The Effectiveness of Smoking Cessation Methods for Smokers in Public Health Maternity Clinics: A Randomized Trial

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Abstract: Little insight is available in the literature on how best to assist the pregnant smoker in public health maternity clinics to quit during pregnancy. A randomized pretest/posttest experiment was used to evaluate the effectiveness of two different self-help cessation methods. Three hundred and nine pregnant women from three public health maternity clinics were assigned randomly to one of three groups with one-third assigned to each: a control group; a group receiving the American Lung Association's *Freedom From Smoking Manual;* and those receiving *A Pregnant Woman's Self-Help Guide to Quit Smoking*. Using a saliva thiocyanate (SCN) and behavioral report at mid-pregnancy and end of pregnancy to confirm cessation or reduction, 2 per cent in the control group quit and 7 per cent reduced their SCN levels substantially. Of the women assigned to the ALA method, 6 per cent quit and 14 per cent reduced their SCN levels substantially. Of the women who used the *Guide,* 14 per cent quit and 17 per cent reduced their SCN levels substantially. Results of this trial indicate that health education methods tailored to the pregnant smoker are more effective in changing smoking behavior than the standard clinic information and advice to quit and/or the use of smoking cessation methods not tailored to the needs of the pregnant smoker. (*Am J Public Health* 1985; 75:1389–1392.)

Introduction

During the last 30 years, numerous published reports have confirmed that cigarette smoking during pregnancy is detrimental to the health of the fetus, the newborn infant, and to the future growth and development of the child. A dose-response relationship exists between smoking during pregnancy and decreased birthweight, stature, prematurity, and infant morbidity. The earlier during pregnancy a woman gives up smoking, the greater the reduction in risk of a low birthweight infant. With early, complete cessation during pregnancy, the risk may be reduced to a level similar to that of the nonsmoker.[1–7] Nevertheless, a number of reports indicate that a large proportion of pregnant women do not yet fully appreciate the role of smoking as an etiologic factor in infant morbidity and mortality; many women continue to smoke during pregnancy.[8–11] Almost all smoking cessation intervention studies conducted among pregnant populations often have significant design and methodological problems and/or have reported no beneficial results.[12–17]* This report presents the results of an investigation to evaluate the effectiveness of low-cost, self-help smoking cessation methods for public health clinic populations initiated at the first prenatal visit.

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Methods

This study was conducted over a 12-month period from October 1983 to September 1984 in three of five high-volume Public Health Maternity Clinics of the Jefferson County Health Department in the metropolitan area of Birmingham, Alabama. Women using the three study clinics represented approximately 60 per cent of the annual cohort of 4,000 maternity clinic users. Screening interviews at first visit of over 2,400 pregnant women showed that for women who smoked at conception, approximately 22 per cent had quit prior to their first prenatal visit. Thus, pregnant women who smoke at their first visit, as a group, might be considered less able or less motivated to quit on their own.

Of the 1,838 pregnant women who presented for their first visit at the three clinic sites during the study period, 460 (25 per cent) were identified as current smokers. A woman was defined as a smoker if she reported smoking at least one cigarette in the last seven days. Approximately 80 per cent (368/460) agreed to participate. Of the 368 pregnant smokers, 30 (8 per cent) were not eligible to participate in the study because of late entry into care (≥32 weeks month). Of the remaining 338, nine women left the system or moved from the Birmingham area, and 10 chose to abort or miscarried between baseline and mid-point observation.

Multiple attempts were made to bring pregnant smokers together for a peer-led, focused group discussion on cessation methods. This method was not found to be feasible in this setting because of the inability to have the women attend scheduled group meetings during clinic hours. The 10 women who participated in the group discussions were dropped from the evaluation and impact analysis, leaving 309 as study participants.

Methods

Evaluation Design

Almost all smoking cessation research has ignored the critical issue of size determination and power in planning such studies.* The final group size, 80 or more women per study group, was based on preliminary observation suggesting that smokers in the control group exhibited a quit rate during pregnancy of 2 per cent ($P_1 = .02$), and smokers in one

of two treatment groups exhibited at least a 10 per cent higher quit rate during pregnancy (P_2 = .12).[18]

A prospective, randomized pretest-posttest control group design was used to evaluate intervention effectiveness.[19] Following informed consent and baseline assessment, 309 pregnant smokers who had entered care before the seventh month were assigned randomly to one of three study groups using a computer-generated random identification number system.

Approximately one-third of all study participants within each clinic were randomly assigned to Group #1 (control group).

Another one-third of the pregnant smokers, randomized to Group #2, received a standardized health education skills counseling session lasting 10 minutes. The patient was taught how to use the *Freedom from Smoking Program Manual* of the American Lung Association (ALA). This manual uses a 17-day self-directed plan to quit. They were also given a booklet, *Because You Love Your Baby,* prepared for pregnant smokers and distributed by the ALA. This booklet presents information on the dangers and risks of smoking and the benefits of quitting.

The remaining pregnant smokers, randomly assigned to Group #3, received the same information booklet, *Because You Love Your Baby,* and the same 10-minute skills counseling session. However, they were taught to use a different self-help manual, *A Pregnant Woman's Self-Help Guide to Quit Smoking*. This guide for pregnant women uses a self-directed seven-day quit plan and includes 10 skills:

- Learning the smoke-holding method,
- Learning how to begin to stop,
- Discovering why you want to stop,
- Learning why you smoke cigarettes,
- Learning smoking signals,
- Making a stop-smoking contract,
- Making a stop-smoking buddy contract,
- Learning breathing exercises and how to relax,
- Learning light exercises, and
- Learning how to deal with physical reactions to quitting.

A pre-trial pilot study with 30 pregnant smokers, 8–12 from each of the three study clinics, was used to develop and revise the *Pregnant Woman's Self-Help Guide to Quit Smoking*. Three pregnant ex-smokers who participated in the pilot and had used the *Guide* served as editorial consultants in its development. An educational assessment of 100 pregnant smokers and patient flow studies at each clinic provided documentation for using these types of methods designed for Group #2 and Group #3.

To control for variation in intervention content, duration, and interaction, the 10-minute health education skills training component for Groups #2 and #3 was provided at each clinic by the same person using a standardized protocol. An education prescription form, "Quit Smoking Prescription," was also used to standardize discussion topics and content. The three interventionists were females with Bachelors Degrees in Community Health Education.

All study participants (Groups #1, #2, and #3) were exposed to the smoking cessation advice routinely given by medical/nursing staff at their respective clinics. The health effects of smoking were discussed as part of a 30-minute prenatal education session at the first clinic visit. Maternity clinic staff recommended to all women that they stop smoking. Unobtrusive observational studies prior to study onset of the clinic prenatal education session documented that about 2–3 minutes were devoted to smoking cessation. No major changes in clinic staff, patient education behavior, methods, or materials were observed during the course of the study.

Measurement

All subjects received a brief screening interview, and a self-administered baseline observation consisting of a standardized patient assessment form eliciting information on smoking practices, health beliefs, and strength of commitment to quit. The 16-item Health Belief Scale used has a reliability of .87 (Cronbach Alpha-internal consistency) and test-retest reliability of .93 (Pearson-stability). Saliva thiocyanate (SCN) was measured during the first prenatal visit on mothers who reported they were smoking. All participants were reassessed approximately four to eight weeks after first visit (mid-point observation) and during the last month of pregnancy or within 48 hours of birth (final observation). Only one follow-up observation (final) was performed for women who entered care (trial) at the sixth or seventh month of pregnancy.

Cessation was determined by behavioral report at mid-point and end of pregnancy and confirmed by the SCN test. To ensure informed consent and to promote veracity, the women were informed that the SCN test confirmed exposure to cigarette smoke.[20] Because SCN concentration levels are generally higher in saliva than other extracellular fluids and higher during pregnancy, a value of 100 μg/ml of SCN was used as a cut-off for cessation and not 85 μg/ml. Because of the dose-response relationship between smoking and increased risk, reduction was also documented from the behavioral report and a reduction of at least 30 per cent from a baseline SCN value at each observation point (e.g., 200 μg/ml to 140 μg/ml).[21–29] It is important to note that three recent studies of small samples of pregnant women have confirmed SCN levels from 0.0 to 80.0 μg/ml in serum from passive exposure to cigarette smoke.[30–32] It remains unclear among pregnant smokers what the upper limits of the SCN level are due to passive smoking exposure. All women lost to follow up at either the mid-point or end-point observation, approximately 10–15 per cent in each group, were considered intervention failures (smokers).

Results

As noted in Table 1, the 92 women who refused to participate (460 minus 368) were very similar to the participants on variables assessed. Data in Table 1 also confirmed that the random assignment method used in this study was successful. Recruiting 80 per cent of the eligible pregnant smokers, using multiple sites, and including two follow-up observations strengthened the internal validity of the results of the study.

Data on the behavioral impact of the smoking cessation interventions on the pregnant smokers assigned to each of three study groups are reported in Table 2.

The mean SCNs for all baseline between group comparisons were similar. An Analysis of Variance and the Tukey Multiple Range Test supported the rejection of the null hypothesis as shown by the confidence intervals in Table 2. Of the women in Group #2 and Group #3 who quit or reduced, their mean SCNs were reduced from 121 μg/ml to 55 μg/ml (quit) and 184 μg/ml to 105 μg/ml (reduced), respectively.

An examination of the characteristics of those who quit versus those who did not quit revealed that age, education, and race were not predictors of cessation. The pregnant

TABLE 1—Comparability of Study Groups and Eligible Nonparticipants by Selected Baseline Variables

Baseline Variable	Group #1 Controls	Group #2 Health Education (ALA)	Group #3 Health Education (Guide)	Study Totals	Nonparticipant Totals
Mean Age	24.1	23.5	23.1	23.6	23.4
% Blacks	54.0	49.0	62.0	57.0	56.0
Mean Education	11.7	11.5	11.4	11.5	11.2
Mean Month of Entry	3.8	3.8	3.5	3.7	3.7
Mean SCN Ug/Ml	166.5	157.9	150.8	159.3	Not Collected
N	104	103	102	309	92

TABLE 2—Confidence Intervals and Proportions of Pregnant Women by Smoking Status and Group Assignment

Group	Quit		Quit and/or Reduced		N
	Proportion	95% C.I.	Proportion	95% C.I.	
Group #1 Control	2%	0.00–0.05	9%	0.03–0.15	104
Group #2 Health Education (ALA)	6%	0.01–0.11	20%	0.12–0.28	103
Group #3 Health Education (Guide)	14%	0.07–0.21	31%	0.22–0.40	102
Differences					
#3–#1	0.12	0.05–0.19	0.22	0.11–0.33	
#2–#1	0.04	(−0.01)–0.09	0.11	0.02–0.20	
#3–#2	0.08	(−0.00)–0.16	0.11	(−0.01)–0.23	

smokers who quit, however, entered prenatal care on the average one full month earlier than the pregnant smoker who did not quit (2.8 vs 3.8). Additionally, of the 22 quitters in this study, most (12) were light smokers (one to nine cigarettes/day); five smoked 10 to 19 cigarettes/day; and five smoked 20+ cigarettes/day at initial prenatal visit.

All of the 22 women in Group #1, Group #2, and Group #3 who verbally reported quitting were confirmed as nonsmokers by the SCN test. In this study, the SCN test proved to be a valid and efficient method to document cessation among pregnant smokers. Only 3 per cent (false negatives), 10 of 309 end-point SCN tests, had a value of ≥100 μg/ml and verbally reported not smoking in the last seven days. The SCN data provides support for the accuracy of the reported cessation data. The use of a cotinine test, however, may have improved the quality of measurement somewhat. The cost differential per test, however, is still substantial (Thiocyanate = $4 vs cotinine = $15).

Discussion

The evidence from this trial indicates that the smoking behavior, (cessation and/or significant reduction) of approximately one of five smokers was changed due to exposure to the methods used in Group #2 and one of three in Group #3. Sexton and Hebel in their 1984 study of 935 predominantly private practice patients in Baltimore City[17] reported a quit rate of 43 per cent as against a 20 per cent quit rate of the pregnant smokers randomized to a control group with saliva thiocyanate used to confirm cessation; they included in their reported quit rates, 17 per cent of the treatment group subjects who quit prior to randomization and 16 per cent of the control group who quit prior to randomization. Thus, the quit rates attributable to the cessation intervention are approximately 27 per cent and 3 per cent.

A comparison of results between our trial (14 per cent) and the Baltimore trial (27 per cent) suggests that the difference in quit rates is probably attributable to baseline differences in education (11.3 vs 12.3), age (23.5 vs 24.9), and type of health care setting (public vs private), and, most importantly, selection criteria (≥32 weeks vs ≥18 weeks). If our trial had used ≥18 weeks as an exclusionary criterion, our quit rate would be increased from 14 per cent (14/102) to 22 per cent (13/60). If further adjustments by age, education, and income level to the Birmingham quit rates were possible, most (if not all) of the observed difference between the two studies would be eliminated. This comparison and the predictors of cessation observed in the Birmingham study provides suggestive evidence that the use of the *Guide* by private practice patients would produce higher quit rates.

A pre-trial patient education assessment survey at three clinics of 300 pregnant women revealed that only 50 per cent remembered having been told during their first visit that they should stop smoking during pregnancy. A survey of all clinic nurses (n = 80) also indicated that none had training in smoking cessation methods, and less than 20 per cent were very confident of their ability to educate these women about how to stop. Data from these patient and provider assessments documented that the patients wanted methods to use on their own not available in the clinics, and that the staff had received no specific training and were not confident in their ability to assist these women to quit. Our study addressed the first need to develop a self-help methodology to be integrated into an ongoing public health maternity clinic program.

This study found, as did Baric and Donovan,[12,13] that pregnant smokers need more than information and advice to quit: the information and advice provided by clinic staff to Group #1 were ineffective in changing smoking behavior. We also observed that, if a woman is motivated to quit using the *Guide*, she is unlikely to start again later in pregnancy. Lack of resources prohibited the documentation of the durability of the intervention, post-delivery. Future cessation studies should document smoking practices at a minimum through the first postpartum clinic visit, and if possible up to one year postpartum.

Evidence from this research indicated that *A Pregnant Woman's Guide to Quit Smoking* can be used in prenatal care

education as a core smoking cessation/reduction method by pregnant smokers. From this experience and qualitative data collected from the Group #3 users the original *Guide* has been extensively revised and is available for distribution.[33] Beyond this core method and the brief health education cessation skills training used in this study, other low-cost methods may, if applied in combination, produce additional smoking behavior change among pregnant smokers, i.e., clinic chart reminders for clinic nurses and physicians; written reinforcing messages; and brief verbal and written systematic reinforcements either during routine prenatal care or sent to the home.[15,17,34,35] To achieve 30–40 per cent quit rates and 30–40 per cent reduced exposure, a more powerful multi-component program will need to be applied. This type of intervention may be beyond the ability and resources of many health departments.

Beyond the observed behavior change, the cessation methods applied in this study demonstrated a high degree of feasibility and acceptability among pregnant women and public health maternity clinic staff. Given the tenacity of smoking behavior, however, much work remains to be performed to determine the most effective and efficient cessation methods for pregnant smokers.[36]

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