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Antiretroviral Therapy Among HIV-Infected Pregnant Women on Their Offspring

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Abstract

The risk of mother-to-child transmission (MTCT) of human immunodeficiency virus (HIV) infection is approximately 30%. However, antiretroviral drugs can reduce MTCT to less than 2%. This study was designed to determine the effect of antiretroviral therapy among HIV-infected women and its maternal and neonatal outcomes in Iran. The study is a retrospective analysis of mother-infant data from Shiraz, Southern Iran, between 2006 and 2012. HIV-infected pregnant women were divided into two groups of intervention (receiving treatment or chemoprophylaxis) and control (not receiving any treatment). Maternal and neonatal information were extracted and recorded. The data were entered into SPSS software and were analyzed. The mother-to-child transmission was 2.9% in the intervention group compared to 15.8% in the control group (OR=0.01, 95% CI: 0.002-0.125, p<0.0001). The infant HIV infection rate was significantly higher in male infants (OR=2.76, CI 95% 2.213-3.327), NVD delivery (OR=3.78, CI 95% 3.140-4.409), and breastfeeding (OR=26, CI 95% 7.87-85.90). Treatment intervention significantly reduces the HIV transmission from infected mothers to their infants. However, the rate of vertical transmission in Iran remains higher than those reported in developed countries despite treatment interventions, and additional preventive measures appear necessary.

Keywords: Chemoprophylaxis; Treatment; Pregnancy; HIV; Mother-to-Child Transmission.

Introduction

About half of the 33.4 million people infected with HIV (Human Immunodeficiency Virus) in the world are

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women, and about half a million children infected with HIV are infected through vertical transmission (1, 2). If a woman infected with HIV becomes pregnant, there is a chance of 35% of mother-to-child transmission (MTCT). Perinatal HIV infection can occur during pregnancy, at delivery, or during lactation. About 9% of the infants who were HIV-negative at birth would be infected after 18 months through breastfeeding (3, 4). It is estimated that 200,000 infants annually in the world become infected with HIV through mother-to-child transmission (5).

Strategies for the treatment of pregnant women with HIV in the pharmacological area and recognition of the ways to prevent perinatal and during labor transmission have made considerable progress. In the US and Europe, using antiviral drugs has dramatically decreased the risk of mother-to-child transmission of HIV infection. Among factors with a key role in such a reduction, universal screening of pregnant women with HIV, cesarean delivery, and if possible, avoiding breastfeeding by mothers can be mentioned (6, 7).

However, with antiretroviral drugs and effective viral suppression, the risk of infants' infection through mother-to-child transmission has declined to less than 2% in Europe and the United States (2, 4). It is thus recommended that all pregnant women with HIV, regardless of CD4 count and HIV RNA level, receive antiviral prophylaxis to prevent mother-to-child transmission. The post-exposure prophylaxis (PEP) in infants has also been suggested to reduce the risk of HIV acquisition. Post-exposure prophylaxis can protect the infant against the virus that may have been transmitted to the embryo during labor or during passage through the birth canal (8-11). Antiviral prophylaxis in infants whose mothers have received HIV care late in pregnancy is very important. These women, even in cases of receiving the treatments in the best conditions, may be detected at high risk of viremia, which may last for weeks or months to be suppressed (12-14).

Some data suggest that a combination of antiviral drugs with the aim of complete viral suppression can decrease the risk of vertical transmission of HIV infection. The data also showed that a woman with no detectable viral count, despite the low risk, can still transmit the HIV infection to her child. Thus, regardless of the number of viruses, antiviral prophylaxis is recommended for all pregnant women to prevent mother-to-child transmission (15).

Data available on HIV infection in Iran are different. Sedaghat et al. (16) estimated that the number of infected patients will increase from 88,000 in 2010 to 105,000 in 2014. According to the latest report of HIV cases recorded by the end of 2013 in Iran, which was provided according to statistics collected from the Universities of Medical Sciences and Health Services, a total of 26125 people with HIV were identified in the country. The mother-to-child transmission accounts for 3.2% of cases (17).

No study has been done on the vertical transmission of HIV and the effect of prophylaxis on infants' infection in Iran so far. Also, similar studies have been conducted in limited countries in recent years. Therefore, this study was designed to determine the effect of chemoprophylaxis or therapy in women with HIV and its maternal and neonatal outcomes.

Materials and Methods

The study is a retrospective analysis of mother-infant data from the records of the Shiraz Counseling Center for Behavioral Disorders. Eligible subjects were HIV-infected pregnant women who accessed the service between April 2006 and March 2012 and delivered newborns. Their infants were followed up for 18 months. Other subjects who HIV diagnosed in their infants in follow-up period were also included in the study. Infants with persistence of antibody beyond 18 months of age and/or a positive virological marker of infection, regardless of age, were considered HIV-infected. The research protocol was previously approved by the Ethical Committee of Shiraz University of Medical Sciences (Project number 3850/2012).

According to the protocol of Iran's AIDS Society, pregnant women with HIV should receive treatment or chemoprophylaxis; however, in some circumstances, such as lack of prenatal detection or lack of mothers' cooperation, this may not happen. Mothers who used the IMOD or lacked cooperation in referring to the center and in completing the questionnaire were excluded from the study.

Accordingly, the study population was divided into two groups: HIV-infected pregnant women who received treatment or prophylaxis, defined as the intervention group, and HIV-infected pregnant women who received no treatment or chemoprophylaxis, or received incomplete treatment or chemoprophylaxis, defined as the control group. Mothers whose diagnosis of HIV was made after their infant's infection was confirmed were also included in the control group.

Information collected includes: demographic and epidemiologic characteristics of the pregnant women, age at pregnancy, smoking, use of Methadone, hookah, opium, heroin and alcohol, other diseases (such as diabetes, hepatitis C, Hepatitis B, tuberculosis, hypertension), hemoglobin concentration, gravidity and parity, educational level, place of residence (urban or

rural), type of delivery (normal vaginal delivery or cesarean), gestational age at delivery, number of CD4, time of diagnosis (before pregnancy, during pregnancy, perinatal and postnatal), clinical stage according to the WHO, in case of receiving intervention, the type and duration of intervention, the reason for not-receiving the treatment or chemoprophylaxis. Also, the information on newborns, such as the following, was recorded: Sex, birth weight, prematurity, infant feeding (breast milk or formula), survival status (dead or alive newborn), diagnosis time of neonatal infection with HIV, history of hospitalization from birth to 18 months, and the follow-up period after birth.

Data were cleaned, edited, entered into a computer, and analyzed using the Statistical Package for the Social Sciences (SPSS) version 18.0 (SPSS Inc., Chicago, IL). The data obtained were described using frequency tables and corresponding graphs. To describe qualitative properties, frequencies and percentages were used, while mean and standard deviation were used for quantitative traits. To determine the relationship between qualitative variables, the chi-square test and the Fisher exact test were used, and quantitative variables were analyzed using the t-test. The T-Test was used to confirm normal distribution, while the Mann-Whitney test was used when normality was rejected. The statistical significance level was set at 0.05 for all tests, so that P-values < 0.05 indicate statistically significant differences.

Results

HIV-infected Pregnant Women

Of the 81 pregnant women who participated in this study, 34 and 47 were assigned to the intervention and control groups, respectively. The mean age of the women was 29.21±5.77 years in the intervention group and 28.27±4.57 years in the control group, with no significant difference (P=0.422). There was no significant difference in gravidity or parity between the intervention and control groups (P=0.158 and P=0.845, respectively). Regarding educational status, in the intervention group, 2 patients were illiterate, 20 patients had an education level below diploma, and 14 patients had a college or higher level of education. Whereas, in the controls, there were 4 illiterate people, 30 people with an education level below diploma, and 13 subjects with a college or higher level of education. There was no significant difference between the two groups regarding educational level (P = 0.123). In the intervention group, 24 women were urban residents, and 10 were rural residents. However, in the control group, 31 women lived in urban areas, whereas 16 lived in rural areas. Two study groups had no significant difference regarding the place of residence (urban or rural) (P=0.660). Regarding prenatal care, the women in the two groups did not differ, with 37 patients (78.7%) in the control group and 32 patients (94.1%) in the intervention group receiving prenatal care (P = 0.065).

The mean hemoglobin level before delivery was 11.61±1.44 mg/dl and 11.63±0.96 mg/dl in the intervention and control groups, respectively, and no significant difference was observed between the two groups (P=0.932). The mean CD4 cell count before delivery was 373.44±173.45 cells/mm3 in the intervention group and 352.20±148.23 cells/mm3 in the control group, with no significant difference (P=0.682).

Cesarean delivery was significantly higher in the intervention group, so that 70.6% of the women in this group had cesarean section, while the frequency of this type of delivery in the control group was 46.8% (P=0.033). The mean gestational age in the intervention group was 37.06±2.41 weeks, while it was 38.48±1.59 weeks in the control group, a difference was significantly lower in the intervention group (P=0.002).

Diagnosis of HIV infection in the control group was as follows: 6 subjects (12.8%) before pregnancy, 7 patients (14.9%) during pregnancy, 6 patients (12.8%) during labor and 28 cases (59.5%) after delivery. Diagnosis of infection in the intervention group was as follows: 16 subjects (47.1%) before pregnancy and 18 patients (52.9%) during pregnancy (P<0.0001). Only 3 patients had received HIV treatment before pregnancy and all of them were in the intervention group.

According to the WHO criteria (in patients diagnosed before delivery), in the control group, 10 patients (76.9%) were in stage I, and 3 patients (27.1%) were in stage III. No patient in this group was in stages II and IV. In contrast, in the intervention group, 31 patients (91.3%) were in stage I, 1 (2.9%) in stage II, 1 (2.9%) in stage III, and 1 (2.9%) in stage IV. The difference in disease stage between the two groups was not significant according to WHO criteria (P=0.152). In the control group, 34 patients (72.3%) were not treated due to lack of knowledge about infection, and 13 patients (27.7%) were not treated due to lack of cooperation. In the intervention group, 22 patients (64.7%) had received prophylaxis, and 12 patients (35.3%) had been treated.

Characteristics of the Newborns

In the control group, 28 newborns were male and 19 were female, whereas in the intervention group, 13 were male and 21 were female. The two groups did not differ regarding the gender of newborns (Table 1). The mean birth weight of newborns in the intervention and control groups was 2794.12±579.28 g and 3005.53±475.82 g,

Table 1. Comparison of characteristics and outcomes of the newborns of HIV-infected pregnant women between the two intervention and control groups

		Intervention group N (%)	Control group N (%)	P value
Gender	Male	13 (38.2)	28 (59.6)	0.058*
	Female	21 (61.8)	19 (40.4)	
Prematurity	+	9 (26.5)	7 (14.9)	0.260**
	-	25 (73.5)	40 (85.1)	
Infant survival	Alive	33 (97.1)	41 (87.2)	ns†
	Dead	1 (2.9)	6 (12.8)	
Breastfeeding	+	0 (0)	33 (70.2)	<0.0001**
	-	34 (100)	14 (28.8)	
Progression to HIV	+	1 (2.9)	3 (15.8)	<0.0001**
	-	33 (97.1)	16 (84.2)	
Hospitalization	+	3 (8.8)	22 (46.8)	0.031**
	-	31 (91.2)	25 (53.2)	

*chi-square, **Fisher exact, †ns=not significant

Table 2. Neonatal and maternal factors associated with newborns' HIV infection

		HIV infected newborn		P value*
		+	-	
Time of diagnosis	Before pregnancy	2 (6.3)	20 (40.8)	<0.0001
	During prenatal care	1 (3.1)	24 (49)	
	During delivery	1 (3.1)	5 (10.2)	
	Following delivery	28 (87.5)	0 (0)	
Gender	Male	21 (65.6)	20 (40.8)	0.029
	Female	11 (34.4)	29 (59.2)	
Type of delivery	NVD	20 (62.5)	15 (30.6)	0.005
	C/S	12 (37.5)	34 (69.4)	
breastfeeding	+	26 (81.2)	7 (14.3)	<0.0001
	-	6 (18.8)	42 (85.7)	

*chi-square test

respectively; however, the t-test showed no significant difference in weight between infants born to women in both groups (P=0.076). Prematurity was observed in 26.5% of infants in the intervention group and 14.9% in the control group, with no significant difference (Table 1). One case of a dead baby in the intervention group (2.9%) and 6 cases in the control group (12.8%) were found (Table 1). The cause of death in all 6 cases of the control group was reported as HIV, but in the intervention group, the only cause was due to congenital heart disease (CHD). None of the infants in the intervention group were breastfed, whereas in the non-intervention group, 28.8% of infants were breastfed (Table 1).

At the 18-month follow-up, the admissions cases were reported as 3 in the intervention group and 22 in the control group (Table 1). The causes of being hospitalized in the control group were as follows: seven infants due to respiratory infections, 3 with diarrhea and vomiting, 3 due to low platelet count, 2 with jaundice and hepatomegaly, 2 due to Failure to thrive (FTT) and lung infections, 2 infants of FUO (fever with unknown origin), an infant with oral thrush, infectious diarrhea and BCG lymphadenopathy, one case of jaundice, and one with Bacille Calmette-Guérin (BCG) lymphadenitis. However, the cause of admission in the intervention group included two cases of pulmonary infection and one CHD case.

Mother-to-child Transmission of HIV

The mother-to-child transmission of HIV infection was significantly higher in the control group (2.9% in the intervention group versus 15.8% in the control group, P<0.0001) (Table 1). The odds ratio (OR) of MTCT of HIV was 0.01 (95% CI: 0.002-0.125) among mothers who received any intervention compared to mothers who received no treatment or chemoprophylaxis.

According to Table 2, the neonatal HIV infection rate in mothers with prenatal diagnosis was lower (P<0.0001). Also, the infant HIV infection rate was significantly higher in male infants (OR=2.76, CI 95% 2.213-3.327), NVD delivery (OR=3.78, CI 95% 3.140-4.409), and breastfeeding (OR=26, CI 95% 7.87-85.90).

Discussion

Based on the results of this study, the rate of mother-to-child transmission in women with intervention was 2.9%, and in women who received no treatment intervention, it was 15.8%. According to the latest report of recorded HIV cases in Iran in 2013, based on statistics collected from the Universities of Medical Sciences and Health Services, the mother-to-child transmission rate accounted for 3.2% of all HIV infection cases (17). However, there are no reports of the MTCT rate in the population of pregnant women in Iran, and this is the first study about mother-to-child transmission of HIV in this country. Therefore, it is not possible to compare these results with other data presented in Iran.

In comparing the results of this study with studies in other countries, in Lussiana et al. (18) the study in Angola, 68 women (65.4%) received antiviral combination therapy, but the other 36 women (34.6%) had not been treated due to being diagnosed after labor. The transmission rate from mother to child in the intervention and non-intervention groups was reported as 8.5% and 38.9%, respectively. In a cohort study in South Africa by Chetty et al. (19) among 260 infants born to HIV-pregnant women who were under Prevention of Mother-to-Child Transmission (PMTCT) programs, the rate of transmission from mother to child was 2.7% (6 cases). In Goswami and Chakravorty study (20), which was conducted by 4 years survey in India, despite enrolling 248 women who received treatment for HIV infection in the study, only 46 newborn babies were assessed due to the inability to follow up. Of these 46 cases, mother-to-child transmission was reported in only one case; according to the exclusion of many subjects from the study, the results are not comparable.

In the most recent study performed over a 6-year period in Ethiopia by Koye and Zeleke (21), among a total of 509 infants from mothers receiving antiretroviral treatment, there were 51 cases (10%) of MTCT. Neubert et al. (22) evaluated 118 mother-infant pairs treated for HIV therapy in pregnancy and in HIV exposed newborns from 2000 to 2010. Based on the results of this study, the overall Transmission risk in the group, regardless of risk factors and completion of prophylaxis, was 1.8%. If transmission prophylaxis was complete, transmission risk was 0.9%. In two studies in Brazil, the rate of vertical transmission in all female patients (treated and untreated) was much lower than in our study (9.9% and 9.7%, respectively) (23, 24). In Warszawski et al.'s study (25) in France, in women with HIV infection who had received an antiretroviral regimen during pregnancy, the vertical transmission rate was 1.3%. Also, another study in the United Kingdom and Ireland by Townsend et al. (26), the overall rate of mother-to-child transmission was 1.2%. In both studies, the rate was lower than the transmission rate in our study.

Data suggest that the combination of antiviral drugs with the goal of complete suppression of the virus can reduce the risk of perinatal transmission of HIV infection (15). Pharmacologic intervention with antiviral drugs during pregnancy follows two separate but related purposes: Treatment to reduce perinatal transmission of HIV and treatment of the mother infection if needed. Women with no need for treatment are also recommended to receive antiviral prophylaxis to prevent the mother-to-child transmission of HIV infection (8). With prophylaxis and effective viral suppression, the risk of infant infection through MTCH has declined to less than 2% in Europe and the United States (1). In our study, the transmission rate was higher than 2%; however, this can be attributed to the smaller number of patients undergoing intervention. In our study, only one infant of a woman undergoing medical treatment developed HIV infection, but given the small sample size, the vertical transmission rate was calculated to be more than 2 %. Thus, the vertical transmission rate of 2.9% can be attributed to the smaller sample size in this study compared to other studies.

Based on the results of this study, among the studied variables, lack of therapeutic intervention, NVD, male infant, and breastfeeding were associated with increased risk of mother-to-child transmission. Few studies have been conducted on risk factors for vertical transmission of HIV. All of these studies agree on the reducing effect of therapeutic intervention (regardless of type of treatment regimen) on the HIV- infection risk of infants (1, 2, 23, 25). Vertical transmission occurs in three ways: during pregnancy, during labor and delivery, and through breastfeeding (1). As the most common way babies get infected is during the fetus's passage through the birth canal, with cesarean delivery, the possible transmission of this way will be reduced (2). Breastfeeding is also one of the transmission ways of HIV from mother to child, so that the risk of vertical transmission in infants breastfed by infected mothers is 5-20% higher than infants who were not breastfed (1). Accordingly, with cesarean delivery and avoidance of breastfeeding, the mother-to-child transmission of HIV infection can be largely prevented (1-5).

In our study, the male gender was associated with increased risk of infant HIV infection, while in a similar study conducted in France, in contrast to our study, the female gender had a higher risk for HIV infection (25). Also, in studies done in Ethiopia (21) and Brazil (23), living in the village was reported as a risk factor of vertical transmission. However, in our study, no significant differences were observed in the infection rate among infants living in urban and rural areas.

In our study, infants born to mothers in both groups showed no significant differences in prematurity or low birth weight. Some studies have mentioned that using therapeutic intervention in women with HIV can cause prematurity and low birth weight in their newborns (1, 2). However, as noted, such a relationship was not confirmed in the present study.

It should be mentioned that maternal hypertension and low hemoglobin level, which are known factors influencing the incidence of fetal prematurity and low birth weight (12), had no significant differences in the two groups, and therefore, were not considered as confounding variables.

Conclusion

According to the results of this study, treatment intervention significantly reduces the mother-to-child transmission of HIV. Yet, the rate of vertical transmission in Iran is still higher than the reported rate in developed countries despite treatment interventions. More preventive measures seem to be necessary. Possible reasons for the higher rate of vertical transmission in this study compared to other studies can be the vaginal delivery in mothers with HIV, as well as breastfeeding which were higher in our study population than in other studies.

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Conflict of Interest

The authors have no potential conflicts of interest to declare.

Authors' Contributions

All authors have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data, and have been involved in drafting the manuscript or revising it critically for important intellectual content. All authors read and approved the final manuscript.

Informed consent

Written informed consent was obtained from all participants in the study, and written consent to participate was obtained from the parents of the patient (younger than 16 years of age). Written informed consent for publication of clinical details and images was also obtained from all participants and from the parents of participants under the age of 18.

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