



Vaginal delivery in women with HIV in Italy: results of 5 years of implementation of the national SIGO-HIV protocol

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Abstract

Purpose To evaluate the maternal and neonatal safety of vaginal delivery in women with HIV following the implementation of a national protocol in Italy.

Methods Vaginal delivery was offered to all eligible women who presented antenatally at twelve participating clinical sites. Data collection and definition of outcomes followed the procedures of the National Program on Surveillance on Antiretroviral Treatment in Pregnancy. Pregnancy outcomes were compared according to the mode of delivery, classified as vaginal, elective cesarean (ECS) and non-elective cesarean section (NECS).

Results Among 580 women who delivered between January 2012 and September 2017, 142 (24.5%) had a vaginal delivery, 323 (55.7%) had an ECS and 115 (19.8%) had an NECS. The proportion of vaginal deliveries increased significantly over time, from 18.9% in 2012 to 35.3% in 2017 ($p < 0.001$). Women who delivered vaginally were younger, more commonly nulliparous, diagnosed with HIV during current pregnancy, and antiretroviral-naïve, but had a slightly longer duration of pregnancy, with significantly higher birthweight of newborns. NECS was associated with adverse pregnancy outcomes. The rate of HIV transmission was minimal (0.4%). There were no differences between vaginal and ECS about delivery complications, while NECS was more commonly associated with complications compared to ECS.

Conclusions Vaginal delivery in HIV-infected women with suppressed viral load appears to be safe for mother and children. No cases of HIV transmission were observed. Despite an ongoing significant increase, the rate of vaginal delivery remains relatively low compared to other countries, and further progress is needed to promote this mode of delivery in clinical practice.

Keywords HIV · Pregnancy · Mode of delivery · Delivery complications

Introduction

The national guidelines for the prevention of HIV mother to child transmission issued by panels from US, Canada and European countries have endorsed vaginal delivery as the preferred mode of delivery in the presence of low or undetectable maternal plasma viral load, promoting since the early 2000s a substantial change in clinical practice and

a significant reduction of the rates of elective cesarean delivery [1–5].

In Italy, the 2011 national HIV guidelines [6] recommended cesarean delivery at week 38 in women with detectable viral load, stating at the time that the data on the benefit of cesarean delivery in women with undetectable viral load were inconclusive, given the limited number of cases of transmission and the low rates of adverse events that most commonly involved women with more advanced immune deterioration [7–9].

In 2011, in order to collect further evidence on the safety of vaginal delivery in women with HIV and promote uniform clinical practice among obstetric centers caring for these women in Italy, the HIV Study Group of the Italian Society of Gynaecology and Obstetrics

The members of the SIGO-HIV Study Group are listed in acknowledgement section.

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(SIGO-HIV Study group) released a clinical protocol, to be implemented and evaluated in a national observational study that started in 2012. Obstetric centers were encouraged to enter the study, and the HIV/AIDS Italian Expert panel recommended since 2013 in the national HIV guidelines the SIGO-HIV Protocol as the reference to be followed for eligibility and implementation of vaginal delivery in HIV [10]. We here show the results of this multicenter observational study.

The objective of the present analysis was to evaluate the maternal and neonatal safety of vaginal delivery in women with HIV and to define the impact of the introduction of the SIGO-HIV Protocol for vaginal delivery in clinical practice during the first 5 years of its implementation.

Methods

The study protocol (“Protocollo di Parto vaginale in pazienti HIV+ in terapia antiretrovirale altamente attiva (HAART) con carica virale non dosabile e CD4+ > 200/mm³ stabili da almeno 4 settimane al momento del parto”) obtained central ethics approval on November 30, 2011 (OIRM/S. Anna—Ordine Mauriziano di Torino Ethics Committee, ref. 54081/C28.2) and was subsequently approved by the Ethics Committee of each participating center. Twelve centers (listed in acknowledgements) agreed to participate, providing data on all the women followed during the study period. All the women who presented during routine antenatal care at the clinical sites were screened for eligibility for vaginal delivery, according to the criteria reported in Table 1. Eligible women were offered vaginal delivery and provided a signed

Table 1 Eligibility and exclusion criteria for vaginal delivery

Eligibility criteria
Maternal age ≥ 18
Singleton pregnancy
Cephalic presentation
Gestational age between 37 weeks 0 days and 41 weeks 4 days
Spontaneous or induced labor
On HAART regimens started before or at gestational week 20, with good therapeutic compliance
Undetectable (< 50 copies/ml or lower according to local techniques) plasma HIV-RNA for at least 4 weeks before delivery
CD4+ $\geq 200/\text{mm}^3$ for at least 4 weeks before delivery
Able to understand and provide informed consent
Exclusion criteria
Preterm premature rupture of membranes
Premature rupture of membranes by more than 6 h
Treatment (HAART) not done or poor therapeutic compliance during pregnancy
Plasma HIV-RNA measurement not available
Detectable HIV-RNA during the 4 weeks preceding delivery
CD4+ < 200/mm ³ during the 4 weeks preceding delivery ^a
HIV diagnosed during the 4 weeks preceding delivery
HCV coinfection ^b

Fourteen cases with minor violations of the above criteria were included in the protocol and had vaginal delivery. The minor violations for these cases are the following (one or more per pregnancy): delivery before week 37: 6 cases (two at week 35, four at week 36); HAART started after gestational week 20: 4 cases; pre-delivery HIV-RNA between 50 and 100 copies/ml: 2 cases; CD4 count below 200/mm³ or not reported: 3 cases; HCV-positive: 2 cases

The following conditions did not represent contraindications to vaginal delivery: HBV coinfection; positive streptococcus B swab; previous cesarean section; pregnancy achieved with assisted reproductive technology; prelabor rupture of membranes with labor occurring within 6 h

^aLow CD4+ count (CD4 < 200/mm³), being associated with an advanced immunodeficiency and an higher risk of vertical transmission, was considered an exclusion criterion for vaginal delivery

^bAs per Italian Guidelines on Cesarean section (2011) that recommend elective cesarean section in women with HCV/HIV coinfection with no HAART or with HIV viral load > 50 cp/ml and offer of cesarean section to women with HCV/HIV coinfection with HAART and HIV viral load < 50 cp/ml with explanation of its potential risks and benefits and information about no proven efficacy of cesarean section to reduce vertical transmission of HCV

informed consent. In all centers, vaginal delivery was equally proposed to women with and without a previous cesarean section. The analysis considered all pregnancies who delivered at the participating centers between 1/1/2012 and 30/9/2017. Data collection used the forms and procedures of the National Program on Surveillance on Antiretroviral Treatment in Pregnancy (Ethics approval: ref. no. 578/2001 from the Ethics Committee of the I.N.M.I. Lazzaro Spallanzani in Rome) [11]. Treatments and dosages were decided by the treating physicians, usually according to existing guidelines.

Mode of delivery was classified as “elective cesarean section” (ECS), “non-elective cesarean section” (NECS) or “vaginal delivery”. ECS was defined as a scheduled cesarean prior to the onset of labor and prior to ruptured membranes or rupture of membranes ≤ 5 min prior to delivery. NECS was defined as a cesarean performed after the onset of labor or ruptured membranes > 5 min prior to delivery. The vaginal delivery group included all the women who delivered according to the protocol. The ECS and NECS groups included all the pregnancies with ECS and NECS, excluding (for consistency with the selection criteria of the other group) the cases with late presentation or late HIV diagnosis (> 32 weeks), multiple pregnancy, and delivery before 32 weeks.

The main outcomes evaluated were delivery complications, HIV transmission, maternal and infant mortality, birth defects, low and very low birthweight. Gestational age was determined on the basis of the last menstrual period, ultrasound biometry, or both. Low birthweight was defined by values below 2500 g, and gender- and gestational age-adjusted percentiles for birthweight were calculated according to national reference standards [12]. The major birth defects were defined according to the Antiretroviral Pregnancy Registry definition [13].

Peripartum (defined as the time between admission for delivery and a week after admission) delivery complications were classified into three different categories: (1) hemorrhagic events or anemia (including postpartum hemorrhage with hemodynamic instability, substantial blood loss or acute anemia requiring surgery or blood transfusion); (2) fever/infections (including endomyometritis, bacteriemia/sepsis, pneumonia, wound infection); (3) other complications.

Variables were summarized as proportions and medians with interquartile ranges. Quantitative variables were compared by the Mann–Whitney *U* test and categorical data by the Chi square test or Fisher test, as appropriate, and odds ratios (OR) and 95% confidence intervals (CI) were calculated. Temporal trends were analyzed by the Chi square test for trend. *p* values < 0.05 were considered significant. All statistical analyses were performed with the SPSS software, version 22 (IBM Corp, Released 2013, Armonk, NY, USA).

Results

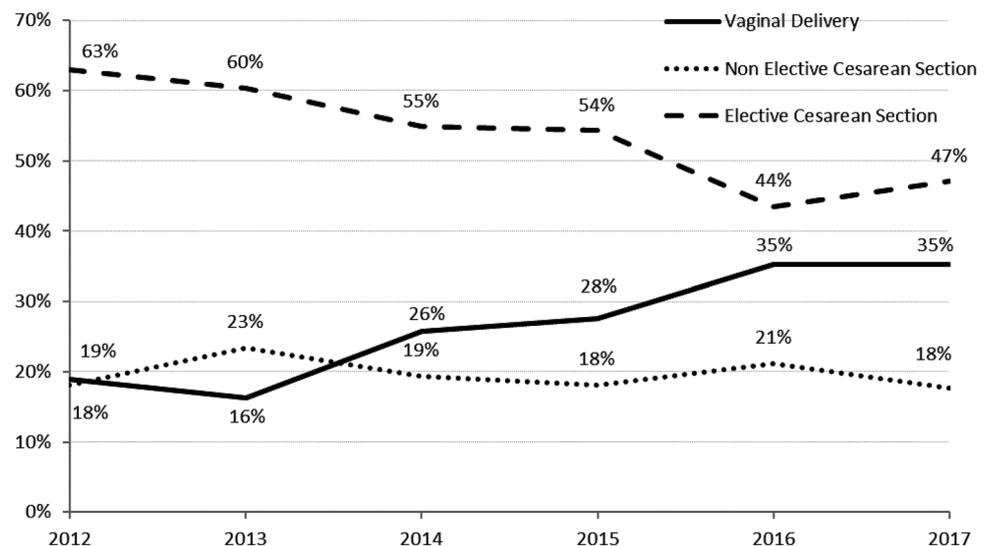
All the results reported here are based on the data extracted from the general database on January 17, 2018. Overall, among 580 evaluable pregnancies reported by twelve centers (median number per center: 36 pregnancies), 142 (24.5%) had a vaginal delivery according to the protocol, 323 (55.7%) had an elective cesarean section and 115 (19.8%) had a non-elective cesarean section. Considering all cases, the proportion of vaginal deliveries increased significantly over time, from 18.9% in 2012 to 35.3% in 2017 ($p < 0.001$, Chi square for trend).

Excluding women with nonelective cesarean section (n : 115) and women who were not eligible for vaginal delivery because of obstetrical or non-obstetrical reasons, reported in detail in Table 2, 142 out of 333 potentially eligible women (42.6%) had a vaginal delivery between 2012 and 2017. This proportion increased significantly over time, with rates of 33.4% in 2012–2013, 43.5% in 2014–2015 and 60.0% in 2016–2017 ($p = 0.001$, Chi square for trend) (Fig. 1).

The general characteristics and clinical outcomes according to the three modes of delivery are reported in Table 3. Overall, compared to women with elective cesarean delivery, women who delivered vaginally were younger, more commonly nulligravida, nulliparous, diagnosed with HIV during current pregnancy, and antiretroviral-naïve (Table 3). In terms of clinical outcomes, women with vaginal delivery had a slightly longer duration of pregnancy, which translated in a significantly higher birthweight (Fig. 2). Almost all the outcome measures, as expected, were significantly worse in the group with emergency cesarean section, reflecting the presence of obstetrical or infant conditions that favoured earlier delivery (including birth defects that were significantly more common in this group), often with low birthweight/prematurity. No differences were observed among the three groups for intrauterine growth delay. The rates of low Apgar score and HIV transmission were minimal, with no differences according to the mode of delivery. There were no cases of vertical transmission in vaginal delivery group; instead, there were two cases in cesarean section group. First case was a 25-year-old Italian woman with vertically transmitted HIV infection who presented to care during the second trimester of her first pregnancy. She was not taking any therapy, her viral load was $> 200,000$ cp/ml and CD4+ count was 656 cells/mm³. She started antiretroviral therapy (TDF/FTC/RAL) at 32 weeks of gestational age and had an elective cesarean section at 38 weeks of gestational age, with intrapartum intravenous AZT administered. Neonatal prophylaxis with AZT was promptly started. The neonatal HIV RNA remained undetectable during the first

Table 2 Mode of delivery according to potential eligibility for vaginal delivery

Potentially eligible for vaginal delivery: 333	142 had a vaginal delivery, 139 with information on previous cesarean section 14 with previous cesarean section (10.1%) 125 without previous cesarean section (89.9%)
	191 had elective cesarean section 112 with previous cesarean section (58.6%) 79 without previous cesarean section (41.4%)
Not eligible for vaginal delivery: 132	53 had elective cesarean section for obstetrical reasons Placental disease (<i>n</i> : 6) Breech presentation (<i>n</i> : 13) Genital infections (<i>n</i> : 5) IUGR/signs of fetal distress (<i>n</i> : 13) Previous myomectomy (<i>n</i> : 4) Liver abnormalities/cholestasis (<i>n</i> : 5) Other (<i>n</i> : 7)
	79 had elective cesarean section for non-obstetrical reasons Detectable or not available HIV-RNA at third trimester (<i>n</i> : 56) Low CD4 counts (<i>n</i> : 3) Insufficient duration of treatment in pregnancy (<i>n</i> : 7) HCV–HIV coinfection (<i>n</i> : 13)
Cases with nonelective cesarean section excluded (<i>n</i> : 115)	

Fig. 1 Mode of delivery, years 2012–2017

week but it became positive in the following examinations. Antiretroviral therapy with 3TC/ABV/LPV/r (the virus showed resistance to NNRTI) was started. Two-year follow-up revealed psychomotor retardation and spastic diplegia. The second case was represented by a 31-year-old Nigerian woman already diagnosed with HIV infection (with an infected child), who presented at 32 weeks of gestational age with preterm prelabor rupture of membranes for over 24 h, with no antiretroviral therapy taken and no blood examinations performed during pregnancy. Cesarean section was performed and intrapartum intravenous AZT was administered. Neonatal HIV PCR was positive early in two consecutive tests and neonatal therapy with

AZT + 3TC was started. Patau Syndrome (deafness, corpus callosum hypoplasia, optic nerve hypoplasia, bilateral polydactyly, left ventricular hypertrophy with mitral prolapse) was diagnosed. The child died due to respiratory failure caused by RSV infection.

The analysis of delivery complications showed no differences between vaginal and elective cesarean delivery, while non-elective cesarean delivery was associated with a significantly higher rate of complications compared to elective cesarean delivery.

The overall rate of previous cesarean section was 34.9% (375/576), with significant differences among the three groups, with only ten per cent of the women with vaginal

Table 3 Population characteristics and main clinical and laboratory outcomes

	All (n: 580)	Vaginal (n: 142)	ECS (n: 323)	NECS (n: 115)	Vaginal vs. ECS*	Vaginal vs. NECS*	ECS vs. NECS*
<i>Clinical and demographic information</i>							
Age (years) (median, IQR) (n: 580)	33 (28 to 37)	31 (27 to 35)	33 (28 to 37)	34 (30 to 37)	0.011	0.001	0.293
Foreign origin (%) (n: 565)	60.9 (344/565)	66.2 (90/136)	57.2 (182/318)	64.9 (72/111)	0.075	0.829	0.159
Route of infection (sexual/other) (%) (n: 489)	86.5 (423/489)	86.8 (99/114)	86.2 (237/275)	87.0 (87/100)	0.863	0.973	0.838
Nulligravida (%) (n: 579)	21.6 (125/579)	27.5 (39/142)	18.9 (61/322)	21.7 (25/115)	0.040	0.291	0.518
Nulliparous (%) (n: 579)	45.4 (263/579)	52.8 (75/142)	40.1 (129/322)	51.3 (59/115)	0.011	0.809	0.037
At least one previous cesarean section (%) (n: 576)	34.9 (201/576)	10.1 (14/139)	47.5 (153/322)	29.6 (34/115)	<0.001	<0.001	<0.001
HBV-coinfected (%) (n: 566)	9.4 (53/566)	12.1 (17/140)	8.6 (27/313)	8.0 (9/113)	0.243	0.277	0.828
Symptomatic HIV Disease (CDC stage B or C) (%) (n: 577)	2.9 (17/577)	2.8 (4/142)	2.8 (9/321)	3.5 (4/114)	0.994	0.752	0.704
HIV diagnosis during current pregnancy (%) (n: 572)	21.2 (121/572)	28.6 (40/140)	16.6 (53/319)	24.8 (28/113)	0.003	0.499	0.056
Months from HIV diagnosis (median, IQR) (n: 572)	58 (12 to 117)	49 (-2 to 109)	68 (20 to 131)	39 (0.5 to 106)	0.015	0.673	0.009
Antiretroviral-naïve at start of pregnancy (%) (n: 577)	27.6 (159/577)	34.5 (49/142)	23.1 (74/321)	31.6 (36/114)	0.010	0.621	0.072
On ARV at conception (%) (n: 578)	64.4 (372/578)	59.2 (84/142)	66.8 (215/322)	64.0 (73/114)	0.114	0.426	0.596
First CD4 count in pregnancy (cells/mm ³ , median, IQR) (n: 566)	498 (346 to 676)	508 (364 to 624)	497 (341 to 681)	476 (344 to 707)	0.900	0.898	0.993
Plasma HIV-RNA copies < 50/ml at third trimester (%) (n: 505)	88.3 (446/505)	98.6 (140/142)^a	83.5 (232/278)	87.1 (74/85)	<0.001	<0.001	0.424
<i>Pregnancy outcomes</i>							
Week of delivery (median, IQR) (n: 580)	38 (37 to 39)	39 (38 to 40)	38 (38 to 38)	37 (36 to 38)	<0.001	<0.001	<0.001

Table 3 (continued)

	All (<i>n</i> : 580)	Vaginal (<i>n</i> : 142)	ECS (<i>n</i> : 323)	NECS (<i>n</i> : 115)	Vaginal vs. ECS*	Vaginal vs. NECS*	ECS vs. NECS*
Z-score for birthweight (median, IQR) (<i>n</i> : 542)	-0.22 (-0.84 to 0.36)	-0.28 (-0.98 to 0.39)	-0.21 (-0.8 to 0.34)	-0.09 (-0.85 to 0.48)	0.444	0.342	0.754
Birthweight (g, median, IQR) (<i>n</i> : 542)	3000 (2710 to 3280)	3100 (2840 to 3440)	3030 (2750 to 3250)	2857 (2462 to 3137)	0.011	<0.001	<0.001
Low birthweight (%) (<i>n</i> : 546)	12.8 (70/546)	6.5 (9/139)	10.7 (32/299)	26.9 (29/108)	0.157	<0.001	<0.001
Delivery complications, any ^b (%) (<i>n</i> : 579)	11.2 (65/579)	12.7 (18/142)	8.4 (27/322)	17.4 (20/115)	0.150	0.290	0.007
Anemia/hemorrhage	6.6 (38/579)	7.0 (10/142)	5.0 (16/322)	10.4 (12/115)	0.371	0.334	0.040
Fever/infection	2.8 (16/579)	2.1 (3/142)	1.9 (6/322)	6.1 (7/115)	0.554	0.095	0.022
Other	3.1 (18/579)	4.2 (6/142)	2.2 (7/322)	4.3 (5/115)	0.217	0.962	0.221
Intrauterine growth restriction (BWZ < 10th centile) (%) (<i>n</i> : 542)	12.4 (67/542)	14.4 (20/139)	11.8 (35/296)	11.2 (12/107)	0.453	0.463	0.866
Apgar score < 7 at 5 min after birth (%) (<i>n</i> : 556)	1.4 (8/556)	0.7 (1/136)	1.3 (4/311)	2.8 (3/109)	0.519	0.233	0.262
HIV transmission (%) (<i>n</i> : 568)	0.4 (2/568)	0 (0/139)	0.3 (1/316)	0.9 (1/113)	0.507	0.266	0.446
Major birth defects (%) (<i>n</i> : 559)	5.7 (32/559)	5.9 (8/135)	3.9 (12/311)	10.6 (12/113)	0.332	0.176	0.008

Bold values indicate statistical significance and italic values indicate *p* value close to statistical significance. Same font used for *p* value and source data

ECS elective cesarean section, NECS non-elective cesarean section, ARV antiretroviral treatment, IQR interquartile range, BWZ birthweight Z-score (adjusted for gender and gestational age)

**p* value: Chi square or Fisher test for categorical variables, Mann–Whitney *U* test for quantitative variables

^aTwo cases with detectable low HIV-RNA (< 100 copies/ml) allowed to deliver by vaginal route

^bMultiple complications observed in a few cases

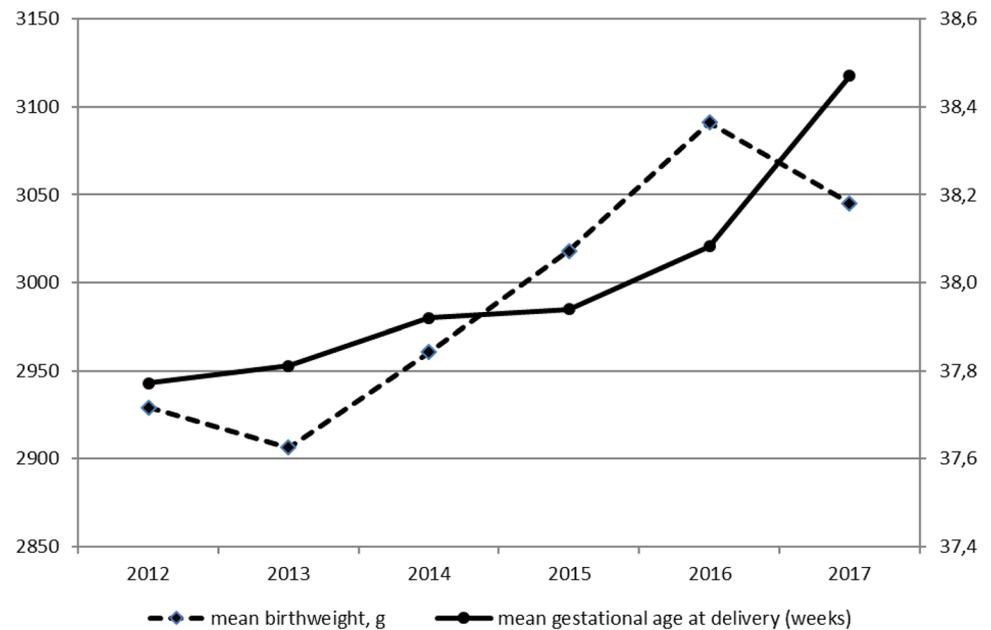
delivery reporting previous cesarean sections, compared to almost half of the women with ECS and almost 30% of the women with NECS (Table 3).

Following a previous cesarean section, women had a significantly higher likelihood of delivering again by elective cesarean section compared to vaginal delivery (odds ratio 8.083, 95% CI 4.462–14.642, $p < 0.001$). History of previous CS, however, did not affect the rate of delivery complications that were equally common in women with (10.5%, 21/200) and without (11.5%, 43/375) previous CS (odds ratio 1.104, 95% CI 0.635–1.918, $p = 0.726$).

Discussion

We here showed a first comprehensive evaluation of the national SIGO-HIV Protocol for vaginal delivery in HIV, based on almost six hundred cases followed at twelve participating centers since its implementation in 2012. The main eligibility criterion was represented by undetectable HIV-RNA plasma viral load (< 50 copies/ml in 2012). This approach is common to most national guidelines from European countries, while other European (France,

Fig. 2 Mean birthweight and mean gestational age at delivery, 2012–2017



Sweden, Denmark and Holland) and non-European countries (Canada, US) have selected a less stringent approach, considering eligible for vaginal delivery also women with low-level detectable HIV-RNA (usually no more than 150–1000 copies/ml, according to the individual national guidelines) [2–5, 14–19].

Since the implementation of the protocol, the rate of vaginal delivery increased significantly over time, almost doubling between 2012 and 2017, from 18.9 to 35.3% considering all cases, and from 33.4 to 60.0% considering only potentially eligible cases. These favourable findings clearly indicate increasing confidence in this approach to delivery in HIV-infected women in Italy.

Despite this positive significant increase, the overall rate of vaginal delivery in HIV (24.5%) remains still lower compared to other western countries that have achieved rates up to 50% or higher [19–26]. The corresponding 75.5% rate of delivery by cesarean section (elective or non-elective) still represents more than twice the national rate in the Italian general population [27]. This strongly indicates a persisting preference for cesarean section in HIV-infected women that is particularly marked in the presence of a previous cesarean section. The overall rate of previous cesarean section in this case series was 34.9%, but large and significant differences were observed among the three groups defined by mode of delivery. Although vaginal delivery was allowed in women with history of cesarean section, this occurrence was highly uncommon, and women with a previous cesarean section were eight times more likely to repeat ECS compared to having a vaginal delivery. This association is consistent in direction and size of effect with the data from Orbaek et al. that

showed an 11-fold higher likelihood of this occurrence (aOR 11.0; 95% CI 4.5–26.8) [23].

We did not collect information on the attitudes and beliefs of women and clinicians on this matter and are, therefore, unable to indicate the actual reasons underlying this preference. It could be speculated that in women with HIV, even in the absence of a substantial risk of transmission and of obstetrical reasons mandating ECS, clinicians might consider repetition of ECS a safer option, even if the guidelines for the general population recommend a trial of labor. On the other side, women with HIV who had already experienced a cesarean delivery with no major complications and who had been informed in previous pregnancies of the protective role of this approach against HIV transmission might have considered this option more reassuring. Given the significant trend observed, it is also likely that in the next future rates will show a further increase, reducing or eliminating the current gap with other countries.

The overall rate of vertical HIV transmission was minimal (0.4%), with just two cases of transmission, none of which occurred among the women who had a vaginal delivery. Such figures are fully consistent with the low rates of transmission (usually below 1%) observed in women who had a vaginal delivery with low or undetectable viral load [19–26]. Although the numbers are relatively limited, this is a favorable finding that may further encourage clinicians to adopt this approach in clinical practice.

No maternal or infant mortality was observed and infant morbidity was low. The interpretation of this finding should, however, take into account the eligibility criteria that excluded preterm cases. In general, adverse outcomes were more frequent in the group with non-elective cesarean

section, reflecting the presence of obstetrical or infant conditions that may lead to emergency delivery; this also includes congenital defects that were significantly more frequent in the group with non-elective cesarean delivery.

The rate of delivery complications in the early postpartum period was limited (11.2%), with no significant differences between vaginal delivery and ECS, while, not unexpectedly, NECS was associated with a significantly higher rate of complications. Our overall rate of delivery complications was consistent with the studies of Reitter et al. [21] and Briand et al. [24] and with the systematic review by Kennedy et al., [25] but lower compared to the rate in the study by Livingston et al. (19%) [20]. Most of these studies, however including the systematic review, found a significant higher occurrence of complications with ECS, compared to vaginal delivery [24–26], while we observed no significant difference. This finding may have different possible explanations, represented by differences in the selection of centers (all participating centers in this study were reference HIV centers with long-term expertise in HIV and pregnancy), limited sample size, underreporting, or different populations studied. We cannot exclude, in particular, preferential selection of women at lower risk, based on information that we were unable to capture. Although it is well known that the risk of maternal complications increases with the number of ECS performed [28–34], in our study history of previous CS was not associated with increased risk of delivery complications that were equally common in women with and without previous cesarean section.

Conclusion

During the first 5 years of implementation of the national SIGO-HIV protocol for vaginal delivery, we found no evidence of major additional risks for vaginal delivery in HIV-infected women with undetectable HIV-RNA. Offering vaginal delivery in such context might slightly but significantly extend pregnancy duration compared to a strategy of elective delivery at 38 weeks and lead to a slightly higher birthweight. Elective cesarean section remains recommended when HIV-RNA is not suppressed in late pregnancy or when preterm labor occurs. Despite the increasing adoption of vaginal delivery among women with HIV, there is still room for improving the opportunities to achieve undetectable HIV-RNA in late pregnancy and to have a vaginal delivery.

To ensure a wider implementation of the SIGO-HIV protocol, all health care professional should be involved: gynaecologists, midwives, infectivologists and neonatologists.

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Author contributions CT conceived the idea for the study and managed the project. CT, PM, MR and MF designed the study. CT, GM, MS, BT, IC, LF, AS, GS, AV, SD, AM, MB, VF, TT, PM and MR substantially contributed to acquisition of data. MF and CP were responsible for statistical analysis. CT and MF drafted and finalised the manuscript. All the authors gave final approval to the final version to be published.

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Compliance with ethical standards

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical approval The study protocol (“Protocollo di Parto vaginale in pazienti HIV+ in terapia antiretrovirale altamente attiva (HAART) con carica virale non dosabile e CD4+ > 200/mm³ stabili da almeno 4 settimane al momento del parto”) obtained central ethics approval on November 30, 2011 (OIRM/S. Anna—Ordine Mauriziano di Torino Ethics Committee, ref. 54081/C28.2) and was subsequently approved by the Ethics Committee of each participating center (Twelve centers, listed in acknowledgements). Data collection used the forms and procedures of the National Program on Surveillance on Antiretroviral Treatment in Pregnancy (Ethics approval: ref. no. 578/2001 from the Ethics Committee of the I.N.M.I. Lazzaro Spallanzani in Rome).

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