NORTHSIDE HOSPITAL

THE IMPACT OF HEMATOPOIETIC STEM CELL TRANSPLANTATION ON PRIMARY CAREGIVER LEVEL OF BURDEN AND DISTRESS

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Treatment Schema

	Pre-BMT	Day 0	Day 7[1]	Day 30[1]	Day 365[2]
Patient	BSI-18 BFI BPI	BSI-18 BFI BPI	BSI-18 BFI BPI	BSI-18 BFI BPI	BSI-18 BFI BPI
Caregiver	Demographics BSI-18 BFI Burden Interview	BSI-18 BFI Burden Interview	BSI-18 BFI Burden Interview	BSI-18 BFI Burden Interview	BSI-18 BFI Burden Interview

[1] Assessment can be done +/- 3 days

2 Assessment can be done +/- 7 days

1.0 OBJECTIVES

Primary Objectives:

1.1 To investigate the level of distress and feelings of burden in caregivers of HSCT patients.

Secondary Objectives:

1.2 To investigate the impact of patient distress, fatigue and pain on the level of caregiver distress and burden.

1.3 To investigate the impact of caregiver distress and burden on overall patient survival and length of patient hospitalization.

1.4 To identify common characteristics of caregivers who report significantly more feelings of burden or distress.

2.0 BACKGROUND

Hematopoietic stem cell transplant (HSCT) is an established treatment for certain hematologic malignancies[1]. The process of undergoing HSCT is intense and time consuming. Patients and their caregivers are required to commit to several months of treatment and close follow-up. At our institution, the Blood and Marrow Transplant Program at Northside Hospital, the transplant process includes frequent, if not daily, visits to the clinic, and at times lengthy hospital stays for the patient. Our program requires patients to have a full-time caregiver to assist them with transportation, treatment compliance, nutritional intake and emotional support. Patients are not allowed to be alone, go to public areas, or independently manage their medications. Patients are most commonly out of work for extended periods of time. The need for a caregiver places an extra burden on the patient and their loved ones, as caregivers are not able to work full time while caring for an HSCT patient. Many studies have looked at the quality of life and various psychological symptoms in patients undergoing HSCT. Studies have analyzed the impact of HSCT on patient health related quality of life (HRQOL) during and after HSCT. However, little is known about the impact of HSCT on spouses/partners or other primary caregivers.

The process of serving as a caregiver for a loved one going through HSCT is rigorous and stressful. Much of the psychosocial support that exists in transplant centers focuses on the patients with little support for the caregivers. Friends and family also tend to place emphasis on the patient undergoing the treatment and give less attention to the patient's caregiver. Even with the presence of community support groups and education from the transplant programs, caregivers typically report experiencing high levels of distress. Caregivers often express feeling the weight of the world on them, as they are left to worry about everything outside of transplant (i.e. finances, child care), in addition to being very concerned with the patient's health. They feel a sense of responsibility for the patient improving medically.

More recently, transplant programs have begun to identify needs of HSCT caregivers. Researchers have begun to recognize caregivers as an important and often overlooked participant

in the HSCT process. The current literature on HSCT caregivers suggests that caregivers for HSCT patients do report feeling stressed, exhausted emotionally and physically, and in need of support[2, 3, 4]. One study identified high levels of stress and depression pre-transplant[5]. A 2004 study by Gaston-Johansson[6] found that primary caregivers of patients with breast cancer scheduled for BMT experience fatigue, anxiety, burden of care, and low quality of life.

Due to these previous findings, it was clear that level of burden, fatigue and distress were essential properties to be measured in HSCT caregivers. Each of these areas will be measured by a specific, psychometrically sound instrument. The Burden Interview, The Brief Fatigue Inventory, The Brief Pain Inventory and the Brief Symptom Inventory-18[7, 8, 9, 10, 11, 12, 13, 14] were selected due to there previous use in oncology settings.

The purpose of this study is to examine the impact of HSCT on the caregiver's level of burden, depression, anxiety, somatic symptoms, fatigue and overall distress. It will also examine if caregiver burden leads to an increase in the patient's hospital utilization and overall outcome. In addition, we hope to identify these caregiver symptoms as they relate to the patient's overall functioning. Therefore, each patient will also complete self-report measures in order to assess if the patient's level of distress impacts the caregivers' functioning. The patients will complete self-report measures assessing symptoms of psychological distress, pain and fatigue and these scores will be matched to their particular caregiver.

3.0 DRUG INFORMATION

There are no drugs associated with this study.

4.0 PATIENT SELECTION

4.1 Patient eligibility

- 4.1.1 Any patient undergoing autologous or allogeneic HSCT at The Blood and Marrow Transplant Program at Northside Hospital will be eligible.
- 4.1.2 Patients must have a single primary caregiver.
- 4.1.3 Patient must be willing to comply with all assessments as outlined in the protocol.
- 4.1.4 Patient must be willing to sign informed consent.

4.2 Caregiver eligibility

- 4.2.1 Must be the primary caregiver for an autologous or allogeneic HSCT patient at The Blood and Marrow Transplant Program at Northside Hospital.
- 4.2.2 Caregiver must be willing to comply with all assessments as outlined in the protocol.
- 4.2.3 Caregiver must be willing to sign consent.

5.0 TREATMENT PLAN

Pre-BMT Patient Completes: BSI-18, BFI, BPI
Caregiver Completes: Demographic Form, BSI-18, BFI, Burden Interview

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Days 0, 7, 30 and 365 Patient Completes: BSI-18, BFI, BPI
Caregiver Completes: BSI-18, BFI, Burden Interview

	Pre-BMT	Day 0	Day 7[3]	Day 30[3]	Day 365[4]
Demographics[1]	X				
BSI-18	X	X	X	X	X
BFI	X	X	X	X	X
BPI[2]	X	X	X	X	X
Burden Interview[1]	X	X	X	X	X

[1]caregiver only
[2]patient only
[3]assessment to be done +/- 3 days
[4]assessment to be done +/- 7 days

6.0 ADVERSE EVENT REPORTING

Adverse events are further defined as "Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment." [15]

Patients will be monitored by the investigators and data maintained by the Clinical Research Program. All Adverse Events will be graded with the Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0.

http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf

Due to the non-treatment nature of this protocol, there are not expected to be any adverse events. However, should a patient experience an adverse event that is specifically related to participation in this study, the following reporting criteria will apply. Patients will be followed through Day 365 for protocol-related adverse events.

6.1 Procedure for reporting Serious and Unexpected Adverse Events

Serious Adverse Events will be reported by telephone or email to the Institutional Review Board within 24 hours of notification of event. Written report will follow within 10 working days. Serious adverse events will be reported for a period of one (1) year post-transplant.

6.2 Definition of Serious and Unexpected Adverse Events:

Serious Adverse Events are defined as one of the following:

a. Death
b. Life-Threatening
c. Hospitalization (initial or prolonged)
d. Disability
e. Congenital Anomaly
f. Requires Intervention to Prevent Permanent Impairment or Damage

Unexpected is defined as:
Not previously reported with the agents/devices or procedures being undertaken. Symptomatically and pathophysiologically related to known toxicity but differs because of greater severity than previously reported.

7.0 RISKS and TOXICITIES

7.1 There are no expected risks associated with participation in this study. However, there may be an indirect or direct increase in psychological distress related to the completion of the psychological measures. Patients and caregivers will be monitored per programmatic protocol for any increases in psychological distress and these symptoms will be managed according to programmatic standards. All participants will be asked to contact the principal investigator, who is a licensed psychologist, if they experience an increase in psychological distress.

8.0 STATISTICAL CONSIDERATIONS/DATA ANALYSIS

8.1 We will plan to accrue 50 autologous and 50 allogeneic patient/caregiver dyads. This number of patients will be sufficient to perform an initial analysis to examine levels of distress and associated outcome variables. We expect that patients will be accrued over 1-2 years.

8.2 Data analysis will be performed on the information gathered to evaluate the impact of HSCT on the caregiver's level of burden, depression, anxiety, somatic symptoms, fatigue and overall distress. It will also examine if caregiver burden leads to an increase in the patient's hospital utilization and overall outcome. In addition, we hope to identify these caregiver symptoms as they relate to the patient's overall functioning. The analysis will include t-tests to look at correlations, as well as more complex statistical procedures (e.g., manova, and multiple regression analyses) to identify relationships between variables.

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