Original Investigations

Perinatal outcomes of 25 hiv-infected pregnant women: hacettepe university experience

İnkaya et al. Outcomes of HIV Pregnancies in Turkey

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Abstract

Objectives: To evaluate perinatal outcomes of HIV-infected pregnant women in Turkey.

Methods: Maternal characteristics, pregnancy complications, laboratory findings (HIV virus load, CD4 cell count, CD4/CD8 ratio), neonatal features and final HIV status of the baby are retrospectively analyzed.

Results: The sample includes 26 singleton pregnancies, from 25 HIV-infected women. The participants’ ethnicities are Turkish (n=18), East European (n=4), Asian (n=2) and African (n=2). The majority (76.9%) of the women aware of their HIV status before becoming pregnant. Four cases (15.3%) are diagnosed during pregnancy and two cases (7.8%) at the onset of labor. The results for median HIV viral load, CD4 count, and CD4/CD8 ratio at birth are 20 (0-34 587), 577 (115-977), and 0.7 (0.1-1.9), respectively. The positive HIV viral load rate is 5.5% in eighteen women taking anti-retroviral treatment. The rates of gestational diabetes mellitus, gestational hypertension, intrauterine growth restriction, and preterm delivery are 3.8%, 3.8%, 7.6%, and 8%, respectively. The mean gestational week at birth is 38 weeks and mean birthweight is 2972 ±329g. There are two HIV infected babies, with an infection rate of 8.3%. There is one needle-related accident during surgery.

Conclusion: Timely diagnosis of HIV infection during pregnancy is important for preventing mother to child transmission (MTCT). HIV infected mother may give birth to HIV negative babies with the help of multidisciplinary team, composed of perinatology, infection diseases, and pediatrics specialists.

Keywords: HIV; Pregnancy; Antenatal Care; Turkey

Introduction

According to estimations in 2015, 36.7 million people are infected globally with HIV (1). Among them, 17.8 and 2.1 million are “women over 15 years of age” and children, respectively. Nearly half of infected women have access to treatment, whereas only 43% of children are under treatment (1). Treatment coverage for children is restricted, which gives importance to preventive measures in early childhood, such as preventing mother-to-child transmission (MTCT). The number of newly-infected children decreased by 47%, since 2010. Maternal antiretroviral therapy (ART) is the backbone of MTCT preventive measures but, as of 2016, 24% of pregnant women in need cannot access ART (1).

Over the last 30 years, the HIV landscape was revolutionized by the advent of new class antiretrovirals (ARVs). Currently, HIV-infected people enjoy a similar life-expectancy and quality of life as their uninfected counterparts. Annually, up to 8800 (95% CI 8400-8800) HIV-infected women give birth in USA (2). An orchestrated team effort is necessary for good reproductive health, family planning preconception health services, and prevention of MTCT (3).
As reported by the Turkish Ministry of Health in 2019, over 20,000 people are living with HIV infection in Turkey (4). Despite the low prevalence of HIV (<0.001) in Turkey, the number of newly diagnosed cases increases by 452% after 2010 (5). As well, women constitute 25% of those living with HIV/AIDS (PLWHA) in Turkey (6). MTCT is recognized in 1982 as a mode of HIV infection and numerous prevention efforts are introduced thereafter (7). Pre-conception counselling, antenatal HIV screening, ART, and access to perinatal follow-up are key preventive measures (3, 8). As a result of successful implementation, the MTCT rate in the UK decreases from 25.6% in 1993 to <0.5% in 2011, which is deemed a huge success (8, 9). Furthermore, the ACTG076 study confirms that zidovudine monotherapy lowers the risk of MTCT and ART can further decrease that from 10.4% to 1.2% (10, 11). Concerns regarding the teratogenicity risk of ART were alleviated by emerging data and, subsequently, maternal ART became the cornerstone of MTCT prevention strategies (12). MTCT in a non-breastfeeding setting will occur during pregnancy, which emphasizes the importance of prenatal care (8). As well, premature rupture of membranes is associated with increased MTCT risk (13). Use of a planned caesarean section (CS) is found to lower the risk of transmission from 10.5% to 1.8% (14). In addition, maternal viral load at delivery is another major risk factor. If perinatal maternal viral load is below 50 copies/ml, MTCT risk drops below 0.5%, regardless of treatment delivery mode (15).

Despite the growing problem of HIV infection in Turkey, there is a scarcity of real-world data from Turkish research centers. This study aims to evaluate the XXXXX Antenatal Care/HIV cohort, in terms of obstetric and perinatal outcomes.

Materials and Methods

XX XXXXX University Hospital is a tertiary referral center, located at the capital city of the Turkish Republic. The center provides multidisciplinary treatment for HIV-infected people, as well as for high-risk pregnancies. The XXXXX HIV cohort is composed of 636 PLWHA, as of October 2017, who are registered in the Infectious Diseases Clinics of XXXXX University. Among the cohort, 92 (14.4%) are female. This study consists of all HIV-infected pregnant women who delivered at the hospital between January 2009 and October 2017. Early pregnancy losses before the 22nd gestational week are excluded from analysis. During the study period, 26 deliveries are noted, in 25 pregnant women who delivered at the hospital between January 2009 and October 2017. As a result of successful implementation, the MTCT rate in the UK decreases from 25.6% in 1993 to <0.5% in 2011, which is deemed a huge success (8, 9). Furthermore, the ACTG076 study confirms that zidovudine monotherapy lowers the risk of MTCT and ART can further decrease that from 10.4% to 1.2% (10, 11). Concerns regarding the teratogenicity risk of ART were alleviated by emerging data and, subsequently, maternal ART became the cornerstone of MTCT prevention strategies (12). MTCT in a non-breastfeeding setting will occur during pregnancy, which emphasizes the importance of prenatal care (8). As well, premature rupture of membranes is associated with increased MTCT risk (13). Use of a planned caesarean section (CS) is found to lower the risk of transmission from 10.5% to 1.8% (14). In addition, maternal viral load at delivery is another major risk factor. If perinatal maternal viral load is below 50 copies/ml, MTCT risk drops below 0.5%, regardless of treatment delivery mode (15).

The data is extracted from patient files, as well as from the hospital's digital records. Maternal age, obstetric history (gravida, parity, etc.), coexisting diseases, and length of hospital stay are recorded for each patient. Main pregnancy complications, such as gestational diabetes mellitus, preeclampsia/gestational hypertension, preterm contractions, and premature preterm ruptures of membranes, are also noted. Laboratory findings on HIV virus load, CD4 cell count, CD4/CD8 ratio, and hemoglobin concentration are noted separately during pregnancy and at birth. Neonatal features, such as birthweight, Apgar scores at first and fifth minute, gestational week at birth, neonatal intensive care unit administration, hospitalization length, and final HIV status, are analyzed. Antiretroviral prophylaxis with nevirapine was administered to all babies regardless of maternal and neonatal plasma HIV RNA result for 12 weeks. Antiretroviral treatment was commenced to all babies with positive plasma/cord blood HIV RNA (detectable plasma HIV RNA).

The data is analyzed using SPSS software program, version 23. Qualitative data is presented as percentage and frequency, whereas quantitative data is presented as mean, standard deviation, and number. For known HIV-positive women, there is an integrated pregnancy follow-up program at the hospital center. PLWHA over eighteen years of age are routinely followed up in the infectious diseases department. All HIV-infected patients willing to conceive undergo extensive pregnancy counselling and, if special help is needed, the Divisions of Perinatology and Andrology are involved. Upon pregnancy, the women are referred to the Division of Perinatology for regular follow-ups. The antenatal care program is initiated quickly after pregnancy diagnosis, to prevent MTCT for cases involving known HIV infection. The center will also accept newly diagnosed PLWHA, referred from other centers, for pregnancy follow-up. The follow-up is comprised of routine prenatal ultrasonography examinations, combined or triple-test aneuploidy screening tests, glucose challenge test between the 24th to 26th gestational week, and a non-stress test after the 37th gestational week. Further evaluations are completed according to obstetric indications until delivery. A pediatric infectious disease consultation takes place in the last trimester, to further inform parents on postnatal management.

HIV-infected pregnant women are evaluated on diagnosis, as recommended by international guidelines (3). All patients undergo routine testing, including complete blood count, extensive biochemical work-up, virological work-up (viral load, genotypic ART resistance testing), immunological work-up (CD4/CD8 count), and documentation of childhood immunization and diseases. ART is started before genotypic resistance testing, as recommended by international guidelines. The treatment regime is mainly composed of a Nucleoside reverse transcriptase inhibitor (NRTI) and a protease inhibitor (PI) such as boosted-lopinavir (LPV/r). PI is preferred, as pregnancy outcomes with high genetic barrier Integrase and strand transfer inhibitor (INSTI)-based regimes are obscure and INSTIs were...
introduced recently in Turkish market. Pregnant women are checked on a monthly basis for HIV viral load and side effects of treatment. If the maternal HIV viral load cannot be suppressed below 200 copies/ml, or viral-rebounds during the third trimester, the daily dose of lopinavir/r is increased by 50% (3x400/100mg), without checking plasma drug levels. If a HIV-infected woman presents late in the course of pregnancy, or viral load remains high during the last trimester, intensive ART with NRTI, PI, and raltegravir is given.

CS after the 38th gestational week is performed after counselling with parents. Regardless of maternal HIV viral load, a zidovudine (ZDV) infusion given before surgery and continued until cordon-clamping. All the newborns were bathed twice and admitted to pediatric wards for close monitoring. Institutionally, breast feeding of PLWHA was clearly forbidden at all times and neonates were fed through formulay compounds. Antiretroviral prophylaxis was started with zidovudine syrup. Neonates born to mothers with unsuppressed HIV viral load were further evaluated for combined antiretroviral regimes as dictated by Turkish Guidelines (16).

The study protocol was reviewed and approved by a local review board (XXXXXX University Non-Interventional Clinical Studies Board decision GO-18/186-29, March 20, 2018).

Results

During the study period, 26 singleton pregnancies in 25 HIV-infected women are recorded. Total number of cases increases from 2009 to 2017, as shown in Figure 1. Mean maternal age at birth is 27.5 ±6.6 years. Most participants (n=18, 72%) are of Turkish ethnicity. Of the remaining 8 women, three had East European, two had Asian, and two had African origin. A previous abortion is noted in ten (38.4%) of the 26 women, six of which have a single abortion, three have twice miscarried, and one has three previous abortions. Overall, there are twelve primigravid women (46.2%) in the study group.

Six coexisting diseases are noted in the 25 women, including chronic Hepatitis C (CHC), major depressive disorder, asthma and tuberculous empyema. Twenty women (76.9%) knew their HIV status before becoming pregnant and eighteen were already on ART. Two HIV-positive patients refuse to take medications during pregnancies. Two women (15.3%) in the study group were diagnosed during pregnancy and the remaining two (7.8%) were diagnosed at onset of labor. ARVs was delivered to the latter four cases immediately after diagnosis. Of the two women presenting at delivery, one delivered with CS under zidovudine (ZDV) prophylaxis and the last one did not receive perinatal prophylaxis, due to late admission and urgent CS.

Laboratory test results are obtained for the twenty participants. The median HIV viral load, CD4 count, and CD4/CD8 ratio at the first trimester are 2203 copies/ml (0-529 000), 460/mm3 (26-786), and 0.7 (0.04-1.3), respectively. We analyze the laboratory parameters for all the women, except the two diagnosed at birth. The results for median HIV viral load, CD4 count, and CD4/CD8 ratio are 20 copies/ml (0-34 587), 577/mm3 (115-977), and 0.7 (0.1-1.9), respectively.

The blood HIV viral load is under 200 copies/ml at birth in the twenty pregnant women. After excluding the two participants with missing data, four women (16.7%) are found to have an HIV viral load below 20 copies/ml before delivery. Within the study sample, two refused treatment, one was receiving ART, and one had a late diagnosis. The positive HIV viral load rate is 5.5% in the eighteen women receiving ART. There are 23 participants with full data on CD4 count and CD4/CD8 ratio. When participants are classified into groups, according to their CD4 count, seventeen are below 500/mm3, two are between 350-500/mm3, two are between 200-350/mm3, and two are above 200/mm3. The women are further divided in terms of CD4/CD8 ratio. From this, eight are above 1, nine are between 0.5-1, three are between 0.2-0.5, and three are below 0.2.

There were 3 PLWHA with CD count below 200 copies/ml. Two of these were late presenters, they presented on term thus they did not receive any prophylactic treatment. Third-women was on trimethoprim/sulfamethoxazole (1 ds tablet/day) prophylaxis during gestation however, it was discontinued after pregnancy was diagnosed. Immunization of the PLWHA is of concern. All the patients applying to our center has been evaluated for childhood vaccinations and respective serology results. Immunization includes conjugated pneumococcus, polysaccharide pneumococcus, seasonal influenza, diphtheria-tetanus-acellular pertussis, mumps-measles-rubella, varicella zoster, hepatitis B and hepatitis-A vaccines. Live cell vaccines are deferred in pregnant woman. All vaccinations are performed according to Turkish HIV treatment guidelines (16).

After excluding data from of one participant with late admission and lacking data, the remaining 25 women were evaluated for pregnancy-related complications. Three instances of hospitalization during pregnancy were noted (two with pneumonia and one with gastroenteritis). One woman (3.8%) developed insulin-dependent gestational diabetes mellitus. Additionally, gestational hypertension was present in one (3.8%) women. We did not observe a premature rupture of membranes among any of the participants. Four women were hospitalized, due to preterm contractions, and two of those women delivered before the 37th gestational week. As a result, the preterm delivery rate is 8%. Also, intrauterine growth restriction was recorded only in two cases (7.6%).
There were eleven male (42.3%) and fourteen female (53.8%) babies born to HIV-infected mothers in the study sample. Delivery data displayed a mean gestational week at birth of 38 weeks, with a range of 35 0/7 to 40 1/7 weeks. There were two (7.7%) vaginal deliveries within the group and CS rate was 92.3%. Mean birthweight was 2972 ±329g. Mean Apgar scores at first and fifth minute were 8.4 and 9.4, respectively. Neonatal resuscitation in the delivery room is performed for one infant after birth. Furthermore, the HIV status of two babies could not be retrieved from patient files. Of the remaining 24, only two were HIV-infected, showing a low MTCT rate of 8.3%. There were no stillbirths, perinatal mortalities, or congenital abnormalities.

One HIV-infected baby was born to a 39 year-old mother, gravida 2 and parite 1, whose HIV status is detected within the first trimester. The expectant woman has a high viral load (256,000) at the time of diagnosis and is given treatment immediately. The baby’s HIV RNA was 56, CD4 was 266, and CD4/CD8 ratio was 0.4 at birth. The baby was delivered via CS in the 38th gestational week and weighs 3230g. Records for the other HIV-infected baby show the mother was diagnosed with HIV at delivery. The maternal laboratory findings were HIV RNA 11,100copies/ml, CD4 count 562/mm³, and CD4/CD8 ratio was 0.8. The CS delivery was performed in the 38th gestational week and the 3470g fetus was transferred to the neonatal intensive care unit.

Mean hemoglobin decrease after delivery was 1.7 ±0.9 and there was no need for red blood transfusion for either infant. A surgical site infection develops in one mother (3.8%), treated with empiric antibiotics and wound care. There was one needle-stick occurred during delivery affected a member of surgical team but antiretroviral prophylaxis was deferred as the index-patient had undetectable HIV RNA.

Discussion
Despite decreasing trends in across the world, HIV infection incidence is increasing in Turkey, due to lack of knowledge and stigma (4, 5). Effective interventions must include multidisciplinary teams and involvement of relevant stake holders. This, in turn, necessitates increasing scientific information available at every level. In this study, we evaluate obstetric and perinatal outcomes of HIV-infected women in the XXXXX cohort. This is the first scientific report on obstetric outcomes in the HIV-infected Turkish population.

In accordance with increasing HIV incidence in Turkey, the number of HIV-positive pregnancies is also increasing. This may be due to changes in epidemiology and understanding of HIV infection among the population at risk (17). We also show a near five-fold increase in HIV-positive pregnancy rates over the last three years.

Contrary to previous reports, our study records intentional pregnancies among the woman receiving ART. Unintended pregnancies risk harm to the mother and to the baby. Furthermore, unintended pregnancies among HIV-infected women are associated with delayed antenatal care, poor fetal outcomes, and poor retention of postpartum care (18, 19).

HIV-infected sero-discordant or sero-concordant partners are recommended to receive reproductive counselling before conception, including identification of coexisting conditions and risk factors associated with adverse maternal and fetal outcomes (20). Ideally, all sexually active women require screening for HIV infection before considering pregnancy (3). Raffe et al. report 72% of pregnant women know their HIV status before conceiving (8). Furthermore, in a study of a large British cohort, antenatal HIV serostatus awareness is shown to increase from 24.6% between 2000 and 2006 to 12.5% between 2007 and 2011 (9). Republic of Turkey Ministry of Health recommends a HIV screening test with the consent of the pregnant woman in new prenatal care management guidelines in 2018 (21).

Most centers, though, test all pregnant women in their first trimester and at birth. Our results show the importance of HIV screening during pregnancy in Turkey, as 15.3% of participants are diagnosed during pregnancy and 7.8% are diagnosed at onset of labor.

Risk of MTCT has been affected by many factors including high maternal viral load, lower CD4 count of the mother, mother with AIDS defining disease, premature rupture of the amniotic membrane, preterm delivery and breastfeeding (22). As maternal viral load is the main determinant of the above mentioned risk factors, ART delivered during pregnancy is the cornerstone of MTCT elimination strategies. Recent guidelines recommend the use of ARTs, regardless of viral load and immunologic status, as the preventative affect is present irrespective to these factors. Furthermore, ART drugs can affect the fetus through the placenta and act as a pre-exposure prophylaxis (23).

Initiation of PI-based ART is associated with preterm deliveries in univariate analysis but not multivariable analyses (24). Main goal of ART during pregnancy is to suppress the virus to an undetectable level at the time of delivery so that MTCT will be infrequent event. Maintaining a pregnancy-compatible ART is recommended to all women. Women conceived under ART should be evaluated for the possible adverse outcomes of certain antiretroviral drugs. Dolutegravir was accused to lead neural tube defects (NTD) in the newborn however, recent data shows decreased NTD risk when compared to previous report (25, 26). However, debate over antiretroviral associated NTD is not over yet, so that drugs with better safety profile should be preferred during pregnancy such as lopinavir, ritelgravir and efavirenz (especially in resource poor settings). In our cohort 2 MTCT events were seen. Underlying reason for
transmission was late diagnosis in one case and high viral load at first trimester and delivery in the second case. High viral load at birth is related with the increased risk of MTCT according to our findings together with literature information.

PI-based treatments, including ritonavir, are deemed to cause preterm delivery (3). The potential mechanism underlying this effect remains obscure. Our results demonstrate that preterm delivery rate with PI-based treatments is 8%. Despite preterm delivery risk, PI-based ART promises various advantages compared to other regimes. In a resource-poor setting, with little access to genotypic resistance testing, high genetic barrier of PIs provides opportunity to administer ART without genotypic resistance test results. Moreover, PIs are potent drugs and lower viral load instantly (27). As distribution volumes may change during the third trimester, lopinavir levels are usually checked beforehand (28). In our study, we do not have access to therapeutic drug monitoring for ARTs. Therefore, we closely monitor the pregnant women for HIV viral load at the third trimester. In a case of virologic rebound during third trimester, daily dosing of is increased by 50%, as recommended by Manawi et al (29).

In addition to the importance of MTCT, HIV-positive pregnancies are vulnerable to several other complications. A previous study shows no increased risk in preeclampsia, preterm birth, or smallness for gestational age, in women receiving treatment (30). A more recent meta-analysis demonstrates an two-fold increase in risk for preterm delivery and low birthweight in HIV-positive pregnancies (31). Our results show a preterm delivery rate of 8% and IUGR rate of 7.2%. The number of cases is low in this study, so we cannot calculate a definitive frequency of prematurity among these cases.

The mode of delivery is dependent on multiple factors in HIV infected pregnant women. Previously, elective CS was recommended to minimalize the risk of MTCT in all these pregnancies (15). With the findings of recent studies, vaginal delivery is shown to be safe for neonates if maternal viral load is <1000 copies/mL. Thus, CS should be performed only for obstetric indications such as placenta previa, previous CS history, malpresentation, fetal distress etc. (32). High rate of CS in our study shows, clinicians tend to choose elective CS most probably due to medicolegal issues.

Pregnancy-induced hypertension and preeclampsia are important causes of maternal morbidity and mortality. Fortunately, studies report risk of preeclampsia is not increasing in HIV-infected women (33, 34). We also show that frequency of preeclampsia is only 3.8%. GDM is another concern for HIV-positive pregnant women, due to related medication and infection. Previous studies, however, find risk of GDM is not increasing in HIV-positive expectant women, as compared to healthy pregnancies (35, 36). Our findings are in concordance with data found in the relevant literature.

The major limitation of current study is the small number of cases which is conducted at one center. Missing and unreliable data because of the retrospective design of the study is the other limitation of the study.

Timely diagnosis of HIV infection during pregnancy is important for preventing mother to child transmission (MTCT). HIV infected mother may give birth to HIV negative babies with the help of multidisciplinary team, composed of perinatology, infection diseases, and pediatrics specialists.

REFERENCES


Table 1. Maternal characteristics and main findings

<table>
<thead>
<tr>
<th>Maternal characteristics</th>
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<tr>
<td>Mean Age</td>
<td>27.5 ± 6.6</td>
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<tr>
<td>Ethnicity</td>
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<tr>
<td>Turkish</td>
<td>18 (72%)</td>
</tr>
<tr>
<td>East European</td>
<td>3 (12%)</td>
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<tr>
<td>Asian</td>
<td>2 (8%)</td>
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<tr>
<td>African</td>
<td>2 (8%)</td>
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<tr>
<td>HIV diagnosis</td>
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<tr>
<td>Before conception</td>
<td>20 (76.9%)</td>
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<tr>
<td>pregnancy</td>
<td>4 (15.4%)</td>
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<td>At birth</td>
<td>2 (7.7%)</td>
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<tr>
<td>Treatment</td>
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<tr>
<td>Before + during pregnancy</td>
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<tr>
<td>Started in pregnancy</td>
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<td>None</td>
<td>1 (3.8%)</td>
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<tr>
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<tr>
<td>During Pregnancy (n=20)</td>
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<tr>
<td>HIV viral load</td>
<td>2203 copies/ml (0-529 000)</td>
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<td>CD4 count</td>
<td>460 /mm³ (26-786)</td>
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<td>CD4/CD8 ratio</td>
<td>0.7 (0.04-1.3)</td>
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<td>At birth (n=24)</td>
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<td>HIV viral load</td>
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<tr>
<td></td>
<td>GHT</td>
</tr>
<tr>
<td>------------------</td>
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<td>1 (3.8%)</td>
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**Fetal**

<table>
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<tr>
<th></th>
<th>Gestational week</th>
<th>Birthweight</th>
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<th>Apgar 5\textsuperscript{th} minute</th>
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<td></td>
<td>38 (35 0/7 - 40 1/7)</td>
<td>2972 ± 329</td>
<td>8.4 ± 1.47</td>
<td>9.4 ± 1.47</td>
</tr>
</tbody>
</table>

Abbreviations; GDM: Gestational diabetes mellitus, GHT: Gestational hypertension, IUGR: Intrauterine growth restriction

**Figure 1. Total number of deliveries among HIV infected women**