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Effects of Smoking Cessation with Voucher-Based Contingency Management on Birth Outcomes

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Abstract

Introduction—This study combined data from three controlled trials to examine whether smoking cessation using voucher-based contingency management (CM) improves birth outcomes.

Methods—Participants (N = 166) were pregnant women who participated in trials examining the efficacy of voucher-based CM for smoking cessation. Women were assigned to either a contingent condition wherein they earned vouchers exchangeable for retail items by abstaining from smoking or to a noncontingent condition where they received vouchers independent of smoking status. Birth outcomes were determined by review of hospital delivery records.

Results—Antepartum abstinence was greater in the contingent than noncontingent condition, with late-pregnancy abstinence being 34.1% vs. 7.4% ($p < .001$). Mean birth weight of infants born to mothers treated in the contingent condition was greater than infants born to mothers treated in the noncontingent condition (3295.6 ± 63.8 g vs. 3093.6 ± 67.0 g, $p = .03$) and the percent of low birth weight (< 2500 g) deliveries was less (5.9% vs. 18.5%, $p = .02$). No significant treatment effects were observed across three other outcomes investigated although each was in the direction of improved outcomes in the contingent vs. the noncontingent condition: mean gestational age (39.1 ± 0.2 weeks vs. 38.5 ± 0.3 weeks, $p = .06$), percent of preterm deliveries (5.9 vs. 13.6, $p = .09$), and percent admissions to the Neonatal Intensive Care Unit (4.7% vs. 13.8%, $p = .06$).

Conclusions—These results provide evidence that smoking-cessation treatment with voucher-based CM may improve important birth outcomes.

Keywords

vouchers; contingency management; birth outcomes; gestational age; preterm birth; birth weight; low birth weight; cigarette smoking; smoking cessation

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Introduction

Maternal smoking is a leading preventable cause of poor pregnancy outcomes and increased infant morbidity and mortality.^{1,2} Treatment-development research on smoking cessation during pregnancy has largely focused on brief (5–15 min) interventions such as advice from health professionals, pregnancy-specific self-help materials, and feedback on levels of biochemical markers of smoking.³ While helpful, cessation rates are often low (<20%) with differences between intervention and control conditions averaging only about 6%.^{3–5}

More effective interventions are needed^{4,5}, which was the rationale behind our effort to investigate voucher-based contingency management (CM). Voucher-based CM is an intervention wherein patients earn vouchers exchangeable for retail items contingent on recent abstinence from drug use or achieving other therapeutic goals.⁶ This intervention was initially developed to treat cocaine dependence⁷ and was subsequently demonstrated to be efficacious with a wide range of substance use disorders.⁸ The treatment is designed to use the basic behavioral process of reinforcement, thought to play a causal role in how drugs promote addiction, to increase abstinence from drug use.⁸ Results from several controlled trials conducted with pregnant smokers have supported the efficacy of voucher-based CM for increasing cessation rates^{9–11} and in one trial for increasing sonographically estimated fetal growth rates.¹¹ In this latter trial, 82 women who were smoking upon entering prenatal care were randomly assigned to receive voucher-based CM wherein vouchers were earned contingent on abstinence or to a control treatment wherein vouchers of similar value were delivered independent of smoking status. To estimate treatment effects on fetal growth, a subset of women (n = 57) received two ultrasound assessments at approximately 30 and 34 menstrual weeks of pregnancy. Abstinence at an end-of-pregnancy assessment was greater (41% vs. 10%) in the abstinence-contingent vs. control conditions and estimated fetal growth rates were also greater. Of relevance to the present study, several measures of birth outcomes reported from that trial were in the direction of improved outcomes among those treated in the intervention compared to control condition, but none achieved statistical significance. Considering the strong association between ultrasonographic measures of intrauterine growth rate and birth weight¹² and the relatively small number of women included in the trial, it seemed plausible that the failure of these differences to achieve significance may have resulted from being insufficiently powered to detect them. The purpose of the present study was to follow-up the suggestive results on birth outcomes reported in the earlier trial using a larger sample of women treated with the same two treatment conditions.

Methods

Study Population

Study participants were enrolled in one of three controlled trials examining the efficacy of voucher-based CM for smoking cessation conducted in a university-based research clinic.^{10,11,13} Two of these trials have been published^{10,11} and one has yet to be reported.¹³ The unpublished trial was conducted for staff-training purposes following unexpected staff turnover between the pilot¹⁰ and fully-randomized¹¹ trials. A total of 183 women were enrolled in these trials. Seventeen of those women were excluded from the present study due to abortions (12), multiple births (3), and missing birth records (2), leaving 166 women who contributed data. Of the 17 exclusions, 8 were from the intervention and 9 from the control conditions described below. The local Institutional Review Board approved each trial and all participants provided informed consent. Treatment conditions were the same across trials except that the first 32 participants in the initial trial were assigned to treatment conditions as consecutive admissions to pilot test the interventions while all of the remaining women were randomly assigned to treatment conditions. There were only two changes made in the

study protocol between the pilot and other trials, one being a procedural decision made during the pilot study to verify abstinence using urine rather than salivary cotinine, and the other a decision made after completion of the pilot study to exclude women at > 25 weeks gestation to assure adequate treatment exposure.

Women were recruited into the trials from local obstetric practices and Women, Infants, and Children (WIC) program. To be eligible, women had to report smoking at entry into prenatal care, reside within the county in which the study clinic is located, plan to remain in the area for 6 months following delivery, and speak English. Women were queried about smoking status using a multiple-choice question that enhances accurate reporting among pregnant women.¹⁴ Trial exclusion criteria included incarceration, previous participation in a trial on incentives for smoking abstinence during pregnancy, residing currently with someone who participated in a prior trial on this topic, taking antipsychotic or opioid substitution medications, and > 25 weeks gestation in the two latter trials.

Assessments

At the trial intake and all subsequent assessments, study participants completed questionnaires (e.g., sociodemographics, current smoking status/history) and provided breath and urine specimens. Modified versions of this battery were completed at 1 month after the study-intake assessment, towards the end of pregnancy (≥ 28 weeks gestation), and at 2-, 4-, 8-, 12- and 24-weeks postpartum. These assessments were scheduled with all participants including study dropouts. Women earned \$35 for completing assessments independent of smoking status. Smoking status was biochemically verified with urine-cotinine testing using enzyme immunoassay and a cutpoint of $\leq 80\text{ng/ml}$, with results from end-of-pregnancy assessment confirmed by an outside laboratory using gas chromatography. The cotinine cutpoint for abstinence was set higher than typical related to our use of enzyme immunoassay for biochemically verifying abstinence in the incentive program.^{15,16} All birth outcome information was obtained from review of the hospital delivery summary.

Treatment Interventions

These treatment conditions have been described previously.^{10–11} All study participants were assigned to one of two treatments: an abstinence-contingent voucher condition or a noncontingent voucher control condition. Women began their cessation effort on a Monday and reported to the clinic daily for 5 consecutive days for abstinence monitoring. The frequency of abstinence monitoring decreased to twice weekly in week 2 where it remained for the next 7 weeks, then decreased to once weekly for 4 weeks, and then to every other week until delivery. During the postpartum period, abstinence monitoring was increased to once weekly again for 4 weeks, and then decreased to every other week through 12 weeks postpartum when it was discontinued. Voucher value in the abstinence-contingent condition began at \$6.25 and escalated by \$1.25 per each consecutive negative specimen to a maximum of \$45.00 where it remained through the remainder of the intervention save for positive results or a missed visit. Positive test results or failure to provide a scheduled specimen reset the value of vouchers back to their initial low level, but two consecutive negative tests restored voucher value to the pre-reset level. Smoking status was biochemically verified at each of these abstinence-monitoring sessions so that the abstinence contingency could be implemented. Biochemical verification of abstinence was based on breath CO specimens ≤ 6 ppm during the initial 5 days of the intervention and on urine cotinine beginning in week 2 through the remainder of the study. Women in the noncontingent voucher control condition received the same schedule of assessments but vouchers were delivered independent of smoking status and at values of \$11.50 per visit antepartum and \$20.00 per visit postpartum. Voucher earnings did not differ significantly between treatment conditions and averaged about \$450 (range = \$0–\$1,180) per women. In

addition to the voucher-based incentives, participants in both treatment conditions received usual care for smoking cessation provided through their obstetric clinics, which typically involved provider inquiry regarding smoking status and a discussion of the advantages of quitting during pregnancy, and pregnancy-specific pamphlets on smoking cessation and relapse prevention from our staff.^{17,18}

Statistical Methods

Demographic and smoking characteristics were compared between treatment conditions using t-tests for continuous measures and chi squares tests for categorical variables. Cochran-Mantel Haenszel tests were performed for treatment comparisons of percent abstinence at the end-of-pregnancy assessment and 12- and 24-week postpartum assessments, percent low birth weight infants, percent preterm deliveries, and percent NICU admissions utilizing trials as strata. Breslow-Day tests were used to evaluate homogeneity of treatment effects across trials. There was no evidence that odds ratios (OR) associated with treatment condition for any outcomes were different across trials so raw treatment percentages are presented for each outcome, while odds ratios and associated confidence intervals are adjusted for strata. Mean birth weight, mean gestational age, and mean percent of scheduled antepartum smoking-status assessments that were negative were compared across treatment conditions based on two-way analyses of variance with treatment and trial as fixed factors. The treatment by trial interaction term was used to test whether treatment effects were different across trials. For all analyses involving birth weight, pre-pregnancy BMI was also used as a covariate. Lastly, a series of regression models were examined to evaluate potential mediators of the treatment effects on birth weight. All analyses were performed using SAS Version 9 statistical software (SAS Institute, Cary NC). Statistical significance was determined based on $\alpha = .05$.

Results

Participant Characteristics

Study participants were socioeconomically disadvantaged women who started smoking at an average age of about 14 years, smoked about a pack/day pre-pregnancy, and most lived with other smokers (Table 1). Only two baseline characteristics differed significantly between those assigned to the contingent and noncontingent voucher conditions, and both would be expected to predict better outcomes in the control condition: the contingent condition included more women with < 12 years of education, and more women in the contingent condition reported that smoking was allowed in their homes. Neither difference was significantly associated with birth outcomes.

Smoking Status

Seven-day point-prevalence abstinence at the end-of-pregnancy assessment was significantly greater in the contingent compared to the noncontingent control condition (Figure 1, upper panel; C-M-H χ^2 [1] = 18.9, $p < .001$; OR=7.5, 95% CI: 2.8 – 20.0). There was no evidence that this treatment effect was heterogenic across trials (Breslow-Day χ^2 [2] = 0.3, $p = .87$).

For a measure of abstinence more representative of smoking status throughout antepartum, we examined the proportion of all scheduled antepartum smoking-status assessments at which women were biochemically confirmed abstinent. There were an average of 29.1 ± 0.4 and 29.3 ± 0.3 tests scheduled in the contingent and noncontingent conditions, respectively. The percent of tests negative was greater in the contingent than noncontingent conditions (Figure 1, bottom panel; $F[1,160] = 28.9$, $p < .0001$). Differences between treatment conditions were not trial dependent ($F[2,160] = 2.6$, $p = .07$), but there was a significant main

effect of trial ($F[2,160] = 10.7, p < .0001$), with Trial 2 producing lower absolute abstinence levels across both treatments compared to the two other trials.

Smoking abstinence levels remained significantly greater in the contingent compared to the noncontingent condition at the 12-weeks postpartum assessment (23.5% vs. 2.5%; C-M-H $\chi^2 [1] = 15.9, p < .0001$; OR=11.2, 95% CI: 2.6–48.3) conducted during the final week of the incentive program, and at the 24-weeks postpartum assessment (14.1% vs. 1.2%; C-M-H $\chi^2 [1] = 8.9, p = .003$; OR=13.0, 95% CI: 1.6–103.1), conducted 12 weeks after the incentive program was discontinued. There was no evidence that these treatment differences were heterogenic across the three trials.

Birth Outcomes

Main effects—Mean birth weight differed significantly between treatment conditions, with infants born to mothers treated in the contingent condition weighing on average 202 g more than those born to mothers treated in the noncontingent condition (Table 2, $F[1,159] = 4.8, p = .03$). That difference between treatment conditions reflects an upward shift in the distribution of birth weights of infants born to mothers treated in the contingent compared to the noncontingent condition (Figure 2). The percent of low birth weight (< 2500g) deliveries was 12.6 percent lower in the contingent than noncontingent conditions (Table 2, C-M-H $\chi^2 [1] = 5.8, p = .02$, OR=0.29, 95% CI: 0.10–0.83) and that difference is also discernible in the distribution of birth weights in the two treatment conditions (Figure 2).

Regarding the three other birth-outcome measures examined, treatment effects approached but did not achieve statistical significance. Among mothers treated in the contingent compared to the noncontingent condition, infants on average were born 0.6 weeks (4.2 days) later (Table 2, $F [1,160] = 3.6, p = .06$), there were 7.7 % fewer preterm (< 37 weeks) deliveries (Table 2; C-M-H $\chi^2 [1] = 2.8, p = .09$; OR=0.40, 95% CI: 0.13–1.21), and 9 % fewer NICU admissions (Table 2, C-M-H $\chi^2 [1] = 3.5, p = .06$; OR=0.35, 95% CI: 0.11–1.12). There was no evidence that treatment effects were significantly different across the three trials for any of these outcomes measures.

Mediational analyses—Following recommended guidelines for mediational analyses²⁰, a series of linear regressions were used to explore possible mechanisms involved in treatment's effects on birth weight. In separate models adjusting for maternal pre-pregnancy BMI, three predictors of mean birth weight were identified. Treatment in the contingent condition was a significant predictor ($t[163] = 2.36, p = .02$) associated with an estimated 209 g increase in birth weight, mean gestational age was a significant predictor ($t[163] = 12.2, p < .0001$) associated with an estimated increase of 183 g per additional week of gestation, and percent of antepartum negative smoking tests was a significant predictor ($t[163] = 2.50, p = .01$) with complete abstinence being associated with an estimated 313 g increase in mean birth weight. When the three predictors were included in a model together, treatment condition was no longer a significant predictor ($t[161] = 0.23, p = .82$) with the estimated effect of treatment in the contingent condition being reduced to only 16 g. Mean gestational age ($t[161] = 11.93, p < .0001$) and percent of negative tests ($t[161] = 2.17, p = .03$), by contrast, remained significant predictors in this model, with respective estimated increases in birth weight of 180 g per each additional week of gestation and 216 g for complete vs. no abstinence. Treatment in the contingent condition was associated with an average increase of .6 weeks of gestation, which would equal 108 g by the above estimate, and 39 percent negative smoking tests, which would equal 84 g by the above estimate. Combined, those two estimates equal a 192 g increase. Add in the 16 g unrelated to these two mediators and you account for 208 of the 209 g estimated increase when treatment condition was modeled alone.

Discussion

This study provides evidence from controlled trials that voucher-based CM for smoking cessation during pregnancy improves several birth outcomes that affect newborn morbidity and mortality.^{21,22} Those treated with this incentive-based intervention compared to controls had a greater mean birth weight by an average of 200–210 g and lower percent of low-weight deliveries by approximately two-thirds. We reported previously that this treatment increases sonographically estimated fetal growth rate¹¹, which is consistent with the present results. As was discussed above, these same birth outcomes were examined in that earlier trial.¹¹ While neither achieved statistical significance, each was in the direction of improved outcomes among infants born to mothers treated in the contingent condition. Considering that the birth outcome results in that study were based on a total of only 73 women, it seemed plausible that the failure to observe significant differences between treatment conditions was attributable to being underpowered for those outcomes. The purpose of the present study was to examine those outcomes in a larger sample. The significant differences observed in the two birth weight measures in the present study suggest that our concern about being underpowered in the earlier study was justified. Whether abstinent-contingent vouchers also improve the three other birth outcome measures examined in that earlier trial (mean gestational age, % preterm deliveries, % NICU admissions) remains unclear. The consistent trends across each of those measures in the direction of improved outcomes among infants born to mothers treated in the contingent condition is certainly consistent with that possibility but will have to be confirmed in future studies.

Future studies will also be necessary to more fully characterize the mechanisms through which this treatment alters birth outcomes. Our exploratory analyses identified two independent mediators of treatment's effects on birth weight, mean gestational age and the percent of antepartum negative smoking tests. The former is a well-established determinant of birth weight that is adversely affected by maternal smoking.^{21,22} The latter represents the main focus of the intervention (smoking abstinence) and its role in increasing birth weight independent of gestational age in the present study likely reflects abstinence-related increases in fetal growth, an outcome of this treatment that we have reported previously.¹¹ That is, the observed changes in birth weight in the present study likely reflect a combined effect of treatment increasing gestational age and reducing fetal growth restriction. Presumably, treatment is altering both mediators by changing maternal smoking, although modeling relationships between maternal smoking and these two outcomes can be complicated considering that the critical periods for each can differ, with smoking in the first trimester increasing risk for early delivery and in the second and third trimester more the risk for fetal growth restriction.^{19,22} The present results provide an important initial step in characterizing some of the mechanisms involved, but a more complete characterization will require additional studies involving larger samples.

Turning back to main effects of treatment, a recent meta-analysis on interventions for promoting smoking cessation during pregnancy examined effects on perinatal outcomes across 21 published studies.³ In that meta-analysis, smoking-cessation treatments were reported to alter both of the birth outcomes on which significant treatment effects were observed in the present study. Treatment was estimated to increase mean birth weight by 53g and decrease the relative risk for low birth weight deliveries by 17%.³ Clearly there are considerable differences between the size of the treatment effects reported in that meta-analysis and those observed in the present study. Treatment effects in the present study were more than three-fold greater than those reported in the review. At least part of the explanation for these differences in treatment-effect size is that treatment effects on antepartum abstinence rates in the meta-analysis and the present study also differed by more than three-fold, with, for example, the average difference in late-pregnancy abstinence levels

between intervention and controls in the meta-analysis being 6% whereas in the present study that difference was 27%. A potentially important message to be gleaned from this comparison of results from the meta-analysis and present study when considering strategies for reducing smoking during pregnancy is that the extra treatment effort and costs involved in achieving lower smoking rates appear to translate into proportionately greater improvements in important birth outcomes.

Another encouraging aspect of this positive relationship between the size of treatment effects on antepartum abstinence and effects on birth outcomes is that there is plenty of room for improvement. Even with the incentive-based approach used in the present study, which the Lumley et al. meta-analysis identified as producing the largest quit rates, the majority of women who received the intervention nevertheless failed to quit. In terms of strategies to increase the percent of women who respond to this treatment, increasing the monetary value of the voucher appears to be the most likely to succeed, although other options such as combining the treatment with a pharmacotherapy also merit investigation. Increasing voucher monetary value has been demonstrated to increase the size of treatment effects obtained when using this approach to treat other substance use disorders.^{8,23,24} Women in the contingent condition in the present study on average earned ~\$450 in vouchers across a nine-month period. When considered in the context of further improving birth outcomes, increasing voucher value further seems like a prudent option to investigate.

Also important to consider in evaluating the merits of this treatment approach is that the intervention is also associated with increases in breastfeeding duration.²⁵ A subgroup of 158 of the 166 women who contributed data to the present study were followed through 24-weeks postpartum and queried about whether they were breastfeeding. Significantly more women treated with contingent than noncontingent vouchers reported continuing to breastfeed through 12-weeks postpartum. Both the increases in birth weight reported in the present study and these breastfeeding outcomes have the potential to contribute longstanding health benefits that may well justify the extra costs involved in providing this type of treatment.^{14,26,27}

In closing, we want to acknowledge three limitations of this study. First, we studied a largely rural, Caucasian population in the U.S. Whether similar outcomes can be achieved in more diverse or urban populations or other countries will have to be investigated. Second, our use of monetary incentives may preclude extending this treatment approach to less economically advantaged countries or settings, although one should not assume that the same value incentives as were used in the present study will be necessary in other settings. Incentive values should be tailored to the particular economic context and population targeted.²⁴ Third, while the present study is based on data collected prospectively and exclusively in controlled trials involving the same two treatment conditions, the plan to combine the results across trials was made post-hoc. An important next step will be to examine the reliability of the treatment effects observed in the present study in a single, appropriately powered, randomized controlled trial.

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Figure 1.

Upper panel shows 7-day point-prevalence smoking abstinence in the contingent (open bar) and noncontingent (closed bar) treatment conditions at end-of-pregnancy assessment (upper panel). Treatment conditions differed significantly ($P = .001$). Bottom panel shows mean percent of all antepartum smoking-status tests that were negative for recent smoking in each treatment condition. Brackets represent $1 \pm \text{SEM}$. Treatment conditions differed significantly ($P < .0001$).

Figure 2.

Birth weights of infants born to mothers treated in the contingent (left column) and noncontingent (right column) treatment conditions. Each symbol represents an individual infant's birth weight and the solid line in each column represents the least square mean weight for that condition. The dashed line demarcates the 2500 g cutoff for low birth weight. Mean birth weight differed significantly between treatment conditions ($P = .03$) as did the percent of low birth weight deliveries ($P = .02$).

Table 1**Participant Baseline Characteristics**

	Contingent (N=85)	Noncontingent (N=81)	p-values
Demographics			
Age (years)	23.8(5.5)	23.3(4.7)	.54
% Caucasian	93	96	.34
Education			.03
% ≥ 12 years of education	53	70	
% < 12 years of education	47	30	
Prepregnancy BMI (kg/m ²)	25.6(6.8)	26.3(6.7)	.51
Weeks pregnant at baseline	9.9(3.8)	9.2(3.3)	.25
% Primigravida	49	49	.99
% Prior preterm delivery	5	12	.08
% Married	19	17	.80
% With private insurance	19	16	.64
% Working for pay outside of home	42	47	.55
Smoking Characteristics			
Age first started smoking cigarettes	14.1(2.5)	13.8(2.4)	.47
Cigarettes per day pre-pregnancy	20.3(10.1)	21.6(8.5)	.86
% Living with another smoker	76	78	.84
% With no smoking allowed in home	26	41	.04
% With none or few friends/family who smoke	18	16	.78
% Attempted to quit pre-pregnancy	56	70	.06
Number of quit attempts during pregnancy	1.1(2.7)	0.9(2.3)	.52
Nicotine withdrawal questionnaire total score	1.8(0.9)	1.5(0.9)	.07
Psychiatric Symptoms			
Stress rating	5.7(2.5)	5.4(2.6)	.46
BDI	10.7(7.2)	10.5(7.4)	.82
% History of depressive symptoms	40	37	.69

Note: Values represent means (SD) unless otherwise indicated.

Significance based on t-tests for continuous variables and chi-square tests for categorical measures.

Table 2

Infant outcomes at delivery

Measure	Contingent (n = 85)	Noncontingent (n = 81)	P values
Birth Weight (grams)	3295.6±63.8	3093.6±67.0	.03
% Low birth weight	5.9	18.5	.02
Gestational Age (weeks)	39.1±0.2	38.5±0.3	.06
% Preterm births	5.9	13.6	.09
% NICU admissions	4.7	13.8	.06

Values represent mean ± standard error, unless specified otherwise. NICU: neonatal intensive care unit.