



GIIMO
Gruppo Italiano Interdisciplinare
Manipolazione e Aferesi per Terapie Cellulari

GIIMA
Gruppo Italiano Interdisciplinare
Manipolazione e Aferesi per Terapie Cellulari

SidEM
Società Italiana di Ematologia e Medicina
Trasfusionale

VI Congresso Nazionale

V ASSEMBLEA ASSOCIATIVA GIIMA

29 NOVEMBRE 2019 ROMA
BETTOJA HOTEL MASSIMO D'AZEGLIO

Welcome coffee

09.45: Apertura del Congresso **Lanza F.**

Sessione I
CAR-T: Aspetti regolatori, metodologici, clinico-assistenziali
Moderatori: Saccardi R. - Bacigalupo A.

10.00: Aspetti regolatori: normativa JACIE - **Saccardi R.**
10.20: Sviluppi metodologici - **Tassi E.**
10.40: Sistemi di produzione: generazioni CAR-T e applicazioni nei tumori solidi - **Guidoboni M.**
11.00: Aspetti trasfusionali e standardizzazione della raccolta dei linfociti finalizzati alla produzione di CAR-T **Ruggeri A.**
11.20: Applicazioni cliniche - **Avenoso D.**
11.40: Aspetti assistenziali infermieristici - **Renzi F.**

Sessione II
dalla parte del paziente
Moderatore: Rigacci L.

12.30: L'esperienza del percorso di cura all'interno di un programma trapianto. L'attesa del donatore
Viola M. - Spadoni S.
13.00: Lunch

Sessione III
Gli studi GIIMA in collaborazione con GITMO - SIDEM
Moderatori: Ostuni A. - Martino M.

14.30: Manipolazione delle PBSC (survey GITMO/SIDEM): **Lanza F.**
15.00: Risultati della survey GITMO - GIIMA - SIDEM su approcci per LAF - ECP - **Calme A.**
15.20: Valore predittivo nella mobilitazione del donatore allogenico delle CD34+ basali: risultati e proposta di studio multicentrico - **Martino M. - Gori M.**

Sessione IV
Novità in tema di mobilitazione, raccolta e manipolazione di cellule staminali
Moderatori: Lanza F. - Agostini V.

15.40: Ottimizzazione del percorso di mobilitazione e aferesi - **Milone G.**
16.00: Mobilitazione: modelli di farmaco economia **Lazzaro C.**
16.20: Standardizzazione del prodotto leucoferetico dal punto di vista tecnico - **Pierelli L.**
16.40: Modelli organizzativi Lab Processazione **Agostini V.**
17.00: Conclusioni e compilazione ECM

Comitato Scientifico
Francesco Lanza
Vanessa Agostini
Chiara Bonini
Alessandro Calme
Massimo Guidoboni
Paolo Longoni
Massimo Martinelli
Cristina Reborello
Riccardo Saccardi
Luca Scornato
Silvia Spadoni

Informazioni
L'evento è stato accreditato al Ministero della Salute con il n. 2773-274415 ed ha ottenuto n. 7 crediti ECM per:
Medici di Area Interdisciplinare
Biologi
Tecnici Sanitari di Laboratorio Biomedico
Infermieri
Soci GIIMA Quota gratuita
Non Soci € 40,00
Possibilità di iscrizione all'Associazione GIIMA in sede congressuale € 20,00 quota associativa, informazioni: www.giima.it

Segreteria Organizzativa
Proeventi
PROVIDER N.2773
Info: info@proeventi.it
www.proeventi.it

Valore predittivo nella mobilitazione del donatore allogenico delle CD34+ basali: risultati e proposta di studio multicentrico

Massimo Martino M.D.

Identification of hematopoietic progenitor cell donor characteristics predicting successful mobilization: results of an Italian multicenter study

*Giambattista Bertani,¹ Luca Santoleri,¹ Massimo Martino,² Roberta Fedele,² Tiziana Moscato,²
Paola Marengo,³ Giovanni Grillo,³ Elisa Zucchetti,³ Ivana Lotesoriere,³ Giuliana Lando,¹
Clara Cesana,¹ Roberto Cairoli,⁴ and Silvano Rossini¹*

BACKGROUND: Peripheral blood (PB) hematopoietic progenitor cells (HPC) collected by apheresis are the first-choice source for allogeneic stem cell transplantation. The target HPC dose is usually considered to be 4×10^6 CD34+ cells/kg of the recipient, but higher doses are required in reduced-intensity conditioning and haploidentical transplants. Thus, prolonged stimulation and repeated collections or failure to reach HPC target may occur, increasing risks for donors and recipients. We carried out a retrospective multicenter study on healthy donors, to identify donor variables which may correlate with HPC mobilization.

STUDY DESIGN AND METHODS: HPC allogeneic donations from sibling and unrelated donors performed in two centers from 1995 to 2012 were analyzed. We defined a mobilization cutoff of 50×10^6 CD34+ cells/L and tested somatic variables, blood counts, and granulocyte-colony-stimulating factor (G-CSF) dose and molecular form.

RESULTS: A total of 360 donors were analyzed (male, 201; female, 159; sibling, 348; unrelated, 12; median [range] age, 44.8 [13-80] years). Median peak CD34+ in PB was $54.4 \times 10^6/L$ (range, 5×10^6 - 299×10^6). By multivariate analysis, we identified the following variables to correlate with good mobilization: 1) male sex ($p < 0.0005$); 2) younger age ($p = 0.007$); 3) higher baseline (premobilization) white blood cell (WBC) count ($p < 0.0005$); 4) higher G-CSF dosage ($p < 0.0005$); and 5) use of lenograstim rather than filgrastim ($p < 0.002$).

TABLE 1. Donor characteristics*

Physical variables	
Related/unrelated	348/12
Age (years)	44.8 (13-80)
Sex, male/female	201/159
Body weight (kg)	72 (44-135)
BMI	24.8 (16.2-47)
Blood cell counts (before G-CSF)	
Hb (g/dL)	14.3 (10-17)
WBC count ($\times 10^9/L$)	6.5 (3.1-14)
PLT count ($\times 10^9/L$)	231 (90-478)
Mobilization variables	
G-CSF form, lenograstim/filgrastim/ missing data	266/41/53
G-CSF dose ($\mu g/kg$)	9.86 (5.1-16.4)

* Data are reported as number or median (range).

TABLE 2. Effect of the considered variables on the odds of achieving a good mobilization

Variable	OR	SE	p value	95% CI
Male sex	2.51	0.64	0.0005	1.52-4.15
Age*	0.97	0.01	0.007	0.96-0.99
WBC count†	1.19	0.10	0.030	1.02-1.40
G-CSF dose‡	1.34	0.10	0.0005	1.15-1.56

* 1-year increase.

† $1 \times 10^9/L$ increase.

‡ $1 \mu g/kg$ increase.

TABLE 3. Results of multivariate analysis of use of lenograstim versus filgrastim as growth factor in addition to the four variables age, sex, WBC count, and G-CSF dose

Variable	OR	SE	p value	95% CI
Male sex	2.49	0.64	0.0005	1.50-4.15
Age*	0.97	0.01	0.005	0.95-0.99
WBC count†	1.21	0.10	0.019	1.03-1.43
G-CSF dose‡	1.34	0.11	0.0005	1.15-1.56
G-CSF type (lenograstim)	2.38	0.69	0.002	1.36-4.19

* 1-year increase.

† $1 \times 10^9/L$ increase.

‡ $1 \mu g/kg$ increase.

Basal CD34⁺ cell count predicts peripheral blood progenitor cell mobilization and collection in healthy donors after administration of granulocyte colony-stimulating factor

We analyzed factors predicting CD34⁺ cell mobilization and collection after granulocyte colony-stimulating factor (G-CSF) administration in 47 healthy donors. Basal CD34⁺ cell count and sex were the two variables that significantly predicted a better CD34⁺ cell mobilization, and greater age was the only variable associated with lower CD34⁺ cell yields.

haematologica 2004; 89:1530-1532

(<http://www.haematologica.org/2004/12/1530>)

Javier de la Rubia, José I. Lorenzo, Marta Torrabadella,
Pedro Marín, Andrés Insunza, Miguel A. Sanz
Spanish Group of Allogeneic Peripheral Blood Stem Cell
Transplantation, Hospital La Fe, Valencia, Spain

Table 1. Donors' characteristics.

	No.	Median (range)
Age (years)		44 (4-74)
Sex		
Male/female	22/25	
Baseline CBC		
WBC ($\times 10^9/L$)		6.3 (4.3-17.2)
Hb (g/dL)		14.1 (10.2-17.6)
Platelets ($\times 10^9/L$)		248 (134-359)
Baseline CD34 ⁺ (cells/ μL)		2.25 (0.34-7.12)
G-CSF		
Dose ($\mu g/kg$)		12 (10-22)
Days		4 (4-6)
$\leq 12 / > 12$ ($\mu g/kg/day$)	26/21	
Body weight (kg)		66.5 (22-110)
Apheresis		1 (1-2)
Blood volume processed (L)		12.3 (4.39-31.68)
Required CVA	4	

CBC: complete blood count; WBC: white blood cell count;
CVA: central venous access

Table 2. Factors affecting PBPC mobilization.

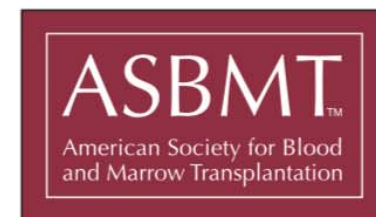
Univariate analysis		
Variable	r	p
Baseline CD34 ⁺ cell count	0.30	0.04
Sex	0.23	0.11
Age	-0.27	0.06
Weight	0.08	0.58
Baseline WBC count	0.29	0.05
G-CSF dose	0.09	0.55
G-CSF ≤ 12 vs. > 12 $\mu g/kg/day$	0.13	0.38
Multivariate analysis		
Baseline CD34 ⁺ cell count	0.4	0.012
Sex	0.3	0.03

*Data available in 42 donors.



Biology of Blood and Marrow Transplantation

journal homepage: www.bbmt.org



Basal CD34⁺ Cell Count Predicts Peripheral Blood Stem Cell Mobilization in Healthy Donors after Administration of Granulocyte Colony–Stimulating Factor: A Longitudinal, Prospective, Observational, Single-Center, Cohort Study



Massimo Martino ^{1,*}, Mercedes Gori ², Annalisa Pitino ², Massimo Gentile ³, Antonia Dattola ¹, Antonella Pontari ¹, Ernesto Vigna ³, Tiziana Moscato ¹, Anna Grazia Recchia ⁴, Santina Barilla' ¹, Giovanni Tripepi ⁵, Fortunato Morabito ^{3,4}

¹ Hematology and Stem Cell Transplant Unit, Department of Hemato-Oncology and Radiotherapy, Grande Ospedale Metropolitano Bianchi-Melacrino-Morelli, Reggio Calabria, Italy

² Institute of Clinical Physiology (IFC-CNR), Rome, Italy

³ Hematology Unit, Department of Hemato-Oncology, Ospedale Annunziata, Cosenza, Italy

⁴ Unità di Ricerca Biotecnologica (URB), Aprigliano ASP Cosenza, Italy

⁵ CNR-IFC Research Unit of Reggio Calabria, Reggio Calabria, Italy

Article history:
Received 24 January 2017
Accepted 20 March 2017

Key Words:
Stem cell transplantation
Healthy donors
CD34⁺
Stem cell mobilization
Granulocyte colony-
stimulating factor

ABSTRACT

A longitudinal, prospective, observational, single-center, cohort study on healthy donors (HDs) was designed to identify predictors of CD34⁺ cells on day 5 with emphasis on the predictive value of the basal CD34⁺ cell count. As potential predictors of mobilization, age, sex, body weight, height, blood volume as well as white blood cell count, peripheral blood (PB) mononuclear cells, platelet count, hematocrit, and hemoglobin levels were considered. Two different evaluations of CD34⁺ cell counts were determined for each donor: baseline (before granulocyte colony-stimulating factor [G-CSF] administration) and in PB after G-CSF administration on the morning of the fifth day (day 5). A total of 128 consecutive HDs (66 males) with a median age of 43 years were enrolled. CD34⁺ levels on day 5 displayed a non-normal distribution, with a median value of 75.5 cells/ μ L. To account for the non-normal distribution of the dependent variable, a quantile regression analysis to predict CD34⁺ on day 5 using the baseline value of CD34⁺ as the key predictor was performed. On crude analysis, a baseline value of CD34⁺ ranging from .5 cells/ μ L to 1 cells/ μ L predicts a median value of 50 cells/ μ L on day 5; a value of 2 cells/ μ L predicts a median value of 70.7 cells/ μ L; a value of 3 cells/ μ L to 4 cells/ μ L predicts a median value of 91.3 cells/ μ L, and a value ≥ 5 predicts a median value of 112 cells/ μ L. In conclusion, the baseline PB CD34⁺ cell count correlates with the effectiveness of allogeneic PB stem cell mobilization and could be useful to plan the collection.

© 2017 American Society for Blood and Marrow Transplantation.

Donors' Characteristics Stratified by Median Values of CD34 at Day Five

Characteristic	Overall	Below Median	Above Median	P Value*
Sex, % males	51.56	48.44	54.69	
Age, yr	43.24 (34.77-53.96)	46 (34.69-56.34)	42.68 (35.23-51.97)	
BW, kg	72.5 (62-82)	68 (56-80)	75 (63-84.5)	.02
Height, m	1.69 (1.61-1.78)	1.68 (1.6-1.75)	1.7 (1.65-1.78)	
BV, L	5 (4.30-5.70)	4.80 (3.93-5.60)	5.23 (4.40-5.95)	.03
Basal WBC, $\times 10^9$ /L	6.71 (5.53-7.6)	6.48 (5.43-7.28)	6.82 (5.71-7.69)	
PBMCs, %	40 (35-42)	40 (35-42)	40 (35-42.85)	
Basal Hb, g/dL	14.25 (13.05-15.05)	13.9 (13-15)	14.45 (13.3-15.2)	
Basal HCT, %	42 (39.45-44.2)	42 (39.25-44.1)	42.65 (39.7-44.6)	
Basal platelet count, $\times 10^9$ /L	231.5 (203.5-257)	222.5 (199.5-251)	234 (211.5-263.5)	
Basal CD34 ⁺ levels, cells/ μ L	2 (2-4)	2 (1-3)	3 (2-4.5)	<.001

Data are median and interquartile range and percent frequency for gender only.

PBMC indicates peripheral blood mononuclear cells; Hb, hemoglobin; HCT, hematocrit.

* P value: chi square test for gender and U-Mann-Whitney for all other variables. Only significant differences were reported.

M. Martino et al. / Biol Blood Marrow Transplant 23 (2017) 1215–1220

Table 2
Univariate Analysis of Factors Affecting CD34⁺ Mobilization on Day Five after G-CSF administration

Factor	Quantile Regression					
	I Quantile (25%)		II Quantile (50%)		III Quantile (75%)	
	Slope	P	Slope	P	Slope	P
Sex: female versus male	-7	.51	-6	.59	-9	.59
Age, yr	-.2	.50	-.1	.80	.2	.80
BW, kg	.3	.50	.5	.10	1.2	.10
Height, cm	.8	.20	1.0	.20	1.5	.20
BV, L	4.0	.40	7.0	.10	15.0	.10
Basal WBC, × 10 ⁹ /L	4.0	.10	3.3	.30	2.5	.70
PBMCs, %	.3	.70	.20	.90	.4	.80
Basal Hb, g/dL	4.5	.10	4.0	.30	2.4	.60
Basal HCT, %	1.3	.30	.20	.90	1.3	.60
Basal platelet count, × 10 ⁹ /L	.1	.50	.0	.80	.2	.30
Basal CD34 ⁺ levels, cells/μL	10.5	<.001	13.7	<.001	19.6	<.001

Table 3
Multivariate Analysis of Basal CD34⁺ Levels and CD34⁺ Mobilization Levels on Day Five after G-CSF Administration*

	Quantile Regressions		
	.25	.50	.75
Slope	9.38	12.2	20.95
95% CI	(2.78-15.98)	(5.67-18.72)	(10.39-31.51)
P	<.001	<.001	<.001

CI indicates confidence interval.

* Model adjusted by age, sex, and blood volume.

Table 4
Multivariate Analysis of Basal CD34⁺ Levels and CD34⁺ Mobilization Levels on Day Five after G-CSF Administration*

	Quantile Regressions		
	.25	.50	.75
Slope	11.01	12.20	21.15
95% CI	(3.35-18.67)	(6.45-17.95)	(10.95-31.35)
P	.005	.000	.000

* Model adjusted by age, sex, and body weight.

Table 5
Multivariate Analysis of Baseline CD34⁺ as Predictor of Total CD34⁺/kg cell Dose Collected on Day Five

	Baseline CD34 ⁺		
	2 versus ≤ 1 (10 ⁶)	3-4 versus ≤ 1 (10 ⁶)	≥ 5 versus ≤ 1 (10 ⁶)
Logistic regression			
Dependent variable: total CD34 ⁺ /kg cell dose collected on day 5 (0: < 4; 1 ≥ 4)			
Odds ratio	2.640	5.320	6.500
95% CI	(.97-7.23)	(1.80-15.71)	(1.46-28.92)
P	.060	.002	.014
Linear regression			
Dependent variable: total CD34 ⁺ /kg cell dose collected on day 5			
Slope	.804	2.077	2.791
95% CI	(-.64-2.25)	(.64-3.51)	(.99-4.59)
P	.272	.005	.003

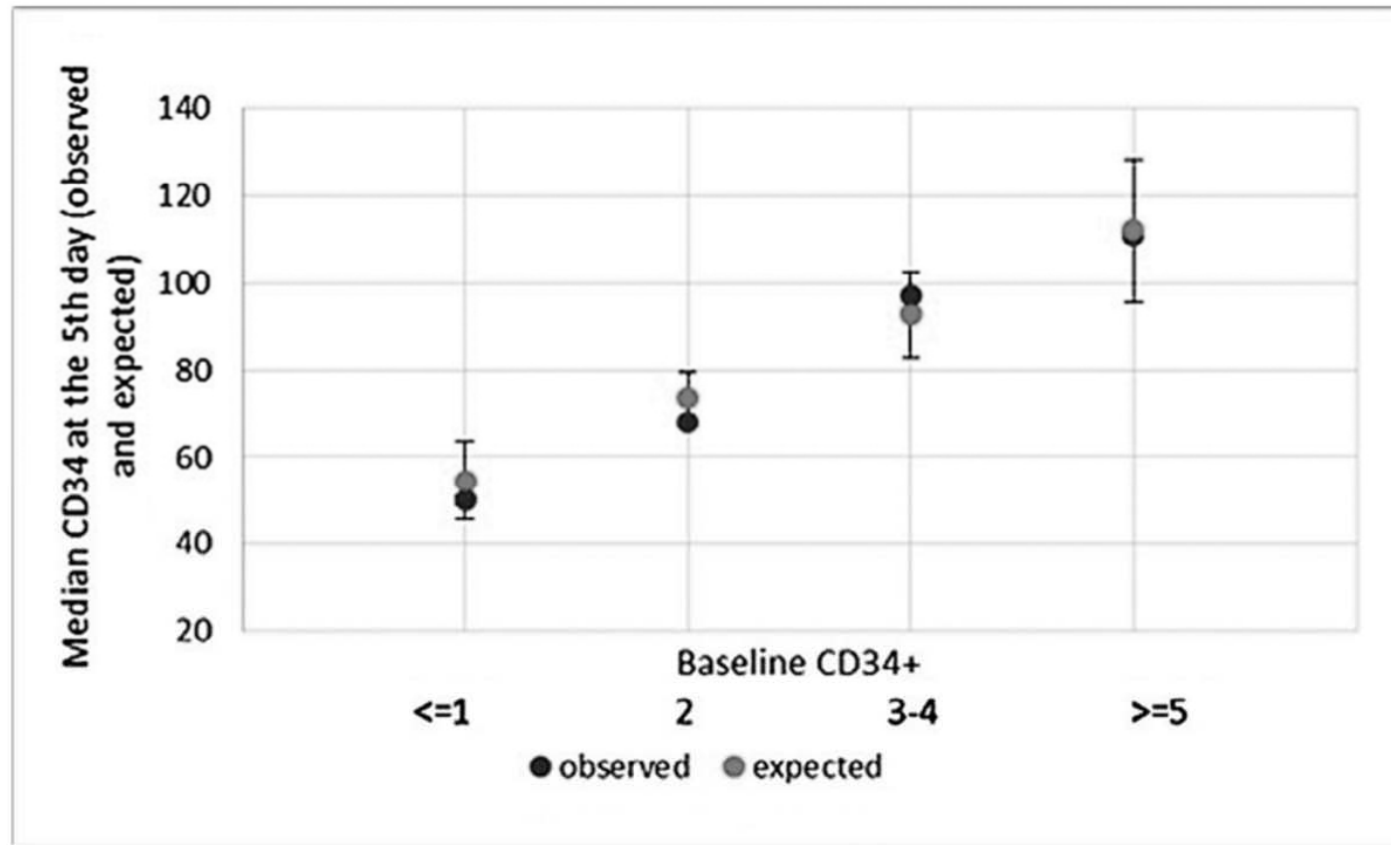


Figure 2. Scatter plot of observed and predicted median values of CD34⁺ on day 5 (with 95% confidence interval on model data) on baseline CD34⁺ model adjusted by age gender and blood volume (CD34⁺ cell counts/ μ L).

Harvesting peripheral blood progenitor cells from healthy donors with a short course of recombinant human granulocyte-colony-stimulating factor

M. Martino, F. Morabito, I. Callea, A. Pontari, G. Irrera, G. Pucci, A. Dattola, G. Messina, G. Console and P. Iacopino *The Bone Marrow Transplantation Unit, Azienda Ospedaliera 'Bianchi-Melacrino-Morelli', Reggio Calabria, Italy*

Table 4. Comparison of collected cell counts harvested on days 4 and 5

	Group I (day 4)	Group II (day 5)	<i>P</i> -value
Number of donors	68	31	
Age (years)*	41 (18–62)	46 (16–63)	0.315
Gender (male/female)	40/28	15/16	0.386
Donor weight (kg)*	74.5 (47–119)	65 (48–105)	0.129
Recipient weight (kg)*	73 (45–103)	65 (40–100)	0.152
CD34 ⁺ cells per µL blood*	35.6 (3.1–185)	44.5 (24.8–198)	0.006
Leukocytes (× 10 ⁹ L ⁻¹)*	40.3 (20–70.9)	43.3 (23.4–76.3)	0.356
CD34 ⁺ cell dose collected (× 10 ⁶)*	283 (78.5–1240)	435.6 (120–1064)	0.060
CD34 ⁺ cell dose collected × 10 ⁶ kg ⁻¹ donor*	4 (1.3–17.5)	6.4 (1.7–17.7)	0.007
CD34 ⁺ cell dose collected × 10 ⁶ kg ⁻¹ recipient*	4.2 (1–17.4)	6.1 (1.9–16.4)	0.025
Volume of processing (L)*	15 (9–21.1)	13.5 (10.4–18)	0.286
Number of donors who collected a CD34 ⁺ cell dose ≥4 × 10 ⁶ kg ⁻¹ with the first aphaeresis	36 (53%)	24 (77.4%)	
Number of leukapheresis/donor			
1	36 (53%)	24 (77.4%)	
2	31 (45.5%)	6 (19.3%)	
3	1 (1.5%)	1 (3.3%)	

*Values expressed as median with range.

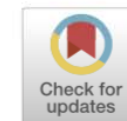


Biology of Blood and Marrow Transplantation

journal homepage: www.bbmt.org



Challenge to Predict Mobilized Peripheral Blood Stem Cells on the Fourth Day of Granulocyte Colony-Stimulating Factor Treatment in Healthy Donors: Predictive Value of Basal CD34⁺ Cell and Platelet Counts



Massimo Martino^{1,*}, Mercedes Gori², Tiziana Moscato¹, Virginia Naso¹, Anna Ferreri¹, Fabio Provenzano¹, Barbara Loteta¹, Maria Cristina Sanguedolce³, Giuseppe Console¹, Antonia Dattola³, Giulia Pucci³, Massimo Gentile⁴, Antonella Morabito⁵, Anna Grazia Recchia⁶, Giovanni Tripepi⁷, Annalisa Pitino²

ABSTRACT

A longitudinal, prospective, observational, single-center cohort study on healthy donors was designed to identify predictors of CD34⁺ cell mobilization on day 4 after granulocyte colony-stimulating factor (G-CSF) administration. As potential predictors of mobilization, age, sex, body weight, height, blood volume, WBC count, peripheral blood (PB) mononuclear cell count, platelet (Plt) count, and hematocrit and hemoglobin levels were considered. Two different evaluations of CD34⁺ cell counts were determined for each donor: baseline (before G-CSF administration) and in PB on day 4 after G-CSF administration. One hundred twenty-two consecutive healthy donors with a median age of 47.5 years were enrolled. The median value of CD34⁺ on day 4 was 43 cells/ μ L (interquartile range, 23 to 68), and 81.1% of donors had ≥ 20 cells/ μ L. Basal WBC count, Plt count, and CD34⁺ were significantly higher for the subjects with CD34⁺ levels over median values on day 4. A multivariate quartile regression analysis, adjusted by sex, age, basal CD34⁺, and basal Plt count, showed a progressively stronger relationship between baseline CD34⁺ and Plt levels and the CD34⁺ levels on day 4. The basal CD34⁺ cut-off level to predict the levels of CD34⁺ on day 4 was either ≤ 2 cells/ μ L or ≥ 3 cells/ μ L and that of basal Plt count was $\leq 229 \times 10^9/L$ or $\geq 230 \times 10^9/L$, respectively, to determine whether mobilization therapy should or should not be attempted. PB stem cell mobilization with G-CSF was highly effective on day 4, and herein we describe a model for predicting the probability of performing PB stem cell collection after a short course of G-CSF.

© 2019 American Society for Blood and Marrow Transplantation.

Donor Characteristics Stratified by CD34⁺ Median Values on Day 4

	All	CD34 at Day 4		P
		Below Median	Above Median	
Sex, % men	54.9	54.1	55.7	.86
Age, yr	47.5 (36-55)	52 (36-57)	43 (35-52)	.15
Weight, kg	72.5 (60-82)	71 (60-80)	75 (62-82)	.43
Height, m	1.7 (1.6-1.8)	1.7 (1.6-1.8)	1.7 (1.6-1.7)	.72
BV, L	5 (4.2-5.7)	4.9 (4.2-5.6)	5.2 (4.3-5.7)	.49
Baseline WBC count, $\times 10^9/L$	6.7 (5.4-7.6)	6.1 (5.4-7.1)	7 (6-8.1)	.005
Baseline hemoglobin, g/dL	14.2 (13.2-15.1)	14 (13-14.9)	14.6 (13.3-15.3)	.17
Baseline HCT, %	42.1 (39.4-44.8)	42 (39-44.2)	42.4 (40.2-45)	.55
Baseline platelets, $\times 10^9/L$	230 (202-257)	210 (190-234)	245 (221-271)	<.001
Baseline CD34 ⁺ , cells/ μ L	2 (2-4)	2 (1-3)	3 (2-4)	<.001

Values are expressed in median (range). HCT indicate the hematocrit.

Table 2

Multivariate Analysis of Basal CD34⁺ and Plt Levels Based on CD34⁺ Mobilization Levels on Day 4 after G-CSF Administration*

Quantile regression			
	.25	.50	.75
Dependent variable: total CD34⁺/kg cell count on day 4			
Basal CD34⁺ levels	1.1	6.6	9.8
95% confidence interval	−6.2 to 10.3	1.2-12.12	1.9-17.7
<i>P</i>	.57	.02	.01
Basal Plt levels	.2	.2	.3
95% confidence interval	.1-.3	.1-.3	.1-.4
<i>P</i>	.00	.00	.01

Data are regression coefficients, 95% confidence intervals, and *P* values. Each regression coefficient indicates the increase for each quantile of total CD34⁺/kg cell count on day 4 for each unitary increase in basal CD34⁺ and Plt levels (see Statistical Analysis for further details).

* Model adjusted by age and sex

both basal CD34⁺ and basal Plt counts significantly predicted (*P* = .00 for both variables) the study outcome.

Table 3

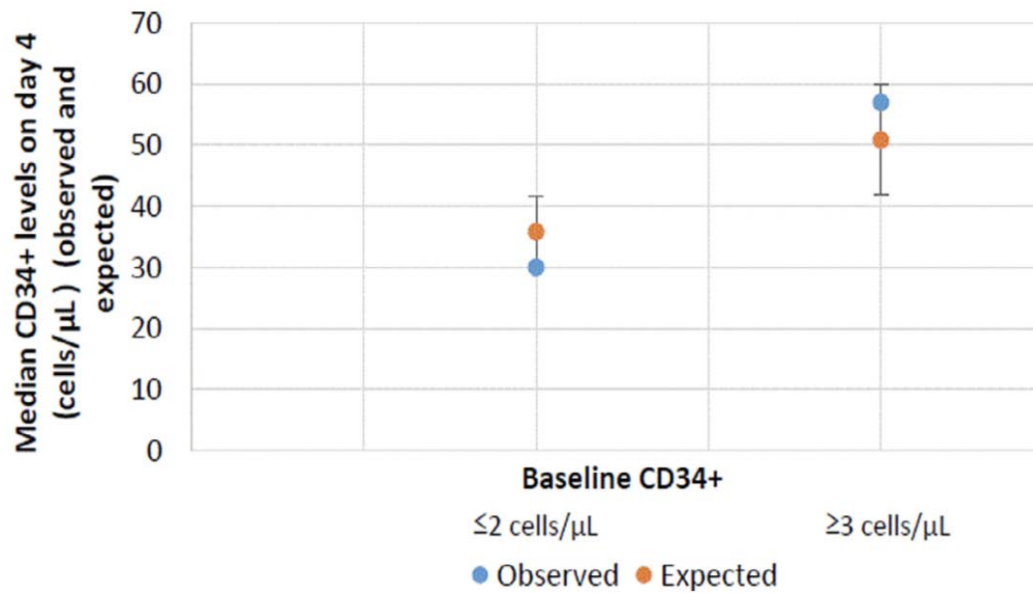
Multivariate Analysis of Basal CD34⁺ and WBC Count Levels based on CD34⁺ Mobilization Levels on Day 4 after G-CSF Administration*

Quantile Regression			
	.25	.50	.75
Dependent variable: total CD34⁺/kg cell count on day 4			
Basal CD34⁺ levels	.5	7.6	8.9
95% confidence interval	−6.2 to 7.2	3.7-11.4	2.0-15.8
<i>P</i>	.82	.00	.01
Basal WBC count levels	4.8	5.0	7.1
95% confidence interval	.0-9.4	−.4 to 10.4	2.2-12.6
<i>P</i>	.05	.07	.00

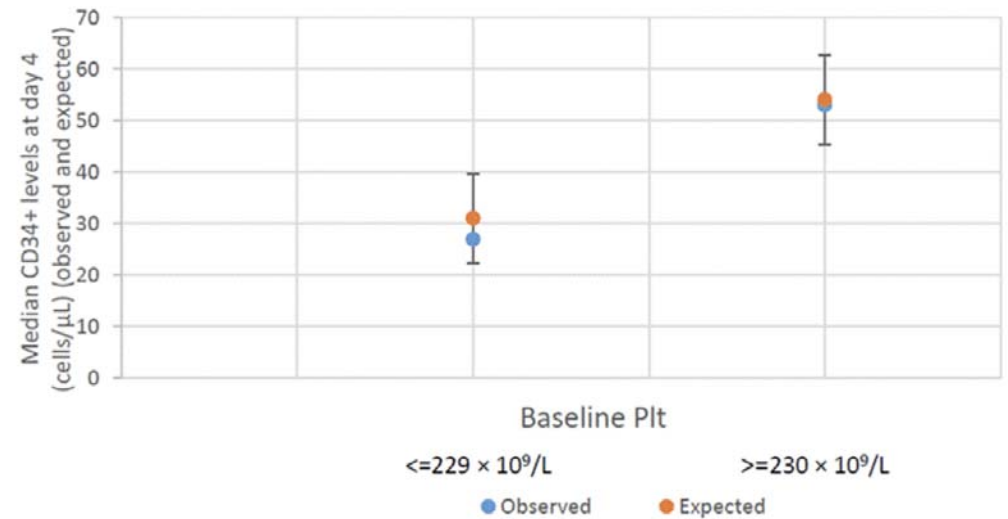
Each regression coefficient indicates how much increases in different quantiles the dependent variable (total CD34⁺/kg cell count on day 4) for each unitary increase in basal CD34⁺ and WBC levels (see Statistical Analysis for more detail).

* Model adjusted by age and sex.

An age- and sex-adjusted multivariate quartile regression analysis, including WBC count instead of Plt counts as a predictor, did not provide statistically significant results (*P* = .07) for median quantile values



Scatter plot of observed and predicted median values of CD34+ levels on day 4 (with 95% confidence intervals on model data) of the baseline CD34+ level (≤ 2 versus ≥ 3 cells/mL) adjusted by age, sex, and baseline Plt levels.



Scatter plot of observed and predicted median values of CD34+ cell counts on day 4 (with 95% confidence levels on model data) and basal Plt levels (≤ 229 versus ≥ 230 $\times 10^9/L$) adjusted by age, sex, and baseline CD34+ levels (cells/mL).

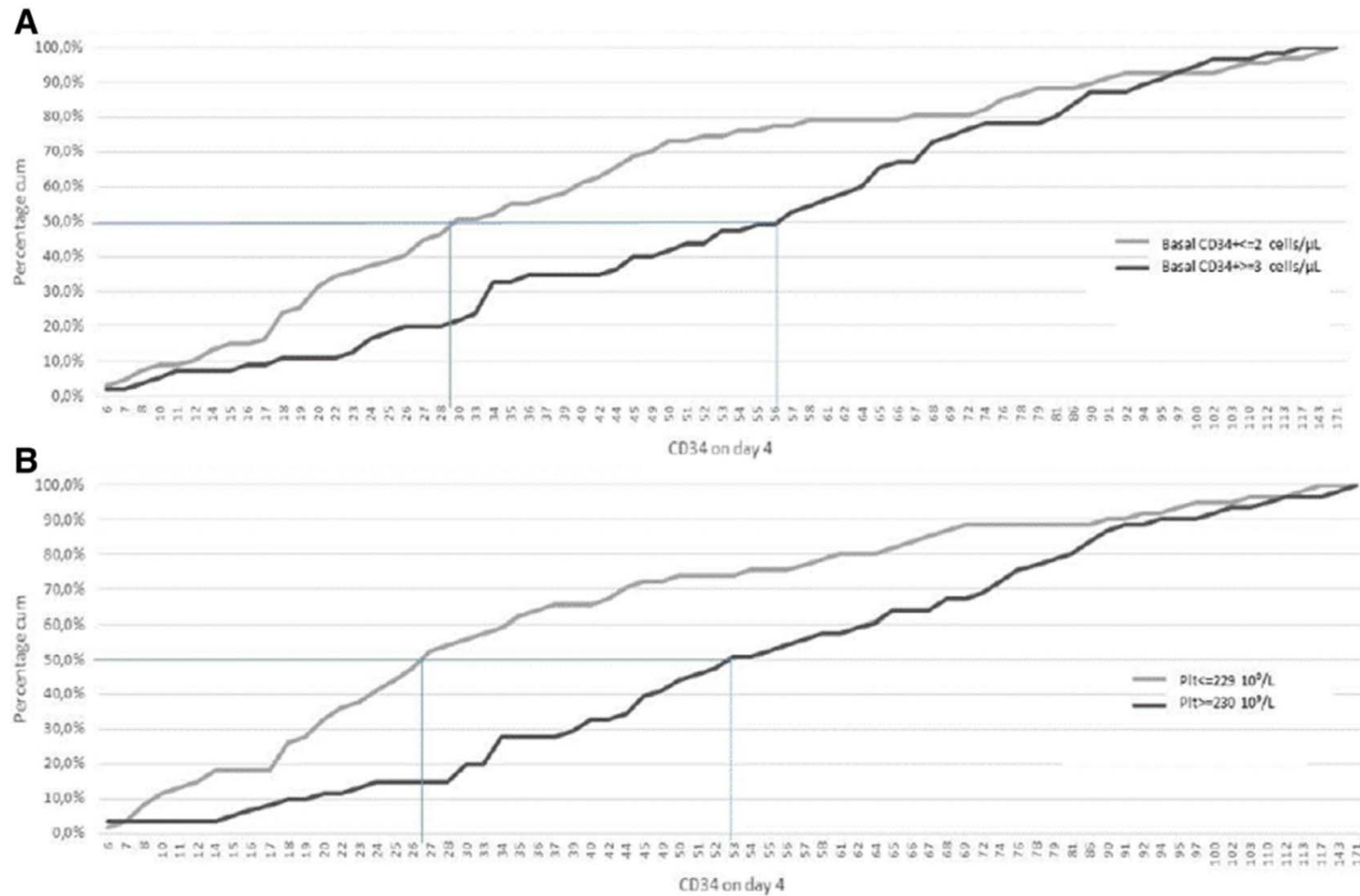


Figure 3. Cumulative distribution of CD34⁺ levels on day 4 based on baseline CD34⁺ (A) and platelets (B) categories.