

Human Immunodeficiency Virus and Pregnancy: A retrospective descriptive cross-sectional study of prevalence, maternal, obstetrical and neonatal outcome, at a tertiary care hospital in the Sultanate of Oman

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Abstract

Objective: To investigate the prevalence of human immunodeficiency virus (HIV) in pregnant women, and the maternal, obstetrical and neonatal outcome over a thirteen year period (2005-2017) at the Sultan Qaboos University hospital, a tertiary hospital in Muscat, Oman.

Methods: Our study design was a retrospective descriptive cross sectional study of HIV positive women in the department of obstetrics and gynaecology. We had an unlimited sample size due to the rarity of the disease and aimed to include all pregnant Omani women who tested positive for HIV in their antenatal screening (ANS) during the period 1 st of January 2005 to 31 st December 2017 with the exclusion of non-Omanis. Ethical approval was obtained from hospital ethics committee and patient records were reviewed using the hospital information system (HIS) service.

Results: There were a total of 13,688 women with 104,281 pregnancies over the study period. The prevalence of Omani pregnant women with HIV was 0.1% (1:1000) with 0.03% of seropositive pregnancies (3:10,000). Of these seropositive pregnancies, 78.6% were known HIV carriers, whilst 21.4% were newly diagnosed cases. The live birth rate was 90.3% with 9.7% ending up in miscarriage. All the miscarriages were to known HIV positive mothers who were managed in accordance to international guidelines. Of the livebirths, 10.7% were unknown HIV positive mothers with a mean gestational age of 39.67 weeks and a mean birth weight of 3.21kg. The rate of mother to child transmission (MTCT) of HIV in this group was 33.3%. In contrast, 89.3% of the livebirths to known HIV positive mothers had delivered neonates with a mean gestational age was 37.48 weeks and a mean birth weight of 2.63kg with 0% MTCT. Modes of delivery, antepartum, intrapartum and postpartum complications as well as long-term neonatal outcomes were analysed according to the status of the mother at first presentation.

Conclusion: Strategies have been placed by programmes in the Sultanate to focus on pregnant women wellbeing and protection of newborns against HIV infection. Strict implementations on preventing mother to child transmission (MTCT) allowed preventing HIV in children

possible. Antiretroviral therapy (ART) significantly reduces vertical transmission of HIV, in addition to abstinence of breastfeeding. More importantly, all HIV-positive pregnant women should follow the prevention of MTCT programs set out by the ministry of health.

Introduction

Human immunodeficiency virus (HIV) infection remains a major global public health issue. Humans acquire it via exchange of bodily fluids, mainly through unprotected heterosexual intercourse, and women consequently pass it on as mother to child transmission during pregnancy, childbirth, and breastfeeding. Other known means of transmission include homosexual unprotected intercourse, use of infected syringes by drug abusers and blood transfusions (1).

According to a report issued by the World Health Organisation (WHO) in 2019, approximately 38 million people were living with HIV globally (2). In 2016, the American Foundation for Aids Research (amfAR) census showed that 51% of all adults living with HIV were women and it is believed to be the leading cause of death for women in the reproductive age group worldwide (3,4).

In the absence of any intervention, mother to child transmission (MTCT) ranges from 15-45% (4). With advancements in healthcare improved access to and availability of antiretroviral therapy (ART), there has been a 50% reduction in new HIV cases. Preventative strategies have reduced MTCT to less than 5% (4).

In Oman, the first notified case of acquired immunodeficiency syndrome (AIDS) was in 1984 (5). Up until 2019 the total number of cases of HIV/AIDS registered with the ministry of health (MOH) was 3232. Of those 884 (27.4%) were female. Majority of which lie in the childbearing age; 63.1% between the ages of 25-49 years, and 17.6% between the ages 15-24 years (5). There has been an exponential increase in the number of documented HIV cases in the recent years, and this has been attributed to the decrease in stigmatisation, applying protocols of detection such as antenatal screen (ANS) of pregnant women and their contacts as well as availability of treatment in health institutions (5). The most common mode of transmission to children is through MTCT from HIV infected woman.

Oman has established the maternal and child health programme in 1987, with aim to identify and care for all pregnant women and their offspring. In 2009, HIV testing was made mandatory for all women attending antenatal clinic (ANC) for early detection, support, management, and prevention of transmission. In a study conducted by MOH between 2009 and 2014, the testing coverage for HIV in pregnant women was 98% with a prevalence of 0.02% and an annual rate of HIV in the new-born due to MTCT of 0.01% or 10 per 100,000 live births (6).

In Sultan Qaboos University Hospital (SQUH), a study looked into the prevalence of HIV-1 and 2 among pregnant women during a 10-year period between January 1995 and December 2005 found a prevalence of 0.13% (7). The study however did not look into the outcomes of the patient or their offspring's and it did not give information on whether or not patients were on ART or their antenatal management.

Worldwide, studies have been done to look into the effects on pregnancy and outcome. For example, a retrospective study published in 2015, looked into the maternal and perinatal outcome of HIV infected women in a tertiary hospital in Nigeria. They concluded that HIV-

positive status increased adverse birth outcome of pregnancy such as anaemia, puerperal sepsis, low birth weight, preterm births and higher caesarean section rate amongst women who tested positive for HIV. It also showed that ART appeared to reduce the risk of preterm births in HIV-positive cohorts (8).

On the contrary, a prospective observational study published in 2015 looked into antiretroviral therapy in relation to birth outcomes in Dar es Salaam, Tanzania. They not only compared the outcome of ART vs non-exposure to ART during pregnancy and outcome, but also the outcomes of the ART therapy used (eg. monotherapy zidovudine vs HAART –highly active antiretroviral therapy) and found that there was an increased risk of adverse birth outcomes associated with the use of HAART (9).

Objective

The objective of this study is to investigate the prevalence of HIV in pregnant Omani women, and to identify the maternal, obstetrical and neonatal outcome over a thirteen-year period (2005-2017) at SQUH, a tertiary hospital in Muscat, Oman.

Methodology

This was a retrospective descriptive cross-sectional study of HIV positive pregnant women that were managed and delivered in the department of Obstetrics and Gynaecology (OBGYN) at SQUH. We set an unlimited sample size during the period of 1st of January 2005 to 31st of December 2017 due to the relative low prevalence of the disease and included all pregnant Omani women who tested positive for HIV 1 or 2 on antenatal screen (ANS) during this period. We excluded all non-Omani's to get a true prevalence of HIV in the Omani population.

After obtaining ethical approval from the hospital's ethics committee, we proceeded to collect data from the hospital information system (HIS).

Our data collection sheet included a variety of variables. The variables included: Initial demographics, past medical, surgical, and obstetrical history and allergies. Each woman who was tested positive was then divided to the number of pregnancies and each pregnancy was considered as a separate case.

Each case was then looked into further details: whether or not HIV status was known during the pregnancy, the gestation at first presentation whether it was a single or multi-fetal pregnancy, the viral load and CD4 count per trimester, the use of ART and the gestation at which they have started treatment, compliance to medication, the outcome of pregnancy the mode of delivery the confounding obstetrical complications, the antepartum complications, the acquired antepartum opportunistic infections, the intrapartum complications, whether or not they received intrapartum ART prophylaxis and postpartum complications. We also looked at whether or not these patients were advised for or against breastfeeding.

Data collected with regards to fetal outcomes included gestational age at delivery, birth weight, gender, APGAR scores, whether or not they required neonatal intensive care unit (NICU) admission. Additionally, neonatal prophylactic ART, postnatal HIV status on testing, emergency visits and OPD visits were explored.

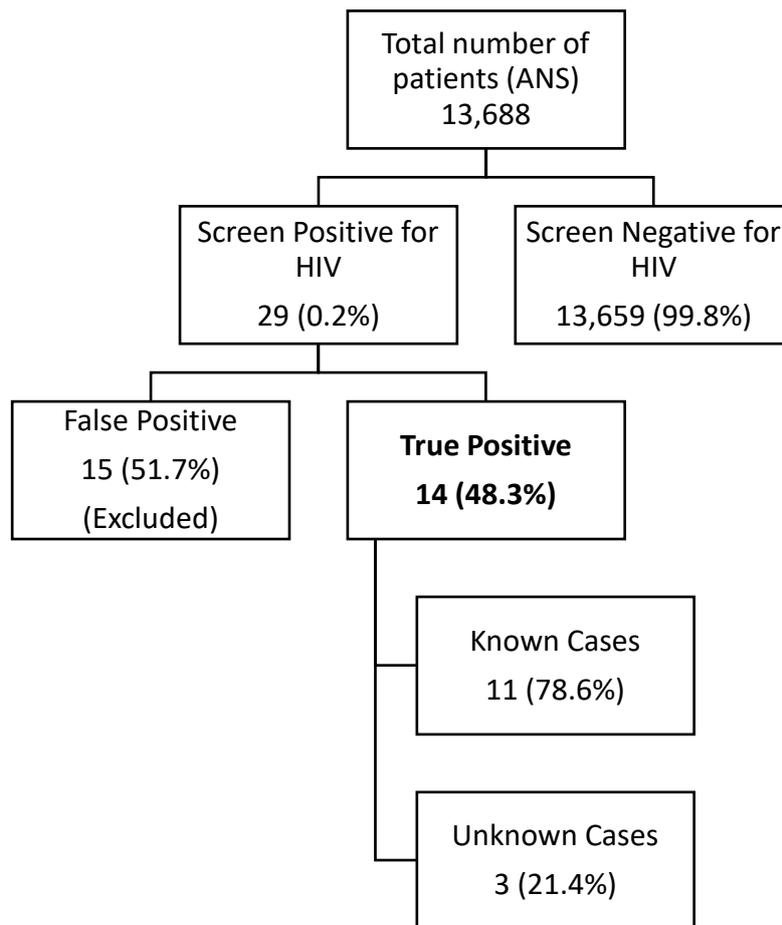
Data were then transferred to EpiData and the information analysed using Statistical Package for the Social Sciences (SPSS) to calculate measures of central tendency and dispersion.

Results & Analysis

A total of 104,281 antenatal screens (number of pregnancies) were done over the period of 1st of January 2005 to 31st of December 2017. Excluding repeated pregnancies, this number dropped to 13,688 corresponding to the number of patients, to achieve prevalence.

Twenty-nine Omani pregnant women tested positive for HIV on ANS. Fourteen of them (48.3%) had proven positive to HIV after further testing with polymerase chain reaction (PCR). Therefore, the true prevalence of Omani pregnant women in SQUH who tested positive for HIV was 0.1% or 1:1000 women. There were 31 pregnancies amongst these fourteen women, and therefore the prevalence of seropositive pregnancies was 0.03% (3:10,000 pregnancies). The remainder 15 women (51.7%) were false positives to HIV on initial screening.

Eleven out of the fourteen patients were known HIV carriers (78.6%) and three of the fourteen women (21.4%) were newly diagnosed cases at time of first presentation (not known prior to having HIV as shown in diagram 1).



Of the 31 pregnancies, there were three miscarriages (9.7%) and 28 live births (90.3%). Of the miscarriages, all were known to have HIV, with singleton pregnancies, which presented in their

first trimester in OPD. All (100%) were on ART from the first trimester and miscarried during the first trimester. One of three was medically managed with misoprostol; one was surgically managed with suction evacuation, and no data available for the 3rd miscarriage. The viral load was <1000 copies/ml and in fact undetectable (<50 copies/ml) and the CD4 count was >500 cells/mm³ in two thirds of the cases. No data available for the third miscarriage.

Of the twenty-eight live births, three (10.7%) had unknown HIV status, as they presented in the 3rd trimester during active labour. Routine ANS screening identified them as seropositive. All were singleton pregnancies and did not receive antenatal ART due to their unknown status. One in three (33.3%) had a normal vaginal delivery, whilst the remainder two (66.7%) ended up in emergency caesarean section (one with suspected chorioamnionitis, and the other breech in labour). There were no known antepartum complications, confounding factors or known acquired infections. One of the three had intrapartum fever (suspected chorioamnionitis). None of the patients received intrapartum ART prophylaxis due to their unknown status, whilst 66.7% suffered from puerperal fever (one who delivered by emergency caesarean section for suspected chorioamnionitis, whilst the other normal vaginal delivery had suffered with breast engorgement).

The mean gestational age at delivery was 39.67 weeks of gestation (SD ±0.58, range 39-40 weeks gestation) with a mean birth weight of 3.21kg (SD ±0.35, min 2.92kg, max 3.60kg). All three were advised to breastfeed as per routine and all were advised to discontinue breastfeeding and offered Cabergoline after ANS status revealed positive for HIV. One patient refused to stop breastfeeding.

All three (100%) neonates were born females with APGAR 9 and 10 at one and five minutes respectively, and none required admission to the NICU post-delivery. Two out of three babies (66.7%) received postnatal ART with one (33.3%) testing positive for HIV. None of them had visits to the emergency room and only 33.3% had OPD visit to follow up HIV status (one did not attend their appointment, whereas the other was lost to follow up).

The viral load of the mother with seropositive infant after birth was 4644 copies/ml with a CD4 count of 395 cells/mm³. The viral load of the other mother who had a spontaneous vaginal birth was 22333 copies/ml with a CD4 count of 401 cells/mm³. The third unknown HIV patient (who delivered by emergency caesarean for breech in labour) had no documented viral load/CD4 count post-delivery.

Of the 25 known HIV positive pregnancies, 16% presented to OBGYN in the first trimester, 68% in the second trimester and 16% in the third trimester. All known cases were following up with the infectious disease (ID) team. 100% were on ART during pregnancy. Eighty per cent (80%) were on ART prior to pregnancy, 4% were started in the first trimester and 16% in the second trimester. With regards to compliance to medication, 87% were compliant with their medication.

Table 1 illustrates the percentage (%) of patients according to viral load and CD4 count per trimester.

Table 1

Trimester	Viral Load* (copies/ml)	CD4 count** (cells/mm ³)
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	<1000	>1000	<500	>500
1 st (%)	61.9	38.1	46.7	53.3
2 nd (%)	100	0	41.2	58.8
3 rd (%)	92	8	43.8	56.2

* A viral load of <1000 is considered suppressed

** A CD4 count <500 is considered immunocompromised

Of the twenty-five pregnancies, 96% were singleton with one set of twins (4%).

With regards to mode of delivery: 45.8% had spontaneous vaginal delivery, 8.3% were induced (one for postdate and the other for unprovoked deceleration), 20.8% had elective caesarean section (for previous caesarean section, fetus with intrauterine growth restriction (IUGR) and diaphragmatic hernia), and 25% had emergency caesarean sections (one for previous two caesarean sections in labour-twin pregnancy at 33 weeks gestation, was booked for elective caesarean but attended with preterm labour, one was breech in labour- also booked for elective caesarean section, two with premature rupture of membrane and prolonged latent phase and one with preterm labour with uncontrolled retroviral disease).

The vast majority (72%,) had no obstetrical cofounding factors, 8% had diabetes mellitus, 4% with gestational diabetes, 4% with obstetric cholestasis and 12% had other factors such as iron deficiency anaemia, chronic idiopathic thrombocytopenic purpura and fundal fibroid uterus.

With regards to antepartum complications, 40% had no antepartum complications, 20% had vaginal infections (candiasis etc), and 40% had other complications which include; 40% IUGR/small for gestational age (SGA) of which 25% had associated diaphragmatic hernia, 10% with carpal tunnel syndrome, 10% admitted for glycaemic control associated with hypokalaemia, 10% with fetal pelvic ureteric junction dilatation, 20% with threatened preterm labour of which 50% were associated with thrombocytopaenia and pyelonephritis.

With regards to acquired opportunistic infections (pneumocystis jirovecii pneumonia, mycobacterium avium complex), 4% suffered from pneumonia but this was deemed to be community acquired. The majority (75%) did not suffer from intrapartum complications, 4.2% suffered from intrapartum pyrexia (patient with pyelonephritis) and 20.8% from others such as meconium stained liquor (83.33%) and 16.67% with PPRM (at 37 weeks gestation).

All patients (100%) received intrapartum ART prophylaxis. Two thirds (66.7%) had no postpartum complications, whilst 4.2% had postpartum haemorrhage, 4.2% had puerperal fever, 8.3% had anaemia, and 16.7% had other complications such as first degree perineal tear (25%), second degree perineal tear (25%), UTI post caesarean section (25%) and 25% with pulmonary oedema and hypertension (suspected congestive cardiac failure).

Only 92% were advised to refrain from breastfeeding with an alarming 8% advised to breastfeed by breastfeeding nurse- this was documented in the patient's notes. Nonetheless, they were subsequently asked to refrain from breastfeeding once HIV status was alerted.

The mean gestational age at delivery was 37.48 weeks (SD±1.96, range 33-40 weeks gestation), 36% of which were preterm deliveries (<37 completed weeks of gestation).

There was a total of 26 neonates (1 set of twin), 2 of which delivered elsewhere, so the following results are of the remainder 24 neonates.

The mean birth weight was 2.63kg (SD±0.53, range 1.49kg to 3.79kg). Half of which were male, and the other half female. All delivered live birth of APGAR ≥ 6 at 1 minute and ≥ 8 at 5 minutes.

All neonates (100%) received postnatal ART prophylaxis and tested negative for HIV post-delivery. One third of the neonates (33.3 %) required NICU admissions and four neonates (18.2%) attended the emergency room. Majority (81.8%) attended follow up in OPD for further repeat testing of HIV and follow up.

Discussion:

The prevalence of HIV in pregnant women during the study period was comparable to the preceding ten year study at SQUH during the period 1995-2005 (prevalence of 0.1% and 0.13% respectively). This value was ten times higher compared to the national prevalence of HIV in pregnant women conducted by the MOH in Oman (0.02%) during the screening period between 2009-2014, but still in keeping with the national prevalence of the general population of <1.0% (10).

Surprisingly, there was a high false positive rate on initial testing (51.7%) which were identified after 2011. After further investigations, it was noted that there was an upgrade to fourth generation ELISA by the hospital laboratory which deemed it more sensitive but not specific to HIV than previous tests.

These false positive results were included in our initial assessment of prevalence, as our aim was to identify those who had a positive result in the ANS, but were excluded in our analysis, as they would subsequently obscure the true results and analysis of MTCT.

The prevalence of miscarriages amongst the total number of HIV positive pregnancies was 9.7%, which reflects the general background miscarriage rate of 10-20% (11) and unlikely to be related to the HIV as these patients were appropriately managed prior and during their antenatal period, compliant to medications which was reflected on their suppressed viral loads at the time of miscarriage.

When looking at the unknown HIV positive women who did not receive any prenatal care at SQUH, all delivered to term with appropriate birth weights for gestational age and APGAR scores. The indications for caesarean sections were warranted for obstetrical and fetal causes. It comes to no surprise that the neonate born with HIV was from the patient who had an emergency caesarean for suspected chorioamnionitis. Despite receiving postnatal ART, the patient refused to refrain from breastfeeding and refused Cabergoline, which further added to the MTCT. Nevertheless with no intervention, the MTCT was 33.3%, which reflects the background transfer of HIV by MTCT in the absence of intervention (4).

Only one third of these infants born to HIV positive patients were followed up in SQUH OPD. Ideally, all infants born to seropositive women are routinely followed up to 18 months

regardless of their status. The infant that was followed up was the one who tested positive initially and further referred to a paediatric tertiary centre for communicable diseases. The poor follow up for the other two infants was a result of missed appointment to parents who left against medical advice post-delivery, and one loss to follow up but was detected again at 2 years of age by the family screening programme.

With regards to the known HIV positive women, 84% were seen in OPD by the end of the second trimester. This is seen as ideal as referral from the infectious disease department to OBGYN aims for the patient to be referred once pregnancy is identified and to be seen once viability is confirmed for management of pregnancy, labour, and breastfeeding advice. With regards to the remainder 16% that were seen in the third trimester: one missed her second trimester appointment and attended in active labour, two had no follow up and attended during their 3rd trimester in active labour and one received a late appointment at 34 weeks.

Compliance rate to ART in this cohort was 87%. It was noted that reasons for non-compliance to medications were due to change in medications, side effects such as diarrhoea and vomiting, dizziness, abdominal pain and low socioeconomic class.

When looking at the viral load in each trimester, 92% were suppressed to undetectable levels by the third trimester (12).

With regards to mode of delivery, the vast majority had vaginal births. Caesarean sections were related to obstetrical and fetal factors rather than HIV per se. The exception was for the emergency caesarean section done for a patient with uncontrollable retroviral disease. This patient was non-compliant to her medications due to personal reasons and vomiting with a viral load of 63,681 copies/mL and a CD4 count of 123 cells/mm³ in the third trimester. As a strategy to prevent MTCT, caesarean section was done in order to minimise the risk of transfer.

Similarly, the majority of patients had no cofounding factors, whereas 12% exhibited anaemia of pregnancy, which as mentioned previously may have an increased risk of development due to HIV status. This was demonstrated in the study done in a tertiary hospital in Nigeria published in 2015 where a significant 8.1% of seropositive pregnant women had anaemia compared to 3.1% of the control group (8). However, it is not unusual to have anaemia in pregnancy. According to the WHO criteria, 52% of pregnant women from undeveloped or developing countries are anaemic compared with 20% from industrialized nation. This is mainly attributed to high fetal demands for iron and render iron deficiency the most common cause of anaemia in pregnancy, with other causes contributing less frequently (13).

Likewise seen in the antepartum complication of pregnancy where a fifth of the patients suffered from vaginal infections, in particular candidiasis. It is recognised that approximately 20% of asymptomatic women have vaginal colonization with *Candida* and there is a 30-40% increased rates of colonization in pregnancy and uncontrolled diabetes. In addition to immunosuppression and antimicrobial therapy, these factors attribute to symptomatic candidiasis (14). Therefore, we cannot conclude that the 20% of the pregnant women with vaginal infections is a direct cause of their HIV status alone. The same is true for the SGA/IUGR fetuses where in fact Congenital infections such as *Toxoplasma gondii*, rubella, cytomegalovirus, herpes simplex virus (HSV), varicella-zoster virus, *Treponema*, and HIV only contribute to 5–10% of fetal growth restriction, whereas maternal diseases such as anaemia of pregnancy and malnutrition and utero-placental dysfunction in which pre-eclampsia and abruption come under have a wider role (15).

Fortunately, there were no documented opportunistic infections in the seropositive pregnant women, which reflect the good compliance to medication, with suppressed viral loads and immunocompetence of the patients.

When looking at the intrapartum complications, only 4.2% suffered from intrapartum pyrexia-source of infection identified from the data as pyelonephritis. A fifth with meconium stained liquor and 4% with PPRM. Again, there are multiple factors that could lead to this, the normal process of labour and stresses of labour being some.

SQUH has shown excellent management of these seropositive women during active labour where all received intrapartum ART prophylaxis and postnatal ART prophylaxis. It was unfortunate that 8% of the patients were advised as routine to breastfeed, but if we look at the Swiss cheese model of accident causation, they were eventually picked up in time to advise to stop and this would be considered a near miss, as none of the neonates were affected by HIV.

The postpartum complications that occurred are no different to the general population. One thing to note is postpartum haemorrhage. SQUH practices delayed cord clamping during active management of 3rd stage of labour. Concerns regarding this could be raised in view of the belief that delay in separation of the placenta may increase exposure of the fetus to maternal blood. The WHO recommendation for prevention and treatment of postpartum haemorrhage has stated that the proven benefits of a 1 – 3 minute delay in clamping the cord outweigh the theoretical, and unproven harms, and late cord clamping is recommended even among women living with HIV or women with unknown HIV status as long as there is no acute fetomaternal compromise (16).

With regards to preterm delivery, where 36% were delivered at <37 weeks gestation. This included the twin pregnancy that attended at 33 weeks with labour pains; emergency caesarean was done for her in view of her obstetrical history of previous 3 caesareans. This in turn skewed the mean gestational age at delivery as well as mean birth weight in view of preterm and twins (1.49kg and 1.66kg). Likewise, two other 33 weeks gestation foetuses ended up in emergency caesarean section; one for breech in labour (birthweight 2.05kg) and the other for preterm labour with uncontrolled retroviral disease mentioned previously (birthweight 2.0kg). Therefore, when looking at the mean gestational age, as well as birth weight, we are more inclined to attribute it to obstetrical factors rather than HIV with the exception to the last patient. To justify this, although preterm births are higher in HIV positive cohort as shown in the study done in Nigeria comparing to the control group, ART in fact reduced the risk of preterm birth in HIV positive cohort (8) which our patients were all on.

The NICU admissions were for small for gestational age foetus, prematurity, presumed sepsis, respiratory distress and congenital diaphragmatic hernia (CDH) with multiple birth defects. Whereas the emergency attendance was due to suspected sepsis (norovirus at 5 weeks age, other with CDH/multiple birth defects), one at 8 months with viral upper respiratory tract infection and one with community-acquired pneumonia.

With regards to OPD follow for HIV status monitoring, the following infants had regular follow up in OPD for PUJ dilatation and hydronephrosis; persistent metabolic acidaemia to a mother with systemic lupus erythematosus/Sjogren disease; mega meatus for circumcision at nine months; stridor with no cardiac cause found; left congenital diaphragmatic hernia with

pulmonary hyperplasia, multiple jejunal perforation, cholestasis, delayed milestones, subtle dysmorphism and now deceased.

Looking at birth defects, we cannot conclude HIV as direct cause per se in this study. However, the fetus with multiple congenital anomalies – (born with left CDH, pulmonary hyperplasia, multiple jejunal perforation, cholestasis, delayed milestones and subtle dysmorphism), was born to a mother who was on Trizivir a combination of Abacavir, Lamivudine and Zidovudine prior to pregnancy. Looking at the drug Food and Drug Administration (FDA) label; data available from the Antiretroviral Pregnancy Registry (APR) show no difference in the overall risk of birth defects for Abacavir, Lamivudine, or Zidovudine compared with the background rate for birth defects of 2.7% (17). Therefore, these birth defects are unlikely related to medication administered.

Conclusion

Strategies have been placed by programmes in the Sultanate of Oman to not only focus on pregnant women's wellbeing, but also on the protection of newborns against HIV infection. By strict implementations on preventing MTCT, preventing HIV in children has become possible. ART significantly reduces vertical transmission of HIV, in addition to abstinence of breastfeeding. An established interaction between researchers, clinicians, healthcare workers and pharmacists has provided better care of mothers and their children. More importantly, all HIV-positive pregnant women should follow the prevention of MTCT programs set out by the MOH and ideally, their male partners should be involved in the antenatal care.

Obstacles and limitations

This study focused on pregnant women presenting at a single centre which is a tertiary care facility rather than a multi centre trial. The disease under investigation is of low prevalence nationally and therefore analysis of results was limited to the low number of cases obtained. Not all deliveries were conducted in the centre, and high level of loss to follow up due to individual and structural factors.

Disclosure

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