
A Comparison of Two Antismoking Interventions Among Pregnant Women in Eleven Private Primary Care Practices

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Despite the dangers of smoking during pregnancy having been widely publicized, few studies have actually examined the effectiveness of antismoking interventions among pregnant women in the private primary care obstetric setting. A randomized experimental study involving 24 private physicians and 109 pregnant smokers was conducted comparing the American Lung Association's Because You Love Your Baby smoking intervention (ALA) to a standard-of-care protocol (non-ALA). The non-ALA protocol was based upon the smoking interventions that study physicians said they commonly used among pregnant women. Self-reported smoking rates were obtained by questionnaire at the first prenatal visit, at 32 to 36 weeks' gestation, and at the six-week postpartum visit. By the time of the first prenatal visit, both groups reduced by half the number of cigarettes smoked. By 32 to 36 weeks, the groups decreased the daily average by an additional 2.3 (ALA) and 1.8 (non-ALA) cigarettes, a nonsignificant difference between the groups. Fifteen (28 percent) of the ALA group compared with 9 (16 percent) of the non-ALA group reported quitting at the 32- to 36-week visit ($P = .10$). Only 9 percent of the ALA group and 10 percent of the non-ALA were nonsmokers at the postpartum visit. Pregnancy alone is a powerful motivator for women to decrease their smoking. Although the difference between the ALA and non-ALA protocols did not attain statistical significance, the percentage of those who quit was comparable to the results obtained in other controlled trials. The ALA Because You Love Your Baby protocol should be used until more effective methods are available.

There is growing concern among physicians and public health officials regarding smoking during pregnancy. Despite massive public information efforts, recent studies indicate that 22 to 38 percent of pregnant women smoke throughout pregnancy.^{1,2} Maternal cigarette smoking is associated with increased risk of placenta previa, abruptio placentae, spontaneous abortion, premature rupture of membranes, prolonged rupture of membranes, and low birthweight.³ There appears to be a dose-response relationship, and a safe level of smoking has not been determined.³⁻⁷ In light of the effects of smoking in pregnancy,

one might expect many reports of smoking interventions for pregnant women. In fact, there are only a handful of trials reported in the medical literature.⁸⁻¹⁵ All of these trials were conducted in public health clinics, in patients' homes, or in hospital-based obstetric clinics (Table 1). Only one study was conducted in a primary care setting, and this study was based in a health maintenance organization.¹³ While moderately effective, many of the interventions tested are time consuming and costly, making widespread adoption in the primary care setting unlikely.

In 1982 the American Lung Association (ALA) developed the Because You Love Your Baby smoking intervention designed specifically for physicians who treat pregnant smokers. While comprehensive, the ALA intervention is relatively easy to use and adapts well to the private obstetric setting. The treatment relies on personal physician counseling, a method the smoking cessation literature suggests can play an important role in helping

Submitted, revised, December 27, 1988.

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TABLE 1. REVIEW OF STUDIES DESCRIBING SMOKING INTERVENTIONS AMONG PREGNANT WOMEN

Author	Date	Type	Site	Treatment	Quit No. (%)
Baric et al ⁸	1976	CT	Hospital	Personal counseling	63 (14.2)
Donovan ⁹	1977	CT	Hospital	Personal counseling	280 (none listed)
Danaher et al ¹⁰	1978	UT	Clinic	Six 2-h counseling sessions with psychologists	11 (27)
Ershoff et al ¹³	1983	CT	HMO	Personal counseling	57 (49.1)
Langford et al ¹⁴	1983	CT	PH clinic	½-h presentation and pamphlet, or home visit, pamphlet, and presentation	(control 37.5) 77 (23)
Sexton and Hebel ¹¹	1984	CT	Home	Personal counseling, telephone follow-up, mail reminders, gift certificates, 45-min counseling intervention	463 (28)
Windsor et al ¹²	1985	CT	PH clinic	ALA	103 (6)
Olds et al ¹⁵	1986	CT	Home	ALA + self-help guide 75-min nurse visitation every 2 wk	102 (14) 310 (none listed)

CT—controlled trial; UT—uncontrolled trial; HMO—health maintenance organization; PH—public health; ALA—American Lung Association materials (Freedom From Smoking manual and Because You Love Your Baby pamphlet)

patients quit smoking.¹⁶⁻¹⁹ Before implementation by those who provide obstetric services, the program needs to be field tested and shown to be effective. This paper reports the results of a controlled trial designed to test the effectiveness of the ALA smoking-in-pregnancy intervention compared with primary care physicians' usual interventions for smoking cessation in pregnancy (non-ALA intervention).

METHODS

The Practices

Twenty-four physicians in 11 practices from the upper peninsula of Michigan and upper Wisconsin participated in the study. Twelve of the participants were family physicians and 12 were obstetricians. All physicians were male. The average age of physicians was 43 years (SD = 10.7 years) in the ALA group and 41 years (SD = 6.7 years) in the non-ALA group. All of the physicians were board certified, except for one family physician who was board eligible. Upon agreeing to participate, each physician was sent a brief questionnaire to identify the anti-smoking interventions study physicians used among their pregnant patients. Interventions that received a 70 percent or greater response rate were used to formulate a standardized smoking cessation protocol (non-ALA) reflective of local practice standards. A no-treatment condition was not included because absence of smoking cessation efforts

would be both unethical and not representative of services normally rendered to pregnant smokers by physicians.

Study practices were randomized to treatment and control groups using the following method. The practices were divided into roughly equal groups based on their number of projected deliveries. A coin was tossed to assign the groups to experimental and control conditions. Practices were randomized in this study rather than physicians to avoid contamination of protocols and the confusion that would result by having two distinctly different protocols running simultaneously in the same practice. Each practice volunteered a staff member to be a practice representative. These individuals were responsible for coordinating all aspects of the study in their offices. None of the study practices were informed about the identity of other practices included in the trial, nor were they offered information about the study design.

The Interventions

The two antismoking interventions differed with respect to time required and materials used. The non-ALA treatment was a minimal intervention that consisted of the physician discussing three items at three visits during the woman's prenatal care and recommending quitting at each of these visits (Table 2). The protocol was explained to all the non-ALA physicians and practice representatives by a member of the research staff. The ALA intervention was considerably more involved and is summarized in Table 2. To ensure standardization of the intervention

TABLE 2. SYNOPSIS OF NON-ALA AND ALA TREATMENT PROGRAMS

Non-ALA	ALA
Counseling by a physician on three occasions during the pregnancy with a suggestion to quit after each session. Counseling included discussion of:	Physician counseling each visit
Nicotine's effect on the developing fetus	Use ALA Because You Love Your Baby flip chart
Smoking-related complications of pregnancy	Monitor smoking at each visit and recommend patient quit smoking at each visit
Physician's belief that maternal smoking is harmful to a developing fetus	Distribute Because You Love Your Baby packets.
Remove ashtrays from the waiting room and do not allow staff to smoke in view of patients	Show slide tape presentation at each woman's first obstetrics visit
	Encourage patients to send for the <i>Freedom From Smoking</i> manual
	Post a Because You Love Your Baby poster in your waiting room
	Remove ashtrays from the waiting room and do not allow staff to smoke in the view of patients

ALA—American Lung Association

and to avoid bias, the American Lung Association representative from the upper peninsula of Michigan trained all the ALA physicians and their staff in the use of these materials. Compliance with both the ALA and non-ALA interventions was checked at the midpoint using a chart audit. The practice representatives reviewed every chart for compliance with the protocols. Upon completion, the practice representative returned the audit forms to the research office for analysis. In addition, each physician filled out a terminal audit that sought to determine the extent to which he complied with the protocols. These audits revealed that ALA and non-ALA study physicians used their group's intervention as instructed with only minor deviations. Some physicians delegated some of the intervention tasks to nurses or physician assistants in their practices.

The Patients

All women who presented for initial prenatal care between August 5, 1985, and June of 1986 and who were not over 28 weeks' gestation were invited to participate in the study. After giving informed consent, each pregnant woman was assigned a code number and had a questionnaire packet placed in her chart. The first questionnaire was admin-

TABLE 3. REASONS FOR DROPOUT: A COMPARISON OF ALA AND NON-ALA TREATMENT GROUPS

Reason	ALA	Non-ALA
Miscarriage	3	4
Therapeutic abortion	2	0
Moved	5	6
Incomplete data set	4	4
Total dropouts	14	14
Final sample size	53	56

ALA—American Lung Association

istered by the practice representative or her delegate at the first prenatal visit prior to her exposure to the intervention. Questionnaires were also distributed in a similar fashion at 32 to 36 weeks' gestation and at the six-week postpartum visit. Data collection concluded in March of 1987.

A total of 644 women reported to all practices for prenatal care during the course of the study. Five refused to participate. Of the remaining 639 women, 433 (68 percent) were nonsmokers. The smokers totaled 206 (32 percent). Of the total smokers, 69 (34 percent) said they quit prior to their first prenatal visit because they were pregnant. The remaining 137 (21 percent of the original sample) were considered smokers for the purposes of this study. A smoker was defined as any woman who reported that she was still smoking at her first prenatal visit. Women who quit smoking before their current pregnancy or who quit before their first prenatal visit were not considered smokers. During the study seven smokers had miscarriages, two had therapeutic abortions, 11 moved from their practice and were lost to follow-up, and eight had incomplete data sets that could not be used for purposes of analysis; dropout rates were similar in both groups (Table 3). The total number of pregnant smokers that completed all questionnaires was 109, 53 in the ALA group and 56 in the non-ALA group.

A sample size of 50 in each group was sufficient to detect a difference of five cigarettes per day in smoking between the treatment and control groups (power = .80; type I error = .05). The interval data were analyzed using analysis of variance and the Student *t* statistic. The chi-square statistic was used for analysis of nominal level data.

RESULTS

The demographic characteristics of the groups are displayed in Table 4. The groups were comparable on all variables measured. Before the study, there was no significant difference between the groups in length of time

TABLE 4. DEMOGRAPHIC VARIABLES: A COMPARISON OF PREGNANT SMOKERS IN THE ALA AND NON-ALA TREATMENT GROUPS

Variable	ALA (n = 53) No. (%)	non-ALA (n = 56) No. (%)	P value
Marital status			.64
Married	34 (64)	41 (73)	
Divorced	3 (6)	2 (4)	
Single	13 (24)	11 (19)	
Separated	3 (6)	2 (4)	
Race			.98
White	52 (98)	55 (98)	
Native American	1 (2)	1 (2)	
Employment status			.49
Full time	16 (30)	13 (23)	
Part time	13 (25)	19 (34)	
Unemployed	24 (45)	24 (43)	
Educational attainment			.35
Junior high	1 (2)	0 (0)	
High school	44 (83)	44 (79)	
College	7 (13)	12 (21)	
Postgraduate	1 (2)	0 (0)	
Average years smoked	8	9	.19
Smoker's average age in years	24	25	.19

ALA—American Lung Association

smoked (Table 4) or in average number of cigarettes smoked (Figure 1).

The trend in smoking can be seen in Figure 1. At the first prenatal visit prior to any physician intervention, both groups had nearly halved their self-reported smoking rates. While there was a further decrease in smoking rates at 32 to 36 weeks, it was small for both groups—about two cigarettes per day. At the postpartum visit, both groups had increased the number of cigarettes smoked to levels higher than reported at the first obstetric visit yet considerably lower than pre-pregnancy rates. None of the differences between groups in mean cigarettes smoked were statistically significant ($P > .05$).

The quit rate showed a similar pattern. The greatest reduction occurred at 32 to 36 weeks favoring the ALA intervention, though the difference was not statistically significant (Table 5). There was no significant difference between groups at the postpartum visit.

Women in this study who smoked 20 or more cigarettes before this pregnancy were significantly more likely to be smokers at their first prenatal visit than were women who reported smoking fewer than 20 cigarettes prior to their pregnancy ($\chi^2 = 8.12$, $P < .05$). Women who reported another smoker in the household were significantly more likely to be smokers at the first prenatal visit ($\chi^2 = 13.57$, $P < .05$).

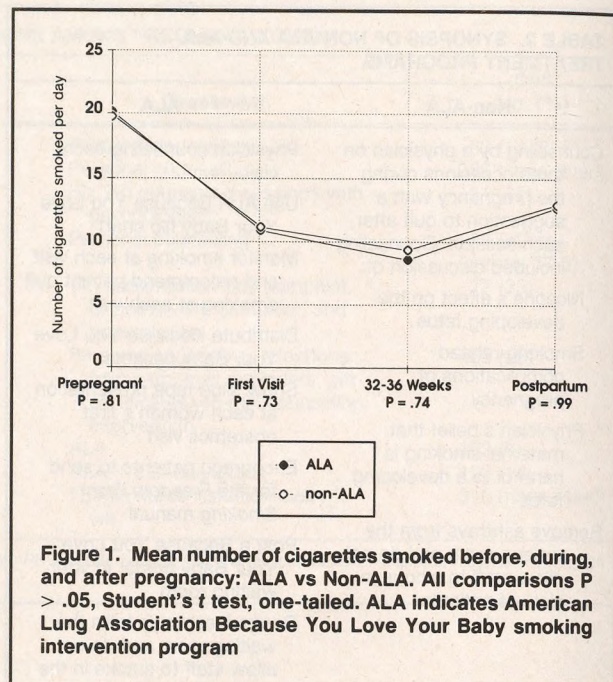


Figure 1. Mean number of cigarettes smoked before, during, and after pregnancy: ALA vs Non-ALA. All comparisons $P > .05$, Student's *t* test, one-tailed. ALA indicates American Lung Association Because You Love Your Baby smoking intervention program

Reasons cited by patients for smoking cessation or reduction are given in Table 6.

DISCUSSION

Smoking cessation has become an important topic in preventive medicine circles. Physicians are bombarded with patient education materials designed to help smokers quit. Most of these materials, however, have not been tested for effectiveness in physicians' offices. This controlled trial is the first of the American Lung Association's Because You Love Your Baby smoking intervention. Though the results did not indicate a statistically significant advantage for the ALA protocol, the trend in smoking cessation at 32 to 36 weeks favors the ALA protocol over the standard intervention. The lack of statistical significance may be due, in part, to increased effort among the control group physicians. All of the physicians knew they were participating in a study of smoking cessation.

There are several possible criticisms to this study's design. First, the study design required that practices rather than individuals be randomized. Actually, this strengthened the design because the chance for cross-contamination was minimized. The question is raised, however, of comparability of patient groups. The lack of significant differences between the two groups of smokers, especially in their pre-pregnancy and first obstetric visit smoking

TABLE 5. QUIT RATES OF PREGNANT SMOKERS FOLLOWING INTERVENTION

Time	ALA No. (%)	Non-ALA No. (%)	P value
32 to 36 weeks	15 (28)	8 (14)	.07*
Postpartum	5 (9)	6 (10)	.29*

* Chi-square with 1 df
ALA—American Lung Association treatment intervention

TABLE 6. REASONS CITED BY PATIENTS FOR SMOKING CESSATION OR REDUCTION

Reasons	ALA No. (%)	Non-ALA No. (%)
What I learned at my doctor's office during this pregnancy	8 (16)	5 (11)
The fact that I was pregnant	34 (68)	36 (80)
All other reasons (spouse, friend, childbirth class, sickness, "other")	8 (16)	4 (9)

$\chi^2 = 8.9; P = .11$
ALA—American Lung Association treatment intervention

rates, leads one to think that the two groups are quite similar. More information regarding previous quit attempts, degree of nicotine addiction, and social support would have been helpful to assure comparability. Second, in most smoking-cessation trials, smoking rates are confirmed with serum or saliva thiocyanate levels or carboxyhemoglobin levels.^{20,21} The research budget was not sufficient for these tests. Since the groups appear comparable, one would expect underreporting to occur at the same rate in both groups. Also, in a smoking-in-pregnancy cessation trial by Windsor et al,¹² self-reported quit rates were very accurate when confirmed with salivary thiocyanate levels. Third, there was no external verification that physicians followed the protocols, since the audits were performed by the practice representatives. Finally, it would be difficult to generalize the results of this study to the general population. While being fairly representative of the rural upper Midwest, the demographic characteristics of the study population are not representative of other regions of the United States. In addition, the demographic and practice characteristics of the physicians in this study may not be representative of physicians delivering obstetric care as a whole.

Despite these limitations there were some noteworthy findings. In this study the mean cigarette consumption in

both the treatment and control groups had decreased by one half at the time of the first obstetric visit. Also, 34 percent of the originally identified smokers quit smoking entirely by the time of the first prenatal visit prior to any physician intervention. This spontaneous cessation has been noted in other trials and implies that many pregnant smokers are aware that smoking is hazardous to their babies and are motivated to quit at that time.^{8,9,11,12} Compared with pregnancy itself, both protocols had a paltry effect on smoking rates. The mean decrease following intervention was very small, about two cigarettes in each group. The vast majority of women cited pregnancy as the reason they cut back or quit (Table 6). Few women in either group attributed their smoking cessation or reduction to information learned at the physician's office.

Although there was not a statistically significant difference in smoking cessation between the ALA and the non-ALA groups, the ALA quit rate of 28 percent at 32 to 36 weeks was quite successful compared with other recent trials (Table 1). The group studied by Windsor et al¹² was able to achieve a 14 percent quit rate with an intensive self-directed seven-day quit plan. Sexton and Hebel,¹¹ in a 1984 study of 935 predominantly private practice patients, achieved a quit rate of approximately 28 percent that was attributable to an intensive and costly regimen not practical in most busy practices. The ALA intervention achieved an identical rate with a much more efficient program. The good ALA quit rates may be a function of heightened public awareness of smoking-related complications in pregnancy.

Despite the ALA quit rate being comparable to that of Sexton and Hebel using a much less labor-intensive method, 28 percent is still far from satisfactory. Pregnant smokers still smoking at the first prenatal visit constitute a special class of smokers. They appear to be resistant to physicians' usual counseling strategies and frequently have other smokers in the household. On the other hand, these data suggest that late pregnancy may be an opportune time to reinforce women's motivation to quit. The average drop in cigarette consumption was nearly maintained at the six-week postpartum visit, suggesting that these new mothers continue to be motivated. Perhaps with some additional reinforcement at the end of pregnancy, the women who had quit at the 32- to 36-week follow-up but who were smoking again at the six-week postpartum visit might have continued smoke-free.

This and other studies support the notion that pregnancy is a powerful motivator for smoking reduction and cessation. Future interventions should pay particular attention to the group of women who report smoking heavily at the first prenatal visit and who have other smokers at home. These women are at greater risk of smoking-related complications of pregnancy. They need to be further characterized, and innovative interventions

must be developed specifically for them. The American Lung Association Because You Love Your Baby intervention represents a step in that direction. These preliminary results are encouraging, and further testing of the ALA program is needed. The ALA has added a self-help manual to the program that may increase its effectiveness. Until better methods are developed and tested, physicians should consider using the ALA program with their pregnant smokers. It is inexpensive, easy to use, and readily available from any local American Lung Association office.

Acknowledgments

This investigation was supported by research grants from the American Academy of Family Physicians and the Upper Peninsula Health Education Corporation. The following physicians and their clinic staff gave their time to provide the data on which this paper is based: William Addison, MD, Larry Andrieni, MD, Drake Austin, MD, James Batti, MD, Richard Bectel, MD, Ronald Bissett, MD, Richard Bojanen, MD, Robert Cook, MD, Michael Conley, MD, Steven Dosh, MD, Donald Fitch, MD, Raymond Hockstad, MD, Raymond Koivunen, MD, William LeMire, MD, Edward Matuga, MD, Steven Menhennet, MD, Thomas Noren, MD, Leslie Rose, MD, Herbert Sandmire, MD, Richard Schaefer, MD, Donald Sipes, MD, Thomas Vanderhorst, MD, and Edward Vogel, MD.

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