Fecal Microbiota Transplantation
Great 8+ QIO Group Educational Webinar

Presented by Tom Moore MD, Department of Medicine, University of Kansas
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Thank you for joining fecal microbiome therapy conference call. All lines are in a listen only mode.

I would like to introduce Tom Moore, he completed his residency at Baylor college. He holds an academic employment with the department of medicine in the University of Kansas in Wichita Kansas. He holds professional certification with the Americans desire any of hygiene diet -- [Indiscernible] hygiene medicine. He held the title of Lieutenant Commander in the reserves. He chairs the department of infectious disease in Louisiana. Thank you for joining us today.

Thank you. We will talk about fecal microbiome therapy. There has been an increase in interest in this topic. There was an increase of cases reported in 2008. One thing that I find interesting, we are witnessing the first scientific understanding. It will change our previously held concept on who we are and disease itself. It sounds like I am overstateing it but I am not. We are going to talk about fecal microbiota transplant. This was described in 1958 [Indiscernible] . Whenever I have talked about this in the past, older providers will come up to me and tell me that back in the 50s their job was to gather stool from parents who had a child with the infectious disease. And this is not new but it has gone through a renaissance. There is the understanding and conclusion that repopulating the gut floor with healthy bacteria is more effective. And restoring the ecosystem that is critical in Portland to -- important to resist other diseases. The rates of this infection continue to increase. There is a reason report of cases with no prior antibiotic exposure. There is epidemic strain [Indiscernible] reported from hospitals. And it has replaced oral [Indiscernible] early in the description of this disease. It is not because the organism is less susceptible to it but a reduction [Indiscernible] . The new agent that we have, is [Indiscernible] because there are no new agents that have been approved. They are all in clinical trials. There are 14,000 people who die in the United States. Between 2000 to 2007 deaths increased by 400% and more than half of those were elderly. And half of infections were president on admission. This is just to show you the rates and mortality rates increase with age. As you can see, it
steadily increases as the poor -- person gets older. I will show you the evidence -- we had 10 pregnant women and 23 generally healthy persons. We talked about the vehicle -- fecal and him. -- enema. The cure rate is about 85%. And I think right -- 90% of that is cured by and enema. Now we can talk about fecal microbiome which is a very exciting topic. Most recently, DNA analyzed a large number of organisms. And this has become available. And this allows individuals and researchers to get a rough idea on the population of bacteria that we have in our system. What has been found is, if you were to use the human body as an example. In the human body our DNA would only constitute 1 foot of our daddy -- body. And the rest of it is all bacteria. And this was not appreciated earlier. The concept about health and disease has been a primary process. -- Binary process. What we have found out, microbiology changes as we age. When you look at the population of bacteria. This is representative in this graph. You can see that the baby who is breast-fed versus bottle said -- fed is quite different. Healthy people have this distribution of bacteria in the colon. We are not clear why that is. But what is interesting, there has been recent studies that have indicates -- I am sure -- not sure what has happened. Can you still see my slides?

What you can see, when there is a transplant the health of the [Indiscernible] increases. This is also for inflammatory colon disease and other diseases as well. As one ages, the bacteria can't -- population will change as well. As with the diet. The elderly patient are primarily eating things that are a comfort to them. High in carbohydrates and sweets. And there bacteria is significantly less diverse versus those who snack on a -- cheeses. The but microbiota is -- the energy is harvested in a different way. It has been shown that given antibiotics will alter the colon. And there are other side effects which are listed right here. One of the reasons this came up, it is well known in Canada where these is the main export - - beef is the main export. When you give cattle antibiotics it increases their weight. And this is also have been found true in poultry. So the question is, can this happen in humans? We study childhood obesity. The rates in obesity in children dashed -- seem to be linked to antibiotic use as a child. I know it seems crazy. But this is a prevailing [Indiscernible] . And this leads to a variety change of in the metabolism. This shows you diverse city -- diversity of microbiota. This is an explanation of dysbiosis. This is a relatively new concept in which either bacteria in the gut will talk to each other in a variety of ways. That healthy bacteria is essentially forming aviaries your -- a barrier against infection. And this is a very vital process in humans. Because there is a healthy colon. If you are exposed -- require [Indiscernible] you will need to have [Indiscernible] . Even when patients -- especially when the patient is elderly. We have had patients who had to sell their home and liquidate their assets to continue to pay for their medication. By getting this fecal microbiome therapy will lead to restoration. This is one example. If you have a patient with infection, their symptoms will improve but [Indiscernible] is still positive. But if you give them fecal microbiome therapy, what is interesting right after you give it to them there's stool is come -- completely clear. I have seen is in three occasions. We have given the patient [Indiscernible] the disease was completely cleared. This essentially like your lawn. Where you have traveled -- throughout -- and you have weeds . and you end up with a lawn of weeds. So what do you do? You use poison and see the long -- feed the lawn and then the organism will restore the long. -- lawn.

Or you can put in new sod, which is just like fecal microbiome therapy. In terms of speed that there he is most -- fecal microbiome therapy is the best way . This is not a new concept. This is been reported in animals. It has been observed in horses, zebras and in other animals. This is a simple method. Recently
there was a survey performed by CDC. Basically what we found in the survey, those doing fecal microbiome therapy. We started to see a pickup. In 2012 there was a larger survey that also included my cases which are shown right here. This is a partial list. There have been over 700 cases treated but there are many more that Matt. -- then that.

As you can see on this light we have enema and eight colonoscopy. And -- a colonoscopy. And you can see there is a high rates -- rate.

The total success rate is about 95%. It is not clear why there is a difference right here. In my personal opinion, you are going right into the colon. This is a survey by listing there is sites where people can get these transplants. There are several of these. But this is a older list. There are more people doing this.

Now we can go over the providers attitude. In general 50% who responded, essentially the majority responded would consider transplant for [Indiscernible] . This is from 2012 and more than likely this has changed. And this is why I showed the map because there are other places where you can go.

When we do the transplant, most people will do this after three episodes. In Scandinavia, legal -- fecal transplant is the first course of therapy. This seems to be the study that spurred most of the activity. This was a study I helped with. Here you have first infusion versus [Indiscernible] therapy. You can see there is a 81% and then it went to 94%. And the treatment of success. The monitoring board for this study halted this study because there was a significant difference. And who do we do that transplant? -- the transplant? And there was an interest in therapy -- transplant for another diseases. FDA had to do something. Because people were trying to do fecal transplant for autism. And there was no evidence that this would help. We do not know the long-term health effects giving someone else's fecal microbiome . So ADA said we need more information -- FDA said that we needed more information. The recommendation was , that fecal transplant be allowed. But FDA said that you cannot have a transplant went out [Indiscernible] a -- without [Indiscernible] and you had to provide FDA with all of the information provided to the patient. All of which is fine. But for someone who is coming in and are very ill it is too cumbersome to set all of this up. There were two things that happened. There was a YouTube video that showed others how to do this themselves at home. They were mitigating -- mimicking what was going on in Canada. After some discussion between the FDA, we got the FDA to relent and some degree. They will allow discretion. Basically what this means, they would allow fecal transplant for [Indiscernible] only . Basically in July of 2013 bailout transplants. As long as there was an informed consent with the patient and they understand that this is nontraditional therapy. We are now crafting new language. And the comment period and it on the 30th. The FDA is going to change the use of fecal transplant that the donor is related to the patient. Because this clearly shows that your bio [Indiscernible] is similar to your family versus a stranger. In Stockholm they have a nurse that is a walking stool bank. She is regularly screened. And obviously there are protections built-in. Their success rate is no different. But there is a risk of transmission. One of the reasons FDA decided to go without language because they wanted to prevent the open sale of stool over the Internet. This is something clearly that the FDA wants to take care of. The language FDA has crafted -- it will make it difficult for people to develop a national stool bank. There is research at MIT that have created an open [Indiscernible] . They will shift overnight -- shipped overnight stool. In Canada they are
investigating -- they went out and found someone who was a no core mobility. And someone who was
born vaginally which is important because when you look at infants that were born via a C-section they
did not have the mothers [Indiscernible] and that persist for a period of time. And the presumption is
that it is not healthy. Whereas babies who were born by vaginal delivery and a swallowing
[Indiscernible] . They found this patient who was born by vaginal delivery and did not receive
antibiotics as a child. And they took her stool and screened it for a variety of pathogens. This is also in
a clinical trial. Another thing they are doing in Canada, they are taking this stool of donors and putting
it in and such reviews -- in a interviews. And they make it into an -- a capsule. And the success rate
mimics one is given through a tube. This has been referred to in the press as the blue pill -- poop pill --
poop pill .

And the question is, who do you take the stool from? From the relative order the stool bank -- or the
stool bank/ -- ? I believe we should take it from the relative. There is good scientific evidence -- as you
see right here their legal [Indiscernible] and will not -- fecal [Indiscernible] will not help. Any kind of
antibiotic treatment within 12 weeks. Anyone with high risk sexual behavior or history of HIV.
Anybody with a history of interplanetary -- inflammatory or Bolivian -- malignant GI disease or
history of G.I. surgery.

You can go to the Internet and you will be able to see the working group protocol from 2010 and it will
provide some guidance on how to do fecal transplant and how to screen people. By the FDA
recommendation they recommend screening. If you have an elderly lady getting stool for her elderly
spouse that -- if you have been married 40 years to each other the likely transmission is ridiculously
slow -- low.

Screening is relevant in risk of transmission to the operator or handler of tissue sample. The testing we
do is routine bacterial culture for enteropathogens .

If you are going to do this through [Indiscernible] you need to check for HIV. And these are all of the
things that we recommend. This is the estimated success rates. You can see it is at least 95%. And the
other significant success rate is 85%. There are risks to this procedure. The stool bank's main -- bank
my go away.

New pathogens may be introduced with the donor stool sample. Potential for physical complications
from instillation procedure.

This is from Norway. The colleagues in Scandinavia which support this material, you can see there is a
number of treatment -- transplant centers. The stool is prepared either fresh or frozen. The number of
cases you can see do not have any adverse effects. And the cases that have reported adverse effects.
The most common is failure to resolve the RCDI. There was one report of peritonitis after the
colonoscopy. My old -- mild enteritis and upper GI bleeding. This is a timeline of things that I was
mentioning. In 2012 FDA rules that stool is a biological drug. Here in 2013 FDA rules IND required
for all fecal microbiome transplant. In conclusion, the reason we do fecal transplant is that it is
relatively cheap. And it is more effective at resolving recurring [Indiscernible] . It is easy to be
performed and done at home. Need for screening is limited. I was in Ohio, and there was a discussion
on how satisfied the patients were with that treatment. Most patients do not care where the stool comes from they only want to get better. Although the patient was put up -- off by the treatment plant they did change their mind once they realized how well the treatment works.

If you have a question please press star one on your touchtone telephone. If you are using a speakerphone, you will need to pick up your handheld set before you press start one. Smack I --

I want to thank Dr. Moore for his presentation.

We have a question from Linda.

When you were doing that transplant by NG what keeps the asset from [Indiscernible] ?

You put the patient on [Indiscernible] prior to the infusion. They typically do not do it through the NG two. -- tube.

If you have a question please press star one on your touchtone telephone.

I have a question. You shared that you had been working with IDSA on protocols. Will that be available in the future?

Yes. We put together one article on how to file an IND and there will be protocols on how to do fecal transplant using IND.

Those protocols all -- are already out there. How to do the procedure should be available from the IND website.

We do have a question from Charlie.

You are talking about insulin earlier. Will you explain a little bit?

We cannot. Because we do not know. These are preliminary findings. But in the study patients who were on insulin, had a reduction in insulin requirement.

Thank you.

If you have a question press star one on the touchtone telephone.

We have a question from Jill.

I am wondering about the castles and I am wondering why people do not use -- castles -- .
You can get them from the University of Calgary in Alberta. And he will give you the supplier. I think that is the best way to go, if you have a lab that can stuff the castle -- capspill. I think it should be done by the lab do it.

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It has been done through an colonoscopy. It requires someone who is interested in doing it. And that is why all of these centers have popped up because not everyone wants to do it.

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Do we have any more questions?

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I want to take this opportunity to thank Dr. Moore for presenting on this topic to a larger audience. And we appreciate your time.

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Thank you for inviting me.

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Thank you for participating. You may disconnect.

[Event concluded ]

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