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Wide Variations in Blood Product Transfusion Practices among Providers Who Care for Patients with Acute Leukemia in the United States

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Abstract

Background—Transfusion of blood products is a key component of the supportive management in patients with acute leukemia (AL). However high-quality trial evidence and clinical outcome data to support specific transfusion goals for blood products for patients with AL remain limited leading to diverse transfusion practices. The primary objective of this study was to determine the spectrum of transfusion patterns in a variety of care settings among providers who treat AL patients.

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Study design and Methods—A 31-question survey queried providers caring for AL patients about the existence of institutional guidelines for transfusion of blood products, transfusion triggers for hemoglobin (Hb), platelets (PLTs), and fibrinogen in various settings including inpatient, outpatient, and before procedures.

Results—We analyzed 130 responses and identified divergent transfusion Hb goals in hospitalized and ambulatory patients, fibrinogen goals for cryoprecipitate transfusions, and variation in practice for use of certain PLTs and red blood cell products. The least variable transfusion patterns were reported for PLT goals in thrombocytopenia and in the setting of invasive procedures such as bone marrow biopsy and lumbar punctures.

Conclusions—This survey confirmed wide variations in blood product transfusion practices across several clinical scenarios in patients with AL. The findings emphasized the need for large prospective randomized trials to develop standardized evidence-based guidelines for blood product transfusions in patients with AL with the goal of limiting unnecessary transfusions without compromising outcomes.

Keywords

acute leukemia; transfusion; blood products; patterns of practice; transfusion threshold

INTRODUCTION

Remission induction therapy for acute leukemia (AL) requires intensive, cytotoxic treatments, prolonged hospitalization, and aggressive supportive care including transfusion of blood products (red blood cells [RBCs], platelets [PLTs], plasma, and cryoprecipitate). However, other than recommendations for prophylactic PLT transfusions in hospitalized patients with AL and PLT levels of less than 10×10^9/L,[1–3] variables for blood product transfusions are institution and provider dependent. Given lack of consensus, evidence-based transfusion guidelines for AL patients, we hypothesized that there would be wide variations in blood product transfusion practices for AL patients at both the individual provider and institutional levels among providers who manage patients with AL in the United States. To test this hypothesis, we designed a Web-based survey to evaluate transfusion practice patterns for AL patients in a variety of care settings.

METHODS

For this cross-sectional study, we developed a 31-question survey (Appendix S1, available as supporting information in the online version of this paper) to query health care providers caring for patients with AL. We asked about the existence of institutional guidelines for transfusion of blood products, product-specific transfusion thresholds for RBCs, PLTs and cryoprecipitate in various settings including inpatient, outpatient, and before procedures. We also queried the use of irradiated, washed, cytomegalovirus (CMV) seronegative, and leukoreduced RBCs and irradiated, washed, volume-reduced and CMV seronegative PLTs.

The survey was approved by the respective cooperative group chairs and was administered through the Web-based SurveyMonkey platform. A link to the survey was distributed via email to all members of the Eastern Cooperative Oncology Group – American College of

Radiology Imaging Network (ECOG-ACRIN) Cancer Research Group, Alliance for Clinical Trials in Oncology (Alliance), Cancer Trial Support Unit (CTSU), and Southwest Oncology Group (SWOG) by the ECOG-ACRIN Clinical Education and Awareness Team. Survey distribution occurred on July 6, 2015 and closed on August 14, 2015, after 5 weekly reminders. Responses were anonymous, and no incentives were provided to survey respondents. We excluded incomplete surveys from the analysis.

We sought to estimate the number of providers who change RBC and PLT transfusion thresholds depending on the clinical setting (discordance), and whether it was different from that of providers who keep transfusion thresholds the same across the settings (concordance). To this end we used the McNemar statistical test to compare concordance and discordance between RBC transfusion thresholds 7 g/dL and 8 g/dL, and between PLT transfusion thresholds 10×10^9/L and 20×10^9/L used by providers in different clinical settings.

RESULTS

Study Cohort

Surveys were distributed to a total of 9859 recipients including 3653 physicians, with at least 741 in direct care of patients with AL. In total, 304 unique responses were received. Of these, we excluded 138 responses as they were returned by recipients not directly treating patients with AL, and another 36 responses were excluded due to incomplete surveys. The final dataset consisted of 130 responses, 99 of which came from physicians (76%) with the remainder provided by advance practice providers, oncology nursing staff and pharmacists directly involved in care of patients with AL. There were 51 women (39%). The median age of all responders was 45 years old (range, 26-76). The respondents represented 99 institutions in 37 states (**Table 1**).

Transfusion thresholds

Approximately 85% (111) and 78% (102) of responders reported existing institutional transfusion guidelines for hospitalized and ambulatory AL patients, respectively. A hemoglobin (Hb) threshold of 7 g/dL or lower for RBC transfusions in asymptomatic stable hospitalized patients was reported by 61 respondents (47%), followed by 46 (35%) providers who used a Hb level of 8 g/dL. Conversely, in the outpatient setting, of 121 responses the most commonly chosen was the Hb threshold of 8 g/dL reported by 57 recipients (47%), followed by 7 g/dL in 37 (31%) and 7.5 g/dL in 16 (13%) responses (Table 2).

With respect to PLT transfusions, a PLT level of 10×10^9/L or lower was most commonly reported threshold for stable nonbleeding hospitalized patients (81% of responders). Other choices of 15×10^9/L, 20×10^9/L, “only if bleeding or symptomatic,” and “no specific threshold” made up the remaining 19% of responses. The PLT threshold of 10×10^9/L or lower was used by 53% of providers to guide PLT transfusions in nonbleeding ambulatory patients, with an additional 30% of respondents using a higher threshold of 20×10^9/L (Table 3). For procedures, 70% of responders considered a PLT count of 10×10^9/L and higher

adequate for performing bone marrow (BM) biopsies and a PLT level of 50×10^9/L adequate for performing lumbar punctures (LPs; Table 4).

Out of 121 responders who specified fibrinogen thresholds, nearly half reported the threshold fibrinogen level of 100 mg/dL as a trigger for administering cryoprecipitate in the following scenarios: 46% (56) for disseminated intravascular coagulation (DIC), 49% (59) in the post-asparaginase treatment setting, 51% (62) for patient with AL other than acute promyelocytic leukemia (APL) without DIC (Table 5). For patients with APL, 41% (50) of respondents used the threshold of 100 mg/dL followed by 35% (42) of providers who reported using the threshold fibrinogen level of 150 mg/dL. This threshold was used by 15% of providers (18) in DIC, 11% (13) following asparaginase treatment, and 6% (7) in patients with AL other than APL without DIC. Approximately one-fifth of responders reported having no specific fibrinogen threshold for cryoprecipitate transfusion in each case: 18% (22) in DIC, 20% (24) following asparaginase treatment, and 22% (27) in patients with AL other than APL. In the setting of hypofibrinogenemia in patients with APL, 12% of providers (15) had no specific transfusion threshold.

Modifications to platelet and red blood cell products before transfusion

Most providers reported always using leukoreduced and irradiated RBCs (93% and 75%, respectively) in the AL population. Providers reported varying patterns of using CMV-seronegative, washed blood and PLTs. Most frequently these modifications were used in “specific circumstances,” reported by 46 and 54% respondents for CMV-seronegative and washed blood, respectively (Table 6). Washed and CMV-seronegative PLTs were transfused in “specific circumstances” by 48 and 45% of providers, respectively. The remaining responses were split in similar proportions between providers who reported using CMV-seronegative and washed blood and PLTs always or sometimes and those who never used blood products with these modifications (Table 7). Single-donor apheresis PLTs were preferred by 78% respondents, and 56% used such PLTs exclusively.

Concordance and discordance of ambulatory vs in-patient transfusion patterns

Most providers used the same treatment threshold in the inpatient and outpatient settings. For RBC transfusions, responders who used the same transfusion threshold in both inpatient and ambulatory settings were considered “concordant”: 32 responders (25%) used Hb 7 g/dL or lower, while 38 responders (29%) maintained 8 g/dL in both settings. Among “discordant” providers, five responders (4%) used a higher Hb threshold in inpatient than in outpatient settings, and 27 providers (21%) used a lower threshold for hospitalized patients. The difference between the number of concordant and discordant providers was determined to be significant ($p < 0.001$). This indicates a clear preference for the lower Hb threshold in inpatient settings among those providers who take clinical settings into account. Similarly, when responders described their use of PLT thresholds, 56 of them (43%) used the threshold of 10×10^9/L in both hospitalized and ambulatory patients, while seven providers (5%) transfused at the PLT level of 20×10^9/L in both clinical settings. Thirty-nine responders (30%) reported using the threshold of 20×10^9/L in outpatient settings while using a lower one (10×10^9/L or 15×10^9/L) in hospitalized patients. Notably, two providers indicated using higher PLT threshold in hospitalized patients. Overall, the preference among providers who

take clinical settings into account was for the lower PLT thresholds in hospitalized patients ($p<0.001$).

DISCUSSION

Transfusion of blood products is a key component of the supportive management in patients with AL, especially during therapeutic myeloablation when cytotoxic effects of treatment compound disease-induced marrow dysfunction and during BM recovery. At the same time, transfusion of blood products carries risks of complications such as transfusion-associated circulatory overload[4] and lung injury,[5] febrile[6] and hemolytic reaction, and alloimmunization. Given these complications and significant cost associated with blood[7] and plasma[8] transfusions ($761 ± $294 and $410/unit, respectively), there is the need to assess the outcomes with different transfusion strategies and to develop standardized blood products transfusion guidelines for patients with AL.

Regarding Hb transfusion goals, a number of prospective randomized trials explored outcomes associated with liberal and restrictive transfusion strategies in patients without hematological or solid malignancies. Trials conducted in several clinical settings such as critical illness,[9] hip surgery,[10] upper gastrointestinal bleeding,[11] and cardiac surgery[12] showed the same or better outcomes (mortality, myocardial infarction, pulmonary edema, congestive heart failure, stroke, infection, and thromboembolism) achieved with restrictive transfusion goals.[13] However, only two studies evaluated the Hb transfusion goals for patients with AL. A small retrospective study,[14] in which 84 patients with acute myeloid leukemia received RBCs under either the restrictive or liberal transfusion strategy (mean trigger hemoglobin of 8 g/dL and 9 g/dL, respectively), revealed no differences in mortality, therapy response, cardiac complications, the rates of bleeding, and the need for PLT transfusions. Similarly, a recent small prospective pilot study,[15] in which 90 patients with AL were randomized to the restrictive (7 g/dL) and liberal (8 g/dL) transfusion arms, revealed no significant difference in bleeding events, PLT transfusions, and incidence of neutropenic fever. The patients in the restrictive arm received fewer RBC units compared to that in the liberal arm (median of 8 units vs. 10 units).

In our survey of practice, 47% of responders reported using the Hb threshold of 7 g/dL for RBC transfusions in hemodynamically stable, asymptomatic nonbleeding hospitalized patients, while the threshold of 8 g/dL was reported by 35% clinicians. Such a split may suggest that the latter group followed the evidence for the RBC transfusion trigger identified in a small retrospective study mentioned above.[14] Those who chose the more restrictive threshold might have extrapolated the evidence summarized in the AABB RBC transfusion guidelines from non-oncologic settings onto the population of patients with AL. However, in the setting of therapeutic myelosuppression and leukemia, it is unclear whether the restrictive transfusion trigger of 7 g/dL alters clinical outcomes since no large randomized trial has been conducted in this specific population. For ambulatory patients, a greater proportion of clinicians (47%) reported the trigger Hb of 8 g/dL while 31% of respondents reported the threshold of 7 g/dL. Such a pattern may be the result of the transfusion strategy, in which ambulatory patients are given blood to achieve a higher post-transfusion goal and maintain a higher Hb level between clinic visits. Convenient as this may be, such a strategy

has not been validated with respect to clinical outcomes in patients with AL. In this population, the most optimal RBC transfusion threshold remains unknown, and a randomized controlled trial to determine one in the context of mortality and complication outcomes is warranted.

Regarding PLT transfusions in patients with AL, two randomized trials supported benefits of prophylactic PLT transfusion for severe thrombocytopenia below the PLT level of 10×10^9/L in this population.[2,16] Similar studies are lacking to determine the risk of bleeding, benefits of prophylactic PLT transfusions, and PLT thresholds for patients with AL undergoing invasive procedures such as BM biopsy or LP. For such cases, observational studies conducted in patients without hematologic cancers did not show a significant reduction in bleeding risk with prophylactic PLT transfusion.[17] The most recent review of evidence summarized as guidelines from the AABB recommends prophylactic transfusion of PLT in adult patients with therapy-induced thrombocytopenia with a PLT count of 10×10^9/L or lower.[3] However, beyond the recommendation of PLT transfusion for patients undergoing elective diagnostic LP with a PLT count lower than 50×10^9/L (based on very-low-quality evidence), the AABB guidelines do not contain procedure-specific recommendations for PLT transfusions tailored to patients with AL. The results of this survey are concordant with these guidelines. Specifically, the majority of respondents favored the threshold of 50×10^9/L for LPs in all suggested scenarios.

Cryoprecipitate is used to treat leukemia patients with DIC, consumptive coagulopathy associated with APL or due to treatment with asparaginase. Randomized controlled trials that guide the use of cryoprecipitate and establish transfusion thresholds in these patients with AL are lacking, and clinicians are left to extrapolate transfusion triggers and targets established in clinical settings such as trauma[18] and surgery.[19] These guidelines provide evidence for the target level of at least 150 mg/dL.

The majority of the survey responders considered the fibrinogen level of 100 mg/dL a trigger for the transfusion of cryoprecipitate in nonbleeding patients with DIC, after the treatment with asparaginase, and in those with AL other than APL but without DIC. A large fraction of respondents reported having no thresholds for or not transfusing cryoprecipitate at all. Distinct from these patterns, the threshold for prophylactic cryoprecipitate transfusion in nonbleeding patients with APL was notably split almost equally between clinicians reporting 100 and 150 mg/dL. This highlights the heightened concern that a coexisting coagulopathy puts patients with APL at an increased risk of DIC and bleeding. Similarly, a considerable fraction of respondents reported having no specific threshold, and a few would offer no cryoprecipitate transfusion at all in APL patients.

Common to all surveys, the limited response rate of this study can restrict the generalizability of results. However, we believe that the variations in transfusion practices reported in this survey are representative of those among the population of providers who treat patients with AL at large. It is notable that this is the largest survey of provider transfusion practice patterns in the AL population conducted to date in the United States. The survey includes responses from responders practicing at every type of clinical setting

such as national comprehensive cancer centers, university-affiliated hospitals, community hospitals, and private practices representing 99 institutions in 37 states.

We chose to determine variations in transfusion patterns by leukemia providers rather than general hematologists or oncologists. In doing so, we could have underestimated the degree of such variations that exist in a larger community of providers caring for patients with AL since the former group is likely more familiar with standardized practice guidelines. Furthermore, while there might be differences in transfusion patterns between the community and academic settings, the limited sample size in our survey prohibited conduction of a meaningful analysis to address this question. This question should be evaluated in subsequent larger studies. Additionally, it is unclear how transfusion patterns of hospitalized leukemia patients between different hospital settings (e.g. intensive care units) would differ. Finally, there are other potentially important questions regarding transfusions patterns (e.g. use of plasma) that we did not address in an effort to minimize the possibility of lowering response rate to the survey by including too many questions. However, these questions should be evaluated in future studies.

In conclusion, the results of this survey confirm wide variations in blood product transfusion practices present across several clinical scenarios in patients with AL. The most divergent patterns of transfusion thresholds were reported for RBCs and cryoprecipitate, and for certain modifications applied to PLTs and RBCs. The least variation in transfusion patterns appeared in cases of PLT transfusion goals for thrombocytopenia and in the setting of invasive procedures such as BM biopsy and LPs. A PLT level of 10×10^9/L is the most common trigger for PLT transfusions for stable nonbleeding patients in both inpatient and outpatient settings. This, along with the PLT threshold of 50×10^9/L for performing an LP, appear to be most widely accepted practices. The findings of this survey emphasize the need for large prospective randomized trials to develop standardized evidence-based guidelines for blood product transfusions practices in patients with AL with the goal of avoiding unnecessary transfusions without compromising outcomes. Our findings also confirm the need for a randomized trial to determine ideal trigger thresholds for cryoprecipitate transfusion to guide transfusion practices in patients with hypofibrinogenemia associated with AL.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Characteristics of survey responders.

Characteristic	Count (%)
Gender	
Male	79 (61%)
Female	51 (39%)
Age (range, 26-76 years)	
20-29	2 (1.5%)
30-39	27 (21%)
40-49	48 (37%)
50-59	26 (20%)
60-69	21 (16%)
70-79	2 (1.5%)
Undeclared	4 (3%)
Job description	
Clinician	51 (39.2%)
Clinical Researcher	43 (33%)
Clinician/Educator	24 (18.5%)
Basic Science Researcher	3 (2.3%)
Other	9 (7%)
Years post fellowship training (N=99 MD-level responders)	
0-5	22 (22.2%)
6-10	26 (26.3%)
11-20	22 (22.2%)
21 and more	28 (28.3%)
Other	1 (1%)
Institution type (total>130 due to overlapping assignments)	
University/University-affiliated Hospital	67
Community Hospital	32
National Comprehensive Cancer Center	35
Veteran Administration	1
Private practice	14
Number of AML treated yearly (N=114 reporting responders)	
<25	36 (31.6%)
25-50	36 (31.6%)
51-100	29 (25.4%)
>100	13 (11.4%)
Number of ALL treated yearly (N=112 reporting responders)	
<25	82 (73.2%)
25-50	24 (21.4%)
51-100	6 (5.4%)
>100	0

Table 2

The most common reported hemoglobin level thresholds for red blood cell transfusions in hospitalized and ambulatory patients. Hct, hematocrit.

Threshold	Inpatient, N (%) N=130	Ambulatory, N (%) N=121
7 g/dL	61 (47%)	37 (31%)
7.5 g/dL	7 (5.4%)	16 (13%)
8 g/dL	46 (35.4%)	57 (47%)
Only if bleeding or symptomatic	4 (3%)	1 (0.8%)
Other	12 (9.2%)	10 (8.2%)
8.5 g/dL	1	1
9 g/dL	0	1
no specific threshold	5	4
Hct instead of Hb	6	4

Table 3

The most common reported platelet level thresholds for platelet transfusions in hospitalized and ambulatory patients.

Threshold	Inpatient, N (%) N=118	Ambulatory, N (%) N=116
10×10^9/L	95 (80.5%)	62 (53.4%)
15×10^9/L	7 (6%)	14 (12%)
20×10^9/L	8 (6.8%)	34 (29.3%)
Only if bleeding or symptomatic	5 (4.2%)	5 (4.3%)
No specific threshold	3 (2.5)	1 (1%)

Table 4

The reported distribution of platelet thresholds for invasive procedures. LP, lumbar puncture; BM, bone marrow; bx, biopsy; dx, diagnosis.

		Platelet threshold			
		10×10^9/L, N (%)	**20×10^9/L N (%)**	**30×10^9/L N (%)**	**50×10^9/L N (%)**
	BM bx, N=115	81 (**70.4%**)	22 (19.1%)	5 (4.4%)	7 (6.1%)
LP	**new AL dx, no circulating blasts, N=114**	3 (2.6%)	19 (16.6%)	12 (10.6%)	80 (**70.2%**)
	new AL dx with circulating blasts N=108	3 (2.8%)	16 (15%)	12 (11%)	77 (**71.2%**)
	stable leukemia in remission N=114	3 (2.6%)	17 (15%)	11 (9.6%)	83 (**72.8%**)

Table 5

The reported distribution of fibrinogen levels used as thresholds in transfusions of cryoprecipitate for hypofibrinogenemia encountered in DIC, following the treatment with L-asparaginase, non-APL leukemia, and APL leukemia. DIC, disseminated intravascular coagulation; APL, acute promyelocytic leukemia.

		APL, N=121	Acute Leukemia, N=121	Asparaginase, N=121	DIC, N=121
Fibrinogen level	**50 mg/dL**	5 (4.1%)	5 (4.1%)	8 (6.6%)	5 (4.1%)
	100 mg/dL	50 (**41.3%**)	62 (**51.2%**)	59 (**48.8%**)	56 (**46.3%**)
	150 mg/dL	42 (**34.7%**)	7 (**5.8%**)	13 (**10.7%**)	18 (**14.9%**)
	If bleeding or procedure	7 (5.8%)	16 (13.2%)	11 (9.1%)	13 (10.7%)
	No threshold	15 (12.4%)	27 (22.3%)	24 (19.8%)	22 (18.2%)
	No transfusion	2 (1.7%)	4 (3.3%)	6 (5%)	7 (5.8%)

Table 6

Reported patterns of RBC modifications. CMV, cytomegalovirus.

	Leukocyte reduced, N=126	Irradiated, N=127	CMV seronegative, N=123	Washed, N=122
Always, N (%)	117 (**93%**)	97 (**76%**)	20 (16.3%)	16 (13.1%)
Sometimes, N (%)	6 (5%)	16 (13%)	26 (21.1%)	20 (16.4%)
Never, N (%)	1 (<1%)	1 (<1%)	20 (16.3%)	20 (16.4%)
specific circumstances, N (%)	2 (<2%)	13 (10%)	57 (**46.3%**)	66 (**54.1%**)

Table 7

Reported patterns of platelets modifications. CMV, cytomegalovirus.

	Irradiated, N=116	CMV sero-negative, N=113	Washed, N=111	Volume-reduced, N=111
Always, N (%)	80 (69%)	14 (12.4%)	10 (9%)	8 (7.2%)
Sometimes, N (%)	16 (13.8%)	25 (22.1%)	17 (15.3%)	16 (14.4%)
Never, N (%)	8 (6.9%)	23 (20.4%)	31 (28%)	48 (43.2%)
Specific Circum-stances, N (%)	12 (10.3%)	51 (45.1%)	53 (47.7%)	39 (35.1%)
No answer	14	17	19	19