IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 20, Issue 3 Ser.10 (March. 2021), PP 11-15
www.iosrjournals.org

Prevalence of Transfusion Transmitted Infection in B Thalassemia Major Patients

Dr. Mani Kant[1],Dr. Sweta[2],Dr. Syama Prasad Sit[3] ,Prof. Snehansu Chakraborti[4]
[1](Senior Resident,Dept. of Paediatrics,AIIMS,Patna)
[2](Senior Resident, Dept. of Dentistry,GDMC,Durgapur)
[3](Associate Professor, Dept. of Paediatrics,BSMC&H,Bankura)
[4](Professor and HOD,Dept. of Paediatrics,BSMC&H,Bankura)

Abstract
Background: *Thalassemia is the most common monogenic disorder in the world. Main stay of treatment in β Thalassemia major is frequent blood transfusion and chelation therapy. Due to multiple blood transfusions; Transfusion Transmitted Infection (TTI) is a major challenge to the transfusion services all over the world. This study was aimed to estimate the prevalence of blood TTI in multiple blood transfused patients of β thalassaemia major.*
Materials and Methods:*Prospective cross sectional study was conducted at BSMC&H,West Bengal between june 2015 to May 2016 among βThalassemia major patients up to 12 years of age received >5 blood transfusions. Total 200 samples were taken who fulfilled the inclusion criteria made for our study. Seropositivity status data were collected and analysed using Microsoft excel data sheet and IBM SPSver.22. Pvalue <0.005 was considered significant.*
Results: *Out of total 200 thalassemia children enrolled in the study, 112 (56% n=200) were boys and 88 (44% n=200) were girls. 159 (79.5% n=200) were non- tribals and 41 (20.5% n=200) were tribals. Thalassemic children in the study population received first blood transfusion at mean age of 10.75 ± 5.31 months. Total number of Hep.B positive patients in our study was 10 and Hep.C positive was 36.Seropositivity status is multifactorial which was analysed in our study.*
Conclusion*: My study done on transfusion dependent β-thalassemia major children showed significant number of cases were reactive for Anti HCV Ab,HBsAg positive patients were low in no. It was also seen that no. of transfusions is directly proportional to the prevalence of seropositivity especially for HepC . Education level of parents & other socio-economic factors has also some bearing in prevalence of seropositivity bcz patient may acquire infections from sources other than blood or blood products like reused needle & syringes, surgical operations, dental procedures, ear nose procedures etc.*
Key words*: HB_SAg, Anti HCV Ab, β Thalassemia.*

Date of Submission: 08-03-2021 Date of Acceptance: 22-03-2021

I. Introduction

Thalassemia is the most common monogenic disorder in the world. It had been traditionally prevalent in and confined to the Mediterranean basin, Middle East, North India, Southeast Asia and the Indochina Peninsula. However, immigration of those populations to USA, Canada, and Western European countries has resulted in a more universal distribution of the disease.[1] Therefore, it should currently be considered a global rather than a regional health problem. In India approximately 3-10% of people carry thalassemic gene.[2]

The combination of blood transfusion and chelation therapy has dramatically prolonged the life expectancy of these patients, thus transforming thalassaemia from a rapidly fatal disease of childhood to a chronic disease compatible with a prolonged life.[3] On the other hand, frequent blood transfusions leading to iron overload and the chronic nature of the disease have contributed to a whole new spectrum of complications in adolescents and young adults suffering from thalassemia major.[2]Transfusion Transmitted Infection (TTI) is a major challenge to the transfusion services all over the world. The problem of TTI is directly proportional to the prevalence of the infection in the blood donor community. Our study was limited to multiple blood transfused β thalassaemia major patients. This study was aimed to estimate the prevalence of blood TTI in multiple blood transfused patients of β thalassaemia major.

II. Aims & Objectives

HBV and HCV leads to acute hepatitis which clears within 6 months in 80% cases of *HBV* and 20% of *HCV* cases. In the rest, the virus becomes chronic and may progress to chronic liver disease, including

hepatocellular carcinoma and cirrhosis-related end-stage liver disease. WHO estimates that worldwide there are 350-400 million people with chronic *HBV* infection and 170 million people with chronic *HCV* infection. *Hepatitis B* is estimated to result in 5, 63000 deaths and *hepatitis C* in 3, 66000 deaths annually. These infections lead to a high burden of chronic disease, disability and death.

In developing countries, use of reused needles and syringes for therapeutic injections and improper sterilization of invasive medical devices is the major vehicle for transmission of blood borne organisms including hepatitis B virus (*HBV), HCV and HIV1&2*.

Hence the purpose of this study was to evaluate the seropositivity of *Hepatitis B & C* among Thalassemia patients transmitted by blood transfusion.

SPECIFIC OBJECTIVES OF THE STUDY:

The specific objectives of this study were:

1. To estimate the prevalence of Transfusion Transmitted Infections amongst multiple blood transfused patients of β thalassaemia major.
2. To evaluate information regarding blood transfusion dependent β thalassemic patients in relation to age, sex, blood group, total number of transfusion.
3. To determine association of TTIs in relation to number of transfusions.

III. Materials & Methods

STUDY AREA:

Department of pediatric medicine , BSMC&H.

STUDY POPULATION:

Diagnosed cases of thalassemic children upto 12 years of age admitted in indoor of the Department of Paediatric Medicine of Bankura Sammilani Medical college and Hospital, West Bengal.

STUDY PERIOD: One year (1st June 2015 to 31 May 2016)

SAMPLE SIZE: From the previous 3 years record of average number of children admitted with thalassemia to indoor of Pediatric medicine Dept., the expected available patients during my study period was around 200. Therefore, we proposed to study a population of at least 200 consecutive children with thalassemia.

SAMPLE DESIGN:Sample was selected from thalassemic children if they fulfil the inclusion criteria (as mentioned below) and parents voluntarily giving consent to participate in study.

INCLUSION CRITERIA:

a. All diagnosed patients of thalassemia admitted in thalassemia unit of our institution.

b. Age Group—up to 12 completed years irrespective of their age, sex &religion

c. Thalassemic patients whose parents had given consent to take part in the study.

d.Patients who had received at least 5 tarnsfusions

Exclusion Criteria:

a. Patients more than 12 years of age

b. Thalassemic patients whose parents were not given consent to takepart in the study.

c.patients received <5 tansfusions

d.patients who received transfusions from private institutes

e.Patients with clinical evidence of liver disease

STUDY DESIGN: Prospective cross sectional study

PARAMETERS TO BE STUDIED:

For objective no. 1:

HBsAg status of patient

Anti HCV Ab status of the patient

For objective no.2:

Age of the patient

Sex of the patient

No. of transfusions received by the patient

For objective no.3:

To determine whether prevalence of infection is related to the no. of transfusions

STUDY TOOLS:

1.Predesigned proforma

2.HPLC report

3. HBsAg &Anti HCV Ab (by ELISA Kits) reports to be done in dept. of Microbiology

4.Clinical assessment of the patients

[kit used for HCV is manufactured by Immunodiagnostic system, San Diego ;
For HBsAg is Bio test kit from Germany].

Study Technique: After obtaining ethical clearance from the Institutional Ethics Committee, study was conducted among the study population after taking written informed consent from the guardian /parents. Keeping compliance with Helsinki Declaration, 1964 for Medical Research involving Human Subjects, the parents of the selected patients were informed verbally about the study design, the purpose of the study and their right to withdraw their children from the study at any time, for any reason .The entire diagnosed thalassemia patient admitted in thalassemia unit was thoroughly examined and enquired for any blood trasnsfusion transmitted infection by reviewing their previous documents and test reports available with them because in our set up we used to do testing of serological status of all patients 6 monthly . Past history of transfusion and history of hepatitis B vaccination was taken.

Plan for analysis of data:

Data will be collected, recorded & compiled on Microsoft Excel data sheet.Statistical methods (mean, standard deviation) and IBM SPSS ver. 22 was used to analyse the data. Study of significance was analysed by Chi square test for qualitative data and Student t-test for quantitative data. P value <0.05 is considered significant.

IV. Results

Out of total 200 thalassemia children enrolled in the study, 112 (56% n=200) were boys and 88 (44% n=200) were girls. 159 (79.5% n=200) were non- tribals and 41 (20.5% n=200) were tribals. Out of total 200 patients 6(3%) were below 2 yrs of age, in 2to 5 year age group there were 50(25%) patients. 80(40%) & 64(32%) patients were respectively in 6 to 9 & 10 to 12 year age group. Mean age of patients was 7.5 ± 2.94. The youngest patients in the study was 1 year 5 months old & eldest patient 12 years old. Thalassemic children in the study population received first blood transfusion at mean age of 10.75 ± 5.31 months.Their maximum age for first transfusion was 27 months and minimum age, 3 months. In my study mean no. of transfusions received by study population was 55.89±33.53. Maximim no. of transfusions received by a patient was 145, 2 patients one of 11yrs. old & other of 12 yrs old received 145 transfusions ; minimum no. of transfusions i.e. 5 was received by 2 patients one of 1yr 11month old & other one was 2 yrs old female baby.

Table-1: Seropositivity status in relation to number of transfusion

No. Of transfusions	Hep B+	Hep C+
5-25	1	3
26-50	2	3
51-75	2	8
76-100	1	6
101-125	2	11
126-150	2	5
Total	10	36

Maximum no. of seropositive patients were those who received total no. of transfusions between 101 to 125; 2 were HepB reactive & 11 were HepC reactive. In the group which received >125 transfusions; 5 were HepC reactive &2 HepB reactive . Minimum no. of seropositive patients in the group which received transfusions in between 5 to 25; 1 HepB & 3 HepC reactive.

Table-2: Comparison of factors between HepB + & HepB- patients

Factors		HepB positive	HepB negative	p-value
AGE	<2	1	5	0.017
	2-5	0	50	
	6-9	2	78	
	10-12	7	57	
AOFT	0-6	3	41	0.611
	7-12	3	90	
	13-18	4	45	
	19-24	0	10	
	>24	0	4	
NOT	5-25	1	45	0.041
	26-50	2	51	
	51-75	2	46	
	76-100	1	30	
	101-125	2	13	
	126-150	2	5	

Table-3: Comparison of factors between HepC + & HepC- patients

Factors		HepC positive	HepC negative	p-value
AGE	<2	0	6	<0.01
	2-5	3	47	
	6-9	8	72	
	10-12	25	39	
AOFT	0-6	13	31	0.057
	7-12	18	75	
	13-18	5	44	
	19-24	0	10	
	>24	0	4	
NOT	5-25	3	43	<0.01
	26-50	3	50	
	51-75	8	40	
	76-100	6	25	
	101-125	11	4	
	126-150	5	2	

AOFT- Age of first transfusion
NOT- Number of transfusions

V. Discussion

TABLE NO.-4:Seropositivity Status(Indian studies)

Sr.no.	Author	Place	Publication year	Sample size	HIV Positivity	HBsAg Positivity	HCV Positivity
1.	ChakrabartiS et al[4]	Kolkata, India	2006	20	0%	5%	5%
2.	Bhavsaret Al[5]	Ahmedabad, India	2009	100	9%	6%	18%
3.	Twisha Oza et Al[6]	Gujarat, India	2011	193	3.1%	0.52%	7.8%
4.	SoniP et al[7]	Ahmedabad, India	2012	136	0%	1.47%	20.58%
5.	NeerjaH Shah et al[8]	Gujarat, India	2016	55	3.63%	0%	36.36%
6.	Biswas Aritra et al[9]	Kolkata, India	2014	1711	3.74%	3.33%	18.70%
7.	Present Study	Bankura, India	----	200	---	5%	18%

Table no.-5:Seropositivity Status(Foreign studies)

Sr. no.	Author	Place	Publication year	Sample size	HIV Positivity	HBsAg Positivity	HCV Positivity
1.	AKM Rezaul Karim et al[10]	Bangladesh	2013	100	0%	3%	31%
2.	Al-Sheyyab et al[11]	Jordan	2001	143	0%	3.5%	40.5%
3	Mirmomn et al[12]	Iran	2006	732	0%	1.5%	19.3%

5% patients in my study were tested positive for HBsAg; i.e. a total of 10 patients out of 200. In study conducted by Chakrabarty et al[4]& Bhavsar et al[5] has similar findings. Biswas et al[9] has also similar findings with respect to HBsAg positivity. Among foreign studies Al-Sheyyab et al[11] & AKM Rezaul et al[10] has similar findings i.e. 3.5% & 3% seropositivity for HBsAg.

HCV seropositivity is maximum in my study,36 patients out of 200 i.e. 18% were tested positive for Anti HCV Ab. In study conducted by Bhavsar et al[5] exactly 18% and study conducted by Aritra Biswas[9] et al 18.7% patients are tested positive for HCV. These two studies are well matched w.r.t. HCV positivity with my study. Other study had shown very high prevalence of HCV positivity in study population. In Indian studies maximum prevalence in study conducted by Neerja H Shah[8] et al is 36.36% but their sample size was too small. Among foreign studies maximum seropositiovity for HepC in study conducted by Al-Sheyyab et al[11] is 40.5%. By compairing all the studies my study is well matched with study conducted by Hardik Bhavsar et al[5] from Gujrat in 2009.

VI. Summary

Transfusion transmitted infection is the major determinant of prognosis and survival in β -thalassemia. In my study total 200 β-thalassemia major patient comes for blood transfusion in pediatric emergency ,are examined clinically & relevant data were taken w.r.t. Seropositivity for 2 major transfusion transmitted infection i.e. HepB & HepC.

Maximum no. of seropositive patients were in 10-12 yr. age group ; out of 32 seropositive patients in this age group 7 were positive for HepB & 25 for HepC. Minimum no. of seropositive patients were in <2year age group, only single patient in this age group was seropositive for Hep.B, no patient in this age group was positive for HepC. So, as the patients age increases no. of transfusions increases that increases the probability of acquiring transfusion transmitted infections.

Those patients who received their first transfusion below 1 year of age had shown maximum seropositivity. In the group who received their first transfusion below 6 months of age 3 were positive for HepB & 13 for HepC; receiving transfusion between 7-12 months of age make 3 patients HepB reactive & 18 HepC reactive. Those patients whose age of first transfusion was between 19-24 months of age no patients were tested seropositive & also no seropositive patient in the group who received their first transfusion after 24 months of age. Receiving first transfusion at very early age implied that patient will need more transfusions in future & hence more chance of acquiring infections.

VII. Conclusion

In conclusion, my study done on transfusion dependent β-thalassemia major children shows significant number of cases are reactive for Anti HCV Ab,HBsAg positive patients were low in no. It was also seen that no. of transfusions is directly proportional to the prevalence of seropositivity especially for HepC .

HCV and HBV are still prevalent in multitransfused β-thalassemia patients. Strict donor selection, education of patients about benefit of HBV vaccine and standard serological techniques for screening of blood product such as nucleic acid amplification test (NAAT) and PCR by blood bank might reduce the prevalence of TTI. At present, the majority of blood banks including ours in this country are not using NAAT due to the cost, which is 5–6 times as compared to ELISA. We think it is a nationwide issue and needs urgent attention. The government should take measures to cut down the cost of NAAT and make it mandatory for all blood banks in this country so that a patient requiring chronic transfusion will have a minimum risk of TTI.

Lastly, I must admit that this study done in a limited number of study population. The study period is also only one year. So a larger study done on a longer period will be able to define the situation more accurately.

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Dr. Mani Kant, et. al. "Prevalence of Transfusion Transmitted Infection in B Thalassemia Major Patients." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 20(03), 2021, pp. 11-15.