The Effect of Osteopathic Treatment on the Irritable Bowel Syndrome: A Case Series

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ABSTRACT

Irritable bowel syndrome (IBS) is the most common gastrointestinal (GI) disorder seen by healthcare professionals, yet, effective treatment is lacking. The aim of this study was to explore the effects of osteopathic treatment on IBS. Two IBS patients were recruited and received osteopathic treatment over four consecutive weeks at Victoria University Osteopathic Medicine Clinic. The patients were assessed by the Bowel Symptom Scale (BSS) at the pre, mid and post treatment points. Subjects showed varied results throughout the study, however by the end of the study both patients showed a decrease in their overall severity of symptoms. Improvements did occur in the patients' individual presenting symptoms, where abdominal pain, bloating and diarrhoea were all reduced. The preliminary data of two patients indicates that osteopathic treatment may help. However, the results are inconclusive due to an insufficient patient population and inadequate study design. This highlights the need for further research of a larger scale, longer-term, randomised, controlled study.

Key words: Osteopathy, irritable bowel syndrome (IBS), bowel symptom scale (BSS)

Introduction:

Irritable bowel syndrome may be defined as a functional gastrointestinal disorder that is typically seen as a disturbed state of intestinal motility for which no anatomical or pathological cause can be found. It can cause recurring upper and lower GI symptoms, including variable degrees of abdominal pain, constipation and/ or diarrhea, and abdominal bloating.[1]

Irritable bowel syndrome (IBS) is the most common chronic non-infectious gastrointestinal disorder in Western countries for which there is a lack of effective treatment.[2] The disease causes reduced quality of life and represents a multi-billion dollar health-care problem and is second only to the common cold as a cause of work absenteeism.[3] More than one in seven people in the Australian community suffer from IBS, representing approximately 10% of the total attendance to general practitioners,[4] in addition, 39% of patients with IBS take over-the-counter medications for treatment of the condition.[5] IBS affects females twice as much as males[6] and correlates with anxiety and depression. In 50% of IBS patients, the onset begins before the age of 35 years, and in almost all patients who are diagnosed with IBS, the onset occurs before 50 years of age.[7]

IBS follows a chronic, fluctuating and recurrent course, displaying changes in symptom severity and diagnostic category over time. Interestingly, the overall prevalence in the general community remains relatively stable as individuals move in and out of the category of IBS as their symptoms fluctuate.[8]

IBS is not a life-threatening condition, however, it tends to be chronic with 88% of sufferers still being symptomatic 8 years after the onset[9] and also has a profound

impact on their ability to work and enjoy life. These characteristics therefore emphasise the need for a successful treatment for IBS.

Aetiology:

The possible causes of IBS are still uncertain, there are however, certain factors that are more common in sufferers of IBS which may indicate a causative factor. Stress, anxiety and depression have all been shown to correlate with sufferers of IBS. Previous literature suggests that there is a relationship between psychosocial problems, psychiatric disorders and IBS, at least in those who seek medical help for IBS. [10] Adverse reactions to foods are also common, particularly in diarrhea-predominant IBS sufferers. From previous studies it has been found that wheat, dairy products, coffee and tea are the foods predominately citied as provoking the patients' symptoms.[11]

Diagnosis & Management:

The diagnosis of irritable bowel syndrome is mainly one of exclusion. After extensive tests for cancer, ulcerative colitis and other organic diseases have been deemed negative and other red flags in the history such as recent weight loss and rectal bleeding have been ruled out, several common symptoms must be identified. The most widely accepted diagnostic criteria for IBS are the Rome criteria. The Rome criteria state that abdominal pain should be continuous or recurrent for a duration of at least 3 months. Abdominal pain should be relieved by defecation or associated with either a changed stool consistency or frequency. These criteria should be combined with two other

symptoms listed: altered stool frequency; form; or passage (straining, urgency, incomplete evacuation); or the passage of mucus or abdominal bloating.[12]

Research:

Extensive research has been performed on the treatment of IBS. This has included many different therapies such as pharmaceuticals[13], dietary modification[11,14], psychotherapy[15], and Chinese herbal medicine[16]. Despite this, proven effective therapies for IBS to this day are still lacking. More than a decade ago, Klein[17] commented that 'not a single study offers convincing evidence that any therapeutic agent is effective in treating irritable bowel syndrome,' recently Akehurst & Kaltenhaler[18] also came to similar conclusions.

Drug therapy is often used to treat one or more specific symptoms, such as abdominal pain or diarrhoea, but not the entire range of symptoms that make up IBS.[16] Most patients do not require drug therapy for their symptoms and they can usually be helped by reassurance and dietary modifications.[19] Considering the chronic nature of IBS, it would ideally be more beneficial to resort to a treatment option that does not have the long-term effects of drug therapy.

IBS has a high rate of placebo response to therapy and the only method that can reliably evaluate IBS therapies is the randomisation, double-blind, placebo-controlled treatment trial.[16,17,18] This type of method is difficult to accomplish with regard to manual therapy. A randomized controlled trial is possible if a specific treatment is implemented, but this hardly reflects clinical practice as there are various clinical presentations of IBS,

where treatment may need to be modified at the various stages of the patient's management.

About one-third of IBS patients seek alternative treatment[7], manual therapy being one of these. However, there has been very little research into the treatment of IBS using manual therapy techniques. A recent study by Brice and Montford[20] explored the effects of osteopathic treatment of IBS. The results from this study indicated that osteopathic treatment was effective in the treatment of IBS in the short and long term. The study also showed that osteopathic treatment was significantly more effective than allopathic treatment of IBS. The study was randomised and double-blinded and had a 3 month post-treatment assessment, which addressed the chronic nature of IBS and the lasting effects of osteopathic treatment. The greatest limitation for this study was the size of the sample (n=40). The results of this study provide some evidence that osteopathy can help people with IBS and indicates that further study into the efficacy of osteopathic treatment on IBS patients is required.

A study by Bensoussan and associates[16] showed significant improvement in treating IBS with Chinese Herbal Medicine (CHM). This research was a randomised, double-blind, placebo controlled study, with a sample of 116. The major limitation of this study was the short treatment period of 6 weeks. There have been several CHM, psychotherapy and acupuncture studies that have failed to show significant results in the treatment of IBS, where their randomization and blinding techniques have been flawed.[21,22,23,24] Many of the studies are further degraded by the absence of a true control group. Studies with reasonable control groups report more modest benefits,[25,26] or show no benefit at all.[27,28] These trials are further hampered by the absence of clear blinding on

the part of the practitioner. Bensoussan and associates study found that an individualised approach to each patient was the most effective way of treatment. The individual approach to treatment supports the osteopathic approach that each patient is unique and is viewed differently.

An Osteopathic Approach to IBS:

The primary purpose of this study was to explore an overall osteopathic approach to the treatment of IBS rather than testing the efficacy of a specific osteopathic technique. Osteopathy is a holistic approach to the body in which structure and function are considered to be interrelated. Osteopathy is the art of provoking self-correction on the part of the organism and that all human body systems can be stimulated, inhibited or changed by the use of the hands.[29] The aim of the osteopath should be to normalise autonomic activity to the intestine, promote good lymphatic flow and address somatic joint dysfunction.[30] Manual techniques applied to the human form affect body physiology and thus manipulation can intervene in homeostasis and affect the healing mechanisms.[31]

Osteopathic treatment for IBS is anecdotally claimed to be beneficial, though there is very little research to support this. In theory, there are a number of ways that osteopaths may help with IBS. Essentially, the aims of osteopathic treatment centre around the nervous system, the circulatory system, the spine, viscera, thoracic and pelvic diaphragms.[29]

The sympathetic innervation of the gastrointestinal tract (GIT) is received from the lower thoracic to the upper lumbar spinal segments (T4-L2) via the collateral sympathetic ganglia (celiac, superior mesenteric, and inferior mesenteric).[32] Osteopathic

techniques, such as articulation, manipulation and soft tissue massage to these areas may affect the sympathetic tone.[33]

Treatment of the upper cervical spine, cranial base and general sub-occipital area may be beneficial to release tension on the vagus nerve, as it passes through the jugular foramen.[32] The vagus nerve is the parasympathetic innervation of the upper GIT, small intestine and the colon up to the splenic flexure. The mid-cervicals are also of importance (C3,4,5), as this is where the phrenic nerve arises to supply the thoracic diaphragm. Treatment of the pelvis and sacroiliac joints can be treated using MET to address torsion, rotations and shears,[33] which in term may affect the pelvic splanchnic nerves (S2,3,4) that innervate the descending and sigmoid colon (parasympathetic supply).

A somatic related area that may be a maintaining/ predisposing factor to colon dysfunction is the psoas muscle, to which the ascending and descending colons are attached via fascia. The lower ribs may also be affected due to spinal restrictions and through their links with the diaphragm. Key areas of the colon include the ascending and descending colons, caecum, sigmoid, iliocaecal valve area, and the root of the mesentery.[29] It is possible that treatment of these areas and other related musculature with such techniques as MET and counterstrain may help a person suffering from IBS.[33]

The aim of this study was to explore the effects of Osteopathic treatment on patients with IBS over four consecutive weeks. This duration was chosen to investigate the short-term effects of osteopathic treatment.

Materials and Methods:

Participants:

This study was initially intended to utilise 12 IBS patients, however due to unforeseen complications, the original subject numbers could not be recruited. Two 25-year old females were recruited through Victoria University Osteopathic Medicine Clinic (VUOMC) and they completed a consent form (Appendix A, Victoria University Human Ethics Committee). They were previously diagnosed with IBS by their doctor, and a colonoscopy was performed in this diagnosis to exclude serious pathology. Patients were to be excluded from the study if they were not between the age of 20 and 50 years, they did not sign the consent form and had any serious gastrointestinal diseases or pathologies that would be complicated by treatment. These included: pregnancy or breast feeding, liver disease, current alcohol or drug addiction, psychiatric illness or dementia, lactose intolerance, inflammatory bowel disease (ulcerative colitis or Crohn's disease), peptic (gastric or duodenal) ulcers, cancer of the gastrointestinal tract, Coeliac disease, and Diabetes mellitus.

Clinical Measures:

The bowel symptom scale (BSS) was used to monitor the progression of the treatment throughout the study. This particular questionnaire was chosen as it has shown to be valid in a previously published IBS study.[16] The BSS consists of 100-mm visual analogue scales related to each symptom of IBS (pain/ discomfort, bloating, constipation, and diarrhoea) and an overall severity scale. The BSS also includes items for assessing rate of stool passage, rating the degree to which IBS symptoms interfered with life

activities, recording changes in medication usage and fibre consumption. From a previous study, the reliability of the BSS was determined by a test-retest procedure.[16] This method found the BSS to have a high correlation both for total score and for each individual symptom. it was found that the visual analog scales within the BSS had high face validity (100-mm lines with severity marked at the extreme right and absence of symptoms marked at the extreme left), and had high content validity (ie, they incorporate the key domains of interest- pain and discomfort, bloating, constipation, and diarrhoea).

Osteopathic Consultations:

This study was held at Victoria University Osteopathic Medicine Clinic, level 4, 301 Flinders Lane, Melbourne. The consultation room included an osteopathic treatment table and non-restrictive gowns for the patients. Osteopathic treatments were performed by a senior osteopathic student, under the supervision of an experienced osteopath trained in treating visceral conditions.

The patients were required to fill in a BSS just prior to the initial and third treatments and then an additional one a week after the treatment period. At the first consultation, a medical history was taken, particularly focusing on the presenting symptoms, history of presenting illness, past medical history, family history, drug and dietary histories. The first consultation went for one hour for each patient, and the following consultations went for 30 minutes. The assessment of the patients focused on osteopathic examinations and palpatory findings. Such examinations included abdominal examinations, spinal and pelvic testing. All examination procedures during the osteopathic consultations were performed according to the procedures outlined by

Barral[29] and Greenman[33]. The treatments were individually based, dependent on the history of the patient, the major presenting symptoms and the progression of the treatment. Initially an 8-week treatment period was planned with a one and three month follow-up assessment, but due to unforeseen complications and time restrictions, a four week treatment plan and a one week follow-up assessment was performed. Each patient had four osteopathic treatments, with each treatment being performed on a weekly basis. Treatment included massage, high velocity low amplitude (HVLA) techniques, muscle energy techniques (MET), visceral techniques, functional/ fascial techniques and counterstrain.

Case Reports

Patient Number One:

A 25-year old female, who is a naturopathic full time student and a part time medical receptionist and retail assistant, presented to the Victoria University Osteopathic Medicine Clinic (VUOMC) with IBS. Her main complaint was of intermittent generalised lower abdominal pain and tenderness, bloating and diarrhoea. The pain was described to be dull with no radiations and was rated at a seven out of ten at its worst, zero at its least and three at its average severity. The patient described that she felt tired all the time. Factors that aggravated her symptoms were stress, excess alcohol and wheat based products. No factors were found to relieve her symptoms.

The patient was diagnosed with IBS by a gastroenterologist 10 months ago, after a colonoscopy failed to reveal any GIT pathology. Her symptoms started as bloating and then progressed to more diarrhoea dominant IBS. The patient had some naturopathic treatment previously and found that it had some mild short term relief but not in the long-term. The patient described herself as being relatively stressed most of the time. She walks 3 times a week and attends pilates class twice a week. The patient also reported that she has wheat and gluten intolerance.

On assessment it was found that she had motion restrictions in the sigmoid and descending colon, mid-lower thoracic spine, upper lumbar spine and of the upper cervical spine. Hypertonicity was found of the left psoas, QL, gluteus medius, piriformis, thoracic erector spinae (TES), lumbar erector spinae (LES) and suboccipital muscles.

The treatment included gentle visceral articulation and mobilisation of the descending and sigmoid colon, articulation of T6-L2 and of rib 12, and High Velocity

Low Amplitude (HVLA) of T8-10. Soft tissue massage was performed on the TES, LES, and gluteus medius, counterstrain of the psoas, piriformis and QL muscles, and traction of the suboccipital region.

The following week it was discovered that treatment had provided some mild relief and had decreased her diarrhoea, which had been one of her main complaints. This form of treatment continued, with further treatment of the mid and upper cervicals using articulation and manipulation, and treatment of the lumbar vertebrae and pelvis with articulation and muscle energy techniques (MET). There were no adverse reactions that occurred from treatment during the study period for this patient.

Patient Number Two:

A 25-year old female, who works as a dental nurse, presented to VUOMC with IBS. Her main complaint was abdominal pain and bloating. The pain was described as a dull ache stretching across her lower abdomen, with occasional periods of sharp pain and radiations into her lower back bilaterally. Her pain would be there most of the time, being more severe at night time, where her pain would reach a nine out of ten at its worst, one at its least and five at an average. She also experiences diarrhoea intermittently, feels tired all the time and experiences nausea and vomiting occasionally. She found that stress was an aggravating factor, and that a hot water bottle on the abdomen, a back massage or anti-inflammatory medication would help relieve her pain.

The patient had been diagnosed with IBS 18 months prior, after a colonoscopy and gastroscopy had negative results. Her IBS first started when she was experiencing a lot of stress, and it has been fluctuating ever since then. She has seen a naturopath

previously, her diet was adjusted, however, little change was noticed. She also takes medication for depression (Zoloft, 25mg/ per day).

She exercises three times a week at the gym, where she mainly does yoga, but also some weights and cardiovascular training. She smokes 2-3 cigarettes a week and drinks 12 glasses of wine a week. Her work is not too stressful.

The patient also reported that she experiences headaches and neck stiffness everyday. The headaches start at the base of her skull and then spread to behind her eyes.

On assessment it was found that she had tenderness and hypomobility of the ascending, descending and sigmoid colon, and of the upper lumbar region. There was a markedly decreased range of movement (ROM) in her mid-lower thoracic vertebral joints, mid and upper cervical vertebral joints. Hypertonic muscles were discovered at the left quadratus lumborum (QL), psoas, trapezius, suboccipitals, cervical erector spinae (CES), TES and LES. There was also a reduced excursion of the thoracic diaphragm and of the left sacroiliac joint (SIJ).

The treatment included soft tissue massage of the LES, TES, CES and trapezius, counterstrain of the left QL and suboccipitals. Articulation was performed on the mid-lower thoracic, upper lumbar and cervical (C) joints, and manipulation of C4/5 right and of the left occipital-atlantal joint (OA). The psoas, trapezius, and the left SIJ were treated with MET. Light visceral mobilisation was performed on the ascending, descending and sigmoid colon.

On the following consultation it was found that the patient did not find any relief from treatment, and in fact, found that her symptoms had increased in severity. On this consultation the participant was reassured by the practitioner and supervisor that this

reaction to treatment can happen and different alternatives would be taken to make sure that her problem at least would not get worse in severity. During this consultation no direct abdominal treatment was performed, but some gentle techniques were incorporated into treatment, this included cranial therapy of the occiput, balanced ligamentous tension (BLT) of the sacrum and thoracic diaphragm. A 7-day food diary was also requested to the patient for the following week. From the food diary it was discovered that she was lacking in fibre and that chocolate, nuts and alcohol did in fact aggravate her symptoms. The patient was then requested to avoid these foods over the treatment period. After the treatment regime and diet was modified, the patient's symptoms had decreased in severity and she also reported that she felt some relief after the treatment was performed.

Results:

Victoria University Faculty of Human Development Human Research Ethics Committee approved this study and written informed consent was obtained from the participants. The BSS were numbered 1-3 according to the stage that they were in the treatment period. The patients completed the BSS1 (Appendix B) at the start of the first consultation. The BSS2 (Appendix C) was completed by the patients at the start of the third treatment, and BSS3 (Appendix C) was completed one week after the fourth and final treatment. The results from the study are shown in tables and figures below. The results were recorded from the 100mm visual analog scales (VAS) on BSS1-3.

The BSS scores of the patients' IBS severity throughout the study:

IBS Symptomatology	BSS1: Pre-treatment VAS	BSS2: Mid-treatment VAS	BSS3: Post-treatment VAS
Abdominal pain/ discomfort	17	11	11.5
Abdominal bloating/ swelling	4	8	8
Constipation	4	5	5
Diarrhea	92	88.5	62
Overall severity of IBS symptomatology	38	76.5	35
IBS interference with life and activities	7	22.5	6
Fibre consumption	8	9	6

Table 1 – Patient #1 VAS for IBS Symptomatology

IBS Symptomatology	BSS1: Pre-treatment VAS	BSS2: Mid-treatment VAS	BSS3: Post-treatment VAS
Abdominal pain/ discomfort	84	89	71
Abdominal bloating/ swelling	86	95.5	73
Constipation	4.5	3	1
Diarrhea	47	49	43
Overall severity of IBS symptomatology	71.5	74	64
IBS interference with life and activities	57	89.5	49
Fibre consumption	6.5	14	14

Table 2 – Patient #2 VAS for IBS Symptomatology

Rating of Overall IBS Symptoms	**BSS2: Mid-treatment**	**BSS3: Post-treatment**
Patient #1	Stayed the same	A Little Better
Patient #2	Stayed the same	A Little Better

Table 3. Patients' overall IBS severity of their Symptoms when compared to their previous assessment (BSS)

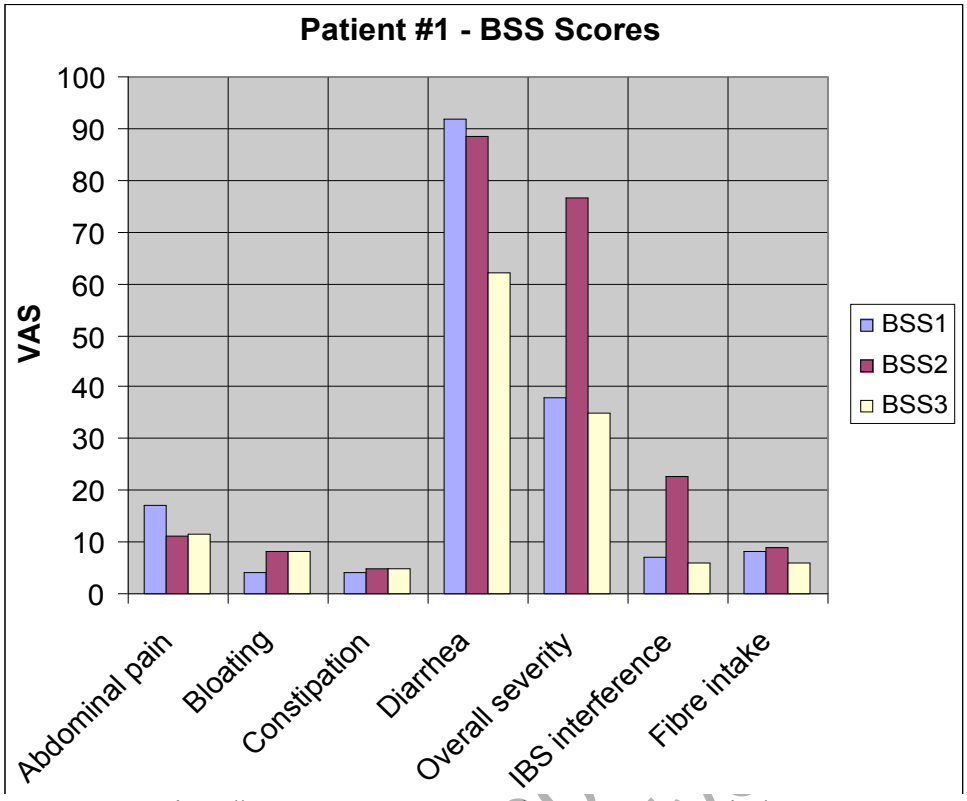

Figure 1. Patient #1 – BSS scores over the treatment period

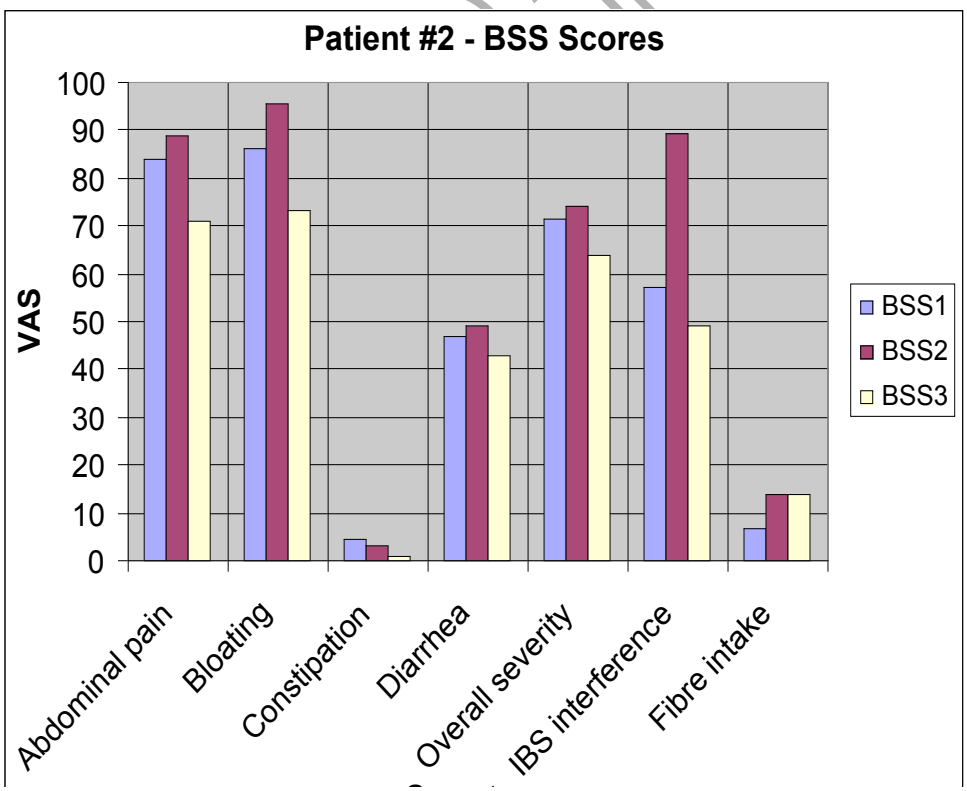

Figure 2. Patient #2 – BSS scores over the treatment period

In Table 1 & 2, items 1-5 (Symptoms of IBS), a high score (100) indicates that the symptoms experienced were very severe, whereas a low score (0) indicates that the symptoms were not present. For item 6 a score of 100 would indicate extreme interference, whilst a score of 0 would indicate no interference. For item 7, a score of 100 indicated that significantly more than normal amounts of fibre have been consumed over the last week, whereas a score of 0 indicates that normal amounts of fibre have been eaten. The 'Rating of IBS Symptoms compared to last time' were included on the BSS2 & BSS3, and there were options for improved (a little better, moderately better, or a lot better), stayed the same or worsened (table 3).

The results show that for both patients the overall symptom severity decreased from baseline by marginal amounts upon completion (table 1&2) and they stated that they felt a little better by the end of the treatment period (table 3).

At the start of the study, the most marked symptoms that the patients presented with were abdominal pain, abdominal bloating and diarrhoea. By the end of the study it was found that there were improvements in these symptoms. There were minor improvements in the interference of their IBS with their daily activities and the fibre consumption was almost at normal on the BSS. During the study, there were a number of factors that had increased in severity, in particular the overall severity of the patients' IBS and the interference with their life and activities.

Patient number one showed a small decrease in abdominal pain and discomfort and an increase in abdominal bloating by BSS2 (figure 1). Constipation showed little change, whilst diarrhoea greatly decreased by 30 on the VAS in BSS3 (table 1). The overall severity and interference with life and activities greatly increased in BSS2 (38.5

& 15.5 increase respectively). Fibre consumption showed minimal change throughout the study.

Patient number two showed a general increase halfway through the treatment period (BSS2). The greatest change in the BSS2 was a 32.5 increase of the patient's interference with life and activities (table 2). Constipation and fibre consumption during the study showed very little changes. By the end of the study (BSS3) the patient showed a decrease in all of her symptoms, overall severity and interference with life and activities.

Discussion:

This case series utilised two IBS patients who received osteopathic treatment over a four-week period. A study of osteopathic treatment of two patients for four consultations each does not allow conclusions to be drawn with regard to intervention and outcome.

Results upon completion of osteopathic treatment showed a decrease in the overall severity of the patients' IBS and also they stated that they felt a little better. There were however some unexpected changes with both patients midway through the study. Patient number one had an unexpected rise in her overall severity and in her interference with life and activities. This may be due to the patient being under more stress at the time, her dietary patterns or her reaction to her previous treatment. It is unknown though why none of her individual symptoms had increased in severity at this stage of the study. Patient number two had a general increase in all of the factors on the BSS, except constipation, where especially her interference with life and activities had greatly increased. It was recorded at this point of the study that the patient had an adverse reaction to the previous treatment and the treatment approach was adjusted to suit the patient. A food diary was requested from the patient and it was discovered that her diet was lacking in fibre and that certain foods did in fact make her symptoms worse. After dietary modifications were made it was discovered that all of the patient's symptoms had decreased in severity. It is hard to distinguish if these improvements were due to the dietary modifications or the change in the treatment regime or both as these adjustments occurred at the same time in the study. Therefore in future research, dietary assessment and modification would need

to occur either months prior to the treatment period or not at all for there to be no confusion with the results of the treatment.

This study was testing IBS in the short-term, as it does not address the chronic nature of the condition, where there is a high relapse rate if treatment is discontinued.[34] The placebo effect appears to be short in duration and has a limited role in the long-term management of IBS. There was also no control group in this study, so it could be suggested that the results at the end of this study are due to a placebo effect. This effect may be explained by an osteopath who is understanding, spends time with the patient and is in direct physical contact. To negate the placebo effect, a study design would need to have a control and treatment group (blinded to the patient) and be of longer duration. It is still unclear how long treatment should continue for and the length of post-treatment assessment, but this remains to be investigated in further research.

The administration of treatment itself may be a contributing factor to the results of this study. The treating practitioner was a final year osteopathic student and obviously may not have the same level of skill or experience as an osteopath that has been in clinical practice for a number of years. Further research would require more experienced osteopathic practitioners, with extensive osteopathic experience.

This study was initially planned to be a randomised, double-blinded, placebo-controlled treatment trial.[16,17,18] Although this is an ideal treatment trial, there were unseen complications in this study. Originally 12 patients were to be recruited from the Epworth hospital, whereby there would be a control and a treatment group. Also a longer treatment period of 8 weeks was to be chosen with a one month post-treatment assessment. Due to

the complications and further time restraints in this study, only 2 patients were recruited through VUOMC and the treatment period was diminished to 4 weeks with a one-week post-treatment assessment. These limitations of the study hinder the outcome of the research, and furthermore deem it a case-series instead of a pilot study.

The purpose of this study was to explore the effects of osteopathic treatment of IBS, but due to the short time frame of treatment period, lack of post-treatment assessment, lack of patient numbers and no control group, the findings are very limited in terms of discovering the full extent of osteopathic treatment and further study is required to explore these factors.

Overall, this study provides some indication that osteopathic treatment may have some benefit in treating IBS, but it remains to be proven whether osteopathy has a role to play the treatment and management of IBS.

Conclusion:

Irritable bowel syndrome is a common condition, where there has been extensive research performed, but still treatment remains unsatisfactory. IBS has a high morbidity resulting from the profound impact on the person's quality of life. The preliminary data of two patients in this study indicates that osteopathic treatment may help. However, the results are inconclusive due to an insufficient patient population and inadequate study design. In the profession of osteopathy we are constantly challenged to justify and provide evidence of efficacious and cost-effective care for a range of conditions. At the present time there is very little research that explores the potential benefits of osteopathic treatment of IBS. Future research would require a larger scale, longer-term, randomised, controlled study in order to show the benefits osteopathic treatment and management of IBS.

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APPENDIX A:

Information to Potential Participants

PURPOSE AND PLAN OF THE STUDY

My name is Daniel Stasiuk. I am a masters student of the osteopathic medicine course at Victoria University. I am conducting research on the effect of osteopathic treatment on Irritable Bowel Syndrome (IBS). The supervisors for this project are Dr. Brian Nicholls, a qualified osteopath, and Dr Jim Kiatos, a qualified doctor and naturopath. I would like to invite you to be a participant in this study. Many treatment options for IBS have been implemented and researched with varying success. The purpose of this study is to explore the effects of osteopathic treatment on IBS, and to determine whether it is a useful treatment option. You are eligible for this study if you are between the ages of 20 and 50 and have been diagnosed with IBS. You are ineligible for this study if you currently have any of the following conditions:

- Pregnant or breast feeding;
- Liver disease;
- Current alcohol or drug addiction;
- Psychiatric illness or dementia;
- Lactose intolerance;
- Inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- Peptic (gastric or duodenal) ulcers;
- Cancer of the gastrointestinal tract;
- Coeliac disease;
- Diabetes Mellitus

Participants in this study will have one osteopathic treatment each week, for a period of four-weeks. Each treatment session will last for approximately _ of an hour.

This study will be conducted at Victoria University Osteopathic Medicine Clinic (OMC), level 4/ 301 Flinders Lane, Melbourne CBD. If you choose to participate in this study, you will be required to attend the clinic to undergo a screening session, which will approximately last for an hour. The screening session will consist of taking a thorough medical history, undertaking a postural analysis and physical tests. During the screening session you will be allocated an identification number so that any forms that you complete will remain confidential. Osteopathic treatment will commence during week 1, following

which you will be required to attend the OMC on a weekly basis for 4 weeks. You will be required to fill out 3 questionnaires regarding your bowel function and symptoms during the treatment period and a subsequent one two weeks after the treatment period. Each form should only take a couple of minutes to complete. The aim of these forms is to monitor your progression throughout the duration of the study.

The osteopathic treatment sessions will involve undressing down to your underwear and wearing a treatment gown, if desired. You will be given the option of having a third person in the room at all times during the treatment, and all treatments will be supervised by a qualified osteopath. A range of treatment techniques may be used during the six treatment sessions. The types of techniques used will be personalised to your presenting symptoms. These techniques will only be carried out with your consent, and you may choose to stop at any time during the treatment session. If at any time you no longer wish to be involved in the study, for any reason, you are free to with draw your consent at any time.

TECHNIQUES THAT MAY BE USED ON PARTICIPANTS

Various techniques will be used throughout the treatment. This may consist of massage, gentle articulation, manipulation, or other various osteopathic techniques. The types of techniques used will be individualised to suit your symptoms and you will be asked for your consent before any treatment is used. If at any time you no longer wish to be involved in this study, for any reason, you are free to with draw your consent at any time.

POTENTIAL RISKS

Certain osteopathic techniques may incur some risk in people with certain medical conditions. A thorough medical history will be taken during the initial screening session to ascertain any risk factors. Prior to any of the manipulative techniques, physical tests will be performed in order to determine if this type of treatment is appropriate and safe for you. If any risks are identified during the treatment or you wish to refuse a certain treatment technique, alternative treatment options will be implemented. Although the risks are very small, manipulation can lead to permanent disability or result in fatalities. To give you a realistic idea of the risks involved with manipulation one researcher reported that no injuries were identified following 5 million neck manipulations. Other research suggests that manipulation is 100-400 times safer than the use of common pain-relieving medications (eg. Aspirin, ibuprofen, voltaren, etc.).

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. You are free to withdraw from the study at any time for any reason. You are also free to refuse any particular treatment modality for any reason, including pain, discomfort, and anxiety about the involved risks. You are encouraged to ask questions and voice any concerns you have about the treatment regime throughout the entire study.

CONFIDENTIALITY

Only the investigators will have access to the data. Forms completed by participants will be coded with an identification number rather than names in order to ensure confidentiality. Any published data will have all personal identifiers omitted.

TO PARTICIPATE

If after reading this information, you are interested in participating in this study please contact either:
Dr. Brian Nicholls (03) 9248 1150 OR
Dr. Jim Kiatos (03) 9248 1191

Any queries about your participation in this project may be directed to the principal researcher (Name: Dr Brian Nicholls 92481150). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).

Participant Consent Form

CERTIFICATION BY SUBJECT

I,
of

certify that I am between 20 and 50 years of age and that I am voluntarily giving my consent to participant in the study entitled The effect of Osteopathic Treatment on Irritable Bowel Syndrome, being conducted at Victoria University by Daniel Stasiuk (B.Sc.).
I certify that the objectives of the study, together with any risks to me associated with the procedures listed hereunder to be carried out in the study have been fully explained to me by Daniel Stasiuk, and that I freely consent to participation involving the use of these procedures.

Procedures:
The study will be conducted over a 4 week period at Victoria University Osteopathic Medicine Clinic (OMC), level 4/ 301 Flinders Lane, Melbourne CBD. I will be required to attend the OMC to undergo a screening session. During this screening session I will be allocated an identification number so that any forms I complete will remain confidential. Osteopathic treatment will commence during week 1, at which time I will be required to attend the OMC on a weekly basis for 4 weeks. During the study I will also be required to complete Bowel Symptom Scale (BSS) Questionnaires.

The types of techniques used will depend upon the nature of my symptoms and will only be implemented if and when I give my consent for these techniques to be used. If I no longer wish to be involved in this study, for any reason, I am free to withdraw my consent at any time.

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this experiment at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed: **..... }**

Witness other than the experimenter: **}** **Date: .....**

.....}

Any queries about your participation in this project may be directed to the principal researcher (Name: Dr Brian Nicholls 92481150). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).

APPENDIX B:

IRRITABLE BOWEL - SYNDROME SCALE (BSS1)

Date:__/__/____ Participants: ID_____
Age_____
Gender_____

INSTRUCTIONS: This questionnaire asks you for your views about your health, how you feel, and how well you are able to do your usual activities. If you are unsure about how to answer any question, please give the best answer you can.

1. PLEASE RATE THE SEVERITY OF YOUR SYMPTOMS **over the last week** by making a cross(X) on the line at the appropriate place:

a) Pain or discomfort in your stomach or abdomen (*do not include chest pain or period pain*):

_____
Not Present — Very severe

b) Feeling as if your stomach or abdomen was bloated or swollen (*do not include bloating due to menstrual pain*):

_____
Not Present — Very severe

c) Constipation (very hard or lumpy stools **or** less than 3 bowel movements a week **or** straining to pass stool):

_____

Not Present — Very severe

d) Diarrhea (very soft or watery stools **or** more than 3 bowel movements a day **or** very urgent need to pass stool):

_____

Not Present — Very severe

e) Please rate the overall severity of your Irritable Bowel Syndrome (IBS) symptoms over the LAST WEEK:

_____

Not Present — Very severe

2. **Over the last week**, how much has you irritable bowel syndrome INTERFERED WITH YOUR LIFE AND ACTIVITIES?

_____

Not at all — Extreme interference

3. **In the last week**, have you eaten MORE FIBRE (eg. Wholemeal bread, high-fibre breakfast cereals, fruit and vegetables, fibre supplements, etc) than you USUALLY eat?

_____

Normal amounts — Significantly more than normal

4. Please WRITE THE NAMES of any MEDICATIONS you have taken **in the last week**, and how often you took them (eg. "once only", "twice a day for four days", etc). Include ALL medications, even headache tablets, antacids and other indigestion medicine, contraceptive pills, vitamins, sedatives, and any herbal medications. If you cannot remember exactly, please write your best guess. If you need more space, please use the back of this form.

MEDICATIONS	HOW OFTEN?
_____	_____
_____	_____
_____	_____
_____	_____

_____ _____
_____ _____
_____ _____
_____ _____

APPENDIX C:

IRRITABLE BOWEL - SYNDROME SCALE (BSS2 & 3)

Date:__/__/____ Participants: ID_____
Age_____
Gender_____

INSTRUCTIONS: This questionnaire asks you for your views about your health, how you feel, and how well you are able to do your usual activities. If you are unsure about how to answer any question, please give the best answer you can.

1. PLEASE RATE THE SEVERITY OF YOUR SYMPTOMS **over the last week** by making a cross(X) on the line at the appropriate place:

a) Pain or discomfort in your stomach or abdomen (*do not include chest pain or period pain*):

_____
Not Present — Very severe

b) Feeling as if your stomach or abdomen was bloated or swollen (*do not include bloating due to menstrual pain*):

_____
Not Present — Very severe

c) Constipation (very hard or lumpy stools **or** less than 3 bowel movements a week **or** straining to pass stool):

_____

Not Present — Very severe

d) Diarrhea (very soft or watery stools **or** more than 3 bowel movements a day **or** very urgent need to pass stool):

_____

Not Present — Very severe

e) Please rate the overall severity of your Irritable Bowel Syndrome (IBS) symptoms over the LAST WEEK:

_____

Not Present — Very severe

2. **Over the last week**, how much has you irritable bowel syndrome INTERFERED WITH YOUR LIFE AND ACTIVITIES?

_____

Not at all — Extreme interference

3. **In the last week**, have you eaten MORE FIBRE (eg. Wholemeal bread, high-fibre breakfast cereals, fruit and vegetables, fibre supplements, etc) than you USUALLY eat?

_____

Normal amounts — Significantly more than normal

4. COMPARED TO LAST TIME you filled in this questionnaire (2 weeks ago),
Do you feel that your irritable bowel syndrome symptoms have: *(tick one answer)*

- o Improved ----------→ **If improved**, are your symptoms: (*tick one answer)*
  - o A little better
  - o Moderately better

- A lot better
- Stated the same
- Worsened

5. Please WRITE THE NAMES of any MEDICATIONS you have taken **in the last week**, and how often you took them (eg. "once only", "twice a day for four days", etc). Include ALL medications, even headache tablets, antacids and other indigestion medicine, contraceptive pills, vitamins, sedatives, and any herbal medications. If you cannot remember exactly, please write your best guess. If you need more space, please use the back of this form.

MEDICATIONS	HOW OFTEN?
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

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