

A department of Maine Medical Center

Spontaneous Preterm Birth Prevention

Approximately 11% of U.S. births occur preterm (< 37 weeks' gestation), 75% of which are spontaneous. Preterm births contribute disproportionately to childhood morbidity and mortality and societal health care costs. Several strategies may reduce spontaneous preterm birth. In each scenario, the clinician should ensure a viable intrauterine pregnancy and no evidence of lethal fetal anomaly.

1. Sonographic cervical length measurement

Eligibility

- a. Women with prior spontaneous preterm birth (SPTB)
- b. Women between 18 and 24 weeks without prior spontaneous birth, if performed as part of a universal cervical length screening program. (This approach is an option, not a requirement)
- c. Suspected short cervix during transabdominal ultrasound examination.

Protocol

- Cervical length measurement and reporting according to CLEAR guidelines
- If prior spontaneous preterm birth
 - a. every 2 week measurements from 16-24 weeks
 - b. weekly measurements up to 24 weeks if shortening to 26-29mm
 - c. if singleton gestation and prior SPTB < 34 weeks, offer cerclage for cervical length ≤ 25mm before 24 weeks, after ruling out preterm labor
 - d. if twin gestation and cervical length ≤ 25mm after ruling out preterm labor, consider physical examination of cervix and if dilated < 4cm before 24 weeks, may consider cerclage
- If no prior spontaneous preterm birth
 - a. single measurement at either time of suspected short cervix or between 18 and 24 weeks' gestation
 - b. if cervical length ≤ 20mm
 - offer vaginal progesterone (see below), after ruling out preterm labor
 - consider physical examination of cervix and if dilated < 4cm before 24 weeks, may consider cerclage*

2. 17 hydroxyprogesterone caproate (17P)

Eligibility criteria:

- Documented previous spontaneous preterm delivery (singleton or twins)
- Viable singleton pregnancy
- ≥ 16 weeks' gestation

Exclusions:

- Heparin therapy
- Hormone sensitive cancer
- Lethal fetal anomaly
- Liver disease
- Multiple gestations
- Thrombocytopenia < 100,000
- Seizure disorder (relative contraindication)
- Uncontrolled hypertension on meds (relative contraindication)
- Allergy to 17P or diluent, peanuts, soy, jam, palm, sesame

Management protocol:

1 ml containing 250 mg 17 alpha-Hydroxyprogesterone Caproate intramuscularly weekly starting no earlier than 16 weeks and continuing through 36 weeks' gestation.

Once treatment begins, the patient will be seen in the office on a weekly basis for her 17P injection and evaluation of signs of PTL. After one month the patient has the option of giving herself weekly injections at home and schedule her OB office visits as needed.

 If cerclage is placed for cervical shortening, continue 17P or consider switching to daily vaginal progesterone (see below)

Adverse effects:

Redness, pain, bruising or lump at the injection site

Supply:

Apothecary by Design (for compounding) Tel: 207-774-5220 Compounding Pharmacy: 207-899-0886

Makena – commercial form

3. Vaginal progesterone

Eligibility

- Progesterone administered vaginally on a daily basis may reduce the risk of SPTB in the following circumstances
 - a. women with a prior spontaneous preterm birth
 - b. women with no prior SPTB and a sonographic cervical length ≤ 20mm

Exclusions

- Allergy to progesterone formulation or soy, peanuts, yams, sesame, or palm
- Hormone-dependent cancer

Management

- Daily progesterone administration vaginally
 - a. from 16-36 weeks or delivery <36 weeks in women with a prior SPTB

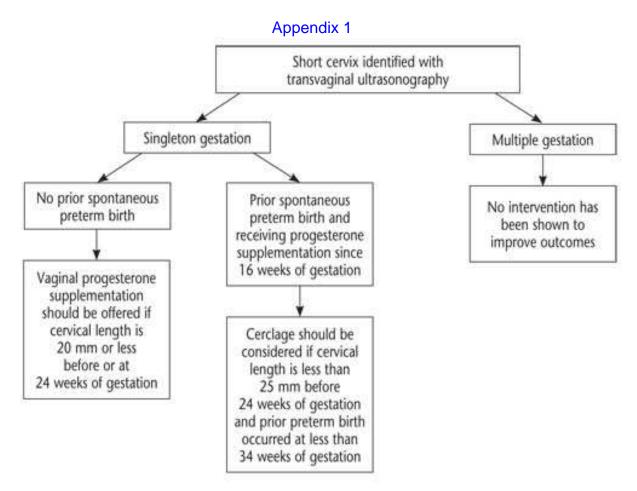
- b. from diagnosis of a cervical length ≤ 20mm between 16 and 24 weeks until 36 weeks or delivery < 36 weeks
- Dosing and formulations evaluated include
 - a. progesterone gel 90mg
 - b. progesterone capsules 200mg

4. Cervical cerclage

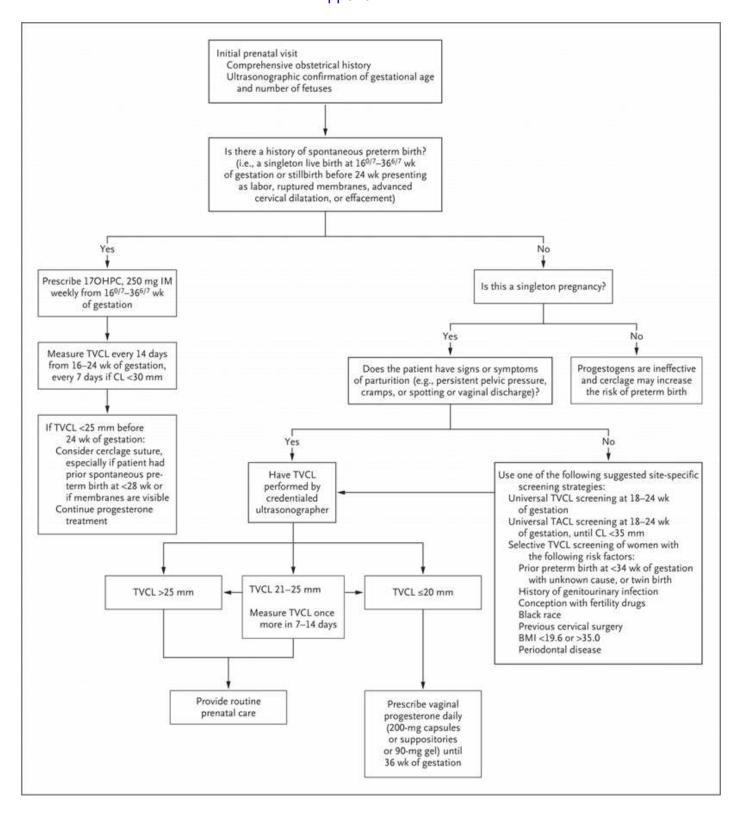
Eligibility

- a. ≥ 3 prior unexplained SPTBs OR
- b. prior delivery consistent with cervical insufficiency OR
- c. prior SPTB and cervical shortening ≤ 25mm between 16-24 weeks without regular uterine contractions in current singleton pregnancy OR
- d. no history of SPTB* short cervix (≤ 20mm) at 16-24 weeks, dilated < 4cm, no regular uterine contractions

*Cerclage efficacy in this situation may be improved with cefazolin 1gm IV immediately pre-operatively followed by doses at 8 and 16 hours postoperatively (dose = 2gm each occasion for patient weight ≥ 100kg) and oral indomethacin 50mg immediately postoperatively, followed by 50mg doses at 8 and 16 hours postoperatively.



Appendix 2



References:

Miller ES, Grobman WA, Fonseca L, Robinson BK. Indomethacin and antibiotics in examination-indicated cerclage. Obstet Gynecol 2014;123:1311-6.

Rafael TJ, Berghella V, Alfirevic Z. Cervical stitch (cerclage) for preventing preterm birth in multiple pregnancy. Cochran Review 2014; Issue 9, Art No. DOI 10:1002/14651858:CD009166.pub2

Romero R, Nicolaides K, Conde-Agudelo A, et al. Vaginal progesterone in women with asymptomatic sonographic short cervix in the midtrimester decreases preterm delivery and neonatal morbidity: a systematic review and metaanalysis of individual patient data. Am J Obstet Gynecol 2013;208:42e1-42e18.

Meis PJ, Klibanoff M, Thorn E, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. N Engl J Med 2003;348:2379-85.

Berghella V, Odebo A, To MS, et al. Cerclage for short-cervix on ultrasonography. Obstet Gynecol 2005;106:181-9.

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.

American College of Obstetricians and Gynecologists. Prediction and prevention of preterm birth. Obstet Gynecol 2012;120:964-70.

lams JD. Prevention of preterm parturition. N Engl J Med 2014;370:254-61.

Final report of the Medical Research Counsel/Royal College of Obstetricians and Gynaecologists multicentre randomized trial of cervical cerclage. MRC/RCOG Working party on cervical cerclage. Br J Obstet G ynaecol 1993;100:516-23.

Foster TL, Moore ES, Sumners JE. Operative complications and fetal morbidity encountered in 300 prophylactic transabdominal cervical cerclage procedures by one obstetric surgeon. J Obstet Gynaecol 2011;31:713-7.

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