

# EFFECT OF CONNECTIVE TISSUE MANIPULATION ON SYMPTOMS AND QUALITY OF LIFE IN PATIENTS WITH CHRONIC CONSTIPATION: A RANDOMIZED CONTROLLED TRIAL

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## ABSTRACT

**Objective:** The purpose of this study was to examine the effects of connective tissue manipulation (CTM) on the severity of constipation and health-related quality of life in individuals diagnosed with chronic constipation.

**Methods:** Fifty patients with a diagnosis of chronic constipation according to Rome III criteria were recruited and randomized to an intervention (n = 25) or control group (n = 25). The intervention group received CTM in addition to the lifestyle advice, whereas the control group was given only lifestyle advice for constipation. All assessments were performed at baseline and at the end of 4 weeks. The primary outcome measure was the Constipation Severity Instrument. Secondary outcomes included Patient Assessment of Constipation Quality of Life Questionnaire, Bristol Stool Scale, and 7-day bowel diary. Differences between groups were analyzed with *t* tests, Mann-Whitney *U* test and  $\chi^2$  test.

**Results:** Compared with the control group, subjects in the intervention group reported significantly greater improvement in total and subscale scores of the Constipation Severity Instrument and Patient Assessment of Constipation Quality of Life Questionnaire ( $P < .05$ ). Based on the results from bowel diaries, the improvements in the number of bowel movements, duration of defecation, stool consistency, and the feeling of incomplete evacuation in the intervention group were also significantly more than the control group ( $P < .05$ ).

**Conclusion:** This study showed that CTM and lifestyle advice were superior to reducing symptoms of constipation and quality of life compared with lifestyle advice alone for patients with chronic constipation. (J Manipulative Physiol Ther 2015;38:335-343)

**Key Indexing Terms:** Constipation; Massage; Quality of Life; Randomized Controlled Trial

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Human subjects and animals: Ethics Committee of Hacettepe University approved the study (LUT 12/35-48).

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Paper submitted June 26, 2014; in revised form April 24, 2015; accepted April 29, 2015.

0161-4754

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<http://dx.doi.org/10.1016/j.jmpt.2015.06.003>

Chronic constipation is a symptom of a condition involving insufficient defecation and whose definition varies from person to person.<sup>1</sup> Health professionals define *constipation* as 3 times or less per week defecation; and the patients define it as the sensation of incomplete bowel evacuation, hard stool, straining, and difficulty in defecation.<sup>2</sup> Chronic constipation is a common condition experienced by the general public; and it reduces the quality of life (QOL) by negatively affecting the physical, mental, and social well-being of individuals.<sup>3,4</sup> In a recent meta-analysis, the global prevalence rate of chronic constipation was reported to be 14%; it was also reported that its incidence rate is correlated with increasing age and low income level, and it is more common among females.<sup>5</sup>

Because the underlying pathophysiology of chronic constipation has not been clearly identified, its treatment has been difficult for both health care professionals and patients.<sup>6</sup> Following the elimination of pathological and secondary causes, the treatment of chronic constipation is

initiated by nonpharmacological treatment methods, such as lifestyle modifications (increased dietary fiber and water intake as well as increased physical activity), defecation training, and physiotherapy approaches.<sup>7</sup> If lifestyle modification and conservative treatment methods do not help the patient, pharmacological treatment methods, such as osmotic laxatives, stimulant laxatives, stool softeners, lubricants, chloride channel activators, and serotonin agents, may be used.<sup>7,8</sup> At the final stage, if the pharmacological treatment is not successful in patients with slow-transit constipation, surgical treatment options, such as segmental, subtotal, or total colectomy, are considered.<sup>8,9</sup> Conservative treatment methods used in patients with chronic constipation may include abdominal massage, connective tissue manipulation (CTM), chiropractic treatment, electrical stimulation, anorectal biofeedback, and exercise.<sup>10–15</sup>

Connective tissue manipulation, one of the conservative treatment methods for chronic constipation, generates local mechanical effects on mast cells in the connective tissue by short and long tractions and thus creates vasodilation by reducing the sympathetic activity. Subsequently, parasympathetic effect increases; and the improvement in the circulation promotes healing process.<sup>16,17</sup> However, there is very little research that examine its effectiveness on constipation and bowel function. In the case report of Holey et al,<sup>11</sup> it was reported that CTM was better than abdominal massage in improving symptoms of constipation. Also, another study revealed that combination of pelvic exercises and CTM played a role in healing bowel functions in women immediately after cesarean delivery.<sup>18</sup>

To the best of our knowledge, there currently is no randomized controlled trial investigating the effects of CTM on constipation.<sup>19</sup> Therefore, the present study aimed to examine the effects of CTM on the severity of constipation and on the QOL of individuals diagnosed with chronic constipation based on Rome III criteria. The primary hypothesis of the present study was that CTM application in addition to lifestyle advice would be much more effective compared with lifestyle advice alone.

## MATERIALS AND METHODS

### Study Design and Participants

In this prospective randomized controlled trial, informed consent forms were obtained from all participants; and they were informed about the study based on the Declaration of Helsinki. The study was approved by local ethics committee of Hacettepe University (LUT 12/35-48). This study was also registered to protocol registration and results system on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT02321124). After comprehensive clinical evaluation, subjects were randomly assigned to the intervention group ( $n = 25$ ) or the control group ( $n = 25$ ) using stratified block randomization

procedure with blocks of 4, using opaque and sealed envelopes containing group allocation number from a computer-generated random number table. The intervention group received CTM in addition to the lifestyle advices, whereas the control group was given only lifestyle advices for constipation.

Participants were recruited if they were older than 18 years and had a diagnosis of chronic constipation according to Rome III criteria. The Rome III classification system is widely used and is a set of standardized symptom-based diagnostic criteria for functional gastrointestinal disorders, including chronic constipation. The Rome III criteria include having at least 2 of the following: (1) straining during at least 25% of defecation, (2) lumpy and hard stool in at least 25% of defecation, (3) sensation of incomplete evacuation in at least 25% of defecation, (4) sensation of anorectal obstruction/blockage in at least 25% of defecation, (5) need for manual maneuvers in at least 25% of defecation, and (6) fewer than 3 defecations per week. In addition, symptoms should begin at least 6 months before the diagnosis; and they should be seen intermittently or continuously for 3 months.<sup>2,8</sup> Exclusion criteria were comorbid neurological, anatomical, or metabolic condition; pregnancy; mental problems preventing cooperation; history of colostomy surgery; history of gastrointestinal, spinal, or pelvic surgery except cholecystectomy, appendectomy, or hysterectomy; comorbid various colonic conditions (intestinal obstruction, peritonitis, bowel perforation, peptic ulcer, gastrointestinal bleeding, or acute inflammation of abdominal organs); history of intestinal cancer; existence of open sore or tumor at the massage region; and abdominal hernia. Patients taking laxatives were excluded or were asked to discontinue the drugs 2 weeks before enrollment.

Patients diagnosed with chronic constipation were recruited by a gastroenterologist from Hacettepe University, Adult Hospital, Gastroenterology Unit; and the patients were evaluated and treated at Hacettepe University, Faculty of Health Sciences, Physiotherapy and Rehabilitation Department, Women's Health Unit.

### Interventions

Connective tissue manipulation was applied 5 days per week for a total of 20 sessions for 4 weeks by the same experienced physiotherapist (first author). Each session lasted around 15 to 20 minutes. While patients were in a sitting position, starting from the lumbosacral region, the lower thoracic, scapular, interscapular, and cervical regions were included in the treatment, respectively (Figs 1-3). The treatment procedure of the present study was planned according to our unreported pilot study before the present study. In this pilot study, symptoms of constipation began to show improvement at the second week. At the end of the fourth week, patients demonstrated approximately normal

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