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**Evaluating the effectiveness of Smoking Cessation
Intervention Program in Low Income Emergency
Department Adult Populations using moderation and
meditational analysis**

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Abstract:

Cigarette and tobacco use is common among ED patients from lower socioeconomic backgrounds. Our goal in this study was to conduct moderation and mediation analysis to evaluate the effectiveness of an enhanced smoking cessation intervention involving enhanced care as compared to standard care for adult smokers in the ED. Our study is a secondary analysis of a two-arm randomized clinical trial conducted by Dr. Bernstein, which involved two intervention arms; one with enhanced care where the subjects received a motivational interview by a trained research assistant, 6 weeks of nicotine replacement therapy (NRT) initiated in the ED, a faxed referral to the state smokers' quitline, a booster call, and a brochure. The subjects in control arm subjects received the brochure, which provided quitline information. We used mediation analysis to assess the treatment effects of the mediators; NRT use and Quitline calls and moderation analysis to evaluate the effect modification or interaction of the moderators; baseline nicotine dependency and craving with the treatment. The outcomes were 7-day abstinence and number of cigarettes smoked per day at three months. We found significant mediation effects with the NRT use on both the outcomes. However, the speaking to a quitline counselor had only marginal mediation effects. We could not detect any interaction or effect modification with either of the two moderators on 7-day abstinence and no. of cigarettes smoked per day.

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Background and Rationale:

Cigarette smoking and tobacco use is a global epidemic affecting about 1 billion people worldwide and killing 6 million people per year (1). In the United States, one of the leading causes of preventable deaths and related illnesses is cigarette use. According to U.S. Department of Health and Human Services, more than 16 million Americans are currently living with a disease attributable to smoking (2). In 2013, 17.8% (42.1 million) of all American adults aged 18 and above smoked and more than 480,000 died from smoking-related illnesses. The total economic cost of smoking in the United States is more than \$300 billion a year (3, 4).

The majority of smokers in the United States come from lower socioeconomic backgrounds as compared to other populations. Poverty status, education and race/ethnicity usually determine smoking behaviors in the United States. There is a wide gap between socioeconomic status (SES) groups with respect to the use of tobacco products. Smoking prevalence remains highest among those who have less than a high school education (28.4%), those with no health insurance (28.6%), and those living below the federal poverty level (27.7%) (5). To address these growing disparities, public policy efforts have been directed in order to increase state Medicaid insurance coverage for evidence-based tobacco cessation treatments (6). Currently, all the 50 states and the District of Columbia offer insurance coverage for tobacco cessation treatment to Medicaid recipients (7), but the degree of coverage for services is different in each state and these services are typically underutilized (8). Interventions delivered in health care settings by physicians have the potential to reach a wide range of smokers, considering that more than 70% of smokers see their physician each year. The Emergency Department (ED) presents a unique opportunity for screening, intervention and referral for treatment, as these low income populations commonly receive care in hospital emergency departments (ED), either for

medical consequences of smoking or for comorbid medical and psychiatric conditions because they often have limited access to primary care providers, who tend to undertreat tobacco use (9,10, 11). Also, there is a greater prevalence of smoking in ED patients than in the general population (12).

Tobacco control efforts have been taking place in ED settings for many years and a recent meta-analysis of 7 ED studies containing 1,986 subjects found enhanced abstinence at one month, with the odds for tobacco abstinence in the intervention arm (enhanced care; brochure, motivational interview and nicotine patches) of 1.47 (95% CI 1.06-2.06), compared to controls (usual care; just brochure) (13). Our study is based on Dr. Steven L Bernstein's randomized clinical trial where they studied the efficacy of an intervention incorporating Screening, Brief Intervention, and Referral to Treatment with nicotine replacement therapy (SBIRT + NRT) and quitline referral for adult smokers in an ED. In the study, the intervention subjects received a motivational interview by a trained research assistant, 6 weeks of nicotine patches and gum initiated in the ED, a faxed referral to the state smokers' quitline, a booster call, and a brochure. The controls received the brochure, which provided quitline information. The primary outcome was biochemically confirmed tobacco abstinence at three months. The study showed that the prevalence of biochemically confirmed abstinence was 12.2% (47/386) in the intervention arm vs. 4.9% (19/388) in the control arm, for a difference in quit rates of 7.3% (95% CI 3.2%, 11.5%). In multivariable logistic modeling controlling for age, sex, and race/ethnicity, study subjects remained more likely to be abstinent than controls (OR 2.72, 95% CI 1.55, 4.75).

The study utilized a multicomponent intervention model, so we wanted to determine which of its individual components were responsible for any improvement compared to the control group. Therefore, we planned to conduct a series of mediator analyses to observe the effects of these

individual mechanisms. These results will be helpful in refining future the intervention for better outcomes. A mediator is a variable that helps in identifying the mechanism or process that underlies an observed relationship between an independent variable and a dependent variable. We also planned to examine a few moderator analyses to determine the effectiveness of the intervention in different subgroups of smokers. A moderator variable is a variable that affects the direction and/or strength of the relation between an independent variable and a dependent variable. Past studies have shown that adherence with nicotine replacement therapy is associated with both short-term (as short as 1-week) and long-term (6 months) smoking cessation treatment outcome (14,15). We hypothesize that since the SBIRT + NRT intervention increases cessation outcomes, NRT adherence is acting as a mediator between the treatment and outcome, hence the participants may be more likely to report appropriate adherence with their NRT and consequently better smoking cessation outcomes. Therefore, we planned to assess adherence with NRT as a mediator. Since the intervention arm incorporated Quitline; we also hypothesized that Quitline use will mediate the relationship between the intervention and smoking cessation outcome, thereby improving the quitting rates. Hence, we plan to test Quitline use as a mediator. Dr. Bernstein's trial has hypothesized that the tobacco intervention may be more efficacious for less nicotine-dependent participants. So, we wanted to examine whether baseline level of nicotine dependency moderates the effect of treatment on the cessation outcome. In addition to nicotine dependency, we hypothesize whether or not the level of craving (greater or lower), measured at the time of discharge from the ED, is likely associated with less smoking and thus more abstinence. Thus, we examined if the level of craving will moderate the effect of treatment on smoking cessation outcome.

Methods:

Study population

Our study is a secondary data analysis of the study conducted by Dr. Bernstein's, which was a single-hospital 2-arm randomized controlled trial of a multicomponent intervention for adult smokers presenting to the ED, with blinded outcome assessment. The intervention arm received a brief motivational interview, provision of six weeks of NRT, initiation of NRT in the ED, active referral to a smokers' quitline, a booster phone call 3 days after enrollment, and provision of a smoking cessation brochure. The control arm received the brochure alone. The study included patients who presented to the adult ED at Yale-New Haven Hospital (YNHH) and their eligibility criteria were (1) 18 years or older (2) have smoked ≥ 100 cigarettes lifetime (3) describe themselves as every or someday smokers (4) smoke at least 5 cigarettes/day (5) insured by Medicaid or are uninsured, and (6) are able to give written informed consent. Dr. Bernstein's study had a sample size of 778 with 353 in each arm, based on 3-month of follow-up, a quit rate in the intervention arm of 20%; in the control arm 12%, and an alpha at 2-sided 0.05 and 80% power. Figure 1 illustrates flowchart of the selection and analysis process.

Outcomes, moderators, and mediators

Our outcomes are 7-day abstinence (dichotomous) and no. of cigarettes smoked per day (continuous) at the 3 month follow-up timepoint.

We examined two mediators. Our first mediator is Quitline calls, which we divided into two groups, have you spoken to a QT counselor (yes/no) or a continuous variable, total quitline calls. Our second mediator is NRT use (continuous), which was evaluated either as total number of single NRT used (NRTmax) or total number of combined NRT's used (NRTcount).

For our secondary data analysis, the moderators are baseline nicotine dependency and craving.

Statistical analysis

For the moderation analysis, we used SAS version 9.3. To perform moderation, we created an interaction term to evaluate the two-way interactions of treatment with the moderators. We used logistic regression for the dichotomous outcome and linear regression for the continuous outcome. We have ran different models with individual variables in each model.

For the mediation analysis, we used SPSS Statistics Desktop software version 22.0 with the process macro (16) for the continuous outcome and MPlus version 7.2 for the dichotomous outcome. To perform mediation, we conducted a series of regression analyses to observe the direct and indirect effect of the treatment on the outcomes. In the first step, we regressed the exposure to outcome to show that the outcome is associated with the exposure. In the second step, we regressed the mediator on the exposure to show that the mediator is associated with exposure. In the next step, we regressed the mediator to the outcome but we included treatment (intervention) in the model to account for the possibility that both the outcome and mediators are caused by exposure. In the last step, we used the previous regression model to test how the effect of exposure changes when the mediator is added to the model. We ran different mediation models with a mediator in each model. We also ran a model with multiple mediators in the same model but the results were not included in this study, since we observed the same mediation effects as the individual model.

Results:

The 778 subjects in this study were followed from October 2010 to December 2012. 774 (99.5%) were alive at 3 months. The table 1 represents the baseline characteristics of study subjects, which were comparable between treatment groups. More than half the study subjects were nonwhite. Mean daily cigarette consumption was comparable between the two groups.

Table 1. Baseline patient characteristics.		
Variable	Usual Care (N = 390)	Intervention (N = 388)
Age, mean, years	40.2	40.8
Sex, no. male (%)	201 (51.5%)	170 (43.8%)
Race/ethnicity, N (%)		
White	157 (40.3%)	148 (38.1%)
African-American	153 (39.2)	155 (39.9)
Hispanic	77 (19.8)	81 (20.9)
Asian/Other	3 (0.8)	4 (1.1)
Cigarettes/day, mean, SD	13.7 (SD = 7.4)	13.4 (SD = 8.1)

Below are the frequency tables describing the characteristics of the moderators (baseline nicotine dependency and craving) and mediators (have you spoken to QT counsellor, total QT calls, NRTcount and NRTmax)

Variable	Usual Care (N = 390)	Intervention (N = 388)
NRTmax, mean, SD	5.5 (SD = 14.3)	24.1 (SD = 24.5)
NRTcount, mean, SD	2.75 (SD = 12.9)	32.8 (SD = 39.4)
Total Quitline Calls, mean, SD	0.31 (SD = 1.07)	0.52 (SD = 1.35)
Craving, mean, SD	4.64 (SD = 2.16)	4.77 (SD = 2.16)
Baseline Nicotine Dependency, mean, SD	13.44 (SD = 8.19)	13.71 (SD = 7.47)

		Frequency	Percent
Valid	no	490	62.9
	yes	137	17.6
	Total	627	80.5
Missing	System	152	19.5
Total		779	100.0

The total no. of cigarettes smoked per day before the trial was, on average, 13 for each group. After the treatment, the no. of cigarettes smoked per day went down to, on average, 5 in the SBIRT + NRT treatment group and 7.62 in the standard care group. Below are the statistics.

	Before Interventions		After Interventions	
	SBIRT + NRT	Standard care	SBIRT + NRT	Standard care
Mean	13.44	13.71	5.01	7.62
Std. Deviation	8.19	7.47	6.00	6.89

For the mediation, the total effect of the treatment on the 7-day abstinence was 0.098. The direct and the indirect effects of the mediators are represented in table 5. Of the four mediators, total QT calls (p=0.03) and NRTmax (p=0.006) significantly mediated the effect of treatment on the outcome 7-day abstinence.

Mediators	Total effect of treatment	Direct effect (β)	Indirect effect (β)	Significance (p-value)	Percentage mediated
Spoken to QT counselor?	0.098	0.088	0.009	p=0.069	9.2%
Total QT calls		0.083	0.014	P=0.03	14.3%
NRT count		0.097	0.000	p=0.987	0%
NRT max		0.053	0.044	p=0.006	44.9%

*This is simple mediation analysis

For the outcome no. of cigarettes per day, the total effect of the treatment was 2.613. The direct and the indirect effects of the mediators are represented in table 6. Of the four mediators, total

NRTcount ($p<0.001$) and NRTmax ($p<0.001$) significantly mediated the effect of treatment on the outcome no. of cigarettes per day.

Table 6. Mediation effects on the no. of cigarettes per day outcome					
Mediators	Total effect of treatment	Direct effect (β)	Indirect effect (β)	Significance (p-value)	Percentage mediated
Spoken to QT counselor?	2.613	2.499	0.113	p=0.097	4.3%
Total QT calls		2.366	0.248	p=0.07	9.5%
NRT count		1.366	1.288	p<0.001	50.7%
NRT max		0.935	1.678	p<0.001	64%

*This is simple mediation analysis

The moderation analysis for the outcome no. of cigarettes per day, was conducted by creating an interaction term between the treatment and the two moderators and a linear regression was performed. The interaction term was not significant for either of the two moderators; baseline dependency and craving. The test for fixed effects of treatment by baseline dependency levels 1, 2, 3 and craving on no. of cigarettes per day, resulted in an insignificant p-values. For the outcome 7-day abstinence, the analysis of maximum likelihood estimates by baseline dependency levels 1, 2, 3 and craving, also resulted in insignificant p values. Below are tables 7 and 8 showing the parameter estimates and p-values of the moderator analysis on the outcomes no. of cigs per day and 7-day abstinence.

Table 7. Test of fixed effects of moderators on no. of cigarettes/day.

Variable	Group Assignment	Estimate	Pr > t
treatment*baselinedependency1	SBIRT + NRT	-1.3152	0.2112
treatment*baselinedependency2	SBIRT + NRT	-1.3563	0.4260
treatment*baselinedependency3	SBIRT + NRT	-2.4195	0.3529
craving*treatment	SBIRT + NRT	-0.4014	0.0939

Table 8. Analysis of Maximum Likelihood Estimates of moderators on 7-day abstinence.

Variable	Group Assignment	Estimate	Pr > t
treatment*baselinedependency1	SBIRT + NRT	-0.0341	0.9449
treatment*baselinedependency2	SBIRT + NRT	-0.4409	0.6041
treatment*baselinedependency3	SBIRT + NRT	13.3825	0.9801
craving*treatment	SBIRT + NRT	-0.1008	0.3485

Discussion and further implications

Our study has shown that at the end of a 3 month study period, nicotine replacement therapy (NRT) has shown a significant mediation of the intervention on the 7-day abstinence and the no. of cigarettes smoked per day. We have also observed that talking to a Quitline counselor has shown some marginal mediation of the intervention on the 7-day abstinence and the no. of cigarettes smoked per day. Craving and baseline dependency have not shown any moderation effect on either of the two outcomes. The absence of moderation may be attributed to the fact that the study had a low power to detect a statistical interaction between the moderators and the treatment. Our study had a limitation that it was performed at a single site on low-income adult population. Despite the fact that patients in this study were diverse with respect to race, ethnicity, and gender, it is unclear whether the same results can be replicated in other patient populations. So, it is not possible to generalize our results. Basing on these observations, further research could be conducted that aim to increase the dosage of the NRT's to improve the cessation rates. Also, further studies can be conducted that can look at whether or not higher Quitline calls to the patients on a regular basis improves the smoking cessation rates. Our outcome endpoint was 3 months. So, it would be interesting to look at the cessation rates over a longer period of time (1yr, 2yrs, etc.) with the proposed interventions. Expanding and conducting trials in other patient population could be useful to determine if similar interventions would yield the same results in other populations too.

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Figure 1: Flow of patients through the trial

