Major Article

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Evaluation of preventive measures for mother-to-child transmission of HIV in Aracaju, State of Sergipe, Brazil

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ABSTRACT

Introduction: The main route of human immunodeficiency virus (HIV) infection in children is from mother to child. The preventive measures established for the Aids Clinical Trial Group protocol 076 (ACTG 076) significantly reduces HIV vertical transmission rates. This study aims to evaluate the implementation of the ACTG 076 protocol in the maternity units of State of Sergipe, Brazilian northeast**. Methods**: This is a descriptive, retrospective study with a quantitative approach, with HIV positive women and children exposed, attending a Maternity reference for high-risk pregnancies. Data were obtained from patient records registered in the years 1994 to 2010. **Results:** Amongst the 110 pregnant women and exposed newborns, the ACTG 076 protocol was fully utilized in only 31.8% of the participants. During the prenatal period, zidovudine (ZDV) was taken by 79.1% of the pregnant women. Only 49.1% of HIV seropositive patients used ZDV during delivery. Two (1.8%) children were considered infected and 50 (45.5%) do not have a conclusive diagnosis to date. **Conclusions:** There were significant deficiencies in the prevention of mother-to-child transmission of HIV, including lack of compliance with the three phases of the ACTG 076 protocol; inadequacies in prenatal care; inappropriate mode of delivery and lack of adequate follow up of exposed children.

Keywords: HIV. Vertical transmission of infectious disease. Zidovudine. Post-exposure prophylaxis.

INTRODUCTION

The identification of the acquired immunodeficiency syndrome (AIDS) in 1981 was a major milestone in the history of mankind. Before its spread across the world, the human immunodeficiency virus (HIV) epidemic was initially restricted to a few cosmopolitan populations. Nowadays, the epidemiology of HIV infection is marked by the increasing occurrence in women, in smaller cities and poorer populations. The increased burden of HIV infection in women leads to substantial increases in children[1,2].

The mother-to-child transmission (MTCT) of HIV, also called vertical transmission, may occur at various moments: during pregnancy, during labor and delivery or after birth through breast feeding[3]. The risk of transmission may range between 30% and 35% during pregnancy, from 60% to 65% during the immediate prenatal period and during labor itself[4,5]. There is an additional of risk between 7% and 22% if the child is breastfed by the mother[6,7].

In order to minimize this problem protocols and prophylactic regimes have been established. In 1994 the Aids Clinical Trial Group (PACTG) 076 Protocol was published detailing the effective use of drug therapy to reduce MTCT. The protocol included the oral administration of the antiretroviral zidovudine (ZDV) during pregnancy and for the newborn, and intravenous use during delivery. The result of this study demonstrated that the use of ZDV reduced vertical transmission by 67.5%[8].

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In Brazil, a 2002 study by Connor et al.[8] was the basis of the implementation of *Projeto Nascer*[9]. This project aims to train all health care providers in maternity hospitals to reorganize services in order to improve the quality of care for pregnant and puerperal women and their newborns. It also intends to reduce vertical transmission of HIV and to control congenital syphilis. According to the Ministerial Protocol of Brazil, all patients have free access to antiretroviral (ARV) drugs as clinically indicated, HIV testing during pregnancy and monitoring of viral load and cluster of differentiation (CD4) count[3,9].

Aracaju, the capital City of Sergipe, has the highest rate of HIV/AIDS in the state. The first adult female case was diagnosed in 1990, and the first case of vertical transmission in 1993[10]. The increasing number of HIV infected children makes the situation alarming, as evidenced by a study conducted at the public maternity hospitals in Sergipe (*Sistema Único de Saúde - SUS*) where a HIV seroprevalence of 0.42% was detected among pregnant women[11].

The benefits of HIV vertical transmission prophylaxis are well known but there are often failures regarding the implementation of the recommended protocols for prevention of MTCT. This study aims to evaluate the use of the ACTG 076 protocol in pregnant women and children exposed to HIV at the main reference maternity hospital in the city of Aracaju from 1994 to 2010.

METHODS

This is a descriptive, retrospective study with a quantitative approach. We included HIV positive mothers and their exposed children, admitted to *Nossa Senhora de Lourdes* Maternity Hospital (MNSL) from July 1994 to April 2010. This institution was selected because it is the referral hospital for all high risk pregnancies in Sergipe treating the majority of HIV positive pregnant women in the State. The data collection began in July 2010 and ended in April 2011.

During the studied period 158 HIV seropositive women were admitted in the reference maternity. A significant number of 110 pregnant women and their exposed children was included. The 48 missing patients were not included because their records were missed when the maternity changed to the new building in 2006. To estimate the significance of the sample[12] we estimated a 50% compliance of the ACTG 076 protocol, with a maximum error of 7% and a 95% Confidence Interval additional 20% patients accounting for patients records not found.

All cases of HIV seropositive pregnant women and their exposed children were identified from the Information System for Reportable Diseases (SINAN). Other sources of information were used to complement the database, namely the State Health Department and outpatient medical records from the sexually transmitted disease/human immunodeficiency virus/acquired immunodeficiency syndrome (STD/HIV/AIDS) service at the University Hospital (HU).

All information was collected on a standard form and then entered into database. The variables for analysis included maternal sociodemographic factors, details of prenatal care and labor and the current status of the child. Residence of individuals was categorized as *Aracaju Metropolitan Area* (which includes *Aracaju (capital), Barra dos Coqueiros, Nossa Senhora do Socorro* and *São Cristóvão)* or *other municipalities of Sergipe*.

Regarding the use of the ACTG 076 protocol, the three phases were separately analyzed. Each step recommended by the protocol included one or more interventions. Phase 1 consisted of the use of ARV during pregnancy; phase 2 was the use of intravenous ZDV during labor and the mode of delivery according viral load result, and phase 3 consisted of treatment with oral ZDV for the child and avoidance of breastfeeding[8].

Data analysis was performed using SPSS version 13. A descriptive analysis of the categorical variables produced simple absolute frequencies and percentage. To compare differences and distribution between proportions the chi-square test ($\chi 2$) was used. To evaluate the influence of prenatal care on the implementation of the ACTG 076 protocol was used Fisher's exact test. The significance value was established as 5% ($p<0.05$).

Ethical considerations

All ethical principles of Brazilian research (Resolution 196/96) were upheld. There was no direct patient contact; therefore it was not necessary to obtain individual consent. This study was approved by the Ethics and Research Committee of Federal University of Sergipe on 1st April 2011, registered number 0183.0.107.000-10.

RESULTS

From 1994 to 2010, there were 158 HIV positive mothers registered at *Nossa Senhora de Lourdes* Maternity Hospital and 110 of these were included in the survey. Maternal age ranged between 17 and 45 years with a predominance of the age group 26 to 35 years (60.9%). There were 64 (58.2%) women living in the metropolitan area of Aracaju. Over half (58.2%) had less than seven years of formal education. Regarding employment status, 17 (15.5%) were employed or self-employed, 15 (13.6%) were unemployed and 38 (34.5%) were housewives and/or students. The majority (68.2%) of participants were in a long-term relationship with a steady partner. The diagnosis of HIV infection had been made before the prenatal period in 53 (48.2%) cases, during the current pregnancy in 40 (36.4%), at birth in 12 (10.9%) and 1 (0.9%) woman was diagnosed after delivery **(Table 1)**.

TABLE 1 - Distribution of sociodemographic characteristics and acquisition factors for HIV seropositive pregnant women in MNSL, State of Sergipe, Brazil, 1994 to 2010.

Variable	Number	Percentage	χ^2	p-value[a]
Age (years)				
17 to 25	17	15.5	38.74	< 0.0001
26 to 35	67	60.9		
36 to 45	26	23.6		
Residence				
Aracaju Metropolitan area	64	58.2	56.96	< 0.0001
other municipalities of Sergipe	45	40.9		
unknown	1	0.9		
Years of education				
0 to 7 years	64	58.2	36.01	< 0.0001
> 7 years	33	30.0		
unknown	13	11.8		
Professional situation				
employed/self-employed	17	15.5	19.38	0.0002
unemployed	15	13.6		
housewives/students	38	34.5		
unknown	40	36.4		
Sexual partnership				
steady partners	75	68.2	172.0	< 0.0001
casual partners	3	2.7		
steady and casual partners	5	4.5		
others	4	3.6		
unknown	23	20.9		
HIV exposure category				
current partner with HIV	14	12.7	123.38	< 0.0001
former partner with HIV	17	15.5		
intravenous drug users	2	1.8		
unknown	77	70.0		
Period of diagnosis of HIV infection				
before pregnancy	53	48.2	97.72	< 0.0001
during pregnancy	40	36.4		
during delivery	12	10.9		
after delivery	1	0.9		
unknown	4	3.6		

HIV: human immunodeficiency virus; **MNSL:** *Nossa Senhora de Lourdes* Maternity Hospital. **χ^2:** chi-square calculated; [a]p-value of chi-square.

Concerning prenatal services, 91.8% of patients attended prenatal appointments, but only 44.5% (49) had less than 6 visits. The results for HIV and syphilis (VDRL - Venereal Disease Research Laboratory) in the prenatal period was positive in 53 (48.2%) and 11 (10%) cases, respectively. It was noted that 79.1% of the pregnant women were on ARV therapy in the prenatal period **(Table 2)**.

Regarding the ACTG 076 protocol, 87 (79.1%) women were taking oral ZDV during pregnancy (phase 1), 54 (49.1%) received intravenous ZDV during delivery, and had a cesarean section if their viral load exceeded 1,000 copies/ml (phase 2). Furthermore, 77 (70%) children received the oral ZDV and were not breastfed (phase 3). Although phases 1 and 3 had high rates of compliance individually, the number

of women who received all three phases of the protocol was only 35 (31.8%) **(Table 3)**.

TABLE 2 - Prenatal care for HIV seropositive pregnant women in *Nossa Senhora de Lourdes* Maternity Hospital, State of Sergipe, Brazil, 1994 to 2010.

Variable	Number	Percentage	χ^2	p-value[a]
Had prenatal care				
yes	101	91.8	169.32	< 0.0001
no	4	3.6		
unknown	5	4.5		
Number of visits				
< 6	49	44.5	43.52	< 0.0001
≥ 6	38	34.5		
no prenatal care	4	3.6		
unknown	19	17.3		
HIV test				
positive	53	48.2	60.54	< 0.0001
not tested	14	12.8		
HIV positive before prenatal care	41	37.3		
unknown	2	1.7		
Use of ARV during pregnancy				
yes	87	79.1	106.70	< 0.0001
no	19	17.3		
unknown	4	3.6		
Syphilis test				
positive	11	10.0	73.49	< 0.0001
negative	66	60.0		
not tested	13	11.8		
unknown	20	18.2		

HIV: human immunodeficiency virus; **ARV:** antiretroviral; **χ^2**: chi-square calculate. [a]p-value of chi-square.

TABLE 3 - ACTG 076 protocol use in HIV positive pregnant women and exposed children in *Nossa Senhora de Lourdes* Maternity Hospital, State of Sergipe, Brazil, 1994 to 2010.

Phases of ACTG 076 protocol	Number	Percentage	χ^2	p-value[a]
Phase 1: during pregnancy				
yes	87	79.1	106.70	< 0.0001
no	19	17.3		
ignored	4	3.6		
Phase 2: delivery				
yes	54	49.1	49.16	< 0.0001
no	54	49.1		
does not apply	1	0.9		
ignored	1	0.9		
Phase 3: after delivery				
yes	77	70.0	124.10	< 0.0001
no	19	17.3		
does not apply (stillbirth)	2	1.8		
unknown	12	10.9		
General: three complete phases				
yes	35	31.8	90.65	< 0.0001
no	65	59.1		
do not apply (stillbirth)	2	1.8		
unknown	8	7.3		

ACTG 076: Aids clinical trial group 076; **χ^2**: chi-square; [a]p-value of chi-square.

Of the 101 pregnant women who were attended during the prenatal, 84 (84.8%) received a phase 1 protocol; 52 (52.5%) received the protocol in phase 2 and 72 (80.9%) completed phase 3. Of the women who did not attend prenatal care, none completed the protocol in Phase 1 and Phase 2. Only in Phase 3 there were 2 (50%) women who did not attend prenatal care but completed the protocol.-However, when evaluating prenatal care influence on the implementation of the protocol, only individuals at the first phase were influenced by prenatal care attendance (Fisher´s exact test: p=0.027) **(Table 4)**.

From 40 women HIV positive before prenatal care attendance, 39 (97.5%) received ARV during pregnancy, and also 46 of 51 with HIV positive during pregnancy received ARV during prenatal care.

During follow up two (1.8%) children were found to be infected with HIV and 56 (50.9%) were confirmed HIV negative, 11 (10%) were lost to follow-up at the clinic and 39 (35.5%) are still being monitored. It is worth mentioning that in one case, the child deemed HIV negative was not old enough to have a definitive diagnosis made.

TABLE 4 - ACTG 076 protocol application in HIV positive pregnant women and exposed children according to prenatal care use in MNSL, State of Sergipe, Brazil, 1994 to 2010.

	ACTG 076 Protocol							
	Phase 1[a]		Phase 2[b]		Phase 3[c]		Complete protocol[d]	
Prenatal	yes	no	yes	no	yes	no	yes	no
yes	84	15	52	47	72	17	34	59
no	0	2	0	2	2	2	0	4
p-value[e]	0.027		0.057		0.184		0.294	

ACTG 076: Aids clinical trial group 076; **HIV**: human immunodeficiency virus; **MNSL:** *Nossa Senhora de Lourdes* Maternity Hospital; [a]Use of antiretroviral during pregnancy: unknown 9 cases; [b]Use of intravenous zidovudine during delivery, value of the viral load and type of delivery: unknown 7 cases; [c]Use of zidovudine syrup in children and no breastfeeding by the mother or crossed from other mother: unknown 17 cases; [d]Complete protocol: unknown 13 cases; [e]p-value of Fisher's exact test.

DISCUSSION

It is known that one of the most effective strategies to reduce vertical transmission of HIV is to reduce the maternal viral load during pregnancy. It is considered that not receiving ZDV during prenatal care, at childbirth and in immediate postnatal period are major factors in the failure to control perinatal HIV transmission[13,14]. The evaluation of preventive interventions during maternity care is important to ascertain if the recommended protocol is being effectively implemented[14]. Knowledge of the patients' sociodemographic characteristics enables more targeted interventions for the population at risk[15].

The predominant maternal age was found to be at the most fertile ages, thereby increasing the probability of future pregnancy and potential HIV transmission. The sociodemographic profile was similar to that found in other studies[16,17], in which patients with lower education levels may have reduced quality of prenatal care. If there was prior knowledge of HIV positivity, there was a more effective reduction in vertical transmission[18]. In 10.9% of pregnant women, the diagnosis occurred during delivery, meaning a missed opportunity for preventive intervention during the prenatal period.

The quality of prenatal care could not be fully evaluated, because we did not know the date of onset or when actions were implemented during visits. In a previous study in Sergipe, 42.1% of pregnant women attended fewer than six consultations[11], a similar rate to that found in this survey (44.5%). This inadequate attendance led to inadequate

testing for HIV (12.8%) and syphilis (11.8%), demonstrating poor quality prenatal care[18].

At first glance, with the exception of phase 2, the use of the ACTG 076 protocol appears to be in accordance with established standards, as most pregnant women and newborns completed phases 1 and 3. However, when analyzing all phases together, the high levels of coverage drop considerably. Lower figures are found in the study by Silva et al.[19], where only 1.5% of pregnant women and newborns received complete prophylaxis as per recommendations. The lower uptake of phase 2 (at birth) when compared to the other studies, is worrying because it is precisely at this stage, where obstetric factors are critical, that most virus transmission occurs[20]. It is worth noting that this intervention during this period does not depend on the pregnant woman, but on the health care staff working at the maternity hospital. The only exception is in cases where the patients should have disclosed their known HIV status when presenting in labor but did not.

A previous retrospective study[17] reported that the rate of vertical transmission of HIV was 6.6% in pregnant women who received the complete ACTG076 protocol and 34% for those who received no intervention. This corroborates the effectiveness of the prophylactic measures proposed by Connor[8].

In the present study, the evidence of the relationship between prenatal attendance and the use of prophylactic ZDV demonstrates that primary care is a significant factor in implementing prophylactic measures. Prenatal visits provide HIV testing and ensure the involvement of HIV seropositive pregnant women in their care.

More than 90% of seropositive patients used ARV, demonstrating that the weaknesses of the system are starting to be overcome. The fact that most pregnant women are already aware of their status before pregnancy influences their adherence to the protocol measures. A lower percentage was found in a study of Lana and Lima[21], where the rate was 44.8%. With respect to the onset of prophylaxis in children, some neonates did not receive oral ZDV for the first 2h after delivery (data not shown). These neonates received the medication during the first 24h, but not during the first two, when it is most effective. This demonstrates the importance of knowing the status of the mother as early as possible to enable timely intervention for the child.

Failures to implement protocol measures increase the chance for mother to child transmission of HIV. A European study revealed that cesarean section is the most effective clinical procedure, even in patients with undetectable viral load, with 90% reduction in the risk of vertical transmission[20].

Another study showed that after implementation of the protocol, 77.1% of the children exposed to HIV were not infected[22]. The numbers of HIV negative children in this study could be higher if all steps of the protocol were completed. It is noteworthy that many exposed children still do not have a final diagnosis, which could represent changes in the proportions observed. This problem was present in another study, which showed that 20% of mothers did not know the HIV status of their children up to eight months after delivery[23].

One of the limitations of this research was the existence of a number of non-registered patients combined with contradictory information found in some records, particularly pertaining to the risk of disease enhancement in the mother during pregnancy, duration of prophylaxis with ZDV in pregnancy and date of onset of prenatal care. This missing information made a more detailed and accurate characterization of the current status of MTCT in State of Sergipe impossible.

This study aimed to evaluate the actual situation in interventions to reduce mother to child transmission of HIV. The findings will contribute to improvement in prenatal services at the main reference maternity unit of Sergipe.

Despite the weaknesses found, many interventions do not depend on a single service, thus it is necessary to work with other sectors such as health system managers, with special attention to quality improvement for prenatal services, professional training and increased population awareness for the prevention of HIV vertical transmission.

Among the 110 pregnant women and newborns here studied, the full ACTG 076 protocol was carried out in only 31.8% of cases. A similar problem was found in another study of the ACTG protocol which demonstrated that only 4 (4.5%) HIV-positive mothers and their exposed children received full or partial interventions as per the recommended protocol[19].

There were two (1.8%) confirmed cases of HIV in children, which reveal important shortcomings to be examined, considering that *Nossa Senhora de Lourdes* maternity hospital is the reference unit for Sergipe. It is important to note that the pregnant women in this study were socioeconomically vulnerable with a relatively low level of education. These factors may have limited the full implementation of preventive measures as recommended by the protocol.

The findings of this study reveal significant shortcomings in the prevention of MTC transmission, including the lack of implementation of the three phases of the ACTG 076 protocol, deficiencies in prenatal care, inadequate modes of delivery and lack of follow-up care for the child.

Although the study population did not cover the entire state, it is worthwhile to bear in mind that the studied maternity unit is the reference centre for all high risk pregnancies in Sergipe, representing the overall state situation. However it is necessary to conduct studies in other hospitals to improve overall generalizability.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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ABSTRACT IN PORTUGUESE

Avaliação das ações de prevenção da transmissão materno-infantil do HIV em Aracaju, Estado de Sergipe, Brasil

Introdução: A principal forma de infecção do vírus da imunodeficiência humana (HIV) em crianças é pela transmissão materno-infantil. As ações profiláticas estabelecidas pelo protocolo *Aids Clinical Trial Group 076* (ACTG 076), reduziram significativamente as taxas de transmissão vertical do HIV. Este estudo objetivou avaliar a aplicação do protocolo ACTG 076 na maternidade de referência no Estado de Sergipe, nordeste brasileiro. **Métodos:** Trata-se de um estudo descritivo, retrospectivo com abordagem quantitativa, com mulheres HIV soropositivas e crianças expostas atendidas em uma maternidade para gestações de alto risco. Os dados foram obtidos dos registros de pacientes registrados nos anos de 1994 a 2010. **Resultados:** Entre as 110 gestantes e recém-nascidos expostos, o uso completo do protocolo ACTG 076 foi utilizado em apenas 31,8% dos participantes. No pré-natal, a zidovudina (ZDV) foi utilizada em 79,1% das gestantes. O uso da ZDV durante o trabalho de parto ocorreu em 49,1% das gestantes HIV reagentes. Duas (1,8%) crianças foram consideradas infectadas e 50 (45,5%) ainda não têm diagnóstico definido. **Conclusões:** Foram detectadas falhas significativas na prevenção da transmissão materno-infantil, dentre as quais, a falta do cumprimento das três fases do protocolo ACTG 076: carências no pré-natal, tipo de parto inadequado e perdas de seguimento para acompanhamento da criança exposta.

Palavras-chaves: HIV. Transmissão vertical de doenças infecciosas. Zidovudina. Profilaxia pós-exposição

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