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Abstract

TITLE: Does the Donor Matter? Donor vs. Patient Effects in the Outcome of Next-Generation Fecal Transplant for Recurrent Clostridium difficile Infection

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ABSTRACT BODY:

Abstract Body: Background: Fecal transplantation (FT) is increasingly recognized as an effective therapy for recurrent Clostridium difficile infection (CDI). However, there are many unanswered questions about the therapy. To date, several aspects of the therapy have been shaped by physician perception/assumptions rather than scientific investigation. These include questions about donor selection and the relative importance of donor-specific factors in therapy success. Prevailing wisdom has held that a donor has much more impact on therapy outcomes than patient characteristics. However, initial experiences during the PUNCH CD study, a Phase 2 open-label trial assessing the safety and effectiveness of RBX2660 (microbiota suspension) for recurrent CDI, led us to hypothesize that outcomes are not donor specific. Methods: Patients with recurrent CDI, defined as at least 3 CDI episodes or at least 2 severe episodes resulting in hospitalization, were enrolled in the PUNCH CD study. RBX2660, a next- generation version of FT containing live human-derived microbes, was administered to all patients via enema. A second dose was permitted if CDI symptoms reoccurred < 8 weeks after the first dose. Four donors were used to prepare the RBX2660 used in the study. The product was manufactured in donor-specific batches that could be tracked to individual patients and outcomes. The same batch was used for 1-4 patients. Donors were randomized to patients for both first and second doses. Patients who required 2 doses could have received RBX2660 manufactured from the same donor or different donors; the same pair of donors could be used in a different order. Thus, it would be possible to see if differences in outcomes could be attributed to specific donors. Results: A total of 34 patients (mean age 68.8 years, 67.6% female) received at least 1 dose of RBX2660. Nineteen patients received 1 dose and 15 patients received 2 doses. The individual donor or the order of donors made no difference in the success or failure of treatment with RBX2660. This was especially clear in the case of 1 patient who received 2 doses of the exact same product (both doses from the same donor and same batch). The first dose failed and the second was a success. The donor to patient results for the cohort receiving 2 doses is shown in Figure 2 as an example. Similar trends were observed for patients receiving a single dose. Conclusion: Based on an analysis of small numbers, it appears that the specific donor does not affect the outcomes of RBX2660 for recurrent CDI. Additional research with a larger patient cohort and comparative analysis of donor and patient microbiota communities is needed to provide more details on patient-specific factors predisposing to success or failure with this therapy.

RBX2660 Outcomes by Donor			
Patient	Dose 1 Donor	Dose 2 Donor	Outcome
1	1	3	F
2	3	1	S
3	3	3	S

4*	1	1	S
5	1	2	S
6	1	2	F
7	3	2	S
8	1	1	S
9	1	2	S
10	3	1	S
11	1	3	S
12	1	2	F
13	1	4	S
14	2	2	S
15	2	3	S
Abbreviations: S = success; F=failure * Both doses of RBX2660 were exactly the same (same donor; same batch)			

(No Image Selected)

Disclosure Status

The following authors have completed their 2015 DDW disclosure:: Lee Jones: No Answer. | Courtney Jones: No Answer.