Buccal Matches Vaginal Misoprostol in Efficacy

BY PATRICE WENDLING
Chicago Bureau

DALLAS — Buccal misoprostol was as effective as vaginal for cervical ripening, but was associated with a significantly higher incidence of tachysystole in a prospective randomized trial of 738 women.

Although tachysystole was increased, maternal and neonatal complications were comparable between groups, Dr. Zoi Russell said at the annual meeting of the Society for Maternal-Fetal Medicine.

The efficacy of misoprostol (Cytotec) for cervical ripening or labor induction has been confirmed in more than 100 randomized trials, but physicians are seeking the optimal route and dose of administration for the synthetic prostaglandin E_1 analogue.

Vaginal routes have the advantage of more sustained activity and greater bioavailability, while oral and sublingual routes have more rapid onset and a lower rate of gastrointestinal side effects, said Dr. Russell of the University of South Florida, Tampa.

Buccal misoprostol was associated with higher rates of intervention for nonreassuring fetal surveillance and tachysystole than was vaginal misoprostol.

In the current study, women at a gestational age of more than 26 weeks with a medical indication for labor induction and an unripe cervix were randomized to initial doses of 100 mcg buccal misoprostol administered between the cheek and gum or 25 mcg misoprostol administered intravaginally, and increased to 200 mcg and 50 mcg after two doses. Doses were given every 3-6 hours in both groups, until a Bishop score of at least 7, labor, intervention, or a total of six misoprostol doses.

In both groups, the median age was 25 years, the initial Bishop score was 2, and the Bishop score at induction was 8.

In all, 364 women were randomized to the vaginal group and 374 to the buccal group. However, 44 in each group were excluded for protocol violations, leaving 320 vaginal patients and 330 buccal patients available for analysis.

The buccal group appeared to deliver faster than the vaginal group when all routes of delivery were included (19.8 vs. 22.5 hours), but the difference did not persist when cesarean deliveries were excluded, Dr. Russell said.

The study's primary outcome of median interval from first dose to vaginal delivery was not significantly different between the buccal (19 hours) and vaginal (21 hours) groups.

There were no significant differences between groups in cesarean rates (111 vs. 103) or cesarean deliveries performed for reasons of nonreassuring fetal surveillance (61 vs. 54).

Buccal misoprostol was significantly associated with higher rates of intervention for nonreassuring fetal surveillance (36 vs. 20) and tachysystole (46 vs. 26), defined as three to six contractions of 1-2 minutes for two consecutive 10-minute periods. However, buccal administration was also significantly associated with less need for oxytocin augmentation (237 vs. 259), said Dr. Russell, who reported receiving no financial support for the study and disclosed no relevant conflicts of interest.

An earlier Cochrane meta-analysis of three small trials with a total of 502 women reported that the buccal route was associated with a trend to fewer cesarean sections than the vaginal route, but concluded that sublingual or buccal misoprostol should not enter clinical use until its safety and optimal dosage have been established by larger trials (Cochrane Database Syst. Rev. 2004;CD004221 [doi: 10.1002/14651858.CD004221.pub2]).

When asked if the current data are enough to support clinical use of buccal misoprostol, Dr. Russell said in an interview that the study was designed as an efficacy study, and as such, showed that "buccal can be at least as effective as vaginal misoprostol in ripening the cervix and induction of labor in the third trimester.

"Although the maternal and neonatal outcomes were similar between the two groups, our study would be underpowered to detect any significant differences in rare but serious adverse outcomes," she said. "That is a question that can only be answered by a much larger study—a safety study." ■