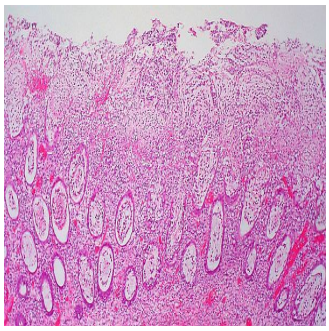
ICU
MANAGEMENT & PRACTICE

Frozen Capsulised Faecal Material Treats CDI



Recurrent *Clostridium difficile* infection (CDI) may be treated with oral administration of frozen encapsulated faecal material from healthy donors, according to results of a preliminary study published in *JAMA*. The treatment resulted in an overall 90 percent rate of clinical resolution of diarrhoea. The Clostridium difficult (C-diff) bacterium is one of the most common causes of infection of the colon.

The use of frozen faecal matter from carefully screened healthy donors has been used for faecal microbiota transplantation (FMT), the reconstitution of normal flora (gut bacteria) by a stool transplant from a healthy individual. FMT has been shown to be effective in treating recurrent CDI, which is a major cause of illness and death in both adult and paediatric patients. Standard treatment with oral administration of the antibiotics metronidazole or vancomycin is increasingly associated with CDI treatment failures, according to available data.

The frozen product used for FMT was administered using a nasogastric tube (a tube that is passed through the nasal passages and into the stomach), a method that was comparable with colonoscopic delivery. Building on this work, the researchers created a capsulised version of the frozen inoculum that can be administered orally and eliminates the need for any gastrointestinal procedures.

The majority of reported FMT procedures have been performed with fresh stool suspensions from related donors. However, practical barriers and safety concerns have prevented its widespread use, the researchers noted.

The study, conducted by Ilan Youngster, MD, MMSc, and colleagues at Massachusetts General Hospital in Boston (MA, USA), aimed to assess the safety and rate of diarrhoea resolution associated with oral administration of frozen FMT capsules for patients with relapsing CDI. It included 20 patients with at least three episodes of mild to moderate CDI and failure of a six- to eight-week taper with oral vancomycin or at least two episodes of severe CDI requiring hospitalisation. Healthy volunteers were screened as potential donors and FMT capsules were generated and frozen, the researchers explained.

Key findings of the study include:

- Of the 20 patients, 14 had clinical resolution of diarrhoea after the first administration of capsules (70 percent) and remained symptom free at eight weeks.
- The six nonresponders were retreated at an average seven days after the first procedure; four obtained resolution of diarrhoea, resulting in an overall rate of clinical resolution of diarrhoea of 90 percent.
- Daily number of bowel movements decreased from a median of 5 the day prior to administration to 2 at day 3, and 1 at eight weeks.
- No serious adverse events attributed to FMT were observed.

In addition, self-reported health rating using a standardised questionnaire scale of l to 10 improved significantly over the study period, from a median of 5 for overall health and 4.5 for gastrointestinal health the day prior to FMT, to 8 for both ratings at eight weeks after the administration.

“If reproduced in future studies with active controls, these results may help make FMT accessible to a wider population of patients, in addition to potentially making the procedure safer. The use of frozen inocula allows for screening of donors in advance. Furthermore, storage of frozen material allows retesting of donors for possible incubation of viral infections prior to administration," the authors said. "The use of capsules obviates the need for invasive procedures for administration, further increasing the safety of FMT by avoiding procedure-associated complications and significantly reducing cost.”

Larger studies should be conducted to confirm these results and to assess long-term safety and effectiveness of FMT capsules, the research team added.

Source: JAMA
Image Credit: Gov.UK

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