

Westchester Medical Center (WMC) Approach to Jehovah’s Witness Acute Myeloid Leukemia (AML)



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Background

We set out to demonstrate a proof-of-concept approach to management of AML in Jehovah’s Witness patients without the use of blood product support.

There are over 8 million Jehovah’s Witnesses worldwide. Their world headquarters is located 30 miles from WMC and the area supports a sizable population of Jehovah’s Witnesses.

Objective

Development of bloodless therapeutic approach to management of AML in adult Jehovah’s Witness patients that is in line with their religious beliefs.

Main Outcome Measures: The primary outcome is overall survival. Secondary outcome is progression free survival. Outcome measures include hemoglobin and platelet counts.

Study

Eligibility criteria include: > 18 years of age, confirmed diagnosis of AML and refusal to accept transfusion of blood products.

The protocol emphasizes the optimization of hemoglobin and platelet count, practicing conservative measures, such as minimizing blood draws and invasive procedures and using prophylactic measures against potential complications such as gastrointestinal bleeding. Our protocol includes: pediatric tubes, limit blood draws, IV iron, erythropoietin, weekly romiplostim, Vitamin B12, folate, and aminocaproic acid. Venetoclax was planned for patients given less hematopoietic burden than traditional intensive chemotherapy.

Pre-transplant measures

Goal collection: $\geq 5 \times 10^6$ CD34 cells to hasten hematologic recovery
Cessation of menses if applicable
IV Iron and EPO (If EPO < 500 μ U/mL, can give 150 units/kg 3 $\times$ /wk or 40,000 units weekly) prior to stem-cell mobilization to target hemoglobin level 10–11 g/dL
Conservative measures
Avoid heparin prophylaxis, aspirin, NSAIDs
Fall and bleeding precautions
Minimize blood work (pediatric tubes, 1 set of blood cultures) and avoid invasive procedures
IV hydration, nasal saline spray
GI prophylaxis (PPI, Senna)
Supplements: Folic acid, vitamin B12, vitamin K 10 mg OD start on Day +1
Initiate G-CSF 480 mcg OD on Day +1
Anemia
When Hgb < 11 g/dL: Restart IV Iron weekly x4 doses
When Hgb < 9 g/dL: Continue weekly iron and restart erythropoietin
When Hgb < 6 g/dL: Complete bed rest with bedside commode, supplemental O2 via nasal cannula with humidified air

Thrombocytopenia
Aminocaproic acid (PO or IV formulation) administered immediately post-transplant
Vitamin K 10 mg PO daily
Romiplostim 4 mcg/kg weekly (can titrate dose based on platelet count and response) starting 2–7 d post-transplant, continued until platelets > 100,000/ μ L
When Plt < 30×10^3 / μ L: No anticoagulation (including heparin flushes), Aminocaproic acid 1 g IV every 4 h (can be titrated as per transplant physician)
When Plt < 10×10^3 / μ L: Titrate Aminocaproic acid to 4 g IV every 4 h
Active bleeding
Discontinue oral PPI and switch to IV PPI
Cryoprecipitate 4 units IV every 8 h (regardless of fibrinogen) and DDAVP 20 mcg in 50 ml NS every 12 h for total 3 doses
If cryoprecipitate ineffective, add prothrombin complex concentrate (2 vials)
Aminocaproic acid 4g IV every 4 h
Xylometazoline 0.1% nasal spray 2 sprays in each nostril every 8 h (hold if BP > 120/90 mmHg)
If bleeding persists: may give Factor VIIa 90 mcg/kg IV every 3 h

Results:

Our first patient using this approach to evaluate efficacy and safety of this bloodless induction protocol was a 57-year-old gentleman with newly diagnosed AML . We initiated Venetoclax and Decitabine along with all supportive interventions outlined prior. Unfortunately, the patient felt unwell after the initial doses of chemotherapy and declined further treatment and left against medical advice.

We saw no qualitative, logistical, or administrative concerns with the bloodless approach. On discharge, the patient’s hemoglobin was 3.8 g/dL and his platelet count was 4 k/mm³

. He eventually was admitted to another hospital, where he expired without AML treatment. We were unable to measure our primary and secondary outcomes, given our patient did not complete treatment.

Conclusions:

Though our initial patient did not complete his induction chemotherapy, from a qualitative analysis our supportive care measures to optimize hemoglobin and platelet counts and limit bleeding risk were delivered without issues and may serve as a model for other centers with patients declining blood products in their leukemia care.