Examining the safety of dental treatment in pregnant women

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Every year, more than 6 million women in the United States become pregnant.[1] Surveys in a variety of populations suggest that only about one-quarter to one-half of women receive any dental care, including prophylaxes, during their pregnancies.[2-5] Utilization of care tends to be lower still in women from low socioeconomic strata and in those who are not aware of the potential link between oral health and pregnancy outcomes.[4-6] Pistorius and colleagues[7] reported that only about 10 percent of dentists performed all necessary treatment in pregnant women and that 14 percent of dentists were against using a local anesthetic in such women. Less than 50 percent of dentists in this survey indicated that they would defer treatment in the first trimester, while 8.5 percent would do so in the second trimester.[7]

Women tend to visit a dentist less often during a pregnancy than beforehand.[5] Among those who did not visit a dentist while pregnant, about two-thirds chose to delay any care until after delivery. Lindow and colleagues[8] reported that, despite widespread knowledge that dental care in the United Kingdom was free through the National Health Service, only 64 percent of pregnant women received even a dental examination during their

ABSTRACT

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Background. Although clinicians generally consider it safe to provide dental care for pregnant women, supporting clinical trial evidence is lacking. This study compares safety outcomes from a trial in which pregnant women received scaling and root planing and other dental treatments.

Methods. The authors randomly assigned 823 women with periodontitis to receive scaling and root planing, either at 13 to 21 weeks' gestation or up to three months after delivery. They evaluated all subjects for essential dental treatment (EDT) needs, defined as the presence of moderate-to-severe caries or fractured or abscessed teeth; 351 women received complete EDT at 13 to 21 weeks' gestation. The authors used Fisher exact test and a propensity-score adjustment to compare rates of serious adverse events, spontaneous abortions/stillbirths, fetal/congenital anomalies and preterm deliveries (< 37 weeks' gestation) between groups, according to the provision of periodontal treatment and EDT.

Results. Rates of adverse outcomes did not differ significantly ($P > .05$) between women who received EDT and those who did not require this treatment, or between groups that received both EDT and periodontal treatment, either EDT or periodontal treatment alone, or no treatment. Use of topical or local anesthetics during root planing also was not associated with an increased risk of experiencing adverse outcomes.

Conclusions. EDT in pregnant women at 13 to 21 weeks' gestation was not associated with an increased risk of experiencing serious medical adverse events or adverse pregnancy outcomes. Data from larger studies and from groups with other treatment needs are needed to confirm the safety of dental care in pregnant women.

Clinical Implications. This study provides evidence that EDT and use of topical and local anesthetics are safe in pregnant women at 13 to 21 weeks' gestation.

Key Words. Local anesthetics; topical anesthetics; dental care; periodontics; pregnancy; pregnancy complications; preterm labor; safety management.

JADA 2008;139(6):685-695.

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pregnancy. Only 26 percent of women in this study had been advised by a health care professional to see a dentist. Collectively, these findings suggest that use of dental services during pregnancy may be driven more by patients' and dentists' attitudes than by economics or convenience.

Attitudes and behaviors among dentists may arise from fear of causing harm to the pregnant woman or fetus, fear of litigation or patients' safety concerns. Notably, however, Hilgers and colleagues[9] found only one case in which a dentist was sued—unsuccessfully—for treating a pregnant woman who subsequently delivered a stillborn infant. Dental care providers also may defer treatment in pregnant women because of fear that the anesthetics, antibiotics and analgesics commonly used in dentistry may lead to fetal malformations or may otherwise harm the fetus. Few drugs, however, are known teratogens, which are deleterious only when the embryo or fetus is susceptible to their actions. Embryogenesis is the period of maximum sensitivity, which usually is considered to occur between the fifth and 10th week of gestation. Moreover, the U.S. Food and Drug Administration[10] considers a number of local anesthetics, antibiotics and analgesics relatively safe for use in pregnant women, meaning that clinicians have several options for treating intraoperative and postoperative oral pain and infection.

Finally, dentists may be concerned that bacteremias caused by some dental procedures may lead to uterine infections, spontaneous abortions or preterm labor. Although microorganisms commonly found in the oral cavity have been isolated from amniotic fluid[11] and in cases of chorioamnionitis,[12] there is no evidence that dental procedures known to induce bacteremias increase a woman's risk of experiencing fetal loss or preterm labor and delivery.[13-15]

Dentists' reluctance to treat pregnant women may arise from a lack of objective data to support safety claims.[16] For example, the Australian National Health and Medical Research Council's 1984 guidelines stated that most dental procedures could be performed safely during pregnancy.[16] However, the council did not present any evidence to support this claim, and the group has not published updated guidelines. The American Academy of Periodontology also recommends that pregnant women with periodontitis receive treatment during pregnancy.[17]

The purpose of this report is to describe safety outcomes related to the provision of dental care in pregnant women. We used data from a multicenter randomized controlled clinical trial (the Obstetrics and Periodontal Therapy [OPT] Trial) conducted to determine if periodontal therapy in pregnant women reduces the risk of preterm delivery.[13] We reported that scaling and root planing was not associated with adverse medical events.[13] Here, we report associations between adverse pregnancy outcomes and essential dental treatment (EDT), anesthetic use during nonsurgical periodontal treatment and combinations of EDT and periodontal treatment. To the best of our knowledge, this is the first report of safety outcomes in a cohort of pregnant women undergoing periodontal therapy and EDT.

SUBJECTS AND METHODS

Details about the OPT trial and its obstetrical and clinical periodontal results have been reported elsewhere.[13] Study personnel, including the authors, recruited women from obstetrics clinics at Hennepin County Medical Center, Minneapolis, the University of Kentucky, Lexington, the University of Mississippi Medical Center, Jackson, and Harlem Hospital, New York City. These clinics serve minority and other underserved groups who are at an elevated risk of experiencing preterm birth. As reported elsewhere,[13] 45.2 percent of participants were black and 42.5 percent were Hispanic.

All women had periodontitis, defined as the presence of four or more teeth with a probing depth of at least 4 millimeters and a clinical attachment loss of at least 2 mm, as well as bleeding on probing at 35 percent or more of tooth sites. Most women were judged to have generalized slight-to-moderate periodontitis. They were ineligible for the study if they had multiple fetuses, required antibiotic prophylaxis before dental treatment, had a medical condition that precluded elective dental treatment, or were likely to have fewer than 20 remaining teeth after treatment of moderate-to-severe caries, abscesses or other nonperiodontal pathoses.

The data coordinating center randomly assigned a total of 413 women to receive scaling and root planing at a time before 21 weeks' gestation; 395 received at least part of this treatment. Clinicians provided periodontal treatment over

ABBREVIATION KEY. CAL: Clinical attachment loss. **EDT:** Essential dental treatment. **OPT:** Obstetrics and Periodontal Therapy.

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one to four visits, and they administered topical or local (injected) anesthetics at their discretion. We monitored the 410 control-group women for safety during their pregnancy and treated them with scaling and root planing after delivery.

The women received comprehensive periodontal examinations at baseline (13 weeks, 0 days' to 16 weeks, six days' gestation), at 21 to 24 weeks' gestation and at 29 to 32 weeks' gestation. All subjects also had monthly visits, during which women in the treatment group received tooth polishings and oral hygiene instruction, and women in the control group received brief examinations only.

Dentists evaluated women in both groups for EDT needs. We defined EDT needs as the presence of one or more of the following:

- odontogenic abscesses;
- decayed teeth that were judged likely to become symptomatic during the course of the study if left untreated;
- fractured or decayed teeth that were judged as adversely affecting the health of adjacent soft tissues.

Treatment. The dentists treated affected teeth with temporary or permanent restorations, endodontic therapy or extraction at a time before 21 weeks' gestation. Overall, the dentists determined that 483 women (58.7 percent) needed EDT; 351 (72.7 percent) of these women completed all recommended treatment. We recorded the number of EDT visits and specific procedures completed, but we did not track the amount or type of local anesthetic administered during these visits or the type of restorative material used.

Serious adverse events. Obstetric nurses monitored subjects for serious adverse events via medical record reviews throughout the trial. In addition, study obstetricians (V.R.L., J.E.F., J.B., S.M.) periodically audited medical records to ensure data accuracy and completeness. Study coordinators also asked subjects about recent adverse events at follow-up visits. We defined two types of events: pregnancies that ended in a nonlive birth, which included spontaneous abortions (losses at a time before 20 weeks' gestation) and stillbirths (losses at a time between 20 weeks' gestation and 36 weeks, six days' gestation); and events that did not result in pregnancy termination. The latter included hospitalizations for more than 24 hours because of labor pains, hospitalizations for any other reason, fetal or congenital anomalies and neonatal deaths. We excluded brief hospital visits (< 24 hours) for laborlike pains on the advice of the OPT Data and Safety Monitoring Board, which judged that false labor is both common in pregnant women and not a true adverse event.

We included hospitalizations for any other reason because the relevant institutional review boards considered them to be serious adverse events, regardless of their relationship to the study. Women were hospitalized during the trial for a variety of reasons, including uncontrolled diabetes, cholestasis, ovarian cysts, preeclampsia, chorioamnionitis, pancreatitis and pyelonephritis.

Physicians diagnosed fetal anomalies via prenatal ultrasonography or at delivery. Two women underwent elective abortions because of fetal anomalies. We did not consider these events to be deliveries before 37 weeks' gestation, but we did count them as anomalies in the analyses of adverse events. The figure depicts the sample population, according to the provision of periodontal treatment (determined principally by study randomization), EDT needs and provision of EDT.

Statistical analyses. We used χ^2 or Fisher exact tests to compare the frequency of each untoward outcome (that is, any serious adverse event, spontaneous abortion or stillbirth, pregnancy ending before 37 weeks' gestation, fetal or congenital anomaly) between dental treatment groups.

We randomized subjects into periodontal treatment groups but not EDT groups. To address potential imbalances between women who received and did not receive EDT, we used propensity-score stratification to adjust analyses according to a woman's likelihood of receiving EDT. (The propensity score considered the probability of receiving EDT to be a function of patients' characteristics that might be associated with experiencing an adverse pregnancy outcome.)[18]

The multivariate model for the propensity to receive EDT included these baseline characteristics: clinical site (Kentucky, Minnesota, Mississippi, New York), race (African-American or other), ethnicity (Hispanic or other), education (> 12 years, 8-12 years, < 8 years), previous pregnancies (yes/no), number of medication classes (out of four salient classes), percentage of tooth sites with clinical attachment loss of 2 mm or more, percentage of tooth sites with bleeding on probing, age and age squared. We tested for EDT according to EDT-propensity interactions for each

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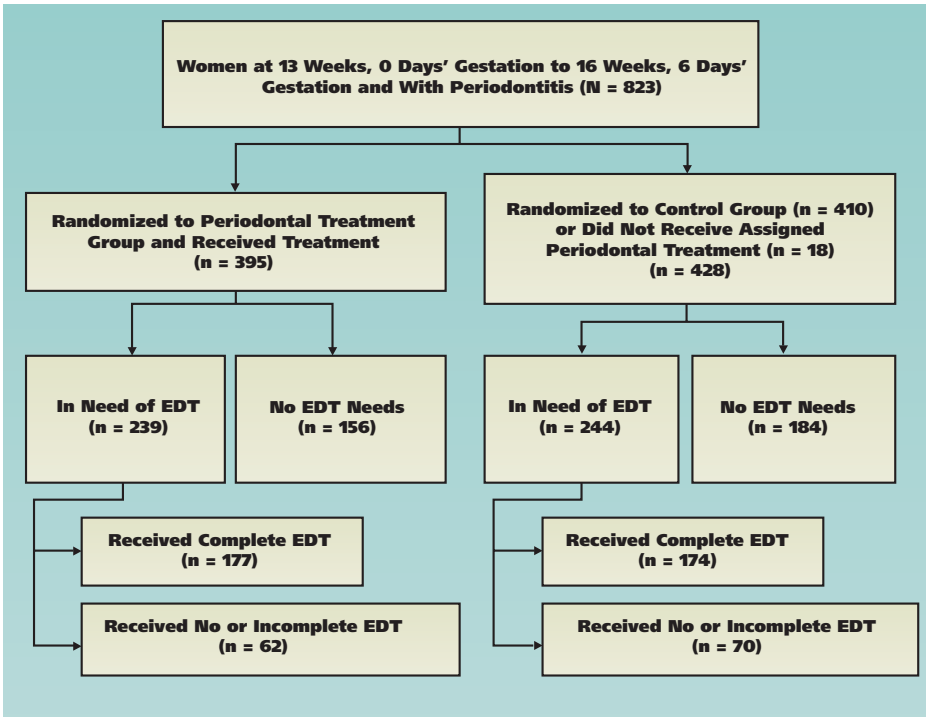

Figure. Treatment disposition of women enrolled in the Obstetrics and Periodontal Therapy Trial. EDT: Essential dental treatment.

untoward outcome. Because no interactions were significant (all *P* values > .15), the final model for the propensity-adjusted analyses was pregnancy outcome = EDT plus EDT propensity, which we analyzed using logistic regression.

We also compared adverse event rates between groups according to EDT and periodontal treatment status. To address potential imbalances between these four groups (received both, either one alone, or neither), our models included a stratification of a propensity score that captures variability in a subject's likelihood of having received these treatments. The propensity score is the first principal component of the estimated probabilities of each patient's receiving periodontal treatment, EDT or both.[19] We derived estimated probabilities by using a multinomial logit model that included the baseline characteristics listed above.

RESULTS

Seven women were unavailable for follow-up and two withdrew their consent. Pregnancy outcome data were available for 814 (98.9 percent) of 823 women. Eighty-two pregnancies ended in live preterm births, six in spontaneous abortions (before 20 weeks' gestation), 13 in stillbirths (from 20 weeks' gestation to 36 weeks, six days' gestation) and two in elective abortions. Ten of the stillbirths occurred in blacks, who made up 44 percent (358 of 814) of the sample with known birth outcomes. No stillbirths occurred after 36 weeks, six days' gestation. We noted 20 fetal or congenital anomalies during prenatal ultrasonography or at birth. One anomaly led to a spontaneous abortion and two led to elective abortions. The frequency of each adverse outcome did not differ significantly ($P > .05$) between clinical centers.

Periodontal treatment. Clinicians performed scaling and root planing across a mean (± standard deviation) of 2.0 (± 0.89) visits and for 127 (± 58) minutes. During this treatment, the clinician administered topical 20 percent benzocaine to 217 (54.9 percent) of 395 subjects, topical 5 percent lidocaine to five subjects (1.3 percent) and topical 1 percent dyclonine to 58 subjects (14.7 percent). The clinician injected local anesthetic as follows: 2 percent lidocaine with 1:100,000 epinephrine in 113 women (28.6 percent), 4 percent prilocaine with epinephrine in 33 women (8.4 percent) and prilocaine without vasoconstrictor in 23 women (5.8 percent). In addition, the clinician injected an unspecified anesthetic in 15 women (3.8 percent).

Summary of EDT. Women who received at least some EDT had a mean of 2.0 EDT visits (range, one to nine visits). A mean of 0.9 teeth were extracted (range, 0 to 10 teeth), while a mean of 0.9 teeth were treated with a temporary restoration (range, 0 to two teeth), 1.9 teeth were treated with permanent restorations (range, 0 to 18 teeth) and 0.1 teeth were treated with endodontic therapy (range, 0 to three teeth). Thirteen subjects received temporary partial dentures to replace extracted teeth deemed strategic for function or esthetics. Again, we did not record the type or amount of anesthetic used or the length of the EDT visits. The distribution of EDT needs and the provision of this care did not differ significantly between periodontal treatment and control groups (χ^2 $P = .47$).

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TABLE 1

Baseline characteristics, according to periodontal and essential dental treatment (EDT).*

BASELINE VARIABLE	NUMBER (PERCENTAGE) OF SUBJECTS†				*P* VALUE‡
	No Periodontal Treatment, No or Incomplete EDT (n = 254)	Periodontal Treatment, No or Incomplete EDT (n = 218)	No Periodontal Treatment, Complete EDT (n = 174)	Periodontal Treatment, Complete EDT (n = 177)	
Clinical Site					
Kentucky	70 (27.6)	65 (29.8)	35 (20.1)	41 (23.2)	
Minnesota	39 (15.4)	41 (18.8)	89 (51.1)	78 (44.1)	< .01
Mississippi	72 (28.3)	54 (24.8)	30 (17.2)	36 (20.3)	
New York	73 (28.7)	58 (26.6)	20 (11.5)	22 (12.4)	
African-American	132 (52)	112 (51.4)	64 (36.8)	64 (36.2)	< .01
Hispanic	91 (35.8)	74 (33.9)	91 (52.3)	94 (53.1)	< .01
Education					
< 8 years	39 (15.4)	33 (15.1)	42 (24.1)	40 (22.6)	.05
8-12 years	155 (61)	123 (56.4)	98 (56.3)	103 (58.2)	
> 12 years	60 (23.6)	62 (28.4)	34 (19.5)	34 (19.2)	
Previous Pregnancy	185 (72.8)	150 (68.8)	136 (78.2)	140 (79.1)	.07
Mean (± SD§) Number of Medication Classes (0-4)	0.22 ± 0.51	0.25 ± 0.50	0.25 ± 0.68	0.38 ± 0.59	.02
Mean (± SD) Percentage of Sites With CAL¶ ≥ 2 mm#	41.2 ± 24.1	42.7 ± 24.6	42.8 ± 26.7	43.4 ± 27.1	.83
Mean (± SD) Percentage of Tooth Sites Bleeding on Probing	68.4 ± 17.4	70.1 ± 17.2	70.9 ± 17.0	68.7 ± 17.3	.43
Mean (± SD) Age (Years)	25.4 ± 5.3	25.5 ± 5.6	26.4 ± 5.7	27.0 ± 5.6	< .01

* For a more detailed summary of the sample's baseline characteristics, see Michalowicz and colleagues.[13]
† Unless otherwise specified.
‡ χ^2 test *P* value reported for tabulated variables; analysis of variance *P* value reported otherwise.
§ SD: Standard deviation.
¶ CAL: Clinical attachment loss.
# mm: Millimeters.

Dental treatment and adverse outcomes. Table 1 lists the distribution of baseline characteristics (used in the propensity scores) among groups, according to EDT and periodontal treatment status. The distribution of characteristics differed significantly between groups ($P < .05$) for clinical site, race, ethnicity, number of medication classes and age.

Table 2 shows the number and percentage of women who experienced a serious adverse event or an adverse pregnancy outcome, according to the need for and receipt of EDT. We report results from both unadjusted and propensity score–adjusted analyses. The proportion of women who experienced any serious adverse events was higher among those who received EDT (12.1 percent for women who received partial treatment and 10.3 percent for those who received completed treatment) compared with those who did not need this treatment (7.6 percent). These differences, however, were not statistically significant ($P = .25$), and they were even less significant in the propensity score–adjusted analyses ($P = .59$, Table 2). Rates of spontaneous abortions/stillbirths, deliveries before 37 weeks' gestation and fetal/congenital anomalies also were similar in women who received partial or complete EDT. The adjusted odds ratios (ORs) for

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TABLE 2

Essential dental treatment (EDT) and risk of serious adverse events and adverse pregnancy outcomes.

VARIABLE	EDT			*P* VALUE
	Not Needed	Needed But Not Completed	Completed	
Serious Adverse Events*				
No. of subjects	340	132	351	
No. (%) of subjects with event	26 (7.6)	16 (12.1)	36 (10.3)	
Unadjusted OR† (95% CI‡)	Referent	1.67 (0.86 - 3.22)	1.38 (0.81 - 2.34)	.25§
Propensity score–adjusted OR¶ (95% CI)	Referent	1.15 (0.69 - 1.89)		.59#
Spontaneous Abortion/Stillbirth**				
No. of subjects	336	131	345	
No. (%) of subjects with event	8 (2.4)	3 (2.3)	8 (2.3)	
Unadjusted OR (95% CI)	Referent	0.96 (0.25 - 3.68)	0.97 (0.36 - 2.62)	> .99
Propensity score–adjusted OR (95% CI)	Referent	1.11 (0.40 - 2.93)		.67
Delivery Before 37 Weeks' Gestation**				
No. of subjects	336	131	345	
No. (%) of subjects with event	43 (12.8)	15 (11.5)	43 (12.5)	
Unadjusted OR (95% CI)	Referent	0.88 (0.47 - 1.65)	0.97 (0.62 - 1.53)	.94
Propensity score–adjusted OR (95% CI)	Referent	1.12 (0.71 - 1.75)		.64
Fetal or Congenital Anomaly††				
No. of subjects	336	131	347	
No. (%) of subjects with event	9 (2.7)	2 (1.5)	9 (2.6)	
Unadjusted OR (95% CI)	Referent	0.56 (0.12 - 2.64)	0.97 (0.38 - 2.47)	.87
Propensity score–adjusted OR (95% CI)	Referent	1.03 (0.39 - 2.68)		.94

* Included spontaneous abortions, stillbirths, hospitalizations of more than 24 hours because of labor pains, hospitalizations for any other reason, fetal or congenital anomalies and neonatal deaths.
† OR: Odds ratio.
‡ CI: Confidence interval.
§ Fisher exact test.
¶ Propensity score–adjusted OR comparing subjects who received any EDT (partial or complete) with those who did not require EDT.
# For the EDT term in the logistic regression model.
** Excludes women who withdrew consent (n = 2), were unavailable for follow-up (n = 7) or who electively aborted their pregnancy (n = 2).
†† Excludes women who withdrew consent (n = 2) or were unavailable for follow-up (n = 7). Anomalies included fetal cardiac dysrhythmia; hydrocephalus and rocker-bottom foot; congenital hip dysplasia and bilateral club foot; unspecified neuromuscular disorder; bilateral absence of radii and ulnae; DiGeorge syndrome; various cardiac defects including dextrocardia, ventricular septal defect and enlarged right atrium; anencephaly; multiple congenital anomalies; multiple fetal anomalies, cystic hygroma, ventriculomegaly, echogenic bowel, pleural fusions, cardiac anomaly; fetal hypoglycemia and polycythemia; trisomy 21 syndrome; two or three large preauricular tags; complete transposition of great vessels; ventricular and atrioventricular septal defects; patent ductus arteriosus, pyloric stenosis; fetal ventriculomegaly; fetal duodenal atresia and mosaic ring chromosome 13 karyotype; missing right hand and portion of distal right arm; fetal bilateral ventriculomegaly.

all adverse outcomes were close to 1, indicating that EDT was not associated with any significant increase in risk for these events.

Table 3 lists the proportion of women who experienced serious adverse events and adverse pregnancy outcomes, according to periodontal treatment status and anesthetic use. We present unadjusted ORs comparing rates according to anesthetic use and designate periodontally untreated control subjects as the referent group. The distribution of serious adverse events, spontaneous abortions/stillbirths, preterm deliveries and fetal/congenital anomalies did not differ significantly between these groups ($P > .05$). The number of events in some treatment subgroups, however, was small.

Table 4 (page 692) shows the rates of all serious adverse outcomes and adverse pregnancy outcomes, according to receipt of complete EDT and periodontal treatment, either treatment alone or neither

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TABLE 3

Risk of serious adverse events and adverse pregnancy outcomes, according to periodontal treatment status and anesthetic use.

VARIABLE	PERIODONTAL TREATMENT				*P* VALUE*
	None	Yes, Without Anesthetic	Yes, With Topical Anesthetic Only	Yes, With Local Anesthetic	
Serious Adverse Events					
No. of subjects	428	163	89	143	
No. (%) of subjects with event	44 (10.3)	16 (9.8)	5 (5.6)	13 (9.1)	
Unadjusted OR† (95% CI‡)	Referent	0.95 (0.52 - 1.74)	0.52 (0.20 - 1.35)	0.87 (0.46 - 1.67)	.62
Spontaneous Abortion/Stillbirth					
No. of subjects	421	162	88	141	
No. (%) of subjects with event	15 (3.6)	2 (1.2)	1 (1.1)	1 (0.7)	
Unadjusted OR (95% CI)	Referent	0.34 (0.08 - 1.50)	0.31 (0.04 - 2.39)	0.19 (0.03 - 1.48)	.17
Delivery Before 37 Weeks' Gestation					
No. of subjects	421	162	88	141	
No. (%) of subjects with event	53 (12.6)	21 (13.0)	13 (14.8)	14 (9.9)	
Unadjusted OR (95% CI)	Referent	1.03 (0.60 - 1.78)	1.20 (0.62 - 2.32)	0.77 (0.41 - 1.43)	.73
Fetal or Congenital Anomaly					
No. of subjects	422	162	88	142	
No. (%) of subjects with event	8 (1.9)	5 (3.1)	1 (1.1)	6 (4.2)	
Unadjusted OR (95% CI)	Referent	1.65 (0.53 - 5.11)	0.56 (0.07 - 4.82)	2.28 (0.78 - 6.70)	.36

* Fisher exact test.
† OR: Odds ratio.
‡ CI: Confidence interval.

treatment. As in Table 2, we present unadjusted and propensity score–adjusted ORs. Again, the distribution of adverse outcomes did not differ significantly between these groups. None of the individual ORs—comparing events in groups receiving EDT and/or periodontal treatment with events in the group that received neither—was significantly greater than 1.

We also compared event rates between those who required but did not receive complete EDT and those who received complete EDT separately in women who received and who did not receive periodontal treatment. Few spontaneous abortions/stillbirths and fetal/congenital anomalies occurred in some of these subgroups (0 to seven). We found no significant differences between EDT groups for women who received or who did not receive periodontal treatment at a time before 21 weeks' gestation (all *P* values > .3; Fisher exact tests). Similarly, for serious adverse events and deliveries before 37 weeks' gestation, there were no significant differences between EDT groups for women who received or who did not receive periodontal treatment (Table 5, page 693). Moreover, the study results showed no significant differences in rates of any adverse event between women who received complete EDT, who needed but did not receive complete EDT, and who did not require EDT (all *P* values > .2; Fisher exact tests for three-way comparisons).

Of the 20 fetal or congenital anomalies, most were judged by an obstetrician (V.R.L.) to have occurred at the time of conception (for example, chromosomal defects) or early in the first trimester before women were eligible for the trial. Only three anomalies (fetal ventriculomegaly, unspecified neuromuscular disorder and fetal cardiac dysrhythmia) (Table 2) were judged to have possibly occurred after subjects were eligible for study enrollment. The rates of these latter events did not differ significantly ($P > .05$) between groups, according to EDT or periodontal treatment.

DISCUSSION

In this population, periodontal treatment and EDT, administered at 13 to 21 weeks' gestation, did not significantly increase the risk of any

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TABLE 4

Risk of serious adverse events and adverse pregnancy outcomes, according to combinations of essential dental treatment (EDT) and periodontal treatment.

VARIABLE	NO PERIODONTAL TREATMENT, NO OR INCOMPLETE EDT*	PERIODONTAL TREATMENT, NO OR INCOMPLETE EDT	NO PERIODONTAL TREATMENT, COMPLETE EDT	PERIODONTAL TREATMENT, COMPLETE EDT	*P* VALUE
Serious Adverse Events					
No. of subjects	254	218	174	177	
No. (%) of subjects with event	24 (9.4)	18 (8.3)	20 (11.5)	16 (9.0)	
Unadjusted OR† (95% CI‡)	Referent	0.86 (0.45 - 1.63)	1.24 (0.66 - 2.33)	0.95 (0.48 - 1.84)	.75§
Propensity score–adjusted OR¶ (95% CI)	Referent	0.87 (0.45 - 1.65)	1.24 (0.64 - 2.39)	0.91 (0.45 - 1.81)	.75#
Spontaneous Abortion/Stillbirth					
No. of subjects	250	217	171	174	
No. (%) of subjects with event	9 (3.6)	2 (0.9)	6 (3.5)	2 (1.1)	
Unadjusted OR (95% CI)	Referent	0.25 (0.04 - 0.98)	0.97 (0.32 - 2.75)	0.31 (0.05 - 1.23)	.13§
Propensity score–adjusted OR (95% CI)	Referent	0.24 (0.04 - 0.94)	1.18 (0.37 - 3.50)	0.38 (0.06 - 1.55)	.09
Delivery Before 37 Weeks' Gestation					
No. of subjects	250	217	171	174	
No. (%) of subjects with event	30 (12.0)	28 (12.9)	23 (13.5)	20 (11.5)	
Unadjusted OR (95% CI)	Referent	1.09 (0.62 - 1.89)	1.14 (0.63 - 2.03)	0.95 (0.52 - 1.73)	.94§
Propensity score–adjusted OR (95% CI)	Referent	1.08 (0.62 - 1.88)	1.30 (0.70 - 2.37)	1.04 (0.55 - 1.93)	.85
Fetal or Congenital Anomaly					
No. of subjects	250	217	172	175	
No. (%) of subjects with event	5 (2.0)	6 (2.8)	3 (1.7)	6 (3.4)	
Unadjusted OR (95% CI)	Referent	1.39 (0.41 - 4.90)	0.87 (0.18 - 3.59)	1.74 (0.52 - 6.13)	.73§
Propensity score–adjusted OR (95% CI)	Referent	1.47 (0.43 - 5.18)	0.90 (0.18 - 3.85)	1.72 (0.49 - 6.30)	.73

* Includes subjects who did not require EDT and those who required EDT but did not receive complete treatment.
† OR: Odds ratio.
‡ CI: Confidence interval.
§ Fisher exact test.
¶ Propensity score–adjusted odds ratio comparing subjects who received periodontal treatment and/or EDT with subjects who received neither treatment. The first principal component accounted for 87 percent of the variability in estimated periodontal and/or EDT treatment probabilities.
# For the EDT term in the logistic regression model.

adverse outcome evaluated. With regard to preterm birth risk, our findings are consistent with those of Lydon-Rochelle and colleagues,[4] who found that rates of preterm deliveries (< 37 weeks' gestation) were similar in women who reported having received or not having received dental treatment during their pregnancy, regardless of whether the care was problem-directed or preventive.

Clinicians' views. The consensus in the obstetrics community is that few risks are associated with routine dental care during pregnancy.[20] Experts recommend that pregnant women defer elective care before eight weeks' gestation, when major organogenesis occurs, as well as during late pregnancy to avoid supine hypotension and general discomfort.[9,10] Many obstetricians, however, believe that dentists are overly cautious about providing dental care to pregnant women.[20]

In a survey conducted in the early 1990s, most obstetricians responded that they would like to be

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TABLE 5

Risk of serious adverse events and delivery before 37 weeks' gestation, according to combinations of essential dental treatment (EDT) and periodontal treatment.

VARIABLE	RECEIVED PERIODONTAL TREATMENT			DID NOT RECEIVE PERIODONTAL TREATMENT		
	EDT Not Needed	EDT Needed But Not Completed	EDT Completed	EDT Not Needed	EDT Needed But Not Completed	EDT Completed
Serious Adverse Events						
No. of subjects	156	62	177	184	70	174
No. (%) of subjects with event	12 (7.7)	6 (9.7)	16 (9.0)	14 (7.6)	10 (14.3)	20 (11.5)
P value	NA‡	$P > .99$*		NA	$P = .53$	
P value	$P = .84$†			$P = .22$		
Delivery Before 37 Weeks' Gestation						
No. of subjects	155	62	174	181	69	171
No. (%) of subjects with event	20 (12.9)	8 (12.9)	20 (11.5)	23 (12.7)	7 (10.1)	23 (13.5)
P value	NA	$P = .82$		NA	$P = .67$	
P value	$P = .91$			$P = .82$		

* Fisher exact test for two-group comparison.
† Fisher exact test for three-group comparison.
‡ Not applicable.

consulted before a dentist provides "some" routine dental treatment (79 percent), provides treatments that induce a bacteremia (79 percent) or prescribes an antibiotic (88 percent).[20] Ninety-one percent of respondents did not want to be consulted before all routine dental care. The vast majority of respondents did not think that stress related to routine dental care is hazardous to the mother (95 percent) or fetus (97 percent). Among general dentists, substantial proportions did not consult an obstetrician before administering routine (78 percent) or emergency (50 percent) dental care.[21]

Dentists and patients may elect to defer care during pregnancy when, in fact, pregnant women may require more, not less, dental care.[9] Changes in local (tissue) and systemic estrogen levels during pregnancy cause vascular changes and qualitative changes in the subgingival oral microbiota that can lead to increased gingival bleeding and exuberant soft-tissue reactions to local irritants.[22,23] Nausea and vomiting may predispose a pregnant woman to experience periods of dental erosion. Thus, guidelines[12,16] generally advocate continued preventive and routine dental care throughout pregnancy.

Randomized controlled trials. In addition to the OPT trial, four randomized controlled trials of periodontal treatment in pregnant women have been conducted.[13,14,24,25] Jeffcoat and colleagues[14] did not report safety outcomes for 366 women randomized into a trial comparing preterm birth rates among women receiving a prophylaxis or scaling and root planing, with and without systemic metronidazole therapy. Lopez and colleagues[15] randomized 400 women to receive scaling and root planing at a time before 28 weeks' gestation or after delivery. Eight women in the treatment group and six women in the control group experienced spontaneous abortions in this study, suggesting that periodontal intervention did not substantially increase the risk of experiencing a spontaneous abortion.

Sadatmansouri and colleagues[24] conducted a trial that included only 30 pregnant women, and they did not report safety data. Most recently, Offenbacher and colleagues[25] reported two "fetal demises" among 67 randomized women for whom birth outcome data were available. Neither the timing nor the group assignment (scaling and root planing at a time before 22 weeks' gestation or six weeks postpartum) was specified for these events.

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We know of no randomized controlled trials or prospective cohort studies of the relationship between nonperiodontal dental care, such as EDT, and pregnancy outcomes.

We explored associations between dental treatment and adverse pregnancy outcomes in all study subjects, including those without EDT needs (Tables 2 and 4) and in only those with EDT needs (Table 5). Regardless of how we grouped women according to EDT needs and provision of care, EDT was not associated with significantly higher risks of experiencing serious adverse events, spontaneous abortions or stillbirths, deliveries before 37 weeks' gestation, or fetal or congenital anomalies. Notably, our results also were qualitatively identical when we used a propensity score that considered periodontal treatment (Table 4) and when we examined associations separately in groups that received periodontal treatment and in those that did not (Table 5).

Study limitations. Our findings should be viewed in light of the OPT study's limitations. Although large by existing standards, we randomized hundreds, not thousands, of women. We had relatively little statistical power to detect differences between groups for infrequent outcomes such as spontaneous abortions/stillbirths or fetal/congenital anomalies, and the OR estimates comparing these events across groups lacked precision. In addition, we considered all pregnancy losses as a single category, despite evidence that early and later pregnancy losses have different etiologies.[26] For more frequent outcomes, such as serious adverse events and preterm deliveries, our estimates of frequencies and ORs were more precise.

Our findings also should be viewed in light of the type and amount of dental care provided. Although a few women in this study received rather extensive treatment during as many as nine visits, most EDT was less extensive and was completed in fewer visits. In addition, we excluded from the trial women who were judged to have fewer than 20 restorable natural teeth or whose treatment needs were so extensive that it was unlikely such treatment could reasonably be completed before 21 weeks' gestation. We did not record the type of materials used to temporarily or permanently restore teeth and, thus, we could not compare risks of adverse outcomes between groups treated with various restorative materials.

Finally, all participants in our trial had periodontitis at baseline. One could argue that any risks associated with EDT may have been masked by the potentially stronger risk factor of periodontitis. Several lines of evidence, however, suggest otherwise. We recruited from clinics that serve predominantly minority women who are, in general, at higher risk than are non-Hispanic whites of experiencing adverse pregnancy outcomes.[27] The rate of stillbirths in black women in this study (10 [2.8 percent] of 358) was higher than the national rate for this group (1.2 percent).[27] This was expected, however, because one of two sites that enrolled predominantly black women recruited from both high-risk and general obstetrics clinics. Our stillbirth rates in non-Hispanic and Hispanic whites were similar to national averages. Also, the rates of adverse events, according to EDT, were similar for groups that received or did not receive periodontal treatment (Table 3). Thus, it appears unlikely that these participants were at an unusually high risk of experiencing adverse outcomes because of their periodontal status. Nonetheless, similar data from women without periodontitis may be needed to establish the safety of dental treatment in this group.

Additional larger studies are needed to determine whether these findings apply to other populations, to other dental and periodontal treatment schemes, and to treatment delivered at other stages of pregnancy. Additional studies also are needed to determine whether various dental restorative materials affect these and other safety outcomes. Several ongoing randomized controlled intervention trials[28-30] should help to define more precisely the risk of adverse pregnancy outcomes associated with nonsurgical periodontal procedures, including the risk of spontaneous abortion and stillbirth. Eventually, it may be possible to combine safety data from the OPT trial with those from other trials to more precisely estimate risks associated with routine dental procedures. Nevertheless, our study provides evidence that dental care providers can safely meet the preventive and routine treatment needs of their pregnant patients.

CONCLUSION

The results of this study show that EDT administered at 13 to 21 weeks' gestation was not associated with an increased risk of experiencing serious medical adverse events, preterm (< 37 week's gestation) deliveries, spontaneous abortions or stillbirths, or fetal anomalies. Use of topical and local anesthetics for scaling and root planing also was not associated with an increased

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risk of experiencing these adverse events and outcomes. Additional large retrospective and prospective studies, as well as studies of other dental treatments, are needed to confirm the safety of dental care during pregnancy. ■

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Disclosure. The authors did not report any disclosures.

This study was supported by grant DE 014338 from the National Institutes of Health/National Institute of Dental and Craniofacial Research.

The authors thank Dr. James Hodges for help with the statistical analyses and for critically reviewing the manuscript; Ms. Helen Voelker for help with database management; and the entire Obstetrics and Periodontal Therapy clinical study team: University of Minnesota, Minneapolis—P. Tschida, I. Olson, J. Osborn, L. Wolff; Hennepin County Medical Center, Minneapolis—L. Simpson, J. Anderson, K. Meyer, J. Danielson, T. Thompson; University of Kentucky, Lexington—D. Dawson, A. Buell, D. Mischel, P. Stein, L. Cunningham, D. Dawson; University of Mississippi, Jackson—S. Vance, G. Young, A. Garner, N. Wood, K. Holmes, R. Johnson; and Harlem Hospital/Columbia University, New York City—S. Lassiter, J. Mays, J. Jackson, E. Rijo, M. Bolden, C. Spicer.

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