

Prior Spontaneous Preterm Birth



General Notes

- Previous pregnancy/delivery records should be obtained and reviewed whenever possible.
- The decision regarding the <u>upper gestational age limit</u> to stop screening for cervical shortening (23^{0/7} vs. 24^{0/7}) as well as the upper gestational age limit beyond which a cerclage should not be offered requires individualization based on previous pregnancy history (number of prior preterm births and gestational age at prior preterm deliveries), as well as the gestational age at which the patient would desire neonatal resuscitation.
 - Though the initial Owen RCT used 23 weeks 0 days as the upper gestational age cutoff for CL screening, the other 4 trials included in the Berghella patient level data meta-analysis (reference #4) evaluating the effectiveness of cerclage for short cervix in the setting of a prior PTB used at least 24 weeks 0 days as the upper gestational age cutoff for cervical length screening
- <u>Abruption:</u> Many women report a history of 'abruption' but this term may be used inconsistently to describe a wide variety of conditions including cervical change associated with preterm labor (which may be clinically difficult to distinguish from placental abruption in some circumstances).
 - Women with a history of delivering preterm following vaginal bleeding in the presence of PPROM, uterine contractions and/or cervical dilation (termed abruption by some practitioners) are candidates for 17P.
 - Women with a history of clinical abruption in the setting of medical conditions (e.g., marked hypertension, drug abuse such as cocaine or amphetamine), without a prior history of spontaneous PTB, are generally not considered candidates for 17P.
 - In cases of ambiguity regarding prior pregnancy history, one reasonable approach might be to not administer 17P, but evaluate the cervical length by transvaginal ultrasound at the time of the fetal anatomic survey



References:

(1) Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 alphahydroxyprogesterone caproate. N Engl J Med 2003;348:2379-85.

- In 463 women randomized to 17-alpha hydroxyprogesterone caproate (17P) starting at 16-20 weeks and continued through 36 weeks' gestation, treatment with 17P significantly reduced the risk of delivery <37 weeks' gestation (36.3% vs. 54.9%, RR 0.66 95% CI 0.54-0.81), delivery <35 weeks' gestation (20.6% vs. 30.7%, RR 0.67 95% CI 0.48-0.93), and delivery <32 weeks' gestation (11.4% vs. 19.6%, RR 0.58 95% CI 0.37-0.91).
- Infants of women treated with 17P had significantly lower rates of necrotizing enterocolitis, intraventricular hemorrhage, and need for supplemental oxygen.

(2) Owen J, Hankins G, Iams JD, et al. Multicenter randomized trial of cerclage for preterm birth prevention in high-risk women with shortened midtrimester cervical length. Am J Obstet Gynecol 2009;201:375 e1-8.

- In 301 women with a prior SPTB <34 weeks and cervical length <25mm, McDonald cerclage placement reduced previable birth (6.1 vs. 14%), perinatal mortality (8.8% vs. 16%, p=0.046), and preterm birth <37 weeks (45% vs. 60%, p=0.01).
- The primary outcome of PTB <35 weeks was observed in 32% of women in the cerclage group vs. 42% in the non-cerclage group (OR 0.67, 95% CI 0.42-1.07, p=0.09). In Kaplan-Meier survival analysis, women with cerclage tended to deliver later across all gestational ages, though this did not reach statistical significance (p=0.053).
- The most significant benefit from cerclage was noted in the subgroup of women (n=64) with a cervical length <15mm who were treated with cerclage (OR for delivery <35 weeks 0.23, 95% CI 0.08-0.66).
- Women were screened with transvaginal ultrasound beginning at 16-20 weeks, with a repeat ultrasound in 2 weeks if the initial CL was ≥30mm; and in 1 week if the initial CL was 25-29mm

(3) Szychowski JM, Owen J, Hankins G, Iams J, Sheffield J, Perez-Delboy A, Berghella V, Wing DA, Guzman ER; Vaginal Ultrasound Cerclage Trial Consortium. Timing of mid-trimester cervical length shortening in high-risk women. Ultrasound Obstet Gynecol. 2009 Jan;33(1):70-5. doi: 10.1002/uog.6283.

- In an analysis of the pre-randomization data from the Owen trial (reference #2 above), 1014 women with a prior PTB <34 weeks' gestation were evaluated with serial cervical length screening.
- 31% developed cervical shortening <25mm by their final scheduled visit
- women underwent a median of 2 scans before being diagnosed with cervical shortening or censoring occurred
- Women with a prior SPTB <24 weeks were at highest risk of developing eventual cervical shortening. However, there was no CL cutoff above which it could be guaranteed that shortening would not be seen at the next CL assessment. In other words, even if the initial

CL was long (>35mm, >40mm), a proportion of these women were still found to have CL shortening on subsequent US.

• These data support serial CL screening until 23-24 weeks' gestation in these highest risk women, regardless of the initial CL measurement.

(4) Berghella V, Rafael TJ, Szychowski JM, Rust OA, Owen J. Cerclage for short cervix on ultrasonography in women with singleton gestations and previous preterm birth: a meta-analysis. Obstet Gynecol 2011;117:663-71.

- Patient-level meta-analysis included 5 trials (504 women) of women with a short cervix
 <25mm and a prior preterm birth between 16-37 weeks. Significant reductions in PTB <35 weeks (by 30%) and in perinatal morbidity and mortality (by 36%) were seen with cerclage.
- The earlier the short cervical length was detected, the greater the benefit from cerclage may be
- It is estimated that >6500 babies per year in the US alone would be saved from perinatal death and 23,100 preterm births would be prevented yearly by this management.

(5) Practice bulletin no. 130: prediction and prevention of preterm birth. Obstet Gynecol 2012;120:964-73

• ACOG currently recommends management of women in a manner similar to this algorithm based on this currently available evidence, including 17-OHPC supplementation for women with a prior singleton spontaneous PTB, serial cervical length screening, and consideration of cervical cerclage placement if cervical shortening <2.50cm occurs.

(6) Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. Am J Obstet Gynecol 2012;206:376-86.

• SMFM currently recommends management of women in a manner similar to this algorithm based on this currently available evidence, including 17-OHPC supplementation for women with a prior singleton spontaneous PTB, serial cervical length screening, and consideration of cervical cerclage placement if cervical shortening <2.50cm occurs.

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These algorithms are designed to assist the primary care provider in the clinical management of a variety of problems that occur during pregnancy. They should not be interpreted as a standard of care, but instead represent guidelines for management. Variation in practices should take into account such factors as characteristics of the individual patient, health resources, and regional experience with diagnostic and therapeutic modalities.

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