Kofinas Perinatal

Providing Care to the Unborn ®

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Cervical insufficiency-preterm labor continuum

Prematurity is responsible for 75-80% of all neonatal morbidity and mortality in the developed countries. ***{Lancet 2002; 360: 1489-97, Obstet Gynecol Survey 2002;57:S9-S34}*** In 1980, 7% of all deliveries were premature (<37 completed weeks). Despite enormous efforts by the obstetrical community to prevent it, in 2005 13% of all deliveries in the United States of America were premature. Advances in perinatal and neonatal care have reduced the mortality due to preterm birth, but morbidity remains a serious problem. Infants born early are at high risk for developmental problems, birth defects, cerebral palsy, mental retardation, visual impairment, hearing loss, and other, sometimes less obvious, central nervous system disorders, including language and learning disabilities, attention-deficit hyperactivity disorder, and behavioural problems. The cost to society of these complications was more than US$26.2 billion in 2005, or $51,600 for each infant born early. ***{The Lancet 2006;368:339}*** These costs refer only to the immediate costs until the baby goes home. The life long costs of special care and special medical expenditures for such neonates are inestimable.

Over the years, the diagnosis of cervical insufficiency and preterm labor were mutually exclusive. This has been detrimental to the outcomes of patients with histories of recurrent pregnancy loss and preterm birth.

The condition of incompetent cervix was first described in 1658 in the book Practice of Physik, published by Cole and Culpepper. The following is a quote from the book: "The second fault in women which hindered conception is when the seed is not retained or the orifice of the womb is so slack that it cannot rightly contract itself to keep in the seed; which is chiefly caused by abortion, or hard labor and child birth, whereby

the fibers of the womb are broken in pieces one from another in the orifice of the womb, overmuch slackened."

The incidence of incompetent cervix has been highly variable and it has been described in various reports in the literature as ranging from 1%-8%. However, it is most likely that the true incidence of incompetent cervix is approximately 1%-2%. It happens more frequently in multiparous and multigravid women. In a recent study done at the Brooklyn Hospital Center (unpublished data) women attending assisted reproductive technology clinics (infertility clinics) have a significantly higher incidence of incompetent cervix. In a group of women studied at our institution the incidence of incompetent cervix was 30%.

The etiology of cervical incompetence is highly variable also. The most common etiological factors are given below:

⇒ **Congenital (primary)**
- ☞ Spontaneous (genetic variability)
- ☞ Induced (DES)

⇒ **Traumatic (secondary)**
- ☞ Conization
- ☞ Laceration
- ☞ Forceful mechanical dilatation

⇒ **Dysfunctional**
- ☞ Uterine irritability with a weak cervix

⇒ **Cervicitis / Stromal destruction**

⇒ **Hormonal**
- ☞ Relaxin

⇒ **Multiple Gestation (infertility)**

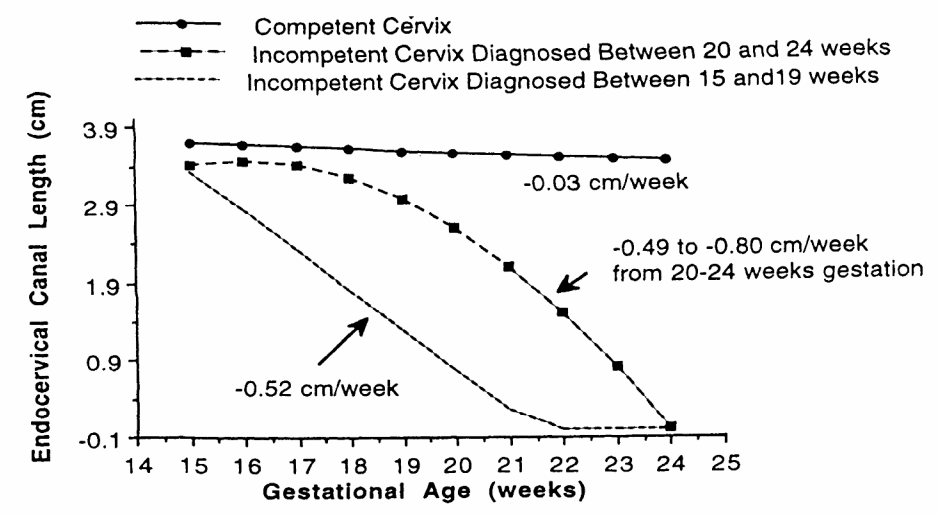
The diagnosis of incompetent cervix is most of the time based on historical factors. History of one or more second trimester painless pregnancy losses is a significant

diagnostic factor to establish a diagnosis of incompetent cervix. Progressive cervical shortening without uterine contractions is also strong evidence of incompetent cervix, especially when the shortening of the cervix is documented by transvaginal sonography. In the non-pregnant state the diagnosis of incompetent cervix may be established with the help of hysterosalpingography. The diagnosis is made when the cervical internal os is dilated on the hysterosalpingography. Effortless and painless introduction of a cervical dilator of type Hegar #8 or type Pratt #15 into the non-pregnant cervix can strongly indicate incompetent cervix. Finally, some investigators have utilized a Foley catheter with a 1ml balloon inserted beyond the internal os. The balloon is inflated to 1ml and traction is applied onto the Foley catheter. According to the degree of traction that is required to pull the Foley out of the cervix the diagnosis of competent or incompetent cervix can be made. It should be noted here however, that setting the diagnosis for incompetent cervix in the non-pregnant state is unreliable and in today's environment, with abundant usage of transvaginal sonography attempting to diagnose incompetent cervix prior to pregnancy should be avoided.

Ultrasonography may be the best means today for the diagnosis of incompetent cervix. Cervical shortening at < 20-25mm without evidence of contractions is suggestive of incompetence cervix. Spontaneous cervical funneling is strongly indicative of incompetent cervix and the same is true for cervical funneling provoked by fundal pressure. Attention should be paid in patients with short cervix secondary to pre-term labor. Usually these patients have evidence of contractions and the cervix locks the presence of funneling. Instead the shortening takes place with the cervical appearance remaining intact and the internal os remaining closed. Many of these patients have the appearance of bulging of the lower segment, either posteriorly or anteriorly below the level of the internal os. This finding is usually strong evidence of pre-term labor, whether the patient has an incompetent cervix or not.

The cervical length of patients destined to deliver at term is pretty stable with a very small degree of progressive shortening at a rate of 0.3cm per week up to 25 weeks. In contrast when the cervical length starts declining at 15 weeks at a rate of 0.5cm per

week, then the patient is destined to deliver prematurely prior to 24 weeks. When cervical shortening starts after 18-19 weeks of pregnancy and the rate of shortening is between 0.49 and 0.8cm per week, patients are also destined to deliver prematurely. (Guzman, obstetrics and gynecology 1998; 92:31-7)



It is of paramount importance to consider cervical incompetence not in a vacuum, but as part of the continuum of cervical incompetence, which ranges on one extreme from complete incompetence of the cervix, which is unable to keep the conceptus even in the absence of contractions to the other extreme where the cervix is competent, but pre-term labor causes pregnancy loss, despite the fact that the cervix is anatomically and physiologically intact.

Very few patients will be on either one of the two extremes and most of the patients will be in a gray zone area where there will be more or less some degree of incompetence and some degree of pre-term labor. Therefore, for successful management of these patients the usage of tocolysis should be considered whenever the suspicion of pre-term labor is made along with incompetent cervix, or whenever certainty does not exist about the presence of labor, it is a good assumption to consider the labor as present and utilize prophylactic tocolysis along with the surgical approach for the treatment of cervical incompetence.

Although the necessity of surgical treatment for incompetent cervix has not been assessed in well-controlled clinical trials, most of the clinical studies have indicated a significant benefit from treating patients with incompetent cervix.

Appendix A presents the calculated risks for deliveries prior to 35 weeks based on cervical length done at or prior to 24 weeks of pregnancy.

Appendix B presents an algorithm for the management of cervical incompetence. I would like to bring to your attention here the fact that tocolysis should be used whenever there is evidence of pre-term labor or a strong suspicion of pre-term labor. This is

because sometimes at <22 weeks it may be difficult to document uterine contractions with external tocodynamometer, although one may see them by ultrasound or the patient may feel them as intermittent pressure. The other issue that I would like to bring to your attention is the use of antibiotics. At our center we use triple therapy for a short course of approximately 3 days, on all patients with cervical dilatation where we expect that the membranes have been exposed to the vaginal environment. For as long as the external os is closed and there is no evidence of endocervical infection during the time of the cerclage (infection usually manifest itself with puss coming out of the cervix during the cerclage procedure) we do not use antibiotics.

The figure in Appendix C presents the various types of surgical treatments most commonly employed today.

The most widely used procedure is the McDonald procedure. This is a simple procedure of cervical cerclage. We use a permanent suture (Mersilene size #2). Ethicon makes one, which is attached to two cutting edge needles on both ends. The needles should be removed and the suture should be threaded through a Mayo ½ tapered size 2 needle. This suture can be removed at 37 weeks of gestation in non-diabetic patients and after lung maturity has been documented in diabetics. With appropriate skills, this suture can be placed as high as the internal.

There will be very few if any instances where one may have to use any of the other techniques. The trans-abdominal technique may be reserved for patients with absolutely no history of preterm labor and complete lack of cervical length (cervix flush with vaginal wall). Once a successful trans-abdominal cerclage is placed, the patient should be delivered by cesarean section. The same is true for the Shirodkar type of cerclage.

For more information on the management of patients with short cervix and / or preterm labor at Kofinas Perinatal, click on the link(s) below:

http://www.kofinasperinatal.org/files/Preterm_Labor_Protocol_v.1.03.pdf

http://www.kofinasperinatal.org/files/Cerclage_for_cervical_incompetence_Protocol_ver_1.005.pdf

APPENDIX A

THE LENGTH OF THE CERVIX AND THE RISK OF SPONTANEOUS PREMATURE DELIVERY

In 2915 pregnant women examined by transvaginal sonography, the average cervical length was found to be 35.2 ± 8.3 mm (10th % =22 mm and the 90th%=48 mm) and 33.7 ± 8.5 mm at 24 and 28 weeks respectively. The cervical length was normally distributed in both gestational ages. The overall rate of preterm delivery prior to 35 weeks gestation in the group was 4.3 %. With this as a reference point relative risks and absolute percent risks are given in the following table for patients examined at 24 weeks:*

Cervical length (mm)	RR for delivery <35 wks	% risk for delivery <35 wks
<40	1.98	8 %
<35	2.35	10 %
<30	3.79	16 %
<26	6.19	26 %
<22	9.49	40 %
<13	19.99	86 %

In patients examined at 28 weeks and beyond, the relative risk is 2.80, 3.52, 5.39, 9.57, 13.88, and 24.94 respectively.

From the Division of Maternal - Fetal Medicine, Department of OB/GYN, The Brooklyn Hospital Center

*Patients examined earlier are most likely at even higher risk than those examined at 24 weeks.

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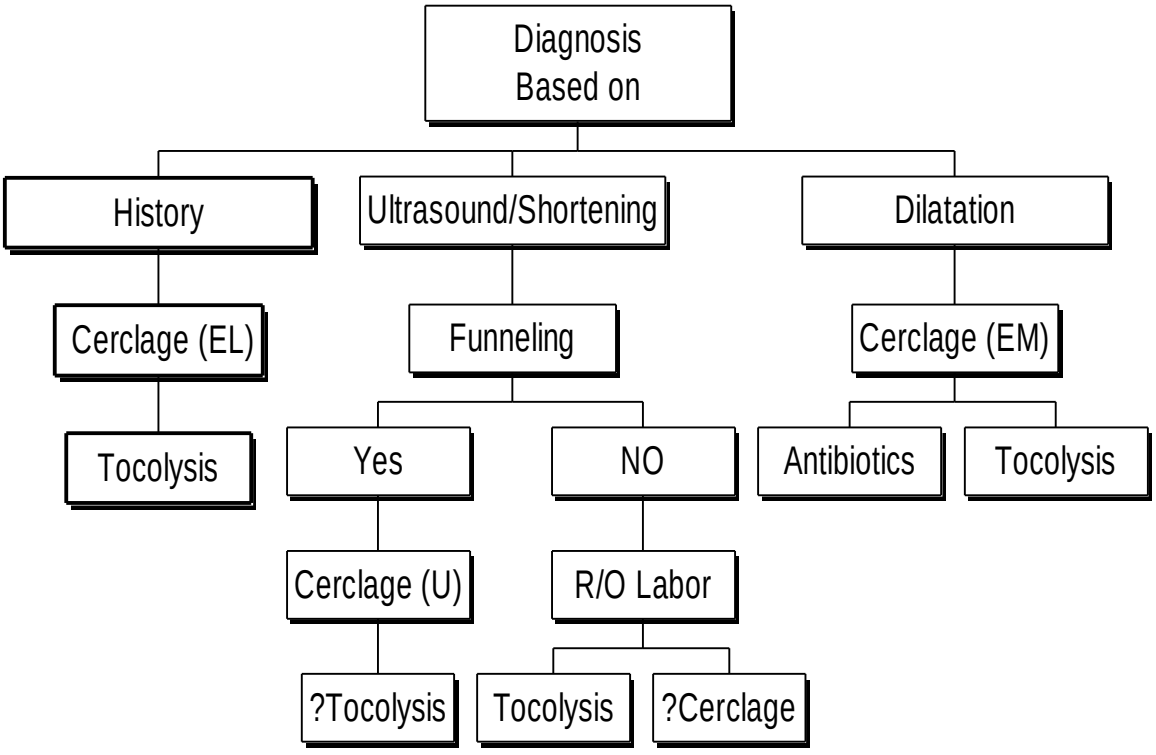
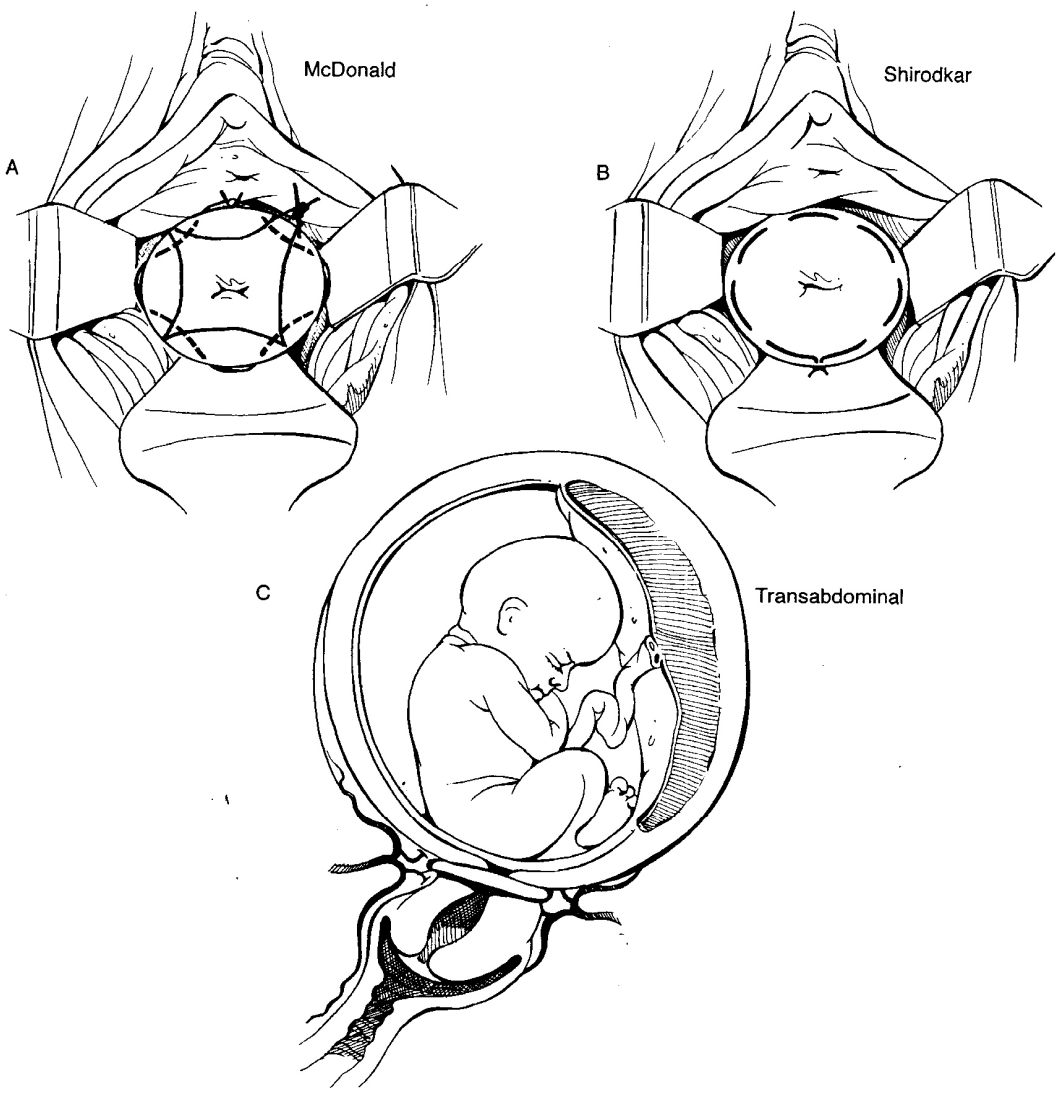
APPENDIX B

Management of Cervical Incompetence



APPENDIX C



A: McDonald type of cerclage

B: Shirodkar type of cerclage

C: Transabdominal type of cerclage (requires major abdominal surgery)