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The Association between Pre-Transfusion Hemoglobin Levels and Thalassemia Complications at Taif City

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Abstract **Original Research Article**

Introduction*:** Thalassemia is a genetic blood disorder classified as one of the major hemoglobinopathies. Studying the correlation between pre-transfusion hemoglobin (Hb) levels and the severity of thalassemia is important for several reasons: preventing complications, optimizing treatment strategies and improving quality of life. This study aimed to assess the correlation between pre-transfusion hemoglobin (Hb) levels and thalassemia-related complications on health outcomes of transfusion-dependent (TDT) and non-transfusion-dependent (NTDT) thalassemia patients. ***Methods: A cross-sectional study was conducted at two hospitals in Taif, Western region of Saudi Arabia, from February to November 2024. Demographic and clinical data were collected from 16 patients with major or intermediate forms of thalassemia. Pre-transfusion Hb levels were measured at five consecutive visits, and thalassemia complications, such as iron overload and organ dysfunction, were documented. ***Results***: The mean pre-transfusion Hb level across TDT and NTDT patients were 8.4 g/dL and 8.9 g/dL respectively, indicating that the difference in mean hemoglobin levels between the two groups was not statistically significant. General anemia's symptoms were reported at enrolment time among all patients in this study, including pallor, fatigue and weakness. However, iron overload and other severe complications, including hypothyroidism and leg ulcers, were not prevalent at the time of enrollment. ***Conclusion***: This study found that maintaining pre-transfusion Hb levels around 8.4 g/dL did not result in severe complications for most patients, suggesting that lower Hb levels may not necessarily lead to immediate severe health issues. These findings could help optimize transfusion practices, reduce healthcare costs, and minimize iron overload risks, particularly in resource-limited settings. However, continuous monitoring is necessary, as complications can emerge over time.

Keywords: Thalassemia, TDT, NTDT.

INTRODUCTION

Thalassemia is a genetic blood disorder classified as one of the major hemoglobinopathies. It is characterized by an abnormally low level of one or more of the primary globin chains, either alpha or beta chains. Genetic mutations disrupt normal hemoglobin production, leading to ineffective red blood cell production, hemolysis, and related complications (Taher *et al*., 2023). Both alpha and beta thalassemia follow an autosomal recessive inheritance pattern, affecting both genders equally. In this pattern, both parents must carry at least one copy of the disease allele, which can be passed to their children according to Mendel's Law of Segregation. The severity of the condition can vary depending on whether the mutations are in the alpha or beta globin genes. Carriers generally do not exhibit symptoms but can transmit the gene to their children (Cappelli *et al*., 2024).

In 2018, the highest prevalence of thalassemia in the world was reported in the Kingdom of Saudi Arabia (Olwi *et al*., 2018). The records of the Saudi

Ministry of Health indicated that the incidence of thalassemia varies by region, with some areas showing higher rates than others. The eastern and southern areas had the highest incidence rates, while the central and northern regions showed the lowest rates of thalassemia (Faris *et al*., 2022). Moreover, the eastern and southwestern regions had a greater prevalence of hemoglobinopathies compared to other areas, with 13.6 cases of thalassemia per 1000 individuals in Saudi Arabia (Makkawi *et al*., 2021). Further research indicated an increased incidence of alpha thalassemia in Saudi Arabia, with rates varying from 5.9% in the Eastern area to 0.4% in the North (Alsaeed *et al.*, 2017). In 2022, premarital screening has been found that the α-thalassemia trait at Makkah city was reported with the highest frequency of hemoglobin abnormality (Moustafa *et al.*, 2022).

In clinical practice, the clinical classification of thalassemia is currently frequently used in relation to blood transfusion requirements (Vitrano *et al*., 2017). Transfusion-dependent thalassemia (TDT) is characterized by a patient's inability to manufacture enough hemoglobin to survive outside of blood transfusions. Patients with thalassemia who do not require frequent lifelong transfusions are referred to as non-transfusion-dependent (NTDT) patients. In specific clinical settings, such as pregnancy, surgery, and illness, they can need numerous transfusions, usually for predetermined lengths of time (Taher *et al*., 2013, Taher *et al.*, 2014). Frequent red blood cell (RBC) transfusions guarantee survival, restore physiological growth throughout childhood, and improve anemia, compensatory bone marrow expansion, bone alterations, and splenomegaly. Historically, researchers have observed a variety of physical and psychological health complications associated with ineffective erythropoiesis and chronic anemia, including iron overload, abnormal blood pressure, endocrinopathies, notably diabetes mellitus (DM), extramedullary hematopoiesis (EMH), chronic leg ulcers, pulmonary hypertension (PHT), and thrombosis (Borgna-Pignatti *et al*., 2010). These issues have significantly diminished in recent years due to improved care for TDT patients through frequent blood transfusions and iron chelation therapy (Vitrano *et al*., 2017). The Thalassemia International Federation (TIF) recommends administering blood transfusions to TDT patients at a rate that maintains their pre-transfusion hemoglobin levels above 9–10.5 g/dL, or higher (11–12 g/dL) in cases of cardiac or other complications (Taher *et al*., 2014).

The correlation between pre-transfusion hemoglobin levels and the severity of thalassemia problems underscores the need for customized treatment approaches, preventing complications and reducing the financial costs. By meticulously monitoring and regulating hemoglobin levels prior to transfusions and understanding these dynamics, healthcare professionals may profoundly influence the general health and quality of life of thalassemia patients, mitigating severe consequences and fostering improved long-term results (Cappellini *et al*., 2014). Thus, the aim of this study is to assess the correlation between pre-transfusion hemoglobin (Hb) levels and thalassemia-related health problems. Pre-transfusion hemoglobin values are crucial in addressing medical complications linked to thalassemia. Numerous studies indicated that keeping hemoglobin levels above specific thresholds may aid in minimizing complications associated with anemia, as well as preventing organ damage and reducing the necessity for frequent blood transfusions (Musallam *et al*., 2021, Shash, 2022).

MATERIALS AND METHODS

This is a cross-sectional study performed at two hospitals in the Western region of Saudi Arabia. Children's Hospital and Armed Forces Hospital at Taif City. The study participants were patients with thalassemia who attended the hematology clinic between January and December 2024. The study's inclusion criteria included all male and female patients with major or intermediate forms of thalassemia who attended the hematology clinic at any age during the study period. Patients with other forms of genetic anemia such as sickle cell anemia were excluded. Also, patients whose Hb levels had decreased more than 2 g/dL from baseline due to severe infection or blood loss were excluded.

Demographic data: sex, age, nationality, and type of thalassemia were collected from all patients. Patients were categorized into two groups: TDT and NTDT. TDT (transfusion-dependent thalassemia) referred to individuals with thalassemia who needed regular blood transfusions to survive, while NTDT (non-transfusion-dependent thalassemia) referred to those who did not require lifelong, regular transfusions for survival.

Pre-transfusion hemoglobin levels were reported for each patient for five consecutive instances, starting from the time of enrolment. Pre-transfusion Hb levels were collected every six to eight weeks during the study period. For NTDT patients with follow-up visits scheduled less frequently than every five months.

At the time of patients' enrolment, the physician documented the general anemia symptoms and other complications associated with thalassemia. The complications included in this study were iron overload, as indicated by Magnetic Resonance Imaging (MRI) and serum ferritin levels, hepatic and cardiac iron overload, hypothyroidism, hypogonadism, and leg ulcers.

Ethical Statement

The study was approved by the Research Ethical Committee of the Applied Medical Science College at Taif University as well as the research ethical

committee of the Armed Forces Hospital at Taif city number; H-02-T-078.

Statistical Analysis

Descriptive statistics were used to summarize the demographic and clinical characteristics of the patients, including age, gender, type of thalassemia, and nationality. Data entry was performed using Microsoft Excel, and further statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 25 (IBM Corp., Armonk, NY).

Categorical variables, such as gender and type of complications, were expressed as frequencies and percentages. Continuous variables, including haemoglobin (Hb) levels, were expressed as means and standard deviations. The mean pre-transfusion haemoglobin levels were calculated for both transfusion-dependent thalassemia (TDT) and non-transfusion-dependent thalassemia (NTDT) groups. Independent samples t-tests were used to compare the mean Hb levels between TDT and NTDT groups, assuming data normality.

RESULTS

A total of eleven patients from Children Hospital and five patients from Armed Forces Hospital with either transfusion-dependent thalassemia (TDT) or non-transfusion-dependent thalassemia (NTDT) were included in this study. There were 8 male and 8 female patients. The majority of study participants were younger than 9-year-old 69% (n=11/16) and Saudi 56.3% (n=9/16). The main demographic characteristics of the patients are shown in (Table 1). Thalassemia patients with chronic disorders such as diabetes, kidney failure or cancer, as well as patients with other genetic anemia were not included in this study.

The majority of patients in this study were diagnosed with thalassemia major and classified as TDT, accounting for 62.5% (n = 10/16), while 37.5% (n = 6/16) were identified as having thalassemia intermedia and considered NTDT. An independent samples t-test was conducted to compare the mean hemoglobin (Hb) levels between TDT and NTDT groups. The analysis revealed that the average pre-transfusion Hb level among TDT patients was 8.4 g/dL, whereas NTDT patients had a slightly higher mean Hb level of 8.9 g/dL. However, the difference was not statistically significant (p-value: 0.213) (Figure 1). In addition, TDT patients had a wider range of Hb compared to NTDT. Since the p-value is greater than 0.05, there is no statistically significant difference in mean Hb levels between the TDT and NTDT groups on this study. Moreover, there was no apparent trend linking nationality (Saudi vs. Non-Saudi) or gender (male and female) and Hb levels before blood transfusion. Each group showed a similar range of Hb levels.

General anemia's symptoms were reported at enrolment time among all patients in this study, including pallor, fatigue, weakness, and lethargy. Only 12.5% (n = 2/16) of TDT patients showed mild cardiomegaly when investigated before blood transfusion (Table 2). Moreover, splenomegaly was diagnosed in 31% (n = 5/16) of TDT pediatric patients (Table 2). Similarly, alloimmunization was noticed among 31% (n = 5/16) of TDT patients. Iron overload was reported in two patients with TDT when the liver was examined with Magnetic Resonance Imaging (MRI). The result of this study also showed that the majority of patients with TDT and NTDT had not experienced any of the severe complications associated with thalassemia including iron overload, as indicated by MRI and serum ferritin levels, hepatic and cardiac iron overload, hypothyroidism, hypogonadism, and leg ulcers at the time of enrolment before blood transfusion. Similarly, hypertension was not recorded in any cases before blood transfusion in this study. Thus, the result of this study showed no major differences between TDT and NTDT in terms of thalassemia complications. In addition, there was no association between the pre-transfusion Hb level at a concentration of ≤ 8.4 g/dL and hepatic and cardiac iron overload, hypothyroidism, hypogonadism, and leg ulcers.

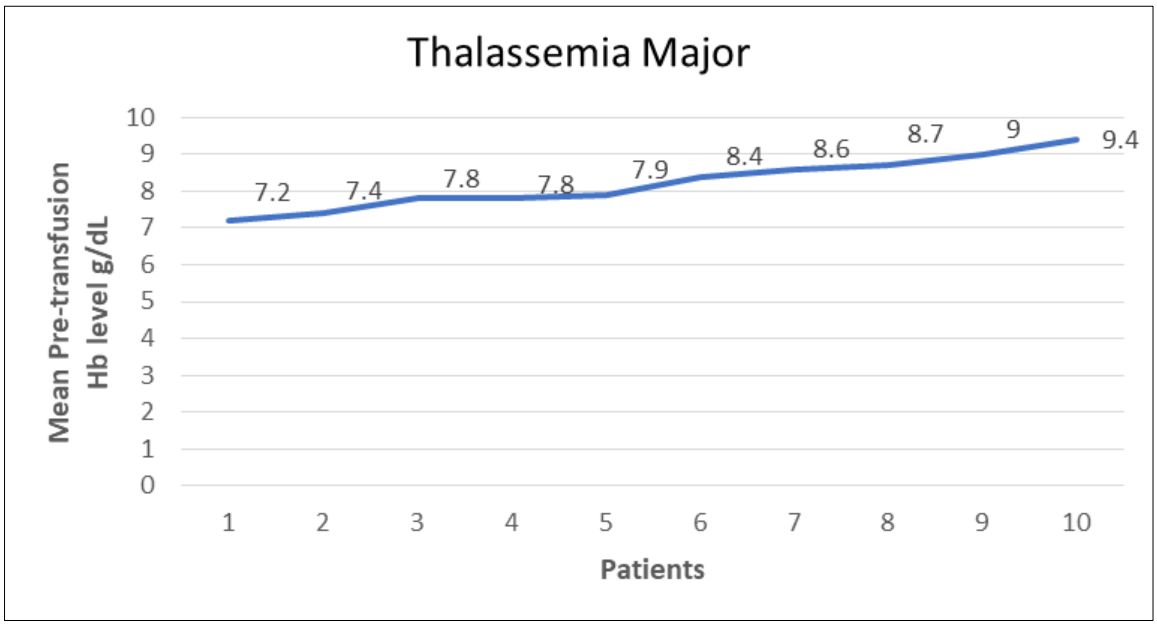
Table 1: Shows the main demographic characteristics of the patients, Mean Pre-transfusion Hb level g/dL and types of thalassemia based on blood transfusion need (TDT and NTDT) and based on the severity of the disease (Major and Intermediate)

Patient	Gender Male (M) Female (F)	Age Year	Nationality Saudi (S) Non-Saudi (NS)	Mean Pre-transfusion Hb level g/dL 5 consecutive times	Type of Thalassemia according to blood transfusion need	Type of Thalassemia based on the severity of the disease
Patients from Children Hospital						
1.	F	11	S	8.4	TDT	Major
2.	F	3	NS	8.6	TDT	Major
3.	M	8	NS	7.4	TDT	Major
4.	M	2	NS	7.9	TDT	Major
5.	F	7	NS	7.8	TDT	Major
6.	M	3	NS	9.1	NTDT	Intermediate

7.	F	8	S	9.4	TDT	Major
8.	M	4	S	8.1	NTDT	Intermediate
9.	M	11	NS	7.8	TDT	Major
10.	F	3	S	8.7	TDT	Major
11.	M	2	S	8.0	NTDT	Intermediate
Patients from Armed Forces Hospital						
12.	F	3	S	9.0	TDT	Major
13.	F	26	S	8.0	NTDT	Intermediate
14.	M	8	NS	7.2	TDT	Major
15.	F	30	S	9.0	NTDT	Intermediate
16.	M	16	S	9.78	NTDT	Intermediate

Table 2: Shows the presence of the main complications, including splenomegaly, cardiac complications, alloimmunization and blood pressure, that were observed in patients from two hospitals (Children's Hospital and Armed Forces Hospital)

Patient	Splenomegaly	Cardiac complication	Alloimmunization	Blood pressure
Patients from Children Hospital				
1.	Splenomegaly	mild cardiomegaly	Present	Normal
2.	-	-	-	Normal
3.	Splenomegaly	-	-	Normal
4.	-	-	-	Normal
5.	Splenomegaly	-	Present	Normal
6.	-	-	-	Normal
7.	-	-	Present	Normal
8.	-	-	-	Normal
9.	-	mild cardiomegaly	-	Normal
10.	-	-	-	Normal
11.	-	-	-	Normal
Patients from Armed Forces Hospital				
12.	-	-	-	Normal
13.	-	-	-	Normal
14.	-	-	Present	Normal
15.	Splenomegaly	-	-	Normal
16.	Splenomegaly	-	-	Normal



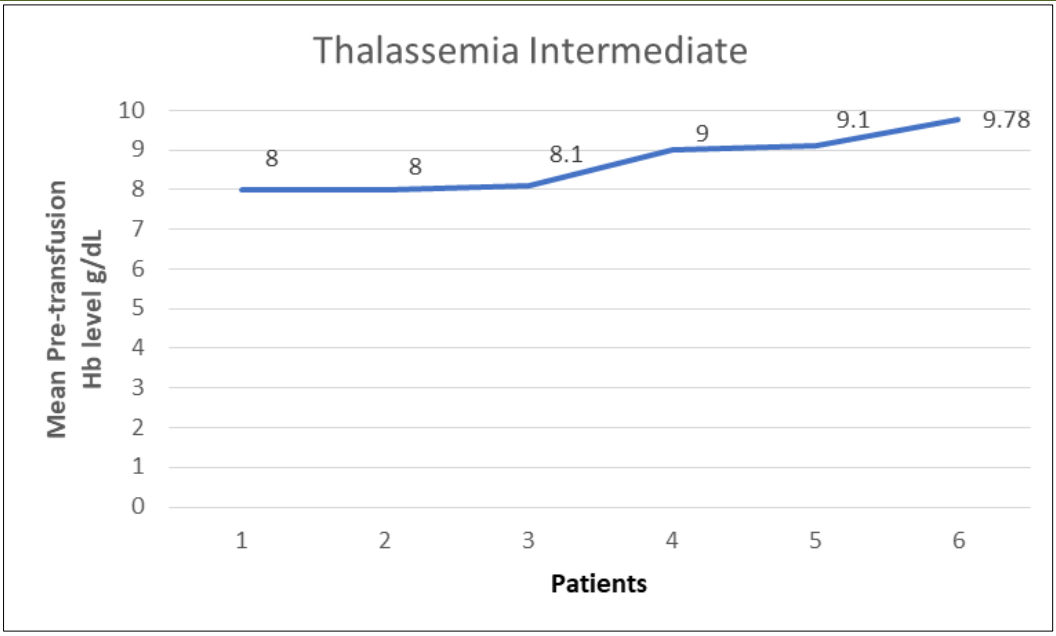


Figure 1: Comparing hemoglobin (Hb) levels between the TDT (10 patients) and NTDT (6 patients) groups. The median and range for each group. p-value: 0.213

DISCUSSION

In order to optimize outcomes for patients with transfusion-dependent thalassemia (TDT) and non-transfusion-dependent thalassemia (NTDT), many studies advise keeping pre-transfusion hemoglobin levels above 9 g/dL (Farmakis *et al*., 2022, Cappellini *et al*., 2018, Coates, 2024, CDC, 2024). According to the Thalassemia International Federation, it has been recommended to maintain hemoglobin levels between 9 and 10.5 g/dL to prevent and reduce serious health complications and inhibit inefficient blood production (Farmakis *et al*., 2022). Similarly, Cappellini *et al*., reported in their review that preserving appropriate hemoglobin levels is essential for lowering problems such as inadequate erythropoiesis, enhancing quality of life, and shielding thalassemia patients' organs from harm (Cappellini *et al*., 2018). In addition, a research study was published in Blood Journal indicated better survival rates when hemoglobin levels are above 10.5 g/dL (Coates, 2024). Recently, the Centers for Disease Control and Prevention (CDC) advises maintaining pre-transfusion levels of 9–10.5 g/dL in transfusion-dependent thalassemia patients (CDC, 2024).

On the other hand, some studies have reported lower hemoglobin levels, such as the 8.2 g/dL value cited in certain cases. A review of the literature discusses the pathophysiology of iron overload in patients with thalassemia, emphasizing that anemia-induced hypoxia can stimulate increased intestinal iron absorption. The resulting combination of iron overload and chronic anemia leads to oxidative stress, which may cause significant damage to vital organs, including the liver, heart, and endocrine glands (Pinto and Forni, 2020). Although hemoglobin levels as low as 8.2 g/dL may be observed in some instances, the majority of evidence supports maintaining higher hemoglobin targets to promote better health outcomes and reduce the risk of complications.

In the current study, the mean pre-transfusion hemoglobin (Hb) level among TDT patients was 8.4 g/dL, which is below the generally recommended target range for thalassemia patients in the absence of severe health complications. A higher mean pre-transfusion Hb level of 8.9 g/dL was observed among NTDT patients. Consistent with our findings, Farmakis *et al*., (2022) highlighted several criteria for initiating blood transfusion therapy, including Hb levels below 7 g/dL. Nonetheless, current guidelines recommend maintaining pre-transfusion Hb levels between 9 and 10 g/dL to optimize clinical outcomes (CDC, 2024).

The result of this study found that most pediatric thalassemia patients exhibited common anemia symptoms, such as pallor, fatigue, and weakness, while only a small percentage experienced mild heart hypertrophy (12.5%), spleen issues (31%), or alloimmunity (25%). Additionally, most patients, whether transfusion-dependent (TDT) or non-transfusion-dependent (NTDT), did not show severe complications such as iron overload, hypothyroidism, or organ damage at the time of enrollment. The study in Thailand, found that while infections and growth disorders are the most frequent problems, not all thalassemia patients suffer from serious complications (Surapolchai *et al*., 2023). Similarly, research conducted in the West Bank reported that many thalassemia patients, especially in the early stages of the condition, did not experience any significant complications (Faranoush *et al*., 2023). Another study, however,

contradicted these findings. A study suggested that low hemoglobin levels (≤8.2 g/dL) may raise the risk of complications, including organ damage and iron overload (Tantiworawit *et al*., 2016). Significant complications, including cardiac and hepatic damage or endocrine disorders were indicated in several studies in individuals with thalassemia major, despite their absence at the onset of the disease (Cappellini *et al*., 2014). In summary, while some patients may avoid major complications early on, others emphasize the need for close monitoring as risks can increase over time.

Despite the valuable insights provided by this study, several limitations must be acknowledged. Small sample size: The study included only 16 participants, limiting the generalizability of the findings and reducing the statistical power to detect significant associations or trends. Moreover, potential for confounding variables: factors such as nutritional status, comorbidities not captured in records, and variations in transfusion protocols between hospitals may have influenced patient outcomes.

CONCLUSION

The findings of this study suggested that there may be a degree of individual variation in how patients respond to lower Hb levels. Many factors can determine the severity of the complications, such as the patient's overall health. In addition, this study suggested that maintaining a lower Hb level (8.4 g/dL observed in this study) without suffering severe health consequences could reduce the need for frequent transfusions and lower healthcare costs. Thus, preserving blood supplies and the overall healthcare burden. This could be especially important in areas where blood resources are limited or difficult to access. Fewer transfusions would also reduce the risk of iron overload, a major complication for thalassemia patients. Iron chelation therapy, which is often necessary after frequent transfusions, is resource-intensive and can be difficult for some patients to manage. Reducing the need for transfusions would help minimize the need for these treatments, ultimately reducing both costs and complications.

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