USING INCENTIVES TO REDUCE CIGARETTE SMOKING DURING PREGNANCY

Title
"Using Incentives to Reduce Cigarette Smoking During Pregnancy"

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Data Collection Time Period: September 2016-end February 2017

IRB approved: through Peoria IRB for 12 months from July 2016 to July 2017

Funding: provided from grant funding through UICOMP Department of Family and Community Medicine

Background
Smoking is one of the most common risk factors for many health conditions worldwide. However, it is often under addressed in pregnancy. Smoking during pregnancy increases the risk of premature birth, low birth weight, some birth defects including cleft lip and cleft palate. A history of prenatal smoking exposure increases risks of SIDS even after birth. It increases risks of miscarriage and causes numerous adverse affects to the placenta. (5) With the rising issue of childhood obesity, it is also a major concern that smoking during pregnancy doubles the risk of childhood obesity (11). According to the Pregnancy Risk Assessment and Monitoring system in 2011, 10% of women reported smoking during the last 3 months of pregnancy, among women who were already smoking up to 3 months prior to pregnancy, only 55% of them quit and among those who did quit, 40% relapsed within 6 months after delivery (5). The other concern is the monetary effects of the cigarettes themselves, as well as the health costs attributable to the smoking during pregnancy.

There are several options for smoking cessation when a woman finds out she is pregnant. Pharmacological interventions include nicotine replacement, varenicline, or buproprion. One systematic review showed no statistical significance between nicotine replacement and placebo (2). Varenicline and buproprion, while used for cessation in pregnancy, are category C (animal studies have shown an adverse effect on the fetus). Another systematic review evaluated psychosocial interventions including counseling, health educations, feedback, incentives, and social support.

Although studies are limited, the most effective intervention appears to be related to incentives for smoking cessation. One randomized controlled trial showed a significant increase in smoking cessation using monthly incentives. The smoking cessation rate in the experimental group for pregnant women that were smokers prior to pregnancy was 32% when given $50 per month. This was significantly better than the 9% quit rate in the group only receiving $15 for participation. In that study, smoking cessation was verified via salivary thiocyanate analysis (4). Another study of pooled data from three controlled trials demonstrated a 34.1% quit rate for those subjects that received greater incentives vs. 7.4% quit rate for those that only received participation vouchers (4).

Research Question
Can monetary incentives help improve smoking cessation during pregnancy?

Goals and Objectives
The goals and objectives of this study are to improve the rates of smoking cessation during the course of pregnancy, along with determining if providing financial incentives is a plausible method to promote wellness and decrease prenatal risk to fetuses.

Methods and Designs
This study was done at a specific site for OB care where the rate of smoking is much higher than the average stated by the CDC. The rate of smoking during pregnancy has been 54-65% over the last several years at the study site clinic. Pregnant smokers were recruited over a 12-month enrollment period and followed until delivery. The study participants were recruited from a rural clinic at which the family medicine residents provide the OB care. Based on previous studies of this type, the expected participation rate was 71% meeting inclusion criteria, with an estimated 6% withdrawal rate (3).

The family medicine residents as well as the supporting family medicine residency faculty provide prenatal care for pregnant patients at this clinic. In addition, high-risk obstetrical patients were co-managed by the perinatologist but continued to remain in the study. The patients at this clinic were delivered at the hospital affiliated with the family medicine residency. The residents, with faculty support, performed the deliveries. If there was a patient that was transferred for delivery to another facility, the records were obtained with patient consent.

The pregnant women that had their prenatal care at this clinic were given informed consent and the study was discussed with them. The subjects who agreed to the study were given a multiple choice questionnaire (Appendix 1) assessing the individual's smoking status over the previous month and were given a saliva test for cotinine. Those individuals that indicated that they had smoked within the last month or tested positive for cotinine on the saliva test were eligible to be enrolled and continue with the study. Those patients that had a negative initial questionnaire AND tested negative for the salivary test did not proceed with the study. All participants who are evaluated were given a $20 gift card at that initial visit. The gift card could not be used to purchase tobacco, alcohol, or firearms.

Demographic data was collected from the study participants that would be continuing with the study including education level, race, age at the time of becoming pregnant, and insurance status. Clinical data was collected including parity, single or multiple gestation, history of previous preterm birth, drug use during pregnancy, genital infections during pregnancy, and adequacy of prenatal care.

In summary, the Inclusion Criteria was less than or equal to 20 weeks gestation at the first visit to the clinic, current smoking status at the first office visit, and participant answered yes to smoking questionnaire and had a positive cotinine saliva test. Patients were excluded from the project if they were greater than 20 weeks at first office visit, had quit prior to coming to the first office visit, or answered not smoking to questionnaire and had a negative cotinine saliva test

Once the patients were enrolled, they were evaluated monthly (separated by at least 24 days) until delivery. They received a monthly participation gift card worth $20. With each monthly visit they completed a smoking status questionnaire and submitted a saliva sample for cotinine testing. Those patients that tested negative for the cotinine saliva test were given three additional $20 gift cards for a total of $80 in gift cards. In review, if they tested positive for the cotinine saliva test and were still smoking they only received a $20 gift card. If they tested negative and so were not smoking, then they received $80 in gift cards. To reiterate, these gift cards could not be used for tobacco, alcohol, or firearms. If a smoking patient joined the study at the first month of pregnancy, they could potentially receive $80 in gift cards for the following 8 months of pregnancy if they remained smoke-free for the remainder of their pregnancy.

Demographics

- Rural Community Clinic
- 100 % Caucasian
- 8 total participants enrolled to date
- 100 % Medicaid Insurance coverage
- Education level: 7/8 some high school, 1/8 some college
- Average age 24 years and 51 days

Results:

The goal of the study was to recruit at least 10 participants that met the inclusion criteria of being a pregnant, expectant patient who was a current smoker and tested positive on the initial cotinine saliva test. During the data collection phase, we have been able to recruit 8 participants so far meeting inclusion criteria, within the 6-month window of data collection (Sept 16- Feb 2017), prior to preliminary reporting. Out of the 8 study participants, 2 patients have transferred (25%) to other obstetrics providers and 2 patients had miscarriages (25%). Thus 4 patients continue to participate within the study at the time of reporting. From these participants, 1 out of 4 has successfully quit smoking during pregnancy to date. For data purposes, the initial patients were included in the data interpretation, as they continued to smoke during their pregnancies despite not continuing with OB care (whether they transferred care or had miscarriages they continued to still smoke cigarettes). Thus, the smoking quit rate among the 8 participants has been 1 out of 8 or 12.5%(P=0.5959). That leaves 3 out of 8 that remain in the study, yet have not quit smoking during pregnancy (37.5%).

The average age of study participants was 24 years and 51 days. All study participants were from a low socioeconomic status, with 100% of enrolled study participants receiving Medicaid Insurance coverage at this particular rural county clinic. 100% of the pregnant participants enrolled were Caucasian. 7 out of 8 participants had some high school education only, with 1 out of 8 having some college education. Out of the 7 participants that had some high school education, only one participant had achieved a GED. No study participants were under the age of 18 when recruited. The official calculated incidence rate of smoking within this rural clinic was found to be 33/51 (64.7%) from beginning of Feb 2012 to start of Sept 2016.

Conclusions:
Due to logistical challenges leading to a delay in the onset of the study at the time of IRB approval, we have not been able to complete a complete 10 pregnancy cycles to date. As such, the study is ongoing. The data thus far demonstrates preliminary quit rate of 12.5 % (N=8 total participants enrolled). The expected quit rate was at least 50% (the average quit rate for women in pregnancy per the CDC). However, these preliminary results are not statistically significant at the time of reporting results (P = 0.5959). This was calculated from X^2 test result 0.28125 and 1 degree of freedom. The study had a high loss of participation attrition rate (2 patients lost to miscarriage, 2 lost to transfer).

There were certain challenges that were faced, the predominant challenge being the ability to recruit the minimum number of participants intended to participate in the study. The limited sample size and unfortunate attrition rate has been difficult to overcome up to now. Increasing the study size and being able to recruit additional study participants would yield a higher power in the study. Another challenge was the limited timeframe from starting the study to time of reporting data, which made it difficult to formulate significant conclusions when the study is not yet complete. Also, another challenge included difficulty with the use of the cotinine saliva tests due to difficulty with inducing saliva in some patients. As such, we will consider switching to the urinary cotinine testing in future, which yields an equally acceptable sensitivity and specificity. We hope to see this study continued, and renewed, thus compiling enough data to achieve statistically significant conclusions in the future.

Discussion:
Smoking in pregnancy is a serious concern and health risk for both the patient and the fetus. Our goal was to reduce cigarette smoking during pregnancy by using monetary incentives to increase the quit rate. Other studies have looked at the influences in smoking behaviors in pregnant women. Some studies have compared rural areas to urban areas and the effects of these locations and demographics on the quit rate. A paper comparing smoking behaviors between Urban and Rural women smoking during pregnancy enrolled through a Kansas WIC program had interesting results. The results indicated that low-income, rural pregnant women smoked at significantly higher rates before, during, and after pregnancy (6). This is an interesting avenue to explore for research for our residency program as we provide OB care at both urban and rural areas. It would be enlightening to continue this research and bring in another site for this study located at one or both of our urban clinics. Higher smoking rates in rural areas have been found to be the consensus in other studies as well; a paper by Shoff and Yang in the NIH Public Access (10) drew similar conclusions. Both of these papers stated that further studies need to be done to find the needs that can be addressed to help decrease the cigarettes smoking in rural areas. We hope that as we continue this project providing monetary incentives or expand upon it with different avenues we can continue to help decrease cigarette smoking in pregnancy.

Acknowledgments:
- Dr. Griebel as our attending supervisor
- Dr. Lanser as our attending suport
- Mason District Health Department
- Nursing staff at MDHD
- Dr. Na'Allah as research supervisor
- UICOMP Department of Family and Community Medicine for grant support

Conflict of interest: The authors of this paper have no conflicts of interest to disclose.

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Appendix 1.

Cigarette Smoking Questionnaire

Which of the following statements best describes your cigarette smoking over the last month? (circle one)

A. I have smoked daily over the last month

B. I have smoked daily over the last month, but have cut down

C. I have smoked occasionally over the last month

D. I have not smoked at all over the last month

Appendix 2.

Table 1: Tobacco Use in Pregnancy with Incentives (N=8)