ORIGINAL ARTICLE

Osteopathic management of chronic constipation in women patients. Results of a pilot study

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Summary

\textit{Background and aims:} Constipation is a common problem in western countries. The aim of this pilot study was to determine the effectiveness of osteopathic manipulative treatment (OMT) for the treatment of constipated women with functional constipation (FC) or defecation disorders (DD).

\textit{Methods:} Twenty-one constipated females referred to a tertiary center were recruited. A course of OMT, weekly for four weeks, was given. Clinical questionnaire, Bristol stool form scale and patients’ subjective perception of constipation, bloating and abdominal pain, were recorded. Total and segmental colonic transit time (CTT) were performed before and after OMT.

\textit{Results:} Eleven patients had FC and 10 DD, as defined by Rome III criteria. After OMT, the Knowless Eccersley Scott Symptom score ($P = 0.020$), the oro-anal transit time ($P = 0.002$), the right ($P = 0.005$) and left ($P = 0.009$) CTT had decreased while the stool frequency ($P = 0.005$) and the Bristol Stool Form scale ($P = 0.003$) had increased. After OMT, the intensity of constipation, and the Patient assessment of constipation symptoms score did not change but a decrease of abdominal pain, bloating, quality of life score and drug use was found.

\textit{Conclusions:} This study shows OMT has potential benefit for treating functional constipation in women. Further randomised trials are required to confirm these results.

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Abbreviations

BSF  Bristol stool form
CAM  complementary and alternative medicine
CC  chronic constipation
CTT  colonic transit time
DD  defecation disorders
FC  functional constipation
IBS  irritable bowel syndrome

Table 1  Diagnostic criteria for irritable bowel with constipation, functional constipation, and functional defecation disorders.

Irritable bowel syndrome with constipation (IBS-C)
Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis
Recurrent abdominal pain or discomfort at least 3 days per month in the last 3 months associated with 2 or more of the following
1. Improvement with defecation
2. Onset associated with a change in frequency of stool
3. Onset associated with a change in form (appearance) of stool
4. Irritable bowel syndrome with constipation (IBS-C)
   (a) hard or lumpy stools (Bristol Stool Form Scale 1–2
      (separate hard lumps like nuts [difficult to pass] or sausage
      shaped but lumpy) > 25% of bowel movement) and
   (b) loose ( mushy) or watery stools (Bristol Stool Form
      Scale 6–7 (fluffy pieces with ragged edges, a mushy stool
      or watery, no solid pieces, entirely liquid) < 25% bowel
      movements)

Functional constipation (FC)
1. Must include 2 or more of the following
   (a) Straining during at least 25% of defecations
   (b) Lumpy or hard stools in at least 25% of defecations
   (c) Sensation of incomplete evacuation for at least 25% of defecations
   (d) Sensation of anorectal obstruction/blockage for at least 25% of defecations
   (e) Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
   (f) Fewer than 3 defecations per week
2. Loose stools are rarely present without the use of laxatives
There are insufficient criteria for IBS

Defecation disorders (DD)
1. The patient must satisfy diagnostic criteria for functional constipation
2. During repeated attempts to defecate must have at least 2 of the following
   (a) Evidence of impaired evacuation, based on balloon expulsion test or imaging
   (b) Inappropriate contraction of the pelvic floor muscles
   (i.e., anal sphincter or puborectalis) or less than 20% relaxation of basal resting sphincter pressure by
   manometry, imaging, or EMG
   (c) Inadequate propulsive forces assessed by manometry or imaging

Introduction

Chronic constipation (CC) is a functional disorder usually described as a persistent, difficult, infrequent and/or incomplete defecation [1]. In a meta-analysis, the estimates of the prevalence of constipation in North America ranged from 1.9% to 27.2%, affecting more women than men (2.1/1 ratio) [2,3]. In 2006, the Rome III criteria identifies three different types of CC (Table 1): two functional bowel disorders (1): irritable bowel syndrome with constipation (IBS-C) and functional constipation (FC), and (2) defecation disorders (DD), belongs to the anorectal disorders [4].

Laxatives and diet partially resolve constipation [5], but could have side effects [6] and represent an underestimated cost [7]. Moreover, constipation is not relieved for many patients [8]. In addition to the drug treatment of FC, lifestyle and dietary modifications (increased physical activity and a fibre-rich diet) are widely accepted and recommended as first-line therapy. Because these methods were not effective for every patient, many people have focused on alternative and complementary medicine (CAM) to look for a safe and effective therapy for constipation including acupuncture [9], massage therapy and yoga [10].

The effect of osteopathic manipulative treatment (OMT) on CC was poorly studied. In a pilot study, semi-standardised OMT improved stool consistency, constipation symptoms, severity of constipation and reduced laxatives use [11]. Other osteopathic [12] or chiropractic [13] studies can be found, but they only concern case studies, and no studies focused on the different types of constipation as defined by the Rome III criteria.

The aim of this pilot study is to evaluate the osteopathic manipulative treatment and to objectivise its effects, over a four-week period, for people suffering from CC (FC or DD).

Methods

The study was registered by the Agence nationale de sécurité du médicament et des produits de santé (ANSM) under the following Recherche clinique et biologique number: 2014-A01107-40. The study was planned and conducted in accordance with the Declaration of Helsinki and ethical laws pertaining to the medical profession. This study was not funded externally. All patients provided written informed consent before inclusion in the trial.
Patients

Twenty-one women outpatients, referred to our tertiary center for treatment of CC according to the Rome III criteria [1], were included in this study.

Before inclusion, a full evaluation assessed the functional character of the constipation by failing to find an organic cause for their complaint (morphological evaluation, endoscopy or radiology, and absence of metabolic, endocrinologic and neurologic etiologies). Patients with IBS with constipation (Table 1), drug addiction, or previous major digestive surgery were excluded from the study.

Before OMT, a single investigator (MB) confirmed the validity of the initial CC diagnosis and divided the patients into two groups: FC and DD [4], by using anorectal manometry and colonic transit time (CTT) measurement [14].

Procedures

The schedule is shown in Fig. 1. In addition, participants were asked about their drug intake before inclusion and at the end of OMT. Baseline data were recorded 1 to 4 weeks before the first OMT session. Patients were also asked to not change of lifestyle (diet, physical activity) during the study.

Questionnaires

Before the first consultation and on the last visit, patients filled 4 questionnaires:

- the Knowless Eccersley Scott Symptom score (KESS score), an 11-items tool for diagnosis of constipation uses four-to-five-points Likert scales scored on a linear integer scale [15], 45 being the maximal constipation;
- the Medical Outcomes Study Short-Form Health Survey (SF-36) asks 36 questions to measure functional health and well-being from the patient’s point of view [16];
- the Patient Assessment of Constipation Quality Of Life (PAC-QOL) is a self-reported 28-items questionnaire, used to measure the quality of life of patients [17] into 4 subscales: physical discomfort, psychosocial discomfort, worries and concerns and satisfaction, higher scores = more impact on quality of life;
- the Patient Assessment of Constipation Symptoms (PAC-SYM) is a 12-items questionnaire developed to assess symptom frequency and severity of CC [17].

In addition, patients filled the Bristol stool form scale (BSF) after each stool output to appreciate stool consistency [1] in seven visual levels (1 and 2 correspond to constipation while 5—7 correspond to diarrhea). Before each OMT session, patients completed 2 Visual Analogic Scales (VAS), from zero (minimal intensity) up to 9 (maximal intensity), about their abdominal pain and bloating, and a five-point Likert scale for the intensity of constipation from zero (minimal) up to 4 (maximal intensity) as previously described [18,19]. A change of one point being significant for these scales [19].

Measure of CTT

Segmental CTT was measured according previously described method [20]. Oro-anal transit time was the sum of the three segmental CTT. Normal values of oro-anal transit were previously established between 24 and 65 hours [21].

Osteopathic management

A single osteopath (AB) performed all OMT sessions. Four sessions, spaced from one-week, were performed, each lasted around 1 hour. In the first part of each consultation, all patients were tested through direct visceral, osteo-articular, muscular and fascia tests [22,23]. Every treatment was based on the individual patient’s findings, but the selection of techniques for each area was standardized. As an

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**Figure 1**   Trial design. After clinical evaluation (i.e. quality of defecation, intensity of abdominal pain and bloating, stool consistency, treatment used, delivery history), the patients completed the initial questionnaires and the osteopathic session started by osteopathic tests and was followed by OMT. Before inclusion, all patients stopped taking digestive medications or laxatives one week before the CTT measurement and the clinical evaluation in order to verify the Rome III criteria for functional constipation. All along the study, each patient had a stool calendar to register, after all stool output, the time of defecation and the consistency of stools according to the BSF scale. Before all medical visits and osteopathic sessions, patients completed VAS and Likert scale. The measure of CTT was performed before the study and at the end of osteopathic treatment using radiopaque markers. BSF: Bristol stool form; CTT: COlonic transit time; i: initial; f: final; OMT: osteopathic manipulative treatment; Q: questionnaires.
example, all somatic dysfunctions on psoas muscle were treated with the technique of trigger point where the patient is supine.

At the beginning of each session, a careful case history was carried out to ascertain the type of problem the patients have. The osteopath enquired about the existence of a pain, its nature, or other symptoms experienced, the circumstances of its onset, and what aggravated it or alleviated it, the existence of other health problems and the medications taken. The osteopath then carried out an examination that would consist of a visual assessment of posture and movement, and manual assessment of the muscle tone and range of movements of spine and other joints. Then, the osteopath started to feel the areas of restriction in spinal mobility and begin to stretch or loosen muscles.

In patients with osteopathic pelvic dysfunction, we performed a stabilisation of anterior and lateral pelvic curves through exercise or OMT that utilised techniques of muscle energy, balanced ligamentous tension [24], myofascial release to assist muscles to keep the spine upright and sufficiently flexible to support good posture [25]. After an overall visceral technique, the mesenteric lift was systematically implemented [26]. This technique was also used as a test before and after all OMT. The used abdominal movement enabled us to know if there was a restriction in mobility. The patient was supine, knees bent, the practitioner was at the patient’s head and applied both hands above the patient’s pubis. The practitioner, during inspiration, brought his hands towards the patient’s hand, and at the end towards the pubis. The diaphragm and subcollitipal muscles had already been treated. Then, direct and specific visceral techniques were applied based on dysfunctions found on each patient. The techniques were performed from the last organ involved in digestion to the first organ involved [27]. This means that treatment could begin with the sigmoid colon, the left colon, the splenic flexure, the transverse colon, the hepatic flexure, the right colon, the cecum, the ileocaecal valve, the peritoneum, the duodenojejunal angle, the liver and the gall bladder, the pylorus and the stomach [28].

Outcome measures

The primary outcome was the improvement of the KESS score.

The secondary outcomes were CTT, drug intake, constipation (stool frequency and VAS constipation), and quality of life.

Statistical analysis

Analysis was done in intention-to-treatment population by MB and reviewed by the Clinical Research Unit of the Avicenne Hospital. Data is shown as mean ± standard deviation. Baseline demographic and clinical data were compared by means of a non-parametric Wilcoxon test for paired or non-paired series using Statbox 6.1 software for Windows (Optima, Paris, France) for quantitative parameters, while qualitative parameters were analysed using a chi square test. The level of significance was set at \( P < 0.05 \).

Results

The 21 women included in the present study were between 18 and 70 years old (48.6 ± 14 years); their body mass index (BMI) was between 18 and 37.2 kg/m\(^2\) (25.0 ± 4.8). The duration of the disorder ranged between 10 and 20 years. These patients had 1.3 ± 1.2 children, 8 patients (38%) were nulliparous and 9 patients (42.8%) were sedentary without any physical activity and were unemployed or retired. Eleven women had FC (52%) and 10 women had DD (48%).

Pre-test

Clinically, the 2 groups were comparable for stool frequency, SF-36, PAC-SYM, PAC-QOL, KESS scales, VAS intensities for abdominal pain and bloating and Likert scale for constipation (Table 1). In contrast, BSF scale and rectosigmoid transit time were higher in DD patients than in FC patients (\( P = 0.040 \), and \( P = 0.009 \), respectively).

Primary outcome

In the study sample, the KESS score decreased at the end of the study for the whole population (\( P = 0.020 \)) and for the 2 groups separately (\( P = 0.014 \) and \( P = 0.05 \) for the FC and DD groups, respectively).

Secondary outcomes

In comparison with pre-treatment values (Fig. 2), the stool frequency increased at the end of the study (\( P = 0.05 \)), mainly in the FC group (\( P = 0.020 \) (Table 2).

For all patients, stool form increased after the fourth OMT session (Fig. 3; \( P = 0.003 \)). For all patients, stool form increased from 1.5 ± 1.3 before treatment to 2.2 ± 1.5 after the fourth OMT session (\( P = 0.003 \)). This increase was more marked in the functional constipation group (1.2 ± 0.5 vs. 2.2 ± 1.2; \( P = 0.004 \)) than in the defecation disorder group.

Oro-anal transit time was significantly decreased at the end of the study (\( P = 0.002 \)). In all patients, this decrease was significant for the right and the left colon. However, the reduction was mostly observed in the left colon for FC patients (\( P = 0.010 \)) and in the right colon for DD patients (\( P = 0.010 \)), while rectosigmoid transit time did not change for the study sample and in the two groups taken separately. For 45% of patients, CTT was normalized after OMT, whatever the CC phenotype.

For the whole population, as for each group separately, the intensity of VAS constipation did not change significantly. After OMT, patients reported a significant decrease in abdominal pain (\( P = 0.009 \)), not found of each group separately. After each osteopathic session, bloating decreases constantly (Fig. 4; \( P < 0.01 \)). At the end of the study, bloating decreased in the study sample (\( P = 0.002 \), more predominantly in FC patients (\( P = 0.032 \)).

After OMT, no significant variation of the PAC-SYM score was found. In contrast, for the whole population, there was a significant improvement in PAC-QOL score (\( P = 0.030 \), not found significant for each group separately. By comparison
with baseline, the SF-36 were not significantly modified at the end of the study.

After OMT, the number of prokinetics pills taken was reduced by half, (4.2 vs. 2.3) and half of the patients gave up using any type of laxatives (rectal, ballast or lubricant) (Table 3).

**Discussion**

This pilot research study (no control and no randomisation) suggests that OMT could improve CC in FC and DD patients. This effectiveness originates from a subjective point of view, decrease of KESS score, as well as from an objective
Table 2  Data collected according to the constipation phenotype (M ± SD) before and after osteopathic manipulative treatment.

<table>
<thead>
<tr>
<th>Questionnaires</th>
<th>All patients</th>
<th>Constipation phenotype</th>
<th>Functional constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before OMT</td>
<td>After OMT</td>
<td>P</td>
</tr>
<tr>
<td><strong>Stool calendar</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stool frequency (stools per week)</td>
<td>4.8 ± 5.2</td>
<td>7.7 ± 13.0</td>
<td>0.005</td>
</tr>
<tr>
<td>Stool consistency (BSF)</td>
<td>1.5 ± 1.3</td>
<td>2.2 ± 1.5</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>Colonic transit time</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oro-anal transit time (hour)</td>
<td>88 ± 29</td>
<td>64 ± 44</td>
<td>0.002</td>
</tr>
<tr>
<td>Right colonic transit time (hour)</td>
<td>24 ± 17</td>
<td>17 ± 18</td>
<td>0.005</td>
</tr>
<tr>
<td>Left colonic transit time (hour)</td>
<td>40 ± 19</td>
<td>24 ± 27</td>
<td>0.009</td>
</tr>
<tr>
<td>Rectosigmoid transit time (hour)</td>
<td>24 ± 17</td>
<td>20 ± 21</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Scales</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>2.7 ± 0.8</td>
<td>2.4 ± 1.1</td>
<td>0.09</td>
</tr>
<tr>
<td>VAS-bloating</td>
<td>6.0 ± 2.6</td>
<td>3.6 ± 2.7</td>
<td>0.002</td>
</tr>
<tr>
<td>VAS-abdominal pain</td>
<td>4.4 ± 2.3</td>
<td>2.6 ± 2.7</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Significant results are shown in bold. BSF: Bristol Stool Form; KESS: Knowless Eccersley Scott Score; OMT: Osteopathic manipulative treatment; PAC-QOL: Patient Assessment of Constipation Quality of Life; PAC-SYM: Patient Assessment of Constipation Symptoms; SF-36: Medical outcomes study Short-Form health survey; VAS: Visual analogic scale.

point of view (increased stool frequency, decreased CTT). In addition, OMT improves symptoms frequently associated with constipation (hard stool, abdominal pain, bloating) and reduces drug intake.

Despite the increased interest in the use of CAM in the treatment of digestive disorders [29], the literature is poor in papers reporting the effectiveness of OMT in CC patients. A recent systematic review has shown that OMT may be beneficial in the treatment of IBS patients [30]. In CC patients, the current study demonstrates an improvement in KESS score and CTT, contrary to the previous IBS studies [19,31]. Additionally, as in IBS patients, a decrease in bloating was found.

Abdominal massage is used in the treatment of adults CC [32–36] or children CC [37]. Although the results of these trials suggest that abdominal massage could be a promising treatment for CC, these studies were heterogeneous in terms of trial design, patient samples and types of massage [38]. Additionally, in a small group of CC patients, no change in stool frequency, stool consistency, scores of well-being and CTT were found after abdominal massage [39]. Moreover, a high number of massage sessions were found to be necessary to deliver a significant improvement [40] and no decrease in laxative use was established with the massage studies [41]. Nevertheless, abdominal massage was not compared in FC patients and DD patients.

OMT in CC patients was only described in case reports [12,42] or in studies including a limited number of subjects [11,43]. OMT was effective in treating CC for 13 children with cerebral palsy [43] or on 6 adult patients [11]. In these studies, manipulation of the spine and sacrum, trigger on abdomen, direct and indirect visceral technique mostly on ileoaeical, sigmoid and in epigastric region were used. In this new pilot study, we also manipulated psoas, diaphragm and suboccipital muscles. Despite the treatment procedure was semi-standardized, patients were treated according to
their osteopathic dysfunction as performed in osteopath offices. We did not apply a specific osteopathic treatment to a given medical disorder. For a given patient, the treatment could change from one session to another, and equally from one patient to another. Treatment was only related to the osteopathic dysfunctions found in the first part of the osteopathic session. For each type of osteopathic dysfunction, one technique was selected and applied in order to give the biggest reproducibility in the treatment used.

We also selected only women because the CC prevalence is two-fold higher in women [6] and we studied the CC phenotype (FC, DD) because it was not covered by previous studies.

This study shows in CC patients a clinically significant improvement of constipation characterized by an increase of stool frequency, by an improvement of stool consistency and also by a decrease of oro-anal transit time. This improvement was found as well for FC as for DD, and was associated with a decrease of drug intake, and a significant decrease of the intensity of clinical signs associated to CC (bloating, abdominal pain).

We chose to use the KESS score to estimate the importance of constipation because this score was found to be useful in assessing the presence, severity, and pattern of CC symptoms in routine gastroenterological practice [15,44]. CTT was evaluated because this test is easy to perform [18,20], gives objective assessment of colonic motor function, and was previously used to assess the effectiveness of OMT in the treatment of IBS [19].

As in the current study, Brugman et al. report a decrease in laxative intake, a normalization in stool form, an improvement in constipation and in quality of life [11]. However, in this study, the distinction between FC and DD was not assessed. In the same way, CTT was not measured but only estimated by BSF scales. The current study demonstrated a decrease in CTT, but did not show an improvement in PAQ-SYM scores as in the Brugman et al.’s study.

After OMT, the change of objective parameters (stool frequency, BSF, CTT) was not associated with improvement of the subjective “feeling of constipation”, as evaluated by VAS. Nevertheless, bloating and abdominal pain, two subjective parameters associated with constipation were improved. The CTT measurement showed that OMT did not change rectosigmoid transit time in both groups of patients but decreased right CTT in DD patients and left CTT in FC patients.

Despite the improvement in CTT and KESS scores after OMT, improvement in constipation could be attributed to the placebo effect, but these significant results are rarely found in drug studies [45].

This study, as other previous studies is limited by the definition of stool frequency. In the two groups of constipated subjects, some patients reported a great number of hard stools. It is well known that defining constipation based on a patient’s reported stool frequency might prove misleading [46]. The great number of stools is more related to incomplete defecation than a real increase in bowel movements.

Despite the limited group size, the statistical significance of the results is in favour of the effectiveness of OMT in the management of CC. In addition, data of the current study could be used in further studies to calculate the number of subjects needed for a trial designed to validate the effectiveness of OMT in the treatment of CC.

Finally, another limitation of the study is that only one osteopath (AB) was involved in all sessions.

Compared to previous studies on the effectiveness of OMT in treating constipation [11], the results were analysed according to the phenotype of constipation (FC vs. DD). This
study demonstrates specific efficacy of OMT on the different constipation phenotypes: decrease of right transit in DD and decrease of left transit in FC patients. Further studies on larger groups are needed to confirm these results and to suggest a physiological basis for these phenomena.

In order to improve symptoms associated with constipation, such as bloating and to improve quality of life, OMT might be seen as an alternative to prokinetics drugs and/or laxatives. The decrease in bloating found in our previous study on IBS patients [19] and in the present study in CC patients could promote OMT in the treatment of abdominal bloating.

Nevertheless, this study was focused on feasibility, which limits the conclusions that can be deduced from the results shown in this paper. Further intervention studies must be multicentric and have to be carried out on larger samples to validate the results found in the present study.

In this experimental pilot study, in constipated women with two different phenotypes, FC and DD, OMT could increase stool frequency, and decrease CTT, abdominal bloating and drug intake. The promising results of this pilot study need to be confirmed through further multicentric studies to be carried out on larger samples.

**Author contribution**

AB: osteopathic manipulative treatment, redaction of the manuscript; MB: design of the study; selection of the patients, physiological measurements, statistical analysis, redaction of the manuscript; RB: design of the study; selection of the patients; redaction of the manuscript.

**Disclosure of interest**

The authors declare that they have no competing interest.
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