 min), during which unequivocal advice to stop smoking was given. All participants received the self-help materials *Smart Move: A Stop Smoking Guide* from the American Cancer Society and *You Can Quit Smoking* (consumer version) from the Agency for Health Care Policy and Research. This initial inpatient counseling was standardized and was delivered by one of the investigators. Eligible participants were asked to enroll in the study. Consenting patients were then randomly assigned using simple randomization without block assignment to the intensive smoking cessation intervention or to usual care.

Smokers who were randomized to the intensive intervention were asked to meet with a trained tobacco cessation counselor for approximately 60 min on a weekly basis for a minimum of 3 months. Counseling sessions began the week after patients were discharged from the hospital. Sessions were typically conducted with groups of three to six smokers, although counseling for individuals was used when logistically necessary. Counseling sessions included behavior modification training, and focused on relaxation training, contingency contracting, social support, coping skills training, stimulus control, and nicotine fading. In addition, counseling regarding diet, exercise, and other risk factor modification was provided. Smokers in the intensive-intervention group were also provided with individualized adjuvant pharmacotherapy including nicotine replacement therapy and/or bupropion at no cost. Smokers randomized to the usual-care group received no additional information beyond the initial inpatient counseling session. All participants were seen at 3, 6, 12, and 24 months after study enrollment during which a follow-up medical history was obtained and expired carbon monoxide levels were measured. Participants were queried regarding smoking, health status, hospitalization, and adverse clinical events. Participants randomized to the intensive intervention who relapsed during the 2-year follow-up period were retreated as necessary if they restarted smoking. Participants were prospectively tracked for the development of acute coronary syndrome, stroke, coronary revascularization procedures, hospitalization, and death.

Statistical Analysis

Baseline characteristics of the treatment groups were compared by analysis of variance for continuous variables and χ^2 analysis for categoric variables. Smoking cessation efficacy based on an intention-to-treat analysis was reported as both point-prevalence and continuous abstinence rates. For point-prevalence rates, subjects were classified as abstinent if they had reported not smoking during the previous evaluation period and this was confirmed by a negative result for the measurement of expired carbon monoxide. To be classified as continuously abstinent, smokers had to be confirmed as not smoking by their level of expired carbon monoxide at every visit up to that point in the study. Participants were dropped from being considered continuously abstinent after they had a positive test result at any point in time.

Absolute risk reductions (ARRs) and relative risk reductions (RRRs) were calculated. An RRR was defined as 1 − (relative risk). The number needed to treat to prevent one death over the follow-up period was calculated as 1/ARR. Probabilities for the difference in the RRR were calculated using the Fisher exact test. Mortality and hospitalization functions were computed and compared using the Kaplan-Meier method and log-rank (Mantel-Cox) tests, respectively. The influence of baseline patient characteristics on the outcomes of point prevalence and continuous abstinence quit rates, mortality, and hospitalization were evaluated using logistic regression analysis. Data were presented as the mean ± SD where appropriate. An *a priori* level of significance of $p < 0.05$ was considered to be statistically significant.

Results

During the enrollment period from January 2001 though December 2002, approximately 425 patients who were self-identified current smokers and had acute coronary syndrome or decompensated heart failure were admitted to our coronary care unit. Of these, 330 patients met the inclusion/exclusion criteria. These patients were approached concerning participation in the study. Of these, 209 patients agreed to participate in the trial.

A total of 109 smokers were randomized to receive the intensive intervention and 100 smokers were randomized to receive usual care. Baseline demographics and clinical characteristics of the two groups are summarized in Table 1. The treatment groups

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Table 1—*Demographics and Clinical Characteristics of the Two Treatment Groups

Variables	Intervention (n = 109)	Usual Care (n = 100)	p Value
Age, yr	54.0 ± 11.1	55.5 ± 10.8	0.32
Gender			0.08
Male	75 (69)	56 (56)	
Female	34 (31)	44 (44)	
Ethnic background			
White	91 (83)	70 (70)	0.03
African American	15 (14)	25 (25)	0.06
Latino	1 (1)	1 (1)	1.00
Native American	1 (1)	2 (2)	0.61
Other	1 (1)	2 (2)	0.61
Formal education, yr	10.5 ± 5.4	10.9 ± 5.6	0.88
Hospital admission diagnosis			
Non-ST elevation ACS (unstable angina)	52 (48)	48 (48)	0.97
Non-ST elevation MI	35 (32)	32 (32)	0.98
ST-elevation MI	13 (12)	12 (11)	0.95
Anterior	4 (4)	3 (3)	
Inferior	9 (8)	9 (9)	
Heart failure	9 (8)	9 (9)	0.80
Medical history			
CAD	78 (72)	70 (72)	0.924
MI	14 (13)	15 (15)	0.803
Hypertension	29 (27)	31 (31)	0.583
CABG	11 (10)	10 (10)	0.982
PCI	24 (22)	24 (24)	0.507
Heart failure	12 (11)	13 (13)	0.818
Stroke	6 (6)	5 (5)	0.889
Diabetes	32 (29)	32 (32)	0.792
Arrhythmias	12 (11)	10 (10)	0.991
ICD	6 (6)	6 (6)	0.878
Pacemaker	8 (7)	9 (9)	0.853
Previous cancer	4 (4)	5 (5)	0.895
Hospital discharge medications			
Aspirin/clopidogrel	98 (90)	93 (93)	0.583
β-blocker	78 (72)	73 (73)	0.938
ACE inhibitor/ARB	80 (73)	76 (76)	0.785
Statin	71 (65)	63 (63)	0.859
Digoxin	21 (19)	20 (20)	0.894
Diuretic	37 (34)	36 (36)	0.868
Antiarrhythmic	12 (11)	10 (10)	0.991
Oral anticoagulant	20 (18)	21 (21)	0.758
LVEF	47 ± 11	48 ± 13	0.882
Duration of smoking, yr	33 ± 12	34 ± 11	0.536
Cigarettes smoked, No./d	26 ± 14	22 ± 12	0.03

*Values are given as the mean ± SD or No. (%). ACS = acute coronary syndrome; MI = myocardial infarction; CAD = coronary artery disease; CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention; ICD = implantable cardioverter defibrillator; ACE = angiotension-converting enzyme; ARB = angiotensin receptor blocker; LVEF = left ventricular ejection fraction.

were generally well matched with regard to the admitting diagnosis, medical history, left ventricular ejection fraction, and hospital discharge medications. There was significantly greater number of whites in the intensive-intervention group compared to the usual-care group (p = 0.03). There was also a trend toward a higher percentage of African-American patients and women in the usual-care group compared to the intensive-treatment group, but these differences did not achieve statistical significance. Smokers in the intensive-treatment group smoked a significantly greater number of cigarettes per day than smokers in the usual-care group (p = 0.03).

The point prevalence and continuous abstinence smoking cessation rates for the two treatment groups are summarized in Table 2. Five patients (4.6%) in the intensive-treatment group and four patients (4.0%) in the usual-care group were lost to follow-up. At the follow-up visits at which these patients were lost to-follow-up, their data were included as being positive for smoking. Patients in the intensive-treatment group had significantly higher quit rates compared to patients in the usual-care group at all follow-up time intervals for both point-prevalence and continuous abstinence analyses. At the 2-year follow-up, 39% of the intensive-treatment patients were continuously abstinent compared to 9% of the usual-care patients (RRR, 75%; 95% confidence interval [CI], 67 to 84%; p < 0.0001).

Point prevalence and continuous abstinent quit rates were stratified by baseline patient characteristics (*ie*, ethnic background, gender, age, level of education, and admitting diagnosis) to evaluate the impact of these variables on the success of smoking cessation. None of the patient characteristics, other than assignment to treatment, had a significant effect on the subsequent success rate for point prevalence or continuous smoking cessation.

Smokers who were randomized to the intensive-treatment group attended 8.3 ± 5.4 counseling sessions during their initial treatment after hospital discharge. Adjuvant smoking cessation pharmacotherapy was used by 75% of our intensive-treatment patients (bupropion, 7%; nicotine replacement ther-

Table 2—*Smokers With Biochemically Validated Smoking Cessation

Follow-up	Intervention Group (n = 109)	Usual-Care Group (n = 100)	p Value
Point prevalence			
3 mo	75 (69)	15 (15)	< 0.0001
6 mo	65 (60)	15 (15)	< 0.0001
12 mo	51 (47)	12 (12)	< 0.0001
24 mo	43 (39)	9 (9)	< 0.0001
Continuous abstinence			
3 mo	75 (69)	15 (15)	< 0.0001
6 mo	60 (55)	13 (13)	< 0.0001
12 mo	43 (39)	11 (11)	< 0.0001
24 mo	36 (33)	9 (9)	< 0.0001

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apy, 28%; combination, 40%) compared to only 17% of usual-care patients (bupropion, 1%; nicotine replacement therapy, 5%; combination, 11%; p = 0.0001). At the 3-month visit, 34 patients in the intensive-treatment group continued to smoke. Of these, only four patients chose to repeat the treatment intervention. At the 6-month visit, 44 patients in the intensive-treatment group were smoking. Twelve patients elected to repeat the treatment intervention. At the 12-month visit, 58 patients in the intensive-treatment group were smoking. Twelve patients elected to repeat the treatment intervention. At the 24-month visit, 66 patients in the intensive-treatment group were smoking. Retreatment was not offered to those smokers at that time interval. A total of 28 smokers in the intensive-treatment group elected to undergo repeat smoking cessation treatment with a mean of 6.2 ± 9.8 counseling visits per patient.

Over the 2-year follow-up, 25 patients (23%) in the intensive-treatment group were hospitalized compared to 41 patients (41%) in the usual-care group (RRR, 44%; 95% CI, 16 to 63%; p = 0.01) [Fig 1]. Thirty-seven of the 41 hospitalizations in the usual-care group (90%) were due to cardiovascular causes compared to 20 of the 25 hospitalizations in the intensive-treatment group (80%). Among patients in the usual-care group, cardiac hospitalizations included myocardial infarction in 17 patients, unstable angina in 14 patients, cardiac arrhythmia in 2 patients, and decompensated heart failure in 4 patients. The noncardiac hospitalizations in the usual-care group were secondary to a diabetic foot infection complication in one patient, exacerbation of COPD in two patients, and cancer treatment in a fourth patient. In patients in the intensive-treatment group, cardiovascular reasons for hospitalization included myocardial infarction in nine patients, unstable angina in eight patients, cardiac arrhythmia in one patient, and decompensated heart failure in two patients. Noncardiac reasons for hospitalization in the intensive-treatment group included an exacerbation of COPD in three patients, pancreatitis in one patient, and cancer treatment in one patient.

Over the 2-year follow-up period, 12 of the usual-care patients (12%) died compared to 3 of the intensive-treatment patients (2.8%; RRR, 77%; 95% CI, 27 to 93%; p = 0.026) [Fig 2]. The ARR in all-cause mortality was 9.2%. The number needed to treat to prevent one death over the course of the 2 years of follow-up was 11. All 3 deaths in the intensive-treatment group were due to cardiovascular causes compared to 9 of the 12 deaths (75%) in the usual-care group. Of the three noncardiovascular deaths in the usual-care group, two were due to respiratory failure and one was due to cancer.

Hospitalizations and deaths were stratified by baseline patient characteristics including ethnic background, age, gender, and admitting diagnosis. Only age and assignment to a treatment group significantly affected mortality and hospitalization rates. Age was not significantly different between the treatment groups, leaving assignment to a treatment group as the only variable to significantly impact clinical outcomes.

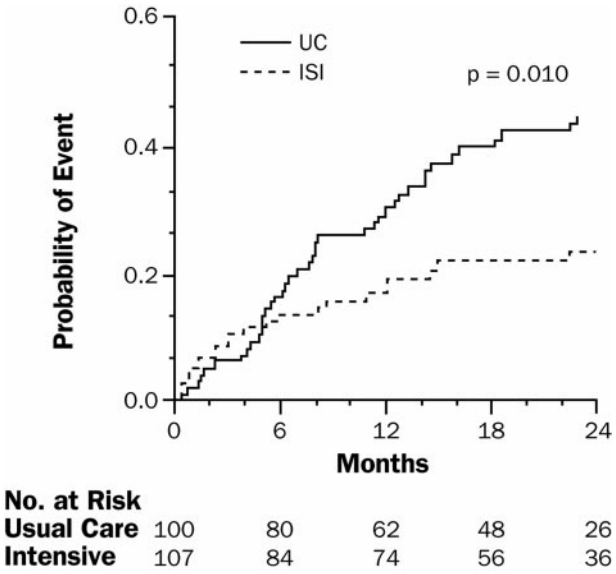

FIGURE 1. Effect of intensive smoking cessation treatment on hospital admissions.

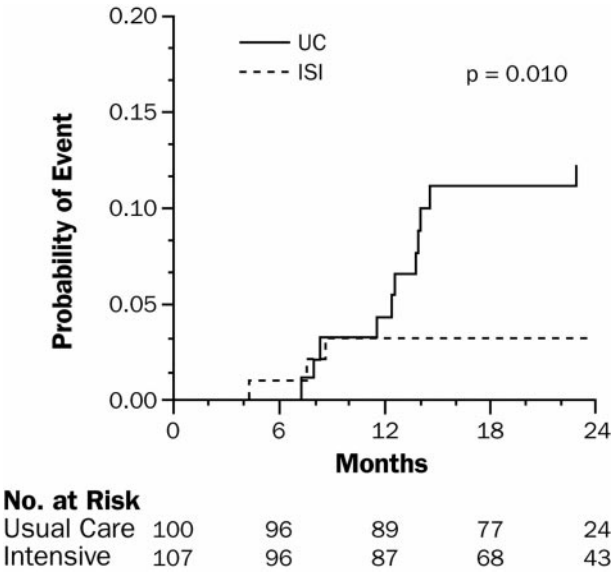

FIGURE 2. Kaplan-Meier curves of all-cause mortality in the intensive-treatment and usual-care groups.

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Discussion

The results of our study demonstrate that an intensive smoking cessation intervention in high-risk smokers with cardiovascular disease is not only effective in achieving smoking cessation, but also reduces hospitalizations and total mortality. This study is the first to demonstrate the effectiveness of a structured smoking cessation intervention in high-risk smokers with cardiovascular disease that not only leads to a reduction in smoking but also to an improvement in the rate of occurrence of adverse clinical events. Several previous studies[3–18] have demonstrated the effectiveness of smoking cessation interventions in reducing rates of smoking in hospitalized smokers, but none of these reported a reduction in morbidity or mortality.

In our trial, the initial treatment period over which counseling sessions were conducted was 3 months, with a provision for retreatment if patients relapsed. Previously published studies evaluating smoking cessation interventions in hospitalized smokers have found the duration of initial treatment to be closely linked to the success of the intervention. Smoking cessation interventions of brief duration or with infrequent contact with smokers have generally been no more effective than usual care. Sixteen randomized controlled trials[3–18] evaluating smoking cessation interventions in hospitalized smokers have been published since 1985 (Table 3).

Smoking cessation treatment significantly improved cessation rates in 10 of these trials.[4,7–12,15–17] The duration of treatment after hospital discharge was ≥ 3 months in 9 of these 10 successful trials. In one of these studies,[8] the duration of post-hospital discharge follow-up was only 1.5 months. In this trial, which was conducted in the Netherlands at 11 different hospitals in 789 smokers, smoking cessation was assessed only by self-report at 3 months. In the

Table 3—*Published Studies Evaluating Hospital Smoking Cessation Interventions**

Study	Drug Tx	BC Validation	Patient Type	Hospitals, No.	Patients, No.	Duration of Intervention	Quit Rates,† %
Rigotti et al[3]	–	+	CABG	1	87	< 1 mo (1 OP contact)	51 vs 51
Taylor et al[4]	+	+	MI	3	173	4 mo (7 OP contacts)	61 vs 32‡
Stevens et al[5]	–	–	Hospitalized smokers	2	1,173	< 1 mo (1 OP contact)	14 vs 14
Reid et al[6]	+	–	Hospitalized CAD	1	254	2 mo (3 OP contacts)	39 vs 36
Feeney et al[7]	+	+	MI	1	198	4 mo (7 OP contacts)	39 vs 2‡
Bolman et al[8]	–	–	Hospitalized CAD	11	789	1–1.5 mo (1 OP contact)	43 vs 34‡
Simon et al[9]	+	+	Hospitalized smokers	1	223	4 mo (6 OP contacts)	33 vs 20‡
Dornelas et al[10]	–	–	MI	1	100	6 mo (7 OP contacts)	55 vs 34‡
Johnson et al[11]	–	–	Hospitalized CAD	1	86	3 mo (5 OP contacts)	46 vs 31‡
Quist-Paulson and Gallefoss[12]	–	+	Hospitalized CAD	1	240	5 mo (5 OP contacts)	50 vs 37‡
Hajek et al[13]	–	+	Hospitalized CAD	17	540	< 1 mo (0 OP contact)	41 vs 37
Rigotti et al[14]	–	+	Hospitalized smokers	1	650	< 1 mo (2 OP contacts)	8.1 vs 8.7
Ockene et al[15]	–	+	Hospitalized smokers	1	261	4 mo (4 OP contacts)	35 vs 28‡
Taylor et al[16]	+	+	Hospitalized smokers	4	660	3 mo (4 OP contacts)	31 vs 21‡
Miller et al[17]	+	+	Hospitalized smokers	4	990	3 mo (4 OP contacts)	27 vs 20‡
Strechen et al[18]	–	–	Hospitalized smokers	1	125	< 1 mo (0 OP contact)	Not reported (no difference)

*Tx = treatment; BC = biochemical; OP = outpatient; + = positive; – = negative. See Table 1 for abbreviations not used in the text.
†Treatment group vs control group.
‡Statistically significant difference in smoking cessation rate.

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six trials[3,5,6,13,14,18] that failed to demonstrate the statistically significant effect of the smoking cessation treatment, the duration of post-hospital discharge treatment was < 1 month in five trials and was 2 months in the sixth trial.[6]

These studies confirm that smoking cessation interventions with a minimum intervention duration of 3 months following hospital discharge are associated with a greater likelihood of success compared to interventions of shorter duration. This is a well-documented dilemma in providing treatment for nicotine addiction. Intensive smoking cessation interventions are the most effective in terms of smoking cessation rates, but are also more expensive and reach a smaller number of smokers. In contrast, lower intensity smoking cessation interventions (*eg*, self-help pamphlets or brochures) can reach a larger number of smokers at a lower cost, but have lower smoking cessation success rates.

Another unique aspect of our treatment protocol was the provision of individualized smoking cessation pharmacotherapy at no cost to the intensive intervention participants. Adjuvant pharmacotherapy was used by 75% of the intensive-treatment smokers (bupropion, 7%; nicotine replacement, 28%; combination, 40%) compared to only 17% of the usual-care smokers (bupropion, 1%; nicotine replacement, 5%; combination, 11%; $p < 0.0001$). Of the 16 previously published trials in hospitalized smokers, only 6 trials[4,6,7,8,16,17] included nicotine replacement therapy as a treatment option. None of these trials included bupropion as a treatment option. Whether adjuvant pharmacotherapy was provided at no cost to the participants in these trials was not stated. It is unknown what impact the availability of free medication had on the outcome of our study.

Structured smoking cessation treatment interventions have been shown to improve smoking cessation rates when initiated in hospitalized cardiac patients. These studies have not previously been shown to reduce morbidity or mortality in these patients. Our study demonstrates that a structured smoking cessation intervention administered to hospitalized smokers with cardiovascular disease reduces smoking as well as clinical event rates and death. We think that our results can be extrapolated to all patients who are hospitalized with acute cardiovascular events. Obviously, smokers have to agree to receive treatment for nicotine addiction. Whether similar results can be obtained in patients identified in the outpatient setting is unknown. During hospitalization has been identified as an opportune time to intervene in smokers.[14] Success in hospitalized patients may be due in part to the occurrence of an acute illness, which may motivate patients to seek healthier lifestyles.

The major limitation of our trial is its relatively small sample size, which limited our ability to perform multivariate analyses to adjust for the impact of other factors on the study outcome. In addition, the provision of adjuvant pharmacotherapy at no cost has not been previously evaluated. It is unlikely that this practice, outside of research environments, can be readily adopted. Whether we could have achieved the same outcomes if smokers had to purchase their smoking cessation medications is unknown.

Smoking cessation treatment should be considered in the larger context of an integrated approach to reducing health risks in the patient with cardiovascular disease. In patients with coronary heart disease, antiplatelet agents, β-blockers, renin-angiotension-aldosterone system-modulating drugs, and statins have all been shown to reduce cardiovascular mortality.[20] When evaluated individually, these classes of drugs have been associated with a risk reduction for vascular events of approximately 25%. The results our study suggest that smoking cessation may be the most effective of all secondary prevention measures in this population of patients.

The American College of Cardiology/American Heart Association[21] have indicated that smokers recovering from acute coronary syndrome should receive counseling along with pharmacologic therapy (*ie*, nicotine replacement and bupropion) and formal smoking cessation programs as appropriate. Our data support this recommendation, with the further finding that a structured intensive smoking cessation intervention with an initial treatment interval of 3 months be used.

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