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ORIGINAL ARTICLE

A Paradigm Shift in the Epidemiology of HIV in Pregnancy at ICTC of a Medical College

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Abstract
Objectives To study the present status and effect of paradigm shift in the epidemiology of HIV amongst pregnant women in urban set up.
Aims The purpose of the study is to evaluate the paradigm shift in overall screening and management strategy of HIV in antenatal women for last four and half years in an urban medical college.
Methods The study was conducted from 1st January 2004 to 30th June 2008 and all registered and unregistered pregnant women who attended ICTC clinic and also for emergency admission (unregistered) were counseled and blood samples were tested as per NACO guidelines with cafeteria choice of opt in and opt out strategy. Reactive women in antenatal period were counseled and discussed about anti-retroviral therapy (ART) and universal treatment regime. Seroprevalent women were counseled about their spouse, personal habits and demographic status. Marked improvement was seen in the use of contraceptive and drug abuse. During labor mother and baby were given nevirapine as per NACO guidelines.
Results The seroprevalence of HIV reactive women in our Centre was 0.23, 0.19, 0.14 and 0.12% in the year 2004, 2005, 2006, 2007 and zero prevalence in 2008 till date. Spouse positivity was noted in 80, 58.33, 72.72 and 70% in the set period from 2004 to 2008.
Conclusion Marked improvement was noticed in all the strategic points from registration, counseling, screening and availability of improved diagnostic kits for screening HIV 1 and HIV 2.

Keywords Integrated Counseling and Testing Centre (ICTC) · Paradigm shift

Introduction

Most countries are making remarkable progress towards mother to child transmission MTCT of HIV which continues to occur in pregnancy, labor and delivery or through breast feeding at a time when there are available effective intervention to curb the infection when better resourced country has reduced at risk of MTCT to less then 2%. An estimated 420,000 were newly infected in 2007. Over 90% of them were in sub-Saharan Africa without treatment and estimated half of the infected children will die before their second birth day [1].

In Asia adult and children living with HIV are 5 million, newly infected 380,000 adult prevalence 0.3% and death of

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HIV infected person 380,000 annually when more than 25 million died of HIV since 1981 [2].

While the global estimate of HIV at the end of 2007 reveals women living with HIV 2 million and death due to HIV 2 million [3].

The National Aids Control of India presents the time trend of HIV prevalence among adults (age 15–49) by sex during 2002–2006 in order to facilitate the comparison of HIV estimate over time by the same methodology. The HIV prevalence for adult males and females together has been showing a declining trend during past 5 years. It was 0.36% in the year 2006 against 0.45% in 2002 [4]. But the goal is to achieve zero prevalence. Majority of HIV infection (90%) in the neonates is due to MTCT; hence seropositive in pregnancy will enable to make a strategy to reduce the transmission. While prevalence of HIV in women from 2002 to 2006 was 0.36, 0.35, 0.33, 0.31 and 0.30% respectively [5].

The most secured manner to avert MTCT of HIV is represented by the appropriate application of antiretroviral medication (ARV), elective cesarean birth and avoidance of breast feeding. MTCT rate can be reduced to less than 2%. WHO guideline advice the use of twin perils of morbidity and mortality with either breast feeding or the use of breast milk substitute in bottle when it is affordable, safe and sustainable avoidance of all breast feeding by HIV infected mother.

Keeping the above theme in reducing MTCT the Government of India and National Aids Control Organization (NACO) started a common protocol throughout the country and in West Bengal from 1st January 2004 in all the medical colleges to study the present prevalence rate and how to reach zero prevalence.

Purpose of present study is to assess the paradigm shift in the strategy to reach the present prevalence.

Methods

The study was conducted from 1st January 2004 to 30th June 2008 at ICTC previously PPTCT clinic. All admitted women booked and unbooked were assessed on the following parameters:

1. Identification details and performance of ICTC;
2. Counseling, testing and referral risk of transmission (excluding pregnant women);
3. Laboratory test details, equipments, consumables staff (for all including pregnant women;
4. Counseling positivity, delivery and administration of nevirapine follow up of the baby, for all registered for ANC or delivery and too monitor the PPTCT service at ICTC; and
5. HIV, TB collaboration activities like cross infection and co infection and information for all patients.

This paradigm shift in the strategic modification is to fulfill NACOS' goal to achieve zero prevalence. Following this protocol WHO strategy III, those blood samples while were considered to be seropositive were further sent to state referral laboratory (SRL) for confirmation and quality assurance of the test kit and test results.

Simple one way protocol of antenatal registration, counseling, informed consent followed by collection of blood for HIV testing was done as per NACO protocol. Three tests were suggested to detect HIV reactive cases. The diagnostic kits supplied varied from time to time in different years.

1st test done by Comb-Aids-RS if it is positive then 2nd test was done by HIV-EIA-Comb. If the 2nd test was positive then 3rd test was done by SD-Biolin. If all the three test was positive the sample was considered to be HIV reactive and further confirmed in SRL.

Results

From the beginning of the PPTCT program, year wise evaluation reflects increase in the number of registrants and women counseled (see Table 1). Out of counseled women HIV test acceptors were 80% in the year 2004 and in the consecutive years it was 98–99.6%.

Women who attended for post test counseling was also significant from 54.45, 95.52, 97.26, 98.76 and 99.27% from year 2004 to 2008 respectively. The number of women who collected reports was only 72.18% in the year 2004 and sensitive improvement in awareness for collection of report was noticed in 95.52%, 97.26, 98.76 and 99.27% from year 2005 to 2008.

Number of reactive women who came for post test counseling was 94.11% in 2004 and 100% in the consecutive years. Amongst the spouse of HIV reactive women, improvement in the acceptance of HIV was also significant and it was 58.8, 75, 84.6, and 90% in the consecutive years and nil in year 2008. It reflects the awareness amongst the spouses for prevention and early detection.

Analysis of socio-demographic data reveals that majority of HIV reactive mother belongs to the group of 22–30 years in the consecutive study year with first pregnancy. Regarding literacy and socio-economic status 70–80% are illiterate and live below poverty line (see Table 2). Regarding fertility control majority had no contraception to start with but the positive benefit of counseling was observed in subsequent year with the acceptance of contraceptive practice it was 80–85%. Hazards of blood transfusion and related STD though insignificant but

Table 1 Service provided in ICTC clinic (PPTCT)

ICTC algorithm	2004	2005	2006	2007	2008
Antenatal registration	8,514	9,581	9,344	9,322	5,120
Counseled	8,651	9,143	9,313	9,322	5,120
ANC tested	6,920 (80%)	8,948 (98%)	9,284 (99.6%)	9,294 (99.6%)	5,117 (99.9%)
No of cases reactive	17 (0.23%)	16 (0.19%)	13 (0.14%0	11 (0.12%)	0
No of women collected report	4,995 (72.18%)	8,548 (95.52%0	90,530 (97.26%)	9,179 (98.76%)	5,080 (99.27%)
No of women attended post test counseling	3,768 (54.45%)	8,548 (95.52%)	9,030 (97.26%)	9,179 (98.76%)	5,080 (99.27%)
No of positive women attended post test counseling and collected reports	16 (94.11%)	16 (100%)	13 (100%)	11 (100%)	0
ICTC client accepting test HIV	0	2,785	2,903	3,190	823
ICTC client reactive	0	13 (0.46%)	16 (0.55%)	17 (0.53%)	6 (0.72%)
Spouse of reactive women accepting test	10 (58.8%)	12 (75%)	11 (84.6%)	10 (90%)	0
Spouse positive	8 (80%)	7 (58.33%)	8 (72.72%)	7 (70%)	0

Table 2 Socio demographic pattern of HIV reactive women

Age (years)	2004	2005	2006	2007	2008
20–25	8	9	7	5	
26–30	4	5	5	4	
31–35	3	1	1	1	
36–40	1	1	0	1	
Primigravida	9	10	8	7	
Multigravida	7	6	5	4	
Illiterate and below BPL	12	11	9	6	
Literate and above BPL	4	5	4	5	
Fertility control					
None	10	4	3	2	
Barrier method	1	4	4	3	
Other method	5	8	6	6	
Sexual promiscuity	10	3	2	1	
Blood transfusion	1	2	1	1	
Other STD	2	1	3	2	

required more awareness and close vigilance in the technical aspect.

Discussion

In our study marked paradigm shift has occurred in all the parameters set by NACO for HIV screening.

1. *Registration* Registration and computerization of all pregnant women in OPD in special registration counter helps in proper documentation.
2. *Counseling* In the universal counseling to start with audio visual motivation, helps in knowledge gathering and subsequent group counseling. In group counseling of 15–20 women at a time for better social response and to save time than individual counseling for more queries were done with strict confidentiality.
3. *Consent* Consent was of cafeteria choice, with opt in and opt out choices open for the group. In the opt in choice for the individual women and spouse, blood was collected for test. In the opt out choice they were discussed about the risk of HIV and advise to come voluntarily to VCTC when they think so. Through this type of choice option response is more than previous strategy of taking voluntary concept prior to testing as it has been entrusted on the patients conscious and helps to gain confidence easily.
4. *Test of blood samples* In 2004–2005 first tests HIV-comb (J Mitra) rapid visual test for the quantitative detection of antibody to HIV I and HIV II including subgroups (C & O) it is less specific and all antigenic version not detected. Second test—Tridot (J Mitra) this test can differentiate between antigens of HIV I and II which gets immobilized by the respective FC fraction of the antibody of the immunofiltration membrane. Third test—More specific than tridot since antigen GP 120 and P 128 of HIV I and GP 36 of HIV II binds with the antibody of the serum to form agglutination of latex particle.

   In 2006–2007 first test Comb-Aid-RS (Span Diagnostic Ltd.) antigen is synthetic peptide prepared genetically by recombinant technique more sensitive and less specific.

   Second test SD-Biolin (Standard Diagnostic) antigen GP 41, P 24 and GP 120 of HIV I and GP 36 of HIV II are detected by this test more specific and highly sensitive.

   In 2007–2008 first test (Comb-Aid). Second test SD-Biolin it is immunochromatographic tests for differentiation between HIV I and II.

   Third test HIV retro-screen test-based on sandwich immunoassay for simultaneous and differential detection of antibody HIV I and HIV II. It is more specific than SD-Biolin (see Table 3). If all the three tests are

Table 3 Algorithm of HIV screening test

Test done (at ICTC)	2004–2005	2005–2006	2007–2008
1st test	Hiv-comb	Comb-Aid-RS	Comb Aid
2nd test	Tridot	SD-Biolin	Sd-Biolin
3rd test	Capillus test	HIV-EIA-Comb	Retro-screen test
Advantages	Detection of HIV I & II antigen	More specific, highly sensitive and can differentiate antigen of HIV I & II	More sensitive and can differentiate between HIV I & II

Table 4 ARV for new born infants of HIV reactive mother

Type and time of treatment (intervention)	ARV drug	Doses	1st dose	Subsequent dose	Duration
Minimal range of ARV treatment	Nevirapine	2 mg/kg	Within 72 h	Once	
ARV during labour	Zidovudine	4 mg/kg	8–12 h after birth	8 mg every 12 h	4 weeks
	Nevirapine	2 mg/kg	Within 72 h	Once	

positive the case is reactive in nonreactive doubtful cases reassess after 3 months, if reactive do PCR and Western blot.

5. *Prevention Strategy* Previously for prevention of MTCT only termination of pregnancy was thought of now with the opt in choice availability of ART continuation of pregnancy may be allowed. As per NACO guideline during intrapartum period optimizing obstetric procedure by cesarean delivery to reduce vertical transmission.
   In imminent delivery single dose 200 mg nevirapine tablet (NNRTI) was given to the mother in the intrapartum state 4 h before the delivery and if delivery occurs earlier or before 4 h another dose of 200 mg nevirapine is also given [6] (Table 4).
   For the baby in the HIV Net 0_{12} trial nevirapine 200 mg given to the mother in labour and 2 mg syrup/kg of the body weight was given to the neonates within 72 hours of birth [7] (Table 5).
6. *Drug therapy* Highly active antiretroviral (HAART) for HIV reactive women with CD4 <200–350/cmm or HIV RNA >1,000 copies/ml then combined three drug therapy one PTI (Retonovir) group of drug with another NNRTI (nevirapine) or two drugs of NRI group (zidovudine and lamivudine). Previously monotherapy with zidovudine was the main stay of ART. Zidovudine 100 mg 5 times a day in the antenatal period and 2 mg/kg in labour followed by 1 mg/kg/h. Zidovudine was admitted after 14 weeks and continued throughout the pregnancy and labour and syrup zidovudine to baby for 6 months ACTG-076, PETRA trial [8].
7. *Postpartum baby care* ART continued to the mother and given to the baby helps to reduce perinatal transmission to 49% but chance of resistance development with nevirapine occurs in 75% in the first year because of mutation of the virus. Hence it is recommended to add a tail dose of zidovudine and lamivudine to the mother for 7 days.
8. *Follow up of the baby* HIV Elisa test before 18 weeks, two regular HIV test at one month apart or if performed after 6 months to exclude HIV infection

Table 5 ARV therapy for HIV reactive women

Case profile and time of treatment (intervention)	Treatment with ARV drug	Before 28 weeks	At 28 weeks	Onset of labor	Until delivery	Postpartum
ARV during labor	Nevirapine	–	–	200 mg	–	–
	Zidovudine	–	–	600 mg	–	–
Only minimal range	Nevirapine	–	–	200 mg	–	–
HIV reactive without related sign	3TC	–	–	150 mg	Every 12 h	7 days
	Zidovudine	–	300 mg every 12 h	300 mg	Every 12 h	7 days
	Nevirapine	–	–	200 mg	–	–
HIV reactive with related sign	Triple therapy	Continue ARV if treatment started before pregnancy with nevirapine 200 mg once daily for two weeks and then every 12 h				

in children with no clinical evidence of the disease. HIV Elisa test cannot distinguish between passively transferred HIV antibody and antibody produce due to infection itself.

Conclusion

Early diagnosis of HIV infection by available methods or by PCR technique should be done. Cafeteria approach strategies will benefit our patients as such an offer given freedom to accept the programme than a prescribed and the protocol contrast to the existing informed choice and consent.

Optimization of labor by avoiding prolonged labor, PROM and taking the advantage of cesarean delivery compared to vaginal delivery [9]. RCOG recommend LSCS for all HIV positive mother >1,000 copies of virus/ml [10]. The CTC guideline advocates LSCS as long as the women could understand the potential benefits [11].

Intervention strategy is to be individualized, option for vaginal delivery ACOG 076 protocol to be followed. In a clinical study at Mumbai intervention shows the perinatal transmission rate 5.8% [12]. Unfortunately breast milk contains the HIV virus and accounts for 14% risk of transmission and 0.7–1% per month [13].

The benefits of paradigm shift observed in the study period are as follows. HIV I and II are diagnosed more accurately by spot test, mother and spouse are more conscious about the antiretroviral therapy during pregnancy, intrapartum and postpartum period along with the neonates. Spouses are more aware of monogamous sexuality and avoidance of drug abuses and taking recourse to proper contraception. Counselors and technicians are aware of more responsibility in the integrated system (ICTC) of intervention. Thus we can achieve zero prevalence and fulfill our target.

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