Original Research Article

# Seroprevalence of HIV infection in thalassemia patients in a tertiary care hospital

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## Abstract

**Background:** The general incidence of thalassemia trait in India varies between 3 and 17%. Children with thalassemia are susceptible to HIV because they receive multiple blood transfusions. Prevalence of HIV infection in thalassemia varies greatly worldwide, from less than 1% to more than 20%. The risk of transfusion transmission of HIV may be alarming due to high seroprevalence of anti HIV–1 viz; 0.5% in blood donors. **Aim and Objectives:** To study the seroprevalence of HIV infection in thalassemia patients. **Materials and methods:** An observational study was done at a tertiary care hospital over a period of one year (January 2014 to December 2014). 250 multitransfused thalassemia patients attending the hospital for blood transfusion were taken. Detailed history was taken after taking consent. 5ml of blood was aseptically collected and HIV tests performed as per kit literature according to NACO guidelines. **Results:** The predominant age group was 0-5 yrs with mean age of 8.7 years with male to female ratio of 1.27:1. Out of 250 samples, 71.6% were of thalassemia major, while 28.4% were of thalassemia intermedia. Seroprevalence of HIV was 0.4 %. One (1.2%) HIV reactive case predominantly belonged to the age group of 0-5 years and had received 0-50 blood transfusions. **Conclusion:** HIV infection is prevalent TTI among multiple blood transfused thalassemia patients and remains a major health problem for these patients. The low prevalence of HIV may be due to mandatory screening of all blood bags, proper selection criteria of donors, use of sensitive tests for screening all blood donors and increase awareness of people against HIV. But the window period of HIV can be further reduced by using improved technology like p24 Antigen detection or HIV viral RNA detection by RT-PCR or HIV minipool nucleic acid testing (MP-NAT).
**Key Words:** HIV infection, Thalassemia.

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## INTRODUCTION

The transfusion of blood and blood products is much safer than ever but far from attaining "zero risk" level at present moment. Patients receiving multiple transfusions are at a high risk for transfusion associated diseases and thalassemic children form one such high risk group. The general incidence of thalassemia trait in India varies between 3 and 17%. Regular blood transfusion in patients with hereditary haemolytic anemia, particularly thalassemia, has improved their overall survival, but carries a definite risk of acquisition of blood borne virus infections.[1,2] Transfusion transmitted infections (TTIs) are dreaded consequence of transfusion as these cases result in long term morbidity and mortality. In India it is mandatory to screen donated blood for anti HIV 1 and 2 (since 1991), anti HCV (since 2000), HBs Ag, syphilis, malaria.[3] TTIs can still occur from blood donations negative for markers for these infections. This residual risk of TTIs transmission from screened blood depend on the safety of donor population, sensitivity of the screening tests used, window period donations and other reasons such as mutant strains.[3] Children with thalassemia are

susceptible to HIV because they receive multiple blood transfusions. Prevalence of HIV infection in thalassemia varies greatly worldwide, from less than 1% to more than 20%[2,3]. HIV prevalence among blood donors is different in various part of country.[4] The risk of transfusion transmission of HIV may be alarming due to high seroprevalence of anti HIV–1 viz; 0.5% in blood donors.[5] Lack of data regarding this prevalence prompted us to conduct this study to provide comprehensive data based on epidemiology of HIV infection in patients with thalassemia. In view of above fact this study was undertaken.

## MATERIALS AND METHODS

**Place of study:** Department of Microbiology, Tertiary care hospital, Mumbai

**Duration of study:** One year (January 2014 to December 2014)

**Study design:** Observational Study

**Sample size:** 250 multitransfused thalassemia patients attending the hospital for blood transfusion were taken.

**Inclusion Criteria:**

- Thalassemia patients coming to tertiary care hospital receiving minimum 3 blood transfusions.

**Exclusion Criteria**

- Patients not suffering from thalassemia.
- Thalassemia patients receiving less than 3 blood transfusions.
- Patients not giving consent for study.

**Ethics permission:** The study was initiated after obtaining approval from the institutional ethics committee.

**Methodology: Study procedure:** Two hundred and fifty thalassemia patients attending the Thalassemia Day Care centre (n=250), who fulfilled the inclusion criteria mentioned above were selected for the study. A detailed history was elicited for each patient and duly recorded in the case record form. These patients were subjected to pretest counselling, after which a written informed consent or assent form for HIV testing was taken for participation in the study after explaining the protocol to the patient in the language that the patient best understood.

**Collection of Sample:** 5 ml of blood was collected from thalassemia patients in a sterile vacutainer. Serum was separated as soon as possible by centrifugation at 2000 rpm for 15 minutes. The serum samples were preserved in sterile vials and testing was carried out. HIV testing was done according to Strategy III as per NACO guidelines. In strategy III HIV testing was done by three test methods – ELISA/Rapid/ Simple (E/R/S), all test utilizing either different principles of test or different antigen coated if based on a common principle. A serum sample was considered negative for HIV if the first test was non-reactive, but if reactive, it was subjected to two other tests. In our study, following HIV antibody tests were used provided by NACO: 1) COMBAIDS-RS Advantage-ST**,** 2) SD HIV-1/2 3.0 and 3) AIDSCAN HIV- 1/2 Trispot test.

1. **COMBAIDS-RS Advantage-ST:** The COMBAIDS-RS Advantage-ST is an immunodot test for the qualitative detection of IgG / IgM antibodies specific to HIV-1 and/or HIV-2 in human serum, plasma or whole blood. **Performance characteristics:** Sensitivity: 100% and Specificity: 100%
2. **SD HIV-1/2 3.0:** The SD Bioline HIV-1/2 3.0 test is an immunochromatographic (rapid) test for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) specific to HIV-1 and HIV-2 simultaneously in human serum or plasma. **Performance characteristics:** Sensitivity: ≥ 99.5% and Specificity: ≥ 98.0%
3. **AIDSCAN HIV- 1/2 TRISPOT TEST KIT:** It is an immunoconcentration based assay for the detection of antibodies to HIV-1 and HIV-2 in human serum or plasma. **Performance characteristics:** Sensitivity: 100% and Specificity: 99.7%. HIV seropositive case was subjected to post-test counselling.

## OBSERVATIONS AND RESULTS

The present study was designed to assess the seroprevalence of Human Immunodeficiency Virus (HIV) infection in thalassemia patients in a tertiary care hospital. A total of 250 multitransfused thalassemia patients attending the hospital for blood transfusion were taken. The blood samples of these patients were collected from the Thalassemia day care centre and processed for anti-HIV antibody tests.

**Table 1:** Distribution of thalassemia cases (n= 250)

| No. of Cases (n) | Thalassemia major | | Thalassemia intermedia | |
|---|---|---|---|---|
| | No. | % | No. | % |
| 250 | 179 | 71.6 | 71 | 28.4 |

Out of 250 thalassemia cases, 179 (71.6%) were of thalassemia major and 71 (28.4%) were of thalassemia intermedia.

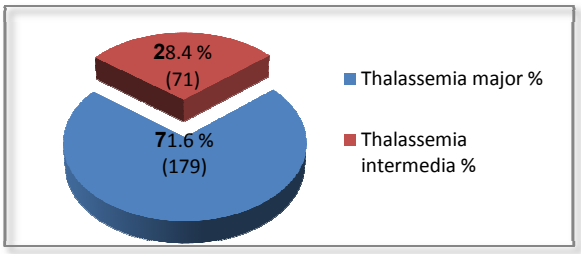


**Figure 1:** Distribution of thalassemia cases

**Table 2:** Age/gender wise distribution of thalassemia cases (n=250)

| Age in Years | Thalassemia Cases | | Total | Percentage (%) |
|---|---|---|---|---|
| | Male | Female | | |
| 0-5 | 44 | 41 | 85 | 34.0 |
| 5-10 | 44 | 40 | 84 | 33.6 |
| 10-15 | 32 | 18 | 50 | 20.0 |
| 15-20 | 16 | 8 | 24 | 9.6 |
| 20-25 | 4 | 3 | 7 | 2.8 |
| **Total (%)** | **140 (56%)** | **110 (44%)** | **250** | **100.0** |

Out of 250 thalassemia cases, 140 (56%) patients were male while female was 110 (44%) with male to female ratio of 1.27:1. Maximum numbers of cases i.e. 85 (34%) were seen in the age group of 0-5 years, followed by 84 (33.6%) in the age group of 5-10 years. 50 (20%), 24 (9.6%) and 7 (2.8%) belonged to the age group of 10-15, 15-20 and 20-25 years respectively. The mean age was 8.7 years (Mean ± 2SD = 8.7 ± 5.43).

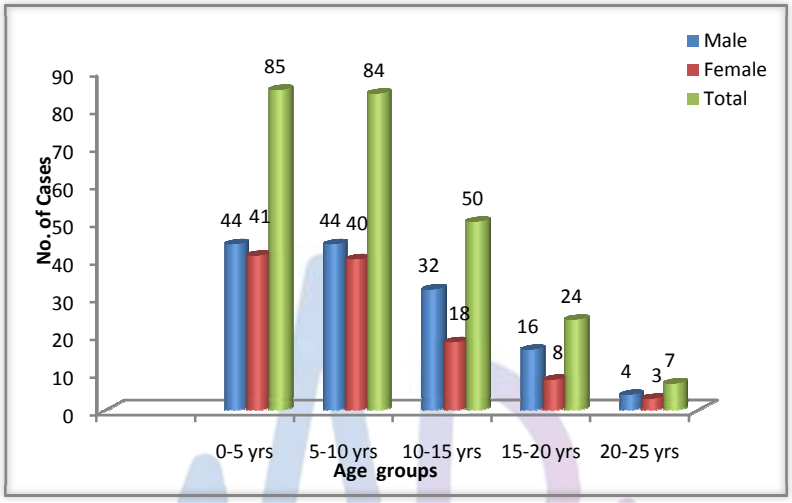


**Figure 2:** Age/Gender wise distribution

**Table 3:** Anti-hiv antibody test

| No. of Cases (n) | Reactive | | Non Reactive | |
|---|---|---|---|---|
| | No. | % | No. | % |
| 250 | 1 | 0.4 | 249 | 99.6 |

In the present study, out of 250 thalassemia cases, 1 patient was reactive for anti-HIV antibody and thus, seroprevalence of HIV was 0.4%.

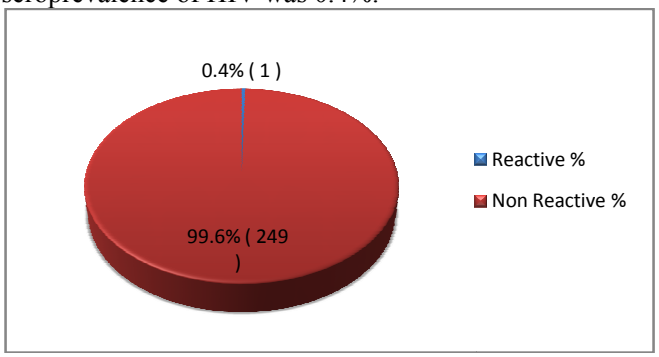


**Figure 3:** Anti-HIV antibody test

**Table 4:** Seroprevalence of Anti-HIV antibody in thalassemia cases in relation to age (years) (n=250)

| Age group of cases (years) | Anti-HIV Antibody test | | Total | *p* value |
|---|---|---|---|---|
| | Non Reactive Cases (%) | Reactive Cases (%) | | |
| 0 - 5 | 84(98.8%) | 1(1.2%) | 85 | |
| 5 -10 | 84(100%) | 0(0.00%) | 84 | |
| 10 -15 | 50(100%) | 0(0.00%) | 50 | 0.745 |
| 15-20 | 24(100%) | 0(0.00%) | 24 | (N.S.) |
| 20-25 | 7(100%) | 0(0.00%) | 7 | |
| **Total** | **249(99.6%)** | **1(0.4%)** | **250** | |

(*p* = Chi-square test, $X^2$=1.949, N.S - Not significant)

In the present study, out of 250 thalassemia patients, only 1 (1.2%) was reactive for anti-HIV antibody belonged to the age group of 0-5 years.

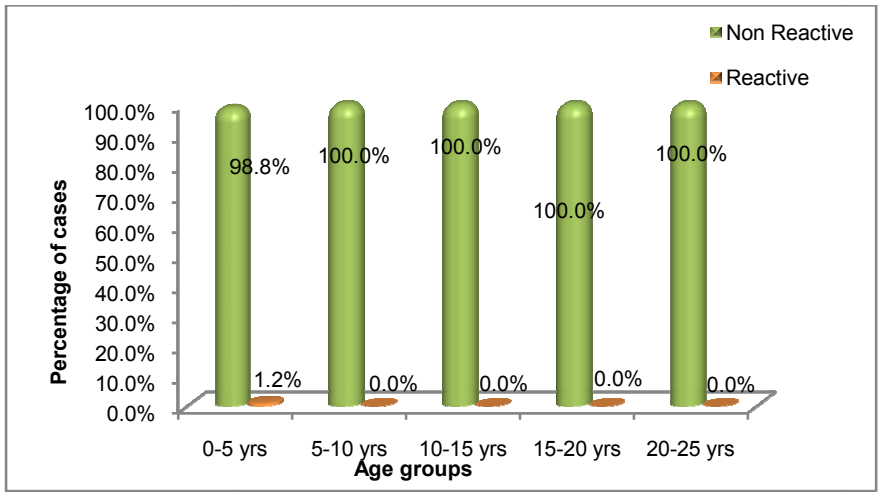


**Figure 4:** Anti-HIV antibody test

**Table 5:** Seroprevalence of anti-hiv antibody in relation to number of transfusions (n=250)

| No of Transfusions | Anti-HIV antibody test | | Total | *p* value |
|---|---|---|---|---|
| | Non Reactive Cases (%) | Reactive Cases (%) | | |
| 0-50 | 83(98.8%) | 1(1.2%) | 84 | 0.739 (N.S.) |
| 50-100 | 74(100%) | 0(0.00%) | 74 | |
| 100-150 | 49(100%) | 0(0.00%) | 49 | |
| 150-200 | 24(100%) | 0(0.00%) | 24 | |
| >200 | 19(100%) | 0(0.00%) | 19 | |
| **Total** | **249(99.6%)** | **1(0.4%)** | **250** | |

(*p* = Chi-square test, $X^2$=1.984, N.S - Not significant)

In the present study, out of 250 thalassemia patients, only 1 (1.2%) was reactive for anti-HIV antibody had received 0-50 blood transfusions**.**

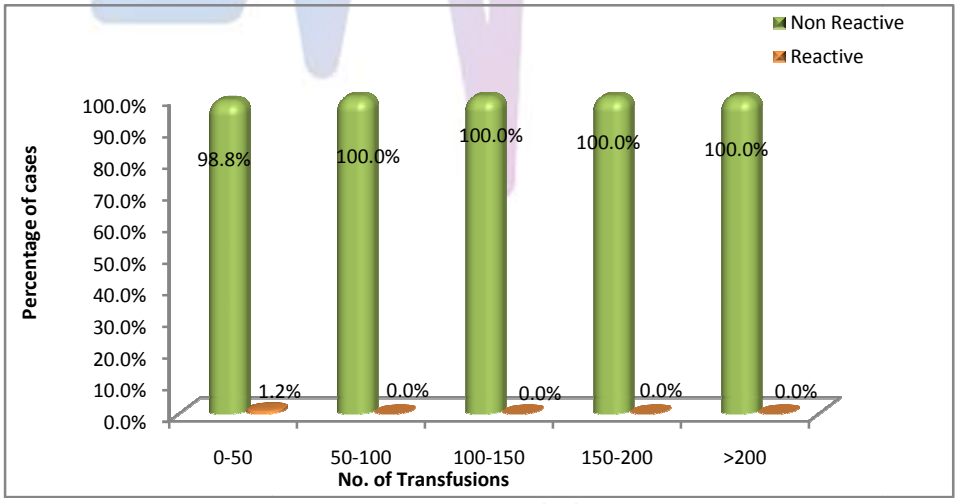


**Figure 5:** Anti-HIV antibody test

## DISCUSSION

Thalassemia is recognized as the most prevalent blood disorder in the world. However, Beta-thalassemia is the most common autosomal single-gene disorder worldwide, found in more than 60 countries with a carrier population of up to 150 million.[6] Beta-thalassemia major is one of the major public health problems in India. The general incidence of thalassemia trait in India varies between 3 and 17%.[7] It is estimated that there are about 65,000-67,000 beta-thalassemia patients in India with around 9,000-10,000 cases being added every year.[8] Patients with thalassemia major require repeated transfusions of blood

exposing them to the risk of Transfusion-Transmitted Infections (TTIs). The probability of acquiring TTIs is related to the probability of being exposed to the infected units of blood. This probability depends on the prevalence of carriers among the blood donors in the population and the number of units transfused. Thus, the infection rate of TTIs increases with age in subsequent years. The incidence of HIV infections in Indian pediatric patients with thalassemia is high due to high prevalence of HIV in the general population.[8,9] In the present study, a total of 250 multitransfused thalassemia patients attending the hospital for blood transfusion were taken. The blood samples of these patients were collected from the Thalassemia day care centre and processed for anti-HIV antibody after taking written informed consent. Prevalence of thalassemia major was reported higher than thalassemia intermedia. It might be due to thalassemia major is a clinical presentation where the patient has severe symptomatic anaemia with onset usually within 1 year of life, requiring regular and frequent blood transfusions while thalassemia intermedia is symptomatic thalassemia but not requiring transfusion at least during first few years of life and patients are able to survive into second decade of life without chronic hypertransfusion therapy.[10] In the present study, out of 250 thalassemia cases 179 (71.6%) were of thalassemia major and 71 (28.4%) were thalassemia intermedia. [Table 1] However, study conducted by Eiman Hussein[11] showed thalassemia major 76% and intermedia 24%. Similarly, study conducted by Miromomen *et al.*[12] 2006, showed 77.7% and 22.3% of thalassemia major and intermedia respectively. Most of these studies mentioned were in accordance with present study. In the present study, out of 250 thalassemia cases, 85 were in the age group of 0-5 years, followed by 84 in the age group of 5-10 years. 50, 24 and 7 were in the age group of 10-15, 15-20 and 20-25 years respectively. The mean age was 8.7 years (Mean ± 2SD = 8.7 ± 5.43). [Table 2] So, the maximum number of patients belonged to age group of 0-5 years i.e. 34 %, followed by 5-10 years of age group i.e. 33.6%. Similarly, the study conducted by Rezaul Karim *et al.*[13] and Bhavsar *et al.*[2] reported 34% and 38% of cases in age group of 4-7 years and 0-5 years respectively. Likewise, Ankita *et al.*[14] and Shah S.M.A *et al.*[15] noted 39.51% and 38.8% of cases in the age group of 0-5 and 1-5 years respectively. While a study conducted by Nadhim[16] at Tikrit, showed 32% patients belonged to 5-10 years of age group. These studies were in concordance with present study. Table 2 showed male to female ratio of 1.27:1, which was comparable with the study conducted by Mirmomen *et al.*[12] where male to female ratio was 1.29:1. Similarly, Hossainuddin *et al.*[17] and Dhaval *et al.*[18] showed male to female ratio of 1.33:1 and 1.63:1 respectively. HIV transmission through donated blood has become very rare after testing became mandatory for HIV-1 on 1989 and HIV-2 on 1993.[25] In the present study, 250 samples of thalassemia cases were tested for anti-HIV antibody, out of which 1 case (0.4%) was found to be reactive. [Table 3]. This study was comparable with Meena Sidhu *et al*[26], having HIV prevalence of 0.72%. Other studies by Roopam Jain *et al.*[3] and Ankita Patel *et al*[14] reported prevalence of HIV of 1.04% and 1.23% respectively. However, Kundan Mittal *et al*[22] and Rushdi *et al*[27] reported 0% seroprevalence in their respective studies. [Table 6]. The low prevalence of HIV may be due to mandatory screening of all blood bags, proper selection criteria of donors, use of sensitive tests for screening all blood donors and increase awareness of people against HIV.

**Table 6:** Comparison of anti-hiv antibody prevalence reported by various authors with present study

| Sr. No. | Author | Year | No. of Cases | Anti- HIV antibody (%) |
|---|---|---|---|---|
| 1 | Rushdi *et al.*[27] | 2012 | 200 | 0 |
| 2 | Roopam Jain *et al.*[3] | 2012 | 96 | 1.04 |
| 3 | Sangita Shah *et al.*[24] | 2013 | 210 | 1.42 |
| 4 | Ankita Patel *et al.*[14] | 2014 | 81 | 1.23 |
| 5 | Eiman Hussein[11] | 2014 | 200 | 0 |
| 6 | Kundan Mittal *et al.*[21] | 2015 | 211 | 0 |
| 7 | Meena Sidhu *et al.*[26] | 2015 | 138 | 0.72 |
| 8 | Srivastav M *et al.*[28] | 2015 | 66 | 1.5 |
| **9** | **Present Study** | **2015** | **250** | **0.4** |

In the present study, out of 250 thalassemia patients, only 1 (1.2%) was reactive for anti-HIV antibody belonged to the age group of 0-5 years. [Table 4]. Similarly, a study conducted by Hardik *et al*[2] reported 1(2.63%) HIV reactive case belonged to the age group of 0-5 years, whereas, Ankita *et al*[14] reported 1(3.12%) reactive cases in the age group of 0-5 years. However, Sangita *et al*[24] in their study reported 1 (0.47%) reactive case in the age group of 7-9 years, while, Prakash *et al*[20] showed 2 (2.5%) anti-HIV antibody reactive thalassemia cases in the age group of 6-10 years. Most of the above mentioned studies were in accordance with our study. In relation to age and seropositivity of HIV, it was found that there was no significant correlation between age and seropositivity. Similarly, this has also been reported by Kundan Mittal *et al*[21], Rezaul Karim *et al*[13] and Dhaval *et al*[18] In the present study, out of 250 thalassemia patients, only 1 (1.2%) was reactive for anti-HIV antibody had received 0-50 blood transfusions. [Table 5] While a study conducted by Meena Sidhu *et al*[26] where 1 (3.03%) reactive for anti-HIV antibody had received 50-100 blood transfusions. Similarly, Hardik *et al.*[2] in their study found 3 (5.88%) anti-HIV antibody reactive cases had received 0-50 blood transfusions. However, study conducted by Jagdish Goyal

*et al*.[19] reported 1 (1.37%) anti-HIV antibody reactive case which had received more than 200 blood transfusions, whereas Mathur *et al.*[23] showed 5 (5.43%) reactive cases had received more than 50 blood transfusions. In relation to number of transfusions and seropositivity of HIV, it was found that there was no significant correlation between number of transfusions and seropositivity. Likewise, this has also been reported by Prakash *et al.*[21] and Dhaval *et al.*[18]

## SUMMARY AND CONCLUSIONS

The present study was conducted in a tertiary care hospital, seroprevalence of HIV was studied in thalassemia patients.

1. A total 250 thalassemia patients were included in the study, out of which 71.6% were of thalassemia major, while 28.4% were of thalassemia intermedia.
2. Most of the thalassemia cases were seen in the age group of 0-5 years (34%), followed by 5-10 years (33.6%). The mean age was 8.7 years with male to female ratio of 1.27:1.
3. Seroprevalence of HIV was 0.4%.
4. One (1.2%) HIV reactive case predominantly belonged to the age group of 0-5 years and had received 0-50 blood transfusions.
5. Seropositivity of HIV was not significantly correlated with age and number of blood transfusions received.

## CONCLUSIONS

1. HIV infection is prevalent TTI among multiple blood transfused thalassemia patients and remains a major health problem for these patients.
2. The low prevalence of HIV may be due to mandatory screening of all blood bags, proper selection criteria of donors, use of sensitive tests for screening all blood donors and increase awareness of people against HIV. But the window period of HIV can be further reduced by using improved technology like p24 Antigen detection or HIV viral RNA detection by RT-PCR or HIV minipool nucleic acid testing (MP-NAT).
3. At present, the majority of blood banks in our country are not using NAT due to the cost, which is very high as compared to ELISA. If there is decrease in the cost of NAT and also making it mandatory in all blood banks, then it will further minimize the risk of TTIs in the patients requiring chronic transfusion.

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