ACR Appropriateness Criteria[®]

<u>Clinical Condition:</u>

Variant 1:

Assessment of Gravid Cervix

Patient: 16–24 weeks' gestation; at risk for preterm delivery, cervix <3 cm long; suggestion of funneling by transabdominal ultrasound examination; or postcerclage.

Radiologic Procedure	Rating	Comments	RRL*
US cervix transvaginal	9	Assess for change in cervical length several times over a 3–5 minute period. Record shortest closed cervical length. May add description of U-shaped or V- shaped funnel.	0
US cervix transperineal	7	This procedure is reserved for women in whom TVU is uncomfortable or unacceptably invasive. Record shortest closed cervical length. May add description of U-shaped or V-shaped funnel.	0
US cervical stress test	7	This is a complementary study that may be performed in high-risk women with a normal TVU study. This procedure should not be performed in the setting of a dynamic cervix or short cervical length. It should be performed only in settings with provisions for labor and delivery. Record shortest closed cervical length. May add description of U-shaped or V-shaped funnel.	0
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			

ASSESSMENT OF GRAVID CERVIX

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Summary of Literature Review

Introduction

Because preterm birth (PTB) is the major contributor to perinatal mortality and morbidity in the United States, the identification of women at risk for preterm delivery (<37 weeks' gestational age) is an important clinical priority. In the United States the overall frequency of PTB is 12.5%, of which two-thirds are spontaneous preterm birth (sPTB) and one-third are for obstetrical indications [1]. Although the e PTB <32 weeks represents only 1%–2% of all deliveries, it accounts for 60% of perinatal mortality and almost 50% of long-term neurological morbidity [2].

Transvaginal ultrasound (TVU) is the study of choice for assessment of the gravid cervix. It is safe, well accepted by women, reproducible and widely available. Approximately 75% of women with asymptomatic cervical shortening will have a negative digital study, thus reinforcing the role of TVU in cervical assessment. Cervical functional or closed length (CL) is the single most reproducible and reliable parameter and furthermore is the single best predictor of PTB, with an inverse relationship between CL and the likelihood of PTB. Cervical length measurements before 14 weeks' gestation are limited and difficult to measure in a low-risk population because the cervix is not yet distinct from the lower uterine segment. Risk factors for short CL include congenital factors (collagen disease, Müllerian duct anomalies, diethylstilbestrol exposure, and biological variation), trauma during obstetrical delivery, gynecological manipulations (dilatation and curettage, dilation and extraction, hysteroscopy), or surgical treatment of cervical intraepithelial neoplasia. Shortening or effacement of the cervix begins at the internal cervical os and proceeds caudally. CL is not significantly modified by parity, race, or maternal body mass index [3-6].

A CL >25 mm is considered normal between 14–24 weeks' gestation. A normal CL has a high negative predictive value in high-risk women for PTB, which supports expectant management. Between 14 and 28 weeks the CL remains stable with a bell-shaped curve with the 50th percentile at 35 mm, 10th percentile at 25 mm, the fifth percentile at 20 mm, and the second percentile at 15 mm [5,6]. The median cervical length is 40 mm prior to 22 weeks, 35 mm at 22 to 32 weeks, and 30 mm after 32 weeks [4,6]. A CL below the 10th percentile is consistently associated with PTB; however, there is no single threshold value for subsequent development of PTB. A sonographic short cervix diagnosed by TVU is the most powerful predictor of PTB. Fifty percent of women with a CL <15 mm will deliver prior to 32 weeks [7]. The earlier in gestation that a short CL is demonstrated, and the shorter the CL, the greater the risk of PTB [6,8,9]. A short CL at 16 to 28 weeks has a strong association with PTB, and even more so if it occurs in a women with a prior PTB or a woman who is earlier than 24 weeks [3-6,10].

Currently, one of the more controversial questions related to PTB is whether low-risk women with a singleton pregnancy should undergo a TVU CL screen at 22 weeks' gestation. Although there is insufficient evidence to recommend routine screening of asymptomatic pregnant women with TVU cervical length [11], 2 randomized controlled trials have shown a 35%-45% reduction in PTB in women with cervical shortening <15-20 mm, who were treated with vaginal progesterone preparations [12,13]. A recent meta-analysis of 5 trials of women treated with progesterone for asymptomatic midtrimester cervical shortening demonstrated a reduction of PTB up to 45% [12-16] in women with a CL measurement ≤ 25 mm with no history of PTB. This suggests that a screening TVU CL in the second trimester (19–24 weeks) could be used to identify a group of women with a singleton pregnancy who would benefit from prophylactic progesterone to prevent sPTB. In a 2012 practice bulletin, the American

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College of Obstetricians and Gynecologists did not mandate universal CL screening in women without a prior history of PTB but also did not recommend against using such a screening strategy [17]. Similarly, the Society for Maternal Fetal Medicine published recommendations that state that there is insufficient evidence to support a universal screening of CL; however it is a reasonable practice for the individual physician to choose.

The role of cervical cerclage is less well-defined. A meta-analysis performed by Berghella et al [18] included the recommendation that cerclage should be offered only to women with a history of PTB and CL \leq 25 mm. Insertion of a cervical pessary has also demonstrated a variable decrease in the incidence of PTB [19]. Ongoing research is needed to determine which of these options will be the most effective to decrease sPTB in pregnant women. In women with multiple gestations there is an increased risk of PTB but no evidence to support a specific intervention. Nonetheless, identification of a short cervix in this population may help guide interventions such as antenatal corticosteroid to promote lung maturation.

Imaging Modalities Overview

TVU is the gold standard for objective cervical assessment. TVU is considered safe in women who have documented premature rupture of membranes [20]. It has limited ability to assess cervical softness or distensibility. It is recommended to observe the cervix for a minimum of 3 minutes to detect spontaneously occurring cervical shortening (also termed a dynamic cervix) and record the best shortest CL of the cervix [21,22]. Shortest "best" closed CL is defined as "the technically most optimal of at least three separate measurements of the cervical length from the internal to the external os along the endocervical canal obtained in millimeters [23]." Although funneling into the cervical canal is associated with a short cervix, it is not an independent predictor of PTB [3,6]. If the patient cannot tolerate TVU, transperineal ultrasound (TPU) may be used. Transabdominal ultrasound is not considered reliable for cervical assessment. Initial studies on measuring CL by 3-D ultrasound or magnetic resonance imaging have not demonstrated any measurable benefit as compared to CL TVU [24,25]. Elastography is an investigational tool used to document the degree of cervical stiffness/softness which, in addition to cervical length, might constitute a complementary method of identifying cases at risk for preterm delivery. Promising investigational technologies for assessment of the gravid cervix, such as elastography or measures of collagen properties and organization, must be validated before clinical application [26].

Because most low-risk women with a midterm short CL do not deliver preterm, further research on risk assessment for sPTB is needed. Furthermore, the risk reduction for PTB in women with an intervention remains less than 50%. The corollary of this statement is that most PTBs occur in low-risk women with a normal cervical length at midtrimester.

Transvaginal Ultrasound

TVU CL is a safe, acceptable, reproducible technique that can provide high-quality measurements of the cervix. TVU is considered safe in women who have documented premature rupture of membranes [20]. Early cervical changes associated with later PTB occur at the internal os, thus they can be detected early by TVU.

The evaluation should be performed with an empty bladder and without undue pressure on the anterior lip of the cervix, which can falsely elongate the cervix. This may be avoided by withdrawing the probe to ensure that the anterior and posterior lips of the cervix are of equal thickness. The image of the cervix should occupy at least 75% of the image and include the entire length of the cervix, from the internal cervical os to the external cervical os. A brief interval of 15 minutes between voiding and TVU may avoid focal myometrial contractions that can give the false impression of a longer cervix [27]. There is no definitive recommendation on the time period for which the cervix should be monitored to detect spontaneous changes, however monitoring for 3 minutes with a minimum of 3 measurements to obtain the shortest measurement of cervical length has been recommended. [22]. Additional measurements to describe the U-shaped or V-shaped funnel at the internal cervical os may be added. In a postcerclage patient it is often helpful to describe the CL in relationship to the cerclage sutures.

Transvaginal Ultrasound with a Cervical Stress Test

If the cervix remains normal in appearance, a "cervical stress test" can be applied to elicit a dynamic cervix. It is recommended that this maneuver only be carried out in locations with provisions for labor and delivery. If the cervix is already dilated, shortened, or dynamic in appearance, a cervical stress test should be avoided.

A cervical stress test is performed by either applying transfundal pressure while scanning transvaginally or examining the patient during a Valsalva maneuver or coughing or while standing [28,29]. Transfundal pressure is considered the most effective stress technique in eliciting cervical changes during the active assessment of the

cervix. It is defined as applying moderate pressure on the maternal abdomen in the direction of the uterine axis for 15 seconds. A positive response is defined as any decrease in endocervical canal length accompanied by an increase in funnel width and length [30]. It is important to monitor the cervical appearance for at least a couple of minutes after the maneuver as it may take time to elicit changes. Because some patients will initially have a completely normal-appearing cervix, these important maneuvers may identify additional women at risk for preterm labor. Only 1 best shortest closed CL measurement should be reported, thus if the shortest length is after a cervical stress maneuver, then that measurement is reported.

Transperineal Ultrasound

The TPU method of cervical assessment is considered to be dependent on the experience of the sonographer and failure to obtain an optimal image can occur in 0%–12% [31,32] of cases primarily due to shadowing by bowel gas or the pubic symphysis. If the external os is obscured by rectal gas, then maneuvers such as elevating the hips or clenching the buttocks may be helpful to dislodge rectal gas.

Although the overall mean length of the cervix on TVU is shorter by about 2 mm compared with TPU, in the clinically critical 14–20 week gestational age range the mean cervical length at TPU has been demonstrated to average 5.5 mm less than TVU [32]. Moreover, when discrete pairs of cervical length measurements (the TPU and TVU measurements) were compared for individual patients, the mean absolute difference between these measurements was also 5.5 mm [32]. Investigators who assessed the reliability of TPU in 3 gestational-age groups: 10–14 weeks, 20–24 weeks, and 30–34 weeks demonstrated that as the pregnancy progressed, the correlation between TVU and TPU measured CL became stronger, and the difference between the 2 methods became smaller [31]. These studies suggest that TVU should be considered the optimal modality to image the cervix in most situations, in particular prior to 20 weeks. TVU may be avoided in women in whom amniotic membrane rupture is suspected or documented in order to avoid the theoretical risk of infection; however, this is not an evidence-based decision [20,33]. In fact, several investigators have shown that a short cervical length is an independent risk factor for subsequent development of chorioamnionitis [34-36].

In summary, TPU should be reserved for and offered to women at increased risk for PTB but for whom TVU is unacceptably invasive or uncomfortable.

Transabdominal Ultrasound

Although most obstetrical sonographic examinations are performed transabdominally, this is less reliable than either TVU or TPU for evaluating the cervix. Using this approach, bladder overdistension as well as myometrial contractions can change the appearance of the lower uterine segment and cervix, creating a deceivingly normal appearance in women with cervical effacement, shortening, or frank dilatation. Furthermore, an underdistended bladder may preclude adequate cervical visualization for any one of a variety of reasons: acoustic shadowing from the pubic symphysis, refractive shadowing from the bladder-uterine interface, loss of the acoustic window provided by the urinary bladder and/or amniotic fluid, or an inability to manually displace the fetal head or other presenting part superiorly away from the lower uterine segment. Even when visible on a transabdominal scan, the cervical length measurement may not be possible. Therefore, if a patient has a clinical history or sonographic findings suspicious for cervical pathology, consideration should be given to cervical scanning using a TVU approach. A recent study evaluated the threshold level for CL above which the risk for short CL on TVU is very low. Prevoid transabdominal CL \leq 35 mm will detect 100% of TVU CL \leq 20 mm with 41% specificity. To achieve this high sensitivity, 60% of patients required a TVU CL study [36].

Discussion of the Imaging Modalities by Variant

Variant 1: Patient: 16-24 weeks' gestation; at risk for preterm delivery, cervix <3 cm long; suggestion of funneling by transabdominal ultrasound examination; or postcerclage

TVU is the first method of choice. TPU may be performed in a patient in whom TVU is unacceptably invasive or uncomfortable. A cervical stress test may be applied if the cervix appears normal. If the cervix is dynamic or short, then it should not be performed. The cervical stress test should only be performed in setting where there are provisions for labor and delivery. If cervical length assessment is indicated, transabdominal examination may not be reliable, and performance of TVU or TPU is recommended.

Summary of Recommendations

• The risk of spontaneous preterm birth increases as cervical length decreases. The risk is highest when a short cervix is detected prior to 24 weeks' gestation.

- Cervical length below the 10th percentile (25 mm) between 16 and 28 weeks' gestation by TVU is consistently associated with an increased risk of spontaneous preterm birth.
- The single most reliable parameter and best predictor of preterm birth is a transvaginal measurement of closed cervical length. The shortest best measurement of closed cervical length should be reported.

Summary of Evidence

Of the 40 references cited in the *ACR Appropriateness Criteria*[®] Assessment of Gravid Cervix document, 4 are categorized as well-designed therapeutic studies. Additionally, 36 references are categorized as diagnostic references including 1 well-designed study, 4 good quality studies, and 11 quality studies that may have design limitations. There are 20 references that may not be useful as primary evidence.

The 40 references cited in the ACR Appropriateness Criteria[®] Assessment of Gravid Cervix document were published between 1994–2014.

While there are references that report on studies with design limitations, 9 well-designed or good quality studies provide good evidence.

Safety Considerations in Pregnant Patients

Imaging of the pregnant patient can be challenging, particularly with respect to minimizing radiation exposure and risk. For further information and guidance, see the following ACR documents:

- ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [37]
- <u>ACR-ACOG-AIUM-SRU Practice Parameter for the Performance of Obstetrical Ultrasound</u> [38]
- ACR Guidance Document on MR Safe Practices [39]
- ACR Manual on Contrast Media [40]

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria[®] Radiation Dose Assessment Introduction document.

Relative Radiation Level Designations				
Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range			
0 mSv	0 mSv			
<0.1 mSv	<0.03 mSv			
0.1-1 mSv	0.03-0.3 mSv			
1-10 mSv	0.3-3 mSv			
10-30 mSv	3-10 mSv			
30-100 mSv	10-30 mSv			
	Relative Radiation Level Designat Adult Effective Dose Estimate Range 0 mSv 0 0 mSv 0 mSv 0 1 mSv 0.1-1 mSv 1-10 mSv 30-100 mSv			

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to <u>www.acr.org/ac</u>.

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.