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RESEARCH ARTICLE

EFFECTS OF HAART ON MATERNAL AND FETAL OUTCOME

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Abstract

Introduction: HIV infection among pregnant women has emerged as a global public health issue with serious medical, economic and social impact .HIV infection is a global epidemic that now.

Objective of the study: 1.To evaluate the effect of HAART on pregnancy in HIV-infected women. 2.To evaluate the effect of ART on foetal, outcome.affects 39.9 million people worldwide . Mother-to-child-transmission of HIV is a major route of HIV infection in children .This is a prospective observational study conducted in the Department of Obstetrics and Gynaecology, from Nov 2022 to Jan2024 for 15 months at GMC, Nandyal & PPTCT centre of Nandyal district.

Conclusion: It is imperative that every HIV infected pregnant woman should get access to proper antenatal care throughout her pregnancy and every effort should be made to ensure that her child is born free of HIV. Antenatal care and close monitoring in pregnancy can optimise the outcome for HIV infected women and baby.Though present sample size was small to be of statistical significance, our results suggest that better couple education will probably lead to earlier diagnosis, initiation and compliance of therapy to prevent transmission. Our study proves that with the improvised HAART therapy there is better feto maternal outcome which is almost similar to other reference studies conducted elsewhere.

Introduction:-

HIV infection among pregnant women has emerged as a global public health issue with serious medical, economic and social impact [1].HIV infection is a global epidemic that now affects 39.9 million people worldwide [2]. Mother-to-child-transmission of HIV is a major route of HIV infection in children [3].Universal screening of all pregnant women is the most crucial for identification and delivery of optimal care in time to the HIV infected pregnant women for better feto-maternal outcome Antiretroviraldrug prophylaxis has dramatically reduced feto-maternal transmission. India has the third largest population of HIV. It has an estimated 2.4million (2011) people living with HIV. Prevalence of HIV in india is 0.27%in the adult population. Of these, women constitute 39%, while childrenless than 15 years of age constitute 7%[3].Adult HIV prevalence in indiahas shown a steady decline from an estimated peak

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of 0.38% in 2001-2003 to 0.22% in 2017. The decline reflects the impact of scaled up HIV prevention intervention under the national aids control program.

According to current NACO guidelines, pregnant women who are HIV positive should have immediate lifelong art to treat HIV and improve her own health. The benefits of antiretroviral treatment in decreasing mother to child transmission of HIV infection are largely undisputed.

Although antiretroviral medications have the potential to improve health they may also result in unwanted adverse effects that may also compromise successful pregnancy and delivery resulting in adverse pregnancy outcome. Over the last decade, treatment for the prevention of mother to child transmission of HIV has moved from AZT to the use of highly active antiretroviral therapy (HAART) with global transmission rates dropping to 1-2%. WHO had recommended use of HAART[TLD regimen –Tenofovir-300mg,Doleutagravir-50mg],once a day to reduce risk of HIV transmission and improve survival [2]. According to WHO globally, there were 1.2 million [950 000–1.4 million] pregnant women with HIV in 2023, of which an estimated 84% [72–>98%]received antiretroviral drugs to prevent mother to child transmission HIV infection itself has been associated with varying rates of adverse pregnancy outcomes such as increased spontaneous abortions,stillbirths, perinatal and infant mortality, intrauterine growthrestriction, low birth weights and chorioamnionitis. With the introduction of HAART, the rate of these complications decreased[5,6].

Objective of the study:

1. To evaluate the effect of HAART on pregnancy in HIV-infected women.
2. To evaluate the effect of ART on foetal, outcome.

This is a prospective observational study conducted in the Department of Obstetrics and Gynaecology, from Nov 2022 to Jan2024 for 15 months at GMC, Nandyal & PPTCT centre of Nandyal district. After getting institutional ethics committee approval, study was started Consent of HIV positive pregnant women was taken to include patients in the study. All the HIV positive pregnant women attended to ANC & PPTCT centre of Nandyal were included randomly. All basic lab investigations like complete blood picture, blood sugar, LFT, RFT, urine albumin & sugar were done. Pregnant women were followed up after delivery upto 12 weeks postpartum and new born babies upto 18 months. Adverse effects of ART drugs and opportunistic infections were monitored and treated. Descriptive analysis of data was done and represented in percentage.

Inclusion criteria:
ANC women attending the OPD either already diagnosed as HIV positive or diagnosed during study and on HAART and women who gave consent for the study.

Exclusion criteria :

1. HIV positive Women who refuse to participate in the study and who have lost of follow up.
2. HIV positive pregnant women with cardiovascular diseases, chronic hypertension, autoimmune diseases and diabetes mellitus.

During the antenatal care, all women attending the antenatal clinic were counselled regarding the HIV infection with special reference to the possibility of HIV transmission from the parents to their children. After taking informed consent,those who were found to be seropositive for HIV underwent confidential post-test information and counselling regarding the vertical transmission and importance of their delivery in the PPTCT centers. HIV infected pregnant women were initiated on the new triple drug TLD regimen(Tenofovir-300mg, Lamivudine-300mg, Doleutagravir-50mg). Those mothers already on ART continued on the same regimen. ART was continued throughout ANC, during labor, delivery, postpartum during breastfeeding and lifelong thereafter. After delivery first dose of Nevirapine was given to Infant between 6-12 hours of delivery and continued for 6 wks or 12 weeks. In

infants, if viral load is >1000 copies, dual prophylaxis with zidovudine is given as per NACO guidelines 2021.Dry blood spot test (DBS) for HIV detection(RNA PCR assay) is done for infants after delivery. If DBS is positive , test is repeated after 15 days. If this is positive, again testing done after 15 days. If this is positive, infant is declared as positive. ELISA testing is done at 6weeks, 6 months, 12 months & 18 months. If the baby is HIV positive at 18 months ,life long ART is given. If negative, ART is stopped.

All HIV positive pregnant women were numbered , neither their name nor their address were taken into the master chart in order to maintain the confidentiality of the patient information.

Results:-

During our study period of 16 months duration, **74** HIV positive women were identified

Table 1:- Distribution of pregnant women as per age & parity.

Age(years)	Number	Percentage(%)
18-20	**10**	14
21-30	**52**	71
31-40	**11**	15
41-50	**0**	0
Parity	Number	Percentage
G1	38	51
G2	25	34
G3	9	12
G4	1	1.5
G7	1	1.5

In our study, 71% of women are in 21-30 years of age, 15% in 31-40 years & 14% in 18-20years of age. 51% of cases constitutes Primigravida, 49% cases are multigravidas.

Table 2:- Distribution of HIV positive mothers according to education.

Education	Number	Percentage
Illiterate	5	7%
Primary	20	27%
Secondary	38	51%
Higher secondary	11	15%

In our study, the prevalence of HIV is 51% among mothers who completed secondary education, followed by primary education (27%), higher secondary education(15%)& illiterates(7%).

Table 3:- Distribution of HIV positive mothers according to husband's occupation and serodiscordancy.

Occupation	Number	Percentage
Professional	2	3%
Skilled	24	32%
Semi-skilled	36	49%
Unskilled	12	16%
Serodiscordancy	Number	Percentage
Husband positive	46	62%
Husband negative	28	38%
Status unknown	nil	0

HIV infection rate was more in women whose husbands were semiskilled workers(49%), and skilled workers(32%) and unskilled workers (16%), followed by professionals(3%) . Women whose husbands were HIV positive were affected by 62%, whereas with HIV-ve husbands, the rate was 38%.

Table 4:- Distribution of HIV positive mothers according to their known or unknown status.

cases	NUMBER	percentage
New cases	30	41%
Known cases	44	59%

Table 5:- Distribution of HIV positive mothers according to the time of diagnosis and route of transmission.

Time	Number	Percentage
During pregnancy 1st trimester 2nd trimester 3rd trimester	 35 29 10	 45% 39% 14%
Route	Number	Percentage
heterosexual	74	100
Parent to child	nil	
Not specified	nil	

About 59% of the women were diagnosed before pregnancy, whereas 41% were diagnosed during pregnancy, with 45%, 39% and 14% during the 1st , 2nd and 3rd trimesters respectively. Heterosexual transmission was more common (100%), parent to child transmission and other non specific routes are not seen.

Table 6:- Characteristics of CD4 count in HIV positive mothers.

CD4 count {base line}	number	CD4 count {current}	number	percentage
100-200	0	100-200	0	0
200-300	16	200-300	5	7
300-500	45	300-500	48	65
>500	13	>500	21	28

About 28% of women had CD4 count >500, 65% had in the range of 200-500, 7% in between 200-300.

Table 7:- Outcome of HIV positive pregnancy.

outcome	number	percentage
MTP	3	4%
Abortion	2	3%
Live births LSCS Vaginal delivery	65 36 (25 male + 11 female) 29 (14 male + 15 female)	88% 49% 39%
IUD	3	4%
Still birth	1	1%

About 88% of women had live birth, 4% had MTP, 3%had abortion and 4% had IUD,1% had still birth.

Table 8:- Obstetric complications in HIV positive mothers.

Complications	number	percentage
PIH	2	3%
IUGR	2	3%
PTB	2	3%
Anemia Mild Moderate Severe	 29 45 nil	 39% 61%
GDM	1	1%

Anaemia was the most common complication(100%) in all affected women,61% observed with moderate anaemia, 39% with mild anaemia, followed by PIH (3%), PTB (3%), IUGR(3%), GDM (1%).

Table 9:- Characteristics of HIV positive babies.

Birth weight	number	percentage

<1 kg	0	0
<1.5 kg	1	1%
1.5-2 kg	3	4%
2-2.5 kg	20	27%
2.5-3 kg	47	64%
>3kg	3	4%

About 64% of the babies were between 2.5-3 kg, 27% between 2-2.5kg, 4% were between 1.5-2.5 kg and 4%>3kg

Table 10:- Neonatal outcome.

outcome	number	percentage
Congenital malformation	1	1%
NICU admission	4	5%
Breast feeding	63	97%
Formula feeding	2	3%

About 5% of the babies needed NICU admission and 97% babies were breast fed.

Foetal Outcome:

All 65 live babies born to women on anti retroviral therapy are assessed for APGAR as routine, all babies fall in normal range of APGAR as 7-9.

Physical and neurological development of infants are normal. No renal or liver damage found. All babies are treated with nevirapine and zidovudine prophylactically based on gestational age of mother and viral load. At 36 weeks of gestation, viral copies <1000 the babies are treated with nevirapine only for 6 weeks. If viral copies > 1000, then the babies aretreated with both nevirapine and zidovudine till 18 months in our study dual therapy is givento 13 babies. 46 days after birth, all babies are treated with co-trimoxazole syrup for a duration of 16 months. No other opportunistic infections were detected.

Discussion:-

The management of the pregnant woman with human immunodeficiency virus (HIV) infection has evolved significantly over time in light of advancements in drug development and a greater understanding of the prevention of vertical HIV transmission (transmission of HIV during pregnancy, labor and delivery, and breastfeeding). the risk of HIV transmission from mother to infant has declined to historically low levels with the use of antiretroviral medications. Contributions to this successful prevention effort include universal testing of pregnant women for HIV infection, life-long antiretroviral therapy (ART) administration to all individuals infected with HIV including pregnant women, the use of cesarean delivery (when appropriate), and appropriate infant antiretroviral prophylaxis management[7,8]. The combination of antepartum, intrapartum, and infant antiretroviral prophylaxis is recommended to maximize infant pre-exposure and postexposure prophylaxis and suppress maternal viral load below the limit of detection throughout pregnancy to decrease the risk of transmission. Dolutegravir has high and durable virologic potency, it leads to more rapid viral decline. it is dosed once daily, and it is better tolerated than protease inhibitors. Rates of stillbirth, neonatal death, small for gestational age, and preterm birth with dolutegravir-based regimens, started before or during pregnancy, are comparable with other antiretroviral regimens. In our study the adverse effects of HAART therapy is negligible

In the year 2010-11, the positivity rate of HIV was 6.74% among the general population and among pregnant women it was 0.46% during the same period. Prevalence of HIV positive pregnant women in 2019 in India was 0.24%.By 2022-23, the positivity rate among pregnant women came down to 0.05%,as perAndhra Pradesh State AIDS Control Society (APSACS) report.

In our study total number of deliveries conducted at our district during the period of our study was 35,800 and the number of HIV positive pregnant women were 74. Hence the HIV prevalence rate in our study is 0.20% which was lesser compared to study by yadav et.al (0.40%) and chauhan et.al (0.44%). Studying the profile of HIV positive mothers delivered, it was found that majority of the patients (71%) were in the age group of 21-30 years, which was similar to study by chauhan et.al (72 %).In our study 51% of cases are primigravida, 49% cases are multi-gravidas, while in sundari et.al 40% are primigravida, 60% cases are multi-gravidas. In our study, the prevalence of HIV is 51% among mothers who completed secondary education, followed by primary education (27%). HIV infection rate was more in women whose husbands were semiskilled workers(49%), and skilled workers(32%). Women whose husbands were HIV positive were affected by 62%, whereas with HIV-ve husbands, the rate was 38%. About 59% of the women were diagnosed before pregnancy, with 45%, 39% and 14% during the 1st,2nd and 3rd trimesters respectively. Heterosexual transmission was more common (100%), parent to child transmission and other non specific routes are not seen

In our study 59% patients were preconceptionally diagnosed as seropositive and 41% were detected to be seropositive during present pregnancy, this is compared with study done by chauhan et.al and mohanasundari et.al which showed that 55% and 20% patients were detected seropositive during present pregnancy whereas 45% and 80% were detected preconceptionally respectively.

CD4 count is used to assess the immune system of patients and it also monitors the effectiveness of the Antiretroviral treatment[9]. In our study, we observed that 7% had CD4 counts in the range of 201-300 and 65% had range of 300-500 and 28% had >500 range. In the study by chauhan et.al 10.2% patients reported CD4 count < 200, 22.5% between 201-350 and 20% between 351-500 and 55% >500%. In the study by sundari et.al 8% patients reported CD4 count < 200, 32% between 201-500 and 52% of patients reported >500%. Women with irrespective of CD4 counts are started on ART and is continued throughout the pregnancy, hence the risk of transmission to fetus is minimal. Since majority of patients in our study had CD4 counts 300-500 and >500, it shows the improved clinical outcomes in Sero-positive mothers.

Total 56% patients were delivered vaginally where as 44 % patients underwent caesarean section for obstetric indications. As can be seen in the study by yadav et.al it and chauhan et.al was found that 60% and 80% of patients delivered vaginally whereas 40% and 20% patients delivered via Caesarean Section respectively. However, in the era of Triple drug therapy and HAART, Vaginal Birth has once more become the safer option for Seropositive women to deliver, with minimal risk of transmission.

Out of 65 babies delivered, 61 babies had successful outcome and went home with mother.

In our study anaemia was the most common complication(100%) in all affected women, followed by PIH (3%), PTB (3%), IUGR(3%), GDM (1%).This is similar to study by mohanasundari et.al was PIH(16), anaemia (16), PTB(12), Abortion (20). About 64% of the babies were between 2.5-3 kg, 27% between 2-2.5kg, 4% were between 1.5-2.5 kg and 4%>3kg. According to yadav et.al birth weight of the babies was below 2.5 kgs in 40% HIV positive babies and 47.67% of the Non HIV positive babies. According to chauhan et.al study was out of 40 babies delivered, 37 babies had successful outcome and went home with mother. According to mohanasundari et.al study weight of the babies between 2-2.5 kg(45.5%), around 9% women had birth weight <2 kg and only 4% of women had IUGR.

Only few complaints of nausea and vomiting for initial few days with anti retroviral drugs as adverse effects. No other side effects like Rash, Fever, Abdominal pain, Bowel upset, Respiratory symptoms, Lypodystrophy, Nausea , Anorexia , Headache, Insomnia, Neutropenia, Peripheral neuropathy, Fatigue.

Conclusion:-

It is imperative that every HIV infected pregnant woman should get access to proper antenatal care throughout her pregnancy and every effort should be made to ensure that her child is born free of HIV. Antenatal care and close monitoring in pregnancy can optimise the outcome for HIV infected women and baby.Though present sample size was small to be of statistical significance, our results suggest that better couple education will probably lead to earlier diagnosis,initiation and compliance of therapy to prevent transmission. Our study proves that with the improvised HAART therapy there is better feto maternal outcome which is almost similar to other reference studies conducted elsewhere.

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