OMT for the Prevention and Management of Chronic Constipation and Distal Intestinal Obstructive Syndrome in Cystic Fibrosis: A Pilot Study

Sara E. Modlin, DO; Kristian Borofka, DO; Danielle Franzini, DO; Alaina C. Klene-Bowns, DO MPH; Victor A. Nuno, DO

Context: Cystic fibrosis (CF) is an autosomal recessive genetic disorder primarily affecting the lungs and digestive system. Patients with CF often have multiorgan dysfunction, including chronic lung infections, pancreatic insufficiency, chronic constipation, and distal intestinal obstructive syndrome (DIOS).

Objective: To understand the impact of osteopathic manipulative treatment (OMT) on the prevention and management of gastrointestinal symptoms in patients with CF.

Methods: This study used OMT for physical manipulation of the viscera, spine, and other somatic components to improve bowel symptoms and prevent DIOS. These effects were achieved by releasing myofascial restrictions found in the abdomen and somatic structures with the intent to optimize the autonomic and lymphatic systems and improve range of motion.

Results: Four of 5 participants had a decrease in pain, and 3 participants had a reduced need for laxatives during treatment. Four participants had an overall increase in satisfaction with their bowel movements while being treated with OMT.

Conclusion: These findings support the use of OMT as a method for the management of chronic constipation and DIOS in the CF population. However, because of the small population size, more research with larger populations is needed.

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Cystic fibrosis (CF) is a genetic disorder affecting approximately 30,000 people in the United States.1 This disease manifests itself in multiorgan systems, primarily targeting the lungs and gastrointestinal system. Chronic constipation is a common issue for many patients, and 5.9% of patients older than 18 years have distal intestinal obstructive syndrome (DIOS).1 The incidence of DIOS is greater in the adult population (35.5/1,000 patient years) than in the pediatric population (6.2/1,000 patient years) with CF.2 Constipation in patients with CF is defined as (1) abdominal pain and/or distention, (2) reduced frequency of bowel movements, and (3) symptom relief with laxatives.3 In contrast, DIOS is defined as abdominal distention and pain with a fecal mass at the ileocecal junction.2 There are several proposed mechanisms for DIOS. One includes pancreatic insufficiency with inadequate doses of pancreatic enzymes leading to malabsorption of fat, which causes slowed intestinal transit and increased viscosity in the...
intestines. However, DIOS is also seen in pancreatic-sufficient patients, indicating that this may not be the sole contributor. Dysmotility has been suggested to add to this disease process, along with abnormal mucins and water balance seen in the gastrointestinal tract and lungs of these patients. Similarly, constipation in patients with CF has analogous proposed mechanisms, which suggests a role for osteopathic manipulative treatment (OMT) in the management of bowel dysfunction in these patients because OMT has been suggested to improve intestinal motility. The role of OMT as a preventive and therapeutic modality for patients with CF has yet to be determined.

Recent advancements in medical care available to patients with CF have led to increased life expectancy, with the average age of survival estimated to be 41.6 years as of 2015. As the life expectancy continues to increase, patients at risk for new or worsening bowel symptoms developing becomes a more prevalent complication. In patients with irritable bowel syndrome, OMT has been found to decrease abdominal pain, constipation, and diarrhea. Müller et al found that their participants’ mean pain levels, determined by a visual analog scale, dropped from 64.5 to 12.9 in the OMT group compared with 63.7 to 49.7 in the sham control group (P<.01). Osteopathic manipulative treatment has also been shown to be beneficial for patients with postoperative ileus, with reports of decreased time to flatus and decreased length of hospital stay. This finding supports the use of OMT for gastrointestinal dysfunction and the exploration of its role in the prevention and treatment of gastrointestinal dysfunction associated with CF. The goal of this pilot study was to test the effectiveness of OMT in the management of chronic constipation and the prevention of DIOS in patients with CF. In addition, we aimed to create a protocol for expansion into a larger study.

Methods
This crossover study involved the participation of patients with CF and chronic constipation. Patients were recruited via social media posts and advertisements placed in multiple CF media outlets. This trial was approved by the institutional review board of Touro University California, and informed consent was obtained.

Inclusion criteria were defined as a diagnosis of CF; symptoms of bowel dysfunction, including constipation, abdominal discomfort, and distention at least 2 times in the past 6 months; consistent use of pancreatic enzymes for pancreatic insufficiency; use of at least 1 medication for constipation; willingness to maintain an elective bowel treatment plan during the study; and willingness to receive 4 OMT protocol sessions within a 5-month period.

Exclusion criteria were defined as age younger than 18 years; currently receiving OMT from another provider or received OMT within 1 month of the start of the study; currently on an organ transplant list; non-compliance with pancreatic enzyme use; or forced expiratory volume less than 40%.

Participants submitted an intake questionnaire and then were asked to complete a validated survey using an analog scale weekly throughout the study. The survey evaluated participants’ levels of constipation, diarrhea, abdominal distention, abdominal pain, and steatorrhea. Sequential division of participants into group 1 or group 2 was performed. Group 1 received 4 treatments with OMT 1 month apart followed by 4 months without OMT. Group 2 received 4 months without OMT followed by 4 treatments with OMT 1 month apart (Figure).

All OMT was performed by the same licensed osteopathic physician (V.N.) who was board certified in neuromusculoskeletal medicine. All treatment sessions followed a predetermined protocol consisting of diagnosis and treatment as discussed below.

Diagnosis Protocol
An osteopathic structural examination using passive motion testing of the spine, pelvis, sacrum, thoracic diaphragm, and ribs was performed. Special attention was paid to tissue texture changes, specifically looking for
viscerosomatic reflexes in the thoracolumbar spine (sympathetic reflexes) and craniosacral area (parasympathetic reflexes). The abdomen was assessed with particular attention given to the stomach, hepatic and splenic flexures, cecum, and sigmoid colon in their respective mobility and motility. An abdominal examination was performed to assess bowel sounds, tympany, tenderness to palpation, and hepatosplenomegaly. The physician spent approximately 45 seconds visually screening the patient for Chapman reflexes or lymphatic nodules.14

**Treatment Protocol**

The treating physician was blinded to individual participant information and to survey results. The treatment protocol focused on normalizing autonomic tone, improving lymphatic drainage, and releasing intestinal restrictions. Participants received rib raising, suboccipital release, lumbosacral decompression, and ligamentous articular release/myofascial release directed at the following areas: thoracic inlet, thoracoabdominal diaphragm, sacrum, pelvis, and 3 to 5 of the segments determined to have the greatest dysfunction in the spine and ribs. A direct visceral technique was applied to the viscera to free restrictions at the hepatic and splenic flexures and mobilize the cecum and sigmoid colon. Additionally, a colonic milking technique was applied, with the physician working distally to proximally along the colon with small circular motions. This technique is used to physically move fecal matter, free fascial restrictions, and induce lymphatic drainage.

While in the treatment phase, the participants continued their weekly surveys; they reported hospitalizations, changes in bowel habits, and/or medication doses, as well as changes in activity level and other symptoms in the electronic survey form. The data collected from the electronic survey were analyzed, and survey results from each participant’s treatment and control periods were compared.

**Results**

Sixteen CF participants initially inquired about enrollment in the study. Of those, 8 met the criteria and were enrolled in the study. Two participants dropped out while in the control phase before receiving treatment: 1 participant elected to instead pursue acupuncture for bowel disease and the second participant did not complete the study because of the distance of the clinic from her home. A third participant stopped the study after 2 treatments to pursue chemotherapy for a prior known cancer. Of note, she did feel that the treatments were of benefit and wanted to continue being treated outside of the study. Five participants (4 women and 1 man) completed the study. Group 1 (4 OMT sessions 1 month apart followed by 4 months without OMT) consisted of participants 1, 2, and 4, and group 2 (4 months without OMT followed by 4 OMT sessions 1 month apart) consisted of participants 3 and 5. Participants were allowed to choose their group.
Participants had a large range (0-20) of previous hospitalizations for bowel obstruction. Of the 5 participants, 1 was admitted to the hospital for DIOS directly before starting the treatment phase, and no DIOS episodes or hospitalizations were reported during the treatment phase.

Participants’ survey responses were divided into treatment and nontreatment phases. Three patients reported either no increase or a decrease in escalating need for laxatives from baseline while in the treatment phase. Participants 3, 4, and 5 reported a decrease in abdominal pain severity while being treated. Participant 2 was found to have an equivocal pain scale, and participant 1 was found to have an increase in “not very severe pain” of 14% during the treatment phase. Participants 2, 3, 4, and 5 all experienced a decrease in severity of bowel distention while being treated (participant 1 did not have abdominal distention). Four participants reported an increase in satisfaction with bowel movements while being treated, and 1 participant reported an equivalent satisfaction rating in both treatment and nontreatment phases. Participants 1, 3, 4, and 5 reported less interference of bowel function with their daily lives while in the treatment phase; however, participant 2 had an increase in reporting “quite a lot” of interference during 19% of the study period.

Osteopathic examination findings recorded during each treatment session revealed significant restriction in the mobility at the colonic flexures in all participants, with no consistent changes in the mobility of the colon after treatments. Chapman points were consistently found in all participants corresponding to the stomach, small intestine, and ascending colon. Descending colon Chapman points were consistently found in participants 1, 2, 3, and 5. Only 1 participant had Chapman points corresponding to the cecum. On examination of the spine, a group curve that varied between T2-7 was consistently found on all participants at every treatment session. Tissue texture changes in this region were consistently described as boggy. Viscerosomatic changes at the level corresponding to the colon (T12-L2) were not consistently found in these participants.15

Owing to the small number of participants, we were unable to determine whether there was carryover effect in this crossover design.

Discussion
The structural examination at each visit during the treatment phase of the study revealed consistent findings among the participants individually and as a group. The vertebral group curve with corresponding boggy tissue texture changes in the upper thoracic region (T2-8) of every patient throughout treatment sessions was consistent with the vertebral level for the sympathetic innervation to the lungs (T2-7).15 A Chapman point located in the third and fourth intercostal spaces was consistently found among participants and correlates with the upper and lower lung fields, respectively. These findings seemed to be manifestations of the chronic lung disease associated with CF. Chapman points correlating with the small intestine and ascending colon were also consistently found. Chapman points correlating to the cecum were minimally reported. In patients with DIOS, an obstruction at the ileocecal valve, Chapman points were observed in the small intestine but not in the cecum; the impact of treating the small intestine with OMT in patients with this condition should be further investigated.

The number of times the participants had to increase their laxatives from baseline was improved in 3 patients during the treatment phase of the study. Participant 3 had a 47% increase in laxative use during the control phase compared with a 0% increase in laxative use during the treatment phase. This participant was part of group 2, which meant there was no possibility of a carryover effect from the treatment phase. Four participants reported increased satisfaction, and 4 participants reported a decrease in interference with their daily lives while in the treatment phase. Future studies with a larger sample needs to be completed to determine whether these results can be applied to the greater CF population. Even though this study had a different population of participants, these data show consistency with the Muller et al11 review
showing that OMT reduced irritable bowel syndrome symptoms, including pain and decline in general well-being. This study did not touch on the treatment of active DIOS; however, with the decrease in length of stay and time to flatus found in Baltazar et al., there could be consideration of OMT as a therapy for active DIOS.

The low recruitment numbers in this study could be rectified by performing a follow-up study at a CF treatment center. We hope to be able to expand this study to a larger population and develop an increased level of confidence that our OMT protocols can offer a beneficial treatment to the larger population of CF patients.

These data are promising; however, this study would need to be expanded over a larger population and over a longer time to observe whether this OMT protocol is an effective tool in the prevention of DIOS.

Conclusion
The intention of the study was to evaluate OMT as a potential treatment in addressing symptoms of chronic constipation and preventing DIOS. Overall, participants experienced decreased pain, increased satisfaction with bowel movements, and a reduction in the need to use laxatives from baseline while being treated with OMT. These findings could support the use of this treatment modality in the prevention and treatment of gastrointestinal symptoms in patients with CF.

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Author Contributions
All authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; all authors drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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