**Transplantation**

*What Is the Future of Generics in Transplantation?*

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**Keywords:** respiratory syncytial virus; solid organ transplant; stem cell transplantation; viral infection

**Abstract**

Generic immunosuppressive drugs are available in Europe, Canada, and the United States. Between countries, there are large differences in the market penetration of generic drugs in general, and for immunosuppressive drugs in particular. The registration criteria for generic immunosuppressive drugs are often criticized. However, it is unlikely that the criteria for registration of narrow therapeutic index drugs are going to change, and bioequivalence studies, performed in healthy volunteers, will remain the backbone of the registration process. It would be good if the registration authorities would demand that all generic variants of an innovator drug have the same pill appearance to reduce errors and promote drug adherence.

To allow for safe substitution, a number of criteria need to be fulfilled. Generic substitution should not be taken out of the hands of the treating physicians. Generic substitution can only be done safely if initiated by the prescriber, and in well-informed and prepared patients. Payers should refrain from forcing pharmacists to dispense generic drugs in patients on maintenance treatment with innovator drug. Instead, together with transplant societies, they should design guidelines on how to implement generic immunosuppressive drugs into clinical practice. Substitutions must be followed by control visits to check if the patient is taking the medication correctly and if drug exposure remains stable. Inadvertent, uncontrolled substitutions from 1 generic to another, initiated outside the scope of the prescriber, must be avoided as they are unsafe. Repetitive subsequent generic substitutions result in minimal additional cost savings and have an inherent risk of medication errors.

Pediatric Transplantation

Group visits in the pediatric heart transplant outpatient clinic

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Keywords: pediatrics; heart transplantation; group visits; outpatient

Abstract

The “GVM” has emerged as an alternative to traditional individualized appointments in the ambulatory care setting. We hypothesized that group visits could successfully be utilized in a PHtx clinic. Seven patients, ages 1–18 yr old, and their families participated in a total of 11 group visits in lieu of individualized appointments. Patients were divided into two groups based on whether they were greater or less than one yr post-transplant. Patient/provider satisfaction, medication adherence, and content retention were ascertained via questionnaires and free-response tests. Total clinic throughput time, including per-patient clinic utilization time, was compared to historical data. Six of seven patients completed the study with one dropout. Overall satisfaction ratings were 3.98 of 4 with all patients reporting that they would “strongly recommend” group visits to others. Health information retention tests demonstrated improvement between pre- and post-tests in eight of nine (89%) of the group visits. Overall clinic utilization decreased by nearly 50% while providing 70 min of face-to-face time with the provider. Medication adherence neared 100% for all patients. The GVM can be successfully applied to the PHtx population with high patient and provider satisfaction, more face-to-face time, excellent content retention, and greatly improved clinic efficiency.

Pediatric Transplantation

Sexually transmitted infection screening and reproductive health counseling in adolescent renal transplant recipients: Perceptions and practice patterns. A study from the Midwest Pediatric Nephrology Consortium

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Keywords: kidney transplantation; pediatric; patient education; psychosocial; sexuality; contraception; counseling

Abstract

We wanted to identify practice patterns and perceived barriers among pediatric nephrologists regarding STI screening and reproductive health counseling in adolescent renal transplant recipients. We created an online Likert-scaled survey. Response rate was 54%. The majority (83%) believed STI risk in their patients was similar to or higher than healthy teens. Interestingly, while 67% felt moderately or very confident in asking about sexual activity and counseling about safer sex, only 43% routinely or always inquired about sexual activity, and only 42% routinely or always counseled about safer sex. Fifty-four percent routinely or always discussed contraceptive options and implications of unintentional pregnancy. Fifty-one percent routinely or always referred patients to a gynecologist or adolescent provider for contraception prescription. The most common counseling mechanism was informal discussions in clinic (87%). Ten percent had no mechanism in place. Major barriers included time limitations, adolescents’ fear regarding confidentiality, and lack of professional training. This is the first report of perceptions and practice patterns of pediatric nephrologists regarding STI screening and reproductive health counseling. Providers seem to recognize the importance of counseling; however, translation into practice remains low. Professional training in this area and increased encounter time could improve counseling delivery and thereby reduce risk in this population.

The Journal of Heart and Lung Transplantation

Post-transplant lymphoproliferative disease in heart and lung transplantation: Defining risk and prognostic factors

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Background

Heart and lung transplant recipients have among of the highest incidence rates of post-transplant lymphoproliferative disease (PTLD). Despite this, there is a paucity of data specific to this group. We collated data on heart, lung and heart–lung transplant recipients with PTLD to identify disease features and prognostic factors unique to this group of patients.

Methods

Seventy cases of PTLD were identified from a single institution (41 heart, 22 lung, 6 heart–lung and 1 heart–kidney transplant) from 1984 to 2013. Demographics, immunosuppression, treatment, response, complications and survival data were analyzed. Uni- and multivariate Cox regression analyses were performed to identify prognostic factors.

Results

The incidence of PTLD was 7.59% in heart–lung, 5.37% in heart and 3.1% in lung transplant recipients. Extranodal disease (82%) with diffuse large B-cell lymphoma (72%) was the most common presentation. Bone marrow involvement (13%) and central nervous system disease (3%) were uncommon. Heart transplant recipients had later onset of PTLD (>1 year post-transplant), with less allograft involvement, compared with lung and heart–lung recipients. Poor prognostic markers were bone marrow involvement (HR 6.75, p < 0.001) and serum albumin <30 g/liter (HR 3.18, p = 0.006). Improved survival was seen with a complete response within 3 months of treatment (HR 0.08, p < 0.001). Five-year overall survival was 29%.

Conclusion

This analysis is the largest to date on PTLD in heart and lung transplant recipients. It provides a detailed analysis of the disease in this group of patients and identifies unique prognostic features to aid risk stratification and guide treatment allocation.
Keywords:

PTLD, heart transplant, lung transplant, post-transplant malignancies

http://www.jhltonline.org/article/S1053-2498%2815%2901295-4/abstract
Transplant Infectious Disease

Opportunistic infections complicating solid organ transplantation with alemtuzumab induction

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Keywords: opportunistic infection; alemtuzumab; SOT

Abstract

Opportunistic infections remain a common complication of solid organ transplantation. Despite significant changes in immunosuppression and infectious diseases prophylaxis, data are limited on the contemporary epidemiology and outcomes of opportunistic infections. Alemtuzumab, a potent lymphocyte-depleting antibody, has been used with increased frequency in solid organ transplant recipients in the last decade. A literature review was performed to summarize the current understanding of the epidemiology, risk factors, and outcomes of opportunistic infections complicating solid organ transplantation with and without alemtuzumab induction therapy. Areas where data are limited regarding opportunistic infections in solid organ transplantation with alemtuzumab induction are indicated.