

Treatment of a Jehovah's Witness using a transfusion-free autologous stem cell transplant protocol

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High-dose chemotherapy (HDCT) followed by autologous peripheral blood stem cell transplantation (APBSCT) is the standard treatment for multiple myeloma and relapsed or high-risk lymphomas. To avoid bleeding complications and to treat profound anemia posttransplant, as a rule, patients are given transfusions after APBSCT. But Jehovah's Witnesses decline transfusions based on religious convictions, making the treatment of these patients' hematologic malignancies a special challenge. The authors of this report describe a transfusion-free APBSCT protocol with acceptable morbidity and mortality used on 48 Jehovah's Witnesses. Infectious complications due to transfusion are avoided; anemia is managed mainly with prophylactic erythropoietin, IV iron therapy, and volume support; and thrombocytopenia is managed solely with the use of hemostatic agents, vitamin K, and oprelvekin. Only 1 of the 48 patients died because a transfusion was withheld, and only 1 had a major bleed, which resolved upon administration of cryoprecipitate. The experiences gained in treating this patient population suggest that HDCT and APBSCT can be safely performed without the use of blood products.

High-dose chemotherapy (HDCT) followed by autologous peripheral blood stem cell transplantation (APBSCT) is the standard treatment for some hematologic malignancies. It has been shown to prolong survival in multiple myeloma^{1,2} and to provide the best option for long-term survival in patients with relapsed or high-risk Hodgkin's lymphoma and non-Hodgkin's lymphomas, when compared with standard chemotherapy.^{3,4} Serious adverse events include drug-related organ damage, infection, severe anemia, and risk of bleeding from thrombocytopenia. For these reasons, transfusion support, with an average of three platelet and three red blood cell transfusions per patient, is almost universally administered.⁵ For patients who refuse blood for religious reasons, HDCT with APBSCT frequently is still not performed at most major transplant centers because physicians believe that this procedure cannot be safely performed in patients without transfusion support.

The greatest concern among physicians is the potential for a gastrointestinal (GI), intracranial, or pulmonary bleeding complication. Although these complications can be life-threatening, they may be managed without the use of routine platelet transfusions. The Center for Bloodless Medicine & Surgery at Pennsylvania Hospital, a community hos-

pital with a small transplant center performing only APBSCT, performed this procedure with few modifications with acceptable morbidity and mortality on 48 Jehovah's Witnesses. In this article, we describe our experience.

Jehovah's Witnesses' beliefs

Physicians face a unique challenge when treating Jehovah's Witnesses. According to the Watchtower Bible and Tract Society, members of this religious group number more than 6.5 million worldwide, with more than 1 million residing in the United States.⁶ Jehovah's Witnesses belong to a Christian religion that strictly adheres to Biblical passages that prohibit the eating and storing of blood (see Genesis 9:3, 4; Deuteronomy 12:14, 23; Leviticus 17:10, 113-114; and Acts of the Apostles 15:20, 28-29).⁷ According to these biblical texts and Jehovah's Witnesses' beliefs, once blood has been removed from the body, it should be disposed of and not returned to the body. This prohibition applies to what Jehovah's Witnesses define as the four prima-

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ry blood components: red blood cells, white blood cells, platelets, and plasma.⁷

Individual Jehovah's Witnesses, with appropriate knowledge and counsel, are free to make their own decisions about minor blood components, such as albumin, globulin, fibrin, and clotting factors. Additionally, an individual congregant can decide whether and how he or she will accept transplantations of organs, tissue, bone, or stem cells.⁸ Processes that entail blood leaving the body, such as autologous banking, are generally unacceptable. As long as continuous circulation is maintained, procedures such as cell salvage and dialysis may be acceptable.⁹

A common misconception is that congregants will refuse other medical treatments. In fact, Witnesses are generally conscientious about their own health, abstaining from harmful activities such as drinking and using tobacco, and readily pursue medical treatments.¹⁰⁻¹² Modern science continues to develop non-blood alternatives and techniques that are acceptable to this patient population. It is vital that informed physicians and hospital coordinators educate health-care providers about these lifesaving alternative treatments.

Case study

In August 2001, a 20-year-old woman (who recounts her own story on page 781) presented with a history of weight loss, fatigue, and chronic abdominal pain. Laboratory analysis revealed a hemoglobin level of 9 g/dL and an elevated serum lactate dehydrogenase level (541 U/L). A CT scan uncovered hepatosplenomegaly and masses in her lungs, liver, and spleen. A bone marrow biopsy demonstrated a normal chromosome pattern with no evidence of malignant disease. She underwent a liver biopsy, which yielded classic Hodgkin's lymphoma (CD15+, CD30+, and CD20-). The patient was diagnosed with stage IVB Hodgkin's lymphoma involving the liver and the spleen. She subsequently

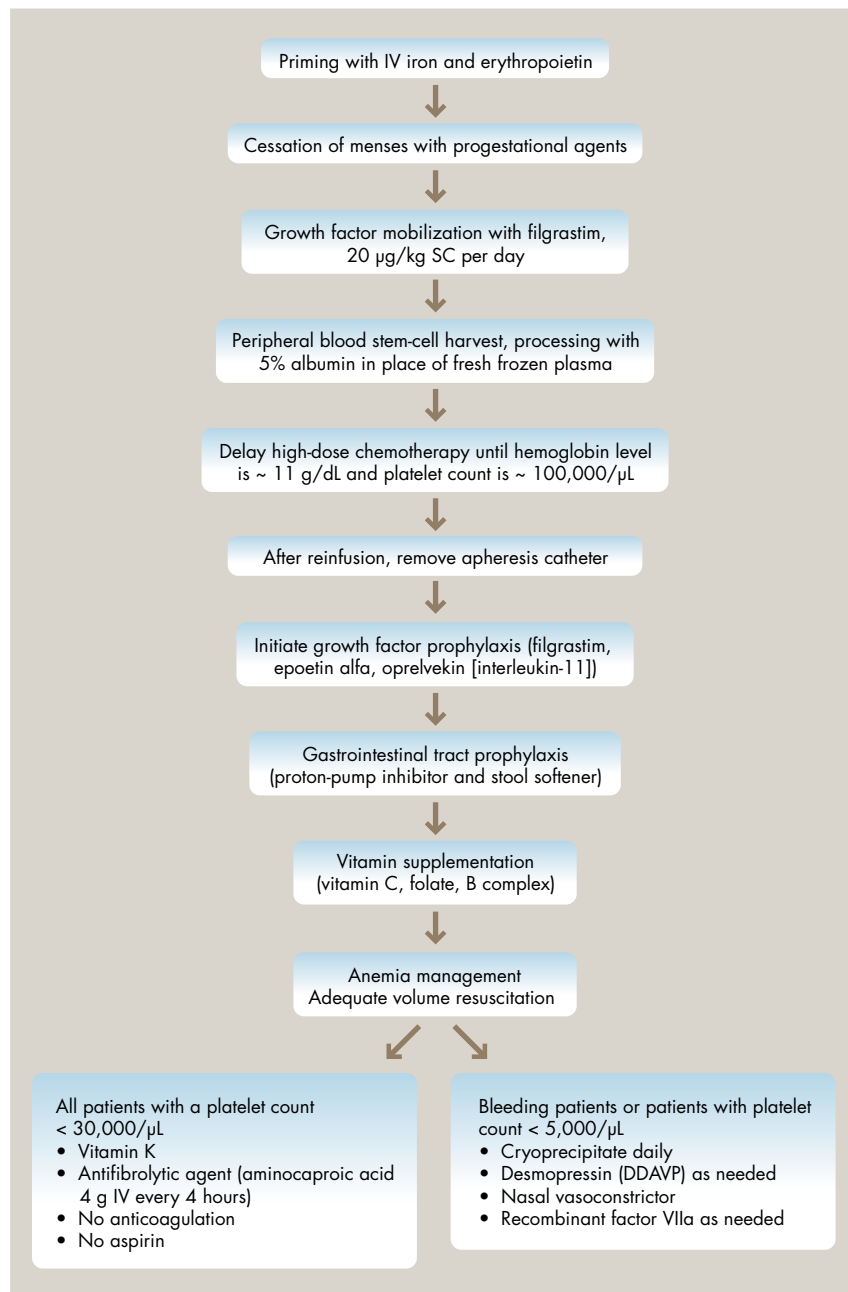


FIGURE 1 Bloodless stem cell transplant schema

underwent 6 cycles of treatment with Adriamycin (doxorubicin), bleomycin, vinblastine, and dacarbazine (ABVD) at standard transplant doses. This regimen yielded a partial response on a CT scan but a normal gallium scan.

The patient was closely observed until February 2002, when gallium scanning revealed new and increased uptake in the paratracheal region, demonstrat-

ing recurrent disease. She was symptomatic with weight loss, night sweats, and fatigue. It was determined that the patient should receive salvage chemotherapy followed by an APBSCT. Since she was a Jehovah's Witness and refused transfusion support, her treating doctors declined to perform a stem cell transplant, and the patient was referred to the Center for Bloodless Medicine & Sur-

gery at Pennsylvania Hospital.

Although the patient refused to receive red blood cell plasma or platelet transfusions, she would accept erythropoietin, interleukin-11 (oprelvekin [Neumega]), granulocyte colony-stimulating factor (G-CSF; filgrastim [Neupogen]), peripheral blood stem cells, and minor blood components. In March 2002, the patient was able to tolerate 2 cycles of salvage chemotherapy with ifosfamide (IFEX), carboplatin, and etoposide (ICE), although she experienced pancytopenia, including a 2-g/dL decline in hemoglobin level to 8.6 g/dL.

In May 2002, the patient began our bloodless stem cell transplant protocol (Figure 1). The major modifications of our standard stem cell transplant procedure follow: All blood-management strategies are incorporated into the bloodless schema. Such strategies include priming for optimal hemoglobin levels, maintaining euvolesmia, minimizing iatrogenic blood loss, and using growth factors and hemostatic agents. Priming consists of IV iron and erythropoietin to maximize hemoglobin levels in anticipation of a 5-g/dL drop due to HDCT. The process of apheresis also causes a 2-g/dL drop in hemoglobin level, necessitating a delay in HDCT until it reaches 11 g/dL. Additionally, the cryopreservation substitutes albumin in place of fresh frozen plasma.

TABLE 1

Patient characteristics

	Mean	Range
Age, yr	44.9	21–70
	Number	Percent
Gender		
Male	19	39.6
Female	29	60.4
Diagnosis		
Multiple myeloma	23	47.9
Non-Hodgkin's lymphoma	15	31.2
Hodgkin's lymphoma	8	16.7
Breast cancer	2	4.2

The patient began treatment with epoetin alfa (Procrit), 40,000 U subcutaneously once a week, and iron dextran, 500–1,000 mg every 4 weeks, to obtain maximum levels of hemoglobin prior to APBSCT. G-CSF mobilization (20 µg/kg/d of filgrastim in divided doses) was administered in the 4 days preceding APBSCT to mobilize stem cells out of the bone marrow and into the peripheral circulation for collection. Three large-volume (20–21 L) apheresis collections yielded only 1.49×10^6 CD34+ stem cells/kg. Although this amount may be suboptimal, the patient agreed to proceed knowing this treatment offered the best chance of long-term survival. During apheresis, her hemoglobin value dropped 1.4 g/dL, from 8.8 g/dL to 7.4 g/dL. Her platelet count also declined, from $213 \times 10^3/\mu\text{L}$ to $84 \times 10^3/\mu\text{L}$.

Apheresis raises two concerns in the Jehovah's Witness population. The first concern centers on the traditional use of fresh frozen plasma as a storage medium for the stem cells. Because plasma is defined as a primary blood component, Jehovah's Witnesses cannot accept this product. An alternative was found in 5% albumin. The second concern is the small number of red blood cell contaminants among the collected stem cells. Because the red blood cells are not the intent of the transplant and are not used for nutritive purposes, many Jehovah's Witnesses deem their presence acceptable.

This patient's HDCT was delayed 40 days until she had regained an adequate hemoglobin level (defined as 11 g/dL). Because her treatment with ICE resulted in profound pancytopenia, HDCT was significantly delayed in this patient compared with our other bloodless transplant patients. Only 18 of our 48 Jehovah's Witnesses had required a delay (average delay, 17.6 days).

At the onset of HDCT in June 2002, the patient's hematocrit value was 33.9%, her hemoglobin level was 11.3 g/dL, and her platelet count was $118 \times$

$10^3/\mu\text{L}$. She received induction chemotherapy with a total dose of etoposide (2,100 mg/m²), carmustine (BiCNU; 300 mg/m²), and cyclophosphamide (6,000 mg/m²), with no immediate drug toxicity, followed by reinfusion of 1.49×10^6 CD34+ stem cells/kg. She was placed on prophylactic antifungal, antibiotic, and antiviral therapy. During her stay, anemia was managed with epoetin alfa (40,000 U once a week until the hemoglobin value was > 11 g/dL). Her lowest hemoglobin level was 7.4 g/dL on day 15. Post-HDCT thrombocytopenia was managed with aminocaproic acid (Amicar), when her platelet count fell below $30 \times 10^3/\mu\text{L}$. Oprelvekin was also used to help facilitate platelet maturation.¹³ During this patient's hospital stay, no bleeding complications occurred, despite her platelet count falling to a low of $3 \times 10^3/\mu\text{L}$ on days 9–12. Her platelet count recovered to $20 \times 10^3/\mu\text{L}$ on day 15. She was discharged on day 21 without any major complications. Four years posttransplant, she remains in remission.

Discussion

Transfusion of allogeneic blood has numerous associated risks. Many patients and physicians fear transfusion-transmitted diseases, such as HIV and hepatitis B and C; however, the known risk of transmitting these diseases is small. More common complications are due to immunosuppression, which may increase the risk of cancer recurrence and significantly increase the risk of infection. In trauma patients, it has been shown that the risk of infection increases with each additional unit of blood transfused.¹⁴ Currently, about three red blood cell and three platelet transfusions are administered per patient following HDCT and APBSCT.⁵ Preliminary data comparing infection rates in our bloodless patients with those who are liberally transfused post transplant show that transfused patients have on average 0.82 infections per patient, whereas those who do not receive

transfusions have only an average of 0.50 infections per patient.¹⁵

Using these strategies, HDCT and APBSCT can be safely performed without the use of blood products. At the Center for Bloodless Medicine & Surgery at Pennsylvania Hospital, 48 Jehovah's Witnesses have been treated for lymphoma (23 patients), multiple myeloma (23 patients), and breast cancer (2 patients) with standard transplant doses followed by APBSCT without the use of blood products. These patients range in age from 21 to 70 years old (Table 1). The national rate of mortality in our center is 2 of 48 patients (4.17%), compared with a mortality rate of 2%–4% associated with the use of APBSCT for lymphomas and multiple myeloma.^{16,17} Our first and only mortality related to withholding a transfusion occurred in a patient with a pretransplant hemoglobin level of 7 g/dL that reached a nadir of < 2 g/dL. The bloodless protocol was then altered to require a hemoglobin level of 11 g/dL and a platelet count of $100 \times 10^3/\mu\text{L}$ prior to HDCT. Our second death was due to hospital-acquired pneumonia, which occurred immediately after reinfusion and was not related to our bloodless protocol.

Although HDCT causes anemia and thrombocytopenia, these complications can be adequately managed without the use of transfusion support. Prior to HDCT, epoetin alfa and IV iron are used to reach an ideal hemoglobin level of 11 g/dL. Aside from the iron dextran our patient received, two other options for IV iron treatment have since become available—iron sucrose (Venofer; 125 mg once a week for 4 weeks) and sodium ferric gluconate (Ferrlecit; 300 mg once a week for 3 weeks). After HDCT, further anemia is avoided and managed with meticulous blood conservation (limiting the number and volume of laboratory samples), maintenance of euvolemia, and the adjustment or elimination of antihypertensive medications. Post-transplantation, epoetin alfa is contin-

TABLE 2
Hemoglobin levels

	Mean	Range
Hemoglobin level at onset of high-dose chemotherapy, g/dL	11.92	7–15.3
Lowest hemoglobin level, g/dL	6.62	2–11.3
Change in hemoglobin level, g/dL	5.31	2–7.7
Hemoglobin level at day +30, g/dL	9.97	5.5–13.7
Hemoglobin level at day +60, g/dL	12.61	10–16.1

ued. Although small randomized studies have demonstrated that epoetin alfa can decrease the need for transfusions only in allogeneic^{18,19} and not autologous^{20,21} transplants, our endpoint is not the avoidance of transfusions but a more rapid recovery of hemoglobin levels. In our bloodless transplant patients, the average decline in hemoglobin level was 5.3 g/dL, with a nadir of 6.6 g/dL. Within 30 days post transplant, the average hemoglobin level was 10.0 g/dL, and by 60 days, it was 12.6 g/dL (Table 2).

Thrombocytopenia is managed by administering hemostatic agents, Aminocaproic acid, vitamin K, and oprelvekin. One retrospective review has shown an overall incidence of acute bleeding in 34% of autologous transplant patients.²² To avoid bleeding complications in our bloodless patients, our bloodless protocol makes use of oprelvekin to help facilitate the maturation of megakaryocytes into platelets.¹³ The efficacy of oprelvekin in bloodless transplants is unknown, but it has been proved that this recombinant IL-11 product reduces the requirement for platelet transfusions following conventional chemotherapy.²³

With these preventive measures, there was one case of a major GI bleed; it occurred in a 25-year-old male who was profoundly thrombocytopenic, with a platelet count < $10 \times 10^3/\mu\text{L}$ for 7 days. Although this patient was given aminocaproic acid and vitamin K, he experienced nosebleeds, hematemesis, and hematochezia. On the fifth day of his GI bleed, with a hemoglobin level of 2.5 g/dL and a platelet count of $1 \times 10^3/\mu\text{L}$, he was given cryoprecipitate despite a normal fibrinogen level. Within hours, the bleeding ceased. Since that experience, cryoprecipitate has been added to our bloodless protocol (Figure 1).

All but 10 patients had a platelet count of < $10 \times 10^3/\mu\text{L}$; in some of them, the count was as low as $1\text{--}2 \times 10^3/\mu\text{L}$. However, there was never a case of bleeding when the platelet count remained above $5 \times 10^3/\mu\text{L}$. The duration of this critical period in thrombocytopenia averaged 4.3 days, with a recovery to $20 \times 10^3/\mu\text{L}$ in approximately 12.1 days. Platelet counts reached $50 \times 10^3/\mu\text{L}$ an average of 15.6 days after reinfusion. By 30 and 60 days post transplant, platelet counts averaged $178 \times 10^3/\mu\text{L}$ and

TABLE 3
Platelet levels

	Mean	Range
Lowest platelet count, $\times 10^3/\mu\text{L}$	6.4	1–43
Days to lowest platelet count	7.85	4–13
Duration of grade 4 thrombocytopenia*, days	4.33	0–14
Days to platelet count > $20 \times 10^3/\mu\text{L}$	12.05	0–21
Platelet count at day +30, $\times 10^3/\mu\text{L}$	178	12.1–403
Platelet count at day +60, $\times 10^3/\mu\text{L}$	210	107–386

* Platelet count < $10 \times 10^3/\mu\text{L}$

$210 \times 10^3/\mu\text{L}$, respectively (Table 3).

Our blood-management strategies can be applied to all cases of thrombocytopenia and anemia. Most transplant centers have protocols with defined “transfusions triggers” for both red blood cells and platelets. We do not advocate the use of such triggers. Our center provides treatment for patients with most medical conditions without the use of blood products. In our experience, 100% of patients with a hemoglobin level of ≥ 5.1 g/dL and 85.7% of patients with a hemoglobin level as low as 2.5–3.0 g/dL survive.²⁴ Additionally, our transplant patients with a hemoglobin level as low as 7 g/dL remained clinically stable. Our experiences with low hemoglobin values indicate that rather than using a predetermined hemoglobin level as a trigger, the decision to transfuse or not should be based on individual patient needs and the patient’s clinical response to profound anemia.

Currently, many doctors will transfuse all patients whose platelet count falls below $10 \times 10^3/\mu\text{L}$. In our transfusion-free transplant patients, we have not had a case of serious bleeding as long as the platelet count stayed above $5 \times 10^3/\mu\text{L}$, supported solely with the use of hemostatic agents, vitamin K, and oprelvekin. We believe that lower standards can be applied to both hemoglobin and platelet transfusions to minimize the use of blood from a currently strained supply and to avoid hazardous transfusion risks.

Our bloodless protocol only requires a few simple modifications from a standard APBSCT protocol. Patients are traveling from all over the United States to Pennsylvania Hospital for this treatment, which is expensive and not reimbursed by some insurance companies, as it is out of network. Therefore, patients are being denied treatment and are dying of potentially curable malignancies. We are hopeful that other transplant centers would be

willing to provide this treatment and incorporate some of the techniques to reduce transfusion exposure.

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Bloodless stem cell transplant: a patient's perspective

By Ericka Peterson-Hobson as told to Randi Londer Gould

"WE GOVERN OUR LIVES on Bible commands," says Ericka Peterson-Hobson, a 26-year-old Philadelphia woman who is one of Jehovah's Witnesses. Her Bible prohibits the use of blood products, and had she been in good health, that restriction would not have become an issue. But in 2002, Ms. Peterson-Hobson needed a stem cell transplant to treat her Hodgkin's lymphoma, a procedure usually followed by a blood transfusion. For Ms. Peterson-Hobson, using blood posttransplant was not an option. She explains her story:

My family has been Jehovah's Witnesses since the 1970s. We follow scripture, God's commands. And the commandment to abstain from blood is recorded in the Bible at Acts 15, Verse 20, 28, and 29. It has saved us from diseases.

In December 1999, I had the sharpest pain in my right side. The agony was so strong, I couldn't speak. It was like someone had stuck a knife in my abdomen and was twisting it. My parents took me to the emergency room, but the pain went away, so they sent me home after taking an x-ray.

Other tests also found nothing. But the pain came back a month later, stronger. I thought it was cancer, and I didn't want to alarm my parents. I was petrified. Instead of telling someone, I tried to talk myself out of it. But when I would lie down, I could feel a large lump in my stomach. I usually slept on my stom-

ach, but it got to the point where I couldn't. Finally, I told my father, and we went back to the doctor. When he felt my abdomen, he looked as though he wanted to cry. My life is governed by my faith, and we started praying.

The doctor took blood to run some tests. On a Monday in July 2000, he met me and my parents in his office. I saw his lips moving, but I had no idea what he was saying. I was 20 years old, just starting my life. It was the worst moment of my life. I had goals I wanted to accomplish. I had only been baptized for 2 years and I was just grasping our beliefs. I wanted to study my religion, but I hadn't had a chance.

Chemotherapy shrank my tumor. They didn't say I was in remission but I felt well. I thought I could start all over. People threw parties for me.

I felt fine, but I was still sick. When I went for a checkup a year-and-a-half later, they told me my cancer had recurred. That's when my physicians sent me to Dr. Ford at the Center for Bloodless Medicine & Surgery at Pennsylvania Hospital.

She told me I needed a stem cell transplant and that it could be done with or without blood. I didn't even inquire about the blood option.

For me there is no exception to the prohibition on blood. If someone can't cure your ailment without blood, you accept the possibility of death. I have a greater hope: as recorded in the Bible I could be resurrected in a better life. That is comforting to me and I was at

ease. But of course I was scared.

Undergoing the transplant was a tough time. I got high-dose chemotherapy, I was bedridden, and all my hair fell out. I was so thin and weak I could barely talk. But as soon as I got the injection of my cells, I felt myself rejuvenate. After that, my recovery was remarkable. My sister-in-law is a nurse and knew of a patient who got someone else's blood and was in the hospital for 4 months.

I have given a lot of Jehovah's Witnesses hope. They have said, "You are a trailblazer for us." It made my heart rejoice when we heard that doctors are getting involved in bloodless care. Back in the day it was very difficult for us. There was a lot of controversy. But now, Dr. Ford tells me that a number of Jehovah's Witnesses come from out of town to see her.

I'm in remission and I feel good now, although I still am fatigued. I'm newly married, to a high school friend who was inspired by me to become one of Jehovah's Witnesses. I lost a part of my youth, but the experience has matured me. God and Jesus Christ have really helped me in my life. I preach to others door to door. My job is not to convert the world but to share Bible truths. I'm enjoying life.

I ask myself: "What are the odds of living so close to a hospital that offers bloodless care?" I pray that more doctors learn about the procedures without blood.