ORIGINAL ARTICLE

The Effect of Visceral Manipulation on Abdominal Pain and Quality of Life in Adult Patients with Functional Dyspepsia: A Pilot Study.

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Submitted: 14/12/2024. Revised edition: 29/01/2025. Accepted: 30/03/2025. Published online: 01/06/2025.

Abstract

Background: A pilot study was conducted to determine the effect size of visceral manipulation (VM) sessions on abdominal pain and quality of life in adult individuals with functional dyspepsia (FD).

Methods: Twenty-nine subjects diagnosed with FD participated in a pre-post-study design. The participants were subjected to a two-week treatment regime involving VM intervention sessions. Each session lasted for 30 minutes and was conducted five times a week. Data were collected using the Abdominal Pain Index (API) and Short-Form Nepean Dyspepsia Index (SF-NDI) instruments. The Friedman test was used for analysis. with a significance level set at $p < 0.05$. This study was approval by the Health Research Ethics Committee of the Health Polytechnic, Ministry of Health, East Kalimantan, Indonesia (Ethics No. DP.04.03/7.1/12146/2023).

Results: Among FD patients, there was a significant reduction in abdominal pain, pain time, duration, and intensity before and after the VM intervention (all $p < 0.05$). The quality of life also improved in the following domains: anxiety, activity limitation, eating and drinking, knowledge, and work/study (all $p < 0.05$)**.**

Conclusion: After 2 weeks of VM intervention in FD patients, we found a significant reduction in abdominal pain and improved in quality of life. Although the small sample size limits the generalizability of the findings, the observed improvement in abdominal pain and quality of life may hold clinical relevance for this population.

Keywords: *Abdominal pain, functional dyspepsia, pilot study, quality of life, visceral manipulation.*

Introduction

Functional dyspepsia (FD) is a most common chronic upper gastroduodenal disease without obvious organic causes or metabolic disturbances [1,2]. FD is characterized by symptoms such as upper abdominal discomfort or pain, early satiety, postprandial fullness, bloating, and nausea, which can significantly affect the quality of life of patients. FD is classified as chronic if it has lasted for the last 3 months, with the incidence of symptoms having been felt for at least 6 months prior to diagnosis. Globally, the prevalence of FD varies, with women having a slightly higher prevalence than men, at 25.3% vs 21.9% [3]. The pathophysiology of FD involves abnormalities in gastric motility, gastric neuromuscular function, and visceral hypersensitivity [4,5].

Dyspepsia accounts for one of the top 10 diseases in Indonesia, with a prevalence of 40–50% [6]. Additionally, the prevalence of FD among individuals aged 26 to 35 years is estimated to be as high as 50% [7]. Moreover, it has been reported that FD cases constitute nearly 30% of general practice and up to 60% of gastroenterology practice [8]. Despite the availability of various treatment options, the management of FD remains challenging due to the heterogeneity of symptoms and the limited efficacy of existing therapies in some patients.

The gastroduodenal region, comprising the stomach and duodenum, exhibits remarkable physiological mobility and motility, essential for normal functioning. Impairment of this motility can have significant implications, leading to functional disturbances in the organ itself and its surrounding structures [9]. Such limitations in organ motion may result in various pathological effects, including irritation, visceral spasm, dysmotility, increased tension, inflammation, visceral hypersensitivity, and emotional distress [10]. These motility disturbances often manifest as FD, a condition characterized by chronic or recurrent upper abdominal pain or discomfort, often accompanied by bloating, early satiety, or nausea [1,2].

Pharmacological interventions have been a primary focus in the management of FD, but their efficacy has been variable. Studies have shown that many pharmacological interventions provide only temporary relief and are not consistently superior to placebo [3]. Furthermore, not all treatments are effective in all cases of functional dyspepsia, highlighting the need for alternative approaches [11]. In this context, nonpharmacological therapies have gained attention as potential interventions for FD. Conservative interventions, such as dietary modifications, psychological interventions, exercise, and complementary therapies, have shown promise in reducing the symptoms of patients with FD [12,13,14,15].

The ineffectiveness of drug therapy alone in managing FD has prompted a shift towards a more comprehensive and holistic approach to patient care. Nonpharmacological therapies offer the advantage of addressing the multifactorial nature of FD, targeting not only the physical symptoms but also the psychological and social aspects of the condition [16]. Abdominal manipulation therapy, including visceral manipulation (VM), has been suggested as a potential treatment for FD. Lee and Maeng noted the potential effectiveness of VM for FD patients but emphasized the need for further studies to establish its efficacy [17].

The theoretical basis of VM posits that adhesions or limitations in the visceral tissues may alter neurophysiological processes and biomechanics potentially leading to pain and discomfort. VM is a manual therapy technique aimed at improving the mobility and function of abdominal soft tissues and organs through specific, gentle manoeuvres [18,19]. In recent years, non-pharmacological approaches, such as VM, have gained increasing recognition as viable treatments options for visceral disorders, including FD. While existing evidence supports the use of VM for certain gastrointestinal disorders, such as functional constipation, its efficacy in treating FD remains insufficiently established [20].

A pilot study was conducted to examine the effects of VM interventions on abdominal pain and the quality of life in individuals with FD. The

study aimed to quantify the short-term effects of VM sessions incorporating three specific techniques: lesser omentum stretching, stomach mobilization, and duodenum mobilization. We hypothesize that the combined effects of these interventions would have the capacity to have immediate changes in pain and quality of life.

Methods

Study participants

Twenty-nine FD patients participated in this nonrandomized pre-post pilot study. Participants were recruited from Wiyata Husasa Physiotherapy Clinic. Inclusion criteria were: (1) referral to outpatient physiotherapy with an FD diagnosis; (2) FD without gastritis for at least 3 months; (3) ability to read and write the Indonesian language; and (4) age 20 - 60 years. Exclusion criteria included: (1) gastritis; (2) diabetes/pancreatitis; (3) liver and biliary tract disease; (4) gastrointestinal tumour or malignancies; (5) Helicobacter pylori infection; and (6) use of analgesic medications. All participants provided written informed consent before enrollment into the study. The study received ethical approval from two institutions: the Faculty Ethics Review Committee (FERC) of UiTM Puncak Alam Campus (Approval ID: 500-FSK (PT.23/4)) and the Health Research Ethics Committee of the Health Polytechnic, Ministry of Health, East Kalimantan, Indonesia (Ethics No. DP.04.03/7.1/12146/2023).

To monitor the study, participants were carefully screened for any ongoing treatments, including medications and supplements, before enrolling in the study. Those who were taking any such treatments (medications and supplements) that could potentially interfere with the outcomes of VM were excluded from the study. This information was used to ensure that there were no significant differences between the experimental groups at the start of the study. And, Throughout the study, participants were regularly monitored and asked to report any new treatments or changes to their existing treatments.

Outcome measures

The primary outcomes were adherence rate, adverse events, and recruitment feasibility. Adherence rate was measured as the percentage of completed VM sessions of a maximum of 10 sessions (5 times per week for 2 weeks). Every session began and ended with questions. Participants were asked about adverse effects during the session, including a ticklish sensation, pain, light-headedness, and nausea. A non-serious adverse event was defined as an event that results in minor discomfort and does not require session or study termination. The number of participants who gave their consent and signed up each month served as a gauge of recruitment feasibility.

The secondary outcome was abdominal pain and quality of life among individuals with FD. Abdominal pain was measured using the Abdominal Pain Index (API), which includes pain frequency, pain time, pain duration, and pain intensity [21]. It consists of a questionnaire that asks patients to rate the severity of their abdominal pain on a scale from 0 to 10. The API may also include questions about the location and type of pain, as well as any associated symptoms. Furthermore, the frequency of pain is evaluated on a six-point scale that ranges from never to persistent pain throughout the day. The API demonstrated good construct validity for children and adolescents with chronic pain [19,22].

The Short-Form Nepean Dyspepsia Index (SF-NDI) was used to evaluate the quality of life. The SF-NDI is a valid instrument that can measure the disease-specific impact of FD on quality of life, which included anxiety, daily activity limitation, eating/drinking, knowledge/control, and work/study [23]. The questionnaire consists of 10 items, and each item is measured by a 5-point Likert scale ranging from 0 (not at all or not applicable), 1 (a little), 2 (moderately), 3 (quite a lot), and 4 (extremely). Individual items in each subscale are accumulated to obtain a quality-of-life score ranging from 0 to 100. Patients with scores above 15 on the SF-NDI indicate a significant reduction in quality of life.

Study protocol

Three licensed physiotherapists with 5-20years of clinical experience participated in this study. All therapists had received advanced training in VM and maintained clinical caseloads consisting of 80-85% visceral disorder cases, with approximately 85% of these being FD referrals from internal medicine doctors. Trained assessors conducted baseline and post-treatment measurements after completing standardized training to ensure measurement consistency and reliability. Participants were recruited through the outpatient physiotherapy clinic following referral for FD symptoms. The assigned physiotherapist evaluated each patient for study eligibility. Eligible patients who provided informed consent were enrolled in the study.

Participants received ten 30-minute VM sessions over two weeks (5 sessions/week). The decision to measure the effects of VM over a two weeks was based on the following considerations: (1) Previous studies by Silva et al [23] and Eguaras et al [24] had demonstrated VM effectiveness within two weeks; (2) Two weeks was deemed optimal to maintain participant engagement and minimize dropout rates, and ensuring the integrity of the data collected; (3) Conducting a longer-term study requires more resources, including time, funding, and personnels. Given these constraints, two weeks were a practical and feasible choice for this pilot investigation.

To minimize the risk of overreporting bias in our study, we implemented several strategies: (1) We used well-established and validated questionnaires that are designed to reduce bias and increase the reliability of self-reported data (such as the API and SF-NDI questionnaires). These instruments have been widely used in similar studies and have demonstrated robust psychometric properties; (2) Participants were blinded to the specific hypotheses of the study to reduce the likelihood of response bias. They were informed that the study aimed to assess the general effects of VM without disclosing the expected outcomes; (3) Participants were asked to complete their self-reports at regular intervals throughout the study rather than relying on a single point of data collection. This approach helped in capturing consistent and reliable data over time, reducing the risk of any single instance of overreporting significantly impacting the overall results; (4) We emphasized the anonymity and confidentiality of participant responses, encouraging honest and accurate reporting. Participants were reassured that their responses would be anonymized and used solely for research purposes, and; (5) In our data analysis, we applied statistical techniques to identify and control for potential outliers and overreporting to ensure that the results were not unduly influenced by biased reporting.

The VM intervention consisted of a standardized treatment protocol incorporating gastric and duodenal mobilization techniques along with lesser omentum stretching.

(1) Stretching the lesser omentum: The participant lies supine with both limbs bent. The practitioner stands on the left side of the patient. Both hands of the practitioner are placed on the left and right sides of the median line below the xiphoid process, with the fingers just above the stomach wall. With both hands, the practitioner slowly applies posterior pressure to the inside of the abdomen and performs stretching of the lesser omentum.

(2) Oscillations on the stomach: The participant lies supine with both limbs bent. The practitioner stands on the left side of the patient. The practitioner places the fingers of both hands on the abdomen in the gastric region and applies pressure posteriorly until the hands fully reach the gastric wall. Oscillatory movements are applied to the stomach.

(3) Frontal plane stomach mobilization: The participant lies on his right side. The practitioner stands behind the patient and places both hands on the left lateral costal margin (ribs 6-7) below the diaphragm. With both hands, he performs caudomedial mobilization of the stomach, followed by

counter-directional mobilization of the stomach craniolaterally.

(4) Transverse plane stomach mobilization: Patient lies right lateral decubitus, and the practitioner stands behind him. Using costal contact, the practitioner rotates the stomach medially to the right. Then, the practitioner performs the reverse movement with lateral rotation of the stomach to the left.
(5) Sagittal plane stomach mobilization: The stomach mobilization technique in the sagittal plane follows the same procedure as the frontal and transverse plane mobilizations. The practitioner's left hand is placed on the anterior part of the left costal margin at the level of 6^{th}-7^{th} ribs. The right hand is positioned on the posterior part of the left shoulder. With both hands, the practitioner mobilizes the stomach via the ribs in the sagittal plane by pressing the stomach in the anteroposterior direction and the right hand in the posteroinferior direction.
(6) Duodenum mobilization: Participant lies in a side-lying position, facing to the right, and both limbs slightly bent. The practitioner places both hands on the medial part of the abdomen, lateral to the ascending colon, then apply pressure to the inside of the posteromedial abdomen and stretches medially and craniocaudally. The practitioner maintains this position briefly until tissue relaxation is achieved.

Statistical analysis

The SPSS 16.0 program was used for statistical analysis of the obtained e measurement data. Since the data did not meet the assumption of normal distribution, Friedman's non-parametric test was applied. Descriptive statistics (mean age, gender, occupation, education, and marital status) were calculated for the study participants. Cohen's effect size was computed to assess baseline and post-intervention effect sizes for the aforementioned variables.

Results

Demographic characteristics of the study participants

A total of 33 subjects were screened for eligibility in this study. Of these, 29 met the inclusion criteria and completed the VM intervention, while 4 were excluded. The demographic characteristics of the participants are summarized in Table 1.

Primary outcomes: adherence and feasibility

The 29 participants who met the inclusion criteria completed the intervention with a 100% retention rate. Throughout the 2-week VM intervention, all participants tolerated the treatment well, with no significant or serious side effects reported. Seven participants experienced a ticklish sensation during the first VM intervention. Three participants felt a slightly uncomfortable sensation during the first abdominal VM mobilization but showed no resistance reaction or other signs of side effects. The remaining participants reported a comfortable sensation during the abdominal VM intervention. Notably, no dropouts occurred during the 2-week intervention period, and all participants provided positive feedback on the pilot study. Twenty-three participants reported improvements within the first week, including easier breathing, better sleep patterns, and increased abdominal comfort. The remaining 6 participants reported similar benefits after the second week of treatment. All participants noted a significant positive impact and expressed a desire for a long-term continuation of the therapy.

Secondary outcomes: Effect of visceral manipulation on abdominal pain and quality of life in FD patients

Table 2 presents the results of Friedman tests assessing abdominal pain changes in FD subjects across three time points (baseline, 1-week treatment, and 2-week treatment). The analysis revealed statistically significant differences in four pain-related parameters: (1) pain frequency

at baseline (mean difference = 3.52±0.57, p=0.001), after 1-week treatment (mean difference = 2.31±0.54, p=0.001), and after 2-week treatment (mean difference = 0.59±0.50, p=0.001); (2) pain time at baseline (mean difference = 1.48±0. 1, p=0.001), after 1-week treatment (mean difference = 1.17±0.38, p=0.001), and after 2-week treatment (mean difference = 0.59±0.50, p=0.001); (3) Pain duration at baseline (mean difference = 2.66±0.48, p=0.001), after 1-week treatment (mean difference = 1.52±0.51, p=0.001), and after 2-week treatment (mean difference = 0.59±0.50, p=0.001); and (4) Pain intensity at baseline (mean difference = 3.52±0.51, p=0.001), after 1-week treatment (mean difference = 2.10±0.67, p=0.001), and after 2-week treatment (mean difference = 0.59±0.50, p=0.001).

Table 3 shows significant changes in FD subjects' quality of life as indicated by Friedman test results: (1) anxiety of at baseline (mean difference = 3.14±0.58, p=0.001), after 1-week treatment (mean difference = 1.93±0.75, p=0.001), and after 2-week treatment (mean difference = 1.31±0.47, p=0.001); (2) limitation of daily activities at baseline (mean difference = 3.31±0.47, p=0.001), after 1-week treatment (2.07±0.46, p=0.001), and after 2-week treatment (mean difference = 1.03±0.19, p=0.001); (3) Eating and drinking at baseline (mean difference = 3.45±0.51, p=0.001), after 1-week treatment (mean difference = 2.03±0.42, p=0.001), and after 2-week treatment (mean difference = 1.03±0.19, p=0.001); (4) Knowledge and control at baseline (mean difference = 3.17±0.71, p=0.001), after 1-week treatment (mean difference = 1.34±0.48, p=0.001), and after 2-week treatment (mean difference = 1.00±0.00, p=0.001); and (5) Work and study at bseline (mean difference=3.14±0.58, p=0.001), after 1-week treatment (mean difference = 2.00±0.38, p=0.001), and after 2-week treatment (mean difference = 1.07±0.26, p=0.001). These results demonstrate a statistically significant improvement in the quality of life from baseline to 1-week treatment and 2-week treatment.

Discussion

The pilot study aimed to determine the effect size of VM sessions on abdominal pain and quality of life in adult individuals with functional dyspepsia (FD). The results demonstrated high levels of adherence, positive feedback, and satisfaction, indicating that VM intervention was well-received. These findings suggest that VM may be a promising alternative for those with FD.

Participant feedback highlighted several reasons for the favourable reception of VM, including perceived comfort, relaxation, reduced abdominal pain, and improved quality of life. The aforementioned positive outcomes served to reinforce the participants' acceptance of VM. Furthermore, no significant adverse effects were observed, supporting the safety of VM. Finally, the findings of this study demonstrated that VM intervention can significantly reduce abdominal pain and improve the quality of life of FD patients during the two-week treatment period. These results align with concurrent findings from studies by Maeng and Lee (2015) and Silva et al. (2018), which support the notion that visceral manipulation therapy holds promise as a therapeutic modality for individuals grappling with functional dyspepsia [17,19].

A multitude of mechanisms have been identified to explain the effects of VM, as supported by various studies. Mechanical effects- arising from physical forces such as compression, stretching, mobilization, and oscillations of body tissues and organs- have been shown to enhance proprioceptive communication through mechanical interactions within the body. This, in turn, may reduce pain threshold, structural abnormalities, and faulty posture [26]. From a neurological perspective, VM is believed to stimulate the parasympathetic nervous system, promoting relaxation and reducing anxiety [27]. The combined effects of these mechanisms can enhance visceral mobility and function, as well as

improving emotional well-being, thereby contributing to a better quality of life [20].

Given the encouraging results of this preliminary study, clinicians should consider incorporating visceral manipulation as a therapeutic approach for patients with functional dyspepsia [24]. The study's strengths lie in its focus on the potential clinical benefits of visceral manipulation, particularly in alleviating abdominal pain and improving patients' quality of life. These findings offer preliminary evidence that could facilitate the development of more effective treatment strategies for managing functional dyspepsia.

Nevertheless, this study has several limitations. First, the small sample size and lack of a control group may limit the generalizability of the findings. Second, standardizing manual therapy interventions is challenging due to the variability in pressure and sensitivity among practitioners. Finally, the study design did not assess the long-term sustainability of symptom reduction.

Future research should prioritize large scale randomized controlled trials to further examine the efficacy and safety of VM in patients with FD.

Conclusion

The results of this pilot study suggest that VM may benefit adult patients with FD, as evidenced by reduced abdominal pain and improved quality of life. The findings indicate that this manual therapy approach could serve as a promising adjunctive treatment option for individuals with FD, a condition with limited treatment options.

Given its non-invasive and relatively safe nature, VM presents an appealing therapeutic option for individuals seeking complementary or alternative treatments. This study lays the groundwork for further research into VM's role in managing abdominal pain and enhancing the quality of life in FD patients.

Ethics approval and consent to participate:

The research had been approval by the Faculty Ethics Review Committee (FERC) of the Faculty of Health Sciences, UiTM Puncak Alam Campus (Approval ID: 500-FSK (PT.23/4)) and received ethical approval from the Health Research Ethics Committee of the Health Polytechnic, Ministry of Health, East Kalimantan, Indonesia (Ethics No. DP.04.03/7.1/12146/2023). During the research, the researcher pays attention to the ethical principles of information to consent, respect for human rights, beneficence and non-maleficence.

Patient consent for publication

Written informed consent was obtained for anonymized patient information to be published in this article.

Authors' Contributions

AA: Conceptualization, Data Curation, Formal Analysis, Methodology, Validation, Visualization, Writing – Original Draft, Review & Editing; HM: Supervision, Visualization, Writing – Review & Editing

Acknowledgement

The authors gratefully acknowledge the Samarinda Physio Wiyata Clinic for granting permission to conduct this study at their clinic.

Conflict of interest

The authors declare no conflict of interest.

Funding

This research did not receive external funding.

Table 1. Demographic data of the participants characteristics

	Frequency	**Percentage**
Demographics	**n = 29**	
Gender		
Male	12	41.4
Female	17	58.6
Age groups		
20-35	6	20.7
36-45	9	31.0
>46	14	48.3
Marital status		
Single	0	0.0
Married not at home	0	0.0
Married at home	27	93.1
Divorced/Widower	2	6.9
Educational level		
Junior high school	0	0.0
High school	0	0.0
Bachelor's degree	29	100
Employment status		
Civil servant	4	13.8
Private employee	1	3.4
Self-employed	8	27.6
Retired	5	17.2
Not working	11	37.9

Table 2. Results of VM Effect on FD patients' abdominal pain.

	Baseline	**1 weeks**	**2 weeks**	**Significance**
Outcome measure	(Mean±SD)	(Mean±SD)	(Mean±SD)	***p-value***
Pain frequency	3.52±0.57	2.31±0.54	0.59±0.50	0.001*
Pain time	1.48±0.51	1.17±0.38	0.59±0.50	0.001*
Pain duration	2.66±0.48	1.52±0.51	0.59±0.50	0.001*
Pain intensity	3.52±0.51	2.10±0.67	0.59±0.50	0.001*

SD: standard deviation; * $p<0.05$

Table 3. Results of VM Effect on quality of life in FD patients.

	Baseline	1 weeks	2 weeks	
Outcome measure	Mean±SD	Mean±SD	Mean±SD	**Significance**
Anxiety	3.14±0.58	1.93±0.75	1.31±0.47	0.001*
Daily activity limitation	3.31±0.47	2.07±0.46	1.03±0.19	0.001*
Eating/drinking	3.45±0.51	2.03±0.42	1.03±0.19	0.001*
Knowledge/control	3.17±0.71	1.34±0.48	1.00±0.00	0.001*
Work/study	3.14±0.58	2.00±0.38	1.07±0.26	0.001*

SD: standard deviation; * $p<0.05$

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