



A Brief Note on Graft Loss and Clostridium Difficile Disease are Correlated during Transplantation

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Abstract

Solid organ transplant recipients (SOT) frequently experience infectious diarrhea as a result of Clostridium difficile infection (CDI). Within the Swiss Transplant Cohort Study (STCS), our objective was to evaluate the incidence, risk factors, and outcomes of CDI. Between May 2008 and August 2013, we conducted a case-control study on SOT recipients in the STCS who were diagnosed with CDI.

Keywords: Antibiotic; Antibacterial; Clinical practice; Complication Infectious

Introduction

By age at transplantation, sex, and transplanted organ, we matched two control subjects for each case. Conditional logistic regression was used in a multivariable analysis to identify risk factors and evaluate the CDI outcome. Two hundred fifty-eight SOT recipients, including 174 matched controls and 87 CDI cases, were included. The lung had the highest CDI rate, at 1.48, with a 95 percent confidence interval (CI) of 0.93 to 2.24. The overall rate was 0.47 per 10,000 patient days. In a multivariable analysis, the development of CDI was independently linked to antibiotic treatment (HR 4.51, 95 percent CI 2.03- 10.0) and confirmed infections [1]. Receivers who acquired CDI posttransplant had a higher risk of graft loss. The management of SOT recipients may benefit from these findings.

In Europe, the most common cause of infectious diarrhea is Clostridium difficile, with a reported incidence rate of 7 cases per 10,000 patient-bed days. Due to numerous risk factors, including severe underlying diseases, immunosuppression, recent surgery, antibiotic treatment, ganciclovir prophylaxis, gastric acid suppression, and prolonged hospital stay, solid organ transplant (SOT) recipients are more likely than the general population to develop CDI [2]. The clinical spectrum of CDI includes asymptomatic colonization to fulminant pseudomembranous colitis, according to a meta-analysis of SOT recipients that was recently published. There is a lack of and conflicting information regarding the severity of CDI and its effect on graft function in SOT;

A recent Spanish cohort study and two US studies reported a favorable prognosis for CDI in SOT recipients, despite the fact that some authors have described a worse outcome for SOT recipients. These aspects are crucial because recent CDI treatment guidelines prioritize reducing CDI recurrence by stratifying patients according to their clinical severity [3]. The European Society for Clinical Microbiology and Infectious Diseases (ESCMID) and the most recent US American guidelines recommend oral metronidazole as the first option for patients with nonsevere CDI and oral vancomycin for severe CDI. Fidaxomicin achieved significantly lower rates of recurrence of CDI in two clinical trials. Accordingly, the ESCMID guidelines recommend the use of fidaxomicin for patients at risk for recurrent CDI.

All SOT recipients are enrolled in the Swiss Transplant Cohort Study (STCS), an observational national cohort that is followed at six Swiss university centers [4]. The cohort structure and data definitions

have previously been published. All SOT recipients who signed written informed consent and were prospectively enrolled in the STCS between May 2008 and August 2013 were included in this study.

Result

The ethics committees of all participating centers approved the protocol. Standardized electronic case report forms (eCRFs) were used to collect patient data in the STCS database at enrollment, six months, twelve months, and annually following transplantation [5]. Demographic information, infections, antibiotic and antiviral prophylaxis, induction and maintenance immunosuppressive treatments, medical co-morbidities, and surgical complications were among the clinical data extracted from the STCS database. We conducted a nested case-control study, using incidence density sampling to match two controls to each case based on gender, type of transplant, age at transplantation (differences 10 years), and risk factors that are not typically recorded in the STCS database [6]. The STCS database defined controls as SOT recipients without captured CDI. The hospital records and local laboratory databases were checked to ensure that none of these recipients had CDI. We gathered additional information from the local laboratory databases and hospital charts for each and every case and control, including the type of anti-infective treatment given in the three months prior to CDI, the consumption of a proton pump inhibitor (PPI), and the length of stay in the hospital and intensive care unit (ICU). We also collected the clinical severity of CDI for each case, which we divided into three categories (definition below): due to CDI, the antibiotic treatment for CDI, the peak white blood cell count, the platelet nadir, and hospital and ICU admission. The multivariable analyses did not include any clinical variables for which missing data were present.

Discussion

Specifically trained infectious diseases specialists at each center use

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standardized definitions to record the occurrence of infectious events in order to ensure a uniform assessment of the STCS's infectious disease events.¹⁷ The following criteria were used to define proven CDI: the presence of symptoms (diarrhea) and/or clinical signs (evidence of pathologic findings in endoscopy or radiology) [7], as well as the isolation of the pathogen (through culture or antigen) and detection of Clostridium difficile–toxin. According to the American College of Gastroenterology's 2013 proposal, CDI clinical severity was graded as mild-to-moderate, severe, or severe and complicated, without taking serum albumin level into account because this value was only available for a small percentage of patients.¹² Mild-to-moderate disease was defined as diarrhea with any additional signs or symptoms that did not meet the criteria for severe or complicated diarrhea. Abdominal tenderness or leukocytosis of more than 15 000 cells/mm³ was indicators of severe disease. One or more of the following criteria were required for a disease that was severe and complicated: ICU admission for CDI, hypotension, fever greater than 38.5 degrees Celsius, paralytic ileus or significant abdominal distension, mental status changes, leukocytosis greater than 2 G/l, leukopenia less than 35 G/l, serum lactate levels greater than 2.2 mmol/l, and end organ failure. Clinical recurrence was defined as the recurrence of diarrhea following therapy discontinuation, the presence of *C. difficile* or its toxin in the stool, and the requirement for retreatment. Since the *C. difficile* strains were unavailable for further analysis, it was impossible to differentiate between reinfection and relapse [8]. The STCS Infectious Diseases Working Group's criteria were used to define infections during the three months prior to CDI. An isolated pathogen, clinical signs and/or symptoms, and treatment were required for a confirmed bacterial infection. The presence of pathology corresponding to virus replication in biopsy tissues was required for a known viral disease. The presence of non-organ-specific clinical symptoms and the detection of virus replication constitute a viral syndrome. We used the EORTC/MSG Consensus Group definitions for fungal infections. We defined graft loss as follows: dialysis after renal transplantation, recurrence of insulin dependence following pancreas transplant after a heart, liver, or lung transplant, transplantation. Mortality from all causes and mortality from suspected CDI were separately analyzed.

Descriptively, the baseline characteristics of patients are separated for those with and without CDI. In addition, follow-up and outcome information, as well as CDI-specific information for patients who have experienced at least one CDI episode, are presented. Taking into account death prior to CDI as a competing risk, cumulative incidence rates for the initial CDI episode were determined by transplant type.

Conclusion

Univariate and multivariable conditional logistics regression models were used to investigate the risk factors for CDI post-SOT based on the case-control study. In the case-control study, we determined risk exposure either at transplantation or when adequate three months prior to the first CDI occurrence. We adjusted for the multiple testing issue using the conservative Bonferroni method because there were a lot of potential risk factors and few CDI events. The final, generic-only multivariable model was based on the univariate analysis as well as the clinical relevance of potential risk factors, excluding hospitalization due to an excessively large confident interval. Using logistic regression models without risk adjustment, we also looked into the likelihood of recurrent CDI episodes. We also used Cox proportional hazard (PH) models to see how CDI affected the number of graft deaths and losses. We employed noninformative censorship regarding the outcome (death or graft loss). Time-to-event analyses considered CDI to be a time-dependent risk factor. In addition to CDI, the graft loss analysis included baseline and time-dependent risk factors such as surgical complications, medical issues, rejection, and relevant infections. Plotting Schoenfeld residuals to see the effect over time confirmed the PH assumption. When the PH assumption was proven to be correct, despite the strong effect and lack of direction change, no restrictions were imposed, and interpretation was unimpeded.

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