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The effects of a patient activation intervention on smoking and excessive drinking cessations: results from the PAADRN randomized controlled trial

F. D. Wolinsky^{1,2,3}, Y. Lou⁴, S. W. Edmonds^{2,3,5}, K. G. Saag⁶, D. W. Roblin^{7,8}, N. C. Wright^{6,9}, M. P. Jones⁴, and P. Cram^{2,10,11} on behalf of the PAADRN Investigators

¹Department of Health Management and Policy, University of Iowa, 145 North Riverside Drive, CPHB N211, Iowa City, Iowa City, IA 52242, USA

²Department of Internal Medicine, University of Iowa, Iowa City, IA, USA

³College of Nursing, University of Iowa, Iowa City, IA, USA

⁴Department of Biostatistics, University of Iowa, Iowa City, IA, USA

⁵CADRE, Iowa City VA Healthcare System, Iowa City, IA, USA

⁶Department of Internal Medicine, University of Alabama, Birmingham, AL, USA

⁷Kaiser Permanente, Atlanta, GA, USA

⁸Department of Health Management and Policy, Georgia State University, Atlanta, GA, USA

⁹Department of Epidemiology, University of Alabama, Birmingham, AL, USA

¹⁰Department of Medicine, University of Toronto, Toronto, Canada

¹¹Division of General Internal Medicine and Geriatrics, Mt. Sinai/UHN Hospitals, Toronto, Canada

Abstract

Summary—Patients may exhibit risky bone health behaviors. In a large pragmatic clinical trial, we tested whether a tailored patient activation DXA result letter accompanied by a bone health brochure led to smoking and excessive drinking cessations. The intervention did not, however, alter these risky bone health behaviors.

Introduction—Besides dual-energy x-ray absorptiometry (DXA) screening and pharmacotherapy when indicated, beneficial bone health behaviors including proper calcium and vitamin D intake and weight-bearing and muscle-strengthening exercise should be encouraged. Similarly, risky bone health behaviors like smoking and excessive drinking should be discouraged. We examined whether a direct-to-patient activation intervention led to smoking and excessive drinking cessations.

Correspondence to: F. D. Wolinsky.

Trial Registration: clinicaltrials.gov identifier NCT01507662.

Compliance with ethical standards

Conflicts of interest F. D. Wolinsky, Y. Lou, S. W. Edmonds, D. W. Roblin, M. P. Jones, and P. Cram, have no conflicts of interest.

Methods—The Patient Activation after DXA Result Notification (PAADRn) pragmatic clinical trial enrolled 7749 patients between February 2012 and August 2014. Interviews occurred at baseline and 12 and 52 weeks later. Intervention subjects were mailed an individually tailored DXA results letter accompanied by a bone health educational brochure 4 weeks post-DXA. Usual care subjects were not sent these materials. Smoking and excessive drinking were assessed by self-report at each interview. Intention-to-treat linear probability models were used.

Results—Mean age was 66.6 years, 83.8% were women, and 75.3% were Non-Hispanic-Whites. Smoking was reported at baseline by 7.6% of the intervention group vs. 7.7% of the usual care group ($p = 0.873$). Excessive drinking was reported at baseline by 6.5% of the intervention group vs. 6.5% of the usual care group ($p = 0.968$). Intention-to-treat analyses indicated no significant differences between the intervention vs. usual care groups at either 12 or 52 weeks post-DXA (all p values > 0.346).

Conclusion—An individually tailored DXA result letter accompanied by an educational brochure did not lead to smoking or excessive drinking cessations in patients who received DXA.

Keywords

Clinical trials; Drinking; DXA; Osteoporosis; Smoking

Introduction

It is estimated that three million osteoporotic fractures will occur in the United States (U.S.) in 2025 at a cost of 25.3 billion dollars [1]. Currently, the primary U.S. strategy for reducing osteoporotic fractures involves screening for osteopenia and osteoporosis using dual-energy x-ray absorptiometry (DXA) [2], followed by appropriate pharmacotherapy when indicated [3]. Encouraging beneficial bone health behaviors like proper calcium and vitamin D intake and weight-bearing and muscle-strengthening exercise, and discouraging risky bone health behaviors like smoking and excessive drinking are relegated to secondary strategies, largely because of the greater difficulty of bringing about meaningful and enduring behavioral change [3, 4].

Success rates for these primary and secondary strategies for reducing osteoporotic fractures in the U.S., however, are low. Seven-year cumulative DXA screening incidence rates range from 42.7 to 58.8% in traditional fee-for-service Medicare [5], and the lifetime prevalence rate in Medicare Advantage Organizations is 69% [6]. Pharmacotherapy rates range from 23.3% within 2 years of an osteoporosis diagnosis or a fragility fracture to 28.5% within 12 months post-discharge for a hip fracture [7, 8]. Approximately 41% of those 65 years old or older are vitamin D deficient, and less than half meet their estimated average requirement for calcium [9]. Only 21.9% of 65–74-year-olds and only 17.2% of those 75 years old or older meet CDC guidelines for adequate physical activity and exercise [10]. Cigarettes are smoked by 8.4% of older adults [11]. Forty percent of older adults drink alcohol, and 3.8% identify themselves as binge drinkers (i.e., five or more drinks per episode) who engage in that behavior somewhat more often than younger adults [12].

To increase rates of guideline-concordant pharmacotherapy, proper calcium and vitamin D intake, weight-bearing and muscle-strengthening exercise, osteoporosis knowledge, care satisfaction, and health-related quality of life, we conducted the Patient Activation after DXA Result Notification (PAADRN; NCT-01507662) trial, a pragmatic randomized controlled trial (RCT) [13–15]. We enrolled 7749 patients presenting for DXA testing at three U.S. health care centers. Our intervention consisted of an individually tailored results letter that explained patients' DXA results and fracture risks accompanied by a bone health brochure. In this short communication, we test the hypothesis that the patient activation intervention reduced smoking and excessive drinking. This hypothesis is consistent with Bandura's social learning theory [16–18] which states that people may learn new (or change old) behaviors by observation, imitation, and modeling, especially when those learning mechanisms capture their attention and motivate them toward the desired behavioral change. Accordingly, we focused the bone health brochure on self-efficacy and outcome expectations by providing informational accuracy, written persuasion, and emotional arousal specifically targeting the risks associated with smoking and excessive drinking [19, 20].

Methods

Design and sample

Between February 2012 and August 2014 we identified patients potentially eligible to participate in the PAADRN pragmatic RCT by reviewing the electronic scheduling records for DXA testing appointments of patients referred to DXA testing at the University of Iowa (UI), the University of Alabama at Birmingham (UAB), and Kaiser Permanente of Georgia (KPGA) by their providers [13–15]. These three sites were chosen because of the diversity of their academic affiliations, osteoporosis research and clinical programs, geographic locations, and patient populations served. We excluded patients less than 50 years old, prisoners or patients with overt cognitive disability, and patients who did not speak or read English, were deaf, or lacked access to a telephone. Baseline telephone or face-to-face interviews were conducted by trained research assistants from up to 28 days before or up to 3 days after their baseline DXA. Randomization to the intervention or usual care groups occurred 2 weeks after their baseline DXA (and thus after their baseline interview). Other trained staff, also blinded to the patients' randomization status, conducted the follow-up telephone interviews at 12 and 52 weeks post-DXA. All investigators were also blinded to the patients' randomization status until after the last 52 week follow-up interview for the PAADRN study was completed. The study protocol, including the process for consenting patients, was approved by the Institutional Review Boards at UI, UAB, and KPGA. The full PAADRN protocol is available online at <https://clinicaltrials.gov/ct2/show/NCT01507662>.

Intervention

Intervention patients were notified of their DXA results via an individually tailored letter accompanied by an educational brochure [13–15, 19, 20]. The letter included the clinical impression of each patient's DXA result (normal, osteopenia, or osteoporosis), their 10-year fracture risk, and the suggestion that the patient bring the letter to their next physician visit and discuss it with their provider. The brochure explained osteoporosis and reviewed the benefits of proper calcium and vitamin D intake, exercise, fall prevention, and cessation of

smoking and excessive alcohol intake. Intervention materials were mailed to patients from the UI coordinating center 4 weeks post-DXA. Usual care patients received their DXA results based on the practices of their physicians and healthcare systems.

Outcomes

We asked three questions about smoking at the baseline interview and two questions about smoking at each follow-up interview that were taken from or modeled after those used in the Centers for Disease Control and Prevention (CDC) Behavioral Risk Factor Surveillance System (BRFSS; <https://www.cdc.gov/brfss/questionnaires/>). The baseline questions were “Have you smoked at least 100 cigarettes in your entire life?”, “Do you now smoke cigarettes every day, some days, or not at all?”, and if so, “On the days you smoke, how many cigarettes do you smoke per day?” The follow-up questions were “Do you now smoke cigarettes every day, some days, or not at all?”, and if so, “On the days you smoke, how many cigarettes do you smoke per day?” Current cigarette smokers were coded “1” and former smokers and non-smokers were coded “0.” We asked two questions about alcohol consumption during the baseline and follow-up interviews that were also modeled after the CDC’s BRFSS. The first was “Do you drink alcohol?”, and if so, the second was “How many drinks do you have on a typical day?” Consistent with the recommendations of the American Federation for Aging Research (https://www.afar.org/docs/AFAR_INFOAGING_GUIDE_ALCOHOL_ABUSE_2016.pdf), excessive drinking was defined as having more than one drink on a typical day, with excessive drinkers coded “1” and moderate drinkers and abstainers coded “0.”

Covariates

The covariates included self-reported age, sex, race, education, health, history of chronic obstructive pulmonary disease, history of depression, fractures after age 40, parental hip fractures after age 50, patient prior DXA testing, fracture risk, prior diagnoses for osteopenia or osteoporosis, current or former osteoporosis medication use, and study site.

Analysis

Baseline characteristics of the intervention and usual care patients were compared using bivariable methods. Multivariable linear probability models (LPMs; i.e., ordinary least squares regression) with random effects were used to adjust for the clustering of patients within physicians among those with complete follow-up data. LPMs have an intuitive advantage over logistic regression because the regression coefficients from LPMs are directly interpretable as marginal effects rather than as odds ratios from logistic regression models. Nonetheless, in sensitivity analyses we replicated the LPMs using logistic regression with random effects. Two LPMs were estimated each for smoking and excessive drinking. The first models only contained the indicator variable for the intervention vs. usual care groups, providing crude results adjusted only for the clustering of patients within physicians. The second models adjusted for clustering as well as all covariates. We also conducted heterogeneity of treatment effect (HTE) sensitivity analyses to see whether the results were moderated by self-efficacy or patient treatment preferences at baseline, or by changes in self-efficacy at 12 weeks post-DXA, or by baseline DXA results (normal, osteopenia, or osteoporosis). All *p* values are two-tailed, with those ≤ 0.025 deemed

statistically significant based on a Bonferroni correction for testing each outcome over two different time periods (baseline to 12 weeks, and baseline to 52 weeks). All statistical analyses were performed using *SAS 9.4* (SAS Inc., Cary, NC).

Results

The PAADRN CONSORT patient flow chart and descriptive baseline data for the covariates have previously been described [14]. Approximately 54% (7749) of the 14,280 patients known to be eligible for the study consented to participate and were enrolled. Follow-up interviews were completed by 86.8% at 12 weeks post-DXA and by 77.7% at 52 weeks post-DXA. Because previous analyses [14] of these data have shown that using inverse probability of treatment weighting (IPTW) to adjust for potential attrition bias associated with loss to follow-up have yielded comparable results to those obtained when only complete cases were analyzed, here we used the latter approach because it is more straightforward.

In general, there were no meaningful differences between patients assigned to the intervention and usual care groups on the baseline covariates [14]. Mean age was 66.6, 83.8% were women, and 75.3% were Non-Hispanic-Whites. The prevalence of osteoporosis (19.5%) and osteopenia (53.1%) were higher than recent national estimates (10.3 and 43.9%) because PAADRN patients were recruited from patients presenting for DXA testing rather than from the general population like the National Health and Nutrition Examination Survey [14]. The percentage of patients with one or more prior DXAs was 67.1%, with no meaningful difference between the intervention vs. usual care groups (66.9 vs. 67.3%, $p = 0.719$).

Table 1 contains the unadjusted bivariable analysis of the effect of the PAADRN intervention on smoking and excessive drinking cessations. As shown, the prevalence of smoking in the intervention vs. usual care groups at baseline (7.6 vs. 7.7%, $p = 0.873$), 12 weeks post-DXA (7.1 vs. 6.8%, $p = 0.675$), and 52 weeks post-DXA (6.1 vs. 6.6%, $p = 0.412$) were not statistically significantly different. Rather, both groups showed equivalent meaningful declines in the prevalence of smoking over the course of the study ($p < 0.001$ for both groups at both time points). Similarly, the prevalence of excessive drinking in the intervention vs. usual care group at baseline (6.5 vs. 6.5%, $p = 0.968$), 12 weeks post-DXA (5.7 vs. 5.2%, $p = 0.346$), and 52 weeks post-DXA (5.0 vs. 4.9%, $p = 0.961$) were not significantly different, although once again both groups showed equivalent meaningful declines in the prevalence of excessive drinking ($p < 0.001$ for both groups at both time points).

Table 2 contains the results of the two LPMs for both smoking and excessive drinking. The first model only adjusts for the clustering of patients within physicians, while the second further adjusts for all of the covariates. As shown, these results also indicate that there were no statistically significant effects of the PAADRN intervention on smoking and excessive drinking cessations. The results of the sensitivity analyses using multivariable logistic regression (not shown but available on request) were comparable. The results of the sensitivity analyses testing for effect moderation due to self-efficacy, patient treatment

preferences, DXA results at baseline, or by changes in self-efficacy at 12 weeks post-DXA (not shown but available on request) revealed no HTEs.

Discussion

We tested the hypothesis that an individually tailored, direct-to-patient DXA results letter accompanied by a bone health brochure led to smoking and excessive drinking cessations. Our hypothesis was based on Bandura's social learning theory [16–8] which posits that behaviors may either be learned or relearned based on observation, imitation, or modeling, especially when these mechanisms capture a patient's attention and motivate them towards the desired behavioral change. Accordingly, our bone health educational brochure focused on self-efficacy and outcome expectations by providing informational accuracy, written persuasion, and emotional arousal specifically targeting the risks associated with smoking and excessive drinking. We used baseline and 12 and 52 week post-DXA interview data on the 7749 patients enrolled in the PAADRN pragmatic RCT [13–5, 19, 20] with LPMs for effect estimation. The results showed that while both the intervention and usual care groups showed meaningful declines in both the prevalence of smoking and excessive drinking over the course of the study ($p < 0.001$ for both groups on both smoking and excessive drinking at both 12 and 52 weeks post-DXA), those declines in risky bone health behaviors were not significantly different between the two groups.

There are five plausible reasons why our patient activation intervention was not successful. The first three are related and actually led us to anticipate the possibility of failing to reject the null hypotheses in the original protocol (<https://clinicaltrials.gov/ct2/show/NCT01507662>). To start with, the dose (or intensity) of PAADRN's intervention was quite low. Traditional Screening, Brief Intervention and Referral to Treatment (SBIRT) programs involve 5–10 min of universal screening that targets one or two risky health habits with an interventional message along with referral to behavioral health care [4]. Second, our interventional message was not delivered by a physician or other health care worker who might have brought some sense of positional authority and influence to the situation [4]. Rather, we simply postal mailed the intervention materials to patients who were encouraged to read, reflect upon, and then take the DXA results letter and brochure to their next physician visit for discussion [13–5]. Third, we did not offer referral to behavioral healthcare for counseling sessions and follow-up, or pharmacotherapy, which are important when trying to modify risky health behaviors [4]. Taken together, these first three reasons are crucial when trying to change addictive behaviors like smoking and excessive drinking, especially when the study outcomes focus on cessation of these unhealthy behaviors. The reason is that although low dose interventions that are not delivered by a health care provider and are not accompanied by referral to behavioral counseling or pharmacotherapy may move a patient through one or more of the three early transtheoretical stages of behavior change (pre-contemplation, contemplation, and preparation), such interventions are not likely to bring about the two latter stages (action and maintenance) [21]. At the same time, however, the low intensity, impersonal delivery, and lack of referral are in keeping with the purpose of pragmatic RCTs and the development of a highly scalable intervention.

A fourth plausible reason for our intervention's lack of success involves the PAADRN sample itself. The percentage of patients with one or more prior DXAs was high (67.1%). Even though there were no meaningful differences in these percentages between the intervention and usual care groups, each of the patients who were smokers or excessive drinkers and reported having had prior DXAs should already have been well-motivated to change their unhealthy behaviors in order to protect their bones. Moreover, the prevalence of smoking and excessive drinking among PAADRN patients was relatively low at baseline (7.6 and 6.5%, respectively). Furthermore, although on average PAADRN patients agreed with 4.7 out of the 9 statements reflecting a desire for obtaining more information about their health on the Krantz Health Opinion Survey [22], which is comparable to prior studies, PAADRN patients agreed with only 2.1 out of the 7 statements reflecting a desire for actively participating in their health care, which is substantially lower than that reported in prior studies. Thus, these sample characteristics collectively exerted a floor effect that constrained the opportunity for the intervention's success. The final plausible reason why our patient activation intervention was not successful involves the extensive amount of osteoporosis-related data collected during the baseline and follow-up interviews. Asking such an extensive number of questions about osteoporosis self-efficacy and knowledge, patient treatment preferences, and the like may have created a co-intervention that overwhelmed our actual intervention.

PAADRN has three limitations worth noting. First, it was powered on the primary outcome of guideline-concordant pharmacotherapy, and not on detecting differences on the secondary and tertiary outcomes. Given the large sample and remarkable similarity of the declines in the prevalence of smoking and excessive drinking between the intervention and usual care groups, however, it is not likely that our failure to reject the null hypotheses was due to statistical power. Second, our outcomes were ascertained via patient self-reports, which could involve inaccuracies that may or may not have been random. This is especially problematic when risky health behaviors like smoking and excessive drinking are the outcomes of interest [11, 12]. Finally, many PAADRN patients had a prior DXA and thus may have already interacted with health care providers about decreasing their risky health behaviors like smoking and excessive drinking, which may have decreased the effectiveness of the patient activation intervention among them, although additional HTE sensitivity analyses (data not shown) did not find this to be the case.

In conclusion, both the intervention and usual care groups had significant reductions ($p < 0.001$) on both smoking and excessive drinking prevalence at both 12 and 52 weeks post-DXA. Those declines in risky bone health behaviors, however, were not significantly different between the two groups. Future direct-to-patient interventions should consider augmentation with clinician follow-up for initial discussion, referral to counseling, and the potential for pharmacotherapy.

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Table 1

Bivariable analyses of the effect of the intervention letter and bone health brochure on smoking and excessive drinking cessations

Risky bone health behavior	Intervention	Usual care	<i>p</i> value
Currently smokes cigarettes			
Baseline	7.57% (295/3898)	7.66% (295/3849)	0.873
12 weeks	7.08% (240/3391)	6.82% (226/3315)	0.675
52 weeks	6.12% (188/3074)	6.63% (200/3017)	0.412
Currently drinks alcohol excessively			
Baseline	6.52% (254/3898)	6.49% (250/3850)	0.968
12 weeks	5.74% (195/3399)	5.21% (173/3318)	0.346
52 weeks	4.96% (153/3082)	4.94% (149/3018)	0.961

Table 2

Estimates from linear probability models with random effects for the clustering of patients within physicians of the effect of the intervention letter and bone health brochure on smoking and excessive drinking cessation

Risky bone health behavior	At 12 weeks post-DXA		At 52 weeks post-DXA	
	Crude	Adjusted ^I	Crude	Adjusted ^I
Currently smokes cigarettes				
Regression coefficient	0.001	0.003	-0.006	-0.006
P value	0.859	0.683	0.415	0.365
Currently drinks alcohol excessively				
Regression coefficient	0.005	0.005	0.000	0.001
P value	0.412	0.403	0.954	0.909

^I Adjusted for patient age, sex, race, education, self-rated health, history of chronic obstructive pulmonary disease, history of depression, fractures after age 40, parental hip fractures after age 50, patient prior DXA testing, fracture risk, prior diagnoses for osteopenia or osteoporosis, current or former osteoporosis medication use, and study site