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J Matern Fetal Neonatal Med. Author manuscript; available in PMC 2010 December 8.

Published in final edited form as:
J Matern Fetal Neonatal Med. 2010 December ; 23(12): 1360–1364. doi:10.3109/14767051003702786.

Second trimester cervical length and risk of preterm birth in women with twin gestations treated with 17 alpha hydroxyprogesterone caproate

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Abstract

Objective—To compare rates of preterm birth before 35 weeks based on cervical length measurement at 16-20 weeks in women with twin gestations who received 17 alpha hydroxyprogesterone caproate (17OHPC) or placebo.

Methods—This is a secondary analysis of a randomized, double-blind, placebo-controlled trial of twin gestations exposed to 17OHPC or placebo. Baseline transvaginal ultrasound evaluation of cervical length was performed prior to treatment assignment at 16-20 weeks. Cervical length measurements were categorized according to the 10^{th}, 25^{th}, 50^{th} and 75^{th} percentiles in the women studied. The effect of 17OHPC administration in women with a short (25^{th} percentile) and long (75^{th} percentile) cervix was evaluated.

Results—Of 661 twin gestations studied, 221 (33.4%) women enrolled at 11 centers underwent cervical length measurement. The 10^{th}, 25^{th}, 50^{th}, 75^{th} percentiles for cervical length at 16-20 weeks were 32, 36, 40 and 44 mm, respectively. The risk of preterm birth < 35 weeks was increased in women with a cervical length < 25^{th} percentile (55.8 vs. 36.9%, p=0.02). However, a cervical length >75^{th} percentile at this gestational age interval was not protective for preterm birth (36.5 vs. 42.9%, p=0.42). Administration of 17OHPC did not reduce preterm birth before 35 weeks among those with either a short or a long cervix (64.3 vs. 45.8%, p=0.18 and 38.1 vs. 35.5%, p= 0.85, respectively).

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Presented at the 29^{th} Annual Society for Maternal-Fetal Medicine Meeting, January 31, 2009, San Diego, CA., Abstract #19

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Conclusion—Women with twin gestations and a cervical length below the 25th percentile at 16-20 weeks had higher rates of preterm birth. In this subgroup of women, 17 OHPC did not prevent preterm birth before 35 weeks gestation. A cervical length above the 75th percentile at 16-20 weeks did not significantly reduce the risk of preterm birth in this high risk population.

Introduction

Sonographic measurement of the cervix has been used to identify women with twin gestations at increased risk for preterm birth[1,2]. Goldenberg et al. evaluated 147 twin pregnancies at 24 and 28 weeks gestation showing that a cervical length of ≤ 25 mm at 24 weeks was associated with an increased risk of preterm birth before 32, 35 and 37 weeks gestation[1]. In that study, 17.7% of the women with a twin pregnancy had a short cervix at 24 weeks compared with only 9.1% of women with singletons, suggesting that cervical shortening occurs earlier in multiple gestations. Furthermore, Guzman et al. showed that 50% of twin gestations with a cervical length < 20 mm identified at 15-24 weeks gestation delivered before 32 weeks[3]. Interventions such as cervical cerclage placement for short cervix[4,5] and home uterine activity monitoring[6] have not decreased the rate of preterm birth in twin gestations.

In women with a singleton gestation and a history of prior spontaneous preterm birth, weekly injections of 17 alpha hydroxyprogesterone caproate (17OHPC) have been shown to reduce the risk of recurrent preterm delivery[7]. Although the exact mechanism of how 17 OHPC works in the prevention of recurrent preterm birth is uncertain, there is evidence that its anti-inflammatory properties may blunt inflammation mediated parturition[8,9]. These findings led to studies of progesterone supplementation in other populations at risk for spontaneous preterm birth such as women with a short cervix and those with multiple gestations. Fonseca reported that weekly vaginal progesterone reduced the rate of preterm birth in women with a short cervix < 15 mm (identified at 20-25 weeks gestation) without regard to risk factors[10]. Although this study enrolled 25 women with twin gestations, the number was too small to allow specific assessment of the effect of 17 OHPC on twin gestations.

A recent randomized trial found no reduction in the rate of preterm delivery in women with twin gestations receiving weekly 17 OHPC compared with placebo[11]. The mechanism of preterm birth in multiple gestations may be related to uterine distention suggesting that it would be unaffected by 17OHPC. However, there may be a subset of women with a twin gestation identified to have early second trimester cervical shortening in which there is an inflammation-mediated component to preterm parturition. Therefore, we sought to evaluate the rates of preterm birth before 35 weeks gestation in women with a twin gestation who received 17OHPC compared with placebo based on their cervical length measurement at 16-20 weeks.

Materials and Methods

This study is a secondary analysis of the Maternal Fetal Medicine Units Network (MFMU) STTARS trial, which was a 2 year (April 2004 to February 2006) placebo controlled, double blind, randomized clinical trial conducted at 14 academic medical centers designed to evaluate whether 17 OHPC was effective in the prevention of preterm birth in twin gestations. Each center's institutional review board approved the study protocol. The study protocol has been previously described[11]. Maternal and neonatal outcomes of this population have been reported in a previous publication[11].

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This analysis includes data from women with twin gestations who underwent transvaginal ultrasound evaluation of cervical length at 16 – 20 weeks gestation prior to randomization to treatment assignment. Cervical length measurement was not required by the study protocol, and was performed at the discretion of the obstetrical care providers. If obtained, endovaginal sonography was used to measure cervical length in a standardized fashion as previously reported[1].

Pregnancies in which the viability of any of the fetuses was in question on the last US before randomization, monoamniotic twin gestation, suspected twin to twin transfusion syndrome, ultrasonographic growth discordance greater than 3 weeks, planned non-study progesterone therapy after 16 weeks, in place or planned cerclage, major uterine anomaly, selective fetal reduction, anticoagulation therapy and chronic medical illness such as insulin dependent diabetes mellitus and pharmacologically treated chronic hypertension were not randomized into the STTARS trial.

Cervical length measurements were analyzed to determine the 10^{th}, 25^{th}, 50^{th} and 75^{th} percentiles in the women studied. The number of women with cervical length measurements below the 10^{th} percentile was inadequate to allow statistical analysis. The 25^{th} percentile was therefore chosen as a threshold for a short cervix. Women with a short cervical length defined as below the 25^{th} percentile were compared with women with a cervical length at or above the 25^{th} percentile to determine whether differences existed in rates of preterm birth. In addition, women with a cervical length above the 75^{th} percentile were compared with those whose cervical length measurement was at or below the 75^{th} percentile to determine whether there was a reduction in the rate of preterm birth with a longer cervix. Maternal clinical characteristics and delivery outcomes were recorded. Preterm birth was defined as delivery or fetal death before the 35^{th} completed week of gestation as this was the endpoint in the primary trial. These groups were subsequently analyzed to determine if 17OHPC exposure altered the risk of preterm birth.

Statistical analysis was conducted with SAS software (SAS Institute, Cary, NC). Continuous variables were compared with the Wilcoxon rank sum test. Categorical variables were analyzed by using the Chi square or Fisher's exact test, where appropriate. Stratified analyses were performed to evaluate the possible effect of 17 OHPC exposure on the rate of preterm birth in those women identified to have a short cervix and a long cervix. A nominal p value of <0.05 was considered significant and no adjustments were made for multiple comparisons.

Results

Of the 661 women with twin gestations in the original trial, 221 (33.4%) underwent baseline transvaginal cervical length assessment prior to treatment assignment. These 221 women were enrolled at 11 centers (86% from 5 institutions) and represent 39.3% of the women enrolled at those sites. There was no difference in rates of preterm birth before 35 weeks gestation in women who underwent cervical sonography during the study period compared with those with no cervical assessment (41.4 vs. 38.4%, p=0.46). Clinical and pregnancy characteristics of women who underwent cervical length assessment and those who did not were similar except that women who had a cervical length measurement were older (Table 1). Mean cervical length of the study population at 16-20 weeks gestation was 40.1 ± 7.3 mm (range 16-72). The 10^{th}, 25^{th} and 75^{th} percentiles were 32, 36 and 44 mm. There were 20 women with a cervical length $< 10^{th}$ percentile. Twelve (60%) of women with a cervical length less than the 10^{th} percentile delivered before 35 weeks gestation.

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There were 52 women (24%) with a cervical length below the 25th percentile. One patient in the cervical length ≥ 25th percentile group was lost to follow up. Clinical and pregnancy characteristics of women with a cervix < 25th percentile and greater than or equal to the 25th percentile are shown in Table 2. Women with a short cervix were younger than those with a cervical length above the 25th percentile. Race, gravidity, parity, pregravid body mass index (BMI), history of prior preterm birth, chorionicity and conception by assisted reproductive technology were similar between groups. There was no difference in the gestational age at randomization between women with a short cervix and those with a cervical length at or above the 25th percentile (19.5 ± 1.4 vs. 19.4 ± 1.4 weeks, p=0.54).

The rate of preterm birth before 35 weeks gestation was significantly greater in women with a cervical length below the 25th percentile compared with those with a cervical length at or above the 25th percentile, 55.8% vs. 36.9%, p=0.02. In the subset of women with a short cervix, the rate of preterm birth before 35 weeks was similar in the 17 OHPC and placebo groups (Table 3).

Fifty three women (32.1%) had a cervical length measurement above the 75th percentile. Clinical characteristics of women with a cervix greater 75th percentile and less or equal to the 75th percentile were similar (Table IV). The rate of preterm delivery was not lower in women with a cervical length above the 75th percentile compared with those with a cervical measurement at or below the 75th percentile (36.5 vs. 42.9%, p=0.42). The rate of preterm birth < 35 weeks was similar in those women with a long cervix receiving 17OHPC and placebo as shown in Table V. When excluding the 20 women with a cervical length ≥ 50mm, rates of preterm birth remained similar in both the 17 OHPC and placebo groups (41.5 and 44.7%, respectively).

Discussion

In our analysis, we have shown that treatment with 17OHPC did not reduce the rate of preterm delivery before 35 weeks in women with a short cervix and a twin gestation. In a smaller study, Fonseca found that vaginal progesterone administration was not associated with significant reduction in preterm birth in 24 women with a twin gestation whose cervical length was 15 mm or less[10].

We found higher rates of preterm delivery before 35 weeks in the women with a cervical length below the 25th percentile compared with those with a cervical length above the 25th percentile. This agrees with previous studies evaluating twin gestations showing that a short cervix in the mid trimester of pregnancy is associated with a high risk of preterm birth[2,3].

It is plausible that we were not able to detect a beneficial effect for progesterone therapy in women with twins because of the combination of risk factors present: multiple gestation and a short cervix. A short cervix has been shown to be a stronger predictor of preterm birth than obstetrical history alone in singletons[12-14]. Furthermore, the relationship between a short cervix and preterm birth in multiple gestations is well known[1-3]. Therefore, these two risk factors for preterm birth may be additive and confer such an increased risk for preterm birth that cannot be overcome by administration of 17 OHPC. The route of administration and the formulation of progesterone used in our trial differ from the progesterone used in other studies that have documented a treatment response for premature cervical shortening. Thereby, the ability of differing progestins to alter outcomes for specific indications may vary.

In a previous report by Imseis, a cervical length above 30 mm after 24 weeks was associated with a lower rate of preterm birth[15]. Our study was unable to identify a similar threshold of cervical length in the early second trimester at which the risk of preterm birth was reduced

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in twin gestations. Even those women with a cervical length above the 75th percentile corresponding to 44 mm had a preterm delivery rate of 36%. Therefore, a long cervix at 16-20 weeks may not provide useful clinical information to the obstetrician regarding risk of preterm delivery in twin gestations. Furthermore, a long cervix is likely only reassuring if it is maintained beyond 24 weeks gestation as demonstrated by Imseis[15].

Although only 33.4% of women enrolled in the original trial underwent cervical length assessment prior to treatment assignment, clinical characteristics of these women were similar to those women in whom the cervix was not evaluated. Therefore, we believe that the women included in our analysis were not screened based on risk factors but typically as part of standard clinical practice at the institution where they received prenatal care and are likely representative of the population as a whole.

Our findings, which do not support the initiation of progesterone therapy in women with a twin gestation and a short cervix, are limited by the small number of women included in this secondary analysis, and thus can only be interpreted as hypothesis generating. In order to demonstrate a 50% reduction in the rate of preterm birth with 17OHPC therapy, with type I error 0.05 and power 80%, we would need 74 women in each treatment arm. Furthermore, we defined a short cervix as less than the 25th percentile instead of the more widely accepted 10th percentile, due to the small number of women in the latter group. However, the measurement at the 10th percentile did not represent a substantially shorter cervix with a 4 mm difference between the two percentiles.

Given recent reports showing a reduction in the rate of preterm birth in progesterone treated women with singleton pregnancies and early preterm birth[16] and short cervix[10,17], the observations from this analysis are consistent with the hypothesis that cervical shortening in multiple gestations is related to uterine overdistention and that this distention is not progesterone sensitive.

Appendix

In addition to the authors, other members of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network are as follows:

The Ohio State University — J. Iams, F. Johnson, C. Latimer

Northwestern University — M. Dinsmoor (Evanston Hospital), G. Mallett, P. Simon, M. Huntley, M. Ramos

Drexel University — M. Hoffman, S. Wilson, C. Tocci, M. Lake, M. Talucci

University of Alabama at Birmingham — W. Andrews, J. Sheppard, A. Northen

University of Pittsburgh — E. Daugherty, M. Cotroneo, H. Simhan

University of Utah — K. Anderson, F. Porter (LDS Hospital), A. Guzman (McKay-Dee Hospital Center), K. Jolley (Utah Valley Regional Medical Center), S. Quinn (LDS Hospital)

Columbia University — R. L. Berkowitz, S. South, L. Paley, S. Bousleiman, V. Carmona

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Wake Forest University Health Sciences — P. Meis, M. Swain, K. Johnson, K. Lanier, C. Leftwich

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Acknowledgments

Supported by grants from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (HD27869, HD21410, HD40512, HD34136, HD34208, HD40485, HD27915, HD40544, HD40560, HD27917, HD40500, HD34116, HD40545, HD27860, HD36801).

The authors wish to acknowledge subcommittee members who contributed as follows: Elizabeth Thom PhD (protocol development and statistical analysis), Allison Northen RN and Margaret Cotroneo RN (protocol development and coordination between clinical research centers).

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Table 1

Maternal and pregnancy characteristics of women based on whether cervical length assessment was performed at 16-20 weeks

	Cervical US performed (n=221)	Cervical US not performed (n=440)	P value
Maternal age*	30.6 ± 6.8	29.2 ± 6.9	0.02
African American (%)	51 (23.1)	104 (23.6)	0.87
Primigravida (%)	71 (32.1)	124 (28.2)	0.29
Primipara (%)	106 (48.0)	190 (43.2)	0.24
Prepregnancy BMI (kg/m^2)*	26.6 ± 6.8	27.0 ± 6.8	0.50
Prior preterm birth** (%)	19 (16.5)	31 (12.4)	0.29
Monochorionicity (%)	29 (15.0)	62 (17.3)	0.49
Assisted reproductive technology (%)	57 (25.8)	99 (22.5)	0.35

* Mean ± Standard deviation

** Evaluated on a subset of multiparous women

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Table 2

Maternal and pregnancy characteristics of women based on cervical length

	Cervix < 25th percentile (n=52)	Cervix ≥ 25th percentile (n=169)	P value
Maternal age*	29.0 ± 6.5	31.0 ± 6.8	0.046
African American (%)	16 (30.8)	35 (20.7)	0.13
Primigravida (%)	19 (36.5)	52 (30.8)	0.44
Primipara (%)	25 (48.1)	81 (47.9)	0.99
Prepregnancy BMI (kg/m^2)*	27.5 ± 7.6	26.4 ± 6.5	0.59
Prior preterm birth** (%)	5 (18.5)	14 (15.9)	0.77
Monochorionicity (%)	8 (18.2)	21 (14.1)	0.48
Assisted reproductive technology (%)	10 (19.2)	47 (27.8)	0.22

* Mean ± Standard deviation

** Evaluated on a subset of multiparous women

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Table 3

Rate of preterm delivery before 35 weeks for women based on cervical length measurement

	17 OHPC	Placebo	P-value
Cervix < 25th percentile	18/28 (64.3%)	11/24 (45.8%)	0.18
Cervix ≥ 25th percentile	25/73 (34.4%)	37/95 (39.0%)*	0.53
P-value	0.006	0.54	

* one patient lost to follow up

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Table 4

Maternal and pregnancy characteristics of women based on cervical length

	Cervix > 75th percentile (n=53)	Cervix ≤ 75th percentile (n=168)	P value
Maternal age*	31.0 ± 6.9	30.4 ± 6.8	0.52
African American (%)	9 (17.0)	42 (25.0)	0.23
Primigravida (%)	39 (73.6)	111 (66.1)	0.31
Primipara (%)	32 (60.4)	83 (49.4)	0.16
Prepregnancy BMI (kg/m^2)*	26.4 ± 7.1	26.7 ± 6.7	0.61
Prior preterm birth** (%)	30 (93.8)	66 (79.5)	0.09
Monochorionicity (%)	10 (22.2)	19 (12.8)	0.15
Assisted reproductive technology (%)	40 (75.5)	124 (73.8)	0.81

* Mean ± Standard deviation

** Evaluated on a subset of multiparous women

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Table 5

Rate of preterm delivery before 35 weeks for women based on cervical length measurement

	17 OHPC	Placebo	P-value
Cervix > 75th percentile	8/21(38.1%)	11/31 (35.5%)	0.85
Cervix ≤ 75th percentile	35/80 (43.8%)	37/88 (42.1%)*	0.82
P-value	0.64	0.52	

* one patient lost to follow up