The Case for an Oxytocin Infusion Safety-Interlock System for Active Management of Labor (POSI)

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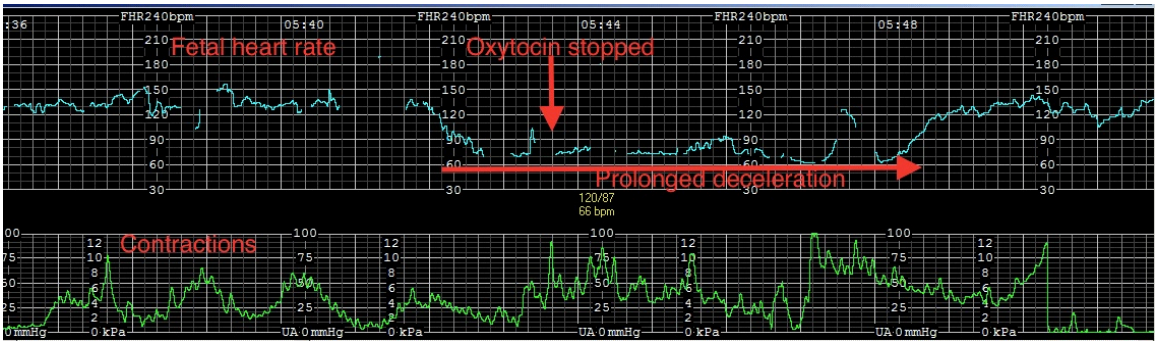
The following case report illustrates the potential clinical benefits of implementing a safety interlock for oxytocin infusion during active labor management.

Report of case: A 32yo G1P0 at 41weeks gestational age was admitted with ruptured amniotic membranes (ROM). She had no significant medical or surgical history and had had an uncomplicated prenatal course. Oxytocin was started four hours after ROM due to irregular contractions and titrated per protocol while the patient was monitored with continuous external fetal monitoring and external tocometry. Nine minutes after increasing the oxytocin infusion, fetal heart deceleration correlating with a tetanic contraction was noted by an MD monitoring the tracings at the nursing station. The MD immediately went to the patient's room and stopped the oxytocin infusion two minutes into the deceleration. As the MD arrived at the bedside, the patient's RN was preparing to call the MD regarding the deceleration. A prolonged six-minute deceleration was followed by subsequent reassuring tracings after resolution of the tetanic contraction. [See Figure]



In this case, the RN did not stop the oxytocin, and had the MD not observed the deceleration, the additional delay in stopping the oxytocin would have been several minute (based on the time to page the MD + time for the MD to reach the bedside or call the RN in the room).

Parturient Oxytocin Safety Interlock (POSI): We propose that a safety interlock, capable of automatically stopping the oxytocin infusion under these conditions, could increase the margin of safety during active management of labor. Between the 1960's and 1980s [1,2,3,4,5,6], several studies were published on the use of automated oxytocin infusion systems to titrate contraction frequency with feedback from both external tocometers and internal pressure transducer catheters. None used fetal heart monitoring into their algorithms. Today, these systems would be classified as "physiologic closed-loop control systems" (as defined in standard IEC 60601-1-10), that adjust oxytocin rate to a contraction state. They were not commercially adopted.

We are proposing a "safety interlock" that will stop (and not re-start) the oxytocin infusion when indicated. The POSI would be inherently safe, as there is no significant clinical risk caused by automatically pausing an oxytocin infusion used for active management of labor. Conversely, there are significant risks in poor fetal outcomes with prolonged decelerations, recurrent late decelerations, and fetal bradycardia[7]. A smart "real-time clinical decision support" system (RT-CDS) that uses fetal heart and uterine contraction data to automatically pause oxytocin infusion has the potential of decreasing both maternal and fetal morbidity and mortality. The POSI could be implemented in compliance with ASTM F2761, the standard for an Integrated Clinical Environment (ICE), in a manner similar to the ICE-based PCA infusion safety interlock research prototype, implemented by the MGH MD PnP research program. [8,9]

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