Research

#### **OBSTETRICS**

# Cesarean section for HIV-infected women in the combination antiretroviral therapies era, 2000–2010

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OBJECTIVE: Elective cesarean section (CS) is a proven method to prevent mother-to-child transmission (MTCT), but is no longer recommended for women with antiretroviral therapy resulting in a low viral load (VL): <400 copies/mL in French and <1000 copies/mL in US quidelines. We sought to describe mode of delivery practices in human immunodeficiency virus (HIV)-infected women and their association with MTCT and postpartum complications.

STUDY DESIGN: All deliveries from HIV-1-infected women in the French Perinatal Cohort (Agence Nationale de Recherches sur le Sida/Enquête Périnatale Française) 2000 through 2010 (N = 8977) were analyzed, with additional details for 2005 through 2010 (n = 4717).

**RESULTS:** Vaginal deliveries increased from 25% in 2000 to 53% in 2010. Over 2005 through 2010, 4300 women had VL before delivery <400 copies/mL; among them only 49.3% delivered vaginally, 22.0% had nonelective CS, and 28.7% had elective CS. Elective CS were performed for scarred uterus in 45.4%, other obstetrical indications in 37.1%, and solely because of HIV in 15.7%. Of the 417 women with VL >400 copies/mL, 48.9% had elective CS as recommended, 25.9% had nonelective CS, and 25.2% had vaginal delivery. The MTCT rate did not differ according to the mode of delivery in term deliveries (>37 gestational weeks) in 2000 through 2010: 0.3% after both vaginal delivery and elective CS with VL <50 copies/mL, 4.0% vs 5.3%, respectively, with VL >10,000 copies/mL. In case of preterm delivery, MTCT rates tended to be higher with vaginal delivery. Postpartum complications were more frequent following CS than vaginal deliveries (6.5% vs 2.9, P < .01).

**CONCLUSION:** Our findings suggest that HIV-infected women on antiretroviral therapy with low VL can safely opt for vaginal delivery in the absence of obstetrical risk factors.

Key words: cesarean section, human immunodeficiency virus, mode of delivery, mother-to-child transmission, viral load

Cite this article as: Briand N, Jasseron C, Sibiude J, et al. Cesarean section for HIV-infected women in the combination antiretroviral therapies era, 2000—2010. Am J Obstet Gynecol 2013;209:335.e1-12.

protective effect of elective cesarean section (CS) was proved in the absence of antiretroviral (ARV) therapy or with zidovudine monotherapy, leading to 2- to 5-fold reductions in motherto-child transmission (MTCT) of human immunodeficiency virus (HIV) compared to vaginal delivery, both in large observational studies and in a randomized clinical trial.<sup>1-3</sup> Elective CS at 38 gestational weeks was thus recommended for all HIV-infected women in all industrialized countries from 1997 through 1998. Subsequently, the use of combination ARV therapy (cART) was

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Received Feb. 9, 2013; revised May 5, 2013; accepted June 12, 2013.

L.M. has received lecture honoraria from Merck Sharp & Dohme, Bristol-Myers Squibb, Abbott, and Gilead.

This work was supported by Agence Nationale de Recherche Sur le Sida et les Hépatites Virales (Inserm-ANRS). Grants from Abbott, latec, ViiV Healthcare, and Parexel were obtained through contract with the ANRS, promoter and main funding support of the ANRS-Enquête Périnatale Française, to support pharmacovigilance studies. These entities were not involved in any part of the study, design, data collection, statistical analysis, interpretation, or drafting the manuscript.

The authors report no conflict of interest.

Preliminary data were presented as a poster at the 33rd annual meeting of the Society for Maternal-Fetal Medicine, San Francisco, CA, Feb. 11-16, 2013, and at the 16th International AIDS Society Conference, Rome, Italy, July 17-20, 2011.

Reprints not available from the authors.

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found to be the most effective means of preventing MTCT (PMTCT).<sup>4-9</sup> Several observational studies suggested that there was no longer any additional benefit from elective CS beyond that conferred by cART and viral suppression,<sup>4,7,10-12</sup> although some continued to show a protective effect.<sup>5,12</sup>

Since 2002, French national guidelines recommend vaginal delivery for women with low viral loads (VLs) <400 copies/ mL. However, no study was able to define a threshold below which elective CS has no benefit for MTCT. This has led to differences in clinical practice and national guidelines, where the VL threshold above which CS is recommended varies between countries: 400 copies/mL in France<sup>4,13</sup>; 1000 copies/mL in the United States, 14 Canada, <sup>15</sup> and Spain <sup>16</sup>; and 50 copies/mL in the United Kingdom<sup>17</sup> as well as the European AIDS Clinical Society. 18 Differences in mode of delivery practices in HIV-infected women between Europe and the United States were reported several years ago.6

In France, although most HIVinfected women now achieve a VL <400 copies/mL before delivery, their rate of cesarean (elective and nonelective) remains well above that of the general population.<sup>19</sup> This is a cause for concern because of the risks of CS, including short-term maternal and neonatal complications (and risks for future pregnancies including uterine rupture, placenta accreta, and repeat cesarean). 20,21 The persistently high cesarean rate may be due to obstetricians and/ or patients feeling reassured by avoiding vaginal delivery to avoid intrapartum transmission, even with a low VL.

Our objectives were to evaluate mode of delivery practices in France in the cART era with regard to: (1) the rate of MTCT of HIV, (2) how current guidelines were actually applied, and (3) the frequency of postpartum complications.

## MATERIALS AND METHODS The ANRS French Perinatal HIV Cohort (EPF)

The nationwide Enquête Périnatale Française (EPF) has prospectively collected data on HIV-infected pregnant women and their children in centers throughout France since 1984, as detailed elsewhere.4 No specific recommendations for obstetric and HIV care were made, but investigators were encouraged to follow current French guidelines.<sup>13</sup> Informed consent was obtained from the mothers, with an overall participation rate of 95%. This cohort was approved by the Hôpital Cochin Institutional Review Board and the French data protection agency (Commission Nationale Informatique et Libertés). Since 2005, EPF has been divided into a detailed cohort (EPF-CO1) in larger maternity units accounting for two-thirds of enrollment, and a less detailed cohort (EPF-CO11) in generally smaller maternity units.

### **Study population**

The overall analysis was conducted among the 8977 pregnancies from women infected with HIV-1 delivering in participating hospitals from Jan. 1, 2000, through Dec. 31, 2010, among them 4745 in 2005 through 2010, after excluding 1276 women with missing data on mode of delivery or VL.

#### Variables studied

Main outcome was the mode of delivery, with 3 categories: vaginal delivery; elective CS, defined as before the onset of labor and intact membranes; and non-elective CS. Five types of indication for CS were recorded in the detailed EPF-CO1 since 2005: repeat cesarean (scarred uterus), premature rupture of membranes, other maternal or obstetrical indications, fetal indications, and PMTCT of HIV. Postpartum complications and hospitalization >7 days were also collected in the EPF-CO1.

Sociodemographic, obstetrical, and HIV treatment data included age, geographic origin (categorized as sub-Saharan Africa, metropolitan France, or other origins), gestational age (GA) at booking in the maternity, type of ARV therapy and time of treatment initiation and cessation, and GA at delivery, preterm birth being defined by GA <37 weeks. CD4 cell counts and plasma HIV-1 RNA VLs obtained closest to the time of delivery, not >7 days after delivery, were collected for all women. For

some analyses, we considered only the last VL before delivery. Maternities were classified according to their perinatal care level: maternity only (level 1), onsite neonatology (level 2), and neonatal intensive care (level 3).

A child was considered infected if HIV-1 DNA or RNA polymerase chain reaction was positive on 2 samples or HIV-1 antibodies were detected at 18 months of age, or uninfected in other cases.

#### Statistical analysis

We first described modes of delivery from 2000 through 2010, according to whether the VL nearest to delivery was > or <400 copies/mL, the threshold to recommend elective CS in French guidelines. We then compared the MTCT rate according to mode of delivery, VL, and preterm birth in the subgroup of women treated with cART.

A detailed analysis of the mode of delivery was performed for the recent period 2005 through 2010, in which systematic cART was recommended (N = 4717). We identified factors associated with vaginal delivery separately according to VL categories (> or <400 copies/mL). We performed multivariate logistic regressions with mode of delivery (vaginal vs cesarean) as the dependent variable, adjusting for all noncollinear variables found to be associated with P < .20 in univariate analysis, using  $\chi^2$ or Fisher exact test for categorical variables, Student t or Wilcoxon test for continuous variables as appropriate. We then described the indications for CS in women in the EPF-CO1 with available data (N = 4001).

We also compared the frequency of postpartum complications and prolonged postpartum hospitalization (>7 days) according to mode of delivery and CD4 lymphocyte counts.

#### RESULTS

# Mode of delivery and transmission rates over the period 2000 through 2010

The rate of vaginal delivery increased from 25% in 2000 to 53% in 2010, with a parallel decrease in elective CS (57-26%), and a stable proportion of

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