Background: Probiotic supplementation has been promoted for a variety of health conditions. Increased marketing and over-the-counter (OTC) access in pharmacies, health food stores and grocery chains has also led to increased availability of these agents. Since safety of probiotic supplementation within the hematopoietic cell transplant (HCT) population is unknown, we sought to evaluate the incidence and outcomes of bacteremia due to organisms common to many of these OTC probiotic supplements in a population of HCT recipients.

Methods: We reviewed all blood culture results from a cohort of HCT recipients transplanted at Fred Hutchinson Cancer Research Center in Seattle, WA between 2002-2011. Patients with at least one positive blood culture for common probiotic organisms (*Lactobacillus* species, *Bifidobacterium* species, or *Streptococcus thermophilus*) within one-year post-HCT were considered cases for this study. Patients with evidence of preexisting bacteremia from these agents (3 months prior to HCT) were excluded. Data were collected from center databases, which contain archived laboratory data, patient demographics, and clinical summaries.

Results: A total of 18/3799 (0.47%) HCT recipients developed bacteremia with *Lactobacillus* species within one-year post-HCT; no events with *Bifidobacterium* species or *S. thermophilus* were identified. Patients who developed these events had a median age of 49 years (IQR: 41, 53), and the majority were allogeneic transplant recipients (n=13, 72%). Most patients had a singular positive blood culture (n=17 [94%]); one patient developed prolonged bacteremia (30 days). Positive blood cultures for *Lactobacillus* species occurred at a median of 84 days post-transplant (IQR: 34, 127), with most (n=12 [67%]) occurring within the first 100-days. The overall incidence rate of Lactobacillus bacteremia was 1.54 cases per 100,000 patient-days; the highest incidence occurred during the first 100-days post-transplant (3.31 cases per 100,000 patient-days). Incidence did not deviate significantly by year of transplant. At the time of diagnosis, most HCT recipients were inpatient (n=12 [67%]) for a median of 37 days (IQR: 6, 78) prior to development of bacteremia. Among outpatients (6/18 [30%]), four were admitted within 30 days after their first positive culture. Eight patients (44%) were diagnosed with acute graft-versus-host disease of the gut prior to the development of bacteremia. No Lactobacillus-attributed mortality was observed during follow-up.

Conclusion: Organisms frequently incorporated in available OTC probiotic supplements are infrequent causes of bacteremia after HCT. Studies evaluating the use of probiotics among these high-risk patients are needed.

312

Parametric Response Mapping as a Diagnostic Indicator of Bronchiolitis Obliterans Syndrome

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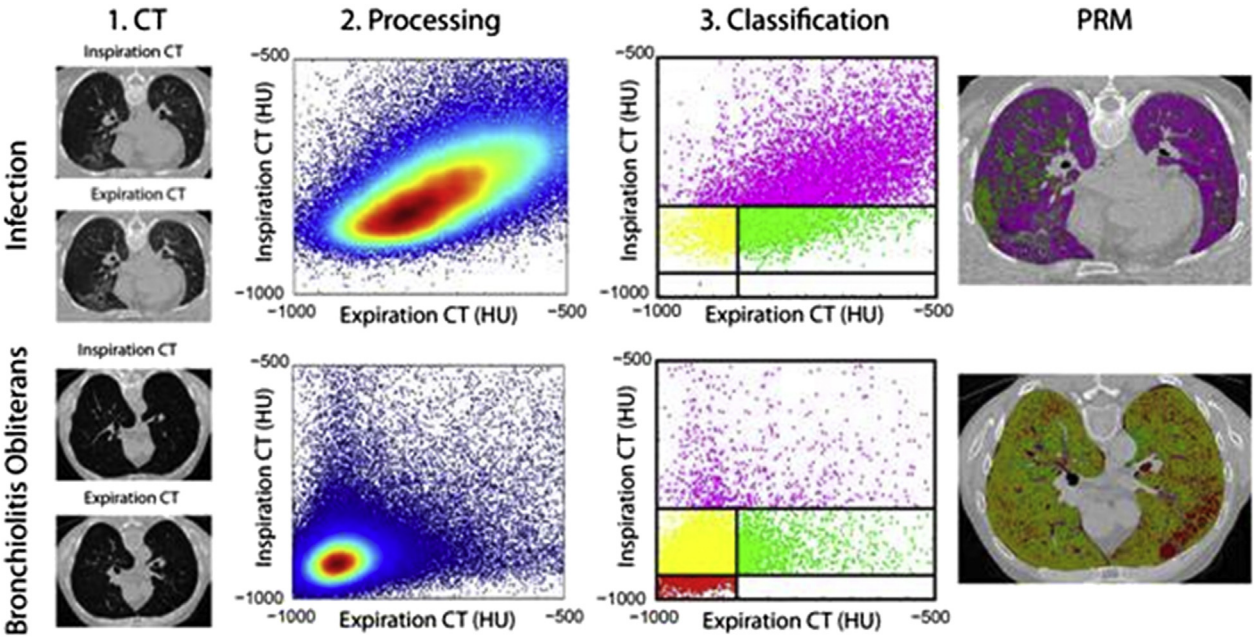
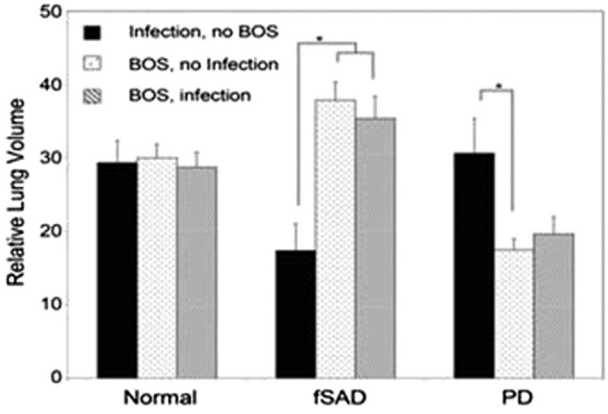
Bronchiolitis obliterans syndrome (BOS) is associated with significant morbidity and mortality following allogeneic stem cell transplant (SCT). Defined by NIH consensus criteria, the diagnosis is often confounded by the presence of concurrent infectious complications in affected patients, making interpretation of spirometry and imaging studies difficult. We now report a novel imaging biomarker that identifies obstructive small airway disease, even in the presence of infectious pneumonitis. A computed tomography (CT)-based image processing technique termed parametric response mapping (PRM) has been generated at our center to capture parenchymal alterations consequent to lung disease. PRM is performed from a biphasic (inspiratory and expiratory) high-resolution-CT (HRCT), with subsequent image co-registration of the paired HRCT data, and classification of individual voxels within the lung parenchyma as either (a) normal, (b) severe emphysematous disease, (b) functional small airway disease (fSAD)





characteristic of BOS or (d) parenchymal disease (PD) characteristic of infection (Figure). Spatial information is retained allowing for visualization and quantification of disease within individual lobes. The relative volumes for each classification are determined by normalizing the sum of all voxels within a particular class to the total lung volume. Using HRCT, broncho-alveolar lavage (BAL) and spirometry data, 55 SCT recipients were classified into one of 3 groups: A) Infection, no BOS (n=11); B) BOS, no infection (n=34); and C) BOS + Infection (n=9). BAL were performed within 1 week of the HRCT, in all 55 patients. Mean values (±SE) for functional small airway disease (fSAD), parenchymal (infectious) disease (PD), and normal lung parenchyma were determined for each group (Figure).

Results: Distinct imaging profiles were identified for patients with BOS and for patients with an acute infectious pneumonitis. In particular, the %fSAD was significantly greater in patients with BOS when compared to those with infection alone, 38±2% vs 17±4%, p=0.05. There was no difference in the %fSAD for subjects with BOS, whether a concurrent infection was present or not, 35±3% (BOS) vs 38±2% (BOS + Infection), p=31. Patients with an acute infectious pneumonitis had significantly higher levels of PD than patients with BOS, 30±4% vs 17±1.5%. In 7 of the 34 (21%) BOS cases, significant increases in fSAD (>30%) were present when radiographic features characteristic for BOS (air trapping, bronchiectasis, septal lines) were either absent or minimal on HRCT. There were no differences in PRM imaging by the type of infection. PRM provides a major advance in our ability to diagnose small airway obstruction that characterizes BOS, even in the presence of an active pulmonary infection. A prospective trial comparing PRM with spirometry and standard HRCT as an early indicator of BOS is planned.

CRA -DATA MANAGEMENT

313

Transplant Center Survey of CIBMTR Internal Assessments

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Background: The University of Maryland Blood and Marrow Transplant (BMT) team has firmly established a culture of continuous quality improvement to assure the utmost accuracy of CIBMTR data. In early 2012, Minas and Ruehle reported the significance of auditing 10 commonly used data points. In early 2013, Minas and Ruehle set out to further improve CIBMTR data accuracy by combining their original set of commonly used data points with 19 additional ones.

Methods: To explore the internal assessments (IA) audit activities used by other transplant centers to ensure CIBMTR data accuracy, the University of Maryland BMT team developed an anonymous survey consisting of 6 quantitative and 3 qualitative questions. One hundred and thirty seven NMDP (National Marrow Donor Program) and CIBMTR (Center for International Blood and Marrow Transplant Research) affiliated transplant centers (TC) were invited to participate. The survey was administered using Survey Monkey.

Results: A total of 86 (62.8%) responses were received. Of these, 57% were from centers that transplanted over 100 patients per year. Most TC (89%) performed some type of IA for their CIBMTR forms. Centers reported that IA were most often conducted by a quality assurance manager (46%). Of the TC that performed IA, 76% reported using FACT (Foundation for the Accreditation of Cellular Therapy) and additional data points as opposed to only FACT data points. Fifty-six percent of TC that conducted IA reported that audits were performed on 10%-30% of patient data on a regular basis, while another 19% reported performing IA for 100% of patient data. Internal assessments were most commonly performed on a quarterly basis (35%).

Conclusion: Most TC participate in some sort of IA. The majority of TC perform IA using FACT and additional data points, which likely improves accuracy of the data. Although time is a consideration, completing 100% IA assures the most accurate data. Surveys such as these provide us with knowledge of how all transplant centers assure quality CIBMTR data and prepare for external audits, such as CIBMTR and FACT.

N.M. Minas, K. Ruehle. CIBMTR Monthly Internal Assessment Improves Quality of Registry Data. ***Biology of Blood and Marrow Transplantation***. Volume 18, Issue 2, Supplement, Page S239, February 2012 [abstract].

N.M. Minas, K. Ruehle. A Culture of Continuous Quality Improvement Improves Registry Data**. *Biology of Blood and Marrow Transplantation.*** Volume 19, Issue 2, Supplement, Pages S169-S170, February 2013 [abstract].

314

Extending the Bridg Model with Hematopoietic Cell Transplant Concepts

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Organizing data into coherent groups, i.e. data domains, is key to understanding relations between complex subject areas such as information collected around one simple