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ORIGINAL ARTICLE

SAFETY AND EFFICACY OF THALIDOMIDE IN CHILDREN WITH TRANSFUSION DEPENDENT THALASSEMIA: A QUASI RANDOMIZED CONTROL TRIAL IN A TERTIARY CARE HOSPITAL IN BANGLADESH

MD. MEHEDI HASAN[1], MD. ANWARUL KARIM[2], ATM ATIKUR RAHMAN[2], CHOWDHURY YAKUB JAMAL[2], SOUMITRA PAUL[3], FARAH AKTHER[4], REZWANA RAHMAN[5], MOKLESUR RAHMAN[6]

Abstract

Background: *Thalidomide has been shown as a promising treatment option for reducing transfusion volume in adults with â-thalassemia. It induces ã-globin expression in erythroid progenitor cells, but its efficacy on children with transfusion-dependent â-thalassemia (TDT) remains unclear. This study aimed to determine the safety and efficacy of thalidomide in TDT children.* ***Methods:*** *In this phase 2, single-center, quasi-randomized, single-blind clinical trials, 60 patients of 3-18 years who attended in the Department of Pediatric Hematology and Oncology, Bangladesh Medical University (BMU), Dhaka, Bangladesh from February 2023 to January 2024, were randomly assigned to receive placebo or thalidomide for 12 weeks. The primary endpoint was the change of hemoglobin (Hb) level in the patients. The secondary endpoints included the red blood cell (RBC) units transfused and adverse effects.* ***Results:*** *In the placebo-controlled period, Hb concentrations in patients treated with thalidomide achieved a median elevation of 14.5 (range, 5.0 to 34.0) g/L, whereas Hb in patients treated with placebo did not significantly change. Within the 12 weeks, the mean RBC transfusion frequency for patients treated with thalidomide and placebo was 0.73 ± 0.9 times and 2.9 ± 0.6 times, respectively (P < 0.001). Significant increase in Hb concentration and reduction in RBC transfusions were associated in children with E-â Thalassemia in comparision with â-thalassemia major (P < 0.001). No unfavorable effects were observed on kidney and liver functions. Mild adverse events including drowsiness, dizziness, pyrexia, pruritus, abdominal pain, nausea, constipation, facial edema were more frequently found in (60%) patients treated with thalidomide.* ***Conclusion:*** *This study concludes that thalidomide is an effective and well-tolerated drug that can significantly increase Hb levels and reduce transfusion burden in children with TDT patients.*

Keywords: *Safety and Efficacy, Thalidomide, Transfusion Dependent Thalassemia*
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1. Assistant Professor, Pediatric Hematology and Oncology, Satkhira Medical College Hospital, Satkhira, Bangladesh.
2. Professor, Department of Pediatric Hematology and Oncology, Bangladesh Medical University, Shahbag, Dhaka, Bangladesh.
3. Assistant Professor, Department of Pediatric Hematology and Oncology, Bangabandhu Sheikh Mujib Medical University, Shahbag, Dhaka, Bangladesh
4. Assistant Professor, Department of Pediatric Hematology and Oncology, National Institute of Cancer Research & Hospital, Dhaka, Bangladesh
5. Assistant Registrar, Department of Pediatric Hematology and Oncology, National Institute of Cancer Research & Hospital, Dhaka, Bangladesh
6. Assistant Registrar, Department of Pediatric Hematology and Oncology, Rangpur Medical College Hospital, Rangpur, Bangladesh.

Correspondence: Dr. Md. Mehedi Hasan, Assistant Professor, Dept. of Pediatric Hematology & Oncology, Satkhira Medical College Hospital, Satkhira, Bangladesh., Email- dr.mehedihasan33@gmail.com, ORCID ID-0009-0002-2243-1306

Introduction

Thalassemia is a well-established monogenic hematological disorder characterized by defective synthesis of á or â globin subunits of hemoglobin leads to ineffective erythropoiesis and hemolysis due to an imbalance in globin chains.[1-3] Thalassemia patients are categorized as transfusion-dependent (TDT) or non-transfusion-dependent (NTDT) based on their transfusion needs.[4] Globally, an estimated 40,000 children are born annually with β-thalassemia of whom approximately 26,000 require regular blood transfusions.[2,5]

Hematopoietic stem cell transplantation (HSCT) remains the only definitive curative option for TDT patients.[2, 6] However , its widespread adoption is hindered by limitations such as the scarcity of suitable donors, high initial costs, lack of specialized treatment centers and transplant-related complications.[2, 5, 7]Alternative treatment options include blood transfusions, iron chelation therapy, splenectomy, gene therapy and erythroid maturation agents.[2, 5] Long-term transfusions pose challenges like iron overload, transfusion-transmitted infections, and alloimmunization.[5] While gene therapy holds promise, its long-term efficacy remains under evaluation.[8]

One promising approach involves pharmacological induction of fetal hemoglobin (HbF) production to lessen the severity of TDT.[8] Various HbF-inducing agents, including hydroxyurea (HU), butyrate derivatives, azacitidine, decitabine and trichostatin-A have shown promise in reducing clinical complications in TDT patients.[9]

Thalidomide, an immunomodulatory drug, has shown potential in small studies and case reports to significantly and persistently increase hemoglobin levels with minimal side effects compared to other HbF inducers.[10-13] It is believed to induce gamma-globin gene expression by increasing reactive oxygen species (ROS)-mediated p38 mitogen-activated protein kinase (MAPK) signaling and histone acetylation, while simultaneously suppressing NF-êB induction by inflammatory cytokines like tumor necrosis factor-á (TNF-á), vascular endothelial growth factor (VEGF), and prostaglandin E2 (PGE2).[9, 14]

However, the studies primarily focused on adolescents and older age groups. Due to the scarcity of data on thalidomide's safety and efficacy in children with TDT, it is not widely used in this age group. This quasi-randomized controlled trial aims to bridge this knowledge gap by evaluating thalidomide's safety and effectiveness in children with TDT. It may help in planning a cost effective and easily available alternative treatment option for TDT patients in developing countries where HSCT is very costly.The aim of the study was to assess the efficacy and safety of thalidomide as a treatment for children with TDT.

Methods

We performed a Quasi-randomized controlled trial that included 60 transfusion-dependent thalassemia (TDT) patients of either gender and 3-18 years of age who attended in the Department of Pediatric Hematology and Oncology, Bangladesh Medical University (BMU), Dhaka, Bangladesh from February 2023 to January 2024.

Children between 3 and 18 years diagnosed with thalassemia who require either: At least eight blood transfusions annually, or A minimum of 100 ml of packed red blood cells (RBCs) per kilogram of body weight annually or Frequent transfusions to maintain a hemoglobin (Hb) level above 7 g/dL for at least two years before enrollment in the study were included.[3]

Patients having any active systemic illness, impaired liver or kidney function, severe cardiopulmonary or cerebrovascular diseases, history of blood clotting disorders, recent history of fracture or major surgery within past 3 months, use of medications that could significantly affect hemoglobin levels within the past 3 months were excluded.

Informed written consent was obtained from the parent or guardian at the time of enrollment. Following enrollment, participants were quasi randomly allocated to either the placebo or thalidomide group in a 1:1 ratio with each group consisting of 30 patients.

Data collection included demographics, medical history, clinical parameters, and blood transfusion requirements. Patients received thalidomide or placebo at a dose of 2-5 mg/kg/day for 12 weeks.[15] Baseline evaluation was conducted before starting thalidomide. Follow-up visits occurred every two weeks for the first 12 weeks. CBC was done every 2 weeks and biochemical tests (S. Ferritin, SGPT, S. creatinine, LDH, S. billirubin) were done every monthly. Hb electrophoresis was done at the beginning & at the end of 12 weeks of placebo-controlled period. All investigations were done in Department of Pediatric Hematology and Oncology, BMU.

Red blood cell transfusions were provided if hemoglobin levels dropped below 7.0 g/dL. Treatment efficacy was assessed after 12 weeks. The study employed a specific response classification system to evaluate the effectiveness of thalidomide treatment. Excellent Response: Patients who experience an increase in total Hb of at least 2 g/dL or maintain a level above 7 g/dL and become transfusion-independent for at least 6 weeks, Good Response: Patients who achieve an Hb

increase between 1 and 2 g/dL, or if the Hb increase is less than 1 g/dL but they maintain a level above 7 g/dL and need infrequent transfusion , No Response: Patients with an Hb increase of less than 1 g/dL who remain transfusion-dependent.[3]

Patients who achieved significant hemoglobin increase and remained transfusion-free for 6 weeks continued the assigned treatment for further evaluation. The placebo-controlled phase ended after all participants completed their initial 12-weeks follow-up. Statistical analysis was then conducted using IBM SPSS version 25. A p-value of less than 0.05 was considered statistically significant.

This trial is registered at http:// www.clinicaltrial.gov as # NCT06098014.

Results

A total of 60 patients were assessed & randomized to receive placebo (n = 30) or thalidomide (n = 30) treatment. The average age was 8.9 years, 67% of them were male and 33% were female. Seven patients received splenectomy. 20% of participants had BTM while 80% had EBT. Baseline mean Hb, HbF & s.bilirubin are almost similar in both groups. (Table-I).

Table I

		Total(n=60)	Thalidomide(n=30)	Placebo(n=30)	p-value
Age , y (mean±SD)		8.9±3.7	8.9±3.8	8.9±3.6	0.500
Sex, n (%)	Male	40 (66.7)	20 (66.7)	20 (66.7)	0.976
	Female	20 (33.3)	10 (33.3)	10 (33.3)	
Diagnosis, n (%)	β-TM	12 (20)	7 (23.3)	5 (16.7)	0.685
	E-βT	48 (80)	23 (76.7)	25 (83.3)	
Splenectomy, n (%)	Yes	7 (11.7)	3 (10.0)	4(13.3)	0.628
	No	53 (88.3)	27 (90.0)	26 (86.7)	
Hb before treatment, g/dL (mean±SD)		6.8±1.0	6.5±.92	7.1±1.0	0.031
Hb F, % (median & range)		34.3 (1.0, 94.4)	34.2 (1.0, 93.3)	34.5 (2.5, 94.4)	0.488
Total bilirubin, mg/dL (median & range)		2.3 (.6, 6.5)	2.5 (.6, 6.5)	2.1 (.6, 5.8)	0.121
Ind bilirubin, mg/dL (median & range)		1.6 (.4, 5.2	1.6 (.4, 3.8)	1.5 (.5, 5.2)	0.440

Baseline demographic characteristic of the patients

β-TM Beta thalassemia major, E-βT E-Beta thalassemia.

Table II

Hb levels of the study cases at indicated time points

Time	Cases, n	Hb (g/dL), Mean ± SD		p-value
		Thalidomide	Placebo	
Pre-treatment	30	6.5±0.9	7.1±1.0	0.031
End of Week 4	30	7.9±1.0	7.6±1.1	0.326
End of Week 8	30	8.2±0.9	6.8±1.1	0.000
End of Week 12	30	8.2±0.9	6.8±1.6	0.000

Significant increase in hemoglobin (Hb) levels was found among patients receiving thalidomide treatment (Table II). This represents a mean elevation of 1.7±0.8 g/dL.

Table III

Responses of the patients to the study drug

Responses	Thalidomide, n (%)	Placebo, n (%)	p
Excellent response	10 (33.3)	0 (0.0)	.000
Good response	16 (53.3)	1 (3.3)	
No response	4 (13.3)	29 (96.7)	

Among the 30 participants in the thalidomide group: Ten patients (33.3%) achieved an excellent response, sixteen patients (53.3%) achieved a good response while Four patients (13.3%) exhibited no response (Table III).

Table IV

Changes of HbF in the study cases treated with thalidomide or placebo

	Thalidomide	Placebo	p
Hb F at week 0, %	31.9 (1.0, 93.3)	37.8 (2.5, 94.4)	.600
Hb F at end of week 12, %	40.7 (3.5, 93.8)	16.4 (.6, 66.4)	.000
Change in Hb F, %	7.3 (-22.3, 50.7)	-10.5 (-73.0, 20.7)	.000

In Table IV shows Thalidomide significantly increased the Hb F ratio of the patients, which rose from 31.9 % to 40.7 % after the end of 12 weeks.

Table V

Changes of transfusion requirement in the study cases treated with thalidomide or placebo

	Thalidomide	Placebo	p
Mean transfusion frequency	0.7 ±0.9	2.9±0.6	.000

In Table V shows Mean transfusion frequency was 0.7 ±0.9, which was reduced significantly in Thalidomide treated patients.

Mild adverse events[16] including drowsiness, dizziness, fatigue, pyrexia, anorexia, abdominal pain, constipation, facial edema and pruritus were reported in patients of both groups, where grade I dizziness, drowsiness, constipation and pruritus were more frequently reported in patients treated with thalidomide.

Discussion

Transfusion dependent thalassemia (TDT) is a serious health burden globally. Thalidomide an immuno-modulatory drug has shown to be safe & effective in adult patients with TDT, but its safety & efficacy in children with TDT has not been comprehensively determined, and there is a certain degree of uncertainty. The present study was conducted with the view of assessing the efficacy and safety of thalidomide in treating children with TDT.

This study investigated the safety and efficacy of thalidomide compared with a placebo control group having equal number of patients. Baseline characteristics such as age, sex, diagnosis, previous splenectomy were found similar in both groups.

In this study the mean age of participants was 8.9±3.7 years with a male predominance (67% overall). In a study, Begum et al.[15] reported similar age distribution (9.75±4.11years) and male dominance (55%) in TDT children. However, some studies included patients of a higher age group of 18.4±5.6y, and 27.2±7.9y respectively.[3, 17] Additionally, 10.0% and 13.3% of participants in the thalidomide and placebo groups, respectively, had undergone prior splenectomy.

The study showed that after 12 weeks of treatment hemoglobin (Hb) concentration increased in the thalidomide group from a baseline mean of 6.5±0.9 g/dL to 8.2±0.9 g/dL with an average increase of 1.7±0.8 g/dL compared to placebo group (baseline 7.1±1.0g/dL to 6.8±1.6g/dL) which is statistically significant (P< .05) (Table-II). In their study Yang et al.[17] found a significant increase in hemoglobin (Hb) levels in thalidomide treated patients from 6.8 g/dl at baseline to 9.7 g/dL, with an average increase of 2.9 g/dL. The observed improvement in Hb level is also comparable with the findings of Chen et al.[3] & Lu et al.[7] showing mean increase of Hb levels 1.4 g/dL & 1.5 g/dL respectively following thalidomide therapy.

The present study showed after twelve weeks, the thalidomide treated group had significantly higher rates of both excellent (33.3%) and good responses (53.3%) compared to the placebo group (Table-III). This finding is comparable with the study of Ali et al.[18] where patients treated with thalidomide demonstrated 25.8% excellent response, 51% good response. Chen et al.[3] also demonstrated significantly higher response rate in thalidomide group (40.8% excellent response & 28.6% good response) than placebo group.

The study also identified a significant increase in Fetal Hemoglobin (HbF) levels in the thalidomide group compared to the placebo group. Thalidomide treatment significantly increased the HbF percentage from 31.9% to 40.7%, with an average of 7.3 ± 18.8% ($p < 0.05$) in twelve weeks (Table IV). This result is comparable with Chen et al.[3] whose study documented a significant increase in the HbF ratio of patients treated with thalidomide (from 10.8% to 55.2% in twelve weeks). This finding is also consistent with the study by Yang et al.[17] where average HbF percentage significantly increased from a pretreatment level of 41.9±23.4% to 54.3±23.0% after treatment.

We observed a significantly lower frequency of blood transfusions in the thalidomide group compared to the placebo group (0.7 ± 0.9 vs. 2.9 ± 0.6, $p = 0.000$) (Table-V). This suggests that thalidomide might be effective in reducing blood transfusion dependency in TDT patients. These findings are consistent with Chen et

al. who also reported a significantly lower blood transfusion frequency in the thalidomide group compared to the placebo group.[3] Thalidomide's ability to induce fetal hemoglobin (HbF) production might explain the observed rise in hemoglobin (Hb) levels and reduced need for blood transfusions.

The study compared the biochemical profiles of both groups before and after twelve weeks of treatment (Supplementary Table I). Regarding liver function measured by SGPT levels & kidney function, as indicated by S. creatinine levels, our study found no significant changes in both the study groups which is consistent with previous studies.[3, 18, 19]

In the present study S. total (TBIL) and indirect bilirubin (IBIL) levels decreased in Thalidomide treated patients (P>0.05). This finding is consistent with the observations of Chen et al. and Ali et al.[3] who reported significant changes in TIBL & IBIL levels following Thalidomide treatment.

In the present study S. LDH level decreased in thalidomide group, though this decrease was not statistically significant (P> 0.05). This finding is comparable with the findings of Ali et al.[18] who reported significant reduction of LDH.

The study observed a decrease in S. Ferritin levels (from 2419.6±1367.4 to 2189.0±1418.7 ng/mL) in thalidomide-treated patients compared to the placebo group, although this difference was not statistically significant (p >0.05). Begum et al.[15] and Ali et al.[18] also reported significant decrease in S. Ferritin levels in their study. The decrease in serum ferritin may be due to both fewer blood transfusions and enhanced red blood cell production.

The study compared the occurrence of side effects between patients receiving thalidomide and those receiving placebo (Supplementary Table II). While mild adverse effects like drowsiness, dizziness, fever, nausea, vomiting, abdominal pain, constipation, and facial edema were reported in the thalidomide group, of which drowsiness was the most frequent adverse effect (16.7%) followed by skin itching (10%) & constipation (6.7%). There were no statistically significant differences between the groups (P> 0.05 for all comparisons). This aligns with the findings of Chen et al.[3] who reported similar observations in their study which documented mild adverse events.

In the present study there was no hematological toxicity or bone marrow suppression in the participants throughout the treatment period. This finding is consistent with the study by Yang et al.[17] This finding is in contrast to the study by Li et al. showing neutropenia (n = 10), thrombocytosis (n = 9) in thalidomide treated patients.[20] Another study by Ali et al. also demonstrated similar findings where 1.1% patients experienced neutropenia.[18] The absence of hematological toxicity observed in the present study may be due to the lower dosage of thalidomide used & shorter follow up period compared to other studies.

The observed increase in Hb levels, improved treatment response, elevated HbF levels, reduced blood transfusion frequency and the mild and transient nature of side effects in the thalidomide group compared to the placebo group suggest a potential therapeutic benefit for this medication in this patient population.

Conclusion

The study found thalidomide to be safe & well-tolerated for children with TDT, making it an alternative treatment option due to its affordability and easy availability, especially in low- and middle-income countries.

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Conflict of Interest

No author has any conflict of interest to disclose for this manuscript. The authors themselves are responsible for their ideas and views expressed in this article, which do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated.

Ethical Approval

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Formal ethical clearance was obtained from the Institutional Review Board, BMU. Written informed consent was obtained from all participants (parents or legal guardians for minors) & confidentiality was maintained of all participant information and data.

Trial registration: This trial is registered at http://www.clinicaltrial.gov as # NCT06098014.

Authors' contributions

Md. Mehedi Hasan contributed to the concept and design. Md. Mehedi Hasan, Md. Anwarul Karim, Atm Atikur Rahman, Chowdhury Yakub Jamal, Md. Salauddin Mia, Rezwana Rahman, Farah Akther, Moklesur Rahman performed data collection and compilation. Md. Anwarul Karim, Rezwana Rahman , Farah Akther contributed in data analysis and manuscript writing. All authors revised and approved the manuscript.

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