Reaffirmed January 2023

Induction of Labor Protocol for Singleton Pregnancies Indications:

1. Maternal desire for induction of labor at or after 39w0d dated by US prior to 22w gestation in an uncomplicated pregnancy without indication for earlier delivery[1]
2. Continuing the pregnancy is believed to be associated with greater maternal or fetal risk than intervention to deliver the pregnancy **Contraindications[2]:**
    1. Active genital Herpes Simplex infection
    2. Placenta or vasa previa
    3. Umbilical cord compromise/prolapse
    4. Fetal malpresentation (breech, transverse lie)
    5. Non-reassuring fetal status indicating need for urgent delivery
    6. Previous classical cesarean section or myomectomy entering into the endometrial cavity

Pre-induction Assessment

1. Determination of gestational age (See Ultrasound Pregnancy Dating Guideline)
    a. Elective induction of labor at or after 39w0d is appropriate given the following criteria are met:
        i. Pregnancy was dated by IVF dating or US prior to 22w gestation
        ii. No maternal or fetal indications for earlier delivery
    b. Postdate indications are recommended to be scheduled no later than 42 6/7 due to increased risk for perinatal morbidity and mortality, with ANFS testing initiated at 41 0/7.[3]
    c. Sub-optimally dated pregnancies is indicated at 41 0/7 unless indication for earlier delivery exists.[4]
        i. Amniocentesis for fetal lung maturity is NOT recommended as a routine component of decision making for induction for sub-optimally dated pregnancies.[4]
    d. Indicated inductions prior to 39w0d must have rationale documented (Category II tracing, vaginal bleeding, oligohydramnios, preterm premature rupture of membranes, pre-eclampsia, ect)
2. Indication for induction determined and documented 3. Ultrasound evaluation:
    a. Fetal Presentation always documented
    b. Fetal growth/AFI as clinically indicated
4. Cervical exam with documentation of Bishop score
5. GBS prophylaxis as per protocol
6. Evaluation of fetal heart rate via continuous electronic fetal monitoring, with presence of reassuring pattern for 20 minutes prior to initiation of induction

Methods for Induction of Labor

1. Favorable Cervix (Bishop score $\geq$ 6 or cervical dilation $\geq$ 3 cm)
    a. Cervical Ripening is not needed

b. Amniotomy: performed if cervix adequately dilated and fetal head well engaged to prevent cord prolapse
    i. Early amniotomy
        1. Meta-analysis of 7 RTCs found a shorter time to delivery in induced labors with early AROM, without increase in cesarean delivery or infectious morbidity[5]
        2. Cochrane review of 12 RTCs and quasi-randomized control trials found modest reduction in the number of cesarean births with early augmentation for mild delays in labor progression with oxytocin and AROM, as well as a reduced time to delivery without increased risk of maternal or neonatal morbidity[6]

c. Oxytocin: Administer as per **Oxytocin Induction/Augmentation Protocol**

2. Unfavorable Cervix (Bishop Score $\leq$ 6 or cervical dilation $\leq$ 2 cm)
    a. Mechanical Ripening
        i. Balloon catheter
            1. To be used in patients **WITHOUT** latex allergy
            2. Insertion of balloon catheter above the internal cervical os either digitally or with a speculum and ring forceps and filled with 60-80 ml saline
            3. Membranes intact: maximum time: 24 hours
            4. Can be used with Oxytocin or PG if no contra-indications exis ii. Cook Catheter

            1. To be used in patients with latex allergy or when clinically indicated
            a. Insertion of Cook catheter balloons through cervix, then inflate uterine balloon with 40 ml saline and pull back until uterine balloon abuts cervical os. Then fill vaginal balloon with 20 ml saline. When in proper position, fill both uterine and vaginal balloon to maximum of 80 ml saline
            b. Maximum time: 12 hours

            2. Mechanical Ripening + Misoprostol
                a. Recent studies have shown that the combined use of misoprostol and cervical balloon catheters (both single and double-balloon catheters) reduce the intervention to delivery time interval and number of NICU admissions in women with an unfavorable cervix[7]
                b. Additionally, combined use of misoprostol and balloon catheters was associated with fewer episodes of uterine hyperstimulation[7]
                c. Another study showed double balloon catheter with oral misoprostol for IOL was associated with shorter labors, greater increase in bishop score and lower need for

oxytocin use, without differences noted in uterine tachysystole, APGAR scores, or NICU admission[8]

i. Both above studies used oral misoprostol in combination with double balloon catheters. Additionally research is needed to assess the safety and efficacy of vaginal misoprostol use with double balloon catheters[7,8]

iii. Procedure

1. Materials – Foley balloon (latex is preferable, but if unavailable or latex allergy), 3-8 10 ml saline flushes, speculum and ring forceps are optional.
    a. Placement should be as sterile as possible. Iodine prep prior to either blind or speculum insertion is encouraged.
    b. Foley is threaded through cervix either blindly by feel or with ring forceps with the aid of a speculum to visualize cervix. Foley balloon should be advanced beyond the internal os prior to inflation.
    c. Foley balloon is inflated with 30 ml saline. At this point placement should be assured by digital exam and very gentle tension on Foley. The balloon should be palpable with gentle tension, but should not be within the cervical canal.
    d. Inflate the balloon with up to 80 ml (total) saline. Higher volume in Foley balloon (60 – 80 ml) may be associated with increased chance of delivery within 12 or 24 hours, and increased cervical dilation at time of expulsion (Delaney et al., 2010; Levy et al., 2004)
    e. Ridged stylettes should not be used to aid in placement due to concerns about sterility, increased risk of accidental AROM, and potential fetal injury that may occur with blind insertion
2. Foley balloon induction is not associated with high risk of tachysystole
3. Foley balloon is safe to use in TOLAC inductions
4. Foley balloon combined with vaginal misoprostol has been shown to decrease length of induction without decreasing risk of Csection. Cytotec or Cervidil may be combined with Foley balloon for induction.
5. Traction on Foley balloon is not associated with decreased time of induction or decreased risk of C-section and should not routinely be used beyond taping Foley to inner thigh (Lutgendorf et al.,

2012) iv. Special circumstance: Premature Rupture of membranes

1. Theoretical concerns regarding increased risk of ascending infections with the use of mechanical dilators has limited their use
2. Multiple studies have not found a statistically significant increased risk of ascending infection[7,10-13] neonatal outcomes[10,11,12] or increased rate of cesarean delivery[10,12] with the use of intracervical balloons (ICB) for IOL after term PROM.
    a. Cabrera et al did not an increased rate of cesarean delivery when ICB was used for IOL after PROM.[7]
    b. One study did use ppx abx for those with PROM and ICB[10]
3. Mackeen et al. (2018) found an increased risk of intraamniotic infections in patients $\leq$ 34 weeks gestation who presented for IOL after membrane rupture than those induced with oxytocin alone.[12]
4. Currently, there is an ongoing multicenter trial in the US focusing on double balloon catheter for IOL in patients with PROM and PPROM[15]. Results are not yet available.
5. There is conflicting data regarding decreased length of labor
    a. Amorosa et al found no difference in duration to delivery with ICB + oxytocin vs. oxytocin alone[11]
    b. Mackeen et al found the interval to delivery was nearly halved (736 vs 1354 min $p<0.01$) in women who underwent IOL with ICB compared to misoprostol.[12]
6. Only two study reported a maximum time length of ICB use before removal of 8-12 hours.[10,14]
7. Although data is conflicting regarding whether ICB use for PROM shortens the duration of labor, given that overall safety of ICB use in PROM as described above, the use of ICB is a reasonable for IOL in patients with a singleton term ($\geq$ 37w gestation) pregnancy presenting with PROM that are not in labor and have a bishop score <6 with no contraindications to vaginal delivery or clinical signs of infection.
    a. Multiple gestation pregnancies were excluded from the above trials and therefore safety/efficacy in this group is unknown.

v. Artificial rupture of membranes

b. Oxytocin: See Oxytocin Induction/Augmentation Protocol
c. Prostaglandins (PG)
    i. Dinoprostone (PGE2)

1. Intravaginal inserts (Cervidil) containing 10 mg of prostaglandin E2 in a timed-release formulation (released at 0.3mg/hr)
2. Insert is left in place until active labor begins or for 12 hours with maximum of 2 doses
3. Oxytocin may be initiated per protocol 60 minutes after removal of insert if the patient deemed a candidate for oxytocin
4. Advantages
    a. Less risk of tachysystole
    b. Fewer vaginal exams needed
    c. Can be removed

ii. Misoprostol (PGE1) ****Not to be administered to patients with prior Csection or uterine scar (except with 2nd trimester IUFD)****

1. Vaginal dosing
    a. 25 microgram tablet
        i. Starting dose, not to be re-dosed sooner than at 4 hour intervals
        ii. Oxytocin can be initiated per protocol 4 hours after last dose of 25 mcg tablet
        iii. Maximum dose: 6 doses (total)
    b. 50 mcg tablet
        i. Can be used if dose of 25 mcg has resulted in minimal to no cervical change after 4 hours
        ii. Not to be re-dosed sooner than 6 hour intervals
        iii. Maximum dose: 6 doses (total)
2. Oral dosing
    a. Recent Cochrane review noted oral misoprostol is as effective as vaginal misoprostol and vaginal dinoprostone.[16]
    b. A systematic review found that low dose oral Cytotec (2025 mcg) administered every 2 hours was as effective as vaginal dinoprostone and vaginal misoprostol with lower rates of cesarean delivery and uterine hyperstimulation[17]
    c. A multicenter RCT found that in patients with an unfavorable cervix, IOL with 50 mcg oral misoprostol every 4 hours had similar safety and effectiveness as foley catheter[18]
    d. 25-50 mcg every 2-4 hours
    e. 25-50 mcg tablets swallowed with a sip of water. Sublingual and buccal dosing has not been well studied

f. Starting dose of 25 mcg for at least 2 doses, may be uptitrated to 50 mcg with goal of 2-3 contractions/10 minutes
    i. At 2 hours, if ≥3 contractions/10 minutes (over 30-minute period), further Cytotec should be withheld until contractions space
    ii. Digital exam are not necessary if patient is without symptoms of active labor and fetal status is reassuring – may be ideal for patients with PPROM/PROM

3. Monitoring during administration of PG Ripening agent
    a. 30 min of reassuring fetal heart rate and contraction monitoring prior to cervical ripening
    b. Continuous fetal heart and contractions monitoring once the prostaglandin dose is administered
    c. Hold PG if 3 contractions/10 minutes averaged over 30 minute period, or if patient is more than 3 cm dilated regardless of effacement, when maximum dose of PG reached, or active labor is obtained.
4. Side effects: nausea, diarrhea, fever

Management of complications of cervical ripening 1. Hyperstimulation

a. Lateral decubitus positioning of patient
b. Intravenous fluid bolus
c. Inhaled oxygen
d. Physician notification
e. If possible, removal of prostaglandin delivery system
f. Temporary reduction or discontinuation of oxytocin administration
g. Uterine relaxant therapy (terbutaline 0.25 mg subcutaneously) may be considered if contractions are refractory and there are not contraindications

Unsuccessful induction Definition

1. First stage of labor
    a. A prolonged latent phase of labor (greater than 20 hours in nulliparous women and 14 hours in multiparous women) is not an indication for cesarean delivery.[19]
    b. Cesarean delivery for active phase arrest should be reserved for women at or beyond 6 cm dilation with rupture membranes who fail to progress despite 4 hours of adequate uterine activity (≥200 MVUs) or at least 6 hours of oxytocin administration with inadequate uterine activity and no cervical change.[19]

2. Second stage of labor
    a. If maternal and fetal conditions permit, pushing for at least 2 hours in multiparous and 3 hours in nulliparous women should be allowed before diagnosis second stage arrest. Longer durations may be appropriate in individualized cases, such as epidural analgesia or fetal malposition.[19]
    b. Manual rotation for fetal malposition or operative delivery can be considered as an alternative to cesarean section if patient is an appropriate candidate.[19]
3. Failure of Induction
    a. If maternal and fetal status allow, latent labor can be extended up to 24 hours or longer with oxytocin administration for at least 12-18 hours after membrane rupture before deeming the induction a failure. [19]

Management of labor induction in a patient with a prior cesarean

1. Elective repeat Cesarean delivery (ERCD) and TOLAC have different risks to the mother and the fetus (see tables 2 and 3 below from Guise et al, 2010), decision on delivery route should involve discussion of:
    a. Success and failure rates of TOLAC
    b. Incidence of uterine rupture, including discussion of patient related factors that affect this
    c. Future reproductive goals and implication of multiple C-sections to future pregnancy risk
    d. Maternal and perinatal risk with uterine rupture
    e. Neonatal risk with TOLAC and ERCD
    f. Risk of peripartum hysterectomy secondary to uterine rupture

Table 2. Summary of Strength of Evidence and Findings for Maternal Outcomes for Trial of Labor Compared With Elective Repeat Cesarean Delivery

Maternal Outcome	Number of Studies/Subjects	Grade of Evidence	Direction of Effect	Magnitude of Effect Absolute Risk (95% CI)
Maternal death	12/402,883	High	Significantly reduced by TOL (P=.027)	TOL: 0.004% (0.001–0.015%) ERCD: 0.013% (0.004–0.042%)
Uterine rupture	8/63,499	Moderate	Significantly increased by TOL (P<.001)	TOL: 0.47% (0.28–0.77%) ERCD: 0.026% (0.009–0.082%)
Hysterectomy	8/402,059	Moderate	No significant difference (P=.50)	TOL: 0.17% (0.12–0.26 %) ERCD: 0.28% (0.12–0.67%)
Hemorrhage	6/47,754	Low	Insufficient data to evaluate	Insufficient data to evaluate
Transfusion	9/401,307	Moderate	No significant difference (P=.25)	TOL: 0.9% (0.4–2.0%) ERCD: 1.2% (0.5–2.6%)
Infection	22/354,060	Low	No significant difference	TOL: 4.6% (1.5–13.5%) ERCD: 3.2% (1.3–7.3%)
Surgical injury	4/53,282	Low	Insufficient data to evaluate	Insufficient data to evaluate

CI, confidence interval; TOL, trial of labor; ERCD, elective repeat cesarean delivery.

Table 3. Summary of Strength of Evidence and Findings for Neonatal Outcomes for Trial of Labor Compared With Elective Repeat Cesarean Delivery

Neonatal Outcome	Number of Studies/Subjects	Grade of Evidence	Direction and Magnitude of Effect (95% CI)
Perinatal death	5/76,899	Moderate	Significantly increased by TOL (P=.002) TOL: 0.13% (0.06–0.30%) ERCD: 0.05% (0.007–0.38%)
Neonatal death	6/108,328	Moderate	Significantly increased by TOL (P=.001) TOL: 0.11% (0.06–0.20%) ERCD: 0.06% (0.02–0.15%)
Respiratory conditions	4/5,599	1. Bag/mask ventilation: Low 2. Transient tachypnea of the newborn (TTN): Low	1. TOL 5.4% (3.5–7.6) vs ERCD 2.5% (1.6–1.6%) 2. TOL: 3.6% (0.9–8%) ERCD: 4.2% (1.9–7.3%)
Hypoxic–ischemic encephalopathy	3/62,829	Low	Insufficient data to evaluate direction of risk
Sepsis	3/2,846	Low	Insufficient data to evaluate direction of risk
Trauma	2/41,899	Insufficient	Insufficient data to evaluate direction of risk
NICU admissions	8/65,121	Low	Insufficient data to evaluate direction of risk
Neurological outcomes	0	Insufficient	Insufficient data to evaluate direction of risk
Breastfeeding outcomes	0	Insufficient	Insufficient data to evaluate direction of risk

CI, confidence interval; TOL, trial of labor; ERCD, elective repeat cesarean delivery; NICU, neonatal intensive care unit.

2. Candidates[20]
    a. No other contraindication for vaginal delivery
    b. One previous low-transverse or low-vertical cesarean delivery.
    c. If type of cesarean is unknown, can be considered unless there is a high clinical suspicion of previous classical uterine incision (i.e. extremely preterm gestational age)
    d. History of two prior cesarean sections can be considered on a case-by-case basis
    e. No other history of uterine scars or previous rupture
    f. Physician immediately available throughout active labor capable of monitoring labor and performing an emergency cesarean delivery
    g. Availability of anesthesia and personnel for emergency cesarean delivery
    h. Pre-induction criteria med (see: Pre-induction assessment above)
3. Contraindications to TOLAC[20]
    a. Previous classical or T-shaped incision or prior uterine corpus surgery
    b. Previous uterine rupture
    c. Medical or obstetric complication that precludes vaginal delivery

   d. Inability to perform a cesarean delivery because of unavailable surgeon, anesthesia, sufficient staff, or facility
   e. More than two uterine scars
4. Management
   a. Appropriate counseling of patient in regard ro risk and benefit of TOLAC based on patient uterine scar and prior indication for cesarean with documentation of counseling in chart.
   b. Induction methodology:
      i. Bishop score $\geq$ 6: low dose oxytocin per protocol with amniotomy as indicated.
         1. Amniotomy is not associated with increased risk of uterine rupture, and is recommended in patients with a favorable cervix.
      ii. Bishop score < 6: cervical ripening with Intracervical balloon catheter or low dose Pitocin.
         1. Transcervical Foley bulb is not thought to increase risk of uterine rupture, and is recommended in cases of an unfavorable cervix as a single agent.
         2. Oxytocin slightly increases risk of rupture (0.7 to 0.9 %), but is an acceptable agent for induction or augmentation in TOLACs
      iii. **Prostaglandin use is contraindicated for IOL with prior uterine scar due to increased risk of uterine rupture.**[20]
5. Monitoring during labor
   a. Continuous fetal heart rate and contraction monitoring
   b. Nurse must notify physician for any evidence of tachysystole, hyperstimulation, or non-reassuring fetal status.
   c. CNMs should only manage induction of patients with previous cesarean with active co-management by the OB service physician team
6. IUFD induction
   a. Third trimester inductions should proceed in a similar manner to those with a live fetus; however, C-section should only be recommended for maternal indications
   b. <= 28 weeks – Vaginal Cytotec 200-400 mcg every 4 hours (ACOG practice bulletin # 107, 2007)
   c. Prior C-section
      i. Cytotec is an option at < 26 weeks, although we recommend decreased dose (25 – 50 mcg vaginally) every 4 hours
      ii. There is limited data to guide induction in patients with prior classical C-section, decision for induction and method of induction should be customized based on patient desires and attending recommendations.

iii. Risk of uterine rupture may be higher in IUFD inductions. Close observation for maternal signs of rupture should be routine.

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