

Recommendations for clinical practice This meta-analysis provides convincing evidence that elective cesarean delivery substantially reduces the risk of vertical transmission of HIV. It is important that this conclusion is supported by recent data from the European Mode of Delivery Collaboration,¹ a randomized controlled trial of 370 mother-infant pairs that showed an 80% reduction of risk of vertical transmission and minimal surgical complications for elective cesarean delivery. Given the low rate of antiretroviral therapy and the lack of information on viral load in this meta-analysis, the important question of whether elective cesarean delivery confers a clinically significant benefit when added to combination therapy remains unanswered.

Providers should offer cesarean delivery to their prenatal patients with HIV, while helping them weigh the benefit of preventing HIV transmission against the risks of surgical delivery. It should be kept in mind that elective cesarean delivery is only 1 component of a comprehensive strategy to reduce vertical transmission, which includes early detection through prenatal screening, use of antiretroviral therapy throughout pregnancy and in the neonatal period, and avoidance of breast-feeding.

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■ PERINEAL MASSAGE TO PREVENT PERINEAL TRAUMA DURING PREGNANCY

Labrecque M, Eason E, Marcoux S, et al. Randomized controlled trial of prevention of perineal trauma by perineal massage during pregnancy. *Am J Obstet Gynecol* 1999; 180:593-600.

Clinical question Can perineal massage during pregnancy prevent perineal trauma at birth?

Background There is clear evidence supporting the restrictive use of episiotomy to minimize perineal trauma during delivery, but data documenting the benefits of other interventions are sparse.¹ Perineal massage during pregnancy has been advocated to increase elasticity and reduce the risk of perineal trauma from episiotomy or spontaneous tears.

Population studied Participants included a total of 1527 pregnant women who had a previous vaginal delivery ($n = 493$) and who had not ($n = 1034$) from 5 hospitals in Quebec, Canada. Women at high risk of cesarean delivery were excluded.

Study design and validity This was a randomized single-blind controlled study of 10 minutes of perineal massage daily beginning in the 34th or 35th week of pregnancy compared with usual obstetric care. The study was well designed and had adequate power to detect significant differences in outcomes. Randomization was stratified by history of previous vaginal birth, specialty of attending physician, and hospital. Physicians were encouraged to limit use of episiotomies. All participants were provided with information on episiotomies and perineal trauma, and the study nurse also taught women in the experimental group perineal massage. This massage consisted of introducing 1 or 2 fingers 3 to 4 cm deep into the vagina and applying and maintaining pressure, first downward for 2 minutes and then for 2 minutes to each side of the vaginal entrance. Women were given a bottle of sweet almond oil to use for lubrication.

Participants in the massage group were instructed to keep daily diaries recording whether massage was done, and a postpartum questionnaire was given to determine the frequency of massage. The 2 instruments were used to calculate the degree of compliance. Using a standardized form, physicians provided information on the state of the perineum immediately after the delivery. All participants completed a postpartum questionnaire assessing their experience with perineal massage, feelings of control, and satisfaction with the delivery. Analysis was by intention to treat.

Outcomes measured The primary outcome measure was delivery with an intact perineum (no laceration or unsutured first-degree tear). Secondary outcomes were rate of episiotomy and severity of perineal tears. Additional outcomes included satisfaction with the delivery experience and sense of control.

Results Among women without a previous vaginal birth, 24.3% from the perineal massage group and 15.1% from the control group were delivered vaginally with an intact perineum, for an absolute difference of 9.2% (95% confidence interval, 3.8% - 14.6%; $P = .001$; number needed to treat = 11). There was no difference in this group in the proportion of deliveries with episiotomy, and there was no significant difference in the number of third- and fourth-degree perineal lacerations. The incidence of delivery with an intact perineum increased with greater frequency of massage for women without a previous vaginal birth. There was no statistically significant difference between treatment and control groups in the proportion of women with previous vaginal deliv-

ery who had intact perineums. No difference was found between groups in the risk of sutured tears, satisfaction with the birth experience, or sense of control. Women who practiced third trimester perineal massage found this to be a highly acceptable practice, and more than 85% said they would recommend perineal massage to another pregnant woman.

Recommendations for clinical practice This large study provides data suggesting that the practice of third trimester perineal massage can increase the likelihood that women without a previous vaginal birth will deliver with an intact perineum. Unfortunately, there was no clinically significant reduction in the episiotomy rate or the incidence of third- and fourth-degree tears, which account for most of the morbidity associated with perineal birth trauma. Although most studies have lacked the power to demonstrate the efficacy of this technique, another large trial² has also demonstrated beneficial effects of perineal massage in nulliparous women, after controlling for birth weight and maternal age. On the basis of the available data, pregnant women without a previous vaginal delivery should be offered information about the potential benefits of third trimester perineal massage.

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LEUKOTRIENE RECEPTOR ANTAGONISTS VERSUS INHALED STEROIDS IN ASTHMA

Malmstrom K, Rodriguez-Gomez G, Guerra J, et al. Oral montelukast, inhaled beclomethasone, and placebo for chronic asthma: a randomized controlled trial. *Ann Intern Med* 1999; 130:487-95.

Clinical question Should we be prescribing oral antileukotriene medication instead of inhaled steroids for maintenance in chronic asthma?

Background Inhaled steroids are the current standard maintenance therapy for chronic asthma. Oral leukotriene receptor antagonists may be appropriate alternatives, particularly for patients who have difficul-

ty using inhalers. This is the first published study directly comparing the efficacy of an inhaled steroid with a leukotriene receptor antagonist in chronic asthma.

Population studied The study was conducted in 895 healthy nonsmoking patients aged 15 to 85 years with chronic asthma for at least 1 year before enrollment. All of these adult patients had mild to moderate asthma with a forced expiratory volume in 1 second (FEV₁) between 50% and 85% of predicted that was responsive to β -agonists with at least a 15% improvement over baseline FEV₁, daytime asthma symptom score of at least 64 out of 336 possible, and a required average of at least 1 puff of a β -agonist medication every day. Ten percent of the patients were taking theophylline. Patients were excluded who had recently used inhaled or oral steroids, cromolyn, nedocromil, long-acting β -agonists, antimuscarinics, or long-acting antihistamines. Patients were recruited from 36 clinical sites in 19 different countries. None of the clinical sites was in the United States.

Study design and validity This randomized double-blind clinical trial had a 2-week placebo run-in period, a 12-week treatment period, and a 3-week placebo washout period. Patients were randomized to 1 of 3 arms: oral placebo with placebo inhaler (n = 257), 10 mg oral montelukast with placebo inhaler (n = 387), or oral placebo with 200 μ g per day inhaled beclomethasone (n = 251). Subjects filled out daily diary cards documenting daytime asthma symptoms, morning and evening peak flows, and use of an as-needed short-acting β -agonist (albuterol).

The primary goal of the study was to show the efficacy of montelukast over placebo in chronic asthma. Though the montelukast/beclomethasone comparison was not the primary question, it was prespecified in the trial design and appropriately accounted for statistically. The power of the study was adequate with respect to primary outcomes. A total of 92.8% of patients randomized to the beclomethasone arm and 91.5% in the montelukast arm completed the 12-week treatment phase of the trial.

Outcomes measured Primary outcomes were change in pulmonary function over baseline and change in daytime asthma symptom scores.

Results Both agents worked better than placebo, and beclomethasone significantly outperformed montelukast in every clinically relevant outcome reported. FEV₁ improved over baseline by 0.7% in the placebo group, 7.4% in the montelukast group, and 13.1% in the beclomethasone group. Daytime asthma symptom scores showed a statistically significant difference of 5.8% in favor of beclomethasone. This difference may not be clinically significant. Results for secondary outcomes including β -agonist use, morning and evening