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# HYDROXYUREA TREATMENT AND REDUCTION IN TRANSFUSION DEMAND IN B-THALASSEMIA MAJOR: EVIDENCE FROM THE HOSPITAL-BASED STUDY IN KARACHI

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**Abstract**

**Background:** β-thalassemia major is a hereditary hemoglobin disorder caused by mutations in the β-globin gene, leading to ineffective erythropoiesis and transfusion dependence. Blood transfusions are the primary management strategy of this disorder, but are associated with complications including iron overload and alloimmunization. Hydroxyurea (HU), through production of fetal hemoglobin (HbF), has emerged as a promising therapeutic option to produce better therapeutic outcomes in managing the severity of disease.

**Objective:** This study was aimed to evaluate the effectiveness of HU in reducing transfusion requirements among patients with β-thalassemia major in a welfare hospital in Karachi, Pakistan.

**Methodology:** A cross-sectional survey-based study was conducted on 150 patients diagnosed with β-thalassemia major at AL-Mustafa hospital, Karachi. Data was retrieved from diagnostic laboratory records of patients, aged between 3 months and 26 years. Hematological parameters, transfusion frequency, treatment regimens, and adverse effects were assessed and compared between patients receiving conventional transfusion therapy and those on HU. Statistical evaluation was performed by applying chi-square and frequency distribution.

**Results:** The mean age of patients was 2.17 ± 0.918 years. HU therapy demonstrated a significant improvement in hemoglobin profiles and clinical status. A reduction in transfusion frequency was observed in the majority of patients on HU therapy. Additionally, HU use was associated with fewer transfusion-related complications. The results were statistically significant with a p-value <0.05.

**Conclusion:** Hydroxyurea showed considerable efficacy in improving hematological outcomes and reducing transfusion dependency in β-thalassemia major patients. These findings support the potential role of HU as an effective therapeutic alternative, particularly in resource-limited settings where transfusion-related complications remain a major clinical concern.

## Introduction

Thalassemia is an autosomal recessive hemoglobin disorder resulting from hereditary mutations that impair globin chain synthesis. More than 199 mutations have been identified, with disease severity varying according to the type of genetic defect. Alpha thalassemia (α-thalassemia) arises from deletions or mutations in the α-globin gene, while beta thalassemia (β-thalassemia) is primarily caused by point mutations in the β-globin gene, leading to reduced or absent β-chain production[1]. β-thalassemia major, the most severe form, manifests as progressive anemia, jaundice, and growth failure, necessitating lifelong blood transfusions and iron chelation therapy[2].

The prevalence of β-thalassemia is highest in the Mediterranean region. Middle East, South Asia, and Southeast Asia, with Pakistan recording approximately 9.7 million carriers annually[3]. Regular transfusion therapy, though life-sustaining, contributes to complications such as iron overload and transfusion-transmitted infections, placing additional socioeconomic burdens on affected the affected families[4].

Treatment strategy for β-thalassemia patients is based on anemia severity and type of thalassemia, Transfusions and iron chelation therapy have been efficacious in lengthening lifespan, refining quality of life and managing comorbidities among β-thalassemia patients[5]. Moderate to severe thalassemia patients require blood transfusions, every few weeks. A hemoglobin level greater than 9 g/dl is typically required to be maintained with regular packed red cell transfusion(pRBC) to sustain sufficient erythropoiesis [6]. The transfusion treatment is aimed to retain the hemoglobin in plasma in particular ranges as mentioned above and to resist anemia in β-thalassemia major[7]. Blood transfusion therapy is dependent on several factors such as hematocrit levels and hemoglobin as well as the weight of the individuals.

Hydroxyurea (HU), a ribonucleotide reductase inhibitor, has emerged as an adjunct therapy with potential to reduce transfusion requirements in patients with thalassemia [8]. Its mechanism involves the induction of fetal hemoglobin (HbF) synthesis, which balances globin chain assembly, reduces hemolysis, and prolongs red blood cell survival[9]. Clinical evidence supports that HU can significantly improve hemoglobin levels and decrease transfusion dependency, with some patients achieving transfusion independence[10]. The drug is well absorbed orally, with recommended pediatric doses of 10–15 mg/kg and adult doses around 500 mg/day[11].

Hydroxyurea thus represents a promising therapeutic strategy for β-thalassemia major, particularly in resource-limited regions, offering improved clinical outcomes while reducing the risks and costs associated with chronic transfusion therapy[12].

## 2. Methods

This is a cross-sectional and prospective, survey-based study was conducted over a period of six months December 2024 to June 2025 at a tertiary care hospital in Karachi, Pakistan, following approval from the Institutional Review Board and the hospital's ethical committee. A total of 150 patients of either

sex, aged ≥3 months, with confirmed clinical and genetic diagnosis of β-thalassemia major were included.

Data was collected through a structured Google form and patient medical records. Information regarding demographics, laboratory parameters, treatment regimens, and clinical outcomes was obtained. All patients were initially transfusion-dependent; 87 patients were then prescribed HU. Based on treatment modality, patients were categorized into three groups:

- Group 1 (n=63): Transfusion-dependent patients receiving blood transfusions only.
- Group 2(n=14): Patients treated exclusively with HU after demonstrating favorable response, where transfusions were discontinued.
- Group 3(n=73): Patients receiving both HU and blood transfusions concurrently.

Standard HU dosing was 10–15 mg/kg/day for children and 500 mg/day for adults. Treatment response was assessed by change in transfusion requirement frequency, hemoglobin levels, and overall clinical status. Adverse effects were also documented.

Statistical Package for Social Sciences (SPSS) version 22.0 was used for evaluating the results. Chi-square was applied to understand the link of categorical predictor variables within the study groups. The p- value <0.05 considered as significant. The descriptive data results were presented in the form of mean ± standard deviation and percentages.

## 3. **Results**

A total of 150 patients with β-thalassemia major were evaluated, comprising 79 (52.7%) males and 71 (47.3%) females. The mean age of the cohort was 2.17 ± 0.91 years, with age groups from minimum 3 months to maximum 22 years. Frequency distribution analysis revealed that the majority of patients were clustered within the 1–3 years' age group.

Out of 150 participants, 72 (48.0%) reported a positive family history of thalassemia major. Gene mutation profiling revealed that IVSI-5 was mutated in 14 patients. while Fr 41–42 was observed least frequently. In the group receiving only blood transfusion, two patients were found to have hemoglobin (Hb) levels <5 g/dl. No patient in the hydroxyurea receiving group exhibited Hb levels less than 5 g/dl, while three patients in the combined therapy group (blood transfusion + hydroxyurea) had Hb levels below 9g/dL. Hb values between 11–13 g/dl were observed exclusively in the hydroxyurea group. Combination therapy demonstrated better outcomes, with most patients had Hb levels within 8–10 g/dl. Transfusion dependency varied among these groups; some patients required up to two transfusions weekly, while those receiving HU were observed to, require fewer transfusions (Table 1).

Among all groups, groups 1(patients exclusively on blood transfusion therapy) and group 3 (on combination therapy with blood transfusion+ HU) showed more patients with increased values of both direct and total bilirubin (p=0.001 and p=0.014), as compared to group 2 (patients on HU only). As levels of bilirubin could be temporarily increased due to blood transfusion, the quick breakdown of mature red blood cells in transfused blood produces bilirubin more rapidly than the liver can filter it out. Other parameters such as serum creatinine levels of thalassemia patients. Other parameters such as

serum creatinine levels of thalassemia patients were not affected significantly by HU therapy as most of the patients in each group have shown normal values (p=0.011) (Table 2).

Adverse effects varied significantly across treatment groups. Majority of dermatological manifestations were more reported in group 3 (combined therapy,37%) followed by group 1 (blood transfusion group,13 %); with least effects observed in group 2 (hydroxyurea receiving patients,3%), (p=0.001). Similar pattern was observed with hematological complications i.e., highest percentage of patients of group 2 and group3 have shown adverse hematological effects receiving blood transfusion and combined therapy respectively (p=0.002). Gastrointestinal adverse effects were recorded more in blood transfusion receiving groups in (p=0.002). Other complications including renal and hepatic problems were found statistically greater in group 1 and group 3 than in HU receiving group ($p < 0.05$.and $p < 0.01$) (Table 3).

The most frequently observed dermatological manifestation was skin rash (group 1: 8.0%, group 2: 1.3%, group 3: 19.3%). Gastrointestinal complaints were mainly abdominal pain, reported in the same proportions. Hematological adverse effects, primarily decreased Hb and platelet counts, were higher in group 1 (16.0%) compared to group 2 (0.7%) and group 3 (14.7%) (Table 4).

**4. Discussion**

Thalassemia is known as a hereditary hemolytic anemia resulting from defective or absent synthesis of one or more globin chains of hemoglobin[13]. The present study was conducted to assess the clinical and therapeutic profile of β-thalassemia major patients, with a particular focus on hydroxyurea (HU) therapy.

Our findings demonstrated that the demographic profile of enrolled patients was consistent with previously published reports, showing predominance of male patients compared to females. Most of the patients reported a positive family history of thalassemia, prominence the genetic inheritance pattern of the disease[14]. These results are in correspondence with Tiwari et al., who emphasized the role of inheritance in the disease transmission[15]. Genetic mutation analysis in our study revealed IVSI-5 as observed mutation, followed by CD15, Fr 8-9, and Fr-16, which is comparable to the observations of Hashemi et al. This finding reflects a similar mutational spectrum in thalassemia populations across the region of Kerman and the borders of Sistan and Baluchestan[16].

Evaluation of therapeutic outcomes exhibited that HU had a beneficial impact on hematological and biochemical parameters. Patients receiving HU therapy demonstrated higher hemoglobin levels, mean corpuscular volume (MCV), and mean corpuscular hemoglobin (MCH) compared to those depend on solely on blood transfusion. These results are consistent with the studies of Gao et al. which also reported improved hematological indices with HU therapy[17]. Biochemical parameters, particularly calcium levels, remained within the normal range across all treatment groups[18].

A key finding of this study was the significant reduction in blood transfusion necessities among patients treated with HU, either alone or in combination with transfusion therapy. The frequency of transfusions reduced from weekly to monthly intervals, thereby reducing complications associated with transfusion

dependency, such as iron overload, transfusion-related reactions, and consequent healthcare costs. These findings are aligned with earlier studies which documented reduced transfusion frequency and improved clinical outcomes in thalassemia patients treated with HU.

With respect to safety, HU was generally well tolerated. Dermatological adverse effects, such as hyperpigmentation and skin rash, were more commonly reported in the transfusion-dependent group compared to HU-treated patients. Similarly, gastrointestinal adverse effects were infrequent and limited mainly to abdominal discomfort, which was mild and manageable. Hematological adverse effects were least reported in the HU group, supporting its safety profile in comparison with transfusion-only therapy. This is in concordance with reports suggesting that HU, though an antimetabolite, is not associated with serious hematological toxicity in thalassemia patients. Nevertheless, musculoskeletal complaints, including bone and joint pain, were observed across all groups, consistent with findings by Piga et al., highlighting the chronic nature of skeletal complications in thalassemia[19-22].

Overall, the present study supports the therapeutic benefits of HU in thalassemia major, particularly its ability to reduce transfusion burden and improve hematological parameters with minimal toxicity. In developing countries like Pakistan, where blood transfusions are associated with both clinical and financial challenges, HU emerges as an important adjunct in the management of thalassemia. However, long-term monitoring is essential to ensure sustained efficacy and safety of HU therapy.

## 5.Conclusion

This study provides a comparative analysis of HU treatment and blood transfusions in patients with beta thalassemia major. From the results, it is concluded that there is an important consideration for hydroxyurea to be used as a potential therapeutic drug in beta thalassemia major patient as it improves hematological abnormalities clinically. The limitations of our study included a small sample size with an unequal distribution of patients, the absence of some laboratory reports, and the lack of a control group to compare the exact effects of drug therapies along with their related adverse effects. On biochemical levels, further investigations are needed.

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## Informed consent

Informed consent Ethics approval of this study was obtained from the ethics committee of Al-Mustafa Hospital Karachi Pakistan. Approvals of the patients' guardians for publication of the patient data were obtained orally during data record.

**Table 1 Analysis of Various parameters of different treatment groups of β thalassemia major patients**

| Parameters | Groups (N=150) | | |
|---|---|---|---|
| | Group 1 | Group 2 | Group 3 |

| | | Blood transfusion B.T (n=63) | Hydroxyurea HU (n=14) | B.T +HU Both (n=73) |
|---|---|---|---|---|
| **Ranges of Hb** | <5 n (%) | 2 (1.3) | 0 (0.0) | 3 (2.0) |
| | 5-7 n (%) | 38 (25.3) | 2 (1.3) | 39 (26.0) |
| | 8-10 n (%) | 23 (15.3) | 9 (6.0) | 31 (20.7) |
| | 11-13 n (%) | 0 (0.0) | 3 (2.0) | 0 (0.0) |
| **Mutated genes** | CD30 n (%) | 2(1.3) | 3(2.0) | 4(2.7) |
| | CD5 n (%) | 3(2.0) | 1(0.7) | 5(3.3) |
| | Fr 41-42 n (%) | 3(2.0) | 0(0.0) | 3(2.0) |
| | IVSI-5 n (%) | 14(9.3) | 1(0.7) | 20(13.3) |
| | Others n (%) | 41(27.3) | 9(6.0) | 41(27.3) |
| **Transfusion regimen** | Once Weekly n (%) | 2(1.3) | 0(0.0) | 2(1.3) |
| | Twice Weekly n (%) | 1(0.7) | 0(0.0) | 1(10.7) |
| | After 2 Weeks n (%) | 25(16.7) | 0(0.0) | 26(17.3) |
| | After 3 Weeks n (%) | 14(9.3) | 0(0.0) | 14(9.3) |
| | After Months n(%) | 4(2.7) | 0(0.0) | 11(7.3) |
| | Monthly n (%) | 17 (11.3) | 0(0.0) | 19(12.7) |
| | None n (%) | 0(0.0) | 14(9.3) | 0(0.0) |

Percentages are calculated based on the total sample (N = 150). Data is presented as frequency (n) and percentage (%).

**Table 2 Biochemical parameters of β-thalassemia major patients receiving blood transfusion, Hydroxyurea and both**

| **Biochemical levels** | | **Groups (N=150)** | | | **p-Value** |
|---|---|---|---|---|---|
| | | **Group 1** Blood transfusion (n=63) | **Group 2** Hydroxyurea (n=14) | **Group 3** (B.T +HU) Both(n=73) | |
| Levels of direct bilirubin n (%) | Increased | 14 (9.3) | 7(4.7) | 38 (25.5) | 0.001 |
| | Normal | 49 (32.7) | 7 (4.7) | 35 (23.3) | |
| Levels of total bilirubin n (%) | Increased | 9 (6.0) | 5 (3.3) | 26 (17.3) | 0.014 |
| | Normal | 54 (36.0) | 9 (6.0) | 47 (31.3) | |
| | Yes | 58 (38.7) | 10 (6.7) | 53 (35.3) | 0.011 |

| | | | | | |
|---|---|---|---|---|---|
| Serum creatinine level (normal) n (%) | No | 5 (3.3) | 4 (2.7) | 20 (13.3) | |
| Ca levels(mg/dl) | Mean± S.D | 9.2± 0.474 | 9.4± 0.645 | 9.3 ±0.500 | 0.439 |

$p < 0.05$ statistically significant

**Table 3 Adverse effects associated with blood transfusion and hydroxyurea treatments**

| **Parameters** | | **Groups (N=150)** | | | **p-Value** |
|---|---|---|---|---|---|
| | | **Group 1 Blood transfusion (n=63)** | **Group 2 Hydroxyurea (n=14)** | **Group 3 (B.T +HU)Both( n=73)** | |
| **Dermatological symptoms n (%)** | Yes | 13 (8.7) | 3 (2.0) | 37 (24.7) | 0.001 |
| | No | 50 (33.3) | 11 (7.3) | 36 (24.0) | |
| **Hematological symptoms n (%)** | Yes | 31 (20.7) | 5 (3.3) | 54 (36.0) | 0.002 |
| | No | 32 (21.3) | 9 (6.0) | 19 (12.7) | |
| **Gastrointestinal symptoms n (%)** | Yes | 30 (20.0) | 9 (6.0) | 54 (36.0) | 0.007 |
| | No | 33 (22.0) | 5 (3.3) | 19 (12.7) | |
| **Other adverse effects n (%)** | Yes | 40 (26.7) | 11 (7.3) | 67 (44.7) | 0.0 |
| | No | 23 (15.3) | 3 (2.0) | 6 (4.0) | |
| **Renal problem n (%)** | Yes | 5 (3.3) | 4 (2.7) | 20 (13.3) | 0.011 |
| | No | 58 (38.7) | 10 (6.7) | 53 (35.3) | |
| **Hepatic problem n (%)** | Yes | 18 (12.0) | 8 (5.3) | 39 (26.0) | 0.008 |
| | No | 45 (30.0) | 6 (4.0) | 34 (22.7) | |
| **Other side effects n (%)** | Yes | 21 (14.0) | 0 (0.0) | 29 (19.3) | 0.015 |
| | No | 42 (28.0) | 14 (9.3) | 44 (29.3) | |

$p < 0.05$ statistically significant

**Table 4 Complications associated with β thalassemia major patients**

| **Parameters** | | **Groups (N=150)** | | |
|---|---|---|---|---|
| | | **Group 1 Blood transfusion( n=63)** | **Group 2 Hydroxyurea (n=14)** | **Group 3 (B.T +HU) Both(n=73)** |
| **Dermatological adverse effects** | Hyperpigmentation n (%) | 0 (0.0) | 0 (0.0) | 4 (2.7) |
| | Skin rash n(%) | 12 (8.0) | 2 (1.3) | 29 (19.3) |
| | Swelling face n (%) | 1 (0.7) | 1(0.7) | 1(0.7) |
| | All n (%) | 0 (0.0) | 0 (0.0) | 3 (2.0) |
| | None n (%) | 50 (33.3) | 11 (7.3) | 36 (24.0) |
| **Gastrointestinal adverse effects** | Abdominal pain n (%) | 20 (13.3) | 7 (4.7) | 36 (24.0) |
| | All n (%) | 1 (0.7) | 0 (0.0) | 11 (7.3) |
| | Constipation n (%) | 4 (2.7) | 1 (0.7) | 1 (0.7) |
| | Diarrhea n (%) | 3 (2.0) | 0 (0.0) | 0 (0.0) |
| | Loss of appetite n (%) | 0 (0.0) | 1 (0.7) | 1 (0.7) |
| | Nausea and vomiting n (%) | 2 (1.3) | 0 (0.0) | 5 (3.3) |
| | None n (%) | 33(22.0) | 5 (3.3) | 19 (12.7) |
| **Hematological adverse effects** | All n (%) | 1(0.7) | 0(0.0) | 9(6.0) |
| | Decreased Hb n (%) | 24(16.0) | 1(0.7) | 22(14.7) |
| | Decreased PLT n (%) | 24(16.0) | 1(0.7) | 22(14.7) |
| | Neutropenia n (%) | 0(0.0) | 1(0.7) | 5(3.3) |
| | None n (%) | 32(21.3) | 9(6.0) | 19(12.7) |
| **Other therapy related side effects** | Ear pain n (%) | 1 (0.7) | 0 (0.0) | 0 (0.0) |
| | Body ache n (%) | 17 (11.3) | 3 (2.0) | 22 (14.7) |
| | Joints pain n (%) | 11 (7.3) | 4 (2.7) | 22 (14.7) |
| | Leg pain n (%) | 10 (6.7) | 3 (2.0) | 23 (15.3) |
| | Weakness n (%) | 1 (0.7) | 1 (0.7) | 0 (0.0) |
| | None n (%) | 23 (15.3) | 3 (2.0) | 6 (4.0) |

Percentages are calculated based on the total sample (N = 150). Data presented as frequency (n) and percentage (%).

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