Letters

Five-Year Follow-up of a Randomized Clinical Trial Testing Mailed Nicotine Patches to Promote Tobacco Cessation

Our previous randomized clinical trial demonstrated that smokers receiving nicotine patches by mail (5 weeks of nicotine patches) were more likely to report 30-day point prevalence abstinence at 6 months compared with smokers not mailed nicotine patches. The current project extends this research by recontacting participants after 5 years.

Methods | Briefly, attempts were made to recontact participants from the original randomized clinical trial (924 to be recontacted; 75 did not consent to recontact). Those contacted and providing verbal informed consent to participate in the follow-up completed a telephone interview asking about current smoking and, for those not currently smoking, length of time since tobacco cessation (ie, 30 days, 6 months, or since the last interview). Attempts were made to relocate those lost to contact. Participants reported as deceased were recorded. The primary outcome was 30-day point prevalence smoking abstinence at 5 years, and the secondary outcome was prolonged 6-month abstinence at 5 years. Analyses were conducted using SPSS version 26 (IBM) and used logistic regressions with a 2-tail test, with a P value less than .05 indicating significance. The project was approved by the Centre for Addiction and Mental Health standing institutional review board.

Results | Of the 999 initial participants, a total of 518 were successfully recontacted and interviewed, including 258 of 500 participants randomized to the intervention group and 260 of 499 participants randomized to the control group. Of the 518 respondents, 276 (53.3%) were female, and the mean (SD) age was 55.9 (11.4) years.

Full Sample Analysis | Compared with participants who did not receive mailed nicotine patches, those who received mailed nicotine patches at baseline did not report increased tobacco cessation rates at 5-year follow-up (30-day point prevalence abstinence, 11.2% [56 of 499] vs 12.4% [62 of 500]; odds ratio [OR], 1.12; 95% CI, 0.76-1.65; P = .56); prolonged 6-month abstinence, 8.6% [43 of 499] vs 10.8% [54 of 500]; OR, 1.28; 95% CI, 0.84-1.96; P = .25). Participants who were not recontacted (n = 481) were assumed to be confirmed smokers.

Per-Protocol Analysis | Compared with participants who did not receive patches, those who received nicotine patches at baseline and reported using them by posttreatment (8 weeks; n = 246) did not report increased 30-day tobacco cessation rates at 5-year follow-up (11.2% [56 of 499] vs 14.6% [36 of 246]; OR, 1.36; 95% CI, 0.87-2.13; P = .18). However, compared with participants who did not receive patches, the rate of prolonged 6-month abstinence at the time of the 5-year follow-up was higher among participants who used the patches (8.6% [43 of 499] vs 13.4% [33 of 246]; OR, 1.64; 95% CI, 1.02-2.66; P = .04), and the death rate was lower (4.8% [24 of 499] vs 1.6% [4 of 246]; OR, 0.33; 95% CI, 0.11-0.95; P = .04).

Discussion | Providing a single course of free nicotine patches by mail to a proactively recruited general population sample of smokers did not lead to increases in 5-year tobacco cessation. Further, the evidence that the tobacco cessation rate was higher at 5 years among the subgroup who used the patches compared with the control group who did not receive patches is ambiguous. This means that lower death rates at 5 years among persons who used the patches likely reflect the tendency of these individuals to follow generally healthier practices (or to have different characteristics at baseline) rather than being the result of the mailed nicotine patch intervention. Limitations of our trial include that responses were self-reported and that only half of participants could be recontacted and agreed to participate in the 5-year follow-up.

There is value, at least in the short term, to use nicotine patches as part of large-scale initiatives to promote tobacco cessation among smokers in the general public. However, additional supports and interventions will be needed to maintain tobacco cessation.

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Estimation of Glomerular Filtration Rate With vs Without Including Patient Race

Glomerular filtration rate (GFR) is critically important for determining drug dosing as well as prognosis and treatment in patients with kidney disease. Despite its importance, we rarely measure it directly. Instead, we use serum creatinine level to estimate GFR (eGFRcr). Because serum creatinine is determined by diet and muscle mass as well as GFR, we use age, sex, race (African American vs non–African American), height, or weight to adjust the estimation of GFR.1-3

Using race in the equation to estimate GFR is problematic because race is a social rather than a biological construct. People self-define their race in different ways, and many people are of mixed race, making any single category flawed. We sought to compare estimated GFR with vs without including patient race in the analysis using a data set that had been previously used to develop the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation,3 the guideline-recommended GFR-estimating equation for adults, and to determine whether height and weight might substitute for race.

Methods | The CKD-EPI equation was developed using a pooled data set from 10 studies of patient groups with and without chronic kidney disease, all of whom had measured GFR values using urinary clearance of iothalamate and serum creatinine traceable to an international reference standard.3 Race was classified as African American or other and assigned by the study participants or the investigator. Performance of the equation was evaluated using root mean square error (RMSE) and bias. RMSE was computed for the regression of measured GFR (mGFR) on eGFRcr on a logarithmic scale. Bias was computed as the median value for the difference between eGFRcr and mGFR (eGFRcr – mGFR). We compared median bias and RMSE between equations using Wilcoxon signed rank tests. Analyses were performed from May through June 2019 using SAS software version 9.4M6 (SAS Institute). The Tufts Health Sciences Institutional Review Board deemed the study exempt from review owing to the use of deidentified data.

Results | Among the 8254 participants in the development data set, 2601 (31.5%) were African American, 3606 (43.6%) were...