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The Impact of Iron Overload in Transfusion-Dependent Beta Thalassemia Major Patients in Peshawar

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ABSTRACT

Background: Patients experiencing transfusion as a result of thalassemia are highly prone to various clinical complications that are influenced by age and inherited characteristics such as consanguinity. **Objective:** The purpose of the research was to determine demographic factors, family history, and clinical outcomes of 293 Pakistan-based patients with TDT. **Study Design:** Cross-sectional study. **Settings:** Hayatabad Medical Complex, Peshawar, Pakistan. **Duration:** Six months from July to December 2023. **Methods:** Information about age, gender, consanguinity, family history, number of blood transfusions received per month, iron overload, and medication status and chelation therapy treatment were recorded. Descriptive statistics, chi square tests and binary logistic regression were conducted. Odds ratios (ORs) were adjusted, and presented with 95% confidence intervals (CIs), where p is < 0.05. **Results:** The mean age was 11.78 ± 6.29 years (range: 2–34), and 58.7% were male. The largest age group was 6–10 years (36.2%). 69.6% were consanguineous and 51.9% had a positive family history. 59.4% of patients had iron overload. The mean transfusion burden was 1.82 ± 0.83 units/month. The frequency of blood transfusion had significantly high association with iron overload ($\chi^2 = 19.892$, df = 3, $p < 0.001$). A univariable logistic regression revealed that for each additional transfused unit/month, the odds of iron overload rose by 1.624 (95% CI: 1.134 – 2.325; p = 0.008). Proper medication was associated with lower odds (OR = 0.141, 95% CI: 0.042–0.476, p = 0.002), while absence of chelation therapy was strongly associated with iron overload (OR = 45.541, 95% CI: 10.007–207.251, $p < 0.001$). **Conclusion:** Iron overload was highly prevalent in the subject population and presents an independent risk factor for transfusion burden and chelation therapy.

Keywords: *Thalassemia, Transfusion-dependent patients, Clinical complications, Genetic counseling, Morbidity.*

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INTRODUCTION

Beta-thalassemia is a genetic hemoglobin disorder, more frequent than alpha-thalassemia and includes major and minor subtypes. Beta-Thalassemia major or recently titled as Transfusion-dependent thalassemia (TDT), particularly prevalent in the Middle East and Africa, is the clinical face of the severe disease.[1,2] Clinical features of phenotypically less severe Beta-Thalassemia Minor or NTDT (Non-Transfusion-dependent thalassemia) are variable, making diagnosis of NTDT challenging. Apart from these two, other phenotypes such as β-thalassemia intermedia and HbE/β-thalassemia phenotypes show a wide spectrum of disease severity.[3]

Each year, globally, 60,000 newborns are diagnosed with Beta-thalassemia mutations, with most of them born in developing nations. The prevalence of the condition is approximately 1.5 percent of the world population, and the number of carriers is approximately 80 to 90 million globally.[4] The elevated incidence of β-thalassemia mutations in nations like Pakistan and India, where rates may rise up to 73%, is largely caused by consanguinity, which is common in regions like Southeast Asia, the Mediterranean basin, and Africa. This cultural custom, which is deeply ingrained in family ties along with tradition, challenges public health attempts focused on managing and preventing the disease.[5,6]

METHODS

Patients with mutations may have normal development and a very modest phenotype, or they may have severe anemia, growth retardation, hypersplenism, and other morbidities that may later necessitate frequent transfusions.[7] The consequent iron overload is treated with iron chelation treatment and is useful for lowering liver iron and serum ferritin. Even the chornic iron over load in NTDT patients, where infrequent transfusions are done, needs iron chelation, according to clinical research, especially the most recent THALASSA study.[8] Interestingly, the body's own iron homeostasis mechanism is upset by iron overload, which raises the intracellular labile iron concentration and outside of cells non-transferrin-bound iron.[9]

A hereditary condition affecting the globin component of the hemoglobin molecule is known as a hemoglobinopathy. Thalassemia syndrome is caused by a genetic alteration of the globin protein-coding region that modifies protein production.[10] Beta-Thalassemia major (BTM) is one of the most prevalent hereditary hemoglobinopathies in Pakistan with more than 100,000 active cases according to population surveys and careful estimates. It has one of the highest rates of TDT patients in the world.[11,12] So far, more than 200 unique point mutations and rare gene deletions have been identified.

The reasons for this peak incidence in Pakistan of transfusion-dependent thalassemia in the world are consanguineous marriage trends, high fertility rates, low levels of education, no screening of partners before marriages and early marriages.[13] The risk of transmission of the thalassemia trait has increased due to lack of diagnostic facilities and the prevalence of cousin marriages as a cultural norm.[14] The same can also be found in other hematological conditions prevalent in the area with the similar mode of transmission such as sickle cell anemia, familial polycythemia vera and alpha-thalassemia.[15,16]

This study aimed to assess the demographic and clinical features of patients dependent on transfusion and to establish the relationship between age and consanguinity, iron overload, and selected organ-related and treatment-related complications, to gain better insight into disease patterns and risk factors in the local population.

METHODS

To evaluate the demographic and clinical conditions of the patients who require transfusions and suffer from the associated complications, this cross-sectional research was carried out at a tertiary care hospital over a period of six months (July to December 2023). Ethical approval was obtained from Hayatabad Medical Complex (Approval: 1307 dated 22-6-2023). Based on an expected prevalence of 8%, a 95% confidence level, and a 5% margin of error, the minimum required sample size was calculated to be 114 participants. To increase statistical power and account for potential data loss, a larger sample was recruited. A total of 293 samples were successfully collected and analyzed, which exceeds the minimum requirement and reduces the ultimate margin of error. Sampling of participants carried out using consecutive sampling.[17] Demographic and clinical data were gathered using a structured data collection form which included age, gender, consanguinity, family history, number of blood transfusion units received per month, iron overload status, organ-specific complications, medication status, chelation therapy and complications associated with chelation therapy. Patients or caregivers were interviewed and demographic and clinical data were gathered through medical records and pertinent laboratory studies, all while the patients were being enrolled in the study consecutively with informed consent being given. To ensure consistency in clinical parameter assessment and recording, standard clinical definitions and documented diagnoses were used.

Eligible patients according to the set inclusion criteria during the study period were consecutively recruited. Patient/caregiver interviews and medical records were used to determine age, gender, consanguinity status, family history, transfusion frequency, medication status, iron overload, organ-related complications, and chelation therapy. Blood transfusion units were recorded as units received per month based on the blood transfusion history. Age was recorded in years and categorized into 1–5, 6–10, 11–15, 16–20, 21–25, and ≥26 years for categorical analysis. Iron overload was measured as per the study classification and later dichotomized for regression analysis as no iron overload and iron overload (including mild cases).

The Statistical Package for the Social Sciences (SPSS) version (25.0) was used for data cleaning and statistical analysis. Frequencies and percentages were used to summarize categorical variables. The associations between categorical variables were analyzed using Pearson chi-square test. To determine independent factors related to iron overload, binary logistic regression was used. Blood units received in a month, gender, consanguinity status, family history, proper medication and chelation therapy were considered as independent variables, and binary iron-overload status as the dependent variable.[18] Odds ratios (ORs) with 95% confidence intervals (CIs) were presented. The Hosmer–Lemeshow test was used to assess model fit, and $p < 0.05$ was taken as the cut-off for statistical significance.

RESULTS

Among the 293 participants, 58.7% (n=172) were male, while 41.3% (n=121) were female. In 69.6% (n=204) of the participants consanguinity was reported, while 30.4% (n=89) had no consanguinity. 51 % (152) of individuals had a family history, and 48 % (141) did not. Regarding blood transfusions, 45.4% (n=133) received 2 units per month, followed by 38.9% (n=114) receiving 1 unit, 10.2% (n=30) receiving 3 units, and 5.5% (n=16) receiving 4 units. 9.6% (n=28) reported taking proper medication and 90.4% (n=265) reported not taking proper medication. The participants received chelation therapy, 73.7% (n=216), while 26.3% (n=77) did not receive chelation therapy, 59.4% (n=174) had iron overload, while 40.6% (n=119) had no iron overload show in the table (1).

Most participants were in the age group of 6 to 10 years (36.2%) followed by the 11 to 15 years group (27.3%). The age group of 14.3% of participants were aged 16-20 year, and 13.3% were aged 1-5 years. The 21-to-25-year age group accounted for

5.5% of the study population and the age group ≥26 years accounted for 3.4% of the study population.

When the participants who received 1 unit of blood each month were evaluated, 44.7% (n=51) were found to be iron overload and 55.3% (n=63) were not iron overload. Of those who received 2 units, 68.4% (n=91) had iron overload, while 31.6% (n=42) did not have iron overload. If the participant was receiving 3 units per month, they were determined to have iron overload by 60.0% (n=18) and no iron overload was found in 40.0% (n=12). Of those with 4 units, 87.5% (n=14) were found to have iron overload while 12.5% (n=2) did not have iron overload. Overall, 59.4% (n=174) had iron overload, while 40.6% (n=119) had no iron overload shown in the table (3).

Table 1: Sociodemographic and clinical characteristics of study participants

Variable	Category	Frequency (n)	Percentage (%)
Gender	Male	172	58.7
	Female	121	41.3
Consanguinity	Yes	204	69.6
	No	89	30.4
Family history	Yes	152	51.9
	No	141	48.1
Blood transfusions / month	1 unit	114	38.9
	2 units	133	45.4
	3 units	30	10.2
	4 units	16	5.5
Proper medication	Yes	28	9.6
	No	265	90.4
Chelation therapy	Yes	216	73.7
	No	77	26.3
Iron overload status	No iron overload	119	40.6
	Iron overload*	174	59.4

Table 2: Distribution of participants according to age category

Age category (years)	Frequency (n)	Percentage (%)
1–5	39	13.3
6–10	106	36.2
11–15	80	27.3
16–20	42	14.3
21–25	16	5.5
≥26	10	3.4
Total	**293**	**100.0**

Table 3: Association between number of blood transfusions per month and iron overload

Blood units/month	No iron overload n (%)	Iron overload n (%)	Total
1 unit	63 (55.3)	51 (44.7)	114
2 units	42 (31.6)	91 (68.4)	133
3 units	12 (40.0)	18 (60.0)	30
4 units	2 (12.5)	14 (87.5)	16

The binary logistic regression analysis revealed that factors significantly predicting iron overload were blood transfusion frequency, proper medication and chelation therapy. For each additional unit of blood transfusion per month, odds of iron overload increased by 1.624 times (95% CI: 1.134–2.325, p = 0.008). However, participants who were taking the proper medication had 85.9% decreased odds of developing iron overload compared to those who were not taking the proper medication (adjusted OR = 0.141, 95% CI: 0.042–0.476, p = 0.002). Those who were not being treated with chelation therapy had 45.541 times the odds of iron overload relative to those being treated with chelation therapy (95% CI: 10.007–207.251, p < 0.001).

Family history, consanguinity, age and gender were not statistically significant factors for predicting iron overload (p > 0.05). Model statistics: Omnibus $\chi^2 = 104.547$, df = 7, p < 0.001; Cox & Snell $R^2 = 0.300$; Nagelkerke $R^2 = 0.405$; Hosmer–Lemeshow $\chi^2 = 10.837$, df = 8, p = 0.211; overall classification accuracy = 74.1% shown in the table (4)

Table 4: Binary logistic regression analysis of factors associated with iron overload

Predictor	B	SE	Wald	p-value	Adjusted OR	95% CI for OR
Age (years)	0.202	0.133	2.299	0.129	1.224	0.943–1.589
Blood units/month	0.485	0.183	7.017	0.008	1.624	1.134–2.325
Male gender*	0.053	0.292	0.033	0.855	1.055	0.595–1.869
Consanguinity (Yes)*	-0.400	0.313	1.637	0.201	0.670	0.363–1.237
Family history (Yes)*	0.026	0.287	0.008	0.929	1.026	0.584–1.800
Proper medication (Yes)*	-1.958	0.620	9.978	0.002	0.141	0.042–0.476
Chelation therapy (No)*	3.819	0.773	24.394	<0.001	45.541	10.007–207.251
Constant	-1.135	0.539	4.440	0.035	0.321	—

DISCUSSION

The findings reveal that the younger age groups are more dominant, and consanguinity, family history, and iron overload are very prevalent. The findings show the presence of long-standing sociocultural beliefs and sickness among Pakistani

people. The large interrelations between age and several clinical outcomes suggest that there is a compounding effect on the development of the disease and prolonged exposure to the therapy, despite the relatively lower prevalence of organ-specific issues.

A study conducted by Huma Riaz *et al. and* Waheed U *et al.* found that 0.8% (3) individuals had sickle cell anemia, 45 (12.9%) had beta thalassemia major, and 115 (32.9%) had beta thalassemia trait.[19,20] This showed a significant decline in emotional fortitude and physical activity as a result of the condition's developmental retardation, exhaustion, and frequent blood transfusions. Additionally, Khurana *et al*.[21] noted that poor social integration and school absences are prevalent problems that lead to decreased overall functioning.

In contrast to the pre-transfusion Hb of 8.2 ± 2.1 g/dL in our evaluation, prior research revealed a mean pre-transfusion Hb of 9.63 ± 0.91 g/dL at presentation in TDT patients exhibiting EMH.[22] The cause of IDA in adolescence could be reduced iron intake or increased iron loss, iron deficiency, chronic blood loss, pregnancy, or even parasite infection. Children with a high IDA connection would perform poorly in cognitive, mental, and physical domains, with these deficits persisting into adulthood and impacting economic productivity and work efficiency.[23]

The large disparity between the two groups was a noticeable outcome. 51 percent of the patients were children down to the age of twelve, and 72 percent of the participants in the control group were adults of 18 years and above. This fact is consistent with studies indicating that thalassemia typically presents in childhood, and early diagnosis is usually made before the child attains 6 years.[24] The accumulation of iron ions in aging cells leads to an excess of reactive oxygen species, which may cause DNA damage and prevent it from repairing itself, leading to an increase in aging.[18,25] More than half of the subjects were observed to suffer iron overload, the cumulative effect of repeated blood transfusions, which is also in line with past research conducted in the same environment. Even though organ-specific complications, such as cardiac, hepatic, renal, and pulmonary involvement, were relatively less frequent, their occurrence also has clinical implications due to their morbidity and mortality.[26] The observed association between increasing age and clinical complications suggests a progressive pattern of disease burden, potentially reflecting longer exposure to transfusion and chelation therapy with increasing age, as documented in previous literature.[27]

CONCLUSION

This analysis demonstrates that a substantial number of clinical complications in patients who are dependent on transfusion are present, especially in young patients and those who are related. Although the cases of severe organ complications were rare, iron overload and the problems associated with the treatment underline the necessity of efficient screening, frequent monitoring, and treatment. The results highlight the role of preventive strategies, genetic counseling, and care optimization in minimizing morbidity of the disease in Pakistan.

LIMITATIONS

The design of this study is cross-sectional, which does not allow causal interpretation, and the study is done in one center, which might exclude the possibility of generalization. Along with that, the use of self-reported data to measure some of the variables and the absence of comprehensive biochemical tests could have also affected the results.

SUGGESTIONS / RECOMMENDATIONS

The study suggests identifying iron overload and other complications early and establishing regular monitoring and frequent screening for patients with transfusion-dependent thalassemia. Enhance genetic counseling to address the high rate of consanguinity and minimize disease occurrence. Enhance specific preventative measures and streamline the treatment regimens to reduce long-term complications and optimize patient outcomes.

LIMITATIONS OF STUDY

This study has several limitations. First, its cross-sectional design precludes establishing causal relationships between iron overload and the observed clinical complications. Second, the study was conducted at a single tertiary care center in Peshawar, which may limit the generalizability of the findings to the broader population of patients with transfusion-dependent β-thalassemia major in Pakistan. Third, participants were recruited using a hospital-based sampling approach, which may have introduced selection bias. Additionally, some demographic and clinical information, including family history and consanguinity status, was self-reported and may be subject to recall bias. The assessment of iron overload relied primarily on available clinical and laboratory records without incorporating advanced modalities such as MRI T2* or serial serum ferritin measurements for all participants. Furthermore, detailed information regarding transfusion duration, cumulative transfusion burden, adherence to iron chelation therapy, and socioeconomic factors was not comprehensively assessed. These limitations should be considered when interpreting the study findings.

CONFLICT OF INTEREST / DISCLOSURE

The authors declare no conflict of interests related to this study.

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