The New Pitocin Protocol

Ben Klug, PGY-3
Oxytocin is a polypeptide hormone produced in the hypothalamus and secreted from the posterior lobe of the pituitary gland in a pulsatile fashion. It is identical to its synthetic analog, Pitocin.

- $\frac{1}{2}$ life 3-6 minutes
- HCA $\frac{1}{2}$ life 10-12 minutes
- HCA= High Alert Medication= lowest possible dose that is effective
- Historically, synthetic oxytocin was diluted by placing 10 units in 1000 mL of an isotonic solution
- Today use 60 units in 1000 mL crystalloid to allow the infusion pump setting to match the dose administered
Oxytocin

- Contractions
- Let-down
- Social behavior
  - Fear
  - Trust
  - Wound healing
  - Autism
- Empathy
- Romantic attraction
Endogenous levels: 2-4 maternal, 3 fetal = 5-7 total

Exogenous oxytocin able to produce contractions at approximately 20 weeks of gestation, with increasing responsiveness with advancing gestational age. There is little change in myometrial sensitivity to oxytocin from 34 weeks to term.

Once spontaneous labor begins, the uterine sensitivity to oxytocin increases rapidly due to increase in myometrial oxytocin binding sites.

Progress during spontaneous labor is not related to increasing oxytocin concentration, uterine contractions are not associated with changes in plasma oxytocin concentration, and hypocontractile labor does not appear to be the result of a deficit of oxytocin.

Inverse relationship of duration and number of available receptors (may equal abnormal ctx patterns).
High or Low

- Protocols differ as to initial dose (0.5 to 6 mU/min), time period between dose increments (10 to 60 minutes), and maximum dose (16 to 64 mU/minute), but success rates for varying protocols are strikingly similar.

- A literature review of randomized trials of high- versus low-dose oxytocin regimens for augmentation or induction of labor concluded high-dose oxytocin decreased the time from admission to vaginal delivery, but did not decrease the incidence of cesarean delivery compared with low-dose therapy.

- High-dose regimens are associated with a higher rate of tachysystole than low-dose regimens and, in some studies, this has resulted in a higher rate of cesarean delivery for nonreassuring fetal heart rate tracings, but no significant difference in neonatal outcomes.
### Examples of oxytocin infusion protocols

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Starting dose, milliunits/minute</th>
<th>Incremental increase, milliunits/minute</th>
<th>Dosage interval, minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-dose</td>
<td>0.5 to 1</td>
<td>1</td>
<td>30 to 40</td>
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<tr>
<td>Alternative low-dose</td>
<td>1 to 2</td>
<td>2</td>
<td>15 to 30</td>
</tr>
<tr>
<td>High-dose</td>
<td>6</td>
<td>6</td>
<td>15 to 40</td>
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<td>The incremental increase should be reduced to 3 milliunits/minute if hyperstimulation is present, and reduced to 1 milliunit/minute if recurrent hyperstimulation.</td>
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<td>Some clinicians limit to a maximum cumulative dose of 10 units and a maximum duration of 6 hours.</td>
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<tr>
<td>Alternative high-dose</td>
<td>4</td>
<td>4</td>
<td>15</td>
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</tbody>
</table>

Oxytocin should be administered by trained personnel who are familiar with its effects. It should be administered using an infusion pump that provides precise flow rate to ensure accurate minute to minute control. Most clinicians will not administer more than 40 milliunits/minute as the maximum dose.

Steady State- dynamic equilibrium

- 50% of steady state in 1 half life
- 75% in 2 half lives
- 87.5 % in 3 half lives
- 90% in 3.3
- 94-97% in 4-5 half lives. (clinical steady state)
Goal

- Pit increased until there is normal progression of labor, or strong contractions occurring at two- to three-minute intervals, or uterine activity reaches 200 to 250 Montevideo units.

- There is no benefit to increasing the dose after one of these endpoints has been achieved.

- To continue or not continue? Conflicting evidence.
  - Discontinuation prolongs labor
  - No benefit of continuing once in active labor.

- No consensus reached/recommended.
Goal: Healthy Mom and Healthy Baby

Understand guiding principles and standard approaches for the safe delivery of oxytocin.

Understand the historical perspective of the development of the recommended guidelines and checklist for oxytocin.

Recognize new data supporting the standard oxytocin practices and neonatal outcomes.
Perinatal Safety Initiative Key Points

- All recommendations are based on evidence based medicine.
- Oxytocin Audit was from April ’13-Sept ’13 and 14,398 patients were audited in study
- Compliance parameters that were audited:
  - Monitoring prior to Pitocin
  - Pelvic adequacy
  - Pre-Use checklist
  - In-Use checklist
  - FHR tracing “adequate for interpretation >95% of the time”
  - Ctx tracing “adequate for interpretation >95% of the time”
- Outcome parameters during audit:
  - Route of delivery
  - NICU admission
  - 1 minute Apgar <7
  - 5 minute Apgar<7
- Outcomes statistically better when Pitocin was decreased or stopped when FHR didn't meet criteria
- Compliance to protocol resulted in decreased C/S rate by 3%
- This is the first study to document improved newborn outcomes with use (and proper interpretation/management) of EFM.
- Only evidence based approach to oxytocin management
- It is no longer ok when a nurse sees tachysystole or abnormal FHR pattern to continue tl Pitocin—even with a Dr order—utilize chain of command.
- Oxytocin is a High Alert Med. Use lowest possible dose to achieve desired therapeutic effect.
- Biologic ½ life of oxytocin is 10-12 minutes
- Steady state of plasma concentration takes 30-40 minutes
- There is an inverse relationship between duration and dosage of Pitocin and the number of receptor sites available for uptake.
- 90% of women at term, will have a successful induction with 6 milliunits or less of Pitocin
- If Pitocin is discontinued for less than 20-30 minutes and FHR is reassuring and contraction frequency, intensity and duration are normal, you may restart the Pitocin at no more than ½ the rate that cause the hyperstimulation.
- If Pitocin is discontinued for > 30-40 minutes, resume at the initial dose ordered.
- Once active labor is established, Pitocin should be discontinued to avoid receptor down regulation.
Trumps “In my experience…”

Trumps “I feel like it today.”

Trumps “I’m the doctor and I say so.”

Mandates chain of command for alternative approaches to care.
Tachysystole
Tachysystole

- By ACOG definition: greater than 5 contractions in a 10 minute period, average over 30 minute period.
- HCA definition: greater than 5 contractions in a 10 minute period, averaged over 20 minutes.
Why It Matters

- More time between contractions = more time to maximally perfuse fetus
- SpO2 of fetus lowest at 92 sec after peak of contraction and takes approx 90 sec to return to normal. Therefore, contractions every 2 min or more = incomplete perfusion
- Progressive desaturation occurs with approximately 5 minutes of tachysystole
- According to Bakker study: significantly more acidemia when tachysystole present in labor.
Oxytocin Induction Flowchart

Pre-Induction Checklist Completed

Yes

Initiate oxytocin as prescribed

No

Notify physician for completion. Oxytocin cannot be initiated without completed checklist.

In-use Checklist completed every 30 minutes

No

Turn off oxytocin until checklist can be completed

Yes

Once complete and tracing meets criteria, restart oxytocin at previous rate.

>2 variable (>60 bpm x 60 sec.) or >1 late decelerations

Yes

Decrease by half or discontinue oxytocin. Once resolved, restart oxytocin at half previous rate.

No

>6 ctx/10 min (over 20 min.) or ≥ 2 contr lasting ≥30 seconds

Yes

Decrease oxytocin by 25%

Notify physician when criteria are not met and oxytocin has been decreased/discontinued. Upon review, should the physician interpret the tracing to be free of late or variable decelerations as outlined in the protocol, oxytocin may be restarted after documentation in the medical record reflects these findings. If concern remains by RN that FHR or uterine activity do not meet criteria for continuation of oxytocin, the ANM is Maintain interpretable FHR and Uterine Activity Tracing throughout induction.
Oxytocin Audit
April- September, 2013

- Each HCA facility audited designated number of consecutive charts of women whose labors were induced with oxytocin.
- Number determined to represent a statistically valid sample size for each facility.
- Audits conducted by local, AWHONN and FHRM instructors.
- N= 14,398 charts
Compliance Parameters

- Monitoring prior to starting Pitocin
- Pelvic adequacy
- Pre-Use checklist
- In-Use checklist
- FHR tracing (95% of the time)
- Ctx tracing (95% of the time)
Outcome Parameters

- Route of delivery (SVD, OVD, or C/S)
- NICU admission
- 1 minute apgar <7
- 5 minute apgar <7
Results

Compliance with Oxytocin Management & FHM
ALL FACILITIES

- Oxytocin Used to Induce Labor
- Estimated Fetal Wt Reviewed Prior to Oxytocin - 74%
- Adequacy of PeVtIs Reviewed Prior to Oxytocin - 75%
- Used Pre-Oxytocin Checklist - 81%
- FHR Tracing Adequate >95% - 68%
- UC Tracing Adequate >95% - 68%
- Used In-Use Oxytocin Checklist - 41%
- Oxytocin Stopped or Decreased - Abnl UC - 25%
- Oxytocin Stopped or Decreased - Abnl FHR - 31%
- Oxytocin Stopped or Decreased - Both FHR & UC Abnl - 34%

N=14399

Compliance Data Points Missed

1/13/2014
Slide: 10
Abnormal FHRT recognized
Oxytocin stopped or decreased

Non-compliant
Compliant

NICU Admit*
1 min Apgar*
5 min Apgar*
Composite*
Composite Protocol Compliance
All 9 Steps

NICU Admit*
1 min Apgar*
5 min Apgar <7
Composite*

• Non-compliant
■ Compliant
Compliance and the Cesarean Rate

FHRT only*  Total protocol*

Non-compliant  Compliant
Results

- Outcomes statistically better when Pitocin was decreased or stopped when FHR didn't meet criteria
- Compliance to protocol resulted in decreased C/S rate by 3%
- This is the first study to document improved newborn outcomes with use (and proper interpretation/management) of EFM.
- Only evidence based approach to oxytocin management
- It is no longer ok when a nurse sees tachysystole or abnormal FHR pattern to continue the Pitocin—even with a Dr order—utilize chain of command.
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- If Pitocin is discontinued for > 30-40 minutes, resume at the initial dose ordered.
- Once active labor is established, Pitocin should be discontinued to avoid receptor down regulation.
Importance of Results

- System compliance is suboptimal
- Non-compliance involves:
  - Behavior/attitude/leadership
  - Work ethic/patient load
  - Knowledge deficit
- Compliance yields significantly improved outcomes
Importance of Results

- First study to document improved newborn outcomes with the use (and proper interpretation/management) with EFM.

- Avoids past errors of looking at diagnostic tool and expecting it to yield therapeutic results.

- Establishes clear definition of abnormal.

- Pending peer review/publication, HCA protocol is the only evidence-based approach to oxytocin management.
Where We Are Now

- Self Audit- 12/13
- Plan for improvement- 1/15/14
- Implement plan- Spring 2014
- Repeat 3 month audit- 4/14/14
- Goal= 95% compliance with protocol and checklists
Oxytocin Induction Flowchart

Pre-Induction Checklist Completed

- Yes
  - Initiate oxytocin as prescribed

- No
  - Notify physician for completion. Pilocin cannot be initiated without completed checklist.

In-use Checklist completed every 30 minutes

- Yes
  - Turn off oxytocin until checklist can be completed

- No
  - Once complete and tracing meets criteria, restart oxytocin at previous rate.

>2 variable decelerations

- Yes
  - Decrease by half or discontinue oxytocin. Once resolved, restart oxytocin at half previous rate.*

- No
  - >5 cbx/10 min (over 20 min.) or ≥2 contr lasting >100 seconds

- Yes
  - Decrease oxytocin by 25%

Notify physician when criteria are not met and oxytocin has been decreased/discontinued. Upon review, should the physician interpret the tracing to be free of late or variable decelerations as outlined in the protocol, oxytocin may be restarted after documentation in the medical record reflects these findings. If concern remains by RN that FHR or uterine activity do not meet criteria for continuation of oxytocin, the ANM is

Maintain interpretable FHR and Uterine Activity Tracing throughout induction.
**Induction of Labor Checklist (May be completed prior to admission)**

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If ALL the above answers are YES, complete the remainder of the document. Otherwise, physician to clarify.

**Contraindications to Labor Induction (May be completed prior to admission)**

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If ALL the answers to the contraindications to labor induction are NO, complete the remainder of the document.

**Indication for Induction (May be completed prior to admission)**

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☐ ☐ For inductions not medically indicated, confirmation of gestation of at least 39 weeks is documented.

If no box is marked YES in this section, physician (resident or attending) to clarify. Proceed with induction when checklist is completed.

Document deviation from the checklist due to unexpected circumstances such as fetal intolerance to labor, tachysystole, etc., in the medical record.

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**Physician Signature** ____________________________  **Date** __________  **Time** __________

**Fetal Assessment (minimum 30 minute tracing prior to initiation)**

☐ Two 15 beat times 15 second accelerations (or as appropriate for gestational age) in previous 30 minutes, or BPP of 6/10 present in previous 4 hours, or adequate variability in previous 30 minutes.

☐ No late decelerations.

☐ No more than 2 variable decelerations exceeding 60 seconds, and decreasing for greater than 60 beats per minute from baseline, in the previous 30 minutes.

If not met, the provider will review Fetal Heart Rate (FHR) tracing and provide appropriate documentation.

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**Physician or RN Signature** ____________________________  **Date** __________  **Time** __________
Before We Begin…

- Pre-checklist completed
- Signed order on chart
- Current H&P
- Prenatal Record
- Indication
- Pelvis adequate per Dr.
- Estimated fetal weight
- Gestational age
- LDR consent signed
- Physician available
- Cvx assessed & documented
- Fetal presentation
- Fetal assessment
  - 30 min FHT, Reactive
  - 8/8 BPP in 4 hours
  - No lates
  - No greater than 2 variables>60 sec and decreasing >60 beats
In-Use Checklist

- Complete q 30 min- must be stopped if unable
- At least 1 15x15 accel in 30 min or mod var for 10 of last 30 min.
- No more than one late
- No more than 2 variables > 60sec, or decreasing 60 beats in last 30 min
- No more than 5 ctx/10min averaged over 20 min.
- No 2 ctx greater than 120 secs
- Uterus palpates soft between ctx.
- If IUPC must be less than MVU <300mm Hg, resting tone <25mm Hg
Hard Stops

- FHR pattern does not meet criteria. If Dr. document no variables/lates can continue. If RN not agree→ chain of command. May be restarted at ½ when resolves.

- Oxygen. If resolves restart at ½.

- Continuous tracing. Interruptions >10min.

- Checklists

- Tachysystole (not irritability), decrease by at least 25%
Problems

- Same protocol, “different rules”
- New staff
- Lack of communication
- Lack of understanding of protocol
Future Data

- Rates of c/s with IOL
- Apgar outcomes
- NICU admissions
Questions?
DOES IT HURT?
CAN I GET YOU A BEER OR SOMETHING?

WHY NO ONE USES MIDHUSBANDS...
Sources

- ACOG
- Uptodate
- HCA Perinatal Safety Initiative