

Conclusions: The use of antibiotic prophylaxis in pediatric HSCT decreased the incidence of bacteremia during transplant. The use of antibacterial prophylaxis in pediatric patients undergoing HSCT should be considered, and prospective studies are needed to confirm our results.

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Improvement of Blood Glucose Control on the Bone Marrow Transplant (BMT) Unit: A Retrospective Review of Our Quality Improvement Pilot Program

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Background: Multiple studies of improved glycemic control in critically ill patients have yielded contradictory results. Few studies on inpatient hyperglycemia exist in the BMT population. We undertook a quality improvement project to improve blood glucose (BG) control with a goal of increasing the proportion of time that patients on our BMT service spent within the range of 70–200 mg/dl.

Methods: With the Division of Endocrinology, an algorithm for the initiation and modification of finger sticks and anti-hyperglycemic medications was created and implemented on the Tufts Medical Center BMT service for admissions between 4/1–6/30/13 that were predicted to be > 48 hours in duration (intervention). Using the Remote Automated Laboratory System (RALS), the percent of time in each BG range (<70, 71–110, 111–140, 141–199, >200) was calculated for the entire floor in the three months prior to implementation (baseline) and during the three months of the pilot program. As the oncology service is included in this

calculation and was not part of our intervention, admissions were analyzed for comparison. With IRB approval, retrospective data of admissions >48 hours was collected to evaluate BG, length of stay, and infectious complications.

Results: The baseline cohort included 64 BMT admissions, while there were 70 BMT admissions in the intervention cohort and 102 oncology admissions not part of the intervention. 14% of patients in each of the three admission groups had a history of diabetes. 30% of all patients on BMT were discharged on steroids, compared to 10% on oncology. On admissions when finger stick evaluation of BG was initiated (36% in the BMT intervention cohort, 25% in the BMT baseline cohort, ($P = 0.25$), more patients received short acting insulin as per the algorithm (21% vs 6%, $P = 0.016$), but there was no difference in the number transitioned to long acting insulin. In the intervention cohort, the proportion of time spent in the BG range of 71–199 increased, with less time spent with a BG < 70 or > 200 (Figure 1, $P < 0.0001$). Fewer BMT patients were hyperglycemic within 48 hours of a documented infection in the intervention group compared to the baseline cohort, but the overall rate of infection among the three groups was low. Within each cohort on BMT, 6 admissions had a discharge BG > 200, and 3 were discharged on new anti-hyperglycemic medications.

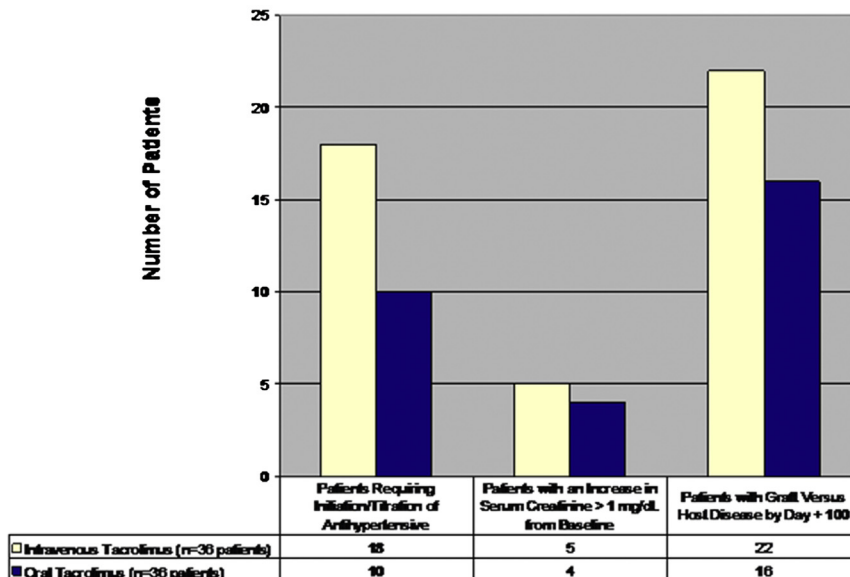
Conclusions: We were able to demonstrate the feasibility of implementing a program to control and track blood glucose. Not only were we able to limit hypoglycemic episodes, there was a lower rate during the intervention compared to baseline. The results of this retrospective study will allow the design of larger trials to determine whether BG control has an impact on length of stay, infectious complications, and mortality.

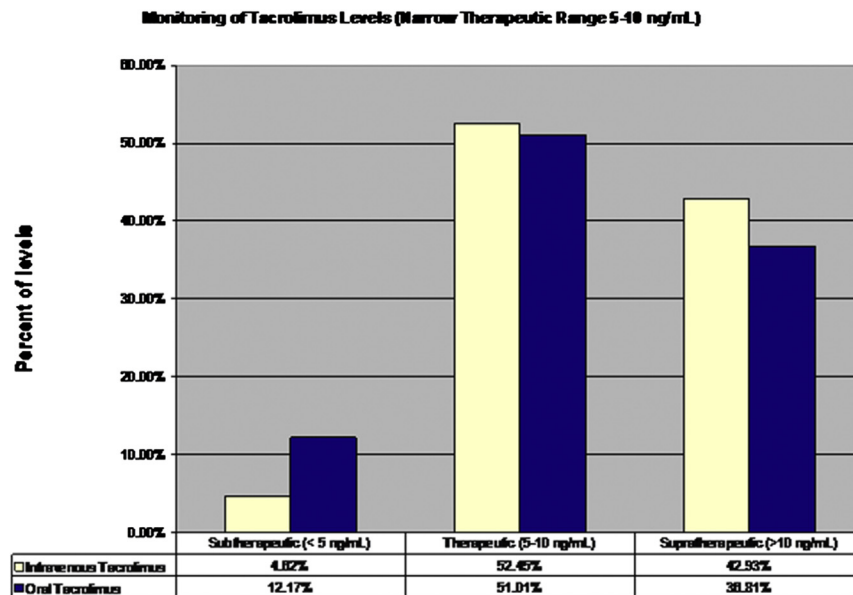
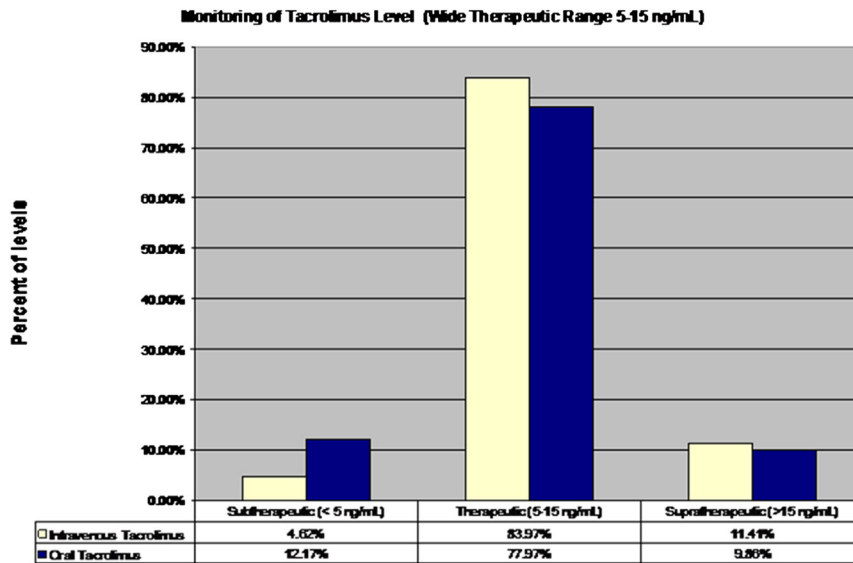
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Retrospective Analysis of Oral Versus Intravenous Tacrolimus in Patients Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

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Safety Endpoints





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Background: Patients undergoing allogeneic hematopoietic stem cell transplant (HSCT) require immunosuppression to prevent complications associated with graft versus host disease (GVHD). Tacrolimus is used as part of combination GVHD prophylaxis. Tacrolimus is available as an oral formulation but is often administered as a continuous IV infusion due to concerns of absorption and toxicity. We report our experience substituting oral tacrolimus for IV tacrolimus as a component of GVHD prophylaxis regimens in patients admitted for HSCT.

Methods: We conducted a retrospective chart review of 36 patients who underwent an allogeneic HSCT and received oral tacrolimus and 36 patients who received IV tacrolimus. The primary endpoint was percent of tacrolimus levels in therapeutic range. Other pertinent endpoints included the

incidence of GVHD through day 100 post-transplant, increases in serum creatinine greater than 1 mg/dL from baseline, initiation or titration of scheduled anti-hypertensive agents, incidence of dialysis, cost, and hospital length of stay.

Results: Groups were similar at baseline in terms of age, gender, indication for transplantation, source of stem cells, parental nutrition, and length of stay for transplant admission. The percent of therapeutic tacrolimus levels was similar between groups (< 10% difference in percent of therapeutic levels, see Tacrolimus Monitoring Figures). The number of peripheral laboratory draws was reduced from 368 to 44 draws as the majority of levels obtained while on oral tacrolimus (n = 301 levels) were drawn from existing central lines. No difference was noted in safety endpoints or the occurrence of acute GVHD to day +100 post-transplant (See "Safety Endpoints Figure"). Based on the average wholesale price of tacrolimus formulations, this change in practice resulted in a cost savings of up to \$290000.

Conclusion: Our institution experience with oral tacrolimus for GVHD prophylaxis supports continuation of this practice as a viable alternative to IV tacrolimus and results in significant cost savings.

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Palifermin Use in Lymphoma Patients Undergoing Autologous BEAM Transplants

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Background: Palifermin is a human recombinant keratinocyte growth factor. It was approved by the FDA in 2004 for decreasing the incidence and duration of oral mucositis in patients receiving high dose chemotherapy and stem cell rescue. Approval followed two randomized, placebo-controlled, multicenter trials conducted in patients with hematologic malignancies undergoing myeloablative conditioning with TBI. After approval, palifermin use was extended to non-TBI based conditioning regimens. In 2008, our institution began use of palifermin in lymphoma patients undergoing BEAM conditioning and ASCT. Our goal in this study was to assess the efficacy of such a strategy in a non-TBI based transplant group.

Methods: From 1/2008 through 6/2013 we performed 75 BEAM/ASCT on lymphoma patients using palifermin. We compared this group to the preceding 75 lymphoma patients who received BEAM auto-conditioning without it. The two cohorts were compared for incidence of fever, positive blood cultures, positive urine cultures, TPN use, PCA use, and length of stay (LOS). Data was collected retrospectively.

Results: Results are summarized in the table below. Of note, there was a statistically significant difference ($p < 0.05$) of fewer febrile episodes in the palifermin group and TPN use. However there were no statistically significant differences in positive blood cultures, urine cultures, PCA use, or LOS.

Conclusion: Mucositis has been associated with increased incidence of fever. Inflammation rather than infection has been postulated as the mechanism for mucositis fever. Significantly fewer patients developed fevers in the palifermin group though there was no difference in the incidence of positive cultures. Palifermin reduced the use of fever workups and the empiric use of antibiotics. TPN use was also curtailed by palifermin administration. Despite its mechanism of action of decreasing mucositis, neither PCA use nor LOS differed substantially between the groups. It may be that mucositis is not a major rate-limiting step to discharge as symptoms often tend to resolve shortly after engraftment. Further analysis comparing time to engraftment with length of stay may help

Table

Comparison of Patient Arms (Palifermin vs. No Palifermin)

Characteristic	Palifermin (N=75)	No Palifermin (N=75)	P-value
Fever	46	72	<0.05
Positive Blood Cultures	5	11	NS
Positive Urine Cultures	11	5	NS
TPN	17	58	<0.05
PCA	52	56	NS
Mean LOS	21	22	NS
Median LOS	21	21	NS
Range for LOS	12-36	12-37	N/A

NS: Not statistically significant (using P value of <0.05)

answer this question. Important future studies should include pharmacoeconomic analysis of the relationship between palifermin, TPN antibiotics, and growth factor use as well as overall cost and outcomes of performing BEAM/ASCT with and without palifermin. A CIBMTR retrospective study with additional data collection analyzing palifermin use in BEAM auto-patients may be an expeditious way to answer many of these questions.

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A Prospective, Randomized Clinical Trial of Cryotherapy Vs. Supersaturated Calcium Phosphate Rinses Vs. Saline Rinses for the Prevention of Oral Mucositis in Patients with Multiple Myeloma (MM) Receiving High-Dose Melphalan (HDM) and Autotransplantation

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Background: Oral mucositis (OM) is a major complication of HDM. Previous studies analyzing the role of oral cryotherapy (CT) in the prevention of OM are small or include patients treated with multiple conditioning regimens.

Study Purpose: To compare the efficacy of CT plus saline solution (SS) mouth rinse vs. SS alone vs. supersaturated calcium phosphate rinses (Caphsol®) to prevent HDM-induced OM in patients with MM undergoing autotransplantation

Methods: One hundred and seventeen MM patients, scheduled to receive HDM (140-200 mg/m²) followed by autotransplantation at the Audie L. Murphy Memorial Veterans Hospital in San Antonio, Texas, were randomized to the above mentioned groups (Table 1). Patients were assessed daily for OM until discharge or resolution of OM, using the World Health Organization (WHO) mucositis scale. Duration

Table 1

Patient Characteristics

	Total	Caphsol®	Cryotherapy	Saline Solution	p-value
Patients, n	117	39	40	38	
Age, median (range)	62 (39-75)	62 (45-68)	62 (39-75)	61.5 (43-70)	0.7696
Gender, n (%)					0.8962
Male	110 (94)	36 (92)	38 (95)	36 (95)	
Female	7 (6)	3 (8)	2 (5)	2 (5)	
Race/Ethnicity, n (%)					0.5164
Caucasian	56 (48)	23 (59)	16 (40)	17 (45)	
African Americans	40 (34)	11 (28)	15 (37)	14 (37)	
Hispanic	21 (18)	5 (13)	9 (23)	7 (18)	
Karnofsky score, n (%)					0.8394
70	1 (1)	0 (0)	1 (2.5)	0 (0)	
80	16 (14)	6 (15)	6 (15)	4 (11)	
90	100 (85)	33 (85)	33 (82.5)	7 (89)	
Serum Creatinine, mean (SD)	1.12 (0.67)	1.28 (0.93)	1.00 (0.29)	1.09 (0.63)	0.1715
Diabetes, n (%)					0.9912
Yes	30 (26)	10 (26)	10 (25)	10 (26)	
No	87 (74)	29 (74)	30 (75)	28 (74)	
Dentures, n (%)					0.6336
Yes	32 (27)	9 (23)	13 (32)	10 (26)	
No	85 (73)	30 (77)	27 (68)	28 (74)	
Smoking, n (%)					0.9122
Yes or history	89 (76)	30 (77)	30 (75)	29 (76)	
Never	28 (24)	9 (23)	10 (25)	9 (24)	