



Centre for  
Digestive Diseases  
*The Centre of Excellence in Gastroenterology*

Level 1, 229 Great North Road,  
Five Dock, NSW 2046  
Phone: 61 2 9713 4011  
Fax: 61 2 9712 1675  
Web: [www.cdd.com.au](http://www.cdd.com.au)

# PROFOUND REMISSION FOUND IN TEN ULCERATIVE COLITIS PATIENTS USING INTENSIVE COLONIC LAVAGE FOLLOWED BY FECAL MICROBIOTA TRANSPLANTATION: A CASE SERIES

Stephen Fairley<sup>1</sup>, Lachlan J Fairley<sup>1</sup>, Sarah L Fairley<sup>1</sup>, David A Uprichard<sup>1</sup>, Anoja W Gunaratne<sup>2</sup>, Thomas J Borody<sup>2</sup>.  
<sup>1</sup> Townsville Gastroenterology Day Surgery, Martinez Avenue, West End, Queensland, Australia.  
<sup>2</sup> Centre for Digestive Diseases, Five Dock, New South Wales, Australia.

## Introduction

The etiology of ulcerative colitis (UC) is unknown. With the various descriptions of dysbiosis of the gut microbiota in UC, there is a suggestion that UC may be driven by yet to be discovered pathogen/s which live in the colonic biofilm and are pathologically causing the colitis. Microbial manipulation by Fecal Microbiota Transplantation (FMT) is a promising therapeutic. We describe here a series of patients treated with intensive colonic lavage followed by FMT.

## Methods

This was a retrospective, single-centre study conducted in Australia between Jan 2020 to Jan 2021. Included patients had confirmed diagnosis of moderate to severe active UC ( $\geq 3$  diarrhoeal stools/day) and underwent a bowel preparation with a concerted attempt to remove the stool followed by lavage in an attempt to remove colonic biofilm and FMT. This was done with the standard bowel preparation, followed by additional bowel preparation with a combination of high dose ascorbic acid oral bowel preparation. This was followed by colonic lavage using a colon hydrotherapy equipment with water, soap and water, then saline.

Secondly, we attempted to substantially reduce any remaining or residual flora in the biofilm in the colon of the patients by finally washing the colon out with diluted povidone iodine solution (0.3% concentration), both during the colonic hydrotherapy and again at the time of the colonoscopy, prior to direct infusion of 300ml of fresh/frozen FMT material, into the ileum and caecum via a colonoscope. FMT material was processed from healthy donor stools, in accordance with Australian and International guidelines. Second FMT was provided via same route if a patient remained symptomatic at follow-up between 3 -12 weeks. During and following the treatment process, regular clinical data were collected from patients at follow-up consultations, pathology tests and colonoscopy.

## Results

Ten consecutively treated patients were included. Patients' characteristics, clinical symptoms and laboratory findings are shown in Table 1 & 2. The data showed that 9/10 patients achieved clinical symptom remission and 8/10 patients had normal calprotectin levels 6 weeks post treatment. All patients were in steroid free remission with none on immune modulators or monoclonal antibody therapy.

## Conclusion

Such findings have never been reported in consecutively treated FMT cases nor has there been a report showing such complete clinical response in severe UC cases. Overall, these findings encourage us to further assess the effect of the novel lavage solutions on biofilm removal and its relation to engraftment. The optimal lavage combination may well result in prolonged remission in a larger proportion of treated UC patients. At that time, a controlled trial of the novel therapy will be appropriate.

Table 1: Characteristics of the patients

Patient	1	2	3	4	5	6	7	8	9	10
Age (y) (M/F)	27 (F)	60 (F)	42 (F)	49 (F)	18 (F)	39 (F)	40 (M)	41 (M)	52 (M)	26 (M)
Year diagnosed UC at colonoscopy	2006	2004	2004	1995	2020	2000	2011	2000	1993	2006
Previous ongoing treatment received	Steroids, Sulfasalazine	Budesonide, prednisolone 50mg/d, mercaptopurin 50mg, lopermide 12mg	Steroid up to 25mg/d, Sulfasalazine, 5-ASA	Sulfasalazine, 5-ASA	Sulfasalazine	Sulfasalazine	Budesonide, prednisolone 20-50mg/d, mercaptopurin 100mg,	ASA, azathioprine 200mg/d with infliximab	Regular 5-ASA and intermittent prednisolone	Steroids, 5-ASA, azathioprine
Duration of previous treatment (y)	14	15	16	25	8 months	20	9	20	27	14
Duration of current symptoms when presenting to the centre (m)	3	1	8	3	8	24	6	1	3	3
Colonoscopy changes observed prior to FMT	Moderately active colitis with erythema mucopurulent exudate and contact bleeding to the splenic flexure	Macroscopic pancolitis with indeterminate colitis with features of lymphocytic colitis	Moderately active colitis to the splenic flexure with histologically moderately active chronic UC	Moderately active proctitis	Moderately active chronic colitis	Moderately active left sided colitis with rectal sparing, with histologically ulceration and active chronic colitis	Moderately severe left sided colitis with mucosal ulceration, contact bleeding and mucopurulent exudate	Very severe left sided colitis from anus to transverse colon with confluent ulceration and small pseudo polyps	Moderately active proctosigmoiditis with histologically active chronic proctitis	Mildly active colitis to 35 cm
Date of Colon washout by using colon hydrotherapy equipment and 1st FMT via colonoscopy	06/05/2020	10/07/2020	13/08/2020	26/08/2020	10/09/2020	14/10/2020	26/10/2020	05/11/2020	20/11/2020	03/12/2020
Date next FMT received via colonoscopy	27/05/2020	Not required	Not required	Not required	21/01/2021	6/11/2020	12/11/2020	08/01/2021	Not required	28/01/2021
How many FMT's received	2	1	1	1	2	2	2	2	1	2
Duration of Clinical Remission (m)	8	7	5	5	1	3	2.5	1.5	2	1
Colonoscopy macro changes observed at 2 <sup>nd</sup> FMT	Completely healed mucosa	No colonoscopy done as no 2 <sup>nd</sup> FMT was required	No colonoscopy done as no 2 <sup>nd</sup> FMT was required	No colonoscopy done as no 2 <sup>nd</sup> FMT was required	Complete resolution of her proctitis and sigmoiditis, but residual inflammation in descending colon	There were tiny patches in the rectum and sigmoid colon.	Colitis appeared to be much improved	Rectum and distal sigmoid look relatively normal, changes in the proximal sigmoid and descending colon have very severe disease with confluent ulceration and small pseudo-polyps of residual mucosa	No colonoscopy done as no 2 <sup>nd</sup> FMT was required	Normal colonic mucosa
Current/No medications after FMT	Sulfasalazine	Off all medications	Off all medications	Off all medications	Off all medications	Off all medications	Off all medications	Off all medications	Oral 5-ASA	Off all medications
Clinical symptoms / Other important information	Asymptomatic	Asymptomatic Patient's comment "Thank you for giving my life back"	Asymptomatic	Asymptomatic	After one-month clinical remission, she is experiencing a few symptoms including urgency and diarrhoea	Asymptomatic Patient's comment "It's like a miracle after 20 years of suffering".	Asymptomatic	Asymptomatic. Patient's comment "He feels "fantastic"	Asymptomatic	Asymptomatic

Table 2: Changes to the clinical symptoms and laboratory findings of the patients at pre and post treatment

Patient	1		2		3		4		5		6		7		8		9		10	
Pre- or Post-Treatment	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Frequency of BA/d	10-15	1-2	20	1	6-8	1	3	1	5	2-3	6	2	6-12	1-2	20	2-3	10	1	8	0-2
Blood (B), mucus (M) nocturnal BA (NBA), urgency (U) present	B/NBA/U	N	B/M	N	B	N	B/M/U	N	B/M/U	U	B/U	N	B/M/U	N	B/M/U	N	B/M/U	N	B/M/U	N
Stool consistency	D	N	D	N	D	N	D	N	D	D	D	N	D	N	D	N	D	N	D	N
Weight (loss [-] or gain [+]) kg	-3	+3	-10	+12	NC	NC	NC	NC	NC	NC	-10	+12	NC	NC	-20	+10	NC	NC	NC	NC
Albumin levels result g/L (>35)	N	N	N	N	N	N	N	N	N	N	N	N	N	N	26	38	N	N	N	N
Hb levels g/L (115-165)	N	N	N	N	113	N	N	N	114	N	N	N	N	N	125	143	N	N	N	N
ESR mm/h (1-12)	23	N	N	N	27	N	N	N	18	9	N	N	N	N	N	N	N	N	N	N
CRP mg/L (<5)	12	N	12	N	N	N	N	N	N	N	N	N	N	N	36	4.2	N	N	N	N
Calprotectin levels ug/g (<50)	ND	26	5360	43	245	<1	784	42	939	853	168	38	788	33	>6000	219	261	23	267	55

BA: bowel actions; D: diarrhoea; Y: yes; N: normal; NC: no change, Blood (B), mucus (M) urgency (U), nocturnal bowel actions (NBA); ND: not done; +: gain; -: loss

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