# ECV Cost Effective if Odds of Success Are Good

### BY KATE JOHNSON Montreal Bureau

BANFF, ALTA. — An attempted external cephalic version and subsequent delivery costs more than a planned cesarean section for a term breech pregnancy, but it is still cost effective, based on national success rates for the maneuver, Jonathan Tan said at the annual meeting of the Society for Obstetric Anesthesia and Perinatology.

"ECV [external cephalic version] is cost

effective when compared to scheduled cesarean for breech delivery if the probability of ECV success is above 46%, "said Mr. Tan, a medical student at State University of New York at Stony Brook.

"The 58% national average for ECV success in the United States puts us right in the range of cost-effectiveness, but it is still important to note that ECV costs more than a planned cesarean delivery," Mr. Tan said.

A scheduled cesarean delivery costs

around \$7,200 while an ECV costs about \$1,200 with an additional cost of \$5,000 for a vaginal delivery, he said. However, not all ECV attempts are successful, and not all successes result in a vaginal delivery; "there are other indications for cesarean section," he said.

In his analysis using a computer-based decision model, Mr. Tan used rates from the literature for successful ECV, spontaneous reversion, and probability of unanticipated emergency cesarean to calculate an incremental cost-effectiveness ratio of \$31,600 per quality-adjusted life year gained for conducting a trial of ECV.

Although the American College of Obstetricians and Gynecologists currently recommends that all women near term with breech presentations should be offered a trial of ECV (ACOG Practice Bulletin Number 13, 2000), "in many hospitals in the United States, cesarean section is the exclusive method of management," he said.

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- Similar bleeding profile when compared with placebo<sup>1,3,4</sup>
- Favorable tolerability and safety<sup>1,3,4</sup>
  - Clinical symptoms of breast discomfort, breast pain, and breast tenderness were similar to those with placebo after 6 months<sup>4</sup>
  - FDA approved as safe and effective

Activella 0.5 mg/0.1 mg is indicated in women who have a uterus for the treatment of moderate to severe vasomotor symptoms associated with menopause and the prevention of postmenopausal osteoporosis. When prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and non-estrogen medications should be carefully considered.



#### IMPORTANT SAFETY INFORMATION

Estrogens with or without progestins should not be used for the prevention of cardiovascular disease or dementia. (See CLINICAL STUDIES and WARNINGS, Cardiovascular disorders and Dementia in prescribing information.)

The estrogen plus progestin substudy of the Women's Health Initiative (WHI) reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) per day, relative to placebo. (See CLINICAL STUDIES and WARNINGS, Cardiovascular disorders and Malignant neoplasms, *Breast cancer* in prescribing information.)

The estrogen-alone substudy of the WHI reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 6.8 years and 7.1 years, respectively, of treatment with oral conjugated estrogens (CE 0.625 mg) per day, relative to placebo. (See CLINICAL STUDIES and WARNINGS, Cardiovascular disorders in prescribing information.)

The Women's Health Initiative Memory Study (WHIMS), a substudy of the WHI study, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with CE 0.625 mg combined with MPA 2.5 mg and during 5.2 years of treatment with CE 0.625 mg alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women. (See CLINICAL STUDIES, WARNINGS, Dementia and PRECAUTIONS, Geriatric Use in prescribing information.)

Other doses of oral conjugated estrogens with medroxyprogesterone acetate and other combinations and dosage forms of estrogens and progestins were not studied in the WHI clinical trials and, in the absence of comparable data, these risks should be assumed to be similar. Because of these trials, estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

Other warnings include: gallbladder disease, hypercalcemia, and visual abnormalities.

Activella should not be used in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of cancer of the breast; known or suspected estrogen-dependent neoplasia; active deep vein thrombosis, pulmonary embolism, or history of these conditions; active or recent (e.g., within the past year) arterial thromboembolic disease (e.g., stroke, myocardial infarction); liver dysfunction or disease; known hypersensitivity to the ingredients of Activella 0.5 mg/0.1 mg; known or suspected pregnancy.

In a clinical trial, the most commonly reported adverse events (reported at a frequency of  $\geq$ 5%) were back pain, headache, pain in extremity, nausea, diarrhea, nasopharyngitis, endometrial thickening, and vaginal hemorrhage.

REFERENCES: 1. Activella [package insert]. Princeton, NJ: Novo Nordisk Inc; 2007. 2. Loose-Mitchell DS, Stancel GM. Estrogens and progestins. In: Hardman JG, Limbird LE, eds. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 10th ed. New York, NY: McGraw-Hill; 2001:1598. 3. Panay N, Yikorkala O, Archer DF, Gut R, Lang E. Ultra-low-dose estradiol and norethisterone acctate: effective menopausal symptom relief. *Climacteric*. 2007;10:120-131. 4. Data on file. CTR. Novo Nordisk Inc, Princeton, NJ.

Please see brief summary of prescribing information on following page.