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Falls in Bone Marrow Transplant Patients:

A Retrospective Study

by

Lura Henderson, R.N., B.S.N.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science College of Nursing University of South Florida

Major Professor: Susan C. McMillan, Ph.D., A.R.N.P. Cindy Tofthagen, Ph.D., A.R.N.P. Versie Johnson-Mallard, Ph.D., A.R.N.P.

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Keywords: peripheral stem cell transplant, oncology, falls, risk factors, Morse Fall Scale

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Dedication

This is dedicated to my amazing family. To my father, Robert, thank you for always being there for me, to listen and lend advice, and financially aiding in my graduate school endeavors. To my mother, Reena, thank you for believing in me, encouraging me to aim high, and for introducing me to civic opportunities at a young age. To my wonderful fiancé, Kelly, I am so blessed to have you in my life and thank you for your love, support, advice, and for being my rock while I am in graduate school. To my cousin, Steven Jones, who in his short life, inspired me to become a Bone Marrow Transplant Nurse in his honor.



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Falls in Bone Marrow Transplant Patients:

A Retrospective Study.

Lura Henderson

ABSTRACT

Falls are a contributing factor to increased morbidity in the elderly and chronically ill populations and can affect overall quality of life. The literature indicates that oncology patients are a particularly vulnerable population who are further at risk for falls due to increased age, treatment related fatigue, side effects of medications, comorbidities, decreased muscle tone, altered mental status, and anemia. Although patients with cancer are at a high risk for falls, this is not a well-documented patient problem in the nursing literature. This study examined the validity of the use of the Morse Fall Assessment Tool for use with Bone Marrow Transplant patients and explored other variables that might influence fall outcomes.

This study was a retrospective chart review. The sample consisted of a total of 59 patients, which included 29 fallers and 30 non-fallers on a bone marrow transplant unit.

There were 22 males and 37 females, ranging in age from 20 to 70 with a mean age of 53.9 (SD= 12.2). The results of this study indicate that there is a significant difference between fallers' (M= 43.8) and non-fallers' (M= 26.8) scores on the Morse Fall Scale (p= 0.000). Significant differences between groups were found with history of



falls (p= 0.042), secondary diagnosis (p= 0.015), and muscle weakness (p= 0.025). Laboratory results from fallers and non-fallers revealed significant differences in platelet count (p= 0.003), BUN (p= 0.032), glucose (p= 0.009), and phosphorous (p= 0.001).

This is the first study to document falls in the bone marrow transplant population. This study should be a stimulus for future studies conducted in the oncology and/or bone marrow transplant population. Studying falls in these patients is essential to understanding the physiological risk factors that may contribute to patient falls. Findings lay the foundation for studying falls in the bone marrow transplant population. It is crucial to study falls in this population in order to make appropriate assessments and interventions to keep this population free from injury.

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Chapter I

Introduction

Falls are a contributing factor to increased morbidity in the elderly and chronically ill populations and can affect overall quality of life. Preventing falls has been an area of concern and a focus of research for decades. Multiple intrinsic factors can contribute to increased patient falls such as acute and chronic illnesses, medications, increased age, mental status, and muscle tone (Krauss, Evanoff, Hitcho, Ngugi, Dunagan, Fischer, et al. 2005). Therefore, preventing patient falls is a high priority and is included in the *National Patient Safety Goals Hospital Program* written by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) as goal number nine to "reduce the risk of patient harm resulting from falls" (JCAHO, 2008).

Shever and colleagues (2008), concluded that patients who received high nursing surveillance (patient care once every two hours) experienced 157 falls compared to 324 falls experienced by patients who received limited or no high nursing surveillance. This study suggested that the additional \$191 high surveillance costs per hospitalization is associated with a cost savings of \$17,483, an amount estimated to cover the medical expenses for a patient who has fallen (Shever, Titler, Kerr, Qin, Kim, & Picone, 2008). This savings is of considerable importance for nursing and hospital administrators. As of October 1, 2008 if a patient experiences a fall while in the hospital, Medicare will no longer pay hospitals for the increased costs of care related to injury. In addition, Medicare forbids hospitals to charge patients for the increased medical expenses associated with



falls and other hospital-acquired conditions (Centers for Medicare and Medicaid Services, 2008).

Oncology patients are a particularly vulnerable population who are further at risk for falls due to increased age, treatment related fatigue, side effects of medications, comorbidities, decreased muscle tone, altered mental status, and anemia. Although patients with cancer are at a high risk for falls, this is not a well-documented patient problem in the nursing literature (Holley, 2002). Fall risk-assessment tools utilized in nursing are not designed for cancer patients and may not accurately represent or predict falls in the oncology population (O'Connell, Baker, Gaskin, & Hawkins 2007).

Problem Statement

While the importance of identifying fall risk factors in oncology patients is high, empirical analysis has been limited. Oncology nurses need to be cognizant and have a detailed understanding of falls and associated risk factors in their patient populations (Holley, 2002). The purpose of this study was to evaluate the validity of the use of Morse Fall Assessment Tool for Bone Marrow Transplant (BMT) patients by known group comparisons and exploration of other variables that might influence fall outcomes.

Research Objectives

The following objectives guided this study:

1. To determine if there was a significant difference in the Morse Fall Assessment Score in BMT patients who fall and those who do not fall.

2. To determine if there were significant differences in age, gender, diagnosis, history of falls, confusion, muscle weakness, blood laboratory values, blood pressure, temperature, and medications taken within 24 hours between fallers and non-fallers.



Definition of Terms

Falls are defined as any sudden, unanticipated incident that causes a person to accidently land on any lower surface (Pearse, Nicholson, & Bennett, 2004). It is also suggested that "a fall is a sudden, unintentional change in position causing an individual to land at a lower level, not as a consequence of a sudden onset of paralysis, epileptic seizure, or force" (Overcash, 2007, p. 342). The general theme of falls definitions are that they are spontaneous and do not result from loss of consciousness. Falls can be further differentiated into anticipated physiological falls which includes ambulation difficulty and confusion, unanticipated physiological falls that occur when a patient faints or seizes, and accidental falls such as tripping or slipping (Morse, Black, Oberle, & Donahue, 1989).

Significance to Nursing

Nurses are committed to providing safe environments for their patients. Assessment and prevention of patient falls are top priorities to nurses and risk management. In the view of risk management, failure to identify patients at risk for falls and appropriately providing interventions may lead to a decreased level of safety and the potential for malpractice lawsuits (Tommasini, Talamini, Bidoli, Sicolo, & Palese, 2008). Patient falls may occur as a result of environmental factors and intrinsic patient characteristics such as incontinence, medications, muscle weakness, confusion, and anemia (Krauss, et al., 2004; Dharmarajan, et al., 2006).

The hospital that is the target of this study is currently using the Morse Fall Assessment Tool without any validity data signifying that this tool is sensitive for use in Bone Marrow Transplant patients. Understanding oncology falls risk factors may enable



nurses to appropriately and more accurately identify patients at higher risk of falling. Assessment of patient falls and ensuring proactive interventions to prevent injury from falls are important issues in nursing research. Identification of fall risk factors in the bone marrow transplant population should be explored to determine the validity of the Morse Fall Assessment Tool. Exploration of other variables that might influence fall outcomes identifies potential oncology risk factors while adding to the current nursing literature.



Chapter II

Review of the Literature

This chapter reviews current nursing literature relevant to patient risk factors for falling. The first part of the review discusses patient risk factors and falls in the general population. This is followed by a review of current studies of risk factors and falls in the oncology population. Current falls assessment tools are then discussed. This chapter ends with a synthesis of the literature and illustrates that falls research in the bone marrow transplant population is crucial.

Risk Factors and Falls in General Population

Morse and colleagues are well known in the nursing literature for their research on patient falls and for encouraging the use of the *Morse Fall Scale* in hospital settings. Their study, published in 1989, was the first study of this widely used scale. In a prospective study by Morse and colleagues (1989), the *Morse Fall Scale* was utilized to predict patient daily risk factors for falling in acute medical and surgical, long term geriatric, and rehabilitative units with 2689 patients over a four month period to determine the feasibility of using this scale in nursing practice. Measures used to predict patient falls were: history of falling, presence of secondary diagnosis, use of ambulatory aids, current intravenous administration, gait characteristics, and mental status. Patients were identified as low risk of falling if the score was less than 20, medium risk for falling if scores ranged from 25-40, and were considered high risk if given a score greater than 45. Nurses scored patients' risk of falling daily, documented fall prevention interventions,



and if a fall occurred, documented the type of fall and attributing factors. Analysis of patient falls revealed that 61.9% were physiological anticipated falls, 13.6% were unanticipated falls, and 24.5% were accidental falls. Further, 76.9% of patients who fell were considered to be high risk for falls. This scale was found to be a convenient and effective predictor of patient falls and guided nursing staff in implementing fall prevention strategies. However, oncology patients were not identified as specifically included.

Stevenson, Mills, Welin, and Beal (1998) conducted a retrospective, descriptive, comparative study designed to compare 301 hospitalized fallers and 301 hospitalized non-fallers matched as well as possible by age and medical diagnosis at discharge. The purpose of this study was to increase nursing knowledge beyond established risk factors of age and medical diagnosis, by comparing groups of fallers and non-fallers in an acutecare setting. Of 602 patients, 54% were female and 46% were male with a median age of 61.8 years. Cardiac patients represented the majority of the group at 23.2%. The remaining diagnoses were psychiatric (14%), rehabilitation (9.8%), gastrointestinal (8.8%), cancer (8.1%), orthopedic (6.9%), pulmonary (6.2%), neurologic (3.9%), and various others (19%). The authors designed a data-collection form associated with fall risk factors identified in the literature and content validity was evaluated by the hospital's nursing research group. Data for this study was retrospectively collected from medical records and incident reports of patients who had fallen. Logistic regression was their method of data analysis and aided in estimating the odds ratios to interpret their results. Collinearity was not found to be present among the independent variables. The primary risk factors associated with falls and increased odds ratio of falling in this study were



incontinence (11.3), length of stay > 18 days (9.9), dependent for ambulation (6.0), independent for hygiene (2.5), and lack of regular exercise (2.0). Stevenson and colleagues concluded that no two studies have found the same set of fall risk factors. Therefore, it was suggested that risk factors for falls are patient population specific and each hospital should evaluate and modify fall risk factors on a continuing basis (Stevenson, Mills, Welin, & Beal, 1998).

In a case control study by Krauss and colleagues (2005), patient risk factors that were significantly correlated with an increased risk of falling included: gait or balance deficits, confusion, activity level, use of sedatives and/or hypnotics, antiarrhythmic, nonnarcotic analgesics, and diabetes medications. The aim of this study was to identify possible risk factors of falling in the hospital and describe the events leading up to the fall. Ninety-eight inpatient falls were matched to three hundred and eighteen controls that had the same length of hospitalization stay until the index fall occurred. Environmental circumstances revealed that 82% of patients fell in their rooms, while 85% of those falls occurred without needed assistance, and the majority of patient activity prior to falling pertained to toileting needs. Further, it was noted that 42% of patients who used assistance devices at home were actually using one in the hospital compared to 53% of the controls. Care related risk factors indicated the higher the number of patients a nurse had, the more likely one of their patients would fall. These investigators recommended that nursing efforts should be focused on making scheduled rounds to offer ambulation or assistance for toileting, utilizing bed rails, improving nurse-patient ratios, and monitoring patients taking medications known to increase risk of falls.



O'Hagan and O'Connell (2005) conducted a retrospective analysis to examine the relationship between patient blood pathology levels and patient falls in the acute-care setting. These researchers used a convenience sample of 220 patient charts. These charts were divided among patients that fell and were matched on variables of casemix type and length of hospitalization among those patients who did not fall. Included as variables were age, gender, presence of intravenous therapy, history of falls, confusion and continence status as these are documented in the literature as known patient risk factors. There was no statistical difference found in the blood pathology levels for the variables of Na, K, Cl, bicarbonate, urea, creatinine, Ca, P, Mg, bilirubin, liver enzymes (ALT, AST), GGT, total protein, albumin, globulin, Hb, RCC (red cell count), PCV, MCHC, MCV, RDW, platelets, ESR, leukocytes, mature neutrophils, lymphocytes, monocytes, eosinophils, or basophils. The variable found to be of significance was alkaline phosphatase with p = 0.036. These elevated values are typically seen in patients with liver or bone disease and have been present in cancer or orthopedic patients. Chi-squared tests were conducted to determine the relationship of the above mentioned variables with those who fell and those who did not fall. In this study, the only variable of significance was confusion 24 hours prior to the fall with p=0.001. These authors questioned the reliability of fall risk assessment tools as they found the majority of the risk variables insignificant in their findings including gender, continence status, medications, intravenous therapy, and history of falls. Implications for nursing should include continual and regular patient falls assessment as patients in the acute-care setting are prone to frequent changes in acuity (O'Hagan & O'Connell, 2005).



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In a prospective analysis by Hitcho and colleagues (2004), data on patient characteristics, fall environments, and injury were obtained through interviews with patients and/or nurses and a review of incident reports and medical records. Two hundred patient falls were studied with falls occurring in medical, cardiology, neurology, orthopedics, surgery, oncology, and women and infant services. A total of 183 patients actually fell, 168 (92%) of these patients fell once during the investigation, 13 (7%) fell twice, and two (1%) fell three times. The difference between falling once and repeatedly falling was gender. In this study, the men tended to fall more than the women (p=0.03). Confusion (44%), muscle weakness (81%), diabetes (39%), urinary frequency (36%), and lower extremity problems (38%) accounted for the majority of patient falls. It is likely that medications may have contributed to these falls as well. Those who received central nervous system (58%) or vasoactive/blood pressure (56%) medications 24 hours prior to the fall were at risk for falling; whereas patients who received a sedative were least likely to fall at 12%. The majority of falls occurred at night (59%), in the patient's room (85%), and with no assistance (79%). The medicine and neurology units had the highest fall rates both at 6.12 falls per 1,000 patient days and had higher nurse patient ratios at 6.5 and 5.3, respectively. The oncology unit had the third highest rate of falls at 3.75 falls per 1,000 patient days with an average nurse-patient ratio of 4.6. Falls were more likely to occur between day 10 and 11 of the hospital stay on the oncology floor with a range of (1 to 38) (Hitcho, et al., 2004). This is of particular importance for oncology nurses as these patients may have an increased risk of falls around this time due to chemotherapy and anti-emetic side effects, radiation, and treatment related fatigue.



Dharmarajan, Avula, and Norkus (2007) studied 362 ambulatory older adults hospitalized from June 2001 through December 2004. The purpose of their study was to identify whether a relationship exists between anemia laboratory values and the occurrence of falls in older individuals in long term care and community settings. The sample ranged in age 59 to 104 years old and included 166 males and 196 females. A majority of these patients (210) lived in the community and the remaining 152 were nursing home residents. Patient demographics included history of prior falls, Hgb, Hct, serum iron, total iron binding capacity (TIBC), ferritin, serum B12, and serum folate were collected (if available) from medical records. The authors used the World Health Organization (WHO)'s definition of anemia defined as Hgb < 12.0 in females and Hgb < 13.0 in males. These investigators did not find a significant difference between gender distribution, Hgb level, proportion of anemia, length of hospital stay, and serum albumin levels in patients from nursing homes and the community. Interestingly, Hispanic patients were reported to have significantly higher mean hemoglobin levels (p=.018) and significantly less anemia (p=.001) than African American, white, and Asian patients. It was also noted that anemia occurred more frequently in fall patients compared with controls (p=.001). Further, they found patients had a 22% decreased risk for falls for every 1.0g/dL increase in Hgb (p<0.001) and 1.9 fold increased risk for falls in the presence of anemia (p=0.008) (Dharmarajan, et al., 2007).

Risk Factors and Falls in Oncology Patients

O'Connell, Cockayne, Wellman, and Baker (2005), conducted a prospective study to examine fall risk factors and the circumstances of patient falls in oncology and palliative care settings. Two hundred and twenty-seven patients and twenty-four nurses



participated in this study. Of this sample group, 34 patients fell and 193 did not fall. The measures utilized in this study were the Eastern Cooperative Oncology Group (ECOG) performance scale, total confusion score, orientation to person, time, and place score, muscle strength test, history of prior falls, and self-rated fatigue level. The post-falls questionnaire was answered through patient interview and nurse interview or selfadministration. Results of this study indicated that fallers had a significantly higher mean age of 74.79 compared to 66.45 (p=0.000). The percentage of female fallers was 55.9% (n=19) and non-faller females were 50.3% (n=97). Chi-square tests indicate there was no significant gender difference between fallers and non-fallers. Chi square tests were used to determine significance of previous history of falls and it was determined that fallers and non-fallers were equally likely to have a fall in the preceding 12 months. It was determined that fallers had reduced physical functioning and were more likely to have answered incorrectly on one of the questions on orientation compared to non-fallers. The self-rated fatigue level of fallers was significantly higher than those of non-fallers (p=0.01). These investigators questioned nurses on what could have caused the fall, and reasons they cited included poor condition of the patient, patient lack of knowledge regarding use of equipment, lack of nursing assistance, ambulating factors, and elimination issues. Length of hospitalization for these oncology patients ranged from 1 to 33 days with a mean length of stay at 11.38 days. This study identified three fall risk factors not previously mentioned in the literature: ECOG performance scale, muscle strength test, and self-rated fatigue score. It was recommended by these authors that on admission, oncology and palliative care patients' levels of physical and cognitive function be assessed by the ECOG performance scale, the self-rated fatigue scale, muscle



strength test, and the orientation in person, place, and time score. These items would be very helpful in a falls risk assessment tool for oncology and palliative care settings (O'Connell, Cockayne, Wellman, & Baker, 2005).

In 2007, nurses in Australia studied patient risk factors associated with an increased incidence of falls in oncology and medical settings (O'Connell, Baker, Gaskin, & Hawkins, 2007). The purpose of their study was to analyze whether items on the current Falls Risk-Assessment Tool (FRAT), which measures cognition and physical functioning levels, were truly indicative of distinguishing between fallers and nonfallers in oncology and medical settings. Numerous FRAT tools utilized across nurse practice settings have limited application for specialty populations, such as oncology. Oncology patients have occasionally been included in falls studies; however, they are not the focus of falls research interest. This study was retrospective (reviewed falls within the past 12 months and whether they occurred in the community or hospital) and the prospective portion studied current hospital patients and fall status. The retrospective group included 184 male and 193 female patients with ages ranging from 23 to 97 years (M = 73). The prospective portion contained 14 men and 20 females with ages ranging from 46 to 89 (M = 77). Twenty-nine patients of the prospective component were medical patients and the remaining five were oncology patients.

For this study, the nurses used a FRAT that included sections on demographics, prior history of falls, continence issues, physical functioning, confusion, orientation (person, place, and time), muscle strength, and fatigue. Demographics were recorded from the patient's chart and patients were asked if they had fallen within the past 12 months. Physical functioning was determined through the ECOG scale with scores



ranging from 0-4. Lower scores indicated greater physical functioning which are as follows: 0 fully active, 1 somewhat restricted, 2 ambulatory and able to perform activities of daily living (ADLs), restricted to bed or chair > 50% of hours awake, and 4 completely disabled and not able to perform ADLs or ambulate. The bedside confusion item was analyzed through the modified mini-mental state examination. Patients were asked to recite the months of the year in reverse order. This was scored 0-4, with 0 being normal and 4, inability to perform. Orientation was measured by asking the patient to repeat his or her name, the year and month, and location. The correct responses were summed and scores could vary between 0 and 4, with the lower scores indicating higher degrees of orientation. Muscle strength was evaluated as 1, 2, or 3 indicating firm, medium, or weak, respectively. Finally, fatigue was determined using a symptom distress scale. Patients were asked to quantify their fatigue from the past 24 hours on a 100 point visual analog scale, where 0 indicated "feeling very tired" and 100 represented "feeling your best."

The study was conducted in a private hospital during a fourteen month period. Research assistants collected demographics from patient charts and conducted a 10 minute fall assessment of each patient using the detailed FRAT described above within 48 hours of hospital admission. From this data, the researchers concluded that a prior history of falls within the past 12 months was not related to whether they had fallen during the current admission. Further, they concluded that muscle strength can differentiate between fallers and nonfallers in the hospital setting. They agreed that those who fell tended to be more confused and less oriented than nonfallers. Yet, after applying the Bonferroni adjustments, the authors found no significant difference between the FRAT items of fallers and nonfallers (O'Connell, et al., 2007).



Overcash (2007), conducted a descriptive, prospective, and quantitative study aimed at exploring the incidence of falls that occur in community-dwelling older oncology patients and how these falls relate to scores on a comprehensive geriatric assessment (CGA) consisting of depression, age, functional status, and cognition screening instruments. The sample consisted of 165 oncology outpatients aged 70 years or older at a cancer center. The four measures that were utilized in this study are Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL), Geriatric Depression Scale (GDS), and the Mini-Mental State Examination (MMSE). Each patient was screened once using the CGA instrument. The relationship among falls and each of the four scales was determined by using a point biserial correlation, and a multiple regression analysis aided in constructing a model to predict falls in this patient population. The most significant correlation was between IADL total scores and falls. These scores were found to be predictive of falls when controlling for age and gender using multiple logistic regression. For instance, a score of 9 of a possible score of 24 suggests an 81% risk of a fall compared to a score of 17 of 24 which suggests a 43% risk of a fall. The author concluded that there is limited research in the area of falls and oncology patients which made comparisons in the literature difficult. In the future, research needs to include an increased sample size and study more potential risk factors in oncology patients such as sensory deficits, anemia, fatigue, and medications (Overcash, 2007).

Falls Assessment Tools

Kim, Mordiffi, Bee, Devi, and Evans (2007), conducted a prospective descriptive design in an acute care hospital in Singapore to evaluate the sensitivity, specificity,



positive predictive value (PPV), and negative predictive values (NPV) of the Morse Fall Scale (MFS), St. Thomas Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY), and the Hendrich II Fall Risk Model (HFRM). One hundred and forty-four patients were studied for the inter-rater reliability study from the medical (38.9%), oncology (36.1%), and surgical (25%) units. These patients were screened within 24 hours of admission during the week and on the next business day for Saturday, Sunday, or public holiday admissions. Sensitivity measures the actual number of patients with high-risk scores who fell divided by the total number of patient falls. Specificity measures the actual number of patients with low-risk scores who did not fall divided by the total number of patients who did not experience a fall. Literature review reveals, the sensitivity of the MFS ranged between 72% and 83% with the specificity ranging between 29% and 83%, the sensitivity of STRATIFY ranges from 54% to 93% depending on the cutoff score, and the HFRM sensitivity and specificity were 74.9% and 73.9% respectively. Results of the validity study, which included 5489 patients, revealed that even though MFS and STRATIFY specificities were high, the low sensitivity renders these as ineffective tools to predict patients at high risk of falling. This study indicated that HFRM with a sensitivity of 70% and specificity of 61.8% appeared to be the more appropriate tool for predicting patients at risk for falling (Kim, et al., 2007).

Nurse researchers in Taiwan conducted a quasi-experimental study to determine the effectiveness of fall prevention among hospitalized patients based on a modified Fall Risk Factors Assessment Tool. Upon review of 108 patient fall cases between 1996 and 2001, these nurses discovered that falls actually occurred more often in patients with a fall risk factor of less than three points (56.5%) than the patients who actually received a



higher score of more than three points (43.5%). It is possible that the high risk patients did not fall because the nurses were more conscious of the higher score and may have adopted fall prevention interventions, causing the falls rate to decrease. These chart audits revealed that the current hospital assessment tool was not as accurate for high risk fall patients. The control group (n=43) contained patients who had fallen before the implementation of the new FRAT between March 1 through November 30, 2001. The same dates (March 1 – November 30, 2002) were used a year later for the use of the experimental group (n=39) who had fallen after the implementation of the new FRAT (Hsu, et al. 2004).

After reviewing the literature, the authors of this study added "balance, lower limb muscle strength, and the will of patient getting off bed" to their current FRAT which also assessed patients for consciousness level, walking capability, self care level, history of falls, and medicine administered throughout hospitalization. Further, information was collected for the experimental group to determine activity patterns prior to the fall and reasons why patients did not utilize call lights. Both groups were more likely to fall while they were "sober" (as opposed to "sleepy" or "lost"), weak/needing support, and while attempting to get out of bed. The majority of the falls occurred during evening and night time shifts (3pm to 7am) even though patients had family or friends present. This study further supports research conducted by O'Connell, et al. (2007), by indicating prior history of falls is not a good predictor of patients' likelihood of falling during the current hospital admission. Fifty-one percent of the control group and sixty-seven percent of the experimental group indicated they had no history of falling in the past; however, they proceeded to fall during current hospitalization. The control group had an unequal



representation of fallers with all scores which indicated the old FRAT is not a good predictor of the likelihood of patient falls. After the implementation of the new FRAT, the experimental group experienced less patient falls correlating with lower scores and an increase in falls as the FRAT scores increased. Patients' walking ability and fall assessment scores signify significant differences (p < .01). Interviews with these patients indicate that they did not want to bother their nurse or caregiver and tried to help themselves (Hsu, et al. 2004).

Statistical data revealed that 71.4% of patients in the experimental group had been appropriately identified by nurses as being at a higher risk for falls due to poor balance and weaker lower limb muscle strength. Further, the modified risk assessment tool identified high risk patients 74.4% of the time compared to the control group and the use of the old assessment tool at 60.5%, with the average assessment score increasing from 2.74 to 3.64. The correlation between falls and assessment scoring showed statistically significant differences (p < .01), signifying that the modified Fall Risk Factor Assessment Tool is better than the original FRAT at correctly identifying high risk patients. While this study adds another perspective to patient fall risk factors, the authors agree that further research needs to be conducted in this area and the falls assessment tool can always be improved (Hsu, et al. 2004).

Synthesis of Literature

Numerous research studies indicate that risk factors for falling in the general population include: history of falling, increased age, co-morbidities, gender, altered mental status, gait characteristics, incontinence, length of hospitalization > 18 days, medications (sedatives/hypnotics, antiarrhythmics, nonnarcotic analgesics, antidiabetics),



and abnormal lab values (Morse, et al., 1989; Stevenson, et al., 1998; Krauss, et al., 2005; O'Hagan & O'Connell, 2005; Hitcho, et al., 2004; Dharmarajan, et al., 2007). Tommasini, Talamini, Bidoli, Sicolo, and Palese (2008) noted that 21% of elderly patients were diagnosed with fevers prior to falling in the hospital. Research by Hitcho, et al. (2004) noted that the oncology unit had the third highest rate of falls at 3.75 falls per 1,000 patient days. Falls were more likely to occur between day 10 and 11 of the hospital stay on the oncology unit with a range of (1 to 38) (Hitcho, et al., 2004). This is of particular importance for oncology nurses as this may mean that these patients have an increased risk of falls around this time due to chemotherapy, radiotherapy, treatment related fatigue, and anti-emetic side effects. O'Connell, Cockayne, Wellman, and Baker (2005) noted that hospitalization for oncology patients also ranged from 1 to 33 days with a mean length of stay at 11.38 days. Their study identified three fall risk factors not previously mentioned in the literature: performance status as measured by the ECOG score, muscle strength test, and self-rated fatigue score. These items might be very helpful in a falls risk assessment tool for oncology and palliative care settings (O'Connell, Cockayne, Wellman, & Baker, 2005). Further, O'Connell, Baker, Gaskin, and Hawkins (2007), concluded that muscle strength can differentiate between fallers and nonfallers in hospital oncology and medical patients. Overcash (2007) found a significant correlation between Instrumental Activities of Daily Living (IADL) total scores and falls.

Research indicates that the Morse Fall Assessment Tool has a sensitivity of 72%-83% with specificity ranging between 29%-83%. Results of a validity study conducted by Kim, et al. (2007), which included 5489 patients, revealed that even though the Morse Fall Scale (MFS) specificities were high, the low sensitivity renders this as an ineffective



tool to predict patients at high risk of falling. In addition, the Morse Fall Scale measures patient's history of falling. Multiple authors question the reliability of fall risk assessment tools as they have found two risk variables insignificant in their findings such as gender and history of falls (O'Hagan & O'Connell, 2005; O'Connell, Cockayne, Wellman, & Baker, 2005; O'Connell, et al., 2007; Hsu, et al., 2004). While nursing studies add additional perspectives to patient fall risk factors, the authors agree that further research needs to be conducted in this area and that falls assessment tools can always be improved (Hsu, et al. 2004). Further, Stevenson and colleagues concluded that no two studies have found the same set of fall risk factors. Therefore, it is suggested that risk factors for falls are patient population specific and each hospital should evaluate and modify fall risk factors on a continuing basis (Stevenson, Mills, Welin, & Beal, 1998).

Currently no studies on risk factors and falls have been reported in the bone marrow transplant population. The majority of these patients receive high-doses of chemotherapy or high-dose chemotherapy with total body irradiation prior to transplantation. Bone marrow transplant patients are among the most acutely ill oncology patients and require excellent clinical care and monitoring. Nurses need to have a better understanding of patient risk factors and ways to prevent patient falls. A retrospective chart review may make a contribution to oncology falls research and improve the quality of life in these patients.



Chapter III

Methods

The purpose of this study was to evaluate the validity of the use of Morse Fall Assessment Tool for Bone Marrow Transplant (BMT) patients by known group comparisons and exploration of other variables that might influence fall outcomes. This chapter outlines the research methods. First the sample and setting are described. Variables included in the chart audit are then discussed. Research procedures and approval by the University of South Florida and Florida Hospital's Institutional Review Boards are then discussed. This section concludes with data analysis and methods to answer the objectives of this study.

Sample

This study was conducted on a Bone Marrow Transplant Unit (BMTU) at a large, public, metropolitan, hospital in Florida. Total enumeration was utilized to include the most recent 30 patients on the BMTU who had fallen and a matching group of 30 of these patients, randomly selected from BMT non-fallers within the same time frame. According to Hitcho, et al. (2005), the mean number of days in the hospital prior to falls in oncology patients is 10.5. For comparison purposes, the Morse Fall Score of the nonfallers were collected within 24 hours of day 11 of admission. Patients under the age of 18 and falls associated with physical therapy sessions were excluded.



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Instruments

A chart audit form (Appendix A) was developed for this study based on the work of Morse, et al. (1989), Krauss, et al. (2005), Hitcho, et al. (2005), O'Connell, et al. (2005), Dharmarajan, et al. (2007), O'Connell, et al. (2007). Demographic variables audited included age, gender, diagnosis, history of falls, confusion, and muscle weakness. Blood laboratory variables included white blood count, platelets, hemoglobin (Hgb), hematocrit (Hct), sodium (Na), chloride (Cl), potassium (K), glucose, bicarbonate, carbon dioxide, albumin, calcium, blood urea nitrogen (BUN), creatinine, and alanine transaminase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (alk. phosphatase), bilirubin (liver enzymes), blood pressure, temperature, medications taken within 24 hours of fall, and the Morse Fall score (Appendix B).

Inter-rater reliability was utilized to evaluate the consistency of the chart audit form. An additional hospital employee used the same chart audit form to collect information from five patient charts from each group. These forms were then compared to the principal investigator's forms to determine inter-rater reliability. This guided whether any changes needed to be made to clarify items on the chart audit.

Validity was initially built in by the process of carefully basing the audit form on variables found in the literature. In addition, comparison of known groups provided evidence of validity of the Morse Fall Scale in bone marrow transplant patients. The scores of fallers and non-fallers, who were expected to have contrasting scores on this scale, were compared (Burns & Grove, 2005).



Procedures

First, approval was sought from the Nursing Science Review Board at Florida Hospital. Following approval, it was reviewed by the Institutional Review Board (IRB) at Florida Hospital. The letter of approval from Florida Hospital was appended to the application for the IRB at the University of South Florida (USF). The IRB granted exempt status so this study could be exempt for the requirement for signed consent. This is the usual procedure for retrospective chart reviews.

After approval by the USF IRB, the Risk Manager was contacted to identify the most recent 30 bone marrow transplant patients who had fallen and had Morse Fall Scores recorded within 24 hours before the fall. Patient unique identifier numbers and pertinent information from the incident report were recorded and taken to medical records for further demographic information. Further, demographics and Morse Fall Scores were collected on 30 randomly selected bone marrow transplant patients who had not fallen. For comparison purposes, the Morse Fall Score of the non-fallers was collected within 24 hours of day 11 of admission based on research by Hitcho et al. (2005).

Data Analysis

Demographic data was analyzed using frequencies, percentages, means, and standard deviations. To answer objective one, if there was a significant difference in the Morse Fall Assessment Score in BMT patients who fall and those who do not fall, independent t-tests were utilized to determine if there was a significant difference in the Morse Fall Assessment Score in BMT patients who fall and those who do not fall.

To answer objective two, if there were significant differences in age, gender, diagnosis, history of falls, confusion, muscle weakness, blood laboratory values, blood



pressure, temperature, and medications taken within 24 hours between fallers and nonfallers, independent t-tests were utilized to determine if there were significant difference in age, blood laboratory values, and temperature between fallers and non-fallers. Differences in gender significance, diagnoses, history of falls, secondary diagnosis, ambulatory aids, intravenous administration, confusion, and muscle weakness were determined with chi-square tests. The level of statistical significance for this study was set at p < 0.05.



Chapter IV

Results, Discussion, and Conclusions

This chapter presents the findings of the retrospective study. The results, discussion of the results, limitations of the study, implications for nursing and research, and conclusions are presented.

Results

Demographic Data

The sample consisted of a total of 59 patients, which included 29 fallers and 30 non-fallers, 22 males and 37 females, ranging in age from 20 to 70 years with a mean age of 53.9 (SD= 12.2) (Table 1). An independent t-test was utilized to determine if there was a significant difference in age among fallers and non-fallers. No significant difference was found. Of the patients who fell (n=29), three patients had repeated falls (Table 2). The most common diagnoses in this sample were: acute myeloid leukemia (AML), multiple myeloma (MM), and non-hodgkins lymphoma (NHL) (Table 3).

Table 1. Mean and Percent of Demographic Variables for Fallers and Non-Fallers.

	Mean Age	% of Females	% of Males
Fallers	55.6	55	45
Non-Fallers	52.1	70	30



The majority of falls occurred during day shift hours of 7am to 7pm (55%) and the night shift experienced 45% of those falls. The mean number of days in the hospital prior to a patient experiencing a fall on the bone marrow transplant unit was 14.5.

Number of Falls	Frequency	Percent
One Fall	26	89.7
Two Falls	2	6.9
Three Falls	0	0
Four Falls	1	3.4

Type of Cancer	Frequency	Percent
Acute Myeloid Leukemia	15	26.3
Multiple Myeloma	12	21.1
Non-Hodgkins Lymphoma	10	17.5
Hodgkins Disease	2	3.5
Chronic Myeloid Leukemia	3	5.3
Acute promyelocytic leukemia	2	3.5
Aplastic Anemia	1	1.8
Chronic Lymphocytic Leukemia	1	1.8
T-Cell Leukemia	3	5.3
Acute Lymphocytic Leukemia	7	12.3
Myelodysplastic Syndrome a Diagnoses (n=57, missing data	$\frac{1}{2}$	1.8

Table 3. Frequency and Percent of Cancer Diagnoses a

a Diagnoses (n=57, missing data on 2 patients)

There were 22 males and 37 females in this study. The fallers consisted of 16 females and 13 males with the non-faller group consisting of 21 females and 9 males.



Chi-square comparison of gender revealed that there is no statistically significant difference between fallers and non-fallers.

Morse Fall Scale

The Morse Fall Scale measured the following six variables: history of falling, secondary diagnosis, use of ambulatory aids, IV therapy, gait characteristics, and mental status. Scores for the MFS can range from 0 through 125. If patients have a score of 0-24 they are at low risk for falling, 25-49 gives patients a moderate risk, and > 50 puts patients at a higher risk of falling. In this retrospective study, fallers (n=29) had a mean MFS of 43.79 (SD= 20.644) and the non-fallers (n=30) had a mean MFS of 26.83 (SD= 12.421). Independent t-tests were utilized to determine if there was a significant difference in the Morse Fall Assessment Score in BMT patients who fell and those who did not fall. There was a statistically significant difference between patients who fell and who did not fall (t=3.839; p=0.000).

The individual variables on the MFS that showed significant differences between groups in this study were: history of falls (p=0.042), secondary diagnosis (p=0.015), and muscle weakness (p=0.025) (Table 4). Difference in groups according to use of intravenous therapy, use of ambulatory aids, and confusion were not significant.



	Faller	Non-Faller	Chi-Square	р
History of Falls	8	2	4.6	0.042
Presence of Secondary Diagnosis	15	6	6.5	0.015
Ambulatory Aids	3	0	3.3	0.112
IV Therapy	29	30	(NS) _a	(NS) _a
Confusion	5	1	3.1	0.103
Muscle Weakness	13	5	5.5	0.025

 Table 4. Chi-square comparisons of Morse Fall Scale Variables between Fallers and

 Non- Fallers.

a Not Significant, no variation in these scores, every patient had an IV

Temperature

The majority of bone marrow transplant patients were afebrile during this chart review. The mean temperature maximum for both fallers and non-fallers was 99.4 (SD= 1.6) and 99.5 (SD= 1.3), respectively. Temperatures greater than 100.5 occurred in 12 patients (n=59). The faller group had five fevers present 24 hours prior to falling (17.2%) and seven non-fallers had fevers present within 24 hours of day 11 of the chart review (23.3%).

Table 5. Temperature in Bone Marrow Transplant Patients.

	Tmax Mean	Tmax SD	Temp > 100.5 (Frequency)	Percent	
Fallers	99.4	1.6	5	17.2	
Non-Fallers	99.5	1.3	7	23.3	
Tmax – Maximum Temperature within 24 hours					

Tmax = Maximum Temperature within 24 hours

Laboratory Values

For this study, laboratory results from complete blood counts (CBC), complete metabolic profile (CMP), magnesium, and phosphorous were collected from both fallers



and non-fallers. The platelet count (p=0.003), BUN (p=0.032), glucose (p=0.009), and phosphorous (p=0.001) were found to be significantly different between fallers and non-fallers (Table 6).

Table 6. Means, t-Scores, and Significance of Laboratory Values of Fallers and Non-Fallers.

	Fallers' Mean	Non-Fallers' Mean	t	р
Hemoglobin	9.86	9.38	1.54	0.129
Hematocrit	28.89	27.36	1.64	0.108
White Blood Count	9.16	0.91	1.6	0.115
Platelets	90.11	31.83	3.1	0.003
Sodium	136.74	137.73	-1.01	0.316
Potassium	3.97	3.84	1.11	0.272
Chloride	104.89	106.17	-1.04	0.303
Carbon Dioxide	25.19	25.07	0.15	0.885
Blood Urea Nitrogen	15.48	10.37	2.2	0.032
Creatinine	0.87	0.82	0.25	0.807
Glucose	135.67	110.67	2.69	0.009
ALT	38.65	35.40	0.42	0.674
AST	30.96	31.13	-0.03	0.974
Alk. Phosphatase	85.27	77.60	0.76	0.449
Bilirubin	0.91	0.94	-0.25	0.802
Albumin	2.7	2.85	-1.27	0.210
Calcium	8.22	8.44	-1.39	0.171
Magnesium	1.78	1.84	-1.14	0.258
Phosphorous	2.54	3.85	-3.71	0.001



Inter-Rater Reliability

Inter-rater reliability was conducted to compare the results of the chart audits between the principal investigator and the lead research scientist at this hospital. A total of ten chart audits were compared for inter-rater reliability, with five chart audits from each group. Chemotherapy, adjunct medication, and diabetic medication were excluded from the total list of items since these proved difficult to obtain during the study. The principal investigator included 18 items from the chart audit for purposes of inter-rater reliability. The following items counted as one point on the chart audit: category of patient (faller versus non-faller), days from admission, date and time of fall, age, gender, diagnosis, blood pressure, temperature, Morse Fall Scale score, primary hematology labs (hemoglobin, hematocrit, white blood count, and platelets), part of the CMP laboratory levels (discussed in the order they are abbreviated from top to bottom sodium, potassium, chloride, carbon dioxide, BUN, creatinine, and glucose), ALT, AST, ALP, bilirubin, albumin, calcium, and magnesium.

The scores of the five fallers charts were averaged together to receive an interrater reliability score of 11.8 out of a possible score of 18. The scores of the five nonfallers charts were also averaged together to receive an inter-rater reliability score of 4.6 out of the possible score of 18.

Discussion

This study may serve to raise awareness of numerous patient falls in the oncology setting and particularly in the BMT setting. Falls are a continued concern for nurses in all settings especially as it is the focus of the Joint Commission's *National Patient Safety*



Goals Hospital Program (2008). Early fall identification and prevention should be the goals of all nurses in their practice setting.

Demographic Data

A list of patients who fell on the Bone Marrow Transplant Unit was obtained from risk management from January 2007 through January 2009. A comparison group of nonfallers was randomly selected for this same time period.

The main limitation of this retrospective study is the relatively small size of the Bone Marrow Transplant Unit. This was not a problem in this study, as the principal investigator had 59 patients from the desired sample size of 60. However, 59 is a relatively small sample size. Limitations can exist with the majority of these patients residing in the same geographical area. Further restrictions exist if previous patient falls were not documented in the hospital-wide Incident Reports. Reporting incidents is strongly encouraged; however, it is not always completed. This can result with some falls going unexamined during this time frame. An additional limitation may have occurred due to the design of the study. Non-fallers were assessed on day 11, based on results of previous research but this study found that the mean number of days when patients fell was 14.5, which is around the time they reached nadir.

The sample largely consisted of females (62.7%) with the three most prominent diagnoses seen were acute myeloid leukemia (AML), multiple myeloma (MM), and non-hodgkins disease (NHL). Consistent with studies conducted previously, (Hsu, et al., 2004; O'Connell, et al., 2005; O'Hagan, et al., 2005; Overcash, 2007) there is no significant gender difference between fallers and non-fallers.



There was no distinctive pattern or events likely linked to falls during the day shift. Patients appeared to fall inadvertently and sporadically throughout the 12 hour shift. However, 77% percent (n=10) of falls on the night shift occurred between 1:30am and 6:20am. This may be the result of patients waking in the middle of the night for toileting needs or carrying out activities of daily living while unable to sleep in the hospital environment.

Morse Fall Scale

The Morse Fall Scale is indeed reliable and valid in the bone marrow transplant population at this hospital. This was supported by evidence that there was a significant difference in Morse Fall Scale scores between fallers and non-fallers. Further study of the validity of the MFS for use in BMT and whether additional variables might be needed is recommended. For other hospitals and patient populations, it is recommended to review the literature on several fall assessment scales and review the circumstances relating to each unit's fall characteristics.

When individual items were evaluated, history of falls was found significant in this bone marrow transplant population. In this study, three patients had repeated falls. The first patient was initially identified on the Morse Fall Scale as being at "moderate" risk prior to falling. On this patient's subsequent admission he was correctly identified as being at "high" risk for falls due to a past history of falling. Two other patients were initially identified as "high" risk patients for falling, which also supports validity of this scale in this population. However, on subsequent admissions these patients were not entered on the MFS as having a history of falling. Yet, history of falls was found



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insignificant in earlier studies (O'Connell, Cockayne, et al., 2005; O'Connell, et al., 2007).

Secondary diagnosis was found to be significant in this retrospective chart review. This is consistent with a case control study by Krauss and colleagues (2005) who found patient risk factors that were significantly correlated with an increased risk of falling included the use of sedatives and/or hypnotics, antiarrhythmic, nonnarcotic analgesics, and diabetes medications.

Muscle weakness was also found to be significant in the bone marrow transplant population. This is consistent with analysis by Hitcho and colleagues (2004), who found muscle weakness contributed to 81% of patient falls. In addition, Hsu and colleagues (2004), found that 71.4% of their patients in an experimental group had been appropriately identified by nurses as being at a higher risk for falls due to poor balance and weaker lower limb muscle strength.

Other contributing factors

Temperatures

Temperatures were assessed to determine if there was a significant difference between fallers and non-fallers. In this study, no significant difference was found with elevated temperatures; however, it is important to note that some patients become confused and weak with elevated temperatures in this population. In the non-faller group, patients had a decreased white blood count (WBC) with a mean of 0.91 with seven patients becoming febrile of day 11. This may be indicative of reaching nadir (decreased blood counts) related to chemotherapy. At nadir patients are less able to mount a fever, which is why oncology nurses monitor for fevers of 100.5. Future studies should consider



temperatures as a study variable in falls research to determine if fevers are a contributing factor to falls.

Laboratory Values

In this study, platelet count, glucose, blood urea nitrogen (BUN), and phosphorous showed significant differences between fallers and non-fallers. The mean platelet count for fallers was found to be higher in fallers as compared to non-fallers with M = 90.11 and M = 31.83, respectively. The reasons for these differences are thought to be that fallers were most likely further out from treatment (i.e. chemotherapy or bone marrow transplant) as compared to the non-fallers. The non-fallers were more likely to be at their nadir (lowest point in their blood counts) and may have been monitored and assessed more frequently. The lower platelet count in the non-faller group may illustrate that these patients were more likely to be receiving active treatment, which can cause a decrease in platelet count known as thrombocytopenia. This may be confirmed by the difference in white blood count (WBC) in both groups. The fallers had recovered their WBC with a mean of 9.16 as compared to the non-faller group whose mean was 0.91. A lower white count can be indicative of current treatment and more frequent nursing assessments.

Glucose levels were found to be higher in fallers (M = 135.7) as opposed to nonfallers (M=110.7). The reasons for this are unclear; however, higher glucose levels are typically found in sicker patients (i.e. infection) or patients who have steroids prescribed for them.

Blood urea nitrogen (BUN) was also found to be more elevated in fallers (M=15.48) as compared to non-fallers (M=10.37). These levels are within the normal



ranges of BUN, 7 to 25. Patients with elevated BUN levels often are dehydrated or have compromised renal function. It is unclear what role this might have played in falls; further research is indicated.

Phosphorous levels were found to be decreased in fallers (M=2.54) when compared to non-fallers (M=3.85). Potential reasons for a lower phosphorous level include nausea, vomiting, and diarrhea. These symptoms often result in the need to ambulate frequently to a bedside commode or bathroom.

Consistent with findings from O'Hagan and colleagues (2005) and Morse and colleagues (1989), this study revealed that there is no statistical difference in hemoglobin levels of fallers and non-fallers in the bone marrow transplant population. Hemoglobin levels were found to be relatively similar in fallers and non-fallers, M=9.86 and M=9.38, respectively. These values both represent anemia; however, this is a common finding in the oncology population. Future studies should consider having non-oncology patients as a control group to determine hemoglobin significance. Future findings may shed light on future nursing implications of monitoring laboratory values more closely.

Vital Signs and Medications

In this retrospective study, it was difficult to gather vital signs and medications taken within 24 hours. During the time frame of January 2007-January 2009 this hospital changed electronic charting systems, thus making it more difficult to obtain certain information needed for the chart review.

Pain medications and sedating anti-nausea medication, such as Ativan, are commonly prescribed on this unit. In addition, steroids are also used in conjunction with



chemotherapy regimens and have the tendency to raise blood glucose levels in these patients; which often requires additional therapy to maintain normal glucose levels.

Inter-Rater Reliability

Inter-rater reliability was not ideal and might have been improved by educating the lead nursing research scientist at this hospital on the use of this chart audit or have a sample chart audit pre-completed as a reference. Difficulties arose with this nursing research scientist not being familiar with the abbreviated version of the drawing of part of the CMP. This abbreviated version allows health care providers to save time. However, it apparently is not universally well known. This part was missed on both the fallers and non-fallers forms. In addition, the age of the patient was missed a lot. The principal investigator used the age of the patient at the time of the initial fall or during the time of day 11. However, this research scientist used the current age of the patient as she was completing the chart audit.

The low scores for the non-fallers resulted from the research scientist looking at Morse Fall score information and laboratory values from the date of admission. The 11 days were not added to the date of admission to achieve accurate results. Subsequently, the directions on the chart audit were amended from stating 24 hours within day 11 for non-fallers to add two words for clarification. The chart audit now states 24 hours within day 11 of admission for non-fallers. The investigator welcomes future studies to utilize her chart audit or modify it for the purposes of patient populations in their setting. It is recommended that all raters discuss the form prior to utilizing it in a study instead of assuming that it is self-explanatory.



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Implications for Nursing

Nursing curriculum should emphasize the importance of identifying and preventing patient falls. Nursing students should be introduced to the *Morse Fall Scale* or other falls assessment scales currently in use in their local communities. Introduction to such scales brings familiarity, a level of comfort, and the ability to accurately assess patients at high risk for falling. Further, unit-specific education on patient safety and interventions to decrease falls should be the focus of all nursing units. In addition, hospital orientation for new nurses should include case studies on how to correctly score patients. Educating staff closes the gap on leaving fall scales open for interpretation by the user.

It is possible that nurses check on patients less frequently during the night shift because they are expected to be asleep. However, 77% of falls on the night shift occurred between 1:30am and 6:20am, it is suggested that nurses and nurses' aides arrange beds in the lowest position, keep call lights within reach, offer frequent toileting and assistance, and make frequent comfort rounds during these times to help decrease and/or prevent patient falls.

Laboratory findings from this study suggest that all patients regardless of treatment modality must be monitored more closely. These values can indicate the extent of treatment a patient is receiving and some of the side effects a patient may experience. For instance, patients with lower phosphorous and electrolyte levels may present this way from side effects of active treatment or simply from nausea, vomiting, or diarrhea while hospitalized. Laboratory values share volumes of information with nurses. Nurses need to



become familiar with laboratory values and the signs and symptoms of laboratory values outside of these ranges to truly assess and keep their patients safe and free from injury.

In this sample, the mean number of days between admission and falling in the bone marrow transplant unit was M=14.5, the time when blood counts are lowest. It should be a priority of nurses and nurses' aides to encourage ambulation and/or assist with exercise at least twice daily to maintain lower extremity strength. Observing ambulatory patients can indicate whether patients may have difficulty with their gait and if they could benefit from physical therapy. Being proactive is essential in patient safety.

Conclusions

This is the first study to document falls in the bone marrow transplant population. This study should serve as a stimulus for future studies conducted in the oncology and/or bone marrow transplant population. Further studies should explore these patients prospectively utilizing known group comparisons of non-oncology patients with a larger sample. Studying falls in these patients is essential to understanding the physiological risk factors that may contribute to patient falls. Findings lay the foundation for studying falls in the bone marrow transplant population. It is crucial to study falls in this population in order to make appropriate assessments and interventions to keep this population free from injury.

Recommendations for Future Research

Nurses wishing to study falls in the bone marrow transplant population should consider doing a prospective study of fallers. A prospective study will enable researchers to examine patient characteristics such as co-morbidities, medications taken within a 24



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hour period, vital signs, temperature, laboratory values, fall assessment scores, and other variables of interest such as nadir.



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Appendices



Appendix A

Chart Audit for Fallers & Non-Fallers (Information from 24 hours prior to fall or 24 hours within day 11 of admission for nonfallers)

Hospi	tal: <u>BMTU</u>		Day	Date
Patien	t Unique ID	Circle:	Faller	Non-Faller
Days f	From Admission:	_	Date & T	ime of Fall:
1.	Age:			
2.	Gender:	Male	F	emale
3.	Diagnosis:			
4.	Blood Pressure prior to Fall	(or ranges on	day 11 for n	on-fallers):
5.	Temperature prior to Fall (or	Tmax on day	11 for non-	fallers):
The fo	ollowing information should	be found on	the Morse l	Fall Assessment Scale.
6.	History of Falls:	Yes	Ν	0
7.	Presence of Secondary Dx:	Yes	Ν	0

Yes

Yes

Yes

Yes

No

No

No

No

12. Morse Fall Score:

11. Muscle Weakness:

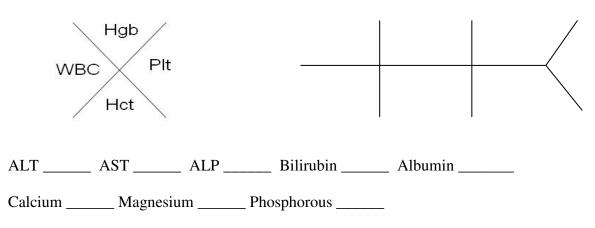
10. Confusion:

8. Use of Ambulatory Aids:

9. Current IV Administration:



The following laboratory values and medication should be collected within 24 hours of the patient fall (or day 11 for non-fallers).



13. Chemotherapy Medication:

	Ordered Information			Administered Information		
Medication	Dose	Route	Schedule	Dose	Route	Times Given

14. Adjunct Medication (e.g. anti-depressants, sedatives, anti-emetics, diuretics, antiarrhythmics, antihistamines, opioids)

Ordered Information			Administered Information			
Medication	Dose	Route	Schedule	Dose	Route	Times Given



15. Diabetic Medication

	Ordered Information			Administered Information		
Medication	Dose	Route	Schedule	Dose	Route	Times Given



Appendix B Morse Fall Scale (MFS) Florida Hospital Orlando

(Adapted from VA National Center for Patient Safet	y Fall Prevention &	Management)
Variables	Numeric	Score
	Values	
1. History of falling	Yes	
(immediate or within 3months)	25	
	No	
	0	
2. Secondary diagnosis	Yes	
(more than 1 diagnosis is listed on the patient's	15	
chart)		
	No	
	0	
3. Ambulatory aid		
None/bed rest/wheelchair/nurse assist (0)	0	
None/bed rest wheelenan/hurse assist (0)	0	
Crutches/cane/walker (15)	15	
Clutches/calle/walker (15)	15	
Examitance (20)	20	
Furniture (30)	30	
(clutching as support)	X 7	
4. IV or IV Access	Yes	
	20	
	No	
	0	
5. Gait/Transferring		
Normal/bed rest/immobile (0)	0	
Weak (10)	10	
Impaired (20)	20	
6. Mental status		
(Patient self-assessment of ambulation)		
Oriented to own ability (0)	0	_
(realistic to mobility level)		
Forgets limitations (15)	15	
(unrealistic self-evaluation)		
	se Fall Scale Score –	T . 4 . 1

Morse Fall Scale Score = Total



Morse Fall Scale Scoring:

0-24 = Low Risk Fall Prevention Interventions 25-49 = Moderate Risk Fall Prevention Interventions >=50 High Risk Fall Prevention Interventions



Appendix C

Letter of Approval from Florida Hospital



Center for Nursing Research & Innovation

February 11, 2009

Dr. Susan McMillan University of South Florida College of Nursing 12901 Bruce B. Downs Blvd - MDC 22 Tampa, FL 33612

Dear Dr. McMillan,

Pending the University of South Florida's IRB approval, Lura Henderson, will be able to conduct her master's thesis titled "Falls in bone marrow transplant patients: A retrospective study" at Florida Hospital, Orlando.

Please feel free to contact me if you have any further questions or concerns.

Sincerely,

M. Lindell Joseph, PhD, RN Florida Hospital Center for Nursing Research & Innovation Lead Research Scientist Mobile (407) 739-6161



Appendix D

IRB Approval from Florida Hospital



Florida Hospital Institutional Review Board 212 K. Winter Fark Street Orlando, FL 32804 Telephone: (407) 303-5581 Fac: (407) 303-5638 FWA 00002060

March 11, 2009

Lura Henderson RN FHCI 601 East Rollins Street Orlando FL 32804

Dear Ms. Henderson:

NOTE: THIS LETTER PERTAINS ONLY TO IRB APPROVAL. THIS STUDY MUST NOT BE INITIATED WITHOUT CLEARANCE FROM THE FLORIDA HOSPITAL OFFICE OF RESEARCH ADMINISTRATION (ORA) AND APPROVAL OF OTHER APPROPRIATE HOSPITAL COMMITTEES AND/OR DEPARTMENTS.

FH 朱 2202-1850; Investigator Initiated Study Title: Falls in Bone Marrow Transplant Patients: A Retrospective Study

Florida Hospital IRB Exempt Designation Date: 03/11/09 Meeting Date for FH IRB Exempt Designation Notification: 04/14/09 Exemption Granted under: 45 CFR 45.101(b) Waiver from Informed Consent Granted under: 45 CFR 45.118(d) Waiver from HIPAA Authorization Granted: No identifying information will be released outside of Florida Hospital

Please be advised that, in response to your request and on behalf of the Florida Hospital IRB, the IRB granted exempt status to the study as noted above.

It is your responsibility to remain in compliance with all applicable state and federal regulations regarding research as well as adhering to the Florida Hospital IRB Handbook for the Protection of Human Research Subjects.

You are reminded that a change in the study of the project that increases risks to subjects requires resubmission and approval of the IRB prior to initiation of the change in study or informed consent (if an informed consent exists for the study).

Laura Oum

Laura Orem, CIP, CIM IRB Program Manager IRB Member Florida Hospital IRB



Appendix E

IRB Approval from the University of South Florida



DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE Institutional Review Boards, FWA No. 00001669 12901 Bruce B. Downs Bird, MDC035 • Tampa, FL 336124799 (813) 9745638 • FAX (813) 9745618

March 6, 2009

Lura Henderson, RN, BSN College of Nursing 85 Davis Blvd. Apt 1D Tampa, FL 33606

RE: Expedited Approval for Application for Initial Review including your <u>Application for</u> <u>Waiver/Alteration of HIPAA Authorization</u> IRB#: 107692 Title: Falls in Bone Marrow Transplant Patients: A Retrospective Study Study Approval Period: <u>Approval START date: 02/25/2009</u> to <u>Approval END date:</u> 02/24/2010

Dear Ms. Henderson:

On Expedited Review Date: 02/26/2009, Institutional Review Board (IRB) reviewed and APPROVED the above protocol for the period indicated above. It was the determination of the IRB that your study qualified for expedited review based on the federal expedited category number #4 -Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Expedited 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt. This approval includes a Waiver/Alteration of Informed Consent.



The IRB also reviewed and APPROVED your <u>Application for Waiver/Alteration of HIPAA</u> Authorization for the above protocol as outlined below:

Your Application for Waiver of HIPAA Authorization has been approved for you to conduct a retrospective review of medical charts maintained at the Florida Hospital in Orlando, involving those patients who received treatment between January 1999 and January 2009 who were fallen on the bone marrow transplant unit, as noted in the application.

Please note: approval of your waiver/alteration of HIPAA authorization is based upon your having satisfied the following HIPAA Privacy Rule mandates:

 The use or disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of the individual;

- 2. The research could not practicably be conducted without the waiver or alteration; and
- 3. The research could not practicably be conducted without access to and use of the PHI.

Please note, if applicable, the enclosed informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on page one of the form. Valid consent must be documented on a copy of the most recently IRB-approved consent form. Make copies from the enclosed original.

Please reference the above IRB protocol number in all correspondence regarding this protocol with the IRB or the Division of Research Integrity and Compliance. In addition, we have enclosed an <u>Institutional Review Board (IRB)</u> <u>Quick Reference Guide</u> providing guidelines and resources to assist you in meeting your responsibilities in the conduction of human subjects research. Please read this guide carefully. It is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-9343, or, for HIPAA-specific questions, please contact Vinita Witanachchi J.D., Assistant Director, HIPAA & COI, at 974-5478.

Sincerely,

Barry Borberen MO

Barry B. Bercu, M.D., Chairperson USF Institutional Review Board

Enclosures: (If applicable) IRB-Approved, Stamped Informed Consent/Assent Documents(s) IRB Quick Reference Guide

