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Predonation Health-Related Quality of Life Scores Predict Time to Recovery in Hematopoietic Stem Cell Donors

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A B S T R A C T

The physical reactions to hematopoietic stem cell donation have been extensively studied, but less is known about factors that predict poorer donation experiences. The aim of this prospective study was to examine demographic and health-related quality of life (HRQOL) factors that might be associated with recovery and side effects. We also described the changes in HRQOL during the donation process. In total, 275 peripheral blood stem cell (PBSC) and 37 bone marrow (BM) consecutive donors completed the SF-36 questionnaire predonation and 4 weeks, and 3 months postdonation. Predonation HRQOL markers were the strongest predictors of time to recovery. Poorer predonation physical health was associated with longer recovery ($P = .017$) and certain side effects in PBSC donors. Poorer predonation mental health was associated with longer recovery in BM donors ($P = .03$) and pain after PBSC donation ($P = .003$). Physical HRQOL scores declined significantly from predonation to 4 weeks postdonation. This was shown both for PBSC and BM donors ($P < .001$ and $P = .009$, respectively), but the decline was much greater for BM donors. There was a return to predonation HRQOL values 3 months after donation in both groups with values well above the mean of the general population ($P < .001$).

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INTRODUCTION

Hematopoietic stem cell transplantation is a curative procedure for life-threatening hematological diseases. During the last decade, peripheral blood stem cells (PBSCs) have replaced bone marrow (BM) as the main source of hematopoietic stem cells. Although the donation process is generally considered safe, side effects are a known risk, and care must be taken to minimize the potential of harm to donors.

Common side effects of BM and PBSC donation are well known [1-6], although studies examining which groups of donors are at increased risk are limited [3,5-13]. The latter is important because strategies to enhance donor safety should be based on findings from these studies and could result in a more personalized approach to higher risk groups. Research in orthopedic surgery has shown a significant relationship between preoperative health-related quality of life (HRQOL) and recovery [14,15]. Specifically, negative mood was shown to exacerbate pain. Given that pain is the most common side effect in the peridonation period, investigation into the relationship between predonation HRQOL and recovery may also be relevant in this setting.

In this prospective study, we aimed to identify the factors that influence donor recovery in a formal manner and those that are most commonly associated with certain side effects. We included both demographic factors and predonation HRQOL scores using the Short-Form 36 Health Survey (SF-36) questionnaire. We also describe the changes in HRQOL predonation and up until 3 months after donation and compare HRQOL between PBSC and BM donors.

METHODS

Study Population

The study population was composed of unrelated donors from the United Kingdom whose BM or granulocyte colony-stimulating factor (G-CSF)-mobilized PBSC donation was facilitated by Anthony Nolan between February and November 2013. All donors passed a rigorous physical eligibility screening (according to World Marrow Donor Association

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recommendations [16]) and were at least 16 years of age with a weight of at least 50 kg and a body mass index (BMI) < 35 for BM donors and <40 for PBSC donors. Donors gave informed consent for the donation process as per normal practice as well as additional informed consent for the HRQOL assessment questionnaires. Ethical approval was obtained from the registry's institutional review board.

Stem Cell Collection Methods

All PBSC donors were mobilized with lenograstim (glycosylated G-CSF; Chugai Pharma, London, UK), which was given at a once-daily dose of 10 μg/kg subcutaneously ± 10% for 4 consecutive days, and apheresis was commenced on day 5. A maximum of 2 apheresis procedures was performed. Donors who donated BM underwent harvest from both iliac crests under general anesthesia. In line with World Marrow Donor Association guidelines, no more than 20 mL/kg donor weight was extracted. Both types of donation were carried out in 1 of 4 collection centers.

Data Collection

Donors were recruited at the time of the donor's medical evaluation, which took place on average 17 days (range, 8 to 30) before donation. Data collection continued on day −4, day −3, and day −2 before donation for PBSC donors and on the day of collection for both types of participants (day 0). We subsequently contacted BM and PBSC donors via telephone 2 or 3 days after donation. Donors were contacted again using an online questionnaire 1 week after donation and weekly thereafter up until complete recovery.

Complete recovery was determined on the day 2 to 3 or weekly questionnaire and defined as the absence of ongoing symptoms as well as return to predonation health. The assessment at each time point involved a self-reported checklist of specific side effects, including allergy, anorexia, back pain, bleeding, bruising, dizziness, fatigue, fever, headache, infection, injection site reaction, insomnia, myalgia, nausea, any other pain, and vomiting. Each side effect was scored using the Common Terminology Criteria for Adverse Events (CTCAE) toxicity index. Demographic factors analyzed as potential influencing factors of time to recovery or side effects were gender, age, BMI, support network (number of dependents, marital status), and being a blood donor.

Health-Related Quality of Life

HRQOL was measured using the SF-36 questionnaire, given to donors (either by post or e-mail) before donation (before the start of G-CSF for PBSC donors) and 4 weeks and 3 months after donation. The SF-36 is a generic indicator of HRQOL derived from the 245-item Medical Outcomes questionnaire. It includes multi-item scales to measure the following 8 dimensions: physical functioning (PF), role limitations due to physical health problems (RP), bodily pain (BP), general health perception, vitality, social functioning, role limitations due to emotional problems, and general mental health. Physical Component Summary (PCS) and Mental Component Summary (MCS) scores provide a broad physical and mental health perspective [17]. Norm-based scoring was used to interpret the different dimensions' and summary scores [17,18]. This scoring is created by computing the 0 to 100 score for a scale and then adjusting this score by the general population's average and standard deviation (SD) on that scale. As a consequence, the population mean and SD of all scores are 50 and 10, respectively, with higher scores reflecting more positive health states.

Statistical Analysis

The primary endpoints were time to recovery and individual side effects at different time points as defined earlier. Characteristics analyzed as potential influencing factors were the previously defined demographic factors and the PCS and MCS measures.

The probabilities of complete recovery were calculated using the Kaplan-Meier estimator, and groups were compared using the log rank test. PCS and MCS measures were split into 4 groups, based on the 25th, 50th, and 75th percentiles. Factors significant in univariate analysis at the ≤.20 level were entered into a stepwise proportional hazards regression analysis.

The influence of the previously defined demographic and HRQOL factors on individual side effects was examined using either a chi-square test, *t*-test, or Mann-Whitney U test. Binary summary scores were established for pain (headache, myalgia, back pain, and any other pain) and any side effect for each time point. In addition, summary scores for each side effect involving all time points from day 0 onward were established. Factors with $P \leq .20$ in the univariate analysis were included in a stepwise logistic regression analysis. Comparison between BM and PBSC donors was performed using the chi-square test for categorical variables and the *t*-test or Mann-Whitney U test for continuous variables.

Our secondary endpoint was to assess changes in SF-36 scores before, 4 weeks after, and 3 months after donation. Paired sample *t*-tests were used to compare the SF-36 scores before and after donation. Stepwise linear regression analysis was performed to identify significant variables that could be used to predict HRQOL (using PCS and MCS scores) at 4 weeks after donation.

All statistical analysis was performed using SPSS software (IBM, Armonk, NY). A 2-tailed $P < .05$ was considered significant.

RESULTS

Characteristics, Side Effects, and Recovery in BM and PBSC Donors

Table 1 shows clinical characteristics of BM and PBSC donors enrolled in the study. A central line was inserted in 5% of PBSC donors (2% of male donors compared with 15% of female donors; $P < .001$); 27% of PBSC donors (74/275) required a 2-day collection.

Figure 1 shows the time course and side effects experienced in PBSC donors. Pain in PBSC donors consisted mainly of bone pain and headache. Pain peaked during administration of G-CSF, with 85% of donors experiencing pain on the third day of G-CSF administration. The pain was graded as CTCAE 1 in 80% of cases, with only 1 donor experiencing grade 3 pain. Fatigue and bruising were the other most common side effects, peaking on days 2 and 3 after donation. Seventy-five percent of donors (207/278) required analgesia during G-CSF administration, and 2.5% of donors still required analgesia 7 days after donation.

All BM donors received general anesthesia. The mean duration of the procedure was 41 minutes (range, 20 to 120). The mean volume of BM harvested was 1209 mL (range, 290 to 1740). Autologous units were not collected, and no donor received an allogeneic transfusion. All except 1 were discharged the day after BM harvest. Figure 2 shows the time course and side effects experienced. Pain in BM donors was generally localized to the site of donation or the throat (after intubation). The peak of pain was reported on days 2 and 3 after donation for back pain (76.5%) and on the day of donation for throat pain (48.6%). Fatigue and bruising were the most common other side effects reactions, peaking on days 2 and 3 after donation. Most side effects were classified as CTCAE grade 1, and no donor experienced grade 3 or 4 side effects in this small cohort. Ten percent of BM donors (3/29) still required analgesia 1 week after donation.

The median time to recovery for BM donors was 10 days as opposed to 3 days for PBSC donors ($P = .001$) (Figure 3A). Only 50% of BM donors believed they had recovered after 1 week, and 68.8% had returned to work, compared with 90.3% and 98.3% of PBSC donors, respectively ($P < .001$). Compared with PBSC donors, significantly more BM donors still experienced pain ($P < .001$) and other side effects in general ($P < .001$) 1 week after donation.

Health-Related Quality of Life

The response rates for the SF-36 questionnaires for PBSC donors were 72% (198/275) before donation, 72% (199/275) 4 weeks after, and 72% (198/275) 3 months after donation. Fifty-eight percent of PBSC donors returned all 3 questionnaires. Nonparticipants were more likely to be younger ($P < .001$) and male ($P < .05$). There was no statistical difference between collection characteristics in those returning versus not returning forms. This included volume of blood processed, presence of a central line, and 1- versus 2-day collection.

The response rates for the questionnaires for BM donors were 75% (28/37) before donation, 59.5% (22/37) 4 weeks after donation, and 67.6% (25/37) 3 months after donation. Forty-nine percent of BM donors (18/37) returned all 3

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