Cytoteccase.com

cytoteccase.com

You might expect the professional organization of obstetricians' (A.C.O.G.'s) priority would be to safeguard the safety and well-being of their patients, but A.C.O.G. clings to the inexpensive and easy intervention to expedite deliveries. Cytotec's low cost and convenience outweighs safety concerns by those in whom we entrust our health and well-being, but that seems to be the reality.

The FDA's Cytotec 2000 warning is re-printed in full above. In May 2005, the FDA issued a similar, follow-up warning.

IN SPITE OF THESE WARNINGS, THE PROFESSIONAL ORGANIZATION OF OBSTETRICIANS STILL CLINGS TO CYTOTEC! Here is ACOG's response to the FDA's "Dear Doctor" letter:

"For Release: October 27, 2000

"Janet Woodcock, MD, Director
"Food and Drug Administration

"Dear Dr. Woodcock:

"The American College of Obstetricians and Gynecologists Committee on Obstetric Practice has met regarding Cytotec (misoprostol). We are expediting the transmittal of the content of their review to the Food and Drug Administration so that the agency can consider it during its review of the labeling of misoprostol.

"On August 23, 2000, G.D. Searle & Co. issued a letter entitled "Important Drug Warning Concerning Unapproved Use of Intravaginal or Oral Misoprostol in Pregnant Women for Induction of Labor or Abortion." This letter cautions that Cytotec (misoprostol) is indicated for prevention of non-steroidal-antiinflammatory-drug-induced gastric ulcers and states, "... Cytotec administration by any route is contraindicated in women who are pregnant because it can cause abortion." The letter further states that Searle has become aware of the drug's use for induction of labor or as a cervical ripening agent prior to termination of pregnancy. Moreover, the letter notes serious adverse events, including uterine hyperstimulation and uterine rupture, which have resulted in fetal and maternal death. Finally, the company cautions, "In addition to the known and unknown acute risks to the mother and fetus, the effect of Cytotec on the later growth, development, and functional maturation of the child when Cytotec is used for induction of labor or cervical ripening has not been established."

"The American College of Obstetricians and Gynecologists (ACOG) is concerned by the content, timing, and tone of this letter. Given that misoprostol is commonly employed in conjunction with mifepristone (RU 486) to achieve nonsurgical early pregnancy terminations, the arrival of the Searle letter within weeks of the U.S. Food and Drug Administration's (FDA) approval of mifepristone could limit the use of this new option for reproductive choice. Also, although the letter correctly points out the potentially serious, but relatively rare, risks of misoprostol when employed for cervical ripening and labor induction, it fails to comment on the extensive clinical experience with this agent and the large body of published reports supporting its safety and efficacy when used appropriately. A recent review of the Cochrane Pregnancy and Childbirth group trials registry identified 26 clinical trials of misoprostol for cervical ripening or induction of labor or both (1). These studies indicate misoprostol is more effective than prostaglandin E2 in achieving vaginal deliveries

within 24 hours and reduces the need for and total amount of oxytocin augmentation. Although these studies do suggest misoprostol is associated with a higher incidence of uterine hyperstimulation and meconium-stained amniotic fluid, these complications were more common with higher doses (> 25 µg) of misoprostol. Other recent reviews and clinical trials support these conclusions (2-4). No studies indicate that intrapartum exposure to misoprostol (or other prostaglandin cervical ripening agents) has any long-term adverse health consequences to the fetus in the absence of fetal distress, nor is there a plausible biological basis for such a concern.

"A review of published reports and of MedWatch, the FDA medical products reporting program, indicates the vast majority of adverse maternal and fetal outcomes associated with misoprostol therapy resulted from the use of doses greater than 25 µg, dosing intervals more frequent than 3-6 hours, addition of oxytocin less than 4 hours after the last misoprostol dose, or use of the drug in women with prior cesarean delivery or major uterine surgery. Grand multiparity also appears to be a relative risk factor for uterine rupture.

Thus, based on recently published series and a detailed review of adverse outcomes reported to the FDA, the ACOG Committee on Obstetric Practice strongly endorses its previous conclusions, published in Committee Opinion Number 228 (November 1999), Induction of Labor with Misoprostol, which states, "Given the current evidence, intravaginal misoprostol tablets appear effective in inducing labor in pregnant women who have unfavorable cervices" (5). Nonetheless, the Committee would like to emphasize that the following clinical practices appear to minimize the risk of uterine hyperstimulation and rupture in patients undergoing cervical ripening or induction in the third trimester:

1. If misoprostol is to be used for cervical ripening or labor induction in the third trimester, one quarter of a 100µg tablet (i.e., approximately 25µg) should be considered for the initial dose.
2. Doses should not be administered more frequently than every 3-6 hours.
3. Oxytocin should not be administered less than 4 hours after the last misoprostol dose.
4. Misoprostol should not be used in patients with a previous cesarean delivery or prior major uterine surgery.

"The use of higher doses of misoprostol (e.g., 50 µg every 6 hours) to induce labor may be appropriate in some situations, although there are reports that such doses increase the risk of complications, including uterine hyperstimulation and uterine rupture (6). There is insufficient clinical evidence to address the safety or efficacy of misoprostol in patients with multifetal gestations or suspected fetal macrosomia.

In conclusion, the ACOG Committee on Obstetric Practice reaffirms that misoprostol is a safe and effective agent for cervical ripening and labor induction when used appropriately. Moreover, misoprostol also contributes to the obstetrician-gynecologist's resources as an effective treatment for serious postpartum hemorrhage in the presence of uterine atony (7-12)."

Sincerely,
Stanley Zinberg, MD, MS, FACOG"