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Outcome of HIV-infected Pregnancy with Antiretroviral Therapy at Chonburi Hospital between 2002-2006

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ABSTRACT

Objectives To compare the pregnancy outcomes in HIV type 1- infection women between good compliance to antiretroviral therapy group and poor compliance therapy group.

Methods Three hundred and twenty one HIV type 1- infected pregnant women were included in a historical cohort study at Chonburi Hospital. The outcome of their pregnancy was compared between good compliance to antiretroviral therapy group and poor compliance group.

Results The prevalence of HIV- infected pregnant women was 1.3% (321/25,012) in our hospital. Antiretroviral therapies were prescribed to all patients. There were two groups of therapy; good compliance group, 235 cases (73.2%) and poor compliance group, 86 cases (26.8%). The outcome of pregnancies (gestational age at delivery, birthweight, Apgar score, neonatal intensive care admission and neonatal death) were compared between the two groups. The good compliance therapy group had less preterm birth (16.6% vs 20.9%, p = 0.37), less low brithweight (15.3% vs 36%, p = 0.001), less low Apgar score (0.4% vs 10.5%, p = 0.003), less neonatal intensive care admission (0% vs 7%, p = 0.01) and less neonatal death (0.4% vs 5.8%, p = 0.002) than the poor compliance therapy group.

Conclusion HIV-infected pregnant women with good compliance to antiretroviral therapy had less bad outcome of pregnancy than the poor compliance therapy patients.

Keywords: Pregnancy outcome, HIV infection, Antiretroviral therapy, Compliance

Introduction

Antiretroviral therapy is recommended during pregnancy to reduce the risk of prenatal transmission of human immunodeficiency virus type 1(HIV-1) infection and to improve maternal health.[1] A 2005 report by United Nation programme on HIV/AIDS (UNAIDS) and the World Health Organization, estimated that globally there are about 17.5 million HIV pregnant women and 700,000 HIV infected children under the age of 15.[2] More than 90 percent of HIV infected children are found to have been infected via peripartum and intrapartum transmission.[3] Incidence and prevalence of HIV infected patients is different among regions.

The first known case of acquired immunodeficiency syndromes (AIDS) in Thailand occurred in 1984. Since then, HIV has become prevalent among all population demographics, including women and children. HIV infection in pregnant women increased in Thailand from 0% in

the year 1989 to a maximum recorded level of 2.29% in the year 1995, after which time the infection rate decreased.[4] In June 2004, a report found that prevalence of HIV among pregnant women in Thailand was 1.04% and that children infected with AIDS from vertical transmission from the mother amounted to more than 10,700 cases.[5]

In developed countries, some studies found no statistical differences in intrauterine growth retardation, low birth weight infants and stillbirths between HIV infected mothers and seronegative mothers.[6] Similarly, some studies showed no increased risk of congenital anomalies among HIV infected mothers when compared to seronegative mothers.[6-9] However, studies do exist to the contrary, and in particular show that HIV infected mothers are at a higher risk of low birth weight and stillbirth.[10,11]

Some studies have found that the use of highly active antiretroviral therapy (HARRT) increased the risk of preterm labor in pregnant women.[8,11] There is now much research into antiretroviral therapy as a means of decreasing the transmission rate of HIV to infants. Chonburi Hospital has practiced antiretroviral therapy since 1996 and has implemented many programmes promoted by the Thai Red Cross Society, the Bangkok perinatal zidovudine study, the access to care program (CARE) and the perinatal HIV prevention trial (PHPT I, II, IV). In addition, since 2006, the hospital has used a pediatric AIDS clinical trials group regimen (PACTG 1032). Thus, the aim of this present study was to determine whether a mother's compliance with an antiretroviral regimen affects the delivery outcome.

Materials and Methods

Patients and samples

The present study recruited HIV infected mothers who gave birth between 2002 and 2006 (inclusive). Data was collected retrospectively for the five year period, including demographic data, antiretroviral drug regimen details, and the outcome at birth. The data was extracted from clinical charts, antenatal care and labor records. The data collection fields used in this study included documentation of infant gestational age at birth, delivery at 196 days or more of gestation, singleton gestation, documentation of the use or non-use of antiretroviral therapy, birth weight, mode of delivery, Apgar score and neonatal care after delivery.

The antiretroviral regimens in HIV infected mothers were first introduced at Chonburi Hospital in 1996. The lists of regimens used at the hospital are outlined below:

1. The perinatal HIV prevention trial (PHPT): This is an international collaboration program which started in 1997 among Chiangmai University, Mahidol University, the Ministry of Public Health, the Harvard school of Public Health in the USA and the Institute de Recherche pour le Development in France. The regimens were PHPT I, PHPT II and PHPT IV.

1.1 PHPT II (year 2001-2003): this was a phase 3, double blind, randomized, three arms, placebo controlled trial. HIV infected mothers were randomly assigned to receive one dose of nevirapine (NVP) 200 mg at onset of labor and another dose if labor was prolonged more than 48 hrs. Infants were randomly assigned to receive NVP 2 mg/kg at 48-72 hours after birth.

1.2 PHPT IV (year 2005-2006): the HIV infected mother received AZT and NVP as per the PHPT II regimen and in addition Didanosine (ddI) 200 mg twice a day from onset of labor through 30 days after the postpartum period.

2 The Thai Red Cross Society regimen (year 2003): The HIV infected mother received AZT 200 mg in the morning and 300 mg in the evening starting from 32 weeks of gestation. At the onset of labor pain a single dose of NVP 200 mg was added to AZT 300 mg every three hours. The infants received a single dose of NVP 2 mg/kg within 72 hours of birth.

3 The Bangkok perinatal zidovudine study (year 2003): This study was conducted at Rajavithi and Siriraj Hospitals. This regimen was AZT 300 mg oral twice a day to 35 weeks of gestation and AZT 300 mg orally every three hours at the onset of labor until delivered. After the conclusion from PHPT II

was known, NVP 200 mg was added during the intrapartum period. The infants were given AZT 2 mg/kg every six hours and a single dose of NVP 6 mg.

4 The access to care program (CARE) (year 2004): This program followed on from the Bangkok study but involved HIV infected mothers being managed by the anonymous clinics.

5 The pediatric AIDS clinical trials group regimen (PACTG 1032) (year 2006): The purpose of this study was to determine which of the three regimens were the most effective in reducing the incidence of NVP resistance mutation. HIV infected mothers received a single intrapartum dose of NVP with concomitant administration of AZT/DDI or AZT/ DDI/ Lopinavir/ Ritonavir.

Our study divided the patients into two groups, a good compliance group comprising of patients who had taken the antiretroviral therapy regimen regularly and missed antiretroviral drug not more than 2 times and a poor compliance group referring to those with an irregular to the treatment regimen and those not include in good compliance. This study was approved by the Ethics committee of Chonburi Hospital.

Statistical Analysis

Statistical analysis was performed using SPSS software version 11.5. Demographic and obstetric data were presented in percentage and range of value. The pregnancy outcomes were compared between each regimen and between the drug compliance by using one-way ANOVA and Chi-square test. The p-value of less than 0.05 is statistically significant.

Results

Among 25,012 parturients who delivered at Chonburi Hospital during five years of the study period (2002-2006), there were 321 HIV- infected parturients (1.3%). Table 1 summarizes the characteristics of these 321 HIV- infected parturients. The mean age of the pregnant patients with HIV who underwent delivery was 27 years and ranged from 16 to 41 years. Of the 321 HIV mothers, the most common level of education was primary school (48%; n = 154), followed by secondary school (37.1%; n = 119), diploma (6.5%; n = 21), no education (5.6 %; n = 18), and Bachelor's degree or above (2.8%; n = 9). The mean gravidity was 2.2, and ranged from 1 to 7. Most of them had a good of participation in antenatal care and the mean number of times was 6.5, and it ranged from 0 to 15 times. Gestational age at the time of delivery was 268.3 days (range 266-287 days). The mean hematocrit level during antenatal care was 33.2%. Most of them were primary cases at Chonburi Hospital (91.9%; n = 295) and the rest were referred cases from other hospitals (8.1%; n = 26). According to HIV infection status, 241 of HIV pregnant women (75.1%) knew the results of HIV test at antenatal care unit. Fifty-eight patients (18.1%) knew at labor room due to lack of result of HIV serology or no antenatal care and only 22 patients (6.9%) knew before antenatal care. Of the 321 HIV mothers in the study, a total of 59 cases (18.4%) were taken from the Bangkok perinatal zidovudine study, 84 cases (26.2%) from the access to care program, 42 cases (13.1%) from the PHPT II study, 16 cases (5.0%), from the PHPT IV study, 32 cases (9.9%) from the Thai Red Cross Society regiman, 4 cases (1.2%) from the PACTG 1032 project, and 84 cases (26.2%) did not participate in any project and were given antiretroviral therapy in the access to care program. Considering the outcome of the compliance of antiretroviral (ARV), 321 HIV positive parturients were classified into 2 groups according to the regularity of receiving the regimen. The first group, which consisted of 235 patients (73.2%), was given antiretroviral drugs regularly and they were defined as good compliance of ARV (group A). The second group, which had 86 patients (26.8%), was given antiretroviral drugs irregularly, and they were labeled as poor compliance of ARV (group B). CD4 levels at ANC were 392.11 cells/ml.

From table 2, it showed that there was a significant difference between group A and group B in the following characteristics: education level, the

number of times of patient attended the antenatal clinic, gestation age, and percentage of referral cases. For education level, it was found that the education level of patients in group A was higher than group B. Group A, 44.7% were primary school level, 39.1% were secondary school level, 8.5% were diploma level and 3.4% were Bachelor's degree and above. Group B, 57.0% were primary school level, 31.3% were secondary school level, 1.2% were diploma level and 1.2% were Bachelor's degree and above. The result revealed that group A had a significantly higher level of education of group A than group B (P = 0.01). For the number of times of patients attending at antenatal clinic, it was found that the mean number of times of group A was 8.33 while that of group B was 1.32, and there was a statistically significant difference (P = 0.001). For the mean of gestation age (GA), it was found that the mean of GA of group A was 270 days, while that of group B was 256.57 days, and there was a statistically significant difference (P = 0.02). For percentage of referral cases, it was found that only 5.1% of group A were referred from other hospitals, while it was 16.3% in group B. Based on this result, it showed that there were significantly more referral cases in group A than those in group B (P = 0.002).

From table 3, it was found that in group A, 158 gave birth by normal labor (67.2%) and in group B, 69 gave birth by normal labor (80.2%). For cesarean section, group A gave birth by cesarean section more than group B did (86.5% and 13.5%, respectively) and the association was statistically significant (P = 0.003). There was no statistically significant difference among women who had delivery with vacuum extraction (V/E), forceps extraction (F/E) or breech assisting. The group B mothers delivered more infants before 37 weeks than group A mothers, but this was not found to be statistically significant (20.9% vs 16.6% respectively, p = 0.37). The birth weight between group A and B infants was found to be significantly different (2,976.8 gm. vs 2,610.4 gm. respectively, p = 0.001). Low birthweight infants (less than 2,500 gm.) were more frequent among group B than group A and the association was statistically significant (36% vs 15.3% p = 0.001). For Apgar score less than 7 at 1 minute, it was found that the patients in group A whose babies had an apgar score of less than 7 at I minute were only 2.6%, while the patients in group B were 16.3%, and the association was statistically significant (p = 0.001). For Apgar score less than 7 at 5 minutes, it was found that the patients in group A whose babies had an apgar score of less than 7 at 5 minute were only 0.4%, while the patients in group B were 10.5 %, and the association was statistically significant (p = 0.003). The types of neonatal care after delivery between group A and group B were as follows:- being with mother in post partum ward, being in sick newborn ward, being in neonatal intensive care unit, and death. It was found that the percentage of newborn infants who were with their mothers in the post partum ward of group A were 95.3% while those of group B were 80.2%. The association was statistically significant (p = 0.01). None of the newborn babies of group A were in NICU, while 7.0% of newborn babies of group B were. The association was statistically significant (p = 0.01). In group A, 0.4% were neonatal death, while 5.8% of group B were neonatal death. The association was statistically significant (P = 0.002).

Discussion

At Chonburi Hospital, HIV infected mothers who attended an antenatal clinic since 1996 received many antiretroviral therapy regimens. These included treatment from programmes involved with the Bangkok perinatal AZT study, Thai Red Cross Society regimen, access to care program, perinatal HIV prevention trial PHPT II, PHPT IV, and PACTG 1032. From 1996, the Bangkok perinatal zidovudine study and the Thai Red Cross Society regimen gave AZT as a single therapy. After year 2002, all programs added more than one medication.

From the present study, there were 321 cases of HIV infected mothers from a total of 25,012 parturients cases (1.3%). This is slightly higher than findings of the Samarn Sayoombhuruginan study which found an HIV prevalence in parturient cases of

1.047%.[5] Chonburi Hospital is a tertiary hospital in the East of Thailand, and therefore it receives a number of referred cases from other hospitals. The majority of HIV mothers had an education level (in both good and poor compliance groups) of primary and secondary school. Education may be an important rule in HIV pregnancy. Many studies[10,12] show that educated women are more likely to know how to prevent HIV infection. In Zambia, during the 1990, HIV rates fell by almost half among educated women but showed little decline for women with no formal schooling.[12] Our study showed that education levels may affect the drug compliance and antenatal visit. Pregnant women in the poor drug group had lower antenatal visits than the good drug group together; these findings show that a higher level of education and maternal self care can affect the delivery outcome.

Previous studies[7,11,13] found that HIV- infected pregnant women are at increased risk of delivering low birth weight and premature infants. Currently, it is accepted that antiretroviral therapy reduces the risk of vertical HIV transmission. While some studies found that antiretroviral therapy increases the risk of preterm labour, low birth weight, low apgar scores and stillbirths[7,11,13], others[14,15] draw conflicting conclusions. Our study found that, the HIV- infected mothers delivered infants at an average gestational age of 268.3 days (38 weeks), which is considered a term pregnancy. This finding differs from that found by Ellis's study.[11] It should be noted however, that Ellis's study occurred before the recommendation for routine use of antiretroviral therapy during pregnancy. Whether maternal antiretroviral therapy in pregnancy would have an impact on risk of preterm and low birth weight delivery is still unknown. Further studies are needed to address these important issues.

When compared to drug compliance, the poor compliance group had a higher rate of preterm delivery than the good compliance group (20.9% vs 16.6% respectively). The present study shows that the preterm birth rate for both good and poor compliance groups was not statistically different, and this finding is consistent with the findings of Kowalska, et al.[13] The rate of low birth weight was lower among infants within the poor compliance group than the good compliance group (36% vs 15.3% respectively) and the low apgar scores at 1 and 5 minutes were also higher in the poor compliance group. The reason for the differences in these results is related to the mother's level of education, adequacy of antenatal care and maternal self care.

More than antiretroviral therapy during pregnancy, drug compliance also has an impact on the risk of preterm delivery.[7] Now, antiretroviral drug therapy have become widely used during pregnancy to reduce risk of HIV transmission. But, there is no study comparing drug compliance effects on perinatal outcome. Although anemia can occur at any stage of HIV disease, the frequency and screening increase as the infection progresses, with most patients with advanced disease experiencing this hematologic abnormality.[16] In the present study, anemia was common in poor compliance groups, but no statistical significance was found according to minimizing transmission risk. The French perinatal cohort[17] and the Swiss neonatal HIV study group[18] demonstrated reduced rates of perinatal HIV-1 transmission among women who received zidovudine and underwent elective cesarean delivery, but there were other clinical situations in which its utilization was more controversial.[3] From this study, the good compliance group had higher cesarean delivery rate than those in the poor compliance group. Thus most indications of the good compliance were due to elective cesarean delivery, to prevent vertical transmission.

Concerning neonatal outcome after delivery, low apgar scores in the poor compliance group were more frequent than in the good compliance group. The Apgar score is used to estimate a baby's general condition at birth, measuring such characteristics as heart rate, breathing, and muscle tone. From Ruth's study[7], it was found that antiretroviral therapy, either monotherapy or combination therapy, was not associated with increased rates of premature

delivery, or with low birthweight, low apgar score, or stillbirth in their infants. However, the association between drug compliance and perinatal outcome requires further study for confirmation.

Generally, it is possible to experience some limitations which are associated with a retrospective study such as completeness of medical information or inhomogeneous distribution of variables between the studied and controlled group. Though there were no such limitations found in this study a better possible design, such as a prospective cohort study, may give more valid and reliable results. From this study, HIV-infected pregnant women with good compliance to antiretroviral therapy had less bad outcomes of pregnancy than the poor compliance therapy patients. It seeks to recommend HIV-infected women to attend ANC regularly and comply to treatment protocol in order to expect the best possible outcomes.

Table 1. General characteristics of patients

Characteristics	
Total	321
Age (mean±SD) (years)	27.0±5.23
range (years)	16-41
Education, n (%)	
No education	18 (5.6)
Primary school	154 (48)
Secondary school	119 (37.1)
Diploma,	21 (6.5)
Bachelor's degree or above,	9 (2.8)
Gravidity (median)	2
Numbers of ANC (median)	7
Gestational age at delivered (days, mean +SD)	268.3+20.6
Hematocrit level at ANC (%, mean +SD)	33.2+4.0
Refer, n (%)	
Primary case	295 (91.9)
Referral case	26 (8.1)
Documented of HIV status, n (%)	
before ANC	22 (6.8)
at ANC	241 (75.1)
at labor	58 (18.1)
Regimens of antiretroviral therapy, n (%)	
1) Bangkok perinatal zidovudine study	59 (18.4)
2) Access to care program (CARE)	84 (26.2)
3) PHPT project	
- PHPT II	42 (13.1)
- PHPT IV	16 (5.0)
4) Thai Red Cross society project	32 (9.9)
5) PACTG 1032 project	4 (1.2)
6) Not participated in any project and were given antiretroviral therapy with CARE program	84 (26.2)
Compliance of ARV, n (%)	
Good	235 (73.2)
Poor	86 (26.8)
CD4 levels at ANC (cells/ml, mean ±SD)	392.11 ± 209.4

Table 2. Characteristics of good compliance treatment group compare to poor compliance treatment group

	Good Compliance (A) (n = 235)	Poor Compliance (B) (n = 86)	P-Value
Age (years) mean ± SD	27.18 ± 5.35	26.53 ± 4.83	0.11
Educational level, n (%)			0.01*
- No education	10 (4.3)	8 (9.3)	
- Primary school	105 (44.7)	49 (57.0)	
- Secondary school	92 (39.1)	27 (31.3)	
- Diploma	20 (8.5)	1 (1.2)	
- Bachelor's degree or above	8 (3.4)	1 (1.2)	
Gravidity (median)	2	2	0.20
Numbers of ANC (median)	9	2	0.001*
GA days (mean ± SD)	270.03 ± 17.95	256.57 ± 26.88	0.02*
Hematocrit (%,mean ± SD)	33.41 ± 3.78	32.14 ± 5.67	0.18
Referral, n (%)			0.002*
Primary case	223 (94.9)	72 (83.7)	
Referral case	12 (5.1)	14 (16.3)	

*P < 0.05

Table 3. Mode of delivery, outcome and neonatal care

	Good compliance (A) (N=235)	**Poor compliance (B) (N=86)**	**P-Value**
Route of delivery, n (%)			
N/L	158 (67.2)	69 (80.2)	0.02*
C/S	64 (27.2)	10 (11.6)	0.003*
V/E	8 (3.4)	2 (2.3)	0.47
F/E	3 (1.3)	3 (3.6)	0.20
Breech	2 (0.9)	2 (2.3)	0.29
Outcome of delivery			
Gestational age, n (%)			
< 37 wk.	39 (16.6)	18 (20.9)	0.37
≥ 37 wk.	196 (84.4)	68 (79.1)	
Birth weight mean ± SD, n (%)	2,976.8 ± 461.5	2,610.4 ± 728.9	
< 2,500 gm.	36 (15.3)	31 (36)	0.001*
≥ 2,500 gm.	199 (84.7)	55 (64)	

Apgar score at 1 min., n (%)			
< 7	6 (2.6)	14 (16.3)	0.001*
≥ 7	229 (97.4)	72 (83.7)	
Apgar score at 5 min., n (%)			
< 7	1 (0.4)	9 (10.5)	0.003*
≥ 7	234 (99.6)	77 (89.5)	
Neonatal care after delivery, n (%)			
1. Post partum ward	224 (95.3)	69 (80.2)	0.01*
2. Sick newborn	10 (4.3)	6 (7.0)	0.32
3. NICU	0 (0%)	6 (7.0%)	0.01*
4. Early neonatal death	1 (0.4%)	5 (5.8%)	0.002*

*P < 0.05

Conclusion

This study found that between 2002 and 2006, the incidence of HIV infected parturient women at Chonburi Hospital was 1.3%. Preterm birth in poor compliance with antiretroviral therapy patients were higher than good compliance, but no statistically significant. The good compliance group had higher cesarean section rate than those in the poor compliance group. The risk of low birth weight was significantly higher among infants from the poor antiretroviral regimen compliance group. The poor antiretroviral regimen compliance group also had a significantly higher rate of low apgar score, NICU admission, and early neonatal death. The reasons of these findings may be attributed to an inadequate antenatal care and poor antiretroviral therapy compliance.

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ผลของการตั้งครรภ์ในสตรีที่ติดเชื้อเอดส์และได้รับการรักษาด้วยยาต้านไวรัสที่โรงพยาบาลชลบุรี ระหว่าง พ.ศ. 2545-2549

สมบูรณ์ เพ็ชรเจริญ

วัตถุประสงค์ *: ศึกษาผลของการตั้งครรภ์ในสตรีที่ติดเชื้อเอดส์และได้รับการรักษาด้วยยาต้านไวรัสที่โรงพยาบาลชลบุรี ระหว่าง พ.ศ. 2545 – 2549*

วัสดุและวิธีการ *: สตรีตั้งครรภ์ที่ติดเชื้อเอดส์ 321 คนที่มาฝากครรภ์และคลอดที่โรงพยาบาลชลบุรีและได้รับยาต้านไวรัสเอดส์ ระหว่าง พ.ศ. 2545-2549 เปรียบเทียบผลของการตั้งครรภ์ระหว่างกลุ่มที่ได้รับการรักษาด้วยยาอย่างสม่ำเสมอ และกลุ่มที่ไม่ได้รับการรักษาสม่ำเสมอ*

ผลการศึกษา *: อุบัติการณ์ของสตรีตั้งครรภ์ที่ติดเชื้อเอดส์ คิดเป็นร้อยละ1.3 (321/25,012) มีการสั่งให้การรักษาด้วยยาต้านไวรัสเอดส์สำหรับผู้ป่วยทุกคน พบว่ากลุ่มที่ได้รับยาสม่ำเสมอ มี 235 คน คิดเป็นร้อยละ 73.2 กลุ่มที่ได้รับยาไม่สม่ำเสมอมี 86 รายคิดเป็นร้อยละ 26.8 เปรียบเทียบผลของการตั้งครรภ์ระหว่าง 2 กลุ่ม ได้แก่ อายุครรภ์ที่คลอด น้ำหนักทารกแรกเกิด คะแนนแอปการ์ การรับไว้ดูแลรักษาในหอผู้ป่วยทารกวิกฤตและจำนวนทารกที่เสียชีวิตหลังคลอด พบว่ากลุ่มที่ได้รับยาสม่ำเสมอ มีอัตราคลอดทารกก่อนกำหนดน้อยกว่า (16.6% VS 20.9%, P = 0.37), ทารกแรกเกิดน้ำหนักน้อยมีจำนวนน้อยกว่า (15.3% VS 36%, P = 0.001), คะแนนแอปการ์น้อยมีจำนวนน้อยกว่า (0.4% VS 10.5%, P = 0.003) การรับไว้ดูแลรักษาในหอผู้ป่วยทารกวิกฤตมีน้อยกว่า (0 % VS 7%, P = 0.01) และจำนวนทารกที่เสียชีวิตหลังคลอดมีน้อยกว่า (0.4% VS 5.8%, P = 0.002) เมื่อเปรียบเทียบกับกลุ่มผู้ป่วยที่ได้รับยาไม่สม่ำเสมอ*

สรุป *: สตรีตั้งครรภ์ที่ติดเชื้อเอดส์ที่ได้รับการรักษาด้วยยาต้านไวรัสเอดส์สม่ำเสมอ พบมีผลที่ไม่ดีของการตั้งครรภ์น้อยกว่า เมื่อเปรียบเทียบกับกลุ่มที่ได้รับยาต้านไวรัสเอดส์ไม่สม่ำเสมอ*