THE POWER OF POOP:
Fecal Material Transplant

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Lecture Objectives

- History of FMT
- Description of fecal material transplant
- Medical uses
- Explain the technique of collecting the poops for transfusion
- Explain the regulation in the transfusing poops
- Other animals benefitting from poops transfusion
History

- Originated in China millennia ago
- Fecal transplant first documented in 4th century - Chinese medical literature mentions to treat food poisoning and severe diarrhea
- Years later Li Shizhengen used “yellow soup” made of fecal matter and water which was drunk by the patient
- “Golden soup” which contained fresh, dry fermented stool to treat abdominal disease
- Fresh warm camel feces was recommended by Bedouins as a remedy for bacterial dysentery;
History

- It has been used by Veterinary medicine over 100 years ago and has been used for decades in many countries as first line treating C. difficile
- Used in US sporadically since 1950 without regulation and gained popularity when it was published in 1958 by Ben Eiseman and colleagues – team of surgeons from Colorado treated four critically ill patients with colitis using fecal enemas - returned rapidly to a good health.
- Effective in 90% treatment of stool enemas in where antibiotics did not work
History

- CDD (Center for Digestive Disease) Sydney, Australia been using this as an option treatment for more than 20 years
- May 1988 treated the first idiopathic colitis in USA
- UC has written publication reports of successful treatments
FMT

- Definition
- Medical Uses
  - Clostridium difficile infection
  - Ulcerative colitis
  - Autoimmune and neurologic conditions
- Side Effects
FMT

- **Technique**
  - Donor selection
  - Specimen preparation
  - Administration
  - Autologous restoration of gastrointestinal flora
  - Standardized filtrate
  - Publish stool bank in the USA
- **Mechanism Action**
- **Regulation**
- **Other animals treated with FMT**
Other terms for FMT

This is the transfer of fecal material containing bacteria and natural antibacterial from healthy individual into a disease recipient.
Terminology

- Terms used:

  Fecal bacteriotherapy
  Fecal transfusion
  Fecal transplant
  Stool transplant
  Fecal enema human Probiotic infusion (HPI)
  Fecal microbiota transplantation
What is fecal bacteriotherapy

- Process of transplantation of fecal material from a healthy individual into a recipient
- First line treatment for treating patients suffering from CDI – Clostridium difficile infection
It involves restoration of the colonic micro flora by introducing healthy bacterial flora through infusion of stool by enema, orogastric tube, or orally in the form of capsule containing freeze dried material obtained from a healthy donor.
Fecal Microbiota Transplant

- Procedure in which fecal matter or stool is collected from a tested donor, mixed with saline or other solution strained and placed in patient by
  - colonoscopy
  - endoscopy or duodenal tube
  - sigmoidoscopy or rectal tube
  - enema
  - Via special tablets enclosed in a shell which dissolves in the intestines
Purpose

- Purpose is to replace good bacteria that has been killed and suppressed by use of antibiotics causing bad bacteria that over populate the colon
- Infection causes condition of C difficile
- Infection resulting in debilitating and sometimes fatal diarrhea
- Cure may happen within hours or a few days
Healing Clostridium difficile

- C diff is a very serious infection – CDC reported 347,000 Cases and 14,000 died (2012)
- Highly effective treatment – low cost, low risk and highly effective – life saving treatment to help physicians and patients.
- Not currently covered by the insurance as it still classified as an experiment treatment
Medical Uses

1. Clostridium difficile infection treatment
   - 85-90% effective when antibiotics does not work
   - Recover after 1 treatment in most cases
   - Effective and simple procedure
   - Reduced the incidence of antibiotic resistance
Medical Uses

• Once considered last resort therapy due to its unusual nature and invasiveness compared to taking pills and lack of Medicare coverage for donor stool

• It has been recommended that FMT be elevated to first-line treatment for patients with clinical deterioration and severe replacing
2. Ulcerative colitis and gastrointestinal condition

- Multiple and recurrent infusions are required to achieve cure.
- Not highly recommended because it's not a one-time treatment.
- Published experience treating colitis shows that multiple and recurrent infusions are required to achieve prolonged remission or cure.
3. Autoimmune and neurologic conditions – obesity, metabolic syndrome, diabetes, multiple sclerosis and Parkinson diseases

- Not proven as treatment but have positive effect wherein the symptoms on Parkinson’s disease patient decreased
- Promising results in the treatment of irritable bowel syndrome, Crohn’s disease and Ulcerative colitis recreated the incidence of antibiotic resistance
In all documents dating back to the 4th century China, there has never been a single serious side effect reported from fecal transplant!
Technique

- Standard practice guidelines for performing FMT
  - Preparation of material
  - Donor selection and screening
  - FMT Administration
  - May also be delivered in the form of pill
Technique

Donor Selection

- Require careful selection and screening
- Exclude those who test positive for certain diseases
- Exclude donor carrying any pathogenic gastrointestinal infection
- Close relative is often the easiest way to select
- Donors must be tested for wide array of bacterial and parasitic infections
Donor Selection

- Complete a screening questionnaire similar to which is done at blood banks and for organ or tissue transplants
- Donors who meet the criteria undergo blood work testing for HIV, hepatitis A, B and C and syphilis
- They also need to submit stool to be tested for parasite and C difficile
Donors

- Suitable donors are family members preferred
- Fecal matter must be tested
- Health insurance coverage – may not cover the cost of these screening tests which may cost $1500.00 – $2000.00
Donor criteria

- Exclude people who participate in high-risk sexual behaviors or use illicit drugs,
- Anyone who has had a tattoo or body piercing within the last 6 months
- Has recently been incarcerated
- Individuals who have traveled to areas of the world where endemic diarrhea is prevalent
- In terms of gastroenterological criteria, clinicians should exclude potential donors who have inflammatory bowel disease, irritable bowel syndrome, chronic constipation or history of malignancy or polyposis
- For intestinal microbiota, clinicians should exclude if they received antibiotics in the preceding 3 months
- Prospective donors with high risks factors for HIV and viral hepatitis
- Persons with significant gastrointestinal or autoimmune disease or history of malignancy are not acceptable
Technique

- **Specimen Preparation**
  - Approximately 200-300 grams of fecal material is recommended for treatment for optimum results
  - Fresh stools must be used within 6 hours
  - Frozen samples can also be used without loss of efficacy
  - Saline is the preferred diluting solution than water to avoid relapse
  - Prepared and administered in a clinical environment to ensure that precautions are taken
Technique

- **Administration** – numerous techniques have been recommended
  - Procedure involves single or multiple infusion of bacterial fecal flora originating from a healthy donor by enema through a colonoscope or nasogastric or nasoduodenal tube
  - Colonoscopy method have 90% success rate
  - NG tube has 81% success rate
Technique

- Autologous restoration – started in 2009
  - Patient can donate its own stool before anticipated treatment with antibiotics
Public stool bank in USA started in 2012 from MIT (Massachusetts Institute of Technology) founded Open Biome

- Provides frozen, ready to administer stool samples supports clinical research into the use of fecal transfer to other indications
Regulation

• Interest surged in 2012 and 2013 – measured by clinical trails
• In US, the FDA have public meeting and on May 2013, FDA announces that it had been regulating human feces as a drug however the American Gastrointestinal and Gastroenterology associations stated that FMT falls within biological products.
• It argued that FMT is used to prevent, treat or cure a disease or condition then it is a product for such use would require an “investigational new drug” (IND)
In July 2013 FDA issued a guidance on the IND.

In February 2014 the co-founders of OpenBIome from MIT recommended that human stool should be considered a tissue product not a drug just like blood.

In March 2014, FDA issued a proposed update that when finalized it will supersede the July 2013 enforcement policy for FMT treatment.
Regulation

- Proposed interim discretionary enforcement period if
  - Informed consent is used, mentioning investigational aspect and risks
  - Stool donor is known to either patient or physician
  - If stool donor and stool are screened and tested under the directions of the physician. Some doctors and patient have been worried that the proposal if finalized would shutter the stool bank which sprung up using anonymous donors and ship to providers
As of 2015 FMT for recurrent C difficile infections can be done without mandatory donor and stool screening but can not be performed for other indications without IND.
Other Tested Animals

- Coprophagia term to use for the elephants, hippos, koalas and pandas—all have sterile intestines and to digest vegetation they need bacteria by eating their mother's feces.
- Veterinary medicine—fecal bacteriotheraphy are known as transfaunation used to treat ruminating animals like cows and sheep by feeding them with rumen contents of a healthy animal to other individual of the same species to colonize its gastrointestinal tract with normal bacteria.
Cost of FMT

- No fee for the transplant itself
- Procedure is performed during a colonoscopy or sigmoidoscopy which is usually suffering from chronic diarrhea and recurring c. dif infection
- Most insurance will cover costs of the patients lab test and the colonoscopy
- Patients are recommended to call insurance of co pay, deductibles and out of network or out of state providers
These instructions are for fecal transplant at home using an enema bag or bucket hung on a wall, which will maximize flow up the colon from the force of gravity.

Syringes and enema bottles can also be used but try to use the enema bag method as often as possible, for maximum effect.

These are solo instructions and do not require assistance from another person.
FMT Area

- Put enema bag, lubricant, tissues, paper towels, plastic bag, diagram of colon & timer within easy reach together with anything you need to be comfortable.
- Put pillow, rug and towel near your behind.
- The cushion should go underneath the towel so that it raises your rear end. This will use gravity to keep the FMT in.
Collect sample

- Collect stool sample from relative or next of kin. Do not use sample if it does not look healthy. Sample should look like 2, 3 or 4 on the Bristol Stool Chart. Request this chart from any pharmacy or drug store.
- Keep sample at room temperature and use within 2-3 hours unless freezing.
- If you are going to freeze some sample, separate it into portions and put it in the freezer.
- Heat distilled water in microwave so that it is tepid (the temperature of a baby’s bottle). Too hot will kill the FMT and too cold will be uncomfortable for you to hold in.
Stool Preparations

- To make saline add ¼ tsp. sea salt to 1 cup distilled water. Do not use table salt with additives.
- Put sample in blender or zip lock bag and lightly mush/blend with water.
- If blending don’t overdo it as too much air will reduce the potency of the sample. Zip-lock bags require less clean up than blender-method and expose the microbiota to less turbulence, but the process is somewhat more revolting as you are closer to the poop and have to mush it by hand through the bag. Your choice.
- Add as much water as necessary to make the FMT the consistency of paint. Too thick will block the nozzle and too runny will be harder to hold in and reduce the potency of the FMT.
Getting ready

- Take care not to expose the sample to any more air or water than absolutely necessary as this will reduce its quality.
- Make sure enema nozzle switch is shut.
- VERY important or it will spurt everywhere!
- Pour FMT slurry into enema bag using kitchen strainer & funnel
- Hang enema bag on hook.
- Lift tube high in the air (to prevent spill), release nozzle to let air out, lower gradually until all air is released.
- Close nozzle once you can see all air has gone and FMT has reached the nozzle
Stool transfusion

- Prepare for entry with a little lubricant
- Lie down on your left side making sure your rear is raised on the cushion.
- Lift up your right leg and slowly, gently insert a nozzle.
- A little discomfort is normal but do not continue if it is painful.
- It can help to dilate the entry with a finger before insertion.
- Open the enema nozzle switch.
Transfusion Procedure

- Feel the FMT flowing. If it’s not flowing sit up, carefully holding the nozzle in place and shake the enema bag to get it flowing.
- Lie down and take a deep breath as the FMT flows in. Hold your butt tight. Congratulate yourself for having got this far. Think of all the good bugs that are going to repopulate your gut. Breathe.
- If you feel like you are going to expel the FMT then turn off the enema nozzle. You can put more in later.
- Lie on your left side for 10 minutes. Massage the FMT gently up your colon.
- Switch off the enema nozzle, then remove the nozzle and put it straight into the plastic bag. Wipe yourself if necessary.
- Lie on your stomach for 10 minutes.
- Lie on your back for 10 minutes. Massage the FMT gently across your colon.
Frozen FMT Instructions

- Frozen FMT allows you the flexibility that a donor doesn’t.
- But it is reported not to have the same ‘hit’ as fresh as the quality is compromised by freezing in home refrigerators.
- There are three ways to freeze FMT. When you do a fresh FMT you can pour some of the slurry into ice cubes and keep them to use as needed.
- Add a few drops of liquid glycerol to preserve it, not too much as it is a laxative.
June 13, 2016 – patient with multiple sclerosis had c-diff issues for couple of years. She has been taking a lot of medication and can’t get rid of c-diff. Found doctor who recommended FMT and got better within a day.
Patient quote: I was dying in the hospital bed and after 6 days of throwing up and trying every medical possible the only option I had was an FDA approved procedure.

24 hours later I was cured and alive to tell my story.

My procedure was done by endoscopy because my colon was swollen so much that there was no way the procedure would take going directly in the colon
November 25, 2015

Patient had C-diff infection for at least a year.

She was pregnant with second child and asthmatic. She suffered from SARS and was put on so many strong intravenous antibiotics.

She started having bowel/stomach issues about a month after she was treated and got well.

It turned into “Ulcerative Colitis” that ended up dehydrating her to the point that her water sac was compromised and her daughter born a few weeks early and at first, not breathing. (She’s since become the healthiest kid not even an ear infection after almost 13 years)
- Her ulcerative colitis continues so she keeps on calling the insurance but can’t get medical facility/insurance to call me back much less perform a FMT.
- She has been a walking, gassing, unreliable, weight gaining (I used to be a size 5 I’m a size 14 now), pooping mess of a woman for over a decade.
- FMT was not FDA approved and that’s not recommended, but sometimes you gotta do what you gotta do.
- FMT finally healed her
CASE # 2

- June 24, 2015
- Patient had new strain of C-Diff for a year.
- They kept giving the old meds (which didn’t work and only made it worse).
- When the MD started lobbying the ins. co. for the new meds, they wouldn’t pay because those meds were so expensive (thousands of dollars).
- Meanwhile, patient was researching alt. med. methods.
- Patient almost died and by babying the gut with high doses of quality probiotics and going vegan patient kept herself alive but didn’t dent the C-Diff.
- Then she learned about fecal transplant and had no qualms.
She knew it was not approved but just about 6 mo. into this she learned of the clinical trials that had been approved and she applied for the program.

Doctor spent a lot of time going over the history, etc. and giving a lot of advise. Because patient had it so long, she thought it was in remission, not gone.

Patient cannot take antibiotics again without it coming back. So far patient been able to control normal mishaps with antibiotics.
Patient restrict time in public, eat organic and slowly switched from vegan to vegetarian to adding some organic meat. This is like a sword over my head though.

Fecal transplant works. It’s not mainstream in this country (although it is in others) because there’s no money in it for the pharmaceutical companies. Its called GREED over HEALTH!
Case #3

- **June 29, 2015**
- On April 28th husband was so dehydrated from diarrhea that he was not even aware he was taken to the hospital.
- The ED doctor literally saved his life by diagnosing C-diff within 45 minutes after admission.
- Spent the next 5 days in the ICU isolation unit not knowing whether he would live or die.
- After 5 days he was well enough to go on a floor still in isolation and was sent home after 14 days.
• He had gone from building homes to a walker and 20 pounds lighter.
• He was re-admitted after 4 days and then they were talked to about a FMT.
• They agreed to the procedure and within 2 hours patient was walking and eating.
• Two weeks later it came back but there is no mistaking the smell. They found out patient has Salmonella and need to be treated first.
• Patient got better and on hold for the FMT if it comes back.
• Patient is on Amoxicillin for the salmonella and Vancomycin for the C-diff. If it returns patient is planning on doing a FMT using wife’s fecal matter or one from a bank in Boston.
Case #4

- **January 24, 2016**
- Patient contacted C-Diff 20 years ago, it would raise its ugly head off and on, but more frequently as the years went by.
- She also came in contact with MERSA after Sclerotherapy and the drugs for MERSA put her into a real horrible place with C-Diff.
In the past 20 years she had “irritable bowel syndrome” (IBS) so her life rotated around “where’s the bathroom, and Depends”.

She had FMT August 6, 1915, the happiest day of her life.

She walked in for the procedure and walked out a new person.
On Aug. 9, her husband had a very, very unexpected heart attack, she needed to rush to the hospital 80 miles away and was with him for several days in the hospital, not one problem from IBS. Not only was the C-Diff gone, but also the IBS gone (not always happens I understand)

Lesson for everyone: be careful when introducing new food you have not eaten for years, it will take a bit for your body to tolerate them.
November 25, 2015
(Patient) - can you email me which Kaiser you went to?
You must be in California right?
My Kaiser medical care acts as though I’m a monkey wanting to throw my poop at them.
They barely even address the matter of recurrent C-Diff....hell they barely even return my messages.....They used to be so good.
I used to really go to bat for them every time someone would say “Oh they are butchers”...then they opened up a new facility in Northern California and it seems all hell broke loose.

I was without a PMD, thus no referral for the GI, and when I did get both, they let me go along with C-Diff for weeks and then it took them 5 days to just open the chart and read the results and even then they didn’t prescribe medicine for it right away.
They ended up calling me as I was boarding a plane to Texas to tell me “you have C-Diff”...I was literally boarding the airplane when they called me....I was so sick, I thought maybe I’d try changing the scenery after 6 months in bed sicker than a dog...so I was going to my nieces in Texas....I was boarding a plane with a highly contagious infection when they finally contacted me to tell me I had C-Diff. I knew I couldn’t use the restroom on the plane for obvious reasons.
I just sat in my seat and prayed to God no one would get sick and prayed that I didn’t have to go to the bathroom...I made it to Texas alright, took the medicine and felt better than I’d felt for months. You’d think they’d follow up with me.

NOPE. And I pursue them and call them and I’ve written two letters to Member Services with complaints and STILL I get zero! It’s like they hate me.
Case #6

- **January 20, 2016**
- I just had my FTP today and I had C DIFF twice, once from antibiotic suffered over a year until I finally got a $2,000 antibiotic that stopped it (2012 -2014), then again this past October, 2015.
- Took Vancomycin from Oct. to yesterday then had the transplant today. Now I am hoping it won’t come back but realistically know that I have to be aware of everything I do, where I go etc...The spores live and the only way to kill them is to use straight purex on all surfaces etc...and wash everything in hot, hot, purex water and wash your hands.
• If you use bathrooms be aware of using covers on seats and wash, wash, wash.

• I also read on this site that a mother thinks her daughter caught it from eating somewhere where the food was prepared from someone who must not have washed their hands this is so scary but one never knows where the spores are lurking.

• Highly contagious. I smell like a bottle of purex because I cleaned everytime I used the restroom I never want to catch this or have anyone I know catch it. It is deadly. Read up on C Diff!
Case # 7

- After surviving a near-fatal car accident, Kaitlin Hunter found herself battling a devastating bacterial infection in her colon that also threatened her life.
- The persistent infection was beaten through a little-known technique involving the transplant of fecal matter from Hunter's mother, which put healthy bacteria back into her colon.
Following the July procedure, "I've been so happy," said Hunter, 20, of Marietta, Georgia. "I'm cured."

Her struggle began more than a year earlier when she was released from a hospital in Sacramento, California.

A June 2011 car accident fractured her lower spine, lacerated her liver and colon, and broke all 10 toes. Emergency crews used the Jaws of Life to cut Hunter from her dad's car, and then she was flown to the hospital, where she spent the next month.
Upon her release, Hunter flew home to Georgia. It hadn't been the summer vacation she imagined, but she thought she was getting better.

But "right when I got off the plane, I went to the hospital. I was having extremely bad stomach pain. A month later, we found out it was C. diff," Hunter said, using the abbreviation for the bacteria Clostridium difficile.
• In the hospital after her accident, doctors followed standard care and put Hunter on antibiotics to prevent an infection.

• In spite of the antibiotics -- or possibly because of them -- C. diff infected her colon, causing severe stomach pain, diarrhea and vomiting.

• Hunter, who stands 5 feet 7 inches tall, lost 40 pounds during her struggle. Her weight plummeted to 85 pounds.
It's believed that antibiotics, which kill harmful infection-causing bacteria, also weaken the beneficial, healthy bacteria percolating in the colon. With the colon's defenses down, C. diff grows rampant, releasing a toxin and inflaming the colon.

C. diff infections kill about 14,000 people in the United States every year, according to the Centers for Disease Control and Prevention, and the number and severity of total cases have increased dramatically over the past decade.
'Brand-new' treatment
Increasingly, doctors are taking a different approach. Instead of continued assaults on bacteria, "fecal matter transplants" recolonize the colon with new bacteria from a healthy donor.
"This is brand-new for most gastroenterologists," said Dr. Suku George, Hunter's treating physician. "We are very excited about this."
• George had never deposited fecal matter by colonoscopy into a patient until Hunter wanted to try it.
• Hunter's mother "donated" one of her stools for the procedure. Next, the hospital lab carefully diluted it, and George pumped the foreign fecal matter right into Hunter's colon.
• The result ended Hunter's struggle with C. diff.
• A study published in March reported a 91% cure rate after just one fecal matter transplant, and a 98% cure rate when combined with an additional round of antibiotics.
References

- All FMT websites
- All Power of Poop websites
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