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Implementation and outcomes of recommended folic acid supplementation in Mexican-American women with prior neural tube defect-affected pregnancies

Marilyn Felkner, Dr.P.H.*, Lucina Suarez, Ph.D., Kate Hendricks, M.D., M.P.H., T.M., Russell Larsen, Ph.D., M.P.H.

Texas Department of Health, Austin, TX, USA

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Abstract

Background. Upon discovering an NTD incidence rate of 27/10,000 in a Texas border county, the Texas Department of Health initiated folic acid intervention for prevention of recurrent NTDs in this predominantly Mexican-American population. This paper describes compliance of this population with USPHS folic acid recommendations and the impact of supplementation on pregnancy outcomes.

Methods. Based upon information from active surveillance, field teams personally contacted women having NTD-affected pregnancies to enroll them in FA intervention. Enrollees were provided FA at home visits at 3-month intervals throughout the project.

Results. Of 405 women identified with NTD-affected pregnancies, 299 (73.8%) enrolled in the intervention. One hundred ninety-three pregnancies occurred among 138 women. FA supplementation of 0.4 mg/day or more occurred during the last month preconception in 161 (83.4%) of the 193 pregnancies. No NTDs were detected in the 130 livebirths to women who received supplementation nor were NTDs detected in the 23 supplemented women who experienced pregnancy loss.

Conclusions. Supplementation was successful in preventing recurrent NTDs in Mexican-American women.

Keywords: Neural tube defects; Folic acid; Mexican Americans; Dietary supplementration; Intervention studies

Introduction

Neural tube defects (NTDs) are common birth defects, affecting 4000 U.S. pregnancies annually. In 1991, the British Medical Research Council Vitamin Study Research Group published their landmark findings that the relative risk of recurrent NTD-affected pregnancies was reduced 72% in women who received 4 mg of folic acid (FA) daily during the periconceptional period compared with women receiving no FA supplementation [1]. Consequently, in 1991, the U.S. Public Health Service recommended FA supplementation for women with prior NTD-affected pregnancies [2].

In 1991, concurrent with the MRC findings and prior to the USPHS recommendation, six anencephalic births occurred in 6 weeks in Cameron County, Texas. An investigation of this event demonstrated an NTD incidence rate of 27 cases per 10,000 among babies conceived from 1990 to 1991 in this Texas–Mexico border county [3] (20.5 per 10,000 for >20 weeks gestation) [Texas Department of Health. An Investigation of a Cluster of Neural Tube Defects in Cameron County, Texas. Unpublished data 1992: Table 6]. This rate contrasted with the incidence rate of 10 cases per 10,000 for the United States as a whole [4]. In response to this situation, the Texas Department of Health initiated the Texas Neural Tube Defect Project in the 14 Texas–Mexico border counties, an area in which 95% of the births are to Mexican-American women. The project included multi-source active surveillance, a case-control study, and a FA intervention for prevention of recurrent NTDs.

* Corresponding author. Fax: +1 512 458 7616.
E-mail address: marilyn.felkner@tdh.state.tx.us (M. Felkner).

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Hispanics consistently have higher rates of NTDs than other ethnic groups [3,5,6], and some research has suggested that FA supplementation is less efficacious in Hispanics [5], implying that an inherent genetic or metabolic condition unrelated to FA intake might predispose them to NTDs. Furthermore, many Mexican-American women on the Texas–Mexico border are poor, poorly educated, and more Spanish-proficient than English-proficient, making it less likely that mainstream public awareness campaigns and patient education promoting FA would effectively influence their behavior. This paper describes how well Mexican-American women with prior NTD-affected pregnancies complied with the USPHS FA recommendations, after enrolling in the FA intervention program. We also assess the impact of this supplementation on pregnancy outcomes using a population-based cohort design. Women who chose not to enroll were not followed.

Methods

Data for this study came from the surveillance and intervention components of the Texas Department of Health's Neural Tube Defect Project; all components of the project were reviewed and approved by the Internal Review Board of the Texas Department of Health. The surveillance component was designed to identify all cases (infants or fetuses) having a diagnosis of anencephalus (International Classification of Diseases 9th revision, Clinical Modification, code 740), spina bifida (code 741), or encephalocele (code 742.0). Three field teams reviewed charts and medical records from hospitals, birthing centers, radiology clinics, and abortion centers to identify women with NTD-affected pregnancies. All Mexican-American women with nonsyndromal NTD-affected pregnancies who delivered/aborted in one of the 14 Texas–Mexico border counties from January 1993 to May 2000 were eligible for intervention. For this analysis, only women with index pregnancies prior to August 31, 1999 (one gestation period prior to the end of the study), were included to allow for an adequate follow-up period. All women with index pregnancies prior to August 31, 1999, were observed through May 2000.

The overarching goal of the intervention was to facilitate compliance with the USPHS recommendation that women with previous NTD-affected pregnancies take daily high dose FA (4 mg) 1 month prior to conception. To achieve that goal in a population in which a majority of pregnancies are unplanned and in which the interpartum interval may be short, the intervention was structured to provide some form of supplementation at all times. Enrollees were encouraged to notify the field team workers of plans to conceive 3 months in advance, anticipating that this would increase the odds that high dose supplementation could be implemented at least 1 month prior to conception.

Initial contact with women was made through home visit, telephone, or letter within 2 weeks of identification of an NTD-affected pregnancy. Initial contact was followed by a home visit generally within 6 weeks postpartum. At this visit, the field team nurse described the project and obtained written consent from enrollees. The field team nurse then discussed the enrollee's contraceptive plans and practices and drew blood for laboratory tests including serum folate, RBC folate and serum B_{12}. Women with subsequent abnormal values were referred for follow-up with their personal physicians but remained in the intervention. Only one woman had a clinically low serum B_{12} level; thus, obscuring low B_{12} diagnoses through use of high-dose folate was not a significant issue in this population.

After laboratory evaluation, enrollees were assigned FA dosage based, not upon their stated plans for pregnancy, but upon their contraceptive practices. Enrollees who had been sterilized or whose partners had been sterilized were given multivitamins but no additional supplementation. Enrollees using "a reasonable method of contraception"—injections, oral contraceptives, IUDs, and condoms were provided with low-dose FA. Low-dose supplementation consisted of daily consumption of 0.4 mg of FA as a component of a Miles One-a-Day multivitamin. Enrollees who were attempting to conceive or not adequately contracepting—using withdrawal, rhythm, abstinence, or barrier methods—were provided with high-dose FA. High-dose supplementation consisted of a 4 mg daily dosepac containing three 1 mg FA tablets and one Stuart Natal 1 + 1 multivitamin/multimineral tablet with 1.0 mg of FA. Women using physician-prescribed vitamins in any dosage continued to use those vitamins but remained in contact with field team members.

The enrollees received a calendar and two urine pregnancy tests along with instructions about recording the dates of menses and use of the pregnancy tests. Enrollees were to notify the field office team to report the decision to discontinue contraception or attempt pregnancy, missed menses or suspicion of pregnancy, results of pregnancy tests, or any concerns in general.

FA was provided throughout the project at follow-up home visits no more than 3 months apart. At these visits, the field team evaluated supplementation compliance based on observation of supplement containers and enrollees' self-reports, and contraceptive information and menses calendars were reviewed. Home visits were also made in response to notification of any situations that would affect FA supplementation dosage, and dosage was changed as indicated. Enrollees with positive pregnancy tests had blood drawn for CBC, RBC and serum folate and serum B_{12}. Visits at 3-month intervals were continued throughout pregnancies and at approximately 4 months postpartum for determination of pregnancy outcome and reassessment of enrollees' FA supplementation requirements. Generally, field team members observed infants at postpartum home visits; in cases in which enrollees delivered outside the study area, enrollees reported birth outcomes via letter to field team members. Field team members recorded outcomes of