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Retrospective Analysis of 37,287 Observation Years after Peripheral Blood Stem Cell Donation



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A B S T R A C T

Donor safety is of utmost importance in the setting of hematopoietic stem cell donation. Follow-up is indicated to detect potential long-term risks for donors. We sent a follow-up questionnaire to 15,445 donors of peripheral blood stem cells (PBSCs) or bone marrow (BM) within a retrospective study design. The return rate was 91.3%, resulting in 37,287 observation years for PBSC donors and 25,656 for BM donors. Most donors assessed their health conditions as very good or good and had not been hospitalized or received long-term medical treatment including prescribed medication for more than 4 weeks since donation. Although there were no differences in the frequency of reported health events, BM donors more often rated their general health as very good or good. Ninety-five percent of donors after BM or PBSC donation would consider a second stem cell donation. In total, 93 malignancies were reported. The standardized incidence ratio (SIR) for a diagnosis of any type of cancer after PBSC donation was .94 (95% CI, .70 to 1.24) with a SIR below 1 indicating a lower risk than in the age- and sex-matched population. The SIR for a diagnosis of leukemia was 0 (95% CI, 0 to 1.88). In summary, we found no evidence that either PBSC or BM donation are associated with increased risks of malignancies or other severe health problems.

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INTRODUCTION

Allogeneic stem cell donors undergo either bone marrow (BM) harvest in general anesthesia or leukapheresis after mobilization of hematopoietic stem cells with recombinant human granulocyte colony-stimulating factor (rhG-CSF). Although both procedures are regarded as safe [1–6], it is a common understanding that there is a need for long-term follow-up of large donor cohorts to identify and further minimize potential risks for donors [2,7–9].

Long-term donor follow-up is of special relevance for peripheral blood stem cell (PBSC) donors as concern was raised, based on experimental results [10] or clinical data [11], regarding potential correlations between short-term rhG-CSF application and the development of hematologic malignancies. Increased incidences of very rare events are difficult to prove for methodologic reasons [12].

From March 1992 to January 2009, 16,270 stem cell donations of 15,531 donors from DKMS Germany had been carried out, of which 11,540 were PBSC and 4730 were BM donations. Single-center results of DKMS' prospective PBSC donor follow-up have been published before [4]. A small but statistically significant lower absolute neutrophil count within the normal range was observed after the follow-up period of 5 years in that study. Four hematologic malignancies among 12 total cancer diagnoses had been observed: 1 acute myeloid leukemia case, 1 chronic lymphatic leukemia (CLL) case, and 2 cases of Hodgkin lymphoma. Statistically, the incidence of Hodgkin lymphoma differed significantly from the age- and gender-adjusted German population.

In this work we present analyses based on a retrospective follow-up project that included the mailing of questionnaires to all DKMS donors who had donated PBSCs or BM from March 1992 to January 2009 and telephone-based interviews of initial nonresponders. In our analyses we especially focused on malignancies, autoimmune disorders, and mental and psychosocial disorders. Malignancies were considered because of the discussion regarding potential long-

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Table 1
Number of PBSC and BM Donors from DKMS Germany Between March 1992 and January 2009

	Absolute Number
PBSC donors	10,863
1 donation	10,522
2 donations	341
BM donors	4337
1 donation	4279
2 donations	58
PBSC + BM donors	331
1 PBSC + 1 BM	322
2 PBSC + 1 BM	5
1 PBSC + 2 BM	4
Total donors	15,531

term risks of rhG-CSF application [10,11]. There is evidence that autoimmune disorders may be induced or boosted by rhG-CSF application [13,14]. Positive psychosocial effects of stem cell donation have been described [15]. There is,

however, also potential for negative emotional stress, for example, in the case of patient death after hematopoietic stem cell transplantation [16].

METHODS

Donations

An overview of all donations by donors from DKMS Germany between March 1992 and January 2009 is given in Table 1. Generally, DKMS' respective policy sets a limit of 2 PBSC plus 2 BM donations per donor. It follows from Table 1 that nearly all donors donated once (95.3%) or twice (4.6%).

The standard mobilization protocol for PBSC donation consisted of daily doses of 7.5 µg/kg lenograstim for 5 to 6 days. In few cases, daily doses of 10 µg/kg filgrastim or single doses of 12 mg PEG-filgrastim [17] were applied. BM harvest was carried out under general anesthesia.

Follow-Up Data

Follow-up questionnaires were sent out from December 2008 to February 2009 to all DKMS donors who had donated PBSCs or BM between March 1992 and January 2009. Only exceptions were known cases of death ($n = 20$) and donors who previously had asked not to be contacted again or were not contactable for other reasons as, for example, emigration ($n = 66$). In total,

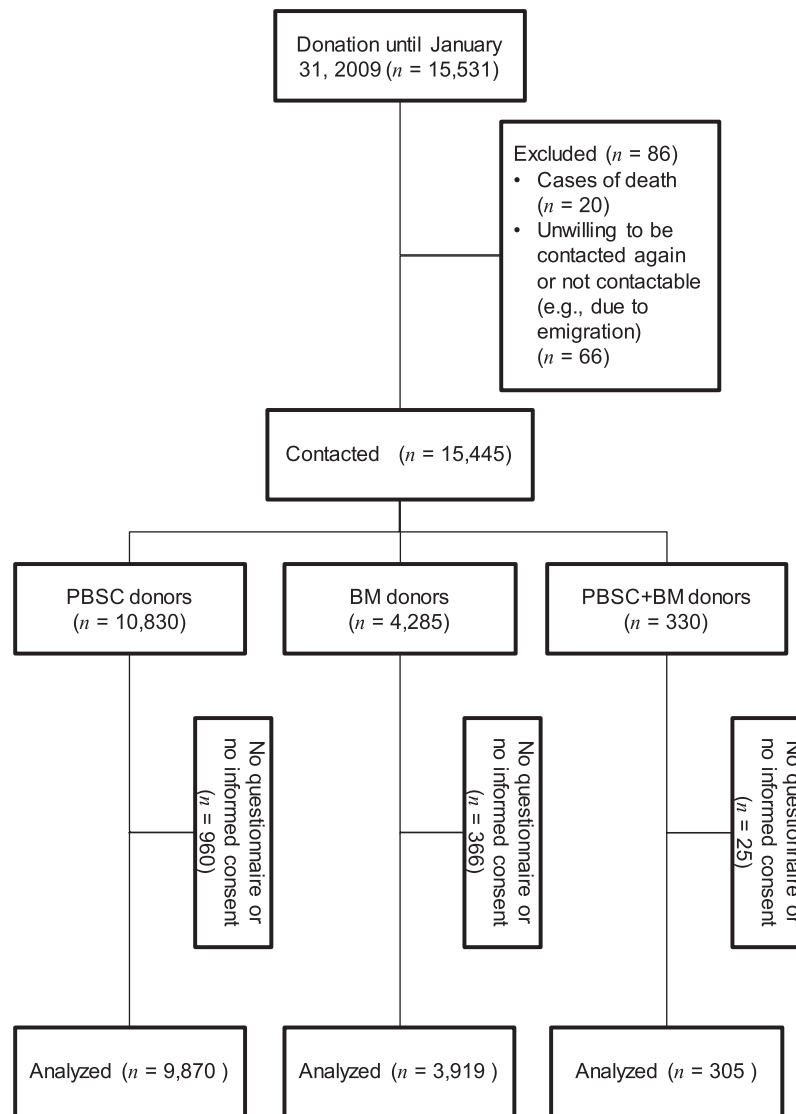


Figure 1. Description of the study population. The study population included 15,531 donors from DKMS Germany who donated PBSCs, BM, or both (PBSCs + BM) until January 2009. In total, 15,445 donors were contacted of which 14,094 gave informed consent and responded to the follow-up questionnaire (9870 PBSC donors, 3919 BM donors, and 305 PBSC + BM donors).

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