INTRODUCTION

In the United States, Clostridium difficile (C. difficile) infection is the most common healthcare associated infection. High risk populations include 65 years or older, less than 1 year old with an underlying condition, male gender, increased hospitalization time, and recent antimicrobial therapy. There are seven stages of C. difficile infection, including: Carrier stage, C. difficile-associated diarrhea, C. difficile-associated colitis, Pseudomembranous colitis, Fulminant colitis, Recurrent CDI, and Extracolonic Infections.

Diagnosis of C. difficile infection is primarily clinical, with a history including recent antimicrobial use and diarrhea. Laboratory tests are performed on unformed stool samples.

Current treatment options for recurrent C. difficile include primarily a course of vancomycin or fidaxomycin; however, fecal transplant is now becoming a viable option. Standard vancomycin for the treatment of C. difficile is 500 mg PO QID. Fecal Transplant implements a donor that undergoes extensive screening and testing, and the feces can be given to the patient via nasogastric tube, colonoscopy, enema, and via capuslated pill.

One of the most important aspects of C. difficile prevention is hand washing with both soap and water. Appropriate contact precautions, including wearing gloves and gowns when working with these patients, is important to reduce the spread as well.

CLINICAL QUESTION

In patients over 18 years old who have developed recurrent Clostridium difficile, is fecal transplantation compared to vancomycin more efficacious in the treatment of recurrent Clostridium difficile infection?

METHODS

Study 1: Duodenal Infusion of Donor Feces for Recurrent Clostridium difficile

Objective: To determine if fecal transplant with vancomycin for the treatment options for recurrent Clostridium difficile is more effective compared to vancomycin alone or vancomycin with bowel lavage.

Methods: Open label, randomized controlled trial using 43 patients comparing three therapies: initial abbreviated vancomycin regimen with bowel lavage and donor feces, standard vancomycin regimen with bowel lavage, and standard vancomycin regimen.

Results:
• The infusion group initially had an 81% cure rate, that increased to 94% after 2 more participants were re-treated with another donor feces.
• The vancomycin alone group had a 31% cure rate.
• The vancomycin plus bowel group had a 23% cure rate.

Number Needed to Treat (NNT): 1.58.

Study Critique: There was no comparison between the standard vancomycin regimen with bowel lavage to the standard vancomycin regimen groups. Both groups were compared to the initial vancomycin regimen with bowel lavage and donor feces, but not to each other. The small population size is also a disadvantage of this study. This study terminated early and was unable to reach its goal of 40 patients per study group and ultimately diminished its statistical power. For patients that were in the vancomycin groups, if their therapy failed, they were able to choose to have the donor feces given off protocol, which adds confounding variables to this study.

Study 2: Randomized Control Trial: Faecal microbiota transplantation by colonoscopy vs vancomycin for the treatment of recurrent Clostridium difficile infection

Objective: To investigate if fecal transplantation is more effective at treating recurrent Clostridium difficile compared to vancomycin standard therapy.

Methods: Open label, blocked randomised clinical trial comparing faecal microbiota transplantation with vancomycin treatment to vancomycin only treatment.

Results:
• The infusion group initially had a 65% cure rate, that increased to 90% after multiple infusions. Two of the patients in this group died before the end of the study due to C. difficile complications.
• The vancomycin only treatment was 26% effective with five of the 19 cured after treatment. Two of the patients in this group died before the end of the study due to C. difficile complications.

Number Needed to Treat (NNT): 1.57.

We used the vancomycin only treatment group and the faecal microbiota transplantation with vancomycin treatment group to determine the NNT. The NNT may be interpreted as 1.57 patients must be treated over a period of 1 year to prevent one recurrence of C. difficile.

Study Critique: Patients involved in infusion group were able to repeat the fecal transplant as many times as needed to improve the cure rate. The small population size is a disadvantage of this study. The early termination of the study caused the study to fall short of the projected power goal of 90% with 41 patients per group.

RESULTS

CONCLUSIONS

According to both of these studies, the difference between the fecal transplant with the vancomycin and the vancomycin only is statistically significant with a P-value 0.0001. Figure 2 provides a visual of the difference in cure rates between the fecal microbial transplant and vancomycin. Research is currently being conducted regarding the most efficient route of delivery for the fecal transplant. Capsulated oral pills are the focus of studies, and at home kits are on the rise. Fecal microbial transplant is more cost effective compared to the regimen of vancomycin, and the adverse effects are not severe and only lasted for a maximum of 12 hours in these studies. Revision of the protocol to exclude the use of initial abbreviated vancomycin treatment for the fecal transplant group may be beneficial for future studies. Currently, these are the only two articles that have pitted fecal microbial transplant and vancomycin directly against each other, although research continues into the effectiveness of the fecal microbial transplant for the treatment of C. difficile.

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